Validation of TKA Smart v1.0 software:

Are the clinical outcomes the same as the TKA 4.3 software?

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Declaration of authenticity and author's rights

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

Signed: Nadia C. Sciberras Date: 28/03/2013

I would like to dedicate this thesis to my husband, Christopher, who never stops supporting me in every project that I undertake and whose encouragement enabled me to undertake this degree.

Abstract

Osteoarthritis (OA) is a common chronic disorder with symptoms ranging from mild pain to complete loss of function thereby severely influencing the patient's quality of life. Although most patients initially benefit from conservative measures, a large number will eventually require surgical intervention, most commonly in the form of a total knee arthroplasty (TKA). Over 90,000 TKAs are performed annually in the United Kingdom.

TKA may be performed either using conventional instrumentation or with the aid of computers, also known as navigated TKA. One disadvantage of using navigation is the increase in total operation time associated with this system. BBraun Aesculap AG (Tuttlingen, Germany) who manufactures the OrthoPilot TKA navigation system has recently introduced a new software, TKA Smart v1.0, that has a simplified registration process and is intended to be more user-friendly when compared to the previous software versions such as TKA 4.3. This, in theory, should result in a shorter operation time.

A randomised controlled trial involving 220 patients is currently being conducted at the Golden Jubilee National Hospital to validate the TKA smart v1.0 software and to investigate the reduction in total operation and registration time. This thesis aims to report the preliminary analysis of the trial. The analysis involves 63 patients (34 females) with an average age of 69.2 years. 34 patients were randomised to TKA 4.3 software.

The preliminary results show that despite the reduction in the number of steps during the registration process, the clinical, functional and radiological outcomes for the TKA Smart v1.0 software are comparable to the older version TKA 4.3. Furthermore, no statistical or clinical significance was present in the total operation time between the two software despite a statistically (but not clinically) significant reduction in registration time between TKA Smart v1.0 software and TKA 4.3 software.

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Finally and above all, I am hugely indebted to my parents Valerie and Carmel and my family as well as my husband Christopher who continuously supported me and encouraged me during this project. They have lifted my moral at times of frustration and have always been there for me whenever I needed them.

Other Work Related To This Thesis

Abstract from this thesis

Sciberras NC, Deakin A, Riches P, Picard F. Validation of TKA Smart v1.0 software: are the clinical outcomes the same as the TKA 4.3 software? Proceedings from the Strathclyde University Research Presentation Day, 2012.

Presentation from this thesis

Oral Presentation: Sciberras NC. Validation of TKA Smart v1.0 software: are the clinical outcomes the same as TKA 4.3 software? Glasgow Orthopaedic Research Initiative (GLORI) meeting, Glasgow, UK, October 2012.

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Chapter 1 – Introduction

1.1 Background

Osteoarthritis (OA) is a common chronic disorder with symptoms ranging from mild pain to complete loss of function thereby severely influencing the patient's quality of life (Jones et al. 2000). The knee is the most commonly involved joint with OA, affecting about 10% of the population over the age of 55 years (Petersson, 1996). Generally, patients are initially treated using conservative measures such as analgesia, physiotherapy, weight loss and activity modification. Although most patients initially benefit from conservative measures, a large number will eventually require surgical intervention, most commonly in the form of a total knee arthroplasty (TKA). Over 90,000 TKAs are performed annually in the United Kingdom (National Joint Registry for England and Wales, 7th Annual Report 2010, Scottish Arthroplasty Project Annual Report 2010).

There are two main ways of performing a TKA, conventional or navigated. One of the main criticisms of navigated TKA is that navigation increases the total operation time (Cheung 2009, Kinzl 2004). Medical companies that own such software are therefore constantly trying to find ways to make the software more efficient with the aim of reducing the total operation time. One such company, BBraun Aesculap AG (Tuttlingen, Germany) who manufactures the OrthoPilot TKA navigation system has recently introduced a new software, TKA Smart v1.0, that has a simplified registration process and is intended to be more user-friendly when compared to the previous software versions such as TKA 4.3. This, in theory, should result in a shorter operation time.

1.2 Project Rationale

BBraun Aesculap AG approached the research department at the Golden Jubilee National Hospital (GJNH) to investigate the reduction in operation time when using the TKA Smart v1.0 software.

As this software has only recently been introduced into the market, it was decided to also validate the software by comparing it to a previous version. This is to ensure that the new software performed as well as, if not better, than the older software despite a potential shorter operation time. For this reason it was decided that the study would be a randomised controlled trial with a computerised tomography (CT) scan done at the six weeks post-operative review. This would enable a detailed and accurate analysis of the knee in addition to eliminating the problem of rotated x-rays.

1.3 Aim of study

1.3.1 Primary and Secondary Outcomes

The aim of this study was to validate the new Smart software to ensure that it is at least as good as the current version, TKA 4.3. Thus the study objectives were to:

1. Determine if the clinical, functional and radiological outcomes following implantation of a knee using the Orthopilot TKA Smart v1.0 software were the same as those following implantation of a knee using the Orthopilot TKA 4.3 software.

2. Determine whether there was a decrease in the registration time and whether any reduction in registration time resulted in a reduction of the operative time when using OrthoPilot TKA Smart v1.0 application when compared to a former version of navigation software (TKA 4.3).

1.3.2 Clinical Benefits

The clinical benefits of such objectives were perceived as being as follows:

1. Ensuring that the clinical outcomes are satisfactory despite the shortened registration process when using OrthoPilot TKA smart v1.0 application.

2. A shorter operative time has a number of benefits for both patient and hospital. If a shorter registration and operative time was demonstrated using the OrthoPilot TKA Smart v1.0 application this would indicate using it instead of the older software.

Chapter 2 – Literature Review

2.1 The Knee Joint

2.1.1 Knee Anatomy

The knee joint is the largest joint in the body. It a synovial joint of the modified hinge type and has three components: the patellofemoral saddle joint between the patella and the patellar groove on the front of the femur and the medial and lateral femorotibial condylar joints between the femur and the tibia. The latter articulations are partly divided by the menisci.

The femur converges towards the knee to meet the nearly vertical tibia at an angle of between 5 to 12 degrees. If this angle is increased, a valgus knee results, conversely a smaller angle leads to a varus knee. The lower end of the femur bears two rounded prominences, the medial and lateral condyles, which are separated posteriorly by an intercondylar fossa but joined anteriorly by a trochlear surface that articulates with the patella. The two condyles are asymmetric resulting in two asymmetric femorotibial articulations. The medial femoral condyle is larger and more curved than the lateral condyle. Furthermore, the medial condyle projects further distally than the lateral condyle. This accounts for the valgus angle between the femur and tibia. Anteriorly the condyles are almost in line with the anterior aspect of the shaft. However both condyles boldly curve posteriorly and project well beyond the femoral shaft in a manner anlagous to the letter J. This has significance during joint movement (Wheeless 2012). The surfaces of both condyles are covered by articular cartilage which is 2 to 4 mm thick. This helps distribute the joint reactive load over a wide area.

The superior articular surface of the tibia (tibial plateau) slopes posteriorly at an angle of between 5 and 8 degrees. It has two slightly concave medial and lateral condyles that are separated by an intercondylar eminence. These articulate with the femoral condyles. The lateral tibial articular surface is almost circular whilst the medial articular surface is oval

with a longer anteroposterior axis. These differences are reflected in the shape of the menisci. The menisci consist of crescentic laminae of fibrocartilaginous tissue and are attached to the tibial plateau. These menisci act to disperse the weight of the body and reduce friction during movement.

The patella is a sesamoid bone within the quadriceps tendon. It has a cartilaginous posterior surface which articulates with the femur. This articular surface is divided by a vertical ridge into a large lateral surface that articulates with the lateral condyle of the femur and a smaller medial surface that articulates with the medial condyle of the femur during extension and flexion of the knee. The patella serves as a fulcrum for the quadriceps muscle. It also protects the knee joint and enhances the lubrication and nutrition of the knee.

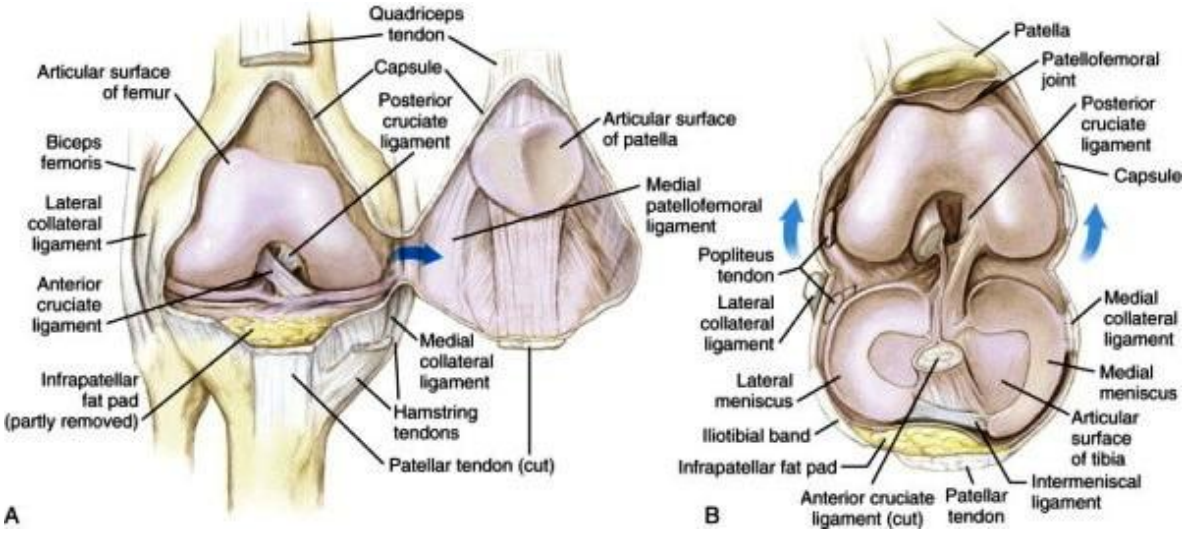


Figure 2.1 Knee Anatomy. (a) Anterior view. (b) Superior view. (From Miller MD, et al. Orthopaedic surgical approaches, Philadelphia, 2008, Saunders.)

2.1.2 Knee Biomechanics

The knee joint is one of the most important joints in the human body. Its roles are to (1) to allow locomotion in horizontal (walking and running) and vertical (bending and

jumping) directions, (2) to offer stability, accommodating for different terrains, and (3) to transmit, absorb and redistribute forces caused during the activities of daily life. This makes the knee joint a joint that is at high risk of injury and degenerative joint disease.

2.1.2.1 Kinematics

Despite being a hinge joint, the knee is a complex joint and unlike other hinge joints (such as the elbow joint), its movements go beyond the flexion-extension movement that is typical of a hinge joint. Extension is the result of quadriceps muscle contraction. Full extension (that is, 0 degrees flexion) is defined when the long axes of the tibia and femur are aligned in the sagittal plane. Some individuals are able to hyperextend (negative flexion) the knee joint to up to -5 degrees. Active knee flexion is due to the action of the hamstring muscles and usually reaches 130 degrees. However passive flexion can reach 160 degrees (Masouros et al. 2010). Kettlekamp (1976) performed kinematic studies of the knee during activities of daily living and concluded that normal gait required 67° of flexion during the swing phase, 83° for stair climbing, 90° for descending stairs and 93° to rise from a chair. Flexion-extension occurs along the sagittal plane. Dennis et al. (1996) observed normal knees using dynamic fluoroscopy coupled with three-dimensional CT scans. They described the flexion axis as varying in a helical fashion, with an average of 2mm of posterior translation of the medial femoral condyle on the tibia during flexion compared with 21mm of translation of the lateral femoral condyle. This pattern of medially based pivoting of the knee explains the observed external rotation of the tibia on the femur during extension, known as the “screw-home mechanism,” and internal rotation of the tibia during knee flexion. This mechanism tightens the soft tissue structures and locks the knee geometry (Masouros et al. 2010). Due to the femoral and tibial condyles, flexion and extension of the knee are not simple hinge movements. These movements involve both rolling and sliding. This results due to the fact that flexion and extension occur about a constantly changing centre of rotation known as polycentric rotation. When plotted this changing centre of rotation describes a J shaped curve about the femoral condyles. Furthermore, during knee flexion, the

femoral condyles translate backwards. This mechanism is known as “roll back” (Figure 2.2). Despite such theories, the roll back mechanism is still a matter of controversy. Indeed in 2004, Pinkserova et al studied knee MRIs with the knee at intervals between full extension and 120° of flexion in both cadavers and volunteers. They concluded that femoral roll back only occurs at the lateral femoral condyle.

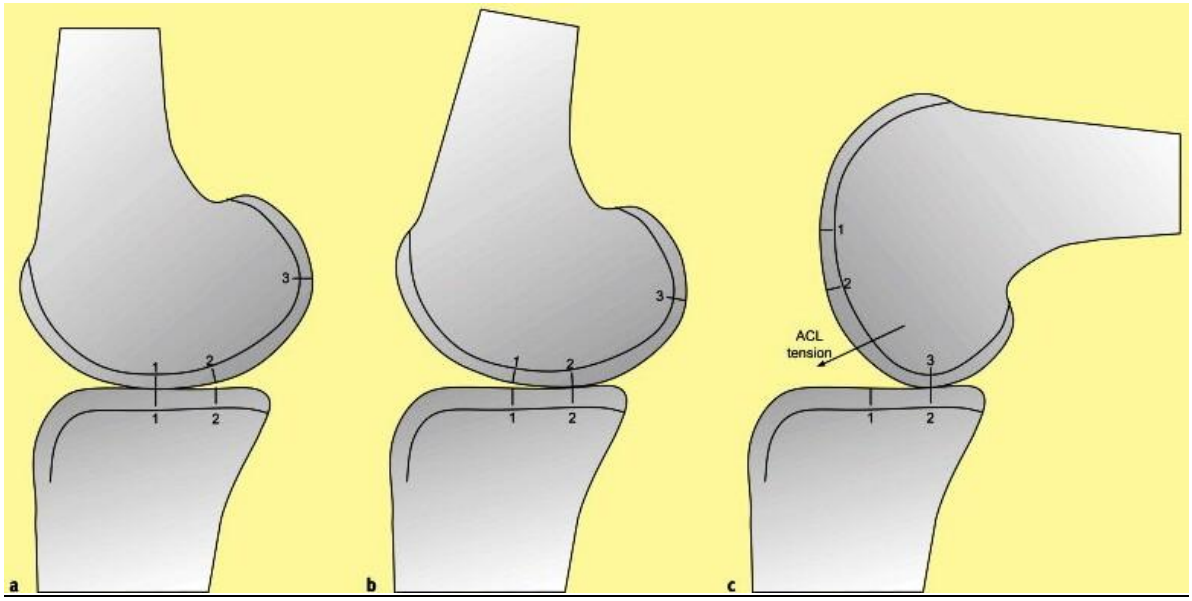


Figure 2.2 Roll back mechanism. (a) Extension - contact located centrally. (b) Early flexion - posterior rolling. (c) Deep flexion - femoral sliding, contact is located posteriorly. (From Masouros SD et al. Biomechanics of the knee joint. Orthopaedics and Trauma. 2010; 24(2):84-91.)

2.1.2.2 Kinetics

The knee lies between the two longest lever arms in the body and is surrounded by powerful muscles. This subjects the knee joints to extreme high forces and moments. Dynamic knee stability is defined as the ability of the knee joint to remain stable when subjected to the rapidly changing loads during activity and is the result of the integration of the articular geometry and soft tissue restraints (passive stability) as well as the activity of the surrounding muscle, known as active stability (Williams et al. 2001).

Due to the incongruity of the tibial and femoral condyles, the bony architecture contributes little to the passive stability of the knee joint. Conversely, the orientation and material properties of the ligaments, capsule and musculotendinous soft tissues of the knee contribute significantly to its stability (Butler 1980, Hsieh 1976). The knee ligaments control the path of joint motion and are the primary restraints to excessive displacement between the bony segments (Woo et al. 1999). The four primary ligamentous contributors to knee stability are the anterior cruciate ligament (ACL), the posterior cruciate ligament (PCL), the medial collateral ligament (MCL) and lateral collateral ligament (LCL). The fibre recruitment of each of these ligaments varies depending on joint angle and the plane in which the knee is loaded (Trent 1976, Hollis 1991). Consequently, in most instances there are several ligaments synergistically contributing to knee stability with one ligament acting as the primary restraint as shown in Table 2.1. Moreover, the knee joint is more stable when loaded under compression, such that the articular surfaces are pushing against each other. This allows direct transmission of the load from one bony segment to the other rather than transmission via insertions of passive stabilisers (Masouros et al. 2010).

The loads that act across the knee joint surface are a result of external forces (an example being the ground reaction force) and the muscle forces required to maintain posture and facilitate body movement. Ligament forces are passive internal forces that are developed in response to joint motion or external loading. Tibiofemoral joint forces of 3.4 times bodyweight occur on walking. These increase to 4.3 times bodyweight on going up stairs and up to 8.5 times body weight on walking downhill (Morrison 1968, Kuster et al. 1994).

The patellofemoral articulation improves the mechanical advantage of the quadriceps mechanism during flexion of the knee. This is because the internal rotation of the tibia that occurs at the start of knee flexion (between 0 to 20 degrees) decreases the Q angle (the angle between the line of action of the patellar tendon and the resultant line of action of the quadriceps muscles) and the lateral directed quadriceps muscle vector. The

movement of the patella anterior relative to the centre of rotation of the knee with further flexion improves the mechanical advantage of the quadriceps muscle.

2.2 Alignment of the Lower Limb

Lower limb alignment plays an important role in the musculoskeletal loading conditions at the knee. Skeletal malalignment of the mechanical axis of the lower limb increases the loading on the knee joint, thereby contributing to the development of osteoarthritis. Lower limb alignment can be described in both the coronal plane (that is, a vertical plane that divides the body into ventral and dorsal sections) and the sagittal plane (a vertical plane that divides the body into right and left halves). As discussed below, the alignment of the lower limb is dependent on both the femoral and tibial axis as well as the angle at which these two bones meet at the knee joint.

The femur and tibia can be described in terms of a mechanical and an anatomical axis in both the coronal and sagittal planes. The mechanical axis of the femur (MAF) is defined as a vertical line joining the centre of the femoral head to the centre of the knee whereas the anatomical axis of the femur (AAF) or the tibia (AAT) is a line drawn along the midpoint of the intramedullary canal of the respective bone. The mechanical axis of the tibia (MAT) is defined as a line joining the tibial knee centre and the centre of the ankle. A line drawn from the centre of the femoral head to the centre of the knee and from the knee centre to the centre of the ankle joint represents the mechanical axis (MA) of the lower limb and is measured by the mechanical femorotibial angle (MFT), commonly known as the hip-knee-ankle (HKA) angle. This is different from the load axis (LA) which is equivalent to a line drawn from the femoral head centre to the centre of the ankle. When the lower limb is in normal alignment (HKA = 0°), the knee centre falls on the load axis. The HKA is expressed as degrees deviation from 180°. In the coronal plane, a negative sign implies a varus alignment (bow-legged) and a positive sign implies a valgus alignment (knock-kneed) (Figure 2.3). Malalignment in the sagittal plane results in either a fixed flexion (positive angle) or a hyper-extension deformity (negative angle).

When analysing hip-knee-ankle x-rays, the following angles are calculated (Figure 2.4). The angle between the anatomical and mechanical axes of the femur is known as the femoral mechanical-anatomical angle (FMA). For a western population of normal healthy adults the mean FMA angle has been measured as 5.8°, SD ±1.9° (Hsu et al. 1990). The femoral mechanical angle (FMA) is the angle formed by the intersection of the MAF and a line tangent to the distal femoral condyles. This line defines the orientation of the femoral articular surface and is normally in slight valgus. More commonly the lateral angle is measured, the lateral distal-femoral angle (LDFA) and its value is of 87°. Similarly, the tibial mechanical (TM) angle is the angle formed by the intersection of the MAT and a line tangent to the joint surface of the tibial plateau. The medial angle is commonly measured in this case and is known as the medial proximal tibial angle (MPTA). This also has a normal value of 87°. The lateral distal tibial angle (LDTA) is the angle between the tibial mechanical axis and the distal tibial articular surface. This normally measures at 90°.

Applied Displacement	Flexion angles (°)	Primary Restraint	Secondary Restraints
Anterior drawer	0	ACL	ITB, MCL, LCL, menisci
	30	ACL	Menisci, MCL
	60 - 120	ACL	
Posterior drawer	0 - 30	PLC, PMC	PCL, LCL, MFLs
	40 - 120	PCL	MFLs
	120 - 140	PCL	
Varus rotation	0 - 60	LCL	ITB, PCL
Valgus rotation	0	MCL, PMC	ACL
	30	MCL	ACL
	60	MCL	
External tibial rotation	0	LCL, PLC	Menisci, MCL
	30 - 90	LCL, PLC	PCL, menisci
Internal tibial rotation	0 - 30	PMC	ACL, MCL, menisci
	60	MCL	ACL, Menisci
Hyperextension			ACL, PMC, PCL, PLC

ITB = Iliotibial band, PLC = Posterolateral corner structures, PMC = Posteromedial corner structures.

Table 2.1 Restraining function of the main knee joint soft tissues. (Modified from Masouros SD et al. Biomechanics of the knee joint. Orthopaedics and Trauma. 2010; 24(2):84-91.)

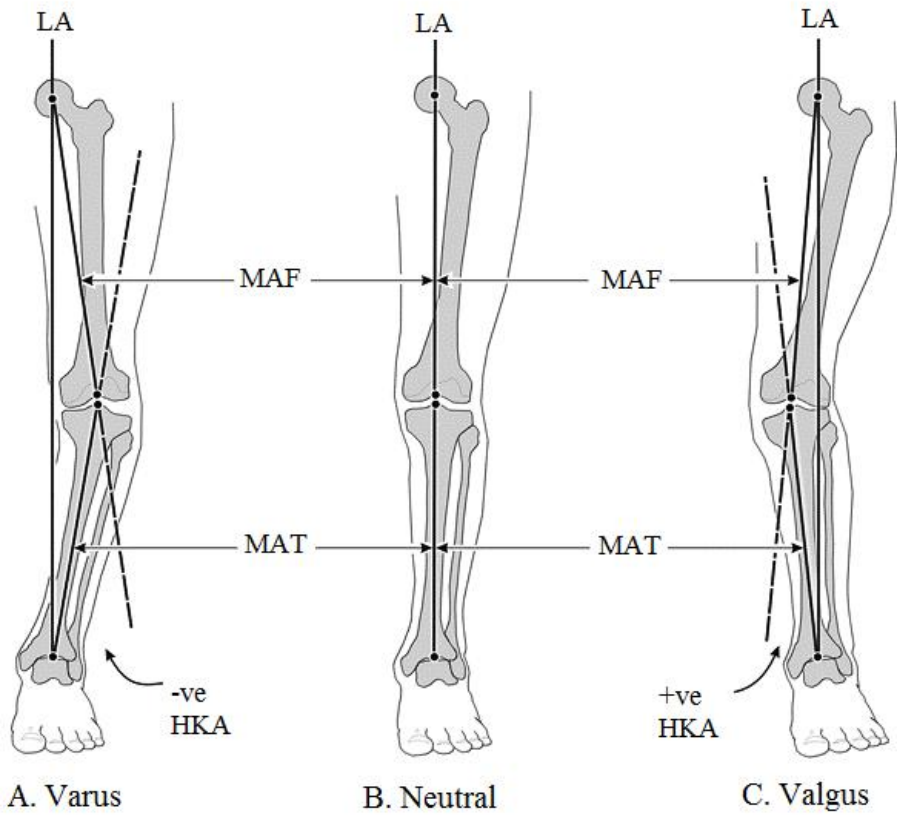


Figure 2.3 Patterns of lower limb alignment in the coronal plane. A. Varus alignment: knee centre is lateral to the load axis (LA). HKA is negative. B. Neutral alignment: knee centre is located on the LA. The femoral (MAF) and tibial (MAT) mechanical axes are collinear. HKA is 0°. C. Valgus alignment: knee centre is medial to the LA. HKA is positive. (Modified from http://www.dynamicchiropractic.com/mpacms/dc/article.php?id=55312 20.01.13.)

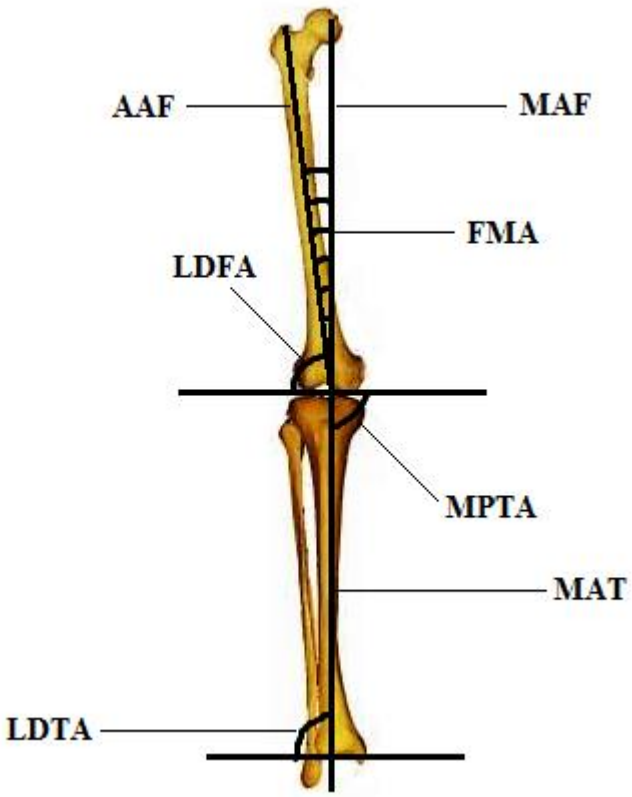


Figure 2.4 Commonly used angles and axes when describing the lower limb alignment. (Modified from http://eorif.com/lower-extremity-alignment 27.01.13.)

2.3 Osteoarthritis

Osteoarthritis (also known as degenerative joint disease) is a chronic irreversible disorder that causes destruction of the articular hyaline cartilage and subchondral bone. The knee is the most commonly involved joint, with knee OA affecting about 10% of the population over the age of 55 years (Petersson, 1996).

Despite its frequency, the aetiology of OA is not fully understood. Most patients suffer from primary (idiopathic) OA, that is, no predisposing cause is known. However, OA may also be secondary in nature when a predisposing cause is present. Such predisposing causes include trauma, meniscal injuries and meniscectomies, deformities

of the joint, inflammatory and infectious arthritis, ligamentous instability of the knee as well as abnormal joint forces resulting from obesity.

OA represents a gradual process of destruction and regeneration (Figure 2.5). During the early stages of the disease, the articular cartilage is glistening in appearance. As the disease progresses, the surface layers of the cartilage flake off while the deeper layers develop longitudinal fissures, a process termed fibrillation. Consequently, the cartilage becomes thin and sometimes denuded. Subsequently, the subchondral bone becomes thickened and sclerotic and cysts develop within it. At the margins of the joint surface, spurlike bony outgrowths known as osteophytes develop. This causes the capsule to stretch. Small parts of these osteophytes may break off and form loose bodies within the joint. Furthermore, the synovium proliferates and may become inflamed (synovitis).

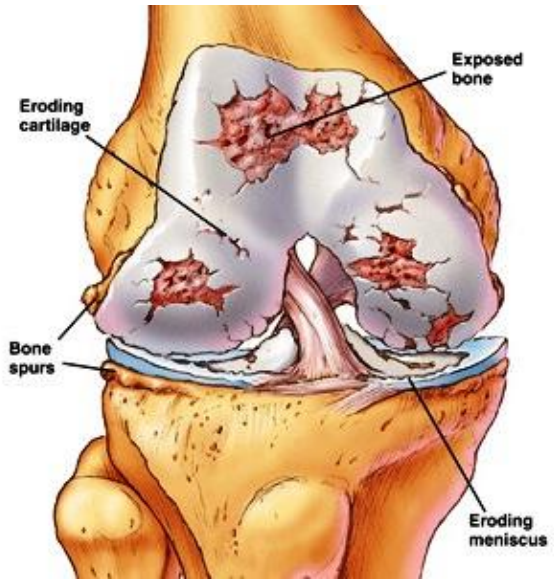


Figure 2.5 Knee Osteoarthritis. Typical changes that occur in an osteoarthritic joint. (From http://www.osteoarthritisblog.com/category/about-knee-osteoarthritis 17.01.13.)

The diagnosis of OA depends on the patient's symptoms and physical examination together with radiological findings. OA may affect one or more compartments of the knee joint. The patient's symptoms may therefore vary accordingly.

The first symptom patients complain of is pain that is worsened with physical activity and weight bearing. Pain is aggravated by stairs, hills and sit to stand manoeuvres. Patients may also complain of early morning stiffness that improves with physical activity. As the disease progresses, the range of motion at the joint decreases and the flexion contractures may develop. At this stage, patients may also complain of a grating sensation in the knee. The surrounding ligaments may also become lax and this leads to joint instability which worsens the pain. As a result of the associated capsular swelling and synovial proliferation, the knee may also swell up. Due to a combination of the above symptoms, the patient may also complain of limping and a reduction in his/her usual activities.

Physical examination of a patient with knee OA may show various signs depending on the patient's symptoms. On inspection of the joint, the knee joint may appear swollen. Furthermore, malalignment (commonly varus) may be evident. The patient may also be walking with a limp. Both active and passive movements of the joint may be restricted. Indeed the patient may suffer from a fixed flexion deformity. On palpation of the joint, crepitus may be very marked. Furthermore, joint line tenderness and joint instability may also be present. Clinical scores are available that aim to objectively determine the clinical severity and the impact that the OA has on the patient's daily life. There are several clinical scores. However none of these scores has been universally accepted, mainly due to the fact that no one score has been able to identify the sole impact that knee OA has on a patient's life. This is because scores do not take into account the fact that patients may have multiple joints involved with OA. Two commonly used scores are the American Knee Society Score (KSS) (Insall et al. 1989) and the Oxford Knee Score (OKS) (Dawson et al. 1998).

The KSS (Appendix 6) consists of two components, the knee score and the functional score. The knee score is completed by the clinician and relies on the knee examination. The functional score assesses the ability of the patient to walk distances, climb stairs and whether the patient needs any walking aids. The OKS (Appendix 7) is a patient reported outcome questionnaire that was developed to specifically assess the patient's perspective of outcome following a TKA. However the OKS has subsequently been validated for use in assessing other non-surgical therapies in knee OA (Xie et al. 2010). Indeed it is routinely used pre-operatively as well as at each post-operative follow-up appointment to assess the outcome of TKA. The OKS consists of twelve questions, five of which relate to pain and seven to function. In the original system, each question was scored 1 to 5, with 1 representing the best outcome. The scores from each question were then added to give a score between 12 and 60 with 12 being the best outcome. However, since then many surgeons have found this scale to be unintuitive which has led to a change in the numerical score assigned to each question (Murray et al. 2007). The newer recommended system scores each question from 0 to 4, with 4 being the best outcome. Thus when summed, an overall score between 0 and 48 is obtained, with 48 being the best outcome. Conversion from the 60 – 12 system to the newer 0 – 48 system and vice versa requires subtraction of the score from 60. To avoid confusion when reporting TKA outcomes, it is recommended that the method of scoring is always stated. The benefit of the OKS score is that it is short, practical, reliable, valid and sensitive to clinically important changes over time (Dawson et al. 1998).

Radiology forms an important tool in the diagnosis of OA as well as when planning a TKA. X-rays should be taken when the patient is weight-bearing. Furthermore, hip-knee-ankle (long-length) x-rays should also be obtained to help establish the alignment of the lower limb. The radiological features of OA include (1) asymmetric narrowing of the joint space, (2) formation of osteophytes at the periphery of the articular surface, (3) increased radiological density of the subchondral bone and (4) the presence of cysts within the subchondral bone (Figure 2.6). Despite these established radiological features, it is important to note that clinical correlation is important as some patients with

symptoms of severe OA may have few radiological signs. Conversely, some patients with severe OA radiologically may have milder OA symptoms than would be expected from radiological analysis. Several scores are available that attempt to grade the degree of OA. The commonest classification system used is the Kellgren and Lawrence grading system (1957) shown in Table 2.2. This system focuses on the presence of osteophytes or joint space narrowing or both. Another classification used is the Alhback staging classification (1968) which primarily focuses on the reduction of joint space as an indirect sign of cartilage loss (Table 2.3).

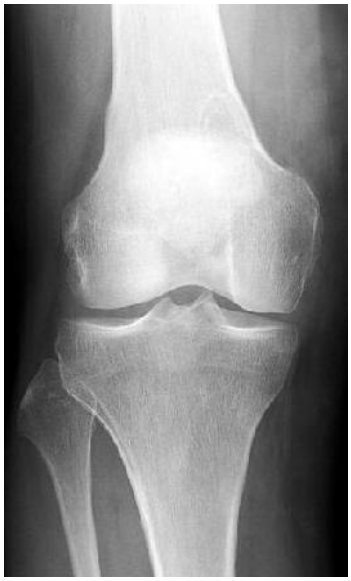
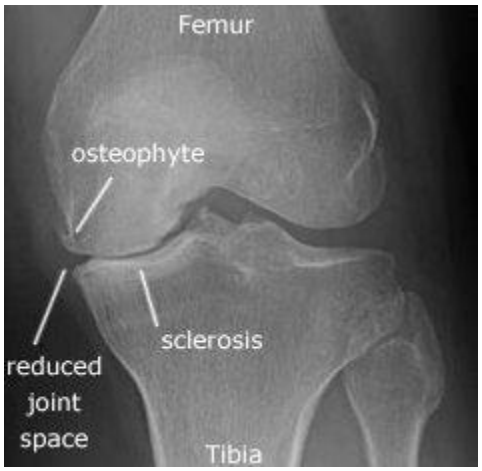
(a)  (b) 

Figure 2.6 Radiological features of knee osteoarthritis. (a) Normal knee x-ray. (b) X-ray showing the four typical radiological features of OA. (a. From www.pogoe.org 24.03.2013, b. From www.orthoanswer.org 24.03.2013.)

The goals of OA treatment are to relieve pain, improve function and prevent disability. The initial treatment of OA is non-operative. This involves the use of non-steroidal anti-inflammatories (NSAIDs), pain relief and methods to reduce the load forces at the joint surface. The latter is achieved by weight loss (if appropriate), alteration in daily

activities to reduce impact-loading exercises, use of a walking stick, use of a valgus unloading knee brace and rubber heel wedges (van Raaij et al. 2010).

The ultimate treatment for OA is surgery. This is indicated when conservative measures fail to provide pain relief and to allow adequate function. Various surgical options are available depending on the age of the patient, the degree of OA and the alignment of the lower limb. For patients over the age of 50 years with OA affecting more than one compartment, a TKA is commonly performed (Section 2.4).

This is done using either conventional instruments or with the help of navigation. Patients in whom the OA predominantly affects one compartment may benefit from a unicompartmental knee arthroplasty (UKA) (Figure 2.7). This is more commonly performed on the medial side. Patients undergoing UKA must be carefully selected. The advantages of this procedure include a faster and better functional recovery when compared to TKA with less morbidity due to minimal postoperative blood loss, smaller incision and less soft tissue damage (Rougraff 1991). UKA is contraindicated in the following circumstances: (1) if ACL is deficient, (2) inflammatory arthritis is present, (3) patient has a fixed varus or valgus deformity, (4) a flexion contracture greater than 10 degrees is present, (5) patient has a flexion of less than 90 degrees, (6) significant OA is present in more than one compartment and (7) if patient had a previous meniscectomy in the opposite compartment.

Young active patients under the age of 50 years who have symptoms of OA related to only one knee compartment, may benefit from a re-alignment procedure in the first instance rather than a replacement procedure. Such procedures, known as osteotomies, can be performed on either the tibia or the femur and are be utilised for both a varus or a valgus malaligned knee. For example, a high tibial osteotomy (HTO) can be performed in a knee with a varus malalignment. This partially shifts the weight bearing stresses from the affected medial compartment to the lateral comparatment thereby allowing the medial cartilaginous space to regenerate.

Grade	Criteria
0	Normal
I	Doubtful narrowing of joint space, possible osteophyte development
II	Definite osteophytes, absent or questionable narrowing of joint space
III	Moderate osteophytes, definite narrowing, some sclerosis, possible joint deformity
IV	Large osteophytes, marked narrowing, severe sclerosis, definite joint deformity

Table 2.2 Kellgren and Lawrence radiological grading of the severity of knee osteoarthritis.

Stage	Criteria
0	No radiographic sign of arthritis
I	Narrowing of the joint space (JSN) (with or without subchondral sclerosis. JSN is defined by a space inferior to 3mm, or inferior to half of the space in the other compartment (or in the homologous compartment of the other knee)
II	Obliteration of the joint space
III	Bone defect / loss <5mm
IV	Bone defect / loss between 5 and 10mm
V	Bone defect / loss >10mm, often with subluxation and arthritis of the other compartment

Table 2.3 Ahlback staging of radiological knee osteoarthritis.

Other surgical procedures that have been described for OA include arthroscopy and fusion. Knee arthroscopy with debridement and washout is a palliative procedure that is occasionally performed. It offers only short term relief and is more beneficial in patients with mechanical symptoms such as meniscal tears that are causing locking of the knee. Indeed Laupattarakasem et al. (2008) conducted a systematic review and concluded that arthroscopy and washout has no role in the treatment of symptomatic knee OA. Arthrodesis (joint fusion) of the knee joint can lead to a painless, stable knee joint. However this is at the expense of range of movement. Consequently, it is rarely performed. Knee arthrodesis is usually reserved for failed revisions TKA.

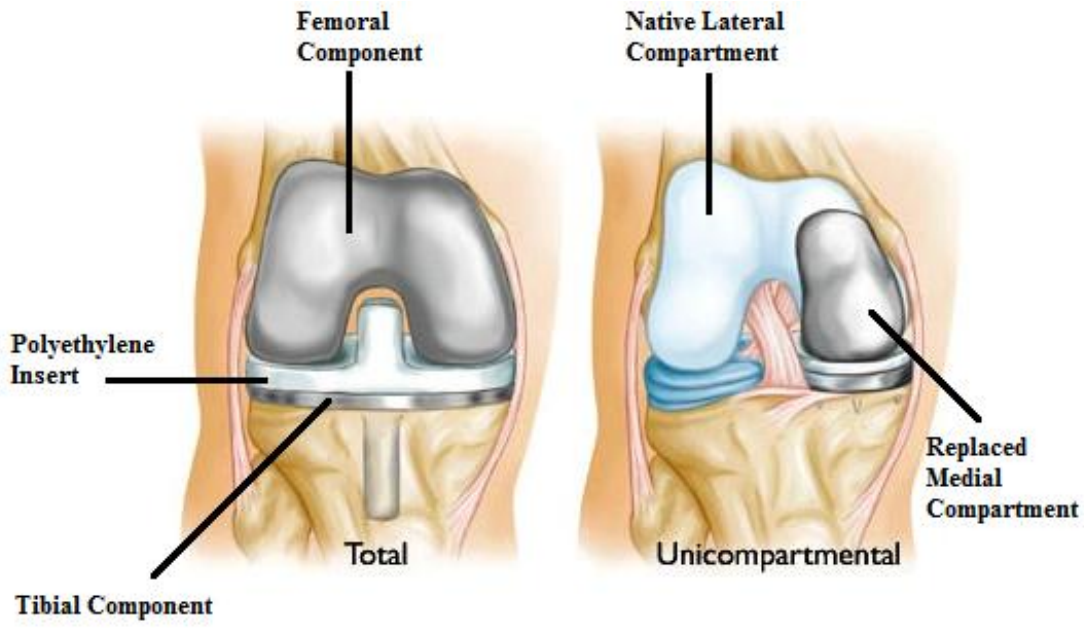


Figure 2.7 Difference between a Total and a Unicompartmental Knee Arthroplasty. (From http://orthoinfo.aaos.org/topic.cfm?topic=A00585 21.01.13)

2.4 Total Knee Arthroplasty

2.4.1 History of Total Knee Arthroplasty

Although resection arthroplasty of the knee was first performed in the 1860s, the first combined femoral and tibial articular surface replacement was only implanted in the 1950s (Shiers 1954). However these implants failed as they were designed on the assumption that the knee acts as a simple hinge joint. Gunston's (1971) recognition of the femoral rollback that occurs during knee flexion was an important landmark in the development of modern TKA implants. The total condylar prosthesis which forms the basis of the current prosthesis used in TKA was designed by Insall at the Hospital for Special Surgery in 1973. Since then several implants have been designed with the quest of achieving the ideal total knee replacement implant.

Throughout the years, patients' expectations following a joint replacement have increased. Patients now expect more of their knee replacement. In addition to improving the implant design, improvements in the surgical technique were required to meet the patients' higher demands. Computer Assisted Surgery (CAS) in total knee arthroplasty has allowed surgeons to improve their surgical technique. By enabling surgeons to have real-time feedback of their actions during surgery, CAS has allowed surgeons to improve the final alignment of the knee following a TKA. Accurate alignment of knee implants is essential for the success of a TKA. It is therefore hoped that such an improvement in alignment will not only result in an improvement in function but also in an increased longevity of the implants. However this is debatable. Recent mid-term studies have shown that the improved alignment obtained with navigated TKA does not necessarily correlate with an improvement in function. In 2007 Ensini et al. showed that at short-term follow-up (28 months) the radiographic improvement did not result in improved clinical scores. Harvie et al. (2012) showed similar results at five-year follow-up. However this study had a small number of patients and a follow-up rate of only 64.8%. Consequently, studies with a large number of patients at long-term follow-up are still awaited on whether the improved alignment with navigation results in better

functional scores and/or better implant survival. The first navigated TKA was implanted by Frederic Picard and his team in 1997 (Delp et al. 1998).

2.4.2 Principles of Total Knee Arthroplasty

The technical goals of knee replacement surgery are (Miller 2004):

1. Restoration of the mechanical alignment
2. Preservation or restoration of the joint line
3. Balanced ligaments
4. Maintaining or restoring a normal Q angle.

2.4.2.1 Restoration of the Mechanical Alignment

When a neutral mechanical alignment is restored, the forces through the leg pass through the centre of the hip, knee and ankle. This allows optimum load share through the medial and lateral sides of the prosthetic implants thereby reducing the potential for aseptic loosening.

Vince et al. (1989) have showed that the majority of prosthetic loosening occurs in knees that were implanted in varus. Similarly, Bargren et al. (1983) observed a failure rate of 67% for knees implanted in varus compared to 29% for those implanted in a neutral position.

2.4.2.2 Preservation or Restoration of the Joint Line

During knee replacement surgery, it is important to recreate the joint line, as this will allow optimal function of the knee ligaments and soft tissue that play an important role

in knee kinematics. Consequently it is of utmost importance that bone cuts are performed accurately as this will enable the prosthesis to recreate the original thickness of cartilage and bone once implanted.

2.4.2.3 Balanced Ligaments

During the degenerative process, ligaments may become scarred or contracted, or in case of excessive deformities, they may become stretched. Thus it is imperative that a well balanced knee in both the coronal and sagittal plane is created during knee reconstruction. This ensures optimum function and wear for the prosthesis. In fact, Ritter et al. (1994) have shown that knee prostheses that are not well oriented or well balanced have a shorter survival time when compared to well aligned and well balanced knees.

2.4.2.4 Maintaining or Restoring a Normal Q Angle

The Q angle describes the extent of coronal angulation of the extensor mechanism at the knee. During knee reconstruction surgery, changes in the femoral, tibial and patellar component positioning can affect the value of the Q angle without any changes in the mechanical alignment. An increased Q angle poses an increased risk of patellar subluxation. This leads to patellar maltracking and can cause chronic anterior knee pain.

2.4.3 Measuring the Outcomes of TKA

The main aim when treating a patient with knee OA is to alleviate the patient's symptoms of pain and decrease in function. As previously discussed (Section 2.3) several scores are available to document the severity of OA. These same scores (eg OKS, KSS) are used post-operatively at every review to enquire whether an improvement has been achieved following a TKA. These scores normally assess the

clinical and functional outcomes. A hip-knee-ankle x-ray at the six week review assesses the radiological outcomes, namely the alignment of the lower limb and the component position. In most centres, short leg films are then taken at subsequent appointments, namely to ensure that any osteolysis that occurs is diagnosed early.

Furthermore, patient satisfaction is also normally assessed at every visit. The patient answers the satisfaction question using one of four possible answers – (1) very satisfied, (2) satisfied, (3) unsure, (4) dissatisfied. Different studies have shown that as many as 19% of the patients undergoing a TKA are either uncertain or dissatisfied with their operation. This rate seems to remain stable despite substantial advances in primary TKA. Indeed, Robertsson et al. (2000) analysed the Swedish registry for TKA operations performed between 1981 and 1995 and found that the percentage of dissatisfied patients remained steady over the years. Moreover there was no difference in the satisfaction rate between patients having a UKA or a TKA. Furthermore, the satisfaction rate did not alter with implantation of the newer TKA implants (Bourne et al. 2010). This suggests that TKA is not achieving its goal of relieving pain and restoring function in a substantial proportion of patients. Consequently, better patient selection is essential. However in a recent review on the five year outcomes of the navigated Columbus TKA, 96% of those attending the five year follow-up review were either satisfied or very satisfied with their knee replacement (Sciberras et al. in press).

2.4.4 Computer Assisted Surgery in TKA

Computer assisted orthopaedic surgery (CAOS) refers to the discipline in which computer technology is used to improve the outcome of orthopaedic surgical procedures. CAOS tools range from an active robotic system capable of performing surgery autonomously to passive or navigation systems that provide additional information during a procedure but do not perform the surgical action. The surgeon controls the intervention but acts on information (DiGioia 2006).

Navigation systems can be classified into three main types: (1) systems that use pre-operative imaging such as CT scans, (2) systems that use intra-operative imaging with fluoroscopy and (3) “image-free” navigation systems, that is, systems that do not require any images preoperatively or intra-operatively. These “image-free” navigation systems rely on information that is collected at the time of surgery. Such information normally includes the centres of rotation of the hip, knee and ankle as well as anatomical landmarks. The system used in the study is an “image-free” navigation system.

CAOS is continuously evolving with newer technologies being produced that further extend the classification of CAOS devices. Two recent technologies are the patient-specific templates and the semi-active (collaborative) robotics. The concept of patient-specific templates combines three-dimensional surgical planning with rapid design and manufacturing of custom cutting or drilling templates. These templates uniquely mate with the bone and incorporate drilling or cutting guides consistent with the surgical plan. Since all the planning and preparation is done pre-operatively, patient-specific templates shorten the preparation time in the operating room and significantly reduce instrumentation (DiGioia 2010). Several systems can be found on the market. Albeit some differences between the different manufacturing companies, all have similar requirements. Firstly CT or MRI images (depending on the manufacturer’s specifications) are acquired well in advance of surgery. These are then sent to the manufacturer for image processing and pre-planning. The surgeon then receives the surgical plan and performs any necessary changes. Once the surgeon is satisfied with the surgical plan, the surgeon finalises and approves the plan. The manufacturer then produces the templates and ships them in sterile packaging to be used in surgery.

The semi-active robots combine the awareness and flexibility strengths of the surgeon with the accuracy, precision and rapid reaction of robotic technology. These semi-active robots allow a high speed surgical burr to only remove bone as determined by a preoperative surgical plan. These systems extend the conventional framework of surgical navigation – tracking the bones and tools of interest in real time, comparing this

information to the surgical plan and communicating it to the surgeon – whilst adding robotic control of the bone cutting tool (DiGioia 2010).

The aim of all these CAOS technologies is to enable the surgeon to align the prosthesis accurately so that the lower limb is in a neutral alignment post-operatively. This is because studies have suggested that coronal lower limb alignment errors of more than 3° are associated with more rapid failure and inferior functional results after total knee arthroplasty (Jeffery et al. 1991, Ritter et al. 1993, Piazza et al. 1998). Poor component positioning, including sagittal plane and rotational malalignment can be related to major clinical problems (Bargren et al. 1983, Stockl et al. 2004). Exact axial alignment promotes longevity of the implant whereas mal-positioning can lead to loosening (Oswald et al. 1993, Wasielewski et al. 1994).

Even though mechanical alignment systems are being continuously improved, it has been estimated that errors in tibial and femoral alignment of over 3° occur in at least 10% of total knee arthroplasties, even when carried out by skilled surgeons using up-to-date mechanical alignment tools (Kluge 2007). This is due to drawbacks of the conventional alignment systems. It has been shown that navigated total knee arthroplasty results in a better implant placement and lower limb alignment with a reduction in the number of outliers of mechanical leg axis > 3° when compared to conventional total knee arthroplasties (Anderson et al. 2005, Lurin et al. 2006). Consequently, an increasing number of knee arthroplasties are being performed using computer navigated surgery.

A reported disadvantage of navigated knee replacement, when compared to conventional knee replacement, is that of a longer operation time. An increase in operation time of up to 20 minutes has been reported in the literature (Kinzl et al. 2004, Cheung et al. 2009). This increase is mainly due to the registration process that is required when using navigation software. The OrthoPilot TKA Smart v1.0 application has a simplified registration process, using a refined set of references, when compared to previous Orthopilot versions such as TKA 4.2 and TKA 4.3. This should therefore result in a

shorter registration time and consequently a reduction in the total operation time. According to the manufacturers (BBraun Aesculap, Tuttlingen) the software has also been designed to be more user friendly, which in itself might reduce the total operation time.

2.4.5 The Navigation Components

The navigation system, such as the Orthopilot navigation system (BBraun Aesculap) that was used in the study, relies on four components: (1) the computer platform, (2) the tracking system, (3) the probe (pointer) and (4) the remote controller.

2.4.5.1 The Computer Platform

The computer platform consists of a localizer, a central control unit and a computer (Figure 2.8).

The Localizer

The localizer is an electronic measuring device that accurately determines the spatial position of several trackers. It receives signals from trackers and then calculates the position of each emitter, thereby determining the position of each tracker. It then relays this information to the central control unit which instantaneously updates the calculation of the position of each tracker. Two types of localizers are regularly used in orthopaedic surgery – optical and electromagnetic. The optical system consists of two or three cameras with a variable field of visibility. This system is highly accurate (<0.1 mm at a distance of 2 meters) (Picard 2007). However, the trackers must always be visible. Conversely when using the electromagnetic system, the trackers do not need to be monitored by a camera. Nonetheless, this system is very sensitive to the “metallic” environment of the operating theatre and this may alter the device’s measurements.

The Central Control Unit and Computer

The central control unit is an electronic device to which the connecting cables of active trackers are connected. It controls the switching sequence of the emitters of each tracker. The succession of these flashes is then sensed by the localizer to which the central control unit is connected.

The computer co-ordinates all the components of the system. It controls and records all the information that is required for the correct functioning of the navigation system as a whole.

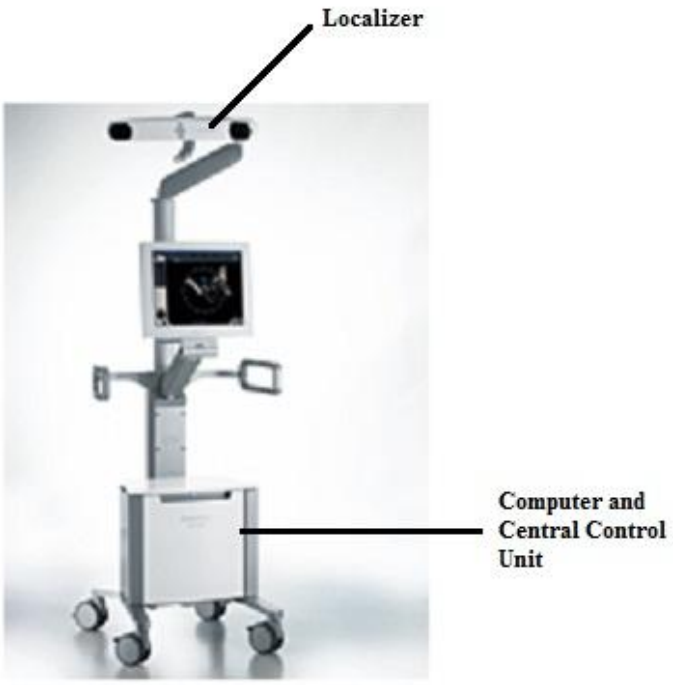


Figure 2.8 The Orthopilot Computer Platform. The computer platform consists of the localizer, the computer and the central control unit. (Aesculap AG, Tuttlingen, Germany)

2.4.5.2 The Tracking System

Trackers (also called “rigid bodies”) are fundamental elements of the navigation system as they allow localisation at any moment of all or a part of the anatomical structures that the surgeon requires. A tracker (Figure 2.9) is rigidly fixed to the femur and tibia by screws. A third tracker is required and this is attached to the probe or to the instrumentation. Trackers emit signals using infrared or electromagnetic signals to allow accurate three-dimensional localisation of the tracker and thus the structure it is attached too.

Physically, trackers consist of three parts (Picard 2007):

1. A support structure made of plastic or metal. This may have a variable geometry. The supporting structure of the trackers used in the study had a planar geometry.

2. Emitters which may use infrared or electromagnetic signals. The infrared signals are emitted by light emitting diodes (LEDs). Unlike with electromagnetic trackers, trackers that use infrared signals have to be continually visible to the localizer in order to be located spatially.

3. Connecting cables that connect emitters to each other and to a central control unit. This allows the active transmission of the infrared or electromagnetic signal. For this reason, trackers that use cables to connect to the central control unit are termed active trackers. Conversely, trackers that do not use such a cable are termed passive trackers. In this case, the localizer is able to determine the spatial position of these passive trackers simply by displaying the emitters. Passive trackers normally have emitters in the shape of a reflecting sphere.

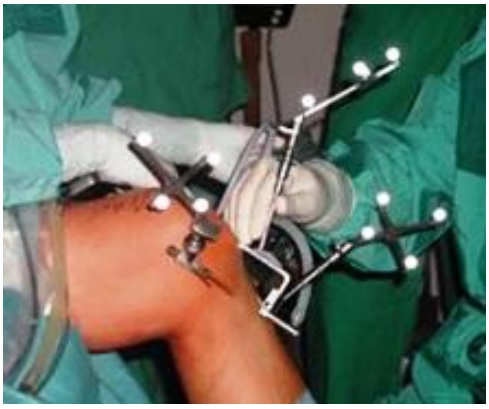
(a)  (b) 

Figure 2.9 Trackers (a) Active trackers connect to the central control unit using cables. (b) Passive trackers do not use cables and are in the shape of a reflective sphere. (From http://www.healio.com 21.01.2013.)

2.4.5.3 The Probe and Remote Controller

The probe (also know as a pointer) is a metal or plastic device that is shaped in the form of a pen to enable the surgeon to point very accurately at a particular reference point. The tip of the probe is tapered and rigid whereas the handle holds the trackers. Consequently, once the probe is calibrated, the tip can accurately (with one millimetre accuracy) be localised in space by the camera.

The remote controller allows the surgeon to remotely control the software without physically touching a keyboard or a screen. This allows the surgeon to progress through the required stages represented on the computer screen as well as to record desired data such as the pre-operative and post-operative alignment and range of motion. This may be in the form of foot pedal (as is the case with Aesculap's Orthopilot system) or a manual controller (as is the case with Stryker's NavSuite).

2.4.6 Steps during a Navigated Total Knee Arthroplasty using an "Image-less" System

The primary goal of CAOS is to optimize the surgical performance with the aim of optimizing the patient's function post-operatively. The principle behind CAOS software is to determine the mechanical axes during the surgical procedure and then to orientate the pre-calibrated cutting guides.

After the patient is anaesthetised (usually using a regional anaesthetic such as spinal anaesthesia), a thigh tourniquet is inflated to reduce the blood loss during the procedure. The knee is then approached in the same way as for a conventional TKA. The first step that is specific to a navigated TKA procedure is the registration process (Section 2.5). To enable this process, trackers have to be fixed to the femur and tibia via bicortical screws. The registration process involves data acquisition followed by a process that relates the collected data of the patient's three-dimensional anatomy to the patient's position and anatomy on the surgical field (Kanlic et al. 2006). All the data is gathered intra-operatively and is of two types – kinematic data and anatomical data. Kinematic data is obtained about the hip, knee and ankle joints to determine the joint centres. This data is mathematically determined by moving adjacent bones that have trackers fixed to them. Anatomic data includes anatomical bone landmarks such as the femoral epicondyles and the tibial condyles. Anatomic data is gathered by digitizing relevant points with the pre-calibrated probe. From the acquired data, the software is able to determine the femoral and tibial mechanical axes in real-time. The knee is then put through the range of motion and the maximum ROM achieved is recorded. Furthermore, any deformities present such as varus-valgus deformities, fixed flexion as well as hyperextension are recorded together with the degree of such deformity.

Following data acquisition, the system automatically calculates an initial optimal implant position. The software also determines the size of femoral component that will be required. However, the surgeon still has full control in deciding whether the chosen femoral size is the correct one. Starting on the tibial side (though this may be changed

according to surgeon's preference), the calibrated tracked jigs are secured. The user interface helps the surgeon orientate the cutting jigs in the correct position to ensure that the cuts made do not notch the anterior cortex of the femur, the right amount of joint surface is resected and that the position of the final implant has the correct femoral rotation and the right amount of posterior tibial slope and rotation. The surgeon then secures the jig and performs the necessary cuts as usual.

Most of the navigation software available come with the option of soft tissue balancing. In addition to giving the surgeon the option to record the original flexion-extension gaps, this aspect of the software also enables the surgeon to predict how changes in the femoral cut or polyethylene size will influence the flexion-extension gaps as well as providing real-time feedback on how any ligamentous releases have influenced the gaps. This ensures that the final result is a well-balanced knee. The soft tissue balancing stage takes place prior to the femoral cuts.

Following the femoral cuts, the trial implants are inserted and the knee is assessed for stability in addition to ROM and alignment. These measurements are again provided by the software. If the surgeon is happy with these measurements, the final implant is cemented in place and the ROM and alignment are once more checked and the final measurements are recorded in the computer's database. The screws are then removed from the femur and tibia. The rest of the operation is the same as for a conventional TKA.

As can be seen, throughout the procedure, the surgeon is the one taking the decisions and is free to alter anything. The navigation system merely acts as a real-time intra-operative measurement tool. Indeed it is important that the surgeon is aware of this as well as the need to question the software when unexpected values are displayed.

2.5 Comparison of the Trial Software: Smart versus TKA 4.3

The Orthopilot Smart v1.0 software is so named as an acronym for simple, mature, accurate, reliable and time-saving. It is marketed as being more user-friendly than

previous software and this together with a shorter registration process should in theory reduce the total operation time. The algorithm for TKA Smart software is based on that used for TKA 4.3 software. The main change is that TKA Smart does not use ankle kinematics during the registration process to identify the centre of the ankle. During the registration process, this step is often omitted by the TKA 4.3 software as the data input from ankle kinematics may not be in agreement with the anatomical landmarks. In such a situation, the software treats the input from the ankle kinematics as an erroneous input. The software then relies on the anatomical ankle points to determine the centre of the ankle for the particular patient (Picard 2012). Since ankle kinematics is a step that is often omitted by the software during the registration process, theoretically the TKA Smart software should have the same clinical outcomes as the older software, TKA 4.3.

During the registration process, the same anatomical and kinematic points are collected for both software with the exception of ankle kinematic data. This data is not required with the Smart software. However, the order of the data collection varies slightly between the two software. The registration process will be discussed using the data collection sequence as used by TKA 4.3. The schematic program flow during the registration process for both software are shown in Figures 2.10 and 2.11. The first step in the registration process is that of determining the knee centre. Using the pointer, the centre point of the trochlea is palpated with the leg held in flexion. This is followed by registration of the hip centre. During this step, the computer displays an image of the pelvis with an overlying ring and a blue arrow. The femur is then moved in a circular fashion so that the blue arrow moves over the circle displayed. To ensure that the hip centre has been registered correctly, the mechanical lateral distal femoral angle (mLDFA) is checked by applying corresponding implant and instrument dependent orientation blocks to the distal femoral condyles in a zero degree slope to the mechanical femoral axis. If the mLDFA seems implausible to the surgeon and does not match the pre-operative plan, the hip centre registration step is repeated. The second joint to be kinematically determined when using TKA 4.3 is the ankle joint. This is done by fixing the tracker to the metatarsal area by attaching a sterile footplate to the foot. The foot is

then dorsiflexed and plantarflexed and the programme records the movement between the foot tracker and the tibial tracker. As previously mentioned, this step is omitted when using TKA Smart. The last kinematic measurement is that to determine the knee joint centre. The knee is flexed and extended for this purpose. The software calculates the knee centre by recording the movement of the femoral tracker in relation to the tibial tracker. Internal and external rotation of the leg are also performed.

The remainder of the registration process involves using the probe to collect anatomical landmarks. The proximal tibial centre is determined by recording the centre of the anterior edge of the anterior cruciate ligament. The medial and lateral tibial reference points are then determined. These steps enable the software to determine the tibial cutting height. The deepest deepest points of any defects present are used to reference this. The medial and lateral posterior condyles are then recorded by selecting the point lying further posterior on the condyle medially and laterally respectively. The anterior cortical point is determined by palpating the most anterior point on the condyle. This point is used to determine the required size of the femoral component. The last few measurements involve the ankle joint. The medial and lateral malleoli are then palpated and the centre of each malleolus is then recorded. Determination of the anterior ankle joint point is the final step in the registration process. The pointer is placed at the anterior edge of the distal tibia as close as possible to the anterior ankle joint gap. This point should lie on the central tibial axis immediately adjoining the ankle joint centre.

When using the TKA Smart software fewer navigation steps are required. The navigation steps have been reduced from twenty-eight when using the older software to twenty-one when using the TKA Smart software. Furthermore, the instrument changes that are required during the navigation process have been reduced from fourteen instrument changes when using TKA 4.3 software to six instrument changes when using TKA Smart software. In addition, a new screen design has been implemented for TKA Smart software. This new screen design has been developed in an attempt to make it easier to understand the information presented.

Input of patient details, operating side and instrument selection

⇩

Knee centre registration (first step in registration process)

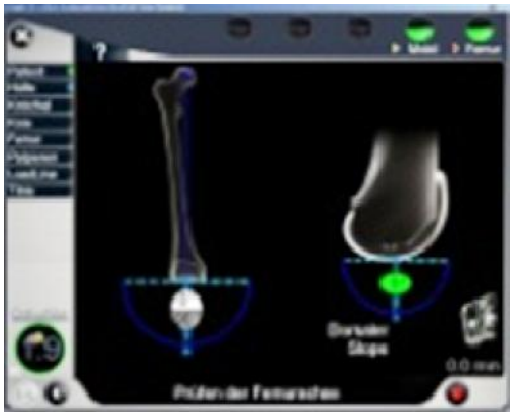
⇩

Hip centre registration

⇩

Plausibility check of LDFA

Figure 2.10 Schematic Program Flow for TKA 4.3.



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Ankle centre registration

⇩

Knee centre registration

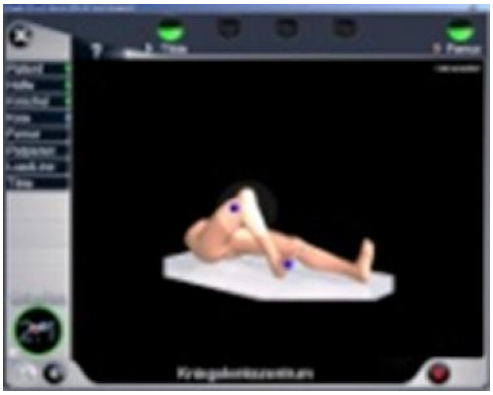


Figure 2.10 Schematic Program Flow for TKA 4.3 (continued).

⇩

Tibia centre registration

⇩

Medial tibia reference

⇩

Lateral tibia reference

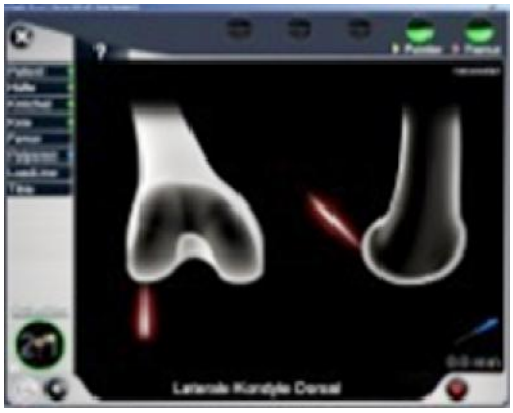
Figure 2.10 Schematic Program Flow for TKA 4.3 (continued).

⇩

Registration of medial posterior condyle

⇩

Registration of lateral posterior condyle



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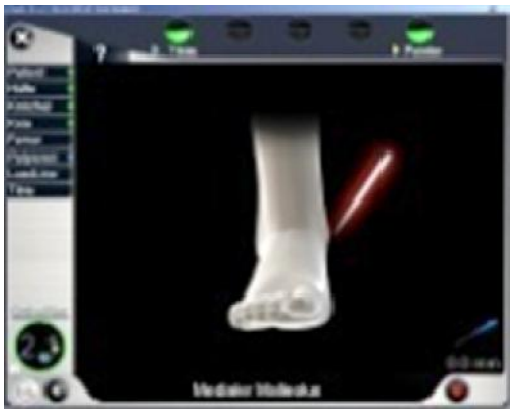
Registration anterior cortical point

Figure 2.10 Schematic Program Flow for TKA 4.3 (continued).

⇩

Registration medial malleolus



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Registration lateral malleolus

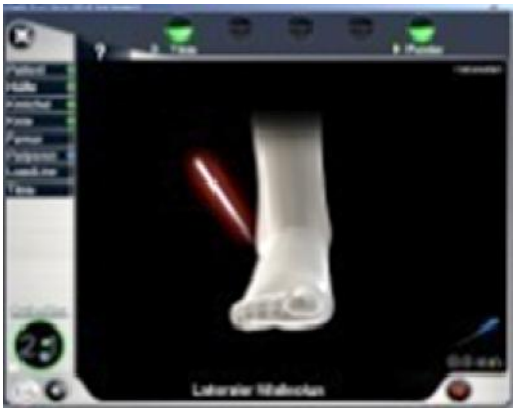


Figure 2.10 Schematic Program Flow for TKA 4.3 (continued).

⇩

Registration anterior ankle joint point (last step in registration process)

⇩

Mechanical axis pre-op

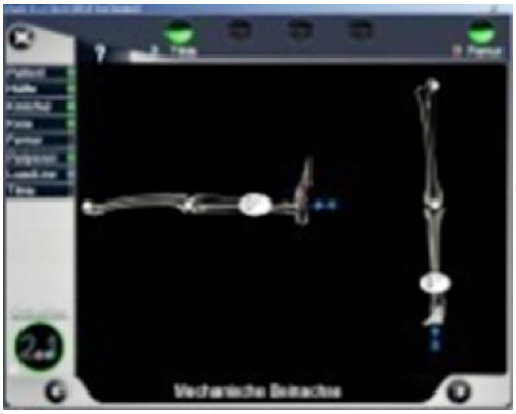


Figure 2.10 Schematic Program Flow for TKA 4.3 (continued).

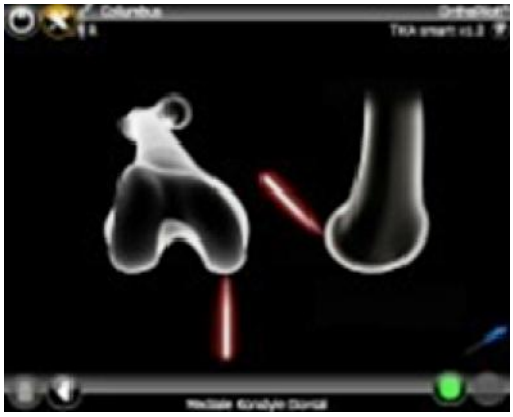
Input of patient details, operating side and instrument selection

⇩

Registration anterior cortical point (first step in registration process)

⇩

Registration medial posterior condyle



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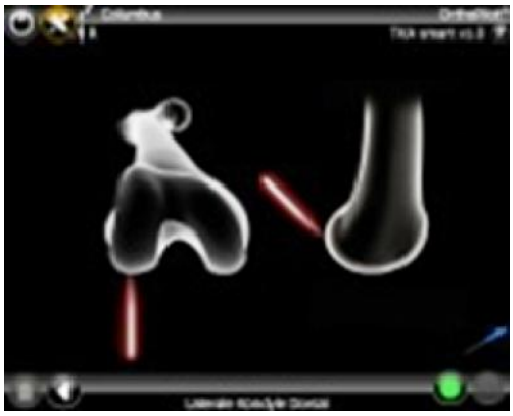
Registration lateral posterior condyle

Figure 2.11 Schematic Program Flow for TKA Smart.



⇩

Tibia centre registration

⇩

Medial tibia reference

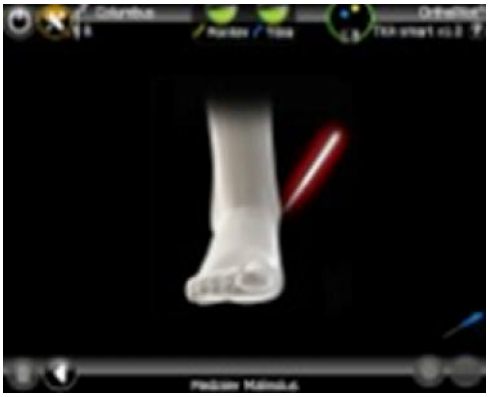
Figure 2.11 Schematic Program Flow for TKA Smart (continued).

⇩

Lateral tibia reference

⇩

Registration medial malleolus



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Registration lateral malleolus

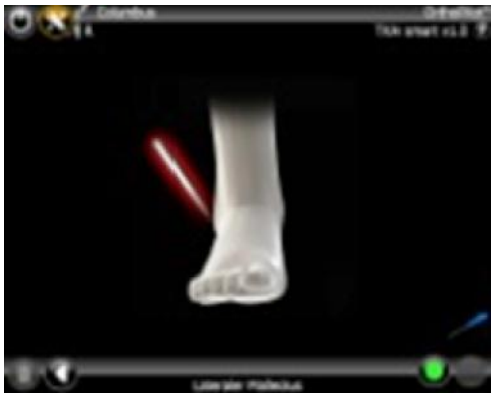


Figure 2.11 Schematic Program Flow for TKA Smart (continued).

⇩

Registration anterior ankle joint point

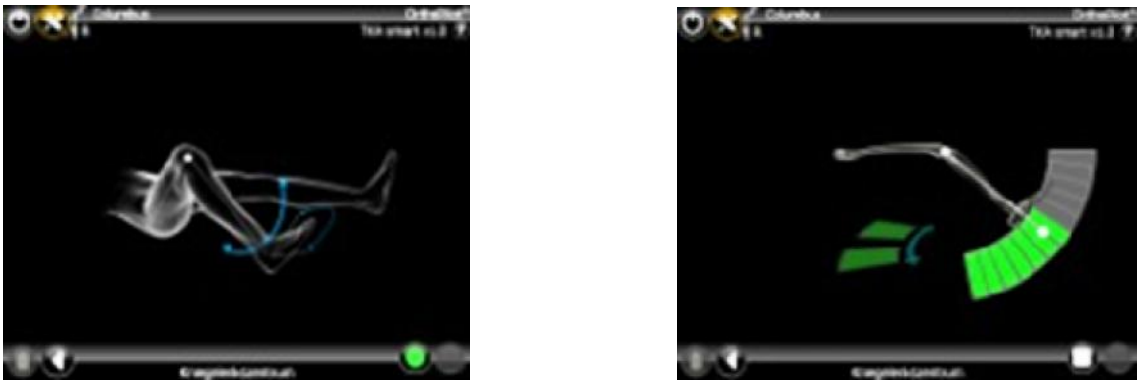
⇩

Hip centre registration

⇩

Knee centre registration (last step in registration process)

Figure 2.11 Schematic Program Flow for TKA Smart (continued).



⇩

Mechanical axis pre-op

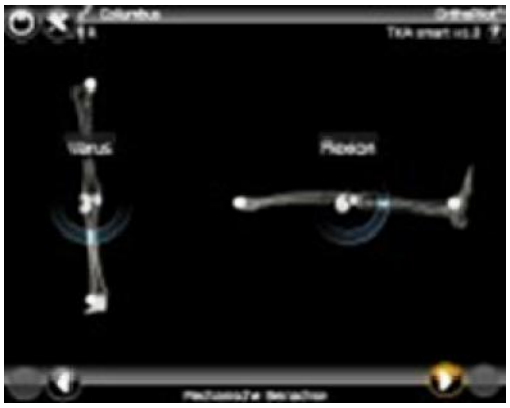


Figure 2.11 Schematic Program Flow for TKA Smart (continued).

Chapter 3 - Clinical Trial

This chapter describes the clinical trial that involved the recruitment of patients who underwent a navigated Columbus TKA using either of the two software. This was done to determine whether despite the change in the algorithm used by TKA Smart software, the software is equivalent to the TKA 4.3 software. In addition, the reduction in registration and total operation time that are associated with TKA Smart was also investigated.

3.1 Materials and Methods

3.1.1 Study Design

The study was a prospective randomised controlled trial. All procedures were carried out by a consultant. Initially three consultants were taking part in the study. However, due to the lack of soft tissue management in the Smart software, one of the consultants left the study as this would have constituted a change to his routine practice. All three consultants used navigation in total knee arthroplasty as their standard practice and all consultants were accustomed with the two versions of the software being investigated. Likewise, all theatre staff was competent in using both systems.

3.1.2 Methodology

The study required ethical approval. Since the Smart software had recently achieved CE marking (24th November 2011), the study did not require approval from the Medicines and Healthcare products Regulatory Agency (MHRA). Both types of software are compatible with the Columbus knee implant which is the preferred implant of the

consultants in the study. The Columbus knee implant is a class III medical product and holds a CE certification.

Prior to submitting an application for ethical approval, NHS sponsorship was sought. A study protocol was submitted to the local research and development department. The NHS National Waiting Times Centre at GJNH accepted to sponsor this study (Study number: Ortho 11-08) in addition to the funding that was received for the purpose of the study by BBraun Aesculap.

The main ethical dilemma in the study was the fact that a change of practice was being created for the purpose of the study. This was due to the fact that CT scans were being used at the six-week review instead of the hip-knee-ankle views that was routinely used. This required liaison with the radiological department as this meant additional work for the staff in that department. In addition, the radiation dose had to be reduced to a minimum to reduce the risks for the patients in the study.

For this purpose, the Imperial knee protocol (Henckel et al. 2006) was adapted for use with the CT scanners used at GJNH (GE Healthcare CT scanner). Unlike the commonly used Perth protocol (Chauhan et al. 2004) that scans the whole leg from pelvis down to the ankle, the Imperial knee protocol limits the areas imaged to the femoral head, knee and tibiotalar joint. The protocol was carried as follows. A scout film was first taken between the iliac crest and the feet to specify the regions to be imaged. The relevant areas, namely the femoral head, 10cm above and below the joint line of the knee and 2cm to 3cm on either side of the tibiotalar joint were then imaged. Since the radiation dose calculation used in the Imperial knee protocol was based on a different scanner, the radiation dose based on the scanner at GJNH had to be calculated. For this purpose, the expertise of the Radiation Protection Adviser and Consultant Medical Physicist for the West of Scotland was sought. A phantom limb was used to enable the calculation of the required dose for the desired regions. The total effective dose for this protocol was calculated to be 0.6mSv which is equivalent to 14 weeks of background radiation (Appendix 1). This dose is considered to fall in the minor risk category for bio-medical

research as it represents an additional risk of lifetime fatal cancer of 1 in 33,000 (International Commission on Radiation Protection 1991). Indeed the additional risk to the patient in the study was actually less as the additional radiation dose was of 0.4mSv. This is due to the fact that all patients require a hip-knee-ankle x-ray six weeks following a total knee arthroplasty. This x-ray has a radiation dose of 0.2mSv at GJNH. Study participants had a CT scan instead of their routine x-ray, thereby reducing the increase in radiation dose.

A meeting was also set up with the arthroplasty service who would normally review the patients post-operation. The aim was to ensure that the arthroplasty practitioners were aware of the study as well as to ensure that all the necessary data was collected. In addition, due to the fact that the KSS was being collected for the purpose of the study only (this is not routinely collected at GJNH), the meeting served to ensure that the arthroplasty practitioners were willing to do this. So as to make it easier on the service, the KSS score was printed on a green paper as this was the colour the service used for scores. In addition, the arthroplasty practitioners were made aware of the fact that no hip-knee-ankle x-rays were to be requested for the patients in the study as these patients were getting the CT scan.

Prior to submission of an application for ethical approval, a letter to the patient's general practitioner (GP) (Appendix 2) and a patient information sheet (PIS) (Appendix 3) were compiled. The PIS was also submitted to the Patient Information Management Group at GJNH to ensure that it was written in a way that the patient would deem easy to read.

Furthermore, a meeting was held with the Research Lay Group at GJNH. This group is composed of members from the local research and development department as well as patients. The purpose of the meeting was to discuss the study with this group to ensure that the study was deemed acceptable from a patient's perspective.

An application was then submitted to the research ethics committee via the Integrated Research Application System (IRAS application number: 88263/269718/1/891). The application was reviewed by the West of Scotland Research Ethics Committee 5 (REC

reference number: 11/WS/0125). A meeting was held with the committee who approved the study following some minor changes, namely an increase in the number of patients required for the study and a slight amendment to the patient information sheet to include the actual risk from the extra radiation dose due to the CT scan. Following ethical approval (Appendix 4), an R&D and Site Specific form were submitted to the Research and Development department at GJNH who did not find any objection towards the study. The study was then accepted by the Medical Director at GJNH (Appendix 4). The study was also registered with the International Standard Randomised Controlled Trials Number register (ISRCTN: 71883082) that holds information on randomised controlled trials worldwide.

A final meeting was held with those involved in the study and those individuals that the study might have an impact on to ensure that those involved were happy with every part of the study and to make sure all those involved knew who to contact in case of problems. The meeting was held by the research fellow who was the point of contact and involved the surgeons, research co-ordinator, members of radiology department, arthroplasty practitioners, secretaries and ward sisters.

For the purpose of randomisation, the sequentially numbered, opaque sealed envelopes (SNOSE) (Doig et al. 2005) system was used (Figure 3.1). In this system a double foil wrapper is used to ensure that the envelope is truly opaque and cannot be read by holding it up against a strong light source. Furthermore, a carbon paper is also placed at the front of the treatment allocation paper so that any writing on the front of the envelope is transferred to the paper inside. The envelopes were prepared as follows. 220 pieces of aluminium foil that were of the same width and twice the height of a standard letter-sized envelope were cut. Subsequently 220 pieces of carbon paper that were of the same size and height as the envelope were cut. ‘TKA Smart’ was printed on 110 A4 sheets to delineate the Smart software. Similarly ‘TKA 4.3’ was printed on another batch of 110 A4 sheets. These were kept as two separate batches. Each A4 treatment allocation paper was then folded into three to fit into the envelope. The carbon paper was placed at the front of the treatment allocation paper with the carbon side facing the paper. A sheet

of foil was then placed over both sides of the carbon-treatment paper combination which was then placed in an opaque, letter-sized envelope with the carbon paper side closest to the front of the envelope. Each envelope was then sealed and signed over the top of the envelope seal. Until this point, the envelopes allocated for the TKA Smart software were kept separate from those used to delineate the TKA 4.3 software. The two batches of envelope were then mixed together and shuffled several times. The envelopes were then sequentially numbered 1 to 220 and placed in a container.

The envelopes were then sequentially opened once a patient was recruited into the study. However, prior to opening the envelope, the patient study number, date and signature of the person opening the envelope were marked on the front of the envelope. Due to the placement of the carbon paper, this information was transferred onto the treatment allocation paper inside the envelope. This ensured that no tampering with envelopes could take place. The allocated individual opening the envelope had no contact with the patients.

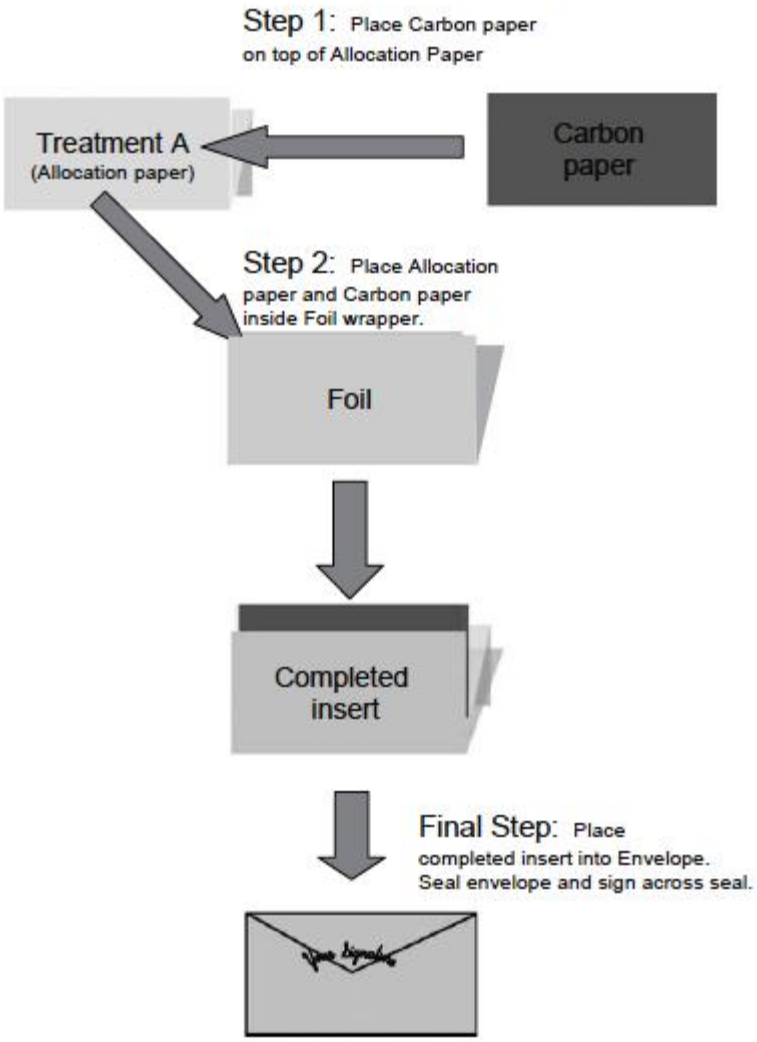


Figure 3.1 Preparation of the envelope insert required for randomisation. (From Doig et al. Randomization and allocation concealment: a practical guide for researchers. Journal of Critical Care. 2005; 20:187 - 193.)

3.1.3 Patient Recruitment

The day prior to pre-assessment, the research fellow went through all the clinical notes of the patients attending for pre-assessment the following day. Suitable patients for the study were thereby identified. All the patients under the care of the surgeons in the study who were suitable to undergo a primary total knee arthroplasty and who fulfilled the

selection criteria were approached for inclusion in the study at the pre-assessment clinic. The patient information sheet was given to each patient and the study was discussed in detail with each patient. The patients were then given a chance to read the patient information sheet and ask any questions. Once a patient was approached, the patient was marked on the hospital waiting list as a potential study patient. This ensured that as much as possible the patient would not be transferred to another consultant's operating list. A list of potential patients for each surgeon with the expected date of admission and operation was compiled and distributed to the consultant's secretary. Although the dates were regularly checked for any changes, the involvement of the secretaries ensured that any last minute changes were more readily detected.

On the day of admission of surgery, each patient was approached and asked whether he/she wished to take part in the study. Written consent was obtained from those who were willing to take part. Once consent was obtained, a study number was allocated to the patient.

The following are the inclusion and exclusion criteria used for the purpose of this study:

Patient Inclusion Criteria

- Patients having a primary navigated knee arthroplasty
- Able to give informed consent
- Able to return for follow-up.

Patient Exclusion Criteria

- Patients with a BMI > 40
- Patients who were known pre-operatively to require patellar resurfacing
- Patients who were unable to give informed consent
- Patients who were unable to attend for follow up.

In the first protocol that was sent to the ethics committee, patients who required the use of an additional soft tissue balancing procedure were excluded from the study. However

since this was going to create a change in practice for one of the surgeons who routinely conducts such a procedure an amendment was sent to the ethics committee and this exclusion criterion was removed prior to the start of the study.

Furthermore a second amendment was later submitted to the ethics committee. This was due to a change in the patients that were referred to GJNH. The GJNH is a waiting times centre that is referred patients from the whole of Scotland including the Scottish Isles. Patients that are referred from far away such as Aberdeen and the Scottish Isles are normally pre-assessed on the day before surgery. In the ethics application (though not in the protocol) it was stipulated that patients would normally have about three weeks to think about the study. Consequently patients that were being pre-assessed the day before surgery were excluded from the study. At the time of submission of the ethics application this was an unusual occurrence for the surgeons in the study. However soon after starting the study, there was a change in the type of referrals to the GJNH and more patients that required pre-assessment on the day before surgery due to the distance were referred to GJNH. So as not to create a large selection bias and to be able to continue recruiting patients at an adequate pace it was decided to submit a second amendment to the ethics committee. This was granted as the patients were still having a 24 hour period to think about the study. Thus for any patient that was being pre-assessed the day before surgery, the patient was approached early in the morning whilst at the clinic and the study was explained. The patient was then approached the following day following 24 hours and asked whether he/she wished to take part in the study.

Once the patient accepted to be in the trial and gave his/her consent, another two copies of the consent were done. One of the copies was given to the patient, another one was kept in the study file that was kept securely locked whilst the original consent form was placed in the patient's case notes together with a theatre data collection sheet Appendix 5). This sheet was filled in theatre at the time of operation. In addition to collecting the total operation time, the sheet also confirmed that the correct software was used at the time of surgery. This sheet was printed on pink A4 sheets to ensure easy identification.

Following consent the patient was randomised to either having the operation performed using the TKA 4.3 software or the Smart software. Once the patient was randomised, the surgeon and the theatre staff were informed of the software to be used. In addition, the arthroplasty service and the radiology department were informed that the patient was in study. This allowed for the necessary arrangements to be done so that the patient would have a CT scan on the same day as the follow-up appointment. Although the original agreement with the local radiology department was that the patients would attend for their CT scan on a Monday, Tuesday or Thursday between the hours of 12 and 2.00pm, further liaison with the radiology department meant that the patients had their CT scan just half an hour prior to their appointment time. This reduced the inconvenience for the patients. However, patients were still informed at the initial encounter of the possibility of having a CT scan during lunch time hours on the day of the follow-up appointment. A letter to the GP notifying the involvement of the patient in the trial was also sent out within two days of the patient's consent.

The patient then underwent a navigated TKA as normal using the Columbus knee replacement implant. The registration time was recorded by the software. This was done by taking a snapshot at the start and end of the registration process (Figures 3.2 and 3.3). The total operation time was defined as the "skin to skin" time and was recorded by an independent theatre person who was not involved in the study. The whole operation was performed by one of the two consultants from start to finish utilising the same approach to the knee as well as same closure methods. The software also recorded the pre-operative and post-operative range of motion and knee alignment. Once the operation was over, the data was collected from a secure system on the computer. Only the research fellow had access to this data. This ensured the maintenance of confidentiality. Furthermore, the theatre data collection sheet was removed from the clinical case notes to ensure that no individual, except for the research team, could identify the software that was used for the purpose of the study.

(a) 

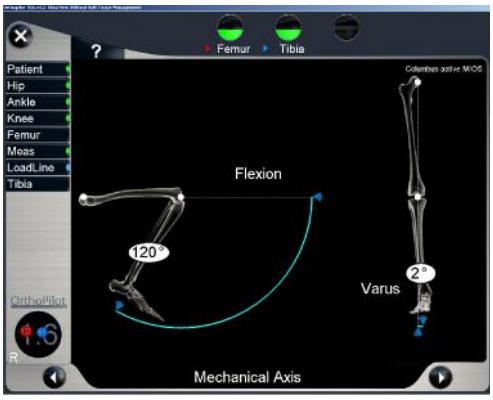
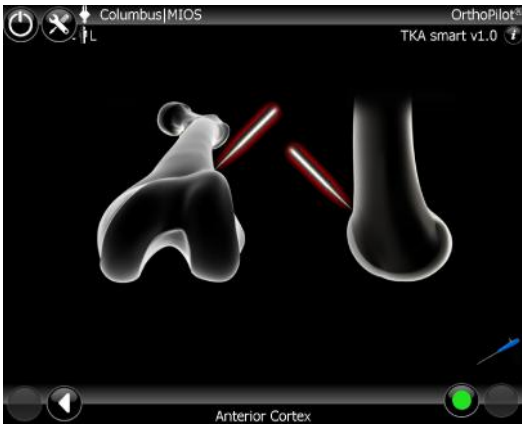
(b) 

Figure 3.2 TKA 4.3 Registration Time. Snapshots taken to mark the start (a) and end (b) of the registration time.

(a) 

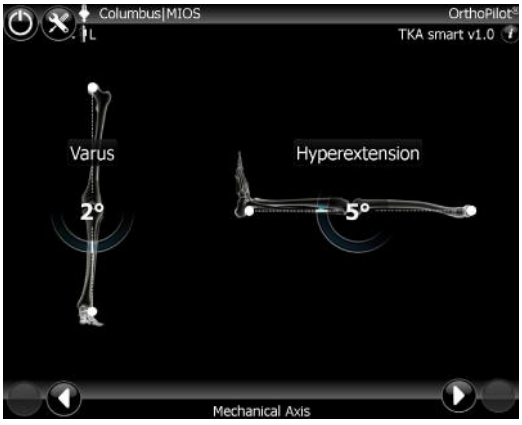
(b) 

Figure 3.3 Smart Registration Time. Snapshots taken to mark the start (a) and end (b) of the registration time.

The patient was then seen by an independant arthroplasty service at six weeks post-operation. At this time the patients had their usual follow-up and scores that were routinely done at GJNH. In addition the KSS score was collected. The patient also had a CT scan as described previously prior to their arthroplasty follow-up. To ensure that no patient missed the CT scan or did not get a KSS score due to a clerical error, a meticulous system was put in place. Once a patient's consent was taken by the research

fellow, the fellow informed the arthroplasty practitioners, arthroplasty secretaries and the radiology secretary who issued the CT scan appointment. When a patient was discharged from hospital, the arthroplasty secretaries informed the research fellow as well as the radiology secretary of the date and time. The research fellow then wrote the details on the radiology request form and handed it in to the radiology secretary. Once the CT scan appointment was done, the radiology secretary informed the research fellow who then wrote the patient's details and details of both the arthroplasty appointment as well as the CT scan appointment on an envelope containing the KSS score sheet. The research fellow then took the envelope to the arthroplasty practitioners the day before the patient's appointment. This helped the arthroplasty practitioners identify the study patients as well as serving as a continuous reminder that the KSS score needed to be collected.

3.1.4 Data Collected

The following data was collected.

Pre-operatively:

1. Demographic Data
    a. Gender
    b. Age at operation
    c. Body Mass Index (BMI)
    d. American Society of Anaesthesiologists (ASA) Score
2. Knee related data
    a. Aetiology
    b. Type of knee (varus/valgus/neutral)

c. Range of Motion (ROM)

d. Degree of fixed flexion if present

e. Oxford Knee Score

3. Radiological Data

a. Kellgren Lawerence Score

b. Ahlback Classification

Intra-operative Data:

1. Date of TKA
2. Side of TKA
3. Registration time
4. Total operation time

Post-operative Data:

1. Complications and Re-admissions
2. Clinical Data

a. Range of Motion (ROM)

b. Degree of fixed flexion if present

c. Degree of extension lag if present

d. Oxford Knee Score

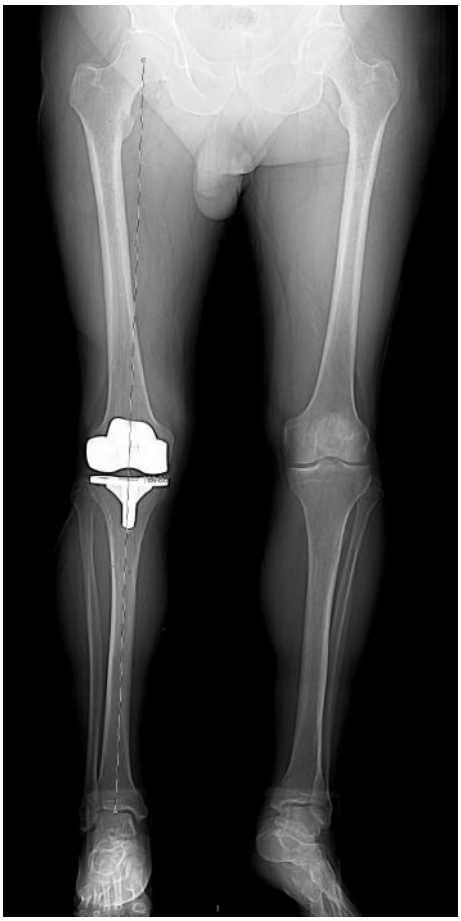
e. Knee Society Score

f. Patient Satisfaction

3. Radiological Data (Figures 3.4, 3.5, 3.6):
    a. Rotational alignment of the femoral component
    b. Coronal mechanical femoral angle
    c. Sagittal mechanical femoral angle
    d. Coronal mechanical tibial angle
    e. Sagittal mechanical tibial angle
    f. Coronal femorotibial angle

The research team was not blinded to the allocation of patients to each group. However the patient, the pre-assessment nurses, the arthroplasty practitioners and the radiologist were blinded as to which software was used. In addition, the theatre staff who were collecting the total operation time were independent from the study.

(a)



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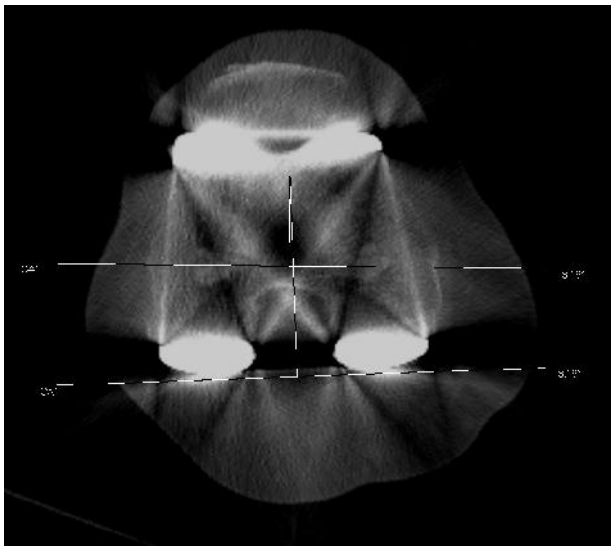


Figure 3.4 CT scan performed at the six week review showing measurements taken. (a) Coronal femorotibial angle (HKA) (b) rotational alignment of the femoral component.

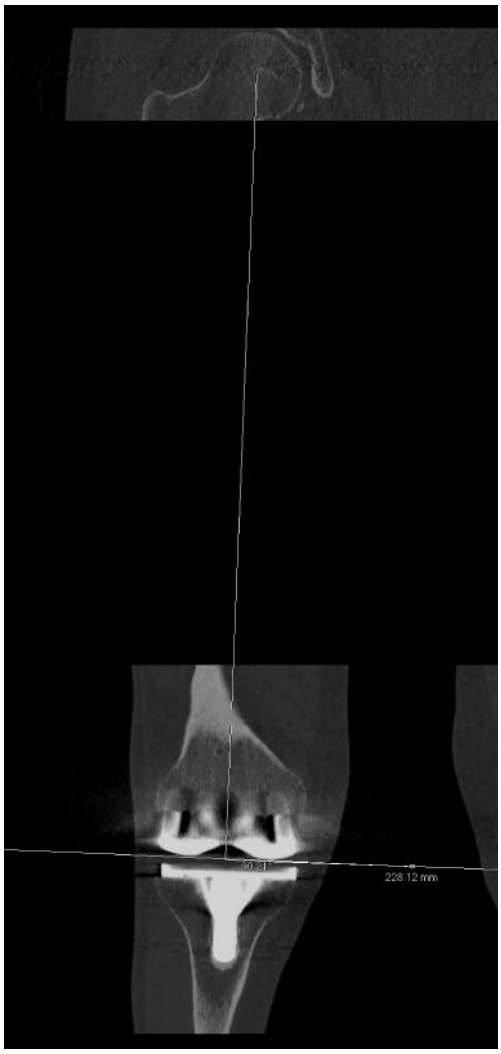
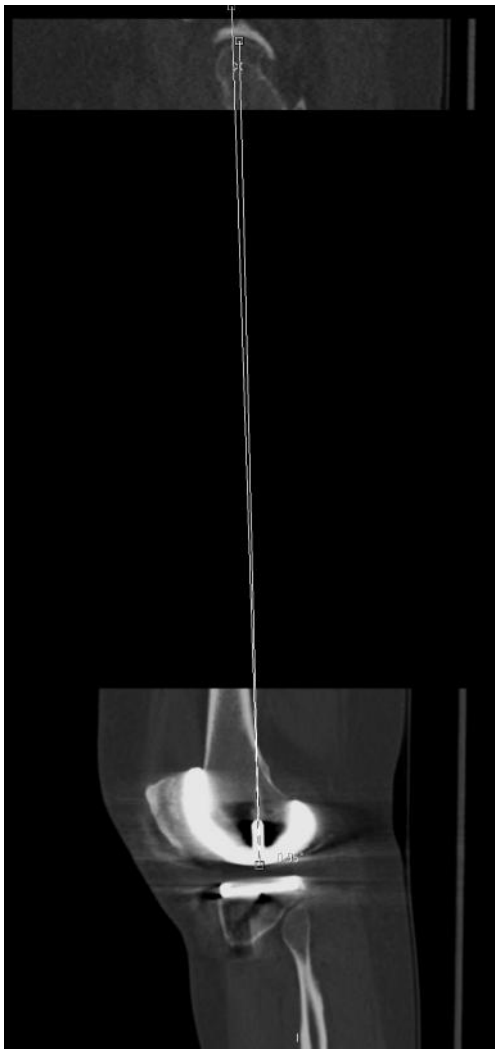
(a)  (b) 

Figure 3.5 CT scan performed at the six week review showing measurements taken. (a) Coronal mechanical femoral angle (b) Sagittal mechanical femoral angle.

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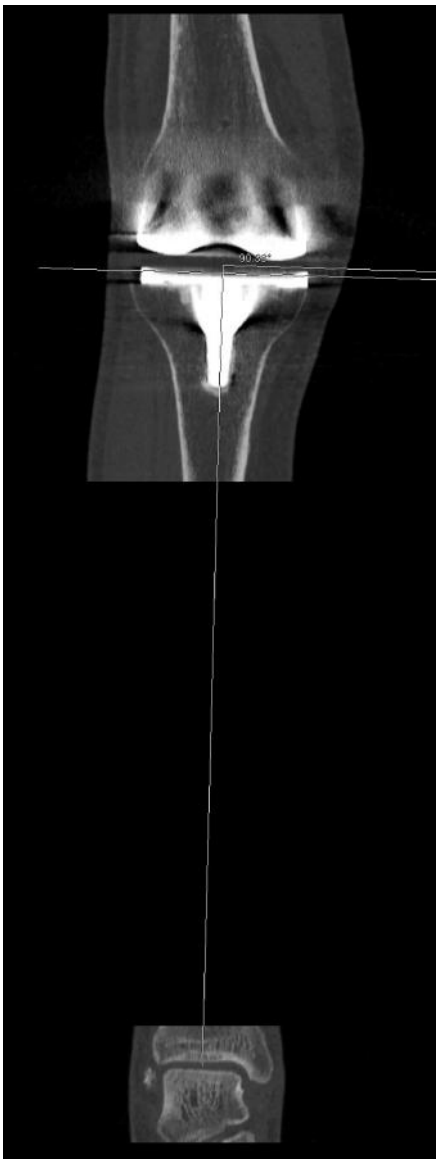
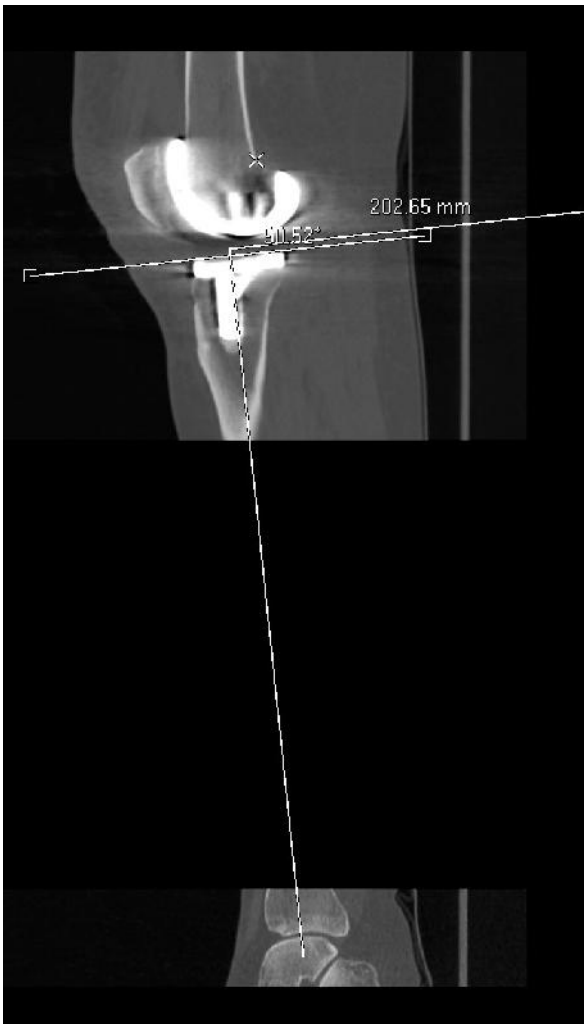
(a)  (b) 

Figure 3.6 CT scan performed at the six week review showing measurements taken. (a) Coronal mechanical tibial angle (b) Sagittal mechanical tibial angle.

3.2 Statistical Analysis

3.2.1 Power Calculation

The number of patients required for the study was calculated as follows. The primary outcome was taken to be the coronal lower limb alignment (mechanical femorotibal angle). It was expected that the mean alignment in each group would be 0° (this is the aimed for value). Based on previous data collected on navigated TKAs at GJNH hospital it was expected that the standard deviation of the alignment in each group would be 2.8°. To show equivalence of the two groups (TKA 4.3 and TKA Smart v1.0 software) an acceptable difference between the two means of 1° was chosen (the limit of the accuracy of the navigation system). For the study to have a power of 80% with an alpha of 0.05, ninety-eight patients were required in each arm of the trial.

This also gave a power of 80% to show a reduction in operation time of six and a half minutes. In addition, due to the short duration for which the patients were going to be in the study, the loss to follow-up was expected to be low. Consequently it was decided that 105 patients would be recruited in each group. However, this was increased to 110 patients in each group following the request of the ethics committee, an extra of twenty-four patients. This meant that twelve patients had to be lost from one group for the power of the study to be affected. Patients could be lost from the study for several reasons. Most commonly this is due to patient withdrawal. Other potential reasons include the use of the wrong software and data not being appropriately collected eg missing snapshots.

The power for this preliminary analysis is of 51% with an alpha of 0.05.

3.2.2 Data Analysis

Data analysis was performed using Excel 2007 (Microsoft Corp, Redmond, WA, USA) and SPSS 21.0 (SPSS Inc., Chicago, IL, USA).

Descriptive statistics were used to describe the cohort characteristics. The mean and standard deviation were calculated using Excel. The 95% confidence interval was also calculated for the clinical outcomes (ROM, alignment, OKS, KSS). ROM and alignment were compared at three different time scales, namely pre-operatively, intra-operatively and at the six week post-operative review. The change from the pre-operative to the six week post-operative OKS was also calculated.

Using SPSS, analysis of variance (ANOVA) tests were performed as follows. A three-way ANOVA test was performed for ROM (pre-operative, intra-operative and six week post-operative review) between the following subject factors – software, gender, side, surgeon, trackers, Kellgren Lawrence grade and Ahlback class. Two-way ANOVA tests were performed for alignment (pre-operative and intra-operative) and OKS (pre-operative and at six week post-operative review) between the previously described subject factors, namely, software, gender, side, surgeon, trackers, Kellgren Lawrence grade and Ahlback class. Since knee score, functional score and hence knee society score were only available at the six week follow-up appointment, a univariate ANOVA test was performed between the same subject factors as previously described. A result was deemed statistically significant if the p value was at 0.05 or less.

Chapter 4 – Results

4.1 Recruitment

This study is an ongoing study. This thesis therefore reports an analysis of the results of patients recruited between February and July 2012. 170 patients attended the relevant pre-assessment clinics at GJNH between 1st February 2012 and 25th July 2012. Of these, 96 patients met the inclusion criteria as shown in Figure 4.1. These patients were approached and the study was discussed. Of these 96 patients, 13 patients declined taking part in the study; four of these patients refused due to the radiation associated with the study. Another 6 patients had to be excluded on admission due to the patient being placed on another surgeon's operating list. Although patients were marked as potential study patients, losing patients to other surgeons was inevitable due to the NHS national waiting time targets. 14 patients did not have a date for their surgery by the 31st July 2012 and were excluded for the purpose of this thesis. 63 patients accepted to take part in the study. Table 4.1 shows the reasons for excluding patients at the pre-assessments clinics. These patients did not meet the inclusion criteria. Consequently these patients were not approached.

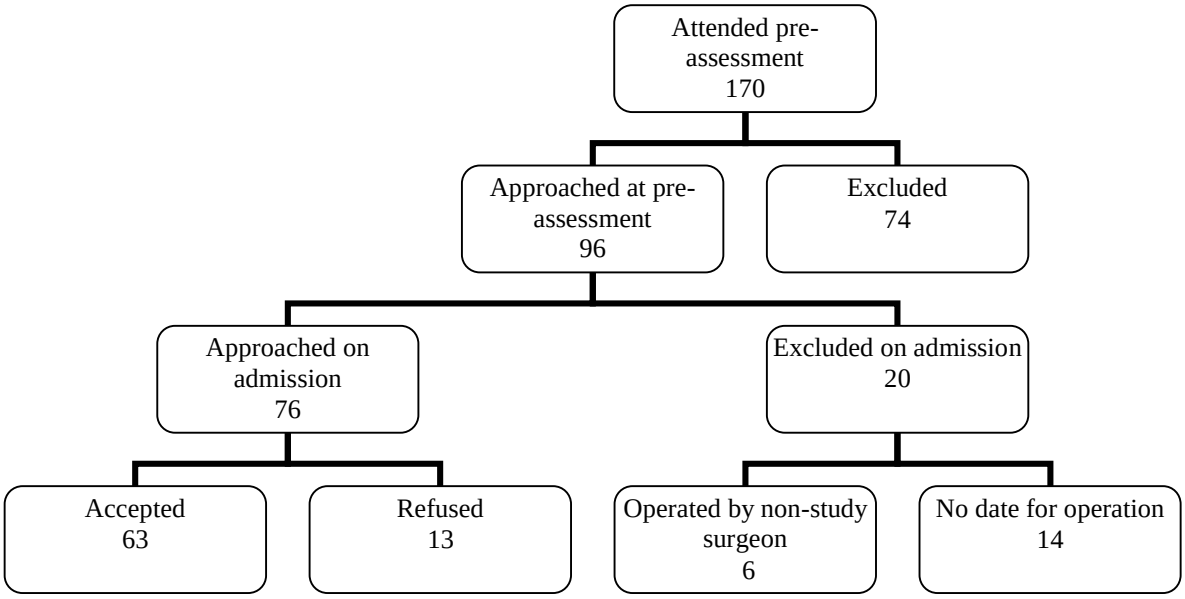


Figure 4.1 Flowchart showing the pathway taken by patients attending pre-assessment clinic.

Reason	Number of Patients
Other operation (eg Revision TKR, Arthroscopy, High Tibial Ostetomy etc)	33
Patient pre-assessed day before surgery (prior to second amendment)	12
BMI >40	11
Being pre-assessed for another surgeon	8
Not fit for surgery	5
Refused operation	3
Not able to return for follow-up	2

Table 4.1 Reasons for exclusion of patients.

4.2 Cohort Characteristics

63 patients (34 females) with an average age of 69.2 years (SD ±8.8 years) were recruited in the study. The mean BMI was of 30.9 (SD ±4.3) and most patients had mild systemic disease (ASA 2). Two patients suffered from rheumatoid arthritis (RA), though neither of these was on disease modifying drugs (DMARDs) that tend to affect the outcome following arthroplasty. Radiologically, most patients had moderate to severe osteoarthritis with 82.5% having a Kellgren Lawrence score of 3 or more and 74.6% falling in Ahlback class 2 or higher. The mean (95% CI) OKS (60 to 12 score used) was of 42.7 (40.9, 44.5) SD ±7.4. 62% of the patients had a varus deformity whilst 24% had a valgus deformity at the knee. The mean deformity was of 2.2° in varus (range -11° to 15°, SD ±5°). The range of motion was from a mean of 2.8° (range -11° to 20°, SD ±6°)

to 115.9° (range 86° to 139°, SD ±15°). The patients' characteristics, scores and knee alignment within the two groups were similar as shown in Tables 4.2 and 4.3.

	TKA 4.3	**Smart**
No of Patients	34	28
Gender (M : F)	13 : 21	15 : 13
Mean Age / years	69.3	69.2
BMI	30.7	31.2
ASA = 2	27	24
OKS	42.8	42.9

Table 4.2 Patient characteristics within the two randomised cohorts.

	TKA 4.3	**Smart**
K / L ≥ 3	27	24
Ahlback Class ≥ 2	34	23
Extension / °	2.7	2.8
Maximum Flexion / °	117.8	113
Varus : Valgus : Neutral	21 : 8 : 5	17 : 7 :4
Mean Alignment / °	- 2.1	- 2.3

Table 4.3 Patient scores, range of movement and knee alignment within the two randomised cohorts.

Intra-operatively, all patients except for one had a medial approach to the knee. The right knee was operated in thirty-five cases. In fifty cases, active trackers were used. All patients had a cruciate-retaining Columbus implant. The lateral parapatellar approach

was used in only one case, with the rest having a medial parapatellar approach to the knee. Four patients had intra-operative issues that would have influenced the recorded time. One of these patients (randomised to TKA 4.3 software) developed difficulties with breathing and hence the surgeon had to stop operating whilst the anaesthetist instituted the appropriate airway management. The other three patients had tracker related problems. In one case (randomised to TKA 4.3 software), re-positioning of the tracker was required, whilst in the other two cases (randomised to each software), two trackers (instead of the usual three) had to be used due to a malfunction of the tracker. Since this requires constant changing of the tracker leads in the console, this inevitably prolonged the registration and operation time.

Post-operatively, patients in both groups had a similar length of stay in hospital. The mean (95% CI) length of stay when using the TKA 4.3 software was of 4.2 days (3.7, 4.8) SD ±1.7 days and that for Smart software was of 4.3 days (3.6, 4.9) SD ±1.8 days. Of note is that at GJNH an enhanced recovery programme is in place to decrease the length of stay of the patients.

Three patients required re-admission within the first six weeks. Two of these re-admissions (one patient from each group) were due to leaking wounds. The third re-admission (randomised to TKA 4.3) was initially re-admitted at the local hospital with an inflamed wound and a possible infection. The only intra-operative finding was of an intra-articular haematoma. However, the patient required a further re-admission to GJNH a week later. At this point the patient's wound was still inflamed and the blood parameters were deranged. Microbiology results from the patient's local hospital were available and this showed the presence of *Enterococcus faecalis* bacterium. The patient underwent further surgery in which the joint was washed out and the polyethylene component was exchanged. The patient did not have any further complications. Intra-articular haematomas increase the risk of a joint infection (septic arthritis) especially in the presence of metal work as in a TKA. This is the likely cause of infection in this patient. Of note is that deep vein thrombosis (DVT) prophylaxis at orthopaedic department at GJNH was changed from aspirin to enoxaparin whilst inpatient and

rivaroxaban on discharge soon after the trial was started. This was as a result of hospital enforcement so as to be in accordance with the Scottish Intercollegiate Guideline Network (SIGN) (2010). Since the introduction of the new DVT prophylaxis regime, it was noticed that more patients were complaining of excessive bruising and swelling. Furthermore, more patients were re-presenting due to leaking wounds. This was not only noticed with the patients in the trial but also in non-study patients undergoing TKA as well as in patients admitted for a total hip arthroplasty who were also given the same DVT prophylaxis regime.

In addition to these three patients, another eight patients had a complication that did not require re-admission. Two patients (TKA 4.3 cohort) had excessive bruising and increased swelling potentially associated with rivaroxaban. Three other patients (Smart cohort) had wound leakage that was sero-sanguinous in nature. One patient (TKA 4.3 cohort) was still struggling with pain at the six weeks post-operative review. Another patient (TKA 4.3 cohort) had a tibial pin site infection which was attributed to suture material within the wound. The remaining patient (Smart software) had a local reaction to the suture material.

All the post-operative data was available. However some pre-operative data was missing. These were one OKS (Smart cohort) and four ROM (3 patients from the TKA 4.3 cohort and 1 patient from the Smart cohort). Since patients were recruited into the study just prior to their operation, it was inevitable that some pre-operative data will be missing as this would have been collected prior to the patients' recruitment. Furthermore, one patient (from TKA 4.3 cohort) was excluded from the study as the patient was unable to attend the six week review appointment at GJNH due to a change in family circumstances and is thus being followed up in the local hospital.

4.3 Primary Outcome: Clinical, Functional and Radiological

4.3.1 TKA 4.3 Software

The mean (95% CI) maximum flexion pre-operatively was of 117.8° (112.9°, 122.7) SD ±14.6°. This decreased slightly to 114° (110.8°, 117.2°) SD ±9.4° intra-operatively whereas the alignment improved from -2.1° (-3.9°, -0.3°) SD ±5.3° to a mean of -0.4° (-0.6°, -0.2°) SD ±0.7° intra-operatively, the negative sign meaning that the alignment is in varus. Similarly, the extension improved from a mean (95% CI) of 2.7° (0.4°, 5°) SD ±6.9° to an intra-operative mean of -0.5° (-1.2°, 0.2°) SD ±2.1°, a negative sign meaning hyperextension and a positive sign implying a fixed flexion deformity. At the six week review, the mean (95% CI) maximum flexion was of 100° (95.9°, 104.1°) SD ±12.1°. The difference between the two post-operative data is due to the fact that at their first review at six weeks post-operation, most patients would still be in pain and stiff and are therefore unable to reach their maximum potential which is demonstrated when the patient is under the influence of an anaesthetic at the time of operation. This decrease in flexion tends to improve by the mid-term review. The decrease in flexion at six weeks is comparable to other studies. Wakankar et al. (1999) reported at decrease of 13.7° in the maximum range of flexion at the six week review.

The OKS improved from a mean (95% CI) of 42.8 (40.2, 45.4) SD ±7.7 pre-operatively to 28.5 (25.9, 31.1) SD ±7.8. The mean (95% CI) improvement in OKS was 14.3 (10.9, 17.7) SD ±10. Two patients had the same OKS at six weeks as pre-operatively. One of these patients was still struggling with pain six weeks post-operatively. Two patients had a decline in the post-op OKS, one patient by one point whilst the second patient had a decline of seven points. However both patients were very satisfied with their operation and were doing well. Indeed one of these patients did not need any walking aids and the second patient needed one walking stick at six weeks post-operatively. Furthermore, both patients had very good scores pre-operatively (28 and 30) which may explain the slight worsening occurring so soon after the operation. The maximum improvement in OKS was of thirty-seven points. The mean (95% CI) KSS was of 133.3 (123.8, 142.8)

SD ±28.3, with the knee score component having a mean score of 69.5 and a mean function score of 63.8. With regards to satisfaction score, none of the patients were dissatisfied with their operation. However two patients were unsure of their satisfaction. One of these patients was still struggling with pain at the six week post-op review. The second patient still had swelling and pain at the review appointment which influenced the satisfaction score. The distribution of the satisfaction scores for both software is shown in Table 4.4. The radiological outcomes for both software are shown in Table 4.5.

4.3.2 TKA Smart Software

The mean (95% CI) intra-operative maximum flexion obtained with the Smart software was of 113.1° (108°, 118.2°) SD ±13.8°. This is similar to the mean pre-operative maximum flexion of 113.4° (107.4°, 119.4°) SD ±6°. Pre-operatively, the patient group randomised to Smart software had a mean (95% CI) fixed flexion of 2.8° (1.3°, 4.3°) SD ±4.1°. This improved to a mean (95% CI) hyperextension value of -1.5° (-2.3°, -0.6°) SD ±0.9°. Similarly, the pre-operative alignment improved from a mean (95% CI) of -2.3° (-4.2°, -0.3°) SD ±1.9° to an intra-operative value of 0.3° (0°, 0.6°) SD ±0.8°. The mean (95%CI) flexion at the six week review was less when compared to the intra-operative value. This was 100° (96.3°, 103.7°) SD ±10°.

The OKS improved from a mean (95% CI) of 42.9 (40.2, 45.6) SD ±7.2 pre-operatively to 24 (21.3, 26.6) SD ±7.1. All the patients randomised to the Smart software had an improvement in the OKS score at the six-week review when compared to the pre-operative OKS score. The mean (95% CI) improvement in OKS was 19 (15.6, 22.4) SD ±9.2. The maximum improvement in OKS was of 35 points whilst the least improvement was of 3 points. The mean (95% CI) KSS was of 153 (143.6, 162.4) SD ±25.4, with the knee score component having a mean score of 81.7 and a mean function score of 71.3. With regards to satisfaction score, all the patients were either satisfied or very satisfied with their operation as shown in Table 4.4. The radiological outcomes are shown in Table 4.5

	TKA 4.3	Smart
Very Satisfied	23	25
Satisfied	8	3
Unsure	2	0
Dissatisfied	0	0

Table 4.4 Patient reported satisfaction scores at the six week review appointment.

Mean Angles / degrees (SD)	TKA 4.3	Smart	p value
Coronal Mechanical Femoral (LDFA)	88.7 (SD ±1.3)	88.4 (SD ±1.7)	0.379
Coronal Mechanical Tibial (MPTA)	89.4 (SD ±1.1)	89.1 (SD ±1.5)	0.421
Sagittal Mechanical Femoral	1.3 (SD ±2.2)	0.3 (SD ±1.9)	0.048
Sagittal Mechanical Tibial	88.8 (SD ±1.8)	88.7 (SD ±1.3)	0.775
Rotational Alignment	- 0.2 (SD ±2.9)	- 0.8 (SD ±2.6)	0.487
Coronal Femorotibial (HKA)	- 0.5 (SD ±1.5)	- 0.3 (SD ±1.7)	0.532

Table 4.5 Radiological outcomes as determined from the CT scan at the six week review appointment.

4.4 Secondary Outcome: Operation and Registration Time

The mean (95% CI) total operation time with the TKA 4.3 software was of 68.6 minutes (64.6, 72.6) SD ±12 minutes whilst the registration time was of 210 seconds (193, 227) SD ±50 seconds.

The mean (95%) total operation time when using the Smart software was slightly less than when using the 4.3 software. This was of 67.3 minutes (62.5, 72.1) SD ±12.9 minutes. Similarly the mean registration time was less when using the Smart software – 166 seconds (146, 186) SD ±54 seconds.

4.5 Comparative Results

4.5.1 Primary Outcomes

4.5.1.1 Range of Movement

There was a statistical difference between the mean pre-operative maximum flexion and the mean maximum flexion at the six week review ($p = 0.002$) as shown in the graph below (Figure 4.2). However, no statistical or clinical significance between the two software was evident when compared for the final mean maximum flexion obtained. As previously discussed, there was an expected drop in the mean maximum flexion that was obtained at the six week review when compared to the intra-operative mean maximum flexion obtained under the influence of the anaesthetic. This is mainly as a result of pain and stiffness that is still present at the six week review. The maximum flexion obtained was not influenced by gender, laterality or initial classification score. The mean maximum flexion obtained was surgeon dependant ($p < 0.001$) with surgeon 1 having a higher post-operative mean maximum flexion when compared to the other surgeons as shown in Figure 4.3. However of note is that surgeon 3 had fewer cases which may have influenced the mean obtained.

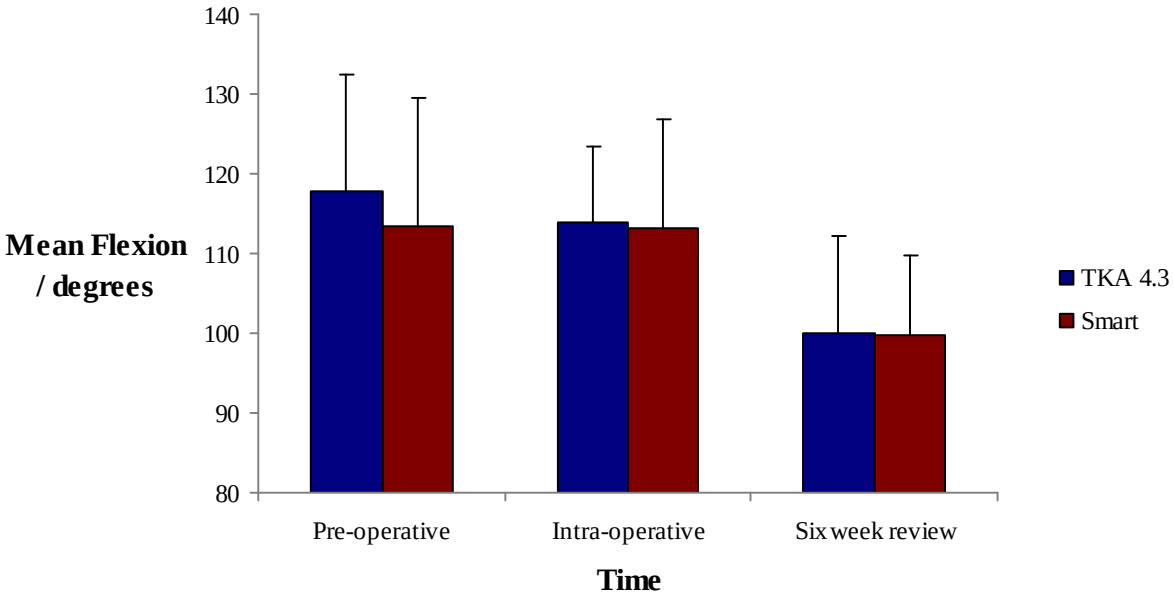


Figure 4.2 Graph showing the mean flexion (degrees) at the pre-operative, intra-operative and six week review assessments for the TKA 4.3 and Smart software.

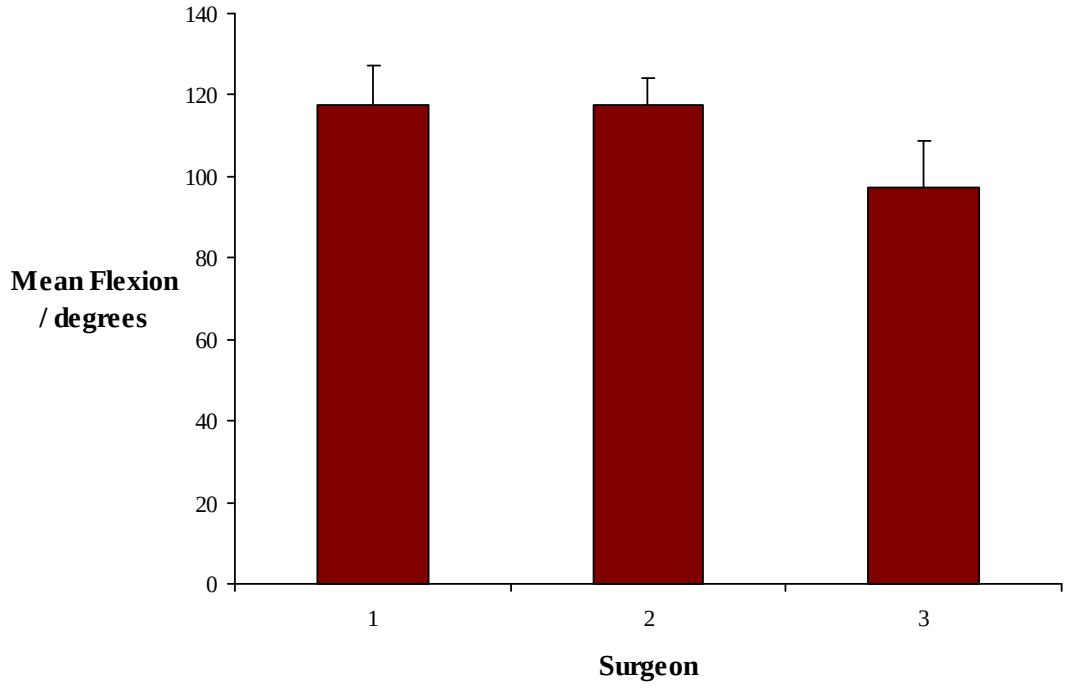


Figure 4.3 Graph of mean flexion (degrees) according to surgeon.

The change from the pre-operative mean extension to the final extension obtained at the six week post-operative review was statistically significant (p = 0.022). However there was no statistical significance between the two software (p = 0.641). Extension was subject to the same affect as flexion, namely a change between the intra-operative value and that at six-week review whereby the extension seemed to change to a more flexed value (that is, a more positive value) six weeks post-operation as shown in Figure 4.4. Once more, this may be as a result of the stiffness that results immediately following a TKA. Furthermore, patients may not be fully compliant with physiotherapy due to pain reasons. This may lead the adoption of a knee in slight flexion. Also, one should note that at the six week post-operative review, a manual goniometer is used which has a different limit of accuracy when compared to the computer software (limit of accuracy 1°).

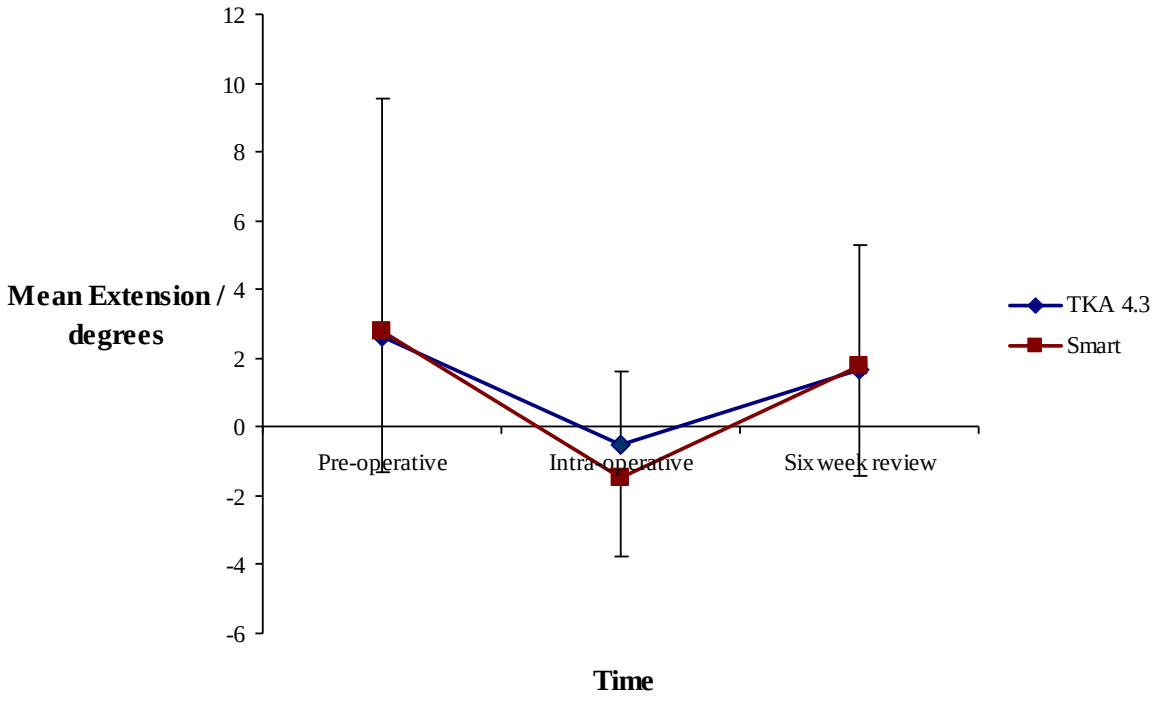


Figure 4.4 Graph showing the progression of the mean extension (degrees) from the pre-operative period until the six week review for both software. For clarity reasons, only positive error bars for TKA 4.3 and negative error bars for Smart have been drawn.

4.5.1.2 Oxford Knee Score

As discussed previously, both software showed an improvement in the mean six-week post-operative OKS when compared to the pre-operative OKS (Figure 4.5). Although this was statistically significant ($p < 0.001$), there was no statistical significance between the two software ($p = 0.216$). The OKS was statistically significantly lower ($p = 0.039$) in males when compared to females, both pre-operatively and at the six-week review appointment as shown in Figure 4.6.

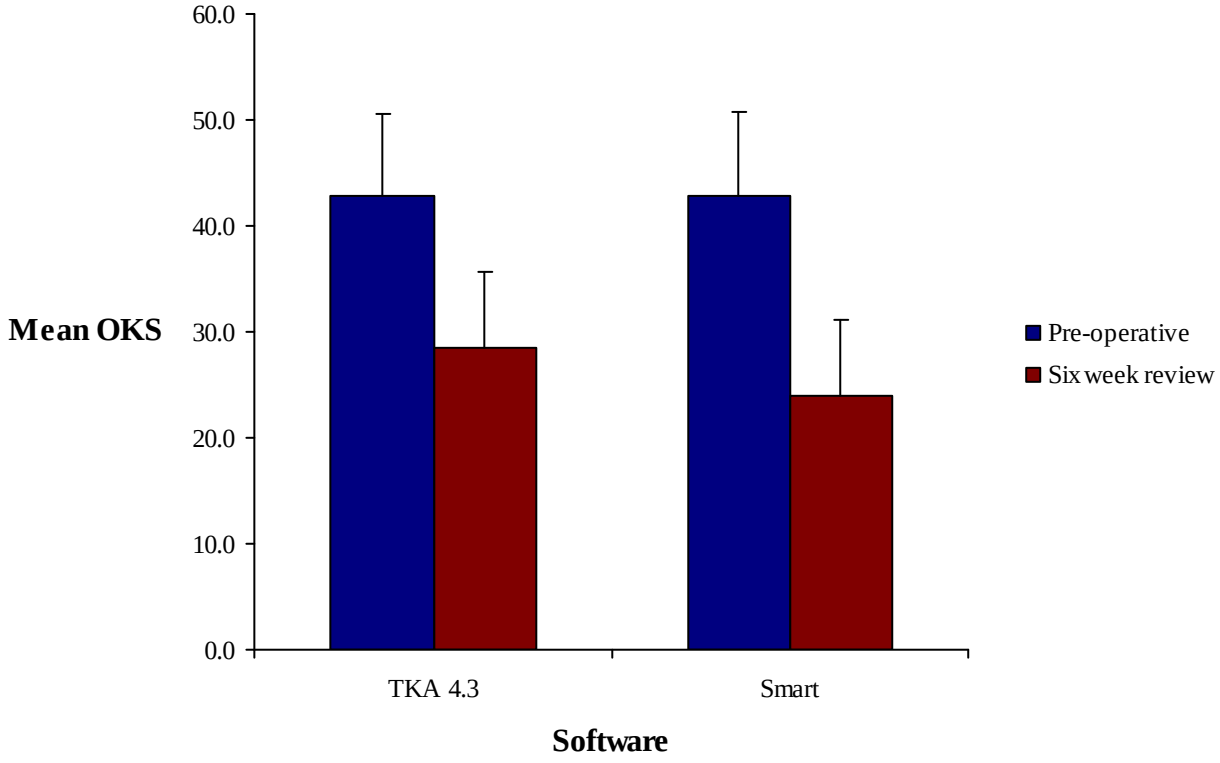


Figure 4.5 Graph showing the improvement in Mean OKS at the six week review when compared to that pre-operatively (60 to 12 score used).

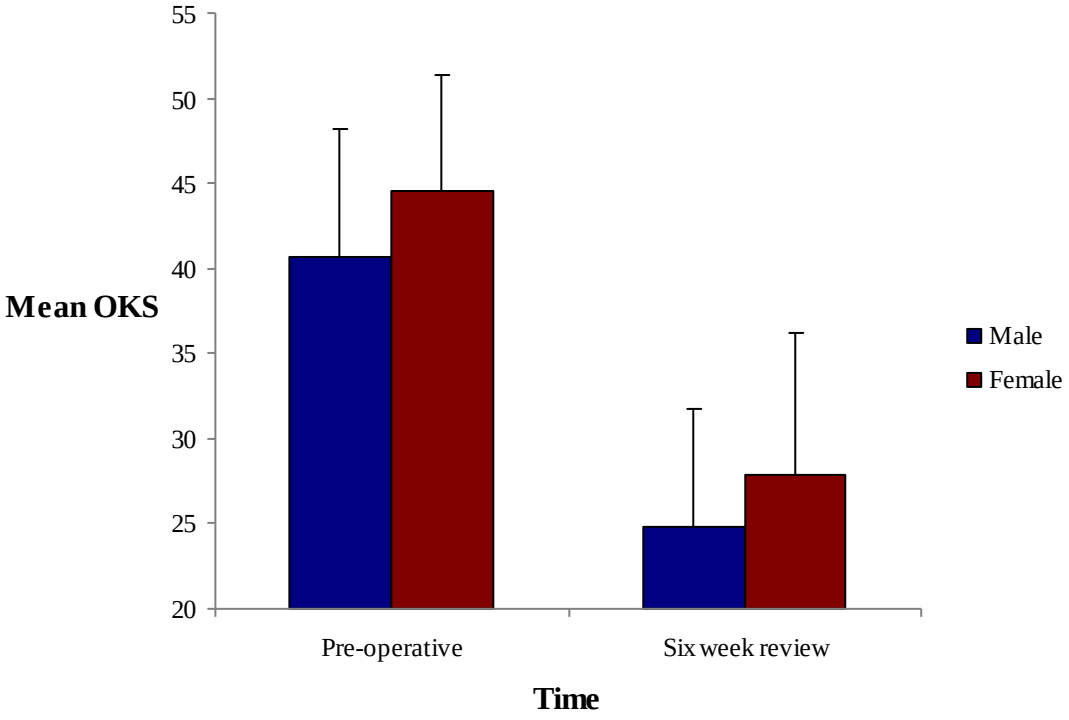
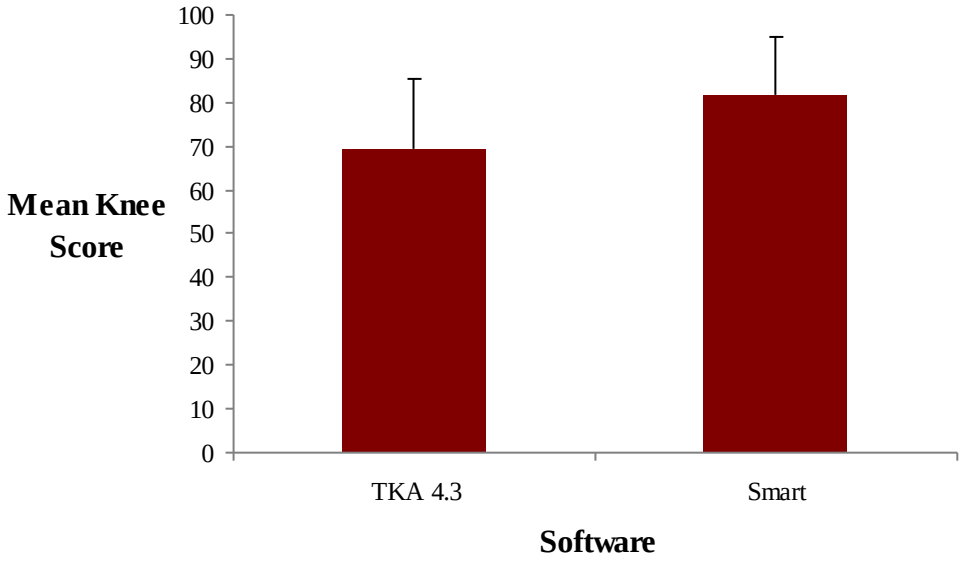


Figure 4.6 Graph of Mean OKS versus Time showing a statistically significantly lower mean OKS in males when compared to females at both the pre-operative and post-operative reviews.

4.5.1.3 Knee Society Score

The KSS as well as its knee score and function score components were higher in the group of patients randomised to the Smart software when compared to the patient group randomised to the TKA 4.3 software (Figures 4.7 and 4.8). However this was not statistically significant. This lack of statistical significance may have been to due to small sample size.

(a)



(b)

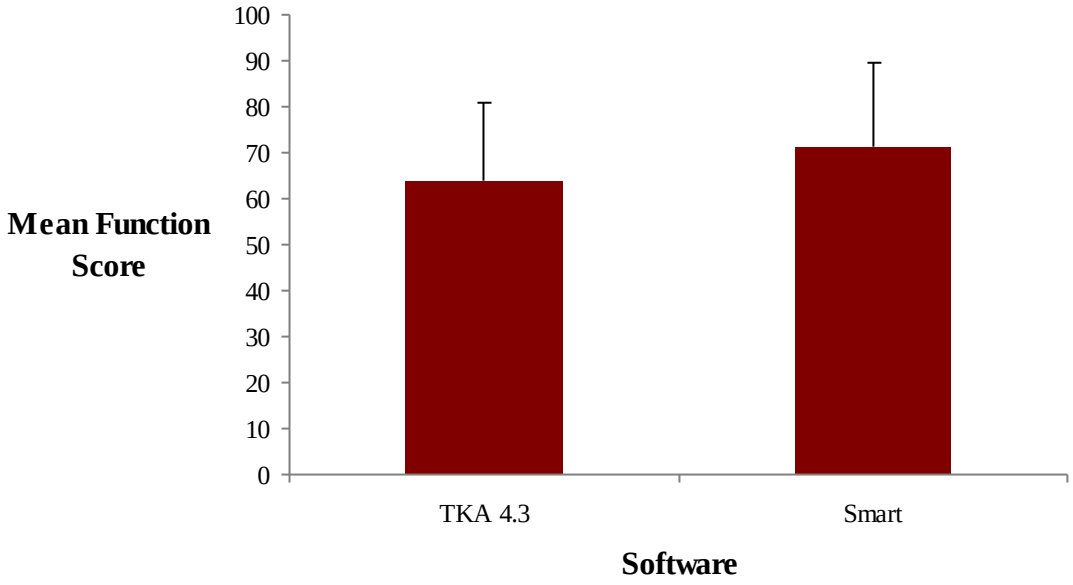


Figure 4.7 Difference in the mean scores of the components of the KSS according to software - (a) Mean knee score. (b) Mean function score

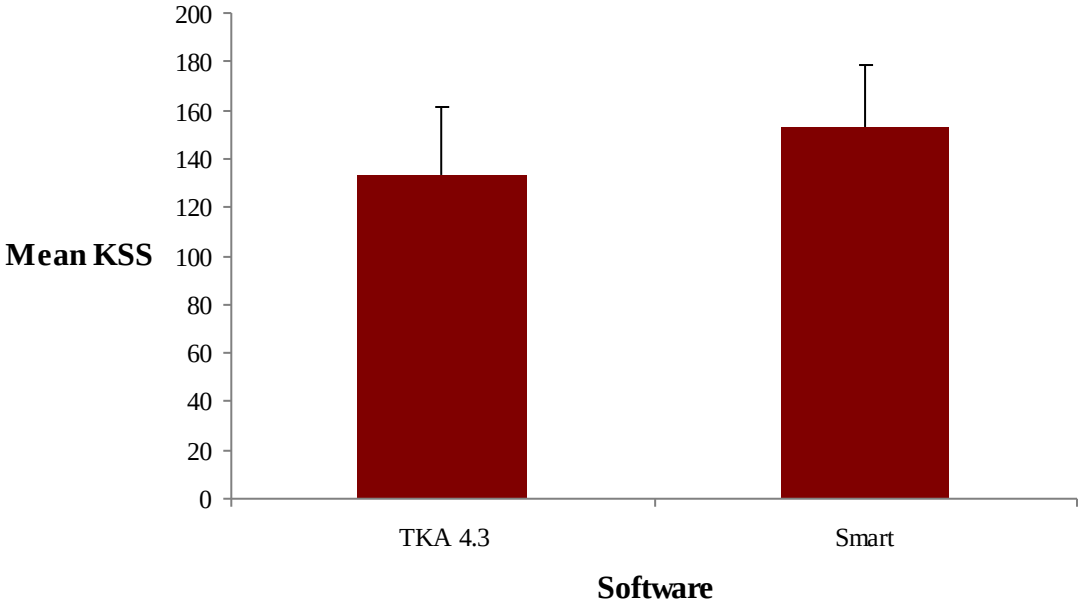


Figure 4.8 Mean KSS score according to software. The post-operative mean KSS score was higher in the cohort randomized to the Smart software albeit this not being statistically significant.

4.5.1.4 Alignment

The analysis of alignment was split into two parts. The first calculation compared the pre-operative alignment with the alignment achieved intra-operatively whilst the patient was anaesthetised. The second part compared the alignment taking into account the alignment that was calculated from the CT scan taken at the time of the six week review.

When comparing the pre-operative to the intra-operative alignment, there was no statistical significance between the two software. Furthermore, when the pre-operative alignment of all the patients was compared to the intra-operative alignment, no statistical significance was reached, albeit an improvement being present as shown in Figure 4.9. Indeed the alignment improved from an initial mean alignment for the population of 2.2° in varus (range: 11° varus to 15° valgus) to an intra-operative mean alignment of 0.2°

varus (range: 3° varus to 2° valgus). The reason for the lack of statistical significance despite a clinical significance may be due to the small population size.

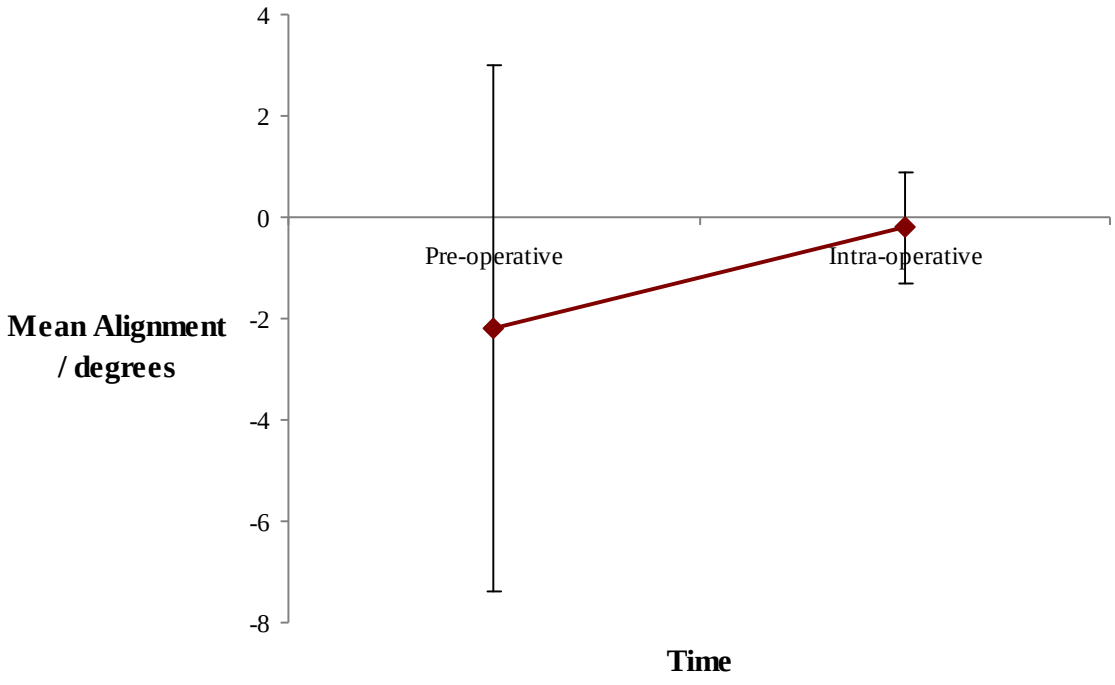


Figure 4.9 Improvement in the intra-operative mean alignment (degrees) when compared to the pre-operative mean alignment (degrees).

When the alignment at the six week review was taken into account, it was found that the mean alignment changed from slight varus intra-operatively to a slight valgus alignment at the six week review as shown in the plot of mean alignment versus time (Figure 4.10). Albeit still not reaching statistical significance ($p = 0.78$), a trend towards statistical significance can be seen suggesting that this lack of statistical significance may be due to the small sample size.

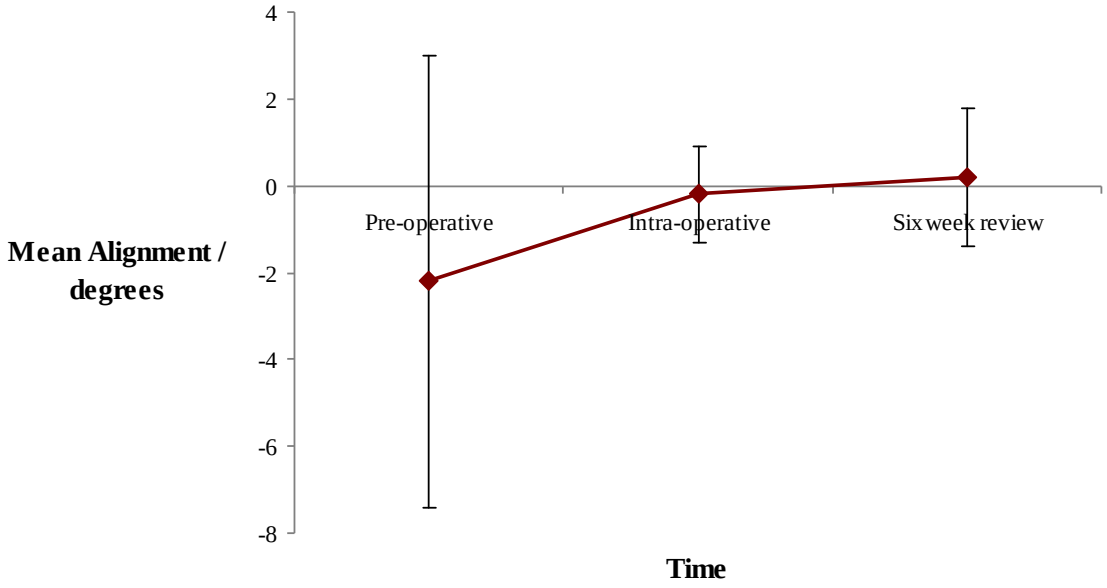


Figure 4.10 Progression of the mean alignment with time. The mean alignment (degrees) progressed from a varus alignment pre-operatively to an almost neutral alignment intra-operatively. This continued to progress to a more valgus alignment at the six week review.

4.5.2 Secondary Outcome

Although the registration time when using Smart software is indeed on average shorter than when using the older version TKA 4.3 (Figure 4.11), the difference of 44 seconds is not clinically significant despite being statistically significant ($p = 0.001$). Furthermore although using Smart software resulted in a slightly shorter operation time (78 seconds), this was neither statistically ($p = 0.681$) nor clinically significant.

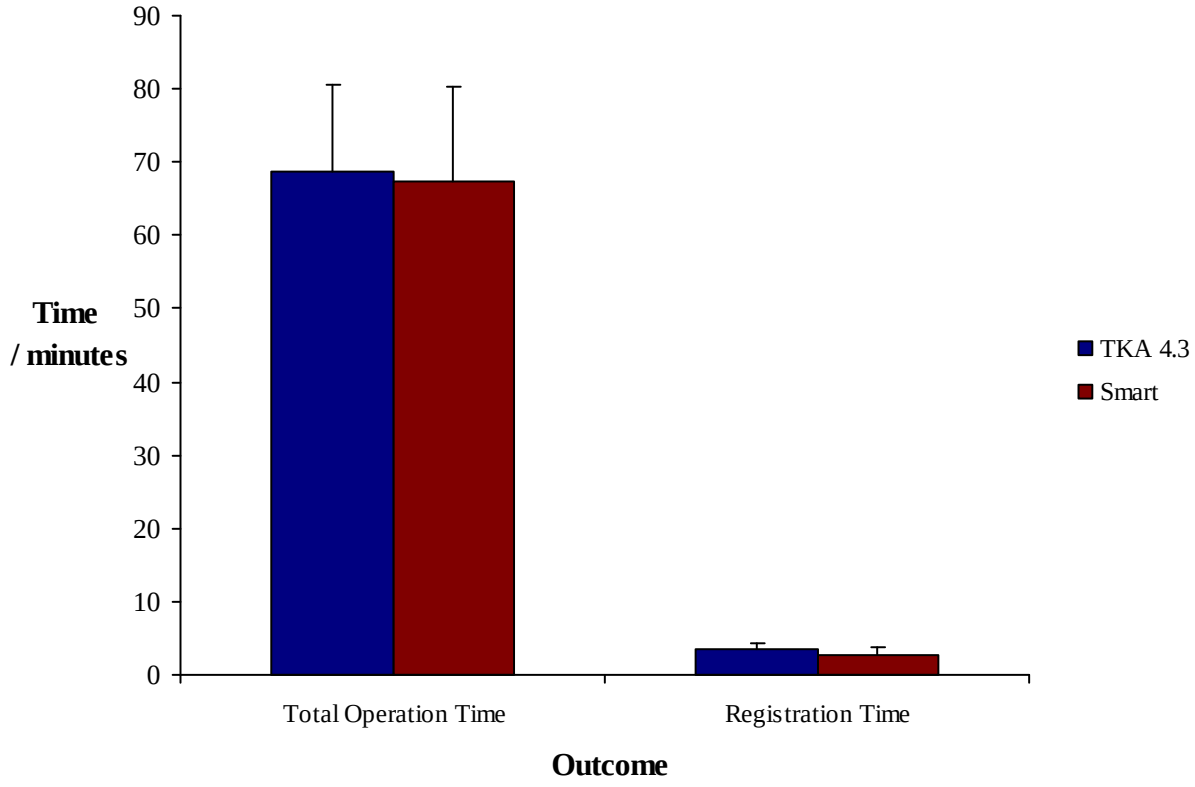


Figure 4.11 The total operation time and registration time were on average shorter when using the Smart software. However this was not clinically significant albeit a statistically significant difference in registration time.

Chapter 5 – Discussion

Clinical, functional and radiological outcomes are normally reported at a minimum of 1 year. Thus there are few studies reporting these outcomes at six-weeks. However, the results of the study show that the short term clinical, functional and radiological outcomes of patients in this study are comparable to short term and mid-term outcomes reported in the literature. The mean maximum flexion for the cohort at six weeks was of 114° (SD ±11.8°). This is similar to the pre-operative maximum flexion of the 115.9° (SD ±15.3°). This is better than the maximum flexion at six weeks reported in another study (Wakankar et al. 1999) and comparable to the mid-term and long-term results reported in the literature (Shurman et al. 1998, Callaghan et al. 2000). Similarly, the mean extension (-0.9°) and alignment (-0.2°) were within the accepted limits. Furthermore, the knee score (75 SD ±16) and function score (67.2 SD ±17.9) components of the KSS were similar with those reported by Schmitt et al. (2011) at twelve weeks.

The radiological measurements for the cohort (Table 5.1) were also within the accepted limits (Schmitt et al. 2011). Of note is that the tibial slope is related to the sagittal mechanical tibial angle as it is the anteroposterior axis of the tibial plateau on the sagittal view. Furthermore, the sagittal mechanical femoral angle is an indication of the amount of flexion that the femoral component is placed in. The sagittal rotation of a femoral component can influence the kinematics of a replaced knee (Chung et al. 2009). A femoral component that is placed in an overly flexed position can cause limited extension or polyethylene wear. Conversely, a femoral component that is placed in an overly extended position relative to the femur, may notch the anterior femoral cortex. It is thought that femoral notching may increase the risk of a supracondylar fracture.

The preliminary results of the study show that in terms of clinical, functional and radiological outcomes, TKA Smart software is equivalent to the TKA 4.3 software albeit having a shorter registration process and the lack of ankle kinematics. The KSS as well

as its knee score and function score components were higher in the group of patients randomised to the Smart software when compared to the patient group randomised to the TKA 4.3 software. This difference in clinical score between the two software was not apparent when the OKS was used. This may be due to the fact that OKS is more subjective and despite asking patients to only consider the knee joint operated, it is

Mean Angles / degrees (SD)	**Cohort Values / degrees**	**Normal Values / degrees**
Coronal Mechanical Femoral (LDFA)	88.5 (SD ±1.5)	87 – 93
Coronal Mechanical Tibial (MPTA)	89.2 (SD ±1.3)	87 – 93
Sagittal Mechanical Femoral	0.8 (SD ±2.1)	0 – 5
Sagittal Mechanical Tibial	88.7 (SD ±1.6)	87 – 90
Tibial Slope	1.3 (SD ±1.6)	0 – 3
Rotational Alignment	- 0.4 (SD ±2.8)	-3 – 3
Coronal Femorotibial (HKA)	- 0.4 (SD ±1.6)	-3 – 3

Table 5.1 Radiological outcomes of patients in the study.

difficult for the patient to do so. For example, one of the question in the OKS asks the patient “Can you do household shopping on your own?”. If the patient is unable to shop on his/her own, the OKS assumes that this is because of the knee. However other factors may prevent the patient from shopping. These may include pain in other joints, medical conditions or social reasons. On the contrary, the KSS is more objective and has both a clinical assessment component (knee score) in addition to a functional component (functional score). Interestingly, the OKS did show gender differences with OKS being somewhat better both pre-operatively and post-operatively in males when compared to females. However this was not the case with the KSS as no gender relations were found.

Despite Smart software having a shorter registration time, this did not really affect the total operation time. This is mainly due to the fact that the total operation time is not entirely dependant on the registration time or the navigation system. Several factors such as anaesthetic issues (as was the case with one of our patients), problems with the surgical trays, need for instruments that are not standard on the tray, etc will all increase the total operation time even though a software with a shorter registration process may be used. Furthermore, the surgeons in the study are accustomed to using the older software without any problems. This is reflected in the short mean registration time of 210 seconds (3½ minutes) when using the older version. However, the difference between the two software may be more marked in surgeons who do not routinely use navigation when performing a TKA and therefore may have a longer registration process. The shorter registration process of Smart software may therefore be more pronounced in such cases.

In addition the mean total operation time of about 67 minutes for a navigated TKA is much shorter than what is normally reported in the literature. An increase in operation time of up to 20 minutes when comparing navigated TKA to conventional TKA has been reported in the literature (Kinzl et al. 2004, Cheung et al. 2009). Indeed the mean operation time of 67 minutes is also less than that normally reported for a conventional TKA. Cheung et al. (2009) had a mean operation time of 98 minutes for conventional TKA and 111 minutes for navigated TKA. Similarly Yasunaga et al. (2009) reported a mean total operation time of 127 minutes for conventional TKA. This strongly suggests that navigation does not really prolong the total operation time if one uses it on a regular basis and is therefore accustomed with the system. Some surgeons use navigation only in cases that are deemed to be difficult. However in such circumstances, the surgeon will inevitably find it harder and longer to operate using the navigation system as in addition to having a more difficult case than usual, the surgeon is having to operate using unfamiliar equipment. The study shows that it is possible to reduce the total operation time (skin to skin) for a navigated TKA if this is used on a regular basis so that both the operating surgeon as well as other theatre staff are familiar with the system.

One of the advantages of using navigation is that the surgeon is able to have real time feedback. Also navigation allows the surgeon to keep a record of the intra-operative results which can then be compared to the end results at the post-operative review. This allows us to perceive any post-operative changes that are occurring. Analysis of the alignment is a clear example of this. Figure 4.10 shows that the alignment continued to change following the operation. Indeed the alignment changed from a slight varus intra-operatively to a slight valgus alignment at the six week review. One might argue that this change is simply due to a measuring error. The operative alignment was measured using the navigation software whereas the alignment at six week was measured from the CT scan which introduces the element of human error. However, the change may be real and it may be that changes in the implant position are occurring during the first six weeks following initial weight bearing by the patient. Thus further studies addressing this possibility are needed. Furthermore, the final results once the study is completed may suggest whether such differences are due to a measuring error or a true change in alignment on weight bearing.

This study has several strengths. It is a double-blinded randomised controlled trials with respect to clinical, functional and radiological outcomes. The study is also being performed by two surgeons who have a different degree of experience with using the navigation system. This ensures that the results can be extrapolated to other centres. The use of CT scans instead of x-rays clearly enhances the accuracy of the radiological outcomes. The main limitation of these results is that these are preliminary results. The power calculation showed that 196 patients were required so that the study would have a power of 80%. The power for this preliminary analysis of the first 63 patients in the study is of 51%. Consequently, there is a high probability of committing a type II error at this stage leading to the failure of rejecting a false null hypothesis. The study is still ongoing and further analysis at the end of the study will be made.

One possible confounding issue is that two months after starting the study, the DVT prophylaxis regime was changed to conform with the SIGN guidelines. The analysis was therefore repeated with the patients having the operation prior to the change in DVT

prophylaxis being excluded. However, the exclusion of those patients did not have a major effect on the findings reported in this thesis, hence they were retained.

Chapter 6 – Conclusion and Further Work

6.1 Summary

This thesis sought to validate the TKA Smart v1.0 software that has recently been launched on the market. The aims were to compare the clinical, functional and radiological outcomes with those of the older software TKA 4.3 to ensure that the outcomes obtained with TKA Smart software are as good as those obtained with TKA 4.3 software. In addition, the possibility of a reduction in total operation time when using TKA Smart software was also investigated.

The preliminary results of this randomised controlled trial show that the six week outcomes in our study are comparable to the one year outcomes of other studies mentioned in the literature. 97% of the patients were either satisfied or very satisfied with their surgery. The mean maximum flexion at six weeks was of 114° (SD ±11.8°) which is comparable to the long-term results reported in other studies (Shurman et al. 1998, Callaghan et al. 2000). Similarly patients had a satisfactory OKS and KSS scores at six weeks, even though at this time most patients would still be recovering from surgery. In addition, the mean alignment of -0.2° is well within the accepted limits of 0° ±3°. Furthermore, the use of CT-scan at six weeks rather than the hip-knee-ankle x-rays standardised the radiological measurements.

The preliminary results of this study indicate that there may be no difference between the two software despite the fact that TKA Smart software uses less reference points and the lack of ankle kinematics during the registration process. However the results presented in this thesis are those of the preliminary study and full completion of the study is required to ensure no difference between the two software. Although no significant change in total operation time was found for the TKA Smart software in the preliminary results, the reduction in the number of steps during the registration process may make the navigation system easier to use for surgeons who are wanting to start

using a navigation system. Furthermore, a difference in total operation time between the two software may be evident once all the patients are recruited.

Moreover, the mean total operation time for patients in the study (67 minutes) is much less than that quoted by Kinzl et al. (2004) and Cheung et al. (2009) who quoted an increase in the mean operation time when using navigation of up to twenty minutes. Certainly this operation time of 67 minutes is even less than that quoted for conventional TKA (98 to 127 minutes). This strongly suggests that navigation does not really prolong the total operation time if one uses it on a regular basis thereby allowing the surgeon and theatre staff to become accustomed with the system. This absolute quantification of the time difference, if any, in total operation time between navigated and non-navigated TKA could be shown by adding a third group of patients undergoing conventional non-navigated TKA. However this was beyond the scope of the study being presented.

6.2 Further Work

An interesting observation is that resulting from the analysis of the alignment. This showed a difference in the alignment between the intra-operative and six week alignment. The alignment changed from a slight varus intra-operatively to a slight valgus alignment at the six week review. However, one must remember that this is only a preliminary analysis and further analysis once the study is completed is required. Analysis of the final 220 patients will prove or disprove such observations. Indeed further studies looking at the difference between intra-operative software measurements and six-week radiological measurements may be required. Furthermore, the final analysis once the randomised controlled trial is finalised will reinforce the results obtained from the preliminary analysis for this thesis.

6.3 Conclusion

The preliminary analysis of the randomised controlled trial suggest that the clinical, functional and radiological outcomes obtained with TKA Smart v1.0 software are comparable to the older version TKA 4.3 despite the reduction in registration steps.

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Appendix 1 – Radiation Dose Assessment

Acute Services Division

NHS
Greater Glasgow and Clyde

Diagnostics Directorate
DEPARTMENT OF CLINICAL PHYSICS AND BIO-ENGINEERING
Health Physics
West House (Ground Floor)
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow G12 OXH

Telephone: 0141 211 3428
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E-mail: andy.brennan@ggc.scot.nhs.uk

memorandum

To: Ms Nadia C Sciberras, Clinical Research Fellow,
Department of Orthopaedics, Golden Jubilee National Hospital,
Agamemnon Street, Clydebank G81 4DY

From: Mr A G Brennan

Date: 10th October, 2011

Subject: **IMPERIAL KNEE CT PROTOCOL**

1. Radiation Dose Assessment

A radiation dose assessment for the proposed examination protocol is tabulated below. My interpretation of the supplied data is that these patients are expected to have 1 additional examination from their involvement in this Study. The additional dose will result from a proposed Imperial Knee CT protocol. I've calculated the dose on the basis of measurements for the Imperial Hip CT protocol. GE has yet to set up the scanner consistent with these protocols. A DLP will be established when this has been done.

Radiological Protocol	Examination	Total Effective Dose (mSv)	Additional Lifetime Fatal Cancer Risk	Risk
Expected	Proposed Imperial Knee CT protocol	0.6 mSv	1 in 33,000	Minor

The total research protocol dose is 0.6 mSv, i.e. the expected dose for the proposed examination protocol at GJNH site.

2. Risk Estimate

0.6 mSv effective dose is equivalent to 14 weeks background radiation and represents an additional risk of lifetime fatal cancer of 1 in 33,000. It is in the Minor Risk category for bio-medical research (ICRP Publication 62, 1991).

A G Brennan
Radiation Protection Adviser
& Consultant Medical Physicist

c.c. Mrs E Philips, CT, Dr Catherine Sinclair, GJNH, Dr G Baxter, Radiology, Mrs P McKay, X-ray

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Appendix 2 – Letter to General Practitioner

Golden Jubilee National Hospital
National Waiting Times Centre Special Health Board
Chair Jeane Freeman
Chief Executive Jill Young

Agamemnon Street
Clydebank G81 4DY
Scotland
Telephone 0141 951 5000

Department of Orthopaedics
Consultant:
Direct Tel:
Fax:
Date:

GP Address

Dear Dr [GP Name],

RE: Patient Name
DOB:
CHI:

This letter is to make you aware that your patient has kindly agreed to take part in a randomised controlled trial being organised by the research department at the Golden Jubilee National Hospital. The study aims to assess a new version of the software that is in use for patients undergoing a primary navigated total knee replacement. The patients will be randomly selected to undergo the operation using either the older version or the newer version of the application. The patient will have routine post-op rehabilitation and follow-up. Thus their participation in this study will have no bearing on their clinical care.

All information from the study will be kept strictly confidential. Patients will be assigned a study code and all personal identifiers will be removed from the data for the purposes of publication and presentation. You will also be informed of any arising issues pertaining to the participation of your patient in this study. At the conclusion of the study we will send you a letter to give you the results of the study.

If you have any questions about the above please do not hesitate to contact me.

Yours sincerely,

[Consultant Name]
Consultant Orthopaedic Surgeon

Appendix 3 – Patient Information Sheet

Golden Jubilee National Hospital
NHS National Waiting Times Centre
Chair Jeane Freeman
Chief Executive Jill Young

Agamemnon Street
Clydebank G81 4DY
Scotland
Telephone 0141 951 5000
Fax 0141 951 5500

Research study
Patient information sheet

Validation of TKA smart v1.0 software

We would like to invite you to take part in our research study. The study is being organised by the Golden Jubilee National Hospital and Aesculap AG (Germany) who manufacture the software.

Before you decide if you would like to be part of this, we would like you to understand why the research is being carried out and what you would need to do as a participant.

Please take the time to read the following information carefully and discuss it with others if you wish in order to decide whether or not you would like to take part.

- **Part one tells you the purpose of this study and what will happen to you if you take part.**
- **Part two gives you more detailed information about how the study will be run.**
- **Part three includes contact details for general information about research and this study in particular.**

A member of our team will go through this information sheet with you

Part one – Purpose of the study

What is the purpose of the study?

The hospital has been supplied with a new version of the software (called TKA smart v1.0) used to perform total knee replacements with the Orthopilot navigation system. The new software is quicker than the older version. We want to make sure that although the operation time is reduced, the clinical results are still satisfactory.

Why have I been invited?

You have been selected as suitable because you are going to have a computer navigated total knee replacement operation under the care of Mr F. Picard, Mr D. Allen or Mr J. Baines. We wish to have a total of 220 patients in the study, and will be asking all patients who are suitable.

Do I have to take part?

No. It is up to you to decide. We will describe the study to you and go through this information sheet, which we will then give to you.

If you do decide to take part in the study we will ask you to sign a consent form to show that you have agreed to take part. You are free to change your mind and stop being in the study at any time, without giving a reason. This will not affect the care you receive.

Similarly, if you choose not to take part in the study you do not have to give us a reason and this will not affect the care you receive.

What will happen to me if I take part?

The type of computer program used in your surgery will be decided by chance rather than by your consultant. This is because we do not know whether using the new program makes any difference. To find out we need to compare different treatments. We put people into two groups. One group has the operation using the older version of the computer program. The other group has the operation done using the new computer program. The results are compared to check they are the same. To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly). Your GP will be notified that you are taking part in this study unless you have any objection to this.

What will I have to do?

Your inpatient stay in hospital will be no different than it would be if you were not taking part in the study. Following the operation it will be arranged for you to have a CT scan of your new knee. This is a very detailed scan using x-rays which allows us to accurately analyse the position of the knee replacement. We will also ask you to complete an additional two questionnaires. Apart from this, you will have the same follow-up appointments as patients who do not take part in the study. All other information for the study will be collected at these routine appointments.

It is important for the study that you are able to attend hospital for your first outpatient appointment about six weeks after your operation. This will normally take place in the afternoon.

What are the possible disadvantages and risks of taking part?

By taking part in this study you will be exposed to a slightly increased dose of radiation than would otherwise be the case. This is because you will have a CT scan rather than the routine x-ray of the whole leg to assess the position of the knee replacement. However, we will be using a CT protocol that reduces the radiation you receive. The dose has been calculated by our radiation protection advisor. This has been estimated to be equivalent to two months worth of extra background radiation with a 1 in 33,000 chance of a cancer risk. This is classified as a minor risk. The ethics committee is happy with this radiation level._ No matter which group you are in you will have the same implant that would normally be used in your knee replacement operation.

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study may help in the treatment of other people having computerised navigated total knee replacement.

What happens when the research study stops?

You will continue to receive the same care as all orthopaedic patients treated at the Golden Jubilee National Hospital.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in part two.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in part two.

This completes part one. If you are considering participation, please read the additional information in part two before making your final decision.

Part two – Further information about the study

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time by speaking to a member of the research team, either by telling them when they are meeting with you, or by asking to speak with them at other times. You may also withdraw from the study by writing to us. You do not have to give a reason for withdrawal and the care you receive will not be affected because of your decision.

If the study is stopped for any reason, you will be told why. Your care will not be affected.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. You can contact them on 0141 951 5966.

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital by contacting:

The Complaints Officer
Golden Jubilee National Hospital
Agamemnon Street
Clydebank
G81 4DY
Telephone 0141 951 5440

In the event that something goes wrong and you are harmed during the research due to someone's negligence then you may have grounds for legal action or compensation. You may have to pay legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of this study will be kept strictly confidential and securely in line with Caldicott principles and the Data Protection Act 1998. If you join the study we will collect data from you for the study on paper forms. This will be kept securely within the Golden Jubilee National Hospital. Copies of this data may be kept on NHS computers which are password protected. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised.

Will my GP be notified of my participation in the study?

We will tell your GP (or other health care practitioner) that you are taking part in this study. This is because they are responsible for your health so need to know what is happening to you. We will ask you to agree to this on the consent form for the study.

Who is organising and funding the research?

The study is organised by the research team at the Golden Jubilee National Hospital. It is sponsored by the Golden Jubilee National Hospital. Aesculap AG (Tuttlingen, Germany), which owns the OrthoPilot TKA smart v1.0 application, are funding the study.

What will happen to the results of the research study?

The result of the study will be published as articles in medical journals. A summary of the result will be sent to your GP to discuss with you. This will also let you know how to ask for copies of the papers. The study data will be kept on a secure database and may be used to follow up the long term outcomes (up to ten years) of your operation. You will not be identified in any report or publication unless we have asked you if this okay and you have agreed to it.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the West of Scotland Research Ethics Committee 5.

Thank you for taking the time to read this information. If you would like any more information on this study, please contact a member of the research team who will answer any of your questions.

Part three – Contact details

For specific information about this study, contact:

Ms Nadia C Sciberras
Clinical Research Fellow
Department of Orthopaedics
Golden Jubilee National Hospital
Agamemnon Street
Clydebank
G81 4DY
Tel: 0141 951 5966

For independent information about this study, contact:

Mr Andrew Kinninmonth
Consultant Orthopaedic Surgeon
Department of Orthopaedics
Golden Jubilee National Hospital
Agamemnon Street
Clydebank
G81 4DY
Tel: 0141 951 5477

For general information about research, contact:

Dr Catherine Sinclair
Research and Development Manager
Golden Jubilee National Hospital
Agamemnon Street
Clydebank
G81 4DY
Tel: 0141 951 5440

Appendix 4 – Ethical and Management Approval

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

West of Scotland REC 5
Ground Floor - Tennent Building
Western Infirmary
38 Church Street
Glasgow
G11 6NT

Date 20 December 2011

Direct line 0141 211 2102
Fax 0141 211 1847
E-mail sharon.macgregor@ggc.scot.nhs.uk

Mr Frederic Picard
Consultant Orthopaedic Surgeon
NHS National Waiting Times Centre
Department of Orthopaedics
Golden Jubilee National Hospital
Agamemnon Street
Clydebank
G81 4DY

Dear Mr Picard

Study title: **Validation of TKA smart v1.0 software: Are the clinical outcomes the same as the TKA v4.3 software?**
REC reference: **11/WS/0125**
Protocol number: **11/ORTH/04**

The Research Ethics Committee reviewed the above application at the meeting held on 14 December 2011. Thank you for attending to discuss the study.

Ethical opinion

The Committee discussed this study and noted that this study will follow normal practice apart from using the new software prior to the operation and then a CT scan will be done instead of or in addition to an x-ray. The CT scan involves radiation but this is a minimum amount, equating to 2 months worth of extra background radiation which carries a cancer risk of 1 in 33,000. The Committee were happy with the radiation levels but noted that this was not explained clearly in the PIS.

There were concerns whether the software had previously be used or trialled elsewhere. The Committee wanted assurance that the new software could not potentially be worse than the current software. Also, there were concerns that the statistics were likely to be under-powered for demonstrating equivalence.

You were then invited to join the meeting and the above questions were discussed with you.

You confirmed that the TKA smart v1.0 was an upgrade of the TKA v4.3 software. The new software is a rearrangement of the registration phase, with the only difference being the flow of the registration.

Also, there is no possibility that the outcome of the surgery could be worse than by using the current system. The Committee then asked why a CT scan in being done if the researchers are certain the new system is better. You clarified that they need the results from the CT scan to prove that the new system works.

The Committee asked if there were arrangements in place to have the scans reported by a Radiologist as they were aware that only one NHS Radiologist was able to do this. You confirmed that a Radiologist, who is independent of the NHS, will report the scans. He will

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be blinded to what software was used as only the surgeons will know this information.

With regards to the possible chance of the study being under-powered, it was suggested that the researcher aims to recruit 125 instead of 105. You agreed to aim for this number.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

1. Please confirm whether data monitoring will be carried out throughout the course of the study.

2. In the Participant Information Sheet, the participants should be clearly told what the risk of radiation is and it is suggested that the example used by the Committee above is stated. (ie. 2 months worth of extra background radiation with a 1 in 33,000 chance of a cancer risk.)

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering Letter		24 November 2011
GP/Consultant Information Sheets	1.0	24 November 2011

Investigator CV		08 November 2011
Other: Radiation Dose Assessment		10 October 2011
Other: Instructions for use of Medical Device - TKA 4.3		
Other: Instructions for use of medical device - TKA easy		
Participant Consent Form	1.0	24 November 2011
Participant Information Sheet	1.0	24 November 2011
Protocol	1.0	24 August 2011
Questionnaire: Knee Society Score		
REC application		24 November 2011

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

11/WS/0125	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

pp JMacgregor

Dr Gregory Ofili
Chair

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*
"After ethical review – guidance for researchers"

Copy to: *Dr Catherine Sinclair, Golden Jubilee National Hospital*

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

West of Scotland REC 5
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Ms Nadia C Sciberras
Clinical Research Fellow
Department of Orthopaedics
Golden Jubilee National Hospital
Agamemnon Street
Clydebank
G81 4DY

Date 17 January 2012

Direct line 0141 211 2102
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Dear Ms Sciberras

Full title of study: **Validation of TKA smart v1.0 software: Are the clinical outcomes the same as the TKA v4.3 software?**
REC reference number: **11/WS/0125**
Protocol number: **11/ORTH/04**

Thank you for your letter of 9th January 2012. I can confirm the REC has received the documents listed below as evidence of compliance with the approval conditions detailed in our letter dated 14 December 2011. Please note these documents are for information only and therefore do not have to be reviewed by the committee.

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Covering Letter		09 January 2012
Participant Information Sheet	1.1	09 January 2012

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

11/WS/0125 **Please quote this number on all correspondence**

Yours sincerely

Mrs Sharon Macgregor
Committee Co-ordinator

Copy to: Mr Frederic Picard, Golden Jubilee National Hospital
Dr Catherine Sinclair, R&D, Golden Jubilee National Hospital

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25 January 2012

Mr Frederic Picard
Consultant Orthopaedic Surgeon
Golden Jubilee National Hospital
Agamemnon Street
Clydebank
G81 4DY

Dear Mr Picard,

Management Approval for a non-commercial research project

I am pleased to tell you that you now have Management Approval for the research project entitled: **Validation of TKA Easy software: Are the clinical outcomes the same as the TKA 4.3 software?** I acknowledge that:

- The project is sponsored by the **National Waiting Times Centre Board.**
- Research Ethics approval for the project has been obtained from the **West of Scotland Research Ethics Committee 3** (reference number: **11/WS/0125**).
- The Site Specific Form for this project has been reviewed and there is no objection to it proceeding at this site.
- The GJNH reference number for this project is: **11/ORTH/04**.

The following conditions apply:

- This study will be subject to ongoing monitoring for Research Governance purposes and may be audited to ensure compliance with the Research Governance Framework for Health and Community Care in Scotland (2006, 2nd Edition), however prior written notice of audit will be given.
- All amendments (minor or substantial) to the protocol or to the REC application should be forwarded to the NWTCB Research Office with a copy of the amendment application and approval letter.

Please report the information detailed above, or any other changes in resources used, or staff involved in the project, to the National Waiting Times Centre Board Research Manager, Dr Catherine Sinclair (0141 951 5440, catherine.sinclair@gjnh.scot.nhs.uk).

Further information about research at the National Waiting Times Centre Board can be found at the following website: www.nhsgoldenjubilee.co.uk/home/research.php.

Yours sincerely,

J Rogers

pp Mr Alistair Flowerdew
Medical Director

cc: Dr Catherine Sinclair, Research Manager, National Waiting Times Centre Board, Golden Jubilee National Hospital, Beardmore Street, Clydebank, G81 4HX

Appendix 5 – Theatre Data Collection Sheet

Validation of TKA smart v 1.0 software

Theatre Data Collection Sheet

Please do not attach any patient labels

Please fill in for every study patient of Mr Picard, Mr Allen and Mr Baines.

Patient Identification Number for this trial:

To be filled in theatre by theatre staff:

Patient's Initials: _____ Last 4 digits of CHI: _____

Software used: _____

Operation Start Time: _____

Operation End Time: _____

To be filled in by research team:

Registration Start Time: _____

Registration End Time: _____

Appendix 6 – Knee Society Score

www.orthopaedicscores.com

Knee Society Score

Six week follow up

Date .....

Study No: **Patient Initials** ☐☐ **Last 4 digits of CHI** ☐☐☐☐

During the past 4 weeks..... Click here for part 2 - FunctionScore

Part 1 - Knee Score

Pain

- ○ None
- ○ Mild / Occasional
- ○ Mild (Stairs only)
- ○ Mild (Walking and Stairs
- ○ Moderate - Occasional
- ○ Moderate - Continual
- ○ Severe

Flexion Contracture (if present)

- ○ 5°-10°
- ○ 10°-15°
- ○ 16°-20°
- ○ >20°

Extension lag

- ○ <10°
- ○ 10-20°
- ○ >20°

Total Range of Flexion

○ 0-5	○ 6-10	○ 11-15	○ 16-20	○ 21-25
○ 26-30	○ 31-35	○ 36-40	○ 41-45	○ 46-50
○ 51-55	○ 56-60	○ 61-65	○ 66-70	○ 71-75
○ 76-80	○ 81-85	○ 86-90	○ 91-95	○ 96-100
○ 101-105	○ 106-110	○ 111-115	○ 116-120	○ 121-125

Alignment (Varus & Valgus)

○ 0	○ 1	○ 2	○ 3	○ 4
		○ 5 - 10		
○ 11	○ 12	○ 13	○ 14	○ 15
		○ Over 15°		

Stability (Maximum movement in any position)

Antero-posterior

- ○ <5mm
- ○ 5-10mm
- ○ 10+mm

Mediolateral

- ○ <5°
- ○ 6-9°
- ○ 10-14°
- ○ 15°

Part 2 - Function

Walking

- ○ Unlimited
- ○ >10 blocks
- ○ 5-10 blocks
- ○ <5 blocks
- ○ Housebound
- ○ Unable

Walking aids used

- ○ None used
- ○ Use of Cane/Walking stick deduct
- ○ Two Canes/sticks
- ○ Crutches or frame

Stairs

- ○ Normal Up and down
- ○ Normal Up down with rail
- ○ Up and down with rail
- ○ Up with rail, down unable
- ○ Unable

Appendix 7 – Oxford Knee Score

OXFORD KNEE SCORE

Date:.....Joint..... Consultant..... **Pre op☐**
Patient Label **6/52☐**
ROM.....to..... **3/12☐**
1yr☐
2yr☐
5yr☐
10yr☐
Other☐

Please tick one answer for each of the following 12 questions relating to your knee in the past 4 weeks.

1. How would you describe the pain you are having from your affected knee?

None ☐
Very mild ☐
Mild ☐
Moderate ☐
Severe ☐

2.Have you had any trouble washing and drying yourself all over because of your knee?

No trouble ☐
Very little trouble ☐
Moderate trouble ☐
Extreme difficulty ☐
Unable to do so ☐

3.Have you had any trouble getting in and out of a car or using public transport because of your knee?

No trouble at all ☐
Very little trouble ☐
Moderate trouble ☐
Extreme difficulty ☐
Unable to do so ☐

4.How long can you walk before the pain becomes severe?

No pain / More than 30 minutes ☐
16-30 minutes ☐
5-15 minutes ☐
Around the house only ☐
Not able to walk at all ☐

5. When standing up after a meal at the table how painful is your knee?

Not at all painful ☐
Slightly painful ☐
Moderately painful ☐
Very painful ☐
Severely painful ☐

PTO

6. Do you limp when you are walking because of your knee?

- ☐ Rarely/Never
- ☐ Sometimes/Just at first
- ☐ Often/not at first
- ☐ Most of the time
- ☐ All of the time

7.Have you been able to kneel down and get up again?

- ☐ Yes easily
- ☐ With little difficulty
- ☐ With moderate difficulty
- ☐ With extreme difficulty
- ☐ No impossible

8.Are you troubled by knee pain in bed at night?

- ☐ No never
- ☐ 1 or 2 nights
- ☐ Some nights
- ☐ Most nights
- ☐ Every night

9.Has pain interfered with your usual daily work?

- ☐ Not at all
- ☐ A little bit
- ☐ Moderately
- ☐ Greatly
- ☐ Totally

10.Have you felt that your knee might suddenly give way or let you down?

- ☐ Rarely/Never
- ☐ Sometimes/ Just at first
- ☐ Often/ Not just at first
- ☐ Most of the time
- ☐ All of the time

11.Could you do the household shopping on your own if you had to?

- ☐ Yes easily
- ☐ A little difficulty
- ☐ Moderate difficulty
- ☐ Extreme difficulty
- ☐ No impossible

12.Could you walk down a flight of stairs?

- ☐ Yes easily
- ☐ Little difficulty
- ☐ Moderate difficulty
- ☐ Extreme difficulty
- ☐ No impossible

Patients Signature.....**DATE**.....

Please check that you have answered all the questions. Thank you

GJNH January 2010