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UNIVERSITY OF SOUTHAMPTON

FACULTY OF HEALTH SCIENCES

**The mechanics of patello-femoral joint
dysfunction – the usefulness of the Q-angle.**

by

Fleur Helen Kitsell

Thesis for the degree of Doctor of Philosophy

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ABSTRACT

FACULTY OF HEALTH SCIENCES

Doctor of Philosophy

THE MECHANICS OF PATELLO-FEMORAL JOINT DYSFUNCTION –
USEFULNESS OF THE Q-ANGLE.

by Fleur Helen Kitsell

Patello-femoral joint syndrome (PFJS) is a common problem that is challenging to treat. The dominant theory of its aetiology is 'patellar mal-alignment', in which the vastus medialis oblique (VMO) muscle is ineffective in controlling patellar position but this is based on assumption. The Q-angle, a frontal plane measure, indicates patellar position relative to the pelvis and tibia; however, there is no standardised measurement protocol and it is assumed to be a fixed value.

The work reported highlights the tension between measurement rigour and clinical utility. Valid measurement of the Q-angle and VMO muscle were established using: motion analysis, magnetic resonance imaging (MRI) and ultrasound imaging, in recreationally active healthy participants, then applied in various experiments involving people with PFJS, with the following conclusions:

- The Q-angle:
 - varied over 60 seconds in relaxed standing
 - exhibited differences in movement patterns of the three markers which form the Q-angle between healthy and PFJS groups during the stance phase of gait
 - was generally at its maximum at the beginning of the stance phase of gait and at its minimum at the end
 - did not correlate with pronation at the sub-talar joint
- VMO muscle size:
 - linear and CSA measures of the VMO muscle correlated well
 - measures of VMO muscle size from ultrasound were shown to be valid when compared with MRI and were equally reliable

- No correlation between the Q-angle and VMO muscle size was found.

These results increase our understanding of the usefulness of the Q-angle, particularly its natural variation of between 3⁰ and 4⁰ in static standing and its different movement pattern during gait in PFJS. It was established that ultrasound imaging provides valid measures of VMO muscle size and the relationships between its CSA and linear dimensions were characterised.

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DECLARATION OF AUTHORSHIP:

I, Fleur Kitsell declare that the thesis entitled “The mechanics of patello-femoral joint dysfunction – the usefulness of the Q-angle” and the work presented in it are both my own, and have been generated by me as the result of my own original research. I confirm that:

- this work was done wholly or mainly while in candidature for a research degree at this University;
- where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;
- I have consulted the published work of others, this is always clearly attributed;
- Where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;
- I have acknowledged all main sources of help;
- where the thesis is based on work done by myself and jointly with others, I have made clear exactly what was done by others and what I have contributed myself;
- parts of this work have been presented/published:

A) oral presentations:

- a. Kitsell, FH; Wilson, AW (1998) – Preliminary study measuring Q-angle of healthy adult subjects while standing in the anatomical position and during the stance phase of the gait cycle, using the Peak-5 video motion analysis system. *Physiotherapy Research Society meeting in Hull, England.*
- b. Kitsell, FH; Wilson, AW (1999) – Variation in the Q-angle of healthy adults over time using the Peak-5 video motion analysis system. *World Confederation of Physical Therapy Meeting in Yokohama, Japan.*

B) published paper:

- a.** Wilson T, Kitsell F (2002) – Is the Q-angle an absolute or a variable measure? Measurement of the Q-angle over one minute in healthy subjects. *Physiotherapy*, 88, 5, 296-302.

Signed.....

Date:

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LIST OF ABBREVIATIONS:

AIIS – Anterior Inferior Iliac Spine

ANOVA – Analysis of Variance

ASIS – Anterior Superior Iliac Spine

CSA – Cross-sectional Area

ICC – Intra-Class Correlation Coefficient

MRI – Magnetic Resonance Imaging

PFJS – Patello-femoral Joint Syndrome

SEM – Standard Error of Measurement

SHPRS – School of Health Professions and Rehabilitation Sciences

SUHT – Southampton University Hospital Trust

U/S – Ultrasound

VL – Vastus Lateralis

VM – Vastus Medialis

VMO – Vastus medialis Oblique

2D – Two Dimensional

3D – Three Dimensional

Chapter One

Introduction, background and rationale for the research

CHAPTER 1

Introduction, background and rationale for the research

1.1 – General Introduction

Patello-femoral joint syndrome (PFJS) has a high incidence with rates of between 3% and 25% being reported in young adults (Thomee et al, 1999; McConnell, 1996; Witvrouw et al, 2000), yet its cause and aetiology remain poorly understood. Symptoms include peri-patellar and retro-patellar pain, which are typically provoked by activities involving knee flexion (Handfield and Kramer, 2000). In the absence of other anatomical causal factors, it is thought that the patella may move abnormally within the femoral trochlear groove during knee flexion and extension, although it is not clear whether this is a cause or effect of PFJS. During knee flexion compressive joint reaction forces are generated within the patello-femoral joint as a result of the tension in the quadriceps muscle and the patellar tendon, which combine to pull the patella against the trochlea of the femur. It is thought that during closed chain activities e.g. the stance phase of gait, the compressive forces generated increase as the knee moves into flexion (Salem and Powers, 2001; Wallace et al 2002). Figure 1.1 below is the anterior view of the left knee.

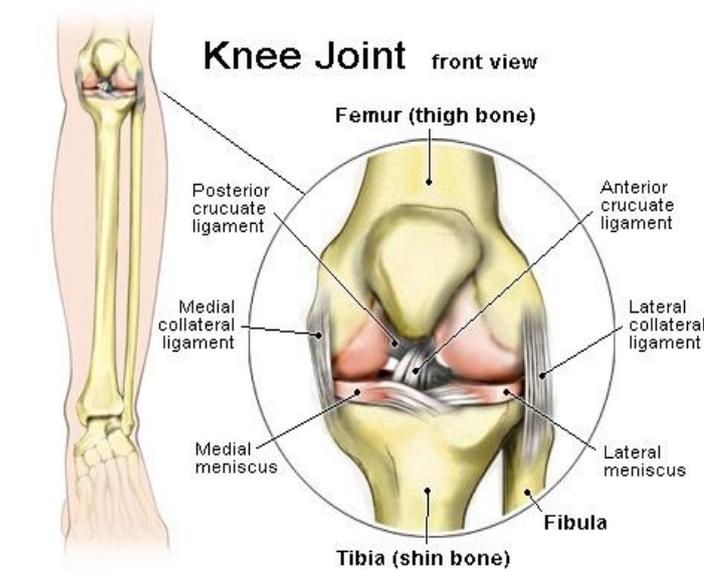


Figure 1.1 –The knee joint, anterior view, left knee (www.thekneedoc.co.uk, with permission)

The Q-angle has become accepted as part of the routine examination of the knee joint in individuals presenting with retro-patellar or peri-patellar knee pain (Powers et al, 1997). It is a two-dimensional (2D) frontal plane measure that gives information about the position of the patella relative to the pelvis and tibia, and the balance between the resultant force of the quadriceps femoris muscle and the line of pull of the patellar tendon (Schulthies et al, 1995). It is the acute angle formed between two imaginary lines drawn between three markers on the: anterior superior iliac spine (ASIS) of the pelvis, centre of the patella and centre of the tibial tubercle on the tibia (see Figure 1.2 below). It was first described by Brattstrom in 1964, and since then has commonly been measured in the clinical situation using a long-arm goniometer, as it is the only measure of patello-femoral joint mechanics available that does not require complex radiographic equipment and measurement techniques. There is a lack of agreement concerning the parameters of the normal range for the Q-angle as it is affected by many things. However, in general, values for healthy individuals (male and female) are accepted as being between 12 to 17 degrees (Woodland and Francis, 1992).

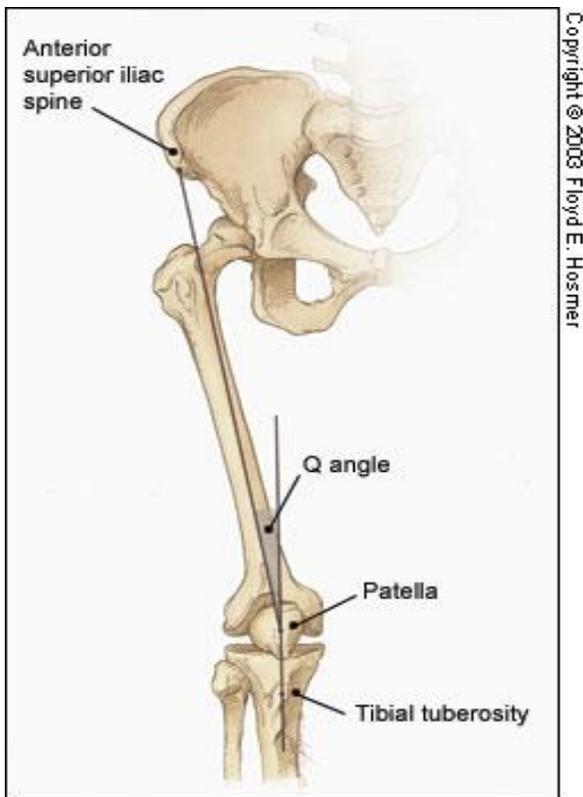


Figure 1.2 – The Q-angle; anterior view, right leg (www.serpentine.org.uk, with permission)

The value of the Q-angle is thought to give useful information on the position of the patella relative to the pelvis and tibia and by extrapolation its position in relation to the femoral groove. This information gives helpful insights into how the patella moves during knee flexion and extension, which is especially useful when managing individuals with PFJS.

Movement of the patella is controlled by the quadriceps muscle group, in particular by the distal portion of the vastus medialis muscle, the vastus medialis oblique (VMO). Conservative management of PFJS often includes techniques that purport to strengthen the quadriceps muscles both as a group and the VMO selectively, as it is thought that a stronger VMO muscle will be able to control patellar movement more effectively (Hanten and Schulthies, 1990; McConnell, 2002).

When the programme of work discussed in the current thesis was started, many articles describing the management of PFJS advised that treatment decisions (including surgery) should be based on the measured value of the Q-angle. This does not happen as frequently now, as a number of researchers have begun to question the value of the Q-angle. The implication of the earlier advice was that Q-angle measurement is both reliable and accurate, and can be used as a clinical management tool. However, a recent study entitled "Comprehensive Physical Examination for instability of the knee" (Lubowitz, 2008) published in the American Journal of Sports Medicine, recommends measuring the Q-angle as part of the assessment of the knee using a long-arm goniometer and did not mention any issues related to measurement validity or reliability.

This thesis examines the precision and accuracy of Q-angle measurement, and measurement of VMO muscle size, leading to the following research question which forms the basis of this programme of research:

- Is it possible to measure the Q-angle reliably in the clinical situation and does it have any relationship with the size of the VMO muscle, and how should this information influence the management of PFJS?

In order to address the above question, valid and reliable protocols were developed to measure the Q-angle both statically, over time, and during the stance phase of gait (dynamic), as well as measuring the size of the VMO muscle, these protocols were then applied under a number of circumstances.

Chapter two contains background information on the anatomy of the knee joint complex, including biomechanical detail of the patello-femoral joint, as well as the role of the VMO muscle, particularly designed for any reader who is not a physiotherapist.

Chapter three contains a review of the literature in key areas related to this body of work, beginning with a detailed discussion of the Q-angle and the issues surrounding its measurement in the clinical situation, followed by the role of the VMO muscle in PFJS, and how to measure its size in order to estimate its strength. As some of this work included the development of new protocols for measurement, the issues of measurement reliability, and the validity of comparing methods of measurement are discussed.

Chapter four describes the equipment, general methods and data analysis used in the various experimental studies. The equipment used to measure the Q-angle was initially done using video motion analysis; and for the measurement of VMO muscle size MRI and ultrasound imaging were used.

Chapter five outlines a small series of experimental studies which involved the development of a new valid and consistent method of measuring the Q-angle using video motion analysis equipment with their results and brief discussion.

Chapter six reports the identification of a meaningful correlation between the CSA and some linear measures of the VMO muscle from MRI images, then the establishment of a valid and reliable protocol for measuring the size of the VMO

muscle using portable real-time ultrasound imaging with participants in relaxed standing.

Chapter seven uses the measurement protocol for the Q-angle established in Chapter five and explores the value of the Q-angle over time, during the stance phase of gait and the effect of an intervention (medial glide patellar tape).

Chapter eight applies the data from both measurement protocols (Q-angle and VMO muscle size) and reports the results of whether there is a relationship between the value of the Q-angle and the size of the VMO muscle. It also reports a brief and illustrative case study of a participant with a history of PFJS.

Chapter nine contains a general discussion of all the findings and Chapter ten reports the conclusions, as well as some suggestions for future research work in this area.

Chapter Two

General Background: anatomy and bio-mechanics of the knee joint complex, vastus medialis oblique (VMO) muscle, and overview of patello-femoral joint syndrome (PFJS)

CHAPTER 2

General Background: anatomy and biomechanics of the knee joint complex, vastus medialis oblique (VMO) muscle, and overview of patello-femoral joint syndrome (PFJS)

2.1 – Introduction

This chapter is divided into six main sections, the first sections cover the anatomy and biomechanics of the knee joint complex and the vastus medialis oblique (VMO) muscle. The condition of patello-femoral joint syndrome (PFJS) is then introduced.

- 2.1 – Introduction
- 2.2 – General anatomy of the knee joint complex
- 2.3 – Patello-femoral joint: anatomy and biomechanics
- 2.4 – The VMO muscle
- 2.5 – Correlation between muscle size and strength
- 2.6 – Patello-femoral joint syndrome
- 2.7 – Summary

2.2 – General anatomy of the knee joint complex

2.2.1 – Structure

In order to understand fully the Q-angle and why its measurement is so challenging and intriguing, it is important to have some understanding of the whole knee joint complex. The knee joint complex consists of articulations between four bones: the femur, tibia, patella and fibula (Figure 2.1). It is the largest joint in the human body, being situated between the body's two longest lever arms, the femur and the tibia, which is thought to account for why it is so susceptible to injury (Nordin and Frankel, 1989). The main two synovial articulations are those between the femur and tibia, and the femur and patella. The tibio-femoral articulation is the main weight-bearing joint and the lower end of the femur divides into two barrel-shaped condyles that sit on the almost flat

surfaces of the upper end of the tibia. The stability of this synovial joint depends greatly on the menisci, ligaments and musculature. The articulation between the tibia and fibula is also important in weight-bearing.

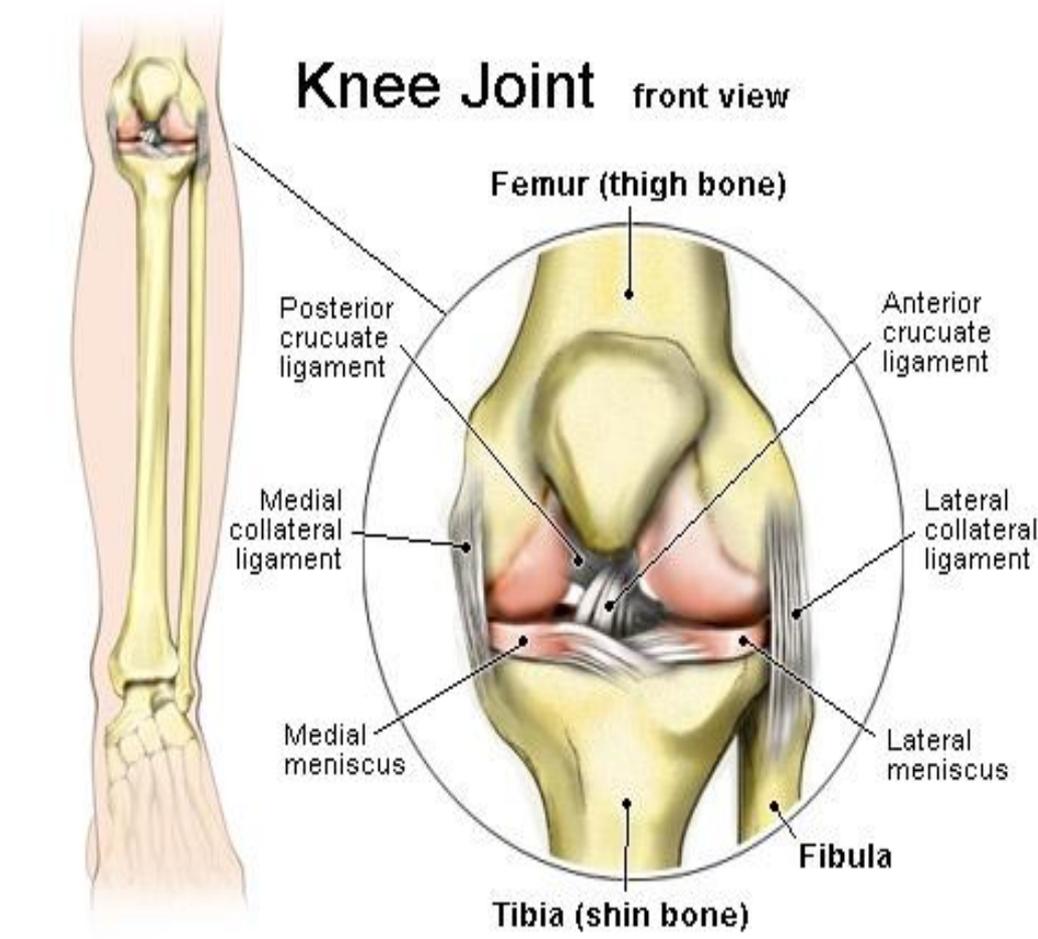


Figure 2.1 – The knee joint, anterior view, left knee (www.thekneedoc.co.uk, with permission)

2.2.2 – The tibio-femoral joint

This joint is a major weight-bearing joint and has three degrees of freedom i.e. it has movement in all three planes (frontal, sagittal and transverse), with the major movements being those of flexion and extension in the sagittal plane. The normal range of flexion is approximately 140° and the normal range of extension is 0° . The range of motion in the transverse plane (internal and external rotation) depends on the position of the knee in the sagittal plane – with very minimal movement occurring when the knee is in full extension. However,

with the knee in 90° of flexion there is approximately 45° of external rotation and 30° of internal rotation. Again movement in the frontal plane is also affected by the position of the knee in the sagittal plane – there is minimal movement possible with the knee in full extension but a few degrees of passive abduction and adduction are possible with the knee at 30° of flexion (Nordin and Frankel, 1989).

2.3 – The patello-femoral joint: anatomy and biomechanics

The patello-femoral joint is a synovial joint; the articulation occurs through the underside of the patella and its contact within the femoral groove in the femur (Figures 2.2 & 2.3). The shape of the articular surfaces and surrounding soft tissues provide static stability; whereas dynamic stability is provided by the vastus medialis muscle that pulls the patella medially, and the vastus lateralis muscle that pulls the patella laterally, and the vastus intermedius and rectus femoris muscles which pull the patella proximally and laterally.

During open chain knee extension (i.e. with the foot free) the patella is drawn through the trochlea of the femur by the quadriceps muscles. The hamstrings muscles provide stability by their opposing forces providing rotational control of the tibia (Fitzpatrick, 2002). When the knee is extended, the lower part of the patella rests against the femur. As the knee is flexed to 90° the contact surface of both the patella and femur shifts cranially and increases in size (Nordin and Frankel, 1989).

The Patellofemoral Joint

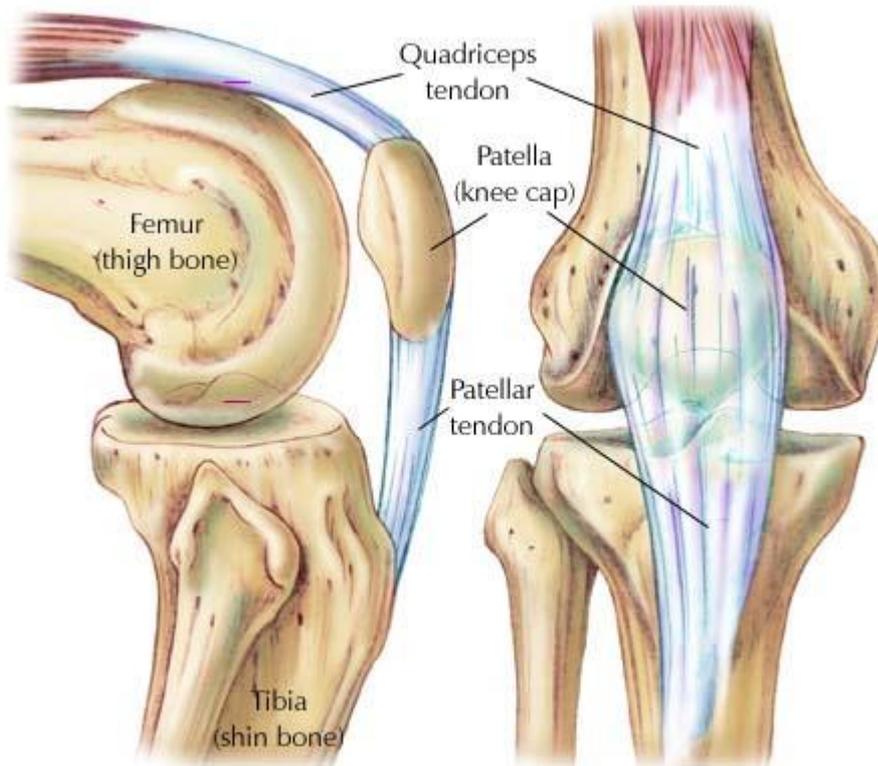


Figure 2.2 – The patellofemoral joint, anterior and lateral views (www.hughston.com/hha/b.pfjoint.jpg, with permission)

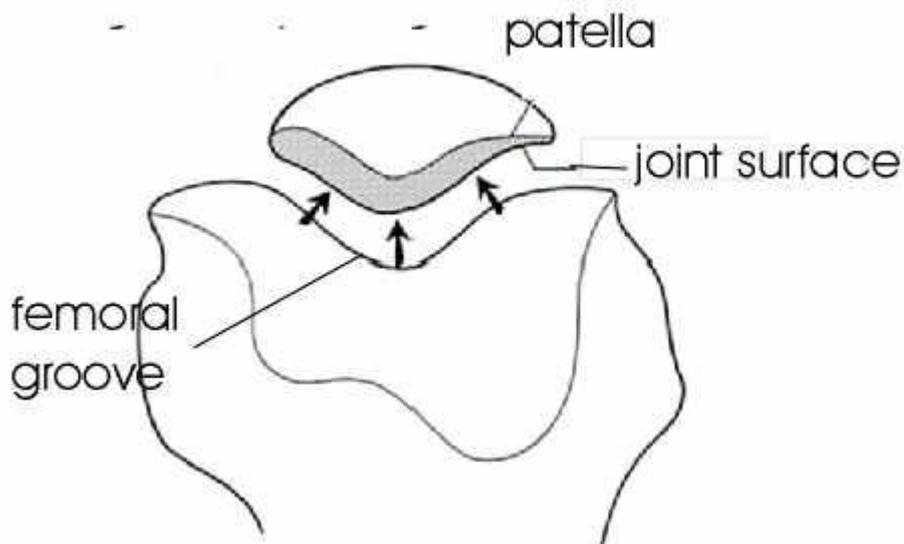


Figure 2.3 – The patello-femoral joint, skyline view (www.kneeguru.co.uk, with permission)

2.3.1 – The patella

The patella is a sesamoid bone and sits within the inferior tendon of the quadriceps muscle. It is basically a plump triangle in shape, with its apex pointing distally and base proximally. The articular cartilage of the patella is the thickest in the body, with a depth of 4-5mm; this cartilage has excellent lubrication and provides a low-friction articulation. The cartilage is subjected to large compressive and shearing forces, which increase with increasing knee flexion in weight-bearing. The articular surface of the patella is divided into a number of facets with the precise number and pattern varying between individuals. Most patellae have a median ridge that starts proximally and goes halfway down the length of the patella, separating its proximal surface into medial and lateral facets; this ridge then tends to veer off medially. Again most patellae also have a transverse ridge on their lateral side, and in about 50% of patellae this ridge also extends medially. Approximately 80% of patellae also have a ridge which creates the so called 'odd' facet at the extreme medial portion of the patella, which articulates with the medial condyle of the femur in full knee flexion (Grelsamer and McConnell, 1998; Staubli et al, 2001).

2.3.2 – Biomechanics of the patello-femoral joint

According to Fulkerson and Hungerford (1990) the patella has four functions:

- To increase the efficiency of the quadriceps muscle
- To centralise the divergent forces of the quadriceps femoris into the quadriceps tendon
- To protect the cartilage at the distal end of the femur, acting as a bony shield
- To improve the aesthetic appearance of the knee joint

The primary or main function of the patella is to increase the efficiency of the quadriceps muscle, and it does this by acting as both a lever and a pulley. Acting as a lever the patella increases the length of the moment arm of the quadriceps muscle from the tibio-femoral joint's centre of rotation and thus increases the mechanical advantage of the quadriceps mechanism; and by acting as a pulley the patella increases the angle of insertion of the patella

tendon into the tibial tuberosity, which reduces the compressive forces at the tibiofemoral joint (Ozkaya and Nordin, 1999). Through these two mechanisms the patella can increase the torque (the ability of a given force to cause rotational motion) of the quadriceps muscle by as much as 50% (Fulkerson and Hungerford, 1990).

2.3.3 – Patellar contact area

At any time only part of the patella articulates with the femoral trochlea. In full extension, with relaxed quadriceps muscles there is thought to be no patello-femoral contact. When moving into flexion the distal portion of the patella articulates with the proximal portion of the trochlea (this is thought to occur by about 15° flexion, but in some patellae is considerably earlier), and as the knee continues to flex the patella contact area moves proximally. At 90° of flexion the superior portion of the patella is in contact with the trochlea, and as flexion increases past this point the contact area of the patella moves inferiorly again. Grelsamer and McConnell (1998) in a review report that there is widespread agreement in the literature that from 0° to 60° of knee flexion the size of the contact area on the patella increases; and that there is less agreement about what happens after 60° of flexion, with some authors stating that the size of the contact area continues to increase, others finding that the size of the contact area remains the same, and still others who find that the size of the contact area decreases. This lack of agreement may stem from the fact that the methods used, this was before the advent of magnetic resonance imaging (MRI), to measure the size of these contact areas, and there is enormous variability between individual persons (Gresalmer and McConnell, 1998). The advent of MRI has led to greater accuracy and reproducibility in calculating these patellar contact areas in both cadavaric specimens (Brechtler et al, 2003) and living persons during weight-bearing (Patel et al, 2003; Salsich et al 2003).

One reason for interest in the size of the patella contact area is due to the fact that the larger the physical contact area the greater the spread of the patello-femoral contact forces. One of the hypotheses for the reduction in pain after the application of tape to the knee, known as the McConnell patellar taping techniques, is the fact that the patella is pressed more firmly to the distal end of

the femur and thus its contact area is increased, spreading the forces more widely and thus reducing pain (Powers, 1998; Fredericson et al, 2002). The physical size of the patella is another factor that is important, and may partly explain why some very inactive and obese people suffer from patello-femoral joint problems, as their patellae are relatively small for the size of the patello-femoral forces that they have to manage. Subjects with a greater degree of tibio-femoral rotation (in full extension or hyperextension) tend to have smaller patello-femoral contact areas and this may be a contributory factor in patello-femoral joint problems (Salsich and Perman, 2007).

2.3.4 – Patello-femoral joint reaction forces

During movement, tension in both the quadriceps muscle and the patellar tendon combine to pull the patella against the trochlea of the femur, thus giving rise to compressive forces; these are known as patello-femoral joint reaction forces (Grelsamer and McConnell, 1998). As the size of the contact area of the patella on the trochlea is relatively small, these compressive forces often reach very high levels, and are always higher than those going through the tibio-femoral and hip joints at the same point in time (Ahmed et al, 1983). In closed-chain activity (i.e. foot in contact with a fixed surface) these compressive forces increase as the knee moves from 0° to 90° of flexion (Figure 2.4); whereas from 90° to 120° , the forces are thought to level off or decrease (Salem and Powers, 2001; Wallace et al, 2002). In open-chain activities the pattern is reversed (Grelsamer and McConnell, 1998).

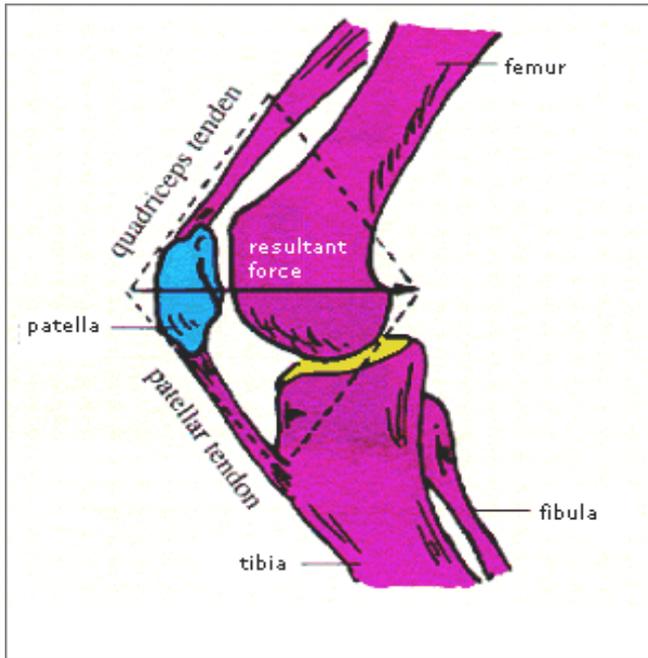


Figure 2.4 – Compressive forces on the patellofemoral joint (www.hksi.org.uk, with permission)

The effects of patello-femoral joint reaction forces on the joint itself, are determined by the interaction between the magnitude of the force and the size of the contact area; according to the equation:

- $\text{Stress} = \text{force} / \text{area}$

A high force with a small contact area results in high joint stress, but an equally high force with a larger contact area will cause relatively little or no stress on the joint; and conversely a relatively low force with a very small contact area may cause relatively high stress on the joint. For example, a study by Powers et al. (2004) used a patello-femoral brace on 15 subjects during free and fast walking. The effect of wearing the brace increased both the compressive forces on the patello-femoral joint and the patellar contact area. However, since the contact area increased by a greater percentage than the compressive force, the overall result was one of decreased stress on the patello-femoral joint. This may also help to explain why many individuals with patello-femoral joint symptoms have greater levels of patello-femoral joint stress while walking (Brechtler and Powers, 2002a) and as a result tend to keep knee flexion to a minimum during

weight-bearing activity (Salsich et al, 2001; Brechter and Powers, 2002b). The complexity of the combined role of the patella (acting as both a lever and a pulley), plus being situated between the two longest lever arms in the body, result in exceptionally high joint reaction forces; and may help to explain the high incidence of PFJS (see Section 2.6).

2.4 – The Vastus Medialis Oblique (VMO) muscle

The vastus medialis (VM) is the medial component of the three superficial parts of the quadriceps muscle and is situated on the inner part of the front of the thigh (Figure 2.5). It attaches to the medial aspect of the femur, via the intertrochanteric line, spiral line, medial linea aspera and medial inter-muscular septum and runs along the inner front down to the base of the patella, via the quadriceps tendon and by the patellar tendon onto the tibial tuberosity. It gains its nerve supply from the posterior division of the femoral nerve (L3 and 4 nerve roots). The VM muscle is thought to play an important role in stabilising the position of the patella in the femoral sulcus; weakness or dysfunction of the distal portion of the VM, termed vastus medialis oblique (VMO), is often observed in patients with PFJS (Peeler and Anderson, 2007). Please see Figure 2.6.

Due to its size and shape, and the different orientation of fibres at its proximal and distal ends (fibres at its proximal end tend to be vertical in orientation and at its distal end the fibres are more horizontal) the VM muscle is sometimes thought to act in two distinct ways.

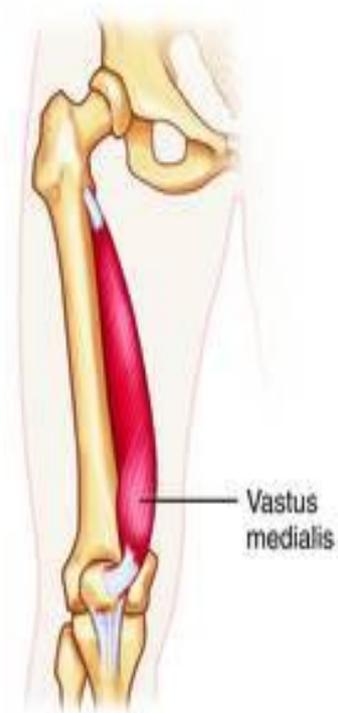


Figure 2.5 – vastus medialis muscle, anterior view right leg
http://img.tfd.com/MosbyMD/thumb/vastus_medialis.jpg (with permission)

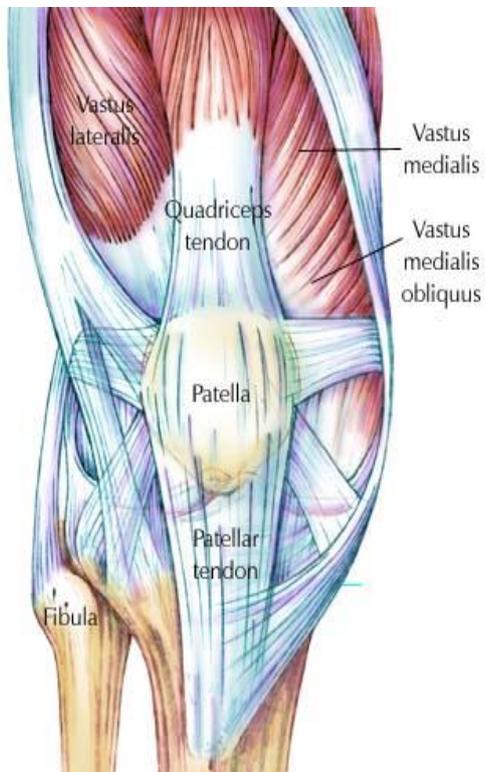


Figure 2.6 - Vastus Medialis Oblique Muscle, (VMO), right leg, anterior view
www.aafp.org/afp/20070115/194-f1.jpg, with permission)

Two cadaveric studies in the late 1990's each concluded that normally there is no clear anatomical and functional difference between the two ends of the VM muscle. The first by Nozic et al (1997) examined the limbs of 50 cadavers and concluded that the VM muscle should be classified as a single muscle with a proximal and distal component. They found that both parts were innervated by branches of the femoral nerve. They found one specimen, out of their sample of 50, which had a fascial plane between the more vertical (proximal end) and horizontal (distal end) oriented muscle fibres. The second study by Hubbard et al (1998) examined 374 cadaveric limbs and found no relationship between the distal fibre angle of the VM muscle and the severity of patello-femoral joint deterioration, and concluded that the VM should not be considered as functioning in two separate parts i.e. the vastus medialis longus (VML) and the VMO.

However, other published work, especially more recently, suggests that the VM does operate in two parts, the distal portion the VMO pulls the patella medially during knee extension while the proximal portion, the VML works with the rest of the quadriceps muscle group and extends the knee (Lieb and Perry, 1968; Powers, 2000; Ono et al, 2005; Blazevich et al, 2006). Thus the distal portion of the VM muscle, the VMO, will be referred to throughout this work.

2.5 – Correlation between muscle size and strength

A positive correlation between muscle size and strength has been established for sufficient muscles in healthy individuals that it is now accepted as a general fact. The muscle size measurement typically used is its cross-sectional area (CSA), although the relationship varies for different muscles (Garfinkel and Cafarelli, 1992; Freilich et al, 1995; Schulties et al, 1995; Stokes et al, 1997; Rankin et al, 2004; Pressler et al, 2006; Segal, 2007).

As it is impossible to isolate the VMO muscle from the rest of the quadriceps muscle group in order to measure its specific strength directly, an indirect method is needed. A number of authors have used surface electrode

electromyography (EMG) to measure muscle activation in the separate components of the quadriceps muscle, based on accepted evidence that a greater level of EMG activity correlates well with the amount of force for contractions of increasing strength produced by the muscle (Enoka and Stuart, 1992). A common way of recording this is to report the timing of onset of activity and level of activity in VM:VL ratios (Voight and Wieder, 1991; Boucher et al, 1992; Thomee et al, 1995), although it is thought to be affected more by muscle control rather than strength. As authors report disparate findings, probably due to differences in subject inclusion criteria and EMG technique, EMG remains a controversial technique for measuring muscle activity (Mc Clinton et al, 2007).

Other authors have shown that linear measures from some muscles correlate well with their CSA, which in turn correlates well with the strength of the same muscle (Loo and Stokes, 1990)

2.6 – Patello-femoral joint syndrome

There is a high reported incidence and prevalence (McConnell, 1996; Thomee et al, 1999; Handfield and Kramer, 2000) of persons suffering pain in the patello-femoral region, with a vast body of literature on the subject and many theories on what the underlying aetiology and patho-physiology might be. As with most topics for which there is a plethora of literature, much of what is written and proposed is contradictory and uncorroborated, albeit fascinating. However, the problem remains a difficult one to diagnose and treat; with many individuals not having a permanent relief of symptoms (Sandow and Goodfellow, 1985; Milgrom et al, 1996; Nimmon et al 1998).

The terminology used to describe pain at the front of the knee is plentiful – historically pain in this area was labelled chondromalacia patellae, although more recently the term has been reserved for those cases where there is specific evidence of pathology e.g. softening and degeneration, in the cartilage of the patella. In the literature there is broad agreement that it is unusual for

there to be any correlation between the presence of degenerative changes in the patellar cartilage and pain (Sanchis-Alfonso et al, 1999). The general term 'anterior knee pain' is often used clinically as a diagnosis for those individuals with the symptom of pain in the anterior aspect of the knee, and while it can be helpful in identifying where the pain is, it serves little other useful purpose. More recently, authors use the title patello-femoral (joint) syndrome e.g. Thomee et al, 1995 and Green, 2005. There have been a number attempts at classifying this condition (Merchant, 1988; Thomee et al, 1999); and the system devised by Wilk et al (1998) seems particularly useful:

1. Patellar compression syndromes
 - a. Excessive lateral pressure syndrome
 - b. Global patellar pressure syndrome
2. Biomechanical dysfunction
3. Patellar instability
 - a. Chronic subluxation
 - b. Acute dislocation
 - c. Recurrent dislocation
4. Direct patellar trauma
5. Soft tissue lesions
 - a. Suprapatellar plica
 - b. Infrapatellar fat pad syndrome
 - c. Medial patellofemoral ligament pain
 - d. Iliotibial band friction syndrome
 - e. Bursitis
6. Overuse syndromes
 - a. Tendonitis
 - b. Apophysitis
7. Osteochondritis dessicans
8. Neurological disorders

Most individuals with patello-femoral pain who seek treatment do so because pain limits their activity. The logical classification system as described by Wilk et al (1998) and listed above is helpful in some cases – but the category 2

(Biomechanical dysfunction) seems to be another 'catch-all' diagnosis that includes all those individuals who do not neatly fit into any of the other categories. Dye and Vaupel (1994) described the patello-femoral joint as the "orthopaedic black hole".

There are thought to be three major models which might explain the pain experienced by persons with PFPS, as can be seen from the descriptions below the models and mechanisms described are interlinked and so it is possible that all could be present to varying degrees in the same individual. These are briefly outlined below:

- The neural model – this is pain which results from direct pressure on or irritation of neural tissue. It is thought that for some patients with PFJS the nerve endings in localized soft tissues are directly stimulated by some noxious or abnormal stimuli; these soft tissues include - cartilage, synovium, the infrapatellar fat pad, the subchondral bone, and in particular the lateral retinaculum. The noxious or abnormal stimulation could be the result of biomechanical mal-alignment which in turn results in hyper-innervation of the tissue; this effect has been shown to be especially focused in areas close to blood vessels. This hyper-innervation can also result in the release of neural growth factor which further stimulates the axonogenesis type of hyper-innervation which further exacerbates the problem, especially in those patients who experience chronic pain. In addition some types of pain arise from noxious chemical stimuli of the nerve endings, especially chronic pain, which can result in hypersensitivity to normally non-painful stimuli i.e. hyperalgesia. Substance P (SP) is one such chemical agent whose presence can lead to localised inflammation and increased sensitivity to pain; it has been found to be at higher levels in some individuals with chronic PFJS (Biedert and Sanchis-Alfonso, 2002; Sanchis-Alfonso and Rosello-Sastre, 2003).

- The homeostatic model – this is the ability of a system to maintain and regulate its internal environment. Dye et al (1998 and 1999) proposed that another explanation for the pain felt in PFJS could be due to some individuals being unable to maintain the proper homeostatic balance within their patello-femoral joint as a result of some noxious stimuli, usually pain. They propose that the persistent presence of injurious biomechanical and/or biochemical conditions can result in the loss of tissue homeostasis, which in turn will contribute to the mosaic of pathophysiology causing PFJS. They propose that this is likely to be a factor in those patients who experience pain, and where there is little or no other evidence from usual measurement to corroborate or explain the pain symptoms.
- The biomechanical model – proposed by several authors (please see below) – which explains the presence of PFJS as being due to some biomechanical dysfunction within the patella-femoral joint.

The primary cause of PFJS in those individuals categorised as having biomechanical dysfunction is thought to be lateral mal-alignment of the patella (McConnell, 1986; Wilson, 2007) i.e. the patella sits more laterally in the femoral sulcus than normal. It is assumed that this is due to the overall lateral pull of the quadriceps musculature, the relative tightness of the lateral soft tissues and relative greater strength of the lateral muscles compared with the medial muscles around the knee (McConnell, 1986; Peeler and Anderson, 2007). A common aim of treatment in such cases is to re-align the patella; this is done by passively moving the patella to the correct position, applying tape to hold it there and strengthening the medial muscles (especially the VMO) to maintain this re-alignment in the longer term (Doucette et al, 1992; Vo, 2002; Ono et al, 2005; Syme et al, 2009). However, the strength or size of the quadriceps muscle group, and the VMO in particular, are rarely objectively measured or quoted as useful outcome measures in the treatment of individuals with PFJS (Crossley et al, 2004; Heintjes et al, 2004).

Boucher et al (1992) report that for a small group of five females who each had a Q-angle measurement of greater than 22 degrees and a diagnosis of PFJS, their VM:VL peak torque ratios were significantly smaller than healthy controls. Another study by Syme et al (2009) found large effect size differences between a control group and two groups of patients with PFJS who underwent an 8 week exercise programme focussing on strengthening the quadriceps muscles generally (group 3) and strengthening the VM muscle specifically (group 2). They do not describe in sufficient detail the exercise programme for Group 2, or discuss how they knew that it was specifically focussing on the VM muscle in comparison to the rest of the quadriceps group. They reported trivial to small differences between the two intervention groups. The overall sample size was 69. Thus there is little substantive evidence in the literature to support the assumption that VMO muscle weakness actually exists, or much information on how to measure VMO muscle strength in order to determine whether or not this intervention is effective or possible (Callaghan and Oldham, 2004; Wilson, 2007).

2.6.1 – Repositioning the patella

The pain associated with PFJS can be severe and often is the symptom that prompts an individual to seek treatment. The majority of patients with PFJS who seek treatment by a physiotherapist are those with some type of biomechanical dysfunction. As mentioned earlier one management technique is to reposition the patella in its proper place within the femoral groove and then encourage it to stay there e.g. by strengthening the VMO muscle, by stretching tight lateral structures around the knee joint complex and/or by applying a brace or tape to keep the patella in the new position (McConnell, 1986; Worrell et al, 1994).

There are a number of physiotherapeutic techniques designed to reposition the patella, the cheapest and easiest of these is patellar taping (Figure 2.7) as devised by McConnell in 1986 (Callaghan, 1997). Patellar taping following the McConnell method has commonly proved effective at relieving pain (Wilson et al, 2003; Ng and Cheng, 2002; Crossley et al, 2002; Herrington and Payton, 1997; Harrison et al, 1999), although the original explanation given by

McConnell (1986) for how this happens has not been borne out by later research, and so its mechanism remains unclear and contradictory. A few authors have reported that the application of patellar tape did not give pain relief (Keet et al, 2007; Kowell et al (1996). The original method of taping devised by McConnell, an Australian physiotherapist, states that taping relieves pain by normalising the position of the patella within the femoral groove (McConnell, 1986). However, subsequent research using X-ray and MRI scans suggests that her regime of taping may reposition the patella initially but it does not allow sustained repositioning of the patella (Fitzgerald and McClure, 1995; Gigante et al, 2001; Zaccherotti et al, 1999; Worrell et al, 1994).



Figure 2.7 – McConnell medial glide patellar tape being applied to the left knee (Grelsamer and McConnell, 1998, with permission)

McConnell's regime of taping is very dependent on the position of the patella relative to the femoral groove. The original article (McConnell, 1986) did not mention the difficulty of defining the precise position or orientation of the patella. Two studies have explored the reliability of the McConnell classification of patellar orientation and quote results of 'poor to fair' for intra-tester reliability and from 'poor to slight' for inter-tester reliability (Fitzgerald and McClure, 1995; Watson et al, 1999). However, Wilson et al. (2003) carried out a multi-centre single-masked study in which they compared three types of McConnell taping –

Medial glide; Lateral glide and Neutral – on 71 patients with PFJS. Patients self-reported pain levels using an 11-point visual analogue scale and all three types of tape produced a statistically significant reduction in pain. The authors concluded, therefore, that the tape is probably unable to sustain the position of the patella in the re-aligned position, and so its original hypothesis of patellar repositioning being the reason for its success in reducing pain should be questioned. Instead it may work through the mechanism of applying general pressure to the patella and thus increasing the patellar contact area within the femoral sulcus and that is how the pain is reduced (Powers, 1998; Fredericson et al, 2002).

2.7 – General Summary

This chapter has described the anatomy of the knee joint complex, including the patello-femoral joint and its biomechanics, and given some information on the quadriceps muscles and VMO muscle in particular. It has given a very brief outline of patello-femoral joint syndrome and some of the biomechanical factors that are thought to contribute to it.

It has been shown that when the patella does not sit centrally within the femoral sulcus, this results in an uneven distribution of force on the under-side of the patella, which may be part of the aetiology in patello-femoral joint syndrome. It is not clear whether this is a cause or effect of PFJS. Finding an effective method of sustaining the repositioned patella within the femoral groove would seem to be very helpful for physiotherapists treating patients who have PFJS. Good levels of correlation between linear measures of muscle size and strength have been shown to be consistent, albeit different for each muscle.

Chapter Three

Review of the Literature

CHAPTER 3

Review of the Literature

3.1 – Introduction

This chapter is divided into three main sections, the first two sections (3.2 & 3.3) reports and discusses pertinent literature on measuring the Q-angle; the third section (3.4) discusses measuring muscle size using real-time Ultrasound. The final section states the aims of the work in this thesis.

The work in this chapter is divided into five parts

- 3.1 – Introduction
- 3.2 – Measuring the Q-angle
- 3.3 – Dominance of the Q-angle in the literature
- 3.4 – Measuring VMO muscle size using ultrasound imaging
- 3.5 – Overall aims and research questions

The literature databases searched included: PubMed, AMED (Allied and complementary medicine) Embase, Ovid Medline and CINAHL (Cumulative Index for Nursing and allied Health literature)

3.2 – Measuring the Q-angle

The Q-angle is a two-dimensional frontal plane measure which gives information about the position of the patella relative to the pelvis, femur and tibia, as it sits in the femoral groove. It is the only measure of patello-femoral joint mechanics which can be taken in the clinical situation which does not require complex equipment, where it is typically measured using a long-arm goniometer, see Figure 3.1 below. There is a lack of agreement concerning the parameters for the normal range for the Q-angle, as it is affected by many factors, however, in general typical values for healthy individuals (male and female) are accepted as being between 12 to 17 degrees (Woodland and Francis, 1992).



Figure 3.1 – Measuring the Q-angle with participant in relaxed standing, using a Long-arm Goniometer (www.uncg.edu/kin/anrl/facilities.html), with permission

The Q-angle was first described in 1964 by Brattstrom, an Orthopaedic Surgeon, in a seminal piece of work published in a special supplement of a major Scandinavian orthopaedic journal describing his work to manage the recurrent dislocation of the patella. He described the Q-angle as an angle with its apex at the patella, which is formed between the ligamentum patellae and the extension of the line formed by the quadriceps femoris muscle's resultant force, which he described as being the "supplement to the valgus angle in the extensor mechanism". He further stated that the Q-angle "consists of the bony physiologic valgus position of the knee (being 8-10 degrees), plus the extra few degrees that are the effect of the slight lateral rotation of the tibia on the femur that occurs when the knee is fully extended" (Brattstrom, 1964). Since that original description, the Q-angle has been quoted extensively in the literature as being a useful measure of the resultant quadriceps group muscle force on the patella, in the frontal plane.

Many texts on the classification, diagnosis and management of patello-femoral joint problems quote Q-angle values, which have been measured in the clinic with a long-arm goniometer. Often comparative data between groups are cited, for example mean Q-angles for:

- individuals with patello-femoral joint problems and healthy controls,
- males and females,
- measures from the left and right legs, and
- measures taken from participants in either supine or standing

In many of these studies very small differences between mean Q-angle values for separate groups are reported as being statistically significant. For example Moss et al (1992) quote a statistically significant difference of 1.9 degrees between the mean Q-angle values of a group of 31 subjects with patello-femoral pain compared with a group of 44 healthy controls; Woodland and Francis (1992) found that a difference of 3.4 degrees between the mean Q-angle for 269 healthy males and 257 healthy females, was statistically significantly different; and Lathinghouse and Trimble (2000) found that a reduction in mean Q-angle of 0.5 degrees following exercise, was statistically significantly different for 22 healthy women.

These differences, while being statistically significant, are numerically very small and have little meaning clinically as the precision of clinical measurements taken with a long-arm goniometer is poor. The standard error of measurement (SEM) for clinical measurements made with a long-arm goniometer is at best four degrees (Eliasziw et al, 1994). A study by Draper et al (2011) report comparisons between Q-angle measurements taken using short-arm and long-arm goniometers, and comparing these values with measures from magnetic resonance imaging (MRI) scans, they reported mean differences of 6° and 7° respectively from the MRI images. Another difficulty when measuring the Q-angle is that there is no consensus regarding measurement protocol, individual authors of published work describe a variety of different measurement protocols, which may take up to 60 seconds to

complete. Researchers report taking Q-angle measurements with subjects in supine or in standing; with the quadriceps muscle group relaxed or contracted; and some give details of foot position, while others do not.

A third difficulty when measuring the Q-angle in the clinic is the reliable identification of the three bony landmarks from which the Q-angle is measured – finding the centre of the anterior superior iliac spine (ASIS), the patella and the tibial tuberosity consistently is not easy. Errors in the identification of either the centre of the patella or tibial tuberosity in the medial/lateral direction (the frontal plane) of 5mm can result in variation of the measured Q-angle of up to 5.53 degrees, and the cumulative effect of error in identification of both distal bony landmarks in the frontal plane can give a variation in the measured Q-angle of up to 8.3 degrees (France and Nester, 2001).

The patella is a sesamoid bone and sits within the common tendon of the quadriceps muscle group, its movement being controlled by this muscle group, in particular the distal portion of the vastus medialis (VM) muscle. Conservative management of patello-femoral joint syndrome (PFJS) often includes techniques which purport to strengthen the quadriceps muscle both as a group and the VM selectively. It is assumed that a stronger VM muscle would be more able to control the position and movement of the patella more effectively as it would be better able to balance the strong lateral pull on the patella exerted by the lateral retinaculum and ilio-tibial band (Blazevich et al, 2006), although conclusive evidence for this hypothesis is still required.

3.2.1 – What does the Q-angle measure?

The value of the Q-angle is believed to correlate positively with the balance, in the frontal plane, between the resultant force of the quadriceps femoris muscle and the line of pull of the patellar tendon (Schulthies et al, 1995). It also identifies the position of the patella relative to the pelvis and tibia (Merchant, 1988; Horton and Hall, 1989; Grelsamer and Klein, 1998). In the literature since Brattstrom (1964) the Q-angle has been described as the acute angle measured between the quadriceps femoris muscle resultant force and the patellar tendon (Hungerford and Barry, 1979). In clinical practice the

quadriceps femoris muscle' resultant force is represented by an imaginary line drawn between the Anterior Superior Iliac Spine (ASIS) and the centre of the patella. The ASIS is used rather than the Anterior Inferior Iliac Spine (AIIS) because it is easier to locate and is very close (in frontal plane terms) to the AIIS; although the proximal attachments of the rectus femoris component of the quadriceps muscle are at the AIIS and a small groove above the acetabulum.

In 1995 Schulthies et al developed a static model of the quadriceps muscle group in which the muscles' resultant force in the frontal plane could be calculated accurately. Their model was a combination of muscle-directed and fibre-directed models for which they subdivided the quadriceps femoris muscle into eight components and used an equation developed by Alexander and Vernon (1975) to calculate muscle cross-sectional area (CSA) and force production, which is based on the assumption that muscle CSA correlates highly with muscle force capability (Schulthies et al, 1995). They compared this to the force that would be generated by using the ASIS as the proximal point to determine the resultant line of force of the muscle. They acknowledged various difficulties with their model, particularly the effect of differences in the superficial and deep parts of the quadriceps muscle group and that the fibre direction can change throughout its length. They tested their procedure on seven male cadaver thighs and concluded that the actual force vector of the quadriceps muscle is more laterally directed than the line drawn between the ASIS and the centre of the patella and thus measuring the Q-angle using the ASIS as a reference point may underestimate the magnitude of the lateral force affecting the patella by about 20%. However, they also concluded that because of the high correlation between the measured and calculated Q-angles, that continued use of the ASIS as the proximal point to represent the resultant force of the quadriceps muscle is valuable. They stated that approximately 84% of the variation of the direction of the quadriceps muscle force on the patella in the frontal plane could be explained by a variation in the measured Q-angle using the ASIS (Schulthies et al, 1995). They do not comment on the fact that the effect of muscle stimulation on cadavers might be different from that on living subjects.

3.2.2 – How to measure the Q-angle

There are a number of ways to measure the Q-angle – in the clinic using simple equipment, typically a goniometer; or using X-ray; computerized tomography (CT); MRI; video or infra-red equipment. This section examines how the Q-angle is measured in clinical practice, typically using a long-arm goniometer.

Forty articles were found in which the Q-angle was measured using a goniometer, only 23 of these describe the measurement protocol followed. The protocols vary in detail from a very brief mention of the bony landmarks used to a thorough description of techniques. Conclusions from these articles suggest that the measured value of the Q-angle can be affected by the following:

- The gender of the individual (Horton and Hall, 1989; Woodland and Francis, 1992; Kuhn et al, 2002; Draper et al, 2011);
- The individual's foot position while the measure is being taken (Olerud and Berg, 1984; Callaghan and Baltzopoulos, 1992);
- The state of contraction of the quadriceps muscle (Guerra et al, 1994; Latinghouse and Trimble, 2000; Sarkar et al, 2009);
- Whether the subject is standing or in supine lying (Woodland and Francis, 1992; Doucette and Goble, 1992);
- The position of the patella in relation to the femoral trochlea (Brown et al, 1984; Sebastianelli, 1993);
- The presence or absence of knee pain (Insall et al, 1976; McConnell, 1986; Moss et al, 1992; Livingston and Mandigo, 1999; Lan et al, 2010);
- Which knee is measured (Thomee et al, 1995; Livingston and Mandigo, 1999; Kuhn et al, 2002);
- The anatomical position of the tibial tubercle (Brattstrom, 1964; Grelsamer and Klein, 1998);
- The amount of knee flexion (Greene et al, 2001); and
- The accuracy of locating the bony landmarks, in particular the centre of patella and tibial tuberosity (France and Nester, 2001)

The above conclusions were drawn from studies measuring the Q-angle in clinical practice, either using a long-arm goniometer positioned over the patella in the way described by Woodland and Francis (1992), or by measuring the Q-angle, using a goniometer or protractor, using the bony landmarks from photographs with the subject in standing or lying supine. The usual protocol when using a long-arm goniometer is to place the centre of the goniometer over the centre of the patella, line up the short arm with an imaginary line joining the centre of the patella with the centre of the tibial tuberosity; and line up the long arm with an imaginary line joining the centre of the patella with the ASIS, the Q-angle being the acute angle formed where these two lines meet. See Chapter 2, Figure 1.2.

3.2.2.1 – Bony Landmarks

Thirty eight of the 40 papers identify the three bony landmarks from which to measure the Q-angle. Some just state what these are: e.g. the tibial tuberosity; whereas others state more precisely which part of the general bony landmark was used e.g. the centre of the tibial tuberosity. Please see Table 3.1 below for full details.

From the 40 studies summarised in Table 3.1 there is a clear consensus that when measuring the Q-angle the bony landmarks to be used are the ASIS, the centre of the patella and the tibial tuberosity, although only some authors specify which part of the tibial tuberosity should be used. A few authors describe how to palpate or measure the specific part of these bony landmarks but that is rare and few authors mention where or how to align the goniometer. The more recent studies seem to favour having subjects in a standing position as this is more functional, although none mention that it is more difficult for the operator to take the measure with the subject in standing, and that this may affect the measure's reliability.

All the measurement protocols described in the articles summarised in Table 3.1 appear to be based on the assumption that the Q-angle is an absolute value - i.e. a measure that does not vary; and few calculate or even question the issue of measurement reliability. A few authors did carry out some reliability analysis

of their measurement technique but on the whole this was not thoroughly done. Reliability was calculated from a small group of repeat measures or using statistical tools which are not very precise which are likely to give an over-optimistic assessment of the level of reliability. Only one paper mentioned the difficulty of reliably identifying the bony markers and calculated the effect this could have on the measured Q-angle (France and Nester, 2001).

Table 3.1 – Summary of participant position and the three bony landmarks used from which to measure the Q-angle, when measuring the Q-angle, using a goniometer, from a series of 40 articles

Study Authors	Participant Position	Proximal bony landmark:	Middle bony landmark:	Distal bony landmark:
Aglietti et al (1983)	Supine; knees extended	ASIS	Centre patella	Middle ant. Tib. tuberos
Olerud and Berg (1984)	Standing (foot position standardised). Supine (legs relaxed, foot free)	ASIS	Centre patella	Centre tibial tuberosity
Brown et al (1984)	Knees extended, patella in groove, extensor relaxed, toes vertical	ASIS	Mid-point patella	Anterior tibial tuberosity
Bourne et al (1988)	Knees extended, unspecified	ASIS	Centre patella	Tibial tubercle
Horton and Hall (1989)	Standing, knees extended	ASIS	Mid-point patella	Tibial tubercle
Kolowich et al (1990)	Knees flexed to 90 ⁰	ASIS	Centre patella	Centre tibial tuberosity
Boucher et al (1992)	Standing in unspecified standard position	ASIS	Centre patella	Centre of tuberosity
Caylor et al (1992)	Standing, knees extended, BW even			
Doucette and Goble (1992)	Supine, knees extended, quadriceps relaxed. Standing	ASIS	Centre patella	Tibial tuberosity
Moss et al (1992)	Unspecified	ASIS	Centre patella	Centre tuberosity
Woodland and Francis (1992)	Standing, knees extended, quadriceps relaxed. Supine, knees extended, quadriceps relaxed	ASIS	Centre patella	Centre tuberosity
Eilert (1993)	Supine	ASIS	Centre patella	Tibial tubercle
Sebastianelli (1993)	Unspecified, but knees extended, patella in trochlea, quadriceps relaxed	ASIS	Middle patella	Tibial tubercle
Galanty (1994)	Supine, muscles relaxed	ASIS	Centre patella	Centre tuberosity
Guerra et al (1994)	Standing, foot position (described); quadriceps relaxed and contracted. Supine – as above	ASIS	Middle patella	Tibial tubercle
Kannus and Niittymak(1994)	Unspecified	ASIS	Mid-patella	Tibial tubercle
Fithian et al (1995)	Unspecified position, but knee 30 ⁰ flexion, patella in femoral trochlea	ASIS	Centre patella	Tibial tubercle
Thomee et al (1995)	Standing, feet parallel and 10 cms apart. Measures taken from photograph	ASIS	Middle patella	Tibial tubercle
Tomisch et al (1996)	Supine	ASIS	Centre patella	Tibial tubercle

Study Authors	Participant Position	Sup. bony landmark	Middle bony landmark	Inferior bony landmark
Grelsamer and Klein (1998)	Unspecified – knee extend, patella in trochlea	ASIS	Centre patella	Tibial tubercle
Heiderscheit et al (1999)	In weight-bearing, nil else	ASIS	Centre patella	Tibial tuberosity
Livingston and Mandigo (1999)	Standing, knees extended, quadriceps relaxed	ASIS	Mid-point patella	Mid-point tibial tuberos
Heiderscheit et al (2000)	Standing	ASIS	Centre patella	Tibial tuberosity
Lathinghouse and Trimble (2000)	Standing, no shoes, knees extended, strong contraction of quadriceps and relaxed quadriceps	ASIS	Mid-point patella	Middle tibial tubercle
Tsujimoto et al (2000)	Supine, knees extended, patellae facing straight, ankle brace used	AP Iliac spine	Centre patella	Centre tibial tubercle
Greene et al (2001)	Supine – fully extended and knee flexed to 20 ⁰ ; foot in neutral	ASIS	Centre patella	Centre tibial tuberosity
France and Nester (2001)	Relaxed standing	ASIS	Centre patella	Centref tibial tuberosity
Kuhn et al (2002)	Standing, straight knees, wearing shoes	ASIS	Centre patella	Centre tibial tuberosity
Devan et al (2004)	Standing	ASIS	Mid-point patella	Tibial tuberosity
Herrington and Nester (2004)	Sitting with knees straight; knees at 20 ⁰ extended and in standing with feet facing forwards	ASIS	Centre patella	Tibial tuberosity
Kishali et al (2004)	Supine and Standing, with quadriceps relaxed	ASIS	Centre patella	Tibial tuberosity
Sutlive et al (2004)	Standing	ASIS	Centre patella	Tibial tuberosity
Pantano et al (2005)	Relaxed standing	ASIS	Centre patella	Tibial tuberosity
Rauh et al (2005)	Comfortable standing, no shoes, quads relaxed, feet forward, shoulder width apart, BW even	ASIS	Centre patella	Tibial tuberosity
Piva et al (2006)	Supine, knees in full extension	ASIS	Centre patella	Tibial tuberosity
Schultz et al (2006)	Standing, knees straight, feet shoulder width apart, toes pointed anteriorly	ASIS	Centre patella	Tibial tuberosity
Carlson and Wilkerson (2007)	Supine, legs extended and relaxed	ASIS	Centre patella	Tibial tuberosity
Boling et al (2009)	Standing	Unspecified	Unspecified	Unspecified
Sarkar et al (2009)	Standing a) Relaxed b) IQA – strong contraction of quads	ASIS	Midpoint patella	Midpoint tibial tubercle
Draper et al (2011)	Supine, quads relaxed, knees 10 ⁰ flexion, alignment standardized using towel and ankle strap	ASIS	Centre patella	Centre tibial tuberosity

3.2.3 – Reliability of Q-angle measurement protocols

Forty articles (since 1976) were found in which the authors discuss the Q-angle and present a data series, with some authors using the measured value to inform treatment decisions. However, only some authors gave a detailed description of their measurement protocol, 19 mentioned the issue of measurement reliability and only 14 studies address it in any kind of meaningful way. Horton and Hall (1989) calculated Pearson product-moment correlation coefficients; Woodland and Francis (1992) calculated test-retest reliability correlation coefficients; Heiderscheit et al (2000); Greene et al (2001); Herrington and Nester (2004); Boling et al (2009); and Draper et al (2011) calculated Intraclass Correlation Coefficients (ICCs) and Caylor et al (1993); Guerra et al (1994); Tomisch et al (1996); Livingston and Mandigo (1999); Lathinghouse and Trimble (2000); Sutlive et al (2004) and Piva et al (2006) calculated ICCs and Standard Error of Measurements (SEMs). See Tables 3.2 and 3.3. Authors who calculated ICCs used the definition of level of reliability suggested by Shrout and Fleiss (1979) or Portney and Watkins (2000), which are similar:

- Below 0.5 = poor reliability
- Between 0.5 and 0.75 = moderate reliability
- Above 0.75 = good reliability

However none mention that Nunnally (1978) and Portney and Watkins (2000) also suggest that measurements used for decision-making or diagnosis need to have a greater level of reliability, perhaps at 0.9. Ten studies concluded that their measurement procedure was reliable (Olerud and Berg, 1984; Horton and Hall, 1989; Caylor et al, 1992; Woodland and Francis, 1992; Guerra et al, 1994; Heiderscheit et al, 2000; Lathinghouse and Trimble, 2000; Herrington and Nester, 2004; Schultz et al, 2006; Draper et al, 2011) and two studies concluded that both their intra-rater and inter-rater reliability were poor (Greene et al, 2001; Sutlive et al, 2004).

Debate continues about the value and meaning of statistical measures of reliability. A number of authors advise that where the reliability of specific values are important no measure is sufficient on its own, even ICCs; and additional analysis, such as the standard error of measurement (SEM), or the Bland and Altman Limits of Agreement is needed in order to be able to make an informed judgement about the reliability of a measure (Rankin and Stokes, 1998; Keating and Matyas, 1998; Chinn, 1990; Bland and Altman, 1986; Whittaker et al 2007).

Pearson correlation coefficients, as used by Horton and Hall (1989) are a measure of relative reliability i.e. the degree to which measures maintain their position in a sample of repeated measures and thus give an indication of consistency of ranking of the measures, without taking into account the actual value of the measurement itself (Bruton et al, 2001). When interpreting a Pearson r-value it is possible to assume, erroneously, that if the r-value is high (i.e. close to 1.0), then the individual measures are very similar, when in actual fact they may be hugely different from each other but in a consistent way (Maher, 1993). Thus most Pearson r-values tend to give an overestimation of the reliability of reported individual measures.

Intra-class correlation coefficients (ICC) as used by Greene et al (2001), and others, have similar properties to the Pearson correlation co-efficient but overcome some of its limitations by using variance estimates calculated using either one-way or two-way analysis of variance (ANOVA), and thus reflect both the degree of consistency and the agreement among measurements (Bruton et al, 2001). There are a number of models of the ICC and it is very important to use the correct version; Shrout and Fleiss (1979) show the importance of this by quoting six different ICCs (range 0.17-0.91) that were calculated from the same set of data, using different models of the ICC. Common errors made in the use of the ICC are not to be specific about which model is being used, and to have an insufficient number of data; Chinn (1991) recommends at least 25 degrees of freedom. Greene et al (2001) quote very poor results when measuring the Q-angle, for both intra-rater reliability (ICCs ranged from 0.14-0.37) and inter-rater reliability (ICCs ranged from 0.17-0.29). They had 24 raters, and reported

slightly higher values when the measures were taken with the knee in extension (supine) rather than with the knee in 20 degrees of flexion, but they do not specify which type of ICC they used to calculate these values (Greene et al, 2001).

Seven studies calculated SEM for either or both intra-rater and inter-raters. All results were less than 4 degrees (see Table 3.2). On the face of it these errors may seem fairly small but in order to put them in to context it is important to bear in mind the size of the Q-angle, which for normal healthy adults is typically between 12 and 17 degrees (Woodland and Francis, 1992) and so an SEM of between three and four degrees is a high percentage variation. Also, according to the calculations suggested by Eliasziw et al (1994) when using a long-arm goniometer to measure joint angles, this would mean that the minimum difference needed to show a true difference in measured values would be between approximately five and six degrees.

Each of the studies which calculated the reliability of the Q-angle assumed that it is a fixed or absolute value which does not vary and that any variation in the measured values was due to measurement error rather than a possible variation in the measure itself, over time.

Table 3.2 – Q-angle reliability quoting Intra-class Correlation Coefficient (ICC) and Standard Error of Measurement (SEM) statistics, from seven reported studies (see key below).

Study	No. of testers	No. of Repeat meas	No. of subject	Knee position	Intra-tester ICC's	Intra-tester SEM's	Inter-tester ICC's	Inter-tester SEM
1	2	2	50	Extend (stand)	0.84 - 0.90	2.01 – 2.23	0.83	2.49
	2	2	50	Flexed (stand)	0.83 for both	0.68 - 2.45	0.65	3.50
2	1	2	16	Extend (stand, relax + contr); Extend (sup, relax + contr)	0.73 - 0.87	1.47 - 2.15	N/A	N/A
3	3	3	5	Extend (supine)	0.63	2.7	0.23	3.7
4	Not known	Not known	Not known	Extend(stand)	Not known	Not known	0.67	1.50
5	1	Not known	Not known	Stand	0.98	Not known	N/A	N/A
6	Not known	Not known	30	Stand	Not known	Not known	0.4	4.2
7	2	Not known	30	Extend(supine)	Not known	Not known	0.7	2.9

Key:

Study 1 = Caylor et al, 1993;

Study 2 = Guerra et al, 1994;

Study 3 = Tomisch et al, 1996;

Study 4 = Livingston and Mandigo, 1999;

Study 5 = Lathinghouse and Trimble, 2000;

Study 6 = Sutlive et al, 2004;

Study 7 = Piva et al, 2006).

ICC = Intra-class Correlation Coefficient

SEM = Standard Error of Measurement

Table 3.3 – Q-angle reliability quoting Pearson Product reliability co-efficient or Intra-class Correlation co-efficients (ICC) from seven reported studies (see key below).

Study	Number of testers	Number of repeat measures	Number of knees	Knee Position	Intra-rater PP/ICC	Inter-rater PP/ICC
1	2	Not given	7	Extended (standing)	0.92	0.78
2	1	2	15	Extended (supine)	0.81	N/A
	1	2	15	Extended (standing)	0.76	N/A
3	1	3	10	Extend (standing)	0.92-0.94	N/A
4	22	N/A	50	Extended (supine) 20 flexion (supine)	N/A	0.20 (L) 0.26 (R) 0.29 (L) 0.17 (R)
	22	N/A	50		N/A	
	3	3	26	Extended (supine) 20 flexion (supine)	0.37 (L) 0.22 (R)	N/A
	3	3	26		0.27 (L) 0.14 (R)	N/A
5	1	2	10	Extend (standing)	0.98	N/A
6	Not known	3	1597	Extend (standing)	Not known	0.83
7	1	2	18	10 ⁰ flex supine	0.78-0.92	N/A
	2	2	18	100 flex supine	N/A	0.56- 0.88

Note:

Study 1 = Horton and Hall, 1989;

Study 2 = Woodland and Francis, 1992;

Study 3 = Heiderscheit, 2000;

Study 4 = Greene et al, 2001;

Study 5 = Herrington and Nester, 2004;

Study 6 = Boling et al, 2009;

Study 7 = Draper et al, 2011

ICC = Intra-class Correlation Coefficient

PP = Pearson Product reliability co-efficient (r)

3.3 – Dominance of the Q-angle in the literature

The Q-angle is mentioned extensively in literature on the knee joint, particularly in literature on the patello-femoral joint. It was first identified by Brattstrom (1964), and since then has become widely accepted as a useful measure and an important part of any full clinical assessment of the knee joint. It is commonly mentioned in literature on Anterior Knee Pain (AKP) and Patello-femoral joint Syndrome (PFJS). However, a review paper on Anterior Knee Pain by Cutbill et al, (1997) concludes that the range of normal values for the Q-angle is variable and that there are minimal quantifiable data supporting its diagnostic relevance. Another review paper by Selfe (2004) concluded that the ICCs for intra-rater and inter-rater reliability for measuring the Q-angle were poor and questions its usefulness, particularly in determining treatment options.

3.3.1– Usefulness of the Q-angle and clinical decisions made on its value

Thirty-two articles were found which reported a series of Q-angle measures taken from various subjects, following varying measurement protocols. The first group of articles reviewed contain a clinical patient series with a management programme and its outcomes, or look at the predictive nature of the measured Q-angle on outcome or injury. The second group are those in which the Q-angle is measured to examine similarities or differences between groups, or where authors are looking to see if the measured Q-angle correlates with other measures or to create a normal database; but has no direct immediate clinical application.

The findings from each paper will be outlined briefly, and then the strengths and weaknesses of the different approaches and findings will be commented on in the summary sections.

3.3.1.2 – *First Group of articles – immediate clinical application (13 articles)*

Insall et al (1976) measured 50 normal knees of hospital personnel and found that the average Q-angle was 14 degrees, they give no other details about the subject group, do not describe their measurement protocol and only quote

average figures for their results. They report that the measures were very constant and varied by no more than a few degrees, but do not elaborate on this. They conclude that measured Q-angles of 20 degrees or more are abnormal and indicative of patellar instability. They used this Q-angle value to allocate individuals to treatment, those with a measured Q-angle of 20 degrees or more underwent a surgical procedure to realign the extensor mechanism by moving the tibial tubercle, others had conservative treatment. One hundred and five knees had this surgical procedure and 76% had an excellent or satisfactory outcome, as measured by patients reporting a relief of pre-operative symptoms when audited (no details given) at a minimum of 2 years following surgery. They do not report post-surgical Q-angle measurements and state that there seemed to be no prognostic factors by which to predict the result of their surgical intervention. This study illustrates the importance attached to the measured value of the Q-angle, despite the measurement protocol itself not being described at all nor subject to any reliability analysis.

Aglietti et al (1983) measured the Q-angle of the right knee of 150 healthy adults and the symptomatic knee of 106 adults to see if there were differences between the two groups. The symptomatic group consisted of patients with recurrent subluxation and/or chondromalacia of the patella. They describe their method of measuring the Q-angle very briefly, and do not describe any reliability analysis for their technique. For the healthy group the average value of the Q-angle for whole group was 15 degrees (males 14 degrees, SD of 3 degrees; females 17 degrees, SD of 3 degrees). The whole group average for the symptomatic group was 18 degrees (males 16 degrees, SD of 5 degrees; females 19 degrees, SD of 4 degrees). These average values between the 2 whole groups were statistically significantly different, as were those between the males and females. For those in the symptomatic group who recovered with conservative management within a 4-year period (35 persons) the one significant factor when compared to the rest of their group was an average Q-angle of less than 18 degrees. Twenty-one of the symptomatic group had 'realignment' surgery as conservative management was not successful, they gave no details about the outcome following surgery. Treatment decisions were not made on the Q-angle value as all symptomatic individuals underwent

conservative management initially, and only those for whom this was not successful underwent surgery. They do not report any repeat Q-angle values following treatment.

Brown et al (1984) took Q-angle measurements pre and post surgery, on individuals diagnosed with an unstable patella who had the Elmslie-Trillat surgical procedure to realign the extensor mechanism by repositioning the tibial tuberosity medially. The purpose was to see if there was any correlation post-operatively between the new value of the Q-angle and the outcome as rated by the Cox rating system. They describe their Q-angle measurement protocol in some detail and state their protocol “yielded the most reproducible results in our hands”, but do not state how they came to this conclusion. Twenty seven knees were followed up for a minimum of 2 years post surgery; 22 (81%) were rated as having had an excellent or good outcome according to the Cox rating scale (Cox, 1982). After surgery they found that a reduction in the measured value of the Q-angle correlated well with the Cox rating scale. All patients with a post-surgical Q-angle of 10 degrees or less had a good or excellent outcome as measured on the Cox scale.

McConnell (1986) recorded the Q-angle of 35 adults with PFJS, ten of whom had a Q-angle of greater than 15 degrees. No measurement protocol or reliability analysis for the Q-angle is given. She describes a new conservative treatment programme developed by herself, and reports a success rate of 90% six months following discharge, most patients having attended for a maximum of 3 sessions and then continued with the exercise regime at home, she does not comment again on the Q-angle.

Whitelaw et al (1989) describe a series of 85 patients with AKP, with 114 affected knees. Of these they report that 19 knees (17%) had a measured Q-angle of greater than 20 degrees, but did not state why the value of 20 degrees was important. No detail is given of the Q-angle measurement protocol at all and there is no mention of any reliability analysis of measures obtained. All patients were given standard doses of NSAID's (ibuprofen or naproxen) and then attended a physical therapy programme 3 times per week for 4-6 weeks.

Overall 87% of patients' knee symptoms improved during the programme with 70% of all patients being able to return to their pre-morbid level of activity. Fourteen patients (18%) worsened with this regime and they had surgical management, 12 had a lateral release procedure in order to realign the patella. No mention is made of the Q-angle of this subgroup.

Doucette and Goble (1992) describe a series of 56 knees with lateral patellar compression syndrome. Several measures, including the Q-angle (in standing and supine) were taken both before and after completion of a physical therapy treatment programme. A brief description of the subjects' position for measuring the Q-angle was given, but no further detail about the measurement protocol or its reliability. Following completion of the exercise programme the group were subdivided into three subgroups. Group 1 (43 knees) became pain-free after an average of 8 weeks treatment, Group 2 (8 knees) had no decrease in symptoms after 14 weeks of treatment, and Group 3 consisted of 5 normal healthy control knees. For group 1 the Q-angle values post-treatment in both standing and supine decreased slightly, but this was not significant (17.65 to 16.53 degrees for supine; and 17.86 to 16.55 degrees for standing); for group 2 the Q-angle values post-treatment also decreased slightly but by a smaller margin (18.62 to 18.50 degrees for supine; and 19.75 to 19.38 degrees for standing) and the same happened for those in group 3 (17.20 to 16.80 degrees for supine; and no change from 17.00 degrees for standing). They concluded that the measured Q-angle was not a useful predictor for determining outcome following treatment, and make no comment on whether their measurement protocol could have affected this. It is worth noting that all their average Q-angles were high and outside of the range of between twelve and seventeen degrees, which a number of authors consider to be normal (Woodland and Francis, 1992).

Moss et al (1992) measured the Q-angle of three groups of people. Group 1 consisted of subjects with patellofemoral pain (21 knees); Group 2 consisted of healthy subjects (30 knees) and Group 3 consisted of a mixed group of subjects of 14 asymptomatic knees and 10 symptomatic knees. Q-angle values were measured from pictures from a video camera, no measurement reliability is

mentioned. They found that Q-angle was significantly greater (by 12%, or 1.9 degrees) in those subjects with symptomatic knees ($p=0.01$). They acknowledged that a difference in average Q-angle of 1.9 degrees was small but felt that it was still a useful statistic as it formed part of a predictive equation, created by them, using discriminant analysis which was 89% accurate in predicting which subjects would or would not have patellofemoral stress syndrome. The equation used an individual's weight, pelvic width, and Q-angle. They suggested that with proper screening individuals susceptible to patellofemoral stress syndrome could be identified prior to becoming symptomatic and that preventative corrective procedures should be introduced at that stage. As yet there has been no follow-up study published describing such a scheme.

Kannus and Niittymaki (1994) described a series of 49 consecutive patients with unilateral PFPS. Twenty-two variables (including the Q-angle) which are thought to have an outcome-predictive role were measured both before and after completion of the six week treatment protocol of relative rest, NSAID's and intensive quadriceps muscle exercises. They state what the Q-angle is, but do not describe their measurement protocol, and give very brief details only of some of the other measures taken. All 22 pre and post treatment variables were compared to see if they correlated with the general outcome as measured by a self-completed visual analogue score (VAS) for pain, and the Lysholm and Tegner functional knee scoring systems. There was no statistically significant difference in Q-angle measures immediately following treatment nor at six months follow-up. In general those with higher measured Q-angles had a poorer outcome. The authors do not mention the issue of measurement reliability for any of their chosen clinical measures when discussing their results.

Thomee et al (1995) reported a set of bilateral Q-angle measures taken from a group of 60 females. The main purpose of their study was to compare muscle function in individuals with and without patellofemoral pain before and after participation in one of two types of muscle strengthening programme. The group was subdivided into 40 individuals who had unilateral pain arising from the patellofemoral joint, and 20 healthy controls. Subjects had their Q-angle

measured only before participation in the strengthening programme. Each subject stood at right angles to a video camera with their feet 10 cms apart with the Q-angle measurements made using a goniometer on a 28-inch television screen. The reported results for group 1 were: symptomatic knee mean Q-angle of 16.8 degrees (SD of 4.6); asymptomatic knee mean Q-angle of 16.4 degrees (SD of 5.4); for group 2: the right knee mean Q-angle was 17.9 degrees (SD of 5.2); for the left knee the mean Q-angle was 15.1 degrees (SD of 4.9). There were no statistically significant differences between the average measured values for the two subgroups, no mention was made of statistical tests for significance between the right and left Q-angle measurements of the control groups, but the values are different. They did not mention measurement reliability when discussing their results.

Devan et al (2004) measured the Q-angle of both knees of 53 healthy women, in college athletic teams, measures were taken with the women in standing with a long-arm goniometer, using bony landmarks of the anterior superior iliac spine, the midpoint of the patella and the tibial tubercle. No further details are given and no reliability analysis is reported. They found mean differences between the right and left knees reporting results of 12.8 and 11.2 degrees respectively. The measures were taken as part of a series of measures exploring muscle balance/imbalance in athletes, and they report that 9 of the athletes who sustained an overuse knee injury during the season had an 'excessive' Q-angle for at least one knee, but they do not clarify what their threshold level of measured Q-angle was.

Sutlive et al (2004) measured the Q-angle of 78 knees with PFJS from 45 participants on active military duty, they measured the Q-angle in standing but do not describe their protocol at all. The purpose of their study was to see the effect of using foot orthoses for individuals with PFJS. They carried out inter-rater reliability analysis calculation ICC (2,1) and SEM. They do not give details of the number of testers or the number of repeat measures used in their reliability analysis; so it is not possible fully to understand the meaning of the ICC values. They report an inter-rater ICC of 0.4 and SEM of 4.2 degrees, and an average Q-angle for the group of 9.2 degrees. They recognise their

measurement reliability was low and that this 'may pose a threat to the internal validity of our investigation'.

Rauh et al (2005) measured the Q-angle of 421 (235 boys) High School cross-country runners at the beginning of the season as one measure looking at risk factors for injury. All measures were taken by the same tester using a standard method, brief details of this are given i.e. subjects were in comfortable standing (without shoes), with their quadriceps muscles relaxed, feet facing anteriorly shoulder-width apart, and body weight distributed evenly over both feet. The three bony landmarks (ASIS, centre of patella and tibial tuberosity) were marked with a dot to aid measurement. No reliability analysis for any of the measurement protocols was mentioned. The incidence of injury for each runner was recorded throughout the season. They reported that the incidence of lower limb injury was greatest in: girls, those who had a larger measured Q-angle and a history of previous injury. They conclude that measured Q-angle may be a useful predictor of injury in cross-country runners of High School age. However they do not give details of what constitutes a 'larger measured Q-angle'.

Schultz et al (2006) measured the Q-angle of 79 healthy National Collegiate Athletic Association Division 1 female athletes. The measures were part of a range of measures taken to explore the effects of Navicular drop and Q-angle on neuromuscular response to a weight-bearing perturbation. The Q-angle was measured with subjects in standing, their feet shoulder width apart, knees straight and their toes pointed anteriorly. The ASIS, centre of patella (determined by palpation) and tibial tubercle were the bony landmarks used. Measures were taken by the same experienced investigator and recorded to the nearest degree, using a standard goniometer. Intra-tester reliability was determined by taking repeat measures from 15 individuals within one week of the first measure, and being blinded to the original value. Calculating the ICC value from a total of 30 measurements is considered good practice, following the recommendation of Chin (1991) that the number of measurements used in the calculations should exceed 25. ICC (2,k) of 0.84 and measurement error of 1.4 degrees were reported, these values would be considered good in general reliability terms, but not high enough for the results of the measurements to be

used for diagnostic or treatment purposes (Portney and Watkins, 2000). Their results suggest that higher Q-angle and Navicular drop values when present together cancel each other out, when subjects are exposed to a weight-bearing perturbation.

3.3.1.3 – Summary of findings from the above articles

Of the thirteen articles presented here that report a series of measured Q-angle data from patient groups, only two address the issues of measurement reliability. Sutlive et al (2004) calculated inter-tester ICC values, but gave no details of the number of testers or the number of repeat measures taken, so it would be impossible to try and replicate their work. In addition they only report reliability testing using one method of analysis which is deemed insufficient; they reported an inter-tester ICC of 0.4 and recognise that this is low.

According to Portney and Watkins (2000) this would be considered a poor level of reliability and so it would be difficult to use their measured value of the Q-angle in any meaningful way. Schultz et al (2006) calculated intra-tester ICCs (0.84) and measurement error (1.4 degrees), using two tests for analysing results is considered good practice and their results would be considered to show a good level of reliability, but their ICC value is less than 0.9, the level suggested by Portney and Watkins (2000) as being the threshold necessary for diagnostic or treatment decisions to be made on its value.

3.3.1.4– Second Group of articles – no immediate clinical purpose (21 articles)

Olerud and Berg (1984) undertook a series of repeat Q-angle measures on 34 healthy subjects in three conditions;

- a) standing 2.5 m in front of a camera and being filmed;
- b) standing with their foot position standardised, measured with a long-arm goniometer;
- c) supine, with their legs relaxed and knees extended and the foot position not standardised, measured with a long arm goniometer.

They give no further details of their measurement protocol and calculate reproducibility by comparing a repeat and original measure from 12 subjects in each case, but do not describe which test their *r*-value is calculated from. They

calculated a reliability co-efficient from 24 measures which is close to the minimum of 25 recommended by Chinn (1991). They report that the measured Q-angle from the photographic method i.e. condition a) was very reproducible with $r=0.95$; as was the method with the person in a standing position, with the foot position standardised i.e. condition b) with $r=0.96$. They also report that the values obtained with the subject in a supine position i.e. condition c) varied from those obtained with the subjects in a standing position, but were also reproducible with $r=0.71$. A further 12 subjects had their Q-angle measured in standing with their foot in 15 degrees of outward rotation, neutral and 15 degrees of inward rotation and the measured Q-angle increased with inward rotation of the foot ($p=0.001$). Twenty-two subjects had their Q-angle measured in standing in 25, 15 and 10 degrees of pronation, neutral and 10, 15 and 25 degrees of supination (the position of the foot was maintained by using a wooden wedge underneath the foot), and the Q-angle decreased as the foot position moved from pronation to supination. Their reliability analysis would be considered good, although only one method of calculating it was used; their reliability figures for the first 2 conditions, a) and b) were above the 0.75 threshold which are considered good; whereas their reliability for the measures taken in supine (0.71) would be considered moderate; this is particularly interesting as in practice it is easier to position the goniometer when taking measures with the subject in supine rather than in standing, although standardising foot position with subjects in supine is done less often. They conclude that foot position must be standardised when measuring the Q-angle due to its effect on the measured value.

Horton and Hall (1989) report a series of measures taken on a group of 100 healthy young adults (aged 18-35 years) in standing with their knees in full extension. The mean Q-angle for 50 males was 11.2 degrees (SD of 3.0); and that for 50 females was 15.8 degrees (SD of 4.5); a difference of 4.6 degrees. Using a point biserial correlation calculation the relationship between Q-angle and gender was significant ($p =0.001$). They also report that none of the males had a Q-angle of 20 degrees or greater, but 13 of the 50 females had a Q-angle of greater than 20 degrees. They state that their Q-angle measurement protocol was 'in the manner suggested by the literature' but give no specific

reference or any further details. All measurements from each subject were made by the same investigator. Their measurement reliability was calculated on a subgroup of seven subjects, however, the number of repeat measures was not given, nor the number of testers, and so it is not possible to know whether these calculations were appropriate. They used just one tool to determine their reliability – the Pearson product-moment correlation coefficient – and quote r values of 0.92 for intra-rater reliability and 0.87 for inter-rater reliability for repeat measures, which they consider to be good. They used string between the anterior superior iliac spine and centre of the patella in order to ensure the long-arm of the goniometer was correctly positioned.

Boucher et al (1992) report Q-angle measures taken from a group of 18 female subjects. Measures were taken with the subjects standing in a standardised position parallel to the frontal plane of a camera. The Q-angle was calculated from the film using specially designed software. No measurement protocol or reliability analysis is reported. The groups were subdivided into two, the first had no knee pain and had a mean Q-angle of 8.25 degrees; the second had knee pain and a mean Q-angle of 21.05 degrees. They do not report how many subjects were in each group.

Caylor et al (1992) report a set of Q-angle measures taken from two groups of subjects. Group 1 consisted of 50 subjects (18 males, 32 female) with a diagnosis of anterior knee pain (AKP) and Group 2 consisted of 26 control subjects (9 male, 17 female). Measures were taken in standing with the knee extended and the body weight evenly distributed over both feet, they give a detailed description of their measurement protocol. An initial reliability study was carried out on the group of 26 healthy controls by two testers who had completed 3 hours of training in taking Q-angle measurements. The Q-angle for both knees of each subject were measured twice in each of two positions (knee extended and slightly flexed) by each tester, the two testers then repeated the process until in total each tester had measured the Q-angle of each knee 16 times; all measurements being taken during one session. Intra-class correlation coefficients (details of specific model not given) and Standard Error of Measurement (SEM) were calculated. The intra-rater ICC values for Q-

angle measures taken with the knee extended were 0.84 and 0.90, and the SEM values were 2.01 and 2.23 degrees; the Inter-tester ICC was 0.83 and SEM was 2.49 degrees. The intra-rater ICC values for Q-angle measures taken with the knee slightly flexed were 0.83 for each tester, and the SEM values were 0.68 and 2.45 degrees; the Inter-tester ICC was 0.65 and SEM was 3.50 degrees. Due to the poorer reliability of the Q-angle measurements taken with the knee partially flexed, this measurement was not taken from the group of subjects with AKP. The average measured Q-angle (with the knee extended) for the group with AKP was 12.4 degrees (SD of 5.1) and for the healthy controls was 11.1 degrees (SD of 5.5). The difference between the 2 groups was not statistically significant ($p=0.07$). The authors conclude that for this group of subjects there was no difference in Q-angle between those with AKP and those without. Their reliability analysis would be considered good and their reliability results above 0.75 also good, although only one individual had met the reliability threshold of 0.90 recommended by Portney and Watkins (2000) as being the level of reliability necessary for diagnostic or treatment decisions.

Woodland and Francis (1992) report a set of Q-angle measures taken from the right knee of healthy young adult subjects, 269 males and 257 females. The measurements were taken in both supine and standing, with the knee in full extension, with the patella directed into the sagittal plane and foot position disregarded; by the same investigator. Subjects were asked to keep their quadriceps muscles as relaxed as possible for all measures. They report average values for males of 12.7 degrees (SD of 0.071) in supine and 13.6 (SD of 0.70) in standing; and for females an average of 15.8 degrees (SD of 0.072) in supine and 17.0 degrees (SD of 0.073) in standing. When these results were put through an ANOVA test they revealed significant differences between the values for males and females in both positions and also a significant difference between measures taken in supine and standing positions. Before the study measures were taken a test-retest reliability was calculated on 15 subjects (they do not specify which test was used) and an r value of 0.81 is reported for measures taken in a supine position, and 0.76 for those taken with the subjects in standing. Using 30 measures for their reliability analysis would be considered good, but all their results are below the 0.90 threshold

recommended by Portney and Watkins (2000). They conclude that gender and the position in which the Q-angle measure is taken affect its value, they also quote that many of the individuals in their group of healthy individuals had Q-angle measurements that would be considered abnormally high.

Guerra et al (1994) report a set of Q-angle measures taken of the right knee from a convenience sample of 60 healthy adults (30 males and 30 females) taken under four randomly ordered test conditions. For all conditions the foot position was standardised to neutral. The conditions were:

- 1) in standing with quadriceps muscles relaxed,
- 2) in standing with quadriceps muscles contracted isometrically,
- 3) in supine with quadriceps muscles relaxed, and
- 4) in supine with quadriceps muscles contracted isometrically.

The measurement protocol was clearly described, and foot position was controlled. They undertook a preliminary reliability study and calculated ICCs (using model 2,1 and 2,3) and SEM were calculated, but do not give details of the number of testers or measures used in this analysis. They report ICC values of between 0.73 and 0.87 and SEM values of between 1.47 and 2.15 degrees; for the four positions. It is not possible to comment fully on their reliability analysis as they give insufficient details, all ICC values fall below the 0.90 threshold recommended by Portney and Watkins (2000) and at least one falls into the moderate banding suggested by Portney and Watkins (2000). In the relaxed standing position the mean Q-angle value for the males was 8.6 degrees (SD of 3.79); for the females it was 13.5 degrees (SD of 4.75). In the contracted standing position the mean Q-angle value for the males was 7.4 degrees (SD of 3.70); for the females it was 12.0 degrees (SD of 4.09). In the relaxed supine position the mean Q-angle value for the males was 8.4 degrees (SD of 4.52); for the females it was 14.2 degrees (SD of 3.49). In the contracted supine position the mean Q-angle value for the males was 6.6 degrees (SD of 4.31); for the females it was 10.7 degrees (SD of 3.22). A two-way multivariate analysis of variance for repeated measures (MANOVA) was used to examine differences between genders and among the test conditions. The MANOVA showed a significant difference between the men and women for all test conditions and among the test conditions. The separate gender

ANOVA's showed a significant effect of quadriceps contraction for both the males and the females. They conclude that it is important to standardise the protocol for measuring the Q-angle as it appears to be affected by the contractual condition of the quadriceps muscle as well as gender and whether the subject is in a standing or supine lying position.

Tomisch et al (1996) measured the Q-angle of the right knee of 27 healthy subjects; the purpose of their study was to determine the reliability of various measurements involving the position of the patella. They state that the Q-angle was measured with subjects in supine, and used a length of string stretched from the ASIS to the centre of the patella to assist them. Three physical therapists took the measurements. They calculated intra-tester and inter-tester ICCs (type 2,1) based on one set of 3 repeat measures for each tester, this number of measurements is too few to make their calculations meaningful being based on a group of 6 measurements. They report an average intra-tester reliability ICC of 0.63, this is considered moderate by Portney and Watkins (2000), an inter-tester reliability ICC of 0.23, this is considered poor by Portney and Watkins (2000). They report intra-tester SEM of 2.7 degrees and inter-tester SEM of 3.7 degrees. They conclude that these low 'agreement coefficients were clinically unacceptable' and that 'treatment decisions based on these measurements should not be made'. This conclusion is completely appropriate based on their analysis and results, but it is interesting that they make this very general conclusion and do not question their own measurement protocol (and lack of detail) or suggest that it might be possible to develop a more reliable measurement protocol.

Heiderscheit et al (1999) report a series of Q-angle measures taken from the right knee of 32 healthy pain-free subjects (16 males and 16 females). They were investigating whether or not the value of the Q-angle had any influence on the variability of lower extremity co-ordination during running. Q-angle measures were taken with subjects in standing, they do not give any further details of their measurement protocol, and no reliability analysis was carried out on the Q-angle measurement protocol. They subdivided their group into two smaller groups, those with a Q-angle of greater than 15 degrees (HQ) and

those with a Q-angle of 15 degrees or less (LQ), they do not give details of the size of these two subgroups. The mean Q-angle for the HQ group was 18.4 degrees (SD of 2.5) and the mean value for the LQ group was 11.8 degrees (SD of 1.8); these were statistically different from each other. In their discussion they conclude that there was no difference in continuous relative phase (CRP) during running for those individuals with a low or high Q-angle, and thus Q-angle did not influence this aspect of lower extremity co-ordination while running, although the group with the higher mean Q-angle value had greater variability in CRP than the group with a lower mean Q-angle. When discussing their results they do not mention the issue of measurement reliability.

Livingston and Mandigo (1999) reported a series in which bilateral Q-angle values were measured in 75 subjects. Following completion of a 'knee questionnaire' measuring the presence of knee pain during static activity i.e. prolonged standing, and dynamic activity i.e. walking, jogging, or stair climbing subjects were assigned to one of 3 groups.

- Group 1 were asymptomatic - 50 subjects,
- Group 2 had unilateral knee pain - 11 subjects, and
- Group 3 had bilateral knee pain - 14 subjects.

Q-angle measures were taken bilaterally with the subjects in standing with the knees extended and the quadriceps muscle relaxed, all measurements for a given subject were taken by the same investigator. A brief description of the measurement protocol was given, and some pre-testing reliability analysis was carried out although no details for this are given. They quote a value of 0.67 for the intertester ICC (2,1), and an SEM of 1.5 degrees; and conclude that reliability was therefore good. This is surprising as according to both Portney and Watkins (2000) and Shrout and Fleiss (1979) this value would be considered as moderate only. Differences in mean Q-angle by group, limb and gender were analysed using an analysis of variance procedure. Differences between Q-angles (right minus left) were calculated so that the magnitude and direction of within-subject bilateral asymmetry could be evaluated. Correlation coefficients were used to determine the degree of association between the Q-angle and other variables i.e. pain, group and gender measures. For the entire sample the average Q-angle for both the right and left knees was 11.5 degrees,

despite the fact that almost half of the subjects had a difference of at least 4 degrees between their right and left Q-angles. One significant difference between groups was that 36 (72%) of those in group 1 had a left Q-angle which was greater than their right Q-angle, and in group 3, 12 (86%) had a right Q-angle value higher than their left. They also report that the size of the Q-angle in symptomatic knees and the difference between Q-angle values positively and significantly correlated with the extent of pain. They point out how the act of summarising data can lead to a compromise between simplicity and accuracy and mask individual differences.

Heiderscheit et al (2000) measured the Q-angle of 32 healthy individuals, looking at the influence of the Q-angle on running kinematics. The same individual measured the Q-angle of the right knee of all subjects, in standing with a goniometer using the centre of the patella, the anterior superior iliac spine and the tibial tuberosity as the bony landmarks. They undertook some preliminary Intra-rater reliability testing by having the same tester measuring 10 knees on 3 consecutive occasions. They report ICCs values of 0.92 - 0.94 and conclude that their Q-angle measurement protocol was good. This group are the first to have all reliability calculations exceed the 0.90 threshold set by Portney and Watkins (2000). They found no mean difference in mean Q-angle values between the 16 males and 16 females, and no correlation between the Q-angle and any of the kinematic variables. They suggest that measuring the Q-angle dynamically might be more useful.

Lathinghouse and Trimble (2000) measured the Q-angle of 22 healthy women (aged between 18-30 years). Small reflective markers were placed on the ASIS, the midpoint of the right patella and the middle of the right tibial tubercle. Subjects stood, without shoes, with their feet shoulder-width apart and with their weight evenly distributed over both feet; in front of and parallel to the frontal plane of a video camera. Each subject's foot position was marked to ensure it was the same for all measures taken. Measures were taken under two conditions:

- a) Standing with the quadriceps muscles relaxed, and
- b) Standing with the quadriceps muscles fully statically contracted.

Each subject then exercised their quadriceps muscles vigorously by riding a cycle ergometer for 5 minutes at 55% of their maximum heart rate, keeping the bony markers in place so when the Q-angle measures were taken after exercise the bony markers were still in position, thus reducing the potential for error in re-identifying the position of the bony markers. Immediately following this exercise subjects were filmed in their previously recorded position. The same tester made all Q-angle measures and intra-rater reliability was assessed for 10 subjects by repeating the Q-angle measures on different days and then calculating ICCs (3,1) using a 2-way analysis of variance. They report an ICC of 0.98 and a method error of 0.37 degrees and so felt reassured that their technique had good reliability. Their ICC result exceeds the threshold of 0.90 recommended by Portney and Watkins (2000), however it was calculated on 20 measures rather than the minimum of 25 recommended by Chinn (1991). They found that there was a statistically significant difference in the Q-angle values when comparing the relaxed versus the contracted status of the quadriceps muscle, both before and after vigorous exercise. There was no relationship between the state of contraction and the effect of exercise. They also noted a linear relationship between the value of the Q-angle with the quadriceps relaxed and the amount it decreased when the quadriceps were contracted ie. the greater the resting value of Q-angle the greater the decrease in Q-angle when the quadriceps were contracted.

Greene et al (2001) used a group of 25 healthy physiotherapists who worked in orthopaedics and had them each measure the Q-angle of both knees of each other. The purpose of their study was to explore the reliability of Q-angle measurement by the same and several individuals and then to compare these clinical measurements with those taken from radiographs. Their intra-rater reliability was undertaken by a sub-group of three individuals who measured the Q-angle of 13 individuals a total of three times. All measures were taken with subjects in supine with the knee in two positions – fully extended and in 20 degrees of flexion with the foot in neutral; using a pocket goniometer. The bony landmarks used were the ASIS, centre of the patella and centre of the tibial tuberosity. Their reliability calculations were the ICCs (type not specified). They report intra-rater reliability ICC values between 0.14 and 0.37; inter-rater

reliability ICC values between 0.17 and 0.29, and reliability between clinical (goniometric) measurements and those taken from a radiograph of 0.13 to 0.32. They concluded that measurement reliability of the Q-angle is poor. Their ICC values were calculated from a good number of measures (39) which exceeds the minimum number recommended by Chinn (1991), but as they do not specify which ICC model was used it is difficult to comment on their results. Shrout and Fleiss (1979) reported a range of r-values between 0.17 and 0.91 when different models of ICC were used on the same data set.

France and Nester (2001) explored the effect of errors on the identification of the bony anatomical landmarks used to measure the Q-angle. They used the centre of the tibial tuberosity, (found by manual palpation), the centre of the patella (found by manual palpation, checked by using a ruler) and the area above the anterior superior iliac spine (found by manual palpation). The three-dimensional position of each marker was found while subjects stood in the relaxed standing position, using a MacReflex motion analysis system, using their measurement protocol which they had previously shown to have a 0.25 degree measurement error. Three recordings of each subject were taken. They then manipulated the co-ordinates of each marker in 1mm increments to see the effect this had on the Q-angle. They report variations in the Q-angle of 0.12–0.56 degrees; 1.13-5.53 degrees and 1.02-5.18 degrees with changes of 1-5mm in medial/lateral direction of the ASIS, patella and tibial tubercle respectively. When the bony markers were manipulated in a vertical direction there were much smaller effects on the Q-angle, with a maximum change of 1.46 degrees found for a 5mm manipulation of the tibial tuberosity. When errors in bony marker identification are compounded maximum differences of 8.3 degrees are reported. They recognise the difficulty of accurately identifying the bony landmarks of the centre of the tibial tuberosity and centre of the patella, but report that that in order to keep the Q-angle to within 3 degrees of its 'true' angle, marker identification needs to be within 1-2mm; which they suggest is rarely achievable. They are the first to report in the literature that measured Q-angle values may be less reliable than they appear, and are affected by the ability of the tester to correctly identify the bony landmarks.

Kuhn et al (2002) measured the Q-angle from both legs of 40 healthy males in standing using a long-arm goniometer. Subjects wore shoes and stood with straight knees. The bony landmarks used were the centre of the patella, the tibial tuberosity and the anterior superior iliac spine. The same tester took all measures, reliability was determined by the tester taking repeat measures and when he achieved 2 identical measures, this was the value recorded. They gave each subject full-length foot orthoses for both feet to neutralise pronation of the foot and then took repeat measures, following the same protocol. They report different average values of the Q-angle with and without the orthoses and from these results conclude that using a foot orthosis is beneficial in reducing the Q-angle of individuals who have foot pronation. They do not mention the issue of measurement reliability when discussing their results.

Herrington and Nester (2004) explored the effect of centring the patella in the femoral trochlear groove on the reliability and accuracy of Q-angle measurement. They measured the Q-angle of 109 healthy individuals (51 male). Initially subjects were in long-sitting and the bony landmarks of the ASIS, centre of the patella and tibial tubercle were marked, the knee was then put in a relaxed position of 20 degrees of flexion (in order to sit the patella within the trochlear groove, and its centre marked again and the distance between the two marks noted. Q-angle measures were taken with subjects in standing with their feet facing forwards (position standardised by using tape on the floor), the same experienced physiotherapist palpated and marked the ASIS, centre of patella and tibial tubercle and a photograph taken using a digital camera. Q-angle values were measured from the photograph with a goniometer, using both positions of the centre of the patella. Intra-rater reliability was determined by 10 Q-angle photographs being randomly selected and repeat Q-angle measures taken – an ICC (type not specified) of 0.98 was reported; and ICC (type not specified) of 0.99 for repeat measures of the distance between the two positions of the centre of the patella. Their reliability analysis used 20 measurements, which is a little below the minimum recommended by Chinn (1991), and it is always difficult to comment meaningfully on ICCs when the model used is not specified; however their quoted results of 0.98 and 0.99 respectively exceed the threshold of 0.90 recommended by Portney and Watkins (2000). They report

that of their 109 subjects 68 had a laterally displaced patella in standing, with the average displacement for females being 6.6mm (range 1-16mm) and 5.9mm for males (range 1-12mm); and 28 subjects had medially displaced patellae in standing, with the average for females being 2.5mm (range 1-7mm) and 2.3mm for males (range 1-6mm). They suggest that subjects with laterally displaced patella have measured Q-angle values that are lower than they really are and subjects with medially displaced patella have measured Q-angle values greater than they really are.

Kishali et al (2004) measured the Q-angle of both knees of 180 healthy elite soccer and taekwondo athletes (116 males) in supine and standing positions. Their purpose was to create a normal database for the Turkish population. The measurement protocol is briefly described, a modified goniometer was used and subjects were instructed to keep their quadriceps muscles relaxed; foot position was not mentioned. All measures were taken by the same investigator, there is no mention of reliability analysis. They report the results in Table 3.4:

Table 3.4 – Q-angle values for soccer and taekwondo players in Turkey, as reported by Kishali et al (2004)

Gender	Sport	Position	Right Knee (degrees)	Left Knee (degrees)
Male	Soccer	Standing	15.15	14.42
Male	Soccer	Supine	13.82	13.02
Male	Taekwondo	Standing	13.80	12.96
Male	Taekwondo	Supine	12.69	11.85
Female	Soccer	Standing	16.52	16.08
Female	Soccer	Supine	16.04	15.44
Female	Taekwondo	Standing	18.00	17.40
Female	Taekwondo	Supine	17.06	16.57

In their discussion they comment on the significant differences in mean angle found between the 2 different sports, gender and position, they do not mention the issue of measurement reliability.

Pantano et al (2005) measured the Q-angle of 204 college students, in order to see if there was any relationship between knee valgus angle during a single limb squat and the measured Q-angle. They hypothesised that individuals with a larger Q-angle would also have a greater knee valgus angle. Q-angle measures were taken from each subject's right knee with a long-arm goniometer by the same experienced physiotherapist; subjects were in relaxed standing and bony landmarks of the ASIS, the centre of the patella and the tibial tuberosity were used. A second physiotherapist (blinded to the first value) measured the Q-angle following the same protocol, and if the two values were within 5 degrees of each other the subject was included in the study. They do not mention measurement reliability and found no relationship between the measured Q-angle and knee valgus angle during a single limb squat.

Piva et al (2006) measured the Q-angle of the affected leg of 30 subjects with (PFJS), as part of a set of repeat measures taken by 2 experienced physiotherapists in order to determine their inter-tester reliability. The three bony landmarks of the ASIS, centre of patella and tibial tubercle were palpated and a mark placed on them with which to line the goniometer. Subjects were supine with the knee in full extension. Each of the two physiotherapists took the measurement within the same assessment session, but were blinded to the results of each other. Reliability of the two sets of measurements were determined by calculating the ICC (2,1) and SEM. The inter-tester ICC was 0.7; and the SEM was 2.9 degrees. Using the definitions of Shrout and Fleiss (1979) they conclude that there was only moderate agreement between the two sets of Q-angle measures, but comment that their results were more reliable than a number of other authors.

Carlson and Wilkerson (2007) measured the Q-angle of both knees of 52 healthy subjects in supine with their legs extended and relaxed. The ASIS, centre of patella and tibial tuberosity were the bony landmarks used, and were marked with a pen to aid measurement. A standard goniometer was used and the average of three measurements was used. They report an average Q-angle for the males of 13 degrees (range 10 – 15 degrees) and an average for the females of 15.9 degrees (range 14 – 20 degrees). They comment that their

results are similar to those in other published papers, and make no further reference to reliability.

Boling et al (2009) measured the Q-angle of 1597 midshipman from the United States Naval Academy. Measures were taken with participants in a standing position using a standard goniometer. The Q-angle was recorded in three separate trials and the average used. Pilot intra-rater reliability testing (no details given) gave $ICC_{(2,k)}$ results of 0.83. The cohort size is impressively large, but it is difficult to comment on the reliability as there are too few details given.

Draper et al (2011) measured the Q-angle of both knees of 18 healthy subjects, using: a long-arm goniometer, a short-arm goniometer and then compared these to measures taken from MRI images. Participants were in supine with their knees flexed to 10^0 . Two testers each took two measures from each knee on two occasions. They analysed all measures using ICCs and reported the following:

- Intra-tester ICC = 0.92 (long-arm goniometer) and 0.88 (short-arm goniometer)
- Inter-tester ICC = 0.78 (long-arm goniometer) and 0.56 (short-arm goniometer)
- MRI intra-tester ICC for tester 1 = 0.87
- MRI intra-tester ICC for tester 2 = 0.76
- MRI inter-tester ICC = 0.83
- MRI and long-arm goniometer; ICC = 0.4
- MRI and short-arm goniometer; ICC = 0.44

In general the measures taken with a goniometer tended to underestimate the value of the Q-angle when compared with the MRI values. These results all look good, but as only one method of reliability analysis was carried it is important to be cautious when interpreting their results.

3.3.1.5 – Summary of findings from the above articles

Of the twenty-one articles presented here which report a series of measured Q-angle data from non-patient groups, seventeen addressed the issue of measurement reliability and nine carried out this analysis well, following recommendations. However, most only calculated one recognised measure of reliability, typically ICC calculations; but did them well and according to recommendations specifying which model was used and having a large enough sample of measurements. Of these seven studies two reported ICC values that exceeded the 0.90 threshold set by Portney and Watkins (2000); these were Lathinghouse and Trimble (2000) and Heiderscheit et al (2000).

3.3.2 – Overall Summary of issues affecting measurement of the Q-angle

In general it is interesting to note that of the articles presented above, the group of thirteen articles that involved a patient series which had direct implications for clinical management only two authors addressed the issue of measurement reliability in any meaningful way i.e. Sutlive et al (2004) who report an inter-tester ICC of 0.40 and recognise that this is low; and Schultz et al (2006) who report an intra-tester ICC of 0.84, which is considered good but is still below the threshold of 0.90 recommended by Portney and Watkins (2000) as being the level necessary for diagnostic or treatment decisions to be made on its value. In contrast for the group of twenty-one articles which mainly included healthy subjects and had a less immediate and direct impact on clinical practice, the issue of measurement reliability was much more established and addressed more often and more thoroughly, although only two authors report ICC values which exceeded the 0.90 minimum recommended by Portney and Watkins (2000). Despite this lack of measurement rigour, the conclusions drawn by authors seem to be generally accepted by clinicians, who recognise that in order to measure the Q-angle accurately and reliably a strict protocol must be followed. There is also general consensus that normal values for the Q-angle are 15 degrees or less and that the following factors may affect the value of the measured Q-angle; although there is no consensus on whether the effect is to increase or decrease the measured value:

- **Gender** – it appears that females have larger Q-angles than males; the reasons for this are not clear, but it is suggested that this may be due to the relatively greater ratio of pelvic width to height in women compared to men;
- **Position of the foot** – it appears that an increase in pronation correlates with an increase in Q-angle;
- **Contraction of the quadriceps muscles** – overall it appears that contracting the quadriceps muscle will decrease the Q-angle as this will pull the patella laterally;
- **Whether the subject is standing or lying** – overall greater Q-angles were reported when subjects were in standing;
- **Anatomic position of the patella in the femoral sulcus** – a more laterally situated patella will tend to give a smaller Q-angle
- **Anatomic position of the tibial tubercle** – a more laterally positioned tibial tubercle will give a relatively larger Q-angle
- **Presence of patello-femoral pain** – it appears that patello-femoral pain is usually associated with a larger Q-angle
- **Which knee is measured** – there appears to be no consensus at all on which knee is likely to be associated with a larger Q-angle; although it is thought that leg dominance might be a factor; however all studies agree that individuals very rarely have equal Q-angles bilaterally;
- **Knee flexion** – it appears that knee flexion is usually associated with a reduced Q-angle

The Q-angle measure quickly became accepted as being a useful and important part of a full examination of the knee joint, following its first mention by Brattstrom (1964), despite the fact that he did not describe a protocol for its measurement, nor mention the issue of measurement reliability. The volume of literature which has as its focus the measurement of the Q-angle and the use made of its value when known, as reported here, did not appear to take our understanding of its measurement and impact a great deal further forwards. Most authors appeared to be aware of what others had done before them, and made reference to their work, but did not critically question what had been

done, and thus the thinking around the issues surrounding its measurement appeared rather to go around in circles rather than advancing in a productive way. Most studies, but not all, had relatively small sample sizes, and accepted the measurement protocol used by others in an unquestioning way; or questioned it in what seems to be quite small matters of detail e.g. the position of the foot, whether to measure the left or right knee; rather than examining or critically questioning the fundamental challenges of clinical measurement protocol and reliability.

Clinical measurement reliability has gained greater recognition in recent years and authors increasingly tend to address the issue, even if only partially. It is interesting that only one published paper (France and Nester, 2001) explored the fact that accurate identification of the bony landmarks from which the Q-angle is measured has an impact on the measured value.

The position and movement of the patella is controlled by the VMO muscle, and Selfe's (2004) review of primary research on the management of patello-femoral joint syndrome acknowledged that there is a vast amount of literature of variable quality. He reported that most recent research work had focussed on the topics of: anatomy and biomechanics; muscle parameters and taping techniques with the greatest amount of clinical research being carried out on healthy subjects. His review included a published paper on some experimental work that forms part of the programme of research for this thesis (Wilson and Kitsell, 2002). One of his conclusions was that the available evidence does not support the use of measuring the Q-angle (Selfe, 2004). The conclusions of this review paper support the need to determine whether the Q-angle is a useful clinical measure or not, which is the main theme of this programme of research.

3.4 – Measuring VMO muscle size using ultrasound imaging

The vastus medialis oblique (VMO) muscle is the distal portion of the Vastus medialis (VM) muscle. Details of its size, orientation of muscle fibres, angle at distal insertion have been studied in cadavers (Ono et al, 2005; Blazevich et al,

2006), but studies of its size in vivo are rare, it is usually measured as part of the quadriceps complex. As stated earlier (Section Chapter 2, Section 2.5), it has been established that there is a positive correlation between muscle size and strength for sufficient muscles in healthy individuals that it is now accepted as a general fact. The muscle size measurement typically used is its cross-sectional area (CSA), although the relationship varies for different muscles (Garfinkel and Cafarelli, 1992; Freilich et al, 1995; Schulties et al, 1995; Stokes et al, 1997; Rankin et al, 2004; Pressler et al, 2006; Segal, 2007).

As it is impossible to isolate the VMO muscle from the rest of the quadriceps muscle group in order to measure its specific strength directly, an indirect method is needed. A number of authors have used surface electrode electromyography (EMG) to measure muscle activation in the separate components of the quadriceps muscle, based on accepted evidence that a greater level of EMG activity correlates well with the amount of force for contractions of increasing strength produced by the muscle (Enoka and Stuart, 1992). A common way of recording this is to report the timing of onset of activity and level of activity in VM:VL ratios (Voight and Wieder, 1991; Boucher et al, 1992; Thomee et al, 1995), although it is thought to be affected more by muscle control rather than strength. As authors report disparate findings, probably due to differences in subject inclusion criteria and EMG technique, EMG remains a controversial technique for measuring muscle activity (Mc Clinton et al, 2007).

Other authors have shown that linear measures from some muscles correlate well with their CSA, which in turn correlates well with the strength of the same muscle (Loo and Stokes, 1990)

Walton et al (1997) reported work comparing the accuracy of CSA measurements of the quadriceps muscle group taken from MRI and static B-mode ultrasound imaging (USI) on a group of 10 healthy individuals at the mid-thigh point. They found no significant difference between the two sets of measures (Walton et al, 1997). MRI is able to image the CSA of muscles of every size, the images are clear and it is easy to differentiate between muscle

and other tissues; however it is often inaccessible, also costly, time-consuming and expensive; but is now seen as the 'gold standard' for imaging muscles and other soft tissues (Reeves et al, 2004).

In order to overcome the need to use complex hard to access equipment or time-consuming techniques to measure muscle CSA, Loo and Stokes (1990) investigated whether there was a relationship between identified linear measures from real-time ultrasound images of the quadriceps muscle and its strength. Their purpose in exploring such a relationship was that if such a relationship were found then it might be possible to measure muscle size using small portable equipment in the clinical setting. Loo and Stokes (1990) used a real-time ultrasound (RUS) system to scan the quadriceps muscle of 19 healthy females, and tested quadriceps muscle strength (isometric maximal voluntary contraction) using a Cybex II dynamometer (Loo and Stokes, 1990). They identified various linear measures from the scanned muscle images and compared these with muscle strength measures to see if there was an acceptable level of correlation between the two. They found moderate levels of correlation between the various linear measures and muscle strength: ranging from $r=0.50$ to $r=0.75$. Since then, other authors have also explored the relationship between linear measures and muscle strength and/or CSA on various muscle groups and have reported the following:

Correlation between Linear and CSA measures from ultrasound images for various muscles:

- Linear measure (thickness) from quadriceps muscle group and their CSA: 32 elderly men; $r=0.70-0.76$ (Sipila and Suominen, 1991)
- Linear measures from posterior neck muscles (width and depth) and their CSA: 46 healthy males; $r=0.63-0.96$; 53 healthy females; $r=0.71-0.84$; higher levels of correlation occurred when linear measures were multiplied together (Rankin et al, 2005)
- Linear measures from the semispinalis capitis muscle (width and depth) and its CSA: 6 junior ice hockey players; $r=0.73-0.79$; all correlations were calculated with the width and depth measures multiplied together (Rezasoltani et al, 2002)

- Linear measures from Multifidus and its CSA: 51 healthy individuals $r=0.92-0.97$ (Hides, J et al; 1994)
- Linear measures from the Anterior tibial muscles and their CSA; 17 healthy women; $r=0.75-0.90$; higher levels of correlation occurred when linear measures were multiplied together (Martinson and Stokes, 1991)
- Linear measures (various) from the masseter muscle and its CSA; 39 healthy subjects (19 males; 20 females); $r = 0.86-0.97$; higher levels of correlation occurred when linear measures were multiplied together (Close et al, 1995)

Correlation between linear and strength measures for different muscles:

- Linear measure (thickness) from quadriceps muscle group and strength: 126 healthy individuals; $r=0.71$ (Freilich et al, 1995)
- Linear measure (thickness) was related to bite force and EMG activity of the masseter muscle (Bakke et al, 1992)

From the results listed above, it is clear that there is a useful relationship between the linear and CSA or strength measures of muscles, but that this relationship varies between muscles and so the relationship must be established for each muscle. Measuring the size of the quadriceps muscle group (for both CSA and linear measures) has typically been done at the level of the mid-thigh and standardised protocols are now used. In order to identify the level of correlation between muscle size and strength for the VMO muscle, it would be necessary to determine the relationship between linear and CSA measures, as this relationship has not been established in the literature and it is not possible to separate out strength measurement from one portion of the group of four quadriceps muscles. A new measurement protocol would need to be developed in order to take measures from the VMO muscle alone, rather than the whole of the quadriceps at the mid-thigh level which has traditionally been used.

3.5. Overall Aim and Research Questions

The aim and purpose of this programme of research is to address the following questions:

The Q-angle:

1. Can the Q-angle be measured reliably, with a measurement of error of less than one degree? If so then –
 - a) Does the Q-angle vary over time, in relaxed standing?
 - b) Does the application of McConnell's medial glide patellar tape alter the measured value of the Q-angle?
2. Can the Q-angle be measured during functional activity i.e. the stance phase of walking? If so then –
 - a) Does the Q-angle have its maximum value at heel strike?
 - b) Does the Q-angle increase with increasing levels of pronation at the sub-talar joint?
 - c) How do the three bony markers from which the Q-angle is derived move, when viewed from the frontal and sagittal planes?

The VMO muscle

3. Do linear measures of the VMO muscle correlate with its CSA when measured at the same level, from images taken with an MRI?
4. Are linear measures from the VMO muscle, taken from real-time ultrasound images, as accurate and reliable as those taken from MRI images? If so then
 - a) Is there a difference in VMO muscle dimensions between sitting and standing?
 - b) Is there any correlation between the value of the Q-angle and the size of the VMO muscle?
 - c) Is there any difference in size of the VMO muscle between individuals with PFJS and those without?

One of the consensus recommendations from an *International Research Retreat on Patellofemoral Pain Syndrome: Proximal, Distal and Local Factors*

held in 2009, and reported by Davis and Powers (2010), was to establish how the complex imaging and modelling techniques relate to more simple clinical measures, and so understanding more fully if the Q-angle is a useful clinical measure will be of great value.

The body of work reported in this thesis aims to answer the questions posed above using equipment and techniques that are accessible and easy to use in the clinical environment.

Chapter Four

Equipment and General Methods

CHAPTER 4

Equipment and General Methods

4.1 – Introduction

In order to establish valid and reliable protocols for measuring the Q-angle and the size of the vastus medialis oblique (VMO) muscle, a variety of equipment and methods were used. Measuring the Q-angle initially was done using the Peak Video Motion Analysis technology and later the Vicon technology. As there was no agreed standardized protocol or gold-standard against which to compare the results, measurement reliability only was analysed and validity could not be assessed. The situation differed when developing the protocol for measuring the size of VMO muscle using ultrasound imaging, as the results could be compared with those obtained when using the gold-standard of magnetic resonance imaging (MRI), in order to assess validity, as well as reliability of repeated measurements.

The approach followed throughout this work was based on the idea that valid and reliable measurement techniques and protocols are essential in order to achieve useful results that are clinically applicable. In the clinical environment it is undoubtedly helpful to have meaningful and accurate information when assessing symptoms, the effect of interventions and/or the natural progression of any presenting condition. In order for a measurement to be able to do this it is important to understand how much natural variability any measure may have, as well as how much inherent variability the measurement protocol includes, in order to determine effectively how much actual or real change has occurred.

This chapter is divided into six parts:

- 4.1 – Introduction
- 4.2 – Equipment and methods for measuring the Q-angle
- 4.3 – Equipment and methods for measuring VMO muscle size
- 4.4 – Participants and recruitment processes
- 4.5 – Ethical considerations
- 4.6 – Statistical analysis

4.2 – Equipment and methods for measuring the Q-angle

The initial studies to establish a valid and reliable method for measuring the Q-angle used the Peak-5 video motion analysis equipment. This was later upgraded to the Peak Motus system, both supplied by Peak Performance Technologies, Denver, Colorado, USA. For the later studies, the motion analysis system had been replaced with a Vicon (460) system (Vicon, Oxford). Each of the experimental chapters (Chapters 5 – 8) states which motion analysis system was used.

4.2.1 Peak-5 and Peak Motus systems

The Peak system is an optical motion capture system based on the use of video. Participants were filmed using Panasonic F15HS cameras that recorded to Panasonic AG5700 video recorders, each camera took pictures at the rate of 50Hz and SVHS video tapes were used. When more than one camera was used the cameras were genlocked, which synchronised the shutters of the cameras so that they opened at the same time, and the video was then synchronized using the 'event synchronisation unit' from Peak Performance Technologies.

Before data could be captured the area in which participants were to stand while being filmed had to be calibrated – this was done following the guidelines set out by Peak. For 2D filming a rod of known length (1.0m) was placed in the

area (Figure 4.1), it was filmed and then two points were digitized from the video tape in the X and Y axis, and then this information was uploaded to the software which then calculated the calibration, translating the distances into the number of pixels. For 3D filming a calibration frame (Figure 4.2) was placed in the area to be filmed (the length of each rod in the frame was also 1.0m), the calibration frame rods were then filmed by each camera used and then digitized in the same way, from the video images, and the distances calibrated by the Peak performance software.



Figure 4.1 – 2D calibration rod, 1.0m in length



Figure 4.2 – 3D calibration frame for video motion analysis, each rod is 1.0 m in length

The system was relatively straightforward to use and could be operated by the author after some training and familiarization with the equipment, but did not require specialist technical support during filming or when digitizing the data gathered.

4.2.1.1 – Process of filming

All filming took place within the Biomechanics Laboratory of the School of Health Professions and Rehabilitation Sciences of the University of Southampton. Participants wore dark cycling shorts with holes cut over the relevant bony landmarks (anterior superior iliac spine, the patella and the tibial tuberosity), to allow the reflective markers to be placed directly on the skin while also giving a dark contrast background to aid in the detection of the digitization process (Figure 4.3).

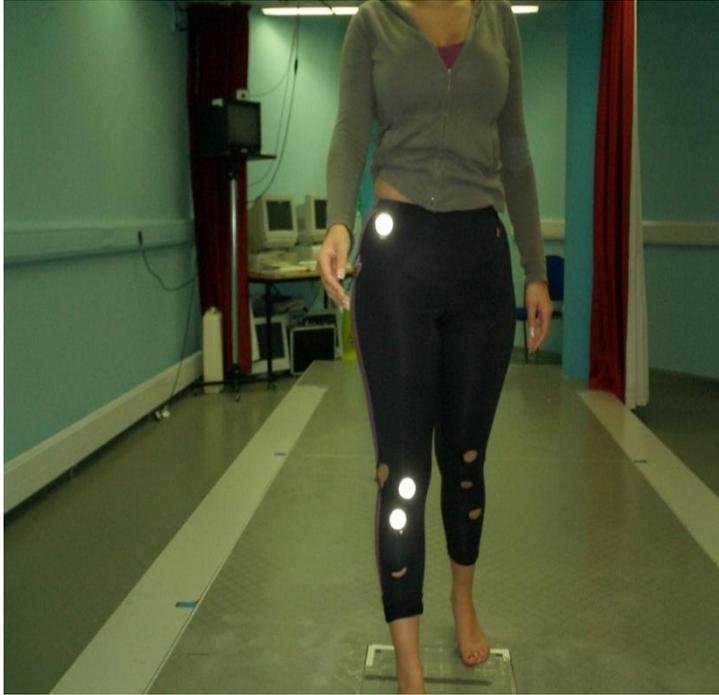


Figure 4.3 – Reflective marker placement for measuring the Q-angle in relaxed standing using the Peak video motion analysis system

For 2D filming, participants stood with their frontal plane parallel to the plane of the camera, and all 3D filming required participants to walk along a walkway, and the cameras were placed on tripods or other mounts at the required angle to the plane of the walkway. Each participant was asked to stand in a relaxed position with their knees straight, but not locked back, and their quadriceps muscles' relaxed. In order to check that the quadriceps muscles were relaxed the operator checked that the patellae were 'loose' and could be moved passively. After filming the data was digitised, following manufacturer's instructions, please see Appendix 00A for details.

4.2.2 - Vicon Motion Analysis System

Later still the motion analysis system was upgraded to the Vicon system, another more sophisticated 'optical motion capture system, this enabled better 3D analysis than the Peak video motion analysis system and software, which was proving to be rather cumbersome for the volume of data generated in 3D analysis.

The Vicon system used was the 'Vicon 460' system with six 'V-cam' cameras from Vicon Motion Systems, Oxford, UK. The Vicon sampled at 120Hz. The cameras were positioned in a circular fashion around the capture volume (the space in which the markers to be captured will be placed). A static calibration was performed by placing the L-frame in the centre of the capture volume which defined the origin point and set the global axis. The L-frame was orientated so that the global X axis pointed forward, the Y axis to the right, and the Z axis pointed upwards. A dynamic calibration was then performed by the operator, this involved waving the calibration wand around the capture volume. The system used its own proprietary algorithms to calibrate the system. A calibration was deemed successful if the mean residual error of the calibration was below 1mm. The residual error gives an estimation of the error from each camera, the mean is then the average from all the cameras. The software used was the Vicon Workstation v5.2.4. The q-angle was calculated using a custom written kinematic model in Vicon Bodybuilder v3.6 software.

4.2.2.1 – Process of data capture

The process of capturing data using the Vicon was the same as that for the Peak system. Each participant had reflective markers placed on the relevant bony landmarks; as this system was more sophisticated and more sensitive, there was no longer any need for the same degree of contrasting backgrounds and so participants did not need to wear the dark cycling shorts.

4.2.2.2 – Marker reconstruction Process.

Although the Vicon system was also an optical motion analysis system there was no requirement for digitization of the data as the system works on the basis that the camera captures data in 2D and then using its internal algorithms the camera converts the data to 3D and then reports it. The one disadvantage with this system is that there is no recognizable image to replay should the operator wish to review the activity that was filmed e.g. walking along the walk-way, but the data capture and general ease of use are much greater than for the Peak motion analysis system.

4.3 – Equipment and methods for measuring VMO muscle size

The initial study to measure the size of the VMO muscle, described in Chapter 6, Section 6.2, required participants to have an MRI image of their right knee. The equipment used was an extremity scanner in the radiology department of a local hospital. The MRE scanner used was an 'Esaote open MR scanner' with a 0.2 tesla magnet. The knee was imaged using the following sequence – Coronal T1, Coronal STIR, Sagittal T1, Sagittal TSE T2, Axial STIR; following normal protocol for the scanning a knee. The scanning process took between 30 and 40 minutes.

Once the relationship between the CSA and linear measures of the VMO muscle had been established, all subsequent images of the VMO muscle were taken using portable ultrasound equipment in the School of Health Professions and Rehabilitation Sciences at the University of Southampton. The ultrasound scanner used was an 'Aquila' (Esaote S.p.a. Genova, Italy). The linear transducer was used, its diameter was 60mm and the frequency used was 8MHz. The gain, the time-gain compensation (TGC) and focal depth were adjusted in order to obtain a clear image for each participant.

4.3.1 – Process of image capture

The MRI scans and initial ultrasound images were taken with participants in a long-sitting position. Each participant wore a pair of shorts and sat on a plinth, with a back support (a hip flexion angle of about 100° - 110°) with his legs out in front and a pillow placed at the lateral side of the knee in order to prevent any lateral rotation of the hip. Please see Figure 4.4 for an example of an MRI scan.



Figure 4.4 – MRI image from a typical participant. Muscle tissue is darker than bone or other soft tissues, and the vastus medialis oblique (VMO) is the main muscle (kidney-shaped) seen on the right of the image, the central pale area is the femur bone.

For ultrasound imaging, a water-based gel was applied over the area of the VMO (this was done following manufacturer’s guidelines in order to facilitate a constant link between the transducer head and the skin over the VMO in order to protect the machine and gain as clear an image as possible. As this was real-time ultrasound the image was directly visible on the screen and so when the view of the VMO was deemed to be as clear as possible then that image was captured. A total of three images were taken in each imaging session. For example of an ultrasound scan please see Figure 4.5.

Ultrasound images taken with the participant in relaxed standing followed the same process for image capture used for video filming, described in Section 4.2.1.1. Following capture of the image the CSA measure was identified by tracing around the outside border of the muscle and linear measures (described in Chapter 6, Figure 6.3) were identified and measured using the Imagej software available from (<http://rsb.info.nih.gov/ij/docs/index.html>).



Figure 4.5 – example of an ultrasound image of a VMO muscle, the VMO is on the right and is kidney shaped

4.4 – Participants and recruitment processes

Healthy participants were all recruited from the staff and student body of the University of Southampton, by means of posters (Appendix 0A). Participants with PFJS were recruited from local orthopaedic out-patient clinics and physiotherapy departments, once permission had been gained to approach those individuals who met the relevant inclusion and exclusion criteria (please see section 4.4.2).

4.4.1 – Issues and permission

A protocol for the initial study involving healthy recreationally active participants was submitted to the School of Health Professions and Rehabilitation Sciences Ethics Committee, and the two studies in which individuals with patello-femoral joint syndrome (PFJS) were recruited were submitted to the Local NHS Research Ethics Committee for approval. In addition, the study which required participants to undergo a magnetic resonance image (MRI) scan was submitted to the internal research scrutiny process as required by the Southampton University Hospitals NHS Trust (see Appendices A, A1, A2). The protocol was scrutinised and for Risk Assessed and Peer Reviewed by the University (see Appendices F and G).

Individuals with PFJS were recruited from local orthopaedic out-patient clinics and physiotherapy departments. A copy of a sample letter to the head of such a physiotherapy department seeking permission to approach their patients can be found in Appendix B.

4.4.2 – Inclusion and Exclusion criteria

- *Inclusion criteria for all healthy participants:*
 - Healthy and recreationally active at least twice each week
 - Aged 18 – 35 years (to decrease the chances of there being some signs of early OA in the knee joint complex)
 - Able to understand written and spoken English
- *Additional Inclusion criteria for participants with PFJS*
 - A diagnosis by a relevant health professional (e.g. doctor, physiotherapist) of PFJS which prompted the seeking of treatment
 - Symptoms of PFJS for a minimum period of 6 weeks
- *Exclusion criteria for all healthy participants*
 - Injury to lower limb or back, requiring treatment, within the previous five years
 - Neurological or other general physical disability
- *Additional exclusion criteria for individuals with PFJS*
 - Had already begun physiotherapy treatment
- *Additional exclusion criteria for participants undergoing an MRI scan*
 - Heart pacemaker
 - Pregnancy
 - Metal implants e.g. hip replacement
 - An eye injury involving metal at any time in your life

4.4.3 – Participant information and consent

Once an individual had expressed an interest he/she was given a Participant Information Sheet which outlined the study and what the participant would be required to do, for an example please see Appendix C. Each Participant Information Sheet made clear that a participant could withdraw at any time

without prejudice. Those participants who were still interested, after reading the information sheet, were invited to make an appointment for him/her to attend at the relevant site – for most studies this was the Biomechanics Laboratory at the School of Health Professions and Rehabilitation Sciences at the University of Southampton; and for those who agreed to have an MRI scan this was the Emergency X-ray Department at Southampton General Hospital. At that initial appointment the study was again explained to each participant and their role within it, and if the participant was still interested then he/she signed a consent form. For an example please see Appendix D.

4.5 – Ethical considerations

All measures and data gathered for this programme of work carried no risk to participants. An example copy of a submission to a local Research Ethics committee is found in Appendix E, and formal approval in Appendix E1. All participants gave their written, informed consent and were free to withdraw from the study at any time.

4.6 – Statistical analysis

The main types of statistical analysis used in this study were those to do with measurement reliability, validity and correlation. The specific tests used are each outlined within the relevant chapter in which the experiment is described. In addition Chapter 3, Section 3.2.3 discusses the issues of statistical analysis for measurement reliability, and so only brief descriptions will be used here.

4.6.1 – Measurement reliability

A number of authors advise that where the reliability of specific values are important no measure is sufficient on its own, even intraclass correlation coefficients (ICCs) and a second measure should always be used (Bland and Altman, 1986; Rankin and Stokes, 1998). For the reliability analysis in this body of work the Bland and Altman Limits of Agreement test was used, as this gives a visual representation and so it is easy to see if there is any bias or consistent

variation between sets of measurements, for example if one set of measures is consistently larger or smaller than another set, something which may not be obvious when analyzing the data using ICC's. Portney and Watkins (2000) recommended that ICC values of 0.9 or above should be the threshold set for reliability between different sets of measures when clinical decisions will be made on their value.

4.6.2 – Measurement validity

Measurement validity is usually tested when a new form of, or new measurement tool is involved and it is important to see if the results achieved compare favourably to the existing tool and processes. Again there is debate in the literature about which statistical tests are most appropriate. When comparing ultrasound measurements with the accepted gold standard of MRI, the convention has recently been accepted that comparing data sets using Pearson correlation coefficients and Bland and Altman Limits of Agreement tests are the tests of choice (O'Sullivan et al, 2009). The purpose of agreeing tests will mean that in future the data from multiple studies might be able to be grouped allowing study results to add to previous work. In this body of work sometimes that was done, at other times the ICC was used, as that is also a useful test for comparing validity in measurement.

4.6.3 – Measurement correlation

Some of the work described in Chapter 6, explored the level of correlation between two sets of measures, i.e. the linear and CSA measures taken from the VMO muscle. Pearson's correlation coefficients were used to measure the level of correlation. Levels of correlation of $r=0.7$ or above were set as a threshold, as other authors have stated that this is required for measures values to be clinically meaningful (Sipila and Suominen, 1991; Rankin et al, 2005).

Chapter Five

Establishing a valid and reliable protocol for measurement of the Q-angle using Video Motion Analysis

CHAPTER 5.0

Establishing a valid and reliable protocol for the measurement of the Q-Angle using Video Motion Analysis

5.1 – Introduction

Due to the previously described inaccuracies and problems when using a long-arm goniometer to measure the Q-angle, it was important to establish a valid and reliable measurement method using other equipment. Thus the purpose of the work carried out and reported in this chapter was to establish a valid and reliable measurement protocol for measuring the Q-angle using a video motion analysis system designed by Peak Performance Technologies, Denver, Colorado, USA.

The work in this chapter is divided into five parts:

- 5.1 – Introduction
- 5.2 – Measurement protocol for validity and consistency using mock static Q-angles drawn on a flat board, using the Peak-5 manual digitisation process
- 5.3 – Applying the same measurement protocol using mock static Q-angles drawn on a flat board, using the Peak-5 automatic digitisation process
- 5.4 – Applying the same measurement protocol piloted on three human participants using the Peak-5 manual digitisation process, to test consistency
- 5.5 – General Discussion and Conclusions

5.1.1 – Measuring the Q-angle

The literature review in Chapter 3 concluded that there were a number of weaknesses in current practice when measuring the Q-angle in the clinical situation. Firstly there is no universally agreed measurement protocol, and secondly there is an assumption that the Q-angle is an absolute value, with no

recognition that the value itself may vary during the time taken to make the measurement. Typically it takes up to 60 seconds for a clinician to measure an individual's Q-angle in the clinical situation using a long-arm goniometer; and so it is possible that even when using a reliable, accurate and valid measurement protocol, the Q-angle itself may vary during the time required for the measurement to be taken.

One of the challenges of biomechanical measurement techniques is to be able to take measures in real-life situations. However, it is often difficult to standardise and control the environment in real-life leading to a tension between the scientific rigour needed for measurement precision, accuracy and repeatability as well as the need for valid representative measurements. For example Q-angle measurements taken with a long-arm goniometer are much easier to take reliably with the participant in long-sitting with the quadriceps muscle group fully relaxed. However, measures of the Q-angle size taken in this position may be less valid than those taken with participants in standing, which is a more functional position (Holmes and Clancy, 1998; Lathinghouse and Trimble, 2000; Wilson and Kitsell, 2002). Participants in standing tend to have to make constant minor adjustments in response to natural postural sway. These postural adjustments often involve small contractions of the quadriceps muscle group; which may in turn affect the position of the patella and thus alter the value of the Q-angle.

The aim of the series of experiments described in this chapter was to develop a valid and reliable measurement protocol for the Q-angle, with a variation of one degree or less; while participants were in a relaxed standing position, using the Peak-5 video motion analysis system. The equipment used, and general methods have been described in Chapter 4 and so only brief descriptions of methods used will be given here.

5.2 – Measuring a mock static Q-angle (part I)

5.2.1 – Background:

An initial pilot test for validity and consistency was carried out using a flat 2D board with mock Q-angles drawn on it. The accuracy and reliability of the measurement protocol for measuring the Q-angle with the Peak-5 Video Motion Analysis System used in this work needed to match those achieved by Selfe (1998) and Scholz and Millford (1993) as reported earlier i.e. to have a variation of one degree or less.

5.2.2 – Aim:

The aim of the following test was to establish the validity and consistency of a protocol for measuring mock Q-angles (drawn angles on a flat board), using the Peak-5 Video Motion analysis system.

Question: Is the following measurement protocol able to measure a mock Q-angle both validly and consistently, with a variation of less than one degree matching that achieved by Selfe in 1998?

5.2.3 – Method

A 2D spatial model representing the Q-angle was developed using the Peak-5 software and the area in which the object to be videoed would be placed was calibrated following the manufacturer's guidelines using a one metre rod (Figure 5.1). Then three reflective markers were placed on a flat static board to mimic a Q-angle. The true value of this angle was measured using a protractor and then recorded. The board was filmed for 60 seconds (using SVHS video tapes at a picture rate of 50 pictures per second) with the plane of the lens of the camera being parallel to the flat surface of the board and its axis perpendicular to it, following manufacturer's instructions. This same procedure was repeated for three different angles, giving a data set of 3,000 pictures for each mock Q-angle. A static board was used so that there would not be any variability in the angle itself, any variation in the measured angles could only be due to the measurement protocol or equipment used.

The following day two individuals (both experienced users of the equipment, listed as Tester A and Tester B) independently manually digitised the first picture per second in each data set for each of the three angles, using the Peak-5 Video Motion Analysis system software (for further details please see Chapter 4, Section 4.2). The value of these Q-angles was calculated by the Peak-5 software, resulting in a data set of 60 angles for each 60 seconds worth of video tape. In order to test the consistency of the manual digitisation process, each Tester independently repeated the digitisation process twice more the following day, with a gap of at least six hours between each digitisation session. Thus there were three data sets of 60 values for each digitised mock Q-angle from each Tester, and the mean was calculated for each data set. The difference between each of the three mean digitised Q-angles and the true Q-angle value was calculated, and from this the mean difference between the mean digitised Q-angle and true Q-angle value was calculated for each Tester.



Figure 5.1 – One-metre calibration rod for 2D video motion analysis

5.2.4 – Results

The overall mean difference for Tester A between each true angle and the mean digitised mock Q-angle was 0.7 degrees, and for Tester B was 0.8 degrees (see Table 5.1 below). The direction of difference between the digitised and true Q-angle values was not important it did not matter whether the differences were larger or smaller than the true angle.

Table 5.1 – Mean differences between the three sets of digitised and true mock Q-angles for Tester A and Tester B, using manual digitisation

True Angle	Tester A - Difference between true angle and mean of 3 sets of digitised angles (degrees)	Tester B – Difference between true angle and mean of 3 sets of digitised angles (degrees)
1 (48 degrees)	0.6	0.6
2 (30 degrees)	0.7	0.9
3 (19 degrees)	0.7	0.9
Mean	0.7	0.8

5.2.5 – Conclusion

This measurement protocol, using the Peak-5 Video Motion Analysis System achieved the parameter set i.e. a variability of less than one degree, matching that reported by Selfe (1998), illustrating that it was sufficiently accurate and consistent to be applied to measure the actual Q-angles on real participants.

5.3 – Measuring a mock static Q-angle (part II)

5.3.1 – Background

The initial study described above used the manual digitisation facility of the Peak-5 software. This requires the operator to view each required video image and manually identify the centre of each reflective marker on the screen using a computer mouse. However, the Peak-5 software has an automatic digitisation facility which means that the software identifies the centre of the marker and records it automatically. However, occasionally the software is unable to

identify a marker, and this is recorded as missing data, and then the operator has to identify the marker manually as before. It is probable that using the automatic digitisation facility is more accurate in locating the centre of a small reflective marker on a screen and is also a great deal quicker, however, as there are times when for some reason this process does not work, it was felt to be important that the initial tests for consistency were carried out with the operator using the manual digitisation process. However, as we then planned to use the measurement protocol for larger participant groups it became obvious that using the manual digitisation process was not really feasible nor desirable and so a further consistency test was carried out using markers on a flat board with mock Q-angle values.

5.3.2 - Aim:

The aim of the following test was to establish the validity and consistency of the protocol for measuring mock Q-angles (drawn angles on a flat board), using the Peak-5 Video Motion analysis system, using the automatic digitisation process.

Question: Is the Q-angle measurement protocol described above as valid and consistent when the automatic digitisation process on the Peak-5 video motion analysis system is used?

5.3.3 - Method:

A 2D spatial model representing the Q-angle was developed using the Peak-5 software and the area in which the object to be videoed would be placed was calibrated following the manufacturer's guidelines using a one metre rod (Figure 5.1). Then three reflective markers were placed on a flat static board to mimic a Q-angle. The true value of this angle was measured using a protractor and then recorded. The board was filmed for 60 seconds (using SVHS video tapes at a picture rate of 50 pictures per second) with the plane of the lens of the camera being parallel to the flat surface of the board and its axis perpendicular to it, following manufacturer's instructions. This same procedure was repeated for five further angles, giving a data set of 3,000 pictures for each mock Q-angle.

Each video data set was then digitised using the Peak-5 automatic digitisation process by the same operator, again the first picture per second in each data set for each of the three angles. The value of these Q-angles was calculated by the Peak-5 software, resulting in a data set of 60 angles for each 60 seconds worth of video tape.

5.3.4 – Results:

The mean range in variability for the digitised value of the Q-angle compared with the true value of the Q-angle was 0.69 degrees, with an overall mean of standard deviation of 0.16 degrees. The level of variability between the digitised and true mock Q-angle is virtually the same as the initial pilot test which used the same methodology but had the operator manually digitise each marker on each video frame (see Table 5.2 below). This experiment has already been published (Wilson and Kitsell, 2002), which is why the data is reported to two decimal places, rather than just to one decimal place as in Section 5.2.

Table 5.2 – Mean differences between the six sets of digitised and true mock Q-angles for automatic digitisation

Angle	Range over 60 seconds (degrees)	SD of range over 60 seconds (degrees)
1	0.58	0.13
2	0.57	0.15
3	0.87	0.20
4	0.61	0.15
5	0.91	0.20
6	0.60	0.15
Mean	0.69	0.16

5.3.5 – Conclusion

The level of variability for this measurement protocol, using the automatic digitisation facility on the Peak-5 video motion analysis system gives a variability which is within the one degree threshold set, and also reported by Selfe in (1998), and so can be used in confidence for future experiments.

5.4 – Measuring a real static Q-angle

5.4.1 – Background:

This experiment used the same measurement protocol described above and used human participants, rather than a flat board, to see if real Q-angles could be measured with the same level of consistency as before. There was no way of testing validity against a 'gold standard' at this time, as it was expected that using the Peak-5 video motion analysis system would be far more valid and accurate than using a goniometer, which is why the measurement protocol using the Peak-5 system was being developed. However as the investigator is an experienced physiotherapist, she would be able to apply a 'sense check' to the results, being able to determine if they seemed probable. In addition comparing the results to the ranges for healthy participants reported in the literature would also give a sense of whether the results were likely to be realistic.

5.4.2 – Aim:

The aim of this experiment is to see whether the same measurement protocol for measuring the mock Q-angle on a flat board can be effectively applied to the Q-angle of a real participant.

Question: Can the measurement protocol outlined above, achieve the same level of consistency when applied to the Q-angle of real participants?

5.4.3 – Method:

The same 2D spatial model representing the Q-angle using the Peak-5 software was used, and the area in which the participants were to be videoed was calibrated following the manufacturer's guidelines using a one metre rod (Figure 5.1). Three healthy subjects, (see Chapter 4 for further details) each had three reflective markers placed on the relevant bony landmarks to identify the Q-angle - the anterior superior iliac spine (ASIS), the centre of patella, and the centre of the tibial tubercle. Each subject wore a pair of black lycra cycling shorts with holes cut in them enabling the reflective markers to be placed directly on to the skin, but also giving a dark background to accentuate the contrast between the

reflective markers and the skin. This was done to ensure the reflective markers would show up as brightly as possible on the video images and thus aid the digitisation process (Figure 5.2). Each subject stood in a comfortable relaxed standing position with his/her weight evenly distributed on both legs (following the protocol of Livingston and Mandigo, 1997) and his/her toes just touching a line drawn parallel to the frontal plane of a camera lens - ensuring his/her anterior aspect was parallel to the frontal plane of the camera. This was checked with a spirit level. Each participant was then videoed for 60 seconds followed by a period of 60 seconds rest. This method was repeated until there were five sets of video data for each subject.

The picture rate for the video camera was the same as before, i.e. 60 pictures per second. The reflective markers on the first picture per second on each of the 60 images in the five data sets were then manually digitised by the researcher and the Q-angle calculated using the Peak-5 Video Motion analysis software, as before. The mean Q-angle value was then calculated for each of the five data sets. Each image in each data set was then re-digitised manually by the same researcher one week later and a second mean Q-angle value was calculated in the same way.



Figure 5.2 – Reflective marker placement for measuring the Q-angle in relaxed standing using the Peak video motion analysis system

From this the following analysis was done:

- The difference between each mean Q-angle for each of the five pairs of measures i.e. between the first and repeat set of digitised data (1 week apart);
- The overall mean difference of Q-angle value from all five data sets for each subject; between the first and repeat set of digitised measures (1 week apart);
- The overall mean difference in Q-angle between the first and repeat set of digitised measures (1 week apart).

Note: Actual values of the Q-angle were not important, the differences between pairs of measures was of interest, as this was testing consistency of measurement.

5.4.4 – Results:

Table 5.3 illustrates the following results:

- The difference between each mean Q-angle for each of the five pairs of measures i.e. between the first and repeat set of digitised data (1 week apart) was 0.8 degrees
- The overall mean difference of Q-angle value from all five data sets for each subject; between the first and repeat set of digitised measures (1 week apart); was 1.0 degree
- The overall mean difference in Q-angle between the first and repeat set of digitised measures (1 week apart); was 1.1 degree

The overall mean of all three means listed above is 1.0 degree.

Table 5.3 – Mean differences between the first and repeat calculation of Q-angle values (1 week apart) of 5 data sets on 3 different participants, by the same tester, with Range and Standard Deviation (SD)

Participant	Data Set	Difference in Q-angle value between first and second digitisation of data sets, 1 week apart, (degrees)	Mean difference (degrees)	SD	Range (degrees)
1	1	0.1	0.8	0.4	0.1 - 1.4
	2	0.7			
	3	1.4			
	4	0.9			
	5	0.9			
2	1	0.3	1.0	1.4	0.2 – 3.8
	2	0.3			
	3	0.2			
	4	0.2			
	5	3.8			
3	1	0.4	1.1	1.1	0.4 – 3.2
	2	0.8			
	3	0.4			
	4	3.2			
	5	0.8			

Overall Mean Difference between first and repeat digitisation = 1.0 degree

5.4.5 – Conclusion:

Overall the mean difference between each set of mean Q-angle values, as determined by the small consistency test, meets the criteria set i.e. it has a variation of one degree or less which enables this protocol to be used for the future research programme.

5.5 – General Discussion and Conclusions

5.5.1 – Discussion

The results achieved using this protocol for measuring mock and real Q-angles appears to be sufficiently accurate and consistent. The mean variation of each set of repeat digitised measures from each true angle in each experiment is less than one degree. These results match the level of consistency reported by Selfe (1998), which was the threshold set. Most Q-angle values are reported to one decimal place only, as in the pilot studies using the flat board the value of the true angle was measured with a hand-held protractor, which can only measure to a precision of one degree, whereas the software on the Peak-5 Video Motion analysis system could report values of several decimal places. The values obtained from the Peak-5 software were rounded up to one decimal place, and then when means from each data set were calculated these were also rounded up to one decimal place.

However, the experiment reported in Section 5.4 (Table 5.3) which reports the results of Q-angle measurements on real participants illustrates that the difference between each pair of mean angles was generally less than one degree, the standard deviation for data sets from Participant 2 and Participant 3 were both greater than 1.0 and two pairs of mean Q-angle values had a difference of greater than three degrees which was a concern (Participant 2, data set 5; and Participant 3, data set 4). On re-viewing the video tapes there was no obvious reason in terms of quality of image or participant movement to explain why these particular data sets should have been more difficult to digitise. As there were only three participants, it was not possible to draw any conclusions about why this variation occurred.

It was noted that the mean difference between the true and mean digitised angle values for both Testers was very slightly larger for the true angles of 19° and 30° , especially for Tester B, than it was for the true Q-angle of 48° for both testers (in the experiment reported in Section 5.2, Table 5.1). This might be important, as many reported mean Q-angle results include values in this range for healthy individuals (Woodland and Francis, 1992) and those with patello-

femoral joint syndrome (Lin et al, 2008). However as only three different angles were used it is difficult to know if this is a concern, and as the level of consistency for all angles is within the parameter set i.e. within one degree, there should be no unease. However, it would have been beneficial to have kept the raw data so that further analysis could be carried out.

The concept of how much variability in measurement testing is acceptable is a difficult one, as the need for consistency in measurement is largely dependent on what decisions the measurement data will be used to determine (Portney and Watkins, 2000). Thus the level of variability chosen as being acceptable for the protocols used in this work, were those determined and used by Selfe(1998), who also used the Peak-5 Video Motion Analysis System.

These small tests of validity and consistency illustrate that when the measurement protocol is applied to the Q-angle on real participants, it is consistent enough to use for this planned research. However, these small tests of consistency and variability cannot count as a formal reliability study, as both the number of participants and the number of repeat measures was too small, and this is acknowledged as a weakness in this body of work. For thorough reliability testing Chinn (1991) recommends a data set of at least 25 measures.

5.5.2 – Conclusions

The results reported in these small studies of validity and consistency have illustrated that the Q-angle can be measured in the clinical situation, with participants in relaxed standing, with a measurement variation of one degree or less.

The findings illustrate that the measurement protocol is both valid and consistent, as long as the work is carried out by the same operator, since inter-rater reliability was not examined. However, as the reliability testing for the Q-angle measurement protocol was not thorough, it did not have enough repeat measures, and so those conclusions must be treated as tentative.

Chapter Six

**Establishing a valid and reliable protocol
for the measurement of vastus medialis
oblique (VMO) muscle size using
ultrasound imaging**

CHAPTER 6.0

Establishing a valid and reliable protocol for the measurement of vastus medialis oblique (VMO) muscle size using ultrasound imaging

6.1 – Introduction

In order to explore whether there was any relationship between the size of the VMO muscle and the value of the Q-angle, it was necessary to establish a way of measuring the size of the VMO in the clinical situation. Access to the current gold standard – Magnetic resonance imaging (MRI) – is very expensive and time-consuming. The purpose of the work carried out and reported in this chapter was to establish a valid and reliable measurement protocol for measuring the size of the vastus medialis oblique (VMO) muscle.

This work in this chapter is divided into six parts:

- 6.1 – Introduction
- 6.2 – Validity of linear measures from the VMO muscle and their correlation with cross-sectional area (CSA) measures, using MRI images
- 6.3 – Validity and reliability of measuring the VMO muscle size using ultrasound images, compared with MRI images
- 6.4 – Reliability and correlation between linear and CSA measures of the VMO muscle size using real-time ultrasound (RUS) – in standing
- 6.5 – The effect of posture on VMO muscle size and shape
- 6.6 – General Discussion and Conclusions

6.1.1 – Measuring the size of the VMO muscle

The gold-standard for measuring the size and clarity of soft-tissues in humans is currently magnetic resonance imaging (MRI) (Reeves et al, 2004). However, MRI scans are very difficult to access, especially for individuals who are not unwell, are expensive and are time-consuming to obtain, and so alternative valid, accurate and reliable measurement options are needed in order to enable

measures of muscle size to be more easily available for research and other purposes. Several authors have shown that muscle size measurements taken from real-time ultrasound (RUS) images are both valid and reliable (Pretorius and Keating, 2008), although at the time of writing this had not been specifically demonstrated for the VMO.

The majority of existing work to measure the muscle size of the quadriceps muscle from RUS images has involved images being taken at the level of the mid-thigh, as at that point it is possible to image all four parts of the quadriceps muscle effectively. However, the current work is interested only in the VMO portion of the quadriceps muscles, specifically its distal aspect where it engages with the patella. Thus it required the development of a new measurement protocol in order to measure the size of the VM muscle at its distal end where it inserts into the medial retinaculum and patella (Lin et al, 2008) and is termed vastus medialis obliquus (VMO) as described in Chapter 2.

6.2 – Validity of linear measurements from the Vastus Medialis Oblique (VMO) muscle and their correlation with CSA measures, using MRI

6.2.1 – Background

The gold-standard for measuring the size and clarity of soft-tissues in humans is currently magnetic resonance imaging (MRI), see chapter 3.0 for further details (Reeves et al, 2004). However due to difficulties in accessibility and the cost and the time-commitment required by participants to obtain an MRI scan it was decided to explore other options for measuring the size of the VMO muscle, particularly real-time ultrasound (RUS).

A number of researchers have reported the effective use of RUS images for measuring the size of muscles e.g. the cervical multifidus muscle (Fernandez-de-las-Penas et al, 2008) the lumbar multifidus muscle (Hides et al, 1994), various abdominal muscles (Jhong-Lin et al, 2010; Hides et al, 2007; Jansen et al, 2009), the lower fibres of the trapezius muscle (O’Sullivan et al, 2007),

anterior hip muscles (Mendis et al, 2010) and the anterior tibial muscles (Martinson and Stokes, 1991). A systematic review of thirteen studies on the validity of using RUS for measuring muscle size as an alternative to images obtained from MRI or computed tomography (CT) by Pretorius and Keating (2008) concluded that RUS can provide valid measurements of skeletal muscles. They concluded that, due to the varied nature of the populations in the reviewed studies, it was possible to generalise this statement, rather than restrict it only to the particular muscles used in the studies they reviewed. However, they acknowledge that further studies were needed to validate this conclusion for symptomatic participants.

Thus there is evidence enough to accept that RUS is both valid and reliable as a tool for imaging the muscles of asymptomatic participants, as long as a clearly defined measurement protocol is followed. However the size of the RUS image is limited by the size of the ultrasound machine transducer head. As the average diameter of a transducer head of a typical ultrasound machine is 4-5cms, this means that a typical machine and transducer can only directly obtain full images of muscles which have a similar or smaller diameter than the transducer head and thus limits it to rather small muscles. It is possible to take images of larger muscles with Ultrasound using the technique of compound scanning (Stokes et al, 1997). This was used by Young et al (1985) in early work exploring the use of ultrasound to measure skeletal muscle size but this is also time-consuming and complex and so is now rarely used in practice. It was clear that the diameter of the VMO muscle at its distal end (where it attaches to the patella) was likely to exceed the diameter of the transducer head of a normal RUS machine, and so this problem needed to be overcome, if RUS imaging was to prove a viable alternative to MRI.

Fortunately several authors have reported useful levels of correlation between various linear measures and the cross-sectional area (CSA) measures of specific muscles, thus allowing RUS to be used to measure muscles which are larger than the size of the transducer head (Sipila and Suominen, 1991; Martinson and Stokes, 1991; Hides et al, 1994; Close et al, 1995; Rankin et al, 2006). These levels of correlation have been found to be different and specific

for each muscle so far trialled, (Chapter 2, Section 2.5) so this relationship needed to be examined for the VMO muscle.

The distal portion of the VM muscle is easily distinguishable as its muscle fibre angle is more horizontal than in the more proximal parts of the muscle (Ono et al, 2005), and due to this its CSA is relatively large for its volume and thus it is easy to image at this point (Blazevich et al, 2006). As mentioned above the correlation relationship between the CSA and linear measures has been shown to differ for each muscle reported to date, and so the actual linear measures to be used would need to be determined from MRI images before they could be measured on RUS images. Any linear measures chosen would need to be easy to identify on images from different subjects to facilitate the development and use of a reliable measurement protocol. The threshold for acceptable correlation between CSA and linear measures of the VMO muscle was set to $r=0.7$ or above, as this is what other authors for other muscles have reported as being clinically meaningful (Sipila and Suominen, 1991; Martinson and Stokes, 1991; Hides et al, 1994; Close et al 1995; Rezasoltani et al, 2002; Rankin et al, 2005).

6.2.2 - Aims

At the time of writing, there were no reported studies describing whether a correlation existed between linear and CSA measures of the VMO muscle, and so it was first necessary to determine whether or not there is a useful level of correlation between some identified linear and CSA measures of the VMO muscle using images from MRI scans. If a close relationship was found then it would be appropriate to explore whether measures taken from MRI and RUS images were sufficiently similar to allow RUS images to be used in further work. Therefore two aspects of validity need to be studied. The first of these, relating to the correlation of linear and CSA measures is addressed in this experiment. Comparison between MRI and RUS measures is dealt with in Section 6.3.

The aims of this study were to:

- Examine the relationship between linear and CSA measurements of the VMO muscle from MRI images
- Establish the reliability of measurements made from MRI images

Question: Is there an acceptable level of correlation between the CSA and any linear measure of the distal portion of the VM muscle ($r = 0.7$ or above), using measures taken from MRI images?

It was decided to limit recruitment to male subjects, as there are documented gender differences in CSA measures of the quadriceps muscles, with males typically having a larger CSA (Freilich et al, 1995; Montes, 2001). Also females often have higher levels of body fat in the thigh, compared to males, and so eliminating females should make imaging of the VMO muscle more straightforward. Pretorius and Keating (2008) reported that variations in muscle size exist between gender, backgrounds, ages, conditions (symptomatic versus asymptomatic), muscles and muscles groups and activity levels; also restricting the participants to the same gender would avoid one possible cause of inherent variation.

6.2.3 – Method

Twelve healthy, recreationally active adult males, aged between 18 and 30, were recruited and screened for contraindications to MRI following the normal procedure used in the radiology department of Southampton University Hospitals Trust (Appendix H). Each participant was healthy with no history of lower limb pathology or injury requiring treatment and was recreationally active. For further details on recruitment and participant criteria please see Chapter 4.

Participants were scanned using a magnetic resonance extremity (MRE) scanner, please see Chapter 4, as this is routinely used in clinical practice to obtain images of the knee joint. Each participant was positioned in long-sitting with his right knee in extension, the quadriceps muscle relaxed and a lateral support placed at the side of the knee to prevent lateral rotation of the hip.

Each participant had his right knee scanned and several images or slices were produced, at intervals of 7mm (following normal procedure for examining the knee joint using MRI), between the junction of the middle and upper third of the tibia through to the junction of the lower and middle third of the thigh, thus ensuring the whole of the distal end of the VM muscle would be included (See Figure 6.1). These images were examined by the researcher looking first at the distal images through to the proximal ones. It was agreed that the first image which did not include the patella would be the one from which measures would be taken; this rule was easy to apply to each set of images, and thus ensured a level of consistency in identifying the image from which measures would be taken, as well as ensuring that a sufficiently distal portion of the VM muscle would be visible in the image, where it inserts into the medial retinaculum. At its distal aspect the VM muscle has a good CSA to volume ratio (Blazevitch et al, 2006), which should facilitate ease of measurement, and in addition this point is as close to the cephaloid or proximal border of the patella (the base) as possible. CSA and linear measures from the MRI images were then taken using the 'Imagej' software, with all measures taken by the same investigator. For further details please see Chapter 4.

Once the images had been obtained, the CSA measure of the VMO was obtained by manually tracing around the inside edge of the border of the VMO muscle image, following the procedure used by Whittaker et al, (2007); and from this the ImageJ software (Imagej software available from <http://rsb.info.nih.gov/ij/docs/index.html>) calculated the value of the CSA. In addition it was necessary to find some appropriate linear measures to see if there was any correlation between these linear measures and the CSA. These linear measures would need to be easily and consistently identified from each image, and so would need to have clear bony or other landmarks to ensure they could be consistently identified. These linear measures are defined and illustrated in Figure 6.2.



Figure 6.1 – MRI scan of a typical participant. Muscle tissue is darker than bone or other soft tissues, and the vastus medialis oblique (VMO) is the main muscle (kidney-shaped) seen on the right of the image, the central pale area is the femur bone.

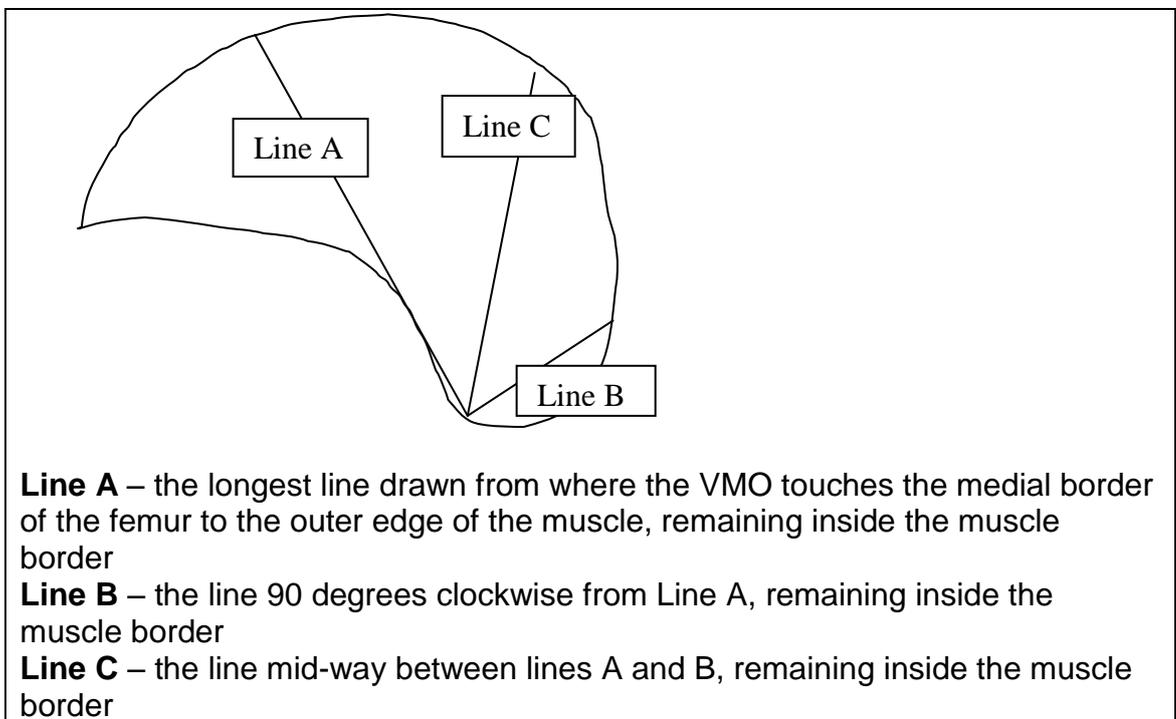


Figure 6.2 – Diagram of a typical cross-section of the vastus medialis oblique (VMO) muscle on a magnetic resonance image taken at the base of the patella, showing the three linear measures – Line A, Line B and Line C

6.2.3.1 – Statistical analysis for Reliability Testing

In order to examine the correlation between linear and CSA measurements on MRI scans, the intra-rater reliability of making the manual measurements needed to be established. Measurements were made by the investigator, as described above, on the same set of scans from the 12 participants on two separate occasions. From these two data sets (initial and repeat) Intra-class correlation coefficients (ICCs) and Bland and Altman Limits of Agreement were calculated. These two statistical tests were chosen as these have been used by others in this field and so these results could be compared to the work of others (Stokes et al, 1997; Rankin and Stokes, 1998; O'Sullivan et al, 2007). It is reported by Rankin and Stokes (1998) that neither calculation is sufficient on its own to provide sufficient information, but when used together they are more effective in determining the reliability of repeat measures. The ICC is used as it reflects both correlation and agreement between pairs of measures; and the Bland and Altman Limits of Agreement illustrate the level of agreement between pairs of measures (Rankin and Stokes, 1998; Bruton et al, 2001; O'Sullivan et al, 2007).

It was hoped ICCs of 0.9 or above would be achieved for the reliability between repeat measures, as this is stated by Portney and Watkins (2000) as being an appropriate level of reliability for measures used for decision-making or diagnosis. They acknowledge that setting limits is somewhat arbitrary as limits must be based on the precision of the measured variable and how the results will be used.

6.2.3.2 – Statistical analysis for relationship between CSA and linear measures

The relationship between linear and CSA measures was examined using Pearson correlation coefficients for each identified linear measure, multiples of linear measures and the corresponding CSA, as previous researchers have done (Loo and Stokes, 1990; Rankin et al, 2005). A level of correlation of 0.7 or above would be accepted, as Kline (1986); quoted by Stokes et al, (2007) states that correlation coefficients of above 0.7 are required in order for the relationship to be considered clinically significant.

6.2.4 – Results

6.2.4.1 Intra-rater reliability of CSA and Linear measures from the VMO muscle:

The ICCs between the set of first and repeat linear and CSA measurements ranged from 0.95 to 0.99 as listed in Table 6.1 below. The difference between each pair of measures was calculated (following the guidelines set by Bland and Altman, 1986) and from this the mean difference for each pair of linear and CSA measures were calculated (initial and repeat). These differences were all very small ranging from -0.15mm to -0.74mm. When the difference between pairs of measures were plotted against their mean, almost all values were within the 95% confidence intervals set (Mean difference \pm 2xSD), see Figure 6.3 below. Full data in Appendices J and K.

Table 6.1 – ICC and Bland and Altman results for first and repeat set of linear and CSA measures taken from the same set of MRI images. ICC figures in bold have met or exceeded the threshold level of 0.90. All Bland and Altman 95% Limits of Agreement contain the number 0.

	ICC		Bland and Altman		
	ICC Coefficient	95% Confidence Limits	Mean difference	SD of differences	95% Limits of Agreement
Line A	0.99	0.96 to 0.99	-0.58	1.39	-3.36 to 2.20
Line B	0.96	0.87 to 0.99	-0.50	1.93	-4.36 to 3.36
Line C	0.95	0.84 to 0.99	-0.74	2.36	-5.46 to 3.98
CSA	0.99	0.97 to 1.00`	-0.15	2.02	-4.19 to 3.89

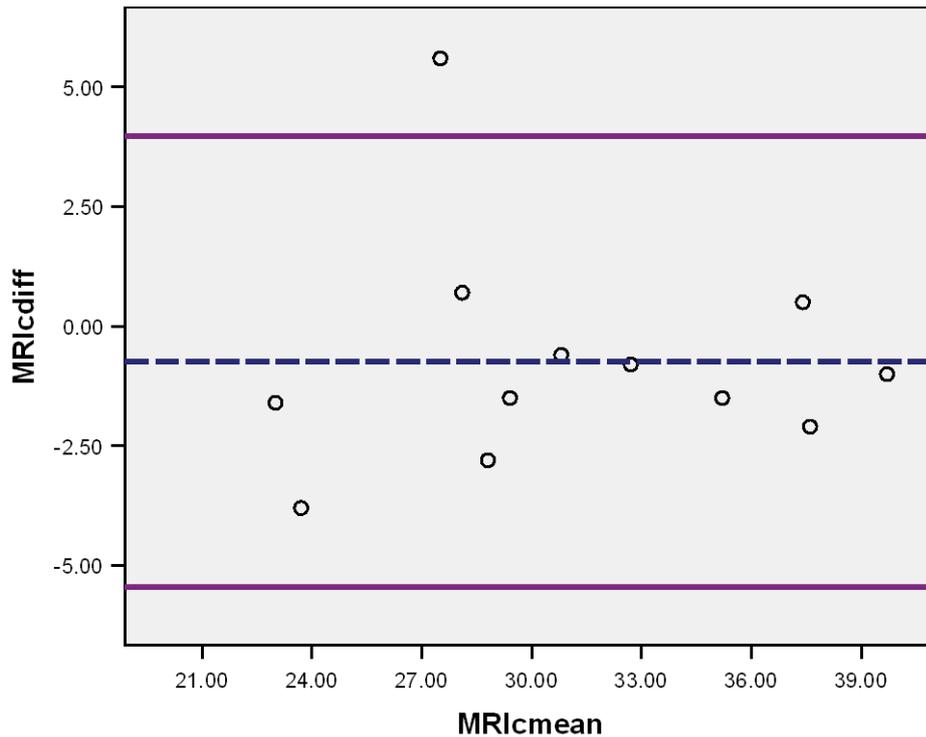


Figure 6.3 – Bland and Altman Plot showing differences scores between first and repeat Line C measure plotted against mean scores for first and repeat measures. Dashed line shows the mean difference score (-0.74 mm). The solid dark pink lines show the 95% upper and lower limits of agreement which are 2 standard deviations above and below the mean difference score (-0.74 +/- 4.72).

6.2.4.2 Correlation between the CSA and linear measures

Pearson’s correlation coefficients ranged between 0.32 and 0.87 for the single and combined linear measurements. Line C had the highest level of correlation $r=0.87$, see Table 6.2 and Figure 6.4 below, with line B having a poor level of correlation of $r=0.32$. The threshold level of correlation set as being clinically acceptable was 0.7. The linear measures were then multiplied together and Pearson correlation coefficients were calculated for these multiples with the CSA, as many authors of earlier work had found higher levels of correlation between CSA and multiplication of linear measures. As can be seen from Table 6.2 below, the level of correlation for multiples of linear measurements with CSA for this group of participants also increased.

Table 6.2 – Pearson correlation coefficients for each line measure and multiplication of line measures with the CSA. Measures were taken from the MRI images of the VMO muscle. Figures in bold indicate Pearson correlation coefficients above the $r = 0.7$ threshold level set.

Linear measure	Correlation with CSA measure (r)
A	0.65
B	0.32
C	0.87
AxB	0.64
AxC	0.87
BxC	0.72

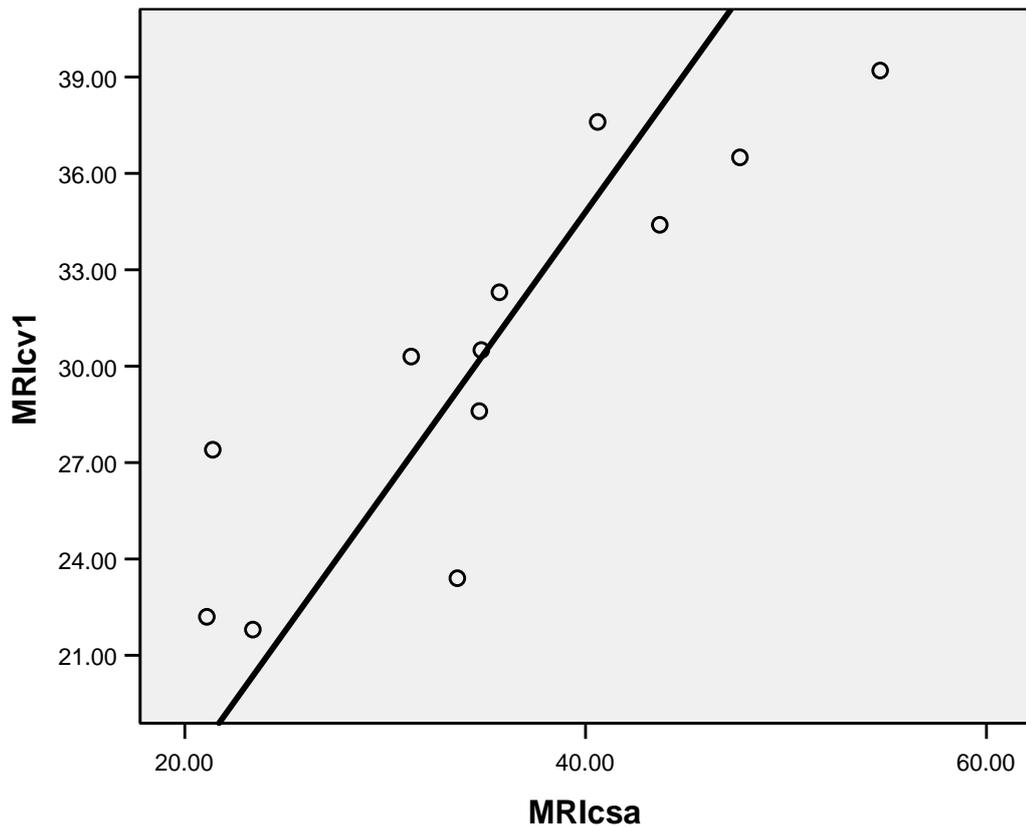


Figure 6.4 – Regression plot of CSA and Line C from MRI images of VMO muscle, $r=0.87$

6.2.5 – Conclusions

- The measurement protocol for measuring the CSA and linear measures from the MRI images, has been shown to have high levels of intra-rater reliability, and thus can be used with confidence by the researcher in this work.
- Linear measure C alone and multiples of other linear measures which include linear measure C exhibit good levels of correlation with CSA measures from the distal end of the VM muscle, when the procedure outlined here is followed.

This will allow linear measure C alone or multiples involving line measure C to be used as an indicator of the CSA of the distal VM muscle, and will be used in future work to represent its size and therefore strength.

6.3 – Validity and reliability of measuring VMO muscle size using ultrasound imaging compared with MRI images

6.3.1 - Background

Having established that the measurement protocol for obtaining linear measures from the MRI images was sufficiently reliable and there was a useful level of correlation between the CSA and linear measures of the VMO muscle using measures taken from MRI images; it was then necessary to see if linear measures from images of the VMO muscles taken with RUS were valid compared with those taken from MRI images. Firstly it was necessary to establish if the ultrasound measures were reliable, and if so then it would be appropriate to test for validity. As MRI images were taken with participants in long-sitting, the first section of this work, uses RUS images taken with participants in long-sitting.

Many researchers have shown that it is possible to take valid, accurate and reliable measurements of muscle size from images using real-time US equipment. A review of thirteen studies by Pretorius and Keating (2008), confirms this is the case; they state that due to the variability of the participants

and muscles studied in the articles which met their stringent review criteria, that these results can be generalised to all muscles.

Two previous studies have compared measures taken from US and MRI images of the quadriceps muscle group (Walton et al, 1996; Reeves et al, 2004) both of these studies used a compound scanning technique, which is when a number of images are taken and then added together allowing a compound image to be formed. The compound scanning technique was used in order to overcome the problem that the size of the transducer head was smaller than the CSA of muscle being imaged. A third study by O'Sullivan et al in (2009) examined the validity of RUS measurements of the trapezius muscle compared with MRI, for 18 healthy participants, using both Pearson's correlation, and Bland and Altman analyses. They found good correlation for muscle thickness measures from images taken at the level of T8 ($r=0.77$), with very small mean differences on the Bland and Altman tests, which were evenly distributed around and close to 0; a moderate level of correlation from images taken at the level of T5 ($r=0.62$), a fair level of correlation for images taken at the C6 level ($r=0.52$); and no correlation for images taken at the level of T1. The authors suggest that the difference in correlation at the different spinal levels was due to the clarity of anatomical reference points, from which the images were taken.

A fourth study by Mendis et al (2010) compared the CSA measures of the anterior hip muscles from both MRI and RUS images. They also used ICC (model 3.1) to compare each pair of measures for each muscle and reported values of between 0.81 and 0.89 and no statistically significant differences between the mean CSA for each set of measures using images from MRI and RUS for each muscle.

Walton et al (1996) compared the agreement of CSA and volume measures taken from MRI and US images of the quadriceps femoris muscle group of the left leg at the junction of the proximal one third and distal two-thirds, of 10 healthy participants (six male). They took one set of scans using MRI and Ultrasound on the same day, with subjects in the supine position. They used a compound scanning technique for their RUS images, which involves taking

several scans in order to build a picture of the whole muscle at the chosen point, using the Cavalieri technique. They did not comment on their own measurement protocol reliability. They found no statistically significant difference between both data sets using the Wilcoxon matched pairs test, and 95% confidence intervals of between -9.27 and 8.39 cm² for Bland and Altman Limits of Agreement, with a mean difference of 0.08% between CSA measures in each data set.

Reeves et al (2004) compared the agreement of CSA measures, taken from MRI and US images of the Vastus Lateralis muscle on the right leg at the level of its proximal insertion in six healthy participants, with participants in the supine position. They took one set of scans using MRI and Ultrasound on the same day. They also used a compound scanning technique for their RUS images, which involved taking several scans in order to build a picture of the whole muscle at the chosen point. They used ICCs only to assess their intra-rater measurement reliability (initial compared with repeat from the same scans with a 3-day interval), and quote ICCs of between 0.997 and 0.999 with a mean error of 2.6%). They plotted the CSA from the MRI images on one axis and the CSA from the US images on the other, showing a correlation coefficient of $r=0.99$.

The study by Mendis et al (2010) compared the validity of RUS imaging to measure anterior hip muscle size (CSA) with MRI images. They obtained bilateral images of the iliopsoas, sartorius and rectus femoris muscles from nine healthy participants (5 males) in the supine position. They took two images using RUS in the same session, and removed the transducer head from the skin between each image capture. They compared MRI and RUS measures for each muscle using ICCs and obtained values of 0.81 to 0.89. They also used an ANOVA test to assess differences between the mean CSA for each imaging technique for each muscle, and found no significant differences between them.

6.3.2 – Aims

- The primary aim of this experiment was to establish whether the linear measurements on RUS images are valid, compared with MRI as the gold standard in the same participants; prior to this it was necessary
- To examine the reliability of a protocol for measuring linear measures of VMO from RUS images

Questions:

- Are linear measures of the distal portion of the VM muscle taken from RUS images valid in comparison to those taken from MRI images of the same participants?
- What is the reliability of linear measurements taken on ultrasound images?

6.3.3 – Method

The same twelve adult males who participated in the MRI study described above (Section 6.2) were the participants for this study. In addition to the MRI scans each participant had RUS images taken, using the technique described in Chapter 4. Briefly, each participant was positioned in long-sitting with his right knee in extension and with a soft support on the outside of the knee to prevent lateral rotation of the hip, as before. Two ultrasound images were taken of the VMO muscle, at the level of the base of the patella of the right knee, using real-time Ultrasound equipment (Aquila, Pie Medical, UK), using a 8MHz linear transducer (Figure 6.5). The transducer head was removed from the skin, between each image. In addition six participants returned two days later and had two additional images taken following the same procedure. All ultrasound images were taken by the same investigator.

Once the ultrasound images were obtained, linear measures A, B and C (identified in the previous study and following the same procedure) were measured from each image, using the Imagej software, with all measures being taken by the same investigator.



Figure 6.5 – Participant having US scan of his VMO muscle, right leg, in long-sitting

Reliability and consistency of the ultrasound measurements were tested in the following ways –

- a) reliability of making repeated linear measures from the same images
 - a. linear measures were taken from the same images of all 12 subjects on two separate occasions, a week apart;
- b) reliability of procedure for obtaining images
 - a. within session: two images were taken from all 12 subjects on the same occasion, and linear measures from each image were taken and compared between the two;
 - b. between sessions: two images were taken from six subjects on two separate occasions, two days apart, following the same imaging protocol

6.3.3.1 - Statistical analysis

ICCs and Bland and Altman Limits of Agreement were calculated for the repeat measures taken from the same image, and the measures taken from repeat images.

Once the reliability testing of the RUS images described above was completed, the linear measures (A, B and C) from the MRI scans and US images were compared using ICCs and Bland and Altman Limits of agreement; in order to

determine the level of agreement between these two methods of obtaining muscle size measures of the VMO muscle.

6.3.4 – Results:

6.3.4.1 Validity Results

6.3.4.1.1 - Level of agreement and validity of linear measures taken from the MRI and US images of the same subjects

The ICC results in table 6.3 show that there is a very good level of agreement between all linear measures taken from the MRI and US images of the same subjects excepting linear measure C which shows only a moderate level of agreement. Linear measures A and B both exceed the threshold of 0.90. The Bland and Altman results support this and show the greater differences between the measures for Line C. The mean difference for the Line C measures is 2.81mm, showing that on average the MRI measures were larger than the US measures (Figure 6.6). Full data in Appendices J, K, L and M.

Table 6.3 – ICC and Bland and Altman Limits of Agreement for linear measures A, B and C, and multiplication of these measures, comparing readings from MRI and US images; with the US values being subtracted from the MRI values. ICC figures in bold exceed the 0.9 threshold level set.

	ICC		Bland and Altman		
	ICC Coefficient	95% Confidence Limits	Mean difference	SD of differences	95% Limits of Agreement
Line A	0.97	0.88 to 0.91	0.20	2.60	-5.00 to 5.40
Line B	0.92	0.73 to 0.98	-0.53	2.46	-5.45 to 4.39
Line C	0.74	0.11 to 0.93	2.81	5.06	-7.31 to 12.93

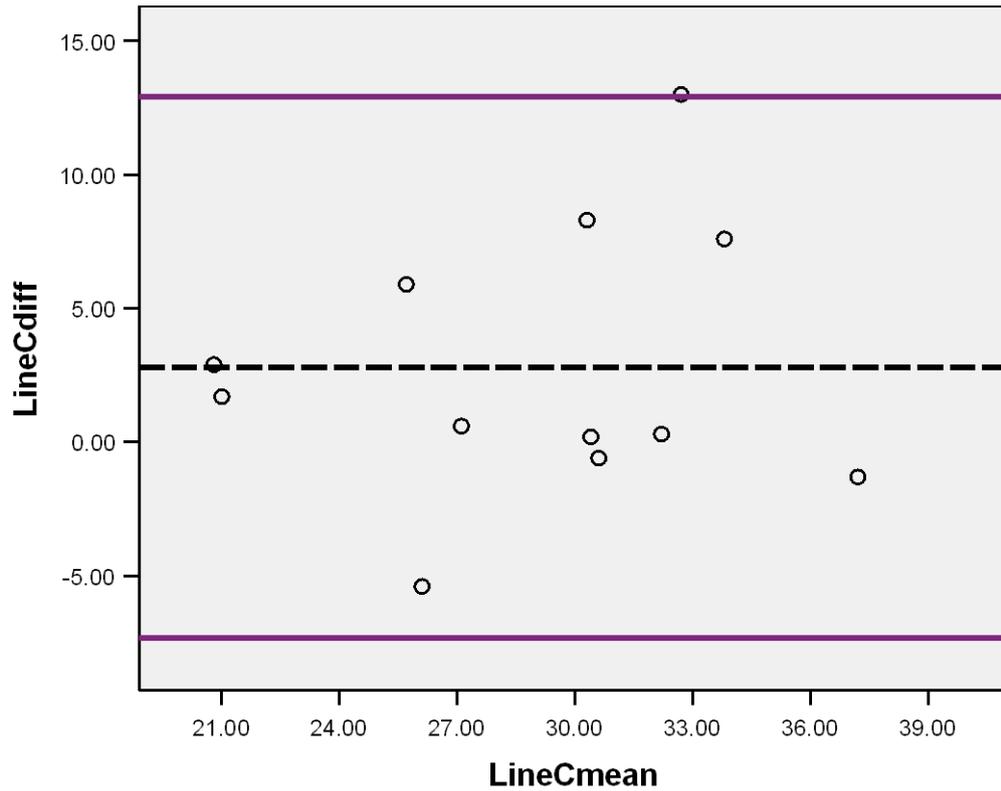


Figure 6.6 – Bland and Altman Plot Showing difference scores for line measure C between measures taken from MRI and US scans. The dashed line shows the mean difference score (2.81mm). The 95% upper and lower limits of agreement represent 2 standard deviations above and below the mean difference score (2.81 +/- 10.12).

6.3.4.2 – Reliability Results

6.3.4.2.1 - Intra-rater reliability: repeat measures from the same US images:

Results listed in Table 6.4, and illustrated in Figure 6.7 below, show that the intra-rater reliability for taking initial and repeat linear measures from the same 12 US images is very reliable and consistent. All ICC values are well above the 0.9 threshold and the mean differences are all less than 1mm on the Bland and Altman test. Full data in Appendix L.

Table 6.4 – ICC and Bland and Altman Limits of Agreement for repeat measures A, B and C from the same US images

	ICC		Bland and Altman		
	ICC Coefficient	95% Confidence Limits	Mean difference	SD of differences	95% Limits of Agreement
Line A	0.995	0.982 to 0.999	0.68	1.03	-1.38 to 2.74
Line B	0.986	0.950 to 0.996	-0.42	1.02	-2.46 to 1.62
Line C	0.988	0.958 to 0.996	-0.49	1.15	-2.79 to 1.81

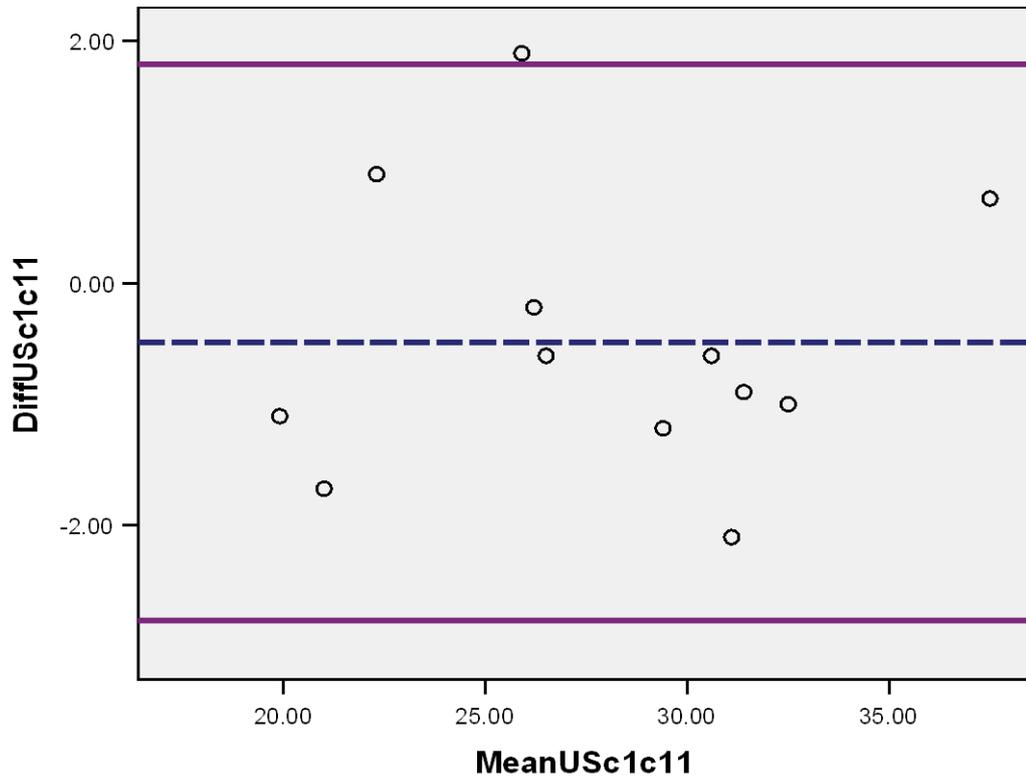


Figure 6.7 – Bland and Altman Plot showing differences scores between first and repeat line measure C plotted against mean line C values for first and repeat measures, taken from the same US scans. The dashed line shows the mean difference score (-0.49 mm). The solid dark pink lines show the 95% upper and lower limits of agreement which are 2 standard deviations above and below the mean difference score (-0.49 +/- 2.30).

6.3.4.2.2 - Intra-rater reliability: measures taken from repeat US images in the same session, for all twelve subjects:

The results shown in Table 6.5, and illustrated in Figure 6.8 below, show that the intra-rater reliability for measurements taken from repeat US images is also reliable and consistent. All ICC values are at 0.9 or above, and the mean differences range from 1.5 through to 3.06 mm. Full data Appendix M.

Table 6.5 – Intra-class Correlation Coefficients and Bland and Altman Limits of Agreement for line measures (A, B and C), from repeat US images

	ICC		Bland and Altman		
	ICC Coefficient	95% Confidence Limits	Mean difference	SD of differences	95% Limits of Agreement
Line A	0.966	0.881 to 0.990	-1.04	3.06	-7.16 to 6.12
Line B	0.900	0.654 to 0.971	-0.23	2.51	-5.25 to 4.79
Line C	0.979	0.928 to 0.994	-0.78	1.50	-3.78 to 2.22

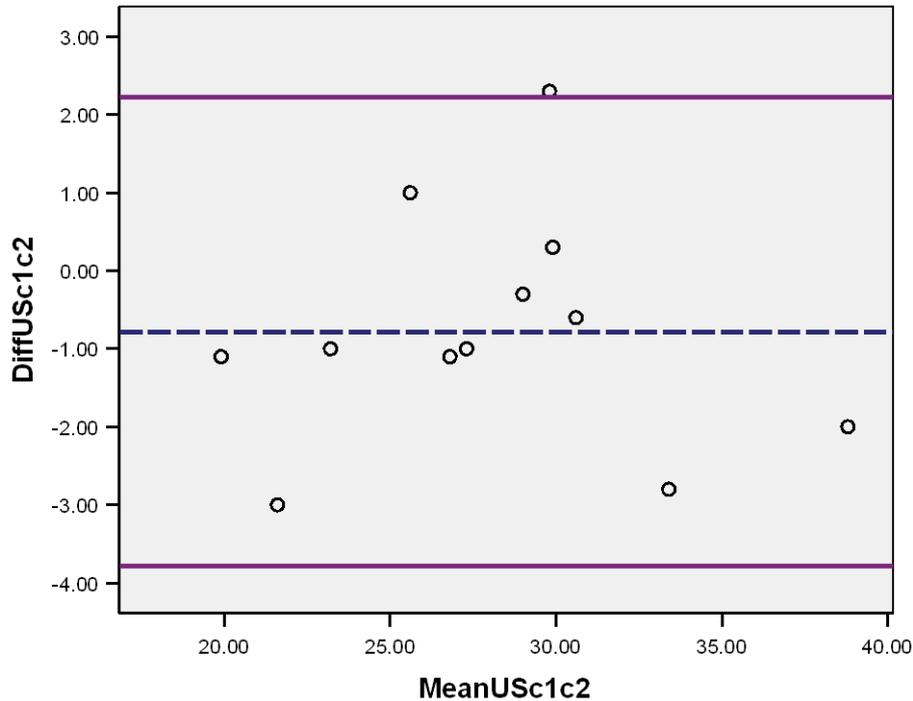


Figure 6.8 – Bland and Altman Plot showing differences scores between first and repeat linear measure C plotted against mean scores for first and repeat measures, taken from separate images. Dashed line shows the mean difference score (-0.78 mm). The solid dark pink lines show the 95% upper and lower limits of agreement which are 2 standard deviations above and below the mean difference score (-0.78 +/- 3.00).

6.3.4.2.3 - Intra-rater reliability of measures taken from repeat images for six participants on two separate occasions, two days apart:

The results shown in Table 6.6, and illustrated in Figure 6.9 below, show that consistency of line measures A, B and C from the six individuals who were scanned twice, is again very high. All ICC values comfortably exceed 0.90. The mean differences are all less than 1mm, ranging from 0.08 through to 0.47 mm, with the Standard deviation of differences also being very small.

Table 6.6– ICC and Bland and Altman Limits of Agreement for linear measures A, B and C from separate US images of six subjects taken two days apart.

	ICC		Bland and Altman		
	ICC Coefficient	95% Confidence Limits	Mean difference	SD of differences	95% Limits of Agreement
Line A	0.995	0.964 to 0.999	-0.08	1.26	-1.34 to 1.18
Line B	0.983	0.879 to 0.998	0.35	1.00	-1.65 to 2.35
Line C	0.970	0.786 to 0.996	0.47	0.82	-1.17 to 2.11

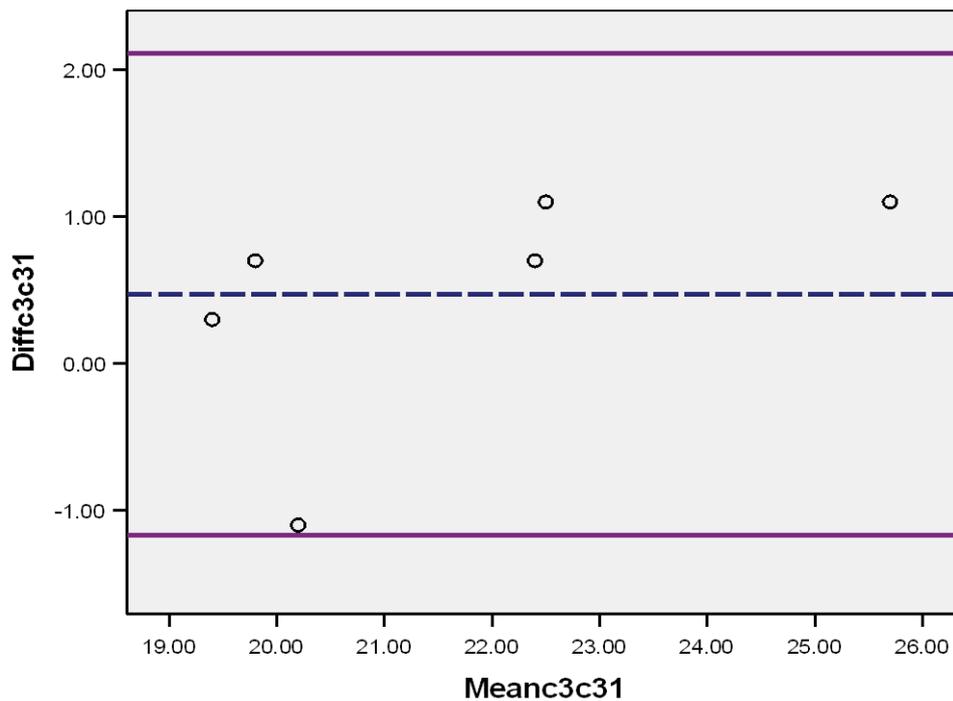


Figure 6.9 – Bland and Altman Plot showing differences scores between first and repeat line measure C plotted against mean scores for first and repeat measures, taken from separate scans, 2 days apart. Dashed line shows the mean difference score (0.47 mm). The solid dark pink lines show the 95% upper and lower limits of agreement which are 2 standard deviations above and below the mean difference score (0.47 +/- 2.11).

6.3.5 – Conclusion

- The findings demonstrate that there is sufficient agreement between the linear measures from the MRI and RUS images, showing that RUS is valid enough, to be used to measure the size of the VMO muscle in future work; however the technique of taking RUS images, in particular the practice of applying pressure to the RUS transducer head, has to be improved.
- The findings also illustrate that the measurement protocol is sufficiently reliable and consistent, when used by the same investigator, to allow the protocol to be used with confidence.

NB: Fortunately the problem of applying too much pressure to the transducer head while taking ultrasound scans was overcome in later studies – please see Section 6.4.

6.4 – Reliability and correlation between linear and CSA measures of the VMO muscle using RUS – in standing

6.4.1 - Background

In Chapter 5, Section 5.4, a reliable protocol for the measurement of the Q-angle of participants in relaxed standing, using the Peak-5 video motion analysis system, was demonstrated. The next logical step was to explore whether it would be possible to develop a reliable protocol for taking images of the VMO muscle using RUS from participants in relaxed standing, as this would then allow us to see if there was any relationship between the size of the VMO muscle and the Q-angle from subjects in relaxed standing. One of the great benefits of using portable real-time US to image muscles is that it allows the possibility of taking images from participants in different body postures e.g. sitting, lying and standing (Coldron et al, 2003).

The following authors have reported experiments in which they have taken images of muscles using RUS, from participants in different postures:

- Coldron et al, (2003) compared lumbar multifidus muscle size in 20 healthy participants in both prone and side-lying. They carried out a very thorough analysis, reporting correlation coefficients of 0.90 for the right side and 0.91 for the left side; included regression plots of measures from the side-lying and prone lying; Bland and Altman Limits of Agreement and paired t-tests for the means of each set of measures and found no significant differences between any of them; concluding that there was no difference in multifidus muscle size and shape between the two postures.
- Ainscough-Potts et al, (2005) compared the transverse abdominis and internal oblique muscle size in three different sitting postures of 30 healthy participants. They analysed their measurements using ICCs and report results of between 0.97 and 0.99 between postures; they also compared means of measurements using t-tests. They found no significant differences in either muscle size between two positions in which both muscles were relaxed, but once they introduced an element of instability there was a corresponding significant increase in muscle thickness.

6.4.2 – Aims

This experiment aimed to:

- establish whether it was possible to achieve the same level of measurement consistency from RUS images of the VMO muscle obtained from participants in a relaxed standing posture, as achieved when they were in long-sitting
- examine the relationship between CSA and linear measures made on ultrasound scans of the VMO taken from participants in relaxed standing

Questions:

- What is the reliability of measuring the size of the VMO muscle using ultrasound imaging with the participant in a relaxed standing posture?
- Are CSA and linear measures on these ultrasound scans highly correlated?

6.4.3 – Method

Ten of the 12 adult males who participated in the earlier MRI and RUS tests described above were the participants in this study. Each participant had two images of his VMO taken using RUS while he was in relaxed standing, i.e. standing with his weight evenly distributed over both feet, with confirmation of the relaxed muscle being made by the patella being able to be moved passively by the investigator (See Figure 6.10). There was an interval of at least five minutes between each scan, and the transducer head was removed from the leg of the participant between each scan.

The linear measures A, B and C (used in the previous study) were identified on the images and were measured (See Figure 6.2). Again all scans and measurements on each RUS image were taken by the same investigator using the 'Imagej' software.



Figure 6.10 – Participant having RUS image of his right vastus medialis oblique (VMO) muscle while in relaxed standing

The intra-rater reliability of the technique of taking RUS images from participants in long-sitting was established in Section 5.4. The intra-rater reliability of the technique of taking RUS images from participants in relaxed standing was examined in two ways:

- a) Within-scan measurements - reliability of taking repeat linear measurements from the same scans of all participants on two separate occasions, two days apart; by the same investigator, and
- b) reliability of taking scans within the same session – two images were taken from all participants on the same occasion, by the same investigator, and linear measures using the Imagej software were taken from each scan and compared.

6.4.3.1 - Analysis of data

ICCs and Bland and Altman Limits of Agreement were calculated for the repeat measures taken from the same scan, and the measures taken from repeat scans.

As it was possible to image the whole CSA of the VMO muscle for all ten subjects in this group, Pearson's correlation coefficients were also calculated to establish the level of correlation between the linear measures A, B and C, as well as multiplications of the linear measures, with the CSA measures.

6.4.4 – Results:

6.4.4.1 – Intra-rater reliability: repeat measures from the same RUS images (within-scan measurements):

Results listed in Table 6.7, show that the intra-rater reliability for taking repeat linear measures from the same images of the VMO was very reliable and repeatable, all pairs of measures for Line B and C had ICC's of above the 0.90 threshold level set. Line A had a lower level but was still high at 0.83; it had the lowest mean difference at 0.02mm and the highest SD, suggesting there was probably an outlier. All mean differences between pairs of measures were 0.57 mm or less and all 95% limits of agreement for the Bland and Altman calculations contained the number 0, showing there was no systematic bias.

The variability for the pairs of CSA measures were greater than for the linear measures, but again the ICC was high at 0.98 and the mean difference was 2.27 cm². Full data in Appendices P and Q.

Table 6.7 – ICC and Bland and Altman Limits of Agreement for repeat measures A, B and C; and CSA, from the same RUS images for all ten participants, taken in relaxed standing. ICC figures in bold exceed the set threshold of 0.9.

	ICC		Bland and Altman		
	ICC Coefficient	95% Confidence Limits	Mean difference mm	SD of differences mm	95% Limits of Agreement
Line A	0.83	0.32 to 0.96	0.02	3.56	-7.10 to 7.14
Line B	0.99	0.96 to 1.00	-0.11	0.99	-2.09 to 1.87
Line C	0.96	0.85 to 0.99	-0.57	1.71	-3.99 to 2.85
CSA	0.98	0.93 to 1.00	-2.27	6.34	-14.95 to 10.41

6.4.4.2 - Intra-rater reliability: measures taken from repeat scans, within the same session:

Results in Table 6.8 below illustrated that the intra-rater reliability for measurements taken from repeat scans was also reliable and consistent. There was no difference between the level of reliability between repeat measures taken from the same images than these taken from a second set of images, showing that both the taking of the images and then taking the measures from the images was very reliable. In this case all ICC values were above the 0.9 threshold, and mean differences for the linear measures were smaller being 0.20 mm or below and all 95% limits of agreement for the Bland and Altman calculations contained the number 0, showing there was no systematic bias. Full data Appendix R.

The results for the CSA measures are as reliable as for the linear measures for this set of results.

Table 6.8 – ICC and Bland and Altman Limits of Agreement for repeat linear measures A, B and C and CSA, from repeat US images for all ten subjects, taken in relaxed standing. ICC figures in bold exceed the set threshold of 0.9.

	ICC		Bland and Altman		
	ICC Coefficient	95% Confidence Limits	Mean difference	SD of differences	95% Limits of Agreement
Line A	0.98	0.93 to 0.99	-0.17	1.36	-2.89 to 2.55
Line B	0.99	0.97 to 1.00	0.01	0.86	-1.71 to 1.73
Line C	0.97	0.90 to 0.99	-0.20	1.32	-2.84 to 2.44
CSA	0.99	0.98 to 1.00	-0.14	3.57	-7.28 to 7.00

6.4.4.3 - Correlation between the linear measures, multiplication of linear measures and CSA measures:

Table 6.9 illustrates that each linear measure and multiplication of linear measures correlated well with the CSA measurement taken; each correlation being above the 0.7 level set as a threshold for this programme of work. It is interesting to note that once again Line C had the highest individual level of correlation ($r=0.86$) for the individual linear measures and it was at almost the same level as that for the measures taken from MRI images ($r=0.87$).

Table 6.9 – Pearson correlation coefficients between the CSA and linear measures A, B and C and multiplication of linear measures from US images of the VMO muscle taken in relaxed standing, $n=10$. All figures in bold all met or exceeded the threshold set of 0.7.

Linear Measure	Pearson Correlation Coefficient (r)	P values from paired t-test
A	0.75	
B	0.76	
C	0.86	
AxB	0.72	
AxC	0.86	
BxC	0.82	

6.4.5 – Conclusions

- Taking consistent RUS images of the distal portion of the VMO muscle from participants in relaxed standing is technically more difficult than when participants are in long-sitting; however the reliability of the technique is good. The ICCs from initial and repeat linear and CSA measures from the images were all high with three being above the 0.90 threshold, and mean differences between pairs of measures were very small.
- The level of correlation between the CSA and linear measurements was high, all being above the threshold set,
- The technical difficulties in the earlier studies of applying too much pressure to the US transducer head when taking the image, which affected line measure C in particular, have been overcome, as evidenced by the consistency of measures and its level of correlation with the CSA measure.

6.5 Effect of posture on VMO muscle size and shape

6.5.1 – Background

In Sections 6.3 and 6.4 of this chapter it was established that it was possible to take reliable RUS images of the VMO muscle from participants in long-sitting and relaxed standing, and that these measures were valid compared with MRI measures as well as the linear measures being highly correlated with CSA. It was now possible to compare the level of agreement between the CSA and linear measures taken from the US images of subjects in these two different positions to see if there was any effect of posture on the measurements. As has already been described in Section 6.4 two authors have compared muscle size measures, taken from RUS images, from participants in different postures, and found no significant differences as long as the muscles being measured remained relaxed.

However, a study by Fulton et al, (2008) explored the effect on muscle thickness of the Transversus Abdominis muscle as participants performed an

upper limb task which required the participant to maintain their postural stability. They reported a significant change in the thickness measure. They analysed their measurements using a random coefficient analysis regression (mixed model) and found significant differences between younger and older subjects as well as a non-linear increase in muscle thickness. They acknowledge a limitation of their study was relatively poor consistency in measurement of muscle thickness, reporting ICC figures of 0.52 for baseline measures and 0.32 for repeat performance of the test between weeks. As they only used one test of reliability for their measures, their results should be treated with caution.

Thus it is possible that the VMO muscle in relaxed standing may show an increase in thickness (Linear measure C, is most closely related to thickness) compared to its measure in long-sitting, due to weight-bearing and the increased instability of standing compared to long-sitting. This section used data from sections 6.3 and 6.4 to perform retrospective analysis to compare measures taken in the two postures.

6.5.2 Aim

The purpose of this further data analysis was to establish whether there were differences in the CSA and linear measures of the VMO muscle taken from RUS images, when a participant was in long-sitting or relaxed standing.

Question: Does posture affect the CSA and linear measures of the VMO muscle made on RUS images?

6.5.3 – Method

The mean measures from the two existing complete data sets in Sections 6.3 and 6.4 were used in the analysis i.e. CSA and linear measures A, B and C taken from US images of the VMO muscle taken in long-sitting and relaxed standing; from the 10 healthy recreationally active male participants. The data were compared using ICCs, Bland and Altman Limits of Agreement, and paired T-tests, following the methods used by others (Ainscough-Potts, 2005; Coldron et al, 2003).

6.5.4 – Results

As can be seen from Table 6.10 below, three ICCs were above the threshold of 0.90, and all were above the 0.80 level, showing good to very good levels of agreement between the two sets of measures. All Bland and Altman limits of agreement 95% confidence intervals include 0, showing that there was no consistent level of difference between the two sets of measures; although there was a much higher level of mean differences for all sets of measures, than those taken from repeat measures from images when participants were in the same posture (see Tables 6.3, 6.4, 6.5, 6.7 and 6.8). This suggests that the VMO muscle does not adopt a different shape in relaxed standing compared with that in long-sitting, although our sample size of ten was really too small to be certain.

The regression plot for Line C (Figure 6.11) shows no significant differences between measures of Line C, taken from images obtained in both postures.

Table 6.10 – Comparison of measures taken from ultrasound images in long-sitting and relaxed standing: ICC and Bland and Altman Limits of Agreement for CSA and linear measures A, B and C. ICC figures in bold exceed the set threshold of 0.9.

	ICC		Bland and Altman (mm)		
	ICC Coefficient	95% Confidence Limits	Mean difference	SD of differences	95% Limits of Agreement
Line A	0.81	0.23 to 0.95	-2.10	4.07	-10.24 to 6.04
Line B	0.98	0.92 to 1.00	2.46	1.40	-0.34 to 5.26
Line C	0.91	0.64 to 0.98	1.91	3.20	-4.49 to 8.31
CSA	0.87	0.46 to 0.97	5.11	23.04	-40.97 to 51.19
Line AxB	0.91	0.65 to 0.98	9.15	17.14	-25.13 to 43.43
Line AxC	0.89	0.54 to 0.97	4.97	21.87	-38.77 to 48.71
Line BxC	0.83	0.32 to 0.96	13.56	14.17	-14.78 to 41.90

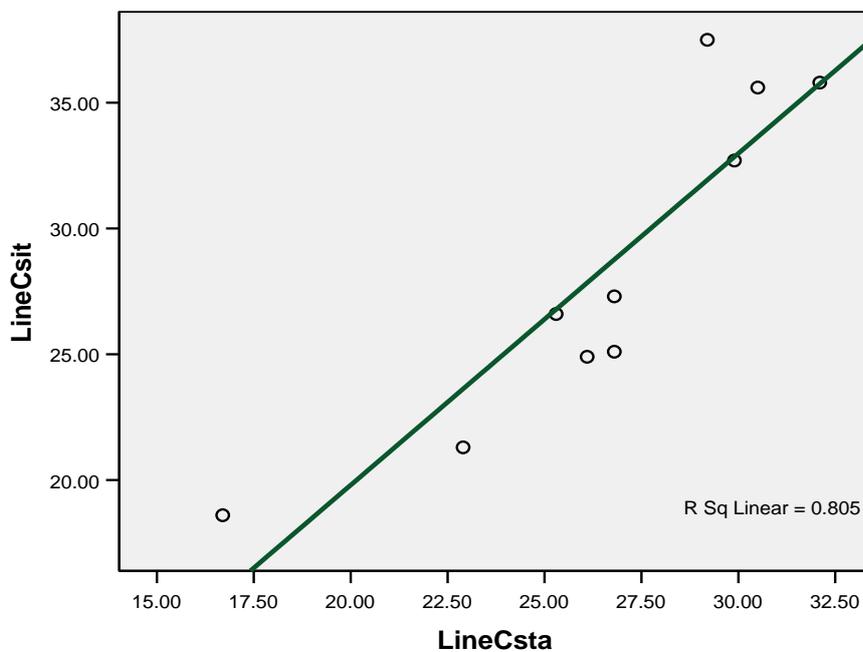


Figure 6.11 – Regression Plot of Linear measure C from US images taken in long-sitting against those taken in relaxed standing; $r=0.91$.

When the two sets of mean data were compared using T-tests (Table 6.11), there were no statistically significant differences between them. The mean data showed that linear measure A was slightly larger when taken in relaxed standing and linear measures B and C and the CSA were slightly larger when taken in long-sitting, but none of these differences were significant.

Table 6.11 – Mean, standard deviation (SD) and T-test results, comparing measures taken in relaxed standing and long-sitting

Measure	Mean mm	SD mm	T-Test
A – sitting	42.5	5.7	P=0.37
A – standing	44.6	4.3	
B – sitting	25.2	4.8	P=0.27
B – standing	22.7	4.9	
C – sitting	28.5	6.5	P=0.45
C – standing	26.6	4.4	
CSA – sitting	112.4	35.8	P=0.73
CSA – standing	107.3	30.8	

6.5.5 – Conclusion

There were no important or consistent differences between the CSA and linear measures A, B, and C, taken from US images of the VMO muscle in long-sitting and relaxed standing. Posture, therefore did not influence the measures taken.

6.6 General Discussion and Conclusions for Studies in Chapter 6

6.6.1 – General Discussion:

This chapter reported a number of studies which were designed to establish a valid and reliable protocol for the measurement of the vastus medialis oblique (VMO) muscle, using ultrasound images taken with a portable ultrasound machine. A positive answer was found.

Prior to addressing this question it was necessary to establish a number of other things:

- Is there a meaningful correlation between the CSA and linear measures of the VMO muscle, when measures are taken from images obtained using the gold standard for muscle imaging, namely MRI scans? And prior to this it was necessary to establish whether CSA and linear measures of the VMO could be taken reliably from MRI images
- Can the CSA and linear measurements of the VMO muscle be made as validly and reliably from ultrasound images as they are from MRI images? And prior to this it was necessary to establish whether ultrasound images could be taken reliably from participants
- Is there any effect of posture on the size and shape of the VMO muscle?

6.6.1.1 – Correlation between the CSA and linear measures of the VMO muscle

Other researchers have reported that there is a meaningful correlation between the CSA and linear measures for other muscles (see Chapter 3). This was important to establish as it was felt likely that the CSA of the VMO muscle might be larger than the size of the ultrasound transducer head, at least for some participants, rendering it impossible to capture the full size of the VMO muscle with the portable ultrasound equipment, as outlined in Section 6.2. Although it should be noted that a study by Yeong-Fwu et al (2008) took ultrasound scans of the VMO from 58 participants (89 knees) in Taiwan and was able to image the CSA of all participants, using a normal ultrasound machine transducer head.

6.6.1.1.1 – Reliability of taking CSA and linear measures from MRI images

First of all a number of repeat measures of the CSA and linear measures A, B and C were taken from the MRI scans and tested for repeatability. All ICCs for the initial and repeat measures exceeded 0.9, which Portney and Watkins (2000) consider to be a necessary minimum threshold for the consistency of clinical measures. These results are in line with those of other authors who studied different muscles, most of whom report ICCs of initial and repeat intra-rater measures of 0.9 or above for example (Rankin and Stokes, 1998; O’Sullivan et al, 2007).

All mean differences between pairs of initial and repeat measures as calculated following the procedure outlined by Bland and Altman Limits of Agreement (1986) were all very small (range -0.15mm to -0.74mm). All differences were negative, showing that the mean repeat set of measures taken were slightly larger than the initial set. It is difficult to know whether this is something to be concerned about or not, the only other paper who report on this is the paper by Rankin and Stokes (1998), who also found that for one of their researchers (a relative novice in the use of ultrasound imaging) the repeat set of measures were larger than the initial ones. The repeat set of measures were closer in agreement to that of a more experienced researcher who was also participating, they also report that this was not evident in the ICC results (as is the case here) and suggest that this difference may be due to the fact that the researcher in question was a relative novice.

Each 95% confidence interval for the Bland and Altman Limits of Agreement contained the number 0 and a range which was similar above and below 0; however the minimum of the confidence interval was slightly further away from 0 than the upper limit, again illustrating the small level of consistent systematic bias in the measurement technique, i.e. the repeat measures were consistently slightly larger than the first set of measures.

6.6.1.1.2 - Correlation between CSA and linear measures from the MRI image

Three linear measures from the VMO muscle were identified (A, B and C) and Pearson correlation coefficients were calculated between each one and the CSA; as well as multiples of the linear measures with the CSA. It was felt that a minimum level of correlation of $r=0.7$ was required in order for the correlation to be considered useful. Pearson correlation levels of above 0.7 have been found by other researchers for the following muscles:

- Width and Depth measures from posterior neck muscles (semispinalis capitis, semispinalis cervicis, multifidus and rotators) of 53 healthy females (Rankin et al, 2004), $r = 0.66-0.84$;
- Multiples of width and depth measures from semispinalis capitis for six junior ice hockey players (Rezasoltani et al, 2002);
- Linear measures from lumbar multifidus for 51 healthy individuals (Hides et al, 1994);
- Linear (anterior/posterior and lateral) for lumbar multifidus for 120 healthy individuals (Stokes et al, 2004);
- Linear measures of the anterior tibial muscles for 17 healthy women (Martinson and Stokes, 1991);
- Linear measures from the masseter for 39 healthy subjects (Close et al, 1995)

In this work Linear measure C exhibited the highest individual level of correlation with the CSA of the muscle ($r=0.87$) as shown in Table 6.2. Each multiplication involving linear measure C also produced a Pearson correlation coefficient greater than the $r=0.7$ threshold when correlated with the CSA i.e. line A x C $r=0.87$; and line B x C $r= 0.72$. Linear measure A has a correlation of $r=0.65$, which is not close enough to the $r=0.7$ threshold level stated by Kline (1986) and quoted by Stokes et al (2007) as being clinically useful. These results support those of the authors listed above.

However, it is interesting that when linear measures were multiplied together they did not show a higher level of correlation than line C on its own. This was different from others who found that when linear measures were multiplied

together these multiples gave a higher level of correlation with CSA than individual linear measures (Loo and Stokes, 1990; Stokes et al 2005). It is not clear why there was this difference. Apart from this point, these results fit in well with those of the other researchers (listed above) who have explored correlation relationships between line and CSA measurements of other skeletal muscles.

Linear measure C is the line which is closest to measuring anterior-posterior muscle thickness, and the authors listed above have also shown that this particular linear measure tends to correlate very well with the CSA of the muscle; thus this work supports the developing pattern that anterior/posterior muscle thickness appears to have an effective correlation between the CSA of the same muscle. Thus if only one linear measure can be taken, then the anterior/posterior thickness would be the one of choice.

In summary it has been established that taking CSA and linear measures from MRI scans is highly repeatable, and that there is a meaningful level of correlation between the CSA and linear measures of the VMO muscle.

6.6.1.2 – Validity and reliability of measuring VMO muscle size using ultrasound imaging compared with MRI

As described in Section 6.3 it was established that it was possible to measure the VMO muscle size as validly and reliably using ultrasound images as it was using MRI images, when repeat measurements were assessed using two measures of reliability testing, namely ICC and Bland and Altman Limits of Agreement, as advocated by Rankin and Stokes (1998).

The high levels of reliability found are consistent with the results reported by others (Pretorius and Keating, 2008). The results also show that the level of consistency between repeat measures taken from the same image is greater than those taken from repeat images; however again all ICCs met or exceed the 0.90 threshold, although those from repeat scans did not exceed it to the same extent as when repeat measures were taken from the same scans. By default it also showed that the investigator's technique of taking ultrasound images and

taking linear measures from these images was also very reliable which means that RUS imaging will be able to be used in further work.

However, when the linear measures from the RUS images were compared with those obtained from the MRI scans there was a lower level of agreement and consistency than when comparing repeat measures from the same RUS or repeat RUS images. The threshold set for acceptability was an ICC value of 0.90. The level of agreement for line measures A and B exceeded this threshold, whereas that for Line C did not. When re-examining the US images it was clear that the superior border of the muscle had a slightly flattened appearance, which suggested that despite careful technique during the scanning procedure, too much pressure was being applied to the transducer head. This particularly affected line measure C (which is a close approximate on the anterior-posterior thickness of the VMO) and accounts for the fact that on average line measure C taken from US images was smaller than those taken from MRI images. This affected the level of agreement between line measure C from the MRI and US images, resulting in it being only moderate (0.72) when using the definitions recommended by Portney and Watkins, (2000). However, this pressure must have been applied in a consistent way as the level of agreement between line measure C from repeat RUS images exceeded the 0.9 level. It was important that this technical problem was remedied as line measure C showed the highest degree of correlation with the CSA (from the MRI images) and so would be the line measure of choice taken to represent VMO muscle size in future work. This issue of applying too much pressure during the imaging process has been highlighted by other authors (Dupont et al, 2001; Reeves et al, 2004; Teyhen et al, 2007).

A number of other authors have also compared measures taken from images of the same muscles using both MRI and RUS, see Section 6.3.1. Hides et al (2006) compared linear muscle measures taken from images of the transverses abdominis and internal oblique muscles from both RUS and MRI images. They compared each set of measures using ICC (model 3) and reported values of between 0.78 and 0.95; however only using one statistical tool for measuring

agreement is not considered sufficient to be confident of showing full agreement between the two sets of measures.

Mendis et al (2010) compared the CSA measures of anterior hip muscles taken from both MRI and RUS muscle images. They also used ICCs (class 3.1) to compare each pair of measures for each muscle and reported values of between 0.81 and 0.89 and no statistically significant differences between the mean CSA for each set of measures using images from MRI and RUS for each muscle.

Pretorius and Keating (2008) report a review of 13 studies in which investigators compared measures of muscle size taken from RUS images and either MRI or CT. Ten of these studies report Pearson correlation coefficient values, three also report t-test between mean values. None of the studies used Bland and Altman Limits of Agreement, which seemed surprising, given the clear purpose of the Limits of Agreement is to test the level of Agreement between two different measurement tools or methods.

A more recent study by O'Sullivan et al (2009) examined the validity of RUS measurements of the trapezius muscle compared with MRI, using both Pearson's correlation, and Bland and Altman analyses and found good correlation for muscle thickness measures from images taken at the level of T8 ($r=0.77$), with very small mean differences on the Bland and Altman tests, which were evenly distributed around and close to 0; a moderate level of correlation from images taken at the level of T5 ($r=0.62$), a fair level of correlation for images taken at the C6 level ($r=0.52$); and no correlation for images taken at the level of T1. The authors suggest that the difference in correlation at the different spinal levels was due to the clarity of anatomical reference points, from which the images were taken.

6.6.1.3 – Effect of posture on VMO muscle size

It was also necessary to establish whether there were any statistically significant differences found for any of the measurements taken in the two postures of long-sitting and relaxed standing, because in order to compare the value of the

Q-angle and size of the VMO muscle in a meaningful way, it would be important to have all measures taken from participants in the same posture – ideally relaxed standing. We found no statistically significant differences in measures taken from images from participants in both postures. These results support the findings of Coldron et al (2003) and Ainscough-Potts et al (2005) who also found no significant effects of posture on muscle size measures for the lumbar multifidus, and transverse abdominis, internal oblique muscles of healthy participants respectively as long as the muscles remained relaxed.

It was thought possible that linear measure C might be larger when measured in relaxed standing, due to low-level muscle contraction needed to maintain position in weight-bearing in a posture less stable than long-sitting; in accordance with the findings of Fulton, et al (2008). However, this was not the case in this work. This may be due to the fact that the VMO was relaxed during both sets of measurements (evidenced by a patella which could be moved passively) and any low-level muscle contraction required to maintain the position in weight-bearing may have come from elsewhere in the quadriceps muscle group or any contribution made by the VMO was not sufficiently great to effect a detectable difference in muscle thickness.

The results reported in Section 6.5 show that it was possible to take good reliable RUS images of the VMO muscle of healthy individuals who are in a relaxed standing posture. Taking RUS images of this aspect of the VMO muscle from an individual in relaxed standing is technically more difficult than with the participant in long-sitting, as the operator needs to be at the height of the knee joint, which usually requires sitting or kneeling on the floor, while operating the RUS equipment. Despite the quadriceps muscles, including the VMO being relaxed – as determined by the operator being able to move the subject's patella passively – the investigator observed that the VMO muscle was 'more rounded' in the standing position, and so the temptation to apply pressure to the transducer head in order to gain a broad field of view and thus obtain an accurate and clear picture of the VMO muscle felt greater than when the subject was in long-sitting.

Various other researchers have taken ultrasound images from muscles during dynamic events e.g. while they perform a voluntary contraction or balance activity i.e. an isometric maximal voluntary contraction (MVC); and two have also mentioned the issue of applying pressure, as discussed below.

These have been divided up by muscle group for ease of reference:

- *Posterior neck muscles:*
 - Rezasoltani et al, (2002) took US images of the semispinalis capitis muscle while subjects performed an MVC, the participants were six ice hockey players; they did not mention any technical issues regarding the US imaging techniques;
- *Quadriceps muscle group:*
 - Montes, (2001) took US images from the rectus femoris and vastus intermedius muscles of 38 healthy individuals who performed a maximum voluntary contraction and mentions that **“special care was taken to avoid pressure with the probe on the subjects’ tissue during the test”**;
- *Abdominal muscles:*
 - Hides et al, (2006) took US images of the transversus abdominis muscle during the “drawing-in” movement of 13 elite male cricket players, they did not mention any technical issues regarding the US imaging techniques;
 - Hides et al, (2007) measured the intra-rater reliability of a novice US operator who took scans of the abdominal wall during a “drawing in” movement – they do not specifically mention the issue of applying pressure to the transducer head but **did suggest that movement of the transducer head during the imaging may have resulted in the low ICC values reported for the measures taken from the repeat scans**;
 - Hides et al, (2007) took US images of the abdominal muscles during a simulated unilateral weight-bearing task of 19 healthy participants – again they did not mention the issue of applying pressure through the transducer head on the muscle; but state

“their simulation was undertaken in supine lying to “avoid the confounding variables of balance control which would be present in the standing position”;

- Springer et al, (2006) took US images of the lateral abdominal muscles of 32 healthy participants while undertaking an abdominal drawing-in procedure; they did not mention any technical issues regarding the US imaging techniques;
- Ainscough-Potts, et al (2006) – took US images of the transverse abdominis and internal oblique muscles of 30 healthy subjects in various sitting postures, including the relatively unstable position of sitting on a gym ball with one foot raised; they did not mention any technical issues regarding the US imaging technique.

All of the studies listed above took ultrasound images under very controlled conditions, with subjects in non-weight-bearing. It may be that this particular phenomenon was only particularly apparent in the present study due to the images being taken in weight-bearing, and included the need for participants to maintain and control their balance while the image was being taken.

There were high levels of correlation between the linear and CSA measures of the images taken in relaxed standing. Line C, showed the highest level of correlation for an individual line measure, giving an almost identical correlation value ($r=0.86$) to that found for MRI ($r=0.87$) in the same group of individuals (see Section 6.5).

However, no reliability testing was performed to examine the reliability of the technique on different days (all scans were taken during the same session); this is a weakness of this reliability testing. In order to determine whether the technique could be used to measure changes in VMO muscle size over time or in response to an intervention, between-day repeatability would need to be established.

6.6.2 – General Conclusions

The summary findings and conclusion of the experiments reported in this chapter are:

1. It is possible to take valid and reliable measures of the size of the VMO muscle using portable ultrasound equipment, which are consistent with those obtained from the acknowledged 'gold standard' of MRI images, and:
2. There is a meaningful level of correlation between the CSA and linear measures of the VMO muscle; allowing linear measures to be used instead of CSA if necessary
3. There was no effect of posture on the Linear and CSA measures of the VMO muscle obtained from ultrasound images of healthy participants in long-sitting or relaxed standing.

Chapter Seven

Exploring the Q-angle: over time, during the stance phase of gait, and the effect of an intervention

CHAPTER 7.0

Exploring the Q-angle: over time, during the stance phase of gait, and the effect of an intervention

7.1 – Introduction

Within the literature on the Q-angle there has always been the implied assumption that its value is an absolute or non-varying fact, and thus by implication any variability in its value must be due to measurement error. Having established a valid and reliable protocol for measuring the Q-angle using the Peak-5 video motion analysis equipment, in Chapter 5, it now seemed appropriate to apply this measurement protocol and measure to the Q-angle in a variety of circumstances.

The work in this chapter is in nine parts:

- 7.1 – Introduction;
- 7.2 – Measuring the Q-angle over time;
- 7.3 – Measuring the Q-angle during the stance phase of gait;
- 7.4 – The Q-angle and Pronation at the sub-talar joint, during the stance phase of gait;
- 7.5 – The pattern of movement of the three markers which form the Q-angle, during the stance phase of gait;
- 7.6 – The effect on the Q-angle of applying McConnell medial glide patellar tape;
- 7.7 – The influence of exercise on the effect of medial-glide patellar tape on the Q-angle;
- 7.8 – Medial glide patellar tape, how does it affect the Q-angle;
- 7.9 – General Discussion and Conclusions

7.2 – Measuring the Q-angle over time

7.2.1 – Background

The time required to measure the Q-angle in the clinic using a long-arm goniometer can often take up to 60 seconds, and there has been no questioning in the literature of whether the Q-angle itself may vary during this time. Thus the first thing to be explored was to see whether the Q-angle would vary during a period of 60 seconds, while participants were in the relaxed standing position.

7.2.2 – Aim

The purpose of this first part of the work was to use the measurement protocol established in Chapter 5, to measure the Q-angle during a 60 second period while participants stood in the relaxed standing position.

Question: Two elements were explored:

- Does the Q-angle vary during a 60 second period, when participants are in relaxed standing? And if so -
- Is there any consistency in this pattern of variation over time?

7.2.3 – Method

Fifty-one healthy recreationally active participants were recruited, 27 female and 24 males; mean age 32 years; age range 19-38 years. The experimental procedure was described in Chapter 5, Section 5.4). Briefly, each participant had three reflective markers placed on his/her right leg on the relevant bony landmarks to identify the Q-angle - the anterior superior iliac spine (ASIS), the centre of the patella, and the centre of the tibial tubercle. Each participant wore a pair of black lycra cycling shorts with holes cut in them enabling the reflective markers to be placed directly on to the skin, but also giving a dark background to accentuate the contrast between the reflective markers and the skin. This was done to ensure the reflective markers would appear as brightly as possible on the video images and thus aid the digitisation process. Each participant stood in a comfortable relaxed standing position with his/her weight evenly distributed on both legs (following the protocol of Livingston and Mandigo, 1997)

and his/her toes just touching a line drawn parallel to the frontal plane of a camera lens, ensuring his/her anterior aspect was parallel to the frontal plane of the camera, this was checked with a spirit level. Each participant was then videoed for 60 seconds.

The picture rate for the video camera was the same as before, i.e. 60 pictures per second. The data were filtered with a Butterworth filter and then automatically digitised by the Peak-5 software, with any markers which were not detected by the software, manually digitised by the operator, and the Q-angle calculated using the Peak-5 software, as previously (Section 5.4). To simplify the calculations, data analysis was conducted on every first picture frame per second, thus giving 60 measurements for inclusion in the data analysis per participant. From these data the maximum and minimum Q-angle values for each participant were identified and the range recorded. The group mean Q-angle value and standard deviation were also calculated. The repeatability coefficient as described by Bland and Altman (1986) was then calculated and in addition the $(\text{range divided by the mean}) \times 100$ was calculated to give a percentage of the mean by which the Q-angle varied during the period of 60 seconds (Wilson and Kitsell, 2002).

Repeated testing: Twenty (ten males) of these same participants were additionally videoed for a further four periods of 60 seconds, with a break of five minutes between each video period; this was performed in order to see if there was a consistent pattern for an individual in variation of the Q-angle during a 60 second period. Thus 100 data sets were obtained. The video tape data was digitised by the same individual and Q-angle values calculated at one second intervals for the 60 seconds for each data set, in the same way as before. The minimum and maximum values of the Q-angle were recorded and the range between the minimum and maximum values plotted.

An extended chi-square test was undertaken to see if there was any consistency in trial number which gave the greatest or smallest range in Q-angle.

7.2.4 – Results

7.2.4.1 - Data for the group of 51 subjects:

The mean range between the maximum and minimum values of the Q-angle over 60 seconds was 3.12 degrees (range 1.46 degrees to 6.97 degrees; SD = 1.2 degrees), as shown in Table 7.1 and Figure 7.1. There was no relationship between the variation of the Q-angle and gender; the mean range for males was 3.04 degrees, and for females was 3.18 degrees. As can be seen in the histogram (Figure 7.2), all participants had some change in Q-angle during the 60 second period of filming, and 25 participants (49%) had a range in Q-angle variation of over 3.0 degrees. (Please see Appendix S for complete data).

Table 7.1 – Group Q-angle data (n=51): Mean range, mean standard deviation and repeatability coefficient.

Statistic	
Mean Group range (degrees)	3.12
Mean Group Standard Deviation	1.2
Repeatability Coefficient	3.4

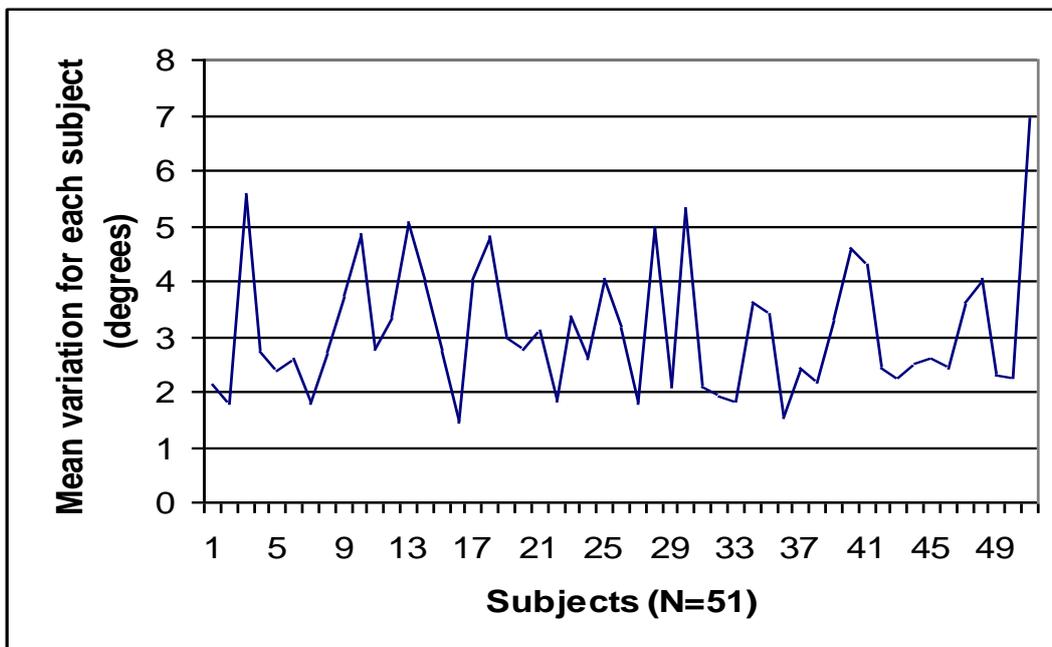


Figure 7.1 – Variation in Q-angle over 60 seconds for each subject (n=51)

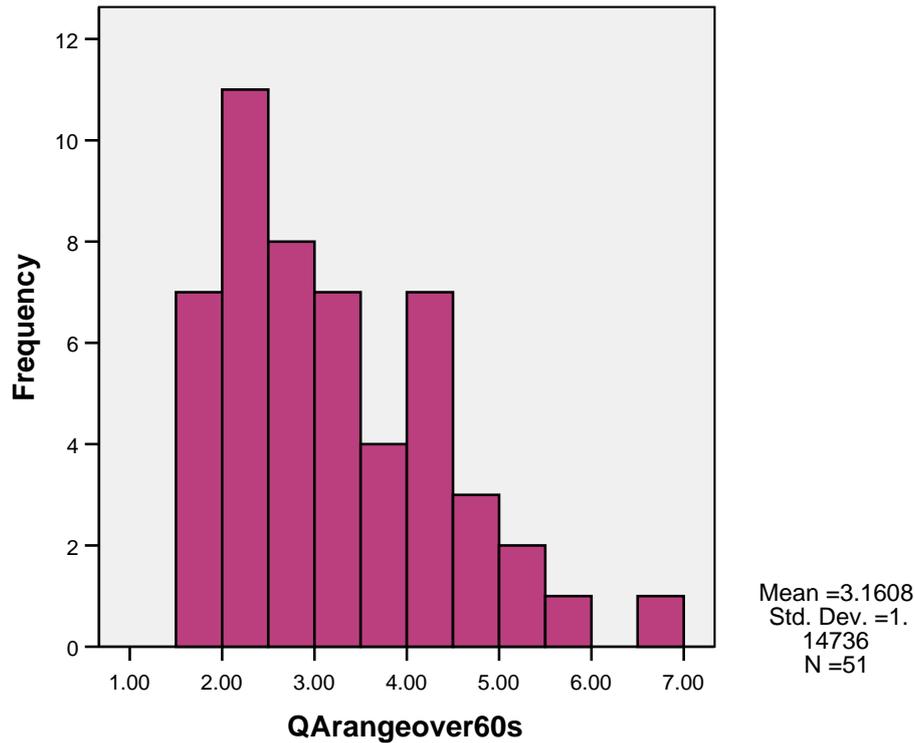


Figure 7.2 – Variation in Q-angle over 60 seconds by participant (n=51)

7.2.4.2 – Repeated tests in the subgroup of 20 participants:

The mean range between the maximum and minimum values of the Q-angle over 60 seconds was calculated for each of the 100 data sets; and the mean of the five data sets for each participant was calculated. The smallest range of change in the Q-angle for an individual was 2.0 degrees; and the largest was 7.9 degrees. The mean range for the group was 4.0 degrees (SD of 1.9). The histogram (Figure 7.3) shows again that all participants experienced a change in Q-angle during each 60 second period, with 12 of the 20 data sets (60%) having a range of change greater than three degrees, which is larger than the 49% for the results for the 51 subjects described above. The extended chi-square value of $X^2=5.38$ was not significant, showing that there was no consistency between trial number and the largest or smallest range in Q-angle.

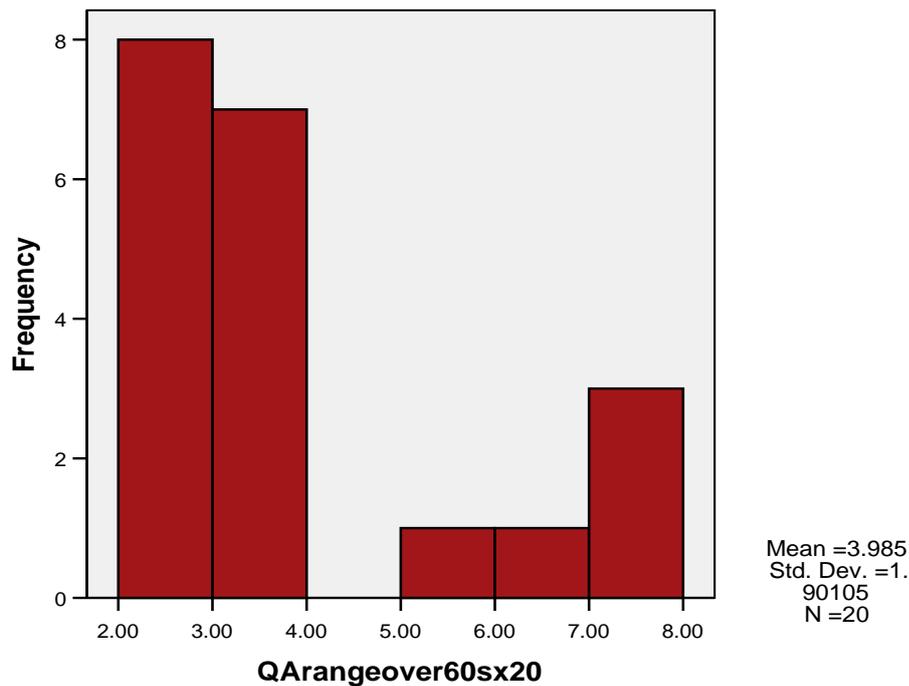


Figure 7.3 – Mean range in Q-angle during 60 seconds from the 5 repeat data sets for 20 participants

7.2.5 – Conclusion

As this measurement protocol for measuring the Q-angle has been shown to be accurate to within one degree, these results suggest that for a healthy individual the Q-angle varies on average between two and five degrees during a 60 second period in relaxed standing. This is particularly interesting and has important implications for the measurement of the Q-angle in clinical practice. No previous author has reported a variation in the Q-angle during its measurement period. This novel finding raises questions about the clinical meaningfulness of Q-angle values measured and reported.

There were no differences between the genders and only the right leg was included, so there were no complications between measures from different legs.

7.3 – Measuring the Q-angle during the stance phase of gait

7.3.1 – Background

The earlier work described in Chapter 5 established a reliable protocol for measuring the Q-angle of healthy individuals in relaxed standing, with the knee joint in extension. During flexion and extension of the knee the patella moves within the femoral sulcus and it is commonly believed that one of the main contributing factors to some patello-femoral joint problems is that the patella moves differently i.e. it does not track normally in the femoral sulcus (Wilson, 2007; Sarsich and Perman, 2007; Souza et al, 2010). One of the purposes behind measuring the Q-angle is that its value gives an indication of where the patella sits in the femoral sulcus in relation to the pelvis and tibia, and thus some insight into how it might track during flexion and extension of the knee.

The purpose of this next stage of the investigations was to see if it was possible to measure the Q-angle dynamically i.e. during flexion and extension of the knee. It was decided that this would be most clinically relevant if it could be measured during the stance phase (heel-strike to toe-off) during normal relaxed gait, as most symptoms of PFJS occur during weight-bearing (Wilson et al, 2003; Ryan and Rowe, 2006; Mei-Hwa et al, 2009).

Moss et al (1992) first described a procedure to measure the Q-angle dynamically. They filmed individuals while running on a treadmill at a fixed speed (3.5m per sec; 12.6 km per hour). They used video cameras and placed marks on top of the running shorts to represent the ASIS, and directly on to the midpoint of the patella and tibial tubercle, and were able to measure the Q-angle throughout the weight-bearing part of the running cycle. They did not mention any reliability or validity testing of their procedure, but also measured the Q-angle of their subjects statically, although they did not describe how they performed this. Their purpose was to compare the value of the Q-angle with various other joint angles, particularly pronation of the sub-talar joint, and so their results will be explored in Section 7.4.

In a normal knee the Q-angle is thought to be at its maximum when the knee is fully extended, and then to decrease with increasing flexion of the knee, becoming zero by the time the knee is flexed to 90 degrees (Brattstrom, 1964; Grelsamer, 1998). In normal individuals during relaxed gait in a flat shoe or barefoot, at heel-strike the knee is almost fully extended and then it gradually moves into flexion as the weight is taken over the foot, it then moves into extension again as the heel rises and then into flexion by toe-off (Whittle, 1996).

7.3.2 – Aim

The purpose of this study was to see whether the maximum value of the Q-angle would occur at the beginning of the stance phase of gait and the minimum value at the end of the stance phase.

Question: Will the Q-angle be at its maximum at the beginning of the stance phase of gait (heel-strike) and then gradually decrease, increase and finally decrease again as the end of the stance phase, being at its minimum value at toe-off?

7.3.3 – Method

Thirty healthy recreationally active individuals were recruited and had reflective markers placed on the ASIS, centre of patella and centre of tibial tuberosity of both legs. Participants walked at their own preferred comfortable walking pace along a 10m walkway, as it is accepted that healthy individuals walk in a very consistent way when asked to walk at their preferred comfortable walking pace (Dillon et al, 1983; Perry, 1992; Powers et al, 1997). Each participant undertook a period of familiarisation consisting of at least 10 repeat walks, once he/she was comfortable and at ease the data were collected.

Two synchronised video camera were used, one placed behind the participant, so that the start and end points of the stance phase of gait (heel-strike and toe-off) could be correctly identified, the second camera was in front of the participant, with the lens parallel to his/her frontal plane as he/she walked along the walkway. Participants were videoed while walking three times along the walkway and typically the video data from the stance phase of gait on the third

walk across the calibrated section of the walkway was digitised using the automatic digitising facility of the Peak-5 software. All data were collected and analysed by the same operator. As data were collected from both legs, 60 data sets were expected, although due to technical difficulties only 59 data sets could be digitised successfully; 29 from left legs and 30 from right legs. The value of the Q-angle throughout the stance phase of gait was recorded (at one second intervals) and then the specific value at the start and end of the stance phase were recorded, and these compared to see if they were the maximum or minimum values.

7.3.4 – Results

A total of 59 data sets were collected and from these the value of the Q-angle determined at the start of the stance phase of gait (heel-strike) and at the end of the stance phase of gait (toe-off), and then these compared with the values recorded throughout the whole of the stance phase to determine whether or not the Q-angle values were the maximum or minimum values at these two points. Example data in Figures 7.4 and 7.5.

- Maximum Q-angle values:
 - 35 of the 59 data sets (59%) showed the maximum value of the Q-angle occurred at heel-strike;
 - 18 of the 29 left leg data sets (62%) and 17 of the 30 right leg data sets (57%) had maximum Q-angle values at heel-strike;
 - 54 of the 59 data sets (92%) showed the maximum value of the Q-angle occurred within the first half of the stance phase of gait;
- Minimum Q-angle values:
 - 37 of the 59 data sets (63%) showed the minimum value of the Q-angle occurred at toe-off;
 - 20 of the 29 left leg data sets (69%) and 17 of the 30 right leg data sets (57%) had minimum Q-angle values at toe-off;

- 46 of the 59 data sets (78%) showed the minimum value of the Q-angle occurred within the second half of the stance phase of gait.

7.3.5 – Conclusion

Most of the healthy individuals studied followed the expected pattern of variation in Q-angle during the stance phase of gait – 59% had the maximum value of Q-angle at heel-strike; and 63% had the minimum value at toe-off. Actual levels of knee flexion were not measured, which is a limitation.

7.4 – The Q-angle and Pronation at the sub-talar joint, during the stance phase of gait

7.4.1 – Background

As outlined above in Section 7.3, we illustrated that it is possible to measure the Q-angle during the stance phase of gait using the Peak-5 Video Motion analysis system. The majority of healthy participants in our sample of 30 illustrated the expected pattern of the Q-angle being at its highest at the initial point of the stance phase of gait (heel-strike); and it being at its lowest at the end point of the stance phase (toe-off); however, a significant minority did not. We were not able to draw any firm conclusions as to why this might be so, but it is possible that this might be due to the effect of rotation in the transverse plane at any part of the lower limb and pelvis. Measuring rotation in the transverse plane during walking requires complex equipment and analysis (Ramsey and Wretenberg, 1999) and was beyond the scope and capability of this work programme at the time of testing.

However, a number of researchers have suggested that there is a link between the value of the Q-angle and the amount of pronation which occurs at the sub-talar joint in the foot (Tiberio, 1987; Perry, 1992; Nawoczinski et al, 1998).

However, there is disagreement between authors as to whether the Q-angle is decreased or increased when compared to the amount of pronation at the

subtalar joint. The assumption of some authors is that as sub-talar joint pronation increases so will internal rotation of the tibia on the femur and, as the tibial tubercle will now be relatively more medially placed, then the value of the Q-angle will decrease (Tiberio, 1987; Powers et al, 2002; Powers, 2003). However, others take a contrary view and state that the opposite occurs (Olerud and Per Berg, 1984; Lathinghouse and Trimble, 2000).

Powers et al, (1995) measured sub-talar joint pronation in 15 female subjects with patello-femoral pain, and compared this with a group of 15 female healthy controls. They took all measures in non-weight-bearing using a long-arm goniometer, they undertook a reliability study for the sub-talar joint measurement and report ICCs of 0.86 and 0.87; but give no second measure of reliability. They reported a larger average value of sub-talar joint pronation for individuals with patello-femoral pain (8.9 degrees) compared with that for healthy controls (6.8 degrees) which was statistically significantly different. They did not measure the Q-angle. Olerud and Per Berg, (1984) measured sub-talar joint pronation and Q-angle of 34 healthy volunteers; they found that Q-angle values increased with the amount of sub-talar joint pronation. They plotted repeat measures on separate axes of a graph and found them to correlate well, and so concluded their technique was reliable; they used three different measurement techniques and got different results, but again these correlated well. One of the difficulties they identify is that of taking both of these measurements at the same time. As subjects were asked to increase the amount of sub-talar joint pronation actively, they observed that the tibia was rotating laterally on the femur, but were unable to quantify this rotational element and its effect on the Q-angle. Sub-talar joint pronation is affected by movements in all three planes and includes – adduction, anterior translation and plantarflexion of the talus on the calcaneus (Grelsamer, 1998). However, most of the movement takes place in the frontal plane (adduction of the talus on the calcaneus) and typically it is frontal plane measures of sub-talar joint pronation that are quoted, which is very similar to the Q-angle in this respect.

7.4.2 – Aim

The amount of sub-talar joint pronation varies throughout the stance phase of gait and so the present study set out to see if there was any correlation between this measure and the Q-angle during the stance phase of gait, when measured in the frontal plane.

Question: Does the value of the Q-angle correlate with the amount of pronation at the sub-talar joint, during the stance phase of gait, when both are measured in the frontal plane?

7.4.3 – Method

Thirty-one healthy recreationally active individuals were recruited from the University of Southampton staff and students, further details in Chapter 4. Once recruited, an appointment was made for each participant to attend the Biomechanics Laboratory at the School of Health Professions and Rehabilitation Sciences at the University of Southampton.

All data was gathered from the right leg, to avoid any complications in data analysis between values taken from the right and left legs and thus would make data analysis simpler. The Q-angle was measured following the protocol used in Section 7.3; and sub-talar joint measurement was undertaken at the same time, with markers being placed following the protocol described by Callaghan and Baltzopoulos (1994). Participants stood in relaxed standing and two reflective markers were placed over the distal end of their Achilles tendon and two over the posterior aspect of their calcaneus with the sub-talar joint in the neutral position (see Figure 7.6). Two synchronised cameras were used to gather data, one camera in front of the participant to gather the Q-angle data, and the second behind the participant to gather the sub-talar pronation data, both with their frontal planes parallel to each other and to the joints in question. Participants walked along the walkway in bare feet. The percentage time of the stance phase of gait, at which the maximum and minimum Q-angle and sub-talar joint angles occurred were identified, and then Pearson's correlation coefficients for these timings were calculated.

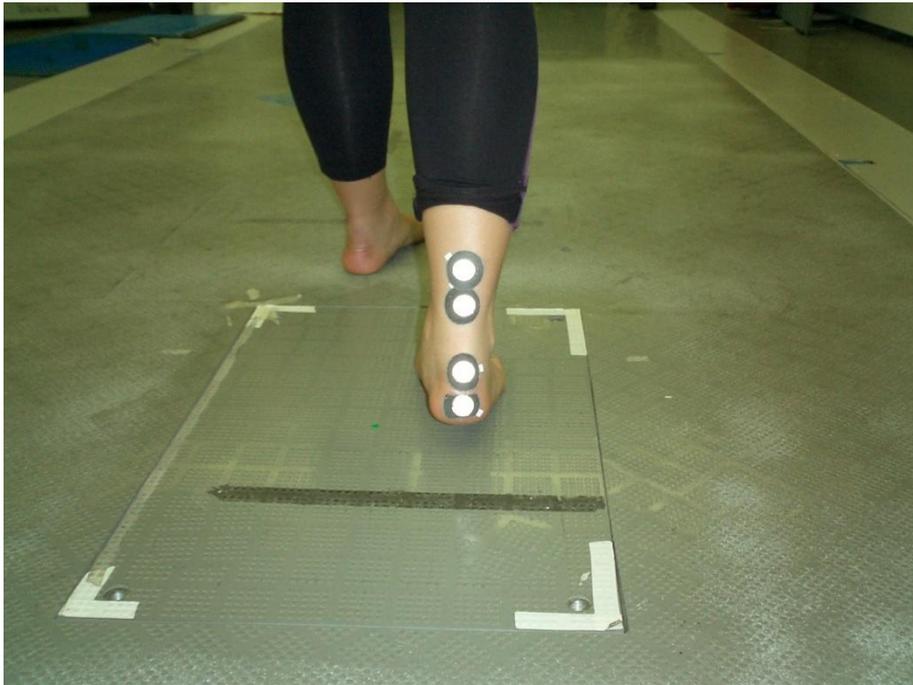


Figure 7.6 – Reflective markers for measuring the amount of pronation at the sub-talar joint

7.4.4 – Results

Thirty one data sets were collected however, due to technical difficulties only 27 data sets could be digitised successfully.

- Time of maximum Q-angle:
 - 15 of the 27 individuals (56%) had their maximum Q-angle at heel-strike; this ties in with the previous study when 59% of the participants had their maximum Q-angle at heel-strike.
- Time of minimum Q-angle:
 - 14 of the 27 individuals (52%) had their minimum Q-angle at toe-off; this is smaller than the 63% of the previous sample who had their minimum Q-angle at toe-off.
- Time of maximum sub-talar joint pronation:
 - 6 of the 27 subjects (22%) had their maximum value of sub-talar joint pronation at toe-off; it was expected that this would correlate with the maximum value of the Q-angle.

- The Pearson correlation coefficient of $r=-0.123$ ($p=0.54$) confirms that there was no meaningful correlation between the two events (see Figure 7.7).
- Time of minimum sub-talar joint pronation:
 - 21 of the 27 subjects (78%) had their minimum value of sub-talar joint pronation at heel-strike; it was expected that this would correlate with the minimum value of the Q-angle which tends to occur at toe-off;
 - The Pearson correlation coefficient of $r=0.006$ ($p=0.79$) found there was no meaningful correlation between the two events.
 - The Pearson correlation coefficient between minimum sub-talar joint pronation and maximum Q-angle $r=-0.083$ ($p=0.681$) illustrated that there was no meaningful correlation between these events either.

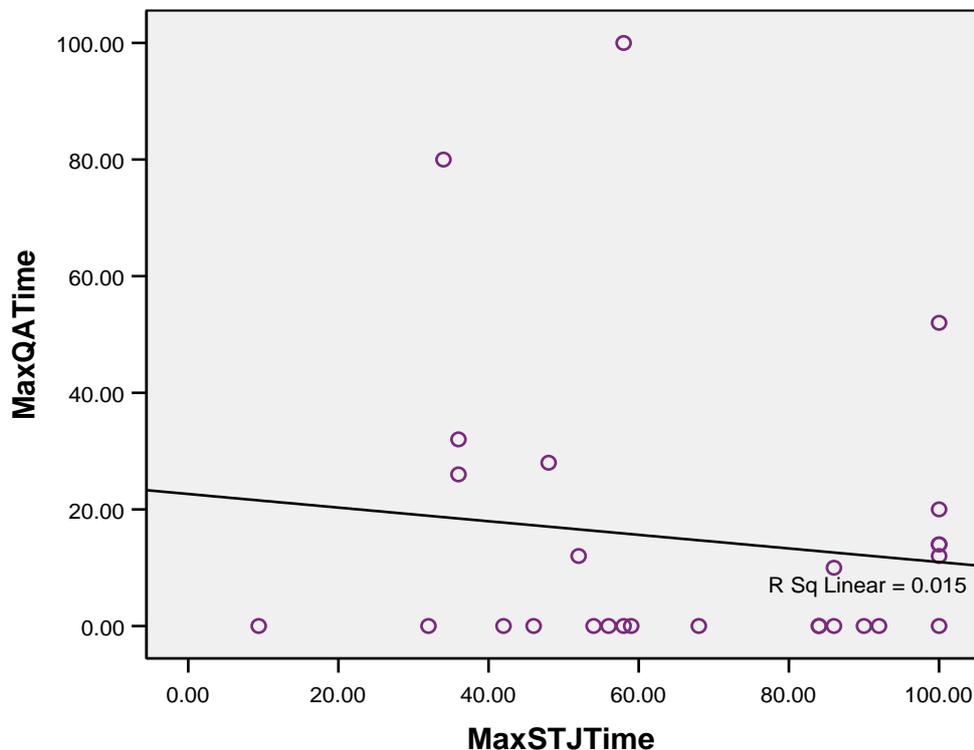


Figure 7.7 – Regression plot of the Time (seconds) at which the maximum Q-angle occurred over the Time at which the maximum amount of sub-talar joint pronation occurred.

7.4.5 – Conclusion

The data from this group of healthy individuals shows that the Q-angle and sub-talar joint pronation do not correlate with each other, when measured in the frontal plane during the stance phase of gait and there is no meaningful relationship between them.

7.5 – Pattern of movement of the three markers which form the Q-angle, during the stance phase of gait

7.5.1 – Background

The work in sections 7.3 and 7.4 has highlighted the fact that measuring the value of the Q-angle and sub-talar joint pronation, of healthy individuals, during dynamic movement (i.e. the stance phase of gait), gives a rather different and more complex picture than when these measurements are taken on participants who are not moving or who are in non-weight-bearing postures. The complexities of weight transference and the interplay of rotational movements happening in all three planes at the same time highlight the limitations of measures taken statically. It brings into focus the tensions between trying to find simple and clinically useful methods of taking functional measures which are complex and multifaceted, against the need for controlled and standardised measurement protocols but which are limited in the picture they give.

Individuals with idiopathic PFJS are often reported as having a larger Q-angle than healthy controls, as it is assumed that there is some mal-alignment of the patella which may either cause or be the result of the symptoms, typically reported by individuals with this complaint; however, the literature is contradictory on this point.

Up until this point all the experimental work on the Q-angle had been performed in 2D using one camera for each angle being measured, mirroring what happens in clinical practice where a goniometer is typically used, and was relatively simple to carry-out. It then seemed appropriate to examine the Q-angle in more detail using 3D video analysis. By now the Peak-5 video motion

analysis system software had been upgraded to the Peak Motus system which made 3D testing much more feasible. The Q-angle is a 2D frontal plane measure but all of the three bony landmarks from which the measurement is derived are points which move independently of each other during motion. During any kind of activity, including relaxed standing, the markers are affected by movement in all three planes.

- The marker on the pelvis (ASIS) moves very little in relation to the other two during relaxed standing, it shifts a little in all three planes as a result of the body continually 'righting' itself in order to maintain its balance – termed postural sway. During walking the pelvis moves extensively in all three planes i.e. frontal, sagittal and transverse.
- The patella moves relatively freely, it is a sesamoid bone within the combined tendon of the quadriceps muscle and so its level of movement is largely dependent on the degree of contraction within the quadriceps muscle. In relaxed standing the quadriceps muscle contracts predominantly isometrically, i.e. there is minimal change in overall muscle length, however, there are small changes in length at a local level resulting in the patella moving slightly anteriorly and superiorly within the femoral groove. During walking the knee undergoes a cyclical pattern of flexion and extension; during flexion the patella moves distally along the line of the femoral sulcus and proximally during extension. Since the femoral sulcus is a curved channel this results in movement of the patella marker in all three planes i.e. frontal, sagittal and transverse. In addition the skin over the patella tends to be quite 'loose' it is not tightly tethered as it is on other parts of the body, and so there may well be a difference between the amount of skin movement over the patella and the movement of the patella itself. In order to overcome these difficulties some researchers have used intracortical pins which are attached directly to the patella (Grabiner et al, 1994) so that any movement which occurs can be isolated to the patella itself.
- The tibial tuberosity marker is fixed in relation to the tibia, but during relaxed standing the level of contraction in the quadriceps muscle varies according to adjustments needed to counterbalance postural sway; this

typically results in the tibia rotating medially or laterally relative to the femur. During walking and the final few degrees of knee extension the tibia also rotates relative to the femur. In addition the position of the foot (particularly the talus bone) in turn can affect the position of the tibia. Grelsamer and Klein (1998) state that when measuring the Q-angle it is the position of the tibial tubercle marker which has the greatest impact on the size of the measured angle. This is at least in part to the fact that the line between the centre of the patella and the centre of the tibial tubercle is short compared to the line between the centre of the patella and the ASIS, and so relatively speaking the position of the tibial tuberosity will have a greater impact on the Q-angle value

7.5.2 – Aim:

The purpose of the present experiment was to track the three markers from which the Q-angle is derived, on two groups of participants (those with Patellofemoral joint syndrome and those without), and to observe their pattern of movement from each of the three planes - the frontal, sagittal and transverse during the stance phase of gait.

Question: Is there any difference between the pattern of movement of the three markers which form the Q-angle, of healthy participants and those with Patellofemoral joint syndrome (PFJS), when viewed from the frontal, sagittal and transverse planes?

7.5.3 – Method

Ethical approval for this study was granted by Southampton and South West Hampshire Local Research Ethics committee (191/01). Eighteen subjects with idiopathic PFJS were recruited from Physiotherapy departments from two local hospitals in Southampton and 24 healthy recreationally active individuals were recruited from within the student body of the University of Southampton (Recruitment Poster – Appendix 0A). Inclusion and Exclusion criteria are detailed in Chapter 4, Section 4.4. Following recruitment participants were given an information sheet (Appendix C), which explained the process to them, as well as a consent form (Appendix D). Once participants had confirmed their

agreement to be involved an appointment was made for them to attend the Biomechanics laboratory at the school of Health Professions and Rehabilitation Sciences at the University of Southampton.

Reflective markers were placed over their ASIS, patella and tibial tuberosity, as described previously (Chapter 5, Section 5.4). On this occasion a 3D spatial model representing the Q-angle was defined on the Peak Motus software and the area of the 10m walkway to be videoed was calibrated using a 3D calibration frame, following manufacturer's guidelines. The two cameras were synchronised using a time-code generator and positioned following manufacturer's guidelines with the angle between them being approximately 85 degrees. For analysis the stance phase of gait was subdivided into three phases (according to Perry, 1992; as described by Whittle, 1996).

The three phases are (see Figure 7.8):

- Initial contact – from heel strike to the point where the whole foot is flat on the floor i.e. heel strike through to toe down; during this period the limb gradually takes the full weight of the body;
- Mid-stance – the period during which the whole foot is in contact with the floor, and the contra-lateral limb is swinging through, i.e. toe down through to heel rise; during this period the limb takes the whole weight of the body all of the time;
- Terminal stance – the period during which the foot is lifted from the floor i.e. from heel rise until toe off; during this period the weight is gradually transferred from this limb to the other limb.

The movement of the three markers from which the Q-angle is measured were observed during each of these phases of the gait cycle.

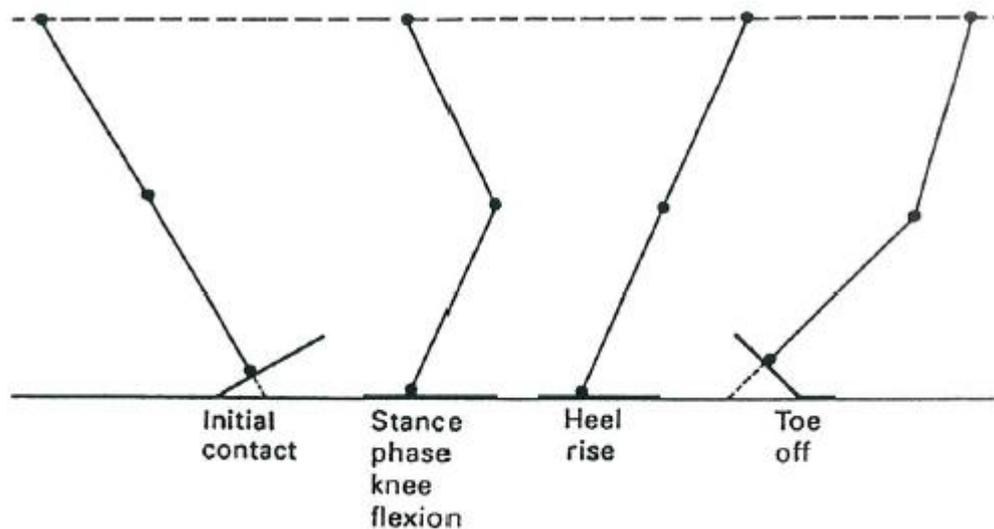


Figure 7.8 – Pictorial representation of the 3 phases of the gait cycle, as described by Whittle, 1996.

7.5.4 – Results

Age and gender of the two groups were recorded; there was no particular attempt to match between the groups (Table 7.2) as this was a preliminary observation study. However all participants were between the ages of 18 and 40 years and were normally recreationally active, in line with participants in the other studies (see Chapter 4).

Table 7.2 – Participant details – those with patello-femoral joint syndrome (PFJS) and those without

Category	Participants with PFJS	Healthy participants
Mean Age, years	35.8	21.1
Number of males	11	12
Number of females	7	12
Total number	18	24

7.5.4.1 - Static Q-angle data

The Q-angle data for each group were normally distributed when tested for skewness and kurtosis, and using the unrelated t-test there was no significant difference between the two mean values ($p=0.559$). The standard deviation and range of Q-angle values among the group with PFJS was very much larger

than that of the group of healthy participants. The range in Q-angle values for those with PFJS was 25 degrees, compared with a range of nine degrees for those without (see Table 7.3).

Table 7.3 – Mean static Q-angle values for participants with PFJS and healthy participants

PFJ Status	Mean Q-angle, degrees	SD	Min Q-angle, degrees	Max Q-angle, degrees	Range degrees
Healthy Group	16	3.14	12	21	9
PFJ S Group	15	7.03	4	29	25

7.5.4.2 - Dynamic Q-angle data - Observations on data from the frontal, sagittal and transverse planes during stance phase of gait, when plotted over time:

Knee flexion and extension occur in the sagittal plane; rotation of the pelvis, femur and tibia occur in the transverse plane, and the Q-angle is a frontal plane measure. Data from the frontal and sagittal planes only are included, as following digitization of the data it was clear that the data from the transverse plane varied so much that it was difficult to make sense of. The data are shown graphically and illustrate the movement patterns of the three markers from which the Q-angle is formed, they do not illustrate movement of the knee joint itself.

At times during the stance phase of gait the transverse plane movement for all three markers was in the same direction, at other times it was in opposing directions for individual markers which therefore tended to cancel each other out; with the overall result of large resultant swings of movement which were difficult to follow. It is interesting that most other authors also limit their observations and calculations to frontal and sagittal plane movements only;

unless they have access to very expensive and complex motion analysis equipment laboratories (Ramsey and Wretenberg, 1999).

The mean length of time for the stance phase of gait for the healthy participants as measured on their right leg was 0.72 seconds, whereas it was 0.62 seconds for the affected leg for those with PFJS. This difference was statistically significant ($p=0.001$). Thus participants with PFJS spent less time taking weight on their affected leg than did healthy controls for the stance phase that was digitised.

7.5.4.2.1 – The frontal plane view:

Figure 7.9 shows the change in Q-angle over time during the stance phase of gait for each individual participant; and Figure 7.10 is the group mean data in a composite line. Data for participants with PFJS are shown in violet and healthy controls are shown in blue. There is little difference between the two groups i.e. healthy participants and those with PFJS. The healthy participants tended to begin with a higher mean Q-angle which soon after reduced slightly and then remained a few degrees below that of the PFJS group throughout the rest of the stance phase, except at the end during the final aspects of the terminal phase when the Q-angle increases for the majority of participants with PFJS and steadily decreased for the healthy controls. Thus the pattern of variation in Q-angle for the healthy controls behaved as expected (assuming it is closely related to knee flexion and extension) whereas for those with PFJS the opposite pattern occurred. This is shown particularly clearly in Figure 7.10.

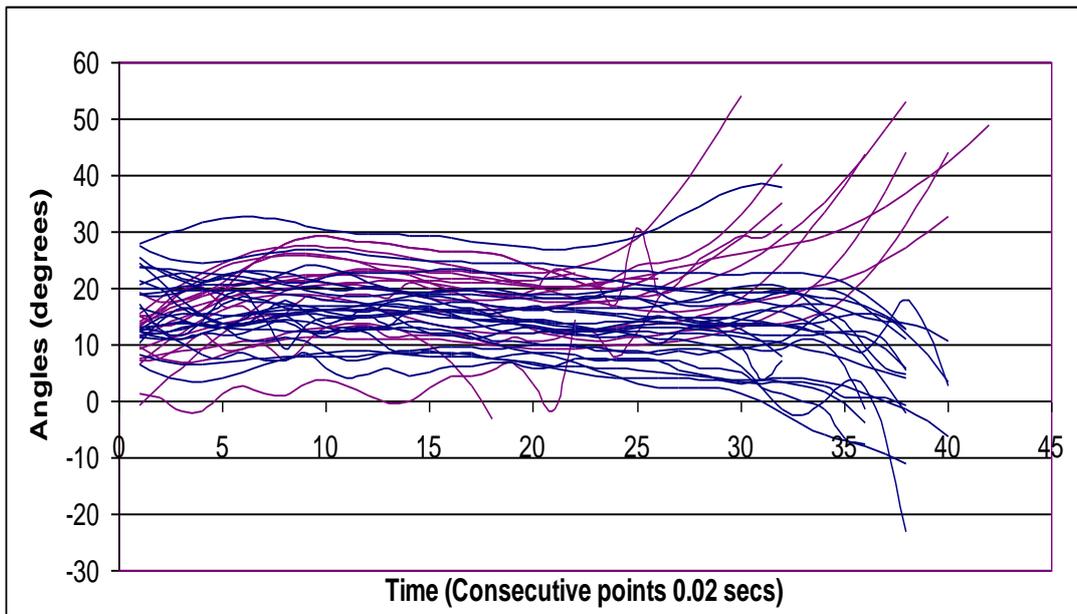


Figure 7.9 – Individual data of the Q-angle over time during the stance phase of gait for participants with PFJS and those without, i.e. the frontal plane view. Participants with PFJS in Violet, participants without in Blue.

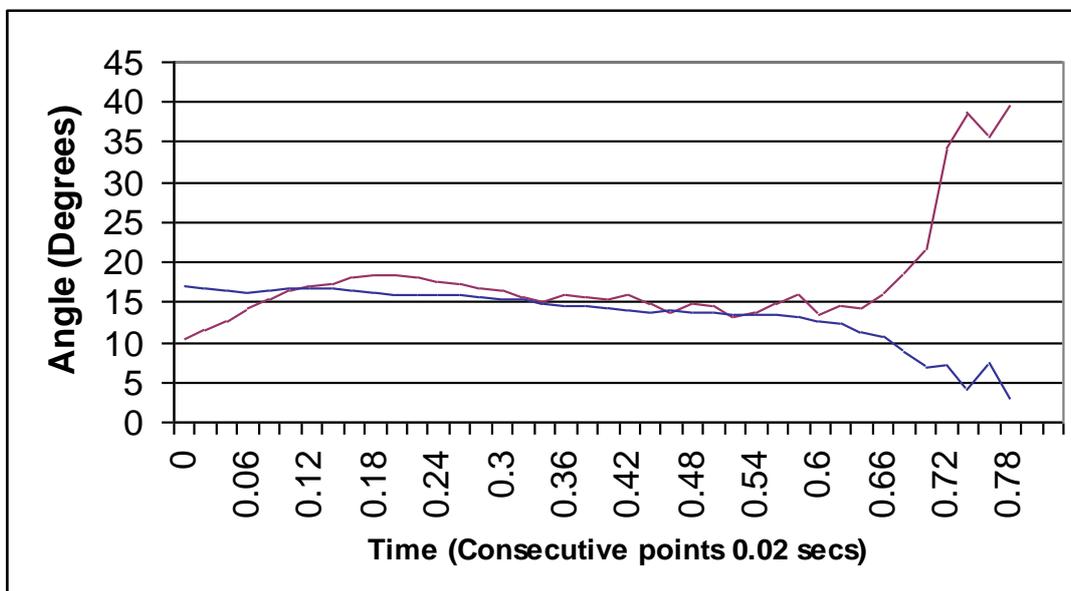


Figure 7.10 – Combined data of the Q-angle over time during the stance phase of gait for participants with PFJS and those without, i.e. the frontal plane view. Participants with PFJS in Violet, participants without in Blue.

7.5.4.2.2 – The sagittal plane view:

The sagittal plane view gives information about the forwards/backwards movement of the markers and the resultant angle formed between them. It is very much linked to the amount of knee flexion/extension that is occurring. Once again Figure 7.11 showed the change in the sagittal plane over time during the stance phase of gait for each individual subject; and Figure 7.12 is the group data in a composite line. Once again, data for participants with PFJS are shown in violet and healthy controls are shown in blue.

Figure 7.12 shows that there was much more clustering of the data from the healthy participants (dark blue lines), compared to the data from the PFJS participants which shows a greater spread. The data from all the healthy participants followed the same basic pattern – an initial increase, followed by an almost equal decrease in value followed by a large increase, all data lines are smooth and without blips. The data lines were very similar to those of knee flexion in healthy subjects during the stance phase of gait (Perry, 1992).

In contrast the movement in the sagittal plane for participants with PFJS were much more varied and all lacked the smoothness of the healthy participants. The overall amount of change was less for those participants with PFJS, again this was seen more clearly in Figure 7.12 which is the composite group data.

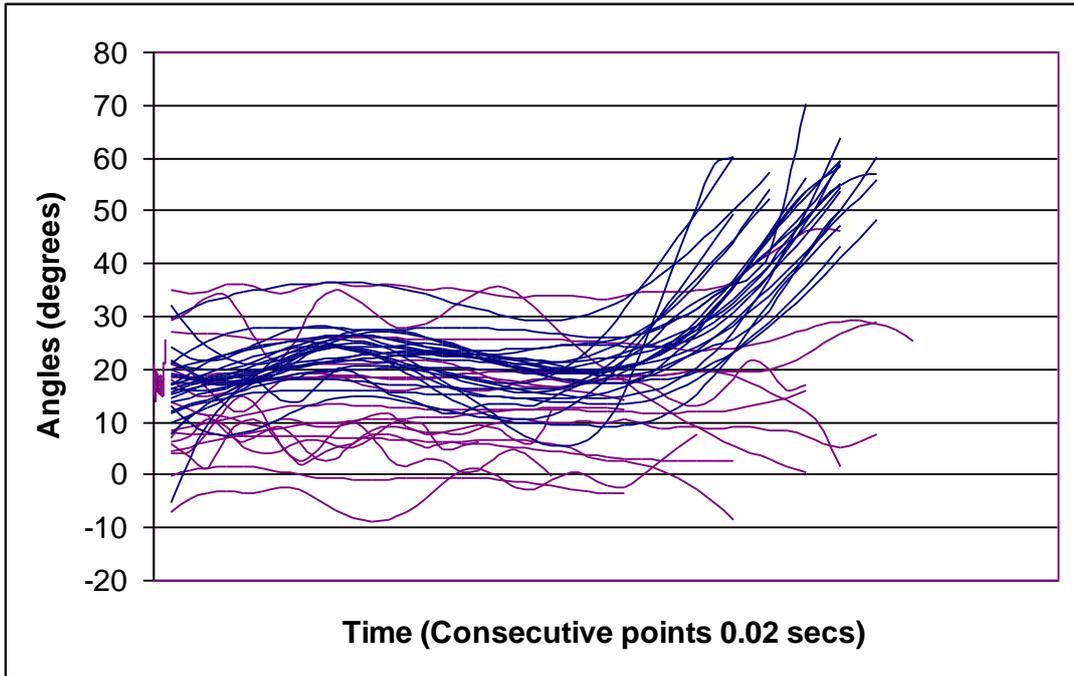


Figure 7.11 – Individual data of the marker movement from the sagittal view, over time during the stance phase of gait for participants with PFJS and those without. Participants with PFJS in Violet, participants without in Blue.

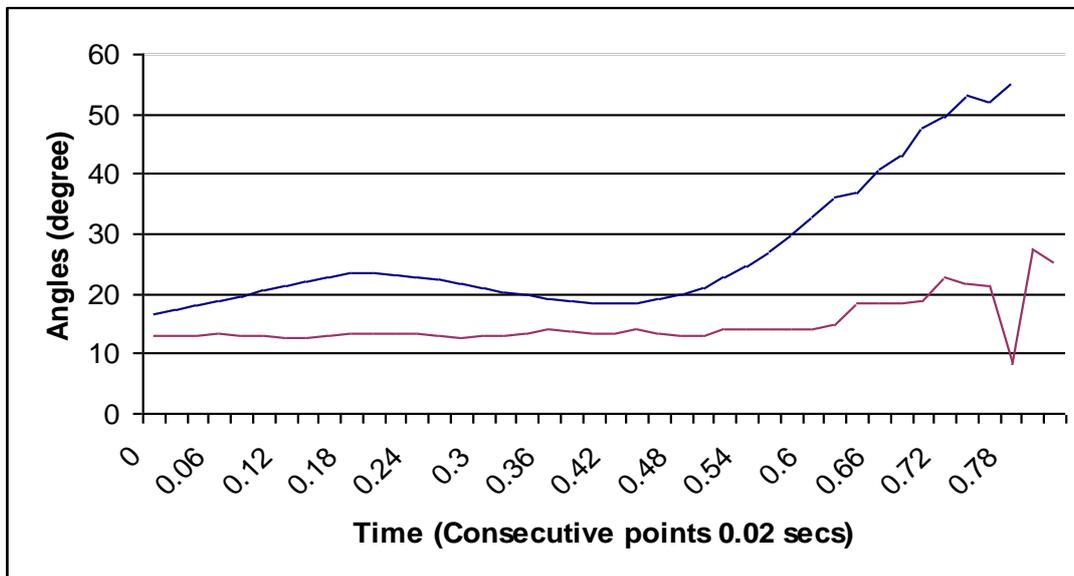


Figure 7.12 – Combined data of the marker movement from the sagittal plane view, over time during the stance phase of gait for participants with PFJS and those without. Participants with PFJS in Violet, participants without in Blue.

7.5.5 – Conclusions

Observations of the three markers, from which the Q-angle is measured, in the frontal and sagittal planes during the stance phase of gait have shown that there are some differences in movement patterns between those with PFJS and healthy controls. Differences between the two groups included the pattern of change in the Q-angle (frontal plane) and in the range of change and pattern of movement in the sagittal plane. The pattern of movement in the sagittal plane for those with PFJS indicated that they walked with a straighter knee than healthy participants, as previously reported in the literature. A novel finding was that the group of individuals with PFJS spent a shorter time in weight-bearing on their affected leg than expected from previous reports but since our data did not include that of the contra-lateral limb, it is difficult to comment meaningfully on this finding.

7.6 – The effect on the Q-angle of applying McConnell medial glide patellar tape

7.6.1 – Background

The application of McConnell medial glide patellar tape is a commonly used intervention treatment technique by physiotherapists for individuals with PFJS whose cause is thought to be due to a patella which sits relatively laterally, rather than in the centre of the femoral sulcus. This taping regime was originally devised by McConnell who published a patient series in 1986, describing her regime applied to a group of 35 patients (male and female) with persistent patello-femoral pain syndrome. She reported a 96% success rate, in terms of the patients reporting either no pain or a significant reduction in pain, as well as all the disappearance of all the positive passive tibiofemoral joint findings (as determined by the treating physiotherapist) following application of the tape. She suggested that its effectiveness was for two main reasons:

- the tape maintained the patella in a more optimal position in the femoral sulcus, once it had been moved there by the physiotherapist; and

- it enhanced the contraction ability of the distal portion of the VM muscle, due to the reduction in pain and the fact that the patella was in a more optimum position;

Since that time her taping protocol has been investigated by a number of individuals who report a variety of outcomes. The current general view is that applying the tape is very effective intervention for reducing pain (Bockrath et al, 1993; Callaghan, 1997; Powers et al, 1997; Crossley et al, 2002; Wilson et al, 2003; Bizzini et al, 2003; Lan et al, 2010), although the mechanisms by which it does this are not yet agreed (Crossley et al, 2000; Callaghan et al, 2002; Pfeiffer et al 2004).

Some authors have reported that the application of the medial glide tape does move the patella medially (Worrell et al, 1994; Larsen et al, 1995; Pfeiffer et al, 2004); however others have not found that the tape holds the patella in a more effective or optimal position in the centre of femoral sulcus (Bockrath et al. 1993; Vo, 2002; Ono et al, 2005). Some authors report that the tape does enhance the neuromuscular recruitment of the distal portion of the vastus medialis (VM) muscle, using EMG to record the recruitment of the vastus medialis and vastus lateralis muscles within the quadriceps muscle group during a functional step-down task (Cerny, 1995; Mungovan et al, 1996; Ryan and Rowe, 2006); although others have reported opposite results (Nicholas et al, 1996; Keet et al, 2007).

A sesamoid bone sits within a tendon as it passes over a joint - the patella is a sesamoid bone which sits within the common tendon of the quadriceps muscle group and is the largest sesamoid bone in the human body. In common with all sesamoid bones it has no firm attachments and is therefore relatively mobile when the tendon within which it sits is relaxed. Thus with the knee joint extended and the quadriceps muscle group relaxed the patella can be moved passively. However when the knee is flexed beyond 30 degrees the patella sits more deeply within the femoral sulcus at the distal end of the femur (Grelsamer, 1998), and when the quadriceps muscle group is contracted; the patella is not easily moved passively.

In theory, altering the position of the patella, in the frontal plane, will have an effect on the Q-angle; thus if medial-glide patellar tape does alter the position of the patella, by moving it medially, and both of the other markers stay in the same place then it should have the effect of increasing the Q-angle.

7.6.1 – Aim

The purpose of this preliminary intervention study was to see whether the application of the medial-glide patellar tape alters the Q-angle.

Question: Does applying medial-glide tape to the patella, following the procedure outlined by McConnell (1986), alter the value of the Q-angle?

7.6.2 – Method

Ten of the healthy recreationally active males participated in this small study, this time the Vicon motion analysis system was used as the laboratory had upgraded its motion analysis system from the Peak to the Vicon (see Chapter 4, Section 4.2). Both knees had markers attached and were filmed by the Vicon, following the same procedure described in Chapter 5 (Figure 7.13). Initial Q-angles were calculated for both knees. Each participant then had McConnell medial glide patellar tape applied to his right knee (see Figure 7.14); following this the Q-angle of both knees were measured again. Both sets of Q-angles were compared using a paired T-test to see if there were any significant differences between them.

Bilateral measurements were made so that the left knee (which did not have tape applied) could act as a type of control for the measure of the Q-angle following application of the tape. The tape was applied following the procedure outlined by McConnell (Grelsamer and McConnell, 1998). A rigid, nonstretch tape (zinc oxide tape of 5cms width was used) and was placed on the lateral border of the patella (with the subject in long-sitting, with his quadriceps muscle group relaxed), the skin on the medial side was lifted towards the patella and the tape was pulled medially and anchored just short of the hamstring tendons. The tape was split, at the point it crossed the patella so that the reflective

marker placed on the centre of the patella could remain in its same position on the skin and its position on the skin was not affected by the application of the tape.

Thus two Q-angle measures were taken from each knee:

- Initial baseline Q-angle measure in relaxed standing
- After application of the medial glide patellar tape

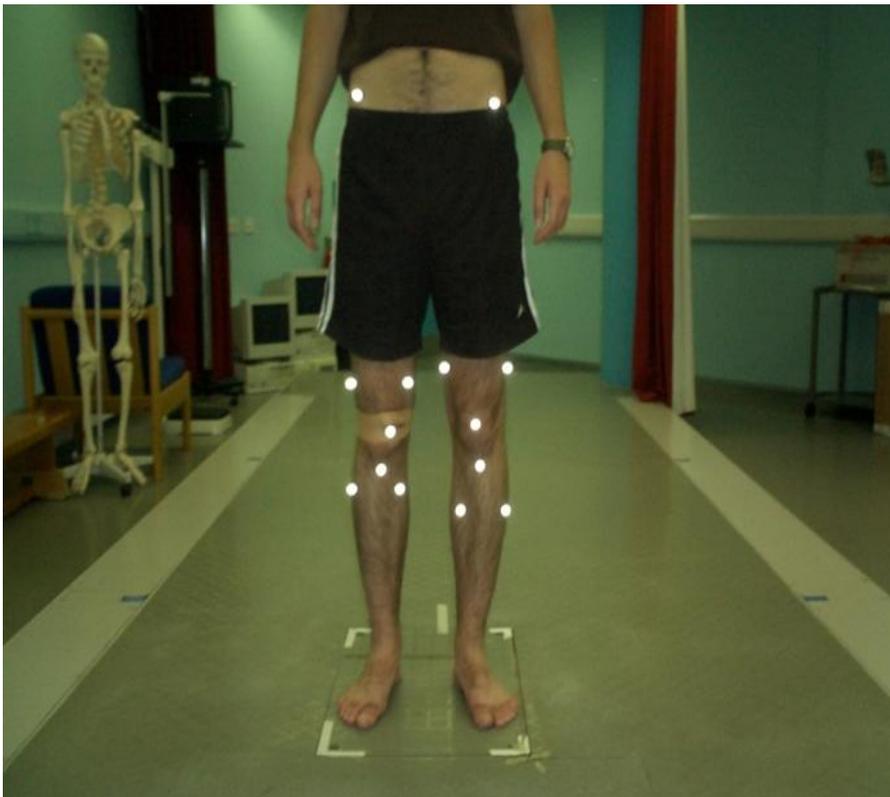


Figure 7.13 – Participant with McConnell medial glide patellar tape on the right knee, in relaxed standing, being imaged by the Vicon apparatus



Figure 7.14 – Applying the McConnell medial glide patellar tape, left knee

7.6.4 – Results

As can be seen from Table 7.4, medial glide patellar tape altered the Q-angle for each participant (Qar2). In each case the Q-angle was increased, with the average increase being 13 degrees (range 7-18 degrees). For the left leg which had no tape applied the average change in Q-angle was one degree. When a paired T-test was calculated comparing the second set of Q-angle measures (post-tape) with the initial measures; there was a statistically significant difference between the 2 sets of measures for the right leg (with the tape) but no statistically significant differences between the sets of measures for the left leg (no tape applied).

Table 7.4 – Q-angle values (degrees), with and without medial glide patellar tape for the right leg and without tape for the left leg

Subject	Q-angle without tape QAr1	Q-angle with tape QAr2	Difference QAr2 – QAr1	Q-angle without tape QAI1	Q-angle without tape QAI2	Difference QAI1 – QAI2
	RIGHT LEG			LEFT LEG		
1	8	18	+10	11	11	0
2	12	20	+8	26	29	+3
3	7	25	+18	12	12	0
4	3	21	+18	18	20	+2
5	7	25	+18	10	10	0
6	6	20	+14	2	2	0
7	9	23	+14	22	22	0
8	11	18	+7	17	19	+2
9	10	24	+14	17	18	+1
10	17	25	+8	14	16	+2
	Mean = 9	Mean =22	Mean +13	Mean= 15	Mean= 16	Mean +1
	SD = 3.8	SD = 2.8		SD = 6.7	SD = 6.4	

7.6.5 – Conclusion

Applying medial glide patellar tape to the right leg of ten healthy volunteers altered the value of the Q-angle, increasing it on average by 13 degrees. However, it is not clear how much of this change in Q-angle was due to the medial movement of the patella and how much was due to the medial movement of the skin over the patella.

7.7 – Influence of exercise on the effect of medial-glide patellar tape on the Q-angle

7.7.1 – Background

As outlined above, McConnell (1986) hypothesised that the application of the medial glide patellar tape had the effect of maintaining the re-aligned patella within the femoral sulcus, and was able to sustain this during activity. Other authors have questioned whether it is possible for a relatively small piece of zinc oxide tape applied on the skin to do this, bearing in mind the forces that

would go through the joint during strenuous activity, such as running, or cycling (Larsen et al, 1995; Callaghan, 1997; Crossley et al, 2000; Pfeiffer et al, 2004).

Two authors have reported studies in which they investigated whether any change in patellar position, following the application of medial-glide patellar tape using McConnell's protocol, was maintained after a period of exercise. Larson et al (1995) recruited 20 healthy men, and used radiographs with the knee in 40 degrees of flexion to assess the position of the patellar: initially, following application of the medial glide patellar tape and again once participants had completed a 10-15 minute exercise protocol. They reported significant differences between the initial patellar position and after application of the tape ($p=0.003$), but these differences were lost following completion of the exercise protocol ($p=0.835$). They concluded that the tape was not effective at maintaining the new position of the patellar after exercise. For three participants the tape did not move the patellar a significant amount, however, they do not report any reliability testing for any of their measures so their results need to be treated with some caution.

Pfeiffer et al (2004) carried out a small study on 18 healthy women to test whether there was any maintenance of the effect of altered patella position after a period of exercise. They used the same exercise protocol used by Larsen (1995), which involved running around an indoor circuit, but no further details were described. They used MRI images of the knee, taken using an MRE extremity scanner with the knee in four positions of flexion (0, 12, 24 and 36 degrees). They also found that the tape did not maintain the altered patella position after the period of exercise; this was true for all four positions of knee flexion.

7.7.2 – Aim

The purpose of the present study was to see whether the application of patellar tape would maintain its effect on the Q-angle after 5 minutes of moderately fast cycling, during which the knee would be subjected to repeated flexion and extension.

Question – Does the medial glide patella tape maintain its effect on the Q-angle after a period of cycling for five minutes?

7.7.3 – Method

The ten participants in this study were the same as those in Section 7.6. The Q-angle measurements and application of the medial glide patellar tape were carried out in the same way. Following application of the medial glide patellar tape each participant cycled at a fixed speed (between 45 and 50 rpm) on a static bicycle (Kettler 'LK1', Kettler GB Ltd, Worcestershire, UK) for five minutes. The saddle height was individually adjusted to ensure that during cycling both knees would flex beyond 90 degrees on every revolution of the pedals – thus ensuring that the tape was subjected to repeated stretch (See Figure 7.15). Following the period of cycling the Q-angle of both knees was again measured using the Vicon apparatus, in relaxed standing (QA3, in Table 7.5).



Figure 7.15 – Participant on bicycle, with medial glide patellar tape and Vicon reflective markers

7.7.4 – Results

As can be seen in Table 7.4 the mean value of the Q-angle for the group of ten healthy volunteers did not change after the five minute period of cycling, the mean remained at 22 degrees. However looking at individuals there were small changes of one or two degrees for seven of the 10 subjects.

Table 7.5 – Q-angle of the right knee, before and after cycling with tape (QA2 and QA3)

Subject	Q-angle with tape, before cycling (QA2)	Q-angle with tape, after cycling for 5 mins (QA3)	Difference (QA2 – QA3)
1	18	18	0
2	20	22	-2
3	25	25	0
4	21	20	+1
5	25	24	+1
6	20	19	+1
7	23	23	0
8	18	19	-1
9	24	25	-1
10	25	26	-1
Mean	22	22	

7.7.5 – Conclusion

The medial glide patellar tape did maintain its effect on the Q-angle after participants cycled at a speed of 45-50 rpm for five minutes.

7.8 – Medial glide patellar tape – mechanism of Q-angle alteration

7.8.1 – Background

When the medial glide patellar tape is applied to the knee it moves both the skin and patella medially (see description of applying the tape in Section 7.6.2). The reflective marker placed at the centre of the patella was left alone during the application of the tape, the tape was split along its length for this purpose, and thus it was not possible to determine whether the effect on the Q-angle was due

to the medial movement of the skin, the medial movement of the patella or a combination of both of these things. However after applying the tape it was clear that the patella marker, which prior to the application of the tape had been at the centre of the patella, was no longer in this position; due to the fact that the skin over the patella had been moved medially more than the patella itself. Thus the following small investigation was carried out to try and determine if any change in the Q-angle was due to the movement of the patella, or whether it was largely due to movement of the skin.

When markers are placed on the skin over bony landmarks, it is never clear how much of any resultant movement is due to the skin or movement of the bone or both. Ramsey and Wretenberg (1999) are clear that it is impossible to predict with any degree of accuracy what is happening unless bony markers are invasive and are attached to the bone itself, sometimes called intra-cortical pins or osteal pegs. However, this invasive technique was not available for this work.

7.8.2 – Aim

The purpose of the present small pragmatic study was to try and understand whether change in Q-angle, after application of the tape, was due to the skin movement or movement of the patellar itself.

Question – Is the change in value of the Q-angle, following application of the medial glide patellar tape, due to movement of the patellar, the skin over the patella or both?

7.8.3 – Method

The ten participants in this study were the same as those in Sections 7.6 and 7.7. The Q-angle measurements and application of the medial glide patellar tape were carried out in the same way. Following the five minutes of cycling the patellar marker was removed by the investigator and re-sited at the centre of the patella (leaving the tape in place) and the Q-angle was measured again (QA4 in Table 7.6). This set of Q-angle measures was then compared with the original set of measures (QA1) to see if there were any differences between

them. The distance that the patella marker was moved laterally in order to replace it at the centre of the patella was also noted in mm.

7.8.4 – Results

As can be seen from Table 7.6 there is little difference between the Initial and Final mean Q-angle measures, being seven and nine degrees respectively. However when individual measures are examined, five of the group of 10 had differences of three degrees or more. Also in general those individuals who had a greater difference between their initial and final Q-angle values had a larger movement of their patella marker. A regression plot of the initial Q-angle measure (QA1) was plotted against the final Q-angle measure (QA4) to see if there was any correlation between them (See Figure 7.16). The plot gives an r value of 0.64 showing that there is a moderate level of correlation.

Table 7.6 – Initial Q-angle, before application of tape (QA1) and final Q-angle, after tape applied and the patella marker replaced in centre of patella (QA4), and the difference between them, n=10

Subject	Final Q-angle, after replacement of the patella marker (QA4) degrees	Initial Q-angle (QA1) degrees	Difference (QA4-QA1) degrees	Lat distance (mm) patella marker moved to replace in centre of patella for measure QA4
1	9	8	-1	12
2	8	12	4	12
3	1	7	6	20
4	5	3	-2	2
5	4	7	3	12
6	2	6	4	12
7	8	9	1	5
8	9	11	-2	5
9	10	10	0	10
10	14	17	-3	16
Mean	7	9	2	11

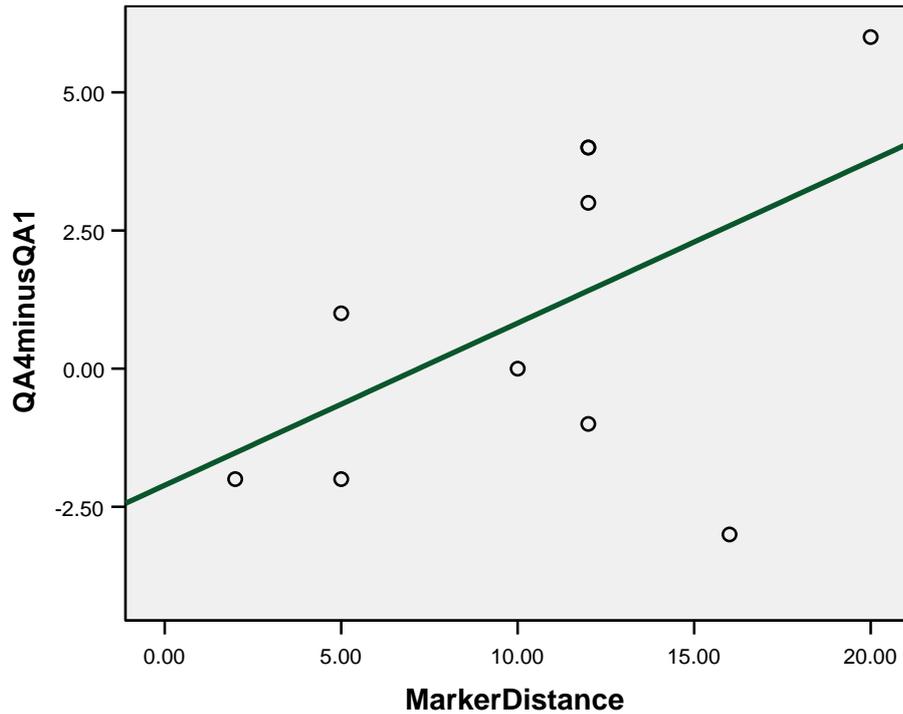


Figure 7.16 – Regression plot of the difference between the original and final Q-angles over the lateral distance moved by the patella marker over the original Q-angle, $r=0.64$

7.8.5 – Conclusion

The above results show that it is possible, in some individuals, to move the patella medially by applying medial glide patellar tape following the protocol of McConnell (1986); however for other individuals the application of the tape only has the effect of moving the skin medially. Further studies to investigate this by comparing healthy individuals with those with PFJS would also be very interesting.

7.9 – General Discussion and Conclusions

In Chapter 5 a valid and reliable protocol for measuring the Q-angle using the Peak-5 video motion analysis equipment was established. The work described in this chapter uses this measurement protocol to explore the Q-angle in a variety of circumstances:

- The static Q-angle over a 60 second time period;
- The dynamic Q-angle during the stance phase of gait; including its relationship with sub-talar joint pronation, and
- The effect on the Q-angle of applying an intervention, medial glide patellar tape.

The results will be summarised and discussed and then conclusions summarised.

7.9.1. – Measuring the Q-angle over time

The Q-angle of 51 participants in a relaxed standing posture were measured using the Peak-5 Video Motion Analysis system following the measurement protocol established in Chapter 5. Results showed that the Q-angle varied during the period of 60 seconds for all participants, measured while in relaxed standing, and this has important clinical implications. The mean range in variation for all data sets from all participants was between 3.0 and 4.0 degrees with no consistent pattern in the variation being observed. When the measurement variation for this protocol (one degree), was added then the effect is that the Q-angle value could vary on average from between 2.0 and 5.0 degrees during the 60 second time period tested. This finding suggests that when the Q-angle is measured in the clinical situation with participants in relaxed standing, the value recorded is not an absolute measure as previously assumed, but rather a snapshot in time of the individual's Q-angle within a given range.

The recording of an accurate measure of the Q-angle value is further compounded when the standard error of measurement (SEM) using a goniometer is added in. According to Eliasziw (1994) the SEM using a long-arm

goniometer to take a range of motion measure of a joint is at best 4 degrees. So when this tool is used to measure the Q-angle, which itself varies on average by between three or four degrees during the time required to take the measurement; the resulting measure is unlikely to be accurate or reliable. Since mean Q-angle values for healthy individuals are quoted as being between 12 and 17 degrees (Woodland and Francis, 1992), measured values with a long-arm goniometer could be as much as 50% lower or higher than actual Q-angle values. This raises questions about the validity of this measure as well as the usefulness of quoting statistically significant differences between the mean Q-angle for comparison groups of as little as 1.8 degrees (Moss, 1992).

Variation of the Q-angle over time is likely to contribute to the low levels of reliability reported for measuring the Q-angle, in addition to the other factors already accepted as affecting its value as outlined in Chapter 2 Section 2.3. Greene et al (2001) reported poor intra-rater ICCs of 0.14 to 0.37 and inter-rater ICCs 0.17 to 0.29; for a group of 50 participants (some of whom had symptoms of anterior knee pain) who all acted as observers and participants. They also reported poor levels of correlation when clinical and radiograph measures were compared, ICCs of 0.13 to 0.32. They concluded that the poor correlation was independent of individual knee symptoms, gender and examiner experience level; and noted that there is a need for a better method to evaluate patella-femoral alignment and that evaluation or treatment of patella-femoral symptoms should not be based on Q-angle measurement using their methods.

Recognising the inherent difficulties of measuring the Q-angle in the clinical situation, Peeler et al (2010) reported results of applying a simplified Q-angle measurement technique on a group of 54 participants. They chose to replace the marker usually placed at the centre of the patella with a marker placed at the mid-point of the quadriceps tendon, immediately superior to the base of the patella, as they felt the procedure for identifying this landmark would be more consistent than that for identifying the centre of the patella; which is generally acknowledged as being difficult (Herrington and Nester, 2004; France and Nester, 2001). Peeler et al, (2010) measured the Q-angle of participants who were lying supine. They reported intra-rater ICC coefficients for three

examiners ranging between 0.64 to 0.76; and inter-rater ICC coefficients of 0.69 to 0.82; they also calculated the overall mean SEM to be 2 degrees and the overall coefficient of variation as being 17%. They did not comment on the fact that it is unusual for inter-rater reliability to have higher ICC values than intra-rater reliability and that none of the ICCs met the 0.9 threshold recommended by Portney and Watkins (2001) as being essential for measures from which clinical decisions are made. They concluded that measurement of the simplified Q-angle was more consistent than measurement of the traditional Q-angle, and recommended its use to assist clinicians when evaluating the effectiveness of a particular surgical or rehabilitation intervention designed to treat patello-femoral joint mal-alignment or related pathologies.

In light of the above it was disappointing to find a recent article in the American Journal of Sports Medicine entitled “Comprehensive Physical Examination for instability of the knee” (Lubowitz et al, 2008), which includes the measurement of the Q-angle. The authors state that the Q-angle is a measure of patello-femoral joint instability and larger Q-angles denote less stability. They recommend a measurement protocol using a goniometer with the patient in the supine position. They make no mention of, or reference to, any of the literature which questions its validity or reliability.

To date, many researchers report studies which involve measurement of the Q-angle and acknowledge the time required to take the measurement, but have failed to suggest that the value of the Q-angle might vary during that time period.

7.9.2 Measuring the Q-angle during the stance phase of gait

The purpose of this series of three small studies was to explore what happens to the Q-angle during the stance phase of gait. The first study explored whether the maximum value of the Q-angle would occur at the beginning of the stance phase of gait and the minimum value at the end. Thirty recreationally active participants were asked to walk at their own preferred comfortable walking pace along the walkway, known as ‘free walking’. A number of gait analysis studies

have shown that when healthy individuals are permitted to 'free walk' at their own preferred pace; this pace is very consistent over repeat walks and is much easier for subjects to do rather than trying to follow a metronome and walk at a prescribed unnatural pace (Dillon et al, 1983; Perry, 1992; Powers et al, 1997). This study was based on the assumption that the value of the Q-angle is directly linked to the level of knee flexion (movement in the sagittal plane). Actual knee flexion was not measured (a weakness of the present studies) as the camera system was only set up to video movement occurring in one plane i.e. the frontal plane (the plane of the Q-angle) and it was assumed that on average the knee flexion and extension movement during walking for the group of healthy participants would follow the usual pattern for adults when walking as described by Whittle (1996).

However, during walking there is also rotation (transverse plane) of the pelvis, thigh and lower leg and these are all likely to affect the Q-angle, as each of these body parts has one of the bony markers from which the Q-angle is derived. Movements in the transverse plane are very difficult to quantify, especially during a functional activity like walking, when more than one joint is involved, and require more sophisticated technology than was available at the time of the present study. The results show that the majority of participants illustrate the expected pattern of timing for the maximum and minimum values of the Q-angle, despite the fact that the affect of rotary movements in the transverse plane have not been addressed.

A significant minority of participants, in this group, did not follow this expected pattern, 24 (41%) data sets did not have the maximum value of Q-angle at heel strike, and 22 (37%) did not have the minimum value of the Q-angle at toe-off.

Possible reasons for these results could be:

- Q-angle values and the amount of knee flexion and extension were not directly related; or
- Q-angle values did relate directly to the amount of knee flexion and extension, but participants did not have their greatest level of knee extension at heel-strike; and also did not have their greatest level of knee flexion at toe-off; as there are other points in the stance phase cycle

where knee flexion and extension occur, and the maximum values could have occurred at these points instead; or

- Other factors affected the size of the Q-angle to a greater degree than the effect of the level of knee flexion and extension; these could include the amount of rotary motion in the transverse plane across the whole of the lower limb and pelvis, which was not addressed in this study.

Measuring the Q-angle during the stance phase of gait has not been reported by other authors, so it is not possible to discuss these findings in relation to those of others. The only other study found where the Q-angle has been measured dynamically is that by Moss et al (1992) who measured the Q-angle of individuals on a treadmill, at a fixed running speed. They reported that mean time for the minimum Q-angle to be reached in their asymptomatic group was 0.099 seconds – however, as their data were collected during running, rather than free-walking it is not possible to make any direct comparisons.

In order to further understand more fully the effect of other biomechanical factors on the Q-angle it would be necessary to undertake further experimental work exploring the bones and joints directly above and below the patella-femoral joint – ie. tibial rotation, femoral rotation and knee valgus as proposed by Powers (2003). A number of researchers have recently reported work in this area and suggest that that some of the predisposing factors to patella-femoral joint problems may well be due to the way the femur rotates rather than the way the patella rotates on the femur (Salsich and Perman, 2007; Souza et al, 2010). An international symposium on Patello-femoral Pain Syndrome held in 2009 and reported in 2010, recognised the inconsistent findings of research in this area and the challenge posed by the number of relatively small studies using non-standardised measurement protocols. It produced a list of agreed areas for further research, including: an increased understanding of 3D motion analysis, how to measure muscle performance, the role of the VMO muscle, the effect of the structure and movement occurring at the proximal (hip) and distal (foot and ankle) joint; in order to increase our knowledge and understanding of the many biomechanical factors connected to this area of research (Davis and Powers, 2010).

The purpose of the next experiment undertaken was to see if there was any correlation between the measure of sub-talar joint pronation and the value of the Q-angle during the stance phase of gait, the details are described in Section 7.4. Thirty-one recreationally healthy participants had reflective markers placed on their right leg and their Q-angle and sub-talar joint pronation values measured during the stance phase of gait. The results showed that there was no meaningful relationship between the maximum or minimum values of the Q-angle and level of sub-talar joint pronation, during the stance phase of gait of the 27 healthy individuals whose data was analysed. This was unexpected, as most authors suggest that in theory there should be a link between the two measures. However, on reflection perhaps it ought not to have been a surprise. The majority of healthy individuals with normal anatomy of their lower limb, tend to heel-strike slightly on the lateral side of their heel, as a result of their bipedal reciprocal gait cycle and the lateral shift in weight which occurs from one side to the other as alternate limbs are brought through, and thus the effect of the rotation movements in the transverse plane during walking quite possibly outweigh the effect of movements in the other planes.

It is clear that the Q-angle for most healthy individuals is at its greatest at heel-strike, possibly on account of the knee being at its most extended at that point; and so once again the rotational elements of gait (movement in the transverse plane) seems to have a tremendous effect on the final values of both the Q-angle and sub-talar joint pronation. Moss et al (1992) also found no meaningful correlation between the amount of pronation and the value of the Q-angle of healthy individuals when running at a fixed speed on a treadmill, they also suggest that the rotational components would affect both the Q-angle and sub-talar joint measurements, and conclude that lack of measurement of these rotational components was a limitation of their study.

Messier et al (1990) also explored the amount of pronation that occurs at the sub-talar joint during running, they placed markers on the Achilles tendon and a heel-marker (presumably on the outside of the participants running shoe, this point was not clear) as participants wore the shoes they were wearing when

they first became symptomatic. They recruited 36 participants (26 males, aged between 16 and 50 years; these were divided into two groups, 16 with PFJS and 20 controls) who ran on a treadmill at a speed equivalent to their average training pace. They measured static Q-angle values and dynamic sub-talar joint pronation. No validity or reliability data are reported. They report several results including the maximum value of pronation and time taken to reach this value and again found no differences between sub-talar joint pronation between the two groups, and no relationship between dynamic sub-talar joint pronation and static Q-angle values.

Overall the literature for this area of work is contradictory. Other authors (Schultz et al, 2006; Dierks et al, 2008) have also found no meaningful relationship between sub-talar joint pronation and other lower limb movements when it is measured during a functional weight-bearing activity, again suggesting that measuring movement at this joint in just one plane is insufficient to explain what happens.

The third study exploring the Q-angle during the stance phase of gait plotted the pattern of movement over time of the three markers from which the Q-angle is formed (the markers are on the anterior superior iliac spine, the centre of the patella and the centre of the tibial tubercle). Eighteen participants with idiopathic PFJS and 24 healthy recreationally active individuals were recruited. Reflective markers were placed on the three bony landmarks, their initial static Q-angle was measured, and participants again walked along the walkway at their own preferred 'free walking' pace. The mean for the two static Q-angles were 15° and 16° for those with PFJS and the healthy participants respectively. The difference between the two mean values was not statistically significant, but the range of values for those with PFJS was almost three times as great (25°) as for the healthy participants (9°) which was interesting and supports the findings of others (Hvid et al, 1981; Messier et al, 1991).

The dynamic data was reviewed from a frontal and sagittal view; the transverse view was not analysed as the data in this plane varied hugely and it was not possible to capture it in a meaningful way with the equipment available. The

data showed that there was a typical regular pattern in movement of the three markers which form the Q-angle when viewed from the frontal and sagittal planes; there were some differences between these patterns for healthy individuals and those with PFJS; especially during the initial and terminal phases of stance. Another difference noted was that the mid-stance phase of the cycle typically started earlier (as measured in percent of gait cycle) and lasted longer for those subjects with PFJS. It is possible that this might be because during this phase the knee is kept in relative extension. This is in line with the findings of other studies (Dillon et al, 1983; Nadeau et al, 1997; Powers et al, 1999; Hamill et al, 1999), who all reported that individuals with PFJS typically exhibited less movement in the sagittal plane when compared with healthy individuals i.e. those with PFJS walked with a straighter knee, and this was also true for the data presented here, although as a direct measure of knee flexion was not taken it is not possible to comment definitively.

A benefit of allowing participants to walk at their own preferred pace is that they are more relaxed and thus their analysed gait is much more typical for them and thus more valid. Repeat trials have shown that participants replicated their own preferred walking speed with great consistency (Krebs, 1998). However, a disadvantage of allowing participants to walk at their own preferred pace is that there is variation between participants, which makes combining or averaging group data over time difficult.

As stated in the results (Section 7.5.4.2) the mean length of time for the stance phase of gait for the healthy participants as measured on their right leg was 0.72 seconds, whereas it was 0.62 seconds for the affected leg for those with PFJS, this difference is statistically significant ($p=0.001$). Thus participants with PFJS spent less time taking weight on their affected leg than did healthy controls during the stance phase that was digitised.

The reasons for this are not clear but could be:

- participants with PFJS walked more quickly (velocity); or
- walked at the same velocity but took more steps per unit of time (cadence) i.e. a greater number of shorter steps, than healthy controls; or
- had an asymmetric gait style or limp.

However, as data was only collected from one leg per participant it was not possible to make meaningful comparisons, although participants with PFJS did not appear to be limping. Powers et al (1999) found that their group of 15 participants with PFJS walked at a significantly slower rate (velocity and cadence) than a group of ten healthy controls.

7.9.3 – The effect on the Q-angle of applying McConnell’s medial glide patella tape

The next study explored the effect on the Q-angle of applying medial glide patella tape as initially described and recommended by McConnell in 1986. This is a commonly used intervention treatment technique applied to the patellae of individuals where there is thought to be patellar mal-alignment. McConnell suggested that the application of the tape would maintain the patella in a more optimal position in the femoral sulcus, once it had been moved there. Ten healthy recreationally active males had the medial glide tape applied to their right knee, following the protocol described by McConnell (described in Section 7.6.2). The application of the medial glide patella tape did alter the value of the Q-angle for this group of healthy participants, on average by +13 degrees, when this was measured in relaxed standing using the Vicon equipment. The Q-angle on the left leg, which did not have any tape applied, altered on average by +1 degree; illustrating a significant difference between these two means. However, the tape pulls both the patella and the skin medially, and as the patella marker remained on the skin, it is not possible to say how much of the alteration of the Q-angle was due to medial patella movement and how much was due to the medial movement of the skin over the patella. The fact that the Q-angle on the left leg varied on average by only one degree suggests that the change in Q-angle on the right leg was due to the

application of the tape, it also showed that the technique of measuring the Q-angle was consistent between measurement sets.

A number of other authors have also undertaken work to see if the application of medial glide patellar tape does re-align the patella. One of the difficulties of assessing this, is that the application of the tape is thought to be effective when participants are in weight-bearing and it is difficult to measure patella position accurately or reliably when individuals are in standing (Crossley et al, 2000). Measures of patella position using X-ray are acknowledged as being valid and reliable (Bockrath et al 1993; Larsen et al, 1995), but it is not usual to take X-ray pictures of the knee in standing, and has only relatively recently become available using MRI in some specialist centres.

Worrell et al (1994) reported a case study in which they applied medial glide patellar tape to a 15 year old girl with anterior knee pain and a history of patellar subluxation. They took MRI scans of the knee in eight different positions of flexion (10° , 17° , 25° , 30° , 34° , 39° , 41° , and 45°) pre- and post-tape and reported a significant change in lateral patella displacement. They measured knee flexion with a goniometer, but do not discuss their choice of knee flexion positions, describe their measurement technique for lateral patellar displacement (LPD), but do not mention the issue of reliability. All MRI scans were taken with the subject in supine.

Pfeiffer et al (2004) report a study in which they applied medial glide patella tape to 18 healthy women and assessed the position of the patella before and after its application. They reported significant differences in the position of the patella pre and post application of the tape with the knees in 0° , 12° , 24° and 36° of flexion. They describe their measurement protocol for measuring the lateral patellar displacement in detail, and undertook a brief reliability study, but only analysed repeat measurements using correlation statistics (unspecified), they reported a correlation of 0.999. All MRI scans were taken with the participant sitting.

Lan et al (2010) report the effects of applying medial glide patellar tape to a group of 100 individuals with patello-femoral pain; they took measures from X-ray pictures and report no significant differences in lateral patellar displacement pre- and post-taping for their group. They described their measurement protocol for the lateral patellar displacement but do not mention the issue of accuracy or reliability at all.

Thus our results support that of the few others authors listed above for healthy individuals, although all the studies reported in the literature have measured the position of the patellar of healthy participants in non-weight-bearing and few have mentioned the issue of measurement reliability. Also the measurement protocol used in this work had participants in standing. It is interesting that the large study by Lan et al (2010) in which all participants had patello-femoral joint problems did not show a significant difference in lateral patellar displacement after application of the tape, although 66% of their participants reported a significant reduction in pain of more than 20mm when measured using a visual analogue scale. In summary there are too few studies and too little attention to measurement rigour to allow any definitive conclusions to be drawn from the body of work reported to date.

A small number of authors have also tested whether the application of the medial glide patellar tape can maintain the realigned position of the patella after a period of exercise, Larsen et al, 1995 and Pfeiffer et al 2004. This study involved the same ten healthy recreationally active males who had the medial glide tape applied to their right knee, following the protocol described by McConnell (described in Section 7.6.2). Following application of the tape they cycled for 5 minutes on a static bicycle at a constant speed of between 45 and 50 rpm. There was no significant change in Q-angle following this period of cycling. This suggests that the tape maintained its effect on the skin and patellar during this period of repeated flexion and extension of the knee joint. Participants did work up a sweat while cycling but the period of time was short (5 minutes) so presumably the repeated tension on the tape and sweat of the individuals was not sufficient to have any effect on the tape. This contradicts the findings of Larsen (1995) and Pfeiffer et al (2004) both of whom found that

the following the period of exercise their participants' lateral patellar displacement measure was no longer significantly different from the pre-tape measure. The exercise protocol used by both Larsen and Pfeiffer et al, was the same and involved running around an indoor circuit, and took participants 15 or 20 minutes to complete. The difference in results could be due to the difference in type and duration of the exercise session or the strength of the tape. In fact Larsen et al (1995) cite the work of three other authors who report work on taping the ankle joint following inversion sprains, and state that for ankle taping the tape tends to break down after 10 – 15 minutes.

Following the period of cycling the patellar marker was removed by the investigator and re-sited at the centre of the patella (leaving the tape in place) and the Q-angle was measured for a fourth time. This was done to try to understand if the change in Q-angle was due to medial movement of the patella itself or medial movement of the skin over the patella. Any change in the Q-angle of three degrees or less was likely to be due to the natural variations in the Q-angle which occur over a 60 second period (Wilson and Kitsell, 2002), however variations greater than three degrees might be due to actual medial movement of the patella, by the tape. The results show that the mean difference between the two sets of measurement was only two degrees, which suggests that most movement of the patella marker was due to skin movement rather than movement of the patella itself.

However, there was a difference of greater than three degrees for three of the ten participants and a difference of three degrees for a further two participants. The correlation between QA4-QA1 (the difference between the original, pre-tape, and final Q-angles) and the lateral distance moved by the patella marker when it was replaced at the centre of the patella was $r=0.64$; illustrating that the larger difference between the original and final Q-angle values was positively correlated with a larger degree of movement of the patella. While this correlation is lower than the 0.7 threshold which is accepted as being clinically meaningful (Martinsen and Stokes, 1991) and the group of participants was very small, it does suggest that for some individuals both the skin and the patella were moved medially by the application of tape, and that for these

individuals there was a greater effect on the value of the Q-angle. However, for other individuals there appears to have been little, if any, medial movement of the patella by the tape. This is interesting and it would be interesting to follow-up on a larger scale, as the number of participants and pragmatic nature of the test, renders any findings tentative. It would be interesting to test why these differences occur - whether it might be due to inconsistencies with the tension applied to the tape, or whether some individuals have more mobile skin and soft tissue. As the patella is a sesamoid bone, and the taping is applied with the knee in extension when all the associated soft tissues are in a relaxed state, it could be linked with differences in extensibility of relaxed soft tissues between individuals; as well as to explore differences between those with PFJS and those without.

7.9.4 – General Conclusions

The work reported in this chapter has used the established valid and reliable method of measuring the Q-angle developed in Chapter 5 and applied it in a number of circumstances, from which the following conclusions are summarised:

1. The Q-angle can be measured over time and for this group of 51 healthy participants it varied on average by between 3.0 and 4.0 degrees during the period of 60 seconds, and thus when measuring the Q-angle in the clinical situation it should not be seen as an absolute or unvarying measure, but a snap-shot in time of its value
2. The Q-angle can be measured during the stance phase of gait, and the variation in Q-angle for most of the 27 healthy participants followed the expected pattern:
 - 59% had the maximum value of Q-angle at the heel-strike, and
 - 63% had the minimum value at toe-off; although a limitation is that actual knee flexion angles were not measured
3. For the group of healthy 27 participants there was no meaningful correlation between the maximum or minimum values of the Q-angle and sub-talar joint pronation ($r=-0.123$ and $r= -0.083$) during the stance phase of gait

4. There were differences as well as similarities in the pattern of movement of the three markers from which the Q-angle is formed, between healthy participants and those with PFJS, when viewed from the frontal and sagittal planes during the stance phase of gait:
 - Sagittal plane – participants with PFJS walked with a straighter knee than healthy participants
 - Frontal plane – participants with PFJS started with a lower average Q-angle than healthy participants, then it increased and remained a few degrees above that for the healthy group, increasing again during the terminal phase
 - The participants with PFJS on average spent a shorter time in weight-bearing on their affected leg compared with the healthy participants
5. The application of McConnell's medial glide patellar tape to ten healthy participants did alter the value of their Q-angle increasing it on average by 13 degrees
 - The tape maintained its effect on the Q-angle after a period of 5 minutes cycling at a speed of between 45 and 50 rpm
 - For some participants the application of the tape appeared to move the skin medially, rather than the patella itself

Chapter Eight

**The relationship between the Q-angle and
the size of the vastus medialis oblique
(VMO) muscle in healthy participants;
and a Case Study**

CHAPTER 8.0

The relationship between the Q-angle and the size of the vastus medialis oblique (VMO) muscle in healthy participants; and a brief Case Study

8.1 – Introduction

The purpose of the work carried out and reported in this chapter was to explore the relationship between the value of the Q-angle and the size of the vastus medialis oblique (VMO) muscle in healthy participants; and then to report a case study for an individual with a history of patello-femoral joint syndrome (PFJS).

The chapter is divided into four parts:

- 8.1 - Introduction;
- 8.2 - Correlation between the value of the Q-angle and the size of the VMO muscle, in healthy participants;
- 8.3 – A short case study of an individual with a history of patello-femoral joint syndrome (PFJS);
- 8.4 – General Discussion and Conclusions

In Chapter 6 it was established that there was good correlation between the three identified linear measures and the cross-sectional area (CSA) of the VMO muscle, in the young healthy participants studied. Also measures from images taken using a portable real-time ultrasound scanner (RUS) were as valid and reliable as those taken from MRI images. In Chapter 7 the Q-angle was explored further, using the measurement protocol developed in Chapter 5 and found both differences and similarities in behaviour of the Q-angle when compared between individuals with and without patello-femoral joint syndrome (PFJS). It now seemed appropriate to explore whether any links existed between the value of the Q-angle and the size of the VMO muscle.

8.2 – Relationship between the value of the Q-angle and the size of VMO muscle

8.2.1 - Background

One commonly used physiotherapy intervention when treating individuals with PFJS is to encourage specific exercises to strengthen the distal portion of the VM muscle (the VMO) as it is thought that weakness in this muscle may be a contributory factor in those cases in which patella mal-alignment is suspected (McConnell, 1986; Crossley et al, 2002; Collins et al, 2008; Lin et al, 2008). It has also been established, by a number of authors (Garfinkel and Cafarelli, 1992; Freilich et al, 1995; Schulties et al, 1995; Stokes et al, 1997; Rankin et al, 2004; Pressler et al, 2006; Segal, 2007), that the size of a healthy muscle correlates well with its ability to produce a force and thus is an indirect measure of its strength. Thus it was of interest to explore whether there was any relationship between the size of the VMO muscle (as measured by the linear measures A, B and C) and the value of the Q-angle.

One published study in the literature has attempted to examine this aspect to some degree. Lin et al (2008) looked at the association between sonographic morphology of the VMO muscle with patellar alignment (measured using X-ray) in 58 patients (89 knees) with patello-femoral pain syndrome (PFPS). They specifically measured the level of patella tilt and congruence angle with each knee in 45° of flexion, and explored correlation between these measures and the VMO insertion levels, fibre angles and volume. They calculated VMO volume by taking a series of ultrasound images at 2 mm increments for the portion of the VMO which inserted into the patella. They calculated Pearson correlation coefficients of $r=0.45$ between patellar tilt angle and volume of VMO and $r=0.12$ between patellar congruence angle and volume of VMO. Their intra-rater reliability testing was insufficient – the rater took two measures on each day at a 1-day interval and then compared the average of these 2 measures, using ICCs. For the VMO cross-sectional area measures they report an ICC of 0.84, unfortunately this does not meet the 0.9 threshold recommended by Portney and Watkins (2001) as being necessary for clinical decision making, and they did not report a second measure of reliability; and so

it is not possible to draw any conclusions from their work despite the large sample size.

8.2.2 – Aim

The aim of the present experiment was to see if there was any correlation between the value of the Q-angle and the size of the VMO muscle.

Question – Is there any correlation between the value of the Q-angle and the VMO muscle size in young healthy individuals, using measurements taken with participants in relaxed standing?

8.2.3 – Method

The same ten healthy recreationally active males who participated in earlier experimental work, had the Q-angle of both of their knees measured while in relaxed standing. This was performed following the same protocol used for earlier work (see Chapter 5, Section 5.4); using the Vicon motion analysis system. Seven reflective markers were placed on both legs (Figure 8.1); participants stood in relaxed standing and recordings were captured for 60 seconds. From these recordings the average static Q-angle was calculated, for both the right and left legs. The CSA and Linear measures A, B and C, already obtained from RUS images taken while participants were in relaxed standing were used and Pearson's correlation coefficients were calculated between these measures, the linear measures multiplied together, and the Q-angle data to see if there was any was any meaningful correlation between them. In addition a regression plot for Linear measure C over Q-angle was plotted to see if there was a meaningful relationship between this particular linear measure, as it had shown the highest level of correlation with the CSA measure of the VMO muscle in earlier work reported in Section 6.2.

To be consistent with the earlier reported results of correlation between measures, a minimum level of $r=0.7$ was considered essential to determine whether or not the correlation was meaningful and clinically significant, in accordance with the recommendation of Kline (1986), as quoted by Stokes et al. (2007).



Figure 8.1 – Participant with reflective markers for Q-angle measurement, using the Vicon motion analysis system, in relaxed standing

8.2.4 – Results

The Pearson correlation between the individual linear measures (A, B and C), as well as multiples of these measures (AxB, AxC, BxC) and the CSA measure of the VMO muscle; with the value of the Q-angle were calculated. There was no meaningful level correlation between any of the linear measures or multiple of linear measures from the VMO muscle and the Q-angle, when measured in relaxed standing (Table 8.1). All r values were below 0.5, excepting that for the multiple of Line A x B which had a correlation of 0.52. The regression plot (Figure 8.2) of linear measure C and the Q-angle also showed no meaningful relationship.

Table 8.1 – Pearson correlation coefficients between: CSA, line measures A, B and C and multiplication of line measures of the VMO muscle with the Q-angle; all measures being taken in relaxed standing

Measures	Correlation Coefficient
Line A	0.33
Line B	0.49
Line C	-0.15
CSA	0.45
Line A x B	0.52
Line A x C	0.02
Line B x C	0.26

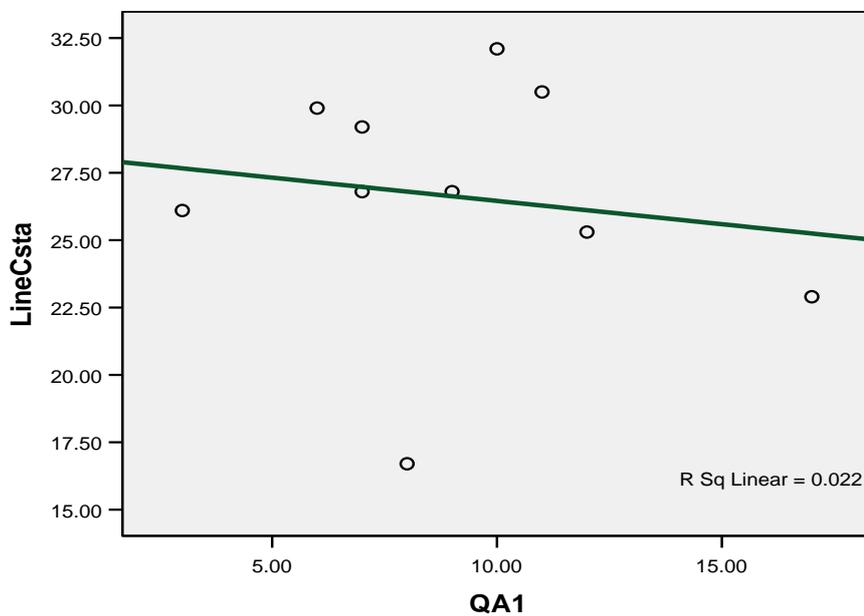


Figure 8.2 - Regression plot of Line C plotted over Q-angle, showing that there is no meaningful relationship between the two sets of measures, (n=10). R=0.022.

8.2.5 – Conclusion:

In the sample of 10 healthy males tested, there was no meaningful level of correlation ($r > 0.7$) between any measure of VMO muscle size (CSA and linear measures) and the value of the Q-angle; from a series of measurements taken while participants were in relaxed standing.

8.3 – Case Study

8.3.1 – Background

Having established the lack of correlation between the size of the VMO and the value of the Q-angle for young healthy individuals, it then seemed appropriate to see if there was any correlation between the size of the VMO and the value of the Q-angle for individuals with PFJS. The work of other researchers has shown that the Q-angle is not necessarily higher in those with PFJS (Caylor et al, 1992; Thomee et al, 1995), although other authors have reported opposite results (Moss et al. 1992; Livingston and Mandogo, 1999). It is commonly believed by some clinicians that a higher Q-angle may be indicative of mal-alignment of the patello-femoral joint (McConnell, 1986; Devan et al, 2004; Draper et al, 2009).

The original plan for the next stage of this work was to recruit a group of 20 males with PFJS in their right knee and to take the whole series of measures from them – Q-angle and VMO muscle size etc, and then to see if there was any meaningful similarities or differences for this group compared with the group of healthy male participants. Two local orthopaedic clinics were approached and their referral data showed that on average there were 5 to 6 new referrals to the physiotherapy team each week for individuals with this diagnosis. Thus a study protocol was written and ethical permission obtained from the Southampton and South West Hampshire Research Ethics Committee (A), in February 2006 (No: 05/Q1702/160); and we then proceeded to recruit participants who met the inclusion criteria.

Unfortunately from this point in time the number of referrals from these two clinics of individuals with PFJS dropped to almost zero. This appeared to be due to a change in referral patterns and patient pathways which occurred, at least in part, due to financial pressures and the resultant need to curtail the provision of some existing services. However, it took several weeks before this situation was established. Of the very few referrals of individuals with a diagnosis of PFJS to the physiotherapy clinics during this time, none met the inclusion criteria (see below). Once it became evident that there had been a

deliberate change in referral practice, it was also clear that there was little prospect that the referral rate would change. In order to recruit suitable participants it was agreed that individuals who had a history of PFJS would be sought and tested instead. Unfortunately due to the lack of remaining time available this recruitment process only yielded one individual who met the inclusion criteria, and so his results are presented here, as an illustrative example.

8.3.2 – Aim

The aim of the present illustrative case study was to see if there were any similarities or differences between the Q-angle measurements and the size of the VMO muscle, as described in Chapters 6 and 7, when taken from an individual with a history of PFJS:

- Effect of posture on CSA and linear measures from ultrasound images of the VMO muscle
- Effect on the Q-angle of applying medial glide patellar tape
- Effect of cycling on the medial glide patellar tape
- Whether the medial glide patellar tape moves the patella or the skin or neither

Question – As there any similarities between the series of measures taken from an individual with a history of PFJS and the healthy participants already measured?

8.3.3 – Method

One participant with a history of PFJS in his right knee, although no active symptoms for the past two years; was recruited as an illustrative case study. His body mass index was calculated, then he had bilateral Q-angle measures taken in relaxed standing, ultrasound images taken in both standing and long-sitting. He then had medial glide patellar tape applied to his right knee, followed by repeat Q-angle measure taken, then did 5 minutes of cycling at a speed of between 45 and 50 rpm, followed by another Q-angle measurement, the marker

on the centre of his patella was replaced on the centre of his patella (as it had moved following application of the medial glide patellar tape).

The following measures were taken:

- RUS images of the VMO muscle from his right leg were taken:
 - in long-sitting, and
 - relaxed standing, following the same protocol used for the group of ten healthy subjects
- Q-angle was measured using the Vicon motion analysis equipment, in relaxed standing, following the established measurement protocol.
 - Initial
 - After application of medial glide patellar tape
 - After cycling for 5 minutes
 - After re-positioning the patellar marker on to the centre of the patella

All measures were taken and the results compared with the mean measures from the group of healthy participants reported in Section 8.2:

8.3.4 - Results:

As can be seen in Table 8.2, the subject with a history of PFJS had a much larger initial Q-angle (QA1) and a larger Q-angle after application of the medial glide patellar tape (QA2) compared to the mean for the healthy group, although the level of change following application of the tape was smaller than the mean for the group of healthy participants, being 8 degrees rather than 13 degrees.

After cycling for 5 minutes the value of the Q-angle for the Case Study participant remained the same (i.e. no change between QA2 and QA3), and after replacement of the patella marker back to the centre of the patella (QA4) the Q-angle was three degrees higher than its initial value (QA1), whereas the mean value for the group of ten healthy participants it was slightly smaller (by two degrees); however both differences were within the three degrees of natural variation found and reported in Chapter 7, Section 7.2. The lateral distance moved by the patella marker when it was replaced on the centre of the patella

after application of the medial glide patellar tape was similar between the case study participant and the mean for the group of healthy participants, being 10mms for the case study participant and 11mms for the healthy group. Thus apart from an initial larger Q-angle there was little difference between Q-angle measures for the case study participant and the group of healthy participants.

Table 8.2 – Q-angle measurements from the right leg for the Case Study participant with a history of PFJS on his right leg, and the mean for the group of healthy participants.

QA1 = initial measure in relaxed standing

QA2 = measure following application of the medial glide patellar tape

QA3 = measure following cycling for 5 minutes

QA4 = measure following repositioning of the patellar marker in the centre of the patella after application of the tape

	QA1 degree	QA2 degree	QA2-QA1 Degree	QA3 degree	QA4 degree	Difference QA4-QA1 degree	Lat dist patella moved (mm)
Case Study	19	27	+8	27	22	+3	10
Healthy (Mean)	9 (3-17)	22	+13	22	7	-2	11

Table 8.3 reports the BMI and measures of the VMO muscle size, taken from ultrasound images obtained with participants in long-sitting. Linear measures A, and B were smaller in the case study participant; whereas linear measure C and the CSA measures were larger. However, there are no significant differences between any of the data for the case study participant with PFJS and the group of ten healthy participants, when the measures were compared using an unrelated T-test ($p=0.33$).

Table 8.3 – BMI, CSA and linear measures from the ultrasound images of the VMO muscle of the right leg from the case study participant and the mean for the healthy participants, in long-sitting

	BMI	Line A mm	Line B mm	Line C mm	CSA mm²
Case Study	24.8	39.0	25.8	35.1	129.3
Healthy Group Mean (range)	26.0 (21.9- 30.9)	42.5	25.2	28.5	112.4

Table 8.4 reports the BMI and measures of the VMO muscle size, taken from ultrasound images obtained with participants in relaxed standing. Only line measure A is smaller for the case study participant; whereas linear measures B and C and the CSA measures were larger. However, there are no significant differences between any of the data for the case study participant with PFJS and the group of ten healthy participants, when the measures were compared using an unrelated T-test ($p=0.17$).

Table 8.4 – BMI, CSA and linear measures from the ultrasound images of the VMO muscle of the right leg from the case study participant and the mean for the healthy participants, in relaxed standing

	BMI	Line A mm	Line B mm	Line C mm	CSA mm²
Case Study	24.8	40.1	23.8	34.4	120.6
Healthy Group Mean (range)	26.0 (21.9- 30.9)	44.6	22.7	26.6	107.3

8.3.5 – Conclusion

All measurements taken from the case study participant with a history of PFJS are not significantly different from those of the group of ten healthy participants.

8.4 – General Discussion and Conclusions

8.4.1 – General Discussion

Ten healthy recreationally active male participants and one case study participant (equivalent to the healthy group, except with a history of PFJS, but no active symptoms for the previous two years) were recruited and each had his right Q-angle measured in relaxed standing and his right VMO muscle imaged using ultrasound, in both relaxed standing and long-sitting; using the valid and reliable measurement protocols established in Chapters 5 and 6.

The Q-angle values for the healthy participants measured in relaxed standing were analysed to see if there was any correlation between them and any measures (CSA or linear) taken from ultrasound images of the VMO muscle also taken in relaxed standing. The threshold set was $r=0.7$, as this is recommended as being a minimum level of correlation useful clinically (Kline, 1986; as quoted by Stokes et al, 2007). There were none. As our measurement protocols have been established as being both valid and reliable then this suggests that these measures have no relationship with each other.

The reason this relationship was being tested was to see whether it would provide evidence to support the assumption that a stronger VMO muscle is more able to maintain the position of the patella in the femoral sulcus, and thus potentially reduce some of the symptoms that are thought to arise when this is not the case. McConnell (1986) suggested that maintaining the patella in a more optimum position in the femoral sulcus would reduce symptoms of pain and ineffective activity in the VMO muscle. A number of studies on the management of individuals with PFJS recommend specific quadriceps exercises including a focus on the VMO muscle in particular (McConnell, 1986; Witvrouw et al, 2000; Heintjes et al, 2003; Green, 2005); although the long-term benefits are not yet fully proved. Following the assumption that muscle size is positively related to its strength, especially the CSA of a muscle, as discussed in Chapter 3 Section 3.10, it was thought possible that the CSA measurement of the VMO muscle might illustrate a useful level of correlation with the Q-angle, but this was not the case. However, it should be noted that there was a

moderate level of correlation between Line B and the Q-angle ($r=0.45$); however as there were so few participants it is difficult to draw any specific conclusions from this result; in some ways this was surprising as it was Line C that had shown the highest level of correlation with the CSA, which in turn tends to be the measure that is quoted as relating more closely to muscle strength. Future work on a much larger group of participants would be interesting in order to explore this fact further.

One issue that is important to note is that for all the measurement protocols devised and followed in this body of work, for measuring the value of the Q-angle and the size of the VMO muscle, had the quadriceps muscle relaxed – which was done for ease of consistency and standardisation for the measurement protocol, and checked by ensuring the patella was ‘loose’ and could be passively moved by the investigator. A common criticism of earlier reported measurement work as been that the state of contraction of the quadriceps muscles was not always standardised, this is discussed in Chapter 3 and Chapter 5. However, when the patella is ‘loose’ with the VMO muscle relaxed, it is less likely to have a direct effect on the position of the patella and hence the Q-angle – so by standardising the measurement protocol in this way it may have inadvertently eliminated the opportunity to capture any effect the VMO muscle has on the position of the patella and thus the value of the Q-angle. Lagthinghouse and Trimble (2000) showed that for a group of 22 healthy women, there was a statistically significant decrease in the value of the Q-angle when the measure was taken while the quadriceps muscle was isometrically contracted, compared to when the quadriceps muscle was relaxed. They took all measures from video images with participants in standing, and reported reliability of their measurement testing using ICCs (intra-rater 0.98) but gave insufficient details to be able to replicate their analysis. They also quoted method error between their two sets of repeat measures of 0.37° .

It was disappointing only to be able to recruit one individual as an illustrative case study participant, rather than a full group of 20 participants with PFJS as originally hoped, however the results from that participant are interesting. The initial value for the Q-angle for the case study participant was higher (19°) than

the mean for the healthy group (9°), and was higher than the highest value for a healthy participant (17°). Once the medial glide patellar tape was applied the Q-angle increased for both the case study participant (by 8°) and the healthy participants (by 13°); however once the marker which was originally on the centre of the patella was replaced due to the shift which occurred as a result of applying the tape, the resultant Q-angle for the case study participant was three degrees higher than the original value, whereas it was two degrees smaller for the healthy group. As both of these values sit within the three degrees of natural variation of the Q-angle over time identified in Chapter 7, Section 7.2, it must be concluded that these results do not show any differences between the case study participant and the healthy group.

There were no significant differences between the BMI and linear and CSA measures of the VMO muscle in either long-sitting or standing from the healthy group and the case study participant, as shown in Tables 8.3 and 8.4. BMI values have been shown to correlate positively with muscle size (Fulton et al, 2009) and so as the BMI for the case study participant is slightly smaller than the mean for the healthy group (24.8 as compared to 26.0), it was interesting to note that the CSA of the VMO muscle was larger for the case study participant when measured from images taken in both relaxed standing and long-sitting. To date most of the work reporting the use of ultrasound imaging to measure muscle size has been done on the muscles of healthy participants, and that is appropriate as it is necessary to understand first what the range of 'normal' is, before trying to make meaningful observations or decisions based on muscle size measures when there is pathology present. In recent years an increasing number of studies have been published showing that there is an effect on muscle size in the presence of pathology, although it is not clear which is the cause and which is the effect, assuming that muscle size is directly related. On the whole these relate to muscle size measures of paraspinal or abdominal muscles (Hides et al, 1994; Raney et al, 2007; Fernandez-de-las-penas et al, 2008).

It would be very interesting to be able to measure the Q-angle during a functional activity as well as the size and shape of the VMO at the same time,

as it is that functional real-time measurement which would be able to give definitive answers to these questions.

8.4.2 – General Conclusions

1. There was no meaningful correlation between any measure of VMO muscle size (CSA and linear measures) and the value of the Q-angle; while participants were in relaxed standing.
2. All measurements taken from the case study participant with a history of PFJS were not significantly different from those of the group of ten healthy participants.

Chapter Nine

General Discussion

CHAPTER 9.0

General Discussion

9.1 – Introduction

The literature reviewed in Chapter 3 illustrated the difficulties which exist when trying to measure the Q-angle in the clinical situation; as there is no consensus for a standardized measurement protocol authors have used and reported results from a variety of different measurement protocols which make comparisons difficult. In addition, few authors have reported or considered the concept of measurement reliability, and often those that did, did not carry this out in a thorough way; although measurement reliability is now more commonly and effectively addressed.

The literature also highlighted the difficulty in using accepted gold-standard methods to measure the size of the vastus medialis oblique (VMO) muscle, due to the cost and lack of access to equipment in specialist facilities, especially to magnetic resonance imaging (MRI). It was necessary to find an alternative way to measure the size of the VMO muscle in order to answer the questions posed at the beginning of this work, and ultrasound imaging was used.

This Chapter will draw together the findings of the experimental work carried out and reported in Chapters 5, 6, 7 and 8, and discuss them in relation to the literature. It includes: establishing valid and reliable protocols to measure the value of the Q-angle and the size of the VMO muscle; the application of these measurement protocols in a variety of circumstances; and the exploration of any relationship between them the value of the Q-angle and the size of the VMO muscle.

The chapter is divided into the following sections:

- 9.1 – Introduction
- 9.2 – Establishing a valid and reliable protocol for measuring the Q-angle, using video motion analysis
- 9.3 – Measuring the Q-angle over time, in relaxed standing
- 9.4 – Measuring the Q-angle during the stance phase of gait
- 9.5 – The effect on the Q-angle of applying McConnell's medial glide patellar tape in healthy participants
- 9.6 – Establishing a valid and reliable protocol for measuring the size of the vastus medialis oblique (VMO) muscle
- 9.7 – Correlation between the value of the Q-angle and linear and CSA measures of the VMO muscle taken from ultrasound images of healthy participants
- 9.8 – A brief illustrative case study of an individual with a history of PFJS
- 9.9. – Limitations of the present studies
- 9.10 – Summary

9.2 – Establishing a valid and reliable protocol for measuring the Q-angle, using video motion analysis

In Chapter 5 a protocol for measuring the Q-angle was devised and tested by two Testers, mock and real Q-angles were measured using the Peak Video Motion Analysis system. The mean variation for each set of repeat digitised measures from each true Q-angle in each experiment was less than one degree. These results matched the level of consistency reported by Selfe (1998), which was the threshold set. As with all mean values, the data for individuals from which the mean was calculated varied, with some results being lower and some above the threshold of one degree for variability, as reported in Section 5.4. Deciding how much variability in measurement is acceptable is a

challenge, as the requirement for consistency is largely dependent on what decisions the measurement data will be used to determine (Portney and Watkins, 2000).

The small tests of validity and consistency reported above confirm that the devised measurement protocol was suitable to measure the Q-angle on real participants, as long as the work was carried out by the same investigator, as no proper test of inter-rater reliability was carried out. It was recognized that the tests of consistency and variability reported here were not formal reliability studies, as both the number of participants and the number of repeat measures were too small, which is acknowledged as a weakness in this body of work. For thorough reliability testing a greater number of participants (minimum 20) and repeat measures on different days would be required (Chinn, 1991).

9.3 – Measuring the Q-angle over time, in relaxed standing

The Q-angle of 51 participants, in relaxed standing, was measured over 60 seconds using the protocol established in Chapter 5. Results showed that the Q-angle varied during this time period for all participants, which has important clinical implications. The mean range in variation for all data sets from all participants was between 3° and 4° with no consistent pattern in the variation being observed. When the measurement variation for this protocol (one degree) is added as well as the standard error of measurement (SEM) of 4° for using a goniometer (Eliasziw, 1994) then the resultant effect is that the Q-angle value could vary by as much as 9° during a typical 60 second time period. This finding suggests that when the Q-angle is measured in the clinical situation with participants in relaxed standing, the value recorded is not an absolute measure as previously assumed, but rather a snapshot in time of the individual's Q-angle within a given range. Mean Q-angle values for healthy individuals are reported as being between 12° and 17° (Woodland and Francis, 1992), values measured with a long-arm goniometer could be as much as 50% lower or higher than actual Q-angle values. This raises questions about the validity of this measure as well as the usefulness of quoting statistically significant differences between the mean Q-angle for comparison groups of as little as 1.8° (Moss, 1992).

These results are likely to help explain the low levels of reliability reported by others when measuring the Q-angle using a goniometer in addition to those factors already accepted as affecting its value as outlined in Chapter 3 Section 3.2. One or two authors have also questioned the wisdom of measuring the Q-angle using a goniometer and then basing clinical decisions for treatment based on its value (Greene, 2001; Selfe, 2004; Peeler, Leiter and Anderson, 2010). No researcher to date has suggested that the value of the Q-angle might vary during the time it takes to make the measure.

In light of the above it was disappointing to find a recent article in the *American Journal of Sports Medicine* entitled “Comprehensive Physical Examination for instability of the knee” (Lubowitz et al, 2008) which includes the measurement of the Q-angle. The authors state that the Q-angle is a measure of patello-femoral joint instability and larger Q-angles denote less stability. They recommend a measurement protocol using a goniometer with the patient in the supine position. They make no mention of, or reference to, any of the literature which questions its validity or reliability.

9.4 Measuring the Q-angle during the stance phase of gait

Three small studies were carried out to explore what happens to the Q-angle during the stance phase of gait, assuming that the value of the Q-angle was directly linked to the level of knee flexion (movement in the sagittal plane). Actual knee flexion was not measured (a weakness of the study) as the camera system was only set up to video movement occurring in one plane i.e. the frontal plane (the plane of the Q-angle), it was assumed that on average knee flexion and extension movement during walking for the group of healthy participants would follow the usual pattern for adults when walking as described by Whittle (1996).

The first study explored whether the maximum value of the Q-angle would occur at the beginning of the stance phase and the minimum value at the end. Thirty recreationally active participants were asked to walk at their own preferred comfortable walking pace along the walkway, known as ‘free walking’. The

results showed that the majority of participants illustrated the expected pattern of timing for the maximum and minimum values of the Q-angle, despite the fact that the affect of rotary movements in the transverse plane were not addressed.

However, a significant minority of participants, in this group, did not follow this expected pattern, 24 (41%) data sets did not have the maximum value of Q-angle at heel strike, and 22 (37%) did not have the minimum value of the Q-angle at toe-off. Possible reasons for these results could be:

- Q-angle values and the amount of knee flexion and extension were not directly related; or
- Q-angle values did relate directly to the amount of knee flexion and extension, but participants did not have their greatest level of knee extension at heel-strike; and also did not have their greatest level of knee flexion at toe-off; as there are other points in the stance phase cycle where knee flexion and extension occur, and the maximum values could have occurred at these points instead; or
- Other factors affected the size of the Q-angle to a greater degree than the effect of the level of knee flexion and extension; these could include the amount of rotary motion in the transverse plane across the whole of the lower limb and pelvis, which was not addressed in this study.

Measuring the Q-angle during the stance phase of gait has not been reported by other authors, so it was not possible to discuss these findings in relation to those of others. The only other study found where the Q-angle was measured dynamically is that by Moss et al (1992) who measured the Q-angle of individuals on a treadmill, at a fixed running speed. They reported that the mean time for the minimum Q-angle to be reached by their asymptomatic group was 0.099 seconds – however, as their data were collected during running, rather than free-walking it was not possible to make any direct comparisons.

9.4.1 Q-angle and amount of pronation at the sub-talar joint during the stance phase of gait

The purpose of the next experiment was to see if there was any correlation between the measure of sub-talar joint pronation and the value of the Q-angle during the stance phase of gait; the details are described in Chapter 7, Section 7.4. This was explored because the literature on the relationship is contradictory, with some authors stating that there would be a positive correlation between the two (Olerud and Per Berg, 1984; Lathinghouse and Trimble, 2000) and other stating there would be a negative correlation (Tiberio, 1987; Powers et al, 2002; Powers 2003). However, all authors who report on this agree there will be some correlation. Thirty-one recreationally healthy participants had the Q-angle and sub-talar joint pronation values of their right leg measured. The results showed that there was no meaningful relationship between the maximum or minimum values of the Q-angle and level of sub-talar joint pronation, during the stance phase of gait of the 27 healthy individuals whose data were analysed. This was unexpected, as most authors suggest that in theory there should be a link between the two measures. However, on reflection perhaps it ought not to have been a surprise. The majority of healthy individuals with normal anatomy of their lower limb, tend to heel-strike slightly on the lateral side of their heel, as a result of their bipedal reciprocal gait cycle and the lateral shift in weight which occurs from one side to the other as alternate limbs are brought through, and thus the effect of the rotational movements in the transverse plane during walking quite possibly outweigh the effect of movements in the other planes.

It is clear that the Q-angle for most healthy individuals is at its greatest at heel-strike, possibly on account of the knee being at its most extended at that point; and so once again the rotational elements of gait (movement in the transverse plane) seems to have an effect on the final values of both the Q-angle and sub-talar joint pronation. Moss et al (1992) also found no meaningful correlation between the amount of pronation and the value of the Q-angle of healthy individuals when running at a fixed speed on a treadmill, and they also suggested that the rotational components would affect both the Q-angle and

sub-talar joint measurements, and conclude that lack of measurement of these rotational components was a limitation of their study.

Messier et al (1990) also explored the amount of pronation that occurs at the sub-talar joint during running of 36 participants 16 with PFJS and 20 healthy controls. They measured static Q-angle before the running test, and sub-talar joint pronation during running. No validity or reliability data were reported. They found no differences in sub-talar joint pronation between the two groups, and no relationship between dynamic sub-talar joint pronation and static Q-angle values.

Other authors (Schultz et al, 2006; Dierks et al, 2008) have also found no meaningful relationship between sub-talar joint pronation and other lower limb movements when it is measured during a functional weight-bearing activity, again suggesting that measuring movement at this joint in just one plane is insufficient to explain what happens. In order to understand more fully the effect of other biomechanical factors on the Q-angle it would be necessary to undertake experimental work exploring the rotation movement of the bones and joints directly above and below the patello-femoral joint – i.e.. tibial rotation, femoral rotation and knee valgus as proposed by Powers (2003). A number of researchers have recently reported work in this area and suggest that some of the predisposing factors to patello-femoral joint problems may well be due to the way the femur rotates rather than the way the patella rotates on the femur (Salsich and Perman, 2007; Souza et al, 2010). An international symposium on Patello-femoral Pain Syndrome held in 2009 and reported in 2010, recognised the inconsistent findings of research in this area and the challenge posed by the number of relatively small studies using non-standardised measurement protocols. The Symposium produced a list of agreed areas for further research, including: an increased understanding of 3D motion analysis, how to measure muscle performance, the role of the VMO muscle, the effect of the structure and movement occurring at the proximal (hip) and distal (foot and ankle) joint; in order to increase our knowledge and understanding of the many biomechanical factors connected to this area of research (Davis and Powers, 2010).

9.4.2 – Exploring the pattern of movement of the three markers which form the Q-angle, for healthy participants and those with idiopathic PFJS, during the stance phase of gait

The third study exploring the Q-angle (Chapter 7, Section 7.5) during the stance phase of gait, using video motion analysis, plotted the pattern of movement over time of the three markers from which the Q-angle is formed (on the anterior superior iliac spine, the centre of the patella and the centre of the tibial tubercle). Data from 18 participants with idiopathic PFJS and 24 healthy recreationally active individuals were analysed. The data were reviewed from a frontal and sagittal view; the transverse view was not analysed as the data in this plane varied greatly and it was not possible to capture it in a meaningful way with the equipment available.

The data (Chapter 7, Figures 7.6, 7.7, 7.8 and 7.9) showed that there was a typical regular pattern in movement of the three markers which form the Q-angle when viewed from the frontal and sagittal planes; there were some differences between these patterns for healthy individuals and those with PFJS; especially during the initial and terminal phases of stance. Another difference noted was that the mid-stance phase of the cycle typically started earlier (as measured in percent of gait cycle) and lasted longer for those subjects with PFJS. It is possible that this might be because during this phase the knee is kept in relative extension. This is in line with the findings of other studies (Dillon et al, 1983; Nadeau et al, 1997; Powers et al, 1999; Hamill et al, 1999), who all reported that individuals with PFJS typically exhibited less movement in the sagittal plane when compared with healthy individuals i.e. those with PFJS walked with a straighter knee, and this was also true for the present data, although as knee flexion was not measured directly, it is not possible to comment definitively.

As stated in the results (Section 7.5.4.2) there was a statistically significant difference between the mean length of time for the stance phase of gait between the two groups, 0.72 seconds for the healthy group and 0.62 seconds for those with PFJS ($p=0.001$). Thus participants with PFJS spent less time

taking weight on their affected leg than did healthy controls during the stance phase which was analysed.

The reasons for this are not clear but could include:

- participants with PFJS walked more quickly (velocity); or
- walked at the same velocity but took more steps per unit of time (cadence) i.e. a greater number of shorter steps, than healthy controls; or
- had an asymmetric gait style or limp.

However, as data were only collected from one leg per participant it was not possible to make meaningful comparisons, although participants with PFJS did not appear to be limping. Powers et al (1999) found that their group of 15 participants with PFJS walked at a significantly slower rate (velocity and cadence) than a group of ten healthy controls.

9.5 The effect on the Q-angle of applying McConnell's medial glide patellar tape in healthy participants

The next study (described in Chapter 7, Section 7.6) explored the effect on the Q-angle of applying medial glide patellar tape as initially described and recommended by McConnell in 1986. The application of the medial glide patellar tape to ten healthy recreationally active male participants did alter the value of their Q-angle, on average by +13 degrees, when measured in relaxed standing using the Vicon motion analysis system. The Q-angle on the left leg, which did not have tape applied, altered on average by +1 degree. The difference was statistically significant. The fact that the Q-angle on the left leg varied on average by only one degree suggests that the change in Q-angle on the right leg was due to the application of the tape, it also showed that the technique of measuring the Q-angle was consistent between measurement sets.

A number of other authors have also undertaken work to see if the application of medial glide patellar tape does move the patella medially. One of the difficulties of assessing this is that the application of the tape is meant to be effective when participants are in weight-bearing and it is difficult to measure patellar position accurately or reliably when individuals are in standing (Crossley et al, 2000). Worrell et al (1994) reported a case study in which they applied medial glide patellar tape to a 15 year old girl with anterior knee pain and a history of patellar subluxation. They took MRI scans of the knee in eight different positions of flexion (10° , 17° , 25° , 30° , 34° , 39° , 41° , and 45°) pre and post tape and reported a significant change in lateral patellar displacement (LPD) they did not mention the issue of reliability; so their results can only be considered tentative. All MRI scans were taken with the subject in non weight-bearing, supine.

Pfeiffer et al (2004) applied medial glide patellar tape to 18 healthy women and assessed the position of the patella before and after its application. They reported significant differences in the position of the patella pre and post application of the tape with the knees in 0° , 12° , 24° and 36° of flexion. They described their measurement protocol for measuring the LPD, and undertook a brief reliability study analyzing repeat measurements using correlation statistics (unspecified). They reported a correlation of 0.999; but as it is not clear exactly what this statistic is their results can only be considered tentative. Again all MRI scans were taken with the participant non weight-bearing, sitting.

Lan et al (2010) report the effects of applying medial glide patellar tape to a group of 100 individuals with patello-femoral pain; they took measures from X-ray pictures and report no significant differences in LPD pre and post taping. They described their measurement protocol for the LPD but do not mention measurement accuracy or reliability, and so their results can only be considered as tentative. All X-rays were taken with participants in non weight-bearing, supine.

Thus the present results support those of the few other authors listed above for healthy individuals, although the measures taken in the work reported here

were taken from participants in relaxed standing, compared with the literature where measures were taken with participants in non-weight-bearing. Few authors reported any measurement reliability analysis; results cannot be considered to be definitive. It was interesting that the large study by Lan et al (2010), in which all participants had patello-femoral joint problems, did not show a significant difference in LPD after application of the tape, although 66% of their participants reported a significant reduction in pain of more than 20mm when measured using a visual analogue scale. In summary, there are too few studies and too little attention to measurement rigour in those that exist to allow any definitive conclusions to be drawn from the body of work reported to date.

9.5.1 – Influence of exercise on the effect of medial glide patellar tape on the Q-angle of healthy participants

A small number of authors have explored whether the application of medial glide patellar tape maintains the more medial position of the patella after a period of exercise (Larsen et al, 1995; Pfeiffer et al 2004). The same ten healthy recreationally active males reported in the section above cycled for 5 minutes on a static bicycle at a constant speed of between 45 and 50 rpm, following application of the tape. There was no significant change in Q-angle following this period of cycling. This suggests that the tape maintained its effect on the skin and patellar during this period of exercise which involved repeated flexion and extension of the knee joint, deliberately designed to stress the tape. This contrasts with the findings of Larsen (1995) and Pfeiffer et al (2004) both of whom reported that following a period of 15 - 20 minutes of exercise the participants' lateral patellar displacement measure was no longer significantly different from the pre-tape measure. Both studies used the same exercise protocol which involved running around an indoor circuit. The difference in results could be due to the difference in type and duration of the exercise session or the strength of the tape. In fact Larsen et al (1995) cited the work of three other authors who reported studies on using tape for inversion sprains of the ankle joint, and stated that for ankle taping the tape tends to break down after 10-15 minutes, so the 5 minutes of cycling used in this study was probably too short to really test the tape.

9.6 – Establishing a valid and reliable protocol for measuring the size of the vastus medialis oblique (VMO) muscle

Due to the difficulties in accessing the accepted gold-standard methods to measure the size of the vastus medialis oblique (VMO) muscle, a valid and reliable method for measuring the size of the VMO muscle in the clinical situation was sought. Previous authors have reported valid and reliable methods for measuring the size of various other muscles using real-time ultrasound (RUS) images obtained from a portable ultrasound machine and so this was the method of first choice. In order to do this it was first necessary to establish a number of things:

- Whether there was a meaningful level of correlation between the CSA and linear measures of the VMO muscle, when measures were taken from images obtained using the gold standard for muscle imaging, namely MRI scans. And prior to this it was necessary to establish whether CSA and linear measures of the VMO could be taken reliably from MRI images.
- Whether it was possible to make CSA and linear measurements of the VMO muscle as validly and reliably from ultrasound images as it was from MRI images. And prior to this it was necessary to establish whether ultrasound images could be taken reliably from participants.
- Was there any effect of posture on the size and shape of the VMO muscle using ultrasound imaging.

9.6.1 – Correlation between the CSA and linear measures of the VMO muscle taken from MRI images

Other researchers have reported a meaningful correlation between the CSA and linear measures for a number of other muscles (see Chapter 2, Section 2.5). It was important to establish whether this relationship existed for the VMO muscle as it was felt likely that the CSA of the VMO muscle might be larger than the size of an ultrasound transducer head, at least for some participants, which could greatly restrict recruitment of participants to the study. Although a study by Yeong-Fwu et al (2008) took ultrasound scans of the VMO from 58 participants (89 knees) in Taiwan and was able to image the CSA of all participants, their

group clearly had small enough muscles to be within the field of view but this would not be the case for people with larger muscles.

Reliability of CSA and linear measures from MRI images

Twelve adult healthy recreationally active males were recruited and had the VMO of their right leg imaged using MRI (see Chapter 6, Section 6.2). The CSA and three linear measures – A, B, and C were made by the same investigator on two occasions. The two data sets were tested for repeatability using the ICC (model 3,1) as intra-rater reliability only was being tested, and Bland and Altman Limits of Agreement.

All ICCs for the initial and repeat measures exceeded 0.9, which Portney and Watkins (2000) consider to be a necessary minimum threshold for the consistency of clinical measures. These results are in line with those of other authors who studied different muscles, most of whom report ICCs of initial and repeat intra-rater measures of 0.9 or above for example (Rankin and Stokes, 1998; O'Sullivan et al, 2007).

All mean differences between each pair of initial and repeat measures following the procedure outlined by Bland and Altman Limits of Agreement (1986) were very small (range -0.15mm to -0.74mm). All differences were negative, showing that the repeat measures taken were larger than the initial set. It is difficult to know whether this ought to be a concern, the only other paper who report on this is the paper by Rankin and Stokes (1998), who also found that for one of their researchers (a relative novice in the use of ultrasound imaging) the repeat set of measures were larger than the initial ones. They reported that this difference was not evident in the ICC results (as was the case here) and suggested that this difference may be due to the fact that the researcher in question was a relative novice, also the case here. This result gives added weight to the recommendation that more than one statistical test for reliability should be carried out on all data, in order more fully to understand it (Bland and Altman, 1986; Rankin and Stokes, 1998; Keating and Matyas, 1998; Whittaker et al, 2007).

Each 95% confidence interval for the Bland and Altman Limits of Agreement contained the figure 0 and a range which was similar above and below 0; however the minimum of the confidence interval was slightly further away from 0 than the upper limit, again illustrating the small level of consistent systematic bias in the measurement technique, i.e. the repeat measures were consistently slightly larger than the first set of measures, which was not apparent from the ICC analysis.

Correlation between CSA and linear MRI measures of the VMO muscle

Pearson's correlation coefficients were calculated between each of the three linear measures A, B, and C and the CSA measure, as well as multiples of the linear measures with the CSA (as has been reported by others). It was felt that a minimum level of correlation of $r=0.7$ was required in order for the correlation to be considered useful, as recommended by Kline (1986) and quoted by Stokes et al (2007). Pearson's correlation coefficient levels between linear and CSA measures of 0.7 or above for various other muscles have been reported by others (Martinson and Stokes, 1991; Close et al, 1995; Rezasoltani et al, 2002; Rankin et al, 2004; Hides et al, 1994; Stokes et al, 2004).

In this work Line C exhibited the highest individual level of correlation with the CSA of the VMO muscle, as shown in Table 6.2. Each multiplication involving line measure C also produced a value greater than the $r=0.7$ threshold when correlated with the CSA. Line C was the line which was closest to measuring anterior-posterior muscle thickness, and the authors listed above have also reported that measures of muscle thickness tend to correlate meaningfully with the CSA of the muscle. Thus if only one linear measure can be taken, then the anterior/posterior thickness would be the one of choice.

One interesting point of note was that when the linear measures were multiplied together and the multiples correlated with the CSA, they did not show a higher level of correlation than Line C on its own. This was different from others who found that multiples of line measures produced a higher level of correlation with the CSA than the individual measures alone (Loo and Stokes, 1990; Stokes et al 2005). It is not clear why there was this difference. Apart from this point, these

results were in accordance with those reported by others (cited above) who also explored correlation relationships between linear and CSA measurements of other skeletal muscles.

In summary, it was established that taking CSA and linear measures from MRI scans is highly repeatable, and that there is a meaningful level of correlation between the CSA and linear measures of the VMO muscle.

9.6.2 Validity of linear and CSA measures of the VMO muscle taken from ultrasound images compared with MRI

Ultrasound images of the VMO muscle of the right knee were taken from the same 12 adult healthy recreationally active males as in the previous section. The three measures – Line A, B and C and the CSA were measured by the same investigator, tested first for intra-rater reliability and then compared with the measures taken from the MRI images. The intra-rater reliability ICC results for repeat measures from the same scan were all above the 0.9 threshold and the mean differences were all less than 1mm when compared using the Bland and Altman Limits of Agreement. The intra-rater reliability ICC results for measures taken from repeat ultrasound images were all at 0.9 or above and the mean differences ranged from 1.5 through to 3.06 mm.

These high levels of repeatability are consistent with the results reported by others (Pretorius and Keating, 2008). The results also show that the level of consistency between repeat measures taken from the same image is greater than those taken from repeat images, as would be expected due to the errors inherent in the imaging technique. However, again all ICCs met or exceeded the 0.90 threshold, although those from repeat scans did not exceed it to the same extent as when repeat measures were taken from the same scans. By default it also showed that the investigator's technique of taking ultrasound images and taking linear measures from these images was very reliable.

When the reliability of linear and CSA measures from the RUS images were compared with the reliability of measures from the MRI scans, there was a lower level of agreement and consistency than when comparing measures from the

same RUS or repeat RUS images. The threshold set for acceptability was an ICC value of 0.90. The level of agreement for line measures A and B exceeded this threshold, whereas that for Line C did not. When re-examining the US images it was clear that the superior border of the muscle had a slightly flattened appearance, which suggested that despite careful technique during the scanning procedure, too much pressure was being applied to the transducer head. This particularly affected Line C (which is a close approximation of the anterior-posterior thickness of the VMO) and accounts for the fact that on average measures of Line C taken from US images was smaller than those taken from MRI images. This affected the level of agreement between line measure C from the MRI and US images, resulting in it being only moderate (0.72) when using the definitions recommended by Portney and Watkins, (2000). However, this pressure must have been applied in a consistent way as the level of agreement between Line C from repeat RUS images exceeded the 0.9 level. This issue of applying too much pressure during the imaging process was highlighted by other authors (Dupont et al, 2001; Reeves et al, 2004; Teyhen et al, 2007).

A number of other authors also compared measures taken from images of the same muscles using both MRI and RUS, see Section 6.3.1. A review of 13 studies (Pretorius and Keating, 2008) report the analysis methods used when measures taken from MRI or CT images were compared with those taken by RUS. Ten studies reported Pearson correlation coefficient values, three also reported t-test results between mean values. However, none of these studies used Bland and Altman Limits of Agreement, which seemed surprising, given the clear purpose of the Bland and Altman Limits of Agreement is to test the level of agreement between two different measurement tools or methods, and was first published by them in 1986.

Another recent study by O'Sullivan et al (2009) examined the validity of RUS measurements of the trapezius muscle compared with MRI, for 18 healthy participants, using both Pearson's correlation, and Bland and Altman analyses. They found good correlation for muscle thickness measures from images taken at the level of T8 ($r=0.77$), with very small mean differences on the Bland and Altman tests, which were evenly distributed around and close to 0; a moderate

level of correlation from images taken at the level of T5 ($r=0.62$), a fair level of correlation for images taken at the C6 level ($r=0.52$); and no correlation for images taken at the level of T1. The authors suggest that the difference in correlation at the different spinal levels was due to the clarity of anatomical reference points, from which the images were taken.

Mendis et al (2010) compared the CSA measures of anterior hip muscles taken from both MRI and RUS muscle images. They also used ICC (model 3.1) to compare each pair of measures for each muscle and reported values of between 0.81 and 0.89 and no statistically significant differences between the mean CSA for each set of measures using images from MRI and RUS for each muscle.

Thus the results for this work again compare well with that reported by others.

9.6.3 – Effect of posture on ultrasound measures of VMO muscle size

It was necessary to establish whether there were any statistically significant differences between measurements of VMO muscle size taken in long-sitting and relaxed standing, because in order to compare the value of the Q-angle and size of the VMO muscle in a meaningful way, it would be important to have all measures taken from participants in the same posture – ideally relaxed standing. No statistically significant differences in measures taken from ultrasound images from the 12 participants in both postures. These results support the findings of Coldron et al (2003) and Ainscough-Potts et al (2005) who also found no significant effects of posture on muscle size measures for the lumbar multifidus or abdominal muscles of healthy participants respectively as long as the muscles remained relaxed.

It was thought possible that Line C of VMO might be larger when measured in relaxed standing, compared to long-sitting, due to the low-level of muscle contraction needed to maintain balance in a weight-bearing posture which is less stable than long-sitting; in accordance with the findings of Fulton, et al (2008) who explored the effect of maintaining balance on the size of the Transversus Abdominis muscle. However, there was no effect in this study.

This may be due to the fact that the VMO was relaxed during both sets of measurements (evidenced by a patella which could be moved passively) and any low-level muscle contraction required to maintain the position in weight-bearing may have come from elsewhere in the quadriceps muscle group or any contribution made by the VMO was not sufficiently great to effect a detectable difference in muscle thickness.

However, one weakness of the present study was that no reliability testing was performed to examine the reliability of the technique on different days, as all scans were taken during the same session. In order to determine whether the technique could be used to measure changes in VMO muscle size over time or in response to an intervention, between-day repeatability would need to be established.

9.7 – Correlation between Q-angle value and linear and CSA ultrasound measures of the VMO muscle in healthy participants

One of the main aims of this programme of work was to test to see if there was any correlation between the value of the Q-angle and the size of the VMO muscle. This was done, based on the assumption that muscle size is positively related to its strength and thus a larger muscle would also be a stronger muscle, as discussed in Chapter 2, Section 2.5). The Q-angle and VMO muscle size of ten healthy recreationally active males and one case study participant (equivalent to the healthy group, except with a history of PFJS, but no active symptoms for the previous two years) were studied. Each had his right Q-angle measured in relaxed standing and his right VMO muscle imaged using ultrasound, in both relaxed standing and long-sitting; using the valid and reliable measurement protocols established in Chapters 5 and 6.

No meaningful level of correlation value were found above $r=0.7$, recommended as being a minimum level of correlation useful clinically (Kline, 1986; as quoted by Stokes et al, 2007). As our measurement protocols have been established as being both valid and reliable then this suggests that Q-angle and VMO muscle size measures have no relationship with each other. However, a

moderate level of correlation between Line B and the Q-angle was found ($r=0.45$); although as there were so few participants it is difficult to draw any specific conclusions from this result. It was surprising that line B showed the highest level of correlation as in the earlier work it was Line C that had shown the highest level of correlation with the CSA, which in turn tends to be the measure that is quoted as relating more closely to muscle strength. Future work on a much larger group of participants would be interesting in order to explore this fact further.

One issue that is important to note is that all the measurement protocols devised and followed in this body of work had the quadriceps muscle relaxed – this was done for ease of consistency and standardisation of the measurement protocol, and checked by ensuring the patella was ‘loose’ and could be passively moved by the investigator. A common criticism of earlier reported measurement work has been that the state of contraction of the quadriceps muscles was not always standardised and this is discussed in Chapter 3 and Chapter 5. However, when the patella is ‘loose’ with the VMO muscle relaxed, it is less likely to have a direct effect on the position of the patella and hence the Q-angle – so by standardising the measurement protocol in this way it may have inadvertently eliminated the opportunity to capture any effect the VMO muscle has on the position of the patella and thus the value of the Q-angle. Lathinghouse and Trimble (2000) showed that for a group of 22 healthy women, there was a statistically significant decrease in the value of the Q-angle when the measure was taken while the quadriceps muscle was isometrically contracted, compared to when the quadriceps muscle was relaxed. They took all measures from video images with participants in standing, and reported reliability of their measurement testing using ICCs (intra-rater 0.98) but gave insufficient details to be able to replicate their analysis. They also quoted method error between their two sets of repeat measures of 0.37^0 .

This conundrum illustrates quite nicely the tension that exists in clinical measurement – namely the need to balance the demands of measurement rigour with the competing demands of valid and clinically meaningful measures – these two competing demands are hard to balance effectively.

9.8 – A brief illustrative case study of an individual with a history of PFJS

It was disappointing only to be able to recruit one individual as an illustrative case study participant (as explained in Chapter 8, Section 8.3), rather than a full group of 20 participants with PFJS as originally planned, however the results from that participant are interesting. The initial value for the Q-angle for the case study participant was higher (19°) than the mean for the healthy group (9°), and was higher than the highest value for a healthy participant (17°). Once the medial glide patellar tape was applied the Q-angle increased for both the case study participant (by 8°) and the healthy participants (by 13°); however once the marker which was originally on the centre of the patella was replaced due to the shift which occurred as a result of applying the tape, the resultant Q-angle for the case study participant was three degrees higher than the original value, whereas it was two degrees smaller for the healthy group. As both of these values sit within the three degrees of natural variation of the Q-angle over time identified in Chapter 7, Section 7.2, it must be concluded that these results do not show any differences between the case study participant and the healthy group. As the case study participant had had no active symptoms for two years, it is possible that he was no different from the group of healthy participants.

No significant differences between the BMI and linear and CSA measures of the VMO muscle were found in either long-sitting or standing from the healthy group and the case study participant, as shown in Tables 8.3 and 8.4.

To date most of the work reporting the use of ultrasound imaging to measure muscle size has been performed on the muscles of healthy participants, as it is necessary to understand first what the range of 'normal' is, before trying to make meaningful observations or decisions based on muscle size measures when there is pathology present. In recent years an increasing number of studies have been published showing that there is an effect on muscle size in the presence of pathology, although it is not clear which is the cause and which is the effect, assuming that muscle size is directly related. On the whole these

relate to muscle size measures of paraspinal or abdominal muscles (Hides et al, 1994; Raney et al, 2007; Fernandez-de-las-penas et al, 2008).

It would be very interesting to be able to measure the Q-angle during a functional activity as well as the size and shape of the VMO at the same time, as it is that functional real-time measurement which would be able to give definitive answers to these questions.

9.9. Limitations of the present studies

There are a number of limitations within the studies reported and discussed in this body of work, as follows:

9.9.1 – Measurement protocol, validity and reliability testing

In order to completely fulfill the requirements of measurement rigour needed to allow a measurement protocol to be accepted as both valid and reliable, there needs to be sufficient data collected to be analysed. These data need to include:

- Sufficient numbers of initial measures and testers,
- A sufficient number of repeat measures (both within and between sessions), especially on different days

For a number of the small studies reported in this thesis, i.e. establishing the measurement protocol for the Q-angle, as well as for some of the ultrasound imaging for the VMO muscle size, these requirements were not achieved.

9.9.2 – comprehensiveness of measures taken

When measuring the Q-angle over time, with participants in relaxed standing, it would have been interesting also to have measured the Q-angle with subjects in non weight-bearing e.g. long-sitting in order to compare results. The assumption used to measure the Q-angle over time in relaxed standing was that the small contractions made in order to maintain posture might affect the Q-angle, and so it would have been interesting to compare these results with measures over the same period of time in non weight-bearing.

When exploring the Q-angle during the stance phase of gait, a more comprehensive scope of measures would have enhanced our ability to understand what was happening. For example, it would have been interesting to take actual measures of knee flexion and extension rather than to make assumptions. It would also have been beneficial to have taken measures from both legs, so that comparisons could be made between them to assess symmetry.

The body mass index (BMI) data were measured for some participant groups but not all, resulting in some incomplete conclusions being able to be drawn.

9.9.3 – State of quadriceps muscles

Another weakness is that all measures taken required the relaxation of the quadriceps muscles, which inadvertently may have mitigated against learning useful information about the role of the VMO muscle in controlling the position of the patella, as the VMO was relaxed at the time. However, this was done in order to help meet the demands of measurement rigour in order to standardize the measurement protocols.

9.9.4 – Clinical participants

The case study participant did not have any active symptoms of PFJS, only a history of having symptoms, so the results can only be treated as interesting and speculative, rather than giving any definitive information. The intention to study a group of patients with PFJS in the later experiments was not feasible, so conclusions cannot be drawn about the relationship between the Q-angle and VMO muscle size, or the effects of medial glide patellar taping on the Q-angle in patients.

9.10 Summary

The initial rationale for undertaking this body of work led to several aims:

- to examine whether the Q-angle was an absolute or fixed measure or whether it had a natural variation;
- to explore the Q-angle during a functional activity; and
- to see whether the VMO muscle had an effect on the control of the position of the patella, as determined by whether there was any correlation between the value of the Q-angle and the size of the VMO muscle.

The findings show that the Q-angle did have a natural variation during a 60 second time period of relaxed standing; there was a difference in pattern of movement of the three markers from which the Q-angle is formed between healthy participants and those with PFJS, during the stance phase of gait; and there was no correlation between the size of the VMO muscle and the value of the Q-angle.

These results add to our understanding of the usefulness of Q-angle measurements made using a goniometer from participants who are in relaxed standing. This work suggests that differences in measured Q-angle of greater than 9° are required for any real differences in value to be certain. These results help to explain the generally low levels of reliability reported by the few authors who tested for reliability in their Q-angle measurement protocols. The study also characterized the VMO muscles using ultrasound imaging, showing a high correlation between its CSA and linear measurements. This work forms the basis for several avenues of future research, as outlined in the next chapter.

Chapter Ten

General Conclusions and Future Research

CHAPTER 10.0

General conclusions and future research

10.1 – Introduction

This chapter summarises the conclusions drawn from the experimental work carried out and reported in Chapters 5 through 8; and then suggests some areas for future research. It is divided into three sections:

- 10.1 – Introduction
- 10.2 – General Conclusions
- 10.3 – Areas for future research

10.2 – General Conclusions

1. It was possible to develop a protocol to measure the Q-angle of participants in relaxed standing, using the Peak Video Motion Analysis system, with a variability of one degree or less
2. The Q-angle varies, on average by between 3.0 and 4.0, degrees during the 60 seconds it typically takes to make the measure in the clinical situation, and thus when measuring the Q-angle in the clinical situation it should not be seen as an absolute or unvarying measure, but a snapshot in time of its value
3. There were differences as well as similarities in the pattern of movement of the three markers from which the Q-angle is formed, between healthy participants and those with PFJS, when viewed from the sagittal and frontal planes during the stance phase of gait:
 - Sagittal plane – participants with PFJS walked with a straighter knee than healthy participants
 - Frontal plane – participants with PFJS had a lower mean Q-angle than healthy participants at the start, it then increased

and remained a few degrees above that for the healthy group, increasing again during the terminal phase

- Participants with PFJS on average spent a shorter time in weight-bearing on their affected leg compared with the healthy participants.
4. The Q-angle for the majority of healthy participants followed the expected pattern of variation during the stance phase of gait – being at its maximum value at heel strike and at its minimum value at toe-off, although a limitation is that actual knee flexion angles were not measured
 5. There was no meaningful correlation between the maximum or minimum values of the Q-angle and the amount of sub-talar joint pronation during the stance phase of gait, for healthy participants
 6. The application of McConnell's medial glide patellar tape to ten healthy participants significantly altered the value of their Q-angle
 - The tape maintained its effect on the Q-angle after a period of 5 minutes cycling at a speed of between 45 and 50 rpm
 - For some participants the application of the tape appeared to move the skin medially, rather than the patella itself
 7. Real-time ultrasound imaging was demonstrated to be a valid and reliable tool for measuring the size of the VMO muscle, when compared with the acknowledged 'gold standard' of MRI
 8. There was a clinically acceptable level of correlation between the CSA and linear measures of the VMO muscle ($r > 0.7$); allowing linear measures to be used instead of CSA measures if necessary
 9. There was no effect of posture on the linear and CSA measures of the VMO muscle obtained from ultrasound images of healthy participants whether imaged in long-sitting or relaxed standing, this demonstrated the utility of ultrasound for studying the VMO in a functionally relevant posture and enabled comparisons to be made between VMO muscle size and the Q-angle
 10. There was no meaningful correlation between the value of the Q-angle (measured in relaxed standing) and the linear or CSA measures of the

VMO muscle of ten healthy recreationally active males, all values were less than the Pearson's correlation coefficient threshold level of $r=0.7$ set

11. There was no difference between any of the measures of Q-angle and VMO muscle size between the ten healthy recreationally active males and the illustrative case study participant, with a history of PFJS but no current symptoms

10.3 – Areas for future research

Having formed the conclusions listed above it would be interesting to apply all measurement protocols to participants with PFJS, as most of the work reported here was carried out on healthy participants, as well as explore several other areas of related work, especially to address the following to answer these questions:

1. Does the Q-angle of individuals with PFJS also vary during a 60 minute period, when measured with participants in relaxed standing, and if so, is the level of variation the same as that for healthy individuals?
2. Is it possible to establish a measurement protocol to help understand the effect on the Q-angle of rotational movements (transverse plane) of the femur, pelvis, tibia and foot that occur during the stance phase of gait?
3. Is the size and shape of the VMO muscle of individuals with PFJS the same as that for healthy individuals, and are there useful levels of correlation between its linear and CSA measures?
4. Is it possible to establish a standardised measurement protocol, using ultrasound, to measure VMO muscle size which includes some contraction of the quadriceps muscle, in order to gain more insight into the active effect of the VMO on the patella?
5. Is it possible to use functional MRI equipment to image the Q-angle and VMO muscle during weight-bearing and flexion/extension of the knee joint, and thus see in real-time if/how the VMO controls the position of the patella?
6. Does the medial glide patellar tape maintain its effect on the Q-angle after a longer period of exercise e.g. 30 minutes?

Managing the tension between the measurement rigour rightly seen as necessary for decision making, with the need for measurement protocols that can be applied in the clinical situation will continue to be an interesting challenge. Forming a consensus of opinion about what is fundamental and essential information i.e. the very essence required for a particular measurement, including an accepted level of variability and understanding of the context in which the measure is taken and the judgement, skill and capability needed by those taking the measurement will continue to energise individuals as we seek to establish an acceptable balance between the two valid and competing ends of the same spectrum.

Appendices

Process of digitisation using the Peak and Vicon imaging systems

Once filming was completed the video tape (when using the Peak system) was then replayed to ensure all relevant data had been captured, and then the data was filtered using the Butterworth filter, this is a 'second order low pass' filter which cleaned the data at a frequency of 12 Hz, following manufacturer's guidelines. The data were then digitized using one of two processes – manual or automatic.

- The manual process required the operator to place the cursor on the computer screen on the centre of each reflective marker and click on it using the mouse, this information was then transferred to the Peak software and the Q-angle data calculated.
- The automatic process required the operator to manually digitize the first frame of all reflective markers and then the software automatically would search and find all subsequent markers and transfer their position detail to the relevant software, from which the Q-angle data was calculated. In most cases when the automatic digitization process was used there were some markers which were not found by the process and these were registered as 'missing data' and were manually digitized by the operator.

Following the digitization process the software then used direct linear transformation (DLT) to calculate the position of the markers relative to the calibration rod or frame.

Professor Roger Briggs Head of School

University of Southampton Highfield Southampton SO17 1BJ United Kingdom
Tel +44 (0)23 8059 2142
Admissions +44 (0)23 8059 5260
Fax +44 (0)23 8059 5301
Email sotpadm@soton.ac.uk
Web www.sohp.soton.ac.uk/sohp/

Email: Secretary:

Volunteers Wanted for research into anterior knee pain!

- Are you male, healthy and aged 18-35 years?
• Would you be willing to have an MRI scan and Ultrasound scan taken of your right leg?

NB: We can pay all travel expenses

Diagram of vastus medialis muscle and text box detailing the research procedure: Where and What? - Southampton General Hospital to have an MRI scan of your right leg... Why? - We will then compare the results of the 2 measurements to see if those from the Ultrasound scan are as accurate as those from the MRI scan.

- If you are interested then please contact – Fleur Kitsell on 01962 – 892697
• (Approved by Southampton and South West Hants Research Ethics Committee – 05/Q1702/160)

R&D PROJECT DETAIL FORM

R&D No: RHM

R&D OFFICE USE ONLY

HCS 0153

Date Received:

Finance:

IPR:

NRR (Tick) Yes : No:

15 NOV 2005

**PLEASE COMPLETE IN TYPESCRIPT OR IN BLACK INK AND BLOCK CAPITALS
REFER TO GUIDANCE NOTES TO ASSIST COMPLETION
PLEASE DO NOT LEAVE ANY BLANKS - PLEASE INDICATE A BLANK FIELD WITH "N/A"**

PART A - LOCAL PERSONNEL

Principal or Chief Local Investigator:

Title: Ms First Name: Fleur Surname: Kitsell

PART B - PROJECT DESCRIPTION

Study Type:
(Tick one as main study type)

Before-After Trial		Case Control		Case Note Review	
Cohort Observation		Interviews		Database Analysis	
Epidemiology		Questionnaire		Laboratory Study	x
Participant Observation		Cross-Sectional		Re-Analysis of Data	
Randomised Controlled Trial		Controlled Trial without randomisation		Other: (specify)	

Is this a pilot study?

Other? (e.g. Investigator-Led; Phase I/II/III, Mechanistic; IMP)

PART C ORGANISATIONAL LOCATION IN SOUTHAMPTON (The completion of this section is mandatory)

NHS Trust: (please tick) Directorate: (please tick) NHS/Academic Programme: (please tick)

SUHT	<input checked="" type="checkbox"/>	Cancer Care		Allergy and Inflammation Sciences	
Soton City PCT		Cardiothoracic		Bone and Joint	
West Hants NHS Trust		Child Health		Cancer Sciences	
		Clinical Support		Cardiovascular	
		Critical Care		Endocrinology & Metabolism	
		Head & Neck		Health Services Research	
NHS Inpatients		Medicine/Elderly Care		Human Genetics	
NHS Outpatients	<input checked="" type="checkbox"/>	Neurosciences		Human Nutrition	
NHS Day Patients		Obstetrics & Gynae		Maternal and Fetal Physiology	
WTCRF		Ophthalmology		Mental Health	
General Practice/Health Centre		Trauma & Orthopaeds	<input checked="" type="checkbox"/>	Molecular Biology & Infection	
RCMB CIU		Pathology		Neurosciences	
Other: (specify)		Radiology		Respiratory Cell and Molecular Biology	
		Surgery		Tissue Remodelling and Repair	
		Other: (specify)		National Cancer Research Network	
				Stroke Recovery	
				Non-programme	
				Other: (specify) PhD project - The mechanics of patello-femoral joint dysfunction - the usefulness of the Q-angle.	

PART D – NATIONAL PRIORITY AREAS (The completion of this section is mandatory)

APPENDIX A

Please indicate which priority areas your study falls within (tick more than one if appropriate):

Cancer	<input type="checkbox"/>	Coronary Heart Disease	<input type="checkbox"/>	Children's Services	<input type="checkbox"/>
Diabetes	<input type="checkbox"/>	Emergency Care	<input type="checkbox"/>	Mental Health	<input type="checkbox"/>
Older People	<input type="checkbox"/>	Primary Care	<input checked="" type="checkbox"/>	Reducing Inequalities	<input type="checkbox"/>
Waiting Times	<input type="checkbox"/>	Improving the patient experience	<input type="checkbox"/>	Building capacity to deliver health & social care	<input type="checkbox"/>
Renal Disease	<input type="checkbox"/>	Respiratory Disease	<input type="checkbox"/>	Chronic neurological disease	<input type="checkbox"/>

PART E – SPONSORS & FUNDERS

Project's main funding category:
(please tick as many boxes as apply)

	<u>Non-Commercial, Externally Funded</u>	<u>Own Account</u>
Commercially Funded	<input type="checkbox"/>	Research Council <input type="checkbox"/> DH/NHS <input type="checkbox"/> Trust <input type="checkbox"/> University <input type="checkbox"/>
Altruistic (commercial but not for commercial gain)	<input type="checkbox"/>	Other Government <input type="checkbox"/> Charity <input checked="" type="checkbox"/> Other (Please specify) <input type="text"/>

Funders:

Funder Name	Funder Reference (if any)	Local organisation receiving grant:	Sum Awarded	Funding Start Date	Funding End Date
PPEF		PhD Student – University of Southampton	£5,670	1 Sept '05	31 Aug '06

Funding Allocation:

	Year 1	Year 2	Year 3	Year 4	Year 5	TOTAL
SUHT	N/A					
UNIV	N/A					

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PART F – USE OF NHS RESOURCES

The following information is necessary to help the Trust manage its R&D budget allocation. All research costs borne by the NHS must be identified, to ensure that our R&D budget allocation is adequate, and that it is appropriately distributed amongst the directorates. If you need help with this section of the form, please contact R&D Finance Manager, on x5146.

NOTE: The part of the study based at SUHT is for study participants to attend and receive an MRI scan on their leg. As a result of negotiation with the Medical Physics and Bioengineering department a fee per scan has been agreed which will cover all costs relating to the scan. The lead investigator will recruit participants to the study.

Please give an estimate below of the local site **NHS resources** involved in setting up the project, and those likely to be involved in the analysis and write-up.

Staff type/grade/name	Set-up hours	Analysis & write up (Hours)	WTCRF (Tick if yes)	Costs fall to NHS? (tick if yes or indicate %)

Subjects:

Please indicate in the tables below all of the additional NHS resources, over and above standard or routine care, that will be required to undertake the research.

Indicate if the information is given per participating subject(S) or per project (P).

Please estimate the number of participants to be recruited in the local site for each financial year (1st April to 31st March)

Total Number of Participants	Financial Year 2005/2006	Financial Year 2006/2007	Financial Year 2007/2008	Financial Year 2008/2009	Financial Year 2009/2010	Financial Year 2010/2011
12	12					

a) Direct Staff costs (Include all NHS staff time that may be involved, including the co-investigators, research nurses allied health professionals involved in treatment and the time for project management and supervision.)

Staff type/grade/name	Hours	Indicate 'S' or 'P' S = subject P = project	WTCRF (tick if yes)	Costs fall to NHS? (tick if yes or indicate %)
See note above				

b) Direct non-staff costs (Include any additional consumables, over and above those used in routine care, that will be provided by the NHS. This can include printing, stationery, books, conferences, consumables (catheters, forceps etc)

Item	Quantity Used	Indicate 'S' or 'P' S = subject P = project	Cost per item (if known)	Costs fall to NHS? (tick if yes or indicate %)
See note above				

c) NHS equipment used for research

Item	Location e.g. WTCRF	Purchase cost (if known)	Hours used (per week or per subject)	Indicate 'S' or 'P' S = subject P = project	Costs fall to NHS? (tick if yes or indicate %)
See note above					

d) Additional facility costs arising from the involvement of participants in research (Include additional activity [e.g., outpatient sessions, day case attendances, inpatient day], over and above routine care, that may be required as a result of the project. This should include sessions in the WTCRF in the appropriate column)

Mode of Attendance	Number of additional visits, attendances or days		Number of patients		Costs fall to NHS? (tick if yes or indicate %)
	WTCRF	Non WTCRF	WTCRF	Non WTCRF	
Outpatient visits					
Day case attendances					
Extra in-patient days					
Operating theatre sessions					
Other (specify)					

e) Support departments (Include additional diagnostic support services, over and above routine care, that may be required as a result of the project.) All costs to be obtained from the supporting directorate involved.

Support Service	Type and volume of service	Cost per subject or project	Indicate if cost 'S' or 'P'	Costs fall to NHS? (tick if yes or indicate %)
Pharmacy	N/A			
Radiology	See note above			
Pathology	N/A			
Other				

PART G – PROJECT REGISTRATION & APPROVALS (The completion of this section is mandatory)

Directorate Approval
(Please tick as appropriate)

Directorate Peer Review	<input type="checkbox"/>
External Grantor	<input type="checkbox"/>
Commercial	<input type="checkbox"/>

(The protocol conforms to ICH GCP and has been scientifically reviewed)

For non-commercial research please attach copy of peer review report form or other evidence of peer review.

As R&D Co-ordinator I confirm that the research has been discussed and appropriately reviewed

Date: 5/10/05 Print Name: [Signature] ✓

Job Title: Consultant Radiologist, Lead Co-ordinator Signature: [Signature]

Supporting Directorate Approval

The supporting directorate will provide the information necessary to complete Section (e) of Part G of the Project Detail Form. Please tick and name person contacted to confirm that agreement & costs have been established (if applicable). For Pharmacy please note that a signature is required.

Supporting Directorate	Yes	Name
Radiology	<input type="checkbox"/>	
Pathology	<input type="checkbox"/>	
Other (please specify)	<input type="checkbox"/>	
Other (please specify)	<input type="checkbox"/>	
Pharmacy	<input type="checkbox"/>	Signature: _____ Date: _____

Financial Probity

NHS support costs as identified on project detail form will be met from: (Please tick below)

Directorate / SUHT R&D Budget:	<input type="checkbox"/>
External, Non-Commerically Funded	<input type="checkbox"/>
Commercial Sponsor:	<input type="checkbox"/>

Please obtain the signature of the Clinical Service Director

I confirm as CSD that this research can take place

Date: _____ Print Name: _____

Job Title: _____ Signature: _____

Please send this completed & signed form, a copy of your completed ethics form, as well as your peer review report form, to the R&D office, Trust Management Offices, Mailpoint 18, SGH

FOR OFFICE USE: *Please sign to confirm all paperwork has been checked for accuracy*

Signature: W. ROSENBERG Position: Director of R & D Date: _____

Signature: M.G. CAWTE Position: R&D Finance Administrator Date: 10/11/05

SUPPORT FOR SCIENCE: PRIORITIES & NEEDS:

no costs
just student
time
26/1

PLEASE NOTE THAT THE FULL APPROVAL CANNOT BE GRANTED WITHOUT A COPY OF A COMPLETED ETHICS FORM (PARTS A, B & C)

APPENDIX 11

Information Management & Technology Directorate

Data Protection Office

Old Nurses Home, Mailpoint 79

Southampton General Hospital

Tremona Road

Southampton SO16 6YD

Tel: 023 8079 5079

Fax: 023 8079 4741

e-mail address: Danni.Howe@suht.swest.nhs.uk

20 July 2005

Data Protection Reference No: DP 0116/05

Fleur H Kitsell
Wessex Deanery
Highcroft
Romsey Road
Winchester
SO22 5DH

Dear Fleur,

Research & Development Number: RHM HOS 0153 – The mechanics of patello-femoral joint dysfunction

Thank you for returning the Data Protection Guidance pack duly completed as part of the Ethics Committee submission.

I am pleased to advise you that you comply with the principles of the Data Protection Act 1998 and the response will be held on file within this department. Please ensure that data is anonymised, secure, password protected and cannot be accessed by any unauthorised person.

If I can be of any further assistance, please do not hesitate to contact me.

Yours sincerely,

Dannie Howe
Data Protection Officer
Corporate Information Services Directorate

copy to: Research & Development Department

Data Protection Notice:

Your response will be held in the Corporate Information Directorate. You have the right to apply for a copy of your information and to have any inaccuracies corrected.

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University
of Southampton

APPENDIX A2

Southampton 

University Hospitals NHS Trust

Research Governance Office

Legal Services
Room 4033, Building 37
University Road
Southampton
SO17 1BJ
Tel: 023 8059 8848/9
Fax: 023 8059 5781

Directorate of Clinical Governance

Mailpoint 18
Southampton General Hospital
Tremona Road
Southampton
SO16 6YD
Tel: 023 8079 4519
Fax: 023 8079 8678

21st November 2005

Dear Ms Fleur Kitsell

**RE: NHS Research Governance and identification of nominated
Research Sponsor**

'The mechanics of patello-femoral joint dysfunction - the usefulness of the Q-angle'

(SUHT R&D ref: HOS 0153 – UoS ref: 3807)

We are writing to confirm that Southampton University Hospitals NHS Trust and the University of Southampton, are prepared to act as co-sponsors for this study under the terms of the Department of Health Research Governance Framework (RGF) for Health and Social Care.

Both organisations fulfil the role of research sponsor in ensuring management, monitoring and reporting arrangements for research. We understand that you will be acting as the Chief Investigator responsible for the daily management for this study, and that you will be providing regular reports on the progress of the study to SUHT on this basis.

We would like to take this opportunity to remind you of your responsibilities under the terms of the RGF and encourage you to become fully conversant with the Research Governance Framework on Health and Social Care document, which is available from the following link:

www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/

Please do not hesitate to contact us should you require any additional information or support. May we also take this opportunity to wish you every success with your research.

Yours sincerely,

Research Governance Manager
University of Southampton

Professor William Rosenberg
Director Research and Development
Southampton University Hospitals
NHS Trust

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Fleur Kitsell
3 Bay Tree Yard, Off West Street, Alresford, Hants. SO24 9UJ

Ms Anne Drummond
Physiotherapy Manager
Southampton General Hospital
Tremona Road
Southampton
Hants. SO16 6YD

19 June 2006

Dear Anne

Re Project: Mechanics of the patello-femoral joint – the usefulness of the Q-angle.

Following on from my letter of February, I'm now in a position to recruit volunteers with non-traumatic patello-femoral joint syndrome (PFJS), from your triage clinics.

I enclose a poster and participant information sheet, and ask that you display these in the clinic area, and let me know when it would be convenient for me to come and talk to the physiotherapy staff in the triage clinics to explain the project and seek their assistance in identifying possible suitable participants.

I hope this is all satisfactory.

With kind regards.

Fleur Kitsell MSc MCSP
Part-time PhD student

Enc



Professor Roger Briggs Head of School

University of Southampton	Tel +44 (0)23 8059 2142
Highfield	Admissions +44 (0)23 8059 5260
Southampton	Fax +44 (0)23 8059 5301
SO17 1BJ	Email sotpadm@soton.ac.uk
United Kingdom	Web www.solhp.soton.ac.uk/solhp/

Email:
Secretary:

PARTICIPANT INFORMATION SHEET

Study title – Mechanics of the patello-femoral joint – usefulness of the Q-angle.

You are being invited to take part in a research study. Before you decide 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 us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

1.0 – What is the purpose of the study?

Many people suffer from pain in the front of their knee which is thought to be due to a problem with the knee-cap (patella) moves when their knee bends and straightens. Our understanding of what causes these symptoms and how best to treat them is not clear. There are many theories of possible causes and claims for effective treatment, but little good quality evidence to support these claims. One theory is that the size of a muscle on the inside of the thigh, just above the knee cap (vastus medialis) may be important, and so it is essential that we have accurate and reliable methods of measuring this muscle. We know that magnetic resonance imaging (MRI) scans are accurate and reliable, but they are expensive and time-consuming and so we plan to compare this method with another method using Ultrasound. The advantage of Ultrasound is that the equipment is much cheaper and the procedure is much quicker.

Twelve individuals (10 who are healthy and 2 who have symptoms of Patello-femoral joint syndrome (PFJS) will have their vastus medialis muscle (VM) measured. Measurements will be taken with MRI and ultrasound. The results will be compared and if we find that measurements taken from the ultrasound images are just as accurate and reliable as those taken with the MRI scanner then we will be able to use ultrasound in future studies.

Once we had decided which is the most appropriate tool to measure the vastus medialis muscle, the second part of the research is for 20 individuals who have PFJS and 10 healthy individuals to have a series of measurements taken in order for us to try and understand which are useful measurements which show differences between healthy individuals and those with PFJS. These measurements are:

- *Pain – in relaxed standing, during walking, during resisted concentric and eccentric contraction, and while stepping down from an 8 inch high step; using an 11-point numerical rating scale;*
- *Q-angle – during relaxed standing using the Peak Motus Video Motion analysis system;*
- *Pattern of movement of the three points from which the Q-angle is determined, during the stance phase of gait from the frontal and sagittal planes, using the Peak Motus Video Motion analysis system;*
- *VM muscle size using MRI or ultrasound being dependent on the outcome of the first study;*
- *Quadriceps torque – during both concentric and eccentric resisted contractions; using the Biodex dynamometer; and*
- *Timing of onset of VM and vastus lateralis (VL) muscle activity while stepping down from an 8 inch high step; using a surface-electrode electromyography (EMG) measurement system.*

NB: - the Q-angle gives information about how the kneecap (patella) sits on the front of the knee.

APPENDIX C

One common treatment for this condition is the use of tape across the knee-cap which is believed to help it move more normally and also to relieve pain. In order to try and understand whether or not taping does do this, we will take two sets of the above measurements, one with tape applied and one without.

2.0 – Why have I been chosen?

You have been chosen because you fit the criteria for our study which are –

- you are male and aged between 18 and 35 years and are healthy, or
- you are male and aged between 18 and 35 years and have symptoms of PFJS, and are otherwise healthy

3.0 – Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form. You will be free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. If you would like further general information on taking part in research, there is a charity called 'Consumers for Ethics in Research (CERES) who publish a leaflet called 'Medical Research and You' which you may find interesting to read. Their address is – PO Box 1365, London, N16 0BW; and their website address is – info@ceres.org.uk.

4.0 – What will happen to me if I take part?

You will need to attend the MRI suite at Southampton General Hospital and will have an MRI scan taken of your affected leg or your right leg if you do not have any symptoms of PFJS. This will take approximately 45 minutes. You will also need to attend the Biomechanics Laboratory at the School of Health Professions and Rehabilitation Sciences to have an ultrasound image taken of your vastus medialis muscle, near the knee, taken on the same leg. This will take approximately 15 minutes.

I also need a group of people to attend the Biomechanics Laboratory at the School of Health Professions and Rehabilitation Sciences for a further set of measurements, on your affected or right leg. You will need to wear a pair of shorts, and undertake the following tasks:

- Walk up and down a 10m walkway with 3 reflective markers placed on the front of your leg so we can film the way the markers move as you walk. You will be videoed from the waist downwards, so will not be able to be identified from the video tape.
- Sit on a machine, and bend and straighten your leg against a weight, this will enable us to measure how strong the muscles on the front of your thigh are.
- Step down from an 8-inch high block, with EMG electrodes stuck on the front of your thigh to measure when the particular muscles start to work.
- We then will put the tape on your knee cap and get you to repeat all of the above activities.

This whole process should take about 1 hour and 45 minutes

5.0 – What do I have to do?

Attend the MRI suite at the hospital and the Biomechanics Laboratory at the School of Health Professions at the University of Southampton, please bring along a pair of shorts, so that we can see the thigh and knee of your affected leg, if you have PFJS, or your right leg if you are completely healthy. We also ask that you do not participate in any sport during the previous 24 hours.

6.0 – What are the possible disadvantages and risks of taking part?

There are no known risks from any of the measurement tools being used in this study. However, if you are one of the participants with PFJS, you may find that some of the above activities will reproduce your knee pain or give you some discomfort, if that happens then you will be asked to stop the activity at that point.

7.0 – What are the possible benefits of taking part?

There will be no particular benefit to you from taking part in this study, however the information we get may help us to treat people with patello-femoral joint syndrome (PFJS) more effectively in the future.

8.0 – What if something goes wrong?

If you have any concerns about any aspect of the way you have been approached or treated during the course of this study, please notify the University of Southampton and/or the Southampton University NHS Trust. normal National Health Service complaints mechanisms are available to you.

9.0 – Will my taking part in this study be kept confidential?

Yes, all information collected about you during the study will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it.

10.0 – What will happen to the results of the study?

This study is the final piece of a body of work for a PhD, which is due to be finished by the autumn of 2007 and results from the study within it will be submitted for publication in Physiotherapy and Sports Medicine Journals and presented at Physiotherapy conferences. If you would like a copy of any of these planned publications then please let me know. All data in publications will be anonymised.

11.0 – Who is organising and funding the research?

This particular study *is being organised by the University of Southampton* and funded by the Private Physiotherapy Education Foundation (PPEF), this funding covers the cost of the MRI and ultrasound scans and also enables us to refund your travel expenses.

12.0 – Who has reviewed the study?

This study has been reviewed by the two PhD supervisors, two senior members of the academic staff at the School of Health Professions and Rehabilitation Sciences at the University of Southampton, the Trustees of the PPEF and the Southampton and South West Hants Local Research Ethics committee.

13.0 – Contact for Further Information

If you would like to know any further information about this study then please feel free to contact myself the researcher – Fleur Kitsell, *or my supervisor - Professor Maria Stokes* – in the following ways:

Fleur Kitsell:
Phone – 01962-738806
Email – fhk51@soton.ac.uk

Professor Maria Stokes:
Phone – 02380-592142
Email – m.stokes@soton.ac.uk

Thank-you very much for reading this information sheet, and for considering participating in this study.

If you do choose to participate you will be given a copy of this participant information sheet and a signed consent form to keep.

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Professor Roger Briggs Head of School

University of Southampton
Highfield
Southampton
SO17 1BJ
United Kingdom

Tel +44 (0)23 8059 2142
Admissions +44 (0)23 8059 5260
Fax +44 (0)23 8059 5301
Email sotpadm@soton.ac.uk
Web www.sohp.soton.ac.uk/sohp/

Email:
Secretary:

Centre Number:
Study Number:
Participant Identification Number for this trial:

CONSENT FORM

Title of Project: Mechanics of patello-femoral joint dysfunction – usefulness of the Q-angle.

Name of Researcher: Fleur Kitsell

Please initial box

1. I confirm that I have read and understand the participant information sheet dated Jan '06 for the above study and have had the opportunity to ask questions.
2. I confirm that I am happy to be video-taped while walking along a walkway, I understand that the video will be from the waist downwards, and therefore I will not be able to be identified from it.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand that sections of any of my medical notes may be looked at by responsible individuals from the Physiotherapy Department. I give permission for these individuals to have access to my records.
4. I agree to take part in the above study.

Name of Participant

Date

Signature

Name of Person taking consent
(if different from researcher)

Date

Signature

Researcher

Date

Signature

1 for patient; 1 for researcher; 1 to be kept with hospital notes

(version 3 – Jan '06)

Nov '05

05/01702/160
APPENDIX E

Online Form

APPLICANT'S CHECKLIST

All studies except clinical trials of investigational medicinal products

REC Ref: 05/01702/160

Short Title of Study: Mechanics of the patello-femoral joint – usefulness of the Q-angle

CI Name: Ms Fleur Helen Kitsell

Sponsor: University of Southampton

Please complete this checklist and send it with your application

- Send ONE copy of each document (except where stated)
- ALL accompanying documents must bear version numbers and dates (except where stated)
- When collating please do NOT staple documents as they will need to be photocopied.

Document	Enclosed?	Date	Version	Office use
Covering letter on headed paper	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No			
NHS REC Application Form, Parts A&B	Mandatory			
NHS REC Application Form, Part C (SSA)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No			
Research protocol (6 copies) or project proposal	Mandatory			
Summary C.V. for Chief Investigator (CI)	Mandatory			
Summary C.V. for supervisor (student research)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No			
Research participant information sheet (PIS)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No			
Research participant consent form	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No			
Letters of invitation to participants	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
GP/Consultant information sheets or letters	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
Statement of indemnity arrangements	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No			
Letter from sponsor	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
Letter from statistician	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No			
Letter from funder	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No			
Referees' or other scientific critique report	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No			
Summary, synopsis or diagram (flowchart) of protocol in non-technical language	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
Interview schedules or topic guides for participants	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
Validated questionnaire	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
Non-validated questionnaire	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
Copies of advertisement material for research participants, e.g. posters, newspaper adverts, website. For video or audio cassettes, please also provide the printed script.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No			

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WELCOME TO THE NHS RESEARCH ETHICS COMMITTEE APPLICATION FORM

This page is important. An application form specific to your project will be created from the answers you give.

1. Select one research category from the list below:

- Clinical trials of investigational medicinal products (including phase 1 drug development)
- Clinical investigations of medical devices
- Research administering questionnaires for quantitative analysis
- Research involving qualitative methods only
- Research limited to taking and working with new samples
- Non-interventional research

If your work does not fit any of these categories, select the option below:

- Other research

1a. Please answer the following questions:

a) Does your study involve the use of any radiation?	<input type="radio"/> Yes	<input checked="" type="radio"/> No
b) Will you be taking new samples?	<input type="radio"/> Yes	<input checked="" type="radio"/> No
c) Will you be using existing samples?	<input type="radio"/> Yes	<input checked="" type="radio"/> No

2. Is your research confined to one site?

Yes No

3. Does your research involve work with prisoners?

Yes No

4. Does your research involve adults unable to consent for themselves through physical or mental incapacity?

Yes No

5. Is your work an educational project?

Yes No

6. Is your project an audit or service evaluation?

Yes No

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NHS Research Ethics Committee **NHS**
Application form

This form should be completed by the Chief Investigator, after reading the guidance notes. See glossary for clarification of different terms in the application form.

Short title and version number: (maximum 70 characters – this will be inserted as header on all forms)
Mechanics of the patello-femoral joint – usefulness of the Q-angle

Name of NHS Research Ethics Committee to which application for ethical review is being made:
Southampton & South West Hampshire

Project reference number from above REC:

Submission date:

RESEARCH INFORMATION

A1. Title of the research

Full title: The mechanics of patello-femoral joint dysfunction – the usefulness of the Q-angle.

Key words: mechanics, patello-femoral joint, Q-angle

A2. Chief Investigator

Title: Ms

Forename/Initials: Fleur Helen

Surname: Kitsell

Post: PhD Student

Qualifications: MSc MCSP Cert Ed (FE)

Organisation: University of Southampton

Address: (Home) 3 Bay Tree Yard,
Off West Street, Aresford,
Hants.

Post Code: SO24 9UJ

E-mail: fhk51@hotmail.com

Telephone: 07730-938644

Fax:

A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application

A3. Proposed study dates and duration

Start date: 01/08/2005

End date: 31/10/2006

Duration: Months: 15 ; Years:

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A4. Primary purpose of the research: *(Tick as appropriate)*

- Commercial product development and/or licensing
- Publicly funded trial or scientific investigation
- Educational qualification
- Establishing a database/data storage facility
- Other

A6. Does this research require site-specific assessment (SSA) of each research site? *(Advice can be found in the guidance notes on this topic.)*

Yes No

If No, please justify:

All testing will take place in the MRI suite at the SGH site and in the Biomechanics Laboratory in the School of Health Professions and Rehabilitation Sciences at the University of Southampton. Recruitment of patients is from orthopaedic triage clinics held at the SGH (Southampton Hospital University Trust) and the Stoneham Centre (Southampton City PCT).

If Yes, Part C of the form will need to be completed for each research site and submitted for SSA to the relevant Local Research Ethics Committee. Do not submit Part Cs for other sites until the application has been booked for review and validated by the main Research Ethics Committee.

Management approval to proceed with the research will be required from the RD Department for each NHS care organisation in which research procedures are undertaken. This applies whether or not the research is exempt from SSA.

A7. What is the principal research question/objective? (Must be in language comprehensible to a lay person.)

The overall aim of this work is to gain a greater understanding of the mechanics of the patello-femoral joint and in particular the usefulness of the Q-angle measure.

The overall question is –

Does the Q-angle value correlate with any of the following measures?

- a) size of the Vastus Medialis Oblique (VMO) muscle
- b) degree of retro-patellar and/or peri-patellar pain
- c) quadriceps muscle strength
- d) timing of onset of EMG activity of the VMO and Vastus lateralis muscles during a step-down test

A8. What are the secondary research questions/objectives? (If applicable, must be in language comprehensible to a lay person.)

As part of the above additional questions are –

- a) do linear and cross-sectional area (CSA) measures of the VMO muscle correlate sufficiently ($r > 0.7$)
- b) do linear measures of the VMO taken by MRI and Ultrasound correlate sufficiently ($r > 0.9$)
- c) does medial glide patellar tape alter the value of the Q-angle, when applied to individuals with PFJS

A9. What is the scientific justification for the research? What is the background? Why is this an area of importance? (Must be in language comprehensible to a lay person.)

Individuals with patello-femoral joint syndrome (PFJS) are numerous with cited incidence rates of between 3% and 25% in young adults, yet its cause remain poorly understood. The main symptoms are pain underneath and around the patella, which are typically provoked by activities involving knee flexion. In the absence of other anatomical abnormalities it is thought that the pain is related to how the patella moves on the femur during knee flexion and extension, although it is not clear whether this is a cause or effect of PFJS. The Q-angle is believed to be a measure of patello-femoral joint mechanics; it is a 2-dimensional frontal plane measure with its value being greatly affected by the position of the patella. It is thought that the value of the Q-angle is helpful in determining treatment options for patients with PFJS. Many authors suggest that a Q-angle value above 15 degrees suggests that the patella is not sitting on the femur in a normal position, although this is contradicted by other studies. In addition to pain, individuals with PFJS are also thought to have weakness and atrophy of their quadriceps muscles, as well as an altered pattern in the timing of the activity of the medial (VMO) and lateral components of the muscle. A commonly used physiotherapy intervention to treat patients with PFJS is medial glide patellar taping, which is thought to normalise the position of the patella, alter the way it moves and thus reduce the symptoms. However, again, the literature here is contradictory.

A10. Give a full summary of the purpose, design and methodology of the planned research, including a brief explanation of the theoretical framework that informs it. It should be clear exactly what will happen to the research participant, how many times and in what order. Describe any involvement of research participants, patient groups or communities in the design of the research.

This section must be completed in language comprehensible to the lay person. It must also be self-standing as it will be replicated in any applications for site-specific assessment on Part C. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.

This study is in two parts, the first part (Study A) is a methodological study and will involve 12 individuals – 10 who are healthy and 2 who have patello-femoral joint syndrome (PFJS). It has 2 purposes –

- a) to determine the level of correlation between linear measures of the vastus medialis (VM) muscle and its corresponding cross-sectional area, with data taken from MRI images;
- b) to determine whether linear measures of the VM muscle taken from ultrasound images are as accurate as those taken from MRI images.

Previous studies on other muscles (multifidus, masseter, the anterior tibials, and the quadriceps as a group) have each shown that there is a correlation between linear and cross-section area measures, but that it varies between muscles. Each subject will have their VM muscle imaged by both MRI and ultrasound. Previous studies on other muscles have also

shown that linear measures from both MRI and ultrasound images are sufficiently in agreement with each other to be used interchangeably.

Subjects will attend the MRI suite at SUHT and will have an MRI scan taken of their quadriceps muscle, by the radiography team, this will take approximately 45 minutes. They will also have an ultrasound scan taken of their vastus medialis muscle by the chief investigator who is a physiotherapist trained and experienced in the use of muscle imaging with ultrasound, this will take approximately 15 minutes. Three subjects will have an additional 2 ultrasound scans taken on separate occasions for a small reliability study.

The second part of the study is to determine whether there is any correlation between the Q-angle value, of individuals with PFJS, and other key measurements, namely: the size of the VM muscle, the level of pain suffered, the strength of the quadriceps muscle and the timing of the onset of surface EMG activity of the medial and lateral aspects of the quadriceps muscle. Also to see whether the application of medial glide patellar tape alters the value of the Q-angle. Twenty individuals with PFPS will be recruited along with ten healthy controls.

The protocol for study B will vary depending on whether MRI or ultrasound imaging is used to measure VM muscle size. If ultrasound imaging can be used, then all measurements can be taken in the School of Health Professions, Biomechanics Laboratory, at the University of Southampton; each subject will need to attend for approximately two hours. Firstly they will have relevant anthropometric measures of: body weight, height, lower limb leg length taken; and then specific measurements taken under 2 conditions – with McConnell medial-glide patellar tape and without patellar tape, the order of these being determined using a randomised technique. If MRI is required to measure VM muscle size then all subjects will need to attend the MRI suite at SUHT for the MRI imaging which will take approximately 45 minutes, with all other measures being taken in the Biomechanics Laboratory.

All subjects will have the following measurements taken under the 2 conditions specified above –

- a) Static Q-angle in relaxed standing, using the Peak Motus Video Motion Analysis system,
- b) VM muscle size – using MRI or ultrasound (please see notes above)
- c) Pain – in relaxed standing, during walking, during resisted concentric and eccentric contraction on the Biodex isokinetic dynamometer, and while stepping down from an 8-inch high step; this will be self-recorded using a 11-point numerical rating scale with points from 0–10.
- d) Pattern of movement of the 3 markers from which the Q-angle value is determined – during the stance phase of gait; using the Peak Motus Video Motion Analysis system, with analysis of the frontal and sagittal plane views
- e) Quadriceps torque – using the Biodex isokinetic dynamometer
- f) Timing of onset of the medial and lateral activity of the quadriceps muscle when stepping down from an 8-inch block as measured by surface EMG

A11. Will any intervention or procedure, which would normally be considered a part of routine care, be withheld from the research participants?

- Yes No

A12. Give details of any clinical intervention(s) or procedure(s) to be received by research participants over and above those which would normally be considered a part of routine clinical care. (These include uses of medicinal products or devices, other medical treatments or assessments, mental health interventions, imaging investigations and taking samples of human biological material.)

Additional Intervention	Average number per patient		Average time taken (mins/hours/days)	Details of additional intervention or procedure, who will undertake it, and what training they have received.
	Routine Care	Research		
Other	0	1		In phase one (Study A) each subject will have both an MRI and an U/S scan of their quadriceps' muscles, three subjects with have an additional two U/S scans for the reliability study. In phase 2 (Study B) each subject will have either an MRI or an U/S scan. Each MRI scan takes about 45 minutes, and each U/S scan takes about 15 minutes. The MRI scans will be undertaken in the MRI suite by an experienced radiographer

			following usual protocols; the U/S scans will be undertaken by the lead investigator who is an experienced musculoskeletal physiotherapist trained by the UK Association of Sonographers for this technique.
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A13. Give details of any non-clinical research-related intervention(s) or procedure(s). (These include interviews, non-clinical observations and use of questionnaires.)

Additional Intervention	Average number per patient	Average time taken (mins/hours/days)	Details of additional intervention or procedure, who will undertake it, and what training they have received.

A14. Will individual or group interviews/questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could take place during the study (e.g. during interviews/group discussions, or use of screening tests for drugs)?

Yes No

The Information Sheet should make it clear under what circumstances action may be taken

A15. What is the expected total duration of participation in the study for each participant?

The study is in two parts. For the first phase (Study A) each of the 12 subjects (10 who are healthy and 2 who have PFJS) will attend the MRI suite at SUHT for one visit only where they will have their MRI scan. Each MRI scan takes approximately 45 minutes. Each subject will also attend the Biomechanics Laboratory at the School of Health Professions at the University of Southampton for their ultrasound scan, which will take approximately 15 minutes. Three healthy subjects will attend on 2 further occasions for a repeat ultrasound scan.

For phase 2 (Study B) if U/S is used to measure muscle size then each participant will attend the Biomechanics Laboratory in the School of Health Professions of the University of Southampton on one occasion lasting for approximately two hours. If MRI is used to measure muscle size then each participant will attend the Biomechanics Laboratory for approximately 1.75 hours and in addition the MRI Suite at SUHT for approximately 45 minutes.

A16. What are the potential adverse effects, risks or hazards for research participants either from giving or withholding medications, devices, ionising radiation, or from other interventions (including non-clinical)?

None. All of the measurement tools are accepted as safe and low risk. MRI scans cannot be taken on patients with metal implants, so they will be excluded. Muscle imaging with U/S has no documented risks, and British Medical Ultrasound safety guidelines will be followed.

A17. What is the potential for pain, discomfort, distress, inconvenience or changes to lifestyle for research participants?

Minimal. All participants need attend on the basis described above. For those subjects with PFJS in Study B some of the measurements may cause the onset of their patello-femoral pain – for example stepping down from the 8-inch block and performing tasks against resistance. The nature of patello-femoral joint syndrome is that pain associated with it is self-limiting, such that when an individual ceases the activity which has caused the pain then the pain will disappear. Before the start of any activity with the potential to cause pain subjects will be advised to cease the activity should their pain arise.

A18. What is the potential for benefit to research participants?

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There are no immediate direct benefits to research participants.

A19. What is the potential for adverse effects, risks or hazards, pain, discomfort, distress, or inconvenience to the researchers themselves? (if any)

None.

A20. How will potential participants in the study be (i) identified, (ii) approached and (iii) recruited?

Give details for cases and controls separately if appropriate:

Healthy participants will be recruited following normal procedure at the University of Southampton, with posters explaining the study and inviting participation being displayed in staff and student common rooms. Interested individuals will be asked to contact the lead researcher. On doing so they will be given a participation information sheet outlining details of the study and measurement protocol. They will be invited to discuss the project with the investigator; and if willing to participate will then sign a consent form and be included in the study.

Participants with PFJS will be recruited from the orthopaedic triage knee clinics hosted by SUHT and SCPCT. Individuals who meet the inclusion criteria will be given an information sheet at the time of referral to physiotherapy outlining details of the study and the measurement protocol. They will be invited to discuss the project with the investigator; and if willing to participate will then sign a consent form and be included in the study.

A21. Where research participants will be recruited via advertisement, give specific details.

Not Applicable

A poster advertising the study is enclosed with the application.

If applicable, enclose a copy of the advertisement/radio script/website/video for television (with a version number and date).

A22. What are the principal inclusion criteria? (Please justify)

Inclusion criteria for the participants with PFJS are –

- a) Male – as they tend to have less superficial soft tissue in the thigh and so the VM muscle will be easier to image with the U/S scanner
- b) Aged 18–35 – so they are skeletally mature but have minimal, if any, osteoarthritic changes in the weight-bearing joints
- c) Been diagnosed with insidious onset PFJS by an advanced practitioner physiotherapist in the orthopaedic triage (knee) clinics, according to the following – their knee pain can be provoked by at least two of the following activities: prolonged sitting, kneeling, deep squatting, ascending or descending stairs, patellar compression.

Inclusion criteria for healthy participants are a) and b) above

A23. What are the principal exclusion criteria? (Please justify)

Exclusion criteria for participants with PFJS are –

- a) Knee pain thought to come from any source other than the patello-femoral joint, as determined by the advanced practitioner physiotherapist in the triage clinic – the study is concerned only with PFJS and so any other problems resulting in knee pain will be irrelevant
- b) Any other known medical problems or impairments affecting their neuro-musculoskeletal system – as this may affect participants' ability to undertake some of the tests
- c) Knee pain arising from trauma to the knee joint – PFJS arising from trauma to the knee, is thought to result in different patterns of muscle weakness and so this would confuse the data
- d) Presence of metal implants – MRI can result in heat generation in the tissues, so individuals with metal implants cannot participate in the study
- e) skin allergies or disorders – as this would prevent ultrasound images from being taken and also surface electrode EMG.

A24. Will the participants be from any of the following groups? (Tick as appropriate)

- Children under 16
- Adults with learning disabilities
- Adults who are unconscious or very severely ill
- Adults who have a terminal illness
- Adults in emergency situations
- Adults with mental illness (particularly if detained under Mental Health Legislation)
- Adults with dementia
- Prisoners
- Young Offenders
- Adults in Scotland who are unable to consent for themselves
- Healthy Volunteers
- Those who could be considered to have a particularly dependent relationship with the investigator, e.g. those in care homes, medical students
- Other vulnerable groups

Justify their inclusion.

Healthy volunteers are being included in the first phase of the study in order to determine the most useful way of measuring VM muscle size. Healthy volunteers are also included as a control group in the second phase of the study to act as a comparison to subjects with PFJS.

A25. Will any research participants be recruited who are involved in existing research or have recently been involved in any research prior to recruitment?

- Yes No Not Known

If Yes, give details and justify their inclusion. If Not Known, what steps will you take to find out?

It is possible that the healthy volunteers from the University community may have been involved in recent research projects, as that is an occupational fact in University employment. Subjects with PFJS will not be involved in other research. This will be clarified at the time of recruitment to the study.

A26. Will informed consent be obtained from the research participants?

- Yes No

If Yes, give details of who will take consent and how it will be done. Give details of any particular steps to provide information (in addition to a written information sheet) e.g. videos, interactive material.

If participants are to be recruited from any of the potentially vulnerable groups listed in A24, give details of extra steps taken to assure their protection. Describe any arrangements to be made for obtaining consent from a legal representative.

If consent is not to be obtained, please explain why not.

All interested individuals will be given a comprehensive information sheet and have the opportunity to ask the lead researcher any questions about the study. A copy of the information sheet is enclosed with this application.

Copies of the written information and all other explanatory material should accompany this application.

A27. Will a signed record of consent be obtained?

- Yes No

If Yes, attach a copy of the information sheet to be used, with a version number and date.

A28. How long will the participant have to decide whether to take part in the research?

Any healthy volunteer can take as long as he likes to decide whether or not to participate in the study. However the data will be gathered over a 6-month period, so that will be the upper limit. For subjects with PFJS, their participation must occur before physiotherapy treatment can start, so they will have a one week time frame to decide whether or not to participate.

A29. What arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? (e.g. translation, use of interpreters etc.)

Participants who are unable to understand verbal explanations in English will not be recruited to the study.

A30. What arrangements are in place to ensure participants receive any information that becomes available during the course of the research that may be relevant to their continued participation?

Since each participant attends for one session only this is not relevant.

A31. Does this study have or require approval of the Patient Information Advisory Group (PIAG) or other bodies with a similar remit? (see the guidance notes)

Yes No

A32a. Will the research participants' General Practitioner be informed that they are taking part in the study?

Yes No

If Yes, enclose a copy of the information sheet/letter for the GP with a version number and date.

A32b. Will permission be sought from the research participants to inform their GP before this is done?

Yes No

If No to either question, explain why not

Since this is exploratory study which will have no impact on the treatment or outcome of an individual's PFJS, there seems little point in informing a participants' GP of their involvement.

It should be made clear in the patient information sheet if the research participant's GP will be informed.

A33. Will individual research participants receive any payments for taking part in this research?

Yes No

A34. Will individual research participants receive reimbursement of expenses or any other incentives or benefits for taking part in this research?

Yes No

If Yes, indicate how much and on what basis this has been decided:

Participants will receive reimbursement of travel expenses and refreshments following data collection.

A35. What arrangements have been made to provide indemnity and/or compensation in the event of a claim by, or on behalf of, participants for negligent harm?

This study is covered by University of Southampton Indemnity Insurance

Please forward copies of the relevant documents.

A36. What arrangements have been made to provide indemnity and/or compensation in the event of a claim by, or on behalf of, participants for non-negligent harm?

This study is covered by University of Southampton Indemnity Insurance.

Please forward copies of the relevant documents.

A37. How is it intended the results of the study will be reported and disseminated? (Tick as appropriate)

- Peer reviewed scientific journals
- Internal report
- Conference presentation
- Other publication
- Submission to regulatory authorities
- Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- Written feedback to research participants
- Presentation to participants or relevant community groups
- Other/none e.g. Cochrane Review, University Library

A38. How will the results of research be made available to research participants and communities from which they are drawn?

If requested then peer-reviewed published material from the study will be made accessible to any participant who wishes to receive it.

A39. Will the research involve any of the following activities at any stage (including identification of potential research participants)? (Tick as appropriate)

- Examination of medical records by those outside the NHS, or within the NHS by those who would not normally have access
- Electronic transfer by magnetic or optical media, e-mail or computer networks
- Sharing of data with other organisations
- Export of data outside the European Union
- Use of personal addresses, postcodes, faxes, e-mails or telephone numbers
- Publication of direct quotations from respondents
- Publication of data that might allow identification of individuals
- Use of audio/visual recording devices
- Storage of personal data on any of the following:
 - Manual files including X-rays
 - NHS computers
 - Home or other personal computers
 - University computers

- Private company computers
 Laptop computers

Further details:

Data Protection guidelines will be followed for the storage of data obtained.

A40. What measures have been put in place to ensure confidentiality of personal data? Give details of whether any encryption or other anonymisation procedures have been used and at what stage:

All subjects involved with this research project will be given a code number and all data collected on that individual will be labelled using the relevant code to ensure anonymisation throughout the study.

A41. Where will the analysis of the data from the study take place and by whom will it be undertaken?

The data to be analysed will be undertaken by the lead researcher and will be carried out on a university of Southampton computer.

A42. Who will have control of and act as the custodian for the data generated by the study?

The lead researcher.

A43. Who will have access to the data generated by the study?

The lead researcher and the 2 supervisors via the lead researcher.

A44. For how long will data from the study be stored?

5 Years Months

Give details of where they will be stored, who will have access and the custodial arrangements for the data:

The data will be stored for 5 years after completion of the PhD. The anonymised data from the healthy individuals will be added to the database of normative data held by the University of Southampton.

A45-1. How has the scientific quality of the research been assessed? (Tick as appropriate)

- Independent external review
 Review within a company
 Review within a multi-centre research group
 Internal review (e.g. involving colleagues, academic supervisor)
 None external to the investigator
 Other, e.g. methodological guidelines (*give details below*)

The University of Southampton operates a peer review system, and this protocol has been through that process and accepted. It has also been reviewed by the Trustees of the Private Physiotherapy Education Foundation (PPEF) to which a successful application for funding has been made.

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:

If you are in possession of any referees' comments or other scientific critique reports relevant to the proposed research, these must be enclosed with the application.

A45-2. Has the protocol submitted with this application been the subject of review by a statistician independent of the research team? (Select one of the following)

- Yes – copy of review enclosed
- Yes – details of review available from the following individual or organisation (give contact details below)
- No – justify below

A48. What is the primary outcome measure for the study?

This is an exploratory study rather than an intervention study, so the outcomes are the answer to the research questions posed. The main question being whether the size of the VM muscle and the value of the Q-angle correlate in any meaningful way.

A49. What are the secondary outcome measures? (if any)

Does the application of McConnell's medial glide patellar tape have any effect of the size of the Q-angle?

A50. How many participants will be recruited?

If there is more than one group, state how many participants will be recruited in each group. For international studies, say how many participants will be recruited in the UK and in total.

The study is in 2 parts – the first part of the study requires 10 healthy individuals and 2 individuals with PFJS. The second part of the study requires 20 individuals with PFJS and 10 healthy controls.

A51. How was the number of participants decided upon?

If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.

The study is exploratory and several measurements will be taken, however a key measurement is muscle size, and a recent study by Callaghan and Oldham in 2004 also included measurements of quadriceps muscle size. Following their recommendations a sample size of 20 males will be required for a power of 0.8 ($p < 0.05$).

A52. Will participants be allocated to groups at random?

- Yes
- No

If yes, give details of the intended method of randomisation:

No

A53. Describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

In the first part of the study linear regression and multiple linear regression analysis will be used to determine the level of correlation between the linear and CSA measures of the VMO. To compare the levels of agreement for the measures from the MRI and ultrasound the Bland and Altman tests for limits of agreement will be used as well as Intra-class correlation coefficients for repeat measurements to test reliability.

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Two sets of measures will be taken – one without patellar tape and one without. All interval/ratio data will be checked for normal distribution. Q-angle, VM muscle size Quadriceps peak torque, and timing of onset of EMG activity are interval/ratio data and so will be analysed using parametric statistics eg. analysis of variance. The pain measures which are ordinal will be analysed using the Wilcoxon signed rank test. The frontal and sagittal plane view data of the marker movement will be plotted graphically. Tests of correlation between the Q-angle and size and VM muscle and other measures will be carried out using linear regression analysis and ordinal regression analysis (for pain measurements). Independent t-tests will be applied to compare data from individuals with PFJS and healthy controls.

A54. Where will the research take place?(Tick as appropriate)

- UK
 Other states in European Union
 Other countries in European Economic Area
 Other

If Other, give details:

All MRI scanning will be undertaken in the MRI suite at SUHT. All other measures will be taken in the Biomechanics Laboratory of the School of Health Professions and Rehabilitation Sciences at the University of Southampton.

A55. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK, the European Union or the European Economic Area?

- Yes No

A56. In how many and what type of host organisations (NHS or other) in the UK is it intended the proposed study will take place?

Indicate the type of organisation by ticking the box and give approximate numbers if known:

- | | Number of
organisations |
|--|----------------------------|
| <input checked="" type="checkbox"/> Acute teaching NHS Trusts | 1 |
| <input type="checkbox"/> Acute NHS Trusts | |
| <input type="checkbox"/> NHS Primary Care Trusts or Local Health Boards in Wales | |
| <input type="checkbox"/> NHS Trusts providing mental healthcare | |
| <input type="checkbox"/> NHS Health Boards in Scotland | |
| <input type="checkbox"/> HPSS Trusts in Northern Ireland | |
| <input type="checkbox"/> GP Practices | |
| <input type="checkbox"/> NHS Care Trusts | |
| <input type="checkbox"/> Social care organisations | |
| <input type="checkbox"/> Prisons | |
| <input type="checkbox"/> Independent hospitals | |
| <input checked="" type="checkbox"/> Educational establishments | 1 |
| <input type="checkbox"/> Independent research units | |
| <input type="checkbox"/> Other (give details) | |

Other:

A57. What arrangements are in place for monitoring and auditing the conduct of the research?

As this project forms part of the PhD the study will be closely monitored by its supervisors and the University of Southampton.

Will a data monitoring committee be convened?

Yes No

If Yes, details of membership of the data monitoring committee (DMC), its standard operating procedures and summaries of reports of interim analyses to the DMC must be forwarded to the NHS Research Ethics Committee which gives a favourable opinion of the study.

What are the criteria for electively stopping the trial or other research prematurely?

The general criteria used for stopping any research prematurely are if it becomes clear that there are any hazards for participants or if it is not possible to recruit sufficient numbers in order for the study to be meaningful.

A58. Has external funding for the research been secured?

Yes No

If Yes, give details of funding organisation(s) and amount secured and duration:

Organisation: Private Physiotherapy Education Foundation
 Address: c/o PhysioFirst, Cedar House
 The Bell Plantation, Watling Street,
 Towcester, Northants
 Post Code: NN12 6GX
 UK contact: Chairperson of Trustees – Mrs Jean Kelly
 Telephone: Fax:
 E-mail:
 Amount (£): £5,670 st Duration: 12 Months

A59. Has the funder of the research agreed to act as sponsor as set out in the Research Governance Framework?

Yes No

Has the employer of the Chief Investigator agreed to act as sponsor of the research?

Yes No

Sponsor (must be completed in all cases)

Name of organisation which will act as sponsor for the research:
 University of Southampton

Status:
 NHS or HPSS care organisation Academic Pharmaceutical industry Medical device industry Other

If Other, please specify:

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Address: School of Health Professions and Rehabilitation Sciences
Building 45, University of Southampton, Highfield,
Southampton, Hants

Post Code: S017

Telephone: 02380-592142

Fax:

E-mail:

The responsibilities of the sponsor may be shared between co-sponsors. If this applies, name the lead sponsor for the REC application in this box and enclose a letter giving further details of co-sponsors and their responsibilities.

Sponsor's UK contact point for correspondence with the main REC

Title: Forename/Initials: Surname:

Address:

Post Code:

Telephone: Fax:

E-mail:

A60. Has any responsibility for the research been delegated to a subcontractor?

Yes No

A61. Will individual researchers receive any personal payment over and above normal salary for undertaking this research?

Yes No

A62. Will individual researchers receive any other benefits or incentives for taking part in this research?

Yes No

A63. Will the host organisation or the researcher's department(s) or institution(s) receive any payment or benefits in excess of the costs of undertaking the research?

Yes No

A64. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share-holding, personal relationship etc.) in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?

Yes No

A65. Other relevant reference numbers if known (give details and version numbers as appropriate):

Applicant's/organisation's own reference number, e.g. RD(if available):
Sponsor's/protocol number: **3806**
Funder's reference number:
International Standard Randomised Controlled Trial Number (ISRCTN):
European Clinical Trials Database (EudraCT) number:
Project website:

A66. Other key investigators/collaborators (all grant co-applicants should be listed)

Title: _____ Forename/Initials: _____ Surname: _____
Post: _____
Qualifications: _____
Organisation: _____
Address: _____ Telephone: _____
Postcode: _____ Fax: _____
E-mail: _____

A67. If the research involves a specific intervention, (e.g. a drug, medical device, dietary manipulation, lifestyle change etc.), what arrangements are being made for continued provision of this for the participant (if appropriate) once the research has finished?

Not Applicable

A68. What do you consider to be the main ethical issues which may arise with the proposed study and what steps will be taken to address these?

There are not thought to be any ethical concerns with this work. All of the measurement tools to be used are safe and low risk, and all measurements will be undertaken by appropriately trained and experienced individuals. The MRI scans will be undertaken in the MRI suite by an experienced radiographer following usual protocols. Muscle imaging with ultrasound has no documented risks, and British Medical Ultrasound safety guidelines will be followed. All other measurements will be undertaken by the lead investigator who is an experienced musculoskeletal physiotherapist and who is fully trained in the use of all equipment in the Biomechanics laboratory in building 45 in the University of Southampton. The equipment for all measurements in this study have been used in earlier work by the lead investigator excepting the ultrasound for muscle imaging. The lead investigator has successfully attended approved training by the UK Association of Sonographers for this technique.



A70. Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/degree:
PhD

Name of educational establishment:
University of Southampton

Name and contact details of educational supervisor:
Professor Maria Stokes – m.stokes@soton.ac.uk; 02380-596868
Dr Peter Jackson – Peter.Jackson@suht.swest.nhs.uk; 02380-796738

A71. Declaration of supervisor

I have read and approved both the research proposal and this application for the ethical review. I undertake to fulfil the responsibilities of a supervisor as set out in the Research Governance Framework for Health and Social Care.

Signature:

Print Name:

MES

Date:

(dd/mm/yyyy)

10/11/05

A one-page summary of the supervisor's CV should be submitted with the application

A72. Declaration by academic sponsor

To be completed by an authorised person on behalf of the academic institution acting as sponsor for student research.

I can confirm on behalf of my academic institution that any necessary indemnity or insurance arrangements will be in place before this research starts, as required by the Research Governance Framework for Health and Social Care.

Signature:

Print Name:

Post:

RESEARCH GOVERNANCE MANAGER

Institution:

UNIVERSITY OF SOUTHAMPTON

Date:

(dd/mm/yyyy)

11/11/05

2. List of research sites

List below all research sites you plan to include in this study. The name of the site is normally the name of the acute NHS Trust, GP practice or other organisation responsible for the care of research participants. In some cases it may be an individual unit, private practice or a consortium – see the guidance notes.

Principal Investigators at other sites should apply to the relevant local Research Ethics Committee for site-specific assessment (SSA) using Part C of the application form. Applications for SSA may be made in parallel with the main application for ethical review (once the main REC has validated the application), or following issue of a favourable ethical opinion. Approval for each site will be issued to you by the main REC following SSA.

1. Name of the research site:

Southampton University NHS Trust – Southampton General Hospital Site
School of Health Professions and Rehabilitation Sciences, University of Southampton

Principal investigator for the study at this site:

Title: Ms Forename/Initials: Fleur Surname: Kitsell

Post: PhD student

Address: SHPRS, Building 45,
 Highfield Campus
 Southampton, Hants.

Postcode: SO17 1BJ

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PART B: Section 7 – Declaration

- The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
- I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
- If the research is approved I undertake to adhere to the study protocol, the terms of the full application of which the main REC has given a favourable opinion and any conditions set out by the main REC in giving its favourable opinion.
- I undertake to seek an ethical opinion from the main REC before implementing substantial amendments to the protocol or to the terms of the full application of which the main REC has given a favourable opinion.
- I undertake to submit annual progress reports setting out the progress of the research.
- I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer.
- I understand that research records/data may be subject to inspection for audit purposes if required in future.
- I understand that personal data about me as a researcher in this application will be held by the relevant RECs and their operational managers and that this will be managed according to the principles established in the Data Protection Act.
- I understand that the information contained in this application, any supporting documentation and all correspondence with NHS Research Ethics Committees or their operational managers relating to the application, will be subject to the provisions of the Freedom of Information Acts. The information may be disclosed in response to requests made under the Acts except where statutory exemptions apply. ^

Signature: 

Date: (dd/mm/yyyy) 10/11/2005

Print Name: FLEUR KITSELL

This form should be completed by the Principal Investigator for each site (see glossary)

Part C should be completed and sent with the relevant enclosures to each NHS Research Ethics Committee, which needs to consider site-specific issues. See guidance notes at the COREC website for further information about the application procedure.

The data in this box is populated from Part A.

Short title and version number:

Mechanics of the patello-femoral joint – usefulness of the Q-angle

Name of NHS Research Ethics Committee to which application for ethical review is being made:

Southampton & South West Hampshire

Project reference number from above REC:

Name of NHS REC responsible for SSA:

Southampton & South West Hampshire

SSA reference (for REC office use only):

Questions C1, C4, C5, C6, C7, C8 and C13a correspond to questions A1, A2, A65, A10, A12, A13 and A29 on main application form respectively and will populate automatically:

C1. Title of the research (Populated from A1)

Full title: The mechanics of patello-femoral joint dysfunction – the usefulness of the Q-angle.

Key words: mechanics, patello-femoral joint, Q-angle

C2. Who is the Principal Investigator for this study at this site?

Title: Ms Forename/Initials: Fleur Surname: Kitsell

Post: PhD student

Qualifications: MSc, MCSP, Cert Ed (FE)

Organisation: University of Southampton

Address: SHPRS, Building 45.

Highfield Campus

Southampton, Hants.

Post Code: SO17 1BJ

E-mail: fhk51@hotmail.com

Telephone: 07730-938644

Fax:

A copy of a current CV (maximum 2 pages of A4) for the Principal Investigator(s) must be submitted with the application

C2-1. Give the names and posts of other investigators or members of the research team responsible to the local Principal Investigator for this site.

Include all staff with a significant research role. If the site is a network or consortium, list all participating investigators below.

Title:

Forename/Initials:

Surname:

Position:

Qualifications:

Role in the research team:

C3. Indicate the number of trials/projects within the organisation that the local Principal Investigator has been involved with in the previous 12 months:

0

How many are still current (active or recruiting)?

C4. Chief Investigator (Populated from A2)

Title: Ms Forename/Initials: Fleur Helen Surname: Kitsell

Post: PhD Student

Qualifications: MSc MCSP Cert Ed (FE)

Organisation: University of Southampton

Address: (Home) 3 Bay Tree Yard,
Off West Street, Alresford,
Hants.

Post Code: SO24 9UJ

E-mail: fhk51@hotmail.com

Telephone: 07730-938644

Fax:

C5. Other relevant reference numbers if known (Populated from A65)

Applicants/organisation's own reference number, e.g. RD(if available):

Sponsor's/protocol number:

Funder's reference number:

International Standard Randomized Controlled Trial Number (ISRCTN):

European Clinical Trials Database (EudraCT) Number:

Project website:

C6. Give a full summary of the purpose, design and methodology of the planned research, including a brief explanation of the theoretical framework that informs it. It should be clear exactly what will happen to the research participant, how many times and in what order. Describe any involvement of research participants, patient groups or communities in the design of the research.

(Populated from A10)

This study is in two parts, the first part (Study A) is a methodological study and will involve 12 individuals – 10 who are healthy and 2 who have patello-femoral joint syndrome (PFJS). It has 2 purposes –
 a) to determine the level of correlation between linear measures of the vastus medialis (VM) muscle and its corresponding cross-sectional area, with data taken from MRI images;
 b) to determine whether linear measures of the VM muscle taken from ultrasound images are as accurate as those taken from MRI images.

Previous studies on other muscles (multifidus, masseter, the anterior tibials, and the quadriceps as a group) have each shown that there is a correlation between linear and cross-section area measures, but that it varies between muscles. Each subject will have their VM muscle imaged by both MRI and ultrasound. Previous studies on other muscles have also shown that linear measures from both MRI and ultrasound images are sufficiently in agreement with each other to be used interchangeably.

Subjects will attend the MRI suite at SUHT and will have an MRI scan taken of their quadriceps muscle, by the radiography team, this will take approximately 45 minutes. They will also have an ultrasound scan taken of their vastus meadialis muscle by the chief investigator who is a physiotherapist trained and experienced in the use of muscle imaging with ultrasound, this will take approximately 15 minutes. Three subjects will have an additional 2 ultrasound scans taken on separate occasions for a small reliability study.

The second part of the study is to determine whether there is any correlation between the Q-angle value, of individuals with PFJS, and other key measurements, namely: the size of the VM muscle, the level of pain suffered, the strength of the quadriceps muscle and the timing of the onset of surface EMG activity of the medial and lateral aspects of the quadriceps muscle. Also to see whether the application of medial glide patellar tape alters the value of the Q-angle. Twenty individuals with PFPS will be recruited along with ten healthy controls.

The protocol for study B will vary depending on whether MRI or ultrasound imaging is used to measure VM muscle size. If ultrasound imaging can be used, then all measurements can be taken in the School of Health Professions, Biomechanics Laboratory, at the University of Southampton; each subject will need to attend for approximately two hours. Firstly they will have relevant antropmetric measures of: body weight, height, lower limb leg length taken; and then specific measurements taken under 2 conditions – wit McConnell medial-glide patellar tape and without patellar tape, the order of these being determined using a randomised technique. If MRI is required to measure VM muscle size then all subjects will need to attend the MRI suite at SUHT for the MRI imaging which will take approximately 45 minutes, with all other measures being taken in the Biomechanics Laboratory.

- All subjects will have the following measurements taken under the 2 conditions specified above –
- a) Static Q-angle in relaxed standing, using the Peak Motus Video Motion Analysis system,
 - b) VM muscle size – using MRI or ultrasound (please see notes above)
 - c) Pain – in relaxed standing, during walking, during resisted concentric and eccentric contraction on the Biodex isokinetic dynamometer, and while stepping down from an 8-inch high step; this will be self-recorded using a 11-point numerical rating scale with points from 0–10.
 - d) Pattern of movement of the 3 markers from which the Q-angle value is determined – during the stance phase of gait; using the Peak Motus Video Motion Analysis system, with analysis of the frontal and sagittal plane views
 - e) Quadriceps torque – using the Biodex isokinetic dynamometer
 - f) Timing of onset of the medial and lateral activity of the quadriceps muscle when stepping down from an 8-inch block as measured by surface EMG

C7. Give details of any clinical intervention(s) or procedure(s) to be received by research participants over and above those which would normally be considered a part of routine clinical care. (These include uses of medicinal products or devices, other medical treatments or assessments, mental health interventions, imaging investigations and taking samples of human biological material.)
 (Populated from A12)

Additional Intervention	Average number per patient		Average time taken (mins/hours/days)	Details of additional intervention or procedure, who will undertake it, and what training they have received.
	Routine Care	Research		
Other	0	1		In phase one (Study A) each subject will have both an MRI and an U/S scan of their quadriceps' muscles, three subjects with have an additional two U/S scans for the reliability study. In phase 2 (Study B) each subject will have either an MRI or an U/S scan. Each MRI scan takes about 45

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			<p>minutes, and each U/S scan takes about 15 minutes. The MRI scans will be undertaken in the MRI suite by an experienced radiographer following usual protocols; the U/S scans will be undertaken by the lead investigator who is an experienced musculoskeletal physiotherapist trained by the UK Association of Sonographers for this technique.</p>
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C8. Give details of any non-clinical research-related intervention(s) or procedure(s). (These include interviews, non-clinical observations and use of questionnaires.)
(Populated from A13)

Additional Intervention	Average number per patient	Average time taken (mins/hours/days)	Details of additional intervention or procedure, who will undertake it, and what training they have received.

C9a. Give the name of the research site for which the PI is responsible: (Please give the name only. Further details of locations should be given in C10. The name of the site is normally the name of the acute NHS Trust, GP practice or other organisation responsible for the care of research participants. In some cases it may be an individual unit, private practice or consortium – see the guidance notes. Each GP practice is a separate site unless a formal consortium/network is in place.)

Southampton University Hospitals NHS Trust – Southampton General Hospital site.
Southampton University – School of Health Professions and Rehabilitation Sciences, Building 45

If you wish to add further information about the definition of the site, please do so below:

C9b. Give the name of the NHS or other organisation with which the PI holds the necessary contract (substantive or honorary) to undertake the research at this site:

Southampton University Hospitals Trust (pending)
Southampton City PCT (pending)

C9c. For NHS sites, give the name and contact details of the Research Governance contact for the research site at the care organisation or consortium:

Title: Dr
Forename/Initials: David
Surname: Breen
Address: Radiology R+D Co-ordinator
Department of clinical Radiology, SUHT,
Tremona Road, Southampton, Hants Telephone: 02380-795103
Postcode: S016 6YD Fax:
E-mail: David.Breen@suht.swest.nhs.uk

C9d. For non-NHS sites, give details of the arrangements for the management and monitoring of the research at this site:

This research will be monitored by the normal procedure for Research Governance for PhD students within the School of Health Professions and Rehabilitation Sciences at the University of Southampton. The project has 2 experienced

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supervisors (Professor Maria Stokes and Dr Peter Jackson) who have monthly meetings with the lead investigator who is undertaking this study as part of her PhD.

C10. Specify all locations or departments at which research procedures will be conducted at this site. Include details of any centres at other NHS care organisations where potential participants may be seen and referred for inclusion in the research at this site. Give details of any research procedures to be carried out off site, for example in participants' homes.

The MRI Unit at SUHT
The Biomechanics Laboratory at the School of Health Professions and Rehabilitation Sciences (building 45), University of Southampton

C11. How many research participants/samples is it anticipated will be recruited/obtained from this organisation in total?

Males with patello-femoral joint syndrome (PFJS) – 22 are needed
Health males to act as controls – 10 are needed

C12a. Give details of who will be responsible for obtaining informed consent locally, their qualifications and relevant expertise and training in obtaining consent for research purposes:

The Principal Investigator – is a Physiotherapist and has carried out other research trials and obtained valid consent.

C13a. What arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? (e.g. translation, use of interpreters etc.) (Populated from A29)

Participants who are unable to understand verbal explanations in English will not be recruited to the study.

C13b. What local arrangements have been made to meet these requirements (where applicable)?

Not Applicable

C14. In addition to informing the GP (if required), what arrangements have been made to inform those responsible for the care of the research participants in the host care organisation of their involvement in the research?

Subjects will be recruited from the Physiotherapy triage clinics and so the clinics will know who has agreed to participate. Pre-treatment measures only are taken, no further measurements are required and so will not affect treatment.

C15. Are the facilities and staffing available locally adequate to perform any necessary procedures or interventions required for the study, and to deal with any unforeseen consequences of these? (This should include consideration of procedures and interventions in both control and intervention arms of a study.)

Yes No

If Yes, give the information necessary to justify your answer. If No, indicate what arrangements are being made to deal with the situation:

MRI measurements will be taken in the MRI suite with its fully qualified radiographers; Ultrasound measures will be taken by the Principal Investigator who has attended training and is familiar with the use of Ultrasound for muscle-size measurement; all other measurements have been taken by the Principal Investigator in previous studies.

C16a. Give brief details of a contact point where participants may obtain further information about the study.

From the Principal Investigator, by email, phone or in person.

C16b. What is the contact point for potential complaints by research participants?

To the project supervisors – Professor Maria Stokes and Dr Peter Jackson.

C16c. Is there a local source where potential participants can obtain independent information about being involved in a research study? See guidance notes.

The Physiotherapy triage clinics.

C16d. Please specify the headed paper to be used for the participant information sheet.

University of Southampton – School of Health Professions and Rehabilitation Sciences.

C17. If any extra support might be required by research participants as a result of their participation, what local arrangements are being made to provide this?

Participants can claim for their travel expenses, funds for this are included in the grant obtained.

- The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
- I undertake to abide by the ethical principles underpinning the Declaration of Helsinki and good practice guidelines on proper conduct of research.
- If the research is approved I undertake to adhere to the study protocol, the terms of the full application of which the main REC has given a favourable opinion and any conditions set out by the main REC in giving its favourable opinion.
- I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Controller.
- I understand that research records/data may be subject to inspection for audit purposes if required in future.
- I understand that personal data about me as a researcher in this application will be held by the relevant RECs and their operational managers and that this will be managed according to the principles established in the Data Protection Act.
- I understand that the information contained in this application, any supporting documentation and all correspondence with Research Ethics Committees relating to the application will be subject to the provisions of the Freedom of Information Acts. The information may be disclosed in response to a request under the Acts except where statutory exemptions apply.

Signature of the local Principal Investigator *

Date: 10/11/05 (dd/mm/yyyy)

Print Name: FLEW KITSELL

* The Chief Investigator should sign where s/he is also the local Principal Investigator for this research site.

PART C IS NOW COMPLETE AND SHOULD BE SUBMITTED to the NHS Research Ethics Committee responsible for the site-specific assessment.



**SOUTHAMPTON & SOUTH WEST HAMPSHIRE
RESEARCH ETHICS COMMITTEES (A)**

1ST Floor, Regents Park Surgery
Park Street, Shirley
Southampton
Hampshire
SO16 4RJ

STA/hph
27 January 2006

Ms Fleur Helen Kitsell
PhD Student
University of Southampton
(Home) 3 Bay Tree Yard,
Off West Street, Alresford,
Hants.
SO24 9UJ

Tel: 023 8036 2466
023 8036 3462
Fax: 023 8036 4110

Email: GM.E.hio-au.SWHRECA@nhs.net

Dear Ms Kitsell

Full title of study: The mechanics of patello-femoral joint dysfunction - the usefulness of the Q-angle.
REC reference number: 05/Q1702/160

Thank you for your letter of 23 January 2006, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

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.

Ethical review of research sites

The favourable opinion applies to the research sites listed on the attached form.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Application		16 January 2006
Investigator CV - Fleur Kitsell		01 November 2005
Investigator CV - Professor M Stokes		01 October 2005
Protocol	Final	06 November 2005
Covering Letter		11 November 2005
Peer Review		24 May 2005
Statistician Comments		02 June 2005
Compensation Arrangements		11 November 2005
Advertisement	2	01 November 2005
Participant Information Sheet	4	23 January 2006

Participant Consent Form	4	23 January 2006
Response to Request for Further Information		23 January 2006
Letter from Funder		21 August 2005

Research governance approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final research governance approval from the R&D Department for the relevant NHS care organisation.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

05/Q1702/160	Please quote this number on all correspondence
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With the Committee's best wishes for the success of this project

Yours sincerely

Mr Edward Carter
Chair

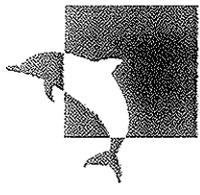
Email: GM.E.hio-au.SWHRECA@nhs.net

Enclosures:

Standard approval conditions

Site approval form

Copy to: Dr Peter Hooper
University of Southampton
Highfield
Southampton
Hants
SO17 1BJ



University of Southampton

School of Health Professions and Rehabilitation Sciences

RISK ASSESSMENT FORM

To be completed in accordance with the attached guidelines

Activity:

Ten healthy males aged 18-35 years and 22 males aged 18-35 years with patello-femoral joint syndrome (PFJS) will be recruited and have various measurements taken. The first part of the study (study a) will consist of participants having their quadriceps muscle scanned with MRI and ultrasound and the two sets of measure compared. The second part of the study (study b) will consist of all participants attending a research laboratory at the School of Health Professions and Rehabilitation Sciences and having a series of measurements taken. These measures are:

- Pain – in relaxed standing, during walking, during resisted concentric and eccentric contraction, and while stepping down from an 8 inch high step; using an 11-point numerical rating scale;
- Q-angle – during relaxed standing using the Peak Motus Video Motion analysis system;
- Pattern of movement of the three points from which the Q-angle is determined, during the stance phase of gait from the frontal and sagittal planes, using the Peak Motus Video Motion analysis system;
- VMO muscle size using MRI or ultrasound being dependent on the outcome of Study A;
- Quadriceps torque – during both concentric and eccentric resisted contractions; using Biodex dynamometer; and
- Timing of onset of vastus medialis and vastus lateralis activity while stepping down from an 8 inch high step; using electromyography

All measures will be taken under 2 conditions i.e. with and without the application of McConnell medial glide patellar tape.

Location(s):

MRI scans will be undertaken at Southampton General Hospital. Ultrasound imaging and all other measurements in a research laboratory at the School of Health Professions and Rehabilitation Sciences of the University of Southampton.

Significant Hazards:

There are not thought to be any ethical concerns with the procedures involved in this study: MRI, Ultrasound imaging, electromyography, Motion analysis system and strength testing equipment. Following normal procedure the proposal will be submitted to the Local Research Ethics Committee (LREC) once the outcome of the funding application is known. All of the measurement tools are accepted as safe and low risk. The only concern for subjects undergoing MRI scanning are pregnancy or metal implants in the tissues, and since we will be using the extremity MRI scanner

and subjects will all be male without previous injury; this will not be a problem. Muscle imaging with U/S has no documented risks, but British Medical Ultrasound safety guidelines will be followed.

Who might be exposed/affected:

The researcher and participants.

Existing control measures:

MRI scans will be undertaken in the MRI suite of Southampton General Hospital by experienced radiographers following normal procedures. The Ultrasound imaging will be undertaken by the researcher who is an experienced musculoskeletal physiotherapist trained by the UK Association of Sonographers for this technique. All other measurements will be undertaken by the researcher who has received appropriate training in these measurement methods and is experienced in their use; and will follow all health and safety guidelines as normal procedure.

Risk evaluation: Low / Medium / High

Can the risk be further reduced: Yes / No (if yes, detail below)

Further controls required: No

Date by which further controls will be implemented: N/A

Are the controls satisfactory: Yes / No

Date for reassessment:

Completed by:

.....
name

.....
signature

.....
date

Supervisor/manager:

If applicable

.....
name

.....
signature

.....
date

Reviewed by:

.....
name

.....
signature

.....
date

APPENDIX 4



School of Health Professions & Rehabilitation Sciences

Project Evaluation Form/Peer Review Report (PeerRev II)

for external Ethics Committees, R & D submissions and University Research Support Office (RSO)

Instructions for completion:

Sections A & B to be completed by School Research Office from Peer Review Form PeerRev I.

Section C to be completed by **supervisor/research mentor**.

On completion section C please return to SoHPRS Research Office (Highfield Campus, Bldg. 45/ room 0022), University of Southampton, Southampton SO17 1BJ

Principal Investigator: Kitsell, Fleur

Project Title: The mechanics of patello-femoral joint dysfunction

Peer Review Ref. No.: PeerRev 05-020

Supervisor (if applicable): Professor Maria Stokes

Co-workers (if applicable): n. a.

Research environment

1. In the RAE 2001, the School of Health Professions and Rehabilitation Sciences was the third highest rated School of its kind in the UK.
2. Formalised and individual research training is provided for students and staff in the School and all staff have research mentors.

To be signed by: Head of School / Deputy Head of School / Director of Research / Head of Postgraduate Education AFTER sections A, B, C on page 2 have been completed.

Name LS (please print)

Position HEAD of SCHOOL

Signature _____ Date 24th May 05

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The following statements should be confirmed by ticking where appropriate.

Section A - Assessment of quality and usefulness of project

First Peer Reviewer:

- 1. The project is of high scientific quality
- 2. The project is worthwhile and values for money (actual costs/time)
- 3. The project is feasible
- 4. The project has been peer-reviewed

✓
✓
✓
✓

Second Peer Reviewer:

- 1. The project is of high scientific quality
- 2. The project is worthwhile and values for money (actual costs/time)
- 3. The project is feasible
- 4. The project has been peer-reviewed

✓
✓
✓
✓

Section B - Assessment of the expertise of the investigators

*The Principal Investigator, co-workers and/or supervisor have **

First Peer Reviewer:

- 1. Knowledge of the methodology
- 2. Knowledge of the topic area
- 3. Appropriate experience relevant to the chosen topic

✓
✓
✓

Second Peer Reviewer:

- 1. Knowledge of the methodology
- 2. Knowledge of the topic area
- 3. Appropriate experience relevant to the chosen topic

✓
✓
✓

* Point 1 along with either point 2 or 3 should be ticked in order for the investigator or supervisor to be deemed to have appropriate expertise.

Outcome: Peer review has accepted the project.

Signature: _____

Name: i

Position: Research Manager/ Peer Review Co-ordinator

Date: 25/5/05

Section C - Assessment of resources and support

- 1. Appropriate equipment is available
- 2. Appropriate IT /software packages are available
- 3. Appropriate supervision/support is available
- 4. Collaboration has been agreed by all parties involved (internal & external)

✓
✓
✓
✓

Signature: _____

Name:

Position: Supervisor / Research Mentor

Date: 25/4/05

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Department of Clinical Radiology
Southampton General Hospital
Southampton
SO16 6YD
Tel: 023 8079 4021

Dear

An appointment has been made for you to have an MRE scan at the MR Extremity Unit, which is situated within the **Emergency X-Ray Department** at Southampton General Hospital.

Please attend on:

Date:

Time:

Location: Emergency X-Ray Department, Level C, East Wing, Southampton General Hospital.

On arrival at the hospital, make your way to the main entrance. Once inside, follow the "Emergency Department" signs through the hospital. Once you see "Emergency X-Ray" signs follow these until you arrive at the Emergency X-Ray Reception. Then, please press the bell (by orange sign) and proceed into the Emergency X-Ray department. A member of staff will attend to you shortly.

MRE means **Magnetic Resonance Extremity Scanning**. You will be required to lie still on a couch inside the scanner and the pictures of you will be made using a magnetic field.

The scan should take between 30 and 45 mins. but please expect to be in the department at least for 1 hour.

Some patients cannot undergo MRE scanning because of the strong magnetic fields, please contact the department **IMMEDIATELY** if:

You have a heart pacemaker

You ARE or MAY be pregnant

You have metal objects or implants in your body (i.e. Hip replacement)

You have ever in your lifetime had an injury to your eyes involving metal i.e. welding, metal work, etc.

We are unable to provide child-care so please make alternative arrangements.

We advise you to leave plenty of time for parking.

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APPENDIX J

Initial CSA and Line measures from MRI scans for 12 Healthy participants (see Section 6.2)

Participant	Slice used	Line A mm	Line B mm	Line C mm	CSA mm ²
1	9	37.46	22.29	21.78	23.4
2	17	57.84	19.46	36.51	47.7
3	14	38.98	22.53	30.19	21.4
4	9	44.50	15.21	37.58	40.6
5	5	41.31	18.12	22.16	21.06
6	3	29.80	22.44	28.61	34.7
7	10	42.42	20.90	28.37	33.64
8	7	50.43	24.74	39.24	54.7
9	7	37.24	25.47	30.51	34.8
10	14	37.12	24.72	30.34	31.3
11	7	46.80	33.35	34.37	43.7
12	11	40.38	26.15	32.30	35.7

APPENDIX K

Repeat CSA and Line measures from MRI scans for 12 Healthy participants (see Section 6.2)

Participant	Slice used	Line A mm	Line B mm	Line C mm	CSA mm ²
1	9	36.24	26.36	25.63	24.8
2	17	57.61	21.84	38.60	49.9
3	14	39.43	22.59	27.36	20.1
4	9	44.61	12.03	37.07	37.2
5	5	41.05	18.89	23.79	24.5
6	3	32.84	22.86	30.13	32.8
7	10	41.29	18.77	27.71	34.7
8	7	50.78	25.40	40.19	55.9
9	7	37.62	26.33	31.15	33.1
10	14	38.71	24.72	32.35	29.9
11	7	45.47	35.52	35.94	44.7
12	11	41.80	25.70	33.05	36.9

APPENDIX L

Initial Line and repeat Line measures from US images for 12 Healthy participants, same scan (see Section 6.3)

Participant	Line A ₁ mm	Line A ₂ mm	Line B ₁ mm	Line B ₂ mm	Line C ₁	Line C ₂ mm
1	42.30	40.60	19.60	20.40	20.10	19.70
2	55.20	57.90	20.40	19.80	35.70	32.60
3	36.20	35.80	21.70	19.20	25.40	23.90
4	40.50	42.90	17.70	15.30	30.00	32.10
5	41.80	38.60	17.50	19.40	19.30	24.70
6	25.10	28.80	28.60	24.70	22.70	26.90
7	42.20	38.90	20.30	18.80	28.80	25.70
8	48.90	49.40	28.20	26.80	36.20	34.10
9	38.80	39.40	25.10	26.42	30.30	27.85
10	36.50	36.20	25.30	24.15	30.90	26.70
11	46.30	44.76	30.30	33.80	26.10	29.84
12	41.30	42.80	26.70	25.70	32.00	30.70

APPENDIX M

Initial Line and repeat Line measures from US images for 6 Healthy participants, REPEAT scan (see Section 6.3)

Participant	Line A ₁ mm	Line A ₂ mm	Line B ₁ mm	Line B ₂ mm	Line C ₁	Line C ₂ mm
1	42.30	44.80	19.60	18.70	20.10	18.70
2	55.20	51.90	20.40	21.80	35.70	32.80
3	36.20	34.90	21.70	21.60	25.40	21.90
4	40.50	43.80	17.70	18.80	30.00	32.90
5	41.80	39.40	17.50	16.40	19.30	21.40
6	25.10	25.80	28.60	29.30	22.70	20.30

APPENDIX N

Initial CSA and Line measures from US images for 10 Healthy participants, in standing (see Section 6.4)

Participant	Line A mm	Line B mm	Line C mm	CSA mm²
1	32.70	18.80	19.60	56.00
2	38.20	23.00	25.70	95.60
3	41.90	24.70	26.80	93.80
4	40.10	24.00	25.20	76.00
5	48.40	25.10	34.30	136.50
6	47.20	29.70	32.70	138.10
7	42.50	20.70	24.80	85.50
8	40.70	23.70	35.60	144.20
9	47.30	26.50	34.90	148.00
10	44.90	36.10	21.10	136.00

APPENDIX O

Repeat CSA and Line measures from US images for 10 Healthy participants, in standing, same scan (see Section 6.4)

Participant	Line A mm	Line B mm	Line C mm	CSA mm²
1	32.20	17.80	18.70	51.70
2	39.90	24.20	26.30	106.6
3	43.90	24.50	26.00	93.90
4	40.40	24.90	25.70	79.90
5	52.80	22.50	37.50	148.00
6	45.40	28.50	31.30	122.10
7	40.80	19.20	24.30	82.60
8	42.20	23.70	36.20	144.20
9	48.50	25.30	35.90	157.40
10	42.50	34.10	21.20	128.0

APPENDIX P

CSA and Line measures from US images for 10 Healthy participants, in standing, different scan (see Section 6.4)

Participant	Line A mm	Line B mm	Line C mm	CSA mm ²
1	37.20	14.90	17.10	51.70
2	41.60	19.10	25.30	83.70
3	43.60	25.10	26.30	98.90
4	44.50	20.20	24.50	77.40
5	49.80	18.80	32.90	148.60
6	45.40	25.10	29.00	138.70
7	42.30	19.70	25.60	102.30
8	47.30	16.20	32.70	110.60
9	42.60	22.40	31.00	120.00
10	52.0	33.20	22.50	160.20

Q-angle data - Range and Standard Deviation during 60 seconds for 51 healthy participants, in relaxed standing

Participant	Q-angle range (degrees)	Standard Deviation, SD
1	2.14	0.42
2	1.80	0.33
3	5.59	1.04
4	2.71	0.57
5	2.39	0.50
6	2.61	0.47
7	1.80	0.37
8	2.72	0.50
9	3.73	0.70
10	4.84	1.18
11	2.76	0.49
12	3.35	0.58
13	5.05	1.47
14	3.94	0.76
15	2.71	0.52
16	1.46	0.36
17	4.03	0.87
18	4.82	0.56
19	2.99	0.44
20	2.77	0.51
21	3.11	0.60
22	1.85	0.42
23	3.35	0.80
24	2.60	0.42
25	4.03	0.70
26	3.15	0.72
27	1.77	0.38
28	4.96	0.88
29	2.10	0.41
30	5.32	1.04
31	2.08	0.40
32	1.90	0.32
33	1.83	0.39
34	3.62	0.85
35	3.42	0.62
36	1.53	0.29
37	2.44	0.55
38	2.17	0.41
39	3.34	0.52
40	4.58	0.71
41	4.28	0.89
42	2.43	0.39
43	2.25	0.49
44	2.51	0.57
45	2.61	0.48
46	2.43	0.42
47	3.61	0.62
48	4.04	0.82
49	2.29	0.40
50	2.25	0.43
51	6.97	1.33

Is the Q-Angle an Absolute or a Variable Measure?

Measurement of the Q-angle over one minute in healthy subjects

Key Words

Q-angle,
patellofemoral joint,
variability.

by Tony Wilson
Fleur Kitsell

Summary

Background and Purpose The quadriceps angle (Q-angle) is currently the only measurement of patellofemoral mechanics available in the clinical situation which does not necessitate the use of sophisticated radiographic equipment. It is generally assumed that for a given subject position and measurement procedure, the Q-angle is an absolute value rather than one which may vary with time. However, this assumption has never been tested. The purpose of this study was to determine whether the Q-angle varies with time.

Methods The Q-angle of 51 healthy subjects was measured continuously for one minute in the standing position using a video motion analysis system of proven accuracy and reliability.

Results The Q-angle varied by an average of 3.12° (1.46°-6.97°) over the one minute tested, with a repeatability coefficient of 3.4°.

Conclusion The data indicate that when measured in the standing position the Q-angle is not an absolute measure, but one which varies with time. It is proposed that when the Q-angle is measured in the clinical situation with a goniometer, the value achieved is not a definitive measurement, but a snapshot in time of the individual's Q-angle within a given range.

Introduction

The quadriceps angle (QA) is a measure of patellofemoral mechanics routinely made by physiotherapists. It is claimed to be the angle formed by the resultant force of the quadriceps femoris muscle on the patella and the line of pull of the patellar ligament (Ficat and Hungerford, 1983; Garrick, 1989). Clinically it is taken by drawing imaginary lines from the anterior superior iliac spine to the centre of the patella, and from the tibial tuberosity through the centre of the patella, and measuring the acute angle in between

(Caylor *et al*, 1993; Lathinghouse and Trimble, 2000) (fig 1). Normal values are reported to range from 10° to 14° for male subjects and 14.5° to 17° for females (Insall *et al*, 1976; Aglietti *et al*, 1983; Horton and Hall, 1989; Caylor *et al*, 1993; Woodland and Francis, 1992).

The Q-angle is one of the few measures of patellofemoral joint mechanics available in the clinical situation not requiring sophisticated radiographic equipment; other measurements, such as the 'A-angle' (Arno, 1990) have been shown to be unreliable (Ehrat *et al*, 1994; Selte *et al*, 1996). The Q-angle is considered an important factor in the development of a variety of soft tissue conditions. An abnormally high or low Q-angle has been repeatedly cited as predisposing to anterior knee pain syndrome (Aglietti *et al*, 1983; Brown *et al*, 1984; Garrick, 1989; Moss *et al*, 1992; Holmes and Clancy, 1998), a condition said to affect up to 25% of the population (McConnell, 1986). It has also been implicated in the genesis of conditions such as patellar instability, chondromalacia patellae, patellofemoral arthritis, hyperpronation of the foot and ankle, plantar fasciitis, iliotibial band syndrome and trochanteric bursitis (Insall *et al*, 1976; James *et al*, 1978; Aglietti *et al*, 1983; Huberti and Hayes, 1984; Hughston *et al*, 1984; D'Amico and Rubin, 1986; Fulkerson and Hungerford, 1990; Shambaugh *et al*, 1991; Powers *et al*, 1995). Furthermore, the value of the Q-angle has traditionally had a significant effect on the choice and nature of treatment for these conditions.

The Q-angle was first described by Brattstrom in 1964 and the accepted technique for measuring the Q-angle using the anterior superior iliac spine as

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measure?
Measurement of the
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296-302.

the proximal landmark was originally detailed by Insall *et al* in 1976. Since then there have been repeated debates on accepted normative values (Messier *et al*, 1991; Shambaugh *et al*, 1991; Woodland and Francis, 1992; Galanty *et al*, 1994; Thomee *et al*, 1995), appropriate subject position for measurement (Aglieiti *et al*, 1983; Woodland and Francis, 1992; Galanty *et al*, 1994; Guerra *et al*, 1984), foot position (Hvid *et al*, 1981; Olerud and Berg, 1984; Brown *et al*, 1994; Cowan *et al*, 1996), contraction status of quadriceps (Guerra *et al*, 1994; Biedert and Gruhl, 1997; Lathinghouse and Trimble, 2000) and validity (Schulties *et al*, 1995).

Reliability of measurement of the Q-angle has also proved to be a contentious area, with six reported studies (Horton and Hall, 1989; Woodland and Francis, 1992; Caylor *et al*, 1993; Guerra *et al*, 1994; Livingstone and Mandigo, 1999; Lathinghouse and Trimble, 2000) all reporting different levels of reliability, ranging from fair to very good. However, all six studies used correlation coefficients as their measure of reliability, but these alone are not considered a precise measure of reliability because they describe how two sets of scores vary together, not the extent of agreement between them (Bruton *et al*, 2000).

A key assumption in all studies on the Q-angle, and one which is plainly central to the measurement of reliability, is that it is an absolute measure rather than one which may vary with time. To the authors' knowledge, this assumption has never been tested.

There is no accepted 'gold standard' for measuring the Q-angle. The identification of the bony landmarks and the placement of markers on the skin have always been fraught with difficulty. For instance, where precisely is the centre of the patella? In the clinical situation the Q-angle is usually measured with a long-arm goniometer with the subject either standing or supine. The accuracy of any measurement taken with a goniometer relies largely upon the skill of the tester and the clarity of the procedure. However, even in the hands of skilled and experienced clinicians, it is well documented that measurements taken with a goniometer are neither particularly reliable nor repeatable (Boone *et al*, 1978; Elveru *et al*, 1988; Hogeweg *et al*, 1994). Despite this, goniometric measurement of the Q-angle remains in widespread clinical use and researchers have quoted significant differences in the Q-angle between two studied groups of as little as 2° or less (Aglieiti *et al*, 1983; Moss *et al*, 1992).

In contrast to goniometric measurement, the Peak-5 video motion analysis system* is of proven accuracy and reliability. It has been shown to measure accurately limb angles to within one degree (Scholz and Milford, 1993; Bratton and Ross, 1994; Selfe, 1998). The spherical markers used in the Peak-5 system make it easier to identify the bony landmarks, because the system calculates the central point of the marker and uses this in its computations. It also allows measurements to be taken easily over a set period of time without disturbing the subject, which makes it an ideal tool for exploring the behaviour of the Q-angle over time.

The purpose of this study was to make repeated measurements of the Q-angle in asymptomatic subjects in the relaxed standing position over one minute to investigate the stability of the Q-angle measurement over time, and thus allow an assessment of the extent to which the Q-angle is a variable or an absolute measure.

The Q-angle has been measured in the standing position (D'Amico and Rubin, 1986; Horton and Hall, 1989; Caylor *et al*, 1993; Cowan *et al*, 1996; Livingstone and Mandigo, 1999; Lathinghouse and Trimble, 2000) and supine position (Insall *et al*, 1976; Aglieiti *et al*, 1983; Woodland and Francis, 1992) and has been shown to differ in value for each position (Woodland and Francis, 1992; Guerra *et al*, 1994). However, all the conditions to which an abnormal Q-angle is believed to predispose are conditions of weight-bearing, and so its value in lying, a predominantly asymptomatic position in the conditions outlined above, is of limited use. Therefore in concordance with Holmes and Clancy (1998) and Lathinghouse and Trimble (2000), standing was considered to be the most useful position from which to take measurements.

The time span of one minute was chosen because this approximates to the time a therapist would take to identify the bony landmarks and measure the Q-angle in the clinical situation.

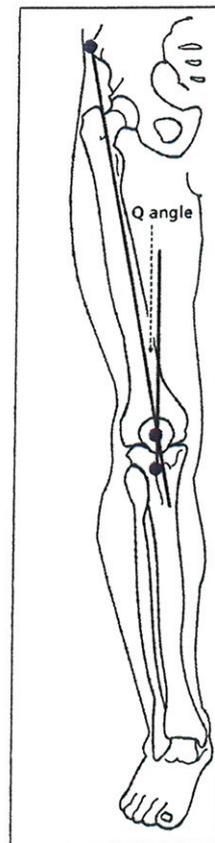


Fig 1: The Q-angle

* Peak Performance Technologies Inc, 7388 South Revere Parkway #601, Englewood, Colorado 80112.

$$CV = \frac{SD}{\text{mean}}$$

Method

Subjects

Fifty-one healthy adults were recruited to the main study from the staff and students at Southampton University – 24 men and 27 women, aged 19 to 38 years. Subjects were excluded if they:

- Were over 40 years old – this was to minimise any compromising effects of possible joint degeneration.
- Had any history of injury to the right lower limb.
- Had any history of surgery to the right lower limb.

Procedure

All testing was done in the biomechanics laboratory of the physiotherapy department at the University of Southampton. Informed consent was obtained beforehand from all subjects.

An initial study was conducted to ensure that the measurement procedure matched the reported accuracy and reliability of the Peak-5 video motion analysis system (Selfe, 1998). Three reflective markers were placed on a static object in such a way as to mimic a Q-type angle of known value. These were then filmed for one minute. The markers were then moved to mimic a different Q-type angle of known value and filmed once more for one minute. This was repeated six times in total. Each video was then digitised by the same tester using the Peak-5 automatic digitising facility.

For the main study, subjects were asked to stand in a comfortable position with their weight evenly distributed on both legs and their toes just touching a line drawn parallel to the frontal plane of the camera lens. It was emphasised that they were to stand in a relaxed position and should avoid obvious contraction of their quadriceps, a factor which has been shown to decrease standing Q-angle (Guerra *et al.*, 1994; Lathinghouse and Trimble, 2000). An observer ensured that the subjects maintained a relaxed stance throughout the one minute tested. The camera was placed six metres from the subjects and its orientation repeatedly checked with a spirit level.

Reflective markers were then placed on the centre of the right anterior superior iliac spine, the centre of the right patella and the centre of the right tibial tuberosity. All the anatomical landmarks were

determined by careful palpation by the same experienced tester; this is the method used in nearly all previous studies of the Q-angle. It is essential to note that for the purposes of this study the actual value of the Q-angle was not important. We were looking at how the measured Q-angle changed over time.

Each subject was then filmed for 60 seconds using SVHS tapes at a picture rate of 50 per second. This was the set rate for the equipment used. The data were filtered with a Butterworth filter and automatically digitised using the Peak-5 video motion analysis system, in accordance with the manufacturer's instructions.

To simplify the calculations, data analysis was conducted using every 50th measurement – one measurement every second. This meant that 60 measurements were included in the analyses for each individual. From these data the maximum and minimum Q-angles were identified for each individual and the range calculated. The group mean range and standard deviation were also calculated. The repeatability coefficient as described by Bland and Altman (1986) was then calculated. As an additional computation, range/mean $\times 100$ was also calculated for each individual. This gave the percentage of the mean by which the Q-angle varied during the one minute tested for each individual. The group mean for this measure was also calculated.

Results

Table 1: Accuracy trial of six Q-type angles measured for 60 seconds

Angle	Range (°)	SD
1	0.58	0.13
2	0.57	0.15
3	0.87	0.20
4	0.61	0.15
5	0.91	0.20
6	0.60	0.15

Table 2: Mean range, mean standard deviation and repeatability coefficient of the Q-angle for group (°)

Mean range	3.12
Mean standard deviation	1.2
Repeatability coefficient	3.4

Table 3: Q-angle range over 60 seconds and standard deviation for 51 subjects (°)

Subject	Range	SD
1	2.14	0.42
2	1.80	0.33
3	5.59	1.04
4	2.71	0.57
5	2.39	0.50
6	2.61	0.47
7	1.80	0.37
8	2.72	0.50
9	3.73	0.70
10	4.84	1.18
11	2.76	0.49
12	3.35	0.58
13	5.05	1.47
14	3.94	0.76
15	2.71	0.52
16	1.46	0.36
17	4.03	0.87
18	4.82	0.56
19	2.99	0.44
20	2.77	0.51
21	3.11	0.60
22	1.85	0.42
23	3.35	0.80
24	2.60	0.42
25	4.03	0.70
26	3.15	0.72
27	1.77	0.38
28	4.96	0.88
29	2.10	0.41
30	5.32	1.04
31	2.08	0.40
32	1.90	0.32
33	1.83	0.39
34	3.62	0.85
35	3.42	0.62
36	1.53	0.29
37	2.44	0.55
38	2.17	0.41
39	3.34	0.52
40	4.58	0.71
41	4.28	0.89
42	2.43	0.39
43	2.25	0.49
44	2.51	0.57
45	2.61	0.48
46	2.43	0.42
47	3.61	0.62
48	4.04	0.82
49	2.29	0.40
50	2.25	0.43
51	6.97	1.33

The results of the preliminary study are presented in table 1. They show that for the six one-minute videos digitised, the measurement for the static Q-angle varied by less than one degree. This concurs with the level of accuracy and reliability for the Peak 5 motion analysis system reported by Scholz and Milford (1993) and Selve (1998) and confirmed the accuracy of our technique.

In the main study, each subject generated 3000 items of data (50 frames per second × 60 seconds). We were specifically interested in the range of the Q-angle over one minute, not in how the Q-angle changed between fractions of a second. To perform a 'traditional' reliability study inclusive of each item of data would have been both time-consuming and of little use. Instead we looked at the range of change across individuals and the group as a whole using, as previously stated, one measurement every second.

The group data are presented in table 2 and individual data in table 3. The group mean range of change for the Q-angle over the one minute measured was 3.12° (SD 1.2°) (table 2). The maximum individual range was 6.97° (subject 51), the minimum 1.46° (subject 16) (see table 3). The repeatability coefficient for the group was 3.4°; this indicated that for 95% of the subjects the difference between the maximum and minimum value of the Q-angle was 3.4°.

An example graph illustrating the lack of pattern in the Q-angle change over time is also presented in figure 2.

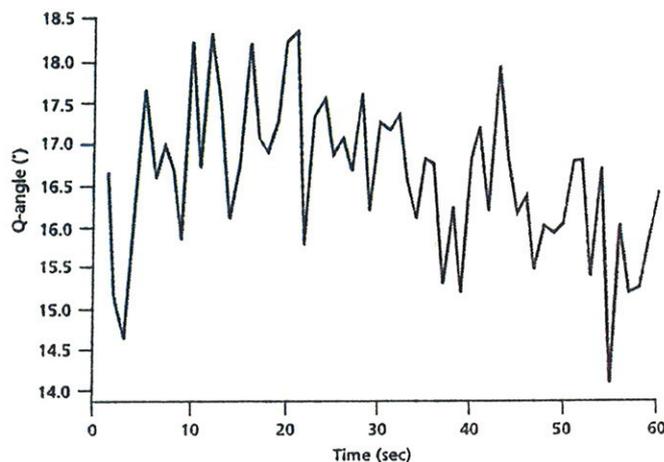


Fig 2: Example of individual Q-angle showing absence of any pattern

Discussion

The results of this study show that the mean range by which the Q-angle varied for the 51 asymptomatic subjects tested was 3.12° when measured over a one-minute period in the standing position with a repeatability coefficient of 3.4°. Graphs drawn for each individual show clearly that the change in the Q-angle with time illustrated no particular pattern; there was neither a steadily increasing nor progressively decreasing Q-angle over the one minute tested, and this made it impossible to predict the Q-angle at any one point in time (fig 2).

This study represents the first evaluation of the Q-angle in any position over time. The results cast doubt on the previously held assumption that, for a given individual and measurement procedure, the Q-angle is an absolute value. The one-minute period over which the subjects were measured is comparable to the length of time it takes to identify the bony landmarks and take the actual measurement in the clinical situation.

The findings suggest that when the Q-angle is measured in the clinic in the standing position, the value attained is not an absolute measure as previously thought, but rather a snapshot in time of the individual's Q-angle within a given range.

The possible reasons for these changes in the Q-angle are manifold, ranging from postural sway to an inherently problematic measurement construct; plainly this requires more research. The argument for measuring the Q-angle in a non-weightbearing position and so minimising the potential problems associated with postural sway seems at first sight to be persuasive. However, physiotherapists are primarily interested in the Q-angle because of its causative relationship with a variety of musculo-skeletal complaints ranging from anterior knee pain to plantar fasciitis. All these conditions are, as mentioned earlier, conditions of weightbearing. We know that the value of the Q-angle differs in standing from lying (Woodland and Francis, 1992; Guerra *et al*, 1994). We also know that the above conditions seldom cause problems in lying. Therefore, measurements gained in such positions seem of limited clinical value.

The significance of these changes in the Q-angle over one minute also needs to be

addressed. In short, are relatively small changes in the Q-angle of under five degrees of any importance? Functionally, small changes in the Q-angle over time may well be of little significance. From a measurement point of view, however, temporal variations in the Q-angle are tremendously important.

For any measurement to be useful, it is imperative to know how accurate it is. Most studies of the Q-angle assume an accuracy to within one degree (Aglietti *et al*, 1983; Woodland and Francis, 1992; Caylor *et al*, 1993), and occasionally to within half a degree (Horton and Hall, 1994). In addition, many authors have identified significant differences in the Q-angle between studied groups of three degrees or less and such differences have been influential in diagnosis (Aglietti *et al*, 1983), choice of treatment (Brown *et al*, 1984), and experimental findings (Moss *et al*, 1992). If the Q-angle naturally varies by approximately three degrees, then the value of such findings and assertions is open to question.

These changes also make measurement of the reliability of the Q-angle difficult because of the possibility of a natural divergence from one measurement to another. It was for this reason that we did not conduct a repeat reliability study on the subjects themselves, having already shown the accuracy of our technique. It would be of more use to examine the reliability of variability of the Q-angle. In other words, is the variability in the Q-angle over one minute consistent over time? Studies are presently under way examining this question.

The measurement tool used in this study was of proven accuracy and reliability, shown to be accurate to within one degree in the measurement of a Q-type angle. Its accuracy and reliability was superior to those values reported with the long-arm goniometer (Woodland and Francis, 1992), string (Caylor *et al*, 1993) and pen lines (Hvid *et al*, 1981) used in previous studies. It is important to reiterate that we were not looking at the actual value of the Q-angle, but how the measured Q-angle varied with time. We thus avoided the problems associated with the reliability of identifying the appropriate bony landmarks.

The Q-angle is an important clinical measure. To the authors' knowledge it is the only measurement of patellofemoral

mechanics readily available in the clinical situation which does not involve sophisticated radiographic equipment. A key assumption has always been that it is an absolute measure rather than one which changes with time. This study has shown that for asymptomatic subjects measured over a one-minute period in the standing

position, the Q-angle varies by 3.12° with a repeatability coefficient of 3.4°. These results were attained on asymptomatic subjects and so cannot be generalised to people with symptoms. Studies looking at symptomatic groups are currently in preparation.

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Key Messages

- The Q-angle has been shown to vary by approximately 3° over one minute when measured in the standing position in asymptomatic subjects. This would suggest that the Q-angle is not an absolute measure but varies with time.
- It is proposed that when the Q-angle is measured in the clinical situation with a goniometer, the value achieved is not a definitive measure, but a snapshot in time of the individual's Q-angle within a given range.
- Treatment decisions based upon precise Q-angle values are open to question.

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