Assessment of anteroposterior knee joint laxity and tibial rotation using non-invasive navigation in healthy volunteers

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‘This thesis is the result of the author’s original research. It has been composed by the author and has not been previously submitted for examination which has led to the award of a degree.’

Signed: 

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Abstract

The knee joint displays a wide spectrum of laxity, from inherently tight to excessively lax even within the normal, uninjured population. The assessment of AP knee laxity in the clinical setting is performed by manual passive tests such as the Lachman test. Non-invasive assessment based on image free navigation has been clinically validated and used to quantify mechanical alignment and coronal knee laxity in early flexion. When used on cadavers the system demonstrated good AP laxity results with flexion up to 40°. This study aimed to validate the repeatability of the assessment of anteroposterior (AP) knee joint laxity using a non-invasive image free navigation system in normal, healthy subjects.

Twenty-five healthy volunteers were recruited and examined in a single centre. AP translation was measured using a non-invasive navigation system (PhysioPilot) consisting of an infrared camera, externally mounted optical trackers and computer software. Each of the volunteers had both legs examined by two Examiners twice. The Lachman test was performed through flexion in increments of 15º. Coefficients of Repeatability (CR) and Interclass Correlation Coefficients (ICC) were used to validate AP translation. The acceptable limits of agreement for this project were set at 3mm for anteroposterior tibia translation.

The most reliable and repeatable AP translation assessments were at 30º and 45º, demonstrating good reliability (ICC 0.82, 0.82) and good repeatability (CR 2.5, 2.9). The AP translation assessment at 0º, 15º, 75º and 90º demonstrated poor reliability (ICC $\leq$ 0.75), and poor repeatability (CR $\geq$3.0mm).

The non-invasive system was able to reliably and consistently measure AP knee translation between 30° and 45° flexion, the clinically relevant range for this assessment. This system still requires further validation in-vivo prior to its use in a clinic setting to quantify abnormal knee laxity and improve the assessment of knee instability and ligamentous injuries.

Acknowledgements

I am grateful for the assistance of all individuals who have contributed to this project, aiding to the project's completion.

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Glossary

Abbreviation	Definition
ACL	Anterior cruciate ligament
Abduction	Movement which draws a limb away from the midline of the body
Adduction	Movement which brings limb closer to the midline of the body
AFTA	Anatomical femoral-tibial alignment
Anterior	Front
AP	Antero-posterior
Arthrodesis	The artificial induction of joint ossification between two bones via surgery
BMI	Body mass index; body weight (kg) divided by square of height (m2)
CAOS	Computer-assisted orthopaedic surgery
CAS	Computer-assisted navigation surgery
CI	Confidence interval
Coronal plane	Vertical plane dividing the body into anterior and posterior sections
CT scan	Computer tomography scan
Diaphysis	Shaft (mid-section) of a long bone
Distal	Away from a point of origin or attachment
Extension	Movement decreasing the angle between bones of the limb at a joint
FAA	Femoral anatomical axis
FAD	Force application device
Femoral epicondyle	Bony protrusions located on the distal end of the femur; medial (medial epicondyle) and lateral (lateral epicondyle)
Flexion	Movement that increases the angle between bones of the limb at a joint
FMA angle	Femoral joint surface mechanical-anatomical joint angle
FM	Femoral mechanical axis
Goniometer	Instrument that measures angles

HJC	Hip joint centre
HKA	hip-knee-ankle angle
Hyperextension	Extension of a joint beyond the normal range. With respect to the knee joint, extension beyond 0°in sagittal plane
In-vitro	Procedure performed in a controlled environment rather than a living organism
In-vivo	procedure occurring or being carried out in a living organism
IR	Infrared
IM	Intramedullary
Lateral	Away from the midline of the body or structure
LBA	load-bearing axis
LCL	Lateral collateral ligament; rounded, narrow ligament located on the lateral aspect of the knee
MA	Mechanical axis
Malleolus	Bony prominence on either side of the ankle. Medial malleolus is the medial surface of the lower end of the tibia; lateral malleolus is the lower extremity of the fibula
MCL	Medial collateral ligament; broad, flat, membranous band on the medial aspect of the knee
Medial	Toward the midline of the body or structure
MFT axis	Mechanical femoro-tibial axis
MFTA	Mechanical femoro-tibial alignment
MRI scan	Magnetic resonance imaging scan
OA	Osteoarthritis
Osteophyte	Bony outgrowth or protuberance
Patello-femoral joint	Articulation between the underside of the patella and the groove within the distal femur
PCL	Posterior cruciate ligament
Posterior	Back
Proximal	Nearest to the point of origin or attachment
ROM	range of motion
Sagittal plane	Vertical plane passing from anterior to posterior dividing the body into right and left sections

SD	Standard deviation
SPSS	Statistical Package for the Social Sciences
Subchondral	Below the cartilage
Supine	Lying on back
TAA	Tibial anatomical axis
Tibial Plateau	Proximal articular surface of the tibia; consisting of a medial and lateral tibial plateau
Tibial Plafond	Distal articular surface of the tibia at the ankle
TKA	Total knee arthroplasty
TM	Tibial mechanical axis.
TMA	Tibial mechanical axis
Transverse plane	Horizontal plane dividing the body into superior and inferior, perpendicular to the coronal and sagittal planes
UKA	Unicompartmental knee arthroplasty
Valgus	Outward angulation of the distal bony segment of a joint
Varus	Inward angulation of the distal bony segment of a joint

1 Introduction

1.1 Background

The knee joint is one of the largest and most complex joints in the human body. The measurement of normal coronal alignment is difficult to define even within the normal healthy individual, because there is such a large variation of coronal alignment (Jenny et al 2005). Our understanding of static normal knee alignment remains poor, despite extensive research. A greater understanding of what normal coronal alignment is, will inevitably aid with knee ligamentous injury reconstruction surgery; and its implications in individual patients may further improve knee reconstruction alignment and post-operative outcomes (Clarke 2012a, Deep 2014).

Only a small percentage of normal adult knees demonstrate a neutral mechanical axis, without joint line obliquity (Barrack *et al* 2014). Various studies using computer tomography have demonstrated that up to 98% of the normal population do not have neutral alignment and up to 75% of these individual have a coronal alignment greater than 3º from neutral (Eckhoff et al 2005). A healthy individual's mechanical femoro-tibial alignment (MFTA) has been shown to differ when lying supine in a non-weight bearing position compared to standing in a weight-bearing position. This effect is less profound in the normal unaffected population, in comparison to those who have arthritic knees. (Deep 2014, Deep et al 2012).

There is a fraction of the population for whom neutral mechanical alignment may be abnormal. Constitutional varus knees, a condition where patients have varus alignment of 3º or more since reaching skeletal maturity, are individuals who are unlikely to benefit from correcting their MFTA back to neutral (Victor et al 2014, Bellemans et al 2012).

The normal population also displays a wide spectrum of knee joint laxity from inherently stable to excessively lax, even if uninjured. Laxity of the knee joint is dependent on the shape of the bony surfaces as well as its surrounding supporting soft tissues (Küpper et al 2007, Cross 1996). Due to the incongruent nature of the knee joint, the surrounding soft tissue structures (ligaments, menisci and tendons),

play a crucial role in knee support and providing stability to the knee joint throughout its range of motion (ROM) (Woo et al 2006).

The amount of AP laxity attainable in a normal knee is dependent on the anterior cruciate ligament (ACL), which is the primary brake to anterior translation of the tibia, resisting approximately 90% of these displacing forces. AP translation and laxity is greatest at 30º of flexion as the ACL is lax (Amis et al 2010). In this position non- pathological knees can anteriorly translate between 2 and 10mm (Sheldon 1994). Anterior laxity diminishes as knee flexion increases particularly beyond 90º, and when extending the knee towards 0º. Posterior knee translation is greatest at 90º of knee flexion and varies from 0 to 6mm (Amis et al 2010).

The amount of anteroposterior (AP) laxity is also dependent on the amount of force applied during clinical examination as well as knee positioning. The assessment of AP laxity in the clinical setting is performed by a range of manual passive tests. These include the anterior/posterior draw test, Lachman test, and the pivot shift tests; which can all diagnose cruciate ligament deficiency to varying degrees of accuracy when used by experienced clinicians. (Detailed descriptions of each of these test is available in Section 2.6). These tests are considered sensitive enough to diagnose cruciate ligament injuries, but are subjective and do not allow for quantitative comparisons between patients or clinicians (Mitsou et al 1988, Edixhoven et al 1989, Lopomo et al 2010, Dejour 2012). These tests are routinely measured using passive ROM whilst the patient is supine or sitting to indicate the status of the knee joint laxity. These types of measurement can result in poor inter-rater repeatability and reliability, and are not assessing the loaded knee joint or native alignment (Rowe et al 2000). Therefore the current gold standard instrument used in the clinical setting for AP laxity assessment is the KT1000 arthrometer. This instrument does allow the clinician to attain quantitative AP laxity measurements for AP laxity in increments as small as 1mm. The KT 1000 is however subject to poor intra-rater and inter-rater reproducibility and has varied reliability and repeatability in the literature (Wiertsema et al 2008).

When discussing different types of reliability or repeatability a definition for these terms is helpful to aid the readers understand the author's views of these definitions. *'Inter-rater reliability'*, this refers to the degree of agreement to which different raters produce consistent estimates /results when measuring the same variable. *'Inter-rater repeatability'* refers to the closeness of agreement of different methods in which each examiner performs individual tests to measure a set variable, and 'intra-rater repeatability' refers to the consistency of how each individual examiner performs the test.
'Inter-rater reproducibility' is the agreement between examiners obtaining results of variables using their own method of assessment on identical test subjects.

ACL injury is the most common ligamentous injury to occur in the knee joint (Mavrogenis et al 2013, Küpper et al 2007), and causes increased anterior tibial translation and laxity, disrupting natural knee biomechanics and kinematics, resulting in joint instability with increased loading on supporting soft tissues (Amis et al 2010, Dujarin 2011).

The knee displays complex rotational motion, largely due to the contours of the femoral and tibial condyles. Tibia rotation is difficult to assess accurately and reliably in the clinical setting (Branch et al 2010), with devices such as the rotameter have been developed to aid with this assessment.

ACL reconstruction can be performed with or without the assistance of computer assisted navigation surgery (CAS). CAS helps reduce surgical error in ACL reconstruction by allowing the surgeon to accurately identify key bone landmarks required during reconstruction. The implementation of CAS in knee arthroplasty surgery is even more profound especially in TKA surgery, where it has been shown to improve overall MFTA, with more accurate implant placement and reduced outliers and possible prosthetic wear (Smith & Rowe 2013, Picard et al 2007a, Kim et al 2005, Anderson et al 2005, Chauhan 2004).

Non-invasive navigation is a relatively new concept. A Non-invasive navigation system based on image free computer navigation uses similar software algorithms to

those in CAS. However rather than bone pins holding optical trackers in place over the distal femur and proximal tibia (invasive navigation) as performed in CAS; in non-invasive navigation fabric straps are used to hold the optical trackers in position, with the optical trackers mounted on metal base plates on top of the skin. Therefore mounting of the optical trackers is significantly different between invasive (CAS) and non-invasive image free navigation. The invasive navigation system is used in orthopaedic theatres across the United Kingdom. Soft tissue artefacts limit the accuracy of the non-invasive navigation system, largely due to the design of the pre-validated optical set of trackers (Picard 2007, Clarke 2012a). Due to the limitations of these trackers, a new set of optical trackers has been developed with a modified design to reduce soft tissue artefact by producing a smaller moment arm. An updated non-invasive navigation infrared camera with updated software has also been developed and allows for the assessment of anteroposterior (AP) knee joint laxity and tibia rotation through the range of flexion. Further development has added the ability of the software to measure AP laxity and tibia rotation throughout flexion.

Optical motion analysis systems are another means of analysing joint kinematics and motion through a defined capture area. These systems also use infrared signals or magnetic fields to capture body motion, with each system having its own algorithms to process the data acquired. These systems use tracker balls which are mounted to defined body landmarks using a variety of model designs to record the position of the external markers as the subject moves (Clinical Gait Analysis 2014, Vicon 2016, Kertis 2009). Optical motion systems have been shown to have an accuracy of 0.1mm and are frequently used in gait analysis laboratories but are largely limited to this artificial clinical environment (Miller 2002, Kertis 2009, Gibbs et al 2005, Dunias et al 2013, Huddleston et al 2006).

1.2 Project rationale

There are knowledge gaps in our understanding of the normal native knee and how to identify what normal laxity is within a healthy, uninjured knee. However we are still lacking understanding of what normal limb mechanical alignment is.

Image free navigation has been shown to improve ACL prosthesis positioning and TKA post-operative alignment, whilst giving the surgeon intra-operative real-time feedback. A non-invasive means of assessing intra-operative alignment and soft-tissues could have numerous potential clinical applications; from identifying and quantifying ligamentous soft-tissue injuries, to planning and following-up TKA (Clarke 2012). In the clinical setting; supine, bi-pedal and mono-pedal loaded mechanical alignments measurements could be performed using the non-invasive navigation system to assess the relationship between these alignment measures. These assessments in a clinical setting could aid the surgeon identify patient specific post-operative goals and tailor the surgery to meet these goals, potential improving patient satisfaction, as well as restoring patient specific native anatomy (Clarke 2012a, Barrack *et al* 2014).

1.3 Hypotheses

- The newly designed optical set of trackers with a smaller moment arm and less soft tissue artefact will out-perform the pre-validated set of optical trackers

- The non-invasive navigation system with its newly updated infrared camera, will validate the assessment of AP laxity and tibial translation through the range of flexion.

1.4 Aims

The aims of this project are as follows:

- Perform a pilot study to validate a new and pre-validated set of optical trackers using a non-invasive computer navigation system, to identify the optimal tracker set for volunteer testing

- Validate the assessment of anteroposterior (AP) knee joint laxity and tibia rotation through flexion in 25 volunteers, using a non-invasive computer navigation system

2 Literature review

This literature review provides pertinent information about the basics of the knee joint anatomy, kinematics and mechanical and anatomical alignments. Soft-tissues and in particular the anterior cruciate ligament (ACL) are analysed in regards to their roles in anteroposterior (AP) laxity, and tibia rotation. The basics of AP laxity and tibia rotation are also analysed in the review. The principals of ACL reconstruction and total knee arthroplasty (TKA) are reviewed with a particular focus on computer assisted navigation. Non-invasive navigation technology is a relatively new technology, and the available studies are analysed in detail.

2.1 The knee joint

The knee joint is one of the largest and most complex joints in the human body. This synovial joint consists of two articulations; the tibio-femoral (TF) joint - *distal aspect of the femur and proximal aspect of the tibia* - and the patello-femoral (PF) joint - *articulation between the underside of the patella and the trochlear groove within the distal femur*-. The TF joint consists of a medial and lateral compartment, as depicted in *Figure 2.1* below (Wings 2013, Amis et al 2010).

The TF joint has a large range of motion (ROM) flexing up to 160º passively in the sagittal or anteroposterior (AP) plane and has coupled rotations in two additional planes of motion (mediolateral plane and tibial axis), resulting in incongruence between the articular surfaces through part of knee ROM (Amis et al 2010).

The PF joint similarly has a complex three dimensional ROM across the TF joint in flexion, in order to allow the quadriceps to extend the knee. The PF joint articulates between the patella and femoral trochlear groove (Amis et al 2010).

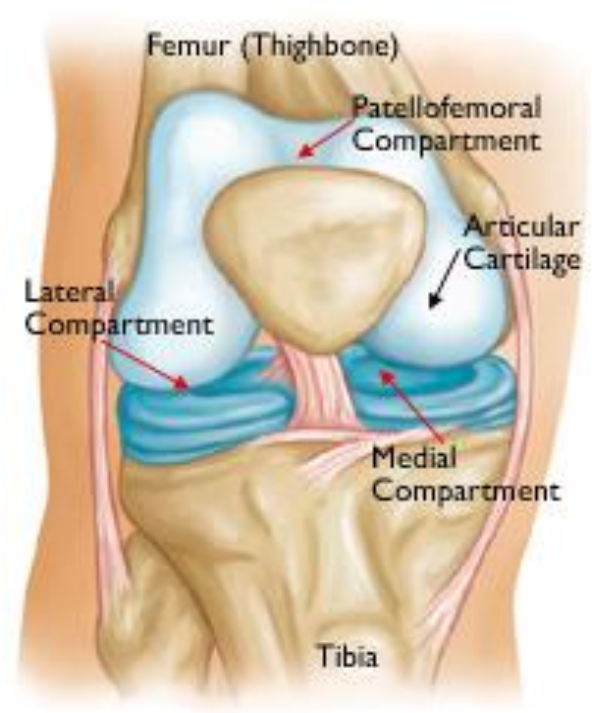


Figure 2.1 Normal knee joint displaying the tibio-femoral (TF) and patello-femoral (PF) joints, demarcated with red arrows (American Academy of Orthopaedic Surgeons (AAOS) 2010)

2.1.1 Knee joint kinematics and principle axes

Human body kinematics describes the motion of joints, locomotion and gait (Woo 1999). The complex TF joint of the knee can move in six different directions of motion; three rotations and three translations in three principle axes; epicondylar axis, anteroposterior axis and tibial shaft axis, as shown in *Figure 2.2*. *Translations* of the knee occur along these principal axes and are commonly referred to as proximal-distal, medial-lateral and anterior-posterior translation. *Rotations* about these axes are referred to as internal-external, flexion-extension and varus-valgus (abduction-adduction) rotations as shown in *Figure 2.2* (Amis et al 2010, Woo 1999).

The knee joint acts like a hinge joint, with the TF joints primary motion being flexion and extension in the anteroposterior (AP) plane, with some AP translation. In the AP plane, full knee extension (0^o) occurs when the tibia and femur are aligned in the long mechanical femoro-tibial axis (MFT axis). Active knee flexion is produced

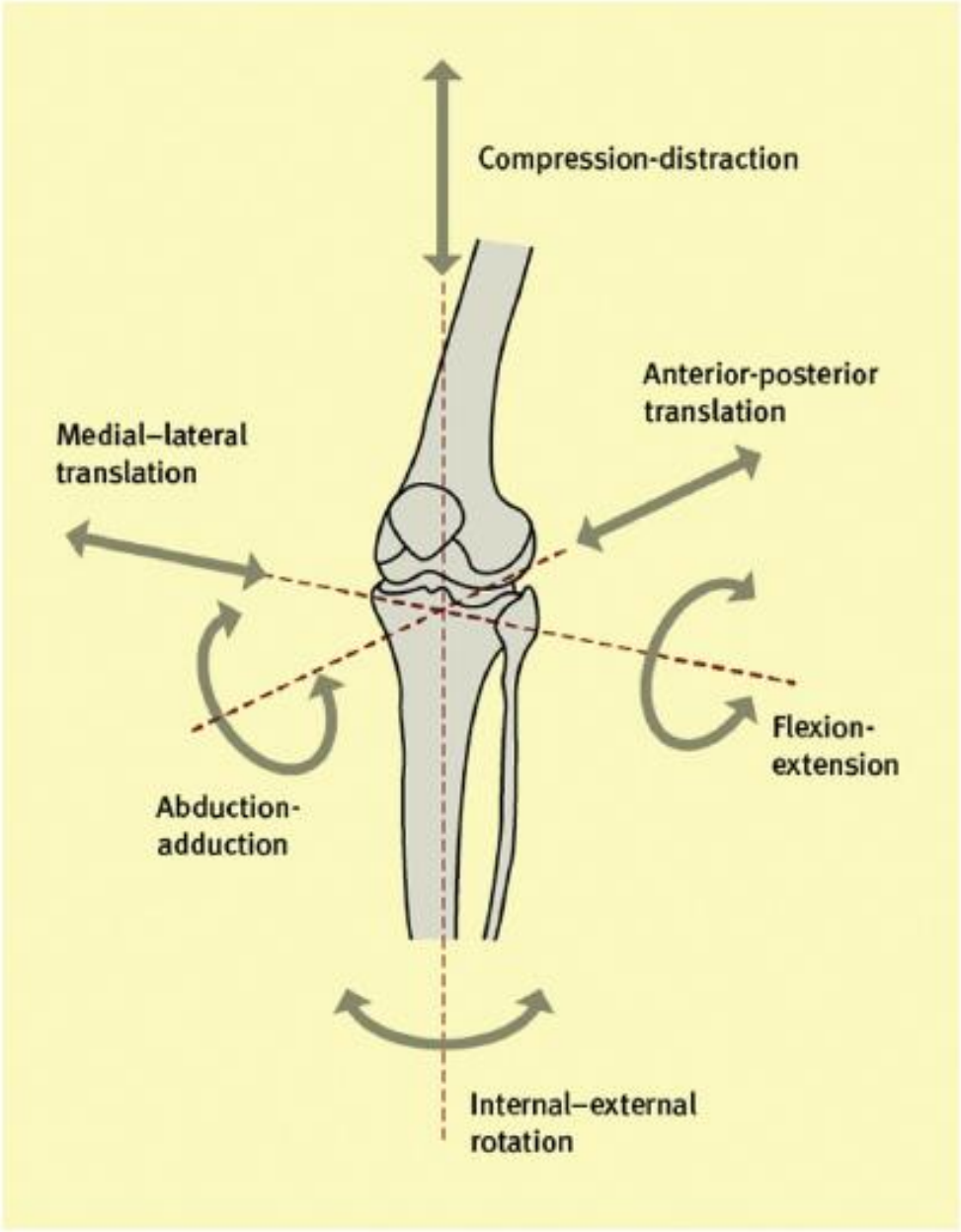


Figure 2.2 Illustrating the six degrees of motion of the human knee joint, with the three principal axes demonstrated with their rotations (Shenoy et al 2013)

primarily by the hamstring muscles contracting, and active flexion usually achieves around 130º - 140º in normal healthy knees, and passive flexion can reach 160º (Amis et al 2010).

In the epicondylar or mediolateral (ML) plane the knee is able to move in a varus and valgus motion with some ML translation. Finally in the tibial axis, the tibial bone can rotate in regards to the femur producing internal and external rotation of the knee (Wings 2013, Amis et al 2010, Woo 1999).

2.1.2 Mechanical axis of knee

The orientation of the femur and tibia at the knee joint from an anatomical and functional perspective is best described in terms of the bones' mechanical axes. In a standing position the orientation of these axes reflects alignment, from the centres of the hip, knee and ankle in a mechanical femoro-tibial alignment (MFTA). This alignment can be neutral, varus (bowlegged - *inward angulation of the distal bony segment*), or valgus (knock-kneed - *outward angulation of the distal bony segment*) as shown in *Figure 2.3* (Cooke *et al* 2007).

The MFTA is a line from centre of the femoral head running distally to the centre of the tibia plafond, and has also been referred to as Maquet's line (Haddad et al 2014, Denham et al 1991). The mechanical femoral-tibia alignment (MFTA) is approximately 180º or neutral (Amis et al 2010).

The mechanical axis of the femur (FM) runs from the centre of the femoral head distally to the mid-condylar point of the knee between the anterior and posterior cruciate ligaments. The tibial mechanical axis (TM) is a line from the centre of the tibial plateau running distally to centre of tibial plafond in the ankle. At 180º the FM and TM are collinear and both pass through the centre of the knee following the load-bearing angle (LBA) (Cooke *et al* 2007).

The angle produced between the femoral (FM) and tibial mechanical axes (TM) is the hip-knee-ankle (HKA angle). In neutral alignment (*Figure 2.3B*) the HKA angle nears 180º. The HKA is positive in valgus deformities lying medial to LBA, and in varus deformities the HKA is negative lying lateral to LBA (Cooke et al 2007).

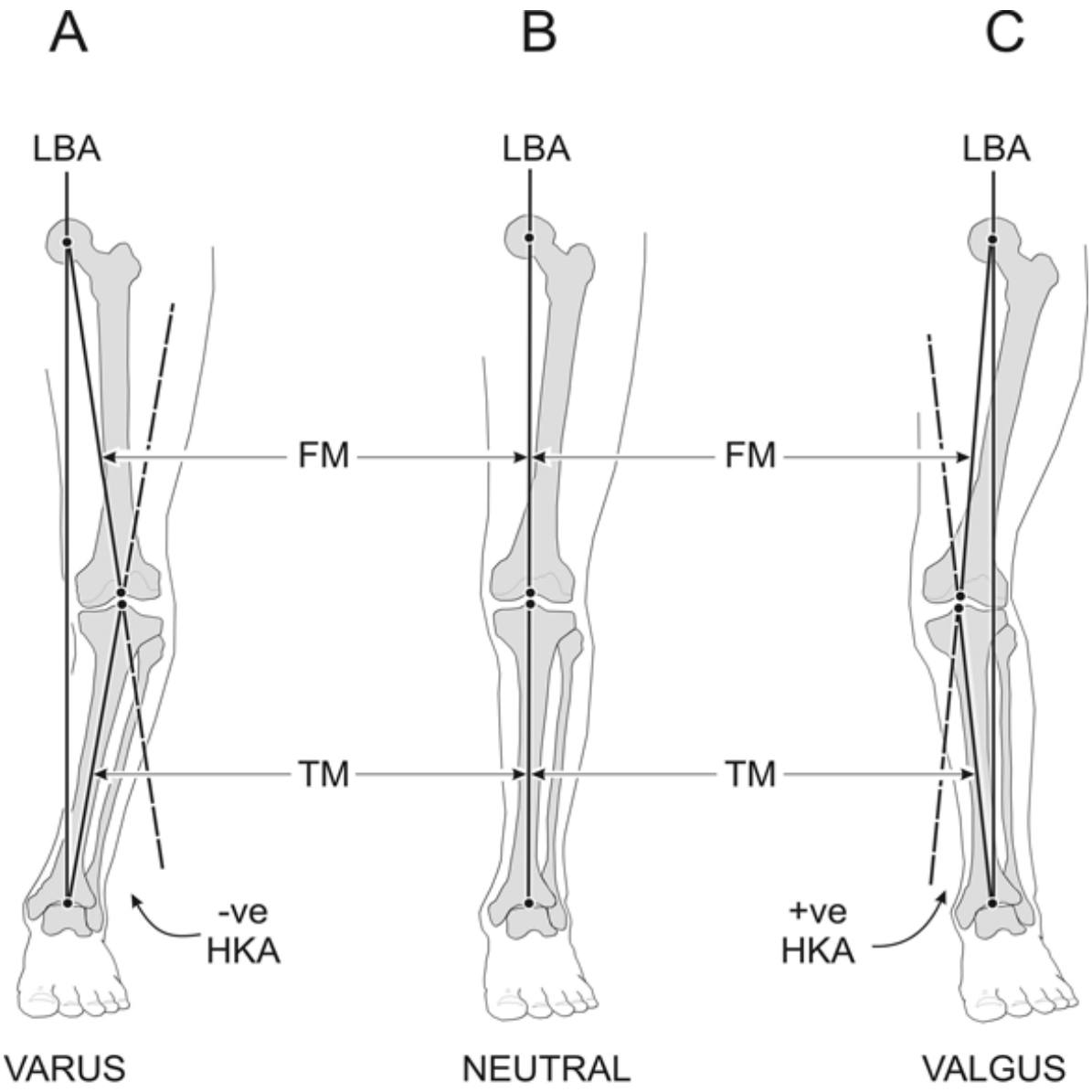


Figure 2.3 Coronal plane lower limb alignment patterns; A. Varus alignment: knee centre is lateral to the LBA (load baring axis). B. Neutral alignment: knee centre is located on the LBA. C. Valgus alignment: knee centre is medial to the LBA (Cooke et al 2007)

2.1.3 Anatomical axis of the knee

The anatomical alignment of the femur at the knee joint is approximately 9º of valgus from the coronal midline, with the tibial anatomical alignment 3º of valgus from the midline. This results in a femoral mechanical-anatomical joint angle (FMA angle) of approximately 6º of valgus as depicted in *Figure 2.4* (Haddad et al 2014). Therefore in the coronal plane there is approximately 6º of valgus between the anatomical femoral axes and the anatomical tibial axis and the mechanical femoral axis (Amis et al 2010).

The tibial mechanical (TM) and tibial anatomical axes overlap whereas the femoral mechanical axis (FM) and femoral anatomical axis are between 5º and 7º apart depending on the individuals height and pelvic width (Shenoy et al 2013).

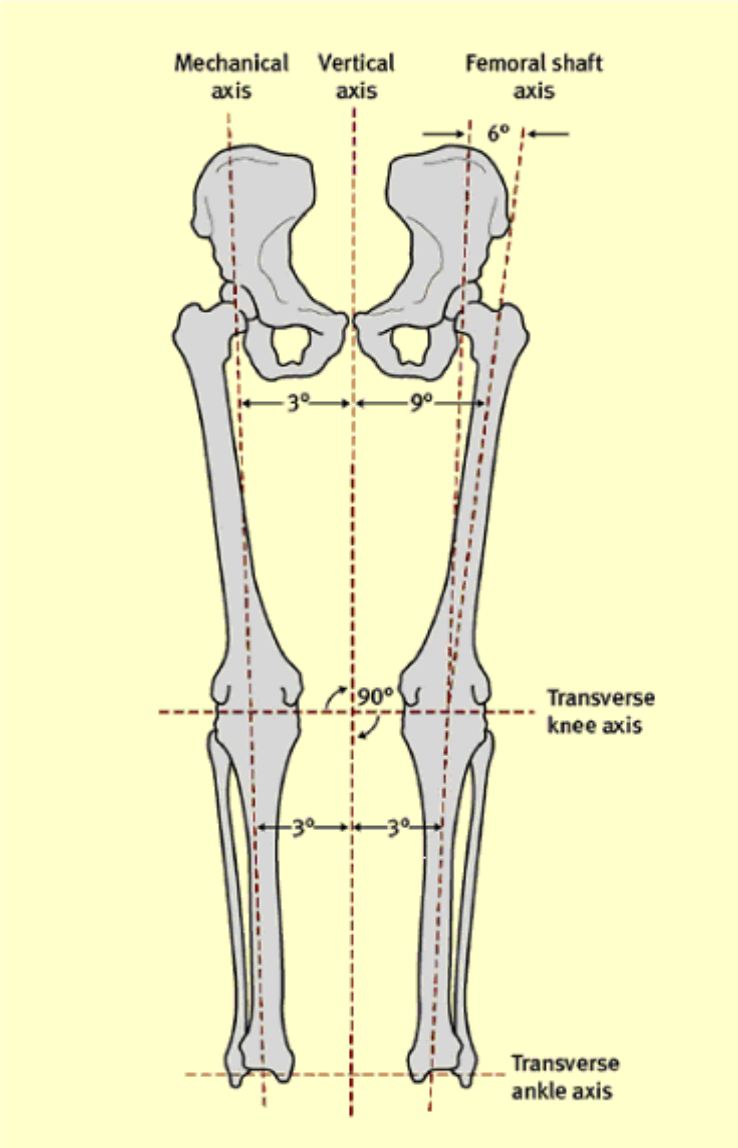


Figure 2.4 Illustration of the anatomical and mechanical axes of the lower limb (Shenoy et al 2013)

Therefore the overall alignment in the coronal plane can be considered as either the mechanical femoral-tibial alignment (MFTA) or the anatomical femoral-tibial alignment (AFTA) as depicted in *Figure 2.5* (Haddad et al 2014, Toms et al 2014).

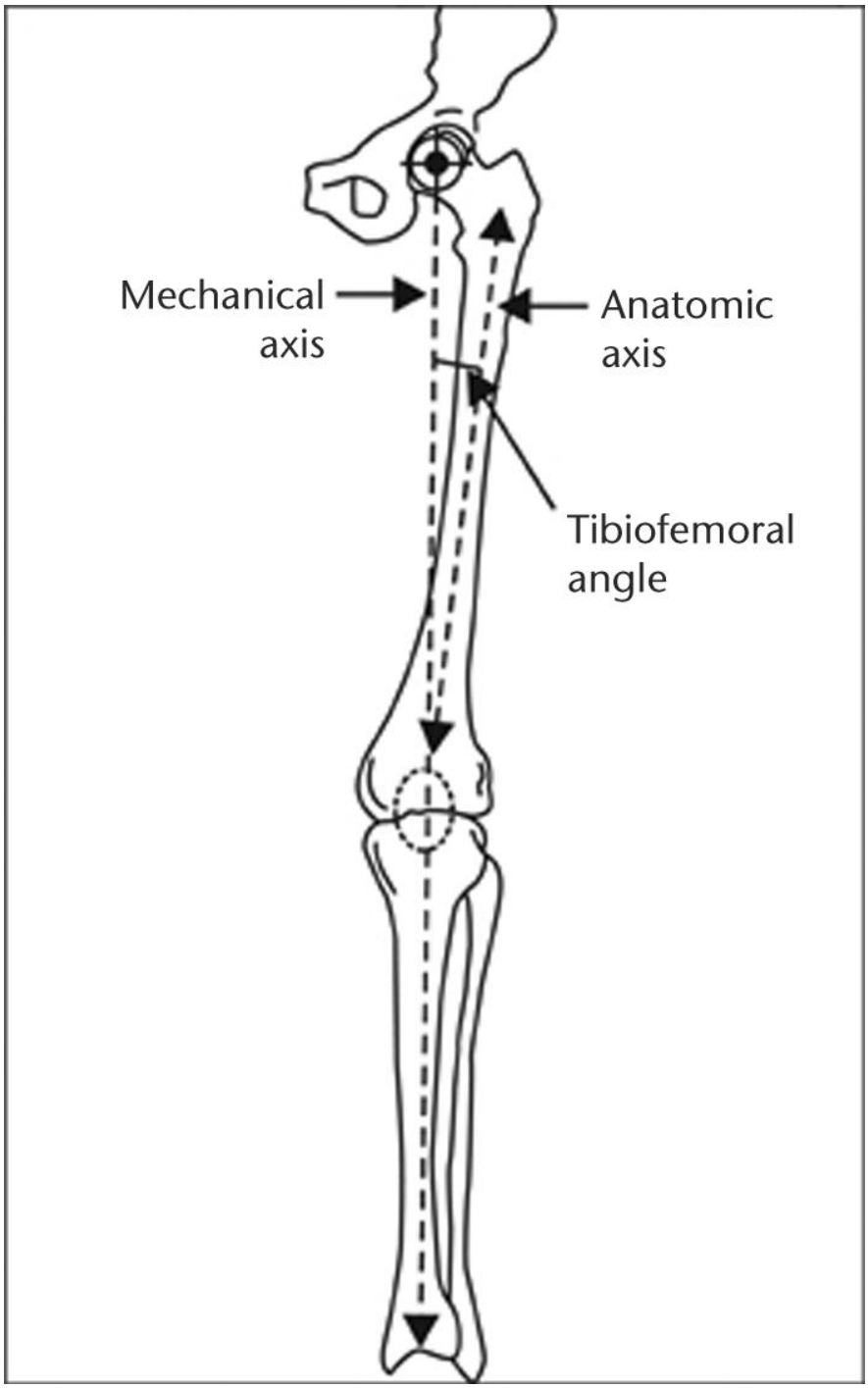


Figure 2.5 The relationship between the mechanical and anatomic axis demonstrating the tibio-femoral angle (Toms et al 2014)

2.2 Anterior Cruciate Ligament (ACL)

2.2.1 Background to the ACL

The anterior cruciate ligament (ACL) attaches anteriorly on the intercondylar eminence of the tibia, and posteriorly on the intercondylar notch on the postero-medial aspect of lateral femoral condyle as shown in *Figure 2.6 and 2.7* (Ghosh & Deeham 2013, Performance orthopaedics 2014). The ACL is considered to consist of two functional bundles the antero-medial (AM) and postero-lateral (PL) bundles which provide anteroposterior (AM bundle) and rotational (PL bundle) stability in the knee as shown in *Figure 2.8* (Huang 2014, Woo et al 2006, Amis & Van Arkel 2013). The PL bundle may also influence anterior translation at 30º flexion, frequent position of the knee during sporting activities (Picard 2007).

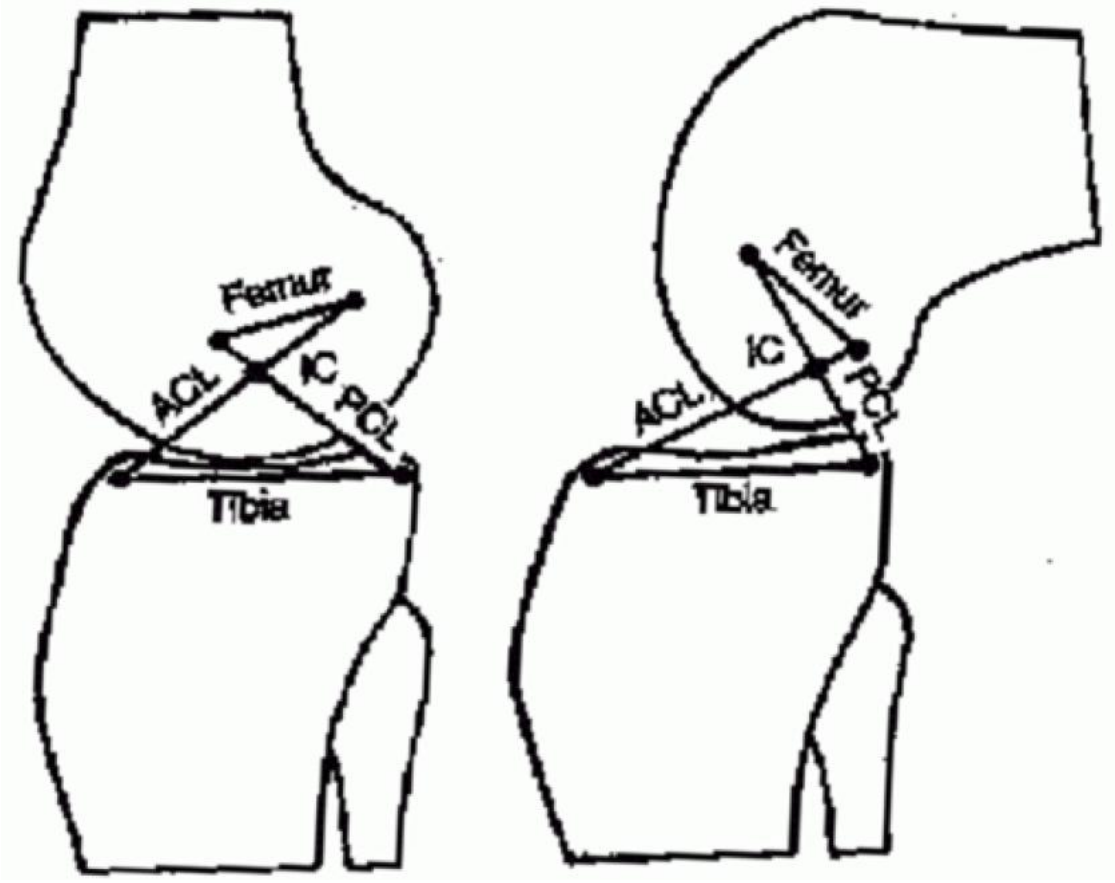


Figure 2.6 Anterior and Posterior Cruciate Ligament attachments in the knee (Performance orthopaedics 2014)

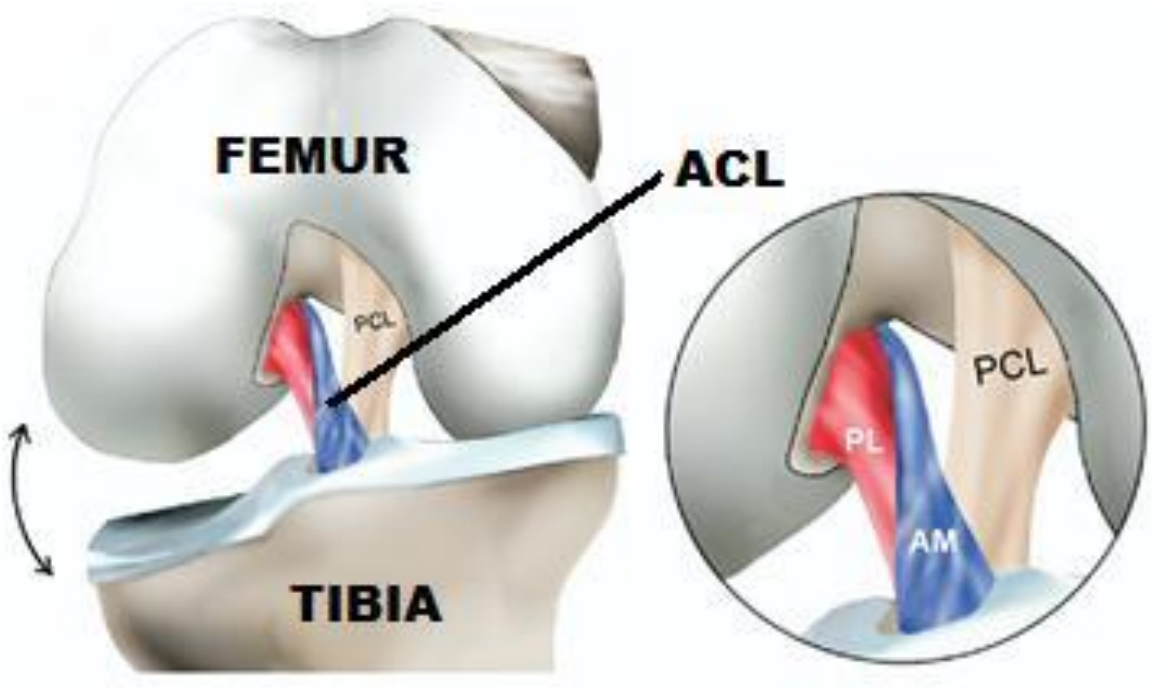


Figure 2.7 Illustration of the two functional bundles of the anterior cruciate ligament (ACL); the antero-medial (AM) and postero-lateral (PL) bundles (Performance orthopaedics 2014)

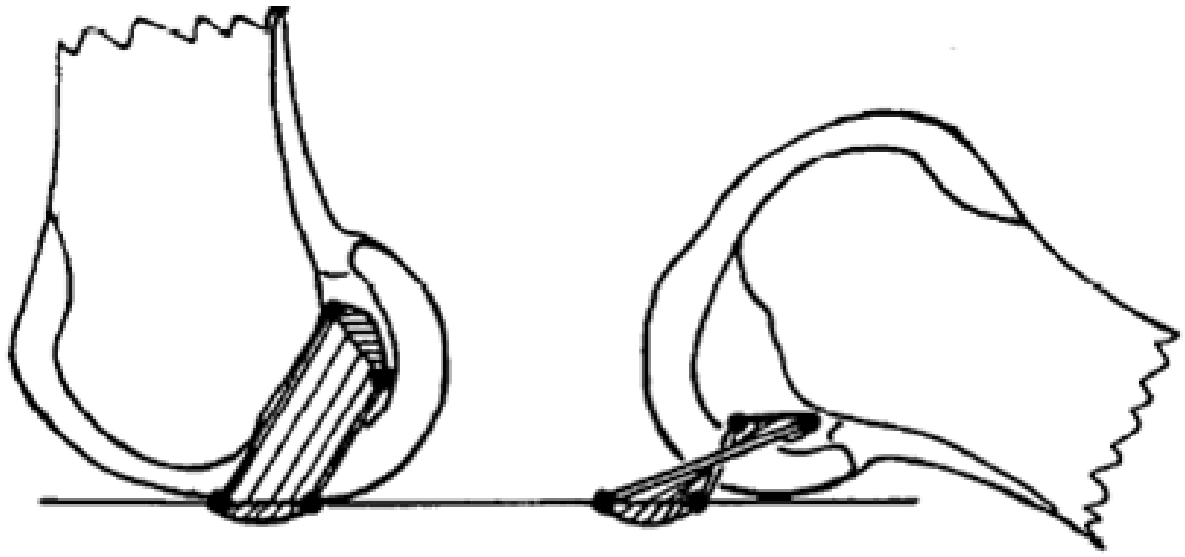


Figure 2.8 The antero-medial fibre area on the tibia attaches antero-proximally to the femur when the knee is extended. The posterior-lateral fibres attach posterior-distally to the femur in extension. The image above shows how the ACL twists as the knee flexes and how the femur rolls posteriorly on the tibia. (Amis & Van Arkel 2013)

When the tibia translates anteriorly the ACL stretches and the elastic tension in the ACL rises rapidly. The ACL is a primary brake to anterior dislocation and translation of the tibia, resisting approximately 90% of these displacing forces. The ACL can also act as a secondary restraint to (1) internal tibia rotation, (2) valgus tibia rotation at full extension, and (3) prevents knee hyperextension. The ACL also controls the screw home mechanism of the knee (Amis et al 2010, Amis & Van Arkel 2013).

The ACL plays an integral role in knee flexion and extension. In early knee flexion the ACL slackens allowing the femur to roll posteriorly over the tibial plateau. As the knee continues to flex, the ACL tightens and the motion changes from a roll back to a continuous rolling, as well as sliding motion preventing knee dislocation in deep flexion as shown in *Figure 2.9* (Amis et al 2010, Amis & Van Arkel 2013, Shenoy et al 2013). The ACL tightens during the screw home mechanism in knee extension, aiding to stiffen the knee in extension, reducing energy requirements to stabilise the knee during standing and also heel strike in gait (Amis & Van Arkel 2013).

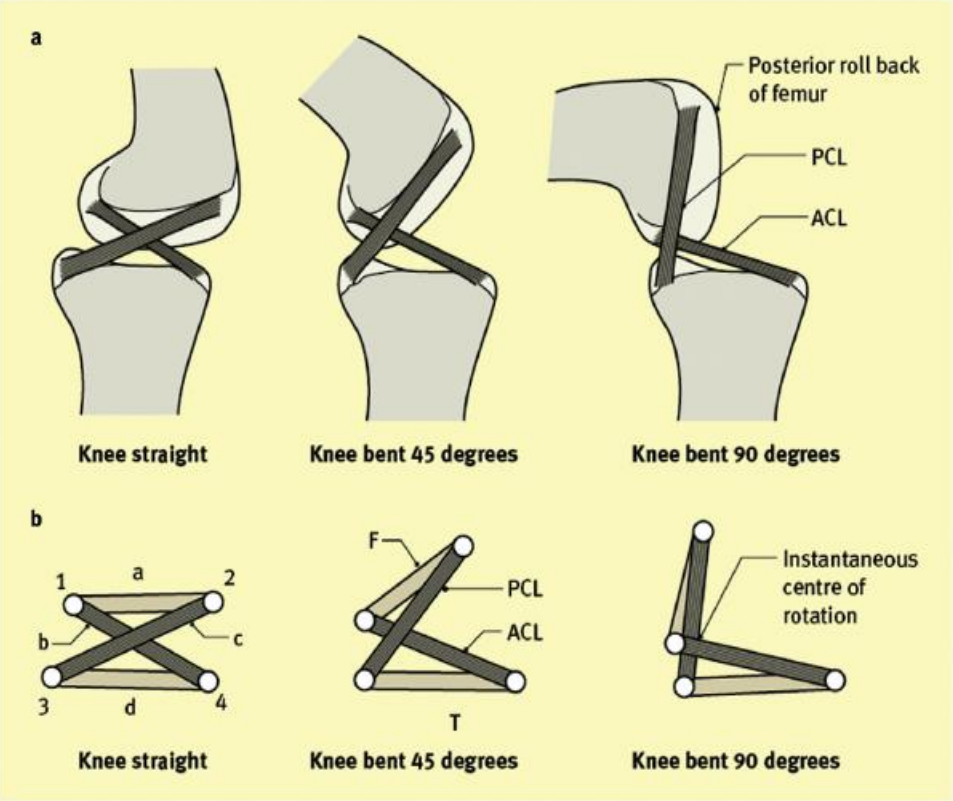


Figure 2.9 The ACL and PCL guide femoral roll back in flexion, b. four-bar linkage formed by the fixed distance between femoral attachments of the ACL and PCL (Shenoy et al 2013)

2.2.2 ACL injuries

ACL injury and rupture is the most common sporting injuries to occur to young athletes (Mavrogenis et al 2013), with 90% of all knee ligament injuries involving the ACL (Woo et al 2006). Disruption of the ACL results in increased anterior tibial translation, as well as medial displacement of the centre of rotation of patient's knee. This disrupts natural knee biomechanics and kinematics, resulting in increased loading on soft tissues and increases risk of subsequent knee injuries. (Amis et al 2010, Dujardin 2011).

ACL injury/deficiency diagnosis is not always possible by laxity measurement alone (Lachman test and pivot-shift test) or even with the gold standard instrumentation use (KT-1000/2000), due to the wide spectrum of physiological laxity even in normal knees (Dujarin 2011, Amis *et al* 2008). Therefore the concept of a 'side to side difference' was developed, where a difference of 3mm or greater of AP laxity between either side of a patients knees is highly suggestive of ACL injury (Amis *et al* 2008).

2.2.3 ACL injuries increase AP and rotational laxity

When the ACL is severed, there is a statistically significant increase in AP translation and internal rotation (Lipke et al 1981). Injuries acquired during sporting activities, often result in increased rotational laxity. When the ACL and posterior-lateral structures are injured, there is increased tibia translation and external rotation (Alam et al 2013).

2.2.4 ACL Reconstruction

Anterior Cruciate Ligament (ACL) reconstruction produces good results in terms of ligament surgery, but has a failure rate of 5 – 20% according to literature (Amis *et al* 2008). Causes for failure are multifactorial; including graft type (synthetic or patellar tendon/hamstring), quality of graft, graft fixation and positioning, and the origin of ACL failure (Picard 2007).

The cruciate ligament tissue fails when it length is exceed by 20% (+/- 14-27% depending on the literature). The ACL is reported to have a length of 32 mm and therefore an extension of 7mm could result in ACL rupture. The viscoelastic nature of the ACL has a more significant limit at only 6%, and when the ACL is stretched beyond this limit may result in permanent stretching, representing an elongation of only 2mm. Therefore the ACL must inherently change its length by 2mm during knee function by being slack for part of knee motion (Amis & Van Arkel 2013).

ACL reconstruction can be performed by arthroscopic techniques using specific portal and views, and computer assisted navigation surgery (CAS). Picard suggested that the position of the femoral and tibial tunnel should be placed in the native origin and insertion of the ACL. The femoral attachment location is most important in regards to graft length change (Amis & Van Arkel 2013, Picard 2007).

The use of CAS further aids the surgeon in identifying the correct anatomical position for tunnelling and ACL positioning as well as ensuring the knee kinematics are maintained. Reconstruction of both bundles by CAS may be better suited for patients who present with major knee instability, strongly positive pivot-shift test and large degrees of AP laxity, and convention laparoscopic repair for single (AM bundle) bundle reconstruction for the less complex presentations (Picard 2007).

2.3 Other supportive soft tissue structures and their roles

Due to the complexity of the two articulations tibio-femoral (TF) and patello-femoral (PF) of the knee joint, additional support from the surrounding soft tissue structures (the menisci, capsule, tendons and ligaments) is required with simple bony articulations to maintain stability of the knee (Amis et al 2010, Woo et al 1999, Woo et al 2006) as shown in *Figure 2.10*.

Ligaments transfer the large loads place through them in a longitudinal direction, from bone to bone. This uniaxial transferring of loads aids ligaments to maintain smooth movement of the joint during normal physiological conditions, and restrain excessive joint movements under large loads. Each ligament provides stability in more than one direction of motion whilst also restraining knee motion if external loads are applied (Woo et al 2006).

If any of these soft tissue structures were to be damaged the fluent overall motion of the knee would be disrupted and could lead to instability and further structural damage due to the remaining structures compensating and carrying increased loads (Woo et al 1999).

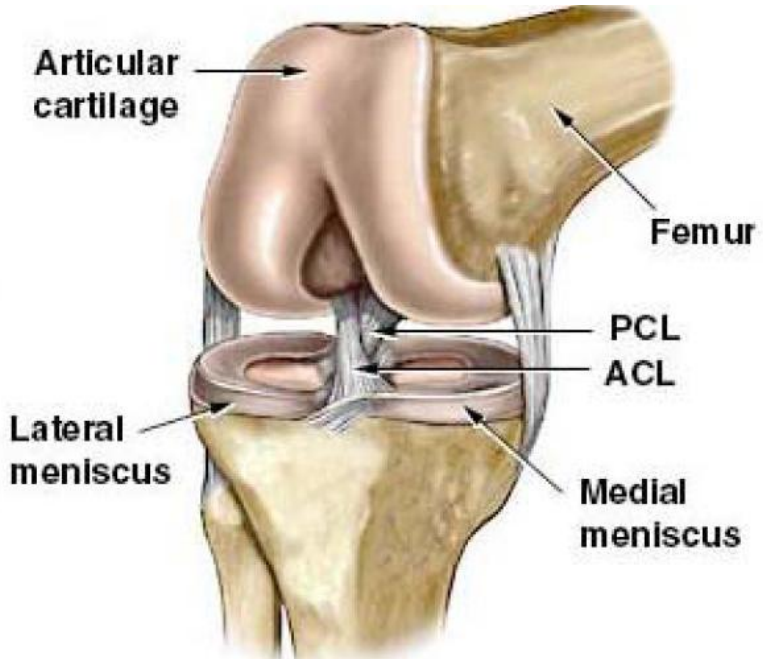


Figure 2.10 Image depicting the knee joint with its surrounding, supportive structures (ACL, PCL, menisci and collateral ligaments) (Performance orthopaedics 2014)

2.3.1 Medial collateral ligament

The medial collateral ligament (MCL) is broad, flat, membranous band on the medial aspect of the knee. The MCL acts as the restraint to internal tibia rotation and valgus angulation. The MCL also acts as an additional restraint to external tibia rotation and anterior tibial translations (Amis et al 2010, Woo et al 2006)

2.3.2 Lateral collateral ligament

The lateral collateral ligament (LCL) is a rounded, narrow ligament located on the lateral aspect of the knee. The LCL acts as the restraint to varus angulation and external tibial rotation in conjunction with the postero-lateral corner. The LCL is also a secondary restraint to posterior translation (Amis et al 2010, Woo et al 2006).

2.3.3 Meniscal ligaments

The knee contains two crescent-wedge shaped fibrocartilage menisci attached to the tibia plateau as shown in *Figure 2.11*, whose chief function is protecting the surrounding articular cartilage during weight-bearing. The menisci also play a role in knee stability; lubrication and nutrition of the knee joint (Ghosh & Deeham 2013). The meniscus-meniscal ligament complex, deep MCL and menisco-femoral ligaments all act as primary restraints to tibial rotation and as additional restraints to AP translation (Amis et al 2010).

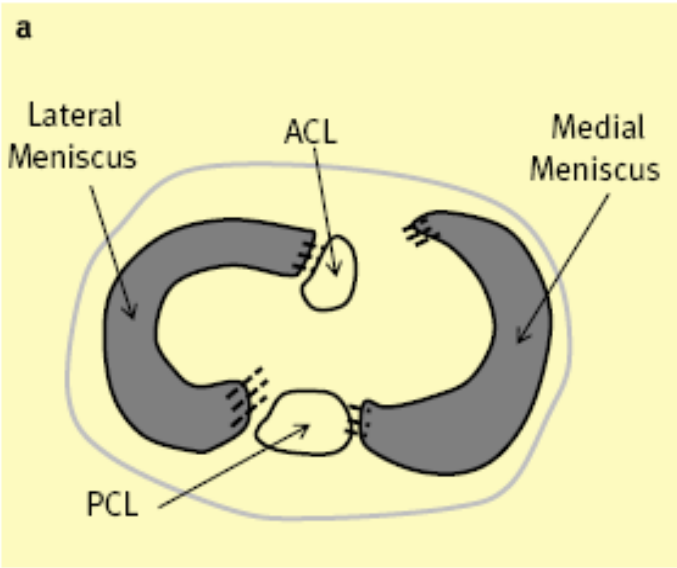


Figure 2.11 The tibial plateau with two crescent-wedge shaped menisci (Amis et al 2013)

2.4 Antero-Posterior (AP) laxity and translation

Laxity of the knee joint depends on the shape of the bony surfaces as well as its surrounding, supporting soft tissues. The joint capsule, collateral and cruciate ligaments and menisci aid support the knee joint and improve bony fit between the incongruent surfaces (Küpper et al 2007, Cross 1996).

The knee joint displays a wide spectrum of laxity, from inherently stable to excessively lax, even within the normal, uninjured population. Excessive joint laxity can occur with soft tissue injury, ligament tears and joint hypermobility syndromes (Marfan's and Ehlers-Danlos syndromes), potentially leading to joint dislocations, subluxations, and inflammatory arthritis (Küpper et al 2007).

In full extension, anteroposterior (AP) translation is minimal due to the screw home mechanism of the knee (more information in *AP rotation section*). AP translation is greatest at 30º of flexion as anterior knee restraints are at their most lax (Amis et al 2010). In this position normal (non-ligament pathology) knees can anterior translates between 2 and 10mm (Sheldon 1994). Anterior laxity diminishes as knee flexion increases, particularly beyond 90º (Amis et al 2010).

Posterior knee translation is greatest at 90º of knee flexion and varies from 0 to 6mm. The amount of AP and posterior translation is dependent on the amount of force/load applied as well as knee positioning. When these variables are controlled, normal knees will have a left to right AP laxity of 2mm or less (Sheldon 1994).

2.5 Antero-Posterior (AP) rotation and rotational laxity

In full extension there is no rotation in the knee due to interlocking of the femoral condyles with the tibial condyles. Flexion of the knee aids rotation, with maximal internal and external knee rotation occurring at 90º of flexion, and maximal abduction and adduction occurring at > 0º and ≤ 30º of flexion (Wings 2013). Alam *et al* noted that tibia external rotation is significantly greater at 30º compared to 90º of knee flexion (Alam et al 2011).

Rotational mobility of the femur is a fundamental problem when trying to measure tibio-femoral internal and external rotation. Femoral rotation is greatest nearer full extension, and is controllable near 90º of flexion. This is evident clinically with rotational instability occurring with weight-bearing closer to full extension (Alam et al 2013).

2.5.1 Rotational knee kinematics and the screw home mechanism

The knee moves with a natural rolling motion to initiate flexion and at end range of flexion attains a gliding motion as shown in *Figure 2.12*. The knee has two contact points in flexion; medially the femur contacts slightly anterior on the tibia, and laterally the femur contacts considerably posterior on the tibia (Amis et al 2010).

The complex rotational motion noted in the knee during flexion and extension is largely due to the contours of femoral and tibial condyles. The femur has a larger medial condylar joint surface area contacting the tibia compared to the lateral condyle (Amis et al 2010). This is due to the medial tibial plateau being slightly concaved, whereas the lateral tibial plateau being flat or slightly convex (same convex shape as lateral femoral condyle), allowing for smaller surface contact area on the lateral TF joint compartment as shown in *Figure 2.13*. Therefore the centre of contact on the medial side remains constant in AP positioning but the lateral condyle rolls posteriorly towards the posterior horn of the lateral meniscus, and is less stable than the medial side (Amis et al 2010, Amis et al 2013).

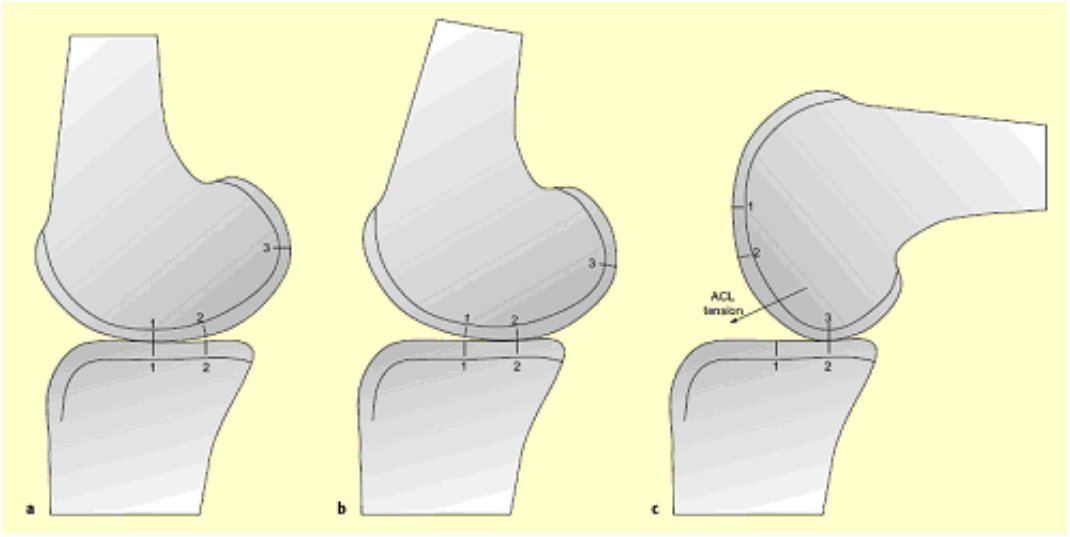


Figure 2.12 Knee joint kinematics during flexion. a – Full extension femoral contact is located centrally. b Early flexion: posterior rolling of the femur; contact continuously moves posteriorly. c Deep flexion: femoral sliding; contact is located posteriorly; the unlocking of the ACL prevents further femoral roll back (Amis et al 2010)

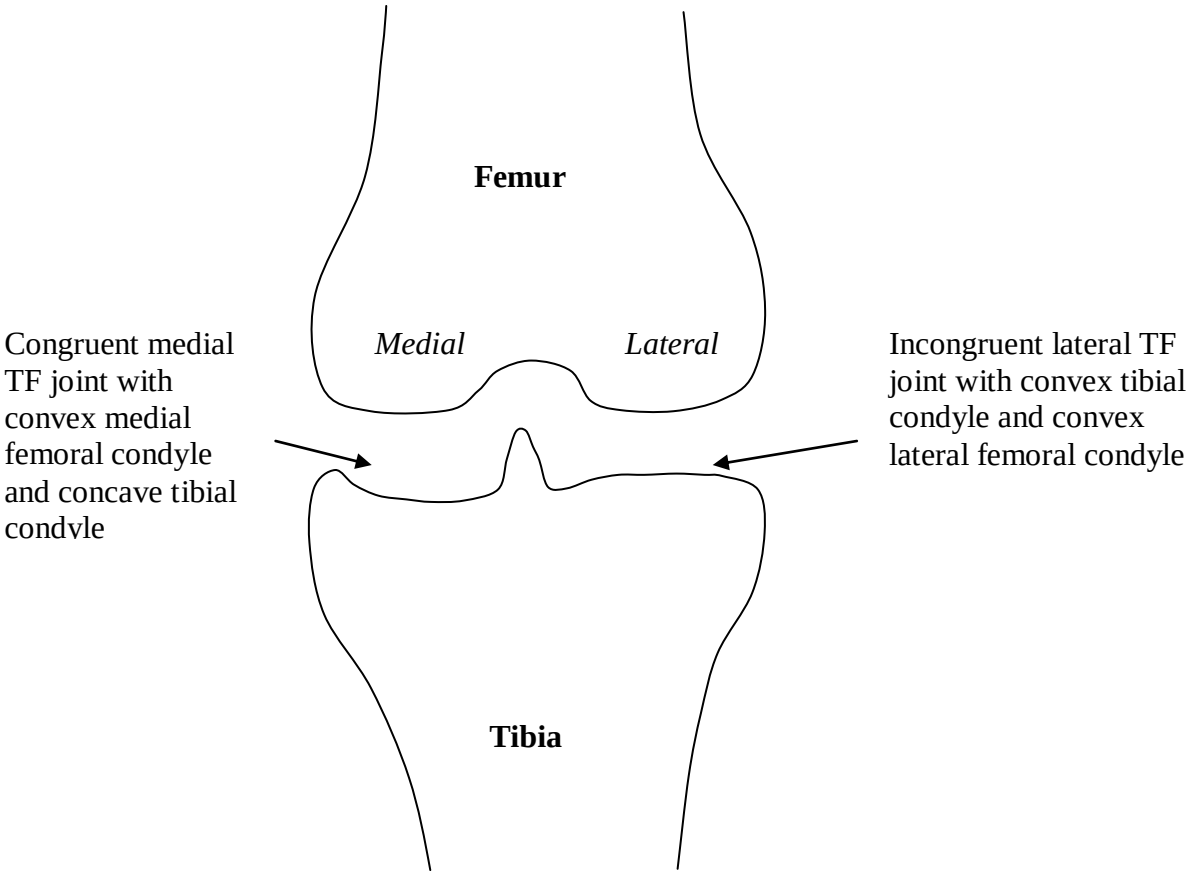
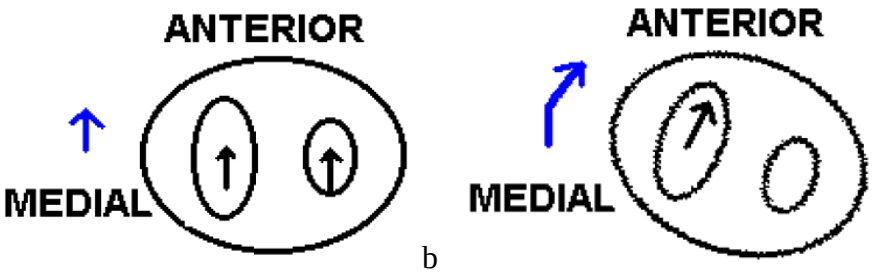


Figure 2.13 depicting the congruent medial TF joint and incongruent lateral TF joint

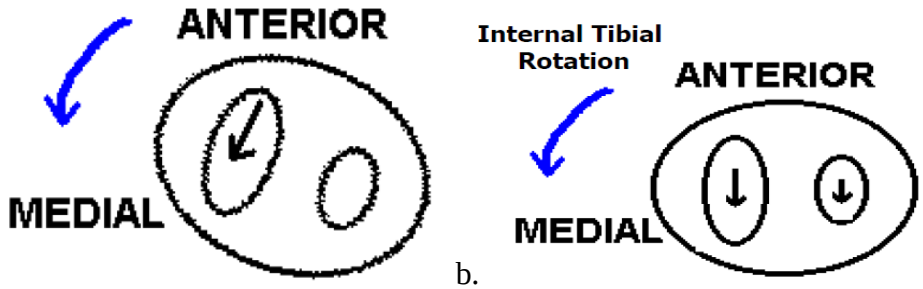
In knee extension the tibia rolls anterior on the femur elongating the PCL which pulls on the tibia causing it to glide anteriorly on the femur as shown in *Figure 2.14a* (Wings 2013). During the last 20º of knee extension to 0º, prolonged anterior glide on the medial side produces external tibia rotation, as the shorter glide of the lateral condyle rotates the tibia and tightens the collateral ligaments in full extension, as seen in *Figure 2.14b*. This is known as the screw home mechanism and is a key element to knee stability for standing upright (Wings 2013, Wheeless 2014).

As flexion initiates the ACL in turn pulls on the tibia causing it to glide posteriorly inducing internal tibia rotation as the tibia rolls posteriorly. This process is initiated by the popliteus, reducing tension on collateral ligaments allowing flexion to be initiated, and is known as the reverse screw home mechanism (Wings 2013, Wheeless 2014). This is shown in *Figures 2.15.a and b.*



a. b

Figure 2.14 *a*. Axial view of anterior tibial glide on the femur, persisting on the tibial medial condyle (longer articulate surface). *b*. The prolonged tibia anterior glide induces external tibia rotation (screw-home mechanism) (Wings 2013)



a. b.

Figure 2.15 *a*. Flexion from full extension results in the ACL pulling on the tibia causing the tibia to glide posteriorly on the longer medial tibial condyle. *b*. The early posterior tibia glide produces internal tibia rotation (reverse screw-home mechanism) (Wings 2013)

2.6 Testing anteroposterior (AP) laxity

2.6.1 Testing anteroposterior (AP) laxity in a clinic setting

In the clinical setting the assessment of anteroposterior (AP) laxity and ligament integrity is performed by manual passive testing. Tests such as the Lachman test, anterior/posterior draw test and the pivot shift tests can diagnose cruciate ligament deficiency when used by experienced clinicians, but are subjective and do not allow for quantitative comparisons between patients or clinicians (Küpper et al 2007, Mitsou et al 1988, Edixhoven et al 1989, Lopomo et al 2010).

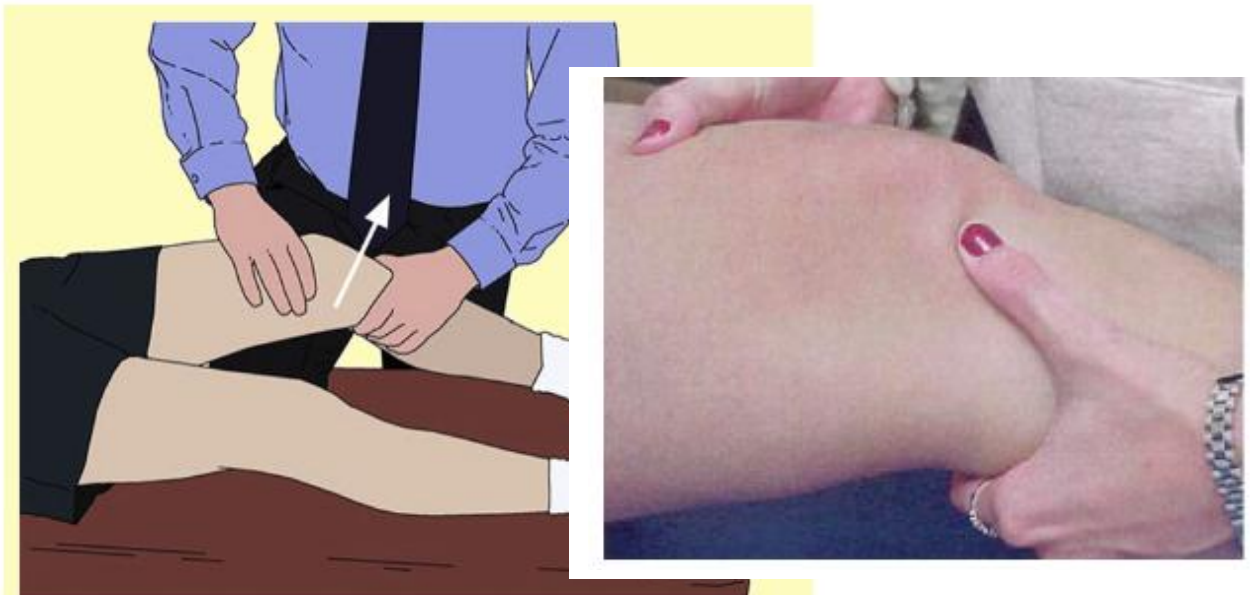
2.6.2 Anterior draw test

The anterior draw test is performed with the patient lying supine and the patient's knee flexed to 90º, and the ipsilateral foot immobilised. An anterior force is applied to the tibia to assess for AP laxity, as shown in *Figure 2.16*. The anterior draw test is classically used to assess for ACL injuries, with a positive test demonstrating increased AP translation. This test however has poor sensitivity and specificity when compared to Lachman and pivot-shift tests in isolating ACL injuries, but is still used clinically in association with these other tests (Ghosh & Deeham 2013).

Figure 2.16 Anterior draw test, with clinician applying an anterior force to the tibia (Ghosh & Deeham 2013)

2.6.3 Lachman test

The Lachman test is a clinical assessment performed at 30º of knee flexion with the patient lying supine. One of the clinician's hands stabilises the antero-lateral distal femur and the other hand is placed posterior to the proximal tibia, and an anterior draw force is applied to assess tibio-femoral translation as shown in *Figure 2.17a and 2.17b* (Ghosh & Deeham 2013, Winson et al 1997). Hurley *et al* demonstrated that the more proximal the clinician places their hand on the tibia (*Figure 2.17b*), the greater the ACL strain measured and the more specific and sensitive the Lachman test (Hurley *et al* 2004).



a. *b.*

Figure 2.17 *a*. Lachman test performed at 30º of knee flexion with clinician's applying anterior draw force to tibia and posterior force on the femur (Ghosh & Deeham 2013), *b.* Hurley depiction of proximal positioning of clinician hand on the tibia, with contralateral hand stabilising the antero-lateral distal femur (Hurley *et al* 2004)

Tibia anterior translation beyond the femur with a soft, spongy endpoint is indicative of a positive test. The degree of AP displacement can then be graded when compared to the contralateral uninjured leg, as shown in *Table A* (Ghosh & Deeham 2013). The Lachman test has reported ACL rupture with a diagnostic accuracy of 73 to 99%, especially when experienced clinicians are performing the test, offering high specificity and sensitivity (Ghosh & Deeham 2013, Winson et al 1997).

Quantitative grading of ligament laxity[5]

Grade	Degree of translation (mm)
I	0–5
II	6–10
III	>10

Table A. Demonstrating quantitative grading of ligament laxity (Ghosh & Deeham 2013)

Wiertsema *et al* conducted a study assessing the Lachman test against the KT1000 arthrometer, two commonly used assessment tools to diagnose ACL tears in a clinical setting. Wiertsema noted that the KT1000 showed inadequate reproducibility even when used by an experienced KT1000 clinician, whereas the Lachman test demonstrated high intra-examiner and inter-examiner reproducibility (Wiertsema et al 2008).

The Lachman test has a far more consistent acceptance of reliability and repeatability in current literature. However, the current gold standard instrument used in the clinical setting for AP laxity assessment is the KT1000 arthrometer. This instrument does allow the clinician to attain quantitative AP laxity measurements. The KT1000 arthrometer has shown variable reliability and repeatability in the currently available literature, with poor intra- and inter-rater reproducibility when using this instrument (Wiertsema et al 2008).

A meta-analysis of the Lachman test, anterior draw test and pivot-shift test showed that the Lachman test had the highest sensitivity for diagnosing ACL ruptures, and the pivot-shift test had the highest specificity. When there is a low probability of ACL injury, a negative Lachman test makes a rupture very unlikely (<3%). The review also showed that when there is a high probability of ACL injury, a positive pivot-shift is highly indicative of ACL rupture (>90%) and the need for further imaging may be unwarranted (Van de Plas et al 2005).

2.6.4 Pivot-shift test (PST)

The PST best mimics the event of subluxation due to ACL loss. Amis *et al* states the PST most closely correlates with ACL deficient (ACLD) patients functional scores, and is best performed in conjunction with the Lachman's test to assess the degree of rotatory instability in ACLD (Ghosh & Deeham 2013, Amis et al 2008, Lopomo et al 2010).

To perform the pivot-shift test (PST), first the hip is abducted which relaxes the iliotibial band, and then an internal rotation and valgus force is applied whilst gradually flexing the knee from full extension as shown in *Figure 2.18,* with a progressive subluxation occurring between 20º to 40º of flexion in ACL deficient knees, (Ghosh & Deeham 2013, Lopomo et al 2010, Matsumoto 1990). Matsumoto used the PST to demonstrate a sudden reduction of knees in cadavers with ACL deficiency, and thought this effect was caused by the increasing posteriorly directed tension on the iliotibial band (Matsumoto 1990).

Lachman and pivot-shift tests demonstrate greater anterior tibia translation and greater AP laxity when there is a complete ACL rupture compared to all different forms of partial ACL rupture (Dejour 2012). The PST may be more reliable in identifying postero-lateral partial ACL ruptures as reported by Petersen & Zantop (Peterson & Zantop 2006).

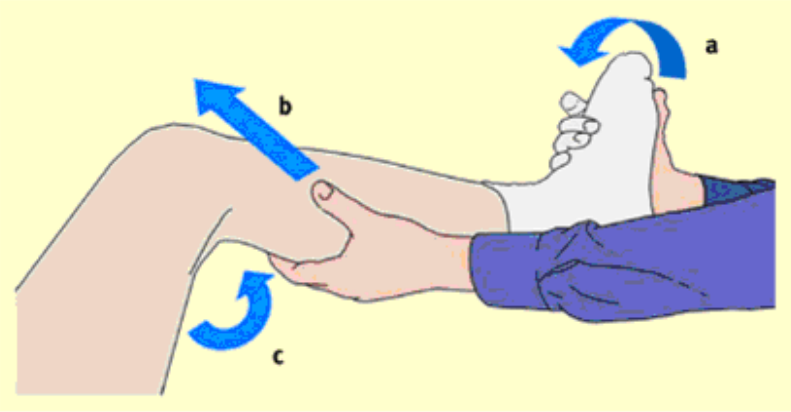


Figure 2.18 Pivot-shift test, a. Clinician placing an internal rotation of lower limb, b. a valgus force is applied, c. gradually flexes the knee from full extension (Ghosh & Deeham 2013).

2.6.5 Previous methods of assessing anteroposterior (AP) laxity

Knee laxity in the past was often measured using an isolated AP translational laxity measure with paired x-rays to assess laxity. This method was unable to correct for tibia rotation in regards to the femur and was also harmful with the use of ionising radiation. The development of the 'knee tester' KT -1000 has led to a more clinic and patient friendly method of testing laxity (Amis et al 2008).

2.7 Instruments used to assess anteroposterior (AP) translation and laxity

2.7.1 Currently available instruments used to assess anteroposterior (AP) translation and laxity in a clinical setting

Devices with quantitative measurements have been created to measure anteroposterior (AP) translation of the tibia (KT-1000 arthrometer), and tibia rotation (Rotameter) with repeatability and reliability and to within ±1mm of accuracy, in the clinical setting (Amis et al 2008, Küpper et al 2007, Lorbach et al 2009).

Alternative investigations have been developed; including planar stress radiography, magnetic resonance imaging (MRI) and stereophotogrammetric analysis in the research setting to more accurately measure knee joint displacement (Küpper et al 2007). MRI has become the preferred imaging modality for diagnosing ligamentous and meniscal injuries, as well as avascular necrosis and articular cartilage defects (Ghosh & Deeham 2013). However, MRI alone has a poor accuracy level at distinguishing between partial and complete ACL tears, ACL muciod degeneration and post-traumatic haematoma, with significant overlap among all the different pathological types (Van Dyck *et al* 2012*)*.

Even though instrumentation is widely available and used in the clinical setting a combination of good clinical assessment with the use of instruments leads to optimum results. This was shown by Dejour who found that a combination of Lachman and pivot-shift tests with stress radiographs produced values that could distinguish between complete and partial ACL tears, and in combination gave both clinical and objective data. This method therefore out performs the MRI alone and would aid the surgeon more in early identification of different rupture types and more prompt and appropriate treatment (Dejour 2012).

2.7.2 Non-invasive means of measuring knee kinematics

Over the last two decades there has been an exciting development in the field of bioengineering and wireless sensor monitoring of human movement (Gibbs et al 2005, Darwish et al 2011). These small, cheap and accurate monitoring devices have been shown to be extremely beneficial in healthcare and especially rehabilitation of patients whom have undergone orthopaedic joint replacement (Gibbs et al 2005, Darwish et al 2011, Dunias et al 2013, Ascari et al 2013). There are numerous means of monitoring human movement, but due to the complexity of human movement there is no suitable single device available at present for long term human monitoring (Gibbs et al 2005, Huddleston et al 2006).

Currently there are numerous devices that can be placed onto the human body for assessing movement, body shape, posture and gesture measurements. These devices come in the form of gloves, leotards, stocking devices with either sensors embedded in the fabric or externally mounted on the stocking which can be placed on the elbow, knee, hip (Gibbs et al 2005, Lorussi *et al* 2004).

Optical motion system analysers

There are a range of video and optical motion analysis systems with varying means of data capture with active or passive tracker markers. Some optical motion systems use infrared cameras and others use magnetic fields to capture body motion. Each system has its own programming and algorithms to process the data acquired, which is ascertained from body landmarks (hip or knee joint centre, joint kinematics and kinetics) which are defined by external markers visible to the motion capture systems (Freeman 2005, Kertis 2009). Optical cameras record the position of the external markers as the subject moves through a defined capture area. At least two cameras are needed to detect the markers for the system to identify the markers 3D coordinates. Each camera only identifies a defined marker in 2D, and therefore multiple cameras are required to attain a 3D coordinate of each marker. The markers located are then given labels to identify their anatomical position (LMT: Left Mid-Thigh). Each of these cameras are synchronised to record data at the same frame rate

50-250 frames / second (Visual 3D 2016, Vicon 2016, Kertis 2009). There are a variety of different marker sets that can be used to assess joint motion and kinematics; using a variety of model designs in which to place these markers; such as Helen-Hayes model (shown below in *Figure 2.19*), Gaitlab model and the Cleveland Clinic model (Clinical Gait Analysis 2014, Kertis 2009). The optical motion system software then determines the orientation of joint and motion between segments. Optical motion systems have been shown to have an accuracy of 0.1mm (Miller 2002).

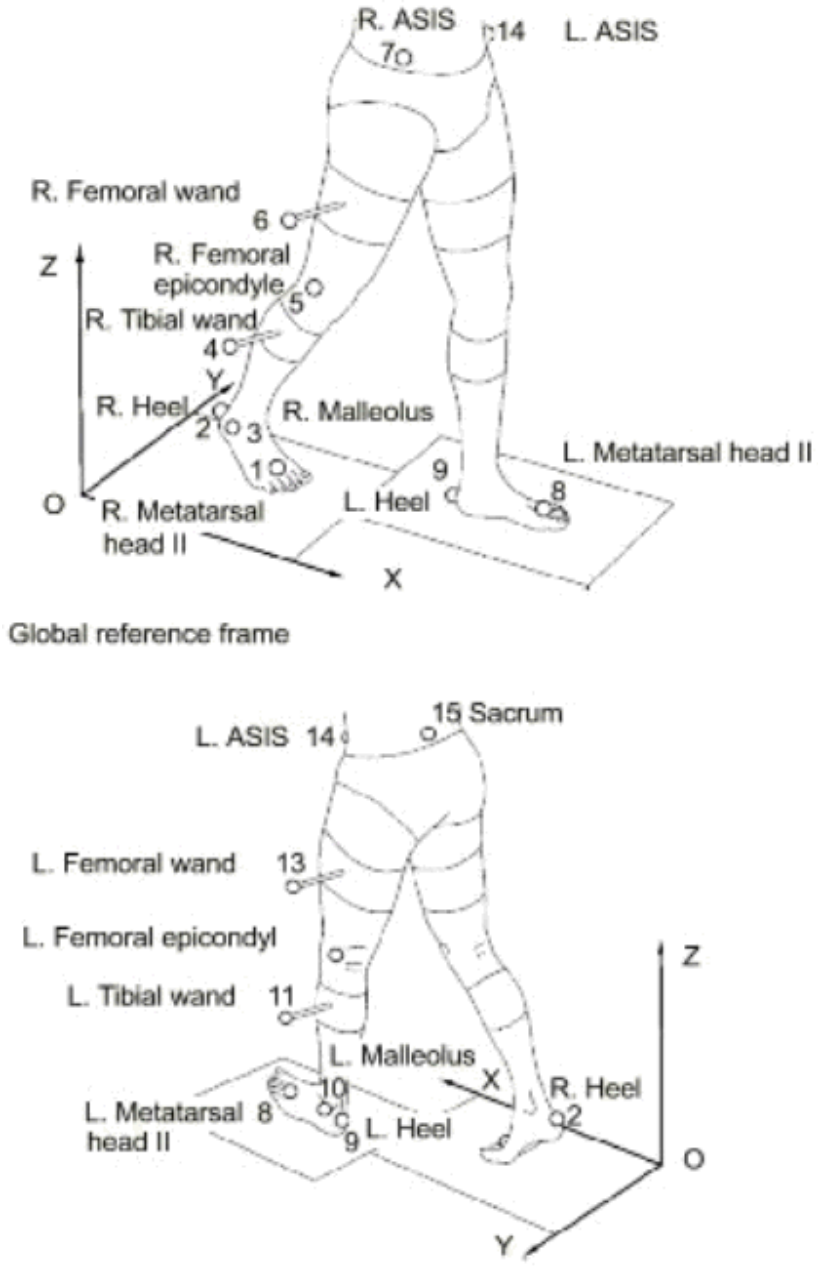


Figure 2.19. Image depicting the marker positions using the Helen-Hayes model (Clinical Gait Analysis (2014))

Optical motion analysers have been used in the clinical setting for pre- and post-treatment assessment of upper and lower limb pathology. To analyse upper limb joint kinematics and motion, these systems have been used in children with myelomeningoceles and cerebral palsy and adults with stroke (Slavens et al 2009, Strifling et al 2008, Konop et al 2009, Hingtgen et al 2006).
Lower limb models are generally used to analyse gait pathologies; with different models used to analyse gait in children with cerebral palsy (common pathology analysed, Gage et al 2001), hereditary spastic paraplegia and osteogenesis imperfecta (Wolf et al 2011) for assessing potential treatment options and trying to improve quality of life for these individuals (Buczek et al 2010)

Motion analysis has also greatly influenced orthopaedic surgery and the assessment of post-treatment progress for example; in children with applied casts for club feet (El-Hawary et al 2008), resistance training for patients for people with multiple sclerosis (Gutierrez et al 2005), forefoot and midfoot post-op outcomes and orthotic and shoe modifications and associated kinematics (Wren et al 2011, Canesco et al 2010).

There are a number of commercially available optical motion systems. Vicon is one of the commonest and traditional systems used in the clinical setting for gait analysis. Optotrak and Optitrak, Visual3D, AMASS and Motion Analysis Corporation (MAC) are other optical motion systems which are commercially available, and can incorporate EMG, force plates, active trackers, eye-trackers and other third party instrumentation to aid with gait analysis (Vicon 2016, Visual3D 2016, Clinical gait Analysis 2014, Kertis 2009). All of these systems offer precise measurements of human motion and are frequently used in gait analysis laboratories but are limited to this artificial clinical environment and are expensive due to the cost of the machinery and professionals required for use (Kertis 2009, Gibbs et al 2005, Dunias et al 2013, Huddleston et al 2006).

Accelerometers

Accelerometers are inertial sensors measuring acceleration in a number of axes, by means of a mechanical sensing element comprised of a proof mass and mechanical

suspension system. These sensors can be body-mounted and are typically worn as a band or belt around the wrist, hip or lower leg, and are used for monitoring daily physical activity attaining both quantitative and qualitative data. These devices are small, cheap, light-weight and relatively unobtrusive and are able to perform small sampling intervals (seconds to minutes) and store large amount of data for its relative size. Accelerometers are based on biomechanical principles and are used in one of three modes; (1) measurement of velocity and position; (2) vibration sensor; (3) sensor for tilt, inclination and orientation. The data they acquire is only useful when it is put into a metric of biological significance (heart rate, energy expenditure) or physical activity (ambulatory or stationary) (Freedson *et al* 2005). These devices are able to measure static and dynamic acceleration during gait changes and balance with ambulatory recorders. Accelerometers are still only used in the research setting and are still in the processes of further validation for use in community monitoring of gait and balance (Culhane *et al* 2005).

Accelerometers have varying reliability and repeatability within the literature; with simple, cheap bi-axial accelerometers demonstrating a limited ability to assess body posture and position with poor reliability and repeatability. More expensive and sensitive tri-axial accelerometers have been demonstrated to have high accuracy and sensitivity even when measuring subtle changes in acceleration. Accelerometers have a range of accuracy from ultralow range 0.1g to high range tri-axial devices 100g. (Chee Han *et al* 2014, Gibbs et al 2005, Dunias et al 2013, Tao et al 2012).

Electrogoniometers

Electrogoniometers are electrical goniometers used in the clinical setting to measure and detect alterations in electrical change produced by angular displacement and joint movement (range of motion (ROM)). They consist of one or two potentiometers or strain gauges between two end blocks and can be used in a uniaxial or biaxial direction to provide continuous joint movement information. These devices have been shown to be accurate and precise to within 1mm and/or 1º, low-cost, easy to set up, repeatable and portable for recording dynamic motion in a clinical setting allowing clinician to analyse dynamic knee kinematics in a range of daily activities Electrogoniometers are also light, flexible and easy to wear, and less fragile than

accelerometrs and gyroscopes (Rowe *et al* 2000, Myles 2002, Smith & Rowe 2013, Bronner *et al* 2010).

Electrogoniometers have been extensively tested in upper limb (wrist, elbow and shoulder) in diverse tasks, as well as lower limb (knee and ankles) in analysing gait in the sagittal plane, healthy volunteers ROM and pathological lower limb diagnoses mid-range movements (Felson *et al* 1991, Vingard *et al* 1991).

Electrogoniometers like accelerometers are externally mounted and are prone to movement around the joint whilst mounted, leading to potential erroneous data collection, limiting long-term monitoring suitability in community setting. Electrogoniometers are less reliable and accurate at the extremes of ROM, and have during gait analysis compared to static ROM. Any shift from a monitor's original placement will lead to errors in measurements and angle estimation as the assessment is no longer in the same sagittal alignment plane, leading to erroneous data collection (Bronner et al 2010, Gibbs et al 2005, Tao et al 2012, Rowe et al 2001).

2.7.3 Ideal joint laxity measurement device

The ideal laxity measurement device would be able to accurately and precisely measure joint laxity, with a wide spectrum of laxity measures from normal physiological knees to pathological knees (ACL deficient knees, joint hypermobility syndromes), be easily mounted and have a system to wirelessly deliver information to the clinician (Küpper *et al* 2007).

There is currently a decisive gap between clinical laxity measures and engineering models, possibly due to the different goals of the clinician in developing treatment protocols and the engineers of accurately calculating strain and stresses on ligaments (ACL). Better collaboration between clinicians and engineers to develop an optimal model/system that measures laxity to the appropriate level of detail is required (Küpper et al 2007).

2.7.4 Assessing anteroposterior (AP) translation and laxity in a follow-up setting

Atallah *et al* states that monitoring in follow-up clinics could give possibly inaccurate follow-up assessment results, largely due to subjective clinical assessments and subjective scoring system questionnaires, with instantaneous 'snapshot' assessments of patient's state (Atallah *et al* 2011, Rowe *et al* 2000, Wu *et al* 2008). These assessments are valuable as outcome measures post-surgery, but have little indication of resulting knee joint kinematics and the actual functional ability of the patient post-operatively and post rehabilitation (Rowe *et al* 2000).

Knee kinematics in a clinical follow-up setting are routinely measured using active and passive range of movement (ROM) whilst the patient is supine or sitting to indicate the status of the knee joint. These types of measurement often result in poor inter-examiner repeatability and reliability (Rowe *et al* 2000).

Active and passive ROM has not been demonstrated to accurately reflect joint movement exhibited by patients in normal daily activities (Hazelwood *et al* 1994). To accurately assess the dynamic behaviour of the knee joint, knee motion should be recorded during numerous real-life daily and functional activities (Rowe *et al* 2000).

2.8 Image-free computer assisted navigated TKA

Osteoarthritis (OA) is a progressive multifactorial disease, and is the commonest form of arthritis and one of the leading causes of disability worldwide, with a growing prevalence and impact on the socioeconomic and health service (NICE 2014, Felson et al 2004, Felson et al 1991). It is estimated to affect 10% of the population above the age of 55, with the knee joint most often affected (Clarke 2012a, Felson et al 2004). Total Knee Arthroplasty (TKA) is an effective and cost efficient procedure performed on patients with end stage knee arthritis greatly improving these patients' quality of life and physical function (Cross 3rd et al 2006, Van der Linden 2007). The indications for TKA are multifactorial, but the single universally agreed upon indication is the presence of OA with progressively worsening knee pain which is refractory to analgesic therapies (Cross et al 2006).

There are extremely large numbers of patients having primary TKA; with over 6500 patients in Scotland have a TKA performed annually (Minns Lowe et al 2009, Scottish Arthroplasty Project Annual Report 2012, Jüni et al 2003). TKA can be performed either by the conventional method or with the use of computer assisted navigation surgery (CAS). CAS helps reduce surgical error in TKA as is the consensus in literature (Smith & Rowe 2013). The implementation of CAS in TKA surgery has also shown to improve overall mechanical femoro-tibial alignment (MFTA), with more accurate implant placement and reduced outliers and possible prosthetic wear and aids with soft tissue management (Smith & Rowe 2013, Picard et al 2007a, Kim et al 2012, Anderson et al 2005, Mavrogenis et al 2013, Chauhan 2004). Image free navigation systems have been shown to have an accuracy of within 1° or 1mm in supine MFTA acquisition (Bae et al 2011).

CAS can be image-free (no computer tomography (CT) or magnet resonance imaging (MRI) images) or image-based with the use of CT or MRI images to aid the navigation systems but also provide the patient with significant radiation exposure in the case of CT use (Mavrogenis et al 2013). This section will focus on image free computer assisted navigation. *Figure 2.20* depicts the image-free navigation system used in an orthopaedic theatre (Picard 2007, Picard et al 2007b).

Figure 2.20 Image of the image-free OrthoPilot computer assisted navigation system (Picard et al 2007b)

Image-free CAS is an invasive navigation system requiring fixed trackers positioned at specific anatomical landmarks on the femur and tibia, a computer platform and tracking system (optical camera) with a pointer for triangulation, as displayed in *Figure 2.21*. A registration process (see *Appendix 1*) is required to quantify 3-D knee kinematics of the knee, by attaining hip, knee and ankle centres reducing patient and surgeon radiation exposure (Mavrogenis et al 2013). The computer navigation system can be set as either *active* or *passive*. *Active navigation tracking* can prohibit the surgeon from moving past a predefined zone or even perform a certain surgical task. *Passive navigation tracking* provides information displayed on a monitor guiding the surgeon, but the surgeon controls the surgery and is free to make decisions intra-operatively (Mavrogenis et al 2013, Jenny et al 2004, Jenny et al 2010).

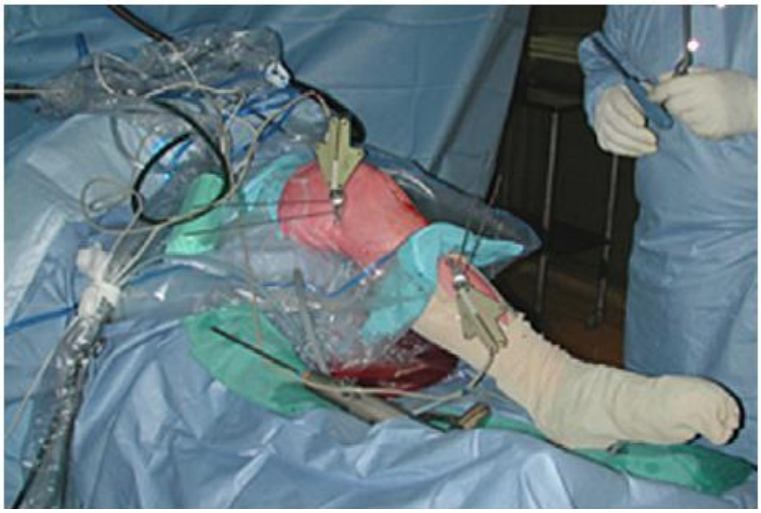


Figure 2.21 Shows active trackers mounted on the femur and tibia for an ACL reconstruction (Picard et al 2007b)

The computer displays are easily readable and also simple to follow and alter intra-operatively (Picard et al 2007b). The real-time feedback attained from navigation allows the surgeon to optimise implant positioning and alignment, reducing intra-operative errors and improving post-operative outcomes, and has been in clinical use for 10 years now and was initially pioneered in knee surgery to optimise bone resections (Picard et al 2007a, Mavrogenis et al 2013, Jenny 2010). Picard noted that the learning curve for navigation is relatively small and after as little as ten uses, additional surgical time may be reduced by half, especially in navigated ACL reconstruction (Picard et al 2007b).

Image-free navigation has also been shown to quantify kinematics of the femur and tibia, with mapping of particular tibia movements corresponding to the integrity and function of cruciate ligaments (Lopomo et al 2010). As this technology requires invasive placement of optical trackers in bone, it is currently limited to the operative setting (Lopomo et al 2010, Russell et al 2013).

CAS has not as yet shown any significant improvement in functional outcome of patients when compared to conventional un-navigated TKA (Smith & Rowe 2013, Molfetta et al 2008), although studies of the long-term outcomes of CAS should be coming out soon, and may tailor how future TKA is performed.

2.9 Non-invasive navigation studies

Non-invasive navigation technology is relatively new concept. This technology was initially validated by Clarke *et al* in extension (Clarke 2012a, Clarke et al 2012b), and Russell *et al* further validated the system in early flexion in cadavers (Russell et al 2013, Russell et al 2012, Russell et al 2014a, Russell et al 2014b). These studies will be analysed in more detail.

2.9.1 Clarke et al

Clarke *et al* (Clarke 2012a, Clarke et al 2012b) validated a non-invasive adaptation of a commercially available image-free navigation system, using similar software algorithms to measure sagittal and coronal alignment in extension to ±1º (Clarke 2012a). Clarke validated the non-invasive system coronal supine MFT angle, by comparison of a custom made leg model, an electrogoniometer, and repeatable MFTA assessment on 30 healthy volunteers. Varus-valgus stress angles were validated to 1.5º, and standing bi-pedal MFT angle to 3º. Clarke used fabric straps to hold the optical trackers in position to quantify 3-dimension knee kinematics in supine and standing (Clarke 2012a, Clarke et al 2012b).

Clarke further assessed 30 patients with the non-invasive infra-red navigation system with end stage OA prior to TKA, during TKA and six weeks post TKA. The non-invasive navigation data of supine MFTA, standing MFTA and varus-valgus stresses were compared to the invasive navigation data acquired during TKA operation. The varus-valgus angulation data was greater intra-operatively prior to knee replacement in comparison to pre-operative assessments, with invasive and non-invasive stress angles on prosthetic knees both demonstrating fewer variations (Clarke et al 2012a). Post TKA for all knee replacement types the bi-pedal MFTA change to more varus and extension, suggesting soft tissue restraints were removed in TKA (ACL), and plays an essential role in weight bearing alignment (Wings 2013). This is in-keeping with Amis *et al*, ACL tightens during the screw home mechanism in knee extension, aiding to stiffen the knee in extension, reducing energy requirements to stabilise the knee during standing and also heel strike in gait (Amis & Van Arkel 2013).

2.9.2 Russell et al

Russell *et al* used the non-invasive technology to validate and quantify anteroposterior knee joint laxity in early flexion in cadavers (Russell et al 2013, Russell et al 2012). Russell used 12 cadaveric lower limbs to compare the non-invasive infra-red navigation system against a commercially available image-free navigation system. Russell noted that the non-invasive system was repeatable and reliable at sagittal and coronal alignment in extension to ±2º of the commercially available validated invasive navigation system (Russell et al 2013). Russell used a set force of 100Nm to assess AP translation, at 10º increments from full extension to 60º of flexion. Russell found from full extension to 40º of knee flexion the non-invasive navigation system was as accurate as the commercially available navigation system, particularly at the clinically relevant range of 20º to 30º. Varus-valgus stress measurements were validated, to within ±3º of the invasive navigation system up to 30º of flexion (Russell et al 2013, Russell et al 2014a).

Using the same 12 cadaveric limbs, Russell attempted to quantify rotational laxity of the knee using the non-invasive navigation system with non-invasive fabric straps. Manual torque was applied and measured using a force application device. The tibia was rotated to the end range of internal and external rotation at increments of 10º from full extension to 90º of flexion. Russell demonstrated that the non-invasive navigation system was comparable with a commercially available navigation system at assessing full tibia internal and external rotation by foot position (Russell et al 2014b).

2.9.3 Additional studies

The non-invasive navigation system was used to assess collateral ligament laxity in 267 knees in an Indian population. Deep noted that the supine MFTA in extension and at 15º was within ±2º coronal alignment. A 10Nm force was applied to all knees to assess varus-valgus stress angle at 0º and 15º. Deep found that women had a valgus and men a varus supine MFTA at 0º extension. Collateral ligament laxity was extremely variable in this population group and women were more lax than men at 0º and 15º when valgus stresses were applied (Deep 2014, Deep *et al* 2012).

2.10 Summary of the literature review

The knee joint is complex consisting of two articulations. The complexity of these articulations signifies that more than simple bony articulations are required to maintain stability of the knee and the surrounding soft tissues are essential for knee congruity, natural kinematics and motion (Amis et al 2010). The laxity of these soft tissues supporting the knee varies within the normal, uninjured population giving a wide spectrum of knee laxity. During normal flexion and extension of the knee joint, the amount of anteroposterior (AP) knee laxity and tibia rotation varies greatly throughout this range of motion. This is partly due to the complex screw-home mechanism during knee extension and during flexion the way in which the femur glides and then slides over the tibia due to the incongruent nature of the femoral and tibial condyles.

The knee joint therefore relies on important structures such as the ACL, which plays a key role as the primary brake to anterior translation and potential dislocation of the tibia, resisting up to 90% of these displacing forces. The ACL can also act as a restraint to tibia rotation and prevents knee hyperextension (Amis et al 2010, Amis et 2013). ACL injury and rupture is the commonest soft tissue injury involving the knee joint and results in knee joint instability, with a significant increase in AP translation and rotational laxity (Lipke et al 1981, Mavrogenis et al 2013, Woo et al 2006). ACL injuries are not always possible to detect by laxity measurements alone (Lachman test and pivot-shift test) or even with current gold standard instrumentation KT-1000due to the wide spectrum of physiological laxity present within normal knees between different subjects; and the high intra and inter-user variability and subjectivity of the instrumentation and clinical tests (Dujarin 2011, Amis et 2008).

Laxity measures such as the Lachman test have been reported to detect ACL rupture with a diagnostic accuracy of 73 to 99%, especially when performed by experienced clinicians and when combined with other laxity measures such as the pivot-shift test, offering high specificity and sensitivity (Ghosh & Deeham 2013, Winson et al 1997). Devices with quantitative measurements have also been created to measure AP translation of the tibia (KT-1000 arthrometer), and tibia rotation (Rotameter) with

repeatability and reliability to within ±1mm of accuracy, in the clinical setting. These devices have demonstrated less accuracy than passive laxity measures and also demonstrate larger intra- and inter-user variability (Amis et al 2008, Küpper et al 2007, Lorbach et al 2009).

There is a large variation in coronal alignment among normal, asymptomatic individuals and it is therefore difficult to define what normal coronal and sagittal alignment actually are. Anatomical knee differences exist between males and females, and also between different races which may affect the coronal and sagittal alignment (Deep 2014, Hunter et al 2008). The majority of lower limbs do not have a neutral mechanical alignment in the coronal plane and in a small fraction of the population neutral mechanical alignment may be abnormal. Mechanical femoro-tibial alignment (MFTA) differs when someone is lying supine in a non-weight bearing position, to when standing in a weight-bearing position. This is less noticeable in the normal population, when compared with pathological knees (Deep 2014).

The elderly population are frequently affected by osteoarthritis (OA), one of the leading causes of disability worldwide. Total Knee Arthroplasty (TKA) is an effective and cost efficient procedure performed on these patients with end stage knee OA greatly improving these patients' quality of life and physical function (Cross et al 2006, Van der Linden 2007). Image-free computer assisted navigation is one way in which TKA are performed and has been shown to have an accuracy of within 1° or 1mm in supine MFTA acquisition (Bae et al 2011). The real-time feedback attained from this navigation technology allows the surgeon to optimise implant positioning and alignment, reducing intra-operative errors and potentially improves post-operative outcomes, and reduces the percentage of alignment outliers in TKA (Picard 2007, Mavrogenis et al 2013, Jenny et al 2010, Mullaji et al 2013). Numerous clinical case studies have demonstrated that image-free navigation produces consistently accurate placement of knee components as well as improving coronal limb alignment. The component alignment accuracy is essential in the long term survival of the arthroplasty, with the possibility of restoring natural knee kinematics (Sikorski 2008, Jenny et al 2004, Christensen et al 2013, Brandt et al 2008).

Non-invasive navigation technology is relatively new concept, using a non-invasive adaptation of a commercially available image-free navigation system, with similar software algorithms to measure sagittal and coronal alignment in extension to ±1º. This technology differs from the invasive image-free navigation which is limited to intra-operative use because rigid fixation using bone pins hold the optical trackers in place, whereas in non-invasive navigation the optical trackers are mounted on a metal base plate on top of the skin, allowing for assessment outside the theatre setting. The non-invasive navigation system (PhysioPilot) was initially validated by Clarke *et al* in extension on healthy volunteers, patients with OA and patients post TKA (Clarke 2012a, Clarke et al 2012b). The non-invasive navigation system (PhysioPilot) was later validated by Russell *et al* in early flexion in 12 cadaver lower limbs, directly comparing the PhysioPilot system to a commercially available image-free navigation system (OrthoPilot) (Russell et al 2013, Russell et al 2012, Russell et al 2014a). A new updated non-invasive navigation infrared camera with new updated software has been developed and allows for the assessment of anteroposterior knee joint laxity and tibia rotation through flexion.

The aim of the thesis was to validate the repeatability of the assessment of anteroposterior (AP) knee joint laxity using the newly updated non-invasive image free navigation system in normal, healthy subjects.

2.11 Aims of this thesis

There are still limitations in the current methods of measuring anteroposterior knee joint laxity, with knowledge gaps in regards to coronal knee alignment and coronal laxity. The first aim of this thesis is to perform a pilot study to validate a new set of optical trackers against a pre-validated optical tracker set to identify the optimal tracker set for future volunteer testing. The new optical tracker set was developed with a smaller moment arm then the previously validated optical tracker set with the aim of reducing soft tissue artefacts from being skin mounted. This study will require a set protocol for a standardised assessment, with the exact system set-up and tracker positioning identified, method for system registration and the set angular measurements of AP laxity and tibia rotation assessment, hand positioning and force applied to be created. Examiners trained in clinical examination of the knee and capable of operating the image-free non-invasive navigation system will be needed to perform a series of initial tests to validate the new set of passive optical trackers and compare them to the original (pre-validated) optical trackers. The pilot study will provide essential information as to which optical tracker set is more reliable and repeatable at assessing AP knee joint laxity and tibia rotation. The optimal tracker set will then be taken forward for the validation of the assessment of AP knee joint laxity and tibia rotation in healthy volunteers using the non-invasive computer navigation system.

Following the identification of the optimal optical tracker set, the next aim is to validate the assessment of AP knee joint laxity and tibia rotation through flexion in 25 healthy volunteers, using the non-invasive computer navigation system. 25 volunteers from the Biomedical engineering department at Strathclyde University will be recruited and examined using the protocol identified in pilot study. Each of the volunteers will have both legs examined by two Examiners performing two registrations each on each limb. From this registration the supine mechanical femoral-tibial alignment (MFTA) will determined and assessment of AP knee joint laxity and tibia rotation through flexion using the Lachman test will be performed in increments of 15º, from 0º to 90º of flexion (0º, 15º, 30º, 45º, 60º, 75º, 90º) using a standardised force. Additional tests such as the pivot shift-test, maximum passive

flexion assessment and bipedal and monopedal loaded MFTA assessment will also be performed during the examination process. The data will be analysed using statistics to assess the reliability and repeatability of the AP laxity and tibia rotation assessment and assess if the non-invasive navigation system is validated in assessing healthy volunteers through flexion.

If the non-invasive system is validated throughout flexion for the assessment of AP laxity and tibia rotation, it potentially could be used on patients with pathological knees in order to identify ligamentous and potentially arthritic pathologies as well. The system potentially could also be used in patients' post-TKA to assess their post-operative range of motion as well as function and alignment.

Pilot study

(Optimal tracker set identification)

3 Methodology for pilot study (optimal tracker set identification)

3.1 Aim of pilot study

The aim of this pilot study was to validate a new set of optical trackers against a pre-validated set of optical trackers using a non-invasive computer navigation system, and identify the optimal set of optical trackers which would provide the most repeatable and reliable data acquisition to take forward for volunteer testing.

3.2 Ethics

Departmental ethical approval was required for the pilot study and testing of volunteers in the Strathclyde Biomedical Engineering department. The ethics application submitted was approved and access granted in May 2014.

3.3 Background for pilot study (Optimal tracker set identification)

A new updated non-invasive navigation infrared camera with new updated software had been developed (Spectra NDI - BBraun Aesculap) and allowed for the assessment of anteroposterior (AP) knee joint laxity and tibia rotation through the range of flexion.

There are limitations in the current methods of measuring anteroposterior (AP) knee joint laxity using the non-invasive navigation system. The pre-validated optical trackers previously validated in early flexion by Clarke (Clarke 2012), are mounted on a metal base plate, as depicted in *Figure 3.1*, which itself is mounted onto the examined leg and held in place by a fabric strap with rivets at the ends of the straps, as depicted in *Figure 3.2*. *Figure 3.3* shows the various lengths of fabric strap available, the pre-validated optical trackers as well as the pointer tracker which was used for the registration process.

The pre-validated set of trackers are angled at 60˚from the coronal plane to allow the four optical tracker markers (balls) mounted on the angled tracker to be sensed by the infrared optical camera. Due to the trackers' large vertical length, a large moment arm is produced from the skin surface, and makes the pre-validated tracker prone to movement on the skin as well as being knocked during AP laxity assessment.

A new set of optical trackers was developed with a modified design, with the aim to produce a smaller moment arm and reduce soft tissue artefacts from being skin mounted. *Figure 3.4* shows the femoral new optical tracker with a flat superior metal base plate demonstrating a modified design compared to the elevated pre-validated trackers, with a reduced moment arm from the skin surface, aiming to reduce soft tissue artefact during examination. This superior metal base plate contained four optical markers mounted on top of a curved metal base plate which was mounted on the distal femur, with metal attachments for the fabric straps to be incorporated.

Figure 3.5 depicts the tibial tracker with a superior base plate mounted with optical markers on a curved metal base plate designed to fit around the tibia. *Figure 3.6* shows the padding present under the curved base plate, which was present on both the tibia and femur new optical trackers. The padding made the newer set of trackers more comfortable to wear than the solid metal base plate of the pre-validated set of trackers. Fabric straps were incorporated on the curved metal base plate, and were used to mount the new optical trackers to the examined leg.

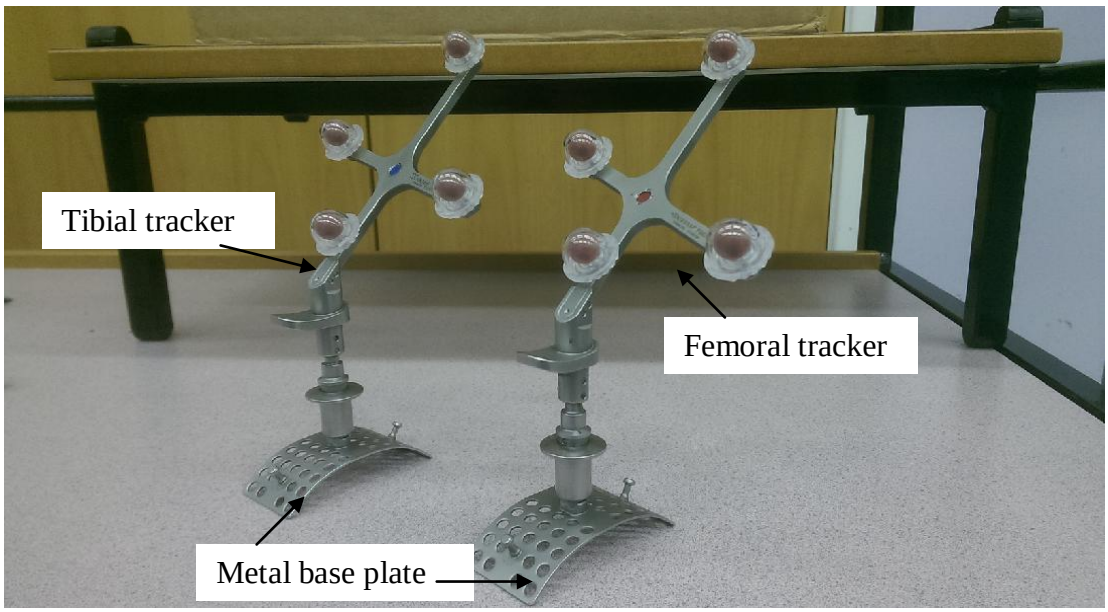


Figure 3.1 This images shows the pre-validated set of optical trackers mounted on their metal base plates (femoral tracker has a red dot and the tibial tracker a blue dot in the centre of trackers)

Figure 3.2 Depicts an example of the set-up of each volunteer assessment. The pre-validated passive optical trackers are mounted on the femur and tibia using fabric straps to secure the base plate holding the optical tracker in place

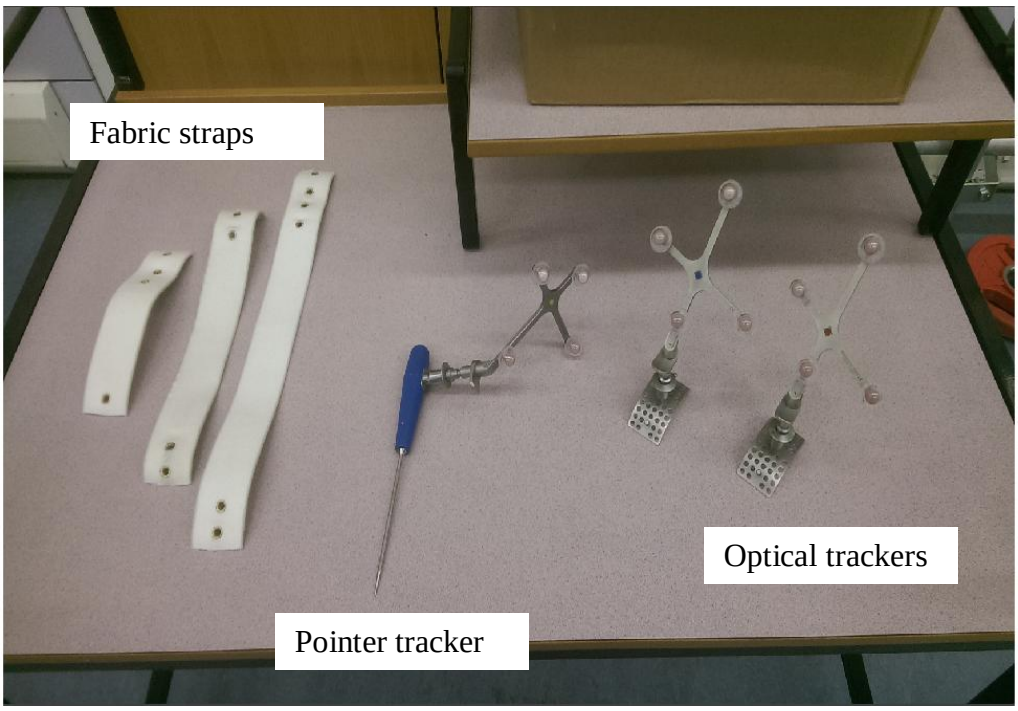


Figure 3.3 Image showing the pre-validated set of optical trackers mounted on metal base plates, pointer tracker and fabric straps with rivets at the ends of the straps to mount the base plates to the examined legs.

Figure 3.4 The femoral new optical tracker with the surface metal plate containing four optical markers mounted on top of a curved metal base plate, with metal attachments for where the fabric straps were incorporated

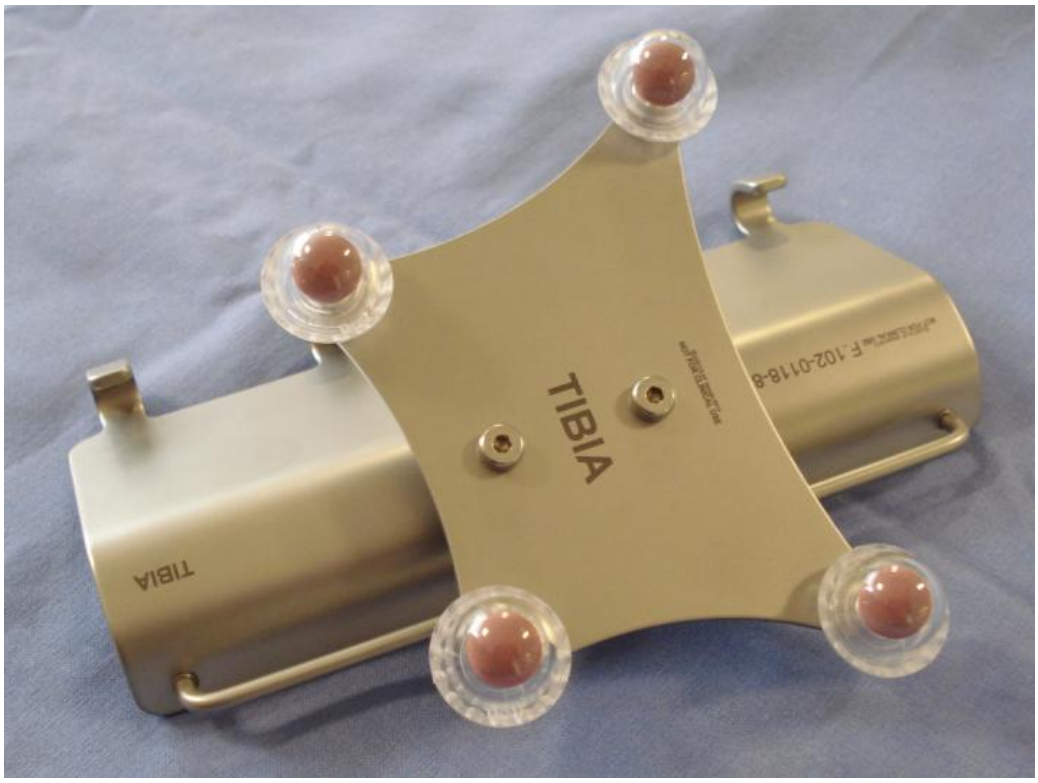


Figure 3.5 Tibial new optical tracker, with surface plate and mounted markers and curved metal base plate which was designed to fit around the tibia

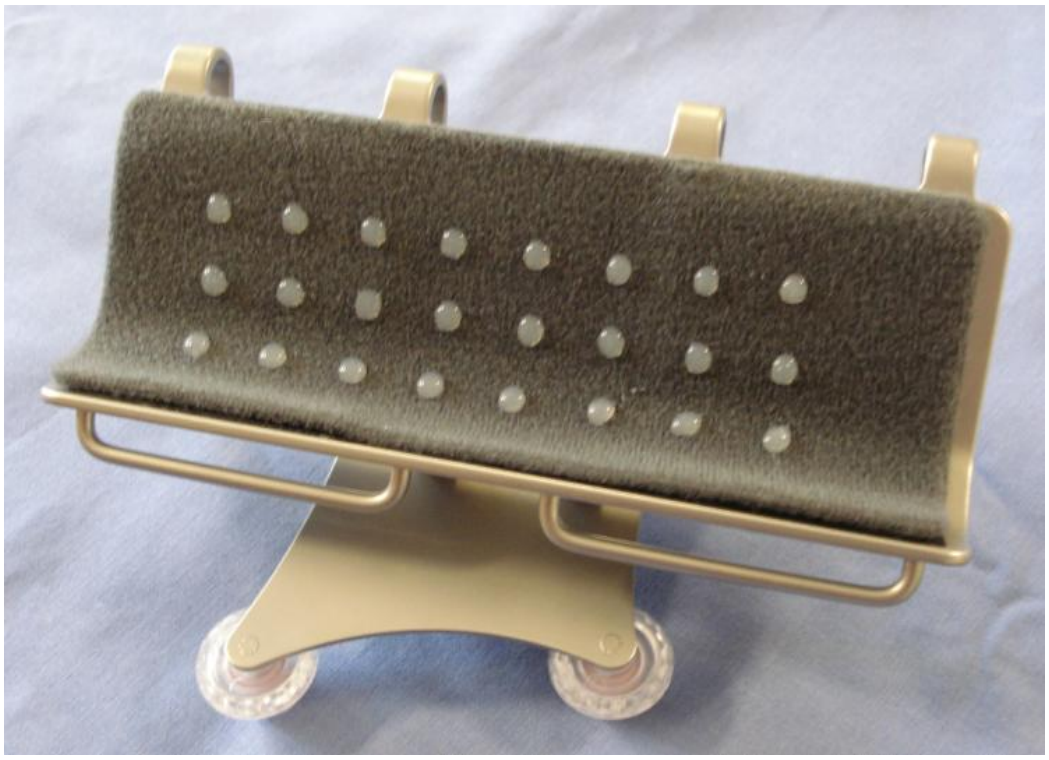


Figure 3.6 The padding present under the curved metal base plate of the tibial tracker which was also present on femoral new optical tracker

3.4 Method for pilot study

Two Examiners trained in clinical examination of the knee, and capable of operating the image-free non-invasive navigation system (PhysioPilot), undertook a series of initial tests to validate the new set of passive optical trackers and compare them to the pre-validated optical trackers using the non-invasive navigation (PhysioPilot) system. Both Examiners tested each set of optical trackers on one another, to identify the optimal set of optical trackers.

The PhysioPilot optical camera was positioned two metres away (on a tripod stand) from the plinth where one the Examiners would lie to be examined. A set of the optical trackers were mounted using fabric straps to secure the base plate holding the tracker in place. The femoral base plate was placed 8cm proximal to upper pole of patella overlying the vastus medialis obliquus muscle. The tibial base plate was placed 10cm distal to tibial tuberosity, over the centre of the tibia to maximise tracker exposure to the localising infrared optical camera, as demonstrated in *Figure 3.3*.

Following the set-up of the equipment a series of ten registrations (*see Appendix 1: Registration process*) and examinations (*see Appendix 2: Examination process*) of the right and left leg of each Examiner was carried out for both the new and pre-validated set of trackers, using a protocol designed by both Examiners (*see Appendix 3: Protocol for volunteer testing*). Therefore twenty registrations and examinations were performed with each set of trackers on each of the Examiners, totalling eighty registrations in the initial testing phase.

After each registration and examination, the trackers were taken off and replaced (don-doff) prior to the next assessment. The replacement of the trackers was readily repeatable as both the pre-validated and new set of trackers both left faint impressions on the Examiners legs to identify the outline of the tracker borders. Therefore the trackers could be replaced over the outlined area of skin. Both tracker sets were secured by fabric straps which were tightened to a comfortable level for

each Examiner to wear, but prevented the trackers from moving independently, to prevent any soft tissue artefact.
Both Examiners were healthy and had no past medical history of knee injuries. After the acquisition of the supine MFTA in extension, both Examiners carried out AP laxity assessments at increments of 15º using the Lachman test from 0º to 90º of flexion for six examinations and 30º solely for the other four examinations. Additional tests during the examination process were: pivot shift-tests, maximum passive flexion assessment and bipedal and monopedal loaded MFTA assessment.

The averages of each variable performed were analysed to identify the most accurate and reliable set of optical trackers to take forward to volunteer testing.
The force used to assess AP laxity was not measured as a compatible force application device was not available at the time of testing. Other commercially available force application devices were too cumbersome and interfered with the optical trackers positioning and where therefore not used during the pilot study.

4 Results from pilot study

4.1 Supine MFTA in extension assessment

Examiner 1 - supine MFTA in extension results

Using the pre-validated optical trackers Examiner 1 achieved an average supine MFTA in extension of 2º varus in the right leg and 1.6º of varus in the left leg.

Using the new set of optical trackers Examiner 1 acquired an average alignment of 1.4º of valgus in the right leg; demonstrating a **3.4º** difference in coronal alignment between the two trackers over ten registrations of the right leg. Examiner 1 acquired an average alignment of 2.7º of valgus in the left leg; demonstrating a difference of **4.3º** in coronal alignment between the two trackers over ten leg registrations. A larger standard deviation is noted with the new set of trackers.

Table 1 below shows the summary results for supine MFTA in extension acquired by Examiner 1. The full set of supine MFTA in extension results are noted in *Appendix 6*.

***Table 1:** Examiner 1 Supine MFTA in extension (º) results*				
Tracker type	***Right knee***		***Left knee***	
	Average (º)	Standard deviation	Average (º)	Standard deviation
Pre-validated optical tracker	2.0	3.4	1.6	3.8
New optical tracker	-1.4	4.0	-2.7	4.9

Table 1 Results of supine MFTA acquisition in extension by Examiner 1 using both sets of trackers

Examiner 2 - supine MFTA in extension results

Examiner 2 using the pre-validated optical trackers acquired an average supine MFTA in extension of 1.5º varus in the right leg and 3.5º of varus in the left leg.

Examiner 2 using the new set of optical trackers acquired an average supine MFTA in extension of 1.9º of valgus in the right leg and 1º of valgus in left leg. Examiner 2 demonstrated a difference of **3.4 º** differences in coronal alignment between the two trackers in the right leg registration and a difference of **4.5º** in coronal alignment between the two trackers in the left leg, with larger standard deviations noted with the new set of trackers.

Table 2 shows the summary results for supine MFTA in extension acquired by Examiner 2, with the full set of supine MFTA in extension results noted in *Appendix 7*.

Table 2: ***Examiner 2 Supine MFTA in extension (º) results***				
Tracker type	***Right knee***		***Left knee***	
	Average (º)	Standard deviation	Average (º)	Standard deviation
Pre-validated optical tracker	1.5	2.9	3.5	2.7
New optical tracker	-1.9	3.0	-1.0	3.6

Table 2 Results of supine MFTA acquisition in extension by Examiner 2 using both sets of trackers

4.2 AP laxity and tibial rotation assessment

Following the acquisition of supine MFTA in extension, both Examiners proceeded to perform AP laxity measurements in increments of 15º using the Lachman test from 0º to 90º of flexion. The increments were measured using the non-invasive image free navigation system with the knee angles being demonstrated on the laptop screen.

Examiner 1 - AP laxity and tibial rotation results

From 0º to 30º there appears to be an increase in AP laxity with both sets of trackers in both legs assessed, with similar laxity noted at 30º and 45º using the pre-validated trackers. Post 45º the AP laxity progressively reduces up to 90º, with both trackers demonstrating a similar pattern as seen in *Graphs 1 and 3*. There was no side to side difference greater than 3mm noted at any interval with both sets of trackers for Examiner 1. The new optical trackers showed less AP laxity at all intervals when compared to the pre-validated optical trackers.

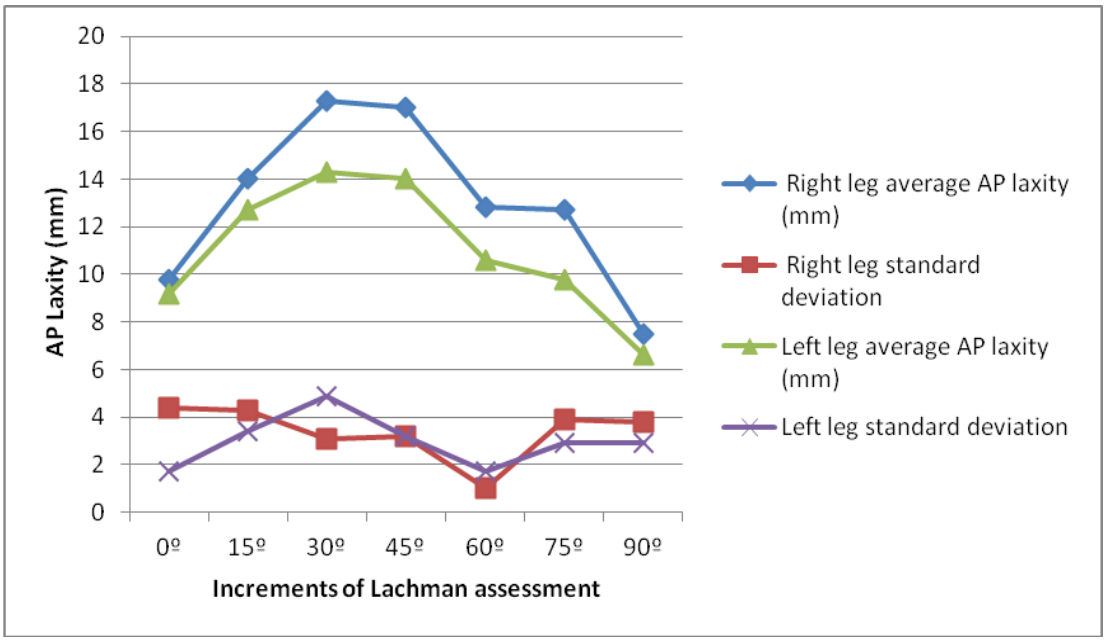
The tibial rotation acquired by Examiner 1 demonstrated from 0º to 45º there was more medial rotation in both legs with both tracker sets. From 60º to 90º there appears to be more lateral rotation in both sets of trackers in both legs assessed, as shown on *Graphs 2 and 4*.

The summary AP laxity results achieved by Examiner 1 for both tracker sets are demonstrated in *Table 3*. The full set of AP laxity results are noted in *Appendix 6*.

Table 3: *Examiner 1 - AP laxity and tibial rotation results using the pre-validated and new optical tracker sets*									
Assessment	**Degrees**	***Pre-validated optical tracker set***				***New optical tracker set***			
		Right knee		***Left* knee**		***Right knee***		***Left* knee**	
		Average	Standard deviation	Average	Standard deviation	Average	Standard deviation	Average	Standard deviation
AP laxity (mm)	0º	9.8	4.4	9.2	1.7	6.0	1.0	7.3	2.1
	15º	14	4.3	12.7	3.4	10.6	3.0	9.3	4.2
	30º	17.3	3.1	14. 3	4.9	13.6	5.3	12.2	3.9
	45º	17.0	3.2	14.0	3.2	11.8	3.8	11.3	4.5
	60º	12.8	1.0	10.6	1.7	8.2	2.6	10.0	3.6
	75º	12.7	3.9	9.8	2.9	7.6	2.1	9.3	3.8
	90º	7.5	3.8	6.6	2.9	7.0	4.1	9.0	3.6
Medial rotation (º)	0º	11.0	4.7	8.5	4.6	7.2	1.1	12.7	3.5
	15º	7.8	1.5	7.0	1.4	6.4	2.8	7.3	5.8
	30º	6.4	3.4	7.9	5.5	8.1	5.3	8.0	5.2
	45º	6.2	6.2	8.0	3.5	9.0	5.1	5.3	1.5
	60º	6.0	5.5	6.8	6.8	6.4	3.6	3.7	0.6
	75º	5.7	3.8	4.4	4.9	3.8	2.2	4. 7	3.2
	90º	5.0	3.2	6.6	5.0	6.4	1.8	3.3	2.0
Lateral rotation (º)	0º	3.5	1.8	3.7	4.3	2.6	3.3	5.0	3.6
	15º	5.2	3.0	5.6	5.3	4.8	5.8	4.0	2.0
	30º	5.4	2.7	6.0	2.9	5.4	4.9	5.0	3.5
	45º	5.6	3.7	6.0	3.6	7.4	3.2	4.0	1.0
	60º	8.3	2.8	7.8	5.4	7.0	7.4	5.7	4.0
	75º	8.2	4.5	10.4	2.1	6.0	6.0	7.3	3.5
	90º	5.5	2.5	7.8	3.7	6.8	12.4	6.0	1.5

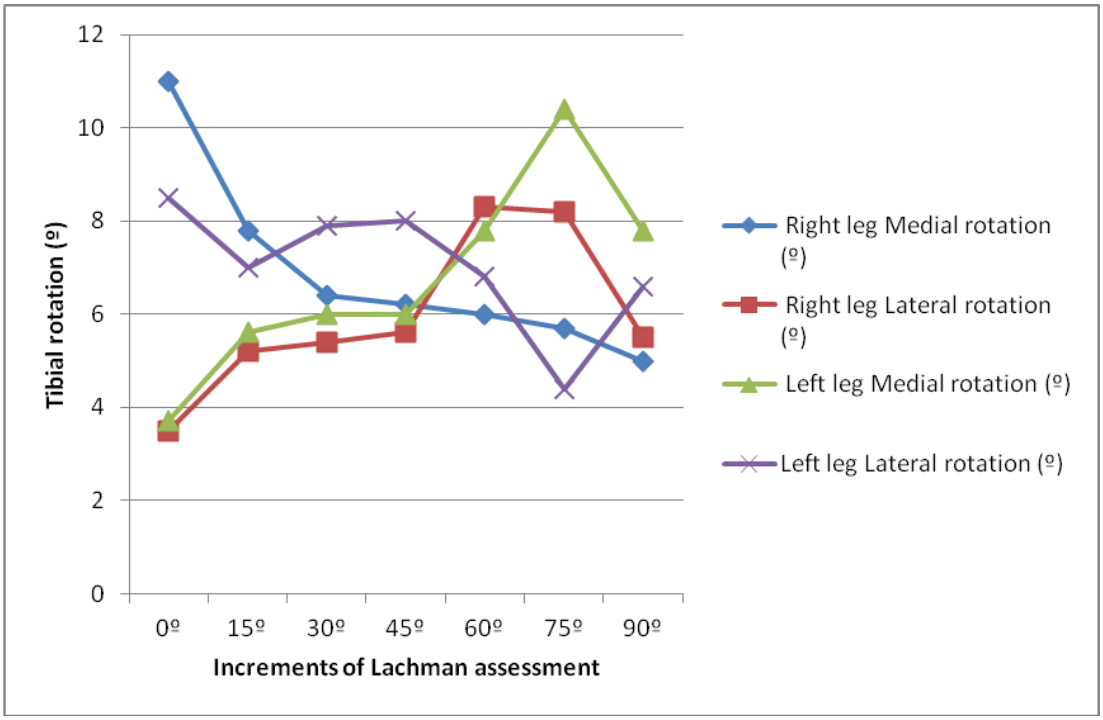
Table 3 Examiner 1 - AP laxity and tibial rotation results of both legs assessed using the pre-validated and new optical tracker sets

Graph 1



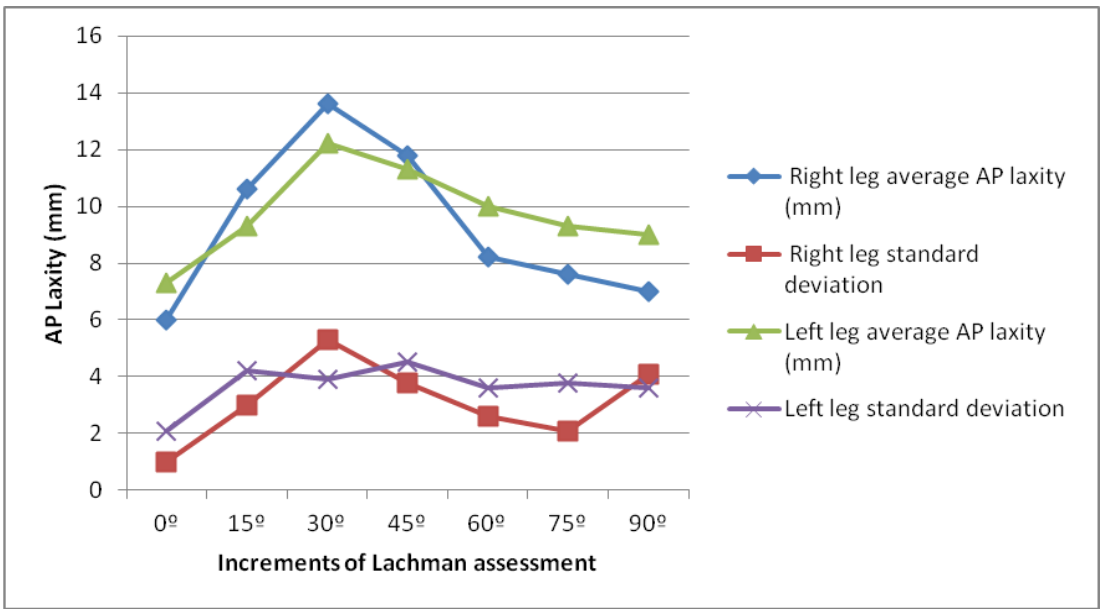
Graph 1 Demonstrating pattern of AP laxity from 0º to 90º using the pre-validated optical tracker set

Graph 2



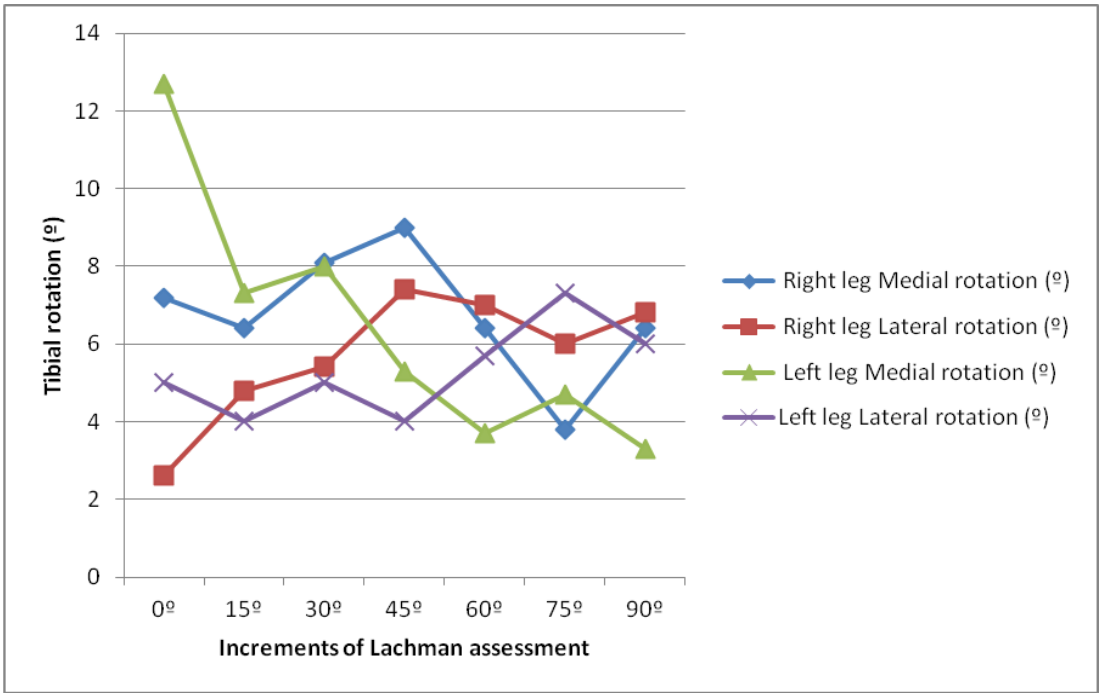
Graph 2 Depicting the pattern of tibial rotation (medial and lateral) from 0º to 90º using the pre-validated optical tracker set

Graph 3



Graph 3 Demonstrating pattern of AP laxity from 0º to 90º using new optical tracker set

Graph 4



Graph 4 Depicting the pattern of tibial rotation (medial and lateral) from 0º to 90º using new optical tracker set

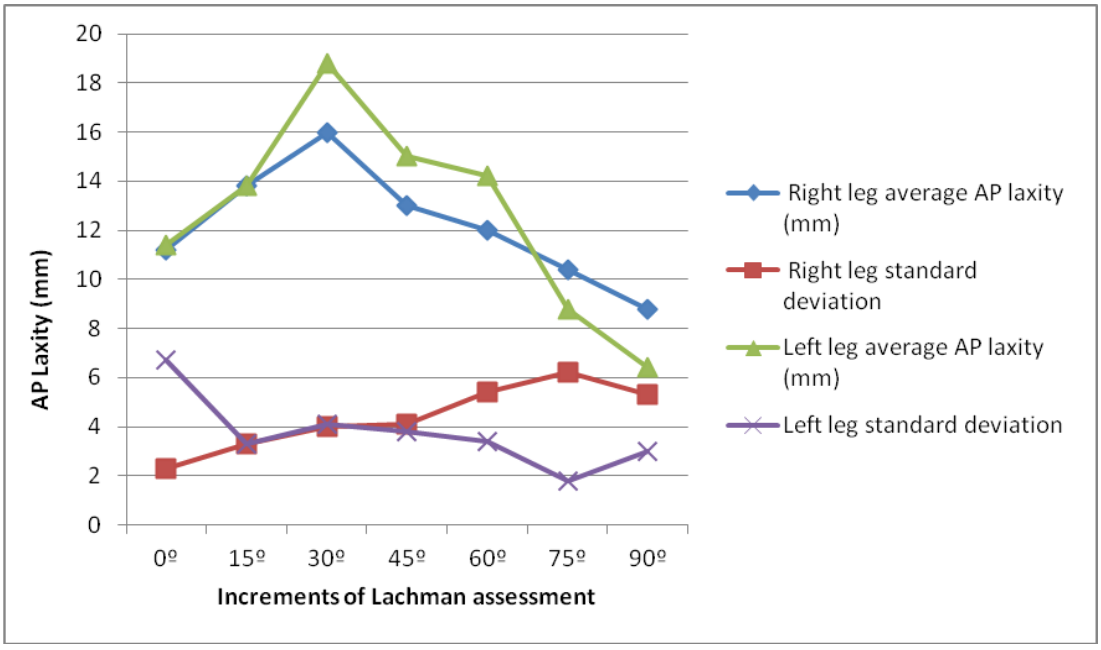
Examiner 2 - AP laxity and tibial rotation results

Examiner 2 demonstrated a similar pattern to Examiner 1 with an increase in AP laxity with both sets of trackers in both legs from 0º to 30º. From 45º, the AP laxity progressively reduces up to 90º as shown in *Graphs 5 and 7*, with both tracker sets demonstrating this pattern. There was no side to side difference greater than 3mm noted at any interval with the pre-validated optical set of trackers, but with the new set of optical trackers at intervals 0º, 15º and 45º, Examiner 2 demonstrated a side to side difference of greater than 4mm (as seen in *Graph 7*). The new trackers showed less AP laxity at all intervals when compared to the pre-validated trackers.

The tibial rotation achieved by Examiner 2 demonstrated more medial rotation in both legs from 0º to 30º, and from 45º to 90º there was more lateral rotation for both tracker sets as noted in *Graphs 6 and 8*.

The summary AP laxity results acquired by Examiner 2 are shown in *Table 4* below for both tracker sets. The full set of AP laxity results are noted in *Appendix 7*.

Graph 5

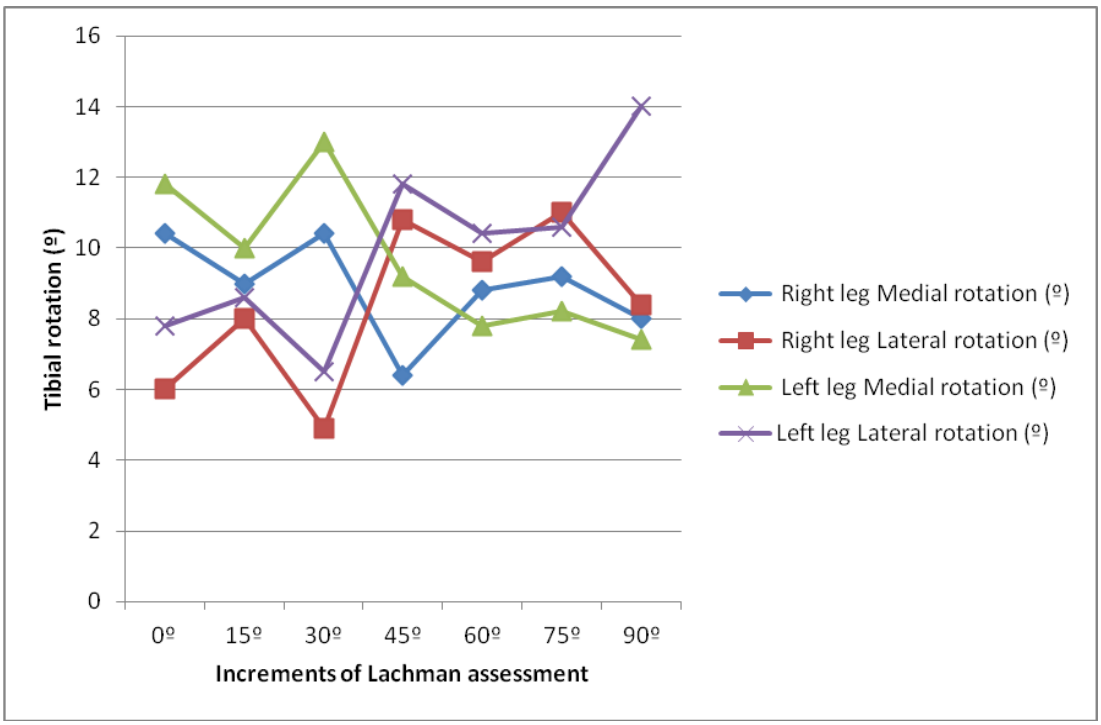


Graph 5 Demonstrating pattern of AP laxity from 0º to 90º using the pre-validated optical tracker set

Table 4: *Examiner 2 - AP laxity and tibial rotation results using the pre-validated and new optical tracker sets*									
Assessment	**Degrees**	***Pre-validated optical tracker set***				***New optical tracker set***			
		Right knee		***Left* knee**		***Right knee***		***Left* knee**	
		Average	Standard deviation	Average	Standard deviation	Average	Standard deviation	Average	Standard deviation
AP laxity (mm)	0º	11.2	2.3	11.4	6.7	7.0	1.6	11.3	7.4
	15º	13.8	3.3	13.8	3.3	9.8	4.0	14.7	5.5
	30º	16.0	4.0	18.8	4.1	12.3	2.0	13.1	4.7
	45º	13.0	4.1	15.0	3.8	8.8	3.4	13.2	4.7
	60º	12.0	5.4	14.2	3.4	10.8	3.4	12.0	5.9
	75º	10.4	6.2	8.8	1.8	9.8	3.4	11.3	5.0
	90º	8.8	5.3	6.4	3.0	8.4	3.0	9.5	2.7
Medial rotation (º)	0º	10.4	3.7	11.8	2.9	6.8	4.1	6.5	2.8
	15º	9.0	5.2	10.0	1.6	7.8	7.3	11.2	9.1
	30º	10.4	2.8	13.0	2.7	10.6	4.5	10.0	5.5
	45º	6.4	3.0	9.2	4.0	6.2	2.3	11.0	5.1
	60º	8.8	3.6	7.8	1.5	6.0	2.1	9.5	4.6
	75º	9.2	5.1	8.2	3.9	5.4	3.6	8.0	3.5
	90º	8.0	3.3	7.4	2.1	3.2	2.8	9.7	4.1
Lateral rotation (º)	0º	6.0	4.2	7.8	4.0	2.8	3.8	6.0	4.8
	15º	8.0	2.2	8.6	6.6	6.4	1.3	7.2	4.4
	30º	4.9	3.5	6.5	5.1	5.9	2.2	6.0	2.7
	45º	10.8	1.3	11.8	2.9	4.6	3.4	6.0	4.0
	60º	9.6	4.5	10.4	7.4	9.0	2.9	6.3	5.9
	75º	11.0	4.4	10.6	6.1	6.4	2.6	8.0	3.9
	90º	8.4	3.3	14.0	5.8	6.2	2.2	5.7	1.9

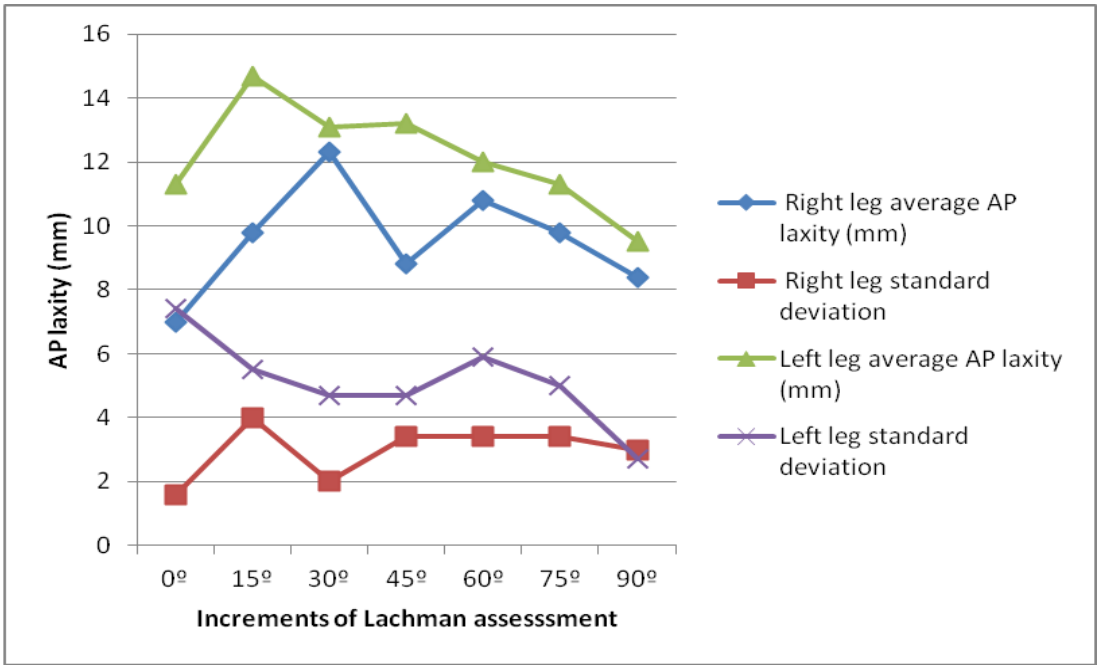
Table 4 Examiner 2 - results of AP laxity and tibial rotation assessment for both legs using the pre-validated and new optical tracker sets.

Graph 6



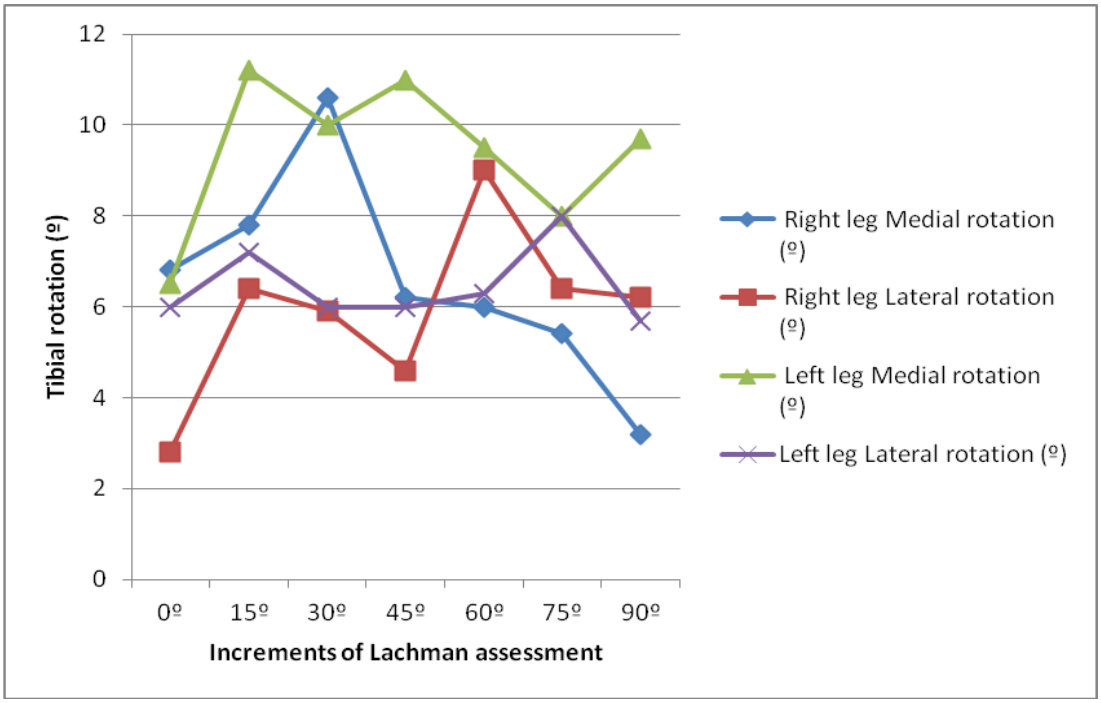
Graph 6 Depicting the pattern of tibial rotation (medial and lateral) from 0º to 90º using the pre-validated optical tracker set

Graph 7



Graph 7 Demonstrating pattern of AP laxity from 0º to 90º using new optical tracker set

Graph 8



Graph 8 Depicting the pattern of tibial rotation (medial and lateral) from 0º to 90º using new optical tracker set

4.3 Pivot-shift test and maximum flexion assessment

The final assessment of AP laxity for each examination was the pivot-shift test. Maximum flexion was performed by passively flexing the examined knee to end range of motion.

Examiner 1 - pivot-shift test and maximum passive flexion results

There is comparable anterior draw between the right (35mm) and left (32mm) leg with the pre-validated trackers, and a similar anterior draw between both legs with the new trackers (23.4mm, 21.7mm). The new trackers did show 10mm less anterior draw for both legs than the pre-validated trackers. The rotation from the pivot shift was comparable between both sets of trackers in both legs.

The pivot shift rotation was comparable between the pre-validated tracker set (19º, 19.9º) and new tracker set (17.4º, 18º).

The maximum passive flexion was comparable between both legs (153.1º; 154.9º) with the pre-validated trackers, and showed a normal range of passive flexion. The new trackers showed high comparability with maximum passive flexion results between each leg assessed (125.7º; 124.3º), but acquired 30º less flexion in both legs, due to difficulty with the new optical tracker being identified by the infrared optical camera post 125º of flexion.

The summary results for the pivot-shift test and passive maximum flexion by Examiner 1 for both tracker sets are shown in *Table* 5. The full set of pivot-shift test and passive maximum flexion results, are demonstrated in *Appendix 6*.

Table 5: *Results of the pivot-shift test and passive maximum flexion for Examiner 1 using the pre-validated and new optical tracker sets*								
	Pre-validated optical tracker				***New optical tracker***			
Assessment	***Right***		***Left***		***Right***		***Left***	
	Average	Standard deviation	Average	Standard deviation	Average	Standard deviation	Average	Standard deviation
Pivot-shift anterior draw (mm)	35.0	7.1	32.0	14.9	23.4	13.4	21.7	9.0
Pivot-shift rotation (º)	19.0	3.9	19.9	5.9	17.4	4.0	18.0	11.8
Maximum flexion (º)	153.1	3.4	154.9	4.1	125.7	6.0	124.3	8.0

Table 5 Examiner 1 - results of the pivot-shift test and passive maximum flexion for both legs assessed using both the pre-validated and new optical tracker sets

Examiner 2 - pivot-shift test and maximum passive flexion results

Examiner 2 showed comparable pivot-shift anterior draw between both legs with the pre-validated trackers (45.6mm, 47.8mm), and similar pivot-shift anterior draw between both legs with the new trackers (22.1mm, 20.4mm). The new trackers attained 20mm less anterior draw, almost half the anterior draw noted with the pre-validated trackers for both legs.

The rotation from the pivot shift test was comparable between both legs with the pre-validated set of trackers (40.4º, 44º), but the new tracker set again only averaged half the rotation noted in the pre-validated trackers in both legs (23.3º, 20.7º).

Maximum flexion is extremely comparable between both legs with the pre-validated trackers (162.5º, 160.6º), with a normal passive range of flexion. The new trackers also showed high comparability between each leg assessed (134º, 129.4º), but acquired 30º less flexion in both legs assessed, due to the difficulty of the new trackers being identified by the optical camera post 125º of flexion.

The summary pivot-shift test data acquired by Examiner 2 is shown in *Table 6* below. The full set of pivot-shift test and passive maximum flexion results, are demonstrated in *Appendix 7*.

Table 6: ***Results of the pivot-shift test and passive maximum flexion for Examiner 1 using the pre-validated and new optical tracker sets***

	Pre-validated optical tracker				***New optical tracker***			
Assessment	***Right***		***Left***		***Right***		***Left***	
	Average	Standard deviation	Average	Standard deviation	Average	Standard deviation	Average	Standard deviation
Pivot-shift anterior draw (mm)	45.6	17.3	47.8	16.9	22.1	11.9	20.4	10.2
Pivot-shift rotation (°)	40.4	15.2	44.0	31.3	23.3	6.3	20.7	15.5
Maximum flexion (°)	162.5	5.6	160.6	5.3	134.0	10.0	129.4	15.2

Table 6 Examiner 2 - results of the pivot-shift test and passive maximum flexion for both legs assessed using both the pre-validated and new optical tracker sets

4.4 Bipedal and monopedal load MFTA assessment

Both Examiners demonstrated comparable bipedal and monopedal loaded MFTA acquisition for both sets of trackers. The results are comparable with the initial supine MFTA in extension acquired in both legs. Results for the summary bipedal and monopedal load MFTA measurements for Examiner 1 are shown in *Table 7* below.

Table 7: ***Results of the bipedal and monopedal loaded MFTA assessment for Examiner 1 for both legs using the pre-validated and new optical tracker sets***

	Pre-validated optical tracker				***New optical tracker***			
Assessment	***Right***		***Left***		***Right***		***Left***	
	Average	Standard deviation	Average	Standard deviation	Average	Standard deviation	Average	Standard deviation
Bipedal loaded MFTA (°)	0.6	2.6	0.1	2.9	0.4	3.6	0.5	5.5
Monopedal loaded MFTA (°)	1.9	3.1	0.4	3.0	1.8	3.9	0.4	5.6

Table 7 Examiner 1- results of the bipedal and monopedal loaded MFTA for both legs assessed using both the pre-validated and new optical tracker sets

Results for the summary bipedal and monopedal load MFTA measurements for Examiner 2 are shown in *Table 8* below. The full set of mono-pedal and bi-pedal loaded MFTA results are demonstrated in *appendices 6 and 7*.

Table 8: ***Results of the bipedal and monopedal MFTA assessment for Examiner 1 using the pre-validated and new optical tracker sets***

	Pre-validated optical tracker				***New optical tracker***			
Assessment	***Right***		***Left***		***Right***		***Left***	
	Average	Standard deviation	Average	Standard deviation	Average	Standard deviation	Average	Standard deviation
Bipedal loaded MFTA (°)	1.6	2.3	3.4	5.7	1.3	4.4	3.6	5.8
Monopedal loaded MFTA (°)	2.3	2.1	3.5	5.6	2.1	4.5	3.1	5.9

Table 8 Examiner 2 - results of the bipedal and monopedal loaded MFTA for both legs assessed using both the pre-validated and new optical tracker sets

4.5 Optimal set of trackers

From the data accumulated during initial testing it was concluded that the optimal set of optical trackers is the **pre-validated set**. The pre-validated set of optical trackers was more consistent and demonstrated greater repeatability by both Examiners when acquiring the supine MFTA in extension, AP laxity, tibia rotation and pivot-shift measurements.

The newer set of trackers were more difficult to use and acquire consistent data for the variables tested, due to the positioning of the optical tracker markers on the base plate reducing the detection of the tracker markers by the optical infra-red camera. The new optical tracker set therefore failed at the essential criteria required for volunteer testing and so was discarded, and the pre-validated optical trackers taken forward for volunteer testing.

Volunteer testing studies

5 Methodology

5.1 Aim of volunteer testing

To validate the assessment of anteroposterior (AP) knee joint laxity and tibial rotation through flexion in 25 volunteers using a non-invasive computer navigation system.

5.2 Volunteer testing

After the identification of the optimal tracker set, the pre-validated optical trackers were selected for volunteer testing. The two Examiners recruited 25 volunteers from the Biomedical Engineering department at Strathclyde University. All volunteers were either staff or students within this department. Volunteers were recruited by placing posters (*Appendix 4*) within the Biomedical Engineering department, sending out emails to all Biomedical Engineering staff and students, and by approaching staff and students personally to discuss the project and recruit them for testing.
Recruitment occurred during the months May - July 2014. Only staff and students that met the inclusion criteria were tested; healthy university individuals within the Biomedical Engineering department, within an age range of 18 – 70 who are able to mobilise independently. The exclusion criteria were; volunteers with history of knee fractures or knee ligament injuries, pregnant, allergy to both fabric or plastic, insufficient mental capacity to consent.

Objective of volunteer study

To validate the assessment of anteroposterior (AP) knee joint laxity and tibial rotation through flexion in 25 health volunteers, using a non-invasive computer navigation system. If this validation process is successful the non-invasive navigation system could be used to assess patients with knee pathologies.

Methodology

The volunteers were given a participant information sheet prior to assessment containing information pertinent to the project (see *Appendix 5*) and if they were happy to proceed the volunteer signed a consent form. Each volunteer had their

weight and heights measured and were appropriately dressed in short trousers for the assessment. The Strathclyde Biomedical Engineering laboratories were used for all volunteer testing.

The same protocol from the pilot study was used during volunteer testing; as the pilot study was used to identify the optical tracker set and finalise the protocol. All volunteers were examined using a non-invasive navigation system (PhysioPilot, BBraun Aesculap) consisting of an infrared camera (Spectra NDI), externally mounted optical trackers and computer software. The PhysioPilot optical camera was positioned two metres away (on a tripod stand) from the plinth where the volunteers would lie to be examined (*Figure 5.1*). Passive optical trackers were mounted using fabric straps to secure a base plate holding the tracker in place. The femoral base plate was placed 8cm proximal to upper pole of patella overlying the vastus medialis obliquus muscle. The tibial base plate was placed 10cm distal to tibial tuberosity, over the centre of the tibia to maximise tracker exposure to the localising infrared optical camera (*Figure 5.2*). Following the set-up of the equipment a registration process was performed, which included initial identification of key bony landmarks and manipulations of the volunteer's leg to achieve a virtual three dimensional model of the lower limb. From this registration the supine mechanical femoral-tibial alignment (MFTA) was determined and assessment of AP knee joint laxity and tibia rotation through flexion using the Lachman test was carried out in increments of 15º, from 0º to 90º of flexion (0º, 15º, 30º, 45º, 60º, 75º, 90º). Additional tests such as the pivot shift-test, maximum passive flexion assessment and bipedal and monopedal loaded MFTA assessment were also performed during the examination process. Full details of each step of the examination process are present in *Appendix 2*.

The force used to assess AP laxity was not measured as a compatible force application device was not available at the time of testing. No commercially available force application devices was used in volunteers testing as they were too cumbersome and interfered with the positioning of the optical trackers.

A registration was required prior to each examination process to acquire the supine MFTA in extension. The supine MFTA in extension is the key step in each

assessment as it is the coronal alignment which the non-invasive navigation system uses to measure the AP laxity and tibia rotation variables. Each of the volunteers had both legs examined by two Examiners who performed two registrations each on each limb. Therefore each volunteer had eight registrations and eight examinations performed. After each registration and examination, the trackers were taken off and replaced (don-doff) prior to the next assessment. As stated previously the pre-validated trackers base plate left a faint impression on the skin over the distal femur and proximal tibia on the examined leg (volunteer). This allowed for the identification of the base plate outline of the tracker borders, and the easy replacement of the optical trackers over the outlined area of skin, in the same position as the initial assessment. The tracker sets were secured by fabric straps which were tightened to a comfortable level for each volunteer to wear but not allow the trackers to move independently, to prevent any soft tissue artefact.

The series of examinations were performed over a two month period between June and July 2014. 200 registrations and examinations were performed on the 25 volunteers during this project, with each registration/examination recording 33 separate data points. Each volunteer examination session lasted between 80 and 100 minutes.

The temperature in the laboratory was not kept constant as no temperature conditioning facilities were available. The same protocol for registration and examination was performed by both Examiners to compare intra- and inter-Examiner reliability and repeatability. The protocol (see *Appendix 3*) was initially tested by both Examiners when identifying the optimal set of optical trackers for use on the volunteers, and any problems within the protocol or software were highlighted and modified prior to volunteer testing.

The protocol used in this project allowed for the analysis of anteroposterior (AP) laxity throughout knee flexion whilst optical trackers were in place. This allowed for the assessment of the repeatability of the registration process as well as the seven assessments of AP laxity in increments of 15º from 0º to 90º. Several independent variables remained constant such as degrees of flexion assessed, same volunteer for

eight registrations/examinations. Therefore the main changes between the seven assessments of AP laxity analysed was a new system registration (eight for each volunteer), and the re-attachment of the optical trackers.

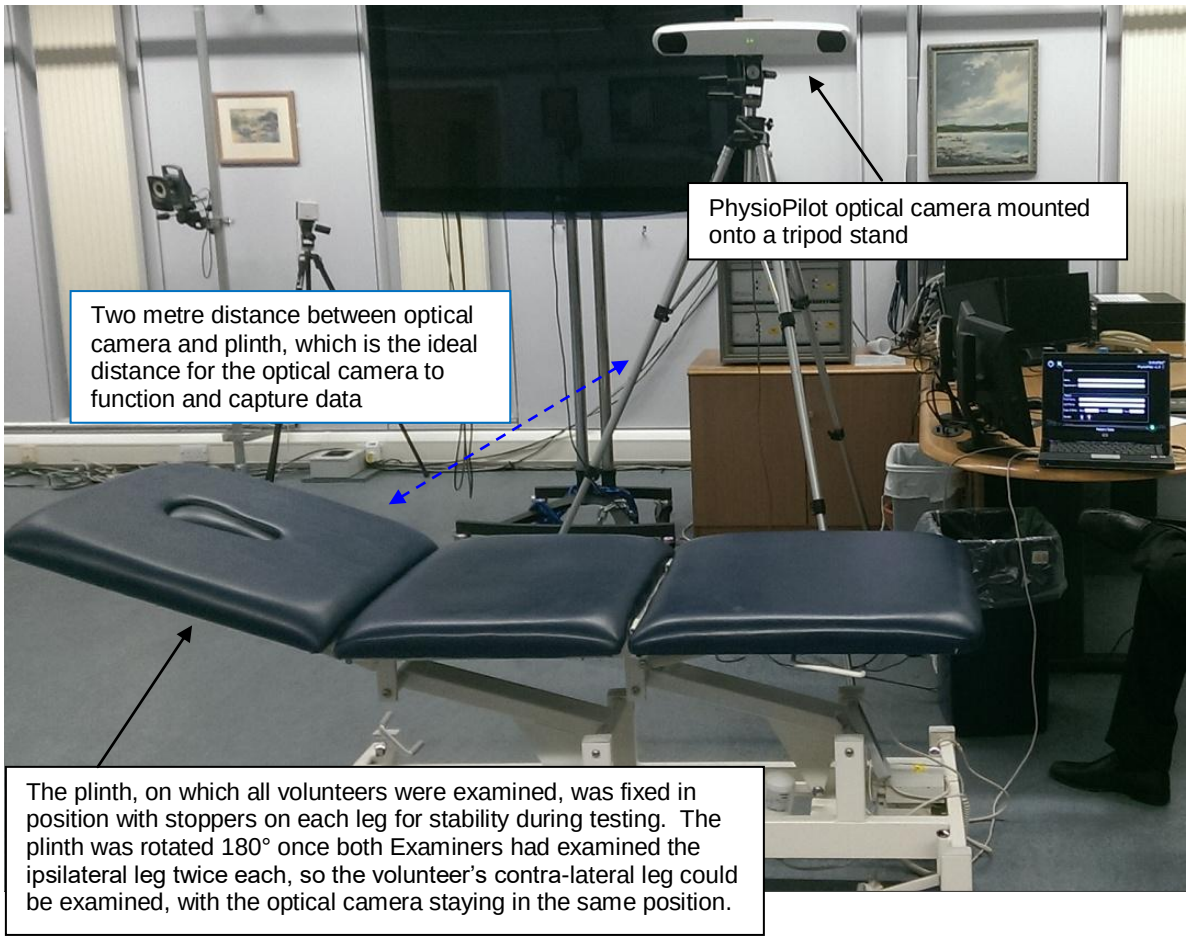


Figure 5.1 Image depicting the layout of the PhysioPilot optical camera, positioned two metres away from the plinth, with a laptop connected to the optical camera

Figure 5.2 An example of the set-up of each volunteer assessment; with the volunteer relaxed whilst lying supine in short trousers. Passive optical trackers mounted on the femur and tibia using fabric straps to secure the base plate holding the optical tracker in place, with the laptop visible for the Examiner to perform volunteer testing

5.3 Statistical methods

To assess the inter- and intra-Examiner reliability between both Examiners, Interclass Correlation Coefficient (ICC) calculations were performed using IBM SPSS® Statistics Ver17.0 software. Calculations for the inter- and intra-Examiner repeatability were performed using repeatability coefficients (CR) using Microsoft Excel ®. Calculations to test for normality of data for coronal alignment and AP laxity were performed using Microsoft Excel STAT ® and Minitab Ver 17®.

Interclass correlation coefficient (ICC)

ICC (2, 1) calculations were used to assess the reliability of each Examiners method in regards to tracker fixation to measure the supine MFTA in extension (°), tibia rotation (°) and tibial translation (mm) on each of the volunteers (Fleiss *et al* 1979). ICC (2, 1) calculations were chosen as each volunteer was examined by two Examiners, to assess a number of variables. Reliability was calculated for each of the individual variables measured (Fleiss *et al* 1979).

Using Fleiss - Kappa benchmark scale for strength of agreement, the strength of reliability for each variable was assessed. An ICC coefficient ≥0.90 demonstrated excellent reliability, ICC coefficients between 0.90 and 0.75 demonstrated very good reliability, ICC coefficients 0.75 to 0.40 indicated moderate to good reliability and ICC coefficients ≤ 0.40 indicated poor reliability (Fleiss et al 1979, Watkins et al 2000).

Image free navigation systems have been shown to have an accuracy of within 1° or 1mm (Bae et al 2011). Therefore a CR of supine MFTA of ≤2° (+/- 1°) would demonstrate excellent precision of the device (PhysioPilot). It is essential that all supine MFTA in extension (coronal alignment) acquired from the registration process be within (+/- 1°) of the initial supine MFTA acquired for each of the Examiners, to ensure consistent coronal alignment is maintained for the assessment of AP laxity and tibia rotation variables.

Repeatability coefficients (CR)

Repeatability coefficients (CR) were used to demonstrate the repeatability between test – retest measurements of each method assessed in regard of tracker fixation (Bland, Altman 1986; Altman, Bland 1987). The CR is defined as the interval within which 95% of the test-retest values lie; the 95% limit of agreements proposed by Bland and Altman which inevitably lies within 2 standard deviations of the test – retest differences (Bland, Altman 1986). As the repeated (retest) measurement is the same as the method measurement (test), the CR should be zero. The CR is calculated using the corrected standard deviation of the differences (95% limits of agreement) by 1.96 as described by Bland-Altman (Bland, Altman 1986) in the equation below;

$$CR = 1.96 \times \sqrt{\frac{\sum (d_2 - d_1)^2}{n - 1}}$$ or could be more precisely calculated by (1.96 *SD) (Bland 2000).

CR = Coefficient of repeatability

$\sum$ = sum of

d2 = standard deviation of 2nd test

d1= standard deviation of 1st test

n= number of tests

A gold standard range of +/- 3° alignment has become a widely used reference for which to compare the final results of alignment in total knee arthroplasty (Kim et al 2005, Mahaluxmivala et al 2001). Total knee replacement that falls out with +/- 3° has been associated with increased failure rates and early aseptic loosening (Ritter et al 2002, Berend et al 2004). Therefore a CR of 3° expresses that 95% of all measurements are within the range of +/- 1.5°. In a clinical setting the KT1000 is used to assess tibial translation and identify any cruciate ligament injuries or deficiencies, and if anterior tibio-femoral translation on the examined knee is ≥3mm compared to the contra-lateral (normal) knee during dichotomous testing then ACLD is diagnosed (Leith & Arneja 2009). Therefore a CR of ≤3mm demonstrates the relevant precision for this testing of cruciate ligaments (Lachman test). A CR of 3mm expresses that 95% of all measurements are within the range of +/- 1.5mm.

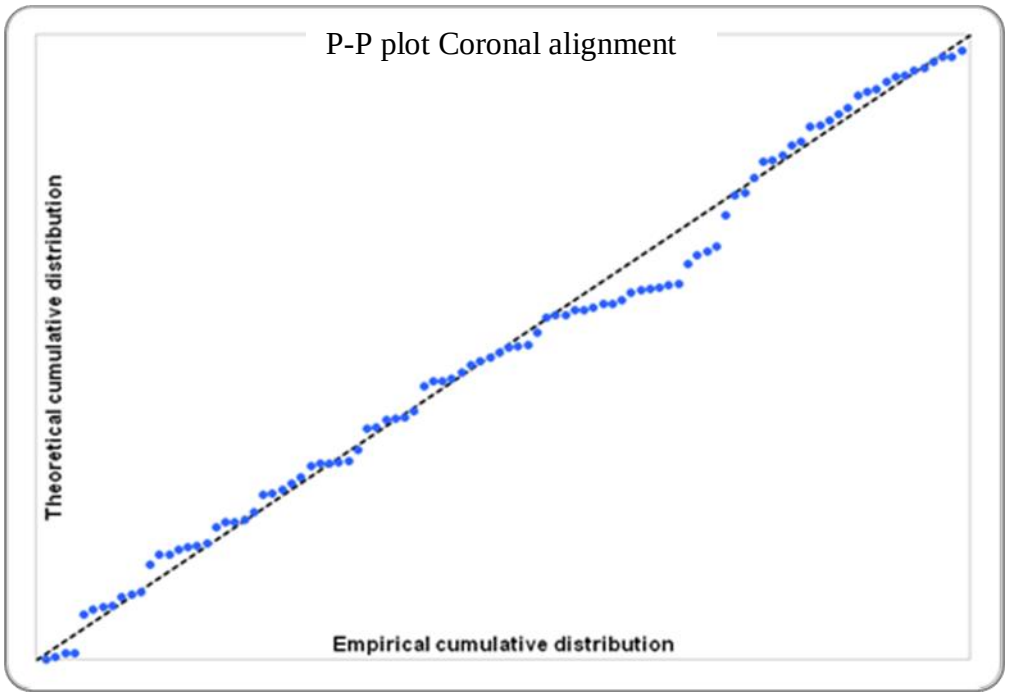
Acceptable limits of agreement for this project are set at 1° for the MFTA acquisition (as the software has been validated to this standard by Clarke and Russell *et al* (Clarke 2012a, Russell et al 2013)) and 3mm for anteroposterior tibial translation.

Test for normality (coronal alignment)

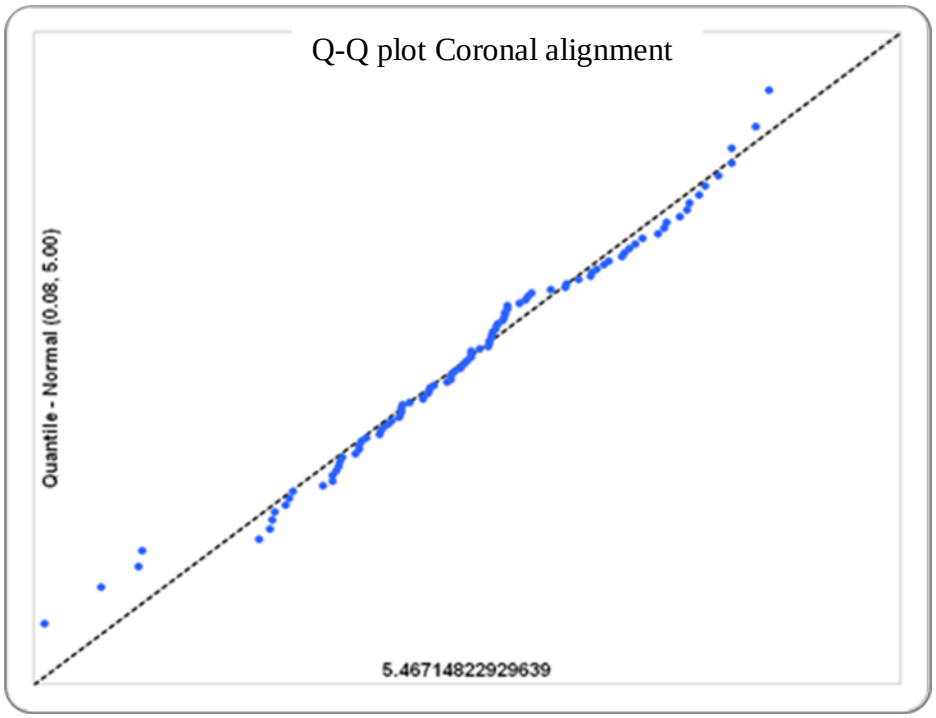
To test for normality of the coronal alignment for all the 25 volunteers, a Shapiro-Wilk and Kolmogorov- Smirnov tests were performed.

Each of these tests had a null hypothesis (H0): The coronal alignment from all 25 volunteers follows a normal distribution. The alternative hypothesis (H1): The coronal alignment from all 25 volunteers does not follow a normal distribution

The Shapiro-Wilk test = 5.47. α-value 0.05; mean 0.08; Standard deviation 5.0; p-value 0.18, w-value of 0.981. As the computed p-value is greater than the significance α-value =0.05, we cannot reject the null hypothesis (H0).
The P-P and Q-Q plots demonstrate a normal distribution of the coronal alignment data acquired for all 25 volunteers.

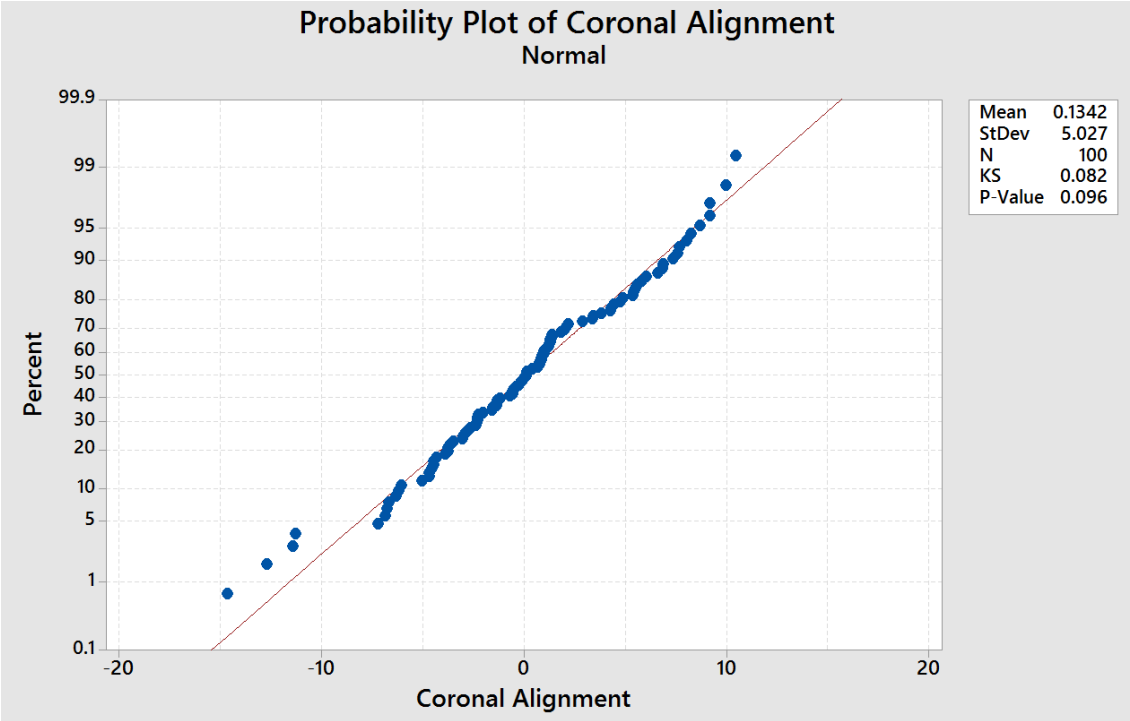


P-P plot coronal alignment depicting a normal distribution of coronal alignment data for all 25 volunteers.



Q-Q plot coronal alignment depicting a normal distribution of coronal alignment data for all 25 volunteers.

Kolmogorov- Smirnov tests also demonstrated a normal distribution of data for coronal alignment, with a p-value 0.10; below the significance α-value=0.05.



KS plot coronal alignment depicting a normal distribution of coronal alignment data for all 25 volunteers.

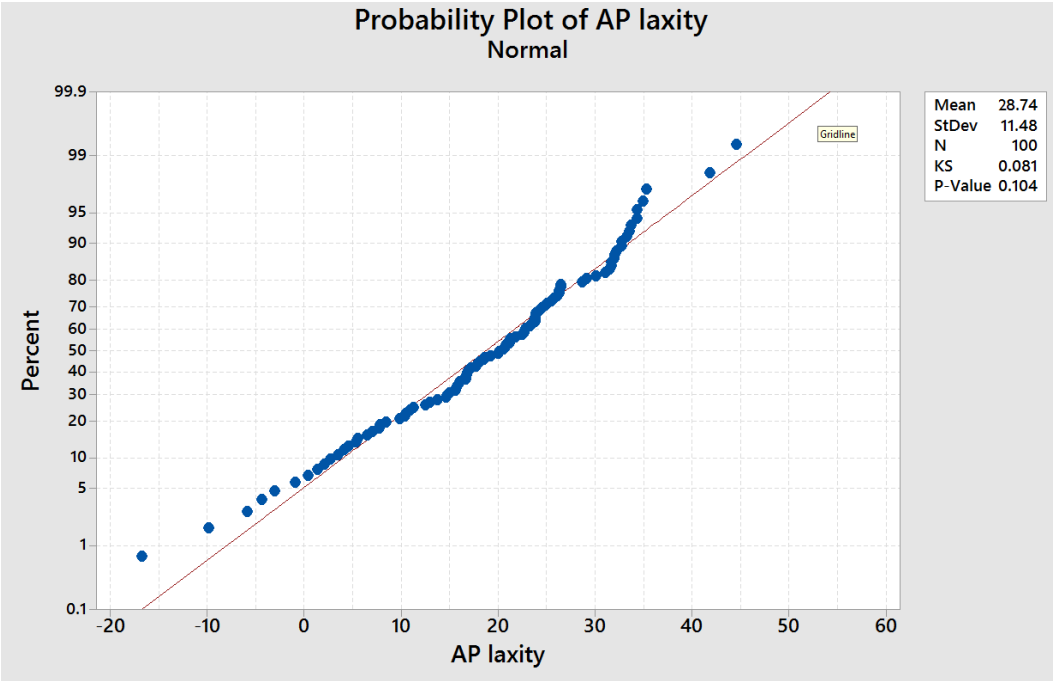
Test for normality (AP laxity)

To test for normality of AP laxity assessments for all the 25 volunteers, a Shapiro-Wilk and Kolmogorov- Smirnov tests were performed for AP laxity at 30º, as this is the laxity interval that Lachman test is most commonly performed in the clinical setting for the standard population.

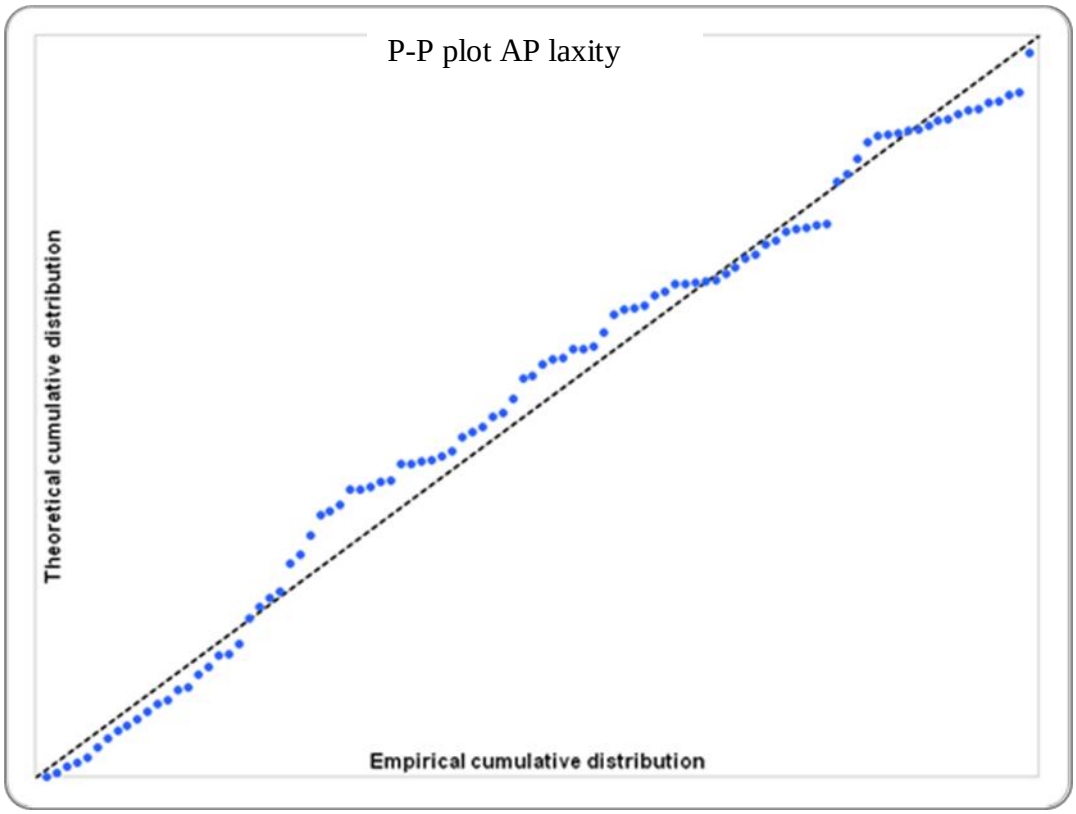
Each of these tests had a null hypothesis (H0): The AP laxity from all 25 volunteers follows a normal distribution. The alternative hypothesis (H1): The AP laxity from all 25 volunteers does not follow a normal distribution

The Shapiro-Wilk test = 10.44. α-value 0.05; mean 28.82; Standard deviation 11.5; p-value 0.08, w-value of 0.977. As the computed p-value is greater than the significance α-value =0.05, we cannot reject the null hypothesis (H0).
The P-P and Q-Q plots demonstrate a normal distribution of the AP laxity data acquired for all 25 volunteers.

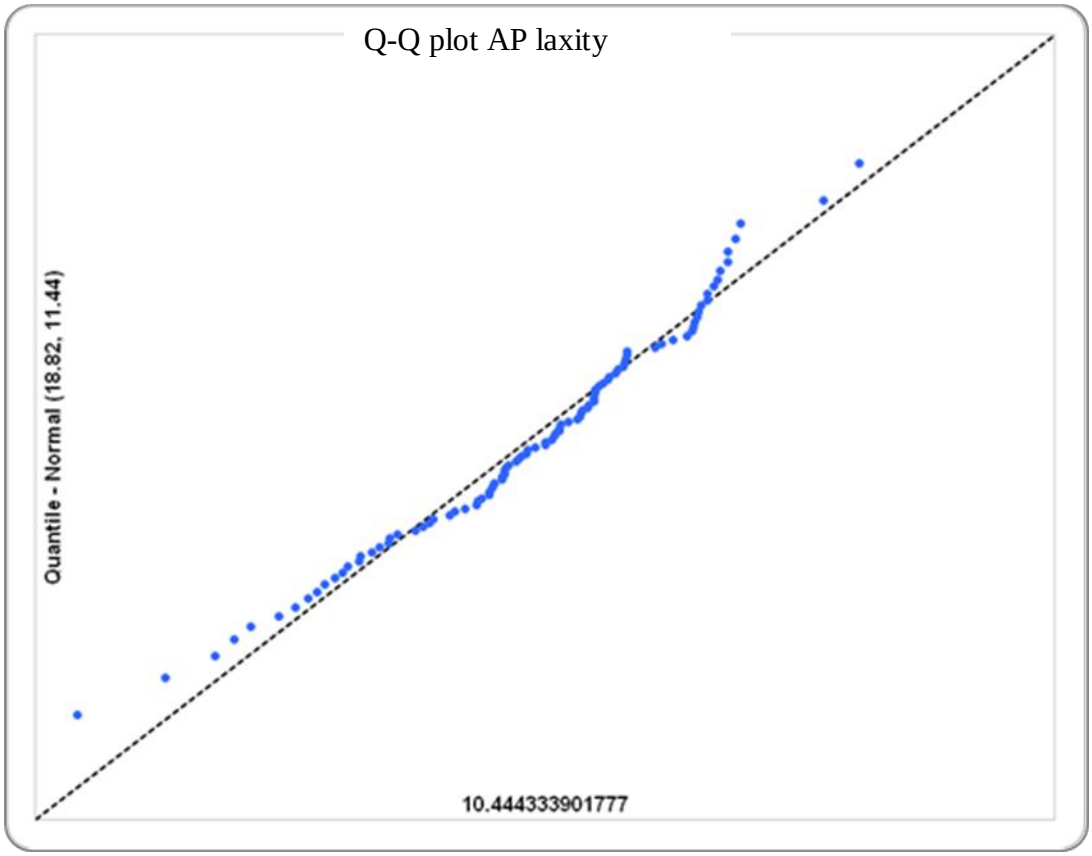
The Kolmogorov- Smirnov tests also demonstrated a normal distribution of data for coronal alignment, with a p-value 0.10; below the significance α-value=0.05.



KS plot AP laxity depicting a normal distribution of AP laxity data for all 25 volunteers.



P-P plot AP laxity depicting a normal distribution of AP laxity alignment data for all 25 volunteers.



Q-Q plot AP laxity depicting a normal distribution of AP laxity data for all 25 volunteers.

6 Results from volunteer testing

6.1 Demographics of volunteers

Of the 25 volunteers; 14 were male and 11 were female. The average BMI was 24.3 (18.5 – 46.3), and the average age was 33 years and 2 months (18 – 60 years old). The coronal alignment and AP laxity assessment for all volunteers showed a normal distribution.

6.2 Supine MFTA in extension assessment

All 25 volunteers assessed

The overall average supine MFTA in extension for all 25 volunteers was 1º valgus. Examiner 1's average was 0.5º valgus, Examiner 2's average 1.5º valgus. The average supine MFTA and standard deviation for both Examiners is highly comparable (2.5; 2.4), as shown in *Table 9* below. The full set of supine MFTA in extension data from volunteer testing for both Examiners is present in *appendices 10 and 11*.

***Table 9:* Right leg supine MFTA in extension (º) results for all volunteers**					
Examiner 1	**Examiner 2**	**Average Right knee**		**Average Left knee**	
Average(º)	Average(º)	Average(º)	Standard deviation	Average(º)	Standard deviation
-0.5	-1.5	-1.0	2.4	-0.5	2.5

Table 9 Right leg supine MFTA acquisition in extension results for all volunteers assessed by both Examiners using the pre-validated sets of optical trackers

The average supine MFTA in extension for the left leg of all 25 volunteers was comparable with the supine MFTA noted in the right leg.

In the initial 80 registrations (in the first 10 volunteers) Examiners 1 and 2 were not consistently within +/- 1º of the initial coronal alignment assessment for supine MFTA acquired in extension. However in the final 120 registrations (final 15 volunteers), Examiners 1 and 2 demonstrated consistent supine MFTA in extension within +/- 1º of the initial coronal alignment attained for these final 15 volunteers.

Due to the initial outliers from the first 10 volunteers, analysis of the data was performed on two different sections;

1- All 25 volunteers examined
2- The last 15 volunteers examined

Last 15 volunteers assessed

Examiner 1 achieved an average supine MFTA in extension of 0.2º valgus, which is comparable with Examiner 2 (1.1º valgus), and the overall average supine MFTA in extension of 0.7º valgus. For both Examiners there was a smaller standard deviation for last 15 volunteers compared to all 25 volunteers for the acquirement of supine MFTA in extension, and is demonstrated in *Table 10* below.

***Table 10*: Right leg supine MFTA in extension (º) results for last 15 volunteers**					
Examiner 1	**Examiner 2**	**Average Right knee**		**Average Left knee**	
Average(º)	Average(º)	Average(º)	Standard deviation	Average(º)	Standard deviation
-0.2	-1.1	-0.7	1.7	-0.5	1.7

Table 10 Right leg supine MFTA acquisition in extension results for last 15 volunteers assessed by both Examiners using the pre-validated sets of optical trackers

The average supine MFTA in extension for the left legs of the last 15 volunteers was comparable with the right leg assessments with both Examiners remaining consistently with +/- 1º coronal alignment validated for the software.

6.2.1 Inter-and intra-Examiner reliability and repeatability

Supine MFTA in extension assessment - Interclass Correlation Coefficient (ICC)

To assess the reliability of each Examiners method in measuring supine MFTA in extension, interclass correlation coefficient (ICC 2, 1) calculations were performed using IBM SPSS® Statistics Ver17.0 software. The Fleiss - Kappa benchmark scale for strength of agreement was used to demonstrate reliability. ICC coefficient ≥0.90 demonstrates excellent reliability, ICC coefficients between 0.90 and 0.75 demonstrate very good reliability, ICC coefficients 0.75 to 0.40 indicate moderate to

good reliability and ICC coefficients ≤ 0.40 indicate poor reliability (Fleiss *et al* 1979, Watkins *et al* 2000).

All 25 volunteers

Examiner 1 demonstrated good reliability (0.72), and Examiner 2 moderate reliability (ICC of 0.61), with moderate reliability shown in the comparison inter-Examiner ICC (0.52) as shown in *Table 11* below.

Table 11: Interclass correlation coefficient (ICC) for supine MFTA in extension for all 25 volunteers		
Examiner 1	**Comparison**	**Examiner 2**
0.72 (0.40;0.77)	0.52 (0.27;0.70)	0.61 (0.39;0.76)

Table 11 Supine MFTA in extension Interclass correlation coefficient (ICC) for all 25 volunteers assessed

Last 15 volunteers

Examiner 1 demonstrated an improved ICC with very good reliability (0.80), with Examiner 2 also demonstrating an improved ICC with very good reliability (0.76). The comparison ICC between both Examiners remained at moderate reliability (0.49), as shown in *Table 12 below.*

Table 12: Interclass Correlation Coefficient (ICC) for supine MFTA in extension for the 15 volunteers knees		
Examiner 1	**Comparison**	**Examiner 2**
0.80 (0.68;0.91)	0.49 (0.16;0.72)	0.76 (0.57;0.87)

Table 12 Supine MFTA in extension Interclass correlation coefficient (ICC) for the last 15 volunteers assessed

Supine MFTA in extension assessment - Coefficient of repeatability (CR)

To assess the repeatability between the test – retest measurements repeatability coefficients (CR) were calculated using Microsoft Excel ®. A CR of ≤3° for supine MFTA in extension expresses that 95% of all measurements are within the range of +/- 1.5°, in keeping with the gold standard range for KT 1000 assessment of ligamentous laxity between both lower limbs and the alignment of the insertion of knee prosthesis in total knee arthroplasty (Kim et al 2005, Mahaluxmivala et al 2001).

All 25 volunteers

Examiner 1 demonstrated good repeatability with a CR of 2.94 within the 95% limits of agreement (LOA), with Examiner 2 demonstrating poor repeatability with a CR of 4.62, outside the 95% LOA, as shown in *Table 13*.

Table 13: ***Coefficient of repeatability (CR) for supine MFTA in extension for all 25 volunteers***	
Examiner 1	**Examiner 2**
2.94	4.62

Table 13 Supine MFTA in extension coefficient of repeatability (CR) for all 25 volunteers assessed

Last 15 volunteers

The CR calculated for supine MFTA in extension post learning curve for the last 15 volunteers examined is Examiner 1 demonstrated an improved CR of -1.60 demonstrating good repeatability, and Examiner 2 also demonstrated an improved CR of -2.27 depicting good repeatability as demonstrated in *Table 14*..

Table 14: ***Coefficient of repeatability (CR) for supine MFTA in extension for the last 15 volunteers***	
Examiner 1	**Examiner 2**
-1.60	-2.27

Table 14 Supine MFTA in extension coefficient of repeatability (CR) for last 15 volunteers assessed

6.2.2 Summary of reliability and repeatability for supine MFTA in extension

Examiner 1 demonstrated more reliable and repeatable supine MFTA in extension acquisition than Examiner 2. The comparison reliability for supine MFTA acquisition in extension between both Examiners is moderate. Examiner 1 Bland-Altman supine MFTA data showed a narrower confidence internal and narrower data distribution spread than Examiner 2 for all 25 and the last 15 volunteers assessed. The difference in supine MFTA in extension acquisition between both examiners is most likely due to differences in technique by both Examiners and will be discussed in further detail in the *Discussion section.*

The supine mechanical femoral-tibial alignment (MFTA) is the initial crucial step in examining volunteers and allows the non-invasive navigation software to create a coronal plane in which to assess AP laxity. The poorer supine MFTA acquisition by Examiner 2 could lead to potentially more erroneous AP laxity and tibia rotation measures, and therefore give a less accurate validation of the non-invasive navigation system on the volunteers. Examiner 1 demonstrated more reliable and repeatable supine MFTA acquisition, therefore the rest of the thesis will focus solely on the data from Examiner 1.

6.3 AP laxity and tibial rotation assessment

Post supine MFTA acquisition in extension, a series of AP laxity assessments were performed in increments of 15º from 0º to 90º of flexion using the Lachman test.

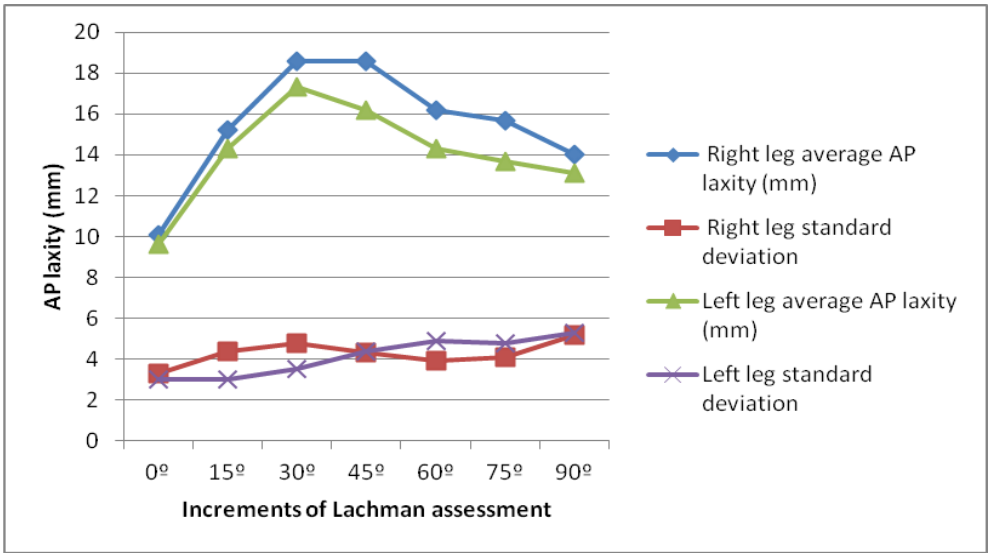
All 25 volunteers assessed

Examiner 1 demonstrated in all 25 volunteers an increase in AP laxity in both legs from 0º to 30º, with similar laxity noted at 30º and 45º in the right knee. From 45º to 90º the AP laxity progressively decreased, with both legs demonstrating a similar pattern. These patterns are demonstrated in *Graph 9*. There was no side to side difference greater than 3mm recorded on any volunteer or noted at any interval in both legs. The overall average laxity from the volunteers tested appears to be slightly greater in the right leg at all increments.

The tibial rotation acquired for all 25 volunteers assessed demonstrates that from 0º to 45º there appears to be more medial rotation recorded in both legs, and from 60º to 90º there appears to be more lateral rotation in both legs, as seen in *Graph 10*.

The summary data of AP laxity and tibia rotation assessments performed by Examiner 1 on all 25 volunteers as well as the last 15 volunteers is shown in *Table 15* below. The full set of AP laxity and tibia rotation data is present in *Appendix 10*.

Graph 9

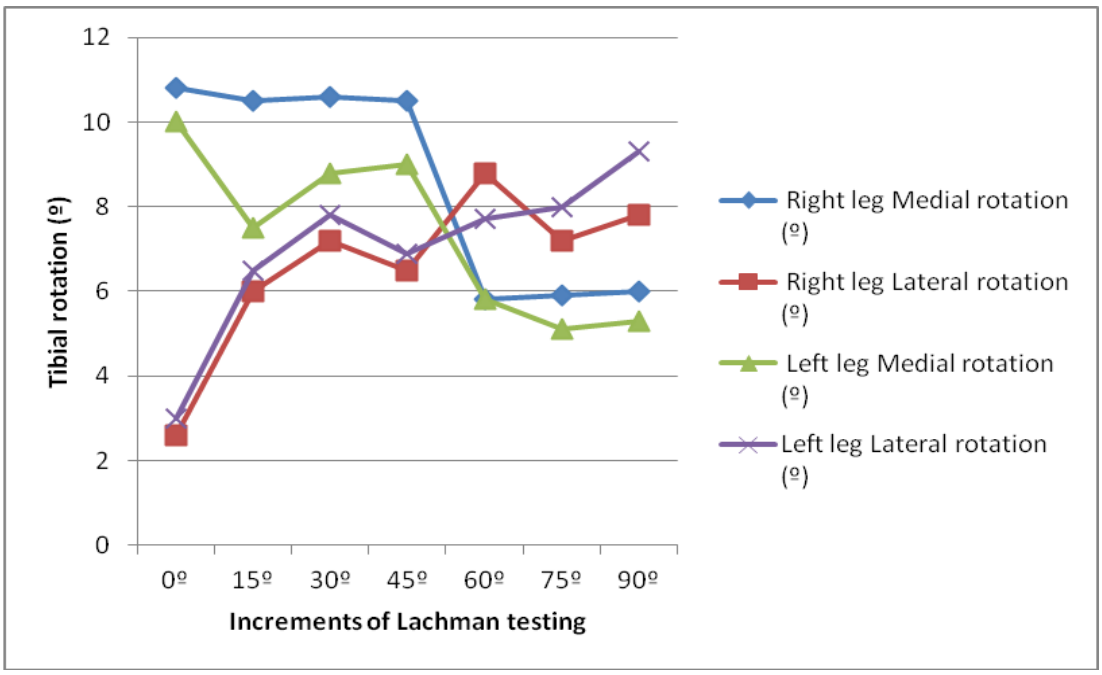


Graph 9 Demonstrating pattern of AP laxity from 0º to 90º in all 25 volunteers assessed using the pre-validated optical tracker set

Table 15: *AP laxity and tibial rotation results for Examiner 1 in all 25 volunteers and the last 15 volunteers assessed*									
Assessment	**Degrees**	***All 25 volunteers***				***Last 15 volunteers***			
		Right knee		***Left knee***		***Right knee***		***Left knee***	
		Average	Standard deviation	Average	Standard deviation	Average	Standard deviation	Average	Standard deviation
AP laxity (mm)	0º	10.1	3.3	9.6	3.0	9.7	3.5	9.6	2.8
	15º	15.2	4.4	14.3	3.0	16.2	5.0	14.0	3.3
	30º	18.6	4.8	17.3	3.5	19.5	5.4	16.6	3.8
	45º	18.6	4.3	16.2	4.4	19.4	4.5	15.0	4.4
	60º	16.2	3.9	14.3	4.9	16.7	4.0	13.3	5.4
	75º	15.7	4.1	13.7	4.8	15.7	4.2	12.9	4.6
	90º	14.0	5.2	13.1	5.3	14.1	5.6	12.7	4.9
Medial rotation (º)	0º	10.8	3.1	10.0	3.5	11.4	3.2	10.5	3.7
	15º	10.5	4.7	7.5	3.7	12.1	5.0	7.2	3.2
	30º	10.6	5.2	8.8	3.8	12.4	4.7	8.2	4.0
	45º	10.5	4.9	9.0	4.3	11.2	4.6	9.4	4.5
	60º	5.8	4.1	5.8	3.7	5.7	3.8	4.9	2.6
	75º	5.9	3.7	5.1	3.8	6.2	3.6	4.3	2.8
	90º	6.0	3.7	5.3	8.4	5.2	3.7	5.3	10.1
Lateral rotation (º)	0º	2.6	2.2	3.0	2.7	2.2	1.9	2.6	2.7
	15º	6.0	3.6	6.5	3.7	5.9	3.5	6.5	3.7
	30º	7.2	4.3	7.8	4.8	6.6	4.8	7.2	4.7
	45º	6.5	3.9	6.9	4.1	6.2	3.9	7.0	4.6
	60º	8.8	3.1	7.7	3.4	9.2	3.3	7.2	3.2
	75º	7.2	3.1	8.0	3.9	7.3	3.3	7.5	4.1
	90º	7.8	3.0	9.3	3.8	8.2	2.9	8.5	3.2

Table 15 AP laxity and tibial rotation results for all 25 volunteers and last 15 volunteers legs assessed by Examiner 1

Graph 10

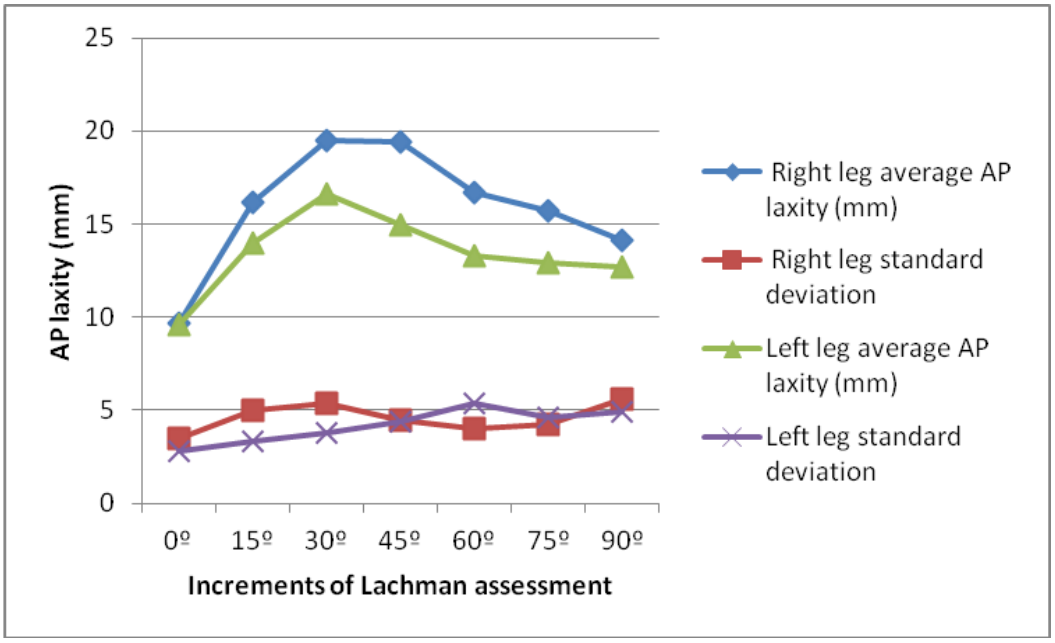


Graph 10 Depicting the pattern of tibial rotation (medial and lateral) from 0º to 90º in all 25 volunteers assessed using the pre-validated optical tracker set

Last 15 volunteers assessed

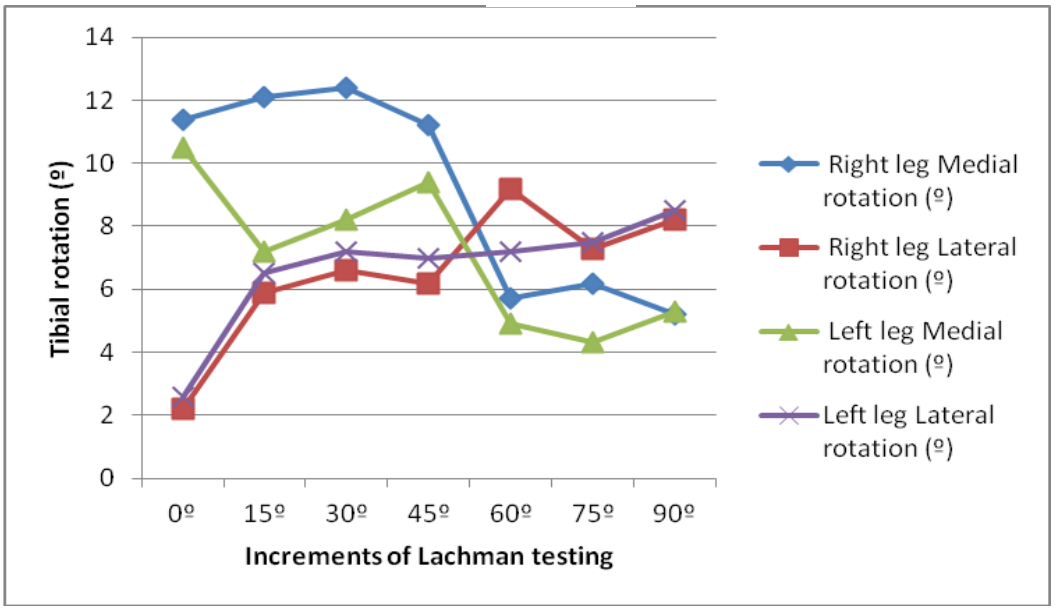
The AP laxity and tibia rotation data acquired for the last 15 volunteers demonstrated a similar trend to that of all 25 volunteers. This is demonstrated in *Graphs 11 and 12*.

Graph 11



Graph 11 Demonstrating pattern of AP laxity from 0º to 90º in the last 15 volunteers assessed using the pre-validated optical tracker set

Graph 12



Graph 12 Depicting the pattern of tibial rotation (medial and lateral) from 0º to 90º in the last 15 volunteers assessed using the pre-validated optical tracker set

6.3.1 Intra-Examiner reliability and repeatability for Examiner 1

AP laxity and tibial rotation assessment - Interclass Correlation Coefficient (ICC)

All 25 volunteers

The ICCs calculated for Examiner 1 AP laxity assessments show moderate reliability at all increments throughout flexion for all 25 volunteers assessed, as shown in *Table 16* below.

Examiner 1 demonstrated moderate reliability at 0º lateral rotation and poor reliability at 0º medial rotation. Due to the poor ICC reliability calculated up to 60º of AP laxity and at 0º medial and lateral rotation, no further ICC calculation were calculated for all 25 volunteers assessed.

***Table 16*: AP laxity and tibial rotation Interclass Correlation Coefficients (ICC) for all 25 volunteers assessed by Examiner 1**

Assessment	Interclass correlation coefficients (ICC)
AP laxity 0º	0.55 (0.31;0.72)
AP laxity 15º	0.57 (0.34;0.74)
AP laxity 30º	0.59 (0.32;0.73)
AP laxity 45º	0.55 (0.33;0.78)
AP laxity 60º	0.54 (0.27;0.70)
Medial rotation 0º	0.07 (-0.22;0.35)
Lateral rotation 0º	0.64 (-0.43;0.78)

Table 16 AP laxity and tibial rotation Interclass correlation coefficients (ICC) for all 25 volunteers assessed

Last 15 volunteers

The ICC calculations for Examiner 1 AP laxity assessments show very good reliability at 30º, 45º, 60º and 75º assessments, and good reliability is demonstrated at 0º, 15º and 90º increments, as shown in *Table 17*.

ICC calculation for the tibial rotation shows poor reliability for 0º and 15º medial rotation and moderate reliability at 0º and 15 º lateral rotation. Due to the poor reliability demonstrated at 0º and 15º medial and lateral rotation, no further analysis on tibia rotation was assessed through the range of flexion.

The ICCs calculated for the last 15 volunteers are more reliable through the range of flexion for AP laxity and tibia rotation assessments than those attained for all 25 volunteers.

***Table 17*: AP laxity and tibial rotation Interclass correlation coefficients (ICC) for the 15 volunteers knees assessed by Examiner 1**	
Assessment	**Interclass correlation coefficients (ICC)**
AP laxity 0^o	0.70 (0.45;0.84)
AP laxity 15^o	0.72 (0.50;0.86)
AP laxity 30^o	0.82 (0.65;0.91)
AP laxity 45^o	0.82 (0.64;0.91)
AP laxity 60^o	0.79 (0.54;0.89)
AP laxity 75^o	0.76 (0.53;0.87)
AP laxity 90^o	0.73 (0.51;0.84)
Medial rotation 0^o	0.41 (0.06;0.68)
Lateral rotation 0^o	0.69 (0.43;0.83)
Medial rotation 15^o	0.20 (-0.16;0.52)
Lateral rotation 15^o	0.70 (0.49;0.85)

Table 17 AP laxity and tibial rotation Interclass correlation coefficients (ICC) for the last 15 volunteers assessed

AP laxity and rotation assessment - Coefficient of repeatability (CR)

A CR of ≤3mm demonstrates the relevant precision for this testing of cruciate ligaments (Lachman test). A CR of 3mm expresses that 95% of all measurements are within the range of +/- 1.5mm.

All 25 volunteers

The CR calculated for AP laxity and rotation for all 25 volunteers show poor repeatability throughout the range of flexion, being out with the 95% LOA of 3mm as shown in *Table 18*.

***Table 18**. AP laxity and tibial rotation coefficient of repeatability (CR) for all 25 volunteers assessed by Examiner 1*

Assessment	Coefficient of repeatability (CR)
AP laxity 0^o	4.41
AP laxity 15^o	5.80
AP laxity 30^o	4.22
AP laxity 45^o	4.54
AP laxity 60^o	4.54
Medial rotation 0^o	6.53
Lateral rotation 0^o	5.47

Table 18 A laxity and tibial rotation coefficient of repeatability (CR) for all 25 volunteers assessed.

Last 15 volunteers

The repeatability (CR) for AP laxity assessments for the last 15 volunteers assessed showed good repeatability shown at 30º, 45º and 60º, being within the 95% LOA, with poor repeatability demonstrated at 0º, 15º, 75º and 90º of AP laxity, all outwith the 95% LOA, as shown in *Table 19*.

The CR calculated for the tibia rotation showed poor repeatability at 0º and 15º medial and lateral rotations.

Table 19. AP laxity and tibial rotation coefficient of repeatability (CR) for last 15 volunteers assessed	
Assessment	**Coefficient of repeatability (CR)**
AP laxity 0^o	3.72
AP laxity 15^o	4.78
AP laxity 30^o	2.52
AP laxity 45^o	2.92
AP laxity 60^o	3.33
AP laxity 75^o	4.64
AP laxity 90^o	5.63
Medial rotation 0^o	5.07
Lateral rotation 0^o	4.20
Medial rotation 15^o	6.73
Lateral rotation 15^o	4.86

Table 19 AP laxity and tibial rotation coefficient of repeatability (CR) for last 15 volunteers assessed

6.3.2 Inter-Examiner reliability and repeatability

The review of AP laxity and tibia rotation reliability and repeatability between both Examiners is available in *Appendix 16*, for all 25 volunteers and the last 15 volunteers assessed.

6.4 Pivot-shift test and maximum flexion assessment

All 25 volunteers assessed

The final assessment of AP laxity was the pivot-shift test. Examiner 1 demonstrated comparable anterior draw (43.5mm, 42.4mm) and pivot-shift rotation (25º, 23.2º) between both legs examined. The maximum passive flexion attained by Examiner 1 for all 25 volunteers is also extremely comparable between both legs examined (148.3º, 148.5º) with both legs demonstrating a normal range of passive flexion, as shown in *Table 20*. The full set of AP laxity and tibia rotation data is present in *Appendix 10*.

***Table 20*: Pivot-shift test and maximum passive flexion data acquired from all volunteers assessed by Examiner 1**

Assessment	*Right*		*Left*	
	Average	Standard deviation	Average	Standard deviation
Pivot-shift anterior draw (mm)	43.5	17.3	42.4	18.5
Pivot-shift rotation (º)	25.0	9.3	23.2	7.7
Maximum flexion (º)	148.3	6.4	148.5	6.4

Table 20 Pivot-shift test and maximum passive flexion data acquired from all 25 volunteers assessed by Examiner 1

Last 15 volunteers assessed

Examiner 1 demonstrated good comparability in both legs for the pivot-shift anterior draw (44.6mm, 42.9mm) and pivot-shift rotation (24º, 22.5º). The maximum passive flexion for the last 15 volunteers assessed is comparable between both legs examined (149.2º, 147.6º), as shown in *Table 21* below. The pivot-shift anterior draw and rotation, as well as the maximum passive flexion data for the last 15 volunteers are comparable with the data acquired in all 25 volunteers.

Table 21: Pivot-shift test and maximum passive flexion data acquired from last 15 volunteers assessed by Examiner 1				
Assessment	***Right***		***Left***	
	Average	Standard deviation	Average	Standard deviation
Pivot-shift anterior draw (mm)	44.6	17.2	42.9	16.5
Pivot-shift rotation (°)	24.0	10.1	22.5	7.8
Maximum flexion (°)	149.2	6.6	147.6	6.2

Table 21 Pivot-shift test and maximum passive flexion data acquired from last 15 volunteers assessed by Examiner 1

6.4.1 Intra-Examiner reliability and repeatability

Pivot-shift test and maximum flexion assessment - Interclass Correlation Coefficient (ICC)

All 25 volunteers

The ICC for both the pivot-shift anterior draw (0.59) and pivot shift rotation (0.42) show moderate reliability, with the ICC calculated for maximum passive flexion demonstrating very good reliability (0.77), as shown in *Table 22.*

Table 22: Interclass correlation coefficients (ICC) for the Pivot-shift test and passive maximum flexion for all 25 volunteers assessed by Examiner 1	
Assessment	**Interclass correlation coefficient (ICC)**
Pivot-shift anterior draw	0.59 (0.37;0.75)
Pivot-shift rotation	0.42 (0.15;0.63)
Maximum passive flexion	0.77 (0.63;0.87)

Table 22 Pivot-shift test and passive maximum flexion Interclass correlation coefficients (ICC) for all 25 volunteers assessed

Last 15 volunteers

Examiner 1 demonstrated an improvement in ICC calculation for the last 15 volunteers' assessment of pivot-shift anterior draw (0.64) and pivot-shift rotation (0.44), but still demonstrated only moderate reliability. The ICC calculated for the maximum range of passive flexion also improved and showed very good reliability (0.82) as depicted in *Table 23*.

Table 23: *Interclass correlation coefficients (ICC) for the Pivot-shift test and passive maximum flexion for the last 15 volunteers assessed by Examiner 1*	
Assessment	**Interclass correlation coefficient (ICC)**
Pivot-shift anterior draw	0.64 (0.36;0.78)
Pivot-shift rotation	0.44 (0.20,0.69)
Maximum passive flexion	0.82 (0.63;0.91)

Table 23 Pivot-shift test and passive maximum flexion Interclass correlation coefficients (ICC) for the last 15 volunteers assessed

Pivot-shift test and maximum flexion assessment - Coefficient of Repeatability (CR)

All 25 volunteers

Examiner 1 demonstrated poor repeatability at both the pivot-shift anterior draw (8.57) and pivot-shift rotation (12.32) assessments, with both assessments being well out with the 95% LOA. The maximum passive flexion showed good repeatability (2.46) being with the LOA of 3mm as shown in *Table 24*.

Table 24*. Pivot-shift test and passive maximum flexion coefficient of repeatability (CR) for all 25 volunteers assessed by Examiner 1*	
Assessment	**Coefficient of repeatability (CR)**
Pivot-shift anterior draw	8.57
Pivot-shift rotation	12.32
Maximum passive flexion	2.46

Table 24 Pivot-shift test and passive maximum flexion coefficient of repeatability (CR) for all 25 volunteers assessed.

Last 15 volunteers

The repeatability for both the pivot-shift anterior draw (6.43) and the pivot-shift rotation (10.82) improved in the last 15 volunteers assessed by still demonstrated poor repeatability. The repeatability calculated for the maximum range of passive flexion (1.52) also improved and still shows good repeatability.

Table 25. Pivot-shift test and passive maximum flexion coefficient of repeatability (CR) for the last 15 volunteers assessed by Examiner 1	
Assessment	**Coefficient of repeatability (CR)**
Pivot-shift anterior draw	6.43
Pivot-shift rotation	10.82
Maximum passive flexion	1.52

Table 25 Pivot-shift test and passive maximum flexion coefficient of repeatability (CR) for the last 15 volunteers assessed.

6.4.2 Inter-Examiner reliability and repeatability

The review of inter-Examiner reliability and repeatability of the pivot-shift test and maximum passive flexion for all 25 volunteers and the last 15 volunteers assessed is shown in the *Appendix section (Appendix 17*).

6.5 Bipedal and monopedal load MFTA assessment

All 25 volunteers assessed

Examiner 1 demonstrated comparable right leg bipedal load MFTA (0.1º valgus) and monopedal load MFTA (1.0º valgus) acquisition with the initial supine MFTA acquired in extension of 0.5º valgus, as shown in *Table 26*.

The left leg showed similar good coronal alignment between supine MFTA in extension (0.1º varus), bipedal load MFTA (0.6º varus), and monopedal load MFTA (1.1º varus).

Table 26*: *Bipedal and monopedal loaded MFTA results for all volunteers assessed by Examiner 1

Assessment	Average	Standard deviation
Bipedal loaded MFTA (º)	-0.1	4.9
Monopedal loaded MFTA (º)	-1.0	4.3

Table 26 Bipedal and monopedal loaded MFTA results for all volunteers assessed by Examiner 1

Last 15 volunteers assessed

Results for the bipedal and monopedal load MFTA for the last 15 volunteers assessed by Examiner 1 are shown in *Table 27*. Examiner 1 demonstrated comparability for right leg bipedal load MFTA (0.8º valgus) and monopedal load MFTA acquisition (1.3º valgus) within +/-1º of the initial supine MFTA acquired of 0.2º valgus.

The left leg showed similar good comparability in coronal alignment acquisition between supine MFTA in extension (0.4º varus), bipedal load MFTA (1.3º varus), and monopedal load MFTA (1.0º varus). Both the monopedal and bipedal loaded MFTA for both legs were within +/- 1º coronal alignment of the supine MFTA in extension.

***Table 27*: Bipedal and monopedal loaded MFTA results for last 15 volunteers assessed by Examiner 1**		
Assessment	Average	Standard deviation
Bipedal loaded MFTA (^{o})	-0.8	4.1
Monopedal loaded MFTA (^{o})	-1.3	4.3

Table 27 Bipedal and monopedal loaded MFTA results for last 15 volunteers assessed by Examiner 1

6.5.1 Intra-Examiner reliability and repeatability

Bipedal and monopedal load MFTA assessment - Interclass Correlation Coefficient (ICC)

All 25 volunteers

The ICC calculation of the bipedal load MFTA (0.76) demonstrated very good reliability, and for the monopedal loaded MFTA (0.65) demonstrated moderate reliability as demonstrated in *Table 28* below.

***Table 28*. Bipedal and monopedal loaded MFTA Interclass correlation coefficient (ICC) for the last 25 volunteers assessed**	
Assessment	**Interclass correlation coefficients (ICC)**
Bipedal loaded MFTA	0.76 (0.66;0.82)
Monopedal loaded MFTA	0.65 (0.45;0.79)

Table 28 Bipedal and monopedal loaded MFTA Interclass correlation coefficient (ICC) for the last 25 volunteers assessed

Last 15 volunteers

The ICC for the bipedal loaded MFTA improved for the last 15 volunteers to (0.80), still demonstrating very good reliability. The ICC for the monopedal loaded MFTA also improved (0.72) and demonstrated good reliability as shown in *Table 29*.

***Table 29*. Bipedal and monopedal loaded MFTA Interclass correlation coefficient (ICC) of the last 15 volunteers assessed**	
Assessment	**Interclass correlation coefficients (ICC)**
Bipedal loaded MFTA	0.80 (0.59;0.91)
Monopedal loaded MFTA	0.72 (0.48;0.85)

Table 29 Bipedal and monopedal loaded MFTA Interclass correlation coefficient (ICC) of the last 15 volunteers assessed

Bipedal and monopedal load MFTA assessment - Coefficient of Repeatability (CR)

All 25 volunteers

CR calculated for bipedal loaded MFTA was (2.62) demonstrated good repeatability, with the CR for the monopedal loaded MFTA acquisition (4.98) showing poor repeatability, as it is outwith the 95% LOA of 3°, as shown in *Table 30* below.

***Table 30*. Bipedal and monopedal loaded MFTA Coefficient of repeatability (CR) for the last 25 volunteers assessed**	
Assessment	**Coefficient of repeatability (CR)**
Bipedal loaded MFTA	2.62
Monopedal loaded MFTA	4.98

Table 30 Bipedal and monopedal loaded MFTA Coefficient of repeatability (CR) for the last 25 volunteers assessed

Last 15 volunteers

Examiner 1 demonstrated an improved repeatability in the last 15 volunteers for both bipedal and monopedal loaded MFTA acquisition with a CR (1.87) and (2.98) respectively, both depicting good repeatability as shown in *Table 31* below.

***Table 31*. Bipedal and monopedal loaded MFTA Coefficient of repeatability (CR) of the last 15 volunteers assessed**	
Assessment	**Coefficient of repeatability (CR)**
Bipedal loaded MFTA	1.87
Monopedal loaded MFTA	2.98

Table 31 Bipedal and monopedal loaded MFTA Coefficient of repeatability (CR) of the last 15 volunteers assessed

6.5.2 Inter-Examiner reliability and repeatability

The review of inter-Examiner reliability and repeatability of bipedal and monopedal load MFTA for all 25 volunteers and the last 15 volunteers assessed is shown in the *Appendix section (Appendix 18)*.

6.6 Summary of results

Prior to volunteer testing the PhysioPilot system validated a new set of optical trackers against the pre-validated optical trackers. The new optical trackers performed sub-optimally in comparison to the pre-validated tracker set, not consistently acquiring supine MFTA acquisition in extension, demonstrating 'side to side' differences of 3mm or greater, and not being able to assess maximum passive flexion post 125º due to loss of detection form PhysioPilot optical camera. The new optical trackers were designed to reduce the moment arm noted in the pre-validated optical trackers, but due to the positioning of the optical tracker balls being mounted flush to the base plate, the new set of trackers failed to be detected by the infra-red optical camera system. Due to the poor performance of the new optical trackers these trackers were discarded, and the pre-validated optical trackers were used in volunteer testing.

The PhysioPilot system demonstrated consistent and comparable supine MFTA in extension acquisition by both Examiners in the final 15 volunteers knees assessed post learning curve, consistently within the pre-validated +/-1º coronal alignment validated by Clarke and Russell *et al*; (Clarke 2012, Russell et al 2013).

The most reliable and repeatable AP laxity measures performed by Examiner 1 were at 30º, 45º and 60º, due to difficult Lachman examination technique in early and late flexion; and no standardised force. Unfortunately due to no force application device compatible with the software at the time of testing the non-invasive navigation system was not able to be validated through flexion in this study, and the initial hypothesis not validated.

Maximal AP laxity was demonstrated at 30º of flexion, in accordance with Amis *et a*l (Amis et al 2010). The non-invasive system was able to reliably and consistently measure AP knee laxity between 30° and 45° of flexion, the clinically relevant range for this assessment. This system could therefore be used to quantify abnormal knee laxity and improve the assessment of knee instability and ligamentous injuries in a clinic setting.

However this study only analysed data for Examiner 1 who assessed 25 volunteers with a learning curve noted in the first 10 volunteers. No standardised force was used during AP laxity assessment, and Examiner 1 is a trainee orthopaedic surgeon; and therefore any clinical use of the PhysioPilot system should be with caution until the non-invasive navigation system is validated in the assessment of AP laxity and tibia rotation through flexion.

The bi-pedal and mono-pedal loaded MFTA acquired for all volunteers were within +/-1º coronal alignment of the supine MFTA in accordance with Deep *et al* (Deep et al 2014), demonstrating consistent MFTA assessment in supine and loaded axes by the PhysioPilot system, even post examination of AP laxity.

7 Discussion

Navigated image free systems are available in orthopaedic theatres to provide an accurate and repeatable means of prosthetic implantation and re-alignment of the lower limb coronal axis to within +/- 3° of neutral. Non-invasive navigation is based on image free navigation using a similar software algorithm, and fabric straps to hold the optical trackers in position. A limited number of studies have been performed using non-invasive navigation software, and the system is still to be validated for AP laxity and tibia rotation assessment in live subjects to 90º.

The purpose of this paper was to validate the assessment of anteroposterior (AP) knee joint laxity and tibia rotation through the range of flexion (0º to 90º) in knee joints of healthy volunteers, using a non-invasive image free navigation system (PhysioPilot).

7.1 Pilot study (optimal tracker set identification)

An updated non-invasive navigation infrared camera had been developed and allowed for the assessment of anteroposterior (AP) knee joint laxity and tibia rotation through the range of flexion. There are limitations in the current methods of measuring AP knee joint laxity using the non-invasive navigation system as the pre-validated optical trackers producing a large moment arm and are prone to movement during assessment. Therefore a new set of optical trackers with a smaller moment arm was developed to try and alleviate the limitations and improve the accuracy, reliability and repeatability of AP laxity assessment. Examiner 1 and Examiner 2 carried out testing on one another to validate the new set optical trackers against the pre-validated set of optical trackers using the non-invasive navigation system.

The data accumulated during initial testing demonstrated the optimal set of optical trackers was the **pre-validated set**. The pre-validated set of optical trackers demonstrated good repeatability by both Examiners when acquiring the supine MFTA in extension, with the acquisition of supine MFTA being constantly within the +/- 1º coronal alignment previously validated for each Examiner assessment. The

pre-validated trackers also demonstrated good intra- and inter-Examiner reliability and repeatability with the acquisition of data for AP laxity and tibia rotation, pivot-shift tests, bipedal and monopedal loaded MFTA, and demonstrated a full ROM for the assessment of passive maximum flexion angle.

The new set of trackers were designed to reduce the moment arm noted in the pre-validated optical trackers which increases soft tissue artefacts from the skin surface potentially resulting in errors. However the new optical tracker set was not as reliable or repeatable as the pre-validated optical tracker set for acquiring data for any of the variables assessed. A possible explanation for the poor results attained using the new tracker set is the positioning of the optical markers (balls). The new tracker markers were mounted flat on a metal base with all four markers sitting in the same plane (sagittal plane) as the optical infrared camera as shown in *Figure 7.1*. The infrared camera requires at least three markers to be visible and reflect the infrared signal at all times so the optical camera can identify where in space the optical trackers are for the software to accurately record the measured variable. With the positioning of the markers on the new tracker being parallel to the camera, only two markers were easily visible to the optical infrared camera (*Figure 7.1*) and therefore resulted in difficult to attain data which was poor; as the examined leg would have to be rotated toward the camera in order for the tracker set to be detected. This resulted in erroneous supine MFTA acquisition in extension, anteroposterior translation and tibia rotation data, as well as a limited range in which passive flexion could be assessed 125º (30º less than the pre-validated optical trackers).

Motion analyses systems use a larger number of cameras to detect the trackers than the non-invasive navigation system (PhysioPilot). PhysioPilot only has two optical infrared cameras to detect the four femoral and four tibial tracker markers, and can detect these trackers in a 160 º field of view. Motion analysis systems such as Vicon have eight to twelve cameras positioned all around a laboratory to detect the trackers in a 360 º field of view, and therefore have a higher recognition and accuracy of detecting the trackers mounted on test subjects. The Vicon system which also uses infrared to detect the tracker markers interfered with the PhysioPilot optical camera

system and reduced the PhysioPilot camera from recognising the optical trackers mounted due to Vicon infrared interference, and was therefore was not used.

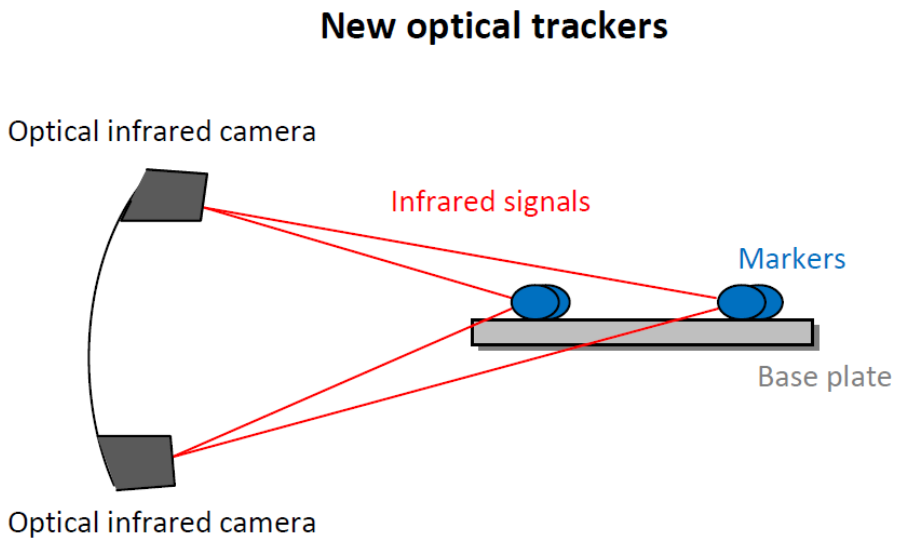


Figure 7.1 Image depicts optical camera sending infrared signals which only detect 2 of the new optical tracker markers, due to the markers mounting positioning flat on the base plate.

The pre-validated tracker set had its markers elevated, angled at 60 º off the base plate from the coronal plane and allowed for easier capture of the infrared signal from the optical camera, with no need for any manipulation of the examined limb to aid in data acquisition (*Figure 7.2*). Because the pre-validated optical tracker markers were elevated off the metal base plate, the marker balls were more easily sensed by the infrared optical camera allowing for the full assessment of flexion through range (up to 160º), as well as more reliable and repeatable supine MFTA acquisition, AP translation and tibia rotation, and were therefore the obvious choice of optical trackers to take forward for volunteer testing.

The pre-validated trackers were mounted to the Examiners by fabric straps, similar to the way small portable devices such as accelerometers and electrogoniometers are mounted when trying to analyse joint motion and kinematics. Electrogoniometers are as accurate the PhysioPilot system in recording joint motion to 1mm (Rowe *et al* 2000, Myles 2002, Smith & Rowe 2013), however are not compatible with the PhysioPilot system and also interfered with the positioning of the optical trackers for the non-invasive system and were therefore not used in this study.

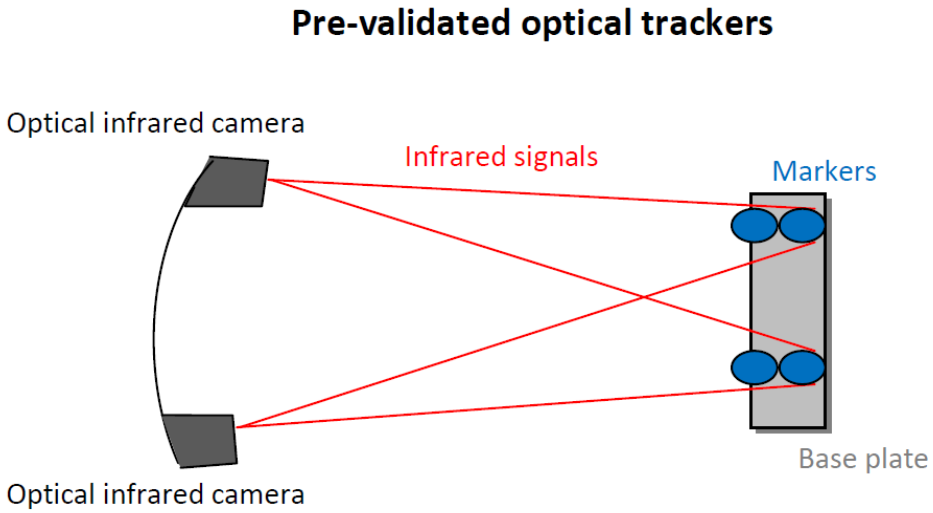


Figure 7.2 Image depicts optical camera sending infrared signals which detect all 4 of the pre-validated optical tracker markers, due to the markers mounting positioning at 60° on the base plate.

7.2 Volunteer testing

7.2.1 Supine MFTA in extension

The supine MFTA acquisition in extension is the coronal alignment attained from the registration process using the non-invasive navigation system. The system uses the hip, knee and ankle centres acquired during the registration process to produce a mechanical femoro-tibial alignment (coronal alignment). The acquisition of supine MFTA in extension is the initial vital step of the examination process and is essential for assessing AP laxity and tibia rotation. When an erroneous supine MFTA is recorded, the non-invasive navigation system then uses an erroneous coronal alignment during lower limb assessment, with a high likelihood of producing erroneous data acquisition for AP laxity, tibia rotation and pivot shift testing. It is therefore essential that all supine MFTA in extension acquired be within +/- 1º of the initial coronal alignment gained from the first registration process, or the coronal alignment the navigation system uses will be out with its 95% coefficient of repeatability and all data attained will be erroneous.

Learning curve

The supine MFTA acquired in extension by both Examiners for the first 10 volunteers (80 registrations) was not within +/- 1º of the initial (supine MFTA in extension) coronal alignment assessment. When the data from the first 10 volunteers (80 registrations) was removed for both Examiners, the supine MFTA acquired in extension for the final 15 volunteers (120 registrations) was consistently within +/- 1º coronal alignment to the initial supine MFTA acquisition for each volunteer.

A possible explanation for the outliers in the first 80 registrations is the natural learning curve of the Examiners with the non-invasive navigation software. This is in keeping with Picard who noted a learning curve with the first ten assessments of the commercially available invasive navigation system in orthopaedic theatre. As the non-invasive navigation system is based on the invasive navigation system, a learning curve of ten patient assessments is to be expected, and was shown in this thesis, and is in accordance with the data from clinical trials (Picard 2007).

Due to the initial outliers from the first 10 volunteers analysis of the data was performed on two different sections;

1- All 25 volunteers examined
2- The last 15 volunteers examined (post the learning curve)

Supine MFTA in extension analysis

The average supine MFTA in extension acquired for all 25 volunteers by both Examiners was similar to that of the last 15 volunteers assessed. There was a smaller standard deviation for the last 15 volunteers' supine MFTA results which demonstrates both examiners improvement their reliability and repeatability in attaining supine MFTA with the system post-learning. This is reinforced with Interclass correlation coefficients (ICC) showing an improvement from good reliability for Examiner 1 (0.72) and Examiner 2 (0.61) in all 25 volunteers; to very good reliability (0.80) and (0.76) respectively in the last 15 volunteers. The repeatability coefficients (CR) were smaller as well for the last 15 volunteers.

A possible reason for both Examiners only attaining very good reliability and repeatability in supine MFTA acquisition even post-learning curve is; the physiological range of laxity measured in the reliability assessment (ICC) was high as the range of laxity in normal knees is high. Even though errors from technique were improved with more experience with the non-invasive navigation technology, the physiological range of laxity remained high and therefore the supine MFTA acquisition results improved but not significantly. If a wider cohort of volunteers were assessed and if pathological knees (excessive laxity) were included the ICC reliability measure may have improved significantly with more experience.

There was moderate comparative reliability (0.52 and 0.49) between both Examiners. This shows that although both Examiners improved their own ability to use the navigation system and acquire reliable and repeatable supine MFTAs in extension for the same volunteers, these alignments were not comparable. This demonstrates a high inter-user variability for the non-invasive navigation system. A possible reason for the high inter-user variability is; difference in technique between both Examiners in performing the registration process. During the registration process the pointer tracker used to identify the key bony landmarks for knee and ankle centres had a wide range in which these landmarks could be identified and if each of the Examiners identified these points differently, then a separate supine MFTA would be attained for each Examiner. The data collected shows that each Examiner was able to consistently attain supine MFTA within +/- 1º of their initial supine MFTA in extension assessment, but these coronal alignments were different for each Examiner.

Summary

Examiner 1 demonstrated more reliable and repeatable in acquisition of supine MFTA in extension when compared to Examiner 2. As previously stated the acquisition of supine MFTA in extension is the critical initial step in the examination process, as it produces the coronal alignment which the navigation system uses during the assessments of AP laxity, tibia rotation, pivot-shift testing and monopedal and bipedal MFTA acquisition. Therefore as Examiner 1 has more reliable and repeatable supine MFTA in extension assessments, the author made the decision to

proceed only analysing data acquired by Examiner 1 for AP laxity, tibia rotation, pivot-shift, passive maximum flexion, monopedal and bipedal MFTA acquisition.

7.2.2 AP laxity and rotation assessment

A series of AP laxity assessments in increments of 15º from 0º to 90º of flexion were performed by Examiner 1 using the Lachman test. The AP laxity assessment for all 25 volunteers and the last 15 volunteers both demonstrated a similar pattern of AP laxity. There was an increase in AP laxity from 0º to 30º with similar laxity noted at 30º and 45º in the right knee. This trend is in keeping with the fact that in full extension AP translation is minimal due to the screw home mechanism of the knee (Amis et al 2010, Amis et al 2013), and AP translation is greatest at 30º of flexion as anterior knee restraints (anterior cruciate ligament) are at their most lax (Amis et al 2010). Anterior laxity diminishes as knee flexion increases, particularly beyond 90˚ (Amis 2010). Examiner 1 showed this trend from 45º, with the AP laxity progressively reducing from 45º to 90º, with both legs demonstrating a similar pattern.

The force used to examine both of the volunteer's knees by Examiner 1 was not standardised as no force application device was available or compatible with the non-invasive software at the time of testing. Other commercially available force application devices were trialled during initial and volunteer testing, but were found to be too cumbersome and also interfered with the optical trackers positioning and the detection of the optical trackers from the optical camera. Due to these issues, no force application device was used during initial and volunteer testing.
The force used during the Lachman test throughout flexion by examiner 1 was subjective, and the force he used was the force he was trained to use when performing Lachman test at 30º in a clinical setting. However he attempted to use this force on all increments of assessment (0º to 90º). It was therefore not feasible to validate the non-invasive technology during this project without a force-application device.

Examiner 1 found it easier to measure AP laxity at 30º and 45º as the knee is most lax at these degrees of flexion. Examiner 1 found it difficult to orientate and place his hands at the appropriate positions at 0º and 15º AP laxity assessment and produce the anterior draw force for performing the Lachman test. This was due to the volunteers' leg being so close to the plinth with little space for Examiner 1 to move his hands. Examiner 1 also had difficult performing the Lachman test at 75º and 90º of flexion due to limited space behind the knee around the popliteal fossa, to accurately place his hands and produce a consistent force.

The tibial rotation data acquired for all 25 volunteers was similar to that of last 15 volunteers, and demonstrated that from 0º to 45º there is more medial rotation in both legs. This is in keeping with the reverse of the screw home mechanism, with the tibia internally rotating and rolling posteriorly during the initiation of flexion, due to the posterior glide on the longer tibial medial condyle (Wings 2013, Amis 2013, Wheeless 2014).

Examiner 1 demonstrated that from 60º to 90º there is more lateral rotation in both legs for all 25 volunteers and last 15 volunteers. Femoral rotation is greatest nearer full extension and due to the incongruent nature of the lateral tibio-femoral compartment, there is more lateral rotation during the gliding motion of the femur between 60º to 90º of flexion (Alam et al 2013), as shown by Examiner 1.

AP laxity Reliability and repeatability

Reliability (ICC) and repeatability (CR) calculations for Examiner 1 in regards to the assessment of AP laxity for all 25 volunteers showed moderate reliability throughout flexion. The reliability and repeatability of AP laxity assessment improved for the last 15 volunteers and showed very good reliability at 30º, 45º and 60º, with good reliability demonstrated at 0º, 15º, 75º and 90º increments.

Possible explanations for the improved reliability in the last 15 volunteers are; (1) the improved consistency of the Examiner with the software, (2) the Lachman test is clinically performed at 30º, and therefore Examiner 1 who was trained to perform this test at this increment, was more reliable at this interval assessment (3) and more

space was available to place both hands for the test. Due to difficulties of hand positioning and reduced hand space, and also difficulty gaining adequate torque for Lachman test at 0º, 15º, 75º and 90º; the reliability and repeatability was reduced at these increments. The non-invasive navigation system is also only validated in early flexion up to 40º by Russell *et al* on cadavers; with poor AP laxity and varus/valgus measures demonstrated post 40º when compared to a commercially available invasive navigation system (Russell et al 2013). Therefore the poorer reliability and repeatability shown in late flexion (75º and 90º) by Examiner 1 may also be due to the non-invasive navigation system not acquiring as accurate a coronal alignment in late flexion. AP laxity assessments in this project were assessed on living volunteers with live knee joint kinematics differing from cadaveric knee joint kinematics, which may also influence the reliability and repeatability results from the non-invasive navigation system.

Tibial rotation reliability and repeatability

Reliability (ICC) and repeatability (CR) calculations for tibial rotation in all 25 volunteers and the final 15 volunteers were poor at 0º and 15º for medial rotation and moderate at 0º and 15º for lateral rotation. Due to the complex nature of the reverse screw home mechanism unlocking the knee in early flexion, with increased medial rotation it was difficult for Examiner 1 to standardise tibial rotation and therefore the reliability and repeatability of medial and lateral rotation in early flexion was poor and no further analysis at higher increments were analysed.

7.2.3 Pivot-shift and maximum passive flexion assessments

The pivot shift test

Amis *et al* states that the pivot-shift test most closely correlates with ACL deficient (ACLD) knee scores, and is best performed in conjunction with the Lachman test to assess the degree of rotatory instability (Amis et al 2013, Amis et al 2008). Although all volunteers assessed in this project had no known ACLD, both the pivot-shift and Lachman tests were performed to validate the non-invasive PhysioPilot software.

Examiner 1 demonstrated comparable pivot-shift anterior translation and pivot-shift rotation between both legs assessed for all 25 volunteers and the last 15 volunteers, with minimal improvement in the last 15 volunteers assessment. The pivot-shift test is a difficult test to perform for an orthopaedic research trainee, and Examiner 1 only had brief training with this technique and was not able to further improve the technique during volunteer testing. This is demonstrated by the large standard deviations in the last 15 volunteers, as well as the moderate reliability (ICC) and repeatability (CR) calculations. More experience and practice is required for more reproducible and repeatable results.

Maximum passive flexion

Examiner 1 demonstrated extremely comparable passive maximum flexion assessment for both legs in all 25 volunteers' knees as well as the last 15 volunteers, with a smaller standard deviation in the last 15 volunteers assessed, and an improved reliability (ICC) and repeatability (CR). Examiner 1 found the assessment of passive maximum an easier test to perform compared to the pivot-shift test and therefore demonstrated better reliability and repeatability at this assessment.

7.2.4 Bipedal and monopedal load MFTA assessment

The final assessment in each examination was the acquisition of bipedal and monopedal loaded MFTA. Examiner 1 showed comparable bipedal and monopedal loaded MFTA acquisition with the initial supine MFTA acquired for all volunteers assessed in both legs for all 25 volunteers and the last 15 volunteers. Both the monopedal and bipedal loaded MFTA were within +/- 1º coronal alignment of the supine MFTA in extension. These results are in accordance with Deep *et al* study using the same non-invasive software on native Indian participants (Deep 2014).

The reliability (ICC) and repeatability (CR) of Examiner 1 for bipedal and monopedal loaded MFTA acquisition improved for the last 15 volunteers with both assessments showing very good reliability and repeatability, whereas in all 25 volunteers monopedal loaded MFTA demonstrated moderate reliability.

The monopedal loaded MFTA assessment is less reliable and repeatable than the bipedal loaded MFTA, as the monopedal loaded MFTA is assessed with volunteers standing on the examined ipsilateral leg; with less stability and more movement occurring in the examined leg than that produced during standing on both legs (bipedal loaded MFTA) resulting is less accurate monopedal load MFTA acquisition.

The improved reliability and repeatability results for the last 15 volunteers may be due to a better and more consistent supine MFTA acquisition in extension, as well as more consistent acquisition and improved method of assessing bipedal and monopedal load MFTA for these volunteers. Some of the factors improved in the method by Examiner 1 were to produce a consistent layout of the equipment; 1. by reducing movement of optical trackers on volunteers' skin whilst assessing monopedal and bipedal MFTA by increasing the tightness of the straps prior to the volunteers mobilising, 2. reduced assessment time with less more consistent MFTA acquisitions, 3. cleared all paths to reduce the risk of volunteers hitting trackers on surrounding equipment 4. supplied a rail for volunteers to hold during monopedal MFTA acquisition to reduce movement of the ipsilateral examined limb.

7.2.5 Limitations of the study

There is currently no force application device available for use with the non-invasive navigation software (PhysioPilot), and therefore the Examiners were not able to validate the assessment of AP laxity and tibia rotation through flexion with this system.

The study was performed by junior orthopaedic trainees who are less experienced at examining volunteers and therefore the reliability and repeatability of supine MFTA acquisition, the Lachman and pivot-shift testing and monopedal and bipedal loaded MFTA assessments, may well be less accurate than that achieved by a senior orthopaedic registrar or consultant. This was demonstrated by the learning curve

required for both Examiners with the software and only minimal improvement in the pivot shift testing in volunteers, even post learning curve.

The non-invasive navigation system (PhysioPilot) is only validated in early flexion up to 40º for AP laxity and tibia rotation assessment by Russell *et al* on cadavers (Russell et al 2013). Therefore the moderate reliability(ICC) and repeatability (CR) shown in late flexion (75º and 90º) by Examiner 1 may also have been due to the non-invasive navigation system not acquiring as accurate a coronal alignment in late flexion and therefore attaining less reliable AP laxity and tibia rotation values.

A small sample size of volunteers was a possible reason for the Examiners only attaining good reliability and repeatability in supine MFTA acquisition even post-learning curve as the physiological range of laxity measured in the reliability assessment (ICC) was high as the range of laxity in normal knees is high. The physiological range of laxity remained high and therefore the supine MFTA acquisition results improved but not significantly. If a wider cohort of volunteers were assessed and if pathological knees (excessive laxity) were included the ICC reliability measure may have improved significantly with more experience.

7.2.6 Potential further studies and developments of the non-invasive navigation technology

There is an analogous project currently being written up by Examiner 2; the assessment of varus-valgus forces through flexion on healthy subjects using the non-invasive navigation system (PhysioPilot).

The non-invasive navigation system has not been tested in flexion on pathological knees; such as patients with ligamentous injuries, osteoarthritis or total knee arthroplasty patients. If granted ethical approval for patient testing, validating this system on pathological knees would allow the system to be used in numerous potential clinical applications, from identifying and quantifying ligament injuries (ACL), to planning and follow-up of TKA. In addition the PhysioPilot system could

be also used to measure patient outcomes post injury or TKA and thus monitor post-operative progress.

The PhysioPilot system has also not tested for consistency of optical tracker positioning (pen marking the tracker positions on distal femur and proximal tibia) before don/doff trackers to ensure all subsequent re-attachments of the trackers would be in the same position. The registration and examination process would need to be repeated to assess if the non-invasive navigation system is accurately attaining coronal supine MFTA acquisition in extension and if all variables tested are repeatable.

The non-invasive software has yet to be validated against a gold standard gait analysis system such as Vicon. The Vicon system uses infrared technology similar to that of the PhysioPilot system with optical tracker balls to analyse gait. As both Vicon and the PhysioPilot system use infrared technology with similar optical tracker balls to analyse and capture gait and limb movements; it would be practical to analyse and validate the assessment of AP laxity and tibia rotation using both PhysioPilot and Vicon. It would be interesting to assess if Vicon captures the optical trackers in the same axis and area in space as PhysioPilot and whether both systems can produce similar MFTA acquisition from the detections of bony anatomy during the registration process.

There is currently no force application device available for use with the PhysioPilot system which is essential for validating the system. When a force application device becomes available the assessment of AP laxity and tibia rotation will need to be performed on healthy live subjects through flexion to validate the PhysioPilot system.

8 Conclusion

The PhysioPilot non-invasive system demonstrated consistent and comparable supine MFTA acquisition in extension in the final 15 volunteers assessed, consistently within the pre-validated +/-1º coronal alignment by Clarke (Clarke 2012) and Russell *et al* (Russell et al 2013).

The non-invasive system was able to reliably and consistently measure knee AP laxity between 30° and 45° of flexion, which is the clinically relevant range for this assessment. This system could be used in trials to quantify abnormal knee laxity and improve the assessment of instability in the knee in a clinical setting.

Moderate AP laxity results outside the limits of agreement were achieved at 0º, 15º, 75º and 90º, possibly due to difficulties in hand placement and lack of standardisation in the force used during the Lachman examination in early and late flexion. The software has been previously validated to 40º of flexion in cadavers, but due to no standardised force in AP laxity assessment in this study, the software cannot be validated throughout the whole range of flexion in living subjects.

The data analysed in this study is from only Examiner 1 who is a trainee orthopaedic surgeon, who assessed 25 volunteers with a learning effect demonstrated in the first 10 volunteers. Therefore any clinical use with the non-invasive navigation system in assessing AP laxity and tibia rotation, should be with caution until the system is fully validated.

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10 Appendices

Appendix 1 (Registration process)

PhysioPilot registration process

The registration process using the image-free PhysioPilot navigation system software is based on algorithms used in the OrthoPilot navigation system developed by B.Braun Aesculap (Melsungen, Germany); which is validated; commercially available software used in computer assisted orthopaedic surgery.

The PhysioPilot optical camera was positioned two metres away (on a tripod stand) from the plinth where the volunteers would lie to be examined. A wire was used to connect the PhysioPilot optical camera to a laptop to allow the Examiner to view the non-invasive software and each step in the registration and examination process (*Appendix 1 and 2*), as shown in *Figure A*.

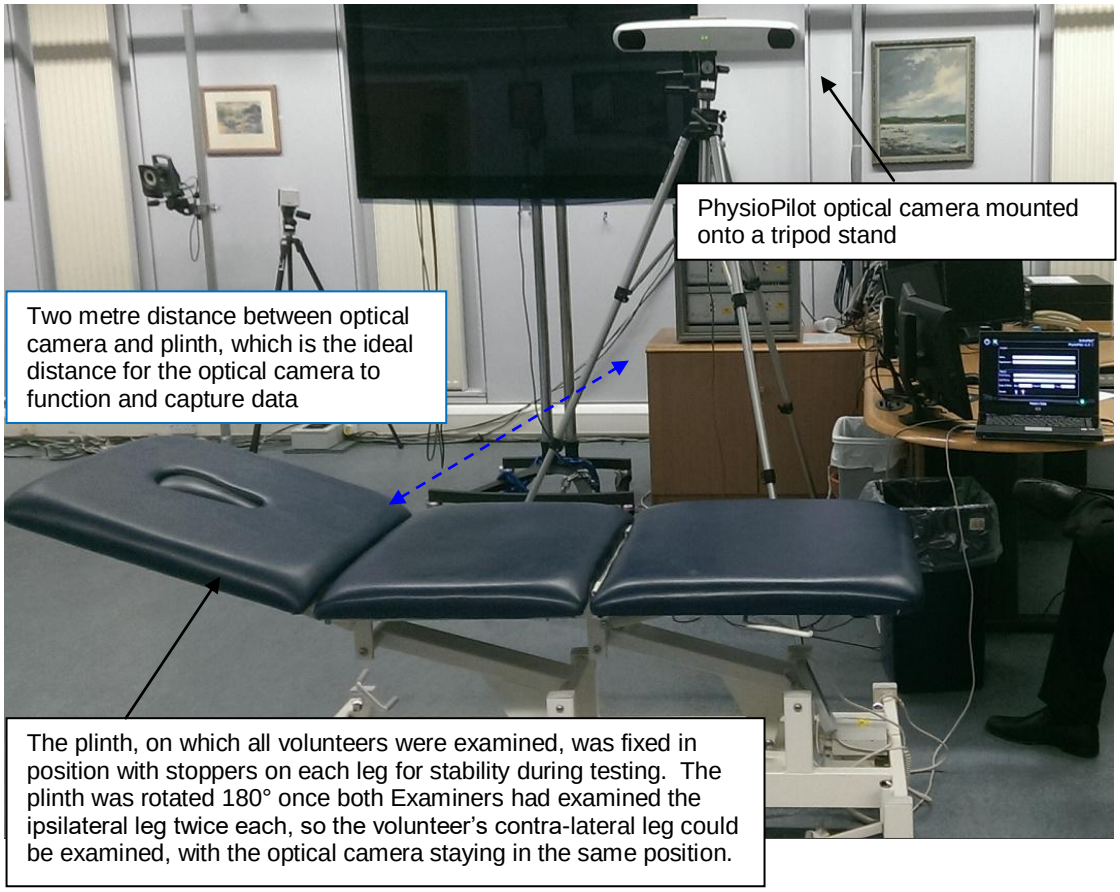

Figure A Image depicting the layout of the PhysioPilot optical camera, positioned two metres away from the plinth, with a laptop connected to the optical camera

Each volunteer was asked to relax whilst lying supine, to minimise muscle contractures and ensure all movements were passive. Passive optical trackers were mounted using fabric straps to secure a base plate holding the tracker in place. The fabric straps and method of tracker fixation have been previously validated by Clarke and Russell *et al* (Clarke 2012, Russell et al 2013). The femoral base plate was placed 8cm proximal to upper pole of patella overlying the vastus medialis obliquus muscle. The tibial base plate was placed 10cm distal to tibial tuberosity, over the centre of the tibia to maximise tracker exposure to the localising infrared optical camera (as shown in *Figure B* below).

Figure B An example of the set-up of each volunteer assessment; with the volunteer relaxed whilst lying supine in short trousers. Passive optical trackers mounted on the femur and tibia using fabric straps to secure the base plate holding the optical tracker in place, with the laptop visible for the Examiner to perform volunteer testing.

Once the set-up was complete, the registration process identified hip, knee and ankle centres by performing the identification of specific bone landmarks and a series of lower limb movements. The key bony landmarks identified were on the distal femur (medial and lateral epidcondyles), and on the distal tibia (medial malleolus) and distal fibula (lateral malleolus) using a pointer tracker. An example of one of the Examiners using the point tracker to identify femoral bony landmarks is shown in *Figures C and D* below.

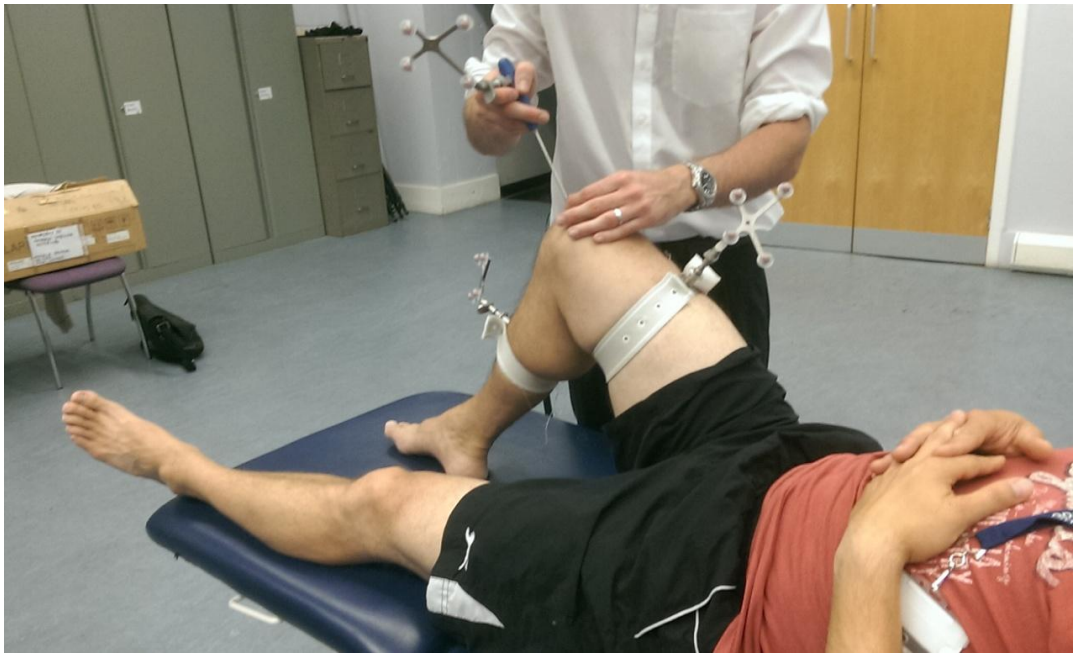

Figure C Image depicting one of the Examiners using the point tracker to identify the femoral bony landmarks (femoral medial epicondyle).

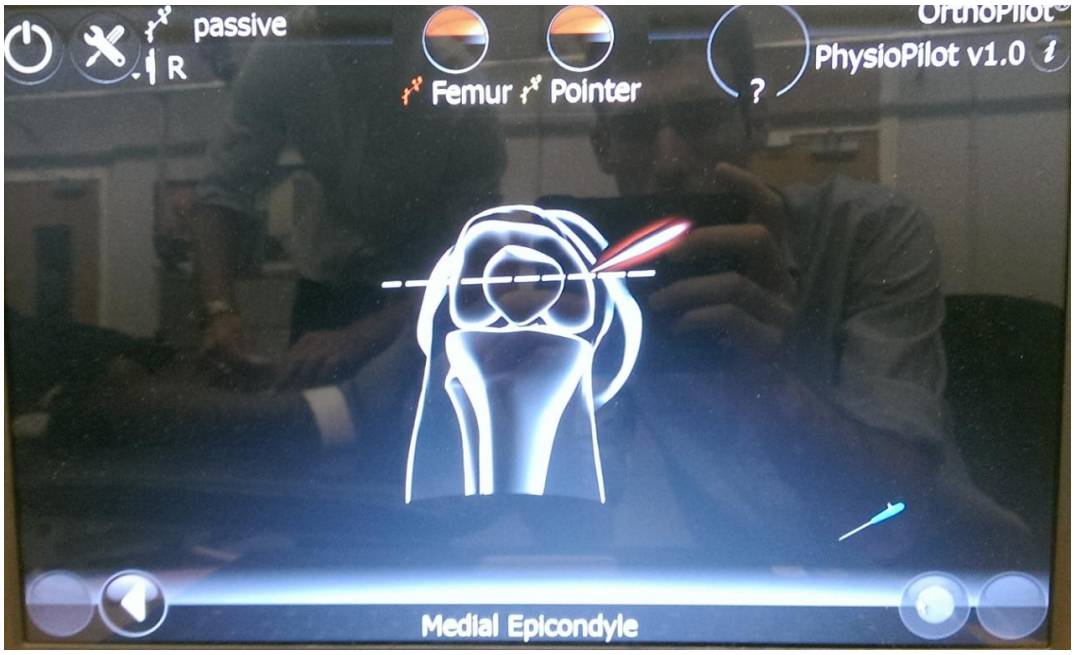

Figure D PhysioPilot software Image noted by the Examiner on laptop screen when identifying key femoral bony landmarks (femoral medial epicondyle).

Next the kinematic knee and ankle centres were identified by placing the point tracker on the centre of the (patella) knee and centre of the dorsum of ankle as shown in *Figure E and figure F*.

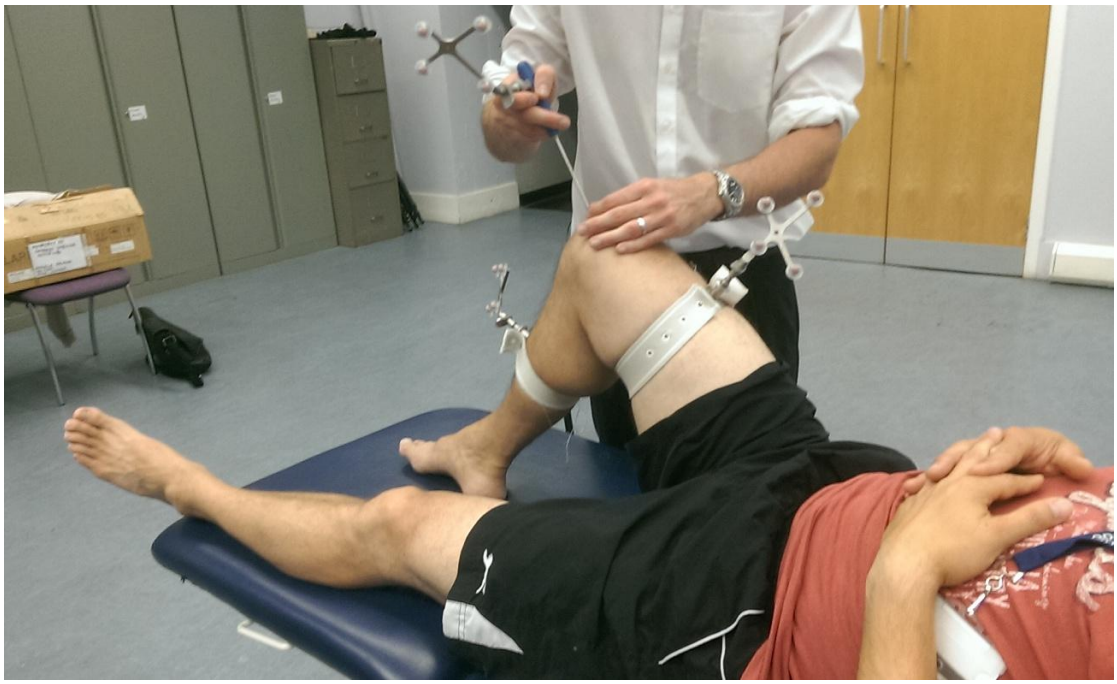

Figure E Image depicting one of the Examiners identifying using the point tracker to identify the knee centre, by placing the point tracker on the centre of the knee (patella).

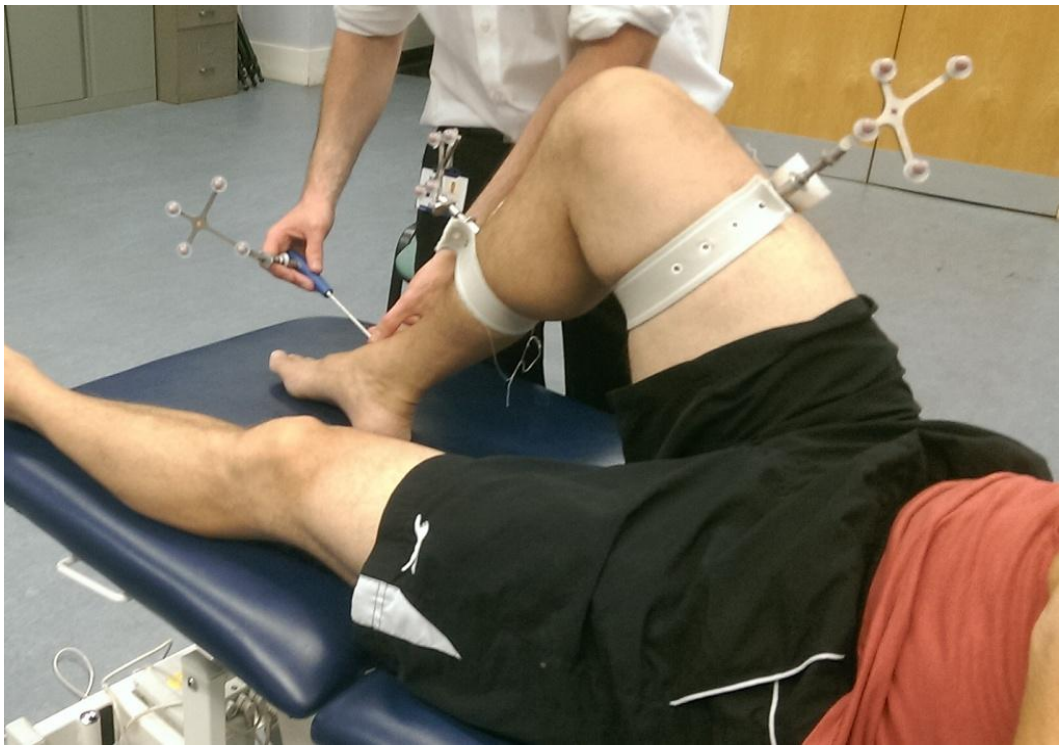

Figure F Image depicting one of the Examiners identifying the kinematic ankle centre using the point tracker, placing it over the centre of the dorsum of ankle

The next step required slow, controlled circumduction of the thigh on the examined ipsilateral leg to identify the kinematic hip joint centre as shown in *Figures G and H*.

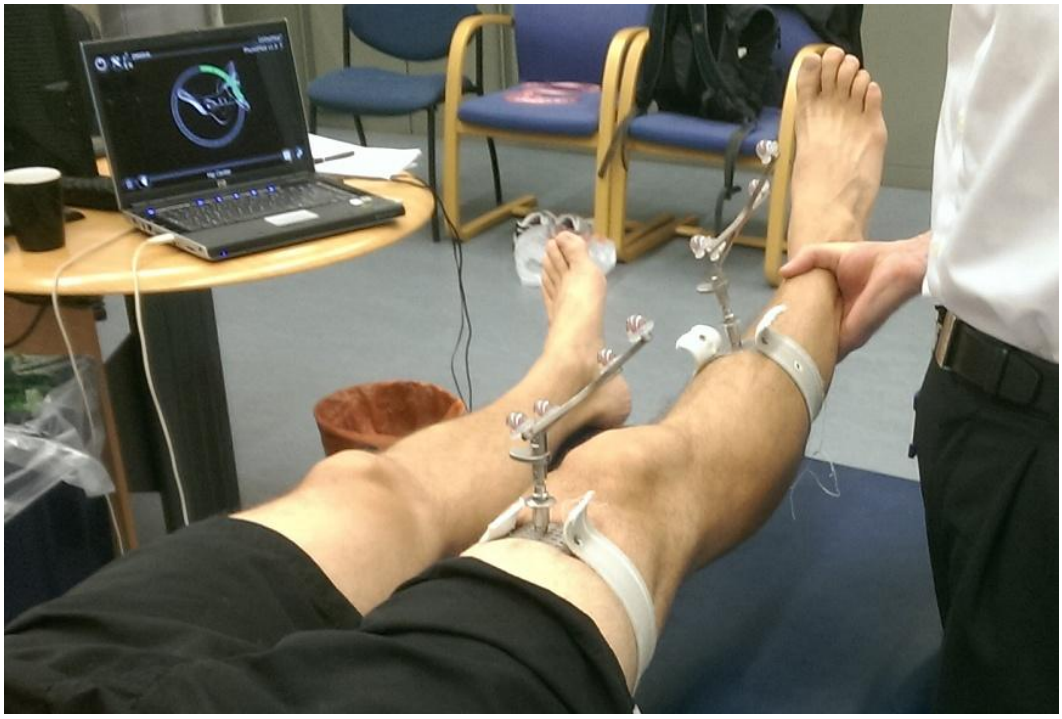

Figure G. Image showing one of the Examiners using a circumduction motion to identify the kinematic hip centre

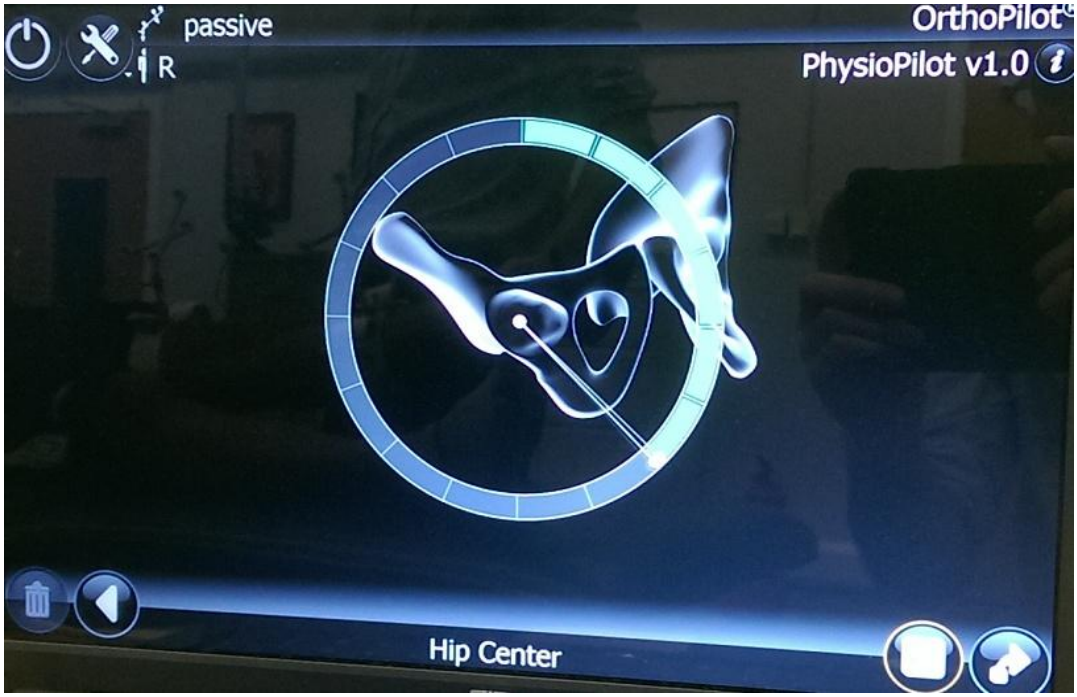

Figure H PhysioPilot software image showing the Examiner moving volunteer's examined leg in a controlled circle (circumduction), passing through each green point of the circle so the software could calculate and identify the kinematic HJC.

The final step prior to acquiring the supine coronal mechanical femoro-tibial axis MFTA in extension was; internal and external rotation of the ankle at 90˚ of flexion and then extending the knee to 0˚.

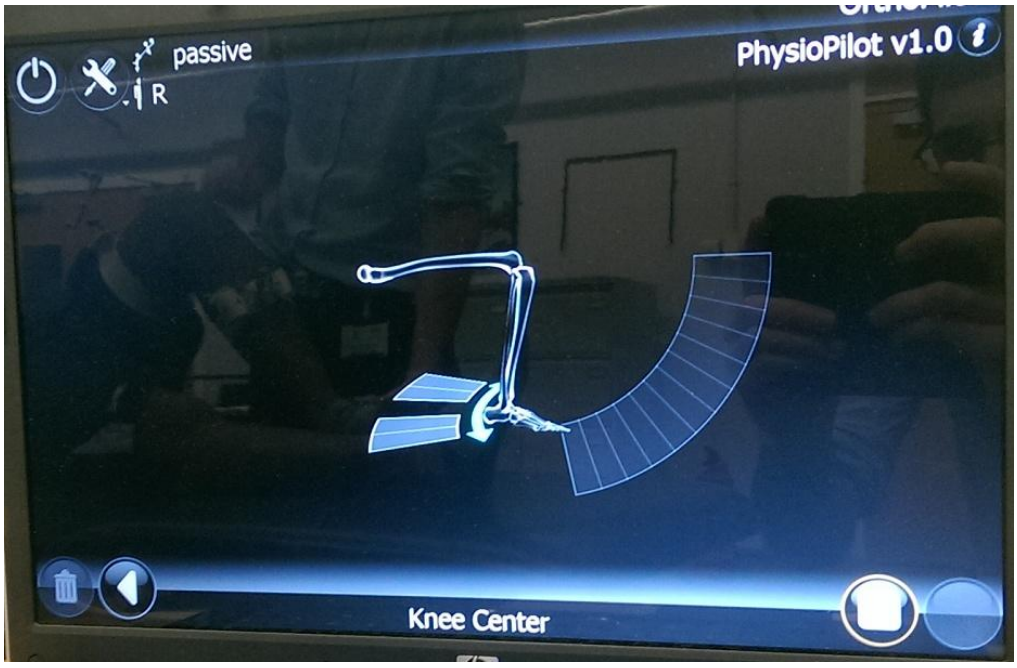

Figure I Software image of the internal and external rotation of the ankle at 90˚.

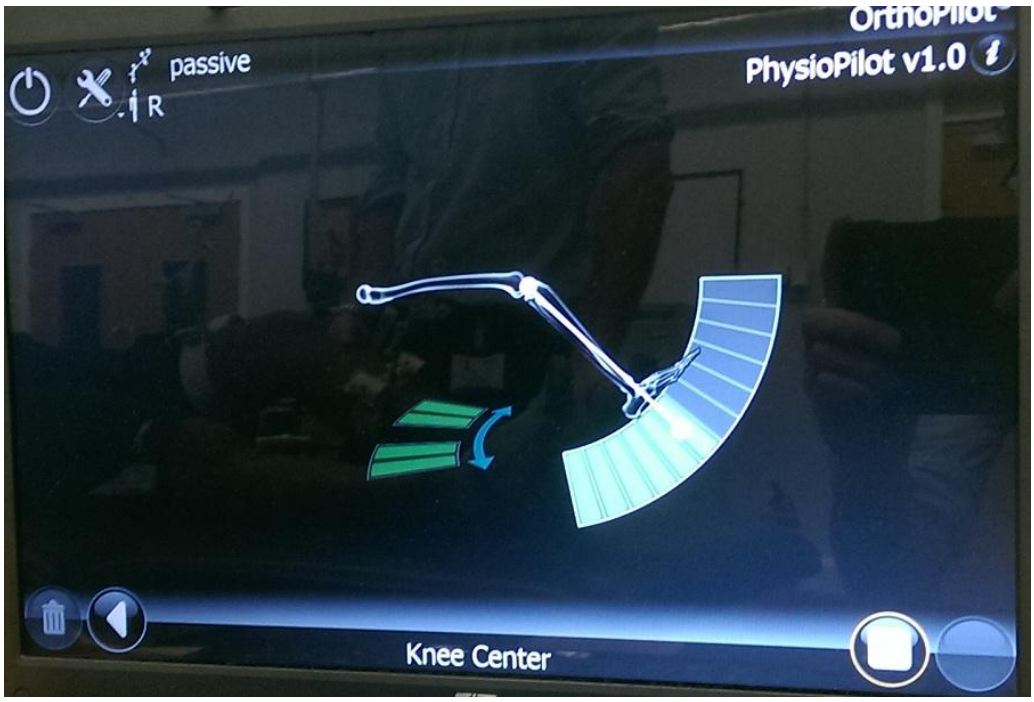

Figure J Software image of the slow extension of the knee to 0˚.

An initial registration was performed on all volunteers and coronal alignment noted; an example of an initial supine MFTA acquisition in extension is shown in *Figure K*.

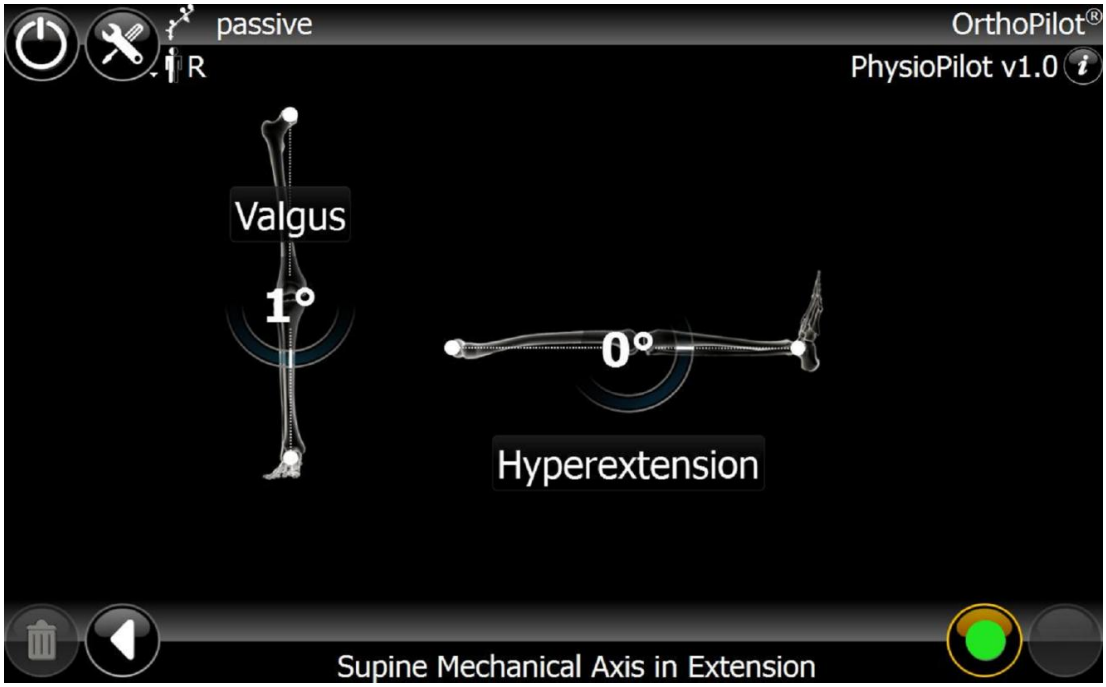

Figure K PhysioPilot image of initial supine MFTA acquisition in extension

A second registration was then performed and if the coronal alignment was not within 1° coronal alignment of the first attempt, then the registration process was repeated, to reduce any errors made during the examination process (Van Dyck et al 2012) and ensure repeatable MFTA alignment in coronal plane throughout flexion. Reducing errors in the supine MFTA acquisition ensures that all AP laxity testing would be carried out within the same plane of flexion and ensure more repeatable data acquisition. An example of the same patient having a repeat registration is depicted in *Figure L* below, showing that the second registration is within 1° coronal alignment of the first registration and therefore the rest of the testing could commence.

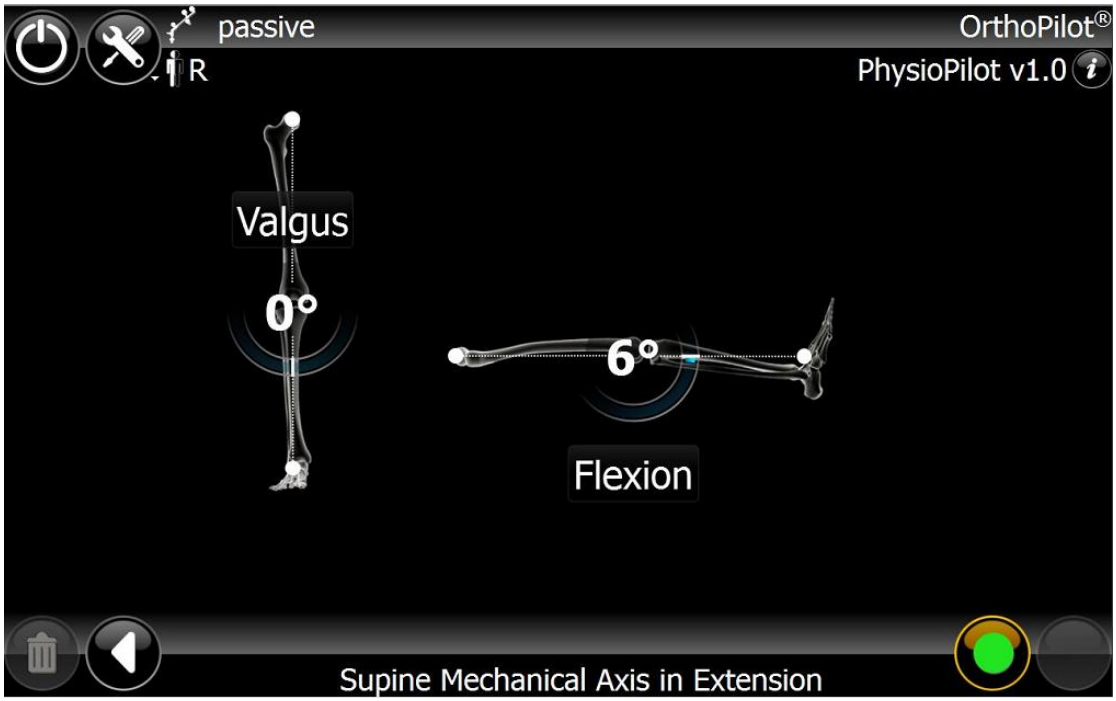

Figure L PhysioPilot image showing second supine MFTA in extension, within 1° coronal alignment of the first registration.

Appendix 2 (Examination process)

Examination process

Once the supine MFTA in extension was acquired, a varus and valgus force was applied, using the forces routinely used in clinical examination.

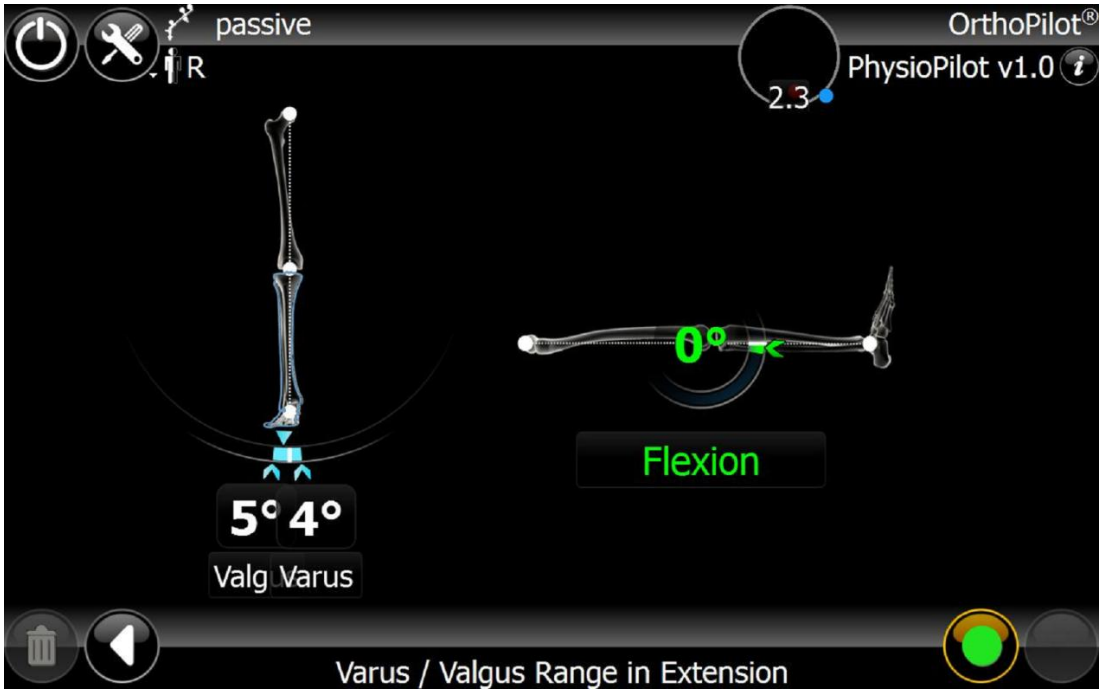

Figure M PhysioPilot image showing varus and valgus testing in extension

PhysioPilot was used to assess the anteroposterior (AP) laxity and standardise tibia rotation for all 25 volunteers. Both Examiners were blinded to all recorded data in regards to AP laxity and tibia rotation. Only the initial supine MFTA acquisition was not blinded to both Examiners. AP laxity and tibia rotation were assessed in increments of 15º using the Lachman test from 0º to 90º of flexion (0º, 15º, 30º, 45º, 60º, 75º, 90º) in all 25 volunteers. *Figures N and O* demonstrates one of the Examiners performing the Lachman test at 0º and 30º.

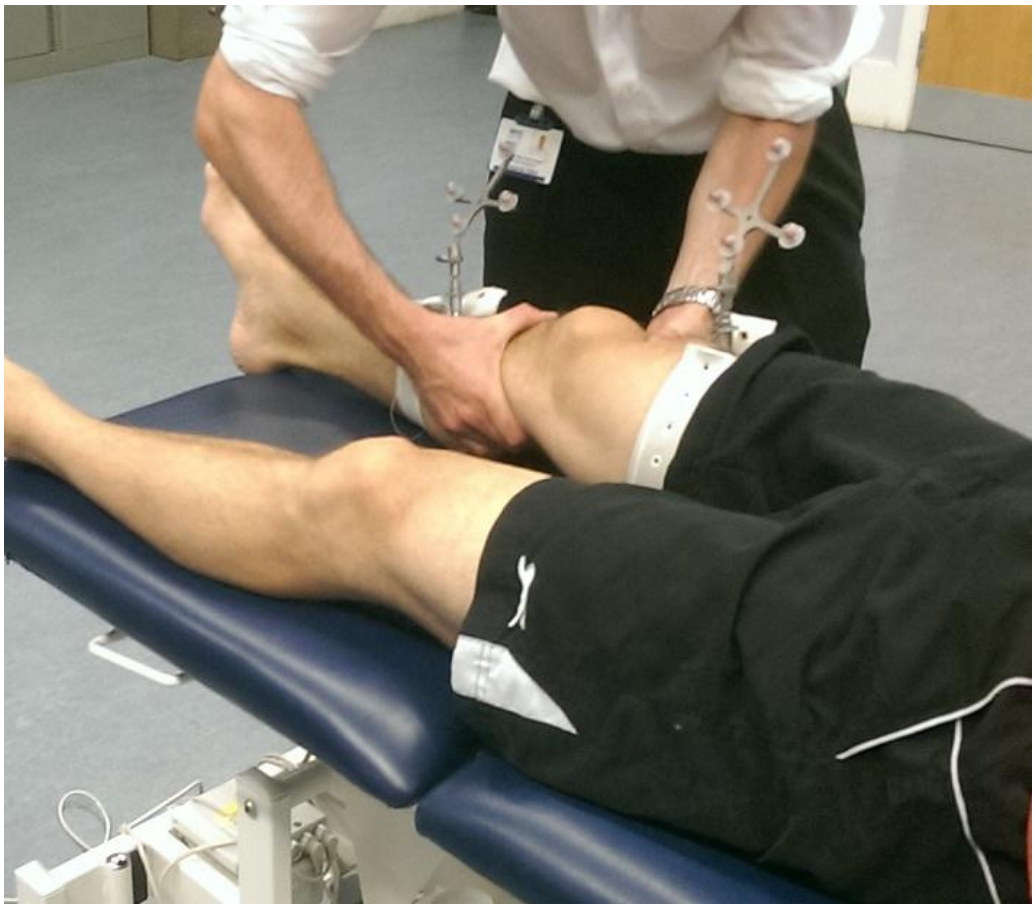

Figure N image shows one of the Examiners performing the Lachman test at 0º

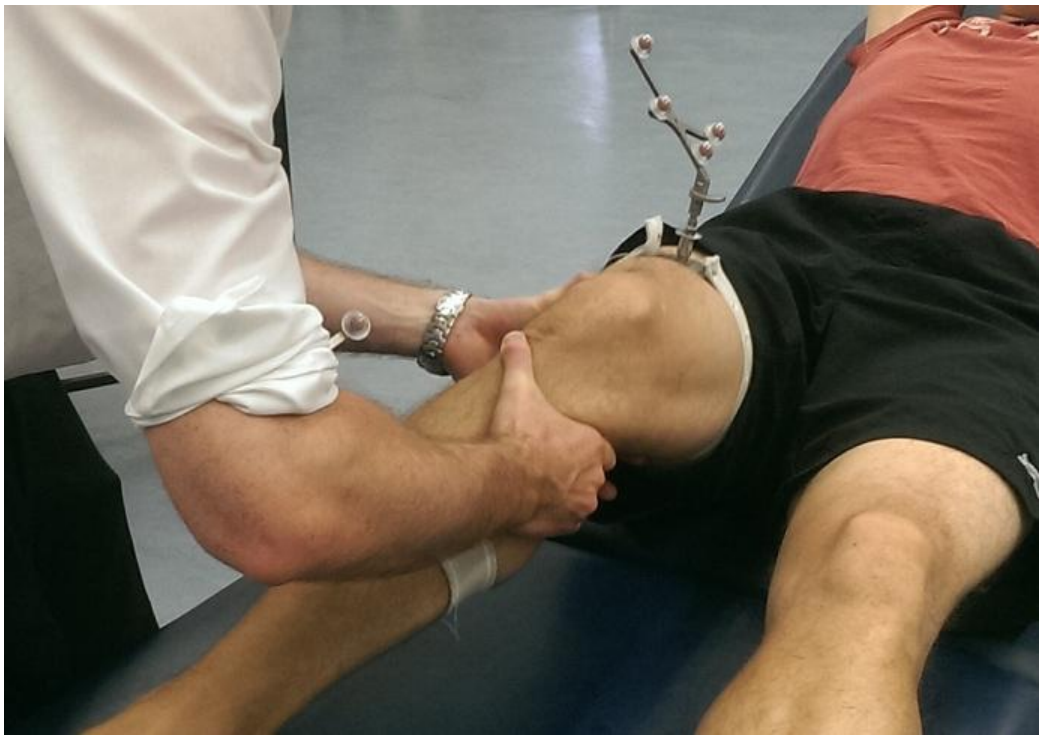

Figure O depicts one of the Examiners performing the Lachman test at 30º

The tibia rotation recorded during the Lachman test was not at maximal internal or external knee rotation, but instead was the rotation produced when the Lachman testing was performed at each increment. An example AP laxity assessment at 0º is shown in *Figure P*.

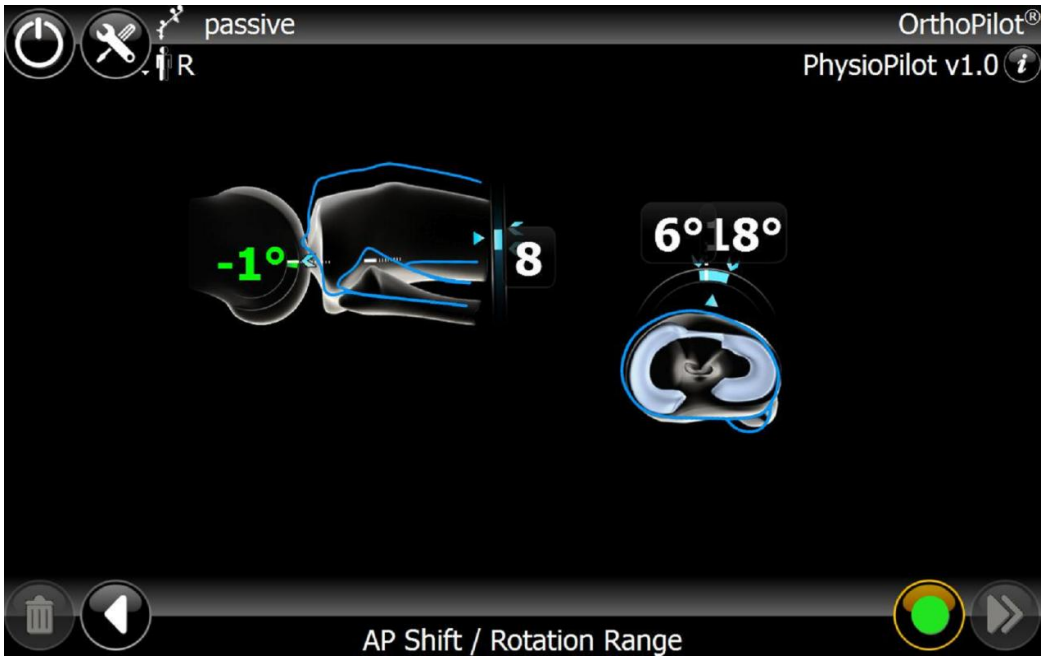

Figure P shows the PhysioPilot software assessing AP laxity at 0º, with the tibial translation shown on the left side of the image and the amount of tibia rotation produced by the Lachman test on the right side of the image.

The load/force applied during the Lachman test was equivalent to that used in routine clinical examination of the knee in a clinical setting. The forces were not measured during the examinations as no force application device was available. A pivot-shift test was performed post AP laxity assessment.

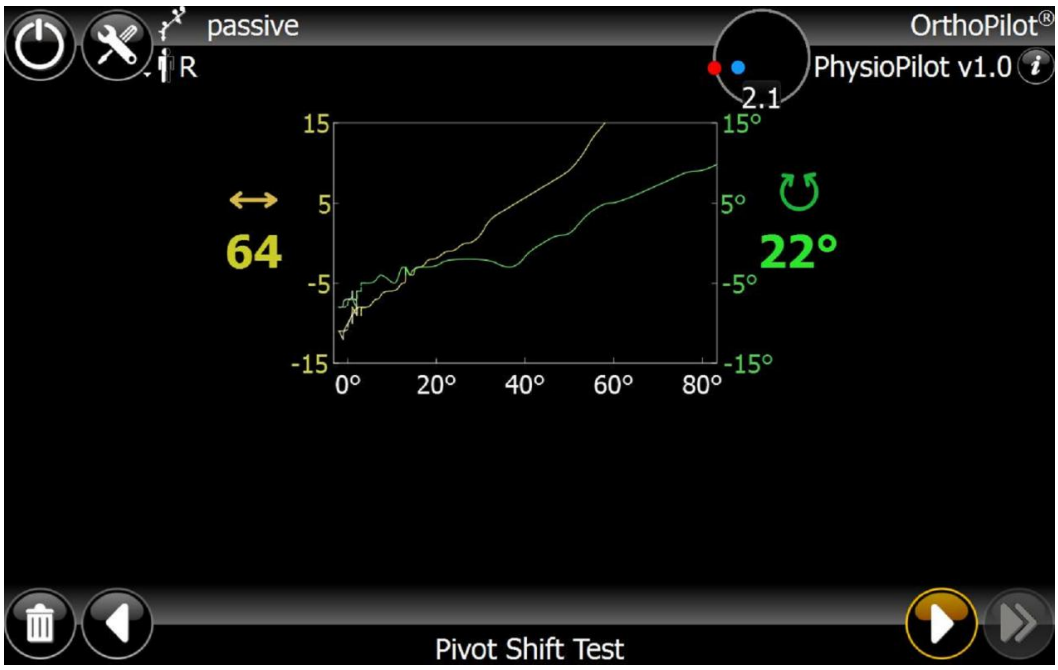

Figure Q shows the information attained from the pivot-shift test, with the green line representing the amount internal rotation produced from the tibia during the pivot-shift manoeuvre, and the yellow line representing the amount of tibial translation produced during the test.

Post pivot-shift testing, an assessment of maximum flexion was performed for each examination by passively flexing the examined knee to end range of motion.

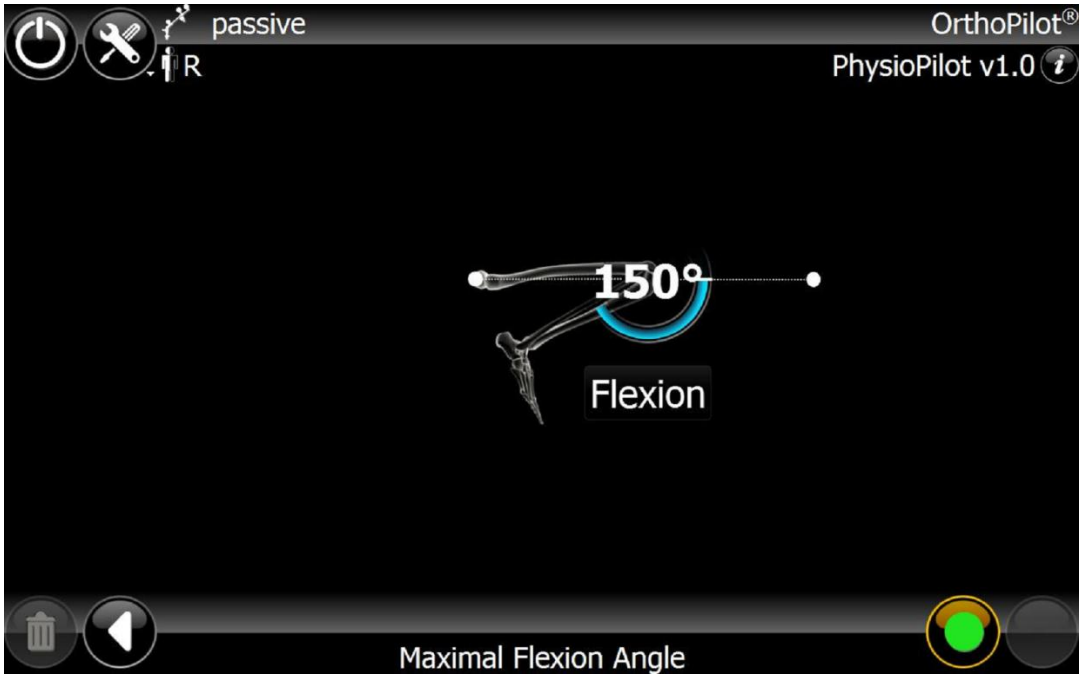

Figure R Software image showing maximum passive flexion in a volunteer.

Finally the volunteer was asked to stand on a ladder on the top step to assess the bipedal and monopedal loaded mechanical axis. The top step was required as the optical camera was unable to identify the optical trackers when the volunteer was standing on the ground or first step of the ladder. Once the bipedal loaded axis was recorded the volunteer was asked to stand on the examined (ipsilateral) leg only to assess the monopedal loaded mechanical axis. The volunteer had a support bar to hold onto for their safety, and to aid with their balance and reduce any risk of falling or injury.

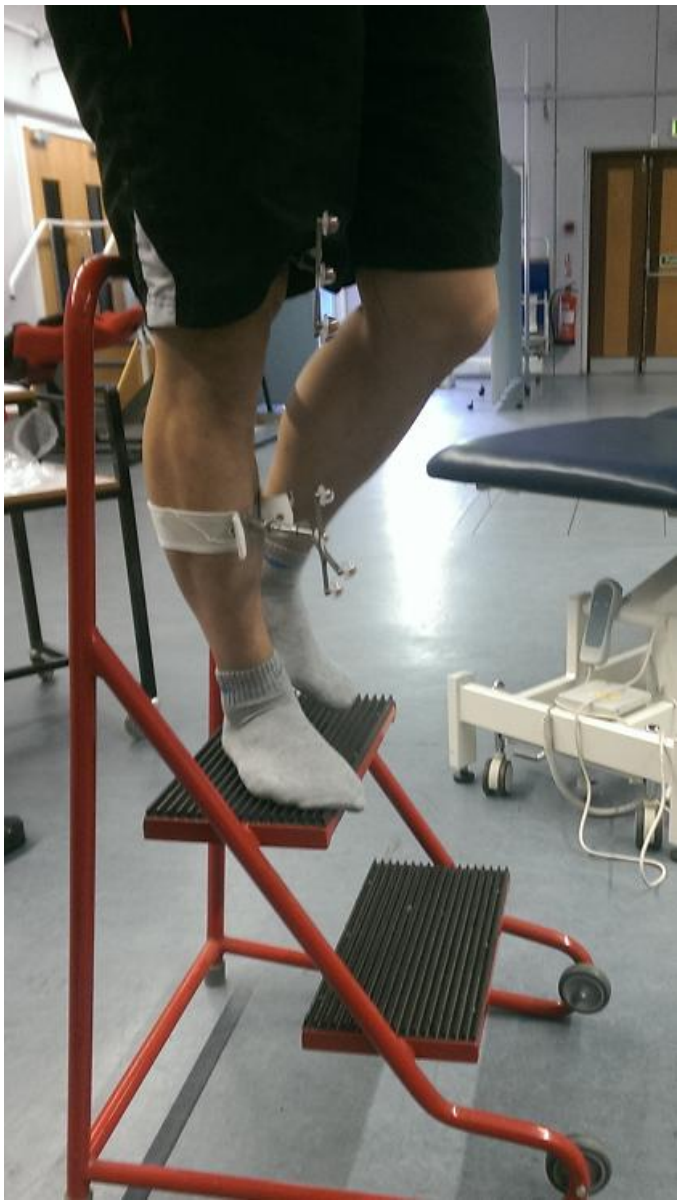

Figure S depicts volunteer performing monopedal load MFTA on the top step of the ladder, by standing on their examined leg, with their contralateral leg lifted off ladder step.

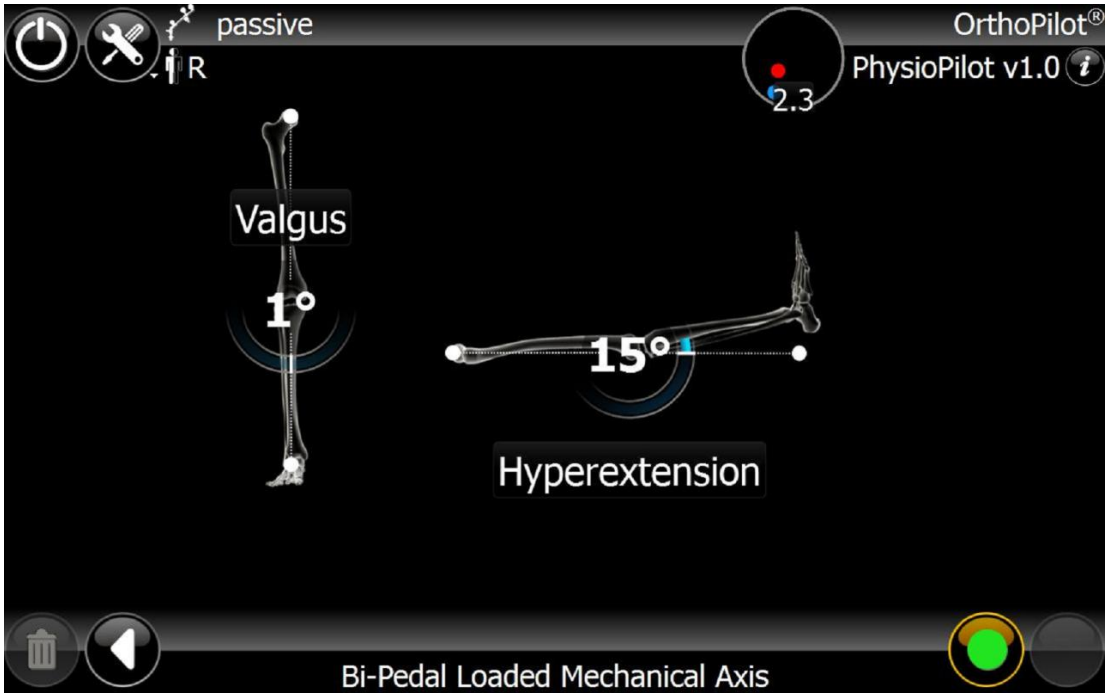

Figure T Shows the PhysioPilot software image of bi-pedal loaded MFTA assessment on a volunteer

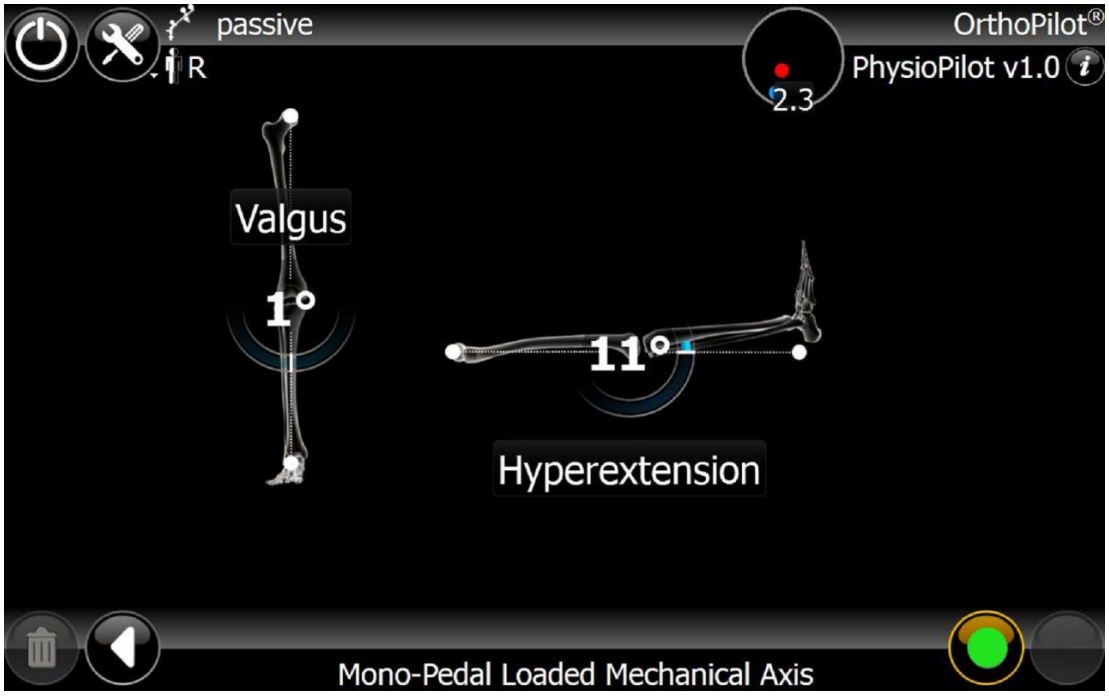

Figure U Shows the PhysioPilot software image of mono-pedal loaded MFTA assessment on a volunteer

Appendix 3 (Protocol for volunteers testing)

- Two Examiners performing all testing
- 25 volunteers tested
    - All volunteers tested don/doff trackers (same day)
- PhysioPilot used to assess AP laxity and standardise rotation.

PhysioPilot *(non-invasive tracker system, validated by Clarke 2012)*

- Written informed consent on volunteers with no knee symptoms (assess age and BMI (height and weight))
- Volunteers appropriately dressed in shorts for assessment
- Volunteer asked to relax whilst lying supine, to minimise muscle contractures, ensure all movements are passive
- Set up optical reader 2m away from volunteer
- Attach trackers (fabric straps with base plate added (20mm wide – standardised)) to volunteer
- Femoral plate placed 8cm proximal to upper pole of patella overlying the vastus medialis obliquus muscle
- Tibial plate placed 10cm distal to tibial tuberosity, over the medial aspect to maximise tracker exposure to localising camera
- Passive trackers
- Registration process using software
    - Register system by following prescribed lower limb movements and localising key bony landmarks
- Identify important bony structures on distal femur (epidocndyles) and distal tibia (medial malleolus) / fibula (lateral malleolus)
- Identify kinematic hip joint centre (HJC) using slow, controlled circumduction of the thigh.
- Identify kinematic ankle centre placing point tracker to dorsum of foot
- Identify rotational centre of knee by placing pointer tracker over centre of knee
    - Flexing and extending knee between 0˚ and 90˚

- Rotation the tibia on the femur at 90˚ of flexion, assessing internal and external rotation.

Series of experiments

Clinician blinded to all recorded alignment data except initial supine coronal mechanical femoro-tibial (MFT) angle registration.

If initial and second registration of coronal alignment is not within 2˚ then registration needs to be repeated

- Use flexion angles on tracker systems to ensure limb stabilised at particular angle measurement prior to testing
- AP laxity at -15º, 0º, 15º, 30º, 45º, 60º, 75º, 90º, increments of 15º
- Assess knee centre rotation at 90º of flexion
- Perform Pivot-shift test

NHS SCOTLAND
Golden Jubilee National Hospital

Volunteers Required

University of Strathclyde Glasgow

Appendix 4 (Poster)

The assessment of knee joint laxity, varus and valgus stress testing and rotation using a non-invasive computer navigation system in healthy participants at

What is the purpose of this investigation?
The investigation aims to validate a non-invasive navigation technology similar to Vicon in the assessment of knee joint ligament laxity, varus and valgus stress testing and knee long bone rotation in normal subjects.

This technology uses fabric straps to hold optical trackers in position on the leg, to quantify 3-dimensional knee kinematics.

Who can take part?
Recruitment is of the staff and students from the Biomedical Engineering department within an age range of 18-70 who are able to mobilise independently, and with no previous history of knee fractures or ligament injuries.

When is it taking place?
Study will be taking place from 10/06/2014 to 10/08/2014

Where is it taking place?
Strathclyde University premises in the Biomechanics laboratory, Biomedical Engineering Department.

What will you do in the project?
Participants will be asked to wear short trousers for adequate exposure and examination of the participant's knee. The participant will be required to lay on a couch, relaxed for between 30 minutes to 1hour for the lead investigators to exam their knee and record the movement of the knee using the computer navigation system.

No payments or other incentives are available.

Project Supervisor

Name: Professor Philip Rowe (chief investigator)
Department: Biomedical Engineering department
Telephone: 0141 548 3032
E-mail: philip.rowe@strath.ac.uk

If you are interested in taking part please contact:

Name: Dr Roberto Alho / Dr Fraser Henderson
Department: Biomedical Engineering department
Telephone: 0141 552 4400
E-mail: roberto.alho@strath.ac.uk / fraser.henderson@strath.ac.uk

Appendix 5 (Participant information sheet)

Name of department: Biomedical Engineering

Title of the study: Assessment of knee joint laxity and rotation using a non-invasive computer navigation system in healthy volunteers at Strathclyde University

Introduction

My name is Roberto Alho, I am a doctor and one of the orthopaedic research fellows at the Golden Jubilee National Hospital. I am a student performing my MPhil thesis at Strathclyde University on the above title.

I am recruiting 30 healthy volunteers to validate a novel non-invasive computer system assessing knee joint laxity and long bone rotation.
The system has been previously validated by Jon Clarke (Clarke, J, V. (2012) The non-invasive measurement of knee kinematics in normal, osteoarthritic and prosthetic knees. *Strathprints Institutional Repository, University of Strathclyde, Glasgow)* for the measurement of knee flexion.
This technology uses fabric straps to hold optical trackers in position on the leg, to quantify 3-dimensional knee kinematics.

What is the purpose of this investigation?

The project aims to validate a non-invasive navigation technology similar to Vicon in the assessment of knee joint ligament laxity and knee long bone rotation in normal subjects, for future clinical use.

Do you have to take part?

Your participation is voluntary and you are free to withdraw your data in addition to withdrawing from the project at any time, without having to give a reason and without any consequences. You are asked to wear short trousers for adequate exposure and examination of your knee. Still images may be taken during the assessment but any identifying features of you will be removed.

What will you do in the project?

Recruitment is of staff and students from the Biomedical Engineering department. No payments or other incentives will be used. A single assessment of each individual will be performed on the Strathclyde University premises in the human performance laboratory, Biomedical Engineering Department. The study will be taking place from 10/06/2014 to 10/08/2014 in the Biomedical Engineering department.

You will be required to lay on a couch, relaxed for between 30 minutes to 1hour for the lead Examiner to exam your knee and record the movement using the computer navigation system. Fabric straps will be used to hold optical trackers in position on your leg. A pointer will be used to identify bony landmarks, which is not invasive or painful. Stress tests as well and knee laxity tests will be performed to assess your knee and is not painful, but may cause some discomfort after the examination. The trackers may also cause some discomfort during or after the examination and if too uncomfortable during examination, these trackers can be removed and the examination stopped and performed at another date.

Why have you been invited to take part?

I am recruiting 30 healthy volunteers to validate a novel non-invasive computer system assessing knee joint laxity and long bone rotation.

Inclusion criteria - Healthy university individuals (staff and students) within the Biomedical Engineering department and within an age range of 18 – 70 who are able to mobilise independently. **Exclusion criteria –** volunteers with history of knee fractures or knee ligament injuries, pregnant, allergy to both fabric and plastic, insufficient mental capacity to consent.

What are the potential risks to you in taking part?

The risks of skin damage with placement of optical tracker bands are small a formal skin assessment will be done prior to placement of trackers on each individual. Risk of injury during clinical examination are small but may cause some discomfort (lead Examiner is competent in this examination). There is also the possibility that a knee abnormality is found in an otherwise healthy individual and if this occurs this would be highlighted to you and appropriate further actions discussed.

What happens to the information in the project?

The raw data collected will be stored in the computer of the computer navigation system, which is stored in a secure location in Strathclyde University. The data collection sheet containing the volunteers' names, corresponding numbers, time and date of assessment will be stored in Strathclyde University in a locked filling cabinet with only lead Examiner access. No personal data will be held on a computer in this study, all data will be anonymised prior to writing the thesis and publication. The anonymised data will be stored permanently at the Golden Jubilee National Hospital for future reference or comparison studies.

The University of Strathclyde is registered with the Information Commissioner's Office who implements the Data Protection Act 1998. All personal data on volunteers will be processed in accordance with the provisions of the Data Protection Act 1998.

Thank you for reading this information – please ask any questions if you are unsure about what is written here.

What happens next?

If you are happy to be involved in the project, you can email the lead researcher Dr Alho; email to state you are willing to consent and partake in the project, and/or you could return the consent form to the lead researcher on your first session.

Researcher contact details:

Dr Roberto Alho
Department: Biomedical Engineering department / Golden Jubilee National
Telephone: 0141 552 4400 / 0141 951 5000
E-mail: roberto.alho@strath.ac.uk / roberto.alho@gjnh.scot.nhs.uk

Chief Investigator details:

Professor Philip Rowe
Department: Biomedical Engineering department
Telephone: 0141 548 3032
E-mail: philip.rowe@strath.ac.uk

This investigation was granted ethical approval by the Departmental Ethics Committee.
If you have any questions/concerns, during or after the investigation, or wish to contact an independent person to whom any questions may be directed or further information may be sought from, please contact:

Linda Gilmour
Secretary to Departmental Ethics Committee
National Centre for Prosthetics and Orthotics
Department of Biomedical Engineering
Curran Building, 131 St James Road
Glasgow
G4 0LS
Telephone: 0141 548 3298
Email: linda.gilmour@strath.ac.uk

NHS SCOTLAND
Golden Jubilee National Hospital

University of Strathclyde Glasgow

Consent Form

Name of department: Biomedical Engineering

Title of the study: Assessment of knee joint laxity and rotation using a non-invasive computer navigation system in healthy volunteers at Strathclyde University

- I confirm that I have read and understood the information sheet for the above project and the researcher has answered any queries to my satisfaction.
- I understand that my participation is voluntary and that I am free to withdraw from the project at any time, without having to give a reason and will in no way influence my standing or relationship within the University.
- I understand that I can withdraw my data from the study at any time.
- I understand that any information recorded in the investigation will remain confidential and no information that identifies me will be made publicly available.
- I consent to being a participant in the project
- I consent to being recorded in still images as part of the project

Print Name:	
Signature of Participant:	Date:

Appendix 6 (Initial testing: assessing optimal set of optical trackers) - Examiner 1

Examiner 1 - Pre-validated optical trackers

Table A showing data for *right leg* initial testing with the *pre-validated optical* straps by Examiner 1											
Assessment		**Registration number**									
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Supine MFTA in extension (º)		3	1	0	2	2	3	1	2	3	2
Flexion / extension (º)		0	1	1	0	-1	-1	1	0	0	0
Varus in extension (mm)		10	11	10	3	9	8	0	4	3	9
Valgus in extension (mm)		0	3	0	8	4	5	10	5	8	4
AP laxity (mm)	0º	18	7	9	10	10	5				
	15º	22	15	13	11	13	10				
	30º	22	14	17	16	15	16	22	16	17	16
	45º	19	15	14	22	14	18				
	60º	13	13	11	13	13	14				
	75º	19	7	14	11	12	13				
	90º	1	5	11	9	9	10				
Medial rotation (º)	0º	5	3	1	2	5	5				
	15º	7	4	7	7	8	0				
	30º	7	6	9	5	7	1	6	2	9	5
	45º	10	2	0	7	7	7				
	60º	10	9	3	4	5	5				
	75º	13	5	4	1	2	9				
	90º	9	3	6	4	2	5				
Lateral rotation (º)	0º	12	2	10	1	3	2				
	15º	5	6	8	5	4	7				
	30º	5	3	5	3	8	9	5	13	5	3
	45º	9	9	15	1	13	19				
	60º	12	0	10	4	9	15				
	75º	7	8	12	3	6	13				
	90º	0	8	8	3	4	7				
Pivot- shift test	Anterior draw (mm)	37	34	28	36	24	42	46	33	28	36
	Rotation (º)	14	18	23	25	16	16	22	18	23	25
Maximum flexion (º)		141	144	144	146	144	141	148	137	144	146
Bi-pedal loaded MFTA (º)		3	3	3	-2	2	1	-4	-1	3	-2
Bi-pedal loaded MFTA flexion / extension (º)		7	6	8	-1	3	-5	7	0	8	-1
Mono-pedal loaded MFTA (º)		3	3	5	0	2	6	-4	-1	5	0
Monopedal loaded MFTA flexion / extension (º)		7	6	6	0	3	-10	7	0	6	0

Table B showing data for ***left leg*** initial testing with the ***pre-validated optical*** straps by Examiner 1											
Assessment		**Registration number**									
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Supine MFTA in extension (º)		3	2	1	3	2	-1	1	2	0	3
Flexion / extension (º)		-1	0	1	2	-1	1	0	0	0	-1
Varus in extension (mm)		5	6	3	0	8	2	7	4	6	3
Valgus in extension (mm)		6	5	9	9	6	9	5	-1	5	9
AP laxity (mm)	0º	9	9	8	10	12	7				
	15º	18	10	13	13	14	8				
	30º	23	10	11	16	18	11	16	18	11	11
	45º	14	16	8	14	15	12				
	60º	11	9	7	11	10	11				
	75º	10	2	7	10	7	8				
	90º	7	6	6	7	3	11				
Medial rotation (º)	0º	6	11	1	0	4	0				
	15º	9	12	0	6	13	2				
	30º	10	12	4	5	10	8	5	10	8	7
	45º	7	2	11	7	3	7				
	60º	7	8	16	7	1	7				
	75º	7	4	6	7	2	3				
	90º	6	10	10	6	6	1				
Lateral rotation (º)	0º	4	13	10	7	3	14				
	15º	7	5	8	6	4	6				
	30º	6	5	19	4	8	10	4	8	10	3
	45º	1	9	4	1	7	9				
	60º	1	1	17	1	8	7				
	75º	2	14	14	2	11	11				
	90º	0	6	10	0	10	13				
Pivot- shift test	Anterior draw (mm)	14	53	51	25	25	16	21	53	51	27
	Rotation (º)	16	17	20	15	21	29	13	17	20	28
Maximum flexion (º)		143	151	148	144	145	146	137	145	148	144
Bi-pedal loaded MFTA (º)		0	2	-2	0	7	-4	0	0	-2	0
Bi-pedal loaded MFTA flexion / extension (º)		-7	0	4	-5	2	-5	-3	-2	4	-5
Mono-pedal loaded MFTA (º)		1	2	-1	0	7	-5	1	0	-1	0
Monopedal loaded MFTA flexion / extension (º)		0	0	11	3	2	5	-1	-2	11	3

Examiner 1 - New optical tracers

Table C showing data for *left leg* initial testing with the *new optical* straps by Examiner 1											
Assessment		**Registration number**									
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Supine MFTA in extension (º)		-4	0	2	1	-4	8	6	-2	4	3
Flexion / extension (º)		2	2	2	-1	2	1	0	0	1	-1
Varus in extension (mm)		-2	-2	3	6	13	3	8	7	5	3
Valgus in extension (mm)		10	10	5	3	-3	7	3	2	8	5
AP laxity (mm)	0º	7	7	7	5	6	7				
	15º	14	14	8	12	12	8				
	30º	16	16	8	10	13	8	8	22	12	8
	45º	16	16	12	8	15	12				
	60º	4	4	11	8	9	11				
	75º	4	4	9	8	9	9				
	90º	0	0	9	7	10	9				
Medial rotation (º)	0º	0	0	2	3	0	2				
	15º	2	2	3	3	1	3				
	30º	1	1	8	3	2	8	10	1	6	3
	45º	11	11	6	3	10	6				
	60º	16	16	1	1	3	1				
	75º	16	16	6	3	0	6				
	90º	29	29	1	0	2	1				
Lateral rotation (º)	0º	9	9	7	7	6	7				
	15º	7	7	4	11	5	4				
	30º	8	8	6	13	15	6	0	11	5	14
	45º	15	15	5	14	4	5				
	60º	3	3	8	12	5	8				
	75º	3	3	4	4	7	4				
	90º	4	4	6	9	6	6				
Pivot- shift test	Anterior draw (mm)	40	40	5	7	27	5	15	20	17	20
	Rotation (º)	17	17	20	15	10	20				
Maximum flexion (º)		120	120	135	125	120	135	123	124	133	135
Bi-pedal loaded MFTA (º)		-1	-1	0	8	-4	0	4	2	-4	0
Bi-pedal loaded MFTA flexion / extension (º)		6	6	5	2	8	5	0	-2	0	5
Mono-pedal loaded MFTA (º)		1	1	2	8	-3	2	4	2	-1	2
Monopedal loaded MFTA flexion / extension (º)		8	8	5	2	5	5	10	-2	3	5

Table D showing data for *left leg* initial testing with the *new optical* straps by Examiner 1											
Assessment		**Registration number**									
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Supine MFTA in extension (º)		1	2	-8	-11	-1	-1	-1	-5	3	-6
Flexion / extension (º)		-1	-1	0	-3	-3	-3	-5	1		
Varus in extension (mm)		-2	-2	4	5	3	6	8	7	9	7
Valgus in extension (mm)		11	11	7	8	5	3	3	2	6	7
AP laxity (mm)	0º	9	9	5	8	7	5				
	15º	14	14	8	6	8	12				
	30º	19	19	10	11	8	10	11	9	14	11
	45º	16	16	7	11	12	8				
	60º	13	13	6	11	11	8				
	75º	12	12	5	11	9	8				
	90º	13	13	6	8	9	7				
Medial rotation (º)	0º	2	2	9	4	2	3				
	15º	2	2	4	6	3	3				
	30º	10	10	7	7	8	3	7	6	14	5
	45º	4	4	3	5	6	3				
	60º	5	5	2	10	1	1				
	75º	4	4	11	7	6	3				
	90º	2	2	3	5	1	0				
Lateral rotation (º)	0º	3	3	10	6	7	7				
	15º	6	6	16	16	4	11				
	30º	0	0	7	1	6	13	1	4	2	6
	45º	4	4	7	5	5	14				
	60º	3	3	4	4	8	12				
	75º	7	7	6	1	4	4				
	90º	8	8	4	6	6	9				
Pivot- shift test	Anterior draw (mm)	30	30	11	29	5	7	27	5	13	30
	Rotation (º)	12	12	20	41	20	15	10	20	10	12
Maximum flexion (º)		122	122	135	138	135	125	135	125	144	139
Bi-pedal loaded MFTA (º)		-8	-8	-2	-4	0	8	0	8	0	1
Bi-pedal loaded MFTA flexion / extension (º)		-2	-2	1	4	5	2	5	2	10	3
Mono-pedal loaded MFTA (º)		-8	-8	0	-4	2	8	2	8	2	2
Monopedal loaded MFTA flexion / extension (º)		-2	-2	1	9	5	2	5	2	12	8

Appendix 7 (Initial testing: assessing optimal set of optical trackers) - Examiner 2

Examiner 2 - Pre-validated optical trackers

Table E showing data from *right leg* initial testing with the *pre-validated* optical straps by Examiner 2										
Assessment		**Registration number**								
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Supine MFTA in extension (º)		-1	3	0	1	1	2	0	-1	2	2
Flexion / extension (º)		7	-3	1	1	6	7	3	2	0	0
Varus in extension (mm)		11	1	8	4	5	0	3	9	2	4
Valgus in extension (mm)		-3	8	6	7	5	12	8	4	6	1
AP laxity (mm)	0º	11	10	15	11	9	11				
	15º	10	11	16	14	18	14				
	30º	22	13	18	16	9	16	17	16	12	14
	45º	18	12	13	10	7	12				
	60º	17	10	5	18	10	10				
	75º	16	13	0	10	13	13				
	90º	13	12	0	11	8	12				
Medial rotation (º)	0º	15	6	6	13	12	13				
	15º	12	10	9	8	6	8				
	30º	8	6	13	13	6	13	9	5	9	15
	45º	10	9	12	12	11	9				
	60º	4	11	16	7	10	11				
	75º	7	5	16	11	7	5				
	90º	14	6	6	10	6	6				
Lateral rotation (º)	0º	2	5	12	6	5	6				
	15º	5	2	6	14	13	14				
	30º	6	2	5	5	5	8	5	3	8	0
	45º	8	4	11	4	5	4				
	60º	12	8	13	5	6	8				
	75º	5	13	18	12	7	13				
	90º	5	13	11	6	6	13				
Pivot- shift test	Anterior draw (mm)	23	67	73	43	43	33	28	36	51	32
	Rotation (º)	53	65	30	35	22	39	23	25	26	53
Maximum flexion (º)		155	169	172	160	160	160	144	146	164	160
Bi-pedal loaded MFTA (º)		4	6	0	1	2	0	3	-2	0	2
Bi-pedal loaded MFTA flexion / extension (º)		6	-1	5	6	3	10	8	-1	3	7
Mono-pedal loaded MFTA (º)		4	6	0	2	1	1	5	0	1	3
Monopedal loaded MFTA flexion / extension (º)		8	-1	5	1	3	8	6	0	-1	-4

Table F showing data from *left leg* initial testing with the *pre-validated* optical straps by Examiner 2											
Assessment		**Registration number**									
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Supine MFTA in extension (º)		3	3	2	4	2	2	3	1	2	3
Flexion / extension (º)		2	-1	-1	-2	4	-1	0	-2	1	-1
Varus in extension (mm)		5	3	6	8	1	3	4	3	14	5
Valgus in extension (mm)		2	4	3	1	4	4	7	9	-5	1
AP laxity (mm)	0º	8	9	15	21	4	11				
	15º	12	15	16	17	9	15				
	30º	20	15	22	25	14	15	24	11	21	17
	45º	20	17	18	15	10	17				
	60º	13	13	10	19	16	14				
	75º	5	7	5	9	8	7				
	90º	5	6	4	2	10	5				
Medial rotation (º)	0º	14	7	14	16	8	7				
	15º	6	7	18	16	3	7				
	30º	20	12	9	22	9	12	9	8	11	12
	45º	16	8	12	12	11	8				
	60º	8	4	22	13	5	4				
	75º	5	3	13	17	5	3				
	90º	22	13	16	21	8	13				
Lateral rotation (º)	0º	5	6	10	12	8	6				
	15º	10	7	8	11	10	7				
	30º	6	7	8	10	3	7	8	10	8	2
	45º	6	15	9	11	5	15				
	60º	8	10	7	8	6	10				
	75º	11	10	12	4	4	10				
	90º	7	9	10	6	5	9				
Pivot- shift test	Anterior draw (mm)	56	43	57	72	40	43	33	51	20	61
	Rotation (º)	43	24	53	39	117	24	22	20	21	49
Maximum flexion (º)		155	162	157	163	168	152	158	155	144	154
Bi-pedal loaded MFTA (º)		4	4	4	9	13	1	4	4	0	-9
Bi-pedal loaded MFTA flexion / extension (º)		6	1	0	-2	-5	-2	0	-7	-5	3
Mono-pedal loaded MFTA (º)		4	6	3	9	12	2	3	5	0	-9
Monopedal loaded MFTA flexion / extension (º)		8	2	5	-4	-3	-7	5	-7	3	3

Examiner 2 - New optical tracers

Table G showing data from *right leg* initial testing with the *new* optical straps by Examiner 2											
Assessment		**Registration number**									
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Supine MFTA in extension (º)		-6	-4	3	0	-4	2	-2	-4	-3	1
Flexion / extension (º)		7	1	-3	5	2	6	4	2	-1	3
Varus in extension (mm)		4	10	0	-3	3	8	3	0	3	-6
Valgus in extension (mm)		2	0	7	6	4	0	7	6	5	13
AP laxity (mm)	0º	5	9	7	8	6	5				
	15º	4	13	6	11	5	10				
	30º	13	16	12	11	11	11	8	10	11	14
	45º	13	12	7	6	6	8				
	60º	10	16	12	9	7	8				
	75º	6	15	11	9	8	7				
	90º	5	13	9	8	7	7				
Medial rotation (º)	0º	9	13	4	5	3	8				
	15º	1	5	5	8	20	8				
	30º	7	7	6	7	12	6	3	14	18	14
	45º	6	4	10	5	6	16				
	60º	4	9	7	4	6	5				
	75º	4	3	11	2	7	3				
	90º	1	7	4	4	0	3				
Lateral rotation (º)	0º	0	0	1	9	4	7				
	15º	7	8	5	5	7	7				
	30º	4	10	8	6	5	4	14	4	4	6
	45º	6	9	0	3	5	5				
	60º	7	12	11	10	5	8				
	75º	3	9	6	9	5	9				
	90º	5	8	4	5	9	8				
Pivot- shift test		8	22	34	29	40	31	15	22	7	15
		27	25	24	15	22	18	20	16	22	35
Maximum flexion (º)		139	138	119	140	143	131	125	117	137	139
Bi-pedal loaded MFTA (º)		1	-5	-3	-4	2	5	8	-1	-1	-5
Bi-pedal loaded MFTA flexion / extension (º)		9	9	7	5	1	1	2	0	9	7
Mono-pedal loaded MFTA (º)		1	-3	-3	-5	1	6	8	-1	-1	-4
Monopedal loaded MFTA flexion / extension (º)		9	7	7	5	5	6	2	0	9	0

Table H showing data from *left leg* initial testing with the *new* optical straps by Examiner 2											
Assessment		**Registration number**									
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Supine MFTA in extension (º)		-5	-9	3	-4	-6	2	0	1	-5	3
Flexion / extension (º)		-4	-3	-1	-2	-5	-2	2	-4	-7	-3
Varus in extension (mm)		6	10	11	3	1	4	6	4	3	3
Valgus in extension (mm)		2	7	0	6	5	5	2	5	7	5
AP laxity (mm)	0º	10	22	5	12	2	17				
	15º	13	23	10	8	16	18				
	30º	10	12	11	12	21	21	13	8	10	12
	45º	10	11	8	13	21	16				
	60º	8	8	8	11	23	14				
	75º	15	12	7	9	19	6				
	90º	10	7	7	8	14	11				
Medial rotation (º)	0º	6	8	8	10	5	2				
	15º	14	28	8	5	3	9				
	30º	18	13	6	17	3	11	12	5	5	6
	45º	18	9	16	9	4	10				
	60º	13	10	5	15	3	11				
	75º	10	6	3	12	11	6				
	90º	7	13	3	11	14	10				
Lateral rotation (º)	0º	7	6	7	1	1	14				
	15º	4	14	7	5	13	12				
	30º	5	3	4	5	11	8	4	5	9	5
	45º	1	7	5	4	13	6				
	60º	5	5	8	3	17	0				
	75º	5	10	9	3	14	7				
	90º	8	5	8	4	4	5				
Pivot- shift test	Anterior draw (mm)	32	23	31	9	26	22	27	10	4	26
	Rotation (º)	69	29	18	22	29	23	22	38	26	17
Maximum flexion (º)		155	143	153	121	117	110	129	117	127	148
Bi-pedal loaded MFTA (º)		4	3	6	5	4	0	3	8	-2	5
Bi-pedal loaded MFTA flexion / extension (º)		6	-2	-4	1	-6	7	-6	-10	4	-3
Mono-pedal loaded MFTA (º)		4	2	5	6	3	0	4	7	-3	3
Monopedal loaded MFTA flexion / extension (º)		8	-2	-2	6	-6	3	-6	-7	8	-3

Appendix 8 (Summary results for Examiner 1 assessment for optimal set of optical trackers)

Pre-validated optical trackers

Table I showing the initial testing data acquired by Examiner 1 using the *pre-validated optical* tracker set					
Assessment		***Right knee***		***Left knee***	
		Average	Standard deviation	Average	Standard deviation
Supine MFTA in extension (º)		2.0	3.4	1.6	3.5
Flexion / extension (º)		0.1	5.3	-0.6	4.0
Varus in extension (mm)		6.9	4.0	4.4	2.7
Valgus in extension (mm)		4.4	3.5	6.0	3.3
AP laxity (mm)	0º	9.8	4.4	9.2	1.7
	15º	14.0	4.3	12.7	3.4
	30º	17.3	3.1	14. 3	4.9
	45º	17.0	3.2	14.0	3.2
	60º	12.8	1.0	10.6	1.7
	75º	12.7	3.9	9.8	2.9
	90º	7.5	3.8	6.6	2.9
Medial rotation (º)	0º	3.5	1.8	3.7	4.3
	15º	5.2	3.0	5.6	5.3
	30º	5.4	2.7	6.0	2.9
	45º	5.6	3.7	6.0	3.6
	60º	8.3	2.8	7.8	5.4
	75º	8.2	4.5	10.4	2.1
	90º	5.5	2.5	7.8	3.7
Lateral rotation (º)	0º	5.0	4.7	8.5	4.6
	15º	5.8	1.5	7.0	1.4
	30º	6.4	3.4	7.9	5.5
	45º	11.0	6.2	8.0	3.5
	60º	6.0	5.5	6.8	6.8
	75º	5.7	3.8	4.4	4.9
	90º	5.0	3.2	6.6	5.0
Pivot- shift test	Anterior draw (mm)	35.0	7.1	29.0	14.9
	Rotation (º)	19.0	3.9	19.9	5.9
Maximum flexion (º)		143.1	3.4	144.9	4.1
Bi-pedal loaded MFTA (º)		0.6	2.7	0.4	3.2
Bi-pedal loaded MFTA flexion / extension (º)		3.1	4.7	-2.0	3.8
Mono-pedal loaded MFTA (º)		1.8	3.3	0.6	3.3
Monopedal loaded MFTA flexion / extension (º)		2.4	5.8	2.3	4.2

New optical trackers

Table J showing the initial testing data acquired by Examiner 1 using the *new optical* tracker set					
Assessment		***Right knee***		***Left knee***	
		Average	Standard deviation	Average	Standard deviation
Supine MFTA in extension (º)		-1.4	4.0	-2.7	4.9
Flexion / extension (º)		1.3	1.4	-2.0	2.1
Varus in extension (mm)		5.4	4.7	4.3	3.8
Valgus in extension (mm)		3.9	4.1	7.7	1.8
AP laxity (mm)	0º	6.0	1.0	7.3	2.1
	15º	10.6	3.0	9.3	4.2
	30º	13.6	5.3	12.2	3.9
	45º	11.8	3.8	11.3	4.5
	60º	8.2	2.6	10	3.6
	75º	7.6	2.1	9.3	3.8
	90º	7.0	4.1	9.0	3.6
Medial rotation (º)	0º	2.6	3.3	5.0	3.6
	15º	4.8	5.8	4.0	2.0
	30º	5.4	4.9	5.0	3.5
	45º	7.4	3.2	4.0	1.0
	60º	7.0	7.4	5.7	4.0
	75º	6.0	6.0	7.3	3.5
	90º	6.8	12.4	6.0	1.5
Lateral rotation (º)	0º	7.2	1.1	6.3	3.5
	15º	6.4	2.8	12.7	5.8
	30º	8.1	5.3	8.0	5.2
	45º	9.0	5.1	5.3	1.5
	60º	6.4	3.6	3.7	0.6
	75º	3.8	2.2	4. 7	3.2
	90º	6.4	1.8	3.3	2.0
Pivot- shift test	Anterior draw (mm)	23.4	13.4	21.7	9.0
	Rotation (º)	15.4	4.0	18.0	11.8
Maximum flexion (º)		125.7	6.0	134.3	8.0
Bi-pedal loaded MFTA (º)		-0.7	4.3	-2.7	3.2
Bi-pedal loaded MFTA flexion / extension (º)		2.7	3.7	3.3	4.0
Mono-pedal loaded MFTA (º)		-1.9	3.5	-2.2	4.1
Monopedal loaded MFTA flexion / extension (º)		4.4	4.0	6.0	5.3

Appendix 9 (Summary results from Examiner 2 assessment for optimal set of optical trackers)

Pre-validated optical trackers

Table K showing the initial testing data acquired by Examiner 2 using the *pre-validated optical* tracker set					
Assessment		***Right knee***		***Left knee***	
		Average	Standard deviation	Average	Standard deviation
Supine MFTA in extension (º)		1.5	2.9	3.5	2.7
Flexion / extension (º)		3.0	3.5	0.0	2.0
Varus in extension (mm)		4.4	3.7	5.8	3.9
Valgus in extension (mm)		5.3	4.5	2.1	3.5
AP laxity (mm)	0º	11.2	2.3	11.4	6.7
	15º	13.8	3.3	13.8	3.3
	30º	16.0	4.0	18.8	4.1
	45º	13.0	4.1	15.0	3.8
	60º	12.0	5.4	14.2	3.4
	75º	10.4	6.2	8.8	1.8
	90º	8.8	5.3	6.4	3.0
Medial rotation (º)	0º	6.0	4.2	7.8	4.0
	15º	8.0	2.2	8.6	6.6
	30º	4.9	3.5	6.5	5.1
	45º	10.8	1.3	11.8	2.9
	60º	9.6	4.5	10.4	7.4
	75º	11.0	4.4	10.6	6.1
	90º	8.4	3.3	14.0	5.8
Lateral rotation (º)	0º	10.4	3.7	11.8	2.9
	15º	9.0	5.2	10.0	1.6
	30º	10.4	2.8	13.0	2.7
	45º	6.4	3.0	9.2	4.0
	60º	8.8	3.6	7.8	1.5
	75º	9.2	5.1	8.2	3.9
	90º	8.0	3.3	7.4	2.1
Pivot- shift test	Anterior draw (mm)	45.6	17.3	47.8	16.9
	Rotation (º)	40.4	15.2	46.0	31.3
Maximum flexion (º)		162.5	5.6	158.6	5.3
Bi-pedal loaded MFTA (º)		1.9	2.2	4.5	6.7
Bi-pedal loaded MFTA flexion / extension (º)		4.9	3.3	-2.5	3.9
Mono-pedal loaded MFTA (º)		2.25	2.0	4.8	6.5
Monopedal loaded MFTA flexion / extension (º)		2.4	4.4	-2.4	5.1

New optical trackers

Table L showing the initial testing data acquired by Examiner 2 using the *new optical* tracker set					
Assessment		***Right knee***		***Left knee***	
		Average	Standard deviation	Average	Standard deviation
Supine MFTA in extension (º)		-1.9	3.0	-1.0	3.6
Flexion / extension (º)		3.0	3.2	-2.9	2.4
Varus in extension (mm)		1.4	4.8	5.3	3.3
Valgus in extension (mm)		5.4	3.9	4.3	2.4
AP laxity (mm)	0º	7.0	1.6	11.3	7.4
	15º	9.8	4.0	14.7	5.5
	30º	12.3	2.0	13.1	4.7
	45º	8.8	3.4	13.2	4.7
	60º	10.8	3.4	12.0	5.9
	75º	9.8	3.4	11.3	5.0
	90º	8.4	3.0	9.5	2.7
Medial rotation (º)	0º	6.8	4.1	6.5	2.8
	15º	7.8	7.3	11.2	9.1
	30º	10.6	4.5	10.0	5.5
	45º	6.2	2.3	11.0	5.1
	60º	6.0	2.1	9.5	4.6
	75º	5.4	3.6	8.0	3.5
	90º	3.2	2.8	9.7	4.1
Lateral rotation (º)	0º	2.8	3.8	6.0	4.8
	15º	6.4	1.3	9.2	4.4
	30º	5.9	2.2	6.0	2.7
	45º	4.6	3.4	6.0	4.0
	60º	9.0	2.9	6.3	5.9
	75º	6.4	2.6	8.0	3.9
	90º	6.2	2.2	5.7	1.9
Pivot- shift test	Anterior draw (mm)	22.1	11.9	20.4	10.2
	Rotation (º)	23.3	6.3	30.7	15.5
Maximum flexion (º)		134	10.0	129.4	15.2
Bi-pedal loaded MFTA (º)		-2.0	2.7	-1.6	3.0
Bi-pedal loaded MFTA flexion / extension (º)		5.9	3.6	-2.1	5.3
Mono-pedal loaded MFTA (º)		-1.9	2.2	-1.0	3.1
Monopedal loaded MFTA flexion / extension (º)		5.3	3.6	-1.0	5.5

Appendix 10 (Full volunteer data collection set performed by Examiner RA)

Volunteers	Supine MFTA in extension (°)				AP laxity 0º (mm)				AP laxity 15º (mm)				AP laxity 30º (mm)				AP laxity 45º (mm)				AP laxity 60º (mm)			
	Right knee		Left knee		Right knee		Left knee		Right knee		Left knee		Right knee		Left knee		Right knee		Left knee		Right knee		Left knee	
1	-9	-3	-4	-1	13	7	14	12	15	10	15	15	18	18	18	20	10	13	30	24	9	14	21	21
2	4	1	-4	4	8	15	15	12	18	28	19	11	23	30	22	16	19	13	18	11	14	14	15	9
3	-3	-4	-2	2	8	10	8	14	22	20	17	18	23	22	15	19	18	23	13	17	24	13	21	15
4	-5	-2	0	-1	9	11	6	10	13	9	11	14	23	18	15	19	21	15	11	16	17	8	16	9
5	-5	-4	2	1	10	8	8	7	18	27	12	15	14	19	14	18	21	15	14	18	18	16	10	14
6	4	3	3	1	10	7	10	11	12	17	13	9	16	12	22	17	24	29	24	16	18	20	11	15
7	2	4	-2	-3	8	6	10	9	14	19	16	12	20	19	16	20	25	20	23	18	18	25	20	14
8	-1	-2	-3	-4	8	10	14	10	11	15	13	18	15	18	17	23	16	20	16	11	17	25	25	20
9	-3	-4	-2	2	8	10	8	14	18	27	12	15	23	22	15	19	18	13	30	24	9	14	21	21
10	-5	-2	0	-1	9	11	6	10	12	17	13	9	23	18	15	19	21	13	18	11	14	14	15	9
11	0	0	1	2	7	8	10	10	13	12	15	13	17	20	19	16	15	18	19	18	13	14	19	15
12	1	0	1	1	6	7	13	15	12	13	21	19	12	14	24	21	24	25	17	18	24	24	17	15
13	0	0	1	-1	9	11	11	13	22	23	15	13	14	16	17	18	24	27	21	24	17	15	13	13
14	1	0	-2	-2	11	14	16	15	12	13	22	20	19	17	23	21	15	13	21	18	15	14	8	8
15	-1	0	1	0	9	10	8	8	12	14	16	13	20	20	15	14	17	16	18	15	18	16	8	10
16	1	2	3	3	8	8	10	7	8	10	10	11	15	11	13	15	17	18	11	10	11	9	17	15
17	0	1	-1	-1	8	6	8	6	11	10	17	12	13	14	14	11	20	22	13	10	16	13	15	15
18	-2	-2	-2	-1	13	15	12	11	19	15	16	14	19	19	20	19	17	15	21	18	17	17	8	11
19	0	-2	0	1	8	10	9	11	12	16	13	14	15	17	19	20	18	17	12	13	13	14	10	13
20	-1	-2	-2	0	10	11	11	9	18	16	11	14	18	22	15	18	16	14	17	14	16	14	11	15
21	1	0	0	1	12	10	7	8	14	17	13	11	20	20	17	17	20	21	12	14	14	17	12	10
22	0	0	-2	-2	6	9	6	8	12	15	10	12	14	16	13	12	17	16	15	13	14	12	11	8
23	-1	0	2	2	12	9	10	8	18	13	13	11	21	20	14	14	17	14	12	13	17	18	16	17
24	-2	0	2	3	8	11	5	7	12	16	16	17	17	17	11	14	13	17	16	17	18	19	16	18
25	2	2	3	2	17	21	7	8	17	15	12	14	18	23	14	17	22	19	19	19	16	18	13	15

Volunteers	AP laxity 75º (mm)				AP laxity 90º (mm)				Medial rotation 0º				Lateral rotation 0º				Medial rotation 15º				Lateral rotation 15º			
	Right knee		Left knee		Right knee		Left knee		Right knee		Left knee		Right knee		Left knee		Right knee		Left knee		Right knee		Left knee	
1	12	12	25	23	13	17	16	18	0	5	1	0	14	14	16	15	15	11	5	8	3	7	5	5
2	11	16	11	8	11	11	8	4	6	0	5	4	6	10	7	10	2	4	10	1	8	5	9	9
3	24	13	14	9	19	10	13	9	5	2	0	4	14	20	9	9	1	5	4	9	10	10	5	7
4	15	13	16	12	15	13	16	15	1	3	0	8	11	9	13	9	4	4	1	19	9	6	19	4
5	16	15	11	12	13	14	13	14	2	4	3	12	11	10	10	6	7	6	3	3	5	17	7	14
6	14	22	17	21	12	22	17	19	9	3	6	5	7	9	6	7	8	4	6	8	5	7	6	6
7	22	12	16	12	19	19	11	11	6	2	6	6	6	12	5	10	5	11	17	5	9	8	2	8
8	12	17	14	19	13	14	13	17	4	3	4	3	7	8	10	9	2	10	4	4	11	7	10	6
9	12	12	25	9	19	10	13	9	2	4	3	12	11	10	10	6	7	6	3	3	5	17	7	14
10	11	16	11	12	15	13	16	15	9	3	6	5	7	9	6	7	8	4	6	8	5	7	6	6
11	12	13	16	14	11	15	14	12	1	0	3	3	10	9	8	8	5	0	5	5	13	12	3	6
12	21	21	11	15	28	24	24	18	6	0	3	6	12	15	16	16	6	7	11	8	15	14	7	7
13	8	11	16	15	5	7	15	14	5	0	0	1	5	10	14	13	5	2	4	9	13	17	11	7
14	18	23	12	10	15	13	14	12	0	2	4	5	11	11	7	6	8	9	13	10	12	6	4	10
15	16	16	13	15	6	0	0	2	0	5	0	1	17	14	18	14	4	5	3	5	24	15	16	14
16	11	8	5	7	19	17	9	14	1	0	1	3	13	14	10	13	6	6	0	8	9	8	10	6
17	15	14	6	10	13	12	5	12	2	2	8	2	13	12	9	10	7	5	3	4	12	10	9	10
18	17	16	16	13	15	16	14	13	3	1	2	0	8	11	8	11	11	3	6	8	6	13	7	6
19	15	15	12	11	15	15	12	11	5	4	5	2	11	6	11	11	15	13	7	9	1	7	7	6
20	14	12	9	16	14	11	12	16	2	0	0	0	10	10	12	15	2	2	8	6	18	14	6	10
21	14	18	11	13	14	12	12	15	1	1	6	1	8	10	6	10	5	4	6	3	12	11	9	10
22	15	14	13	14	13	15	15	9	4	5	5	5	11	8	4	5	7	11	4	6	9	4	10	10
23	21	17	12	14	15	6	16	13	2	0	2	0	7	10	4	8	5	8	9	6	8	8	0	1
24	22	18	10	15	18	17	14	17	4	4	1	3	15	14	11	7	0	6	8	3	19	17	5	5
25	20	19	12	15	18	21	12	13	4	2	0	1	13	12	12	12	4	4	8	7	16	15	4	6

Volunteers	Pivot- shift test Anterior draw (mm)				Pivot- shift test Rotation (º)				Maximum flexion (º)				Bi-pedal loaded MFTA (º)				Mono-pedal loaded MFTA (º)			
	Right knee		Left knee		Right knee		Left knee		Right knee		Left knee		Right knee		Left knee		Right knee		Left knee	
1	45	33	63	70	31	36	24	26	153	154	149	150	-2	-4	-9	0	0	1	-5	0
2	38	32	60	60	14	20	13	17	147	144	144	139	4	7	0	6	0	1	-10	-4
3	29	37	37	51	21	17	16	21	150	146	147	144	0	2	-2	7	-4	-4	10	14
4	49	48	28	30	22	28	31	38	161	158	159	156	4	8	4	9	3	5	-7	-9
5	43	53	46	52	17	13	26	25	157	157	153	152	1	1	12	6	-6	-3	-7	-10
6	40	49	58	73	34	23	21	19	161	154	150	147	7	1	-1	-6	-5	-3	-2	-6
7	62	62	49	33	33	23	28	28	133	141	146	141	-4	-2	9	5	3	0	12	12
8	44	35	76	65	30	23	34	46	158	155	150	136	-2	-4	-2	-4	-5	-6	-15	-17
9	41	41	66	47	22	28	31	38	137	140	142	150	4	7	-5	-1	-9	-8	-13	-15
10	64	52	35	40	17	13	26	25	152	149	142	145	-3	-4	1	-4	-7	-4	-6	-3
11	53	61	54	57	10	8	29	23	152	155	143	142	-7	-8	-2	3	0	1	-5	-3
12	48	37	30	31	26	28	20	25	146	141	151	150	-2	-1	1	2	2	-2	2	4
13	51	52	58	60	43	48	28	27	150	148	158	156	-5	-2	1	3	0	-1	-1	2
14	64	60	40	45	32	36	41	27	149	151	154	159	1	-3	2	4	1	-3	-2	-2
15	37	50	71	63	14	21	23	22	142	145	148	143	-4	-3	-8	-7	-1	3	-3	-1
16	51	50	64	70	28	28	29	17	143	142	143	137	-1	1	-1	-4	-4	-3	2	1
17	40	44	85	70	18	10	9	15	151	150	146	144	-2	0	3	1	2	-2	3	3
18	46	51	69	84	27	29	26	19	158	156	156	155	-1	1	-5	-2	0	-1	-5	-1
19	68	57	64	64	34	29	26	34	157	159	154	155	2	-1	6	5	2	-1	-2	3
20	76	77	32	28	32	28	32	36	139	143	140	143	1	1	3	0	3	4	3	2
21	58	73	30	26	27	25	18	22	143	147	138	141	1	1	3	2	-3	0	3	0
22	83	73	38	43	14	17	15	20	145	149	152	149	1	4	-3	-1	3	5	0	6
23	29	36	52	66	14	21	21	14	155	154	149	151	0	-2	4	2	0	-2	3	4
24	43	38	27	30	23	23	21	24	157	158	144	145	-2	-2	1	2	2	4	7	4
25	54	44	71	65	18	22	31	26	146	150	156	154	3	4	1	3	4	4	-2	2

Appendix 11 (Full volunteer data collection set performed by Examiner FH)

Volunteers	Supine MFTA in extension (º)				AP laxity 0º (mm)				AP laxity 15º (mm)				AP laxity 30º (mm)				AP laxity 45º (mm)				AP laxity 60º (mm)			
	Right knee		Left knee		Right knee		Left knee		Right knee		Left knee		Right knee		Left knee		Right knee		Left knee		Right knee		Left knee	
1	-1	-7	-1	-2	13	16	11	12	12	12	16	15	20	15	13	21	9	19	25	12	11	21	20	20
2	4	-1	0	10	17	8	20	8	25	6	14	19	21	14	26	22	21	17	16	22	23	15	14	18
3	-3	0	-3	-3	10	17	20	9	11	11	25	16	16	24	27	11	30	24	28	15	35	18	20	15
4	-7	-7	-3	-2	9	14	11	9	10	16	12	12	14	14	10	21	17	19	10	31	20	16	11	15
5	0	-3	1	4	9	7	6	17	14	16	13	20	17	19	10	18	19	9	20	13	16	10	10	12
6	1	2	1	2	11	11	11	14	28	13	27	19	19	11	27	21	20	15	20	19	25	18	27	20
7	-3	-4	-4	-3	8	6	7	6	16	12	8	11	18	17	10	15	20	22	17	20	19	23	15	13
8	-1	-4	-5	-2	5	10	8	6	11	9	16	9	10	12	15	9	13	17	20	12	16	21	21	16
9	-3	0	-3	-3	10	17	20	9	11	11	25	16	16	24	27	11	30	24	20	13	16	10	10	12
10	-7	-7	-3	-2	9	14	11	9	10	16	12	12	14	14	10	21	17	19	20	19	25	18	27	20
11	0	-2	1	3	11	16	7	8	14	25	13	15	18	29	17	18	21	22	16	15	15	26	16	17
12	-1	-1	-1	0	8	8	11	9	15	25	14	16	20	29	16	21	20	19	16	25	24	17	21	18
13	-1	0	-1	-2	11	13	7	10	22	16	12	9	23	20	18	16	26	29	16	14	24	26	16	16
14	-1	1	1	-1	12	5	11	11	14	6	13	12	26	8	10	12	28	16	7	9	21	8	15	8
15	-2	-2	-1	-1	8	8	5	7	10	12	13	9	17	14	11	8	12	14	9	12	2	11	6	8
16	1	-1	5	4	8	12	12	14	12	13	11	14	14	11	18	14	12	14	8	9	17	14	11	8
17	1	0	-1	0	5	7	8	8	7	12	10	10	10	12	9	11	9	12	14	10	6	15	9	7
18	-3	-4	-1	0	13	8	9	9	14	18	14	11	18	20	17	12	13	20	10	16	16	19	11	19
19	-1	-1	0	2	13	7	8	12	14	8	5	11	14	13	9	13	16	16	11	8	15	14	11	9
20	-1	-3	-1	0	13	7	7	6	12	19	11	10	11	18	13	6	10	15	10	8	12	15	10	6
21	-1	-1	-1	-1	8	15	13	7	12	7	7	16	16	12	9	19	11	16	9	12	14	16	12	10
22	-2	-2	-2	-2	8	10	5	7	8	9	14	16	11	12	13	15	9	12	10	11	11	11	12	13
23	-2	-2	4	4	7	6	12	11	10	10	11	9	18	13	9	11	13	10	11	11	18	15	18	15
24	2	3	2	3	10	5	10	8	26	24	18	12	25	20	10	14	25	22	14	13	16	21	13	11
25	-4	-4	1	1	18	17	7	10	18	21	11	13	12	19	10	10	20	26	14	14	13	16	15	10

Volunteers	AP laxity 75º (mm)				AP laxity 90º (mm)				Medial rotation 0º				Lateral rotation 0º				Medial rotation 15º				Lateral rotation 15º			
	Right knee		Left knee		Right knee		Left knee		Right knee		Left knee		Right knee		Left knee		Right knee		Left knee		Right knee		Left knee	
1	22	21	24	23	17	23	27	22	14	9	9	1	6	12	2	14	4	6	16	6	8	12	8	7
2	19	22	22	19	14	26	23	16	10	1	15	0	11	26	3	23	15	5	8	8	12	9	7	11
3	32	18	17	13	25	14	13	7	4	8	11	4	10	10	4	7	0	1	6	13	10	14	12	2
4	20	23	18	19	22	17	14	23	3	9	10	9	14	6	2	7	5	5	11	11	22	15	5	8
5	14	15	8	18	11	10	8	16	10	6	9	6	4	5	5	5	1	4	8	7	14	15	11	8
6	21	26	23	17	21	36	18	23	3	4	3	12	13	15	8	4	21	5	6	8	13	23	22	7
7	20	21	13	16	20	12	12	15	6	7	3	6	18	11	12	9	14	8	3	15	18	17	9	10
8	19	18	14	14	20	21	9	16	5	1	3	7	13	12	8	1	5	5	9	6	11	9	4	10
9	14	15	8	18	17	23	27	22	14	9	9	1	6	12	2	14	0	1	6	13	10	14	12	2
10	21	26	23	17	14	26	23	16	10	1	15	0	11	26	3	23	5	5	11	11	22	15	5	8
11	16	19	19	20	21	10	23	25	4	3	3	3	10	12	7	5	2	0	2	5	17	19	7	6
12	31	26	27	18	30	30	25	8	1	6	8	2	14	3	3	8	7	14	6	7	10	7	3	2
13	22	20	24	17	19	13	22	17	5	8	6	7	6	9	8	9	8	4	4	3	16	17	9	8
14	19	9	16	13	14	9	11	13	0	1	0	5	10	8	7	5	6	0	0	6	9	6	9	8
15	0	5	6	3	0	0	0	0	3	2	2	0	13	8	8	13	7	1	0	18	5	25	13	2
16	20	10	9	14	15	1	9	9	0	2	2	0	13	9	5	10	3	6	3	3	18	14	7	9
17	8	12	8	10	13	14	10	6	1	2	1	6	10	15	12	8	5	3	1	5	19	24	13	13
18	12	22	10	18	17	19	16	13	1	0	2	2	8	5	8	7	3	0	5	0	11	15	13	13
19	20	15	11	21	15	18	15	13	7	5	3	6	9	6	12	10	6	2	4	2	13	10	11	11
20	12	12	10	12	10	16	3	6	4	0	1	4	11	10	8	5	3	5	3	0	10	11	12	12
21	19	14	10	17	13	19	13	13	2	2	1	6	6	6	7	3	4	2	0	5	15	4	14	14
22	12	13	11	16	14	10	13	10	6	3	4	6	2	7	3	4	4	4	3	5	5	4	14	16
23	22	20	19	9	25	17	17	12	6	4	5	0	5	6	8	10	5	3	0	0	6	8	17	18
24	27	22	17	14	26	25	17	17	6	2	5	8	8	14	3	5	9	6	3	4	8	11	13	5
25	17	25	7	18	20	20	14	18	0	1	0	1	12	15	8	13	2	1	2	4	14	18	11	12

Volunteers	Pivot- shift test Anterior draw (mm)				Pivot- shift test Rotation (º)				Maximum flexion (º)				Bi-pedal loaded MFTA (º)				Mono-pedal loaded MFTA (º)			
	Right knee		Left knee		Right knee		Left knee		Right knee		Left knee		Right knee		Left knee		Right knee		Left knee	
1	25	37	51	38	43	55	48	59	151	157	144	146	1	-4	-9	-1	-10	-3	-2	-5
2	43	37	37	60	25	39	35	65	136	132	137	138	-1	-1	1	4	1	0	0	-2
3	42	29	31	52	46	47	37	31	149	150	142	145	-6	-5	-6	-2	-7	-2	-8	-8
4	20	24	40	44	34	35	39	30	146	142	152	151	0	0	2	-1	0	-3	-3	-6
5	82	43	54	44	28	36	36	48	140	139	156	157	5	6	-4	-1	-2	-1	6	5
6	68	57	30	31	41	70	44	49	162	153	157	157	10	5	2	3	1	-1	10	4
7	48	73	25	45	32	34	37	44	151	156	146	149	4	1	-5	-8	-1	-7	5	2
8	19	36	21	43	35	30	29	22	141	145	146	152	6	3	7	2	9	4	4	4
9	44	70	27	30	45	21	33	23	158	152	141	143	-2	-7	-2	0	-2	-2	-1	-5
10	40	84	29	24	29	25	33	46	157	150	164	156	8	3	2	8	2	8	9	1
11	32	20	54	46	26	15	22	29	161	157	139	131	-4	-5	3	3	4	3	-3	-5
12	22	34	41	30	40	16	21	29	162	152	140	152	-5	-7	0	3	1	2	-6	-7
13	46	57	51	54	21	41	19	37	142	133	158	147	-1	-7	-2	-2	-1	-3	-1	-4
14	27	36	84	66	26	22	29	28	152	149	145	145	12	8	2	4	0	4	11	9
15	53	81	51	50	15	16	30	17	154	153	142	144	8	14	-8	-6	-9	-12	9	13
16	48	27	26	51	18	25	26	19	139	140	147	152	9	3	1	-4	-4	-8	8	3
17	76	77	54	57	39	36	49	45	162	151	154	155	-4	2	-1	-2	-1	0	-4	2
18	83	73	58	70	21	22	29	33	148	145	161	158	1	0	4	-2	4	-3	1	-1
19	43	38	85	70	44	28	20	33	160	159	146	145	1	-1	-7	3	-8	2	3	1
20	71	53	42	66	28	12	25	28	156	156	152	158	-4	-3	-1	-6	-5	-11	-3	-2
21	64	64	71	55	25	27	29	31	164	163	146	140	-3	1	1	4	0	4	-2	2
22	30	26	68	57	48	32	26	22	155	150	138	129	2	-4	-5	-7	-5	-10	3	-4
23	22	21	48	73	36	50	15	16	153	151	147	133	-2	-3	0	5	-1	4	-2	-4
24	42	34	19	36	37	30	18	25	141	145	146	152	0	0	2	-1	0	-3	-3	-6
25	27	29	44	70	34	41	39	36	158	152	141	143	5	6	-4	-1	-2	-1	6	5

Appendix 12 (Summary results from both Examiners assessment on all 25 volunteers right leg)

Table M depicting average ***right leg*** data acquired from all volunteers by both Examiners							
Assessment		**Examiner 1**		**Examiner 2**		**Overall**	
		Average	Standard deviation	Average	Standard deviation	Average	Standard deviation
Supine MFTA in extension (º)		-0.5	2.5	-1.5	2.4	-1.0	2.5
Flexion / extension (º)		1.7	4.7	3.5	5.1	2.6	4.9
Varus in extension (mm)		4.5	3.4	2.5	3.1	3.5	3.4
Valgus in extension (mm)		4.4	3.6	8.2	3.4	6.3	4.0
AP laxity (mm)	0º	10.1	3.3	10.2	3.6	9.9	3.5
	15º	15.2	4.4	14.2	5.7	14.7	5.1
	30º	18.6	4.8	16.6	5.0	17.6	5.0
	45º	18.6	4.3	17.1	5.5	17.9	5.0
	60º	16.2	3.9	16.8	5.8	16.5	4.9
	75º	15.7	4.1	18.0	6.2	16.9	5.4
	90º	14.0	5.2	17.0	7.4	15.5	6.5
Medial rotation (º)	0º	2.6	2.2	4.1	3.2	3.3	2.8
	15º	6.0	3.6	5.0	4.2	5.5	3.9
	30º	7.2	4.3	6.1	5.2	6.6	4.8
	45º	6.5	3.9	4.3	5.1	5.4	4.6
	60º	8.8	3.1	14.3	2.7	11.5	3.1
	75º	7.2	3.1	13.8	2.7	10.5	3.2
	90º	7.8	3.0	12.8	3.4	9.4	3.6
Lateral rotation (º)	0º	10.8	3.1	9.9	4.4	10.4	3.8
	15º	10.5	4.7	12.8	5.3	11.7	5.1
	30º	10.6	5.2	13.6	6.7	12.1	6.2
	45º	10.5	4.9	14.6	7.0	12.5	6.4
	60º	5.8	4.1	3.7	5.6	4.75	5.6
	75º	5.9	3.7	3.4	6.5	4.7	6.3
	90º	6.0	3.7	4.3	5.8	6.0	5.9
Pivot-shift test	Anterior draw (mm)	43.5	17.3	40.4	16.3	42.0	16.8
	Rotation (º)	25.0	9.3	37.6	11.2	31.3	12.1
Maximum flexion (º)		148.3	6.4	147.7	8.1	148.0	7.3
Bi-pedal loaded MFTA (º)		-0.1	4.9	-2.0	4.1	-1.0	4.6
Bi-pedal loaded MFTA flexion / extension (º)		-2.5	11.5	-4.2	8.9	-3.3	10.2
Mono-pedal loaded MFTA (º)		-1.0	4.3	-2.4	4.7	-1.7	4.5
Monopedal loaded MFTA flexion / extension (º)		0.6	9.2	-1.0	8.2	-0.2	8.7

Appendix 13 (Summary results from both Examiners assessment on all 25 volunteers left leg)

Table N depicting average ***left leg data*** acquired from all volunteers by both Examiners							
Assessment		**Examiner 1**		**Examiner 2**		**Overall**	
		Average	Standard deviation	Average	Standard deviation	Average	Standard deviation
Supine MFTA in extension (º)		0.1	2.1	0.1	2.7	0.1	2.4
Flexion / extension (º)		0.0	4.9	0.3	4.8	0.0	4.8
Varus in extension (mm)		4.6	3.4	2.7	3.6	3.6	3.6
Valgus in extension (mm)		4.6	3.5	6.8	3.5	5.7	3.6
AP laxity (mm)	0º	9.6	3.0	9.6	3.2	9.8	3.1
	15º	14.3	3.0	13.3	4.2	13.8	3.7
	30º	17.3	3.5	14.5	5.2	15.9	4.6
	45º	16.2	4.4	14.5	5.6	15.4	5.1
	60º	14.3	4.9	13.9	4.7	14.1	4.8
	75º	13.7	4.8	14.8	5.0	14.2	4.9
	90º	13.1	5.3	13.8	6.0	13.5	5.6
Medial rotation (º)	0º	3.0	2.7	4.5	3.6	3.8	3.2
	15º	6.5	3.7	5.3	4.3	5.9	4.1
	30º	7.8	4.8	6.2	3.8	7.5	4.5
	45º	6.9	4.1	5.6	3.6	6.2	3.9
	60º	7.7	3.4	7.8	4.4	7.8	4.0
	75º	8.0	3.9	7.5	4.2	7.7	4.0
	90º	9.3	3.8	8.4	4.5	8.8	4.2
Lateral rotation (º)	0º	10	3.5	7.3	4.0	8.7	4.0
	15º	7.5	3.7	9.9	4.3	8.7	4.1
	30º	8.8	3.8	10.0	5.3	8.9	4.7
	45º	9.0	4.3	9.6	5.2	9.3	4.8
	60º	5.8	3.7	5.9	3.8	5.9	3.9
	75º	5.1	3.8	7.4	4.3	6.2	4.2
	90º	5.3	8.4	6.1	3.0	5.7	6.3
Pivot-shift test	Anterior draw (mm)	42.4	18.5	42.3	18.1	42.4	18.9
	Rotation (º)	23.2	7.7	28.5	9.2	25.8	8.9
Maximum flexion (º)		148.5	6.4	150.5	8.3	149.5	7.4
Bi-pedal loaded MFTA (º)		1.6	4.9	2.1	4.5	1.9	4.7
Bi-pedal loaded MFTA flexion / extension (º)		-5.2	9.5	-7.1	8.7	-6.2	9.1
Mono-pedal loaded MFTA (º)		1.1	4.7	1.5	5.0	1.3	4.8
Monopedal loaded MFTA flexion / extension (º)		-3.1	9.0	-2.2	7.9	-2.7	8.4

Appendix 14 (Inter-Examiner reliability and repeatability - AP laxity and rotation - Interclass correlation coefficient (ICC))

All 25 volunteers

To assess the reliability of AP laxity assessment between Examiner 1 and Examiner 2, interclass correlation coefficient (ICC) were calculated for all 25 volunteers assessed and are shown in the table below.

The ICCs' calculated for Examiner 1 shows poor reliability for AP laxity assessment throughout the range of flexion. Examiner 2 demonstrated a similar pattern of poor reliability for AP laxity assessment throughout the range of flexion. The comparison ICC between Examiner 1 and Examiner 2 demonstrates poor comparability between the AP laxity assessments from 0º to 60º.

ICC calculations for the tibial rotation at 0º performed by both Examiners is shown in the table below. Examiner 1 showed extremely poor reliability at 0º medial rotation (0.07) and poor reliability for 0º lateral rotation (0.64). Examiner 2 demonstrated equally poor reliability at 0º medial and lateral rotations. Once again there was poor comparability between the two Examiners at 0º medial (0.06) and 0º lateral (0.05) rotation.

***Table O**: AP laxity and tibial rotation Interclass correlation coefficient (ICC) for all 25 volunteers assessed by both Examiners*

Assessment	Examiner 1	Comparison	Examiner 2
AP shift 0º	0.55 (0.31;0.72)	0.14 (-0.15;0.41)	0.44 (0.18;0.64)
AP shift 15º	0.57 (0.34;0.74)	0.28 (0.00;0.51)	0.42 (0.15;0.63)
AP shift 30º	0.59 (0.32;0.73)	0.32 (0.09;0.55)	0.28 (-0.00;0.53)
AP shift 45º	0.55 (0.33;0.78)	0.45 (0.19;0.65)	0.25 (-0.02;0.50)
AP shift 60º	0.54 (0.27;0.70)	0.30 (0.03;0.54)	0.14 (-0.15;0.41)
Medial rotation 0º	0.07 (-0.22;0.35)	0.06 (-0.35;0.28)	0.13 (-0.15;0.40)
Lateral rotation 0º	0.64 (-0.43;0.78)	0.05 (-0.33;0.23)	0.15 (-0.14;0.42)

Table O AP laxity and tibial rotation Interclass correlation coefficient (ICC) for all 25 volunteers assessed by both Examiners

Last 15 volunteers

Reliability (ICC) calculations for the AP laxity assessment from 0º to 90º of flexion for Examiner 1 and Examiner 2 post-learning curve on the last 15 volunteers assessed were calculated and are shown in the table below.

The ICC calculated for Examiner 1 is more reliable throughout the range of flexion, when compared to all 25 volunteers assessed. Examiner 1 demonstrated good reliability at 30º, 45º and 60º assessments. Poor reliability is demonstrated at 0º, 15º, 75º and 90º increments.

The ICC calculated for Examiner 2 shows poor reliability throughout the range of flexion. The comparison reliability (ICC) between both Examiners is poor throughout the range of flexion, except at 90º (0.68) demonstrating poor comparability.

ICC calculation for the tibial rotation at 0º and 15º for both Examiners is shown in the table below. Examiner 1 demonstrated poor reliability at 0º and 15º medial rotation. Examiner 1 showed poor reliability at 0º lateral rotation (0.68), with an improved but still poor ICC at 15º lateral rotation (0.72).

Examiner 2 demonstrated a similar pattern of poor reliability at 0º and 15º medial rotation. Examiner 2 demonstrated poor reliability at 0º lateral rotation (0.44), with poorer reliability at 15º lateral rotation (0.28).

There was poor comparable reliability between both Examiners when assessing tibia rotation at 0º and 15º. Due to the poor reliability shown by both Examiners at 0º and 15º for tibia rotation, no further reliability (ICC) was calculated.

***Table P*: AP laxity and tibial rotation Interclass correlation coefficient (ICC) for the last 15 volunteers assessed by both Examiners**			
Assessment	**Examiner 1**	**Comparison**	**Examiner 2**
AP shift 0º	0.70 (0.45;0.84)	0.27 (-0.09;0.52)	0.50 (0.18;0.72)
AP shift 15º	0.72 (0.50;0.86)	0.35 (0.00;0.62)	0.48 (0.32;0.61)
AP shift 30º	0.82 (0.65;0.91)	0.39 (0.04;0.65)	0.71 (0.48;0.85)
AP shift 45º	0.82 (0.64;0.91)	0.54 (0.23;0.75)	0.47 (0.14;0.71)
AP shift 60º	0.79 (0.54;0.89)	0.35 (0.00;0.63)	0.46 (0.13;0.70)
AP shift 75º	0.76 (0.53;0.87)	0.19 (-0.17;0.51)	0.35 (-0.00;0.62)
AP shift 90º	0.73 (0.51;0.84)	0.68 (0.43;0.83)	0.67 (0.49;0.85)
Medial rotation 0º	0.41 (0.06;0.68)	0.07 (-0.29;0.41)	0.23 (-0.13;0.54)
Lateral rotation 0º	0.69 (0.43;0.83)	0.36 (-0.03;0.61)	0.44 (0.10;0.68)
Medial rotation 15º	0.20 (-0.16;0.52)	0.00 (-0.34;0.36)	-0.06 (-0.40;0.28)
Lateral rotation 15º	0.70 (0.49;0.85)	0.27 (-0.08;0.57)	0.28 (-0.08;0.57)

Table P AP laxity and tibial rotation Interclass correlation coefficient (ICC) for the last 15 volunteers assessed by both Examiners

AP laxity and rotation - Coefficient of repeatability (CR)

All 25 volunteers

The repeatability of AP laxity assessment through flexion was assessed for Examiner 1 and Examiner 2 on all 25 volunteers, and is shown in the table below. The CR calculated for Examiner 1 shows poor repeatability through flexion.

The repeatability (CR) calculated for Examiner 2 shows poor repeatability through flexion, with all AP assessments outside the acceptable 95% limits of agreement.

The repeatability (CR) calculated for the tibia rotation for both Examiners is shown in the table below. Examiner 1 showed poor repeatability at 0º medial and lateral rotation. Examiner 2 showed poor repeatability at 0º medial and lateral rotation.

***Table Q*: AP laxity and tibial rotation Coefficient of repeatability (CR) for all 25 volunteers assessed by both Examiners**		
Assessment	**Examiner 1**	**Examiner 2**
AP shift 0º	4.41	6.10
AP shift 15º	5.80	7.32
AP shift 30º	4.22	9.90
AP shift 45º	4.54	10.71
AP shift 60º	4.54	12.68
Medial rotation 0º	6.53	11.16
Lateral rotation 0º	5.47	8.82

Table Q AP laxity and tibial rotation Coefficient of repeatability (CR) for all 25 volunteers assessed by both Examiners

Last 15 volunteers

The repeatability of AP laxity assessments through flexion for both Examiners for the last 15 volunteers is shown in the table below. There was an improved repeatability (CR) for Examiner 1 through flexion with good repeatability at 30º, 45º and 60º. Poor repeatability was demonstrated at 0º, 15º, 75º and 90º.

The repeatability (CR) calculated for Examiner 2 demonstrates poor repeatability through flexion.

The CR calculated for the tibial rotation for both Examiners is shown in the table below. Examiner 1 showed poor repeatability at 0º lateral rotation with poor repeatability at 15º lateral rotation, 0º and 15º medial rotation.

Examiner 2 demonstrated poor repeatability at 0º and 15º medial rotation, and 0º and 15º lateral rotation.

***Table R*: AP laxity and tibial rotation Coefficient of repeatability (CR) for the last 15 volunteers assessed by both Examiners**		
Assessment	**Examiner 1**	**Examiner 2**
AP shift 0^o	3.72	4.94
AP shift 15^o	4.78	5.69
AP shift 30^o	2.52	3.11
AP shift 45^o	2.92	6.25
AP shift 60^o	3.33	6.88
AP shift 75^o	4.64	8.87
AP shift 90^o	5.63	4.97
Medial rotation 0^o	5.07	8.00
Lateral rotation 0^o	4.20	6.15
Medial rotation 15^o	6.73	12.89
Lateral rotation 15^o	4.86	9.58

Table R AP laxity and tibial rotation Coefficient of repeatability (CR) for the last 15 volunteers assessed by both Examiners

Appendix 15 (Inter-Examiner reliability and repeatability – Pivot-shift test and maximum passive flexion - Interclass correlation coefficient (ICC))

All 25 volunteers

The reliability for both Examiners performance in assessing the pivot-shift test and maximum passive flexion assessments for all 25 volunteers is shown in the table below.

Examiner 1 reliability (ICC) for both the pivot-shift anterior draw (0.59) and pivot shift rotation (0.42) show poor reliability, with Examiner 2 demonstrating similarly poor reliability for both the pivot-shift anterior draw (0.59) and pivot shift rotation (0.49).
Examiner 1 reliability (ICC) for the maximum passive flexion was (0.78) demonstrating good reliability, with Examiner 2 demonstrating similarly good reliability (0.80).

The comparison ICC for both the pivot-shift anterior draw (0.02) and pivot shift rotation (0.08) are extremely poor. The comparison ICC for maximum passive flexion shows poor reliability (0.69) between both Examiners.

Table S: ***Pivot-shift test and maximum passive flexion Interclass correlation coefficients (ICC) for all 25 volunteers assessed by both Examiners***

Assessment	Examiner 1	Comparison	Examiner 2
Pivot-shift anterior draw	0.59 (0.37;0.75)	0.02 (-0.26;0.31)	0.59 (0.37;0.75)
Pivot-shift rotation	0.42 (0.15;0.63)	0.08 (-0.20;0.36)	0.49 (0.14;0.65)
Maximum passive flexion	0.78 (0.63;0.87)	0.69 (0.51;0.82)	0.80 (0.72;0.90)

Table S Pivot-shift test and maximum passive flexion Interclass correlation coefficients (ICC) for all 25 volunteers assessed by both Examiners

Last 15 volunteers

The reliability for both Examiners performance in assessing the pivot-shift test and maximum passive flexion assessments for the last 15 volunteers is shown in the table below.

The reliability (ICC) calculated for Examiner 1 improved in the last 15 volunteers assessed for both the pivot-shift anterior draw (0.64) and pivot-shift rotation (0.44), but still demonstrated poor reliability.

The reliability (ICC) calculated for Examiner 2 also improved in the last 15 volunteers assessed for the pivot-shift anterior draw (0.63) and pivot-shift rotation (0.53), still demonstrating poor reliability.

The reliability (ICC) for Examiner 1 maximum passive flexion improved (0.82) and showed good reliability, with Examiner 2 showing similar good reliability (0.83).

The comparable reliability between both Examiners for both pivot-shift anterior draw and pivot-shift rotation is poor, with poor comparable reliability shown between both Examiners for maximum passive flexion (0.69).

***Table T**: Pivot-shift test and maximum passive flexion Interclass correlation coefficients (ICC) for the last 15 volunteers assessed by both Examiners.*

Assessment	Examiner 1	Comparison	Examiner 2
Pivot-shift anterior draw	0.64 (0.37;0.79)	0.09 (-0.26;0.43)	0.63 (0.25;0.76)
Pivot-shift rotation	0.54 (0.20,0.69)	0.03 (-0.32;0.38)	0.53 (0.29;0.71)
Maximum passive flexion	0.82 (0.63;0.91)	0.69 (0.45;0.84)	0.83 (0.67;0.91)

Table T Pivot-shift test and maximum passive flexion Interclass correlation coefficients (ICC) for the last 15 volunteers assessed by both Examiners.

Pivot-shift test and maximum passive flexion - Coefficient of repeatability (CR)

All 25 volunteers

The repeatability for both Examiners performance in assessing the pivot-shift test and maximum passive flexion assessments for all 25 volunteers is shown in the table below.

Examiner 1 demonstrated poor repeatability at both the pivot-shift anterior draw (8.57) and pivot-shift rotation (12.32) assessments. The maximum passive flexion showed good repeatability (2.46).

Examiner 2 also demonstrated poor repeatability at both the pivot-shift anterior draw (8.60) and pivot-shift rotation (10.89) assessments. Examiner 2 maximum passive flexion showed good repeatability (2.25).

Table U: Pivot-shift test and maximum passive coefficient of repeatability (CR) for all 25 volunteers assessed by both Examiners

Assessment	Examiner 1	Examiner 2
Pivot-shift anterior draw	8.57	8.60
Pivot-shift rotation	12.32	10.89
Maximum passive flexion	2.46	2.25

Table U Pivot-shift test and maximum passive coefficient of repeatability (CR) for all 25 volunteers assessed by both Examiners

Last 15 volunteers

The repeatability for both Examiners performance in assessing the pivot-shift test and maximum passive flexion assessments for the last 15 volunteers is shown in the table below.

The repeatability (CR) calculated for the pivot-shift test for Examiner 1 improved in the last 15 volunteers when compared to all 15 volunteers assessed, but still showed poor repeatability for both the pivot-shift anterior draw (6.43) and the pivot-shift rotation (10.82).

Examiner 2 also improved his repeatability in pivot shift assessment for the last 15 volunteers assessed, but also showed poor repeatability for both the pivot-shift anterior draw (6.51) and the pivot-shift rotation (10.98).

The repeatability (CR) calculated for the maximum passive flexion for Examiner 1 was (1.52) showing good repeatability, with Examiner 2 demonstrating similarly good repeatability with a CR (1.48).

Table V: ***Pivot-shift test and maximum passive coefficient of repeatability (CR) for the last 15 volunteers assessed by both Examiners***

Assessment	**Examiner 1**	**Examiner 2**
Pivot-shift anterior draw	6.43	6.51
Pivot-shift rotation	10.82	10.98
Maximum passive flexion	1.52	1.48

Table V Pivot-shift test and maximum passive coefficient of repeatability (CR) for the last 15 volunteers assessed by both Examiners

Appendix 16 (Inter-Examiner reliability and repeatability – Bipedal and monopedal loaded MFTA - Interclass correlation coefficient (ICC))

All 25 volunteers

The reliability for both Examiners performance in assessing bipedal and monopedal load MFTA assessments for all 25 volunteers is shown in the table below. Examiner 1 demonstrated good reliability (0.76) for bipedal load MFTA acquisition, and poor reliability (0.66) for monopedal load MFTA acquisition.

Examiner 2 showed poor reliability for both bipedal (0.68) and monopedal (0.63) loaded MFTA. There was poor comparable reliability between both Examiners for both bipedal (0.33) and monopedal load MFTA (0.12) for all 25 volunteers.

***Table W**: Bipedal and monopedal loaded MFTA Interclass correlation coefficient (ICC) for all 25 volunteers assessed by both Examiners*

Assessment	Examiner 1	Comparison	Examiner 2
Bipedal loaded MFTA	0.76 (0.663;0.82)	0.33 (0.05;0.57)	0.68 (0.49;0.82)
Monopedal loaded MFTA	0.66 (0.456;0.79)	0.12 (-0.17;0.39)	0.63 (0.42;0.77)

Table W Bipedal and monopedal loaded MFTA Interclass correlation coefficient (ICC) for all 25 volunteers assessed by both Examiners

Last 15 volunteers

The reliability results for the bipedal and monopedal loaded MFTA for the last 15 volunteers assessed by both Examiners are shown in the table below. Examiner 1 improved his reliability in the last 15 volunteers, still demonstrating good reliability for bipedal loaded MFTA (0.80), and poor reliability for monopedal load MFTA (0.72).

Examiner 2 also improved his reliability in assessing the last 15 volunteers, and demonstrated good reliability for bipedal loaded MFTA (0.76), and poor reliability for monopedal load MFTA (0.70).

The comparable reliability between both Examiners is poor for both bipedal load MFTA (0.49) and monopedal load MFTA (0.26).

Table X: ***Bipedal and monopedal loaded MFTA Interclass correlation coefficient (ICC) for the last 15 volunteers assessed by both Examiners***			
Assessment	**Examiner 1**	**Comparison**	**Examiner 2**
Bipedal loaded MFTA	0.80 (0.59;0.91)	0.49 (0.08;0.68)	0.76 (0.58;0.88)
Monopedal loaded MFTA	0.72 (0.48;0.85)	0.26 (-0.10;0.54)	0.70 (0.45,0.85)

Table X Bipedal and monopedal loaded MFTA Interclass correlation coefficient (ICC) for the last 15 volunteers assessed by both Examiners

Bipedal and monopedal loaded MFTA - Coefficient of repeatability (CR)

All 25 volunteers

To assess the repeatability of the bipedal and monopedal load MFTA acquired for all 25 volunteers assessed by Examiner 1 and Examiner 2, repeatability coefficients (CR) were calculated and are shown in the table below.

Examiner 1 CR for the bipedal load MFTA was (2.62) demonstrating good repeatability, with the CR for monopedal load MFTA (4.98) depicting poor repeatability. Examiner 2 showed poor repeatability for bipedal load MFTA (4.03), and monopedal loaded MFTA (5.23).

Table Y: Bipedal and monopedal loaded MFTA Coefficient of repeatability (CR) for all 25 volunteers assessed		
Assessment	**Examiner 1**	**Examiner 2**
Bipedal loaded MFTA	2.62	4.03
Monopedal loaded MFTA	4.98	5.23

Table Y Bipedal and monopedal loaded MFTA Coefficient of repeatability (CR) for all 25 volunteers assessed

Last 15 volunteers

Assessing the bipedal loaded MFTA post learning curve for the last 15 volunteers assessed Examiner 1 demonstrated an improved repeatability (CR) for bipedal load MFTA (1.87) and monopedal load MFTA improving to (2.25), improving to good repeatability.

Examiner 2 also demonstrated an improved repeatability for bipedal loaded MFTA (2.98) demonstrating good repeatability, and poor repeatability for the monopedal load MFTA (3.35) just out with the 95% confidence interval for last 15 volunteers assessed.

Table Z: Bipedal and monopedal loaded MFTA Coefficient of repeatability (CR) for the last 15 volunteers assessed		
Assessment	**Examiner 1**	**Examiner 2**
Bipedal loaded MFTA	1.87	2.25
Monopedal loaded MFTA	2.98	3.35

Table Z Bipedal and monopedal loaded MFTA Coefficient of repeatability (CR) for the last 15 volunteers assessed