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Development and Validation of a Functional Outcome Measure Package for Total Knee Arthroplasty

By

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This thesis is submitted in fulfilment of the requirements for the degree of PhD in Biomedical Engineering

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Copyright Statement

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Cydnabyddiadau

Yn gyntaf, hoffwn ddiolch o galon i fy nheulu am eu cymorth trwy gydol fy amser yn y brifysgol, yn enwedig dros y tair mlynedd ddiwethaf. Heb help ariannol a chyngor dad, mam a mamgu, ni fyswn i wedi gallu aros yn y brifysgol cyhyd i astudio ac i weithio tuag at y doethuriaeth yma. Hoffwn hefyd ddiolch i ddau o fy ffrindiau gorau; fy mrodyr Goronwy a Gerallt. 'Rydych wedi bod yn arbennig dros y blynyddoedd diwethaf. Bob tro yr oeddwn yn teimlo straen y gwaith, 'roedd y ddau ohonoch yn gallu gwneud i mi wenu a chwerthin. 'Rwy'n lwcus iawn i gael teulu sydd mor ddeallus a chefnogol.

Hoffwn hefyd ddiolch i fy ffrindiau ysgol, sydd wedi fy nghefnogi (yn ffisegol ac yn emosiynnol!) dros y blynyddoedd diwethaf. 'Rwy'n edrych ymlaen i wario mwy o amser gyda chi yn Aberystwyth yn y dyfodol, ac 'rwy'n siwr eich bod chi'n edrych ymlaen i glywed fi'n siarad am unrhywbeth heblaw am y doethuriaeth yma!

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Abstract

Functional improvement is an important outcome following total knee arthroplasty (TKA). According to recent research, three-dimensional motion analysis is the most scientific method of measuring dynamic knee function. Nevertheless, current protocols are too time consuming and complicated for routine clinical use. This study developed a clinic-appropriate motion capture system, and investigated the feasibility of its use in a clinical environment.

A compact motion capture system (Dimensions: 3.5(L)x2.1(H)x1.1(W)m) and bespoke cluster-based biomechanical model were developed. Assessments for quantifying knee range of motion (ROM), knee strength, gait kinematics, and gait stability were incorporated into the software. Most results were reported in real-time.

Validation studies of the assessments against clinical standard tools showed few clinically significant differences between the results, suggesting that the assessments could be used as accurate and reliable alternatives to the traditional tools. The system was then used clinically to report the functional outcome of Medacta GMK Sphere TKA patients. Patients underwent functional testing pre-, 6-weeks, and 1-year post-operatively. Average recorded assessment time was 16.8±2.4 minutes.

On average, knee ROM, gait kinematics, spatio-temporal parameters of gait and gait stability improved post-operatively. Knee strength decreased over the first year however, suggesting that TKA patients require strength training post-operatively in order to optimise functional outcome.

The results reported in this trial were generally consistent with the current literature, implying that the system returned valid data for this patient cohort, and that the Medacta GMK Sphere TKA was successful at improving knee function, especially in frontal and transverse planes during gait.

To conclude, this thesis has shown that motion capture technology can feasibly be used in the clinical environment to assess the function of TKA patients in an

acceptable clinical timeframe. The system developed and presented here can therefore justifiably be used clinically to better report the functional outcome of TKA.

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List of Abbreviations

Abbreviation	Definition
ACL	Anterior cruciate ligament
AJC	Ankle joint centre
ASIS	Anterior superior iliac spine
CNS	Central nervous system
COM	Centre of mass
CRF	Clinical report form
DOF	Degrees of freedom
EQUAL	Extending Quality of Life (Project)
GA	Gait analysis
GMK	Global Medacta Knee
GT	Greater trochanter
HJC	Hip joint centre
JCS	Joint co-ordinate system
KJC	Knee joint centre
LCL	Lateral collateral ligament
MCL	Medial collateral ligament
NHS	National Health Service
NJR	National Joint Registry
OA	Osteoarthritis
OKS	Oxford Knee Score
ORT	Orthogonal/Perpendicular to the uncontrolled manifold
PCL	Posterior cruciate ligament
PROM	Patient reported outcome measure
PSIS	posterior superior iliac spine
ROM	Range of motion
SD	Standard deviation
SEM	Standard error of the mean
SF	Short form
TFJ	Tibiofemoral joint
TKA	Total knee arthroplasty
UCM	Uncontrolled manifold
UHMWPE	Ultra-high molecular weight polyethylene
UKA	Unicondylar knee arthroplasty
VAS	Visual Analogue Scale
WOMAC	Western Ontario & McMasters Universities Osteoarthritis Index

List of Publications

Tawy, G.F., Rowe, P.J., Biant, L.C. Gait variability and motor control in patients with knee osteoarthritis as measured by the uncontrolled manifold technique (**2018**). Gait & Posture **59:** 272-277. (Impact Factor: 2.35)

Tawy, G.F., Rowe, P (**2017**). Is the instrumented-pointer method of calibrating anatomical landmarks in 3D motion analysis reliable? Journal of Biomechanics **53:** 205-209. (Impact Factor: 2.66)

Conference Proceedings

Tawy, G.F., Simons, M.R., Biant, L.C., Rowe, P.J. (**2017**). Investigating gait variability and motor control in knee osteoarthritis. International Society of Biomechanics Congress, Brisbane.

Tawy, G.F., Simons, M.R., Biant, L.C., Rowe, P.J. (**2017**). Use of a novel hospital-based motion analysis system to quantify functional outcome in total knee arthroplasty. International Society of Biomechanics Congress, Brisbane.

Tawy, G.F., Simons, M.R., Biant, L.C., Rowe, P.J. (**2017**). The correlation between patient reported outcome measures and advanced biomechanics in knee osteoarthritis. European Federation of National Associations of Orthopaedics and Traumatology Congress, Vienna.

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Simons, M.R., **Tawy, G.F.**, Rowe, P.J., Biant, L.C. (**2017**). The correlation between muscle strength and variability of gait in knee osteoarthritis. BASK, Liverpool.

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Awards

Winner: Motor Control Student Award (2017)
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Chapter 1. Introduction

Osteoarthritis (OA) is a progressive and debilitating disease which causes severe pain and reduced joint function (Callahan *et al.,* 2015; Marsh *et al.,* 2014). OA of the knee currently affects approximately 4 million people in the United Kingdom; over a quarter of whom are suffering severely from the disease (Osteoarthritis UK, 2016). The current clinical standard treatment for advanced knee OA is total knee arthroplasty (TKA) (Shimmin *et al.,* 2014). Despite its high prevalence, approximately 20% of patients are dissatisfied following TKA (Baker *et al.,* 2007; Selvan *et al.,* 2013). Studies have shown that these dissatisfaction rates are partly due to poor joint function following TKA (Benedetti *et al.,* 2003; Jevsevar *et al.,* 1993; Malviya *et al.,* 2009; Marsh *et al.,* 2014; Rossi *et al.,* 2002).

Patients who have limited joint function post-operatively are more likely to require further treatment (including surgery). This places considerable practical and economic pressure on orthopaedic health services that are already limited in their resources due to increasing TKA rates. TKA rates are growing due to an ageing population and a rise in obesity prevalence (Elbaz *et al.,* 2014; NHS, 2014; Suri *et al.,* 2012). Moreover, younger patients with high activity levels are now routinely undergoing TKA for OA (Brennan *et al.,* 2015; Kurtz *et al.,* 2009). As a consequence, a higher percentage of people are also outliving their prostheses and requiring revision procedures (Greidanus *et al.,* 2011).

These facts highlight the growing importance of optimising functional outcome of patients following TKA. A tool capable of identifying functional deficits is necessary to enable clinicians to develop personalised pre/rehabilitation treatment plans for patients. Such a tool should quantitatively and objectively report key variables which influence knee function and mobility.

Variables which directly influence knee function and mobility are knee range of motion (ROM), knee strength, lower limb kinematics and stability during dynamic

movements. Although the relationship between these variables and the overall functional outcome has been established, these variables are poorly monitored in the orthopaedic environment.

The flexion-extension ROM of the knee is the most commonly monitored functional outcome following TKA as it is believed to represent the overall condition of the joint (Austin *et al.,* 2008; Cleffken *et al.,* 2007; Miner *et al.,* 2003). The clinical standard outcome measure used to assess knee ROM is the manual goniometer. This tool is affordable and portable, but it cannot be used to assess dynamic ROM (Croxford *et al.,* 1998; Rowe *et al.,* 2002). Research has also shown the goniometer to have poor intra-observer reliability and accuracy; especially at high flexion (Austin *et al,* 2008; Edwards *et al.,* 2004; Lavernia *et al.,* 2008; Myles *et al.* 2002). Modern TKA implants designed to facilitate high-flexion are now being commonly used in the orthopaedic environment; thus, an alternative method of reporting knee ROM is becoming increasingly necessary (Lavernia *et al.,* 2008).

Poor knee muscular strength has been linked to pathological gait and reduced mobility in OA patients (Bemben *et al*., 1991; Patterson *et al*., 2008 cited in Callahan *et al*., 2015; Teixiera & Olney, 1996). However, knee strength is rarely reported in the clinical environment, as clinicians do not have access to the appropriate tools. Routine assessments of muscular strength could allow clinicians to identify and address weaknesses which may otherwise deteriorate with time (Henriksen *et al.,* 2011; National Isometric Muscle Strength Database Consortium, 1996).

Walking kinematics and stability can also be affected in this patient group, particularly during mid-flexion following TKA. The current clinical standard method for recording lower limb kinematics is 3D gait analysis (Meldrum *et al.,* 2014). The motion capture technology used during gait analyses is highly effective at detecting changes in the function of the knee joint pre- and post-operatively (Andriacchi & Dyrby, 2005; Hossain *et al*., 2013). This technology can therefore be used to identify patients who would benefit from gait retraining therapy or focused

rehabilitation. It also has the potential to identify mid-flexion instability in patients following TKA. However, due to economic and practical reasons, it is rarely used clinically. As a consequence, many patients continue to have unstable and pathological gait post-operatively. Their mobility therefore continues to be limited.

At present, the orthopaedic environment lacks a standardised functional outcome measurement protocol. The aim of this thesis is therefore to develop a clinic-appropriate motion capture system which could be used by health professionals to assess knee ROM, strength and gait kinematics. We will also investigate the possibility of using motion capture technology to quantify gait stability and identify any mid-flexion instability in TKA. The feasibility of using motion capture technology in the orthopaedic environment will be explained. If successful, such systems could be used in future to aid clinical decision making and improve TKA functional outcome.

1.1 Outline of Investigation

1. Review the current literature and identify the advantages and disadvantages of traditional orthopaedic outcome measures.

2. Review traditional functional outcome measures and develop ideas for ways in which they could be improved when measuring knee function.

3. Design a clinic-appropriate motion capture system.

4. Develop a software application that uses motion capture technology to assess the key features of knee function.

5. Validate the functional assessments against the current clinical standard methods.

6. Use the bespoke motion capture system in a hospital setting to test the feasibility of its use in a clinical environment when assessing a state of the art implant: Medacta GMK Sphere.

7. Record and analyse the functional outcome of Medacta GMK Sphere TKA patients with the bespoke motion capture system and compare the results to other implants and systems.

1.2 Main Aims

The aims of this project are to design, develop and validate a clinic-appropriate motion capture system which could be used to assess knee function in pre- and post-operative TKA patients, and to use it to assess the Medacta GMK Sphere implant.

1.3 Main Research Questions

Is clinical motion analysis a feasible and valid orthopaedic outcome measure?

Does the Medacta GMK Sphere offer an improvement in function compared to other implants?

1.4 Thesis Outline

This thesis has been organised as follows:

Chapter 2 Literature Review: This chapter provides the reader with an extensive review of the literature currently available on the main topics covered by this research. The chapter begins with a description of the anatomy and physiology of a healthy knee joint. This is followed by descriptions of functional changes that occur in the knee with the onset of OA, focusing on knee range of motion, strength and dynamic stability. The conservative and surgical treatments for OA are then

discussed. The tools currently used to assess the functional outcome of TKA are then described. The disadvantages to these methods are highlighted and the argument for using motion capture technology to assess the outcome of TKA as an alternative to current methods is then given. Finally, the limitations to current motion capture protocols are outlined. This literature review also identifies the lack of a method in current orthopaedic practice to identify mid-flexion instability following TKA, and suggests that motion capture technology may provide clinicians with a means of identifying this common post-operative problem.

The purpose of this literature review is to inform the reader of the limitations of current outcome measures used in orthopaedics and show that clinical motion capture technology could offer a plausible alternative.

Chapter 3 Product Proposal: A proposal for a motion capture system that is appropriate for clinical use is presented in this chapter. The chapter begins with key research questions that will be answered in this thesis. Following this are the specific aims and objectives of this study. A description of the ways in which the proposed system will improve on current motion capture technology and protocols is then given. This is divided into five separate sections. The first describes the proposed features the system will have to optimise accessibility and acceptability of 3D motion capture technology to clinicians and patients. The following four sections are applications that will be developed for use with the clinic-appropriate system. These will assess knee range of motion, isometric knee strength, gait kinematics and gait stability; all of which are variables that were established in Chapter 2 as being essential for normal knee function and mobility.

Chapter 4 Product Development: This chapter explains in detail the ways in which the product proposed in Chapter 3 was developed. The hardware used to design the clinic-appropriate system is described, followed by a description of how the traditional software was simplified to suit clinical environments and clinicians. The methods used to develop all four assessments are then described.

Chapter 5 Product Validation: Chapter 5 presents three validation studies that were carried out following the development of the product. The first study presents data collected on the reliability of the calibration pointer used with the system to identify anatomical landmarks for generating the biomechanical model. The second presents data on the validity of the knee ROM and isometric knee strength assessments. Finally, data on the use of the uncontrolled manifold as a method of quantifying stability during gait is given.

Chapter 6 Clinical Trial Methodology: This chapter describes how the validated system was used in a clinical trial of the Medacta GMK Sphere to report the functional outcome of these TKA patients. The chapter outlines the trial and describes the statistical analyses carried out on the data collected. Chapter 6 also explains how biomechanical data of healthy older adults from a previous study were used for comparison against the results recorded in the TKA trial.

Chapter 7 Results: Chapter 7 presents the results on the data recorded by the methods described in Chapter 6. Two case studies are given to highlight the sensitivity of the product, followed by group analyses.

Chapter 8 Discussion: This chapter discusses the results reported in Chapter 7. The data is compared to previously published TKA research and data from healthy older adults.

It also discusses in detail the feasibility of using the system developed in this study in the orthopaedic environment to routinely report knee function in TKA. A critical discussion of the use of the uncontrolled manifold method for quantifying gait stability and identifying mid-flexion instability in TKA is also given. Advantages and disadvantages of the methods used during the clinical trial are provided, along with the clinical implications of the study and intended future work. Comments on the future of 3D motion capture as a clinical outcome measure are given.

Chapter 9 Conclusions: The thesis concludes by returning to the research questions, aims, and objectives. A summary of the main conclusions of the study are given.

Chapter 2. Literature Review

This thesis will describe the development, validation and use of an outcome measure package to assess knee function pre- and post- total knee arthroplasty (TKA).

One of the main aims of TKA is to improve knee function. To be able to assess the outcome of TKA effectively, a comprehensive understanding of the anatomy and physiology of a healthy knee joint is required. This literature review will therefore begin by familiarising the reader with the typical form and function of an adult knee joint.

2.1. Form and Function of the Human Knee Joint

2.1.1. Gross Anatomy and Histology of the Knee Joint

The knee joint (Figure 2. 1) is defined as the articulation between the lateral and medial femoral condyles with the tibial plateau (tibiofemoral joint), as well as the articulation between the patellar notch of the femur with the posterior face of the patella (patellofemoral joint) (Romanes, 2010). Main movement of the knee occurs at the tibiofemoral joint; an incongruent pivot and hinge joint which has six degrees of freedom (Romanes, 2010). Hence, for the purpose of this thesis, any reference to 'the knee joint' (other than where stated) will be to the tibiofemoral joint (TFJ).

The knee is classed as a synovial joint, as it is surrounded by a synovium which secretes synovial fluid into the joint cavity (Romanes, 2010). Synovial fluid is required to nourish and lubricate the avascular articular cartilage situated within the joint. In addition to providing nourishment, this fluid aids with shock absorption during loading. Due to the incongruence of the joint, articular cartilage of the knee is thick.

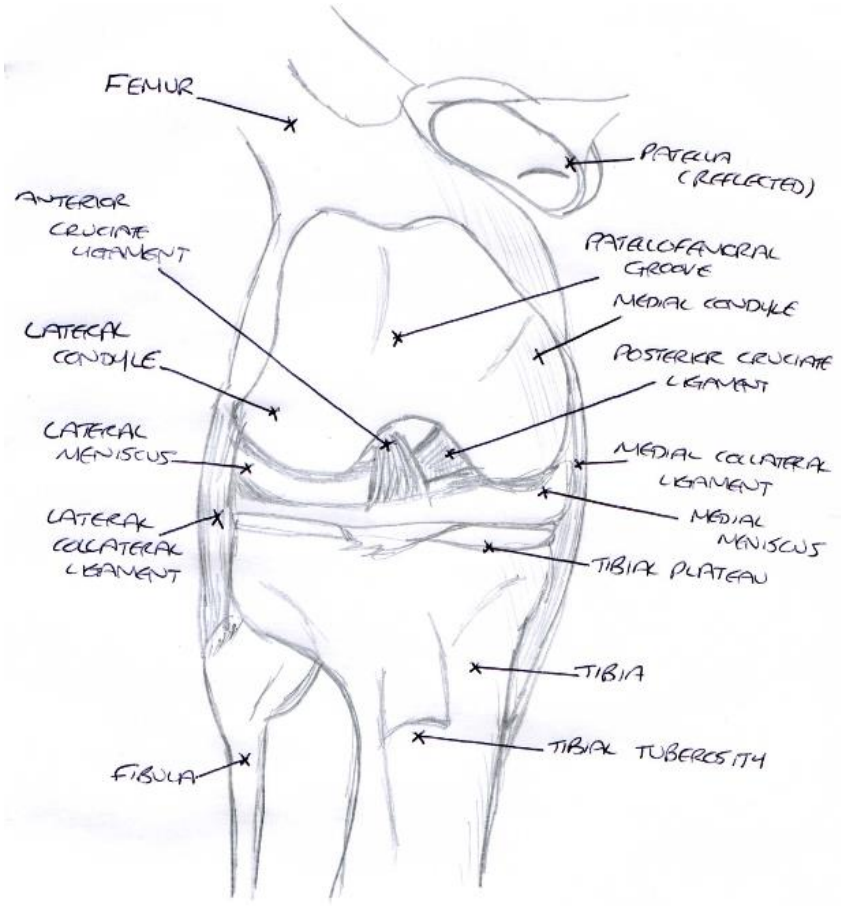


Figure 2. 1: Anatomical drawing of a healthy knee joint (Anterior view).

Microscopically, articular cartilage is structured and arranged in a way which allows it to resist deformation under stress and distribute the load evenly to the underlying subchondral-bone (Hendren & Beeson, 2009; Romanes, 2010). The collagen fibers nearest to the joint capsule are horizontally arranged to resist shear forces, whereas the deeper layers lie perpendicular to the subchondral plate. This allows compression forces to be transferred into, and absorbed by the subchondral-bone below. The cartilage also becomes calcified nearer the bone to aid with force transmission (Romanes, 2010).

2.1.2. Knee Stability

According to van der Esch *et al.* (2008) and Latash *et al.* (2007), a stable knee is one which is capable of maintaining its position and controlled movement of the limb under a variety of loads and perturbations. Thus, functional stability of the knee is essential for good mobility (Latash *et al.,* 2007; Mandeville *et al.,* 2008). Some joints of the human body are mainly stabilised passively due to high congruency of the articulating bones. Despite the fact that the menisci of the knee increase congruency of the joint, the stability of the knee depends upon soft tissue passive and dynamic restraint systems. These include all knee ligaments, the capsule surrounding the knee, as well as the active neuromuscular system (i.e. muscle strength and joint proprioception); all of which are vital for knee stabilisation.

The roles of the main stabilisers of the knee are shown in Table 2. 1. Please refer to Romanes, G.J., 2010, p. 214-221 for further information.

Table 2. 1: The main stabilisers of the knee joint.

Tissue Type	Anatomical Name	Action
Ligament	Anterior cruciate (ACL)	Prevents anterior dislocation and excessive internal/external rotation of tibia and collateral stability of joint
Ligament	Posterior cruciate (PCL)	Prevents posterior dislocation and excessive internal/external rotation of tibia and collateral stability of joint
Ligament	Medial Collateral (MCL)	Prevents medial dislocation of joint and stabilizes the joint medially
Ligament	Lateral Collateral (LCL)	Prevents lateral dislocation of joint and stabilizes the joint laterally
Bone, Muscle & Tendon	Patellar mechanism (Figure 2. 2): includes the patellar bone, the quadriceps muscles and the patellar tendon.	Prevents anterior dislocation of joint
Ligament	Oblique popliteal	This fibrous capsule extends posteriorly from the patellar tendon to strengthen the knee

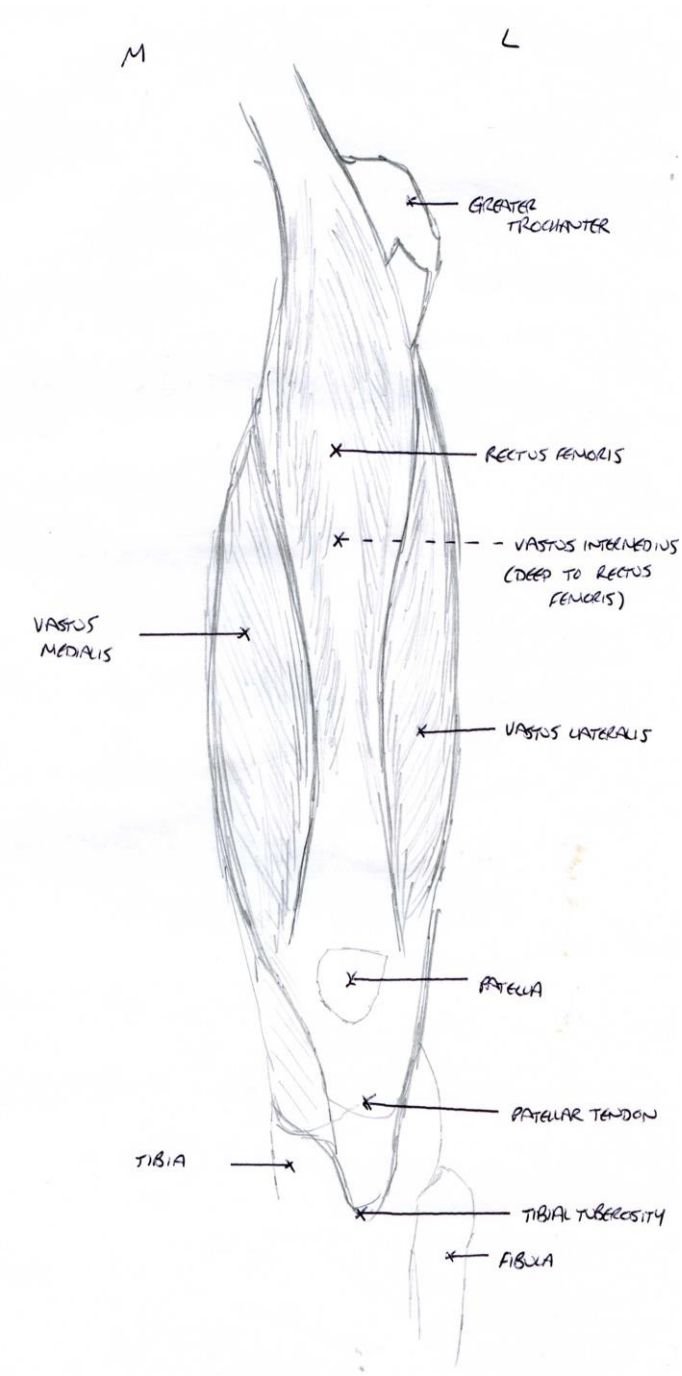


Figure 2. 2: Anatomical drawing of the quadriceps muscles and their insertion to the tibial tuberosity via the patellar tendon.

2.1.3. Knee Range of Motion

According to Shenoy *et al.* (2013), normal stability and alignment of the knee joint are essential, as these variables are responsible for controlling the relative movements of both bony surfaces against one another.

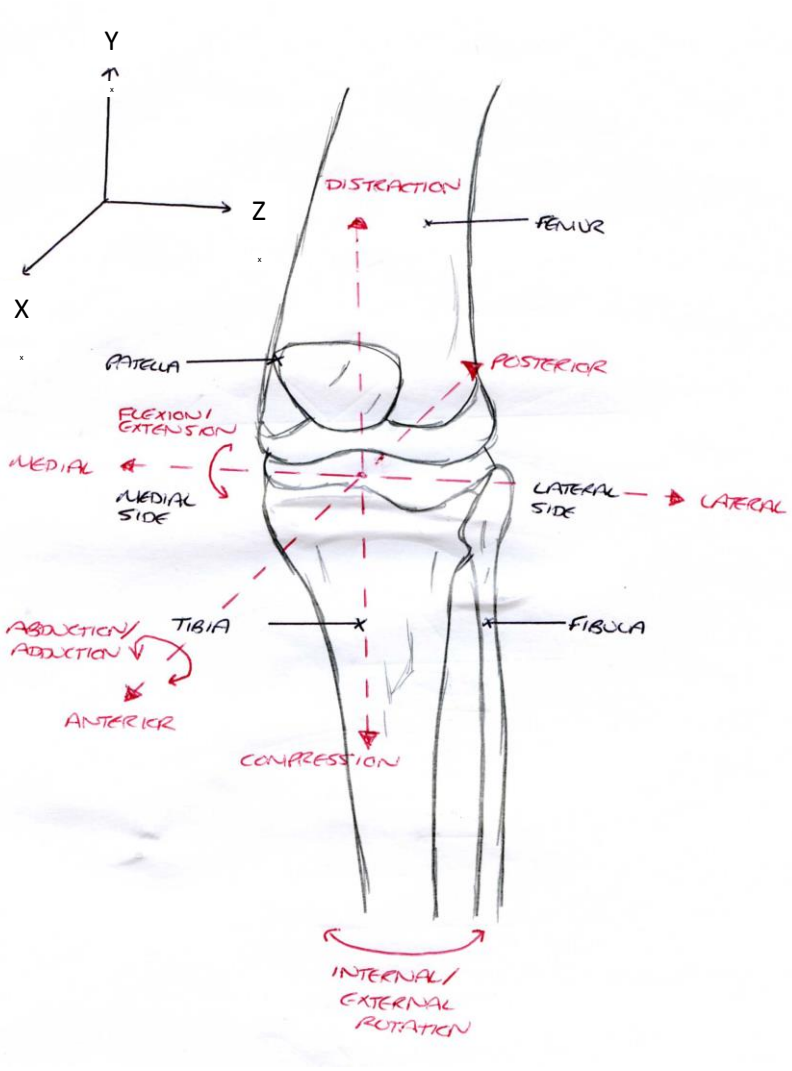


Figure 2. 3: Range of motion of the knee joint.

Figure 2. 3 shows that the knee translates in three orthogonal directions (along the X, Y, and Z axes), and rotates about each of these axes (Grood & Suntay, 1983). The conventional terminology for these translations and rotations with respect to the knee are also described in Figure 2. 3.

Flexion-Extension Rotations

The knee is fully extended when in the anatomical position. Here, and at flexion angles <20° the anterior/extensor femoral facets articulate with the tibial plateau (Figure 2. 4) (Iwaki *et al.,* 2000; Johal *et al.,* 2005). This does not differ between unloaded and loaded conditions (Hill *et al*., 2000). Contraction of the *quadriceps*, *gluteus maximus,* and the *tensor fasciae latae* cause extension of the knee. Hyperextension at the knee is prevented by the tautness of the knee ligaments; however, hyperextension of up to 5° is common (Koo *et al.,* 2011; Shenoy *et al.,* 2013). When these ligaments are taught, the lower leg and thigh become vertically aligned, forming a rigid column (Romanes, G.J., 2010, p.220).

The hamstrings (consisting of *semimembranosus, semitendinosus,* and *biceps femoris* muscles) are the most powerful knee flexors. At flexion angles of >20°, the posterior/flexion facet of the femur come into contact with the tibia (Figure 2. 4) (Hill *et al.,* 2000; Iwaki *et al.,* 2000; Johal *et al.,* 2005). Again, this is true for loaded and unloaded conditions (Hill *et al.,* 2000). Neuromuscular support is said to control flexion of the knee until approximately 120°. Beyond this point, flexion is believed to be passive due to the weight of the body (Rose & Gamble, 2006).

According to Shenoy *et al.* (2013), a healthy knee joint can flex up to 160°. Nevertheless, the degree of flexion required for most activities of daily living is approximately 110° (Insall *et al.,* 1979; Kettelkamp *et al.,* 1970; Laubenthal *et al.,* 1972; Morlock *et al.,* 2001; Rowe *et al.,* 2000). At least 60° flexion is necessary for normal walking, whilst a flexion of >115° at the knee is required for sitting down (Shenoy *et al.,* 2013). Greater knee range of motion may be required in some cultures, for example Asian cultures, where kneeling is required for prayer.

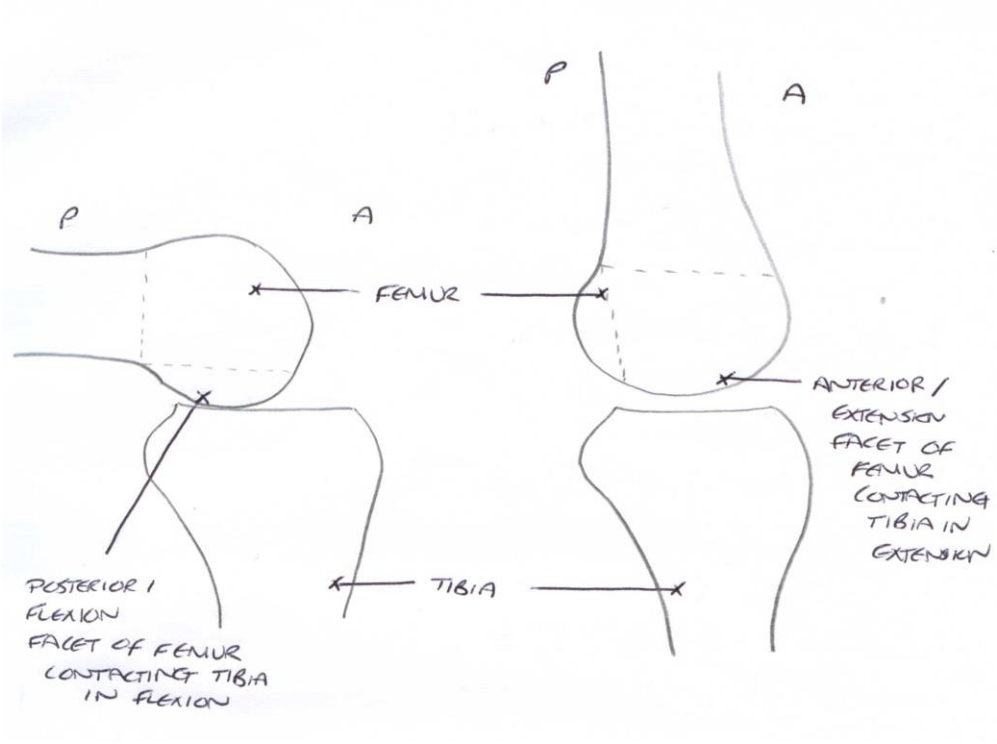


Figure 2. 4: A diagram of the knee in flexion (left) and extension (right) – highlighting the femoral facets in contact with the tibial plateau in each instance.

P = Posterior; A = Anterior

Anterior-Posterior Translations

Due to the fact that the lateral tibial plateau is flatter than the medial tibial plateau, anterior-posterior translations of the medial and lateral femoral condyles differ (Figure 2. 5). As a consequence, anterior-posterior translations of the knee influence the internal-external rotations of the joint.

The medial condyle of the femur is reported to translate anteriorly during flexion and posteriorly during extension (Hill *et al.,* 2000). The opposite is reported in the lateral condyle. The extents of these translations are far greater laterally due to the anatomy of the joint. These translations cause the femur to externally rotate during

knee flexion and internally rotate during extension (Cinotti *et al.,* 2012; Hill *et al.,* 2000).

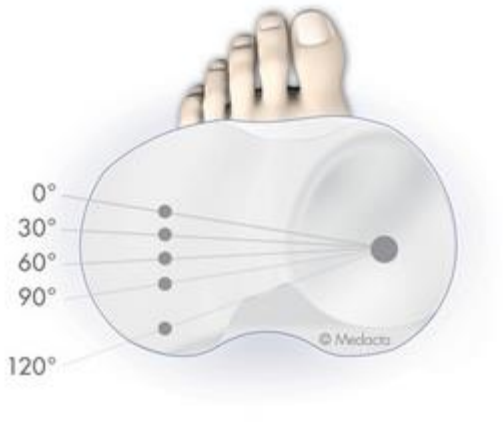


Figure 2. 5: A diagram of the anterior-posterior translations observed throughout knee flexion. Note the fact that little movement occurs medially.

(Source: Medacta International, 2015a)

Posterior translations of up to 25mm have been reported in the lateral compartment during flexion (Dennis *et al.,* 2005; Johal *et al.,* 2005; Pinskerova *et al.,* 2004). When unloaded, the lateral condyle has been reported to translate posteriorly by 4mm between 5° of hyperextension and full extension (0°). It further translates posteriorly by 1mm between 0° and 60° of flexion, then by 13mm between 60° and 110° (Hill *et al*., 2000). Posterior translation during flexion is greater under loaded conditions in this condyle (Hill *et al*., 2000). This mechanism is believed to reduce patellar load and prevent the soft tissues surrounding the joint from becoming impinged as the knee reaches high flexion (Shenoy *et al*., 2013).

Medially, little to no translation has been reported during unloaded conditions (Dennis *et al*., 2005; Hill *et al*., 2000; Johal *et al*., 2005; Pinskerova *et al*., 2004).

However, Hill and colleagues stated that the medial condyle can translate by approximately 4mm anteriorly between 10-45° of flexion when loaded.

It can therefore be deduced that very slight translation of the medial condyle may be observed during gait. This could be coupled with a substantial translation of the lateral condyle in the opposite direction (posterior during flexion and anterior during extension) (Figure 2.5). Gait analysis by Lafortune and colleagues showed this in 1992. Up to 10mm of posterior translation was observed during stance phase. This doubled as the knee flexed to 60° during swing. As the knee extended in the second half of the swing phase, an anterior translation back to neutral was observed (Lafortune *et al*., 1992).

Internal-External Rotations

External rotation of the femur (internal rotation of the tibia) occurs during knee flexion, and internal rotation of the femur (external rotation of the tibia) occurs during knee extension (Cinotti *et al.,* 2012; Hill *et al.,* 2000).

In an unloaded knee the extent of this rotation is 20-30° (Dennis *et al.,* 2005; Hill *et al.,* 2000; Lu *et al.,* 2008). MRI studies by Hill and colleagues (2000) showed that the femur externally rotated by 4° between -5° and 0° knee flexion. A further 1° external rotation was observed between 0° and 60° flexion. The greatest amount of external rotation however (15°), was observed beyond 60° knee flexion. This study was supported by Freeman & Pinskerova (2005) who reported that internal-external rotation of the knee joint is minimal up to 90° flexion. Later studies by Lu *et al.* (2008) and Maderbacher *et al.* (2016) also supported this by showing that the knee rotates by approximately 5-8° between full extension and 90° of flexion.

When the joint is loaded, external rotation of the tibia during full extension 'locks' the knee. This is commonly referred to as the 'screw home mechanism' (Shenoy *et al.*, 2013). This mechanism allows humans to stand quietly for long periods of time without expending large amounts of energy (Shenoy *et al.,* 2013).

A cadaveric study by Liu-Barba *et al.* (2007) found that femora fixed at 30° flexion externally rotated by up to 6° as a load of up to two times body weight was applied to them. Belvedere and colleagues (2011) and Lu *et al.,* (2008) supported this finding by showing that the loaded femur externally rotated by up to 20° when moved through the arc of flexion.

Rotation of the knee in this plane is the most variable output in gait analysis due to differences in biomechanical models as well as inter-individual variability. This rotation is believed to be overestimated in many kinematic studies due to third-angle calculated errors known as cross-talk (Millar, 2017). However, based on cadaveric studies on loaded knees, it can be estimated that the rotation in this plane would not exceed 20° during gait, where knee flexion does not typically exceed 60°. Lu *et al.* (2008) showed that the loaded knee joint rotated by 15° between 0° and 60° knee flexion.

Compression-Distraction Translations

Due to the presence of menisci, the knee joint is also capable of compression-distraction translations (Luger *et al.,* 1997). Healthy knee joints have been found to translate by 2-7mm in this direction, with greatest compression occurring when the joint is fully loaded (Shenoy *et al.,* 2013; Lafortune *et al.,* 1992). Distraction occurs with knee flexion, and compression occurs with extension (Lafortune *et al.,* 1992).

A distraction of 3.2mm was reported by Lafortune and colleagues (1992) at heel strike during a gait analysis. This was followed by a greater distraction of 7.0mm during the swing phase. The joint was compressed when extended and fully loaded (Lafortune *et al.,* 1992).

Valgus-Varus Rotations

According to a study by Yu *et al.* (1997), valgus-varus rotations of the knee are heavily dependent upon knee flexion-extension rotations. Adduction of the tibia

(varus rotation) occurs as the knee flexes, and abduction of the tibia (valgus rotation) occurs during knee extension.

Lu and colleagues (2008) showed in a fluoroscopic study that an unloaded knee joint adducts by approximately 5° as the knee flexes from full extension to 120° flexion. Little change was observed under loaded conditions. Their study agreed with Liu-Barba and colleagues (2007), who reported a maximum rotation of 2° in a loaded cadaveric knee fixed at 30° flexion.

Despite these studies showing little rotation beyond 5° in the frontal plane, gait analyses have shown valgus-varus kinematics to range by up to 12° throughout the cycle, with greatest adduction occurring during swing phase (Bytyqi *et al*., 2014; Ferrari *et al*., 2008; Kabada *et al*., 1990; Lafortune *et al.,* 1992; Shenoy *et al.,* 2013; Teixeira & Olney, 1996; Yu *et al.,* 1997).

Medio-Lateral Translations

A recent fluoroscopic study reported that the knee joint translates medio-laterally by approximately 5mm when unloaded (Lu *et al.,* 2008). Similar results have been reported under loaded conditions. For example, the tibia has been reported to translate medially by approximately 5mm during static, lunging, and chair-rising exercises (Belvedere *et al.,* 2011; Li *et al.,* 2007; Lu *et al.,* 2008).

In gait, where the maximum flexion angle achieved is typically 60°, medio-lateral translation of the tibia is likely to be smaller than reported during higher-flexion activities. Liu-Barba *et al.* (2007) showed that the knee translated medially by approximately 3mm between unloaded and loaded conditions (2.1 times body weight) when the flexion angle of the joint was fixed at 30°. Belvedere and colleagues published similar results in their cadaveric study, which showed the loaded knee joint to translate by 3-4mm between 0° and 60° of knee flexion. Despite these findings, Lavernia and colleagues (1992) described up to 5mm medio-lateral translation of the joint during gait.

2.1.4. Knee Muscular Strength

According to Smidt and Rogers (1982), strength is defined as the tension provided by muscles to successfully initiate and control movements.

Samuel and Rowe stated in 2009 and 2012 that strength of muscles acting on the knee and on other joints of the lower limbs are positively correlated with the extent of function possible at the joint on which they act. They also identified that strength changes through range and function as the knee must produce stabilising moments at a range of angles (Saumuels & Rowe, 2009). Hence, knee strength directly affects a person's ability to carry out everyday tasks such as walking (Samuels & Rowe, 2012; Samuels & Rowe, 2009; Smidt & Rogers, 1982).

Knee strength is often reported in terms of muscular force (measured in Newtons). However, as muscles cross the joint(s) on which they act, a turning effect occurs during contraction. This is known as a moment, or torque, and is responsible for limb movements and stability. As a consequence, it is customary in the scientific literature to report the outcome of strength testing in terms of moments (Nm), or if normalised, as moments per kilo of body mass (Nm/kg) (Smidt & Rogers, 1982).

Young, healthy people have greater muscle mass and consequently produce larger moments about the joints than those who are older or those who present with pathological gait (Bemben *et al,* 1991; Candow & Chilibeck, 2005). This was supported by Samuel and Rowe in 2012, who highlighted that muscular strength reduces at a higher rate in the lower limb than in the upper limb in healthy older adults. Maximum knee flexor and extensor strengths were lower by 22.3% and 25.8% in males in their 80s when compared to males in their 60s. Females in their 80s had maximum knee flexor and extensor strengths that were 30.0% and 16.2% lower than those in females in their 60s.

Candow and Chilibeck (2005) used a Biodex isokinetic dynamometer to measure knee strength in young and older males. They reported that maximum moment

during knee flexion ranged from 127-146Nm and 82-103Nm in the young and older males, respectively. Maximum knee extension moment was reported to be 164-217Nm in young males, and 100-162Nm in older males. Based on the average mass of the young males (81kg) these results suggest an average normalised extension torque of 2.0-2.7Nm/kg and a normalised flexion torque of 1.6-1.8Nm/kg. These values were lower in older males (average mass: 85kg): 1.2-1.9Nm/kg and 1.0-1.2Nm/kg.

A greater range was reported by Samuel & Rowe (2012), who used an isometric dynamometer to collect their data on healthy older males and females. Their study showed that the maximum flexor moment range was 20-110Nm and the maximum extensor moment range was 20-160Nm in older adults.

Although both studies presented gravity corrected data, the protocols used and the populations recruited for the studies were different, potentially explaining the differences in results (Candow & Chilibeck, 2005; Samuel & Rowe, 2012).

Gross and colleagues (1989) and Ushiyama *et al.* (2015) also published data in accordance with those described by Candow & Chilibeck (2005) and Samuel and Rowe (2012). According to Gross *et al.* (1989), females tended to exert less force when flexing and extending the knee, which could be explained by reduced muscle mass and increased amounts of subcutaneous fat in comparison to age-matched males.

2.1.5. Conclusions

Thus far, this literature review has shown the importance of the anatomy of the knee joint in allowing normal but stable knee movements. The roles that the tibial plateau and femoral condyles play in guiding sagittal plane translations and rotations were highlighted. Normal sagittal plane movement of the knee joint was

also shown to highly influence all other rotations and translations of the joint under unloaded and loaded conditions.

The previous section also described the importance of the musculature and structures crossing the knee in stabilising and producing movements at the joint. Normal knee anatomy is therefore essential for the successful completion of acts of daily living such as walking.

2.2. Pathological Changes to the Human Knee Joint

Vahtrik and colleagues (2014) stated that knee range of motion (ROM) is directly related to the conditions of the stabilising features and muscles acting on the joint itself. When the balance between stability, strength and mobility is disrupted in the knee joint, biomechanics is altered causing pain and reduced knee function.

Understanding the relationship between a diseased and a healthy knee joint is important for estimating the success of a treatment targeted at restoring a diseased knee joint.

Pathological changes to the knee joint can arise for numerous reasons; however, this thesis will only be concerned with osteoarthritis (OA) as a cause. According to the National Joint Registry, OA of the knee was the primary reason for carrying out total knee arthroplasty in 96% of cases between 2003 and 2015 (National Joint Registry, 2017). This disease significantly affects knee stability, ROM and strength, consequently affecting overall joint motion and mobility.

In 2007 it was approximated that 7-35% of adults in the UK suffered from OA (Wylde *et al.,* 2007). In recent years, it is feared that these estimated percentages have risen. According to Marsh *et al.* (2014) and Callahan *et al* (2015), OA is the most common cause of physical disability and pain in adults in the UK, and is most

frequently reported in the knee (Urwin *et al.,* 1998). Consequently, it is the leading cause of knee replacement surgery.

2.2.1. Articular Cartilage Degeneration and Osteoarthritis Development

With age, trauma, or excess frictional force exposure, the shape of the knee joint can change dramatically (Moyer *et al.,* 2014; Shenoy *et al.,* 2013). These anatomical alterations lead to a modification in the mechanical alignment of the joint which directly affects ROM and function of the knee (Shenoy *et al.,* 2013).

OA is a complex, progressive disease. It is often classed as idiopathic (of no known cause), or symptomatic (relating to a trauma or injury). Its common causes and symptoms are outlined in Table 2. 2. Please refer to the following references for further information: Hussain *et al.,* 2014; Lawrence *et al.,* 1966; Mahmoudian *et al.,* 2016; Suri *et al.,* 2012; Tetsworth & Paley, 1994.

Table 2. 2: Common causes and symptoms associated with knee osteoarthritis.

Common Causes	Main Symptoms
Old age	Pain
Family History	Stiffness
Obesity	Valgus knee deformity
Trauma	Varus knee deformity
Sport Injuries	Instability
Joint Mal-Alignment	

Given that cartilage cannot regenerate due to a lack of direct blood supply, pathological changes to the joint cannot be easily reversed. The first sign of pathological change within the joint is known as fibrillation, and is described as the sloughing or shredding of articular cartilage. Figure 2. 6 describes the cascade of changes which occurs within an osteoarthritic joint following fibrillation.

The changes outlined in Figure 2. 6 cause pain and reduce the knee's function. These symptoms are used to diagnose and treat the disease.

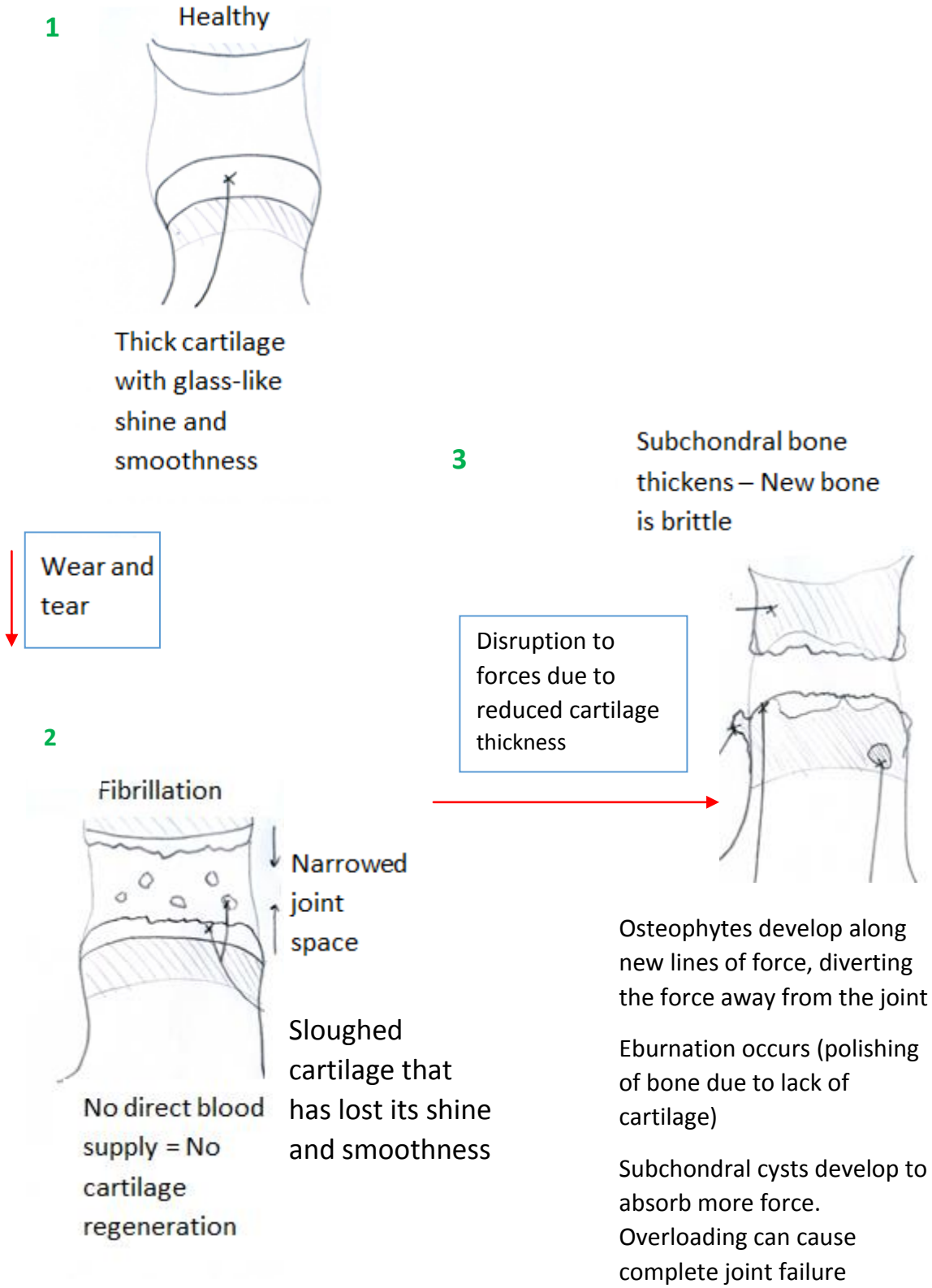


Figure 2. 6: A diagram of the anatomical and mechanical changes often observed within an osteoarthritic knee joint.

2.2.2. Stability of an Osteoarthritic Knee

As a mechanically stable knee is defined as one which is capable of maintaining its position and controlled movement during use, dynamic stability of the joint is essential (Latash *et al.*, 2007; van der Esch *et al*, 2008). Given that OA can significantly alter the anatomy of the knee, its dynamic stability is directly affected. According to Koyama *et al.* (2015) and Mandeville *et al.* (2008), adaptations to the motor control system compromise knee and centre of mass (COM) stability (especially in the sagittal plane) in individuals with OA. For the purpose of this thesis, the term 'COM stability' refers to the stability of the COM position when walking (Qu *et al.,* 2012). A COM position which remains within the base of support signifies that the patient did not lose their balance during the task in question (Black *et al.,* 2007; Qu *et al.,* 2012). These adaptations to the motor control system are believed to be a direct repercussion of reduced muscle strength, increased stiffness and pain at the knee caused by the disease (Koyama *et al.,* 2015). Thus, individuals with OA may find it difficult to maintain their balance during everyday tasks of daily living, such as walking.

A reduction in knee stability has been reported as an increase in gait variability in elderly people when compared to healthy controls (Hausdorff *et al.,* 2001; Hausdorff *et al.,* 1995; Maki, 1997). Although having a variable gait is natural, the extent of variability or patterns observed reportedly differ in adults who are elderly and/or suffering from a gait disorder such as OA (Alkjaer *et al.,* 2015; Mahmoudian *et al.,* 2016). As a consequence, the mechanism by which stability is achieved is altered (Papi *et al.,* 2015; Vieira *et al.,* 2017). This could affect a person's ability to react to perturbations, potentially increasing the risk of falling and limiting the extent and speed of activity the patient feels safe to undertake (Mahmoudian *et al.,* 2016; Lin *et al.,* 2015; Maki, 1997).

By analysing the variability of gait, it is possible to gain insight into the stability of an individual (Almarwani *et al.,* 2016). However, very little is currently known

about the effect of OA on walking stability in terms of variability. This is largely due to the fact that there are no appropriate methods of measuring and quantifying gait stability (Bruijn *et al.,* 2013). The methods currently used in the clinical and research environments to measure stability are described in detail in section 2.4.2 of this thesis (Knee Stability).

2.2.3. Range of Motion of an Osteoarthritic Knee

Malalignment of the knee joint is a direct consequence of the anatomical changes caused by OA. Joint malalignment significantly reduces knee ROM (Baliunas *et al.,* 2002; Shenoy *et al.,* 2013). This loss of function limits a person's ability to carry out daily activities including climbing stairs, walking, rising from a chair, and even standing comfortably (Kaufman *et al.,* 2001). It is therefore no surprise that individuals suffering from OA lose functional independence (Kaufman *et al.* 2001).

A wide range of maximum knee flexion angles in OA patients have been reported in the literature: 85-127° (Bauer *et al.,* 2010; Collins *et al.,* 2014; Ebert *et al.,* 2014; Jakobsen *et al.,* 2010; Karachalios *et al.,* 2009; Lavernia *et al.,* 2008; Miner *et al.,* 2003; Yoshida *et al.,* 2008).

Although individuals with knee ROM of 90° maintain the ability to walk, they may be limited in their mobility, as tasks such as sitting and stair-climbing require higher degrees of flexion (Jevsevar *et al.,* 1992; Shenoy *et al.,* 2013). Rowe and colleagues (2000) stated that a flexion angle of 90° is too constrained for activities such as stair ascent, as the knee must remain highly flexed for a longer period of time than when walking. A more recent study by Collins and colleagues (2014) supported this claim by reporting that people who are unable to reach a flexion angle of >90° at the knee or fully extend the leg (0° flexion) are likely to find it difficult or impossible to carry out day-to-day activities.

Inability to fully extend the leg at the knee (fixed-flexion) is another common problem reported by OA sufferers. Many complain that it is difficult and painful to extend the leg when descending stairs (Kaufman *et al.,* 2001; Teixeira & Olney,

1996). This is often as a result of weakened quadriceps muscles. In these cases, fixed-flexion of the knee is thought to be consciously adopted by the individual, to alleviate knee pain, through reducing movement of the joint under load (Kaufman *et al.,* 2001).

As OA causes reduced ROM at the knee, spatio-temporal gait variables are often worse in individuals with OA than in age-matched healthy adults (see section 2.6.1: Parameters of Gait for further detail). Kinematic studies have consistently shown patients with knee OA to walk at a slower speed, have decreased cadence, and spend a longer time in stance phase than control subjects (Bytyqi *et al.,* 2014; Kaufman *et al.,* 2001; Kiss, 2011; Levinger *et al.,* 2013; McClelland *et al* 2007; Teixeira & Olney, 1996; Yoshida *et al.,* 2008). This altered gait once more suggests that adults with knee OA alter the way they walk to reduce pain at the knee (Teixeira & Olney, 1996).

2.2.4. Muscular Strength of an Osteoarthritic Knee

Knee strength has been found to decrease with age (Bemben *et al.,* 1991; Samuels & Rowe, 2009). This has been linked to reductions of muscle mass known as sarcopenia (Candow & Chilibeck, 2005).

In people suffering from OA, muscle loss is thought to be exacerbated by muscle disuse due to pain in and around the joint (Bemben *et al.,* 1991; Callahan *et al.,* 2015; Petterson *et al.,* 2008). This weakness occurs in both hamstrings and quadriceps muscles (especially *vastus medialis*), reducing both extensor and flexor moments about the knee (Selistre & Mattiello, 2014; Taniguchi *et al.,* 2015). As the disease progresses, muscle strength decreases (Taniguchi *et al.,* 2015). This has been found to affect overall knee function. A study by Murray *et al.* (2015) suggested that OA sufferers who present with weaker quadriceps and hamstrings find it more difficult to stabilise the knee, which prevents them from flexing the knee to a normal degree during swing phase of gait and fully extending the knee

during initial contact. As a consequence, quadriceps weakness is a major contributor to functional limitations in patients with knee OA (Petterson *et al.,* 2008).

Individuals who suffer from knee OA have also been found to have reduced strength in hip abductor muscles (Selisre & Mattiello, 2014). This leads them to adduct the knee when walking. This pathological adduction can be accentuated by poor alignment of the joint (Teixiera & Olney., 1996).

Biomechanically, increased knee adduction is caused by a varus deformity of the joint, whereby the distal end of a limb translates medically. Varus deformities are far more common than valgus deformities, as the medial half of the distal femur is susceptible to higher loads than the lateral. This is primarily due to the angulation of the femur.

2.2.5. Conclusions

A fully functioning knee is clearly dependent on maintenance of the typical anatomy and biomechanics of the joint (Shenoy *et al.,* 2013). Hence, full function is most likely when the joint is correctly aligned and anatomically 'normal'.

Individuals who present to their doctor with knee OA are eligible for treatment for alleviating pain and improving joint function. Due to the complexity of the disease and the nature of the joint, appropriate treatment plans and follow-up assessments are required.

2.3. Osteoarthritis Treatments

A wide variety of treatment options are available to patients suffering from knee OA, with treatment type depending on the severity of the disease (Luyten *et al.,* 2005).

The orthopaedic and physical therapy treatments carried out on OA patients are tailored to restoring frontal and sagittal knee alignment, improving knee ROM, and relieving pain. Consequently, one of the main aims is to re-establish joint function (Rowe *et al.,* 2000 ; Sosdian *et al.,* 2014).

2.3.1. Conservative Treatments

In the UK, the recommended treatments for osteoarthritis are outlined by the National Institute for Health and Care Excellence (NICE Guideline CG177). The most common non-invasive treatments currently prescribed to OA sufferers are given in Table 2. 3. Refer to the following articles for further information on non-invasive OA treatments: Candow & Chilibeck, 2005; Cowan *et al.,* 2010; Gaudreault *et al.,* 2011; Lapane *et al.,* 2012; Maly & Robbins, 2014; Zhang *et al.,* 2008.

Table 2. 3: An outline of non-invasive treatments commonly prescribed to treat osteoarthritis symptoms.

Type of Treatment	Treatment Aim(s)
Non-Steroidal Anti-Inflammatory drugs: Aspirin, Ibuprofen, Naproxen	Reduce inflammation of joint
Analgesic drugs	Alleviate pain
Physiotherapy/Stretching	Alleviate pain & Improve ROM
Cardiovascular Exercises	Weight loss to reduce loading on joint which may alleviate pain & restore muscle strength to improve ROM
Dieting	Weight loss to reduce loading on joint which may alleviate pain

Despite routine implementation of conservative treatments for OA, long-term treatment of the disease is often unsuccessful with non-invasive methods. Although newer treatments such as intra-articular injection of platelet rich plasma or hyaluronic acid are becoming increasingly used, patients with OA often find the signs and symptoms of OA progress with time. Patients suffering from end-stage OA are likely to require a knee replacement procedure to treat persistent symptoms (Hassan *et al.,* 2014; van der Wegen *et al.,* 2014).

2.3.2. Knee Arthroplasty

According to Shimmin *et al.* (2014), knee arthroplasty aims to replicate a healthy knee joint by replacing damaged cartilage, bone and stabilising features with artificial parts.

Factors including age, injury and activity affect the rate of OA progression. A clinical decision is therefore required as to when to schedule elective arthroplasty surgery (Tawy, 2014). Current implants cannot survive indefinitely; thus, implant failure during the patients' lifetime is a possibility if the operation is scheduled too early. An increasing life expectancy coupled with a decrease in average age of TKA patients further complicates matters. If left too late however, the degeneration of the joint and soft tissues, combined with reduced activity of the patient make surgery and rehabilitation far more challenging.

Types of Knee Arthroplasty

Knee arthroplasty procedures are referred to as partial or total – depending on whether a part of the joint, or the whole joint requires replacement. Partial knee arthroplasties involve the replacement of one or more of three compartments of the knee. Hence, they are referred to as unicompartmental, bi-compartmental or tri-compartmental knee arthroplasties.

Unicompartmental procedures which replace either the medial or lateral compartment of the knee joint with prosthetic parts are referred to as unicondylar knee arthroplasties (UKA) (Figure 2. 7).

Figure 2. 7: An example of a unicondylar knee arthroplasty: Global Medacta Knee (GMK) Uni. (Source: Medacta International, 2015c)

On average, patients requiring this type of surgery are younger than those in need of a total knee replacement (Brown *et al.,* 2012). This approach is more conservative than a total knee replacement as it preserves the healthy bone and retains the cruciate ligaments (Brown *et al.,* 2012).

UKAs are carried out to relieve localised knee pain. As medial knee OA is more common, medial UKAs are more widely performed. However, surgical volume of UKA remains low in the UK, with most surgeons only completing one UKA per year. Hence, only 5-10% of knee arthroplasties are UKAs in the UK at present (Walker *et al.,* 2010). According to the NJR, 9.2% of knee arthroplasties carried out in 2016 were UKA (National Joint Registry, 2017).

Unicompartmental procedures also include patellar resurfacing. Occasionally, with age and/ or trauma, patellar OA can arise causing intense anterior knee pain. In cases where the rest of the knee joint is unaffected by OA, or where the disease is at

a manageable stage, the posterior face of the patella can be removed and replaced with a patellar button (Figure 2. 8). Patellar buttons are made from ultra-high molecular weight polyethylene (UHMWPE), and are designed to replicate the healthy cartilage which was once present at the joint.

Figure 2. 8: An example of a patellar button used with Medacta knee arthroplasties. (Source: Medacta International, 2015b)

However, where the medial and lateral compartments of the knee both require replacement, a TKA is usually recommended. In these cases, the whole joint is replaced by one metal femoral component, and one metal tibial plate with an attached UHMWPE plastic surface. This plastic surface articulates with the femoral component.

Total Knee Arthroplasty Prevalence and Demand

The majority of TKA procedures are carried out in adults over the age of 65 who suffer from chronic OA (Collins *et al.,* 2014; Kuiken *et al.,* 2004). OA is deemed as chronic if the patient has suffered from the disease for >6 weeks and if arthritic

changes caused by the disease are unlikely to be alleviated my means other than surgery (Luyten *et al.,* 2005).

TKA is currently the standard treatment for advanced OA sufferers who present with severe radiographic changes to the knee, pain and disability (Dowsey *et al.,* 2012b; Klit *et al.,* 2014; Lewis *et al.,* 2014).

The National Health Service (NHS) and the National Joint Registry (NJR) reported that over 132,000 total knee replacement operations were carried out in England and Wales in 2015; with a further 7,000 operations executed in Scotland (NHS, 2014; NHS Scotland, 2010; National Joint Registry, 2016). These figures include 70,000 privately operated procedures across the UK (National Joint Registry, 2016). Over the next few years, these numbers are expected to rise substantially due to an ageing population and increasing obesity rates (NHS, 2014; Suri *et al.,* 2012).

Accompanying a rise in the number of people undergoing primary TKA is a rise in the number of those requiring revision surgeries. This is a direct repercussion of an increase in life expectancy as well as a decrease in the average age of patients requiring surgical intervention (Brennan *et al.,* 2015; Greidanus *et al.,* 2011; Kurtz *et al.,* 2009).

According to Kurtz *et al.* (2009) and Walker and colleagues (2010), the annual number of TKA procedures will rise by 10% over the next few years. When considering that approximately 50% of all joint related operations in the UK are on the knee, the importance of maintaining efficient treatment plans and a high quality of care in this field can be appreciated (National Joint Registry, 2016).

In response to increasing demand and changing patient demographics, future treatment and rehabilitation plans should address the functional needs of the patients to prevent patient dissatisfaction and poor outcome.

Total Knee Arthroplasty Success

Knee replacement surgery is currently the most effective and successful treatment for advanced OA and its related pain in the knee. However, it is reported that at least 20% of TKA patients are unhappy with the results (Baker *et al.,* 2007; Selvan *et al.,* 2013).

Patient dissatisfaction is often due to the fact that many are unable to regain normal joint function (kinetic and kinematic) following surgery (Benedetti *et al.,* 2003; Jevsevar *et al.,* 1993; Malviya *et al.,* 2009; Marsh *et al.,* 2014; Rossi *et al.,* 2002).

An improvement in knee flexion is one of the most desired outcomes of TKA, as good knee flexion is required for everyday mobility. As previously discussed, a flexion angle of at least 110° is required for carrying out most every day activities (Insall *et al.,* 1979; Kettelkamp *et al.,* 1970; Laubenthal *et al.,* 1972; Morlock *et al.,* 2001; Rowe *et al.,* 2000).

Although the majority of current TKA prostheses aim to allow 130° flexion at the knee, recent studies state that TKA patients rarely achieve this degree of flexion following surgical intervention (Bauer *et al.,* 2010; Collins *et al.,* 2014; Ebert *et al.,* 2014; Jakobsen *et al.,* 2010; Karachalios *et al.,* 2009; Lavernia *et al.,* 2008; Miner *et al.,* 2003; Tarabichi *et al.,* 2010; Yoshida *et al.,* 2008). In fact, some recent studies have reported a worsening in knee motion for up to four months following surgery (Levinger *et al.,* 2013; Mai *et al.,* 2012; McClelland *et al.,* 2011; Myles *et al.,* 2002; Rossi *et al.,* 2002). The greatest predictor of post-operative knee range of motion is pre-operative range of motion, however.

Functional limitation and altered gait biomechanics may be due to prolonged pain post-surgery (Bourne *et al.,* 2010; Brennen *et al.,* 2015; Lewis *et al.,* 2014). One recent study claims that 30% of patients suffer from mild to severe pain in the knee as long as two years after TKR (Dowsey *et al.,* 2012a). Those who suffer pain in the knee long after surgery are less likely to recover normal knee biomechanics and

gait, as they are unable to shift their body weight back onto the affected leg (Henriksen *et al.,* 2011; Vahtrik *et al.,* 2014). Pain and subsequent inactivity result in continued muscle weakness in the affected leg and reduced function (Henriksen *et al.,* 2011; van der Esch *et al.,* 2006; van der Esch *et al.,* 2014; Macdonald *et al.,* 2007).

It is therefore unsurprising that many TKA patients present with weaker quadriceps muscles post-operatively than age-matched healthy controls, even if muscle strength had continued to improve since pre-operative assessments (Vahtrik *et al.,* 2014). This is problematic in that a reduction in leg extensor strength affects knee biomechanics by increasing the load on the joint itself, especially during mid-stance (Vahtrik *et al*, 2014).

Kinematic and kinetic changes to a joint following TKA directly affect spatio-temporal parameters of gait such as stride length and cadence when walking (Blaha, 2004). These two variables are significantly lower in TKA patients than healthy controls, even as long as 12 months post-operatively (McClelland *et al.,* 2011).

According to Mandeville and colleagues (2008) TKA patients also controlled their COM differently to healthy control subjects when walking. This difference is thought to have stemmed from the TKA patients adopting a conservative method to reduce load on the operated knee (Mandeville *et al.,* 2008). As well as avoiding pain, individuals may also experience lack of confidence or trust in the implant, which further affects gait parameters.

Another variable that may influence gait following TKA is the anteroposterior stability of an implant. Blaha (2004) defined anteroposterior instability as paradoxical anterior movement of the femur caused by a lack of medial femoral condyle constraint in the implant. Both condyles are usually free to translate anteriorly and posteriorly in an unloaded TKA implant. However, as was previously discussed in this review, this does not reflect true knee movement when the knee is

loaded. Anterior-posterior instability may influence gait, as patients begin to limit the flexion moment about the knee to prevent this unnerving anterior translation of the femur (Blaha, 2004).

A second commonly described TKA-related instability, known as mid-flexion instability, is also believed to influence walking stability post-TKA (Vince, 2016). The term was coined in 1990 by Martin and Whiteside following a cadaveric study on the effect of moving the position of the joint line on varus-valgus stability of the joint. The study found stability to be unaffected when a neutral joint line was maintained, but if the femoral component was moved by 5mm proximally and 5mm anteriorly the joint became unstable during mid-flexion (30-45^{o} flexion) (Martin & Whiteside, 1990).

Patients who present with what is believed to be mid-flexion instability complain of instability in the implant when ascending and descending stairs (Vince, 2016). Despite being commonly described in the orthopaedic field, the existence of mid-flexion instability has never been confirmed in clinical practice (König *et al.,* 2011; Vince, 2016). Vince (2016) has suggested that what is perceived to be mid-flexion instability i.e. anterior-posterior displacement may be varus-valgus instability due to laxity of the collateral ligaments (Blaha, 2004).

Other studies have completely redefined mid-flexion instability, making it more complicated to determine what exactly 'mid-flexion instability' is (Vince, 2016). For the purposes of this thesis, mid-flexion instability is defined as instability during the mid-stance phase of gait. Martin and Whiteside reported in 1990 that this is the event of the gait cycle most prominently associated with instability during slope and stair negotiation (Vince, 2016).

Regardless of the fact that evidence of mid-flexion instability is sparse and conflicting, it is considered as a considerable source of instability and reduced function following TKA. This means that many new implant designs have focused

on providing patients with stable implant configurations throughout the functional ROM (McClelland *et al.,* 2017).

Altered gait and mobility has long term negative effects on patients' mental and physical wellbeing. Hence, providing patients with an implant that allows them to achieve optimal joint function is the ultimate goal of TKA. As a result, a method of quantifying joint function in clinical practice is needed.

Total Knee Arthroplasty Implants

TKA was originally developed to relieve pain in elderly patients (Kurtz *et al.,* 2009). As a consequence, the implants were not designed for high demand functional activities. Over recent years, the patient demographic has changed, and people now requiring TKA are more active than ever before (Brennan *et al.,* 2015). The need for implants that allow patients to achieve high ROM at the knee with stability and improved function is therefore greater than ever.

Most common modern day implants (Columbus, B Braun; Genesis II, Smith & Nephew; NexGen, Zimmer Biomet; Sigma, DePuy Synthes; Triathlon, Stryker) rely on the congruency between the femoral and tibial parts to provide knee stability in the absence of one or both cruciate ligaments. However, many patients exhibit instability of the knee with these devices. The Medacta GMK Sphere implant (medially stabilised) has been designed to specifically address the issue of this instability, by altering the way in which the implant is stabilised to mimic the anatomical functions of a healthy knee joint, but not its surface anatomy (Medacta International: Castel S. Pietro, Switzerland). By combining both anatomical and mechanical factors it was hypothesised that both mid-flexion and anteroposterior instabilities observed in TKA patients could be removed.

To replicate the articulation movements of a healthy knee in the Medacta GMK Sphere, Freeman and colleagues constrained the medial compartment of the implant with a spherical bearing while using a flat lateral tibial baseplate and

lateral femoral component to allow rotation and the screw home mechanism (Fig. 2.8). Additional medial femoral constraint is given by a high antero-medial polyethylene tibial baseplate (Figure 2. 9). Together, these create a medial 'ball-and-socket' effect, limiting the translation of this condyle.

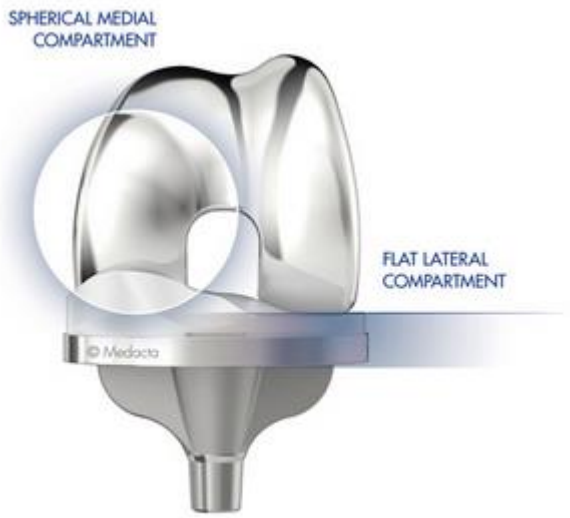


Figure 2. 9: An image of the GMK Sphere Implant, highlighting compartmental design.

(Source: Medacta International, 2015a)

In addition to adapting the articulating surfaces, the patellar groove has been shifted laterally (2mm lateral to midline) and the lateral femoral compartment enlarged anteriorly to better replicate patellar tracking and prevent lateral patellar dislocation (Figure 2. 10) (Medacta International, 2015a).

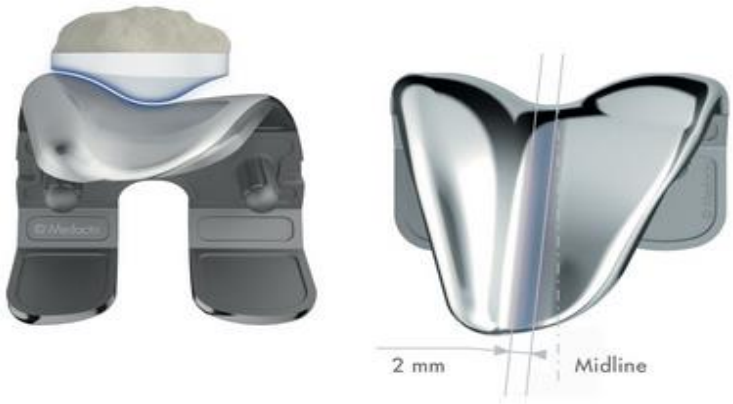


Figure 2. 10: Patellar groove design.

(Source: Medacta International, 2015a)

The components of the implant are also available in a wide variety of sizes to allow for improved implant anatomical matching. Altogether, the surgeon has the option to implant one of 13 femoral components and 6 tibial components (Medacta International, 2015a). Each size differs from the next by 2mm. The plastic inlay which is fixed to the tibial component comes in 7 different thicknesses.

2.3.3. Conclusions

Despite being the standard treatment for restoring function to an OA knee joint, poor functional outcome is often reported in patients who have undergone TKA. In order to meet the increasing functional demands of the changing patient demographic, implants are now required to be longer-lasting and higher-functioning (Blaha, 2004).

The Medacta GMK Sphere TKA has been designed to improve post-operative knee function by providing patients with an implant that better reflects normal knee motion and stability compared to standard implants. This novel implant requires assessment.

In order to determine whether an implant has been successful in terms of functional outcome, the way in which the knee functions pre- and post-operatively must be assessed. The following sections of this thesis will describe current protocols used in the clinical environment to assess knee function.

2.4. Outcome Measures

Outcome measures are used in clinical or rehabilitative environments to track the changes of certain variables over time (Escobar *et al.,* 2007). Measuring the outcome of patients is of critical importance following a new treatment or intervention such as TKA, as the results can be used to gauge the success of the treatment (Beard *et al.,* 2010). Additionally, the results can be used to aid clinicians in future clinical decision making, as the assessments can be used to identify weaknesses, such as the poor post-operative ROM reported previously.

To fully understand the improvement or deterioration of a patient, information should be collected at two or more points in time (Beard *et al.,* 2010; Davies *et al.,* 2002). Normally, results from pre-operative and post-operative assessments of patients are compared during their rehabilitation period.

A clinical outcome measure must fulfil certain criteria to ensure the results recorded are accurate, valid, and reproducible (Beard *et al.,* 2010; Fitzpatrick *et al.,* 1998). These criteria were explained in detail by Fitzpatrick and colleagues in 1998. A tabulated summary of these criteria is provided (Table 2. 4).

According to Baker *et al.,* (2007), the functional improvement of a knee is one of the most important outcomes to investigate following TKA. Subjective and objective outcome measures are used to assess knee function in clinical environments.

The following part of the thesis discusses the advantages and disadvantages of outcome measures most commonly used currently to assess patient outcome (functional and otherwise) following TKA.

Table 2. 4: The features an outcome measure must have for its use to be justified.

(Source: Fitzpatrick *et al.,* 1998)

Feature of Outcome Measure	Definition
Appropriateness	The capability of the outcome measure to obtain results which address the research question
Acceptableness	Ease of use of outcome measure by examiners and patients
Feasibility	Ease of use by examiners, cost-effectiveness and time-effectiveness of outcome measure
Precision	The ability of the outcome measure to provide consistently repeatable results
Accuracy	The ability of the outcome measure to produce results which are near to the true value of interest
Reliability	The capability of the outcome measure to reproduce the same result under the same experimental circumstances
Validity	The ability of an outcome measure to produce factually sound results – often compared to gold standard measurement
Sensitivity	The ability of the outcome measure to discern between different states
Interpretability	The ease at which the results obtained from the outcome measure can be analysed and understood

2.4.1. Subjective Outcome Measures

Subjective outcome measures are based on the patient's own perceptions of their health and wellbeing (Beard *et al.,* 2010). Hence, these types of measures assess pain, quality of life, general wellbeing and occasionally function. Subjective outcome measures are usually questionnaires, and are referred to as 'patient recorded outcome measures' (PROMs). In most cases, the questions are graded, allowing for example, the patient to choose the severity of the pain they feel or functional ability of the affected joint on a scale (Aichroth *et al.,* 1978).

Recent studies claim that PROMs are becoming increasingly used to assess patient progress in orthopaedics (Baker *et al.,* 2007; Beard *et al.,* 2010; Kempshall *et al.,* 2013 Torres-Claramunt *et al.,* 2013). The most obvious reason for this is that only the patient is able to judge certain changes within and surrounding the knee with time. However, the movement of the knee joint during function is difficult for the patient to detect and such subjective measures are responsive to the patient's expectations, which can be manipulated by the clinical service.

This thesis therefore focuses on the development of a bespoke *objective* functional outcome measure package. Consequently, only a brief summary of the main subjective methods used in orthopaedics will be provided in this review. The most common subjective outcome measures, and their advantages and disadvantages are outlined in Table 2.5.

Table 2. 5: Important advantages and disadvantages of subjective outcome measures commonly used to assess TKA outcome.

Name	Use	Advantages	Disadvantages	References
Visual Analogue Scale (VAS)	Measure pain in one dimension	Simple to use/Quick to use/Cheap/Common	Difficult for patients to convert a level of pain to an analogue form	Bullens *et al.,* 2001; Litcher-Kelly *et al.*,2007; Myles *et al.,* 2002; Rannou *et al.,* 2007
Western Ontario & McMasters Universities OA Index (WOMAC)	Assess progress of OA patients (specifically pain, stiffness and physical function)	Valid/Multi-lingual/ Reliable/Sensitive to change/Quick to use/Simple to use/Cheap	Difficult for patients to convert a level of pain to an analogue form	Bullens *et al.,* 2001; Davis *et al.,* 2009; Hossain *et al.,* 2013; Jinks *et al.,* 2002; Salaffi *et al.,* 2003
Oxford Knee Score (OKS)	Assess the progress of TKA patients (specifically, function and pain)	Joint specificity reduces likelihood of results being based on issues dissociated from the knee/Valid/Reliable/ Quick to use/Simple to use/Cheap	Shows floor and ceiling effects when comparing pre- and post-operative data/Some questions are repetitive, making answering them difficult/Difficult for patients to convert a level of pain to an analogue form	Davies *et al.,* 2002; Greidanus *et al.,* 2011; Impellizzeri *et al.,* 2011; Jenny & Diesinger, 2012; Ko *et al.,* 2009; Whitehouse *et al.,* 2005
Short-Forms 12 & 36 (SF-12/SF-36)	Assessing general outcome and wellbeing following intervention	Quick to use/Simple to use/Cheap/Reliable/ Valid/Possible to estimate how overall health correlates with improvement in patients	Difficult for patients to convert a level of pain to an analogue form	Greidanus *et al.,* 2011; Torres-Claramunt *et al.,* 2013; Marsh *et al.,* 2014; Rannou *et al.,* 2007; Salaffi *et al.,* 2003; Ware & Gandek *et al.,* 1998
Euro Quality of Life: 5-Dimenstional (EQ-5D)	Assessing general outcome and wellbeing following intervention	Quick to use/Simple to use/Cheap/Commonly used	Complex scoring system places some patients at a score below 0 which corresponds to 'worse than death'/High ceiling affects	Beard *et al.,* 2010; Giesinger *et al.,* 2014; Torrance *et al.,* 2014;
Forgotten Joint Score (FJS)	Assessing patient awareness of new joint following arthroplasty	Simple to use/Quick to use/Cheap/Valid/Reliable/Repeatable	Difficult for patients to convert a level of pain to an analogue form	Behrend *et al.,* 2012; Giesinger *et al.,* 2015; Thomson *et al.,*2015

2.4.2. Objective Outcome Measures

According to Rahman and colleagues (2015), the way in which the knee functions must be closely monitored pre- and post-operatively to ensure early identification of problems. This review has identified three factors which directly affect knee functional outcome: ROM, strength and stability. For this reason, the following section will discuss the outcome measures typically used by clinicians to assess these parameters.

Knee Stability

Functional assessments used in the clinical environment often fail to address knee stability and its essential role in mobility. Of the assessments that do consider this variable, few provide information on *dynamic* stability, despite the fact that a stable knee is defined as one which maintains its position and *controlled movement* under a variety of loads (Latash *et al.*, 2007; Mahmoudian *et al.,*2016; van der Esch *et al.*, 2008). Furthermore, most fail to measure stability accurately and reliably (Mahmoudian *et al.,*2016).

Clinicians usually test knee stability manually by manipulating the joint with their hands (Mahmoudian *et al.,* 2015). In doing this, they are able to estimate the laxity of the knee ligaments. For quantitative information, surgeons use pre- and post-operative radiographs of the knee (Dowsey *et al.,* 2012a; Jinks *et al.,* 2002; Ko *et al.,* 2013).

Weight-bearing radiographic images are used to measure the mechanical axis of the femur (Figure 2. 11). An appropriate mechanical axis for that knee, with regard to its pre-morbid alignment, is an essential contributor to good knee stability (Colebatch *et al.,* 2009). This axis is determined by measuring the angles between the hip and knee, and knee and ankle (Eckstein *et al.,* 2014). Femorotibial alignment can also be assessed using radiography to determine the valgus-varus angle (Eckstein *et al.,* 2014). Patellar position, which is essential for smooth patellar

tracking is also commonly examined by taking skyline images of the knee (Dowsey *et al.,* 2012a).

One of the greatest disadvantages of relying on radiography to assess stability is that it cannot be used dynamically. For this reason, radiography is primarily used to aid the surgeon with pre-operative planning of joint re-alignment and implant placement. Post-operative radiographs are generally used for verification of the adjusted valgus-varus angle to ±3° and to confirm implant position (Eckstein *et al.,* 2014).

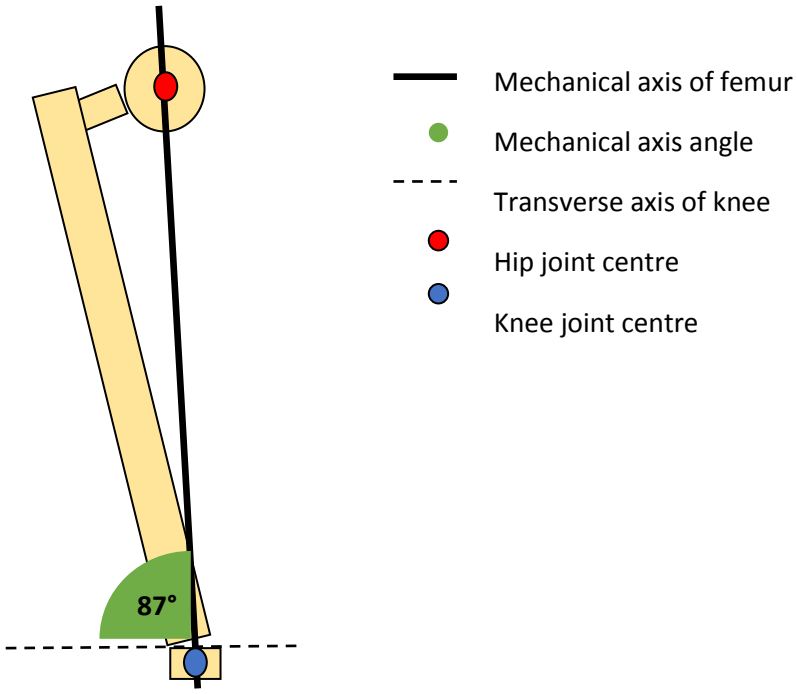


Figure 2. 11: Schematic diagram of the mechanical axis of the femur.

As it is likely that patients suffering from OA find it difficult to maintain stability during activities of daily living such as walking, a quantitative way to assess

stability during motion is required. It was previously stated (2.2.2. Stability of an Osteoarthritic Knee) that a reduction in knee stability is correlated with an increase in gait variability (Hausdorff *et al.,* 2001; Hausdorff *et al.,* 1995; Maki, 1997). Researchers therefore quantify dynamic stability in terms of gait variability. These methods are rarely used clinically however; as they require the collection of multiple gait cycles which can be time consuming to achieve with current gait analysis protocols.

'Variability' in the context of human movement refers to the normal variations that occur between repetitive tasks, for example the natural variations between gait cycles when walking (Stergiou & Decker, 2011).

According to Riva and colleagues, there are multiple ways in which gait variability can be quantified scientifically (Riva *et al.,* 2014). One of the simplest methods is comparing gait cycles or trials statistically using the standard deviation, range, or coefficient of variation of different gait variables. These statistical methods can be applied to the whole gait cycle or to different elements of the gait cycle in order to investigate whether the variability of a certain parameter or parameters changes between or within the cycle (Barnett *et al.,* 2016; Hausdorff *et al.,* 2001; Kiss, 2011; Riva *et al.,* 2014). The variability of spatio-temporal parameters between trials are often analysed in this manner (Almarwani *et al.,* 2016; Barnett *et al.,* 2016; Hausdorff *et al.,* 2001; Herman *et al.,* 2005; Maki, 1997; Owings & Grabinger, 2014; Riva *et al.,* 2014; Schrager *et al.,* 2008).

Other areas of research have concentrated on foot-placement variability during gait to quantify balance, especially in the frontal plane (Bauby & Kuo, 2000; Reissman & Dhaher, 2015). The disadvantage of relying on these methods is that walking stability is phase-dependent. Therefore, by concentrating on spatio-temporal parameters, the capacity to identify phases of the gait cycle that are more variable than others is lost (Dingwell & Kang, 2007).

These traditional methods of quantifying variability, which assume each cycle is independent of its predecessor, are slowly falling out of favour (Dingwell & Kang, 2007; Stergiou & Decker, 2011). Mathematical methods have been used to show that cycle-to-cycle variation in gait is not random despite initially seeming so. This has been attributed to 'motor memory' (Stergiou & Decker, 2011). Traditional methods of quantifying variability also lead to the false assumption that data outside of the mean $\pm$2 standard deviations are errors (Dingwell & Kang, 2007; Stergiou & Decker, 2011).

To quantify variability, measures derived from nonlinear dynamics must be used (Stergiou & Decker, 2011). In 2011, Stergiou and Decker published a review of the most commonly used methods of investigate human movement variability using nonlinear dynamics.

One of the most prominent methods described by Stergiou and Decker (2011) is the Uncontrolled Manifold (UCM) hypothesis. This method considers that a motor task, such as the control of the COM trajectory during gait, can be executed an infinite number of ways (e.g. through adopting variable joint kinematics). This 'redundancy' means that the system has a degree of flexibility to be able to react to any perturbations that may destabilise the task. Corrections to stabilise a task are therefore only applied when the degree of variability exceeds a certain threshold. A benefit to using this method is that stability can be quantified for each percentage of a cycle, enabling the researchers to identify areas of instability. This information may be clinically useful, especially during rehabilitation. In the case of TKA, this approach may allow clinicians to observe anterior-posterior instabilities or mid-flexion instabilities, which have previously been shown as critical factors for good functional outcome.

It is clear from the current literature that there is no routine or appropriate method for measuring dynamic stability in the orthopaedic clinical environment (Mahmoudian *et al.,* 2015). This thesis therefore aims to address this gap in the

literature by implementing the UCM method to investigate cycle-to-cycle instability of the COM in gait of people with OA. The use of this method to quantify mid-flexion instability in patients with the Medacta GMK Sphere TKA will be described. The role of the UCM method as a clinical measure of gait stability will therefore be discussed. Section 3.1.3 of this thesis describes this hypothesis in greater detail.

Knee Range of Motion

According to Miner and colleagues (2003) the ROM of a joint is a direct measure of its condition. Of all pre- and post-operative functional outcomes, the flexion-extension range of the knee is highlighted as the most informative, and is consequently used to quantify TKA outcome (Austin *et al.,* 2008; Cleffken *et al.,* 2007; Edwards *et al.,* 2004; Lavernia *et al.,* 2008; Mai *et al.,* 2012; Sato *et al.,* 2009).

The traditional manual method of measuring the flexion-extension range of a knee in a clinical environment is goniometry (Figure 2.12) (Austin *et al.,* 2008; Edwards *et al.,* 2004; Jakobsen *et al.,* 2010; Lavernia *et al.,* 2008; Mai *et al.,* 2012; Rahman *et al.,* 2015).

Manual goniometers can be used to measure passive or active motion at a joint. An active measurement is one which is recorded as a patient carries out an unaided movement at a joint. If the movement is aided by a clinician however, it is defined as passive. Passive ROM can also be measured by asking the patient to squat. A study by Mai and colleagues (2012) used a long armed goniometer to measure both passive and active flexion at the knee in patients who had recently undergone TKA. They discovered that the mean flexion angle was greater when measured passively by at least 4°. This was also observed by Kuiken and colleagues in 2004. These results suggest that both passive and active measurements should be routinely recorded pre- and post-TKA (Jakobsen *et al.,* 2010).

Figure 2. 12: A photograph of a long-armed goniometer.

Assessment of both passive and active knee flexion-extension ranges are usually carried out with the patient in supine position on a plinth. Initially, the centre of the goniometer is placed at the centre of the knee (on the lateral epicondyle). One arm of the goniometer is then aligned with the greater trochanter and the second arm is aligned with the lateral malleolus. All anatomical landmarks are located by palpation. Figure 2. 13 shows this process in diagrammatic form.

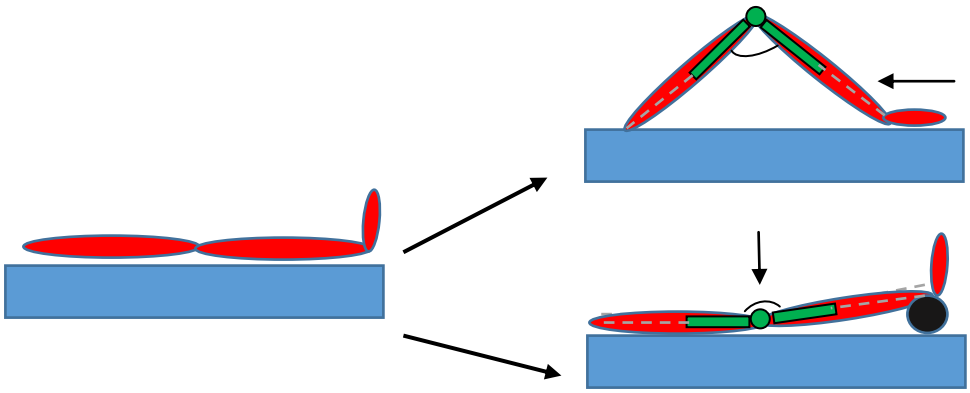


Figure 2. 13: A diagram of goniometer placement during range of motion assessment. Short arrows denote directions of forces applied to the leg by examiners during active flexion and extension trials. An object is occasionally placed under the ankle to measure knee extension.

Manual goniometry has been found to be successful at measuring post-surgical progress in ROM in patients suffering from knee OA (Rowe *et al.,* 2000). This success is reflected in its routine use in orthopaedic clinics (Edwards *et al.,* 2004).

As well as providing an insight into the function of the knee, manual goniometry is inexpensive, non-invasive, and portable (Croxford *et al.,* 1998).

Goniometers are highly reliable (Edwards *et al.,* 2004; Lavernia *et al.,* 2008; Piriyaprasarth & Morris, 2007). Piriyaprasarth and Morris (2007) recently conducted a systematic review of the literature associated with the reliability of tools used to measure knee ROM (including the goniometer). A summary of their results, as well as results from other studies on the reliability of knee ROM assessment methods, are given in Table 2. 6.

Table 2. 6: The reliability of the goniometer as reported in previous studies.

Name	Goniometer	Reliability	Comparative Measure	Reliability
Austin *et al.,* 2008	14" Nexgen 360°	Interobserver ICC >0.900 Intraobserver ICC >0.800	Computer Assisted Navigation (Stryker Navigation system)	Interobserver ICC >0.900 Intraobserver ICC >0.900
Edwards *et al.* 2004	12" #A 4412 Roylan Medical Products	Interobserver ICC = 0.910	Visual Assessment/ Radiography	Interobserver ICC = 0.790/ Intraobserver ICC = 0.990
Brosseau *et al.,* 2004	Universal Goniometer	Interobserver ICC = 0.997 Intraobserver ICC >0.900	Bespoke Parallelogram Goniometer	Interobserver ICC = 0.996 Intraobserver ICC >0.900
Piriyaprasarth & Morris, 2007	Universal Goniometer	Interobserver ICC = 0.620-0.990 Intraobserver ICC = 0.860-0.970	3-Dimensional Motion Capture	Interobserver ICC = 0.990 Intraobserver ICC = 0.990

Despite these positive results (Table 2. 6), it is not uncommon to find conflicting evidence. A study by Myles and colleagues (2002) claimed that the intra-observer reliability can be poor, with errors of between 5 and 10° being recorded between assessors. Discrepancies such as this may be explained by the level of experience and training the assessor had at the time of the study (Collins *et al.,* 2014).

Lavernia and colleagues investigated the differences in results recorded by people of varying clinical backgrounds including a physiotherapist, a surgeon, a clinical fellow, a research fellow and a physical assistant. When compared to radiography, the results obtained by each were found to be significantly different from one another ($p = 0.0001$, one-way Analysis of Variance).

The accuracy of goniometers has also come under scrutiny recently, with studies reporting that goniometric analyses fail to reflect the true knee angle; especially during high flexion (Austin *et al,* 2008; Edwards *et al.,* 2004; Lavernia *et al.,* 2008).

It has been shown that the goniometer often underestimates the angle at the knee during static high flexion tasks; especially in patients with high BMI (Austin *et al.,* 2008, Edwards *et al.,* 2004). Given that the prevalence of obesity is rising, and that high-flexion prostheses are being increasingly implanted, we must begin to question whether the goniometer should remain a suitable outcome measure in future orthopaedic clinics (Austin *et al.,* 2008).

Austin and colleagues reported that 95% of measurements taken by goniometer during flexion were lower than those recorded by computer assisted navigation by at least 5°. 22% of measurements taken by goniometer in a study by Edwards and colleagues (2004) also had at least a 5° difference when compared to results from radiographic images. Given that differences of 5° are believed to be clinically relevant, it is absolutely necessary that the tools used to record ROM are accurate enough to be *within* 5° of the true angle (Chaudhary *et al.,* 2008).

Poor accuracy may be due to incorrect placement of the goniometer during an assessment (Brosseau *et al.,* 2001; Milanese *et al.,* 2014). Again, this suggests that the level of expertise of the assessor affects the results recorded. Studies by Jacobsen *et al.* (2010) and Lavernia *et al.* (2008) corroborate this theory. Jacobsen and colleagues found that experienced physiotherapists were more likely to report a higher knee ROM than less experienced physiotherapists, especially during passive motion.

A further disadvantage to goniometry, highlighted by Rowe and colleagues (2000), is that the manual goniometers cannot reflect dynamic knee ROM as they only allow static measurement. Rowe *et al.* (2000) suggested that ROM should be measured as the patient or subject carries out normal day-to-day activities. Their study suggests that clinicians should use alternative tools to assess knee ROM, such as an electrogoniometer.

Electrogoniometers record continuous joint ROM during functional activities (Figure 2. 14). Electrogoniometry has been found to be simple, reproducible and sensitive, enabling small but meaningful differences in functional ability of patients to be recorded (Myles *et al.,* 2002; Piriyaprasarth & Morris., 2007; Rowe *et al.,* 2000). They can also be used to assess patient activity, by counting the number of times an hour the knee flexed and extended (Kuiken *et al.,* 2004). Foot-switches can also be added for accurate determination of heel strike during gait (Minns, 2005; Myles *et al.,* 2002). However, electrogoniometers are delicate and require very careful attachment. Consequently, electrogoniometers are rarely used clinically.

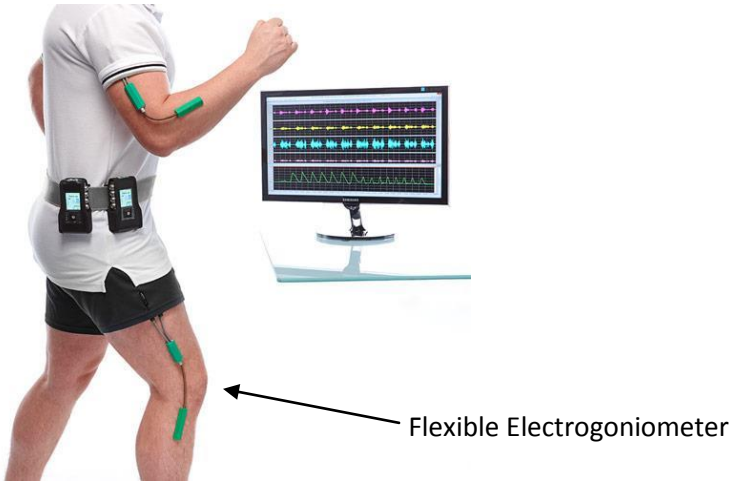


Figure 2. 14: A diagram of an electrogoniometer in use. Note that the angle is recorded and output into a nearby computer.

(Source: Biometrics Ltd., 2016)

More recently, inertial sensors have become accepted as a method of recording joint kinematics, and as such are being increasingly used to report the ROM of joints in research capacities (Cooper *et al,* 2009; Nüesch et al., 2017). Traditional inertial sensors measure acceleration and angular velocity with an accelerometer, and with the addition of a gyroscope, the devices are also able to determine their orientations with respect to an inertial frame (Cooper et al., 2009; van der Straaten *et al.,* 2018). Inertial sensors can be used to reliably quantify joint angles if sensors are placed both proximally and distally to the joint in question (Cooper et al., 2009). For example, to measure knee range of motion, it would be necessary to place one inertial sensor on the thigh, and one on the shank.

In 2017, Vicon Motion Systems acquired a company (IMeasureU) who develop inertial sensors, allowing users to integrate their traditional gait data with those from the inertial sensors. As the leading motion capture company, this event will undoubtedly increase the use of inertial sensors by biomechanics researchers over the coming years, and improve their current accuracy and validity.

Inertial sensors are also being used in the clinical environment more frequently (Cooper et al., 2009). However, due to their novelty, few studies have been published on their uses; a problem which was identified by the journal of Gait & Posture in 2017. As a result of this, Gait & Posture will publish a special issue in 2019 on upcoming technologies, including inertial sensors, and their uses in clinical settings.

Despite their gaining popularity, inertial sensors have their limitations. Firstly, most devices make use of the earth's magnetic field, and are therefore susceptible to drift due to interference from other electronic devices (van der Straaten *et al.,* 2018). This is known as field distortion, and is especially prominent in modern buildings, such as hospitals (Cooper *et al.,* 2009). This is problematic, as the resulting data can be inaccurate, with some studies reporting mean differences >5° between inertial sensors and three-dimensional motion capture systems (the gold standard method of reporting human movement) (van der Straaten *et al.,* 2018). A recent study by Cooper and colleagues aimed to overcome this disadvantage by using complex filtering techniques and biomechanical constraints on their devices. Individuals were asked to bend the knee, whilst the inertial sensors and a 3D motion capture system reported sagittal plane knee kinematics. The largest error between both devices was 3.4°, which is clinically acceptable (<5°). However, the sample size was very small in this study (7 adults), and all participants were young and healthy. Further research is therefore required in order to determine whether these devices are appropriate and valid in older populations with pathological knees.

Other disadvantages to using inertial sensors to report knee ROM include cost. Inertial sensors are far more expensive than manual goniometers and electrogoniometers. One inertial sensor costs approximately £1,000, and given that at least two sensors are required to quantify the ROM of one joint, users would be obliged to spend at least £2,000 on the sensors alone. As well as being expensive,

the devices are far more complicated and time consuming than traditional methods.

Collectively, these limitations imply that the present technology is not affordable, accurate, or appropriate enough for routine clinical use. However, current demand and increasing research into the use of inertial sensors may in future bring down their cost, and make them a more viable alternative to other methods of reporting knee ROM.

To conclude, recent studies suggest that an alternative method of measuring knee ROM is now required in the orthopaedic environment for assessing the TKA population accurately, reliably, and efficiently (Lavernia *et al.,* 2008). The work in this thesis will therefore utilise the current gold standard method of reporting human movement, creating a motion capture-based assessment of passive, active and dynamic knee ROM for OA and TKA individuals.

Knee Muscular Strength Measurement

Muscle strength assessments have been found to aid clinicians in identifying sources of muscle weakness (Henriksen *et al.,* 2011; National Isometric Muscle Strength Database Consortium, 1996). From this clinical evidence, physiotherapists are able to generate patient-specific rehabilitation plans to improve knee strength (Gagnon *et al.,* 1998; Henriksen *et al.,* 2011; Van der Esch *et al.,* 2007; Wiles & Karni, 1982).

Despite this, and the fact that poor muscle strength is often reported amongst TKA patients, knee muscular strength is not routinely assessed following TKA (Henriksen *et al.,* 2011).

Subjective methods such as manual muscle testing are often performed in the clinical environment, but objective methods are less commonly used (The National Isometric Muscle Strength Database Consortium, 1996). During subjective muscular strength testing the patient is asked to flex or extend against resistance

placed on the limb by the examiner. Despite being simple and free, quantitative results cannot be obtained through these methods.

The current clinical standard for measuring knee strength quantitatively is the chair-fixed isokinetic dynamometer (Figure 2.15A) (Candow & Chilibeck, 2005; de Araujo Ribeiro Alvares *et al.,* 2015; Gagnon *et al.,* 1998; Gross *et al.,* 1989; Henriksen *et al.,* 2011; Samuels & Rowe 2012; van der Esch *et al.,* 2014). However, routine use of chair-dynamometers is uncommon for economic reasons. Hospitals rarely invest in chair-dynamometers as they only have one function and often occupy a whole hospital room (Henriksen *et al.,* 2011).

Flexor and extensor knee strengths can also be measured using isomeric strain-gauged devices, such as a myometer (Figure 2.15B) (National Isometric Muscle Strength Database Consortium, 1996; Wiles & Karni, 1983). By exerting a force on the device via a strap attached above the ankle, a voltage output is produced and converted into Newtons (Bemben *et al.,* 1991; Jakobi *et al.,* 2002). These tools are small, relatively cheap to buy, and easier to use than chair-fixed dynamometers (Ushiyama *et al.,* 2015).

Similarly, handheld myometers are used in the clinical environment for quantifying muscular strength (Phillips et al., 2000; Roebroeck et al., 1998). To assess knee flexor and extensor strengths, a clinician would hold the myometer in the palm of their hand while applying force to the patient's shank to flex or extend the knee. The patient would resist this force to the best of their ability, and the force exerted would be recorded by the device (Phillips et al., 2000; Roebroeck et al., 1998). This follows the protocol used during manual muscle testing (Stark et al., 2011).

Stark and colleagues conducted a literature review on the use of handheld myometers in 2011, and concluded that they are unlikely to replace the current clinical standard method of quantifying force, due to their unreliability, especially at larger joints such as the knee (Stark et al., 2011).

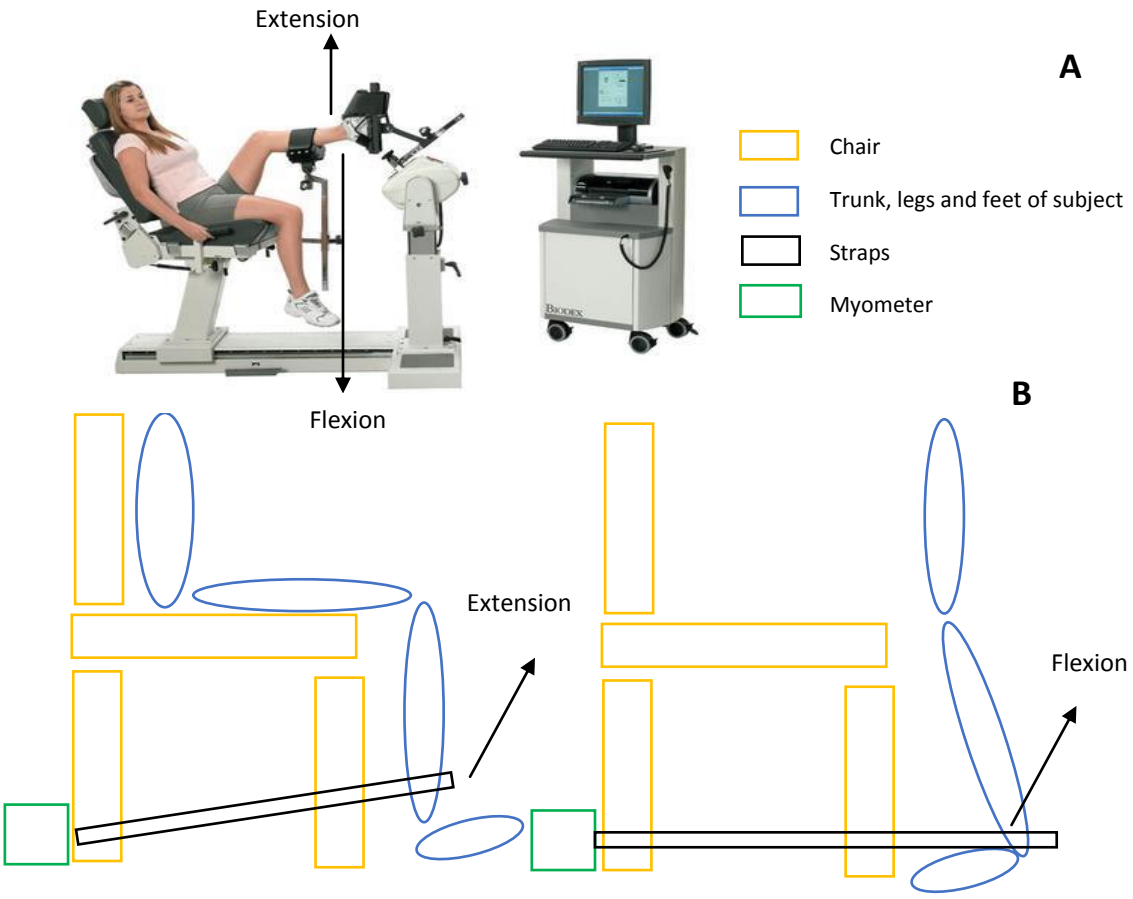


Figure 2. 15: A) An example of a chair dynamometer. B) A diagram of how a myometer could be used in a clinical environment to report knee strength. Notice that the testing can be carried out with the patient sitting and/or standing.

(Photograph Source: Biodex Medical Systems, 2017).

Although these devices are occasionally used to assess muscular strength in a clinical environment, the results often do not reflect the true strength of the knee. This is due to the fact that the protocols used do not take into consideration three variables which directly affect muscular strength (Figure 2.16). These variables are gravity acting on the limb, the moment arm of the force transducer relative to the joint and the angle of the knee (National Isometric Muscle Strength Database Consortium, 1996; Samuels & Rowe, 2009; Smidt & Rogers, 1982).

To show the effect of changing the angle of a joint without considering the alteration in the moment calculation, a simple example is given. If a joint is set at 90º and a force of 50N is applied (shown in orange in Figure 2.16), the moment is equal to the force multiplied by the perpendicular distance (e.g. 0.3m) between the line of action of the force and the axis of rotation. For the weight of the limb (shown in blue in Figure 2.16), there is no moment generated as the perpendicular distance between the line of action of the force and the knee is 0. The moment is therefore 15Nm in total in this example (0.3m x 50N). However, if the angle of the knee is changed to 60º, but all other variables remain the same, the moment arm for the weight of the limb increases from zero as its line of action no longer passes through the knee joint. The moment is therefore now equal to 7.5Nm (0.3m cos 60º x 50N). As is shown in Figure 2.16, this angle can easily be changed during a force assessment. However, the change is rarely taken into consideration by strength measuring tools.

It is reasonable to suggest that using methods which simply report the load on the transducer and which do not consider these biomechanical considerations will result in erroneous data. This suggests that alternative and appropriate methods of calculating knee flexor and extensor strengths which are biomechanically correct should be made available to clinicians using this simple method. The work described in this thesis will propose such a method.

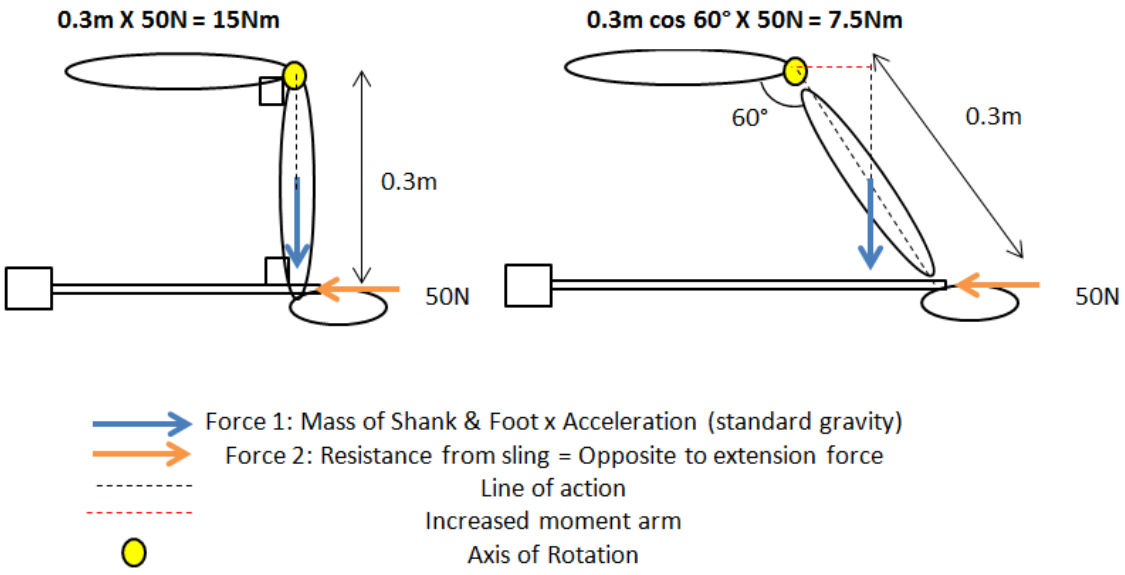


Figure 2. 16: Diagram of the effect of angular change of the knee on knee forces and moments during a strength assessment.

2.4.3. Conclusion

In order to optimise outcome following TKA, a detailed assessment of knee function pre- and post-surgery is required. At present however, few objective scientific assessments are used clinically to test knee function. Of those that are used, many have been reported to be inaccurate, unreliable and inappropriate for assessing dynamic motion.

3D motion capture technology is currently the most accurate and reliable method of reporting pre- and post-operative biomechanics (Jevsevar *et al.,* 1993). This thesis therefore proposes the development of a motion capture-based application for assessing knee function in TKA patients.

The following section of this review will provide the reader with a background into human movement analysis and its current use in the clinical environment.

2.5. Human Movement Analysis

Motion analysis, specifically gait analysis (GA), is becoming increasingly accepted as the 'gold standard' outcome measure for assessing human movement (Jevsevar *et al.,* 1993; McClelland *et al.,* 2009). It is frequently used to evaluate the ability of an individual to carry out tasks of daily living, especially walking (Levinger *et al.,* 2013). However, its place as a clinical outcome measure remains debatable and its adoption into clinical practice limited.

According to recent research, GA is the most effective outcome measure for detecting changes in the function of the knee joint pre- and post-operatively, as other objective tools are often unable to provide accurate enough results (Andriacchi & Dyrby, 2005; Hossain *et al.,* 2013; Jevsevar *et al.,* 1993).

Criticism is given to manual methods of assessing knee function, as they do not reflect dynamic motion of the knee (Rowe *et al.,* 2002). GA however, is an outcome measure used specifically to analyse and interpret patterns of movement during activities of daily living (Baker, 2006). Thus, in this sense, GA has a significant advantage over outcome measures which only provide results under static conditions. It therefore has greater content validity.

Accordingly, one of the main benefits of analysing human movement in this manner is the ability to gather quantitative data about the functional abilities of a person (Cappozzo *et al.,* 2005; McClelland *et al.,* 2007). This data provides researchers and medical professionals with information on joint mechanics and loading, which is dependent upon the alignment and dynamic motion of the joint (Hatfield *et al.,* 2011; Teixeira & Olney, 1996). By providing information on the biomechanics of the knee and other lower limb joints, GA can be used by clinicians and researchers to better manage various pathologies, including OA (Banks, 2005; Teixeira & Olney; 1996). However, pathological gait can only be identified if the assessor has an

understanding of a non-pathological walking pattern (Baker *et al.,* 2006; Benedetti & Pignotti, 1998; Krauss *et al.,* 2012; Whittle, 1996).

The following sections will provide the reader with descriptions of a normal gait cycle and the parameters of gait which are used to assess individuals with gait disorders.

2.5.1. The Gait Cycle

According to Kirtley (2006) and Whittle (1996), the gait cycle is defined as a repetitive movement which involves loading and unloading the limbs, whereby the time between two identical stages of the cycle is recorded.

The normal gait cycle can be divided into two phases known as 'stance' and 'swing'. The stance phase lasts approximately 62% of the gait cycle, and equates to the duration of time that the foot is in contact with the ground (Rose & Gamble, 2006). This phase is essential for bipedal walking, as it is characterised as the time at which the weight of the whole body is transferred onto one limb (known as the stance limb), whilst the contralateral limb propels the body forwards and upwards. Balance and stability is therefore crucial for normal walking.

The swing phase lasts approximately 38% of the normal gait cycle. During the swing phase the limb is propelled forwards, in front of the stance limb to allow forward progression (Rose & Gamble, 2006).

To further understand the gait cycle, the stance and swing phases can be broken down into periods (Figure 2.17). During the stance phase, a limb will undergo the following periods, respectively: loading response, mid-stance, terminal stance, and pre-swing (Whittle, 1996).

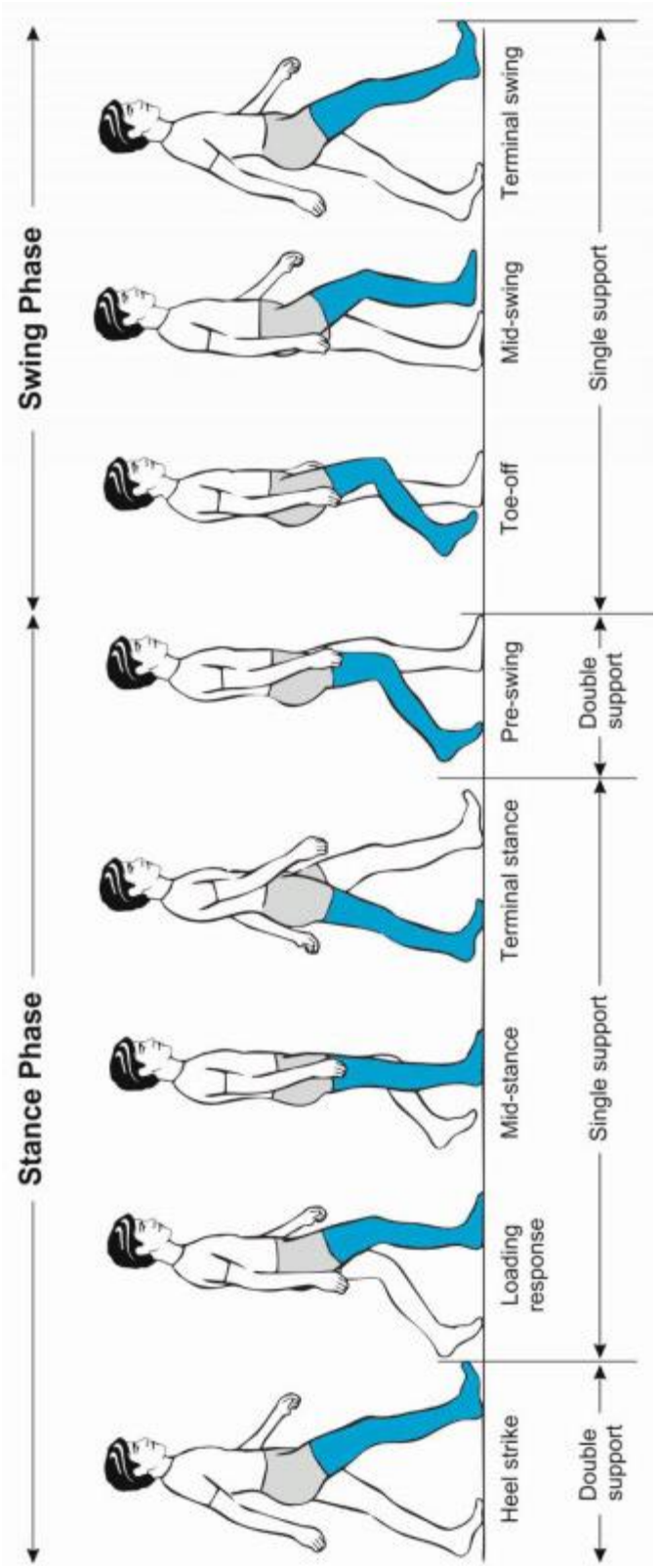


Figure 2. 17: A diagram depicting the phases and periods which make up one gait cycle.

Source: Pirker & Katzenschlager. 2017

In people who have a normal gait pattern, the events, periods, and phases which both limbs undergo are identical; however, the movements are 180° out of phase. Typically, the heel is the first part of the foot to contact the ground during foot-strike and the toe is the last part of the foot to leave the ground during foot-off. This may not be the case in abnormal gait, where the first and last contacts made with the ground are referred to as 'first-contact' and 'final contact'.

Although the gait cycle remains relatively consistent in normal walking, a number of variables including age, sex, and height can affect gait parameters. For example, according to Rose & Gamble (2006), the duration of the stance phase decreases (as that of the swing phase increases) with age.

There are a considerable number of parameters of gait (variables) which can be measured during a gait trial. The most commonly reported parameters include spatio-temporal factors, gait kinematics, and gait kinetics (Rose & Gamble, 2006).

All spatio-temporal parameters of gait can be measured by analysing the foot falls during a gait cycle. These parameters are often recorded automatically by specialised GA software, making it quick and easy for researchers and clinicians to assess the gait of patients, provided they exhibit reciprocal gait.

It should be noted however, that not all people with a normal gait have the same spatio-temporal, kinematic and kinetic results as gait is an inherently variable and individual activity. Nevertheless, the values recorded in people with normal gait fall within a range of values deemed to be non-pathological. This allows variation between different people to be taken into consideration.

2.5.2. Two-Dimensional Gait Analysis

Simple temporal measurements are traditionally measured using 2D GA techniques. These methods were introduced in the early twentieth century to analyse human movement (Minns, 2005). The advantages of 2D GA are that it is simple, quick, and affordable (Minns, 2005).

The equipment required to carry out a 2D temporal GA include a space for walking (such as a gait laboratory), a video camera, and a stopwatch (Robinson & Smidt, 1981). Due to the simplicity of this method, researchers and clinicians are not required to undergo lengthy training sessions to be able to collect data on human movement. If supplemented with a gait mat, spatial parameters of gait can also be recorded.

The most commonly analysed spatio-temporal factors include velocity, cadence, step length, and stride length. These have been found to provide highly reproducible results (ICC > 0.90) which represent different aspects of gait well (Hossain *et al.,* 2013; Meldrum *et al.,* 2014). It is therefore unsurprising that spatio-temporal parameters are often used to describe gait in TKA patients pre- and post-operatively.

Walking Speed

Walking speed is defined as the distance covered per unit of time (usually meters per second).

Gamble & Rose (2006) state that the mean walking speed of a healthy adult increases and then decreases with age, peaking between the ages of 40 and 45 at 1.60m/s. Studies have shown that people in the same age range as those likely to suffer from OA of the knee have a mean walking speed of approximately 1.30m/s (Levinger *et al.,* 2013; McClelland *et al.,* 2010). This speed is reduced, often <1.0m/s, in patients with joint diseases such as OA (Baliunas *et al.,* 2002; Benedetti *et al.,* 2003; Kaufman *et al.,* 2001). Elbaz and colleagues (2014) found that females

and males with severe knee OA had a mean walking speed as low as 0.55m/s and 0.65m/s, respectively.

Walking speed data may also be recorded during activities of daily living in patients suffering from OA. Kaufman *et al.* (2001) found that OA patients ascend and descend stairs slower than their age and gender matched healthy equivalents. It was reported that both control and OA subjects performed slowest when ascending stairs, with those with OA moving at 0.48m/s, and the healthy subjects moving at 0.57m/s (Kaufman *et al.,* 2001).

Aichroth *et al.* (1978) suggested that the ability to walk should be graded according to distance or time. Hence, walking speed and distance covered are often used as outcome measures in orthopaedic research.

Cadence

The number of steps in a certain time frame is defined as 'cadence' (Rose & Gamble, 2006). It has previously been reported that cadence is significantly increased in patients suffering from OA when compared to control subjects who walked at the same walking speed, suggesting that they had shorter stride lengths (Baliunas *et al.,* 2002). Conversely, when subjects are free to decide their walking speed, the cadence tends to be reduced in OA sufferers. Levinger and colleagues (2013) recorded a mean cadence of 113.76 steps/min in people with OA, and a mean cadence of 121.27 in control subjects. Much lower cadences (<50 steps/min) have been reported in TKA patients (Benedetti *et al.,* 2003; Bonnefoy-Mazure *et al.,* 2017).

Stride Length

According to Rose and Gamble (2006), stride length is "*the distance travelled between two successive foot strikes of the same foot"* and consists of a left and right step (Figure 2.18).

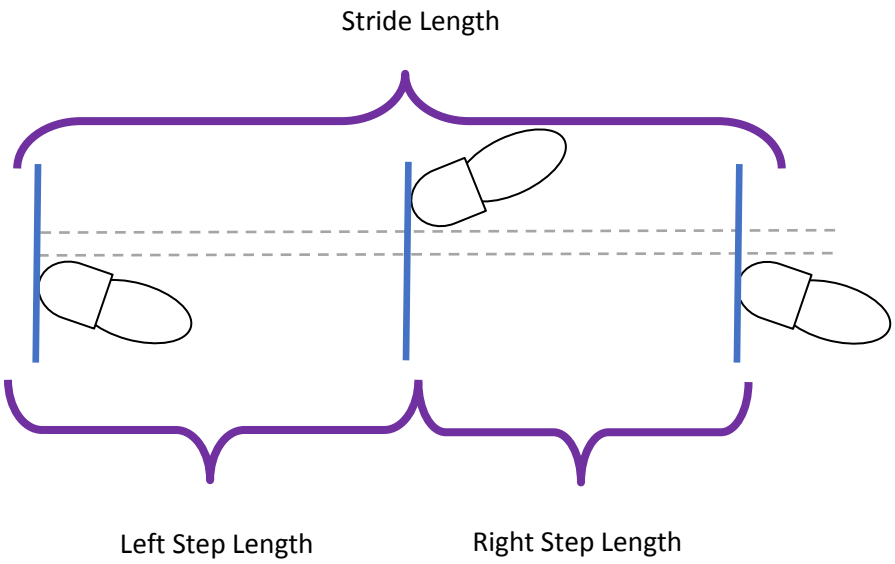


Figure 2. 18: A diagrammatic representation of the definition of stride and step lengths.

Stride length has been found to increase with age, with maximum stride length reaching approximately 1.60m. A recent study found that patients with OA had an average stride length of 1.19m in comparison to controls who had a mean stride length of 1.36m (Levinger *et al.,* 2013).

By understanding these patterns, and what is defined as 'normal' speed, cadence or stride length, clinicians are able to assess the progress of their patients following an intervention such as TKA. However, these global gait parameters do not indicate how that gait was achieved by the joints of the lower limb. Often, symmetrical spatio-temporal gait parameters can be regained, but with asymmetrical joint movements. It is therefore important also to study the movements of the joints themselves.

2.5.3. Three-Dimensional Gait Analysis: Kinematics and Kinetics

An advantage that 3D GA has over 2D GA, is that joint biomechanics in all three planes can be assessed simultaneously (Desloovere *et al.,* 2010). This is crucial in TKA assessments, considering that frontal and sagittal plane knee biomechanics have been shown to differ between OA sufferers, TKA patients, and control subjects (Sosdian *et al.,* 2014).

Most modern 3D GA protocols utilise stereophotogrammetry (motion capture technology). The protocol involves placing retro-reflective markers on anatomical bony landmarks of an individual, then recording the individual carrying out a series of motor tasks while observed by multiple infra-red cameras (Figure 2.19) (Cappozzo *et al.,* 2005; Carse *et al.,* 2013; Davis, 1997). If a force plate is added, kinetics can also be estimated. This technique is currently the 'gold standard' for GA, but is rarely used clinically (Meldrum *et al.,* 2014).

Advantages to using 3D GA include the following:

- The assessment is non-invasive.
- Whole-body measurements and the movement of joints can be recorded easily.
- Multiple measurements (e.g. repetitions of a movement) can be recorded easily.
- Large amounts of valuable data can be collected (Fantozzi *et al.,* 2003).
- A range of parameters of gait, joint kinematics and kinetics can be calculated from recorded trials by specialised software.
- Recordings can be shown to the patients during their treatment programme, allowing them to visualise their progress over time.

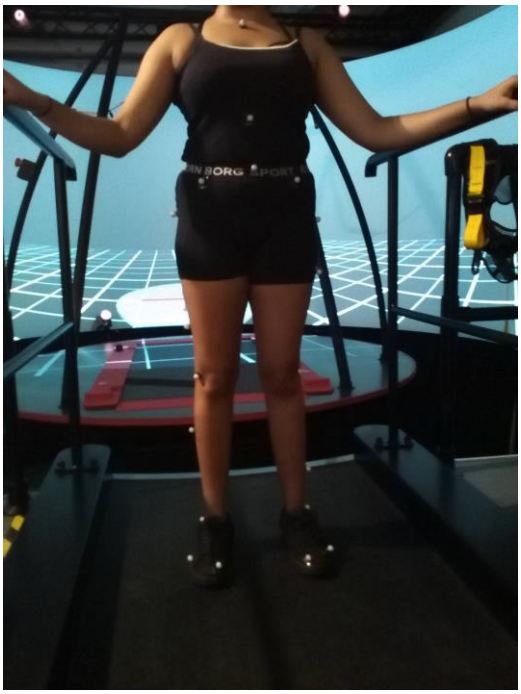


Figure 2. 19: A volunteer wearing retro-reflective markers prior to undertaking a 3D gait analysis.

Joint kinematics are calculated from the positions of retro-reflective markers. The position of theses markers in 3D space are detected by the infra-red cameras within the laboratory (Cappozzo *et al.,* 2005; Davis, 1997). Marker co-ordinates are initially described in terms of the global (or laboratory) reference frame (Davis, 1997). However, as these markers *represent* the underlying anatomical landmarks, these co-ordinates can be translated to an anatomical reference frame (Figure2.20). This enables us to describe the instantaneous position and orientation of the underlying bones and the joint centres (Benoit *et al.,* 2006; Cappozzo *et al.,* 2005; Davis, 1997).

Transformation matrices are used to translate marker co-ordinates in the three-dimensional global reference frame into an embedded anatomical reference frame.

Rigid body mechanics principles are applied to the translated co-ordinates in order to calculate kinematic outputs in the body reference frame.

Consequently, knee ROM in terms of anatomical movement of joints can be calculated by tracking the relative movements of markers placed on the proximal and distal segment of the joint and then calculating the relative angles between these two embedded axis sets (Benoit *et al.,* 2006; Lafortune *et al.,* 1992).

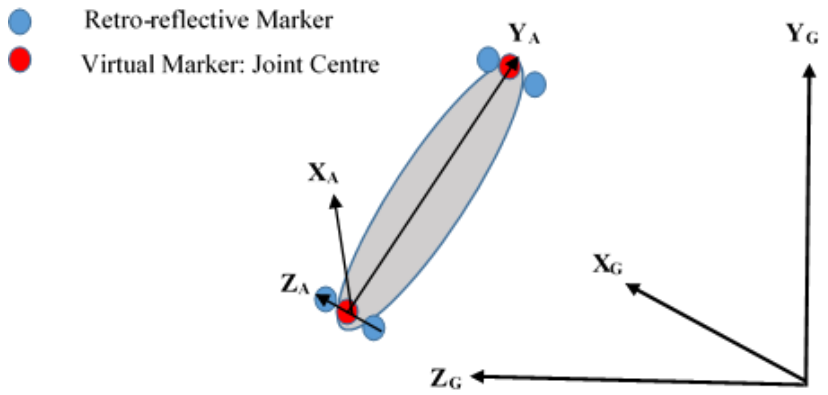


Figure 2. 20: A diagram of a segment with an anatomical reference system (X_A,Y_A,Z_A) within a global reference system (X_G,Y_G,Z_G).

In general, a marker-set of approximately 10-50 individual markers are needed to generate a full biomechanical model with which human movement biomechanics can be investigated.

The forces and moments generated on the floor can be measured with force plates and used to estimate kinetic data which describe the magnitude and direction of forces relative to the joint or joints in question (Minns, 2005). Joint moments can also be estimated using inverse dynamic principles, provided that the perpendicular distance from line of application of the ground reaction force to axis of rotation of the joint is known (Smidt & Rogers, 1982).

Restoring normal knee mechanics is one of the most important aims of OA treatments because ROM, strength, stability and pain levels are dependent upon the mechanics of the knee being within normal ranges.

2.5.4. The Disadvantages of Current Gait Analysis Methodology

Although motion capture technology is effective at describing human movement, a number of disadvantages dissuade clinicians from using the technology beyond the biomechanical research environment. For the purposes of this review, these will be described as being protocol-related or technology-related disadvantages.

Protocol-Related Disadvantages

Despite being essential for most 3D biomechanical assessments of gait, the use of individual retro-reflective markers has been described as inaccurate in location, unreliable in position, and time consuming to administer (Alexander & Andriacchi, 2001; Baker., 2006; Benedetti *et al.,* 1998; Benoit *et al.,* 2006; Sholukha *et al.,* 2013).

One notable source of error which is not controlled by the use of individual markers is 'soft tissue artefact' (Baker, 2006; Leardini *et al*., 2005; Peters *et al*., 2010). This artefact is caused by the movement of a marker in relation to the underlying bone (Baker, 2006; Cappozzo *et al*., 1996). As the markers are often attached directly to skin, movement of the limb naturally causes the soft tissue (especially skin and fat) surrounding the bone to move relative to the bone itself. Consequently, the marker attached to the skin moves to a position where it may no longer truly represent the position of the bony anatomical landmark on which it was originally placed. This error can be amplified if the marker is placed on clothing as opposed to skin; especially if the clothing is loose-fitting (Baker., 2006; Benedetti *et al.,* 1998).

Marker placement is therefore important for 3D biomechanical assessments. However, to further complicate this matter, many bony landmarks used by

biomechanical models are difficult to palpate. As a consequence, placement accuracy is often dependent on the competence and experience of the examiner (Alexander & Andriacchi, 2001; Benoit *et al.,* 2006).

Placement errors translate to errors in kinematic and kinetic data as they affect the anatomical axes calculated from marker positions (Alexander & Andriacchi, 2001; Benoit *et al.,* 2006).

To minimise these errors, participants undergoing gait or motion analysis are required to wear as little clothing as necessary, and where clothing is used it must be tight fitting (Figure 2.19). Males are often requested to carry out the assessments topless to avoid having to place markers on clothing. This state of undress is itself problematic, as it discourages people from taking part in motion analysis studies, as they do not feel comfortable with the protocol. As such they do not consent to participate in motion analysis studies or do not return for follow-up.

Using individual retro-reflective markers also comes with the risk that information on marker position can be lost due to markers becoming occluded or falling off the individual during a trial.

Marker occlusion occurs when the 3D position of a marker cannot be reconstructed by the specialised software, usually because the marker is not in the field of view of two or more cameras. Gap filling techniques can be used by the software to reconstruct the estimated position of the marker; however, these are not always successful or accurate.

Trials where markers are missing are often unusable, as the software which calculates the kinematics and kinetics cannot always compensate for a missing marker. This loss of potentially important data can be detrimental to a study.

In the laboratory, an assessor usually has one of four options in cases where markers become occluded or fall-off the individual; each has its own advantages and disadvantages (Table 2. 7).

Table 2. 7: An outline of four actions which could be taken by an assessor following marker loss.

Action	Advantages	Disadvantage
Re-calibrate participant and re-start analysis	Most likely method to return accurate and reliable results (given that marker placement is correct).	Unfavourable if participant is not coping well with the assessments (e.g. due to pain) as they will be required to spend further time in the laboratory. Hence, it is time consuming
Stop analysis and send participant home	This saves time and saves the participant from having to re-do each trial	Potentially useful data could be lost due to the fact that the assessment was not completed
Place marker back where it was and continue analysis	Saves time and saves the participant from having to re-do the trials they had already done	Doing this introduces further error into the data, as it is unlikely the position of the marker will be exactly the same as it was when calibrated
Place marker back, re-calibrate and continue the assessments	Saves time and ensures a complete set of data is recorded	The data may differ between both sets due to two calibrations

Technology-Related Disadvantages

Motion capture technology also has technical limitations which influence its use as a clinical outcome measure. These typically include complexity, cost and size.

The complexity of current motion capture technology means that using it to record biomechanical data is often very time-consuming (Liebensteiner *et al.,* 2008). Even before beginning recording data, assessors are required to calibrate the cameras, then prepare the individual – taking care to place markers accurately. On completion of data collection, assessors must then process the data using specialised software (a task that can take many hours), before beginning to interpret the complex graphs (Meldrum *et al.,* 2014). The threshold for use by previously untrained clinical researchers is therefore high, putting many off.

3D GA laboratories therefore tend to rely on trained and experienced individuals. Given the facts that so much time and knowledge is currently required to assess one individual, it is unsurprising that 3D GA is not an attractive outcome measure to most clinicians.

A further disadvantage to 3D GA is that the hardware and software are extremely expensive to buy and maintain (Liebensteiner *et al.,* 2008; Minns, 2005). The cost of having a specific room designated for the laboratory should also be considered. This is recommended as it ensures that the privacy of the individual is maintained, and that no background movement of retro-reflective material is detected by the cameras during use. A large space is also necessary so that the individual can achieve steady state walking before having to slow down again.

For the above stated reasons, GA laboratories are not common in hospitals or other clinical environments (Figure 2. 1) (Hossain *et al.,* 2013; Toro *et al.,* 2003). To put into perspective, the UK CMAS (Clinical Motion Analysis Society) community currently (2014) includes only 18 laboratories, and the UK is probably the best supplied country for GA in the world. This presents an accessibility problem to health professionals and patients who could benefit from using such facilities (Toro *et al.,* 2003).

Figure 2. 21: An example of a gait laboratory.

It is therefore unsurprising that GA is not used routinely to assess patient progress in orthopaedics, despite the fact that information provided by such systems have been fundamental to orthopaedic implant design since the 1970s. On the rare occasion that GA is used as an outcome measure, it is highly likely that only a small number of patients are analysed in this manner due to the cost (Myles *et al.,* 2002).

2.5.5. Conclusion

3D GA is currently the most effective way to collect kinematic and kinetic data on patient functional outcome. Despite the fact that GA has major advantages such as being non-invasive, accurate and reliable, issues such as cost and complexity prevent this outcome measure from being used routinely in a clinical environment (Dimancio *et al.,* 2009). However, the cost of the equipment has decreased by a factor of 10 in the last decade and is expected to reduce by a further factor of 10 in the next decade. According to Vicon Motion Systems (motion capture technology

specialists) this drop in price makes the technology likely to be affordable from a capital cost perspective.

Hence, the aim of the work carried out in this thesis is geared to the construction of a smaller and simplified motion capture system which could be used in a hospital setting by operators with typical clinical skills to report functional outcome in orthopaedics. Our proposal is outlined in detail in Chapter 3.

The development of such a system would allow clinicians and researchers to see the potential of clinical GA for use in clinical research and clinical practice. Prior to developing a system for use in this environment however, it is important to understand the current relationship between clinicians (the future users) and biomechanics (the data they will have access to). The final section of this review will therefore discuss the current use of GA in the clinical environment.

2.6. Gait Analysis in the Clinical Setting

Recent orthopaedic research indicates that gait and knee function are better in patients who have had the opportunity to have their gait analysed as part of their rehabilitation programme, in comparison to those who have not (Wren *et al.,* 2011b).

Research has also shown that clinicians are willing to consider data from GA assessments when making treatment plans, to benefit the patient (Davis, 1997; Lofterød *et al.,* 2007; Wren *et al.,* 2011b). Nevertheless, as was stated previously in this review, GA is not routinely carried out prior to, and following treatments such as TKA (Dimancio *et al.* 2009).

In 2007, Baten *et al.* presented work on the feasibility of using motion capture technology in the clinical environment. They stated that the following criteria must be fulfilled for it to be considered as a possibility:

1. The system must be affordable and portable.
2. The results provided must be accurate and reliable.
3. It must not be time consuming.
4. The results must be interpretable to persons who are not from an engineering background.

These four criteria reflect the current disadvantages encountered by motion capture users. By developing ways to address these issues, it is believed that GA could become a more widely used tool – benefiting patients suffering from pathological gait.

2.6.1. Health Professionals and Gait Analysis

In 1981, Robinson and Smidt published a paper discussing ways in which gait could be quantitatively and objectively analysed in a clinical environment. They suggested focusing on spatio-temporal parameters including stride length, step length, cadence and walking speed, as these methods are quick to teach, learn and carry out, and are also cheap (Robinson & Smidt, 1981). Investigation of spatio-temporal parameters in a clinical setting has since been declared as a reliable way to analyse gait in a clinical or hospital setting (Minns, 2005). However, normal symmetrical foot-falls can be achieved even when joints are restricted as the lower leg has some redundancy (extra degrees of freedom than required) (Rowe, 1990). Hence, joints can compensate for each other. It is therefore necessary in orthopaedics to record body segment movement and joint angles to know if the subject is moving normally (Rowe, 1990).

According to Coutts (1999) and Toro *et al.* (2003), physiotherapists tend to analyse gait by eye alone. This method is deemed favourable by health professionals as they have limited time and space to carry out instrumented investigations, and also have

very little money and training opportunities. Coutts (1999) stated that by training physiotherapists to use newer GA technology their observational skills could be improved. It could also save time, as the number of times patients will be required to repeat functional activities could be reduced.

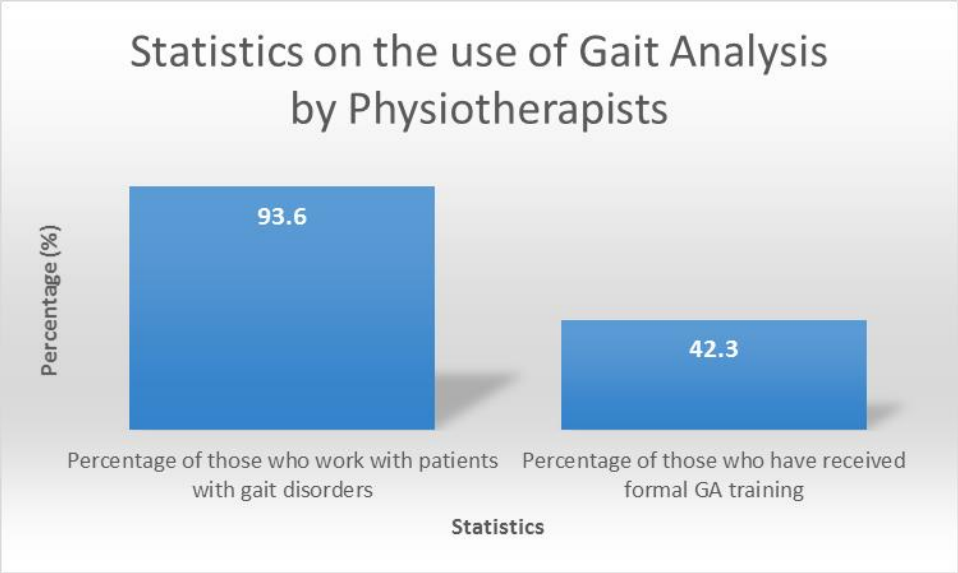


Figure 2. 22: Results from a questionnaire on the use of GA by UK physiotherapists. Statistics were published in a study by Toro *et al.,* in 2003.

Based on the data collected by Toro *et al.* (2003) (Figure 2. 2), it can be inferred that the majority of physiotherapists in the UK are not qualified to analyse gait and are consequently unable to use 3D GA systems. Due to the complexity of current 3D GA technology, long training sessions are usually required to learn how to correctly organise, calibrate, and use the system's hardware and software.

Due to the lack of training available to those with the ability to use GA to assess patient progress the reliability of results collected by those who do use GA can be questioned. A study by Leigh *et al.* (2014) investigated the inter- and intra-tester reliabilities of this outcome method with examiners of different experiences. They

compared results from a biomechanist with 8 years of experience with GA to a physiotherapist with no previous GA experience. Both were asked to assess patients using functional and predictive joint approaches; whereby the former is based on patient movements, and the latter based on marker placement. Unsurprisingly, intra-tester reliability was high (>0.90). Inter-tester reliability was also high, at >0.85 for all measurements. Hence, the authors concluded that it is possible to train physiotherapists with no previous GA experience how to use 3D GA technology and reliably place markers on patients (Leigh *et al.,* 2014). A study by Dimancio *et al.* (2009) reported similar findings.

Although these results seem highly positive, only one physiotherapist was involved in the study by Dimancio *et al.* (2009), and only 2 were involved in the study by Leigh and colleagues (2014). Hence, in future, a larger comparison is needed between experts and novices in 3D GA to determine whether the results reported by both studies are statistically sound.

Another disadvantage to these studies is that the cameras used to capture the data were calibrated by technicians and not the clinicians. If motion capture technology was to become a standard outcome measure in the clinical environment, clinicians would be required to use the software themselves. The software used should therefore be simplified to ensure that training time is minimised, and that an assessment can be carried out by one clinician working on their own.

Simplifying the protocol used to analyse gait with motion capture technology is likely to make it more acceptable to physiotherapists and other health professionals and hence, to widen its clinical use.

2.6.2. Conveying Biomechanical Data

Also contributing to the limited use of clinical GA is the complexity of the results obtained (Loudon *et al.,* 2012). Hence, to make this technology more accessible to

the general public and clinicians, a way to convey biomechanical information in layman terms is paramount (Baten *et al.,* 2007; Loudon *et al.,* 2012; Loudon *et al.,* 2009).

Currently, the data produced by GA software are in the form of complex graphs, which can usually only be fully understood by those who have studied biomechanics (Loudon *et al.,* 2009; Macdonald *et al.,* 2010).

By simplifying the data presentation the examiner and patient will be able to distinguish areas of weakness or strength in performance more easily. In this way, patients would gain a deeper understanding of their gait disorders (Macdonald *et al.,* 2012). This may encourage patients to fully commit themselves to their treatment plans, and motivate them to work on areas of weakness when they are not in the clinic (Loudon *et al.,* 2012; Singh *et al.,* 2012).

Virtual reality and motion capture technologies are increasingly being used together to aid rehabilitation, as well as educating patients on their disabilities (Laver *et al.,* 2011).The most technically advanced systems of all immerse patients in an environment that provides real-time visual feedback (Figure 2.23). This often involves the use of colour-coded graphs, numbers, or avatars of the participant, which they are able to visualise on a nearby computer or projector screen (de Araujo Ribeiro Alvares *et al.,* 2015). These applications allow a computer-participant interaction to improve performance and hence, patient outcome (Laver *et al*., 2011).

Figure 2. 23: An example of a purposeful game used to assess and improve stability. The participant is immersed in a virtual reality and controls the movement of a boat through a pre-determined course. Motion capture technology is used to track her movement.

(Source: Motekforce Link, 2015a)

A study by Macdonald and colleagues (2012) used visual feedback in a stroke rehabilitation setting. 3D images of the participants were used to convey biomechanical data on participant ability. During trials, the lower limb joints of this avatar would glow green, orange or red, based on the level of functional demand at the joints at that precise moment. In addition to being able to visualise the joint activity, the movements made by the patients could be visualised by the examiner and shown to the participant in real time from any angle due to the use of 3D technology (Loudon *et al.,* 2012; Loudon *et al.,* 2009).

These kinds of methods of conveying biomechanical data are deemed appropriate for patient use (Macdonald *et al.,* 2012; Macdonald *et al.,* 2007), however care must be taken to ensure that the immediate feedback does not upset or discourage a patient (Loudon *et al.,* 2012).

A further study, published in 2014 (Carse *et al.,* 2014) investigated the hypothesis that visualisation enabled stroke survivors who required an ankle foot orthosis to understand basic biomechanical concepts. Visual feedback was given to half of the trial participants during testing. Six months following baseline tests, it was found that those in the visual feedback group had better spatio-temporal results, with walking velocity being significantly better when compared to those who's gait rehabilitation was undertaken traditionally (Carse *et al.,* 2014).

Research is fast emerging on the use of visual feedback in the stroke rehabilitation setting (Laver *et al.* 2011); however, little is known of the advantages and disadvantages of its use in an orthopaedic environment. Recent work by Millar (2016) showed improvements in knee function of TKA patients following visualisation, but the group samples were small (15 patients in each group).

2.6.3. Conclusions

Clinical use of 3D GA is rare due to the amount of money, time and training clinicians would need to invest in it for it to be worthwhile. The development of a simpler, cheaper and quicker alternative however, could be a viable option for the clinical environment and for the objective assessment of TKA surgery.

2.7. Summary

This literature review has highlighted the importance of assessing knee function in terms of ROM, strength and stability pre- and post-TKA. Despite this, the current protocols used by clinicians to assess these variables do not provide enough accurate or reliable data on dynamic knee function. Scientifically, 3D GA is a much more appropriate outcome measure, but current protocols and systems prevent it from being a feasible clinical tool for routine use in clinical practice.

The overall aim of this study is therefore to develop a way to incorporate a simplified motion capture system into a typical clinical environment. The goal is to convert current methods successfully used in the research environment to assess knee function into clinical applications which utilise motion capture technology. These will be used to gain easily interpretable information on knee strength, ROM, gait kinematics and gait stability and to evaluate the novel Medacta GMK Sphere implant which was specifically designed to address problems in these factors seen in typical TKA. The following chapter outlines the rationale behind the proposed functional outcome measure package.

Chapter 3. Product Proposal

This chapter hopes to familiarise the reader with the aims and objectives of this study, as well as clarify the rationale behind the project.

3.1. Ten Key Research Questions for this Thesis

1. What are the disadvantages to using traditional outcome measures to assess knee function pre- and post-TKA? (Addressed in the literature review)

2. How could these disadvantages be improved by utilising motion capture technology? (Addressed in the literature review)

3. What are the disadvantages currently associated with motion capture technology? (Addressed in the literature review)

4. Can current motion capture protocols be adapted to make them more acceptable for clinical use?

5. Is it possible to develop an accurate and reliable bespoke software package for health professionals to use with motion capture technology to assess knee function pre- and post-TKA?

6. How can we describe walking stability using motion capture technology?

7. What is the feasibility of using the software package and bespoke motion-capture set-up in a clinical environment to record data on knee function?

8. What are the advantages and disadvantages to using the motion-capture-based package in comparison to traditional methods?

9. Are there any statistical differences between pre-operative and post-operative knee ranges of motion, strength, stability and gait kinematics in patients undergoing a Medacta GMK Sphere TKA?

10. How do patients with the Medacta GMK Sphere TKA compare in function to other published data and concurrent studies?

3.2 Aims and Objectives of Investigation

The disadvantages of the current clinical assessments used in the orthopaedic environment to evaluate knee function were outlined in the literature review of this thesis. Based on these limitations, it was concluded that alternative methods of assessments could be advantageous to health professionals, to allow them to evaluate knee function more effectively and efficiently and hence drive selection of implants and rehabilitation programmes based on scientific evidence.

GA is becoming increasingly used for assessing the dynamic behaviour of joints (McClelland *et al.,* 2011; Rowe *et al.,* 2000; Toro *et al.,* 2003). Nevertheless, routine *clinical* use of motion capture technology is currently highly impractical and economically impossible.

As a result, this project aims to devise a small-footprint motion capture system which could be installed in a clinical environment. A bespoke software package will be developed for use with the system. This package will consist of multiple applications which use motion capture technology to quantitatively assess knee range of motion, strength, gait kinematics and gait stability.

Upon completion, each application will be validated against the equivalent current clinical standard method. Following this, the feasibility of using the system will be tested in a hospital environment.

The Medacta GMK Sphere knee replacement has been introduced to overcome the problem of mid-flexion instability reported in other knee arthroplasty designs. Hence, a study of this procedure would be useful in showing the value of the system whilst providing important clinical information on this novel implant.

If successful, the results from this study may encourage the clinical use of GA to aid clinical decision making and improve mobility in patients with knee OA, by enabling clinicians to make more focused and individualised treatment plans.

Following advice outlined by Baten *et al.* (2007) on the use of GA in a clinical environment, the most important features which will be considered during developing of this product are as follow:

- Accessibility: The system should be usable in clinical environment to ensure patients and health professionals can benefit from it.
- Ease of use by clinician: The user-interface should not be complicated, enabling any health professional to learn how to use the software and hardware easily.
- Familiarity: The tests used should be similar to the traditional protocols to reduce the learning curve of its users.
- Ease of use by patient: The protocol should be acceptable to patients
- Affordability: The cost of the hardware and software should be kept to a minimum.
- Interpretability: The results provided (both as live visual feedback and post-assessment results) should be easy to interpret by those who are not trained biomechanists.
- Time consumption: The whole examination (from hardware calibration to finishing the assessments) should not exceed 30 minutes.
- Footprint: The clinical gait laboratory should be as small as possible in size, to ensure that hospitals can accommodate the system.

The applications which will be developed for this package should also fulfil all criteria described in Table 2.4 (Outcome Measures) to ensure that their clinical use as an outcome measure is justified.

The following sections of this chapter will explain how the proposed product addresses the main issues associated with motion analysis technology when used in orthopaedics.

3.2.1. Addressing Current Problems with Motion Analysis

This thesis proposes the installation of a custom-built motion capture laboratory within an orthopaedic clinic. To ensure that the system fits the criteria previously outlined, an equipment set-up protocol must be devised that takes into consideration camera positions, their configuration, as well as patient and user safety.

Capture Volume Considerations

Given that hospital rooms are often multi-functional our motion capture system must be as space-efficient as possible. Leigh *et al.* (2014) successfully recorded reliable biomechanical data by asking patients to walk on a treadmill rather than on a walkway to minimise the area required for assessments. Our study will replicate this. To further minimise the required capture volume, all assessments will be designed for implementation on the treadmill. Patient calibration will also be carried out on the treadmill; therefore, the floor-space required will not be much greater than the size of the treadmill.

In addition to ensuring that the footprint of the system is minimal, the hardware used should be simple to dismantle and reassemble, or move. As a result, we aim to produce a space-conserving and moveable mounting frame for the cameras.

Ease of Use Considerations

In order for a clinical tool to be desirable to health professionals it must be simple to use and require little training, due to clinical time restrictions. Aspects of motion analysis which require extensive training include calibration of the system and of the patient, data processing, and interpretation of results. The following paragraphs explain how we will address these issues.

To reduce the complexity of system calibration, an application will be developed and incorporated into the software package to detect whether calibration is required before use.

Currently, system calibration generally takes 10-15 minutes. The user begins by masking the cameras. This process is carried out to block the infrared illuminations emitted by other cameras in the field of view of each camera. If this is not done, the illuminations may be reconstructed as markers during assessments.

Next, the user must wave a precision-engineered calibration wand within the field of view of the cameras. This wand is created by the manufacturers of the camera system and its shape is recognised by the software (Figure 3.1). The user must continue to wave the wand until enough frames have been captured of the wand by each camera. The software typically informs the user when enough frames have been captured. Following this, the user must wait for the software to accurately reconstruct the positions of the wand markers from the point of view of each camera for each frame recorded. The software is then able to reconstruct the capture volume by organising the cameras in relation to one another.

Figure 3. 1: An example of a precision-engineered calibration wand (Vicon Motion Systems, Oxford).

Information on the accuracy of the 3D reconstruction of a marker is calculated for each camera during this process. These values must be inspected by the user to ensure that all cameras have been sufficiently calibrated. Errors of <0.5mm are acceptable (Millar, 2017). If one or more cameras have errors greater than 0.5mm, the cameras must be re-calibrated.

Once this step is complete, the wand must be placed on the ground, and levelled so that it is flat with respect to the floor of the capture space. This is necessary to set the volume origin, which enables the software to define the ground, axes of the global reference frame and organise the cameras with relation to the ground. The system is then ready to use.

The main disadvantage to this method is that there is no way to know whether the system needs to be recalibrated between uses. In the past, recalibration was recommended before each test. However, the systems have improved and this recalibration is now only necessary if the cameras have been moved. As there is no way to tell if recalibration is required, users should continue to recalibrate cameras between each use, even if the camera configuration has not been altered since the last use. In the clinical environment, 10-15 minutes is a considerable amount of time, especially when considering that patients arrive to the clinic every 10 minutes in some practices. An easy way to save time would therefore be to check whether the cameras need to be recalibrated and only recalibrate when necessary.

For our system, we propose to create an application that recognises the configuration of markers on an object of known proportions (e.g. the calibration wand). All inter-marker distances will be recorded when the system is properly calibrated. These distances will then be used as the benchmark for future calibration checks. At the start of a session, the calibration wand will be placed in the centre of the field of view of the system. If all inter-marker distances match those saved previously by the application, the operator will be told there is no need to repeat the calibration processes. If the inter-marker distances do not match, recalibration of the system will be necessary as the system is no longer reconstructing the 3D positions of the markers properly. To make this as simple as possible for users, the markers on the known object will be coloured green in the user interface when the system is properly calibrated and ready to use, and red when recalibration is recommended. The only thing users will be required to do is place the calibration wand in the field of view and look at the outcome in the application. This may save 10-15 minutes before each use of the

system by eliminating the need to recalibrate the system if the cameras have not been moved.

Patient calibration can also be complicated and time consuming, as it typically requires the user to attach multiple single markers to limb segments with double sided-tape, and then manually label each marker within a given trial in complex software. We therefore propose the development of a more efficient cluster-based biomechanical model. A cluster will be created for each anatomical segment of the lower limb; each one will consist of 4 retro-reflective markers. Each cluster will be configured differently from the others, enabling the software to uniquely identify each marker on each cluster automatically. The clusters will be attached as a whole to each segment.

Anatomical landmarks are usually defined by sticking individual retro-reflective markers onto the skin. The disadvantages of using these were highlighted in section 2.5.4 of the literature review. For our cluster biomechanical model, we will avoid the use of individual markers by developing a pointer-calibration technique which will consist of a pointer attached to a cluster of asymmetrical markers (known as an instrumented-pointer) (Benedetti *et al*., 1998; Cappozzo *et al*., 1995). This method involves creating a local co-ordinate system from the markers on the pointer. This technique, known as CAST (calibrated anatomical systems technique), was introduced by Cappozzo and colleagues in 1995 (Cappozzo *et al*., 1995). The CAST method has been successful in orthopaedic surgery to calculate the mechanical axis of the femur (Belvedere *et al*., 2011; Smith *et al*., 2014). It is also commonly used in biomechanical research (Besier *et al*., 2003; Cappozzo *et al*., 1995; Fantozzi *et al*., 2003; Hagemeister *et al*., 2005; Lin *et al*., 2015, Remelius *et al*., 2014).

The bespoke software will calculate the position in space at which the anatomical landmark at the end of the pointer lies. The position of each landmark in relation to a segmental cluster will then be saved by the software to track the positions of the landmarks as virtual markers following patient calibration.

Implementing this protocol could have the following advantages over current GA methods which use individual retro-reflective markers:

1. Patients will not be required to wear tight-fitting clothing potentially increasing patient compliance and reducing preparation time.
2. No need to prepare individual markers prior to patient arrival, reducing preparation time for each test.
3. No need for user to manually label anatomical landmarks during data processing following patient calibration and gait trials.
4. No need to worry about markers falling off during trials, as cluster markers will be screwed into the plastic cluster plates.
5. No need to worry about marker occlusion, as reconstruction of a missing cluster marker can be carried out instantaneously by the software using the positions of the remaining 3 markers.
6. Less soft tissue artefact giving more accurate results.

Software used to carry out motion analyses are often complicated, containing many functions and setups not required for routine GA. Due to their complexity, users are required to undergo lengthy training. As was discussed in the previous chapter, health professionals rarely have the time or opportunity to undergo such training (2.6.1. Health Professionals and Gait Analysis). The applications we propose will sit on top of the normal motion capture software and provide to the health professionals only those controls that are needed.

We therefore propose a very simplified version of what is currently available. The aim is to develop a simple user-interface which would provide users with step-by-step instructions on how to carry out motion capture-based assessments. We also aim to custom-write functions for automatically recording assessment results by computer, meaning that health professionals will not be required to pause assessments to write down the results.

The ways in which the results are displayed will also be simplified. As was discussed in 'Conveying Biomechanical Data' (section 2.6.2), the graphs obtained following motion analysis are complicated and can be difficult to

interpret. Thus, we propose that instantaneous and relatable visual feedback be provided. This will involve the use of a virtual avatar and simple numerical feedback. As graphical representation of kinematic results can be invaluable in biomechanics, we propose that there be an option to create these graphs if desired. All data will also be stored for subsequent analysis.

Other important goals will be to ensure that the package is usable by one healthcare professional working on their own, and that a full assessment can be carried out within 30 minutes (Baten *et al.,* 2007).

Acceptability to Patients

As well as being acceptable for use by health professionals, patients must also feel comfortable with the assessments. A major disadvantage to the current GA protocol is that patients are required to wear tight-fitting and revealing clothing (Figure 3.2). This is not a problem in sports biomechanics, but is a problem in the clinical field where older adults are involved. By using a cluster model and pointer-calibration method, patients would no longer be required to wear these specialised clothes for the assessments.

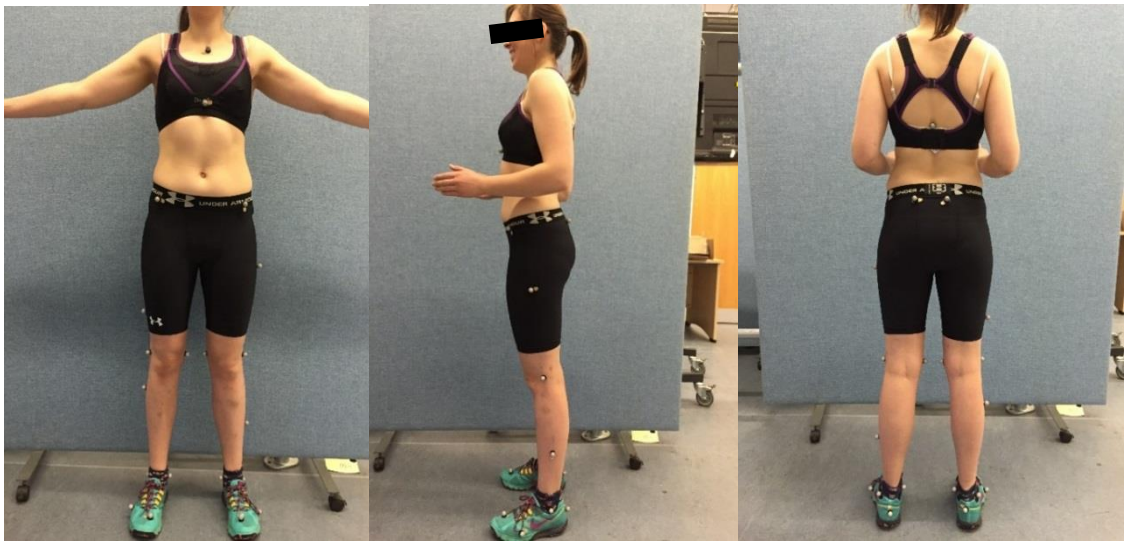


Figure 3. 2: An example of the clothing usually worn by participants undergoing gait analysis.

Together with an optimised laboratory set-up, it is expected that implementing this cluster-based method will make the use of motion capture technology as a clinical orthopaedic outcome measure feasible.

3.2.2. Knee Range of Motion Application

The disadvantages of using manual goniometry to assess knee ROM were discussed in section 2.4.2 of the literature review. The most prominent limitations included the following:

- Inaccurate results recorded during high flexion
- Inability to use the tool to assess dynamic knee flexion-extension angles.

Here, we propose an alternative method to goniometry to address these issues.

Intra-operative motion capture technology has previously been shown to provide surgeons with more accurate knee angles than manual goniometry (Austin *et al.,* 2008). According to a review by Piriyaprasarth and Morris (2007), motion capture should now be considered the most suitable method for assessing knee movement, as it provides least error when compared to manual goniometer-based devices. Given that this type of technology is also capable of recording knee motion dynamically, we aim to use motion capture as a ROM assessment tool.

We propose to use a cluster-based biomechanical model to track movements of the leg during knee flexion and extension on a plinth. Through applying rigid body mechanics, the movement of the underlying bones in relation to one another can be calculated in 3D to determine the knee angle. The main reported outcomes will be maximal knee flexion-extension excursion. This was chosen as an appropriate outcome, as this variable is often reported pre- and post-TKA (Edwards *et al.,* 2004; Mai *et al.,* 2012).

We aim to keep the protocol similar to the current one used with the manual goniometer to minimise the learning curve and maintain user acceptability. A

method of automatically recording and displaying simplified biomechanical data during the assessment will also be implemented.

It is expected that this novel application will be simple to use and provide accurate results on knee flexion-extension ranges.

3.2.3. Knee Muscular Strength Application

Knee muscular strength is a valuable variable to assess following orthopaedic surgical intervention such as TKA as muscle strength positively correlates with functional activity (Henriksen *et al.,* 2011). Muscle strength is therefore a biomarker of function. It was previously discussed (section 2.4.2) that current methods of quantifying knee strength often neglect the influence of gravity and the influence of the angle of the knee on the subject's ability to generate moments. This leads to researchers and clinicians reporting incorrect data.

According to Samuels & Rowe (2012), knee strength examinations should, at a minimum be carried out with the knee bent at a 90° angle, with a force measuring device perpendicular to the leg at a known distance away from the attachment point. In doing this, a realistic representation of the maximal isometric moment produced by the flexors or extensors of the knee can be recorded (Saumuels & Rowe, 2009; Smidt & Rogers, 1982).

In practice, it is common for the angle of the knee to change slightly during the assessment, even if the angle was initially set at 90°. Furthermore, implementing this protocol would restrict health professionals to measuring knee force at 90° angles. Given that the knee functions at a range of 0° to 160° and that isometric strength varies with range (Samuels & Rowe, 2012), an option to assess knee strength at a variety of angles would be advantageous.

The application proposed for development as part of this package will use motion capture technology to calculate the flexor and extensor moments of the knee at different set angles. The aim is to provide health professionals with a

simple assessment to visualise and record strength data but in a scientific manner.

The protocol will be based on that which is used with a digital myometer (please refer to section 2.4.2 for further details).

The angles of the knee, moment arm lengths, and the influence of gravity on the data (i.e. gravity correction) will be calculated by the custom-built application (Figure 3.3). The results of these calculations will be used to determine the real-time moments about the knee.

The protocol proposed here is thought to be appropriate for clinical use as the National Isometric Muscle Strength Database Consortium have recommended this type of examination as the simplest method for collecting accurate data on muscular strength (National Isometric Muscle Strength Database Consortium, 1996). This application will report knee strength in terms of Nm as recommended by Samuels & Rowe (2009).

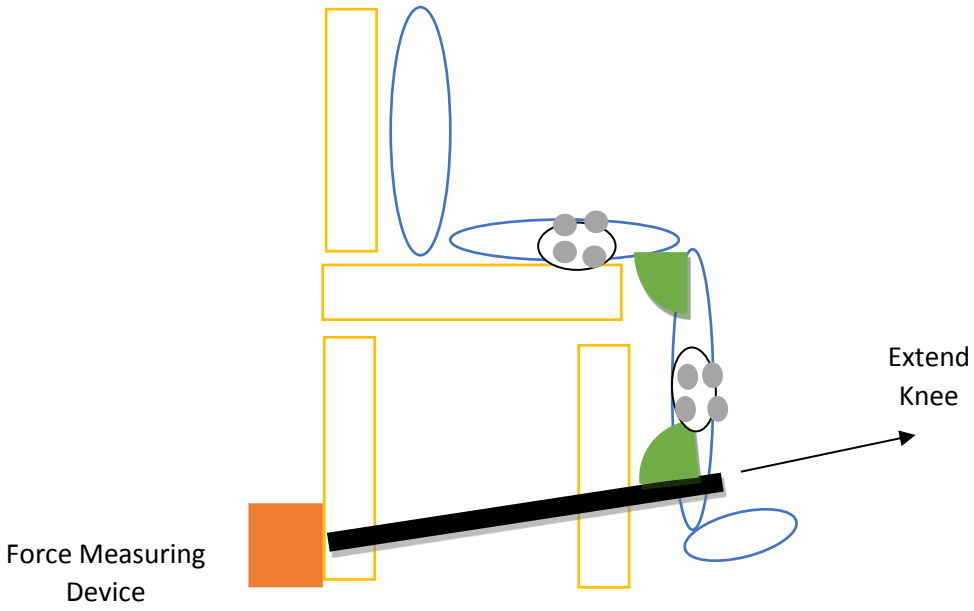


Figure 3. 3: Diagram of a protocol which could be used to calculate knee extensor strength by the custom-built application. Flexor strength could be determined by reversing the chair. Note the use of clusters on lower limb, and the angles required to scientifically calculate the moment about the knee (green).

3.2.4. Clinical Gait Analysis

GA provides researchers and clinicians with valuable quantitative information on human movement and can be used to report the outcome of patients following a treatment such as TKA (Bejek *et al.,* 2006; Cappozzo *et al.,* 2005; McClelland *et al.,* 2007). Clinical GA is not routinely carried out as the equipment is expensive and requires extensive training to use. The marker protocols are also time-consuming and large amounts of space are typically required to record multiple gait cycles.

As we have already described in this chapter, we will implement a cluster-based biomechanical model in this study with a pointer calibration technique to simplify the process of calibration and improve on these disadvantages currently associated with individual-marker-based motion capture (section 3.2.1). The full model will consist of seven clusters; each will be assigned to a segment of the lower limb (pelvis, thighs, shanks and feet). These will be designed to strap over patients clothing.

Anatomical calibration will take place in two phases so that the gait protocol fits in with the analyses of knee ROM and strength. The first calibration phase will be used to define the anatomical landmarks of the thighs, legs and feet, omitting the pelvis. Initially this is necessary as the ROM assessment requires patients to lie in supine position and the strength assessment requires patients to sit on a chair which may or may not have a back. A pelvic cluster would therefore be occluded during these assessments and would be uncomfortable to patients. Prior to the gait assessment, the final cluster will be strapped onto the patient, and the second phase of the calibration will be carried out in which the anatomical landmarks of the pelvis will be calibrated to complete the model.

In real-time, the positions of these “virtual” anatomical landmarks will be calculated from the clusters and will be used to calculate kinematics of the hips, knees and ankles. To comply with the standards recommended by the International Society of Biomechanics, the Grood & Suntay method for

determining joint co-ordinate systems will be used to describe the kinematics (Grood & Suntay, 1983; Wu & Cavanagh, 1995).

To conserve space in the clinic, GA will be carried out on a treadmill. A further advantage of using a treadmill in a clinical environment is that tens-to-hundreds of consecutive cycles can be recorded within a short time period (Alton *et al.,* 1998; Matsas *et al.,* 2000; Sloot *et al.,* 2014). When gait is analysed over-ground, only a couple of consecutive steps can be recorded at a time as the analysis is confined to the middle section of the room. However, studies have shown kinematic and spatio-temporal differences to exist between treadmill and over-ground walking, meaning that the data recorded on a treadmill may not truly represent the individual's gait (Alton *et al.,* 1998). Some of these reported differences include an increased cadence and reduced sagittal plane ROM at the knee (Alton *et al*., 1998; Strathy *et al*., 1983). This has been attributed to small treadmill belt length and the fixed treadmill speed imposed on individuals (Sloot *et al.,* 2014).

A proposed alternative to fixed-speed treadmill walking is self-paced treadmill walking. Such treadmills use feedback from the motion of the individual to control the speed of the treadmill (Sloot *et al.,* 2014). This is believed to enable treadmill users to walk at their natural walking speed during gait analyses (Sloot *et al.,* 2014). As a consequence, a more natural gait should be captured as they change gait as the speed of the treadmill will vary to keep pace with them. Our study therefore proposes the use of a self-paced treadmill with a long belt. The speed of the treadmill will be controlled by the 3D position of one of the pelvic cluster markers. Treadmill belt speed will be programmed to increase as the patient nears the front of the treadmill and decrease as they approach the rear. The aim will therefore be to keep the patient in the middle of the treadmill whilst giving them the freedom to speed up or slow down around their comfortable walking speed.

Self-paced treadmills have previously been used in individuals with pathological gait, but not in patients with knee OA, therefore this study will investigate the feasibility of using the tool in this patient population (van der Krogt *et al.,* 2014).

The main outcomes of interest of the GA application will be knee kinematics in sagittal, frontal and transverse planes. Hip and ankle kinematics, as well as all marker trajectories will also be recorded by the software.

3.2.5. Walking Stability and the Uncontrolled Manifold Hypothesis

Few clinical assessments are currently able to quantify stability during walking and other acts of daily living (Hausdorff & Edelberg, 2001; Mahmoudian *et al.,* 2015). One reason for this is that the way in which the CNS controls movement and reacts to perturbations remains unclear, as normal gait naturally varies from cycle to cycle (Maki *et al*., 1997, Hausdorff *et al*., 1995). This makes analysis of dynamic stability very difficult. As discussed previously (section 2.3.2), mid-flexion knee instability has been reported following TKA. The Medacta GMK Sphere implant is designed to address this issue; hence a method to quantify it in clinical practice is required.

We therefore propose the development of an application capable of quantitatively evaluating the variability of the COM with respect to lower limb kinematics, to assess dynamic stability and to see if mid-stance instability is observable in the data.

The UCM method has been advocated in human biomechanics research to shed light on motor control and motor variability (Black *et al.,* 2007; Qu*,* 2012). A small number of studies have recently investigated the stability of the COM during gait using the UCM method. However, to the best of our knowledge, none of this research has been carried out with TKA patients. This thesis therefore aims to address this gap in the literature by attempting to expand our knowledge on the way in which the CNS adapts to control the COM during walking in subjects with OA and TKA.

In this thesis, the COM is considered stable during gait when its position remains within the base of support (Black *et al.,* 2007; Qu *et al.,* 2012). This is synonymous with a successful walking task. This type of stability is different

from the stability of a signal e.g. the trajectory of the COM naturally fluctuates in the x-, y-, and z-directions during gait, thus the signals are not inherently stable. However, this does not influence the patient's balance, as long as the COM remains within the base of support. Likewise, this does not relate to the mechanical stability of gait. In biological systems, mechanical stability is defined as the ability of the system to withstand and react to internal and external perturbations under a variety of conditions (Latash *et al.*, 2007; Sharifi *et al.,* 2017; van der Esch *et al*, 2008). Given that the UCM model does not take into consideration the internal perturbations affecting an individual, such as ligament laxity, the mechanical stability of the body cannot be determined.

The fundamental basis of the UCM theory proposed by Scholz and Schöner (1999) states that the sheer number of elements provided to us by the musculoskeletal system (such as joint degrees of freedom, or number of muscles which carry out similar functions) gives the CNS an infinite number of ways in which it could organise and execute a task, such as maintaining a stable COM (Latash *et al.,* 2007; Latash, 2012; Zhou *et al.,* 2015). For this reason, the theory is described as 'uncontrolled' (Papi *et al.,* 2014).

When taking walking as an example, we can infer that it is acceptable for the angles at the hip, knee and ankle to vary between cycles, as long as the variability is not large enough to compromise COM stability.

Some studies have suggested that having an 'uncontrolled' method of executing a task creates a motor redundancy, because multiple combinations of motor recruitment lead to the same result. However, this idea has been termed by Bernstein (1967) as 'motor abundance', suggesting that these variable combinations give the CNS the option to be flexible without sacrificing accuracy (Latash, 2012). This is beneficial to us as it enables the CNS to act appropriately to external and internal perturbations which would otherwise affect the end-task (Cashaback *et al.,* 2015; Latash *et al.,* 2007). Mid-flexion instability is an example of an internal perturbation.

This theory therefore suggests that there is no one correct way to execute a task during movement (Domkin *et al.,* 2002; Papi, 2012). Where walking is concerned, we can assume that there are multiple combinations of joint co-ordinates which are capable of maintaining the COM in a stable position; and consequently, having variable gait kinematics does not necessarily affect overall dynamic stability (i.e. the end task). In a case where the extent of variability observed does not affect the end task, the variability is defined as 'good variability' (Latash *et al.,* 2007). Variability which does affect the success of a task is known as 'bad variability' (Latash *et al.,* 2007).

According to Papi *et al.* (2014) the UCM is the sum of all task elements (such as joint degrees of freedom - DOF) which lead to the successful completion of a task, characterised as the mean COM trajectory per gait cycle. Scholz and Schöner (1999) claim that this can provide insight into the structure of the motor control system. The subspace is therefore composed of all combinations of joint angle positions of the lower limb which contribute to keeping the COM stable during walking, and the values within its orthogonal subspace are assumed to do the opposite: cause COM instability (Papi *et al.* 2014; Qu, 2012; Scholz & Schöner, 1999; Zhou *et al.,* 2015).

'Good variability' is therefore the variance across a trial which lies within the UCM (Latash, 2012). Hence, if the variance is orthogonal to the UCM, it is deemed as 'bad variability'. Ultimately, if the proportion of variance within the UCM (||UCM) ('good variability') outweighs the variance perpendicular to the UCM (⊥UCM) ('bad variability'), it can be accepted that the task in question (i.e. stabilisation of the COM) was successful, as the ratio exceeds 0 (Latash, 2012; Papi *et al.,* 2014; Scholz & Schöner, 1999). If the ratio is below 0 then the task was unsuccessful.

Most studies which have implemented the UCM hypothesis have chosen to do so to compare variability whilst carrying out simple tasks such as pointing, reaching, or quiet stance (Cashaback *et al.,* 2015; Domkin *et al.,* 2002; Hsu *et al.,* 2007). Few studies have used the UCM approach to study gait variability as it involves a number of complex movements at multiple joints.

Papi and colleagues (2014) reported motor variability of six healthy adults and one patient following stroke. Trial-to-trial variability was investigated in their study. Results from the study revealed that the stroke patient had a more variable COM trajectory and joint positions than the healthy controls, but that good variability remained larger than bad variability. This suggested that stroke survivors were able to maintain a steady COM whilst walking by increasing joint kinematics variability. These results seem to agree with the theory that motor abundance is a way for the CNS to be adaptable and flexible when necessary; for example, following an injury.

Although this research shows early promising results, many aspects of it could be significantly improved. For example, in the model created by Papi (2012), only the sagittal plane of one leg was considered.

A study by Qu (2012) used the UCM to investigate gait variability during load carriage. Qu's model could be used to analyse both frontal and sagittal plane variability. However, COM trajectories were only recorded at right heel and toe contact time and not throughout the cycle.

We therefore aim to improve on previous work by producing a model which can assess gait variability throughout the gait cycle in both frontal and sagittal planes. This model will be used to assess cycle-to-cycle variability during walking (or other acts of daily living) in order to investigate dynamic instability (Scholz & Schöner, 1999).

The bespoke UCM application will be applied to gait data recorded during treadmill walking. This will enable us to record numerous cycles easily and efficiently. Previous studies have also implemented the treadmill for this purpose (Black *et al.,* 2007; Qu, 2012).

Due to the fact that the number of elemental variables (joint DOF) during walking outweigh the number of task variables (COM stability), we can expect to find that the COM trajectory will vary between one cycle and the next in the same patient. Bernstein called this 'repetition without repetition' (Bernstein, 1967).

The main outcome of interest will be the ratios of 'good' to 'bad' variability between gait cycles.

We plan to investigate if the UCM results recorded with this novel application will provide a means for clinicians to identify phases of the gait cycle at which patients are most unstable, and if the TKA patients involved show any indications of mid-flexion instability. This information could then be used to compare implants, estimate risk of falling, and guide rehabilitative interventions to improve balance and stability during functional tasks (Herman *et al*., 2007; Sinitksi *et al*., 2012).

3.2.6. Overview of Product

This chapter has described the aims of this project, and explained how our proposed product hopes to overcome the disadvantages of current motion capture technology and produce standard orthopaedic outcome measures which are both scientific and clinically practical.

The product (hardware and software) that we will design, validate, and use over the course of this project is novel. If successful, such a system could provide orthopaedic clinicians (specifically healthcare professionals such as physiotherapists) with a simple, effective, and efficient method of reporting the functional outcome of TKA patients. It may also encourage the use of motion capture technology in the clinical environment, to gain a further understanding of the biomechanics which underlies gait disorders such as OA.

Chapter 4. Product Development

Hardware Development

4.1 Gait Laboratory

Traditional gait laboratories have many disadvantages which limit their use as a routine clinical tool. To encourage the use of gait analysis in the clinical environment, our study involved designing a simplified, small-footprint system which could be used as an alternative to traditional motion capture laboratories by practicing clinicians with minimal training. The clinical motion capture laboratory designed for the purposes of this research will now be described.

4.1.1. Equipment

Treadmill

A single-belt, self-paced N-Mill treadmill was used for the duration of this study (Motekforce Link, Amsterdam). The treadmill was 2m long, 0.8m wide and had a step height of 0.18m. It had a maximum speed of 12km/h (Force Link, 2015). The treadmill also had stronger and more reactive motors than traditional treadmills so that it could pace itself to the individual.

The treadmill was equipped with an emergency stop button and adjustable fixed handlebars. These were deemed essential for patient safety (Force Link, 2015). The cost of the treadmill was £13,000.

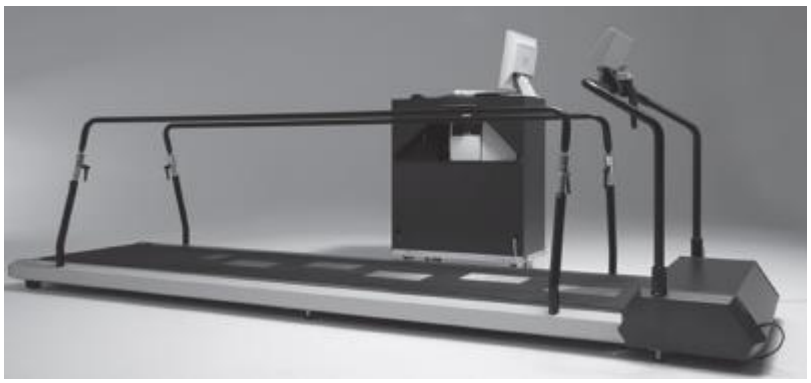


Figure 4. 1: An example of the treadmill used for the research presented in this thesis.

(Source: Photograph adapted from Heeren *et al*., 2013)

The treadmill was interfaced with D-Flow software (Motekforce Link, Amsterdam) enabling any user to control the treadmill with the program application.

Frame

Different camera configurations were trialled during the development phase of this project. One arrangement proved particularly effective. This set-up was used throughout the investigation. The materials used to create and build this setup include:

- 7 1000 x 50 x 50mm Valuframe aluminium square slotted extrusions
- 2 1300 x 50 x 50mm Valurame aluminium square slotted extrusions
- 2 2000 x 50 x 50mm Valuframe aluminium square slotted extrusions
- 4 300 x 50 x 50mm Valuframe aluminium square slotted extrusions
- 8 Valuframe wheels
- Appropriate tools for assembling frame including wrench, nuts, bolts and Allen keys (No machining required).

Photographs of the frames used, and of the ways in which the frames were connected are shown in Figure 4.2. The frames cost approximately £200 in total.

Figure 4. 2: Photographs of the frames used for the motion analysis setup in this study.

Motion Capture Hardware

Eight Vicon Bonita B10 cameras (Vicon Motion Systems, Oxford) were used to capture data (Figure 4.3). Each camera was mounted onto a Bosch MM2 Universal Camera Holder via a ¼" thread. The cameras were connected to each other and the computer via Ethernet cables. The camera specifications are outlined in Table 4.1. The cost of the cameras and camera mounts totalled approximately £19,500.

Figure 4. 3: A photograph of one Vicon camera mounted onto the custom-built frame.

Table 4. 1: The specifications of the Vicon Bonita B10 range according to the manufacturer.

Specification	Vicon Bonita B10
Strobe	68 high powered NIR LEDs at 780nm
Frame Rate	250 frames per second
Resolution	1 megapixel (1024 x 1024)
Wide angle of view (4mm)	70.29° x 70.29°
Narrow angle of view (12mm)	26.41° x 26.41°
Precision	0.5mm in 4m x 4m volume

Software

Vicon Tracker software (version 3.1.3; Vicon Motion Systems, Oxford) was used to stream cluster marker data into D-Flow software (version 3.22.1 CLUSTER1; Motekforce Link, Amsterdam). The Vicon Tracker software recognised and tracked each individual cluster. It also labelled each marker automatically. Custom-written applications in D-Flow were used to locate the labelled clusters, calibrate the patients, and carry out all assessments.

4.1.2. Laboratory Configuration

Two separate "frames" were constructed at the University of Strathclyde. The frames were later transported to the orthopaedic physiotherapy gym at the Royal Infirmary of Edinburgh and placed at either end of the treadmill.

The posterior frame was designed as a 'doorway' for the treadmill (Figure 4.4).

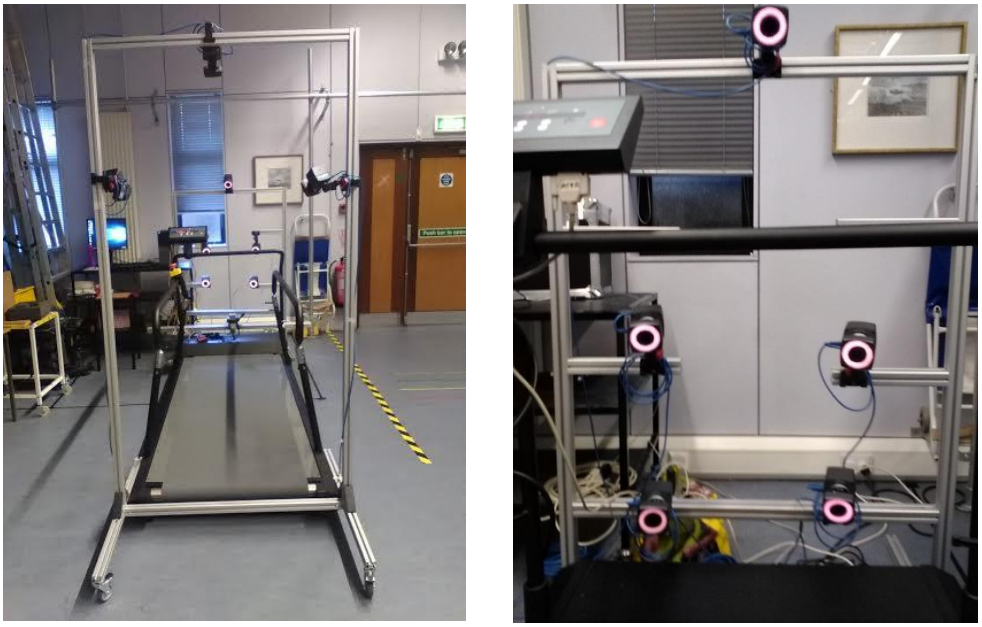


Figure 4. 4: A photograph of the two frames onto which three cameras were mounted.

The anterior frame was shorter, and contained multiple cross members at different heights for optimal camera placement (Figure 4.4). Wheels were screwed into the bottom four corners of both frames for easy mobility in the clinical environment.

Once the frames had been built, three cameras were mounted onto the posterior frame. These cameras face the rear of the subject. Five cameras were mounted onto the anterior frame, which face the front of the subject. The camera internet hubs (to which the cameras were connected), power supplies, and all other electrical hardware were stored at the head of the treadmill in a closed box. Ethernet cables that were connected to cameras ran into the box via grooves in the frames. Duct tape was used to ensure that the cables remained in the grooves. This was done to minimise trip hazards.

Before first use, the cameras and treadmill were configured. Each camera was carefully positioned on the frames in a configuration that ensured that the field-of-view was optimal for the investigation. The cameras were aimed towards the

centre of the treadmill then the settings for each camera were individually adjusted (Figure 4.5).

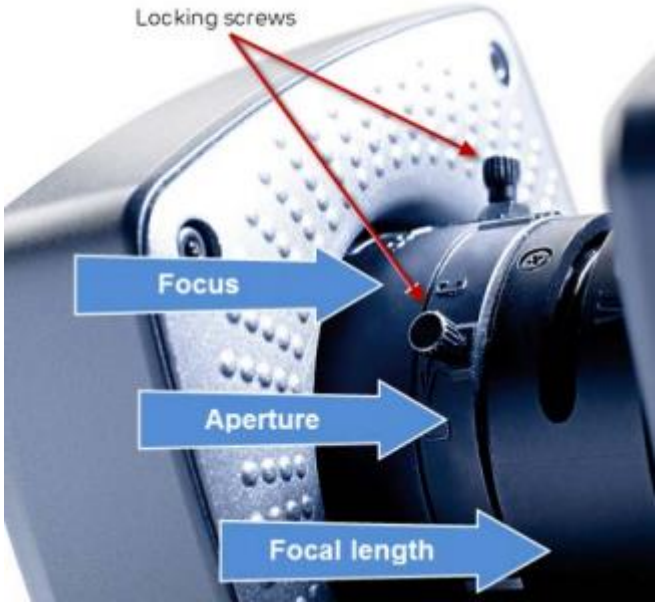


Figure 4. 5: Image of the camera settings adjusted prior to use.

(Source: Vicon Motion Systems, 2017)

The focal lengths were adjusted to ensure that each camera's field of view was sufficient for the assessments. The focuses of all cameras were then optimised by checking that a marker in the field of view of each camera was depicted as a well-defined circle in the software's visualisation window. Finally, the apertures were adjusted so that enough light was hitting the image sensor to give clear images of markers in the field of view.

Overall dimensions of motion analysis system were 3.5(L) × 2.1(H) × 1.1(W)m.

Software Development

D-Flow (Motekforce Link, Amsterdam) was chosen as the development platform for this project, as it allows its users to design and execute clinically-focused applications for real-time use. It is also modular, allowing continued development. Positional information of retro-reflective markers within the field of view can be streamed directly into modules within the software. Using the scripting module, biomechanical models were developed to calculate joint kinematics and kinetics (Figure 4.6). All scripts written within D-Flow were in the Lua computing language (Motekforce Link, Amsterdam).

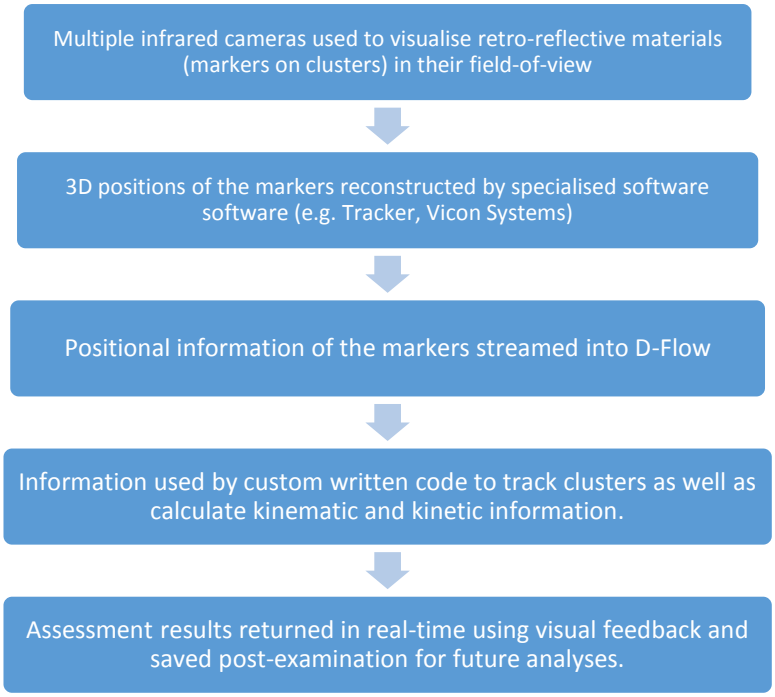


Figure 4. 6: Flowchart showing the general process for retrieving assessment results from D-Flow software.

D-Flow is also a clinician friendly software, as developers can create simple "frontends" (i.e. operator panels) for the applications created within it, as well as provide real-time visual feedback on assessments in a simple and interpretable manner for non-bioengineers (Motekforce Link, Amsterdam).

For these reasons, D-Flow was deemed suitable as a platform for non-engineers to utilise motion analysis technology in the clinical environment.

Vicon Tracker software (version 3.1.3; Vicon Motion Systems, Oxford) was used to stream cluster marker data into D-Flow, as it is compatible with the Vicon Bonita B10 camera range and can track multiple objects (e.g. clusters) at one time.

4.2. Camera Calibration-Checker Tool

This application was developed to identify whether camera calibration is necessary before or between uses by using an instrumented tool. In the past, cameras were mounted on tripods which could easily be knocked. Environmental factors could also affect the response of the cameras. As a result, it was recommended that calibration was repeated before each test. We discovered however, that with modern cameras fixed to a frame, re-calibration was only required if the frame or cameras were moved. An application to check whether system calibration remained satisfactory was therefore needed.

The programmed default setting recognises the 5-marker L-Frame wand used to calibrate Vicon Motion System cameras as the calibration-checker tool (Figure 4.7). However, Vicon are one of many companies that produce motion analysis technology, thus a degree of flexibility was necessary in the event that an L-Frame wand was not available. Thus, a bespoke function was incorporated into the application to allow users to create their own calibration-checker tool from within the user interface.

To record a new calibration-checker tool, users must define the tool by selecting the correct number of markers on the tool (3-5) from the drop-down list then record the positions of the markers by clicking ‘Record Tool’ followed by ‘Finish Recording Tool’. The system must be optimally calibrated at this point in time. During this recording process, the application was programmed to output the x-y- and z-co-ordinates of each marker on the tool in the global reference frame

(the co-ordinate system of the capture volume). This must be done under static conditions (i.e. the tool should not be moved during the recording process). When the 'Finish Recording Tool' button is activated, the averages of the recorded co-ordinates are saved into a text file, along with the number of markers on the tool. The tool is then ready to be used to check camera calibration.

Once a calibration-checker tool has been created, the user can then check the system calibration. To do this, the user must press a button labelled 'Check Camera Calibration' in the user interface. This activates a script that imports and reads the saved text file recorded previously of the calibration-checker tool. The application then calculates the Euclidean distances between the markers saved in the text file (Figure 4.7; Equation 4.1). The distances are then ordered by their lengths using an inbuilt function.

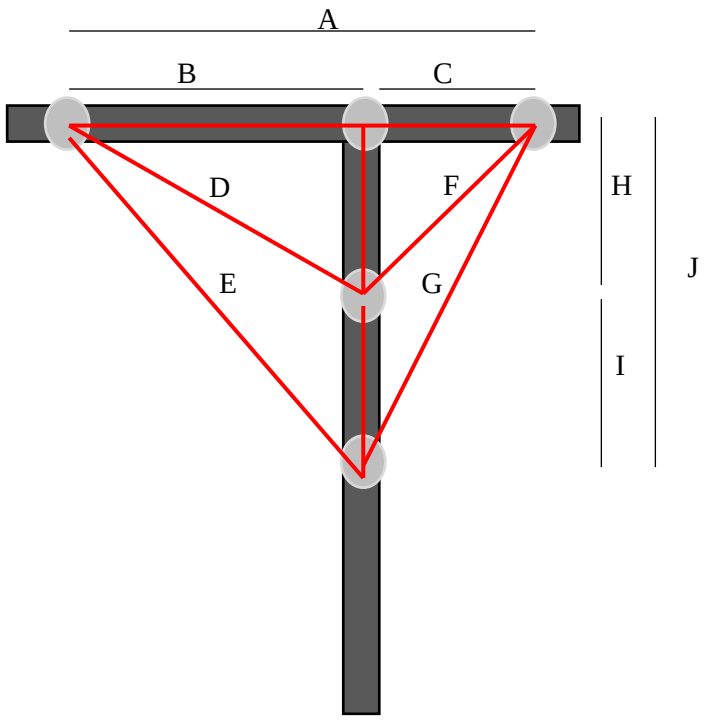


Figure 4. 7: An example of ten distances recorded and saved by the application (A-J) with a 5-marker object such as the 5-Marker L-Frame calibration wand.

$$Euclidean\ Distance = \sqrt{(M1_x - M2_x)^2 + \left(M1_y - M2_y\right)^2 + (M1_z - M2_z)^2}$$

Equation 4. 1

Where,

M1 and M2 are the position of two markers in the global reference frame.

The calibration-checker tool is then held or placed in the field of view of the system. The application then measures the Euclidean distances between the markers on the tool in real-time and orders these distances by their lengths. The calculated Euclidean distances are then compared by the software. If the distances are equal between the live data and the text file data (±3mm), the markers on the visualisation screen appear green. If the distances are not equal (±3mm), the markers appear red, implying that the system should be recalibrated. Unlike when recording the tool, this function is refreshed with each frame, meaning that the user can move the tool during the calibration-check to ensure that the system is well enough calibrated for dynamic use.

4.3. Biomechanical Model

The application developed for use with the clinical gait laboratory relies on sets of custom-written algorithms written in Lua program language as script modules to generate the real-time geometric models.

To create a geometric model, information on the positions of the bones in relation to one another were required. The Vicon Tracker motion capture software was used to report x-, y- and z-co-ordinates of the labelled cluster markers in the global reference frames. These co-ordinates were used to reconstruct “virtual” anatomical landmarks which in turn, were used to create the biomechanical model in the D-Flow software using script modules.

The rationale for a cluster-based biomechanical model was presented previously for this outcome measure package (section 3.2.1). A cluster model recently developed at the University of Strathclyde was available but not appropriate for our investigation because it required the user to be familiar with the Vicon software rather than having it running in the background (Millar, 2017). As a consequence, a new version of this model was developed for this study in D-Flow software (Figure 4.8).

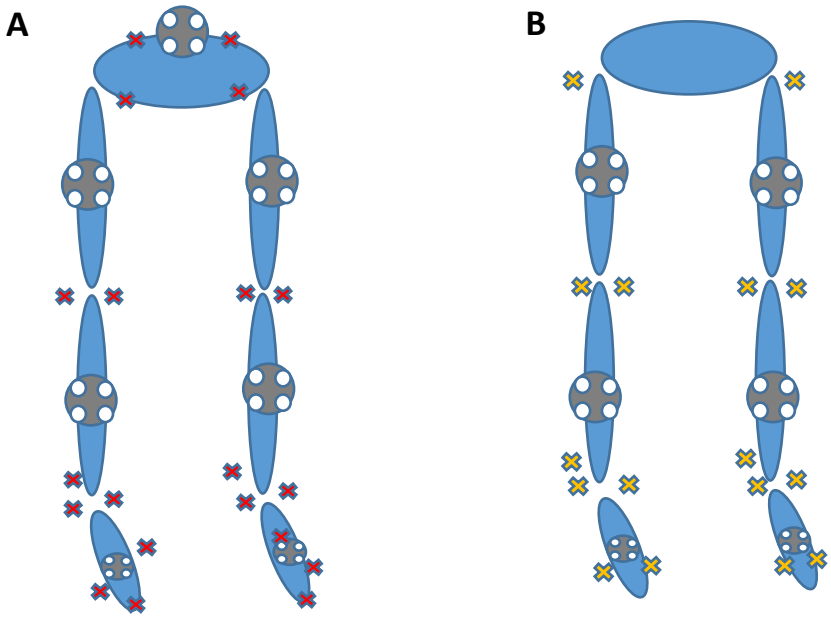


Figure 4. 8A: The University of Strathclyde cluster model (Millar, 2017). B: An adaptation of the University of Strathclyde cluster model developed for the purposes of this outcome measure package.

Red and yellow crosses represent the anatomical landmarks calibrated by pointer technique. The positions of these are tracked with respect to the positions of the segmental clusters (grey).

In the original model (Figure 4.8), a pelvic cluster is used to reconstruct the pelvic anatomical landmarks (anterior and posterior superior iliac spines), from which the hip joint centre (HJC) positions are estimated. This method of defining the HJCs was deemed inappropriate for this newer model, as two of the assessments developed for this functional outcome measurement package

require the patient to lie in a supine position or sit on a chair, thus obscuring Millar's pelvic marker clusters from which the HJCs were referenced. Hence, alternative methods for determining the HJCs were developed for this adapted model. The methods by which the HJCs are calibrated for this model will be explained later in this chapter.

4.3.1 Cluster Development

Six unique plastic clusters (for the thighs, shanks and feet), each with four holes for screws, were 3D printed at the University of Strathclyde. The clusters were designed using PTC Creo computer aided design software (version 3.0; PTC, Needham, MA). 16mm retro-reflective markers were screwed into the clusters through the screw holes. The positions of the markers on each separate cluster differed, to ensure that each cluster was uniquely identifiable.

The configurations of the markers on each cluster were manually saved in Vicon Tracker software (Vicon Motion Systems, Oxford). The markers on each cluster were labelled from 1-4 in the following order: top left (1), bottom right (2), bottom left (3), and top right (4) (Figure 4.9). This was done to prevent programming errors when defining cluster reference frames.

Figure 4. 9: Technique used for labelling each cluster.

The configuration files created for each cluster were saved in Vicon Tracker. This enables the software to recognise and label each cluster automatically when placed in the field-of-view. The configuration files can also be used by the software to reconstruct one missing marker of a known cluster in live-mode. Consequently, this step replaces manual marker labelling and gap-filling, which are usually necessary when using motion capture technology. These automatic recognition and labelling processes greatly reduce the knowledge needed and time taken to record movement. Provided the correct cluster is placed on the correct segment, recognition and labelling are uncomplicated.

4.3.2 Anatomical Calibration

A pointer with 4 fixed retro-reflective markers was created then calibrated and labelled as a cluster using the methods described in section 4.3.1 (Figure 4.10). Two markers were deliberately placed in-line with the pointer tip to create a vector in this direction. A temporary marker (without its base of support) was screwed onto the pointer tip. It was used to determine the position of the pointer tip relative to the fixed markers on the pointer. This was done by calculating the Euclidean distance between the pointer tip temporary marker and the 1st pointer marker (Equation 4.1).

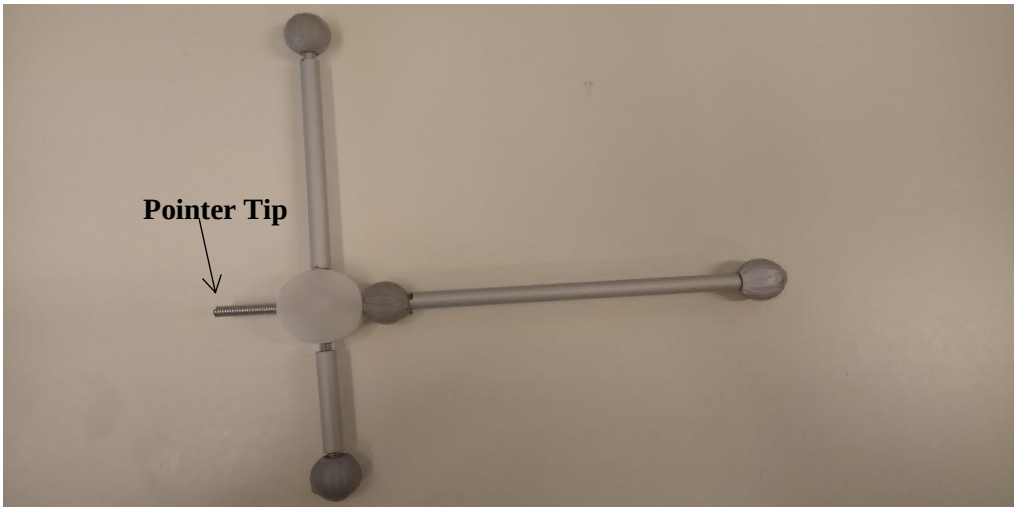


Figure 4. 10: A photograph of the pointer used in this study to calibrate all anatomical landmarks.

Following this, the vector between the 1st (M1) and 2nd (M2) markers on the pointer and their components (V_x, V_y and V_z) were calculated (Equation 4.2).

$$\begin{bmatrix} V_x \\ V_y \\ V_z \end{bmatrix} = \begin{bmatrix} (M1_x - M2_x)^2 \\ (M1_y - M2_y)^2 \\ (M1_z - M2_z)^2 \end{bmatrix}$$

Equation 4. 2

Next, a virtual point that represented the tip of the pointer was created, by extending the vector between the first two markers to the tip of the pointer. This required calculating the extension factor of the vector. The extension factor (EF) was equal to the Euclidean distance between the first marker and the tip of the pointer divided by the Euclidean distance between the 1st and 2nd markers of the pointer. The result was then multiplied by the components of the vector between the 1st and 2nd pointer markers (V_x, V_y and V_z) to give a new vector (NV_x, NV_y and NV_z) (Equation 4.3).

$$\begin{bmatrix} NV_x \\ NV_y \\ NV_z \end{bmatrix} = \begin{bmatrix} V_x \times EF \\ V_y \times EF \\ V_z \times EF \end{bmatrix}$$

Equation 4. 3

The new vector was added to the co-ordinates of the 1st pointer marker. This incorporated the pointer tip into the local co - ordinate system of the pointer, creating a virtual point where the tip was situated.

Once the pointer tip had been reconstructed, the temporary marker was removed. The software could then calculate the position of the tip of the pointer from the recorded location of the remaining markers and thus could be used to point to and record anatomical locations on the body relative to a cluster on that segment.

A custom-written function to save the positions of each anatomical landmark during patient calibration was then developed. To ensure that anatomical calibration could be carried out by one health professional, the method was developed to rely on the use of a footswitch (or any other device which works as

a button). The footswitch is linked to the computer via USB, and is used to activate scripts via a Phidget module within the software package (Figure 4.11).

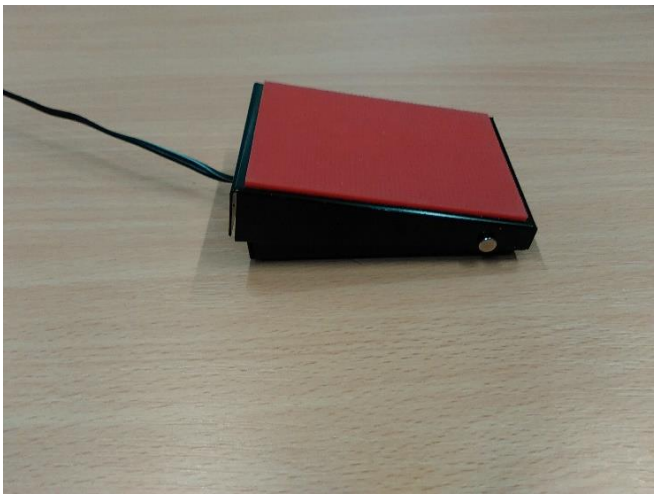


Figure 4. 11: An example of a footswitch which can be connected to the computer and used to register anatomical landmarks during calibration with the pointer.

When activated by the footswitch, the function saves the x-, y- and z-co-ordinates of the pointer tip in the global reference frame alongside those of the attached segment cluster. This takes potential cluster movement during calibration (e.g. from the patient changing their stance) into consideration.

This function was then written into a routine to label the anatomical landmarks. In order for this labelling routine to work, the user must calibrate the anatomical landmarks in a specified order (Table 4.2). These particular anatomical landmarks were chosen for this model as they can be easily palpated and used to estimate the internal joint centres.

Table 4. 2: Anatomical landmark calibration order.

Press	Action	Landmark Name
1	Save pointer position & Label position	Left greater trochanter (LGTRO)
2	Reset pointer position	
3	Save new pointer position & Label new position	Left lateral epicondyle of knee (LLEK)
4	Reset pointer position	
5	Save new pointer position & Label new position	Left medial epicondyle of knee (LLEK)
6	Reset pointer position	
7	Save new pointer position & Label new position	Left lateral malleolus of ankle (LLM)
8	Reset pointer position	
9	Save new pointer position & Label new position	Left medial malleolus of ankle (LMM)
10	Reset pointer position	
11	Save new pointer position & Label new position	Left heel (LHEE)
12	Reset pointer position	
13	Save new pointer position & Label new position	Left 1st metatarsal (LMT1)
14	Reset pointer position	
15	Save new pointer position & Label new position	Left 5th metatarsal (LMT5)
16	Reset pointer position	
17	Save pointer position & Label position	Right greater trochanter (LGTRO)
18	Reset pointer position	
19	Save new pointer position & Label new position	Right lateral epicondyle of knee (LLEK)
20	Reset pointer position	
21	Save new pointer position & Label new position	Right medial epicondyle of knee (LLEK)
22	Reset pointer position	
23	Save new pointer position & Label new position	Right lateral malleolus of ankle (LLM)
24	Reset pointer position	
25	Save new pointer position & Label new position	Right medial malleolus of ankle (LMM)
26	Reset pointer position	
28	Save new pointer position & Label new position	Right heel (LHEE)
28	Reset pointer position	
29	Save new pointer position & Label new position	Right 1st metatarsal (LMT1)
30	Reset pointer position	
31	Save new pointer position & Label new position	Right 5th metatarsal (LMT5)

Reference Frames

Next, a method of tracking these "virtual" anatomical landmarks in live-mode was developed. This method involved reconstructing the calibrated landmark positions (shown in blue in Figure 4.12) from the real-time cluster positions and orientations determined from the cluster markers (shown in white in Figure 4.12). Three reference frames are used to track movements of the segments and underlying bones.

The global reference frame describes the positions of markers in 3D space, whereas cluster reference frames (which lie within the global reference frame) describe the translations and orientations of the segments. Movements of the underlying bones are described using anatomical reference frames with respect to the cluster reference frame associated with that particular limb. For example, the lateral epicondyle of the left knee (within the left thigh anatomical reference frame) is tracked with respect to the left thigh cluster reference frame.

The way in which the anatomical and cluster reference frames were defined for this model will now be described.

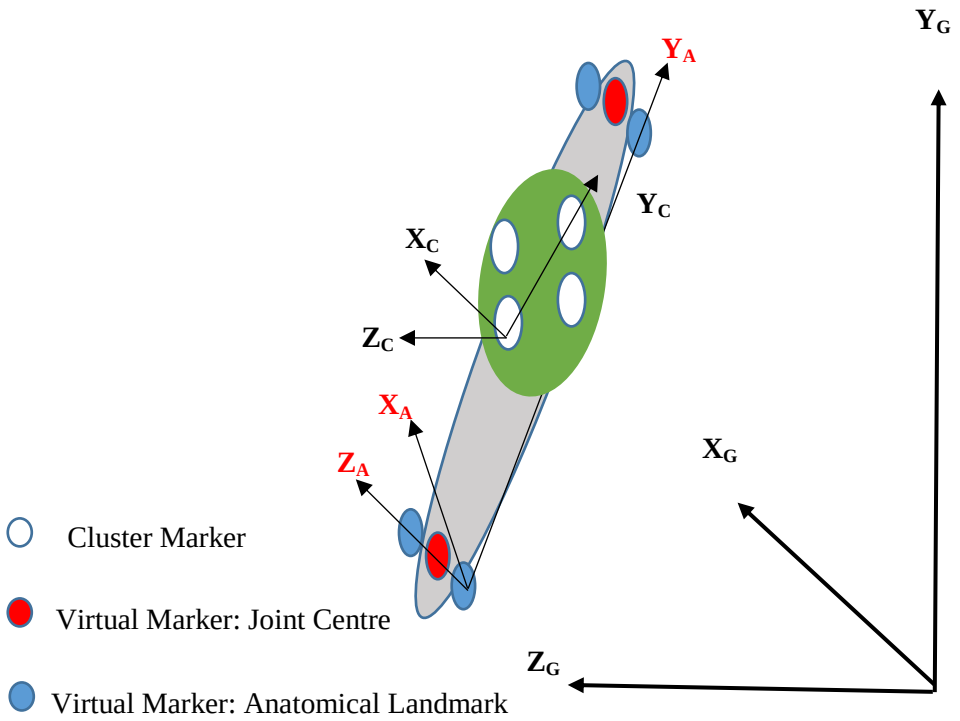


Figure 4. 12: A diagram depicting the differences between global (X_G,Y_G,Z_G), anatomical (X_A,Y_A,Z_A) and cluster reference frames (X_C,Y_C,Z_C) .

Defining the Anatomical Reference Frames

Anatomical reference frames for the thighs, shanks and feet are created using the global co-ordinates of palpable bony anatomical landmarks recorded during calibration (Table 4.2). To define the position of a landmark in the anatomical reference frame, the positions of all landmarks on the same segment must be known. Thus, each segment is defined within the application once all landmarks on it have been calibrated. The anatomical reference frames for each segment of this model are shown in Figure 4.13.

Figure 4.13 shows that the origins of the anatomical reference frames of the thighs and shanks are the knee and ankle joint centres (KJC, AJC). Once a segment has been fully calibrated, the appropriate joint centre can be calculated. Joint centre positions are used to define the anatomical (i.e. mechanical) axes of the thighs and shanks. For the purposes of this application, all axes systems were defined using the right-hand rule as per the International Society of Biomechanics standards (Grood & Suntay, 1983).

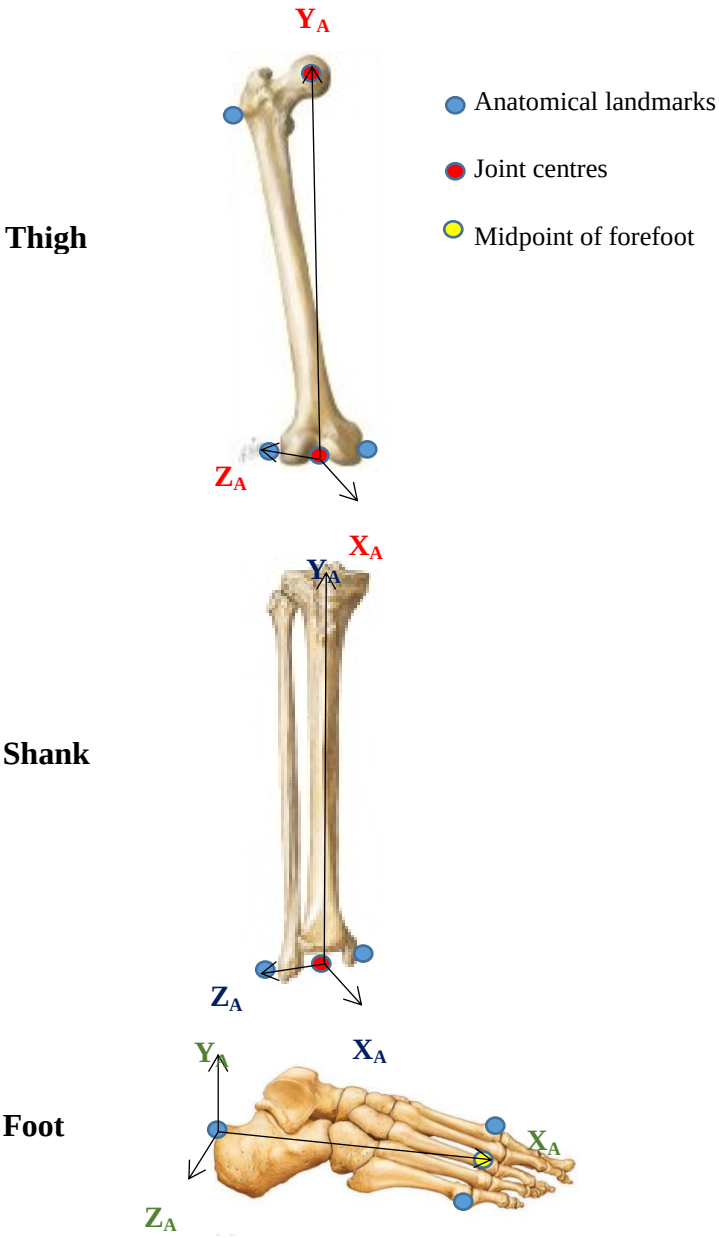


Figure 4. 13: Anatomical reference frames for the thigh, shank and foot segments of the model.

The KJC and AJC were defined as the midpoint between the lateral and medial knee and ankle landmark co-ordinates (Figure 4.14).

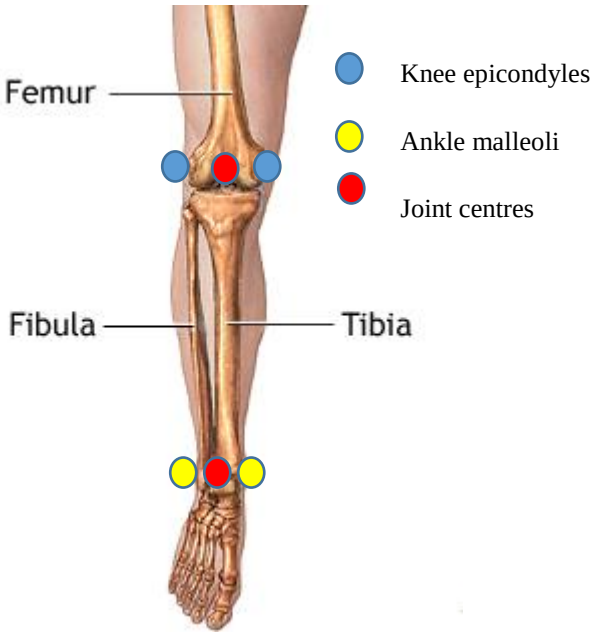


Figure 4. 14: Diagram of the anatomical landmarks used to define knee and ankle joint centres.

The long axes ($\vec{Y}$) of the bones were calculated by subtracting the x-, y- and z-co-ordinates of the distal joint centre (dJC) from the proximal joint centre (pJC) of a segment (Equation 4.4).

In the new model, when the anatomical landmarks of the thigh segments are calibrated, the hip joint centre positions remain unknown because there is no pelvic cluster at that time. Therefore, the long axes of the femora are temporarily defined as the vectors between the KJC and greater trochanter anatomical landmarks. The KJC and AJC are used to define the long axes of the shanks.

$$\begin{bmatrix} Y_x \\ Y_y \\ Y_z \end{bmatrix} = \begin{bmatrix} pJC_x \\ pJC_y \\ pJC_z \end{bmatrix} - \begin{bmatrix} dJC_x \\ dJC_y \\ dJC_z \end{bmatrix}$$

$$\vec{Y} = Y_x, Y_y, Y_z$$

Equation 4. 4

Lateral and medial epicondyles are used for calculating temporary medio-lateral axes ($\vec{T}$) for the thighs, and lateral and medial malleoli are used for the temporary Z axes of the shanks. Equation 4.5 gives an example of how these axes are calculated for the left knee and ankle joints. The equation would be reversed for the axes in the right joints, given that the medio-lateral axis is always positive to the right.

$$\begin{bmatrix} T_x \\ T_y \\ T_z \end{bmatrix} = \begin{bmatrix} MM_x \\ MM_y \\ MM_z \end{bmatrix} - \begin{bmatrix} LM_x \\ LM_y \\ LM_z \end{bmatrix}$$

$$\vec{T} = T_x, T_y, T_z$$

Equation 4. 5

The X-axes (anterior-posterior when in the anatomical position) in the thighs and shanks are then determined using the vector cross product, which produces a vector normal to (i.e. perpendicular to) the plane of the other two vectors (Equation 4.6).

$$\vec{X} = \vec{Y} \times \vec{T}$$

Equation 4. 6

As we cannot assume that the temporary Z axes were orthogonal to both X and Y axes, the temporary medio-lateral axes are then replaced by a true orthogonal medio-lateral axis ($\vec{Z}$) by the cross product of $\vec{X}$ and $\vec{Y}$.

All axes are finally normalised to give unit vectors using Equation 4.7 and Equation 4.8. The X axis is used as an example in this case.

$$|X| = \sqrt{X_x^2 + X_y^2 + X_z^2}$$

Equation 4. 7

$$\hat{X} = \frac{X_x, X_y, X_z}{|X|}$$

Equation 4. 8

The anatomical reference frames in the foot segments are calculated following the same calculations (Equation 4.4 – Equation 4.6). However, in these cases, the heels are the origins of the reference frames and the X axes are defined initially. The reference frames of the foot are created as follow:

1. Midpoint of forefoot is defined as being half way between the 1st and 5th metatarsal heads (Figure 4.13).
2. $\vec{X}_{\mathrm{A}}$ is defined as the vector between the midpoint of the midfoot and the heel (Figure 4.13).
3. A temporary Z axis is defined in the medio-lateral direction as the vector between the 1st and 5th metatarsals (Figure 4.13).
4. $\vec{Y}_{\mathrm{A}}$ is defined as the vector cross product of $\vec{X}_{\mathrm{A}}$ and the temporary medio-lateral axis (Figure 4.13).
5. $\vec{Z}_{\mathrm{A}}$ is defined as the vector cross product of $\vec{X}_{\mathrm{A}}$ and $\vec{Y}_{\mathrm{A}}$ (Figure 4.13)

As in the thighs and shanks, all axes are normalised to give unit vectors using Equation 4.7 and Equation 4.8.

Defining the Cluster Reference Frames

Each segment of this model is assumed to be rigid; therefore, anatomical landmarks on separate segments are represented by different clusters (Table 4.3). Each cluster has its own cluster reference frame (calculated within the global reference frame).

Table 4. 3: A description of the anatomical landmarks associated with each cluster.

Cluster	Anatomical Landmarks
Left Thigh	Left Greater Trochanter Left Lateral Epicondyle of the Knee Left Medial Epicondyle of the Knee
Left Shank	Left Lateral Malleolus of the Ankle Left Medial Malleolus of the Ankle
Left Foot	Left Heel Left 1st Metatarsal Left 5th Metatarsal
Right Thigh	Right Greater Trochanter Right Lateral Epicondyle of the Knee Right Medial Epicondyle of the Knee
Right Shank	Right Lateral Malleolus of the Ankle Right Medial Malleolus of the Ankle
Right Foot	Right Heel Right 1st Metatarsal Right 5th Metatarsal

For the purposes of this application, the origins of each cluster were defined as the second cluster marker (Bottom right marker in Figure 4.15). To create each cluster reference frame the principles used to define the anatomical reference frames were followed (Equation 4.4 – Equation 4.6):

- $\vec{Y}_C$ is defined as the vector between the centres of the 1st and 2nd cluster markers (Figure 4.15).
- A temporary axis is then defined as the vector between the centres of the 3rd and 4th cluster markers (red line in Figure 4.15).
- $\vec{X}_C$ is defined as the vector cross product of $\vec{Y}_C$ and the temporary axis (Figure 4.15).
- $\vec{Z}_C$ is defined as the vector cross product of $\vec{X}_C$ and $\vec{Y}_{C.}$ (Figure 4.15).

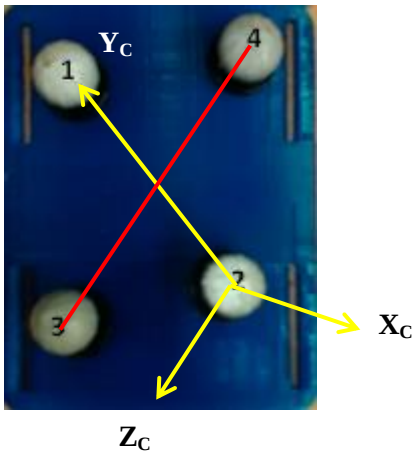


Figure 4. 15: Definition of a cluster reference frame. Note the origin at the second cluster marker. All cluster reference frames were defined in this manner.

Transformation Matrices

The anatomical and cluster reference frames for each segment are defined once all anatomical landmarks on that segment have been calibrated with the pointer. Please note that at this stage of the calibration, the anatomical reference frames for the thighs remain temporary, as the hip joint centres are yet to be determined.

Once the anatomical and cluster reference frames for a segment are known, transformation matrices are constructed to transform points between reference frames. These matrices enable the tracking of segmental and bony movements.

Constructing Global-to-Anatomical Matrices

Global-to-anatomical matrices are used to describe joint movements in the anatomical reference frames. They are calculated on a frame-by-frame basis. Six independent 3 x 3 matrices are generated for this biomechanical model; one for each segment. Each is constructed from the unit vectors defined during construction of the anatomical reference frames (Equation 4.7 – Equation 4.9). They contain the direction cosines for each axis of the orthogonal axis system that creates each anatomical reference frame, allowing marker positions (i.e. anatomical landmarks) to be transformed between reference frames. The

reverse transform is simply given by the transpose of the matrix as it is a unit matrix.

$$[Global \rightarrow Anatomical] = \begin{bmatrix} \bar{X}_x & \bar{X}_y & \bar{X}_z \\ \bar{Y}_x & \bar{Y}_y & \bar{Y}_z \\ \bar{Z}_x & \bar{Z}_y & \bar{Z}_z \end{bmatrix}$$

Equation 4. 9

Constructing Anatomical-to-Cluster Matrices

A fixed anatomical-to-cluster matrix is created for each segment. Anatomical-to-cluster matrices are used to define all calibrated anatomical landmarks and cluster markers within the cluster reference frame. The process is repeated for each segment. These matrices are calculated once at the end of the calibration process.

The co-ordinates used in these calculations are those recorded by the application during pointer calibration. Given that the co-ordinates of the cluster and of the anatomical landmark are saved when a landmark is calibrated, all co-ordinates are static. These co-ordinates will be referred to as 'saved co-ordinates'. These are different from 'live co-ordinates', which are updated with each frame and show the position of the anatomical landmarks in each successive frame.

The process of calculating the live co-ordinates begins by subtracting the saved co-ordinates of a segment's cluster origin marker from the saved co-ordinates of all anatomical landmarks and cluster markers on the same segment (Equation 4.10).

$$\begin{bmatrix} x_N \\ y_N \\ z_N \end{bmatrix} = \begin{bmatrix} x_M \\ y_M \\ z_M \end{bmatrix} - \begin{bmatrix} x_O \\ y_O \\ z_O \end{bmatrix}$$

Equation 4. 10

Where,

x_M, y_M, and z_M are the saved co-ordinates of an anatomical landmark or cluster marker in the global reference frame, x_O, y_O, and z_O are the saved co-ordinates of an origin marker of the same cluster in the global reference frame, and x_N, y_N, and z_N are the resulting new co-ordinates. The new co-ordinates are described in the global reference frame with respect to the origin of the cluster in question.

All resulting co-ordinates are then multiplied by the global-to-anatomical matrix (Equation 4.11). The matrix used depends on the segment. This defines all calibrated anatomical landmarks and cluster markers of a segment in the anatomical reference frame with respect to the cluster origin (x_{anat}, y_{anat}, z_{anat}).

$$\begin{bmatrix} x_{anat} \\ y_{anat} \\ z_{anat} \end{bmatrix} = \begin{bmatrix} \bar{X}_x & \bar{X}_y & \bar{X}_z \\ \bar{Y}_x & \bar{Y}_y & \bar{Y}_z \\ \bar{Z}_x & \bar{Z}_y & \bar{Z}_z \end{bmatrix} \begin{bmatrix} x_N \\ y_N \\ z_N \end{bmatrix}$$

Equation 4. 11

Next, the cluster reference frame is re-defined within the anatomical reference frame. This is carried out as explained previously (Defining the Cluster Reference Frames), but this time the co-ordinates used in the calculations are within the anatomical reference frame (Equation 4.11), not the global reference frame. All axes ($\overrightarrow{cX}$,$\overrightarrow{cY}$, $\overrightarrow{cZ}$) are normalised, and the resulting co-ordinates are used to construct a static anatomical to cluster matrix (Equation 4.12). One is created per segment. All anatomical landmarks defined in the anatomical reference frame can be transferred into the cluster reference frame if multiplied by this matrix.

$$[\text{Anatomical} \rightarrow \text{Cluster}] = \begin{bmatrix} c\bar{X}_x & c\bar{X}_y & c\bar{X}_z \\ c\bar{Y}_x & c\bar{Y}_y & c\bar{Y}_z \\ c\bar{Z}_x & c\bar{Z}_y & c\bar{Z}_z \end{bmatrix}$$

Equation 4.12

Once created, the co-ordinates of each calibrated landmark in the anatomical reference frame, as well as each anatomical-to-cluster matrix are saved into calibration text files.

Constructing Cluster-to-Global Matrices

To track the reconstructed anatomical landmarks in real-time it is necessary to transfer the calibrated anatomical landmark co-ordinates from the anatomical reference frame into the global reference frame via the cluster reference frame. The final calculations therefore construct cluster-to-global matrices. This allows the model to track the anatomical landmarks on each segment with respect to the segment's cluster in real-time.

Firstly, the saved anatomical-to-cluster matrices (Equation 4.12) are multiplied by the saved co-ordinates of the landmarks of the same segment (Equation 4.13). This is necessary to allow dynamic tracking of anatomical landmarks with respect to the cluster origin.

$$\begin{bmatrix} x_{cluster} \\ y_{cluster} \\ z_{cluster} \end{bmatrix} = \begin{bmatrix} c\bar{X}_x & c\bar{X}_y & c\bar{X}_z \\ c\bar{Y}_x & c\bar{Y}_y & c\bar{Y}_z \\ c\bar{Z}_x & c\bar{Z}_y & c\bar{Z}_z \end{bmatrix} \begin{bmatrix} x_{anat} \\ y_{anat} \\ z_{anat} \end{bmatrix}$$

Equation 4. 13

Next, cluster reference frames ($\overrightarrow{gX}$,$\overrightarrow{gY}$, $\overrightarrow{gZ}$) are re-defined using the live co-ordinates of the cluster markers in the global reference frame, as explained previously (Defining the Cluster Reference Frames). Equation 4.7 and Equation 4.8 are then repeated to create the unit vectors, with which the cluster-to-global matrices are created (Equation 4.14). This provides tracking cluster reference frames.

$$[Cluster \rightarrow Global] = \begin{bmatrix} g\bar{X}_x & g\bar{X}_y & g\bar{X}_z \\ g\bar{Y}_x & g\bar{Y}_y & g\bar{Y}_z \\ g\bar{Z}_x & g\bar{Z}_y & g\bar{Z}_z \end{bmatrix}$$

Equation 4. 14

The dynamic anatomical landmark co-ordinates described with respect to the cluster origin are translated into the global reference frame by multiplying the co-ordinates (Equation 4.13) by the cluster-to-global matrix of the cluster on the same segment (Equation 4.15).

$$\begin{bmatrix} x_{global} \\ y_{global} \\ z_{global} \end{bmatrix} = \begin{bmatrix} g\bar{X}_x & g\bar{X}_y & g\bar{X}_z \\ g\bar{Y}_x & g\bar{Y}_y & g\bar{Y}_z \\ g\bar{Z}_x & g\bar{Z}_y & g\bar{Z}_z \end{bmatrix} \begin{bmatrix} x_{cluster} \\ y_{cluster} \\ z_{cluster} \end{bmatrix}$$

Equation 4. 15

The process is completed by adding the position of the respective origin onto the resulting co-ordinates to describe the anatomical landmarks in the global reference frame with global origin (Equation 4.16).

$$\begin{bmatrix} x_{tracking} \\ y_{tracking} \\ z_{tracking} \end{bmatrix} = \begin{bmatrix} x_{global} \\ y_{global} \\ z_{global} \end{bmatrix} + \begin{bmatrix} x_O \\ y_O \\ z_O \end{bmatrix}$$

Equation 4. 16

The co-ordinates of all anatomical landmarks of the model can be tracked and reported in the global reference frame with respect to the global origin in real-time once this step has been completed for each segment. This information cannot as yet be used to calculate joint kinematics and kinetics, as the positions of both hip joint centres remain unknown.

The next developmental step was therefore to define the positions of the HJCs from the reconstructed anatomical landmarks to correct the thigh temporary anatomical axes based on the greater trochanter.

4.3.3. Hip Joint Centre Calibration

Cluster-based biomechanical models usually use the positions of four pelvic landmarks to locate both hip joint centres. As this model does not use these markers, an alternative method for defining the HJC was necessary.

Currently, the most accurate method for identifying the HJC is through functional calibration (Kainz *et al.,* 2015). This method is based on the assumption that the HJC is a ball and socket joint (Picard *et al.,* 2007). Functional calibration of the hip is often carried out during orthopaedic surgery to define the mechanical axis of the femur. The positions of clusters drilled into bone are tracked by infra-red cameras as the leg is moved about the hip joint (Picard *et al.,* 2007). The points recorded by the bespoke software are then fitted to a sphere using a least-squares technique; the centre of which is defined as the HJC (Ahn e*t al.,* 2001; Eberly, 1997). Given the success of functional calibration in theatre, some companies including Motekforce Link have incorporated functional calibration of the HJC into their biomechanical models (Kainz *et al.,* 2015).

This calibration process relies on patients being able to actively move the hip within its full ROM. In non-surgical settings, this usually requires the patient to stand on one leg whilst moving the opposite leg at the hip joint. For accurate and reliable joint centre location, this process may take a couple of minutes to complete. Considering this, the functional method of locating hip joint centres is not appropriate for clinical use, especially in orthopaedics where some patients may not have full range of motion available at the hip. Furthermore, knee OA/TKA patients may struggle to weight bear on one leg for the calibration process due to pain, poor muscular strength or fatigue. This could result in inaccurate location of the hip joint centres being recorded. It was therefore necessary to implement an alternative method.

The method implemented in this model is referred to as the 'greater trochanter (GT) method' (Weinhandl & O'Connor, 2010). As with the functional method, it does not require the use of pelvic markers. According to Weinhandl and O'Connor (2010), this method uses the positions of the left and right greater trochanters to estimate the position of both HJCs. The positions of the HJCs are approximated as a quarter of the distance between both trochanters. This method has previously been shown to be reliable, especially in the sagittal plane (Sinclair *et al*., 2014; Weinhandl & O'Connor, 2010).

Implementing this method saves patients from having to carry out a range of movements at the hip. Patients are simply required to remain within the capture volume (i.e. on the treadmill) following anatomical landmark calibration, while the clinician presses a button in the user-interface to locate the HJCs and redefine the femoral axes.

To calculate the HJCs, the three-dimensional vector between both GTs were calculated then divided by 4. Given that the Z axis was positive to the left, the result was added to the position of the right GT and subtracted from the left GT to give right and left HJCs, respectively (Figure 4.16).

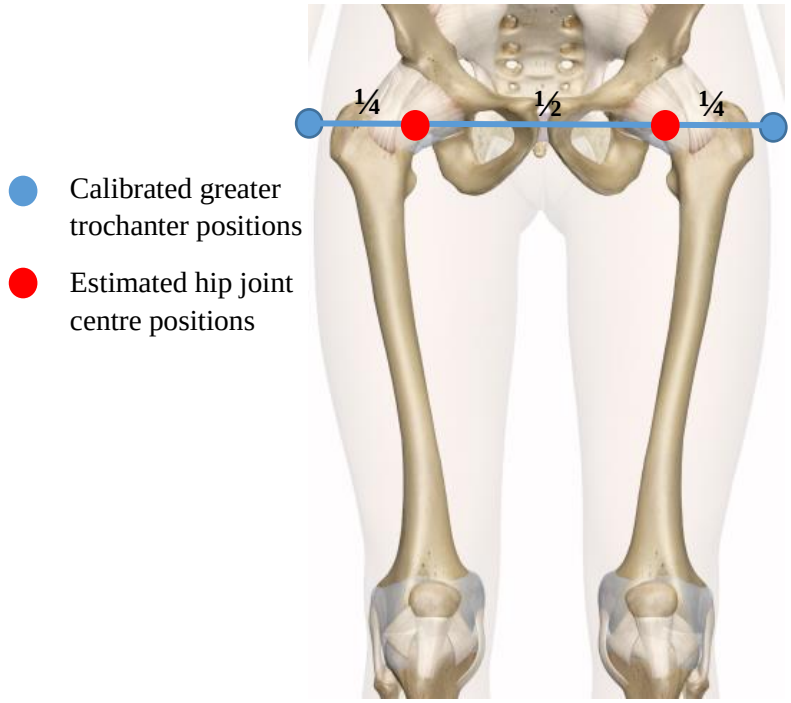


Figure 4. 16: A diagram depicting the Greater Trochanter method of locating the hip joint centres.

Once both HJCs have been identified, the thigh anatomical reference frames are redefined using the positions of the joint centres. This restores the anatomical axes of the thighs. All calculations to track the thigh segments with respect to the clusters on the thighs in real-time are then repeated (as described

previously in this section). The anatomical reference frames of all segments can then be used to calculate joint kinematics and kinetics during dynamic trials. During the gait assessment application a pelvic cluster is added to track movements of the pelvis.

Please refer to Appendix 2.1 (Anatomical Landmark Calibration & Hip Joint Calibration) for step-by-step instructions on patient calibration with the bespoke software package.

4.4. Range of Motion Assessment

This assessment was developed to calculate the active and passive flexion-extension range of movement at the knee joint. Given that knee flexion-extension occurs in the sagittal plane of movement (Figure 4.17), only sagittal plane knee kinematics are calculated by the software during this assessment even though the data is fully 3D. Hence, this section of the thesis will only describe how sagittal plane knee kinematics were calculated. The methods used to define all other joint kinematics are described later in this chapter.

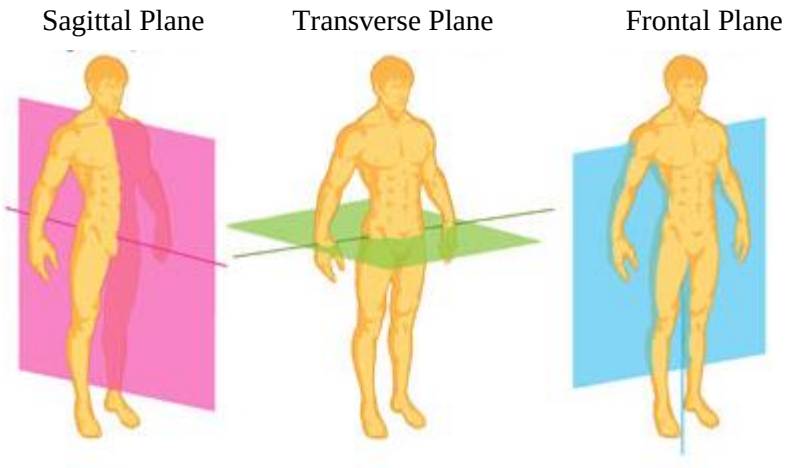


Figure 4. 17: The three planes of movement in the human body.

4.4.1. Sagittal Plane Knee Kinematics

To define the angle of a joint, the positions of the segments interconnecting the joint proximally and distally must be known (Baker, 2003). In the case of the knee joint, the proximal limb is the thigh and the distal limb is the shank. Rotation in the sagittal plane of the proximal segment around the distal segment defines flexion-extension (Baker, 2003).

To describe the rotation of a joint in any plane (sagittal/frontal/transverse), a set of three axes about which the rotations occur must be defined within the joint. This is the joint co-ordinate system (JCS). To comply with the standards recommended by the International Society of Biomechanics, the Grood & Suntay method for determining joint co-ordinate systems was used in this model (Grood & Suntay, 1983; Wu & Cavanagh, 1995).

As per Grood & Suntay's recommendations, the unit base vectors of a joint ($\hat{e}_1, \hat{e}_2, \hat{e}_3$) were defined using one axis from the anatomical reference frames of each of the segments connected to the joint ($\hat{e}_1, \hat{e}_3$). These are fixed axes. The third axis of the JCS, referred to as the floating axis was perpendicular to both fixed axes ($\hat{e}_2$). It is therefore not a fixed axis, but floats in relation to the two fixed axes, remaining perpendicular to both during movement. The rotational motions of a joint occur about these axes.

- $\hat{e}_1$ was defined as the rotation about the proximal medio-lateral axis (flexion-extension, α).
- $\hat{e}_3$ was defined as the rotation about the distal longitudinal axis (internal-external rotation, γ).
- $\hat{e}_2$ was defined as the rotation about the floating axis which was calculated using Equation 4.17 (abduction-adduction, β).

$$\hat{e}_2 = \left(\frac{\hat{e}_1 \times \hat{e}_3}{|\hat{e}_1 \times \hat{e}_3|}\right)$$

Equation 4. 17

The joint axis system for the knee is given in Figure 4.18.

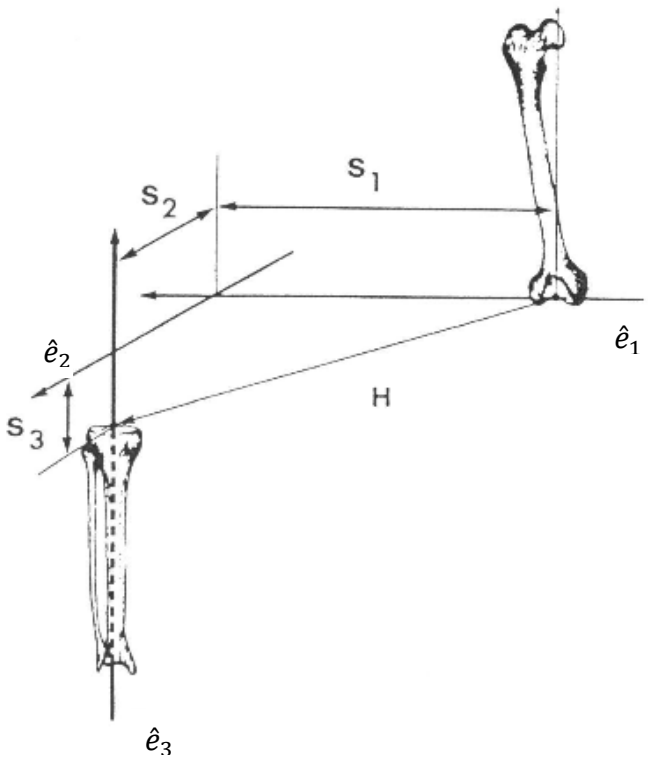


Figure 4. 18: The joint axis system for the knee, as defined by Grood & Suntay (1983).

Joint kinematics were defined as per Cole *et al.* (1993), who extended the methods proposed by Grood & Suntay (1983). This method can be used to describe all joint kinematics in a clinically relevant manner (Cole *et al.,* 1993). The notation used by Cole and colleagues will also be used in this thesis (Table 4.4).

Table 4. 4: Notations used by Cole *et al*., 1993 to define axes used to calculate joint kinematics.

Notation	Definition
$\boldsymbol{\alpha}$	Rotation about $\hat{e}_1$ (flexion-extension).
$\boldsymbol{\beta}$	Rotation about $\hat{e}_2$ (abduction-adduction).
$\boldsymbol{\gamma}$	Rotation about $\hat{e}_3$ (internal-external).
$\hat{\boldsymbol{l}}_{\boldsymbol{i}}$	Longitudinal (Y) axis in the anatomical reference frame of the proximal segment.
$\hat{\boldsymbol{f}}_{\boldsymbol{i}}$	Medio-lateral (flexion/ Z) axis in the anatomical reference frame of the proximal segment.
$\hat{\boldsymbol{l}}_{\boldsymbol{j}}$	Longitudinal axis (Y) in the anatomical reference frame of the distal segment.
$\hat{\boldsymbol{f}}_{\boldsymbol{j}}$	Medio-lateral (flexion/ Z) axis in the anatomical reference frame of the distal segment.
$\hat{\boldsymbol{t}}_{\boldsymbol{i}}$	"Third axis" of the proximal segment defined as the cross product of $\hat{l}_i$ and $\hat{f}_i$ (i.e. the antero-posterior axis (X) of the proximal segment). Also known as reference axis.
$\hat{\boldsymbol{t}}_{\boldsymbol{j}}$	"Third axis" of the distal segment defined as the cross product of $\hat{l}_j$ and $\hat{f}_j$ (i.e. the antero-posterior axis (X) of the distal segment). Also known as reference axis.

To calculate the flexion-extension movements at a joint it was necessary to define reference axes in the segment proximal to the joint (i.e. the thigh in the case of the knee joint) (Grood & Suntay, 1983). This is due to the fact that when a rotation about a fixed axis ($\hat{e}_1$ *or* $\hat{e}_3$) occurs, one segment is considered to rotate, while the other segment remains stationary. The reference axes ($\hat{t}_i$ *or* $\hat{t}_j$) are perpendicular to the axes of rotations and were defined as the cross product of the longitudinal and medio-lateral axes in the anatomical reference frames of the segments (i.e. the X axis of the proximal segment in the case of flexion-

extension). For example, the reference axis ($\hat{t}_i$) in the left thigh segment (proximal segment) is equivalent to the X axis of this segment in the anatomical reference frame.

Joint flexion-extension movements were defined as the angles between $\hat{t}_i$ and the floating axis ($\hat{e}_2$) of the equivalent JCS.

The flexion-extension rotations (α) about $\hat{e}_1$ in all joints were calculated using Equation 4.18. Flexion angles are positive and extension angles negative.

$$\alpha = cos^{-1}(\hat{e}_2 \cdot \hat{t}_i) * B$$

$$B = 1 \; if \; (\hat{e}_2 \cdot \hat{l}_i) > 0$$

$$B = -1 \; if (\hat{e}_2 \cdot \hat{l}_i) < 0$$

Equation 4. 18

In the case of this particular assessment, knee flexion-extension angles were calculated as being the angle between the femoral X axis ($\hat{t}_i$) and the floating axis ($\hat{e}_2$).

4.4.2. Visualisation of Results

An avatar of the participant was developed for use with the application (Figure 4.19). Virtual markers which represented the ankle, knee and hip joint centres were generated using spherical objects within the software. Avatars of the thigh and shank segments were made by calculating the magnitude of the vectors between the proximal and distal joint centres and linking them with solid cylinders. Foot segments were created from the positions of the heel and toe (1st and 5th metatarsals) anatomical landmarks and again shown as cylinders.

An option to visualise or hide the avatar was incorporated into the frontend control panel. Thus, the user can decide whether or not to show the avatar. The markers on the clusters are always visible in the visualisation screen to reassure

the user that the marker data are being streamed into the D-Flow software. The pelvic cluster markers appear blue (only one visible in Figure 4.19), the left limb cluster markers appear red, and the right limb cluster markers appear green (Figure 4.19). Hip joint centres are shown as large red spheres and knee joint centres are shown as large green spheres (Figure 4.19).

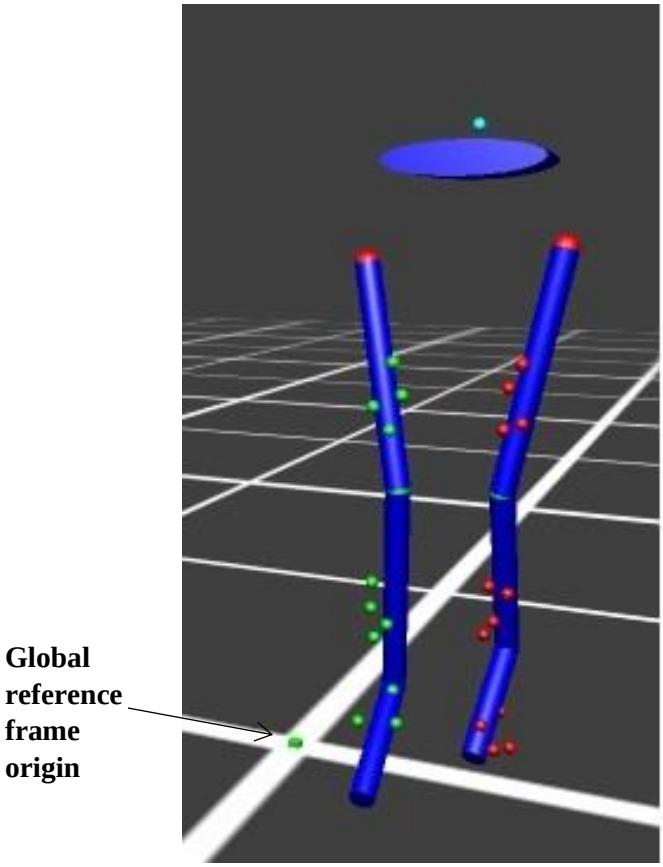


Figure 4. 19: An example of the full avatar.

Red sphere: Hip joint, Green sphere: Knee joint, Blue sphere: Ankle joint.

Numerical feedback can also be made available to the user and participant through the Frontend. In this case, the following data can be visualised on-screen during a live trial:

- Maximum knee flexion
- Maximum knee extension
- The difference between maximum knee flexion and maximum knee extension (knee excursion)
- Live flexion-extension angle

4.4.3. Additional Uses

For ease of use, assessments can be recorded by pressing a footswitch (Figure 4.10). This means that the clinician can be with the patient throughout an assessment, eliminating the need for a second clinician to be present to control the application from the computer.

On occasion it may be useful to return to previously recorded data; For example, to see how a participant is progressing over time. Hence, with every recording a text file is automatically generated containing the angles recorded at each frame, and the maximum flexion or extension values recorded during the same trial.

Please refer to Appendix 2.1 (Range of Motion (ROM) Assessment) for step-by-step instructions on how this application should be used clinically.

4.5. Knee Strength Assessment

The hardware and software described here were engineered to create an assessment of isometric knee flexor and extensor strengths.

4.5.1. Materials

The motion capture laboratory designed for the purposes of this thesis did not include a force measuring device. To measure the isometric strengths of a knee joint, it was therefore necessary to incorporate one into the system. Strain-gauged load-cells measure strain from an applied force as a change in electrical resistance. It is therefore possible to measure force using these devices. A straight bar load-cell was deemed appropriate for measuring knee strength for this application as it is a simple, small, lightweight, and inexpensive tool.

A 1000N load-cell (White Ltd., Oxford, United Kingdom) was incorporated into the motion capture system, by attaching it to the middle of a crossbeam which was then fixed to the bottom of the anterior handlebars of the treadmill (Figure 4.20).

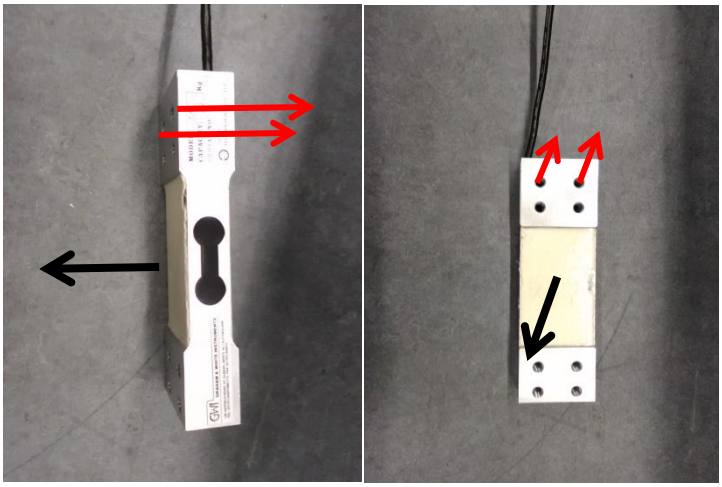


Figure 4. 20: Photographs of the load-cell used in this study. Red arrows show where the load-cell was screwed into the crossbeam then attached to the treadmill. Black arrows show the direction the strap was pulled during assessments.

An adjustable strap was then attached on one end of the vertically mounted load cell. Forces exerted on the free end of the strap were measured by the load-cell as changes in electrical resistance (Figure 4.20). A retro-reflective marker was permanently attached to the proximal end of the strap to ensure that the 3D position of the attachment point could be defined using motion capture software.

To measure the force exerted on the load-cell, it was necessary to convert the voltage output to Newtons. The conversion calculation was determined by calibrating the load-cell. The load-cell was calibrated on 13 separate days to validate the reliability of the load-cell and confirm its appropriateness as a tool to measure isometric knee strength.

Calibration of the load-cell was carried out by attaching calibrated weights of between 9.8N and 98.1N to the load-cell in 9.8N increments. Individual plates weighing 9.8N were used to calibrate the load cell for weights between 9.8N and 39.2N. Beyond this, a plate weighing 49.0N was used. For weights greater than 49.0N, the 49.0N plate was combined with 9.8N plate(s) to bring the total weight to 58.9-98.1N. Individual plates weighing 9.8N could not be used throughout the calibration process as there were not enough 9.8N plates available. The voltage was output directly into the D-Flow software and reported for each weight.

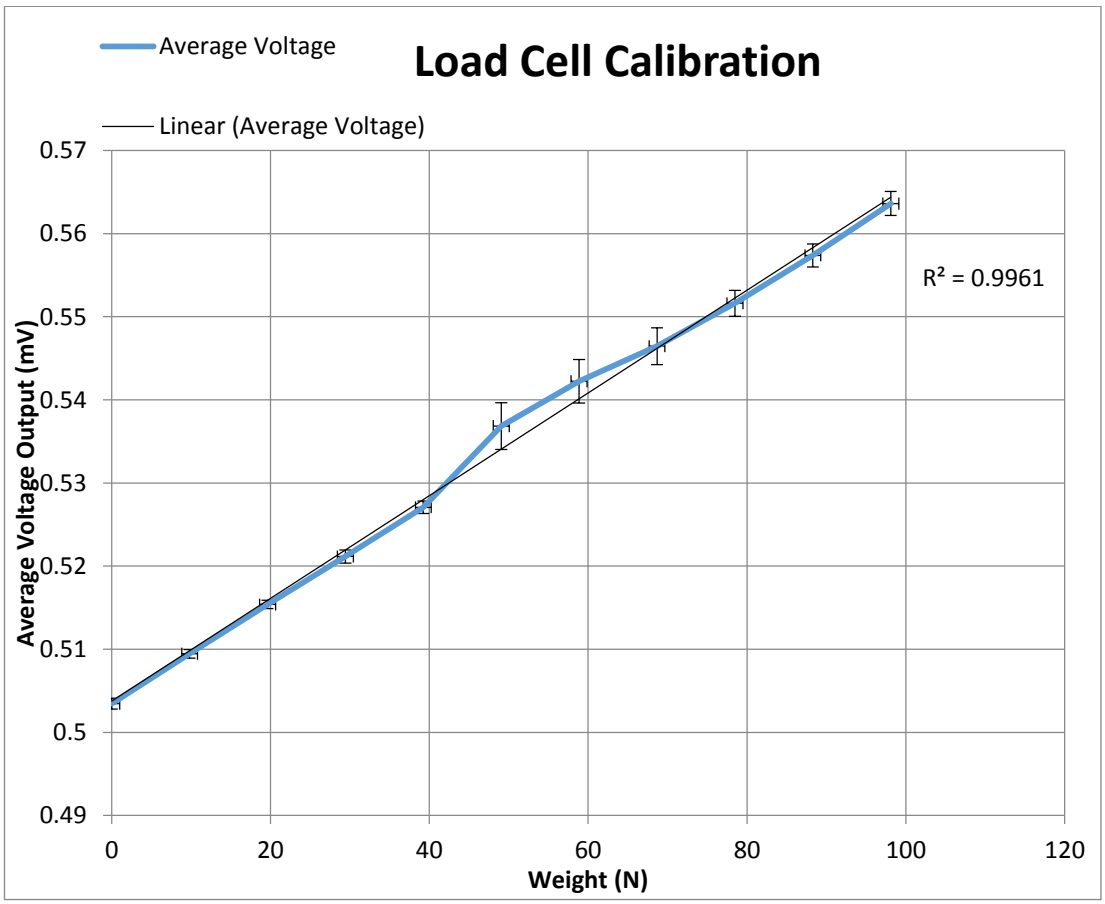


Figure 4. 21: Mean load-cell voltage output (±SD) against weight over 13 days.

The results showed a positive linear relationship between the voltage output and weight applied to the load-cell (Figure 4.21). The discrepancy observed in Figure 4.21 between 40N and 60N is caused by the introduction of the 49.0N plate.

Reliability of the load cell was confirmed by running an intra-class correlation coefficient (ICC) evaluation on the calibration results taken over 13 repetitions. The ICC was calculated according to Shout and Fleiss' schema (1979). The ICC was 0.99 over 13 uses. As ICCs >0.80 are regarded as excellent, it could be inferred that the load cell was an appropriate tool for measuring reliable and repeatable force data.

With the data gained from this calibration process, it was possible to generate a calculation to convert the voltage output directly into force in Newton (Equation 4.19).

$$F = \left(\frac{0.50 - v}{0.006}\right) 9.81$$

Equation 4.19

Where,

v is the live voltage output of the load-cell in millivolts, 9.81 is the standard acceleration of an object on Earth due to gravity in m/s^2, and 0.006 is the average increase in voltage per 9.81N.

4.5.2. Calculating Knee Flexor and Extensor Moments

To determine the flexor or extensor moment about a knee at a particular angle of the knee using this method, the following variables needed to be known:

1. Force exerted against the load-cell
2. Limb weight
3. Angle of the strap
4. Sagittal plane angle of the knee joint
5. Distance between the axis of rotation of the knee and line of action (Moment Arm)

Equation 4.19 was used to calculate the force exerted by the individual against the load-cell. As the assessment was designed for isometric (static) use, the velocity of the limb would be consistently zero under testing conditions. It was therefore not necessary to incorporate this dynamic variable into the calculations.

Gravity correction was carried out on the data to exclude the influence of the weight of the limb on the results. To calculate this force (F_G), the masses of the shank and foot were estimated using Equation 4.20 and Equation 4.21.

$$Shank\ Mass\ (kg) = 0.0465 \times BM$$

Equation 4. 20

$$Foot\ Mass\ (kg) = 0.0145 \times BM$$

Equation 4. 21

Where:

4.65% (0.0465) and 1.45% (0.0145) are the estimated percentage masses of the shank and foot respectively, with regard to whole body mass (BM) (Winter, 2005a).

To calculate shank and foot weight, both masses were summed then multiplied by 9.81m/s^2 (acceleration due to gravity).

To calculate the angle of the strap (Figure 4.22), a vector was created between the proximal and distal attachment points of the strap (direction of force). The AJC of the limb under assessment was defined as the distal point. This point was chosen as the strap would be aligned with the lateral and medial malleoli (the two landmarks used to define the AJC) during testing. The proximal end of the strap was defined by the retro-reflective marker.

The angle in degrees between the ground and the strap (Figure 4.22) was calculated with Equation 4.22.

$$\theta_{G=}\ sin^{-1}\left((G_x \times S_x) + (G_y \times S_y) + (G_z \times S_z)\right)\frac{180}{\pi}$$

Equation 4. 22

Where,

G_x, G_y and G_z are the co-ordinates of the ground vector and S_x, S_y, and S_z are the co-ordinates of the strap vector (Figure 4.22). All co-ordinates are described in the global reference frame.

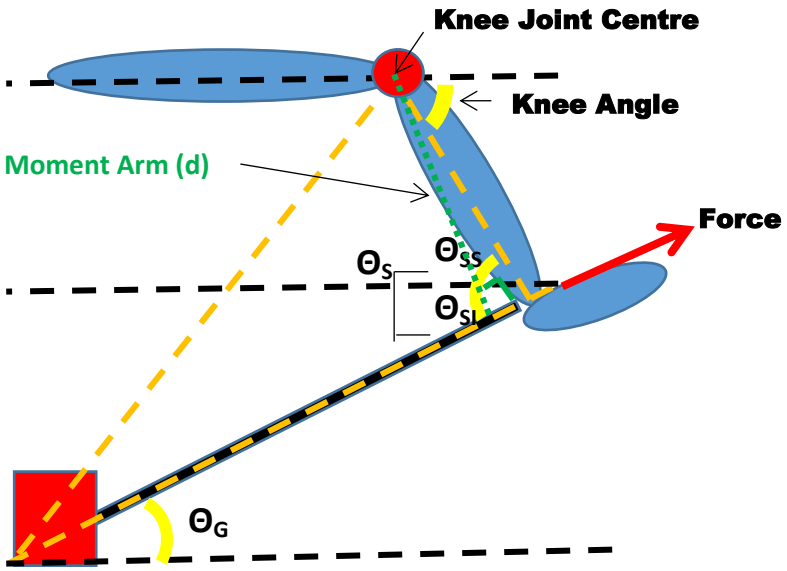


Figure 4. 22: Calculating the strap angle for strength measurement during knee extension.

Once θ_G was known, it was possible to estimate the variable of interest: θ_S. $\theta_{SI}$was defined as being equal to θ_G, and θ_{SS} was defined as being equal to the knee flexion angle (Figure 4.22). As was described in section 4.4 of this thesis, a function to calculate the sagittal plane angle of the knee was written for the ROM assessment. The same function was also called during the strength assessments. The overall strap angle (θ_S) was therefore equal to both θ_{SI} and θ_{SS} angles.

The moment arm (d in Figure 4.22) was then calculated as the shortest distance between the KJC and the line of action (vector of the strap).

Finally, the moment about the knee (M_K), measured in Newton meters, was estimated using Equation 4.23.

$$M_K = d\,(cos(\theta_S \times F_G))$$

Equation 4. 23

Where,

d is the shortest perpendicular distance between the axis of rotation and line of action in meters, θ_S is the angle of the strap in degrees, and F_G is the gravity corrected force exerted against the load-cell in Newton.

4.5.3. Visualisation of Results

Visual and verbal feedback is often given to patients during standard strength tests to encourage maximal exertion (Gross *et al.,* 1989; Jakobi *et al.,* 2002). With this application, an avatar of the patient was made available for use during testing as described in section 4.3.2 of this thesis.

As maximum voluntary isometric contraction is known as the simplest and most accurate way to assess muscle strength (especially in the older population), clinicians using this application also have the option to visualise the maximal force (N), moment (Nm) and normalised moment (Nm/Kg) produced during trials (Candow & Chilibeck, 2005; Jakobi *et al.,* 2002; National Isometric Muscle Strength Database Consortium, 1996).

4.5.4. Additional Uses

Subject body mass must be known for gravity correction of the data. A tab was therefore incorporated into the user interface to allow the user to input the patients' data, including their mass in kilograms, for the software's use. The values input here are used by the software for the appropriate calculations, meaning that users are not required to gain access to or alter the code between patients.

Similar to the assessment which records knee ROM, a footswitch is used to control the recording of all strength assessments. Additionally, all results are saved and exported into text files for future use.

Please refer to Appendix 2.1. (Strength Assessment) for step-by-step instructions on how this assessment should be carried out clinically.

4.6. Gait Analysis

The gait analysis assessment was created to enable clinicians to output and analyse gait kinematics. The variables which are output following a trial include the co-ordinates of the anatomical landmarks and joint centres in the global reference frame, and flexion-extension, abduction-adduction and internal-external rotation angles of all major lower limb joints.

4.6.1. Pelvis Calibration

The biomechanical model described thus far consists of six segments with which knee and ankle kinematics can be defined (Figure 4.8B). Hip kinematics cannot be defined with this model as positions of segments proximal and distal to a joint must be known to be able to calculate its kinematics and the pelvic position was not known in the two previous knee assessments (Baker, 2003). It was therefore necessary to develop an additional calibration process, which would be carried out prior to the gait assessment, to add a pelvic segment to the current biomechanical model.

An additional cluster was created and calibrated for the pelvic segment in the same manner as was reported in section 4.3.1 of this thesis. A pointer calibration method was then implemented for calibrating and tracking the pelvic anatomical landmarks during walking tasks. The methods used to do this were described in section 4.3.2.

The four anatomical landmarks used to create the pelvic segment are the left and right anterior superior iliac spines (ASIS) and left and right posterior superior iliac spines (PSIS) (Figure 4.23).

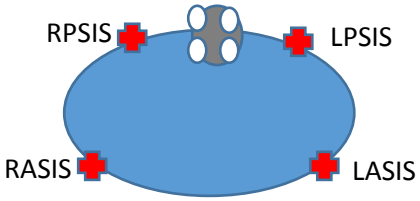


Figure 4. 23: A diagram of the pelvic segment created following an additional calibration step. This is only required when carrying out a full lower limb kinematic analysis.

In accordance with the original calibration, a footswitch is used to save the x-, y-, and z-co-ordinates of each landmark in a given order (Table 4.5).

Table 4. 5: The order in which the pelvic anatomical landmarks are saved and labelled.

Press	Action	Landmark Name
1	Save pointer position & Label position	Left anterior iliac spine (LASIS)
2	Reset pointer position	
3	Save new pointer position & Label new position	Left posterior iliac spine (LPSIS)
4	Reset pointer position	
5	Save new pointer position & Label new position	Right anterior iliac spine (RASIS)
6	Reset pointer position	
7	Save new pointer position & Label new position	Right posterior iliac spine (RPSIS)

4.6.2. Calculating Lower Limb Kinematics

It was previously stated that a JCS must be defined within each joint for its kinematic movement to be described (section 4.4.1). The Grood & Suntay method for describing the JCS was used for all joints in this study (Wu & Cavanagh, 1995; Grood & Suntay, 1983). The joint axis system used for the knee was described in section 4.4.1 (Figure 4.18). Those used for the hip and ankle are depicted in Figure 4.24 and Figure 4.25.

As was previously described:

- $\hat{e}_1$ was defined as the rotation about the proximal medio-lateral axis (flexion-extension, α).
- $\hat{e}_3$ was defined as the rotation about the distal longitudinal axis (internal-external rotation, γ).
- $\hat{e}_2$ was defined as the rotation about the floating axis which was calculated using Equation 4.17 (abduction-adduction, β).

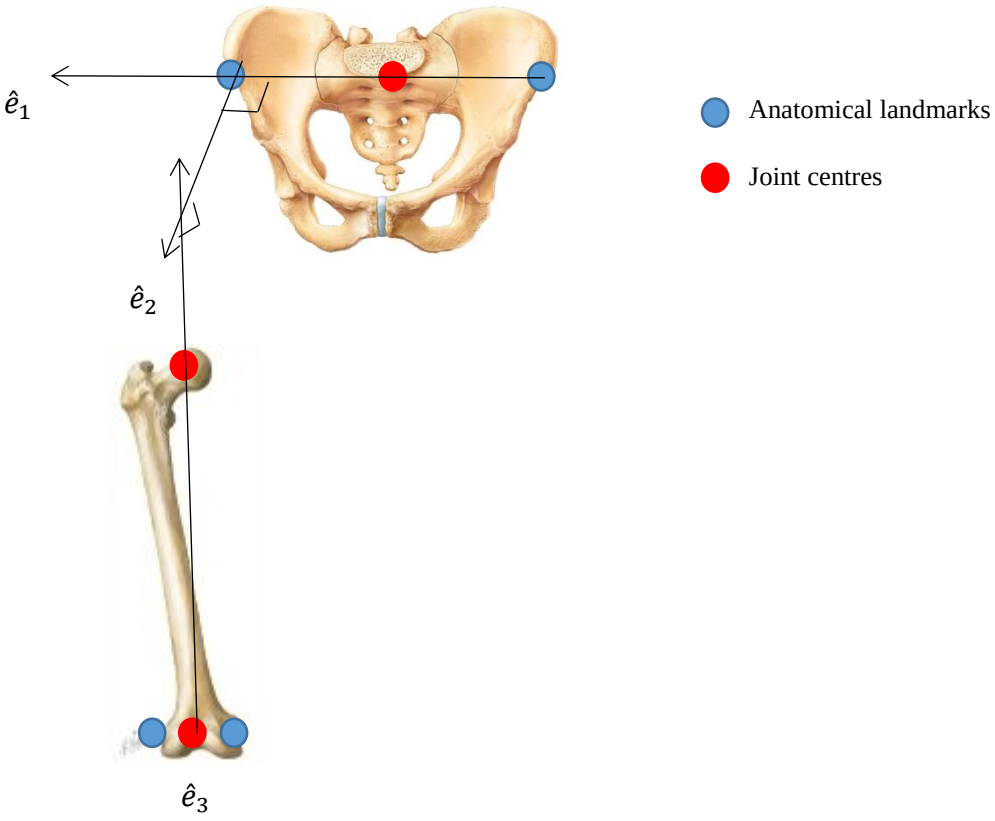


Figure 4. 24: The joint axis system for the hip.

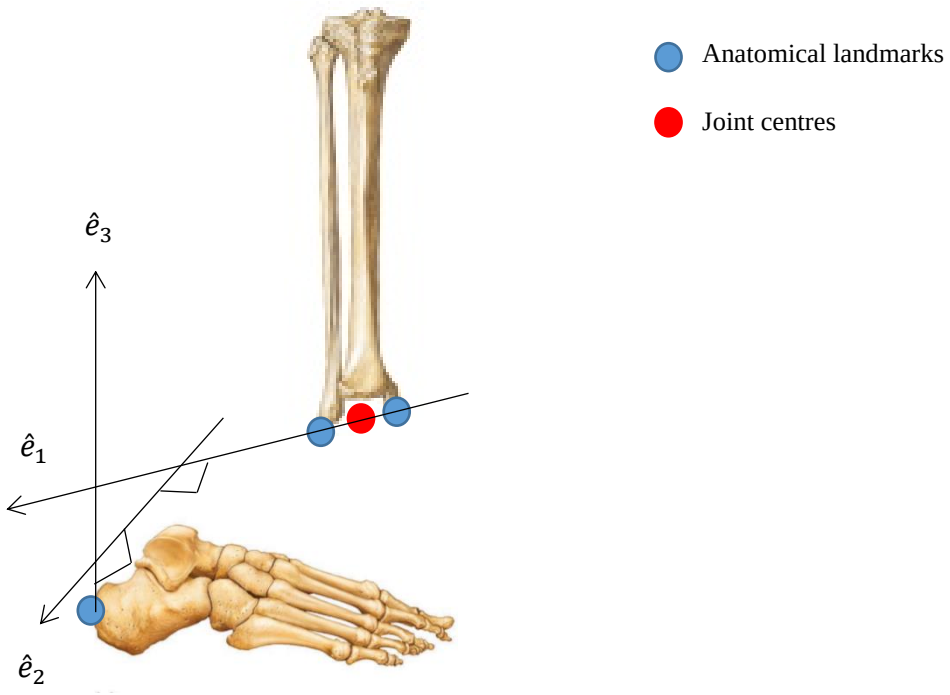


Figure 4. 25: The joint axis system for the ankle.

All joint kinematics were defined according to Cole *et al.* (1993). The notations used in this thesis were described in Table 4.4.

As was previously explained, joint flexion-extension angles were defined by initially creating reference axes in the segments proximal to the joints (section 4.4.1). The reference axes ($\hat{t}_i$) were described as the X axes (in the anatomical reference frames) of the segments proximal to the joint (pelvis, thighs and shanks).

Sagittal plane kinematics could then be described as the angles between $\hat{t}_i$ and the floating axes ($\hat{e}_2$) of the JCS. Hip, knee and ankle sagittal plane kinematics were calculated using Equation 4.18. Flexion angles are positive and extension angles negative.

Frontal plane kinematics for all joints (β) were defined as the rotations about the floating axes ($\hat{e}_2$) of the joints and thus, the angle between the two body

fixed axes: r and $\hat{l}_j$. Equation 4.24 was used to define abduction as positive and adduction as negative in all joints.

$$\beta = cos^{-1}(r \cdot \hat{l}_j) * C$$

$$r = \left(\frac{f_i \times e_2}{|f_i \times e_2|}\right)$$

$$C = 1 \; if \; (\hat{f}_i \cdot \hat{l}_j) < 0$$

$$C = -1 \; if (\hat{f}_i \cdot \hat{l}_j) > 0$$

Equation 4. 24

Where,

r is an axis orthogonal to both the joint's proximal flexion axis ($\hat{f}_i$) and floating axis ($\hat{e}_2$), and $\hat{l}_j$ is the distal longitudinal axis of the joint.

As an example, to calculate knee abduction-adduction angles, the Z axis of the femur ($\hat{f}_i$) and floating axis of the knee JCS ($\hat{e}_2$) were used to calculate *r.* The angle between the resulting axis and the Y axis of the shank ($\hat{l}_j$) described knee kinematics in the frontal plane.

Transverse plane kinematics (γ) were defined as rotations about the $\hat{e}_3$ axes of the JCS. It was therefore necessary (as with sagittal plane kinematics) to define reference axes. In this case however, the reference axes were in the segments distal to the joints($\hat{t}_j$). These axes were perpendicular to the axis of rotation; equivalent to the X axis of the distal segment in the anatomical reference frame or the cross product of $\hat{l}_j$ and$\hat{f}_j$. For the knee, the reference axis ($\hat{t}_j$) in the left shank segment is equivalent to the X axis of this segment.

Internal-external joint kinematics were defined as the angles between $\hat{t}_j$ and the floating axis ($\hat{e}_2$) of the equivalent JCS (Equation 4.25). Internal rotation is positive and external rotation is negative.

$$\gamma = cos^{-1}(\hat{e}_2 \cdot \hat{t}_j) * D$$

$$D = 1 \; if \; (\hat{e}_2 \cdot \hat{f}_j) > 0$$

$$D = -1 \; if (\hat{e}_2 \cdot \hat{f}_j) < 0$$

Equation 4. 25

Continuing the example with the left knee, internal-external rotation angles would be defined as the angle between the flexion axis and reference axis of the joint.

All sagittal, frontal and transverse plane kinematics were calculated as described in this chapter.

4.6.3. Visualisation of Results

Clinicians have the option to view an avatar of the patient and/or real-time kinematic graphs of the hip, knee and ankle joints.

4.6.4. Additional Uses

The primary aim of this assessment is to provide clinicians with a tool to analyse gait. However, some clinicians may also be interested in patient biomechanics during alternative tasks. Thus, a drop-down list of activities of daily living was incorporated into the user interface to give clinicians the freedom to record any of the following tasks:

- Walking
- Step Up
- Stair Ascent
- Stair Descent
- Slope Ascent
- Slope Descent
- Sit-to-Stand

- Stand-to-Sit
- Lunge
- Other

Users of the application also have the ability to control activation and speed of the treadmill belt via the user interface. Activation of the treadmill's 'self-paced mode' is also possible here. When activated, the software tracks the position of the first pelvic cluster marker. If the marker moves towards the front of the treadmill, it triggers an inbuilt function within D-Flow which increases the belt speed. The opposite occurs when the marker moves towards the rear of the treadmill.

On choosing an assessment and starting a trial, the co-ordinates of each anatomical landmark, joint centre, and lower limb joint angles are recorded and saved in a text file. Treadmill belt speed is also output into this file, allowing the assessor to identify the walking speed of the individual post-assessment; especially useful following self-paced tasks. The file is saved under the assessment name to enable the user to easily distinguish between trials following patient examination.

Please refer to Appendix 2.1 (Pelvic Calibration for Walking Assessment & Walking Assessment) for step-by-step instructions on how this application should be used clinically.

4.6.5. Calculating Spatio-Temporal Parameters

It was highlighted in the literature review of this thesis (section 2.5.2) that walking speed, cadence, step length and stride length are commonly used to describe gait in TKA patients. In order to provide clinicians with this data, a script was written in Matlab (ver. R2014a: Mathworks Natick, MA) to calculate and present the averages of these variables post-assessment in a simple figure. To obtain this figure, users are simply required to upload a recorded gait output file into the software and run the script.

When run, a custom-written function identifies the first 50 consecutive gait cycles and time-normalised each cycle to 101% points. This function was programmed to calculate the distances between the x-co-ordinates of the heel and posterior iliac spine anatomical landmarks (anterior-posterior direction) for each recorded frame. An inbuilt Matlab function was then used to plot the results and identify the peaks. The peaks correspond to the times at which the heel is furthest away from the pelvis in the sagittal plane; this coincides with a new foot-strike and thus denotes a new gait cycle. The first 50 consecutive gait cycles were then time-normalised to 101% points and the data was concatenated to give a record of 5050 rows (50 gait cycles x 101 points). The columns of the matrix consisted of all recorded variables. Spatio-temporal parameters were then calculated from the 50 consecutive cycles identified. Although this application was programmed to analyse 50 gait cycles, the script can easily be altered by the user if necessary.

Average walking speed (m/s) and cadence (steps/min) were calculated from variables directly in the gait output file; treadmill belt speed and time.

The right and left step lengths were calculated by measuring the distances between both heel anatomical landmarks during each foot strike, then averaging the results over 50 cycles. Stride length was calculated by summating the right and left step lengths of each cycle and averaging over 50 cycles.

4.7. Walking Stability Assessment

In this thesis, the quantification of cycle-to-cycle variability in gait used a separate custom-written application in Matlab (ver. R2014a: Mathworks Natick, MA). This was necessary, as Lua (the programming language used by D-Flow) is unable to manipulate large three-dimensional matrices; tasks which are required when applying the UCM method to the data.

To apply the UCM method to the gait data, a gait output file must be exported from D-Flow and imported into the Matlab application. The application is

compatible with text and csv files, where the biomechanical model used conformed to the cluster model described in this thesis or to the Human Body Model or Human Body Model 2 built into D-Flow as standards by Motekforce Link (Motekforce Link, Amsterdam).

A detailed explanation of the UCM can be found in chapter 3 (3.2.5. Walking Stability and the Uncontrolled Manifold Hypothesis).

4.7.1. Defining the Hypothesis

The UCM concept can be used to investigate a number of different variables. In this case, the aim was to produce an application which could assess gait variability in terms of COM stability and which could potentially detect mid-stance instability in TKA patients.

Hence, the task variable for this study was the COM trajectory, and the elemental variables were hip, knee and ankle joint angles in sagittal and frontal planes. As such, it was the most ambitious UCM model so far constructed.

Bi-planar geometric models of both legs were generated to link joint kinematics to the position of the COM throughout each gait cycle (Figure 4.26). This allowed the UCM to account for sagittal and frontal plane movements of both limbs. Movements in the transverse plane were considered to be less important, as walking involves moving along the frontal and sagittal planes (Black *et al.,* 2007).

Given that the aim was to investigate gait variability in two planes, the main task variable was divided into two separate variables:

1. COM trajectory in the sagittal plane.
2. COM trajectory in the frontal plane.

Two discreet geometric models were created for each task variable. Flexion-extension angles were used to generate the model in the sagittal plane, and abduction-adduction angles were used for the frontal plane model.

Consequently, the elemental variables for this application were defined as follows:

1. Foot to ground angle, plantarflexion angle, knee flexion angle, and hip flexion angle in the sagittal plane (X and Y directions).
2. Foot to ground angle, ankle abduction angle, knee abduction angle, and hip abduction angle in the frontal plane (Y and Z directions).

The geometric models were built by the software once 50 consecutive gait cycles had been identified and time-normalised to 101% points for each cycle. A custom-written function was used to carry out cycle identification and time-normalisation, as was explained in section 4.6.5.

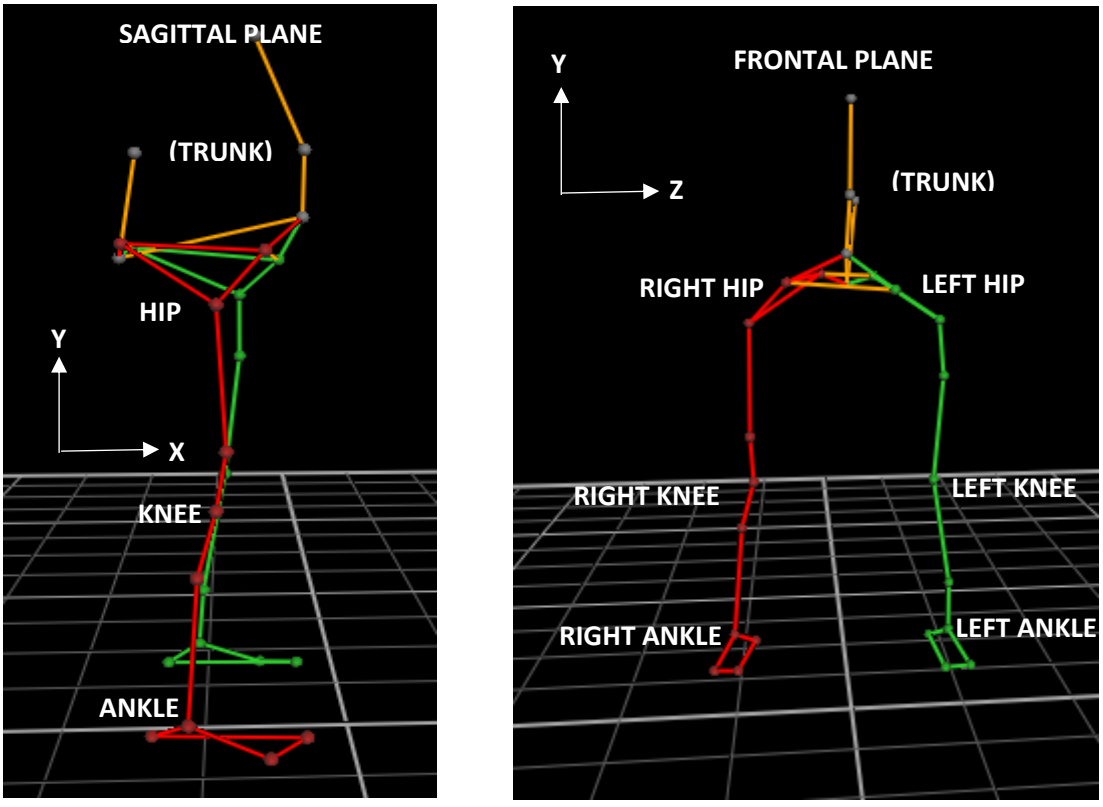
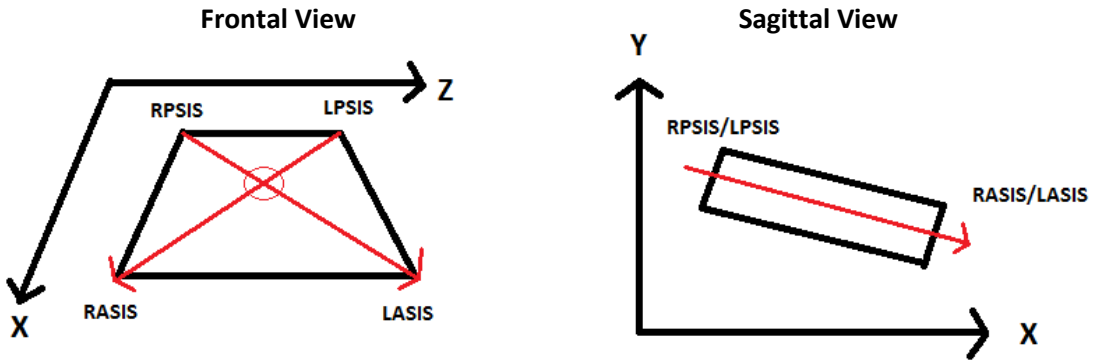


Figure 4. 26: Stick figures in sagittal and frontal planes showing the joints which will be used to create the geometric models.

4.7.2. Defining the Centre of Mass

The first step in creating the geometric models was to define the location of the COM in each plane. The COM was approximated as a fixed point within the centre of the pelvis (Papi, 2012). This was the point of intersection of the RPSIS to LASIS vector and the LPSIS to RASIS vector i.e. the mid-point of the defined pelvis anatomical landmarks (Figure 4.27).



RPSIS: Right posterior superior iliac spine; LPSIS: Left posterior superior iliac spine; RASIS: Right anterior superior iliac spine; LASIS: Left anterior superior iliac spine

Figure 4. 27: Depiction of the way in which the centre of mass (cross) was approximated for the model using the vectors between pelvis markers.

4.7.3. Developing Geometric Models in Sagittal and Frontal Planes

To link the elemental and task variables, geometric models were created in frontal and sagittal planes.

All joint centres, inter-segmental angles and foot-to-ground angles were required to create the models (Equation 4.26 & Equation 4. 27) (Papi, 2012).

$$(x_{COM}, y_{COM}) = f\ (\theta_{GS}, \theta_{AF}, \theta_{KF}, \theta_{HF})$$

Equation 4. 26

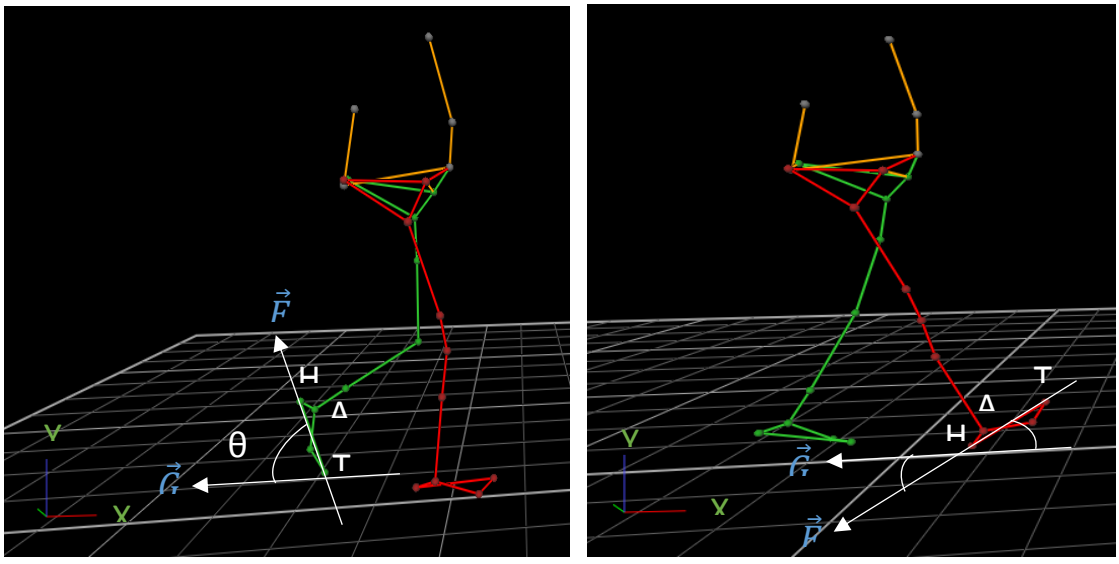
$$(y_{COM}, z_{COM}) = f\ (\theta_{GF}, \theta_{AA}, \theta_{KA}, \theta_{HA})$$

Equation 4. 27

Where,

θ_{AF} is the ankle plantarflexion angle, θ_{KF} is the knee flexion angle, θ_{HF} is the hip flexion angle, θ_{AA} is the ankle abduction angle, θ_{KA} is the knee abduction angle and θ_{HA} is the hip abduction angle. These angles are readily available to the application from the imported gait file. However, θ_{GS} and θ_{GF} (the sagittal and frontal plane angles between the ground and the sole of the foot) must be calculated separately, within the application.

To define θ_{GS} and θ_{GF}, the points of intersection between the foot vector $(\vec{F})$ and the ground vector $(\vec{G})$ throughout a given trial are calculated (Figure 4.28).



H – Heel, A – Ankle (lateral malleolus), T –Toe (1st metatarsal), $\vec{F}$ – Foot vector, $\vec{G}$ – Ground vector, θ_G – Foot-to-ground angle

Figure 4. 28: Diagram showing the way the angle between the sole of the foot and the ground was calculated using the foot and ground vectors.

The foot vector, $\vec{F}$, is calculated from the x-, y- and z-co-ordinates of the heel and 1st and 5th metatarsal anatomical landmarks, as was previously described for creating axes systems in Equation 4.2. The point of intersection (x) between the ground and the foot is calculated using Equation 4.28.

$$x = \frac{(P_2 - P_1) \times V_2}{V_1 \times V_2}$$

Equation 4.28

Where:

P_1 is the initial point of foot vector $\vec{F}$, P_2 is the initial point of the ground vector $\vec{G}$, V_1 is the foot vector and V_2 is the ground vector.

Following this, the foot and ground vectors are re-defined with the initial point of both vectors now being extended to the point of intersection.

Finally, Equation 4.29 is used to calculate the angle between $\vec{F}$ and $\vec{G}$ throughout each gait cycle for both feet.

$$\theta_G = arctan2\left(\frac{\vec{A} \times \vec{B}}{\vec{A} \cdot \vec{B}}\right)$$

Equation 4. 29

4.7.4. Linking the Task Variables and Elemental Variables

The elemental variables (joint positions) are then linked to the task variables (COM position in two planes) through Jacobian matrices: $J(\theta_F)$ and $J(\theta_S)$ (Papi *et al.,* 2012). By doing this, the UCM becomes linearized (Latash *et al.,* 2007).

According to Scholz and Schöner (1999), this linearization is created about a reference point. In the case where COM stability is the task variable, the preferred reference point is the mean joint configuration of all trials. This is due

to the fact that it is assumed that this set of joint angles stabilises the COM (Papi, 2012).

The deviations between joint configurations at each percentage of every gait cycle from the mean joint configurations per plane are calculated using Equation 4. 30 and Equation 4. 31.

$$\text{DMS} = \begin{bmatrix} \theta_{GS} - \overline{\theta}_{GS} \\ \theta_{AF} - \overline{\theta}_{AF} \\ \theta_{KF} - \overline{\theta}_{KF} \\ \theta_{HF} - \overline{\theta}_{HF} \end{bmatrix}$$

Equation 4. 30

$$\text{DMF} = \begin{bmatrix} \theta_{GF} - \overline{\theta}_{GF} \\ \theta_{AA} - \overline{\theta}_{AA} \\ \theta_{KA} - \overline{\theta}_{KA} \\ \theta_{HA} - \overline{\theta}_{HA} \end{bmatrix}$$

Equation 4. 31

Where,

DMS is the deviation matrix for the joint configurations in the sagittal plane, and DMF is the deviation matrix for the joint configurations in the frontal plane.

Using the reference frames, all first-order partial derivatives of the COM positions are linked to the joint positions through $J(\theta_S)$ or $J(\theta_F)$, depending on whether the change in trajectory is in the sagittal or frontal plane, respectively (Equation 4.32 & Equation 4. 33).

$$J(\theta_S) = \begin{bmatrix} \frac{\delta x_{COM}}{\delta \theta_{GS}} & \frac{\delta x_{COM}}{\delta \theta_{AF}} & \frac{\delta x_{COM}}{\delta \theta_{KF}} & \frac{\delta x_{COM}}{\delta \theta_{HF}} \\ \frac{\delta y_{COM}}{\delta \theta_{GS}} & \frac{\delta y_{COM}}{\delta \theta_{AF}} & \frac{\delta y_{COM}}{\delta \theta_{KF}} & \frac{\delta y_{COM}}{\delta \theta_{HF}} \end{bmatrix}$$

Equation 4. 32

$$J(\theta_F) = \begin{bmatrix} \frac{\delta y_{COM}}{\delta \theta_{GF}} & \frac{\delta y_{COM}}{\delta \theta_{AA}} & \frac{\delta y_{COM}}{\delta \theta_{KA}} & \frac{\delta y_{COM}}{\delta \theta_{HA}} \\ \frac{\delta z_{COM}}{\delta \theta_{GF}} & \frac{\delta z_{COM}}{\delta \theta_{AA}} & \frac{\delta z_{COM}}{\delta \theta_{KA}} & \frac{\delta z_{COM}}{\delta \theta_{HA}} \end{bmatrix}$$

Equation 4. 33

The Jacobian matrices are computed for each percentage of the gait cycle throughout a trial. The null space of each matrix is then calculated.

Each null space is defined as the linear subspace of all joint configurations which do not affect the positions of the COM in sagittal or frontal planes. The dimensions were calculated as the number of dimensions of a task variable *(d)* subtracted by the number of elemental variables *(n)* per plane. Hence, both Jacobian matrices have 2 dimensions.

As both Jacobian matrices have the same dimensions Equation 4.34 and Equation 4. 35 are used to define the null space (N) for the matrices relating to both the frontal and sagittal plane configurations.

$$0 = J(\theta) \cdot \varepsilon_{n-d}$$

Equation 4.34

$$N(J) = \begin{bmatrix} \varepsilon_{11} - \varepsilon_{12} \\ \varepsilon_{21} - \varepsilon_{22} \\ \varepsilon_{31} - \varepsilon_{32} \\ \varepsilon_{41} - \varepsilon_{42} \end{bmatrix}$$

Equation 4. 35

4.7.5. Projecting Components of the Deviation Matrix onto the Null Space

Following definition of the null spaces, the deviation matrices are multiplied by the respective null spaces (Equation 4. 36). This projects the deviation matrix into the null space, creating a vector component which is defined as being within the null space (parallel component).

$$\theta_{\parallel} = \sum_{i=1}^{n-d} (N(J)_i^T \cdot DM) N(J)_i$$

Equation 4. 36

Where,

DM is the deviation matrix for the sagittal (DMS) or frontal (DMF) plane.

The vector component perpendicular to the null space is calculated by subtracting the parallel component from the appropriate deviation matrix (Equation 4. 37). These vectors are called the vector projections parallel (good) and perpendicular (bad) to the null space.

$$\theta_{\perp} = DM - \theta_{\parallel}$$

Equation 4. 37

4.7.6. Calculating Variance of Vector Projections

Having calculated the vector projections $\theta_{\parallel}$ and $\theta_{\perp}$, the variability of the COM (task variable) with respect to the lower limb joint positions (elemental variables) per DOF within the UCM is calculated using Equation 4. 38.

$$\sigma_{\parallel}^2 = (n-d)^{-1} \cdot (N)^{-1} \cdot \sum \theta_{\parallel}^2$$

Equation 4. 38

Where,

$\sigma_{\parallel}^2$ is the squared length of the vector within (parallel to) the UCM, n is the number of elemental variables (n=4 here), d is the number of dimensions involved (d=2 per plane), and N is the number of gait cycles (in our case 50) under analysis (traditionally the number of gait *trials* under analysis; each with

one cycle extracted from typically fewer than 10 trials – Papi, 2012; Papi *et al.,* 2014; Scholz & Schöner, 1999).

Lastly, cycle-to-cycle variation per DOF perpendicular to the UCM ($\sigma_{\perp}^2$) is determined using Equation 4.39.

$$\sigma_{\perp}^2 = d^{-1} \cdot (N)^{-1} \cdot \sum \theta_{\perp}^2$$

Equation 4. 39

In order to determine whether the variability of the elemental variables (COM trajectory per percentage of the gait cycle) indicates stability or instability, the ratio between the variation perpendicular to and parallel to/within the UCM is calculated (Equation 4. 40). For simplicity, and to produce symmetric ratio data for subsequent analysis, the values were set to lie between the values of -1.0 and +1.0. Positive values denote good stability, and negative values denote instability.

$$RATIO = \left(\frac{2\theta_{\parallel}^2}{\theta_{\parallel}^2+\theta_{\perp}^2}\right) - 1$$

Equation 4. 40

4.7.7. Graphical Presentation of Results

In the published literature, UCM data are typically reported in terms of the calculated variances parallel (good) and perpendicular (bad) to the null space (UCM). These will often be discussed with reference to the mean kinematic or trajectory results (Papi *et al.,* 2015). To comply with the current standard observed in the literature, a Matlab script was written into the application to generate and output graphs of the calculated variances within and perpendicular to the UCM at each percentage of the gait cycle. Graphs of the

mean joint kinematics recorded over 50 gait cycles are also generated with this Matlab script.

Given the complexity of the UCM hypothesis, a simpler method of reporting the data and visualising the results is also necessary, especially when considering its feasibility as a clinical assessment. Hence, the Matlab script also generates and outputs a graph of the ratio between the variation perpendicular to and within the UCM. This variable is not consistently published in the literature, but it is easier to interpret, as ratios >0 clearly denote areas of the gait cycle that were stable, and ratios <0 denote areas of the gait cycle that were unstable.

Implementing this script within the application means that users are not required to manually generate graphs from the output data which is generally a time consuming task. This may be beneficial to clinicians using the application.

4.8. Summary

This chapter has described the methods used in this study to develop a clinical motion capture system for use in the orthopaedic environment. The system reported addresses certain weaknesses associated with traditional motion capture protocols, which currently prevent clinicians from using the technology routinely to quantify the functional outcome of their patients. The cluster-based biomechanical model developed in this study can be used to report knee ROM and strength as well as gait kinematics and gait stability; all of which contribute to knee function and mobility.

In order to investigate the success of this system as a clinical tool, it must be used in a suitable clinical environment with the target population (TKA patients). However, prior to its clinical use, the bespoke software should be validated against current clinical standard outcome measures, in order to ensure that the data reported is accurate and reliable. The following chapter presents a series of validation studies that were carried out on the system following its development.

Chapter 5. Product Validation

A thorough validation of our bespoke system was necessary for it to be accepted into the clinical and research communities. Thus, three validation studies were carried out to investigate the accuracy and reliability of the results obtained with the orthopaedic outcome measure package.

The methods used in these studies were designed to address the following research questions:

1. Do the co-ordinates recorded by the pointer during calibration differ significantly if the orientation of the pointer is altered?
2. How do the results of the ROM assessments recorded with the clinical standard tool compare to those recorded with the bespoke application?
3. How do the results of the knee strength assessments recorded with a traditional clinical tool compare to those recorded with the bespoke application?
4. Is the bespoke ROM application reliable?
5. Is the bespoke knee strength application reliable?
6. Is kinematic synergy observed in healthy walking adults?
7. Is the motor control assessment sensitive enough to discern differences between healthy adults who have a stable COM and those who have an unstable COM?
8. Can we justify testing the clinical use of this bespoke orthopaedic outcome measure package in the Medacta GMK Sphere clinical trial?

5.1. Study One: Calibration

It is common knowledge in the field of human biomechanics that placement errors translate to errors in kinematic and kinetic data as they affect the anatomical axes calculated from marker positions (Alexander & Andriacchi, 2001; Benoit *et al*., 2006; Della Croce *et al*., 2005).

Although our model uses a pointer-calibration technique to record the positions of bony anatomical landmarks, it is currently unknown whether the way in which the pointer is held against a landmark (i.e. its orientation) during calibration affects the co-ordinates recorded. Thus, this investigation aimed to determine whether changing the orientation of the pointer significantly influences the 3D-position of two virtual landmarks used to create an axis. This investigation could therefore be used to identify pointer orientations which should be avoided during anatomical landmark calibration.

5.1.1. Data Collection Methods

To replicate the positions of two anatomical landmarks (such as the lateral and medial epicondyles of the knee), two red dots were drawn onto two sides of a box (Figure 5. 1). The dots were placed half-way across the width of the box, and a couple of centimetres below the top of the box.

The box was placed onto a stool in the field of view of the cameras. Elasticated straps were used to attach the box to the stool to prevent movement during the investigation.

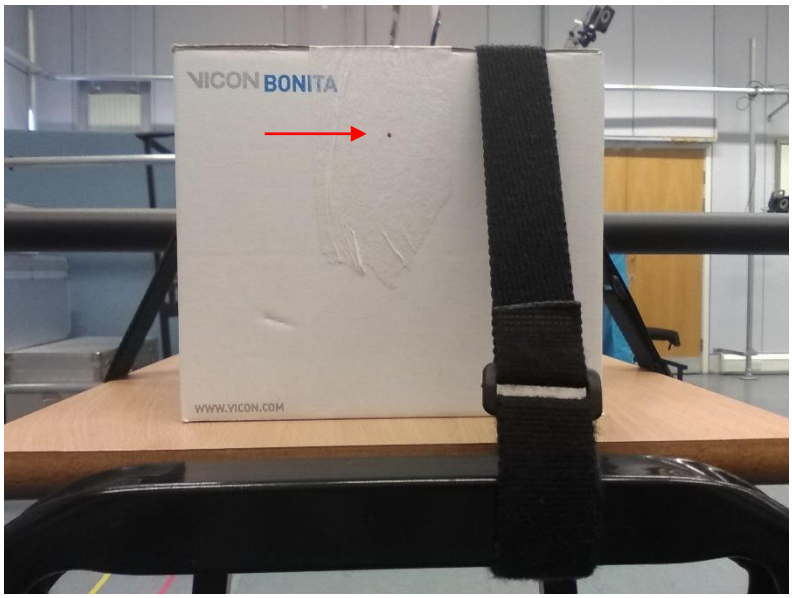


Figure 5. 1: The set-up used to investigate the effect of pointer orientation on x-,y-, and z-co-ordinates recorded. The red arrow shows the dot used as a landmark for the left-hand side of the box.

Ten different types of orientations were investigated. Each of these were analysed with the pointer parallel to the ground as well as perpendicular to the ground. Thus, twenty combinations were recorded for each landmark (Figure 5. 2). Examples of the way in which the pointer was orientated can be seen in Figure 5. 3.

The x-, y- and z-co-ordinates of a landmark were recorded 8 times per orientation, completely removing the pointer from the box between recordings. Three-dimensional graphs of the mean vectors produced between the two points per orientation type were generated with Matlab (ver. R2014a: Mathworks Natick, MA). The x-axis was anteroposterior, the y-axis was vertical and the z-axis was mediolateral.

To confirm that the box did not move as the pointer was used against it, a marker was glued onto the box and the co-ordinates of the marker were recorded as the pointer was used twenty times (once for each orientation).

The cameras were calibrated as recommended by the manufacturers. The image error of each camera was <0.3mm (average camera error = 0.257mm).

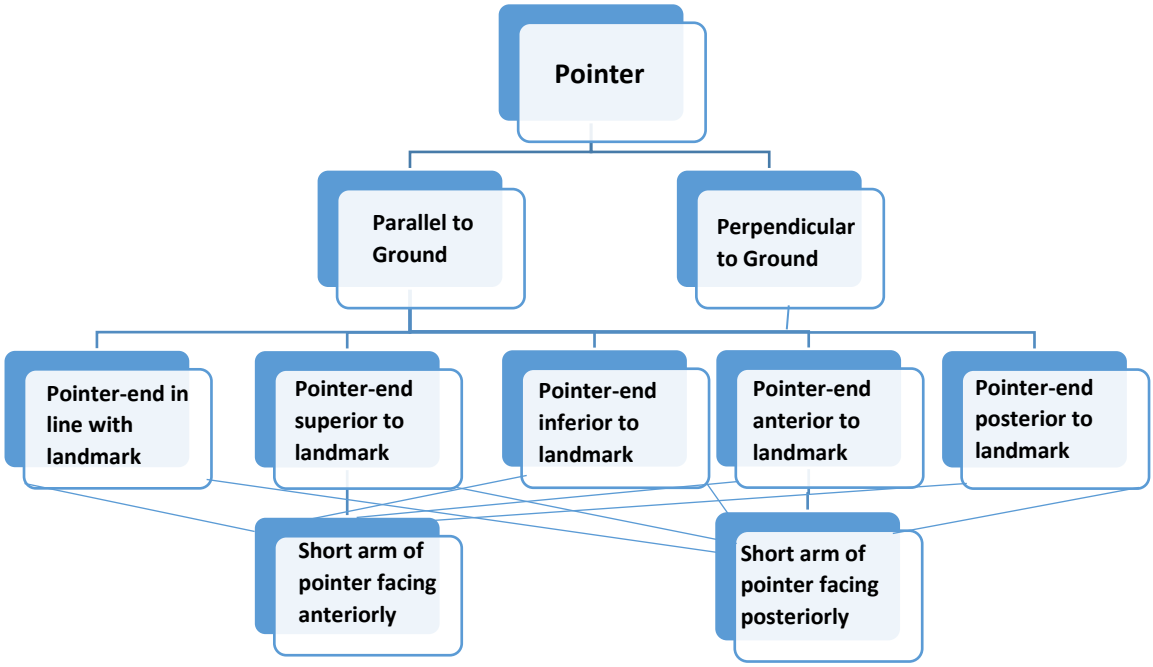


Figure 5. 2: Twenty combinations of pointer orientations used to investigate the effect of orientation on the landmark co-ordinates recorded.

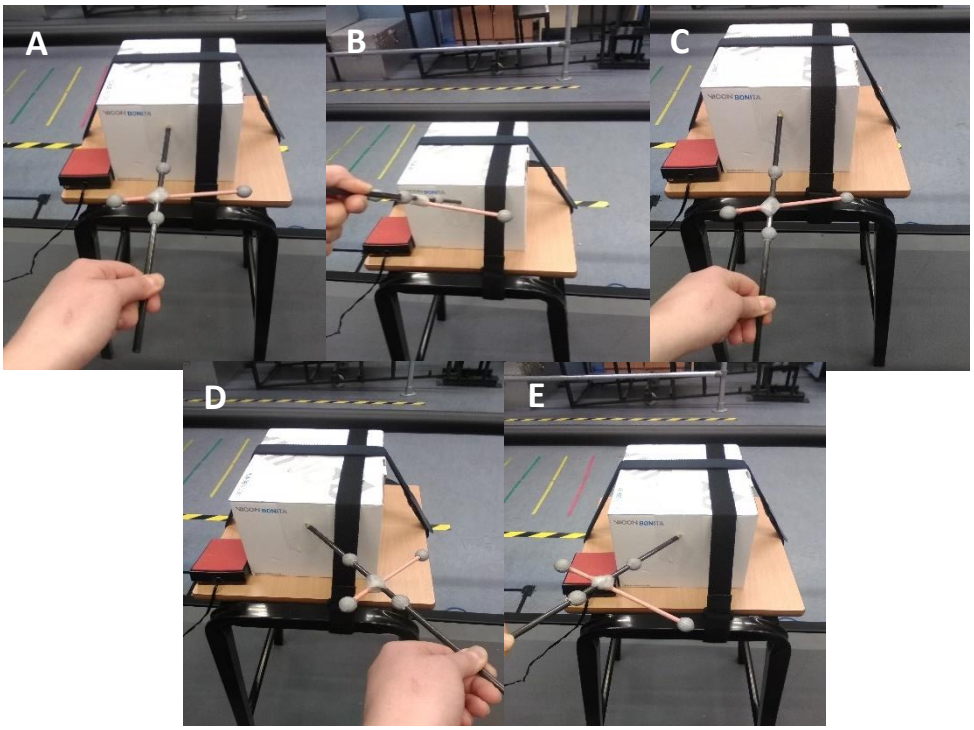


Figure 5. 3: Examples of 5 pointer orientations investigated in this study. In all cases the pointer is parallel to the ground with the short arm of the pointer facing anteriorly. The pointer-end is A: in line with the landmark, B: superior to the landmark, C: Inferior to the landmark, D: Posterior to the landmark, E: Anterior to the landmark.

5.1.2. Analysis of Data

Statistical analyses were carried out in Minitab software (ver. 16: Minitab Inc., State College, PA, USA). Descriptive statistics, t-tests and intra-class correlation coefficients (ICCs) were used to analyse our data. ICCs were determined according to Shrout & Fleiss' schema (1979). The level of significance was set at $\alpha = 0.05$.

The Euclidean distances (Equation 4.1) between mean recorded points were calculated for both landmarks using a bespoke function in Matlab (ver. R2014a: Mathworks Natick, MA).

5.1.3. Results

Average Euclidean distance between reconstructed points were 3.2±1.4mm (range: 0.3-7.1mm) for the left-hand side of the box and 3.3±1.5mm (range: 0.3-7.9mm) for the right.

Greatest mean differences were between the points reconstructed when the pointer was positioned a) posteriorly with the short arm pointing posteriorly, and b) anteriorly with the short arm pointing anteriorly (7.1mm & 7.9mm for left and right landmarks). The x- and y-co-ordinates recorded when the pointer was anterior to the landmark were significantly different to those recorded when it was posterior to the landmark ($p < 0.0001$ & $p = 0.002$, respectively). Co-ordinates recorded along the medio-lateral axis did not differ to a statistically significant extent between these orientations ($p = 0.147$). The average Euclidean distance between points recorded with the pointer anterior to the landmark and posterior to it was 3.4mm.

The x- and y-co-ordinates created when the pointer was superior to and inferior to the landmark differed statistically to one another ($p = 0.032$ & $p < 0.0001$, respectively). Again, the z-co-ordinates were found to be similar ($p = 0.083$). The average Euclidean distance between points recorded with the pointer superior to the landmark and inferior to it was 2.3mm.

The smallest differences in Euclidean distances between points were observed when the pointer was rotated about the medio-lateral axis (0.3mm for both landmarks). No statistical differences were found: $p = 0.055$ for x-co-ordinates, $p = 0.070$ for y-co-ordinates and $p = 0.944$ for the z-co-ordinates.

ICC values of all co-ordinates recorded at both landmarks were excellent (all 0.99).

A 3D graph of the mean landmark positions recorded during each orientation was plotted to visualise the effect these mean values would have on the creation of an axis (Figure 5.4). The magnitude and directions of these vectors changed as the orientation of the pointer changed (Figure 5.4). Mean magnitude was greatest when the pointer was superior to the landmarks with the short arm pointing inferiorly (228.8mm). The smallest mean magnitude was observed when the opposite orientation was assumed was 214.6mm (giving a difference of 14.2mm), highlighting the effect of changing the orientation of the pointer during calibration. On average, moving the pointer from a superior to inferior orientation affected the magnitude of the vector by 1.7mm. When anterior and posterior orientations were adopted, the mean difference in magnitude was 0.4mm.

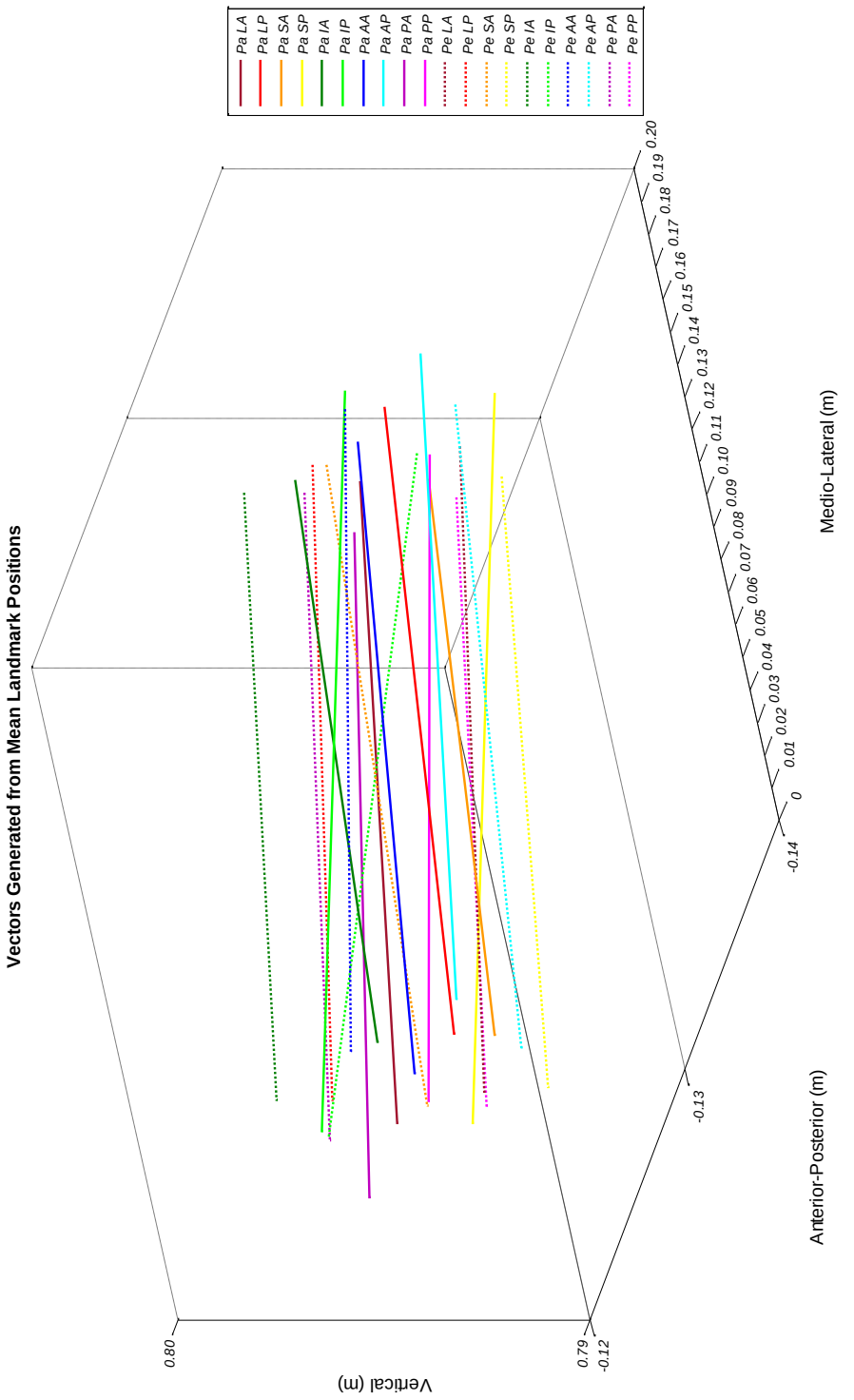


Figure 5. 4: The mean landmark positions recorded per orientation were plotted as vectors to show the way in which pointer orientation would affect the creation of an axis. *Pa = Parallel, Pe = Perpendicular, L = in-line with landmark, S = superior to landmark, I = inferior to landmark, A = Anterior to landmark, P = posterior to landmark, Ant = short arm of pointer orientated anteriorly, Pos = short arm of pointer orientated posteriorly.*

To determine the repeatability of a single point in a given orientation, each x-, y- and z-co-ordinate recorded per orientation were statistically compared. ICC values were 1.0000 for all twenty orientations.

5.1.4. Discussion

Locating an anatomical landmark incorrectly during the calibration stage of a gait assessment can directly affect the kinematics calculated (Baker, 2006; Osis *et al*., 2016; Schwartz *et al*., 2004).

Our results showed that the mean co-ordinates recorded per orientation could change slightly by a few millimetres, which could lead to the production of different axes i.e. that the vector produced changed when the orientation of the pointer was not maintained. This in turn could directly affect kinematics calculated.

Osis *et al*. (2016) found that changing the position of a retro-reflective marker by 10mm resulted in a 7.59° change in knee and ankle internal-external rotation angles and a 5.17° change in knee abduction-adduction rotation angles when running.

The greatest Euclidean distances between reconstructed landmarks in our investigation were 7.1mm and 7.9mm, which were considerably smaller than those reported by Della Croce *et al*. (1999). According to their study, differences of up to 25.0mm were recorded at some anatomical landmarks (smallest difference of 4.8mm), where differences were calculated as the root mean squared distance from the mean position. This difference in magnitude of the error is likely because the landmark was pre-defined in this study, and no palpation was therefore required.

Although our differences were smaller than Della Croce *et al.* (1999), an error of approximately 8mm (our maximum) could increase the kinematic error by around 5° (Osis *et al*., 2016). McGinley *et al*. (2009) stated that clinically acceptable errors were those <5°. This is a maximum cumulative error. Hence

minimising the likelihood of pointer related errors arising due to pointer orientation is paramount for an accurate calibration.

When the pointer was rotated about the anterior-posterior and vertical axes, the results recorded were statistically different for x- and y-co-ordinates. Difference between recorded z- co-ordinates may not have reached statistical significance due to the rigid property of the box. Thus, changing the position of the pointer along these axes should be avoided during calibration, as the error may be even greater when used on skin.

We are confident that the differences highlighted in our results were not due to movement of the box as the pointer was used against it, as y- and z-co-ordinates of a marker glued onto the box remained the same to 3 decimal places as the pointer was used. On occasion, the x-co-ordinate of the landmark became reduced by 0.001mm; otherwise the position was consistent.

The pointer should therefore be held in a neutral position with relation to the landmark when calibrating (i.e. not above, below, posterior or anterior to the landmark). Rotating the pointer about the medio-lateral axis did not have a significant effect on the co-ordinates recorded. Consequently, the pointer could be held in any orientation in this plane when calibrating.

The co-ordinates recorded were highly repeatable and reliable when a particular orientation was used (ICCs = 1.000). This highlights the importance of a consistent calibration technique, suggesting that using a combination of orientations, even about the medio-lateral axis, could be detrimental to the calibration process.

A limitation to this study is that there was no baseline co-ordinate against which the recorded co-ordinates could be compared, but this replicates the clinical situation where the true value is unknown. Furthermore, only one pointer was used in this study.

5.1.5. Conclusion

Despite the increase in use of instrumented-pointers in biomechanical research and orthopaedics to calibrate the 3D position of bony anatomical landmarks, no study to date had investigated the effect of pointer-orientation on the co-ordinates recorded.

Our results showed that the co-ordinates recorded by the pointer differed to a level which could influence kinematic reconstruction. The greatest Euclidean distance between reconstructed landmarks in our investigation was 7.9mm which could have led to a kinematic error of approximately 5°. Errors above 5° are clinically unacceptable. We therefore recommend that the pointer should be consistently held in a neutral position to the landmark (i.e. not inferior, superior, anterior or posterior to the landmark) during anatomical calibration to reduce the chances of introducing error through improper pointer orientation.

Overall, we are confident that the pointer-calibration method can be reliably used to record the position of an anatomical landmark in three dimensions. However, accurate location of the anatomical landmark by palpation is still necessary, regardless of whether a pointer or static marker is used to record its location on the body.

5.2. Study Two, Part I: Knee Range of Motion Assessment

To justify the use of our bespoke system in the clinical environment, we validated the knee ROM and muscular strength assessments against current clinical standard tools. Both assessments were validated together as part of the same investigation, but are described separately for the purpose of this thesis. This section describes the validation of the ROM assessment.

5.2.1. Ethical Approval

Departmental ethical approval for this study was granted by the University of Strathclyde ethics committee on 9th February, 2016. All participants were recruited from the Department of Biomedical Engineering. Participant Information Sheets were distributed to all who were recruited and consent forms were signed on arrival to the laboratory. Examples of the Participant Information Sheet and Consent Form are given in Appendices 1.1 & 1.2.

5.2.2. Data Collection Methods

Participant Data

To take part in this study, participants were required to be able-bodied, have normal lower limb function, and be between the ages of 18 and 35. Those who did not fit these criteria were excluded from the study.

Eleven people (9 females and 2 males) who fitted the inclusion criteria participated in this study. The participants had a mean age of 25.7±3.6 years, a mean mass of 66.0±15.6kg, and a mean height of 1.64±0.10m.

Laboratory Preparation

The motion analysis system described in Chapter 4 was used for the purposes of this study. The system was installed in the Biomedical Engineering Department

at the University of Strathclyde (Biomechanics Laboratory 3, Wolfson Centre). All participants were tested at this site.

The motion analysis system was calibrated before each use using Vicon Tracker software as per the manufacturers' recommendations (version 3.1.3, Vicon Motion Systems, Oxford). The error of each camera was checked prior to use; the system was re-calibrated if any camera error was >0.3mm.

All hardware and software required to use the bespoke orthopaedic outcome measure package were described in Chapter 4.

Participant Preparation

The assessments were clearly explained to each participant before the consent form was signed. Each participant was then allocated a random 8-digit number to pseudo-anonymise the data.

The mass and height of each participant was measured by the researcher using calibrated Kistler force plates (version 9821B, Winterthur, Switzerland) and a stadiometer, respectively. The same force plate was used with each participant. Patient demographics and study results were written in the CRF. An example of the study CRF is given in Appendix 3.1.

Participant Calibration

Thigh, shank and foot clusters were placed on the participant using elasticated Velcro straps (Figure 5. 5). The straps were affixed firmly enough to prevent slipping during movement. Before calibration, each participant was asked to walk to the opposite end of the laboratory to check the comfort of the straps. Straps were then adjusted if required.

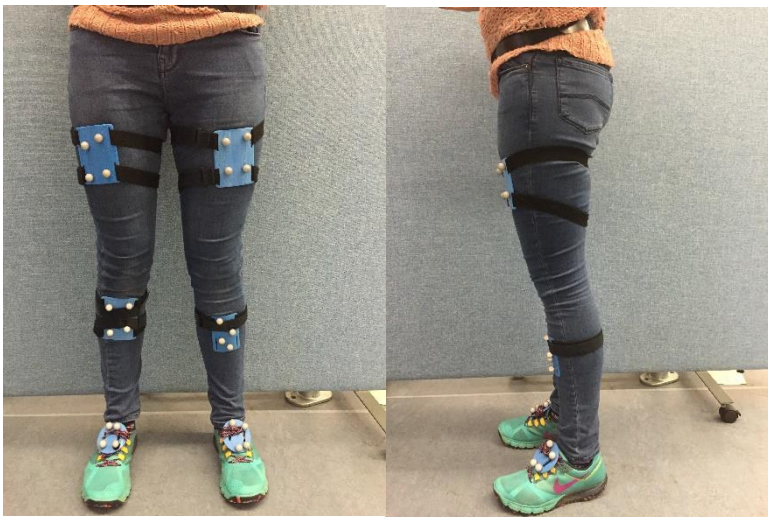


Figure 5. 5: Photographs of a participant wearing the clusters before assessment.

The anatomical landmarks were then calibrated by the researcher as the patient stood on the treadmill (Figure 5.6). Detailed instructions on patient calibration can be found in Appendix 2.1: Directions for Use.

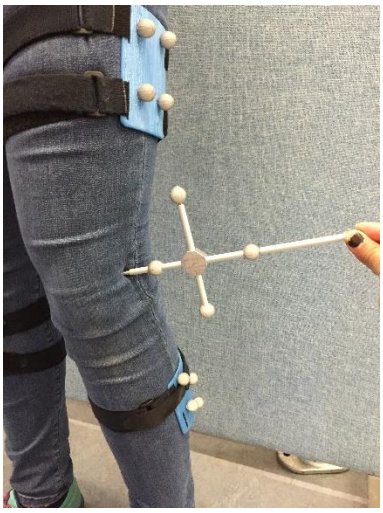


Figure 5. 6: An example of the anatomical pointer being used during calibration.

Passive and Active Knee Range of Motion: Bespoke Application

Following calibration, participants lay in supine position on a plinth on the treadmill. For active ROM assessments, participants were asked to flex the knee as much as possible by sliding their heel towards the bum (Figure 5. 7). Following this, the researcher placed a supporting object below the ankle and asked the participant to extend the knee as much as possible, by pushing the knee into the plinth. The participant was asked to verbally notify the researcher when maximum knee flexion and extension had been achieved. The assessments were then repeated under passive conditions, whereby the researcher assisted the movements of the knee.

Both passive and active assessments were repeated 6 times per leg. All results were recorded into a text file. Maximum flexion, extension and excursion angles were written into the CRF once the participant had left the laboratory.

Step-by-step instructions on how the researcher used the application for this assessment are given in Appendix 2.1.

Figure 5. 7: A participant using the ROM application to assess active knee flexion.

Visual Feedback

No visual feedback was used during this assessment. Thus, the researcher was blind to the results until the participant had left the laboratory. This was done to ensure that the researcher was unaware of the results recorded with the bespoke software package when assessing ROM with the goniometer.

Passive and Active Knee Range of Motion: Clinical Standard

The clinical standard method for measuring knee ROM was then carried out using a 12-inch goniometer.

Passive and active assessments were carried out as described in the previous section. To record the angle of the knee, the researcher palpated the lateral epicondyle of the knee and aligned the centre of the goniometer with this landmark. The two arms were then aligned with the lateral malleolus and greater trochanter; both of which were also located by palpation. The resulting angle was immediately recorded into the CRF.

5.2.3. Statistical Analyses

Statistical analyses were carried out in Minitab software (ver. 16: Minitab Inc., State College, PA, USA). Descriptive statistics and normality tests were used on all sets of data. Non-parametric tests were carried out on non-normally distributed data. Bland-Altman plots were generated to investigate the correlation between both outcome measures. ICCs were also calculated per variable to determine intra-rater reliability of each ROM assessment tool. ICCs were calculated according to Shrout & Fleiss' schema (1979). The level of significance was set at $\alpha = 0.05$.

The main outcomes of interest for this analysis were maximum knee excursions (ROM) during active and passive examinations. Results from both legs were analysed.

5.2.4. Results

Maximum knee ROM recorded by both outcome measures were comparable between the system and the manual goniometer (Figure 5.8), but the spread of the data was greater with the bespoke application.

Passive knee ROM was greater than active knee ROM in both the goniometer and bespoke application. The differences between both passive and active excursion were greater when the application was used (Figure 5.8).

Several results recorded by both outcome measures were deemed as outliers, especially during passive examination (Figure 5.8). All outliers were below the average maximal knee excursion.

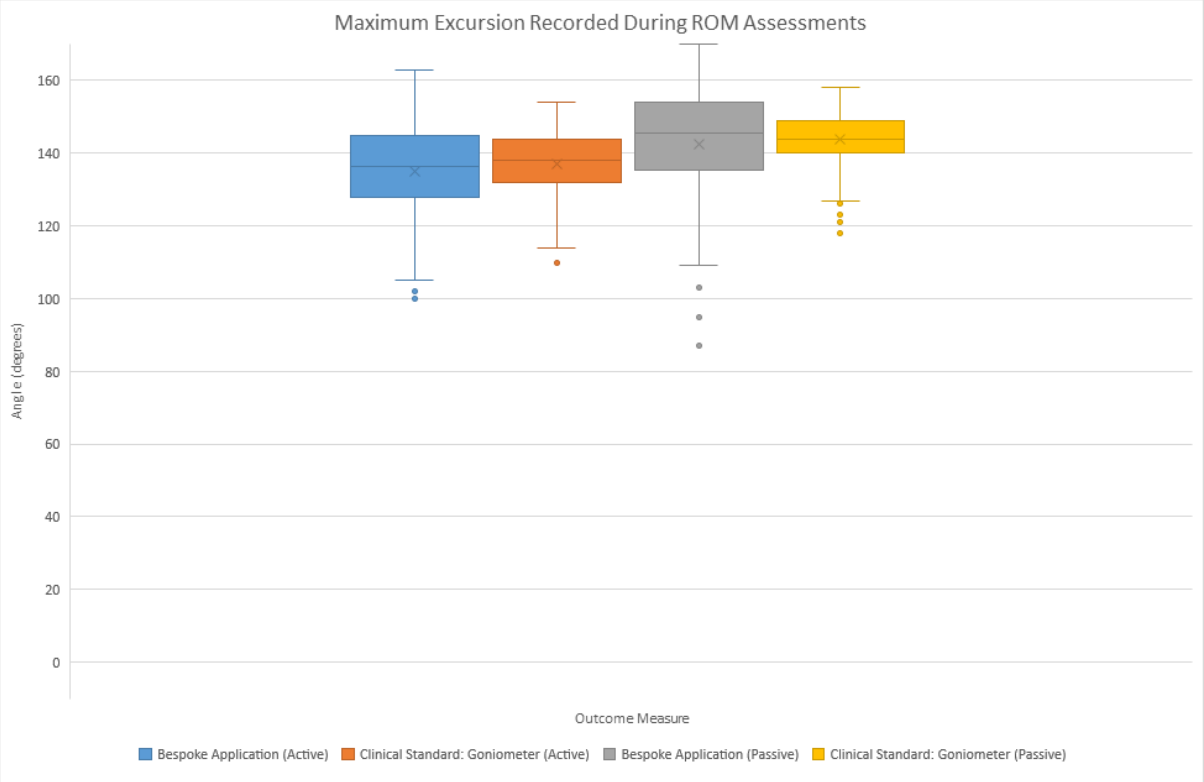


Figure 5.8: Box plots of maximum knee excursions recorded during active and passive ROM assessments with both outcome measures (n = 11).

Descriptive statistics of the results showed that average active and passive knee ROM were lower when recorded with the application in all tasks other than passive motion of the right knee (Table 5.1 – Table 5.4). There were no statistical differences between any of the results, however.

When maximum knee flexion angles were compared statistically, the results showed that the tools returned comparable results in all tasks, except for in the left knee during active flexion ($p = 0.036$; Table 5.1 – Table 5.4). Similarly, both tools were statistically similar in terms of reporting maximum knee extension angles, but in this case, statistical differences were found in the right knee during active assessments ($p = 0.026$; Table 5.1 – Table 5.4).

The descriptive statistics of the results recorded during active knee ROM consolidated what was previously suggested in Figure 5.8; that the data recorded by the application had a greater spread than those recorded with the goniometer. Furthermore, the standard errors of the mean (SEM) were consistently lower when using the goniometer during active knee ROM. Nevertheless, the largest difference was no greater than 0.9°.

Table 5. 1: Descriptive statistics of active ROM recorded in the left leg using both the bespoke application and clinical standard outcome measure. Paired t-tests were used for statistical analyses (n = 11, each including 6 trials).

Task Variable	Active ROM Left Leg								p-Value
	Bespoke Application				Clinical Standard				
	Mean°	SD°	SEM°	Median°	Mean°	SD°	SEM°	Median°	
Maximum Flexion	135.4	13.0	1.6	139.0	139.4	8.8	1.1	141.0	0.036
Maximum Extension	0.1	4.1	0.5	0.0	1.1	1.9	0.2	1.0	0.070
Maximum Excursion	135.3	12.9	1.6	137.5	138.3	9.7	1.2	141.0	0.161

Table 5. 2: Descriptive statistics of active ROM recorded in the right leg using both the bespoke application and clinical standard outcome measure. Paired t-tests were used for statistical analyses (n = 11, each including 6 trials).

Task Variable	Active ROM Right Leg								p-Value
	Bespoke Application				Clinical Standard				
	Mean°	SD°	SEM°	Median°	Mean°	SD°	SEM°	Median°	
Maximum Flexion	137.0	13.9	1.7	140.0	136.3	6.7	0.8	137.0	0.585
Maximum Extension	2.5	5.1	0.6	1.0	0.9	2.4	0.3	1.0	0.026
Maximum Excursion	134.5	14.3	1.8	133.0	135.4	7.6	0.9	136.0	0.722

Table 5. 3: Descriptive statistics of passive ROM recorded in the left leg using both the bespoke application and clinical standard outcome measure. Paired t-tests were used for statistical analyses (n = 11, each including 6 trials).

Task Variable	Passive ROM Left Leg								p-Value
	Bespoke Application				Clinical Standard				
	Mean°	SD°	SEM°	Median°	Mean°	SD°	SEM°	Median°	
Maximum Flexion	140.9	14.3	1.8	145.0	144.3	6.7	0.8	145.5	0.073
Maximum Extension	-0.9	3.2	0.4	-1.0	-1.0	2.3	0.4	-2.0	0.636
Maximum Excursion	141.8	16.2	2.0	146.5	145.3	8.3	1.1	146.0	0.141

Table 5. 4: Descriptive statistics of passive ROM recorded in the right leg using both the bespoke application and clinical standard outcome measure. Paired t-tests were used for statistical analyses (n = 11, each including 6 trials).

Task Variable	Passive ROM Right Leg								p-Value
	Bespoke Application				Clinical Standard				
	Mean°	SD°	SEM°	Median°	Mean°	SD°	SEM°	Median°	
Maximum Flexion	142.7	11.9	1.5	145.0	141.8	6.7	0.8	141.5	0.282
Maximum Extension	-0.3	4.4	0.5	-1.0	-0.4	2.5	0.3	0.0	0.877
Maximum Excursion	143.0	14.1	1.7	143.5	142.2	7.7	0.9	143.0	0.523

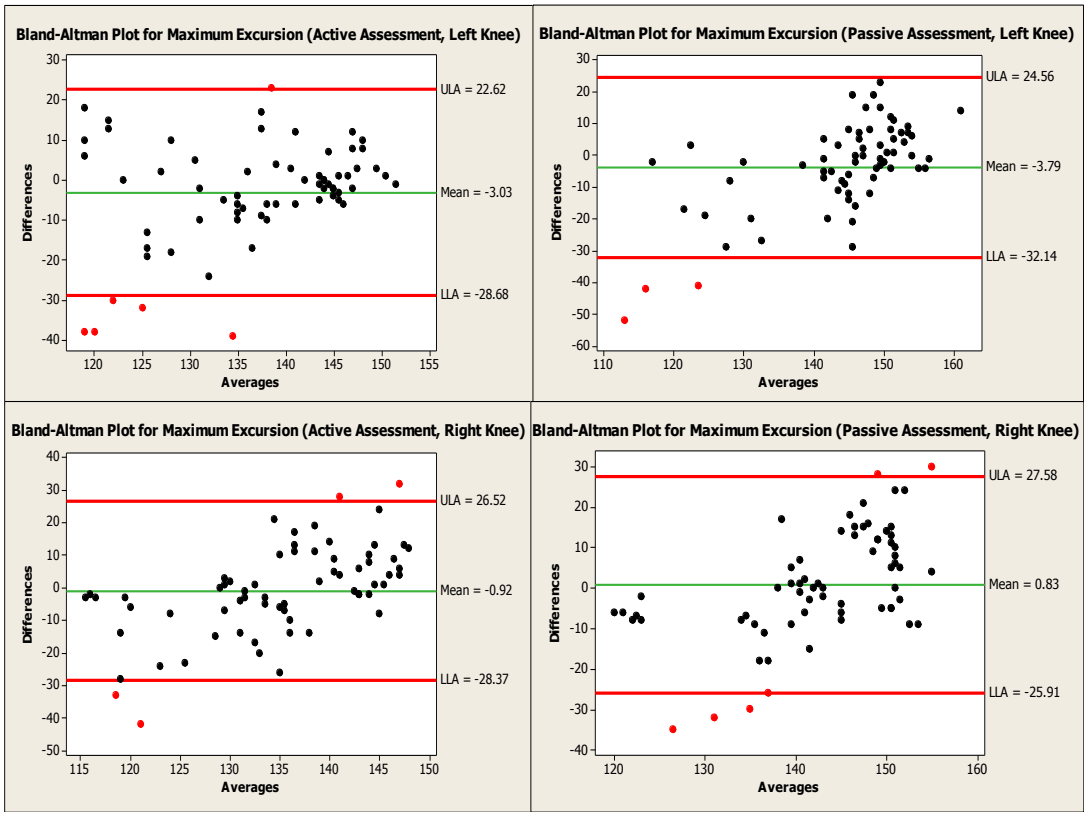


Figure 5. 9: Bland-Altman plots showing the reliability of both tools during ROM assessments. Knee excursions were used for these graphs.

Bland-Altman plots for ROM results recorded in both knees during active and passive movement showed positive trends of differences between the means recorded by both tools (Figure 5.9). However, mean differences did not exceed 5° (ranging from 0.06° to 4.05°).

Table 5. 5: Intra-class correlation coefficients of results recorded with the bespoke application and goniometer (n = 11, each including 6 trials).

Variable	Side	Bespoke Application ICC	Clinical Standard ICC
Active Flexion	**Left**	0.91	0.98
	Right	0.95	0.94
Active Extension	**Left**	0.83	0.79
	Right	0.81	0.85
Active Excursion	**Left**	0.90	0.95
	Right	0.96	0.97
Passive Flexion	**Left**	0.93	0.97
	Right	0.94	0.97
Passive Extension	**Left**	0.96	0.82
	Right	0.98	0.89
Passive Excursion	**Left**	0.97	0.96
	Right	0.96	0.97

ICCs were consistently >0.90 for maximum flexion and maximum excursion values, regardless of tool used. For maximum extension, ICCs ranged between 0.83 and 0.98 for the bespoke application, and between 0.79 and 0.89 for the manual goniometer.

5.2.5. Discussion

Knee joint angles recorded by the bespoke application and goniometer were comparable to one another. However, the spread of the results was greater with the application (Figure 5.8 & Table 5.1 – Table 5.4). Standard deviations were often twice as high in data recorded with the application (Table 5.1 – Table 5.4). According to McGinley and colleagues (2009), repeated measurements are naturally variable. Hence, a degree of variability within- and between-participants is normal. The degree of variability was seen to be greater with the bespoke application. One potential reason is that the application had a much smaller quantification level i.e. was more accurate and responsive, enabling it to better respond to and record the natural variation. Another potential reason for this finding is that the application calculates the positions and orientations of

the underlying bones in 3D to determine the angle between the shank and thigh. Thus, the way in which the flexion movement is executed influences the angle recorded. The application is therefore much more sensitive than the goniometric method as it takes limb rotations into consideration. With goniometry, the assessor is required to record the angle from palpable anatomical landmarks in the side plane which is assumed sagittal. As a result of these factors, recording similar angles between- and within-participants is more likely with the manual method. It should also be noted that the assessor was aware of the angle achieved on previous manual measures when using the goniometer which is likely to have standardised the manual results.

Statistical differences between both tools were only reported at the left knee during active flexion ($p = 0.036$) and at the right knee during active extension ($p = 0.026$). It could be that these differences may have been caused by some participants failing to fully flex or extend the knee during one or two trials carried out with the bespoke application, perhaps due to haste taken by the participant to complete the task. It could also be that due to the number of tests undertaken, as with a p-value of 0.05, 1 in 20 would be different by chance.

No results were statistically different between tools during passive motion. A potential explanation for this is that the assessor was in control of the movements during these trials, thus it was less likely for a trial to be recorded where maximum flexion and extension were not fully achieved.

Despite there being a greater spread in the data when using the bespoke application, ICC values were generally very good (>0.8) to excellent (>0.9) with this method. ICCs calculated from goniometry-based data were also very good to excellent as has been previously reported (Brosseau *et al*., 2004; Edwards *et al*., 2004; Lavernia *et al*., 2008; Piriyaprasarth & Morris, 2007).

Bland-Altman plots were used to investigate the agreement between the results recorded with both tools across the ROM (Figure 5.9). Positive trends of differences suggested that the mean differences between both methods were lower at higher average angles. Clusters of data points between 135° and 150°

were found to have differences close to zero. This suggests that the results with the least mean differences in these assessments were within this range. These maximal values are consistent with average maximal knee ROM (Shenoy *et al.,* 2013).

A recent study by McGinley *et al.* (2009) stated that errors of <2° were acceptable and errors of <5° were reasonable for a clinical tool. The mean differences reported here ranged from 0.06°-4.0.5°. This suggests that our application can confidently be used as an alternative to the goniometer to measure passive and active knee ROM.

The main limitation to this concurrent validity study is that the application could not be used at the same time as the traditional tool to record results simultaneously because of visual obstruction of the markers by the rater. By measuring the data separately for the two methods we introduced more variability into the results than if we had recorded the data simultaneously.

5.2.6. Impact on Future Work

This validation study enabled us to identify problems with the bespoke application which must be addressed prior to its use in a clinical environment.

It was previously inferred that inaccurate data on knee ROM may have been recorded during the validation study due to some participants executing the flexion-extension movement too quickly. To avoid this in future we recommend that participants be given the opportunity to practice the required movement to ensure that the participant understands how to correctly execute the task under assessment conditions.

In terms of ease-of-use, all participants carried out the ROM assessments without any problems. One participant did however comment that the Velcro straps of the clusters began to unravel as the quadriceps and hamstrings contracted during knee flexion and extension. To prevent this from happening in the clinical environment, we recommend that the assessor check that the

participant can fully and comfortably bend the knee *prior* to calibration. It may also be necessary to fasten the strap further with tape, to prevent it from unravelling during the assessment. Movement of the clusters during assessments must be prevented as it would result in a void calibration.

5.2.7. Conclusion

Due to the similarities between the data recorded with both tools, we can infer that the bespoke application is clinically acceptable in terms of accuracy and validity. Although differences between both tools were found, these differences were to be expected, given that the methods used to determine the angle differs greatly between the tools.

Furthermore, our results suggest that the bespoke application records reproducible and reliable results; traits which are essential for a clinical outcome measure. Bland-Altman plots showed reasonable to acceptable agreement between both tools. Consequently, we are confident that we can justify the use of this application in a clinical environment to report knee ROM as an alternative to goniometry.

5.3. Study Two, Part II: Knee Muscular Strength Assessment

This assessment was carried out immediately following the ROM assessment as part of the same investigation, thus the ethical approval granted for the first assessment also covered the strength assessment (section 5.2.1). Given that the strength assessment followed the ROM tests, no additional preparation or calibration processes were necessary. Statistical analyses carried out on the results were described in section 5.2.3.

The outcomes of interest for this assessment were the maximum knee extensor and flexor moments.

5.3.1. Data Collection Methods

Knee Flexor and Extensor Strengths: Bespoke Application

Participants sat upright on a chair, and a non-elasticated strap (which was attached to the load-cell) was placed around one ankle. The strap was aligned with the malleoli of the ankle and the knee adjusted to 90° flexion. The strap was then pulled taught. The bespoke knee ROM application was used to verify this angle.

To measure neuromuscular strength of the knee flexors, patients were asked to pull against the strap with maximal effort (Figure 5.10). Participants were informed not to raise their thighs away from the chair when doing so. Trials where this occurred were discarded. Six trials were carried out per leg for both legs.

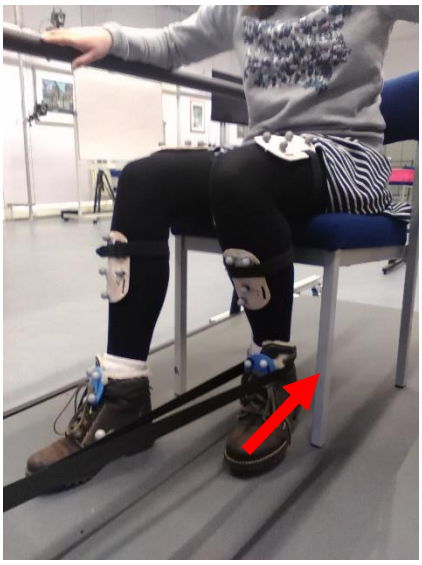


Figure 5.10: An image of a participant pulling their leg against the black ankle strap to record knee flexor strength. The strap is attached to a force measuring device. Pulling direction shown by red arrow.

Following this, the chair was reversed and the assessment repeated to assess extensor strengths. This involved pushing against the strap, as opposed to pulling (Figure 5.11).

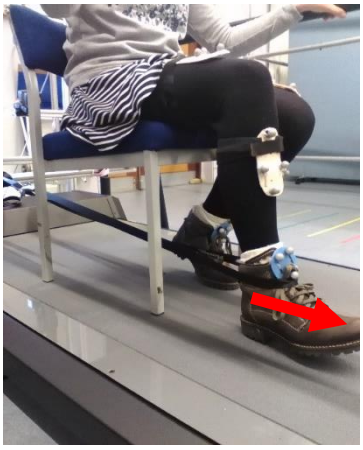


Figure 5. 11: An image of a person pushing their leg against the black ankle strap to record knee extensor strength. The strap is attached to a force measuring device. Pushing direction shown by red arrow.

On completion of all assessments, the maximum flexion and extension moments recorded at both knees for each trial were noted in the CRF.

Detailed instructions on how to carry out this assessment with this application are given in Appendix 2.1.

Visual Feedback

No visual feedback was used during this assessment to blind the researcher to the results.

Knee Flexor and Extensor Strengths: Clinical Standard

A traditional method for measuring knee strength was then carried out using a myometer (Figure 5.12).

The methods used to measure strength of the flexor and extensor muscles acting on the knee did not differ to those used with the bespoke software package. The same chair was used for both assessments for consistency. During the assessments, the maximal forces exerted against the strap were immediately recorded in the CRF.

Figure 5. 12: Multi-Analyser Myometer used in our validation study (MIE Medical Research Ltd., Leeds). Source: MIE Medical Research, 2016.

Only the force could be extracted from the myometer, therefore moments were calculated using Equation 5. 1. This was deemed necessary as knee strength is typically reported in terms of moments as opposed to force.

$$M = F\left(\frac{h\,x}{1000}\right)$$

x = 0.285 for males; x = 0.282 for females

Equation 5. 1

Where:

M is the moment, F is the force given by the myometer, h is the height of the person in millimetres and x is equivalent to the mean lengths of the shank and foot with respect to the total body height (Contini, 1972). It was assumed that the knee remained flexed by 90° when the myometer was in use.

5.3.2. Results

On average, higher knee flexor moments were recorded by the application than the myometer, but the differences were not significant (Table 5.6). The converse was found for extensor strengths (Table 5.6). Results recorded by the application suggest that the knee flexors were stronger than the knee extensors, but myometer results indicate the opposite (Table 5.6).

Table 5. 6: Descriptive statistics of flexor and extensor moments (Nm) recorded in both knees with both outcome measures. Paired t-tests were carried out on the data (n = 11, each including 6 trials except for where stated*, where n=10).

Task	Bespoke Application				Myometer				
Torque (Nm)	Mean	SD	SEM	Median	Mean	SD	SEM	Median	P-Value
Flexion Left Leg	51.0	22.4	2.8	46.0	49.8	17.8	2.2	47.2	0.531
Extension Left Leg	42.7	12.5	1.5	40.0	67.8	27.8	3.4	59.7	<0.0001
Flexion Right Leg	45.5	20.5	2.6	39.5	40.9	13.4	1.7	39.2	0.510
Extension Right Leg	40.7	9.7	1.3	41.0	55.5	25.3	3.3	50.7	<0.0001

The spread of the data was greater with the myometer when extending the knee, but greater with the application when flexing (Table 5.6). Despite this, ICC values were excellent for each assessment type (Table 5.7).

Table 5.7: Intra-class correlation coefficients of moments recorded with the bespoke application and goniometer (n = 11, each including 6 trials except for where stated*, where n=10).

Variables	Bespoke Application ICC	Clinical Standard ICC
Left Flexion Strength	0.86	0.99
Left Extension Strength	0.94	0.99
Right Flexion Strength	0.99	0.99
Right Extension Strength*	0.97	0.96

When both muscle groups were statistically compared, it was found that the moments generated about the knee were significantly different in the hamstrings and quadriceps, except when the bespoke application was used to assess right knee extensor moments (Table 5.8).

Table 5.8: Descriptive statistics of flexor and extensor moments (Nm) recorded in both legs with the bespoke application and clinical standard outcome measure. Paired t-tests were used for statistical analyses (n=11 for left knee, n=10 for right knee).

	Bespoke Application		**Clinical Standard**	
Task Variable	**Mean Moment (Nm)**	**p-Value**	**Mean Moment (Nm)**	**p-Value**
Left Flexors	51.0	<0.0001	49.8	<0.0001
Left Extensors	42.7		67.8	
Right Flexors	45.5	0.890	40.9	<0.0001
Right Extensors	40.7		55.5	

These results suggested that the ratio of knee flexor-to-extensor strength was not 50%. This was confirmed by calculating the percentage strength each muscle group produced. The ratio closest to 50:50 was at the right knee with the application (Figure 5.13). This was consistent with our statistical results (Table 5.8).

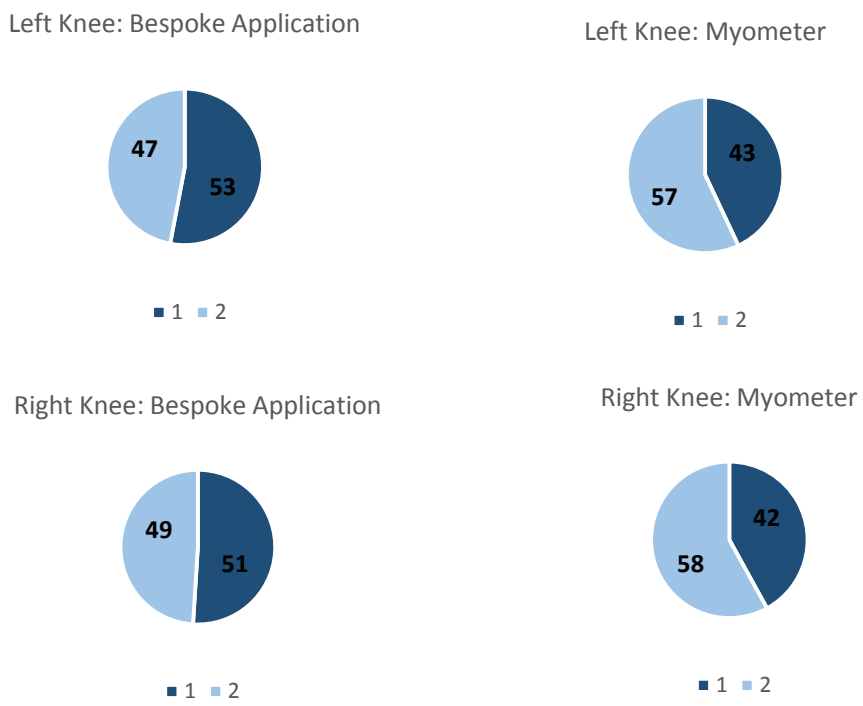


Figure 5. 13: The mean strength ratios of the knee flexors (1) to the knee extensors (2).

Bland-Altman plots for maximum moments about the knee generally showed negative trends of differences between the means recorded by the application and myometer (Figure 5.14). These results showed that as the moment increased, so did the mean difference (Figure 5.14). The differences were considerably lower during flexion. This was consistent with our statistical analyses (Table 5.6), which showed that there were no significant differences between the results recorded during knee flexion.

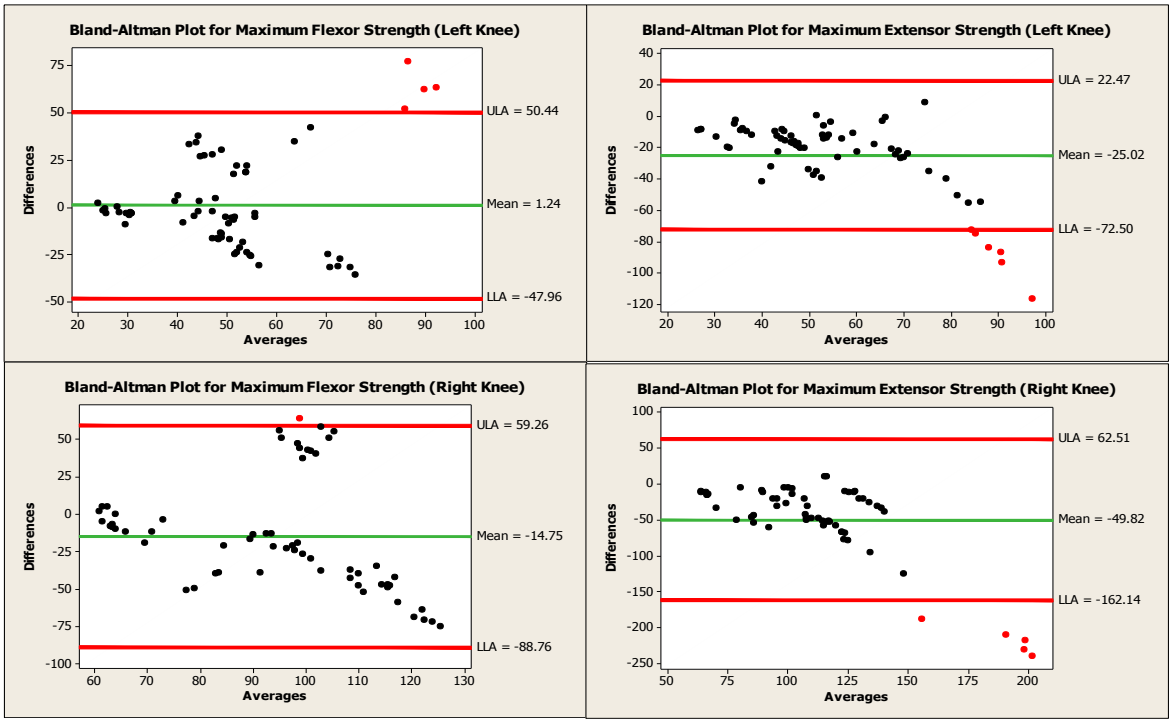


Figure 5.14: Bland-Altman plots showing the reliability of both tools during ROM assessments. Knee excursions were used for these graphs.

5.3.3. Discussion

Knee strengths recorded with both tools were consistent with previously reported knee flexor and extensor strengths in healthy adults (Kong & Burn, 2010; Samuel & Rowe, 2009). The moments recorded in our study could be considered as low, but previous studies have shown that knee muscular strength is lower when the knee is flexed by 90° than when the knee is extended to a greater extent (Kong & Burn, 2010; Samuel & Rowe, 2009).

Flexor strengths were comparable between both tools; however, statistical differences were found between extensor strengths, probably due to the gravity correction implemented in our study (Table 5.6).

According to the results recorded with the myometer, the extensor muscles were significantly stronger than the hamstrings, as has previously been

reported (de Arajuo Ribiero Alvares *et al*., 2015). However, data recorded with the application suggested that the moment generated by the flexors and extensors were largely similar. This was also observed by Kong & Burns (2010), who reported that the ratio of hamstring-to-quadriceps strength was near 50:50 in dominant and non-dominant legs of healthy adults when the knee was bent at 90°.

Differences between both outcome measures were expected for several reasons. Firstly, our method had included the effect of gravity in the calculations used to estimate the forces exerted against the ankle-strap. Secondly, differences may have been accentuated by real-time visual feedback. When using the myometer, each participant could see the amount of force they exerted against the strap on the digital screen. Consequently, participants may have competed against themselves between trials. This would in turn affect the moment calculated.

It is also likely that the angle of the knee changed during the assessments. Although the initial angle was set at 90°, this may have altered during trials. This change in knee flexion angle would only have been taken into consideration by the application and not the calculations used to estimate knee moments when using the myometer. Furthermore, it was assumed that the sling was perpendicular to the axis of rotation when using the myometer. This angle was incorporated into the calculations used in the application, but not in those used for estimating knee moments from myometer force.

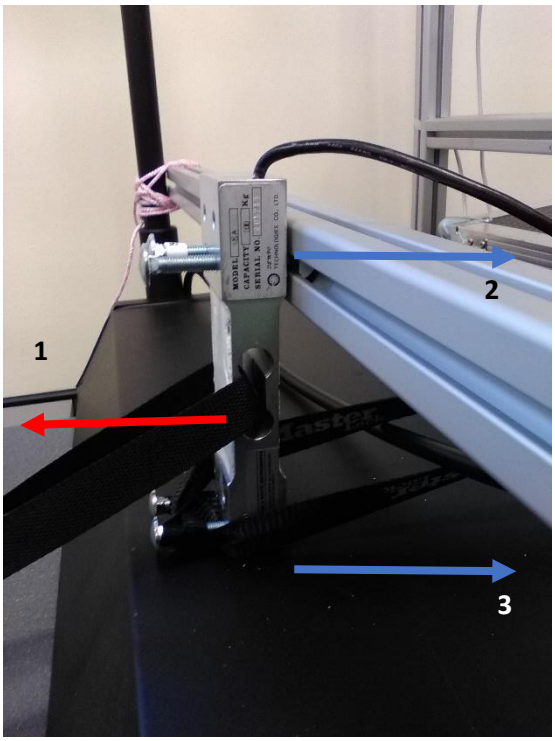
The myometer showed excellent repeatability (ICC = 0.99 for all variables). Although ICC values calculated for data recorded with the application were lower, they were very good (>0.85). These results suggest that both tools can return reliable and repeatable test-retest force data. This supported the current literature on isometric strength testing devices (de Arajuo Ribiero Alvares *et al*., 2015). Based on these results, we can be confident that the data recorded by our bespoke application are reproducible and repeatable.

Bland-Altman plots of the results showed that larger differences were observed as the moment increased because the myometer was measuring greater

moments (especially during extension) than the application. On average, the differences between results were small during flexion, supporting the use of the application in the clinical environment as an alternative to the myometer. However, extensor moments recorded by both tools differed greatly. We therefore cannot conclude that the application can be used as an alternative to the myometer. However, given that the results recorded by the application were consistent with previous findings we are confident that its use in a clinical environment is justified as a more scientifically correct method of testing knee strength.

5.3.4. Impact on Future Work

A limitation to this investigation was that the bar onto which the load-cell was attached twisted when loaded. This potentially affected the change in voltage recorded across the load-cell. Consequently, the accuracy of the resulting force may have been affected during these trials. To prevent this from happening in future, the set-up was re-arranged. The load-cell now has two points of attachment, to resist the moment when loaded (Figure 5.15).



1 = Force applied to load cell from taut ankle strap.

2 = Attachment point 1 to counter moment.

3 = Attachement point 2 to counter moment.

Figure 5. 15: A photograph of the revised load cell set-up.

We also noticed that the treadmill belt moved if the participants held onto the handlebars of the treadmill when flexing or extending the leg. This in turn led to the participant moving, altering the angle of the knee. For consistency, it is therefore advised that participants hold onto the chair when undergoing the strength assessment and not onto the treadmill handlebars.

5.3.5. Conclusion

The results of this validation study showed that there were differences between the moments recorded with the bespoke application and myometer. This was to be expected, given that the way in which force was calculated in both methods differed. Despite these discrepancies, the results were consistent with previous studies. Furthermore, our bespoke application returned reliable and repeatable data. This gives us confidence that the use of this application in a clinical environment is justifiable.

5.4. Study Three: Walking Stability Assessment

Given the novelty of the stability assessment developed for the purposes of our clinical motion capture system, an investigation into its use with gait data from healthy able-bodied participants was deemed necessary. The data collected in this study could then be compared to those recorded in patients with gait disorders such as OA.

5.4.1. Ethical Approval

The data used to validate this assessment were acquired from studies that had previously been carried out at the Department of Biomedical Engineering (University of Strathclyde). Ethical approval was granted for these studies by the Department of Biomedical Engineering, University of Strathclyde in 2015.

5.4.2. Data Collection Methods

Each participant (n = 10) was asked to walk on a self-paced treadmill (Motekforce Link, Amsterdam) at self-selected speed for two minutes. One participant was asked to repeat the assessment whilst being subjected to perturbations, to confirm that the stability assessment is sensitive enough to discern differences between normal and perturbed gait in a healthy individual. These perturbations were applied to the platform into which the treadmill is installed (Computer Assisted Rehabilitation Environment: Motekforce Link, Amsterdam). The platform has 6 degrees of freedom; however, only frontal plane perturbations were applied to the platform to induce walking instability. The participant was unaware of when or how often the platform would be perturbated during the two-minute trial.

All data were recorded with a 12 motion capture camera system (Vicon Motion Systems, Oxford) and later processed in Nexus software (Vicon Motion Systems, Oxford).

Gait output files containing data on walking trajectories and lower limb kinematics from 10 healthy, able-bodied participants were loaded into the Matlab application (ver. R2014a; Mathworks Natick, MA). The UCM was applied to twenty consecutive gait cycles from each participant.

Participants were aged between 24 and 34 years old, had a mean mass of 66.3±11.4kg and a mean height of 1.68±0.10m. Seven were female and three were male.

5.4.3. Data Analysis Methods

Results from both legs in the sagittal and frontal planes were saved and analysed. The variances within ($\sigma_{\parallel}^2$) and perpendicular to the UCM ($\sigma_{\perp}^2$), as well as the balanced ratios of the variances, were the outcomes of interest.

5.4.4. Statistical Analyses

Statistical analyses were carried out in Minitab software (ver. 16: Minitab Inc., State College, PA, USA). Normality tests were completed for all sets of data. Non-parametric tests were carried out on non-normally distributed data. The level of significance was set at $\alpha = 0.05$.

5.4.5. Results

Mean variances perpendicular to and within the UCM for all participants who underwent normal walking trials can be seen in Figure 5.16 and Figure 5.17. In the sagittal plane, a clear relationship is observed between the variances in the left and right legs, suggesting that the degree of kinematic variability in both limbs were similar throughout the gait cycle (Figure 5.16). This was not observed to such an extent in the frontal plane (Figure 5.17).

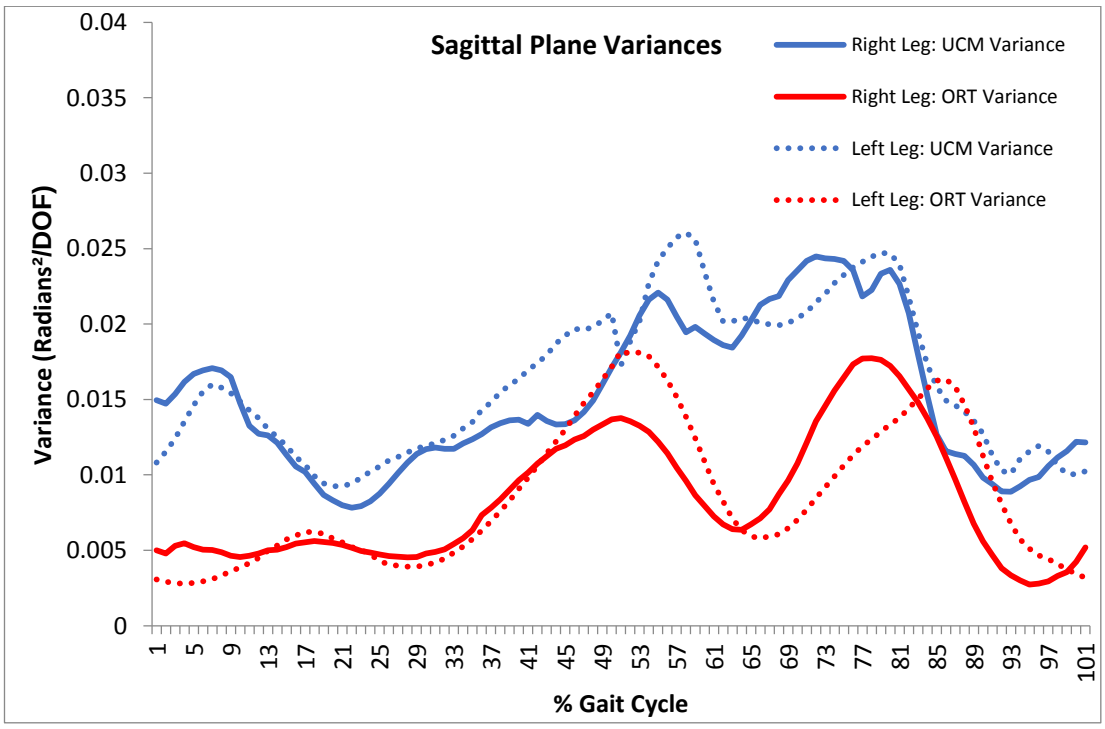


Figure 5. 16: Average sagittal plane variances within (UCM) and perpendicular (ORT) to the linearized UCM from 10 participants. The analysis was based on 20 gait cycles per participant.

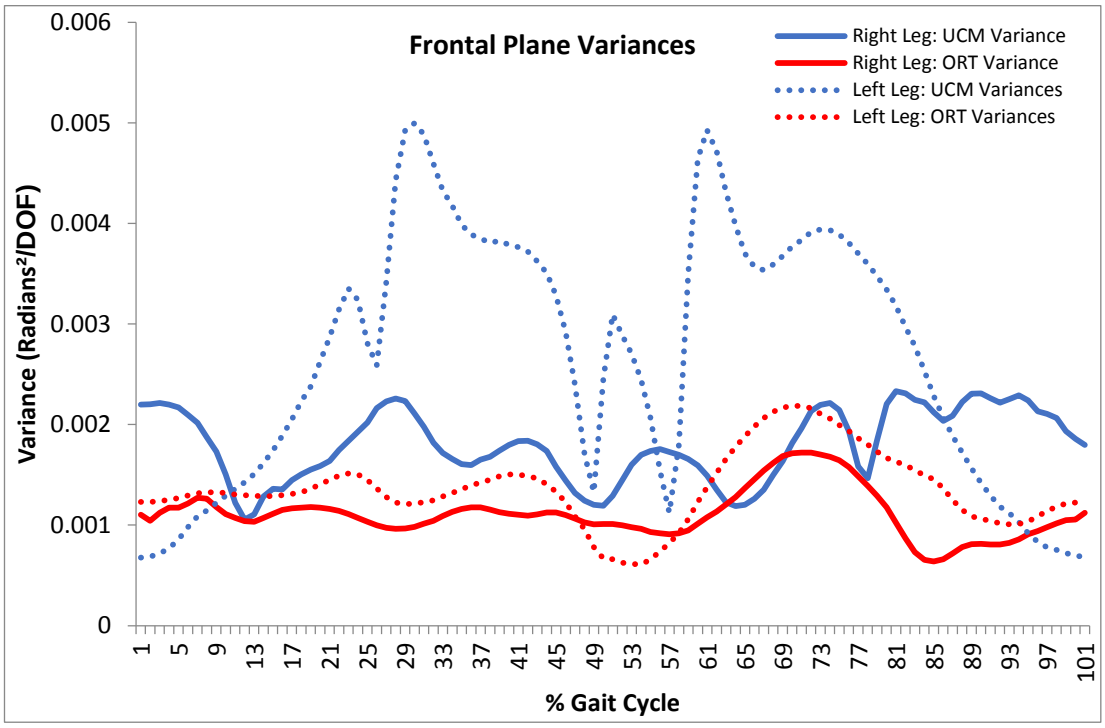


Figure 5. 17: Average sagittal plane variances within (UCM) and perpendicular (ORT) to the linearized UCM from 10 participants. The analysis was based on 20 gait cycles per participant.

Variances within the UCM ($\sigma_{\parallel}^2$) outweighed those perpendicular to it ($\sigma_{\perp}^2$) on all occasions (Table 5.9). These results suggest that kinematic synergy successfully stabilised the COM in both sagittal and frontal planes during normal walking.

Table 5. 9: Statistical analyses of variances recorded in all participants (Descriptive statistics & Wilcoxon non-parametric paired t-tests).

$\sigma_{\parallel}^2$ = variances within UCM; $\sigma_{\perp}^2$ = variances perpendicular to UCM

		$\boldsymbol{\sigma_{\parallel}^2}$			$\boldsymbol{\sigma_{\perp}^2}$			
Plane	**Side**	**Median**	**Mean**	**SEM**	**Median**	**Mean**	**SEM**	**P-Value**
Sagittal	**Right**	0.013	0.016	0.000	0.006	0.008	0.000	<0.0001
	Left	0.012	0.015	0.000	0.007	0.008	0.000	<0.0001
Frontal	**Right**	0.001	0.003	0.000	0.001	0.001	0.000	<0.0001
	Left	0.001	0.001	0.000	0.001	0.001	0.000	<0.0001

The average balanced ratio also remained above 0 throughout the gait cycle in both sagittal and frontal planes (Figure 5.18 & Figure 5.19).

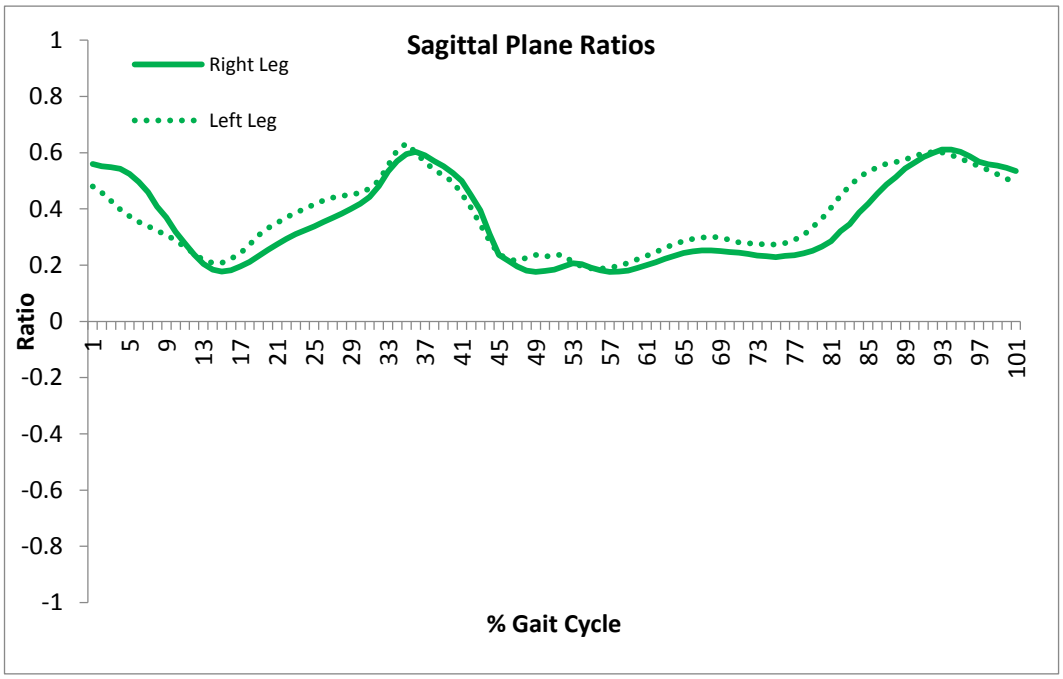


Figure 5. 18: Mean sagittal planes ratios recorded in the participants (n = 10).

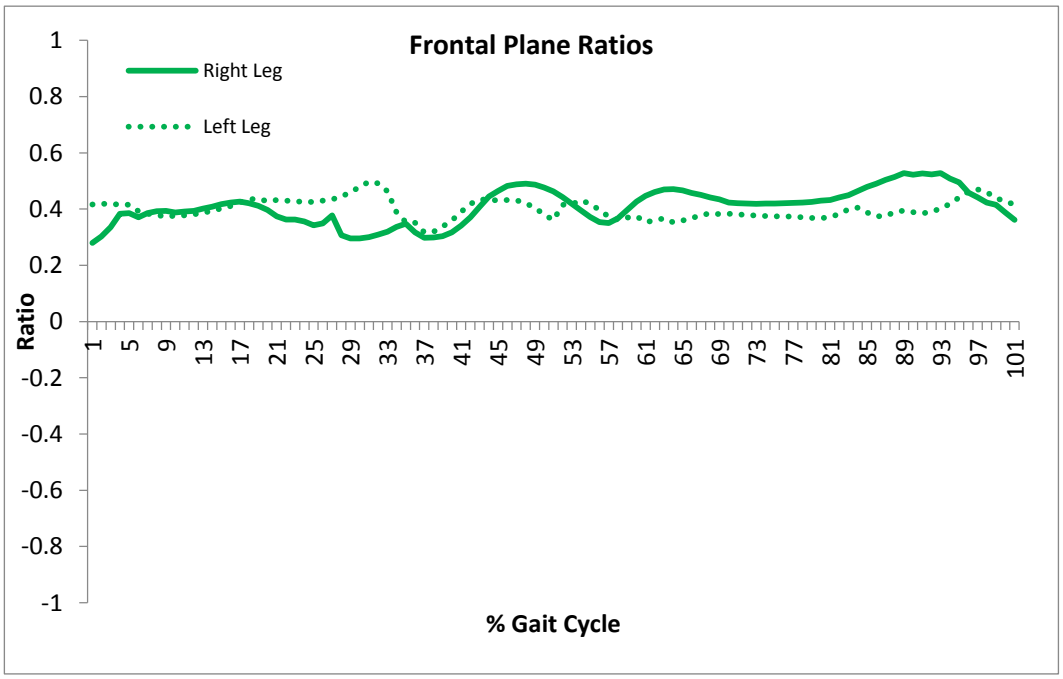


Figure 5. 19: Mean frontal planes ratios recorded in the participants (n = 10).

Sagittal plane ratios were highest during initial contact, terminal stance and terminal swing (Figure 5.18). These results suggest that upregulation of variance within the UCM during these times were beneficial in stabilising the COM during gait. Again, the patterns observed in the ratios between limbs were very similar.

Frontal plane ratios were also found to be similar between limbs, despite the fact that the variances recorded were typically greater on the left side (Figure 5.17 & Figure 5.19). Unlike in the sagittal plane, frontal plane ratios remained relatively consistent throughout the gait cycle. This suggested that the CNS was required to increase kinematic variability during some stages of the gait cycle, especially in the left limb, to maintain a consistently stable COM in the frontal plane.

In one randomly chosen participant, mean sagittal and frontal angles (± SD) were analysed to investigate the level of variability present in normal walking (Figure 5.20A: Sagittal Plane & Figure 5.20B: Frontal Plane). Typical variability in joint kinematics in both sagittal and frontal planes were observed.

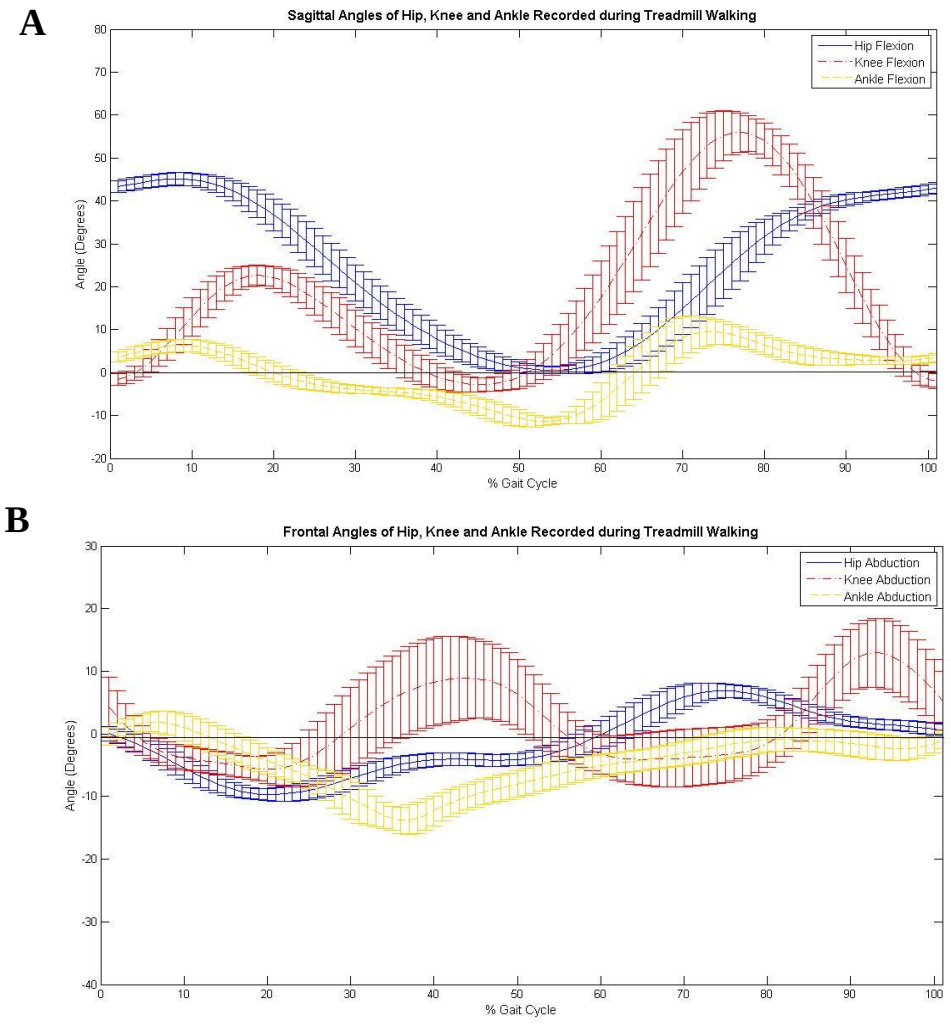


Figure 5.20: Mean and standard deviations of hip, knee and ankle joint angles in the sagittal (Flexion is positive) (A) and frontal (Abduction is positive) (B) planes from one randomly chosen participant (number of cycles = 20).

Despite there being kinematic cycle-to-cycle variability, the trajectory of the COM remained very stable in x- (anteroposterior), y- (vertical) and z- (mediolateral) directions (Figure 5.21).

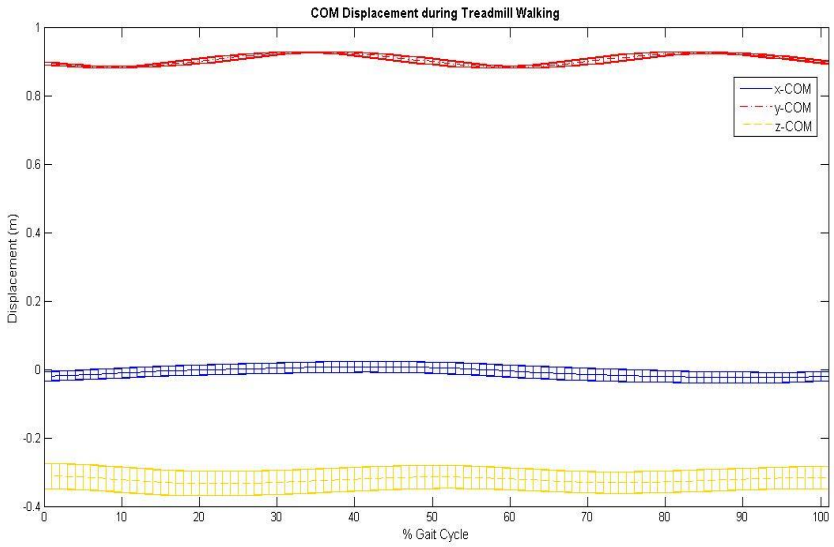


Figure 5.21: Mean and standard deviations of x-, y- and z-displacements of the centre of mass of the randomly chosen participant (number of cycles = 20).

When subjected to perturbation, the randomly chosen participant showed less variability in sagittal plane kinematics (Figure 5.22A). This was especially notable at the hip and knee (Figure 5.22A). Knee flexion variability was found to be greatest at the beginning and end of cycles; converse to the results from the normal walk (Figure 5.20A).

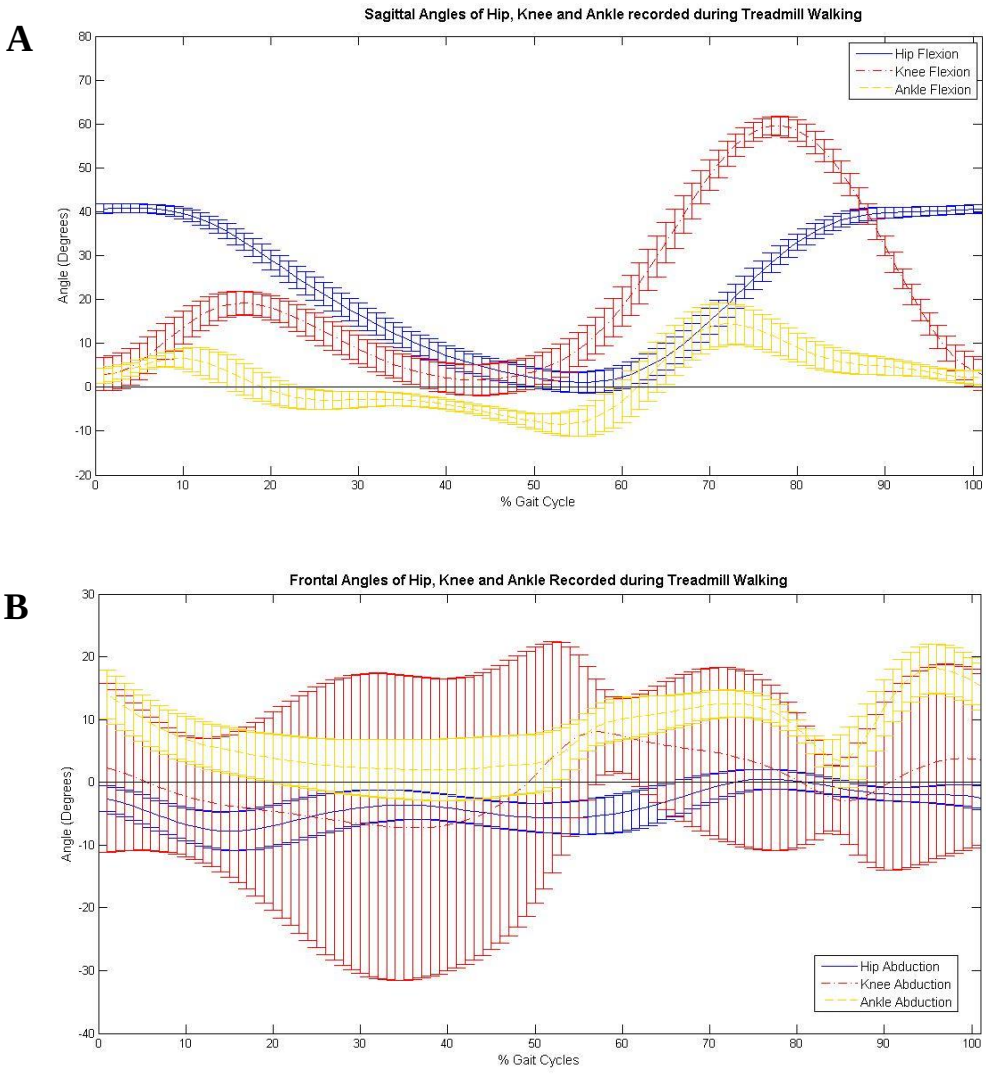


Figure 5.22: Mean and standard deviations of hip, knee and ankle joint angles in the sagittal (Flexion is positive) (A) and frontal (Abduction is positive) (B) planes from the participant who was subjected to perturbation whilst walking (number of cycles = 20).

Statistical analyses showed that sagittal knee and ankle kinematics did not differ between walking conditions; however, hip kinematics were significantly different, indicating a change in walking pattern to a more stereotypical movement in response to the possibility of a perturbation (Table 5.10).

Table 5. 10: Statistical analyses of kinematic and COM results recorded in the randomly chosen individual during normal and perturbed gait (Wilcoxon non-parametric paired t-tests carried out on results).

	Normal Walking			Perturbed Walking			
Variables	**Median**	**Mean**	**SEM**	**Median**	**Mean**	**SEM**	**P-Value**
Hip Flexion (°)	27.4	24.5	0.4	23.8	22.7	0.3	<0.0001
Knee Flexion (°)	14.1	18.3	0.4	14.6	20.6	0.4	1.00
Ankle Flexion (°)	1.9	0.1	0.1	1.8	1.8	0.1	1.00
Hip Abduction (°)	-2.3	-1.6	0.1	-3.7	-3.7	0.1	<0.0001
Knee Abduction (°)	-0.2	1.5	0.2	0.1	-0.4	0.4	0.006
Ankle Abduction (°)	-3.9	-4.5	0.1	7.7	7.6	0.1	<0.0001
X-COM (m)	-0.01	-0.01	0.00	0.01	0.01	0.01	<0.0001
Y-COM (m)	0.91	0.91	0.00	0.93	0.93	0.00	<0.0001
Z-COM (m)	-0.33	-0.32	0.00	-0.17	-0.17	0.00	<0.0001

In contrast to the sagittal plane, greater variability was observed in frontal plane kinematics of the perturbed trial (Figure 5.22B) than the normal walking trial (Figure 5.20B), especially at the knee. The extent of ab-adduction observed in this case is most likely due to cross-talk, however.

Greatest variability was observed between 20 and 50% of the gait cycle in both walking conditions. When perturbed, the hip was found to adduct more, and the ankle to abduct more (Table 5.10). A statistical difference between the mean knee angles recorded during normal and perturbed walking was also observed (Table 5.10). These results indicate a less stereotypical movement was adopted in the frontal plane with the prospect of perturbation.

Stability of the COM was also maintained when perturbed (Figure 5.23). However, variability was visibly greater in the x-direction i.e. anterior-posterior (Figure 5.23) compared to the unperturbed state (Figure 5.21). The positions of the COM during normal and perturbed walking were statistically different from one another (Table 5.10).

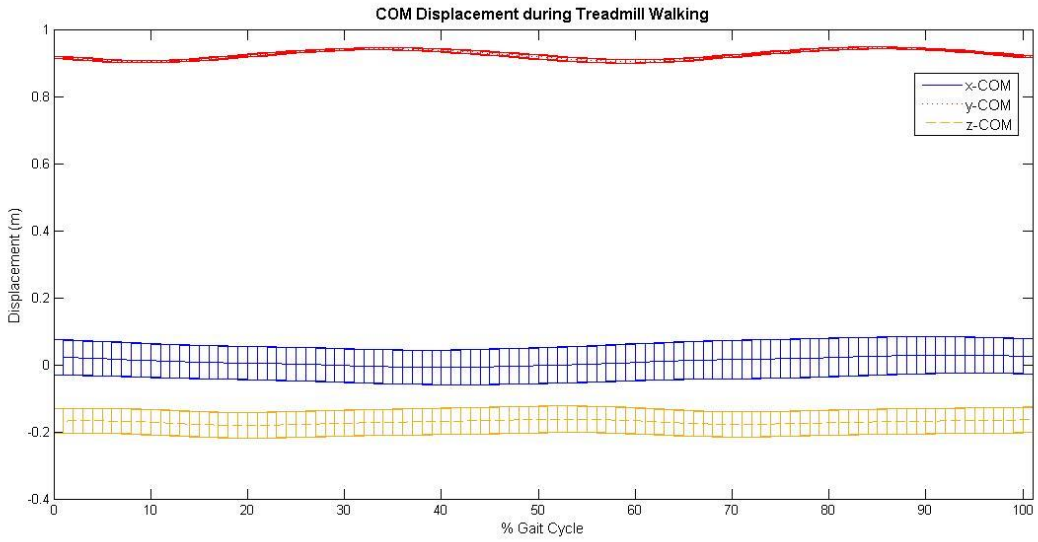


Figure 5.23: Mean and standard deviations of x-, y- and z-displacements of the centre of mass of the participant who was subjected to perturbation whilst walking (number of cycles = 20).

Using these data, inference on the presence or absence of kinematic synergy could not be made (Hsu *et al.*, 2007). Hence, to further investigate the relationship between the variabilities of the COM and gait kinematics the UCM method was applied to all data.

Figure 5.24 (right leg) and Figure 5.25 (left leg) show the components of the variances within and perpendicular to the UCM from the same randomly chosen participant. Regardless of plane, leg, or walking condition, variances within the UCM outweighed variances perpendicular to the UCM (Table 5.11). Thus, the COM can be said to have been stabilised through kinematic synergy in both normal walking and perturbed walking conditions in this participant.

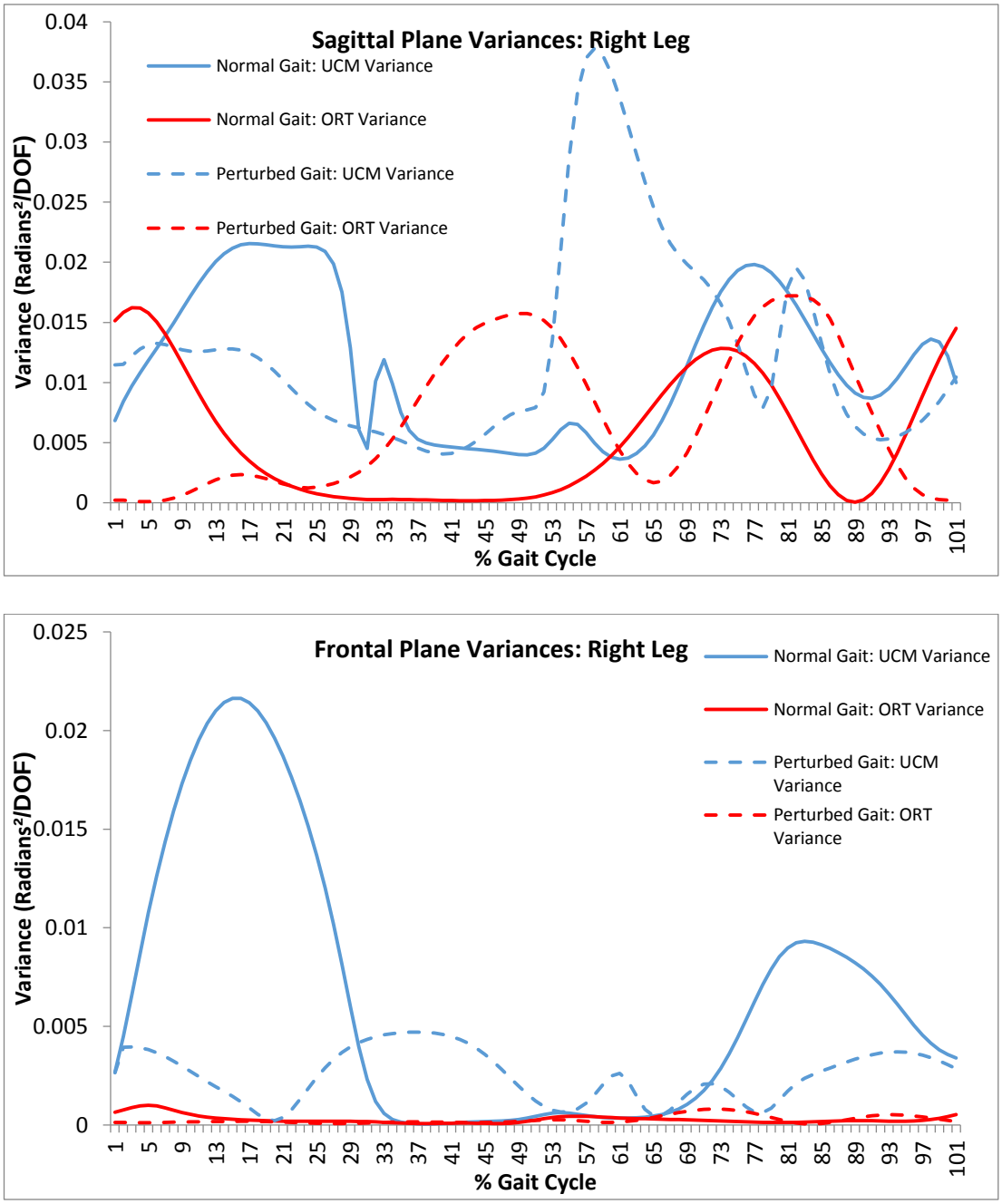
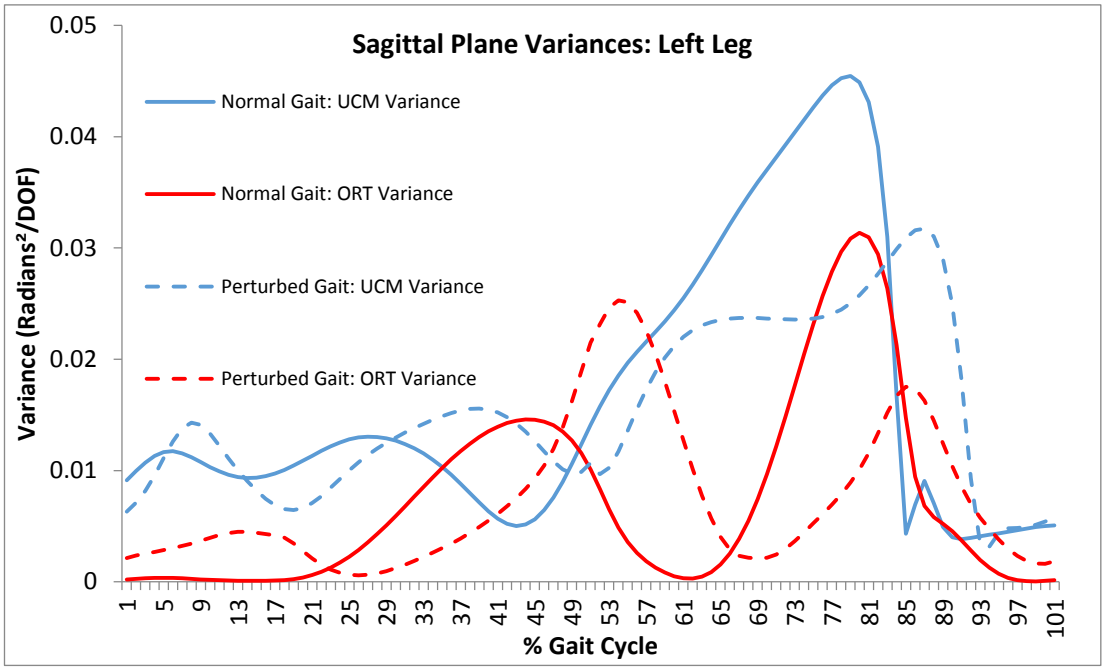


Figure 5.24: Variance within and perpendicular to the linearized UCM from the right leg in the sagittal and frontal planes of the randomly chosen participant

(number of cycles = 20).



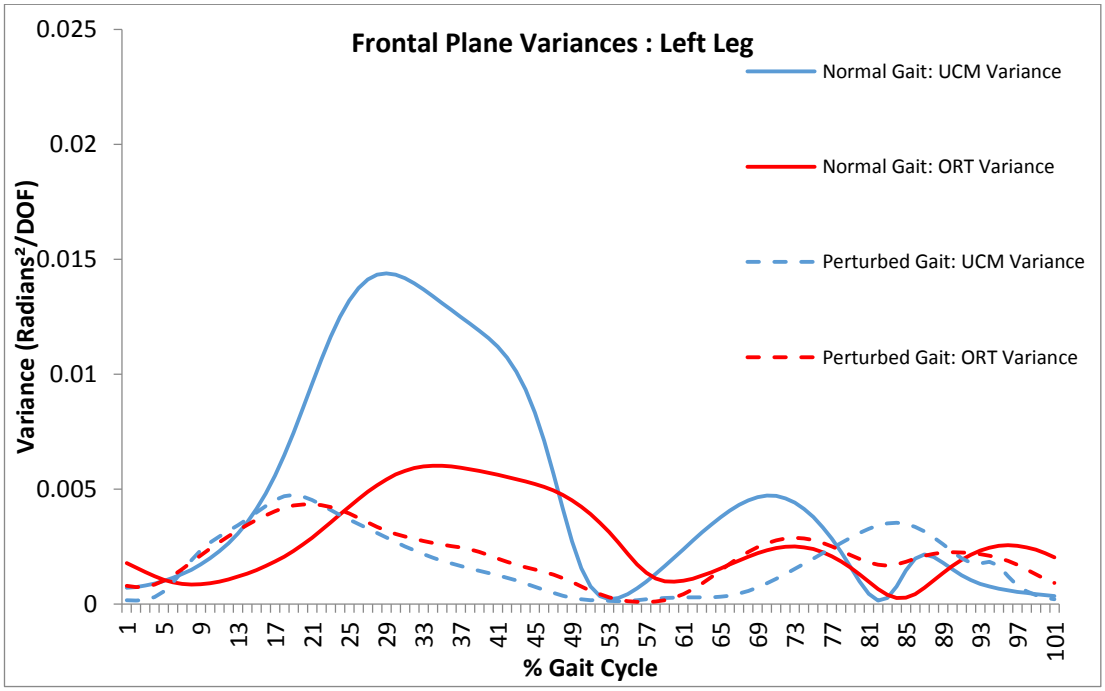


Figure 5.25: Variance within and perpendicular to the linearized UCM from the left leg in the sagittal and frontal planes of the randomly chosen participant

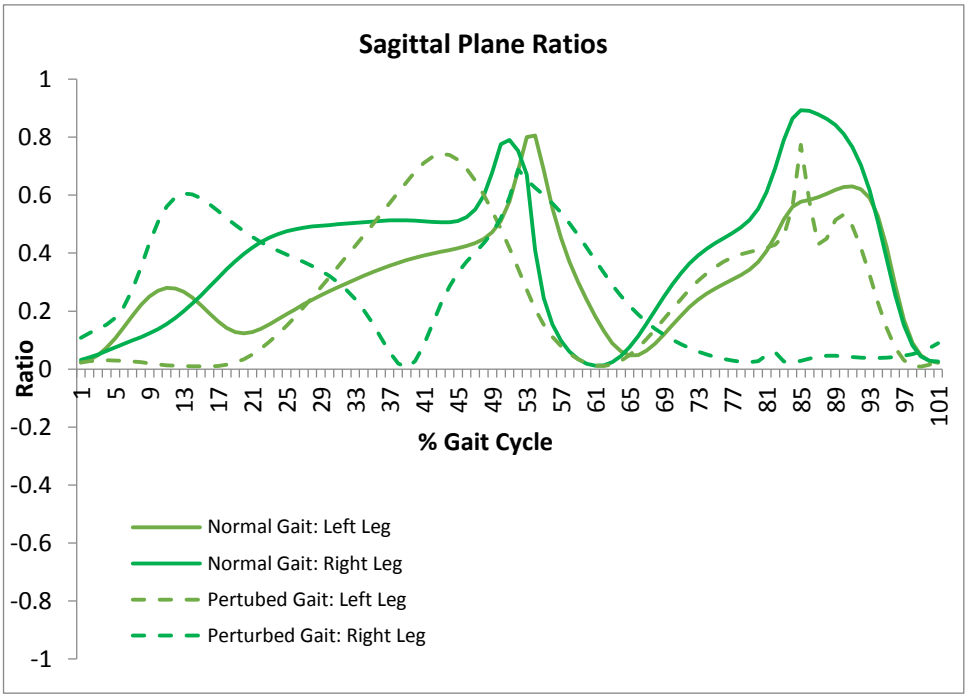
(number of cycles = 20).

Table 5. 11: Statistical analyses of variances recorded in the randomly chosen individual during normal and perturbed gait (Wilcoxon non-parametric paired t-tests carried out on results).

$\sigma_{\parallel}^2$ = variances within UCM; $\sigma_{\perp}^2$ = variances perpendicular to UCM

Plane	Side	$\sigma_{\parallel}^2$			$\sigma_{\perp}^2$			
		Median	**Mean**	**SEM**	**Median**	**Mean**	**SEM**	**P-Value**
	Normal Walking							
Sagittal	**Right**	0.013	0.015	0.000	0.004	0.007	0.000	<0.0001
	Left	0.010	0.012	0.000	0.004	0.006	0.000	<0.0001
Frontal	**Right**	0.001	0.001	0.000	0.002	0.002	0.000	<0.0001
	Left	0.002	0.002	0.000	0.000	0.000	0.000	<0.0001
	Perturbed Walking							
Sagittal	**Right**	0.011	0.016	0.001	0.003	0.007	0.000	<0.0001
	Left	0.010	0.011	0.000	0.003	0.005	0.000	<0.0001
Frontal	**Right**	0.0028	0.004	0.000	0.002	0.002	0.000	<0.0001
	Left	0.004	0.006	0.000	0.000	0.000	0.000	<0.0001

The average balanced ratio achieved from sagittal and frontal plane data for the randomly chosen participant are depicted in Figure 5.26. In each case, 'good variability' (a ratio of above 0) was observed throughout the gait cycle, regardless of the walking condition. This was consistent with our statistical results.



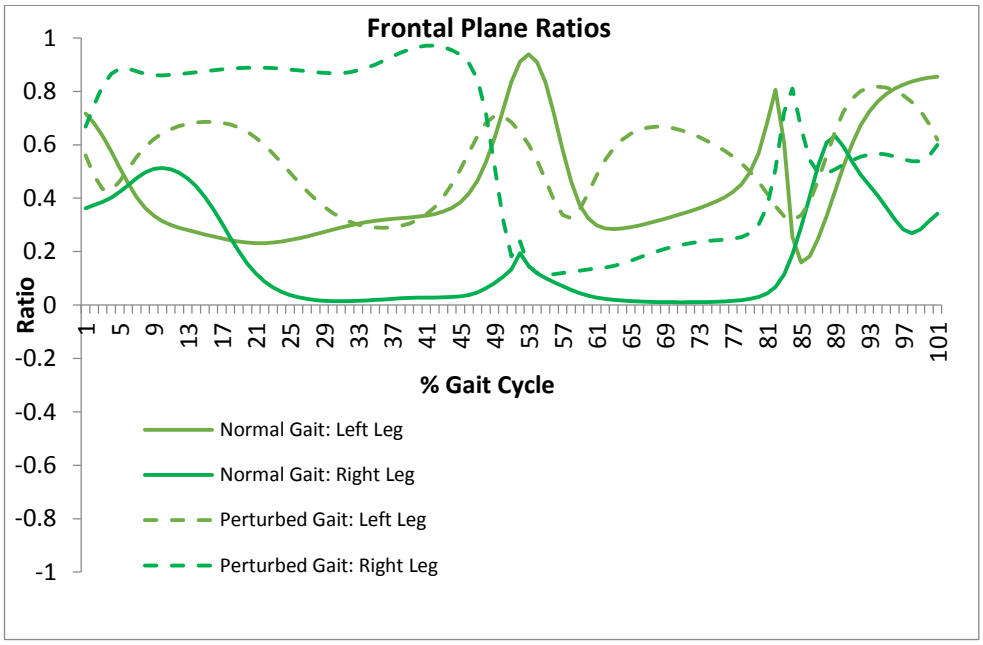


Figure 5.26: The balanced ratio of variance in the sagittal and frontal planes from the randomly chosen participant (number of cycles = 20).

5.4.6. Discussion

When we investigated mean sagittal plane variances across all 10 participants, (Figure 5.16) we found that there were no statistical differences between legs ($p = 0.06$). These results suggested that the variances were generally symmetrical between legs during walking. Given that our participants were able-bodied, and were able to walk normally at a self-selected speed, a symmetrical gait was expected (Kodesh *et al*., 2012; Lythgo *et al*., 2009; Sadeghi, 2003; Schrager *et al*., 2008).

More importantly, however; our results showed that variances within the UCM outweighed variances perpendicular to the UCM in all circumstances (Table 5.9). These results support the UCM theory and the hypothesis that kinematic synergy is used to stabilise the COM during a functional task (Latash, 2012; Latash *et al*., 2007; Sholz & Schöner, 1999).

Balanced ratios of the results further supported our belief that the variability of joint kinematics observed in these participants would not have an adverse effect on the body's ability to maintain a stable COM during walking, as all values were above 0 throughout the gait cycle (Figure 5.18 & Figure 5.19). This however, may not be the case in older adults or subjects with gait disorders.

Based on our results in Figure 5.18, we can infer that the COM was most stable in the sagittal plane during initial contact and during the pre-swing phase of gait. This could be interpreted as corresponding to times at which the CNS introduces greater kinematic variability to upregulate variance within the UCM to ensure that the variance perpendicular to the UCM does not exceed that parallel to it to give a negative ratio and destabilise the COM (Figure 5.16).

However, the results from the randomly chosen individual suggest the opposite. Despite the fact that lower limb joint angles varied throughout the gait cycle in both planes during normal walking (Figure 5.20), sagittal plane variation was smallest at the beginning and end of cycles (Figure 5.20A). During initial contact both feet are in contact with the ground and responsibility for controlling the COM transfers from one limb to the other. For this, a predictable base of support

is required; explaining the reduction in variability at these stages of the gait cycle (Remelius *et al*., 2014; Rose & Gamble, 2006). Kinematic variability was seen to increase in all joints as the single limb stance phase began. This was also seen as the limb entered swing phase (62% of the gait cycle), and to a greater extent. The results from our randomly chosen individual suggest that most sagittal plane kinematic variability occurs when the foot is partially or fully in the air, especially during swing phase. This is the time at which the body is at great risk to perturbations (Remelius *et al*., 2014). As a consequence, the CNS may adopt a more variable (less rigid) gait at these times to prevent internal and external perturbations from causing instability.

In our single subject, less variability was observed in sagittal hip and knee kinematics when perturbed than when walking normally (Figure 5.20 & Figure 5.22). These results could be explained by the participant adopting a more conservative or stereotypical walking pattern so as to maintain a stable COM whilst experiencing perturbed walking. By limiting hip and knee flexion, the average step length would become reduced; a strategy which has previously been described in healthy adults to maintain balance whilst walking on a perturbed platform or when taking short steps on icy ground (Hak *et al*., 2012).

The orientation of the foot during heel strike is vital as it provides the body with a good base of support and balance (Goodworth *et al*., 2015). According to Huber *et al*. (2013), the way in which the foot contacts the ground during foot strike is influenced by the pre-activation of some muscles which act on the knee joint. Conversely, during and immediately following heel strike, the position of the foot influences the muscles activated. According to Huber and colleagues the electromyographic waveforms of these muscles before, during and after foot strike varied during normal walking, as was observed in our study (Huber *et al*., 2013). This is thought to prepare the body for a heel strike event and maintain optimal biomechanics throughout heel strike to stabilise the COM (Huber *et al*., 2013; Townsend, 1985). Under perturbed conditions, the position of the foot during heel strike would be expected to differ to a greater extent than when walking normally. Consequently, this could explain why sagittal plane

kinematics were more varied at the beginning and end of the gait cycle when walking on a perturbed platform than when walking normally.

Frontal plane kinematics were more variable when perturbed, especially at the knee (Figure 5.22B). These results were not unexpected, given that the perturbations applied to the platform were in this plane. Frontal plane perturbations were chosen as this is the plane in which greatest instability is observed during walking (Schrager *et al*., 2008).

When perturbed, the ankle was found to abduct more, and the hip generally showed increased adduction. The 'ankle strategy' and 'hip strategy' could explain these findings. These strategies are used to balance the centre of pressure and COM respectively, in response to perturbations (Kodesh *et al*., 2012). This is akin to standing with a wide stance on a moving bus or train.

Despite seeing a different walking pattern in both planes when perturbed, the COM was found to remain steady in x-, y- and z-directions, as was observed during normal walking (Figure 5.21 & Figure 5.23). This suggested that consistent joint kinematics from cycle-to-cycle were sacrificed for a stable COM, implying presence of kinematic synergy. This was also observed by Hsu and colleagues (2007), who claimed that this could be viewed as a compensation mechanism to support the COM position.

Statistical analyses on UCM results from normal and perturbed walking in our randomly chosen participant confirmed our hypothesis of kinematic synergy in healthy young adults (Table 5.10). We also found that the balanced ratios of variances in both planes remained above 0 regardless of plane or walking condition. Hence, healthy individuals may be able to overcome perturbations during walking due to their abilities to adapt their gait when required.

5.4.7. Impact on Future Work

One limitation to this study is that only one participant was perturbed on the platform. With this limited data it is not possible to determine whether the

changes in variances observed when perturbed can be predicted. It is quite possible that the variances recorded are highly individual, depending on the participant. Hence, further research with a higher number of healthy participants is required.

Although the mean data appeared to follow a trend in this study, the patterns of variances were widely variable and different from the mean in the random individual. This is unlike, for example, the knee flexion pattern during gait, which typically follows a particular trend in individuals and across the group mean. This suggests that UCM data are independent and individual, supporting the results published by Papi and colleagues (Papi, 2012; Papi *et al.,* 2015). As a consequence, there may not be certain variance patterns that patients should strive to achieve. If this is the case, clinicians will find analysis and interpretation of the data time consuming and difficult. As such, this method may prove to be of greater value in the research environment rather than the clinical one. However, its use in the clinical environment should still be investigated to confirm or refute this theory.

One of the main outcomes from this investigation was that average sagittal plane variances were symmetrical in normal gait. Frontal plane variances varied to a greater extent between limbs. Regardless of this fact, variances within the UCM outweighed variances perpendicular to it in both frontal and sagittal planes, suggesting the presence of kinematic synergy in normal reciprocal gait. These outcomes will be of importance when investigating the role of the UCM method in patients with OA and TKA.

5.4.8. Conclusion

The aim of this study was to validate the UCM method and investigate its use with gait data from young participants to gain an understanding of the way in which gait variability affects COM stability in a healthy population.

Although cycle-to-cycle variability was observed in sagittal and frontal plane kinematics in normal walking, stability of the COM was not compromised. This was also found in one perturbed individual. The results presented here support the UCM theory, by showing that adopting a combination of different joint kinematics during walking benefitted COM stability, even when an external perturbation was introduced. It also showed that the UCM method is sensitive enough to identify differences between normal and perturbed gait.

The next step in this research will be to use the UCM method on gait data from TKA patients. The investigation will provide insight on the use of this method as a clinical outcome measure. It is hypothesised that the data recorded may be beneficial clinically to guide rehabilitation and physiotherapy sessions, and potentially identify mid-flexion instability following TKA (Hausdorff, 2007; Pintsaar *et al*., 1996; Sinitksi *et al*., 2012).

5.5. General Conclusions

The research questions which were answered by this validation study were outlined at the beginning of this chapter.

Through this investigation we identified issues associated with pointer orientation during calibration, addressing our first research question. Our results showed that the calibration of landmarks was reliable when the pointer was held in a consistent position. We therefore recommend users take this into consideration when calibrating the anatomical landmarks. Holding the pointer in a neutral orientation (parallel to the landmark) is recommended, as it is easier to maintain a consistent orientation in this position than when the pointer is anterior, posterior, superior, or inferior to a landmark.

As well as improving the calibration reliability and ease of use, the work presented in this chapter has shown that the knee ROM and strength assessments are reliable, and produce results that are comparable to current

clinical standard tools. These aspects of the study successfully answered our 2nd to 5th research questions.

We were also able to report typical cycle-to-cycle variability of gait in healthy adults and to use the UCM method to quantify this. Through this novel investigation we confirmed that kinematic synergy is observed in healthy adults during walking (our 6th research question). The results from this analysis will be valuable when investigating walking stability of TKA patients.

Based on the results presented in this chapter, we can be confident that our system and accompanying software will be scientifically acceptable. The next step in this project is therefore to install the system in a clinical environment and use it to assess the functional outcome of TKA patients.

Chapter 6. Clinical Trial Methodology

6.1 Medacta GMK Sphere Clinical Trial

The main aim of the clinical trial for which this thesis was a part was to investigate the health economics of using patient specific instrumentation versus conventional instrumentation in TKA. Thus, all patients recruited into the trial were randomised into one of two groups. The method of implantation was not the focus of this study and hence, for the purpose of this thesis, all patients will be described as one group.

The results will therefore describe the functional outcome of patients in the Medacta GMK Sphere clinical trial. The novel motion capture system developed and validated during this project was used to obtain these results.

6.1.1. Patient Recruitment

In order to determine the number of patients required to yield statistically significant results for the randomised controlled trial, where the level of significance is 5% ($\alpha = 0.05$) and the power is 90% ($\beta = 0.1$), a sample size equation was used to predict group size. The outcome variable used for the calculation was the minimum clinically important difference in the Oxford Knee Score. Results showed that 162 subjects were required to fulfil this statistical criterion. To allow for patient drop-out, an additional 10 patients were recruited. Hence, this clinical trial aimed to recruit 172 patients in total.

Patient recruitment commenced once the trial had been granted full ethical approval. This study was approved by an NHS research ethics committee (South East Scotland REC 2) on the 29th April, 2015 (REC reference: 15/SS/0058; IRAS ID: 177817) and by the NHS Lothian Research and Development management office shortly thereafter. Copies of the awarding letters are given in Appendix 1.

Patient recruitment took place at elective clinics at the Royal Infirmary, Edinburgh (NHS Lothian). All treatments, as well as pre- and post-operative appointments were carried out at this site.

Eligible patients were those who presented to the elective clinic with symptoms of end-stage OA which merited TKA (as recommended by a consultant orthopaedic surgeon). Patient information sheets were given to all potential participants (Appendix 1). All patients who were informed of the study were given a 24-hour period to read the information sheet and make an informed decision on whether they wanted to participate in the trial. Verbal and written consent was required from each willing participant. A copy of the consent form is given in Appendix 1.

Each patient was randomised into one of two groups (conventional instrumentation group/patient specific instrumentation group) to determine which surgery the patient would undergo. This process was done by block-stratifying 20 patients into equal groups. Envelopes for 172 patients were created with the randomised results prior to the beginning of the trial. The envelopes were opened over the phone once verbal consent had been given, to inform the patient of the result.

Patients were excluded if they presented with inflammatory arthropathy, required bone augmentation, or had ligament incompetence.

This clinical trial continues to recruit patients and to follow them up to 1-year post-operatively. Therefore, the data analysed in this thesis will not include all 172 patients. As per the guidelines outlined by the Consolidated Standards of Reporting Trials, a flow chart of the data recorded for the purposes of the trial, and the data analysed for the purposes of this thesis is included (Figure 6.1). 64 pre-operative assessments were included, with 27 patients undergoing functional assessments at all three time points (pre-, 6-weeks and 1-year post-operatively).

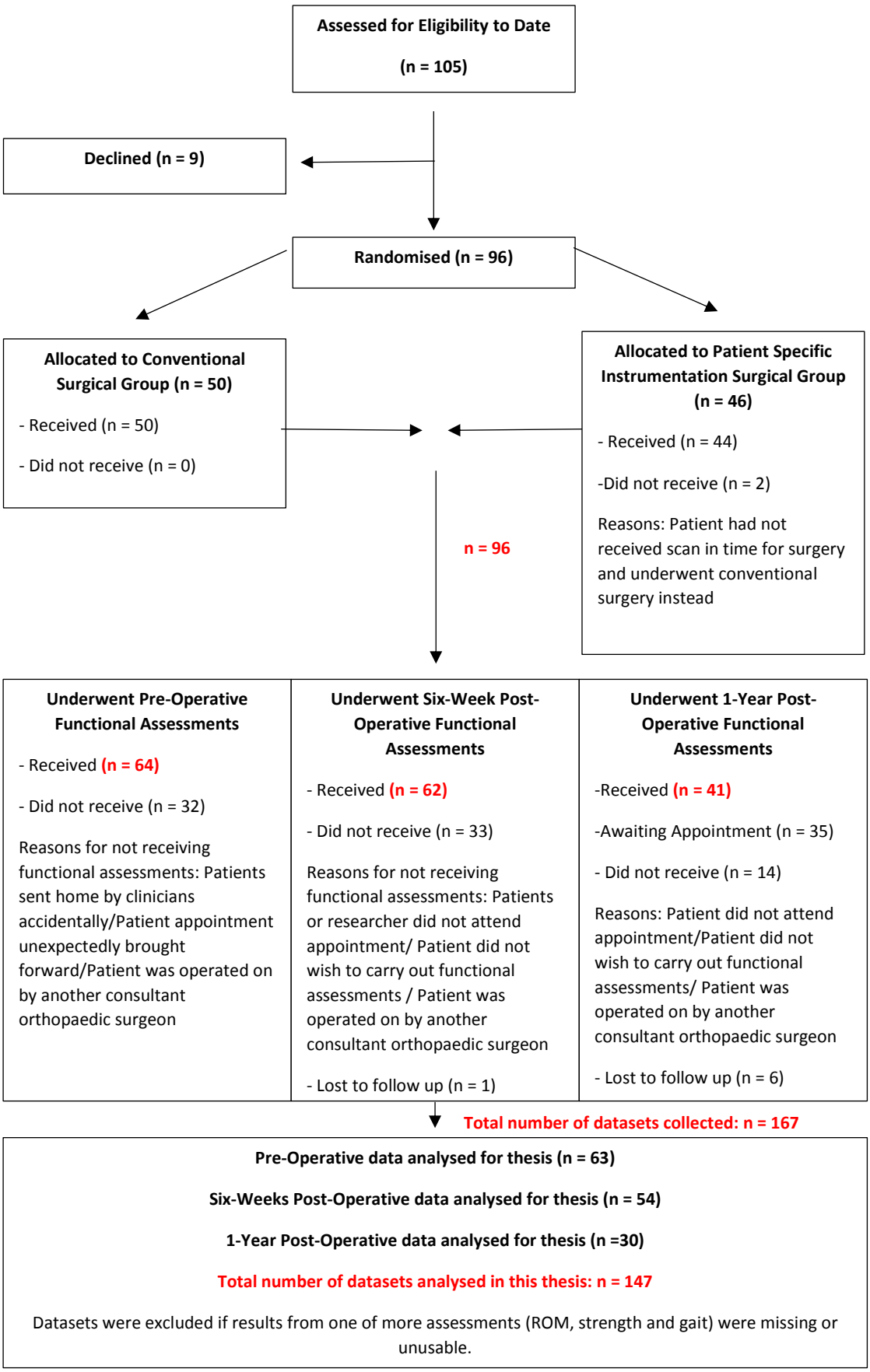


Figure 6. 1: Flow chart of patient recruitment and involvement in trial.

6.1.2. Baseline Assessments for Functional Outcome Investigation

Baseline assessments were carried out on each patient approximately 2 weeks prior to their TKA operation date. These assessments tested knee ROM, strength, gait kinematics, and gait stability.

All functional assessments were carried out within a physiotherapy gymnasium at the Orthopaedics & Trauma Outpatients department (Physio Gym 108, Edinburgh Royal Infirmary). Patients were seen on the same day as their routine pre-operative appointments.

All data collected throughout the clinical trial were recorded by the researcher in a clinical report form (CRF) (Appendix 3).

Pre-Operative Gait Assessments

The methods used to calibrate patients and assess knee ROM and strengths were described in Chapter 5 (sections 5.2.2 & 5.3.1). Patients repeated each assessment 3 times per leg.

After completing the first two assessments, a pelvic cluster was secured on the patient. The pelvic anatomical landmarks were then calibrated as described in Table 4.5.

The final assessment involved treadmill walking. Treadmill speed was slowly increased to a comfortable walking speed. After one minute, the treadmill was set to 'self-paced mode', allowing the patient to guide the speed of the treadmill themselves. Patients walked for 2 minutes in 'self-paced mode'. This was deemed a long enough time to gather kinematic data on at least 50 gait cycles. Following this assessment, all clusters were removed and the patient was thanked and allowed to leave.

Once the patient had left, the results from the gait trials were run through the UCM motor control application. Results of spatio-temporal parameters and maximum and minimum knee joint flexion angles during walking were reported in the CRF as part of the clinical trial reporting requirements. The data were stored and fully analysed after the clinic.

Additional Pre-Operative Assessments

Other assessments carried out pre-operatively included the Oxford Knee Score (OKS), EQ-5D and Short-Form 12 (SF-12). PROMs were completed by the patients themselves and scored by a member of the trial team.

Further neuromuscular testing was also carried out pre-operatively using a chair-fixed isokinetic dynamometer. Electromyography was used during this examination to gain further understanding on the strength of specific knee flexor and extensor muscle strengths and activations. This data forms part of another PhD programme and is not reported here.

All patients also underwent routine radiological assessments to aid the surgeons in creating and verifying the operative plan.

6.1.3. Post-Operative Functional Outcome Investigation

Patients were asked to return to the hospital approximately six weeks following surgery for post-operative observations. Functional tests and PROMs were repeated during this visit.

Patients returned to the hospital for a final follow-up clinic approximately one year post-operatively. All tests were repeated again at this stage.

6.1.4. Assessment Efficiency

An essential feature of a clinical motion capture system is its efficiency. To determine the efficiency of our protocol, all assessments were timed. The timer was started when the patient entered the physiotherapy gym and ended when the last cluster was removed. The calibration protocols and all three functional assessments were included in this recorded time. Assessments were recorded for each clinic: pre-operatively, six-weeks post-operatively and 1-year post-operatively. The assessments were recorded to the nearest minute.

Information on any problems encountered during the assessments were noted in the CRFs.

To support the use of our motion capture system in the clinical environment, the errors of each camera were also reported following each system calibration. This data can be used to investigate the accuracy and reliability of the camera system used in this study.

6.1.5. Data Analysis

As has previously been explained, all data presented in this thesis were calculated in D-Flow (version 3.22.1 CLUSTER1; Motekforce Link, Amsterdam) and Matlab (ver. R2014a: Mathworks Natick, MA) software. Statistical analyses of the data were carried out in Minitab software (ver. 16: Minitab Inc., State College, PA, USA). Normality tests were carried out on all data sets, then appropriate assessments were used to statistically analyse the data. Paired t-tests or two-sample t-tests were used for normally distributed data and 1-Sample Wilcoxon Parametric tests were carried out on non-normally distributed data.

Pearson correlation coefficients were used to correlate subjective and objective data collected in this trial. Pre-operative data from 50 patients were analysed to identify whether there were correlations between OKS and SF-12 PROM scores and the objective methods of assessing knee function. The same analyses were repeated on post-operative data. Thirty patients were included in the 6-week analyses, and 25 patients were included in the 1-year analyses. Not all data from all patients who were included in the thesis (as specified in Figure 6.1) could be used in this particular investigation, as many patients failed to complete all PROM questions. Given the fact that the subjective data was incomplete in a number of cases, only those with complete objective and subjective datasets were included in these correlation studies.

The level of significance for this thesis was set as α = 0.05 and a clinically significant rho value was defined as >0.3 for correlation studies (Kempshall *et al.,* 2013; Kwon *et al.,* 2010; Landis & Koch, 1977).

6.2. EQUAL Project

To better understand the way in which our patient cohort functioned pre- and post-operatively, walking data collected during this project were compared to those of an elderly healthy population.

In the early 2000s the Engineering and Physical Sciences Research Council funded a multidisciplinary initiative on Extending Quality of Life (EQUAL). For the EQUAL project, the biomechanical and functional abilities of older adults (>60 years old) were investigated (Samuel, 2005; Hood, 2011). The available raw data recorded during walking tasks in the EQUAL study were analysed and described for comparison with the patients in this study. The results were also statistically compared to the data recorded in our TKA population.

6.2.1. Patient Information

125 older adults volunteered to participate in the EQUAL project, however only 82 were eligible, based on cognitive and physical medical examinations. Several exclusion criteria were required to ensure that the population best represented healthy older adults (Hood, 2011).

All eligible volunteers attended 2 sessions of biomechanical testing at the University of Strathclyde. Ethical approval for these analyses was granted by the University of Strathclyde (Hood, 2011).

The results of a subset of 30 volunteers were analysed in this comparative study (Figure 6.2). This number was chosen to roughly match the number of TKA patients included in this thesis who attended all three clinics (n = 27).

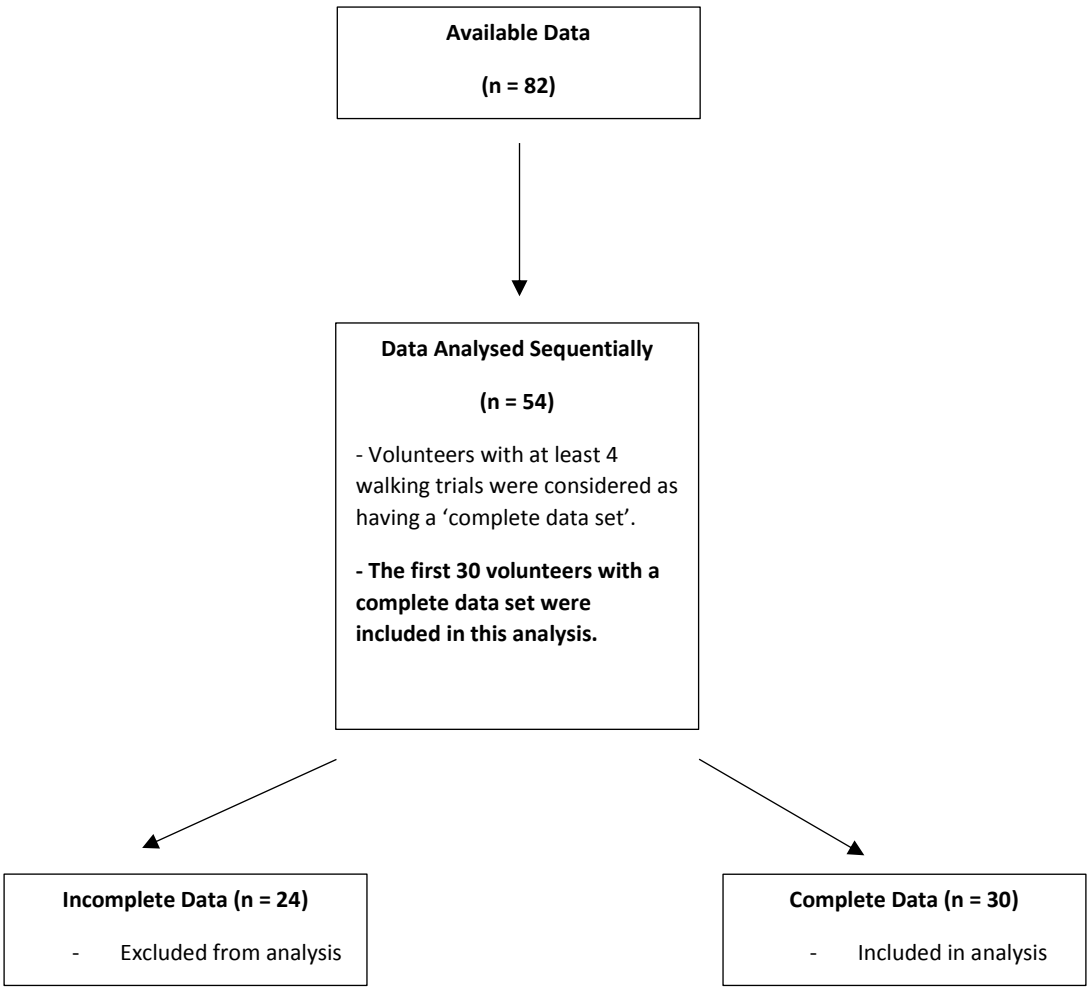


Figure 6.2: Flow chart of the EQUAL project data analysed in this thesis.

6.2.2. Biomechanical Model

The use of different biomechanical models can complicate comparative analyses. In the case of the EQUAL project, a rigid cluster-based biomechanical model with pointer-calibration technique was implemented to analyse movement. As recommended by The International Society of Biomechanics, the Grood & Suntay method for determining joint co-ordinate systems was used to describe joint kinematics. Given the similarities between our model and the model used in the EQUAL project, we are confident that the results reported in this thesis can be justifiably compared to those recorded during the EQUAL project.

6.2.3. Kinematic Assessments

All volunteers involved in the EQUAL project were asked to complete a 10m normal over-ground walking task. Averages of 4 walking trials were recorded per person. Hence, data from the first 30 patients with at least four walking trials were included in the analysis. The first four trials were analysed in the cases where >4 trials had been recorded.

6.2.4. Data Analysis

A Matlab script was used to extract knee kinematics in sagittal, frontal and transverse planes and to calculate spatio-temporal parameters from the chosen raw data (ver. R2014a: Mathworks Natick, MA). The means of all variables over 4 walking trials were calculated per participant.

Statistical analyses of the mean data were carried out in Minitab software (ver. 16: Minitab Inc., State College, PA, USA). Normality tests were carried out on all data sets, then appropriate assessments were used to statistically analyse the data. The level of significance (α) for the statistical tests were set at 0.05.

Chapter 7. Results

This chapter begins by presenting data on the efficiency of the clinical motion capture system described in this thesis. Following this are two case studies. The first case was chosen due to the extremity of the varus deformity of the knee and the novel operative method used by the surgeon to implant the prosthesis. The second case was randomly chosen as a representation of a typical TKA patient. These two conflicting cases aim to highlight the breadth of data recorded in this study and show that the system developed for this project is sensitive enough to measure differences between patients. The functional outcomes of the patients involved in the trial will then be described. Knee ROM, knee flexor and extensor strengths, walking kinematics and gait variability will be reported. Data from the EQUAL project is also presented here. Finally, the relationships between the measures currently used in the clinical environment and those used in this study are explored.

The methods used to obtain all results were described in Chapter 6.

7.1. Assessment Efficiency

Statistics on the lengths of time the entire functional assessment took to complete in the pre- and post-operative clinics are given in Table 7.1.

Table 7.1: Recorded times for assessment protocol.

Clinic	Maximum Time (min)	Minimum Time (min)	Average Time (min)	Standard Deviation for Average Time (min)
Pre-Operative (n = 63)	25.0	14.0	17.4	2.4
Six-Weeks (n = 54)	23.0	11.0	15.7	2.1
1-Year (n = 30)	19.0	13.0	15.2	1.4
All (n = 147)	25.0	11.0	16.8	2.1

Data from 147 assessments were analysed in this thesis (Figure 6.1). All 147 were completed within 30 minutes. Maximum and average assessment lengths decreased as the study progressed and as the patients recovered (Table 7.1).

The results from 27 patients who attended all three clinics were statistically analysed. Paired t-tests showed that there was a significant improvement in assessment time between pre-operative (17.5±2.7 minutes) and six-week post-operative clinics (15.2±2.2 minutes); $p = 0.004$. Further improvement between six-weeks and 1-year (15.2±1.4 minutes) was not observed; $p = 0.834$.

Time-efficiency of the system was dependent on its reliability and ease-of-use in the clinic. Although generally reliable, 20 datasets out of a possible 167 (12.0%) were excluded from group analyses (leaving a total of 147 datasets – see Figure 6.1). These 20 datasets were excluded as the results from one or more assessments were missing or unusable (Table 7.2).

Table 7. 2: Reasons why patient data were excluded from analysis at pre-operative or post-operative stages.

Reason for Exclusion	Number of Incidences
Patient refused to carry out assessment	2
Self-paced function failed	5
Gait data was not recorded	13

Two patients did not wish to carry out the strength assessment one year post-operatively due to ongoing pain in the knee. Other data collected from these patients at 1-year were therefore excluded from the 1-year analysis. Thus, 2 datasets out of a possible 167 (1.2%) were excluded due to incompliance.

Five datasets out of 167 (3.0%) were excluded as the self-paced function failed to work when activated in D-Flow. A further 13 datasets of 167 (7.8%) were excluded as the data from gait assessments were not recorded properly by the software. The reasons behind these incidences were not identified, despite extensive investigation. The actions taken to determine the cause of these failures are described in the discussion.

On a few occasions (exact number not recorded) the D-Flow software abruptly stopped tracking the clusters during assessments of knee ROM or strength. As a result, the live positions of the anatomical landmarks could not be reconstructed, nor the biomechanical data calculated. When this occurred, D-Flow activated an error message to notify the user of the issue. To rectify this problem, the researcher was required to stop the assessment and restart the recording. It was not necessary to recalibrate the anatomical landmarks, but the assessment during which the software stopped working had to be repeated in order to record valid data. As a result, no data was lost for these patients, meaning that the datasets could be included in the analyses.

Table 7.3 describes all other issues encountered during use, and the actions taken by the researcher to overcome them to prevent loss of data.

Table 7.3: Descriptions of the problems encountered during this study, and the way in which they were addressed in the clinic.

Stage	Problem Encountered	Number of Patients Affected	Action
Pre-Calibration	Patient attended clinic in inappropriate clothing	3	Patients changed into spare shorts prior to calibration
	Uncomfortable cluster(s)	3	Cluster position altered prior to calibration
Calibration	Incomplete patient calibration	6	Patient calibration repeated
Assessment	ROM protocol too difficult for patient	1	Protocol altered to suit this patient's abilities
	Gait assessment too long for patient	14	Gait assessment shortened to suit these patients' abilities
General	Camera calibration voided	5	Cameras recalibrated
	Cluster movement due to loose strap(s)	5	Strap(s) tightened and patient recalibrated

The majority of patients who underwent functional assessments for this trial attended the clinic in trousers or shorts. Three patients (1.8%) attended in long

skirts (Table 7.3). Skirts cannot be worn for these functional assessments however, as they occlude the markers on the thigh and shank clusters. These patients were therefore required to change into a spare pair of shorts prior to calibration (Table 7.3).

Prior to calibration it was necessary to strap the clusters onto the legs and feet of patients. The clusters were strapped too tightly on 3 patients (1.8%), causing discomfort and pain (Table 7.3). Clusters that were too tight were identified and loosened prior to calibration. The clusters that were strapped too loosely however, were only identified by their movement following calibration. Given that movement of a cluster voids the anatomical calibration, patients with loose clusters were recalibrated and all assessments repeated.

Patient calibration failed on 6 occasions (3.6%) due to the fact that the pointer markers were occluded by the researcher or the patient during use (Table 7.3). Consequently, the position of the tip could not be defined by the software. Hence, when the user registered a landmark with the footswitch, its position was reconstructed incorrectly. In these cases, patient calibration was repeated.

Table 7.3 also shows that the cameras had to be recalibrated on 5 occasions (3.0%), as some patients used the rear frame as a prop when mounting and dismounting the treadmill. By moving the frame, patients also moved the cameras attached to the frame, voiding the calibration.

On occasion it was necessary to adapt the protocol to suit the needs and abilities of the patients. One patient (0.6%) could not complete the ROM assessment as per the standard protocol, as severe asthma prevented her from lying in supine position for the duration of the test (Table 7.3). She was therefore asked to complete the assessment whilst sitting upright on the plinth.

Fourteen patients (8.4%) were unable to walk on the treadmill in self-paced mode for 2 minutes (Table 7.3). However, as 50 consecutive gait cycles were recorded

before they stopped walking, their gait data could be included in the analyses. Table 7.4 explains why the patients could not complete the walking task.

Table 7. 4: Reasons given by patients as to why they could not walk on the self-paced treadmill for 2 consecutive minutes.

Stage	Number of Patients Affected	Reasons
Pre-Operatively	5	Extreme shortness of breath/Hip pain/Back pain/Dizziness/Frailty
Six-Weeks Post-Operatively	4	Extreme shortness of breath/ Ankle pain/Post-operative pain and swelling from infection/ Recovering from recent fall caused by instability in contralateral knee
1-Year Post-Operatively	5	Knee pain/ Hypersensitivity/ Numbness in foot following surgery/ Swelling

Although only 14 patients were unable to complete the 2 minute gait assessment in self-paced mode, many more patients struggled with the transition between fixed- and self-paced walking. The majority of patients slowed down considerably when the self-paced function was activated. Patients reported that they walked slower on the treadmill as they feared it would continue to gain speed as they walked. Others were worried that they would trip or fall on the treadmill. Some also commented on the fact that they felt they did not feel safe during the gait assessment as they

were unfamiliar with treadmills. Unfortunately we did not record the number of patients who struggled with this aspect of the gait protocol as it was not part of the ethics application and approved case report file.

The average reported camera errors recorded following each system calibration (50 in total) are presented in Table 7.5. The average error of each camera was <0.3mm.

Table 7.5: Average camera error for each camera following system calibration (n = 50).

Camera Number	Average Error (± SD) in mm
1	0.26 (0.03)
2	0.24 (0.06)
3	0.18 (0.02)
4	0.19 (0.03)
5	0.29 (0.08)
6	0.20 (0.04)
7	0.27 (0.04)
8	0.23 (0.07)

7.2. Case Study One

This first case study describes the functional outcome of a patient who will be referred to as 'Patient 10' in this thesis. Patient 10 attended an elective clinic at the Royal Infirmary of Edinburgh in April 2016. The patient suffered from a severe varus deformity of the left knee caused primarily by OA.

7.2.1. Patient History

Patient 10 is an 83-year-old female with a body mass of 65kg and a height of 1.48m (giving a BMI of 29.7kg/m^2). She had a very active career as a physical education teacher, and spent many years running and practicing gymnastics as hobbies. The patient has suffered many sports injuries over the course of her lifetime, including a meniscal tear in the left knee. An open medial meniscectomy was later performed in this knee, which she believes accelerated the progression of OA in her left knee.

7.2.2. Diagnosis and Recruitment

Patient 10 was referred to the Royal Infirmary of Edinburgh with severe bilateral OA by her GP. Over the last few years she had been finding it increasingly difficult to enjoy her hobbies and carry out everyday tasks such as driving.

Patient 10 had no current medical problems, but she did take prescribed medication for hypertension and high cholesterol. She also occasionally self-medicated with aspirin.

The patient presented to the elective clinic with a varus deformity in the left knee >20° under weight-bearing conditions. On examination, she had pain during movement and an unstable joint. X-rays confirmed the poor condition of the joint (Figure 7. 1).

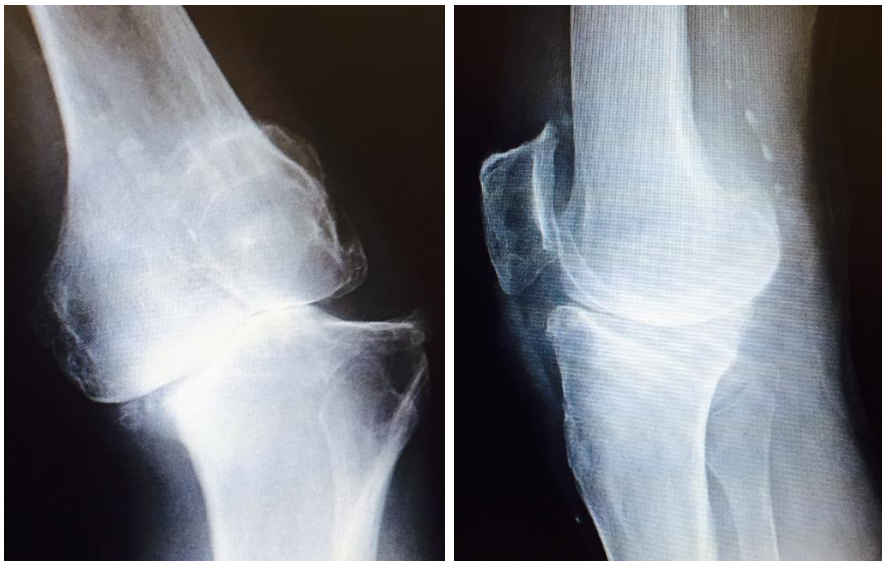


Figure 7. 1: Anteroposterior (left) and mediolateral (right) X-rays of Patient 10's operative knee pre-operatively.

The patient wished to undergo a TKA to improve her quality of life. After explaining the risks and benefits of TKA to the patient, Patient 10 was put on the list for a left TKA. On the same day, she was informed of the trial by a member of the trial team. She was recruited and randomised the following day into the conventional surgery group.

7.2.3. Surgery

Patient 10 returned to the hospital approximately 2 weeks pre-operatively for pre-admission assessments, where she underwent standard pre-surgical tests and saw the consultant surgeon. During this visit, she also attended Physio Gym 108 for functional assessments.

Patient 10 underwent TKA in 2016. In some institutions, patients with severe varus deformities are given a hinge TKA due to the lack of ligamentous support surrounding the diseased joint. However, as the Medacta GMK Sphere is fully congruent medially, the consultant was able to implant a primary TKA.

The patient was encouraged to start walking on the day of surgery. Twenty-four hours after the operation she was able to walk with the support of one walking aid. The patient spent 2 days in hospital before being discharged by hospital staff. She did not suffer any early complications following TKA.

7.2.4. Routine Follow-Up Examinations

Patient 10 returned to the hospital 6 weeks after the operation for a follow-up appointment.

The patient was extremely happy with the knee, claiming that she could carry out her hobbies and other acts of daily living much more easily than previously. She was also very happy with the alignment of the knee – which had not been straight for years. Post-operative x-rays confirmed that the implant alignment was good (Figure 7.2). The patient also demonstrated that she could walk inside and outside the hospital without a walking aid.

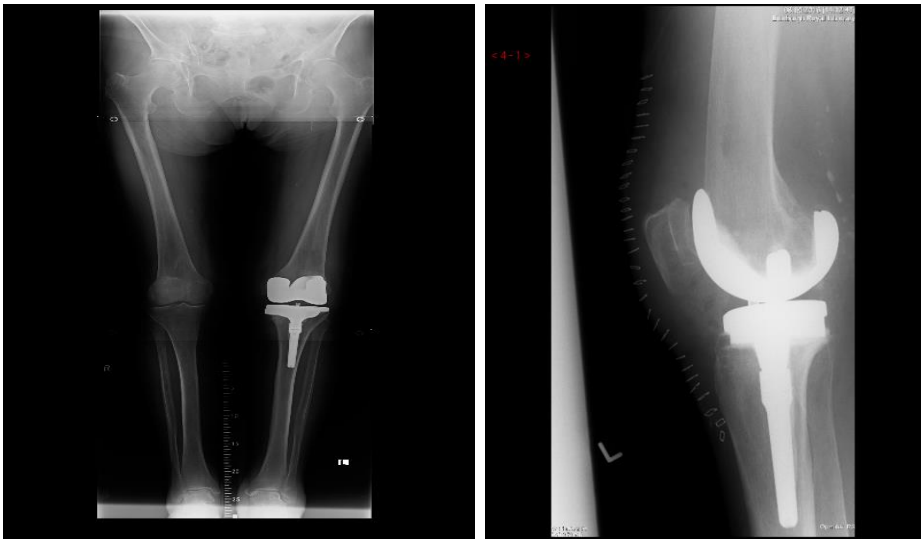


Figure 7. 2:Anteroposterior (left) and mediolateral (right) standing X-rays of Patient 10's knee six-weeks post-operatively.

At 6-weeks post-operatively, the patient no longer felt pain in the knee, nor did she suffer from sensory loss following the operation. She did however comment on the fact that the knee got very hot at night and that it was still swollen. The surgeon reassured her that the inflammation would improve with time.

The patient returned one year later for the second follow-up clinic, when the functional assessments were repeated for a final time. Patient 10 suffered from no medium-term complications.

7.2.5. Functional Outcome

Knee Range of Motion

As expected, Patient 10 achieved greater active ROM in the lesser affected knee than the operative knee. However, the opposite was found under passive conditions (Table 7.6). The patient achieved a maximum flexion angle of 105.5° and a maximum extension angle of 4.0° under active conditions. This was further extended to 1.0° under passive conditions.

Table 7. 6: Knee range of motion results for Patient 10.

Stage	Knee	Active ROM°	Passive ROM°
Pre-Operative	**Operative Knee**	101.5	104.0
	Non-Operative Knee	120.1	95.5
6 Weeks Post-Operative	**Operative Knee**	117.9	118.2
	Non-Operative Knee	141.3	143.8
1 Year Post-Operative	**Operative Knee**	151.0	148.5
	Non-Operative Knee	134.9	146.3

Six-weeks post-operatively, ROM of the operative knee improved by 16.4° actively and by 14.2° passively. The patient achieved 118.2° knee flexion and 0.3° knee

extension. No difference was observed passively (Flexion = 118.5°, Extension = 0.2°).

ROM improved by 21.2° in the non-operative knee under active conditions, and by 47.3° under passive conditions. A further improvement was also observed in passive ROM 1-year post-operatively. Active ROM was found to have decreased by 6.4° 1-year post-operatively, however.

In contrast, ROM of the operative knee continued to improve one year following TKA, exceeding baseline results (Table 7.6). When compared to the data recorded six-weeks post-operatively, active ROM was greater by 33.1° and passive ROM greater by 30.3°. Despite the improvement in maximum knee flexion, maximum knee extension had reduced since the operation (Active = 8.0°, Passive = 6.8°).

Knee Strength

Patient 10's knee flexors were stronger in the non-operative limb than the operative limb pre-operatively (Table 7.7). The opposite was found for the extensors. Baseline strengths of the flexors and extensors were comparable, regardless of the knee examined.

Table 7. 7: Maximum knee flexor and extensor strengths for Patient 10.

Stage	Knee	Max Flexor Strength (Nm)	Max Extensor Strength (Nm)
Pre-Operative	**Operative Knee**	54.4	53.6
	Non-Operative Knee	56.2	52.8
6 Weeks Post-Operative	**Operative Knee**	41.3	40.1
	Non-Operative Knee	40.4	40.9
1 Year Post-Operative	**Operative Knee**	44.5	39.7
	Non-Operative Knee	45.1	40.2

Six-weeks post-operatively, knee strength had reduced (Table 7.7). The extensors were weaker by 13.5Nm and 11.9Nm in the operative and non-operative knees, respectively. Flexor strengths reduced by similar amounts (13.1Nm in operative knee and 15.8Nm contralaterally). The strengths of both muscle groups remained comparable in both knees. The strengths of the muscles on the operative and non-operative sides were more equal than pre-operatively.

Flexor strengths improved during the first post-operative year in both knees, but not enough to return to baseline levels (Table 7.7). Little difference was observed in the extensor muscles between six-weeks and 1-year. Thus, despite restoration of the mechanical axis of the knee and an improvement in knee ROM, knee strength had decreased bilaterally in Patient 10 over the course of the first post-operative year.

Gait Analysis

Patient 10 presented with severely pathological gait pre-operatively due to the extremity of the OA in her left knee. She normally walked with one or two walking aids, depending on how far she was required to walk.

The results confirmed that Patient 10's gait was pathological in the sagittal plane pre-operatively (Figure 7. 3).

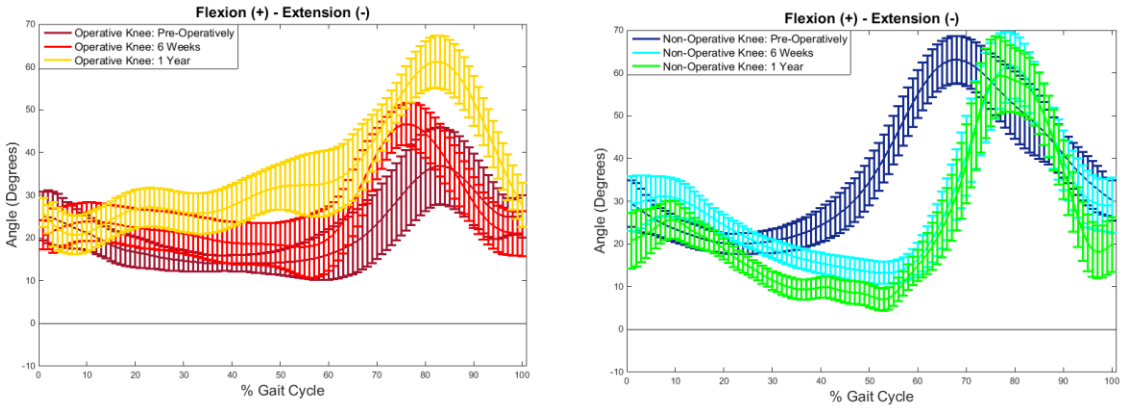


Figure 7. 3: Mean (±2SD) knee flexion angles during pre- and post-operative walking tasks (50 cycles analysed).

Key events during the gait cycle were extracted and are presented in Table 7.8. The data showed Patient 10 to have fixed-flexion at both knees during initial contact pre- and post-operatively. This did not improve in the operative knee, but an improvement of approximately 10° was recorded in the non-operative knee 1-year post-surgery.

The knee flexion angles during mid-swing increased in the operative knee between pre-operative and post-operative assessments, but a slight decrease was recorded in the non-operative knee. Excursion during the stance phase of gait decreased in both knees six-weeks following surgery. Knee flexion excursion during swing phase increased in both knees post-operatively, with greatest excursions occurring at 1-year.

Table 7.8: Mean (±SD) sagittal plane knee kinematics during key events of the gait cycle in Patient 10.

	Operative Knee			Non-Operative Knee		
Event	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**
Initial Contact	25.1 (5.7)	20.7 (3.4)	25.9 (3.4)	29.4 (5.4)	29.4 (6.4)	20.7 (6.4)
Loading Response	24.6 (6.2)	21.6 (5.2)	23.1 (5.2)	27.8 (5.1)	29.8 (6.2)	21.8 (6.2)
Mid-Stance	19.5 (3.8)	23.7 (4.4)	22.9 (4.4)	22.2 (2.9)	29.4 (3.8)	23.4 (3.8)
Terminal Stance	14.4 (2.3)	20.5 (4.7)	25.6 (4.7)	21.1 (2.9)	18.0 (2.3)	10.5 (2.3)
Mid-Swing	36.8 (9.0)	46.7 (4.9)	61.2 (6.0)	63.1 (5.5)	61.8 (7.8)	59.4 (8.0)
Excursion in Stance	11.0 (3.3)	5.9 (2.0)	13.1 (3.8)	38.5 (10.5)	17.9 (6.4)	18.7 (6.1)
Excursion in Swing	19.3 (6.0)	25.6 (9.2)	33.6 (10.3)	32.9 (11.1)	40.6 (13.0)	41.3 (15.3)

The variability of gait, as measured by the standard deviations, did not change substantially during stance, but was slightly greater kinematic variabilities were observed between cycles during swing post-operatively than pre-operatively, especially in the non-operative knee.

Given the extreme varus deformity in Patient 10's left knee, abnormalities in the frontal plane were expected. Figure 7.4 (left) shows the extreme adduction angle of the patient's operative knee during gait pre-operatively. This was consistent with the deformity. The deformity was corrected following surgery (Figure 7.4 – right), enabling the patient to achieve more typical frontal plane kinematics post-operatively.

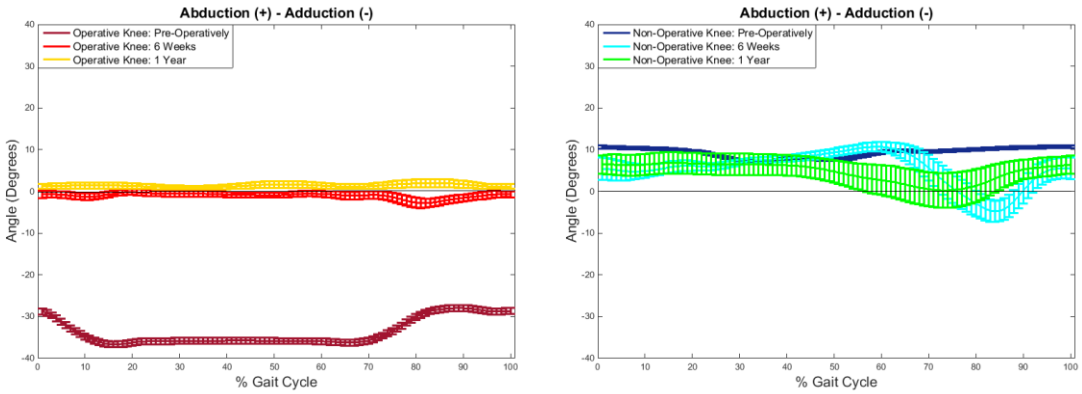


Figure 7. 4: Mean (±2SD) knee abduction angles during pre- and post-operative walking tasks (50 cycles analysed).

Table 7.9 displays the frontal plane kinematics at certain events in the gait cycle. Frontal plane kinematics of the operative knee ranged to a greater extent pre-operatively, suggesting the joint was more stable in this plane following surgery. The smallest ROM during the stance and swing phases of gait were recorded 1-year post-operatively. Six-weeks post-operatively the knee remained in adduction throughout the gait cycle, with very little rotation away from neutral occurring during swing. One year post-operatively, the knee was shown to abduct slightly throughout the gait cycle. As before, the knee did not rotate away from neutral significantly. There was no difference in the variability of the gait events between cycles from baseline to 1-year post-operatively.

Table 7.9: Mean (±SD) frontal plane knee kinematics during key events of the gait cycle in Patient 10.

	Operative Knee			Non-Operative Knee		
Event	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**
Initial Contact	-28.8 (0.7)	-0.7 (0.8)	1.2 (0.6)	10.6 (0.3)	5.4 (2.6)	6.4 (2.2)
Loading Response	-29.7 (0.7)	-0.7 (0.8)	1.2 (0.6)	10.5 (0.3)	5.2 (2.5)	6.4 (2.4)
Mid-Stance	-36.1 (0.7)	-1.1 (0.7)	1.4 (0.7)	10.2 (0.3)	5.3 (1.4)	6.7 (2.5)
Terminal Stance	-35.8 (0.7)	-0.5 (0.7)	0.8 (0.4)	7.1 (0.3)	7.3 (0.7)	6.4 (2.6)
Mid-Swing	-27.9 (0.7)	-2.8 (1.1)	2.0 (0.8)	10.7 (0.3)	-4.8 (2.5)	0.2 (8.3)
Excursion in Stance	7.8 (1.8)	1.1 (0.3)	0.8 (0.2)	3.6 (1.2)	5.9 (1.9)	4.5 (1.3)
Excursion in Swing	8.3 (3.3)	2.1 (0.7)	0.8 (0.3)	1.1 (0.4)	14.9 (4.6)	6.1 (2.3)

The non-operative knee remained abducted by approximately 10° throughout the gait cycle pre-operatively (Table 7.9). A slight adduction of the knee was observed towards the end of the stance phase of gait. Post-operatively, the degree of abduction during stance decreased. Greater adduction was observed during swing, especially six-weeks following TKA. Frontal plane ROM increased in stance and swing phases six-weeks post-operatively. The ROM reduced at 1-year, but continued to outweigh baseline values. Variability between cycles was shown to increase between each assessment.

Transverse plane kinematics of gait altered between assessments in Patient 10 (Figure 7.5). Pre-operative rotations were consistent with the deformity of the patient. Greater ROM was observed in the non-operative knee at all stages (Figure 7.5).

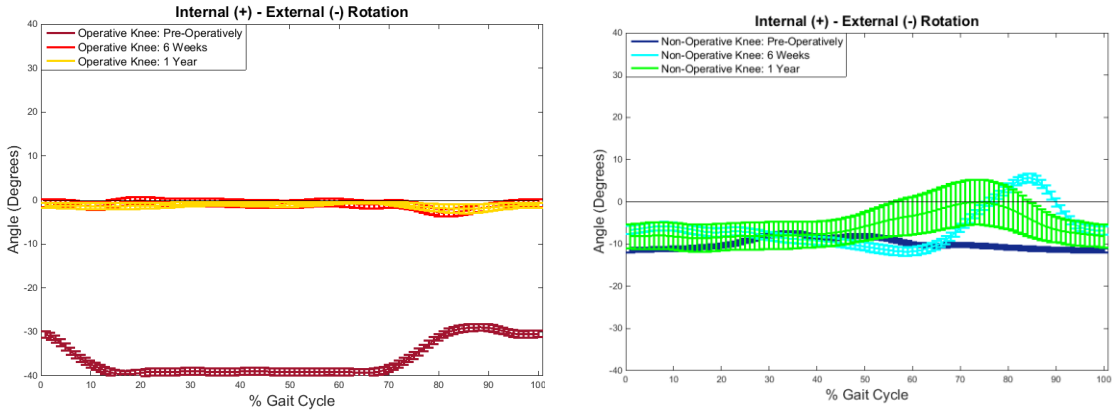


Figure 7. 5: Mean (±2SD) knee internal rotation angles during pre- and post-operative walking tasks (50 cycles analysed).

Transverse plane kinematics of both knees during gait assessments are shown in Table 7.10. These results highlight the limited rotation of the knee in this plane post-operatively in the newly operated knee. Following TKA, the operative knee was found to rotate significantly less in this plane during stance and swing. The variability did not change significantly between assessments, however.

The non-operative knee showed similar transverse plane kinematics between assessments during the stance phase of gait. Greater internal rotation was observed during the swing phase post-operatively than pre-operatively, especially at 6 weeks. Transverse plane ROM increased post-operatively in stance and swing phases of gait. The greatest ROM was observed six-weeks following TKA. Variability of transverse plane kinematics between cycles increased with each visit.

Table 7. 10: Mean (±SD) transverse plane knee kinematics during key events of the gait cycle in Patient 10.

	Operative Knee			Non-Operative Knee		
Event	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**
Initial Contact	-30.6 (0.8)	-0.7 (0.9)	-1.2 (0.6)	-11.4 (0.5)	-6.6 (1.0)	-8.2 (2.8)
Loading Response	-31.6 (0.8)	-0.7 (0.9)	-1.2 (0.6)	-11.4 (0.5)	-6.3 (1.0)	-8.2 (3.0)
Mid-Stance	-38.8 (0.8)	-1.2 (0.9)	-1.4 (0.7)	-11.0 (0.5)	-6.4 (1.0)	8.5 (3.2)
Terminal Stance	-39.0 (0.8)	-0.5 (0.9)	-0.9 (0.5)	-7.6 (0.5)	-8.5 (1.0)	-8.0 (3.2)
Mid-Swing	-28.9 (0.8)	-2.9 (0.9)	-2.0 (1.0)	-10.5 (0.5)	5.6 (1.0)	-0.1 (5.3)
Excursion in Stance	9.1 (2.1)	1.2 (0.3)	0.9 (0.2)	4.0 (1.3)	6.0 (1.9)	5.8 (1.6)
Excursion in Swing	10.3 (4.0)	2.2 (0.7)	1.5 (0.5)	1.3 (0.5)	16.8 (5.3)	8.1 (3.0)

Six-weeks following surgery, the patient's walking speed decreased, but cadence increased (Table 7.11). As a result, the step and stride lengths also decreased six-weeks post-operatively. Walking speed and step and stride lengths improved significantly 1-year post-operatively, surpassing baseline values. Cadence was also highest 1-year post-operatively. Despite these improvements, gait asymmetry increased post-operatively (Table 7.11).

Table 7. 11: Mean spatio-temporal parameters recorded during a two-minute treadmill walking task for Patient 10.

Variable	Pre-Operative	6-Weeks Post-Operative	1-Year Post-Operative
Walking Speed (m/s)	0.42	0.38	1.13
Cadence (steps/min)	56	68.5	83
Step Length (Non-Operative Limb) (m)	0.44	0.36	0.92
Step Length (Operative-Limb) (m)	0.42	0.22	0.62
Stride Length (m)	0.86	0.58	1.54

Walking Stability

Patient 10 expressed a variable gait pre-operatively – especially in the sagittal plane. Examples of sagittal and frontal plane kinematic variabilities exhibited by Patient 10 are shown in Figure 7.6 (standard deviation bars).

There were little differences in sagittal plane variances between legs, even though greater kinematic variability was observed in the non-operative limb (Figure 7.7). Variance within the UCM was found to outweigh the variance perpendicular to the UCM throughout the gait cycle in both limbs. This was also found in the frontal plane (Figure 7.7). Greater variance was observed in the operative limb, especially within the UCM at the beginning and end of the gait cycle.

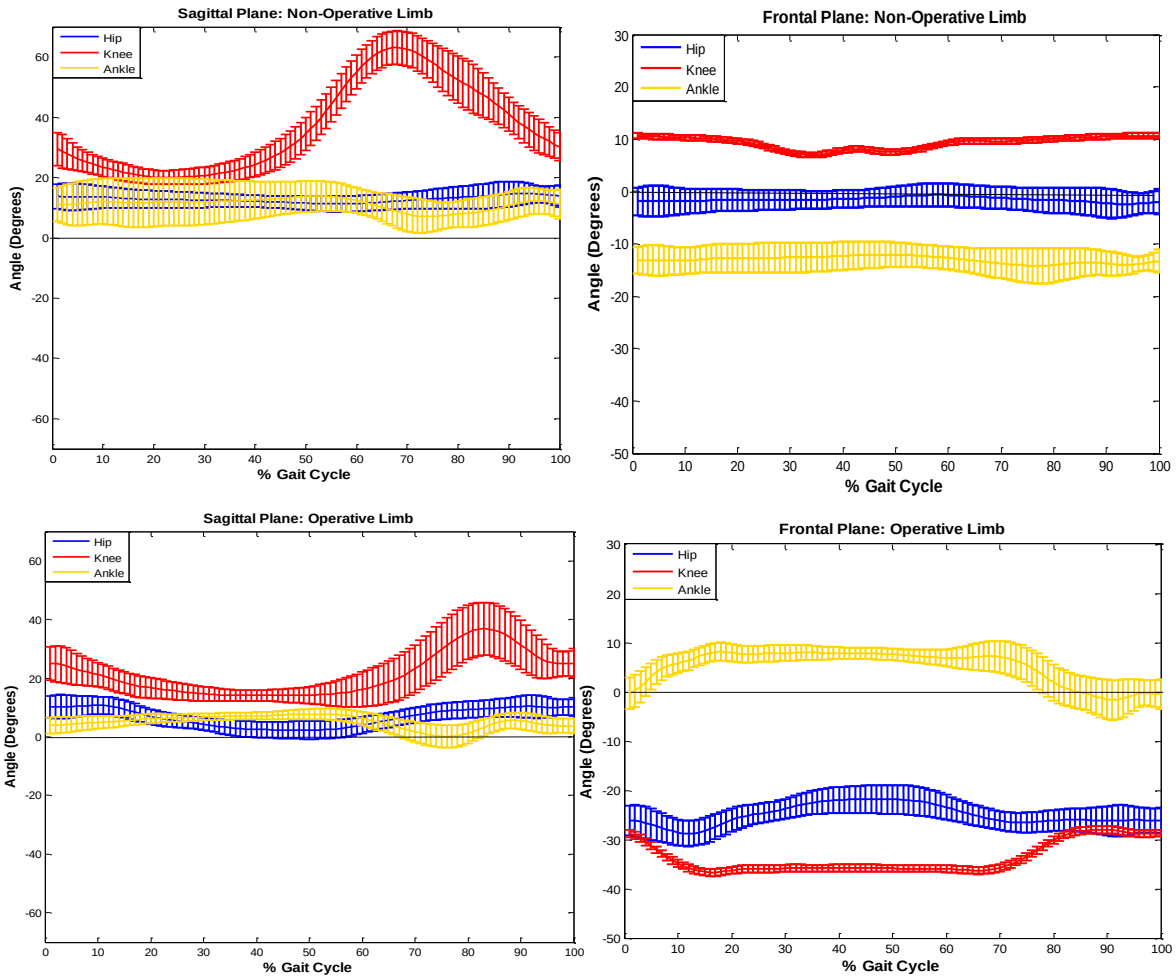


Figure 7. 6: An example of sagittal and frontal plane variability (±2SD) of hip, knee and ankle joints in Patient 10 (50 cycles analysed).

The amount of variance observed pre-operatively was significantly greater in the sagittal plane than the frontal plane (Figure 7.7). This was consistent with the kinematic results. The UCM results suggested that Patient 10 maintained a stable COM in sagittal and frontal planes pre-operatively through adopting a variable gait.

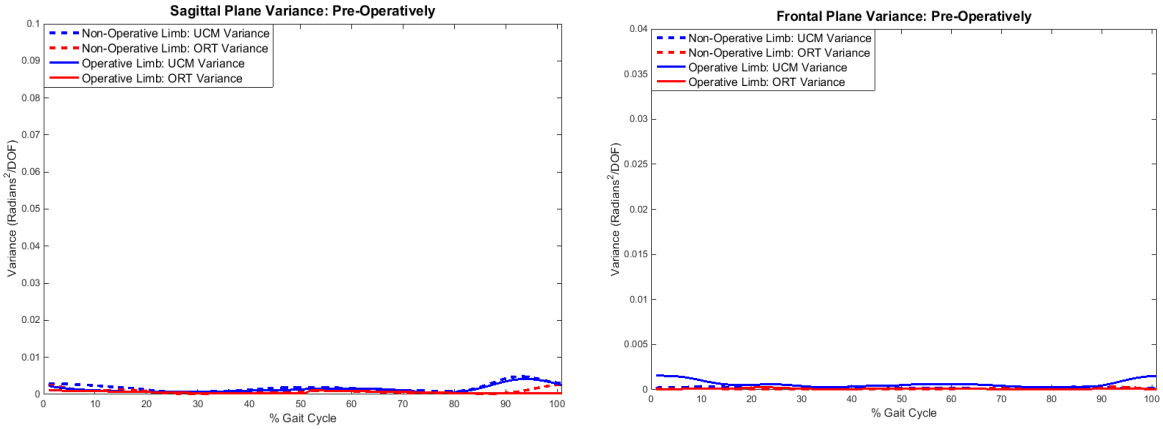


Figure 7. 7: Variances within (UCM) and perpendicular (ORT) to the linearized UCM in sagittal and frontal planes in Patient 10 pre-operatively.

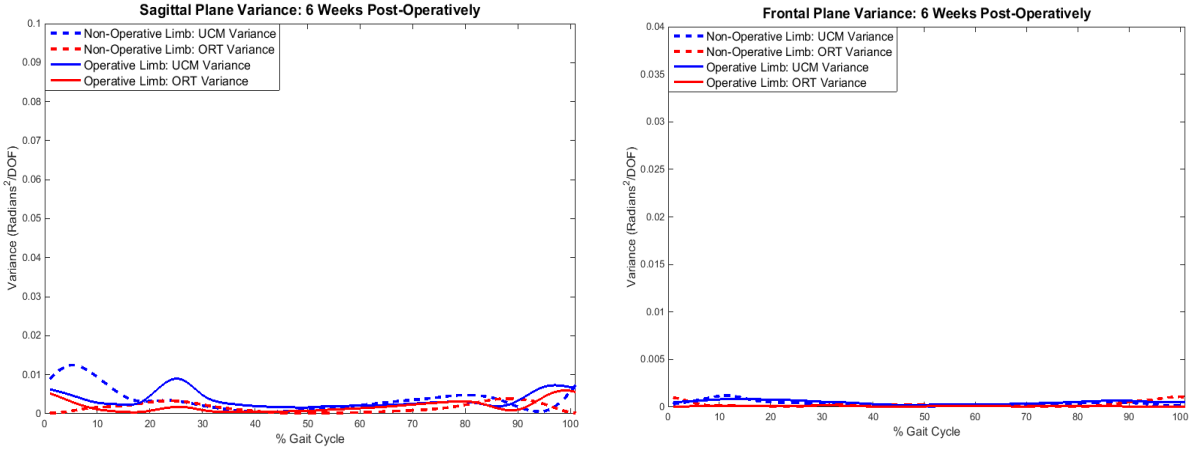


Figure 7. 8: Variances within (UCM) and perpendicular (ORT) to the linearized UCM in sagittal and frontal planes in Patient 10 six-weeks post-operatively.

Cycle-to-cycle kinematics of the hip, knee and ankle remained variable six-weeks post-operatively. Application of the UCM method on the post-operative data showed that variances within the UCM were greater than variances perpendicular to the UCM, as was found pre-operatively. However, the pattern had changed (Figure 7.8 & Figure 7.9).

Both types of variances were greater in the sagittal plane post-operatively. Sagittal plane variance in the affected limb showed a similar trend at six-weeks when compared to pre-operative results, but a second peak was now apparent during stance phase of gait. The variances observed in this plane on the non-operative limb also changed post-operatively, with peak UCM variance occurring early in the gait cycle, rather than towards the end.

Six-weeks post-operatively, frontal plane variance had decreased on the operative side, but increased on the non-operative side. Variances within the UCM were highest during mid-stance and mid-swing in both limbs.

One year post-operatively, the variances in the sagittal plane increased further in both limbs (Figure 7.9). In the operative limb, the variances were greatest at the beginning and end of the gait cycle. In the contralateral limb however, the greatest variance was reported during the swing phase of gait. Variances within the UCM continued to outweigh variances perpendicular to the UCM.

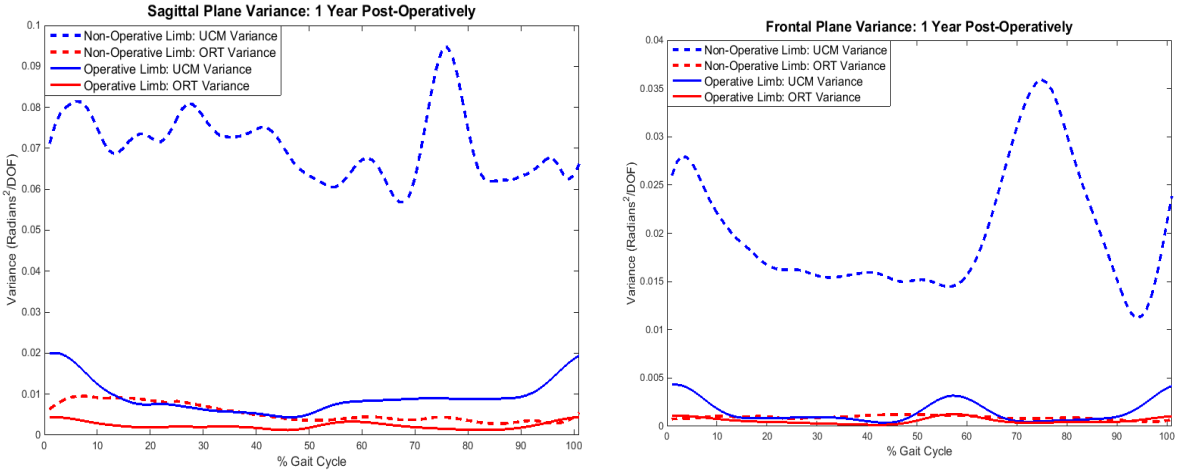


Figure 7. 9: Variances within (UCM) and perpendicular (ORT) to the linearized UCM in sagittal and frontal planes in Patient 10 one year post-operatively.

Frontal plane variances significantly increased one year post-operatively. Similar to pre-operatively, greatest variances in the operative knee were recorded at the beginning and end of the gait cycle. The variances in the non-operative knee were significantly greater 1 year post-operatively, peaking at 75% of the cycle.

Variances within the UCM continued to outweigh variances perpendicular to the UCM, suggesting the presence of kinematic synergy in Patient 10's gait.

Kinematic synergy was confirmed by plotting the ratios of the variances. The ratio remained above 0 throughout the cycle in both planes pre- and post-operatively (Figure 7.10).

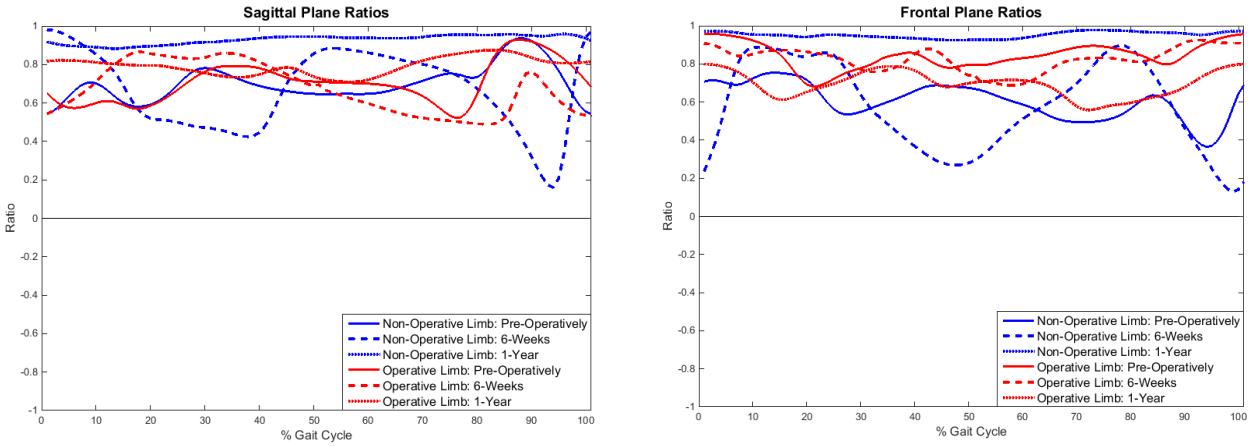


Figure 7. 10: All ratios in sagittal and frontal planes for Patient 10.

7.3. Case Study Two

Case study two discusses the functional outcome of 'Patient 7'. Patient 7 was referred to the Royal Infirmary of Edinburgh by his GP with late- to end-stage knee OA.

7.3.1. Patient History

Patient 7 is a 75-year-old male with a body mass of 103kg, height of 1.88m and a BMI of 29.1kg/m^2. The patient exhibited poor knee function at elective clinic, scoring below average (within the 29th percentile) in the functional component of the SF-12 PROM.

7.3.2. Diagnosis and Recruitment

Patient 7 attended an elective clinic at the Royal Infirmary of Edinburgh in 2016, following a diagnosis of knee OA by his GP. He underwent bilateral knee X-rays and a clinical examination at this clinic. Patient 7 reported that the pain had become so severe in recent months that he believed it was totally affecting his ability to work. He was no longer able to walk without an aid and could only walk for up to 15 minutes at a time.

The patient had predominantly medial OA with a slight varus deformity of the left knee (2.4°). X-rays of the knee are in Figure 7.11.

In addition to knee OA, Patient 7 suffered from bicuspid aortic valve disease (atrial fibrillation) and had pleural plaques. He occasionally self-medicated with paracetamol for knee pain; otherwise he was healthy.

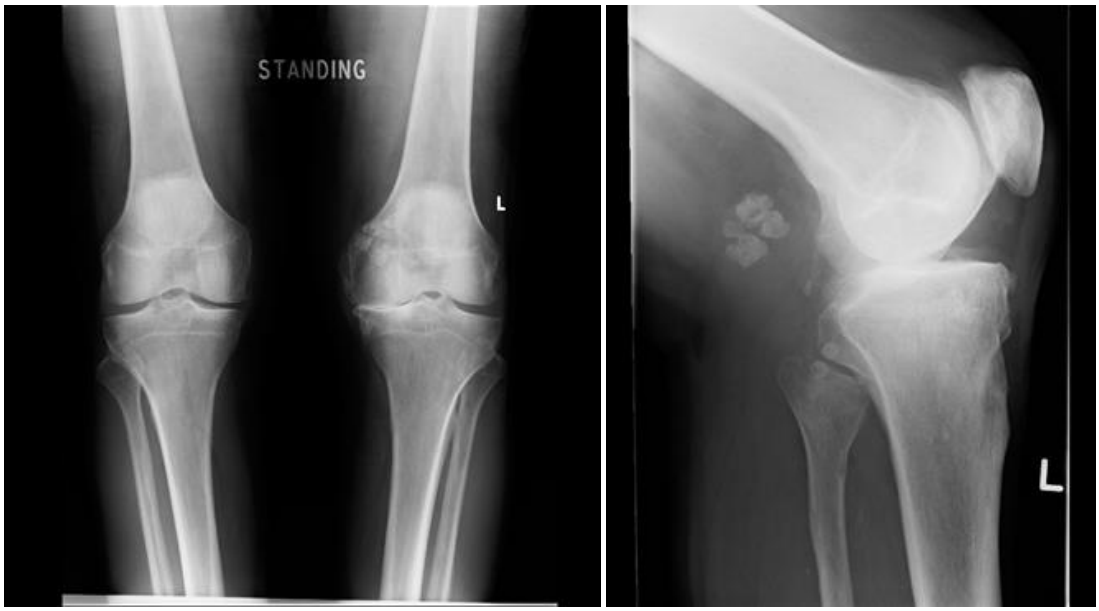


Figure 7. 11: Anteroposterior (left) and mediolateral (right) X-rays of Patient 7's operative knee pre-operatively.

Patient 7 was put on the waiting list for TKA at the elective clinic. He also agreed to participate in the clinical trial, and was fully consented the following day. Patient 7 was randomised into the conventional surgery group.

7.3.3. Surgery

All pre-admission assessments were carried out in July 2016. The operation itself was carried out the following week. The conventional approach was taken by the surgeon.

Patient 7 stayed in the hospital for 3 days following surgery. He did not suffer from any early complications following TKA.

7.3.4. Routine Follow-Up Examinations

Six-weeks post-operatively, Patient 7 returned to the hospital for routine assessments. He was delighted with the outcome, stating that the level of pain in the knee had dramatically reduced. He was also confident that he could already walk greater distances than pre-operatively. The consultant was happy with the alignment of the implant (Figure 7.12) and the state of the healing wound.

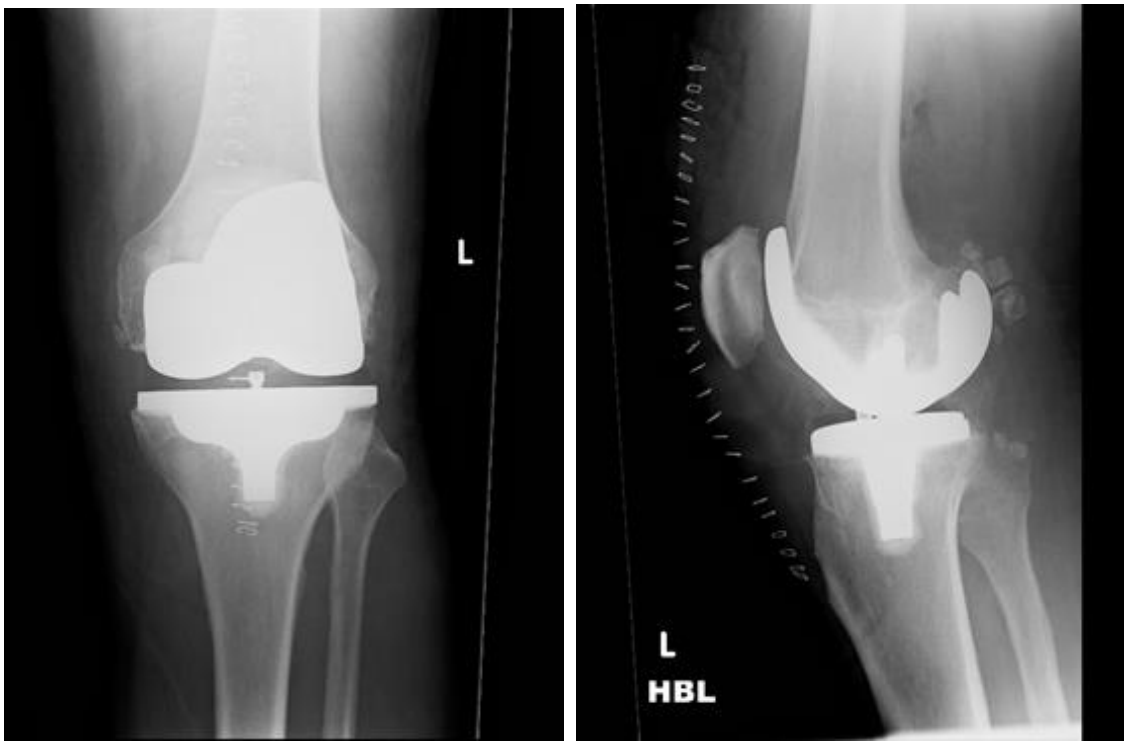


Figure 7. 12: Anteroposterior (left) and mediolateral (right) standing X-rays of Patient 7's knee post-operatively.

One year post-operatively the patient was seen for a final time by the research team. On consultation the patient was found to be progressing well and no complications were reported. The patient was very happy with the outcome of the surgery.

7.3.5. Functional Outcome

Knee Range of Motion

Pre-operatively, Patient 7 achieved greater active ROM at the operative knee than the non-operative knee (Table 7.12). The maximum flexion angle was 124.8° in the left knee and 105.0° on the right. Despite having greater ROM on the left side, the knee was unable to achieve the same degree of extension as the right.

ROM of both knees were lower under passive conditions; especially on the operative side (Table 7.12). Maximum knee extension remained poorer in the operative knee (6.7° compared to 4.0°).

Table 7. 12: Knee range of motion results for Patient 7.

Stage	Knee	Active ROM°	Passive ROM°
Pre-Operative	**Operative Knee**	120.1	95.5
	Non-Operative Knee	104.0	101.5
6 Weeks Post-Operative	**Operative Knee**	89.9	94.8
	Non-Operative Knee	122.2	128.9
1 Year Post-Operative	**Operative Knee**	120.1	124.6
	Non-Operative Knee	140.5	141.9

Active ROM of the non-operative knee improved by 18.2° six-weeks following surgery, and by 36.5° one year post-operatively. Passive ROM improved by 27.4° within the first six weeks and by 40.4° thereafter.

ROM in the operative knee reduced within the first six-weeks by 30.2° under active conditions and by 0.7° passively. Maximum extension remained >5° in the operative knee at this stage (8.8° under active conditions and 10.7° under passive conditions). One year following surgery, active ROM had returned to baseline, but passive ROM had increased by 29.1°. The patient was also able to fully extend the knee (to 1.2°); an improvement on pre-operative measurements.

Passive ROM exceeded active ROM in both knees post-operatively (Table 7.12).

Knee Strength

Patient 7's knee flexors were stronger than the extensors on the operative side during baseline assessments (Table 7.13). No differences in flexor and extensor strengths were observed in the contralateral knee, suggesting that both muscle groups were balanced in the non-operative limb.

As expected, the extensors were stronger on the non-operative side than the operative side. The converse was found with the knee flexors (Table 7.13).

There were no significant differences between muscle strengths six-weeks post-operatively. The extensors of the operative knee were the only muscle group to show a slight deterioration in maximum strength post-operatively (Table 7.13).

One year post-operatively, muscle strength was shown to have decreased in both muscle groups and limbs. The greatest reduction (of 10.7Nm) was recorded in the extensors of the operative knee. Interestingly, a loss of strength was also reported in Patient 10 post-operatively (Table 7.7). These results indicate that TKA patients have weaker quadriceps and hamstrings post-operatively than pre-operatively, despite apparent improvements in knee ROM and knee alignment.

Table 7. 13: Maximum knee flexor and extensor strengths for Patient 7.

Stage	Knee	Max Flexor Strength (Nm)	Max Extensor Strength (Nm)
Pre-Operative	**Operative Knee**	56.2	52.8
	Non-Operative Knee	54.1	54.4
6 Weeks Post-Operative	**Operative Knee**	56.6	50.9
	Non-Operative Knee	55.4	54.8
1 Year Post-Operative	**Operative Knee**	48.7	42.1
	Non-Operative Knee	46.9	48.3

Gait Analysis

Similar sagittal plane kinematics were recorded in both knees pre-operatively (Figure 7.13). Post-operatively, the ROM was found to improve, especially in the swing phase of gait.

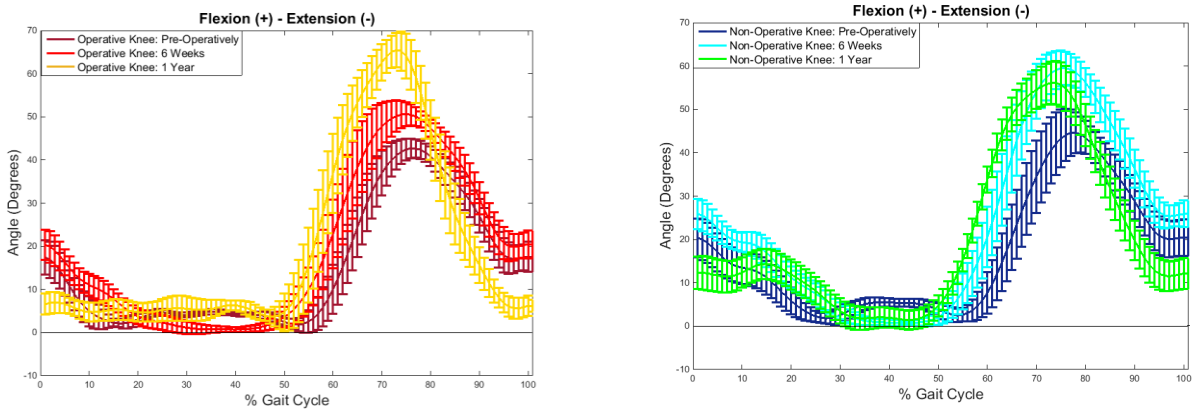


Figure 7. 13: Mean (±2SD) knee flexion angles during pre- and post-operative walking tasks (50 cycles analysed).

Pathological flexion angles were observed during initial contact in both knees, especially six-weeks following surgery (Table 7.14). This improved one-year post-operatively. Both knees were also extended to a greater degree during loading response 1-year post-operatively. The ROM of the knee in this plane during stance was greatest in both knees six-weeks post-operatively.

Table 7.14: Mean (±SD) sagittal plane knee kinematics during key events of the gait cycle in Patient 7.

	Operative Knee			**Non-Operative Knee**		
Event	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**
Initial Contact	17.4 (3.9)	20.3 (3.5)	6.6 (2.4)	20.3 (4.5)	25.8 (3.4)	12.9 (4.7)
Loading Response	15.8 (4.2)	19.0 (3.6)	7.0 (2.5)	19.1 (4.6)	24.7 (3.5)	12.2 (4.6)
Mid-Stance	3.1 (2.2)	9.4 (2.5)	5.0 (2.2)	12.6 (3.9)	18.5 (3.0)	14.0 (3.9)
Terminal Stance	4.4 (0.5)	0.9 (1.2)	5.3 (2.6)	3.6 (1.8)	2.2 (1.6)	2.3 (0.9)
Mid-Swing	42.7 (2.2)	50.6 (2.4)	65.5 (5.7)	44.6 (6.0)	59.5 (3.8)	56.1 (12.7)
Excursion in Stance	15.6 (3.9)	28.5 (7.3)	15.7 (9.1)	18.5 (5.1)	26.8 (8.6)	15.2 (3.5)
Excursion in Swing	25.7 (9.4)	30.8 (11.1)	59.9 (22.8)	29.8 (9.4)	34.1 (12.5)	44.6 (17.4)

Joint excursions during swing increased from one assessment to the next (Table 7.14). The maximum flexion angle achieved during swing also increased with time in the operative knee. Standard deviations did not alter between assessments during stance phase, but they increased during swing (Table 7.14).

Frontal plane kinematics varied by approximately 5° throughout the gait cycle pre-operatively, with greatest ROM being exhibited in the operative knee (Figure 7.14). The operative knee remained in abduction for the duration of the gait cycle (Table 7.15). Similar patterns of rotation were observed in the non-operative knee. However, this knee entered adduction at the beginning of the swing phase.

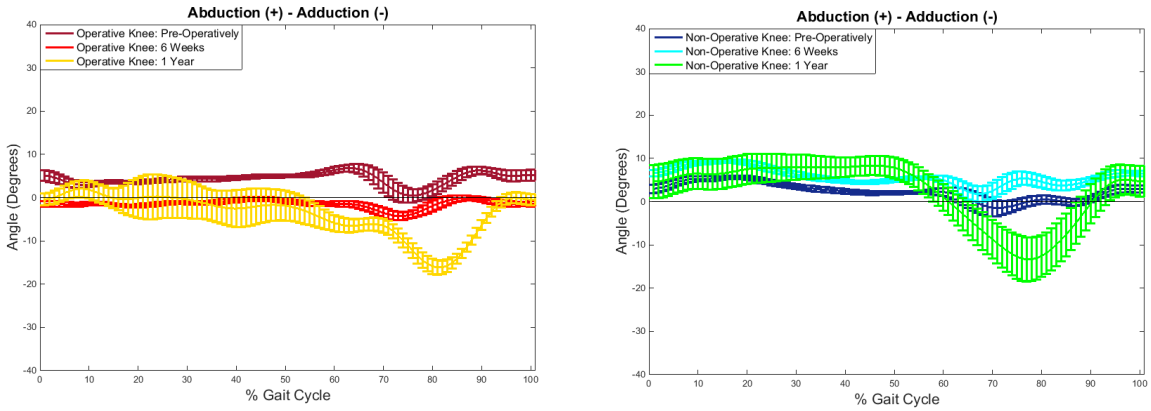


Figure 7. 14: Mean (±2SD) knee abduction angles during pre- and post-operative walking tasks (50 cycles analysed).

Six-weeks post-operatively, the movement pattern of the non- operative knee in the frontal plane did not change, but the ROM had increased (Table 7.15). Furthermore, the knee no longer adducted during the swing phase. The operative knee remained in adduction throughout the gait cycle. Minimal movement in the frontal plane was observed in this knee during stance phase.

Table 7.15: Mean (±SD) frontal plane knee kinematics during key events of the gait cycle in Patient 7.

	Operative Knee			Non-Operative Knee		
Event	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**
Initial Contact	5.1 (1.3)	1.4 (0.6)	-0.4 (1.3)	2.9 (0.9)	6.5 (0.7)	4.5 (4.7)
Loading Response	4.6 (1.3)	1.4 (0.6)	0.1 (1.5)	3.4 (1.0)	7.0 (0.8)	4.9 (4.6)
Mid-Stance	3.5 (0.4)	1.4 (0.4)	0.6 (2.1)	5.3 (0.5)	9.1 (0.4)	6.3 (3.9)
Terminal Stance	4.3 (0.6)	1.2 (0.4)	-0.9 (3.9)	3.2 (0.6)	5.9 (0.6)	8.0 (0.9)
Mid-Swing	0.4 (1.5)	0.1 (0.5)	-16.1 (1.6)	-1.5 (1.9)	1.7 (1.7)	-13.4 (12.6)
Excursion in Stance	3.8 (0.9)	1.7 (0.4)	8.4 (2.0)	3.8 (1.3)	5.3 (1.7)	9.3 (1.8)
Excursion in Swing	6.4 (2.1)	4.1 (1.3)	16.1 (5.4)	4.5 (1.4)	4.9 (1.5)	18.5 (1.6)

One year post-operatively, the ROM of both knees had significantly increased in the frontal plane during gait (Figure 7.14 & Table 7.15). The non-operative knee showed similar trends during stance phase to previous results, but far greater adduction was achieved at the joint during swing phase. The movement pattern of the operative knee resembled that of the non-operative knee, but this knee tended to remain in adduction for the majority of the gait cycle.

Transverse plane kinematics of the both knees exhibited similar patterns pre-operatively (Figure 7.15). Both knees tended towards internal rotation as they flexed in the swing phase of gait. On average, the operative knee remained externally rotated for the duration of the gait cycle, but the contralateral knee was slightly internally rotated during the initial- mid- and terminal-swing phases of gait (Table 7.16).

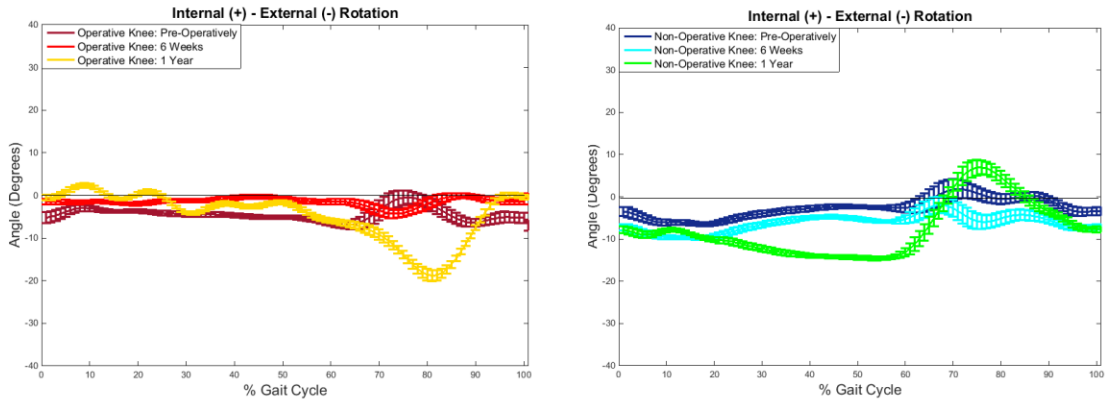


Figure 7. 15: Mean (±2SD) knee internal rotation angles during pre- and post-operative walking tasks (50 cycles analysed).

Six-weeks post-operatively, the operative knee remained externally rotated throughout the gait cycle, but the extent of the rotation was smaller than baseline ROM (Table 7.16). Converse to pre-operatively, the operated knee externally rotated by a few degrees at the beginning of the initial swing phase, before internally rotating during the mid- and terminal-swing phases. The pattern of movement was similar a year following the operation, but external rotation of the joint during the swing phase of gait was more significant (Table 7.16).

Table7.16: Mean (±SD) transverse plane knee kinematics during key events of the gait cycle in Patient 7.

	Operative Knee			Non-Operative Knee		
Event	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**
Initial Contact	-5.1 (1.3)	-1.4 (0.6)	-0.4 (1.3)	-3.5 (1.1)	-7.2 (0.8)	-7.8 (1.4)
Loading Response	-4.6 (1.3)	-1.4 (0.6)	0.1 (1.5)	-4.0 (1.2)	-7.6 (0.9)	-8.5 (1.7)
Mid-Stance	-3.5 (0.4)	-1.4 (0.4)	0.6 (2.1)	-6.1 (0.6)	-9.6 (0.4)	-8.0 (1.7)
Terminal Stance	-4.3 (0.6)	-1.2 (0.4)	-0.9 (3.9)	-3.7 (0.7)	-6.2 (0.6)	-12.7 (0.9)
Mid-Swing	-0.4 (1.5)	-4.3 (1.0)	-23.4 (1.7)	1.8 (2.3)	-1.9 (1.7)	6.9 (2.2)
Excursion in Stance	3.8 (0.9)	1.7 (0.4)	8.4 (2.0)	4.3 (1.5)	5.4 (1.8)	6.8 (1.8)
Excursion in Swing	6.4 (2.1)	4.1 (1.3)	16.1 (5.4)	8.3 (1.9)	5.3 (1.7)	16.8 (1.6)

Greater external rotation was exhibited during stance phase of gait in the non-operative knee when compared to the operative knee and its baseline ROM pre-operatively. Internal rotation occurred between the mid-stance and initial swing phases of gait. External rotation was shown to occur during terminal swing as the knee extended. The ROM increased post-operatively.

Patient 7 was able to walk faster and take longer strides post-operatively than pre-operatively (Table 7.17). Step length symmetry also improved.

Table 7. 17: Mean spatio-temporal parameters recorded during a two-minute treadmill walking task for Patient 7.

Variable	Pre-Operative	6-Weeks Post-Operative	1-Year Post-Operative
Walking Speed (m/s)	0.30	0.54	1.27
Cadence (steps/min)	52	50	70
Step Length (Non-Operative Limb) (m)	0.44	0.60	1.06
Step Length (Operative-Limb) (m)	0.26	0.60	1.08
Stride Length (m)	0.70	1.20	2.14

Walking Stability

Hip, knee and ankle kinematics varied from cycle to cycle in Patient 7 (Figure 7.16). The UCM showed that sagittal plane variances differed greatly between legs pre-operatively, especially during the swing phase (Figure 7.17). Variance within the UCM outweighed the variance perpendicular to the UCM in both limbs, especially on the operative side. Sagittal plane variance in the operative limb peaked during mid-swing, but no such peak was observed on the non-operative side.

Greater frontal plane variances were observed in the operative limb at the beginning and end of the gait cycle. The converse was found in the non-operative limb, where variances were lowest during these phases of the cycle. As in the sagittal plane, variance within the UCM outweighed the variance perpendicular to the UCM. These results suggested that kinematic synergy existed pre-operatively to stabilise the COM in gait.

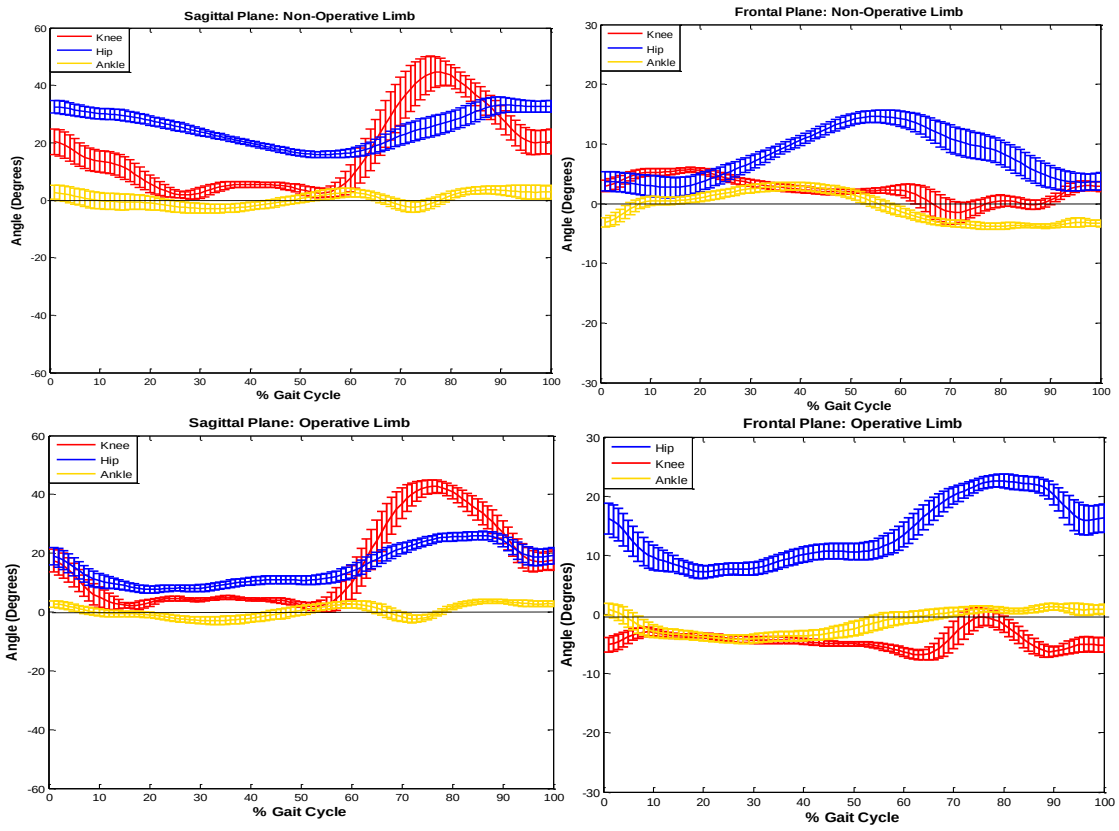


Figure 7. 16: An example of sagittal and frontal plane variability (±2SD) of hip, knee and ankle joints in Patient 7 (50 cycles analysed).

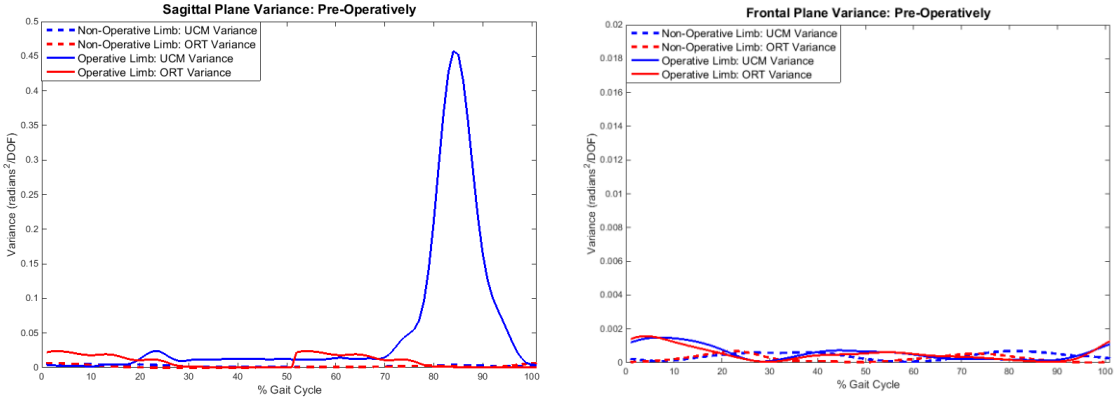


Figure 7.17: Variances within (UCM) and perpendicular (ORT) to the linearized UCM in sagittal and frontal planes in Patient 7 pre-operatively.

The magnitudes of sagittal plane variances remained similar to baseline levels six-weeks post-operatively. The peak in variance within the UCM during swing was no longer observed in the operative limb however (Figure 7.18).

The peaks in frontal plane variances were greater in the non-operative knee than the operative knee at six-weeks; converse to baseline assessments.

Variances within the UCM outweighed variances perpendicular to the UCM six-weeks following surgery.

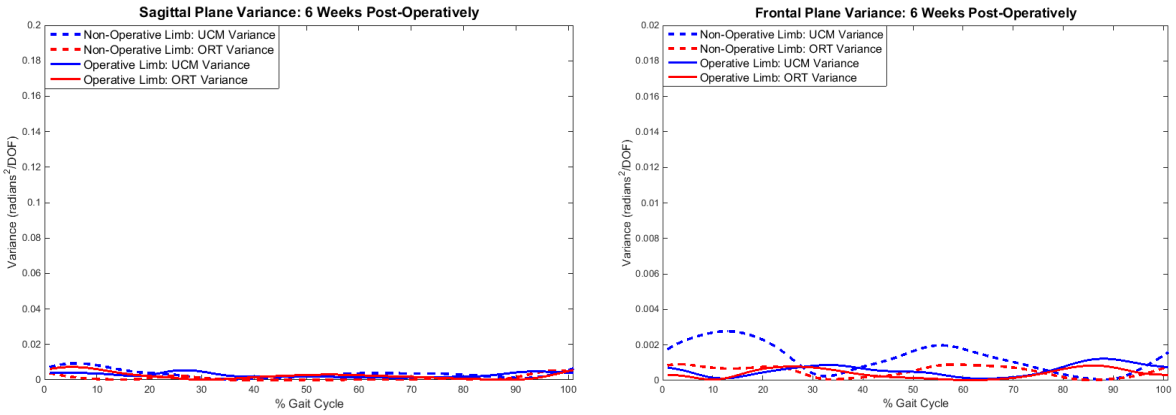


Figure 7. 18: Variances within (UCM) and perpendicular (ORT) to the linearized UCM in sagittal and frontal planes in Patient 7 six-weeks post-operatively.

One year following TKA, the magnitudes of the variances recorded in the sagittal plane increased, but the patterns of the variances were similar to those reported six-weeks following surgery (Figure 7.19). More variance was exhibited in the operative knee.

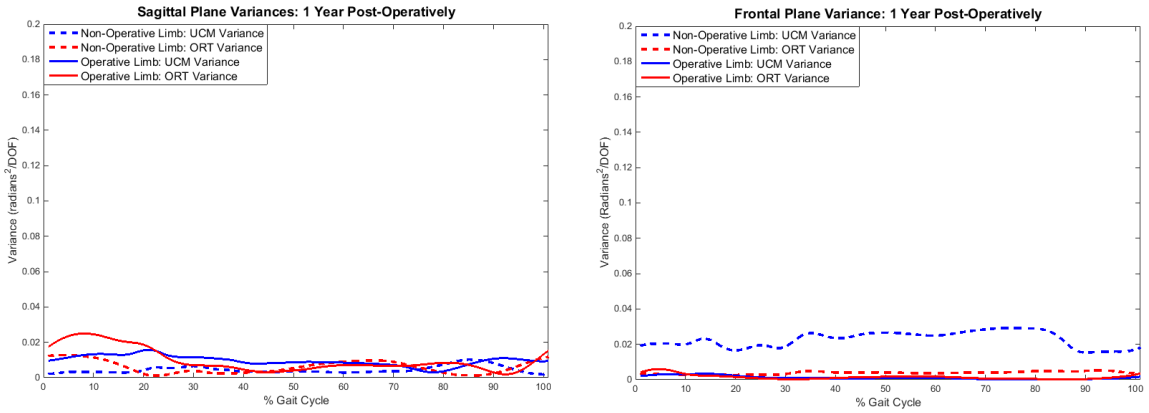


Figure 7. 19: Variances within (UCM) and perpendicular (ORT) to the linearized UCM in sagittal and frontal planes in Patient 7 one year post-operatively.

The magnitudes of frontal plane variances in the non-operative limb did not differ 1 year following surgery, but the patterns were much more consistent throughout the gait cycle. In the operative knee the variances were lower than previously recorded. Variances within the UCM outweighed those orthogonal to the UCM (Figure 7.19).

The ratios of 'good' to 'bad' variances were calculated and plotted to confirm presence of kinematic synergy (Figure 7.20). The ratios remained above 0 throughout the gait cycle in both limbs, thus the hypothesis that the CNS employed a variable gait to maintain a stable COM in this patient can be accepted.

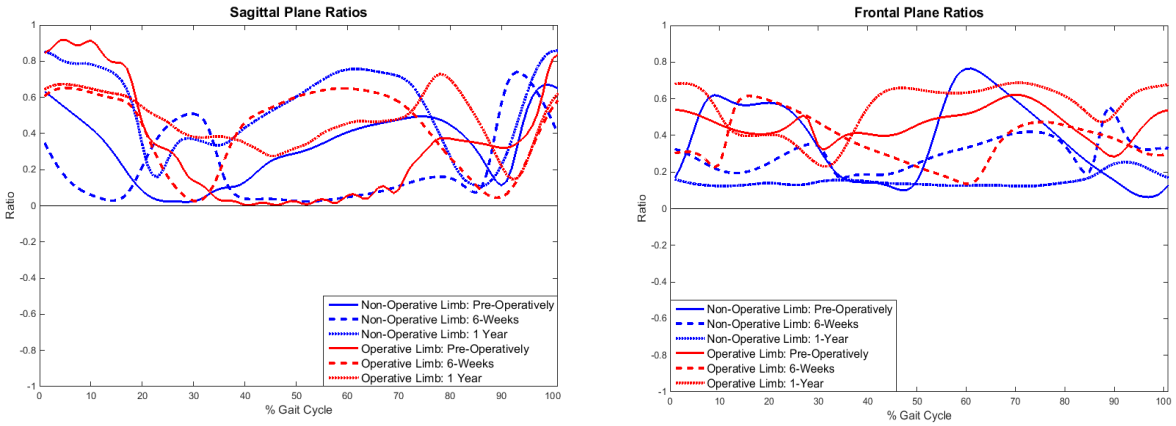


Figure 7. 20: All ratios in sagittal and frontal planes for Patient 7.

7.4. Group Analysis: Patient Population

This section will describe the results of cohorts of patients who underwent functional testing at the Royal Infirmary of Edinburgh with the bespoke motion analysis system for the Medacta GMK Sphere clinical trial.

7.4.1. Patient Demographics

Demographics of all patients whose data were analysed in this thesis are reported in Table 7.18. These demographics are based on the patients' pre-operative ages, heights and masses. The average demographics for the patients who attended all three clinics are also presented in Table 7.18 (n = 27).

Table 7. 18: Mean (± SD) patient demographics.

	Pre-Operatively (n = 63)	**Six-Weeks (n = 54)**	**1-Year (n = 30)**	**Full Dataset (n = 27)**
Sex (Male/Female)	30/33	30/24	17/13	17/10
Age (years)	71.2 (8.4)	70.7 (8.4)	72.0 (8.5)	71.7 (8.9)
Mass (kg)	83.3 (17.1)	85.4 (16.9)	86.3 (15.9)	88.2 (15.6)
Height (m)	1.65 (0.11)	1.66 (0.11)	1.67 (0.11)	1.68 (0.11)
BMI (kg/m²)	30.5 (4.7)	30.9 (4.6)	30.7 (4.2)	31.0 (4.0)
Operative Knee (Left/Right)	39/24	35/19	16/14	16/11

7.4.2. Knee Range of Motion

For the full dataset, pre-operative knee ROM was statistically greater in the non-operative knee than the operative knee (Active ROM $p = 0.004$, Passive ROM $p < 0.0001$ (Table 7.19)). However, there were no statistically significant differences between passive and active ROM in either knee (Operative Knee: $p = 0.198$; Non-Operative Knee: $p = 0.884$).

Table 7. 19: Average ROM (± SD) of both knees pre- and post-operatively.

Stage	Knee	Active ROM°	Passive ROM°
Pre-Operative (n = 63)	**Operative Knee**	100.6 (21.8)	102.0 (22.3)
	Non-Operative Knee	110.3 (19.2)	109.8 (19.0)
6 Weeks Post-Operative (n = 54)	**Operative Knee**	92.6 (22.5)	92.3 (23.5)
	Non-Operative Knee	120.0 (17.5)	119.7 (18.2)
1 Year Post-Operative (n = 30)	**Operative Knee**	116.1 (19.0)	114.7 (18.3)
	Non-Operative Knee	115.1 (24.0)	116.1 (23.8)

Mean maximum knee flexion was greater by approximately 10° in the non-operative knee pre-operatively. These differences were statistically significant: Passive $p < 0.0001$; Active $p = 0.002$ (Table 7.20). Mean maximum extension did not differ under either condition: Passive: $p = 0.709$; Active: $p = 0.789$ (Table 7.20).

The trends between non-operative and operative knee ROM persisted six-weeks post-operatively (Table 7.19 & Table 7.20). ROM had reduced in the operative knee but increased in the contralateral knee. As such, passive and active ROM of the non-operative knee continued to statistically outweigh the operative knee ($p < 0.0001$). Passive and active flexion and extension angles were also statistically different in both knees ($p < 0.0001$). When compared to baseline values, both knees extended to a greater extent six-weeks post-operatively. Improvements in maximal knee

flexion were only observed contralaterally. Despite this, the average maximum flexion achieved on the operative side remained >90°.

Passive and active ROM did not differ in either knee six-weeks post-operatively (p = 0.775 & p = 0.747, respectively).

Table 7. 20: Mean (± SD) maximum flexion and extension angles recorded at the knees of all patients pre- and post-operatively.

Stage	Knee	Active Flexion (max°)	Active Extension (max°)	Passive Flexion (max°)	Passive Extension (max°)
Pre-Operative (n = 63)	**Operative Knee**	108.0 (21.6)	7.3 (5.9)	109.2 (21.7)	7.2 (6.6)
	Non-Operative Knee	117.5 (18.2)	7.1 (6.4)	117.2 (17.0)	7.4 (6.8)
6 Weeks Post-Operative (n = 54)	**Operative Knee**	103.0 (20.5)	10.4 (8.4)	102.3 (21.0)	10.0 (8.1)
	Non-Operative Knee	126.0 (16.1)	6.0 (5.5)	125.5 (16.5)	5.8 (5.3)
1 Year Post-Operative (n = 30)	**Operative Knee**	122.8 (17.1)	6.7 (5.0)	121.0 (15.9)	6.3 (4.9)
	Non-Operative Knee	121.9 (21.8)	6.7 (5.9)	122.8 (21.7)	6.7 (5.7)

One year post-TKA, passive and active ROM of the operative knee improved beyond baseline levels (Table 7.19). Although this was also true for the contralateral knee, ROM of this knee reduced since the six-week visit.

ROM of the operative knee had improved by such a degree that there were no statistical differences between passive or active ROM of this knee and the contralateral knee: p = 0.661 & 0.312, respectively. There were also no statistical differences between passive and active flexion (p = 0.632 & 0.242) and extension angles (p = 0.921 & p = 0.531) (Table 7.20).

Passive and active ROM did not differ within limbs (Operative Knee: p = 0.310; Non-Operative Knee: p = 0.501).

Standard deviations were high throughout this study, showing the extent of variability in the data (Figure 7.19 & Figure 7.20).

To further investigate the change in knee ROM over time, the results of the patients who attended all three clinics were statistically analysed. The patients who attended all clinics had slightly poorer ROM than the general population (Table 7.19 & Table 7.21). The trends observed were similar, however.

Table 7. 21: Average ROM (± SD) of both knees pre- and post-operatively (n = 27).

Stage	Knee	Active ROM°	Passive ROM°
Pre-Operative	**Operative Knee**	100.7 (23.0)	98.6 (20.9)
	Non-Operative Knee	108.1 (24.2)	108.6 (22.4)
6 Weeks Post-Operative	**Operative Knee**	89.5 (20.5)	89.5 (20.5)
	Non-Operative Knee	116.3 (16.3)	115.1 (17.7)
1 Year Post-Operative	**Operative Knee**	114.3 (18.9)	115.9 (19.7)
	Non-Operative Knee	118.8 (23.4)	117.5 (24.0)

Generally across the year, this sub-group of patients achieved poorer maximum flexion and extension angles at the knee joint (Table 7.22). Both operative and non-operative knees improved beyond baseline levels 1-year post-operatively.

Table 7.22: Mean (± SD) maximum flexion and extension angles recorded at the knees of patients pre- and six weeks post-operatively (n = 27).

Stage	Knee	Active Flexion (max°)	Active Extension (max°)	Passive Flexion (max°)	Passive Extension (max°)
Pre-Operative	**Operative Knee**	106.3 (21.0)	5.6 (5.7)	105.1 (19.4)	6.5 (5.2)
	Non-Operative Knee	116.0 (20.8)	7.9 (6.7)	116.4 (19.8)	8.1 (7.0)
6 Weeks Post-Operative	**Operative Knee**	100.0 (18.7)	10.5 (9.5)	100.8 (18.8)	11.2 (9.9)
	Non-Operative Knee	123.1 (15.8)	6.8 (6.1)	122.7 (16.9)	7.5 (6.4)
1 Year Post-Operative	**Operative Knee**	120.7 (16.3)	6.4 (5.0)	122.7 (17.7)	6.8 (5.2)
	Non-Operative Knee	125.8 (20.6)	7.0 (5.9)	124.6 (21.1)	7.0 (6.1)

There were no differences between pre-operative and 6-weeks post-operative ROM of the non-operative knee (Table 7.23). Active ROM almost reached significance in this knee due to a significant increase in maximum active knee flexion (bold in Table 7.23).

Active ROM of the operative knee reduced significantly six-weeks post-operatively as a result of reduced knee extension (Table 7.23). The reduction in passive ROM almost reached statistical significance.

Table 7. 23: Statistical differences between pre- and post-operative (6-Weeks) ROM in both knees (n = 27): Paired t-tests.

Assessment Type		p-Value: Operative Knee	p-Value: Non-Operative Knee
ROM	**Passive**	**0.055**	0.155
	Active	**0.017***	**0.058**
Maximum Flexion	**Passive**	0.307	0.113
	Active	0.133	**0.060**
Maximum Extension	**Passive**	0.154	0.764
	Active	**0.008***	0.881

**Statistical Significance*

The non-operative knee did not improve significantly between six-weeks and 1-year (Table 7.24). Conversely, maximum extension and flexion angles achieved in the operative limb improved greatly over the course of the first year. As a result, ROM also improved significantly.

Table 7. 24: Statistical differences between six-weeks and one-year post-operative ROM in both knees (n = 27): Paired t-tests.

Assessment Type		p-Value: Operative Knee	p-Value: Non-Operative Knee
ROM	**Passive**	**<0.0001***	0.523
	Active	**<0.0001***	0.533
Maximum Flexion	**Passive**	**<0.0001***	0.594
	Active	**<0.0001***	0.443
Maximum Extension	**Passive**	**0.034***	0.753
	Active	**0.037***	0.848

**Statistical Significance*

7.4.3. Knee Strength

For the whole dataset, maximum knee strength was greater in the non-operative knee than the operative knee pre-operatively, especially during flexion (Table 7.25). Differences were statistically significant (Flexion: p = 0.026 & Extension: p = 0.039).

Table 7.25: Mean (± SD) maximum flexor and extensor strengths recorded at the knees of patients pre- and post-operatively.

Stage	Knee	Max Flexor Strength (Nm)	Max Extensor Strength (Nm)
Pre-Operative (n = 63)	**Operative Knee**	49.2 (11.7)	45.2 (10.7)
	Non-Operative Knee	53.9 (18.9)	47.1 (10.8)
6 Weeks Post-Operative (n = 54)	**Operative Knee**	50.3 (10.9)	47.3 (12.6)
	Non-Operative Knee	52.5 (14.2)	49.0 (14.8)
1 Year Post-Operative (n = 30)	**Operative Knee**	44.3 (3.7)	44.3 (7.6)
	Non-Operative Knee	45.8 (4.5)	44.6 (6.7)

Maximum flexor strengths were statistically greater than maximum extensor strengths in both knees pre-operatively (Non-operative Knee: p = 0.004 & Operative Knee: p <0.0001). Strengths generally improved six-weeks post-operatively, except for in the flexors of the non-operative knee (Table 7.25).

Average maximum strengths of the non-operative knee continued to be greater than those of the operative knee, but differences were no longer statistically significant (Flexion: p = 0.224, Extension: 0.410). The flexors of the non-operative knee were significantly stronger than the extensors six-weeks post-operatively (p = 0.001). The differences between both muscle groups in the operative knee almost reached statistical significance (p = 0.06).

One year post-operatively, the strengths of both knees were lower than previously recorded. This is a significant finding, as it indicates that the reduction in strength reported in Patient 10 (Table 7.7) and Patient 7 (Table 7.13) over the course of the first post-operative year was not individual to these patients, but was a general trend across the patient cohort. This finding is especially of interest given the patients were seemingly improving in terms of other functional outcomes such as knee ROM (Table 7.19 & Table 7.21).

Although mean strengths of the knee flexors and extensors had decreased in these patients, the spread of the data was narrower than previously reported (Table 7.25). Both knees were of similar strength 1-year post-operatively (Flexors: $p = 0.941$; Extensors: $p = 0.803$). This was also shown six-weeks following TKA, suggesting that asymmetry in knee strength between limbs improved post-operatively. There were no differences between the strengths of the flexors and extensors in either knee (Non-Operative Knee: $p = 0.413$; Operative Knee: $p = 0.346$), suggesting that knee strength asymmetry also improved within limbs.

Knee strengths of the subgroup of patients who attended all three clinics are displayed in Table 7.26. The average moments generated about the knee were similar to those recorded in all patients (Table 7.25). However, the trends differed in this subgroup. In these patients, all flexor and extensor strengths were found to reduce consistently between pre- and post-operative assessments. This contradicted the data of the whole group between baseline and 6-weeks.

Table 7. 26: Mean (± SD) maximum flexor and extensor strengths recorded at the knees of patients pre- and post-operatively (n = 27).

Stage	Knee	Max Flexor Strength (Nm)	Max Extensor Strength (Nm)
Pre-Operative	**Operative Knee**	51.1 (11.6)	46.9 (13.6)
	Non-Operative Knee	57.2 (21.2)	48.1 (10.5)
6 Weeks Post-Operative	**Operative Knee**	48.8 (6.3)	45.3 (7.3)
	Non-Operative Knee	50.1 (5.9)	46.8 (6.3)
1 Year Post-Operative	**Operative Knee**	45.8 (4.2)	39.5 (5.0)
	Non-Operative Knee	45.9 (4.6)	44.7 (6.9)

Despite the fact that the average strength reduced six-weeks post-operatively, statistical analyses showed that the differences did not reach statistical significance in either knee (Table 7.27).

Table 7. 27: Statistical differences between pre- and post-operative (6-weeks) strength in both knees (n = 27); Paired t-tests.

Assessment Type		p-Value: Operative Knee	p-Value: Non-Operative Knee
Maximum Strength	**Flexor**	0.301	0.081
	Extensor	0.518	0.525

Knee strength further reduced in this subgroup over the course of the first post-operative year, but only flexor strengths reduced by a statistically significant amount (Table 7.28).

Table 7.28: Statistical differences between six-weeks and one-year post-operative strength in both knees (n = 27); Paired t-tests.

Assessment Type		p-Value: Operative Knee	p-Value: Non-Operative Knee
Maximum Strength	**Flexor**	**0.041***	**0.009***
	Extensor	0.734	0.168

**Statistical Significance*

The results from this section of the thesis are of considerable importance, as they show that the patients were weaker bilaterally one year post-operatively than pre-operatively. This is despite improvements in knee alignment, pain levels and knee ROM. As a consequence, these patients are unlikely to be able to successfully complete some acts of daily living at this post-operative stage, especially those which are highly demanding, such as stair negotiation. In turn, some patients may not be able to retain or regain their independence within the first year post-TKA, and could be susceptible to injuries, falls or other biomechanical disorders, as they compensate for these muscular weaknesses elsewhere.

7.4.4. Gait Analysis

Gait kinematics and spatio-temporal parameters of gait are reported in this section of the thesis.

Sagittal Plane Kinematics

Mean sagittal plane kinematics for 63 pre-operative patients (averaged from 50 cycles each) are displayed in Figure 7.21.

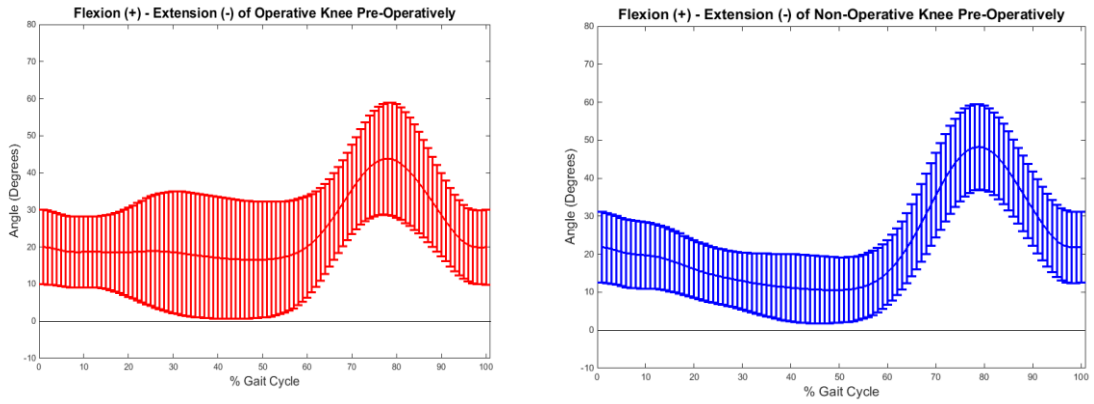


Figure 7. 21: Mean (±2SD) knee flexion-extension angles over 50 cycles of 63 patients pre-TKA.

Key variables from these assessments were extracted from the data and are presented in Table 7.29.

Pre-operatively, patients made initial contact with the treadmill with the knee flexed by approximately 20° (Figure 7.21 & Table 7.29). The non-operative knee displayed a higher degree of flexion at this stage of the gait cycle than the operative knee. The first flexion wave, typically observed in normal walking was missing in the loading response phase. As the stance phase progressed, both knees extended gradually. The non-operative knee achieved a greater maximal knee flexion angle during the swing phase than the operative knee. Rapid extension of both knees

followed during terminal swing in preparation for the next step. Neither knee became fully extended towards the end of the gait cycle.

Table 7.29: Mean (±SD) sagittal plane knee kinematics during key events of the gait cycle in trial patients (pre-operative n = 63; 6-weeks n = 54; 1-year n = 30).

	Operative Knee			**Non-Operative Knee**		
Event	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**
Initial Contact	20.0 (10.0)	23.3 (9.8)	28.2 (11.7)	21.8 (9.3)	20.8 (9.4)	25.6 (9.9)
Loading Response	19.6 (10.0)	22.9 (9.6)	27.6 (11.5)	21.3 (9.1)	20.5 (9.2)	25.2 (9.7)
Mid-Stance	18.7 (9.6)	21.3 (9.1)	25.6 (11.7)	19.1 (8.4)	19.0 (8.7)	24.1 (9.9)
Terminal Stance	18.3 (16.7)	17.7 (8.7)	17.4 (7.3)	12.5 (7.8)	13.1 (7.1)	15.6 (7.9)
Mid-Swing	43.8 (14.6)	46.1 (12.5)	58.3 (9.5)	48.3 (11.6)	47.7 (11.0)	52.1 (11.9)
Excursion in Stance	5.6 (1.1)	9.5 (2.3)	15.0 (4.8)	11.3 (3.7)	10.9 (3.3)	14.6 (4.7)
Excursion in Swing	23.9 (8.4)	22.9 (7.9)	30.1 (10.6)	28.5 (9.8)	26.9 (9.4)	26.5 (9.3)

The only event that showed statistical significance between knees pre-operatively was terminal stance phase, where the operative knee exhibited greater flexion than the non-operative knee (Table 7.29 & Table 7.30).

Table 7.30: Results of paired t-tests on specific sagittal plane kinematic gait events pre-operatively (n = 63).

Gait Event	p-Value
Initial Contact	0.241
Loading Response	0.277
Mid-Stance	0.765
Terminal Stance	**0.013***
Mid-Swing	0.836

**Statistical Significance*

Six-weeks post-operatively both knees remained in fixed-flexion during initial contact (Figure 7.22 & Table 7.29). The first flexion wave was missing, but both knees extended slightly during stance phase. The newly operated knee extended to a lesser degree than the contralateral knee. Average maximum flexion angles achieved during the swing phase of gait remained higher in the non-operative knee. However, mean values had improved when compared to pre-operatively. As expected, both knees extended during mid- and terminal swing phases of gait. As was observed pre-operatively, the only statistical differences between knees were observed during the terminal stance phase (Table 7.31).

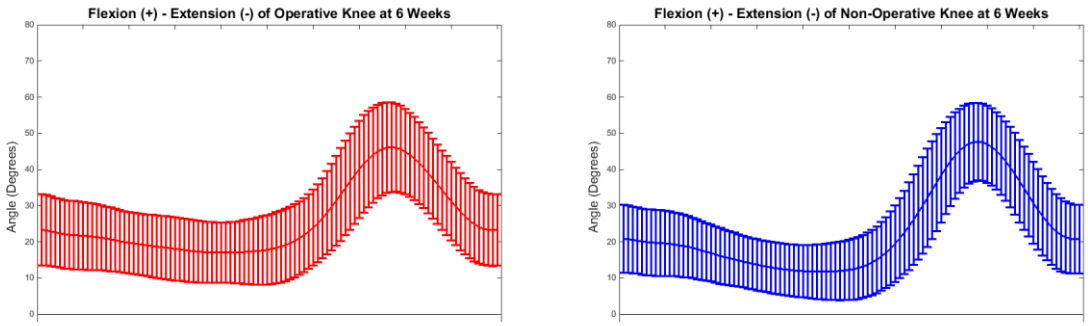


Figure 7. 22: Mean (±2SD) knee flexion-extension angles over 50 cycles of 54 patients six-weeks post-TKA.

Table 7. 31: Results of paired t-tests on specific sagittal plane kinematic gait events 6-weeks post-operatively (n = 54).

Gait Event	p-Value
Initial Contact	0.105
Loading Response	0.111
Mid-Stance	0.083
Terminal Stance	**0.001***
Mid-Swing	0.469

**Statistical Significance*

One year post-operatively, the patients continued to show signs of pathological gait at initial contact (Figure 7.23 & Table 7.29). This persisted into the loading response and mid-stance events of the gait cycle.

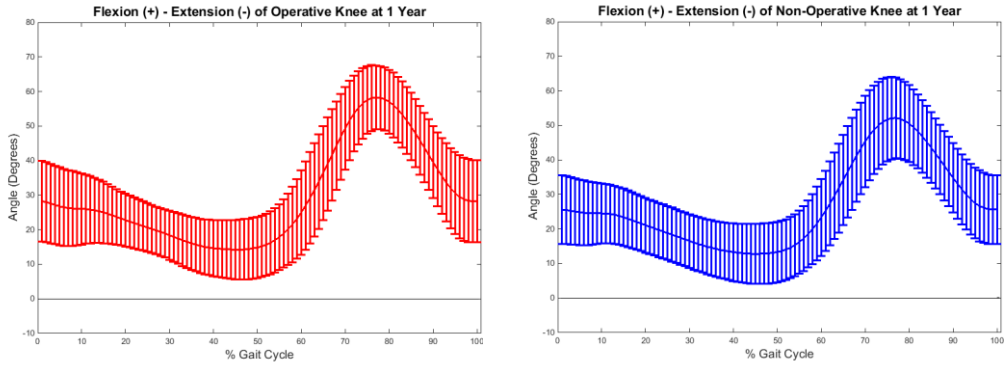


Figure 7. 23: Mean (±2SD) knee flexion-extension angles over 50 cycles of 30 patients one-year post-TKA.

As was previously observed, both knees extended during the latter half of the stance phase before flexing once more during swing. The maximum knee flexion angle achieved was greater than previously recorded in both knees. Statistical

analyses showed that there were no longer any differences between knees during stance phase, but the maximum angle achieved at the knee during swing was now statistically greater in the operative knee than the non-operative knee (Table 7.32).

Table 7. 32: Results of paired t-tests on specific sagittal plane kinematic gait events 1-year post-operatively (n = 30).

Gait Event	p-Value
Initial Contact	0.113
Loading Response	0.147
Mid-Stance	0.228
Terminal Stance	0.168
Mid-Swing	**<0.0001***

**Statistical Significance*

Sagittal plane range of movement at the knee tended to increase post-operatively during stance and swing, but the degree of kinematic variability remained similar over time (Table 7.29).

Figure 7.24 combines the data presented in Figures 7.20-7.23 for all patients and compares these against the data recorded in 27 patients who attended all three clinics.

Although the graphs show differences between both groups, the data during key events of the gait cycle were not vastly different (Table 7.29 & Table 7.33). The greatest difference was observed in the non-operative knee pre-operatively. The subgroup of patients who attended all clinics had slightly better extension during stance and greater ROM during swing. However, differences were within 5°, suggesting no clinical significance.

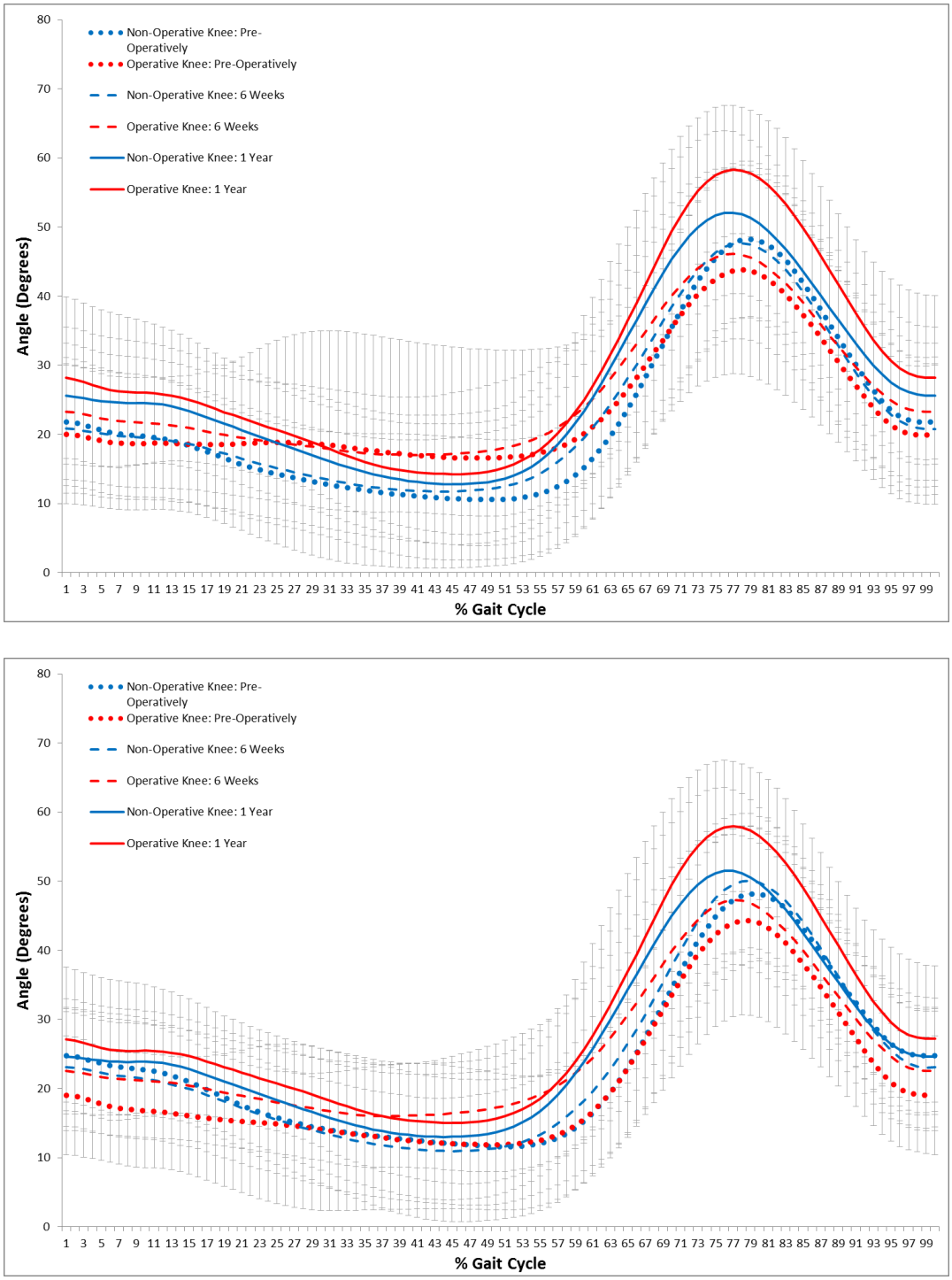


Figure 7. 24: Sagittal plane knee kinematics of all assessed patients (above) and of the 27 patients who attended all three clinics (below).

Table 7. 33: Mean (±SD) sagittal plane knee kinematics during key events of the gait cycle in 27 patients.

	Operative Knee			Non-Operative Knee		
Event	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**
Initial Contact	19.1 (8.6)	22.5 (8.6)	27.1 (10.4)	24.8 (6.8)	23.1 (8.6)	24.6 (8.3)
Loading Response	18.5 (8.5)	22.2 (8.4)	26.6 (10.1)	24.3 (6.8)	22.8 (8.6)	24.4 (8.1)
Mid-Stance	16.4 (8.2)	20.8 (8.1)	25.2 (10.4)	21.9 (6.3)	20.6 (8.5)	23.5 (8.3)
Terminal Stance	13.7 (11.4)	16.5 (7.4)	17.8 (7.5)	13.8 (8.6)	13.0 (7.7)	15.4 (8.2)
Mid-Swing	44.3 (13.5)	47.3 (9.6)	57.9 (9.7)	48.2 (10.5)	50.1 (10.3)	51.5 (12.0)
Excursion in Stance	7.2 (2.1)	9.8 (2.4)	14.8 (4.3)	13.2 (4.4)	12.2 (4.2)	14.8 (4.4)
Excursion in Swing	25.3 (9.1)	24.8 (8.5)	30.7 (10.8)	28.8 (9.2)	27.3 (9.8)	26.8 (9.4)

There were no significant differences in sagittal plane kinematics of the non-operative knee of the subgroup six-weeks post-operatively when compared to the total dataset (Table 7.34). In the operative knee however, the differences were greater, especially during stance. Knee flexion during mid-stance was significantly greater six-weeks post-operatively. There were no differences in the maximum knee flexion achieved during mid-swing between pre- and six-weeks post-operative assessments (Table 7.34).

Table 7. 34: Statistical differences between pre- and post-operative (6-weeks) sagittal plane kinematics in both knees (n = 27): Paired t-tests.

Gait Event	p-Value: Operative Knee	p-Value: Non-Operative Knee
Initial Contact	0.084	0.433
Loading Response	0.061	0.469
Mid-Stance	**0.020***	0.495
Terminal Stance	0.289	0.695
Mid-Swing	0.430	0.594

**Statistical Significance*

There were no further differences in sagittal plane kinematics of the contralateral knee between six- and one-year post-operative assessments (Table 7.35). Knee flexion remained statistically different in the operative knee during mid-stance. Otherwise, the kinematics recorded during stance phase of gait remained similar. During swing however, the maximum knee flexion angle achieved was found to increase significantly between six-weeks and one-year post-operatively (Table 7.35).

Table 7. 35: Statistical differences between 6-weeks and 1-year post-operative sagittal plane kinematics in both knees (n = 27): Paired t-tests.

Gait Event	p-Value: Operative Knee	p-Value: Non-Operative Knee
Initial Contact	0.078	0.490
Loading Response	0.083	0.457
Mid-Stance	**0.038***	0.118
Terminal Stance	0.432	0.137
Mid-Swing	**<0.0001***	0.565

**Statistical Significance*

Frontal Plane Kinematics

During pre-operative gait assessments, the non-operative knee remained abducted by approximately 2° throughout stance (Figure 7.25; Table 7.36). As the swing phase was entered, the knee began to adduct. Towards the end of the gait cycle, the knee returned to an abducted position.

In contrast, the pre-operative knee remained in adduction throughout the gait cycle (Figure 7.25). Greatest adduction of the knee occurred during swing phase, with abduction occurring towards the end of the cycle (Table 7.36).

Paired t-tests were carried out on the data. Despite graphical differences, the data were not sufficiently different between both knees to be statistically significant in any event other than terminal stance (Table 7.37).

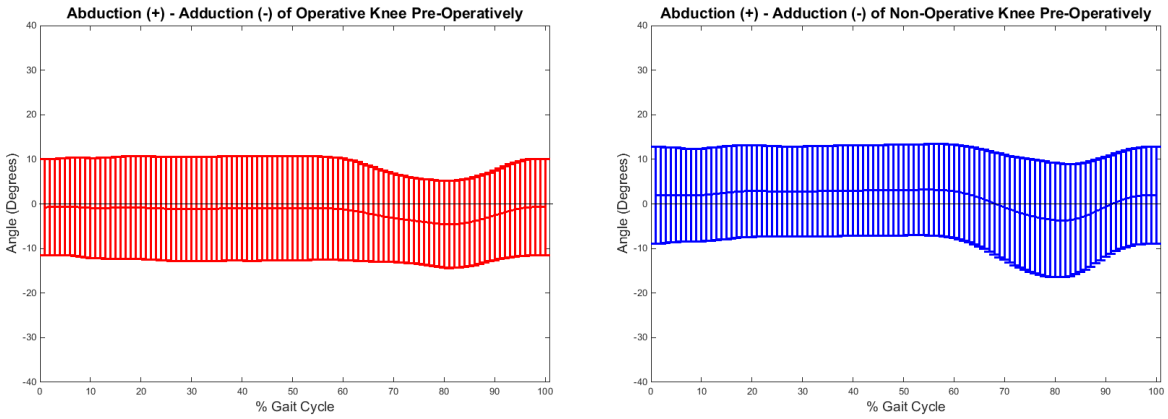


Figure 7. 25: Mean (±2SD) knee abduction-adduction angles over 50 cycles of 63 patients pre-TKA.

Table 7. 36: Mean (±SD) frontal plane knee kinematics during key events of the gait cycle in trial patients (preoperative n = 63; 6-weeks n = 54; 1-year n = 30).

	Operative Knee			Non-Operative Knee		
Event	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**
Initial Contact	-0.7 (10.8)	0.8 (8.2)	1.7 (9.6)	1.9 (10.9)	1.4 (10.3)	0.5 (9.9)
Loading Response	-0.7 (10.8)	1.0 (8.2)	1.9 (9.4)	2.0 (10.7)	1.6 (10.4)	0.7 (9.9)
Mid-Stance	-0.9 (11.3)	2.2 (8.1)	2.6 (9.6)	2.3 (10.4)	2.3 (10.5)	1.2 (9.9)
Terminal Stance	-1.1 (11.6)	3.5 (8.4)	3.4 (8.1)	2.8 (10.1)	3.5 (10.4)	2.8 (10.5)
Mid-Swing	-5.6 (9.6)	-3.3 (8.4)	-3.0 (8.2)	-3.7 (12.7)	-3.4 (9.2)	-5.6 (7.9)
Excursion in Stance	0.9 (0.2)	3.0 (0.9)	2.2 (0.6)	1.2 (0.4)	2.7 (0.8)	2.9 (0.9)
Excursion in Swing	3.9 (1.3)	6.3 (1.9)	6.0 (1.8)	5.8 (2.1)	6.5 (2.0)	6.9 (2.3)

Table 7.37: Results of paired t-tests on specific frontal plane kinematic gait events pre-operatively (n = 63).

Gait Event	p-Value
Initial Contact	0.154
Loading Response	0.149
Mid-Stance	0.085
Terminal Stance	**0.037***
Mid-Swing	0.442

** Statistical significance.*

Six-weeks following surgery, frontal plane rotation of the non-operative knee remained similar to that observed during baseline assessments (Figure 7.26). However, the degree of adduction achieved at the joint during the swing phase was not as large post-operatively.

Frontal plane movement of the operative knee better reflected the contralateral knee post-operatively (Figure 7.26 & Table 7.36). The joint was now abducted during the stance phase and adducted during swing. There were no statistical differences between frontal plane kinematics of both knees (Table 7.38).

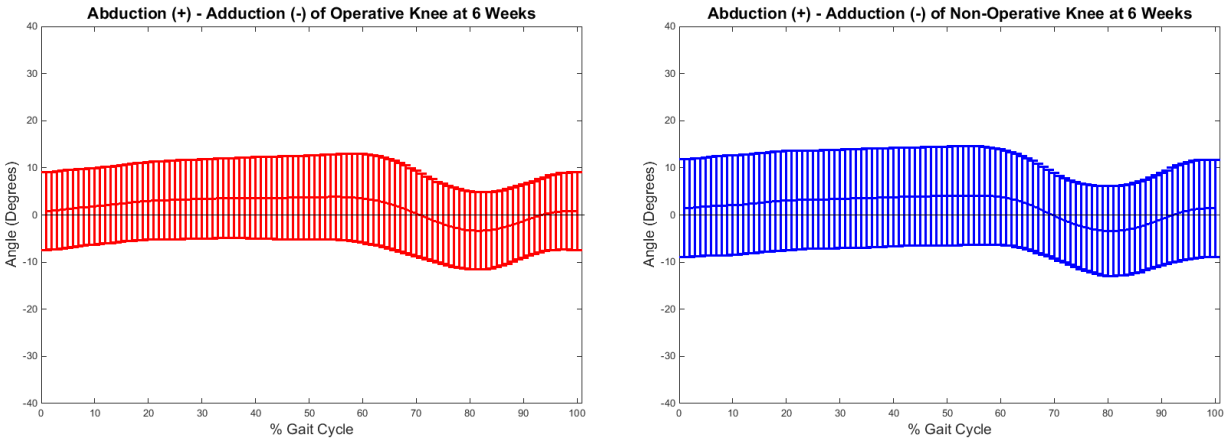


Figure 7. 26: Mean (±2SD) knee abduction-adduction angles over 50 cycles of 54 patients six-weeks post-TKA.

Table 7. 38: Results of paired t-tests on specific frontal plane kinematic gait events 6-weeks post-operatively (n = 54).

Gait Event	p-Value
Initial Contact	0.741
Loading Response	0.758
Mid-Stance	0.934
Terminal Stance	0.993
Mid-Swing	0.522

Trends in frontal plane kinematics did not change between the second and third assessments (Figure 7.27 & Table 7.36). There were no statistical differences between both knees (Table 7.39).

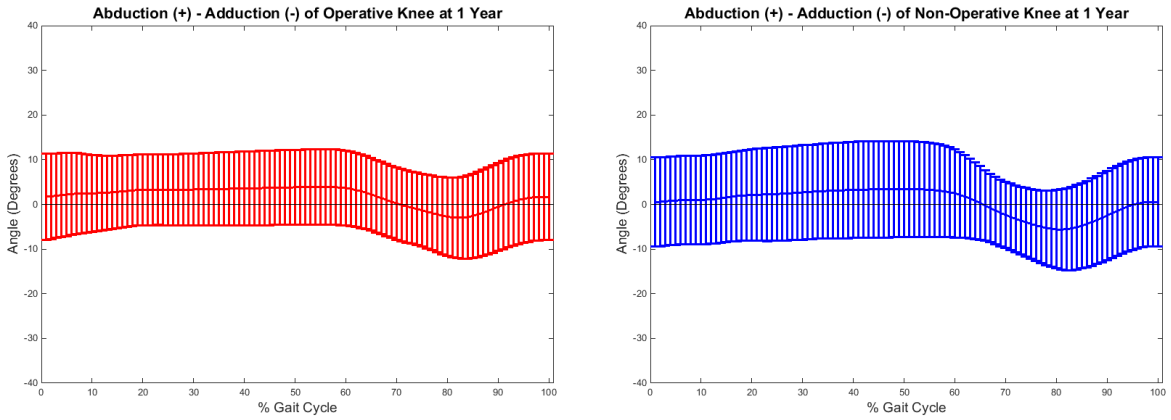
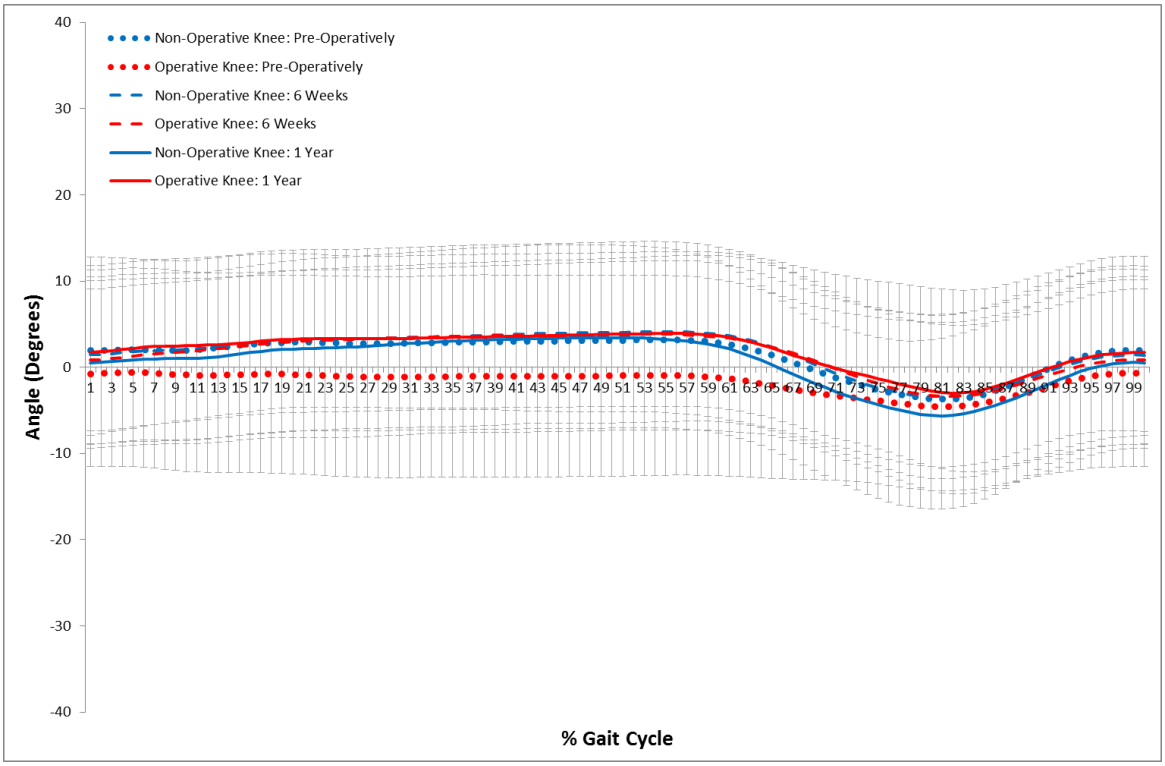


Figure 7.27: Mean (±2SD) knee abduction-adduction angles over 50 cycles of 30 patients one year post-TKA.

Table 7. 39: Results of paired t-tests on specific frontal plane kinematic gait events 1-year post-operatively (n = 30).

Gait Event	p-Value
Initial Contact	0.638
Loading Response	0.622
Mid-Stance	0.576
Terminal Stance	0.794
Mid-Swing	0.281

Figure 7.28 shows the frontal plane data recorded in all patients compared to the data recorded in the 27 patients who attended all three clinics. Few differences were observed between both groups (Figure 7.28; Table 7.36; Table 7.40).



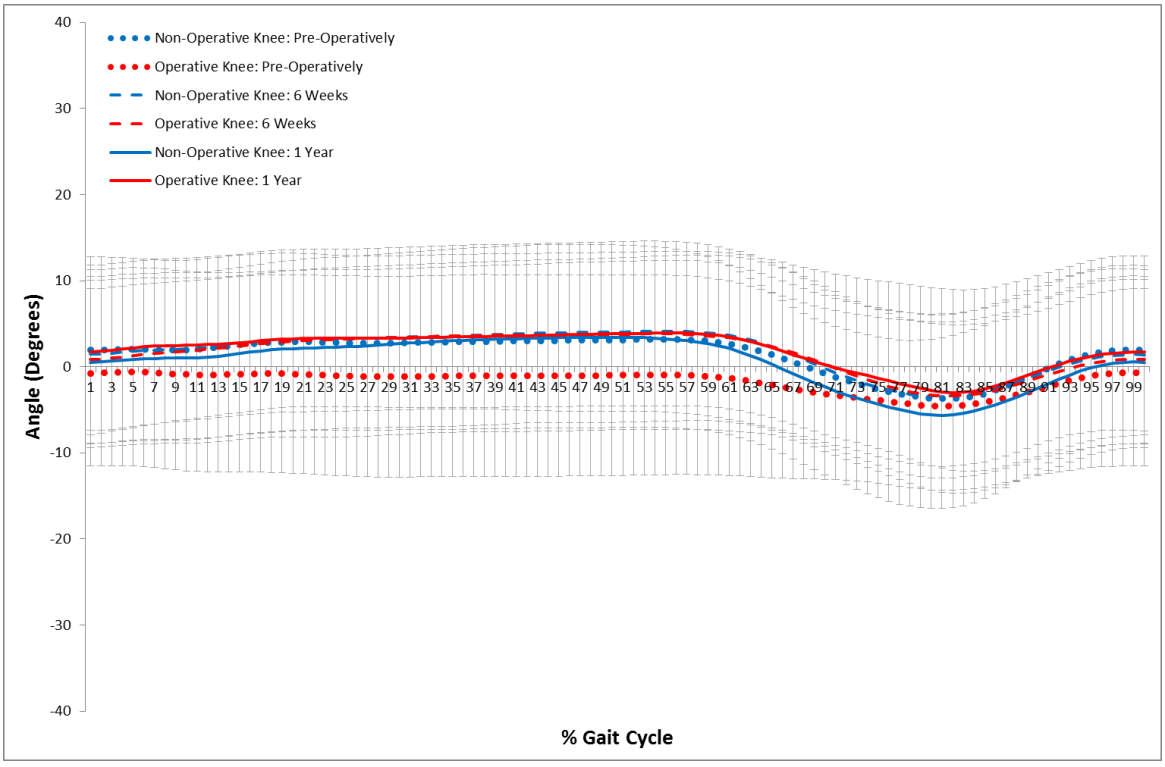


Figure 7.28: Frontal plane knee kinematics of all assessed patients (above) and of the 27 patients who attended all three clinics (below).

Table 7. 40: Mean (±SD) frontal plane knee kinematics during key events of the gait cycle in 27 patients.

	Operative Knee			Non-Operative Knee		
Event	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**
Initial Contact	-2.3 (11.1)	2.6 (7.4)	1.7 (10.0)	1.6 (10.0)	2.1 (8.9)	0.4 (9.7)
Loading Response	-2.2 (11.3)	2.8 (7.5)	1.9 (9.9)	1.7 (9.9)	2.2 (8.8)	0.5 (9.7)
Mid-Stance	-2.5 (12.4)	3.7 (7.7)	2.5 (10.0)	1.8 (9.6)	3.1 (9.0)	0.8 (9.7)
Terminal Stance	-2.1 (13.3)	4.7 (8.1)	3.2 (8.2)	3.1 (9.4)	4.4 (8.9)	2.1 (10.2)
Mid-Swing	-5.5 (10.1)	-2.5 (8.7)	-3.0 (8.7)	-1.9 (13.8)	-4.5 (8.6)	-5.8 (8.1)
Excursion in Stance	0.8 (0.2)	2.2 (0.6)	1.9 (0.5)	1.9 (0.7)	2.7 (0.8)	2.2 (0.7)
Excursion in Swing	3.2 (1.1)	6.3 (2.0)	5.7 (1.8)	4.3 (1.3)	8.0 (2.6)	6.4 (2.2)

Key events of the gait cycle were shown to statistically differ in the frontal plane between pre-operative and six-week post-operative assessments, but only in the operative knee (Table 7.41). No statistical differences were seen in either knee between six-weeks and one-year assessments (Table 7.42).

Table 7.41: Statistical differences between pre- and post-operative (6-weeks) frontal plane kinematics in both knees (n = 27): Paired t-tests.

Gait Event	p-Value: Operative Knee	p-Value: Non-Operative Knee
Initial Contact	**0.024***	0.809
Loading Response	**0.023***	0.753
Mid-Stance	**0.013***	0.468
Terminal Stance	**0.006***	0.439
Mid-Swing	**0.027***	0.641

** Statistical significance.*

Table 7. 42: Statistical differences between 6-weeks and 1-year post-operative frontal plane kinematics in both knees (n = 27): Paired t-tests.

Gait Event	p-Value: Operative Knee	p-Value: Non-Operative Knee
Initial Contact	0.653	0.395
Loading Response	0.646	0.385
Mid-Stance	0.539	0.237
Terminal Stance	0.422	0.260
Mid-Swing	0.570	0.498

Transverse Plane Kinematics

Pre-operatively, both knees remained in external rotation for the duration of the gait cycle (Figure 7.29). The knees exhibited very little rotation in the transverse plane during stance (Table 7.43). Internal rotation was recorded during swing; more notably so in the non-operative knee. There were no differences between transverse plane kinematics of both knees during key events of the gait cycle (Table 7.44)

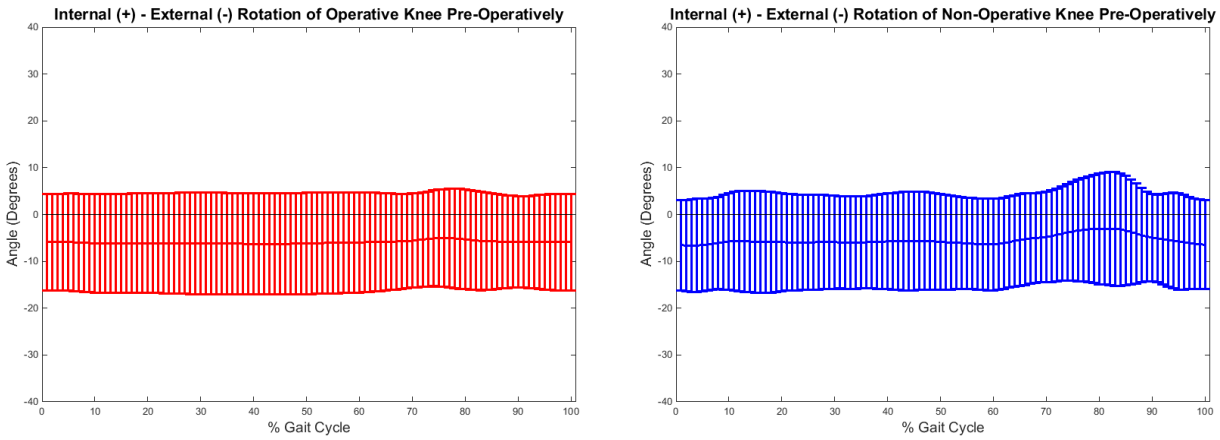


Figure 7. 29: Mean (±2SD) knee internal-external rotation over 50 cycles of 63 patients pre-TKA.

Table 7. 43: Mean (±SD) transverse plane knee kinematics during key events of the gait cycle in trial patients (pre-operative n = 63; 6-weeks n = 54; 1-year n = 30).

	Operative Knee			Non-Operative Knee		
Event	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**
Initial Contact	-5.9 (10.3)	-3.3 (8.6)	-7.2 (8.5)	-6.5 (9.6)	-5.4 (11.4)	-5.4 (10.8)
Loading Response	-5.9 (10.3)	-3.3 (8.6)	-7.1 (8.4)	-6.6 (9.9)	-5.3 (11.5)	-5.5 (10.7)
Mid-Stance	-6.2 (10.5)	-3.2 (8.6)	-6.4 (8.4)	-5.7 (10.8)	-5.1 (11.6)	-6.2 (10.8)
Terminal Stance	-6.2 (10.8)	-3.7 (9.1)	-6.5 (7.2)	-6.0 (9.8)	-5.4 (11.5)	-7.1 (10.5)
Mid-Swing	-5.0 (10.4)	-3.1 (8.3)	-4.9 (7.9)	-3.0 (10.8)	-0.9 (11.0)	-1.3 (11.5)
Excursion in Stance	0.4 (0.1)	1.4 (0.3)	0.8 (0.2)	1.0 (0.3)	1.3 (0.2)	1.8 (0.5)
Excursion in Swing	0.9 (0.3)	1.5 (0.4)	2.5 (0.9)	3.4 (1.1)	4.6 (1.6)	4.6 (1.5)

Table 7.44: Results of paired t-tests on specific transverse plane kinematic gait events pre-operatively (n = 63).

Gait Event	p-Value
Initial Contact	0.747
Loading Response	0.719
Mid-Stance	0.814
Terminal Stance	0.926
Mid-Swing	0.220

No significant changes to transverse plane kinematics were observed six-weeks post-operatively (Figure 7.30). On average, the non-operative knee remained externally rotated by approximately 5° throughout the stance phase of gait (Table 7.43). The knee internally rotated with flexion and externally rotated with extension. The operative knee was less externally rotated throughout the gait cycle six-weeks post-operatively than pre-operatively (Table 7.43). There were no statistical differences between transverse plane kinematics of both knees (Table 4.45).

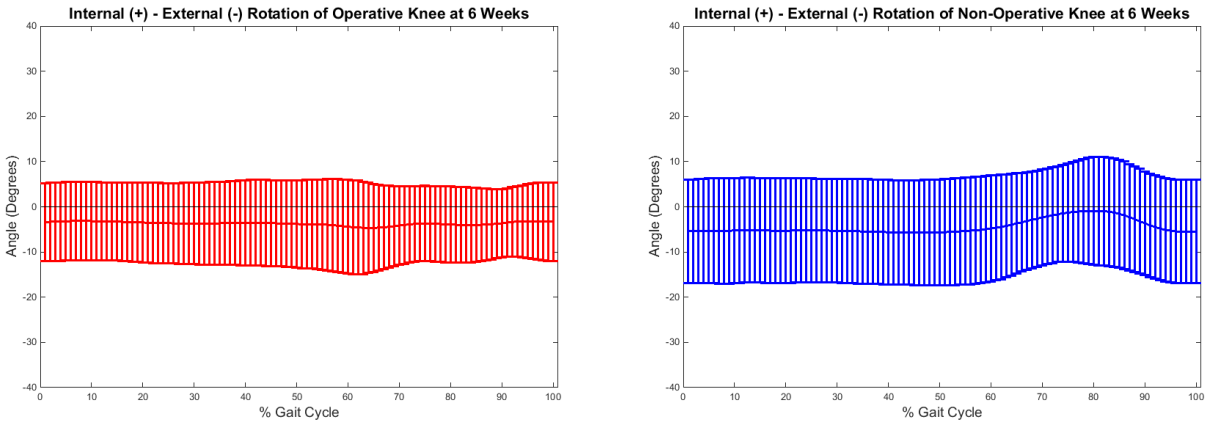


Figure 7.30: Mean (±2SD) knee internal-rotation over 50 cycles of 54 patients six-weeks post-TKA.

Table 7. 45: Results of paired t-tests on specific transverse plane kinematic gait events 6-weeks post-operatively (n = 54).

Gait Event	p-Value
Initial Contact	0.305
Loading Response	0.311
Mid-Stance	0.356
Terminal Stance	0.421
Mid-Swing	0.316

One year post-operatively, transverse plane kinematic trends remained similar to previous data (Figure 7.31 & Table 7.43). The operative knee was however, externally rotated to a greater extent throughout the gait cycle. It also exhibited greater ROM during the gait cycle than at six-weeks post-operatively. There continued to be no differences between knees during certain events of the gait cycle (Table 7.46).

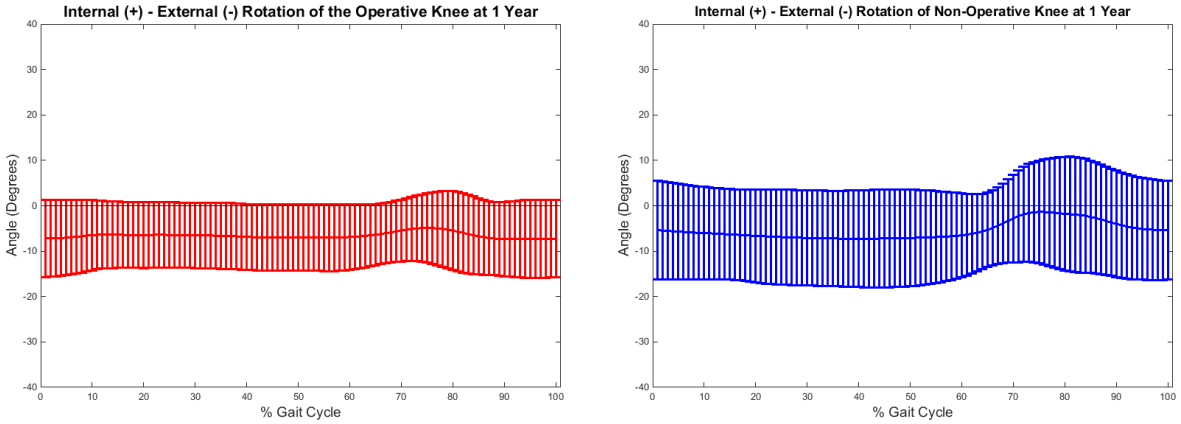


Figure 7. 31: Mean (±2SD) knee internal-external rotation over 50 cycles of 30 patients one year post-TKA.

Table 7. 46: Results of paired t-tests on specific transverse plane kinematic gait events 1-year post-operatively (n = 30).

Gait Event	p-Value
Initial Contact	0.498
Loading Response	0.539
Mid-Stance	0.935
Terminal Stance	0.817
Mid-Swing	0.096

Figure 7.32 shows the combined transverse plane kinematics of all patients during this investigation and the data recorded from 27 patients who attended all three clinics. There were no clinically significant differences between the two groups during the stance or swing phases of gait (Table 7.47).

Transverse plane kinematics did not change between pre-operative and six-weeks post-operative gait assessments in either knee (Table 7.48). There were no further changes in the non-operative knee one year following TKA either. However, external rotation of the operative knee during stance phase was statistically greater one-year post-operatively than six-weeks post-operatively, especially during initial contact and loading response (Table 7.49).

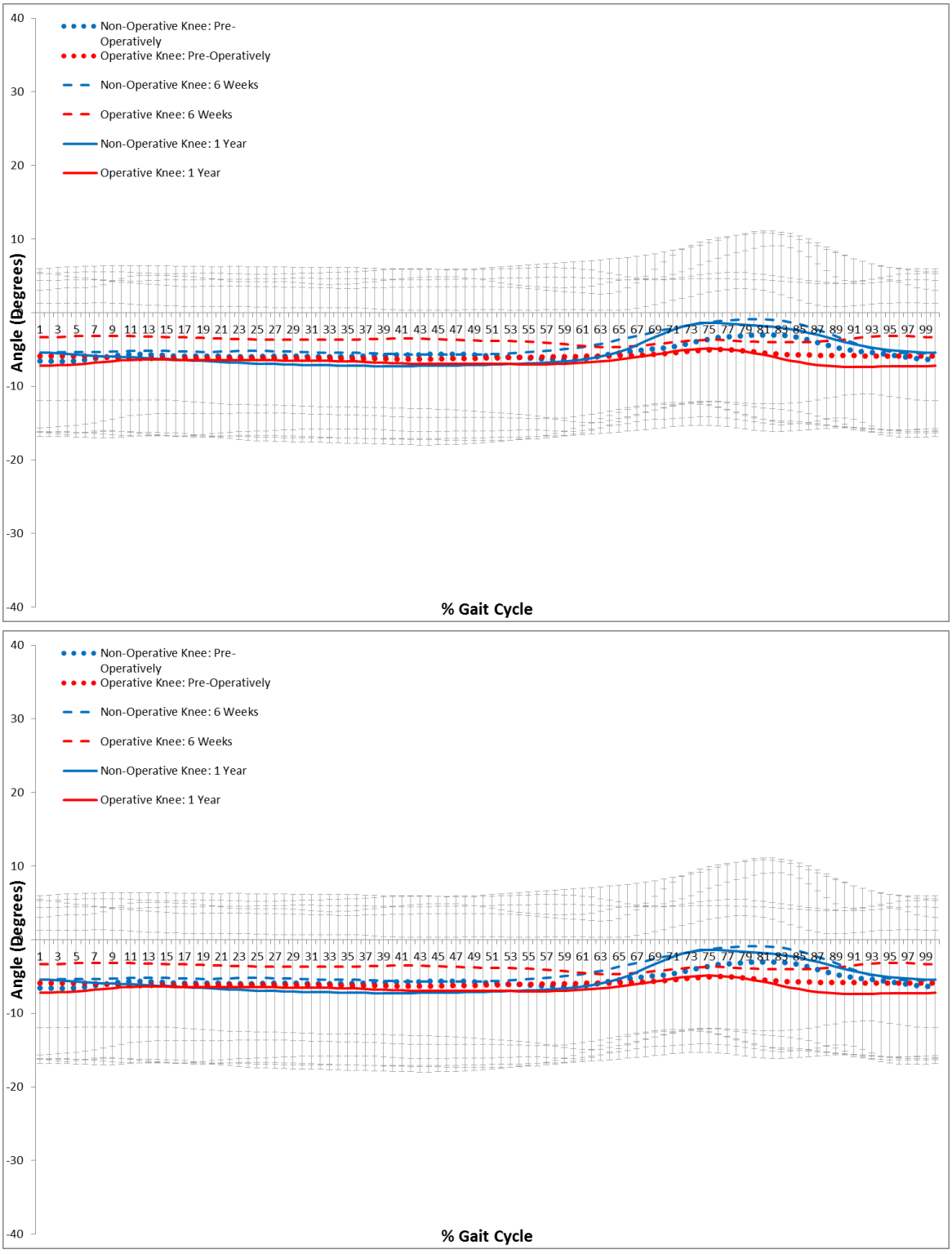


Figure 7.32: Transverse plane knee kinematics of all assessed patients (above) and of the 27 patients who attended all three clinics (below).

Table 7. 47: Mean (±SD) transverse plane knee kinematics during key events of the gait cycle in 27 patients.

	Operative Knee			Non-Operative Knee		
Event	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**	**Pre-Operative Mean (±SD) °**	**Six-Weeks Mean (±SD) °**	**1-Year Mean (±SD)°**
Initial Contact	-6.5 (11.1)	-3.1 (8.9)	-7.9 (8.6)	-6.2 (9.0)	-4.9 (9.7)	-5.0 (10.9)
Loading Response	-6.6 (11.2)	-3.0 (9.1)	-7.8 (8.4)	-6.6 (9.5)	-4.8 (9.7)	-5.1 (10.8)
Mid-Stance	-7.6 (11.8)	-2.9 (9.5)	-6.9 (8.6)	-5.4 (9.4)	-4.5 (9.9)	-5.5 (10.9)
Terminal Stance	-7.7 (12.3)	-3.4 (9.9)	-6.8 (7.1)	-5.6 (8.6)	-5.0 (9.8)	-6.2 (10.5)
Mid-Swing	-5.2 (11.5)	-2.8 (9.0)	-5.4 (8.0)	-4.7 (10.0)	0.3 (10.4)	-1.0 (12.1)
Excursion in Stance	1.3 (0.3)	1.1 (0.2)	1.1 (0.3)	1.4 (0.3)	1.4 (0.5)	1.4 (0.4)
Excursion in Swing	1.7 (0.5)	1.5 (0.5)	2.8 (1.0)	1.4 (0.3)	5.4 (2.0)	4.0 (1.4)

Table 7.48: Statistical differences between pre- and post-operative (6-weeks) transverse plane kinematics in both knees (n = 27): Paired t-tests.

Gait Event	p-Value: Operative Knee	p-Value: Non-Operative Knee
Initial Contact	0.237	0.465
Loading Response	0.230	0.341
Mid-Stance	0.135	0.657
Terminal Stance	0.175	0.737
Mid-Swing	0.179	0.108

Table 7.49: Statistical differences between 6-weeks and 1-year post-operative transverse plane kinematics in both knees (n = 27): Paired t-tests.

Gait Event	p-Value: Operative Knee	p-Value: Non-Operative Knee
Initial Contact	**0.027***	0.986
Loading Response	**0.028***	0.894
Mid-Stance	**0.055**	0.712
Terminal Stance	0.094	0.656
Mid-Swing	0.170	1.000

** Statistical significance*

Spatio-Temporal Parameters

Table 7.50 summarises the spatio-temporal parameters of gait during pre- and post-operative walking assessments. Average walking speed was slow in our patient cohort both pre-operatively and post-operatively, but there were improvements in speed over time. Cadence increased slightly between baseline and six-week assessments, but was lower one year following TKA. This coincided with increases in step and stride lengths.

Table 7. 50: Mean (±SD) spatio-temporal parameters recorded during a two-minute treadmill walking task.

Variable	Pre-Operative (n = 63)	6-Weeks (n = 54)	1-Year (n = 30)
Walking Speed (m/s)	0.34 (0.10)	0.41 (0.22)	0.52 (0.26)
Cadence (steps/min)	66.2 (14.4)	68.3 (19.6)	46.9 (18.7)
Step Length (Affected Limb) (m)	0.31 (0.14)	0.33 (0.22)	0.52 (0.27)
Step Length (Non-Affected-Limb) (m)	0.32 (0.18)	0.35 (0.21)	0.51 (0.24)
Stride Length (m)	0.63 (0.31)	0.59 (0.45)	1.10 (0.62)

Spatio-temporal parameters of gait were analysed again for the patients who attended all 3 clinics (Table 7.51). The results between both groups were largely similar. Statistical analyses on the subgroup were carried out to determine whether spatio-temporal parameters differed between assessments (Table 7.52).

Table 7. 51: Mean (±SD) spatio-temporal parameters recorded during a two-minute treadmill walking task (n = 27).

Variable	Pre-Operative	6-Weeks	1-Year
Walking Speed (m/s)	0.32 (0.07)	0.39 (0.17)	0.52 (0.27)
Cadence (steps/min)	67.4 (14.0)	73.5 (22.6)	46.5 (19.2)
Step Length (Affected Limb) (m)	0.32 (0.14)	0.30 (0.15)	0.53 (0.27)
Step Length (Non-Affected-Limb) (m)	0.30 (0.11)	0.35 (0.17)	0.51 (0.24)
Stride Length (m)	0.62 (0.21)	0.65 (0.31)	1.03 (0.51)

Table 7. 52: Statistical differences of spatio-temporal parameters over time (n = 27): Paired t-tests.

Spatio-Temporal Parameter	p-Value: Baseline – 6 Weeks	p-Value: 6 Weeks – 1 Year
Walking Speed (m/s)	**0.040***	**0.039***
Cadence (steps/min)	0.179	**<0.0001***
Step Length (Affected Limb) (m)	0.597	**<0.0001***
Step Length (Non-Affected-Limb) (m)	0.150	**0.003***
Stride Length (m)	0.608	**<0.0001***

** Statistical significance*

Walking speed significantly improved between pre-operative and six-week post-operative assessments (Table 7.52). However, no other spatio-temporal parameters of gait differed statistically between these assessments. Conversely, all parameters investigated were found to differ significantly between both post-

operative assessments. The data show that patients were walking faster and taking longer strides post-operatively, suggesting that their overall gait and walking confidence was improving. Gait asymmetry was shown to improve one year post-operatively too. Statistical analyses showed that step lengths did not differ pre-operatively or one year post-operatively ($p = 0.482$ & $p = 0.417$, respectively), but that differences in step lengths at six-weeks reached statistical significance ($p = 0.008$).

7.4.5. Walking Stability

The UCM was applied to 50 gait cycles per patient to link the variability in joint kinematics to the variability of the position of the COM per instance of the gait cycle. The average UCM variances and ratios for all patients are reported here.

Pre-operative sagittal plane variances within the UCM outweighed the variances perpendicular to the UCM, suggesting that kinematic synergy was adopted by the CNS in our patient cohort to stabilise the COM pre-operatively (Figure 7.33).

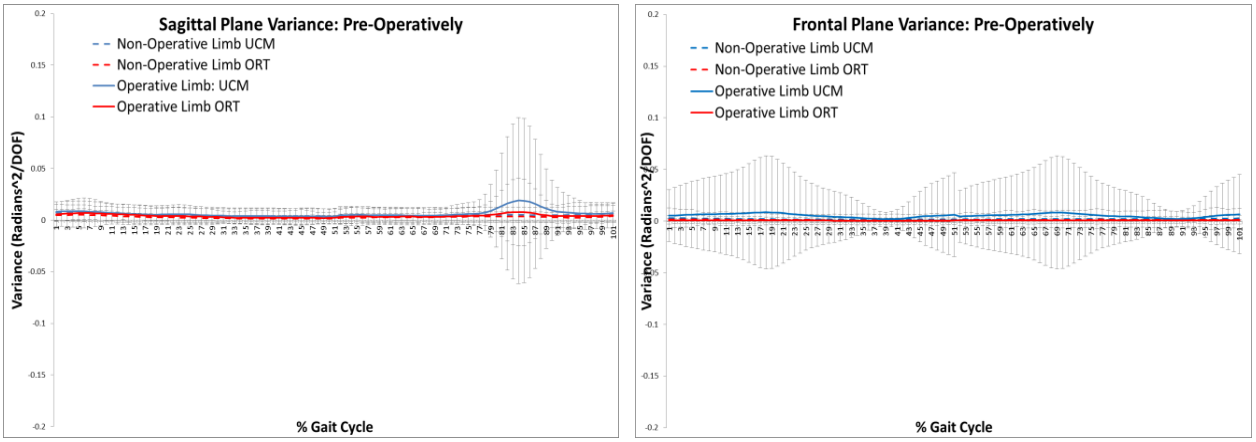


Figure 7.33: Mean (±2SD) variances within (UCM) and perpendicular (ORT) to the linearized UCM in sagittal and frontal planes of 64 patients pre-operatively.

The degree of sagittal plane variance exhibited in the non-operative limb remained relatively consistent throughout the gait cycle (Figure 7.33). Similar levels of control were found in the pre-operative limb during stance phase. However, a sudden increase in both types of variance was observed during swing phase, peaking around 80% of the gait cycle. This was not observed in the contralateral limb.

Frontal plane variance within the UCM of the operative limb was greater than the non-operative limb, peaking at 20% and 70% of the gait cycle. As in the sagittal

plane, variance in the non-operative limb remained relatively constant throughout the gait cycle.

Similar trends were also observed in the subgroup of patients who had attended all clinics, especially in the sagittal plane (Figure 7.34). Frontal plane variances remained largely similar, but the variance within the UCM in the operative limb was smaller throughout the gait cycle. The standard deviations of this variable were also more consistent and narrower in this subgroup.

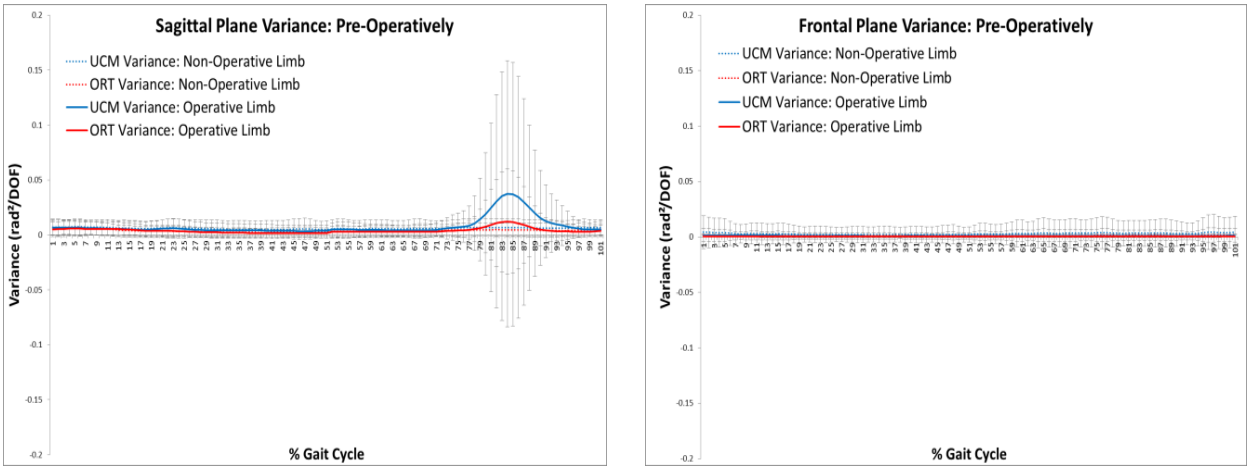


Figure 7. 34: Mean (±2SD) variances within (UCM) and perpendicular (ORT) to the linearized UCM in sagittal and frontal planes of 27 patients pre-operatively.

Six-weeks post-operatively, sagittal plane variances remained similar to baseline levels in the operative limb (Figure 7.35). However, the increases in variances within and perpendicular to the UCM seen during the swing phase of gait pre-operatively were no longer apparent. The magnitudes of the variances in the contralateral limb had increased six-weeks post-operatively. Variances within the UCM were noticeably higher during the beginning of the stance phase of gait. A rapid decrease was then observed towards a level of control which reflected pre-

operative values. A second increase in 'good variance' was observed at the beginning of the swing phase.

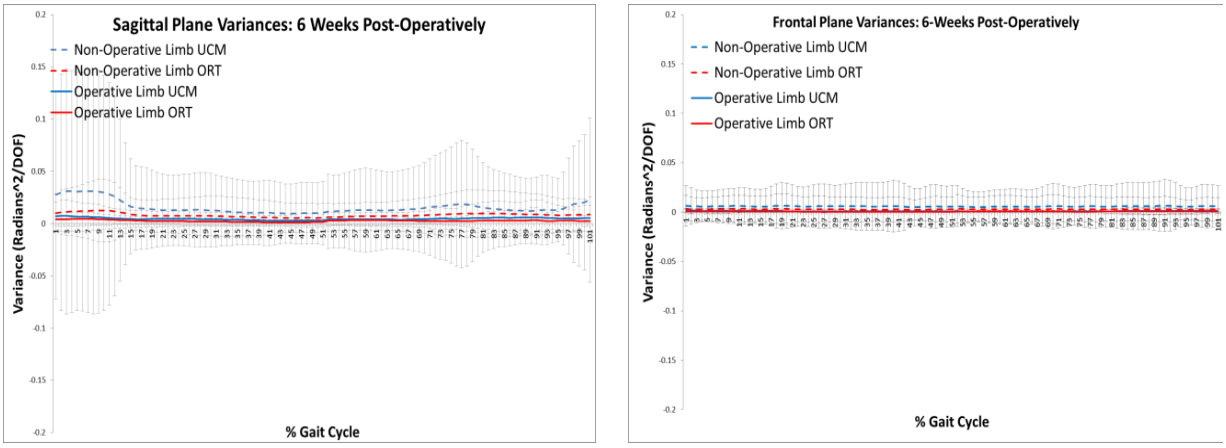


Figure 7.35: Mean (±2SD) variances within (UCM) and perpendicular (ORT) to the linearized UCM in sagittal and frontal planes of 54 patients six-weeks post-operatively.

As before, variances within the UCM outweighed those perpendicular to the UCM throughout the gait cycle (Figure 7.35). These results suggest that kinematic synergy was also adopted by the CNS post-operatively to maintain a stable COM during gait.

The magnitudes of frontal plane variances recorded six-weeks post-operatively remained relatively constant throughout the gait cycle (Figure 7.35). The degree of variance recorded in the frontal plane was less than in the sagittal plane.

In the non-operative limb, variance within the UCM decreased slightly post-operatively, but variance perpendicular to the UCM increased (Figure 7.35). In the operative limb, both variances were greater when compared to baseline data. In this limb, the variance within the UCM clearly outweighed the variance perpendicular to the UCM throughout the gait cycle.

The trends of variances recorded in the 27 patients who visited the clinic on all three occasions were consistent with the general group (Figure 7.36).

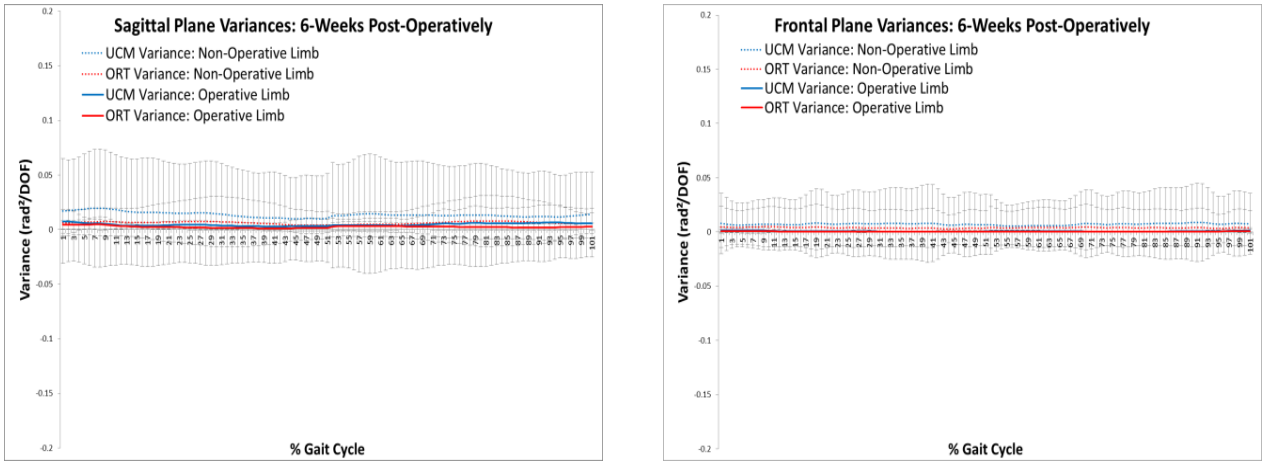


Figure 7.36: Mean (±2SD) variances within (UCM) and perpendicular (ORT) to the linearized UCM in sagittal and frontal planes of 27 patients six-weeks post-operatively.

One year post-operatively, sagittal plane variances within and perpendicular to the UCM had increased slightly in the operative limb, but decreased in the non-operative limb (Figure 7.37). Variances were shown to be greater during the loading response and terminal stance events of the gait cycle. Variances within the UCM continued to outweigh variances perpendicular to the UCM throughout the gait cycle. The results from the 27-patient subgroup were consistent with these findings (Figure 7.38).

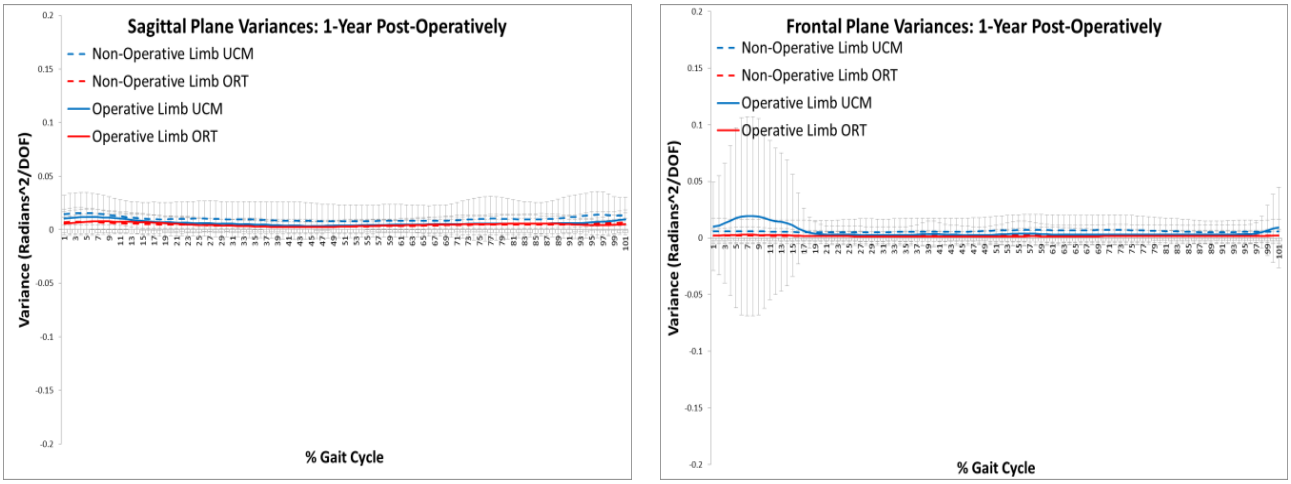


Figure 7. 37: Mean (±2SD) variances within (UCM) and perpendicular (ORT) to the linearized UCM in sagittal and frontal planes of 30 patients one-year post-operatively.

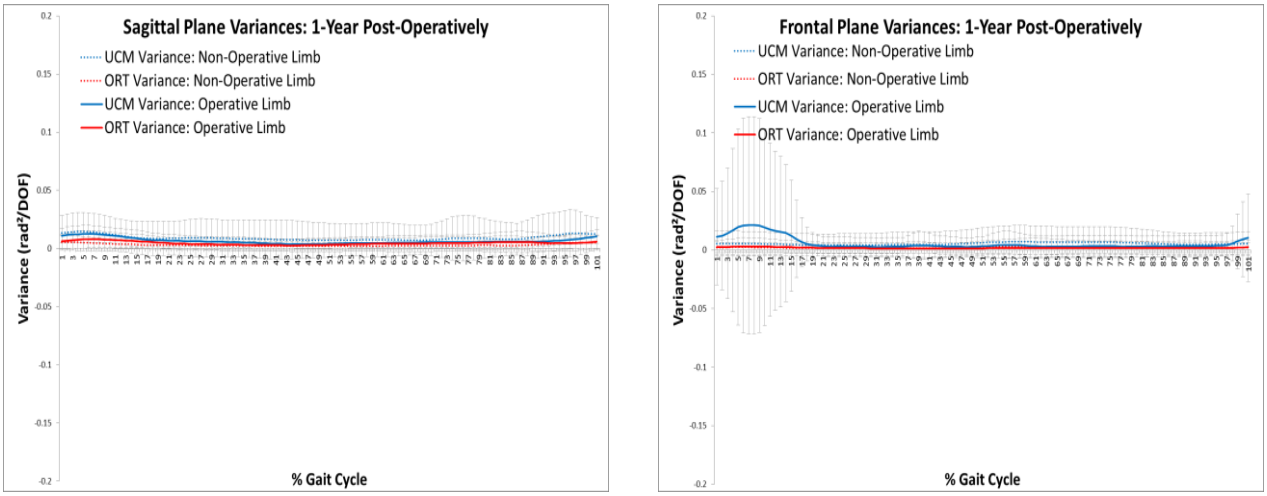
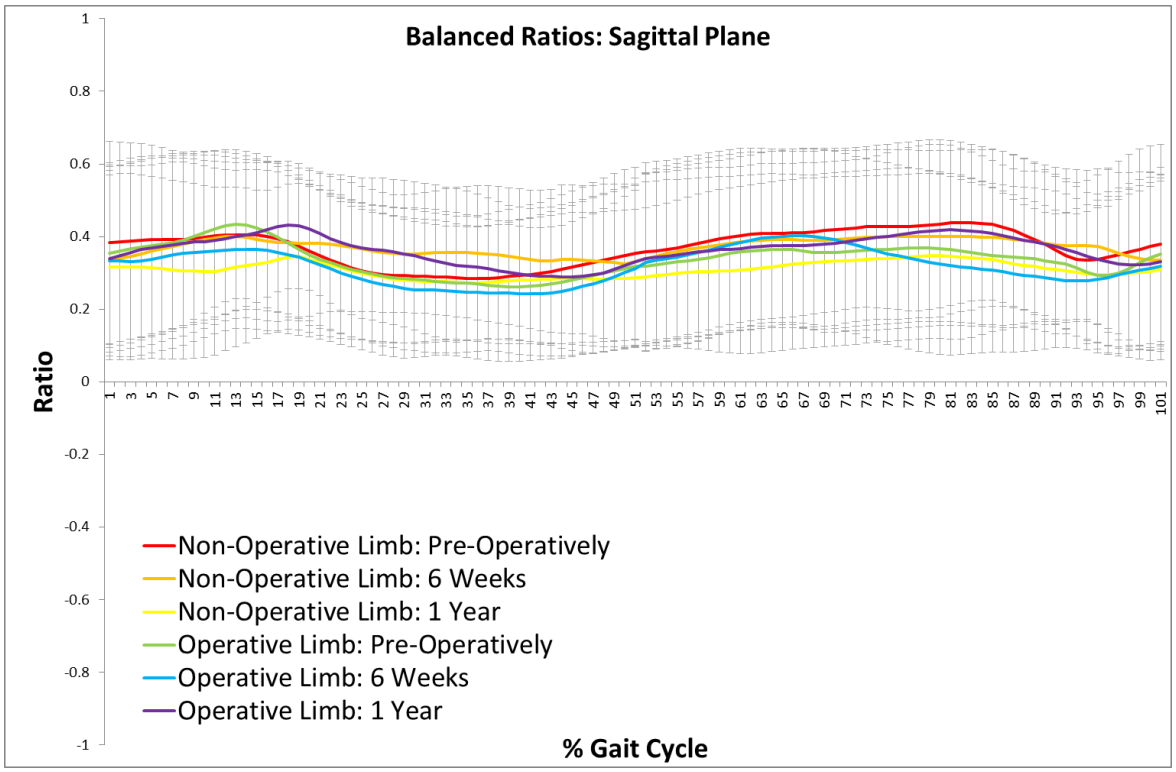


Figure 7.38: Mean (±2SD) variances within (UCM) and perpendicular (ORT) to the linearized UCM in sagittal and frontal planes of 27 patients one-year post-operatively.

Frontal plane variances had increased in both limbs one year post-TKA (Figure 7.37). The magnitudes of the variances in the non-operative limb remained consistent throughout the gait cycle. The variance within the UCM of the operative limb was consistent during the swing phase of gait, but was found to increase at the beginning of stance, peaking during loading response. Variances within the UCM outweighed variances orthogonal to the UCM one year post-operatively. This was also observed in the subgroup of patients who attended all clinics (Figure 7.38).

To further investigate the stability of gait from cycle-to-cycle, the ratios of variances were plotted and analysed. Sagittal and frontal plane ratios remained above 0 throughout the gait cycle, confirming that kinematic synergy had been employed to stabilise the COM in these planes both pre- and post-operatively (Figure 7.39).



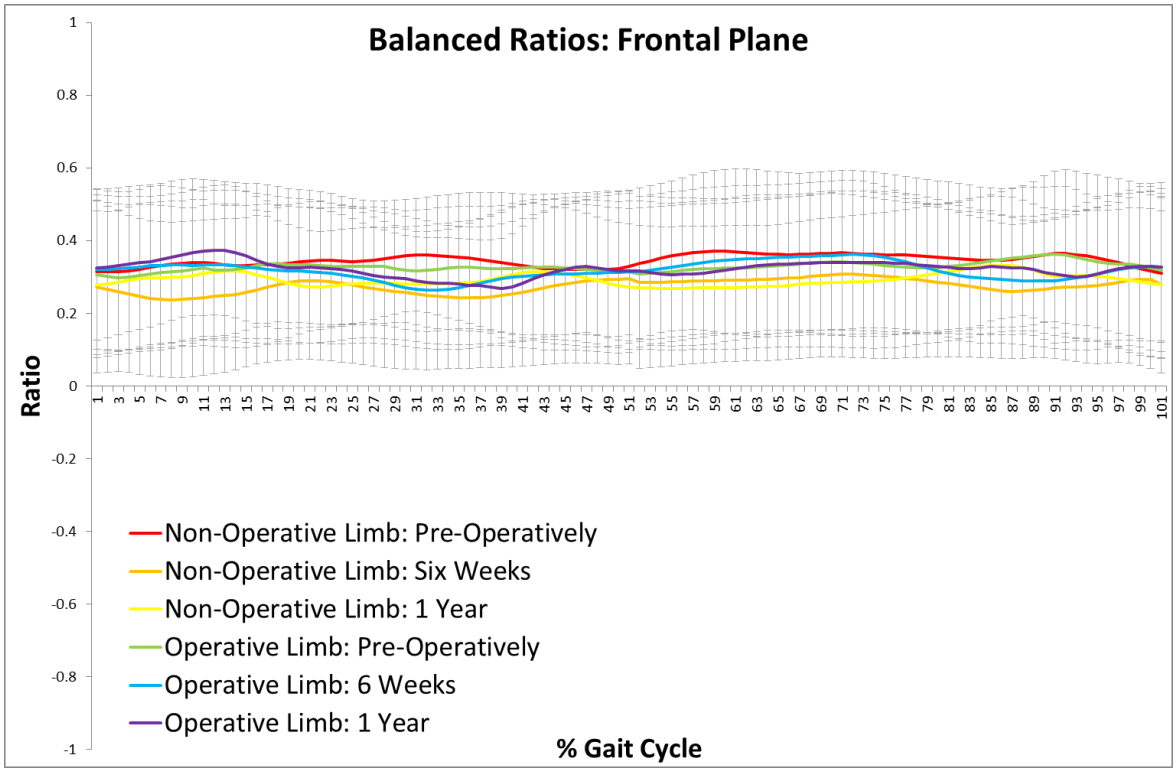


Figure 7.39: Mean (±2SD) sagittal and frontal plane ratios of pre-operative (n = 63), six-weeks post-operative (n = 54) and one-year post-operative (n = 30) patients.

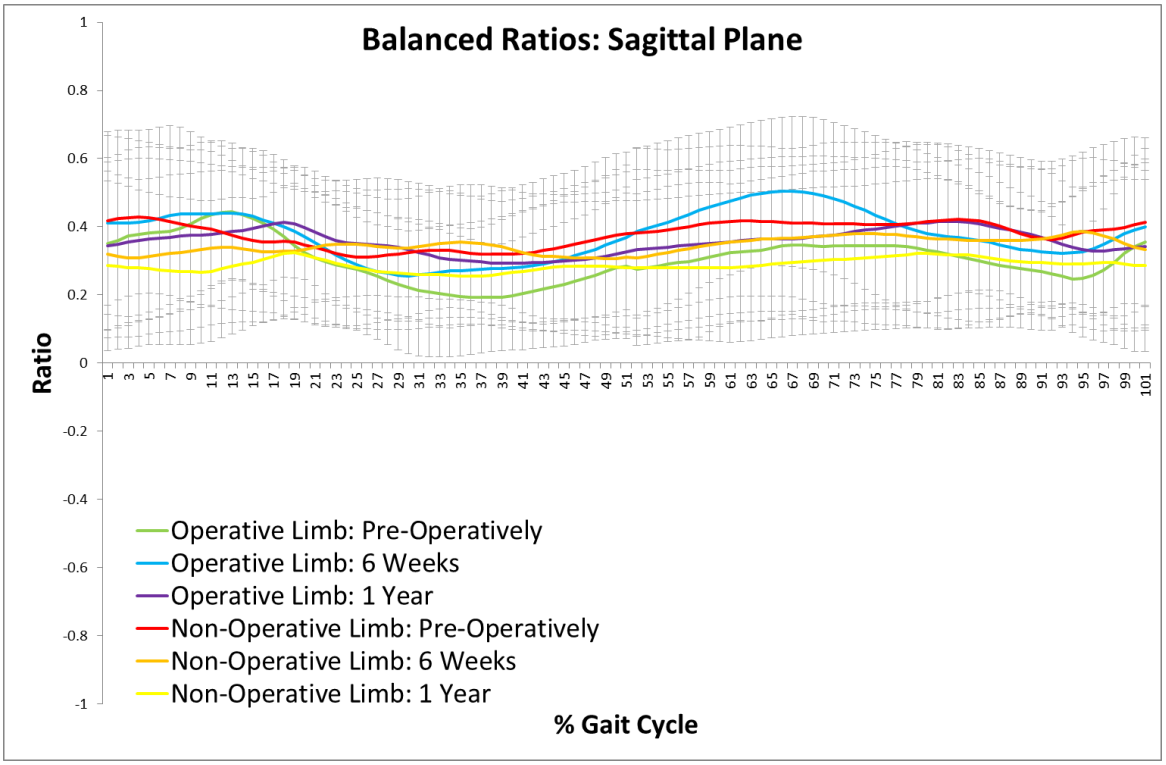
When comparing both sagittal and frontal plane ratios, it could be seen that the values were similar, despite the fact that greater magnitudes of variances were observed in the sagittal plane (Figure 7.39).

Sagittal plane ratios were lowest at initial contact, towards the end of mid-stance and during the first half of the terminal stance stages of the gait cycle, regardless of the side or time recorded (Figure 7.39). Lower ratios were also recorded during terminal swing.

On average, sagittal plane ratios tended to worsen with time in the non-operative limb. In the operative limb, the ratios were worst six-weeks following surgery, but best one year after surgery, showing an improvement with time (Figure 7.39).

Frontal plane ratios were more consistent throughout the gait cycle, but slight increases were observed during mid-stance and at the beginning of the swing phase of gait (Figure 7.39). Highest ratios in the non-operative knee were recorded pre-operatively, showing a reduction in stability in this plane post-operatively. Frontal plane stability of the operative limb improved in the first half of stance post-operatively, but was otherwise lower than pre-operative or 6-week data (Figure 7.39).

Ratios of the 27-patient subgroup are given in Figure 7.40. Sagittal plane trends for the non-operative limb were the same in this subgroup. In the frontal plane however, the ratio was shown to have improved between pre- and post-operative assessments, especially six-weeks post-operatively. Trends for the operative limb were also similar, but ratios recorded six weeks post-operatively were greater during the swing phase of gait. Frontal plane ratios recorded in the operative limb remained similar to baseline levels throughout the gait cycle. The highest ratios were recorded six-weeks post-operatively (Figure 7.40).



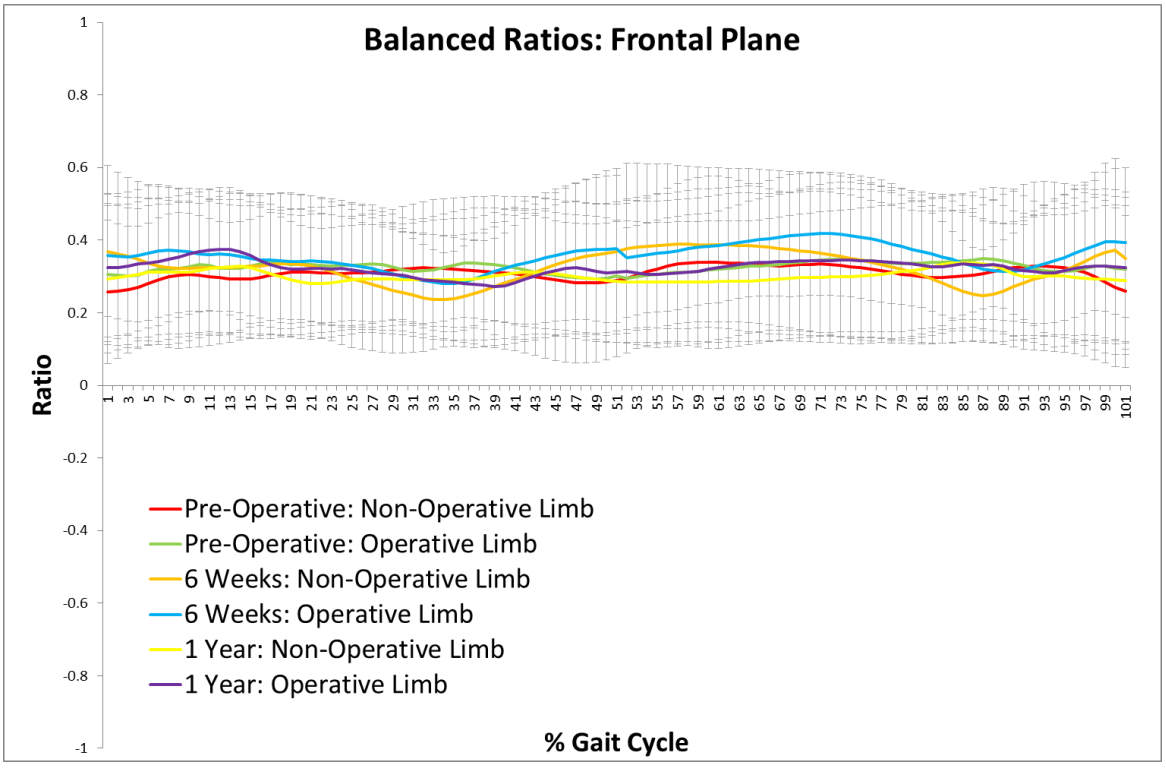


Figure 7.40: Mean (±2SD) sagittal and frontal plane ratios of 27 patients pre- and post-operatively.

Statistical analyses were carried out on the data of the subgroup at key events in the gait cycle to investigate whether differences in ratios over time were statistically significant (Table 7.53 & Table 7.54).

Table 7.53: Statistical differences between pre- and post-operative (6-weeks) ratios in both limbs (n = 27): paired t-tests.

Gait Event	p-Value: Operative Limb		p-Value: Non-Operative Limb	
Plane	**Sagittal**	**Frontal**	**Sagittal**	**Frontal**
Initial Contact	0.394	0.211	0.160	0.061
Loading Response	0.581	0.229	0.067	0.102
Mid-Stance	0.939	0.352	0.533	0.532
Terminal Stance	0.263	0.478	0.761	**0.052**
Mid-Swing	0.170	0.229	0.662	0.704

Table 7.54: Statistical differences between 6-weeks and 1-year post-operative ratios in both limbs (n = 27); Paired t-tests.

Gait Event	p-Value: Operative Limb		p-Value: Non-Operative Limb	
Plane	**Sagittal**	**Frontal**	**Sagittal**	**Frontal**
Initial Contact	0.372	0.504	0.652	0.215
Loading Response	0.441	0.618	0.682	0.333
Mid-Stance	0.264	0.770	0.368	0.973
Terminal Stance	0.258	0.931	**0.028***	0.279
Mid-Swing	0.531	0.205	0.311	0.400

** Statistical significance*

There were no statistical differences between pre-operative and six-week post-operative gait variability in either limb or plane, suggesting that the CNS had not dramatically altered the way in which the COM was stabilised following TKA (Table 7.53). In general, the frontal plane ratios were shown to differ to a greater extent

between assessments, especially during stance phase in the non-operative limb. The differences in these ratios almost reached statistical significance during terminal stance.

Statistical analyses on the data recorded at six-weeks and one-year showed that there were no further changes to the ratios at the events analysed in the operative limb (Table 7.54). However, in the contralateral limb, sagittal plane ratios at terminal stance were statistically different; suggesting that the way in which the COM was stabilised in this plane had altered with time.

Overall, our results support the hypothesis that kinematic synergy was used to stabilise the COM in both sagittal and frontal planes in our patients. The results also showed that the way in which the CNS controlled this stability was altered over time, but that the differences were generally not statistically significant.

7.5. Group Analysis: Healthy Age-Matched Controls

7.5.1. Patient Demographics

The thirty patients involved in the EQUAL Project whose data was analysed in this thesis had a mean age of 71.5 (±6.5) years. Eleven were male and nineteen were female. Results on the heights and masses of these patients could not be included in this thesis as the individual data were not available to us. However, mean demographics for all patients involved in the EQUAL project are given in Table 7.55.

Table 7. 55: Demographics of all patients involved in the EQUAL project. Source: Samuel & Rowe, 2009.

	60–69 years	70–79 years	≥80 years
Men			
Total	15	14	13
Age, years	65.7 ± 3.0	73.6 ± 3.2	81.9 ± 1.9
Height, m	1.73 ± 0.08	1.73 ± 0.06	1.72 ± 0.09
Weight, kg	78.4 ± 15.0	76.3 ± 8.7	81.9 ± 16.8
Women			
Total	15	15	10
Age, years	65.2 ± 2.9	73.5 ± 2.8	83.1 ± 2.8
Height, m	1.63 ± 0.08	1.58 ± 0.06	1.57 ± 0.06
Weight, kg	72.5 ± 14.0	69.8 ± 14.3	63.0 ± 9.8

Values are presented as mean ± standard deviation.

When compared to the demographics of the 27 patients who attended all clinics for the Medacta GMK Sphere trial (Table 7.16), it can be seen that the average age was similar (71.5 compared with 71.7 years). On average, the healthy older adults were lighter, but were of similar heights to the TKA patients.

7.5.2. Gait Analysis

The average spatio-temporal parameters and gait kinematics recorded in the age-matched healthy population (n = 30) will now be compared to the subgroup of TKA patients who attended all assessment clinics (n = 27).

Spatio-Temporal Parameters

The mean spatio-temporal parameters for the healthy older adults compared to the patients in this study are given in Table 7.56.

Table 7. 56: Mean spatio-temporal parameters recorded in healthy older adults (n = 30) and TKA patients (n = 27).

	Mean (±SD)			
Variable	**Healthy Older Adults**	**Patients: Pre-Operatively**	**Patients: 6-Weeks**	**Patients: 1-Year**
Walking Speed (m/s)	1.29 (0.18)	0.32 (0.07)	0.39 (0.17)	0.52 (0.27)
Cadence (steps/min)	116.9 (8.1)	67.4 (14.0)	73.5 (22.6)	46.5 (19.2)
Step Length (m)	0.66 (0.10)	0.32 (0.14)	0.30 (0.15)	0.53 (0.27)
Contralateral Step Length (m)	0.70 (0.20)	0.30 (0.11)	0.35 (0.17)	0.51 (0.24)
Stride Length (m)	1.34 (0.19)	0.62 (0.21)	0.65 (0.31)	1.03 (0.51)

Statistical analyses on the spatio-temporal parameters of gait showed that all pre- and post-operative data from TKA patients differed statistically from the data recorded in healthy older adults ($p < 0.005$). Thus, although all variables had

improved in the patient group post-operatively, they had not improved enough to be within the ranges of those recorded in age-matched individuals. This suggested that gait remained pathological in the TKA patients one year post-surgery. These differences in spatio-temporal parameters observed between the healthy and pathological groups may translate to the kinematic data, as variables such as walking speed highly influence gait kinematics.

Sagittal Plane Kinematics

The average sagittal plane kinematics of the knee in the healthy older adult population is displayed in Figure 7.41. The trend displayed is typical of non-pathological gait. The average flexion angles of the knee at key events during the gait cycle were statistically compared to the data recorded in trial patients pre- and post-operatively (presented previously in this thesis).

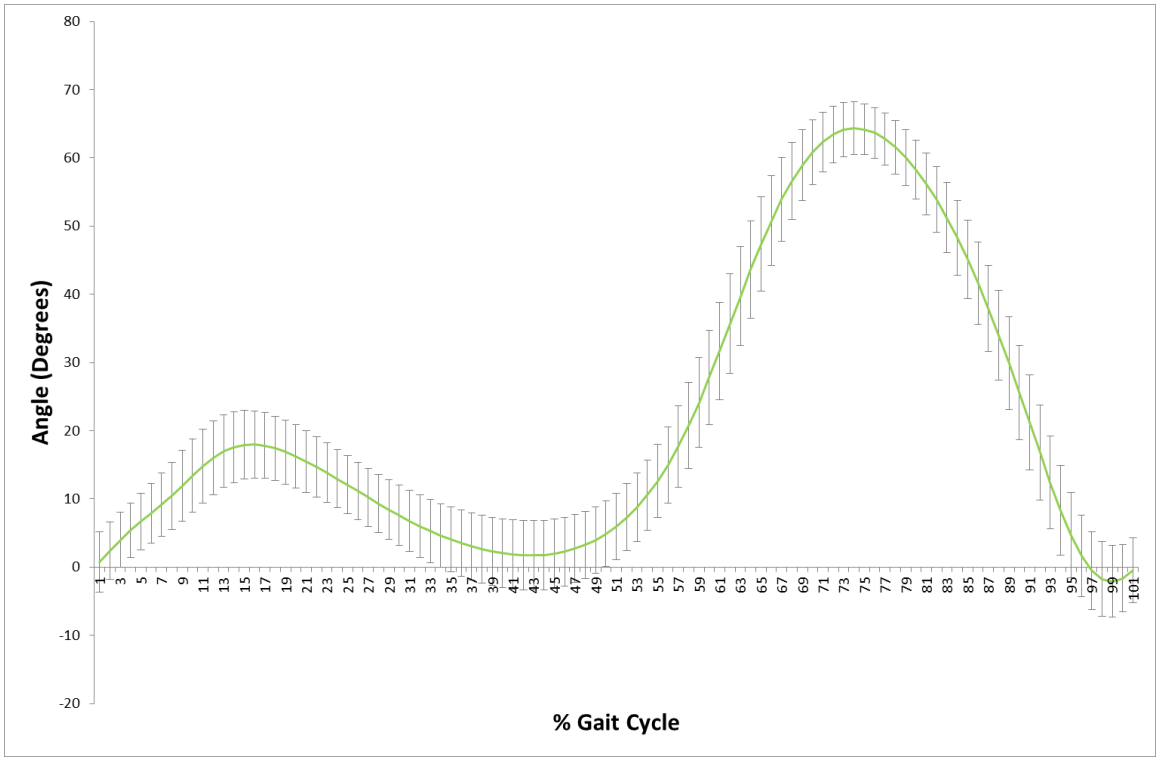


Figure 7.41: Mean (±SD) knee flexion-extension angles over 4 walking trials of 30 older adults.

Table 7. 57: Mean (±SD) sagittal plane knee kinematics during key events of the gait cycle in healthy older adults (n = 30) and TKA patients (n = 27).

	Mean (±SD)						
	Healthy Older Adults	**Patients: Operative Knee**			**Patients: Non-Operative Knee**		
Event	**-**	**Pre-Operatively**	**6-Weeks**	**1-Year**	**Pre-Operatively**	**6-Weeks**	**1-Year**
Initial Contact	0.74 (4.4)	19.1 (8.6)	22.5 (8.6)	27.1 (10.4)	24.8 (6.8)	23.1 (8.6)	24.6 (8.3)
Loading Response	4.0 (4.1)	18.5 (8.5)	22.2 (8.4)	26.6 (10.1)	24. (6.8)	22.8 (8.6)	24.4 (8.1)
Mid-Stance	17.0 (5.3)	16.4 (8.2)	20.8 (8.1)	25.2 (10.4)	21.9 (6.3)	20.6 (8.5)	23.5 (8.3)
Terminal Stance	6.0 (4.5)	13.7 (11.4)	16.5 (7.4)	17.8 (7.5)	13.8 (8.6)	13.0 (7.7)	15.4 (8.2)
Mid-Swing	64.3 (7.2)	44.3 (13.5)	47.3 (9.6)	57.9 (9.7)	48.2 (10.5)	50.1 (10.3)	51.5 (12.0)
Excursion in Stance	35.0 (3.3)	7.2 (2.1)	9.8 (2.4)	14.8 (4.3)	13.2 (4.4)	12.2 (4.2)	14.8 (4.4)
Excursion in Swing	66.4 (3.6)	25.3 (9.1)	24.8 (8.5)	30.7 (10.8)	28.8 (9.2)	27.3 (9.8)	26.8 (9.4)

The healthy older adults were able to extend their knee to a far greater extent during stance phase, especially at initial contact and terminal stance (Table 7.57). They were also capable of flexing the knee more during swing than the TKA patients. Standard deviations were generally lower in the healthy older adults, suggesting that their gait was less variable in kinematics than the patient group.

The differences between the data recorded in the non-operative knee of the TKA group and the healthy older adults were statistically significant at all gait events (p

< 0.05), except for six-weeks post-operatively during mid-stance (p = 0.063). Overall, the data recorded in the operative knee were also statistically different to those recorded in healthy older adults (p < 0.05). However, there was no statistically significant difference between either group pre-operatively during mid-stance (p = 0.787).

Frontal Plane Kinematics

The healthy older adults had a neutrally aligned knee in the frontal plane during initial contact (Figure 7.42 & Table 7.57). Slight adduction occurred during the loading response phase of gait. During the rest of the stance phase, the knee was found to abduct slowly. A more rapid adduction rotation occurred during the swing phase of gait. The knee remained adducted before returning to a more neutral position towards the end of the gait cycle.

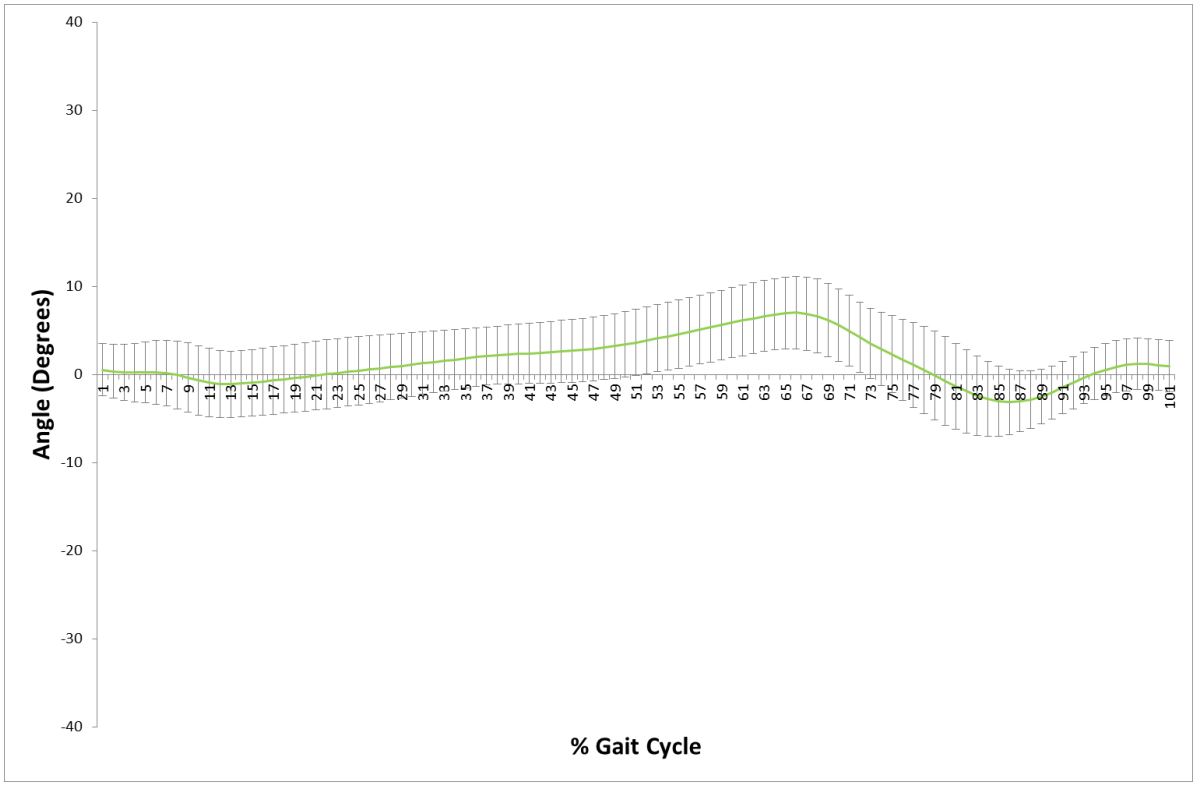


Figure 7.42: Mean (±SD) knee abduction-adduction angles over 4 walking trials of 30 older adults.

Table 7. 58: Mean (±SD) frontal plane knee kinematics during key events of the gait cycle in healthy older adults (n = 30) and TKA patients (n = 27).

	Mean (±SD)						
	Healthy Older Adults	**Patients: Operative Knee**			**Patients: Non-Operative Knee**		
Event	**-**	**Pre-Operatively**	**6-Weeks**	**1-Year**	**Pre-Operatively**	**6-Weeks**	**1-Year**
Initial Contact	0.5 (3.0)	-2.3 (11.1)	2.6 (7.4)	1.7 (10.0)	1.6 (10.0)	2.1 (8.9)	0.4 (9.7)
Loading Response	0.2 (3.2)	-2.2 (11.3)	2.8 (7.5)	1.9 (9.9)	1.7 (9.9)	2.2 (8.8)	0.5 (9.7)
Mid-Stance	-1.1 (3.8)	-2.5 (12.4)	3.7 (7.7)	2.5 (10.0)	1.8 (9.6)	3.1 (9.0)	0.8 (9.7)
Terminal Stance	1.4 (3.5)	-2.1 (13.3)	4.7 (8.1)	3.2 (8.2)	3.1 (9.4)	4.4 (8.9)	2.1 (10.2)
Mid-Swing	-3.1 (2.9)	-5.5 (10.1)	-2.5 (8.7)	-3.0 (8.7)	-1.9 (13.8)	-4.5 (8.6)	-5.8 (8.1)
Excursion in Stance	7.7 (0.9)	0.8 (0.2)	2.2 (0.6)	1.9 (0.5)	1.9 (0.7)	2.7 (0.8)	2.2 (0.7)
Excursion in Swing	10.1 (2.2)	3.2 (1.1)	6.3 (2.0)	5.7 (1.8)	4.3 (1.3)	8.0 (2.6)	6.4 (2.2)

Frontal plane kinematics of the healthy older adults showed similar trends to those reported previously in our TKA population, especially post-operatively. Healthy older adults did however, have a greater ROM at the knee in this plane than the TKA patients (Table 7.58). Standard deviations were lower in the healthy older adults, suggesting that their gait was less variable in frontal plane kinematics.

Statistical analyses showed that there were no significant differences between data reported in the non-operative knee of the TKA patients and those recorded in

healthy older adults, other than six-weeks post-operatively during mid-stance. These differences did not persist one year following TKA, suggesting that frontal plane movement of this limb had been restored to normal within the first post-operative year (Table 7.59).

Despite the fact that the operative knee remained in adduction throughout the gait cycle pre-operatively, the differences were not statistically significant (Table 7.59). Statistically significant differences were reported post-operatively, during mid- and terminal-stance. By one-year, the differences were only significant during mid-stance, suggesting that frontal plane kinematics were improving towards normal post-operatively.

Table 7. 59: P-Values for two-sample t-tests carried out on frontal plane kinematic data of healthy older adults (n=30) and TKA patients (n=27).

Event	**Pre-Operatively**		**Six-Weeks**		**One-Year**	
	Operative	**Non-Operative**	**Operative**	**Non-Operative**	**Operative**	**Non-Operative**
Initial Contact	0.210	0.579	0.182	0.392	0.552	0.946
Loading Response	0.279	0.481	0.109	0.279	0.409	0.892
Mid-Stance	0.575	0.144	**0.006***	**0.032***	**0.052***	0.352
Terminal Stance	0.195	0.383	**0.058**	0.112	0.300	0.735
Mid-Swing	0.084	0.859	0.648	0.463	0.859	0.106

**Statistical Significance*

Transverse Plane Kinematics

The healthy older adult population were shown to have an externally rotated knee joint for the duration of the gait cycle (Figure 7.43). Gradual internal rotation of the joint occurred throughout the stance phase. At the end of the stance phase of gait, the knee joint externally rotated by approximately 15°.

Figure 7.43: Mean (±SD) knee internal-external rotation of the knee joint over 4 walking trials of 30 older adults.

Table 7. 60: Mean (±SD) transverse plane knee kinematics during key events of the gait cycle in healthy older adults (n = 30) and TKA patients (n = 27).

	Mean (±SD)						
	Healthy Older Adults	Patients: Operative Knee			Patients: Non-Operative Knee		
Event	-	Pre-Operatively	6-Weeks	1-Year	Pre-Operatively	6-Weeks	1-Year
Initial Contact	-23.9 (6.6)	-6.5 (11.1)	-3.1 (8.9)	-7.9 (8.6)	-6.2 (9.0)	-4.9 (9.7)	-5.0 (10.9)
Loading Response	-22.8 (6.3)	-6.6 (11.2)	-3.0 (9.1)	-7.8 (8.4)	-6.6 (9.5)	-4.8 (9.7)	-5.1 (10.8)
Mid-Stance	-17.8 (5.6)	-7.6 (11.8)	-2.9 (9.5)	-6.9 (8.6)	-5.4 (9.4)	-4.5 (9.9)	-5.5 (10.9)
Terminal Stance	-13.4 (6.0)	-7.7 (12.3)	-3.4 (9.9)	-6.8 (7.1)	-5.6 (8.6)	-5.0 (9.8)	-6.2 (10.5)
Mid-Swing	-10.8 (7.0)	-5.2 (11.5)	-2.8 (9.0)	-5.4 (8.0)	-4.7 (10.0)	0.3 (10.4)	-1.0 (12.1)
Excursion in Stance	17.0 (1.4)	1.3 (0.3)	1.1 (0.2)	1.1 (0.3)	1.4 (0.3)	1.4 (0.5)	1.4 (0.4)
Excursion in Swing	13.5 (1.1)	1.7 (0.5)	1.5 (0.5)	2.8 (1.0)	1.4 (0.3)	5.4 (2.0)	4.0 (1.4)

Transverse plane ROM of the knee during gait in the healthy older adults far exceeded those recorded in the TKA patients both pre- and post-operatively (Table 7.60). There were also few similarities between the movement patterns. Statistical analyses on key events of the gait cycle were carried out to investigate whether the differences were statistically different. All statistical tests showed that the transverse plane angles recorded at certain gait events were significantly different in both groups ($p < 0.001$). This was expected given the differences observed in the graphs presented.

7.6. Data Correlations

The subjective data collected during this study included the Oxford Knee Score and SF-12 PROMs. The results of these PROMs were correlated against the objective data presented in this chapter to investigate the relationship between both types of data. Strong correlations would suggest that PROMs can continue to be used as alternatives to functional assessments. However, weak correlations would contribute to evidence in the current literature that both subjective and objective scientific outcome measures should be used in the orthopaedic environment to assess this patient population. Details on the statistical analyses were given in Chapter 6.

7.6.1. Pre-Operative Correlations

The pre-operative patient cohort analysed for this investigation was aged 71±9 years with a mean mass of 84.6±17.6kg and mean height of 1.65±0.11m (BMI: 30.8±5.1kg/m^2). The distribution of the pre-operative data were correlated is shown in Table 7.61.

The physical score of the SF-12 indicated that the patients had below average physical function, as expected (Table 7.61). The average OKS was 22 out of a maximum 48, further suggesting that our population presented with sub-optimal knee function.

Table 7. 61: Distribution of the pre-operative data used in the correlation analyses (n = 50).

Variable	Knee	Mean (± SD)	95% CI	Range
OKS	-	22.1 (7.3)	20.0 - 24.1	6.0 - 39.0
SF-12 Physical Score	-	30.2 (8.2)	27.8 - 32.5	12.8 - 56.1
Active ROM (°)	**Operative Knee**	102.9 (22.3)	96.6 - 109.2	45.4 - 148.7
	Non-Operative Knee	112.0 (17.9)	106.9 - 117.1	53.1 - 156.9
Passive ROM (°)	**Operative Knee**	101.9 (21.6)	90.5 – 116.9	44.7 – 148.7
	Non-Operative Knee	111.9 (18.1)	101.1 – 121.1	58.1 – 156.9
Maximum Extensor Strength (Nm)	**Operative Knee**	45.0 (10.9)	39.2 – 50.6	18.8 – 87.9
	Non-Operative Knee	47.1 (11.0)	39.5 – 51.9	21.8 – 84.7
Maximum Flexor Strength (Nm)	**Operative Knee**	48.8 (10.6)	42.0 – 53.4	21.0 – 85.7
	Non-Operative Knee	54.3 (20.1)	44.5 – 54.9	16.0 – 125.6
Knee Flexion at Initial Contact (°)	**Operative Knee**	21.2 (10.0)	14.8 – 25.7	4.6 – 52.9
	Non-Operative Knee	21.6 (9.6)	14.9 – 27.4	1.2 – 42.5
Knee Flexion at Loading Response (°)	**Operative Knee**	20.8 (9.9)	14.2 – 25.6	5.0 – 52.0
	Non-Operative Knee	21.1 (9.4)	14.9 – 26.3	1.3 – 41.9
Knee Flexion at Mid-Stance (°)	**Operative Knee**	19.5 (10.0)	10.7 – 23.9	3.1 – 45.7
	Non-Operative Knee	18.8 (8.4)	13.1 – 24.8	1.9 – 37.7
Knee Flexion at Terminal Stance (°)	**Operative Knee**	17.9 (14.8)	8.3 – 21.6	1.4 – 62.3
	Non-Operative Knee	12.4 (7.9)	6.4 – 16.1	1.3 – 48.7
Knee Flexion at Mid-Swing (°)	**Operative Knee**	49.4 (12.4)	39.7 – 59.8	24.2 – 78.4
	Non-Operative Knee	48.7 (10.9)	41.0 – 57.8	23.0 – 68.4
Step Length (m)	**Operative Side**	0.30 (0.14)	0.22 – 0.38	0.10 – 0.80
	Non-Operative Side	0.30 (0.13)	0.21 – 0.36	0.10 – 0.76
Stride Length (m)	-	0.62 (0.28)	0.44 - 0.76	0.27 – 1.56
Walking Speed (m/s)	-	0.33 (0.09)	0.30 - 0.35	0.15 - 0.51
Cadence (m/s^2)	-	46.6 (2.4)	33.9 – 53.7	26.0 - 103.0

Table 7.62 shows the Pearson correlation coefficients of the OKS and physical scores of the SF-12 against pre-operative functional assessment results. The objective functional assessments were poorly correlated with the subjective scores (Table 7.62). The best correlation was found between flexor strength of the operative knee and the SF-12 score ($r = -0.236$, $p = 0.105$), but the relationship was not considered clinically significant given that the r^2 value (the coefficient of determination) was 0.056 indicating only 5.6% of the variation in one score was accounted for by the variation in the other. The relationship between both variables is shown in Figure 7.44.

Table 7.62: Correlations between pre-operative PROM scores and functional outcome in 50 knee OA patients.

Variable	Knee	OKS r (p-value)	SF-12 Physical Score r (p-value)
Active ROM	**Operative Knee**	0.000 (0.998)	0.001 (0.992)
	Non-Operative Knee	-0.021 (0.886)	0.059 (0.685)
Passive ROM	**Operative Knee**	-0.047 (0.748)	-0.014 (0.925)
	Non-Operative Knee	0.003 (0.984)	0.155 (0.282)
Maximum Extensor Strength	**Operative Knee**	-0.121 (0.404)	-0.196 (0.173)
	Non-Operative Knee	0.011 (0.940)	-0.161 (0.263)
Maximum Flexor Strength	**Operative Knee**	-0.174 (0.226)	-0.236 (0.105)
	Non-Operative Knee	0.114 (0.430)	0.173 (0.229)

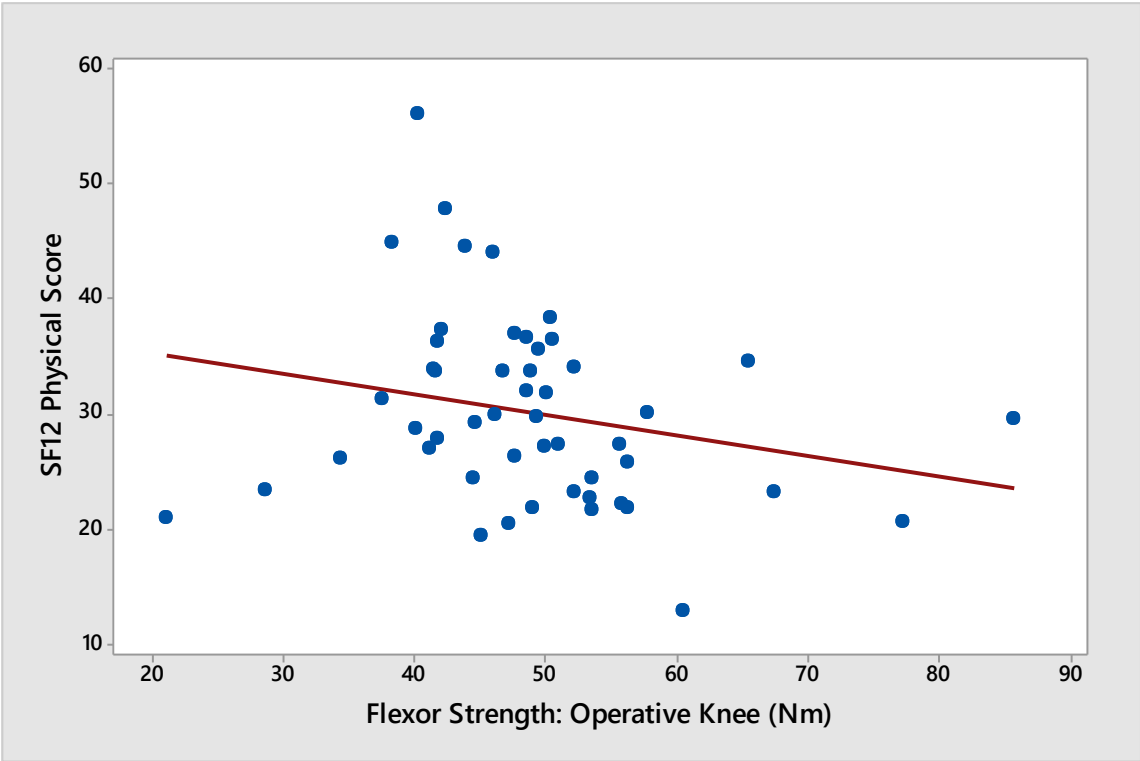


Figure 7.44: The relationship between maximum flexor strength of the operative knee and the physical score of the SF-12 PROM. Differences were not statistically significant (p = 0.105) nor was the correlation clinically significant (r = -0.236) (n = 50).

The worst results were found between both OKS and SF-12 scores and active knee ROM of the operative knee (r = 0.000, p = 0.998 & r = 0.001, p = 0.992, respectively).

Table 7.63 shows the Pearson correlation coefficients of the OKS and physical scores of the SF-12 against sagittal plane kinematics during gait and certain parameters of gait.

Table 7.63: Correlations between PROM scores and gait parameters in 50 knee OA patients.

Variable	Knee	OKS r (p-value)	SF-12 Physical Score r (p-value)
Knee Flexion at Initial Contact	**Operative Knee**	0.033 (0.819)	0.092 (0.524)
	Non-Operative Knee	-0.020 (0.889)	-0.197 (0.170)
Knee Flexion at Loading Response	**Operative Knee**	0.031 (0.830)	0.096 (0.507)
	Non-Operative Knee	-0.030 (0.836)	-0.212 (0.139)
Knee Flexion at Mid-Stance	**Operative Knee**	-0.031 (0.928)	0.088 (0.543)
	Non-Operative Knee	-0.045 (0.757)	**-0.279 (0.049)***
Knee Flexion at Terminal Stance	**Operative Knee**	-0.064 (0.659)	0.047 (0.748)
	Non-Operative Knee	0.009 (0.952)	-0.130 (0.368)
Knee Flexion at Mid-Swing	**Operative Knee**	-0.086 (0.551)	0.054 (0.708)
	Non-Operative Knee	-0.020 (0.889)	-0.107 (0.461)
Step Length	**Operative Side**	0.100 (0.489)	0.188 (0.192)
	Non-Operative Side	0.145 (0.315)	0.226 (0.115)
Stride Length	-	0.194 (0.177)	0.122 (0.398)
Walking Speed	-	0.109 (0.451)	0.262 (0.066)
Cadence	-	0.086 (0.552)	0.134 (0.353)

**Statistical Significance*

The objective functional assessments were poorly correlated with the gait data (Table 7.63). The best correlation was found between knee flexion at mid-stance in the non-operative knee and the SF-12 score ($r = -0.279$, $p = 0.049$). The relationship was not considered clinically significant as the r^2 value was 0.079 indicating only 7.9% of the variation in one score was accounted for by the variation in the other. The relationship between both variables is shown in Figure 7.45.

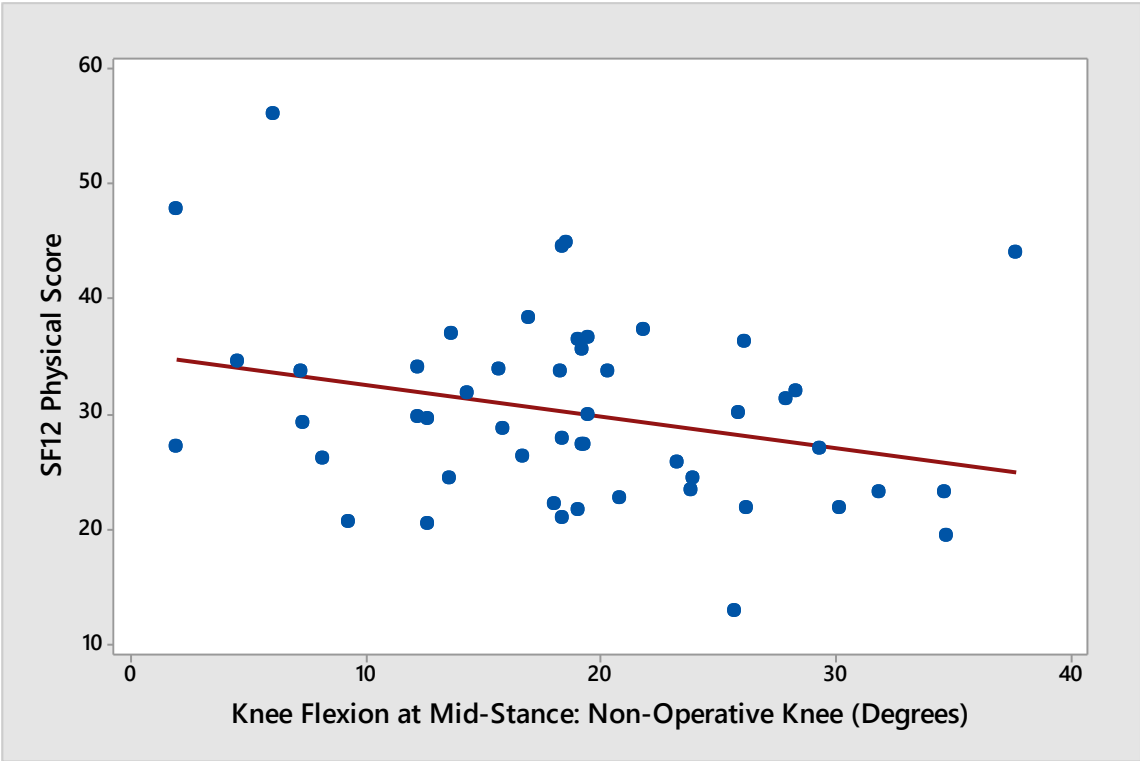


Figure 7.45: The relationship between knee flexion angle of the operative knee at mid-stance and the physical score of the SF-12 PROM. Differences were statistically significant ($p = 0.049$) but the correlation was not clinically significant ($r = -0.279$) ($n = 50$).

Despite there being poor correlations between the objective and subjective outcome measures, the physical score of the SF-12 generally showed better correlations with the functional assessments than the OKS.

7.6.2. Six-Weeks Post-Operative Correlations

Six-week post-operative data of 30 patients (17 males and 13 females) were analysed for this investigation. The patients had a mean age of 70±9 years, a mean mass of 85.5±15.8kg and mean height of 1.65±0.11m (BMI: 31.3±5.0kg/m^2). The distribution of the pre-operative data were correlated is shown in Table 7.64.

Table 7. 64: Distribution of the six-week post-operative data used in the correlation analyses (n = 30).

Variable	Knee	Mean (± SD)	95% CI	Range
OKS	-	32.4 (8.4)	28.5 – 37.2	8.0 – 45.0
SF-12 Physical Score	-	35.7 (9.8)	29.4 – 43.4	18.4 – 55.2
Active ROM (°)	**Operative Knee**	89.3 (24.3)	69.1 – 103.1	51.8 – 144.8
	Non-Operative Knee	118.9 (18.2)	106.6 – 130.3	70.5 – 155.0
Passive ROM (°)	**Operative Knee**	90.1 (25.0)	69.1 – 105.9	48.9 – 153.9
	Non-Operative Knee	119.8 (18.5)	107.5 – 132.4	69.5 – 155.5
Maximum Extensor Strength (Nm)	**Operative Knee**	47.0 (9.3)	40.9 – 49.2	35.7 – 78.5
	Non-Operative Knee	48.9 (15.9)	42.3 – 50.6	33.7 – 122.2
Maximum Flexor Strength (Nm)	**Operative Knee**	49.0 (8.7)	43.3 – 52.9	35.1 – 78.5
	Non-Operative Knee	52.9 (15.7)	45.8 – 53.6	39.5 – 122.1
Knee Flexion at Initial Contact (°)	**Operative Knee**	25.0 (10.1)	20.3 – 29.3	0.4– 50.6
	Non-Operative Knee	23.4 (9.5)	17.1 – 29.5	0.4 – 42.2
Knee Flexion at Loading Response (°)	**Operative Knee**	24.6 (10.0)	19.5 – 28.1	0.4 – 50.4
	Non-Operative Knee	23.0 (9.3)	16.3 – 29.0	0.4 – 40.4
Knee Flexion at Mid-Stance (°)	**Operative Knee**	22.7 (9.5)	15.1 – 27.0	0.1 – 49.4
	Non-Operative Knee	20.7 (9.0)	13.6 – 29.2	0.1 – 35.8
Knee Flexion at Terminal Stance (°)	**Operative Knee**	19.8 (9.4)	14.1 – 22.5	5.2 – 53.6
	Non-Operative Knee	13.5 (6.8)	7.4 – 17.1	1.7 – 26.4
Knee Flexion at Mid-Swing (°)	**Operative Knee**	50.0 (9.4)	42.3 – 56.2	32.8 – 71.3
	Non-Operative Knee	51.6 (9.8)	44.1 – 58.3	33.6 – 73.9
Step Length (m)	**Operative Side**	0.29 (0.12)	0.21 – 0.34	0.10 – 0.58
	Non-Operative Side	0.33 (0.12)	0.27 – 0.37	0.17 – 0.74
Stride Length (m)	-	0.62 (0.21)	0.50- 0.72	0.36 – 1.32
Walking Speed (m/s)	-	0.38 (0.18)	0.27 – 0.44	0.19 – 1.05
Cadence (m/s^2)	-	69.1 (22.0)	54.7 – 86.5	29.5 – 137.0

The physical score of the SF-12 and OKS showed that the patients continued to have below average physical function six-weeks post-operatively (Table 7.64). When compared to pre-operative data, the average scores had improved, however.

Table 7.65 shows the Pearson correlation coefficients of the OKS and physical scores of the SF-12 against pre-operative functional assessment results. The objective functional assessments did not correlate with the subjective scores (Table 7.65). This was consistent with pre-operative findings. The best correlation was found between passive ROM of the non-operative knee and the OKS score, but the relationship was not clinically or statistically significant ($r = 0.220$, $p = 0.243$).

Table 7.65: Correlations between PROM scores and functional outcome in 30 TKA patients (six weeks post-operatively).

Variable	Knee	OKS r (p-value)	SF-12 Physical Score r (p-value)
Active ROM	**Operative Knee**	0.190 (0.315)	0.111 (0.561)
	Non-Operative Knee	0.219 (0.245)	0.106 (0.577)
Passive ROM	**Operative Knee**	0.188 (0.321)	0.100 (0.598)
	Non-Operative Knee	0.220 (0.243)	0.064 (0.738)
Maximum Extensor Strength	**Operative Knee**	-0.144 (0.449)	-0.107 (0.573)
	Non-Operative Knee	0.106 (0.576)	0.169 (0.372)
Maximum Flexor Strength	**Operative Knee**	-0.036 (0.851)	-0.179 (0.345)
	Non-Operative Knee	0.083 (0.662)	0.219 (0.245)

Better correlations were found in the gait data at six-weeks, especially during mid-stance (Table 7.66). This followed pre-operative trends. Although $r > 0.3$ during mid-stance, the differences were not statistically significant. Significant differences were however reported between walking speeds and SF-12 scores. This was the only variable to correlate with one of the PROMs six-weeks post-operatively. The relationship between both variables is shown in Figure 7.46. This figure shows that there are two outliers (highlighted with black rings) which clearly contribute to the correlation reported (Figure 7.46).

Table 7.66: Correlations between PROM scores and gait parameters in 30 TKA patients (six weeks post-operatively).

Variable	Knee	OKS r (p-value)	SF-12 Physical Score r (p-value)
Knee Flexion at Initial Contact	**Operative Knee**	0.137 (0.470)	0.210 (0.264)
	Non-Operative Knee	0.115 (0.544)	0.188 (0.320)
Knee Flexion at Loading Response	**Operative Knee**	0.156 (0.411)	0.238 (0.205)
	Non-Operative Knee	0.126 (0.506)	0.198 (0.295)
Knee Flexion at Mid-Stance	**Operative Knee**	0.176 (0.353)	**0.323 (0.082)**
	Non-Operative Knee	0.274 (0.143)	**0.330 (0.075)**
Knee Flexion at Terminal Stance	**Operative Knee**	0.057 (0.763)	0.193 (0.306)
	Non-Operative Knee	0.280 (0.134)	0.175 (0.356)
Knee Flexion at Mid-Swing	**Operative Knee**	0.205 (0.277)	0.016 (0.933)
	Non-Operative Knee	0.141 (0.459)	0.084 (0.658)
Step Length	**Operative Side**	0.160 (0.400)	0.245 (0.192)
	Non-Operative Side	0.132 (0.488)	0.251 (0.180)
Stride Length	-	0.161 (0.394)	0.275 (0.141)
Walking Speed	-	0.287 (0.124)	**0.386 (0.035)***
Cadence	-	0.078 (0.684)	0.020 (0.917)

**Statistical Significance*

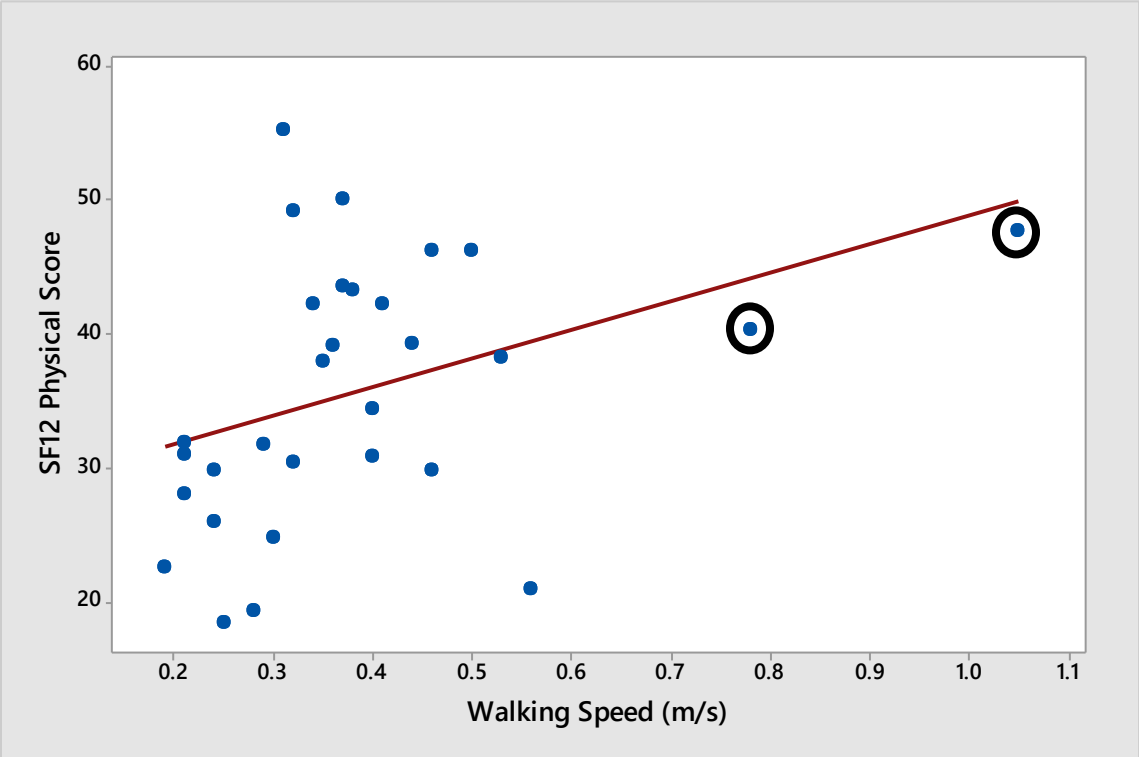


Figure 7.46: The relationship between walking speed and the physical score of the SF-12 PROM. Differences were statistically significant (p = 0.035) and the correlation was clinically significant (r = 0.386) (n = 30). Black rings highlight outliers.

7.6.3. One-Year Post-Operative Correlations

One-year post-operative data from 25 patients (13 males, 12 females) were correlated against the OKS and SF-12 PROMs. The patients had a mean age of 72±9 years, a mean mass of 86.1±16.5kg and mean height of 1.67±0.11m (BMI: 30.8±4.3kg/m^2). The distribution of the correlated data is shown in Table 7.67.

Both scores had improved one-year post-operatively when compared to baseline and six-week data (Table 7.67). However, there was no clear relationship between the scores of the OKS and SF-12 and knee ROM and strength. None of the variables analysed correlated (Table 7.68).

The physical score of the SF-12 correlated with sagittal plane kinematics of the non-operative knee during terminal stance (Table 7.69). Otherwise, there were no correlations between the subjective scores and gait kinematics during specific events. Step lengths also correlated with the SF-12 score one year post-operatively. Walking speed was the only variable to correlate and show statistical difference with both PROMs (Table 7.69). This was consistent with previous findings. Figure 7.47 show the relationships between both PROM scores and walking speed.

Table 7. 67: Distribution of the one-year post-operative data used in the correlation analyses (n = 25).

Variable	Knee	Mean (± SD)	95% CI	Range
OKS	-	39.1 (6.0)	37.0 – 44.0	21.0 – 47.0
SF-12 Physical Score	-	44.7 (8.5)	42.9 – 50.3	21.5 – 55.1
Active ROM (°)	**Operative Knee**	113.4 (18.3)	105.0 – 125.8	57.6 – 146.3
	Non-Operative Knee	115.9 (25.3)	97.6 – 131.0	97.6 – 167.3
Passive ROM (°)	**Operative Knee**	113.7 (18.6)	105.1 – 124.2	62.2 – 158.2
	Non-Operative Knee	114.5 (25.7)	95.9 – 131.4	55.2 – 156.7
Maximum Extensor Strength (Nm)	**Operative Knee**	39.0 (4.5)	36.1 – 41.0	39.7 – 48.0
	Non-Operative Knee	44.3 (7.1)	40.3 – 46.7	37.5 – 73.7
Maximum Flexor Strength (Nm)	**Operative Knee**	46.0 (3.4)	44.1 – 48.8	38.2 – 52.4
	Non-Operative Knee	46.4 (3.5)	44.3 – 48.9	40.6 – 53.2
Knee Flexion at Initial Contact (°)	**Operative Knee**	28.5 (12.3)	24.5 – 34.2	5.8 – 60.1
	Non-Operative Knee	23.4 (10.1)	19.7 – 34.5	8.6 – 53.3
Knee Flexion at Loading Response (°)	**Operative Knee**	27.8 (11.9)	23.8 – 33.2	4.8 – 58.6
	Non-Operative Knee	26.0 (9.7)	19.1 – 33.8	10.1 – 52.9
Knee Flexion at Mid-Stance (°)	**Operative Knee**	25.9 (9.1)	21.7 – 32.1	5.0 – 45.1
	Non-Operative Knee	24.5 (8.3)	18.7 – 31.2	13.6 – 46.0
Knee Flexion at Terminal Stance (°)	**Operative Knee**	17.5 (7.1)	12.8 – 22.7	5.3 – 36.9
	Non-Operative Knee	15.7 (8.4)	9.0 – 21.7	0.9 – 31.1
Knee Flexion at Mid-Swing (°)	**Operative Knee**	60.6 (9.3)	53.9 – 67.4	43.0 – 75.2
	Non-Operative Knee	54.0 (11.1)	47.3 – 62.0	32.6 – 72.2
Step Length (m)	**Operative Knee**	0.49 (0.24)	0.30 – 0.62	0.13 – 1.06
	Non-Operative Knee	0.51 (0.27)	0.31 – 0.66	0.13 – 1.10
Stride Length (m)	-	1.00 (0.50)	0.61 – 1.26	0.28 – 2.14
Walking Speed (m/s)	-	0.53 (0.05)	0.35 – 0.68	0.11 – 1.27
Cadence (m/s^2)	-	47.3 (19.8)	35.0 – 54.2	28.0 – 110.5

Table 7.68: Correlations between PROM scores and functional outcome in 25 TKA patients (one year post-operatively).

Variable	Knee	OKS r (p-value)	SF-12 Physical Score r (p-value)
Active ROM	**Operative Knee**	0.147 (0.495)	0.050 (0.817)
	Non-Operative Knee	0.202 (0.333)	-0.017 (0.935)
Passive ROM	**Operative Knee**	0.110 (0.607)	0.038 (0.859)
	Non-Operative Knee	0.206 (0.324)	-0.052 (0.805)
Maximum Extensor Strength	**Operative Knee**	-0.041 (0.844)	-0.205 (0.326)
	Non-Operative Knee	0.126 (0.548)	0.138 (0.511)
Maximum Flexor Strength	**Operative Knee**	0.176 (0.401)	0.024 (0.908)
	Non-Operative Knee	0.024 (0.911)	-0.095 (0.652)

Table 7.69: Correlations between PROM scores and gait parameters in 30 TKA patients (one year post-operatively).

Variable	Knee	OKS r (p-value)	SF-12 Physical Score r (p-value)
Knee Flexion at Initial Contact	**Operative Knee**	0.042 (0.843)	0.224 (0.281)
	Non-Operative Knee	-0.172 (0.411)	-0.036 (0.864)
Knee Flexion at Loading Response	**Operative Knee**	0.050 (0.812)	0.237 (0.253)
	Non-Operative Knee	-0.162 (0.439)	-0.020 (0.924)
Knee Flexion at Mid-Stance	**Operative Knee**	0.106 (0.613)	0.296 (0.150)
	Non-Operative Knee	0.052 (0.805)	0.211 (0.312)
Knee Flexion at Terminal Stance	**Operative Knee**	0.166 (0.429)	0.218 (0.295)
	Non-Operative Knee	0.234 (0.260)	**0.339 (0.097)**
Knee Flexion at Mid-Swing	**Operative Knee**	0.019 (0.927)	0.195 (0.350)
	Non-Operative Knee	-0.173 (0.407)	-0.060 (0.777)
Step Length	**Operative Side**	0.230 (0.269)	**0.321 (0.118)**
	Non-Operative Side	0.215 (0.302)	**0.340 (0.096)**
Stride Length	-	0.233 (0.263)	0.289 (0.161)
Walking Speed	-	**0.476 (0.016)***	**0.484 (0.014)***
Cadence	-	-0.023 (0.913)	0.179 (0.393)

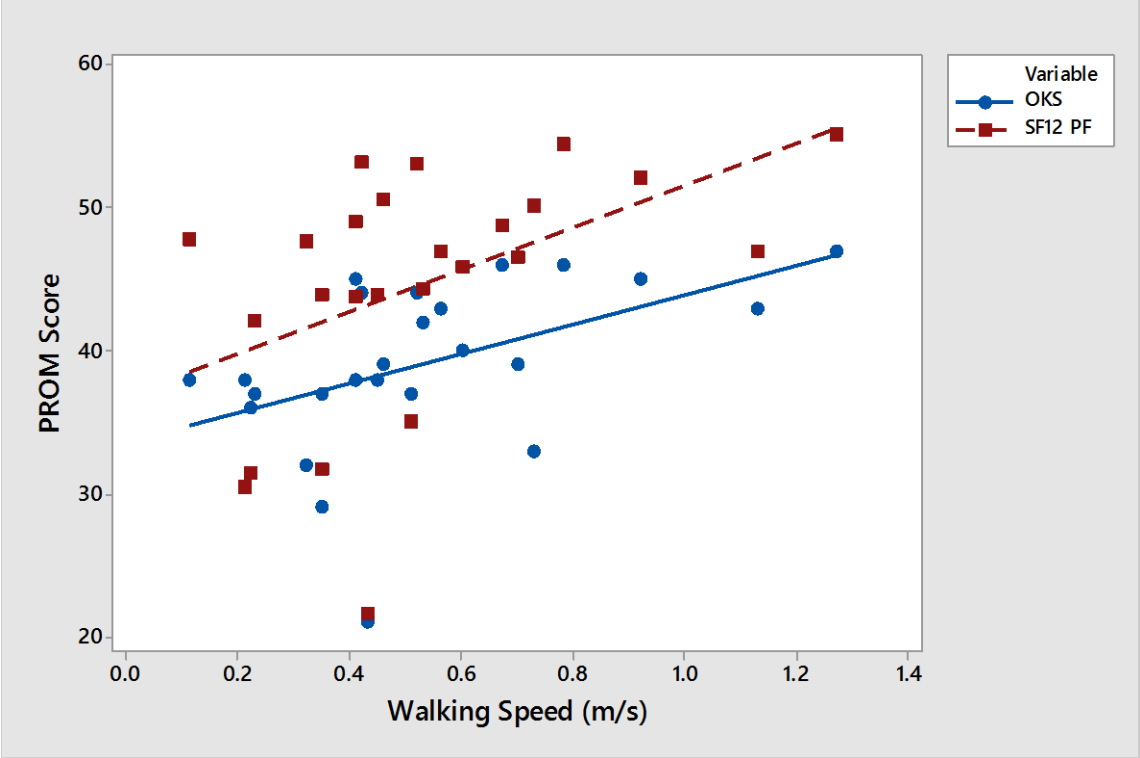


Figure 7.47: The relationship between walking speed and both PROM scores. Differences were statistically significant and the correlations were clinically significant (n = 25).

Overall, this correlation study highlights the fact that the OKS and SF-12 PROMs, which are commonly used in the orthopaedic environment to assess knee function, do not correlate with objective data from functional assessments, especially pre-operatively. These results therefore consolidate our belief that clinicians should only use PROMs to supplement data from objective assessments when analysing knee function.

The results in this chapter have shown the system developed and presented in this thesis to be efficient and effective at collecting scientific data on knee function. We have also shown that this system could feasibly be used in a hospital environment. Detailed discussion of the results and clinical use of this system will follow in the next chapter.

Chapter 8. Discussion

The results presented in chapter 7 showed the capability of the motion capture system as a functional outcome measure for TKA. This chapter discusses the feasibility of using this system (hardware and software) in a clinical environment by arguing the advantages and current limitations to its use. It also describes in detail the results presented in the previous chapter of this thesis, comparing the data to previously published research. The clinical implications of the work described in this thesis and proposed future work, are also reported in this chapter.

8.1. Clinical Motion Capture System

This thesis has described multiple disadvantages to traditional motion capture protocols which prevent its routine use in the clinical environment. The efficiency of the system used in this study to improve accessibility of motion capture technology to clinicians and patients was presented in Chapter 7. Here we will discuss the effectiveness of the hardware and software used for this system, referring where appropriate, to the data presented in Chapter 7.

8.1.1. Clinical Motion Capture Hardware

Treadmill

Baten and colleagues stated in 2007 that a critical feature a clinical GA system must possess is a small footprint. Thus, to minimise the footprint of our system, the capture volume was reduced to the size of a treadmill. Treadmills are an established and appropriate tool for analysing gait in patients, and they are widely used in research and clinical environments (Leigh *et al.,* 2014). This provides the following advantages:

1. Treadmills are acceptable to clinicians.
2. Treadmills are acceptable to patients.
3. Most orthopaedic clinical environments already possess a treadmill.
4. Clinicians are familiar with how to use treadmills.

The treadmill used in this study (N-Mill: Motekforce Link, Amsterdam) was chosen for its compatibility with D-Flow software and its self-paced capacity. A further benefit to using this treadmill was that all assessments could comfortably be carried out on it. It was therefore not necessary to increase the capture volume beyond the dimensions of the treadmill. Long treadmills, such as the N-Mill (2m in length), may also provide data that better represents natural gait when compared to data collected with traditional treadmills, as shorter traditional treadmills are believed to contribute to the statistical differences measured in some biomechanical parameters between over-ground and treadmill gait (Alton *et al*., 1998; Sloot *et al.,* 2014; Strathy *et al*., 1983).

A disadvantage to using this treadmill was the unreliability of the self-paced function implemented in D-Flow. The function failed to activate on 5 occasions (Table 7.2). In an attempt to identify the cause of these failures, the custom-written codes were checked for errors in the scripts which were programmed to activate the self-paced mode, but none were discovered. The log of events in D-Flow was also searched for error messages, but none had been reported, suggesting that D-Flow had not come across any errors when the assessments were being carried out. In addition to checking the custom-written scripts and error logs in D-Flow, parts of the motor were replaced and updated by Motekforce Link. The problem was never fully resolved, however. As a consequence it must be borne in mind that users must be prepared to implement traditional fixed-paced protocols when necessary.

A further disadvantage to this treadmill was its step size (0.18m). Many patients required assistance to step up to or down from the treadmill. In future this could easily be avoided by placing a ramp at the end of the treadmill.

Frame

Traditionally, frames for mounting motion capture cameras surround the entire capture volume, as individual marker-based models use markers on all surfaces of the limbs (Figure 8.1 & Figure 2.19). As we were using a cluster model, it was possible to place all markers on the anterior and posterior surfaces of the segments, eliminating the need to place cameras along the treadmill's length. For this reason, only two camera frames were required – one at the front of the treadmill, and one at the rear (Figure 8.2). The footprint of the system was therefore restricted in a way which did not sacrifice the quality of the data recorded or limit access to the treadmill.

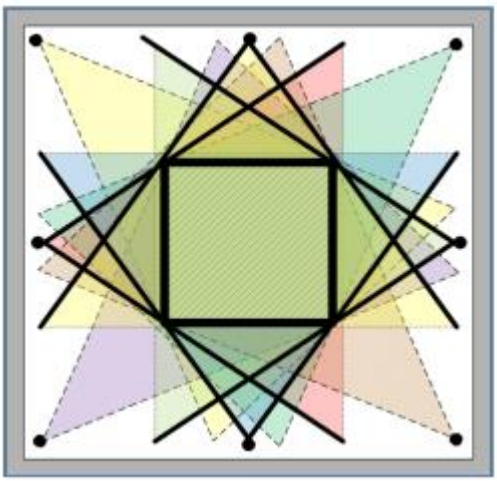


Figure 8.1: An example of the camera configuration typically used in gait analysis to ensure all markers within the capture volume can be seen and reconstructed.

(Source: Vicon Motion Systems, 2017)

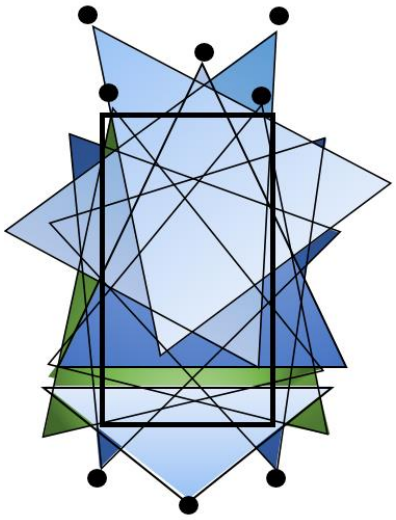


Figure 8.2: A diagram of the camera configuration used in this study to ensure all markers within the capture volume were seen and reconstructed accurately. The lighter blue fields of view represent the cameras higher up on the frames and the green fields of view represent those lower down on the frames.

The frames used for this system were lightweight for portability. However, the lightness of the frames proved problematic in our study as patients who used the rear frame as a prop when mounting and dismounting the treadmill also moved the cameras attached to the frame (Table 7.3). This could be improved in future by installing a ramp for patients to use to avoid step negotiation. Alternatively, a more robust frame could be built. This would be most appropriate for permanently installed systems.

Motion Capture Cameras

Vicon Bonita B10 cameras were chosen for this study as they are cheaper and smaller than the cameras typically used in gait laboratories (Millar, 2017). According to the manufacturers, Bonita B10 cameras are also highly accurate, precise to within 0.5mm translation, and can capture 250 frames per second; enough to detect small movements.

It was previously stated that a successful calibration is one where each camera has a reported error <0.5mm (section 3.2.1). The average error of each camera

was <0.3mm in our study, supporting the use of these cameras in a clinical setting (Table 7.5).

Following Vicon recommendations that accurate determination of a markers' position depends on it being in the field of view of 3 cameras, a minimum of 3 cameras were attached to each frame (Figure 8.2). Five cameras were attached to the front frame to ensure that reconstruction of all markers on the 6 anterior clusters was effective. Only one cluster faced posteriorly (pelvis cluster), thus 3 cameras were deemed sufficient for the posterior frame.

We did not encounter any problems with identifying or tracking markers during this study, suggesting that the camera configuration used was successful.

Summary

- The hardware used for our system was appropriate for the investigation.
- The layout was acceptable to patients.
- On no occasion was it necessary to recapture or process data due to the cameras failing to track the patients' movements, implying that the configuration of the cameras were appropriate for the assessments being carried out.
- The system could be improved in future by placing a ramp at the end of the treadmill to prevent patients from holding onto the posterior frame when mounting and dismounting the treadmill.
- The system has a small footprint: 3.5(L) × 2.1(H) × 1.1(W)m.

We are confident that the hardware used for this motion capture system can feasibly be used in a clinical environment.

8.1.2. Clinical Motion Capture Software

Camera Calibration Application

This application provided the assessor with a method of quickly checking the camera calibration before each use. By placing the calibration wand in the field of view the assessor could identify whether recalibration was necessary from the colours of the markers displayed on the screen. This saved time between uses and also prevented the recording of unusable or inaccurate data due to a poorly calibrated system.

This application is appropriate for a clinical outcome measure as its result is easily interpretable to clinicians and also very simple to use. It also requires no additional equipment and therefore no additional expense.

To comment on the acceptableness of this application to clinicians it would be necessary to carry out a further study where clinicians' feedback on the application is reported.

Biomechanical Model: Cluster Use

Major contributing factors to the limited use of motion analysis in the clinical environment include the facts that traditional biomechanical models are complicated and time consuming. The cluster model developed for this study is more appropriate for the orthopaedic clinical environment than traditional individual marker-based models. For example, patients are not required to change into tight-fitting clothing to carry out assessments with the cluster model. Over the course of this study however, we identified the fact that not all clothes worn by patients are appropriate for this model (Table 7.3). As a result of these incidents, the patient appointment letters were altered with a note to kindly ask patients to wear trousers or shorts when attending the clinic. We recommend that all clinical users of this system take this approach. Spare clothing should however be available for use if required.

Following clinical use of this model, we can infer that the clusters were acceptable to patients. Problems were encountered if they were too tight or

loose, however (Table 7.3). As a consequence, it is recommended that cluster placement and patient comfort are thoroughly checked prior to subject calibration to optimise efficiency and acceptability.

In terms of clinical use, this cluster model may be more acceptable to clinicians than traditional biomechanical models. Implementation of a labelling function meant that the user was not required to label each cluster marker individually following trials. Automating this process saved time in the clinic and simplified the entire protocol.

In terms of expanding use of this model in future, multiple identical sets of the cluster can be created cheaply and quickly through 3D printing. Hence, this system could conceivably be used at multiple different sites without having to alter or personalise the labelling functions and codes used to obtain the biomechanical data.

Biomechanical Model: Anatomical Calibration

A labelling function was implemented in this system to calibrate anatomical landmarks. Despite proving successful in this study, improvements could be made to the visual feedback presented during calibration. At present, the only visual cue available to the user during calibration is a counter that increases by 1 each time a landmark is successfully recorded. However, it is likely for users who are unfamiliar with the protocol to calibrate the landmarks in an incorrect order. Introducing a visual cue to inform users on which landmark should be calibrated next could minimise this risk.

The most significant limitation to the current calibration protocol is that it is not possible to un-register a landmark. Thus, if a mistake is made during calibration, the user must start the calibration process again. Future development work should therefore be undertaken to implement a method of deleting and replacing an incorrect landmark during calibration.

Overall however, the process of calibrating the anatomical landmarks worked well in the clinic. Unsuccessful patient calibration was rare in this study, but did

happen as a result of the pointer being occluded during use (Table 7.3). To overcome this, a function was written into the program that activated an error message on the visualisation screen if the pointer tip could not be reconstructed during calibration. This proved to be successful, as it reduced the likelihood of having to re-calibrate patients.

One worry with the pointer method of calibrating anatomical landmarks was that the orientation of the pointer would affect the reliability of the co-ordinates recorded. Our validation study on this method showed that alternating the orientation of the pointer during use could influence the kinematics (section 5.1). The most reliable method of registering landmarks was holding the pointer in a consistent position at each use. In light of this study, the importance of consistent pointer orientation should be conveyed to clinicians wishing to use the system in future in the user-manual.

Summary

- An alternative simplified method of calibrating motion capture cameras and anatomical landmarks was created.
- The calibration process was acceptable to patients.
- Improvements could be made to the software to aid clinicians during patient calibration and reduce the risk of unsuccessful calibrations.
- Validation of pointer use showed that the calibration method was reliable.

This new protocol was shown to be acceptable to patients and could easily be taught to clinicians. It should be emphasised however, that accurate and precise registration of an anatomical landmark remains dependent upon the clinician's ability to recognise the landmarks by palpation.

8.2. Range of Motion Assessment

A method for measuring knee ROM was included in our clinical outcome measure package to overcome some of the limitations associated with the clinical standard tool (Myles *et al.,* 2002; Piriyaprasarth and Morris, 2007).

8.2.1. Discussion of the Results

Pre-operatively, the patient cohort exhibited mean joint ROM that is typical of end-stage OA (Table 8.1). Regardless of assessment condition, the majority were unable to achieve 110° flexion on the operative side (Table 7.20 & Table 7.22). ROM in the contralateral knee was also limited, but not to the same extent. Most patients involved in this trial had signs of OA in both knees, but the worst affected knee was operated on first. This may explain why greater ROM was recorded in the contralateral knee than the operative knee and why full knee ROM could not be achieved in either knee.

Due to the restricted knee ROM exhibited by the average patient, it can be inferred that certain activities of daily living would have been difficult or impossible for many patients to complete pre-TKA (Meneghini *et al.,* 2007; Rowe *et al.,* 2002).

Although mean recorded ROM was consistent with previous findings, the standard deviations were slightly higher in this study than is typically observed (Table 7.19, Table 7.21 & Table 8.1). This may have been due to the fact that the trial patients had been screened prior to elective clinics, meaning that those with the worst knee pain and knee function were approached as potential study volunteers. Patients with significantly lower ROM than the mean may therefore represent those who had severe stiffness in the joint pre-operatively. Those with significantly higher ROM than the mean may represent the patients whose predominant symptom was pain and not limited function. Our results therefore highlight the facts that OA is a disease that presents very differently in patients

and that patients tolerate variable levels of pain and function before visiting their GP.

The spread of the data reported in this study may also have been greater than previously reported as the method used here was more sensitive to change than those traditionally used clinically (Table 8.1). Hence, differences in ROM between patients may have been measured more accurately in our study.

Table 8. 1: Mean (±SD) knee ROM measured in other studies in patients with end-stage OA.

Authors of Published Studies	**Pre-Operative Active ROM (±SD)°**	**Outcome Measure**
Bauer *et al.,* 2010	111.8 (14.7)	Goniometer
Collins *et al.* 2014	101.6 (12.6)	Goniometer
Jakobsen *et al.,* 2010	95.3 (7.6)	Goniometer
Kwon *et al.,* 2010	127.2 (17.0)	Goniometer
Bytyqi *et al.,* 2014	105.2 (15.5)	Motion Analysis
Miner *et al.,* 2003	102.1 (12.1)	Goniometer
Chaudhary *et al.*, 2008	108.5 (10.3)	Goniometer
Kawamura & Bourne, 2001	107.0 (15.0)	Goniometer
Fan *et al.,* 2010	103.5 (2.0)	Unreported

The maximum pre-operative flexion and extension angles measured in our patients also resembled previously reported data (Table 7.20, Table 7.22 & Table 8.1). As expected, the non-operative knee could flex to a significantly greater degree than the operative knee. Conversely, greater extension was recorded in the operative knee but the differences were not significant. In general, patients were not able to extend the knee fully (0°), agreeing with previous studies that have reported at least one third of knee OA patients to have a flexion contracture at the knee prior to TKA (Campbell *et al.,* 2015*;* Ritter *et al.,* 2007).

Overall, these results implied that reduced ROM in pre-operative TKA patients was due to limited knee flexion to a greater extent than it was due to limited knee extension under non-weight-bearing conditions. This may have significant implications during activities such as standing from a seated position or kneeling, where the ability to achieve high flexion at the knee joint is required (Rowe *et al.,* 2000).

Six-weeks following surgery, mean joint excursion (along with maximum flexion and maximum extension angles recorded) had worsened in the operative knee (Table 7.19-Table 7.22). This result is consistent with previous studies that have shown joint ROM to decrease within the initial post-TKA months (Bauer *et al.,* 2010, Collins *et al.,* 2014, Ebert *et al.,* 2014). At this early post-operative stage, patients are likely to have post-surgical inflammation and pain which limits ROM (Jevsevar *et al.,* 1993).

Although the operative knee could not reach the desired 110° of flexion, average maximum flexion was greater than 90° which is considered as a good outcome at this stage of recovery amongst clinicians.

Meneghini and colleagues (2007) reported the maximal achievable knee flexion angle in 511 TKA patients at least two years post-operatively (mean follow-up time was 3.7 years). The outcomes were classified into four categories (Table 8.2). According to their study, the average degree of flexion measured in our patients at this post-operative stage is considered low-to-normal for patients who have undergone TKA (Meneghini *et al.,* 2007). The mean passive flexion angle achieved in our patient cohort 6-weeks following TKA was equivalent to that of 24.5% of the patients in Meneghini's study, who were at least 2 years post-TKA.

Table 8. 2: Knee flexion outcome post-TKA categorised as per a study on functional outcome by Meneghini *et al*., 2007.

Category	**Post-Operative ROM Range (◦)**
Low Flexion	70-104
Low normal flexion	105-115
Normal flexion	116-125
High flexion	126-140

In terms of the contralateral knee, passive and active ROM increased within the first 6 weeks (Table 7.20 & Table 7.22). A possible explanation for this is that some patients were confident enough with the new implant to increase their activity levels within the first six weeks. This confidence may stem from the requirements of patients to mobilise within hours of the surgery and undergo on-site physiotherapy to encourage activity. It may also be due to the design, which prevents instability, even if muscles are weak.

One year post-operatively, knee ROM had improved beyond baseline levels. This was especially notable in the operative knee (Table 7.19 & Table 7.21). According to Meneghihi and colleagues (2007), the average maximum flexion achieved in both knees at 1-year corresponded to normal post-operative knee flexion. Both knees exceeded 110◦ flexion during the assessments, suggesting that the average patient could achieve sufficient movement at both joints for completing most activities of daily living.

The average ROM recorded at 1-year was similar to other published studies, where knee ROM was measured at least 12 months post-operatively (Table 7.19, Table 7.21, Table 8.3). This is especially encouraging when considering the fact that most of the patients involved in the Medacta study were assessed early (average follow-up time of 9.6 months instead of 12 months). Our data therefore suggest that the Medacta GMK Sphere implant is successful at restoring knee ROM to functionally acceptable levels (>110◦) within the first

post-operative year. Would it have been possible to assess each patient exactly 1-year post-operatively, the average recorded knee ROM may have been greater.

Table 8. 3: Mean (±SD) knee ROM measured in other studies in TKA patients (1-year post-operatively).

Authors of Published Studies	**Active ROM (± SD)°**	**Outcome Measure**
Bauer *et al.,* 2010	107.9 (12.5)	Goniometer
Kwon *et al.,* 2010	132.9 (10.5)	Goniometer
McClelland *et al.,* 2017	117.0 (15.0)	Goniometer
Miner *et al.,* 2003	109.4 (11.8)	Goniometer
Lavernia *et al.,* 2008	117.5 (1.7)	X-Ray
Kawamura & Bourne, 2001	109.0 (13.0)	Goniometer
Khanna *et al.,* 2011	112.7 (8.8)	Goniometer

Passive ROM was generally greater than active ROM in our patient cohort both pre- and post-operatively. This has been reported elsewhere in the literature (Kuiken *et al.,* 2004; Mai *et al.,* 2012). The discrepancies between passive and active ROM in the data may have resulted from patients actively resisting the researcher due to pain or discomfort in the knee. A study by Bennett *et al.* (2009) showed that passive knee ROM of pre-TKA patients was 16.4±13.1° greater when the pain was blocked by anaesthetic, supporting the theory that pain could have been a limiting factor for knee motion pre-operatively.

8.2.2. Clinical Success of Assessment

The accuracy and validity of the ROM assessment was supported by the validation study (Chapter 5). Mean differences between tools did not exceed 5°, suggesting that the differences were not clinically significant. The results recorded in the patients were also found to resemble previously published data,

implying that the assessment returned accurate and valid results when used in this patient population (Chapter 7).

The validation study also showed that this assessment had excellent intra-user reliability (ICCs >0.80; Table 5.5). The reliability of the assessment when used clinically was not investigated due to clinical time restrictions. Further research to investigate both intra and inter-user reliability is therefore necessary to confirm whether the system continues to be reliable under clinical conditions.

Another important aspect of an outcome measure is its interpretability to users. The results reported in this assessment are deemed to be easily interpretable to clinicians. The live angle, as well as maximum flexion, extension and excursion values can all be displayed during assessments for quick identification of all important results. To confirm that clinicians find the results easily interpretable an additional study should be carried out. Such a study could also provide valuable information on the acceptability of the assessment to clinicians.

We are confident that the assessment is acceptable to patients, as all but one patient were able to complete the assessment with ease (Table 7.3).

Overall, this investigation has shown this assessment to be appropriate for measuring knee ROM in TKA patients. It is also feasible for clinical use.

8.3. Knee Muscular Strength Assessment

Knee muscular strength is compromised in TKA patients both pre- and post-operatively. However, strength is rarely measured routinely in the clinical environment. This assessment provides clinicians with a simple and scientific method for assessing knee flexor and extensor strengths.

8.3.1. Discussion of the Results

Our study showed that patients exhibited statistically greater strength in the flexors and extensors of the non-operative knee than the operative knee pre-operatively (Table 7.25 & Table 7.26). This is consistent with previous studies of knee strength in end-stage OA (Selistre & Mattiello, 2014; Taniguchi *et al.,* 2015). Despite this perceived dominance, the differences in strength between limbs did not exceed 10% in our study. According to Krishnan & Williams (2009), differences of up to 10% are common between limbs, even in healthy adults. Given that many of the patients suffered from bilateral OA, it is unsurprising that the average differences in strengths between limbs were not greater than 10%. The statistical differences between limbs may therefore not be clinically significant.

On average, both knees showed statistically greater muscular strength in the flexors of the joint (Table 7.25). This finding is not uncommon in patients suffering from knee OA, as the quadriceps muscles responsible for extending the knee are weakened by the disease (Callahan *et al.,* 2015; Petterson *et al.,* 2008; Selistre & Mattiello, 2014).

Rossi *et al.,* (2002) reported mean maximum extensor strengths of 43.1±17.3Nm in their patients and Samuel & Rowe (2009) reported average flexor and extensor strengths of 47.7±11.3Nm and 55.3±13.3Nm, respectively in similar-aged older adults. The results recorded in this study were similar to those presented in these papers.

Six weeks following surgery, the maximum moments measured about both knees increased (Table 7.25). For some patients, this may be explained by pain alleviation as a result of the operation. Patients with improved pain levels may have returned to activities of daily living and increased their activity sooner. This may explain why strength of the contralateral limb also increased in some patients. Post-operative physiotherapy could also have been beneficial in improving maximum knee strength in some patients, as the exercises recommended to patients post-TKA focus on improving knee strength (Henderson *et al.,* 2017).

However, when the data from the subgroup of 27 patients who attended all three clinics were analysed, it was found that average strengths decreased between pre- and six-week post-operative assessments (Table 7.26). Although the differences were not statistically significant, it does show a slight bias in the larger group data towards people who had better functional outcome in terms of strength. This implies that those with poorer knee function post-operatively were more likely to attend all 3 clinics.

A study by Gagnon *et al.,* (2005) implemented a similar protocol to ours, and found that patients recovering from TKA had average flexor strengths of 41.7±22.1Nm and average extensor strengths of 41.7±25.3Nm when the knee was set at 60°. These values resemble those recorded six-weeks post-operatively, supporting the use of this assessment as an outcome measure for TKA.

One year post-operatively, maximum strengths of both muscle groups decreased bilaterally by such an extent that the results were poorer than pre-operatively (Table 7.25 & Table 7.26). The poorest results were recorded in the contralateral knee. This is a significant finding in this thesis, as it suggests that knee function did not fully improve in these patients post-operatively and that patients were worse off in terms of strength post-TKA. Although striking, other studies have also reported loss of knee strength in TKA patients one year post-operatively. A decrease in strength in both knees following TKA was also

reported by Yoshida and colleagues in 2012. In our study, this reduction in strength may be explained by the fact that a significant number of patients had developed symptoms of OA in other joints following TKA. Furthermore, five of the patients involved in this analysis had undergone a second TKA on the contralateral knee between the six-week and one-year appointment for the first TKA. It is therefore reasonable to suggest that some patients may not have been as active as expected within the first post-operative year. This may have influenced the overall results recorded. More importantly however, it should be considered that these results may accurately represent the early functional outcome of TKA patients. This implies that patients undergoing TKA may require strength training within the first post-operative year in order to prevent the quadriceps and hamstrings from weakening. Failure to target this loss of muscular strength could lead to the development of new biomechanical pathologies or injuries in these patients, which would require further treatment or rehabilitation.

Although muscular strength had reduced in the patients post-operatively, the differences in strengths between limbs and muscle groups had improved, suggesting that the balance between muscle groups was improving. This may be as a result of patients relying less on the contralateral knee during highly demanding functional tasks such as rising from a chair and stair climbing (Pozzi *et al.,* 2015). Reliance on the least affected limb can lead to sub-optimal biomechanics, which can cause injuries in other joints (Mandeville *et al.,* 2007; Pozzi *et al.,* 2015).

8.3.2. Clinical Success of Assessment

Prior to its clinical use, this assessment was validated against the myometer. Our results showed that there were no statistically significant differences between the results recorded during knee flexor assessments, implying that these data were valid and accurate. However, knee extensor strengths were found to differ statistically between tools. This difference was explained by the

corrections implemented in our assessment, which are not taken into consideration by the myometer. The validation study also showed that the assessment produced reliable and repeatable test-retest force data. Further research will be required to confirm this applies in the TKA population and that the assessment is also reliable when used by different assessors.

When used in the clinical environment, the data recorded was consistent with previously published research on knee strength in elderly and osteoarthritic individuals. This implied that the application provided accurate and valid data on knee strength in the target population. The assessment was also sensitive enough to detect changes over time, further supporting the use of this assessment as a TKA outcome measure.

To optimise the acceptability of this assessment, the protocol was designed to replicate a standard myometer-based strength assessment. Most patients completed the assessments with ease and as intended, showing that the protocol was acceptable. Only two patients refused to participate due to ongoing pain in the knee (Table 7.2).

No problems were encountered by the user during clinical use of this assessment; however, further research is required to be able to comment on the acceptability of the assessment to clinicians. Such a study could also be used to confirm that the data is easily interpretable to clinicians.

To conclude, this assessment provides accurate, reliable and valid strength data of TKA patients. We have shown through this investigation that motion capture technology can feasibly be used in the clinical environment to report knee strength scientifically. Future research should concentrate on the inter-user reliability of the tool and its acceptability to clinicians.

8.4. Gait Analysis

Three-dimensional gait analysis is commonly used in the research environment to better understand the way in which certain diseases affect mobility (Cappozzo *et al.,* 2005; McClelland *et al.,* 2007). However, due to the complexity of current motion capture protocols, its clinical use is rare. This system contains a clinic-appropriate gait assessment.

8.4.1. Discussion of the Results

On average, kinematics and spatio-temporal parameters of gait improved following TKA. Despite this, differences between our patient cohort and healthy older adults persisted post-operatively, suggesting that gait biomechanics had not fully restored within the first post-operative year.

Sagittal Plane Kinematics

Sagittal plane gait kinematics of the trial patients were pathological pre-operatively. The data recorded in healthy older adults showed that full extension of the knee normally occurs during initial contact (Figure 7.41). However, this was not observed in the patient cohort (Figure 7.24). This is typical for patients with knee OA (Figure 8.3).

It was previously suggested that many patients may have suffered from flexion contractures pre-operatively, potentially explaining why full extension of the knee was not achieved during gait (Campbell *et al.,* 2015*;* Ritter *et al.,* 2007). The average maximum extension angles achieved pre-operatively during ROM assessments suggested however, that the patients may have been able to extend the knee to greater extents than recorded when walking (Table 7.19 & Table 7.21). Nevertheless, ROM assessments were carried out under unloaded conditions. Significantly higher demand is placed on the quadriceps to stabilise and mobilise a joint during dynamic activities such as gait. Consequently, the

ability to extend a knee to a certain extent in unloaded conditions does not necessarily translate to loaded and dynamic situations (Devers *et al.,* 2011).

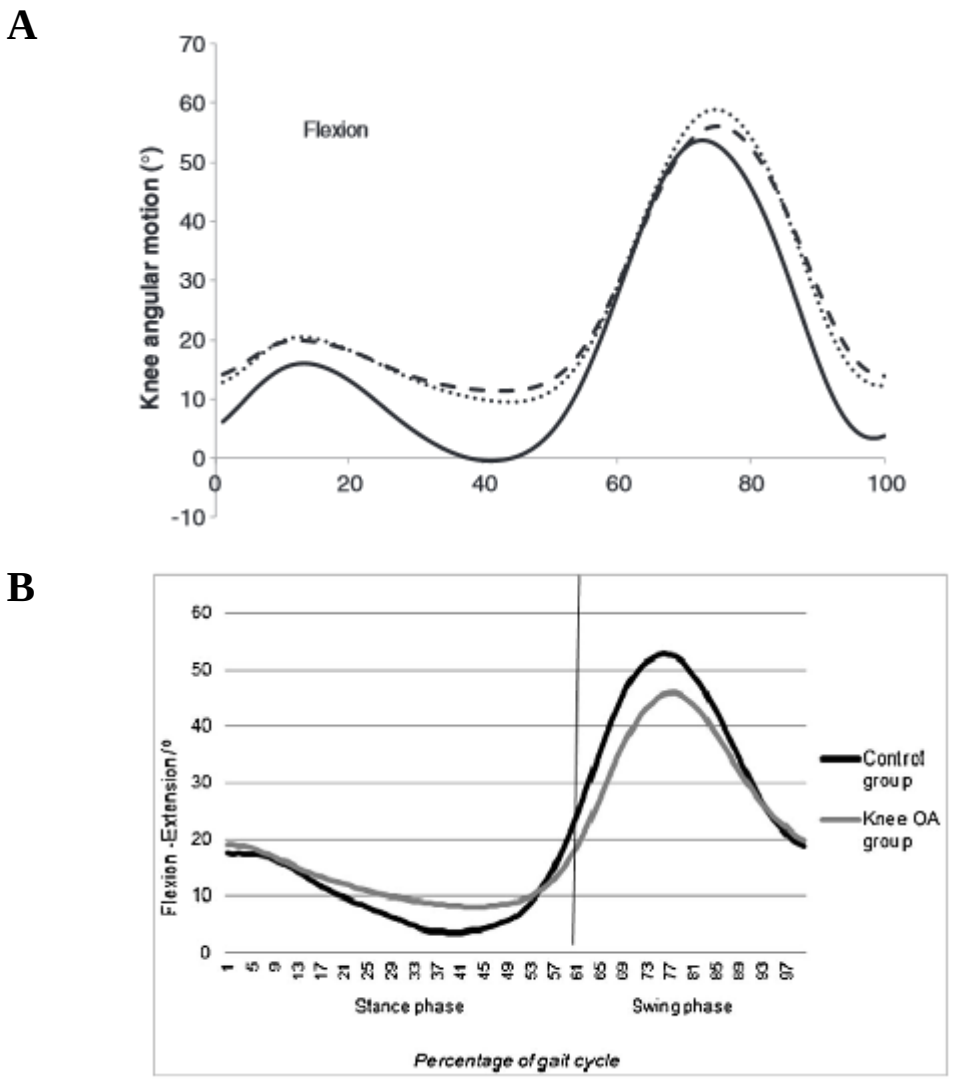


Figure 8. 3: Sagittal plane kinematics during gait recorded by (A) Levinger *et al.*, 2013 (Solid line: Healthy control group; Dashed line: Pre-TKA patient group; Dotted line: 1 Year post-TKA patient group) and (B) Bytyqi *et al.,* 2014. Note the inability for the patients to achieve full extension during the stance phase of gait.

Quadriceps weakness and pain at the knee may have further contributed to the pathological presentation of gait (Kaufman *et al.,* 2001; Murray *et al.,* 2015; Teixeira & Olney, 1996). Studies have shown patients to adopt higher knee flexion angles during stance in order to relieve pain by reducing the load on the joint (Kaufman *et al.,* 2001).

The residual flexion observed during stance may have been accentuated by patients actively lowering their COM during walking tasks. This is often adopted by OA patients as an attempt to improve walking stability, especially during terminal stance (Perry & Burnfield, 2010). Some patients were also found to flex the hip to a greater extent whilst walking (as if stair-climbing) to clear the foot of the treadmill belt. As most patients involved in the trial had never walked on a treadmill before, it is reasonable to suggest that cautious gaits were adopted by patients, contributing to the increased knee flexion observed during stance.

During swing, the healthy knee achieves a maximum flexion angle of approximately 60° (Figure 7.41; Figure 8.3; Jevsevar et al., 1993; Perry & Burnfield, 2010). Average maximum knee flexion angles achieved in our patient cohort were considerably lower than that recorded in the healthy volunteers (Figure 7.24 & Table 7.33). This has been associated with poor hamstring strength (Murray *et al.,* 2015). Limiting flexion during swing is also a pain-avoidance mechanism, as it reduces the load on the joint during extension. This may also have been observed as the patients were walking considerably slower than the healthy older adults. Thus, kinematic differences were to be expected.

Table 8.4 shows the breadth of data that have previously been reported in the literature on sagittal plane kinematics during gait. The data recorded in our study resembled those reported elsewhere (Table 7.33 & Table 8.4), suggesting that our system was capable of reporting valid data on sagittal plane knee kinematics in OA patients.

Six-weeks post-operatively, the patients achieved greater knee flexion in both knees during swing (Table 7.33). However, sagittal plane kinematics worsened during stance; particularly during mid-stance (Figure 7.24 & Table 7.33).

Persistent post-operative pain and weakness of the quadriceps may have contributed to this result (Gustavson *et al.,* 2016). Other reasons for poor knee function on the operative side include surgery-related stiffness and swelling at the joint. It should also be taken into consideration that the patients may not have yet gained trust and confidence in their implant, potentially explaining why they continued to act conservatively and cautiously during gait (e.g. limiting joint ROM and lowering COM to increase stability). According to Webster and colleagues (2015) this behaviour can restrict activities of daily living for months following surgery (Figure 8.3).

Table 8. 4: Examples of sagittal plane kinematics recorded in gait studies of patients with end-stage osteoarthritis.

Authors	**Initial Contact**	**Loading Response**	**Mid-Stance**	**Terminal Stance**	**Mid-Swing**	**Excursion in Stance**	**Excursion in Swing**
Bytyqi *et al.,* 2014	19.0 (7.7)	-	-	-	-	14.8 (4.0)	33.3 (6.4)
Rhaman *et al.,* 2015	-	-	-	-	-	6.0 (3.4)	42.5 (10.2)
Baliunas *et al.,* 2002	-	-	15.0 (7.0)	7.0 (6.0)	-	-	58.0 (7.0)
Alice *et al.,* 2012	6.1 (5.4)	11.0 (6.1)	-	-	40.5 (6.6)	27.1 (5.8)	
Nagano *et al.,* 2012	11.6 (5.0)	-	4.7 (3.3)	-	-	8.3 (4.8)	-

Table 8. 5: Examples of sagittal plane kinematics recorded in studies of TKA gait in patients at least 1-year post-operatively.

Authors	Initial Contact	Loading Response	Mid-Stance	Terminal Stance	Mid-Swing	Excursion in Stance	Excursion in Swing
Benedetti *et al.,* 2003	2.3 (3.5)	12.1 (5.1)	-	33.7 (7.5)	48.9 (5.2)	-	-
Rahman *et al.,* 2015	-	-	-	-	50.6 (7.8)	8.3 (3.7)	-
McClelland *et al.,* 2017	5.4 (5.2)	-	-	-	51.1 (4.8)	10.8 (6.3)	-
Larsen *et al.,* 2015	10.5 (4.4)	-	-	-	-	31.8 (4.4)	53.0 (4.0)
Larsen *et al.,* 2015	5.6 (6.3)	-	-	-	-	31.7 (6.2)	53.0 (6.3)

One year post-operatively, the data recorded during stance continued to differ from previously published research (Figure 8.3; Table 8.5). One explanation for these differences is that many patients were brought back into the clinic some months before their annual appointment was due; the average follow-up time in the 30 patients assessed at 1-year was 9.6 months. A further 5 had undergone a second TKA during the first post-operative year, which would have influenced their recovery. The results recorded in our study may therefore not be a true representation of one year post-operative gait in TKA.

Despite this, the data recorded during mid-swing at one-year was shown to much better resemble previously published studies. Maximum flexion during swing had improved significantly in the operative knee, suggesting that kinematics during swing were improving faster than during stance. This leads us to question whether patients were adopting a conservative gait during stance post-operatively as well as pre-operatively.

Based on feedback from the patients during clinics, we believe this to be true. Many patients continued to struggle to walk on the treadmill post-operatively,

adopting a cautious gait during the assessment. Some commented that they did not feel comfortable enough to take longer strides or walk "naturally" as they did not trust the treadmill. Consequently, it is possible that the variable to influence their gait most substantially was the treadmill. The appropriateness of the protocol used for this clinical system must therefore be addressed.

Frontal Plane Kinematics

Pre- and post-operative frontal plane kinematics of the non-operative knee were consistent with data of healthy older adult volunteers (Figure 7.28 & Figure 7.42). The data were also comparable to frontal plane kinematics recorded in healthy adults with other biomechanical models (Figure 7.31; Figure 8.4; Papi, 2014; Miller, 2017). This implied that frontal plane kinematics of the non-operative knee were within the ranges of normal both pre- and post-operatively.

The movement pattern measured in the pre-operative knee was similar to that observed in the contralateral knee; but the knee remained in adduction throughout the gait cycle. This result was unsurprising given that the majority of patients presented with a varus deformity of the knee (Table 8.6). On average, the severity of this deformity was not large enough to cause statistically significant differences at certain gait events when compared to data from healthy older adults.

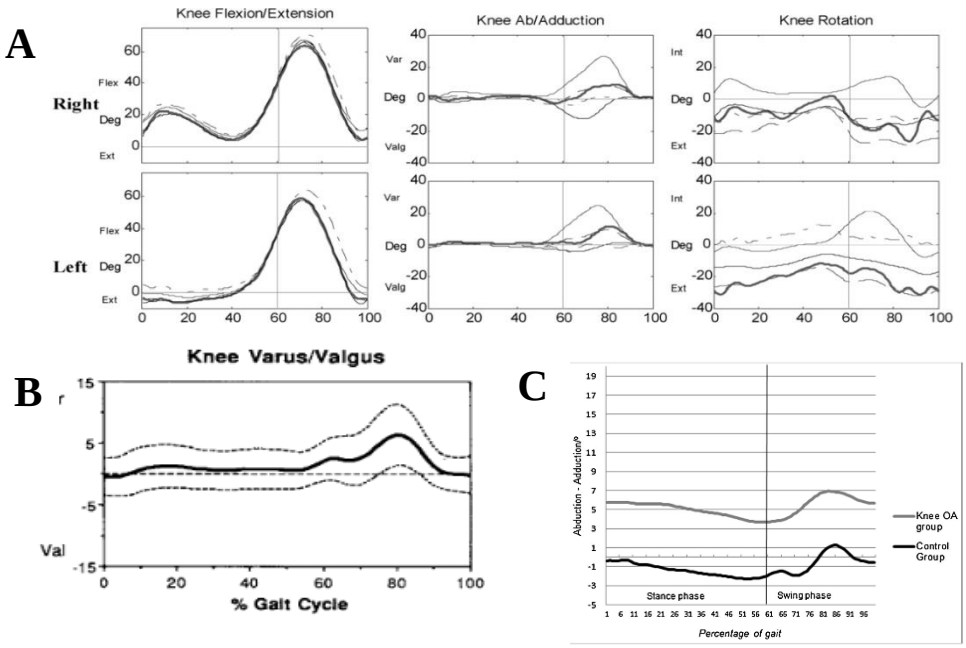


Figure 8. 4: Knee kinematics as calculated by (A)Ferrari *et al.*, 2008 , (B) Kabada *et al.,* 1990 and (C) Bytyqi *et al.,* 2014. The black solid line in A is a cluster model.

Table 8. 6: Average frontal plane deformity of the knee joint in the patient population.

Deformity	**Number of Patients**	**Average Measured Deformity (±SD)°**
Varus	44	5.9 (5.1)
Valgus	19	6.1 (4.6)

Frontal plane kinematics may have been expected to differ from normal data pre-operatively due to the average deformity recorded in the operative knee (Table 8.6). It should be noted however, that although a malalignment of the knee joint of >3° is traditionally considered as pathological, recent research shows that those with non-pathological knees can have a knee alignment of >3° (Bellemans *et al.,* 2012; Thienpont & Parvizi , 2016).

Six-weeks post-operatively, valgus-varus rotation of the operative knee had improved (Figure 7.42 & Table 7.41). The measured kinematics reflected normal patterns of rotation in healthy adults (Ferrari *et al.,* 2008; Miller, 2017; Papi, 2014; Perry & Burnfeld, 2010). This finding suggested that joint rotation in this plane was improving following TKA, and that the implant was performing similarly to a natural and healthy knee joint in this plane.

Within the first post-operative year, frontal plane kinematics continued to improve, with differences between the TKA patients and healthy older adults narrowing in both knees (Table 7.58). These results implied that the patients were regaining normal kinematics in this plane post-operatively. It also suggested that the Medacta GMK Sphere was successful at restoring frontal plane gait kinematics to patients within the first post-operative year.

Transverse Plane Kinematics

Rotation of the knee in the transverse plane has previously been described as the most variable output in gait analysis due to differences in biomechanical models as well as inter-individual variability. Hence, it is difficult to compare the results to previously published data, especially in pathological gait (Ferrari *et al.,* 2008; Maderbacher *et al.,* 2016; Millar, 2017).

Our data showed that minimal internal-external rotation occurred during gait in our patients pre-operatively and six-weeks post-operatively (Figure 7.32). The ROM was shown to increase one-year post-operatively, especially in the contralateral knee during swing.

Freeman & Pinskerova (2005) reported that internal-external rotation of the joint is minimal up to 90° flexion. This was supported by a study by Maderbacher and colleagues (2016) who showed the knee to internally rotate by approximately 5° between full extension and 90° of flexion. The data reported in our study were consistent with these findings.

Our data was also consistent with previous gait studies, which reported that the knee typically remains externally rotated throughout the gait cycle but

internally rotates during swing (Ferrari *et al.,* 2008; Millar, 2016). Our results therefore suggest that the movement patterns observed in this plane better resembled non-pathological gait 1-year post-operatively, showing that the implant was capable of restoring transverse plane kinematics.

The model used to define gait kinematics for the EQUAL project showed far greater tibial rotation during gait, which contradicts the findings previously described. One explanation for this is that the model overestimated transverse plane rotation of the knee; potentially due to cross-talk (Millar, 2017). This may explain why transverse plane kinematics were vastly different between the patient and healthy volunteer groups (Figure 7.32 & Figure 7.43).

Spatio-Temporal Parameters

People with pathological gait have been shown to limit sagittal plane kinematics by reducing stride lengths and walking speeds (Perry & Burnfield, 2010). Our results were consistent with this statement and may explain why gait kinematics in this plane differed greatly to those reported in healthy older adults.

When compared to previous studies, pre-operative walking speeds and cadences were comparable to those recorded in patients with OA in studies by Bytyqi *et al.,* 2014 and Elbaz *et al.,* 2014 (Table 7.50, Table 7.51, Table 8.7). In general however, spatio-temporal parameters were poorer in our patient cohort than in OA patients in other studies (Table 8.7). This corroborates our belief that the patients were adopting cautious gaits due to unfamiliarity and unease with walking unaided on a treadmill (Alton *et al.,* 1998; Matsas *et al.,* 2000).

Walking speeds significantly improved within the first six post-operative weeks (Table 7.52). Improvements in other spatio-temporal parameters did not reach statistical significance. This was not unexpected, given that patients were continuing to recover from the operation at this stage. Significant changes to gait parameters were therefore unlikely to happen within the initial 6 weeks.

Table 8. 7: Spatio-temporal parameters of gait measured in pre-operative TKA patients in a selection of studies.

Authors of Published Studies	**Mean Walking Speed (±SD)(m/s)**	**Mean Cadence (±SD) (Steps/min)**	**Mean Step Length (±SD) (m)**	**Mean Stride Length (±SD) (m)**
Bonnefoy-Mazure *et al.,* 2017	1.00 (0.20)	101.5 (12.9)	0.50 (0.10)	1.10 (0.20)
Elbaz *et al.,* 2014	0.70 (0.26)	-	0.49 (0.10)	-
Levinger *et al.,* 2013	1.13 (0.19)	113.8 (8.4)	-	1.19 (0.15)
Kaufman *et al.,* 2001	1.09 (0.11)	-	-	-
Bytyqi *et al.,* 2014	0.30 (0.10)	-	-	-
Kiss *et al.,* 2011	1.00 (0.10)	-	0.11 (0.03)	0.26 (0.03)
Alice *et al.,* 2012	1.06 (0.21)	103.2 (11.5)	-	-

All spatio-temporal parameters of gait improved significantly within the first post-operative year (Table 7.52). Although the data were similar to those reported by Benedetti and colleagues (2003) in TKA patients, other studies showed TKA patients to have considerably better spatio-temporal parameters 1 year post-operatively (Table 8.8).

It was therefore not unexpected to find statistical differences for each spatio-temporal parameter of gait between the patient and healthy volunteer groups (Table 7.60). These results suggested that spatio-temporal parameters of gait had not returned to normal 1 year following TKA. This is despite the fact that frontal and transverse plane kinematics seemed to have been restored.

Table 8. 8: Spatio-temporal parameters of gait reported in a selection of studies for 1-year post-operative patients.

Authors of Published Studies	Mean Walking Speed (±SD)(m/s)	Mean Cadence (±SD) (Steps/min)	Mean Step Length (±SD) (m)	Mean Stride Length (±SD) (m)
Almarwani *et al.,* 2016	0.95 (0.28)	-	0.53 (0.12)	-
Wiik *et al.,* 2013	1.70 (0.22)	133.0 (8.0)	0.87 (0.10)	1.72 (0.20)
Benedetti *et al.,* 2003	0.85 (0.16)	47.6	-	1.07 (0.15)
Hatfield *et al.,* 2011	1.08 (0.19)	-	-	1.24 (0.16)
Bonnefoy-Mazure *et al.,* 2017	1.30 (0.10)	108.8 (10.1)	0.60 (0.10)	1.10 (0.20)
Levinger *et al.,* 2013	1.18 (0.17)	115.2 (7.5)	-	1.23 (0.16)
McClelland *et al.,* 2014	1.19 (0.20)	116.1 (9.8)	-	1.21 (0.20)
Mandeville *et al.,* 2008	0.94			1.10

Differences between studies are expected due to variations in patient demographics and protocols (e.g. walking condition/distance walked/time spent walking/set walking speed/time of assessment with relation to surgery date). This study may also have patients with particularly poor function when compared to the general literature, as the patients were screened by the trial team for recruitment, meaning that patients with the worst pain and function were recruited. These variables, combined with the use of a self-paced treadmill are likely to have greatly contributed to the results of this study.

8.4.2. Clinical Success of Assessment

We are confident that the model used to calculate joint kinematics in our system is appropriate for clinical use given that the standards outlined by the International Society of Biomechanics were followed (Grood & Suntay, 1983; Wu & Cavanagh, 1995). Rotations in the frontal and transverse planes were

consistent with those reported in the literature for OA and TKA patients, supporting the use of this model as a valid outcome measure. Sagittal plane kinematics were similar to published studies during swing phase, but stance phase data were shown to differ.

Although precautions were taken to ensure that the methods used allowed patients to achieve their natural walking pattern, many patients adopted a conservative gait when on the treadmill due to apprehension and unease with the equipment. This influenced the spatio-temporal parameters and sagittal plane kinematics recorded in this study. Although most patients were able to complete the assessment, some patients could not (Table 7.3 & Table 7.4).

Few studies to date have published on the use of self-paced treadmills. As a result, no standardised protocols exist as of yet (Plotnik *et al.,* 2015). The results from this study imply that the protocol used for this investigation should be altered in future to ensure the better reporting of gait data.

One way in which the protocol could be altered is by increasing the length of time patients acclimatise to the treadmill. Spending more time acclimatising may increase patients' confidence and allow them to adopt a more natural gait during the assessment. According to Matsas and colleagues (2000), healthy young adults were required to walk on a treadmill for 4 minutes before knee kinematics became statistically similar between treadmill and over-ground walking. Spatio-temporal parameters differed statistically for a further 2 minutes. This suggested that healthy young individuals require at least a 6 minute acclimatisation period to report accurate and reliable gait data. Elderly TKA patients are likely to require an even longer acclimatisation period (Matsas *et al.,* 2000). Unfortunately, implementing this would increase each assessment time by at least 10 minutes, which may not be feasible clinically.

Alternatively, improving the safety features of the system could give patients a better sense of security when walking on the treadmill in self-paced mode. This in turn may give them confidence to adopt a more natural gait within a narrower time-frame.

The safety of this system could be improved by the use of a chest harness. The harness could be fitted to a railing above the treadmill and attached to patients prior to the gait assessment (Figure 8.5). This type of harness is commonly used in research gait laboratories and could easily be implemented in the system described in this thesis (Figure 8.5).

Figure 8.5: Photographs of harnesses (red arrows) currently used in research gait laboratories to improve patient safety during assessments. The black arrow shows the direction the harness can be moved in when attached to the railing.

(Source: Motekforce Link, 2015a)

One of the major disadvantages to this assessment for clinicians is that the gait data is currently not displayed in a simple interpretable manner. This may influence clinicians' decisions to use the system. Motekforce Link offers a Gait Offline Analysis Tool for use with their biomechanical models (Human Body Model and Human Body Model 2). The software provides clinicians with a customisable report of the recorded data. The report compares the recorded results to non-pathological gait data for quick and clear identification of

problematic areas of the gait cycle. The data reported can then be used by clinicians to develop individual treatment plans. Implementing a system similar to this may increase the likelihood of the system to be incorporated into routine practice.

A further disadvantage which was identified during use was the inability of the software to record 13 gait assessments into text files (Table 7.2). The scripts used to initiate the recording of data into text files were checked, as were the D-Flow error logs. No issues were identified however. It is possible that these 13 failures were due to the large amounts of data the software was required to export into text files in real-time. Data from the ROM and strength assessments were always exported successfully; this may be explained by the fact that the amounts of data exported from these tests were smaller than the gait assessment. These tests were also shorter than the gait assessment. Motekforce Link offers a recording module within D-Flow which may provide a more robust alternative than the scripting module used in this study. The use of this module to export gait data should therefore be tested in future.

In conclusion, gait analyses are appropriate for assessing the functional outcome of TKA, and can be carried out in a clinical environment. However, further investigation into the use of self-paced treadmills in TKA patients is required to ensure the results best reflect the patients' natural gait.

8.5. Walking Stability Assessment

The final assessment developed for this system uses the UCM method to quantify walking stability. We investigated its potential as a method of identifying gait instability following TKA, specifically during mid-stance.

8.5.1. Discussion of the Results

The results from this study support the statement that gait is a naturally variable activity (Maki *et al.*, 1997, Hausdorff *et al.*, 1995, Hausdorff, 2007).

Pre-operatively, sagittal plane variances within the UCM outweighed those perpendicular to the UCM, suggesting that the kinematic variability adopted during gait was beneficial in stabilising the COM trajectory in this plane. A sudden peak in variance was observed in the sagittal plane during the swing phase of gait in the pre-operative limb (Figure 7.33 & Figure 7.34). According to Remelius and colleagues (2014), the body is most vulnerable to perturbations at this time; therefore, increasing kinematic variability during swing may be a mechanism for maintaining a stable COM during a potentially unstable time. This mechanism was successful in this patient cohort, as mean ratios were shown to increase slightly with the variability, and none tripped or fell while walking on the treadmill (Figure 7.39 & Figure 7.40). Similar ratios were recorded in the non-operative knee, implying that greater control (more variance) was required in the pre-operative limb to achieve the same goal.

Kinematic variability in the frontal plane did not differ greatly between limbs pre-operatively (Figure 7.33 & Figure 7.34). The largest amounts of variance were recorded at mid-stance and initial swing. Minimising the risk of COM instability at these stages may be important as they correspond to times at which the COM is transferred from one limb to the other (Perry & Burnfield, 2010). Frontal plane ratios were >0 throughout the gait cycle in both limbs pre-operatively, indicating that COM stability was successfully maintained in this

plane through adopting a variable gait, especially at the beginning and end of the gait cycle (Figure 7.39 & Figure 7.40).

Six-weeks post-operatively the variances recorded in the operative knee were similar during the stance phase of gait, but had reduced during swing (Figure 7.35 & Figure 7.36). This had no impact on stability, however (Figure 7.39 & Figure 7.40). Variances in the contralateral limb increased post-operatively. Upregulation of good variance in this limb may have been a mechanism of compensating for weakness and stiffness of the operative limb to protect the stability of the COM.

There were no significant changes to the magnitudes of variances recorded in the frontal plane six-weeks post-operatively (Figure 7.35 & Figure 7.36). Given that the ratios recorded at this stage were >0 it can be inferred that the patients continued to maintain a stable COM trajectory during gait (Figure 7.29).

One year post-operatively sagittal plane variances did not differ greatly from those measured six-weeks post-operatively, but the variability between patients had decreased, suggesting that the patients were adopting a more consistent walking pattern in this plane (Figure 7.37 & Figure 7.38). Kinematic synergy was maintained (Figure 7.39 & Figure 7.40).

Frontal plane variances remained similar to six-week data in the non-operative knee. The magnitudes of variances had increased during stance in the operative limb, however; particularly during loading response. This suggests that the CNS was employing a more variable gait in this plane post-operatively to maintain a stable COM. This may be associated with the patient gaining confidence in the implant and limiting movement on the operative side to a lesser extent.

Overall, the data presented suggest that the CNS adopted different methods for each limb to stabilise the COM during gait. Sagittal plane ratios were lowest at initial contact leading into loading response, terminal stance, and towards the end of the swing phase of gait (Figure 7.39 & Figure 7.40). No significant changes were observed between assessments (Table 7.53 & Table 7.54).

At initial contact, the knee is actively extended to 5° by the quadriceps muscles. Body weight is then transferred onto the limb, where an extensor moment from the quadriceps muscles is again required in order to keep the knee stable and prevent collapse (Perry & Burnfield, 2010). Terminal stance and swing also involve active extension of the knee joint (Perry & Burnfield, 2010). These phases of the gait cycle are therefore quadriceps dependent. Given that TKA individuals have been shown in this thesis and in the literature to have reduced quadriceps strength pre- and post-operatively it may be that sagittal plane stability during gait could be improved in this patient population by improving knee strength through quadriceps strengthening exercises (Murray *et al*., 2015).

Corroborating our theory is a study by Aljaker *et al*. (2015), which showed that OA patients had increased soleus H-reflex amplitudes at the same phases of the gait cycle, suggesting increased use of the triceps surae muscle as a compensatory-mechanism due to poor quadriceps function. Although their study simultaneously showed that quadriceps activity was not significantly reduced in their OA population when compared to healthy age-matched controls, the level of knee OA of their patients was not severe enough to merit TKA (Aljaker *et al*., 2015).

Frontal plane variances were measured at much smaller magnitudes than sagittal plane variances. Despite this, the recorded ratios were similar in both planes (Figure 7.39 & Figure 7.40). These results imply that greater kinematic variability is required in the sagittal plane to stabilise the COM in this plane to the same degree as in the frontal plane. This is expected given that the sagittal plane is the main plane of movement at the knee, the plane of progression and the plane which has, by far, the greatest ROM. There were no significant changes to frontal plane ratios between pre- and six-week assessments. However, statistical differences were measured at one-year during terminal stance (Table 7.54). This implies that the way in which the CNS controls COM stability during terminal stance had been altered post-operatively.

As no previous study has used the UCM to analyse cycle-to-cycle variability of gait in TKA patients, the results obtained in this thesis cannot be directly compared to those reported in the literature. However, a small number of other studies have used the UCM to analyse stability of gait in other patient populations (Black *et al.,* 2007; Papi *et al.,* 2014; Sriviastava *et al.,* 2016).

Black and colleagues (2007) investigated the relationship between the variability of the COM and joint kinematics during treadmill walking in pre-adolescents with Down syndrome. Rather than analysing each percentage of the gait cycle, as was done in this investigation, the researchers concentrated on heel strike. The study found that children with Down syndrome had a more variable gait than children who were typically developed, with variance within the UCM being particularly greater (Black *et al.,* 2007). This suggested that a different control strategy was used by the CNS in these patients to stabilise the COM.

Papi *et al.* (2014) and Strivastava *et al.* (2016) investigated the relationship between walking variability and motor control in stroke patients during the stance and swing phases of gait, respectively. Despite having larger amounts of kinematic variability than healthy young adults, COM stability was maintained in the patients in both studies. As was reported by Black *et al.* (2007), the way in which the COM was stabilised in the patient with non-pathological gait differed (Papi *et al.,* 2014; Strivastava *et al.,* 2016).

Similarly to these studies, our investigation has shown TKA patients to adopt a different control strategy for each limb pre- and post-operatively. This may be a way for the patients to compensate for the functional limitations exhibited by the patients in the operative limb (Black *et al.,* 2007; Papi *et al.,* 2014). Unfortunately, it was not possible to compare the variability of gait in the TKA patients to the data recorded in healthy older adults for the EQUAL project as far fewer than 50 gait cycles were recorded per individual in this study. In future, this investigation could be expanded to include age-matched controls.

Mid-Flexion Instability and the Medacta GMK Sphere TKA

The Medacta GMK Sphere TKA implant was designed to provide stability to patients throughout the knee's ROM and thus eliminate the presence of mid-flexion instability. Patients complain of mid-flexion instability during mid-stance when stair climbing or slope walking (Vince, 2016). Although the patients involved in this study did not have their gait analysed during these functional tasks, signs of instability at mid-stance during level walking could indicate the presence of mid-flexion instability during more functionally demanding tasks.

Given that mid-flexion instability is a phenomenon only reported following TKA, discussion of the results will focus solely on the knee that underwent TKA.

Six-weeks post-operatively, the ratio of 'good' to 'bad' variance in the sagittal and frontal planes did not differ during mid-stance when compared to pre-operatively (Table 7.53). The ratios were also >0 during mid-stance. One year post-operatively, the ratio had increased during mid-stance in the sagittal plane. Frontal plane ratios did not appear to change as much. These results imply that the implant was stable during the stance phase both six-weeks and one-year post-operatively. An unstable implant may have led to variable kinematics that contributed to COM instability to a greater extent, bringing the ratio closer to, or below 0. Nevertheless, these results cannot be used to rule out presence of mid-flexion instability since most patients complain of this phenomenon during more demanding tasks of daily living. Future research on the use of the UCM method as a means of identifying mid-flexion instability should therefore analyse the gait of patients during tasks such as stair descent and slope walking.

8.5.2. Clinical Success of Assessment

The biomechanical model used for this assessment is deemed to have been appropriate for the investigation, as recommendations outlined by the International Society of Biomechanics were followed to report gait kinematics.

However, the COM was defined as a fixed geometric centre of the pelvis. This was done to simplify the mathematical model. Improvements to the model could therefore be made by calculating each body segment COM with respect to its mass then summating the results for a better representation of the COM (Papi, 2012).

Due to the novelty of this assessment, it is not possible to comment on its accuracy or precision. However, our results did draw similar conclusions to those reported in other studies, which is that COM stability was maintained in TKA patients pre- and post-operatively by kinematic synergy (8.2.4: Walking Stability). This supports the validity of the data reported in this study.

The reliability of this method was not tested in this study as patients were limited to 30 minute appointment slots; therefore, multiple walking tasks could not be recorded on the same visit. A reliability study of the model could be carried out in future to investigate this.

To simplify use of the assessment for users, it was initially hoped that this assessment could be incorporated into the D-Flow software application. This would enable clinicians to calibrate patients and run all assessments within the same software package. However, limitations of the Lua scripting modules within D-Flow prevented this. As a consequence, clinical use of this assessment is currently infeasible.

For an outcome measure to be successful in the clinical environment, it must provide clinicians with valuable and easily interpretable information on a variable. Although this study has shown that it is possible to use the UCM method on gait data from patients with TKA, the method itself is highly complicated and the results extremely difficult to interpret. Consequently, clinicians are unlikely to use this method.

The simplest way to analyse and interpret the UCM data is to examine the balanced ratios. This simply requires the assessor to understand that a ratio >0 equates to a stable COM with regards to kinematic variability and a ratio <0 suggests that the COM was unstable. The disadvantage of interpreting the data

in this manner is that it cannot be assumed that patients with ratios >0 (as was seen in our study) are/were not at risk of trips or falls whilst walking, nor can it be inferred that they are/were in fact stable during gait. This is due to the fact that variables other than kinematic variability influence gait stability. Furthermore, UCM data are highly variable between patients. It would therefore be difficult for clinicians to determine who requires targeted pre- or rehabilitation and when it is necessary.

This study also investigated the possibility of using the UCM method to identify or rule-out the presence of mid-flexion instability following TKA. The initial problem with this is that mid-flexion instability is poorly described in the current literature (Vince, 2016). Additionally, this study used the UCM method to report COM stability in terms of kinematic variability of hip, knee and ankle joints. Thus, the method cannot be used to identify particular instabilities of the knee joint during a task. As a result, the methods used in this thesis to investigate mid-flexion instability may not have been wholly appropriate.

Due to these disadvantages, we conclude that this outcome measure is not acceptable or appropriate for use in the clinical environment to quantify gait stability. However, we have shown in this thesis that it can feasibly be used as a research tool to investigate the role of kinematic variability in COM stability in TKA patients.

8.6. Summary of Clinical Trial Results

The patients involved in this trial exhibited knee ROM, strength and gait kinematics that were typical of pre-operative TKA patients. Knee ROM and gait kinematics improved over the first post-operative year, suggesting that the operation had been successful at reducing stiffness and improving mobility at the joint. However, the strengths of the flexors and extensors of both knees had consistently worsened in the patient cohort over the first post-operative year. This is a finding of considerable importance, as it suggests that the patients were not achieving optimal functional outcome following TKA, or even returning to pre-operative levels, in terms of strength. Although other aspects of knee function improved post-operatively, reductions in knee strengths would influence the patients' abilities to successfully complete biomechanically demanding tasks of daily living such as stair ascent and descent. This in turn would affect their general mobility, and hence, their perception on the outcome of the surgery. Failure to address muscular weaknesses in TKA patients may also lead to the development of other musculoskeletal disorders which would require further treatment.

Despite reductions in knee strength, the results imply that the Medacta GMK Sphere implant was successful at allowing patients to achieve frontal and transverse plane gait kinematics that were consistent with normal, non-pathological gait. The patients were also shown to maintain a stable COM during gait, with no evidence of mid-flexion instability during level walking.

Sagittal plane kinematics and spatio-temporal parameters of gait remained pathological 1-year post-operatively, but improvements had been observed when compared to pre-operative data, suggesting that the patients were moving towards normal gait. The differences reported may have been attributed to the fact that patients had adopted a conservative and cautious gait during the assessment to increase their stability on the unfamiliar treadmill. Most patients were also assessed prior to their 1-year post-operative date (average follow-up time was 9.6 months), potentially contributing to the differences observed

between the data recorded for this study and those reported elsewhere. The reductions in knee strengths may also have influenced their gait kinematics and spatio-temporal patterns.

When considering all data, we can confidently conclude that the Medcata GMK Sphere was successful at restoring some aspects of knee function and stability within the first post-operative year, but that poor knee strength may have limited the overall functional outcome of these patients.

This thesis does not provide any evidence on the advantages or the disadvantages of the Medacta GMK Sphere over other TKA systems. However, the data does allude to the fact that the implant may provide functional outcome comparable to other TKA designs. This may be due to the implant design and improved technology used intra-operatively. However, to be able to confirm this, a randomised controlled trial on the functional outcome of this implant compared to other common TKA systems would be necessary. We have shown in this thesis that objective and scientific assessment of TKA outcome is possible. As such, a randomised controlled trial on the functional outcomes of multiple TKA systems could feasibly be completed in the clinical environment using the set of methods presented in this thesis.

In order to determine the number of patients required to yield statistically significant results, where the level of significance is 5% ($\alpha = 0.05$) and the power is 80% ($\beta = 0.2$), a sample size equation was used to predict group size for the proposed randomised controlled trial (Noordzij *et al.,* 2010). The outcome variable used for the calculation was the minimum clinically important difference in the knee flexion angle during mid-stance (5°). The standard deviation for this variable was defined as 9.6°, which was the average recorded standard deviation of the knee flexion during mid-stance in this study (Table 7.29). Using the sample size equation, it was estimated that 58 subjects per group are required to fulfil the desired statistical criterion. Thus, in a study where two implants are compared, 116 subjects should be recruited. In the study presented in this thesis, approximately 7% of patients were lost to follow

up (7/96 – Figure 6.1) and 12% of datasets collected were excluded from the analyses due to missing or unusable data. Hence, to account for these potential data losses, the proposed randomised controlled trial should aim to recruit 19% more patients than determined by the sample size equation. Thus, 69 patients should be recruited into each group; a total of 138 if the randomised controlled trial is restricted to the comparison of two implants.

Such a trial would provide clinicians and researchers with scientific data on implant functions, with which they could form a broader understanding of the functional outcome of the Medacta GMK Sphere, and identify whether it truly does offer functional benefits over other common TKA designs.

8.7. Importance of Objective Data Collection

PROMs including the OKS and SF-12 are cheap, quick and efficient methods of reporting functional outcome in the orthopaedic clinic (Greidanus *et al.,* 2011; Torres-Claramunt *et al.,* 2013; Ware & Gandek, 1998). Consequently, they are often favoured over objective functional assessments, which are more time-consuming and costly, despite the fact that they are not designed for reporting functional outcome. However, our correlation study showed that these subjective PROMs did not correlate with true knee function, suggesting that they should not be used to gauge functional outcome of TKA.

Despite showing pathological traits in knee function both pre- and post-operatively, the average OKS suggested that the level of knee pain and reduced function was not severe in our patient cohort. As time progressed, the OKS improved, especially between pre- and six-week post-operative assessments. Thus, patients perceived less pain and better function post-operatively than pre-operatively. However, the OKS did not correlate with any objective outcome measures pre-operatively or six-weeks following TKA (Table 2). Even at 1-year, the only variable to correlate with the OKS was walking speed.

One possible reason for these poor correlations is that the function-aimed questions in the OKS are too easy to achieve, enabling patients to score well. This may be especially true pre-operatively. This has also been suggested by Ko and colleagues (2013). As a consequence, the extent of the physical disability may go unnoticed if the OKS is used as the sole functional outcome measure.

Physical scores of the SF-12 questionnaire followed similar trends to the OKS. The average score was equivalent to the 30th percentile of the population pre- and six-weeks post-operatively, but improved to the 45th percentile one-year post-TKA. Pre-operatively, objective measures of the operative knee did not correlate with the SF-12 score. Post-operatively, some gait variables (particularly spatio-temporal parameters of gait) did correlate to a clinically significant extent with the SF-12 score. However, it was observed that some data points were outliers (Figure 7.46), which would have contributed to the resulting correlation between both variables.

Spatio-temporal parameters of gait were the only objective variables to consistently correlate with both PROM scores. Although these results suggest that the OKS and SF-12 PROMs may be suitable as outcome measures for walking, they should not be used to infer the patient's ability to carry out more functionally demanding tasks such as stair climbing. This is due to the fact that these tasks require the patient to have greater knee ROM and strength, which were found to correlate poorly with both questionnaires.

Our results suggest that some patients who score highly in the PROMs are functioning much more poorly than the results of the questionnaires would suggest, especially with regard to knee ROM. This is consistent with the belief that patients overestimate their abilities when answering PROMs (Herrmann *et al.,* 2011; Myles *et al.,* 2002; Rowe *et al.,* 2000). It is also possible that some questions asked are inappropriate or misleading (Whitehouse *et al.,* 2005). For example, the OKS asks 'Could you do household shopping on your own?' to which many answer 'Yes, easily' as they have no other alternative but to do their own shopping. Despite having significant functional limitations, many patients

carry on with activities of daily life, even if they perform them in an abnormal way. Hence, when answering these questions patients are unknowingly giving clinicians a false understanding of the extent of their disabilities. This supports the view that subjective outcome measures should only be used to supplement results collected objectively.

In conclusion, our study has shown that the OKS and functional component of the SF-12 are poorly correlated to knee function, especially with regard to ROM and strength. These results indicate that orthopaedic clinicians should use objective outcome measures to supplement the data recorded through subjective outcome measures when assessing knee function in TKA patients. It should be emphasised however, that only two PROMs were included in our analyses. Future research should therefore aim to correlate the data of objective outcome measures with other PROMs commonly used in TKA, such as the Forgotten Joint Score and EQ-5D, and perhaps to develop a new score that does correlate with functional outcome measurements.

8.8. Summary of Outcome Measure Package

The results of this study confirm that the bespoke motion capture system can be used to report the functional outcome of TKA, but that there are limitations to the current protocol. In this chapter, each assessment was described in terms of 9 key features an outcome measure must possess for its clinical use to be justified. Table 8.9 summarises each assessment with regards to these features.

Table 8.9: Summary of each outcome measure's features.

✓ = Yes; × = No; - = Not tested; ✓*= Aspects of the assessment may need to be altered.

Feature of Outcome Measure	ROM Assessment	Knee Muscular Strength Assessment	Gait Analysis	Walking Stability Assessment
Appropriate	✓	✓	✓*	×
Acceptable to Patients	✓	✓	✓*	✓*
Feasible	✓	✓	✓	×
Precise	✓	✓	✓	-
Accurate	✓	✓	✓	-
Reliable	✓	✓	✓	-
Valid	✓	✓	✓	-
Sensitive	✓	✓	✓	-
Interpretable	✓	✓	✓*	×

Based on the work presented in this thesis, we are confident that the knee ROM and muscular strength assessments can justifiably be used in the clinical environment to report the functional outcome of TKA (Table 8.9). Although the acceptability and appropriateness of the gait assessment could be improved by altering the current treadmill protocol, it was efficient. It also returned data that were consistent with the current literature. Thus, we can also justify the clinical use of this assessment. We cannot however, justify the clinical use of the UCM method as a clinical outcome measure for assessing gait stability due to its complexity. This thesis has however shown that this method can be used for research purposes.

One of the most significant findings of this thesis is that a motion capture system can feasibly be incorporated into a hospital environment. The compact size (3.5(L) × 2.1(H) × 1.1(W)m) of this system means that there is no need to sacrifice an entire room for its use. Unlike traditional motion capture laboratories, this has the benefit of being easily accessible to clinicians and patients. This was found to be particularly useful in this study, as patients could undergo all functional assessments during routine appointments. If the patients had been required to attend a separate site for functional assessments, it is possible that fewer patients would have agreed to participate in the study.

The most important feature of a clinical motion capture system however is its efficiency. According to Baten *et al.,* (2007), clinicians would only consider 3D motion analysis as an outcome measure if the entire protocol takes no longer than 30 minutes to carry out. Table 7.1 showed that the average assessment was carried out well within the 30 minute limit proposed by Baten and colleagues (2007). More importantly, however, the longest assessment only took 25 minutes. Naturally, the time taken would vary somewhat between users, especially with those unfamiliar with the system. Irrespective of this, our results show that this system could conceivably be used routinely in a clinical environment to scientifically report TKA functional outcome.

8.9. Clinical Implications of Work

Three-dimensional motion analysis is now well established as an effective method of assessing kinematic and kinetic outcome of patients following TKA, but very few studies have proposed a clinic-appropriate protocol.

Over the course of this PhD, three research groups have published studies on the use of two new clinical motion capture systems. Kaneko and colleagues described a system developed by Hitatchi Ltd (Tokyo, Japan) which omits the use of infra-red video cameras, using only inertial sensors (accelerometers, gyroscopes and potentiometers) to report sagittal plane hip and knee kinematics, and pressure sensor insoles to measure balance when walking (Kaneko *et al.,* 2015; Kaneko *et al.,* 2016).

The works of two other research groups in Hong Kong and China describe a system that more closely resembles the one presented in this thesis (Mok *et al.,* 2016; Yeung *et al.,* 2016; Zhang *et al.,* 2015). OptiKnee (InnoMotion; Shanghai, China) is a portable two-camera system that can be used to report knee kinematics during treadmill gait (Figure 8.6). Unlike our system however, only one knee can be assessed at a time and only knee kinematics can be reported (Yeung *et al.,* 2016). In addition to this limitation, anatomical calibration of subjects is complicated with the OptiKnee system.

To calibrate this model, users can either use eight individual markers (a protocol that has been established in this thesis as inappropriate for the clinical environment), or two clusters of four markers (Figure 8.7). Following application of the markers/clusters, the user must then calibrate 12 landmarks on the thigh and shank with a pointer (Yeung *et al.,* 2016; Zhang *et al.,* 2015).

Figure 8. 6: A photograph of the OptiKnee system. (Soure: Zhang *et al.*, 2015)

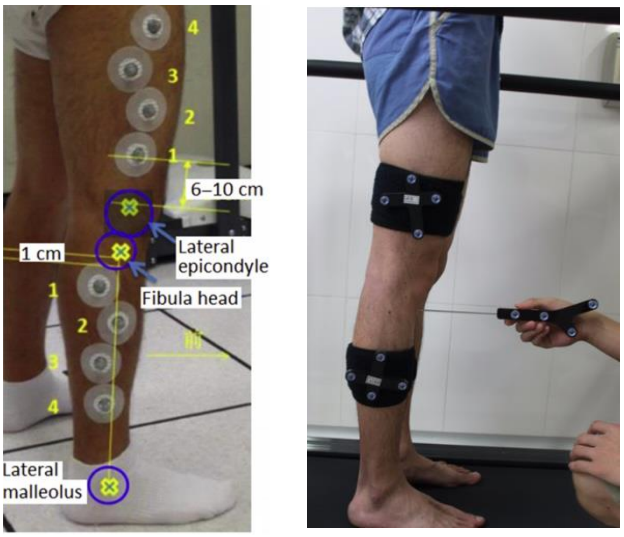


Figure 8. 7: Photograph of the marker-model used for the OptiKnee system. 8 markers or two clusters are placed onto the thighs and shanks then 12 points on both segments are calibrated with an instrumented pointer.

(Source: Yeung *et al.*, 2016 & Zhang *et al.,* 2015)

Unlike the other motion capture systems designed for clinical use, the system described in this thesis does not sacrifice scientific validity or limit the biomechanical model to achieve a simpler protocol and smaller footprint. Most importantly, this unique system could provide clinicians with a means of reporting knee ROM, strength and gait kinematics of the hips, knees and ankles with greater biomechanical and scientific accuracy and reliability than current tools. This information could be used to create patient-specific pre- or rehabilitation treatment plans geared towards improving functional outcome following TKA. We are therefore confident that this system has the potential to be used as a routine orthopaedic functional outcome measure.

8.10. Future Work

From autumn 2017, similar systems to the one described in this thesis will be incorporated into outpatient clinics at the Manchester Royal Infirmary and the Trafford General Hospital. These systems will be used to assess knee function in OA and TKA patients involved in one of three clinical trials. The protocols we intend to implement will be similar to the ones used for the trial described in this thesis. However, we do intend to alter the gait analysis protocol to include a longer warmup period and a harness for patients to use during the walking tasks, with the aim to better report gait biomechanics.

To further support the use of this system as an orthopaedic outcome measure we also intend to evaluate the inter-user reliability of the system and the acceptability of the assessments to clinicians. The data from such a study could be incredibly beneficial for furthering the development and use of clinical motion capture technology.

Further developmental work will also be carried out on the current application, including expansion of the package to report hip ROM and strength. Expanding the research in this manner would introduce more flexibility into the system and potentially increase its appeal to clinicians as a versatile outcome measure.

This thesis has also identified areas that require more research, including, but not limited to, the use of self-paced treadmills in TKA populations and the identification of mid-flexion instability through gait analysis. Research which continues from the work presented here should therefore aim to further exhibit the benefits of clinical motion analysis in orthopaedics and provide suitable methods of identifying functional limitations following TKA to clinicians and patients.

Chapter 9. Conclusions

The main aim of this thesis was to develop and use a clinical motion capture system to report the functional outcome of TKA. Chapter 3 outlined 10 key research questions that were addressed during this investigation to achieve this aim. This thesis concludes by revisiting these research questions.

- Traditional motion analysis technology and protocols were described as being too complex and time consuming; thus a simplified system was proposed.
- The footprint of the system developed during this investigation is 3.5(L)x2.1(H)x1.1(W)m which was shown in this study to be suitable for use in a clinical environment.
- A simplified cluster-based biomechanical model which utilised a pointer-calibration technique was developed. Implementation of this model allowed for automatic labelling, thus eliminating time-consuming labelling and data processing processes. Results could therefore be obtained in real time.
- The pointer method of reconstructing anatomical landmarks was reliable. A neutral pointer-orientation is recommended during use, however. This reduces the likelihood of improper calibration which could influence the kinematic results.
- Four separate assessments were developed for use with the model which quantified knee ROM, strengths, gait kinematics, and gait stability.
- The knee ROM assessment was validated against a goniometer in healthy young adults. There were no clinical significant differences between the data (differences >5◦), suggesting our assessment could be used as an accurate and reliable alternative to the goniometer.
- The knee strength assessment was validated against a myometer in healthy young adults. Data reported during flexor strength did not differ statistically, but differences were reported in extensor strengths. These

differences were explained by the scientific corrections applied to our data. The assessment was therefore deemed appropriate for clinical use.

- The UCM method was applied to gait data of young healthy adults to investigate the use of this technique as a way of quantifying gait stability using motion capture technology. The results from this study confirmed the suitability of using this method on gait data to investigate the role of kinematic variability on COM stability.
- 63 pre-operative patients, 54 six-week post-operative patients and 30 1-year post-operative patients were successfully assessed with this system. 27 patients attended all three clinics.
- Average assessment time was 16.8±2.4 minutes, suggesting that the system can feasibly be used clinically.
- In general, the results reported in this trial were consistent with the current literature, implying that the system returned valid data for this patient cohort.
- On average, knee ROM, gait kinematics, spatio-temporal parameters of gait and gait stability improved in the patients post-operatively.
- Knee strength reduced bilaterally in the patients post-operatively, suggesting that those undergoing TKA require strength training as part of their rehabilitation in order to optimise functional outcome. This is a significant finding.
- At 1-year the patients were found to perform better in terms of knee ROM than other TKA patients. Knee strength, frontal and transverse plane kinematics were consistent with those reported in age-matched controls. Differences in sagittal plane data and spatio-temporal parameters of gait were explained by the patients' inabilities to adapt to the self-paced treadmill.
- Disadvantages to the protocol were identified; specifically in relation to treadmill use. Many patients lacked confidence when walking on the treadmill in self-paced mode due to unfamiliarity with the technology. In turn, many adopted a conservative gait to overcome their fear of falling.

Consequently, the biomechanical data recorded during this assessment may not be truly representative of their natural gait. This raises a question on the validity of using self-paced treadmills with this patient cohort in the clinical environment in future.

- Future research should further investigate the use of the self-paced mode in older adults with pathological gait, with the aim to optimise patient acceptability of treadmill-walking protocols and improve the validity of the data recorded. Use of a chest harness for extra security, and a longer acclimatisation period for the patients on the treadmill, may be necessary.
- The UCM method was concluded to be a valuable research tool for investigating gait stability, but is unfeasible clinically due to its complexity. A simpler method of assessing stability is therefore necessary.
- Objective data from the Medacta GMK Sphere trial poorly correlated with clinical standard subjective PROMs (OKS & SF-12). Present PROMs should therefore only be used to supplement objective data in TKA. This data consolidates the importance of furthering the use of motion capture technology as an outcome measure in the clinical environment.

Finally, to answer our main research questions; The Medacta GMK Sphere was successful at restoring frontal and transverse plane kinematics during gait. Sagittal plane kinematics were consistent with previous studies during swing, but not during stance. Knee ROM was on average greater than typically reported at 1-year, but knee strength had reduced; a significant finding in this thesis. The data reported in this thesis therefore suggest that the GMK-Sphere offers an improvement in function to patients, especially in terms of gait kinematics and knee ROM. A reduction in knee strength may however, have impeded the overall functional outcome of the patients. Overall functional outcome may also have been better were all patients assessed at 1-year and if all had access to physiotherapy to target weaknesses in knee strengths.

As a result of this clinical trial, this thesis has shown that our alternative motion capture system can feasibly be used in the clinical environment to assess TKA patients both pre- and post-operatively in an acceptable clinical timeframe. The system developed and presented here can therefore justifiably be used clinically to better report knee ROM and strength and gait biomechanics.

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Appendix 1

1.1. Validation Study Participant Information Sheet

Participant Information Sheet

Name of department: Department of Biomedical Engineering
Title of the study: Validation and reliability testing of a bespoke orthopaedic outcome measure package for assessing knee function.

Introduction
What is the purpose of this investigation?
This study aims to determine the accuracy and reliability of a bespoke orthopaedic outcome measure package. This package will be used to assess knee range of motion and strength. The results will be compared to those recorded from tools conventionally used in the clinic to assess knee range of motion and strength: the goniometer and myometer, respectively. Despite being commonly used clinically, recent research has shown that the results can be inaccurate and unreflective of true knee function. Our outcome measure package uses mathematics to calculate strength and range of motion at the knee with the hope that the results obtained will better represent true knee function.

Validation of this bespoke tool is necessary in order for it to be accepted into the clinical and research communities.

Do you have to take part?
You are not required to take part in this investigation. It is under each participant's own discretion whether he or she takes part in the investigation. Participants reserve the right to refuse to participate in the investigation, withdraw from the investigation or withdraw their data up to the point of anonymization , without having to provide a reason. For Strathclyde students and staff: participation (or declining to take part) in this study will not affect your standing in the university in any way.

What will you do in the project?
Six tasks will be carried out under two circumstances. Firstly, each assessment will be carried out using the bespoke motion capture based package. Following this, you will be required to repeat the assessment with the tools conventionally used in the clinical environment.

On arrival to the laboratory, clusters with reflective sphere 'markers' will be placed on your legs and feet to track your movement while you perform functional tasks with the bespoke outcome measure package. These clusters will be placed onto your clothing using elasticated Velcro straps (Figure 1).

Anatomical landmarks on your legs and feet will then be calibrated. To locate these landmarks, the investigator will be required to palpate your legs and feet. The landmarks will be recorded by placing a calibration pointer against the landmark (Figure 2). The point is similar to a biro, and is not sharp. The object will not be pushed into the clothing and skin; therefore, the process will not cause pain or discomfort.

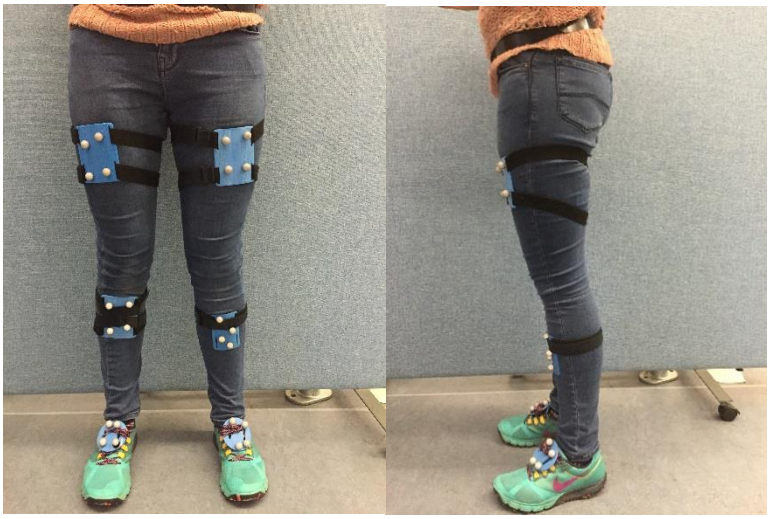


Figure 1: Image of the clusters strapped onto the legs and feet of a participant.

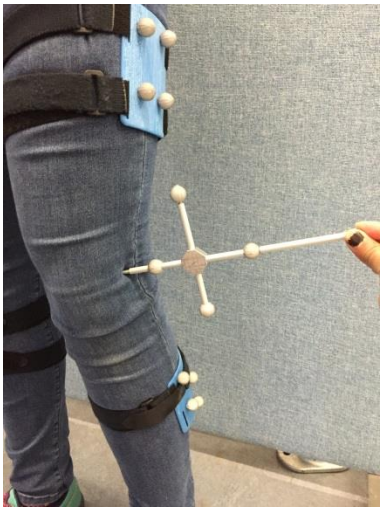


Figure 2: An example of the anatomical landmark calibration process using the calibration wand.

You will then be asked to perform 6 tasks to assess knee range of motion and strength. Each task will be repeated 10 times and on each leg. The tasks which will be completed are highlighted in table 1.

The markers will be removed and you will be asked to repeat each task a further 10 times for each leg (Table 1). This time the results will be recorded using conventionally used clinical outcome measures (goniometer and myometer).

Table 1: Description of tasks to be carried out during this study.

Task Name	Description
Active Knee Flexion	You will be asked to lie on a plinth and you're your heel towards your bum as far as possible. The maximum value will be recorded.
Active Knee Extension	You will be asked to lie on a plinth and push your knee into the plinth as far as possible. The maximum value will be recorded.
Passive Knee Flexion	You will be asked to lie on a plinth and move your heel towards your bum as far as possible. This movement will be aided by the investigator. The maximum value will be recorded.
Passive Knee Extension	You will be asked to lie on a plinth and push your knee into the plinth as far as possible. This movement will be aided by the investigator. The maximum value will be recorded.
Knee Extensor Strength	You will be asked to sit on a chair and a strap will be placed around your ankle. You will then push the leg outwards against the strap, as if going to kick a ball. The maximum value will be recorded. Please refer to figure 3 for a diagrammatic explanation.
Knee Flexor Strength	You will be asked to sit on a chair and a strap will be placed around your ankle. You will then pull your leg against the strap. The maximum value will be recorded. Please refer to figure 4 for a diagrammatic explanation.

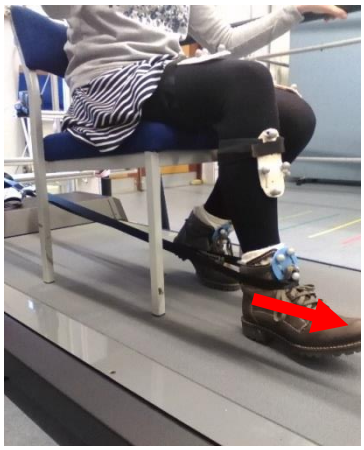


Figure 3: An image of a person pushing their leg against the black ankle strap to record knee extensor strength. The other end of the strap is attached to a force measuring device. Pushing direction shown by red arrow.

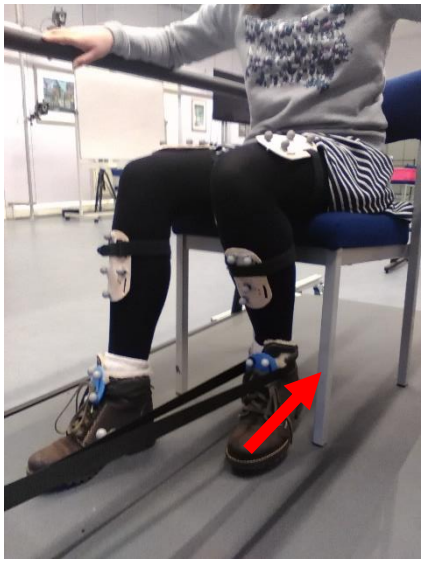


Figure 4: An image of a person pulling their leg against the black ankle strap to record knee flexor strength. The other end of the strap is attached to a force measuring device. Pulling direction shown by red arrow.

Once the data has been collected no further participation will be required. You will not receive any payment or reimbursement for your participation. This study involves no invasive procedures and participants will not be asked to do any high intensity exercise. The investigation will take place in the Biomechanics Laboratory 3 in the Department of Biomedical Engineering, University of Strathclyde. The whole assessment should take no more than 90 minutes to complete.

Why have you been invited to take part?
You have been invited to participate because you are a healthy able-bodied adult. This investigation is aiming to recruit 15 participants.

Inclusion Criteria

- Able bodied
- Normal lower limb function
- Able to perform a number of functional exercises such as bending the knee while lying down or raising the leg while standing on the other leg

Exclusion criteria

- Musculoskeletal, neurological or sensory deficit
- Under the age of 18 or over the age of 35
- Pregnant

What are the potential risks to you in taking part?
This is a very low risk investigation and providing you can complete the tasks outlined in the previous section there should be no risk. All small risks such as slipping and tripping will be mitigated and minimised by the researchers carrying out the study.

What happens to the information in the project?
All data collected from this investigation will be treated confidentially and pseudo-anonymously. The data of each individual will be pseudo-anonymised with a random 8-digit number on arrival to the laboratory. All data will be saved under these codes and not the name of the participant. The data will only be accessible to the investigators through a department designated encrypted computer. Data will be stored on Strathcloud. All data storage and security will be stored in a manner which will comply with the most recent departmental Data Management Plan (December 2015). The results of this study will be submitted for presentation at scientific and clinical conferences and will be submitted for scientific and clinical peer-reviewed publication. All data will be held at the Biomedical Engineering department (University of Strathclyde) for 10 years and then destroyed.

The University of Strathclyde is registered with the Information Commissioner's Office who implements the Data Protection Act 1998. All personal data on participants 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 voluntarily participate in this study please complete and sign the consent form on the next page. If you do not wish to participate then please accept our thanks for taking the time to read this information.

Researcher Contact Details:

Researcher: Gwenllian Tawy
Status: PhD Candidate
Department: Biomedical Engineering

Contact: gwenllian.tawy@strath.ac.uk, 07791184029

Chief Investigator Details:
The chief investigator: Philip Rowe
Status: Professor
Department: Biomedical Engineering
Contact: philip.rowe@strath.ac.uk, 01415483032

This investigation was granted ethical approval by the University of Strathclyde 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 the Departmental Ethics Committee
Department of Biomedical Engineering
Wolfson Centre, 106 Rottenrow
Glasgow G4 0NW
Tel: 0141 548 3298 E-mail: linda.gilmour@strath.ac.uk

1.2. Validation Study Consent Form

Consent Form

Name of department: Department of Biomedical Engineering
Title of the study: Validation and reliability testing of a bespoke orthopaedic outcome measure package for assessing knee function.

- 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 before or during the assessment, without having to give a reason and without any consequences.
- I understand that I cannot withdraw my data from the study after completing the assessment, as my data will be anonymised.
- 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 confirm that I meet the inclusion criteria and that none of the exclusion criteria are present
- For Strathclyde staff and students: I understand that participation (or declining to take part) in this study will not affect my standing in the University in any way.
- I understand that my data will be held at the Biomedical Engineering Department (University of Strathclyde) for 10 years after participation in the study; after this point, I understand that the data will be destroyed.

(PRINT NAME)	Hereby agree to take part in the above project
Signature of Participant:	Date

(PRINT NAME)	
Signature of Researcher:	Date

1.3. IRAS Ethical Approval

The following letter addressed to the principle investigator of the Medacta GMK Sphere trial details the date at which ethical approval for the trial was granted.

South East Scotland REC 02
2 - 4 Waterloo Place
Edinburgh
EH1 3EG

Telephone: 0131 465 5674
Fax:

29 April 2015

Dr Leela Biant
Consultant Orthopaedic Surgeon
NHS Lothian
51 Little France Crescent
Edinburgh
EH16 4SA

Dear Dr Biant

Document	*Version*	*Date*
Covering letter to REC [Covering letter]	1	09 March 2015
Covering letter to REC [Covering letter]	2	03 April 2015
Covering letter to REC [Covering letter]	3	26 April 2015
Covering letter on REC [Covering letter]	4	29 April 2015
GP/consultant information sheets or letters [GP Letter]	1	09 March 2015
Participant consent form [Consent]	2	03 April 2015

Study title: **Randomised controlled trial of patient-specific instrumentation vs standard instrumentation in total knee arthroplasty**
REC reference: **15/SS/0058**
IRAS project ID: **177817**

Thank you for your letter of 29th April 2015. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 27 April 2015

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Covering letter]	4	29 April 2015
Participant information sheet (PIS) [PIS]	4	27 April 2015

Approved documents

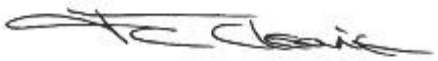
The final list of approved documentation for the study is therefore as follows:

Participant information sheet (PIS) [PIS]	4	27 April 2015
REC Application Form [REC_Form_13032015]		13 March 2015
Research protocol or project proposal [Study Protocol]	2	03 April 2015
Summary CV for Chief Investigator (CI) [CV CI]	1	09 March 2015
Validated questionnaire [CRF Booklet]	2	03 April 2015

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

15/SS/0058	Please quote this number on all correspondence

Yours sincerely



Joyce Clearie
SESREC 2 Manager

E-mail: joyce.clearie@nhslothian.scot.nhs.uk

Copy to: *Susan Shepherd, NHS Lothian*

1.4. NHS Lothian R&D Approval

This letter confirms that our clinical trial was approved by the research and development department at the Edinburgh Royal Infirmary.

University Hospitals Division

NHS Lothian

Queen's Medical Research Institute
47 Little France Crescent, Edinburgh, EH16 4TJ

FM/GM/Approval

1st February 2016

Ms Leela Biant
Orthopaedic Surgery
Royal Infirmary of Edinburgh
51 Little France Crescent
Edinburgh
EH16 4SA

Research & Development
Room E1.12
Tel: 0131 242 3330

Email:
R&DOffice@nhslothian.scot.nhs.uk

Director: Professor David E Newby

Dear Ms Biant:

Lothian R&D Project No: 2015/0244

Title of Research: Randomised controlled trial of patient-specific instrumentation vs standard instrumentation in total knee arthroplasty

REC No: 15/SS/0058

Participant Information Sheet: Version 4 Dated 28th April 2015

Consent Form: Version 2 Dated 3rd April 2015

Protocol: Version 2 Dated 3rd April 2015

I am pleased to inform you that this study has been approved for NHS Lothian and you may proceed with your research, subject to the conditions below. This letter provides Site Specific approval for NHS Lothian.

Please note that the NHS Lothian R&D Office must be informed if there are any changes to the study such as amendments to the protocol, recruitment, funding, personnel or resource input required of NHS Lothian.

Substantial amendments to the protocol will require approval from the ethics committee which approved your study and the MHRA where applicable.

Please inform this office when recruitment has closed and when the study has been completed.

I wish you every success with your study.

Yours sincerely

Fiona McArdle.

Ms Fiona McArdle
Deputy R&D Director

cc: Mr Michael Pearson, General Manager Surgical Services Directorate, RIE

1.5. Clinical Trial Patient Information Sheet

Participant Information Sheet

Bespoke vs Standard Instrumentation in TKR

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Why have I been asked to take part?

You have been asked to take part as you have 'wear and tear' arthritis in your knee and you have been offered treatment with a total knee replacement.

What is the purpose of the study?

Total knee replacements are operations that are offered to patients who have severe arthritis pain that is affecting daily activities that is no longer controlled with painkillers. The operation will replace the worn joints with metal implants and a plastic spacer. Total knee replacements are successful operations in the vast majority of patients. However, a small minority of patients are not entirely satisfied with the outcome of their knee replacement. Researchers are studying whether the precise positioning of the implant has an effect on the outcome. The primary objective of this study is to look at whether patient-specific instrumentation improves implant position and if it leads to improved patient function so that we know what to recommend in the future.

Medacta® International is a company that produces bespoke cutting blocks (Fig. 1) to allow individualised placement of the knee replacement by the surgeon for a particular patient (patient specific implementation). There is no evidence at present that this is more accurate than the standard blocks. In order to try and find out if this is a better approach, half of the patients in this study will have their knee replacement put in using the conventional method, known to be the best available current standard of care, and half will have it put in with patient specific instruments. The patient-specific instruments will be supplied by Medacta® International to the research team, but have no influence over the objective of the study or the results.

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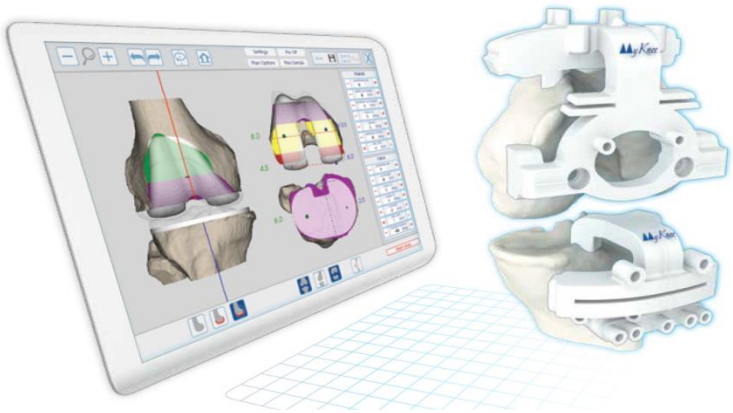

Figure 2: Medacta® International patient-specific cutting block.

The number of knee replacements required by the active ageing population is increasing sharply, which is a significant cost to the NHS. Therefore, the secondary outcome of this study is to do an efficiency evaluation of the surgeries. Single-use instruments will be used in half of the patients to see if this is cost effective. Currently there is no evidence to say that using these instruments are better or worse than current standard re-useable instruments.

What exactly are 'cutting blocks'?

Cutting blocks are designed by engineers to allow surgeons to make precise bone cuts to allow the implants to 'fit'. Off the shelf cutting blocks are already being used in all total knee replacements. The new patient specific cutting blocks allows for planning of the surgery weeks before the operation. An example of the cutting block (Figure 1) will be shown to you in the clinic by the trial team. These blocks are manufactured by Medacta using a 3D printer.

What implants will be used during this study?

There are a number of different knee implants on the market. The Royal Infirmary in Edinburgh use the Depuy PFC and the Stryker Triathlon as the standard implant. The Medacta Sphere knee replacement is used as the standard choice of knee replacement in other centres. To date over 25,000 knee operations have been successfully performed globally using the Sphere. Until now there is no evidence to favour one implant over the other. Patients in this study will receive a Sphere knee replacement as this is the design that can be implanted with the bespoke instruments.

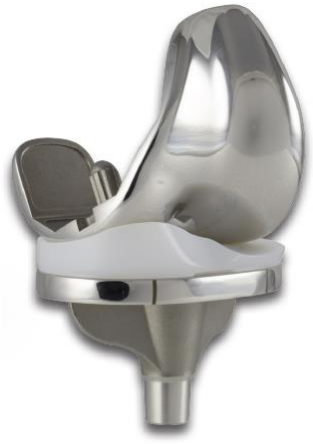

Figure 3: GMK Sphere Implant

Figure 3: DePuy PFC-CR Implant (Standard Implant)

Figure 4: Stryker Triathlon TKR (Standard Implant)

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights. If you decide not to take part in this study, you will not be disadvantaged and you will receive your operation to current standard practice.

What will happen if I take part?

Your treatment will seem very much the same as it would be if you were not in the study. You will not be required to come for additional check-ups if you participate, but the check-ups will take a bit longer. During the check-ups we will ask you to answer some questionnaires about how your knee affects your day-to-day activities. You will get your operation as soon as possible whether you decide to take part in this study or not. All patients in this study will get exactly the same implants. The only difference will be the instruments used by the surgeon during the operation.

As shown in figure 5, half of the patients in this study will have their knee implant put in using the conventional method and the other half will have the implant put in with bespoke (patient specific) instrumentation. Those patients who are allocated to the group which will have their knee implant put in using the conventional method, will be divided into two equal groups, half will be carried out using re-usable conventional instruments (currently standard care), while the other half using single-use conventional instruments.

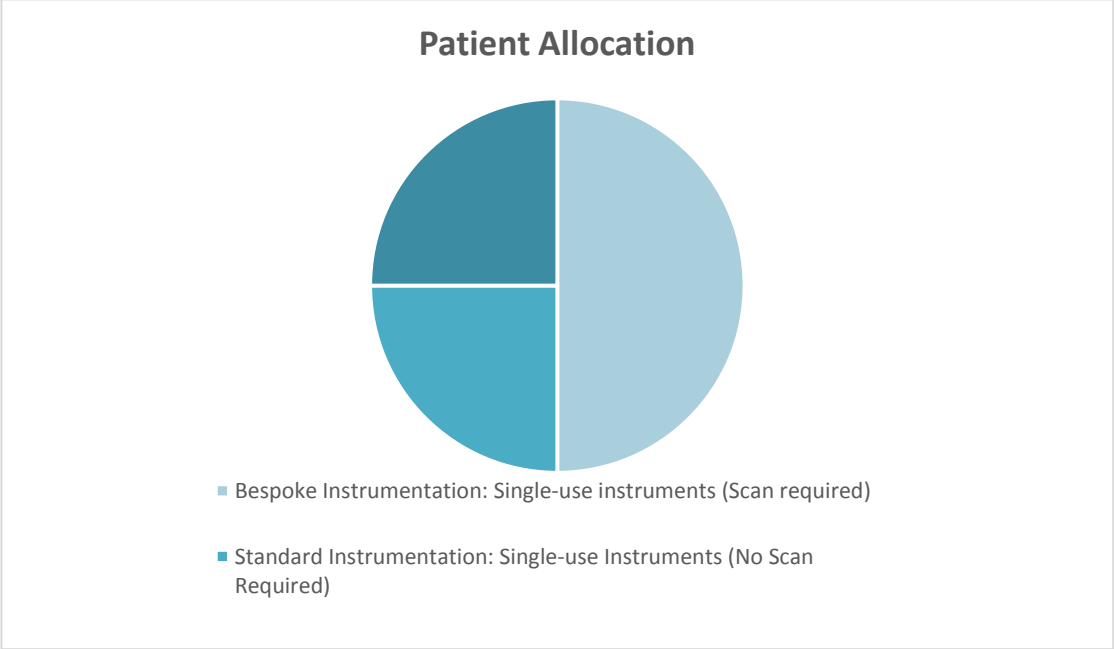

Figure 5: Pie-Chart showing patient allocation to groups

In order to have bespoke instruments made you will be required to attend a 30 minute CT scan session of your ankle, hip and knee before the operation. This CT scan ensures correct alignment of the cutting blocks with respect to your whole leg.

You will be randomly allocated whether or not we will use patient-specific instruments. The randomisation process itself will be done by a computer.

In addition, a few patients will be randomly chosen to have further scans (MRE and CT scans) to see how the knee functions. These scans will ideally happen during the 6 weeks pre-op check-up and the one year post-op follow-up, and they will take no longer than one hour.

MRE (magnetic resonance elastography) scans will be performed look at the muscles around your knee before and after the surgery. This is to see how best to rehabilitate your muscles following your operation and may even help future patients strengthen their muscles before surgery.

The additional CT scans will look at how your knee moves and will help engineers study this precisely. This part is optional as it involves additional radiation and you can opt out.

The operation will be video recorded to allow for timing of key stages such as the length of the operation. This will allow us to investigate whether using single-use instrumentation is economically advantageous to current standard instrumentation in terms of saving time and money. This recorded data will be completely anonymised and you will not be personally identifiable.

During the surgery a small sample of tissue may be taken from your muscle and looked at under the microscope to see how it relates to the scan result.

In addition, you will be followed-up two years after the operation to assess your progress.

What will happen to my tissue at the end of the study?

Once the samples have been analysed they will be immediately disposed of in accordance with the Human Tissue Authority's Code of Practice. No tissue will be kept at the hospital.

Will anything else be expected of me?

Before and after your operation you will be invited to the clinic for examination (routine check-ups). The trial team will place clusters of small markers on your legs and feet, allowing them to use computers to track your movement (Figure 6) during routine activities of daily living. At check-ups you will be asked to do a deep knee bend while lying down and while sitting, as well as walk on a treadmill. The way your knee moves will be recorded by cameras (which can pick up the location of the markers), allowing the researchers to see how much your movement and strength has improved after the operation. Please wear comfortable clothing and shoes for this assessment. This analysis will take approximately one hour.

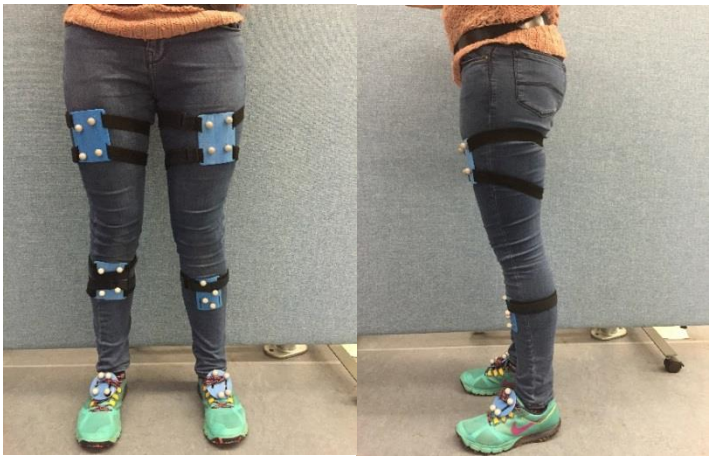

Figure 6: An example of the clusters of markers you will be required to wear during clinical examination.

What are the possible benefits of taking part?

Your recovery will be monitored very closely. You will have clear evidence of the change in your knee movement and ability to perform daily activities. We hope that your help now will give us the information that will allow us to treat patients better in the future by being able to recommend the best treatment for them. However there are no 'real' benefits in taking part.

What are the possible disadvantages and risks of taking part?

There are not many disadvantages. You will be asked to fill out a questionnaire on one additional occasion in addition to the normal routine, which will take 10 minutes.

If you are randomised to the 'patient specific' cutting block group you will be required to undergo a CT scan for the cutting blocks to be manufactured. The most important potential side effect of the CT scan is the use of radiation. The amount of radiation used during the scan is equivalent to around 4 times the amount you would normally receive in a year from background natural sources such as cosmic rays. The average excess risk of developing cancer due to the CT scan is 5 in 10,000 compared to a lifetime risk of 1 in 3.

For clarification and comparative reasons, the radiation doses used during the scans are given below:

i) <u>For subjects undergoing standard surgery - 0.0016 mSv</u>

The X-rays taken as part of the standard surgery group, being X-rays of the extremities (legs), are among the lowest of all radiological imaging procedures.

ii) <u>For subjects undergoing patient-specific surgery - 9.1 mSv (9.9 mSv for 4D CT subgroup)</u>

If you are randomised to this group you will have an ankle, knee and hip CT scan, which are necessary for cutting blocks to be manufactured. The effective dose for the patient-specific surgery comes predominantly from the hip CT scan (8.5 mSv).

It is helpful to put these exposures in context. A range of other, standard radiological examinations using ionising radiation are listed, together with their associated effective doses and cancer risks in the table below [1,2]:

Examination	Effective dose (mSv)	Equivalent natural background exposure	Risk of developing fatal cancer
Chest X-ray	0.014	2 days	1 in 1,400,000
Pelvic X-ray	0.284	6 weeks	1 in 70,000
Barium enema	2.2	1 year	1 in 9,000
CT head	1.4	0.6 years	1 in 14, 000
CT chest-abdomen-pelvis	10	4 years	1 in 2,000
CT coronary angiography	2-30	1 year - 13 years	1 in 700 to 1 in 10,000

[1] HPA-CRCE-012, Frequency and collective dose for medical and dental X-ray examinations in the UK, 2008

[2] British Society of Cardiovascular Imaging, Survey of coronary CT angiography doses, 2014

The cancer risks quoted above must also be considered in context of the approximate 1 in 4 baseline risk of developing fatal cancer during the lifetime in the general population.

You may have one additional scan (MRI/CT) for the study (in addition to those that you would have any way). These additional scans will be performed after your surgery to look at how the implants have improved movement and how your muscles are working around your new knee. The MRI scan is a loud noisy machine and requires you to lie still, but allows your head and shoulders to be outside the machine so claustrophobia is not usually a problem for knee scans even in patients who may be prone to this. The MRI does not involve any extra radiation whereas the CT scan does. The 4D CT scan is an additional scan which is optional and you can opt out of this part of the study. The additional dose of radiation for this extra CT scan is 0.8 mSv

What is the difference between this study and standard care?

Activity	Standard Care	This study
Elective Out Patient Clinic	30 Mins	40 Mins
Pre Admission Clinic*	4 Hours	4 Hours
CT Scan (Patient-Specific Cutting block)	N/A	30 Mins
Pre-Op CT/MRE (20 Patients only)	N/A	30 Mins
Operating Time	Approx. 1 hr	Approx. 1 hr
Hospital Stay	2-5 days	2-5 days
6 Week Appointment*	1 Hour	2 Hours
Post-Op CT/MRE (20 Patients Only)	N/A	30 Mins
1 Year Appointment*	1 Hour	2 Hours
2 Year Appointment*	1 Hour	2 Hours

***** Activity includes 10 minutes for completion of questionnaires.

What if there is a problem?

If you have a concern about any aspect of this study please contact Miss Leela Biant, Consultant Orthopaedic Surgeon, Royal Infirmary of Edinburgh, 0131 242 1000 who will do her best to answer your questions. If you wish to discuss this study with an Orthopaedic Surgeon not involved in the study, please contact Mr Sam Patton at the Royal Infirmary of Edinburgh 0131 242 1000. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Will my taking part in the study be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

With your consent we will inform your GP that you are taking part.

To ensure that the study is being run correctly, we will ask your consent for responsible representatives from the Sponsor and NHS Institution to access your medical records and data collected during the study, where it is relevant to your taking part in this research. With your permission, the study data may be analysed by our research partners at The University of Edinburgh.

What will happen to the results of the study?

The study will be written up as a scientific paper for publication in the public domain, so that other surgeons and hospitals can benefit from this knowledge in care of their patients. You will not be identifiable in any published results. If you would like to know the outcome of the study once it has been completed, we will send you a summary of the results once they are available.

Who is organising the research?

This study is being organised by the Orthopaedic Department of the Royal Infirmary of Edinburgh, and is sponsored by NHS Lothian.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. They have given the study a favourable opinion. NHS management approval has also been obtained.

If you wish to make a complaint about the study please contact NHS Lothian:

NHS Lothian Complaints Team

2nd Floor

Waverley Gate

2 - 4 Waterloo Place

Edinburgh

EH1 3EG

Tel: 0131 465 5708

craft@nhslothian.scot.nhs.uk.

Thank you for taking the time to read this information sheet.

1.6. Clinical Trial Consent Form

CONSENT FORM

Bespoke vs Standard Instrumentation in TKR

Please initial box

Participant ID:

1. I confirm that I have read and understand the participant information sheet (version 2 dated 03/04/15) for the above study and have had the opportunity to consider the information and ask questions. ☐

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

3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Trial team, the Sponsor, from NHS Lothian and the University of Edinburgh, or other authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I agree to my anonymised data being used in future studies. ☐

5. I agree to have my operation video recorded to allow for timing of key stages in the operation. This data will be completely anonymised and I will not be personally identifiable. ☐

6. I agree to have a small sample of tissue taken from my muscle to allow comparison with the scan results ☐

7. I agree to undergo an additional CT scan to allow accurate motion analysis of my knee replacement to be performed. I am aware of the additional radiation involved with this extra scan. I understand that I do not have to consent to this additional scan and can decline this part of the study. ☐

8. I agree to my General Practitioner being informed of my participation in this study. ☐

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

_____	_____	_____
Name of Participant	Date	Signature

_____	_____	_____
Name of Person taking consent	Date	Signature

1x original – into Site File; **1x copy** – to Participant; **1x copy** – into medical records

Appendix 2

2.1. Directions for Use

Start of Session

1. Turn on the computer, cameras and treadmill
2. Open Tracker software
3. Calibrate the cameras
    a. Remove or cover all reflective material in the field of view.
    b. Once you have opened Tracker, the cameras should start flashing red and the reconstructed cameras in Tracker should turn green. Once all cameras in the software are green select all cameras in the left hand pane (under **'System'**) then change the view from **'3D Perspective'** to **'Camera View'**. This drop-down list is in above the main panel (main screen).
    c. Go back to the left hand pane and go to the **'Calibrate'** tab and click **'Start'** under **'Create Camera Mask'**. Once you have clicked this, watch the middle screen which shows each camera view. Once all the white objects (reflective materials) have turned blue click the button a second time.
    d. In the same pane go down to the **'Calibrate Cameras'** subsection and click **'Start'**. Once you have clicked this, red triangles will appear in the bottom right hand corner of each camera. These will turn green as you calibrate and eventually disappear when enough frames have been captured.
    e. Pick up the calibration wand and wave in the field of view. Make sure to capture the floor of the treadmill and to above pelvis height (where the highest marker will be on the patient). Continue waving the wand until all cameras have collected enough frames.
    f. Return to the computer and click the same button for a second time: **'Stop'**.
    g. Wait until camera errors have been calculated.
    h. Check the error of each camera in the bottom left hand pane. Image errors of <0.3mm are acceptable with this system. You should recalibrate if any of the cameras have an error of >0.3mm.
    i. Return to the treadmill and place the wand on the floor as shown in Figure 1. **Do not calibrate the volume origin with the wand facing a different direction.**
    j. Under the **'Set Volume Origin'** tab, click **'Start'** twice.
    k. Change the view back from **'Camera View'** to **'3D Perspective'** (drop down list above the main window).
    l. Wave the wand in the field of view to check that it is tracking correctly.

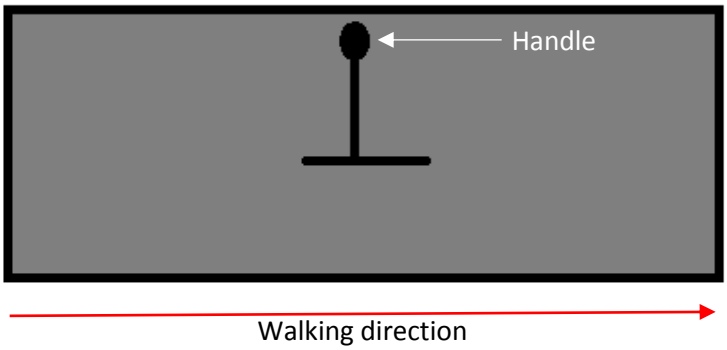

Figure 1: Calibration Instructions

4. Open D-Flow (Cluster version).
5. Open application: File > Applications > C:\CAREN Resources\Applications\ Clinical Assessment OrthoOMEGA Tracker2.caren)
6. As the application loads the treadmill should start up. The treadmill is now in standby mode.

Before Every Patient Arrival

If you suspect that the positions of the cameras have been moved between patients, recalibrate before the next patient.

1. While the application loads, set up the assessment area:
    a. Put the footswitch in the middle of the treadmill
    b. Set-up the plinth, pointer and clusters
    c. Place a chair nearby for the patients
2. Return to the computer and click in the grey space in D-Flow then press F2. This brings up the runtime console.
    a. In the first tab titled **'Hardware'** check that Tracker is streaming into D-Flow and that the treadmill is on (Two green ticks: Figure 2).
    b. In the second tab (**'Patient Information'**), enter the mass (in kg) and height (in mm) of the patient (Figure 3). These details should be in the CRF. **Make sure you enter the correct information for the correct patient.**
    c. In the third tab (**'Patient Calibration'**) click **'Calibrate Anatomical Landmarks'** (Figure 4).
    d. Check that the red numbers in the right hand corner of the screen are both '0'. If they are not 0 press the footswitch once, click the Stop and Return buttons at the bottom of the runtime console.

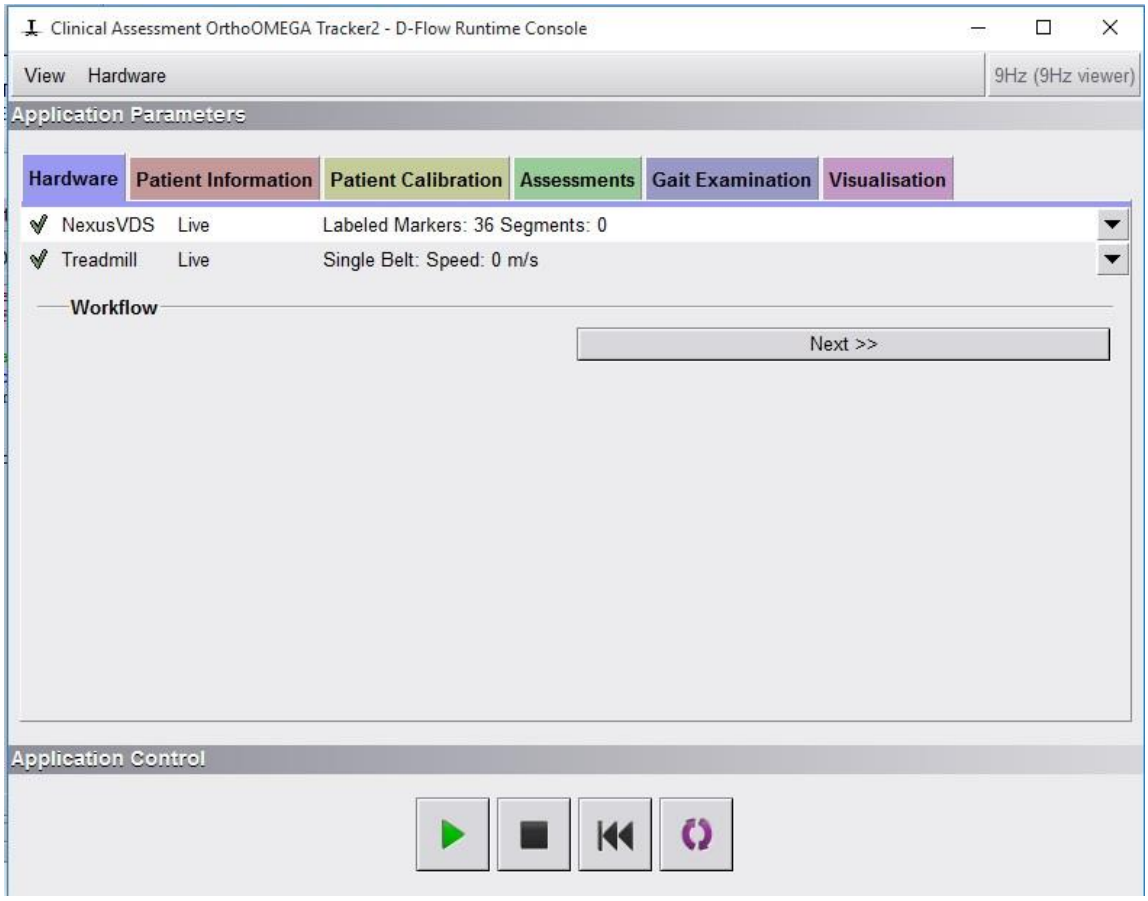

Figure 2: Example of the Hardware tab.

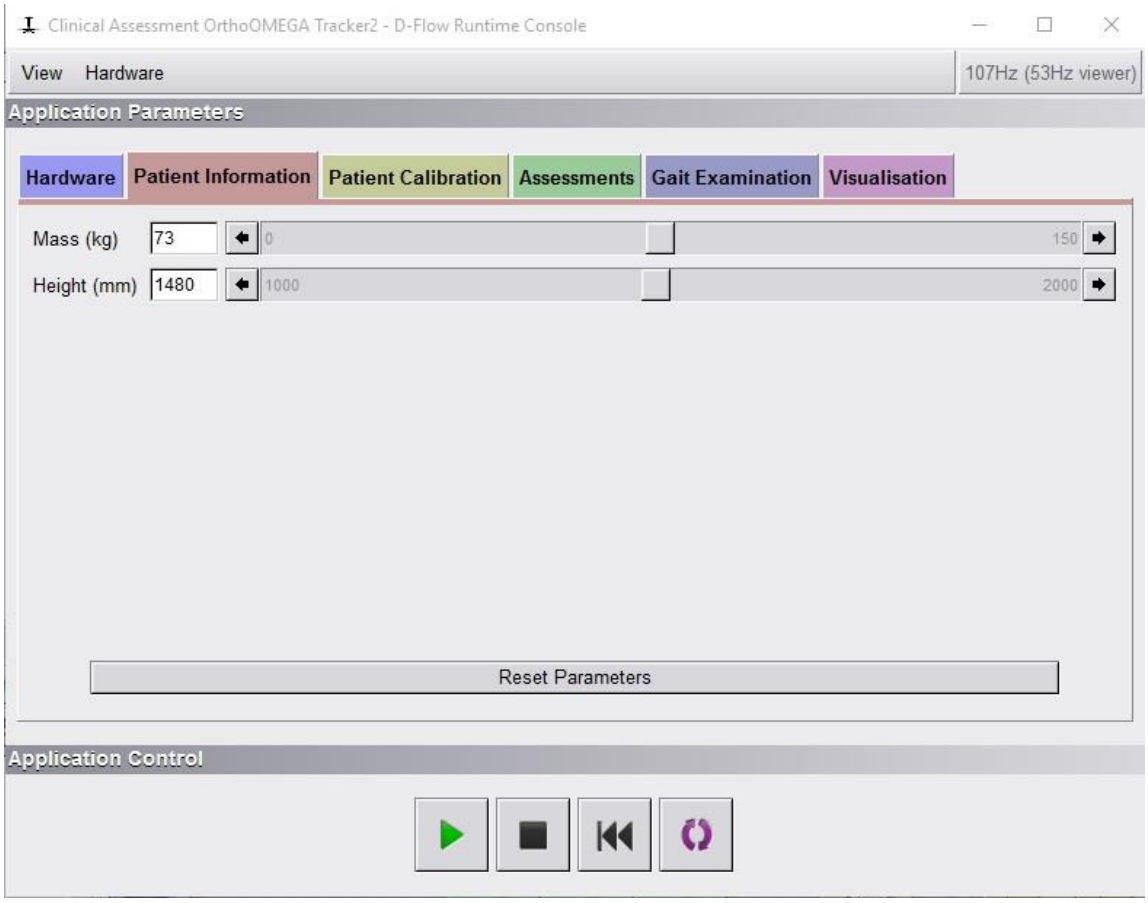

Figure 3: Example of the Patient Information tab.

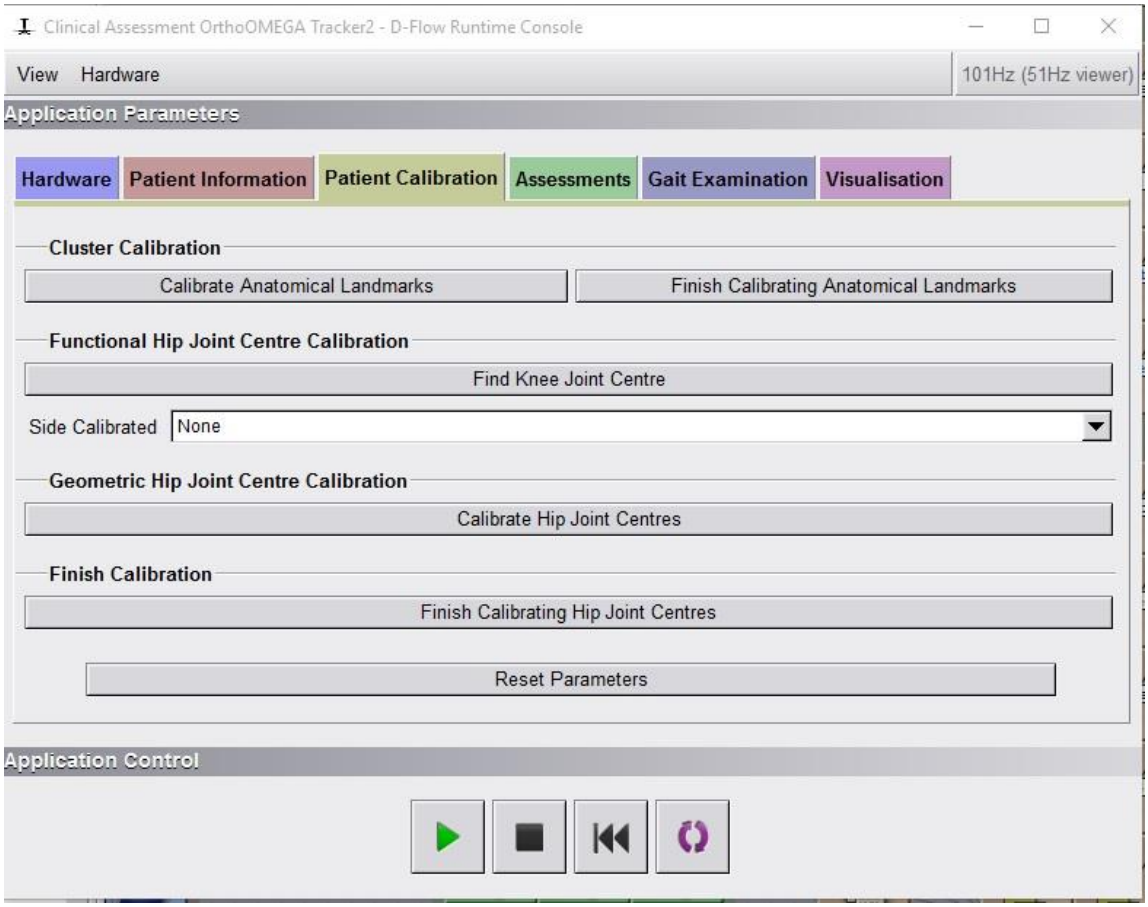

Figure 4: Example of Patient Calibration tab.

Anatomical Landmark Calibration

1. Place the thigh, shank and foot clusters on the patient. Make sure that you place the correct cluster on each segment. The name and orientation of each cluster is written on the back of each one. Tighten the straps enough to prevent slippage during walking, but not too much to cause discomfort to the patient.
2. Ask the patient to stand in the middle of the treadmill.
3. Begin calibrating anatomical landmarks by palpating the landmark. Once the landmark has been located, bring the pointer tip to the landmark and check that the cameras can see the pointer. If the pointer cannot be seen an error message will display. Press the footswitch to log the position of the landmark. The order in which the landmarks should be calibrated are outlined in Table 1. Check that the top right hand number increases as you calibrate. The last number should be 16.
4. Following calibration return to the computer and click **'Stop Anatomical Calibration'**.
5. Go to the **'Visualisation'** tab and click **'Display Avatar'** (Figure 5).
6. Check in the 3D window that the avatar of the patient is now visible and moving as the patient moves.

Table 1: Anatomical landmark calibration order.

Press	Action	Landmark Name
1	Save pointer position & Label position	Left greater trochanter (LGTRO)
2	Reset pointer position	
3	Save new pointer position & Label new position	Left lateral epicondyle of knee (LLEK)
4	Reset pointer position	
5	Save new pointer position & Label new position	Left medial epicondyle of knee (LLEK)
6	Reset pointer position	
7	Save new pointer position & Label new position	Left lateral malleolus of ankle (LLM)
8	Reset pointer position	
9	Save new pointer position & Label new position	Left medial malleolus of ankle (LMM)
10	Reset pointer position	
11	Save new pointer position & Label new position	Left heel (LHEE)
12	Reset pointer position	
13	Save new pointer position & Label new position	Left 1st metatarsal (LMT1)
14	Reset pointer position	
15	Save new pointer position & Label new position	Left 5th metatarsal (LMT5)
16	Reset pointer position	

17	Save pointer position & Label position	Right greater trochanter (LGTRO)
18	Reset pointer position	
19	Save new pointer position & Label new position	Right lateral epicondyle of knee (LLEK)
20	Reset pointer position	
21	Save new pointer position & Label new position	Right medial epicondyle of knee (LLEK)
22	Reset pointer position	
23	Save new pointer position & Label new position	Right lateral malleolus of ankle (LLM)
24	Reset pointer position	
25	Save new pointer position & Label new position	Right medial malleolus of ankle (LMM)
26	Reset pointer position	
28	Save new pointer position & Label new position	Right heel (LHEE)
28	Reset pointer position	
29	Save new pointer position & Label new position	Right 1st metatarsal (LMT1)
30	Reset pointer position	
31	Save new pointer position & Label new position	Right 5th metatarsal (LMT5)
32	Clear pointer position	

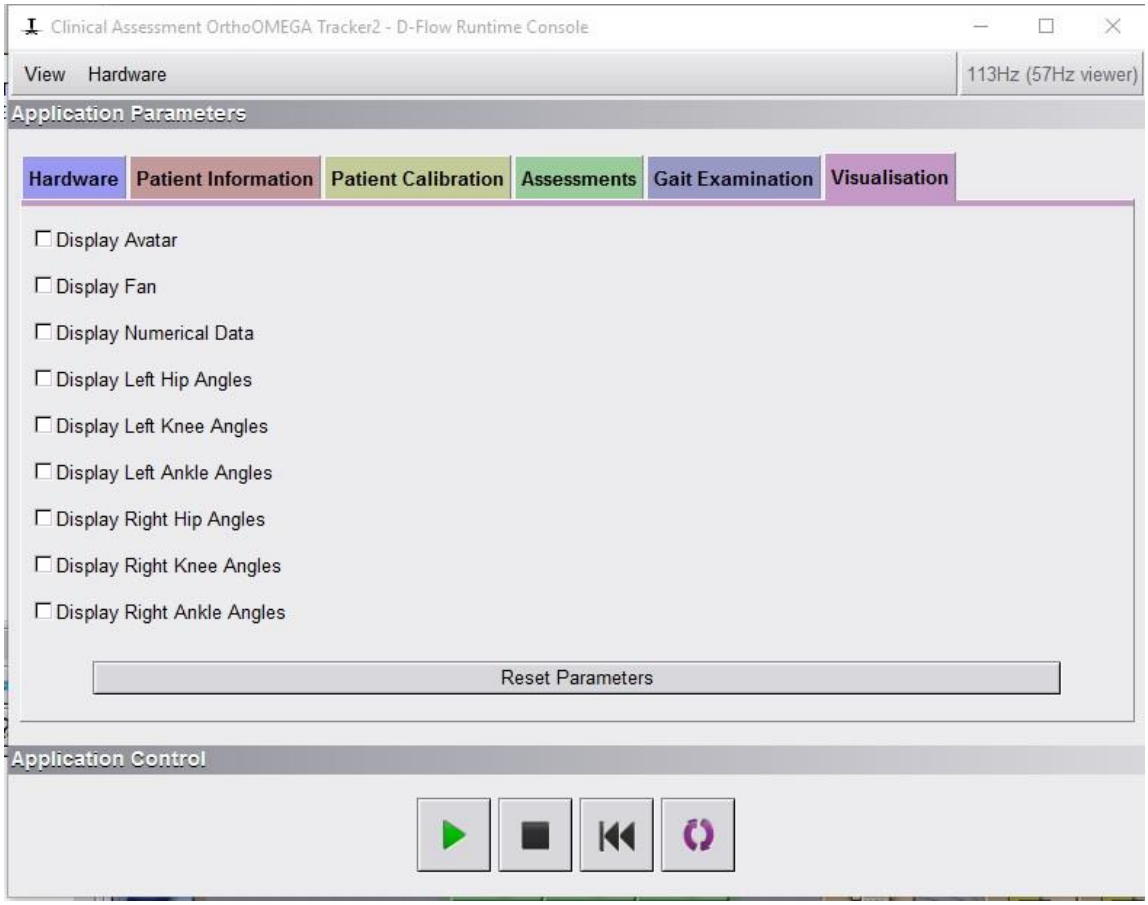

Figure 5: Example of Visualisation tab.

Hip Joint Centre Calibration

To calibrate the hip joint centres, there is an option to use one of two methods. The first is a functional calibration and is not recommended for use with patients suffering from OA as it requires them to stand on one leg and raise the knee to pelvis-height. For this reason, you should use the geometric method with this patient cohort.

1. In the **'Patient Calibration'** tab go to the **'Geometric Hip Joint Centre Calibration'** section and click **'Calibrate Hip Joint Centres'** (Figure 4)
2. Click **'Finish Calibrating Hip Joint Centres'**
3. You should now see that the avatar has been completed, and the hip joint centres have been created.

Range of Motion (ROM) Assessment

1. Ask the patient to step off the treadmill as you move the plinth onto the treadmill.
2. Ask the patient to lie on the plinth.
3. Go to the **'Assessments'** tab and click **'Left'** from the **'Side Examined'** drop-down list (Figure 6).
4. Under **'Range of Motion'** select **'Active Assessment'** from the **'Type'** drop-down list.
5. Ask the patient to bend their left knee as far as they can by sliding their heel towards their bum, (keeping the foot on the bed) then extend it as much as possible. This movement should be repeated **3 times.**
6. As they begin the first movement, press the footswitch. This tells the software to start recording the assessment.
7. Press the footswitch again once they have completed all 3 movements.
8. Return to the computer and click **'End and Save Examination'**
9. Change the side examined to **'Right'**
10. Repeat steps 5-8 for the right leg.
11. Change the side examined back to **'Left'** and select **'Passive Assessment'** under the **'Type'** drop-down list.
12. Repeat steps 5-8, but this time you will assist knee motion by pushing the knee into maximum flexion and extension. **Tell your patient to inform you of any pain or discomfort in the knee. Stop the assessment if necessary.**
13. Repeat the assessment for the right leg by changing the variable in the **'Side Examined'** drop-down list.
14. Ask the patient to come down from the plinth and remove the plinth from the treadmill.

Strength Assessment

1. Ask the patient to step back onto the treadmill and place a chair behind them (facing the front of the treadmill)
2. Ask the patient to sit on the chair and place the black strap (attached to the load cell) around their right ankle (at the height of the malleoli). The knee should be set at a right angle.
3. Go to the computer and select **'Right'** under **'Side Examined'.**
4. Under '**Knee Strength'** select **'Flexion'**.
5. Return to the patient and ask them to pull against the strap as hard as possible **3 times**. Patients can hold onto the bottom of the chair for support.
6. Start recording the trial before the patient starts pulling by pressing the footswitch once.
7. Press the footswitch a second time to finish recording the assessment once they have pulled the strap three times.
8. Move the strap to the opposite ankle.
9. Return to the computer and click **'End and Save Examination'.**

10. Repeat steps 3-7 for the left leg.
11. Ask the patient to stand up.
12. Reverse the chair and ask the patient to sit back down.
13. Repeat steps 3-7 for both legs but choose **'Extension** under **'Type'**

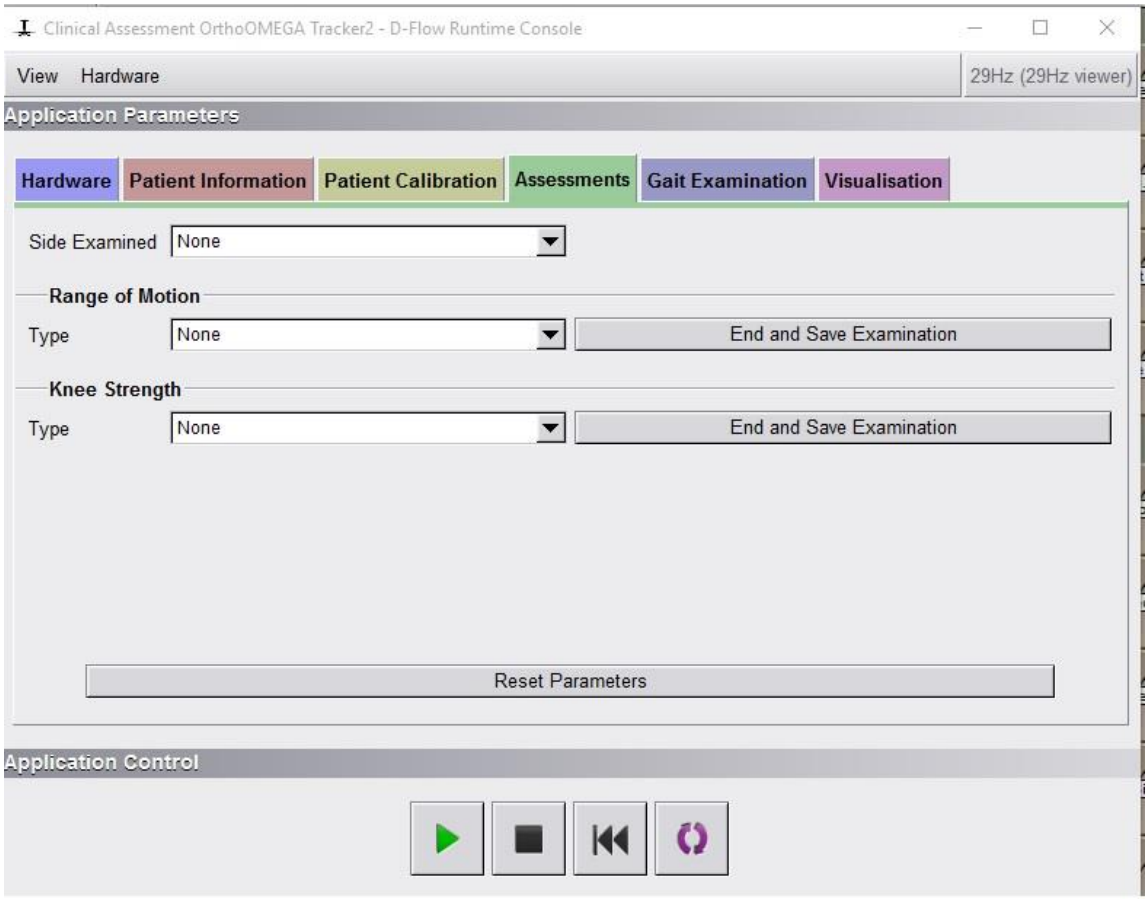

Figure 6: Example of Assessments tab.

Pelvis Calibration for Walking Assessment

1. Remove the chair from the treadmill.
2. Place the pelvic cluster on the patient with the cluster facing the back of the treadmill.
3. Get the calibration pointer and place in the field of view of the cameras.
4. In the **'Gait Examination'** tab (Figure 7) click **'Calibrate Pelvic Landmarks'** and check that the second number in the top right hand corner of the screen remains at '0'. If the number changes to 1, press the footswitch once and click **'Finish Calibrating Pelvis'** then re-click **'Calibrate Pelvic Landmarks'**.
5. Calibrate the anatomical landmarks as outlined in Table 2 by palpating the landmarks. Ensure that the pointer can be seen when pressing the footswitch.
6. Return to the computer and check that the number of landmarks calibrated is 4 then press **'Finish Calibrating Pelvis'**.
7. An avatar of the pelvis should now appear in the 3D screen.

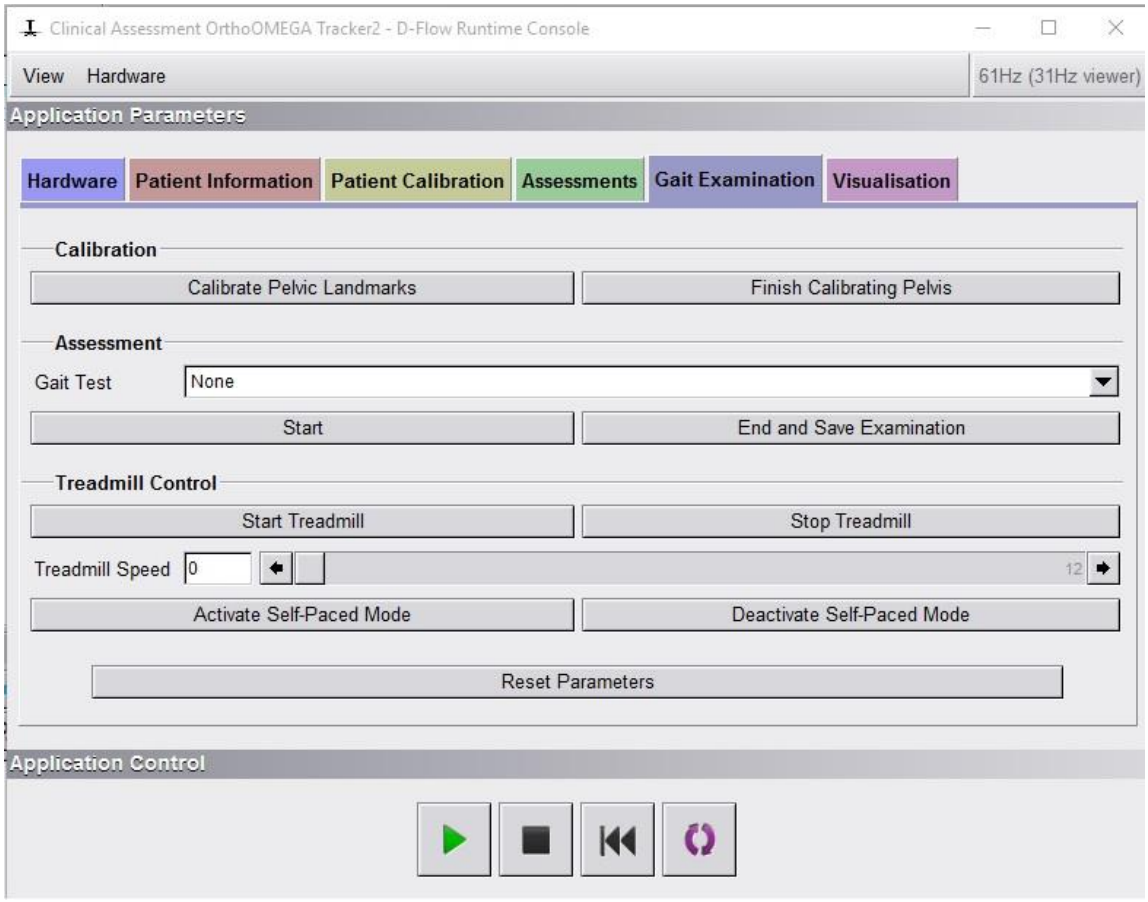

Figure 7: Example of Gait Examination tab.

Table 2: Order for calibrating pelvic anatomical landmarks

Press	Action	Landmark Name
1	Save pointer position & Label position	Left anterior iliac spine (LASIS)
2	Reset pointer position	
3	Save new pointer position & Label new position	Left posterior iliac spine (LPSIS)
4	Reset pointer position	
5	Save new pointer position & Label new position	Right anterior iliac spine (RASIS)
6	Reset pointer position	
7	Save new pointer position & Label new position	Right posterior iliac spine (RPSIS)
8	Clear pointer position	

Walking Assessment

1. Under the **'Assessment'** drop-down list, select **'Walking'** as a gait test.
2. When the patient is ready click **'Start Treadmill'** and slowly increase the speed of the treadmill by clicking the | > | arrow on the slide-bar.
3. Once the patient is at a comfortable pace, stop increasing the speed and let the patient walk for **1 minute**.
4. After one minute, click **'Activate Self-Paced Mode'**. Please warn your patient before activating this function.
5. Click **'Start'** and let the patient walk for **2 minutes** at their own pace. Stop the assessment early if the patient is not able to walk for so long.
6. Click **'End and Save Examination'.**
7. Warn the patient that the treadmill will slowly come to a stop and click **'Stop Treadmill'**
8. Remove all clusters from the patient.

Appendix 3

3.1. Validation Study: Case Report File

Camera Number	Error (mm)
1	
2	
3	
4	
5	
6	
7	
8	

Name:	**Date:**
Date of Birth:	**Gender:**
Mass (kg):	**Height (mm):**

Results using bespoke orthopaedic outcome measure package:

Repetition	Active ROM Assessment (L)			Active ROM Assessment (R)		
	Max	Min	Excursion	Max	Min	Excursion
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

Repetition	Passive ROM Assessment (L)			Passive ROM Assessment (R)		
	Max	Min	Excursion	Max	Min	Excursion
1						
2						
3						
4						
5						
6						
7						
8						

9						
10						

Repetition	**Flexor Strength (L)**			**Flexor Strength (R)**		
	Max Force	**Max Moment**	**Max Moment/BW**	**Max Force**	**Max Moment**	**Max Moment/BW**
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
Repetition	**Extensor Strength (L)**			**Extensor Strength (R)**		
	Max Force	**Max Moment**	**Max Moment/BW**	**Max Force**	**Max Moment**	**Max Moment/BW**
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

Results using clinical standard tools:

Repetition	**Active ROM Assessment (L)**			**Active ROM Assessment (R)**		
	Max	**Min**	**Excursion**	**Max**	**Min**	**Excursion**
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

Repetition	Passive ROM Assessment (L)			Passive ROM Assessment (R)		
	Max	Min	Excursion	Max	Min	Excursion
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

Repetition	Flexor Strength (L)			Flexor Strength (R)		
	Max Force	Max Moment	Max Moment/BW	Max Force	Max Moment	Max Moment/BW
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
Repetition	Extensor Strength (L)			Extensor Strength (R)		
	Max Force	Max Moment	Max Moment/BW	Max Force	Max Moment	Max Moment/BW
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

Comments:

3.2. Clinical Trial Case Report File

This case report file (functional assessment only) was used during pre-operative and post-operative (6-weeks and 1 year) assessments.

Date	
Weight	
Height	
Limb Affected	

Baseline Tests			
Left Leg		**Right Leg**	
Passive Flexion		**Passive Flexion**	
Passive Extension		**Passive Extension**	
Passive Excursion		***Passive Excursion***	
Active Flexion		**Active Flexion**	
Active Extension		**Active Extension**	
Active Excursion		***Active Excursion***	
Knee flexor Strength (1)		**Knee flexor Strength (1)**	
Knee flexor Strength (2)		**Knee flexor Strength (2)**	
Knee flexor Strength (3)		**Knee flexor Strength (3)**	
Maximum		***Maximum***	
Knee extensor Strength (1)		**Knee extensor Strength (1)**	
Knee extensor Strength (2)		**Knee extensor Strength (2)**	
Knee extensor Strength (3)		**Knee extensor Strength (3)**	
Maximum		***Maximum***	

Spatio-temporal Results (2-minute Walk Test)

Velocity (1)		**Cadence (1)**		**Left Stride Length (1)**		**Right Stride Length (1)**	
Velocity (2)		**Cadence (2)**		**Left Stride Length (2)**		**Right Stride Length (2)**	
Velocity (3)		**Cadence (3)**		**Left Stride Length (3)**		**Right Stride Length (3)**	
Average		***Average***		***Average***		***Average***	

Kinematic Results (2-minute Walk Test)

Left Leg		**Right Leg**	
Max. Knee Flexion Angle (1)		**Max. Knee Flexion Angle (1)**	
Max. Knee Flexion Angle (2)		**Max. Knee Flexion Angle (2)**	
Max. Knee Flexion Angle (3)		**Max. Knee Flexion Angle (3)**	
Average		***Average***	
Max. Knee Extension Angle (1)		**Max. Knee Extension Angle (1)**	
Max. Knee Extension Angle (2)		**Max. Knee Extension Angle (2)**	
Max. Knee Extension Angle (3)		**Max. Knee Extension Angle (3)**	
Average		***Average***	
Joint excursion (1)		**Joint excursion (1)**	
Joint excursion (2)		**Joint excursion (2)**	
Joint excursion (3)		**Joint excursion (3)**	
Average Joint Excursion ***Distance Travelled***		***Average Joint Excursion***	

Use of assistive device? Yes / No
Comments: