Investigating the Biomechanical Outcomes of a Robotic-Assisted Versus Conventional Unicompartmental Knee Arthroplasty

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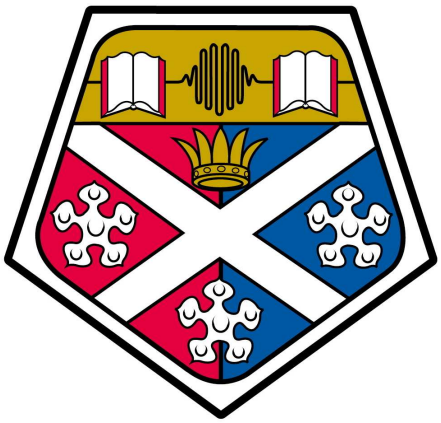
A thesis presented in fulfilment of the requirements for the degree of

Doctor of Philosophy



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Abstract

Unicompartmental knee arthroplasty (UKA) has been gaining popularity in recent years due to its perceived benefits over total knee arthroplasty (TKA), such as greater bone preservation, reduced operating-room time, better post-operative range of motion and improved gait. However there have been failures associated with UKA caused by misalignment of the implants.

To improve the implant alignment a robotic guidance system called the RIO Robotic Arm has been developed by MAKO Surgical Corp (Ft. Lauderdale, FL). This robotic system provides real-time tactile feedback to the surgeon during bone cutting, designed to give improved accuracy compared to traditional UKA using cutting jigs and other manual instrumentation.

The University of Strathclyde in association with Glasgow Royal Infirmary has undertaken the first independent randomised controlled trial of the MAKO system against the Oxford unicompartmental knee arthroplasty – the most common manual UKA used in the UK. This thesis investigates the results from a total of 51 patients (23 Mako, 28 Oxford) that underwent a one year post-operative biomechanical assessment. The assessment analysed the biomechanics of these patients performing walking tasks, stair navigation, sit to stand and deep knee lunges using a 3-dimensional, 12 camera motion analysis system (Vicon Motion Systems, Oxford, UK).

3 month post-operative X-rays confirmed that the implant alignment in the Mako group were significantly more accurate than the implants in the Oxford group. Motion analysis showed that during level walking the Mako group achieved a higher knee excursion during the highest flexion portion of the weight bearing stage of the gait cycle (18.6°) compared to the Oxford group (15.8°). This difference was statistically significant (p-value = 0.03).

When compared to normal patients the Mako group's knee excursion values were comparable with normal healthy knees, however the Oxford group had significantly lower knee excursion angles at this point. Even though there were some differences seen in the two groups with motion analysis, these factors did not necessarily correlate with better perceived patient function when the knee function scores were compared against the knee excursions. Therefore it is still unclear if improved implant alignment and better knee motion directly correlate with improved function.

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List of Abbreviations

ACL Anterior Cruciate Ligament

AKSS American Knee Society Score

AD Arthroscopic debridement

AF Anatomical Frame

AL Anatomical Landmark

CTF Cluster Technical Frames

CT Computed Tomography

CRR Cumulative Revision Rate

DOF Degrees of Freedom

LBA Load Bearing Axis

LCL Lateral Collateral Ligament

MCL Medial Collateral Ligament

MIS Minimally Invasive Surgery

MRI Magnetic Resonance Imaging

OA Osteoarthritis

OKS Oxford Knee Score

PCL Posterior Cruciate Ligament

PCT Point Cluster Technique

PTA Patellar Tendon Angle

RCT Randomised Controlled Trial

RMS Root Mean Square

SKAR Swedish Knee Arthroplasty Register

STA Soft Tissue Artefact

STS Sit to Stand

TKA Total Knee Arthroplasty

UKA Unicompartmental Knee Arthroplasty

Chapter 1

Introduction

In recent years there has been an increase in the number of UKA (Unicompartmental Knee Arthroplasty), a procedure intended to treat medial unicompartmental osteoarthritis of the knee. In the United States between 1998 to 2005 there has been over a threefold increase in the rate of UKA procedures performed compared to TKA (Total Knee Arthroplasty) (32.5% to 9.4% respectively) (Riddle et al., 2008). Long term follow up studies have shown survival rates of UKA can approach those of TKA (Smith et al., 2012; Price et al., 2005).

Advantages that UKA has over TKA include greater bone preservation, smaller incisions, intact cruiciate ligaments, reduced operating room time, better postoperative range of motion and improved gait (Repicci, 2003; Geller et al., 2008). Some in vitro experiments have suggested that unicompartmental replacements can preserve normal knee kinematics (Patil et al., 2005).

Despite these advantages there have still been cases of UKA failures. The main cause of intervention was the progression of Osteoarthritis (OA) on the non-treated articular surfaces (Geller et al., 2008). Other modes of failure have included wear, especially in fixed bearing UKA (Parratte et al., 2008). Malalignment is very badly tolerated in some UKA designs and is very detrimental to long term survival (Swank et al., 2009). There has been a shift into using more mini-

mally invasive techniques, which requires significant technical skill and accuracy (Tria, 2002), and this learning curve has been shown to be a deterrent for many surgeons in adopting UKA (Geller et al., 2008).

At present the most widely used implant for UKA in the UK is the Biomet Oxford partial knee. This implant has a mobile bearing which is more tolerant of surgical malalignment than fixed bearing designs. Slight positional malalignment of the components should not significantly affect the survival rate of the device (Heim et al., 2001). This design may be the reason why the failure rates are low for this implant (Price and Svard, 2011) (Pandit et al., 2006), and why it is currently so widely used.

Recently robot-assisted surgery with preoperative planning has been developed which can can improve the accuracy of implant placement with consistent results (Blyth et al., 2012). Another advantage is the greatly reduced technical skill required to perform the surgery. This new technique could reduce instances of implant malalignment, and potentially give as good as, or better function than the current dominant design in UKA. The rationale for this study was to test this hypothesis.

The usual way to evaluate the outcome of this kind of surgery is a series of patient outcome measures. These can provide evidence of patient health and can also be used to assess the levels of health in populations. Validated clinical scoring systems have been developed for their ease of action and speed of use in large population studies. For knee arthroplasty the American Knee Society score (AKSS) and the Oxford Knee score (OKS) are questionnaires that are widely used outcome measures for knee arthroplasty patients (Medalla et al., 2009). Recording and monitoring outcomes is essential for measuring the success of the surgery and can also be used as a measure of comparison between varying techniques, implants and methods of surgery. While these measures can provide a means of evaluating outcomes, they may not necessarily show up subtle functional

differences between patient groups in relatively small sample sizes.

A more accurate evaluation of motion can be achieved using motion capture cameras and markers. This method can locate positions of markers on the skin (Cappozzo et al., 2005). The camera system itself is accurate to a fraction of a millimetre (Windolf et al., 2008), which along with marker systems provide joint angulation during dynamic activities. The biggest source of error in motion capture systems is due to soft tissue artefact. On the lower limb the errors are within 30mm on the thigh and 15mm on the tibia, thus giving angulation errors of between 3 - 4° (Peters et al., 2010). As this is a more accurate means of measuring function than questionnaire scores, and it may help answer the aims of this research, which is to use a quantitative assessment of human movement investigate if there are any differences between the new robotic assisted system, or the Oxford UKA at 1 year post-operatively.

Both UKA aims to restore normal knee motion by allowing the healthy ligaments to dictate how the femur and tibia articulate. In a normal knee the kinematic pattern consists of internal rotation of the tibia relative to the femur as the flexion angle increases. As flexion increases the condyles translate posteriorly, with greater translation on the lateral condyle, of up to 15mm (Freeman and Pinskerova, 2005). At full extension the knee experiences slight external rotation. This change alignment at high flexion is known as the screw home mechanism (Smith et al., 2003).

During walking the knee exhibits a bi-phasic pattern in the sagittal plane where a the knee experiences a slight flexion followed by an extension during the stance phase of gait, and a large flexion also followed by an extension during the swing phase. During the first and second knee flexion the tibiofemoral joint rotates internally less than 5° (Lafortune et al., 1992), but experiences external rotation at knee extension. An MRI study by Pinskerova et al. (2004) showed that the lateral condyle moves backwards by rolling and sliding, about 20mm,

from 0° to 120°of flexion. On the other hand the medial condyle experiences little movement during this range of motion. This differential is what causes the tibiofemoral joint rotation.

In order to carry out this study, a sub-group was formed from a cohort of patients having had UKA surgery at Glasgow Royal Infirmary between 2010 and 2013 (details in Appendix A). We selected the first 89 of the 139 patients included in the trial as a consecutive sequence at 1 year, in which 67 agreed to attend for biomechanical testing. This study focused on the biomechanics of that sub-group of patients and to investigate if there is any functional difference between groups. Overall clinical effectiveness on a larger clinical trial was collected by other researchers.

H_0 = There is no biomechanical difference in gait between the robotic assisted and conventional Unicompartmental Knee Arthroplasty groups

Chapter 2

Literature Review

2.1 Knee Anatomy

2.1.1 Bony Structures

The knee is the largest joint in the human body (Scuderi, 2010). It is often considered a hinge joint. However it is much more complicated due to the fact that it also provides rotational motion (Scuderi, 2010). The knee is made up of three bones:

- Tibia: The weight bearing shin bone on the lower part of the leg.
- Femur: The thigh bone located at the superior part of the leg (also the longest bone in the body).
- Patella: A bone positioned in front of the knee joint, also called the kneecap.

The joint itself has three components, the distal femur, posterior patella and the proximal tibia and is viewed as consisting of the tibio-femoral and patello-femoral interfaces.

The tibio-femoral interfaces move with the two epicondyles of the distal femur (medial and lateral) which articulate with the medial and lateral condyles of the

tibia (shown in Figure 2.1) (Scuderi, 2010). The femoral condyloid articulations have a distinct shape that corresponds directly to the shape of the tibial plateau (Scuderi, 2010). Generally the femoral condyles are cam-shaped when viewed from the sagittal plane, however the medial condyle has a larger radius of curvature and is more prominent than the lateral condyle (Eckhoff et al., 1996). These shapes give the distal femur an asymmetric shape which in turn allows the medial side of the femur to rotate on the tibia in all 3 axes; as well as being able to translate in a stable manner in the anterior-posterior direction to a limited extent (Scuderi, 2010). On the lateral side the femur can freely translate in the anterior-posterior direction, but can only rotate around the transverse axis near extension (Martelli and Pinskerova, 2002).

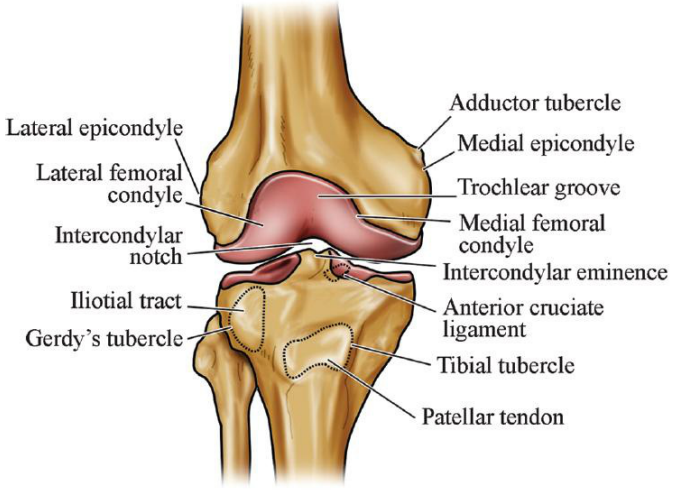


Figure 2.1: Anatomy of the femur and tibia. (Scuderi, 2010)

In normal knees the surgical epicondular axis is defined as a line that passes through the sulcus of the medial epicondyle and the prominence of the lateral epicondyle (Berger et al., 1993). The proximal tibia consists of two condyles separated by the intercondylar eminence (Bellemans et al., 2005). The medial condyle is oval shaped while the lateral condyle is more circular when viewed from the transverse plane (Scuderi, 2010). The medial side is nearly flat and the lateral side is convex (Scuderi, 2010). These shapes accommodate the femoral

condyles. The intercodylar eminence is a spine between the two plateaus that has a notch on the anterior side (Scuderi, 2010). This notch provides attachments for the anterior horn of the medial meniscus, the anterior horn of the lateral meniscus and the Anterior Cruciate Ligament (ACL) (Scuderi, 2010). On the anterior side of the tibia there's a tubercle for insertion of the patella tendon, and lateral to this is Gerdy's tubercle (Illustrated in Figure 2.1) (Scuderi, 2010).

The patellofemoral joint articulates between the patella and the femoral trochlear groove. The articular surface of the patella is divided into two parts – a medial and a lateral facet (Scuderi, 2010). The lateral facet of the patella is broader and deeper than the medial side (Scuderi, 2010). This joint plays a large role in knee stability (Scuderi, 2010). Another role of the patella is the increase in mechanical leverage (Scuderi, 2010). This is achieved by transmitting the extensor force across the knee at a greater distance from the axis of rotation which increases the moment arm thus reducing the required force to extend the knee (Scuderi, 2010).

2.1.2 Meniscus

Between the femoral condyles and tibial plateau sits the meniscus, made up of cartilaginous tissues that attach to the horn of the tibia in a 'figure of 8' shape, shown in Figure 2.2. The meniscus is composed of approximately 70% water and 30% organic matter and of the organic matter, 75% is collagen (Athanasiou and Sanchez-Adams, 2009).

In 1948 it was suggested that the human meniscus had a load-bearing function (Fairbank, 1948). However the meniscus has numerous functions such as enhancing the conformity of the tibio-femoral joint, as well as aiding knee rotation. Due to the shape of the joint the condyles of the femur and tibia meet at one location (Athanasiou and Sanchez-Adams, 2009). The presence of the menisci also causes the load of the body's weight to be spread, thus reducing stress concentrations, which causes the meniscus to bear a lot of the stress caused by many day to day

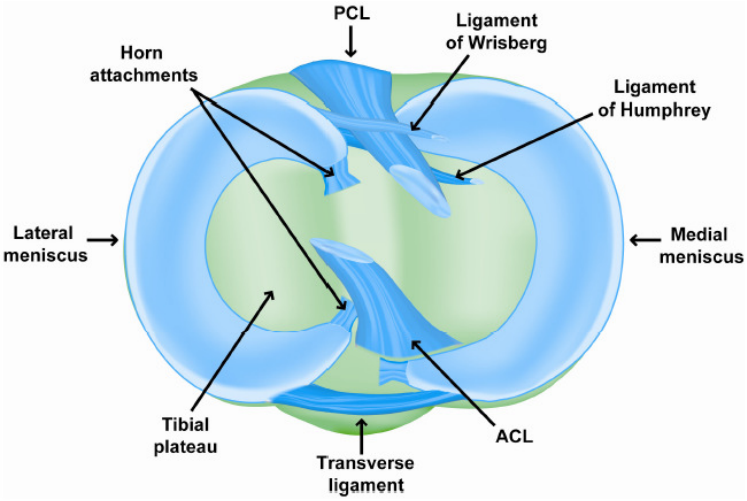


Figure 2.2: Superior view of the tibial plateau. (Athanasiou and Sanchez-Adams, 2009)

activities such as walking or climbing stairs (Athanasiou and Sanchez-Adams, 2009). The proportion of load transmitted indirectly by the menisci has been estimated as between 45 and 70 percent of the applied load with the remaining 30-55% being carried by the articular cartilage of the femoral and tibial surfaces via direct contact in the middle third of each plateau (Shrive et al., 1978).

Additionally the meniscus acts as a shock absorber (Athanasiou and Sanchez-Adams, 2009). Due to the nature of the meniscus the collagen fibres have varying diameters which makes them able to absorb a variety of different frequencies of force (Ghadially et al., 1983). This makes it easier for the meniscus to distort and adapt in response to different shocks experienced during joint movement (Ghadially et al., 1983).

2.1.3 Ligaments

Ligaments are tough bands of fibrous connective tissues that specialise in connecting bones together (Frank, 2004). There are four primary ligaments present in the knee, the Anterior Cruciate Ligament (ACL), Posterior Cruciate Ligament (PCL), Medial Collateral Ligament (MCL) and the Lateral Collateral Ligament (LCL) (Scuderi, 2010). These ligaments are shown in Figure 2.3.

The ACL is a key structure in stabilising the knee joint against anterior translation of the tibia on the femur, and tibial rotational loads (Matsumoto et al., 2001). The bony attachment is located at the posterior part of the inner surface of the lateral femoral condyle (Duthon et al., 2006). From the femoral attachment, the ACL runs anteriorly, medially, and distally to the tibia. Its length ranges from 22mm to 41mm (mean 32mm) and its width from 7mm to 12mm (Amis and Dawkins, 1991). Due to the irregular cross-sectional shape of the ACL the shape changes depending on the angle of flexion; but is generally larger in the anterior-posterior direction and the fibres widen out as they approach the tibial attachment (Bernard et al., 1997). The ligament itself is taut through different portions during the knee's range of motion (Schultz et al., 1984). The anteromedial fibres become tight in 90° flexion, while the posterolateral fibres are tight in full extension showing that the fibre lengths relate to their participation during gait (Schultz et al., 1984).

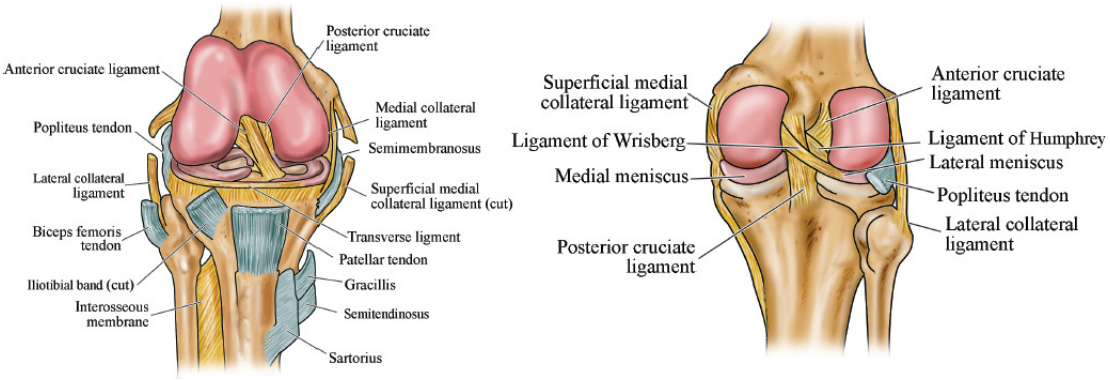


Figure 2.3: Anterior and posterior views of the knee ligaments. (Scuderi, 2010)

The PCL is also a crucial ligament for knee stability as it provides approximately 90% of the resistance to posterior translation of the tibia on the femur (Race and Amis, 1996). The tensile strength of the PCL is almost double that of the ACL (Kennedy et al., 1976). The PCL femoral attachment originates posteriorly in the intercondylar notch at the roof of the medial side of the femoral condyle (Amis et al., 2006). It is attached to the tibia posteriorly to the lateral

meniscus (Amis et al., 2006). The attachment sits between the posterior horns of the two menisci and extends over the rim of the tibia (Amis et al., 2006). Similarly to the ACL, the PCL gets taught at different stages through a range of motion. The anterior and more pronounced aspect of the PCL tightens in flexion whilst the smaller posterior portion tightens in extension (Amis et al., 2006).

On the medial side of the knee the prime stabiliser of the knee is the MCL (Warren et al., 1974). The femoral attachment point is slightly proximal to the medial epicondyle and the tibia attachment is on the medial condyle, 4.6 cm below the tibial articular surface (Scuderi, 2010). The ligament is usually 10-12cm in length (Scuderi, 2010). The primary function of this ligament is to stop valgus deformity by restricting the moments that would push the knee into valgus (Scuderi, 2010).

Studies on the LCL have found an average overall length of 66 mm (range, 59 mm to 74 mm) (Meister et al., 2000). The attachment point on the femur is 3.7 mm posterior to the ridge of the lateral epicondyle and the distal attachment point is on the head of the fibula (Meister et al., 2000). The primary function of the LCL is as a restraint to varus stress of the knee (Scuderi, 2010).

2.1.4 Muscles

Anterior to the knee are the quadriceps. This muscle group consists of four muscles with a common tendon insertion located above the patella, which in turn connects to the tibia via the patellar tendon (Scuderi, 2010). As age increases, the strength of the quadriceps declines leading to some degree of functional impairment (Young et al., 1985). Some small scale projects suggest there may be a connection between the strength of the quadriceps and the development of osteoarthritis (Lankhorst et al., 1985).

Counteracting this muscle group are the hamstrings (semitendinosus, semimembranosus and biceps femoris), located posterior to the thigh (Scuderi, 2010). In

the intact knee joint, activation of the quadriceps muscle generates an anterior shear force on the tibia relative to the femur and activation of the opposing hamstring muscle group counteracts this force, producing joint stability (Hortobágyi et al., 2005).

2.1.5 Kinematics of the Tibiofemoral Joint

Due to the difference in shape of the lateral and medial condyles the articular surfaces of the femur and tibia are incongruent. Therefore different regions of the surfaces are in contact during different periods of gait. One of the roles of the meniscus is to increase the surface area of contact to spread the force exerted by the condyles of the femur (Maquet, 1984). These contact areas are shown in Figure 2.4.

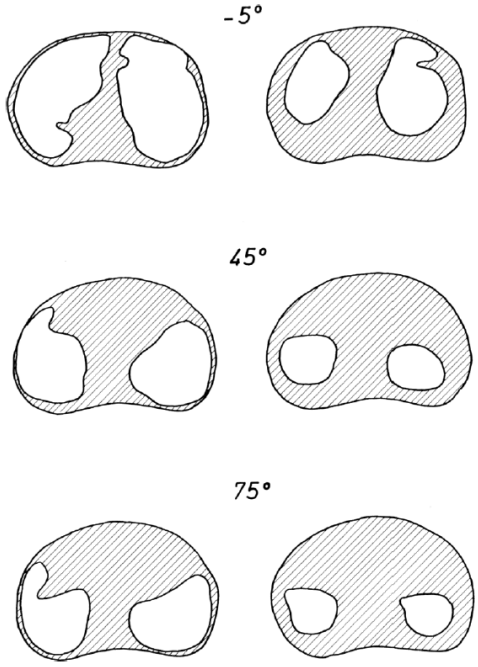


Figure 2.4: Tibiofemoral contact areas in relation to flexion angle. *Left* - with menisci; *right* - without. (Maquet, 1984)

As flexion increases the menisci increase the articulating area because they are under more force from the spherical femoral condyles and thus tend to become more spread out. As discussed in 2.1.3 the ligaments act as proprioceptive stress

transducers as well as restricting motion. Other biomechanical movements that help reduce joint wear are sagittal sliding and rolling components of the knee in flexion. This distributes the load over different parts of the joint thus resulting in lowering wear (Moorehead et al., 2001).

Full extension of the knee includes slight external rotation of the tibia and the tightening of the cruciate ligaments. When the knee is fully extended the medial condyle rolls 10° whereas the lateral condyle rolls 15° locking the knee joint (Kapandji, 1970).

The screw like lock mechanism occurs from the last 20° of flexion to full extension (Smith et al., 2003). This mechanism allows standing for long time periods without undue tiring or use of the extensior muscles. To relieve the knee from this state the popliteus muscle contracts which results in internal rotation of the tibia relative to the femur (Scuderi, 2010).

2.1.6 Knee Mechanical Axis

The mechanical axis is the most cited and useful means of diagnosing a healthy or arthritic knee joint, as well as a measure of the outcome of knee arthroplasty (Cooke et al., 2007).

The Load Bearing Axis (LBA) of the leg is defined by a line running through the centre of the hip joint to the centre of the ankle joint (Cooke et al., 2007) (Figure 2.5). In a neutrally aligned knee the mechanical axis will be a straight line overlapping the weight bearing axis. This line is drawn from the hip centre to the medial tibial spine (The mechanical axis of the femur or FM) and a line drawn from the medial tibial spine to the ankle joint centre (the mechanical axis of the Tibia or TM). This is shown in Figure 2.5 as Hip-Knee-Ankle or HKA. As a convention the HKA angle may be expressed as its angular deviation from 180 (i.e. in neutral alignment HKA = 0°) (Cooke et al., 2007).

However in a non-neutral alignment the LBA doesn't align with the Mechan-

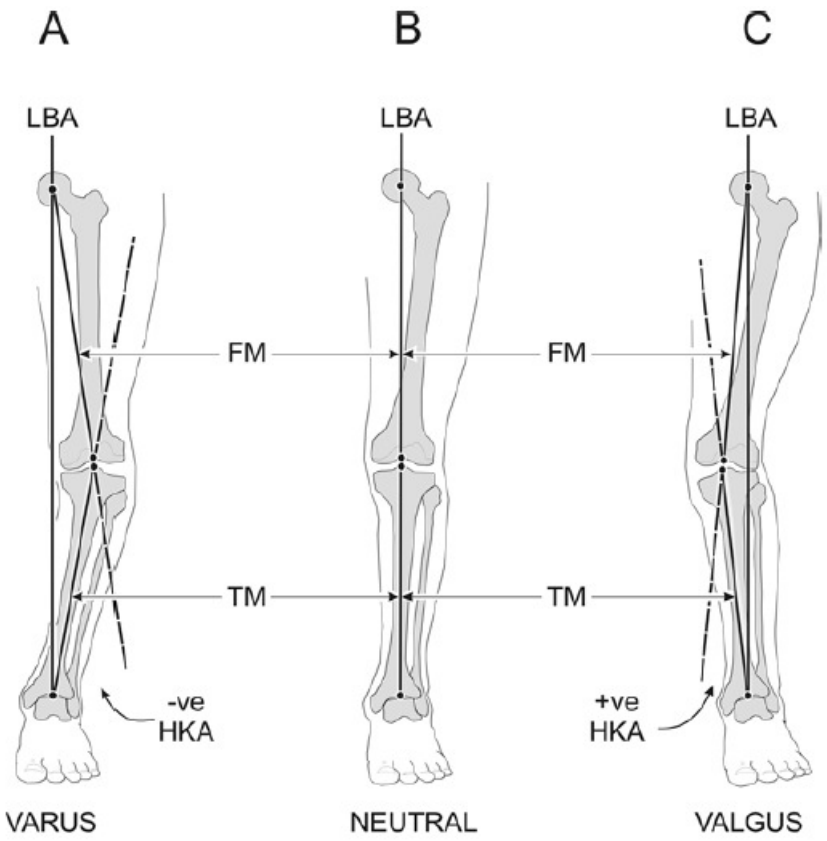


Figure 2.5: Frontal plane lower limb alignment patterns. (Cooke et al., 2007)

ical Axis. In a varus knee the knee centre is lateral to the load-bearing axis, and the mechanical axis passes through the medial compartment of the knee, thus resulting in a bow legged deformity (Cooke et al., 2007).

However in a valgus knee the knee centre is displaced medial to the load-bearing axis resulting in the mechanical axis passing through the lateral side of the knee. This results in a knock kneed deformity (Cooke et al., 2007) (Figure 2.5). Varus deviations are defined with a negative angle and valgus deviations are positive (Cooke et al., 2007).

Misaligned knees have higher stresses due to poor weight distribution and increased joint load as a result of the increased knee moments caused by the altered mechanical axis (Cooke et al., 2007). If left uncorrected this can perpetuate cartilage damage and worsen the effect of osteoarthritis, as discussed in more detail in the next section.

2.2 Osteoarthritis & Degenerative Joint Disease

OA is the most common pathology that affects the synovial joints (Pelletier et al., 2001). Knee OA in particular is the most common form of joint disease (Felson, 1998). It is characterised as a group of anatomical abnormalities involving cartilage loss, subchondral bone lesions and meniscus extrusion (Brandt et al., 2006) (Figure 2.6). This is due to a combination of factors ranging from mechanical to biochemical (Pelletier et al., 2000).

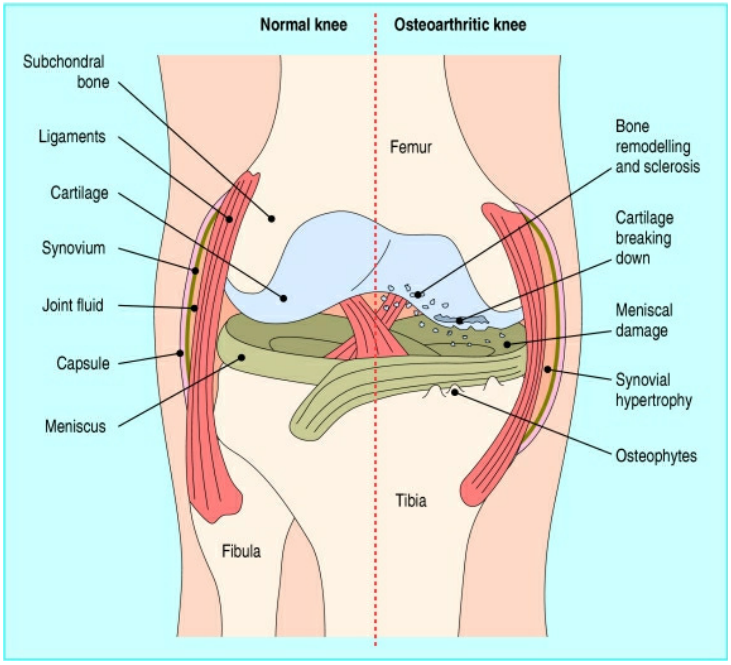


Figure 2.6: Normal and osteoarthritic knee. (Hunter and Felson, 2006)

2.2.1 The Osteoarthritic Joint

The causes of OA are not completely understood, however there are many important determinants such as biomechanical stresses affecting the articular cartilage and subchondral bone, biochemical changes in the articular cartilage and synovial membrane, and genetic factors (Holderbaum et al., 1999). Some of the population may be predisposed to developing OA due to genetic or anatomical abnormalities. Joint misalignment, muscle weakness or poor bone congruence may lead to

the initiation of OA (Hunter and Felson, 2006). Even individuals without any anatomical abnormalities may be susceptible to OA if they frequently perform repetitive or excessive joint loading, or are obese as obesity is a form of static loading that can accelerate the wear of load bearing joints (Felson, 1996).

The initiation of articular cartilage damage is as a response to mechanical loading and focal pressure of joint surfaces (Pelletier et al., 2001). Loss of proteoglycans is followed by damage to the collagen framework of the cartilage and consequently an attempted repair response begins (Simon, 1999). However this inevitably fails and leads to even more thinning of the cartilage giving further degradation and erosion leading to a reduction in its load bearing capacity (Simon, 1999). Fragments of the cartilage matrix are released into the synovial fluid which initiates the biochemical changes of the joint driven by cytokine cascades and the production of inflammatory mediators (Krasnokutsky et al., 2007).

As matrix destruction continues even further the subchondral bone becomes exposed (Simon, 1999). This exposure leads to load bearing being increased, precipitating an increased bone response leading to the subchondral sclerosis which allows cracks to develop in the underlying subchondral bone due to peak stresses(Simon, 1999). This acts as a cavity for synovial fluid to fill which in combination with joint contact forces can lead to subchondral cysts (Durr et al., 2004).

Another characteristic of joints affected by OA are the presence of osteophytes (Simon, 1999). These are formed not only by the degradation of the existing cartilage matrix but also by the production of new connective tissue on the joint surface and at the joint margins (Hashimoto et al., 2002). Osteophytes can limit joint movement and represent a source of joint pain (Brandt, 1999). They are derived from precursor cells within synovial tissue and often merge with or overgrow the original articular cartilage. In this process, mesenchymal stem cells differentiate into chondrocytes (Gelse et al., 2003).

Even though OA is classified as a noninflammatory arthritis, arthroscopic studies suggest that localised inflammatory changes of the synovium occur in up to 50% of OA patients (Ayral et al., 1996). This swelling and deformity may cause even more tension on the intra-articular tissues and structures of the joint causing laxity and decreased stability (Simon, 1999). This lack of stability can lead to abnormal sliding and edge loading thus perpetuating the degenerative wear of the joint (Simon, 1999).

OA also has a large effect on knee stability due to impaired muscle strength (Hurley, 2003). This causes a diminished force output from one muscle group on one side of the knee and creates joint instability and in order to maintain joint function and reduce instability, subjects with knee OA must generate compensatory muscle activity (Sharma, 2001). A study showed significantly reduced internal knee extensor moments in patients with OA compared to normal subjects (Kaufman et al., 2001), and in order to redistribute the load, hip extension torques increased (Pai et al., 1994).

2.2.2 Diagnosing Osteoarthritis

The most common symptoms of knee OA is joint stiffness, pain, swelling and decrease in the range of motion (ROM) (Simon, 1999). Some may feel their joint lacks stability therefore they don't have the confidence to do certain tasks such as walking or ascending/descending stairs (Rejeski et al., 1996). It is common for sufferers of OA to complain about pain in the evenings or after strenuous activities (Simon, 1999). Additionally patients may feel joint stiffness in the morning, but have the pain recede as they move around for 20-30 minutes and 'loosen' the joint (Simon, 1999).

In order to diagnose OA and assess the deterioration and severity of the disease radiographic evidence is required. The main signs of OA using radiography are:

- Joint space narrowing

- Osteophytes
- Subchondral bone damage

2.2.3 Treatments for Osteoarthritis

Treatments for OA vary depending on many factors such as patient age and severity of the joint degradation (Chaganti and Lane, 2011). Typically the first line of treatment is:

- Weight loss (excess weight adds joint stress)
- Prescribing pain killers
- Anti-inflammatory medication (if the joint has become swollen)
- Physiotherapy

If these methods prove ineffective then surgery becomes the next viable option. Even within surgery there are various options available to the patient. One of these is a knee arthroscopy or Arthroscopic debridement (AD) which 'washes out' the knee joint and removes loose fragments of worn cartilage. It is important to note that this is not a solution to OA, however it can help if there are loose fragments in the joint (Laupattarakasem et al., 2008). Randomised Controlled Trials (RCTs) comparing AD with lavage and sham surgery have shown for early OA that AD has no real benefits (Laupattarakasem et al., 2008).

Another solution is to perform an osteotomy. This is a procedure where a bone is cut to change it's alignment (by either making the bone longer or shorter). Due to the misalignment of the mechanical axis the body stresses are localised to one compartment of the knee joint, however by changing the mechanical axis this shifts the weight bearing forces to unload the worn out side of the joint and place the forces on the healthy side. This technique mainly delays the need for a TKA, and is mainly performed in younger patients (Amendola and Bonasia, 2010).

If these solutions are insufficient due to the OA being too severe then the articular surfaces themselves may need replacing with implants (Harwin, 2003). Depending on the type of OA, level of joint damage and age, patients may be given a UKA where one side of the knee is replaced, or a TKA where the whole joint is replaced (Harwin, 2003). UKA and TKA will be discussed in more detail in the next parts of this chapter.

2.2.4 Unicompartmental Knee Arthroplasty (UKA)

When UKA implants were introduced they aimed to be less invasive than TKA by only replacing one compartment of the knee as opposed to the whole joint (Harwin, 2003). Due to the nature of this procedure there are many potential advantages of a UKA compared with a TKA. These include greater bone preservation, smaller incisions, preserved cruciate ligaments, reduced operating-room time, better post-operative range of motion and improved gait (Repicci, 2003). Some in vitro experiments have suggested that unicompartmental replacements can preserve normal knee kinematics (Patil et al., 2005).

The first case of UKA dates back to 1964 with the cobalt-chromium alloy MacIntosh prosthesis. This was a tibial hemiarthroplasty implant. This aimed to correct the varus or valgus deformity by inserting a tibial plateau prosthesis of appropriate diameter and thickness to build up the worn side of the joint (MacIntosh and Hunter, 1972). Meanwhile another implant was also being developed by McKeever (Emerson and Potter, 1985). This was also a tibial hemiarthroplasty implant with a T-shaped fin on the under-surface for added stabilisation. Intermediate follow up reports on both prostheses noted good results in 70% to 90% of patients (MacIntosh and Hunter, 1972), (Emerson and Potter, 1985). A long term follow up study (mean 16.8 years) focused on the remaining 23 McKeever prostheses implanted in patients less than 60 years old and found 13 revised at a mean of 8 years (Springer et al., 2006). The remaining patients still maintained a

high level of pain relief, functional performance and satisfaction with their knee.

A new wave of UKA implants started appearing in the late 60s. Implants such as the Polycentric Knee (Protek, Berne, Switzerland), the Marmor (Smith & Nephew, Memphis, TN) and others. However the results for this new generation of implants were very poor with some studies showing only 58% of the patients showing satisfactory results (Insall and Walker, 1976). In another study of 37 patients with the Marmor implant one third of the patients had poor clinical scores, and one in five had to undergo revision (Laskin, 1978). Additionally one third of the patients experienced at least 2 mm of tibial component settling (Laskin, 1978). As the decade progressed the results of UKA were not as good as the results being seen in total knee arthroplasty (Scott et al., 1991). The whole UKA procedure was nearly abandoned in the United States by the late 1980 due to very unsatisfactory results (Scuderi, 2010). However these failings were the result of an inadequate understanding of the appropriate indications and surgical techniques along with poor early prosthetic designs (Scuderi, 2010). One example illustrated in the Laskin study was that preexisting varus/valgus deformity was routinely 'overcorrected' with insertion of the thickest tibial implant that would permit gliding of the prosthetic joint surfaces (Laskin, 1978). The technique of overcorrection of coronal deformity has since been recognised as a major risk factor for poor outcome after UKA.

However a technique developed in the 1990s by Repicci changed the landscape for UKA. This was using the Minimally Invasive Surgery (MIS) approach (Repicci and Eberle, 1999). Repicci performed the MIS using a 7.5cm cut. Limited surgical access meant the procedure should not be performed in knees in which soft tissues need to be managed and where knee balance could only be achieved with significant ligament release (Repicci, 2003). The slope of the tibial cut and the distal femoral cut can be used to a certain extent to adjust the balance. The technique required technical skill and accuracy but could be mastered (Tria, 2002).

This new UKA technique resulted in smaller incisions, same/next day discharge and faster recovery times (Repicci, 2003). Initially the instruments were modified to allow the surgeons to carry out the operation through the limited incisions (Repicci, 2003). As popularity grew new implants were also developed that were modified for use in MIS (Repicci, 2003).

A study by Price et al. (2001) compared three procedures: 1) UKA performed through a short incision without patellar eversion, 2) UKA performed through a standard incision with patellar eversion and 3) TKA performed through a standard incision. The results indicated that recovery was twice as fast in the MIS group versus the standard UKA group and 3 times as rapid versus the standard TKA group (Price et al., 2001). This showed a significant improvement to short term recovery of the patients. However it is important to note that this was an observational study and not an randomised trial, therefore the data does not carry the same weight.

Another retrospective study conducted by Müller et al. (2004) found no statistically significant differences between MIS and standard open approach in functional outcome or accuracy of implant position. Thirty eight cases after were reviewed with the Oxford knee prosthesis with a standard open approach and 30 cases with a minimally invasive approach. The authors recommended minimally invasive implantation for the treatment of anteromedial osteoarthritis by UKA (Müller et al., 2004).

However there were alignment issues arising with the use of this new approach. A study was conducted on final limb alignment and implant position in the coronal plane of 88 MIS UKA and 64 UKA performed through a standard arthrotomy (Fisher et al., 2003). Findings showed that the tibial components in the minimally invasive UKA were placed in more varus that those in the standard UKA (5.4° vs 4.1° varus respectively). Additionally limb alignment was also different between minimally invasive and standard UKA (3.5° vs 4.3° valgus) (Fisher et al.,

Paper	Implant	Mean Age	Patients	10 Year Survivors
Scott et al. (1991)	Bringham (J & J)	71	64	85%
Heck et al. (1993)	Compartmental I/II (Zimmer), Marmor (Richards)	68	250	91%
Cartier et al. (1996)	Marmor (Richards)	65	60	93%
Ansari et al. (1997)	St. Georg Sled (Link)	70	437	88%
Murray et al. (1998)	Oxford (Biomet)	71	109	97%
Berger et al. (1999)	Miller-Galante (Zimmer)	68	51	98%
Squire et al. (1999)	Marmor (Richards)	71	48	84%
Svard and Price (2001)	Oxford (Biomet)	70	94	95%
Argenson et al. (2002)	Miller-Galante (Zimmer)	66	160	94%
Pennington et al. (2003)	Miller-Galante (Zimmer)	54	45	92%
Naudie et al. (2004)	Miller-Galante (Zimmer)	68	97	90%
Steele et al. (2006)	St. Georg Sled (Link)	67	134	80%
Tada et al. (2011)	Oxford (Biomet)	72	272	98%

Table 2.1: Published 10 year survivorship results of UKA

2003). The alignment results demonstrated a higher standard deviation in the minimally invasive group. Other studies have found that by using a minimally invasive approach with conventional instrumentation as many as 40% to 60% of components may be misaligned more than 2° from the pre-operative plan (Keene et al., 2006). These results indicate that using the MIS approach leads to a less reproducible implant placement and that surgeon experience and skill may be a very important factor in the success of the procedure.

With improvements in the surgical process, implants and patient selection criteria the UKA knee replacements have been shown to give long term results comparable to those of TKA (Table 2.1) in high volume centres with experienced surgeons.

Studies have shown that UKA can continue to give good results into the

second decade of use. A 10 to 20 year survival study was conducted by Price on all Oxford UKA implants in a hospital in Sweden (Price and Svard, 2008). The entire group comprised of 683 knees in 572 patients with a mean age at implantation at 69.7 (range 48-94). (Price and Svard, 2008). The 10 year, 15 year and 20 year survival (all non revised implants) were 94.1%, 93.5% and 92.3% respectively (Price and Svard, 2008). Another long term survivorship study showed similar results with nineteen knees showing a fifteen year survivorship was 93% and the 20-year survivorship was 90% (Foran et al., 2012).

Good survival rates and outcomes are influencing surgeons to perform more UKA procedures. In 2008 UKA accounted for 8% for all knee arthroplasty procedures in the United States, but is growing at triple the rate of total knee arthroplasty (Riddle et al., 2008). This number may still increase as early intervention strategies are becoming more desirable. Additionally, arthritis patients are becoming younger than in the past thus more active, which favours the more conservative and less invasive procedure of UKA as opposed to a TKA (Pennington et al., 2003).

Despite the many advantages associated with UKA, considerable issues still exist, including the problem of early failure of both the femoral and the tibial components (Berend et al., 2005). UKA failures can be attributed to many different factors including the underlying diagnosis, patient selection, prosthesis design, polyethylene quality, and fixation (Kozinn and Scott, 2009). Implant misalignment is very badly tolerated in UKA and is very detrimental to long term survival (Swank et al., 2009).

Despite these problems it can be concluded that with careful patient selection and an experienced and skilled surgeon, UKA is a proven surgical option in treating arthritis of one compartment of the tibio-femoral joint. Results clearly show it is comparable to those of TKA and also has other advantages over TKA. As discussed in this chapter there's a significant increase in the range of motion,

shorter hospital times, decreased cost, smaller incisions and faster rehabilitation. However this procedure may be more variable in outcome thus more susceptible to correct patient indication criteria and advanced surgical skill.

2.2.5 TKA versus UKA

When comparing different types of implant it is very important to analyse objectively not only the data, but also the validity of the data. This is why the type of clinical data or trial must be considered.

Small scale trials can lead to very skewed results. A lot of studies come from specialist centres and may not reflect the results that can be expected from implants or devices in use. Sample sizes are frequently small, and studies underpowered to draw major conclusions or to stratify data based on clinically important variables (Barrack, 2011). Registers collect data at the time of primary surgery and the time of any revision operation, which can give data on CRRs (Cumulative Revision Rates). This gives a large pool of data and narrow confidence limits leading to subgroups large enough for statistical comparison. Despite these advantages there are still limitations to using registers. While using registry data to analyse implant survival is useful there are other factors, such as surgical technique, surgeon, hospital, patient factors, rehabilitation strategies and geographic location, that may have far more impact on revision rate than implant design (Barrack, 2011). Revision rates often differ among different designs by as little as 5% to 10% (Robertsson, 2007) while the other mentioned factors can result in differences in revision rate of an order of magnitude higher (Barrack, 2011). Therefore it is important to know that while national registers are very useful for this kind of implant data it is also important to be aware of any misleading conclusions when interpreting the data.

The first national registry of this kind was created in 1975. It is called the Swedish Knee Arthroplasty Register (SKAR). Several other national registers

have also been set up recently. The SKAR provides many ways to compare TKA with UKA. One observation that can be made with the register is how the age demographics have changed throughout the years regarding TKA and UKA (Figure 2.7). When the data was first collected in the 70's the relative proportion of younger patients was higher in TKA than in UKA. However the relative number of patients younger than 64 has doubled after 1998. This correlates with when the MIS technique was being adopted in Sweden. This is showing a trend that UKA is being targeted for younger patients.

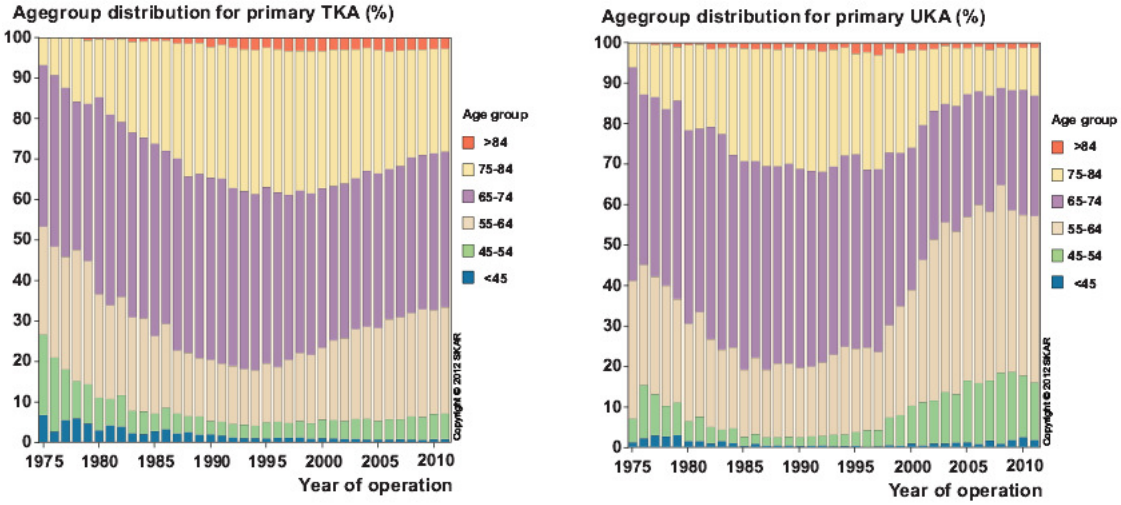


Figure 2.7: The relative distribution of primary TKA and UKA among different age groups. (Lidgren et al., 2012)

Other data that can be acquired from the registry are the difference in CRRs (Figure 2.8). Between the years of 2001 and 2010 the CRRs for UKA was almost double that of TKA. Additionally it shows that age significantly affected the rate of revision, although the age demographics for the two types of procedure were very different. As mentioned earlier the proportion of age of patients younger than 65 at the time of surgery was much higher in the UKA group (30% of patients) than those in the TKA group.

Figure 2.9 shows the percentage distribution and indications for said revisions. It can be seen that the three most common indications for revision in UKA cases are implant loosening, progression of arthritis to other joint compartments, and

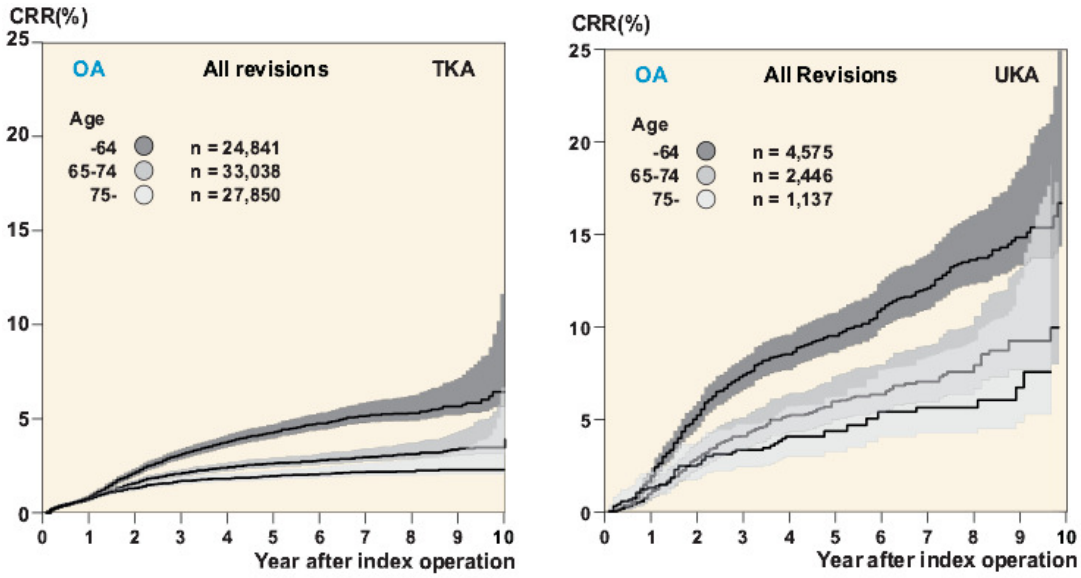


Figure 2.8: The differences in CRRs (2001-2010) between the 3 age groups <65, 65 - 75, > 75 were significant for TKA as well as UKA. (Lidgren et al., 2012)

polyethylene wear. Compared to TKA there is a much lower chance of infection. This means that despite there being a higher CCR in the UKA compared to TKA, there is a much lower risk of serious complications arising such as infection or even amputation (Lidgren et al., 2012).

Additionally using revision as a comparison between TKA and UKA may be somewhat unequal. The bias in using revision as a measure for the two classes of implant is due to the threshold for revision on a UKA being lower than that of a TKA. UKA may be converted to a TKA as it is a much more conservative and less invasive procedure, however removing a TKA and replacing it with another implant is a much more difficult process. In contrast UKA patients and surgeon may see a TKA to be the next logical clinical step and therefore may be more likely to do the revision if there are poor outcomes from the primary procedure. Due to this bias it is unlikely that the CRRs results of UKA will ever be comparable to those of TKA.

Case control studies have been done comparing the two types of arthroplasty by selecting patients with osteoarthritis in both knees and giving them a TKA in one leg, and a UKA in the other and assessing their recovery, ROM and other

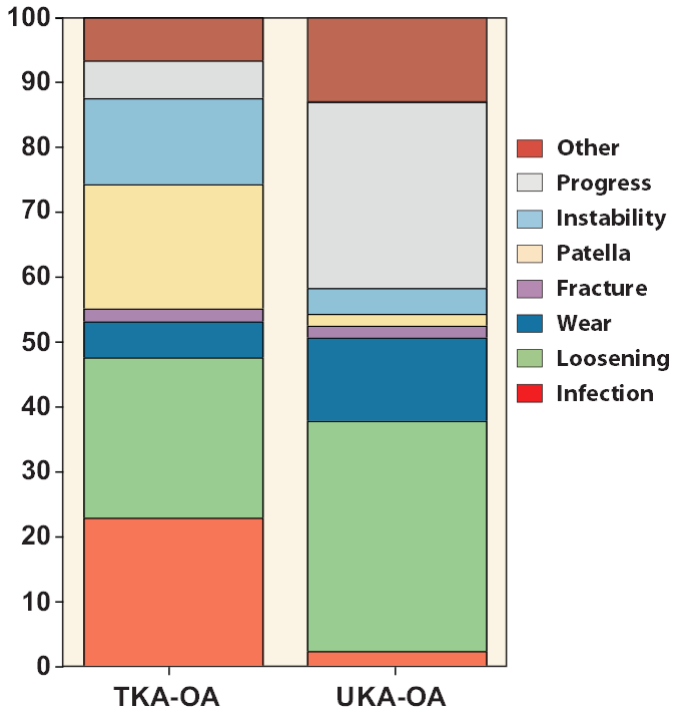


Figure 2.9: Distribution (%) of indications for revision (2001 - 2010) comparing TKA and UKA. (Lidgren et al., 2012)

outcomes.

The first study of this kind was done with a group of 20 patients receiving a UKA on one side and a TKA on the other. After one year there was no statistically significant difference between the two groups other than a slightly increased ROM in the UKA group (Cameron and Jung, 1988).

Another similar study was done by Laurencin et al. on 23 patients. However these patients were split into two groups, one with patella resurfacing on their TKA side and one without. Patient evaluation consisted of chart review, joint registry data, and telephone interviews that focused on patient preference regarding pain, stability, "feel," and ability to climb stairs (Laurencin et al., 1991). The 23 patients studied had an average follow-up period of 81 months (range, 38-153 months). The ROM improved in the UKA side from a pre-operative mean of 106° to 123° post-operatively. ROM for the TKA group improved from 104° to 109° (with no change in the patella resurfacing group). For patients surveyed 31%

stated that their UKA knee was their better knee overall, 15% stated that their TKA knee was their better knee overall, and 54% could find no difference (Laurencin et al., 1991). For the patella resurfacing group 60% stated that their UKA knee was their better knee overall, 10% stated that their TKA knee was their better knee overall, and 23% could find no difference (Laurencin et al., 1991).

A similar Korean study was conducted in which 51 patients were followed up between January 2002 and December 2004. The average follow-up period was 4 years (Kim et al., 2008). The average Knee Society Score (KSS) improved from 53.5 pre-operatively to 90.7 at last follow-up in the UKA knee, and from 50.4 to 89.8 in the TKA knee. The mean range of knee motion also improved from 124.7° to 133.2° in the UKA knee, and from 122.5° to 127.1° in the TKA knee (Kim et al., 2008). For patient preference 45% preferred the UKA knee and 37% preferred the TKA knee. 82% of patients reported being 'very satisfied' or 'satisfied' with both knees.

Another study analysed patients between October 1991 and October 2005. 23 (11 women, 12 men) patients were in this group each receiving a TKA on one side and a UKA on the contralateral side (Dalury et al., 2009). Strict selection criteria were used in selecting patients for a UKA, including an intact ACL, no deformity greater than 10° in any plane, and only moderate degenerative changes on the surface of the patella or on the trochlea (Dalury et al., 2009). Six procedures were performed concurrently, 6 were performed in a staged manner within 3 days, 5 were performed within 12 months of each other, and 6 were performed over 12 months apart (Dalury et al., 2009). During the time of the TKA the average patient age was 68 years (range, 41-89 years), and 69 years (range, 47-88 years) during the UKA. Pre-operative clinical data (Knee Society total scores, pain scores, function scores, ROM) showed no statistically significant difference between the two groups.

The post-operative results showed no statistically significant improvement in

knee scores either, but there was a significant difference between ROM with the UKA at 123° ±9° compared with the TKA of 119.8° ±7°. Additionally knee Society scores improved from 45.9 to 89.7 in UKA and from 42.4 to 90.3 in TKA (Dalury et al., 2009).

As the results show, with careful patient selection UKA can be a very viable option for patients with OA in one side of their knee compared to TKA. Not only is recovery faster but the procedure is less intense for the patient due to it being a much less invasive procedure. Additionally there's some data showing improved range of motion for these patients. If the UKA fails there is still an option for it to be converted to a TKA, which is a much less involved procedure than a revision TKA procedure. Another important difference to note about TKA vs UKA is the difference in alignment philosophy. Ideal post-operative alignment for TKA has been neutral, and often it has been thought that any deviations from neutral would have a large impact on implant survival (Moreland, 1988). Recently this target has been put under question, one reason being a normal knee load more on the medial side (Parratte et al., 2008). With UKA the post-operative limb alignment targets are not so clear. Data has shown over-correction can lead to disease propagation in the opposite side of the knee compartment (Scott et al., 1991) and under-correction can cause an acceleration in polyethylene wear (Barrett and Scott, 1987). The aim of UKA has been stated as "to match the natural anatomy of the patient before the onset of OA restoring them to their normal alignment" (Repicci, 2003). However it is unclear how to ascertain what the 'normal' anatomy of a patient is when they have a diseased knee. Additionally the alignment of their natural limb may even have been the cause of increased wear in the first place.

2.3 The Oxford Unicompartmental Knee Arthroplasty System

The Oxford Unicompartmental Knee Arthroplasty (Biomet Ltd, Bridgend, UK - Figure 2.10) was designed by John Goodfellow and John O′Connor. It was first used on a patient in 1982 (Goodfellow et al., 1988).

The prosthesis consists of a cast cobalt chromium molybdenum alloy femoral component with a spherical articular surface and a cast cobalt chromium molybdenum alloy tibial component, with a flat articular surface. Both of these components are cemented. A polyethylene insert is used to complete the bearing and conforms with the metal components. It is unconstrained and is retained in situ by its shape and soft-tissue tension (Biomet, 2011).

Figure 2.10: Oxford Unicompartmental Knee Arthroplasty Implant. (Biomet, 2012)

To appreciate the design philosophy behind the Oxford UKA an understanding of the articular surfaces, contact areas and pressures is required. Typically the metal implants aim to mimic the anatomical surfaces of the knee (Chapter 2.1). The femoral implants are convex and the polyethylene of the tibial surface is either flat or very shallowly concave. As these shapes are not congruent only certain portions of the articular surfaces can transmit load. Femoral implants

are typically poly-radial and try to match the anatomy of the femoral condyles (Figure 2.11).

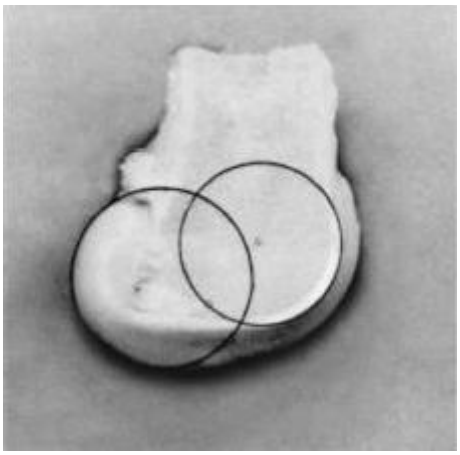


Figure 2.11: Sagittal section of the distal femur illustrating that the sulcus of the trochlea and most of the medial condyle are circular. (O′Connor et al., 1989)

As Figure 2.11 shows, the diameter of the posterior curve is less than that of the anterior curve. The consequence of this is that there is a smaller area of contact in flexion. For a given load the average contact pressure is:

$$P = \frac{F}{A} \tag{2.1}$$

Where,

P = Contact Pressure (N/m^2)

F = Applied Load (N)

A = Area of contact (m^2)

As the equation above shows contact pressure is inversely proportional to the area of contact, thus less congruent surfaces have a higher average pressure at the interface between their articular surfaces. For ultra-high-molecular-weight

polyethylene the wear rate increases exponentially as the contact pressure increases as opposed to linearly as classical wear theory would suggest (Rostoker and Galante, 1979). Additionally experiments have confirmed the hypothesis that wear rate decreases with a larger contact area (Sathasivam et al., 2001).

However a human knee contains a meniscus that alters the articular surface dynamically. Instead of one point of contact the meniscus allows two congruous surfaces with a much better load distribution (Figure 2.12). The mechanism in which load transfer occurs is illustrated by Figure 2.13. Due to the collagen fibres in the meniscus being inclined radially outwards to oppose tensile hoop stresses from the applied load, the stresses are resisted at the anterior and posterior horns by their attachments to the tibia (Bullough et al., 1970).

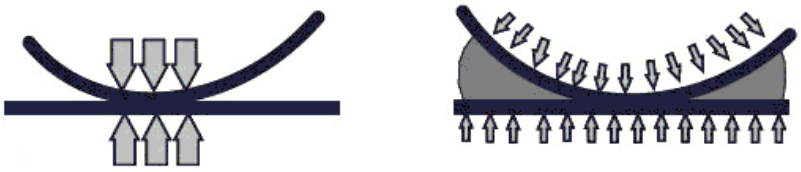


Figure 2.12: Load sharing without meniscus (*left*) and with (*right*). (Goodfellow et al., 2011)

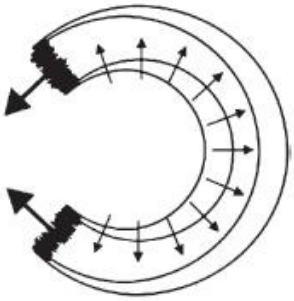


Figure 2.13: Mechanism of radial load transmission in the meniscus. (Shrive et al., 1978)

2.3.1 Implant Design

The design of the Oxford Knee articular surface has not been changed since the first implantation in 1982 (Figure 2.10). The interface between the polyethylene

insert and the femur is designed as a 'ball-in-socket' interaction which allows angular movements of flexion-extension. The insert to tibia interface is 'flat-on-flat' that allows translational movements – a so called mobile bearing.

The implant allows for axial rotation by a combination of translation and spinning at both surfaces. As the mobile bearing does not resist movements imposed upon it by the soft tissues, muscles and ligaments, the meniscal bearing mainly experiences compressive forces orthogonal to its surface which theoretically lessens the risk of implant loosening (Goodfellow and O′Connor, 1978).

The bearing itself aims to create two congruent interfaces in order to maximise load transmission. This is an attempt to mimic the natural meniscus, however due to the fact it's a rigid polyethylene bearing it cannot change shape like a normal meniscus can. For this reason it can only fit one radius of the femoral implant (and the flat on flat surface of the tibial base plate). Due to the bi-spherical nature of the femoral condyles the implant does not match the anatomy therefore the implant can reproduce all but the most anterior part of the condyles (Goodfellow et al., 2011).

Due to the spherical design of the Oxford UKA implant, it is much more tolerant of surgical error with regards to implantation of the components. Some varus/valgus implant malalignment should not affect the knee motion as the spherical femoral component would rotate in the coronal plane, but still have ability for angular movements (Shakespeare et al., 2005). Because of this mobility the joint should function normally, as long as the implant malalignment of the components correspond within the defined limits of the implant design (Callaghan et al., 2000). The specific implant alignment limits for the Oxford UKA are discussed in 2.3.3. A study by Gulati et al. (2009) compared the Oxford UKA implant positioning of 211 patients (98% of implants within femoral varus/valgus limits, and 92% of implants within tibial varus/valgus limits) with Oxford Knee Scores. This study found no statistically significant correlation be-

tween the Oxford Knee scores and the implant positioning. This suggests that due to the design of the Oxford UKA, it may be more tolerant of surgical error and not as badly affected by implant misalignment, especially when compared to anatomically shaped fixed bearing UKA implants.

2.3.2 Surgical Procedure

There are five available implant sizes for the femur that all have different radii (extra-small, small, medium, large, extra-large). For each femoral size there is a matching set of meniscal bearings with seven different thicknesses (from 3mm to 9mm). The size of the femoral implant is chosen pre-operatively using company provided x-ray templates which are placed over x-rays images of the patient. The templates outlines are applied to the image of the medial femoral condyle. The implant should fit with the central peg of the implant parallel to the long axis of the femoral shaft. To allow for the thickness of articular cartilage the outer surface of the component should lie outside the radiographic bone image distally and posteriorly, as illustrated in Figure 2.14.

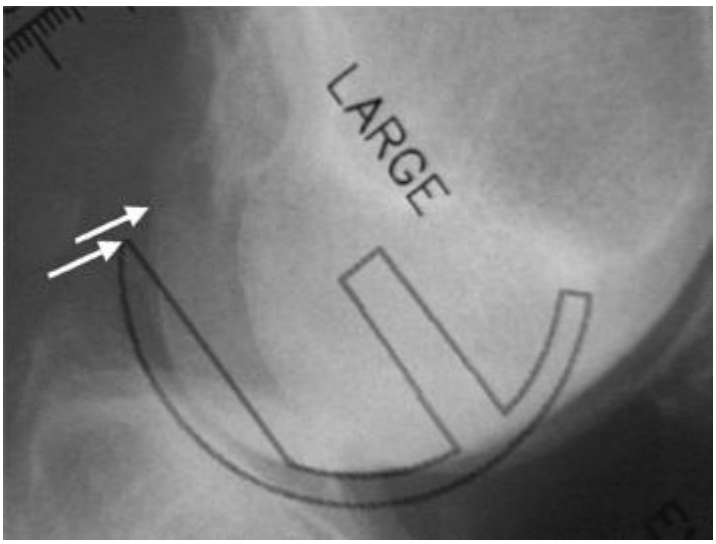


Figure 2.14: Positioning of Oxford UKA using templates over radiographic bone image. Arrows indicate gap needed for articular cartilage. (Goodfellow et al., 2011)

After the first incision the ACL is observed to see if it is still intact, and if the osteoarthritis is limited to the medial compartment. If there are no contraindications the operation can continue. The first task is to remove the osteophytes from the medial margin of the medial femoral condyle and intercondylar notch and then the osteophytes under the MCL.

Once the large osteophytes are removed from the anterior tibia the tibial plateau is cut at a slope of 7° using a saw guide. A stiff narrow bladed saw then makes a vertical tibial cut medial to the origin of the ACL to avoid ligament damage. After the horizontal cut a 12mm wide oscillating saw blade is used to excise the tibial plateau. Once loose it is levered up with a broad osteotome and removed. Then the tibial template is inserted with a 4mm feeler gauge to ensure sufficient room for the polyethylene implant. If not, more bone can be removed.

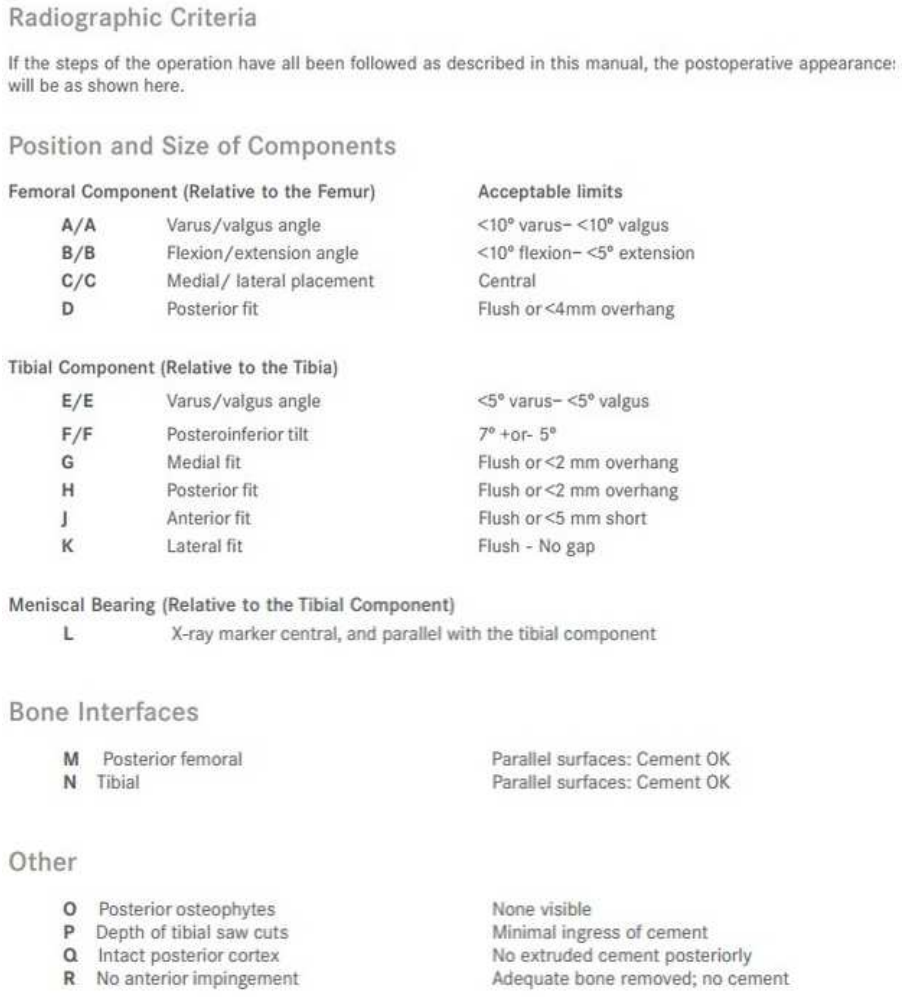
The femoral cut is made by drilling guidance holes using a femoral drill guide. The femoral saw guide is placed into these holes. Once in place a 12mm broad saw blade cuts the posterior facet of the femoral condyle. After the posterior cut has been made a spigot is inserted in order to guide a spherical mill. Once the mill blades are in position the bone can be resected.

As the main cuts have now been made the tibial template and the femoral trial component can be tapped in. The posterior and anterior condyles are trimmed to avoid impingement of the bone against the implant in flexion and extension using a chisel. A bearing trial is then inserted to check for joint stability.

Bone cement is placed on the tibial surface and flattened followed by the actual implant being impacted into position (with all excess cement being removed from margins). For the femoral implant cement is put at the concave surface and impacted into position. While the implants are seating, trial bearings are inserted again to choose ideal bearing thickness. Implantation is complete when the selected bearing is snapped into place. The next step is wound closure.

2.3.3 Implant Positioning Accuracy

The phase 3 instrumentation for the Oxford UKA allows for a minimally invasive surgical approach. As mentioned in Section 2.2.4, this is a demanding procedure, therefore it is very important for the surgeon to achieve accurate positioning of the components according to the Oxford Biomet guidelines. These guidelines proposed by the Oxford group are listed in Figure 2.15, and a graphic representation is given in Figure 2.16. There are 17 implant alignment parameters that can be assessed on post-operative X-rays.



Radiographic Criteria

If the steps of the operation have all been followed as described in this manual, the postoperative appearance will be as shown here.

Position and Size of Components

Femoral Component (Relative to the Femur)		Acceptable limits
A/A	Varus/valgus angle	<10° varus– <10° valgus
B/B	Flexion/extension angle	<10° flexion– <5° extension
C/C	Medial/ lateral placement	Central
D	Posterior fit	Flush or <4mm overhang

Tibial Component (Relative to the Tibia)		
E/E	Varus/valgus angle	<5° varus– <5° valgus
F/F	Posteroinferior tilt	7° +or- 5°
G	Medial fit	Flush or <2 mm overhang
H	Posterior fit	Flush or <2 mm overhang
J	Anterior fit	Flush or <5 mm short
K	Lateral fit	Flush - No gap

Meniscal Bearing (Relative to the Tibial Component)

L X-ray marker central, and parallel with the tibial component

Bone Interfaces

M	Posterior femoral	Parallel surfaces: Cement OK
N	Tibial	Parallel surfaces: Cement OK

Other

O	Posterior osteophytes	None visible
P	Depth of tibial saw cuts	Minimal ingress of cement
Q	Intact posterior cortex	No extruded cement posteriorly
R	No anterior impingement	Adequate bone removed; no cement

Figure 2.15: The 17 radiographic criteria of component position for the Oxford UKA

Several studies have been undertaken to illustrate the accuracy of implantation in different patients groups using these criteria. A compilation of studies

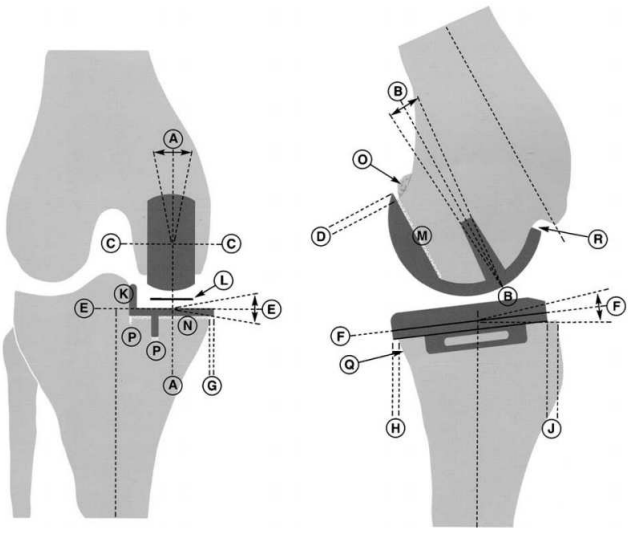


Figure 2.16: Graphic representation of alignment criteria

comparing implant accuracy is shown in Table 2.2. In order to illustrate implantation accuracy, only the parameters that are based on quantified data of the implant have been included. The table shows the percentage of the implants in those said studies that achieve the required positional accuracy based on the guidelines in the 8 categories.

	A	**B**	**D**	**E**	**F**	**G**	**H**	**J**	Subjects
Shakespeare et al. (2005)	100	92	94	99	100	89	67	99	224
Clarius et al. (2010)	96	68	66	98	88	55	23	61	59
Müller et al. (2004)	97	70	50	97	97	83	90	93	30
Kim et al. (2012)	99	89	95	–	–	–	–	–	189

Table 2.2: Comparison of different studies showing implant positioning accuracy within Oxford criteria (in %)

One of these studies was conducted by Shakespeare et al. (2005) in which 224 Oxford knees implanted since 1999 using the minimally invasive approach were analysed using x-rays. All these knees were were implanted either by or under the supervision of the senior author (Shakespeare et al., 2005) at Warwick Hospital, UK. These results show that the femoral positioning (A,B,D) is quite satisfactory with regards to acceptable ranges recommended by the Oxford Group, especially

with femoral varus/valgus (A) where all the implants are within the recommended limits, as illustrated by Figure 2.17.

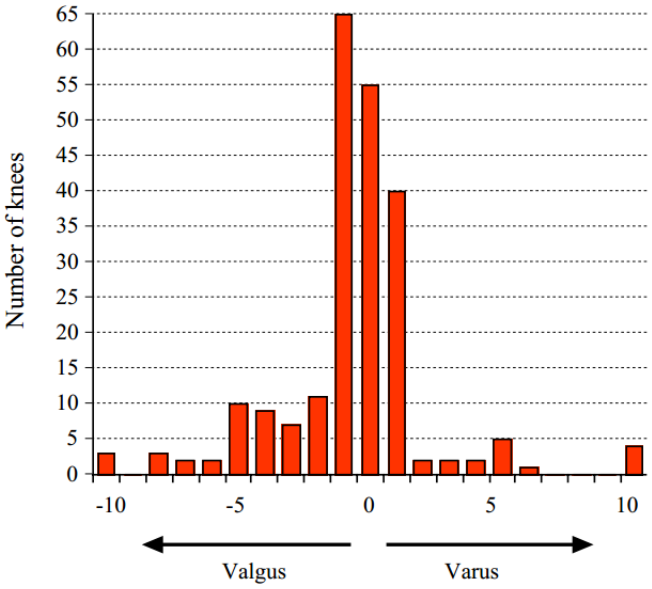


Figure 2.17: Varus/valgus alignment of the femoral components in Shakespeare et al. (2005) study

Similarly the tibia (E,F,G,H,J) also had seemingly high results with regards to positioning, except for the posterior fit of the tibial component (H). 33% of the implants did not reach the back of the tibial plateau thus causing some overhang at the front.

Another study conducted by Clarius et al. (2010) compared the implant positioning of 61 knees using x-rays. The 61 knees were performed through a minimally invasive incision between September 2001 and August 2004 by 8 different surgeons. The radiographic study results showed that a considerable proportion of the implants were not within the recommended limits for several of the positioning criteria. 96% of the femoral varus/valgus criteria (A) had been met, however only 23% of the tibia implants (H) managed to achieve the recommended posterior fit (Figure 2.18). This shows that even with the wide Oxford implant tolerances, in some cases there appears to be a large range of implant position accuracy.

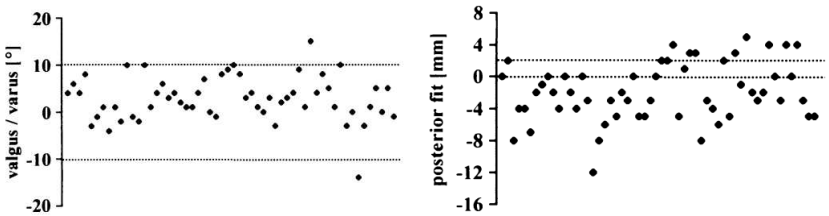


Figure 2.18: Varus/valgus alignment of the femoral components (left) and posterior overhang of tibial implant (right) in Clarius et al. (2010) study

Another study by Müller et al. (2004) compared the accuracy of 30 knees using a minimally invasive incision. These procedures were performed between November 1998 and February 2001 in a Munich hospital, and all performed by one experienced surgeon. These results also showed accuracy variation, with 97% of the implants being within the femoral varus/valgus criteria (A), whereas only half achieved the required femoral posterior fit (D). A further study conducted by Kim et al. (2012) measured the radiological parameters of only the femoral component accuracy for the Oxford UKA for 189 patients. All these knee procedures were performed by one surgeon at the Korea University College of Medicine. These results show similar implant accuracy percentages to the Shakespeare et al. (2005) study.

Overall it can be seen from the data available that the different studies show a wide range of results in terms of implant positioning accuracy. This variation is seen despite the spherical design of the Oxford UKA which allows for inaccuracies in implant positioning. Even experienced surgeons can have less than satisfactory results in some of the criteria. If the radiographic criteria is seen as a measure for how well the procedure has been performed, it shows that the minimally invasive Oxford UKA procedure is a very challenging operation, and errors can be made.

2.3.4 Surgical Outcomes

Pre-operatively the surgeons use sizing templates over X-rays in order to assist them in estimating the correct size of the required prosthesis for the patient.

While template systems in hip arthroplasty cases have been shown to be very useful in prosthesis size selection, positioning, alignment and reducing uncertainties mid operation and cutting down surgical time (Müller, 1992) they should also show a high level of reproducibility in order to be reliable. A study was conducted to assess the reliability of using the Oxford UKA templates on 30 randomly selected patients with osteoarthritis (Bothra et al., 2003). Ten surgeons worked independently and repeated their measurements 2 weeks later. Results showed poor agreement regardless of the surgeon's experience. This concern about reproducibility may be a factor in surgical outcome, and possibly a disadvantage for this UKA system.

Even though surgeon experience did not have an effect on surgical planning repeatability, it did appear to have an impact on outcomes. A one year post-operative study on the Oxford UKA showed that surgeons who were still learning the procedure had lower AKS knee scores than those of experienced consultants (Rees et al., 2004). Additional factors that may have an effect on patient outcomes is the number of UKA cases performed at the unit. One Swedish study found that revision rates were much higher in centres that did fewer than 23 operations annually than those which performed a greater number per year (Robertsson et al., 2001). Other studies have found that more crucial than the number of cases performed is having strict selection criteria and that correct surgical techniques are met (Keys et al., 2004). This is why it is important the surgeons involved in research trials are well trained and experienced with the Oxford UKA and are performing them regularly.

In an early study comparing 15 different medial unicompartmental Oxford Knee arthroplasty patients pre and post-operatively the results found that the patients' sagittal plane angle had a reduced excursion prior to surgery, and an almost normal pattern afterwards (Jefferson and Whittle, 1989). The coronal plane knee angle during the stance phase showed correction from varus to neutral and

the sagittal plane moment pattern was corrected from a pathological 'extension only' to a normal biphasic pattern. Additionally the adduction moment in the coronal plane was slightly elevated prior to surgery, and was normal afterwards.

Mid to long term follow up studies show favourable survival rates. A 6-8 year study on 230 minimally invasive medial Oxford Phase 3 mobile-bearing UKA by Smith et al. (2012) found an 85% survival rate. Price et al. (2005) reviewed 439 medial Oxford knees by three surgeons in Skovde, Sweden between 1983 and 2000. The 15-year survival rate for the entire cohort was 93%.

2.3.5 Implant Articulation

The Oxford implant is a spherical femoral component on a fully congruent mobile bearing that slides on a tibial tray. It relies on knee ligaments to provide stability. Using this design philosophy the Oxford UKA aims to reproduce normal knee motion. To ascertain if this design philosophy achieves the intention of restoring normal knee movement, it is important to analyse Oxford UKA, and see how it compares to healthy knees.

Bradley et al. (1987) investigated the bearing movement of the Oxford UKA, where 16 patients (20 knees; 14 medial, 6 lateral) were examined. On average the radiographs were taken 18 months after the operation. The patients lay supine and, and radiographs were first taken in full extension, with the heel supported, and then at full flexion in neutral rotation. Rotational torque was then applied manually with the knee flexed from 80° to 90° and radiographs were taken at the extreme of each movement. On each radiographic image a chord parallel to the upper surface of the tibial component was constructed on the image of the femoral component, where the articular surface forms part of a sphere. The distance from the anterior end of the tibial component to the constructed point was expressed as a proportion of the overall length of the component. Due to the absolute dimensions of the implanted prosthesis being known, a quantitative

measurement of the movement of the femoral component relative to the tibial component could be made (Bradley et al., 1987).

The bearings were found to move backwards on the tibia through an average distance of 4.4 mm (range 0.0 to 13.5 mm) in the medial compartment and 6.0 mm (range 1.6 to 13.0 mm) in the lateral compartment. At 90° of flexion, radiographs were obtained with the tibia twisted manually to the limits of medial and lateral rotation. On average the bearing movements between the extremes was found to be 6.6 mm in the medial compartment and 5.1 mm in the lateral. Their movements on the tibia were in opposite directions in the two compartments. This study has shown that the Oxford implant follows the movement of the retained ligaments, and moves where they dictate. Therefore this design philosophy does mimic the normal knee as intended as the sliding bearing results in knee kinematics that are the same as normal knees for those tested activities (Bradley et al., 1987). It is worth noting that this data was not gathered under weight bearing conditions as the patients were lying in supine position, therefore it may not demonstrate real world movements of the implant given that the weight of the patient may dampen or even restrict sliding movement of the bearing.

However Pandit et al. (2008) conducted a fluoroscopic study to analyse the knee kinematics and bearing movement during a step-up exercise and a deep knee bend exercise. This study was intended to compare the kinematics of Oxford UKA patients with and without ACL repair to normal patients during the same exercise. The knee kinematics were assessed in the sagittal plane using the knee Patellar Tendon Angle (PTA). This was used because PTA is an indicator of overall knee joint kinematics since it is dependent upon both the patello-femoral joint and the relative positions of the femur Pandit et al. (2008), and can be measured using sagittal plane video fluoroscopy.

There were 10 UKA subjects with ACL repair, 10 UKA subjects with intact

ACL and 22 subjects with normal knees. The average post-surgical follow up times were 3.4 years. The mean age of the patients were 49.2 years, and the average normal age of the normal knees were 34.

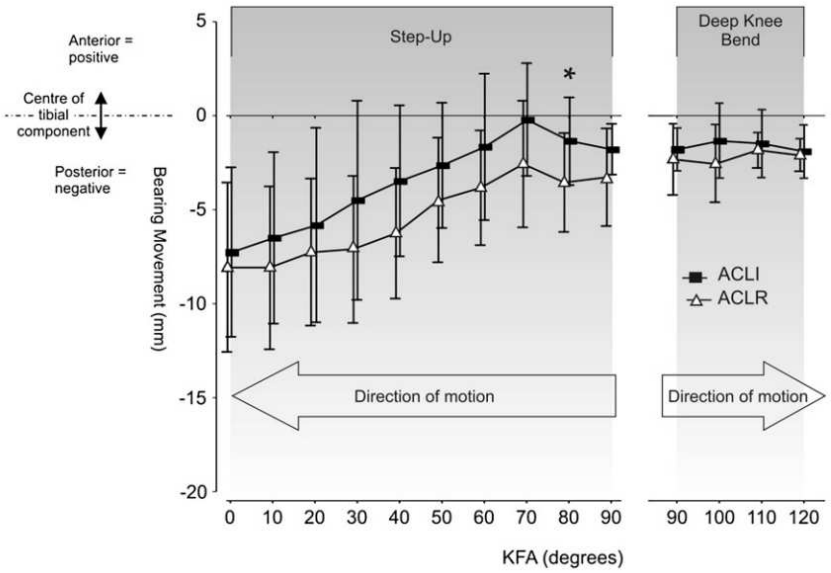


Figure 2.19: Bearing movement for the intact ACL (ACLI), and reconstructed ACL (ACLR), groups plotted against knee flexion angle (KFA), during step-up and deep knee bend exercises (Pandit et al., 2008)

Each patient was instructed to perform a step-up exercise, followed by a weight-bearing deep knee bend. The patients were allowed to touch a side bar for stability. The overall bearing movement for the step-up activity and deep knee bend activity are shown in Figure 2.19. The overall pattern of bearing movement for the intact ACL group was for the bearing to be posterior by approximately 2mm, to the midline of the tibial tray at 90° flexion at the start of the step-up exercise. The bearing then moved anteriorly reaching the midline at a knee flexion angle of 70° as knee flexion further decreased it then moved posteriorly to reach a final position of approximately 7mm behind the midline at full extension Pandit et al. (2006).

Data was then obtained for the bearing movement during the deep knee bend from 90° to 120° of knee flexion. Figure 2.19 shows there is very little bearing motion during this part of flexion. The average position of the bearings was 1.6

mm posterior (range of 3.9mm posterior to 3.0mm anterior) to the midline of the tibial tray.

This data shows evidence of the polyethylene bearing sliding, however it is important to show normal knee kinematics to show that the Oxford design philosophy restores function. The graph illustrating knee kinematics by comparing PTA and the knee flexion angle is shown in Figure 2.20. During the step-up exercise the patients displayed a PTA/knee flexion angle relationship very similar to that of the normal knee. There was no statistically significant differences between either UKA and the normal knees. Similarly during the deep knee bend exercise there were no statistically significant differences between the UKA groups and the normal knees in the PTA/knee flexion angles, this showing the Oxford UKA achieves its objective or restoring knee motion in this case.

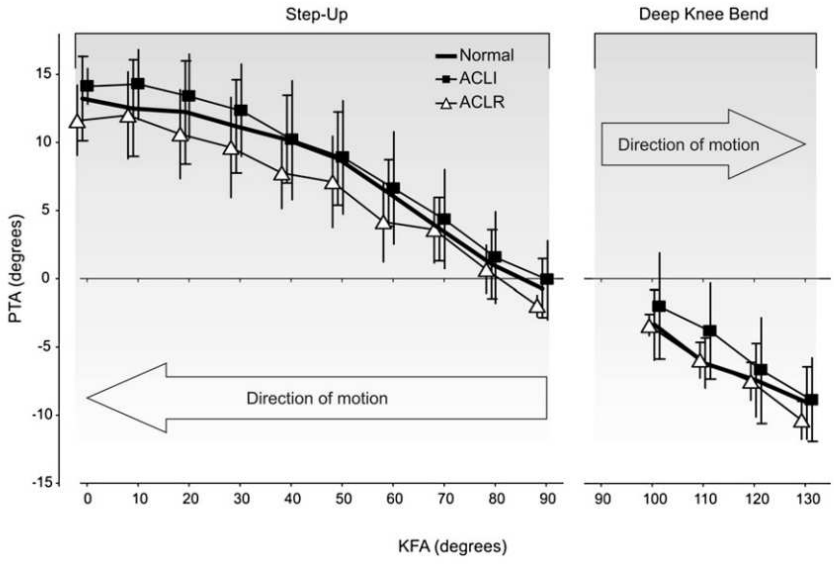


Figure 2.20: Knee kinematics showing relationship between patellar tendon angle (PTA) and knee flexion angle (KFA) for normal, intact ACL (ACLI) and reconstructed ACL (ACLR) knees for both the step-up and deep knee bend exercises (Pandit et al., 2008)

Price et al. (2004) also conducted a fluoroscopic study comparing the biomechanics of the Oxford UKA with normal knees (and with TKA). The kinematics were assessed using the patellar tendon angle. Fluoroscopic images were collected

during 3 different exercises: active knee extension against gravity, active knee flexion against gravity, and a step up exercise. For the active knee extension against gravity task the patients were examined in a semisupine position, moving their knee from approximately 100° flexion to full extension. The femur was supported in a horizontal position to prevent hip rotation and to keep the hip flexion angle constant (Price et al., 2004). During the active knee flexion against gravity task the patients were examined in standing while flexing the knee against gravity, with the femur vertical. Movements were from full extension to approximately 100° knee flexion. The step up exercise involved the subjects placing the foot onto a 30cm platform with the knee flexed at 70°. Fluoroscopic images were taken as they stepped up onto the platform.

In this study there were 5 normal knees, 5 one year post-op UKA knees and 5 ten year post-op UKA knees. The groups however were not age matched. The mean age of the normal group was 28.8 years, whereas the mean one year post-op UKA group age was 66.7 years, and 10 year post-op UKA group 61 years. The results for each exercise showed the normal knee demonstrating an approximately linear relationship between flexion angle and patellar tendon angle. Both groups of both Oxford UKA groups displayed a pattern similar to the normal knee in all 3 exercises (flexion against gravity exercise graph shown in Figure 2.21). Statistical analysis revealed no significant difference between the normal knees and both UKA groups for all three exercises. This experiment demonstrated that the change in patellar tendon angle over the flexion range seen with the medial Oxford UKA is similar to that seen with the normal knee in the sagittal plane.

In summary fluoroscopic analysis of the Oxford UKA has provided evidence to suggest that the Oxford UKA allows for normal kinematics of the knee. In several studies the Oxford UKA patients behaved similarly to normal healthy test subjects. There was evidence to show that during certain tasks the polyethylene bearings do slide, but also that these movements can lead to a knee with normal

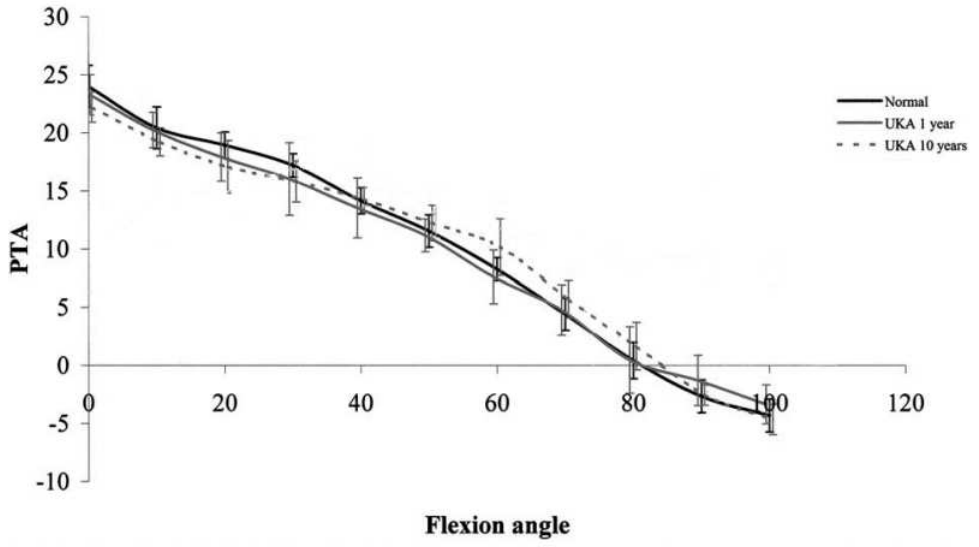


Figure 2.21: Graph of patellar tendon angle against flexion angle during flexion against gravity (Price et al., 2004)

function. It is important to note that in the studies discussed, the sample sizes were small, and only certain tasks confined into small areas were analysed (due to the nature of fluoroscopy). Nevertheless these studies suggest that the Oxford UKA fits in with the design philosophy, and can allow the knee to articulate normally.

2.4 The MAKO Unicompartmental Knee Arthroplasty System

The UKA system developed by MAKO Surgical Inc. (Fort Lauderdale, Florida, USA) includes a surgeon interactive device that features a robotic arm with tactile guidance which is used to prepare the patient's bone for implantation. It has 3 components: robotic arm, optical camera, and operator computer. This system uses pre-operative Computed Tomography (CT) images of the patient's leg to allow accurate planning prior to the operation and intraoperative navigation and implant editing (Lonner and Kerr, 2012). During the bone preparation stage the

system provides a stereotactic interface which constrains the surgeon's cutting tool to only a designated volume during the femoral and tibial cutting stage. This is an alternative to using manual instruments used in the Oxford UKA such as pinned cutting blocks, saws and jigs. Due to the bone resection being performed via robot assistance, surgeon inexperience should not theoretically affect the alignment of the implants in the same way that manual instrumentation might do.

2.4.1 Implant Design

The femoral component is made from cobalt chromium (CoCr) alloy (MakoSurgical, 2013) per ASTM F75. The implant is cast and heat treated, the articular surface is polished, and the cement-contact area is grit blasted. The tibial baseplate is made from a Titanium alloy (MakoSurgical, 2013) per ASTM F136 and is machined from stock material. As with the femoral component the cement-contact area is grit blasted. The tibial insert is made from ultra-high molecular weight polyethylene (UHMWOE) per ASTM F648. The insert is machined from stock material.

When designing the implants, 8 general requirements were made for the system and its constituent components (Banks, 2013), which were:

- Anatomically shaped to minimize bone resection
- Implant sizes should fit patients worldwide
- Bicruciate retaining
- Fixed bearing
- Discrete, unlinked compartmental components for 1, 2, and 3 compartment disease.
- Discrete, unlinked compartmental components for size interchangeability
- Minimal incision

- Bone preparation using surgeon-guided robotic system

In order to imitate the articular surface of the femur, 121 CT scans from 55 healthy knees, 50 knees with medial osteoarthritis, and 16 cadaver knees were collected (Banks, 2013) The CT images were segmented and bone surface models were created using custom programs written in Matlab. This is illustrated in Figure 2.22.

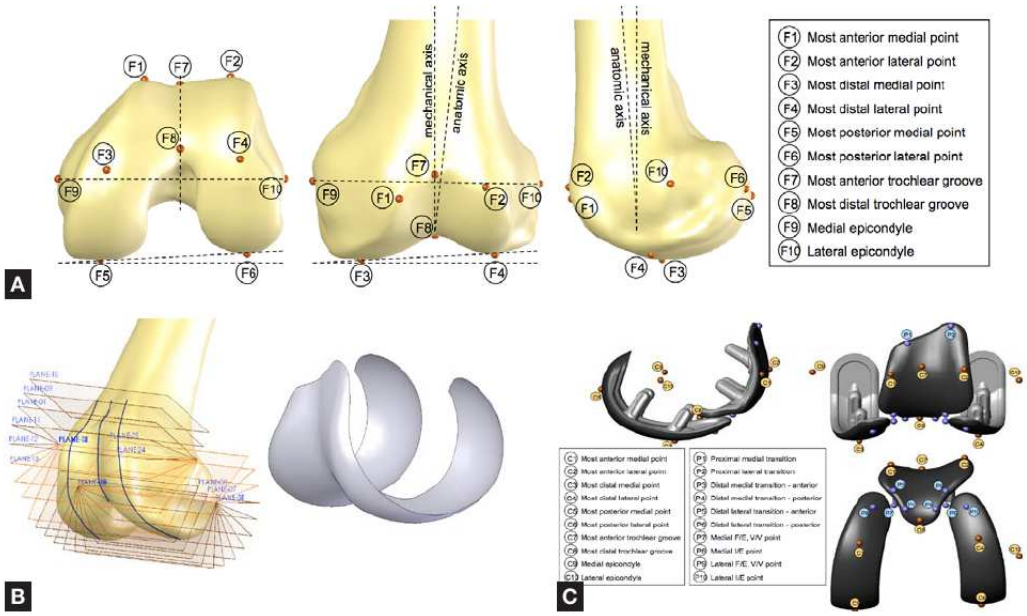


Figure 2.22: A) 10 femoral anatomical landmarks used, B) Data from 121 femur CT scans, C) 10 anatomical marker points corresponding to the implant surface points (Banks, 2013)

Tibial plateau shape was also investigated using a set of 115 CT scans for 55 healthy knees, 50 knees with medial osteoarthritis, and 10 cadaver knees (Banks, 2013). The same methods were used to generate tibial models as used for the femur. The landmarks used are shown in Figure 2.23. Using this data a range of different implant sizes were generated.

As the surgical cuts are being performed using a burr and not a cutting saw the bone-implant interface doesn't have to be straight, and can be curved. To work effectively with the burr and not have to change cutting instruments, all pegs and cement pockets have been shaped to share a common radial dimension

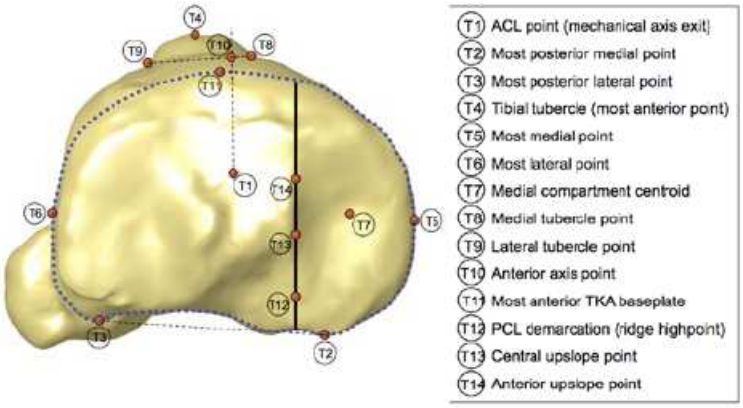


Figure 2.23: 14 tibial anatomical landmarks used (Banks, 2013)

with the cutting tool (Banks, 2013).

With the advantage of a robotic cutting tool the implants aimed to mimic knee kinematics as closely as possible. A study by Yildirim et al. (2013) aimed to compare the Restoris implants, a standard cruciate retaining TKA and a posterior stabilized TKA to see how similarly they resemble normal anatomical movement.

Seven male left knee specimens were used and the knees were dissected to leave only the capsule (Yildirim et al., 2013). Clamps were attached to the quadriceps tendon and a motor was attached to simulate flexion extension motion. Two springs that exerted forces of half the quadriceps tendon were screwed on to the posterior femur and tibia at the hamstrings attachments, providing increasing tension as the knee extended – as would be the case in an intact knee joint (MacWilliams et al., 1999). Markers were used to track bone positions.

The intact knees were tested in flexion from 0-120° and repeated three times to ensure consistent and equal motion. The knee was then replaced with a Mako MCK Restoris implant using the Mako RIO robotic arm. The tests were then repeated three times on the other two TKA implants.

The results showed the UKA was close to the anatomic motion, especially on the medial side. Both TKA implants however showed abnormal motion features. This study may show that an accurate and well implanted UKA can potentially

give close normal to normal knee kinematic function.

2.4.2 Surgical Procedure

One of the features of this system is that the pre-operative implant planning can be done before an operation. This is done by taking a CT scan of the patient's lower extremities and importing it into the MAKO software. The software converts the raw CT scan data into 1mm slices at the knee joint, and 5mm slices through the hip and ankle. This is then segmented, defined, and recombined to produce a patient specific 3 dimensional model. This allows accurate planning of the implant size, alignment and orientation of the bone resection. The implants are superimposed on the 3D model of the joint in order to visualise the implant positions (Lonner and Kerr, 2012).

On the day of the surgery the system is set up before the patient enters theatre. The system's optical camera and the robot are calibrated and the robotic arm is draped. When the patient arrives the knee joint is exposed by means of a minimally invasive quad-sparing incision. Once opened, the knee is inspected by the surgeon in order to make sure the ACL is intact and disease is localised only on the medial compartment – otherwise the patient may have to be converted to a TKA. Once the patient has been deemed suitable the surgery can go ahead. The aim is to match the joint model with the patient's knee. This is achieved by using landmarks on the patient and correlating them to the landmarks established on the model produced by the CT scan. Partially threaded pins are drilled into the proximal tibia and distal femur and tracking arrays are clamped onto these pins as a constant point of reference for the system as to the position of the tibia and femur. The landmarks are identified on the bony surface using optical probes that reference the tracking arrays. Additionally checkpoint screws are inserted into the femur superior to the condylar surface and on the tibia approximately 1 cm below the articular surface. These checkpoints ensure the registration of the

robotic arm relative to the knee remains accurate throughout the procedure.

Once the registration stage has been completed a dynamic soft-tissue balancing algorithm is initiated. A valgus moment is applied to the leg and different points are captured by the system through a passive range of knee motion. This allows the surgeon to see how tight or loose the components will be throughout different angles of flexion-extension. Using this information the initial implant position decided prior to surgery can be adjusted intra-operatively (Lonner and Kerr, 2012).

With the final implant positions decided the bone resection is performed with the robotic arm. The arm is moved into a 'haptic zone' where the system will apply stereotactic boundaries. Any attempt to move outside this zone is met with a brickwall force confining the burr to the designated region of bone, however when in the cutting volume it allows burring without any resistance. This confines the burr to cut only the minimal amount of bone for the implant planned. After the sections of bone have been removed trial implants and meniscal bearings are provisionally implanted to test feel, range of motion, stability and confirm the implant position matches with that of the plan. The trial implants are then removed, the area is lavaged and the real implants cemented into position and the meniscal bearing inserted. Once the cement is set the incision is stitched up and the surgery is complete.

2.4.3 Implant Positioning Accuracy

A Level III pilot study testing the tibial component alignment was published in 2010. In this study 31 patients had the UKA using robotic assisted procedure compared with 27 patients that underwent unilateral UKA using the conventional manual instrumentation. The comparisons determined the error of bone preparation and variance with each technique. The results from this study showed the RMS error of the posterior tibial slope when using manual instrumentation was

3.1° from the planned slope, compared with 1.9° using the robotic arm assistance (Lonner et al., 2010). The variance using manual instrumentation was 2.6 times greater ($p = 0.02$) than the robotic assisted group. (Lonner et al., 2010). In the coronal plane the average error of tibial alignment was 2.7° ±2.1° more varus for the manual instrumentation group compared with 0.2° ±1.8° for the robotic assistance group ($p < 0.0001$) (Lonner et al., 2010). The varus/valgus RMS error was 3.4° manually compared to 1.8° (Lonner et al., 2010).

Another study compared 85 UKA using manual instrumentation to 67 performed with the robotic assisted system. Each was performed using a MIS approach and both aimed to match the natural tibial posterior slope(Coon et al., 2011). The two groups were identical in terms of age, gender and BMI (Coon et al., 2011). The coronal and sagittal alignment of the tibial components were measured on pre and post-operative AP and lateral radiographs and the post-operative tibial component alignment was compared to the pre-operative plan (Coon et al., 2011).

The results show the RMS error of the tibial slope was 3.5° manually compared to 1.2° robotically (Coon et al., 2011). In addition, the variance using manual instruments was 9.8 times greater than the robotically guided implantations ($p < 0.0001$). In the coronal plane, the average error was 3.0 ° ±2.2° more varus using manual instruments compared to 0.3 ° ±1.9° when implanted robotically ($p < 0.0001$) (Coon et al., 2011). The varus/valgus RMS error was 3.7° manually compared to 1.8° robotically.

A more recent study at Glasgow Royal Infirmary compared the accuracy of implant positioning using robotic arm assistance with that achieved using conventional instrumentation in a randomised cohort (Blyth et al., 2012). Fifty patients were randomised to receive UKA with or without the aid of robotic arm assistance (n=25 in each group). Surgery was performed by three surgeons, each contributing equally to both groups. At three months post-operatively, patients received a

CT scan to determine implant placement in the varus/valgus, flexion/extension, and internal/external rotational planes. In all dimensions measured robotic arm assisted surgery greatly enhanced the accuracy of implant placement (Blyth et al., 2012). The tibial slope in particular showed over 70% of the MAKO implants showed an error of less than 2° whereas only 15% of Oxford implants had an error of less than 2° (Blyth et al., 2012).

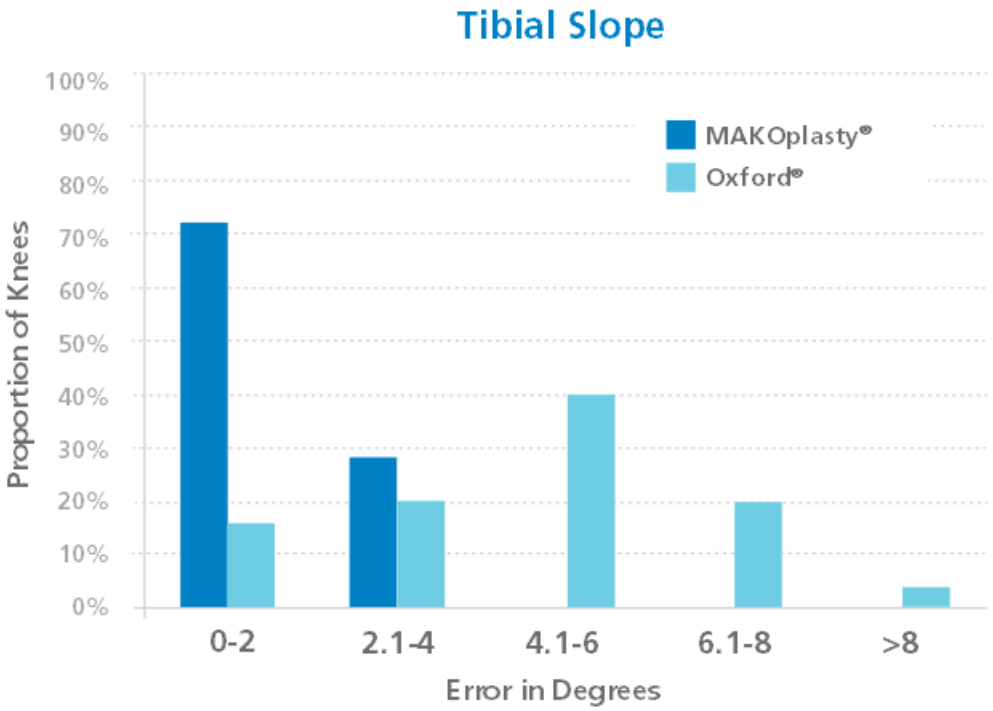


Figure 2.24: Graph showing the tibial slope errors between the MAKO and Oxford implants. (Blyth et al., 2012)

The results show that robotic assisted bone resection does appear to show implants align more accurately to what is planned. It remains to be seen if this necessarily leads to better patient outcome. An additional consideration is if the non-robotic assisted UKA actually require such accuracy. Their designs – particularly mobile bearings – may allow for some alignment inaccuracy by their very design. For this reason the two different groups should be tested against each other to see if more accurate alignment directly leads to better patient outcomes.

2.4.4 Surgical Outcomes

In 2012 Goddard et al. (2012) examined the outcomes of 510 patients that underwent robotic-assisted UKA with the Mako system between July 2008 and June 2010. This was the largest study of its kind and aimed to examine the clinical outcomes of patients who underwent this procedure. The mean age of the patients in this study was 63.7 years (range of 28 to 88 years) (Goddard et al., 2012). Clinical outcomes were evaluated using the Oxford Knee Score and patients without recent follow-up were contacted by telephone. The revision rate and time to revision were also examined. The average length of stay for patients who underwent robot-assisted UKA was 1.4 days (range of 1 to 7 days). At the latest clinical follow-up most patients had a mean Oxford Knee Score of 36.1 $\pm$ 9.92. The revision rate was 2.5% with 13 patients being either converted from an inlay to onlay prosthesis or conversion to total knee arthroplasty (Goddard et al., 2012). The most common indication for revision was tibial component loosening, followed by progression of arthritis. Mean time to revision was 9.55 $\pm$ 5.48 months (range 1 to 19 months). The results show that UKA with a robotic system provides good pain relief and functional outcome at short-term follow-up.

Another study evaluated the early outcomes of robot assisted medial UKA with conventional manual onlay components with 20 patients per group. The aims were to assess how improvements in accuracy affected early patient outcomes (Velyvis et al., 2011). The patients were evaluated clinically using standard outcomes measures (Knee Society, WOMAC and Oxford scores) as well as for modes of failure (Velyvis et al., 2011). Average follow-up for the manual onlay technique was 12 months and for the robotic-assisted inlay technique was 10 months (Velyvis et al., 2011). Patients were not statistically different in terms of BMI, age, or diagnosis ($p > 0.05$). The results showed no statistical difference between the two groups with either clinical outcome measures (Knee society score ($p=0.65$), total WOMAC score ($p=0.75$) and Oxford knee score ($p=0.88$) (Velyvis et al.,

2011)).

While there have been some early studies that compare clinical knee scores of robotic assisted and conventional UKA there have not been any clinical trials that compare the biomechanical functions of the two groups using motion analysis.

2.5 Motion Analysis

2.5.1 Background

The aim of motion analysis is to gather quantitative information about the mechanics of the musculo-skeletal system during locomotor activities via a combination of kinematic and kinetic data (Cappozzo et al., 2005). Stereophotogrammetry is used to obtain instantaneous positions of markers located on the skin to create a kinematic model of the subject, while dynamometers – such as force plates – can be used to collect kinetic data (Medved, 2001). The data can be processed to analyse specific parameters of the motor tasks and comparing different parameters can highlight deviations from normal function or relative differences in motion characteristics of test subjects.

The anthropomorphic model consists of a chain of links (Braune and Fischer, 1987) where each link represents a portion of the human body called a segment. These segments consist of bony and soft tissues. They are considered non-deformable and are therefore represented as rigid bodies. Using 3D motion analysis the inter-segmental joint motion is modelled in three Degrees of Freedom (DOF) with each rigid body segment assigned a 3-dimensional axis system, originating at the joint centre (Cappozzo et al., 2005).

In order to obtain the numerical information that allows body reconstruction movement and morphological data is required. The morphological description of a segment is obtained by representing it as a series of particles relative to an orthogonal set of axes called the local frame (Cappozzo et al., 2005).

The morphology of any segment may be represented with respect to an arbitrary frame. Given a local frame and another frame referred to as the global frame it's possible to calculate the position vectors of the particles of said segment. This is known as vector transformation as illustrated by Figure 2.25 (Cappozzo et al., 2005).

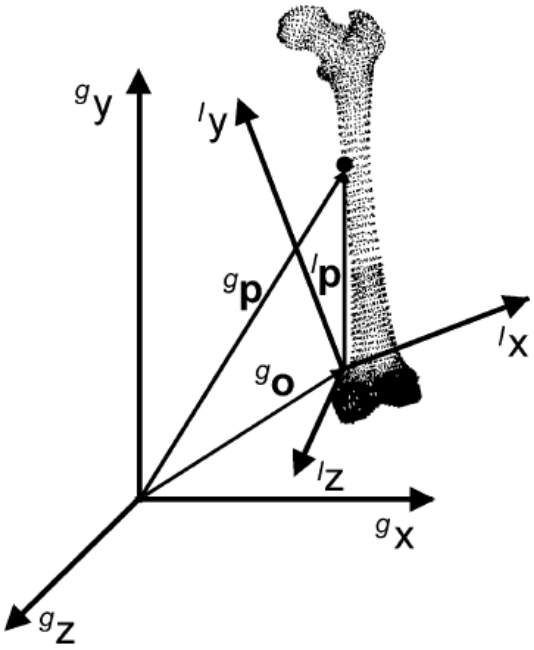


Figure 2.25: Position vector of a particle shown in a global and local frame. (Cappozzo et al., 2005)

The position vector and orientation matrix of each bony segment (local frame) is gathered relative to a global frame of reference. The global frame set of axes is determined using marker position co-ordinates provided by the system itself. This is defined relative to the system's own calibration procedure.

The technique to show segmental movement is by using a cluster of non-aligned markers affiliated with the bony segment (Cappozzo et al., 2005). There are usually more than three markers so the orientation of the clusters in all three axes can be identified, and also to ensure they are visible to a sufficient number of cameras depending on the robustness of the motion capture system used. The position of the marker clusters are arbitrary and non-repeatable. For this reason

anatomic calibration is required on each subject. Calibration points coincide with Anatomical Landmarks (ALs) that are distinctive and repeatable (for example the medial and lateral malleoli) (Cappozzo et al., 2005). These bony landmarks are usually identified by palpation and markers are used to locate them. The movement of the clusters can then be defined relative to these Anatomical Landmarks (ALs) – similar to global frame calibration (Cappozzo et al., 2005). Once the landmarks are confirmed those markers can be removed before any movement tracking takes place. If however the ALs are internal – like the centre of the femoral head – then the location of a superficial AL (such as the anterior superior iliac crest on the pelvis) is used to locate its position using predictive models (Seidel et al., 1995).

In order to get useful biomechanical data from the relative motion between two segments is needed. This is called joint kinematics which describes the relative motion between two contiguous bony segments, the proximal and distal (Cappozzo et al., 2005). This describes the orientation and position of the distal segment relative to the proximal segment and therefore contains complete information about the joint kinematics. Additionally the use of integrated force plates to provide ground reaction force data allows kinetic analysis such as the calculation of inter-segmental joint moments (Moir, 2008).

2.5.2 Errors

There are three main sources of error using stereophotogrammetry to analyse human motion; instrumentation, Soft Tissue Artefacts (STAs) and AL misplacement (Cappozzo et al., 2005).

Instrumentation error can be compensated through system calibration, and by ensuring that each marker is seen by at least two cameras to minimise optical distortion. Also appropriate filtering and smoothing techniques of the incoming data can reduce noise (Chiari et al., 2005).

STA errors however are much more problematic. They are caused by the assumption that markers attached to the skin surface are rigidly connected to the underlying bones. This has been shown to introduce errors at least an order of magnitude larger than stereophotogrammetric errors (Reinschmidt et al., 1997). STA is the effect of the soft tissues the markers are placed upon shifting which moves the markers thus compromising the precision of the calculated joint motion. This error had been discussed years ago (Hoschek et al., 1984).

The gold standard for measuring STAs relative to the underlying bone is by using an external fixation device, for example a femur fracture fixation device (Angeloni et al., 1992). One investigation (Cappozzo et al., 1996) looked at the magnitude and the pattern of skin movement artefacts while subjects performed different tasks. Markers were positioned over anatomical landmarks such as greater trochanter (GT), lateral femoral epicondyle (LE), head of the fibula (HF) and lateral malleolus (LM), and on other locations on the lateral aspect of the shank and thigh. This study confirmed that skin-marker artefacts have amplitudes much greater than seen with photogrammetric errors. Additional findings showed displacements between skin markers and underlying bone were found to be in the 10-30 mm range during walking (Fig 2.26).

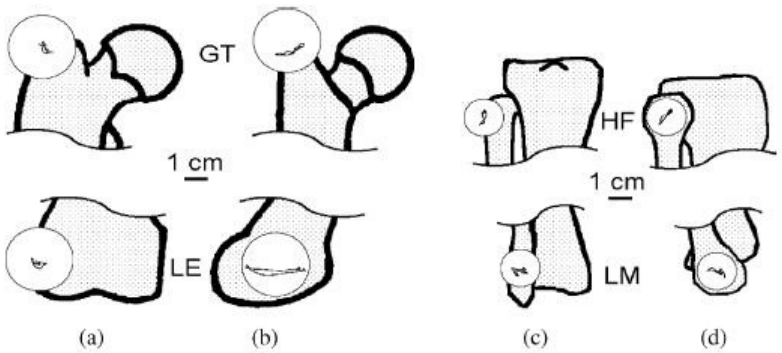


Figure 2.26: Position artefacts trajectories of great trochanter (GT), lateral epicondyle (LE), head of the fibula (HF) and lateral malleolus (LM) skin markers during a walking cycle at natural cadence. (a) and (c) frontal plane, (b) and (d) sagittal plane. (Cappozzo et al., 1996)

The largest deviations were seen with the GT and LE markers. The displacements relative to the underlying bone were roughly proportional to the closest joint angular displacement. However markers located on the lateral portion of the thigh and shank on areas far from the joint exhibited smaller artefact movements. When using clusters made of skin markers the inaccuracies for flexion-extension, adduction-abduction, and internal-external rotation amounted to roughly 10%, 50% and 100% of the respective movement range angle (Cappozzo et al., 1996).

Another similar study (Reinschmidt et al., 1997) aimed to evaluate errors that occur at knee and ankle joint angle when external skin markers were attached over the thigh, shank and shoes of a subject. Intra-cortical Hofmann pins were used to see bone movement, while six skin markers were located in each segment. The skin and bone artefacts were compared to determine the accuracy. The results showed that poor agreement was found in the Coronal and Transverse planes (max difference 6°, and 10.1°respectively). These errors sometimes exceed that of actual motion of the knee. The study concluded that the most reliable results can only occur during flexion/extension of the tibio-femoral joint. The main source of STAs were found at the thigh, so ankle joint calculations showed less error between the two measures. Another important conclusion from this study was that shoe markers can be used to accurately determine ankle joint motion.

One study used a percutaneous skeletal tracker (PST) specifically designed for STA testing (Holden et al., 1997). Pins were inserted into the distal shank of the patient's (three in total) periosteum. Marker clusters were then put halfway up the shank and the dorsum of the foot. The relative difference between the sets of frames was considered a measurement of the STAs.

Rotations along the X and Y axis showed an error less than 3°. On the other hand the Z axis (internal/external rotations) errors were higher reaching 8° (Figure 2.27).

There have been other studies showing similar findings, for example one study

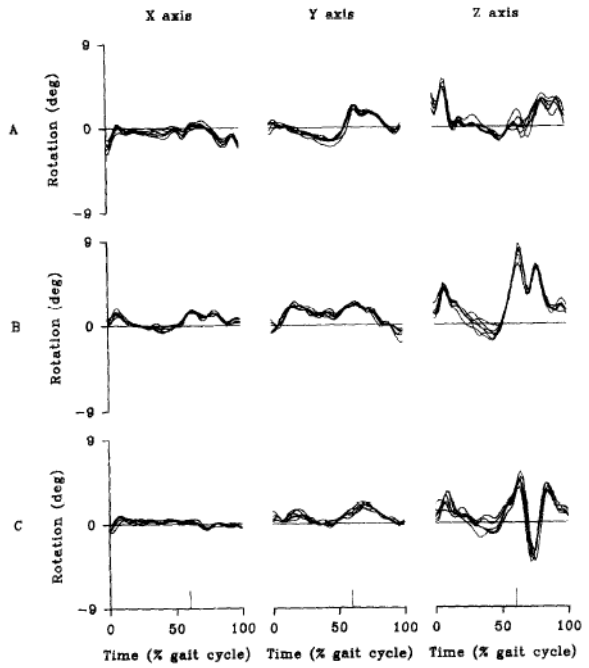


Figure 2.27: Rotational displacements of the surface markers relative to the PST segment of 6 walking trials for three subjects (A,B,C). (Holden et al., 1997)

(Manal et al., 2000) found rotational deviation along the longitudinal axis of the shank during first and last third of stance phase in the range of 4°- 7°. However in all these papers intra-cortical pins and external fixators were being used to track the underlying bone movement. While using this method gives a good description of the bone movement itself the intrusive nature limits their application in daily use. It has also been suggested that the patients that wear those bulky devices, have a non-physiological pattern of locomotion (Cappozzo et al., 2005). Further issues with this technique is the skin motion can become restricted by the pins themselves which could limit the realistic quantification of STAs during activities (Stagni et al., 2005).

A non-intrusive way to measure the soft tissue artefacts relative to the underlying bone movement is by using Roentgen single-plane photogrammetric analysis (RSPA) such as X-ray radiography, fluoroscopy and Magnetic Resonance Imaging (MRI). Studies using X-ray radiography are limited because they can only capture still frames. A recent study (Südhoffa et al., 2007) using low dose X-ray

radiography was used to compare the displacements of three different markers attachment systems at knee flexion angles of 0°, 20°, 40°, and 70°. This study concluded that while the use of elastic straps was accurate for coronal and sagittal plane movements (maximum displacement 1.6°), there were significant errors in the transverse planes (maximum displacement 6.4°). This results to errors in axial rotation so discretion is needed when analysing data from stereophotogrammetry.

Another technique that can be used to measure STAs is fluoroscopy. Fluoroscopy allows participants to move freely whilst simultaneously capturing surface markers and the motion of the underlying skeletal system. A study by Stagni et al. (2005) combined this technique with stereophotogrammetry to measure STAs. Markers were spread all over the lateral surface of each segment, which were then related to the relevant AFs captured using fluoroscopy; the standard deviation of each marker relative to the AF was the measure of STA errors.

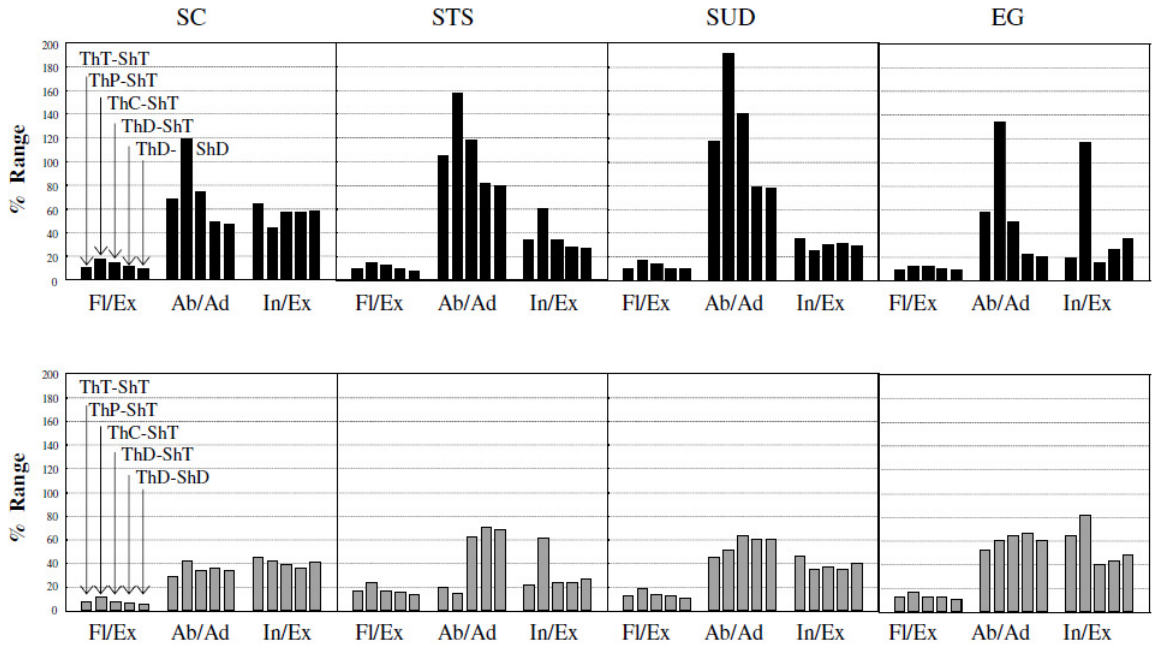


Figure 2.28: RMS difference of knee rotations between 3D fluoroscopy and those evaluated with each cluster combination (ThT-ShT, ThP-ShT, ThC-ShT, ThD-ShT and ThD-ShD) expressed in percentage of the corresponding range. Data are reported for both subjects (1 in black and 2 in grey). (Stagni et al., 2005)

Data (Figure 2.28) showed thigh markers moved considerably more than those of the shank. Additionally errors associated with flexion/extension were considerably lower than those of internal/external rotation and adduction/abduction. These RMS errors reached 117% of range for internal/external and 192% for adduction/abduction.

Another possible technique uses MRI. It does not have the issues of the other comparison techniques, such as invasive pins or exposing the patient to ionising radiation. One study aimed to develop a methodology to compare the 3D movement of the underlying bone and that of body segment external marker set using MRI (Sangeux et al., 2006). Patients were asked to perform a knee extension with three pauses before reaching full extension starting from a flexed knee position. The protocol was shown to result in good geometrical accuracy and reproducibility. The displacements associated with the thigh markers were in the range of 3-22 mm, and the shank markers were much lower at 0-4.5 mm. The errors associated with rotation were at a maximum of 15°.

The results of this study confirmed the previous reports that relative movement between the bone and the markers represents a major source of error which can highly compromise joint kinematics obtained by stereophotogrammetry.

One study compared eleven different marker cluster methods (Manal et al., 2000) to track the motion of the tibia. The study examined the effect of location (proximal vs. distal), physical characteristics (constrained vs. unconstrained) and the attachment method (underwrap vs. overwrap) relative to the body segment. The different marker clusters are shown in Figure 2.29.

Unsurprisingly the results showed that the lowest deviation was seen when the markers were placed distally on the shank. However the attachment method and physical characteristics did not show significant effect on rotational estimates. There were typical STA effects when using skin surface markers therefore they concluded that rigid supports can to be used to reduce this distortion. However

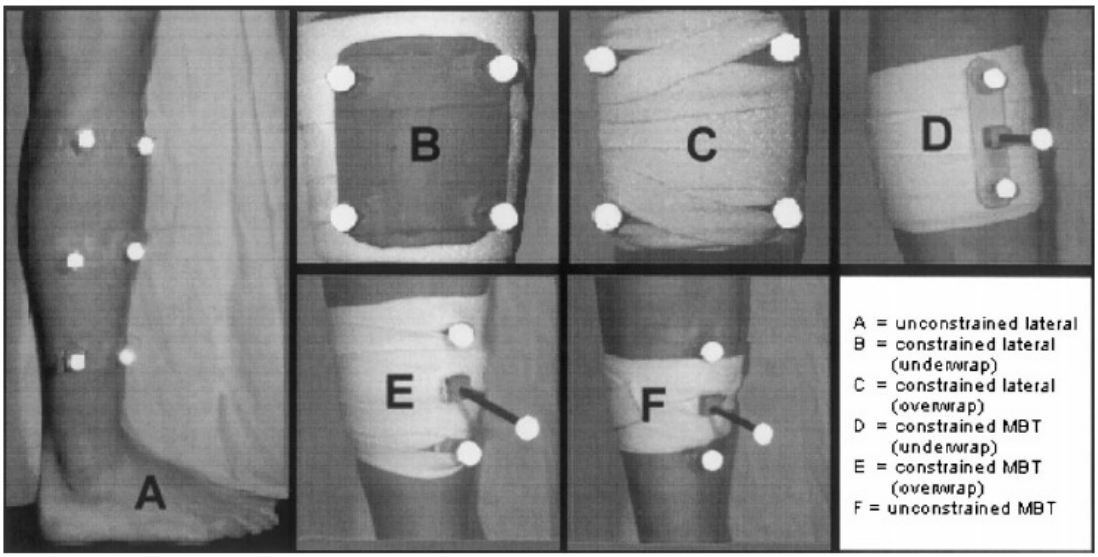


Figure 2.29: Illustration of the various marker sets tested in the marker cluster study. (Manal et al., 2000)

the marker clusters themselves may introduce systematic rigid artefacts associated with their own inertial effects and still does not guarantee a more rigid linkage to the bone (Leardini et al., 2005). Therefore they argued it was important to use minimisation and compensation techniques that are effective in reducing the propagation of deformation and preserve rigid motion of the marker clusters in line with the bone.

A Calibrated Anatomical System Technique (CAST) was developed (Cappozzo et al., 1995) to determine the AF. This technique needs a single static calibration of a number of ALs to identify their local coordinates relative to the Cluster Technical Frames (CTF). This was improved upon by Cappello et al. (2005) and in a study aiming to reduce STA propagation in knee rotations it reduced the RMS error on ab/adduction and internal/external rotation angles from 3.7°and 3.7°to 1.4°and 1.6° respectively (Leardini et al., 2005). The technique itself requires a double calibration of ALs. These two points are taken at the extremes in the range of the specific tasks and uses interpolation between the two configurations to find the ALs at other points during the activity. Although

the accuracy improves using this technique it requires additional time to set up and compute.

Another technique developed was to use dynamic calibration. The proposed idea was a subject and task specific assessment of STAs and for its compensation by means of a dynamic model of the CTF to AL relationship. Four markers were fixed to the pelvis by a rigid plate on a Milwaukee orthoses. Five additional markers were stuck directly on the skin of the thigh, and four on the skin of the shank. A standard CTF was associated with the pelvis, thigh, and shank segments, and another one to the thigh-shank segment (Lucchetti et al., 1998). Marker position data was collected in upright posture and during level walking at natural cadence. Then further tasks were performed with the knee locked in hyperextension with voluntary muscle contraction of hip flexion/extension, hip abduction and adduction, lower limb swing, hip and pelvis rotation.

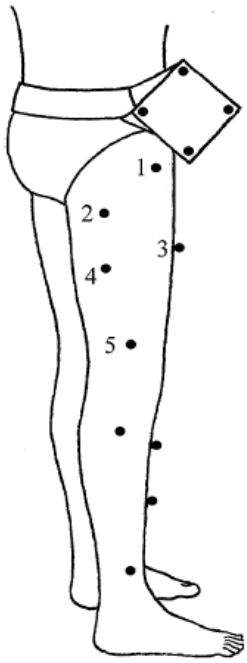


Figure 2.30: Marker locations using the dynamic calibration technique. (Lucchetti et al., 1998)

Using a locked leg posture and displacement positions the data was stored in an 'artefact table.' For each of the positions, the corresponding least distant

values in the artefact table were looked up and the corresponding artefact vector extracted for each thigh-shank based ALs of the femur. The final local positions of these ALs were then corrected by subtracting the corresponding artefact component. The newALs were the basis for the corrected AFs and from the new points the biomechanics of the lower leg was evaluated. Using this technique the knee joint translations had RMS errors of up to 14mm and knee joint rotations of 6°. When the rigid artefactual movement was also compensated for, then r.m.s errors were reduced to less than 4 mm and 3°.

Another lower limb segment pose estimation technique developed at around the same time was the Point Cluster Technique (PCT). This aimed to estimate lower limb segment poses using a large number of markers uniformly distributed on the analysed segment. Each was given an arbitrary mass and the centre of the mass and inertia tensor of the cluster are calculated at each time frame. The eigenvalues and eigenvectors of the inertia tensor are the principal moments of inertia and axes of the 'point cluster.' The change in mass at each frame gives an estimated position of the centre of mass which reflects the translation and rotation of the segment (Andriacchi et al., 1998).

A study using this technique (Alexander and Andriacchi, 2001) tested a patient fitted with an external Ilizarov fixation device attached to the bone. Simultaneous measurements from markers placed on the fixation device were compared to measurements taken from skin-based markers. This technique had reduced positional errors by 33% and orientation errors by 25% compared to the classic rigid-body technique.

Whilst this technique did improve the STA errors the main issue with the PCT in a clinical setting is that it requires a significant number of markers on each body segment. This will be very time consuming and may not be practical. However this technique may be limited by lack of knowledge on skin deformation modelling whilst others have suggested that this technique may be inaccurate for

tasks involving rapid movement and significant impact (Cappozzo et al., 2005).

All the techniques discussed so far treat each body segment separately without imposing any joint constraints, which resulted in apparent dislocations at joints due to STAs. A technique based on global minimisation of the weighted sum of squared distances between measured and model-determined marker positions has been evaluated (Lu and O′Connor, 1999). Joints were seen as perfect ball-and-sockets. This technique was validated by performing the different methods on known joint angles and joint centre positions (Results shown in Figure 2.31 and 2.32).

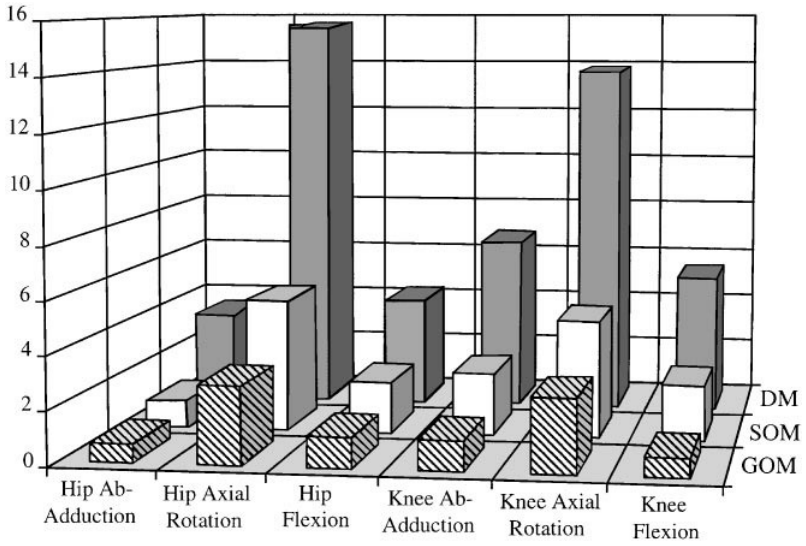


Figure 2.31: Ensemble time averaged errors (in degrees) of the calculated joint angles over the 20 trials. DM is the Direct Linking Method, SOM is the Segment-based Method and GOM is the Global Optimisation method. (Lu and O′Connor, 1999)

With the non-optimized technique of direct linking of external markers average hip and knee joint dislocations were 3.88 and 3.24 cm, respectively. With standard segment-based optimization techniques, the corresponding values were 1.33 and 0.69 cm (Lu and O′Connor, 1999). However using the Global Optimisation Technique the issue of joint dislocations was resolved automatically because joint constraints were included in the formulation. This was particularly evident in the huge reduction in errors of joint angles of ab/adduction and axial rotation.

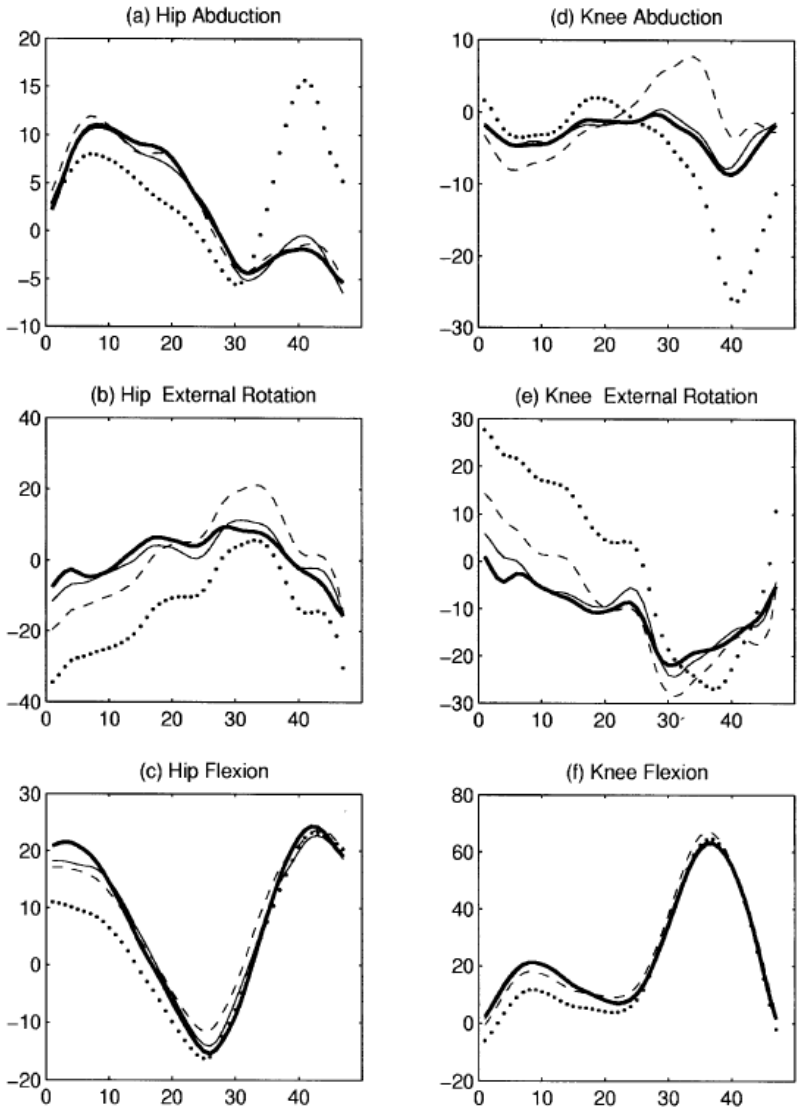


Figure 2.32: Results of the global optimization technique from a simulated trial. Calculated angles in degrees at the hip (a-c) and knee (d-f) joints by using original true values (thick solid lines), a basic direct linking method (dotted lines), a traditional segment-based optimization method (dashed lines), and the proposed global optimisation method (thin solid lines). (Lu and O′Connor, 1999)

The same global optimisation method was used in another study on a single healthy subject for 100 gait cycles. Here the optimised lower limb gait analysis (OLGA) technique (Charlton et al., 2004) was implemented and compared to the Vicon Clinical Manager (VCM) model. The VCM was an implementation of the Newington-Helen Hayes gait model. The study found an improvement in intra and inter-observer repeatability on the OLGA limb model indicated by signifi-

cantly lower standard deviations (S.D.s) in local marker co-ordinate (a measure of rigidity of the marker attachment), together with reduced S.D. in the estimated length of the bone segments. This lower S.D. reflects more accurate joint centre estimations.

While this technique has provided improvements to the previous models there is still a controversial assumption that each segment is connected via a ball-and-socket joint, whereas the lower limb joints are more complex. However it is very difficult to apply these to patients with substantial joint instability or deformity (Leardini et al., 2005). The inclusion of joint constraints into the overall estimation of the bony segments can still yield acceptable results in the movement analysis (Leardini et al., 2005). Whilst there are many different techniques and cluster configurations they all have pros and cons associated with them, therefore there is no consensus regarding a standardised method for testing motion analysis to give optimal results.

The final source of error mentioned is AL misplacement. These key ALs are used to define AFs, therefore any errors in AL location will compromise the accuracy of the kinematic and kinetic data. The ability to locate the bony landmarks accurately is also important in estimating subcutaneous points such as the hip centre (Croce et al., 2005).

The incorrect location of subcutaneous bony ALs through palpation can be caused by three main factors (Croce et al., 2005):

1. The palpable ALs are not points but surfaces, sometimes large and irregular;
2. A soft tissue layer of variable thickness and composition covers the ALs;
3. The identification of the location of the ALs depends on which palpation procedure was used.

In one study (Croce et al., 1999) demonstrated the inter and intra-variability of bony landmark placement. Six registered physical therapists with gait laboratory

	Intra-examiner			Inter-examiner		
Joint	ab-ad	int-ext	flex-ext	ab-ad	int-ext	flex-ext
Hip	2.5	5.3	3.9	5.2	5.6	5.0
Knee	1.7	5.8	1.0	5.2	10.4	3.7
Ankle	3.5	3.9	1.6	10.9	10.3	3.3

Table 2.3: lntra- and inter-examiner precision of the joint angles (RMS) during upright posture (values in degrees). (Croce et al., 1999)

experience served as examiners. The results showed a greater precision in the intra-examiner results than those of the inter-examiner precision. The range of intra-examiner marker precision ranged between 6 - 21 mm and inter examiner marker precision 13 - 25 mm. The inaccuracies in identifying the bony landmarks lead to errors in the AF orientation and therefore on the definitions of joint angles. Internal and external rotation angles were the most affected, with RMS values comparable to the range of motion of the joint itself (Table 2.3).

Other techniques used to find ALs include the use of medical imaging (Taddei et al., 2007). Using specific software the ALs can be selected at the surface of the bone model obtained from medical imaging. While this is much more exact in finding ALs, it's rarely used in 3D motion analysis laboratories. This is due to the lack of medical imaging equipment available in said labs, and the radiation exposure caused by implementing these techniques.

Donati et al. (2007) introduced an alternative anatomical calibration procedure referred to as UP-CAST. Instead of the manual location of prominent bony ALs, a large number of unlabelled points is acquired over prominent parts of the subject's bone using a wand fitted with markers. A digital model of a template-bone is then submitted to isomorphic deformation and re-orientation to optimally match the above-mentioned points. The locations of ALs are automatically made available using a virtual palpation technique (Donati et al., 2007).

The UP-CAST technique was verified on the femur of two volunteers and on

two bare femoral bones. Identification accuracy was assessed using the AL locations manually located on bare bones as reference. The results showed a very high repeatability using the UP-CAST technique compared to conventional palpation (ranges: 0.9 mm - 7.6 mm and 13.4 mm - 17.9 mm respectively). Not only did this technique achieve better repeatability, it also had a shorter application time, and was able to be effectively performed by non-skilled examiners. Another study by the same group involving 5 volunteers and 6 operators with no specific knowledge of anatomy also showed very repeatable results. They showed a limited dispersion of all angles (less than 3 deg) except for the hip and knee internal/external rotation (6° and 9°, respectively) (Donati et al., 2008). For the hip angles, and knee flexion-extension the inter-operator error was equal to the inter-trial error (ranging from 0.1°to 0.9°). Knee internal/external rotation and ab/adduction showed, on average, inter-operator errors, of 8% and 28% greater than the relevant inter-trial errors, respectively. The absolute error was in the range 0.9 - 2.9° (Donati et al., 2008).

While these results show high levels of repeatability there are still limitations for the UP-CAST method. The limitations of these studies are related to the morphological differences between the bone template of the subjects and the requirement that a thin layer of soft tissue cover the area that is being digitised. This prevents this technique being used with overweight subjects. Other issues that prevent it being used in a clinical and research environment are the need for a large database of bone templates and suitable equipment which are rarely found in the majority of gait analysis labs or clinical facilities.

As the studies have shown the precision of AL position has a large effect on joint kinematics. Therefore it is important to reduce these errors by aiming to identify the AL as accurately as possible (Croce et al., 2005)

2.6 Biomechanics

2.6.1 The Gait Cycle

The gait cycle refers to the time period in which one complete cyclic limb movement occurs during locomotion. As the motion is cyclic any point or event could be chosen to define the start of the gait cycle. However it is convenient to use the successive interval between two initial foot contacts (the point at which the first foot comes into contact with the ground). The major events in the normal gait cycle are shown in Figure 2.33.

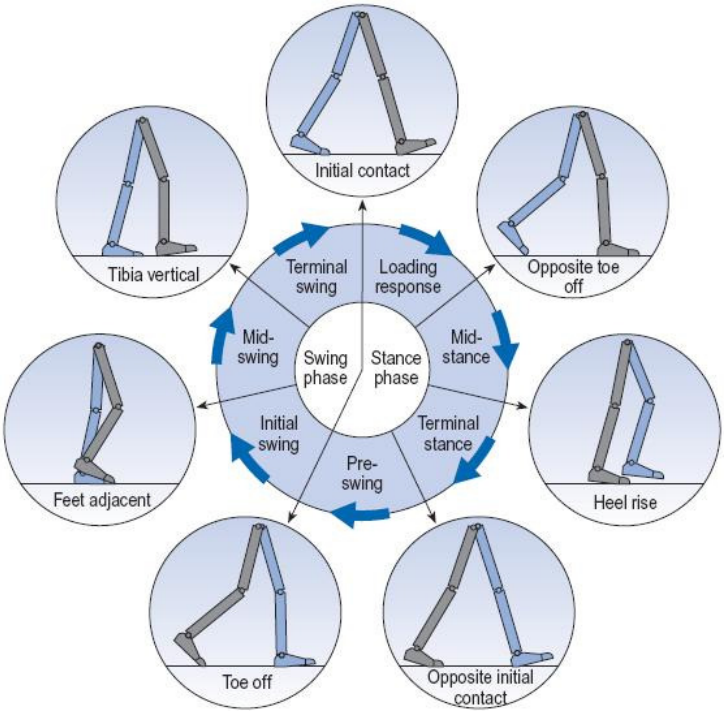


Figure 2.33: Major events in one gait cycle - *Right leg shown in grey.* (Whittle, 2007)

These seven major events can be categorised into two phases: stance phase (when the foot is in contact with the ground) and swing phase (when the foot is moving through the air). The events during the stance phase are: loading response, mid-stance, terminal stance and pre-swing. The events during the swing phase are: initial swing, mid-swing and terminal swing.

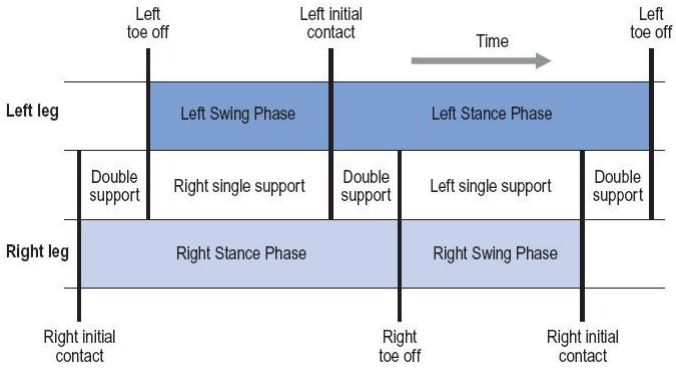


Figure 2.34: Timing of single and double support during gait cycle starting with right initial contact. (Whittle, 2007)

2.6.2 Normal Gait

As defined by Whittle (2007) for flexion-extension (sagittal plane movement) during normal gait the hip flexes and extends only once during the gait cycle. The limit of flexion is reached around the middle of the swing phase and the hip is then kept flexed until initial contact. The peak extension is reached before the end of the stance phase, after which the hip begins to flex again (Whittle, 2007). The knee shows two flexion and two extension peaks in the cycle. Before initial contact the joint is nearly fully extended. The first flexion response occurs during loading and the early part of mid-stance. The knee extends again during the later part of mid-stance then starts flexing again reaching the peak flexion angle during the initial swing phase. It extends again in preparation for the next initial ground contact. The ankle has a much smaller range of motion compared to the knee and hip joint. After initial ground contact the ankle plantarflexes, bringing the forefoot down onto the ground. During mid-stance the ankle becomes dorsiflexed due to the tibia moving forward over the foot. Before the opposite foot has initial contact a major plantarflexion occurs until just after toe off. During the swing phase, the ankle moves back into dorsiflexion until the forefoot has cleared the ground. Afterwards the ankle maintains a somewhat neutral position until the next instance of ground contact.

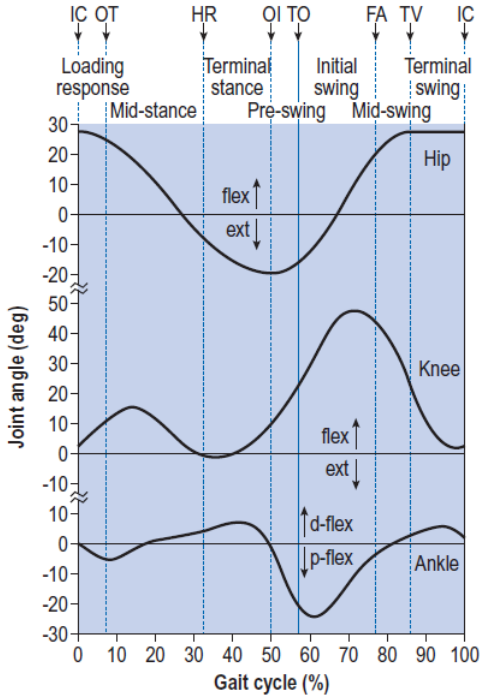


Figure 2.35: Sagittal plane joint angles of normal gait in degrees during one gait cycle. (Whittle, 2007)

2.6.3 Stair Navigation

Navigating stairs is a commonly performed locomotor task used regularly in day to day life. Kinematic and kinetic studies have shown that ascending and descending stairs requires larger ranges of knee flexion angle and knee flexion moment compared to level walking (Andriacchi et al., 1980). Stair negotiation also requires a higher amount of muscle strength and co-ordination than level walking.

A study comparing a TKA population with an age matched control group found patients one year after their surgery showed physical impairments and functional limitations when ascending stairs (Walsh et al., 1998). Their stair-climbing ability was 51% slower than the age matched group.

However, there is a difference in outcome between TKA and UKA. In a study by Weale et al. (2001) it was shown patients with a UKA had a superior functional recovery with a higher performance in descending stairs compared with TKA. However with UKA there are issues with implant accuracy, and any errors in

accuracy are even more pronounced in stair climbing due to the demanding nature of the task. Weinstein et al. (1986) evaluated the relationship between component placement, limb alignment, and function following UKA surgery. It was found that anatomic alignment, prosthetic positioning, and prosthetic design influence the patients' ability to walk and climb stairs (Weinstein et al., 1986). There were wide variations in the placement of the tibial and femoral component among the tested patients. The placement of the femoral component corresponded directly to function during stair climbing and level walking (Weinstein et al., 1986).

As stair negotiation is a more demanding task it may be able to accentuate the differences between the robotic and non-robitic UKA, particularly due to alignment. The improved implantation accuracy of robotic assisted surgery could prove significant in this task.

2.6.4 Sit to Stand

Sit to Stand (STS) movement is a very important task people undertake many times a day in order to change from a sitting position to a standing position and then often to walking. The STS movement is biomechanically demanding due to it requiring more lower extremity joint torque and range of motion than walking or stair climbing (Berger et al., 1988).

This is a significant task to analyse due to the intrinsic nature of the movement. As the patient's buttocks leave the seat the support surface reduces from three points (buttocks and each foot) down to two. The ground reaction force is transferred to the foot. The centre of pressure moves away from the centre of mass and it is at this critical point where postural stability is most challenged (Schenkman et al., 1990). Due to the nature of this task symmetry between joints is crucial in order to carry out this function efficiently.

Patients with lower limb impairment will naturally seek to adjust joint moments according to weakness and pain. This has been found in patients with knee

OA who alter the pattern of movement so that more load is placed on the hip joint, arms and opposite limb, thereby reducing the mechanical load on the knee joint (Su et al., 1998).

A study carried out on TKA patients by Boonstra et al. (2010) compared their loading symmetry ratio before and after their surgery against a healthy control group. Before surgery the patients with TKA did not fully load their affected leg, as measured by the loading symmetry ratio. The load was unevenly distributed to the unaffected knee. However after 1 year of recovery, the patients loaded both legs evenly, comparable to the control participants (Boonstra et al., 2010).

Studies carried out on stroke patients have shown that individuals with high symmetry ratios demonstrated faster STS times than individuals who were more asymmetrical (Lomaglioa and Enga, 2005). While that study in particular is an extreme case of the effects of asymmetry it still demonstrates the importance of restoring the operated knee to as close as possible to the non-operated knee.

2.6.5 Deep Knee Lunge

High flexion weight bearing activities are often done when performing tasks such as kneeling or sitting on the floor with legs bent. As it can be quite difficult task for some TKA to achieve angles of over 120° (Watanabe et al., 2008) it will be worth seeing how the different UKA knees perform in voluntary high flexion weight bearing activities.

2.7 Conclusion

From the literature review it can be concluded that UKA is a viable solution to early stage OA on one compartment of the knee. While TKA is widely accepted as an effective operation which relieves pain and restores function in the majority of cases, UKA can be an early intervention option that may provide a quicker

recovery, less blood loss and more bone conserved. This is also an advantage for the younger OA patient population who are generally more active. Surgical techniques have improved implant alignment over the past few decades and has led to increased longevity of the implant for TKA patients. Implant design has also improved due to a better understanding of the biomechanics of the knee that better mimics the normal knee biomechanics.

Robotic assisted UKA using the MAKO RIO tactile guidance system has been shown to give improved implant alignment. However it still needs to be shown if improved implant alignment necessarily leads to better functional outcome for patients compared to a conventional manual UKA. As this is still unclear, an in depth functional assessment comparing these two groups is required looking at patient biomechanics in a range of different tasks. Using motion analysis these differences – if any – can be seen and compared between these two groups.

2.8 Rationale for Study

The use of a robotic guidance system to help improve UKA implant alignment has potential to give better functional outcomes for patients with early stage unicompartmental knee OA. Using long leg radiographs it has been shown that UKA implants using a MAKO RIO tactile guidance system has more accurate implant alignment and with less outliers.

A large scale extensive objective functional assessment in which the function of the knee is recorded scientifically during activity has not been reported on these two surgical UKA groups. As the OA population of UKA patients tend to be younger there is more emphasis on functional outcome. This is because younger patients expect to be able to return to work, do recreational activities, play sports and other demanding tasks.

2.9 Aims & Objectives

The aim of this thesis was to compare the functional outcome of robot-assisted UKA and conventional UKA. Using motion analysis from Vicon a range of everyday activities including, level walking, sit to stand, stand to sit, stair negotiation and a deep knee lunge could be analysed to compare maximum flexion and extension, and active excursion during function. Additionally ground reaction forces are gathered to see if there are any differences between the two surgical groups.

2.10 Research Questions

1. Is there a functional difference between a conventional UKA group and a robot assisted UKA group when measuring knee kinematics using motion analysis during daily tasks?

2. Is there a functional difference between a conventional UKA group and a robot assisted UKA group when measuring knee kinetics using motion analysis during daily tasks?

3. Are UKA patients 1 year post operation comparable to normal age matched subjects?

4. Is there any correlation between the patient biomechanics and the patients questionnaire scores?

Chapter 3

Methodology

3.1 Subject Recruitment

The sample group for this thesis was formed from a larger group of patients that have had UKA surgery at Glasgow Royal Infirmary from 2010 to 2013 as part of a randomised controlled trial. Once voluntary written informed consent has been obtained from the patient the patient was allocated the next available patient evaluation number. If the patient failed any of the inclusion criteria (Section 3.1.1) for the evaluation the patient did not advance any further into the evaluation. The exclusion criteria (Section 3.1.2) were then applied and patients who met any of these criteria were then excluded. These patients were randomised to receive either a conventional Oxford UKA, or a robotic assisted Mako UKA. Information about the full trial is given in Appendix A. Exclusion

One year after the patients received their UKA they were contacted via telephone and asked if they wished to take part in an assessment at the University of Strathclyde. If they accepted, they were booked in for a session at the Strathclyde Bioengineering Unit. This assessment was included in the study protocol, thus the ethics were covered in the overall trial at Glasgow Royal Infirmary. The subjects for this study were seen for their one year post-op functional testing over

a 16 month period between December 2011 - April 2013.

A total of 139 knees were recruited for the overall study, and the first 89 patients in the series were contacted by phone, which the time of writing had been seen for their one year post-operative assessment at Glasgow Royal Infirmary. A total of 22 patients out of the 89 did not want to take part in the functional assessment tasks at the University of Strathclyde resulting in 67 knees. From these 67 knees, 16 had to be excluded from the final data set due to technical issues, leaving 51 knees in this study. This resulted in a final sub-group of 23 Mako knees and 28 Oxford knees in the group analysis.

3.1.1 Inclusion Criteria

- Male or female subjects may be recruited to the evaluation
- Age - there are no restrictions relating to age of the patient. The patient's age must be considered suitable by the clinical investigator for a uni-compartmental knee arthroplasty using either of the two systems available in the evaluation.
- Subjects who are able to give voluntary, written informed consent to participate in this investigation and from whom consent has been obtained.
- Subjects who, in the opinion of the Investigator, are able to understand this investigation, co-operate with the investigation procedures and are willing to return to the hospital for all the required post-operative follow-ups.
- Subjects who require a uni-compartmental knee arthroplasty for primary surgical management of idiopathic osteoarthritis.
- Patients who in the opinion of the Chief Investigator are considered to be suitable for treatment with a MAKO and OXFORD uni compartmental knee replacement.

3.1.2 Exclusion Criteria

- Patients who, in the opinion of the Investigator, have an existing condition that would compromise their participation and follow-up in the study.
- Patients who require revision knee arthroplasty surgery.
- Patients with any tibial deformity requiring tibial component augmentation.
- Patients whom, in the opinion of the Chief Investigator, require a total knee prosthesis.
- Patients with inflammatory polyarthritis.
- Disorders of the feet, ankles, hips or spine causing significant abnormal gait or significant pain
- Neurological conditions affecting movement
- Patients with a pathology which, in the opinion of the Chief Investigator, will adversely affect healing.
- Patients with other disorders which, in the opinion of the Chief Investigator, will/could impair rehabilitation.
- Contra-indications for use of the device, as detailed in the package insert.
- Women who are pregnant. If there is uncertainty over pregnancy then a pregnancy test will be conducted.
- Subjects who are known drug or alcohol abusers or with psychological disorders that could effect follow-up care or treatment outcomes.
- Subjects who are currently involved in another clinical study with an investigational product.
- Subjects who are currently involved in any injury litigation claims.

3.2 Biomechanical Analysis

3.2.1 Choice of Equipment

As the aim of this thesis was to compare the functional outcomes between two different types of UKA, it was important to acquire a quantitative assessment of human movement in order to answer the aims of the research. There are many different methods of obtaining such data, however for the purposes of this study it was decided that a camera based motion capture system would be used.

An in depth review of motion capture systems as a whole was presented in Chapter 2.5. However there are specific reasons why a camera based technology was chosen for this particular study. The main reason is that this is the current gold standard in capturing quantitative human movement, and it would be one of the most sensitive ways of seeing if there are any differences in motion between the two groups. Another advantage is that the marker system does very little to impede natural human movement. All the markers and marker clusters are very lightweight, therefore they should allow the subject to perform the tasks naturally. Another advantage for the subjects is how quick the set up time is. It takes only a few minutes for the lower limb marker set to be attached, and a static pose to be taken. Once all the markers are attached, and the initial calibration pose is complete, the data collection can proceed uninterrupted.

The hardware used for such purposes is also very accurate, and Chapter 2.5 has shown that most of the errors come from STAs and AL. This hardware has been used for much more precise applications, for example the use of the Vicon system has been used in providing real-time feedback for quad-copters performing cooperative ball throwing and catching (Ritz et al., 2012).

Additionally the software is very simple to use and data collection is very fast. Running pipelines on the patients' data is very simple, and can be done in bulk which speeds up mass data collection. Another very big advantage is that the

files generated by the Vicon system (.3cd files) can be integrated with Matlab, therefore Matlab code can be run on the dataset in order to organise all the data collected very quickly.

A general disadvantage to motion capture systems is their high cost, however a Vicon Motion Capture System already exists within the University of Strathclyde Bioengineering Department, so for this study it is not an issue. The errors inherent with this system has been discussed thoroughly in Chapter 2.5, and also discussed are measures that can be taken in order to minimise them as much as possible. One issue that subjects may experience with this system is that it requires them to wear skin tight clothing in the form of a lycra cycling suit (provided) in order to attach the markers accurately. Some patients may feel self conscious about wearing such clothing, however these patients may opt to wear shorts instead. If the markers are not blocked by the clothing, the data capture should have no issues.

On balance the Vicon Motion Capture System was considered the most favourable system to use for this study. While there are strengths and weaknesses of this system overall it will answer the specific aims of the research.

3.2.2 Kinematics

One year post-operation the patients underwent a biomechanical assessment at the University of Strathclyde Biomedical Engineering Department. The system used for this was a VICON Nexus motion analysis system (Oxford Metrics Ltd., UK) with twelve infra-red cameras, 6 x T40 and 6 x T160 (The T40 camera is 4 megapixel resolution and T160 is 16 megapixel resolution) powered by two MX Giganet servers was used to collect optoelectronic photogrammetric data for biomechanical evaluation. The cameras are mounted onto rails and permanently fixed in place in a space approximately 6 metres in length (Figure 3.1). This data is sampled at a rate of 100Hz.

The camera positions were fixed in order to give optimal performance for gait analysis and eliminated the need to move them each time a new patient came in for evaluation (Figure 3.2).

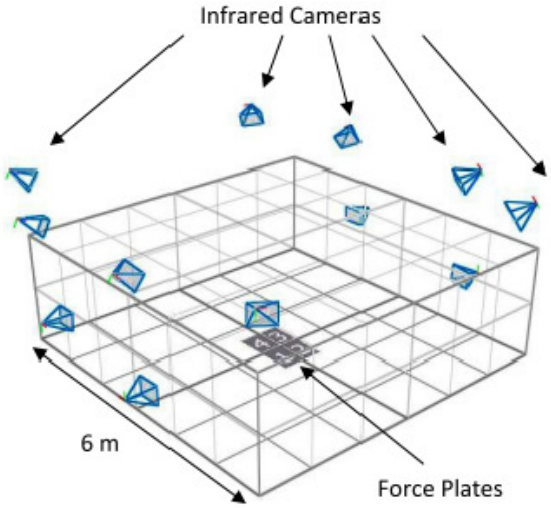


Figure 3.1: Schematic of gait lab

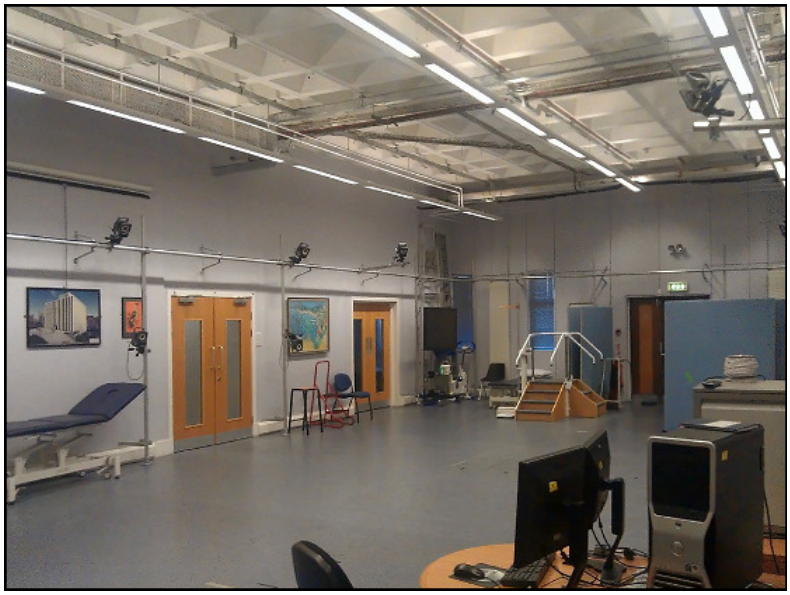


Figure 3.2: Gait lab

The video data is channelled through two MX Giganet servers (Figure 3.3) and shown visually through the Vicon Nexus software on a Dell computer.

Before each test session the lab was set up and calibrated to establish the global reference frame. The calibration tool was a wand (Figure 3.4) that is used

Figure 3.3: Vicon MX Giganet servers

for both static and dynamic calibration.

Figure 3.4: Calibration wand

Individual markers and marker clusters (Figure 3.5) were used to mark anatomical reference points and limb segments. Markers were arranged in four and glued onto a thermoplastic mould oval structure. One for the thigh and one for the shank. These were attached to the skin using double sided tape. An additional waist marker was attached to the small of the back and secured in place by both double sided take and a strap to limit movement. Individual markers were used on the foot at certain points to define the foot segment, and also at different bony prominences on the leg. This data is used to construct an anatomical model of

the patients underlying bone structure. Pictures of the marker set used for this model is shown in Figure 3.6.

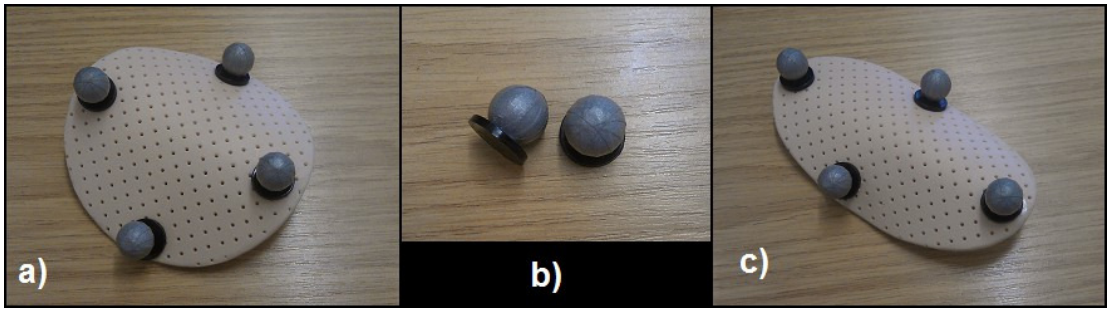


Figure 3.5: Marker clusters for thigh (a) individual 14mm markers (b) and shank clusters (c)

Figure 3.6: Pictures of marker set used for data capture

3.2.3 Kinetics

Four force plates (Kistler Instrumente AG, Switzerland) were used to obtain the ground reaction forces during the patient tasks (Figure 3.7). They were mounted level with the floor and each force plate is embedded within metal frames resulting

in them being completely independent of one another. Before each trial the force plates were zeroed to remove residual electronic outputs. The data was collected on the force plate panels (Figure 3.8) and sent to the Vicon Nexus software on the PC. The data output from the force plates are $F_{(x,y,z)}$;$M_{(x,y,z)}$.

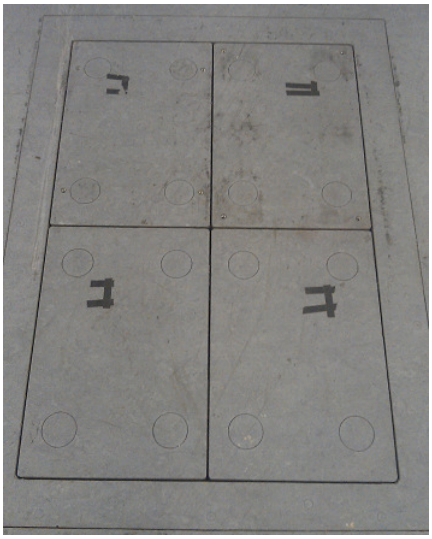


Figure 3.7: Kistler force plates

Figure 3.8: Force plate panel

In addition a custom staircase with instrumented force plate steps (Figure 3.9) were used for kinetic and kinematic analysis for analysing stair climbing, and lunging. The step that provides force readings is the second step in the series of four. Therefore the step platforms providing readings are structurally independent from the staircase apparatus. Therefore the only data acquired will

Figure 3.9: Staircase

be from the instrumented step and the ground. The step height of the stairs are 185mm and the tread depth is 280mm. This is similar to those cited in published literature (Protopapadaki et al., 2007). Additional features include bilateral handrails and a platform at the top of the forth step to allow turning.

3.3 Biomechanical Model for Gait Analysis

The biomechanical model used in this project was of a lower limb model developed at the University of Strathclyde for a study on stroke rehabilitation (Papi, 2012).

In this model the global reference frame is defined as:

- x-axis: forward (anterior), relating to the direction of movement in the locomotor activities
- y-axis: Vertically up, orthogonal to the x-axis
- z-axis medio-lateral positive pointing to the right

This global frame reference is consistent with the International Society of Biomechanics recommendations (Wu et al., 2002).

The lower limbs are modelled as seven rigid segments:

- The pelvis
- Left and right thigh
- Left and right shank
- Left and right foot

AFs of reference are associated to each segment and reconstructed from the known position of identifiable ALs. AFs are defined to meet the requirements of intra and inter-subject repeatability (Cappozzo et al., 2005) and in accordance with the International Society of Biomechanics (ISB)). The palpable ALs used for the purpose of AFs definition are:

- Anterior iliac spine (ASIS)
- Posterior iliac spine (PSIS)
- Lateral and medial epicondyle (LE, ME)
- Lateral and medial malleolus (LM, MM)
- Calcaneus (CA),
- First and fifth metatarsal head (FM, VM).

These points can be identified in both sides of the lower body through palpation following the guidelines from the Vakhum EU project (Sint et al., 2002). However the build an anatomical lower limb model the locations of the internal anatomical points also need to be found. These points are:

- Hip joint centre (HJC)
- Knee joint centre (KJC)
- Ankle joint centre (AJC)

In order to determine the 3D hip joint centre a method developed by Harrington et al. was used. This method was shown to perform reliably in comparison to an ultrasound and was more accurate than most widely used predictive methods (Harrington et al., 2007). It's based on pelvic depth (PD) and width (PW), therefore the identification of posterior and anterior iliac spine on the patient is all that's required to locate the hip joint centre. This is also advantageous from a practical point of view as other methods require the identification of the pubic symphysis on the test subject, which can be an awkward point to identify. The 3D position of the hip joint centre is estimated with the following equations (in mm) for the right leg:

$$\begin{aligned} x &= -0.24PD - 9.9 \\ y &= -0.30PW - 10.9 \\ z &= 0.33PW + 7.3 \end{aligned} \tag{3.1}$$

x, y, z in Equation 3.1 are relative to the reference frame from Table 3.1. The left hip joint centre is determined in the pelvis by making the z-coordinate (mediolateral) negative from the equation (3.1). The knee joint centre on the other hand is determined as the mid point between the medial and lateral femoral condyles. Similarly the ankle mid point is referenced as the mid point of the medial and lateral malleoli.

The marker set used for this biomechanical model is shown in Figure 3.10. This marker set is designed to allow the definition of the AFs, but also makes other considerations in order to minimise soft tissue artefact movement (which as discussed previously is the biggest source of error in motion analysis). For this reason rigid clusters were used to identify bone segments during locomotor tasks rather than single markers on the skin. Additionally the least STAs were found at the distal part of the segments (Cappozzo et al., 2005), therefore they were

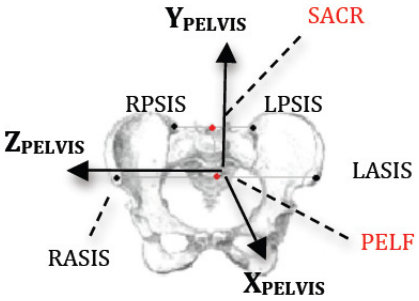
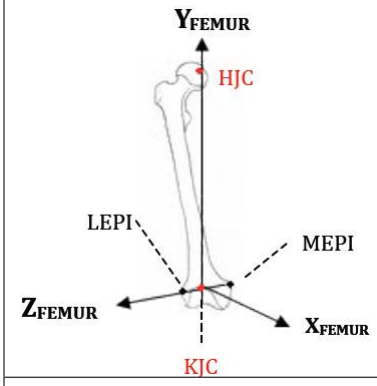
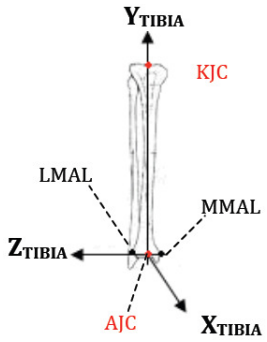
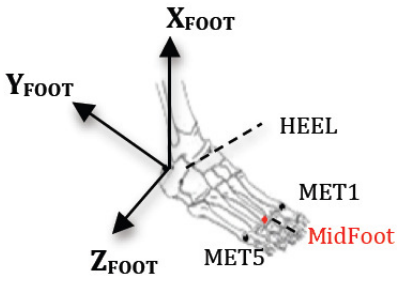
	• Origin: Midpoint between LASIS and RASIS • Anteriorposterior (x) axis: Mutual perpendicular to the other two axes • Mediolateral (z) axis: In direction from LASIS to RASIS • Vertical (y) axis: In direction from LASIS to RASIS • Virtual points: HJC (left and right) defined as for Harringtons et al (2007) SACR midpoint between PSIS PELF midpoint between ASIS
	• Origin: KJC (left and right),midpoint between lateral (LEPI) and medial (MEPI) epycondyles • Anteriorposterior (x) axis: Perpendicular to y-axis and the line in the right direction joining LEPI and MEPI • Mediolateral (z) axis: Mutual perpendicular to the other two axes. • Vertical (y) axis: In direction from KJC to HJC • Virtual points: Left and right KJC as defined above
	• Origin: AJC (left and right), midpoint between lateral (LMAL) and medial (MMAL) malleoli • Anteriorposterior (x) axis: Perpendicular to y axis and the line in the right direction joining LMAL and MMAL • Mediolateral (z) axis: Mutual perpendicular to the other two axes • Vertical (y) axis: In direction from AJC to KJC • Virtual points: Left and right AJC as defined above
	• Origin: Left and right HEEL • Anteriorposterior (y) axis: In direction from MidFoot to HEEL • Mediolateral (z) axis: Mutual perpendicular to the other two axes • Vertical (x) axis: Perpendicular to y-axis and the line in the right direction joining MET1 and MET5 • Virtual points: MidFoot, midpoint between first (MET1) and fifth metatarsal (MET5) markers

Table 3.1: Definitions of AFs

placed on the distal parts of the shank and thigh.

The two clusters for each limb were made by attaching four 14mm diameter spherical reflective markers onto a rigid curved thermoplastic plate as recommended (Cappozzo et al., 1997). The markers were attached directly to the shank or thigh using double sided tape and secured into position using porous tape over the thermoplastic plate. The cluster positioned at the back was secured also using double sided tape, but also by a waistband. Porous tape was also used to secure the cluster into position. The foot segments were identified by placing single 14mm markers directly on the patients foot or over their footwear at ALs (1st and 5th metatarsal head and calcaneus) using double sided tape. STA is a lot less troublesome on the foot therefore markers can be placed directly on these points.

3.4 Procedure

Subjects were systematically involved in data collection over a 16 month period (December 2011 - April 2013). A functional testing session 12 months post-operatively in the Biomedical Engineering Department at the University of Strathclyde is conducted.

On arrival subjects were provided with cycling shorts in preparation for their functional assessment. Baseline measurements of height and weight were taken and all test procedures were explained before starting the trials. The subjects were also given opportunities to ask questions. The patients were asked to do the test in comfortable shoes, however if they wished to do the test barefoot they were also allowed to do so. Each test the patient performed was self paced.

Prior to subject data collection, various calibration protocols were carried out in the biomechanics laboratory in order to calibrate the instrumentation for use. The calibration wand (Figure 3.4) was used for both dynamic and static

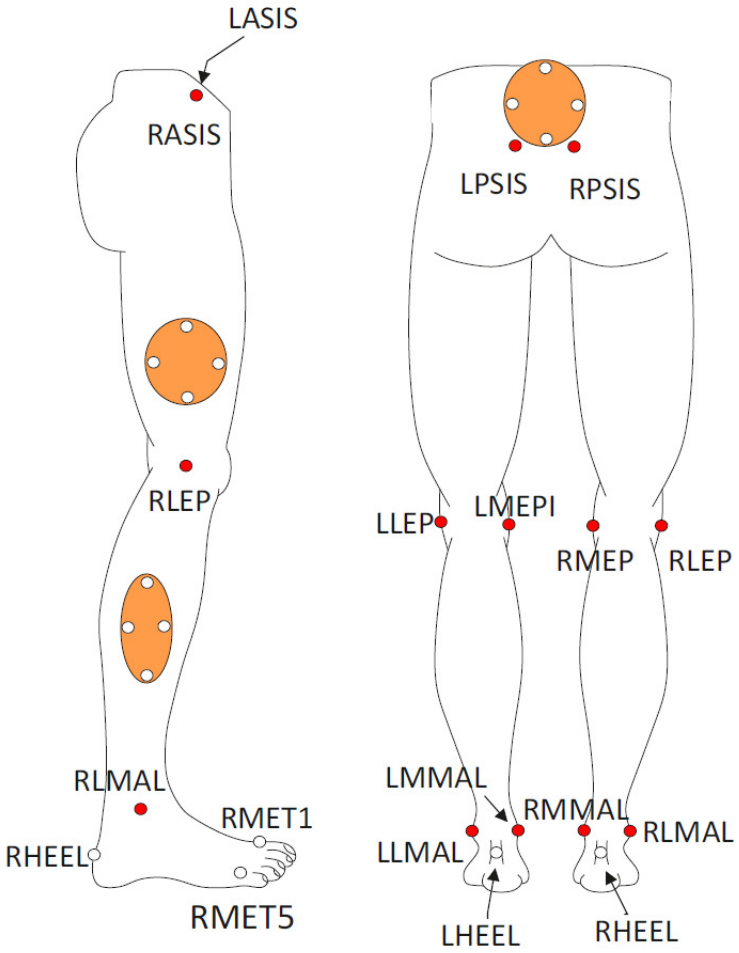


Figure 3.10: Marker set used for this biomechanical model

calibration. The dynamic calibration was done by moving the wand through the capture volume where the subjects would be performing the locomotor tasks, including the area where the stair trials would be conducted. This calibration procedure is done to calibrate the cameras in preparation for the dynamic marker data.

The next step was the static calibration. This method involves a still capture of the wand positioned in the centre of the capture volume with the flanges fixed in the gap between the force plates (Figure 3.11). The wand referenced the origin of the lab (x, y, z = 0, 0, 0) and defined the direction of the orthogonal axes of the global co-ordinate system (Table 3.2) (Figure 3.11). This global frame definition is consistent with the International Society of Biomechanics (lSB) recommendations

Origin	Centre of four force plates
x-axis	Forwards (anterior), relating to the direction of movement in the locomotor activities
y-axis	Vertically up, orthogonal to the x-axis
z-axis	Pointing to the right of the direction of movement. Orthogonal to x and y axis

Table 3.2: Axis definition for the global co-ordinate system

(Wu et al., 2002) and is widely used in the biomechanics community (Cappozzo et al., 2005).

Figure 3.11: Calibration wand defining the global co-ordinates

3.5 Data Analysis Methods

The raw motion analysis data was manipulated and processed using Vicon Nexus 1.7. Markers were then labelled using a custom written marker set file. Additionally events were labelled in the software for 'foot strike' and 'foot off' for each limb on the walking and stair ascending and descending tasks. The specific frames that these events occurred at is used later to define the start and end of the cycle for each task. These frames were identified by two means. The simplest

was by using the force plate data every time the foot came into contact. Foot strike was given by the frame number at which the ground reaction force increased above zero; while foot off was defined by the frame number at which the ground reaction force returned to zero. This is all that is needed for the stair navigation tasks because there is a force plate at each stage during these tasks. However during level walking the second foot strike that is used to denominate the end of the cycle does not come into contact with a force plate. For this stage a second method of finding this point is used. Foot strike in this instance is located at the point at which the foot segment decelerates and ceases forward translation of the heel marker.

In order to measure the weight distribution of each leg during the sit to stand activity, an event was labelled when the back cluster marker was vertical and stopped accelerating. This would indicate the point at which the patient had completed their movement and was fully standing. This marker was to calculate the end point of the movement so the average weight distribution could be calculated from start to finish.

The lunge activity was defined from the point at which the foot first touched the force plate, and when the foot left the force plate in a similar way to how 'foot strike' and 'foot off' were labelled during walking and stair activity. With these two defined points the maximum achieved angle could be calculated during this activity.

After the marker labelling and identification of events, the markers underwent inspection for missing markers. If there were any missing markers the gap-fill function on the software replaced them. Secondly the makers were investigated for any erratic marker movement. This can be done visually, but this can also be done by looking at each marker on its trajectory graph. If there are any unusual spikes (and this can be checked in relation to the other markers on the same cluster) then the erratic section can be removed, and that section can be replaced

Raw BodyBuilder Output Variables
Left Hip Angles (x,y,z)
Right Hip Angles (x,y,z)
Left Hip Moments (x,y,z)
Right Hip Moments (x,y,z)
Left Knee Angles (x,y,z)
Right Knee Angles (x,y,z)
Left Knee Moments (x,y,z)
Right Knee Moments (x,y,z)
Left Ankle Angles (x,y,z)
Right Ankle Angles (x,y,z)
Left Ankle Moments (x,y,z)
Right Ankle Moments (x,y,z)

Table 3.3: List of data variables output from BodyBuilder code

by copying the pattern of movement relative to the remaining markers that are not behaving unusually.

After inspecting all the markers for each task a further smoothing of marker trajectories was done using a Woltring filter. This is included as a plugin on the Vicon Nexus software. All the unlabelled trajectories are automatically removed and then the marker data was filtered using a MSE filter value of 15, as recommended for gait analysis (Peters et al., 2009).

The next step in the Vicon Nexus pipeline is to perform the 'Dynamic Body Language Modelling.' Essentially this is a BodyBuilder code used to output 3-dimensional angles and external inter-segmental moments of the right and left limb. Each output variable is listed in Table 3.3.

The code calculates the position of the lower limb joint centres from the ALs referenced by the markers. By joining these joint centres, the code created a 'stick figure' representing the subject. Joint angles were calculated from the relative position of the proximal and distal segments of each joint. The moments for

each segment were calculated using inverse dynamics. The mass of the individual was included in the analysis, thus the inertial properties of the segments were accounted for within the calculations.

Once the data were processed the .c3d file was read in Matlab using BTK Matlab Wrapper. This is open source software that allows Matlab manipulation and data extraction of .c3d (Barre, 2013). In Matlab the timestamps for each foot strike was used to extract one gait cycle for the limb being analysed. This was done for level gait trials and stair gait during ascent and descent trials. Each task was repeated three times and then averaged. However as the tasks are self paced each patient performed the tasks at different speeds. For this reason the data needed to be aligned, or normalised. The most common technique for temporally aligning gait data is by expressing the data in percentages, from 1 to 100%, of the gait cycle. This approach linearly expands or compresses the time axis of each gait cycle, such that all gait cycles have the same length. The average data set for three trials for right and left lower limbs is output over 100 points. The data was then exported by Matlab to create graphs that averaged the data per group and compared the two for each variable in each task.

3.6 Other Data

While this work focused mainly on the biomechanics of these patients, there is a body of data that there is access to, which can be used in this project. However only specific data will be used to answer questions that need to be answered within the scope of this project.

A very important question that needs to be answered is if the manual Oxford implants have been implanted accurately or not. As the robotic assisted implants claim to be put in very accurately, it is important to ascertain that this project compares 'well placed' robotic-assisted UKA implants with 'well placed' manual

UKA implants. Therefore in order to answer this question access was needed to post-operative scans that measure the positions of the implants. These implant positions can then be compared against the recommended criteria from the manufacturer in order to answer this question and see if the comparisons between the two groups is valid.

Another research question was to see if the patients undergoing UKA were comparable to age matched normal subjects. The University of Strathclyde has an archive of healthy subjects of which 50 knees had undergone walking trials using motion capture, and is readily available. As they were both done using the university's own motion capture system, they could easily be compared to the data that was collected in this biomechanical UKA study.

Additionally it was possible to assess any correlation between the patient biomechanics and their questionnaire scores. The American Knee Society Score (AKSS) and Oxford Knee Score (OKS) data is readily available from Glasgow Royal Infirmary. Additionally there was other information that was accessible such as analgesic use, which can be used to see if the two groups received the same pain medication as to not result in any bias.

3.6.1 American Knee Society Score (AKSS)

The American Knee Society Score (AKSS) is a knee scoring system developed by The American Knee Society that scores "the knee joint" itself and a "functional score" that rates the ability of the patient to walk and climb stairs (Appendix B). This splits the scores into two sections, knee rating and function.

The "knee rating" is based on three parameters, pain, stability and range of motion. A perfectly scoring knee (well aligned knee with no pain and 125° of motion and negligible anteroposterior and mediolateral instability) will score 100 points. 50 points are alloted for pain, 25 for stability and 25 for range of motion. Any flexion contracture, extension lag and misalignment results in deductions.

The "function score" considers only walking distance and stair climbing ability. The maximum score for the function is also 100 and awarded to a patient who can walk an unlimited distance and go up and down stairs normally. 50 points are given in total for walking ability with 10 points per block (approx. 100 metres) with the limit at 50. Another 50 points will be given for being able to walk up and down stairs without using a hand rail, with deductions for amount of rail support needed. Final deductions are given for the use of walking aids. It's theoretically possible to get a negative mark on the function score, which if it happens the score is given as zero.

3.6.2 Oxford Knee Score

The Oxford Knee Score (OKS) is a 12 item self-completed patient based outcome score (Appendix C). It was originally intended to be used in large randomised controlled trials for patients that had received a TKA (Whitehouse et al., 2005). This questionnaire aimed to assess the levels of knee pain and function entirely from the viewpoint of the patient. The questionnaire was designed to be short, practical, reliable, valid and sensitive to clinically important changes (Whitehouse et al., 2005).

Each of the 12 questions in the questionnaire is scored from 1 to 5. Lower scores indicate less pain and higher scores indicate more pain with 1 being no pain, and 5 being severe pain. The final scores are calculated by adding all the item scores together to give an overall score of between 12 and 60, with the *lower* number indicating better overall score. A score of 12 implies no pain or limitation and 60 implies severe pain or limitation.

3.7 Statistical Analysis

The biomechanical data was imported and organised in Matlab, and then exported into the statistical programme IBM SPSS Statistics, an industry standard statistical package that is commonly used for statistical analysis. Each comparative test was first given an Anderson-Darling (AD) test in order to ascertain if the data were normally distributed. If the data were not normally distributed, the Mann Whitney (U) test was used to analyse any statistical differences between. If the data were normally distributed then the comparison used a two tail independent t-test. The alpha level was set at 0.05. The null hypothesis H_0 = no difference between the two surgical groups, and this hypothesis was rejected only when $p < 0.05$. Other group differences such as gender differences, operated knee, and age were evaluated by using the Chi Squared Test.

If there were any specific significant differences in the biomechanics between the two surgical groups they could be compared to questionnaire scores as they are used routinely as a measure of functional outcome after knee replacement surgery. In this case regression analysis was used to investigate whether one variable could predict another variable. The coefficient of determination r^2 ranges from 0-1, and was calculated to show the statistical measure of how well the regression line approximates the real points.

Chapter 4

Results

4.1 Introduction

This chapter presents the results obtained with the methodology described in Chapter 3. The first section will consist of a case study, in which the full kinematics and kinetics are presented for each lower limb joint in the 3 axes for walking, ascending stairs, and descending stairs. A table summarising sagittal plane maximum, minimum and excursion angles for each of these three tasks will also be shown, as well as the stance/swing percentages. The weight balance and knee flexion/extension angles will also be presented in the sit to stand task. Additionally the knee flexion/extension angles and maximum achieved knee angles attained in the deep knee lunge task will also be presented.

The purpose of the case study is to introduce a typical data set, i.e. a patient with a UKA in one knee, and a normal opposite knee. Following the case study a group data inclusion section will be presented, discussing any modifications to the Oxford and Mako groups from Chapter 3. After this the full results of the two groups will be presented. Therefore the case study serves the purpose of stating what data shall be included and presented in the rest of the chapter for the group as a whole.

4.2 Case Study

This case study refers to a 63 year old male of 70kg body mass and 1.74m height. He was recruited into the study in November 2011 and randomised into the Mako group for treating osteoarthritis in his right knee. The randomisation assigned him to 'ID 131'. His operation was performed in December 2011 and he was seen for his biomechanical analysis at the University of Strathclyde Biomedical Engineering unit in January 2013.

4.2.1 Patient History

In June 2011 this patient was seen by a physiotherapist due to complaints of pain in his right knee. He had a 3 year history of medial knee pain which started when he was twisting and turning whilst stripping wallpaper. He described a medial ache in his knee which is brought on when he's walking. The pain occurred after approximately 50 yards of walking, but the pain did not restrict him in the distance he could walk. He used Paracetamol intermittently to deal with the pain. He enjoyed gardening and walking, both of which he felt were being curtailed due to his knee pain.

On examination of his knee he had a low grade effusion. He had a full pain free range of movement within the knee and his ligaments were stable in testing. His patellar restraint test was negative. In standing there was a natural physiological bowing of his tibia and a mild varus deformity of some 5° which was correctable on lying supine.

From the x-rays (Figure 4.1) it was clear that he had significant medial compartment wear, but the other 2 compartments appeared to have been spared.

After the analysis and tests the patient felt he was coping reasonably well and felt on balance that he did not wish to have any surgery at that time. He was told to return for another review if his symptoms progressed any further.

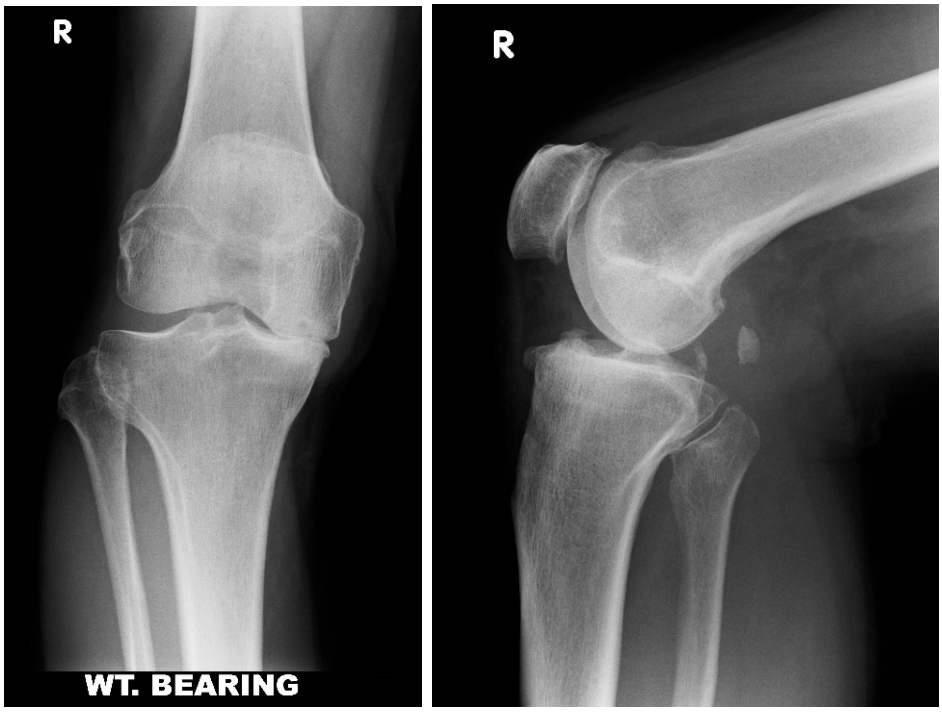


Figure 4.1: X-ray of Patient ID 131's pre-op weight bearing right knee in the A/P plane(left) and sagittal plane (right)

3 months later in September he had returned to see a physiotherapist and was very keen to undergo arthroplasty. He did not have any pain during rest or at night, however he had mechanical pain immediately on weight bearing. His walking distance was significantly curtailed with increasing pain beyond 50 yards, and his pain was localised to the medial side of the knee. He struggled on descending hills and stairs due to the medial pain.

On this examination he did not appear to have significant effusion. He had a well preserved knee range of movement from 0 - 120° and a fixed varus deformity of 5 - 7°. There was also tenderness on palpation around the postero-medial joint line. As the x-rays had shown he had significant medial compartment disease and by this point feels his quality of life is being impeded.

He was told he would be a suitable candidate for a UKA as the patello-femoral and lateral compartments were well preserved. His name was added to the waiting list.

The following month in November he was seen in a pre-op clinic. He had a

constitutional varus as well as intra-articular varus from his arthritis. He was a slim patient, but fairly fit and healthy.

It was explained to him that a UKA may give a good functional result but will only correct him back to his constitutional state. He was also made aware that any knee replacement has a finite lifespan and he may require a revision in the future. The risks and benefits of the surgery were explained to him specifically mentioning infection, stiffness, persisting pain, failure, as well as generalised complications following any major surgery. He was happy with this and had given informed consent.

He was still keen to go ahead with the surgery and was randomised to the MAKO group. His surgery was scheduled for December 2011.

After a successful operation he was seen on March for his 3 month post-op. He said he was "absolutely delighted" with the outcome of his surgery. He had been mobilising independently and experiencing only occasional mild pain. He experienced some stiffness on waking up and occasionally gets some heat and swelling if he has done a prolonged period of exercise. He said it resolved quickly with elevation.

On the examination his wound was found to be clean, dry and well healed. He had a good range of motion of 0 - 135° of active knee flexion with a good straight leg raise. Follow up x-rays (Figure 4.2) showed good implant alignment.

The patient was seen again in December 2012 for his 1 year post-operative assessment. He had been mobilising independently and was still delighted with the outcome of his surgery. He has returned to full activities at home including quite strenuous DIY activities, as well as taking walks. He experiences only occasional discomfort from his knee, which resolves rapidly and does not require him to take any analgesia.

On the examination he had a good range of motion of 0 - 135° of active knee flexion with an excellent straight leg raise. New x-rays gave no cause for concern,

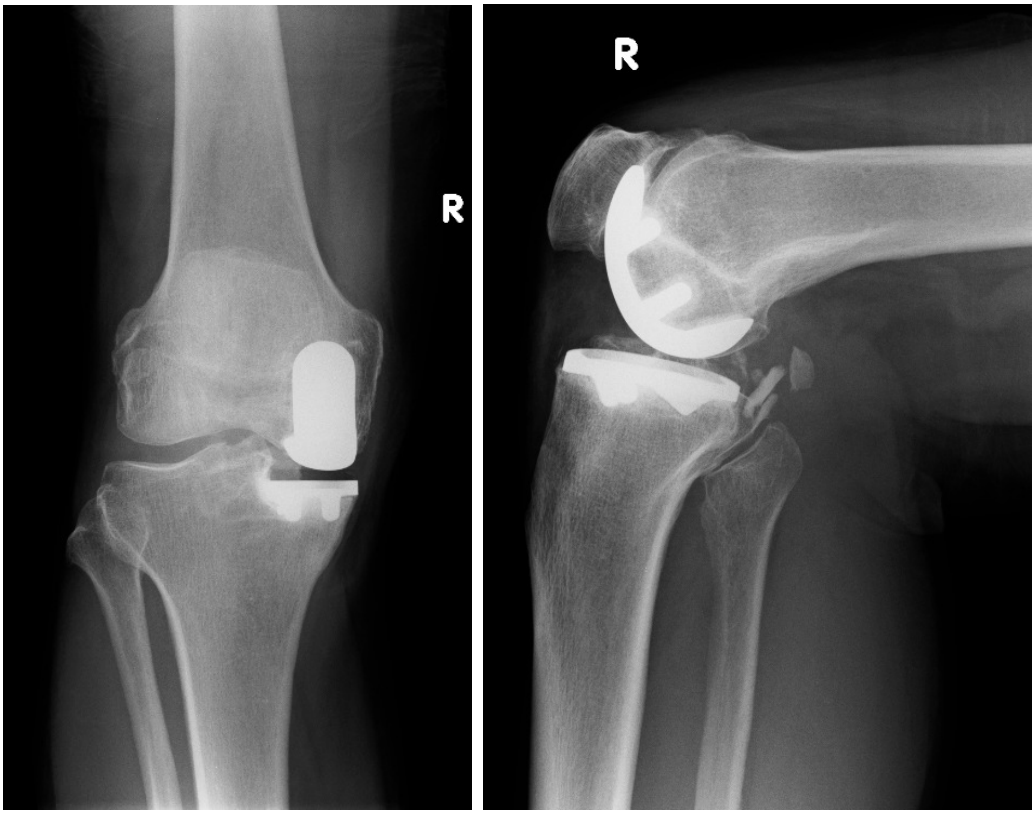


Figure 4.2: X-ray of Patient ID 131's post-op right knee 1 year post op in the A/P plane (left) and sagittal plane(right)

although a small area of lifting to the lateral aspect of the tibial tray in the AP view was noticed. This was to be monitored at his next appointment. After this one year post-operative assessment he was booked in for the biomechanical analysis testing at the University of Strathlyde Biomedical Engineering Unit for January 2013.

4.2.2 Walking

The subject was asked to walk at a comfortable speed from one side of the lab to the other within the visible camera area. This activity was repeated three times per leg. The results of this task are presented with each individual task shown as dashed lines, and the average of these three are shown as the thick black line. Figure 4.6 shows the kinematics of this subjects left non-operated leg, and Figure 4.7 shows the right UKA leg. A comparison of the two legs is illustrated in 4.8.

Additionally a sample of the raw data is shown in tables 4.3, 4.4 and 4.5.

As mentioned in Chapter 4.2.1 this subject has a well replaced and painless operated right leg. The two Figures 4.6 and 4.7 shows that the two leg functions behave in a very repeatable fashion. The error bands are quite small and traces are quite repeatable from one walk to the next.

The leg comparisons in Figure 4.8 show that the flexion-extension angles are repeatable. However in the other two planes there does appear to be more noticeable differences between the two legs. This may be due to actual the differences between the two legs, however it's unlikely to have a similar kinematic pattern in one plane and a completely different pattern in the others. Additionally the shape of the lines are very similar, but they seem to be have an offset. This is typically indicative of deviations of marker placement rather than subject differences. This may give credit to using excursion angles as a more reliable measure of performance than the absolute value.

The kinetic data for each individual leg (Figure 4.9 & 4.10 - left and right respectively) the moment graphs appear quite reproducible. As expected the most deviations are seen in the internal/external rotation plane. When each leg is directly compared in Figure 4.11 the sagittal plane seems the most repeatable compared to the other planes, just like with the kinematics. However the left knee does appear to produce lower knee moments in this plane, however they may be actual physiological differences between the legs as opposed to issues with instrumentation or other technical errors. The peak knee moment for the right UKA knee was 0.99Nm/kg, whereas the healthy knee reached a peak moment of 0.66Nm/kg.

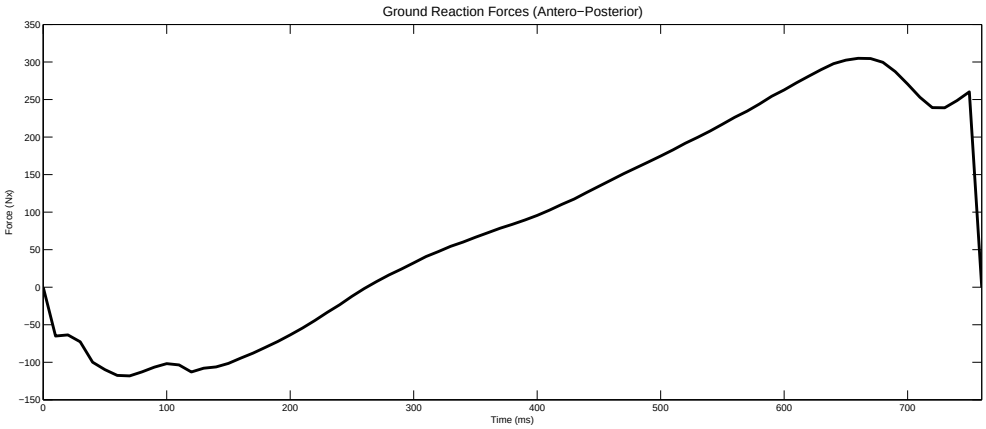


Figure 4.3: Sample of ground reaction forces during walking in the left leg in the antero-posterior direction

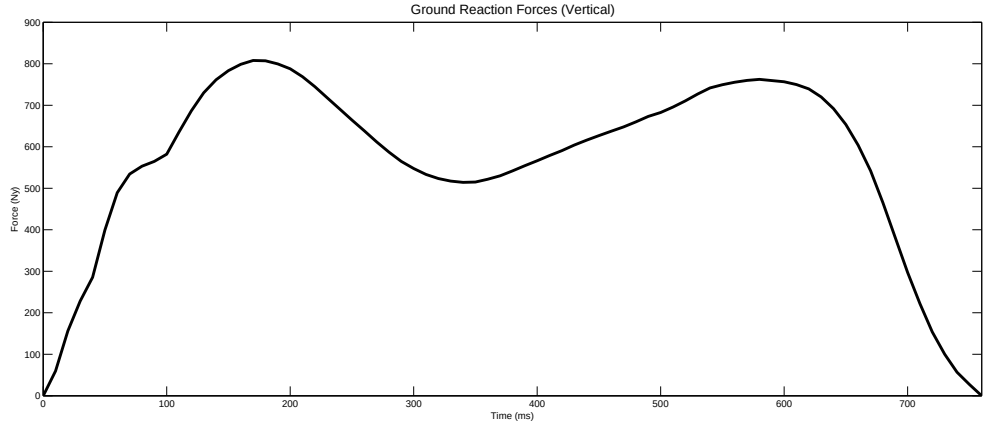


Figure 4.4: Sample of ground reaction forces during walking in the left leg in the vertical direction

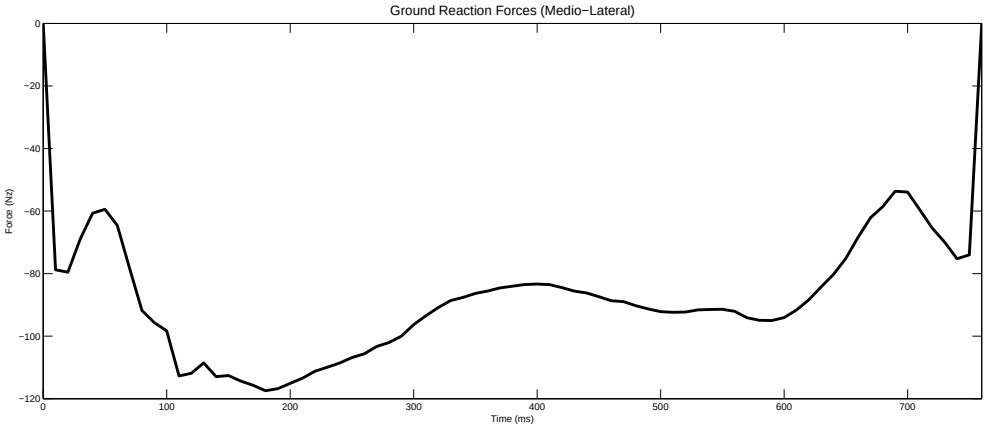


Figure 4.5: Sample of ground reaction forces during walking in the left leg in the medio-lateral direction

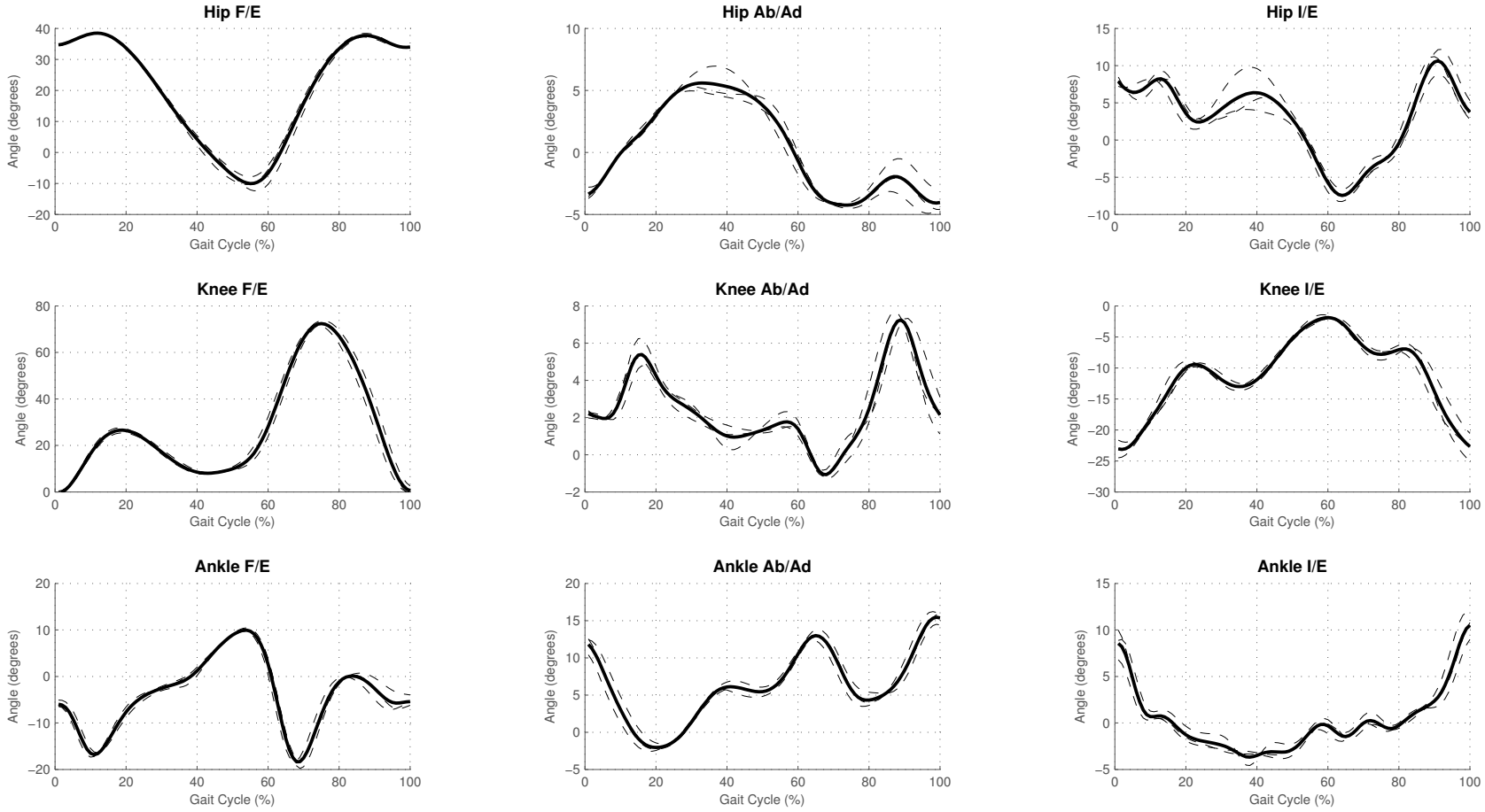


Figure 4.6: Kinematics of Patient ID 131's left (non-operated) leg during level walking

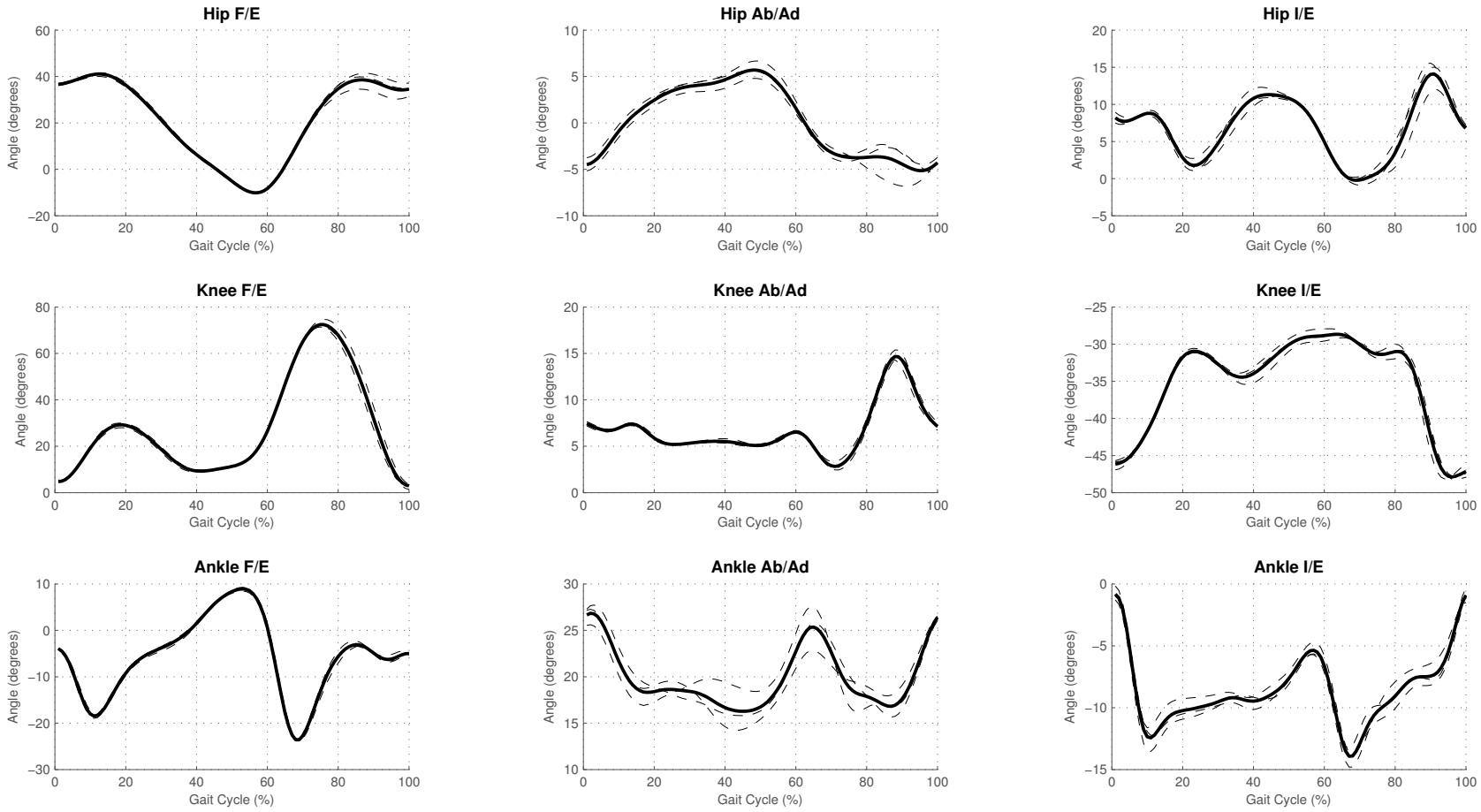


Figure 4.7: Kinematics of Patient ID 131's right (UKA) leg during level walking

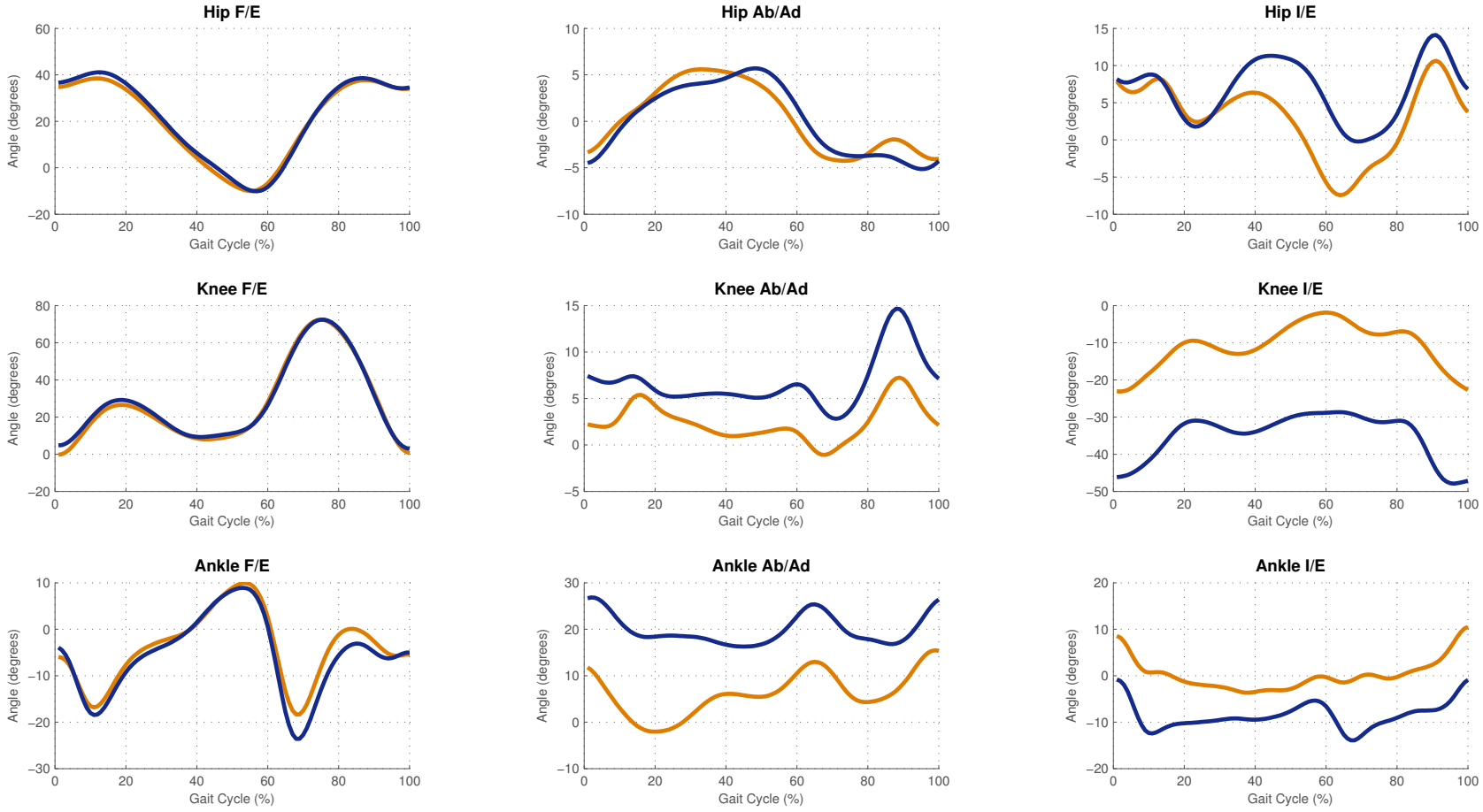


Figure 4.8: Kinematics of Patient ID 131's legs [*left* (non-operated) - orange, *right* (UKA) - blue] during level walking

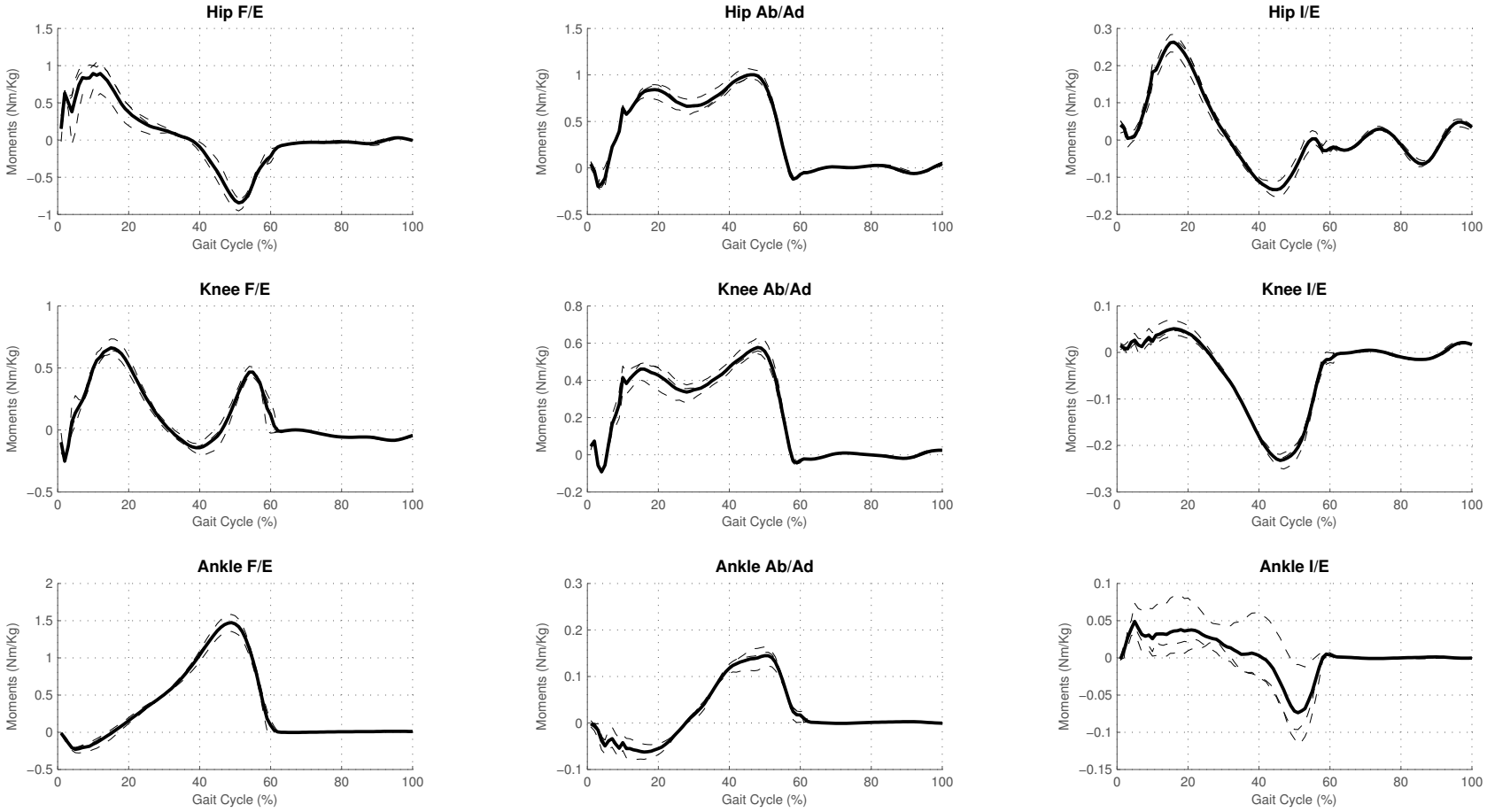


Figure 4.9: Moments of Patient ID 131's left non-operated leg during level walking

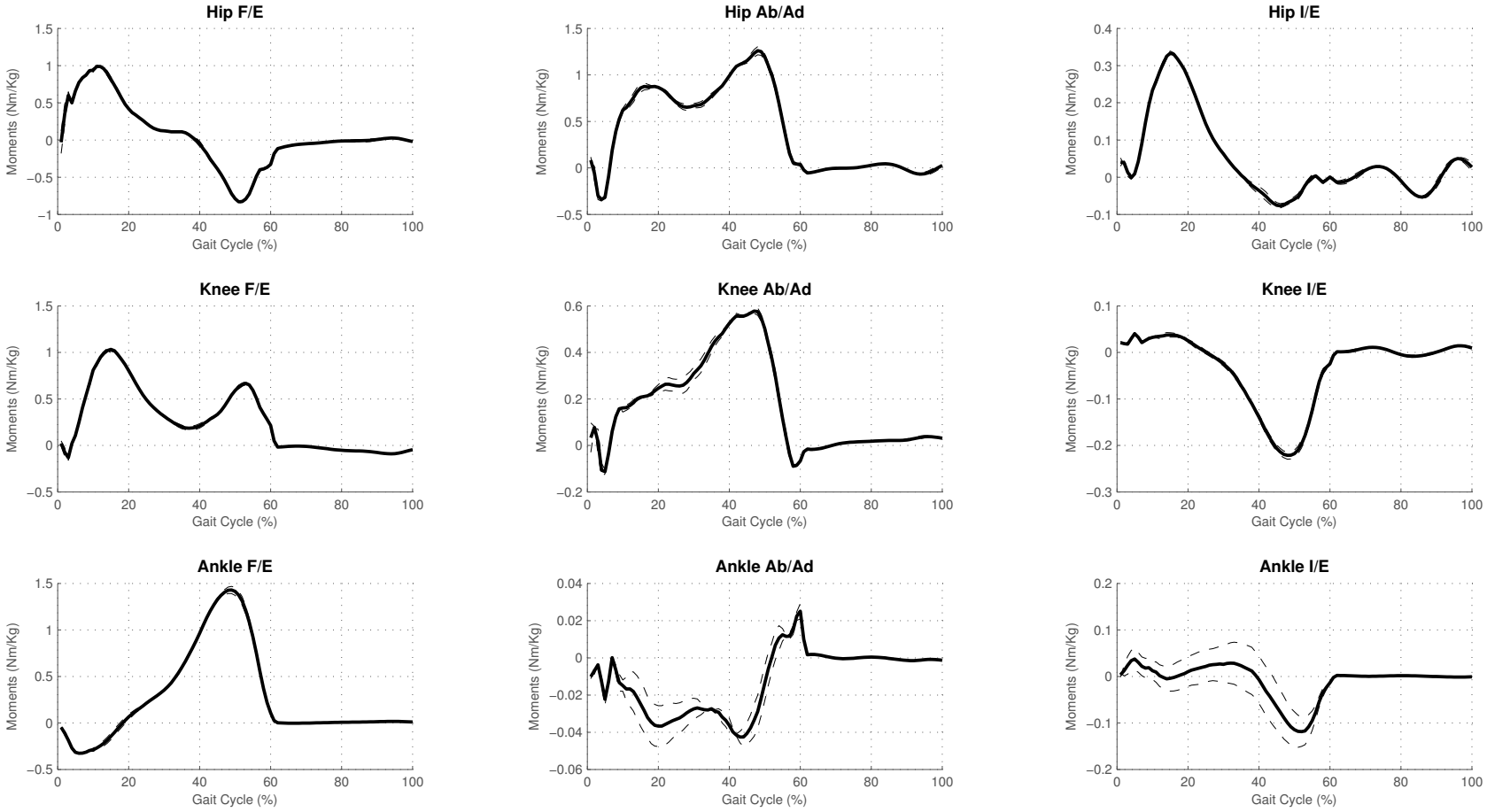


Figure 4.10: Moments of Patient ID 131's right UKA leg during level walking

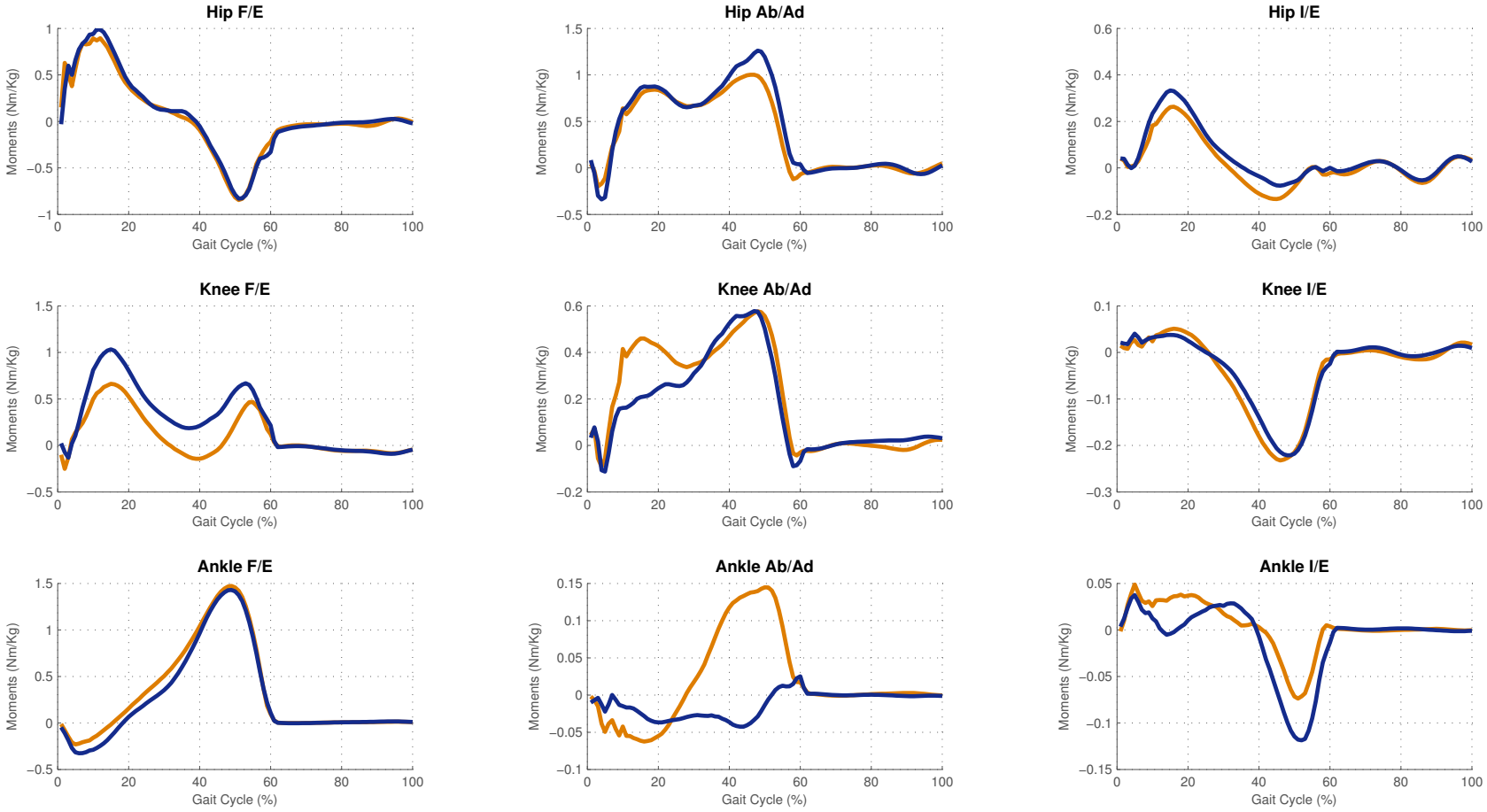


Figure 4.11: Moments of Patient ID 131's legs [*left* (non-operated) - orange, *right* (UKA) - blue] during level walking

4.2.3 Stair Navigation

The patient performed two tasks for stair navigation, ascending and descending stairs.

Raw data for stair ascent is shown in tables 4.12, 4.13 and 4.14, and stair raw descent data is shown in 4.21, 4.22, and 4.23.

Stair ascent graphs are presented in Figure 4.15 (non operated left knee) and 4.16 (UKA right knee). These graphs show each individual leg showing reasonably good repeatability, especially in the sagittal plane. The leg comparison in Figure 4.17 shows the sagittal plane still appears the most comparable of the three planes, but the abduction/adduction and internal/external angles are deviating more than during walking. As stair navigation is a higher flexion task, with the knee flexion reaching peaks of 100°, this leads to accumulating bigger errors; which is shown in the abduction/adduction and internal/external differences between each leg. During stair ascent maximum differences in hip rotation came to 15° at some points, and 20° in the knees.

The moment graphs show other issues with the data. Figures 4.18 (non operated left knee), 4.19 (UKA right knee) and 4.20 (average comparison) show significant vibrational behaviour of the force plates. This behaviour is seen even after the force plate filtering. The reason for this vibrational behaviour is most likely attributed to the patients holding the handrails whilst using the stairs. Even though every effort was made to try and secure the portable stairs it still may not have been fully secure, therefore may have been providing some external forces to the force plate. Additionally some of the patient weight was supported by the handrails, which were not directly connected to the force plates, therefore it may not be fair to use this data to compare moments between the joints. This could be a reason for the huge differences seen in the moment comparisons. Other issues with this data are seen in the left leg at stair ascent at around 90% gait in the ankle where the data suddenly cuts out. This exact artefact is present in all

three of the trials, indicating it isn't a one time error. This type of sudden data drop is not seen in motion, therefore is probably attributed to instrumentation issues.

Similar findings are seen during stair descent, shown in Figure 4.24 (non operated left knee) and 4.25 (UKA right knee). While the sagittal plane kinematics appear the most comparable there does appear to be an offset in the hip flexion/extension angles. Similar abduction/adduction and internal/external angle deviations are seen with maximum differences in hip rotation being 13° and 22° in the knees. The same kinematic rotational and varus/valgus errors, and force plate vibrational issues are also seen in the stair descent tasks. These errors from the stair moments may give rise to dismissing the stair moment data all together due to the inaccuracies.

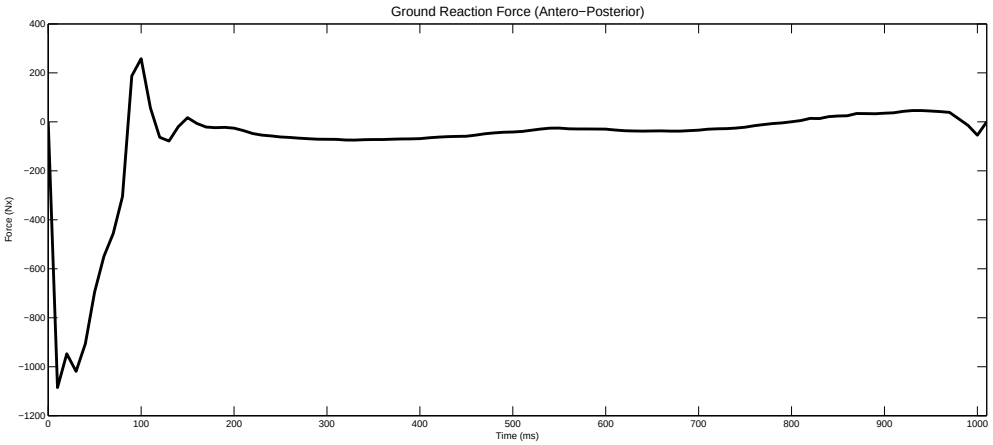


Figure 4.12: Sample of ground reaction forces during stair ascent in the left leg in the antero-posterior direction

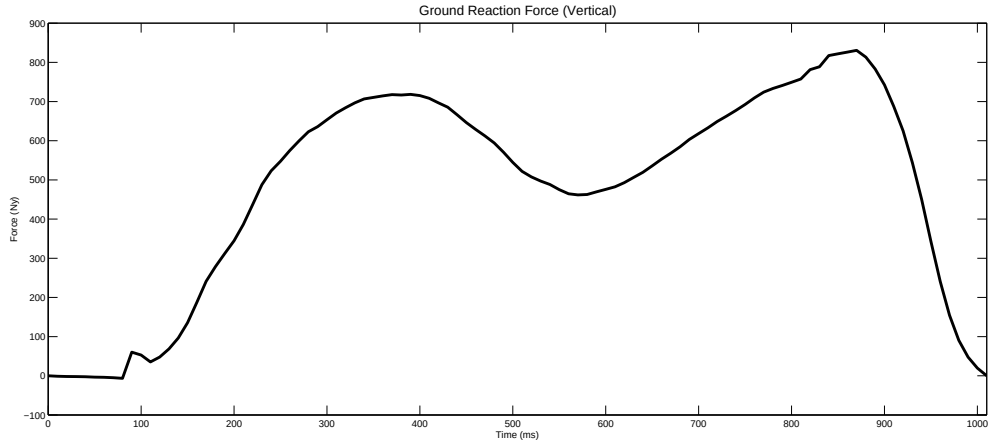


Figure 4.13: Sample of ground reaction forces during stair ascent in the left leg in the vertical direction

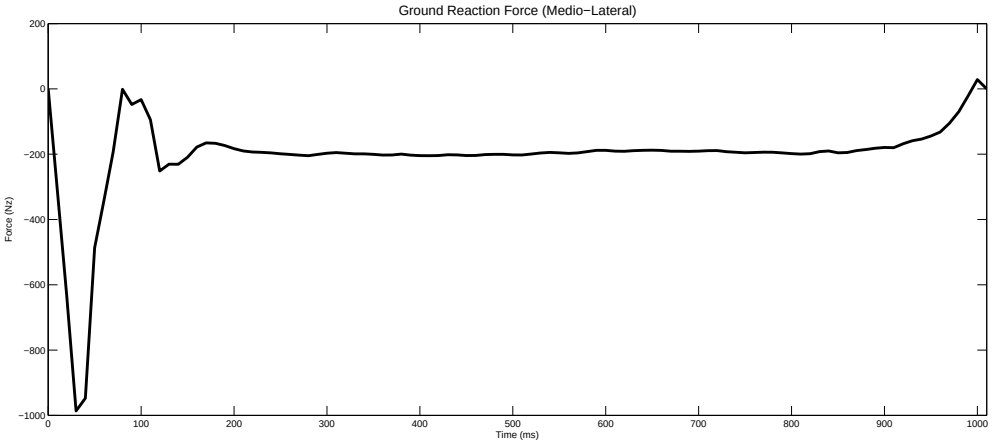


Figure 4.14: Sample of ground reaction forces during stair ascent in the left leg in the medio-lateral direction

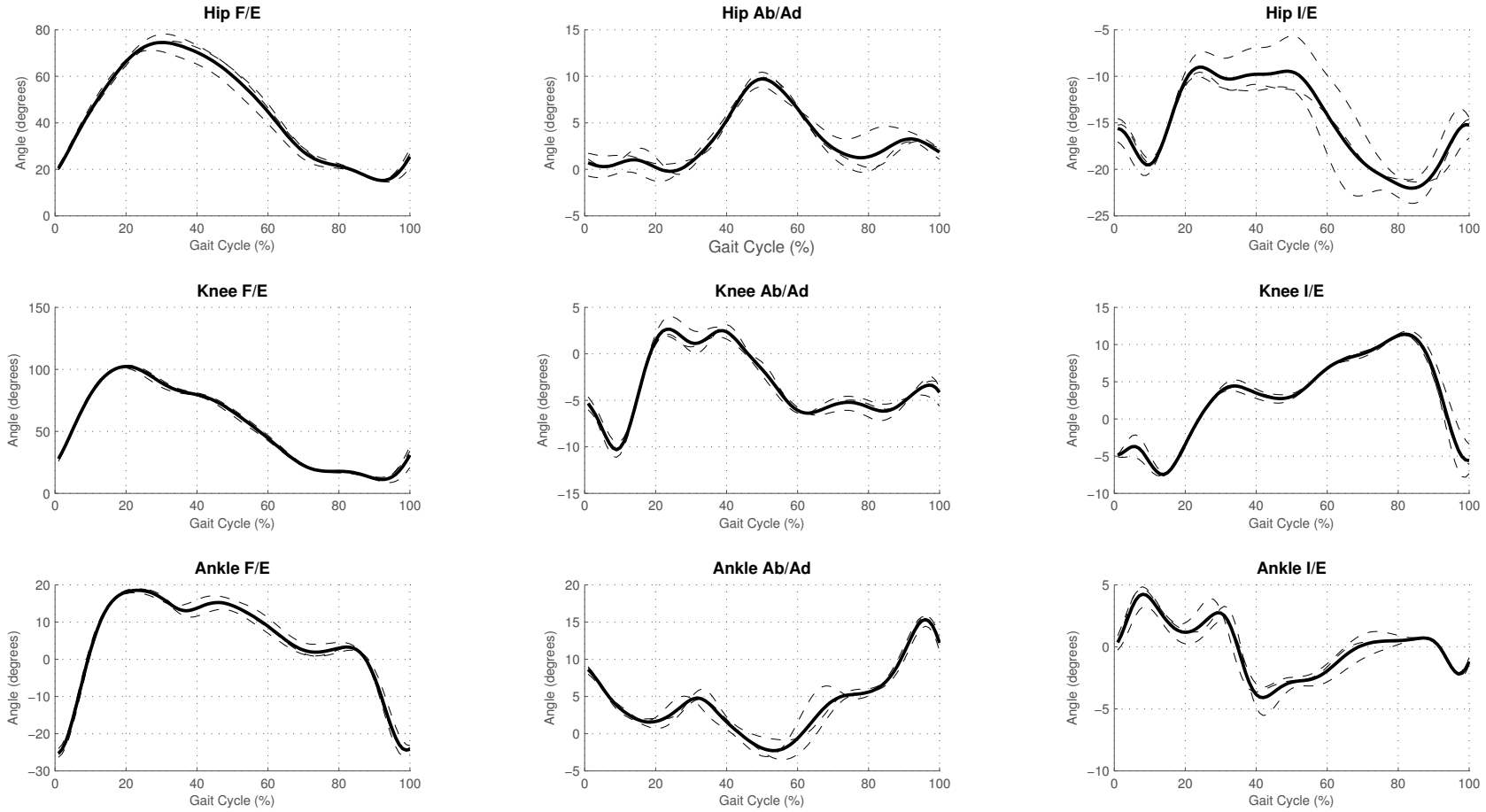


Figure 4.15: Kinematics of Patient ID 131's left (non-operated) leg during stair ascent

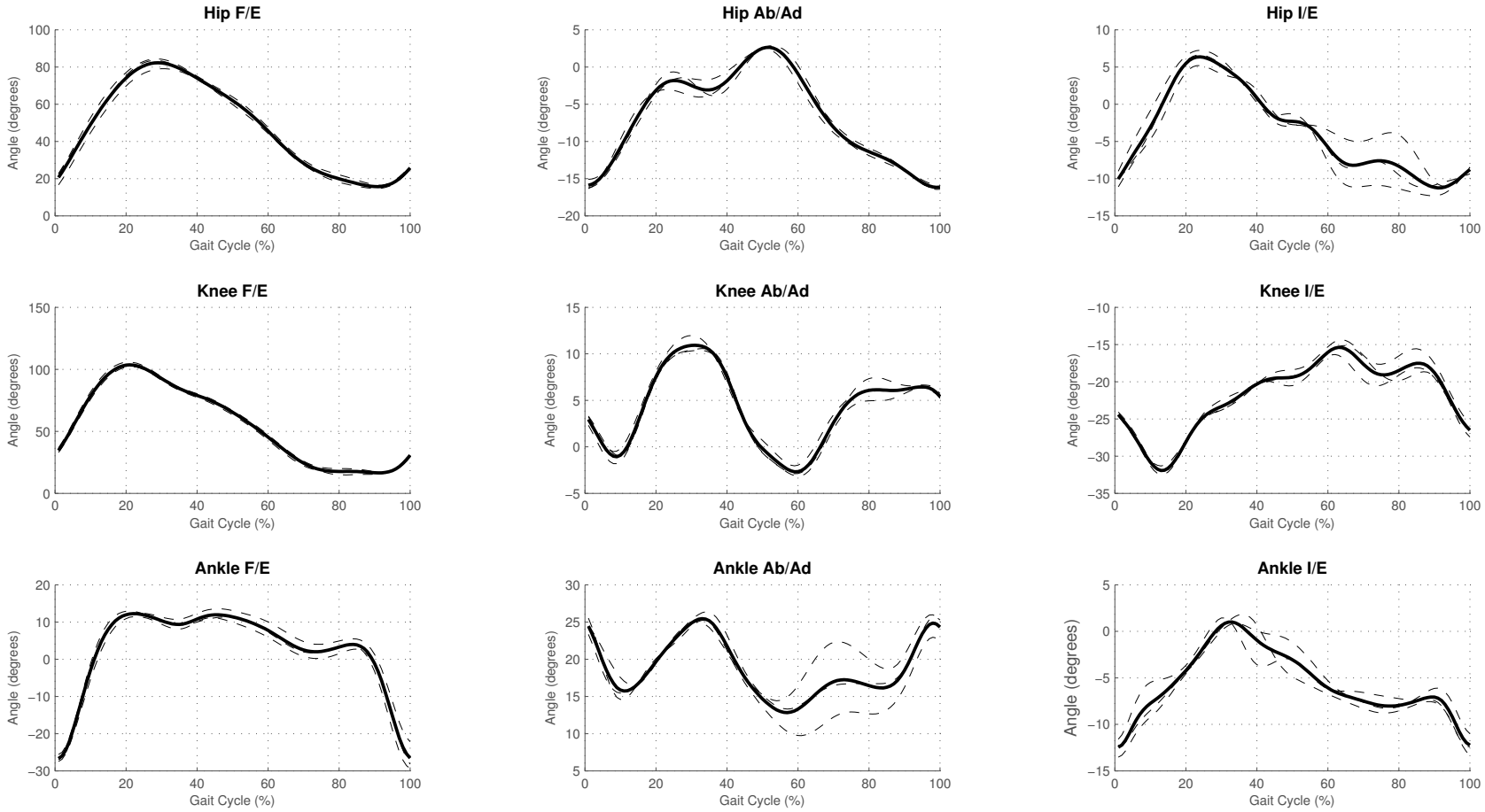


Figure 4.16: Kinematics of Patient ID 131's right (UKA) leg during stair ascent

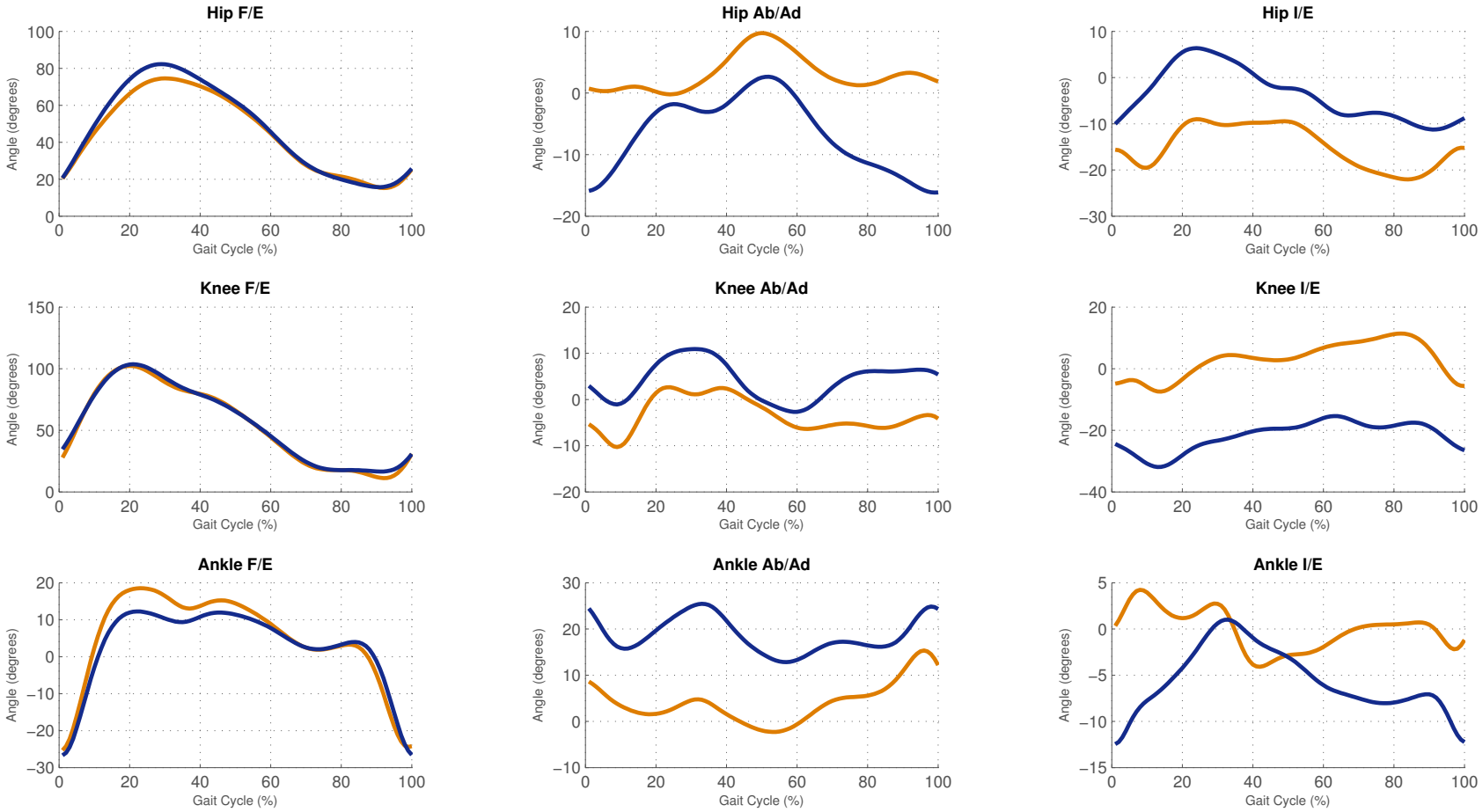


Figure 4.17: Kinematics of Patient ID 131's legs [*left* (non-operated) - orange, *right* (UKA) - blue] during stair ascent

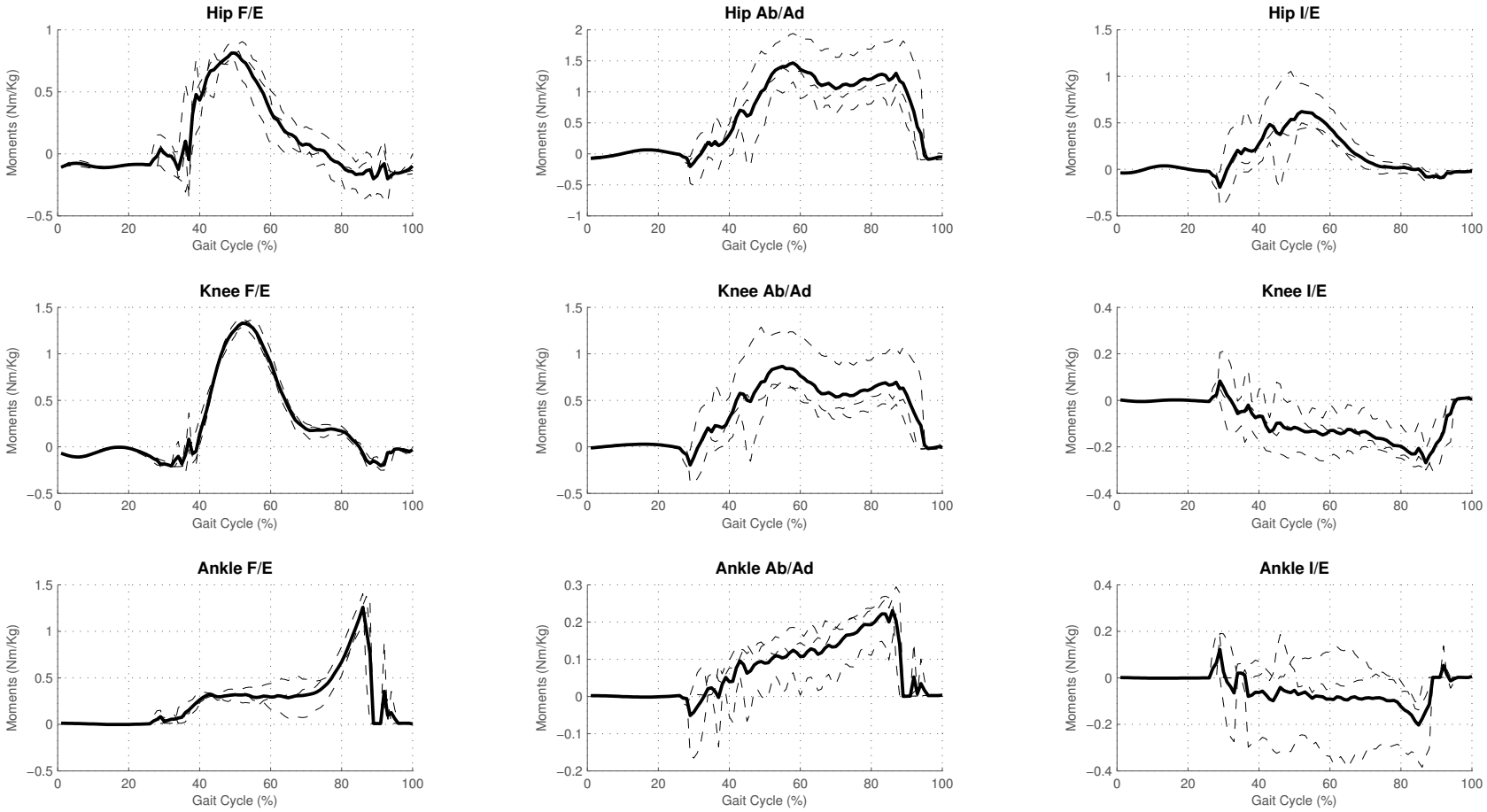


Figure 4.18: Moments of Patient ID 131's left (non-operated) leg during stair ascent

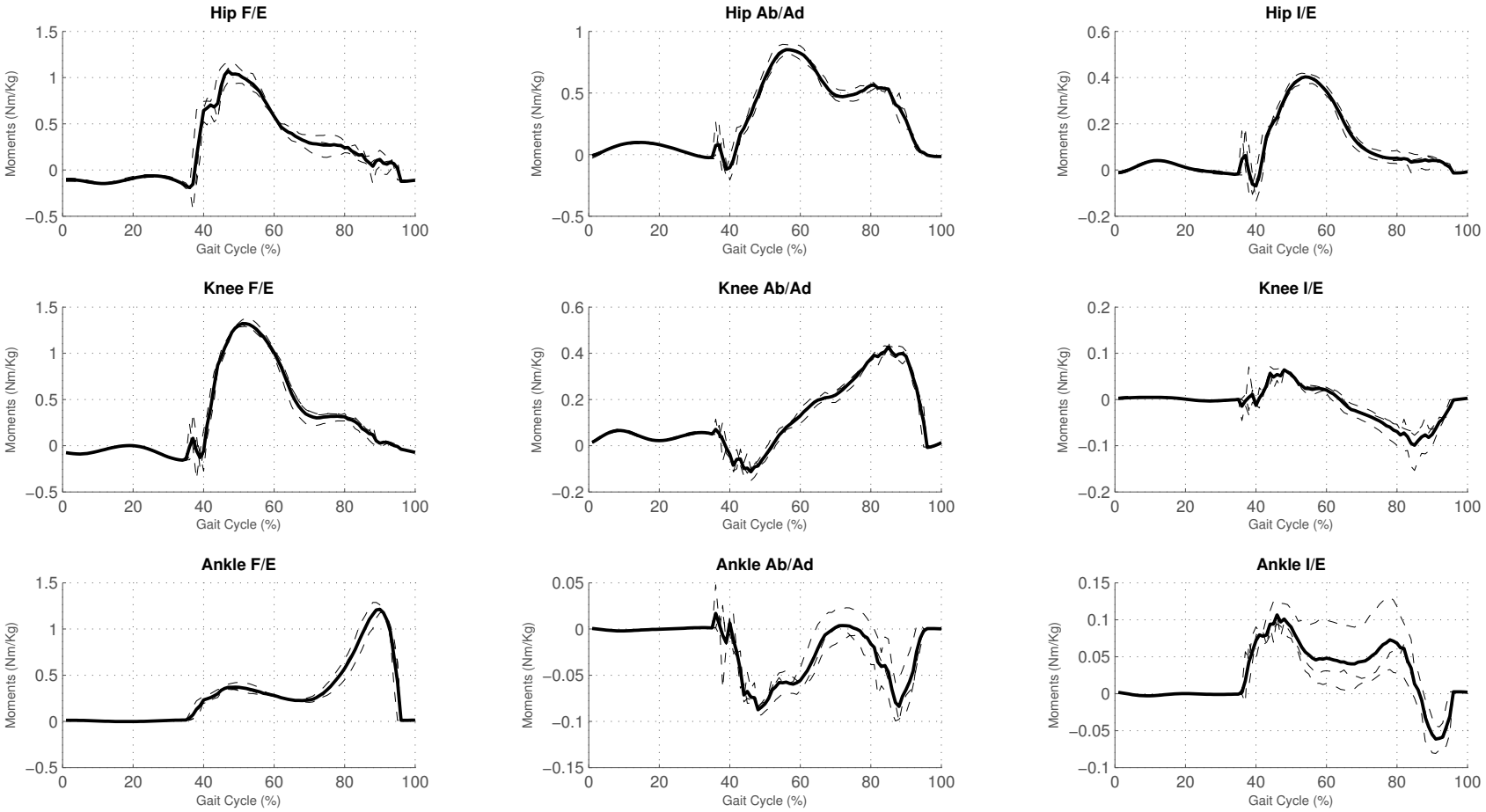


Figure 4.19: Moments of Patient ID 131's right (UKA) leg during stair ascent

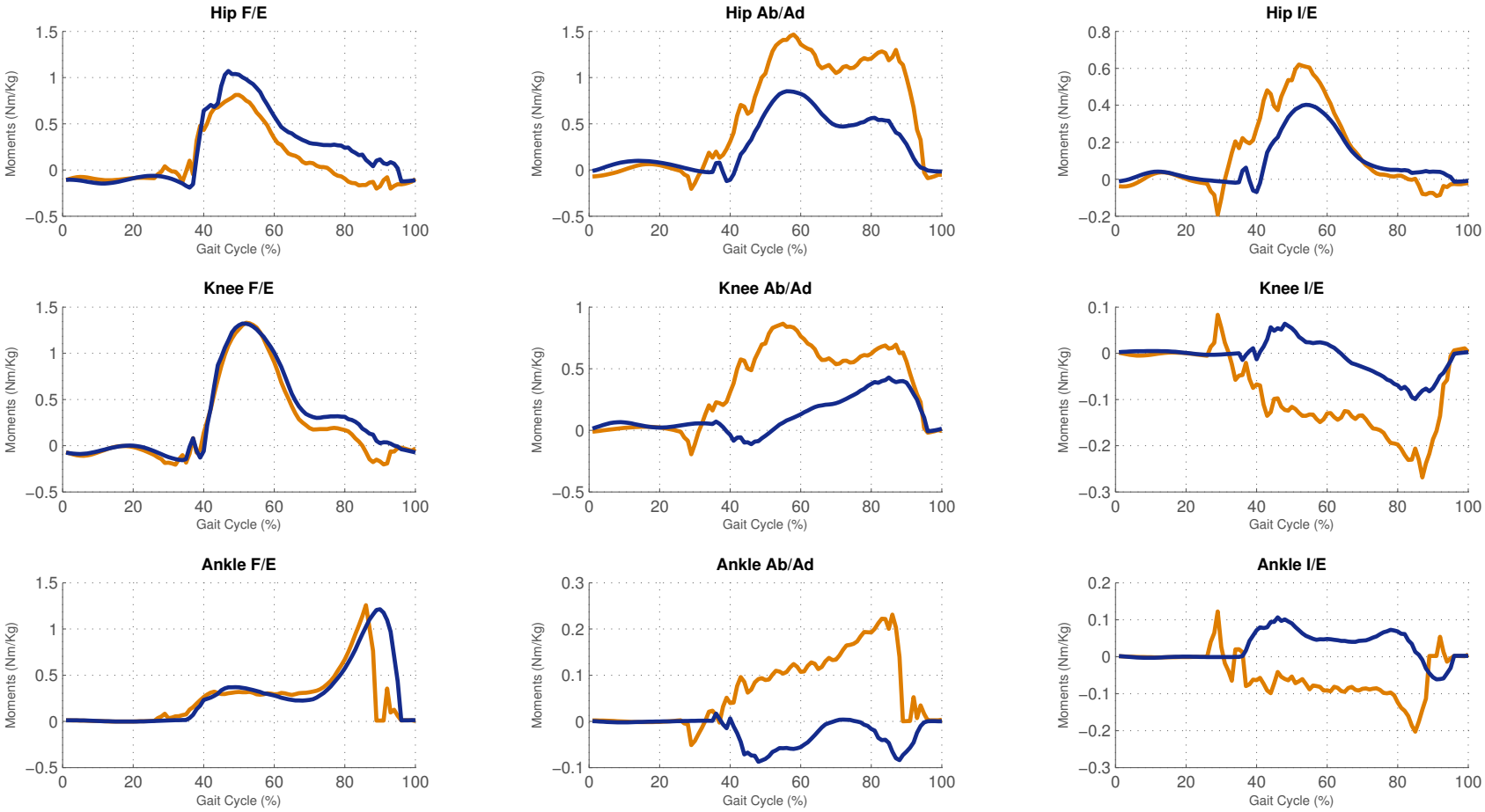


Figure 4.20: Moments of Patient ID 131's legs [*left* (non-operated) - orange, *right* (UKA) - blue] during stair ascent

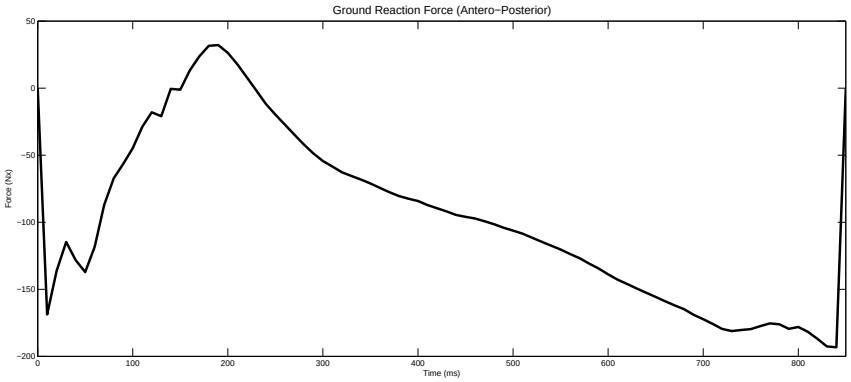


Figure 4.21: Sample of ground reaction forces during stair descent in the left leg in the antero-posterior direction

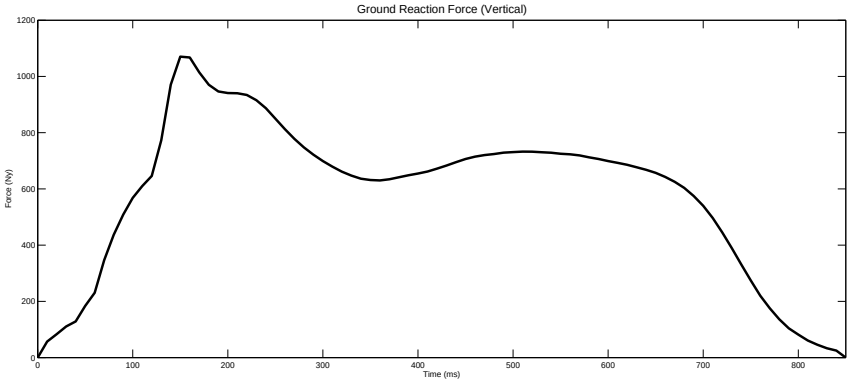


Figure 4.22: Sample of ground reaction forces during stair descent in the left leg in the vertical direction

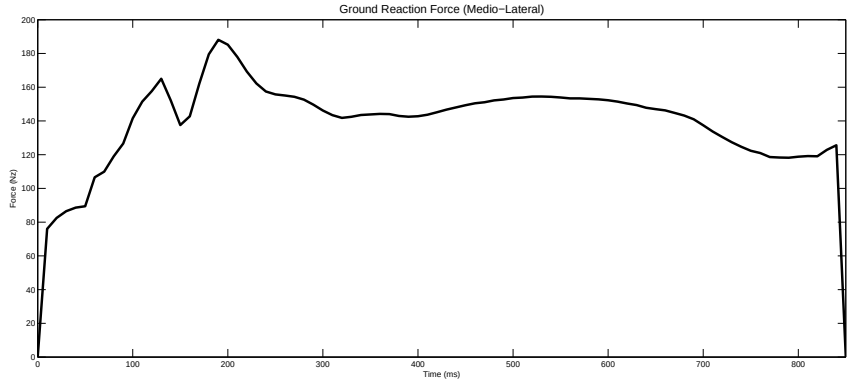


Figure 4.23: Sample of ground reaction forces during stair descent in the left leg in the medio-lateral direction

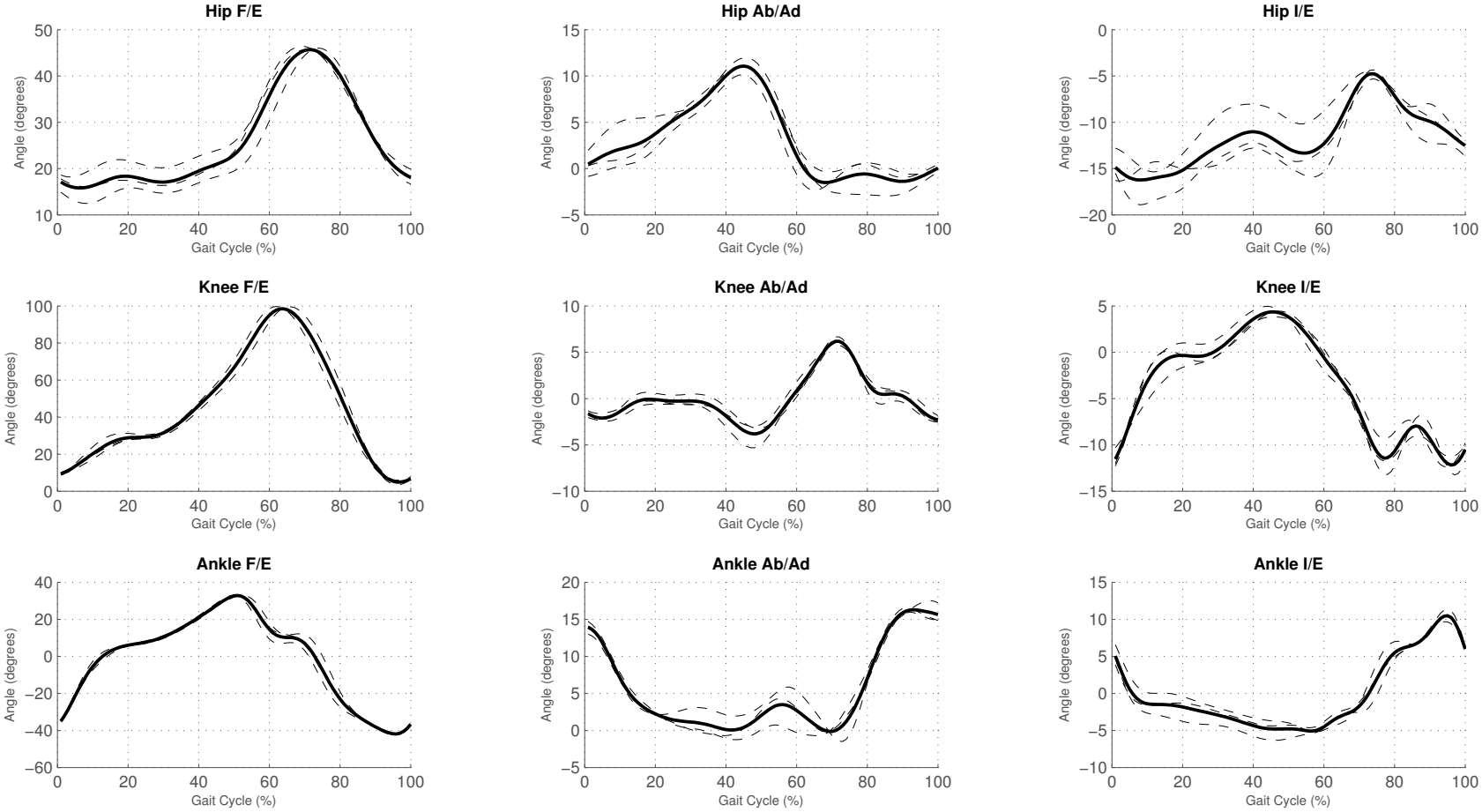


Figure 4.24: Kinematics of Patient ID 131's left (non-operated) leg during stair descent

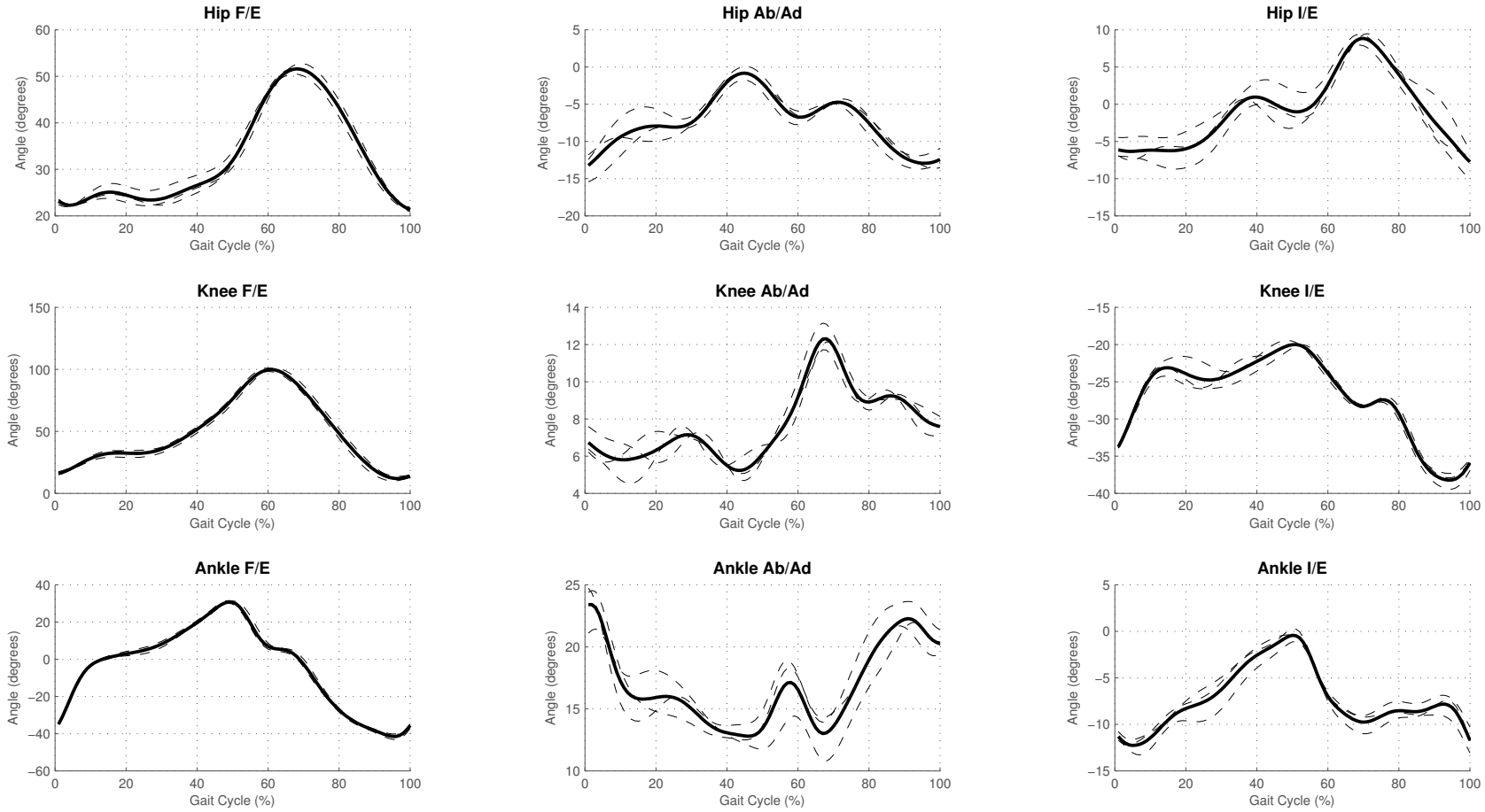


Figure 4.25: Kinematics of Patient ID 131's right (UKA) leg during stair descent

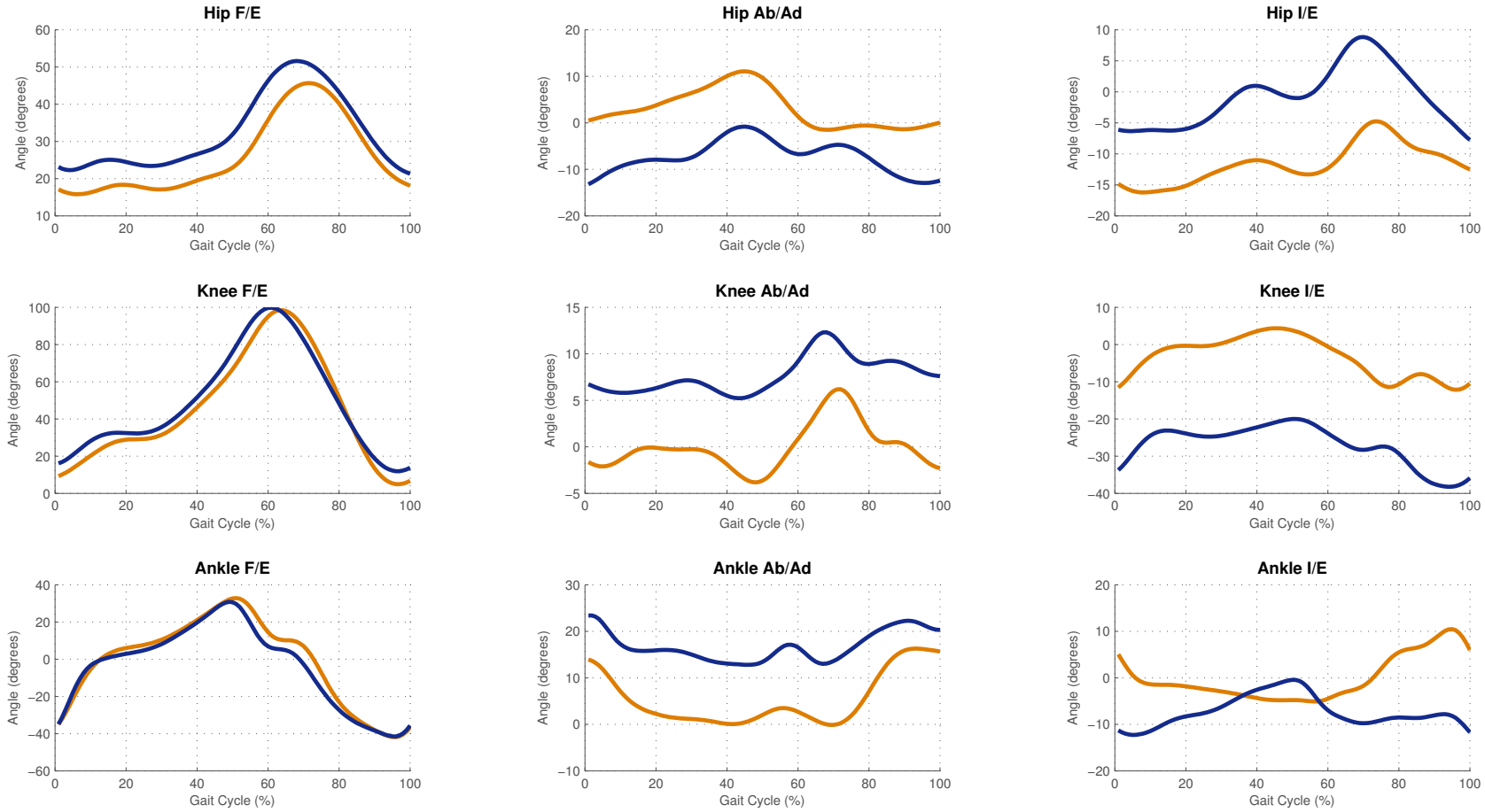


Figure 4.26: Kinematics of Patient ID 131's legs [*left* (non-operated) - orange, *right* (UKA) - blue] during stair descent

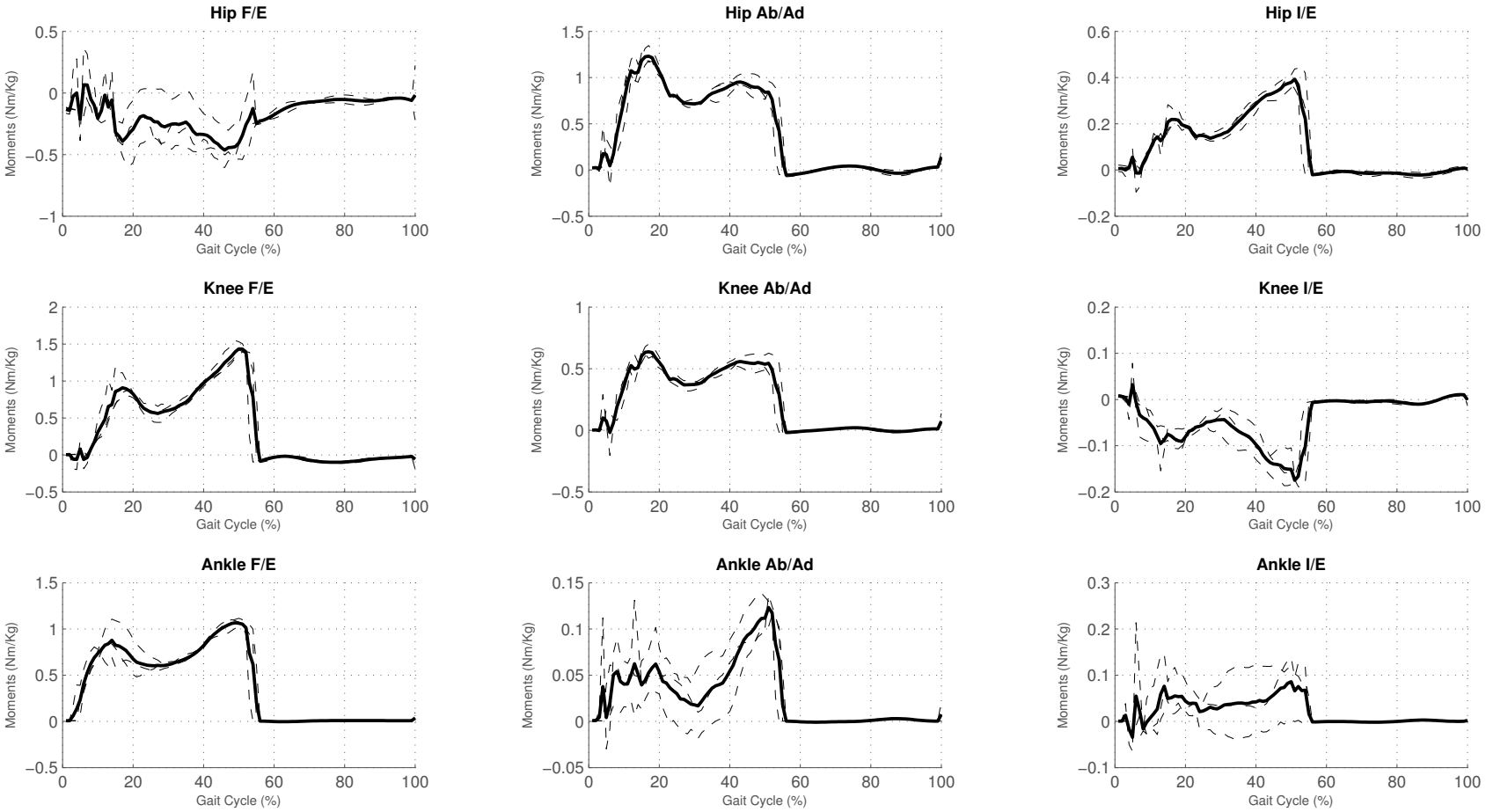


Figure 4.27: Moments of Patient ID 131's left left (non-operated) during stair descent

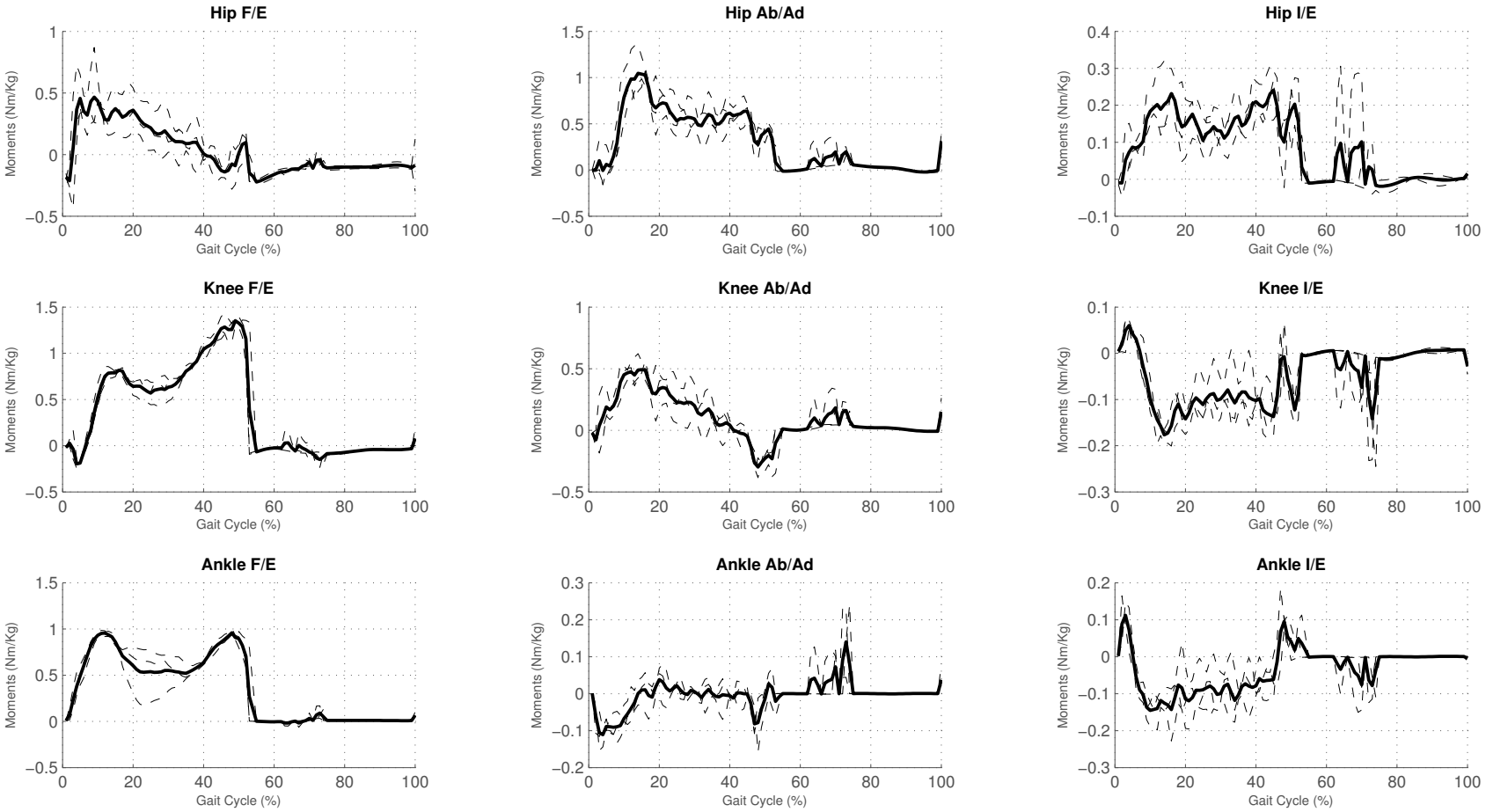


Figure 4.28: Moments of Patient ID 131's right (UKA) leg during stair descent

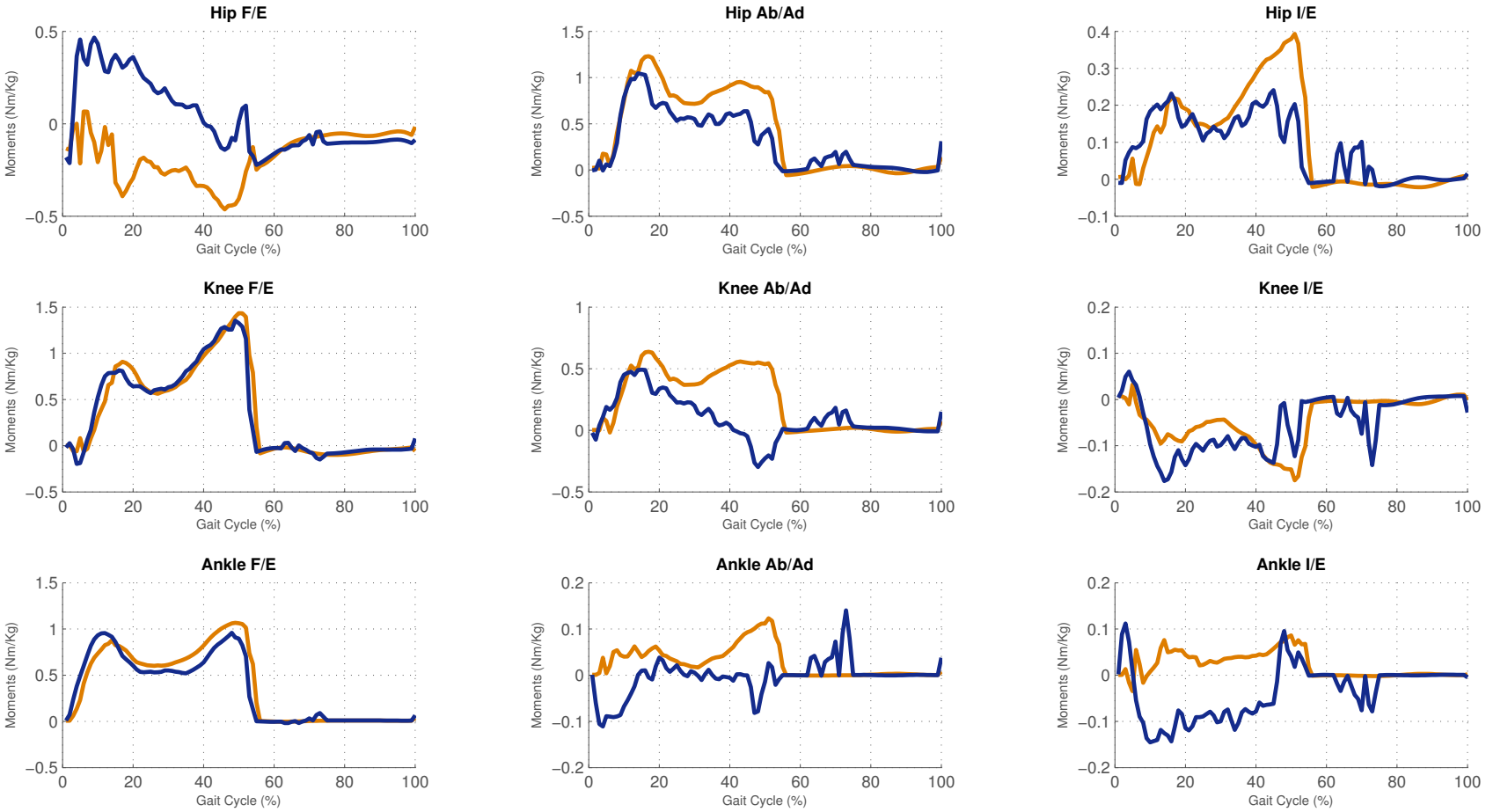


Figure 4.29: Moments of Patient ID 131's legs [*left* (non-operated) - orange, *right* (UKA) - blue] during stair descent

4.2.4 Summary of Angles and Stance/Swing Percentages for Walking and Stair Navigation

Walking	**Left (non-operated)**	**Right (UKA)**
Hip		
Max	38.5°	41.1°
Min	-10.1°	-10.1°
Excursion	48.5°	51.2°
Knee		
Max	72.4°	72.4°
Min	-0.3°	2.9°
Excursion	72.7°	69.5°
Excursion (Foot Strike to Mid-Stance)	26.9°	24.4°
Excursion (Mid-Stance to Terminal Stance)	18.6°	19.9°
Ankle		
Max	9.9°	8.9°
Min	-18.3°	-23.6°
Excursion	28.3°	32.5°
% Stance	65.7	66.0
% Swing	34.3	34.0

Table 4.1: Sagittal Hip, knee, ankle angles and stance/swing percentages for ID 131 during level walking

Ascending Stairs	Left (non-operated)	Right (UKA)
Hip		
Max	74.5°	82.3°
Min	15.2°	15.7°
Excursion	59.3°	66.6°
Knee		
Max	102.3°	103.6°
Min	11.2°	16.5°
Excursion	91.1°	87.1°
Ankle		
Max	18.5°	12.2°
Min	-25.3°	-26.7°
Excursion	43.9°	38.9°
% Stance	34.5	36.2
% Swing	65.5	63.8

Table 4.2: Sagittal Hip, knee, ankle angles and stance/swing percentages for ID 131 during stair ascent

Descending Stairs	Left (non-operated)	Right (UKA)
Hip		
Max	45.7°	51.6°
Min	15.8°	21.3°
Excursion	29.8°	30.3°
Knee		
Max	98.5°	99.8°
Min	4.9°	11.9°
Excursion	93.6°	87.9°
Ankle		
Max	32.9°	30.8°
Min	-41.9°	-41.5°
Excursion	74.7°	72.3°
% Stance	61.2	58.5
% Swing	38.8	41.5

Table 4.3: Sagittal Hip, knee, ankle angles and stance/swing percentages for ID 131 during stair descent

4.2.5 Sit to Stand Force Symmetry Ratio

The ground reaction forces during this activity is shown in Figure 4.30. The force plate data starts when the patient is no longer supported by the seat, so all of

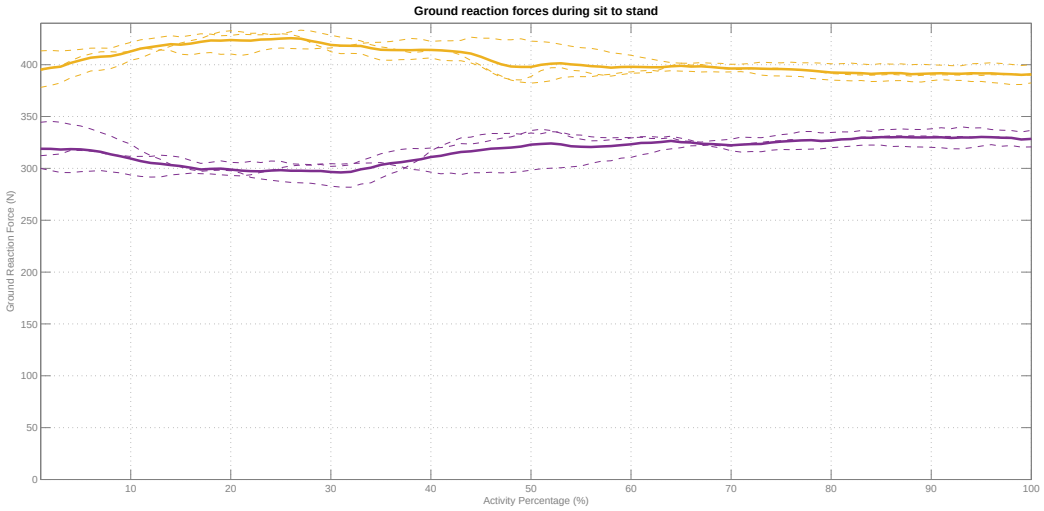


Figure 4.30: Ground reaction forces during the sit to stand activity [*left* (non-operated) - orange, *right* (UKA) - blue]

the weight is going through the force plates. On average during the sit to stand task 12% of the patients' weight was supported on the non-operated leg. Each individual activity is shown by the dashed lines, and the average is shown by the thicker line. As this activity is a measure of leg balance, only the ground reaction forces are shown and not the kinematics of the knee.

4.2.6 Deep Knee Lunge

The summary of the maximum knee angles achieved for each leg is shown in Table 4.4.

Figure 4.31 shows the knee angles throughout the lunge activity. Each task is shown as dashed lines and the average of these tasks is shown as a thick black line.

	Left	**Right**
	132.7°	128.7°
	134.7°	129.5°
	136.3°	129.1°
Average	**134.6°**	**129.1°**

Table 4.4: maximum angle of flexion during deep knee lunge for ID 131 in degrees

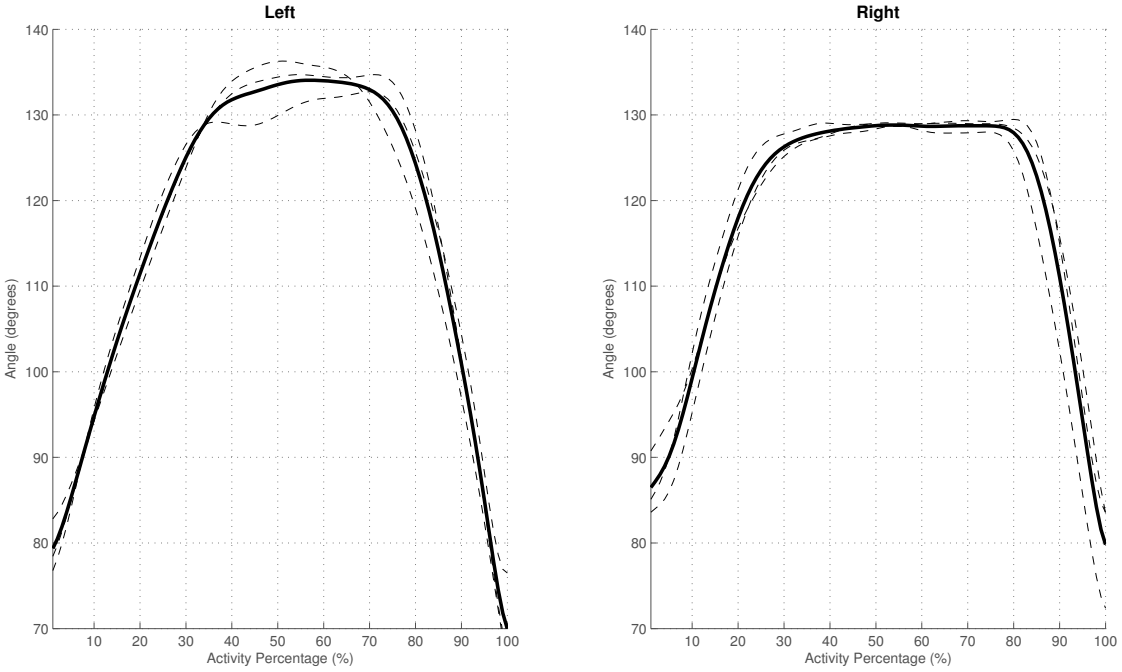


Figure 4.31: Knee angles of Patient ID 131 during the deep knee lunge activity

As shown in Table 4.4 the non-operated knee achieves a higher maximum knee angle during this task than the UKA knee. The difference between the two maximum angles is is 5.5°.

4.2.7 Case Study Summary

From the kinematic data during level walking (Figure 4.8) it appears the knee patterns appear very similar except during the full extension. The non-operated leg can achieve full extension whereas the operated knee reaches a minimum value of 2.9°. The peak flexion angles for both knees however are 72.4°. This could indicate that the operated leg is just as comfortable in flexion during level walking, but may find it slightly difficult to fully extend the knee. It may however simply be a case of marker misplacement, although the 3.2° difference in knee excursion is very minimal and shows that both knees can perform similarly during level walking. In flexion/extension the hips both appear to be very similar in both graph shape, and also in excursion values – the right hip has a 2.7° increase in

range of motion. During toe off the right ankle appears to have greater plantarflexion. The right ankle reaches a minimum angle of -22° while the left ankle reaches -18°. The total excursion difference between the two ankles is 4.2°. Overall the subject's limbs behaved very symmetrically during level walking and the patient was just as comfortable in walking with both his knees.

Stair ascent is a more demanding task which may show more differences between the two knees. However the knee graphs in flexion/extension follow very similar patterns, and the overall difference in excursion angles is 4°. In this plane however the right hip reaches a higher angle, causing an overall increase in hip excursion of 7.3°. This peak occurs during footstrike. However it is important to note that as seen in Figure 4.15 the hip in the flexion/extension plane does not appear very repeatable during this period of the gait cycle. Therefore these differences could simply be a symptom of inaccuracies at these higher flexion angles, or the patient may be experiencing issues with that hip, therefore not being able to produce a repeatable pattern. In the same plane the left ankle appears to reach higher dorsiflexion than the right. This also occurs during foot strike. Looking at Figures 4.15 and 4.16 shows no large differences in the repeatability of the ankle angles, therefore the difference in ankle excursion may be a genuine difference between the ankles, but this difference is only 5° in total.

During stair descent the hip patterns in flexion/extension (Figure 4.26) show similar pattens but with some offset. The actual difference in excursion between the two hips is 0.5°. These offsets may be attributed to camera errors with the camera system as the individual hip trials shown in Figures 4.24 & 4.25 show the individual hip trials are somewhat variable in the hip only. During stair descent the patient starts at the top of the stairs, which are not in the optimum field of view of the cameras, as well as having handrails and other obstructions that may also block the cameras' lines of sight. The non-operated left knee shows higher flexion/extension knee angle excursion in stair descent, achieving 5.7° more range.

For the sit to stand activity the patient appears to be relying more on the non-operated leg for support when standing, and throughout the task of fully supporting their own body weight. The non-operated knee also has greater knee excursion than the UKA knee, by 4.9°.

During the deep knee lunge activity the non-operated left leg reached a maximum of 134.6° and the UKA right leg reached a maximum of 129.1°. While the non-operated knee had an extra 5.5° both knees reached high flexion angles and the subject was comfortable doing three repetitions of this task for each leg.

Overall this case study aimed to see if a well implanted and painless UKA implanted into a patient with localised OA in one knee can achieve similar performance to their healthy and non-diseased knee. The results showed that in this patient the UKA knee performed very comparably to that of their healthy knee. On some tasks such as walking, sit to stand and deep knee lunge the non-operated knee had higher excursion angles, but these variations are very minimal. Overall patient satisfaction is very high with the UKA knee and his standard of life has greatly improved.

4.3 Group Data Inclusion

As mentioned in Chapter 4.2 the purpose of the case study was to introduce and discuss a typical set of data, and determine what data would be kept and analysed for the entire group, and what would not.

From the biomechanical walking data in all tasks it was clear that the data from the sagittal plane was the most reliable. However the angles generated in the abduction/adduction and internal/external angles were very prone to marker placement inaccuracies and soft tissue artefacts. These errors also appeared to accumulate at higher flexion angles. For this reason the abduction/adduction and internal/external angles will not be included in the group analysis, only the

sagittal plane will be analysed. As the kinetic data are derived from the kinematic data the abduction/adduction and internal/external moments will not be used either. However the sagittal plane moments for the knee during level walking will be analysed for the whole group.

An issue that was present in the case study was vibrational noise from the force plates during the stair navigation tasks. In order to investigate the cause of the problems found with the stair data, the stair rig was re-assembled and analysed. When replaying force data through Vicon Nexus it looked as if there were small horizontal forces that were being registered shortly before foot strike onto the force plate. It was seen that the instrumented step was in contact with the steps above and below. The design of these stairs relied on a clearance of 5 or 6cm at the front and back of the instrumented step. What had been unnoticed during the data collection was that there was a bolt that would attach the first step onto the larger framework of the stairs. All the non-instrumented steps are shown with a white line in Figure 3.9, and the instrumented step in yellow. The bottom step was around 10cm from where it should have been. The result of this meant that when the subject stood on the bottom step and/or held the handrail it would be possible for loads to be transmitted to the instrumented step, and this is what was seen throughout the entire data set for the stairs. The sagittal plane kinematic data for the hip, knee and ankle for the stair navigation tasks however will still be analysed for both the groups.

Another more reliable means of analysing sagittal plane knee angles was to plot the excursion values as opposed to the absolute angles. For this reason the knee excursion angles were also be presented along with the observed knee angles.

For the sit to stand activity, all that is needed for analysis is the ratio of weight distribution between the two legs during the activity. Each patient will simply have this ratio in the group comparison, therefore it is not necessary to have this data presented in graph form as shown in Figure 4.30. Additionally as

the purpose of this activity only requires force platform data, there will be no data collection on the kinematics of the knee reported.

Additionally the aim of the deep knee lunge activity is to show the maximum knee flexion of the patients during a voluntary maximum knee flexion weight bearing activity. Therefore only the maximum angle was required to perform the group analysis, which is why graphs showing the knee kinematics throughout the activity (Figure 4.31) are shown in the group analysis.

4.4 Group Analysis

4.4.1 Introduction

This section compares the functional activities for all the tasks. These are walking, ascending stairs, descending stairs, sit to stand and the deep knee lunge activities. The kinematic data for the sagittal plane angles in walking and stair navigation will be graphed, as well as summarised. The walking data was also include knee excursion data and knee moments, both graphed and summarised. The data for the sit to stand and deep knee lunge activities will be presented in tables.

The flowchart in Figure 4.32 (Page 138) provides a summary of the patients in the trial. A total of 139 patients were recruited and randomised out of a total of 259 people seen. This gives a recruitment rate of 54%. Out of the 120 patients excluded 76 did not meet the inclusion criteria, and 44 declined to participate.

Of the 139 knees that were recruited for the overall study, the first 89 patients in the series were contacted via telephone. These 89 knees were the ones that had been seen for their one year post-operative assessment at Glasgow Royal Infirmary. Of the 89 knees included in this thesis there have been 43 Mako knees at 1 year post-op, and 46 Oxford knees post-op. A total of 22 patients out of the 89 did not want to take part in the functional assessment tasks at the University of Strathclyde resulting in 67 knees (30 knees in the Mako group and 37 knees in the Oxford group). From these 67 knees, 16 had to be excluded from the final data set due to technical issues, leaving 51 knees in this study (23 Mako, 28 Oxford). Issues included the force plates not working on occasion, and another technical complication was that some of the cameras were not communicating with the Vicon servers. This led to the cameras not tracking the reflective markers in a way that reflected human motion. This issue was observable during the playback of the marker data. While occasional marker misplacements do occur, it can be

fixed by predicting its motion by use of the other markers in the cluster, however this was not possible during the initial data collection as many of the markers were showing erratic behaviour. Once a Vicon Nexus software update was installed the marker tracking errors were completely resolved and it greatly reduced the issues with the data collection. This resulted in a final group of 23 Mako knees and 28 Oxford knees in the group analysis.

When the patients arrived for their one year post-operative assessment, their age, gender and operated knee were noted in order to be able to compare the demographics, and to see if there were any statistically significant ($p < 0.05$) differences between the two groups using a chi-squared test. The age data is shown in Table 4.5, and the gender and operated knee data is shown in Table 4.6. These tables show the average age of the Mako group was 62.0 and the Oxford group is 63.7. The p-value for the patient ages was 0.33 showing the difference was not statistically significant. The Mako group consists of 56% men and the Oxford group consists of 57% men. The p-value for the patient genders is 0.96, therefore not statistically significantly different. The operated side for the Mako group were 48% on the left knee, and the Oxford group were 68% on the left knee. The p-value for the operated sides was 0.15 thus not statistically significantly different.

Age	**Mako**	**Oxford**
N	23	28
Average	62.0	63.7
St. Dev	6.4	5.4
Max	74	74
Min	52	55
P-Value	0.33	

Table 4.5: Patient Ages (years)

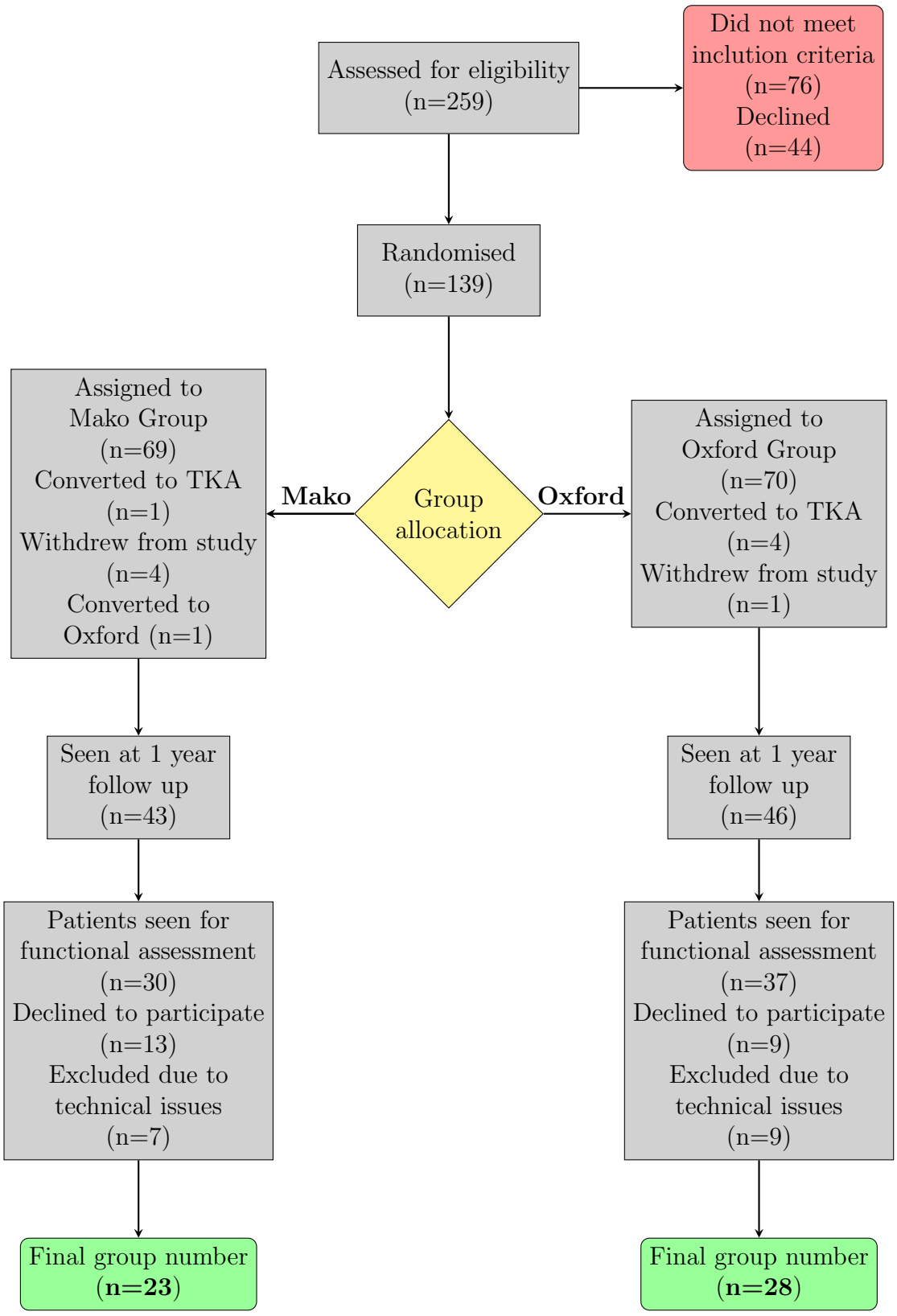


Figure 4.32: Flow diagram breaking down the Mako and Oxford groups and the number of patients at each stage of the trial

	Mako	Oxford	P-Value
N	23	28	
Men/Women	13/10	16/12	0.96
Left/Right	11/12	19/9	0.15

Table 4.6: Other Patient Demographics

4.4.2 Activity Graphs

This section investigates the kinematic graphs for activities of walking, ascending stairs and descending stairs.

First, compound plots for each surgical group and lower limb joint (hip, knee and ankle) will be separately presented. The purpose of these compound plots is to observe any unusual gait cycles within the group and to allow the researcher to investigate if there were any explanations for this unusual behaviour. No unusual behaviour was observed in the gait angles.

Then for each activity a graph for each lower limb joint is presented showing both the mean kinematic pattern for the Oxford UKA group and that for the Mako UKA group. These plots aim to demonstrate the differences – if any – between the Oxford UKA and Mako UKA. The Mako group is shown with an orange line, and the Oxford in navy blue. The dotted lines on the graphs indicate a ± 1 standard deviation (66% confidence interval) from the mean.

Walking Data

Figure 4.33 shows the compound graphs of all the knee angles during the level walking.

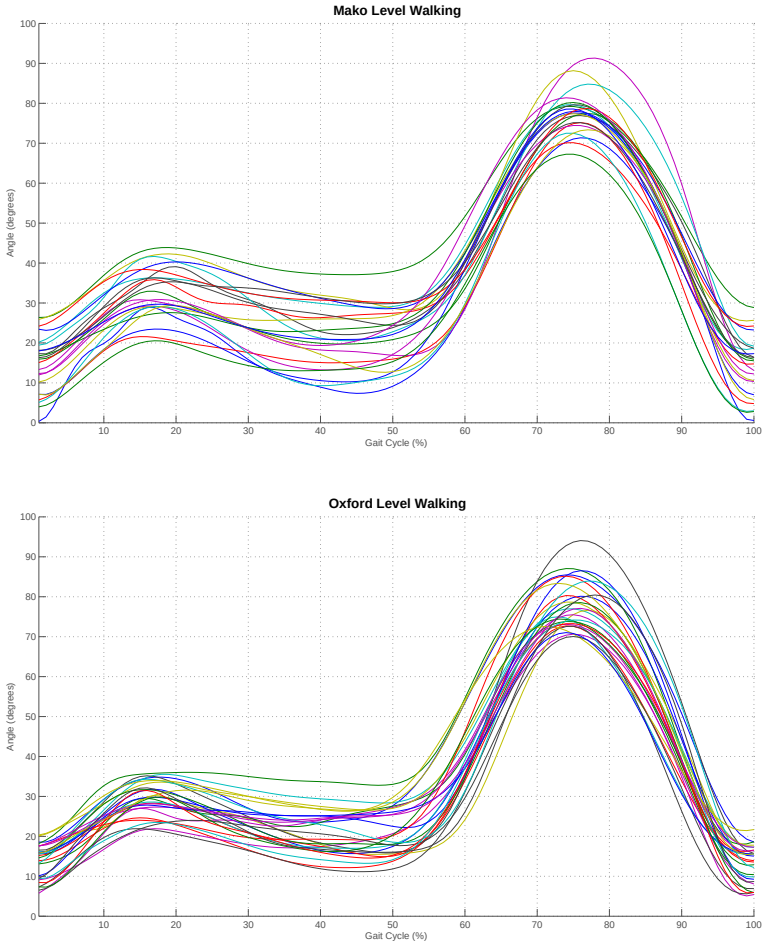


Figure 4.33: Compound graph of the Mako group (top) and Oxford group (bottom) knee angles during level walking

Figure 4.34 shows the average knee angles during the level walking task for the Oxford UKA group and Mako UKA group.

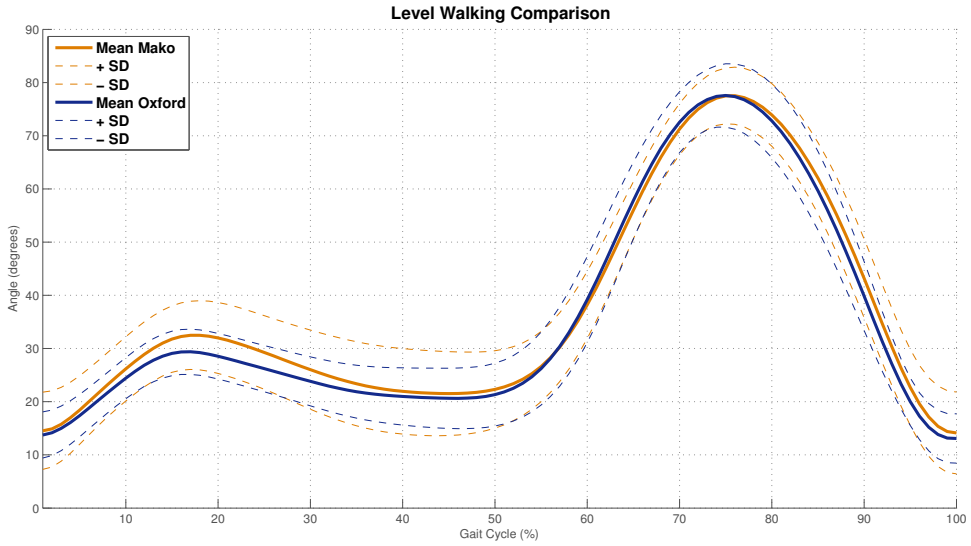


Figure 4.34: Comparison of the Mako and Oxford group knee angles during level walking

Figure 4.35 shows the average knee excursion (change from the minimum) during the level walking task for the Oxford UKA group and Mako UKA group.

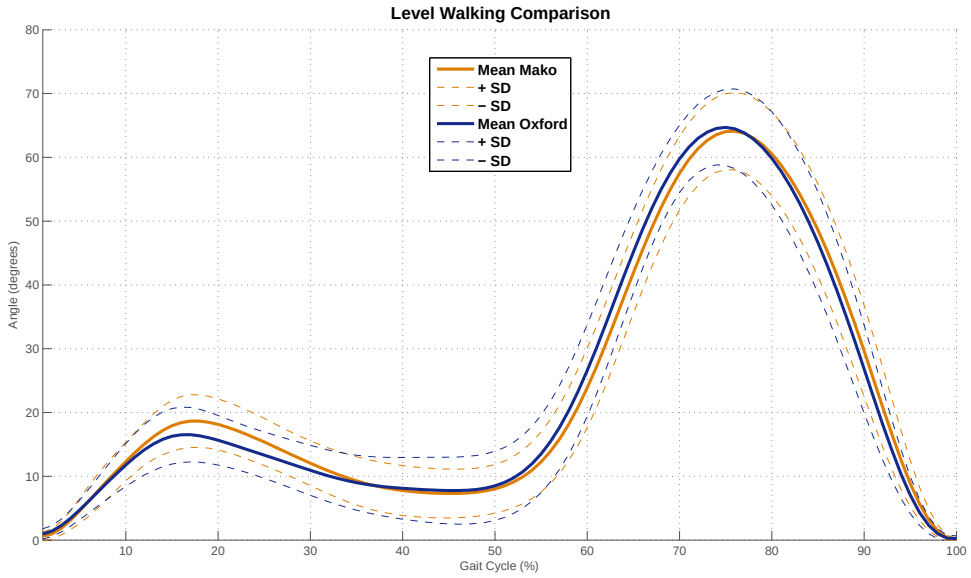


Figure 4.35: Comparison of the Mako and Oxford group knee excursion during level walking

Figure 4.36 shows the compound graphs of all the knee moments during the level walking.

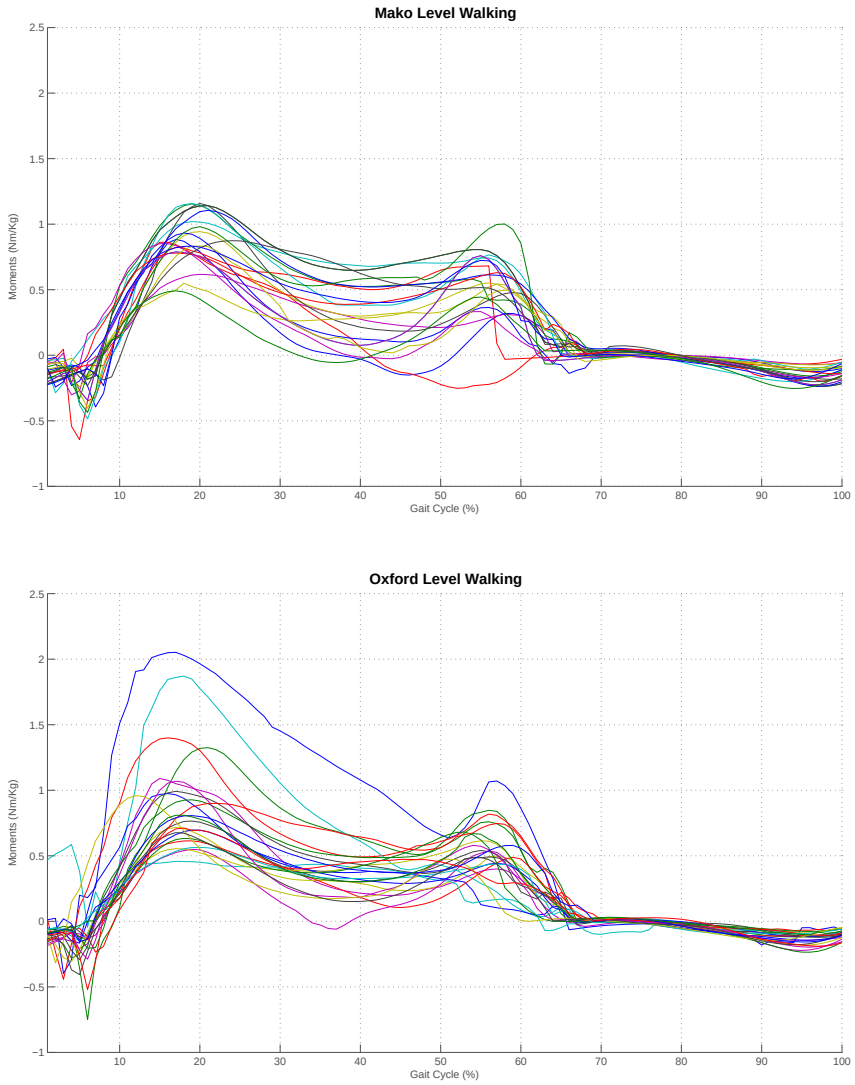


Figure 4.36: Compound graph of the Mako group (top) and Oxford group (bottom) knee moments during level walking

Figure 4.37 shows the average knee moments during the level walking task for the Oxford UKA group and Mako UKA group.

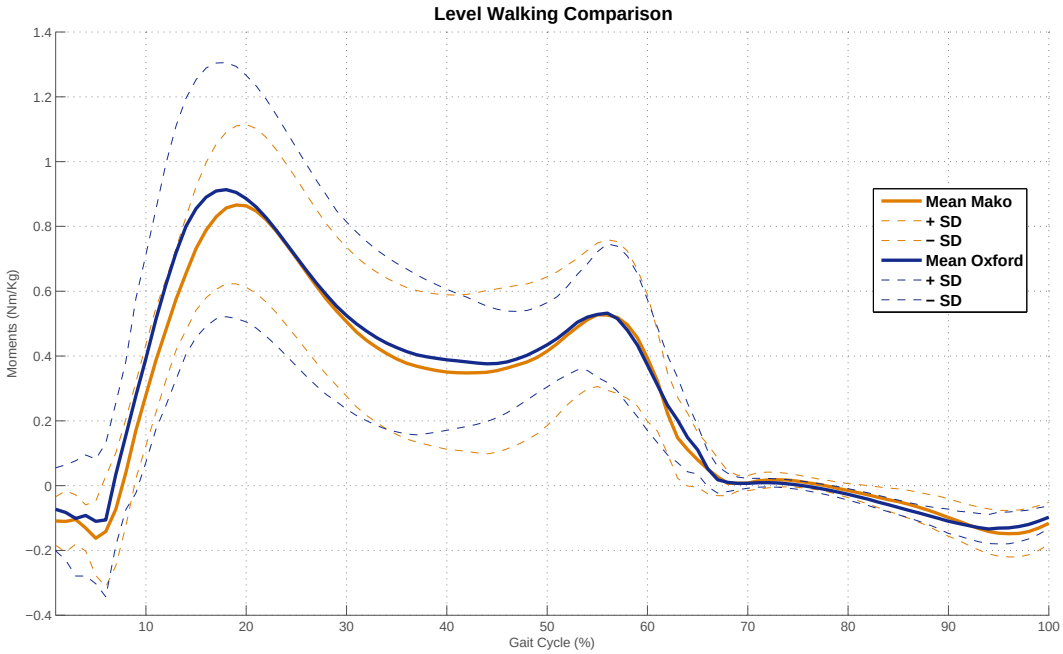


Figure 4.37: Comparison of the Mako and Oxford group knee moments during level walking

Figure 4.38 shows the compound graphs of all the hip angles during the level walking.

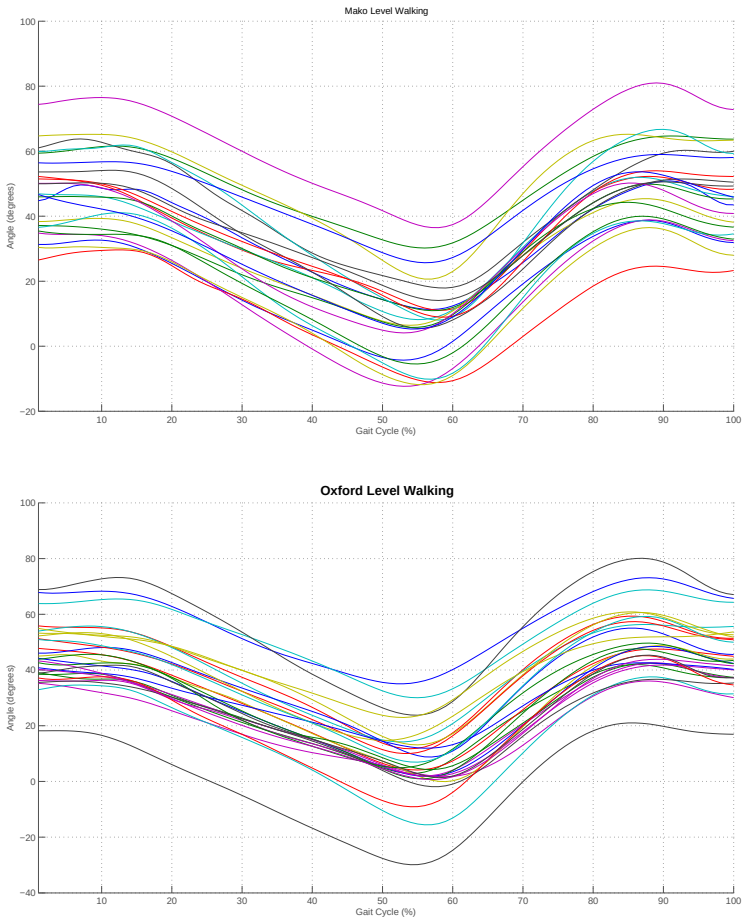


Figure 4.38: Compound graph of the Mako group (top) and Oxford group (bottom) hip during level walking

Figure 4.39 shows the average hip angles during the level walking task for the Oxford UKA group and Mako UKA group.

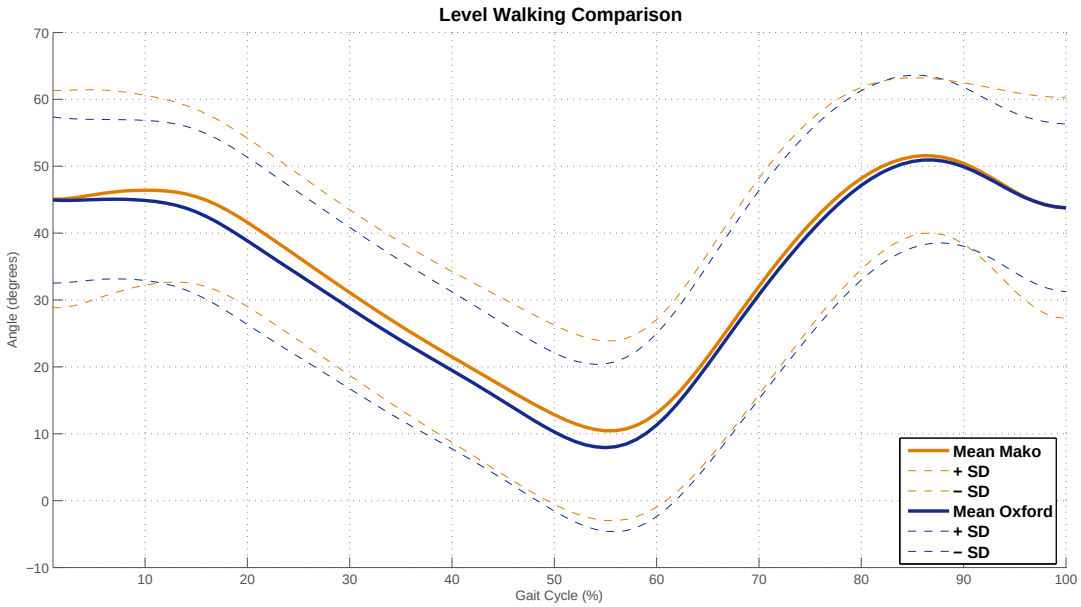


Figure 4.39: Comparison of the Mako and Oxford group hip angles during level walking

Figure 4.40 shows the compound graphs of all the ankle angles during the level walking.

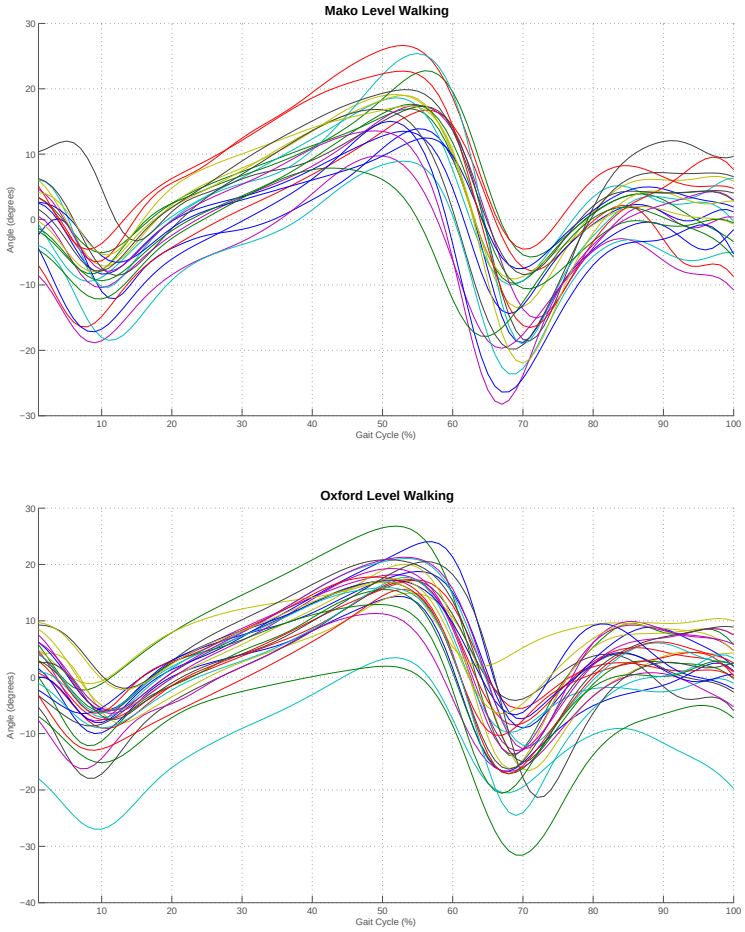


Figure 4.40: Compound graph of the Mako group (top) and Oxford group (bottom) ankle during level walking

Figure 4.41 shows the average ankle angles during the level walking task for the Oxford UKA group and Mako UKA group.

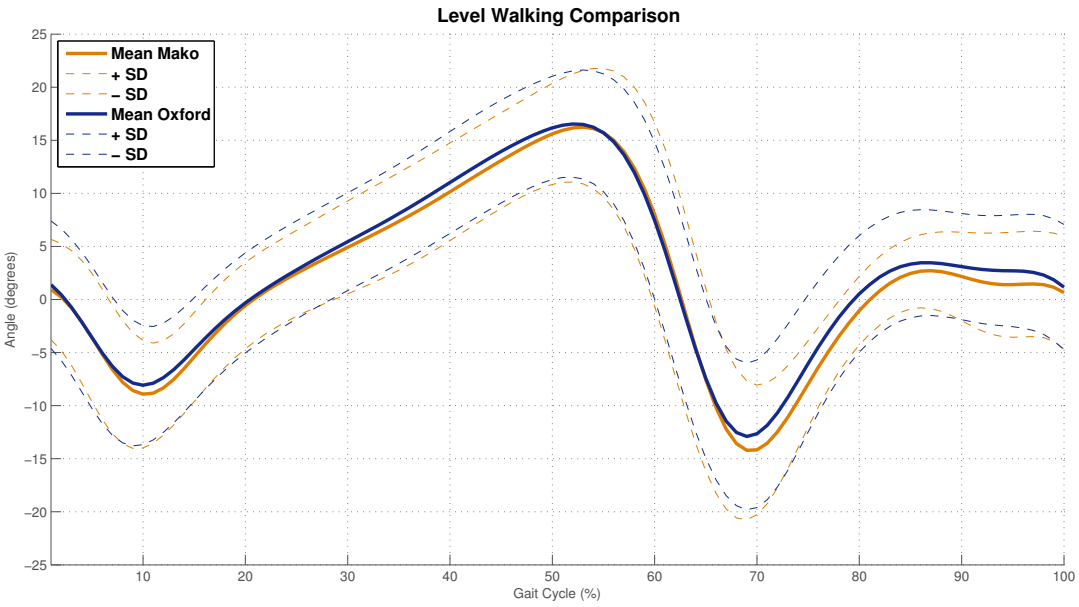


Figure 4.41: Comparison of the Mako and Oxford group ankle angles during level walking

Summary

The data shown in the compound plots (Figure 4.33) show that there are variations between the patients in both groups. While there are ranges in the values shown, the knee angles behave in an overall repeatable fashion. However one patient in the Oxford group did not appear to extend their leg during mid-stance, indicated by a plateau between 20 - 50% of the gait cycle. This means the patient did not extend their knee in preparation for toe off.

During the level walking kinematics shown in Figure 4.34 similar knee flexion/extension patterns are shown. Observing the graphs however shows that the Mako group appears to reach higher flexion angles during the stance phase of gait. Another observation is that in both cases the knees are not completely straight during foot strike. While some slight knee flexion is expected on foot strike due

to shock absorption, the average value of 14.5° for the Mako and 13.7° for the Oxford may be due to slight marker placement errors. Both groups have similar values at this point and are comparable with one another.

A series of t-tests were performed across the full range of the gait cycle (one t-test for each of the 100 individual percentages of the gait cycle). This test showed there was a statistically significant difference ($p < 0.05$) between the Mako and the Oxford group between 18 - 23% of the gait cycle.

In addition to the recorded knee angles the knee excursion angles were presented in Figure 4.35. The purpose of this was to reduce the effect of any errors that may have come as a result of variation in the neutral position of the joints. The graphs show the changes from the recorded individual neutral position not the absolute joint angles recorded. Other than differences in the vertical scale of the graph, it looks similar to that of the recorded absolute knee angles, i.e. the Mako group appears to reach a higher maximum stance knee excursion than the Oxford group. A t-test was also performed on this data set, and once again there were areas of statistical significance at the stance phase. The area of statistical significance was increased to 18 - 25% of the gait cycle.

Figure 4.36 shows the compound plots for the knee moments. Eight people (3 from the Mako group, and 5 from the Oxford group) showed anomalous behaviour such as a sudden drop of the moments to zero which cannot occur. For this reason they were removed from the analysis, from the comparison graph in Figure 4.37 and all future knee moment comparisons. The most likely cause being an inability to deal with a gap in the marker projection. The comparison graph shows the Oxford group has a higher initial peak during stance phase, and a lower peak before toe off. It is important to note at this point that during the initial peaks the standard deviation of the Oxford group is very high, implying a lot of variation in the knee moments for the Oxford group at this point. Again a t-test was performed at each percentage point across the full cycle and there

were no statistically significant differences in the knee moments between the two groups.

Figure 4.38 shows the compound graphs for the hip joints during level walking. While there appears to be a range in the hip angles their overall patterns are very similar to one another, in both surgical groups. The level walking kinematics for the hip joint are shown in Figure 4.39. While it looks like the Mako group has slightly higher hip angle overall during the stance phase it is also clear that the standard deviations for both groups are considerable. A series of t-tests performed across the cycle for the the hip data shows no statistically significant difference between the two groups.

The ankle compound plots in Figure 4.40 show the same overall range of values that are present in the ankle, but still behave similarly with no obvious differences in gait pattern angles in the sagittal plane between individuals. Figure 4.41 compares the ankle joint during the level walking activity. Both groups perform similarly in the ankle joint, and the t-test on this group showed no statistical significance.

In summary, during the level walking activity there was a statistically significant difference between the two groups during the first peak knee angle in stance phase – the highest flexion point during weight bearing. The Mako group reached higher flexion angles in terms of absolute knee angle and the knee excursion. There were no other statistically significant differences in the knee moments or in the hip and ankle angles in the sagittal plane between individuals.

Ascending Stairs

Figure 4.42 shows the compound graphs of all the knee angles during stair ascent.

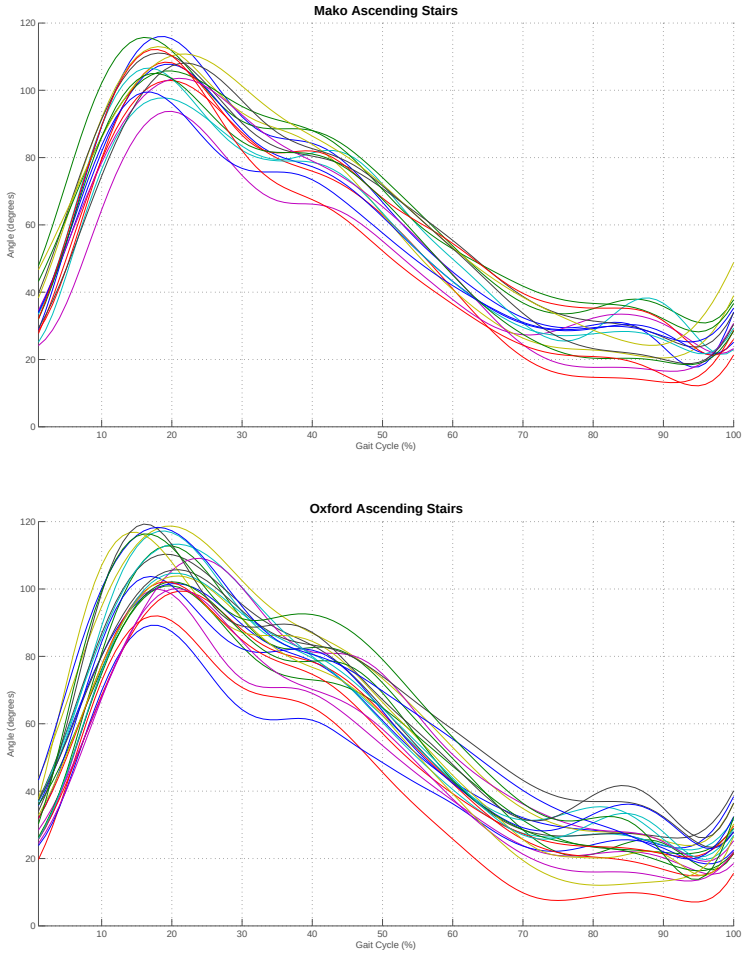


Figure 4.42: Compound graph of the Mako group (top) and Oxford group (bottom) knee during stair ascent

Figure 4.43 shows the average knee angles during stair ascent for the Oxford UKA group and Mako UKA group.

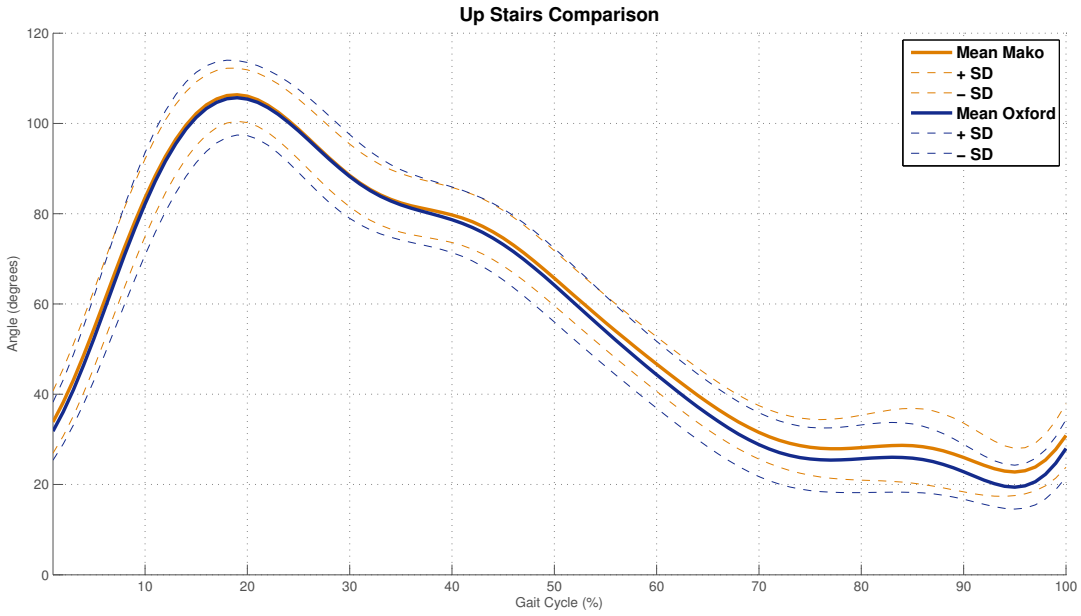


Figure 4.43: Comparison of the Mako and Oxford group knee angles during stair ascent

Figure 4.44 shows the compound graphs of all the hip angles during stair ascent.

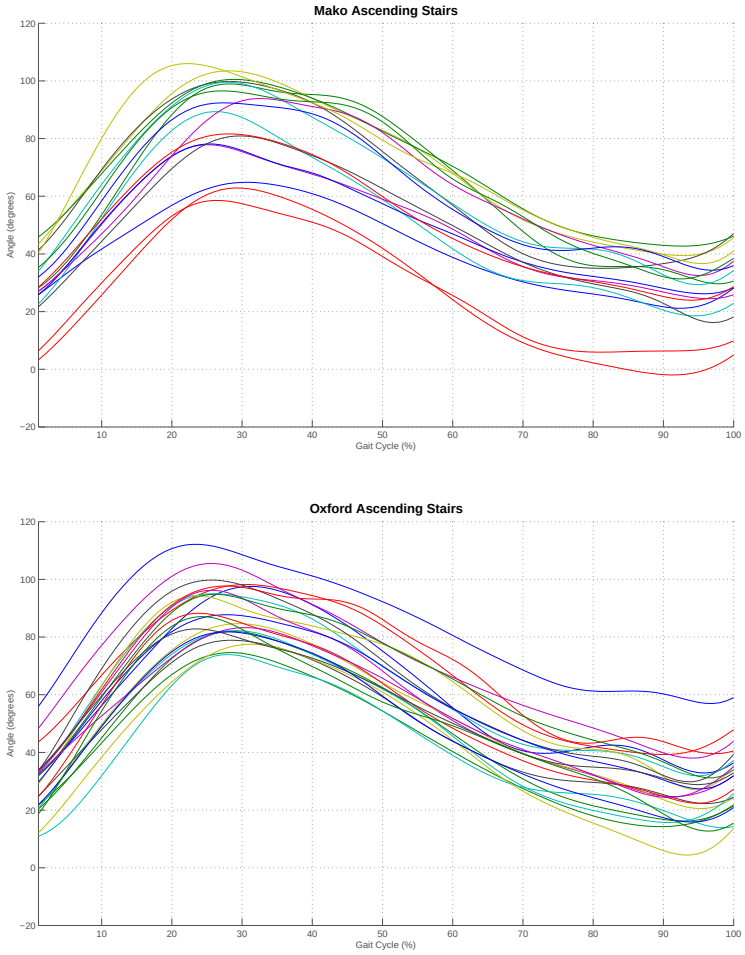


Figure 4.44: Compound graph of the Mako group (top) and Oxford group (bottom) hip during stair ascent

Figure 4.45 shows the average hip angles during stair ascent for the Oxford UKA group and Mako UKA group.

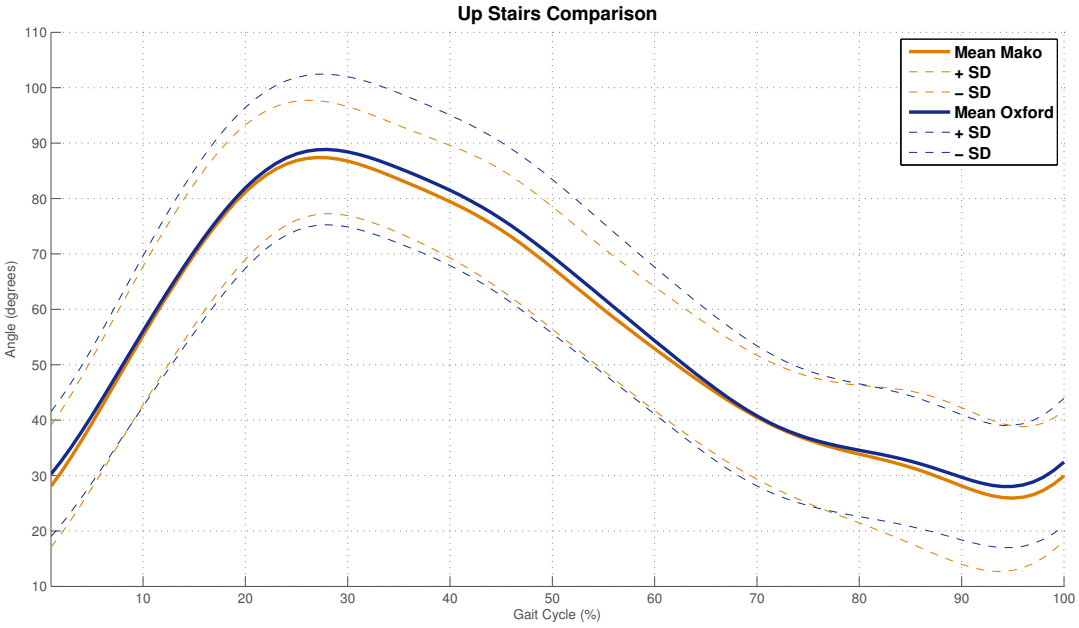


Figure 4.45: Comparison of the Mako and Oxford group hip angles during stair ascent

Figure 4.46 shows the compound graphs of all the ankle angles during stair ascent.

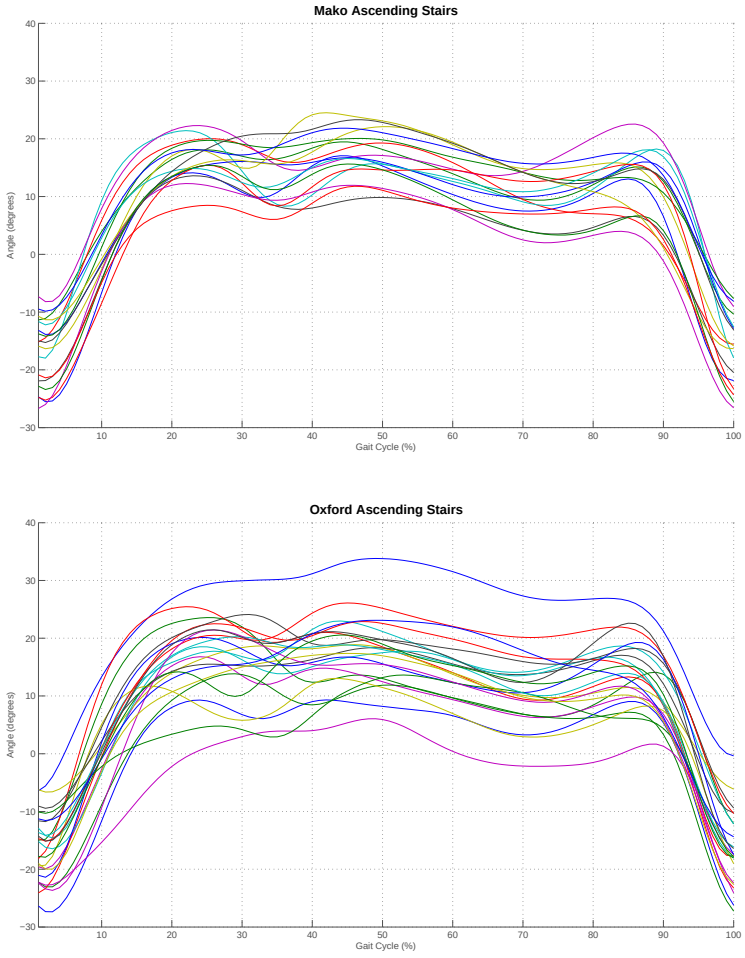


Figure 4.46: Compound graph of the Mako group (top) and Oxford group (bottom) ankle during stair ascent

Figure 4.47 shows the average ankle angles during stair ascent for the Oxford UKA group and Mako UKA group.

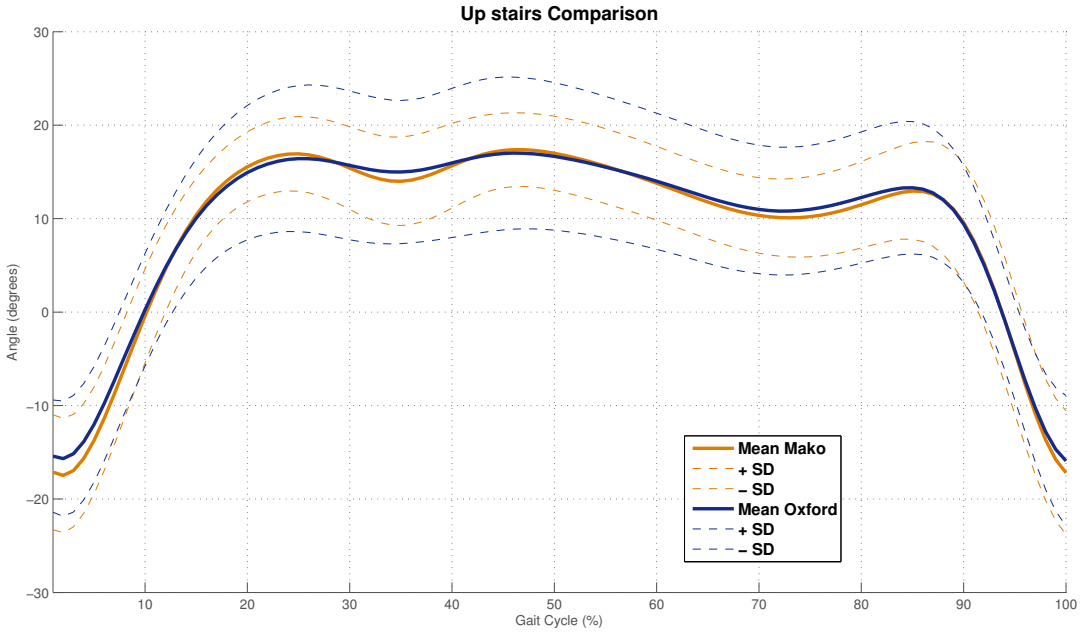


Figure 4.47: Comparison of the Mako and Oxford group ankle angles during stair ascent

Summary

The gait cycle for the stair ascent tasks begin and end at toe off to toe off, not foot strike to foot strike; as explained in the Methodology section in Chapter 3.

The compound plots (Figures 4.48, 4.50 and 4.52) show that the vast majority of patients follow the same pattern in all three joints for this activity. The angle ranges for the knee and hip are similar in both surgical groups. There appears to be a higher range of patient variation values with the Oxford ankles compared to the Mako group.

The knee, hip and ankle comparison plots (Figures 4.43, 4.45 and 4.47 respectively) also show similar behaviour between the two surgical groups. As noticed with the ankle joints there does appear to be a higher standard deviation in the Oxford group compared to the Mako group. However both average plots show a

high degree of similarly.

The t-test performed on the full range of the stair ascent cycle showed no statistically significant differences between the two surgical groups within any of the three joints.

Overall both surgical groups behaved very similarly during the stair ascent task and no statistical difference was seen between the two.

Descending Stairs

Figure 4.48 shows the compound graphs of all the ankle angles during stair descent.

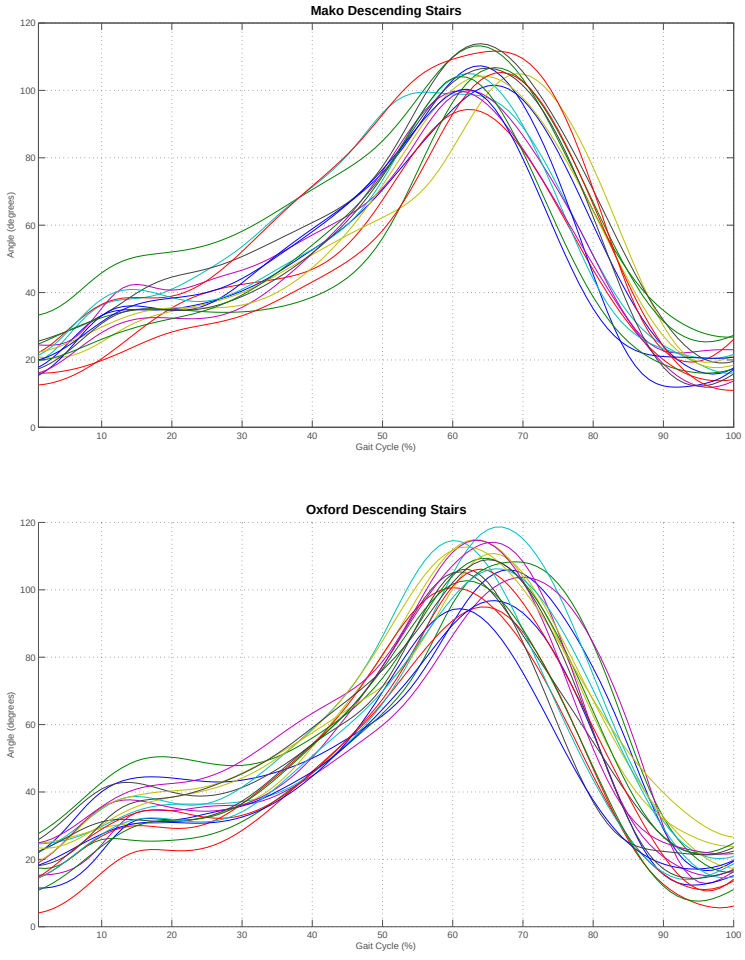


Figure 4.48: Compound graph of the Mako group (top) and Oxford group (bottom) knee during stair descent

Figure 4.49 shows the average knee angles during stair descent for the Oxford UKA group and Mako UKA group.

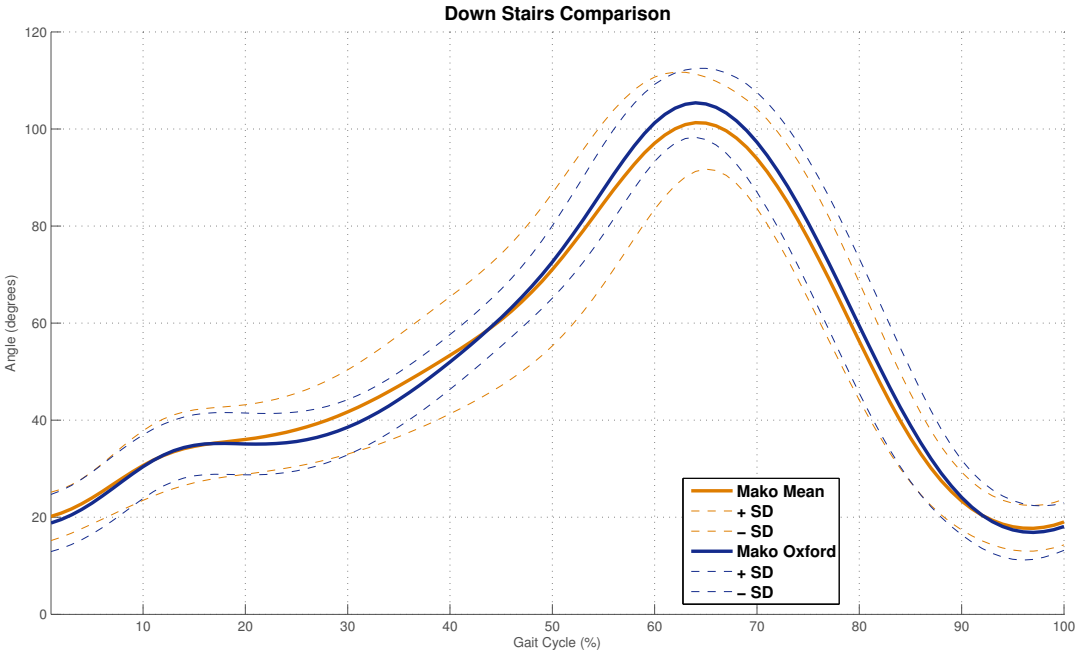


Figure 4.49: Comparison of the Mako and Oxford group knee angles during stair descent

Figure 4.50 shows the compound graphs of all the knee angles during stair descent.

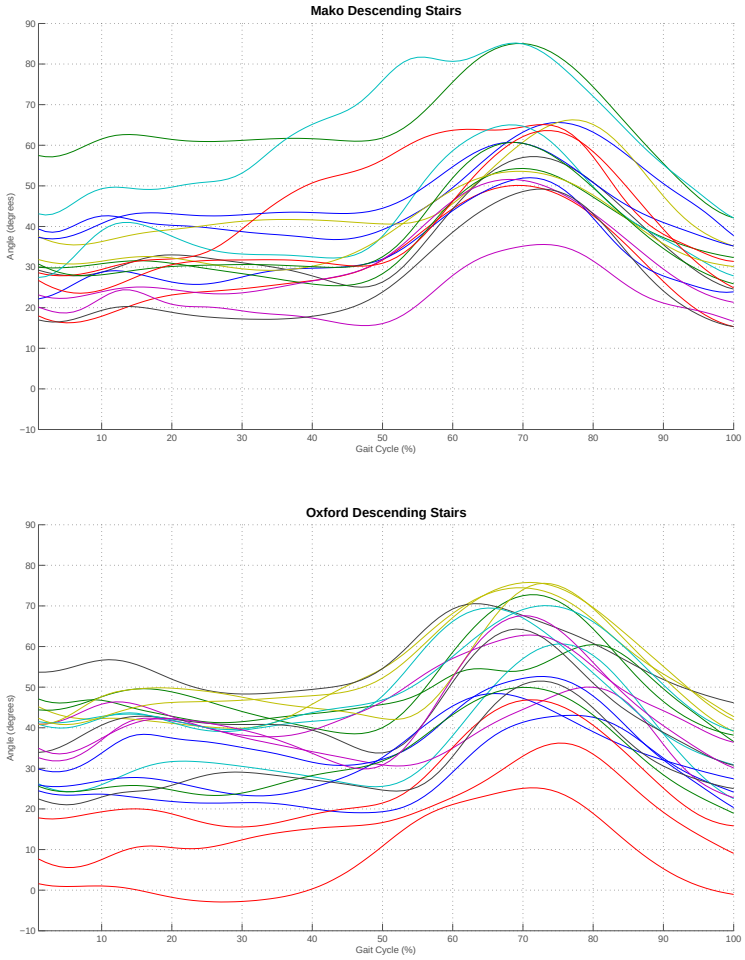


Figure 4.50: Compound graph of the Mako group (top) and Oxford group (bottom) hip during stair descent

Figure 4.51 shows the average hip angles during stair descent for the Oxford UKA group and Mako UKA group.

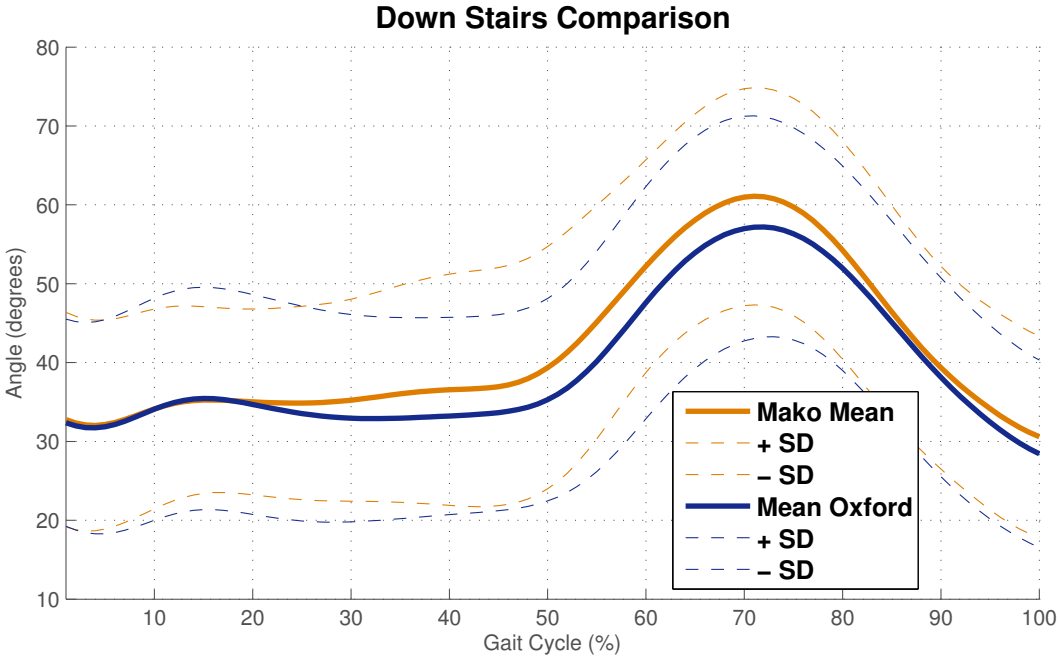


Figure 4.51: Comparison of the Mako and Oxford group hip angles during stair descent

Figure 4.52 shows the compound graphs of all the knee angles during stair descent.

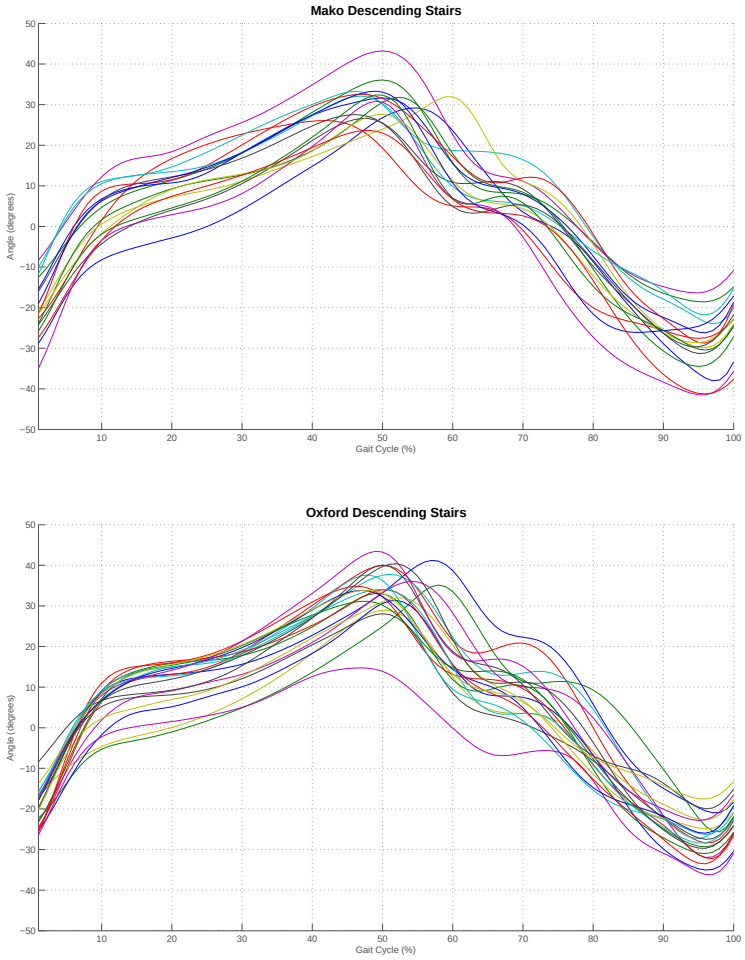


Figure 4.52: Compound graph of the Mako group (top) and Oxford group (bottom) ankle during stair descent

Figure 4.53 shows the average ankle angles during stair descent for the Oxford UKA group and Mako UKA group.

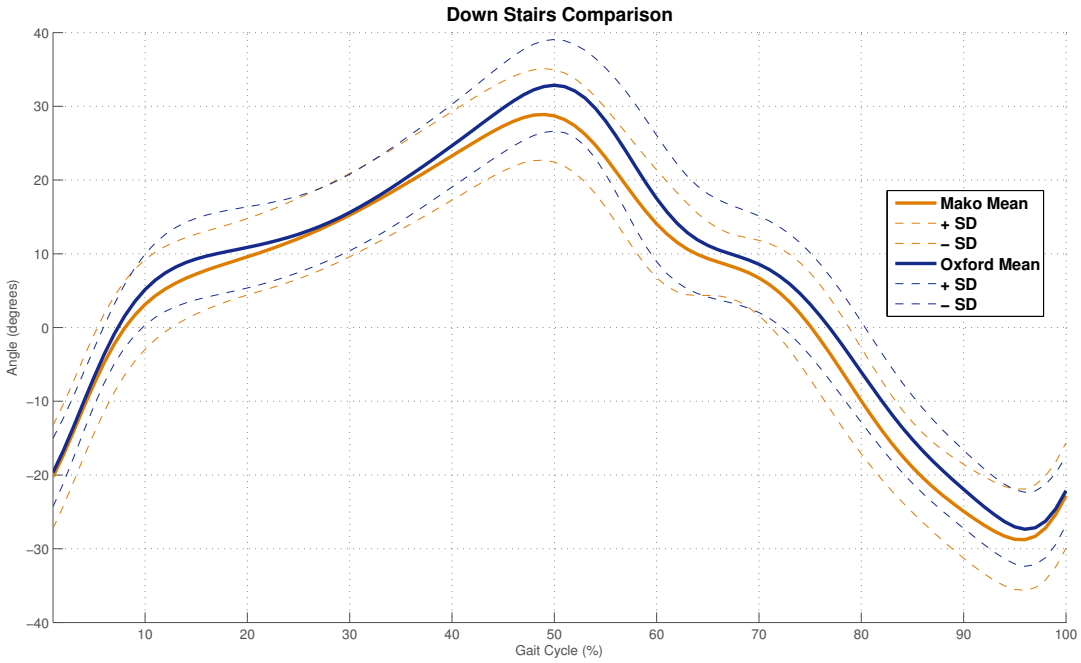


Figure 4.53: Comparison of the Mako and Oxford group ankle angles during stair descent

Summary

Figure 4.48 shows the compound plots for the stair descent task for the knee joint. The knee patterns in both groups appear to follow similar patterns and there are no obvious deviations in either group. The compound plots for the hip joint (Figure 4.50) show the peak angles reached for almost all the patients are at approximately 70% of the stair descent cycle. There are however large variations prior to this point between the patients. The ankle joint plots (Figure 4.52) show similar behaviour across the groups. Most patients follow a similar pattern, and reach their peak angle at around 50% of the stair descent cycle – although a small number of patients achieve the peak angle after 50% of the stair descent cycle.

The comparison plots for the knee at stair descent (Figure 4.49) show that

the Oxford group achieve a higher peak angle than compared to the Mako group. However when a t-test is performed on the gait cycle there was only one point where there was a p-value of less than 0.05 – at 30% of the gait cycle. The statistically significant difference was not at the peak angle. The hip comparison in Figure 4.51 shows that the Mako group reaches a higher peak value than the Oxford group. There is however a large variation in the data as shown by the very large standard deviation in the comparison graph. T-tests on the whole movement cycle showed there was no statistically significant differences between the two surgical groups. The comparison graph for the ankle is shown in Figure 4.53. The Oxford group reaches a higher peak angle compared to the Mako group. This is confirmed by the t-test on the whole group where there's a statistically significant difference between the groups at 52-55% of the gait cycle – the area of the peak angle. Additionally there was a statistically significant difference between the two groups between 83-84% of the gait cycle.

In summary there were no statistically significant differences in the hip angles during stair descent, however there was one point of statistical difference at the knee during the task, as well as two points in the ankle – one of them being at the peak angle.

4.4.3 Comparing Max, Min and Excursion Angles

This section compares the maximum, minimum and excursion angles for the groups during walking, ascending stairs and descending stairs. This analysis is not affected by the timing of the movements but simply assesses the range of movement used at the joints. Due to the biphasic nature of the knee angles during level walking, the knee maximum, minimum and three different flexion angles were calculated. To calculate these three excursions angles, five points on the knee graph were required. These were the maximum knee angle, and minimum knee angle through the entire range, as well the angle at foot strike,

the maximum knee angle during stance, and the following minimum angle during stance.

The total knee excursion was calculated by calculating the range of motion between the maximum and minimum knee angles through the entire range (it may be possible that the overall minimum may be the same as another point, such as the angle at foot-strike). The next knee excursion value is defined as foot-strike (FS) to mid-stance (MS) which is the range between the minimum knee angle at foot strike to the maximum knee angle at stance. The final knee excursion value that is calculated is defined as mid-stance (MS) to terminal stance (TS) which is the angle from the maximum knee angle at stance to the minimum angle during stance. Only the maximum, minimum and total joint excursion were calculated for the hip and ankle during level walking. The maximum, minimum and total joint excursions were also calculated for all the joints during ascending and descending stairs.

Once the angles were calculated for each trial patient the statistical programme IBM SPSS Statistics calculated the probability that the data was normally distributed. By using the Anderson-Darling (AD) test it can be seen if the data set has a normal distribution. The test rejects the null hypothesis of normal distribution when the p-value is less than or equal to 0.05. If that is the case a Mann Whitney (U) test is used to analyse any statistical differences between the two groups rather than a t-test. If the data is normally distributed then the comparison will use a two tail independent t-test.

Normality Tests

Figure 4.54 illustrates an example of the Q-Q plot for the parameter level walking knee excursion. For this example the AD value was 0.290 and the p value 0.597 indicating that this parameter was normally distributed. Therefore a two tail independent t-test was used to compare the level walking knee joint excursion

angles for the two surgical groups. A p-value of less than 0.05 indicates a level of significant difference. The normality tests for walking and stair ascent and descent are shown in Figures 4.7, 4.8 and 4.9 respectively. As the table shows all the data were normally distributed except for the maximum ankle angles during walking. Therefore the statistical significance of the maximum ankle angle data set will be obtained from a Mann Whitney (U) test, and the other variables will be evaluated using a two tail independent t-test.

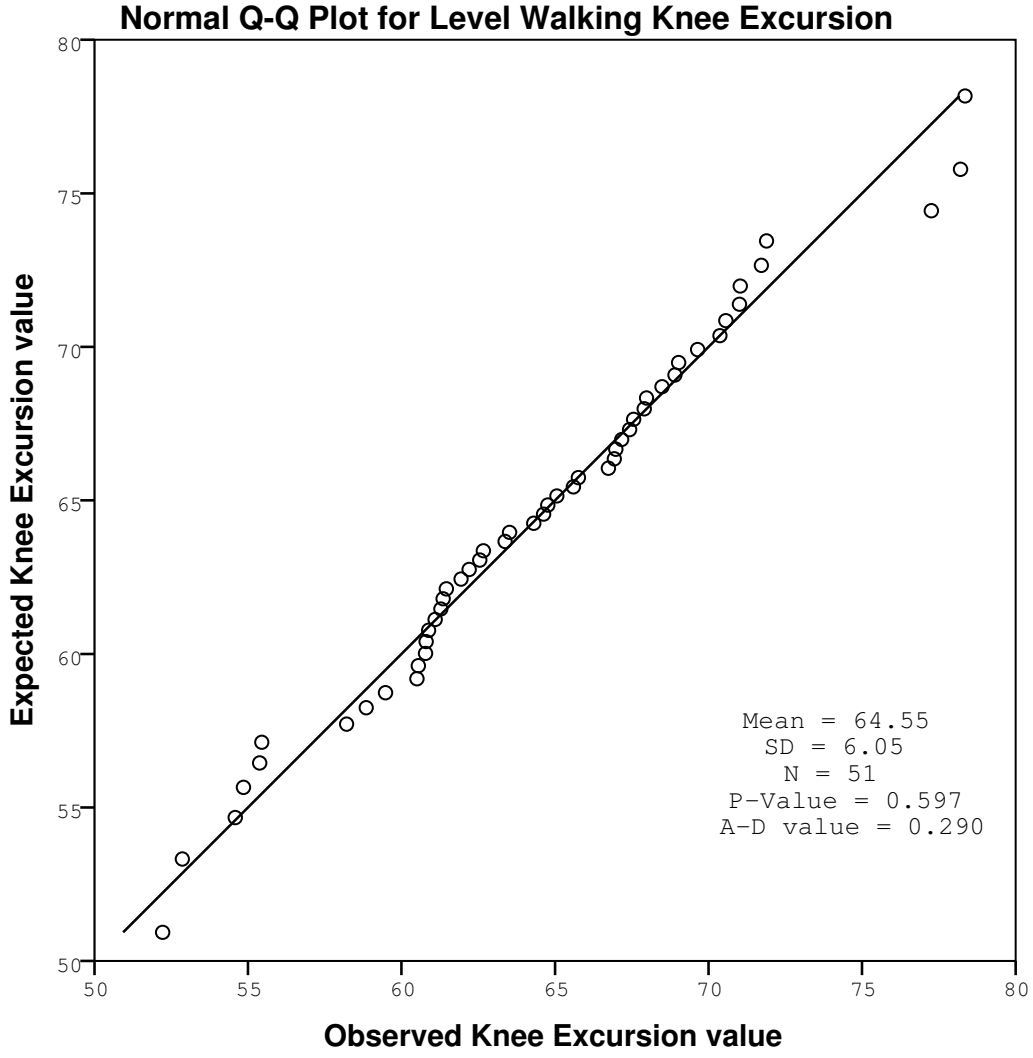


Figure 4.54: Normal Q-Q plot and data for level walking knee excursion

Walking	A-D Value	P-Value
Knee Max	0.64	0.09
Knee Min	0.62	0.10
Knee Excursion (Total)	0.29	0.60
Knee Excursion (FS to MS)	0.22	0.84
Knee Excursion (MS to TS)	0.63	0.10
Hip Max	0.34	0.48
Hip Min	0.56	0.14
Hip Excursion	0.26	0.70
Ankle Max	1.08	**0.01**
Ankle Min	0.40	0.36
Ankle Excursion	0.44	0.28

Table 4.7: Normality tests for maximum, minimum and excursion values for level walking

Ascending Stairs	A-D Value	P-Value
Knee Max	0.28	0.64
Knee Min	0.23	0.80
Knee Excursion	0.31	0.54
Hip Max	0.48	0.22
Hip Min	0.24	0.76
Hip Excursion	0.53	0.16
Ankle Max	0.40	0.34
Ankle Min	0.43	0.29
Ankle Excursion	0.52	0.17

Table 4.8: Normality tests for maximum, minimum and excursion values for stair ascent

Descending Stairs	A-D Value	P-Value
Knee Max	0.32	0.52
Knee Min	0.22	0.83
Knee Excursion	0.20	0.87
Hip Max	0.28	0.63
Hip Min	0.41	0.33
Hip Excursion	0.19	0.90
Ankle Max	0.52	0.17
Ankle Min	0.21	0.84
Ankle Excursion	0.22	0.83

Table 4.9: Normality tests for maximum, minimum and excursion values for stair descent

Walking	Mean Mako	St. Dev	Max	Min	Mean Oxford	St. Dev	Max	Min	P-Value
N	23				28				
Hip									
Max	54.4°	13.0°	81.0°	29.6°	51.8°	13.6°	83.9°	21.0°	0.49
Min	8.6°	26.4°	36.5°	-12.3°	7.2°	12.3°	35.1°	-29.9°	0.70
Excursion	45.8°	21.7°	67.6°	33.3°	44.6°	8.0°	71.7°	30.7°	0.61
Knee (total)									
Max	77.7°	5.4°	91.3°	67.2°	78.0°	6.0°	94.1°	70.0°	0.90
Min	13.9°	7.5°	26.4°	0.3°	12.8°	4.5°	20.3°	5.1°	0.54
Excursion	63.8°	6.3°	78.2°	52.9°	65.1°	5.9°	78.4°	52.2°	0.45
Knee (FS to MS)									
Excursion	18.6°	4.2°	28.6°	10.8°	15.8°	4.2°	23.0°	6.4°	**0.03**
Knee (MS to TS)									
Excursion	12.2°	5.2°	21.5°	3.5°	9.7°	4.9°	19.3°	2.7°	0.09
Ankle									
Max	16.9°	4.8°	26.6°	7.9°	16.9°	5.1°	26.8°	1.9°	0.73
Min	-15.6°	17.4°	-6.4°	-28.2°	-14.7°	6.5°	-1.1°	-31.6°	0.6
Excursion	32.6°	25.1°	44.5°	20.0°	31.6°	5.3°	41.8°	18.0°	0.54
% Stance	66.5	1.9	68.8	62.6	65.6	1.9	68.9	61.0	0.08

Table 4.10: Table of maximum, minimum and excursion angles for each joint during walking (degrees)

Walking	Mean Mako	St. Dev	Max	Min	Mean Oxford	St. Dev	Max	Min	P-Value
N	20				23				
Knee Moment (Peak 1)	0.90	0.24	1.16	0.36	0.94	0.40	2.05	0.55	0.60
Knee Moment (Peak 2)	0.57	0.19	1.00	0.31	0.58	0.17	1.07	0.38	0.85

Table 4.11: Table of maximum knee moments during walking (Nm/kg)

Stair ascent	Mean Mako	St. Dev	Max	Min	Mean Oxford	St. Dev	Max	Min	P-Value
N	17				24				
Hip									
Max	87.3°	10.1°	112.1°	73.9°	89.7°	13.5°	106.0°	58.5°	0.52
Min	23.2°	11.6°	56.0°	4.4°	27.0°	10.6°	42.7°	-2.0°	0.30
Excursion	64.0°	6.0°	74.4°	54.0°	62.7°	6.9°	70.8°	43.7°	0.50
Knee									
Max	106.9°	6.1°	116.0°	93.7°	107.2°	8.6°	119.3°	89.2°	0.90
Min	21.0°	4.8°	30.9°	12.2°	18.6°	4.8°	26.1°	7.1°	0.12
Excursion	85.9°	7.6°	99.9°	72.0°	88.7°	8.3°	102.5°	70.8°	0.28
Ankle									
Max	18.6°	3.9°	24.5°	11.8°	19.4°	6.7°	33.8°	-1.6°	0.63
Min	-17.7°	5.9°	-9.1°	-26.7°	-17.4°	5.7°	-6.4°	-27.4°	0.84
Excursion	36.3°	4.1°	42.6°	30.6°	36.8°	7.5°	47.0°	9.7°	0.81
% Stance	35.0	2.1	39.0	30.5	34.7	2.4	38.6	30.0	0.62

Table 4.12: Table of maximum, minimum and excursion angles for each joint during stair ascent (degrees)

Stair Descent	Mean Mako	St. Dev	Max	Min	Mean Oxford	St. Dev	Max	Min	P-Value
N	17				22				
Hip									
Max	60.0°	12.3°	85.2°	35.6°	58.8°	13.7°	75.8°	25.2°	0.76
Min	27.3°	8.5°	42.1°	15.3°	27.5°	12.2°	46.1°	-2.9°	0.97
Excursion	32.7°	6.4°	43.1°	20.0°	31.3°	4.7°	38.6°	23.9°	0.45
Knee									
Max	104.6°	5.2°	113.9°	94.3°	107.4°	6.7°	118.6°	94.4°	0.15
Min	17.5°	4.7°	26.7°	11.0°	15.8°	5.3°	23.9°	4.1°	0.31
Excursion	87.1°	5.4°	95.4°	77.8°	91.6°	5.7°	100.8°	77.3°	**0.02**
Ankle									
Max	31.2°	4.5°	43.2°	23.7°	34.7°	6.1°	43.4°	14.7°	0.05
Min	-29.1°	7.0°	-16.4°	-41.5°	-27.1°	5.2°	-17.5°	-36.2°	0.33
Excursion	60.2°	5.1°	72.3°	53.6°	61.7°	5.7°	70.1°	50.9°	0.40
% Stance	61.4	2.9	66.8	56.7	62.1	2.9	68.3	57.9	0.45

Table 4.13: Table of maximum, minimum and excursion angles for each joint during stair descent (degrees)

Walking Summary

Table 4.10 compares the mean maximum, minimum and excursion for the lower limb joints during level walking between the two surgical groups as well as the number of patients per group and average stance duration as a percentage of the cycle. The tables also show the standard deviations between these values and the calculated p-values when the groups were compared using the appropriate statistical tests.

From the table it can be seen that there are no statistically significant difference between the two groups in the hip joint angles during level walking. Similarly there was no statistically significant difference between the knee joints over the whole gait cycle. However the differences between the knees become more apparent during weight bearing. From foot-strike to mid-stance the Mako group achieves a higher range of motion than that of the Oxford group - 18.6° compared to 15.8°. This difference is statistically significant – at a p-value of 0.025. The excursion difference between the two groups from mid-stance to terminal stance was 12.2° for the Mako group and 9.7° for the Oxford group. Although the Mako group also achieved a higher range of motion for this weight-bearing portion of the gait cycle, this did not achieve statistical significance (p-value = 0.093).

For the ankle joint there are no any statistically significant differences between the maximum, minimum and total excursion angles between the two surgical groups. The Mako group also spent a longer period of the gait cycle in weight bearing at 66.5% compared to the Oxford group at 65.6%, however the p-value between the two mean values was 0.08.

Table 4.11 compares the two maximum knee moment values achieved during level walking between the Mako and Oxford groups. During the first peak value it can be seen the the Oxford group has a higher standard deviation than those of the Mako group, as observed in Figure 4.37. However the average moments of the Oxford group was 0.94Nm/kg, compared to 0.90Nm/kg for the Mako group.

There was no statistically significant difference between the two groups. Similarly there was no statistically significant differences between the two surgical groups at the second peak knee moment (p-value 0.85).

Stair Navigation Summary

For stair ascent 10 patients (6 Mako, and 4 Oxford) had to be excluded from the analysis. Out of the 6 Mako patients 2 were removed due to force plate errors during the activity meaning the foot strike and foot off events could not be located easily. Two others performed the task one step at a time with both legs, meaning it was not directly comparable to the rest of the group. The final two had to be excluded due to errors the back with marker rotating giving an unrealistic model of the subjects. The 4 excluded Oxford patients were removed due to the same issues with the posterior marker rotating. An additional two patients were removed for the Oxford group during stair descent (exclusions 6 Mako, and 6 Oxford). These extra patients were removed because they descended the stairs one step at a time with both legs.

The stair ascent activity data is shown in Table 4.12. The data shows no statistically significant differences between the two groups during this activity in any of the measurements. The joints don't show any significant differences, and neither do the stance percentage values, with a p-value of 0.62.

Table 4.13 compares the data gathered between the two surgical groups for the stair descent activity. There is no statistically significant difference between the Mako and Oxford surgical groups in the hip joint maximum, minimum and excursion angles.

The knee data for stair ascent shows no statistically significant differences in the knee maximum and minimum angles, however there is a statistically significant difference (p-value = 0.02) in the knee excursion angle. Overall the Oxford group had a higher knee excursion of 91.6° compared to the Mako group at 87.1°.

The ankle data shows the Oxford group reaches a higher mean maximum angle than the Mako group, 34.7° compared to 31.2°. This was illustrated by the ankle graph for stair descent shown in Figure 4.53. The p-value for the comparison was 0.05, but not within the 95% confidence interval.

4.4.4 Sit to Stand Summary

The patients underwent a sit to stand activity in order to measure their weight distribution via each leg during this activity. This was in order to see how reliant the patient was on their non-operated leg compared to their other leg. Patients with implants in both knees were excluded from this analysis, and only patients with a UKA implant in one knee and a healthy non-operated opposite knee were included in this data set. For this reason 9 knees had to be taken out (3 Mako group, 6 Oxford group). Additionally 2 other knees were removed from this data set due to poor positioning of the subjects' feet on the force plates, thus not registering all the weight correctly during this activity. This resulted in 40 patients (19 Mako, 21 Oxford) remaining in this group.

The data set was tested for normality which resulted in a p-value of 0.92 and an AD value of 0.17. This means that the data was normally distributed and a two sample independent t-test can be used to compare the weight distribution between the two surgical groups.

Table 4.14 shows the weight distribution between the two surgical groups. The values shown for the mean weight distributions comparison are in percentages. Positive values indicate a greater percentage of body weight supported by the UKA operated leg, and negative values indicate a greater percentage of body weight supported by the non-operated leg. -100% implies all weight was supported on the non-operated leg, and 100% implies all weight was supported on the operated leg. This was calculated by Equation 4.1 where P is the percentage, o is the ground reaction force on the operated leg, and n is the ground reaction

force on the non-operated leg.

$$P = \left(\frac{2o}{o+n} - 1 \right) \times 100 \tag{4.1}$$

Sit to Stand	**Mako**	**Oxford**
N	19	21
Mean %	-0.9	-1.5
St. Dev	11.1	9.2
Max	18.0	15.2
Min	-27.7	-16.4
P-Value	0.85	

Table 4.14: Table comparing weight distribution percentage during the sit to stand activity

The results show that both groups on average tend to have their weight supported slightly more by the non-operated leg. The Mako group on average supported 0.9% more of their body weight on their non-operated leg, and the Oxford group supported 1.5% more of their body weight on the non-operated leg. However a comparison between the two groups showed no statistically significant difference between the two groups.

4.4.5 Deep Knee Lunge Summary

The purpose of the deep knee lunge activity was to have a comparable and repeatable voluntary maximum knee flexion weight bearing activity. This was a strenuous task that aimed to test the limits of motion of the knee joint, and if the two implants gave different results at these extremes. All the knees with implants were included in this activity.

This data set was tested for normality and the p-value was 0.55 and the AD value was 0.31, showing the data were normally distributed and an independent two tail t-test can be used to compare the maximum knee flexion angles achieved

during the deep knee lunge activity. The deep knee lunge comparison data is presented in Table 4.15.

Deep Knee Lunge	**Mako**	**Oxford**
N	23	28
Mean Max Knee Angle	126.0°	122.6°
St. Dev	10.9°	11.8°
Max	145.4°	145.1°
Min	98.1°	98.2°
P-Value	0.30	

Table 4.15: Table of maximum knee angles for the deep knee lunge task

The data from the table showed on average the Mako group achieved a higher maximum knee flexion angle than the Oxford group. The average angle achieved by the Mako group was 126.0° and the Oxford group 122.6°. The statistical test on the mean maximum knee angles showed no statistically significant difference between the two surgical groups. The p-value was 0.30.

4.4.6 Knee Performance Against Questionnaire Scores

The motion analysis data demonstrated a significant difference in the knee angles during the stance phase of gait between the two surgical groups during level walking.

Various questionnaires are used routinely as a measure of functional outcome after knee replacement surgery. As the scores from these questionnaires are assumed to reflect the function of the patients' knee, it should be seen if this increase in knee flexion during stance phase correlates to a better overall perceived function for the patient. Therefore the relationship between knee flexion excursion during stance phase and questionnaire scores were tested.

Additionally the scores from these questionnaires for each surgical group will be compared to one another to see if there they indicate a functional difference

between the two surgical groups.

American Knee Society Score (AKSS)

Table 4.16 shows the knee scores and Table 4.17 shows the functional scores. An Anderson-Darling Normality test showed this data was not normally distributed (P-value <0.0005), therefore a Mann-Whitney U Test was used. Pre-operatively the Mako group has a higher median knee score of 50 compared to the Oxford group score of 43.5. This difference does not reach statistical significance (p-value = 0.17). 1 year after the surgery the Mako group continued to have a higher average knee score compared to the Oxford group (89 and 83 respectively), and this difference was still not statistically significant (p-value = 0.12). The function scores show the Mako group has a higher average score pre-operatively compared to the Oxford group (60 and 50 respectively) and also a higher score 1 year post-operatively (90 and 80 respectively), but neither reach levels of statistical significance.

AKSS - Knee Score	**Mako**	**Oxford**
Pre-op		
N	23	28
Median	50	43.5
Max	84	71
Min	30	21
P-Value	0.17	
1 Year		
N	23	28
Median	89	83
Max	94	95
Min	58	49
P-Value	0.12	

Table 4.16: AKSS - Knee score

AKSS - Function Score	Mako	Oxford
Pre-op		
N	23	28
Median	60	50
Max	90	90
Min	15	30
P-Value	0.14	
1 Year		
N	23	28
Median	90	80
Max	100	100
Min	40	50
P-Value	0.20	

Table 4.17: AKSS - Function score

In order to test the claim that higher knee excursion during weight bearing is related to the knee function and pain, the knee excursion values during weight bearing were plotted against the AKSS and tested statistically to see if there was any correlation between the two.

Figure 4.55 plots the AKSS Knee Score, and Figure 4.56 plots the AKSS Function Score. The AKSS Knee Score shows very little correlation between the knee excursion angles as the r^2 value was 0.0012, meaning the AKSS Knee Score accounts for 0.12% of the knee excursion values. The AKSS Function Score also showed a weak positive correlation with the excursion angle accounting for less than 5% of the data. Additionally from looking at Figure 4.56 it should be noted that the AKSS Function Score gives values in blocks of 10 points meaning this data is less sensitive to change. All the graphs show a ceiling effect for the AKSS score.

In the AKSS function questionnaire (Appendix B) there were questions regarding stair navigation and if they carried supports to aid with their locomotion

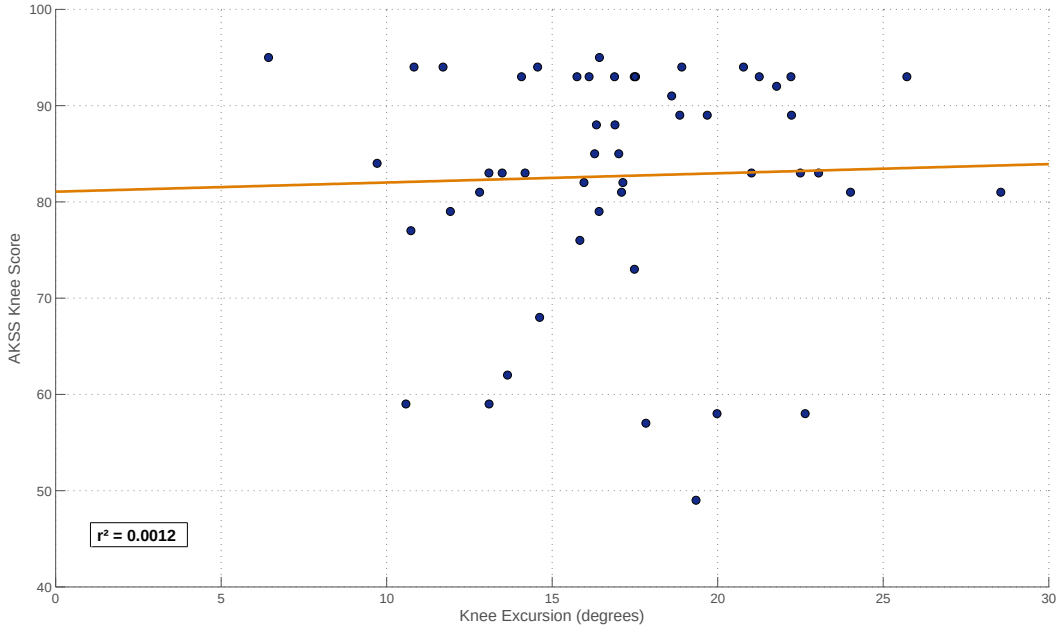


Figure 4.55: AKSS Knee Score

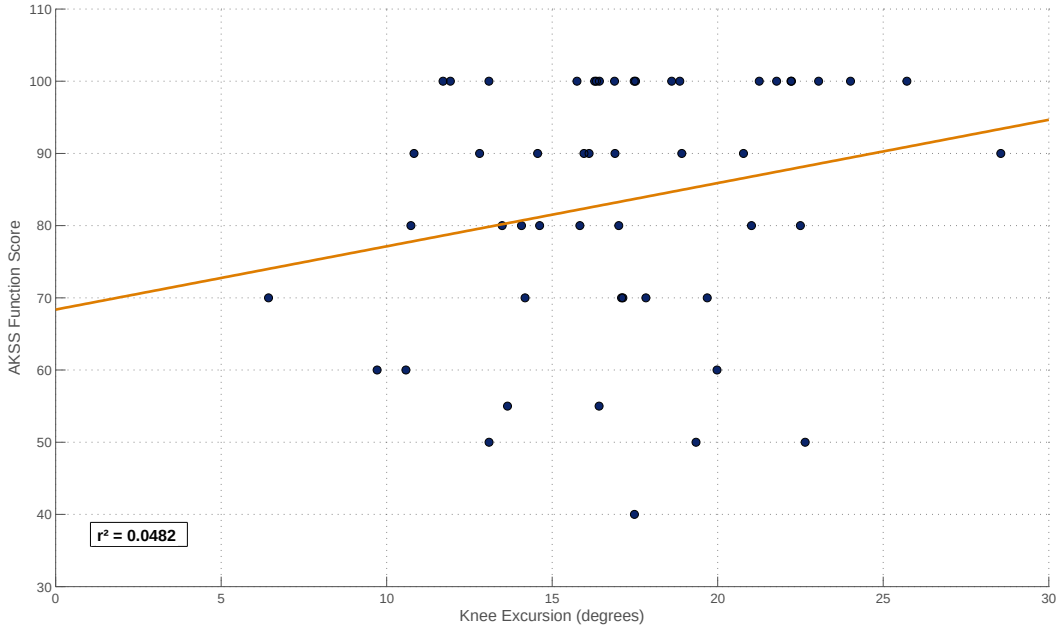


Figure 4.56: AKSS Function Score

as well as questions about their walking. The stair navigation and supports are not specifically relevant to their walking abilities and does not bear relation to

their knee excursion during stance phase. For this reason the knee excursion and the scores for only the walking related question were plotted against each other in Figure 4.57. However this comparison also had a weak positive correlation with an r^2 value of 0.0231.

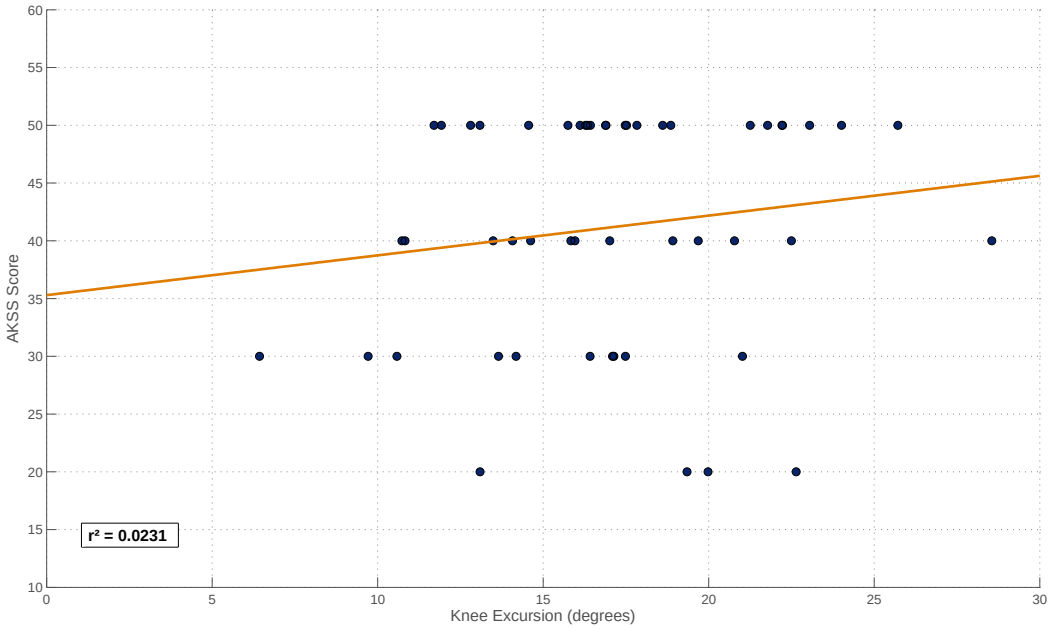


Figure 4.57: AKSS on walking question

Oxford Knee Score

Table 4.18 compares the OKS between the Mako and Oxford group. Neither of these differences are statistically significant.

Figure 4.58 plots the OKS against the knee excursion angle during stance phase to test if the knee angle correlates to a lower OKS. While there is a very slight negative correlation between the two with an r^2 value of 0.0024, meaning this accounts for 0.2% of the data.

The OKS is primarily focused on pain and function, however there was only one question that was specifically relevant to walking. For this reason the knee excursion and the score from that specific question were plotted against each

Oxford Knee Score	Mako	Oxford
Pre-op		
N	23	28
Median	39	39
Max	49	53
Min	23	24
P-Value	0.25	
1 Year		
N	23	28
Median	18	20.5
Max	36	42
Min	12	13
P-Value	0.25	

Table 4.18: Oxford Knee Scores

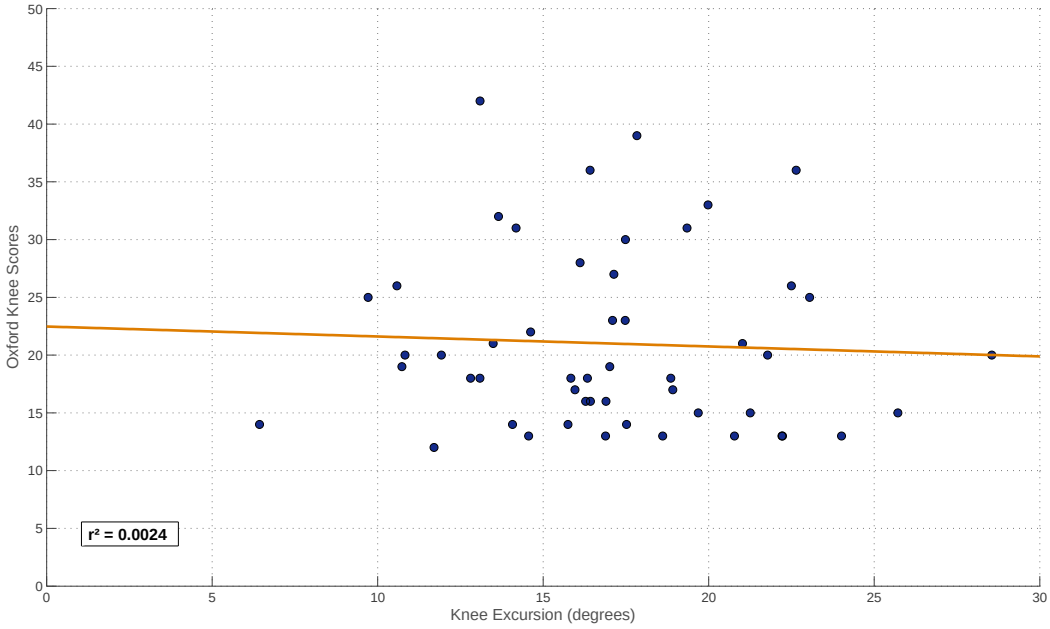


Figure 4.58: Oxford Knee Score

other, shown in Figure 4.59. The comparison between this question alone showed a very weak positive correlation giving an r^2 value of 0.0064.

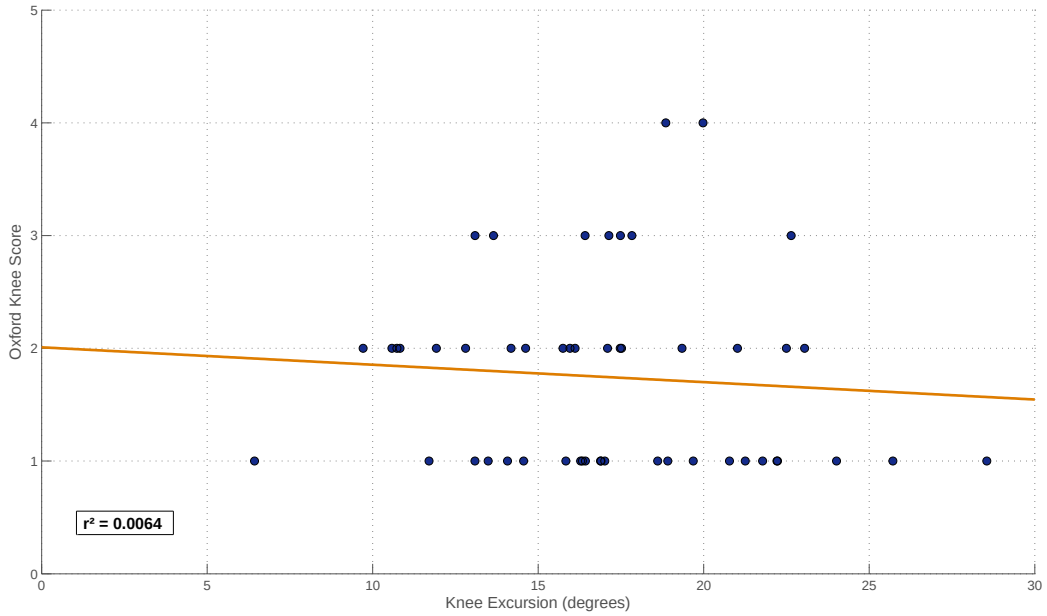


Figure 4.59: Oxford Knee Score on walking question

4.4.7 UKA Patients Compared to Normals

In order to determine if a UKA knee behaves similarly to a healthy knee the cohort of the UKA knees in this clinical trial were compared to a control group. The University of Strathclyde had an archive of healthy subjects of which 50 knees had undergone walking trials using motion capture and the data was readily available. The data collection had ended in 2006. This normal group were in their 60s, 70s and 80s, had no evidence of musculoskeletal or neurological impairments and were from the same geographic region as the UKA group. These subjects were recruited by a mail shot and several presentations to older adult organisations. To be included into the normal group the subject had to undertake medical screening to make sure they had no muscular-skeletal problems. These normal subjects were without health issues which made them the top end of performance for their age.

The comparison between the normals and the UKA cohort are shown in Table 4.19 (age) and Table 4.20 (gender and analysed knee). The data shows that on

average the normals were older than the UKA group by 7.4 years, which was a significant difference (p-value <0.001). However there were no statistically significant differences between the two groups in gender or analysed leg. 44% of the normals were then compared to 57% in the UKA group giving a p-value of 0.20. The normals had equal numbers of left and right knees, and the UKA group consisted of 59% left knees (p-value = 0.37).

Age	**Normals**	**UKA**
N	50	51
Average	70.4	63.0
St. Dev	6.6	5.9
Max	83	74
Min	60	52
P-Value	**<0.001**	

Table 4.19: Comparison of patient age in the UKA group and normals

	Normals	**UKA**	**P-Value**
N	50	51	
Men/Women	22/28	29/22	0.20
Left/Right	25/25	30/21	0.37

Table 4.20: Other Patient Demographics

As the data collected from the normal group had used a different code to calculate joint centres, and to eliminate any marker placement errors the knee excursion angles will be used to compare the UKA group with the normals.

The comparison of the knee excursion angles are shown in Figure 4.60. This graph appears to show differences between the UKA group and the normals. The first peak knee excursion during mid-stance at approximately 15-20% of the gait cycle show that the normals reach a higher peak value compared to the UKA group. The next stage in which a difference is observed is at terminal stance – between approximately 40-50% of the gait cycle. It can be seen that on average

the normals extend their knees further than the UKA group. The UKA line appears to 'plateau' at this point. During mid to terminal swing from approximately 75-100% of the gait cycle the UKA group seem to bring their knees to extension faster than the normals, hence the UKA line appearing shifted to the left. A t-test was performed on the full range of the gait cycle. The statistical test showed four regions through the gait cycle where there was a statistically significant ($p < 0.05$) difference between the UKA group and the normals. These regions were at 3-9%, 13-26%, 36-51% and 80-100%. The initial differences between 3-9% may be due to the procedure of calculating knee excursion as opposed to using the absolute knee angle values. As most of the values will be at 0 degrees any small variation may be significant. This is illustrated on the knee excursion comparison graph in Figure 4.60 where the variation in angle at these percentages are very small.

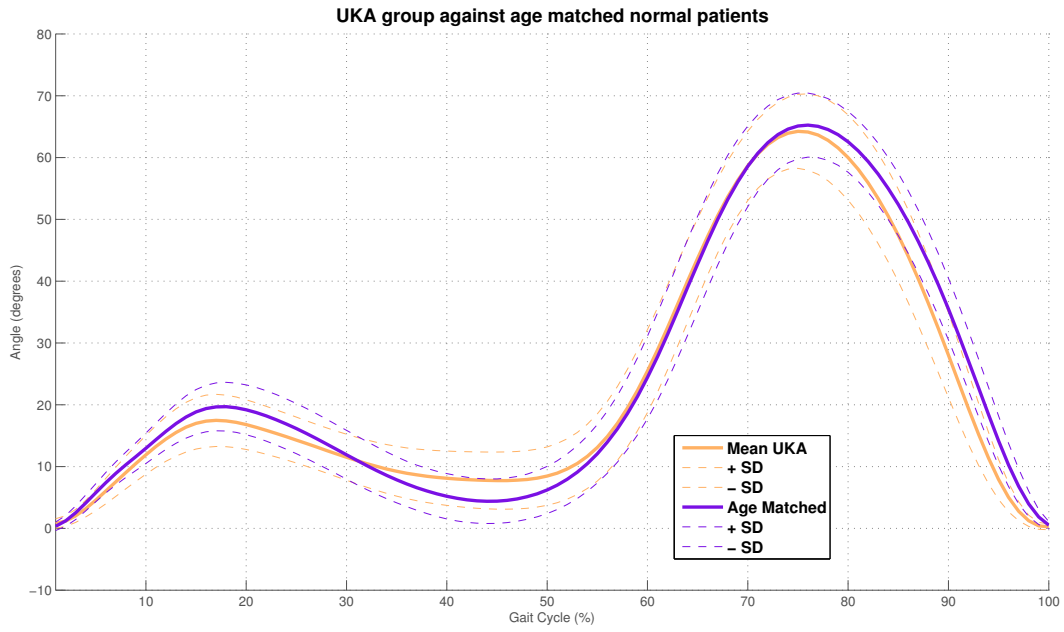


Figure 4.60: Comparison of the knee excursion angles of the whole UKA group compared the the age matched normal patients

Table 4.21 compares the knee excursion values between the normals and the UKA group. From the table it can be seen that there are statistically significant

differences in knee excursion between footstrike to maximum mid-stance angle, and maximum mid-stance angle to terminal stance. From footstrike to maximum mid-stance angle the normals achieve an average of 19.5° of excursion compared to the UKA achieving 17.1°. The p-value was 0.004. From mid-stance to terminal stance the normals achieved an extra 5° of excursion with an average 15.8° compared to the UKA group of 10.8°. The p-value was <0.001. However there was no statistically significant difference in the total knee excursion between the groups (p-value = 0.36).

Additional comparisons will compare the normal group to the Mako and Oxford group individually. These are shown in Tables 4.22 and 4.23 respectively. This shows that just like the combined UKA group, the Oxford group also achieved significantly lower knee excursions between foot-strike to mid-stance, and mid-stance to terminal stance. However a consequence of splitting the groups has shown that there's no statistically significant difference from foot-strike to mid-stance between the normal knees and the Mako knees. The normal knees produce an average 19.5° of knee excursion compared to 18.6° in the Mako group. This difference is not statistically significant (p-value 0.36). However during the same period of gait the Oxford knees on average achieve 15.8 ° of average knee excursion which is statistically significantly less than the normal group (p-value <0.001). However both the Mako and Oxford groups have significantly lower knee excursion values from mid-stance to terminal stance. This is further demonstrated in Figures 4.61 and 4.62.

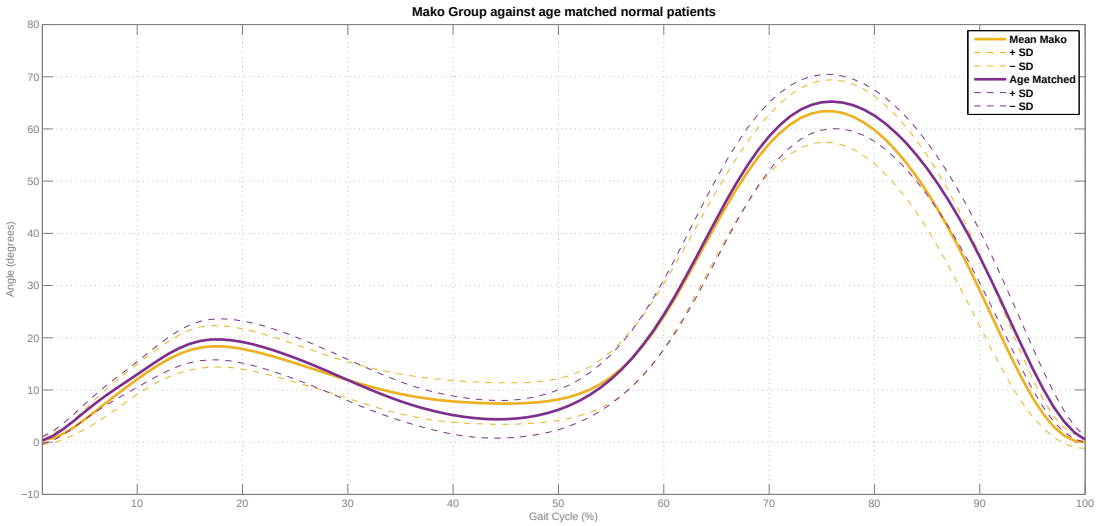


Figure 4.61: Comparison of the knee excursion angles of the Mako group compared to the age matched normal patients

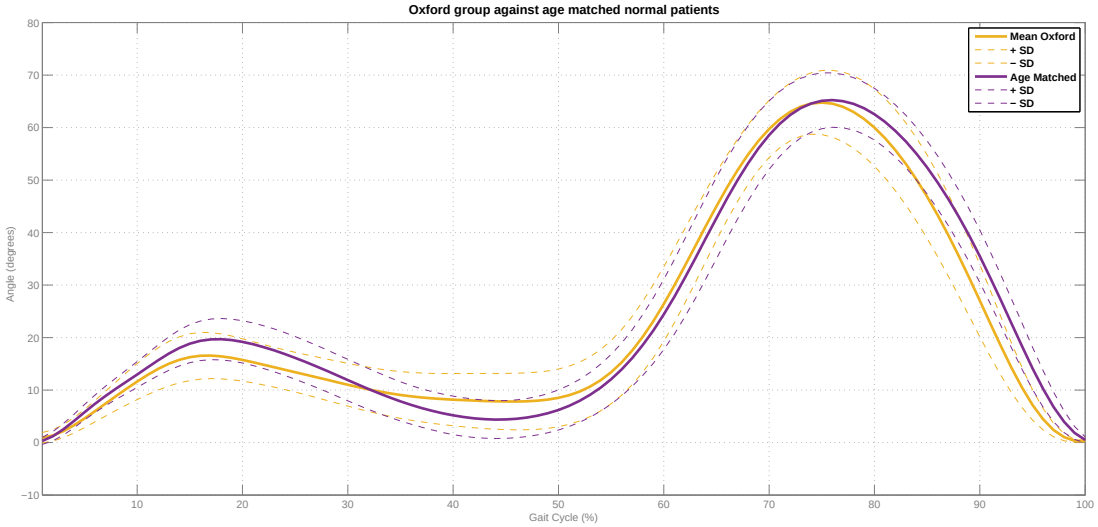


Figure 4.62: Comparison of the knee excursion angles of the Oxford group compared to the age matched normal patients

Walking	Mean Normal	St. Dev	Max	Min	Mean UKA	St. Dev	Max	Min	P-Value
N	50				51				
Knee Excursion									
(Total)	65.6°	5.1°	80.0°	56.2°	64.4°	6.0°	78.4°	52.2°	0.36
(FS to MS)	19.5°	4.0°	28.8°	11.6°	17.1°	4.4°	28.6°	6.4°	**0.005**
(MS to TS)	15.8°	4.3°	24.4°	7.2°	10.8°	5.1°	21.5°	2.7°	**<0.001**

Table 4.21: Table of knee excursion comparing the UKA group against the normal patients (degrees)

Walking	Mean Normal	St. Dev	Max	Min	Mean Mako	St. Dev	Max	Min	P-Value
N	50				23				
Knee Excursion									
(Total)	65.6°	5.1°	80.0°	56.2°	63.8°	6.3°	78.2°	52.9°	0.25
(FS to MS)	19.5°	4.0°	28.8°	11.6°	18.6°	4.2°	28.5°	10.8°	0.36
(MS to TS)	15.8°	4.3°	24.4°	7.2°	12.2°	5.2°	21.5°	3.5°	**0.006**

Table 4.22: Table of knee excursion comparing the Mako group against the normal patients (degrees)

Walking	Mean Normal	St. Dev	Max	Min	Mean Oxford	St. Dev	Max	Min	P-Value
N	50				28				
Knee Excursion									
(Total)	65.6°	5.1°	80.0°	56.2°	65.1°	5.9°	78.4°	52.2°	0.74
(FS to MS)	19.5°	4.0°	28.8°	11.6°	15.8°	4.2°	23.1°	6.4°	**<0.001**
(MS to TS)	15.8°	4.3°	24.4°	7.2°	9.7°	4.2°	23.0°	6.4°	**<0.001**

Table 4.23: Table of knee excursion comparing the Oxford group against the normal patients (degrees)

4.5 Results Summary

In conclusion, differences were seen in the knee joint during level walking between the Oxford and Mako groups. These differences were seen at mid-stance where the Mako group achieved a higher knee flexion compared to the Oxford group. This is shown by a series of t-tests performed across the full range of the gait cycle showing a statistically significant difference ($p < 0.05$) between 18 - 25% of the gait cycle, as well as higher knee excursions seen between foot-strike and mid-stance on the group comparisons. When compared to normal patients there was no statistically significant differences at mid-stance between the Mako and normal groups. However there was a statistical significant difference seen with the Oxford group compared to the normal patients during mid-stance, meaning the Mako patients behave more similarly to normal patients at this region of the gait cycle compared to the Oxford group. However neither knee group managed to achieve comparable levels of knee extension at terminal stance.

No significant differences were seen during stair ascent in any of the joints, but differences were seen during stair descent in the knee excursion values (p-value = 0.02). Overall the Oxford group achieved a higher knee excursion of 91.6° compared to 87.1° in the Mako group.

No differences were seen between the two groups during the sit to stand symmetry. The Mako group achieved a higher maximum deep knee lunge angle of 126° compared to 122.6° in the Oxford group, however this difference for not statistically significant.

The knee excursion angles between foot-strike to mid-stance during level walking were compared to questionnaire scores from the AKSS and OKS. There was no correlation seen between the knee excursion angles and any of the questionnaire scores.

Chapter 5

Discussion

5.1 Introduction

The most common treatment for osteoarthritis in the knee is TKA. However the use of a more conservative UKA has been growing rapidly with a threefold increase in prevalence between 1998 to 2005 (Riddle et al., 2008). UKA is used to treat osteoarthritis that is confined to one compartment (Harwin, 2003). The advantages of this procedure include reduced hospital time, faster recovery, better post-operative range of motion and improved gait (Repicci, 2003; Geller et al., 2008).

However some studies have shown that there have been higher failure rates associated with UKA when compared to TKA, especially due to misalignment (Parratte et al., 2008). As a UKA relies on the remaining structures of the knee for stability and control, the alignment may be more critical than in a TKA. Additionally the UKA procedure is technically demanding and inexperienced surgeons have been shown to produce poorer results compared to highly skilled and experienced surgeons that regularly perform UKA procedures (Robertsson et al., 2001).

It has been shown that using robot-assisted surgery the accuracy of implant

alignment can be greatly improved, as well as giving the ability to make adjustments in implant placement during the procedure based on soft-tissue tension (Pearle et al., 2010). This study aimed to determine if using such technology to improve alignment also causes a measurable improvement in overall patient function. The objective was to compare the functional outcomes between conventional UKA and robotic-assisted UKA by comparing their biomechanics while undergoing a series of tasks (walking, ascending and descending stairs, sit to stand and deep knee lunge). Motion capture was used to gather this data.

The first section of the discussion will address the functional assessment results gathered from the motion capture, followed by a review of the overall clinical outcome, a discussion of the methods of measuring, a look at the potential future of the industry and a finaly a review of this study's aims and objectives.

5.2 Study Bias

Once the trial participants had been recruited for the study they underwent a randomisation process. This randomly assigned them into two groups, and was done electronically. This meant that neither the participants nor assessors influenced which UKA group they were assigned to, thus allocation bias was minimised.

While not explicitly stated to the trial patients which group they were allocated, all Mako test subjects had to undergo an additional CT scan before the operation due to the pre-operative planning of the Mako system requiring this. No sham CT scans were performed for the Oxford groups. Therefore it may have been possible that the patients themselves knew which group they were allocated to. However the assessors for the clinical trial were blinded. The nursing staff taking the clinical data did not know the groups that the patients were allocated to, thus making this a single blinded study. Other factors that were kept the

same for both groups included surgical incision, anaesthesia and post-operative therapy.

This was the protocol for the larger group study, however a sub group of these patients were seen for the biomechanical assessment at the University of Strathclyde. At 1 year post-op they were given a phone call and asked to take part in the bimechanical assessment. As this study focuses on the results of the biomechanical assessment 1 year post-operatively, it is important to try and ascertain that the data for this sub group is a representative sample of the larger group of patients that were recruited for the trial. While there is no biomechanical data on all the patients, there are 1 year post-op functional outcome scores. Therefore the median AKSS scores, and Oxford Knee Scores (OKS) for the larger group, and the sub group can be analysed to see if there are any statistically significant differences between them. Sixty nine patients had been allocated to the Mako group, however 1 was converted to a TKA, 4 withdrew from the study, and 1 had been converted to an Oxford UKA, leaving a final group of 63. The Oxford group originally recruited 70 patients, 4 converted to a TKA, 1 withdrew from the study, however gained an additional patient due to one of the Mako patients being converted to an Oxford, leaving 66 patients in the final group.

AKSS Scores (Mako)	**Overall Group**	**Sub-Group**
Median	171	184
N	63	23
P-Value	0.26	

Table 5.1: Comparison of the Mako overall and sub-group AKSS scores

The AKSS Scores for the Mako and Oxford groups are shown in Table 5.1 and 5.2 respectively. The Mako sub-group has an AKSS Score of 184 compared to the overall group of 171. However this difference is not statistically significant (P-value = 0.26). Both the sub-group and overall Oxford patients have the same AKSS score of 164 (P-value = 0.96).

AKSS Scores (Oxford)	Overall Group	Sub-Group
Median	164	164
N	66	28
P-Value	0.96	

Table 5.2: Comparison of the Oxford overall and sub-group AKSS scores

OKS (Mako)	Overall Group	Sub-Group
Median	21	20.5
N	63	23
P-Value	0.47	

Table 5.3: Comparison of the Mako overall and sub-group Oxford Knee scores

OKS (Oxford)	Overall Group	Sub-Group
Median	19.5	18
N	66	28
P-Value	0.86	

Table 5.4: Comparison of the Oxford overall and sub-group Oxford Knee scores

The Oxford Knee Scores for the Mako groups are shown in Table 5.3 and Oxford groups in Table 5.4. The Mako sub-group has an Oxford Knee Score of 20.5, and the overall Mako group has a score of 21, with no significant difference (p-value (0.47). The Oxford sub-group and overall group have Oxford Knee Scores of 18 and 19.5 respectively, but there is no statistically significant difference between the two (P-value = 0.86).

As there were no statistically significant differences between the AKSS and Oxford Knee Scores between the overall group and the sub-group, there is at least some indication that there has not been a bias, and that the sub-group may be a representative sample of the overall group

Another potential cause of bias in the biomechanical study was the loss of 22 patients that did not wish take part in the University of Strathclyde biomechanical assessment (13 Mako, 9 Oxford). Their absence could have potentially been due

to their knees, for example they felt limited in their movement so didn't wish to take part in what they considered to be a non-essential assessment. Likewise it could be possible that well performing patients did not want to take part either because their lives have returned to normal. Other reasons may include non-knee related health issues, or personal reasons. For this reason the AKSS and Oxford Knee Scores of all the patients that were called will be compared to those patients that did not want to take part in the study to see if they could have caused a bias in the group that came for the biomechanical assessment.

AKSS (Mako)	**Patients contacted**	**Patients declining to participate**
Median	171	163
N	43	13
P-Value	0.38	

Table 5.5: Comparison of the contacted and declined Mako AKSS scores

AKSS (Oxford)	**Patients contacted**	**Patients declining to participate**
Median	163	158
N	46	9
P-Value	0.43	

Table 5.6: Comparison of the contacted and declined Oxford AKSS scores

OKS (Mako)	**Patients contacted**	**Patients declining to participate**
Median	20	25
N	43	13
P-Value	0.20	

Table 5.7: Comparison of the contacted and declined Mako OKS scores

Tables 5.5 and 5.6 and show the AKSS scores between the patients contacted, and the patients declining to participate for the Mako and Oxford groups respectively. In neither of these groups is there any statistically significant difference. The same is observed using the Oxford Knee Scores when comparing the two

OKS (Oxford)	Patients contacted	Patients declining to participate
Median	20	24
N	46	9
P-Value	0.21	

Table 5.8: Comparison of the contacted and declined Oxford OKS scores

groups (Table 5.7 for the Mako group and Table 5.8 for the Oxford group). Neither the Mako (p-value = 0.20) nor the Oxford group (P-value = 0.21) reach levels of statistical significance. This shows that the patients not wanting to take part in this study may not have had an effect on the group of patients that came for biomechanical assessment.

Another potential cause for bias were the 16 subjects that had been excluded from the biomechanical group due to technical issues. Once again the questionnaire scores will be used to determine if these excluded patients were representative of the final group or not. The scores for the patients that came into the Bioengineering Unit at the University of Strathclyde were compared to the group of patients that had to be excluded due to technical issues. The data for the AKSS scores are shown in Tables 5.9 and 5.10 (Mako and Oxford groups respectively), and the data for the Oxford Knee Scores are shown in Tables 5.11 and 5.12 (Mako and Oxford groups respectively). In neither of these comparisons was there any statistical significance between the two groups. The implication of this is that judging by the questionnaire scores none of the patients excluded from the biomechanical group due to technical errors were not causing a bias in the final patient groups.

AKSS (Mako)	Patients seen	Patients with technical errors
Median	183.5	174.5
N	30	7
P-Value	0.42	

Table 5.9: Comparison of the Mako overall and sub-group AKSS scores

AKSS (Oxford)	Patients seen	Patients with technical errors
Median	165	163
N	37	9
P-Value	0.84	

Table 5.10: Comparison of the Mako overall and sub-group AKSS scores

OKS (Mako)	Patients seen	Patients with technical errors
Median	18	19
N	30	7
P-Value	0.89	

Table 5.11: Comparison of the Mako overall and sub-group AKSS scores

OKS (Oxford)	Patients seen	Patients with technical errors
Median	20	21
N	37	9
P-Value	0.58	

Table 5.12: Comparison of the Mako overall and sub-group AKSS scores

Other considerations that are important to note is that I was not blinded when collecting the biomechanical data from the patients, and there weren't any resources to provide another blinded observer to carry out the biomechanical analysis. However, knowledge of the patients' group could not have caused a bias when using the Vicon Motion Capture system. This is because all the biomechanical data generated was produced semi-automatically. The assessor only had control over factors such as such as labelling tracking markers. All the angles and forces generated was done using the pipelines run on the software, therefore the assessor cannot bias the data.

A way to further reduce bias would be to make this a double blind study. In order to achieve this the patients themselves would have to be blinded, and not know which group they got assigned into. In this study the patients could

discover which group they were in by knowing if they had received a CT scan before the surgery, but after being recruited. In order to achieve this a sham CT scan should be arranged for all the patients that were not randomised into the Mako UKA group. Another consideration for blinding the patients is in the operating room itself. During the operation the patients may be able to see the Mako robot, therefore a method of blinding should be used to prevent this bias.

Overall a lot was done to minimise bias in the overall study such as randomisation, providing the patients with the same post-operative care, same anaesthetic protocol, and also having the nursing staff blinded. While there may have been a potential bias in the patients seen for their biomechanical assessment, questionnaire scores seem to suggest that the patients seen were representative of the overall sample. Further possible improvements that could have been made to the study was to make it a double blind study, however the resources were not available for that to be possible.

5.3 Functional Assessment Results

The chart in Figure 4.32 breaks down the patients that were involved in this research report from the randomised controlled trial. Overall the number of analysed patients 1 year post-operatively was 23 for the robotic-assisted UKA group, and 28 in the conventional UKA group (Mako and Oxford group, respectively). There was no evidence of a statistically significant difference in the rate of follow up at 1 year between the two groups. As discussed in Chapter 4.4.1 a total of 16 patients had to be excluded due to technical issues (7 Mako, 9 Oxford). The issues included the force plates not working on occasion, and communication errors between the cameras and the Vicon servers.

An important point to note also is that 22 patients (13 Mako, 9 Oxford) declined to participate in the 1 year post-operative functional assessment which

was voluntary and not part of the routine clinical practice. While there were no specific reasons provided as to why patients decided they did not want to participate, it is important to note the implications of this. Some subjects may have simply not had the time or commitment to take part in what they considered to be a non-essential assessment as they were busy. However it is also worth noting that some of these patients may have been suffering with poor quality of life – possibly due to their knee, and thus did not want to or possibly could not take part. If that is the case then it is possible that only the higher performing subjects were analysed, creating a bias in the population. A more in depth review of the study bias is presented in Chapter 5.2.

The patients were given five tasks, walking, ascending stairs, descending stairs, sit to stand and deep knee lunge. Every patient in both groups completed all of the given tasks.

There were no statistically significant differences in walking between the hip or ankle angles, but there were for the knee angle (but no differences in knee moments). The gait cycles for the knees during level walking are shown in Figure 4.34 and Figure 4.35 (absolute values and knee excursion respectively). The summary from the walking activities are shown in Table 4.10, giving the mean maximum, minimum and excursion angles for the hip, knee and ankle.

From the data it can be seen that during stance phase the Mako group achieve a higher knee flexion angle than the Oxford group. This is shown by the t-test performed on the full range of the gait cycle (one comparative t-test at each of the 100 individual percentages points) giving $p < 0.05$ values at 18 - 23 % in Figure 4.34 and 18 - 25 % Figure 4.35. This is further illustrated in Table 4.10 where there was a statistically significant difference between the Mako and Oxford groups from foot-strike to mid-stance where the Mako group achieves an average knee excursion angle of 18.6° compared to the Oxford group at 15.8°. The p-value is 0.025.

This shows that the differences occur in the knees at loading response/mid-stance. The function of the lower limb during this period is to resist collapse, and to extend sufficiently to achieve the required push-off (Winter, 1980). This is significant because at this stage of gait the muscular activity is the greatest since demands in all three planes must be controlled, and providing shock absorption to lessen the effect of the rapid weight transfer (Perry, 1992). One of the causes of this difference could be due to the nature of the components in the two implant designs.

When describing UKA the Oxford UKA is described as a "mobile bearing" UKA, while implants like the Restoris are described as "fixed bearing". The "mobile bearing" Oxford UKA consists of 2 congruent joint surfaces that do not allow any mobility, but sit on the tibial implant that may slide. The word mobile refers to the polyethylene bearing being allowed to slide on the tibial tray. An implant such as the Mako Restoris consists of a femoral component that has a changing radius of curvature that sits on a polyethylene surface that allows it to slide and rotate non congruently. This is regarded as a "fixed bearing," referring to the polyethylene being fixed to the tibial tray.

The Mako implant aims to mimic the articular surface of the bones, whereas the Oxford implants are congruent with one another. As mentioned in the implant design section for the Oxford implant (Chapter 2.3.1) the femoral implant is a single radius component in order to be perfectly congruent with the polyethylene bearing. However due to the bi-spherical nature of the the medial femoral condyle, the Oxford UKA femoral implant does not reproduce the the anterior aspect of the femoral condyle (Goodfellow et al., 2011). In contrast the Mako UKA femoral implant surface was designed to aim to mimic the surface of the femur using cadaveric specimens (Chapter 2.4.1). This could be achieved due to enhanced bone sculpting ability offered by the burr cutting tool within the Mako RIO robotic arm which facilitates the cutting of curved surfaces on the bone.

This difference in the anterior aspect of the femoral implant may cause the differences seen at lower flexion angles. The tibio-femoral joint in the patients with the Oxford implants may not be tracking anatomical movement at the anterior portion of the femur as closely as normal knees or when compared to patients with the Mako implants.

However the literature does not appear to make this distinction between the biomechanics of mobile and fixed bearing UKA. One study by Catani et al. (2012) used gait analysis to compare 10 patients with the Oxford UKA implants and 10 patients with Optetrak unicondylar knee system. The Optetrak implants would come under the definition of "fixed" bearing, as the femur is multi radius and non-congruent with the polyethylene surface. The pattern of knee joint flexion between the two groups did not show any considerable abnormalities during the loading response phase (Catani et al., 2012), unlike what has been presented in this thesis.

One study by Li et al. (2006) stated that that Oxford UKA implants represent normal knee kinematics closer than non-congruent, multi radius implants (defined earlier as "fixed" bearing). In this study 56 knees in 48 patients (mean age 72) undergoing medial UKA were randomized into a fixed bearing (Miller/Galante) or a mobile bearing (Oxford) UKA, and their 2 year outcomes were compared (Li et al., 2006). According to the results the mobile bearing Oxford knees showed a larger and an incrementally increased tibial internal rotation (4.3°, 7.6°, 9.5° vs. 3.0°, 3.0°, 4.2° respectively at 30°, 60°, 90° of knee flexion) compared to the Miller/Galante knee implants. Additionally the medial femoral condyle in the Oxford knees remained 2mm from the initial position whereas the Miller/Galante knees had a 4.2mm anterior translation during knee flexion (Li et al., 2006). However the conclusion that the Oxford UKA knee implants approximates that of the normal knee is based only on the Li et al. (2006) paper. A meta-analysis by Smith et al. (2009) of the literature concerning mobile and fixed bearing UKA

criticises the work for low sample size and poor randomisation.

Another important consideration is that the data gathered in this thesis on the Mako fixed bearing UKA implants use robotic assistance therefore may not be directly comparable with other fixed bearing UKA in the literature. While the mobile bearing design offers the advantage of self adjusting over the fixed bearing design to accommodate surgical malalignment (Cheng et al., 2003), this advantage may not be relevant when implanted using robot-assistance – where implant alignment is superior to the manual method (Chapter 5.5.1). A case could be made that the Mako robotic-assisted Restoris UKA should have been compared to a manual fixed bearing UKA to give a more direct comparison on the effects of using a robotic system. However the intention of the study was to compare using robot-assisted UKA to the current UK dominant UKA available, and the most widely used UKA in the UK, i.e. the Oxford UKA.

There is no clear consensus for the biomechanical functional effects of using robot-assisted methods to implant UKA compared to that of mobile bearings. Further studies should be conducted on the biomechanical differences of robot-assisted UKA with mobile bearing UKA to observe tracking differences at different flexion angles. Additionally it may be beneficial to compare robot-assisted UKA with manually implanted fixed bearing UKA to see if the previous fixed bearing UKA studies bear any relevance to the robot-assisted method. These differences could be analysed by using fluoroscopy as per the Banks method (Banks and Hodge, 1996).

When the two groups in this study were compared to normal knees from the University of Strathclyde database there were no statistically significant differences between the Mako group and the normal knees in knee excursion from foot-strike to mid-stance. However the conventional (Oxford) UKA did not manage to reach the same level of knee excursion, meaning the robotic-assisted knees behaved more similarly to normal gait during this phase of the gait cycle than

those of the conventional group. The literature suggests that 18-20° is the normal range for knee flexion for healthy patients at this stage of gait (Whittle, 2007; Kerrigan et al., 1998). A study of young patients versus elderly by Kerrigan et al. (1998) showed on average 31 healthy patients (aged 18-36) achieved 19.2 (SD = 5.6) degrees of knee flexion at mid-stance. The groups achieved 18.6° for the Mako and 15.8° for the Oxford groups.

Neither UKA group managed to reach similar knee excursion values to the normal subjects from mid-stance to terminal stance, i.e. they failed to normally extend their knees during push off. The deficit was higher in the Oxford group than the Mako group by approximately 2.5°. It is important to note that while the normal subjects were on average older than the patients, they were given a health screening before taking part. Therefore they were healthier individuals than a typical person of their age and hence their data may be superior to average older individuals. A definitive answer to this issue could only be achieved with an age matched normal group. However if the slightly elite nature of the healthy older adult data is taken into account, then the Mako group were on average akin to normal whereas the Oxford group were below normal.

The other significant difference found between the two groups was the overall knee excursion during stair descent. The conventional Oxford UKA group achieved a total knee excursion value of 91.6° and the robot-assisted UKA group achieved 87.1°. Little literature exists regarding normal knee excursion during stair descent with most papers focused on kinetics rather than kinematics. One study from the University of Strathclyde compared stair ascent and descent for subjects in their 60's, 70's and 80's (Hood, 2011). These subjects were recruited from around Glasgow between 2002 and 2004 and underwent medical screening to exclude those with potential health problems. Again because of this they were a slightly elite older adult group. In the Hood (2011) study the mean knee excursion for patients in their 60's, 70's and 80's were 93.4°, 92.9° and 87.7° respectively.

The overall trend implies that lower excursion angles relates to less performance as the subject ages. However all the patients in that study were made to use handrails to assist in their locomotion, which may have impacted on their overall knee excursion values. Another study conducted by Mian et al. (2007) compared stair descent in young and older adults. The stairs they used were very similar to the ones in this thesis with a step hight of 17cm and tread depth of 28cm. All the participants performed the trials without using the handrails. The younger patients (N = 23, age = 26.6 years ±3.1) achieved an average knee excursion of 86.1° (SD = 5.4), and the older patients (N = 34, age = 73.4 years ±3.7) achieved an average knee excursion of 81.2° (SD = 4.8). Rowe et al. (2000) conducted a study using electrogoniometry on elderly patients undertaking a range of different activities, one of which was stair descent. Twenty patients were recruited, of which the average age was 67 (SD = 8). In this study the average knee excursion during stair descent was 80 degrees.

Overall most studies that have compared two different groups during stair descent seem to imply that greater knee excursion relates to better performance. However the range of average values vary very highly from 80° to 93.4°. Compared to the Hood (2011) study the Oxford group behaves more similarly to normal knee excursion, but compared to the Mian et al. (2007) study and the Rowe et al. (2000) study the Mako group behaves more similarly to the healthy patient group (p-value = 0.58) than the Oxford group (p-value = 0.004). It may be possible that the Oxford UKA group could be over-flexing their knee during stair descent. For this reason it is very difficult to ascertain what the optimal mean value for knee excursion during stair descent is, therefore the differences seen between the Mako and Oxford UKA groups during stair descent are not conclusive. However given that the stair protocol used in the Rowe et al. (2000) and Mian et al. (2007) studies were similar in design with no use of hand rails to those in the current study, their data would seem the better comparison on this basis, and the robotic

Mako group showed more normal performance when descending stairs than the Oxford group. Unfortunately this study did not give instruction to the subjects to use or not use the handrails, and has no means of checking which patients did and didn't. Therefore due to the design flaw of this activity it is difficult to come to any sound conclusion regarding the stair navigation data.

5.4 Functional Assessment Compared to Questionnaire Scores

Questionnaires are used routinely as a measure of function after knee replacement surgery and assumed to reflect the function of the patients' knee. Therefore it might be assumed that any biomechanical differences could correlate with the functional questionnaire scores. The biomechanical differences seen during level walking were compared to the various questionnaire scores reported in Chapter 4.4.6. None of those questionnaire values were correlated to the movement data.

On reflection this may not be surprising because the two different means of measurement are geared towards fundamentally different aspects of function. Questionnaire scores have been developed for their ease of action and speed of use in large population studies. These can be quite crude measures, and as seen in Figures 4.56 and 4.55 can be prone to inaccuracies such as ceiling effects. They are primarily about what the patient can do.

Motion capture using cameras and surface mounted markers can show movement outcomes better than questionnaire scores, and as shown in this study can show subtle functional differences in knee movement during gait between patient groups in relatively small sample sizes.

Given the purposes of these different assessments of function are so different, one being a clinical measure of what the patient can do, and the other a scientific measure of how the knee moves in a certain environment, it can be seen why

the two showed little correlation. The biomechanical measures have shown subtle differences in gait, but for that to be correlated to a clinical questionnaire score or overall function would require a greater sample in order to get a significant correlation.

5.5 Clinical Outcomes

This section will present information on all the patients that took part in the trial. This will include data about the implant alignment 3 months post-operatively, manual implant positioning accuracy, post-operative pain scores and data on hospital discharge times. This is included because this information from a trial of this size may be very relevant to the future of robotics in orthopaedic surgery, and is therefore worthy of discussion.

5.5.1 Implant Alignment

One of the main premises of this study is that using robot-assisted surgery to implant the UKA components results in more accurate implant alignment relative to the surgical plan than by using conventional manual techniques and instrumentation. In order to ascertain if this also applies to this trial, hospital data from Glasgow Royal Infirmary was collected on the alignment of the components 3 months post-operatively compared to their pre-operative plan. It is important to note that the three surgeons taking part in this trial are all experienced, and perform Oxford UKA routinely. This data is shown in Figure 5.1. These tables include all patients that were recruited in the trial, with 66 patients in the Oxford group, and 63 patients in the Mako group. 55% of the Oxford group were male and 54% of the Mako group were male. This difference is not statistically significant.

The graphs show that in all planes the femoral component implantation is sta-

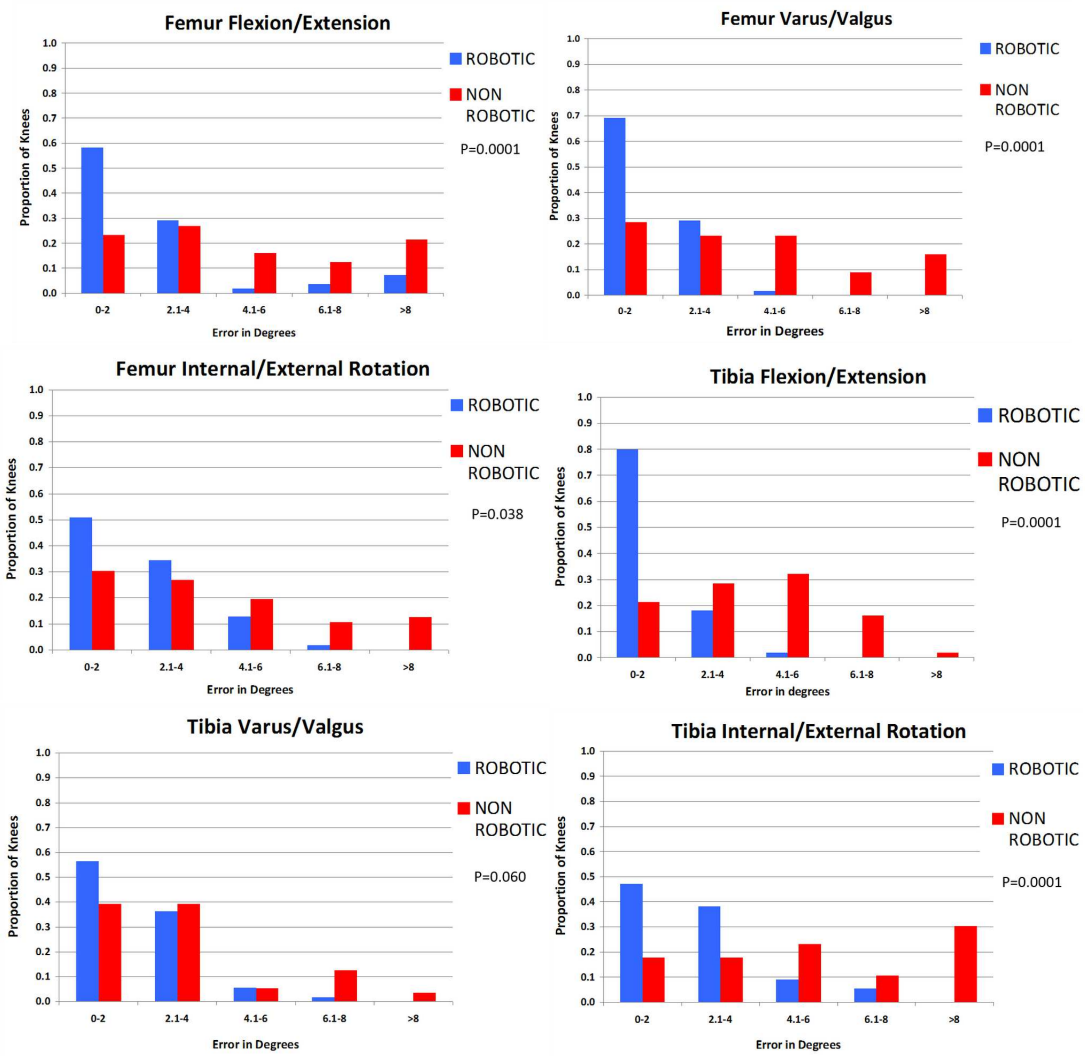


Figure 5.1: Implant alignment comparison between the robotic and non-robotic groups 3 month post operatively

tistically significantly better ($p < 0.05$) using the robot-assisted method. For the tibial component all planes were significantly better except in the robotic group in the coronal plane where the p-value was 0.06. Therefore it can be concluded that the traditional manual surgery was significantly less accurate in all measured parameters except tibial varus/valgus where it was borderline significant.

5.5.2 Accuracy of Implantation of Manual UKA

The previous section (5.5.1) has shown that overall the Mako implants were implanted significantly more accurately to their plan than those of the Oxford group.

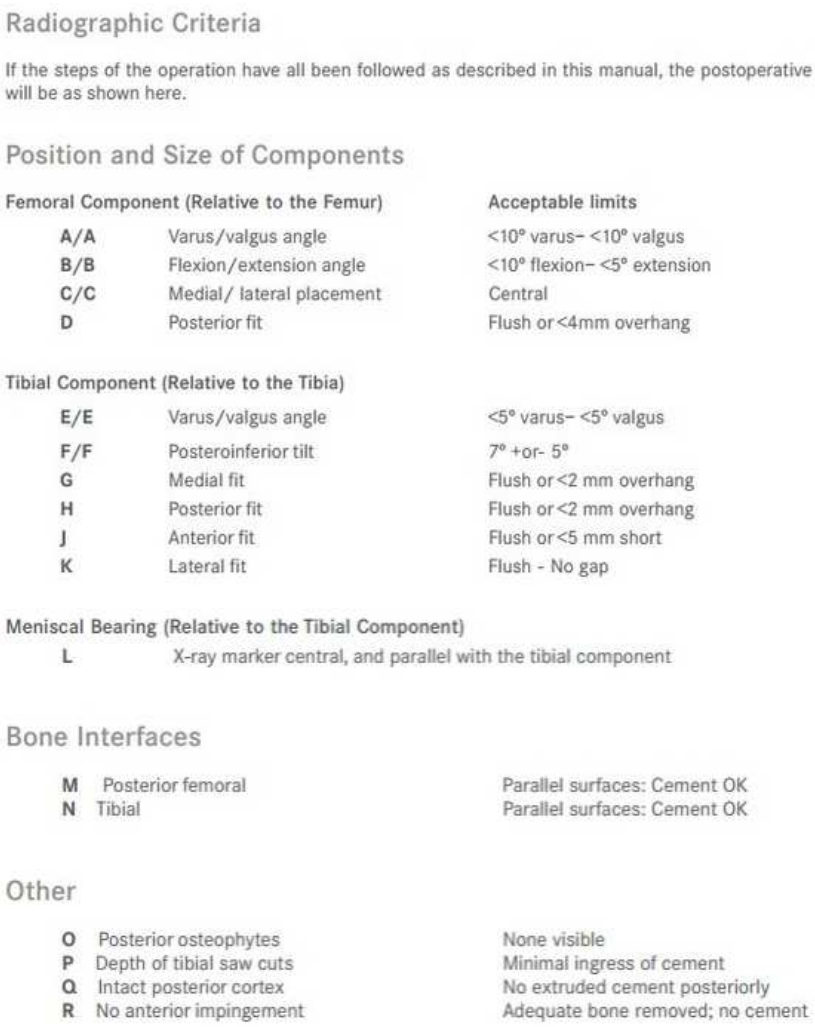
However as discussed in Chapter 2.3 the Oxford components are designed in such a way that allows some deviation from their targeted positioning, due to the spherical design. Therefore it is important to see if these implants are typical of most Oxford UKA in order to ascertain that this study compared well implanted manual Oxford UKA with the robotic-assisted Mako group. Even though the three surgeons involved in the trial were very experienced, and performed knee surgery at one of the largest knee facilities in Scotland, it is still important to evaluate this using objective data.

In order to illustrate if the implants were put in well or not, Biomet's own radiographic criteria will be used as a measure. These were mentioned in Chapter 2.3.3, and have been used in previous studies as a measure of positioning tolerances. Figure 2.17 in the Literature Review had shown a collection of these studies for Oxford UKA using an MIS approach. The full list of these criteria are shown again in Figures 5.2 and 5.3. Out of these parameters, A, B, D, E, F, G, H, and J have numerical ranges, thus can be given a percentage of implants within the recommended range.

Table 5.13 shows the results from this study, and compares them to other studies using these parameters. The data were recorded at Glasgow Royal Infirmary for all the patients in the trial. From this data only the subset of patients that were involved in this biomechanical study were analysed. However in the clinical database parameter H (Posterior fit) was not recorded and therefore was removed from the comparison.

It can be seen from the data that for all but two of the parameters the implants in this study were better placed than in at least one other study. For parameters A and G this study had favourable implant positioning compared to the other studies. For parameters B, D, and J the accuracy seemed to fit the average with regards to the others, and for parameters E and F the data were worse.

Overall, parameter A was highly accurate for most of the studies. It is the



Radiographic Criteria

If the steps of the operation have all been followed as described in this manual, the postoperative appearance will be as shown here.

Position and Size of Components

Femoral Component (Relative to the Femur)		Acceptable limits
A/A	Varus/valgus angle	<10° varus– <10° valgus
B/B	Flexion/extension angle	<10° flexion– <5° extension
C/C	Medial/ lateral placement	Central
D	Posterior fit	Flush or <4mm overhang

Tibial Component (Relative to the Tibia)		
E/E	Varus/valgus angle	<5° varus– <5° valgus
F/F	Posteroinferior tilt	7° +or- 5°
G	Medial fit	Flush or <2 mm overhang
H	Posterior fit	Flush or <2 mm overhang
J	Anterior fit	Flush or <5 mm short
K	Lateral fit	Flush - No gap

Meniscal Bearing (Relative to the Tibial Component)	
L	X-ray marker central, and parallel with the tibial component

Bone Interfaces

M	Posterior femoral	Parallel surfaces: Cement OK
N	Tibial	Parallel surfaces: Cement OK

Other

O	Posterior osteophytes	None visible
P	Depth of tibial saw cuts	Minimal ingress of cement
Q	Intact posterior cortex	No extruded cement posteriorly
R	No anterior impingement	Adequate bone removed; no cement

Figure 5.2: The 17 radiographic criteria of component position for the Oxford UKA

	A	**B**	**D**	**E**	**F**	**G**	**J**	Subjects
This Study	100	78	75	78	67	100	75	28
Shakespeare et al. (2005)	100	92	94	99	100	89	99	224
Clarius et al. (2010)	96	68	66	98	88	55	61	59
Müller et al. (2004)	97	70	50	97	97	83	93	30
Kim et al. (2012)	99	89	95	–	–	–	–	189

Table 5.13: Comparison of implant positioning accuracy within Oxford criteria (in %)

femoral implant that has a large degree of tolerance for misplacement ($\pm 10^{\circ}$ from neutral), due to its spherical shape. The femoral flexion/extension positioning

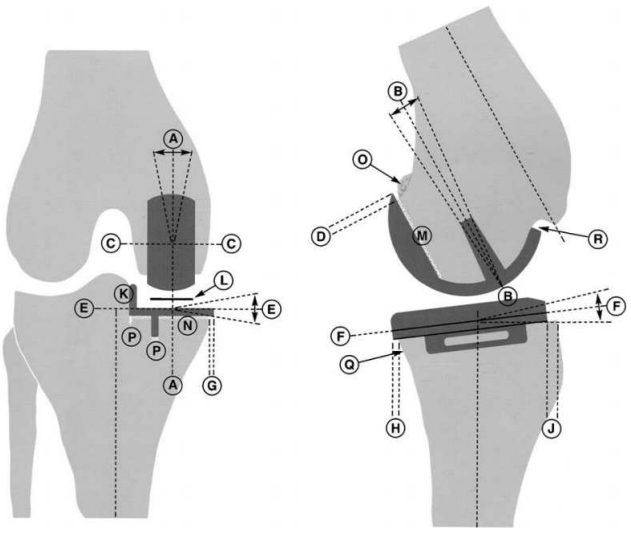


Figure 5.3: Graphic representation of alignment criteria

(parameter B) seems average when compared to the other studies. The same can be said for the posterior fit of the implants (parameter D) and anterior fit of the tibial component (parameter J). However with the tibial varus/valgus and posteroinferior tilt (Parameters E and F respectively) the accuracy was seen to be below the results of the rest of the studies.

It appears that the least accurate implant positioning was seen in the tibial component. Compared to the femur the acceptable limits are smaller, however when compared to the other studies it is below their accuracy ranges. Nevertheless the lowest score was 67% meaning at least two thirds of the patients were within the recommended limits. Another important factor to note is that the sample size for this study is the smallest compared to any of the other studies in the comparison table. With a smaller sample size the effect of a misalignment will have a greater impact on the final numbers compared to a larger group.

Overall this study found that in some parameters this study had very accurate implants, and in others not as accurate. While many of the inaccuracy scores may in part be due to the smaller sample size, it may also illustrate that as a procedure the Oxford UKA is very demanding and even three very experienced surgeons can have issues with performing this procedure within the recommended limits.

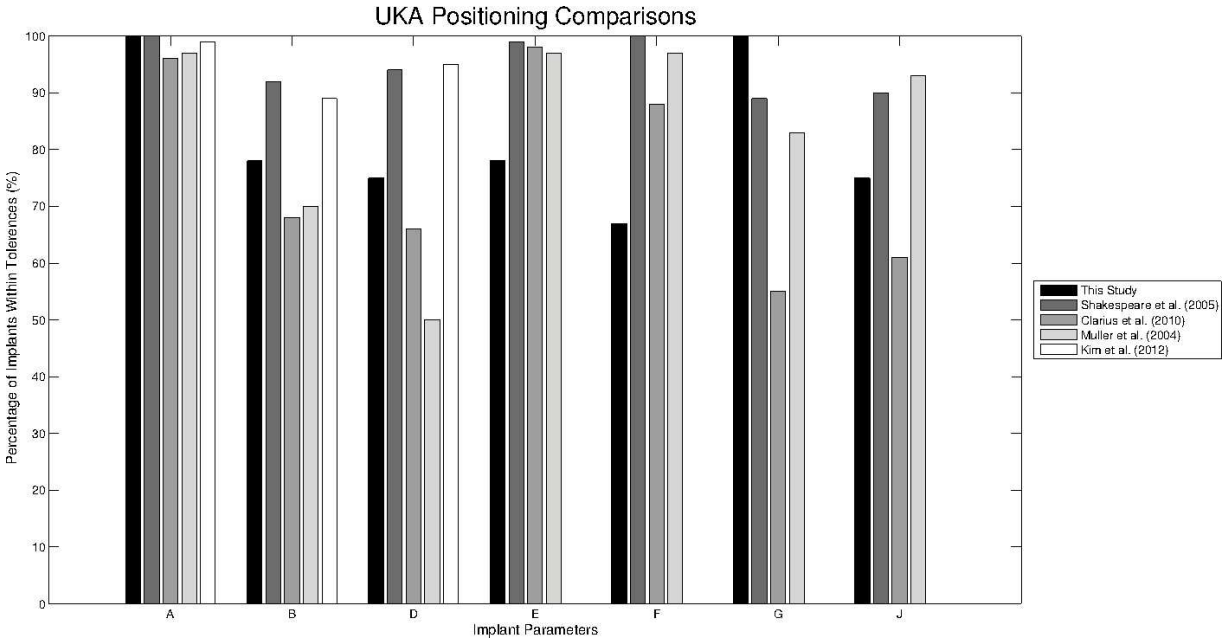


Figure 5.4: Graph comparing implant positioning accuracy within Oxford criteria (in %)

However there is little evidence to conclude that the Oxford UKAs in this study were any worse than other studies reported in the literature and it is well known that trials are conducted in expert centres where the best results can be expected. Hence it seems safe to conclude that the Oxford implants in this trial were at least as accurately implanted as a typical Oxford implant.

5.5.3 Post-Operative Pain

After the operation the patients pain scores were recorded using a Pain Visual Analogue Score (VAS). This score was taken every day for the first 7 days, every week until week 8, and finally again at week 13. The post-operative pain score data is show in Figure 5.5.

As the data shows, both surgical procedures displayed a similar reduction in pain score pattern. However while the trend in both the Mako and Oxford group is similar the Mako patients tend to have roughly half the pain scores that the Oxford group have throughout the period until the 13 week review. At 7

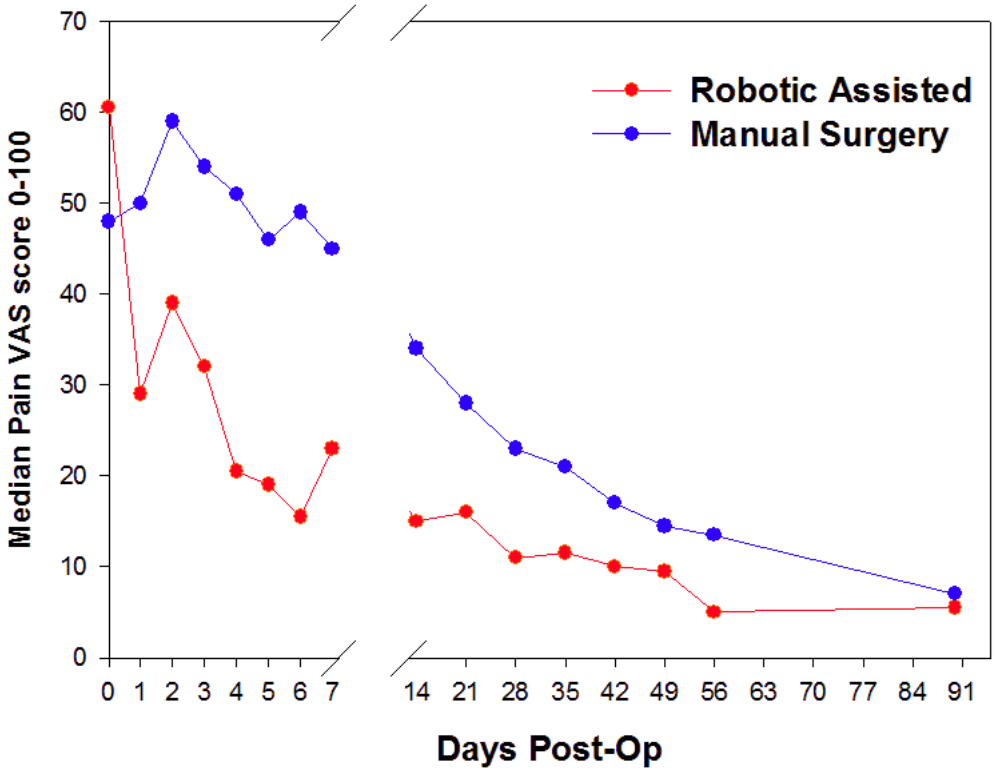


Figure 5.5: Graph showing the Median Pain VAS Scores over time

days post-operative, a Mann-Whitney U Test showed the Mako group to have a significantly lower pain score than the Oxford group with a p-value of 0.041. Eventually after approximately 3 months the pain scores level out.

This Pain VAS score show that the Mako group have less early pain post-operatively. One issue that may cloud this finding would be that the Mako group could have been given more pain medication than the Oxford group, thus causing this effect. However both groups received the exact same protocol for pain management. The data gathered on analgesic use at 14 and 90 days post-operatively for the two groups is shown in Figure 5.6. This shows that the level of analgesic use 14 days post-operatively is almost identical between the two groups (p-value 0.99). Additionally the analgesic use 90 days post-operatively was also not significantly different (p-value 0.84). Hence the differences in analgesic usage would not seem to be the cause of the pain score difference.

Another potential factor that could affect post-operative pain may be the

initial surgical incision performed during the different surgical procedures; a difference could result in the damage to the soft tissues. However in both operations the surgeons deliberately used a quad sparing approach for both groups in order to reach the knee joint to rule out this effect.

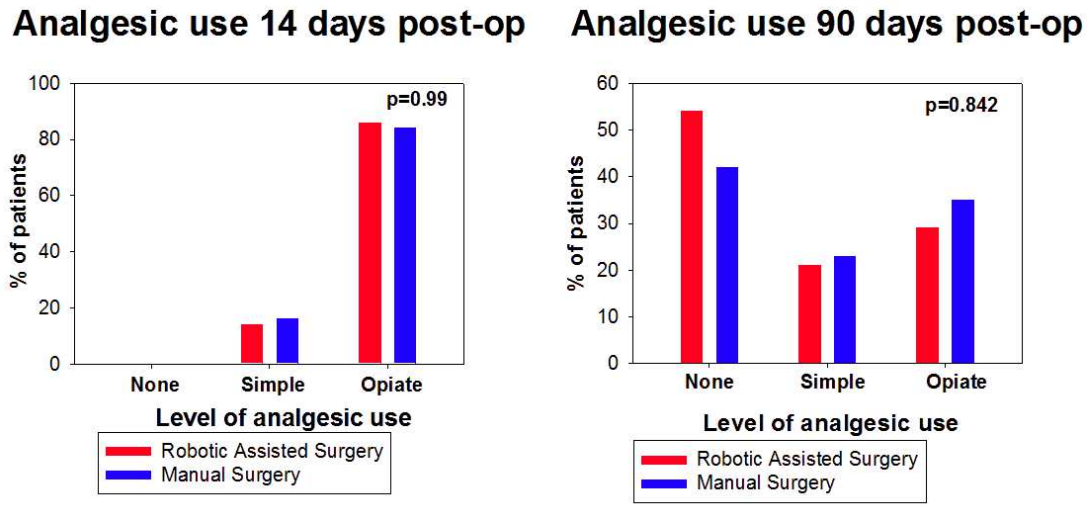


Figure 5.6: Graphs illustrating analgesic use 14 and 90 days post-operatively

Hence the reasons for the Mako patients having less early post-operative pain are not immediately apparent. As illustrated earlier in Chapter 5.5.1 the 3 month post-operative component alignment was significantly better in the Mako group, so there may be a case for implant alignment having an effect on pain, but this isn't likely to be exhibited by 13 weeks.

Another consideration for why the patients in the Mako group experienced less early post-operative pain could be due to the nature of the procedures themselves. The Oxford UKA procedure uses saws to resect the bone which results in straight cuts on the bone surface. In contrast the Mako UKA procedure uses a burr instead of a cutting saw, meaning that the cut can be sculpted and can be curved to match the implants. This approach gives a much more efficient cut than using straight resections and results in less bone loss. This bone loss may be the reason why many patients in the Mako group experience less early post-operative pain than the Oxford group. In order to try and quantify this bone loss it may be

worth examining the depth of resection. Other issues that arise when using a cutting saw is that even a well cut bone surface still creates a stress riser on the corners, however this issue is not present when using a cutting burr due to the rounded edges. Further with a saw cut there are un-cornered cut bone surfaces which many bleed into the joint, but when using the robotic burr the implant and cut bone have a tight fitting match which may reduce the bleeding and hence less short term pain.

Additionally the use of saw blades has an impact on the bone-cement interface. Cutting bone can cause high temperatures, and cutting temperatures over 50°C can result in bone necrosis (Matthews and Hirsch, 1972). It has been reported by Krause et al. (1982) that in some cases during a TKA procedure, saw temperatures exceeded 200°C when irrigation was not used, and bone temperature could reach 130°C. The same study found that cutting burrs with a high feed rate resulted in temperatures below the necrosis limit (Krause et al., 1982). Additionally the Mako procedure makes use of irrigation while the bone is being cut to reduce the bone temperature. Higher temperatures may cause more trauma to the bone than using a burr which may be a source of pain for the patients. A microscopic study on the bone surface using different cuts may give more information.

5.5.4 Hospital Discharge Times

Additional measurements taken were the hospital discharge times for each patient. This data is shown in Figure 5.7.

This data shows that over half of the patients in the Mako group were discharged within 2 days, but under 40% in the Oxford group were discharged in that time. The most common discharge period for the Oxford group fell between 2-4 days. The differences between the two groups was not statistically significant at a p-value of 0.07 in this sample.

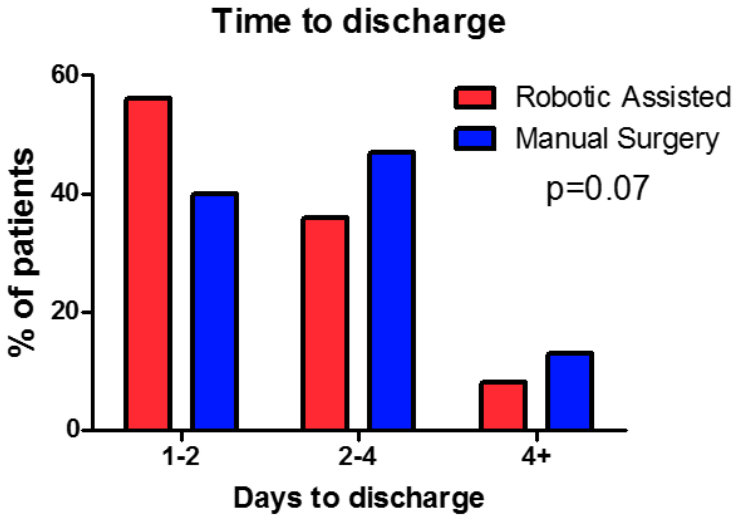


Figure 5.7: Graphs illustrating hospital discharge times

5.6 Outcome Measurement Review

The outcome measurement in this thesis was performed by using a motion analysis system, specifically the Vicon Nexus motion analysis system (specifics discussed in Chapter 3.2). At present using this method to measure the biomechanical outcomes is the current gold standard. However we found that only the sagittal data had sufficient face validity to be trustworthy and a discriminator of outcome.

Given there are also other means to measure human motion, particularly if analysis is limited to the sagittal plane it was considered valuable to reflect on the potential use of other motion capture systems in future studies. As well as optical motion analysis there are other methods to measure biomechanics, which include combining non-optical approaches by using electrogoniometers, or inertial systems that combine gyroscopes, accelerometers and magnetometers. Other methods of measuring motion can be done by the use of video fluoroscopy.

An electrogoniometer is a flexible measuring cable linked to two bases. These bases are attached to the skin and cover two body segments which are moved by the joint that is to be analysed. The output signal from the wire is proportional to the angle of the two bases (Tesio et al., 1995). This provides joint angle data and the device uses kinematic algorithms which is used to determine body posture.

One of the advantages of using electrogoniometers is that measurements do not necessarily have to be conducted within a laboratory environment and do not need external emitters or cameras. Additionally these devices tend to be quite cheap compared to optical systems.

A common issue with electrogoniometers that is present in most forms of motion capture is it is really tracking the soft tissue motion. This results in the position of the linkages relative to the body to change throughout different stages of motion. Another issue is that the accuracy of the electrogoniometers depends on their initial calibrated alignment which can be difficult in some joints, especially those with multiple degrees of freedom.

Inertial sensors tend to combine signals from gyroscopes, accelerometers and magnetometers to give 3D kinematic data. Accelerometers are used to determine the direction of the local vertical by sensing acceleration due to gravity, and magnetic sensors provide stability in the horizontal plane by sensing the direction of the earth magnetic field (Takeda et al., 2009). Only recently has there been inertial sensor systems that may be suitable for clinical use so they have yet to be proven for large scale medical use. One example is the Xsens MVN shown in Figure 5.8. This system combines the data from inertial estimates with other body worn aiding systems like magnetic trackers, so that drift can be prevented (Roetenberg et al., 2013).

Another means of measuring motion is by the use of video fluoroscopy. This technique combines the use of x-rays with video to allow these images to be recorded and played on a monitor. This technique has been used to analyse in vivo 3-D kinematics knees during active extension in unloaded and loaded conditions (Lu et al., 2008). It has also been used to analyse and predict the kinematics of joint replacements (Kessler et al., 2007). A large advantage of using video fluoroscopy is it can track in vivo knee joint kinematics with greater accuracy than other motion capture techniques (You et al., 2007), and can record movements

Figure 5.8: Xsens MVN Suit (Roetenberg et al., 2013)

such as anterior-posterior translations – unlike optical motion capture which relies restricting the joints and not allowing for translations in the biomechanical models.

However some issues that are present with using video fluoroscopy include a limited area of capture. Due to this restricted area only treadmill walking, deep knee lunges or any other activity that can take place in a confined area can be recorded. Additionally the use of fluoroscopy requires ionizing radiation, therefore the patient is exposed to potentially radiation-induced cancer which would require further ethical consideration. While in most clinics all care is taken to ensure the patients do not get radiation burns, the length of the functional assessments taking place in this thesis sometimes lasted over an hour, which could potentially result in a large dose. As this would not get passed ethical screening, using fluoroscopy is not a practical means of measuring motion in a study of this nature.

Overall using optical motion capture may still be the best choice for any future work, especially as the capital cost for such equipment is falling rapidly. A case can be made for using electrogoniometers because only one plane of motion (sagittal) was analysed in this thesis with motion capture. This was due to the

unreliability of rotation and varus/valgus motion. Rotation and varus/valgus motion has been a frequent issue in optical motion analysis systems. One plane of motion can easily be measured using electrogoniometers at a lower capital cost and with greater rapidity for a range of functional tasks. In contrast, the 12 camera Vicon Nexus system at the Biomedical Engineering Department proved to be extremely robust, easy to use and gathered suitable clinical data for the trial. Other optical motion capture systems such as the OptiTrack by NaturalPoint, OR are available at lower capital than the Vicon system and may offer a third alternative which provides quality 3D data cheaply.

5.7 The Future of Robotics in Orthopaedic Surgery

At present orthopaedic robot-assisted haptic surgery is only available for two orthopaedic procedures, Mako partial knee replacement and Mako hip replacement.

While there may not be a large number of procedures available on the market, this may not be the main barrier to stopping widespread use of this technology in orthopaedic surgery. The first major issue with using robotic-assisted techniques in the case of Mako Surgical is the cost of the robot itself. The Mako Rio Robotic System costs nearly 1 million US dollars. However if the use of robotics in orthopaedic surgery continues to grow there will also be more innovation that could potentially drive down costs. An example of this is the company Blue Belt Technologies, PA that developed the NavioPFS surgical system. This is not a haptic system like the Mako Rio but is a hand controlled cutting tool that has its motor controlled via an optical measurement system. This system is open platform which allows surgeons to use whichever implants they prefer. Another advantage is that is costs less than the Mako system at $300,000. However Blue Belt is a relatively new and small company beginning to undertake clinical trials and hence will require time and considerable financial investment to become

widely available.

The determining factor to large scale adoption of this technology in the UK NHS may not necessarily be the purchase price itself, but the overall cost effectiveness of robotic procedures. If using this technology gives the patients a significantly higher quality of life then it may be worth viewing this technology via a cost/benefit approach as opposed to absolute cost of the technology, better outcomes may lead to future cost savings. Some signs of this may be seen with the pain scoring comparison shown in Figure 5.5, where early recovery in the robotic-assisted group was better from a pain perspective than in the conventional group and may lead to cost savings such as less GP or rehabilitation visits or earlier return to work. A fair cost effectiveness analysis including the full economical costs has yet to be completed for this technology.

Another barrier to more widespread use of robotics in orthopaedic surgery may be due to the majority of surgeons themselves not wanting to use what they feel is not fully proven technology and preferring to rely on their manual surgical skill. There is a typical adoption life-cycle seen with most products when they are released (Figure 5.9). The first 2.5% tend to be the innovators, followed by the next 13.5% being early adopters, the next 34% being the early majority, then 34% the late majority and lastly the final 16% are the laggards (Rogers, 2003). At present this technology is in the early adopters stage where a small number of surgeons have taken up using these new techniques to perform surgery. However the alignment data in this study indicates that even the expert surgeons we asked were able to improve surgical alignment using the robot and these gains will be greater in less experienced, precise and careful surgeons.

The early adopter phase may soon end because in January 2014 Stryker, MI completed the acquisition of Mako Surgical for 1.65 billion dollars. As Stryker is currently one of the largest orthopaedic companies in the world, this may be a signal that this technology may be shifting into mainstream orthopaedic surgery,

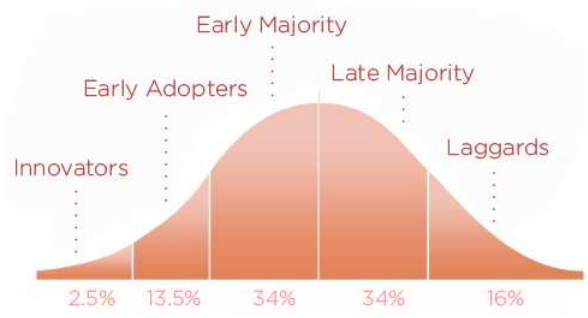


Figure 5.9: Graph illustrating a typical innovation adoption life-cycle (Adapted from Rogers (2003))

and that there is likely to be a new wave of "early majority" surgeons adopting the technology.

An expansion of clinical trials would also help to gain the confidence of more surgeons. A multi-centre study should be the next step for the use of haptic robotics in orthopaedics. The current study was done at a single centre of excellence hospital using three experienced surgeons compared using a robot, and the same three experienced surgeons without a robot. Having multiple centres would include a larger pool of surgeons with different experience levels which could highlight benefits of using a robot-assisted system for UKA, greater than those seen in this study. Using robotic-assisted techniques greatly lessens the technical skill required, hence it may allow less experienced surgeons to perform UKA with success and help with the growing demand for UKA in younger patients. It can also accommodate the use of smaller implants and more minimally invasive procedures in UKA. The technical surgical skill required for such a procedure with conventional means is extreme, hence this new technology may lead to more widespread adoption and with more minimally invasive procedures.

It is also worth noting that the current use of robotics in orthopaedic surgery is to facilitate the cutting of bone by the surgeon in the procedure. However the system can cut bone automatically which may cause some of the more conservative surgeons not to want to adopt this technology. This is a psychological barrier

that may only be overcome by gradual use and trust of the system and technology and with decreasing levels of surgeon involvement in the bone resection procedure until full automation is acceptable.

5.8 Biomechanical Aspects

There were many strengths in the biomechanical aspects of this study, the main being that this was a high quality scientific outcomes measure. Typically clinical trials of this nature rely on questionnaire scores to assess function of the patients, however this study has the added benefit of having biomechanical data on a representative sub-group these patients. In order to generate biomechanical data on these patients, this study used a motion capture system which consisted of high quality cameras, and high spec equipment. Additionally this study had a relatively large sample size for a biomechanical study of this type. It showed a statistically significant difference of a relatively minor nature between the two UKA groups, and also between each UKA group and the normal group. This shows that the biomechanical system was sensitive to the patients' knee movement during gait.

However there were weaknesses with the biomechanical aspects of this study. One weakness was that some patients had to be removed from the biomechanical study due to technical difficulties with force plates, and communication errors between the cameras and the Vicon servers. Another issue with this biomechanical study is that due to marker placement errors and soft tissue artefacts, it is not possible to quantify the direct bone articulation of the joint. This method describes the gross movement of the lower limb segments.

Additionally there were issues with the stair data in this study. The first issue was that the stairs were not assembled correctly, resulting in the instrumented step being in contact with the frame of the stairs. This resulted in small horizontal

forces being applied to the instrumented step every time the patient stepped onto any of the non instrumented steps, and every time the patient held the handrail. Another issue with the stair navigation data was due to a flaw in the study design for those activities. The flaw was that in this study there was no control put in place over handrail usage. For this reason it is very difficult to make a direct comparison between the two groups. While this study showed the Oxford UKA group bending the knee more during stair decent, there was no means of assessing if this was the result of using handrails for support as no video data was taken during the activities.

5.9 Implant Design and Surgical Technique

These two procedures aim to restore normal knee motion by replacing the diseased medial compartment caused by osteoarthritis. Theoretically both implants should restore knee motion to normal, however there has been a difference found between these two groups during walking, where the robotic-assisted group behave more similarly to normal than those in the manual group.

The possible clinical reasons that could account for these differences are, the implant design, implant alignment and surgical technique. The design of each implant aims to allow the ligaments to dictate how the bones should articulate. The design of the Oxford implants consist of 2 articulations, one rotational movement between the constrained femoral implant and the plastic bearing in all three planes, and one sliding movement between the plastic bearing and the tibial implant. The single radius femoral implant should be allowed to slide with the bearing due to the forces applied on it via the soft tissues. The Mako implants consist of a single articulation between the femur and the tibia, where the shape of the femoral implant is such that it aims to resurface the arthritic compartment, and recreate the original bone surface. Just like the Oxford implants the aim is

to allow the soft tissues to control knee articulation.

These differences in implant design could have potential effects on the biomechanics of the knee. The Mako implant is anatomical, replaces the arthritic bone surface and is constrained by the ligaments. However if these implants were not put in accurately they could potentially result in constraining the knee joint because of the lack of tolerance in the design, and restrict motion. Therefore the Mako has the potential hazard that if not put in accurately it is not forgiving to malalignment. Alternatively the Oxford implants allow for potential implantation inaccuracies, as shown in the acceptable limits of the implantation tolerances (for example $\pm 10^{\circ}$ in femoral varus/valgus tolerance). The implants have a large degree of unconstrained mobility, but they are constrained by the ligaments. However if the diagnosis of the patients ligaments are incorrect then this could result in an unstable knee. In this study there was no evidence that the Oxford knee group was unstable during the activities, meaning there was sufficient ligament tension control of the knees. Additionally the Mako group didn't exhibit any signs of constraining the knee joint either, and in some instances showed a better range of motion than the Oxford group.

While it may be hypothesised that the tolerant design of the Oxford implants could lead to instability of the knee, there was no evidence to support this. Similarly the implants in the Mako group had the potential to give constrained articulation, however there was no evidence of this either. The reason for this study not showing these differences could be due to ligamentous stability being an inclusion criterion, therefore the selected patients were able to provide the required knee control. As well as correct patient inclusion for the trial, there is evidence that shows the Mako group had their surgeries performed accurately, and the Oxford surgical accuracy is comparable to other Oxford procedures that have been reported in the literature. Given these were overall well performed surgeries, the design of the implants shouldn't lead to abnormal knee movement.

Theoretically the Oxford design should allow for normal motion, and reported fluoroscopic studies have shown that those patients with an Oxford UKA don't have a statistically significant difference in biomechanics against normal subjects. However in those fluoroscopic studies the weight-bearing activities that the subjects underwent were tasks such as step-ups and deep knee bends. These are high flexion tasks. This study has found differences between the two groups in mid-stance during walking, which are at much lower flexion angles. The single radius implant of the Oxford femoral component matches the anatomy of the femur in the posterior region, which is where the femur tracks during high flexion. However it could be possible that at low flexion angles the polyethylene bearing is not sliding as it is designed to do, which may constrain the knee at these flexion angles, causing potential issues with tracking. On the other hand the anatomically shaped Mako implants may be able to provide more normal knee motion through the entire range of motion due to its design, which aims to resurface the bone. A fluoroscopic study may be performed examining the two different implant designs. This should be done during the walking activity to ascertain if this accounts for higher knee excursion during this range of the gait cycle.

Other differences between the two groups include the surgical techniques employed. During surgery both groups had the same anaesthetic protocol, and the same incisions. The primary difference was the way in which the bones were resected. The bone cut in the Oxford group was performed using a saw. This has the potential to generate heat and could cause thermal necrosis of the bone, which in turn could lead to a source of pain for the patients. On the other hand the bone cuts in the Mako group were implemented using a burr, which made use of a cooling irrigation jet in order to reduce the temperature when burring the bone.

The Oxford design requires flat cuts to be make all around the non-flat bone surface, which leads to more bone having to be removed than with the burr.

A burr allows a curved surface to be cut, resulting in less bone needing to be resected. This extra bone loss could also be another source of pain for the patients in the Oxford groups. Additionally the Mako implants fully cap all the burred bone because they can accurately resect the bone surface, whereas the straight cuts in the Oxford procedure leave exposed bone, which could bleed into the joint causing pain. The result of this could be that the Mako group recovered faster than the Oxford group, and their pain scores reduce at a faster rate than the Oxfords, as shown in Section 5.5.3. Whether this has an effect of the gait of the patients 1 year post operatively is unlikely as by 3 months there was no statistically significant difference between the pain scores of the two groups.

Scientifically it is very difficult to prove with this type of study anything other than a robotically assisted fixed bearing UKA implant has shown more normal knee motion during gait compared to a manually implanted mobile bearing UKA. There may be many elements that could potentially cause this difference, such as the implants, surgical differences such as using a cutting burr instead of a saw, the navigation element of the Mako, or the fact that the bone resection is robotically assisted. It can be argued that the Oxford knees can tolerate some surgical inaccuracies, but the fact is that the Mako implants using the robotic system have been implanted precisely and reproducibly. The differences clearly show that the Mako implants are put in more accurately, and the Mako groups achieve slightly better results during walking, but it is very difficult to put a link between the two. This is because of the multi-factorial differences between the two types of procedures and their approach to UKA, and also in part due to the limitations of this study. All that can be hypothesised is that a group of patients that have a well aligned and anatomical reconstruction of their knee, may be associated with the difference in walking that has been observed.

Chapter 6

Conclusion

This purpose of this study was to compare the functional outcome of Mako UKA and Oxford UKA. The motivation for such work is due to a recent increase in the number of patients receiving UKA. This patient group receiving UKA is typically younger than the most commonly performed knee replacement procedure – TKA. While there are benefits of UKA there have also been issues with poor implant alignment, leading to increased incidence of implant failure. This may be due to the technical difficulty of this operation. However robotic-assisted surgical methods significantly reduce the technical surgical skill of implanting a UKA and give more accurate implant alignment in the knee.

We have shown that with careful patient selection haptic robotic UKA is a viable solution to treat patients with medial compartmental OA. More specifically patients in this study that underwent robotic-assisted surgery had statistically significant improvements in their implant positioning compared to that of the conventional group, as well as a faster recovery. A biomechanical analysis compared the two UKA patient groups doing a range of everyday activities (walking, ascending and descending stairs, sit to stand and deep knee lunge). The differences seen between the two surgical groups were small but significant statistically during level walking and stair descent. The robotic-assisted group achieved a sta-

tistically significantly higher knee excursion from foot-strike to mid-stance compared to the conventional group. When compared with normal patients there was no significant difference between the robotic-assisted UKA group and the normal group, however the conventional UKA group did not manage to achieve similar levels of knee excursion. Neither group managed to achieve normal knee excursion from mid-stance to terminal stance. Additionally no correlation was seen between questionnaire scores and knee excursion during this phase of the gait cycle. The other significant difference was found during stair descent, where the robotic-assisted UKA group achieved a more normal range of motion than the conventional group. However there were flaws in the stair protocol due to not controlling for handrail usage, which has been shown to cause differences in knee excursion during stair navigation. For this reason it is problematic to assume this could be due to the UKA.

There are several implications derived from this work. Firstly it has shown that in this trial three experienced surgeons achieved significantly better implant alignment accuracy using the robotic-assisted method than by conventional means. Since the implant accuracy using the robotic-assisted method doesn't depend on surgeon experience this technique may encourage more surgeons to start performing UKA. Indeed our experienced surgeons only conducted a few saw bone and cadaver practice procedures before implementing the robotic surgery in 5 trial procedures under supervision, before beginning recruitment to the study and unsupervised use of robotic surgery. The learning curve is therefore relatively short. Additionally it has been shown in this work that using motion analysis, subtle differences in biomechanical performance can be found when applied to a relatively small group of subjects (n = 20-30). Further differences that were found may be due to implant design, and as a result of more accurate implant alignment allowing a more anatomical reconstruction of the knee. Fluoroscopic in vivo studies and cadaver studies on the knee motion may give more insight into

these claims. While there were biomechanical differences seen between the two groups, they didn't seem to correlate directly to the patients' perceived function and their clinical significance and relevance to the patient are unclear.

The sample size of this study was comparable to many others that have preceded it, however the technology is relatively new, therefore further studies need to be conducted before any consensus is reached on robotic-assisted UKA. Performing a multi-centre study on robotic-assisted UKA may continue to add robustness to the argument for more minimally invasive surgery overall, and more specifically for robot-assisted techniques. Another limitation of the biomechanical study was no motion capture was performed on the patients pre-operatively. This means there was no baseline data to compare with the patients when they came in for the 1 year post-operative assessment. The patients were randomised in each group, however even this process doesn't necessarily result in perfectly symmetrical patient cohorts.

Overall this study has shown that robotic-assisted UKA results in implant alignment improvements, and faster early recovery. Motion analysis at 1 year post-operatively has shown that during level walking the robotic-assessed group achieved a higher knee excursion during the highest flexion portion of the weight bearing stage of the gait cycle. These knee excursion values were comparable with normal healthy knees, however the conventional UKA group had significantly lower knee excursion angles at this point. Even though there were some differences seen in the two groups with motion analysis these factors didn't necessarily correlate with better perceived patient function, therefore it's still unclear if improved alignment and better knee motion directly correlate with improved function. Given that this was the first study to compare the Mako and Oxford UKA independently from manufacturers, caution needs to be reserved, but it would appear that the Mako is an equal and alternative procedure to the Oxford.

Chapter 7

Future Work

Follow up data collected from Glasgow Royal Infirmary from the subjects in this trial will continue to be collected for a period of 10 years. Therefore mid to long term survival rates and other clinical outcomes will become available. Additionally 1 year motion analysis data will continue to be collected for the remainder of the patients in the trial.

While there was a difference seen between the robotic assisted and manual UKA groups during walking, overall relatively modest clinical benefits have been seen. The benefits seen were improved gait, quicker recovery and less pain. However it is still unclear if these benefits are enough to make it economically worthwhile to implement. It would require a health technology assessment trial, however this is difficult to get for a robot at this price. If the cost of this procedure decreases then this might make it a more economically viable option for UKA.

What the robotic system has proven is that bone resection can be done to a very high degree of accuracy. This has implications beyond UKA and for more difficult procedures where implant accuracy is more crucial for ensuring a good clinical outcome. One such procedure includes performing bi-UKA as an alternative to TKA. Other procedures that could benefit from a precise robot would be joint replacements for elbows, fingers, or for the removal of bone tumours.

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CLINICAL INVESTIGATION PLAN

INVESTIGATION TITLE: MAKOplasty unicondylar knee arthroplasty using MAKOplasty® and the MAKO RIO® System *versus* OXFORD® Partial Knee Arthroplasty

Country:	United Kingdom
Principle Investigator:	Mr Mark Blyth FRCS (Ed) (Tr+Orth)
Co-Investigators:	Professor Philip Rowe Mr Bryn Jones FRCS (Ed) (Tr+Orth) Mr Angus MacLean FRCS (Ed) (Tr+Orth) Dr Phil Riches
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Protocol prepared by:	Philip Rowe Professor of Rehabilitation Science Bioengineering Unit
Protocol Version:	12.3, 30/7/2010
Study Funder:	MAKO Surgical Corp. 2555 Davie Road Ft. Lauderdale, FL 33317 Phone 954.927.2044 Fax 954.927.0446
Study Sponsors:	Greater Glasgow Health Board North Glasgow University Hospitals Division 4th Floor Walton Building Glasgow Royal Infirmary 84 Castle Street, Glasgow, G4 0SF

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Proposed start date: September 2010

Study period: 40 months

Indication: Patients with osteoarthritis of the knee who require a unicondylar knee replacement.

Investigation design: A prospective, randomised, single centre study.

Number of patients: 150, 75 in each group.

Target population: Patients with osteoarthritis of the knee who are suitable for a unicondylar knee replacement.

Length of study: Patients included in this study will be assessed pre-operatively, at 3 months and at 1, 2, 5 and 10 years post-operatively.

Test device: Unicondylar knee arthroplasty a) MAKO unicondylar knee arthroplasty (MAKOplasty®) using the RESTORIS implant and the MAKO RIO® Robotic Arm Interactive Orthopaedic System versus b) OXFORD Unicompartmental Knee Arthroplasty

Safety: Adverse events will be recorded and reported appropriately throughout the study to assess safety.

MAKO Registry of Arthroplasty: All patients given a MAKO arthroplasty will be entered into the MAKO registry of arthroplasty and data required by this registry will be collected and entered into the registry.

Publishing/presentation aims: Data analysis at various time points. Firstly the outcome data from the immediate post-op measures and then the 1 year review followed by clinical outcomes at 2, 5 and 10 years. This data would be suitable for either of the JBJSs or J Biomech or any of the major orthopaedic or biomechanical journals. Podium presentations for BORS, BASK, CAOS, ESSKA, AAOS, EFFORT, ISB, ESB etc…

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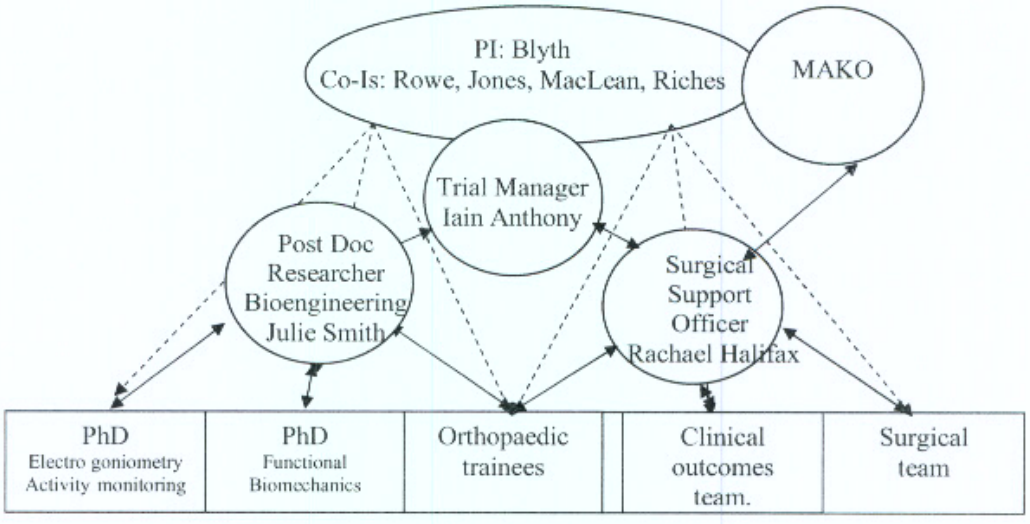
Preamble

All Parties can see much benefit from the establishment of a joint research team in robotic assistive technology for orthopaedic surgery and wish to begin to develop this collaboration using an initial clinical investigation involving MAKO, the Orthopaedic service of NHS GG&C and the Bioengineering Unit and Electronic and Electrical Engineering Dept of the University of Strathclyde. This will establish a research team and collaboration which will then seek further funding for an ongoing programme of work.

The initial clinical investigation will compare MAKOplasty® unicondylar knee arthroplasty with an Oxford unicondylar knee arthroplasty. We would expect the investigation to last 3 years with recruitment finished in 18 months. During this period we would also seek to plan an investigation of day case versus in patient MAKOplasty® using the RIO machine and to seek funding to undertake this second investigation.

Finally we will explore possible future developments of the robotics systems and of the implant design using staff at the University of Strathclyde with the desire to develop the Haptic performance of the RIO robot, it's interface characteristics when operated by a human and eventually a "pre uni" cartilage repair type surgery using the MAKO system. These additional activities will require further funding either from MAKO or external sources but during the first three year period we intend to lay the ground work and seek funding for these further developments using the team developed for the initial investigation.

The programme of work between the partners will be initiated by implementing the clinical investigation proposed in this document and using a research team similar in design to the one outlined below:



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INVESTIGTION PROTOCOL

1. 0 AIM:

To compare the surgical and functional outcomes of a MAKO unicondylar knee arthroplasty using MAKOplasty® and the RIO® Robotic Arm Interactive Orthopaedic System with those from OXFORD Unicompartmental Knee Arthroplasty.

2.0 OBJECTIVES:

2.1 Primary Objective:

To compare alignment in 2 groups of patients undergoing unicondylar knee replacement using the MAKO and OXFORD systems. At 3 months post operation alignment in both groups will be verified with 3D reconstruction scans.

2.2 Secondary objectives

1. To compare the clinical outcome of the two types of unicondylar arthroplasties using the Oxford and AKSS knee scores and other clinical outcome data collected as part of the MAKO register of arthroplasties (SF12, the physical component of the UCL knee score etc)
2. To compare early pain relief and functional return using a pain VAS and the functional section of the AKSS knee score
3. To compare post-operative alignment using 3D reconstruction CT scans between the two groups.
4. To compare the biomechanics of Gait between the two groups
5. To compare the functional outcome at one year when performing a range of activities of daily living as measured by electrogoniometry
6. To compare the patients activity levels at one year when measured with an Activpal
7. To compare the patients satisfaction with the out come using a patient specific outcome measure (Canadian Occupational Performance Measure)
8. To compare quality of life between the two groups using the SF12 and EQ-5D
9. To compare the complication rates between groups. Complications to be measured include superficial and deep infection, neural and vascular damage, bone fracture around the implant, loosening of the implant, dislocation or fracture of the implant, excessive haemorrhage requiring reoperation, reoperation for any reason, thrombotic complications, post operative confusion and death.
10. To compare the operative times between the groups.
11. To compare subjective levels of activity between the groups using UCLA activity scores
12. To compare psychological factors influencing the outcomes between the groups using the HAD (Hospital anxiety and depression) score, the Forgotten Joint Score, the pain catastrophizing scale, somatoform disease scores, and ability to tolerate discomfort (Cold Pressor Test).

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13. To study the interaction between surgeon and RIO robotic system in order to maximize efficiency of the system and develop protocols for faster and more efficient surgery in order to decrease costs associated with surgery.

3.0 ENDPOINTS

3.1 Primary endpoint

The primary endpoint is to demonstrate a minimum improvement of 1° in longleg alignment deviation from neutral in patients in the MAKO group. CT scans with 3D reconstruction will be used to evaluate alignment at 3 months postoperatively.

3.2 Secondary endpoints

1. To quantify the effects if any on early pain relief and functional return of the MAKOplasty® procedure using a pain VAS and the functional section of the AKSS knee score recorded weekly postoperatively for 8 weeks and there after at 3 months and 1 year.
2. Comparison of clinical outcome using the American Knee Society (AKSS) and Oxford Knee scores will be carried out preoperatively, at 3 months and 1,2,5 and 10 years.
3. Comparison of the MAKOplasties performed in the investigation with others in the MAKO register of Arthroplasty using the data collected and entered into the MAKO register of Arthroplasty.
4. To quantify the effect of accurate placement of knee implants on the biomechanics of gait, functional assessment, activity levels, quality of life and patient satisfaction at one year. It is expected that those knees that are implanted more accurately will function subtly better than those that are not. If the MAKO system is shown to improve accuracy, then it may be shown to also improve gait, function, activity, quality of life and patient satisfaction. Detailed comparison of biomechanics of gait, functional assessment, activity levels, quality of life and patient satisfaction at one year and their relationship to accurate placement of knee implants.
5. To demonstrate that the use of the MAKO system does not create an increased complication rate or operative time when compared to the conventional group.
6. To determine patient related factors which contribute to poor post-operative patient satisfaction.
7. To develop protocols for more efficient work practices in order to decrease surgical time.

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4.0 BACKGROUND TO INVESTIGATION

There are a number of sources of surgical inaccuracy when performing a uni-compartmental knee arthroplasty. These include blades skiving through cutting guides or templates not optimally balanced or placed. Hence traditional jig-based resection can compromise implant performance. The MAKOplasty® surgery with use of the RIO® Robotic Arm Interactive Orthopaedic System are new technologies which should allow the prosthesis to be implanted far more accurately than with conventional systems. The RIO® System is a proprietary, FDA-cleared, surgeon–interactive robotic arm system that is said to enable "the orthopaedic surgeon to pre-operatively plan the alignment and placement of knee resurfacing implants and to intra-operatively make complex, anatomic, tissue-sparing and bone-conserving cuts accurately. The robotic arm with tactile guidance adds the sense of touch, making bone resection highly precise and surgeon-friendly". MAKOplasty® is said to be "an innovative, restorative surgical solution that enables orthopaedic surgeons to treat patient-specific, early to mid-stage osteoarthritic knee disease with consistent reproducible precision.

There is a large and growing, yet currently underserved patient population suffering from early to mid-stage osteoarthritis of the knee. It is thought that patients who desire a restoration of lifestyle, minimised surgery, reduced pain and rapid recovery may benefit from unicondular knee arthroplasty and in particular MAKOplasty®. It is this hypothesis that this study aims to evaluate.

This study aims to demonstrate a reduction in variance in implant alignment when using The MAKO system and also to show improved gait, functional ability, activity, clinical outcome and patient satisfaction. We are unaware of other studies published on this system using these highly specific and relevant outcomes.

While Clinical knee scores (AKSS and Oxford scores) may reveal the success of the procedure from a surgical view point they are relatively crude and insensitive outcome measures when related to patient function and satisfaction. It is therefore possible that MAKO surgery may lead to important but subtle improvements in patient function which have a substantial impact on quality of life but which are not detected by the typical knee rating scores used to detect improved surgical outcome. Using knee scores alone increase the chances of making a type II error in which it would be concluded that no differences exist in patient outcome when in fact they do exist and are valuable to the patient but have not been captured by the clinical rating scale outcome measures deployed.

By performing a scientific, precise, accurate and multi dimensional assessment of patient biomechanical performance, functional outcome, activity and satisfaction it will be possible to determine the benefits (if any) of the MAKO system versus the conventional OXFORD system. This data can be used to inform health care service providers such as the UK NHS of the benefits to be gained for their patients in terms of functional outcome by investing in the MAKO system.

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5.0 INVESTIGATION DESIGN

Prospective, randomised, single centre controlled study. Patients will be randomised to receive a MAKO uni-compartmental knee arthroplasty or a conventional OXFORD arthroplasty. The study will continue until a total of 150 patients have been recruited to each group. Using the central limits theory 30 patients in each group are required to estimate the mean and standard deviation. However in order to ensure that the study groups represent generalisable samples, 75 patients in each group will be recruited.

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6.0 DEVICES

The RIO® Robotic Arm Interactive Orthopaedic System is a surgeon–interactive haptic arm used with MAKOplasty® system. Both have proprietary, FDA-clearance.

The OXFORD device is CE marked for Unicondylar Knee Replacement surgery and is in routine use in the UK.

7.0 RISK / BENEFIT ANALYSIS

The perceived benefit of using the MAKO system is to allow for more accurate implantation of the unicondylar knee replacement when compared to conventional methods. This in turn may lead to increased longevity of the implant, better functional outcome, better activity levels, patient satisfaction and Quality of Life. Risks of the MAKO system include the procedure taking slightly longer than conventional surgery and being more costly.

Risks common to both methods are those of unicondylar knee replacement in general. Any surgical procedure poses a potential risk and the procedures undertaken as part of this clinical investigation are no exception. There are known risks associated with the method of anaesthesia (general, local and epidural). In addition there are risks associated with a surgical procedure that involves a device, these include the following: damage to nervous and vascular tissue, infection, long term swelling, fracture of bone surrounding a device, loosening, dislocation or fracture of the device, haemorrhage, decreased range of motion or mobility deformity, allergic reaction to the device (including immunological reaction to device wear debris) and failure of the device to be incorporated into the body – this is not an exhaustive list. A complication may require revision surgery, Very rarely a complication may prove fatal.

The anticipated benefits a patient will experience as a result of participating in this clinical evaluation include: reduction or relief of pain, restoration or improvement in range of motion and mobility, correction or improvement of disfiguring deformity and an improvement in their quality of life. Subjects will be advised of the potential risks and benefits associated with this investigation verbally by the investigator and by writing in the form of the subject information leaflet which will be approved by the ethics committee.

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8.0 SELECTION OF SUBJECTS

8.1 Inclusion Criteria

i) Male or female subjects may be recruited to the evaluation.

ii) Age – there are no restrictions relating to age of the patient. The patient's age must be considered suitable by the clinical investigator for a unicondylar knee arthroplasty using either of the two systems available in the evaluation.

iii) Subjects who are able to give voluntary, written informed consent to participate in this investigation and from whom consent has been obtained.

iv) Subjects who, in the opinion of the Investigator, are able to understand this investigation, co-operate with the investigation procedures and are willing to return to the hospital for all the required post-operative follow-ups.

v) Subjects who require a unicondylar knee arthroplasty for primary surgical management of idiopathic osteoarthritis.

vi) Patients who in the opinion of the Chief Investigator are considered to be suitable for treatment with a MAKO and OXFORD unicondylar knee replacement.

8.2 Exclusion Criteria

i) Patients who, in the opinion of the Investigator, have an existing condition that would compromise their participation and follow-up in the study.

ii) Patients who require revision knee arthroplasty surgery.

iii) Patients with any tibial deformity requiring tibial component augmentation.

iv) Patients whom, in the opinion of the Chief Investigator, require a total knee prosthesis.

v) Patients with inflammatory polyarthritis.

vi) Disorders of the feet, ankles, hips or spine causing significant abnormal gait or significant pain.

vii) Neurological conditions affecting movement.

viii) Patients with a pathology which, in the opinion of the Chief Investigator, will adversely affect healing.

ix) Patients with other disorders which, in the opinion of the Chief Investigator, will/could impair rehabilitation.

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x) Contra-indications for use of the device, as detailed in the package insert.

xi) Women who are pregnant. If there is uncertainty over pregnancy then a pregnancy test will be conducted.

xii) Subjects who are known drug or alcohol abusers or with psychological disorders that could effect follow-up care or treatment outcomes.

xiii) Subjects who are currently involved in another clinical study with an investigational product.

xiv) Subjects who are currently involved in any injury litigation claims.

9.0 INVESTIGATIONAL PROCEDURES

An overview of the procedures each subject will undergo during the course of this investigation is contained in the Investigational Schedule at the front of this protocol and in more detail as follows:-

9.1 Screening Evaluations

9.1.1 Informed Consent

Subjects considered suitable for participation in this clinical investigation by the Investigator will be given a verbal explanation of the nature of their clinical condition, this investigation and follow-up requirements by the research assistants, surgical support officer or trial manager (or a designated deputy), and supplied with the subject information leaflet. Surgeons involved in the study will not consent patients to participate. Each subject will be allowed sufficient time to decide whether they wish to participate in this investigation. Any queries which subjects may have regarding this investigation will be addressed appropriately by the Investigator or another member of the investigative team at the hospital.

Subjects will be instructed that they are free to obtain further information from the Investigator at any time, that they are free to withdraw their consent and to discontinue their participation in the study at any time without prejudice.

If the subject is willing to participate in this investigation written informed consent will then be obtained. Written informed consent from the subject must be obtained before any of the screening procedures are performed. The consent process will be facilitated by GCP trained individuals, including the principal investigator, surgeon co-investigators and research assistant on the trial.

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9.1.2 Subject eligibility and identification

Once voluntary written informed consent has been obtained and it has been confirmed that the patient meets all of the eligibility criteria, the patient will be allocated the next available patient evaluation numbers.

The patient details will be recorded on a patient log. If a patient fails any of the eligibility criteria for the evaluation, the patient must not be advanced any further into the evaluation.

The failure of a patient to meet the eligibility criteria must be documented by the Clinical Investigator and filed with the signed consent form.

The Investigator will also inform the subject's General Practitioner (GP) in writing of the subject's participation in this investigation.

9.1.3 Randomisation

Patients will be randomised to receive a MAKO unicondylar knee replacement or an OXFORD unicondylar knee replacement. This will be performed by a random number generator at the pre-assessment visit. Randomisation will also be stratified to surgeon to reduce the potential for bias.

9.1.4 Clinical Assessments

Each subject considered eligible for entry into this investigation will have the following information and procedures recorded at the pre-investigational examination:-

- Patient identification [initial and evaluation number)
- Demographics (date of birth, sex, weight, height)
- Concomitant medication
- Medical history (past and present)

The following baseline clinical assessment will be performed (within 30 day prior to treatment):-

- Oxford Knee Score, American Knee Society Score, Venous Insufficiency Classification, EQ-5D, Short Form-12 (SF-12) and the Canadian Occupational Performance Measure (COPM), Forgotten Joint Score, pain and stiffness VAS, patient expectations after surgery, Somatic disease assessment and Pain Catastrophizing Scale.
- Cold pressor test
- Short Physical examination as per usual practice

All data entry requirements of the pre-operative schedule for the MAKO registry of Arthroplasty (if randomised to the MAKOplasty Group)

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9.2 Surgical Procedure

9.2.1. Subject pre-operative management

The pre-operative management of each subject enrolled in this clinical investigation will be as per the standard regime used at the investigation centre. Pre-operative management for the device to be used will be undertaken as per the normal clinical practice of the Clinical Investigator. For subjects in the MAKOplasty® arm of the Investigation (n=75) an additional pre-operative CT scan will be required to plan the surgical procedure and pre-programme the haptic device. Preoperative CT scanning and surgical planning for patients in the MAKOplasty® group will be carried out according to the standard protocols and procedures described by MAKO.

9.2.2. Anaesthesia

The method of anaesthesia used will be as per the standard clinical practice of the Clinical Investigator. The anaesthetic protocol will be controlled and standardised for all three surgeons participating in the trial.

9.2.3. Procedure

The surgical technique/approach used in the clinical investigation will be as per the standard clinical practice of the Clinical Investigator. Devices and instruments supplied will be used in accordance with the manufacturer's instruction. All components will be cemented.

Any alteration to the standard clinical practice of the Clinical Investigator will be documented.

9.2.4. Intra-operative assessments

During the operative procedure an assessment will be performed and the following information will be recorded in the subject's case record form:

i. Subject identification
ii. Date of surgery
iii. Details of all devices and components used
v. Soft tissue balancing
vi. Anterior and Posterior cruciate ligament status
vii. Cement use
viii. Details of any problems or complications encountered
ix. Time for the procedure
x. Tourniquet time
xi. Surgeon name and grade
xii. Surgical approach
xiii. Pre-operative and post-operative deformity and range of motion
xiv Extent of cartilage damage as observed in theatre

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A patient Record Label for each device or component used during the procedure will be affixed to the patient's hospital notes and to the case record form.

All peri-operative data required for the MAKO register of arthroplasty will also be collected.

An audio visual record of each surgery will be made in order to monitor work practices and surgeon interaction with the RIO system. Data from these recordings will be used to develop new protocols for more efficient use of the RIO system in order to reduce surgery duration. No changes will be made to the surgical protocol during the period of the trial.

9.3 Immediate post operative assessment and monitoring:

On a daily basis while an inpatient for the first week and on a weekly basis thereafter for 8 weeks the patients will be asked to rate their pain on a pain VAS and to answer the functional section of the AKSS. We will also record their narcotic and PCA usage, their ability to straight leg raise and the rehab prescribed. If in-patients this will be done in person. If patients become outpatients or are discharged then data will be gathered by telephone. We will also use these contacts and subsequent follow up sessions to check for adverse events and to record time to return to driving and time to return to work (if appropriate).

9.4 Follow-Up Assessments

Subjects will be followed up as part of the clinical investigation at the following time points:-

10 days	(Telephone check)
3 months	(± 14 days recommended)
1 year	(± 30 days recommended)
2 years	(± 30 days recommended)
5 years	(± 30 days recommended)
10 years	(± 30 days recommended)

Every effort will be made to follow-up subjects within the time windows indicated.

The following assessments will be completed:-

1. Radiographic Analysis at 1, 2, 5, 10 years
2. All postoperative data collection required for the MAKO registry of Arthroplasty
3. Oxford Knee Score, American Knee society score, the Forgotten Joint Score, patient satisfaction, HAD, EQ-5D, pain and stiffness VAS, Pain Catastrophising Scale and physical exam at each visit
4. Details of any post-operative problems or complications at each visit
5. CT scanning at 3 months.
6. Detailed biomechanical, functional and activity assessment at 1 year
7. SF12, COPM, UCLA,and Somatic disease assessment scores at 1 year

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9.5 Detailed Biomechanical, Functional and Activity Assessment

Subjects will be reviewed at 1 year at the time of their follow up assessment according to the protocol outline in appendix 1.

9.6 Computerised Tomography & radiographic assessment

Radiographs will be standard pre- and post-op X-rays at 1 year, 2 years, 5 years and 10yrs. Also long leg standing X-rays at 3 months which is our standard of care currently for Oxford unicondylar knee replacement.

CT scanning of patients will be carried out according to the following protocol:

-Long leg CT scans to be acquired:

1. Pre-operatively for all patients randomised to the MAKO group
   This is standard practice advised by MAKO for carrying out the MAKOplasty® surgery
2. 3 month post-operatively for all patients in the study (MAKO group and OXFORD group)

-CT parameters and acquisition method will be consistent for all scans. Scans will be carried out at the Nuffield Hospital (Glasgow).,

-Scan parameters:

- Detailed high resolution scan
- Topogram parameters: 1024mm, 120kV, 50mA, 10.5s scan time
- Use of a motion rod during the scan, passing from just proximal to the hip joint centre to a point distal to the ankle joint centre
- 3 scanning regions: Hip, Knee, Ankle
- Hip and Ankle parameters:
  - Effective mAs 100 (CTDIw 7.64mGy)
  - Scan time 7.13s
  - Rotation time 0.75s
  - Feed rotation 10mm
  - FOV not exceeding 500mm
  - Anatomical markers:
    - Hip: Include femoral head and motion rod, centre at the hip
    - Ankle: Include medial and lateral malleoli, centre around ankle joint
  - Slice width 3mm
  - Length of scan 81mm
  - 27 slices
- Knee parameters:
  - Effective mAs 100 (CTDIw 9.04mGy)
  - Scan time 26.76s
  - Rotation time 0.75s
  - Feed rotation 4mm
  - FOV not exceeding 250mm
  - Anatomical markers:

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- Include distal boundary of tibial tuberosity, entire patellofemoral region and motion rod, centre around joint line
- Slice width 1mm
- Length of scan 200mm
- 200 slices

9.7 Cold Pressor Test

In order to assess diference in individual patients ability to deal with discomfort and pain we will ask patients to under go the 'Ice Bucket Test'. Patients will be asked to place one hand in a chilled bath of water 1.5°C +/- 0.5°C. Patients will be asked to keep their hand in the water for as long as they feel comfortable to do so up to a maximum of 300 seconds. With their opposite hands patients will be asked to move a slider bar to indicate their current level of discomfort. The slider bar will be labeled at one end '0' and at the other end '100' and will be connected to a computer which will give a visual output to the patient representing the position of the slider. The system works in effect like a continuously variable visual analogue scale (VAS). We will record the maximum VAS score together with the duration of time the test is tolerated (up to 300seconds max). We will also record the time at which patients reach 30 and 50 on the VAS and the time at which the maximum VAS is recorded.
Any patient suffering from Raynaud's disease, hypothyroidism or carpal tunnel syndrome will be excluded from this test.

9.7 Safety Assessments & Adverse event reporting

At each follow-up assessment details of any adverse event or adverse device effect reported by the subject will be recorded. Details to be recorded include the nature, onset, duration, severity, relationship to the operative procedure or device and outcome of the event.

The occurrence of adverse events (including new illnesses, worsening symptoms of coexisting diseases or additional symptoms) will be identified by spontaneous reports from the subject in response to a standard question (e.g. how have you been since your last visit?) or by clinical/radiological assessment.

According to the European Standard EN 540 for the Clinical Investigation of Medical Devices for Human Subjects, an adverse event is defined as 'any undesirable clinical occurrence in a subject whether it is considered device related or not'. In addition, an adverse device effect, undesirable side effect, is defined as 'a device related adverse event'. A list of potential adverse events and adverse device effects which may be associated with this investigation can be found in Section 6.0 of this protocol.

A record of all adverse events, including details of the nature, onset, duration, severity, relationship to the device, relationship to the operative procedure and outcome, will be made on the relevant section(s) of the subject's file. The subject will be questioned about any adverse event(s) at each subsequent follow-up assessment visit.

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An adverse event or an adverse device effect may be mild, moderate or severe and are usually unexpected. A severe adverse event or adverse device effect is defined as any experience that:

i) is fatal or life threatening
ii) is permanently incapacitating or disabling
iii) requires or prolongs in-patient hospitalisation because of a potential disability, danger to life or an intervention has been necessitated
iv) causes foetal distress, foetal death or a congenital anomaly
v) malignancy results

The Chief Investigator will report adverse events to the Sponsor. Severe adverse events will be reported as they occur and within 1 week. The sponsor will report SUSARs to MHRA. If the adverse event is felt to be device related the chief investigator will also notify the Manufacturer. Monitoring of the Investigation will be undertaken by Prof John Norrie.

10.0 END OF INVESTIGATION

The Investigation is expected to end after the last 10 year assessment. Thus the end data will be expected to be July 2023. However a full report of the findings will be made after all patients have received their one year follow –up examination. This is expected to occur by July 2013.

11.0 STATISTICS AND DATA MANAGEMENT

The sample size for this study is based on the requirement to detect a difference in distribution post operative alignments. Using the central limits theory 30 patients in each group are required to estimate the mean and standard deviation. However in order to ensure that the study group represent generalisable samples, 75 patients in each group will be recruited.

Data will be collected using data collection forms. Data will then be entered into a database managed and stored by OrthoSight. Data will be anonymised prior to entry on the OrthoSight system and the link file will be maintained by the Chief Investigator. No members of OrthoSight will be given access to the link file. The statistical analysis will be performed by Professor Rowe of the bioengineering unit (advised by Prof Norrie, data analysis to include primary outcomes biomechanical, functional and activity data) and the research unit in the Department of Trauma and Orthopaedics at Glasgow Royal Infirmary (clinical outcomes and CT scans). Details of the CT scans will be anonamised. We will calculate a variety of angles between implants and bony landmarks on the CT scans in both groups of patients. The assessor will be unaware of which sample group the patient

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belongs too or other collected variables. All significance tests will be carried out to a 5% significance level.

Patients who complete the surgical phase but fail to complete follow-up postoperatively will be included in the analysis up to the point of last assessment.

Oxford and AKSS scores will be calculated and summarised preoperatively and at post-operative visits at 3 months and 1,2,5 and 10 years. The change in score at each time point will be presented and compared between the 2 groups.

The presence of radiolucencies at 1, 2, 5 and 10 years, patient demographics, surgical time and adverse events will all be summarised and presented. Statistical analysis of these data compared to the age matched control group will be undertaken.

12.0 ETHICAL CONSIDERATIONS

12.1. Ethics Committee Approval

Prior to the initiation of this investigation, the Investigator will submit the protocol and any other documents as may be required to an appropriate Ethics Committee for review and approval. The Committee will be requested to provide a letter documenting approval of this investigation. The Investigator, and any other member of the investigative team, if a member of the Ethics Committee, must not participate in the decision making. A list of the members of the Ethics Committee reviewing this protocol will be requested.

The Ethics Committee approving the original protocol must be notified of, and give approval to, any significant changes to the protocol. The Chief Investigator must notify the Ethics Committee with 10 working days of the discovery of any severe adverse events or severe adverse device effects which occur during this investigation.

12.2. Informed Consent

Each subject will have the nature and the purpose of this investigation explained to them by the Investigator or another member of the investigative team at the hospital. Prior to entry into this investigation the subject must give voluntary, written informed consent to participate by signing the consent form. On the same occasion, the Investigator will also sign the informed consent form. Three copies of the consent form are to be made.

The original copy of the signed consent form will be kept in the investigator file at the study site. A copy will be kept in the patient/hospital notes and a further copy provided to the subject.

12.3. Confidentiality of Subject Records

Confidentiality of subject data will be maintained at all times. Subject anonymity will be guaranteed and all documentation relating to a subject (including radiographs and CT scans) will be kept in secure locations.

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12.4. Declaration of Helsinki

This investigation will be conducted in accordance with the relevant articles of the Declaration of Helsinki as adopted by the 18th World Medical Authority in 1964 and as revised in Tokyo (1075), Venice (1983), Hong Kong (1989), South Africa (1996) and Scotland (2000).

12.5 Good Clinical practice

This investigation will be conducted in accordance with the principles of the European Standard EN540 'Clinical investigation of medical devices for human subjects'.

13.0 REGULATORY REQUIREMENTS

CE Marking for MAKO products and suitable licensing for them to be used in routine surgery in the UK

14.0 STUDY TERMINATION

14.1 Subject Withdrawals form the Investigation

Any subject who wishes to withdraw from this investigation on his/her own accord and for whatever reason is entitled to do so without obligation and prejudice to further treatment. In addition, the Investigator may decide for reasons of medical prudence, to withdraw a subject. In either event, the Investigator will clearly document the date and reason(s) for the subject's withdrawal from this investigation in the clinical research Investigation and should indicate whether or not he considers it was related to the device. The Investigator will also notify MAKO of the subject's withdrawal.

14.2 Termination of the Clinical Investigation

Both the sponsors and the Chief Investigators reserve the right to terminate the study at any time. Should this be necessary, the procedures will be arranged on an individual study basis after review and consultation by both parties. In terminating the study, MAKO and the Chief Investigator will assure that adequate consideration is given to the protection of the patient's interests, and the appropriate bodies such as the LREC/MRECs and Regulatory authorities are informed as appropriate.

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15.0 Investigation schedule:

Action	Pre-treatment	Peri operative	3 months	1 year	2 years	5 years	10 years
Issue patient information leaflet	X						
Obtain written informed consent	X						
Complete demography, medical history, medication, coexisting disease	X						
Radiographic examination	X	X		X	X	X	X
Physical examination	X		X	X	X	X	X
Inform patients GP	X	X	X	X	X	X	X
Complete Oxford/AKSS knee scores	X		X	X	X	X	X
HAD, Pain catastrophising scale, Forgotten Knee Score, EQ-5D	X		X	X	X	X	X
Venous Insufficiency Classification	X			X	X		
Record patient expectations	X						
Allocate randomisation	X						
Complete Makoplasty Register (Makoplasty group only)	X	X	X	X	X	X	X
Pre-operative CT Scan (Makoplasty group only)	X						
Record details of surgery including Post-operative alignment in coronal plane		X					
CT scanning for alignment			X				
Measure pain VAS and function part of AKSS		X (once a week for 8 weeks)	X	X	X	X	X
Assess and record adverse events		X	X	X	X	X	X
Record patient satisfaction			X	X	X	X	X
Detailed Biomechanical assessment of gait				X			
Detailed Functional Assessment				X			
Detailed Activity Assessment				X			
SF-12/ Canadian Occupational Performance Measure/ HAD/ UCLA/, Somatic disease test, patient post-surgical expectations	X			X			
Advise patient when they will next be seen	X	X	X	X	X	X	X

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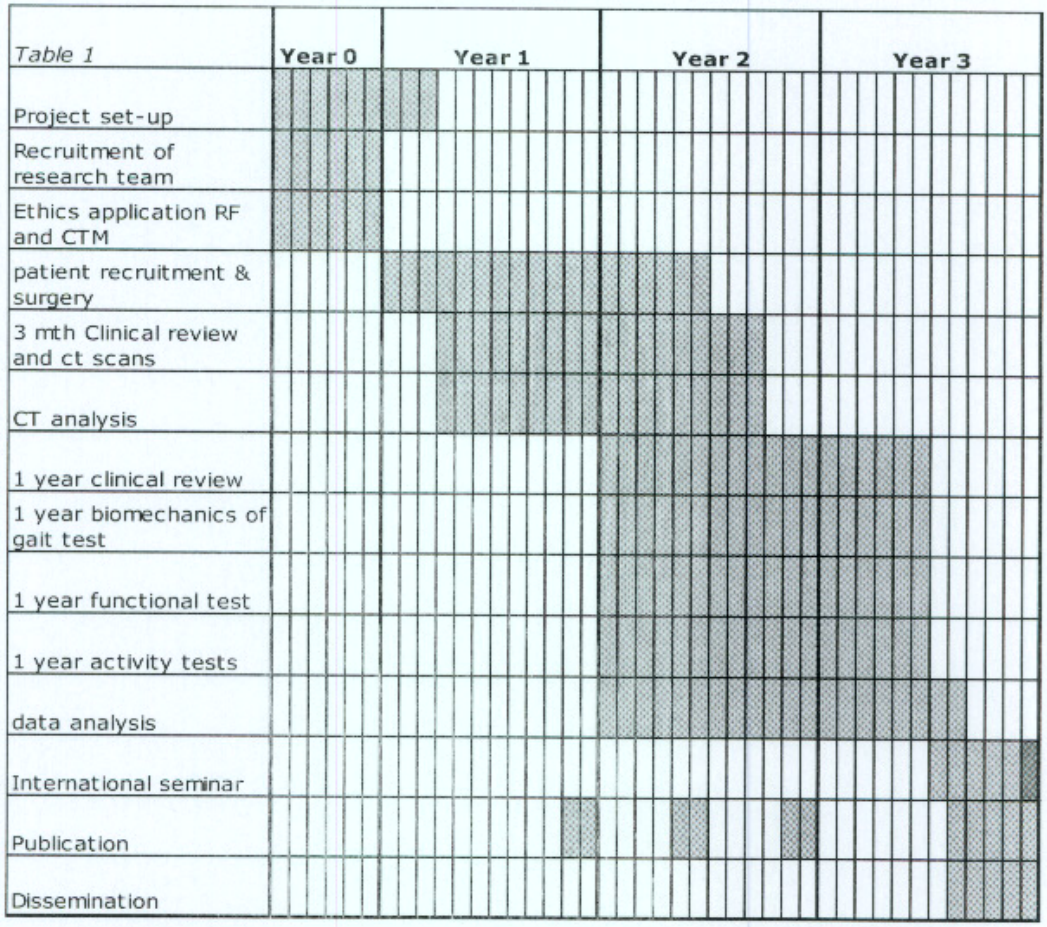
16.0 Timetable



Appendix A - Study Protocol

17.0 APPENDIX 1

Measurement protocol for the Biomechanics, Functional ability, activity level and quality of life assessments

This proposal aims to carry out a multi dimensional and full evaluation of the functional outcome of the unicondylar knee arthroplasty clients in the two study groups indicated above. In line with the recommendations of the WHO International Classification of Functioning, Disability and Health for the assessment of health technologies (WHO ICF 2001) our assessment will examine impairment, ability and participation as separate domains and then look at the associations between them.

17.1 Impairment

Passive and active flexion and passive and active extension of both knees will be measured with the subject lying in supine using a standard clinical manual protractor goniometer. For all manual goniometry measurements flexion will be recorded with a positive sign and extension with a negative sign. The active excursion available will be calculated by subtracting the extension value from the flexion value.

The patients will be asked to rate the pain they experience from the affected knee on a Visual Analogue Scale in the form of a 100 mm long horizontal line with the labels "no pain" (score of zero points) and "worst possible pain" (score of 100 points).

The patient will undertake a routine full biomechanical assessment of their gait using our 8 camera VICON system in the Bioengineering Unit, University of Strathclyde.

Additional data recorded will include clinical rating scores (Oxford score, American Knee Society Score), physical status (age, sex, height, weight, limb length, knee flexor and extensor strength) and clinical outcome measures (complication rate, radiological appearance etc).

17.2 Ability

17.2.1 Overview

In order to assess the patient's functional ability two sets of measures will be taken. The excursion of the knee will be measured during a range of functional activities including gait, stairs, ramp walking, rising to stand and sitting down, transfers into and out of a bath and squatting using flexible electrogoniometry. The activity of the subjects in their daily life will be recorded using a system of Activity monitors called Activpals which will record the time spent lying, sitting, standing and walking and the number and timing of transfers between these states. This functional evaluation using electrogoniometry to assess 13 functional activities and Activpals to record 5 days activity is the most in depth kinematic analysis of the functional outcome of TKR carried out by the scientific community to date and has been published by us in a series of journal articles in Orthopaedic, biomechanical and health science journals

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17.2.2 Functional ability assessment

Two flexible electrogoniometers (M180, Penny and Giles Ltd, Blackwood, Gwent, UK) will be used to measure the flexion - extension angle of the knees with respect to time. The electrogoniometer consists of a central strain gauged flexible shim that runs the length of the device with two end plates attached to the shim. The resulting transducer is flexible in both anterior - posterior and medio-lateral directions and so does not have a specific centre of rotation. This is a major advantage over conventional potentiometer type electrogoniometers that require complex mechanical attachments and linkages to enable polycentric joint movement to occur.

The electrogoniometers will be attached to flexible plastic strips which will be adjusted to the length of the patients' shank or thigh. These plastic strips will be attached to the skin over the lateral boarder of the subject's leg using double-sided tape. One strip will be attached to the shank and one to the thigh. The device will therefore straddle the knee in the sagittal plane with the output of the device giving the flexion - extension angle of the knee.

Small, lightweight, thin profile, footswitches will be attached to the heel and 1st metatarsal area of the soles of both feet. These heel and toe switches will be wired in parallel so that pressing either switch registered as contact between the foot and the floor. In this configuration they can be used to indicate stance or swing of the limb. Both the electrogoniometers and footswitches will be connected via thin flexible cables to a small, lightweight, battery driven, data logger which will power the instruments and record the 4 channels of data (left knee flexion - extension, left foot contact, right knee flexion – extension, right foot contact) at 50 Hertz. . The zero datum for joint measurement will be the knee joint alignment exhibited during standing upright with the knees straight.

The cables and attachments will be held in place using broad, lightweight straps around the shank and thigh. The datalogger will be placed into a pocket on to a bib worn by the subject. The bib will be of a similar design to those worn during athletic events. Data from the datalogger will be downloaded to a portable PC computer using an interface cable between the datalogger and computer.

The subjects will be asked to perform 13 functional activities. All tasks will be performed at the subject's selected speed (free speed). The 13 functions will be:

1. Level walking: level walking;
2. Ascend slope: ascent of a 5 degree slope;
3. Descend slope: descent of a 5 degree slope;
4. Ascend stairs: ascent of a 20 step flight of stairs (165mm riser, 280mm tread);
5. Descend stairs: descent of a 20 step flight of stairs (165mm riser, 280mm tread);
6. Sit down low chair: descent from standing into a low chair (380mm high);
7. Sit to stand low chair: ascent from a low chair to standing (380mm high);
8. Sit down standard chair: descent from standing into a standard chair (460mm high);
9. Sit to stand standard chair: ascent from a standard chair to standing (460mm high);
10. Into Bath : from standing alongside bath, step in and sit down (590mm high);
11. Out of bath: from sitting, stand up and step out to stand alongside bath (590mm high).
12. Getting down to a squatting position
13. Getting up from a squatting position

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The data will be down loaded from the datalogger at the end of the circuit using the Penny and Giles software. The data will then exported to Excel for Windows and Matlab where all further data processing and analysis will be carried out including interpolation using a specially written excel program.

For each of the 13 activities a single cycle of the left and right legs will be identified from the data using the footswitch and electrogoniometer information. Where a number of cycles are available such as during gait and stair negotiation a cycle will be randomly selected from the middle of the data stream in order to avoid cycles during initiation or termination of the activity. Each cycle will then be interpolated to give the joint angle at 100 percentage points throughout the cycle. These standardised cycles will then be amalgamated for the group to give the mean knee joint angle for the group throughout the gait cycle. The upper and lower 95% confidence limits for the group which indicate the band which contains 95% of the normal group data will also be calculated for each percentage point. These bands indicate the inter subject variability in the data and give a "normal" band against which patients can be compared.

For each subject performing each function using each knee, the minimum knee joint angle used during the cycle and the maximum knee joint angle used during the cycle will be recorded. These two values indicate the range of joint motion required to perform the functional activity. In addition the excursion of the joint during the function will be calculated by subtracting the minimum value from the maximum values. The excursion indicates the amount of free knee joint angulation required to perform the task. Tables of minimum joint angle, maximum joint angle and joint excursion will be prepared in excel showing the average value for the normal and patient groups, as will tables of the standard deviation for flexion in each group and the maximum and minimum group values. The knee excursion used by each group on the left knee, the right knee and the mean of both knees will be compared and the mean, standard deviation and 95% confidence limits will be calculated for each activity.

17.2.3 Activity level assessment

The activity level of the subjects will be monitored during 5 days of normal daily life using a system of activity monitoring called Activpal. This consists of a small lightweight box, about half the size of a match box which is attached to the thigh of the subject using sticky tape. This system records the activity of the subject as either lying, sitting, standing or walking continuously during up to 110 hours. The data can be down loaded to a computer at the end of the test session. The data can be used to indicate the total time spent in each activity, the number of transitions between different positions and the timing of the activities during the recording period. It therefore allows an in depth assessment of the subjects true levels of activity in life as indicated by their mobility.

17.3 Participation

Two measures of participation will be used, the Short Form-SF12 (SF-12) which reflects the patients health and well being and the Canadian Occupational Performance Measure (COPM) which is a patient generated outcome measure of the patients satisfaction with the functional outcome of the operation.

Appendix A - Study Protocol

Protocol update approval:

MARK BLYTH		
Principal Investigator (Print)	**Principal Investigator (Sign)**	**Date**
MAKO Representative (Print)	**MAKO Representative (Sign)**	**Date**

Appendix B - AKSS Questionnaire

Addendum

Knee Score (Insall Modification - 1993)

This scoring system is the version of the knee score as modified by Dr. John Insall in 1993. The scoring system combines a relatively objective **Knee Score** that is based on the clinical parameters and a **Functional Score** based on how the patient perceives that the knee functions with specific activities.

The maximum Knee Score is 100 points and the maximum Functional Score is 100 points.

To calculate the two scores the answers to the questions and the findings on the examination are given a value based on the results. To obtain the Knee Score and the Functional Score the result of each question is totaled. Notice that some results are negative to denote that they are deductions to the score.

Knee Findings

Pain **50 (Maximum)**

Walking ☐

(Insert the value associated with the results of question 1)

None	35	
Mild or occasional		30
Moderate	15	
Severe	0	

Stairs ☐
(Result of question 2)

None	15	
Mild or occasional		10

Appendix B - AKSS Questionnaire

Moderate	5
Severe	0

R.O.M. **25 (Maximum)**

(Result of question 9)

8º= 1 point ☐

Stability **25 (Maximum)**

Medial/Lateral ☐

(Result of question 12)

0-5 mm	15
5-10 mm	10
> 10 mm	5

Anterior/Posterior ☐

(Result of question 13)

0-5 mm	10
5-10 mm	8
> 10 mm	5

Deductions

Extension lag ☐

(Result of question 10) ☐

None	0
<4 degrees	-2
5-10 degrees	-5
>11 degrees	-10

Flexion Contracture ☐

Appendix B - AKSS Questionnaire

(Result of question 11)

< 5 degrees	0
6-10 degrees	-3
11-20 degrees	-5
> 20 degrees	-10

Malalignment ☐
(Result of question 14)

5-10 degrees	0
(5º = -2 points)	

Pain at rest ☐
(Result of question 3)

Mild	-5
Moderate	-10
Severe	-15
Symptomatic plus objective	0

(Now, simply total the scores of each of these questions to obtain the total Knee Score for the patient.)

Knee Score **100 (Maximum) =** ☐

Appendix C - Oxford Knee Score Questionnaire

PROBLEMS WITH YOUR KNEE

During the past 4 weeks..

✓tick one box for every question

1 ***During the past 4 weeks*****.....**

How would you describe the pain you usually have from your knee?

None	Very mild	Mild	Moderate	Severe
❑	❑	❑	❑	❑

2 ***During the past 4 weeks*****.....**

Have you had any trouble with washing and drying yourself (all over) because of your knee?

No trouble at all	Very little trouble	Moderate trouble	Extreme difficulty	Impossible to do
❑	❑	❑	❑	❑

3 ***During the past 4 weeks*****.....**

Have you had any trouble getting in and out of a car or using public transport because of your knee? (whichever you would tend to use)

No trouble at all	Very little trouble	Moderate trouble	Extreme difficulty	Impossible to do
❑	❑	❑	❑	❑

4 ***During the past 4 weeks*****.....**

For how long have you been able to walk before pain from your knee becomes **severe**? (*with or without a stick)*

No pain/ More than 30 minutes	16 to 30 minutes	5 to 15 minutes	Around the house only	Not at all - pain severe when walking
❑	❑	❑	❑	❑

5 ***During the past 4 weeks*****.....**

After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your knee?

Not at all painful	Slightly painful	Moderately painful	Very painful	Unbearable
❑	❑	❑	❑	❑

6 ***During the past 4 weeks*****.....**

Have you been limping when walking, because of your knee?

Rarely/ never	Sometimes, or just at first	Often, not just at first	Most of the time	All of the time
❑	❑	❑	❑	❑

Oxford Knee Score© Department of Public Health, University of Oxford, Old Road Campus, Oxford OX3 7LF, UK. **/P.T.O**

Appendix C - Oxford Knee Score Questionnaire

During the past 4 weeks...

✓tick one box for every question

7 ***During the past 4 weeks*****.....**

Could you kneel down and get up again afterwards?

Yes, Easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, Impossible
❑	❑	❑	❑	❑

8 ***During the past 4 weeks*****.....**

Have you been troubled by pain from your knee in bed at night?

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
❑	❑	❑	❑	❑

9 ***During the past 4 weeks*****.....**

How much has pain from your knee interfered with your usual work *(including housework)*?

Not at all	A little bit	Moderately	Greatly	Totally
❑	❑	❑	❑	❑

10 ***During the past 4 weeks*****.....**

Have you felt that your knee might suddenly 'give way' or let you down?

Rarely/ never	Sometimes, or just at first	Often, not just at first	Most of the time	All of the time
❑	❑	❑	❑	❑

11 ***During the past 4 weeks*****.....**

Could you do the household shopping on your own?

Yes, Easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, Impossible
❑	❑	❑	❑	❑

12 ***During the past 4 weeks*****.....**

Could you walk down one flight of stairs?

Yes, Easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, Impossible
❑	❑	❑	❑	❑

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