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Functional Assessment to Compare Electromagnetic Navigated and Conventional Total Knee Arthroplasty

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"This thesis is submitted in fulfilment of the requirements for the degree of PhD in Bioengineering

2011

‘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:

Date:

Acknowledgements

First and foremost, I would like to thank my family for their constant encouragement, patience and support. I really appreciate all the times you listened and helped me talk through ideas. I was fortunate to be supported by some wonderful friends and boyfriend who encouraged me through my stressful times.

I would also like to thank my supervisor Prof. Phil Rowe for all his time, support and guidance throughout this experience.

I'd like to express my thanks to the technicians within the Bioengineering Unit, Stephen Murray and David Robb, who helped with construction of my experimental apparatus.

I would also like to thank Dr ML van der Linden for allowing me to use her healthy elderly electrogoniometry data to produce my functional assessment scoring system.

I would like to thank the two consultants involved in the clinical trial, Mr Mark Blyth and Mr Bryn Jones for their help with all my clinical questions. I would especially like to thank both of the consultant's secretaries - Ms Grace Collins and Mrs Denise Fisher who helped with organising the trial, identifying patients and filing the data. I would also like to take this opportunity to thank the pre-op nurses for their help at the recruitment stage of the process, and the outcomes staff for their help and guidance in the clinics. A special thanks goes to all the participants who took part in the study.

Finally, I'm grateful to the funders, Zimmer GmbH and the sponsors of the trial, Greater Glasgow and Clyde NHS.

Abstract

Navigated Total Knee Arthroplasty (TKA) aims to improve implantation accuracy and longevity of the prosthesis. The potential functional benefits of navigated TKA have not been fully explored using an objective measurement system. This thesis presents the results from 38 navigated and 39 conventional patients within a randomized controlled trial aimed at comparing electromagnetic navigated and conventional TKA. They were functionally assessed at 1 year post operation. The assessment included a kinematic evaluation using flexible electrogoniometry, calculation of the hamstring and quadriceps moment while the knee joint was flexed to 90^{o}, an activity level assessment using an activity monitor and clinical and functional questionnaires. The alignment of the prosthesis within the two surgical groups was analysed using CT scans and a long leg double stance weight bearing radiograph.

From the results, it was concluded that both patient groups had significant functional limitation compared to age matched 'normal' subjects. There were no significant differences between the two surgical groups in terms of clinical questionnaire scores or activity levels. The navigated group resulted in significantly higher knee joint flexion angles during the pre swing phase of level and slope walking. The female navigated group had significantly higher hamstring and quadriceps moments compared to the female conventional TKA group. This difference was not found between the male navigated and conventional groups.

Post operation CT analysis showed significant improvement in frontal femoral and sagittal femoral alignment in the navigated TKA group. The relationship between alignment and functional outcome was investigated to determine whether alignment is a predictor of functional outcome. The clinical scores indicated better function in the 'well aligned' mechanical axis group compared to the 'outlier' group but it failed to reach statistical significance.

It was concluded that the difference in the post operation function of the two surgical groups remains minimal despite the better alignment achieved using navigation. Proving cost effectiveness for navigation systems in TKA remains a challenge.

CONTENT

LIST OF FIGURES

CHAPTER 1:

CHAPTER 2:

CHAPTER 3

LIST OF TABLES

CHAPTER 1:

CHAPTER 2:

CHAPTER 3:

LIST OF ABBREVIATIONS

TKA	Total Knee Arthroplasty
ICF	International Classification of Functioning
SF-36	Short Form 36
RAP	Rotational Axis Pathway
ACL	Anterior Cruciate Ligament
PCL	Posterior Cruciate Ligament
ICR	Instantaneous Centre of Rotation
LPS	Legacy Posterior Stabilized
FFA	Frontal Femoral Angle
FTA	Frontal Tibial Angle
FT	Femoral Tibial
FSA	Femoral Sagittal Angle
TSA	Tibial Sagittal Angle
KJA	Knee Joint Angle
ROM	Range of Motion
OKS	Oxford Knee Score
AKSS	American Knee Society Score
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index
VAS	Visual Analogue Scale
CAS	Computer Assisted Surgery
EG	Electrogoniometer
GPS	Global Positioning Systems
AP	Anterior/Posterior
ICC	Intraclass correlation coefficient
PROMS	Patient Related Outcome Measures
QALYs	Quality Adjusted Life Years

CHAPTER 1. LITERATURE REVIEW

1.1. INTRODUCTION

In the UK, about 8.5 million people are affected by Osteoarthritis (OA), a degenerative joint disease which slowly progresses over time and as a result patients can live with the symptoms for decades (Arthritis Care, 2004). These numbers are expected to rise as the live expectancy age increases (National Institute on Aging, 2006). The rising incidence of obesity also has an impact on the increasing number of patients developing knee OA. Bourne et al (2007) reported a strong link between obesity and the subsequent requirement for joint surgery. Severe OA is considered a major cause of movement impairment leading to disability and reduced quality of life, where one of the most common joints involved is the knee joint (Hendrena L and Beeson P, 2009). OA of the knee joint is caused by abnormal wearing of the articular cartilage leading to narrowing of the joint space, joint deformity and decreased joint mobility (Verberne G et al., 2009). In fact 80% of OA patients have 'some degree of limitation of movement' and 25% cannot perform their required daily tasks (World Health Organization, 2003).

Total knee arthroplasty (TKA) has been proven to be a successful treatment in relieving pain and disability in end stage osteoarthritis, where most reports have 10 year success rates in excess of 90% (Nafei A et al., 1996, Tayot O et al., 2001). There were 6,884 primary knee replacements recorded in Scotland in 2009 (NHS, 2010). This figure is predicted to rise as the percentage of the population who are aged 65 and over increases from a reported 16% in 2009 to a predicted 23% in 2034 (Office for National Statistics 2010). In fact the arthritic population is also changing to include younger patients. It is thought that by 2016 more than half of the TKA patients will be under 65 years of age (McKee J, 2009). This younger group pose two problems. Firstly, they require the prosthesis to last longer. This increases the likelihood of revision knee replacement surgery which is associated with increased problems. Secondly, younger patient's activity levels and lifestyles are different, for example some may still be in employment and active in sports. Therefore there may be a greater functional demand placed on the implant. This is one possible explanation as to why it is thought that this group of younger patients (under 65) will

make up over 50% of the revision TKA numbers by 2011 (McKee J, 2009). It is thought that activity levels greatly influence the wear of the implant and therefore the longevity of the knee replacement (Lavernia C.J et al., 2001). Advances in surgical technique and implant design are aimed at increasing longevity of the implant, as well as increasing range of motion (ROM) and increasing peak flexion angles through high flex implant designs (Huang H.T et al., 2005). High flexion is considered flexion greater than 125^{o} which is thought to then allow higher functionally demanding activities such as squatting and kneeling to be performed post operatively. In recent years computer assisted surgery (CAS) or navigated procedures have been introduced to orthopaedics. Published studies have shown CAS to increase the accuracy of the outcome alignment (Bäthis H et al., 2004), which has been reported to have an effect on implant loosening and the longevity of the knee implant (Jeffery R.S et al., 1991).

TKA patients even 2 years post operation have reported a functional limitation compared to age matched normals (Myles C.M et al., 2002). Although the differences in alignment have been reported between CAS and conventional groups (Chauhan S.K et al., 2004b) little has been reported on whether there is a direct functional difference between patients from these two groups. Furthermore, although alignment accuracy has been shown to improve in the CAS groups in some studies it is unclear which alignment errors, if any, have an impact on functional losses. In conclusion, TKA is a successful surgical intervention to relieve pain and restore function in the growing population with severe knee OA. CAS has shown to be a helpful additional tool in terms of accurate prosthesis implantation but the functional benefits have not been fully explored.

1.2. THE KNEE JOINT

The knee joint is a complex mechanical unit of the lower limb. It works in harmony with the other joints of the lower limb; hip and ankle, to allow smooth ambulation. There are many structures which are involved and influence the movement of the lower limb. Human anatomy describes structures such as muscles, bones, ligaments which have been covered extensively in many textbooks. Reference

has been made to various anatomy and physiology textbooks (Martini F.H, 2004, Seeley R.R et al., 2003, Tortora G.J, 1999, Tortora G.J and Derrickson B, 2007).

1.2.1. Skeletal Structures of the Lower Limb

The diagram in figure 1.1 illustrates the knee joint, and shows the three bones involved; femur (thigh bone), tibia (shin bone) and patella (knee cap).

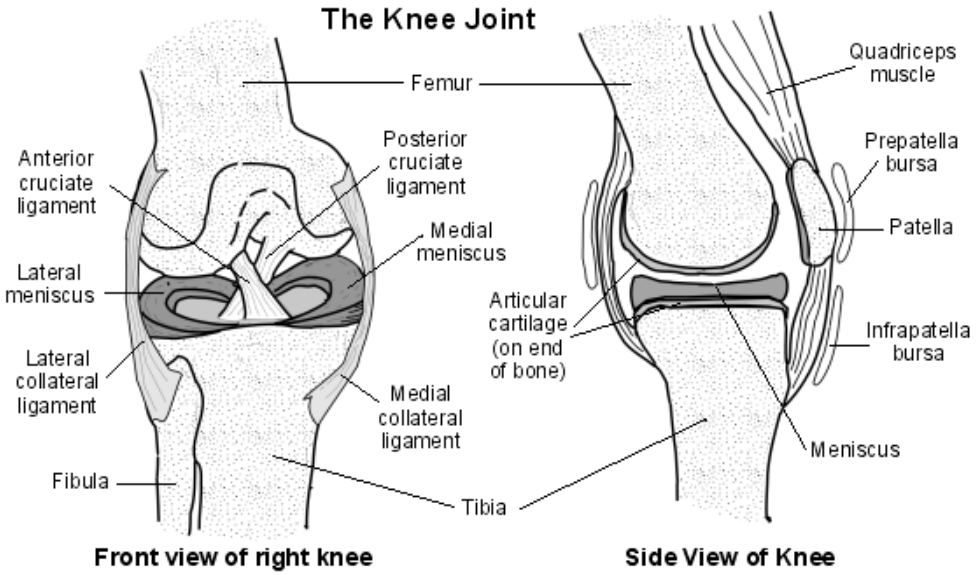


Figure 1.1 Diagram of the knee joint (Patient.co.uk, 2011)

The femur and tibia are long bones and have similar structures. They consist of cortical bone which is dense and compact and forms the hollow cylinder of the long bone middle section. This cylinder is filled with bone marrow. The head of the long bones are formed by a thin layer of cortical bone which is thicker in the mid section and this is filled with trabecular or cancellous bone. This combination of the two bone types allow the ends of the long bones to be easily deformable and dampen the peak forces transmitted through the knee joint. These long bones are the framework of the lower limb and their structure has importance to the knee joints function.

1.2.2. The Pelvis

The pelvic girdle includes the 2 hipbones (the ossa coxae), which are formed by the fusion of 3 bones; the ilium, the ischium and the pubis as seen in figure 1.2. The acetabulum is found on the lateral surface of each hip bone and is a deep

depression (socket) which articulates with the head of the femur, to form the hip joint.

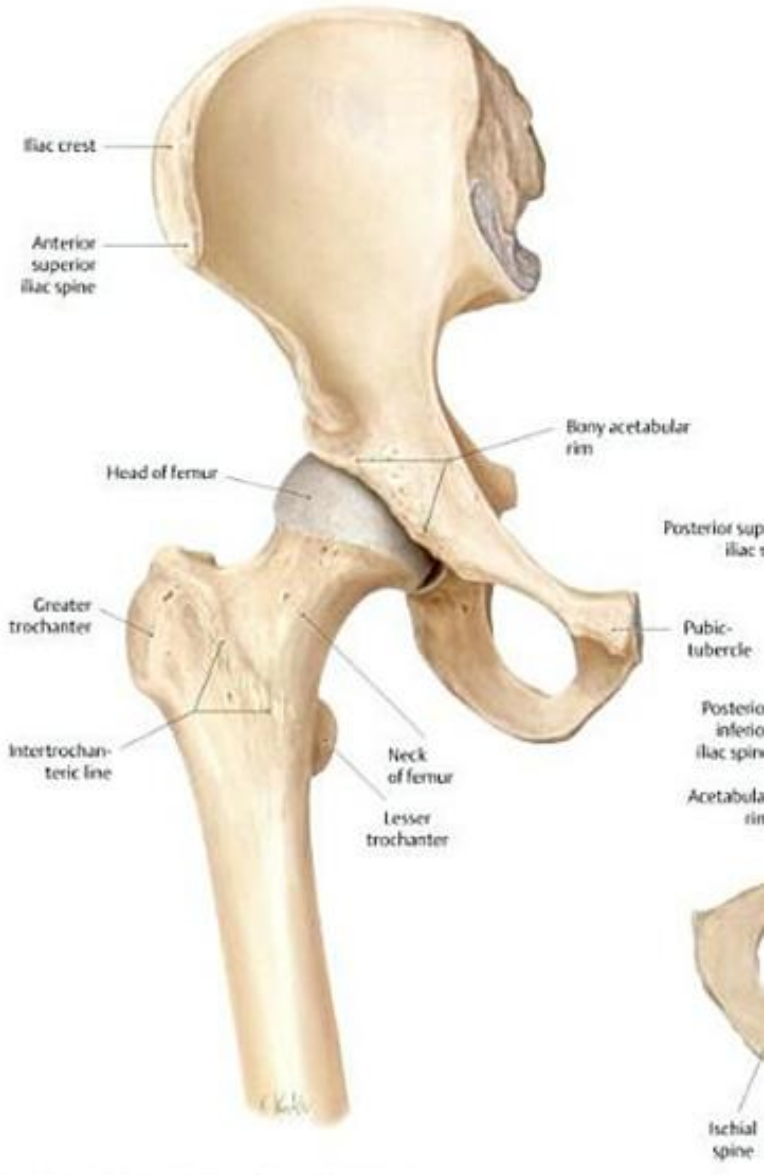


Figure 1.2 Bony landmarks of the Pelvis (Schünke M. et al., 2006)

1.2.3. The Femur

The femur is the strongest and longest bone in the body. As mentioned the proximal end of the femur articulates with the pelvis to form the hip joint which is a ball and socket joint. The femur is also important in the knee joint as it articulates with both the tibia and the patella. The distal end the femur widens to form the medial and lateral condyles.

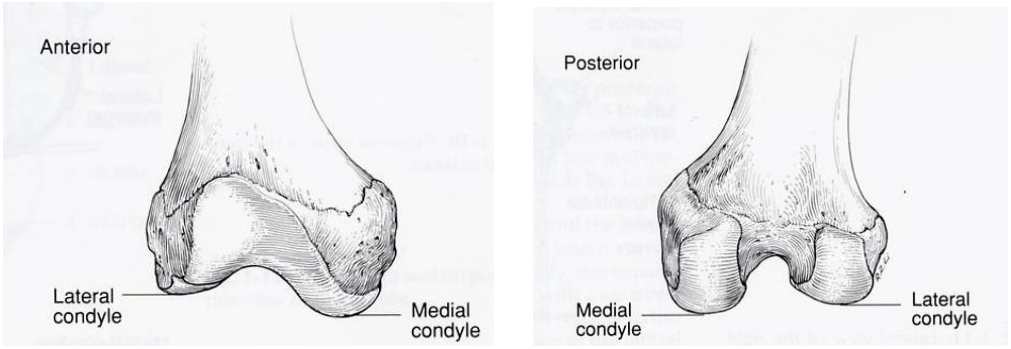


Figure 1.3 Anterior and posterior views of right distal femur. (Tria Jr A.J and Klein K.S, 1992)

Figure 1.3 illustrates that the lateral and medial condyles of the distal femur vary significantly in shape and size. The medial and lateral condyles are separated on the inferior surface by a deep intercondylar fossa. The anterior surfaces of the condyles are separated by the patellar trochlear surface which is a smooth articular surface for the patella to glide over.

1.2.4. The Tibia and Fibula

The tibia is part of both the knee and ankle joint. The tibial condyles are almost flat (figure 1.4) and articulate with the rounded femoral condyles (figure 1.3).

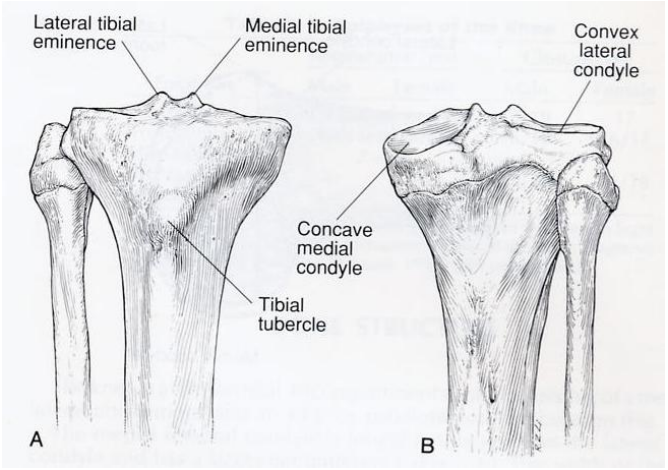


Figure 1.4 (A) Anterior and (B) posterior view of the right proximal tibial. (Tria Jr A.J and Klein K.S, 1992)

The distal end of the tibia widens at the ankle joint to form the medial malleolus. The fibula is lateral and non weight bearing. However it does provide lateral stability to the ankle joint and is important for muscle attachment. The bony projection on the lateral side of the ankle is the lateral malleolus of the fibula.

1.2.5. The Patella

The patella is a small triangular sesamoid bone which is formed within the tendon of the quadriceps femoris. The patellar ligament is attached to the inferior surface of the patella and connects the patella to the tibia. The posterior surface of the patella articulates with the trochlear surface of the femur.

1.2.6. Bones of the Ankle

Figure 1.5 shows the major bones and ligaments of the ankle joint, which consist of 7 tarsal bones. Body weight is transmitted from the tibia to the talus. The articulation of the ankle joint is between the tibia and the talus. The largest of the tarsal bones is the calcaneus (heel bone) which transmits the body weight from the talus to the ground.

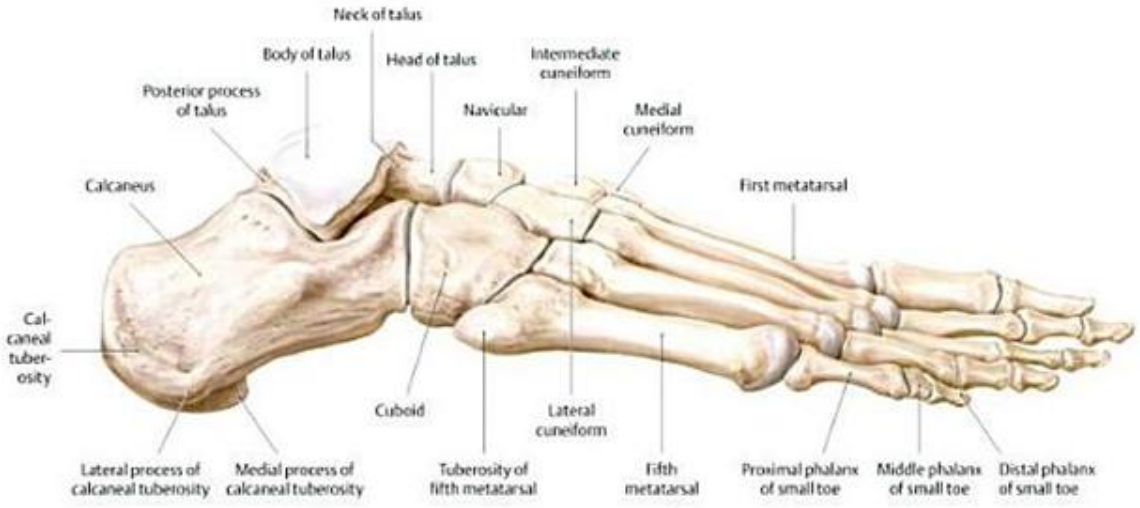


Figure 1.5 Bones and ligaments of the ankle joint. (Schünke M. et al., 2006)

1.3. STRUCTURES OF THE KNEE JOINT

The knee joint is the largest synovial joint in the body. The synovial fluid which has a high concentration of proteoglycans is enclosed within a synovial membrane. This fluid is important for lubrication and nutrient distribution of the

joint. It can also act as a shock absorber i.e. cushions the joint when under compression. The knee joint can be divided into 3 articulations:

- One between the patella and the femur – the patella femoral Joint
- Two between both the medial and lateral condyles of the femur and the tibia – medial and lateral tibia-femoral joints.

As already mentioned the shape of the condyles of the tibia and femur at the knee joint do not conform which leads to instability without additional structures. The femoral condyles are rounded and sit on the almost flattened condyles of the tibia which are set at an incline posteriorly at a variable angle normally described as being between 7 and 11^{o} in Caucasians (Freeman M.A.R and Pinskerova V, 2005). It is the presence of ligaments and muscles which stabilise the joint.

1.3.1. Ligaments of the Knee Joint

Figure 1.6 illustrates another important set of structures within the knee joint – the ligaments. There are seven major ligaments included in the joint and they act together to stabilise it.

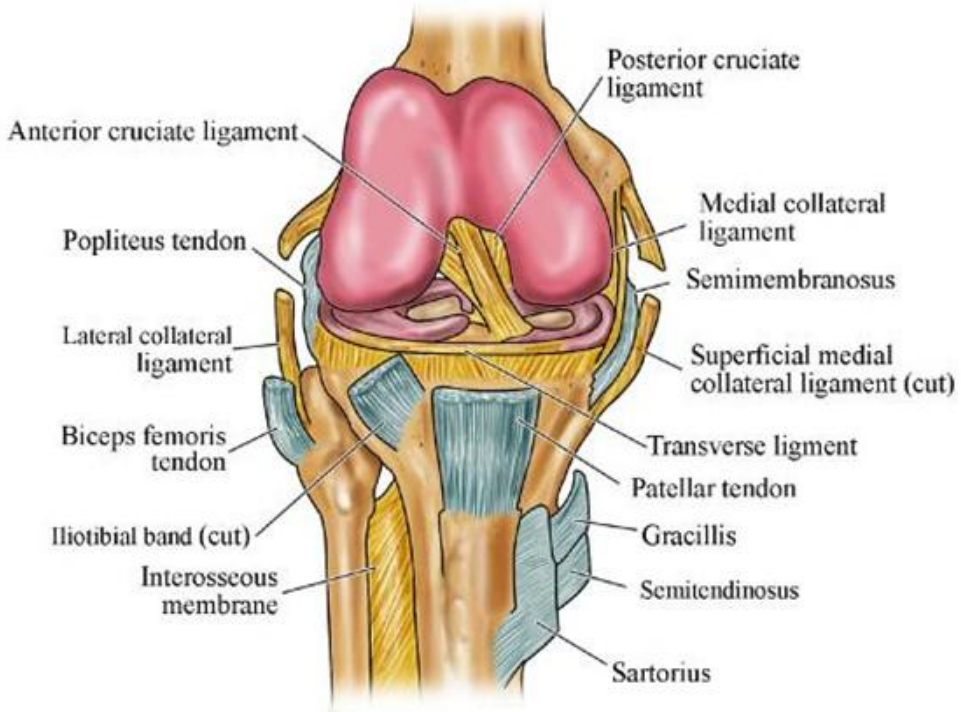


Figure 1.6 Diagram of the knee joint ligaments (Scuderi G.R. and Tria Jr A.J., 2010)

- Anterior and posterior cruciate ligaments (ACL and PCL) limit the anterior and posterior movement of the femur and maintain the alignment of the femoral and tibial condyles. The reference to anterior and posterior is in relation to their attachment to the tibia. They then cross one another and attach to the femur. They add to the internal stability of the joint, and act to restrain from excessive rotation. The anterior cruciate prevents forward displacement of the tibia on the femur. The posterior cruciate prevents backwards displacement. They work together and therefore in all positions of knee movement one of the ligaments is taut.
- Tibial and fibular collateral ligaments reinforce the medial and lateral surfaces of the joints. These ligaments are tightened when the joint is in full extension. The medial ligament opposes valgus forces and external rotation and the medial opposes varus forces and resists internal rotation.
- Two popliteal ligaments extend between the femur and the heads of the tibia and fibula. Their function is to reinforce the knee joint on the posterior surface.
- Patellar ligament, which connects the patella and the tibia, reinforces the knee joint on the anterior surface.

Damage to any of the ligaments of the knee joint can lead to problems with joint stability which is important for maintaining the correct functional position throughout the full range of motion.

1.3.2. Muscles of the Knee Joint

The function of the musculoskeletal system is to provide control of motion. The major movement of the knee joint is flexion/extension with some rotation. The quadriceps muscle group are the main powerful extensors of the knee. The hamstring group (semitendinosus, semimembranosus and biceps femoris) are flexors of the knee joint. The gastrocnemius helps the hamstrings to control rotation in flexion. Finally the popliteus muscle is weakly involved in knee flexion. More importantly it functions to ‘unlock’ the knee joint when in full extension.

The main function of the muscles is movement but they also provide an element of stability for the joints where the quadriceps ‘generate an anterior shear

force on the tibia relative to the femur and … the hamstring group counteracts this force' (Hortobagyi T et al., 2005). In fact dynamic knee joint stability relies on the correct hamstring/quadriceps (H/Q) muscle ratio of 0.5-0.8 as elevated H/Q ratios indicate a weakness in quadriceps strength (Schroer W.C et al., 2010). Quadriceps muscle weakness, which is sometimes as a result of disuse atrophy has been reported in patients with knee osteoarthritis (Jackson B.D. et al., 2004).

1.3.3. Articular Cartilage and Menisci

Articulating surfaces of the joints within the lower limb are lined by articular cartilage (or hyaline cartilage), which (Engin A.E, 1978) is about 4mm in thickness. The thickness is age dependant, and generally increased age is associated with wear of the cartilage and degeneration. The cartilage is extremely smooth providing a very low friction surface for the bones as they move through the full range of motion. The cartilage covers the ends of the femur and the tibia, and the posterior aspect of the patella at the knee joint. Cartilage is composed of a dense connective tissue made up of collagen fibre, elastin and a proteoglycan matrix. The collagen has important mechanical properties such as strength and stiffness. The proteoglycan matrix is composed of huge macromolecular structures which are negatively charged and are extensively hydrated. When a load is applied to the cartilage water is displaced and helps cushion the load. When the load is removed the water helps the cartilage to maintain shape. The 'structure and arrangement of the cartilage components enable it to resist deformation under stress' (Hendrena L and Beeson P, 2009) and through the distribution of the loads through the knee joint it helps to protect the underlying bone at the joint. In fact by distributing the load over the knee joint surface it reduces the contact stresses by half (Soderberg G.L, 1986). Unfortunately articular cartilage once damaged, does not heal itself with new normal tissue, as for example bone does. Surgeons often grade cartilage damage according to a scoring system. They use a four-point score based on the visual appearance of the cartilage on inspection at arthroscopy:-

- Grade I - Softening of the cartilage
- Grade II - Roughening of the surface of the cartilage
- Grade III - Fissures / cracks in the cartilage, going down to bone

- Grade IV - Cartilage loss down to bare bone

Menisci are fibro cartilage pads which cover the majority of the tibial plateau acting as an additional cushion for the knee joint. There is a medial and lateral meniscus which are made up of approximately 74% water (Allen A.A et al., 1995). They are found on the medial and lateral sides lying between the femoral and tibial surfaces. A study by Baratz et al (1986) showed that a meniscectomy led to a decrease in the femorotibial contact area by 75% which led to an increased peak load of up to 235%. This clearly illustrates the role of the menisci in load transmission. The medial and lateral ends of the femur are rounded but are not a uniform circle so when the knee joint flexes its shape on the tibial surface changes. The meniscus adapts so as to conform to this shape therefore increasing joint congruity and enhancing stability. The menisci act as a 'functional extension of the tibial plateau to increase the relative depth of the tibial articular surface' (Allen A.A et al., 1995) which lead to the increased congruity. A further function of the menisci is joint lubrication and nutrition.

1.4. KNEE JOINT KINEMATICS AND KINETICS

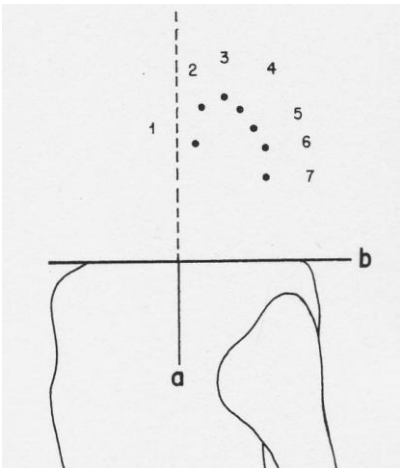
Kinematics deals with joint motion and angles. For analysis purposes the femur and tibia can be thought of as rigid bodies which move in relation to each other. Kinetics studies the forces and moments exerted on the rigid bodies.

1.4.1. Knee Kinematics

The knee joint is sometimes simplified to a hinge joint, however movement of this joint is more complicated. Movement at the knee joint can be described as a combination of rolling and sliding (Steindler A, 1955), with the range of motion being controlled by ligaments. The rolling action helps to 'reduce joint wear by distributing the load over different parts of the joint' (Moorehead J.D et al., 2001). Therefore at each different flexion angle a varied contact area of the condyles transmits the force. Full extension includes slight external rotation of the tibia and the tightening of the cruciate ligaments. This rotation is a result of the fact that as the knee joint fully extends the medial condyle rolls 10^{o} whereas the lateral condyle rolls 15^{o} (Kapandji I.A, 1970). The 'screw-home' mechanism occurs during the last 20^{o} of

flexion to full extension and leads to a knee locked position as a result of external rotation of the tibia in terminal extension (Smith P.N et al., 2003). This allows standing for long periods of time without tiring or using the extensior muscles. To 'unlock' the knee the popliteus muscle contracts which internally rotates the tibia relative to the femur. The early stages of the knee flexion cycle involves femur roll on the tibia and the reminder of the cycle is dominated by the femur sliding anteriorly on the tibial condyles (Smith P.N et al., 2003). This is typically known as 'roll back'

The knee joint has an instantaneous (continuous) centre of rotation (ICR) which, in a normal knee lies above the area of joint contact. A study by Smidt (1973) investigated the instant centre of the knee joint in the sagittal plane. This study concluded that as the knee flexes through 0-90^{o} the mean instant centres fell within a circle with diameter of 23mm and the pathway is shown in figure 1.7. The motion of the centre of rotation also depends on whether or not the flexion/extension movement is completed during a weight bearing activity.



1=0^{o} position
2=15^{o} position
3=30^{o} position
4=45^{o} position
5=60^{o} position
6=75^{o} position
7=90^{o} position

Figure 1.7 Pathway of instant centres with respect to the tibia and femur. (Smidt G.L, 1973)

Figure 1.8 (Moorehead J.D et al., 2001) shows the rotational axis pathway (RAP) and shows that the area of joint contact moves posteriorly as the joint flexes from the position in figure 1.8 (a) to 1.8 (b). It also illustrates that the ICR is located above the area of contact so as the point of joint contact moves posteriorly so too does the ICR. The fact that the centre of rotation varies at the knee joint means that the difficulty in designing a knee joint is increased and that the hinge joint model has to be altered.

Modelling a knee joint prosthesis to behave as the 'normal' knee joint involves considering these factors and including the gliding and rolling actions so that the ICR and point of contact varies over the flexion curve.

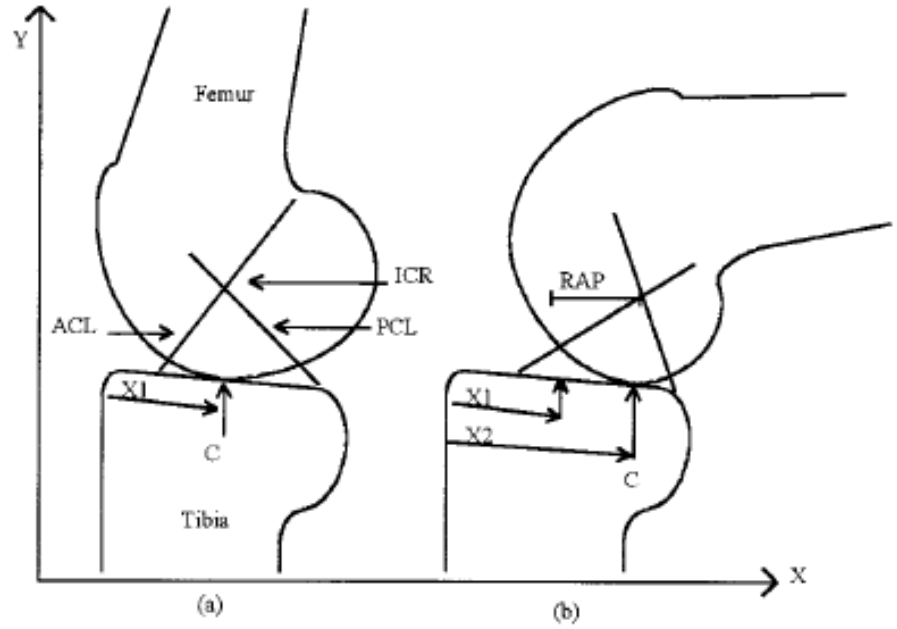


Figure 1.8A normal knee's RAP. (a) A simple sagittal plane model of the knee shows the ICR situated above the area of joint contact (C), in the region where the ACL crosses the PCL. The ICR (or axis) has displacementX1 from the front of the tibial plateau. (b) It shows that flexion causes the ICR to move posteriorly along a RAP to new displacement X2. (Moorehead J.D et al., 2001)

A study by Koo et al (2008) investigated the hypothesis of whether the centre of rotation in the transverse plane of the knee is on the medial side of the knee joint while walking as previously concluded for other non-ambulatory activities. However the study in fact differed by concluding that for walking it was on the lateral side. Since the centre of rotation generally lies above the contact area it is important to understand the ICR as this will suggest the areas where cartilage wear would be found. This study suggests that it is important to look at the kinematics of specific activities individually as they are varied and not always predictable. More importantly it is probable that this factor will be patient specific.

1.4.2. Knee Kinetics

The forces transmitted across the tibiofemoral joint can be 2.8-3.4 times body weight while walking (Smidt G.L, 1973) and 0.79-2.64 times body weight across the patellofemoral joint. As a result of these high forces the knee joint is subject to wear, tear and damage. The highest forces across the tibiofemoral joint occurs when the knee is flexed 5-15^{o} during the stance phase of walking (Smidt G.L, 1973) as shown in figure 1.9.

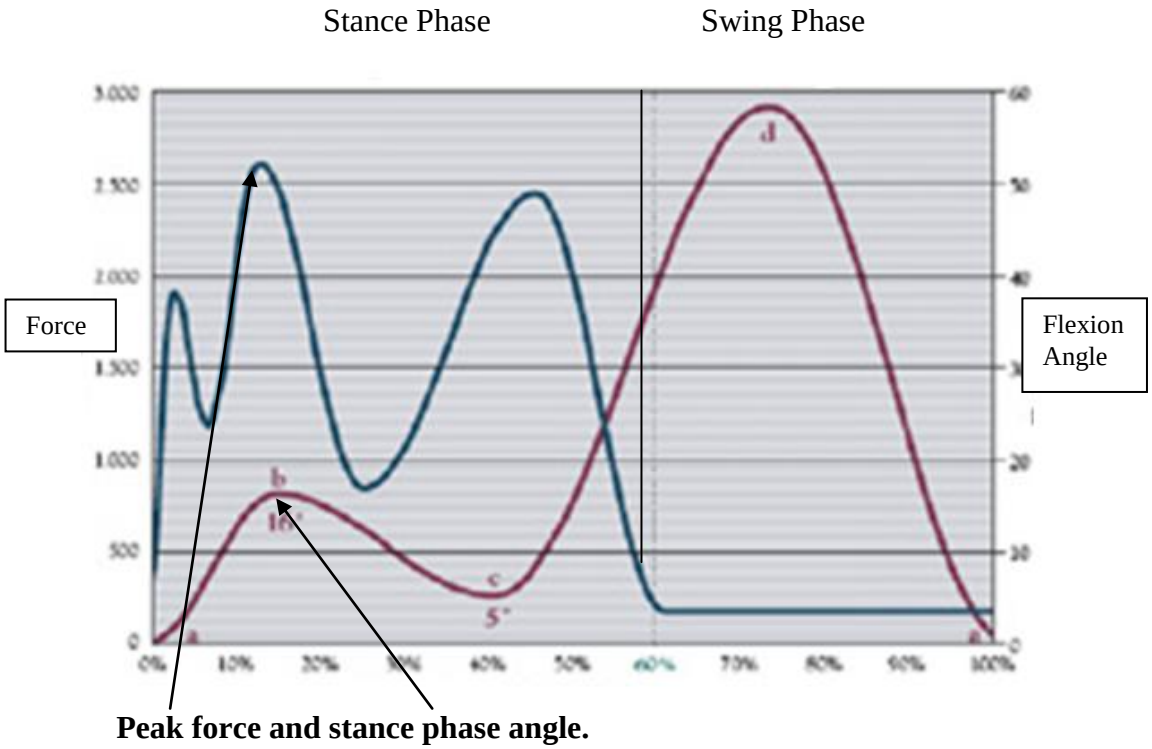


Figure 1.9 Graph showing (a) in red the kinematic gait cycle, (b) in blue the force trace during 1 gait cycle. (ÆQUOS Endoprothetik GmbH, 2007)

It has previously been discussed that the contact area between the tibia and femur varies as the knee flexes. In fact as the knee flexes the contact area between the bones decreases in size and moves posteriorly on the condyles (Ling Z.K et al., 1997) because of femoral roll back which is more pronounced laterally. Therefore high flexion angles in stance phase are transmitted over small contact areas increasing force per area. Activities such as stair ascent/descent have recorded high forces transmitted over the knee joint and therefore are a higher impact activity. The effect of the high forces is then magnified due to the small contact area resulting

from high flexion angles. For an activity such as walking the high peak forces take place during stance phase which relate to flexion angles of around 0-30^{o}. This means that the high forces are distributed over a relatively high contact area. In the rolling stage of knee joint movement (0-30^{o}), the forces through the joint are perpendicular to the joint surface which helps minimises the shearing forces which would contribute to wear and tear of the surface (ÆQUOS Endoprothetik GmbH, 2007). Therefore during the periods of high forces the joint moves with little friction, wear and tear.

1.5. OSTEOARTHRITIS

Osteoarthritis (OA) is the most common form of arthritis in the UK with highest incidence in the age group 65-74 years old (World Health Organization, 2003). It is a chronic disease causing pain and dysfunction. OA also known as 'degenerative arthritis' as it results from 'wear and tear' in the joint. Wear occurs when there is an interaction between two moving surfaces. The major joints which are affected are the hip, knee, spine and fingers. The prevalence of OA at the knee joint is high at 30% of the pensionable population (Zhai G et al., 2007).

1.5.1. Epidemiology

Knee osteoarthritis is also 2–3 times more prevalent in females than males (McKean K.A et al., 2007) however this can depend on ethnicity. Osteoarthritis generally affects several joints. The prevalence of OA has been correlated with age (Williams M.K and Spector T.D, 2006) where increased age is a major risk factor. The frequency and severity of symptoms increases with age in primary OA. By the age of 65, up to 60% of the population has detectable OA in at least one of their joints (Croft P, 1990), but it may be asymptomatic. This disease is rarely found in those under the age of 45 but when it does occur in this age group it is more commonly men and is a result of sport or work injuries.

It has been estimated that there is a heritability factor of 40-60% showing that genes play an important role in the development of this disease (Williams M.K and Spector T.D, 2006). This shows that it is likely to run in families and in fact it is

‘twice as common’ to find OA in ‘first degree relatives’ of people diagnosed with OA.

Other factors which have been reported to be associated with OA are obesity (Bourne R et al., 2007) , where in fact it was reported that ‘losing weight can half this risk’ (Williams M.K and Spector T.D, 2006). Occupational or physical risk factors include excessive bending and sports have also been related to increased risk of radiological OA.

1.5.2. Osteoarthritic Cartilage

In healthy joints the cartilage covers the end of the bones allowing them to glide over one another in a frictionless joint movement. It acts to absorb energy from the shock of the physical movement. OA is a metabolically active, dynamic process where the destruction and repair can be triggered by various biochemical and mechanical factors. Joint loading and metabolic activity could be factors in the initiation and progression of OA. When Deluzio et al (2007) investigated biomechanical features of gait measurements and related them to knee OA they concluded that the ‘dynamic knee adduction moment tends to be higher with knee OA’. Lynn et al (2007) hypothesised that the ‘large adduction moment increases the knee’s medial compartment load causing cartilage breakdown and eventually a varus deformity and medial OA.’ There is evidence that ‘shear stress is detrimental to cartilage health and may lead to the development of knee OA’ causing splitting or separation between the subchondral layer of bone and the intact articular cartilage. These separations are thought to ‘create local stress concentrations and subsequent cartilage degeneration.’ OA can affect either the lateral or the medial compartments of the knee, however it has been noted that the medial side is more commonly involved leading to a possible varus deformity (Lynn S.K et al., 2007). The anatomical reasons for medial compartment deterioration include the fact that the cartilage on the medial side is thinner than that on the lateral side and also that the relatively fixed medial meniscus offers less protection then the more mobile lateral meniscus (Lewek M.D et al., 2004). The normal line of force when a subject walks or climbs stairs passes through the medial side of the knee joint, meaning that the

medial compartment transmits higher forces than the lateral and may as a result contribute to the destruction of the cartilage on this side.

Age has been seen to play a part in the development of OA. Throughout our life cartilage is naturally broken down and replaced. However, with aging the breakdown process becomes faster than the build up which results in cartilage thinning and joint space narrowing. This form of OA is known as primary. In 2007 Temple et al looked at age and site in relation to biomechanical weakening of human articular cartilage. It was reported that the strength and stiffness of the cartilage decreases by 65% from the age of 24 to 90, possibly predisposing the knee joint to the symptoms and signs of OA. It was also found that degradation of the cartilage on the medial femoral condyle occurred earlier. One of the signs of OA is through a radiological investigation where cartilage can be seen to be thinned and the joint space reduced. An early change in cartilage is the increase in water content of the cartilage. This changes the quality and quantity of the proteoglycan matrix and leads to an increase in collagen extractability. Later changes include fibrillation of the cartilage, loss of cartilage substance, osteophyte formation and an increase in bone density below the area of cartilage loss. Chondrocytes which are embedded in the matrix are involved in repairing the cartilage, however the equilibrium of breakdown and repair of cartilage is not balanced in articular diseases such as OA. The repetitive use of the joints over the years leads to irritation and inflammation of the cartilage leading to pain and swelling. Eventually the cartilage begins to degenerate by chipping or forcing cracks. As the disease progresses the protective cartilage also becomes roughened (Moskowitz R.W et al., 1984). The body's mechanism to compensate for this causes the outer edges of the bone to thicken and 'outgrowths' known as osteophytes form which leads to changes in the bones shape. The membranes which line the joint also become inflamed. In severe cases of OA calcification occurs which means deposits of calcium crystals form in the cartilage. Problems occur when these calcium crystals come loose and will cause the joint to be hot, red and swollen (pseudogout). Secondary OA arises in joints which have been previously injured or there has been a developmental abnormality. Both the tibiofemoral and patellofemoral joints of the knee can be affected by OA. This thesis will focus on tibiofemoral OA.

1.5.3. Diagnosis and Assessment of Osteoarthritis

The major symptoms of knee OA are; pain, stiffness, swelling and a possible decrease in the range of motion (ROM). It is also reported that some patients feel their joints crunching or cracking and in some cases the knee will give way due to a lack of joint stability. The pain is reported during walking, stair climbing and in severe cases at night and while at rest. Increased stiffness is usually found in the morning and is associated with mobilization after extended periods of rest. ROM can be reduced due to stiffness and as a result of joint deformities. Osteophyte formation can cause bone enlargement. The reduced ROM can be at either end of the spectrum, a fixed flexion where the lower limb cannot be fully straightened or by a reduced maximum flexion angle.

Many patients repeatedly visit their doctor before diagnosis and then every few months as a result of their symptoms (Arthritis Care, 2004). It is important to assess the stage of OA using evaluation tools which are easy to use and reproducible. A measure of pain, change in strength and ROM are important in assessing the impact of the disease on the patient's life. Questionnaires completed by patients are routinely used to assess the levels of pain, function and the psychological impact the disease has on the patients' quality of life. ROM and stability of the joint are clinical measures recorded by clinicians.

Radiographic evidence of OA is used to assess the deterioration and severity of the disease. Radiographs can be used to observe the joint space narrowing or osteophyte formation. Furthermore radiographs can be used to determine the presence of deformity/malalignment in the lower limb.

In depth investigations into the biomechanics of OA have been carried out through gait analysis where an extensive report of kinetic and kinematic information can be produced. However these research studies are generally conducted on a small subsection of the overall OA population.

1.5.4. Management of Osteoarthritis

Treatments are varied and can be used to control pain and try to slow the progression of the disease. The first methods of treatment are:

- To keep active and mobile as much as possible.

- Weight loss for those overweight as excess weight increases stresses on the joints.
- Pain management using pain killers.
- If the joint becomes swollen, hot and inflamed then anti-inflammatory medication can be affective.
- Physiotherapy exercises - to manage the pain, increase range of motion exercises and strengthen quadriceps.
- Other non-pharmacological treatments - shoe wedges, cushioned shoes and a stick, which all reduce the load on the joint.

There is also new evidence that glucosamine sulphate has a structure modifying effect on knee OA and therefore may help with the symptoms of the disease (Williams M.K and Spector T.D, 2006). Glucosamine is a chemical which is part of the make-up of normal cartilage and it may have a role in making or maintaining cartilage. In theory taking this supplement may help to improve and repair damaged cartilage but studies in this area do not agree on the benefits of this supplement. Finally, regular injections of hyaluronic acid directly into the joint can be beneficial for pain management but this is also a relatively new treatment. Hyaluronic acid is a component of synovial fluid and increases the viscosity of the fluid. It is not understood how it works but it is thought that it may help with the lubrication and shock absorption of the joint (Wikipedia, 2011). Another idea is that it may stimulate cells that make cartilage.

1.6. KNEE JOINT SURGERY

There are various surgical options for knee OA which are dependant on the stage of arthritis and the involvement of the compartments of the knee joint. Knee arthroscopy, which is not a solution to arthritis, can be used to ‘wash out’ the knee and remove loose fragments of worn out cartilage formed as a result of OA. It is not a long term solution but there are controversial claims that it can help. It is generally agreed that washout with OA only works if there is also an associated mechanical problem such a loose body or a torn meniscus. It is no longer thought to be effective just in the presence of OA. Osteotomy is another option for young, active patients who are not yet considered to be candidates for total joint arthroplasty. This surgery

realigns the lower limb mechanical axis. Body weight is generally transferred through one compartment of the knee joint, as a result damage is more extensive on one side of the joint. Osteotomy acts to shift the weight bearing forces to 'unload' the worn out side of the joint and place the forces on the healthy side. This surgery tends to delay the need for total knee arthroplasty (TKA). Finally certain patients can benefit from a uni-compartmental knee replacement. When arthritis is confined to a limited area of the knee joint then this one compartment can be removed instead of the entire joint. This surgery removes less bone and there is less soft tissue disruption. Therefore it has been seen to have faster recovery times and is claimed to have improved functional outcomes which are an advantage to the patient (Harwin S.F., 2003).

In severe cases TKA can be the only practical operative solution. This involves the replacement of the articular surfaces of the femur and tibia and sometimes the patella. Total knee arthroplasty when successful provides marked pain relief and functional improvement in the majority of patients with knee OA.

1.6.1. Total Knee Arthroplasty

Total knee arthroplasty (TKA) or total knee replacement (TKR), is a successful method of alleviating pain, correcting deformities and restoring mobility in patients with advanced osteoarthritis. It is only considered at the end-stage of the disease process. Only a thin layer of bone is removed from the damaged surface of the femur and tibia using special instrumentation which measures to a correct thickness and shape. This removed bone is then replaced by the metal prostheses. The third surface which in some cases is badly damaged is the patella and this too can be resurfaced.

It is important to understand the principals of the surgical technique, as a perfectly designed prostheses implanted incorrectly would lead to problems. In cases of alignment deformities, the surgery involves restoring ligament balance as well as bone resection. For example in the case of the varus knee which is associated with medial compartment osteoarthritis the medial collateral ligament is seen to be shortened due to osteophytes and scarring, whereas the lateral collateral ligament is lengthened due to weight bearing (Savastano A.A, 1980). However this controversial as a growing number of surgeons now believe that once osteophytes are removed and

the joint realigned then the ligaments do not need to be released. In fact correct bone resection would only be required to balance the soft tissues.

Numerous factors play a part in the success of TKA:

- Surgeon and surgical technique
    - Level of surgeon experience
    - Additional assistance in the form of computer navigation
- Prosthesis design
    - Posterior cruciate – sacrificed or preserved
    - Mobile or fixed bearing
    - High flex designs

This operation has a high rate of survival, for example a 10 year follow-up of the Kinematic Condylar prosthesis was 96% (Malkani A.L et al., 1995). Using survivorship or the absence of revision as a measure of success does not take into consideration those prostheses which are causing problems – pain or functional. Therefore the survival rates quoted in literature do not generally relate solely to well functioning prosthesis. Table 1.1 summarises some studies referring to implant survival over various time periods.

Table 1.1 Survivorship of various total knee implants

Paper	Implant	No Patients	Time length	Results
(Attar F.G. et al., 2008)	Press-fit Condylar Knee	n = 354	15 yrs	Overall cumulative = 81.7%
(Nafei A et al., 1996)	Total Condylar Knee	n=348	12 yrs	Overall cumulative = 92.3% OA = 97% RA = 87%
(Pradhan N.R et al., 2006)	Total Condylar Press Fit Condylar (PFC) Kinematic Kinemax Anatomic Modular Knee (AMK) Low Contact Stress (LCS) Load Angle Inlay (LAI) Attenborough	n=587 n=118 n=1091 n=718 n=363 n=149 n=165 n=43	10 yrs 10 yrs 10 yrs 10 yrs 10 yrs 5 yrs	about 89% about 89% about 89% about 89% about 89% 100% discontinued as poor discontinued as poor
(Ritter M.A and Meneghini R.M, 2010)	Cementless prosthesis	n = 73	20 yrs	Overall =76.4% Excluding patella failures = 96.8%

The longest study (Ritter M.A and Meneghini R.M, 2010) quoted in table 1.1 was 20 years where the end point was taken as percentage revised and it concluded that the majority of failures involved the patella rather than the tibial or femoral component. Pradhan's study (2006) looked at a range of prostheses over the years, 1969-1995 and found about a 10% revision rate for most implants. This study used the 'worst case scenario' which means that those patients who had died or were lost to follow up were taken as a failed prosthesis. This may be a misleading percentage as some patients who had died in this time period would have had a 'good' outcome with a prosthesis which would be recorded as 'poor'.

1.6.2. Conventional Instrumentation

The goal of primary TKA is to re-establish the normal mechanical axis with a stable prosthesis resulting in decreased pain and increased functional ability. This is achieved through bone resection and soft tissue balance. To assist the surgeon numerous guides have been developed over the years. They have developed from simple hand implements to sophisticated cutting guides and navigational systems. Instruments such as cutting blocks are used to support and guide the saw blade. Numerous alignment systems can be used to determine the femoral and tibial bone cuts. Conventional methods can be through intra-medullary (IM) or extra-medullary (EM) jigs which include slotted cutting guides. The IM femoral instrumentation involves insertion of the IM rod into the isthmus of the medullary canal to re-establish the anatomic axis. One of the difficulties with this method is the estimation of the rod's insertion point (Nuno-Siebrecht N et al., 2000). Deviations in the insertion point in fact can result in several degrees of malalignment. Despite this IM rods are routinely used for femoral component alignment. IM systems have 'shown higher percentages of femoral component positioning in the desired ranges' in studies compared to EM systems (Engh G.A and Peterson T.L, 1990). In the case of the tibial alignment systems there are various differing opinions. Brys et al (1991) observed that 94% of patients had satisfactory alignment using IM guides, compared to 85% for the EM group. Another more recent study (Reed M.R et al., 2002) found significant difference when comparing IM and EM systems where good alignment was found in 85% of the IM group compared to only 65% in the EM group. In

comparison Denis et al (1993) found that there was satisfactory alignment obtained with both the IM and EM guide systems and in fact the IM group had a wider range of error. Both systems are suitable for the majority of patients; however there are a few exclusion factors for each system. The EM systems are potentially unreliable for patients with abnormal ankle anatomy or excess soft tissue and the IM system is not appropriate in cases of excessive tibial bowing, previous fracture or retained metalwork.

The problems associated with all of these conventional methods of TKA arise from a difficulty in using anatomical reference points and human judgement as this does not ensure a reproducible alignment. Knee geometry is patient specific and severe malalignment and obesity add to the difficulty in achieving correct post operation alignment. It is thought that Computer Assisted Surgery (CAS) could narrow the spread of the alignment resultant outcome range and decrease the outliers and in turn improve the long term functional outcome.

1.6.3. Computer Navigated Surgery

There are three types of navigation surgery, robotic, image-based and image-free systems. The robotic systems use a 'robot' to make the cuts through programmed knowledge. The image-based systems use either pre-operative CT scans or intra-operative fluoroscopy. Therefore this method requires the patient to be exposed to radiation during or prior to their surgery. The third system is image-free where the patient's anatomy is registered intra-operatively and used to calculate the bone cuts orientation.

The principle of computer navigated (or assisted) TKA is that the computer maps the knee joint and the map is reproduced on a screen. The position of the surgeon's hands and instruments are incorporated in this map and the progress of the operation is monitored on the screen. Navigation systems are similar to global positioning systems (GPS) where the surgeon can track instruments in relation to the patient's anatomy. These systems are also useful in TKA for quantifying soft tissue balance – flexion/extension, varus/valgus and degree of laxity. The computer puts together all of the information from the patient and the instruments and then instructs the surgeon where the precise cut should be made. These systems are not intended to

replace the surgeon instead they are designed to assist the surgeon to improve the clinical result. One advantage of navigated surgery is that there is no need for IM instruments to be inserted in the medullary canal which can be associated complications (Chauhan S.K et al., 2004b). However a problem with image-free navigation systems is that they rely on accurate registration of the bony landmarks by the surgeon, introducing human error to the system as with conventional methods. Errors with the input data i.e. the anatomical registration leads to errors in the output measurements and bone cuts.

The two main image free systems used in orthopaedics either use optical or electromagnetic tracking. Optical tracking using infrared light is more common, where optical tracking units are specifically placed and detected by an infrared camera. However the disadvantage found with this system is the problem with 'line of sight' and the fact the equipment and staff themselves can be a problem and block the tracking.

Electromagnetic navigation systems were designed to eliminate the problem of 'line of sight' experienced by optical systems. Trackers are affixed subcutaneously and their location is tracked through an electromagnetic field. Then position sensors are localized within the magnetic field in relation to the patient's anatomical landmarks. One such system is the Zimmer's *iNav*™* Portable Electromagnetic Navigation System which was launched in 2005. It is a portable electromagnetic computer navigation system for knee replacement surgery shown in figure 1.10.

Figure 1.10 The Stealth Station® iNAV™

The system takes the surgeon through all of the steps from fixation of the tracker (image shown in figure 1.11), to recording the relevant landmarks such as the femur anatomical landmarks as seen in figure 1.12.

Figure 1.11 AxiEM Orthopaedic Trackers – Use trackers to track position of the patients' anatomy during the procedure.

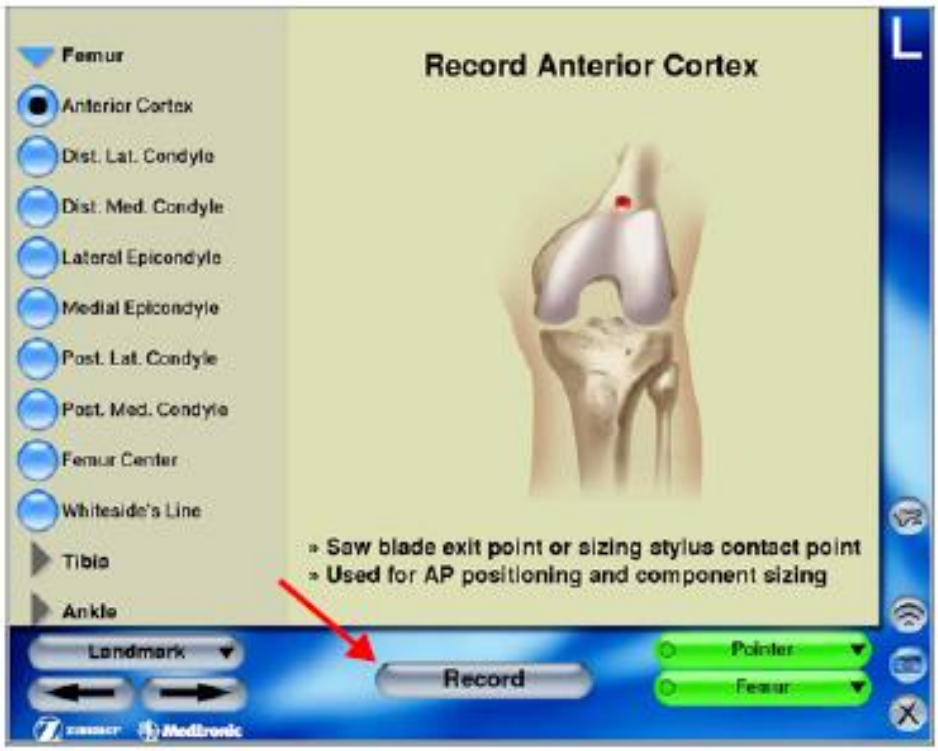


Figure 1.12 iNav screen for the femur anatomical points recording procedure.

From the anatomical mapping the suggested bone cuts are calculated as seen in figure 1.13. The position of the surgeon's hands and instruments are included in the

map of the patient's knee. The progress of the surgery is then monitored on the screen.

Figure 1.13 Navigation of proximal tibia cuts

Important factors to consider when using a computer assisted system are the accuracy of the registration process particularly when using an image free system and especially with respect to determining femoral rotation which depends on being able to define the epicondyle axis. In fact for a surgeon using an image free system they have no more information than one doing conventional surgery with respect to the termination of femoral rotation. A bony landmark registration process has to be completed as the first stage of image free surgery. Studies have recorded high inter-observer variability when surgeons identify medial and lateral epicondyles required for the identification of the epicondylar axis. Yau (2007) reported inter-observer errors of 9^{o} due to medial epicondyle registration and 7^{o} as a result of errors in lateral epicondylar registration. These are significant errors and show the importance of accurate and repeatable registration as it can have a significant impact on the outcome of the surgery. Preoperative deformities and instability related to an arthritic knee can add to the difficulties in this process. There is also the possibility of

computer hardware and software inaccuracies and finally errors in the surgical technique.

The system uses ‘geometric triangulation’ and calculates real time positioning from the magnetic flux variations received by the tracker (a copper coil). The current in the coils varies in relation to orientation within the magnetic field. 3 coils are used in the system. This means that as long as 2 of them were receiving a signal then the EM system was able to transmit a measurable signal. In cases were the signal reception is reduced to 1 coil then the localizer could be repositioned to restore the signal (Lionberger D.R et al., 2008). Due to the presence of the EM field the instruments used are specially produced and iron free. The system measures orientation in real time with uninterrupted feedback tracking the position of the instruments and patient’s anatomy.

Preliminary experience with electromagnetic systems has been reported by a couple of studies. Lionberger et al (2008) compared the accuracy of an electromagnetic (EM) system with an infrared system (IR). The EM system relies on a magnetic field for instrument and lower limb positioning. The accuracy of the system was analysed as operating theatres are ‘subject to a variety of EM and ferric interference’ which may affect it. The two systems resulted in good mechanical alignment outcomes, and in fact the EM system was statistically more accurate for anteroposterior (AP) femoral and tibial measurements. A study by Alan et al (2007) compared limb alignment determined by the EM system and that calculated through the standard evaluation method using radiographs. The study concluded that there was a significant difference between the 2 methods. The difference in the post operation alignment and tibial component alignment recorded from the 2 systems was 1.8^{o} and 0.7^{o} respectively. This study takes the baseline measurement from the radiographs which can be subject to include human error in identifying landmarks for the measurement. There is no way of ensuring that the clinical measurements are made from the same marker positions and the limb in the same, correct position. The aim is to minimise the possibility of errors. No method for measuring the tibiofemoral angle are known to be absolutely accurate. Other studies quoted by Alan et al (2007) compared post-operative limb alignment calculated from IR navigation systems and radiographs found the differences between the 2 methods to ranged from

0.62^{o}-1.58^{o} which is lower that that recorded in this study for the EM system of 1.8^{o}. Tigani et al (2009) concluded that there were no complications with the EM system and that it was safe. In their study the EM alignment recording was compared to radiographs and found to only vary by 0.5^{o}.

1.6.4. Knee Joint Prostheses

The first knee replacements were hinge prostheses but they had issues with insufficient lifespan due to high rates of loosening and mechanical failure as a result of high sheer forces (Shetty A.A et al., 2003). Today there are at least 150 implants in existence (Carr B.C and Goswami T, 2009). Physicians and engineers have and continue to work together to develop an implant to stimulate the 'behaviour of a healthy knee joint'. Therefore advances in the last 30-40 years have seen improvements in surgical materials and techniques which have greatly increased the effectiveness of TKA. In the beginning drawbacks to design were due to the lack of understanding of knee mechanics.

Figure 1.14 Example of a knee prosthesis – Zimmer's NexGen LPS (Zimmer, 2011b)

The Total Condylar prosthesis was designed by Insall at the Hospital for Special Surgery in 1973. This prosthesis concentrated on mechanics and did not try to reproduce normal knee motion. It reported good survivorship after 15 years of 94% (Ranawat C.S et al., 1993). The advances in knowledge with respect to knee biomechanics have led to successful modification in design. Recognising that the

knee does not rotate on a single axis like a hinge but rather the femoral condyles roll and slide on the tibia with multiple instant centres of rotation (ICR) led to ideas based on a polycentric knee replacement design which has improved kinematics. The mechanical problems when designing prostheses include the degree of constraint and surface contact area. The normal knee joint has 6 degrees of freedom in three axes so there is the decision when designing a prosthesis of how to balance freedom of the joint with stability. The more constraints included in the design, the more stable the implant will be but it will not necessarily have as much freedom to move which in turn increases sheer at the component bone or cement interface which can lead to early loosening. Contact area on the other hand relates to wear volume. Wear debris is produced as the tibial and femoral components move in relation to each other during knee joint flexion and extension. It is known that particular debris can lead to osteolysis and aspetic loosening, as seen by the fact that it is the number one cause of revision at 5 years post operation (Fehring T.K et al., 2001). Osteolysis occurs as a result of the body's attempts to 'clean up' the wear particles produced, mainly ultra-high-molecular-weight polyethylene. This can result in the bone being eroded from the implant causing it to loosen (Gupta S.K et al., 2007). The particles stimulate a macrophage induced inflammatory response leading to bone resorption. Macrophages engulf the 'foreign' particles which cause the cells to die and release their chemicals and enzymes which in turn lead to the bone damage. Activity level over time is an important patient factor affecting wear rates.

Advancements in the materials used in the prosthesis have also contributed to the improved long term success. It is now commonly accepted that cobalt–chrome alloys should be used for the femoral components and either titanium or cobalt–chrome for the tibial base plates (Bellemans J et al., 2005). Ultrahigh molecular weight polyethylene is used as the tibial insert. The prostheses can be cemented or cementless. Cement (methylmethacrylate) fixation has a high success rate but it is associated with problems. Cement introduces another potential source of wear debris as it results in another surface interaction site. The cement is not a good transmitter of tensile and shear stresses, so it can add to the technical difficulty of the surgery and increases surgical time. Despite these potential problems many studies have shown that cemented prosthesis designs produced by various different companies can

be successful for 15 years and generally have better results than in cementless designs (Berger R.A et al., 2001a, Dixon M.C et al., 2005, Font-Rodriguez D.E et al., 1997, Ito J et al., 2003, Keating E.M et al., 2002). The cementless method also has technical difficulties for example, for successful integration and stability the interface gap has to be no greater than 0.5mm (Bellemans J et al., 2005).

Posterior Cruciate Ligament Sacrifice or Preservation

The argument as to whether knee ligaments should be preserved or sacrificed has long been an issue. Ligaments in the normal healthy knee contribute to stability and help maintain normal kinematics. When the ligaments are preserved then they impose restrictions on the design of the prostheses, as they dictate the arc of motion through which the joint moves. When the cruciate ligaments are sacrificed then it is the geometry of the prostheses which provides AP stability and has the main influence on the motion of the joint. The anterior cruciate ligament is sacrificed in the majority of cases but the posterior cruciate ligament (PCL) can be preserved. It is claimed by proponents of preserving PCL that an intact PCL 'functions to decrease shear at the bone-cement and cement-prosthesis interface' (Waslewski G.L et al., 1998) as well as providing proprioceptive feedback. In cases where the PCL is sacrificed then it can be substituted by a system of cam-post interaction giving posterior stabilisation, and makes surgical ligament balance easier. Short term trials have not found a great difference in clinical or radiological outcomes between groups where PCL has been retained or sacrificed (Tanzer M et al., 2002). The cam-spine mechanism in posterior sacrificing prosthesis appears to have an advantage as it acts to produce significantly superior flexion angles and knee joint ROM (Harato K et al., 2008).

Mobile or Fixed Tibial Bearings

One theoretical way of incorporating normal kinematics and maximal conformity is with mobile tibial bearings designs. Current mid-term follow up studies of these prostheses have so far shown encouraging results. Mobile bearing designs aim to reduce forces thereby reducing polyethylene wear, along with minimal constraints to normal joint movement. However the minimal constraints

have an associated disadvantage in that it can increase the risk of dislocation. The highly conforming surfaces on the other hand create a favourable and increased area of contact. Another benefit with respect to certain designs of mobile bearing knees such as the LCS rotating platform is the fact that as opposed to the multidirectional wear pattern with a fixed bearing knee they have a uni directional wear pattern which potentially results in much less wear (McEwen H.M.J. et al., 2005). A meta-analysis of fixed versus mobile bearings has found no clinical or radiological advantage (Oh K.J et al., 2009). Trials in this analysis did not find a statistically significant difference in ROM. An advantage of mobile bearings was seen as they reduced the risk of radiolucent lines and complications but it was not statistically significant.

High Flex Designs

Advancement in prosthesis design has recently been in the form of high flex implants designs. Most daily living activities like ascent and descent stairs and sitting in a chair require only a maximum flexion of 120^{o} (Rowe P.J et al., 2000). However activities such as in and out of a bath, kneeling and crouching, which are required for some cultural and religious purposes, require higher knee flexion angles. Average postoperative range of motion (ROM) in clinical trials has been reported as 85-120 (Bassett R.W, 1998, Callaghan J.J et al., 2000, Hardeman F et al., 2006, Hyder N et al., 1995, Sansone V and da Gama Malcher M, 2004). However, new designs to increase the resultant ROM and maximum flexion angle are being tested and the results published. One such design is the Zimmer NexGen LPS Flex which is a posterior stabilised high flexion design. It has been proposed that their extended femoral articulating surface, increased subluxation resistance and low contact point (figure 1.15) allows better posterior clearance and therefore enables stability in deep flexion.

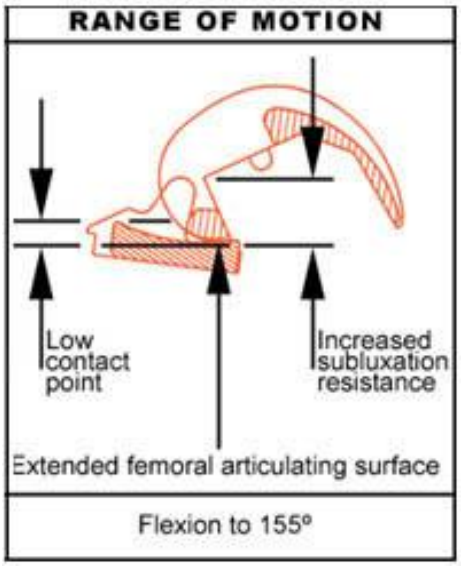


Figure 1.15 Zimmer's LPS high flex (Zimmer, 2011a)

A few studies comparing high flex and standard design have concluded that the high flex design has a superior flexion angle. Weeden et al (2007) concluded that at 1 year post operation the high flex group had a mean ROM of 133^{o} compared to 120^{o} in the standard group. The second point from this study was that there were also significantly more subjects in the high flex group who could flex more than 135^{o}. A final conclusion from this study was that only 52% of the standard group returned to their pre-op ROM compared to 92% of the 'high flex' group having a post-op ROM superior to their pre-op ROM. A study by Han et al in 2007 found increased ROM in the high flex group with mean ROM equalling 136^{o} compared to 126^{o} in the standard group. However this study quoted high incidences of femoral component loosening with the high flex design, which has not been noted in other studies. A study by Kim (2005) disagreed as they found no significant difference between the two implant groups. They recorded a mean ROM of 139^{o} for the 'high flex' group and a mean ROM of 136^{o} for the standard group. Other studies by Nutton (2008) and Seon (2005) also agreed that there was no clinically significant improvement in ROM from the high flex design. The study by Nutton examined functional outcome through an extensive functional assessment using electrogoniometry which did not find a clinically significant difference between the standard and high flex design. They suggested that improved functional score post operation may result because of improved mobility due to a decrease in pain rather than implant design. The recovery

of function was thought to be influenced by the 'general health, sense of well being and expectations' of the patients along with muscle strength, pain and joint stability.

1.7. FUNCTIONAL OUTCOME MEASUREMENTS FOLLOWING TKA

An increasing emphasis has been placed on research into TKA outcomes. At the moment there is a wide range of methods and variables which can be used to record the outcome of TKA. The NHS routinely record and monitor the outcome of TKA using the Oxford Knee Score which gives limited information on pain levels, function and patient's perceived limitations. The range passive of motion of the knee joint is also recorded. However this is just one of a range of questionnaires which can be used – the Hospital for Special Surgery Knee Clinical Rating Score (HSSS), American Knee Society Score (AKSS) to name a few (Davies A.P, 2002). Recording and monitoring is essential for measuring the success of the surgery and can also be used as a measure of comparison between varying techniques, implants and methods of surgery. Other outcome parameters generally used include joint stability and alignment. So what is the best method of measuring these surgical outcomes? Which outcome measures are sensitive enough to pick up changes in patient's outcome?
Outcome measures include:

- Questionnaire scores
- Radiological assessment
- Muscle strength
- Activity monitoring

1.7.1. Questionnaires and Associated Problems

Clinical data can be gathered through questionnaires, which is one of the easiest ways of monitoring routine TKA. They can also be used in research trials to compare various aspects of TKA outcome. There are a range of questionnaires which give information about; range of motion, functional ability (stair climbing, walking distance), pain levels and knee stability. There are many patient related outcome measures (PROMS) which are subjective scores. One example of PROMS is the Oxford Knee Score (OKS) which was developed specially for TKA was The OKS questionnaire was developed through interviews with patients at outcome clinics so

aimed to focus on the needs of the patients. It resulted in a 12 question questionnaire each with 5 possible answers for each question. OKS was developed by Dawson (1998) and was validated against the relevant parts of the Short-Form 36 (SF-36), Health Assessment Questionnaire (HAQ) and the clinician's completed American Knee Society Score (AKSS). It correlated well with the other scores and in fact was found to have a consistently higher completion rate than the longer questionnaire, SF-36. However Whitehouse (2005) reported on the problems and pitfalls of the OKS. They felt firstly that the scoring scale was confusing as 12 equalled the best outcome and 60 equalled the worst outcome. This is an unusual scale as they generally use zero to indicate poor function and higher numbers indicating better health. However in the recent years the Oxford Knee Score has been updated so that 0 equals poor health and 48 indicated the best outcome. This means that within published papers there will be two scales and therefore caution must be taken when comparing studies. They also felt that the patient would require help to answer the questionnaire and therefore they found that they received a high number of incomplete questionnaires (18.9%). However, this problem could be easily overcome through the help of a friend, family member or health professional during the assessment. They also thought that a couple of the questions could have been worded better to decrease the percentage of missing answers. The two questions which caused the most issues were question 4 and 7, investigating walking time and the patient's ability to kneel. Questionnaires can differ in how they define walking ability, for example, whether it has been measured by distance and by time period the patient can walk for. This study also questioned the appropriateness of the 'kneeling' question as patients are sometimes 'not advised' or just do not attempt this task and therefore there were cases where this was the only question which had a negative answer. So the patients were pain free and did not feel functionally limited but did not achieve a prefect score. However if the patient cannot kneel, even if they feel this does not limit them in fact they are functionally limited. Palmer et al (2002) reported that 54% of patients avoided kneeling due to advice however when they attempted the task 64/75 patients could kneel with no or little discomfort, and from those who could not kneel some of them were limited due to other problems or reasons which were not related to their knee joint. The OKS is not subdivided but many of the

questions are pain related (40%). Although pain is an important factor in the outcome of TKA it may overshadow or mask the patient's good functional ability by resulting in a high score. Around about a difference in 5 points in the oxford score is thought to be clinically significant (Liow R.Y et al., 2003).

Another knee score questionnaire which is widely used in research papers is the American Knee Society Score (AKSS). This score is made up of a 'knee' score and a 'function' score. The knee score is subdivided into pain, ROM and stability/alignment of the joint. In fact the pain score makes up half of the knee score which is a significant weighting. The function score refers to the patients' ability to walk distances and method by which they ascend and descend stairs. Walking aids are taken into consideration within this score and have a negative effect on the score. Therefore the functional sub score is calculated from 2 functional tasks which does not give a clear overall picture of the patient's functional ability or limitations.

It is important to consider the length of the questionnaire to be completed; short questionnaires of 10-12 questions are less time consuming but a longer questionnaire gives an overall picture of the patients' functional ability. The longer questionnaires may lead to low completion rates. Who fills in the questionnaires is also important. Clinically based questionnaires such as the AKSS need the expertise of a clinician to complete it but the data is most likely to be objective such as ROM. If it is a patient based questionnaire such as the OKS then it can be influenced by the patient's mood – is this a bad day? Lots of pain? Or even, are they answering what they think the clinicians are expecting of them leading to errors in the score. The questionnaires are patient responses therefore can be based on their expectations. They may have high expectations, recalling their quality of life before the onset of severe OA symptoms instead of remembering the situation immediately prior to the operation. In cases where there is a high expectation of fully returning pain free to daily living their can be a feeling of disappointment and dissatisfaction regarding the outcome of their surgery. Another thing to note is that the younger patient group are generally more active and in some cases they cannot return to the sports they had previously undertaken and therefore feel limited. All these questions are difficult to answer and although questionnaires have the advantage of being quick they are generally highly subjective. Noble et al (2006) found that satisfaction correlated

strongly with ‘age less than 60, absence of residual symptoms, fulfilment of expectations, and absence of functional impairment’. It was concluded that ‘satisfaction with TKA is primarily determined by patients' expectations and not their absolute level of function’. Therefore this suggests that it is important for the patient to have a realistic view of TKA outcome.

Generally the population receiving a TKR have other co-morbidities which have an effect on the patient (Harcourt W.G.V et al., 2001). These can influence the responses to questionnaires, and in fact the patient may not be limited on walking distance by pain from their knee but back or hip problems. For most functional activities limitations from other joints will influence the patient’s performance.

1.7.2. Radiological Assessment

Another method of measuring outcome of TKA is through radiological data either radiographs or CT scans. Many studies have used this as their surgical outcome measure to analyse the placement of the prosthesis. The alignment outcomes of TKA are thought to be important and linked to successful and life spans of the implant (Jeffery R.S et al., 1991). Radiological assessment will be discussed in more detail in section 1.10.2.

1.7.3. Muscle Strength

The stability of the knee joint is linked to physical functioning and the ability to control movement under differing external loads. The stability of the joint is provided by the ‘active neuromuscular system (muscle strength and proprioception) and by passive restraint (ligaments and capsule)’ (van der Esch M et al., 2008). It is thought that muscle weakness and malalignment would lead to instability and therefore before and after TKA these could be factors which influence patients’ functional ability (Silva M et al., 2003). In fact studies have concluded that strength deficits continue after normal TKA rehabilitation (Stevens J.E et al., 2003). The importance of quadriceps strength has been demonstrated in the correlation between improved quadriceps strength and improved gait speed in OA patients (Maly M.A et al., 2006). Schroer et al (2010) found that both hamstring and quadriceps strengths increased from pre-op to 1 year post-op for the involved limb but also for the

uninvolved limb. Prior to TKA, inactivity due to pain would affect both limbs. The contra lateral limb would be used to compensate for or minimise the functional deficits resulting from the affected knee. Many studies have concluded that although patient's muscle strength increases they continue to have muscle weakness years after the surgery and that there is a deficit in muscle strength between the involved limb and the healthy limb. The post operation quadriceps and hamstring strength is important as the stability of the knee joint has been reported to be related to the correct ratio of hamstring to quadriceps (H/Q) strength (Tan J et al., 1995). Quadriceps weakness has been reported in TKA patients whereas there is no significant decrease in hamstring strength which would lead to an altered Q/H radio (Berman A.T et al., 1991). Physiotherapy after TKA therefore plays an important role in the functional outcome of the patient.

Quadriceps strength has been directly correlated with functional score of the AKSS (Silva M et al., 2003). For many activities such as stair climbing the knee extensor mechanism is important and therefore 'it is logical for the quadriceps strength' to be 'associated with the functional score'. In fact this study concluded that since the hamstring weakness had lower correlation to the function score of the AKSS this 'reflected the low level activities' which are assessed by the AKSS. They predicted that if the questionnaire included more vigorous activities such as slope walking then the deficiency would become more apparent and more of a problem for the patient.

1.7.4. Activity Monitoring

The daily activity level of subjects can also be used as an indication of quality of life. Activity levels can be used as a measure of function and recorded using activity monitors such as the activPal as seen in figure 1.16 (PAL Technologies Ltd, Glasgow, UK). This monitor continuously records the number of steps taken by the subject as well as the periods of walking, sitting or lying and standing. This monitor has been validated (Godfrey A et al., 2008, Ryan C.G et al., 2006) and has been used in a number of clinical trials involving various subject groups such as normals, OA patients, lower limb amputees, the elderly and with cerebral palsy patients(Howe T.E

and Rafferty D, 2009, Ryan C.G et al., 2008, Ryan C.G et al., 2010, Tang K et al., 2009).

(a) 

(b)

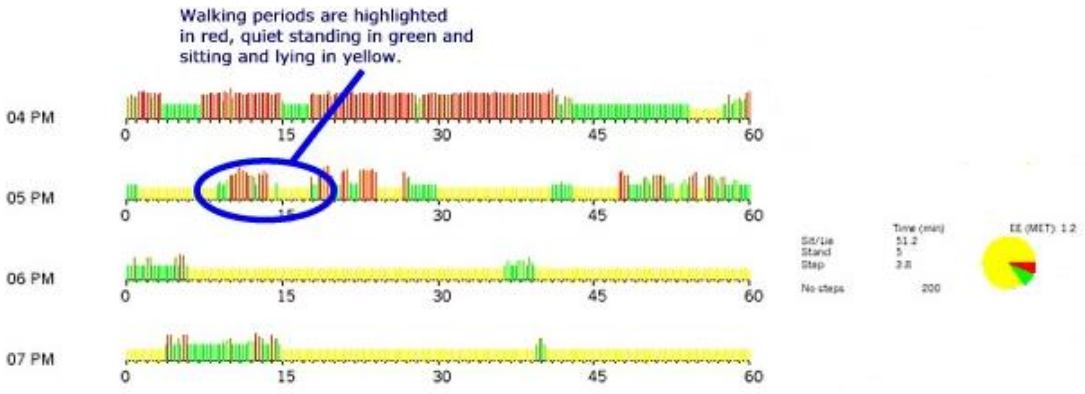


Figure 1.16 (a) Diagram of the ActivPal used for activity monitoring (b) Example of the ActivPAL output

De Groot (2008) compared OA patient's activity levels with age match healthy subjects and found that they had significantly and clinically relevant lower activity levels. However the activity levels of the patients was in fact not as low as expected suggesting that despite pain or lack of mobility the patients are able to maintain a reasonable activity level. They noted that the patients' perceived limitations in daily living (measured in the WOMAC questionnaire) did not always correspond to their actual physical activity. This is another point to be noted as a possible disadvantage of questionnaires compared to non invasive objective measurement systems.

1.8. FUNCTIONAL ASSESSMENT

As already mentioned functional disability can have a large impact on the quality of the patient's life which means that the outcome of TKA has to take function into consideration. A successful TKA includes a good functional outcome along with a decrease in pain. Mobility and the ability to complete certain tasks can be noted and scored in 'functional outcome questionnaires'. Observing patients performing tasks during a 'functional outcome assessments' can give valuable information which maybe missed in the completion of questionnaires and not noted in an interview with the patient.

Functional ability is related to quality of life as it includes whether general daily tasks can be completed. Walking, stair climbing and sit to stand from a chair are taken by most people as basic tasks. However knee OA and TKA can affect the patients' ability to complete these successfully and with ease i.e. without severe pain and stiffness. Limited knee range of motion can also lead to difficulties in bending tasks such as putting on socks and picking objects up from the floor.

It is important to understand the knee biomechanics of these tasks and also how OA and TKA patients vary and adapt compared to normal elderly subjects. Clinical trials have been conducted which have described the general pattern of normal elderly gait, OA gait and gait after TKA showing distinct differences between these three groups.

Gait analysis is a useful objective tool giving quantified data. Results from motion analysis in TKA patients can reflect the restoration of knee function or continuing problems and therefore can be used as an indicator of the surgical outcome. The process of gait analysis cannot be completed for every patient prior to and after TKA as it is time consuming. However observation of the patients gait within a clinic can be important. Gait analysis gathers a substantial volume of data with regards to kinetic and/or kinematic information.

1.8.1. Normal Gait

The gait (walking) cycle can be divided into 2 phases, stance and swing. There are also periods of double support within the walking cycle (figure 1.17). Running is similar to walking in some respects but has no periods of double stance. Stance phase

involves the foot being in contact with the ground and is about 62% of the total cycle. The swing phase (38% of the cycle) is associated with a higher knee flexion angle as the lower limb is raised and propelled forward. Stance phase begins with heel strike, then foot flat to mid-stance, mid-stance to heel off and finally toe off. Swing has two distinct parts, acceleration to mid-swing and mid-swing to deceleration.

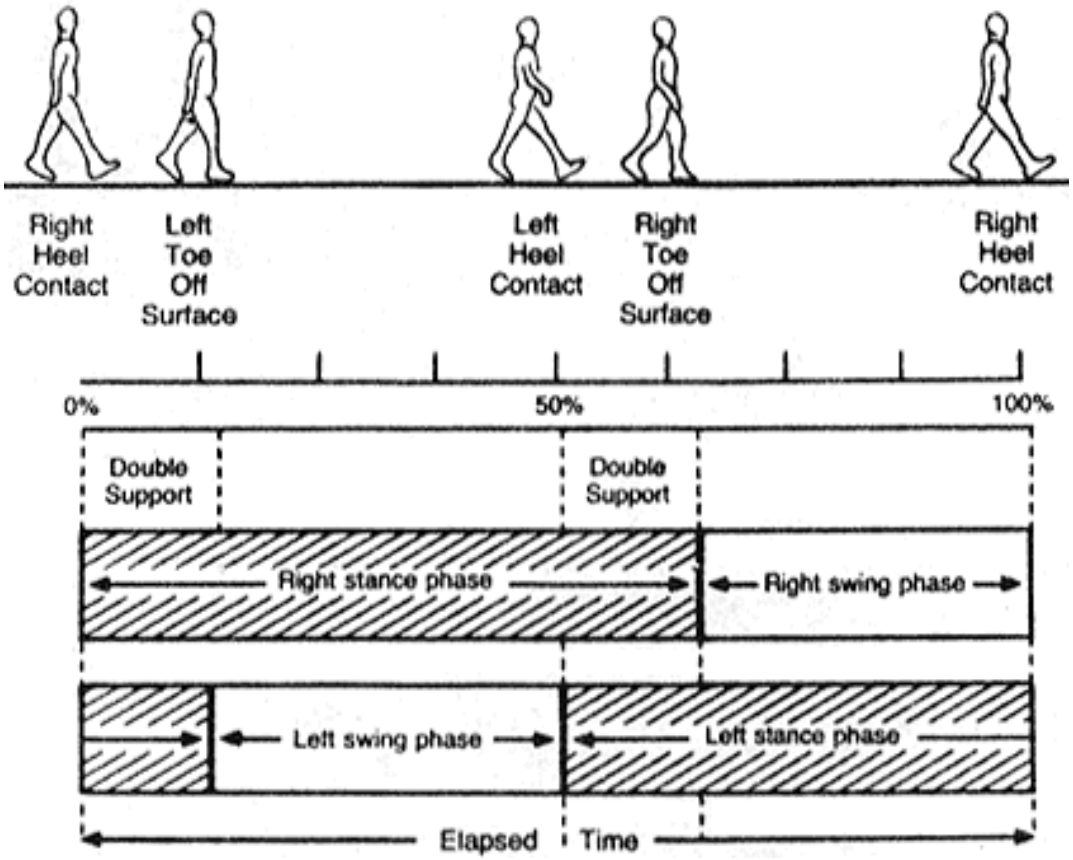


Figure 1.17 Diagram of stance and swing phase of walking.

Normal walking gait has a max of 20^{o} in stance, and 60^{o} in swing phase (figure 1.18). Stance phase is also accompanied with about 5^{o} rotation and about 5^{o} varus/valgus movement (Whittle M.W, 1996). About 25% of the gait cycle has double support. Double stance phase decreases with increasing speed.

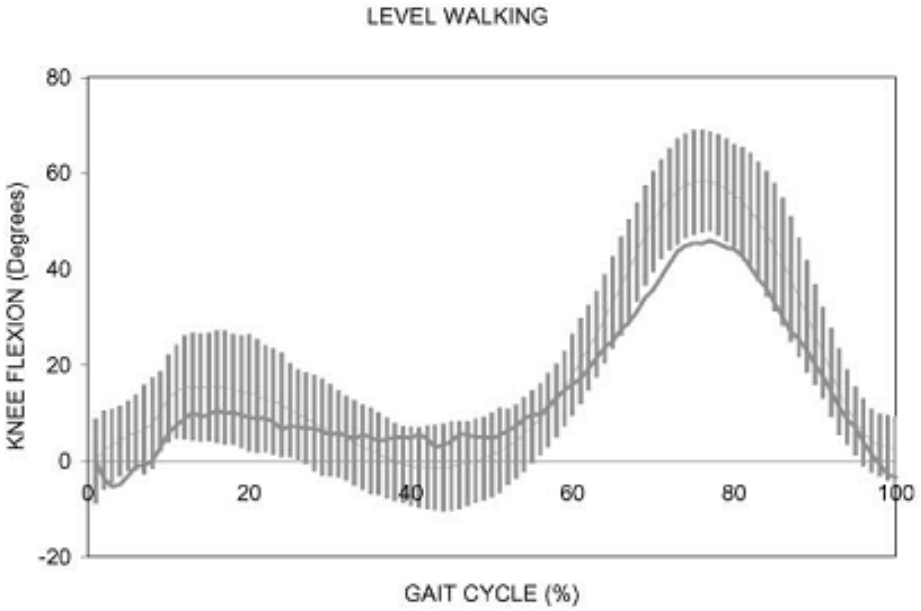


Figure 1.18 Knee flexion pattern during walking. The shaded range represents the normal range, +/-2 standard deviations of the mean. (Whittle M.W, 1996)

Throughout our lifespan our gait pattern changes. It begins with a toddler's gait pattern into adulthood and then into an elderly gait. Increasing age related changes such as decreased muscle strength and a loss of passive range of motion may be associated with gait adaptations (Prince F et al., 1997). Generally Prince's review concluded that the 'extension angle at mid-stance increased by about 0.5^{o} per decade while a decrease by $0.5\text{-}0.8^{o}$ per decade is shown during swing phase'. The final significant difference for the elderly group was that heel strike was not in full extension as in the young group but it was around 5.3^{o}, and therefore they walk on a slightly bent knee.

1.8.2. Arthritic Gait

Studies have investigated the changes in gait between OA patients and age matched healthy subjects. Generally OA patients walk at a 'significantly reduced walking speed, shorter stride length and a prolonged stance phase' (Al-Zahrani K.S. and Bakheit A.M.O., 2002). Another symptom of OA gait is generally a limited or reduced range of motion (Liikavainio T et al., 2008). It is symptoms such as pain, which cause these patients' gait adaptation with shorter periods of single stance on their affected limb and lower walking speeds. Statistically significant variations in

the single limb support (SLS) stance phase percentage of the gait cycle have been reported between genders. It was reported that in females SLS was 35.8-36.2% of the gait cycle compared to 37.0-37.7% in males (Debi R et al., 2009). Stance phase was 63.9-64.1% of the gait cycle in females compared to 62.2-63% in males. These differences are likely to be explained by patient's pain levels. When pain levels are high then the individual avoids supporting their entire body weight on the affected limb. In severe OA the peak knee flexion of 20^{o} during stance phase disappears and the patient walks in almost full extension. Kaufman et al (2001) compared gait characteristics of OA subjects with normal subjects. They concluded that there was a significant difference between the groups for peak flexion angles. The mean difference was 6^{o} during walking and 2^{o} when ascending and descending stairs. This study includes subjects with radiographic OA and at least 6 months of pain and stiffness in their knee. The OA volunteers were at various stages of the disease and are not necessarily at 'end stage' OA and waiting for a TKA. The differences in peak flexion reported between OA and normal group may increase if OA patients waiting on TKA were investigated. In stair walking tasks, especially descent, OA patients adapt their gait pattern as a result of the pain in their knee. They walk one step at a time instead of step over step. This results in a lower peak flexion angle as they protect their affected limb. This group of patients were excluded from Kaufman's study therefore the results may not be a true representation of the OA group.

In fact OA subjects waiting for TKA show a 28% reduction in excursion (maximum-minimum flexion angle) angles when comparing 11 functional activities with an age-matched normal group (Myles C.M et al., 2002). Bejek et al (2006) agreed as they found that when comparing patients with unilateral knee osteoarthritis with age matched healthy subjects the minimum knee joint angle was increased and the maximum knee joint angle was decreased for the OA group. This means that the range of motion has been decreased on both ends of the flexion range for level walking. Reduced knee joint range of motion was found to be compensated by increased pelvic motion which they concluded 'affects the natural mobility of the lumbar spine' and could cause pain in the lumbar region. In severe cases gait cycles can see distinct changes such as a loss in the magnitude of the stance phase peak and a significant decrease in the swing phase peak (Astephen J.L et al., 2008). Also in

some cases there is no distinct knee extension phase normally found at the end of stance phase and the swing phase peak was found to be delayed.

In 40/58 of the patients in the Al Zahrani trial, the ‘rectus femoris was active throughout the stance phase of the cycle,’ compared to activation being ‘observed in early to mid-stance in the control subjects.’ The other muscle showing a varied pattern was the gastrocnemius where contraction ‘was delayed in the patient group compared with that in the healthy subjects.’ This delay in the action of this muscle is thought to be due to the fact that patients with OA have a ‘prolonged stance phase.’ The observed gait abnormalities could be due to instability of the knee joint in stance. The OA knees generated moments at the knee joint for ‘longer periods without a corresponding generation of power’ which may help stabilize the knee during the weight transfer section of stance phase. It was also concluded that there was a ‘reduction of the powers generated by the ankle plantar flexors in pre-swing’ which may be a conscious effort by the patients to facilitate walking at lower speeds for more dynamic stability.’ Instability has also been reported to affect physical function (Fitzgerald G.K et al., 2004) where the patients limit their range of motion and simplify the movement necessary for the activity. Instability also leads to a fear of the knee buckling or giving way particularly on uneven surfaces or stairs.

Subjects with OA have also been seen to exhibit significantly lower knee extensor moments during gait (Kaufman K.R et al., 2001). This can be explained through the fact that contact forces in the knee joint are proportional to the net external reaction moment. This means that large external moments produce large contact forces. Therefore pain can be minimized by reducing the knee extensor moments. The highest extension moment occurred while descending stairs and this is therefore seen as the most difficult activity. The tibiofemoral joint OA is associated with weight bearing pain especially on stairs.

1.8.3. Total Knee Arthroplasy Gait

One of the proposed outcomes of knee arthroplasty surgery is an increase in knee joint ROM which would allow activities such as bending and stair walking to be completed easier. However it has been shown that although the function of the affected knee improves, in fact 2 years after TKA patients still have significantly

lower maximum flexion angles and function compared to normal age matched subjects (Myles C.M et al., 2002). It was noted that the patient's function had improved from pre-op scores but this was minimal (2% improvement).

In some cases a decrease in the ROM post operation has been reported (Harvey I.A et al., 1993). Stiffer pre operative knees in fact gained motion post operation compared to mobile pre operative knees which in many cases lose ROM. In fact a decrease in pain levels has been shown to have the strongest effect on the improved AKSS (Konig A et al., 2000). It has also been reported that there was more of an improvement in walking distances then in ability to walk up and down stairs.

1.8.4. Stair Ascent and Descent

Kinematic pattern for stair ascent and descent are cyclic (figure 1.19).

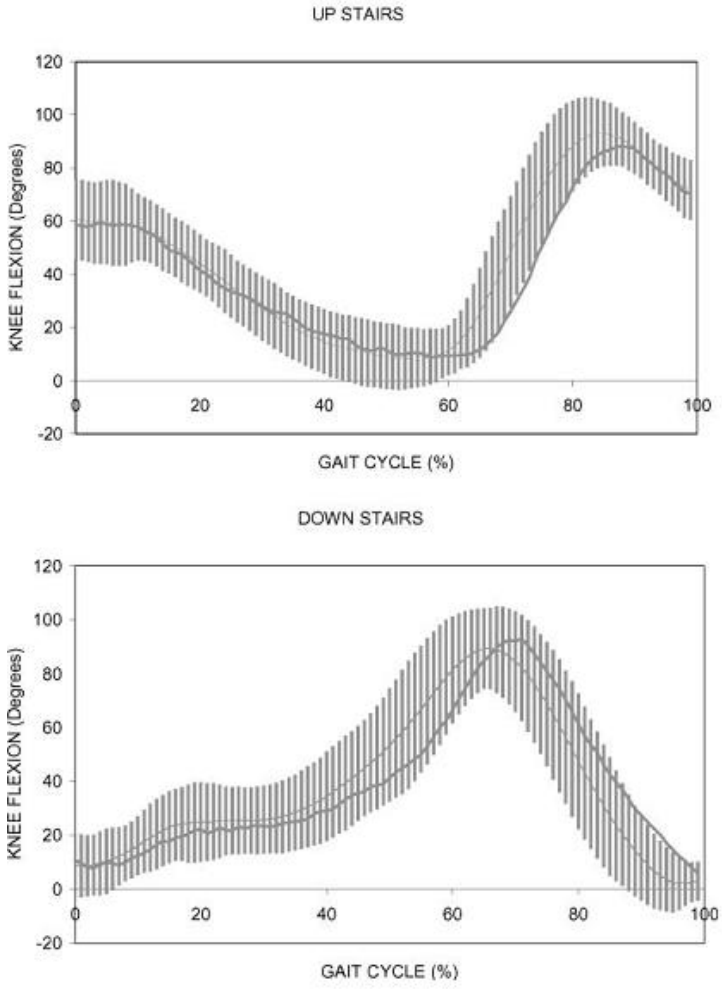


Figure 1.19 Knee flexion angles during ascent/descent stairs. The shaded range represents the normal range, +/-2 standard deviation of the mean.(Whittle M.W, 1996)

The first section of the foot to strike the ground is the forefoot and not the heel as in level walking. Both stair ascent and descent involve an increased joint power which is related to the potential energy that has to be produced (during ascent) or absorbed (during descent) by the muscles (Whittle M.W, 1996). Higher flexion angles are also required to clear the stairs (up to around 100^{o}) (Rowe P.J et al., 2000). Stair descent gait patterns follow a similar cycle as level walking with the most noticeable difference being that the peak flexion angle is notably higher.

The pattern for stair ascent cycles is however slightly different. Instead of the first foot contact at stance phase taking place when the limb is extended, the knee joint is generally flexed to about 60^{o}. The limb then goes into extension, and the power in this action propels the body upwards. Other notable features of stair ascent and descent in comparison to level walking is that the cycle time length is significantly longer (Riener R et al., 2002). The periods of double stance were found to be longer in stair ascent compared to level walking, but this was not the case for stair descent of a normally inclined staircase. This conclusion differs from a study in 2003 by Catani et al where the periods of double stance where statistically significantly increased for both stair ascent and descent.

1.8.5. Slope Walking

Walking on an incline is similar to that of level walking with the one major difference that the body's centre of mass has to be either raised or lowered during each stride. The gait pattern for slope walking is similar to that of level walking. Slope walking records an increase in the magnitude of the flexion angles. In level walking heel strike is associated with full extension of the knee joint, whereas it has been shown that for slope ascent the first foot contact is during knee flexion. The flexion angle is related to the steepness of the incline (Lay A.N et al., 2006, McIntosh A.S et al., 2006).

Heel strike for decent of a slope takes place when the knee joint is almost fully extended. In level walking there is a stance phase flexion peak and then the knee extends again before swing phase. In slope descent, the stance phase flexion angle is increased compared to level walking. The extension period seen in level walking

during late stance phase (prior to swing phase) is not distinct in slope descent and in some cases it can be absent.

1.8.6. Chairs (Sit-Stand)

Sit to stand is a common daily activity but for some people it can be difficult especially if the chair is low. This task requires power from the quadriceps to extend the knee joint and raise the body's centre of mass. There is additional difficulty for patient's with a stiffened knee or if the knee is painful to move through the normal ROM.

Sit to stand and stand to sit cycles both have 7 distinct events which take place. The timing of these vary and are related to age and sex where elderly females were found to take significantly longer to complete the task (Kerr K.M et al., 1997).

Rising phase:

- Initiation of forward lean
- Initiation of knee extension
- Initiation of vertical displacement
- Final forward lean
- Final vertical displacement
- Final knee extension
- Final backward lean (recovery)

Descending phase:

- Initiation of forward lean
- Initiation of knee flexion
- Initiation of vertical displacement
- Final forward lean
- Final knee flexion
- Final vertical displacement
- Final backward lean (recovery)

1.9. OBJECTIVE OUTCOME MEASUREMENT SYSTEMS FOR GAIT ANALYSIS

Assessment of patients as mentioned is routinely conducted through a range of questionnaires (discussed in section 1.7.1) which include limited questions which focus on function. Although these can be used to assess the function prior to and after surgery the patients' responses are subjective and evaluation of the situation may have discrepancies between patients and doctors. Other objective measurement systems which could be used for a biomechanical functional assessment include:

- Electrogoniometers
- Motion AnalysisSystem
- Video fluoroscopy
- Gyroscopes and accelerometers

1.9.1. Electrogoniometers

Electrogoniometers (EG) are an example of unconstrained kinematic measurement devices which can be used within a clinical setting (Kettelkamp D.B et al., 1970, Maupas E et al., 1999, Myles C.M et al., 2006, Myles C.M et al., 2002, Rowe P.J et al., 2000, Rowe P.J et al., 1989, van der Linden M et al., 2006, van der Linden M.L et al., 2007, van der Linden M.L et al., 2008). They allow functional data to be recorded for individual patients. This data can then be used as a sub group of the whole population group being investigated. Systems which allow movement to be measured out with the confinements of a clinical laboratory have the advantage of allowing data to be collected in a natural setting. Also the functional activities undertaken can use normal, unmodified equipment such as a staircase or a bath. These systems have to be relatively small and light weight so they are accepted by the user without affecting or restricting their movement in any way. Electrogoniometry assessments have been used in various research trials involving different joints. These types of assessments are confined to research studies as they involve additional time. Patients with OA (Myles C.M et al., 2002), patellofemoral pain syndrome (Syme G et al., 2009), stroke (Pomeroy V.M et al., 2006) and had a knee replacement have been used as test subjects along with normal healthy subjects (Rowe P.J et al., 2005, Rowe P.J et al., 2000, Rowe P.J et al., 1989).

Electrogoniometers are an electronic version of the routinely used clinical manual goniometer which is used to measure knee flexion in patients while lying on a bed. Electrogoniometers are relatively cheap and give real time results. They can measure joint angles in more than one plane. Electrogoniometers have been used for decades, investigating normal gait (Kettelkamp D.B et al., 1970) although this version of the system was more cumbersome than the flexible electrogoniometers on the market today (Biometrics Ltd, Gwent, UK).

It was shown even in this early stage that it was a reliable measure of knee joint movement despite the possible problem which arises from the difficulty in attachment. Electrogoniometers do not exactly mirror the motion of the natural knee joint which has ICR and the accuracy of this measurement device relies on correct alignment when attaching. As previously discussed, knee rotation can vary with joint angle, while the knee flexes it rotates slightly and this can causes crosstalk between the channels. The electrogoniometer while measuring flexion/extension assumes movement in one plane which is known to be inaccurate. The electrogoniometers are attached to the skin through medical tape and then straps are used to hold the electrogoniometer in place. The system assumes that the skin movement and the underlying bone movement are identical but in fact the soft tissue movement contributes to a measurement error.

Electrogoniometer systems have been validated against the Vicon system and found to be a reliable and accurate method for recording joint angles. Rowe et al (2001) validated the electrogoniometers with the Vicon system which is the 'gold standard' for gait analysis, for level walking in five normal subjects. A good correlation was found. The signal stability and hysteresis effects where also investigated. The electrogoniometer output signal was seen to be stable for a test period of over an hour. A hysteresis effect was seen when testing these instruments but it was minimal and recorded as around 1^{o}.

Pomeroy's study also looked at the agreement between electrogoniometers and the Vicon motion analysis system but this time the systems outcome measure was angular velocity. For this test group, stroke patients, it is advantageous to be able to assess the normality of their gait and benefits of physical therapy intervention within the clinical setting. However generally measuring normal gait parameters involves

the use of laboratory based gait analysis equipment which is expensive and requires user expertise. An additional problem is the transportation of the patients if the test centre is not the clinic. Since electrogoniometers are suitable for clinic settings and do not require a laboratory environment then they have an advantage over VICON motions analysis systems. Pomeroy's study looked at angular velocity and in fact concluded that this parameter measured by the two systems were not interchangeable. They suggested that the sensitivity to change at higher angular velocities may differ between the two systems. Also there where problems with the method of attachment as the reflective Vicon markers were 'placed on the joint line' compared to the electrogoniometer 'arms' attached to soft tissue proximal and distal to the knee joint which could lead to more soft tissue movement. This was suggested as a possible explanation for the lower angular velocity recorded by the electrogoniometer.

Electrogoniometry has been tested for between day repeatability (van der Linden M.L et al., 2008). However although ICC (Intraclass correlation coefficient) values for most of the activities were 0.75 or higher and therefore indicate good reliability they were associated with a large range of values making 'ICC's less appropriate as an indicator of repeatability on their own'. However this study does suggest that electrogoniometry 'exhibits sufficient repeatability to detect changes in functional knee motion before and after surgery in groups of patients'. In fact other studies into repeatability have shown that 'normals' are more repeatable than patient groups and younger groups are more repeatable than older groups (van der Linden M.L et al., 2008).

Footswitches count the number of times the foot makes contact with the ground. They are normally a pressure sensitive resistor working on an on/off system, where they record from heel strike to toe off. They can be used in parallel with the electrogoniometers to distinguish the stance and swing phases of the walking cycles.

1.9.2. Motion analysis System

A commonly used motion analysis system is the Vicon system, which uses infrared reflective light cameras and reflective markers. The Vicon system has been well established and used by academics and clinicians alike. Clinical gait analysis

can be used as a tool allowing extensive kinetic and kinematic data to be recorded from a wide range of patients with varying aliments. Vicon is probably the most commonly used method for measuring joint angles and allows movement of the major joints of the lower limb to be analysed in three dimensions. When at least two cameras identify the marker then a 3D coordinates is estimated using 'geometrical properties of central projection from multi-camera observation and mathematical triangulation method' (Racic V et al., 2009). Simon (2004) raises various issues around systems such as this including the procedure time length and expense. The testing session time length is a significant disadvantage to systems such as Vicon. The system has to be calibrated before each session, and the attachment of the subject markers is time consuming.

The Vicon system is widely used for kinetic and kinematic analysis and is accepted as the 'gold standard'. However as with most measurement systems it is associated with measurement errors and variability from three primary sources:

- The measurement system
- The examiners themselves
- And the subject being tested.

The variability in system accuracy was seen to be minimal compared to the possible errors or variability of data resulting from the other sources i.e. the examiner marker placement and the variations in the subjects between test days (Gorton III G.E et al., 2009). This means that when comparing trial data between test sessions in one site and in multiple sites standard protocols need to be used to minimise the errors in the data which may mask changes in for example gait or in fact show changes which do not exist. The possible system errors are associated with calibrations and errors in the software as analysis programs including anthropometric data which is not subject specific. Anthropometric data used for the subjects is standard which has the obvious problem that each subject anatomy will vary slightly. Therefore this set of average data collected from a selection of the population will not be accurate for each subject. The system has to be calibrated at the beginning of each session to allow the relationship between cameras and test space and between different cameras to be established. The test volume is the area in which the subject will walk in. A static calibration is completed first. Dynamic calibration uses a wand with 2 markers set at

a known distance apart. It is moved within the test volume. This then generates equations which determine the precise relationship between the cameras and the cameras are now not moved for the remainder of the test session. Therefore for the rest of the session a 3D image of markers can be recorded as long as it can be seen by at least 2 cameras.

Studies have shown that variability is mostly due to the examiner and the placement of the external markers (Besier T.F et al., 2003, Charlton I.W et al., 2004, Cowman J et al., 1998, Maynard V et al., 2003, Schwartz M.H et al., 2004). The Vicon system is based on recording the movement of reflective markers which are stuck to bony landmarks on the body. The accuracy of the marker placement has a significant impact on the outcome data. The markers indicate segments which are rigid representations of the body. These segments are non deformable however movement of the soft tissue which differs from the underlying bone introduces soft tissue artefact and one of the most critical sources of error. Peters et al (2009) looked at determining the 'marker locations which undergo least displacement from the intended positions'. It found that the ideal marker positions are on bony landmarks which are 'not impeded by muscle or fatty deposits' such as over the tibial crest and malleolus at the ankle. Therefore locations which have minimal skin movement can minimise the errors. Therefore studying the movement of the normal tibiofemoral (knee) joint, as using reflective markers raises the question of skin movement vs. bone movement (Freeman M.A.R and Pinskerova V, 2005). For example during heel strike of the gait cycle the soft tissue will 'wobble' due to the abrupt action leading to oscillation of the markers 'with respect to the underlying bone inducing noisy kinematic data' (Racic V et al., 2009). In some marker sets clusters markers are used which are attached to the lower limb via velcro straps round the shank and thigh. There have been issues raised of possible skin and velcro movement. Methods which are more reliable such as fixing pins to the bone have ethical disadvantages. It has been discussed that the knee joint has an instantaneous center of rotation and therefore the knee joint centre moves during activities. This is not taken into account in the rigid body model. When studying the knee joint angle the accuracy of the knee joint centre is important but also the calculated hip and ankle joint center. Stagni (2000) concluded that a variation of +/- 30mm in hip joint centre can alter angles and

moments of both the hip and knee joint by up to 25%. Floating axes systems for the markers and joint centers refer to the bony landmarks and are used to calculate movements of the rigid segments. Therefore inaccuracies in marker placements lead to errors in the axes which the kinematic calculations are based on.

The markers attached to the subject are used to capture the position of the subject and segments of the body. The main drawback relates to the visibility of the markers, which are partially solved through the use of multiple cameras. However there are still problems of hidden markers for example, by clothes and even by the swinging arm motion. However this problem also acts to limit the functional activities which can be included in a test session, for example, inclusion of a bath task would not be possible because when the subject sits down in the bath the markers would disappear from the 'line of sight' of the Vicon cameras. Even standard daily activities which studies have reported in their gait analysis session such as ramp and stairs have the problem of hip/waist markers being lost from the 'line of sight' and therefore care has to be taken to position the cameras for these specific tasks so that a sufficient volume is captured by the cameras. One of the main disadvantages to using a Vicon system is that it is an unnatural setting for the subject and is restricted to a gait laboratory. The area of sight of the Vicon only includes a maximum of 2 gait cycles and also the size of the room determines the number of strides the patient takes before they are captured by system. In general the subject may not have fallen into their natural stride and this may alter the gait pattern recorded.

Generally trials are repeated and therefore can be averaged to give a more accurate gait cycle. This also allows cycles to be studied and unusual trials to be identified whether for additional investigation or as an outlier. Within sessions as markers are not moved so the variability of the trials has been found to be minimal. However this is not the case for between sessions variability which has been found to be higher due to the potential for differences in marker placement (Gorton III G.E et al., 2009). This therefore raises questions about the reliability of comparisons between sessions with one examiner and also between laboratories and studies. Variability between sessions can also be contributed to changes in the subjects walking pattern from day to day. Although for healthy individuals day to day

variations would be expected to be minimal, for patient groups the changes may be significant depending on for example their pain levels and the previous activities undertaken that day. Finally fatigue within the course of the day for the patients group may be a factor. Testing sessions using Vicon systems can take a couple of hours, although the patient would not be on their feet and active for all of this time.

Advantages of Electrogoniometers over the Vicon System

Electrogoniometry systems have the advantage over Vicon systems of being portable. This means that they are not confined to a gait analysis laboratory and therefore can be used in a clinical setting. This means that when testing patient groups the functional testing can be conducted in the hospital setting and therefore can be included in clinic appointments. This means that it is possible to cut down on the number of appointments the patients are required to attend. They can complete the biomechanical functional assessments within the same location as their radiology assessment and follow up clinic appointment.

The equipment is attached to the subject and they are then free to move around normally which allows the inclusion of functional tasks possibly difficult to include in a Vicon gait assessment such as in and out a bath. The Vicon system relies on the marker set being in camera view and therefore equipment which obscures the field of vision have to be ruled out such as chairs with solid backs and sides. As cameras are used for the Vicon system then the test area is restricted and in fact only 1-2 gait cycles can be recorded per trial. In comparison with the electrogoniometer system the subjects can walk along a corridors and therefore record numerous cycles in a continuous stream. This also has the advantage of allowing the subject time to fall into their normal walking pattern. Approximately the first and last 2 steps of gait can be referred to as the initiation and termination period of gait. Therefore the steps at the beginning and end of a period of walking have variations in the gait cycle pattern and therefore should be excluded as normal cycles (Miff S.C. et al., 2005).

The Vicon system uses marker sets as mentioned previously which are time consuming to attach. In comparison the electrogoniometer system involves the attachment of two electrogoniometers. The electrogoniometry data can be seen immediately on screen unlike the Vicon systems where the data has to be processed

first. There is also a financial advantage to the electrogoniometry systems in that they are cheaper than the Vicon systems. It is also easier to train staff to use the electrogoniometers rather than the Vicon system especially as the Vicon system uses bodybuilder coding to process the outcome data.

1.9.3. Video fluoroscopy

Video Fluoroscopy is a motion x-ray study of the bones and joints combining traditional fluoroscopy with the use of video technology to capture views of for example the knee joint in motion. The "motion pictures" are superior to, and more revealing than standard, motionless radiological images. This is another method which can be used to analysis knee joint kinematics. It has been used for example, to compare implant designs (Kessler O et al., 2007, Uvehammer J et al., 2000), and to look at 3D kinematics of the normal knee extension under unloaded and loaded conditions (Lu T.W. et al., 2008). Most studies record movements such the tibial or AP (anterior-posterior) translation of the femur. The major disadvantage of standard video fluoroscopy is the 'small field of view of the image intensifier … making it impossible to obtain kinematic data from the knee during level walking' (Zihlmann M.S et al., 2006). However advances in video fluoroscopy making it moveable have allowed knee kinematics of gait and stair climbing to be analyzed. A study by Zihlmann et al (2006) using a moveable fluoroscopic system allowed the knee joint to be tracked as the patient walked. The C-arm fluoroscopic unit, x-ray source and image intensifier are mounted to a unit mover which accelerates and decelerates when required. This fluoroscopic system was validated and the accuracy estimated to be 0.2mm for in plane translation, 3.25mm for out of plane translation and 1.57^{o} for rotation. Dual fluoroscopy systems have also been validated for accuracy and repeatability when measuring six degrees of freedom of dynamic knee kinematics (Li G et al., 2008). These systems have the limitations that as they are not fully moveable so are limited to motions within a restricted area. This means it can only be used for activities such as treadmill walking, stair ascent and descent and lunging. However, they can be used to record small movements of the tibia and femur, for example the rolling and sliding actions of the bones which systems such as electrogoniometry and Vicon systems cannot record.

One of the disadvantages to this system is that it requires x rays and therefore there is an associated radiation dosage. It also raises the ethical question of whether the advantages of this technique over the other methods of analysis outweigh the need for the radiation dosage required for the testing.

1.9.4. Gyroscopes and Accelerometers

An example of a non confined measurement device uses a combination of gyroscopes and accelerometers. Gyroscopes are based on the principles of angular momentum and are used for measuring or maintaining orientation. Accelerometers measure acceleration and gravity induced reaction forces. They can be used to sense inclination, vibration and shock. Various systems have been developed combining gyroscopes and accelerometers to give 3D kinematic data (Favre J et al., 2008, O'Donovan K.J. et al., 2007, Takeda R et al., 2009). As yet there is no clinically suitable system available on the market as the system still suffers from drift and trailing wires. Wireless systems for data transmission are coming but are not available at present.

1.10. ALIGNMENT

One of the most important factors assumed to be related to prosthesis longevity and proper post operation function is lower limb alignment (Jeffery R.S et al., 1991). Alignment is also a well documented measure for comparison of surgical methods i.e. whether it is computer assisted or conventional. Correct alignment of the prosthesis is challenging as the implant has to be ideally positioned in the coronal, sagittal and axial planes. In addition the femoral and tibial components have to be rotationally matched. All these parameters interact and therefore small errors in one may have an effect on another plane. Malalignment and altered joint mechanics can be associated with polyethylene wear, loosening and instability (Zihlmann M.S et al., 2005) which all contribute to prosthesis failure. It is thought that computer assisted or navigated TKA will result in better alignment and possibly a better post operation outcome for the patient. This question of better function with navigated TKA has not been fully explored as up until now function has only been recorded through the use of subjective questionnaires rather than an objective biomechanical study. The

question as to whether malalignment can cause functional problems has not been investigated, for example errors in implant placement resulting in a limited range of motion.

1.10.1. Measuring Alignment through Radiographs and CT Scans

Prior to TKA radiographs are used to determine the severity of the disease and the alignment of the lower limb and to identify if any deformities are present. The malalignment of the mechanical axis will be measured to determine the degree of varus/valgus of the lower limb which has to be corrected during surgery.

Radiographs

The knee is a weight bearing joint and therefore radiographs should be taken under weight bearing conditions. Radiographs are a 2 dimensional representation of the 3 dimensional bony structures. Various radiographic views can be taken of the knee joint which allows an in depth investigation of the joint. For example an anterior posterior (AP) standing view can be used to look at joint space narrowing. Although joint space narrowing is often seen with a modified AP view known as a Rosenberg view.

Long leg standing radiographs are beneficial for investigating deformities and malalignment. They include the hip, knee and ankle joints which make it possible to measure various angles around the knee joint using both the mechanical and anatomical axes of the lower limb. One such angle is the tibiofemoral angle, also known as the mechanical axis alignment. It calculates the degree of malalignment and uses the centre of the hip, knee and ankle joint as reference points.

The accuracy of radiographs has been studied with an intraobsever error of around 2^{o} (Lonner J.H. et al., 1996). Some studies have used standard anterioposterior standing radiographs and others have used long leg radiographs. In a study by Peterson (1988) it was shown that there was a variation in the mechanical axis measured when comparing these two types of radiographs. It was seen that there was a mean difference of 1.4^{o} with a standard deviation of 2.2^{o}. These appear small variations but when the accuracy of the implant position has to be $+/-3^{o}$ of an

optimum alignment then the errors in reading radiographs can have a significant impact on the outcome value.

Also errors in the recorded measurement can occur as a result of the radiograph being taken while the knee is in flexion or rotated. Increased valgus deformities are seen as a result of internal rotation and varus as a result of external rotation.

CT Scans

CT scans give a detailed bone image in 3D, in which the soft tissues can be visualised. CT scanners work on the principal of taking numerous incremental cross sectional slices of the body segment being scanned which are then compiled and used to generate a 3D image. The images can therefore be displayed in the 3 planes to be investigated. CT scans can provide detailed information about the placement and rotation of the knee joint implant and therefore allows a 3 dimensional investigation.

Anatomical landmarks are used in the analysis of CT scans and radiographs. For analysis of CT scans and radiographs the landmarks used are geometrically recognizable. These points include landmarks such as the distal femur which is taken as the most distal points on the medial and lateral condyles or tibial tubercle. Accuracy of analysis such as this relies on the reproducibility of the points used for the measurements. Therefore inter rater repeatability has to be considered.

Journal papers investigating the outcome of TKA look at post operation alignments which are based on calculations from radiographs and increasingly CT scans. It is important to be aware of the possible errors included in these calculations if they are to be used to compare the outcome of different surgical methods and compared different studies. There are two concepts to consider, accuracy, as in the closeness of the measurement to the real value and precision, which is the ‘deviation of a set of repeated measurements from an arbitrary value’ (Victor 2009). A study by Victor et al looked into these errors in determining bony landmarks on CT scans. They found that the intra and inter observer variability was low for the landmarks required to define coordinate systems for the femur and tibia. This means that the points required for the CT analysis could be accurately identified, minimising errors in the analysis.

1.10.2. Alignment Parameters Defined

Mechanical Axis

The mechanical axis is the most cited alignment parameter to be measured as an outcome of knee arthroplasty therefore it is a good measure used to compare methods of surgery. The weight bearing axis of the leg is defined by a line running through the centre of the hip joint to the centre of the ankle joint (figure 1.20). In optimal conditions the mechanical axis will be a straight line overlapping the weight bearing axis. The mechanical axis in fact refers to the angle formed by a line drawn from the centre of femoral head at the hip joint to the medial tibial spine and a line drawn from the medial tibial spine to the ankle joint centre – Hip-Knee-Ankle (HKA)**.**

The mechanical axis:

- Should pass essentially through the centre of the knee joint or just to the medial side of the centre of the knee joint. Distance of this line tangentially from the centre of the knee joint is referred to as the mechanical axis deviation.
- In a varus knee, the mechanical axis deviation (MAD) passes through medial to the medial compartment of the knee and results in a bow legged deformity.
- In a valgus knee the mechanical axis passes lateral to the middle of the knee and results in a knock kneed deformity.

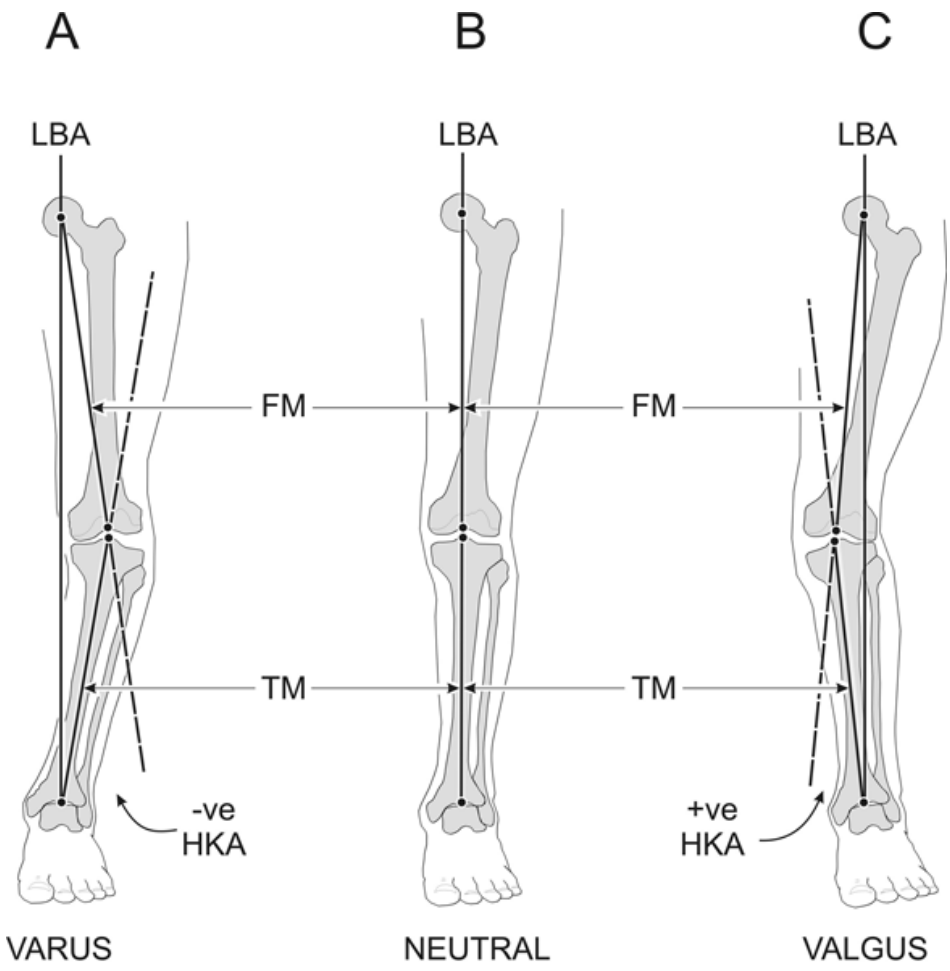


Figure 1.20 Frontal plane lower limb alignments.
A) Varus alignment: HKA is negative. B) Neutral alignment: HKA = 0° femoral and tibial mechanical axes are colinear. C) Valgus alignment: HKA is positive. LBA: load-bearing axis, HKA: hip-knee-ankle angle, FM: femoral mechanical axis, TM: tibial mechanical axis. (Cooke T.D.V et al., 2007)

Deformities are common in OA patients and this result in an altered line of body weight force and the high forces result in wear of the cartilage and progression of the disease. TKA aims to restore the mechanical axis to neutral, however if this is not achieved then the high forces transmitted across the implant would be abnormally high in either the medial or lateral compartment. It is commonly accepted that the aim is to restore the mechanical axis alignment is +/-3^{o} of neutral. However some papers do quote different ranges of either +/-2^{o} or +/-4^{o}, suggesting that there is an element of unknown within even this most cited alignment parameter. The study

by Jeffery et al (1991) did in fact find that the loosening rate was significantly higher for the prosthesis implanted outwith this +/-3^{o} range; 24% compared to only 3% failure of implants within the range. It is unknown if this failure rate would significantly change if the range was altered by +/-1^{o}. Ritter (1994) found that from their study of 421 TKAs the highest rate of aseptic loosening was found when the prosthesis was implanted in varus malalignment. This suggests that in fact not only is the range important but so is the direction of the deviation. Buchanan (1982) analysed alignment and component loosening at an average of 36 months and it was found that 'gradual loosening had not occurred to date' even although 20% of the femoral and tibial components were outside the recommended alignment limits. This suggests that if malalignment affects failure of components it is over a long time span. A similar study with a longer follow up period of 10 years concluded that axial post operation alignment had a significant effect on the failure rate of the prosthesis (Lewallen D.G et al., 1984). The failure rate was almost doubled when the alignment was either varus angulation or more than 8^{o} of valgus. In TKA 7^{o} of valgus alignment was aimed for, as this is the normal average tibiofemoral angle. There is an additional alignment problem associated with failure which is that some knee prostheses drift into deformity. In some cases the prosthesis was not malaligned at the time of the operation but over time had become so. A study by Tew and Waugh (1985) investigated this drift effect and concluded that correctly aligned knees were less likely to drift into malalignment than those which were already slightly malaligned. This poses an additional problem as it suggests that malaligned knees may become worse over time. However the concept that the mechanical axis must always run through the centre of the knee is no longer universally agreed. Parette et al (2010) did not find a significant increase in the survival rates in the 'well' aligned implant group.

Anatomical Axis

The anatomical axis of a bone is represented by a line drawn down the centre of the medullary cavity of the bone. In the femur the angle between the mechanical and anatomical axes is approximately 6° (range 3-8^{o}) (Moreland J.R et al., 1987). On

the other hand in the tibia the mechanical and anatomical axes are essentially represented by the same line.

Frontal Femoral Angle

The frontal femoral (or femoral AP) angle is calculated as the angle between two lines:

- The mechanical axis of femur
- The line connecting the medical and lateral condyles of the implant (figure 1.21).

The angle refers to that on the medial side.

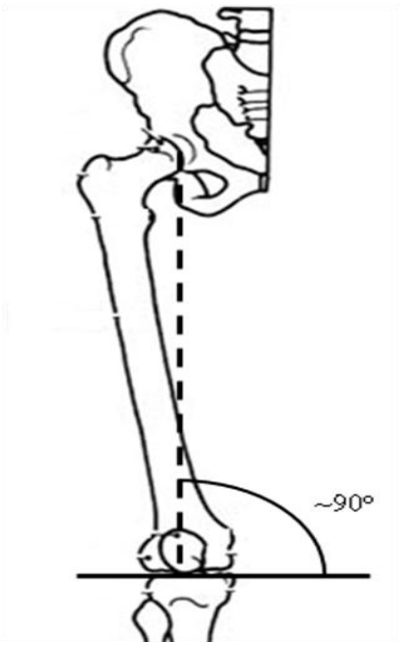


Figure 1.21 Diagram of frontal femoral angle (FFA)

The line connecting the femoral condyles is also referred to as the joint line which is horizontal in most people when in single leg stance (Hungerford D.S. and Hungerford M.W., 2005). In TKA the femoral bone cuts are made so that the joint line is perpendicular to the femoral mechanical axis and therefore the surgeon aims for the FFA to equal 90^{o}.

Frontal Tibial Angle

The frontal tibial (or tibial AP) angle is again the angle between two lines:

- The tibial mechanical axis
- The line connecting the medial and lateral plateau (figure 1.22).

The angle refers to that on the medial side.

In TKA the tibial bone cuts are made so that the joint line is perpendicular to the tibial mechanical axis and therefore the surgeon aims for the TAP angle to equal 90^{o}.

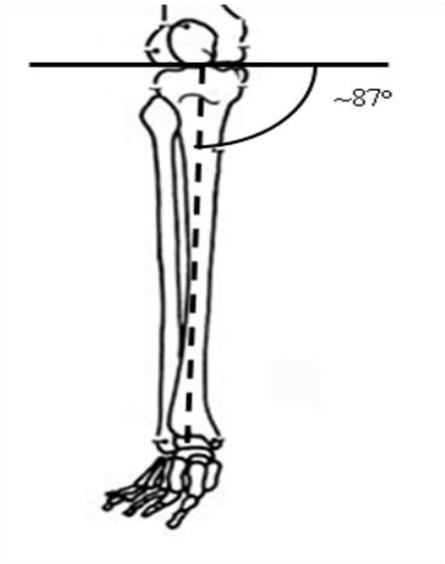


Figure 1.22 Diagram of frontal tibial angle (FTA)

However the 'normal' tibial mechanical axis is not perpendicular to the joint line. The natural TAP angle (figure 1.22) is on average 87^{o} which means that the tibia is in 3^{o} of varus with a 'natural' range of 0-5^{o} (Hungerford D.S. and Hungerford M.W., 2005).

Femoral-Tibial Match or CT Mechanical Axis Alignment

The femoral tibial match is the sum of the frontal femoral angle and the frontal tibial angle (figure 1.23) giving the mechanical axis angle.

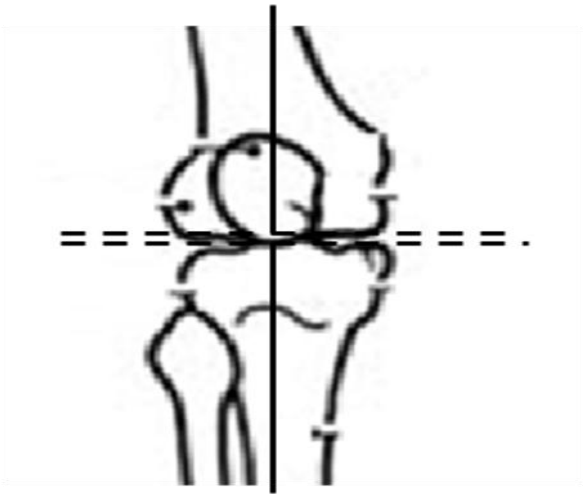


Figure 1.23 Diagram of the FT angle match

This method of calculating the mechanical axis alignment uses CT scans. The conventional method of measuring this parameter is through long leg radiographs. Therefore the major difference between these two measurement techniques is that the radiograph is weight bearing whereas the CT is taken with the patient lying in supine. For both methods the planned distal femoral and proximal tibial cuts are at right angles to the mechanical axis of each bone. Thus when the limb is aligned neutrally with respect to the mechanical axis the distal femoral and proximal tibial cuts are parallel to each other. This assumes that the ligaments are balanced and that there is an equal gap on the medial and lateral sides of the joint space, therefore no lift off. The femoral tibial match angle aimed for in surgery is 180^{o}, assuming that a zero mechanical axis is correct which is likely not to be the case for some of the population as there is variability between anatomy within a population.

Femoral Sagittal Alignment

This measurement is the slope at which the implant is placed in the sagittal plane. It is the angle between the 2 lines:

- The mechanical axis of the femur
- The line marking the bone/implant interface (figure 1.24). This line is formed by joining the points - distal femoral anterior cut and distal femoral posterior cut.

The distal femoral anterior and posterior cuts are difficult to accurately identify on a CT scan. The other unknown is what is the ideal angle? From a literature search this appears to be still fairly unknown. A slope of 4-5^{o} is aimed for by surgeons within the local hospital.

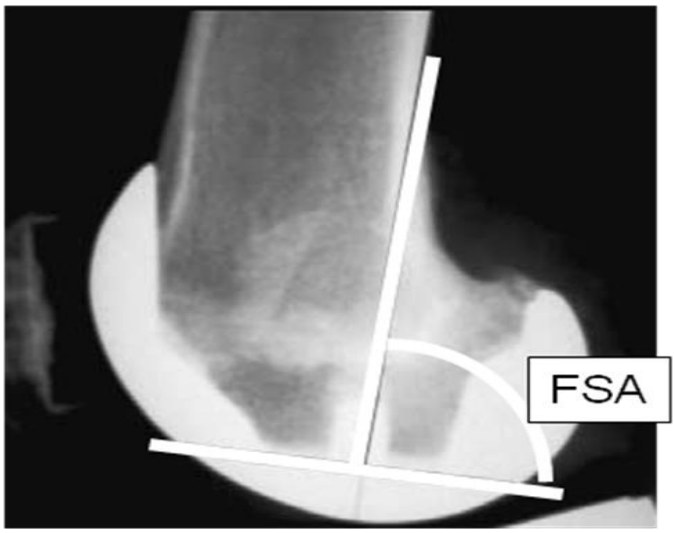


Figure 1.24 Diagram of femoral sagittal angle (FSA)

Tibial Sagittal Alignment (Slope)

Figure 1.25 shows the tibial plateaus slope where the 'normal' range is posteriorly 7-10^{o} in the lower limb's coronal plane (Hungerford D.S. and Hungerford M.W., 2005). Prostheses generally have a manufacturer recommended tibial slope which can be used as a guideline for implantation. This raises the problem that between trials the optimum slope may vary which leads to difficulties comparing papers. Also it poses a question mark over what the surgeon should aim for.

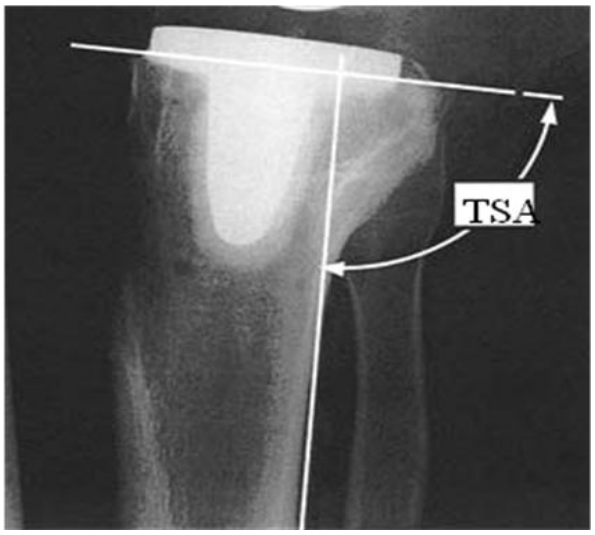


Figure 1.25 Diagram of tibial sagittal angle (TSA)

For some prostheses such as Zimmer LPS flex implant the aim is 7^{o} which is at the lower in of the normal knee range ($7\text{-}11^{o}$). However the PFC Sigma from DePuy Inc and Aesculap e-motion prostheses both suggest 3^{o} of tibial slope (Bäthis H et al., 2004, Song E.K et al., 2007). This suggests that the tibial slope is defined by the prosthesis design rather than an ideal definitive figure. A number of knee systems actually cut the tibia with a zero slope or have the option of a zero slope. In such systems the tibia slope is often built into the component.

Dorr et al (1986) recommends a tibial slope of $5\text{-}10^{o}$, as this is thought to be the slope which will prevent the excessive PCL tension created at high knee flexion angles which in turn leads to increased tibiofemoral contact stress on the polyethylene insert. The loaded knee joint flexion range for walking is only $0\text{-}30^{o}$ (i.e. stance phase of walking), whereas in strenuous activities such as stair climbing stance phase has a flexion range of $0\text{-}60^{o}$. Ostermeier et al (2006) determined that there was no difference in the PCL load when tibial posterior tilt was applied during walking. For the increased flexion range in stair climbing there was in fact a significant lowering of the load on the PCL with a 10^{o} posterior slope. Decreasing the load experienced across any structure of the knee, which brings them into the range of the 'normal' knee joint kinetics is an advantage. Problems have been reported as a result of abnormal knee joint kinematic and kinetics in TKA patients. Overall the incorrect tibial slope is thought to affect range of flexion and also the tension in the PCL.

Femoral Rotational Alignment

The femoral rotational alignment is defined as the angle between the posterior plane of the epicondyles (transepicondylar axis) and the line which joins the posterior limit of the lateral and medial femoral condyles. The lateral femoral condyle is posterior to the medial condyle (figure 1.26). An average of 3^o (range 0-5^o) rotational angle is measured between the line joining the epicondyles and line defining the posterior plane of the condyles (transepicondylar axis) (Hungerford D.S. and Hungerford M.W., 2005).

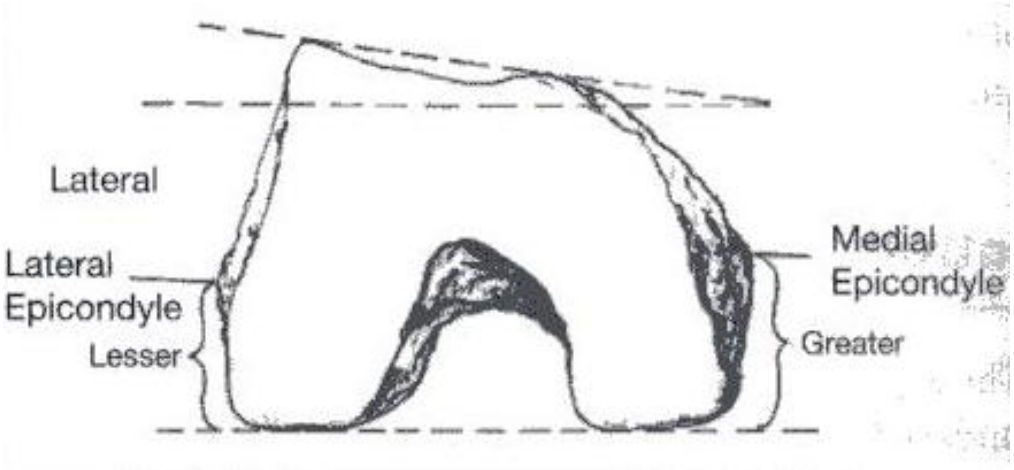


Figure 1.26 Diagram showing the medial and lateral condyles of the femur – used to measure femoral rotation. (Hungerford D.S. and Hungerford M.W., 2005)

The correct rotational alignment of the femur is thought to be critical to a well functioning knee both in relation to patella tracking and also to general knee function. The average rotation is 3^o but there is a normal range of 0-5^o. The rotational alignments of the femoral and tibial components are interdependent. At near full extension the rotational alignment of the femoral component affects the rotational alignment of the tibial component and at high flexion angles the femoral rotation affects the tibial adduction alignment. Difficulties in femoral rotation come from the fact that it is unknown as to what alignment range should be aimed for. Also the difference in male and female anatomy means that the normal rotation is 0-3^o (Berger R.A and Rubash H.E, 2001b). This adds an extra dimension to the problem of quoting a normal range.

It is generally taken that excessive internal rotation would lead to problems such patella tracking and anterior knee pain. This malrotation would cause kinematic changes such as femoral lift off and flexion instability during a normal gait cycle.

Tibial Rotational Alignment

The tibial rotational alignment was measured as described in Berger et al (2001b). The anteroposterior tibial component axis is used to calculate the rotational angle. This axis is the line perpendicular to the posterior margin of the rectangular shaped tibial components. The second line used in the rotational analysis connects the geometric centre of the tibia and the tip of the tibial tubercle. The geometric centre is calculated on the bases that the tibia on the axial CT slice is oval. The 'normal' rotational tibial angle is taken as 18^{o} and anything greater than this equals an excess in internal rotation. It is generally accepted that excessive internal rotation would lead to problems. Finally mal rotation (either external or internal rotation) in the tibial cut would lead to changes in the varus/valgus angle.

1.11. SCIENTIFIC LITERATURE ON FUNCTIONAL OUTCOMES

Functional ability of OA patients has been shown to be significantly limited compared to age matched controls. In general, questionnaire scores which assess pain and function such as the Oxford Knee Score taken pre operation generally show a decreased function. Whether the functional limitation is due to pain levels or a stiff and limited ROM at the knee joint it is difficult to distinguish. In many cases it is a combination of these factors which means that stairs and the bath task become increasingly difficult. These limitations are still evident in TKA patients showing that this groups' functional outcome does not improve to equal the control group after the surgical intervention.

Baseline function – Functional Outcomes

There is some evidence that pre-operative factors may influence the functional outcome of TKA patients. In a multi centre study across 3 countries, Lingard (2004) concluded that there was a significant link between pre and post operation questionnaire scores. If the recorded pre operation scores were low then it was a

possible indicator for low 1 and 2 year post operation scores in the function and pain domain of the WOMAC, and the function domain of the SF-36. As pre operative scores are a possible factor or guideline for post operative function then it raises the question of, at which stage of arthritis progression should TKA be carried out? Kennedy (2003) suggested that from AKSS scores the 'oldest patient were worse off at the time of surgery and gain a little less than those in their 60s and 70s'. However the older age group would be more likely to have co-morbidities which could affect the outcome of the operation. The timing of the operation may be important but there has to be a balance between waiting till the arthritis has progressed so much that the patient does not gain as much from the procedure and operating early where the patient's arthritis could have remained stable for years. The problem with considering young patients for TKA is that they are more likely to be active and they may out live the prosthesis and therefore require revision surgery. The revision surgery has many associated problems and risks, one of which is that these patients have a decreased bone stock for the surgeon to work with to stabilise the prosthesis.

Functional Outcomes of TKA

As just discussed the post operative functional outcome of TKA has been seen to be influenced by both age and pre operative factors. Pre operative status is recorded in questionnaires which include, walking distance or difficulty performing daily tasks as well as pain levels. Another routinely recorded post operative functional outcome measure is ROM. Since stairs and chair activities require about 90-120^{o} ROM (Rowe P.J et al., 2000) it is likely that those patients with less than this range of motion may experience some functional limitation or difficulty. Increased post operative passive range of flexion was seen to positively influence functional ability (Devers B et al., 2009) where only 50% of the trial patients with less than 130^{o} flexion felt that they had 'eliminated functional limitations' compared to 93% of those with over 130^{o}.

Objective outcome measures such as gait pattern, strength and activity levels have all been measured with regards to a TKA patient group. Gait has been shown to become more symmetrical over the first 12 months of recovery and the quadriceps strength has be shown to increase (Yoshida Y et al., 2008). Some of this 'patient'

group approach results recorded by the control group. In this case the peak flexion angles during stance phase (during weight acceptance) for the TKA patient group was not statistically significantly different to that of the control group. However, this functional test using a Vicon motion analysis laboratory only looked at gait pattern during level walking, and so did not the analyses difference in weight bearing angles during more challenging activities such as up and down stairs. They included the 'timed up and go' test and the stair 'climbing test' and found no significant difference in the time the TKA patient group took to perform these tasks compared to a control group. This study excluded those TKA patients with musculoskeletal problems which limited their physical function. Although this controls the variables between the two groups and allows differences in knee function between TKA and controls to be analysed it does not give an accurate representation of the TKA population. The TKA population commonly have co-morbidities and arthritis in multiple joints which will influence physical function.

More often than not this group experiences quadriceps weakness (Silva M et al., 2003) and decreased knee excursion angles during daily activities (Myles C.M et al., 2002) and which result in significant differences in this patient group compared to a control group. Quadriceps weakness can lead to an inadequate extensor mechanism for activities such as stair climbing, sit to stand and even standing endurance (Greene K.A and Schurman II J.R, 2008). Another significant difference between TKA and a control group is that they are slower at completing mobility tests (Rossi M.D et al., 2006). Their walking speed and stride length have been reported to be significantly reduced in the study be Bolanos et al (1998) but in another trial by Wilson (1996) there was no difference in terms of these parameters. When comparing step length, speed, and cadence between a TKA and control group it appears to be patient dependant. The reason for the difference in these gait parameters may indicate different types of implants or varied follow up time periods. In some cases the time allowed for recovery and rehabilitation may be too short to allow the patient group to recover fully. The walking cycle range of motion is reported to be decreased significantly compared to control groups, with a decreased swing phase flexion angle. The flexion angle during loading in stance phase has also been reported to be decreased (Wilson S.A et al., 1996). The lower flexion angles

during loading phase leads to larger contact areas over which the forces are transmitted through the joint and therefore may indicate pain or a desire to protect the prosthesis.

Function Outcomes – CAS versus Conventional

Computer assisted surgery (CAS) has been increasing in popularity however the systems are not yet universally accepted, and their cost/benefit ratio remains a matter for further discussion. A variety of studies have compared this surgical method with conventional TKA from small cadaver studies to larger randomised control trials (RCTs). As previously discussed TKA patient function post operation is important and therefore it is essential to study this domain to compare computer navigation and conventional techniques.

In general there are few studies which look specifically at functional differences resulting from the different surgical methods of TKA, conventional instrumentation or CAS. Some studies have looked at questionnaire scores for clinical functional differences. The American Knee Society Score (AKSS) was used to compare navigation and conventional TKA but neither of the sub scores (knee or function) reported a significant difference (Molfetta L and Caldo D, 2008). The other functional variable measured was the range of motion which again did not result in a statistically significant benefit with the navigation system. Using the same clinical questionnaire scoring system (AKSS), Stulberg et al (2006) came to the same conclusion. However one possible issue with these results was that the follow up period for this trial was only 6 months. This means that some of the patients will still be in the recovery phase and therefore would not have reached the plateau of their recovery. The limitations of questionnaires have already been discussed and therefore more objective measures are required to compare these two surgical methods.

One study which analysed the functional ability of patients at 2 years post operation was Spencer et al (2007). The patient's function was again assessed in this study using questionnaires such as the Knee Society Score (AKSS), SF-36, WOMAC, Oxford Knee Scores (OKS) and Bartlett Patellar pain questionnaire. The functional assessment was completed at 3, 6, 12 and 24 months postoperative. The

OKS and the Bartlett Patellar scores were only completed at 2 years after surgery. The Bartlett Patellar score assesses function in more depth than subjective questionnaires such as the OKS as it includes anterior knee pain, quadriceps strength, and the ability to climb stairs and get out of a chair. However, this study found no significant difference between groups. The anterior pain reported by both groups appeared high with 44% in the navigated group and 47% in the conventional group. Moderate to severe pain was reported by 16% of the navigated and 7% of the conventional group. The results reported that in both the AKSS and the WOMAC scores, there was an improvement from before the surgery to post operation. However there were no statistically significant differences between the two surgical groups. One possible problem could have been that the sample size was small giving a large confidence interval and a lack of power in the statistics. The SF-36 questionnaire can be divided into 8 sub sections. The 'emotional role' score was reported to be significantly improved at 6 months for the navigated group. Finally the satisfaction rates for both groups were high with 86.7% of navigated and 83.3% of the conventional group satisfied with the surgical outcome. Therefore overall there was no difference between the CAS and conventional groups with respect to function. In this study the functional outcome data was extracted from questionnaire scores and the problems with questionnaires has been highlighted previously. A more extensive functional assessment may have highlighted subtle differences in the functional outcome of these two groups. Also the improved prosthesis alignment may not have a significant effect in the short term i.e. 2 years but may have long term improvements such as improved function due to longer prosthesis lifespan. Good functional outcomes are expected from a well aligned TKA.

In conclusion, TKA patients generally have a functional limitation compared to a normal healthy age matched control group. The variations have been shown in the gait flexion angles, walking speed, muscle strength and functional questionnaire scores to name a few. There have not been any published works to date which has seen a significant improvement in function when comparing CAS and conventional TKA groups, however the follow up time for many of these studies have been short and the study methods and data collection limited.

1.12. SCIENTIFIC LITERATURE ON ALIGNMENT OUTCOMES

Malalignment of the mechanical axis of the prosthesis is thought to cause abnormal wear patterns as the contact area changes. As contact stress increases so does the polyethylene wear rate. Studies have investigated contact characteristics of various designs of prosthesis but it was noted that the biomechanical tests are mostly in-vitro, they test the implant as an individual element instead of the collection of systems of muscles and ligaments as in the natural joint. Liau et al (2002) investigated whether malalignment would change the stresses on the tibial component and the loading distribution in the knee joint. It was concluded that in fact the contact stresses do increase in cases of maltranslation, internal rotation and varus tilt.

One of the design features of the mobile bearing prostheses was that they decreased tibiofemoral contact stresses and also accommodated surgical malalignment (Cheng C.K et al., 2003). This study agrees with this claim regarding mobile bearing prostheses as they found that the fixed bearing design had a higher maximum contact pressure. The mobile bearing design also 'offers the advantage of self-adjusting over the fixed bearing design to accommodate surgical malalignment'. Mobile and fixed bearings were compared using a fatigue resistance analysis (Yu T.C et al., 2006). Two out of the five fixed bearings tested failed before completing the 10 million cycles required to pass the ASTM test guidelines. All of the mobile bearings passed.

In the studies which have been published comparing navigation and conventional TKA the most cited outcome is implant alignment. The alignment of the implant can be measured in various planes therefore resulting in anterior/posterior (AP) angles, sagittal angles and rotations. It has to be considered how the parameters interact with each other. Finally some papers have quoted a cumulative error which assumes each parameter has equal weighting in importance. It is possible that this may not be the case and certain alignments may cause more problems.

Alignment of the knee implant is commonly accepted as a factor in prosthesis failure however there are various alignment parameters which can be measured and it

is unclear which ones perhaps have more of an influence on the survival of the prosthesis and also the functional outcome of the patient.

Table 1.2 Trials comparing alignment in CAS and conventional TKA

Paper	Time Period	Outcomes Measured	Results
(Sparmann M et al.) (2003)	2 months AP and lateral x-ray Single leg wt bearing (240 patients)	Mechanical Axis AP femoral component alignment AP tibial component alignment Sagittal femoral component alignment Sagittal tibial component alignment	stat significant stat significant stat significant stat significant NS
(Bäthis H et al.) (2004)	LL wt bearing (160 patients)	Mechanical Axis AP femoral component alignment AP tibial component alignment Sagittal femoral component alignment Sagittal tibial component alignment	N=96% C=78% SS N=92% C=86% SS N=98% C=94% SS N=7.3 C=9.5 SS N=2.5 C=4.5 SS
(Chauhan S.K et al.) (2004a)	CT scan (12 cadaver knees)	AP femoral component alignment AP tibial component alignment Sagittal femoral component alignment Sagittal tibial component alignment Femoral rotation Femorotibial matching in rotation	N=100% C= 5/6 N=100% C= 5/6 stat significant stat significant stat significant stat significant
(Chauhan S.K et al.) (2004b)	CT prior to discharge 6 weeks LL wt bearing (70 patients)	Mechanical Axis AP femoral component alignment AP tibial component alignment Sagittal femoral component alignment Sagittal tibial component alignment Femoral rotation Tibial rotation Femorotibial mismatch Cumulative error of alignment	stat significant stat significant stat significant NS stat significant stat significant stat significant stat significant stat significant

(Stockl B et al.) (2004)	CT and LL standing	Mechanical axis (+/-5) Sagittal femoral component alignment Sagittal tibial component alignment Femoral rotation	N=100% C=94% stat significant NS stat significant
(Anderson K.C et al.) (2005)	LL wt bearing Plain sagittal x-rays (167 patients)	Mechanical Axis -3deg Mechanical Axis -2deg AP femoral component angle - 2 deg Sagittal femoral component angle - 2 deg AP tibial component angle - 2 deg Sagittal tibial component angle (2-5)	N=95% C=84% NS N=88% C=71% SS N=85% C=80% SS N=72% C=63% NS N=97% C=84% SS N=67% C=55% SS
(Bolognesi M and Hofmann A) (2005)	6 weeks LL standing x rays	AP femoral component alignment AP tibial component alignment	N=98% C=90% SS N=100% C=92% SS
(Chin P.L et al.) (2005)	When able to wt bear LL AP / lateral wt bear LL sagittal (90 patients)	AP femoral component alignment AP tibial component alignment Sagittal femoral component alignment Sagittal tibial component alignment	stat significant stat significant NS stat significant
(Decking R et al.) (2005)	3 months LL wt bearing - rotation controlled (52 patients)	Mechanical Axis AP femoral component alignment AP tibial component alignment Sagittal femoral component alignment Sagittal tibial component alignment	stat significant NS NS NS NS
(Jenny J.Y et al.) (2005)	3 month post-op LL wt bearing (470 patients)	Mechanical axis AP femoral component alignment Sagittal femoral component alignment AP tibial component alignment Sagittal tibial component alignment Optimal in all critera	N=92% C=72% SS N=89% C=77% SS N=80% C=71% SS N=89% C=83% SS N=85% C=70% SS N=54% C=31% SS

(Kim S.J et al.) (2005)	4 month LL wt bearing (147 patients)	Mechanical Axis AP femoral component alignment AP tibial component alignment Nav mech outcome V LL x-ray	stat significant stat significant stat significant NS-poor relationship navigation system and LL x rays
(Han H.S et al.) (2006)	Post-op CT (55 patients)	Femoral rotation	NS - less outliers in nav group
(Stulberg S.D et al.) (2006)	X-rays (78 patients)	Mechanical Axis Sagittal femoral component alignment Sagittal tibial component alignment	NS NS NS
(Mullaji A.B et al.) (2007)	Within 4 weeks post-op LL wt bearing (467 patients)	Mechanical axis AP femoral component alignment AP tibial component alignment Both components +/-3 of 90	highly stat significant NS stat significant N=91% C=76%
(Song E.K et al.) (2007)	Min 1 year (86 patients)	Mechanical Axis	NS but S for less Nav outliers
(Molfetta L and Caldo D) (2008)	LL wt bearing (60 patients)	Mechanical axis Femorotibial sagittal	stat significant NS

Table 1.2 lists some of the trials which have been recently published comparing computer assisted or navigated and conventional TKA in terms of alignment outcome. The outcomes of the trials disagree as to the implant alignment benefits of using navigation. The trials in the table vary in size from a small 12 knee cadaver study to larger patient trials. The trials differ in the navigation system used, prosthesis used and the number of surgeons involved in the trial. The papers generally state that the surgeon has experience with the system and had already performed a series of operations using the system. This means that no data during the training period had been included which may have skewed the results. Also it has to be noted that the methods used for the analysis of alignment varies between trials.

The trials use either radiographs or CT scans. The radiographs are mainly double stance long leg weight bearing, however Sparmann et al (2003) used single leg stance. The radiographs were taken in both the AP and sagittal planes to allow the femoral and tibial AP and sagittal angles to be calculated.

In the table it can be seen that in the majority of the trials quoted that the mechanical axis alignment had been significantly improved with the use of the navigation system. In the cases where the mechanical axis had not been significantly different then it was reported that there was a reduction in the outliers within the CAS group (Song E.K et al., 2007). One of the issues still to be resolved is which of the alignment parameters discussed are important? Are they all important or do some of them have a greater influence on the patients pain levels, ROM and functional ability and in deed the longetivity of the implant.

The navigation systems also record the implant mechanical axis alignment. Although this is generally not quoted a study by Kim et al (2005) compared the long leg radiograph results with those obtained by intra operatively using navigation. These results had a weak relationship where as in fact they should be the same measurement. When comparing these published studies it is assumed that the results are accurate. Standard protocols have to be used in the analysis so that any indication of flexion contractures or rotations on the film results in exclusion from the trial.

Most studies report improved implant alignment with the use of a navigation system when compared to conventional instrumentation such as intra and extra medullary rods. A range of parameters such as mechanical axis, AP and sagittal angles in terms of femoral and tibial components have been reported to have been more accurately implanted and with fewer outliers in the CT patients.

1.13. RELATIONSHIP BETWEEN ALIGNMENT AND FUNCTIONAL OUTCOMES

One important question which is still not fully answered is what, if any, alignment factors affect post operation functional outcome. It has been widely but not universally ‘accepted that a deviation … of more than 3^{o} from neutral’ mechanical axis of the limb in either direction ‘reduces longevity of the implant’ (Sikorski J.M, 2008). A larger deviation is assumed to lead to an increase in wear of

the prosthesis and therefore early failure. There is little evidence to directly support this statement especially in the short term and long term studies even contradict this theory (Parratte S et al., 2010). Also there is varying opinions as to what is an allowable error. Some studies when referring to mechanical axis use +/-2^o or +/-4^o as their desired range instead of the more common +/-3^o, leading to the idea that perhaps 'it is more likely that any deviation from neutral will reduce longevity by an amount proportional to the malalignment' (Sikorski J.M, 2008). Studies which use different desired alignment ranges present an additional problem that their results cannot be directly compared to the majority of studies already published. Longstaff et al (2009) investigated various alignment parameters, sagittal femoral, coronal (AP) femoral, rotational femoral, sagittal tibial, coronal (AP) tibial and femorotibial mismatch (mechanical axis) to investigate if there was a relationship between these and functional outcomes. The Knee Society Score (AKSS) was used as a functional outcome measure. A cumulative error score was also calculated which was shown to be associated with poorer function. A good coronal femoral alignment was reported to be associated with a significantly better functional outcome. The other alignment parameters studied showed a trend towards better function with good alignment outcomes. This study concluded that knee arthroplasty is a successful operation and, because of this some of the parameters did not have a badly aligned group. Therefore it was inconclusive with respect to whether they affect functional outcome. Another question which remains unanswered is whether it is individual errors such as tibial rotations which lead to functional problems or if it is in fact the cumulative error which has the greatest impact. Another important issue which has not been able to be addressed so far is soft tissue balance both in extension and flexion and what impact this has on survivorship. For example a patient whose natural anatomy pre diseased state is 3^o varus and after surgery is 3^o valgus they will be within the desired range but if they had no ligament changes due to OA then the surgery will have left the knee slack on the lateral side. If on the other hand this patient after surgery was realigned to 4^o varus (outside the desired range) they would have a knee close to their natural pre diseased state and this situation may be more advantageous for them and result in a better clinical and functional outcome.

One of the proposed advantages to computer assisted arthroplasty is the improved prostheses alignment after surgery. A randomized controlled trial (RCT) comparing conventional and computer assisted TKA looked for a correlation between alignment and function and quality of life was undertaken by Choong et al (2009). As in previous studies the mechanical alignment accuracy of the CAS group was statistically significantly improved compared to the conventional group. Furthermore the patients who had coronal (AP) alignment within the desired range of $+/-3^{o}$ independent of which surgical group they were assigned too, showed improved short form-12 (SF-12) scores and International Knee Society score (IKS). The SF-12 is divided into two parts, a mental and physical component. The mental component was correlated with the coronal alignment. The emotional/mental state of the patient declined, perhaps due to dissatisfaction when their resultant lower limb alignment was not within the desired range. An important point to note is that the focus of alignment and function should be independent of surgical method. If better function is associated with better alignment then this would present an advantage for CAS TKA as this surgical group have been found to produce better overall outcome alignment in a number of published studies.

Stulberg (2006) aimed at comparing the clinical, patient perceived functional result with the radiological results of both a computer assisted group and a manually performed surgery. The second aim was to examine the impact of experience with computer assisted surgery on the manual technique of experienced surgeons. This is important as with some patients, for example severely obese, regaining proper alignment is difficult to visualise or determine using manual instruments. Clinical assessments of both groups took place preoperatively, and postoperatively at four weeks, six months and one year. The functional assessment was examined through the Knee Society scoring system (AKSS) which includes ROM, stability, mobility and patient independence. This study found no significant difference between groups in the clinical and functional scores and ROM at 4 weeks and 6 months post operation. The only score to show a difference was the pain score which at 4 weeks indicated less pain in the CAS group, but at 6 months the groups' scores were not different. The radiograph also failed to show any significant differences in the resultant alignment through analysis of mechanical axis, sagittal femoral and tibial

axes. The mechanical axis alignment range for the CAS group was 3^o valgus to 5^o varus compared to 6^o valgus to 5^o varus for the manual group. In this case CAS surgery resulted in a decrease in the resultant range, therefore the extent of the mal alignment. When comparing this trial to the author's previous trial (Stulberg S.D et al., 2002) it was noted that the same conclusions about manual instruments were not made. On the previous occasion it was concluded that the manual instruments introduced a consistent and significant error but Stulberg's more recent study concluded that there was no significant differences in the resultant alignment of the conventional and CAS TKA groups. One suggestion made by the author was that the radiographs were in fact not sensitive enough to distinguish the small differences between the alignments in the two groups, and CT scans would be more effective. It was also thought that through the extensive use of the navigation system the surgeon had improved his skills for using the manual system. This suggests that computer systems could have a place in training new surgeons and improving the skills of experienced surgeons. Another area which could make use of the system is smaller hospitals where surgeons deal with a low volume of TKA on a weekly basis**.**

So in conclusion the studies mentioned in this section show trends towards better function in computer assisted groups. However in these trials the alignment outcome of the two TKA groups was not always significantly different. In cases where alignment was not significantly improved then the groups were clinically similar and therefore the groups' functional ability would not necessarily be greatly different. A more in depth analysis is required which looks at specific alignment parameters for any correlation to functional ability.

1.14. CONCLUSION

From the literature search it can be concluded that firstly osteoarthritis is a growing problem. It leads to pain and functional disabilities. Total knee arthroplasty is widely accepted as an effective operation which relieves pain and restores function in the majority of cases. Over the course of the past few decades advancements in knee joint prostheses and surgical techniques have led to increased longevity of the implant for TKA patients. A better understanding of the biomechanics of the knee has also contributed to the improvements in the implant design and led to implants

which better mimic the normal knee biomechanics and in turn lead to a better functional outcome. Computer navigated surgery has been shown to result in improved alignment outcomes with regard to various parameters. Improved alignment has been shown to be related to increased implant lifespan. The OA population is changing to include a younger group who may still work and are generally more active. This means that there is a greater focus on functional ability after surgery. So improved alignment is seen in some CAS groups but the functional impact this has on the patient is unclear. An in depth functional assessment comparing these two groups is required looking at ROM during various activities, activity levels and muscle strength. Objective measurement systems such as flexible electrogoniometry can be used to compare TKA groups, analyse and assess whether there are differences in maximum, minimum and excursion angles recorded for a range of daily functional activities. This leads onto determining whether specific alignment outcomes such as rotation result in variations in patient's functional ability. Results from comparing questionnaires from conventional and CAS groups have suggested that certain alignment parameters such as the mechanical axis are related to good functional scores. However this requires a more in depth study with a broader range of parameters to see how they relate to function.

1.15. RATIONALE

The use of computer navigation in TKA has been increasing in the past decade and studies have compared the outcome alignment through standard and long leg radiographs and CT scans. In the majority of cases the CAS group implant alignment was reported to be more accurate with less outliers being recorded for the various parameters, mechanical axis and rotations. The subjective functional outcome of these two groups has also been studied through the use of questionnaires. However to date an extensive objective functional assessment in which the functions of the knee is recorded scientifically during activity has not been reported on these two surgical TKA groups. As the OA population changes and the TKA group increases to include a younger population then there is a greater emphasis on functional outcome where the patients expect to be able to return to work, sports and demanding activities.

1.15.1. Objectives/Aims

The aim of this thesis was to compare the functional outcome of conventional TKA and navigated TKA. Using electrogoniometry a range of everyday activities including, level and ramp walking, stair negotiation, sit-stand and in/out of a bath, could be analysed to compare maximum flexion and extension, and active excursion during function. Differences, if any, in the activity levels and muscle strength of the two groups would be discussed. Finally, through the use of CT scans the outcome alignment would be investigated to show whether there are alignment factors which lead to improved function.

1.15.2. Research Questions and Aims

(a) Is there a functional difference between a conventional TKA group and a computer navigated TKA group when measuring knee kinematics using flexible electrogoniometry during daily tasks?

(b) To develop a 'Total Functional Outcome' scoring system for the knee kinematic electrogoniometry data.

(c) Is there a difference between a conventional TKA group and a computer navigated TKA group when measuring clinical and functional outcomes through questionnaires?

(d) Are the conventional and navigated TKA groups different in terms of implant coronal, sagittal or rotational alignments, as measured through CT analysis?

(e) Can any of the alignment parameters measured predict functional outcome as measured through electrogoniometry or questionnaire clinical and functional scores?

(f) Is there a difference between a conventional TKA group and a computer navigated TKA group when measuring activity levels or hamstring and quadriceps strength?

(g) Does TKA patients' functional outcome relate strongly to their daily activity levels?

(h) Are TKA patients 1 year post operation comparable to normal age match subjects? Is their affected side comparable to their contralateral knee joint?

CHAPTER 2. METHODOLOGY

2.1. Clinical Trial - Introduction/Aim

As discussed in chapter one there has been limited research conducted as to the functional outcomes of conventional versus navigated TKA. Published trials have mainly focused on the outcome alignment of the knee prosthesis as a method of comparing the two surgical methods. These studies have concluded that computer assisted surgery when compared to conventional TKA can lead to a more accurate placement prosthesis components, with fewer outliers within the group. Whether prosthesis of alignment has an effect on patients' functional outcome is still unclear. These studies have investigated optical navigation systems. The navigation systems have been tested in randomised control trials (RCTs) but to date electromagnetic systems have not been extensively tested in an RCT. To address this question a large single centre, randomised, double blind trial was set up to compare conventional TKA with computer navigated TKA. The navigation system used was an electromagnetic iNav system (Zimmer GmbH, Winterthur, Switzerland and Medtronic Inc, Minnesota, US). The study recruited 200 patients randomised into two groups of 100.

It aimed to compare:

- Functional outcome measured objectively using flexible electrogoniometry.
- Implant position post operation using CT scans and weight bearing long leg double stance radiographs.
- Clinical questionnaire scores (WOMAC, Oxford Knee Score and American Knee Society Scores).
- Quality of life using SF-36 questionnaires.
- Passive range of motion while the patient lies supine.
- Activity levels for a typical 24 hours using the Activpal activity monitor.
- Knee extensor and flexor moments using a myometer with the patient sitting with their knee flexed to 90^{o}.

The iNav electromagnetic navigational system is thought to be able to produce accuracy levels to within 1 degree in the coronal plane for implantation of the total knee replacement prosthesis. One opinion within current literature suggests that alignment errors exceeding 3^{o} are associated with early implant failure. The functional benefits of computer assisted surgery, if any, have not been extensively investigated. Instead the focus has been on the alignment outcome of the surgeries as a method of comparison. Therefore navigated and conventional TKA was compared through an in depth objective functional assessment using flexible electrogoniometers.

2.2. CLINICAL TRIAL METHODOLOGY

2.2.1. Ethics

The trial was approved by the Glasgow Royal Infirmary Local Research Ethics Committee (GRI LREC) in March 2007. The trial also gained simultaneous ethical approval from the University of Strathclyde ethics committee.

2.2.2. Test Site

The patients attended their routine 1 year post-operative outcomes appointment in the Orthopaedic clinic in Glasgow Royal Infirmary. The functional assessment was an extension of this routine outcome appointment. A clinic room was used to complete the clinical questionnaires, measure passive range of motion using a manual plastic goniometer and conduct the flexor and extensor moment test. The patient then used this room to change and the electrogoniometers were attached. Then a circuit of locations around the hospital was completed which included walking along a corridor, up and down stairs, up and down a slope, sit to stand to a low and standard chair and in and out of an unfilled bath.

2.2.3. Consent

Participation in the research study was voluntary and the patients were sent information sheets prior to their pre-operative clinical health check appointment. At this appointment they were given a chance to talk through the information and ask questions before they made their decision in accordance to Good Clinical Practice

(GCP) guidelines. Non-involvement in the trial did not change the course of the patients care.

2.2.4. Subject Selection

Patients were taken from the common waiting list for TKA in Glasgow Royal Infirmary. The following inclusion and exclusion criteria had been set.

Trial inclusion criteria:

i) Male or female subjects were considered for recruitment to the trial.
ii) Subjects were at least 18 years of age. There was no maximum age limit. The subject's age had to be considered suitable by the surgeon for a knee arthroplasty using either of the two systems available in the evaluation.
iii) Subjects, who were able to give voluntary, written informed consent to participate in this investigation and from whom consent has been obtained.
iv) Subjects, who, in the opinion of the surgeon, were able to understand the investigation, co-operate with the investigation procedures and were willing to return to the hospital for all the required post-operative follow-ups.
v) Subjects who required a knee arthroplasty for primary surgical management of idiopathic osteoarthritis.
vi) Subjects, who in the opinion of the surgeon, were considered to be suitable for treatment with a Nexgen LPS-Flex total knee replacement.

Trial exclusion criteria:

i) Subjects who, in the opinion of the surgeon, had an existing condition that would compromise their participation and follow-up in the study.
ii) Subjects who required revision total knee arthroplasty surgery.
iii) Subjects with any tibial deformity requiring tibial component augmentation.
iv) Subjects whom, in the opinion of the surgeon, required a constrained prosthesis.
v) Subjects with inflammatory polyarthritis.
vi) Subjects with neurological conditions affecting movement.
vii) Subjects with a pathology which, in the opinion of the surgeon, would adversely affect healing.

viii) Subjects with other disorders which, in the opinion of the surgeon, would have impaired rehabilitation.

ix) Contra-indications for use of the device, as detailed in the package insert.

x) Women who were pregnant.

xi) Subjects who were known drug or alcohol abusers or with psychological disorders that would effect follow-up care or treatment outcomes.

xii) Subjects who were currently involved in another clinical study with an investigational product.

xiii) Subjects who were currently involved in any injury litigation claims.

The primary aim of the study was to compare the 2 surgical methods in terms of implant alignment. Post operative alignment would not be affected by contra lateral knee problems or other joint problems. However these problems may affect the patient's functional outcome Therefore, at the 1 year post-operative appointment the patients were accessed for contra-lateral problems which would affect their function. There were two additional exclusion factors for the electrogoniometry functional assessment.

Exclusion points for Electrogoniometry Functional Assessment.

i) Subjects with osteoarthritis of the contra-lateral knee causing significant abnormal gait or significant pain.

ii) Subjects with a poorly functioning contra-lateral total knee replacement causing significant abnormal gait or significant pain. Subjects with a well functioning contra-lateral total knee replacement were not excluded.

All the patients recruited were on the waiting list for a TKA and received a NexGen LPS-Flex design (Zimmer) through either the conventional or the navigation method. They were assigned a trial number, consecutively from 1 to 200. Two orthopaedic knee specialist consultants in the Glasgow Royal Infirmary preformed all of the surgeries, Mr Mark Blyth and Mr Bryn Jones.

The trial was randomised to eliminate any surgeon bias. The surgeons did not have their own randomisation lists. Therefore there was a possibility of an uneven split of the surgeons performing the procedures within each of the two groups. The randomisation process took place after the patient had been consented. This allowed time for the navigation system to be prepared for surgery, if required. A computer

generated programme assigned trial numbers to each surgical group. 200 patients were recruited to the trial over the period July 2007 to August 2010.

2.3. FUNCTIONAL ABILITY ASSESSMENT

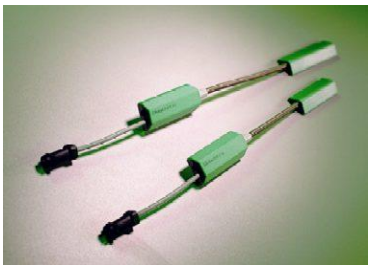
Functional outcome as previously mentioned can be measured using various tools depending on how extensive an assessment is required. Questionnaires are a quick and simple measure of function and limitations experienced by the patients' pre and post-operatively. Studying functional ability more closely involves looking at the patients' biomechanical outcome during specific daily activities. One such method uses flexible electrogoniometers which can record dynamic knee joint angles during, for example, walking tasks.

2.3.1. Introduction to Electrogoniometry

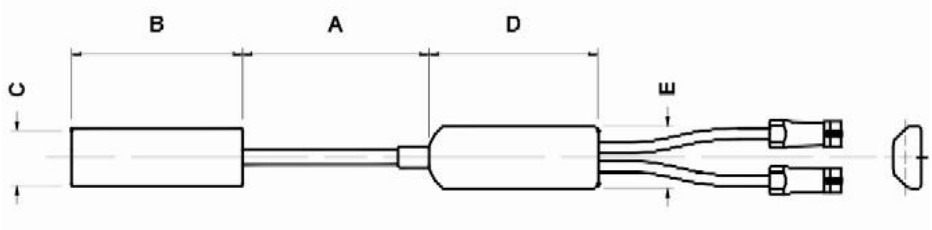
Flexible electrogoniometers (EG) can be used to measure joint angles (figure 2.1). This study investigates knee kinematics. Flexible electrogoniometers are produced by Biometrics Ltd (Cwmfelinfach, Gwent, UK). The 'SG' series are twin axis which means they can simultaneously measure up to two planes of movement.

The 'SG150' electrogoniometer allows measurement of flexion/extension and if required abduction/adduction at the knee joint. This study only dealt with movement in the sagittal plane i.e. flexion and extension at the knee joint. An electrogoniometer can be divided into 3 sections, two end plates separated by a flexible strain gauge (180mm). The strain gauge is protected within a tightly coiled lightweight spring. The distal end plate contains a slider which is attached to the strain gauge. This feature allows the device to vary slightly in length without allowing rotation or excessive tension of the strain gauge which could damage the instrument. The data from the electrogoniometer is fed into a Biometric's DataLOG (figure 2.1).

(a)



(b)



No Channels	A max	A min	B	C	D	E	Weight (g)
2	150	130	70	18	54	20	19

(c)

Figure 2.1 (a) Diagram of Biometrics flexible electrogoniometer (b) Electrogoniometer specifications (c) Diagram of Biometrics datalog

The DataLOG screen displays the input angles. The menu system allows the memory card to be cleared, the system to be zeroed and recordings to be made. Flexible electrogoniometers do not have a specific centre of rotation instead they record the angle subtended between the two end plates. The two end plates are

attached to the lateral side of the subject's leg using double sided medical tape. The device straddles the knee joint with one end plate distal and the other proximal to the knee joint centre and therefore gives the true angle between the two joint segments. Correct attachment of the device is important so that the device is aligned where it lies on the neutral axis (hip-knee-ankle joint centres) when the subject's lower limb is in full extension. A possible problem which has to be considered regarding the knee joint is that the centre is not fixed but polycentric; therefore the centre depends on the degree of flexion at that point in time. However the change in position of the knee joint centre is minimal and therefore assuming a fixed joint centre would lead to minimal errors in measurement. Attachment of the device cannot be directly onto bone; instead it is attached to the soft tissue of the lower limb. Therefore movement of the device from the appropriate axis due to soft tissue is a factor in the accuracy of the device. When the device was used with patients with a fixed flexion deformity it can be difficult to determine the neutral axis, and the point at which to take the zero starting angle. Any flexion deformities have to therefore be added onto the output angles recorded during the analysis process.

Footswitches were used to distinguish swing and stance phase of the walking activities. Footswitches are small, lightweight and thin. They were attached to the sole of the foot using tape - one on the heel and one on the 1st metatarsal area. These heel and toe switches were wired in parallel so that pressing either switch registered as contact between the foot and the floor. They were connected to the datalogger through thin cables.

2.3.2. Suitable for use/Published Work

Electrogoniometers have previously been used to measure joint angle. Over the years they have been developed and modified. Flexible electrogoniometers have been used for over 20 years worldwide in a variety of research applications (Ball P and Johnson G.R, 1993, Ojima H et al., 1991, Rowe P.J et al., 2005, Rowe P.J et al., 1989).

2.3.3. Electrogoniometry Functional Ability Assessment

Flexible electrogoniometry was used to record the dynamic kinematic functional cycle of 12 everyday activities. These tasks were completed within the hospital clinic setting. A circuit was set up to include the tasks listed below which took about 10-15 minutes to complete.

The 12 activities were:

1. Level walking
2. Up slope walking (5^o slope) – sloped walkway was used within the hospital
3. Down slope walking (5^o slope) – sloped walkway was used within the hospital
4. Stair ascent (140mm riser, 270mm tread)
5. Stair descent (140mm riser, 270mm tread)
6. Stand to sit from a high chair (500mm high)
7. Sit to stand from a high chair (500mm high)
8. Stand to sit from a low chair (300mm high with an additional 120mm thick soft cushion)
9. Sit to stand from a low chair(300mm high with an additional 120mm thick soft cushion)
10. Into a bath (560mm height of bath when standing next to it)
11. Out of a bath (560mm height of bath when standing next to it)
12. Weighted deep knee flexion on a single step (step height 450mm)

The maximum, minimum and excursion (maximum-minimum) knee joint angle was extracted from the function cycles produced from the 12 activities above.

2.3.4. Functional Score for Electrogoniometry Knee Kinematic Data

The group mean knee kinematic data will be compared for each of the activities. The electrogoniometry data from all 12 activities was used to produce a Total Functional Score. This would take into account the fact that some patients could not complete all of the functional activities. The score was based on comparing the TKA trial patients to ‘normal’ age matched subjects.

A functional assessment using electrogoniometry has been previously completed on a group of healthy elderly subjects to which we had access. This work had been carried out by Dr Marietta L. van der Linden in the school of Health

Sciences in Queen Margaret University College under the supervision of Professor Philip J Rowe. The study recorded data from 40 aged matched normals. The mean age for this group was 69.4 (+/-6.0) with an age range of 54-80 years old. There were 15 males and 25 females within the group.

The same activities had been completed by the age matched normal subject group therefore this normal data set was used as a baseline for comparison with the TKA patients. Each activity was marked from 0-5 points. Firstly from the 40 normal subjects the mean and standard deviation for maximum knee joint angle for each of the 12 activities and the 5 excursion values for the cyclic activities (level, slope walking and stairs) was calculated. The reason the excursion values were only used for the 5 gait cycle activities was because the other activities started from standing and therefore the minimum angle should be zero and therefore the maximum and excursion values would be equal. The standard deviation value was subtracted from the mean knee angle to give flexion angle ranges for each function. The score depends on how many standard deviations outwith the normal groups mean angle the patient had recorded.

- 5 points was given if the angle was within 1 standard deviation of the average 'normals' knee joint angle.
- 4 points was given if the angle was within 2 standard deviations.
- 3 points was given if the angle was within 3 standard deviations
- 2 points was given if the angle was within 4 standard deviations
- 1 point was given if the angle was over 4 standard deviations of the 'normal' averages but they could complete the task
- And 0 points was give to the patients who could not complete the function.

The score for each task was then added together to give an overall total. This was then converted into a percentage of the maximum. Scores between 0-100 would indicate where on the scale the patient's functional outcome would lie. The 'normal' group average score was 88.7. Therefore patients who score 88.7 or above could be classed as achieving a normal functional outcome post operation.

2.4. ELECTROGONIOMETER CALIBRATION: INTRODUCTION

The electrogoniometers were connected to a biometrics DataLOG which recorded the angular motion of the joint as an electrical output. The electrical signal should change in a linear fashion with change in angular motion. This electrical signal has to be then converted into meaningful output angles using calibration equations. The calibration equations are unique to each electrogoniometer.

2.4.1. Electrogoniometer Calibration: Methodology

Each of the flexible electrogoniometers had to be calibrated with respect to the DataLOG. The connection of the electrogoniometer to the DataLOG was directly through an interconnecting cable (J1000). This system records at 50Hz.

The electrogoniometer was securely attached to a long armed standard plastic manual goniometer using tape. Care was taken that the electrogoniometer was placed so that the middle section i.e. the strain gauge, straddles the centre of the manual goniometer and that it could move through 150^{o} in both directions (figure 2.2).

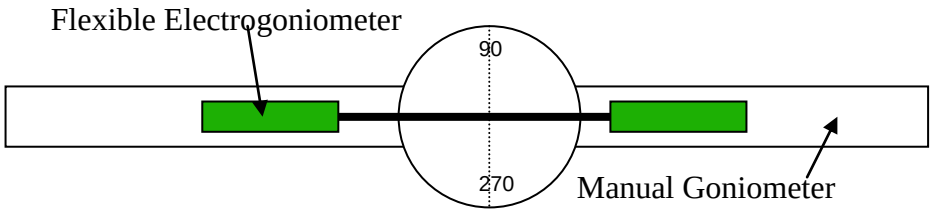


Figure 2.2 Diagram of the setup for flexible electrogoniometer calibration.

Firstly, 200 recordings were taken for positions 0^{o}, +/-90^{o} and +/-150^{o}, which allowed the stability of the electrogoniometer's signal to be analysed. Then a continuous recording of the electrogoniometer's signal was taken as the manual goniometer was moved through the range +150^{o} to -150^{o} and back to +150^{o} in 10^{o} increments. For each increment 200 readings were recorded and an average calculated. The stability of the signal at each increment point was analysed through the calculation of the standard deviation. Using the average electrical output values (computer units - CU) at each increment and the corresponding manual goniometer angles a xy plot was drawn and the equation of the line extracted. This then produced calibration expressions for each electrogoniometer. The best fit line through the data

recorded in the calibration trials was calculated. The electrogoniometers once assigned to either the left or right limb does not flex through the full range tested, therefore each electrogoniometer was retested through its useable range of -20^{o} to 150^{o} (hyper extension to high flexion). Again the calibration equation was extracted from the xy plot.

Before the electrogoniometers were used in the patient functional assessment they were validated against the 8 camera motion analysis Vicon system. The calibration expressions were calculated for the electrogoniometers to be used with the Vicon system in the same way as described for use with the biometrics DataLOG. The electrogoniometer was connected to a biometrics K100 Amplifier then through a cable into a K100 Amplifier base unit from which the output of the various channels can be displayed. The analogue output from this base was through a R1500 BNC cable into the Vicon system. The Vicon system recorded at 120Hz.

2.4.2. Electrogoniometer Calibration: Results

Table 2.1 shows the results of the stability test from electrogoniometer 1. As mentioned the digital output at each angle was recorded and an average of 200 readings was taken. The maximum standard deviation of the measured output over this period was calculated and shows the stability of the signal. From the table it can be concluded that the signal was stable with a maximum deviation of 0.46^{o} from the average output which was associated with the high end of the measured range (high flexion angles).

Table 2.1 Summary of the signal stability of EG 1 at +/-150^{o}, +/-90^{o} and 0^{o}

Angle (deg)	Output (CU)	Standard deviation (CU)	Deviation – Stability of signal (deg)
-150	-3133.44	8.04	0.38
-90	-1925.96	2.95	0.14
0	75.48	3.22	0.15
90	1983.30	1.62	0.08
150	3070.73	9.85	0.46

Figure 2.3 represents an example of the data collected. Each electrogoniometer has a unique calibration expression so a xy plot was required for each electrogoniometer. Flexible electrogoniometers need a calibration equation to allow the electrical output to be converted to the angle it relates to.

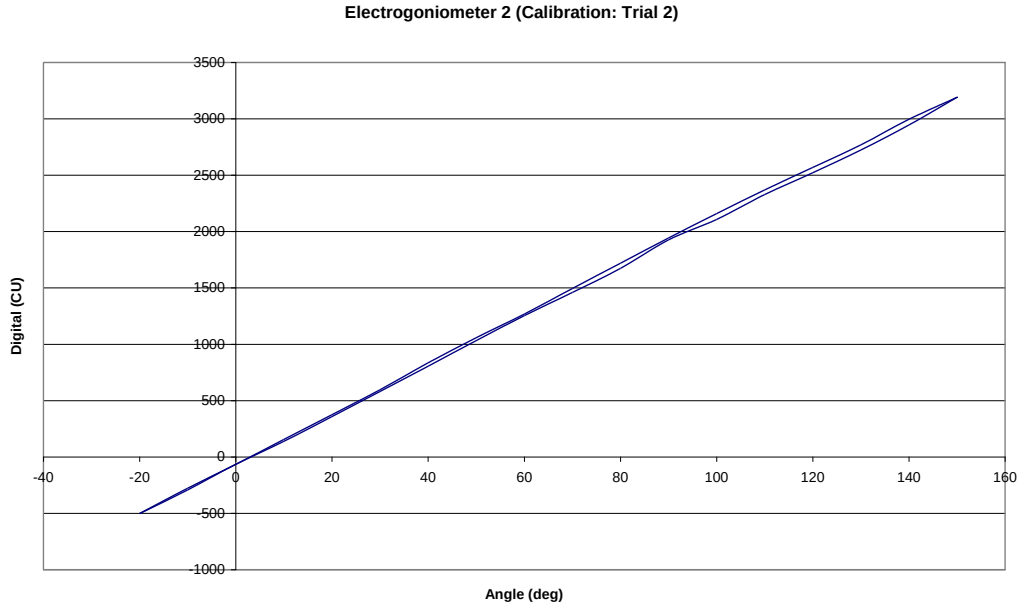


Figure 2.3 The relationship between the applied angle (true angle) and the measured output (in computer units). Example uses electrogoniometer 2 and is recorded through -20 ^{o} to 150^{o}.

Two electrogoniometers (a left and right EG) were used in a validation study with the Vicon system therefore calibration equations for these electrogoniometers were calculated. A summary of the calibration results are recorded in table 2.2.

Table 2.2 Summary of calibration expressions, signal stability and hysteresis effect for 4 EGs with the VICON system

Electrogoniometer	**1**	**3**
Right/Left	R	L
Calibration Expression	y = 70.469x + 133.667	y = 70.697x + 182.696
Signal stability	0.11 % (0.32^{o})	0.11 % (0.33^{o})
Hysteresis	2.08 % (3.54^{o})	1.93 % (3.27^{o})

Table 2.2 shows the expression for each of the electrogoniometers to be used with the VICON system during the validation study. The table includes the signal stability. This was expressed as a percentage of the range tested and also the angle

this relates to. The table also notes the maximum hysteresis effect on each of the EGs. Hysteresis was seen as the deviation of the digital output recordings from the predicted output calculated from the calibration equation. The table shows this effect as a percentage of the tested range and the angle this relates to.

The output signals were found to be stable with the largest variation being recorded by electrogoniometer 3 at 0.11% of the measured range (-20^o to 150^o) which equates to 0.33^o of the full scale. Each electrogoniometer exhibited hysteresis as seen in figure 2.3 as the 'opening up' of the curve. The hysteretic effect was more notable at the high end of the measured range. A maximum hysteretic effect of 3.54^o was recorded from the two electrogoniometers (table 2.2).

Table 2.3 shows the expression for each of the four electrogoniometers to be used with the DataLOG during the clinical trial. Four electrogoniometers were tested, two for everyday use and two spare EGs.

Table 2.3 Summary of calibration expressions, signal stability and hysteresis effect for 4 electrogoniometers with the DataLOG

Electrogoniometer	**1**	**2**	**3**	**4**
Right/Left	R	R	L	L
Calibration Expression	y = 21.236x - 35.147	y = 21.785x - 58.245	y = 21.937x + 21.68	y = 21.783x + 83.313
Signal stability	0.15 % (0.46^o)	0.17 % (0.52^o)	0.16 % (0.47^o)	0.15 % (0.45^o)
Hysteresis	2.12 % (3.61^o)	1.22 % (2.07^o)	1.44 % (2.46^o)	1.57 % (2.67^o)

The output signals were found to be stable with the largest variation being recorded by electrogoniometer 2 at 0.17% of the measured range (-20^o to 150^o) which equates to 0.52^o. Again a hysteresis effect was seen for each of the electrogoniometers which was more notable at the high end of the measured range. There was a difference in the hysteresis effect between electrogoniometers. Electrogoniometer 1 exhibited a maximum hysteretic effect of 3.6^o.

2.4.3. Electrogoniometer Calibration: Discussion/Conclusion

Firstly the electrogoniometer calibration equations are based on a manual goniometer which can be a source of error. A larger source of error would be the user themselves. The accuracy was affected by the precision of the user when moving

through the angles to be measured. The manual goniometer readings were taken as the actual measurements which were used to correlate the CU output to calculate the calibration equation. For this reason increments of 10^o rather than 1^o were used.

The signal was shown to be stable at the selected test angles. Table 2.1 shows that the high end of the flexion range, i.e. +/-150^o showed the least stable signal but deviations were minimal at less than 0.5^o. The hysteresis effect seen in figure 2.4 again shows that the area with the largest signal deviation was at the top end of the range (150^o). The hysteresis effect amounts to a maximum of 3.6^o which is an acceptable error for this test range of -20-150^o. In general the activities completed within this trial use a small section of the tested range of -20-150^o. All of the activities except for the chair and bath test are expected to require less than 100^o. There is minimal hysteresis effect through this 'used' flexion range.

Each of the electrogoniometers has a different calibration expression. These have to be used to convert the digital output from the datalog into output angles.

2.5. ELECTROGONIOMETER ATTACHMENT: INTRODUCTION

One of the factors which affect the accuracy of the electrogoniometers is that the device is attached to the subject's skin. Therefore soft tissue movement can affect the results. It is assumed that the movement of the electrogoniometer attached to the skin follows the movement of the underlying bone.

It is important that the electrogoniometer is aligned so that it lies on the lateral side of the lower limb and on the line which connects the hip center and the ankle center. The strain gauge section of the sensor has to be placed over the knee joint. Therefore attachment of the device in the correct alignment must be repeatable.

2.5.1. Electrogoniometer Attachment: Protocol

The electrogoniometers were attached to plastic strips. The plastic strips were about 200mm long and flexible. Two of these strips were used for each electrogoniometer. One was attached to each end block. The strips allow the electrogoniometer to be attached to the lower limb more accurately, as they made it easier to visualise the line from the knee to the hip joint and from the knee to the ankle joint. They also help to stabilise the position of the electrogoniometer and

minimise the movement. This is because the plastic strips increase the area of attachment so that medical double sided tape can be used at the top and bottom of the strips instead of one piece of tape being used to attach the electrogoniometer end block to the skin. If the electrogoniometer was attached directly to the skin, any movement of the small end block would be difficult to detect.

2.5.2. Electrogoniometer Attachment: Intra-observer Reliability Methodology

The intra observer repeatability of attachment was studied. One subject was used in this test. The electrogoniometers were attached to both lower limbs and then the DataLOG recorded knee joint angles as the subject walked along a hallway and up/down a staircase. Then the electrogoniometers were removed from both limbs. The subject then had a break for 30 minutes before the electrogoniometers were re-attached and the walking trial repeated. This was repeated so that the test was completed four times. The subject was asked to walk at their preferred speed. The speed was not controlled but it can be assumed that each trial would be completed at a similar speed.

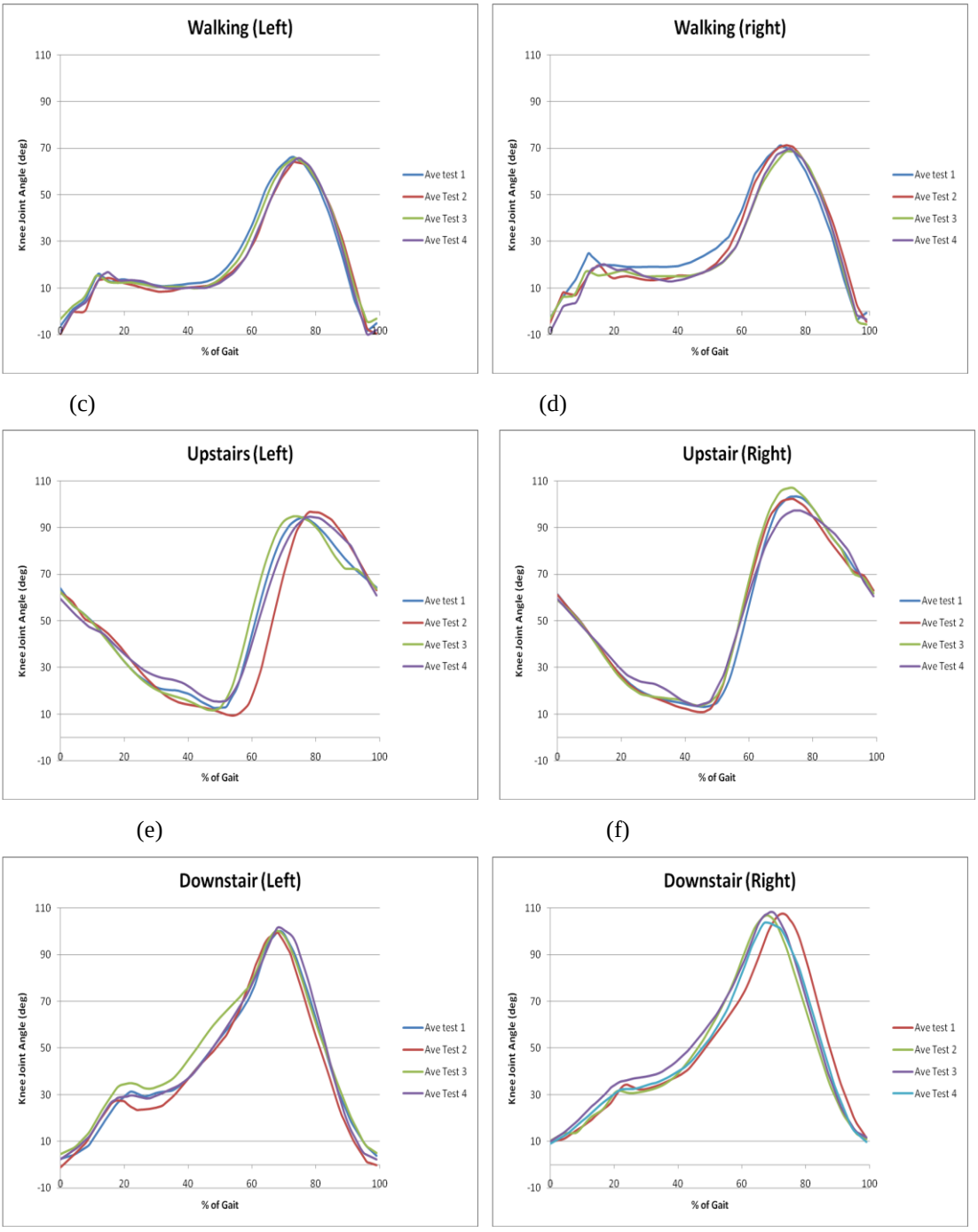
The length of the walkway was sufficient to allow the subject to fall into their natural walking stride. The staircase also allowed the subject to complete at least 5 gait cycles on each side. For each activity an average of the 3 gait cycles was calculated. The average cycle for each of the 4 tests was then graphed to show any variations between the tests. The maximum, minimum and excursion knee joint angles were identified. This would allow the 4 tests to be compared and to determine if the attachment protocol led to repeatable cycles.

2.5.3. Electrogoniometer Attachment: Results

For each activity three cycles were averaged in each test. The maximum, minimum and excursion knee joint angles for each set of three cycles showed a high degree of similarity. Furthermore the standard deviations for each test, left and right limb, were low. The largest standard deviation was seen in the excursion angles in one of the left walking tests at 3.49^{o}. This indicates that the lower limbs show a high degree of symmetry and that the activities, walking and stairs showed a repeatable pattern.

Figure 2.4 shows the left and right limb results for walking, up and downstairs. Each graph has a trace representing each of the 4 tests.

(a) (b)



(c) (d)

(e) (f)

Figure 2.4 Graphs (a) and (b) show the 4 average walking tests for the left and right limb. Graphs (c) and (d) show the 4 average upstair tests for the left and right limb. Graphs (e) and (f) show the 4 average downstair tests for the left and right limb.

Figure 2.4 includes left and right for walking, upstairs and downstairs. Each graph shows the average gait cycles for each of the 4 tests – between each test the electrogoniometer was removed and reattached. Some minor variations are seen as illustrated in figure 2.4. An example is seen in graph (e) where the maximum stance phase peak varies from about 28-33^{o}.

Table 2.4 summarises the average maximum, minimum and excursion knee joint angles for each activity for the 4 tests.

Table 2.4 Average max, min and excursion knee joint angles in degrees for each activity (walk, up/down stairs) for the left and right lower limb

Walk - Left	Test 1	Test 2	Test 3	Test 4	StDev
Average maximum	66.71	64.27	66.01	66.00	1.04
Average minimum	-8.22	-9.75	-4.59	-10.61	2.66
Average excursion	74.93	74.02	70.61	76.62	2.53

Walk - Right	Test 1	Test 2	Test 3	Test 4	StDev
Average maximum	71.11	71.23	68.83	69.94	1.13
Average minimum	-3.36	-5.34	-5.52	-8.78	2.24
Average excursion	74.47	76.57	74.35	78.71	2.06

Up stairs - Left	Test 1	Test 2	Test 3	Test 4	StDev
Average maximum	94.45	97.16	95.09	95.08	1.18
Average minimum	12.39	8.90	11.58	15.05	2.53
Average excursion	82.06	88.26	83.51	80.03	3.50

Up stairs - Right	Test 1	Test 2	Test 3	Test 4	StDev
Average maximum	104.04	102.59	107.24	98.55	3.60
Average minimum	13.06	10.42	13.39	13.44	1.45
Average excursion	90.97	92.18	93.85	85.11	3.80

Downstairs - Left	Test 1	Test 2	Test 3	Test 4	StDev
Average maximum	100.90	101.66	100.97	102.83	0.89
Average minimum	1.83	-1.20	4.45	0.89	2.34
Average excursion	99.07	102.86	96.52	101.94	2.88

Downstairs - Right	Test 1	Test 2	Test 3	Test 4	StDev
Average maximum	108.12	108.09	108.86	105.64	1.40
Average minimum	9.76	8.97	9.80	8.43	0.66
Average excursion	98.36	99.12	99.06	97.21	0.89

The standard deviation of the maximum, minimum and excursion knee joint angles from the four tests are low.

The greatest difference between the 4 tests was in terms of maximum excursion values. The greatest difference was 8.7^{o} during up stairs (right) task. The average difference between the trials was less than 5^{o}.

The right limb had a greater maximum flexion angle during this test. This is likely to be explained by the asymmetrical nature of gait, where the right side appeared to be the dominant limb.

2.5.4. Electrogoniometer Attachment: Discussion/Conclusion

Walking was shown to follow a repeatable pattern. It can also be concluded that the attachment protocol was repeatable as the maximum, minimum and excursion values for the repeated trials only vary by a few degrees. The maximum, minimum and excursion values would be affected by change in walking speed which was not controlled in this test. The subject was asked to walk at their preferred speed but some variations in speed may have contributed to the small variations in recorded gait cycles.

This test shows that the attachment protocol leads to accurate attachment of the electrogoniometer which will be used in the functional assessment to compare conventional and navigated TKA.

2.6. OBJECTIVE VALIDATION STUDY

Flexible electrogoniometers have the potental for easy clinical use to measure the range of motion of joints during various dynamic functional activities (e.g. walking, stair climbing). The study aims to validate the electrogoniometry measurement devices against a motion analysis system - the eight camera Vicon system (Oxford Metrics Ltd), as various activities are performed.

2.6.1. Introduction to Vicon System

The vicon system is a motion analysis system which can be used to collect kinetic and kinematic data about various joints from many groups, patients and normal subjects. This system is known as the ‘gold standard’. The eight cameras are

set up to capture an area within a gait laboratory. They emit infared light which is reflected back from retro-reflective markers worn by the subject. The cameras then detect the reflected light and the Vicon software reconstructs the three dimensional co-ordinates of the marker.

Calibration

The system had to be calibrated: static and dynamic calibration. A fixed L-shaped bar with markers in known postions was used to calibrate the test area. It was positioned on two sides of force plate 2 within the gait lab (figure 2.5).

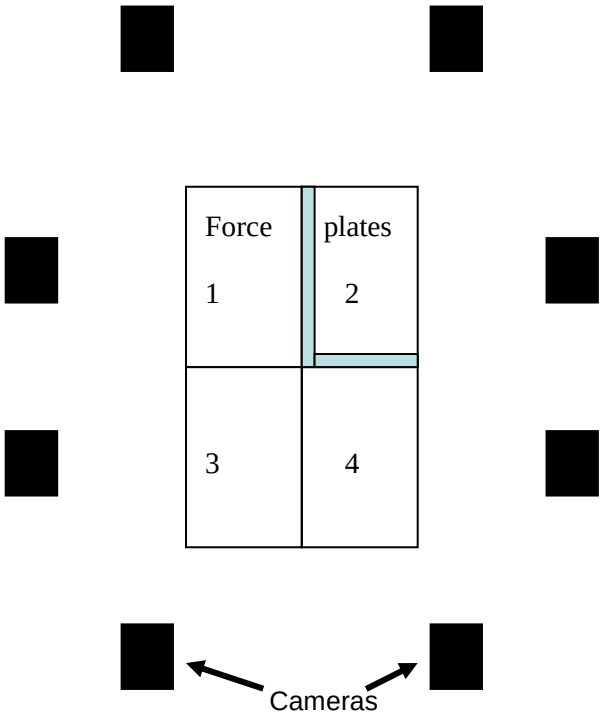


Figure 2.5 Static Calibration Gait Lab Set Up: Consists of 4 force plates and 8 cameras and L-shaped frame on force plate 2.

This arrangement allows the vicon software to determine the axes setup for the test area. Dynamic calibration can be used to calibrate varying test volumes and requires the use of a calabration wand. The wand contains 2 markers set at a specific distance apart. It was moved through the test area for around 15 seconds while the vicon system continuously records the markers position and from this the position of the eight cameras.

Markers

This study investigated the lower limb and more specifically the knee joint. For this a lower limb marker set was used. The spherical reflective markers were 14mm and where either attached as part of a cluster or as individual markers. The thigh and shank clusters consisted of 4 markers attached to a plastic cuff, slightly rounded to lie flat against the shape of the leg. Velcro straps were looped round the thigh and shank and then the plastic cuff was stuck onto these. Problems exist as the markers are not directly attached to the bone and skin movement decreases the accuracy of the output marker co-ordinate. Waist markers were worn on a waist belt. This contained 4 markers attached through double sided tape. Finally the foot markers used were 5 individual markers stuck directly to the skin. These markers covered the bony landmarks:

- Medial maleolus,
- Lateral maleolus,
- Calaneous,
- 1^{st} and 5^{th} metatarsal joint.

Static Trials

No markers were used specifically to mark the bony landmarks of either the knee or hip joint. The hip, knee and ankle joint centres were calculated as virtual points in relation to the clusters. For that reason it was important that the markers were visable during the trials and underwent minimal movement. Clusters of 4 were used on the thigh, shank and waist so that at least 3 markers were visable for the calculations.

Static trials were run to input the calibration points for the right and left ASIS and sacrum at the hip joint, and the right and left medial and lateral epicondyle at the knee joint. Using a pointer (figure 2.6) the position of the mentioned bony landmarks were recorded in reference to the approiate clusters. The pointer contains 2 reflective markers set at a specific distance apart. The landmarks of the hip are referenced to the waist markers, the knee landmarks to the thigh clusters and the ankle to the shank clusters.

Figure 2.6. Diagram of pointer used in the static trials

How important is accurately identifying the bony landmark in the static trials?

The static trials were used to record the position of the bony landmarks of the knee and hip in relation to cluster markers and were used within the bodybuilder program to calculate the knee joint centre (KJC) and hip joint centre (HJC). The hip, knee and ankle joint centres are then used to calculate the flexion angles of the knee joint. The angles are calculated based on the movement of the thigh and shank segments. The thigh segment was formed from the hip to the knee joint centre. The shank segment was formed by joining the knee and ankle joint centre (AJC) (figure 2.7). The accuracy of the pointer static trials was dependant on the researcher's accuracy marking the bony landmarks and therefore was subject to human error. Therefore would varying the recorded static points lead to a significant error factor? The validation study aims to compare the recorded knee joint angles through two systems therefore it was important that the knee joint centre used was as accurate as possible.

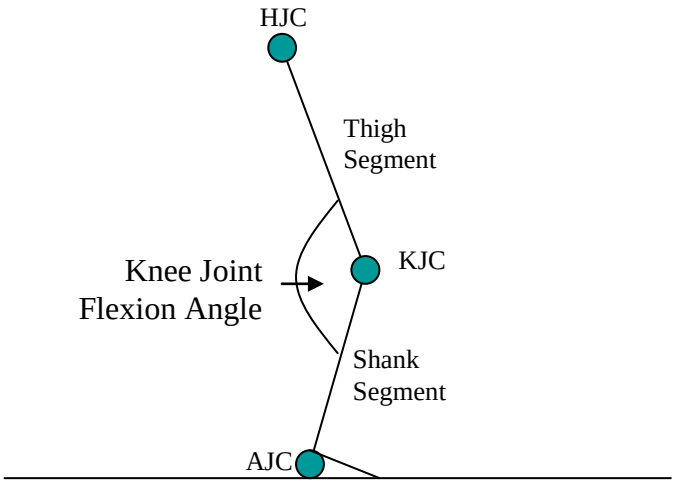


Figure 2.7 Sagittal view of lower limb, indicating thigh and shank segments

It was investigated how varying the position recorded for the medial and lateral epicondyles affected the KJC. The epicondyles were marked as accurately as possible on the skin of the subject's knee. These points were then recorded in a static trial in the Vicon system. The static trials were then repeated by recording points approximately 10mm anterior, posterior, proximal and distal to the accurate position. After the static trials had been completed then the subject completed five walking trials. The results were then analysed in the bodybuilder software. For each of the trials five different knee joint centres were calculated. The resulting walking graphs were not filtered within bodybuilder. Figure 2.8 displays the results of an example walking trial (right limb) graph. It shows that varying the knee joint centre does not change the shape of the graph.

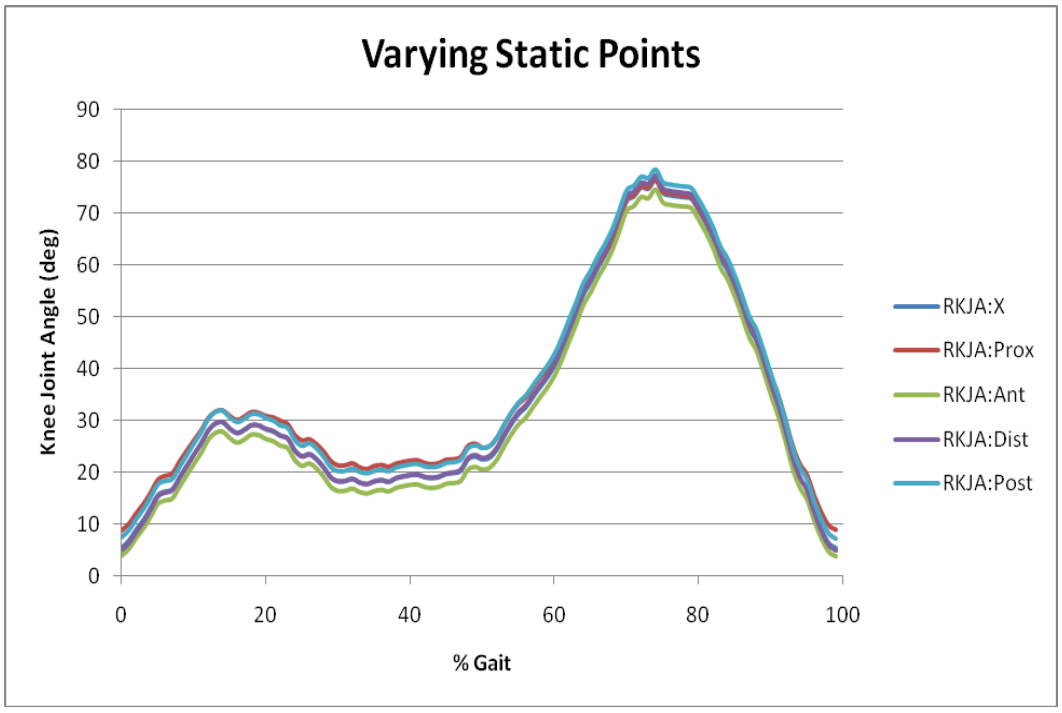


Figure 2.8 Varying static positions of the right medial and lateral epicondyles

The change in maximum and minimum flexion angles points do not vary greatly but shows that by incorrectly marking the static trial the centre of rotation at the knee will vary. If the zero degrees or neutral position of the lower limb varies then there will be discrepancies in the neutral positions determined by the Vicon system and the flexible goniometry systems.

Table 2.5 gives a summary of the maximum flexion angle which relates to the varied position of the KJC during an example of gait. X denotes the 'correct' KJC which was calculated from the static points (lateral and medial epicondyles). The other rows in table 2.5 show the error direction for the static points. This example resulted in variations of 0.5-2^{o}. The static points were moved about 10mm in the different direction however the error movement was not measured and therefore explains the varying errors calculated. This is a small error range and can be seen as negligible. However in the validation study errors or differences between the two systems of a few degrees could possibly be explained by inaccuracies in the static trials.

Table 2.5 Summary of maximum flexion angle during walking gait as the KJC position is varied for the right and left lower limb

Position KJC	Left Limb Max Flexion Angle (deg)	Right Limb Max Flexion Angle (deg)
X	68.16	76.92
Proximal	67.63	77.25
Anterior	66.18	75.05
Distal	67.28	77.92
Posterior	70.34	78.89

It is possible that the static trials at the hip may also add a few degrees of variation to the analysis. Static trials are used to calculate the HJC i.e. the right and left ASIS and SACR. There was a risk that these static points could be incorrect which in turn would result in an incorrect determination of the HJC. The HJC calculation also relies on the use of anthropometric data which is an average of a sub section of the population. Therefore it will not be an accurate representation everyone in the population.

All three joint centres – ankle, knee and hip are therefore important in determining the knee joint flexion angle.

2.6.2. Validation Methodology

The study investigated the concurrent validity and inter-test reliability of flexible electrogoniometers. The output from the electrogoniometers was collected by the Vicon computer via a long cable as an analog input. This meant that both sets

of input data was collected simultanously. Data for the Vicon system was recorded through the use of a reflective marker set previously described. The subject was dressed in shorts and the reflective markers (14mm spheres) were attached to the subject's lower limb using double sided tape. In addition to the marker set an electrogoniometer was attached to each lateral side of the lower limb using double sided medical tape.

The subjects were asked to perform 5 tasks:

1. Level walking:
2. Ascend stairs: ascent of a 4 step flight of stairs (180-190mm riser, 270-300mm tread);
3. Descend stairs: descent of a 4 step flight of stairs (180-190mm riser, 270-300mm tread);
4. Sit down on a standard chair: descent from standing into a standard chair;
5. Sit to stand standard chair: ascent from a standard chair to standing;

Static data was first recorded for the Vicon system analysis including lateral and medial epicondyles, right and left ASIS and SACR.

The first trial recorded was a static stand for the Vicon reference data. The subject stood still with straight lower limbs. This was the starting point and if the subject stands with fully extended knees, should be the zero point for the two systems. At this point the electrogoniometry system was zeroed. However if the leg was not fully extended then the Vicon system start point would not be 0^o.

A difference in the start knee joint angles for the 2 systems would impact the maximum and minimum measurements, but should not alter the excursion values calculated from the two systems. A difference was seen in some cases where the Vicon knee joint angle calculated in the static stand was a few degrees as oppose to 0^o therefore suggesting that the subject did not have fully extended lower limbs and indicates a fixed flexion angle. In these cases, to remove this issue from the test the vicon was corrected so that the starting reading for both systems was the same. If this was not corrected for there would be a shift in the starting points on the trial graphs. The calculation of the 2 zero points differs for each of the systems. The electrogoniometer system relies on accurate attachment of the device and then for the subject to stand with straight lower limbs while the system is zeroed. The vicon on

the other hand calculates the knee angles based on the KJC, AJC and HJC, which are based on bony landmarks and virtual points calculated by the body builder software.

Then the subject completed each of the tasks listed above. Each task was repeated 5 times. The data was then processed and analysed using vicon and bodybuilder software (appendix). The electrogoniometer data was collected through the analog channels and was progressed using the calibration equations previously calculated.

The validation study gained ethical approval from the Bioengineering Department, University of Strathclyde. Ten healthy volunteers were recruited. 4 males and 6 females were the age range was 25-60 years old.

2.6.3. Validation Results

Although each of the tasks was repeated 5 times there were some incomplete cycles. Generally this was as a result of disappearing markers from the Vicon camera 'line of sight'. This could be as a result of missing waist, thigh or shank markers as all were required to calculate knee joint angles. This was a greater problem for the stairs tasks as the waist band was sometimes lost from the camera's line of sight.

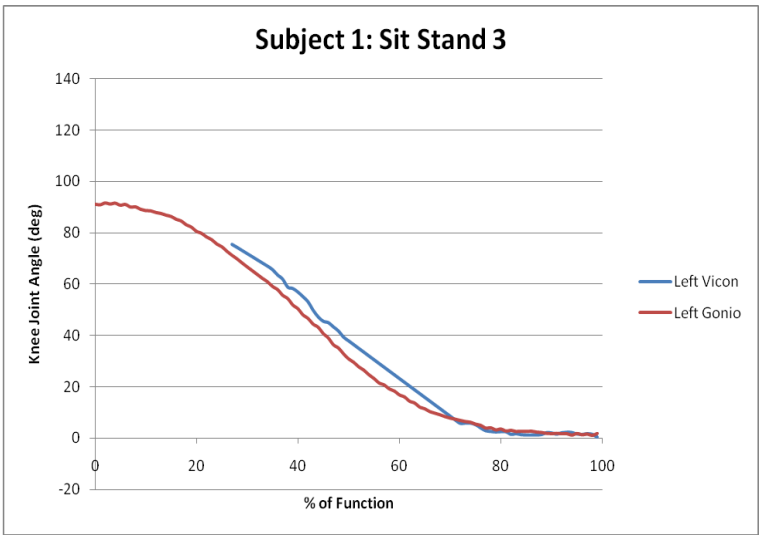


Figure 2.9 Example of a sit-stand trial where the markers where not visible for the complete cycle.

Figure 2.9 shows an example of a sit-stand trial where the markers were missing for about 25% of the gait cycle. The chair used had arm rests but no back so that the

waist band markers could be visible to the cameras. However in a small percentage of these trials 2 or more of the markers were missing and therefore the HJC could not be calculated meaning that there was no knee joint angle output.

For one subject there were errors in the electrogoniometers output trace for up and down stairs. Figure 2.10 shows the output. It can be seen that the basic shape of the trace for the electrogoniometer was the same as that of the Vicon system however the trace is not smooth as expected. In this case there was possibly a problem with noise interference from a loose connection between the electrogoniometer and the computer.

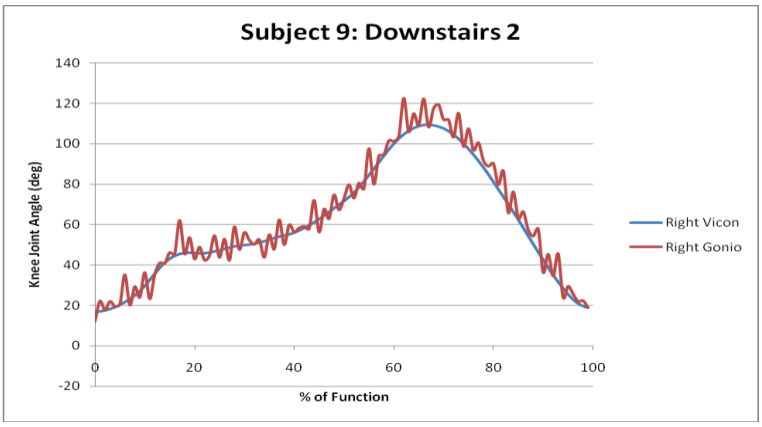


Figure 2.10 Example of a trial where the electrogoniometer gave an error output.

This meant that some Vicon and electrogoniometry trials were excluded from the validation study as they were incomplete.

Table 2.6 Stand-sit validation trials completed by the 10 subjects.

Stand-Sit	Total Trials	Completed Trials	% Completed	Reasons for Incomplete Trials
Subject 1	8	1	12.5	Vicon Markers missing
Subject 2	10	8	80	Vicon Markers missing
Subject 3	10	6	60	Vicon Markers missing
Subject 4	10	3	30	Vicon Markers missing
Subject 5	10	5	50	Vicon Markers missing
Subject 6	10	10	100	Vicon Markers missing
Subject 7	10	8	80	Vicon Markers missing
Subject 8	10	8	80	Vicon Markers missing
Subject 9	10	7	70	Vicon Markers missing
Subject 10	10	10	100	Vicon Markers missing

Table 2.7 Sit-stand validation trials completed by the 10 subjects.

Sit-Stand	Total Trials	Completed Trials	% Completed	Reasons for Incomplete Trials
Subject 1	8	4	50	Vicon Markers missing
Subject 2	10	10	100	Vicon Markers missing
Subject 3	10	8	80	Vicon Markers missing
Subject 4	10	5	50	Vicon Markers missing
Subject 5	10	6	60	Vicon Markers missing
Subject 6	10	10	100	Vicon Markers missing
Subject 7	10	6	60	Vicon Markers missing
Subject 8	10	6	60	Vicon Markers missing
Subject 9	10	9	90	Vicon Markers missing
Subject 10	10	10	100	Vicon Markers missing

Table 2.8 Sit-stand validation trials completed by the 10 subjects.

Squat	Total Trials	Completed Trials	% Completed	Reasons for Incomplete Trials
Subject 1	10	8	80	Vicon Markers missing
Subject 2	0	0	-	Vicon Markers missing
Subject 3	10	10	100	Vicon Markers missing
Subject 4	10	5	50	Vicon Markers missing
Subject 5	10	6	60	Vicon Markers missing
Subject 6	10	10	100	Vicon Markers missing
Subject 7	0	0	-	Vicon Markers missing
Subject 8	0	0	-	Vicon Markers missing
Subject 9	10	6	60	Electrogoniometer
Subject 10	10	10	100	Vicon Markers missing

Table 2.9 Level walking validation trials completed by the 10 subjects.

Level Walk	Total Trials	Completed Trials	% Completed	Reasons for Incomplete Trials
Subject 1	10	9	90	Vicon Markers missing
Subject 2	10	10	100	Vicon Markers missing
Subject 3	10	10	100	Vicon Markers missing
Subject 4	10	9	90	Vicon Markers missing
Subject 5	10	2	20	Vicon Markers missing
Subject 6	10	9	90	Vicon Markers missing
Subject 7	10	7	70	Vicon Markers missing
Subject 8	10	7	70	Vicon Markers missing
Subject 9	10	10	100	Vicon Markers missing
Subject 10	10	9	90	Vicon Markers missing

Table 2.10 Up stairs validation trials completed by the 10 subjects.

Up Stairs	Total Trials	Completed Trials	% Completed	Reasons for Incomplete Trials
Subject 1	10	10	100	Vicon Markers missing
Subject 2	10	9	90	Vicon Markers missing
Subject 3	10	10	100	Vicon Markers missing
Subject 4	10	4	40	Vicon Markers missing
Subject 5	8	4	50	Vicon Markers missing
Subject 6	10	7	70	Vicon Markers missing
Subject 7	10	6	60	Vicon Markers missing
Subject 8	10	10	100	Vicon Markers missing
Subject 9	10	0	0	Electrogoniometer
Subject 10	8	7	87.5	Vicon Markers missing

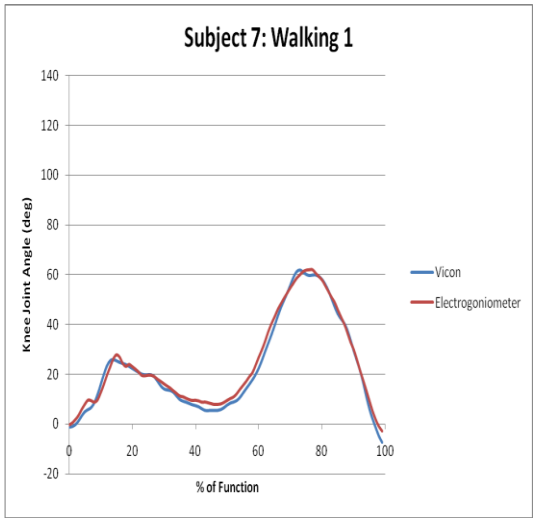
Table 2.11 Downstairs validation trials completed by the 10 subjects.

Down Stairs	Total Trials	Completed Trials	% Completed	Reasons for Incomplete Trials
Subject 1	10	6	60	Vicon Markers missing
Subject 2	10	4	40	Vicon Markers missing
Subject 3	10	4	40	Vicon Markers missing
Subject 4	10	1	10	Vicon Markers missing
Subject 5	10	4	40	Vicon Markers missing
Subject 6	10	7	70	Vicon Markers missing
Subject 7	10	6	60	Vicon Markers missing
Subject 8	10	0	0	Vicon Markers missing
Subject 9	10	0	0	Electrogoniometer
Subject 10	10	5	50	Vicon Markers missing

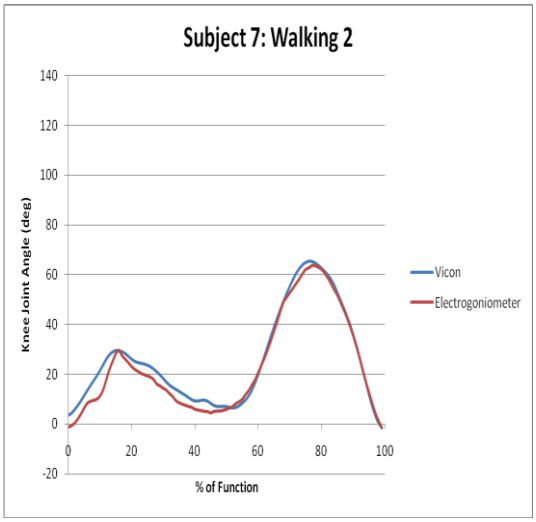
The results in tables 2.6 to 2.11 show the importance of proper camera arrangement so that the field of view includes all of the markers during the complete function cycle and not just intermittently. The software allows gaps in the data to be filled but care has to be taken with this as joining the end points may exclude subtle changes in the gait cycle.

For each subject the activities were completed 5 times giving 10 trials as both left and right lower limb was included. The squat activity was not completed by 3 subjects due to a time constraint on access to the gait lab. Figures 2.11 (a) to (j) presents the 10 walking trials for subject 7 for both systems.

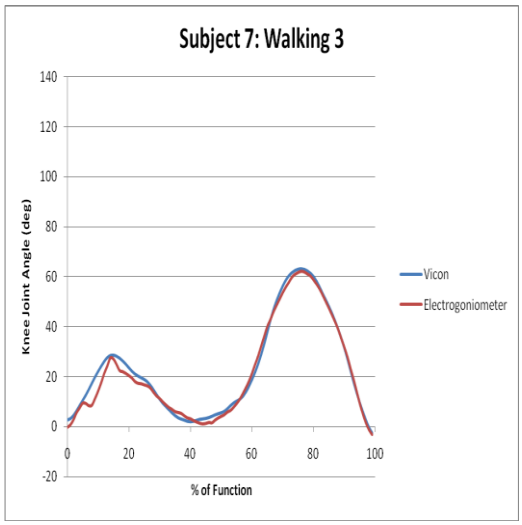
(a)



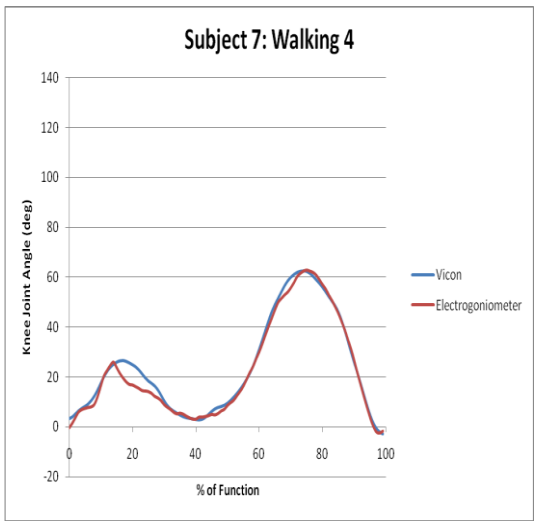
(b)



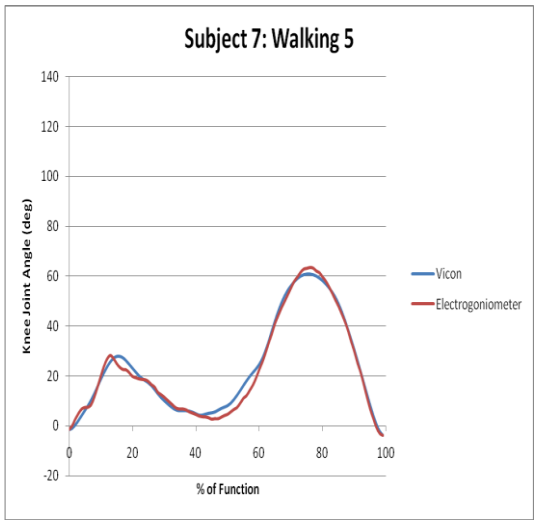
(c)



(d)



(e)



(f)

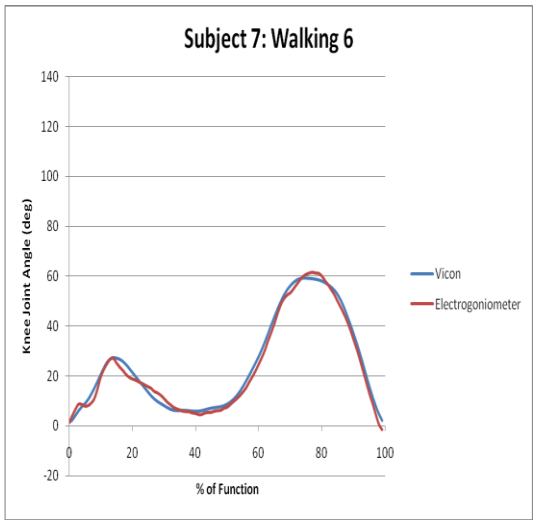
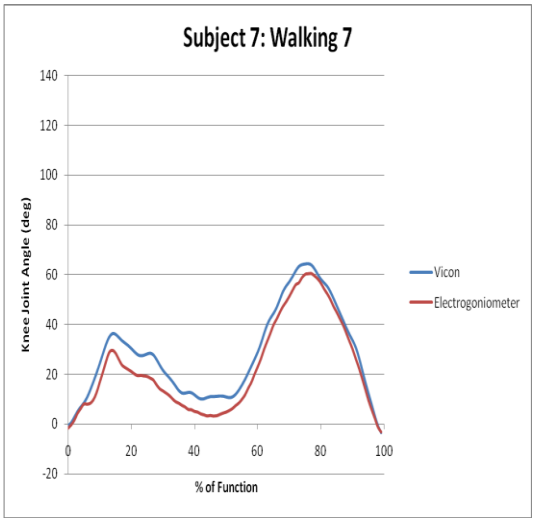
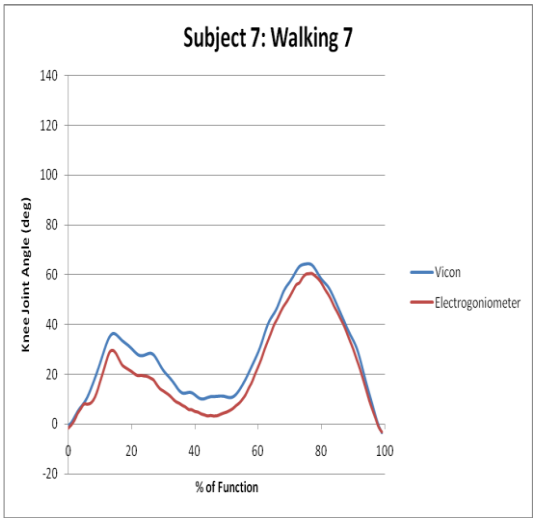


Figure 2.11 One subject's 10 walking trial cycles (a)-(j).

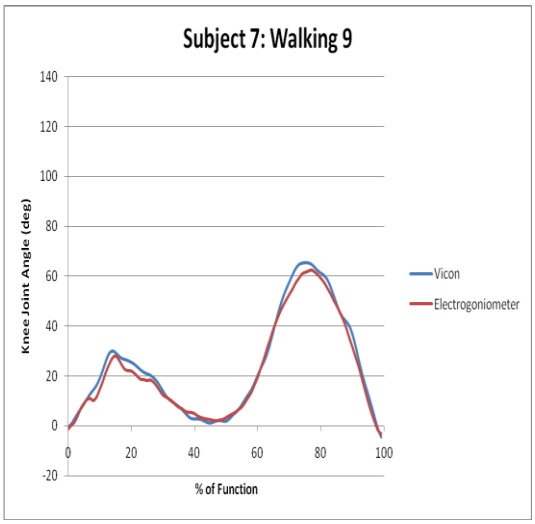
(g)



(h)



(i)



(j)

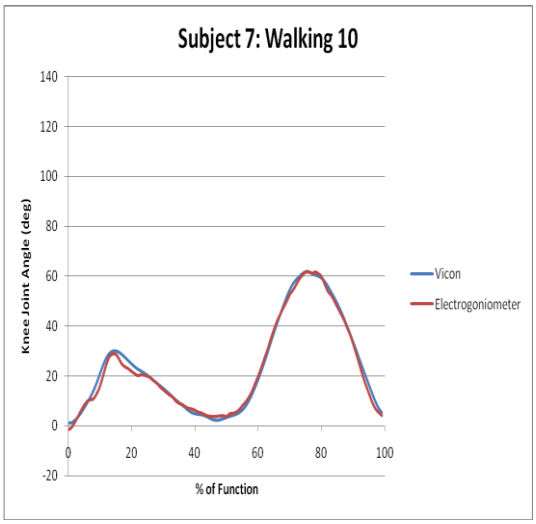


Figure 2.11 cont. One subject's 10 walking trial cycles (a)-(j).

From this subjects data set it can be seen that there was a good correlation between the two measurement systems. In a few of the trials there appears to be differences between the two systems during stance phase.

The differences in the maximum, minimum and excursion values recorded by both systems are within +/-5^{o} of each other as seen in the summary table 2.12.

Table 2.12 Differences between the 2 systems for all 10 subjects– range and average in degrees

Stand/sit	Difference Range	Absolute Average
Max	-3.6 to 3.9	1.4
Min	-4.0 to 3.3	1.5
Excursion	-4.6 to 4.3	2.2

Sit/stand	Difference Range	Absolute Average
Max	-4.2 to 3.0	1.3
Min	-4.8 to 4.1	1.7
Excursion	-3.5 to 4.2	2

Level walking	Difference Range	Absolute Average
Max	-3.3 to 3.6	1.4
Min	-4.5 to 3.3	1.3
Excursion	-4.8 to 4.8	2.5

Upstairs	Difference Range	Absolute Average
Max	-5.6 to 5.0	2
Min	-4.5 to 4.8	1.7
Excursion	-4.7 to 4.9	2.1

Downstairs	Difference Range	Absolute Average
Max	-3.6 to 3.6	1.3
Min	-4.9 to 4.7	2
Excursion	-5.0 to 4.8	2.5

The negative part of the range indicates the trials where the electrogoniometer system measured a greater angle than the Vicon system. However in the majority of the trials the Vicon system output was on average a few degrees higher than the electrogoniometer output. The shapes of the graphs were similar as was the excursion flexion angle.

2.6.4. Validation Discussion/Conclusion

The activities used in the validation study allowed a knee joint range of around 0-100^{o} to be tested. The shape of the graphs from the two systems showed good agreement. There were small variations within the individual cycles. The two systems use different methods for calculating knee joint angles. The electrogoniometer uses the position of the two end blocks of the device to calculate

the angle. Whereas the vicon system uses the visibility and positioning of markers on the subject to then calculate the AJC, KJC and HJC and in turn give the knee joint flexion angle. Therefore it is possible that the errors could be related to the zero (starting) points taken by the 2 systems. The excursion flexion angles were found to be similar between systems therefore indicating a possible shift in the graphs and the starting point.

The electrogoniometers can be concluded as a valid and reliable measurement device for recording knee joint angle during daily activities such as sit-stand and stairs.

2.7. VALIDATION WITH NAVIGATION SYSTEM

As an additional validation study the electrogoniometers were validated with an image free navigation system called Orthopilot® (BBraun Aesculap, Tuttlingen, Germany). It has been used as a surgical tool to aid the surgeon and aims to improve accuracy of knee joint replacement procedures. This system can record the knee joint angle as the lower limb is flexed.

2.7.1. Orthopilot® Navigation System: Introduction

Although this system has been designed for use as a navigation system for total knee replacement, both the hardware and software components of the Orthopilot® system have been utilised for development of a non-invasive system to look at soft tissue balance at the knee joint. It can be used to measure flexion/extension and valgus/varus stresses.

The hardware components consisted of the following (figure 2.12):

- An optical localiser with two cameras to detect infrared (IR) light (Polaris)
- Active trackers (rigid bodies) that emit IR pulses detectable by the optical localiser to determine their relative three-dimensional position in space.
- Pre-calibrated probe with rigid body attachment to digitise anatomical landmarks.
- Foot pedal to enable ‘hands-free’ recording of kinematic joint centres and anatomical landmarks.

Figure 2.12 Diagram of the Orthopilot system

Non-invasive tracker attachments

This commercial system was adapted for non-invasive use through the development of external tracker mounts. A relatively thick and broad elastic material was divided into several different lengths to accommodate typical thigh, calf and mid-foot circumferences. A sequence of eyelets was made at either end of the straps to connect to a metal base plate with attachment for an IR tracker. This also enabled further adjustment of strap size. The stability of this set-up has been validated on volunteers (Clarke J.V. et al 2009).

Software

The high tibial osteotomy (HTO) software for this system was used for determining lower limb alignment. Intra-operatively, this process requires the bi-cortical fixation of screws to both the femur and tibia in order to rigidly attach the IR trackers and permit the registration process. For this study non invasive tracker attachments were used.

The registration process includes various steps to determine the hip, knee and ankle joint centre. The rotational centre of the femoral head is determined first. This requires the femur to be flexed, extended, abducted, adducted and circumducted whilst visual cues are provided on the computer monitor. It is vital to perform these

movements in a slow, steady and controlled manner to avoid moving the pelvis and subsequently moving the centre of rotation of the femoral head in space. The kinematic ankle centre is determined next by attaching a rigid body to the dorsum of the foot using a rubber strap and metal plate. The ankle is dorsi-flexed and plantar-flexed, guided by information on the monitor and the relative position of the trackers on the foot and tibia are used to determine the joint centre.

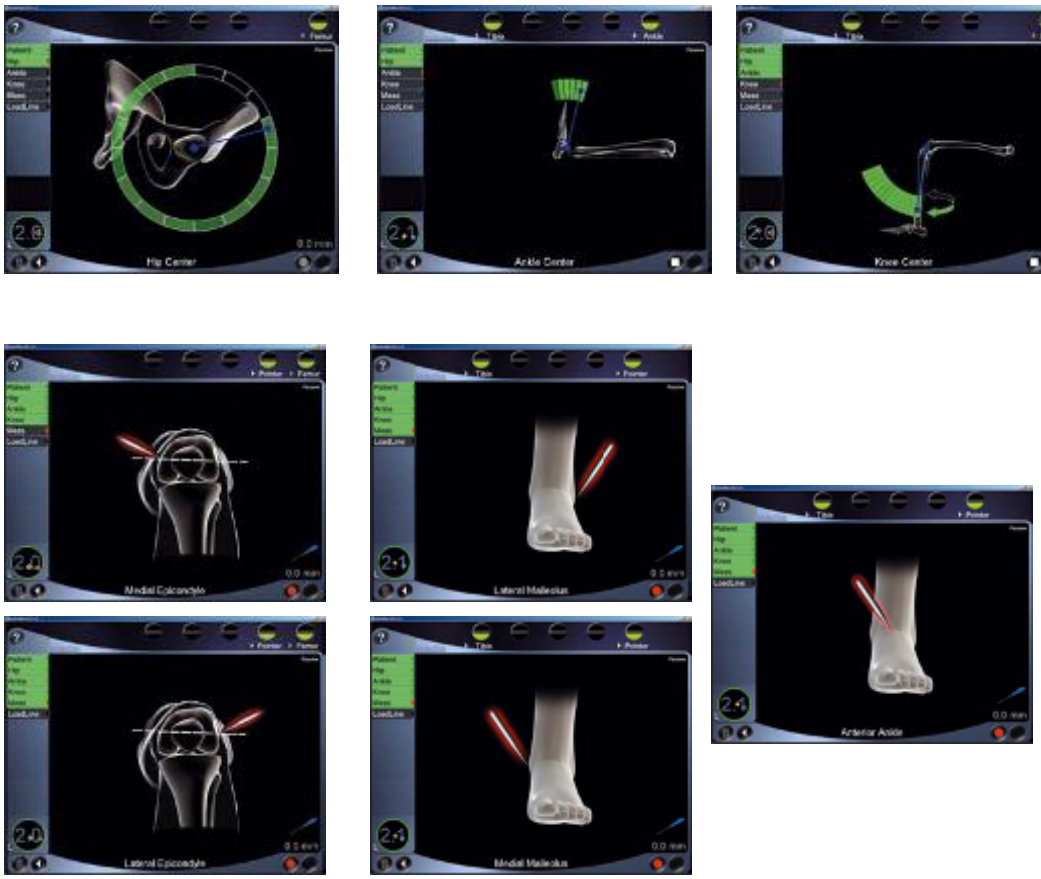


Figure 2.13 Software registration

Finally, the rotational centre of the knee joint is acquired by slowly flexing and extending the knee between 0 and 90° as well as rotation of the tibia on the femur in 90° of flexion. Again, the movements are guided by visual cues on the monitor. To verify the kinematically determined joint centres it is necessary to acquire several relevant anatomical landmarks by digitising them with the tracked probe. The femoral epicondyles are registered to validate the knee centre and the malleoli registered for validation of the ankle.

This kinematic registration process allows visualisation of the mechanical axes of the femur and tibia as well as the resultant mechanical femoral-tibial angle.

2.7.2. Orthopilot® Navigation System: Validation Methodology

The test was set up using one healthy subject. The electrogoniometer was attached to the right lower limb following the previously discussed electrogoniometry attachment protocol. A strap was attached round both the thigh and shank for attachment of the trackers for the navigation system. The trackers were in view of the camera and the electrogoniometer was attached to the datalog as seen in the photo in figure 2.14.

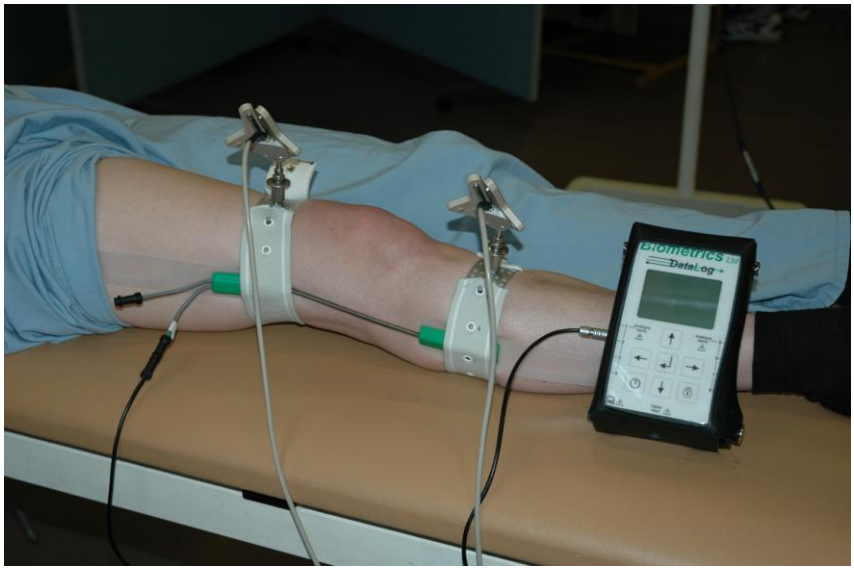


Figure 2.14 Photo of the setup for the validation between the electrogoniometer and the navigation system.

The first step was the registration process for the navigation system which was described in section 2.6.1. 'Introduction to System'. The test flexion range was 0^o to 130^o. Firstly the knee was flexed from 0^o to 10^o in 1^o increments. Then it was flexed through the complete test range (0-130^o) in 10^o increments. The navigation system monitor displayed the knee joint angle it recorded. The leg was held in the desired flexion angle for 10 seconds to stabilise the flexion angle output. At this point the electrogoniometer recorded for a few seconds and a single measurement was taken on the navigation system.

The navigation system does not continuously record flexion angles therefore the measurements from the navigation system was a snapshot. This was a source of possible error when comparing the systems. The electrogoniometer recorded continuously for a few seconds and therefore an average of the output at each test angle was compared to one measurement taken by the navigation system.

To minimise the possible error the leg was held as still as possible in the desired position. The output from the navigation system was visible on the monitor. Therefore this output was used to confirm that the movement if the leg was minimal during the electrogoniometry recording. The knee joint angle recorded by both systems was then plotted to determine the correlation.

2.7.3. Orthopilot® Navigation System: Validation Results

The graphs in figure 2.15 show the results from the validation test between the electrogoniometer and the navigation system over the range of 0-10^{o} increasing in increments of 1^{o}. Figure 2.16 shows the results over the range 0-130^{o} in increments of 10^{o}. The dashed black line indicates pure correlation in a situation where the Pearson correlation coefficient r would equal 1.

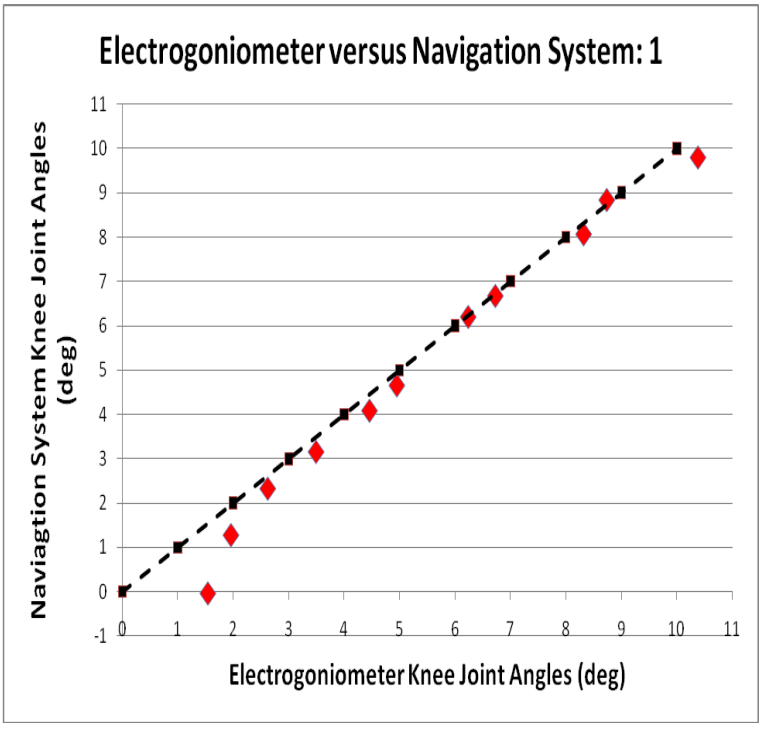
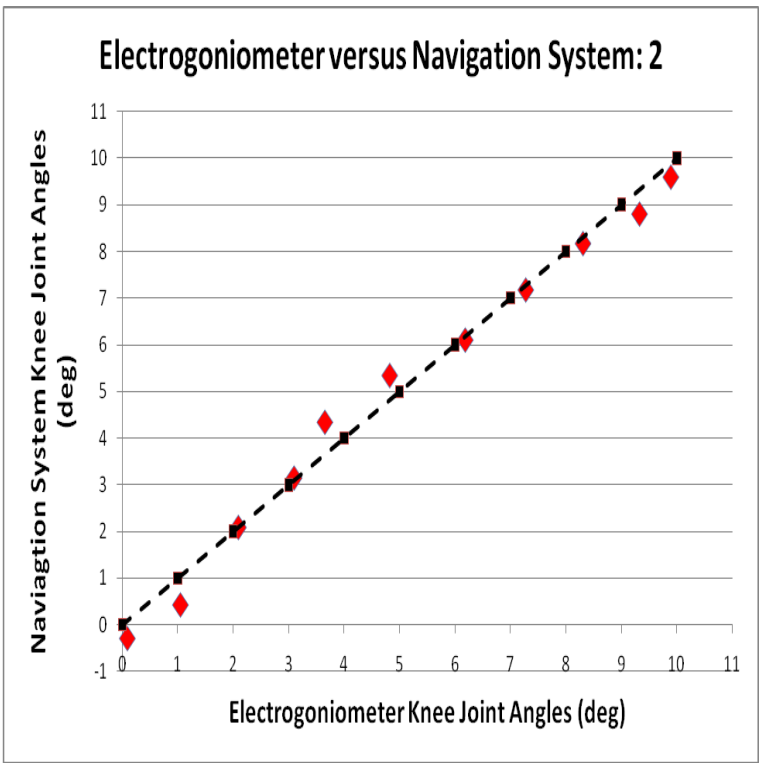


Figure 2.15 Validation of electrogoniometer against navigation system, range 0-10^{o}, increments of 1^{o}.



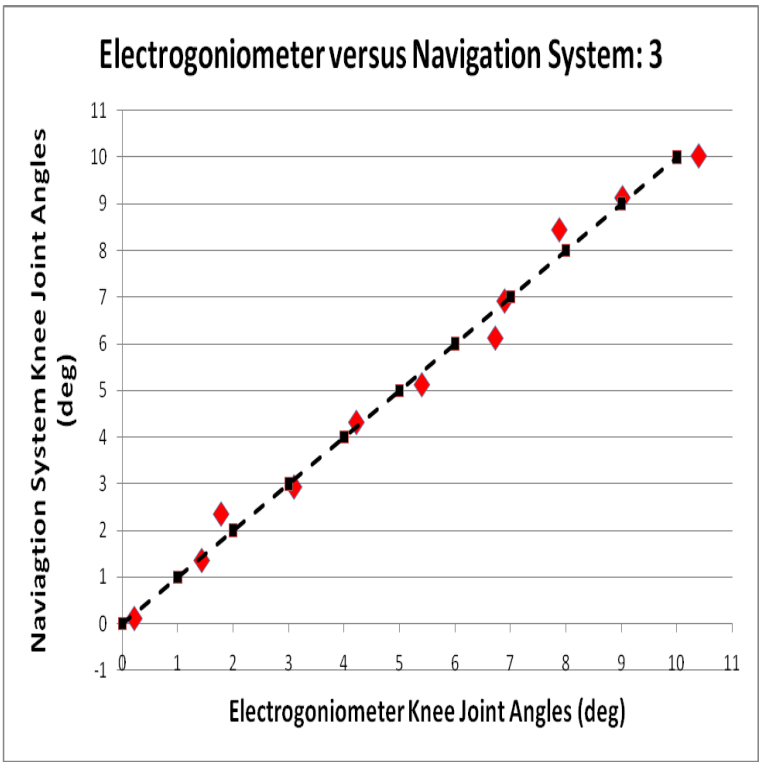


Figure 2.15 (cont) Validation of electrogoniometer against navigation system, range 0-10°, increments of 1°.

The Pearson correlation coefficient for the graphs in figure 2.15 and 2.16 are all r=0.99 suggesting a highly significant correlation between the two systems. The

results in the graphs in figure 2.15 appear to be more scattered but these graphs represent changes by only 1^{o}. The graphs in figure 2.16 show very good correlation within the range $0\text{-}100^{o}$. Between $100\text{-}130^{o}$ the electrogoniometer data output is slightly less than the knee joint angles recorded by the navigation system.

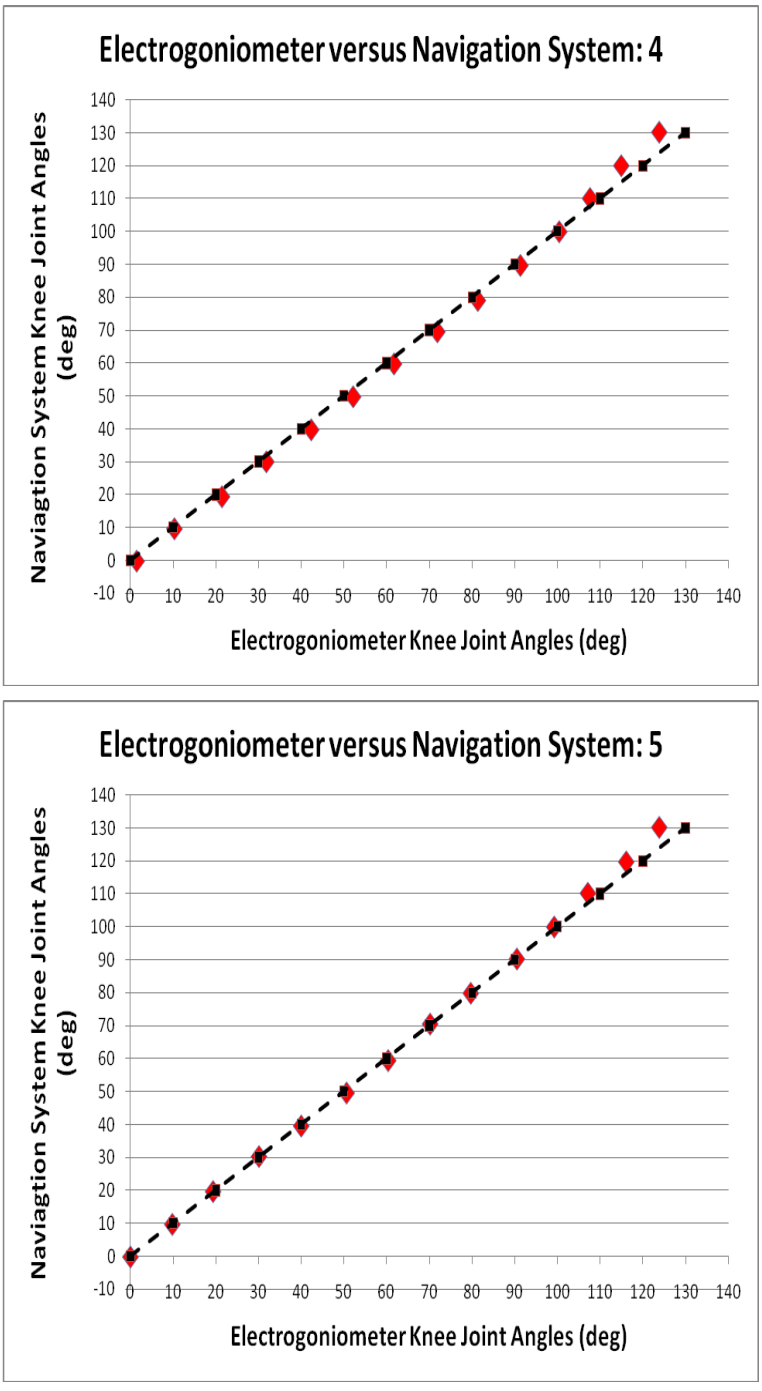


Figure 2.16 Validation of electrogoniometer against navigation system, range $0\text{-}130^{o}$, increments of 10^{o}.

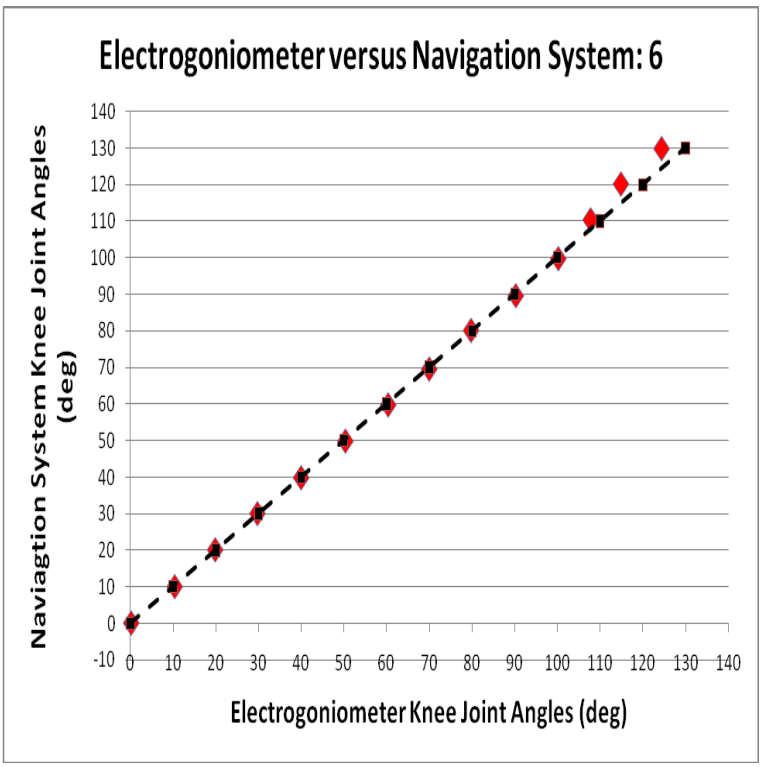


Figure 2.16 (cont) Validation of electrogoniometer against navigation system, range 0-130°, increments of 10°.

2.7.4. Orthopilot® Navigation System: Validation Discussion/Conclusion

Figure 2.16 shows that the electrogoniometer underestimated the knee joint flexion angles compared to the angles recorded by the navigation system. This navigation system has been developed to investigate soft tissue balancing at the knee joint. It aims to measure valgus and varus stresses when the knee joint is in extension. The system was not intended to record high flexion angles. Therefore it may be the source of error at the higher knee joint angles. The source of the difference was unknown and could have occurred as a result of difference in measurement methodology in both systems.

2.8. RADIOLOGICAL EXAMINATION

Radiological examination is part of the standard TKA assessment after surgery. However additional weight bearing long leg radiographs were taken at the pre operative and at 3 months post operation clinical appointment. From these

radiographs, the patients' mechanical axis alignment of the knee joint (varus/valgus) was determined.

At 3 month post operation the trial patients had a CT scan during an additional appointment. This allowed an in-depth alignment study to be conducted. The CT protocol included 27 slices at the femoral neck and head, 135 slices of the distal femur and the proximal tibia and 27 slices of the ankle. These slices were 3mm intervals at the hip and ankle and 1mm at the knee joint. The analysis was completed using Mimic 12.01software (Materialise, Leuven, Belgium).

2.9. IMPLANT ALIGNMENT ASSESSMENT

As previously mentioned implant alignment has been the predominant method of comparing navigated and conventional total knee replacement. Determining the implant alignment allows the accuracy of the surgery to be determined. It allows the variability of various parameters to be analysed and conclusions to be drawn as to the parameters which are more difficult to control.

One of the problems when it comes to comparing outcome alignment factors between previously published papers is that the description of the measurement protocol is generally missing or incomplete. This leads to queries as to whether the methodology between studies was the same. The quoted measurement within papers are compared but it is unknown if like for like is being compared.

The mechanical axis alignment methodology can vary between papers whether standard radiographs, long leg radiographs or CT scans were used for the analysis. Standard radiographs have a problem as they do not include the ankle or hip centre required for accurate mechanical axis measurements. Long leg x-rays also have various problems which can lead to inaccuracies. Firstly in some obese patients it is not possible or difficult to locate the hip centre due to an 'abdominal apron'. Secondly if the patients' lower limb is rotated then the varus/valgus angle to be measured will be inaccurate. CT scans have the issue of being non weight bearing which differs from radiographs.

Instability of the prosthesis can be a problem in all three planes. 'Pure rotational instability is rare after TKA' and instead is more commonly accompanied by varus/valgus or anterior/posterior instability (Berger et al 2001). The rotational

angle of the tibial and femoral components after TKA are thought to be important in terms of the stability of the joint replacement. Also it is thought to be a factor in the longetivity and function of the prosthesis, both of which are important outcome measurements of the surgery.

2.9.1. Radiograph Alignment measurements

Long leg standing radiographs which include the hip, knee and ankle joint are taken in Glasgow Royal Infirmary by the radiographers within the orthopaedic clinic. These are weight bearing and double limb stance. Problems with these radiographs are associated with rotation or fixed flexion which could be present at 3 months post operation. However the protocol for long leg radiographs allows the radiographer to minimise the errors in the radiographs.

The mechanical axis or hip-knee-ankle angle was measured from the long leg standing radiographs.

- Varus – an angle less than 180 deg is referred to as a negative angle.
- Valgus – an angle more than 180 deg is referred to as a positive angle.

2.9.2. CT Alignment measurements

The CT scans were analysed in Materialise software – Mimic 12.01. Mimic is medical imaging software which allows 3D image processing and editing of CT data. Therefore the 3D images are studied in the 3 planes. Each of the alignment measurements were set up so that the particular points could be identified and marked on the specific plane.

The CT slices are taken in the transverse plane which means the images in the coronal and sagittal planes are not clear unless the scans were segmented to give a 3D model of the joint. The software has various shaped tools such as circle and sphere which can be used to indicate the centre of the shape. The angles are calculated as the angle between two lines and therefore four anatomical points have to be identified. The light and dark shading definition can be altered on the CT scans to help visualise the bony landmarks required. However there is always an issue of how the metal of the implant appears in the scan. Figure 2.19 illustrates the metal artefact issue as the outline of for example the implant is difficult to determine

1. Frontal Femoral Angle

The frontal femoral angle (FFA) is the angle calculated between 2 lines: the femoral mechanical axis and the femoral condyle line which joins the medial and lateral condyles.

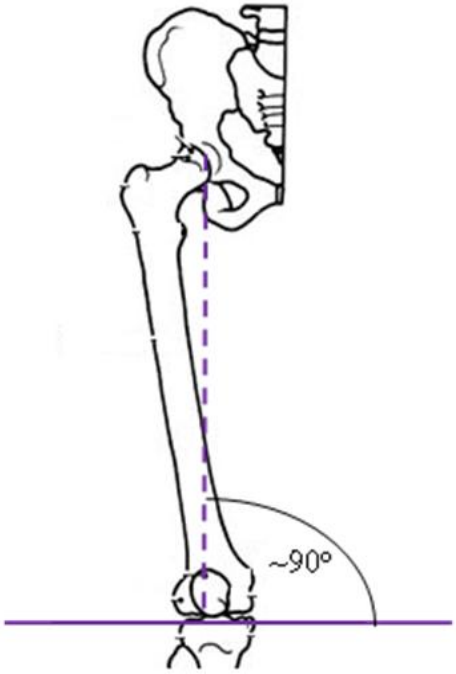


Figure 2.17 Frontal femoral angle

This angle was measured on the medial side of the mechanical axis. The points were located on the axial slices. The four anatomical landmarks were:

- Femoral head center (hip center) – Using the sphere tool the center of the femoral head was located. Figure 2.18 illustrates an example CT scan slide used in the analysis.

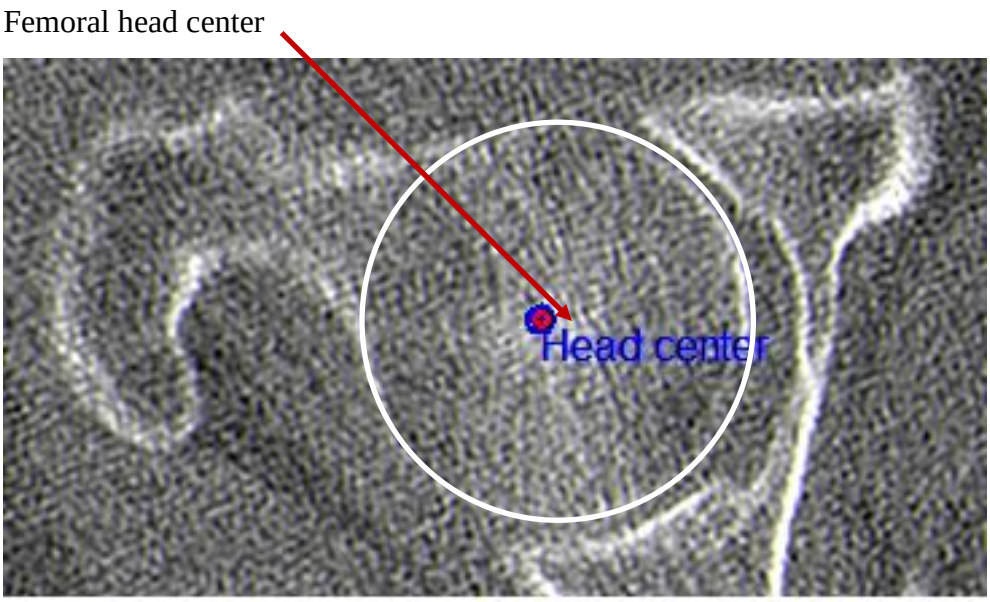


Figure 2.18 Femoral head center

- Femoral center (at the distal end) – this point is located midway between the pegs of the femoral prosthesis. A circle tool was used to indicate the midpoint. Figure 2.19 illustrates an example CT scan slide used in the analysis.

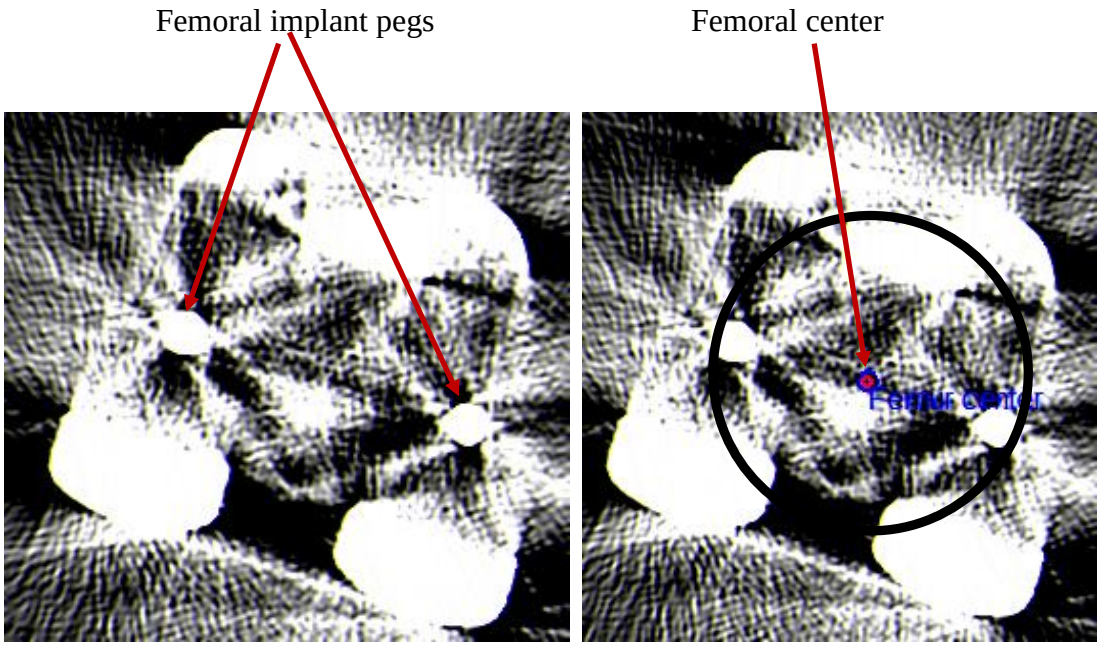


Figure 2.19 Femoral center

- Distal medial and lateral femoral condyles – on the transverse plane move up through the slices starting distal to the femoral prosthesis. Mark the condyles

as they appear. Figure 2.20 illustrates an example CT scan slide used in the analysis.

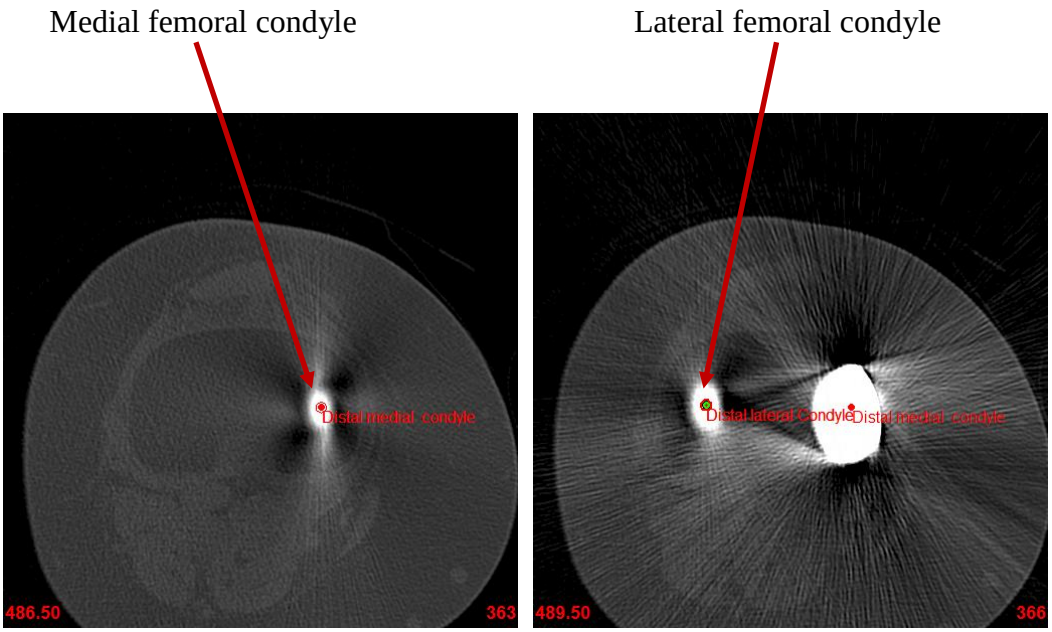
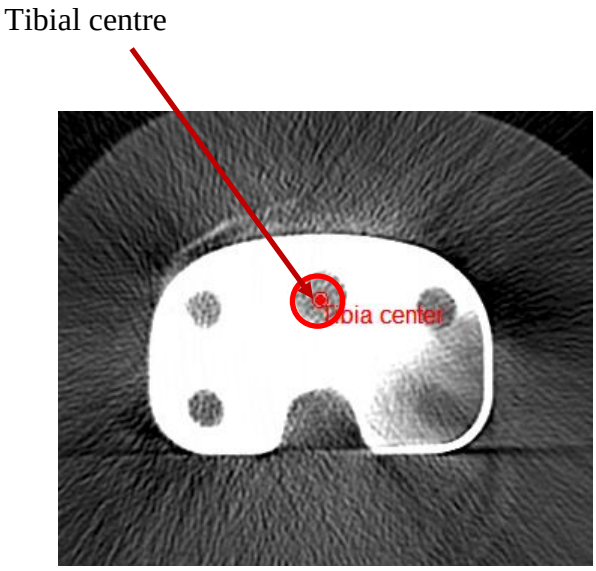


Figure 2.20 Medial and lateral femoral condyles

2. Frontal Tibial Angle

The frontal tibial angle (FTA) is the angle calculated between: the tibial mechanical axis and the tibial plateau. Again the angle was measured on the medial side of the mechanical axis. The four points required were:

- Tibia center – Using the circle tool the center of the stem of the tibial plate can be located. Figure 2.21 illustrates an example CT scan slide used in the analysis.



- **Figure 2.21 Tibial center**

- Medial and lateral plateau - on the transverse plane move down through the slices and mark the plateau as it appears, on the lateral and medial side. Figure 2.22 illustrates an example CT scan slide used in the analysis.

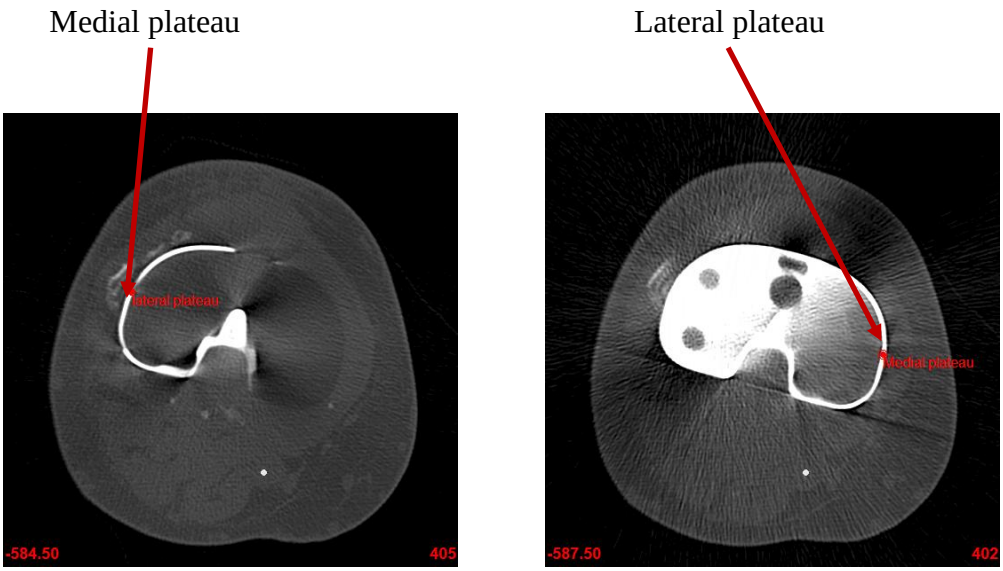


Figure 2.22 Medial and lateral plateau

- Talus center – Ankle center was calculated using the distance measurement tool as the midway point of the talus bone. Figure 2.23 illustrates an example CT scan slide used in the analysis.

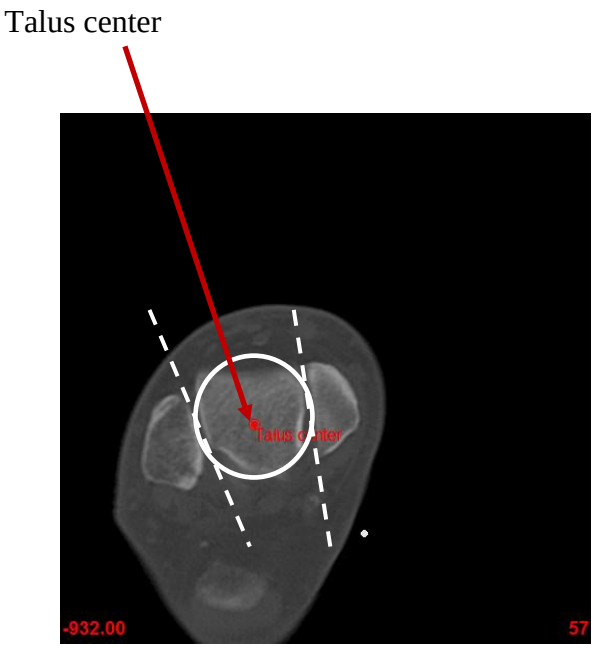


Figure 2.23 Center of talus

3. Mechanical Axis Angle

The mechanical axis angle was calculated by the addition of the frontal femoral angle and the frontal tibial angle.

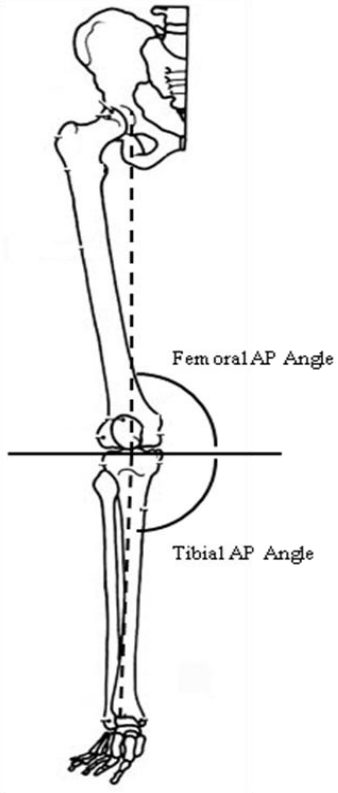


Figure 2.24 Diagram of the mechanical axis angle

This method of calculating the mechanical axis angle assumes that there is ligament balance and equal medial and lateral joint spacing.

The CT measurements allow the angles to be calculated in 3 dimensions and therefore minimise the influence of the problems found in radiographs such as the leg being internally rotated or the presence of a fixed flexion.

4. Sagittal Femoral Angle

This is the angle between 2 lines. The 1st line used was the femoral mechanical axis (the femur head to femur center). The other line indicates the slope of the femoral bone cut in the sagittal plane.

- Femur head center (figure 2.18)
- Femur center (figure 2.19)
- Distal femoral anterior and posterior cut. Figure 2.25 illustrates an example CT scan slide used in the analysis.

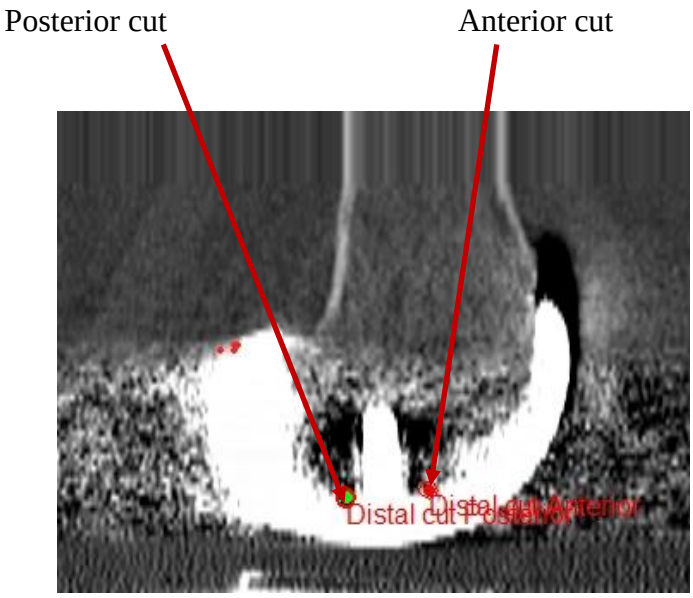


Figure 2.25 Distal Femoral Anterior and Posterior Cut

5. Sagittal Tibial Angle

The sagittal tibial angle is also referred to as the tibial slope. It is the angle between 2 lines. The first line was the tibial mechanical axis. The second line indicates the anterior and posterior cut in the sagittal plane.

- Tibia center – (figure 2.21)
- Talus center - (figure 2.23)
- Anterior and posterior tibial cut. Figure 2.26 illustrates an example CT scan slide used in the analysis.

The tibial cuts can be found on the axial slices as the slices when the tibial plate appears - the interface between the tibial plate and the bone.

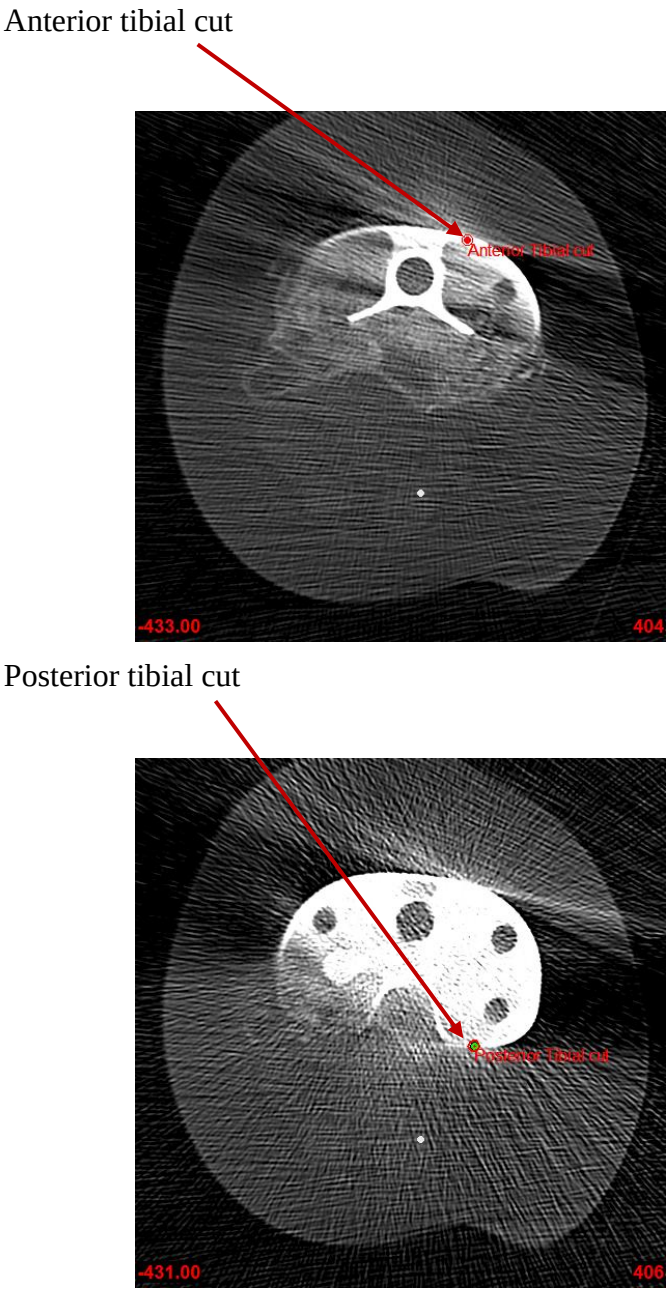


Figure 2.26 Anterior and Posterior Tibial Cut

6. Femoral Rotation

Femoral rotation is calculated as the position of the surgical epicondylar axis (lowest point of medial sulcus to highest point of lateral epicondyle) in relation to posterior condyles:

- Lateral and medial epicondyle
- Lateral and medial posterior condyles

Internal rotation was indicated as a negative and external rotation was indicated as a positive.

One issue with this measurement is that the identification of the sulcus can be difficult in some patients. Yoshino's study found that the medial sulcus could only identified in 33 out of 48 knees (Yoshino N et al., 2001). In this case the alternative is to identify the clinical epicondylar axis. The clinical epicondylar axis is the line connecting the medial and lateral epicondylar prominence. Using this axis gives the condylar twist angle. Subtracting 3^{o} from this angle will give the posterior condylar angle.

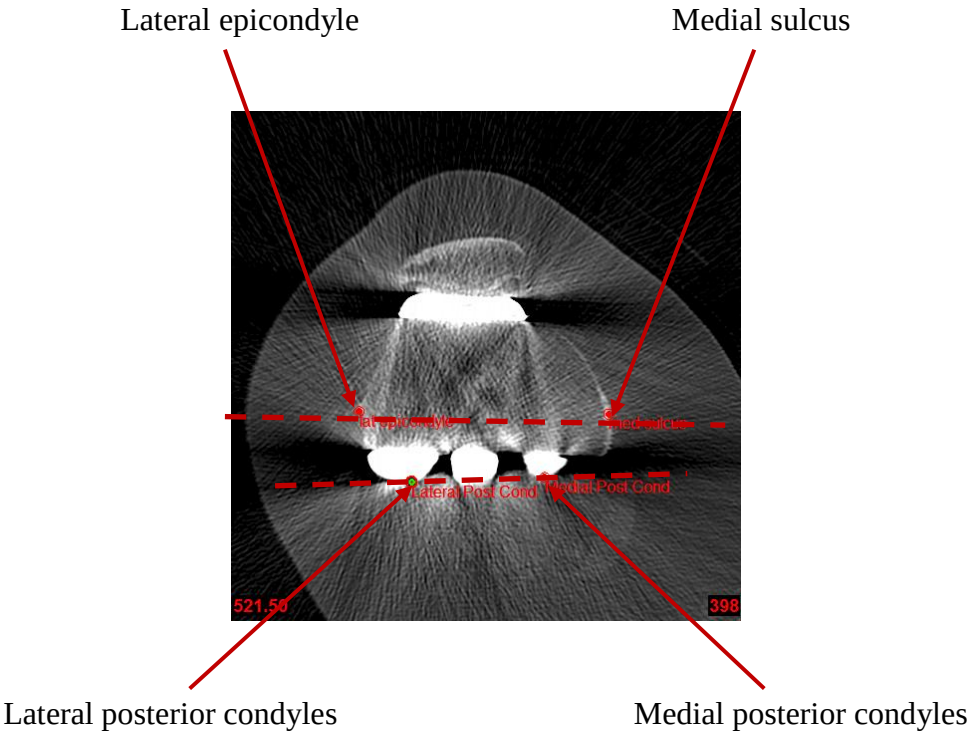


Figure 2.27 Points for femoral rotation

7. Tibial Rotation

Berger's (Berger R.A and Rubash H.E, 2001b) for tibial rotation outlines the landmarks required for the calculation. Line 1 joins the geometric tibia center and the tubercle. Line 2 is the tibial component axis which is perpendicular to the transverse axis of the tibial component. Internal rotation was indicated as a negative and external rotation was indicated as a positive.

- Tubercle (figure 2.28)
- Geometric tibial center - Using the freeform tool in the analysis software the basic oval shape of the tibia was drawn and the center of this calculated.
- Line perpendicular to transverse axis

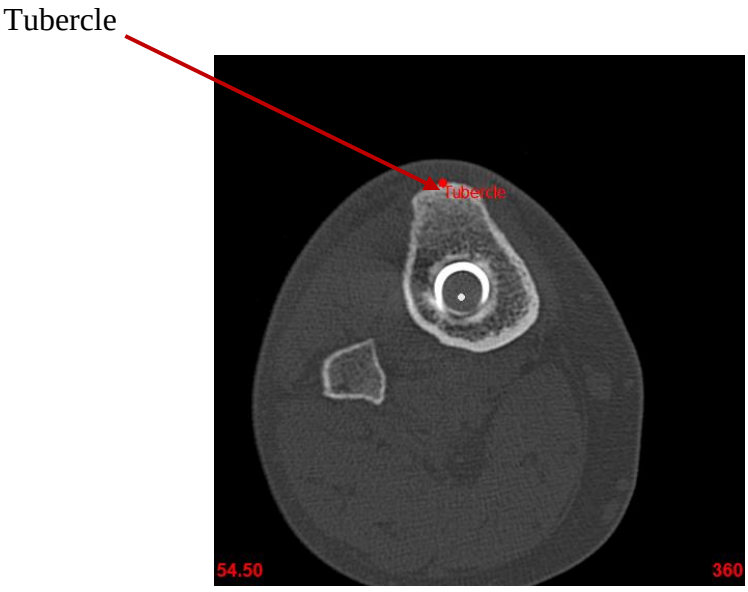


Figure 2.28 Tibial Tubercle

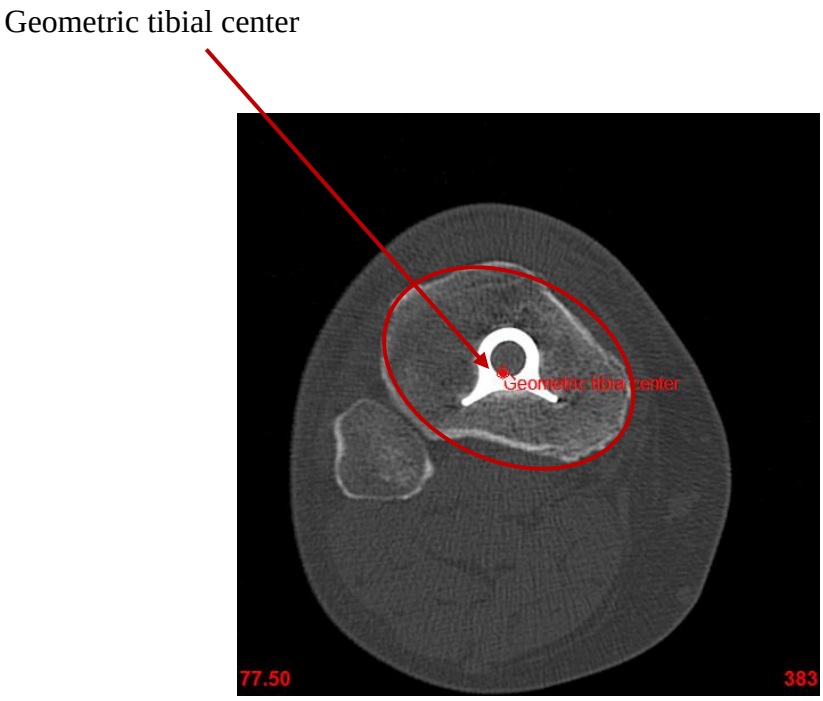


Figure 2.29 Geometric center of tibia

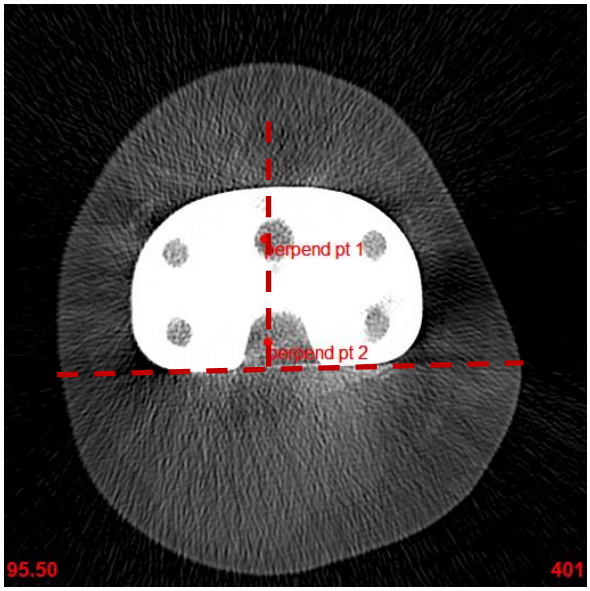


Figure 2.30 Line perpendicular to transverse axis

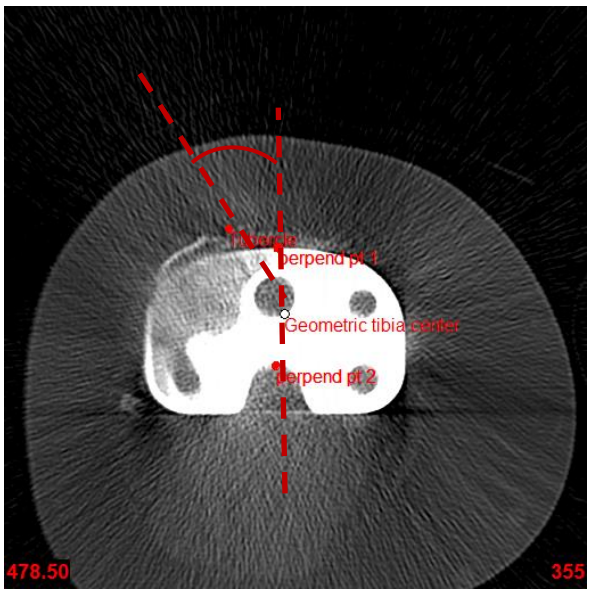


Figure 2.31 Tibial Rotational Angle

8. Combined component rotation

Berger et al (2001b) investigated the relationship of component rotation to patello-femoral problems. In patients with well functioning TKA's without patello-femoral complications the combined component rotation is slightly externally rotated. Combined excessive internal rotation was correlated directly with the severity of the patello-femoral complications.

- Patients with objective findings of lateral tracking and tilting were found to have combined excessive internal rotation within the range 1-4^{o}
- Patients with objective findings of subluxation had combined excessive internal rotation within the range 3-8^{o}
- Patients with dislocation had combined excessive internal rotation range within the range of 7-16^{o}
- Patients with prosthesis failure had combined component rotation ranging from 8-17^{o} of excessive internal rotation

Combined rotation was calculated by adding the femoral and tibial rotations together.

2.10. RADIOGRAPH INTER-OBSERVER RELIABILITY: INTRODUCTION

Long leg standing radiographs, as previously mentioned, have been used in studies to compare the post-operation alignment of navigated and conventional TKA

patients. This study used long leg radiographs in addition to CT scans to assess post-operative alignment. However the question of accuracy and repeatability of the alignment measurements calculated from radiographs and CT scans remains. Both methods rely on accurate identification of the bony landmarks whether in 2 dimensional radiographs or 3 dimensional CT scans. The absolute accuracy of the measurements cannot be assessed. It is known that rotations and flexion at the knee joint can result in errors in measuring the mechanical axis alignment from radiographs. It is important that the radiographs and CT scans are taken correctly and this requires concise, standardized protocols for scanning and limb positioning.

The repeatability between time points and between observers can be analysed. Measurements from radiographs using digital analysis have been shown to be reproducible and accurate with high intraclass correlation coefficients from intra and inter observer tests (Gordon J et al., 2009, Pappas N et al., 2010, Segev E et al., 2010).

2.10.1. Radiograph Inter-Observer Reliability: Methodology

Inter observer correlation was investigated using three observers.

- Observer 1 = Orthopaedic registrar
- Observer 2 = JS
- Observer 3 = Orthopaedic outcomes nurse.

All 3 observers calculated the mechanical axis angle from long leg radiographs for a group of 26 patients within the navigation study. The measurements used the electronic angle and ruler tools on the PACS system (the radiograph software used in Glasgow Royal Infirmary). As the orthopaedic registrar was the most senior observer then these results were taken as the most accurate alignment angles. This allowed the accuracy of the other 2 observers' measurements to be quantified. The inter observer agreement was also assessed by calculating the intraclass correlation coefficient (ICC). An ICC of 1.0 represents a prefect agreement and one of 0 suggests the measurements are random. There is no set acceptable value of intraclass correlation coefficient which represents acceptable agreement. SPSS 17.0 was used to calculate the ICC. The percentage of clinical disagreement was calculated between observers. A difference of $>1^{o}$ between observers measurements represented a clinical

disagreement. Finally the measurements from observer 2 and 3 were plotted against observer 1 to give the correlation coefficient r^2.

2.10.2. Radiograph Inter-Observer Reliability: Results

The intraclass correlation coefficient (ICC) for the inter observer reliability for the mechanical axis alignment for the long leg radiographs was 0.960 (95% CI 0.926-0.981). The clinical disagreement was set at $>1^o$. The observers disagreed in 54% of the cases. If the clinical disagreement level was set at $>2^o$ then the observers only disagreed in 15% of cases (4 radiographs). Table 2.13 summarises percentage of cases where the individual observers differed from each other.

Table 2.13 Summary of differences between individual observers.

	Observer 1 & 2	Observer 1 & 3	Observer 2 & 3
1^o Difference	31%	46%	42%
2^o Difference	0%	8%	8%

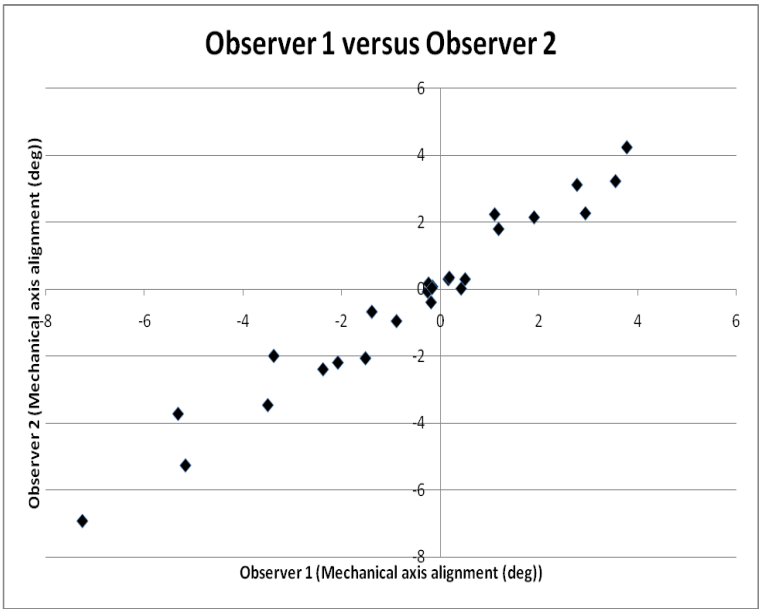


Figure 2.32 Scatter plot of observer 1 versus observer 2

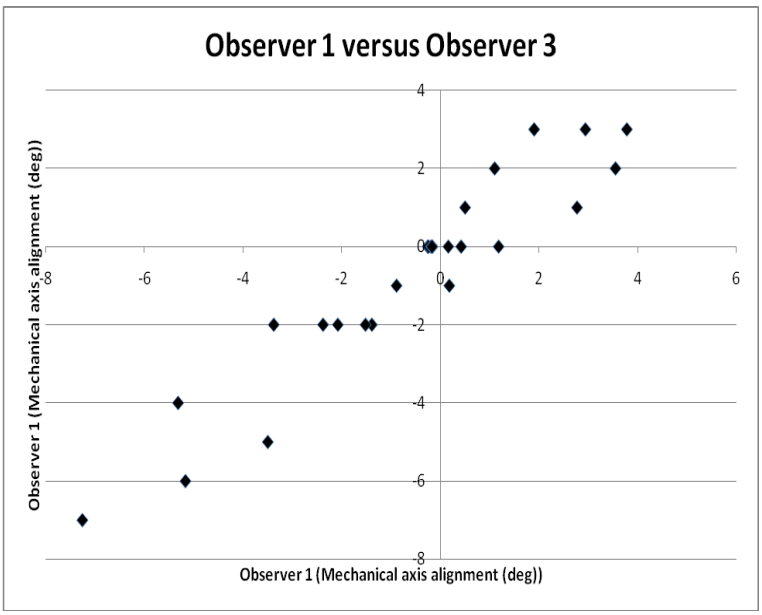


Figure 2.33 Scatter plot of observer 1 versus observer 3

The correlation coefficient for figure 2.32 was r^2=0.9606. The correlation coefficient for figure 2.33 was r^2=0.9011.

2.10.3. Radiograph Inter-Observer Reliability: Discussion/Conclusion

The correlation coefficient shows a good inter observer correlation between the 3 observers. Intraclass correlation coefficients of '0.76' represent a 'high' agreement. Therefore from this it can be concluded that the inter observer reliability of the long leg radiographs was good. The clinical disagreement between observers was 54% which was very high. This value deceased dramatically when the limit was increased to 2^o difference between observers. These measurements are compared to each observers measurements rather than the absolute alignment which was unknown. As the orthopaedic registrar was the most senior observer then these results were taken as the most accurate alignment angles. The scatter plots in figure 2.32 and 2.33 show good correlation and high correlation coefficients.

One of the limitations of this inter observer study was that there was a relatively small number of radiographs included.

2.11. CT INTRA-OBSERVER RELIABILITY: INTRODUCTION

The intra-observer reliability looked at the test-retest reliability of the same measurement calculated by the same observer on different occasions where the smaller the difference between the measurements, the greater the intra-observer reliability of the measurement.

2.11.1. CT Intra-Observer Reliability: Methodology

The intra observer analysis as used to test the repeatability of the CT protocol. The alignment parameter analysed were frontal femoral angle (FFA), frontal tibial angle (FTA), mechanical axis, sagittal femoral angle (SFA) and sagittal tibial angle (STA). The measurements were repeated 3 times by the one observer (JS) to determine the intra observer variations. The analysis was repeated on 3 separate days. 50 CT scans were used in the study. The intra-class correlation coefficient (ICC) and the clinical disagreement were calculated for the measurements. A difference of $>1^{o}$ between measurements represented a clinical disagreement. Again SPSS 17.0 was used to calculate the ICC.

2.11.2. CT Intra-Observer Reliability: Results

The intraclass correlation coefficient (ICC) for the intra observer reliability for the FFA alignment for the CT scans was 0.987 (95% CI 0.979-0.992). The ICC for the FTA was 0.974 (95% 0.959-0.984). The ICC for the mechanical axis alignment was 0.981 (95% 0.969-0.988). The ICC for the SFA was 0.864 (95% 0.794-0.915). The ICC for the STA was 0.891 (95% 0.833-0.933). Therefore the ICC was high for all parameters. The ICC for reliability was lowest for SFA. However even this ICC value was high.

Table 2.14 summarise the intra-observer results for the 5 alignment parameters studied. For each CT scan the mean variation between the 3 repeated measurements was calculated. From this a mean variation from the group of 50 CT scans was calculated for each parameter. For the frontal femoral and tibial angles and mechanical axis alignment it was reported that on average the 3 repeated measurements varied by up to 0.5^{o} with the maximum deviations being less than 1.5^{o}. On the other hand the sagittal measurements showed more variability. The

average variation within scans for the sagittal measurements, femoral was 1.45^{o}, and 1.28^{o} for the tibial angle however the maximum variation was as much as 3^{o}.

Table 2.14 Intra-Observer Results

	Intra-observer variation (deg)			Clinical Disagreement (>1^{o})	Clinical Disagreement (>2^{o})
	Mean	Range	Max StDev		
Frontal Femoral Angle	0.28	0.03-1.14	0.66	2% (1 scan)	0%
Frontal Tibial Angle	0.42	0.05-1.16	0.54	4% (2scans)	0%
Mechanical Axis	0.51	0.12-1.46	0.69	12% (6 scans)	0%
Sagittal Femoral Angle	1.45	0.38-2.73	1.52	78% (39 scans)	18% (9 scans)
Sagittal Tibial Angle	1.28	0.08-2.83	1.57	62% (31 scans)	18% (9 scans)

The clinical disagreement level was set at 1^{o}. At this level there was good agreement between measurements for the frontal femoral and tibial angles and the mechanical axis alignment. However as the variation between measurements for the sagittal femoral and tibial angle was larger the percentage of disagreement at this level was very high. If the disagreement level was changed to 2^{o} then an acceptable level of disagreement was recorded.

2.11.3. CT Intra-Observer Reliability: Discussion

This study demonstrates high intra-observer reliability in the analysis of the frontal femoral angle, frontal tibial angle and mechanical axis alignment. These angles are calculated by registration of four landmarks in the CT. Since the variation in output angles was small it can be concluded that the variation in the position of the landmarks would be minimal as well.

On the other hand the intra-observer reliability for the sagittal femoral and tibial angles was seen to be lower, with high clinical disagreement when the level was set at 1^{o}. Therefore from this it can be concluded that the anatomical landmarks used for the sagittal (slope) alignment parameters were more difficult to identify and less repeatable.

2.12. CT INTER-OBSERVER RELIABILITY: INTRODUCTION

As with radiographs there will be variability in the analysis of alignment parameters between observers using CT scans. The inter observer reliability for the frontal femoral and tibial angle and the mechanical axis alignment measurements was studied using 3 observers. These parameters have previously reported high ICC values for intra-observer reliability.

2.12.1. CT Inter-Observer Reliability: Methodology

The CT inter-observer reliability was investigated. 20 patients CT scans were randomly selected from the trial patient list for analyses by 3 observers (2 researchers, JS, AM and an orthopaedic registrar). The frontal femoral, tibial angle and mechanical axis parameters were completed by each observer. ICC values were calculated using SPSS 17.0. The clinical disagreement was again set at $>1^{o}$.

2.12.2. CT Inter-Observer Reliability: Results

The ICC for the inter-observer variability was greater than 0.94 for all measurements.

- Frontal Femoral Angle - ICC 0.946 (0.891-0.977)
- Frontal Tibial Angle – ICC 0.950 (0.899-0.978)
- Mechanical Axis Alignment – ICC 0.961 (0.920-0.983)

Table 2.15 summaries the inter-observer results including the mean and range of variation seen between the 3 observers. The maximum differences were seen in the mechanical axis alignment (1.7^{o}) and a clinical disagreement of 30%.

Table 2.15 Inter-Observer Results

	Inter-observer variation (deg)			Clinical Disagreement ($>1^{o}$)
	Mean	Range	Max StDev	
Femoral AP	0.55	0.07-1.41	0.70	25% (5 scans)
Tibial AP	0.70	0.03-1.61	0.75	25% (5 scans)
Mechanical Axis	0.76	0.08-1.70	0.92	30% (6 scans)

2.12.3. CT Inter-Observer Reliability: Discussion

The inter-observer reliability was high as seen from the ICC values greater than 0.94. There was also no measurement which disagreed by more than 2^{o}. The clinical disagreement (set at 1^{o}) was low.

2.13. MECHANICAL AXIS: CT VERSUS LONG LEG RADIOGRAPHS INTRODUCTION

The mechanical axis of the lower limb was analysed using both long leg radiographs and the CT scans. Therefore the same measurement was calculated using 2 different methods. The radiograph was 2 dimensional and was taken when the subject was standing therefore it was weight bearing measurement. The CT scan was 3 dimensional and was carried out while the patient was lying supine.

Published studies use both radiograph and CT methods for alignment measurement. However whether the results from these methods are interchangeable has not been fully investigated. The major difference is that one method is weight bearing and the other is non-weight bearing. Even this difference is likely to cause difference in the mechanical axis recorded by the 2 methods. It has been reported that the effect of 0.5 body weight can cause a mechanical axis deviation of 0.4^{o} (Kendoff 2008) and that the difference between supine and double limb standing radiographs on average was 1.6^{o} (Specogna 2007).

2.13.1. Mechanical Axis: CT versus Long Leg Radiographs: Methodology

The same set of 26 long leg radiograph results from the inter observer reliability test in section 2.11 were used in the correlation with the CT data. The ICC was calculated for the correlation of the 2 methods of mechanical axis analysis using SPSS 17.0.

2.13.2. Mechanical Axis: CT versus Long Leg Radiographs: Results

Figure 2.34 shows the radiograph versus CT mechanical axis measurements. The ICC for the mechanical axis parameter was 0.592 (95% 0.272-0.794). Correlation coefficient for the CT mechanical axis versus the radiograph mechanical axis was r^2=0.3952.

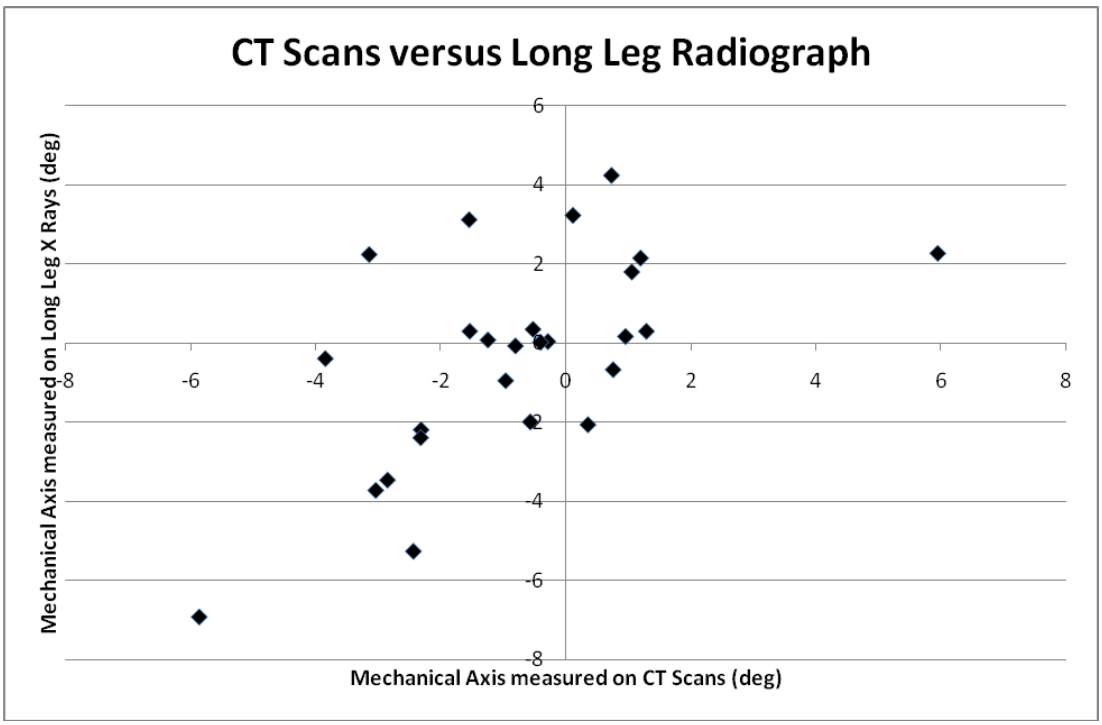


Figure 2.34 Scatter plot of the correlation between CT and long leg x rays

Table 2.16 Difference between CT scan and weight bearing radiograph

	Mean Difference (deg)	Range (deg)
CT versus LL Radiograph	1.67	0-5.37

Table 2.16 shows that the mean absolute difference between the 2 analysis methods was 1.67^{o}. However the range which was seen in the 26 patients was up to 5.37^{o} which was a large difference.

The effect of weight bearing on the mechanical axis alignment measurement was investigated. The deviation of the long leg radiograph compared to the non weight bearing CT scan was reported.

Table 2.17 Direction of deviation reported when comparing CT scan and weight bearing radiograph

CT versus LL Radiograph	Number of Patients	Maximum Deviation (deg)
Varus Deviation	10	3.7
Valgus Deviation	11	5.4

The direction of the variations differed. 21 CT and radiographs differed by more than 0.5^{o}. Of these 11 had a valgus and 10 a varus deviation. The average deviation was

1.7^{o}, however the maximum variations between measurements was high (3.7-5.4^{o}). This highlights the issues when comparing these too measurement techniques in literature but also leads to doubts as to the accuracy of the measurements taken in clinics.

2.13.3. Mechanical Axis: CT versus Long Leg Radiographs Discussion/ Conclusion

The correlation coefficient is low for the measurement of the mechanical axis between the two methods: CT and radiograph. It is well known that flexion contractures and the presence of rotational malalignment of the knee both have an effect on the radiological measurement of the tibiofemoral angle. It has been recorded that the presence of malalignment in either of these planes (sagittal and rotational) can lead to inaccuracies in the mechanical axis angle calculated by up to 6^{o} (Sparmann et al 2003). The CT scans allow measurements to be calculated in 3D and therefore eliminate the possibility from errors in the other planes.

The influence of the CT scan being non-weight bearing has also been reported as a possible explanation for differences measured using a CT scan and radiograph. In our study the mean difference between CT scan (measured in supine) and double limb standing radiographs was 1.67^{o}, which agreed with a paper by Specogna et al (2007). The range of deviations between the 2 analysis methods was large. The direction of the difference between the analysis methods varied between patients and therefore from this small sample set the direction of the deviation could not be predicted.

2.14. ACTIVITY LEVEL ASSESSMENT

The activity level of the subjects was monitored during one full day of normal daily life using a system of activity monitoring called ActivPAL. The ActivPAL was a small lightweight box, about half the size of a match box which was attached to the thigh of the subject using sticky tape. This system records the activity of the subject, including periods of lying, sitting, standing or walking continuously during up to 110 hours. For this assessment the patients were asked to wear the monitor for one day within a week of their appointment. They were asked to wear it on a typical day. In

many cases activity levels vary dependant on the day of the week. Therefore this makes it difficult to prescribe an average day and hence the subjects were asked to self select a typical day. Furthermore, patients tend to have a quieter day the day after their appointment, so two days after the appointment in many cases would be typical.

The data was downloaded to a computer once the ActivPAL was returned by the patient in the post. The data was used to indicate the total time spent in each activity, the percentage of the day spent standing, sitting and walking, and the timing of the activities during the recording period was analysed. It therefore allows an in depth assessment of the subjects true levels of daily activity as indicated by their mobility.

2.14.1. Literature – Activity Monitors

As mentioned in section 1.7.4 activity monitors have been validated for use in a wide variety of subject groups.

2.14.2. Methodology – Testing/Comparing Monitors

ActivPALs have been used in previous studies and have been validated for use as an activity monitor. The 10 activity monitors to be used in the clinical trial were tested to check that they worked. A simple test was performed where 5 monitors were stuck on the front of each thigh of a single subject. The subject then walked for 10 minutes on a treadmill. The number of steps recorded by each of the monitors should be the same.

9 out of the 10 monitors were within 10 steps of each other. The other monitor recorded 100 steps less than the other monitors. This suggested an error in the device which meant that it was not used in any further testing situations.

2.14.3. Activity Monitor Discussion/Conclusion

This test was to check that there was not an error with one specific monitor. One of the monitors did result in a large discrepancy and therefore was not used in the clinical trial.

2.15. QUADRICEPS AND HAMSTRING KNEE MOMENTS

The digital myometer from MIE Medical Research Limited (figure 2.35) was used to measure the magnitude of isometric contractions of the quadriceps and hamstring muscles.

Figure 2.35 Diagram of digital myometer

The digital myometer is a multi force analyser where the transducer measures the force.

2.15.1. Quadriceps and Hamstring Knee Moments: Methodology

The flexion and extension moments were measured around the knee with the knee joint in 90^{o} of flexion for both the operated and non-operated limb. This test uses a digital analyser myometer (MIE Medical Research Ltd, UK).

$$M_{knee} = \text{Force x distance}$$

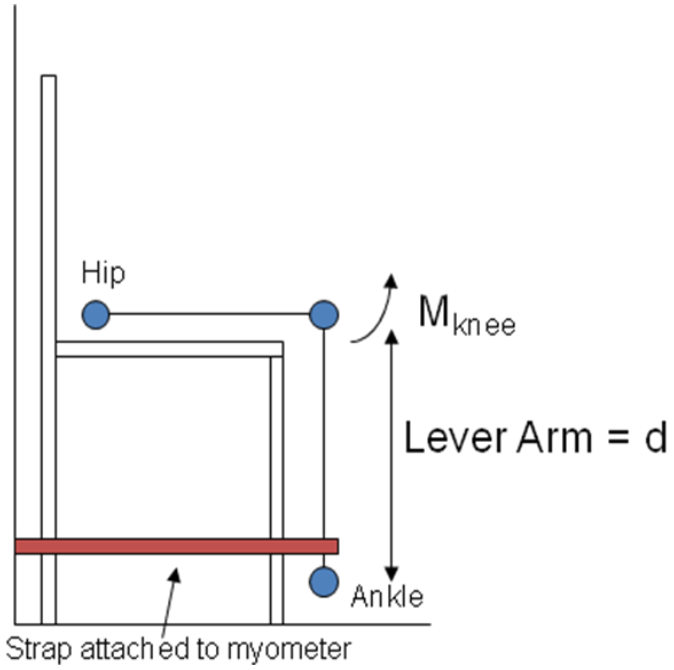


Figure 2.36 Diagram of Quadriceps moment calculation

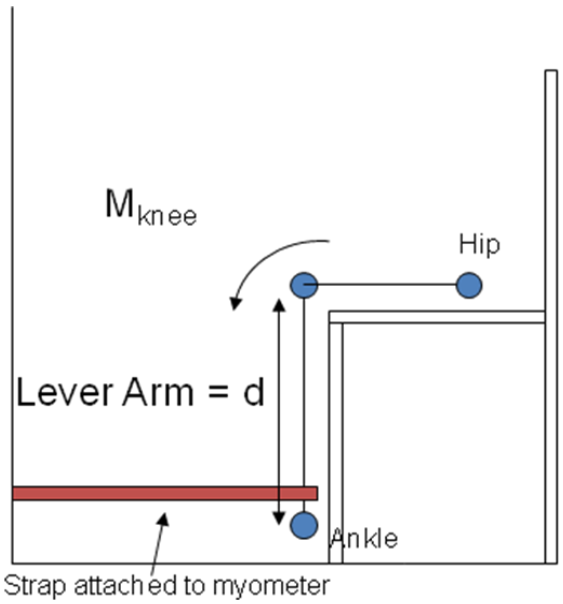


Figure 2.37 Diagram of Hamstring moment calculation

The patient sat in a standard chair and the strap for the myometer was looped round the patient's ankle (figure 2.36). The patient lower limb was set to 90^{o}. The perpendicular distance (or moment arm) from the knee to the ankle was recorded so that the moment of force could be calculated. During the quadriceps test the patients pulled against the myometer strap trying to extend their knee joint. For the hamstring test the patients pulled against the myometer strap trying to flex the knee joint more than the 90^{o} their lower limb was set at to sit in the chair.

2.15.2. Literature – Myometers

The MIE myometer has been used in previously published trials. One such trial measured gluteus maximums muscle strength in children with cerebral palsy (van der Linden M.L et al., 2004). The myometer has also been used to measure knee flexor and extensor strength in TKA patients (Helbostad J.L et al., 2004, van der Linden M et al., 2006). It has also been used to look at same the muscles but in healthy children and children with hypermobility syndrome (Fatoye F et al., 2009). Therefore it is a reliable measurement system for use in functional assessment for comparing navigated and conventional TKA.

2.16. PASSIVE RANGE OF KNEE JOINT MOTION

Passive flexion and extension for both knees was recorded. The subject was lying in supine and a standard clinical long armed manual protractor goniometer was used. For all manual goniometry measurements flexion was recorded with a positive sign and extension with a negative sign. The active excursion available was calculated by subtracting the extension value from the flexion value.

2.17. QUESTIONNAIRE SURVEY – CLINICAL AND QUALITY OF LIFE SCORES

Pain, mobility and function were assessed through a series of questionnaires. Clinical knee scores were recorded from the Oxford Knee Score (OKS) and American Knee Society Scores (AKSS) at each of the patient's assessment appointments, pre-operative, 3 months and 1 year post-operative. Short-Form 36 (SF-36) was completed at pre-operative and 1 year post-operative to assess the patients' general health and the effect that their knee OA/TKA has had on pain/energy levels and also on their emotional/social functioning. The Canadian Occupational Performance Measure (COPM) was completed pre-operatively and 1 year post-operative to calculate the change in performance and satisfaction of patient selected tasks. Finally the Western Ontario and McMaster Universities (WOMAC) Index of Osteoarthritis was used at 1 year post-operative which scores pain, stiffness and difficulty level in performing a variety of activities in depth.

At their 1 year post-operative assessment the patients were also asked to rate the pain they experience in the last 48 hours from the affected knee on a Visual Analogue Scale (VAS) in the form of a 100 mm long horizontal line with the labels "no pain" (score of 0 points) and "worst possible pain" (score of 100 points). Also they were asked to comment on whether or not they felt the operation was a success.

Summary

This chapter sets out the methodology for the functional assessment to compare navigated and conventional Total Knee Arthroplasty. 39 navigated and 38 conventional TKA patients completed 12 activities during which dynamic knee kinematics was recorded using electrogoniometry. Flexible electrogoniometry has

been validated as an accurate and reliable method of recording knee kinematics. The main advantages of this system were that a range of daily activities could be included in the functional assessment and the patient was able to move freely within the hospital.

High intraclass correlation coefficients were reported for inter-observer reliability tests for long leg radiographs analysis and high intraclass correlation coefficients were reported for both the intra and inter-observer reliability tests for CT scan analysis. The CT scan protocol was an accurate and repeatable analysis method which is valid for use in comparing the post operative outcome alignment of the TKA prosthesis in the patients within this clinical trial.

2.18. STATISTICAL ANALYSIS

Statistical analysis was performed using Minitab and SPSS 17.0 software package. Tests for normality and distribution were performed using the Anderson-Darling test. Gender differences and contralateral knee 'status' (whether the contralateral was OA affected, had a TKA etc) were evaluated using the Chi Square Test. Parametric data used paired student t-test to evaluate differences in the two surgical groups. It was used on data which was normally distributed. Alpha level was set at 0.05. The null hypothesis H_o = no difference between the two surgical groups. This hypothesis was rejected only when $p<0.05$. In this case the two groups were statistically significantly different. Non parametric data the Mann-Whitney (U) test was used.

Pearson correlation coefficients (r) were used to show whether and how strongly pairs of variables are related. Correlation coefficient r ranges from -1 to +1. When r equals or is close to 0 then there is no relationship between the variables. If r is positive then it means that as one variable increases then the other variable also increases. If r is negative then as one variable increases the other variable decreases. The closer the r value is to -1 or +1 the stronger the relationship.

Regression analysis was used to investigate whether one variable could predict another variable. The coefficient of determination (r^2) is the square of the correlation coefficient and ranges from 0-1. It is calculated to show the statistical measure of how well the regression line approximates the real points.

CHAPTER 3. RESULTS

3.1. RESULTS INTRODUCTION

The randomised clinical trial (RCT) designed to compare conventional and electromagnetic computer navigated TKA was undertaken at Glasgow Royal Infirmary (GRI). The study was approved by the Glasgow Royal Infirmary Local Ethics committee and the University of Strathclyde. 200 patients were recruited to the trial from July 2007 to August 2010. Once the patients had been recruited and consented they were given a patient trial number. Then they were randomised into either the conventional or navigation TKA group.

Figure 3.1 summarises the consort diagram for the first 120 patients recruited to the trial which were analysed in this thesis. At the time of writing this thesis the remaining 80 recruited trial patients had not reached their one year follow up appointment therefore their data was not available for analysis within this thesis. In order to recruit the first 120 patient subset then 174 suitable patients were approached resulting in a recruitment rate of 69%. 12 patients who had been approached did not meet the trial inclusion criteria. 42 patients decided that they did not wish to participate in the study. They had been given time to read the patient information sheet and had any questions answered. The 120 patients had been randomised with 60 in each arm of the trial.

The extensive one year post-operative functional assessment was analysed to compare the two surgical methods. This included the electrogoniometry assessment of 12 functional activities. The production of standardised function cycle graphs for each task. From these graphs the maximum, minimum and excursion (maximum-minimum) knee joint angles (KJA) were calculated. 3 month post-operative CT scans were analysed to determine the prosthesis alignment. The relationship, if any, was then studied between alignment and function. Knee moments tending to flex or extend the joint and activity levels were also analysed. Finally questionnaires investigating quality of life and function were recorded at pre operation, three months and one year post operation clinics. The questionnaire functional outcome was correlated with the objective functional outcome to investigate the difference between subjective and objective measures.

Consort Flow Diagram:

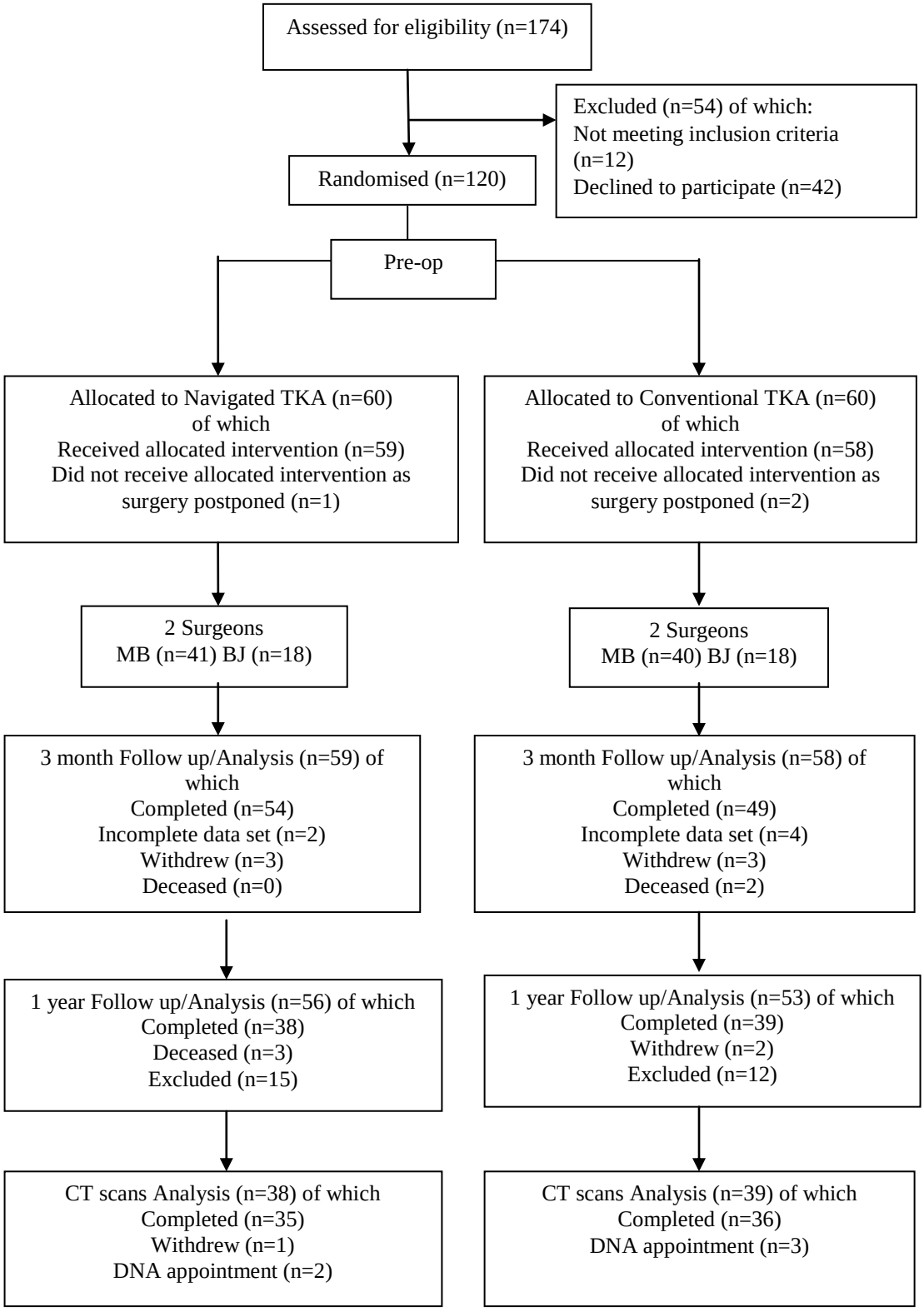


Figure 3.1 Consort flow diagram illustrating the breakdown of the navigated and conventional groups and the number of patients completing each stage of the trial.

The consort diagram (figure 3.1) shows that one patient in the navigated TKA group and two patients in the conventional TKA group had their surgery postponed due to medical reasons. Two surgeons completed all of the surgeries. MB = Mr Mark Blyth the Principal investigator of the clinical trial and BJ = Mr Bryn Jones. Both are orthopaedic consultants at Glasgow Royal Infirmary. MB operated on about 70% of the patients in each group.

Routinely TKA patients are followed up at 3 months after surgery in the GRI. At this appointment two questionnaire scores (American Knee Society Score and the Oxford Knee Score) were recorded for each of the trial patients. At the 3 month post-operative assessment 3 patients in the navigated group withdrew from the trial. 54 navigated patients had a complete data set and 2 patients had an incomplete data set. The data at this appointment was collected by the outcomes nurses in the GRI. In the two cases where the data sets were incomplete there were missing questionnaire scores. The 2 patients with incomplete data continued in the trial and their questionnaire scores were recorded at their one year post-operative assessment. Therefore, 56 patients in the navigated group were seen at the one year post-operative appointment. Prior to this time point 3 patients in the navigated group had died. The cause of death was unrelated to their knee replacement operation.

The primary aim of this study was to compare the post operative alignment of the navigated and conventional TKA groups. Therefore some of the patients recruited to this study were not suitable to complete the full functional assessment. 15 patients in the navigated group were not suitable for the complete functional assessment. These patients were unsuitable for the functional assessment for one of the following reasons:

1. They had severe contra lateral knee OA and were waiting on joint replacement surgery.
2. They had severe OA in their hip affecting their gait.
3. They had severe OA in their ankle joint affecting their gait.
4. They had recently undergone surgery (knee, hip or ankle) and were therefore still recovering.

These factors would affect the patients' gait pattern and therefore their ability to complete the functional assessment. Therefore this thesis presents functional data

from 38 patients in the navigated group. From this group CT scans were missing from 3 navigated patients. 1 patient had withdrawn from the CT scan and 2 patients had cancelled their appointment twice.

In the conventional TKA group 2 patients had died prior to the 3 month post-operative assessment. The cause of death was unrelated to their knee replacement surgery. 3 patients from the conventional group withdrew from the trial at the 3 month post-operative assessment. 49 conventional patients had a complete data set. 4 patients in the conventional group had incomplete questionnaire data. Therefore 53 patients in the conventional group were seen at the one year post-operative appointment. At this time point 2 patients in the conventional group withdrew from the trial. 12 patients in the conventional group were unsuitable for the complete functional assessment. These patients were unsuitable for the functional assessment for the same reasons as those in the navigated group. Therefore this thesis presents functional data from 39 patients in the conventional group. From this group CT scans were missing from 3 conventional TKA patients. The 3 patients had cancelled their appointment twice.

One of the difficulties with this patient group is that they do not always present with pain or problems in solely one knee joint. In many TKA patients OA is found in both of their knee joints and possibly even their spine, hip or ankle joint. It is common to find that OA progresses in other joints during the first year post operation of their TKA leading to the patient requiring further joint surgery. On the other hand some patients find that TKA relieves pain in their other joints, at least for a short period, as they stop protecting their painful knee through adaptive gait patterns which had put increased pressure on their other lower limb joints.

77 patients had been included in the functional assessment as they did not have severe pain or problems in their lower limb joints. Since the kinematics of the contra lateral knee were recorded in the functional assessment then it was recorded whether the contralateral knee joint was:

1. Pain free.
2. Had mild symptomatic OA.
3. Had a previous TKA which was pain free or only gave mild pain and discomfort.

The two surgical groups were made up of patients from each of the three groups outlined above. Table 3.1 summarises the make up of the navigated and conventional groups.

Table 3.1 Contralateral knee 'status'

	Navigated	**Conventional**
Pain Free Contralateral	14	13
Arthritic (mild) Contralateral	8	10
Contralateral TKA	16	16
Total	**38**	**39**

Table 3.1 shows that the division of the two surgical groups in terms of the contra lateral knee was similar. It is common for patients to have bilateral OA which means that both their knee joints have symptomatic and radiographic signs of OA. In these cases both knee joints would likely need to be replaced at some point in the patient's life time. In some cases there is years between knee replacement operations for the two sides. In cases where both knees show advanced signs of OA then the patient requires bilateral TKA which can be simultaneous or staged. There were 2 simultaneous bilateral knees (1 patient) in the navigated and conventional groups respectively. The time period between the two knee operations in staged bilateral was about 3-6 months. There were 4 staged bilateral knees (2 patients) in the navigated group and 2 staged bilateral knees (1 patient) in the conventional group. At the one year post-operative assessment the staged bilateral patients were asked to determine whether they felt functionally limited by the contra lateral knee which was less than one year post operation. It was important to determine whether the patients' function would be affected by the most recent knee operation, which would skew the data. TKA patients continue to improve over the first year and therefore it was difficult to determine whether their improvement and recovery had reached the plateau.

In the staged bilateral cases, the patient's opinion of whether their second knee operation was still affecting them was used to determine whether they could complete the functional assessment. The data for these patients was also analysed for any indications of problems with the second knee operation. The staged bilateral patients completed the 1 year assessment twice i.e. when the first trial knee was 1 year post operation and then when the second knee was 1 year post operation. None

of the bilateral patients included in the study had significant limitations due to one of their two operations. However most of these patients had a preference to which knee gave them the least problems or pain. This was not found to be solely related to the length of time since their operation. Therefore it was not the age of the implant, rather it was related to which operation they felt was more successful

Recording the contralateral knee kinematics allowed an analysis between affected and unaffected to be completed. The navigated and conventional TKA groups vary in the 'status' of the contralateral knee make up. A chi square test showed that the two surgical groups were not significantly different (p=0.884).

3.2. PRE-OPERATIVE DATA

Data collected pre-operatively was used to determine if there were any significant statistical differences between the two surgical groups. Table 3.2 shows the pre operative patient demographics of the two surgical groups.

Table 3.2 Pre operative patient demographics

	Navigated Group	**Conventional Group**	**p value**
Men/Women	22/16	19/20	0.42
Mean Age (range)	65.6 (46-84)	66.3 (49-84)	0.84
Mean Pre-op ROM (^{o})	105.8 (65-140)	106.1 (80-130)	0.92
Mean Pre-op Mechanical Axis (^{o})	3.1 of varus (15 of varus to 12 of valgus)	2.9 of varus (30 of varus to 20 of valgus)	0.63
Deviation from mechanical axis (^{o})	7.7 +/- 3.4	7.6 +/- 6.1	0.83

The navigated group had 58% males and the conventional group had 49% males. Chi Square Test showed that the M:F ratio imbalance was not significant (p=0.42). An independent two sample t-test was used to determine whether there were any statistical differences between the two surgical groups. The p value which would indicate significant statistical differences between the two groups was set at 0.05. There were no differences pre-operatively between the two groups in terms of age. The average age of the navigated group was 65.6 years old (+/- 9.4). The average age of the conventional group was 66.3 years old (+/- 8.9). There was also no statistically significant difference between the navigated and conventional TKA group in terms of pre operative knee joint range of motion (ROM) where the mean

was 106^{o} for both surgical groups. The pre-operative mean mechanical axis alignment for both groups was 3^{o} of varus. The deviation from the mechanical axis irrespective of direction (varus or valgus) was also calculated. The mean deformity to be corrected by the surgical intervention was calculated to be 8^{o} for both surgical groups. The range of deviation was larger for the conventional group. However the number of patients with a deviation greater than 10^{o} was 5 for both the navigated and conventional group. There was no statistically significant difference between the navigated and conventional TKA group in terms pre-operative mechanical axis alignment and deviation from the mechanical axis.

The pre-operative questionnaire scores; Oxford Knee Score (OKS), American Knee Society Score (AKSS) and SF-36 are shown in table 3.3. OKS is an overall knee score. The AKSS is divided into a knee score (which records pain, ROM and joint stability) and a function score. The SF-36 is divided into a physical (or function) score and a mental score (health status).

Table 3.3 Pre operative questionnaire scores for the navigated and conventional groups.

	Navigated Group	Conventional Group	p value
Oxford Knee Score	41.8 (24-52)	42.1 (27-52)	0.84
AKSS (Knee)	45.3 (25-84)	47.6 (24-82)	0.52
AKSS (Function)	51.6 (15-100)	46.9 (5-80)	0.2
SF36 (Physical)	36.5 (11-83)	34 (23-69)	0.33
SF36 (Mental)	47.7 (23-90)	47.4 (24-94)	0.94

An independent two sample t test was used to investigate the differences between the two surgical groups. The p value which would indicate significant statistical differences between the two groups was set at 0.05. Table 3.3 indicates that there were no statistical differences between the two surgical groups in terms of: the OKS, AKSS and SF-36 scores. The principal investigator of the trial, MB completed the majority of the surgeries. MB operated on 71% (n=27) of the 38 patients in the navigated group and 64% (n=25) of the 39 patients in the conventional group.

Therefore in summary, it can be concluded that apart from a slight gender imbalance and slight primary surgeon differences the pre-operative status of the two groups was comparable and no baseline adjustment was required.

3.3. ELECTROGONIOMETRY FUNCTIONAL ASSESSMENT

Flexible electrogoniometry was used to record the dynamic kinematic functional cycle of 12 everyday activities. Each of the 12 activities - level and slope walking, up and down stairs, stand-sit-stand from a high and low chair, in and out of a bath and weighted deep flexion were graphed, inspected and then analysed.

3.3.1. Completion Rates for the Functional Activities

Firstly, as expected the functional ability level of the trial patients varied greatly. There were a small group of patients within each surgical group who found some everyday activities difficult. The functional assessment aimed to investigate a range of activities which varied in difficulty levels. Tasks which require larger knee joint flexion angles are seen to be more difficult and are classed as 'high flexion' activities as they are more challenging. This group includes stair ascent and descent, in and out of a bath and sit to stand from a low chair. Figure 3.2 shows the percentage of patients in each group who were able to complete each task.

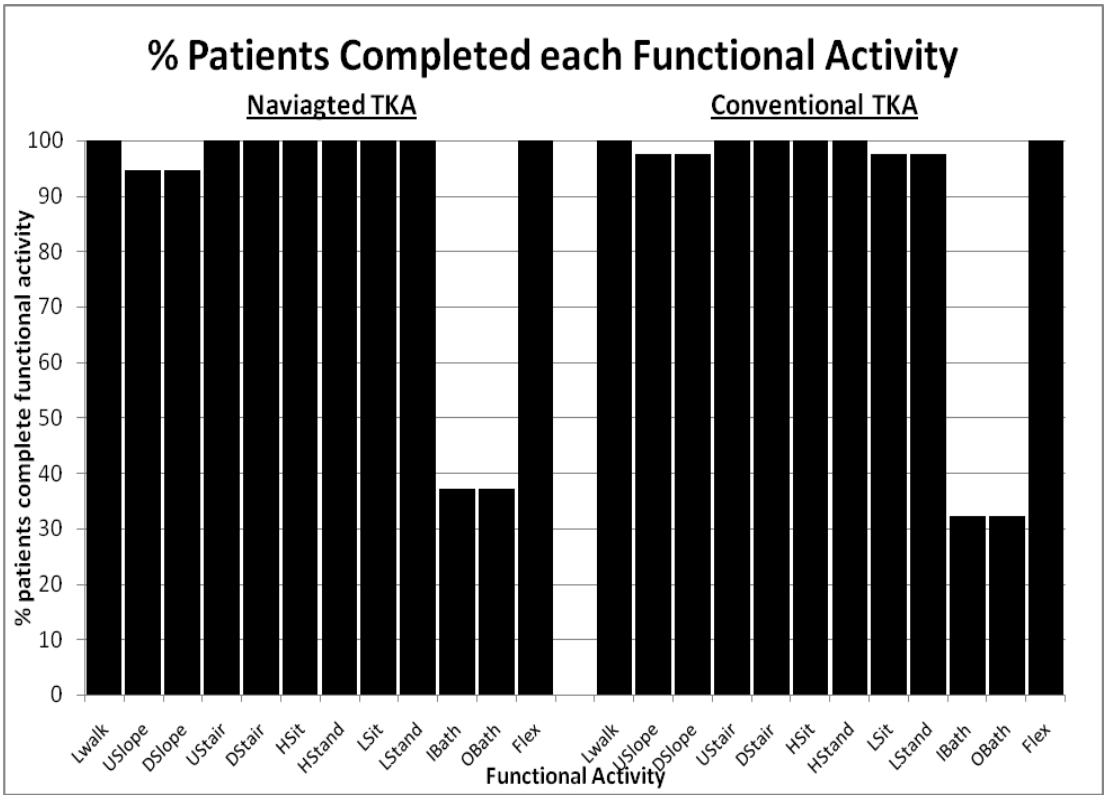


Figure 3.2 Percentage of patients able to complete the functional tasks within each of the two surgical groups.

The percentage of patients who were able to complete 'high flexion' tasks was smaller than the percentage of patients who were able to complete the less challenging tasks. This indicated that a small group within each surgical group had functional limitations. The lowest completion rates were found in the bath task. One of the reasons for not completing this task was that the patient could not flex their knee joint enough to comfortably get into, and out of the bath. It was also reported that the majority of trial patients did not use a bath at home. This meant that a large group of the trial patients did not have the confidence to complete the task, even if they had the ability to flex their knee to get in and out of the bath.

For the majority of tasks the completion rate was 100%. For slope walking there were two patients in the navigated TKA group and one patient in the conventional TKA group who did not complete the task. This was not due to their ability to walk up and down a slope but instead they were unable to walk the distance to complete the test circuit. For these patients it was cardiac problems which limited their activities. This in itself was a clear indication of their limited functional ability. The circuit consists of walking along a corridor, then sitting in the low then high chairs. Then they completed the bath task, if possible. Then they walked up and down a flight of stairs, back along the corridor. The final task was up and down the sloped corridor. The test circuit was completed at the patients' self selected speed. It took around 10 to 15 minutes to complete but for 3 trial patients out of a total of 77 trial patients tested this was too far to walk even with the short break in the middle for the chairs task. Comparing the two groups' completion rates of the two tasks was very similar.

3.3.2. Comparing maximum, minimum and excursion KJA

The maximum, minimum and excursion knee joint angles were calculated for each trial patient. From this the mean group knee joint angle was calculated for each activity. Using the statistical programme Minitab, the probability that the data was normally distributed was calculated. Anderson-Darling (AD) measures how well the data follows a particular distribution, where the better the fit to normal distribution

the smaller the statistic and the higher the p value. Figure 3.3 illustrates an example of the probability plot for the parameter maximum level walking KJA.

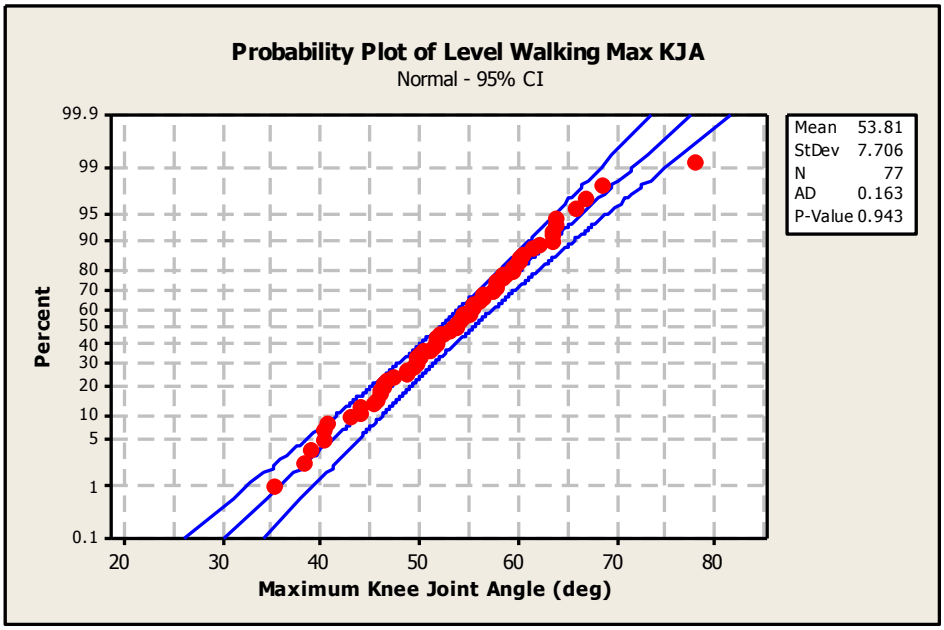


Figure 3.3 Probability Plot for level Walking Maximum Knee Joint Angle (KJA)

For this example the AD value was 0.163 and the p value 0.943 indicating that this parameter was normally distributed.

Most of the maximum, minimum and excursion KJA data sets were normally distributed. However, some of the data sets had outliers such as stairs, low chair and bath. These activities were seen to be more variable (figure 3.4).

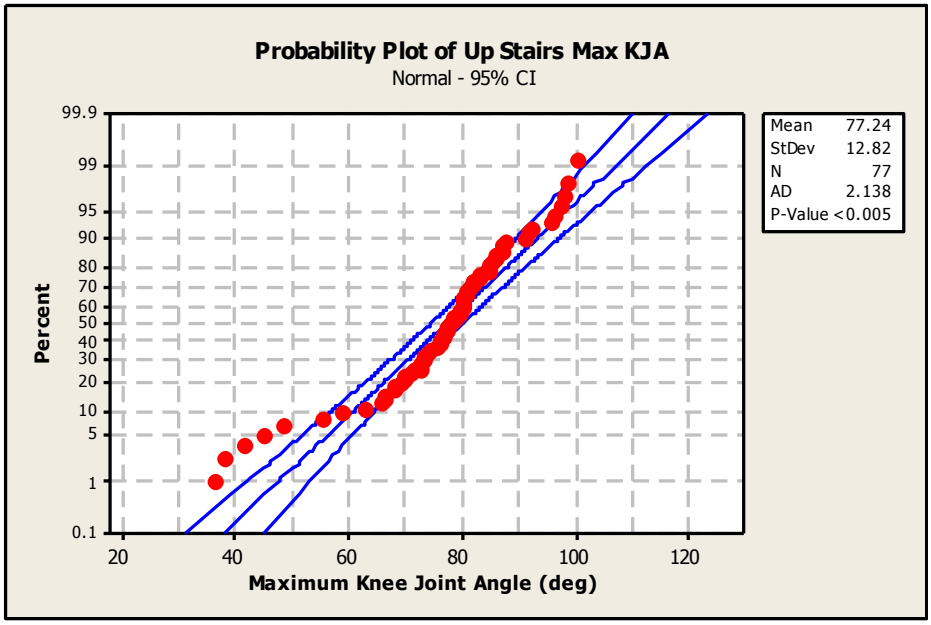


Figure 3.4 Probability Plot for Up Stairs Maximum Knee Joint Angle

Figure 3.4 illustrates an example data set which was not normally distributed, in other word, it was distribution free. The AD value equalled 2.138 and the p value was less than 0.005. There were two methods adopted by the trial patients for stair climbing. The majority used the normal leg over leg method. Those who found stair negotiation difficult walked 'one step' at a time. The one step at a time method was used to limit the peak flexion required by the knee joint. Therefore a large range of maximum knee joint angles were calculated within the two surgical groups. The groups could therefore be divided into two sub groups based on method adopted for this activity. For up and down stairs if the two sub groups were analysed separately the data was normally distributed.

For the parameters where the data was normally distributed then a two sample independent t-test was used to compare the mean maximum, minimum and excursion knee joint angles for the two surgical groups. The p values were calculated where a level of significant difference was set at $p<0.05$. For the parameters which were non parametric and therefore distribution free such as in the case of:

- Low chair stand to sit maximum and excursion KJA data,
- Up stairs maximum and excursion KJA data,
- Down stairs maximum and excursion KJA data,
- Low chair sit to stand excursion KJA data,

A Mann Whitney (U) test was used.

Table 3.4, 3.5 and 3.6 summarise the mean maximum, minimum and excursion values for each of the 12 activities and with regards to the two surgical groups. The tables include the standard deviation, the range within the groups and the p values calculated when the mean group values were compared using statistical tests. The group with the higher mean flexion angles were highlighted in bold for each activity.

Table 3.4 Maximum Knee Joint Angles (KJA) for all 12 activities

Max knee joint angle	Mean Navigated	StDev	Max	Min	Mean Conventional	StDev	Max	Min	p value
Level Walking	53.8	7.9	67.1	35.5	53.8	7.6	78.5	39.1	0.99
Up Slope	**52.2**	7.7	70.3	33.9	51.3	8.4	77.6	34.1	0.63
Down Slope	**56.3**	7.5	68.1	38.3	55.9	8.5	82.4	40.6	0.83
Up Stairs	77.0	13.3	96.7	36.6	**77.5**	12.6	100.8	41.8	0.83
Down Stairs	**76.0**	12.6	97.0	29.1	72.2	16.7	98.0	35.0	0.47
High Chair Stand-Sit	78.9	11.6	100.8	55.8	**80.4**	11.0	103.0	51.7	0.57
High Chair Sit-Stand	78.2	11.8	100.8	38.7	**79.5**	11.5	102.9	52.6	0.62
Low Chair Stand-Sit	89.2	12.2	111.9	44.1	89.2	13.8	118.9	46.9	0.89
Low Chair Sit-Stand	88.0	14.0	112.2	42.5	**90.2**	13.0	120.0	54.1	0.47
Into Bath	91.4	23.2	117.0	51.4	**104.5**	23.2	130.8	59.7	0.22
Out of Bath	93.8	21.5	127.7	63.4	**99.4**	30.3	135.7	52.8	0.64
Deep Flexion	**106.1**	15.2	142.1	79.1	106.0	18.0	145.5	68.9	0.99

From table 3.4 it can be seen that the mean maximum KJA in the navigated group was higher than the mean maximum KJA in the conventional group for four activities (up and down slope, down stairs and deep flexion). In six activities the conventional group recorded a higher mean KJA. The largest difference between group mean angles was for the bath activity. The difference did not reach significance as the completion rates for this activity was low. From the other 10 activities the group mean angles only differed by a few degrees and no statistical significance difference was reported.

Table 3.5 Minimum Knee Joint Angles (KJA) for all 12 activities

Min knee joint angle	Mean Navigated	StDev	Max	Min	Mean Conventional	StDev	Max	Min	p value
Level Walking	0.9	4.5	17.6	-6.1	-0.6	4.1	7.8	-8.9	0.14
Up Slope	0.4	4.6	15.4	-6.3	-0.4	3.8	8.0	-7.8	0.40
Down Slope	0.2	4.9	13.6	-6.3	0.2	4.8	12.4	-9.8	0.98
Up Stairs	4.8	4.9	19.5	-4.6	3.9	4.9	15.4	-6.9	0.47
Down Stairs	4.4	5.1	17.4	-5.0	3.6	5.9	17.0	-6.6	0.53
High Chair Stand-Sit	-0.4	4.3	11.6	-8.3	0.4	3.8	11.7	-6.0	0.40
High Chair Sit-Stand	-0.3	3.4	8.9	-7.0	0.2	3.0	6.8	-5.8	0.58
Low Chair Stand-Sit	-0.6	3.5	8.9	-7.4	-0.7	3.3	5.2	-8.9	0.83
Low Chair Sit-Stand	-0.2	4.4	12.5	-8.7	-0.3	3.7	8.1	-10.0	0.95
Into Bath	-0.3	4.0	8.2	-5.3	-0.1	1.8	2.4	-2.8	0.88
Out of Bath	-0.8	2.6	2.8	-4.6	0.1	2.7	5.5	-5.1	0.49
Deep Flexion	-1.6	2.4	2.7	-9.9	-1.5	2.8	6.2	-6.0	0.86

There was only about a degree of a difference between the two mean minimum KJA calculated for the two groups for each of the tasks. The minimum KJA for all of the activities apart from the stairs activities was around full extension (0^o). During stair ascent and descent the minimum knee flexion angle was around $4\text{-}5^o$.

Table 3.6 Excursion Knee Joint Angles (KJA) for all 12 activities

Excursion knee joint angle	Mean Navigated	StDev	Max	Min	Mean Conventional	StDev	Max	Min	p value
Level Walking	52.9	8.1	64.3	35.8	**54.4**	6.9	72.2	39.5	0.41
Up Slope	**52.0**	7.7	65.2	35.0	51.8	7.0	71.8	34.8	0.89
Down Slope	**56.1**	7.7	68.1	40.5	55.7	7.8	75.4	40.2	0.83
Up Stairs	72.2	12.6	91.3	35.0	**73.6**	9.8	90.5	48.8	0.84
Down Stairs	**71.6**	11.1	86.3	34.1	68.5	14.1	87.9	35.7	0.56
High Chair Stand-Sit	79.3	12.3	104.8	56.6	**80.0**	11.6	103.6	51.1	0.80
High Chair Sit-Stand	78.4	11.7	99.6	45.7	**79.3**	11.7	103.5	54.4	0.73
Low Chair Stand-Sit	89.8	12.4	111.0	47.5	**89.9**	13.6	116.6	50.2	0.95
Low Chair Sit-Stand	88.2	14.4	111.6	50.5	**90.5**	12.5	117.4	61.6	0.61
Into Bath	91.7	22.2	122.2	52.9	**104.6**	22.6	131.0	60.9	0.21
Out of Bath	94.5	20.6	128.3	66.8	**99.3**	28.6	136.0	56.1	0.67
Deep Flexion	**107.7**	15.4	144.3	79.4	107.5	18.0	145.9	69.5	0.96

From table 3.6 it can be seen that the mean excursion KJA in the navigated group was higher than the mean excursion KJA in the conventional group for the same four activities as in the case of the maximum KJA (up and down slope, down

stairs and deep flexion). This was expected as there were minimal differences in the group's mean minimum angles. The conventional group recorded a higher mean excursion KJA in six activities. The largest difference was found between the group mean angles for the bath activity. From the other 10 activities the group mean angles only differed by a few degrees and therefore did not reach statistical significance.

The p values in tables 3.4, 3.5 and 3.6 shows that there was no significant difference between the two groups for any of the functional activities. The lowest p values were seen for the 'into bath' activity but it did not reach significance with the reduced number of patients completing the task. One limitation with the statistical analysis of the above parameters was that a multi variate analysis has not been completed. Therefore the data has not been adjusted by using other factors, for example pre operative status may influence the post operation clinical results.

3.3.3. Electrogoniometry Graphs

In the previous section the mean group maximum, minimum and excursion knee joint angles have been summarised. This section investigates the kinematic pattern for each of the activities. The 12 electrogoniometry activities were graphed - level and slope walking, up/down stairs, stand-sit-stand from a high and low chair, in/out of a bath and weighted deep flexion. Electrogoniometry results from a typical TKA patient illustrating both their operated and non-operated knee joint function cycles for each of the 12 activities was included in this section. These graphs show the typical kinematic pattern found for the activities from the patients within both surgical groups.

Compound plots allowed differences between patients within the one surgical group to be identified for each function. The navigated compound graph therefore included plots from 38 patients and the conventional graph included 39 patients' data. From the compound plots, any unusual gait cycles within the group were identified and investigated further for an explanation. The mean group plots illustrate the differences, if any, between the navigated and conventional TKA groups. The mean cycles were plotted for both the operated and non-operated knee. The dotted lines on the mean graphs indicate +/-1 standard deviation or a 66% confidence

interval of the average function cycles. Vertical lines on the average graphs indicate periods of statistically significant differences between the two surgical groups.

Level Walking

Figure 3.5 shows the knee joint angles in a typical gait cycle for level walking for the operated and non-operated knee joint.

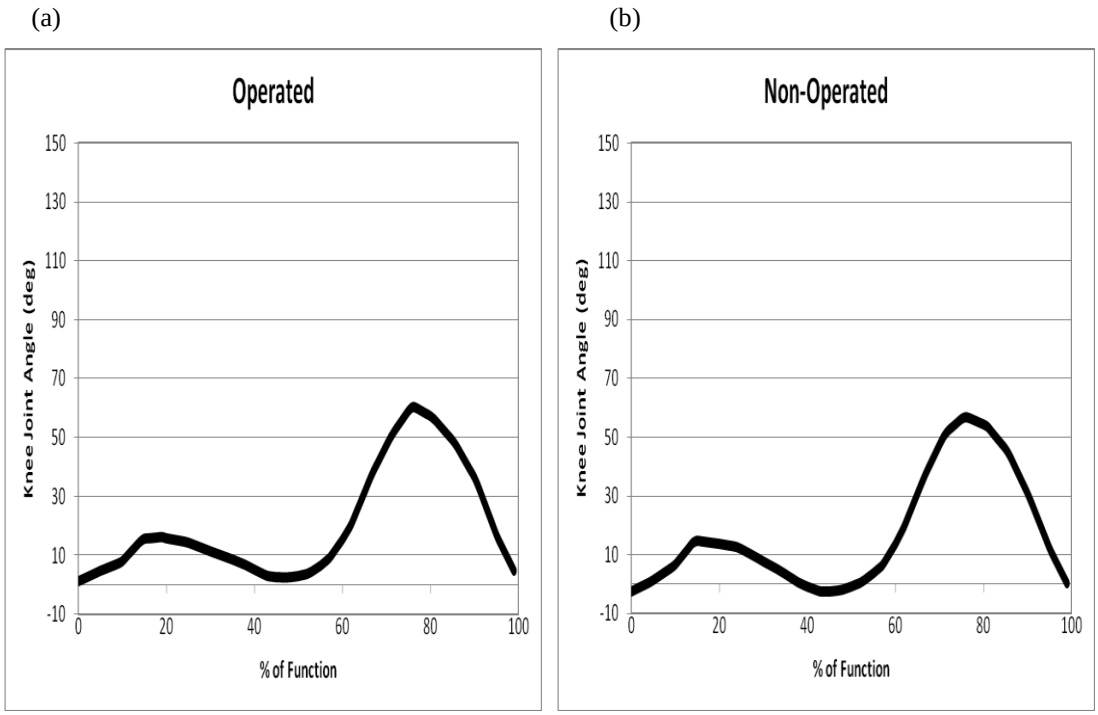


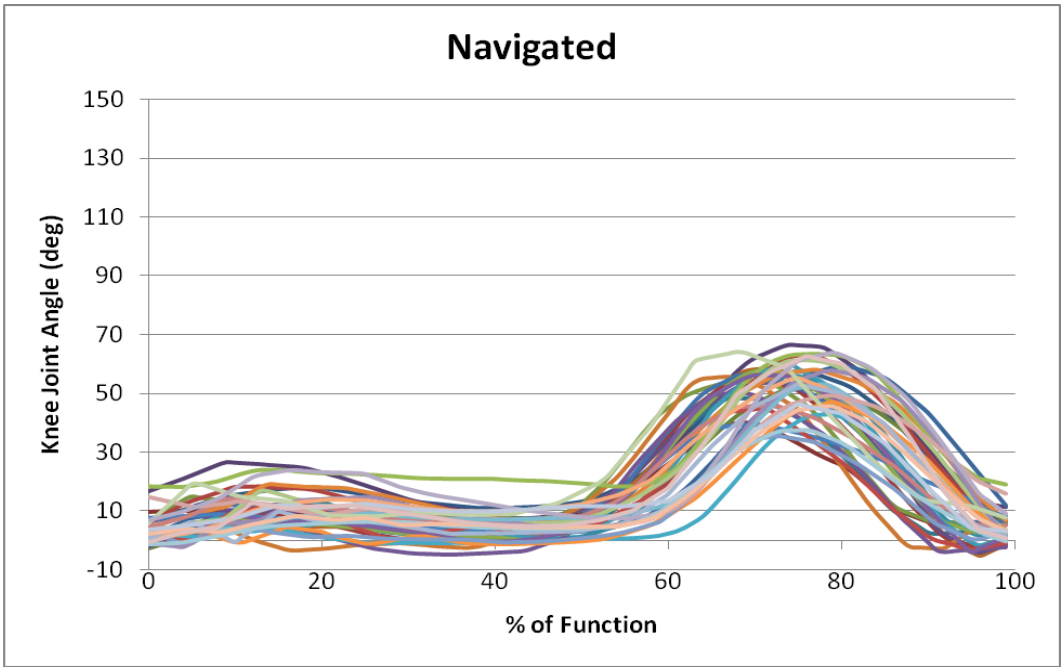
Figure 3.5 Level walking gait cycle normalised for one typical trial patient
(a) Operated knee (b) Non-operated knee

The patient in figure 3.5 showed little difference between their operated and non-operated limb. Both knee joints resulted in a knee kinematic pattern similar to that expected from a 'normal' subject. Normal knee kinematic data recorded using electrogoniometry has been published by Rowe et al (2000).

There was a clear stance and swing phase peak and the knee joint excursion required for level walking was about 60^{o}. The data was smooth and noiseless. The patients show full extension (0^{o}) at initial contact and then a peak stance flexion angle at about 20^{o} during loading response. Subsequently the knee joint extends again into terminal stance and then has to flex rapidly so that toe clearance can take place into swing.

The compound graphs in figure 3.6 shows all the navigated patient's level walking gait cycle.

(a)



(b)

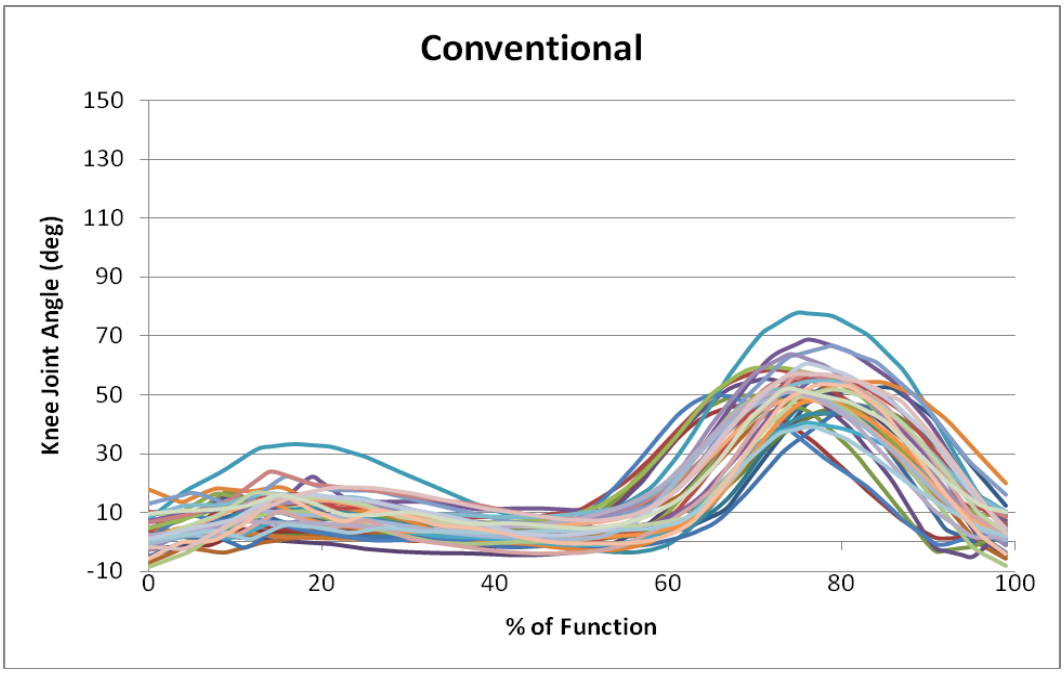
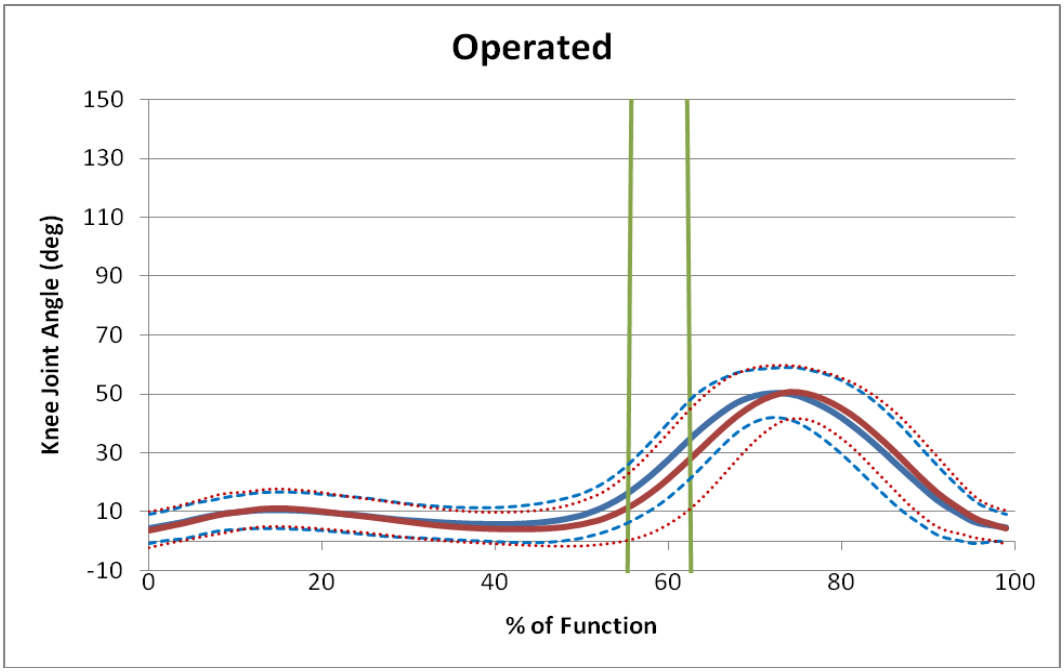


Figure 3.6 Compound plots - Level walking gait cycle normalised

(a) Navigated TKA (b) Conventional TKA

Figure 3.7 shows the average level walking plot for the two surgical groups for the operated and non operated side.

(a)



(b)

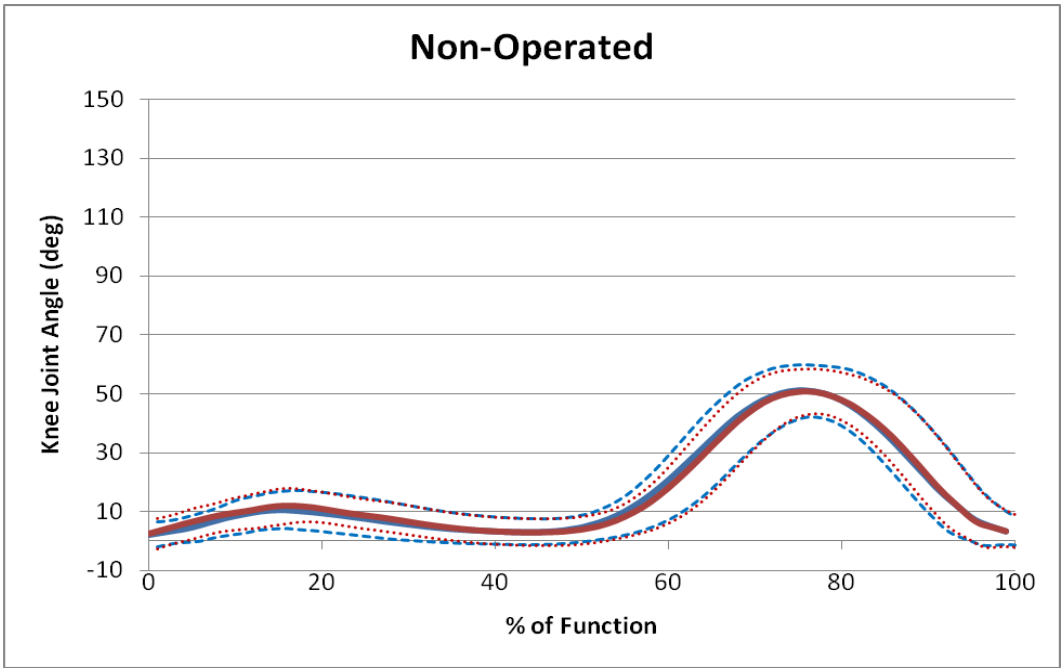


Figure 3.7 Average plots - Level walking gait cycle normalised. Navigated in blue, conventional in red. (a) Operated knee (b) Non-operated knee. Vertical lines show areas of significant difference between the 2 groups.

The group compound plots (figure 3.6) show that there are variations in the kinematic gait pattern between patients. Firstly, stance in 3 navigated and 3 conventional patients begins with a knee flexed 10^{o} or more. Therefore, the 0% point of the gait cycle was not in near full extension as in 'normal' gait. Flexion contractures although commonly corrected during TKA may remain up to $5\text{-}10^{o}$ after surgery. This may result in the lack of full extension at heel strike. Secondly it can be seen that in some cases the stance phase peak knee flexion is absent. Therefore the patient does not flex their knee during the weight bearing section of the cycle. The range of peak flexion in swing phase was also variable ($35\text{-}65^{o}$). In the compound plot for the conventional group (figure 3.6) one patient in particular recorded a significantly higher flexion angle in both the stance and swing phase. They demonstrate a good ability to flex their knee both in stance (weight bearing) and in swing phase.

The average gait cycle (figure 3.7) for each group showed the same general kinematic pattern. There was no statistical difference found in the maximum, minimum or excursion knee joint angles between these two groups for either the operated or non-operated limb. The average level walking gait cycles (figure 3.7) for the two groups on observation, appear to differ at about 50-80% of the cycle for the operated limb. The initial stance phase angle at 0% of the cycle and terminal swing phase angle at 100% of the cycle are similar for both groups showing that the difference was not a result of a timing shift in the plot. The observed differences fall at points other than those previously tested (maximum and minimum KJA) by a t-test. A t-test was performed on the full range of the level walking cycle i.e. at each of the 100 individual percentage time points. There were statistically significant differences between the knee flexion angles in the 'operated' plot ($p<0.05$). The navigated group was found to produce statistically significantly higher knee joint flexion angles between 55-65% of the level walking cycle. The area of significant difference was indicated on figure 3.7 by the green vertical lines.

As previously mentioned walking gait cycles can be divided into two distinct sections: stance and swing phase where stance phase is about 62% of the complete cycle (Ayyappa 1997). However the exact duration of stance phase relates to walking speed, with minimal differences between healthy individuals. Underlying disease

such as OA have been seen to result in higher stance phase durations and higher stance ratios (Teixeira 1996). In the study by Teixeira et al stance ratio for the OA group was 67%. Therefore it was seen that the proportion of the gait cycle which was stance phase was increased from the mean 'normal' of 62% to a mean of 67% for the OA group. This was seen as a 'pain avoidance manoeuvre'.

In walking there is a period of double stance at initial and terminal stance which has been reported to be around 12% each (Ayyappa 1997). In level walking gait the second period of double stance is reported to be around 50-62% of the cycle. Pre swing phase takes place during this period of double stance and is associated with 'push off' where power is generated the advance the limb into swing phase. The area marked by the green vertical lines in figure 3.7 shows that the mean knee joint angle for the navigated group was statistically greater than that of the conventional group. This illustrates an earlier, more vigorous push off phase in the navigated group and suggests an increase in power during push off into swing phase to cause the increase in knee flexion angle. At this point the body is being propelled forward. The statistical difference between the two groups at this time point could be linked to differences in the stance or double stance duration, or in the ratio of stance and swing phase. This needs to be analysed further.

The non operated gait cycles showed no difference between the 2 surgical groups. When comparing operated and non operated side there was no statistical difference between the two knee kinematics recorded. There was no statistical difference between the maximum knee joint angle recorded ($p=0.44$), or during each point of the gait cycle.

Up Slope

Figure 3.8 shows the knee joint angles in a typical gait cycle for up slope for the operated and non-operated knee joint.

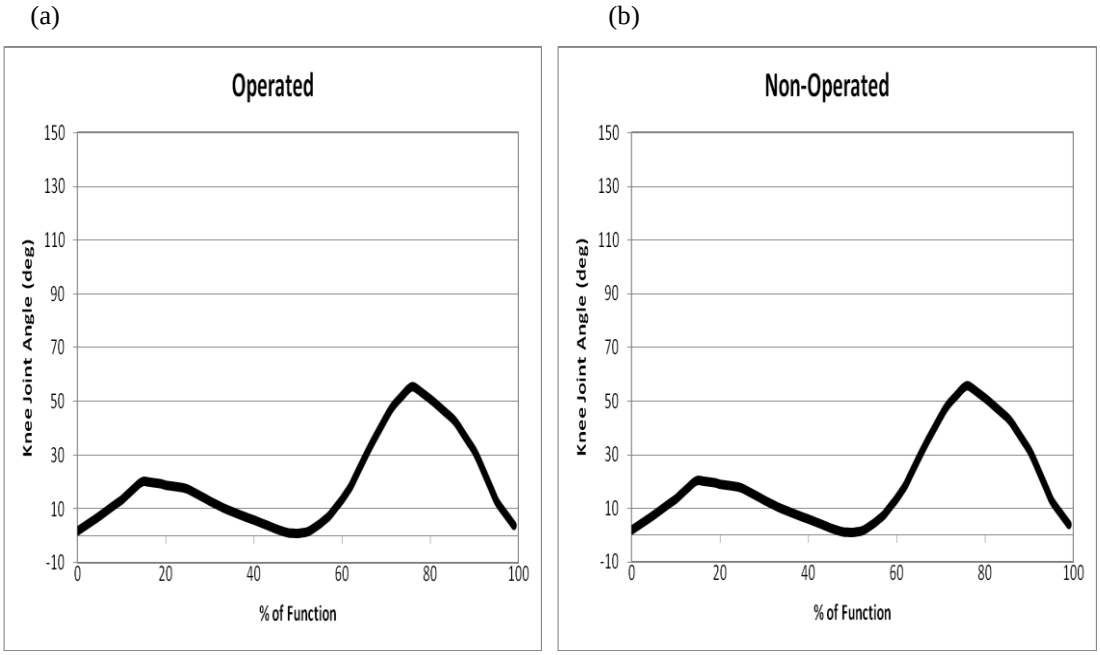
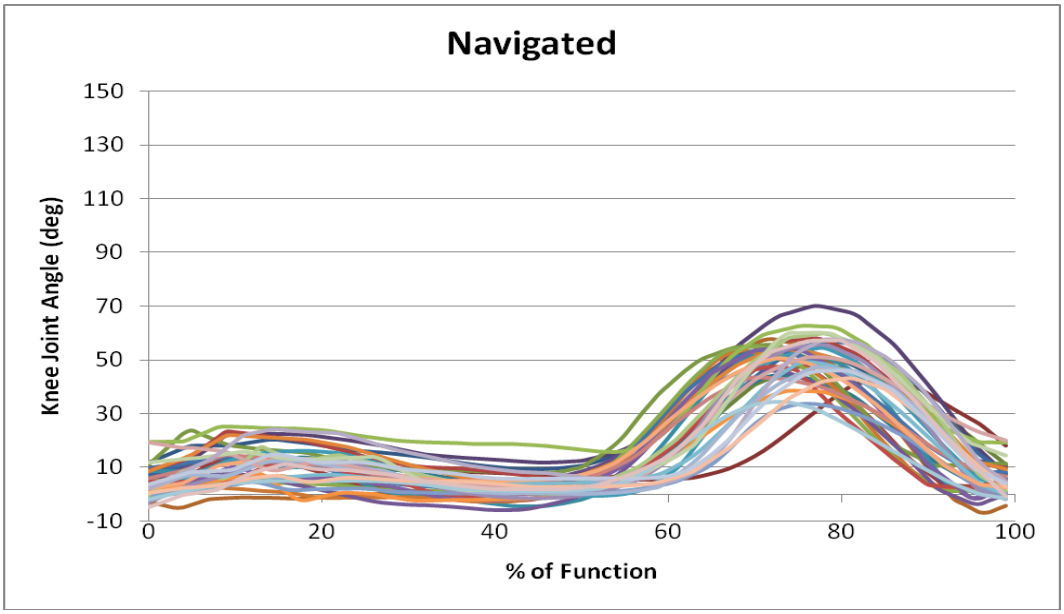


Figure 3.8 Up slope gait cycle normalised for one typical trial patient
(a) Operated knee (b) Non-operated knee

Slope walking follows the same pattern as level walking, where it consists of a stance and swing phase. The differences in the peak flexion angles vary with differing inclines as a steeper slope would require a greater flexion of the knee joint so that the toe clears the ground. The slope used in this study was a gradual incline of 5^{o}. Therefore the differences between this activity and level walking were seen to be minimal.

The up slope compound graphs are shown in figure 3.9.

(a)



(b)

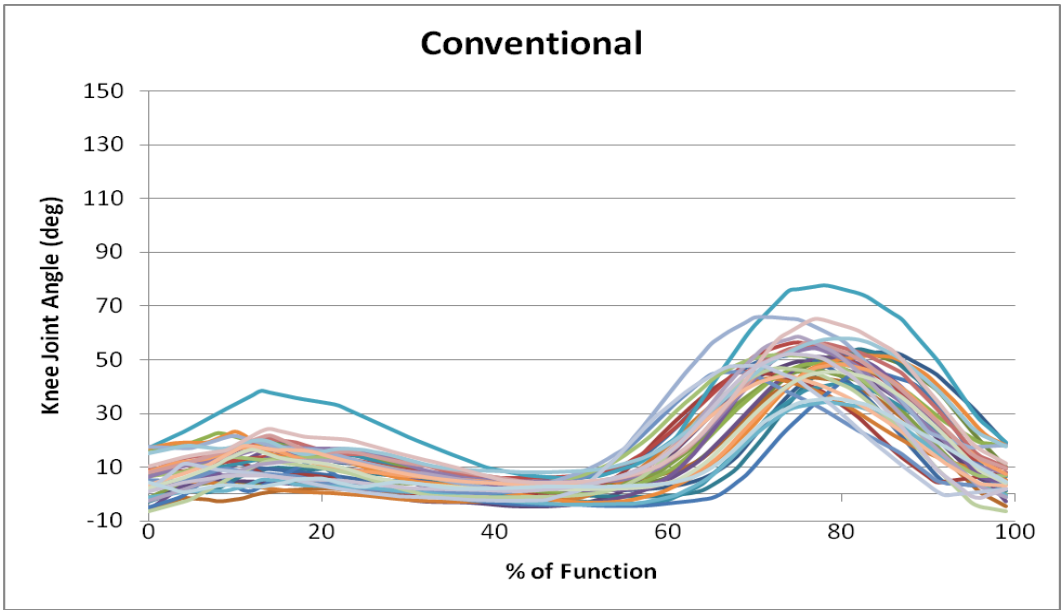
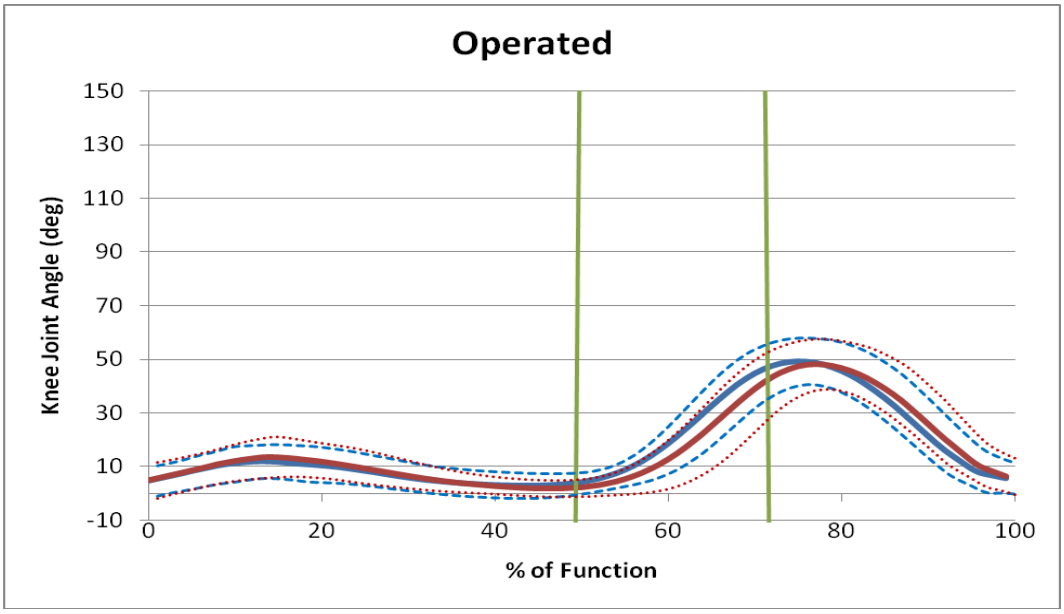


Figure 3.9 Compound plot – Up slope gait cycle normalised

(a) Navigated TKA (b) Conventional TKA

Figure 3.10 shows the average up slope plot for the two surgical groups for the operated and non operated side.

(a)



(b)

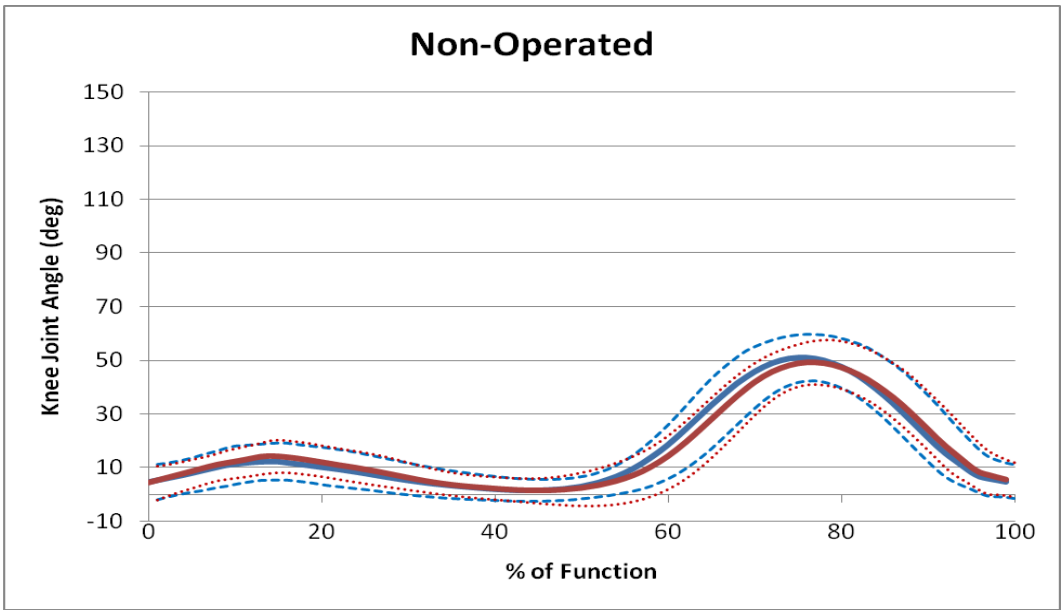


Figure 3.10 Average plots – Up slope gait cycle normalised. Navigated in blue, conventional in red. (a) Operated knee (b) Non-operated knee. Vertical lines show areas of significant difference between the 2 groups.

Figure 3.9 illustrates that the kinematic pattern for up slope walking was similar for patients within both surgical groups. Some variations in the peak flexion angles were present between patients. One patient in the navigated group and three patients in the conventional group had an increased peak flexion knee angle during swing phase compared to the other patients within the same group. For many patients prior to surgery the non-operated limb is their dominant side as they try to protect or limit the pain experienced from the side to be operated on. The plots in figure 3.9 show that the operated and non-operated limbs appear to be functioning to the same level for the 'up slope' activity.

Four patients demonstrated high stance phase flexion angles in the compound plots. This may indicate a problem with their non-operated limb. For example the high flexion angles recorded by the operated limb may indicate that it was used to compensate functionally for any limitations from a painful non operated knee joint. However on investigation none of the four patients had expressed problems with their non operated knee joint. In fact in these four patients both the operated and non operated knee flexion graphs recorded above average knee flexion angles. Therefore they demonstrated good knee kinematics for both knee joints. It was seen that for the majority of the 12 activities these four patients recorded higher flexion angles for their operated limb than the rest of the group.

A two sample independent t-test found no significant difference between the two groups in terms of the maximum, minimum and excursion knee joint angles. It was observed in figure 3.10 that there was a difference in knee joint angles between the two groups at terminal stance and pre swing phase. A t test revealed that from 50-70% of the gait cycle the knee joint angle for the navigated group was statically significantly higher than the mean knee joint angle for the conventional group. The significance level was set at $p<0.05$. The area of significance was highlighted on the plot by the vertical green lines. The size of the area in which the two surgical groups differ was 20% of the whole function. Up slope showed significant differences between the two surgical groups during a greater percentage of the gait compared to level walking. This increased effect would be expected since 'up slope' walking is more difficult and would require more power and increased knee flexion to propel

the patient up the slope. Therefore improved gait function has a greater impact on this activity.

The non operated gait cycles showed no difference between the 2 surgical groups. When comparing operated and non operated side there was no statistical difference between the two knee kinematics recorded. There was no statistical difference between the maximum knee joint angle recorded (p=0.92), or during each point of the gait cycle.

Down Slope

Figure 3.11 shows the knee joint angles in a typical gait cycle for down slope for the operated and non-operated knee joint.

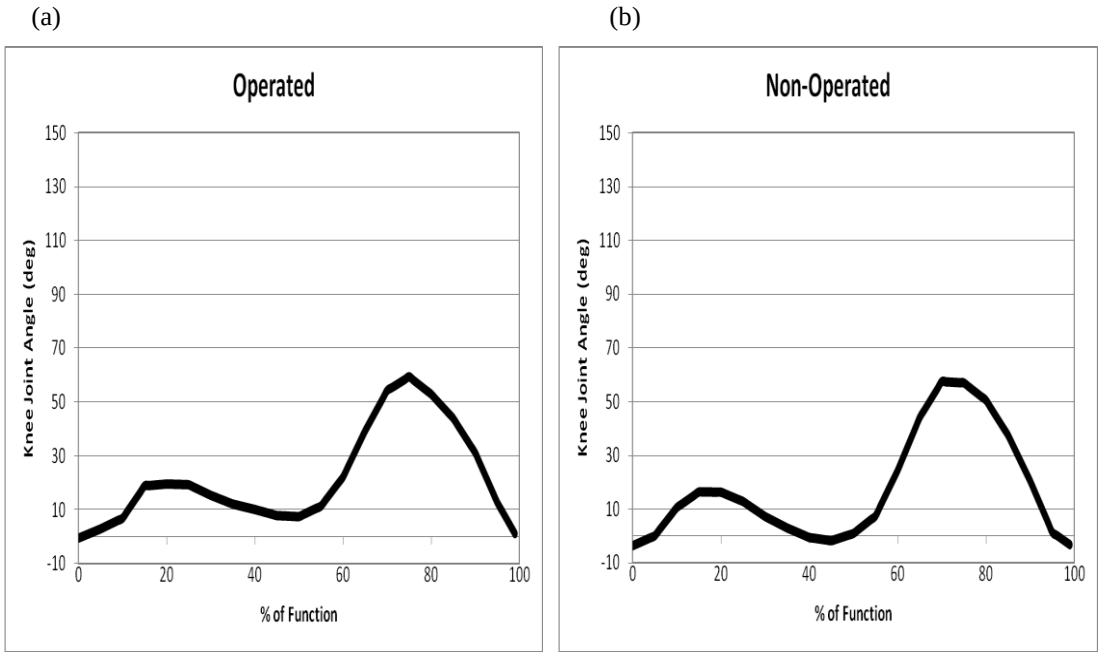


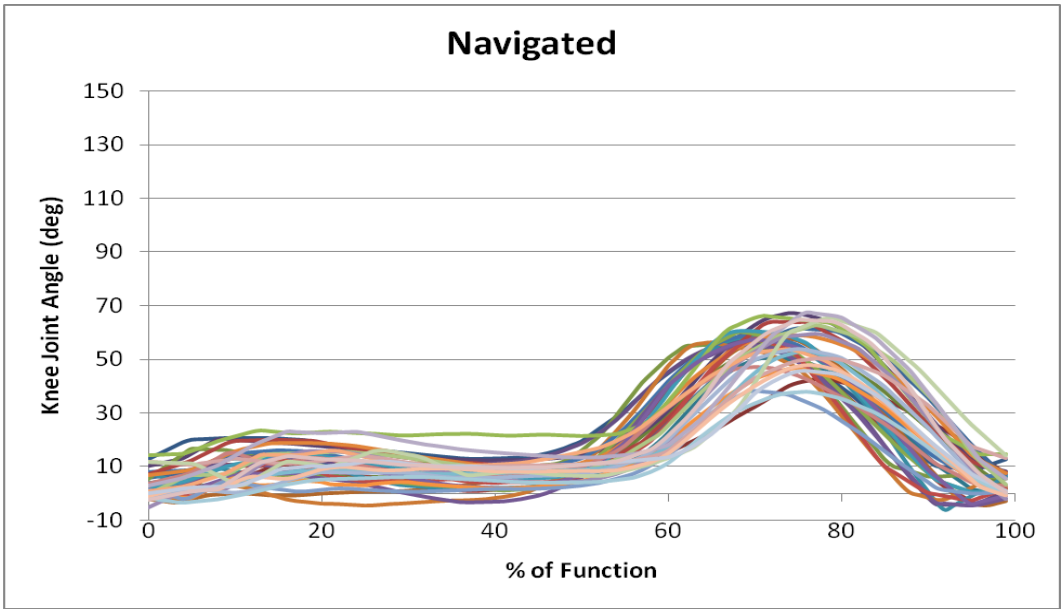
Figure 3.11 Down slope gait cycle normalised for one typical trial patient
(a) Operated knee (b) Non-operated knee

Although the difference was minimal it was seen that at initial stance phase (heel strike) the knee joint was in slight hyper extension for down slope. Another difference observed between 'down slope' and both the 'level' and 'up slope' walking patterns was that in terminal stance phase the 'operated' knee joint did not fully extend to 0^{o}, instead it remains slightly flexed. When walking down a slope the body's center of gravity (COG) has to be lowered therefore if the knee joint remains

flexed at terminal stance phase then the COG descends in a controlled manner during this activity. This mechanism minimises the energy expenditure required to raise and lower the COG.

Figure 3.12 shows the compound graphs for down slope.

(a)



(b)

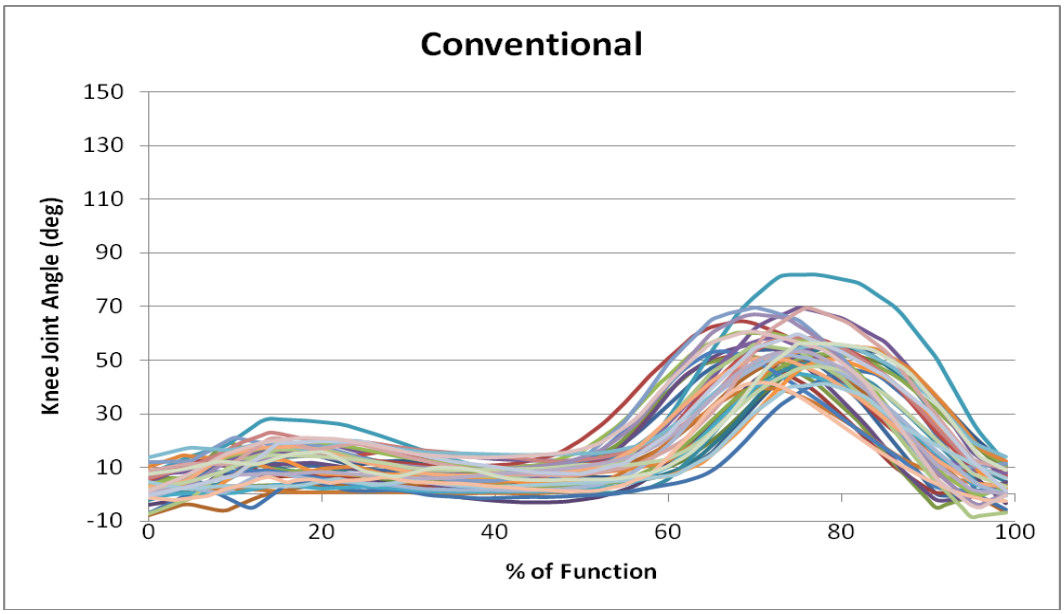
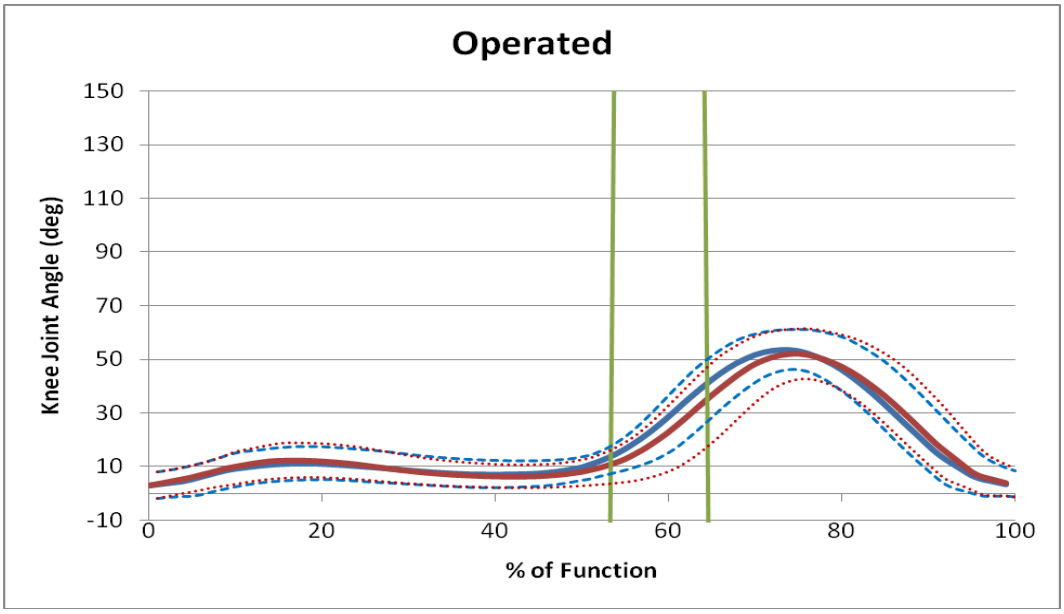


Figure 3.12 Compound plot – Down slope gait cycle normalised

(a) Navigated TKA (b) Conventional TKA

Figure 3.13 shows the average up slope plot for the two surgical groups for the operated and non operated side.

(a)



(b)

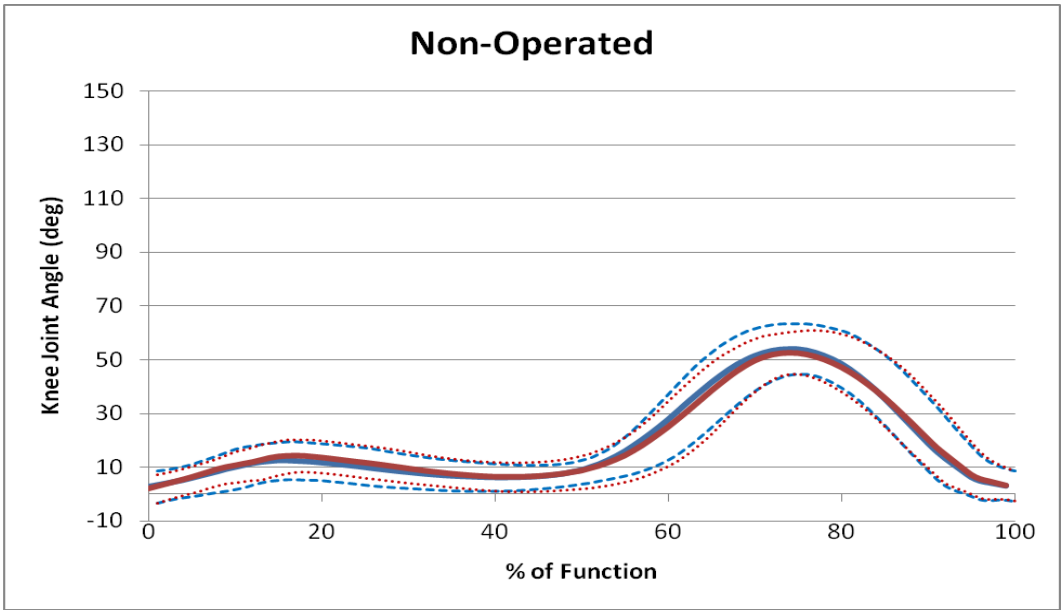


Figure 3.13 Average plots – Down slope gait cycle normalised. Navigated in blue, conventional in red. (a) Operated knee (b) Non-operated knee. Vertical lines show areas of significant difference between the 2 groups.

Figure 3.12 showed one patient had unusually high flexion angles in swing phase compared to the rest of the patient cohort. This patient was in the conventional surgical group. This patient displayed slightly better kinematic function than the rest of the patient group for this particular activity.

Comparing the maximum, minimum and excursion knee flexion angles for the two groups again resulted in no significant difference when using a two sample independent t-test with a significance level of 0.05. The t-test was performed on each percentage time point to look for differences within the cycle. It was identified that there were statistically significantly higher knee flexion angles during terminal stance and initial swing phase ($p<0.05$). This area of significance was indicated on the plots with green vertical lines. The area was between 54-64% of the gait cycle. The percentage of the cycle where differences were observed was the same as that calculated for level walking with a time shift from 55-65% to 54-64%. The percentage of the 'down slope' cycle showed that there were less differences during this activity compared to 'up slope' (50-70%). This would be expected as down slope would require less push off and flexion during pre-swing to clear the ground than either level walking or down slope. Therefore the differences are less apparent when walking down a slope compared to up slope walking.

The non operated gait cycles showed no difference between the 2 surgical groups. When comparing operated and non operated side there was no statistical difference between the two knee kinematics recorded. There was no statistical difference between the maximum knee joint angle recorded ($p=0.76$), or during each point of the gait cycle.

Up Stairs

Figure 3.14 shows the knee joint angles in a typical gait cycle for up stairs for the operated and non-operated knee joint.

(a) (b)

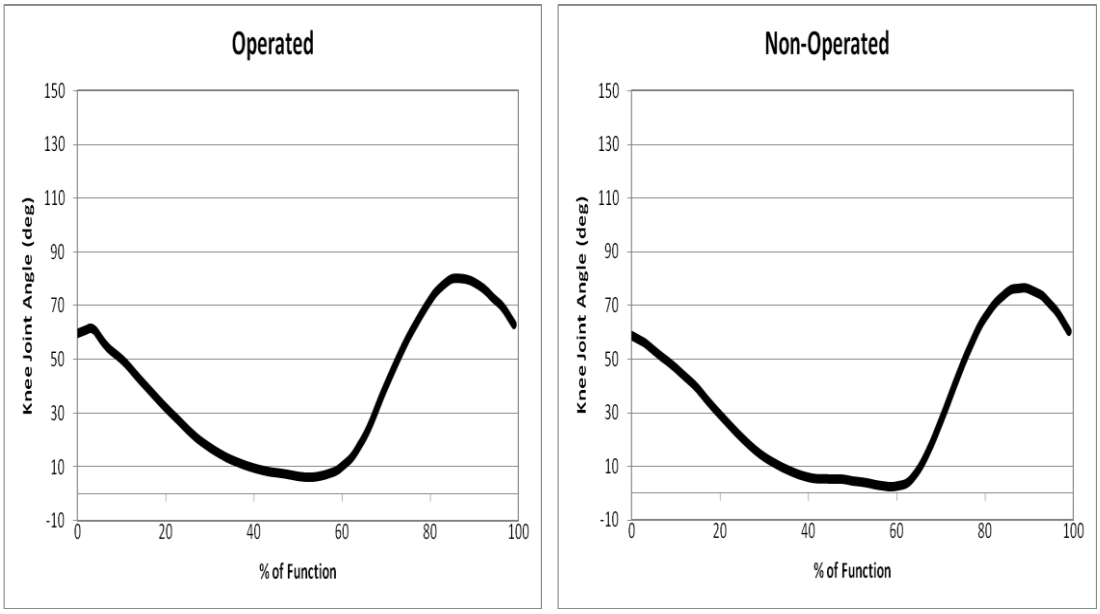


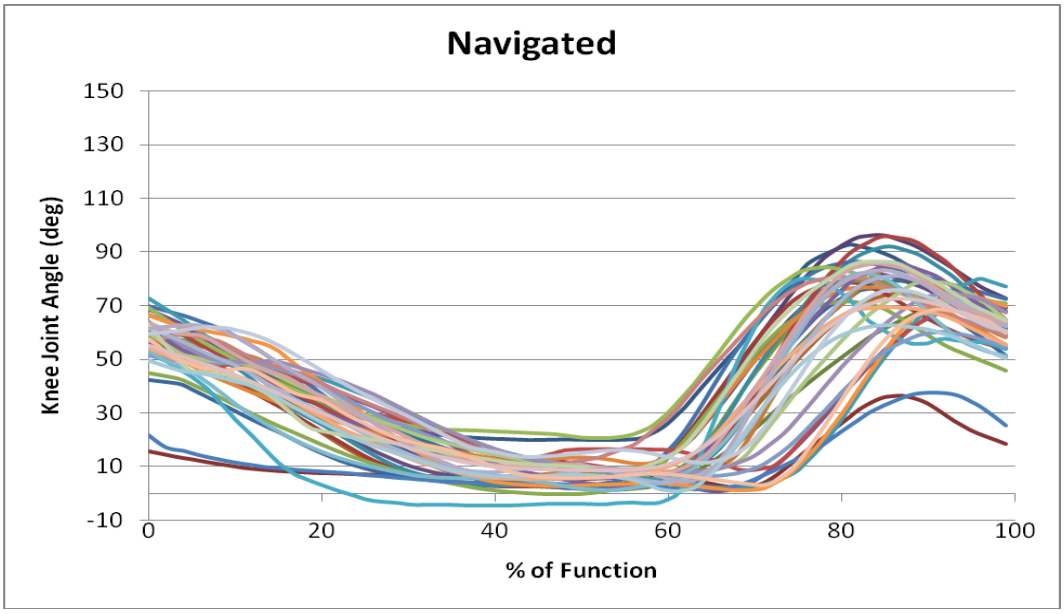
Figure 3.14 Up stairs gait cycle normalised for one typical trial patient
(a) Operated knee (b) Non-operated knee

Stair negotiation is considered a demanding activity by many patients with lower limb problems. Difficulties in stair negotiation prior to surgery in TKA groups results in the presence of a functional limitation. TKA patients with a good functional outcome overcome this limitation and were seen to complete this task with minimal problems. Before surgery there were two problems with the stairs task. Firstly the patient may choose to limit how much they flex the knee joint due to pain. Secondly in some cases a stiff knee means that they cannot flex the knee joint enough to comfortably negotiate stairs normally. This places more reliance on use of the hand rails and eventually forces the patient to change their gait pattern. Normal stair climbing involves only one foot touching each step. An example of step over step is shown in figure 3.14. However an altered method of 'one step at a time' means that the painful knee is lifted up onto each step and never leads the other leg and hence a similar gait pattern is recorded but the maximum flexion angle during the task is lower. Unlike the previous walking cycles, the stair climbing task involves knee flexion (around 60^{o}) at initial stance instead of full extension (figure 3.14). The

knee is then extended to propel the subject up to a higher level and the next step. Finally the knee flexes again in swing phase as it clears the next step.

The compound graphs in figure 3.15 shows variations between patients within the two surgical groups.

(a)



(b)

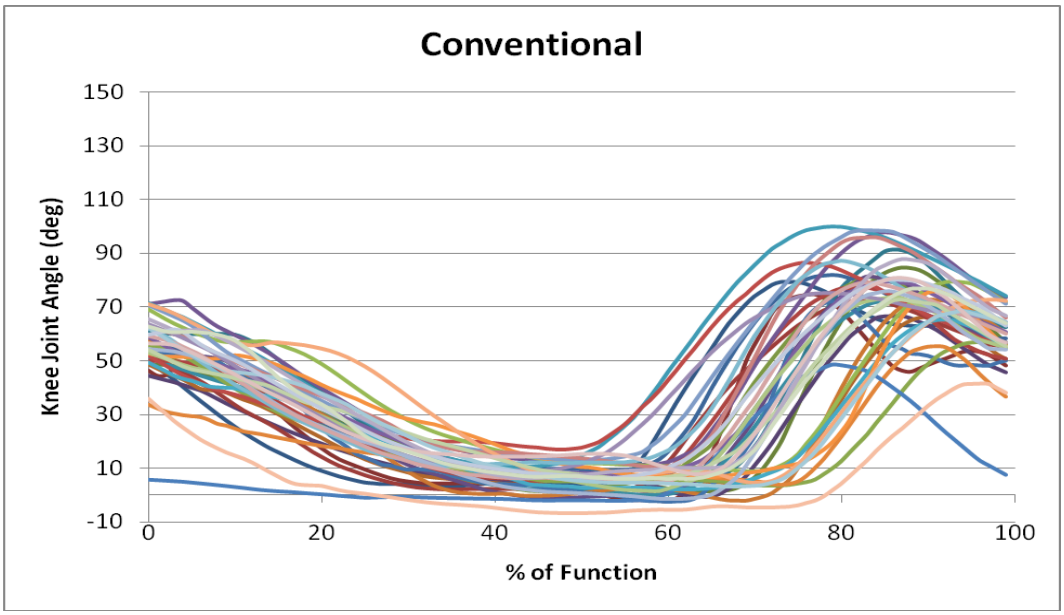
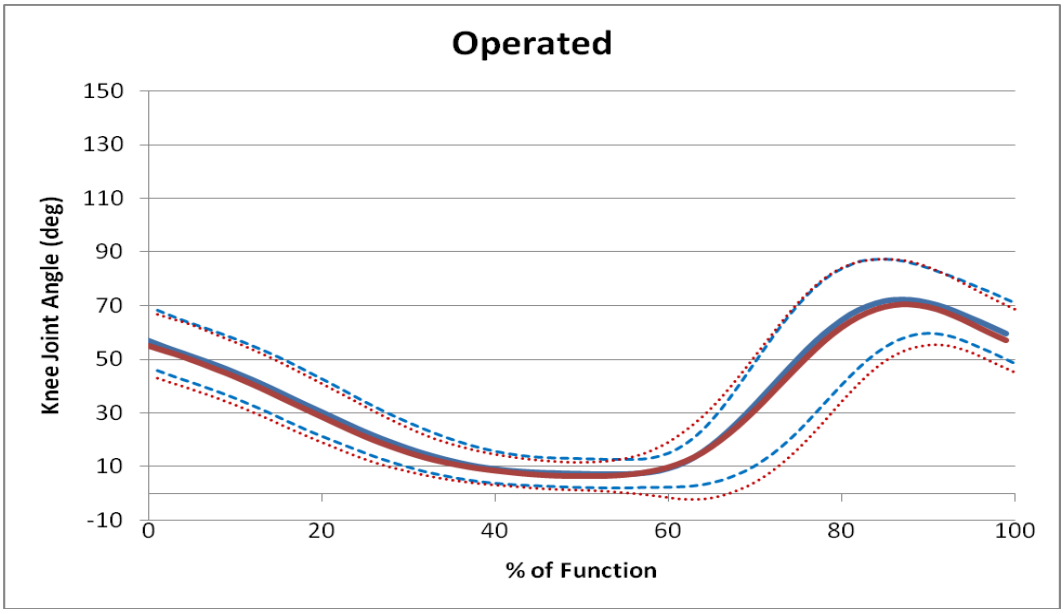


Figure 3.15 Compound plots – Up stairs gait cycle normalised

(a) Navigated TKA (b) Conventional TKA

Figure 3.16 shows the average up stairs plot for the two surgical groups for the operated and non operated side.

(a)



(b)

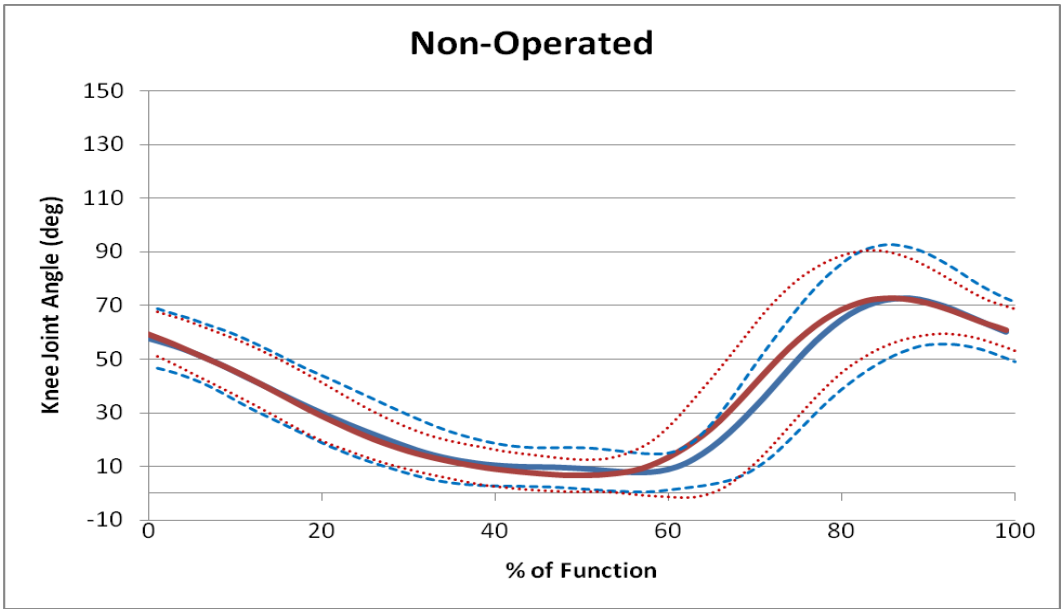


Figure 3.16 Average plots – Up stairs gait cycle normalised. Navigated in blue, conventional in red. (a) Operated knee (b) Non-operated knee

In figure 3.15 the majority of the plots follow the same pattern as that described as a ‘typical’ patient plot in figure 3.14. However a few trial patients were seen to have significantly lower flexion angles at 0% and 100% of the cycle. These illustrate the trial patients who walk one step at a time due to reasons such as pain or lack of confidence.

Due to the fact that there were only a few of these patients in each group they have been included in the average plots. However they could also be classed as outliers as they significantly alter the mean maximum flexion angles. However, not including these patients in the mean plots would result in selection bias. Altered gait pattern was not an exclusion factor but it has to be considered when these results are compared to those in literature, as they may not include patients with poor function and altered gait patterns.

The outliers result in a non Gaussian distribution, therefore a Mann Whitney U test was used to compare the maximum and excursion knee angle for the two surgical groups. There were no statistical differences in these parameters between the two groups. The minimum knee joint angle was found to be normally distributed. A two sample independent t-test found no statistical different between the two groups for this parameter. On observation the mean plots were alike in shape and magnitude throughout the function cycle. Therefore unlike the walking cycles there were no areas of significant differences between the two groups.

The non operated gait cycles showed no difference between the 2 surgical groups. When comparing operated and non operated side there was no statistical difference between the two knee kinematics recorded. There was no statistical difference between the maximum knee joint angle recorded ($p=0.73$), or during each point of the gait cycle.

Down Stairs

Figure 3.17 shows the knee joint angles in a typical gait cycle for down stairs for the operated and non-operated knee joint.

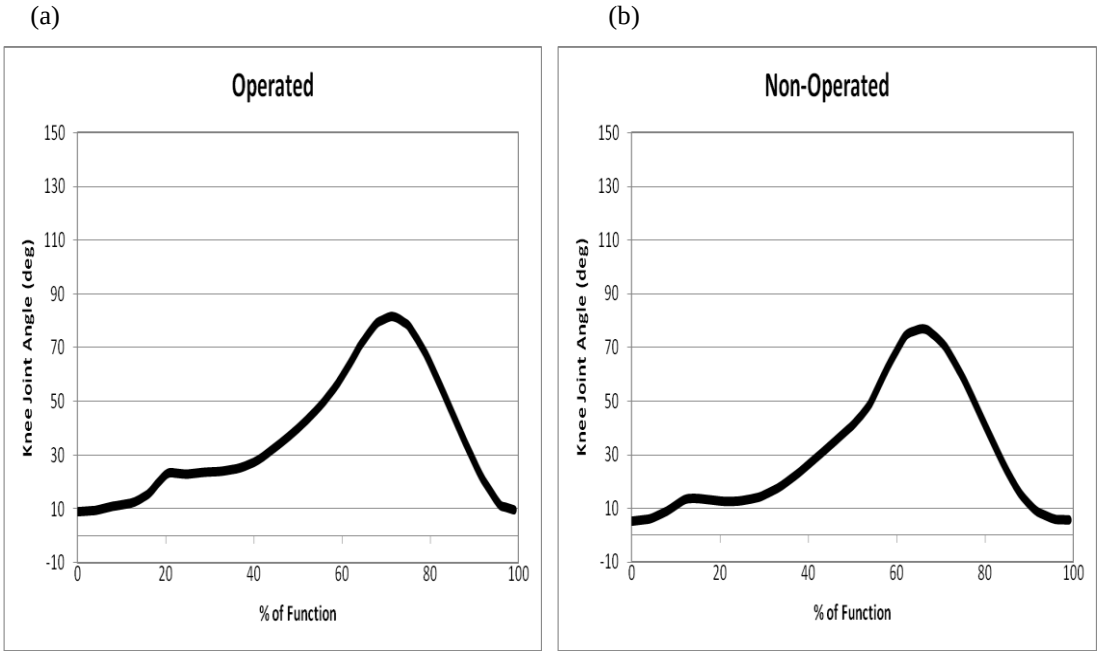
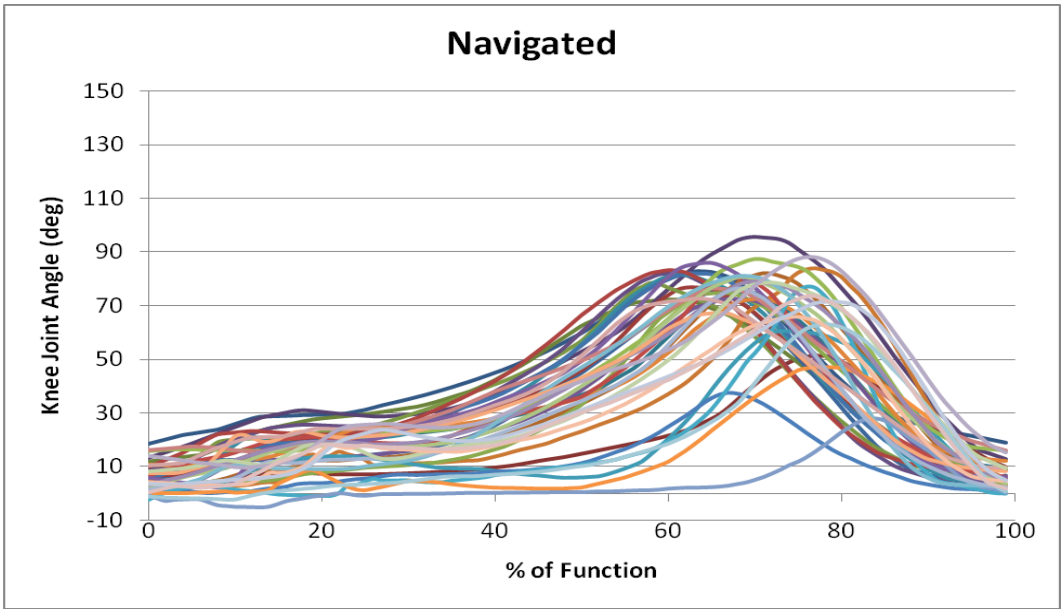


Figure 3.17 Down stairs gait cycle normalised for one typical trial patient
(a) Operated knee (b) Non-operated knee

Stair descent shows a similar basic pattern to walking cycles. However this activity does have significant differences. Firstly the required maximum knee joint flexion angle was significantly higher at around 80^{o}. Also, in walking cycles the general stance phase pattern includes an increase in knee joint angle which is followed by extension of the lower limb and then the knee flexes as it enters into swing phase. The knee joint in stair descent was seen to increase in stance, level off slightly then increase into swing phase. Therefore there was an absence in a return to full or near full extension which means that the initial swing phase knee angle was found to be higher than in walking activities.

The compound graphs in figure 3.18 shows the two surgical group's patient down stairs gait cycles.

(a)



(b)

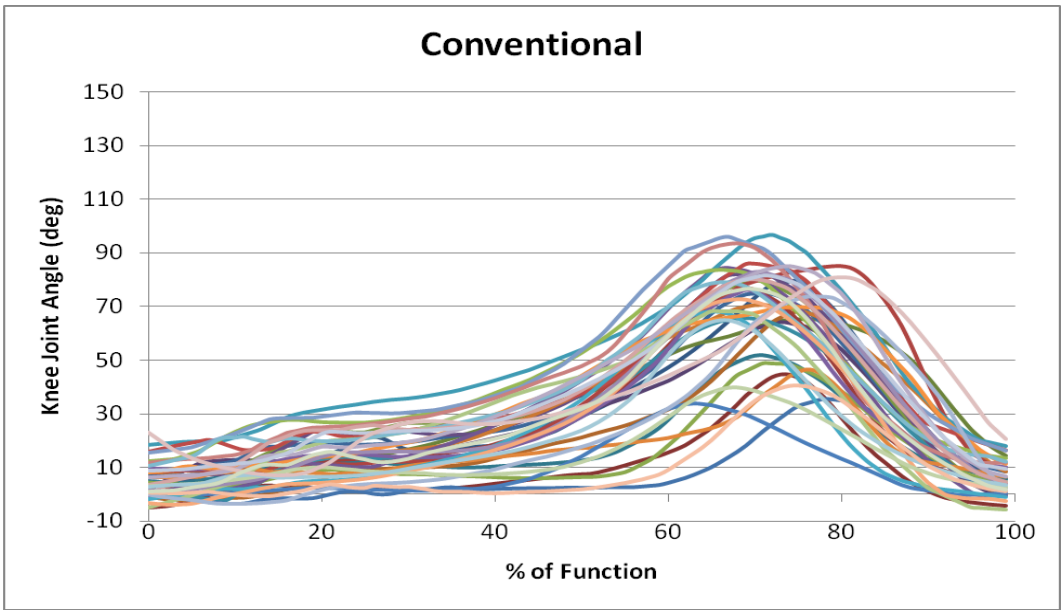
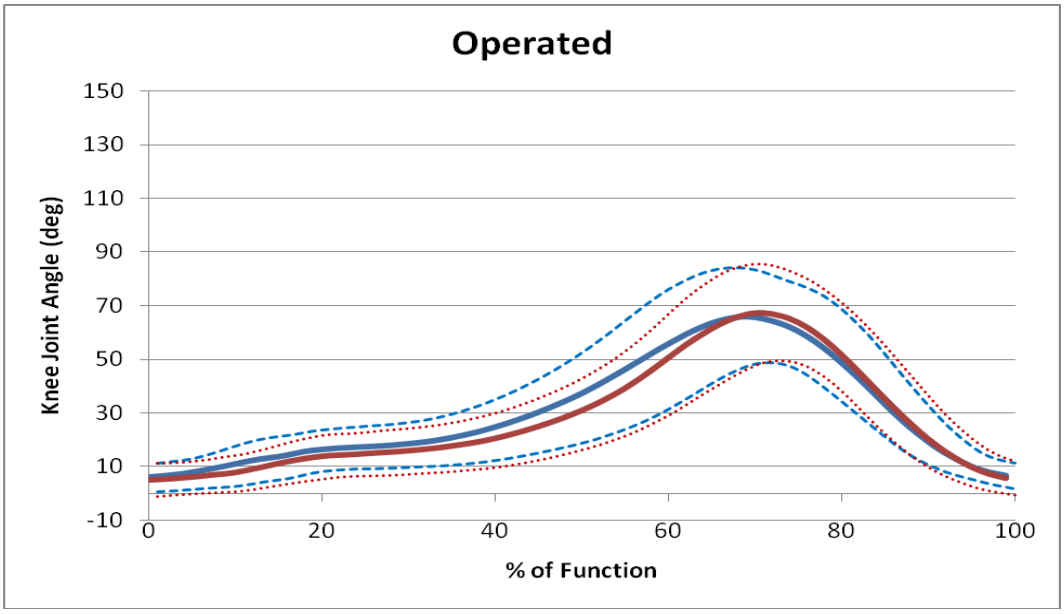


Figure 3.18 Compound plots – Down stairs gait cycle normalised
(a) Navigated TKA (b) Conventional TKA

Figure 3.19 shows the average down stairs plot for the two surgical groups for the operated and non operated side.

(a)



(b)

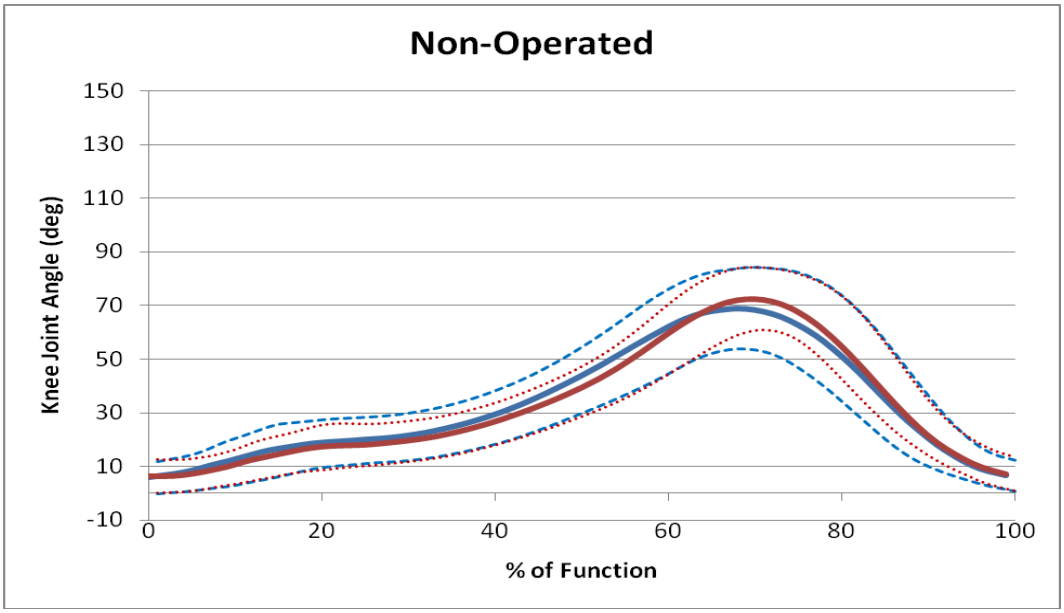


Figure 3.19 Average plots – Down Stairs gait cycle normalised. Navigated in blue, conventional in red. (a) Operated knee (b) Non-operated knee

The compound plots in figure 3.18 illustrate the variations in magnitude of the swing phase knee flexion angle. It shows that more patients change to a method of one step at a time during stairs descent than during the stair ascent task. The kinematic pattern for the trial patients who walked one step at a time was similar to that of someone descending the staircase 'normally'. However there was a significant difference in magnitude of the maximum flexion angle recorded during both stance and swing phase. The presence of the 'one step at a time' sub group with lower flexion angles, lowers the mean maximum flexion angle in the average plots shown in 3.19.

As the data for maximum and excursion knee flexion angles was distribution free, therefore a Mann Whitney U test was used to compare the two surgical groups. No statistically significant differences were found for these parameters. The minimum knee joint angle was normally distributed. A two sample independent t-test found no statistical different between the two groups for this parameter. Since patients with both walking patterns for descending stairs were found in both surgical groups the presence of two stair descent methods did not result in significant difference between the group plots.

On observation of the operated and non operated mean plots the kinematic pattern was similar for the two groups. There were subtle differences between the magnitudes of the knee flexion angles at 40-60% of the cycle where the navigated group recorded a higher knee joint angle. The differences failed to reach significance when the level was set at 0.05.

The non operated gait cycles showed no difference between the 2 surgical groups. When comparing operated and non operated side there was no statistical difference between the two knee kinematics recorded. There was no statistical difference between the maximum knee joint angle recorded ($p=0.31$). However there was a statistical difference between the operated and non operated group at 10-65% of the gait cycle. Therefore the knee joint angles during stance phase were significantly increased in the non operated knee joint. As mentioned previously, down stairs is a high impact activity which has two methods i.e. step over step or one step at a time. 11 patients walked one step at a time. In these cases their non operated maximum knee flexion angle was statistically significantly higher than the operated

knee flexion angle. There was no patients who had a statistically significantly lower maximum knee joint angle in the non operated group. If these patients were removed from the analysis then there was no statistical difference between the operated and non operated sides in the remaining patients.

Stand-Sit-Stand Activity

The stand-sit and sit-stand traces are essentially mirror images of one another. The heights of the two chairs vary in that the high chair height was 500mm and the low chair height was 300mm with a soft cushion with a height of 120mm. The lower chair required more power/energy to be exerted to raise the body to standing. It also was associated with higher knee joint flexion angles.

High Chair Stand-Sit

Figure 3.20 shows the knee joint angles in a typical function cycle for high chair stand to sit for the operated and non-operated knee joint.

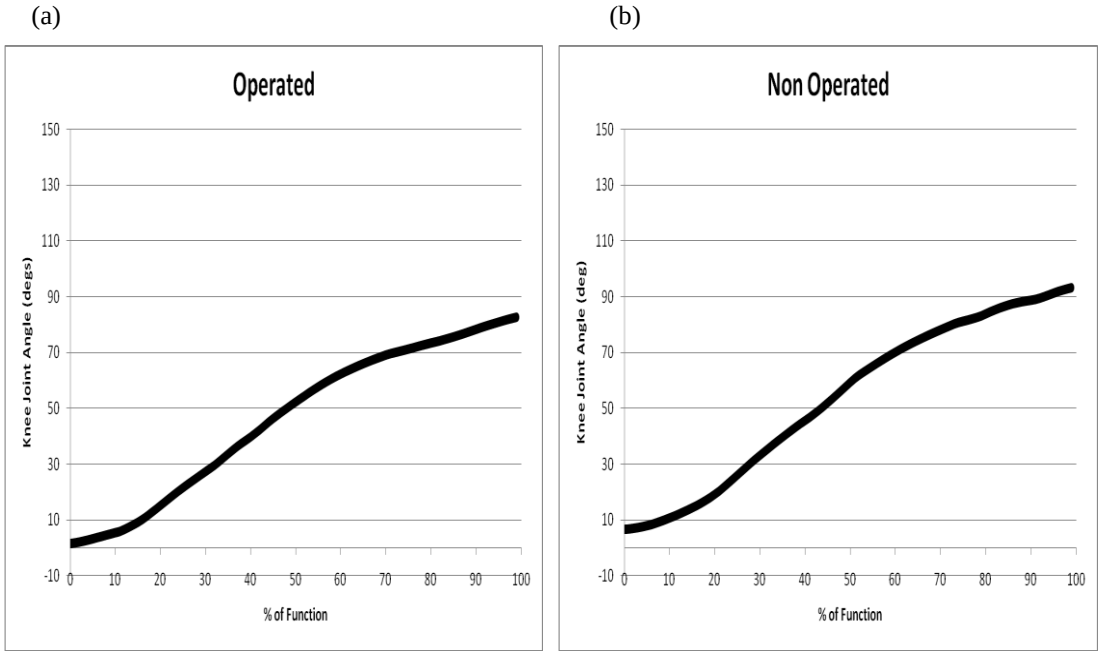
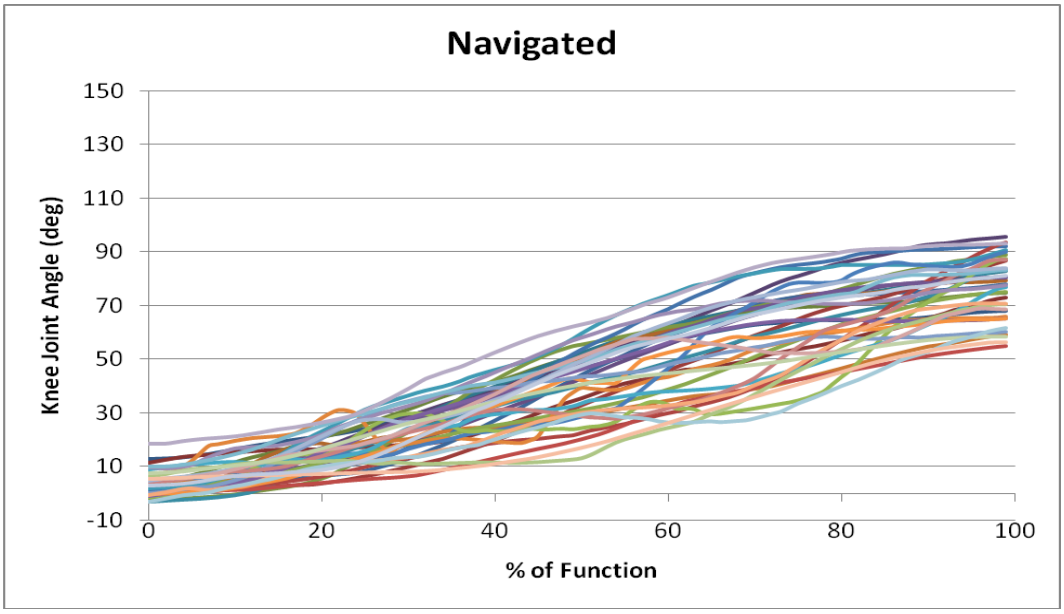


Figure 3.20 High chair stand to sit cycle normalised for one typical trial patient
(a) Operated knee (b) Non-operated knee

Stand to sit activity starts with the patient standing with their knee joints extended. The start (0%) point in this function was around 0-5^{o} of flexion. The knees were then quickly flexed to lower the upper body to a seated position. Figure 3.20 shows that this patient flexed their operated knee to about 85^{o} and their non operated knee flexed to just over 90^{o}. Generally both knees were flexed to within 5-10^{o} of each other.

Figure 3.21 shows compound plots for the entire navigated group for high chair stand to sit on one graph and the entire conventional group on a separate graph.

(a)



(b)

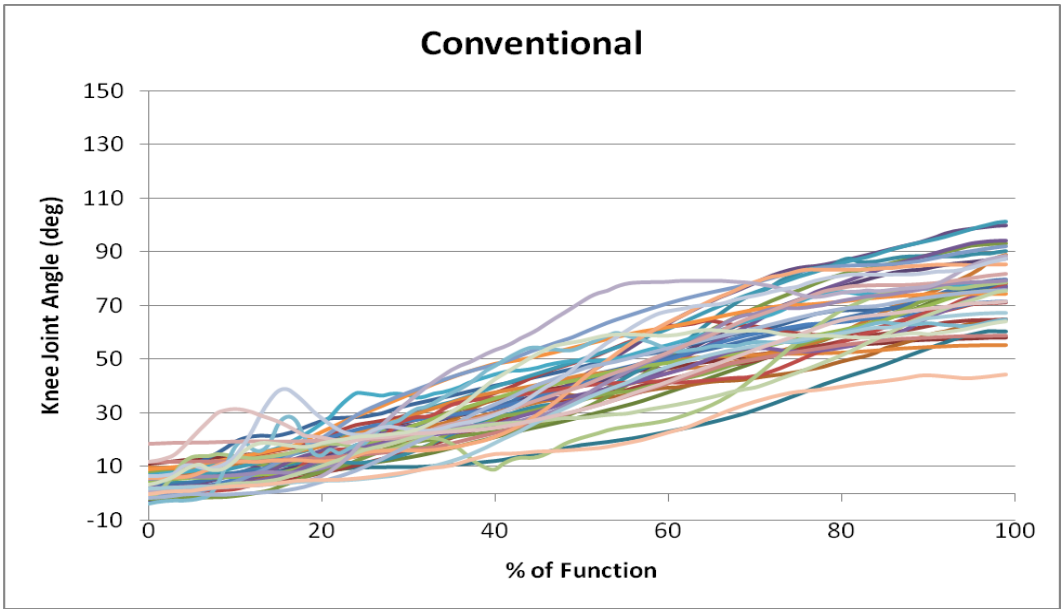
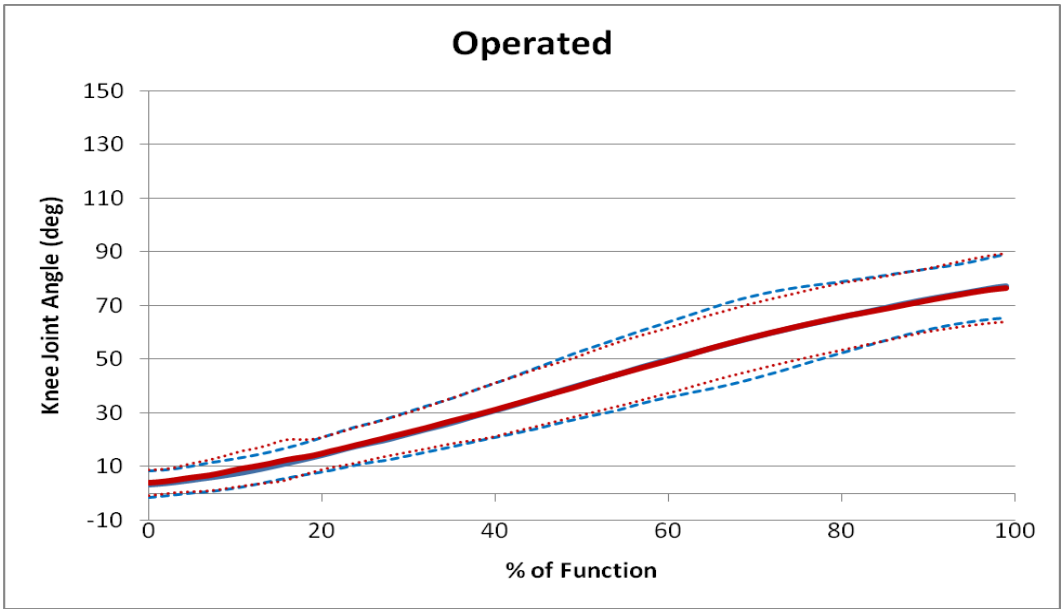


Figure 3.21 Compound plots – High chair, stand to sit cycle normalised
(a) Navigated TKA (b) Conventional TKA

Figure 3.22 shows the average high chair stand to sit plot for the two surgical groups for the operated and non operated side.

(a)



(b)

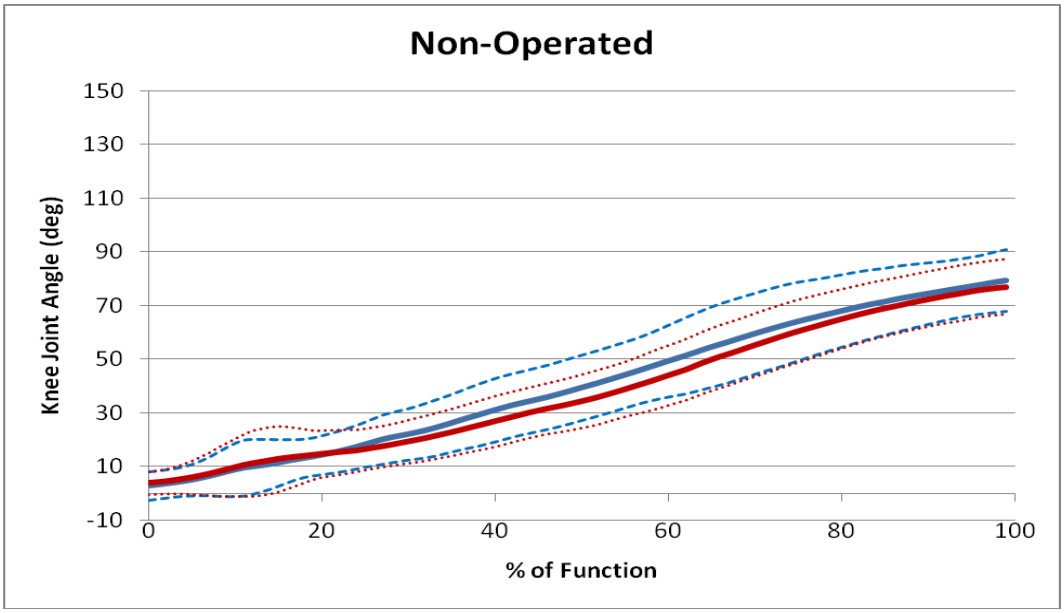


Figure 3.22 Average plots – High chair, stand to sit cycle normalised. Navigated in blue, conventional in red. (a) Operated knee (b) Non-operated knee

Figure 3.21 illustrated the variations observed within the stand to sit activity. The start and end flexion point varied between patients within both the navigated and the conventional surgical groups. The standing point (0% of function) was recorded as between 0-10^{o} of flexion with a few patients starting in hyper extension demonstrated by a negative flexion angle. For the majority of patients the movement from standing to a seated position was smooth. However the compound plot in figure 3.21 shows that some patients did not complete the function in a smooth flexion movement. Some of the patients used the arm rests to stabilise themselves during this movement. This means that the initial flexion was quick but the patient then slowly lowered themselves down during the final section of the function using upper body strength to control the movement.

The average plots for the two surgical groups show that there are minimal differences between the group plots. A two sample independent t-test was used to compare the maximum, minimum and excursion knee flexion angles of the two surgical groups. No statistically significant differences were found for these parameters, nor were there any differences found across the movement cycle as a whole.

The non operated gait cycles showed no difference between the 2 surgical groups. When comparing operated and non operated side there was no statistical difference between the two knee kinematics recorded. There was no statistical difference between the maximum knee joint angle recorded ($p=0.78$), or during each point of the gait cycle.

High Chair Sit-Stand

Figure 3.23 shows the knee joint angles in a typical function cycle for high chair stand to sit for the operated and non-operated knee joint.

(a) (b)

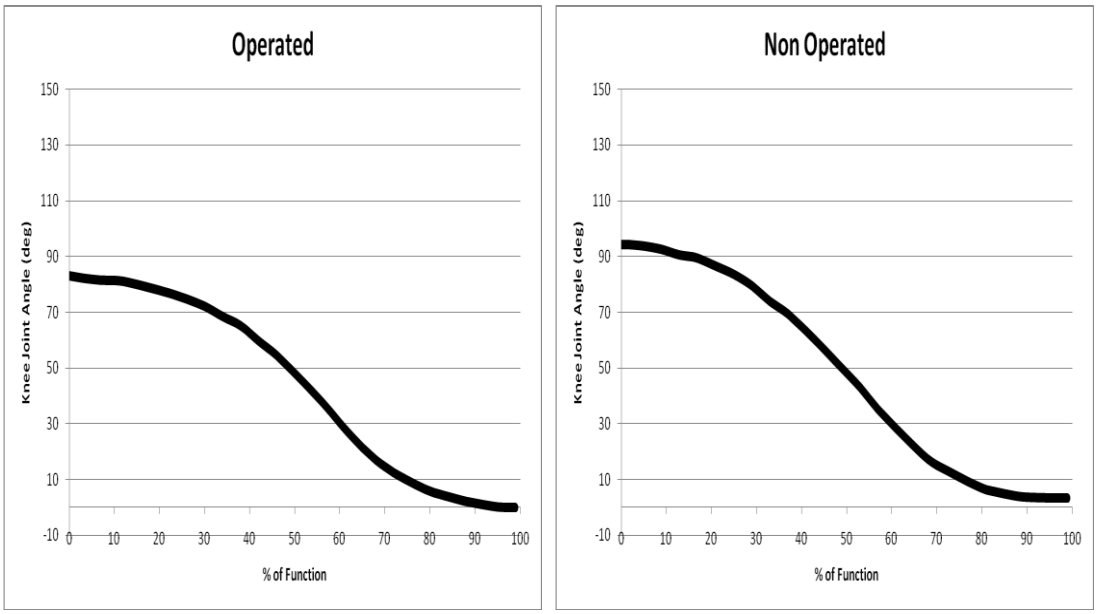
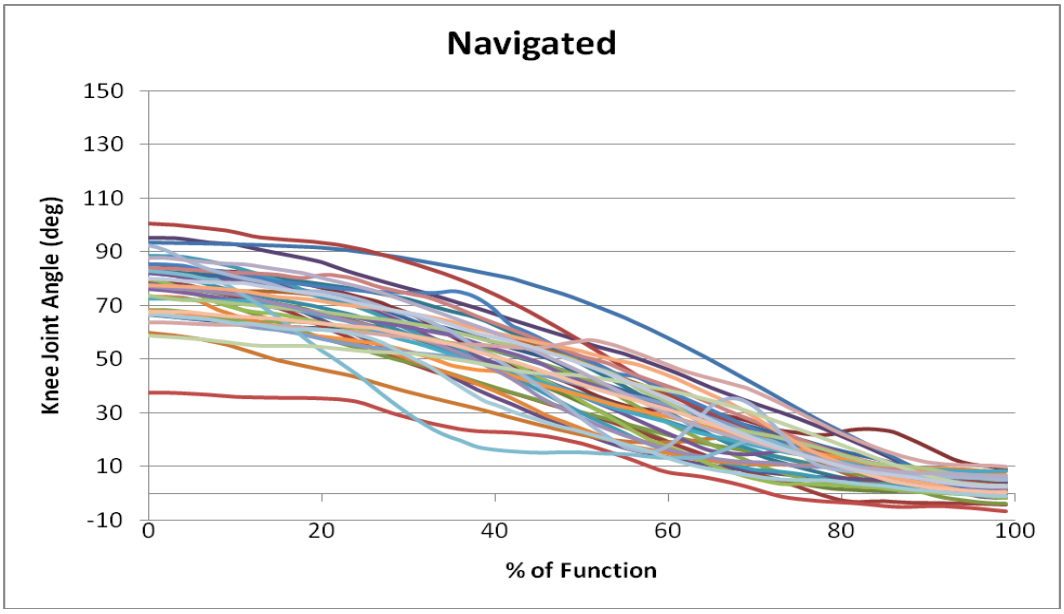


Figure 3.23 High chair sit to stand cycle normalised for one typical trial patient
(a) Operated knee (b) Non-operated knee

The sit to stand activity was the previous task in reverse. Therefore the knee joints started in a flexed position and were extended to raise the patient up off the chair to a standing position.

Figure 3.24 shows compound plots for the entire navigated group for high chair sit to stand on one graph and the entire conventional group on a separate graph.

(a)



(b)

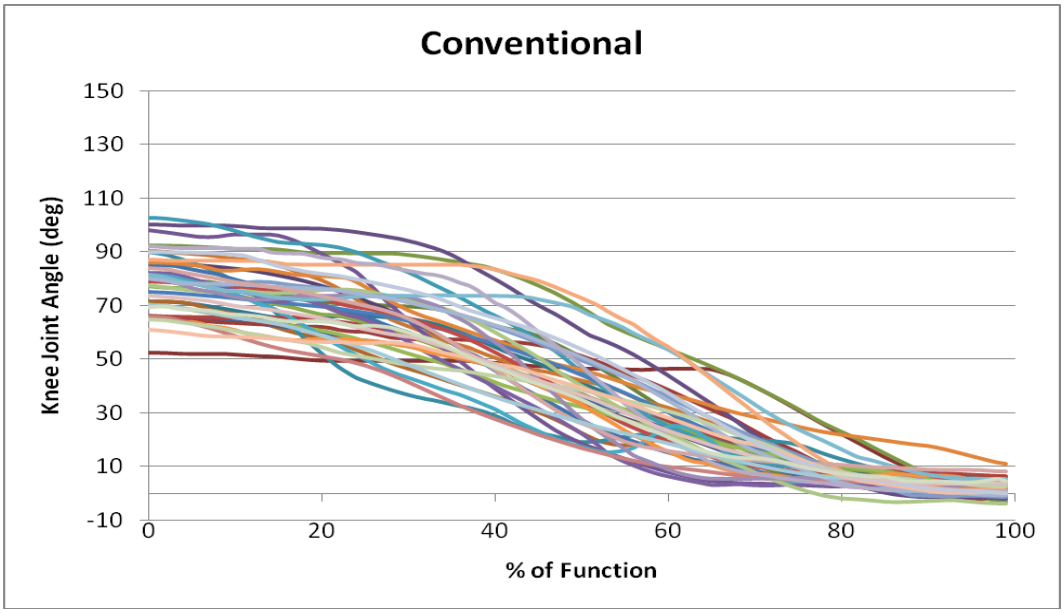
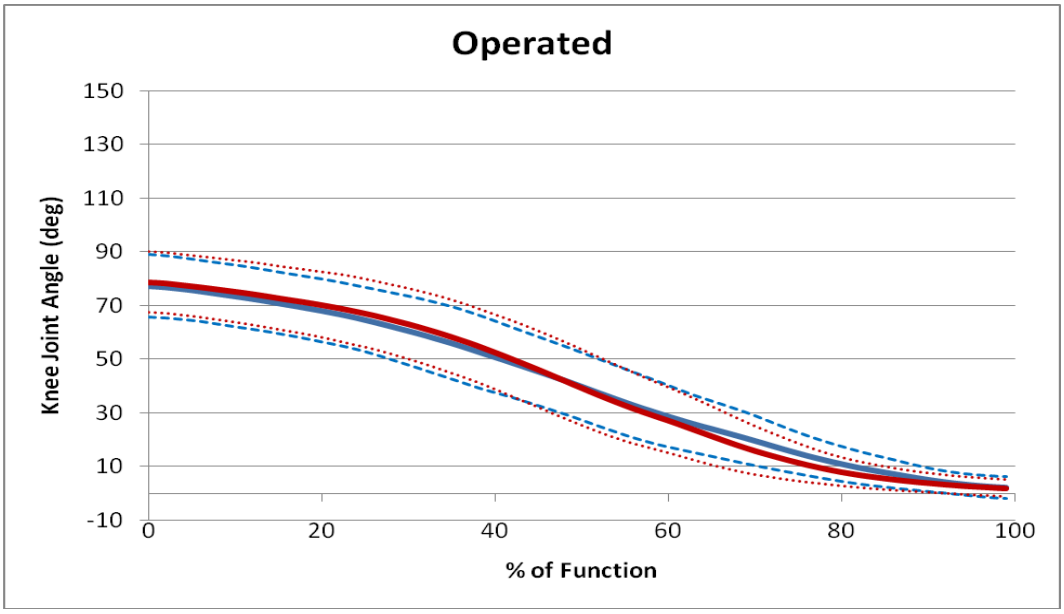


Figure 3.24 Compound plots – High chair, sit to stand cycle normalised
(a) Navigated TKA (b) Conventional TKA

Figure 3.25 shows the average high chair sit to stand plot for the two surgical groups for the operated and non operated side.

(a)



(b)

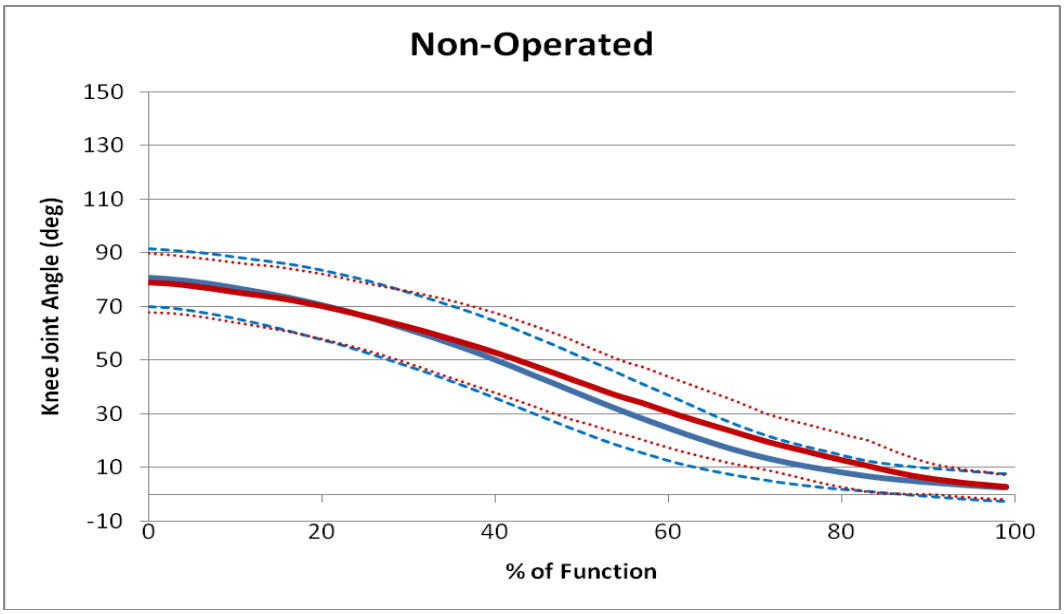


Figure 3.25 Average plots – High chair, sit to stand cycle normalised. Navigated in blue, conventional in red. (a) Operated knee (b) Non-operated knee

Figure 3.24 illustrated the variations observed within the sit to stand activity. The start and end flexion point varied between patients within both the navigated and the conventional surgical groups. Again some of the patients used the arm rests. The arm rest this time were used to push the patient out of the chair to a standing position. In these cases the patient limited their knee flexion angle and used a smaller range of motion for the movement.

Observation of the average plots for this functional activity does not show any major differences in the function cycle. The data was normally distributed and a two sample independent t-test was used to compare the maximum, minimum and excursion knee flexion angles of the two surgical groups. No statistically significant differences were found for these parameters, nor were there any differences found across the movement cycle as a whole.

The non operated gait cycles showed no difference between the 2 surgical groups. When comparing operated and non operated side there was no statistical difference between the two knee kinematics recorded. There was no statistical difference between the maximum knee joint angle recorded ($p=0.93$), or during each point of the gait cycle.

Low Chair Stand-Sit

Figure 3.26 shows the knee joint angles in a typical function cycle for low chair stand to sit for the operated and non-operated knee joint.

(a) (b)

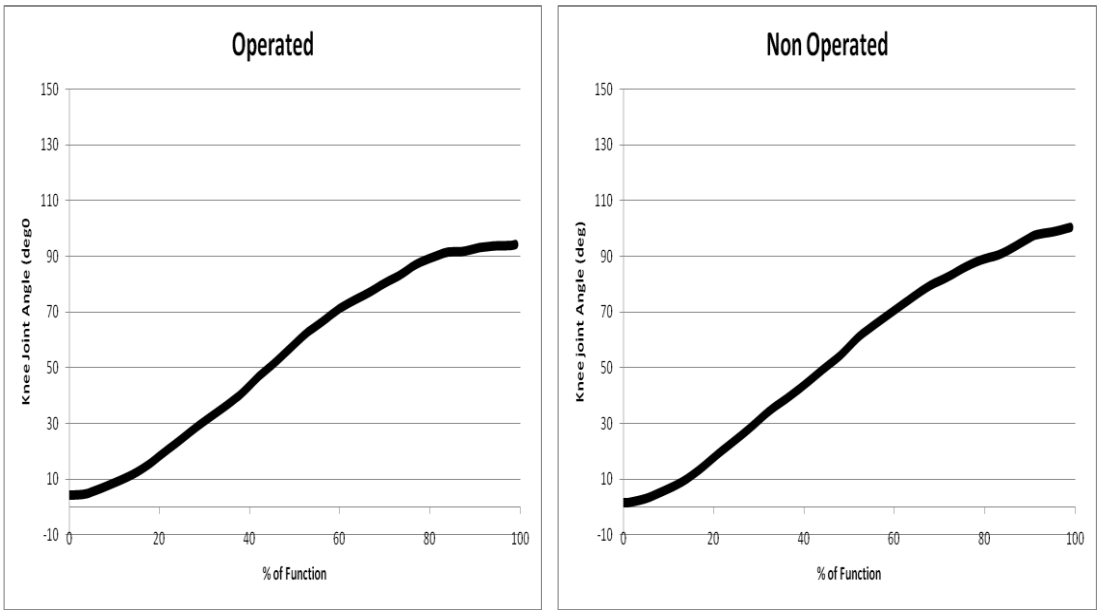
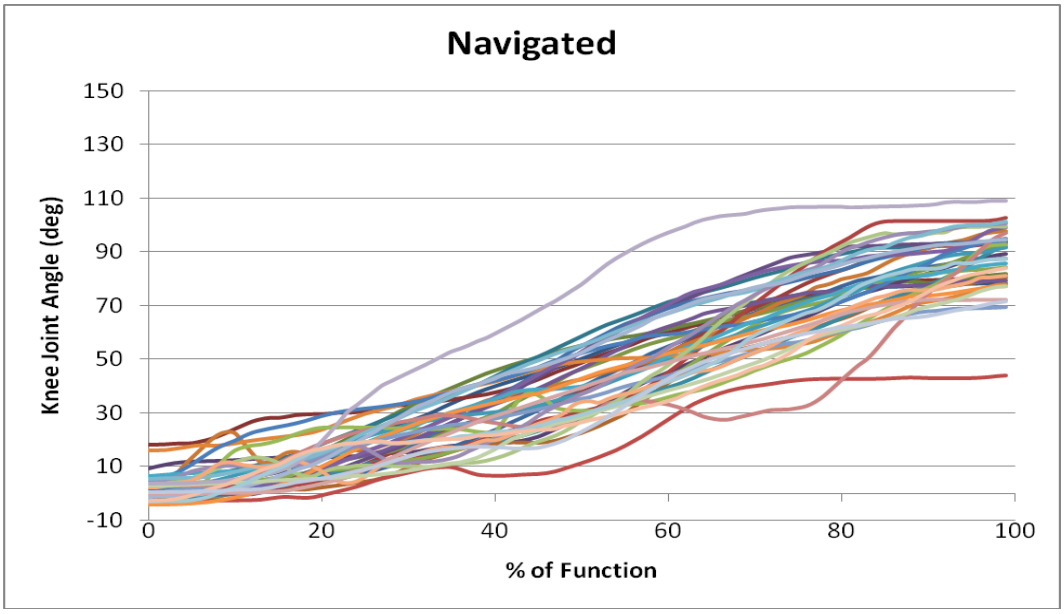


Figure 3.26 Low chair stand to sit cycle normalised for one typical trial patient
(a) Operated knee (b) Non-operated knee

The kinematic pattern for the low chair stand to sit activity was as expected similar to that recorded from the high chair. The difference between the two activities was the flexion excursion required to complete the activity. The lower chair required an increase in the flexion angle. The difference in excursion values between the high and low chair was about for most of the trial patients 10^{o}.

Figure 3.27 shows compound plots for the entire navigated group for low chair stand to sit on one graph and the entire conventional group on a separate graph.

(a)



(b)

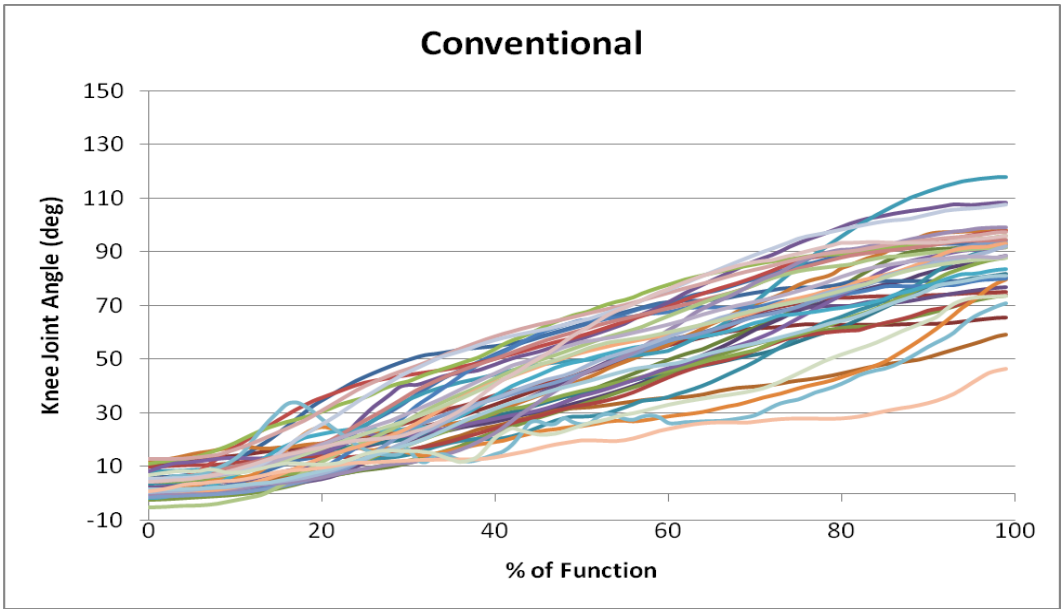
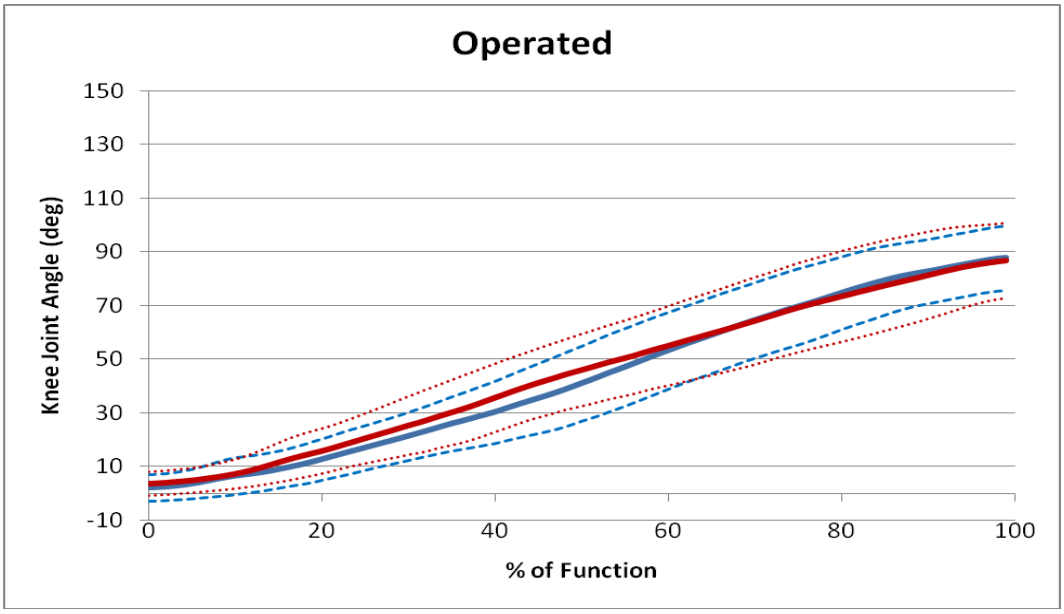


Figure 3.27 Compound plots – Low chair, stand to sit cycle normalised
(a) Navigated TKA (b) Conventional TKA

Figure 3.28 shows the average low chair stand to sit plot for the two surgical groups for the operated and non operated side.

(a)



(b)

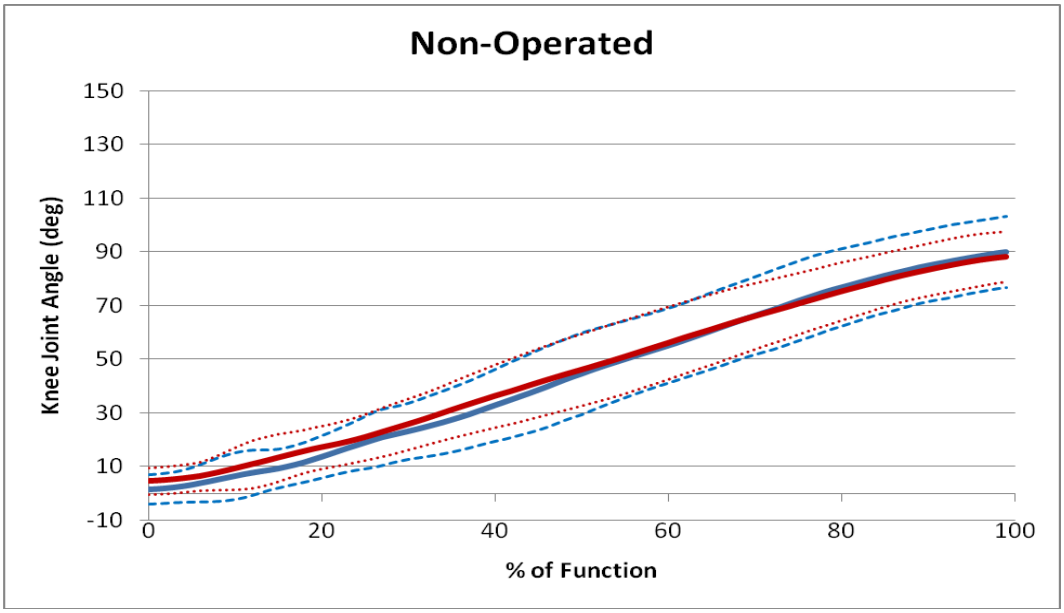


Figure 3.28 Average plots – Low chair, stand to sit cycle normalised. Navigated in blue, conventional in red. (a) Operated knee (b) Non-operated knee

The plots in figure 3.27 show that the standing point, 0% of the function was recorded as 0-10^{o} of knee flexion with a few patients starting in hyper extension. For the majority of patients the movement from standing to a seated position was smooth. The low chair required higher knee flexion angles, therefore this was a more difficult activity to complete for the majority of the trial patients. Many of the patients used the arm rests to stabilise themselves during this movement.

The average plots for the two surgical groups on observation showed minimal differences between the group plots. Again a two sample independent t-test was used to compare minimum knee flexion angles of the two surgical groups. No statistically significant differences were found for this parameter. Since the maximum and excursion knee flexion angle data was distribution free then Mann Whitney U tests was used, but no statistically significant differences were found for these parameters nor were there any differences found across the movement cycle as a whole.

The non operated gait cycles showed no difference between the 2 surgical groups. When comparing operated and non operated side there was no statistical difference between the two knee kinematics recorded. There was no statistical difference between the maximum knee joint angle recorded ($p=0.81$), or during each point of the gait cycle.

Low Chair Sit-Stand

Figure 3.29 shows the knee joint angles in a typical function cycle for low chair stand to sit for the operated and non-operated knee joint.

(a) (b)

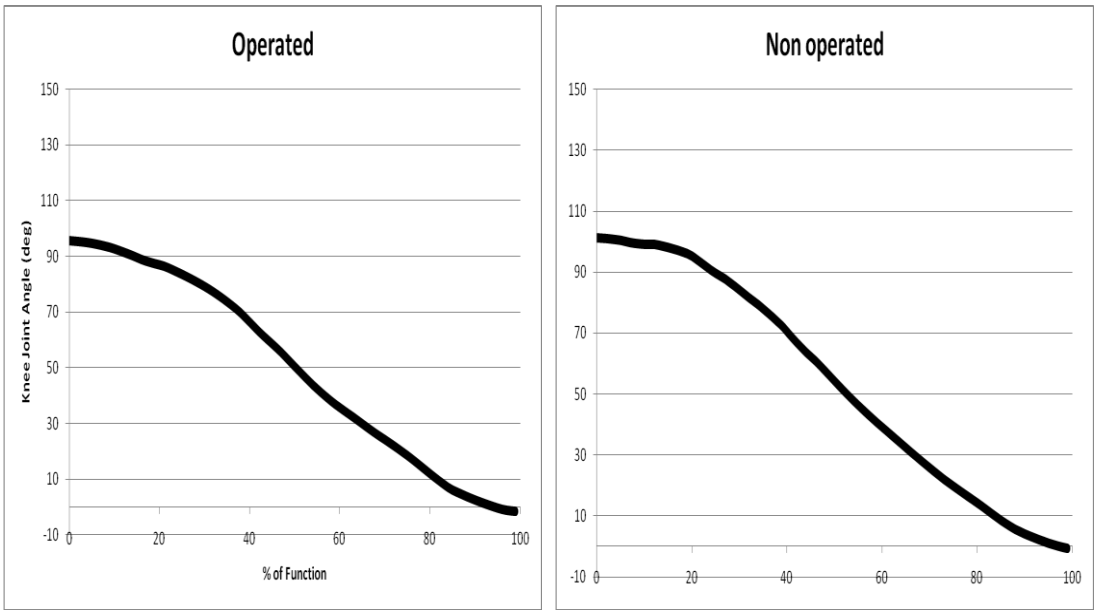
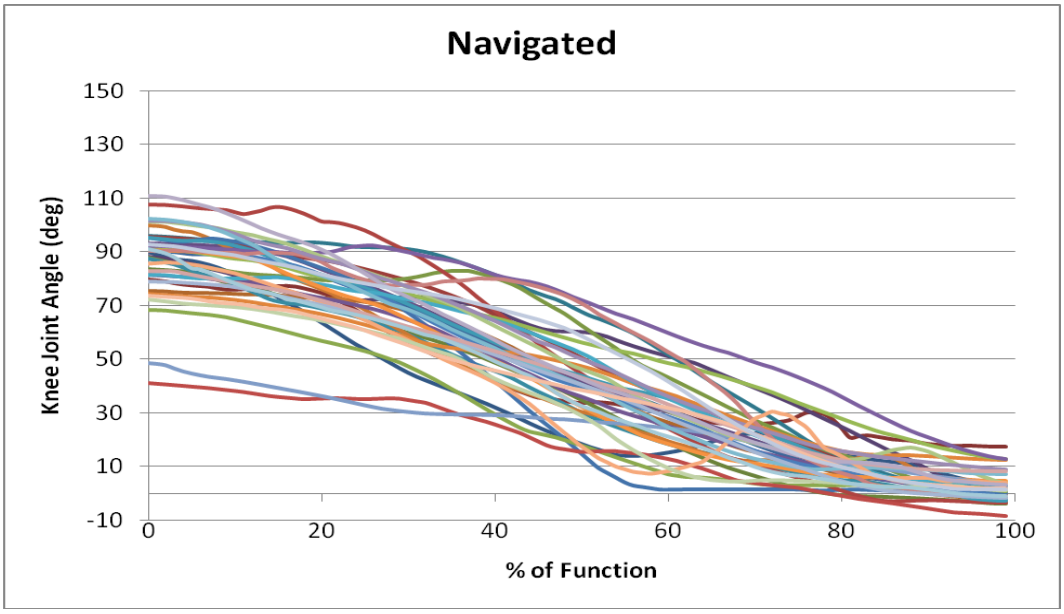


Figure 3.29 Low chair sit to stand cycle normalised for one typical trial patient
(a) Operated knee (b) Non-operated knee

Again the kinematic pattern for sit to stand activity for the low chair was similar to the sit to stand using a high chair. The difference between the two activities was the flexion excursion required to complete the activity. The lower chair required an increase in the flexion angle.

Figure 3.30 shows compound plots for the entire navigated group for low chair sit to stand on one graph and the entire conventional group on a separate graph.

(a)



(b)

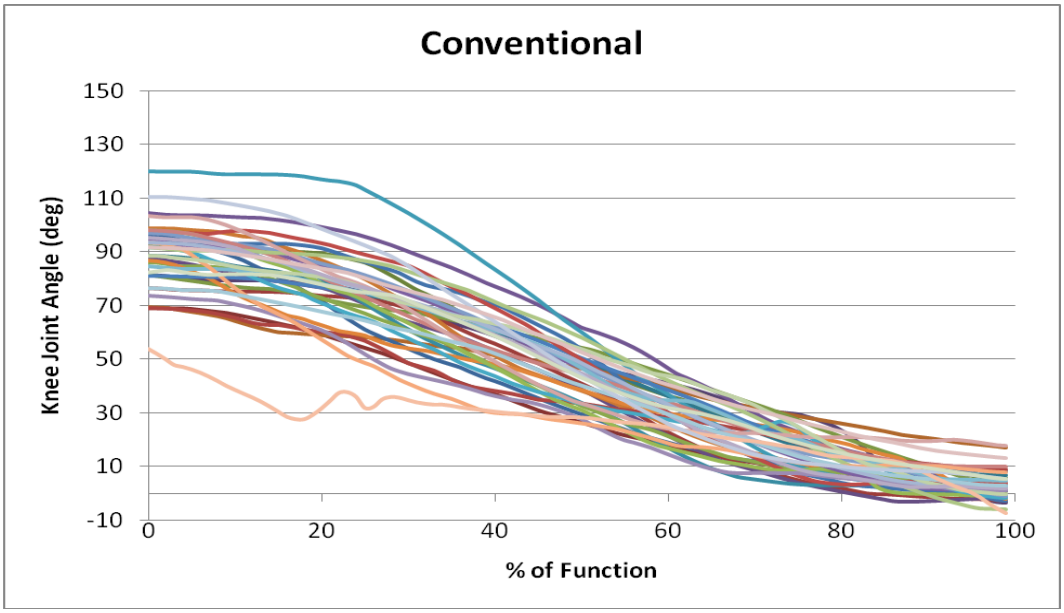
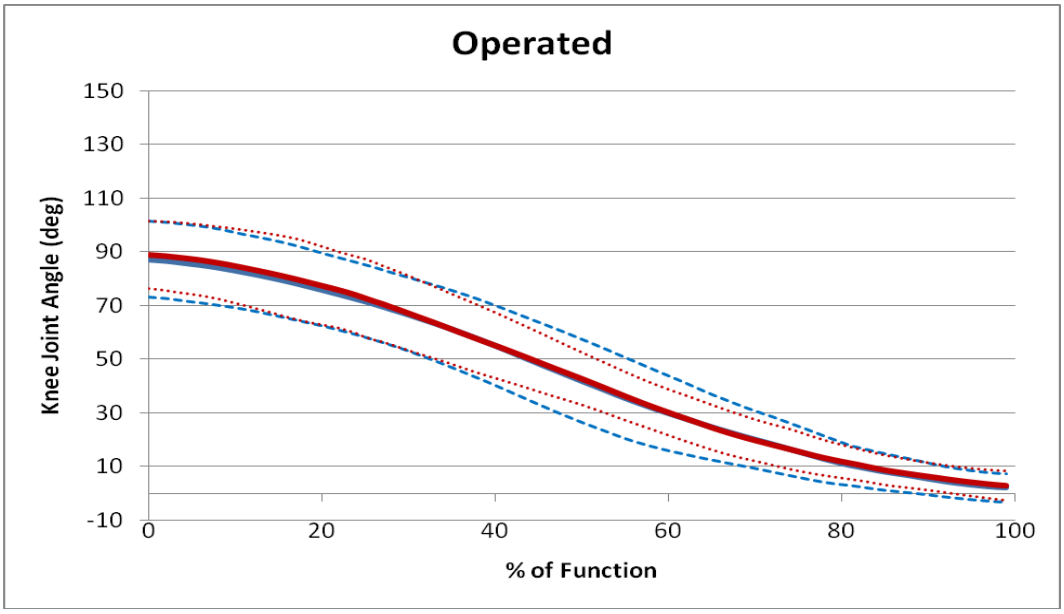


Figure 3.30 Compound plots – Low chair, sit to stand cycle normalised
(a) Navigated TKA (b) Conventional TKA

Figure 3.31 shows the average low chair sit to stand plot for the two surgical groups for the operated and non operated side.

(a)



(b)

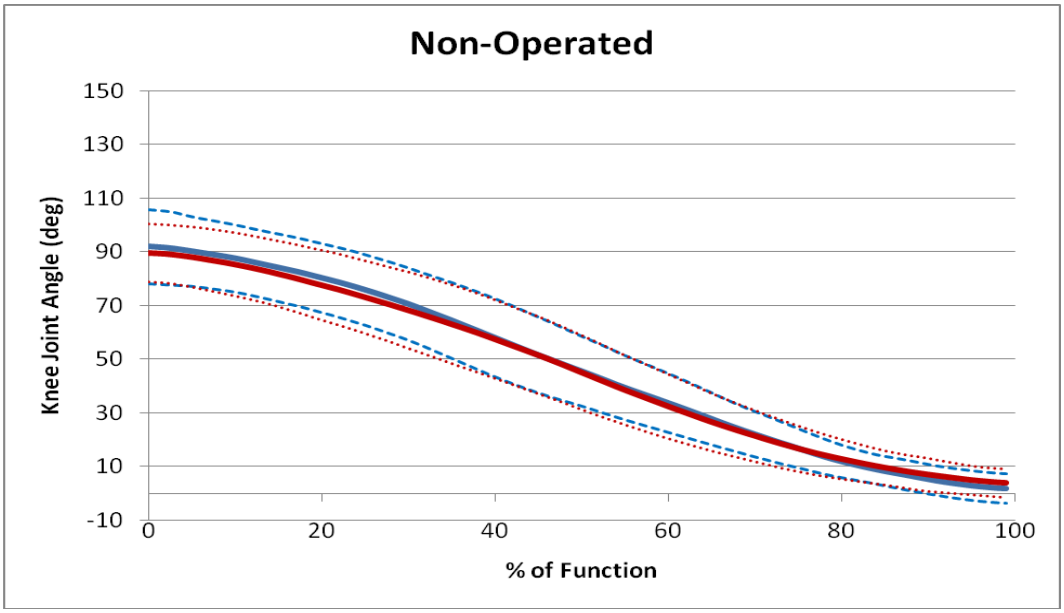


Figure 3.31 Average plots – Low chair, sit to stand cycle normalised. Navigated in blue, conventional in red. (a) Operated knee (b) Non-operated knee

Figure 3.30 illustrates that the starting knee flexion angle varied greatly between patients within each surgical group. The arm rest was used during this activity to push the patient out of the chair to a standing position. The compound plots show that the flexion angle at 0% of the function cycle for three of the trial patients (2 navigated and 1 conventional) was significantly lower than the rest of the group. The maximum knee flexion angle for these three trial patients was around 50^{o}. In these cases the patients rely on their upper body strength to help push them to a standing position. The cushion on the low chair was softer than on the high chair and therefore some of the patients struggled to stand up from this chair as they felt they had 'sunk'.

The average plots for the two surgical groups on observation showed minimal differences between the group plots. A two sample independent t-test was used to compare the maximum and minimum knee flexion angles of the two surgical groups. No statistically significant differences were found for these parameters. The excursion knee flexion data was distribution free. A Mann Whitney U test was used to compare the two groups but concluded that there was no significant differences between the surgical groups, nor were there any significant differences found across the movement cycle as a whole.

Patients were not grouped into those who used arm rest and those who did not. This would have refined the activity and would have allowed a grading analysis of the functioning to be performed distinguishing differences between patients.

The non operated gait cycles showed no difference between the 2 surgical groups. When comparing operated and non operated side there was no statistical difference between the two knee kinematics recorded. There was no statistical difference between the maximum knee joint angle recorded ($p=0.69$), or during each point of the gait cycle.

Bath Activity

The majority of the patients in this study found the bath activity difficult. There were patients within each of the surgical groups who did not use a bath at home, and therefore many refused to complete the activity as they felt it was outwith their 'comfort' zone.

Into Bath and Sit Down

Figure 3.32 shows the knee joint angles in a typical function cycle for into a bath and sit down, for the operated and non-operated knee joint.

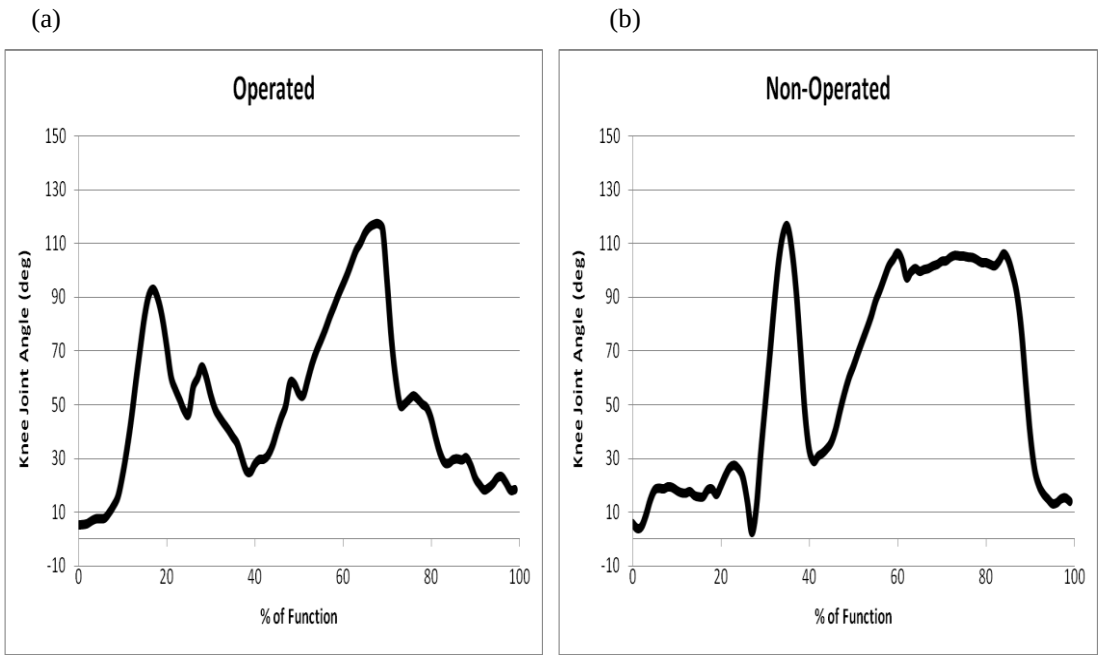
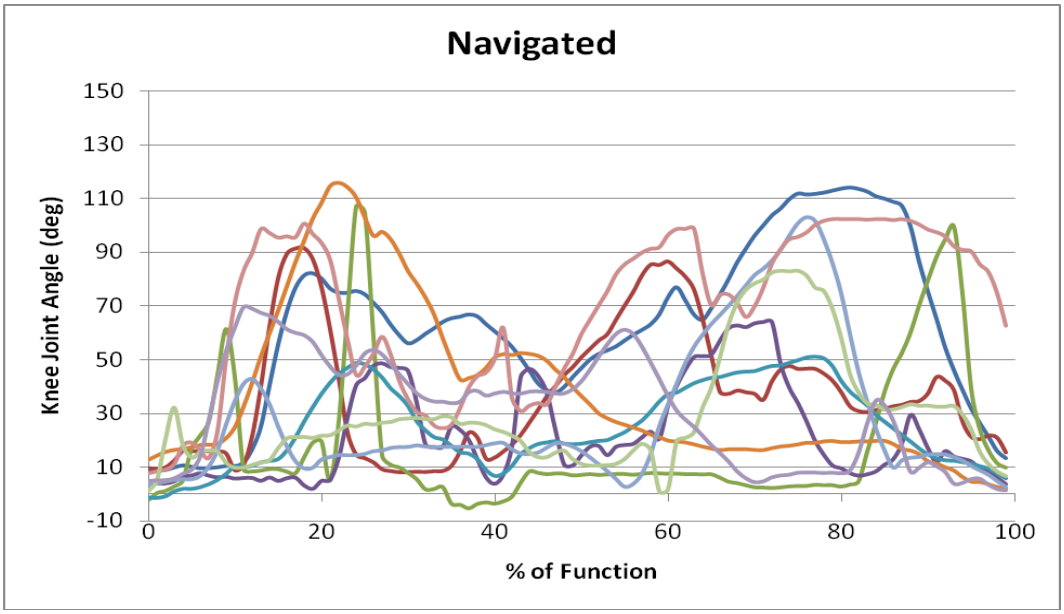


Figure 3.32 Into bath and sit down, cycle normalised for one typical trial patient
(a) Operated knee (b) Non-operated knee

Figure 3.32 show an example plot of a patient stepping into the bath and then sitting down. This gave two flexion peaks. Firstly the leading knee was flexed, which in this case the 'operated' side, to allow the foot to fully clear the edge of the bath. Then the leg inside the bath took the body weight on a flexed lower limb and the second knee was flexed so that the foot cleared the edge of the bath. Then both knees were flexed to lower the body down to a seated position. This patient straightened their legs one at a time. The operated leg first, then the non operated leg. This explains the prolonged flexion state of the non operated leg.

Figure 3.33 shows compound plots for into a bath functional task.

(a)



(b)

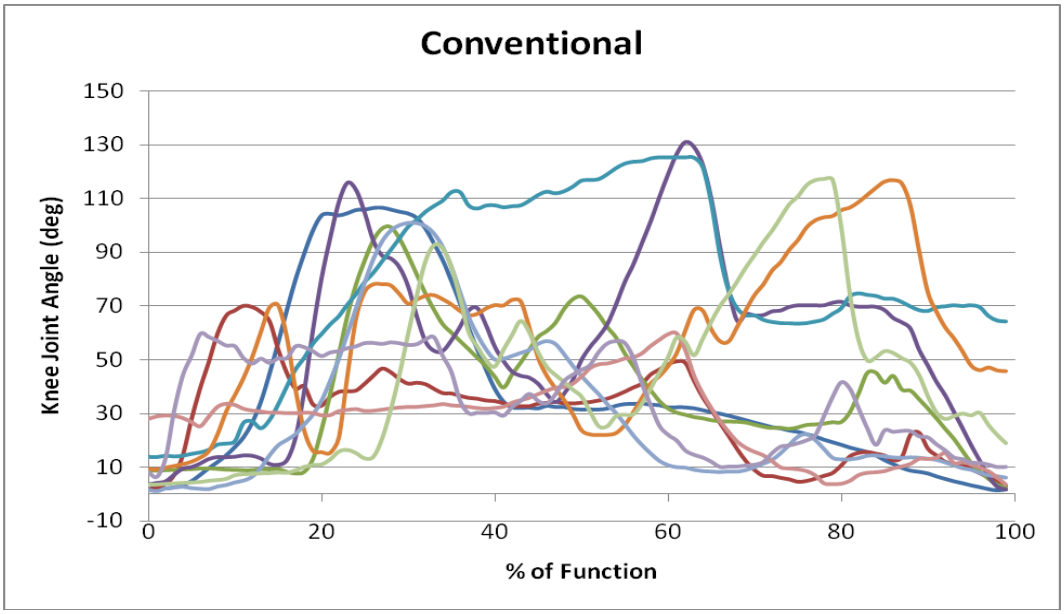
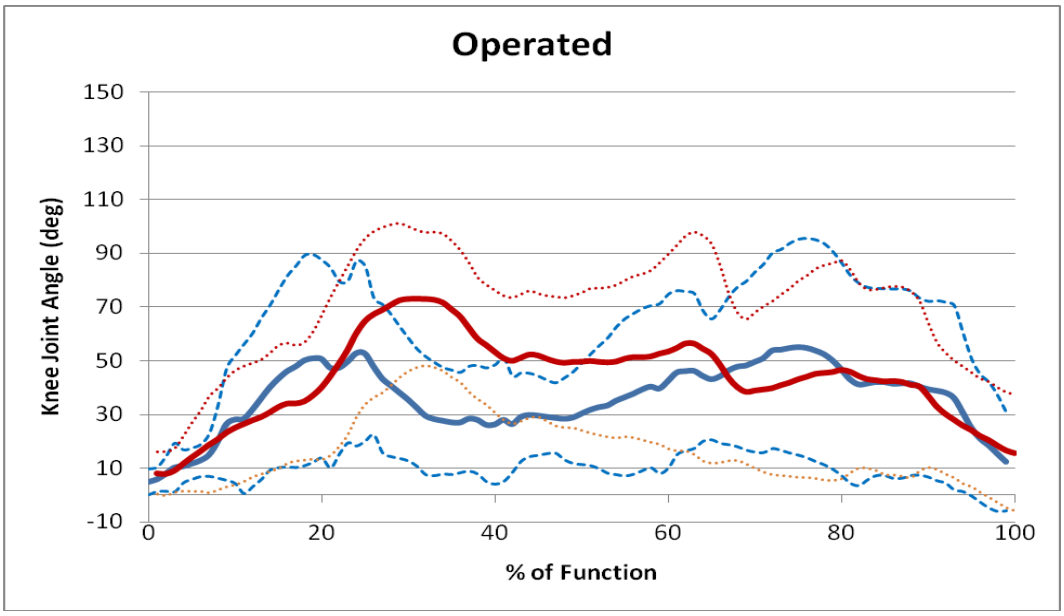


Figure 3.33 Compound plots – Into bath and sit down, cycle normalised

(a) Navigated TKA (b) Conventional TKA

Figure 3.34 shows the average into bath plot for the two surgical groups for the operated and non operated side.

(a)



(b)

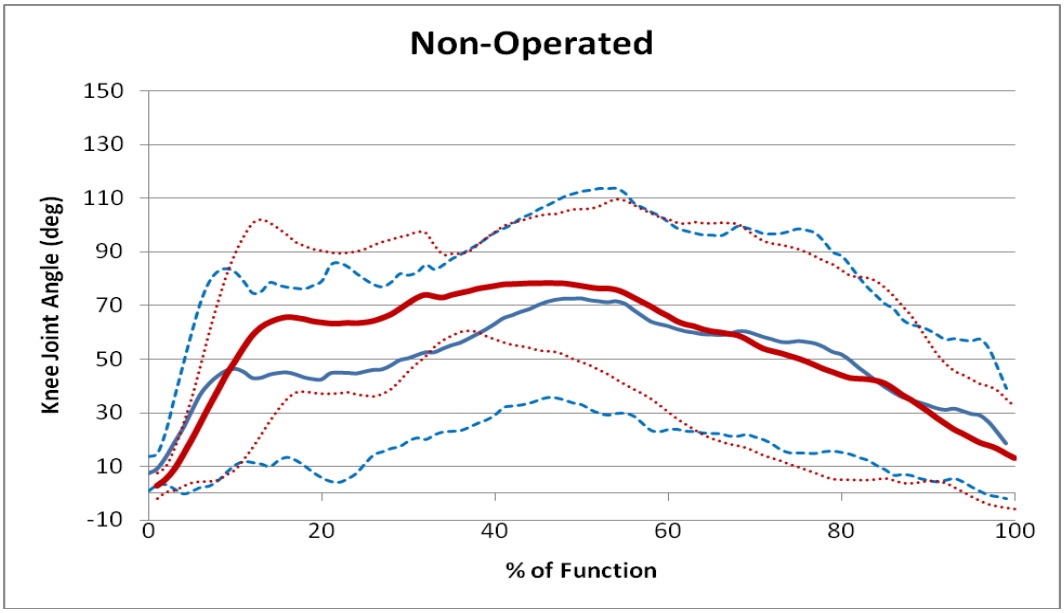


Figure 3.34 Average plots – Into bath and sit down, cycle normalised. Navigated in blue, conventional in red. (a) Operated knee (b) Non-operated knee

It can be seen that the pattern for this activity was highly variable (figure 3.33). The first thing to state was that the activity was not standardised for a particular leading leg. The patients were asked to perform the activity in a way which was comfortable to them, which meant that the leading leg could be either the operated or non-operated side. Some of the patients had adapted their method of getting into a bath so that they could limit the knee flexion required to complete the task. In these cases the patient used high hip flexion to lift a straightened lower limb over the lip of the bath. Another method was to bend the leg behind and lean forward.

The next stage of the task was to sit down which eliminated some patients from the task. It was reported that some patients only stepped into a bath at home to use the shower rather than to sit down in the bath.

The timing of this activity is patient dependant and as already mentioned the method was changeable. As a result there was no repeatable pattern in the compound plots (figure 3.33). This therefore means that the mean plots shown in figure 3.34 have large variation showing the lack of a typical mean function cycle. The magnitudes of the peaks have been lost as the timing of event differs between patients. Therefore the maximum flexion angles calculated from the mean plots were dramatically lowered than the flexion angles required to complete this task.

A two sample independent t-test was used to compare the maximum, minimum and excursion knee flexion angles of the two surgical groups. No statistically significant differences were found for these parameters. The average plots for the two surgical groups on observation showed many differences between the group plots. However as already explained the timing shift between patients was so variable that the mean plots are not representative of the mean function cycle of the group. The majority of the trial patients could not attempt the task, or if they did attempt it they did not sit down resulting in different movement patterns and timing being displayed on the compound plot. Therefore it is not possible to draw conclusions about the relative performance of the two groups from this data.

The non operated gait cycles showed no difference between the 2 surgical groups. When comparing operated and non operated side there was no statistical difference between the two knee kinematics recorded. There was no statistical

difference between the maximum knee joint angle recorded (p=0.97), or during each point of the gait cycle.

Stand and Out of Bath

Figure 3.35 shows the knee joint angles in a typical function cycle for stand up and step out of a bath, for the operated and non-operated knee joint.

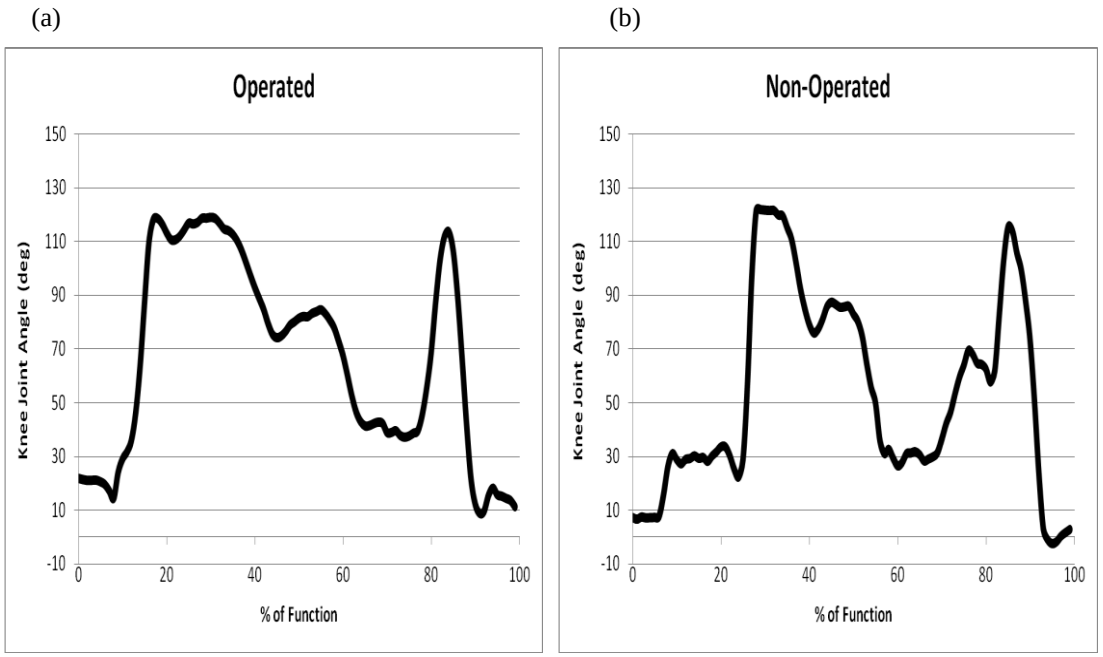
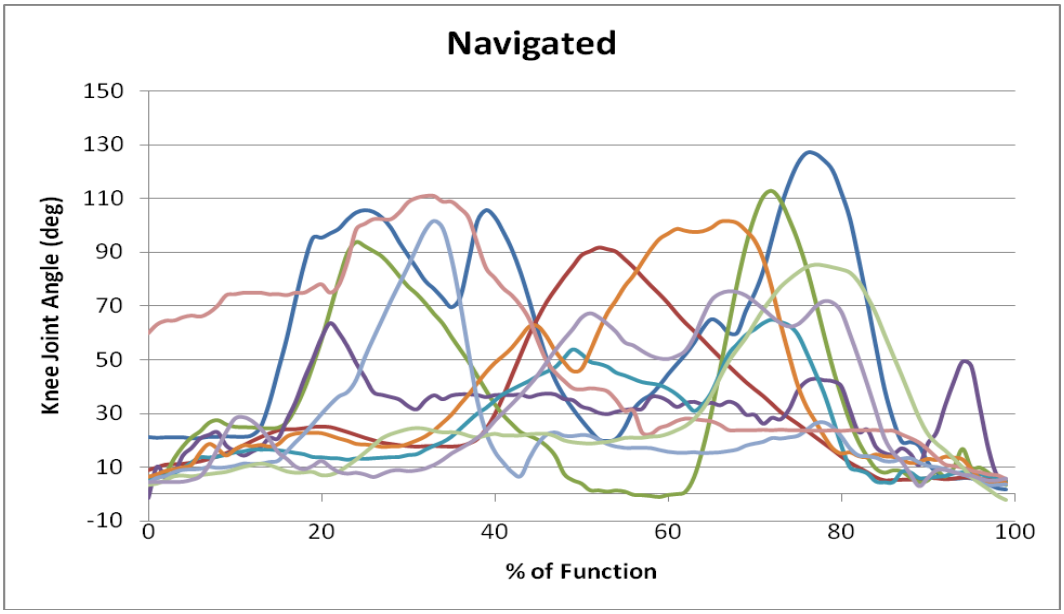


Figure 3.35 Stand up and out of bath, cycle normalised for one typical trial patient (a) Operated knee (b) Non-operated knee

Figure 3.35 illustrates the knee kinematic pattern required for the task of, sit to stand and out of a bath. The patient starts sitting in the bath with their lower limbs extended. They then bend their operated leg, then their non operated leg to around 120^{o}. Then they extended their knees to stand up. They did not fully extend their lower limbs at this stage. They then flexed the first leg to lift it over the side of the bath, then the second leg. The end of the movement was seen where both knee joints were almost fully extended.

Figure 3.36 shows compound plots for the out of a bath functional task.

(a)



(b)

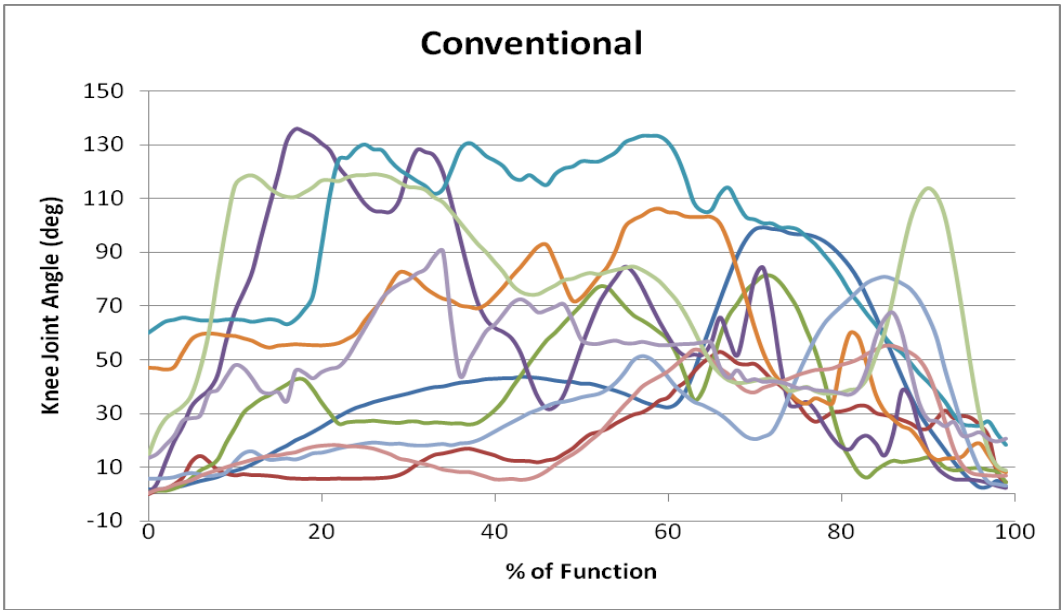
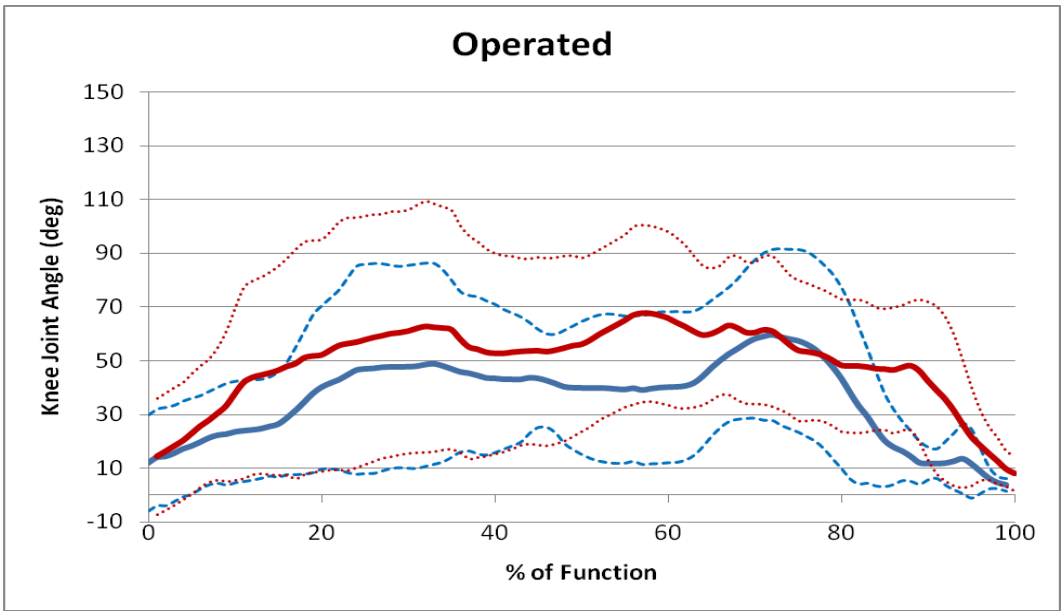


Figure 3.36 Compound plots – Stand up and out of bath, cycle normalised

(a) Navigated TKA (b) Conventional TKA

Figure 3.37 shows the average out of bath plot for the two surgical groups for the operated and non operated side.

(a)



(b)

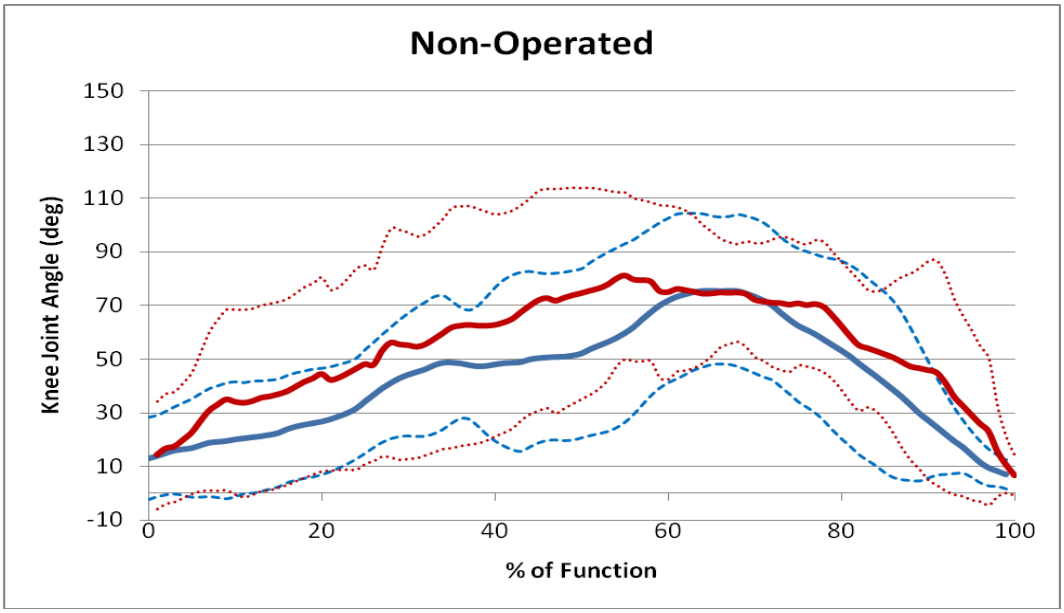


Figure 3.37 Average plots – Stand up and out of bath, cycle normalised Navigated in blue, conventional in red. (a) Operated knee (b) Non-operated knee

As with the ‘into bath’ task, the ‘out of bath’ task was seen to be highly variable in the recorded kinematic pattern (figure 3.36). The patients reported that they had found it difficult to push themselves up from a seated position in the bath, when they had previously attempted the task as it required upper body strength. Another method used was for the patient starting in a seated position to turn over onto bent knees and stand up using their leg strength in addition to upper body strength. However this was an awkward method as a bath is a small space. This method was not an option for some patients as they did not find it comfortable to kneel on there operated knee.

Again the timing of this activity was patient dependant and as already mentioned the method was changeable. This meant that no typical pattern was observed on the compound plots (figure 3.36). This means that the compound plot shown in figure 3.36 had large variation. The mean group function cycle could not be properly defined. The magnitudes of the peaks have been lost in figure 3.37 as the patient timing differs. Therefore the maximum flexion angles calculated from the mean plots were dramatically lowered than the flexion angles required to complete this task.

A two sample independent t-test was used to compare the maximum, minimum and excursion knee flexion angles of the two surgical groups. No statistically significant differences were found for these parameters. The average plots for the two surgical groups on observation showed many differences between the group plots. However as already explained the timing shift between patients was so variable that the mean plots are not representative of the mean function cycle of the group. as with ‘into a bath’ the data was therefore unable to distinguish performance in the two groups.

The non operated gait cycles showed no difference between the 2 surgical groups. When comparing operated and non operated side there was no statistical difference between the two knee kinematics recorded. There was no statistical difference between the maximum knee joint angle recorded ($p=0.73$), or during each point of the gait cycle.

Deep Flexion

Figure 3.38 shows the knee joint kinematics in a typical function cycle for a weighted deep knee flexion, for the operated and non-operated knee joint.

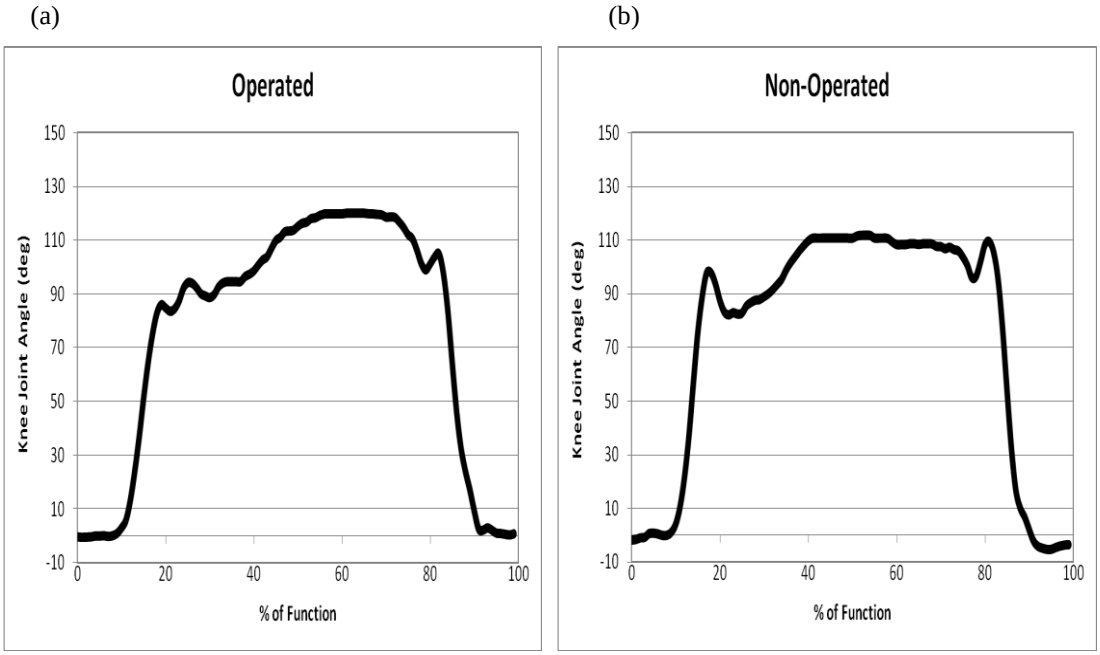
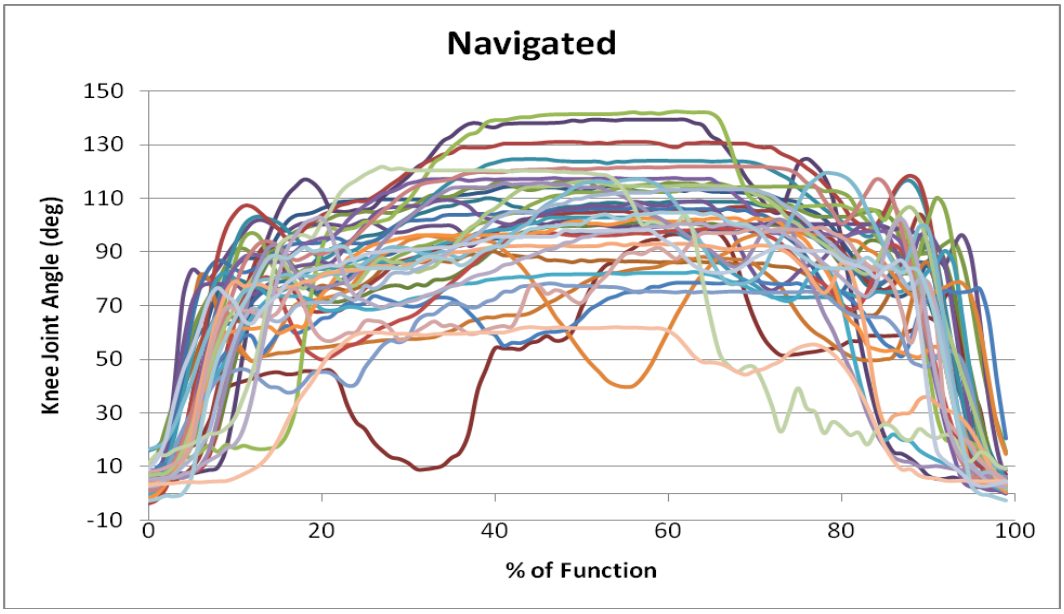


Figure 3.38 Weighted deep flexion cycles normalised for one typical trial patient (a) Operated knee (b) Non-operated knee

The final activity was a weighted deep flexion. This was completed one leg at a time and each deep flexion analysed separately. The foot was rested on a step and then the patient bent into the knee. Figure 3.38 show that the patient from standing on 2 legs lifts one onto the step which is associated with the sharp increase in knee flexion. Then when the patient was comfortable on the step they bent into the knee, which was associated with additional knee flexion. The pause in the execution of the function accounts for the levelling off or dip in flexion angle for about 10% of the cycle. At around 80% of the deep flexion movement the patient lifted their leg off the step which was generally associated with another small peak. It should be noted in these figures that unlike previous data the movements shown occurred one after another rather than simultaneously. They have been presented together for efficiency of reporting the data.

Figure 3.39 illustrates the compound plot for the deep flexion activity for the navigated and conventional groups.

(a)



(b)

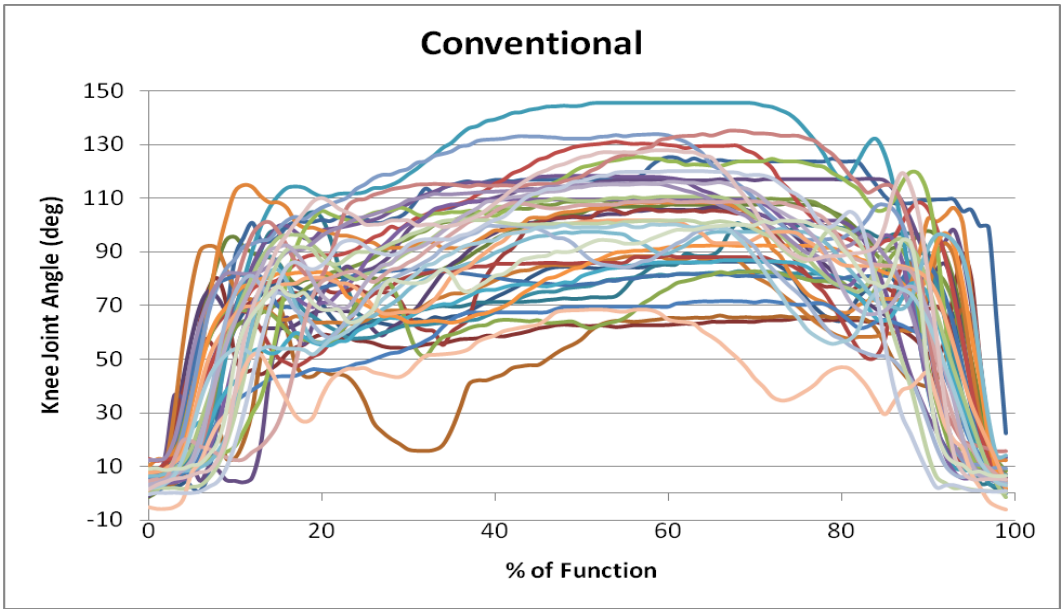
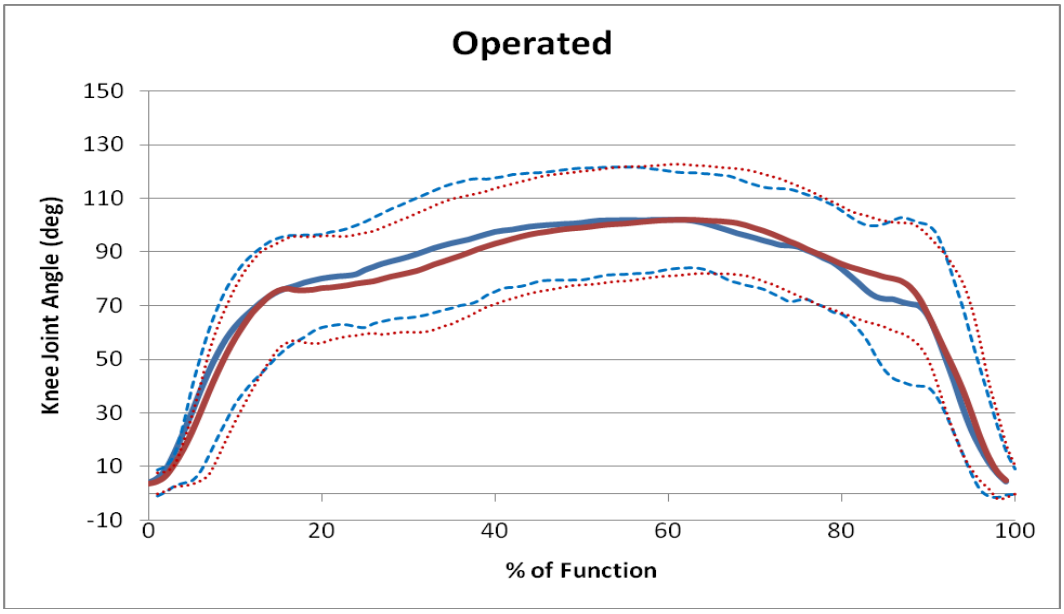


Figure 3.39 Compound plots – Weighted deep flexion, cycle normalised
(a) Navigated TKA (b) Conventional TKA

Figure 3.40 shows the average deep flexion for the two surgical groups for the operated and non operated side.

(a)



(b)

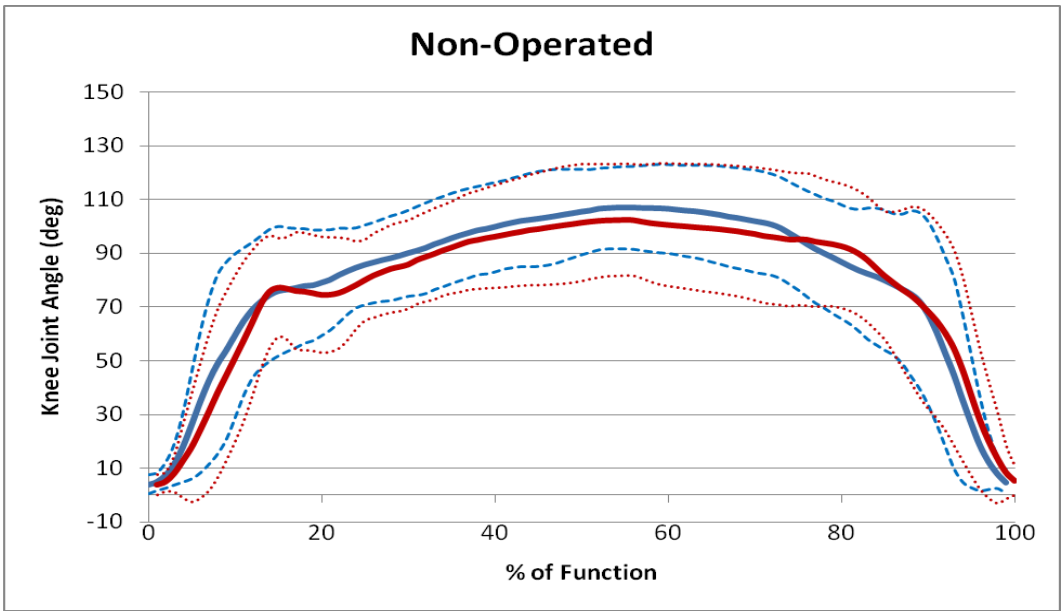


Figure 3.40 Average plots – Weighted deep flexion, cycle normalised. Navigated in blue, conventional in red. (a) Operated knee (b) Non-operated knee

Although figure 3.39 shows some differences between patients the basic pattern was similar. In a few cases it can be seen that there is a sharp dip at around 30% of the function cycle. This indicated that the patient had failed to flex their knee enough to rest it on the step. This resulted in an extension of the knee and a second attempt to lift their foot onto the step occurred immediately. A decrease in knee flexion (a dip) was observed at around 50% of the function cycle in a few patient plots. In these cases the patient rested their foot on the step and actually straightened it out before going into the deep flexion task.

The plots in figure 3.39 show that the deep flexion task was a reproducible activity with a set kinematic pattern.

A two sample independent t-test was used to compare the maximum, minimum and excursion knee flexion angles of the two surgical groups. No statistically significant differences were found for these parameters. The average plots (figure 3.40) for the two surgical groups on observation showed small differences between the group plots. The variations in the timing of this activity within the two groups meant that the mean average maximum flexion angle was decreased.

The non operated gait cycles showed no difference between the 2 surgical groups. When comparing operated and non operated side there was no statistical difference between the two knee kinematics recorded. There was no statistical difference between the maximum knee joint angle recorded ($p=0.98$), or during each point of the gait cycle.

Summary

In summary, the majority of the electrogoniometry functional tasks completed in the functional assessment by the trial patients produced repeatable traces where the kinematic pattern was similar between patients. This allowed mean function plots to be graphed and the kinematic patterns for the tasks to be compared between the two surgical groups. A deep knee flexion task is to be preferred over a functional task such as using a bath to assess high flexion ability as the cycle is repeatable and can be generalised.

Therefore, from the electrogoniometry functional assessment there was no significant statistical difference between the two surgical groups in terms of overall

maximum, minimum and excursion mean knee joint flexion angles for any of the functional tasks investigated. The kinematic function cycles showed repeatable patterns between patients except for the bath activity. There were statistical differences in the level and slope walking tasks during terminal stance and initial swing phase with the navigated group recording a higher flexion angles at this point in the gait cycle.

Comparing the operated and non operated knee kinematics resulted in no statistical difference in maximum knee joint. Down stairs task showed a statistical difference in the two sides during stance phase. The difference was a result of 11 of the patients walking one step at a time which deceased the recorded knee joint angle.

3.3.4. Analysis of walking Gait Cycles

As previously discussed the cyclic activities of level walking and ramp walking and stairs negotiation can be divided into two phases (stance and swing) and within each phase a maximum and minimum knee joint angle can be extracted. Stance phase involves two periods of double stance. One takes place at the beginning of the stance phase and one at the end of the stance phase. Each of these periods of double stance makes up about 12% of the stance phase. The mid section of stance phase is single leg support (SLS) as the opposite limb is in swing phase. Painful lower limbs result in shorter periods of SLS as this period involves full weight bearing through the one knee joint.

Level and slope walking showed statistically significant differences in knee flexion angles between the navigated and conventional groups during terminal stance and initial swing phase. There was no significant difference in the overall maximum flexion angle recorded for the two groups, which (figure 3.41) relates to the flexion peak during swing phase.

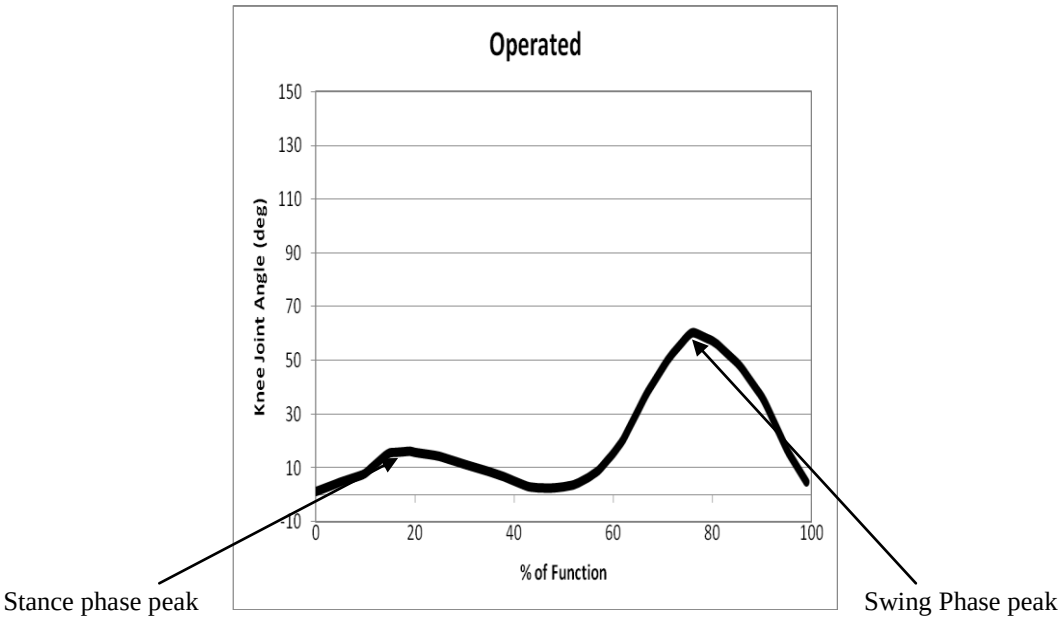


Figure 3.41 Graph illustrating the position of the stance and swing phase peak

The kinematic differences between the mean group plots for level and slope walking occurred around 50-70% of the cycle therefore it was not during either the stance or swing phase peaks within the gait cycle. The mean stance phase ratio from literature (Ayyappa 1997) is 62%. However this figure varies between subjects and is influenced by the presence of disease. Footswitches had been used in this study so that the duration of the stance and swing phase could be calculated. Unfortunately the majority of these footswitches recorded incomplete data. From the trial patients who had foot switch data the percentage of the gait cycle which was stance and swing phase was calculated. Since the data was normally distributed then a two sample independent t-test was used to identify whether there was significant differences between the two surgical groups.

Table 3.7 Level walking swing and stance ratio for operated and non operated sides

Operated	Navigated Average	StDev	Conventional Average	StDev	Ttest
% Stance	61.21	2.11	62.43	2.94	0.20
% Swing	38.79	2.11	37.57	2.94	0.20

Non Operated	Navigated Average	StDev	Conventional Average	StDev	Ttest
% Stance	61.78	2.16	61.59	2.10	0.81
% Swing	38.22	2.16	38.41	2.10	0.81

In the level walking activity, the navigated group for the operated side had a larger proportion of the gait cycle in swing phase but the difference did not reach statistical significance (p=0.2).

Table 3.8 Up slope walking swing and stance ratio for operated and non operated sides

Operated	Navigated Average	StDev	Conventional Average	StDev	Ttest
% Stance	60.75	2.23	63.58	3.00	0.03
% Swing	39.25	2.23	36.42	3.00	0.03

Non Operated	Navigated Average	StDev	Conventional Average	StDev	Ttest
% Stance	60.71	2.63	62.48	2.38	0.07
% Swing	39.29	2.63	37.52	2.38	0.07

In the up slope activity, the operated side for the navigated group had a statistically significantly larger proportion of the gait cycle in swing phase (p=0.03).

Table 3.9 Down slope walking swing and stance ratio for operated and non operated sides

Operated	Navigated Average	StDev	Conventional Average	StDev	Ttest
% Stance	61.08	3.11	61.97	3.04	0.49
% Swing	38.92	3.11	38.03	3.04	0.49

Non Operated	Navigated Average	StDev	Conventional Average	StDev	Ttest
% Stance	59.91	2.92	61.27	2.92	0.21
% Swing	40.09	2.92	38.73	2.92	0.21

In the down slope activity, the navigated group for the operated side had a larger proportion of the gait cycle in swing phase but the difference did not reach statistical significance (p=0.49).

In summary, the stance to swing phase ratio indicated that the navigated group had a larger proportion of the level and slope walking cycles in swing phase. Swing phase indicates periods of SLS for the opposite leg. A larger percentage of SLS indicates more confidence and a more normal gait cycle.

3.3.5. Functional Score

As previously presented there have been minimal differences recorded between the two groups in terms of individual functional activities. None of the maximum, minimum and excursion knee joint angles for each of the 12 activities showed a statistically significant difference between the function of the two groups. Therefore

the next stage of analysis was to group all the activities and determine if the accumulation of all the differences seen in the activities resulted in an overall significant difference between the two surgical groups. Therefore the electrogoniometry data was used to produce a Total Functional Score. This would take into account the fact that some patients could not complete all of the functional activities. The score was based on comparing the TKA trial patients to 'normal' age matched subjects

Comparison of Navigated and Conventional TKA with Normal Data

As already mentioned in the methodology chapter electrogoniometry functional assessment from a group of healthy elderly subjects was available to compare with the TKA patient data. The study recorded data from 40 aged matched normals. The mean age for this group was 69.4 (+/-6.0) with an age range of 54-80 years old. There were 15 males and 25 females within the group.

The mean excursion knee joint flexion angles from the 'normals' data set was extracted for the 12 functional activities completed. Then the two TKA patient groups and the normal subject group were graphed (figure 3.42) showing the mean range of motion used by the three groups to complete the 12 functions. This allowed a comparison between the patient groups and an aged match normal group.

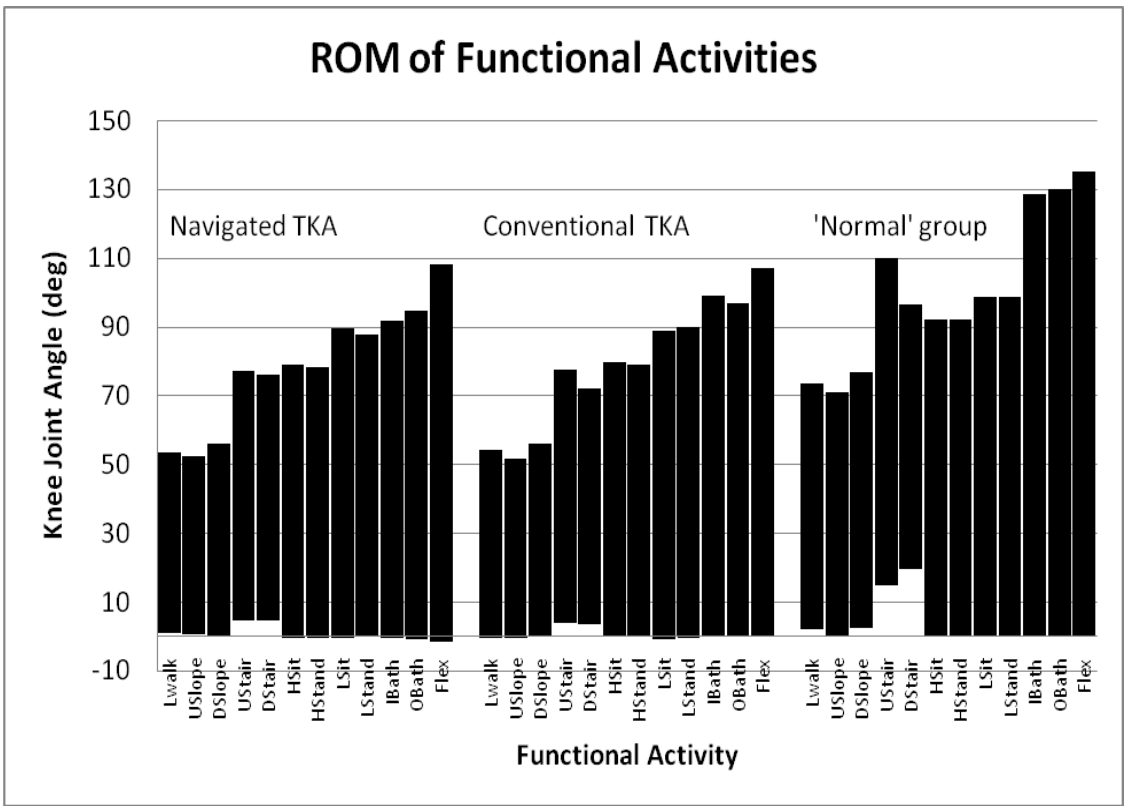


Figure 3.42 ROM of all 12 functional activities for the navigated, conventional and normal groups.

This chart shows that the two TKA groups have significantly lower excursion values and importantly lower maximum knee joint flexion angles recorded for each activity ($p<0.001$). Therefore the patient groups were found to be significantly functionally limited with regards to age matched normals.

When comparing the two TKA groups there were minimal functional differences measured using electrogoniometry, as seen in the previous section. From figure 3.42 a number of observations were made. The level and slope walking plots are similar. The navigated group shows a slight increase in the maximum flexion angle for down stairs which was not statistically significant. The chairs activities show similar excursion values with a slightly higher maximum for the conventional group during sit to stand using a low chair which was not statistically significant. The conventional group also shows increased maximum flexion angles for in and out of a bath which was not statistically significant, but this activity as mentioned previously was only completed by some of the total test group. Finally deep flexion shows an

increased mean maximum value in the navigated group which was not statistically significant.

Each of the functional tasks was scored for each patient. The score awarded depends on how many standard deviations outwith the normal groups mean angle the patient had recorded.

- 5 points was given if the angle was within 1 standard deviation of the average 'normals' knee joint angle.
- 4 points was given if the angle was within 2 standard deviations.
- 3 points was given if the angle was within 3 standard deviations
- 2 points was given if the angle was within 4 standard deviations
- 1 point was given if the angle was over 4 standard deviations of the 'normal' averages but they could complete the task
- And 0 points was give to the patients who could not complete the function.

The maximum knee joint angle for all 12 activities and excursion (maximum-minimum) knee joint angle for the 5 gait (level, slope walking and stairs) were include in the Total Functional Score. The scores from each task was added together and then converted to a percentage of the maximum score possible. Therefore the Total Functional Score ranges from 0-100. The average score for the 'normal' group was 88.7. A TKA patient with a score of equalling or more than the 'normal' group average could be classed as achieving normal functional outcome after surgery.

Table 3.10 summarises the number of navigated patients in each points group for each function.

Table 3.10 Summary of number of navigated in each points group for each function

Navigated TKA Group	5 points	4 points	3 points	2 points	1 points	0 points
Level walking Max	9	12	6	6	5	0
Level Walking Excursion	7	12	8	6	5	0
Up Slope Max	7	15	7	4	3	2
Up Slope Excursion	8	10	10	5	3	2
Down Slope Max	6	11	10	5	4	2
Down Slope Excursion	8	11	11	2	4	2
Up Stairs Max	4	8	16	6	4	0
Up Stairs Excursion	3	5	13	7	10	0
Down Stairs Max	1	11	16	6	4	0
Down Stairs Excursion	4	11	11	5	7	0
High Chair Stand-Sit Max	12	13	3	6	4	0
High Chair Sit-Stand Max	11	14	6	4	3	0
Low Chair Stand-Sit Max	22	4	10	1	1	0
Low Chair Sit-Stand Max	21	9	5	1	2	0
In to Bath Max	0	3	2	1	4	28
Out of Bath Max	1	2	2	1	4	28
Deep Flexion Max	4	10	10	9	5	0

The ‘zero’ point group indicates the number of patients who had not completed the function. The largest incomplete scores were associated with the bath activity. Two patients did not complete the slope activity. Stand to sit and sit to stand from a low chair was a ‘high flexion’ function and therefore theoretically a difficult task. It was seen that the majority of trial patients were in the ‘5 point’ group for these two tasks. Therefore they completed these tasks with a knee flexion angle close to that recorded from the ‘normal’ age matched group. This suggests that for the majority of patients to successfully complete the ‘sit to stand’ from a low chair task a ‘set’ flexion angle was required. The knee joint angle required for the ‘5 point’ group for stand to sit using a low chair was greater than 90^{o}. Therefore this task was not good at differentiating between patients of differing functional levels. A possible change to this task to increase its ability to differentiate between patients would be to time the task and to include whether the arm rests were required. This task differed from, for example level walking where patients could reduce the maximum knee flexion they produced and still competently complete the task. The stairs and bath activities resulted in the largest difference between the TKA groups and the normal subjects.

There were a low number of patients who used a similar maximum and excursion knee flexion angle during these tasks as seen in the low numbers of patients in the ‘5 points’ group.

Table 3.11 summarises the number of conventional patients in each points group for each function.

Table 3.11 Summary of number of conventional in each points group for each function

Conventional TKA Group	5 points	4 points	3 points	2 points	1 points	0 points
Level walking Max	8	9	13	7	2	0
Level Walking Excursion	11	7	13	6	2	0
Up Slope Max	5	14	7	9	3	1
Up Slope Excursion	4	14	13	5	2	1
Down Slope Max	6	7	12	8	5	1
Down Slope Excursion	7	8	17	4	2	1
Up Stairs Max	4	5	20	6	4	0
Up Stairs Excursion	5	5	12	10	7	0
Down Stairs Max	3	11	7	6	12	0
Down Stairs Excursion	5	10	9	5	10	0
High Chair Stand-Sit Max	12	14	7	3	2	1
High Chair Sit-Stand Max	13	10	7	7	1	1
Low Chair Stand-Sit Max	19	8	6	2	2	2
Low Chair Sit-Stand Max	21	9	3	3	1	2
In to Bath Max	2	3	2	1	2	29
Out of Bath Max	2	3	0	1	4	29
Deep Flexion Max	7	7	10	8	7	0

The conventional TKA group in table 3.11 showed similar results to the navigated group in table 3.10. The chairs activity again resulted in the highest number of patients using a maximum knee flexion angle closest to the normals group to complete the task. The stairs and bath activity resulted in the lowest number of patients using similar maximum and excursion angles to normal subjects, to complete the task.

Table 3.12 displays a summary of the percentage of navigated and conventional trial patients who were in the ‘4’ and ‘5’ points groups for each function. Patients within these two points groups are within 2 standard deviations of the ‘normal’ data group mean values recorded for each function. These patients would be classes as having a ‘good’ or better function than the patients within the lower points groups.

17 function parameters have been included in table 3.12. Of these parameters the navigated groups showed a higher percentage of patients within the 'good' function group in 11 of the parameters (as indicated by the bold value). 8 out of 10 gait cycle (level and slope walking and stairs) parameters recorded, also reported a higher percentage of navigated patients within the 'good' function group.

Table 3.12 Summary of percentage of the navigated and conventional group within the '4' and '5' points groups for each function

% of the group within the 4 and 5 point group	**Navigated**	**Conventional**
Level walking Max	**55**	44
Level Walking Excursion	**50**	46
Up Slope Max	**58**	49
Up Slope Excursion	**47**	46
Down Slope Max	**45**	33
Down Slope Excursion	**50**	38
Up Stairs Max	**32**	23
Up Stairs Excursion	21	**26**
Down Stairs Max	32	**36**
Down Stairs Excursion	**39**	38
High Chair Stand-Sit Max	66	**67**
High Chair Sit-Stand Max	**66**	59
Low Chair Stand-Sit Max	68	**69**
Low Chair Sit-Stand Max	**79**	77
In to Bath Max	8	**13**
Out of Bath Max	8	**13**
Deep Flexion Max	**37**	36

For each patient the scores from the 17 parameters where totalled and divided by the maximum score which could be obtained (85). This score was then converted into a percentage. This score represents the percentage of function the TKA patient has at 1 year after surgery with the age matched normals.

Table 3.13 summarises the number of patients and percentage of the surgical group in each functional score bracket.

Table 3.13 Summary of division functional score for the navigated and conventional group

Functional Score Total %	Navigated	Conventional
90-100	1 (3%)	2 (5%)
80-89	3 (8%)	4 (10%)
70-79	8 (21%)	4 (10%)
60-69	9 (24%)	7 (18%)
50-59	5 (13%)	11 (28%)
40-49	7 (18%)	7 (18%)
30-39	4 (11%)	1 (3%)
20-29	1 (3%)	3 (8%)
10-19	0	0
0-10	0	0

Therefore 1 patient from the navigated group and 2 patients from the conventional group achieved a Total Functional Score above the 'normal' group average (88.7). In contrast the 'normal' group scored 80-100 points. Only one subject from the 'normal' subjects group had Total Functional Score outwith 2 standard deviations of the mean.

The majority of the navigated patients were in the 60-69% group. The majority of the conventional group were in the 50-59% group. However in graph form there was not seen to be a great difference in the distribution of the Total Functional Score.

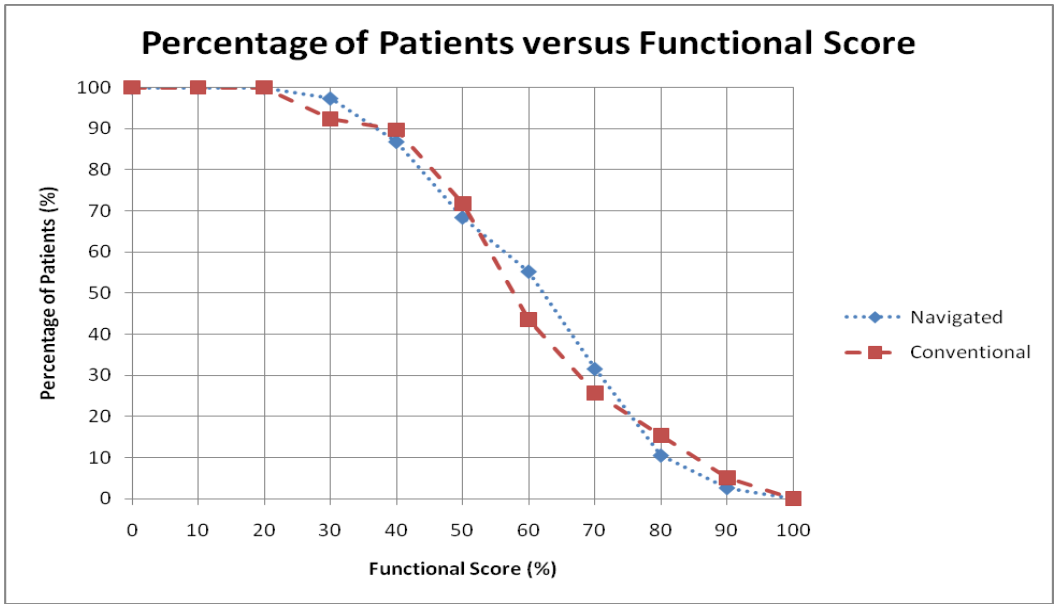


Figure 3.43 Percentage of patients in the navigated and conventional group at each functional score point.

The graph in figure 3.43 illustrates the decrease in the percentage of patients within each group who obtained a certain level of functional score. The two groups were seen to be similar. For example a functional score of 50 or above was obtained by 68% of the navigated group and 72% of the conventional group which did not reach statistical significance.

The bath activity was only completed by a small percentage within the two TKA groups. Therefore the Total Functional Score was re-calculated excluding the bath activity to investigate the impact this activity had on the functional score.

Table 3.14 Summary of division functional score excluding the bath parameter for the navigated and conventional group

Functional Score Total (ex bath) %	Navigated	Conventional
90-100	2 (5%)	3 (8%)
80-89	8 (21%)	6 (15%)
70-79	10 (26%)	6 (15%)
60-69	3 (8%)	10 (26%)
50-59	8 (21%)	5 (13%)
40-49	3 (8%)	6 (15%)
30-39	3 (8%)	2 (5%)
20-29	1 (3%)	1 (3%)
10-19	0	0
0-10	0	0

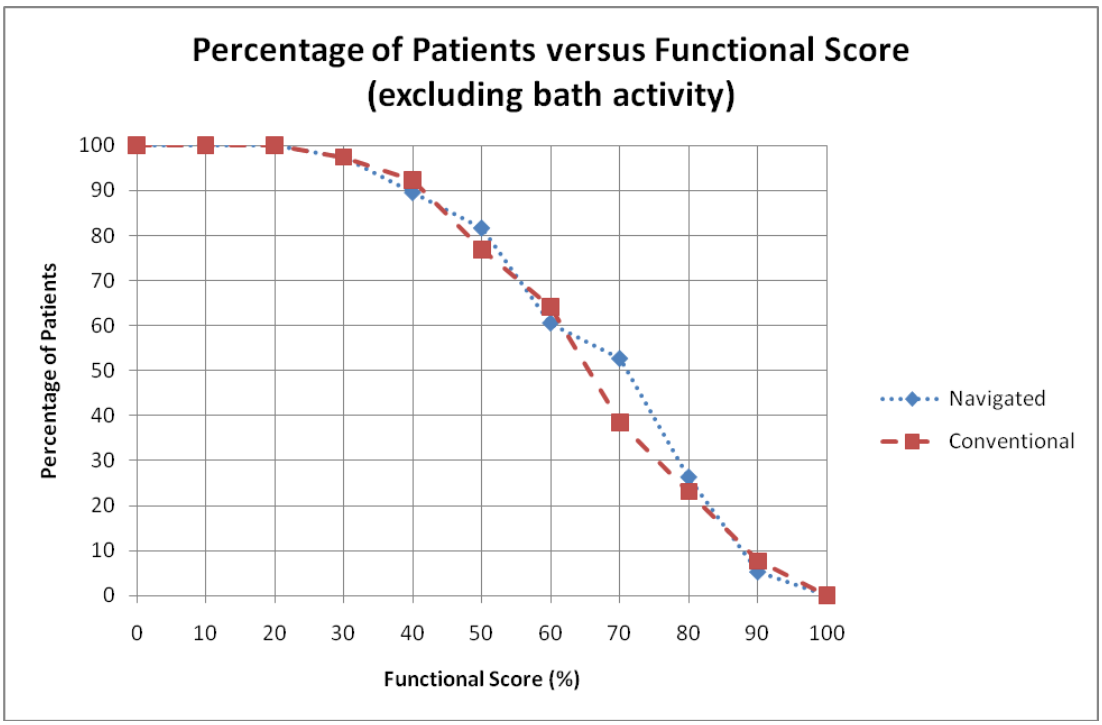


Figure 3.44 Percentage of patients in the navigated and conventional group at each functional score (excluding bath activity) point.

As expected both table 3.14 and figure 3.44 show that excluding the bath activity increases the percentage of patients in both groups who obtained higher functional scores. Excluding the bath activity resulted in an increase in the percentage of patients in each group achieving a functional score of 50% or above. 77% of the conventional group and 82% of the navigated group achieved this level.

The percentage of patients recording 'good' (patients with the '4' and '5' points groups) knee flexion angles for 'gait' activities was higher for the navigated group for 8 out of 10 parameters. There had also been significant differences between the two surgical groups found when comparing the electrogoniometry graphs for gait. Therefore the gait measurements appear to be sensitive to differences between the groups. The results therefore may be obscured when joined with all the other electrogoniometry activity data. Therefore a 'gait function' score was calculated by using the maximum and excursion knee joint angles for the level, slope walking and stairs. This time the maximum total score was 50 and again this score was converted into a percentage.

Table 3.15 Summary of division gait functional score for the navigated and conventional group

Functional Score Gait Total %	Navigated	Conventional
90-100	2 (5%)	3 (8%)
80-89	7 (18%)	3 (8%)
70-79	9 (24%)	8 (21%)
60-69	6 (16%)	7 (18%)
50-59	5 (13%)	8 (21%)
40-49	3 (8%)	6 (15%)
30-39	2 (5%)	2 (5%)
20-29	3 (8%)	2 (5%)
10-19	1 (3%)	0
0-10	0	0

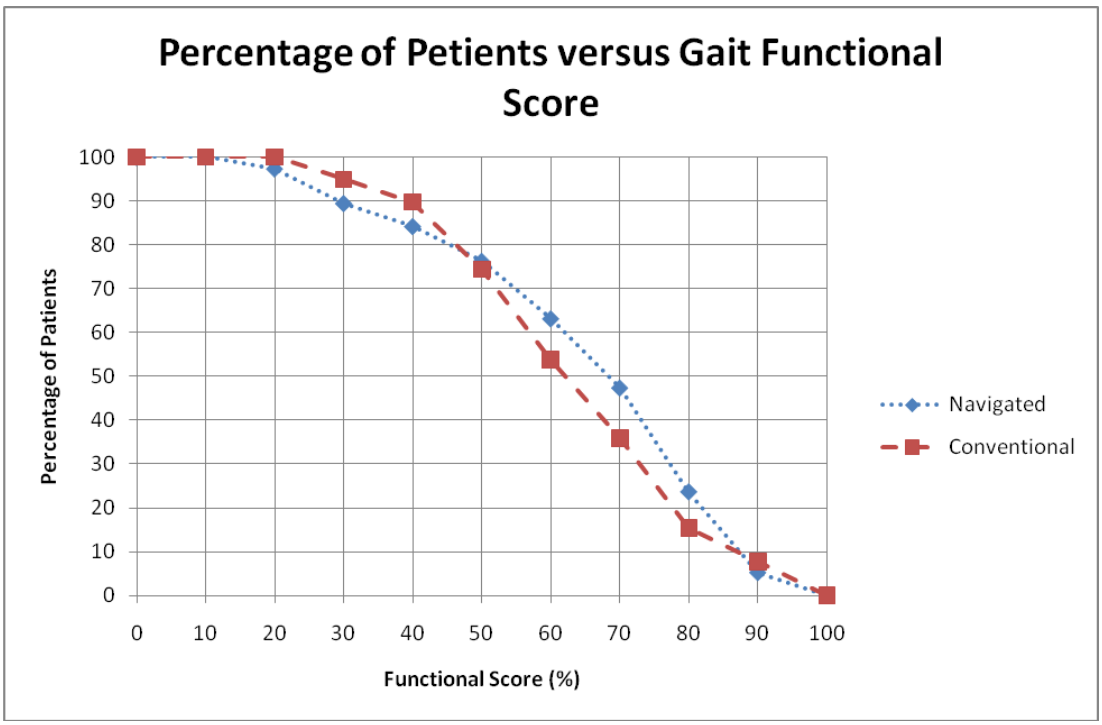


Figure 3.45 Percentage of patients in the navigated and conventional group at each gait functional score point.

The graph in figure 3.45 shows that the percentage of the navigated group obtaining scores of; 60 and above, 70 and above, 80 and above was higher than the percentage of conventional patients obtaining these high scores. Again this was a minimal difference but indicated small improvements within the gait function of the navigated group and a trend towards improved function which did not reach statistical significance.

Tables 3.16 and 3.17 give a summary of the mean functional scores in the three forms discussed previously.

Table 3.16 Functional score for the navigated group

	Navigated (%)			
	Mean	St Dev	Maximum	Minimum
Total Functional Score	59.01	18.57	95.29	10.59
Total Functional Score excluding Bath Activity	65.33	19.38	96	12
Gait Functional Score	61.08	23.70	96	4

Table 3.17 Functional score for the conventional group

	Conventional (%)			
	Mean	St Dev	Maximum	Minimum
Total Functional Score	57.98	19.55	98.82	20
Total Functional Score excluding Bath Activity	63.83	19.71	98.67	22.67
Gait Functional Score	59.64	21.87	100	14

Each of the three methods of calculating the functional score resulted in a higher mean score for the navigated group. Both groups showed large variations in functional levels as seen through the large standard deviation and range of scores obtained. The data was normally distributed so a two sample independent t-test it was found that there was no significant statistical difference between the two surgical groups in terms of the overall functional score ($p=0.45$). There was also no statistical difference between the 2 variations of the functional score; excluding the bath activity $p=0.48$ and gait functional score $p=0.40$. As expected the functional score was increased for both groups when the bath was excluded as this was the activity completed by the fewest patients. However the ability to complete this activity was more subjective. It was not necessarily a physical limitation but instead an emotional decision that the task was not within their comfort zone. Excluding the bath activity may not be valid as to get an overall picture of function the most difficult activity should be included. However different percentages of the two groups completed the bath activity so removing it allowed a more comparable score to be used to compare the two groups. in contrast only 2 of the normal subjects could not complete the bath activity.

Therefore there was a trend for better functional outcome in the navigated TKA group, but the improvement did not reach significance with the numbers tested within this group.

3.4. IMPLANT ALIGNMENT RESULTS

Recent literature has compared navigated and conventional TKA in terms of implant alignment. This involves the analysis of the implant placement. The patients in this study had a CT scan as well as long leg weight bearing radiograph at 3 months after surgery. From the CT scans the mechanical axis, the femoral and tibial component position in the frontal, sagittal and rotational planes were calculated. This analysis was completed on 35 navigated CT scans and 36 conventional CT scans.

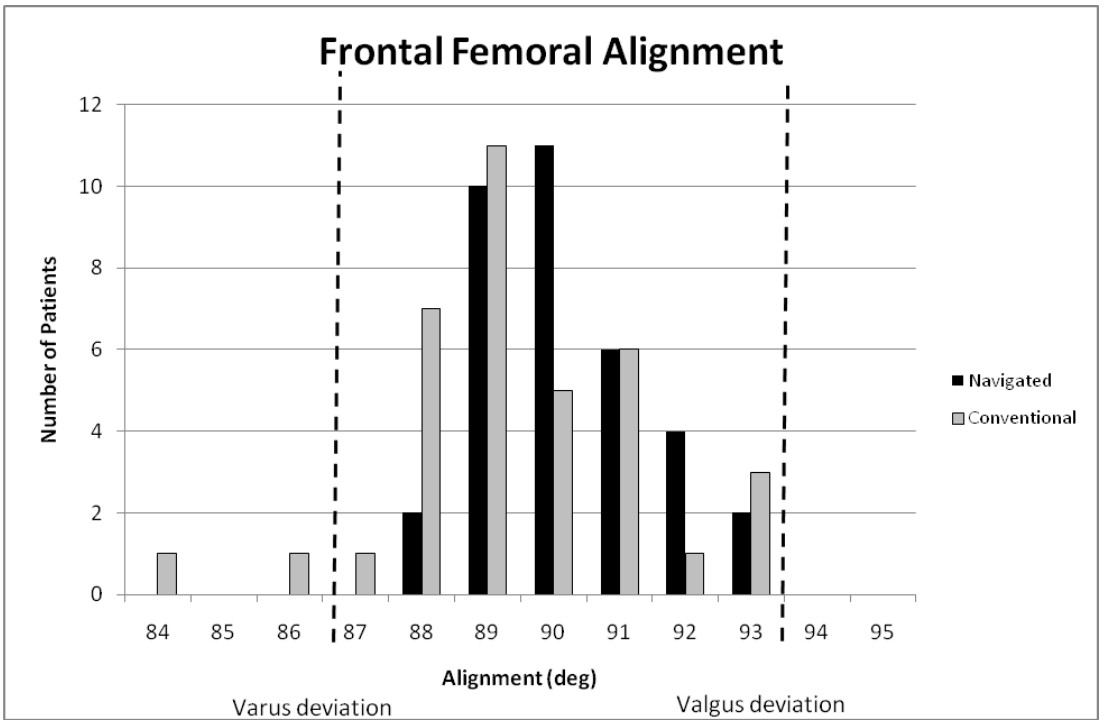


Figure 3.46 Frontal Femoral Alignments. Navigated group shown in black and conventional group in grey. The dotted lines indicated the desired range for implantation.

The femoral implant was aimed to be implanted at 90^{o} in the frontal plane with a range of $+/-3^{o}$. In these terms 100% of navigated and 94% of conventional femoral components were implanted within the desirable range. The frontal femoral component for the navigated patients was implanted within a range of -2^{o} to $+3^{o}$, compared to -6^{o} to $+3^{o}$ for the conventional group. A two sample independent t-test

was used to investigate differences in the alignment outcome. The significance level was set at p=0.05. A significant statistical improvement was found in the navigated group (p=0.04).

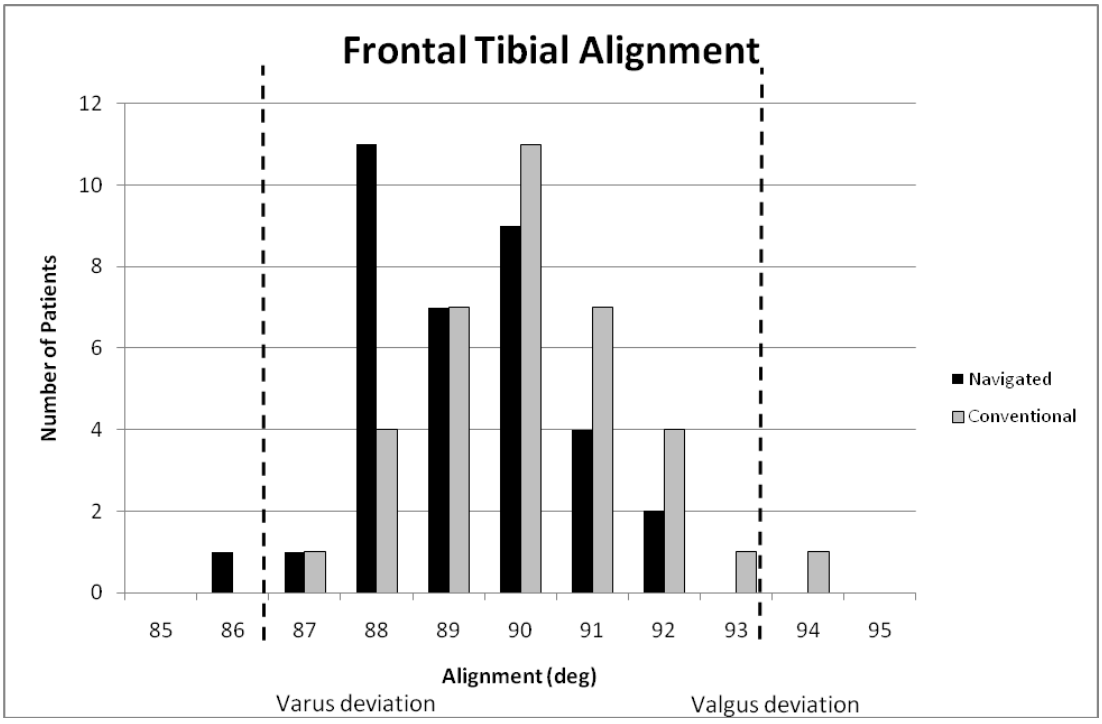
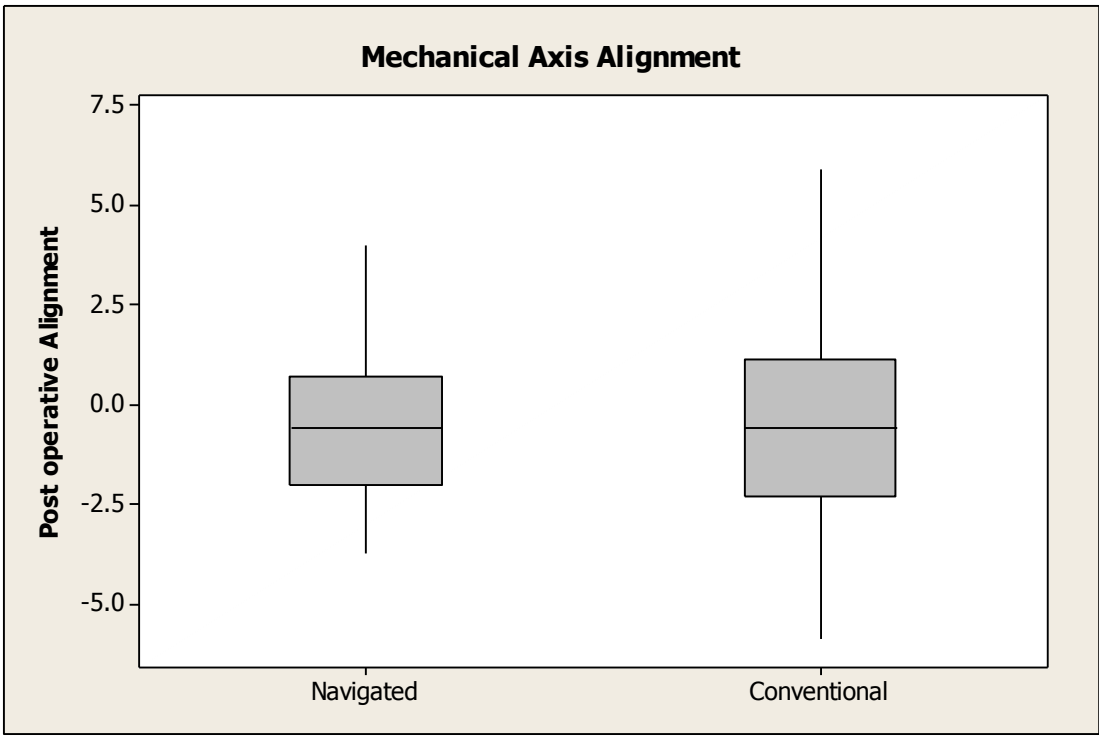


Figure 3.47 Frontal Tibial Alignments. Navigated group shown in black and conventional group in grey. The dotted lines indicated the desired range for implantation.

The tibial implant was also aimed to be implanted at 90^{o} in the frontal plane with a range of $+/-3^{o}$. In these terms then 97% of navigated and 97% of conventional femoral components were implanted within desirable range. The frontal tibial component for the navigated patients was implanted within a range of -4^{o} to $+2^{o}$, compared to -3^{o} to $+4^{o}$ for the conventional group. A two sample independent t-test showed a significant statistical improvement in the conventional group (p=0.01). Although only 1 patient from each group was out with the desired range about a third of the conventional trial patients had been implanted in the neutral alignment. In the navigated group about a third of the patients had been implanted at an alignment of -2^{o}.

(a)



(b)

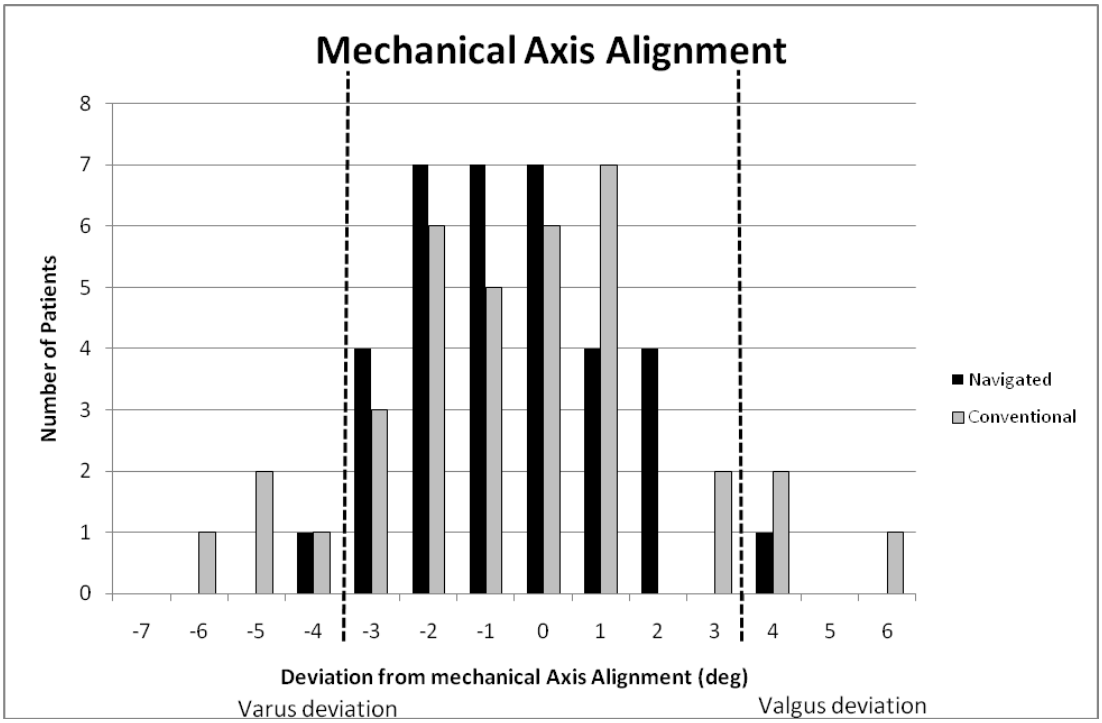


Figure 3.48 Mechanical Axis Alignments. (a) A box and whisker plot of mechanical axis alignment. (b) Bar chart of the mechanical axis alignment. Navigated group shown in black and conventional group in grey. The dotted lines indicated the desired range for implantation.

Varus deviations are denoted as negative alignment and valgus deviations are positive deviations. A mechanical axis alignment of 180^{o} was a neutral alignment and therefore had 0^{o} deviation. The desired range was $+/-3^{o}$. In these terms then 94% of navigated and 81% of conventional femoral components were implanted within desirable range. The mechanical axis alignment range for the navigated patients was -4^{o} to $+4^{o}$, compared to -6^{o} to $+6^{o}$ for the conventional group. Figure 3.48 (a) shows the spread of the resultant alignment for the 2 surgical groups. the mean values are similar but the range of outcome alignments was clearly reduced in the navigated group. A two sample independent t-test was used to investigate differences in the alignment outcome. Navigation showed improvements in terms of increased percentage implanted within the desired range and a reduction in the magnitude of the deviations calculated the improvement. However this did not reach statistical significance (p=0.88).

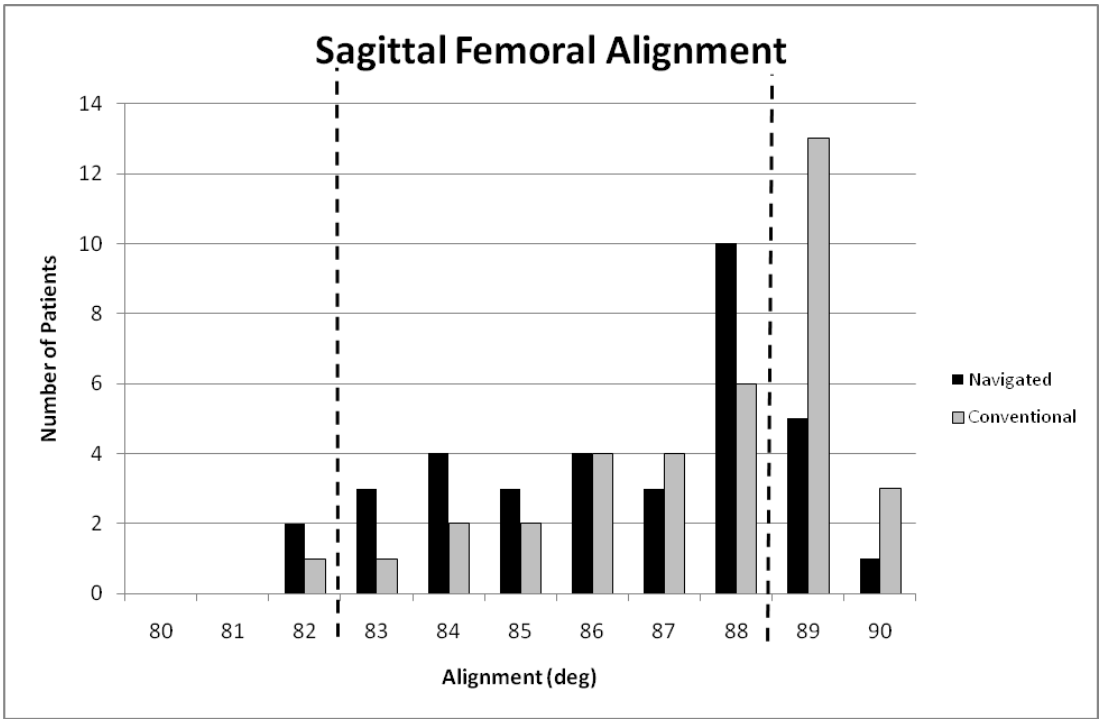


Figure 3.49 Sagittal Femoral Alignments. Navigated group shown in black and conventional group in grey. The dotted lines indicated the desired range for implantation.

The femoral implant was aimed to be implanted at 5^{o} femoral flexion (posterior slope in the sagittal plane) with a desired range of $+/-3^{o}$. A 5^{o} femoral flexion was

measured as an alignment of 85^{o} in the sagittal plane. In these terms then 83% of navigated and 56% of conventional femoral components were implanted within desirable range. It was clear to see from figure 3.48 that the femoral implant was implanted flatter in both patient groups than the desired implant alignment. The range for the sagittal femoral alignment for both of the groups was -8^{o} to 0^{o}. A two sample independent t-test showed a significant statistical improvement in the navigated group (p=0.03).

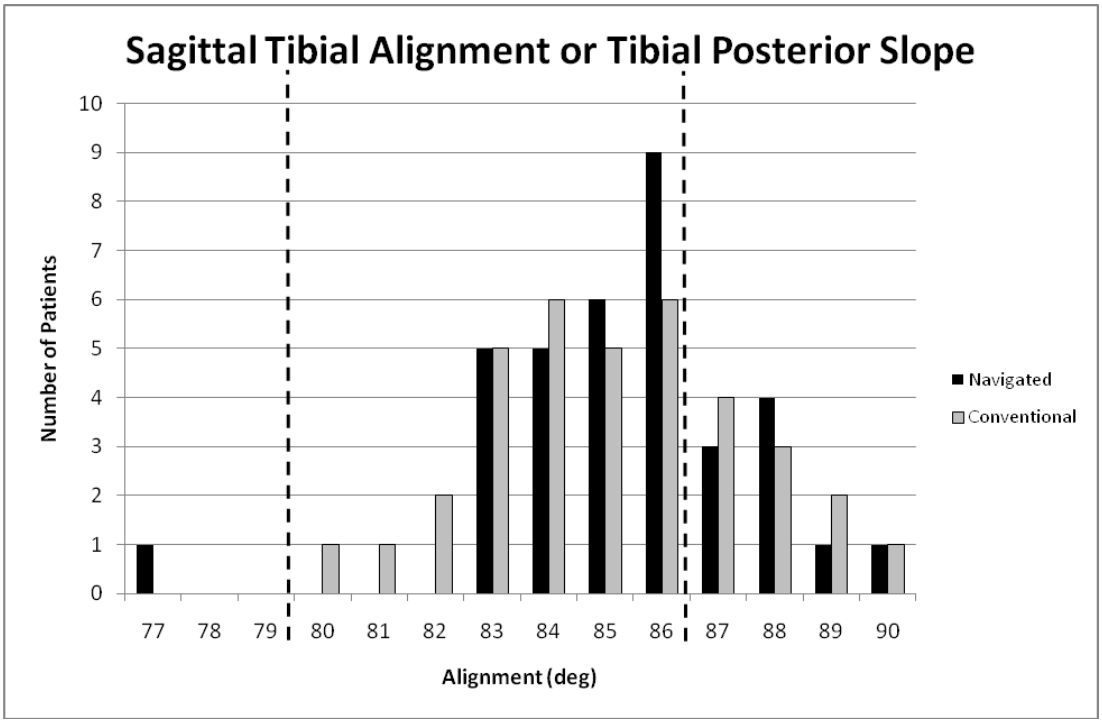


Figure 3.50 Sagittal Tibial Alignments. Navigated group shown in black and conventional group in grey. The dotted lines indicated the desired range for implantation.

The tibial implant was aimed to be implanted at 7^{o} posterior slope in the sagittal plane with a desired range of +/-3^{o}. A 7^{o} posterior slope was measured as an alignment of 83^{o} in the sagittal plane. In these terms then 71% of navigated and 72% of conventional femoral components were implanted within desirable range. The range for sagittal tibial alignment for the navigated patients was -13^{o} to 0^{o}, compared to -10^{o} to +0^{o} for the conventional group. The component was implanted with less posterior slope than aimed for in the majority of patients from both surgical groups. For this alignment parameter the deviation range was larger for the navigated group.

A two sample independent t-test showed no significant statistical difference between the two surgical group (p=0.79).

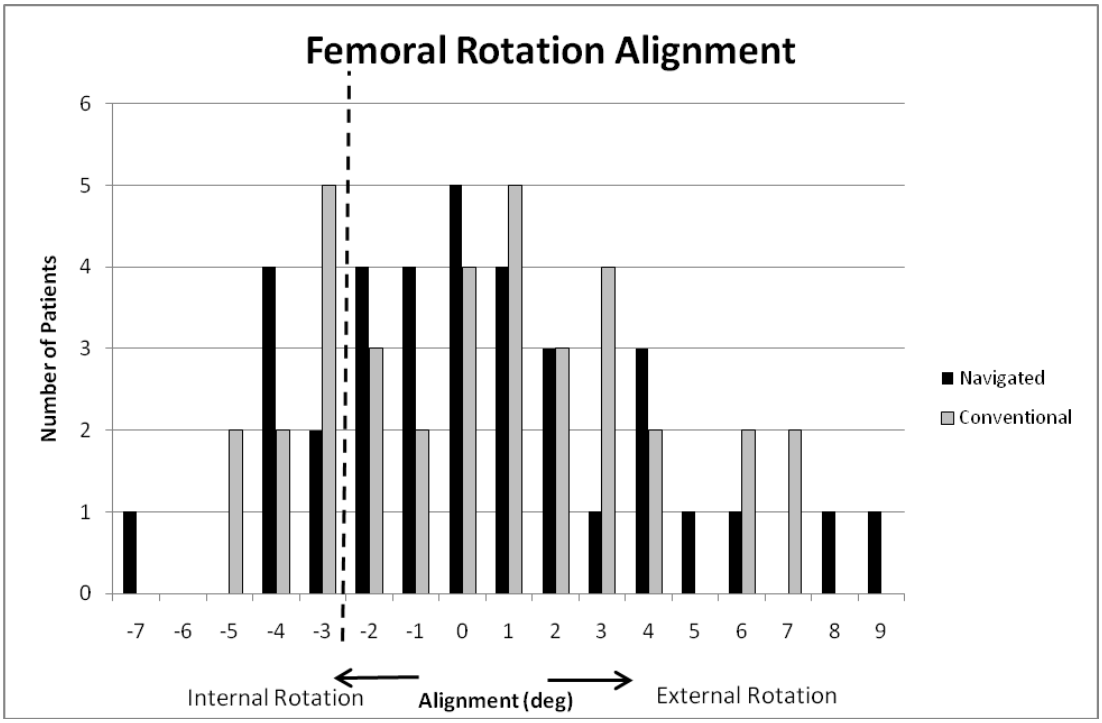


Figure 3.51 Femoral rotational alignment. Navigated group shown in black and conventional group in grey.

The femoral component should be neutral i.e. 0^o or slightly externally rotated to allow for correct patello-femoral tracking. The femoral rotation was corrected for gender. Neutral rotation for female patients was 0.3^o and for the male patients neutral alignment was 3.5^o. Internal rotated components are thought to lead to patello-femoral complications. Internal rotation was seen in some of the patients as indicated on the graph as a negative alignment.

Excess internal rotation was taken as 3 or more degrees. In this case 80% of the navigated components and 75% conventional components were implanted correctly. The femoral rotational alignment for the navigated patients was within a range of -7^o to 9^o, compared to -5^o to $+7^o$ for the conventional group. Therefore the conventional group resulted in a smaller range of outcome alignments. A two sample independent t-test showed no significant statistical difference between the two surgical group (p=0.92).

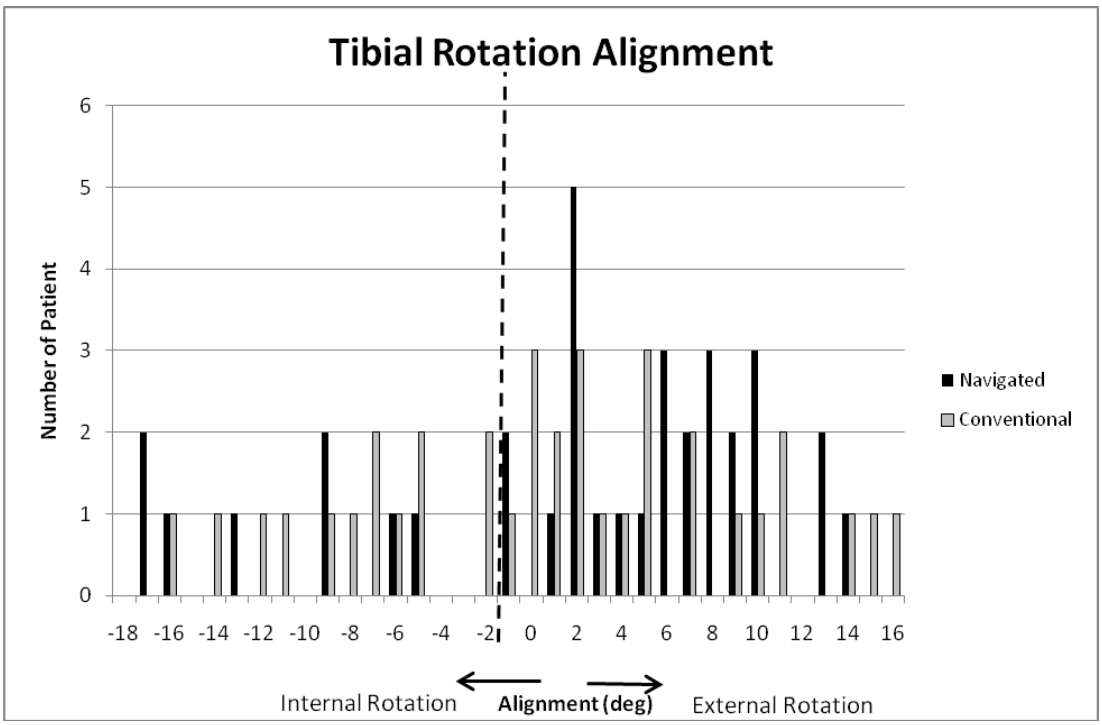


Figure 3.52 Tibial rotational Alignments. Navigated group shown in black and conventional group in grey.

The tibial component should be internally rotated 18^{o}, which corresponds to the alignment of the native knee. This neutral knee position appears as zero degrees in figure 3.51 and therefore the deviations from neutral alignment are displayed. The tibial component should be neutral i.e. 0^{o} or slightly externally rotated. Excessive internal rotation was seen in some of the patients as indicated on the graph as negative alignment.

77% of the navigated group tibial components and 64% of the conventional group were neutral or externally rotated. The tibial rotational alignment for the navigated patients was within a range of -17^{o} to 14^{o}, compared to -16^{o} to $+16^{o}$ for the conventional group. Therefore the navigated group resulted in a smaller range of outcome alignments. A two sample independent t-test showed no significant statistical difference between the two surgical group ($p=0.44$).

It is thought that the combined or relative rotation of the two components, femoral and tibial is important in patello-femoral tracking.

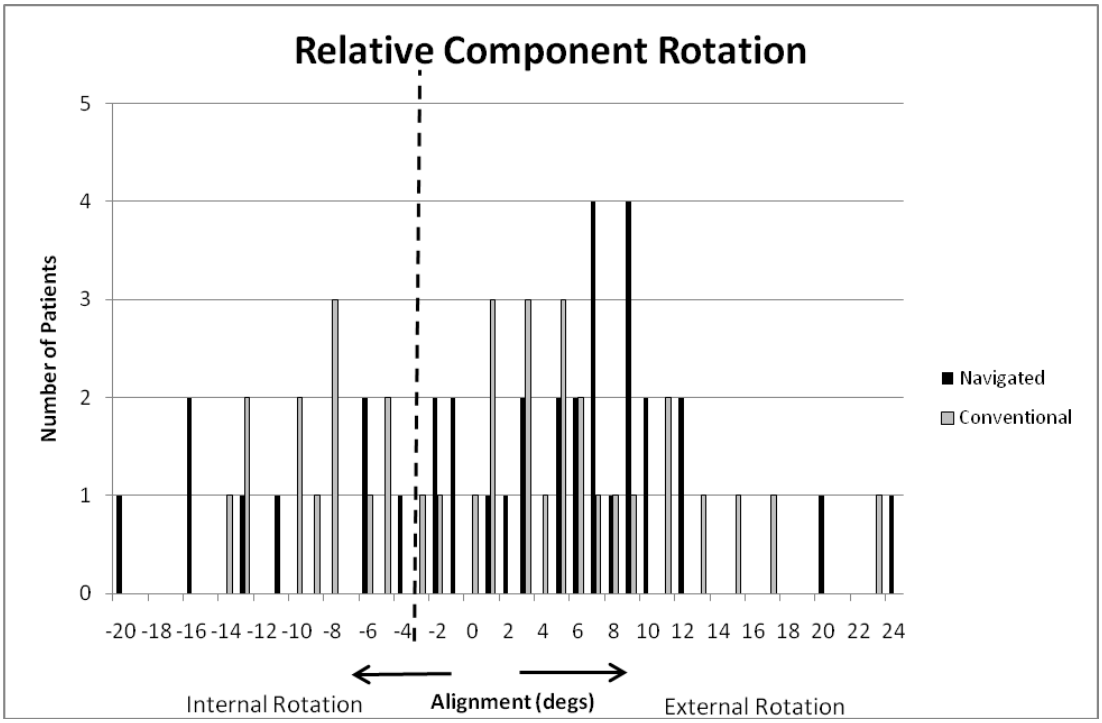


Figure 3.53 Relative component rotational alignment. Navigated group shown in black and conventional group in grey.

Berger et al (2001) reported that patello-femoral problems were seen in implants with a relative internal rotation in excess of 3^{o}.

Neutral and external relative rotation was seen in 77% of the navigated group and 67% of the conventional group. The relative femoral/tibial rotational alignment for the navigated patients was within a range of -20^{o} to 24^{o}, compared to -14^{o} to $+23^{o}$ for the conventional group. Therefore the conventional group resulted in a smaller range of outcome alignments. Excessive internal rotation was therefore seen in 23% (7 patients) of navigated and 33% (12 patients) of the conventional group. A two sample independent t-test showed no significant statistical difference between the two surgical group (p=0.52).

Summary of Alignment Results

Table 3.18 summaries the alignment results for each parameter in terms of the percentage of each surgical group which was implanted within the desired range and the p value from the two sample independent t-tests used to compare the two surgical groups.

Table 3.18 Summary of Alignment Results

	Navigated TKA Group	Conventional TKA Group	p-value
Frontal Femoral Alignment	**100**	94	**0.04**
Frontal Tibial Alignment	97	97	**0.01**
Mechanical Axis Alignment	**94**	81	0.88
Sagittal Femoral Alignment	**83**	56	**0.03**
Sagittal Tibial Alignment	71	**72**	0.79
Femoral Rotation Alignment	**80**	75	0.92
Tibial Rotation Alignment	**71**	61	0.44
Relative Rotation Alignment	**77**	67	0.52

Six out of the eight alignment parameters resulted in improved alignment in the navigated group. The frontal tibial alignment was the same for both groups with 97% of the patients' outcome alignment within the desired range. Finally the sagittal tibial alignment was improved in the conventional group with 72% within the desired range compared to 71% of the navigated group.

From the t-test it was seen that the frontal femoral and sagittal femoral alignment were statistically significantly improved in the navigated group and the frontal tibial alignment was statistically significantly improved in the conventional group.

3.1.4. Alignment Errors

From the summary results in table 3.18 it can be seen that the frontal alignment appears to be most reproducible with both groups resulting in over 90% of the patients having a correct outcome alignment.

Frontal alignment, for example the mechanical axis alignment has been linked to implant longevity. Rotational mal-alignment has been linked with patello-femoral tracking problems. However it is unknown whether one parameter error is more problematic than another in terms of overall longevity and also functional outcome

and outcome range of motion at the knee joint. Another issue which has not been investigated in the literature is whether certain alignment error combinations are found, for example as femoral frontal and femoral sagittal alignment and whether certain combinations of errors cause problems.

Table 3.19 Summary of the number patients from each group with 0 to 5 alignment errors

Number of errors	Navigated TKA Group	Conventional TKA Group
0	11 (31%)	5 (14%)
1	10 (28%)	12 (33%)
2	11 (31%)	6 (17%)
3	2 (6%)	9 (25%)
4	1 (3%)	1 (3%)
5	0 (%)	3 (8%)

There were 31% of the navigated group who had a good alignment in terms of all the parameters measured compared to only 14% of the conventional group. About 90% of the patients in the navigated group had errors in 2 or less alignment parameters. Only 65% of the conventional group had errors in 2 or less of the alignment parameters measured. Tables 3.20 to 3.24 summaries the parameters where the errors were found.

Table 3.20 Summary of the one alignment errors and the number patients from each group

One Alignment Parameter Error	Navigated TKA Group	Conventional TKA Group	Total
Sagittal Tibial	5	4	9
Sagittal Femoral	1	8	8
Rotation Femoral	3	1	4
Mechanical Axis	1		1

From table 3.20 it was concluded that the greatest frequency in errors was found in the sagittal plane which is the implant posterior slope. The errors in the tibial slope were found in both surgical groups but the errors in terms of the femoral slope were found predominantly in the conventional group with only one in the navigated group.

Table 3.21 Summary of the two alignment errors and the number patients from each group

Two Alignment Parameter Errors	Navigated TKA Group	Conventional TKA Group	Total
Rotation - Tibial and Relative	6	4	10
Sagittal - Femoral and Tibial	3		3
Rotation - Tibial Frontal - Mech Axis		1	1
Rotation - Femoral Frontal - Mech Axis	1		1
Rotation - Femoral Frontal - Tibial	1		1
Sagittal - Femoral Frontal - Mech Axis		1	1

The predominant 'two error' combination was the tibial and relative rotation. Since the femoral and tibial rotations were used to calculate the relative rotation then this combination of errors was not surprising. An error in either the femoral and tibial components would lead to a relative rotational error unless balanced by the other component rotation. There were low numbers in the other combination groups (1-3 patients in total). Four out of the 17 patients with two alignment errors had errors in two different planes, therefore the majority had combined errors in one plane – rotational.

Table 3.22 Summary of the three alignment errors and the number patients from each group

Three Alignment Parameter Errors	Navigated TKA Group	Conventional TKA Group	Total
Sagittal - Femoral and Tibial Rotation - Femoral	1	1	2
Rotation - Femoral, Tibial and Relative	1	1	2
Rotation - Tibial and Relative Sagittal - Femoral		2	2
Rotation - Tibial and Relative Sagittal - Tibial		1	1
Rotation - Tibial and Relative Frontal -Mech axis		1	1
Frontal – Tibial, Mech axis, Sagittal - Tibial		1	1
Frontal – Femoral, Mech axis, Rotation - Femoral		1	1
Frontal - Mech axis, Rotation - Femoral Sagittal - Femoral		1	1

The ‘three error’ group combinations were varied. One of the 11 patients had an alignment error in all three planes (frontal, sagittal and rotational). Two patients had only rotational alignment errors. The rest of this group had errors in two planes. Only one patient did not have a rotational error. Therefore it appears that the rotational alignment was most variable and difficult to implant correctly. The majority of this ‘three error’ group were from the conventional group. From these results implanting the prosthesis with the correct rotational alignment appeared to be more difficult with conventional instrumentation rather than with the help of the navigation system.

Table 3.23 Summary of the four alignment errors and the number patients from each group

Four Alignment Parameter Errors	Navigated TKA Group	Conventional TKA Group	Total
Rotation - Tibial and Relative Sagittal - Femoral and Tibial	1		1
Rotation - Femoral, Tibial and Relative Sagittal - femoral		1	1

There were only two patients in the ‘four error’ group and therefore no patterns could be observed. The errors for both of these patients occurred in two planes – rotational and sagittal.

Table 3.24 Summary of the five alignment errors and the number patients from each group

Four Alignment Parameter Errors	Navigated TKA Group	Conventional TKA Group	Total
Rotation - Femoral, Tibial and Relative Sagittal - Femoral and Tibial		2	2
Rotation - Femoral Sagittal - Femoral and Tibial Frontal - Femoral and Mech Axis		1	1

The three patients in the ‘five error’ group were from the conventional group. One patient had alignment errors in all three planes. The other two patients had femoral, tibial and relative rotational problems and errors in both the femoral and tibial sagittal alignment.

There are no obvious links between alignment parameters apart from rotation which was due to the fact that femoral and tibial rotations are used to calculate the relative rotational alignment.

3.5. REGRESSION ANALYSIS – FUNCTION AND ALIGNMENT

The previous sections have demonstrated little difference between the two groups but considering the variation in functional performance and alignment between individuals within the groups the question remains, does alignment affect function? Therefore using all the data from both surgical groups the relationship between function and alignment was investigated. Multiple regression was used to investigate the possibility of functional and alignment associations within this group of TKA patients.

Investigating function and alignment using all of the trial patients increases the number of patients within the alignment 'error' groups. Patients with suboptimal mechanical axis alignment are in the 'at risk' group for early implant failure. The impact of implant alignment 'errors' in the other parameters are unknown. Also the impact that these alignment 'errors' have on the patients function has not been explored.

Therefore figures 3.54 to 3.61 looked at the possible correlation between the Total Functional Score and the alignment parameters measured. The vertical lines indicate the desired alignment range.

Figure 3.54 shows a scatter plot of the Total Functional Score versus the frontal femoral alignment.

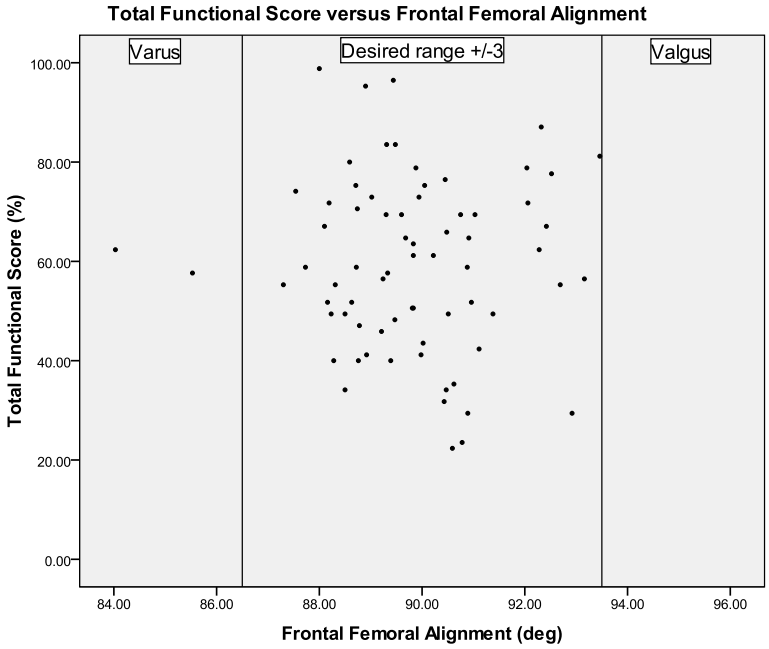


Figure 3.54 Total Functional Score versus frontal femoral alignment

Figure 3.55 shows a scatter plot of the Total Functional Score versus the frontal tibial alignment.

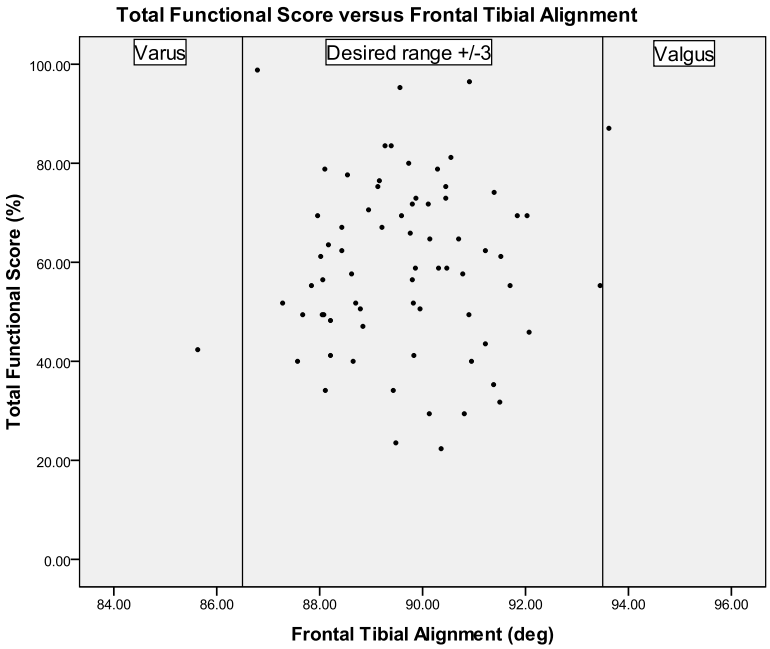


Figure 3.55 Total Functional Score versus frontal tibial alignment

On observation there was no strong correlation between Total Functional Score and frontal femoral or tibial alignment in figure 3.54 and 3.55. For both these alignment parameters there were only two trial patients outwith the desired range of +/-3^{o}. The functional score calculated for the patients within the desired alignment range varied from around 20-100 and the patients who had an 'error' in this alignment parameter fell within this functional score range. Therefore an error in either of these two parameters was not shown to directly relate to a poorer functional score.

Figure 3.56 shows a scatter plot of the Total Functional Score versus the CT scan mechanical axis alignment.

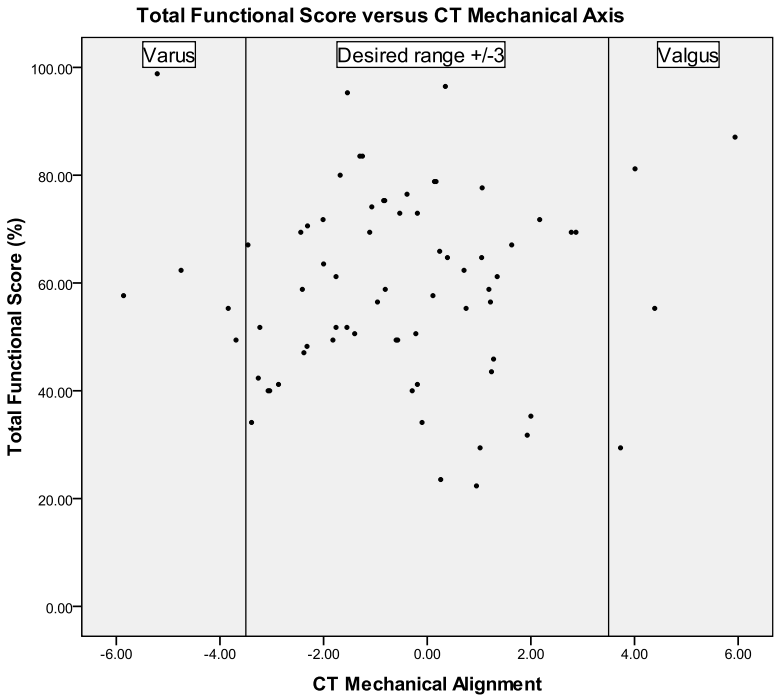


Figure 3.56 Total Functional Score versus CT mechanical axis alignment

Again from observation of the scatter plot in figure 3.56 there was no strong correlation between the Total Functional Score and the mechanical axis alignment calculated using the CT scans. 5 trial patients had excessive varus alignment seen as a negative alignment greater than -3^{o}. The functional scores for these patients were predominately around 50-60 however one patient had a good functional score close to 100. There were four patients with an excessive valgus alignment seen as greater

than +3^{o}. The Total Functional Score for these patients varied from 30-85. Therefore from this data set, excess varus or valgus alignment showed no direct relationship between the alignment error and the Total Functional Score.

For each of the alignment parameters measured a desired range has been quoted. This information was based on literature, prosthesis implant instructions and information from experienced orthopaedic consultants. Outside this range is expected to result in problems for the patients, for example outwith the mechanical axis alignment range has been related to prosthesis longevity. Therefore a linear relationship between the alignment parameters and Total Functional Scores would not be expected. Instead a quadratic relationship fits with the theory that outwith the desired range there would be a decrease in function. The coefficient of determination (r^2) was calculated to show the statistical measure of how well the regression line approximates the real data points.

Figure 3.57 shows a scatter plot of the Total Functional Score versus the sagittal femoral alignment.

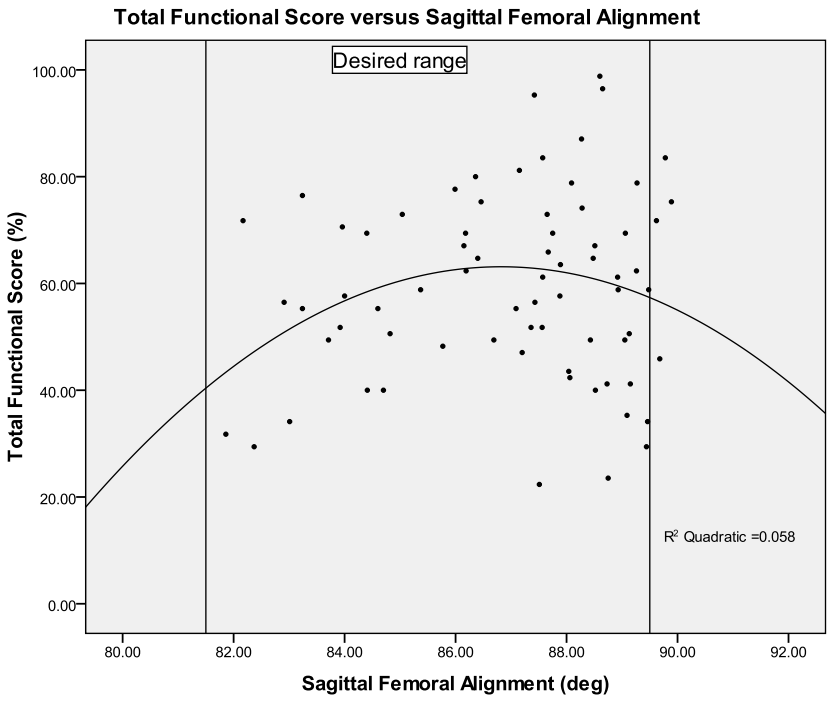


Figure 3.57 Total Functional Score versus sagittal femoral alignment

The quadratic fit line in figure 3.57 suggests that 5^{o} of posterior slope aimed for during surgery does not give the best functional outcome. Instead a posterior slope of around 3-4^{o} results in the best functional outcome. The coefficient of determination, r^2=0.058 which means that the correlation was found to be weak.

A similar quadratic relationship would be expected for the sagittal tibial alignment. On observation figure 3.58 shows that the majority of the tibial components were implanted flatter than the manufacturer's recommendation of a 7^{o} posterior slope. In fact 4-5^{o} of posterior slope gave the highest functional score from this set of patients (figure 3.58). The data appears to have a linear relationship. Fitting a linear and quadratic fit line showed that the quadratic relationship better explained the correlation between sagittal tibial alignment and Total Functional Score.

Figure 3.58 shows a scatter plot of the functional score versus the sagittal tibial alignment.

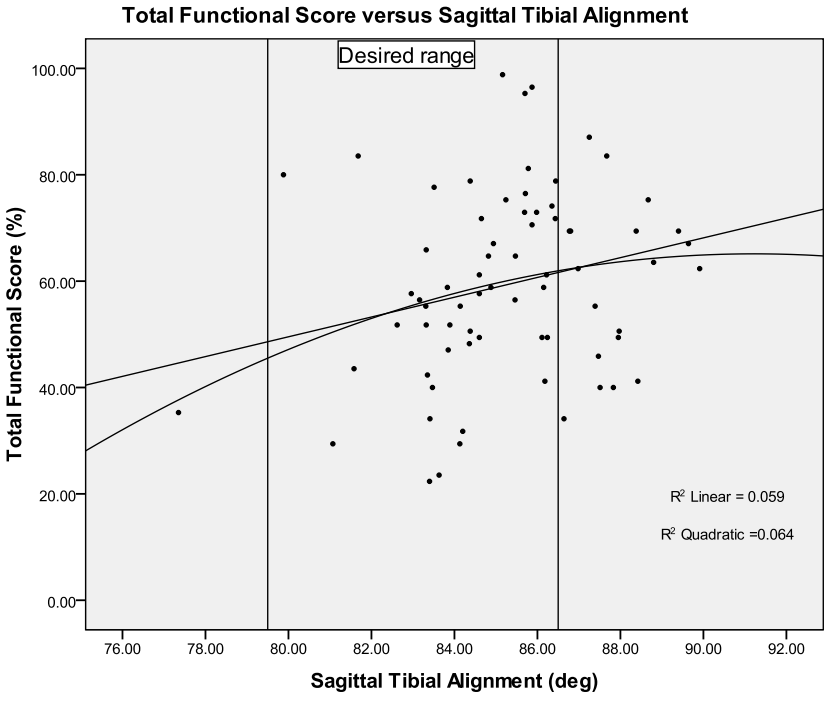


Figure 3.58 Total Functional Score versus sagittal tibial alignment

About 25% of the trial patients resulted in a tibial component implanted with less posterior slope than proposed by the desired range. The Total Functional Score

for this group of trial patients varied from 30-85 which did not indicate a clear decrease in function as a result in an error in this alignment parameter.

Figure 3.58 indicates that the quadratic 'best fit' line approximates the data better than a linear regression line. However the coefficient of determination, r^2=0.064, indicates a weak correlation.

Figure 3.59 shows a scatter plot of the Total Functional Score versus the femoral rotational alignment.

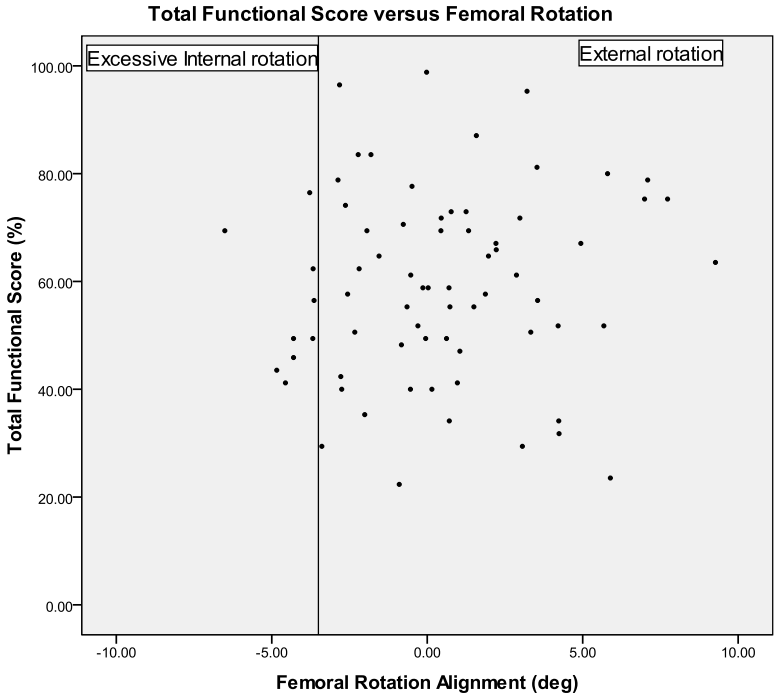


Figure 3.59 Total Functional Score versus femoral rotational alignment

Excessive internal femoral rotation was taken as greater than 3^o. The scatter plot (figure 3.59) shows that the range of Total Functional Scores recorded for trial patients in the excessive rotational group did not differ significantly from those within the desired rotational group (neutral and external rotated). The 'error' group scored 40-75 compared to the 'correctly' aligned group who scored 20-100.

Figure 3.60 shows a scatter plot of the Total Functional Score versus the tibial rotational alignment.

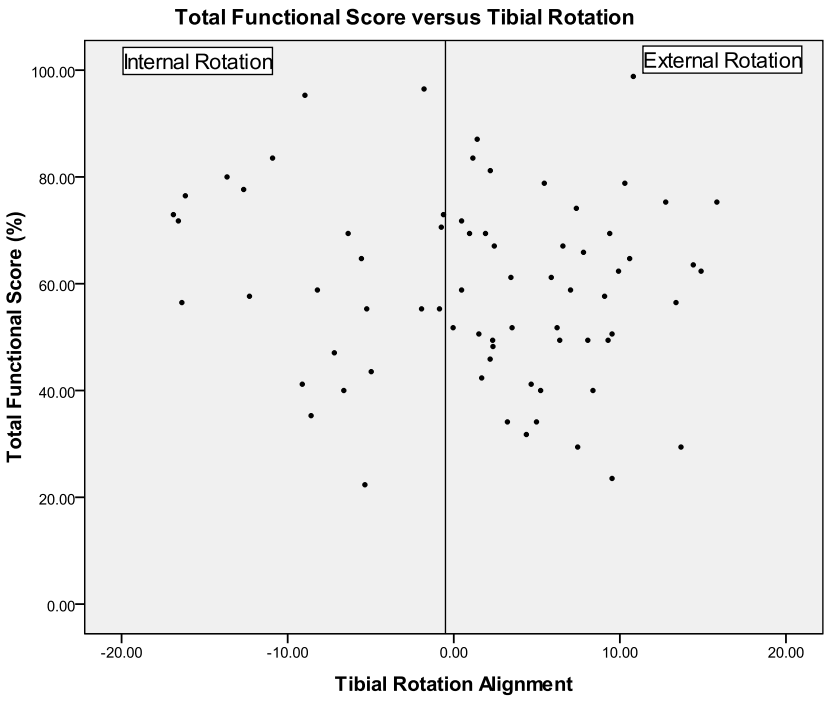


Figure 3.60 Total Functional Score versus tibial rotational alignment

The desired implantation for the tibia component was neutral or externally rotated. Figure 3.60 illustrates that the group of trial patients with an error in the tibial rotation (internally rotated) was large and functionally diverse. The range in Total Functional Score within the two groups (error and desired) did not show a correlation between rotational error and poorer function.

Figure 3.61 shows a scatter plot of the Total Functional Score versus the relative rotational alignment.

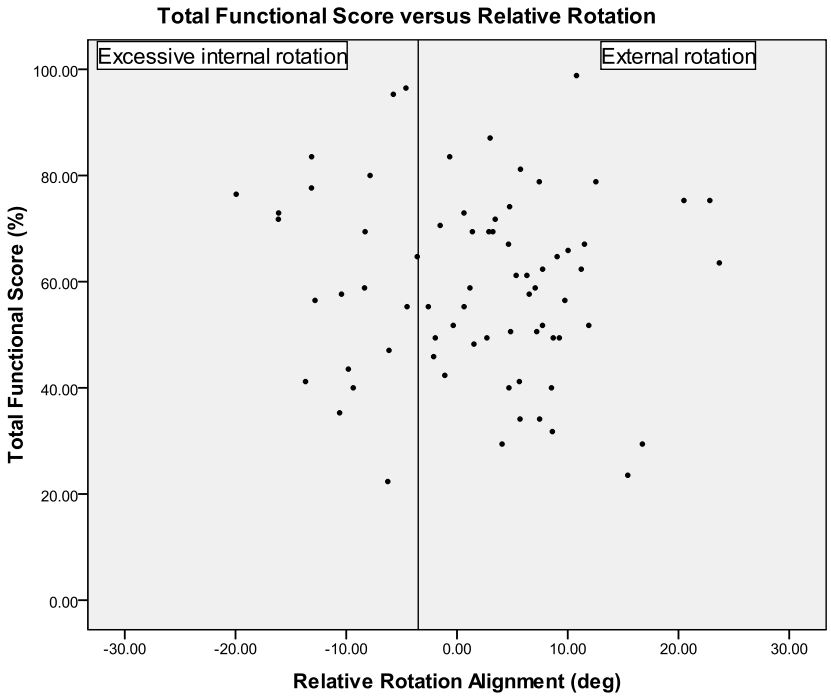


Figure 3.61 Total Functional Score versus relative rotational alignment

Figure 3.61 illustrates that the group of trial patients with an error in the relative rotation (internally rotated) was large, n=20 patients. The range in the Total Functional Score recorded for the two groups (externally and internally rotation) was similar and therefore a correlation between an error in this parameter and poorer function was not indicated by this group of patients.

The mechanical axis alignment, as previously explained was recorded using two methods, a CT scan and a weight bearing long leg radiograph. Section 2.14 investigated the correlation between the mechanical axis recorded using the CT scan and the radiograph. There was a low correlation. The possible reasons for the low correlation were discussed. One of the explanations for the differences between the two measurement systems was that the radiograph was weight bearing. The functional assessment measured knee joint angles during weight bearing activities. Figure 3.62 shows the relationship between the long leg radiograph mechanical axis alignment and the Total Functional Score.

Figure 3.62 shows a scatter plot of the Total Functional Score versus the long leg radiograph mechanical axis alignment.

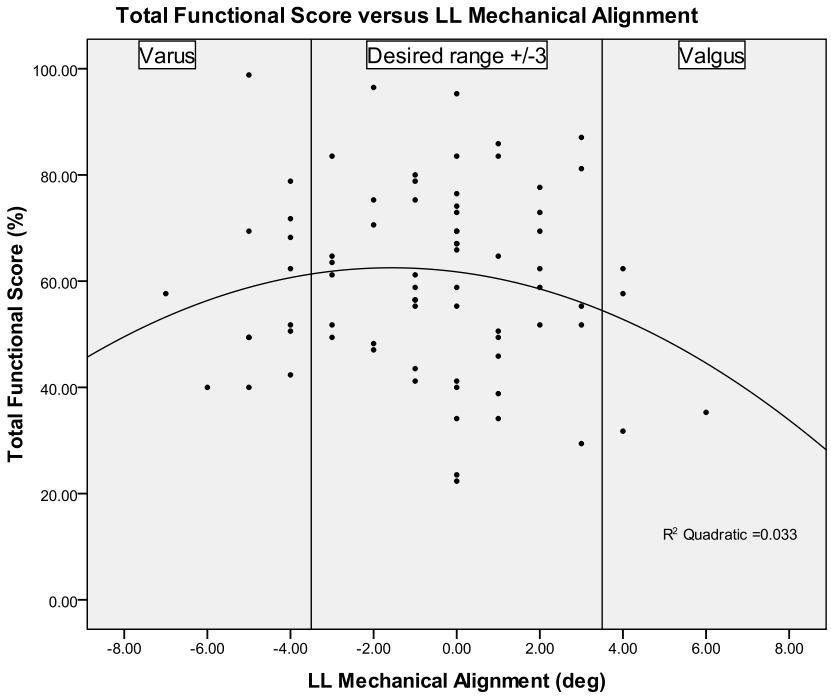


Figure 3.62 Total Functional Score versus long leg mechanical axis alignment

This alignment parameter showed a weak quadratic relationship with Total Functional Score. The coefficient of determination again indicates a weak correlation, r^2=0.033.

From observational analysis of the scatter plot it was seen that the most variable functional score resulted within the group of patients who had a neutral mechanical axis alignment of 0^o. This suggests that a neutral mechanical axis alignment does not always result in a good functional outcome for patients. Instead correct alignment in the two other planes, sagittal axis and rotational alignment are also likely to be influential in functional outcome.

3.5.1. Regression analysis of electrogoniometer activities and alignment

The correlation analysis in the previous section did not result in a strong correlation between Total Functional Score and alignment parameters. Weak correlation was found between the Total Functional Score and sagittal femoral,

sagittal tibial and the mechanical axis alignment calculated using weight bearing long leg radiographs. No correlation was seen between the other alignments and the Total Functional Score. The score was calculated from a range of functional activities. Regression analysis between individual activities and alignment such as gait activities or high flexion activities may show a different result.

Regression of frontal and rotational parameters and electrogoniometry activities.

The individual electrogoniometry functional activities showed no correlation with the frontal or rotational alignment parameters. There was little variation in the scatter plots produced in section 3.5 between alignment and the Total Functional Score, and those produced for alignment and individual electrogoniometry activities (appendix).

Regression of sagittal and LL mechanical axis parameters and electrogoniometry activities.

Table 3.25 summarises the coefficient of determination for the sagittal femoral, sagittal tibial and long leg mechanical axis alignment and each of the 12 individual electrogoniometry activities.

Table 3.25 shows that the r^2 values from the regression analysis were low for all the activities. The table highlights the coefficient values which were greater than 0.1. These values were low but a pattern was still observed where alignment had a greater influence on the high flexion activities - up and down stairs, stand to sit and out of a bath.

Table 3.25 Summary of r^2 values of the electrogoniometry activities

		Sagittal Femoral	Sagittal Tibial	Radiograph Mech Axis
Maximum Knee Joint Angle	Level Walk	0.047	0.022	0.032
	Up slope	0.052	0.073	0.033
	Down slope	0.023	0.062	0.056
	Up stairs	**0.136**	**0.106**	0.04
	Down stairs	0.044	**0.122**	0.055
	High sit	-	**0.104**	-
	High stand	-	0.054	-
	Low sit	-	0.041	0.033
	Low stand	-	0.071	0.031
	In bath	0.089	-	-
	Out bath	**0.136**	0.022	-
	Flexion	0.079	0.081	0.059
Excursion Knee Joint Angle	Level Walk	0.068	0.003	0.032
	Up slope	0.049	0.029	0.019
	Down slope	0.013	0.01	0.035
	Up stairs	**0.104**	0.073	0.02
	Down stairs	0.036	0.095	0.026

From the regression analysis between alignment and the electrogoniometry functional data there was no strong correlations observed. From this data there was a weak relationship between the sagittal femoral and sagittal tibial alignment and the knee joint angles recorded in the high flexion activities.

3.5.2. Analysis of alignment errors and function

The regression analysis in the previous section did not indicate a strong correlation between individual alignment parameters and function for this data set. Within this group of TKA patients there were patients with 0 to 5 implant parameters incorrectly aligned. Table 3.26 summaries the mean Total Functional Score calculated for each error group.

Table 3.26 Parameter error and their associated mean functional score

Group	Mean Functional Score
5 errors	47.84
4 errors	71.76
3 errors	64.34
2 errors	56.82
1 error	59.14
Correctly aligned	57.25

The lowest functional score was recorded for the '5 error' group. However there was no trend seen to suggest that a correctly aligned prosthesis resulted in the best function and that the presence of an increasing number of alignment error lead to a gradual decrease in functional outcome.

3.6. REGRESSION ANALYSIS – FUNCTION AND CLINICAL MEASURES

Routine clinical measures for TKA outcome include measuring passive range of motion and questionnaire scores. Questionnaires are a subjective measure and therefore how accurately they convey the patient's functional outcome is unknown. Functional assessments using electrogoniometry give an objective overview of patients' function but it has the disadvantage of being time consuming.

3.6.1. Regression Analysis – Function and Passive ROM

Recording the knee range of motion (ROM) at the knee joint is an important clinical measure. Passive ROM was measured with the patient lying supine using a manual goniometer. Active ROM has previously been reported as the deep knee flexion activity in the electrogoniometry functional assessment, in which the patient produced their greatest flexion angle. Deep flexion was therefore a weight bearing activity which recorded the patient's maximum active ROM. Table 3.27 summaries the navigated and conventional TKA groups' passive and active ROM.

Table 3.27 Summary of passive and active ROM for the navigated and conventional TKA groups.

	Navigated			Conventional			
	Mean	Range	St dev	Mean	Range	St dev	p value
Passive ROM	114.62	(80-130)	12.23	114.53	(85-135)	11.81	0.97
Active ROM	107.67	(79.3-144.3)	15.45	107.50	(69.5-145.9)	18.05	0.96

Table 3.27 shows that there was no statistically significant difference in the passive ROM between the groups (p=0.97). There was however a significant statistical reduction in the recorded active ROM compared to passive ROM for both of the surgical groups (navigated p=0.034, conventional p=0.047). This means that as a TKA group (n=77) there was a significant statistical reduction in measured active ROM compared to measured passive ROM (p=0.04). Active and passive ROM were measured using two different systems which may account for some of the variation in the measurements. However the result suggests that patients do not use their full passive ROM during weight bearing functional activities. Therefore the non weight bearing measurement recorded in clinics may not completely relate to the active ROM using in daily activities.

All the trial patients were taken as one TKA group and a correlation analysis was carried out. Passive and active ROM had a linear relationship (figure 3.63).

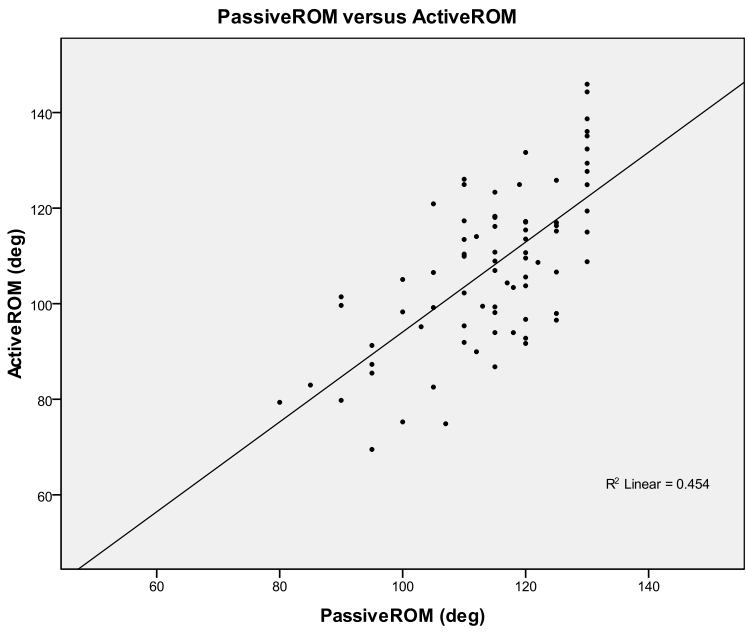


Figure 3.63 Scatter plot of passive ROM versus active ROM for all of the trial patients.

Passive and active ROM data was normally distributed. From observation it can be concluded that there was a trend for increasing passive ROM to be associated with increasing active ROM. The Pearson coefficient (r) for the plot (figure 3.63) was 0.698 (95% CI 0.56 to 0.8). Cohen's scale states that 0-0.1 indicates no correlation, 0.1-0.3 indicates a weak correlation, 0.3-0.5 indicates a moderate correlation and 0.5-1.0 indicates a strong correlation. In this case there was a strong linear relationship between passive and active ROM.

The coefficient of determination r^2=0.454. This indicates that 45% of the active ROM was explained by passive ROM leaving the other 55% of variation unexplained.

Figure 3.64 also showed that there was a linear relationship between Total Functional Score and passive ROM.

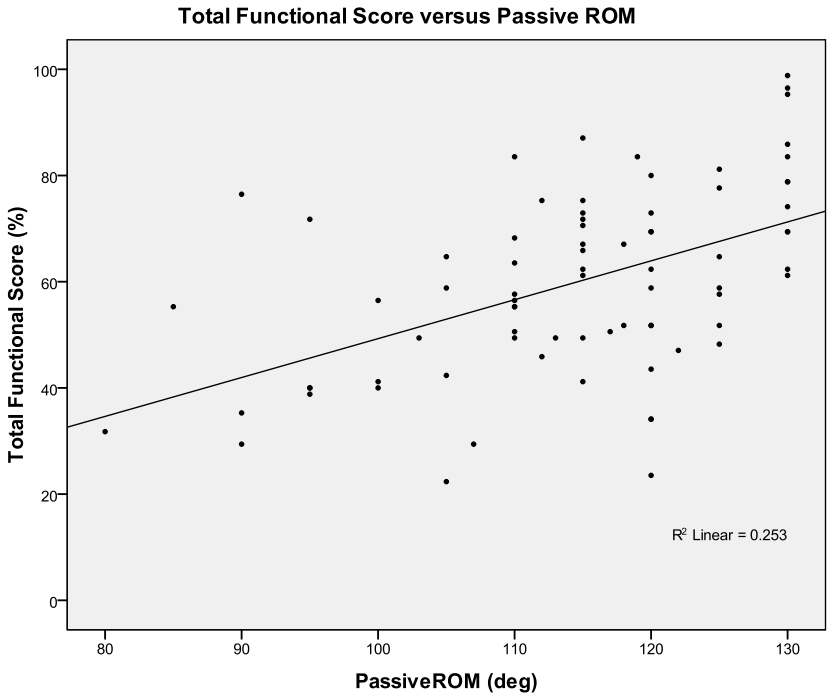


Figure 3.64 Passive ROM versus Total Functional Score for all of the trial patients.

A linear correlation between passive flexion and Total Functional Score was observed where an increase in passive ROM tends to correlate with increasing total functional score. Pearson's coefficient was r=0.503 (95% CI 0.32 to 0.65) indicating a greater spread in the data than that in figure 3.63. There was a weak to moderate

linear relationship between the two variables. The coefficient of determination was r^2=0.253. Therefore passive ROM accounts for about 25% of the total functional score. This shows that about 75% of the variation between the clinically measured passive ROM and the subjective electrogoniometry Total Functional Score was still unexplained.

3.6.2. Regression Analysis – Function and Questionnaire Scores

Various questionnaires are routinely used as measures of functional outcome for TKA. These are assumed to closely reflect the patient's function.

Oxford Knee Score (OKS)

The Oxford Knee Score (OKS) ranges from 12-60 where 12 is the best outcome and 60 the worst outcome. The OKS contains functional questions and questions which relate to pain. There are 5 'pain' questions therefore the pain sub score range from 5-25, again with the lower the score the better the outcome. The 'function' sub score has 7 questions ranging from 7-35 points. It is possible that the presence of pain can mask the functional outcome within this questionnaire. Pain is a significant post-operative problem for some patients and will affect the patient's functional outcome and their willingness to attempt daily activities.

Table 3.28 Summary of the Oxford Knee Scores for the navigated and conventional group

	Navigated			Conventional			
	Mean	Range	StDev	Mean	Range	StDev	p value
Oxford Knee Score	24.46	(14-42)	7.67	25.72	(13-44)	8.25	0.50
Oxford - Function	14.71	(7-28)	4.94	16.14	(8-29)	4.78	0.22
Oxford - Pain	9.86	(5-20)	4.12	9.91	(4-19)	4.36	0.96

Table 3.28 indicates that in terms of the OKS there was no difference between the surgical groups.

The OKS from the whole TKA group were plotted against the electrogoniometry Total Functional Score (figure 3.65).

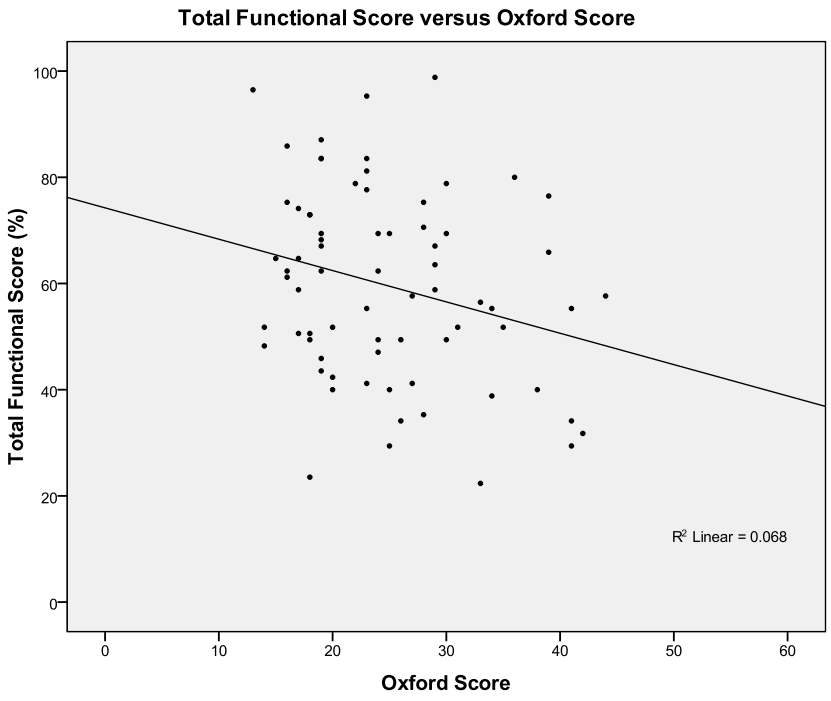


Figure 3.65 OKS versus Total Functional Score for all of the trial patients.

There was a negative correlation between Total Functional Score and the OKS as expected as a low OKS score indicates better functional outcome. Correlation coefficient was r=-0.261 (95% CI -0.04 to -0.46)) and the coefficient of determination was r^2=0.068. Therefore the OKS accounts for only about 7% of the Total Functional Score. These variables showed a weak correlation due to the increased spread of the data.

The correlation was repeated using only the OKS 'function' score to determine whether this correlates better with the Total Functional Score (figure 3.66).

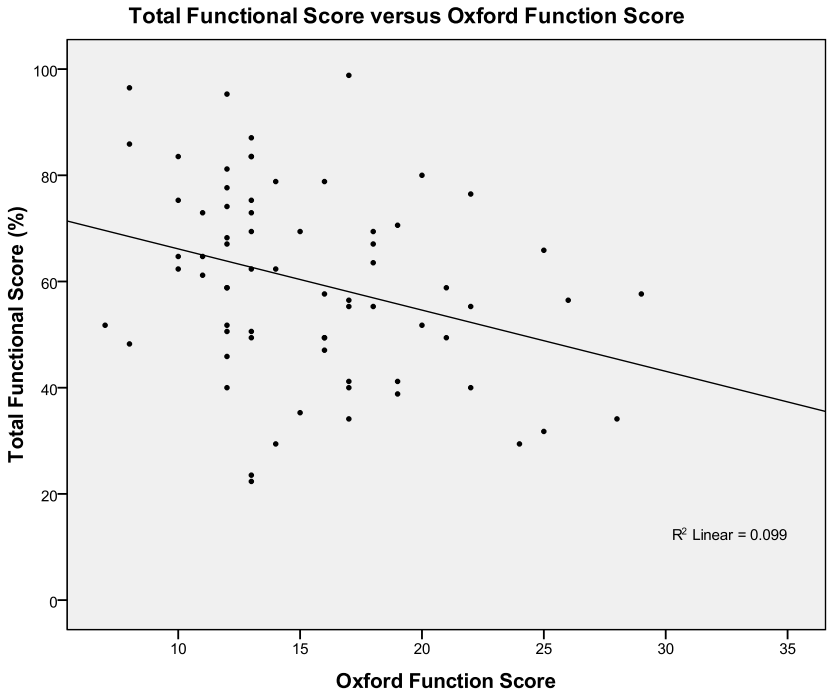


Figure 3.66 OKS function sub score versus Total Functional Score for all of the trial patients.

For figure 3.66 the Pearson's coefficient was r=-0.318 (95% CI -0.10 to -0.51) and the coefficient of determination was r^2=0.099. Therefore the OKS 'function' score accounts for about 10% of the Total Functional Score. Therefore the correlation between the Oxford function score and the Total Functional Score increased compared to the overall OKS. However it still demonstrated a weak to moderate linear relationship.

The questions within the OKS relate to all aspects of the patients outcome and therefore include 'pain' questions. Pain appears to influence the strength of the correlation between the OKS and the Total Functional Score, as the inclusion of the pain questions appear to lower the coefficient of determination.

The pain score from the OKS was correlated with the Total Functional Score to investigate whether there was a relationship between pain and active function as measured by the Total Functional Score (figure 3.67).

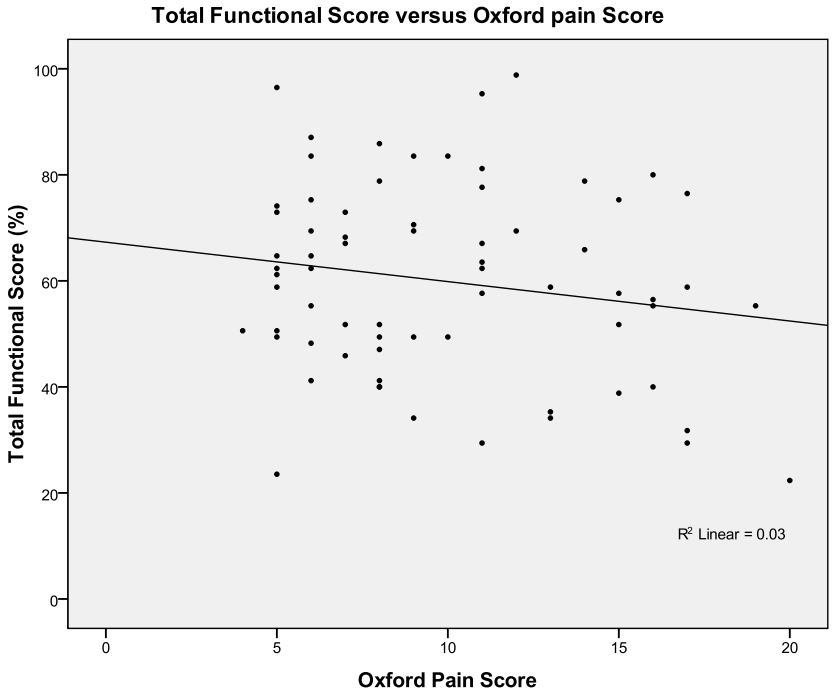


Figure 3.67 OKS pain sub score versus Total Functional Score for all of the trial patients.

The spread of the data in the xy plot suggests that there was no association between there two variables. Using a two sample independent t-test it was concluded that there was no significant correlation between total functional score and the Oxford pain score (p=0.147).

In conclusion, correlation was found between the electrogoniometry Total Functional Score and both the overall OKS and the function sub-score of the OKS. There was no significant correlation between the pain sub-score of the OKS and the electrogoniometry Total Functional Score. This suggests that pain questions in questionnaires can over shadow the post-operative functional outcome. It suggests that pain may limit the patient in how active they are during the day and how difficult they find the daily tasks included in the OKS. In conclusion the patients perceived function recorded in the questionnaires did not have a strong correlation

with the actual function as measured through the electrogoniometry functional assessment.

American Knee Society Score (AKSS)

The AKSS is divided into a knee and a function score. Both scores are scored from 0-100 with the higher score indicating a better outcome. The knee score includes sections on pain, ROM and knee stability. The function score is limited to a question about walking distance and one on the ability to ascend and descend stairs. The use of walking aids had a negative effect on the score, for example using a walking stick equals -5 points. Table 3.29 summarises the mean AKSS scores for the navigated and conventional groups. There was no significant difference found between the groups (as seen from the p values for the AKSS knee and AKSS function).

Table 3.29 Summary of the AKSS for the navigated and conventional group

	Navigated			Conventional			
	Mean	Range	StDev	Mean	Range	StDev	p value
AKSS knee score	82.86	(40-95)	12.26	83.47	(37-95)	12.64	0.84
AKSS function score	75.00	(15-100)	21.47	70.74	(45-100)	16.47	0.35

The scatter plots in figure 3.68 and 3.69 show the correlation of the knee and function sub-score of the AKSS with the Total Functional Score.

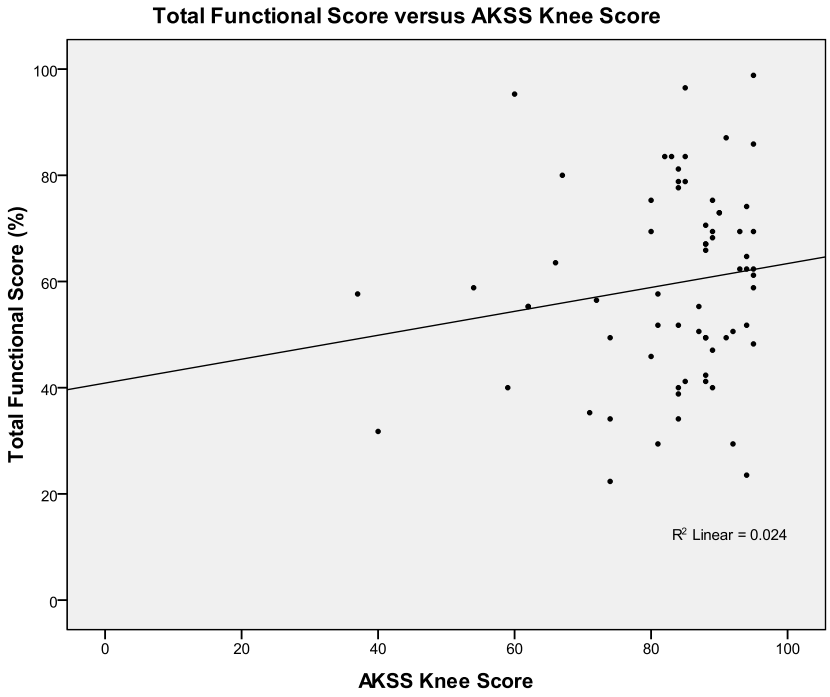


Figure 3.68 AKSS Knee Score versus Total Functional Score for all of the trial patients.

The spread of the data in the xy plot (figure 3.68) suggests that there was no association between there two variables. Using a two sample independent t-test it was concluded that there was no significant correlation between Total Functional Score and the AKSS knee score (p=0.207).

The AKSS knee sub-score was calculated from the passive ROM, pain and knee stability. It has previously been concluded that passive ROM correlates with the electrogoniometry Total Functional Score. The AKSS knee score does not have a strong relationship with the Total Functional Score, therefore this leads to the assumption that pain and knee stability factors do not strongly correlate with the electrogoniometry Total Functional Score.

AKSS function sub-score had a linear relationship with the Total Functional Score (figure 3.69).

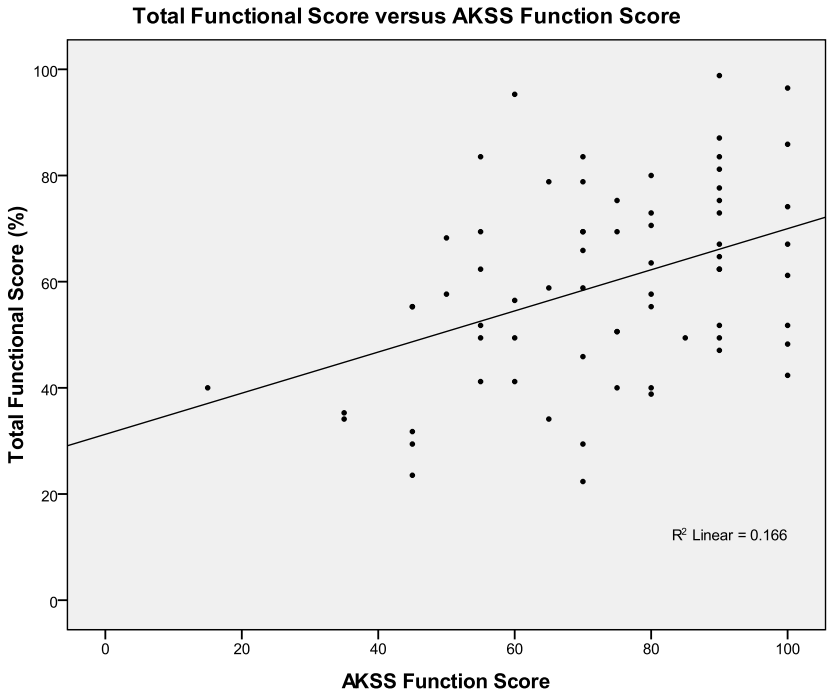


Figure 3.69 AKSS Function Score versus Total Functional Score for all of the trial patients.

The Pearson's coefficient for figure 3.69 was r=0.408 (95% CI 0.20 to 0.58) and the coefficient of determination was r^2=0.166. Therefore the AKSS function sub score accounts for about 17% of the Total Functional Score. The functional sub score of the AKSS questionnaire showed a moderate correlation to the electrogoniometry Total Functional Score.

WOMAC

The WOMAC score ranges from 0-96 where the lower the score, the better the outcome. It can be sub divided into a pain, stiffness and functional score. There are 5 pain questions (0-20), 2 stiffness questions (0-8) and 17 function questions (0-68). Table 3.30 summarises the mean WOMAC scores for the navigated and conventional groups. There was no significant difference found between the groups as seen from the p values.

Table 3.30 Summary of WOMAC scores for the navigated and conventional groups.

	Navigated			Conventional			
	Mean	Range	StDev	Mean	Range	StDev	p value
WOMAC	27.37	(0-72)	19.73	25.54	(0-75)	18.64	0.68
WOMAC -pain	4.33	(0-13)	4.20	4.78	(0-15)	3.99	0.64
WOMAC -stiffness	2.67	(0-6)	1.51	2.27	(0-6)	1.69	0.29
WOMAC -function	19.64	(0-53)	14.55	19.27	(0-54)	13.71	0.91

The scatter plots in figure 3.70-3.73 show the relationship, if any, between the WOMAC clinical outcome scores and the electrogoniometry Total Functional Score. The overall WOMAC score had a negative linear relationship with the Total Functional Score (figure 3.70).

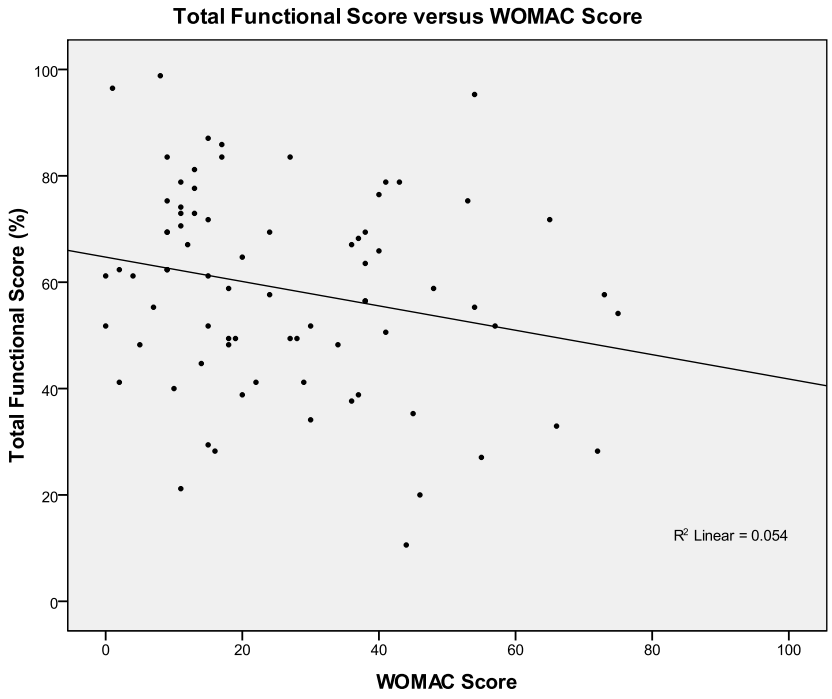


Figure 3.70 WOMAC versus Total Functional Score for all of the trial patients.

Pearson's coefficient for figure 3.70 was r=-0.231 (95% CI -0.008 to -0.43) and the coefficient of determination was r^2=0.054. Therefore the WOMAC score only accounts for 5% of the Total Functional Score. Therefore this questionnaire shows a weak linear relationship with the Total Functional Score.

WOMAC ‘pain’ score had a linear relationship with the Total Functional Score (figure 3.71).

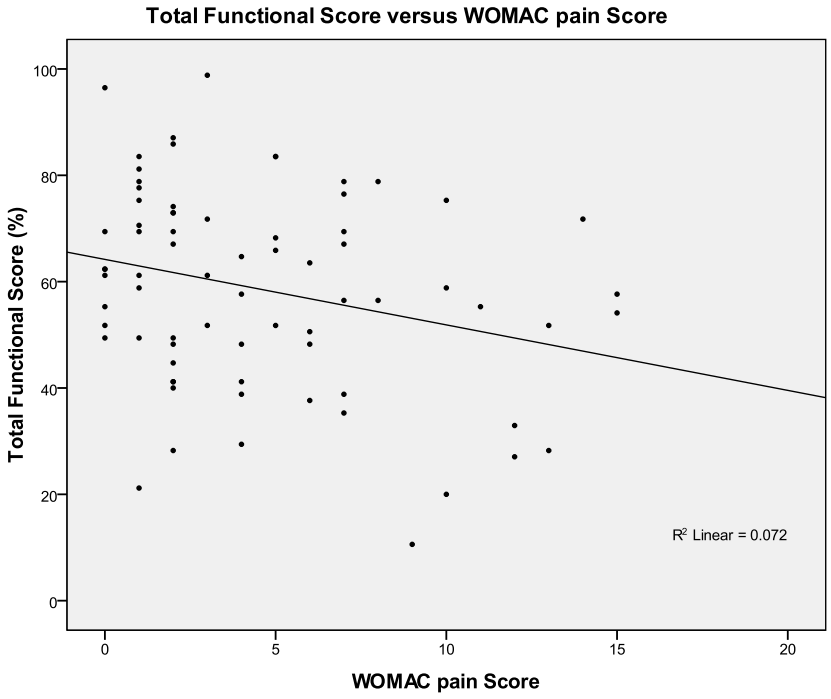


Figure 3.71 WOMAC pain Score versus Total Functional Score for all of the trial patients.

Pearson’s coefficient for figure 3.71 was r=-0.269 (95% CI -0.05 to -0.46) and the coefficient of determination was r^2=0.072. Therefore the WOMAC ‘pain’ score accounts for about 7% of the Total Functional Score. In this case the pain sub score appears to have a relationship with the objective Total Functional Score which was not recorded in the pain scores for the OKS or the AKSS. The WOMAC pain score has a weak linear relationship with the Total Functional Score.

WOMAC ‘stiffness’ score had a linear relationship with the Total Functional Score (figure 3.72).

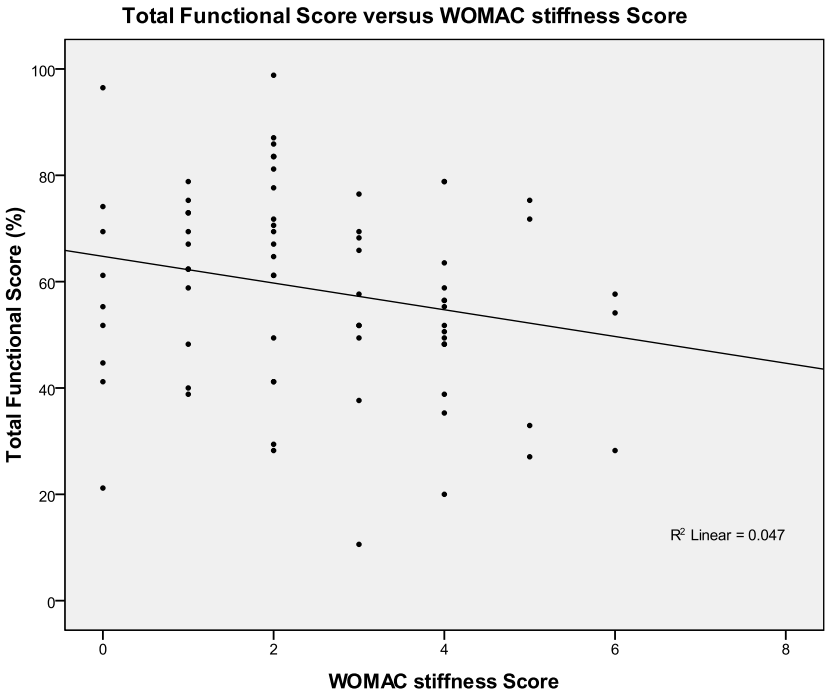


Figure 3.72 WOMAC stiffness Score versus Total Functional Score for all of the trial patients.

However the spread of the data in the xy plot (figure 3.72) suggests that there was no association between there two variables. Using a two sample independent t-test it was concluded that there was no significant correlation between Total Functional Score and the WOMAC ‘stiffness’ score (p=0.066).

WOMAC ‘function’ score had a linear relationship with the Total Functional Score (figure 3.73).

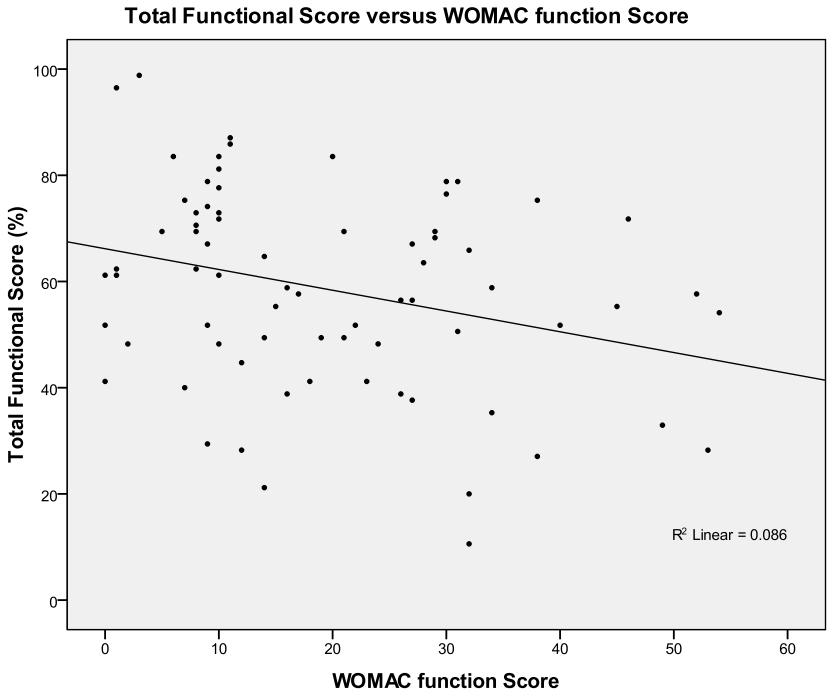


Figure 3.73 WOMAC function Score versus Total Functional Score for all of the trial patients.

Pearson’s coefficient for figure 3.73 was r=-0.294 (95% CI -0.08 to -0.49) and the coefficient of determination was r^2=0.086. Therefore the WOMAC ‘function’ score accounts for about 9% of the Total Functional Score. The WOMAC function score recorded a stronger correlation with the Total Functional Score than the other WOMAC sub scores, however this was still a weak linear relationship.

Unlike the OKS and AKSS pain score, the WOMAC pain score was seen to be weakly correlate with the Total Functional Score. In all three clinical questionnaires; OKS, AKSS and WOMAC, the function sub score was seen to have the strongest correlation with the Total Functional Score.

Visual Analogue Scale

The Visual Analogue Scale (VAS) is a measure of pain from least pain or discomfort (0 points) to worst pain or discomfort (100 points). The previous clinical questionnaires did not report a strong relationship between ‘pain’ and functional

outcome. The pain questions in these questionnaires related specifically to pain during a particular activity such as sit to stand. The VAS records the patients perceived level of pain for the last 48 hours during all daily activities. No statistically significant difference was found between the 2 surgical groups.

Table 3.31 Summary of VAS scores for the navigated and conventional groups.

	Navigated			Conventional			
	Mean	Range	StDev	Mean	Range	StDev	p value
VAS	25.71	(0-86)	25.33	24.77	(0-98)	28.05	0.88

The mean pain score was 27 which indicates that on average the level of pain for the TKA patients was mild-moderate. It is difficult to quantify how pain levels affect function. Many patients live with a constant pain which may slow them down and limit the tasks completed in one day.

Figure 3.74 investigates the relationship between patient perceived pain (VAS) and their Total Functional Score. There was a negative linear relationship between these two parameters as a high VAS score indicates a high pain level.

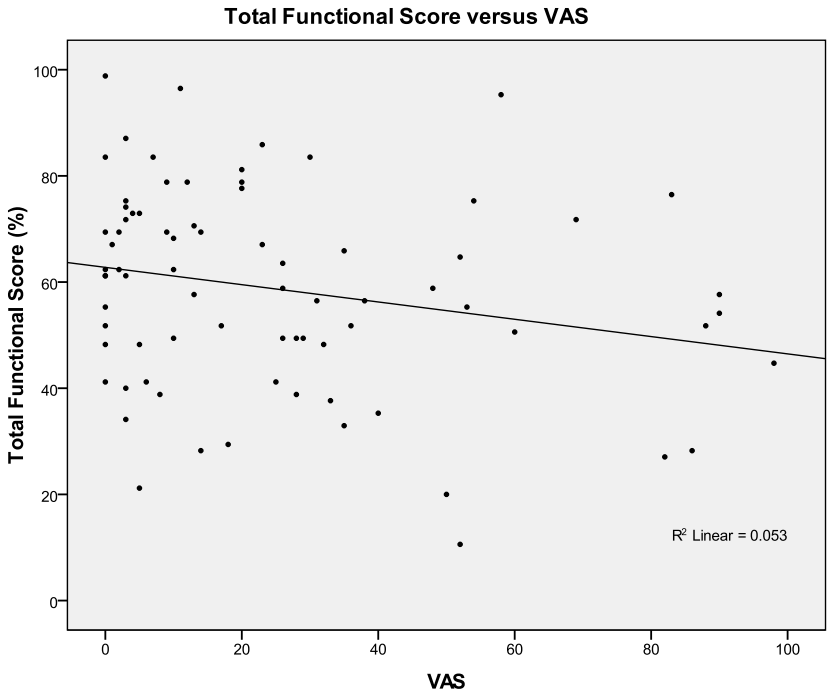


Figure 3.74 VAS versus Total Functional Score for all of the trial patients.

Pearson's coefficient in figure 3.74 was r=-0.229 (95% CI -0.006 to -0.43) and the coefficient of determination was r^2=0.053 suggesting only a weak linear relationship between the two variables. The VAS score accounts for only 5% of the Total Functional Score.

Patient Satisfaction

The patient satisfaction score was recorded for each of the trial patients. Table 3.32 gives a summary of the satisfaction scores for both surgical groups.

Table 3.32 Summary of Satisfaction scores for the navigated and conventional groups.

Patient Satisfaction	Very Unsatisfied (1)	Unsatisfied (2)	Don't Know (3)	Satisfied (4)	Very Satisfied (5)
Navigated		1 patient (3%)	3 patients (8%)	8 patients (21%)	26 patients (68%)
Conventional	1 patient (3%)	2 patients (5%)	2 patients (5%)	13 patients (33%)	21 patients (54%)

It was recorded that the majority of TKA patients were happy with the outcome of the surgery. The percentage of the conventional group who were not happy with the outcome of the surgery was greater than the percentage of the navigated group who were unsatisfied. This could refer to dissatisfaction in their post-operative pain level or functional outcome.

The most important outcome for most TKA patients is to be pain free or have a reduction in the pain they live with on a daily basis. Secondary to this is a good functional outcome, which allows them to feel no limitations in their everyday life.

Figure 3.75 showed no significant correlation between patient satisfaction rates and Total Functional Score (p=0.236).

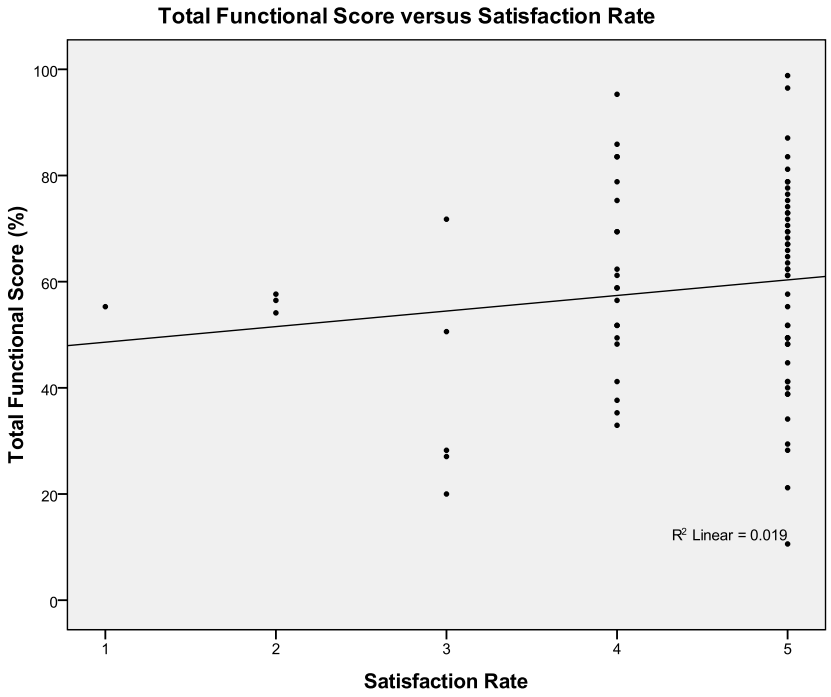


Figure 3.75 Satisfaction Rate versus Total Functional Score for all of the trial patients.

Figure 3.75 shows that a range of post-operative functional outcome was seen in the patients who were 'very satisfied' with the outcome of their surgery. In fact the patients who were unhappy (scoring 1 or 2) recorded a Total Functional Score which equalled close to the average for the whole TKA group. The average TKA patient within the study could complete the majority of functional tests in the assessment competently. This suggests the reason they were not satisfied with the surgical outcome was not function related but was related to their post-operative pain levels. In fact there were patients with a low Total Functional Score who were very satisfied with the outcome of their surgery. This result may link back to the idea that satisfaction is linked to patients expectations (Noble P.C et al., 2006). This small group of patients may have reduced pain levels after surgery and in general are not functional active so do not feel limited.

Figure 3.76 shows the relationship between VAS pain levels and satisfaction rates.

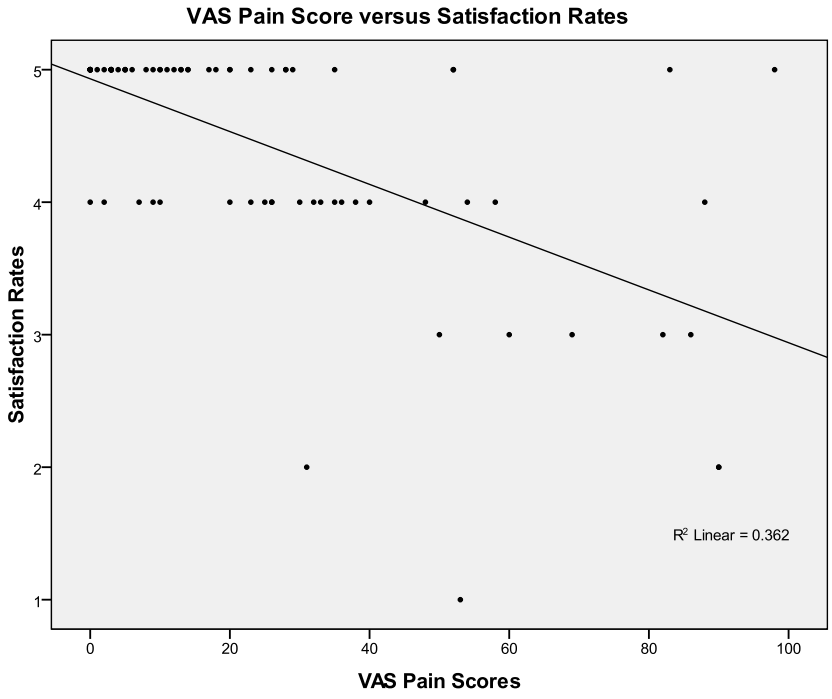


Figure 3.76 VAS pain scores versus Satisfaction Rate for all of the trial patients.

Figure 3.76 shows a strong linear correlation between VAS pain scores and satisfaction, where a decrease in pain directly relates to an increase in satisfaction rates. Pearson's coefficient for figure 3.76 was, r=-0.601 and the coefficient of determination was r^2=0.362. Therefore the VAS pain score accounts for about 36% of the Satisfaction Rate score.

Summary: Function and Clinical Measures

Table 3.33 lists the clinical measures investigated for a correlation with the electrogoniometry Total Functional Score. The p values in bold indicate the variables which had correlation coefficients which were statistically significant. However, the only variable to result in a moderate linear relationship (where r<0.5) was passive ROM. Analysis of the other clinical variables resulted in correlation coefficients less than 0.5 which indicated only a weak relationship. This illustrates the important of ROM measurement as an indicator of functional outcome.

Table 3.33 Summary of r, r^2 and p values

	r	r^2	p
Passive ROM	0.503	0.253	**<0.001**
AKSS function	0.408	0.166	**<0.001**
Oxford Function	-0.318	0.099	**0.008**
WOMAC -function	-0.294	0.086	**0.012**
WOMAC -pain	-0.269	0.072	**0.022**
Oxford	-0.261	0.068	**0.027**
WOMAC	-0.231	0.054	**0.043**
VAS	-0.229	0.053	**0.045**
WOMAC -stiffness	-0.216	0.047	0.066
Oxford Pain	-0.176	0.031	0.147
AKSS knee	0.155	0.024	0.207
Patient Satisfaction	0.137	0.019	0.236

Regression

Analysis of passive ROM concluded that only 25% of the Total Functional Score was predicted from this variable. Therefore 75% of the Total Functional Score was still unexplained. Step wise regression used the variables which were highlighted in bold, in table 3.33 to develop a model which would better predict the Total Functional Score. A model including passive ROM and the AKSS function score resulted in an increase in the coefficient of determination, r^2=0.2917. The addition of further variables did not increase the value of the coefficient of determination. Therefore the best model for predicting electrogoniometry Total Functional Score included passive ROM and the AKSS function score data. This model was estimated to predict around 30% of the objective electrogoniometry Total Functional Score.

3.7. QUADRICEPS AND HAMSTRING MOMENTS

Muscle strength has been reported to decrease in arthritic patients. OA patients 1 week before their operation recorded quadriceps moments of 77.9Nm and hamstring moments of 33.8Nm (Hubley-Kozey C et al., 2008). These were concluded to be decreased compared to a control group and a group with moderate knee OA by 62-67%. These figures were calculated while sitting with the knee joint at 55^o flexion. In this study, the quadriceps and hamstring were measured while the patient was sitting on a standard chair and the knee joint was at approx 90^o. The

peak isometric quadriceps torque (moment) changes with knee angle. The relationship is quadratic therefore it has been concluded that the peak quadriceps moment occurs at a knee angle of 80^{o} (Kong P.W and Burns S.F, 2010). The hamstring moment showed a linear relationship. The peak moment occurred when the muscle was at its 'most lengthened position' and deceased with the shortening of the muscle. Therefore comparison between studies in terms of quadriceps and hamstring moments was difficult as the methodology has to be comparable.

Table 3.34 Summary of the quadriceps and hamstring moments for the 2 groups

	Navigated			Conventional			
	Mean	Range	St dev	Mean	Range	St dev	p value
Quadriceps Moment (Nm)	76.94	(15.2-250)	46.97	54.14	(14.1-198.4)	41.41	0.028
Hamstring Moment (Nm)	41.33	(7.7-80.6)	17.14	32.04	(8.1-82)	16.62	0.019

The navigated and conventional group mean moments are similar to those calculated in Hubley-Kozey's study. However this study looked at patients with severe knee OA prior to surgery, therefore it would be expected that the trial patients would have improved knee strength.

There was a significant statistical difference between the 2 surgical groups in terms of quadriceps and hamstring moments. The mean quadriceps moment for the navigated group was 76.94Nm compared to 54.14Nm for the conventional ($p<0.05$). The mean hamstring moment for the navigated group was 41.33Nm compared to 32.02Nm for the conventional group ($p<0.05$). However, the 2 groups were made up of different proportions of male and females. The navigated group had 58% men and the conventional only 49%. This gender imbalance could be a possible cause for the differences in the quadriceps and hamstring moments. In fact it has been reported than women generate 52.4% lower isometric extension (quadriceps) peak torque values and 44% lower isometric flexion (hamstring) peak torque values than TKA men (Silva M et al., 2003).

Table 3.35 Summary of the quadriceps and hamstring moments for the 2 groups sub-divided into male and female groups.

		Navigated			Conventional			
		Mean	Range	St dev	Mean	Range	St dev	p value
Quadriceps Moment (Nm)	Male	89.35	(17.1-250)	55.17	74.47	(24.6-198.4)	48.50	0.36
	Female	60.70	(15.2-85)	22.54	34.81	(14.1-94,9)	19.77	0.003
Hamstring Moment (Nm)	Male	45.35	(7.8-80.6)	15.91	40.72	(14.6-82)	18.04	0.39
	Female	37.05	(7.7-73.2)	18.36	23.79	(8.1-49.2)	9.86	0.03

Table 3.35 give a summary the results from the male and female sub groups. For both sub groups the navigated group had an increased quadriceps and hamstring moment. The female sub group showed a statistically significant difference between the two surgical groups (quadriceps p=0.003, hamstring p=0.03).

In a healthy knee the Hamstring/Quadriceps (H/Q) ratio ranges from 0.5-0.8 where during rehabilitation 0.6 or greater is aimed for as reported by Kong et al (2010). For the navigated group the mean H/Q ratio = 0.61 and for the conventional group H/Q=0.69. The high standard deviation for the quadriceps moment in tables 3.34 and 3.35 suggests that this measurement was highly variable.

Previously there were differences found between the two groups during the push off phase of level and slope walking. The improved muscle strength in the navigated group could be linked to the improvements seen in the walking activities during the functional assessment.

3.7.1. Regression Analysis – Function and Muscle Strength

The scatter plot in figure 3.77 illustrates the correlation between the quadriceps moment and the Total Functional Score.

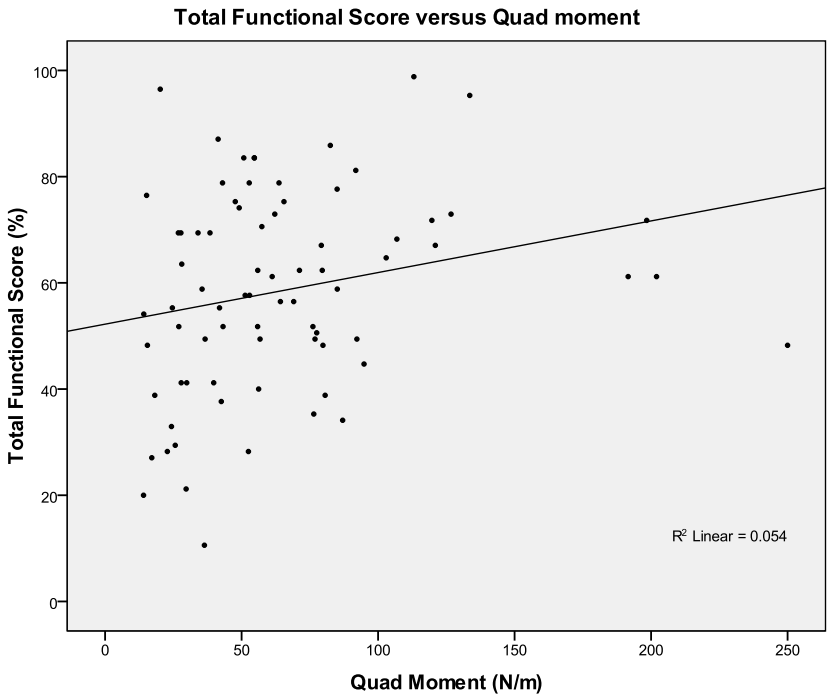


Figure 3.77 Quadriceps Moment versus Total Functional Score for all of the trial patients.

Correlation coefficient for figure 3.77 was, r=0.232 (p=0.044, 95% CI 0.009 to 0.43). There was a weak linear relationship between these two variables. It can be seen that there are 4 outlier patients with exceptional strong muscles compared to the rest of the group. The coefficient of determination was r^2=0.054. Therefore the quadriceps moment accounts for only 5% of the Total Functional Score.

The scatter plot in figure 3.78 illustrates the correlation between the hamstring moment and the Total Functional Score.

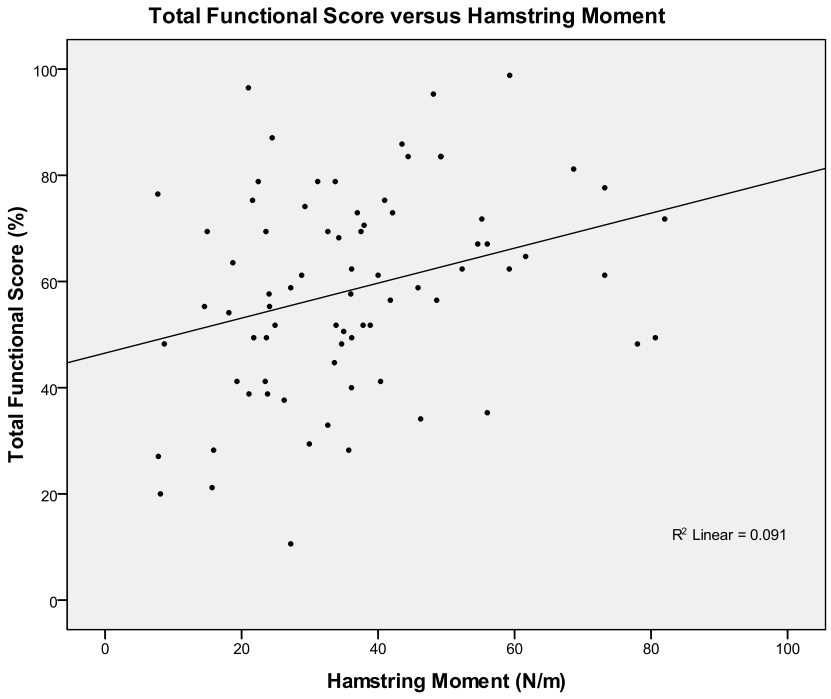


Figure 3.78 Hamstring Moment versus Total Functional Score for all of the trial patients.

Correlation coefficient for figure 3.78 was, r=0.302 (p=0.008, 95% CI 0.008 to 0.49). There was a weak to moderate linear relationship between these two variables. Unlike the quadriceps plot the hamstring moment data does not appear to have any outliers. The coefficient of determination was r^2=0.091. Therefore the hamstring moment accounts for 9% of the Total Functional Score.

3.8. ACTIVITY LEVELS

There are many benefits to physical activity. However the activity level within a population varies greatly. Currently 10,000 steps per day is 'promoted as a target for achieving health-related benefits' (Bohannon R.W, 2007).

Classification of pedometer-determined physical activity in healthy adults:

1. Under 5000 steps/day may be used as a "sedentary lifestyle index"
2. 5,000-7,499 steps/day is typical of daily activity excluding sports/exercise and might be considered "low active."
3. 7,500-9,999 likely includes some exercise or walking (and/or a job that requires more walking) and might be considered "somewhat active."
4. 10,000 steps/day indicates the point that should be used to classify individuals as "active".
5. Individuals who take more than 12,500 steps/day are likely to be classified as "highly active".

Age has been reported to affect the mean steps per day. A group of adults aged 65 or over had a low mean number of steps per day (6565) (Bohannon R.W, 2007). It is common for this age group to suffer from OA or have had joint replacements which will result in a decrease in activity levels. The average steps per day for a group of TKA and THA (total hip arthroplasty) patients was 5737 steps per day (Silva M et al., 2005).

Figure 3.79 shows that within this TKA group there was no strong correlation between age and the number of steps they took in a 24 hour period (r^2=0.006). Therefore their age does not appear to be linked to their activity level.

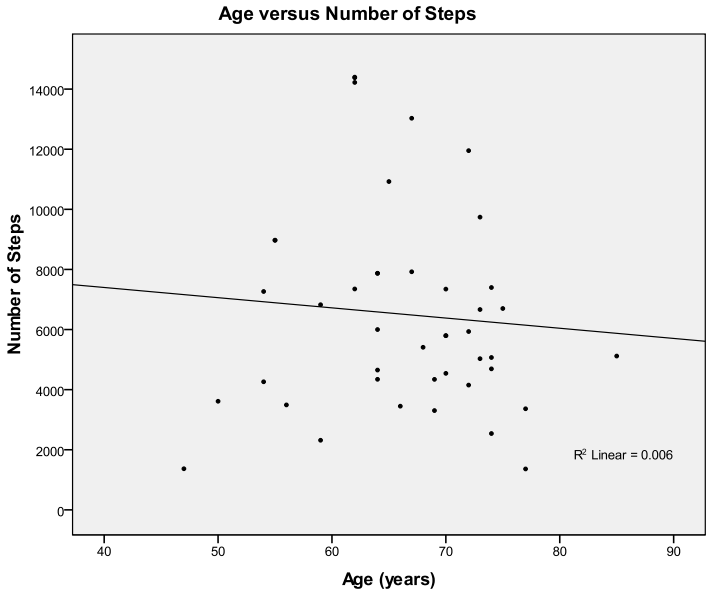


Figure 3.79 Age versus Number of Steps for all of the trial patients.

Table 3.36 summaries the data collected from the ActivPAL for the navigated and conventional TKA groups.

Table 3.36 Summary of activity levels of the navigated and conventional groups.

	Navigated			Conventional			p value
	Mean	Range	St dev	Mean	Range	St dev	
No of Steps	6104	(1340-14380)	3524	6502	(1362-14398)	3318	0.697
% sitting/lying	62.19	(25.2-94.4)	15.19	59.77	(15.68-76.8)	15.68	0.601
% standing	28.04	(3.4-56.9)	12.17	30.21	(13.96-64.3)	13.62	0.578
% walking	9.77	(1.9-19.4)	4.55	10.02	(2.58-24.33)	5.22	0.864
Total hrs	14.15	(4-18)	3.31	14.3	(3-17)	3.01	0.867

Firstly the data presented for the activity levels for the navigated and conventional groups are incomplete. This was due to the ActivPal monitors being returned with no data (navigated 32% and conventional 49%). One possible reason for this was that they had been incorrectly attached. The patients were given an information sheet and they were shown how to use the monitor.

There was no statistically significant difference found between the two groups in terms of number of steps, percentage sitting/lying, standing or walking or in the total number of hours the monitor was worn for. The patients were asked to use the monitor on a typical day within a week of their functional assessment clinic appointment. The table shows a large range in the number of hours for which the monitors were worn. However, only three trial patients in total wore the monitor for less than 10 hours. The mean number of steps recorded for the two TKA groups falls within the figures previously quoted in literature. The data shows that TKA patients were sitting or lying for about 60% of the time period recorded. They were standing for about 30% and walking for only about 10% of the recorded period.

3.8.1. Regression Analysis – Function and Activity Levels

The Total Functional Score calculated from the objective electrogoniometry assessment investigates patient's ability to complete everyday functional activities. Pain levels calculated through questionnaire surveys have not been strongly correlated with the objective Total Functional Score. This suggests that pain may not

fully impact the patient's ability to complete tasks but it is likely to relate to how active they are during the day.

Scatter plot (figure 3.80) investigated the possible relationship between the Total Functional Score and activity levels in terms of number of steps per day.

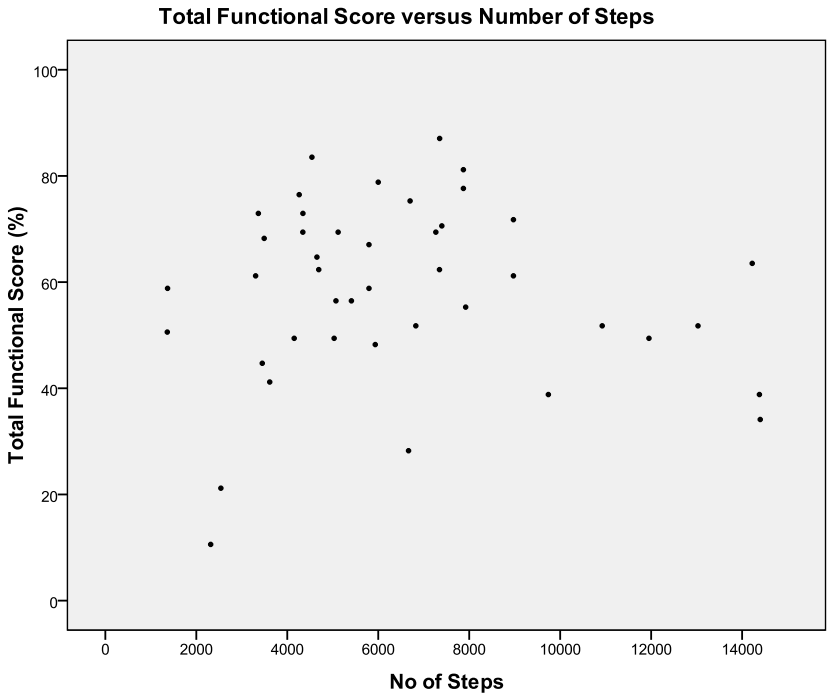


Figure 3.80 Number of Steps versus Total Functional Score for all of the trial patients.

Figure 3.80 clearly illustrates that there was a large variation in the number of steps per day between patients within the whole TKA group. The scatter plot shows that the majority of TKA patients were in the 4000-8000 steps per day group. This graph does not indicate a clear relationship between the number of steps per day and the Total Functional Score. The seven patients who were 'active' (recorded over 10,000 steps) did not record a Total Functional Score more than the average (60%). In fact a 'poor' Total Functional Score of less than 40% was recoded in patients whose activity level ranged from 2000-14000 steps per day.

The ActivPAL also recorded the percentage of the day which was spent sitting or lying, standing and walking.

The scatter plot in figure 3.81 illustrates the correlation between the percentage of the day sitting or lying and the Total Functional Score.

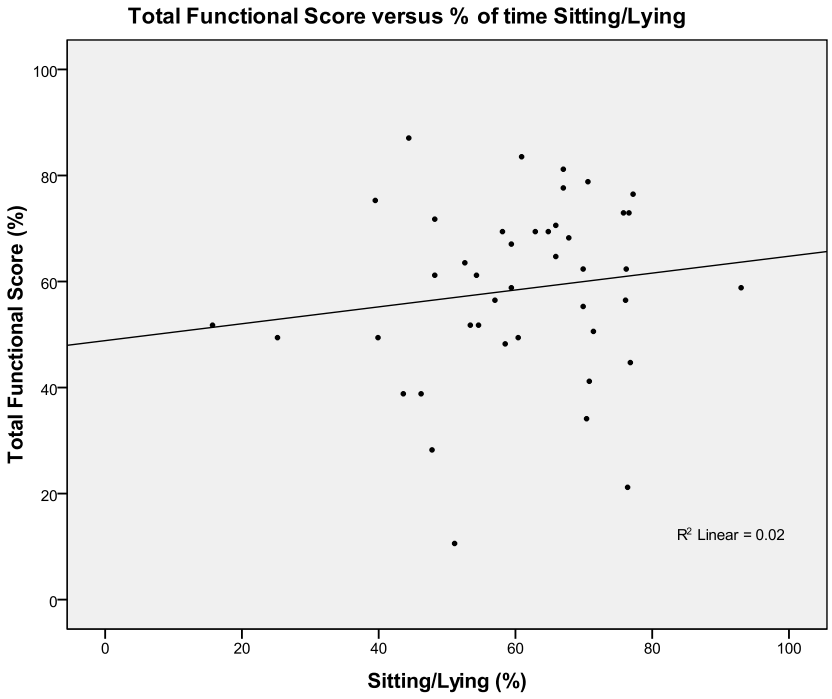


Figure 3.81 Sitting/lying (%) versus Total Functional Score for all of the trial patients.

There was no strong correlation identified in figure 3.81. In fact some of the patients who spent about 80% (the majority) of the day sitting or lying had recorded an above average Total Functional Score. This suggests that even although they have a good post operative function they are fairly inactive.

The scatter plot in figure 3.82 illustrates the correlation between the percentage of the day standing and the Total Functional Score.

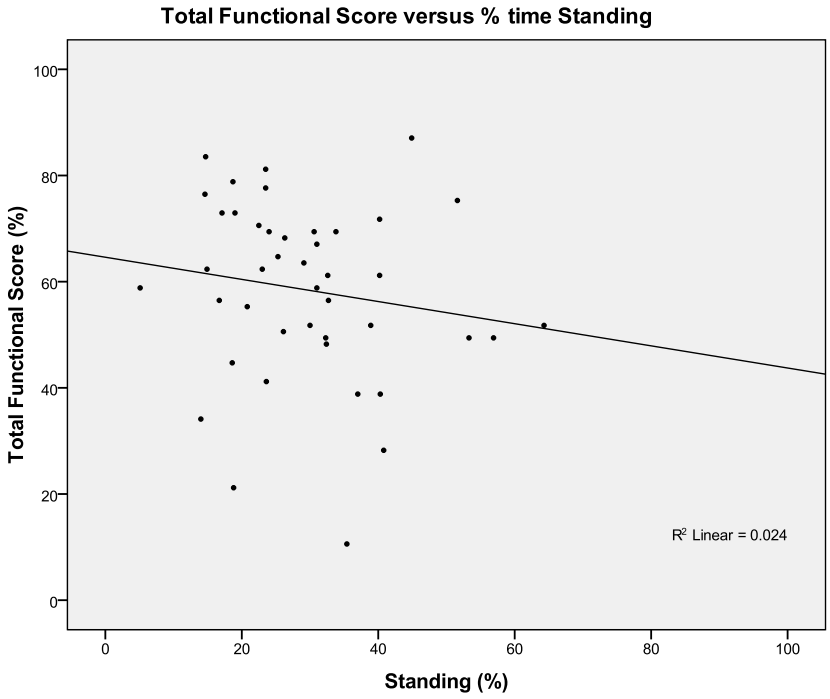


Figure 3.82 Standing (%) versus Total Functional Score for all of the trial patients.

The 'best fit' line for the correlation of the percentage of the day spent standing and the Total Functional Score indicated a negative linear relationship. However it was very weak. From observation of figure 3.82 the data appeared random. The majority of patients fell within the 20-40% standing group and their scores cover the full range of Total Functional Scores. Three patients who spent a lot of their day standing (about 60%) had recorded a Total Functional Score close to the group mean value. These patients had to stand for long periods of time during their working hours.

The scatter plot in figure 3.83 illustrates the correlation between the percentage of the day walking and the Total Functional Score.

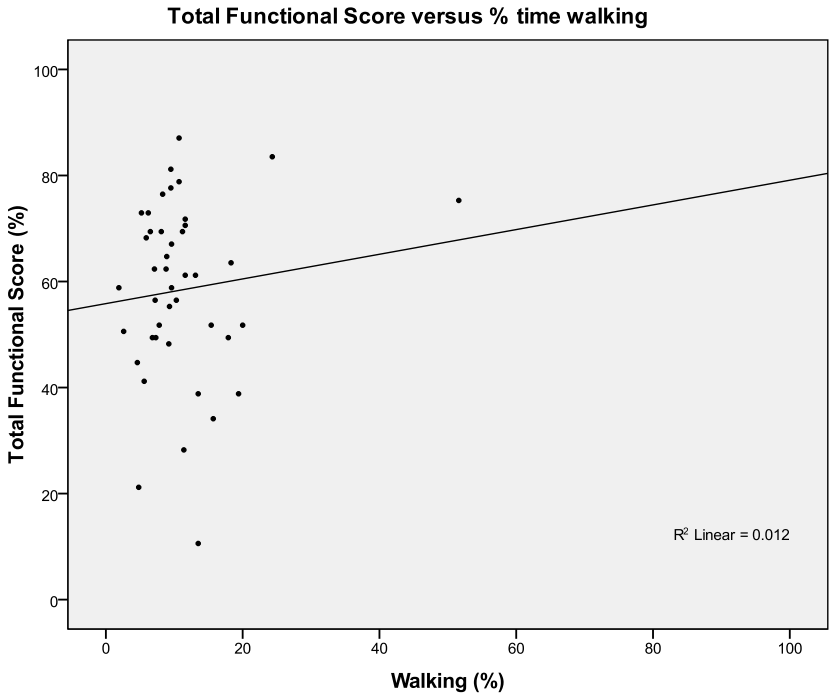


Figure 3.83 Walking (%) versus Total Functional Score for all of the trial patients.

The percentage of the day spent walking again did not show a strong correlation with the Total Functional Score. The majority of the TKA group spent less than 20% of the day walking and the Total Functional Scores varied greatly within this group. Therefore the objective Total Functional Score did not correlate strongly with the activity levels recorded for the TKA patients.

Pain levels have been recorded using the Visual Analogue Scale (VAS). If patients record a good function post operatively but their activity levels are low then it suggests that other factors maybe responsible for the inactive behaviour. Pain and co-morbidities are possible factors which affect daily living and activity levels.

Figure 3.84 identifies a linear relationship between the VAS pain scale and activity levels.

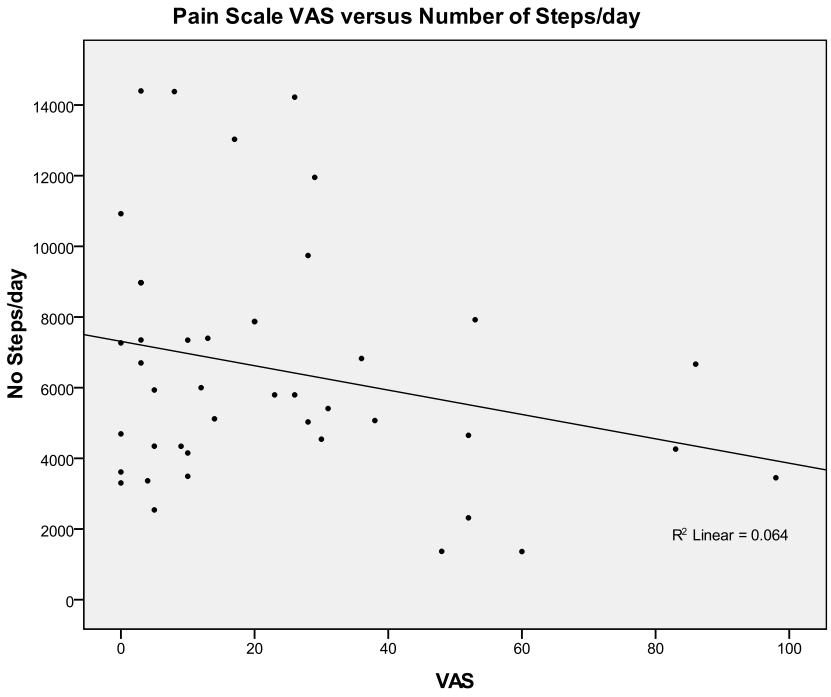


Figure 3.84 VAS pain scale versus the number of steps/day for all of the trial patients.

The relationship is negative as a low VAS score relates to no or little pain and daily discomfort from their TKA knee joint. Correlation coefficient for pain and activity levels, r=-0.25 (95% CI -0.003 to -0.45) indicated a weak relationship. The coefficient of determination, r^2=0.064 means that only 6% of the 'number of steps' parameter was accounted for by VAS pain score.

The mean number of steps per day for the TKA group was 6000 steps. The activity levels ranged for those patients who had little or no knee pain. For these patients other factors such as age and BMI may play a part in their inactive lifestyle.

The patients who had recorded a higher activity level (over 8000 steps/day) in fact recorded little or no pain (VAS<30).

3.9. SF-36 (QUALITY OF LIFE)

The International Classification of Functioning Disability and Health (ICF) address the concept that functioning and disability are complex and that

environmental and personal factors play a role in the overall individuals health condition. The SF-36, a quality of life questionnaire was used to record general health and well being, as well as a patient mental health score. The SF-36 was made up of a physical and mental score. Four mental and four physical scores were added together to give the overall scores:

Physical score:

- Physical functioning
- Limitations due to physical health
- Pain
- General health

Mental score:

- Limitations due to emotional problems
- Energy/fatigue
- Emotional well being
- Social functioning

Table 3.37 gives a summary of the scores calculated from the SF-36 questionnaire. It compares the two surgical groups.

Table 3.37 Summary of SF-36 scores for the navigated and conventional groups

	Navigated			Conventional			
	Mean	Range	StDev	Mean	Range	StDev	p value
SF36 - physical	53.91	(2.5-97.5)	26.75	50.71	(10-92.5)	23.93	0.58
Physical functioning	49.47	(0-100)	29.22	46.79	(0-90)	28.13	0.68
Limitations due PH	41.45	(0-100)	43.21	37.82	(0-100)	45.84	0.72
Pain	60.13	(10-100)	24.93	62.69	(0-100)	26.18	0.66
General health	64.61	(0-100)	24.48	58.97	(15-90)	17.89	0.25
SF36 -Mental	62.09	(19.8-100)	23.95	63.33	(28.3-96.8)	21.27	0.81
Limitations due EP	63.16	(0-100)	43.70	63.25	(0-100)	44.46	0.99
Energy/fatigue	50.26	(5-100)	23.16	51.79	(10-95)	18.90	0.75
Emotional well being	75.05	(44-100)	15.07	73.54	(28-96)	17.16	0.68
Social functioning	59.87	(0-100)	28.20	64.74	(12.5-100)	24.14	0.42

There were no statistical differences between the two surgical groups in terms of the SF-36 score for any of the sub division scores. Within the groups the scores

varied greatly as seen through the range recorded, for example for physical functioning the full range of scores was seen from 0-100 points.

Large community samples have been used to determine population normals for the SF-36 scores. It was reported that this score was affected by age. The mean scores for age groups 18-24, 25-34, 35-54, 45-54 and 55-64 were recorded and compared (Jenkinson C et al., 1993). For the study reported in this thesis, the mean age was 66 years old and the range was 46-84 years old. Jenkinson's study (1993) also identifies that the scores for each category was decreased by the presence of long standing illnesses. All of the patient group reported in this thesis suffer from long term OA. From the VAS pain and satisfaction rate data it can be concluded that the majority of this TKA group have improved in terms of their OA knee illness. However the presence of OA in other joints and co-morbidities was common and therefore they would have continuing health problems. Jenkinson's study also identifies the fact that women had lower scores for each category therefore reported poorer health.

Lyon et al (1994) studied an elderly population including subjects who were 65 years and over with a mean age of 74. This reported population was older than the population in this thesis. The study presents SF-36 scores for patients with long standing disability, who have seen the GP in the last 2 weeks, admitted to hospital in the last year and those who have attended hospital outcomes in the last year.

Table 3.38 compares the mean scores for the thesis TKA group with the 55-64 year old group from Jenkinson's report and Lyon's elderly 'no long standing illness' population scores. The study by Lyon et al also classified the elderly population, in terms of 'been to hospital in the last year' and 'had not attended clinics'. Included in table 3.38 are the mean scores for the elderly group who had 'not been admitted to hospital in the last year' and the group who had 'attended outpatients in the last year'. The majority of the trial population studied in this thesis fell into these two groups as they had attended outcomes clinics but had not been re admitted to hospital since their TKA, therefore these scores from Lyon et al study could be used as a direct comparison to this thesis patient group.

Table 3.38 SF-36 scores for the TKA group and age matched normals for comparison

	TKA Group Mean	Age matched normals (55-64)	Age matched normals (65 and over)	Group similar to patient groups	
			No long standing illness	Not been admitted to hospital in last year	Attended Outpatients in last year
SF36 Physical score	52.7	76.4	75.8	57.3	46.0
Physical functioning	48.1	80.0	73.6	54.1	44.2
Limitations due PH	39.6	78.8	74.6	55.4	38.1
Pain	61.4	78.8	80.5	64.1	55.2
General health	61.8	68.1	74.4	55.4	46.6
SF36 Mental score	62.7	78.4	82.3	69.8	61.8
Limitations due EP	63.2	85.8	90.7	79.5	71.5
Energy/fatigue	51.0	62.9	67.1	52.1	44.3
Emotional well being	74.3	78.0	83.7	74.3	68.8
Social functioning	62.3	86.9	87.8	73.1	62.4

The mean age of the thesis TKA group was 66 years old. The TKA group age range was 46-84 which means that the group was made up of some elderly patients but also some who would be in a younger age group. For this reason table 3.38 consists of SF-36 scores from 2 different age groups - '55-64 years old' and '65 years old and over'. The thesis TKA group SF-36 scores were lower indicating a worse health than both the normals groups, - '55-64' and '65 and over' groups. the 2 final columns in this table quote SF-36 scores from elderly subject groups who have not been admitted to hospital and also those who have attended outcomes clinics. These 2 groups would be likely to be similar to this thesis patient group. In fact, compared to these elderly groups the thesis TKA scores lay within the recorded range for 6 of the 8 categories. The 'General Health' score for the TKA group was higher than the elderly 'patient' group mean score. Therefore due to the outcome of the operation many of the patients in the thesis group appear to feel that there general health was good. The improvement experience in the initial year appears to have an effect on the patients' perceived general health. The 'limitations due to emotional health' was lower than the elderly 'patient' group mean score. Two of the function scores; 'physical functioning' and 'limitations due to physical health' were both at the lower end of the elderly 'patient' group's score.

Since the age range of the TKA group was large it was difficult to find a group for direct comparison. However despite that the recorded SF-36 from the two studies (Jenkinson C et al., 1993, Lyons R.A et al., 1994) used allow comparisons to be made. Overall the TKA group appear to be comparable in terms of health, function and emotional well being compared to an age matched 'patient' group, but report significantly lower SF-36 scores indicating a lower quality of life and health status level.

3.9.1. Regression Analysis – Function and SF-36 (Quality of Life)

The SF-36 questionnaire allowed 'quality of life' including health, function and emotional well being to be subjectively recorded. Therefore regression was used to identify any relationship between patient perceived 'quality of life' and the objectively measured functional outcome.

Table 3.39 lists the correlation coefficient and p values from the regression analysis. The parameters which were significant have been highlighted.

Table 3.39 r and p values for the correlation of SF-36 scores and the total functional score

	Total Functional Score (%)	
	r	p value
Physical functioning	0.344	**0.002**
SF36 - physical	0.234	**0.04**
Limitations due PH	0.226	**0.048**
Pain	0.197	0.086
Social functioning	0.177	0.123
Energy/fatigue	0.129	0.262
SF36 -Mental	0.119	0.302
Limitations due EP	0.092	0.425
General health	0.054	0.64
Emotional well being	-0.042	0.719

Table 3.39 shows that there was correlation between the electrogoniometry functional score and the 'physical functioning' score (p=0.002), the SF-36 overall physical score (p=0.04), and the 'limitations due to physical health' score (p=0.048).

These three parameters were plotted in figure 3.85 to 3.87.

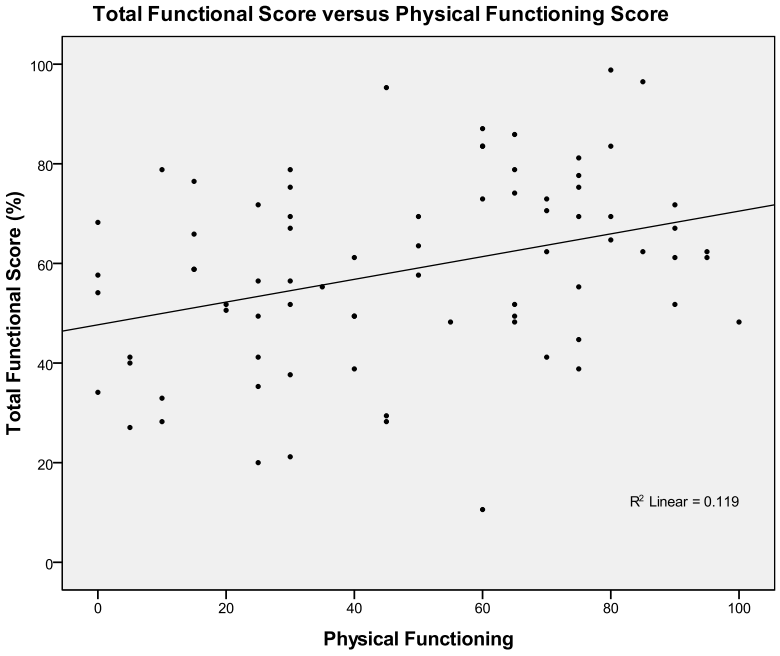


Figure 3.85 'Physical functioning' score versus Total Functional Score for all of the trial patients.

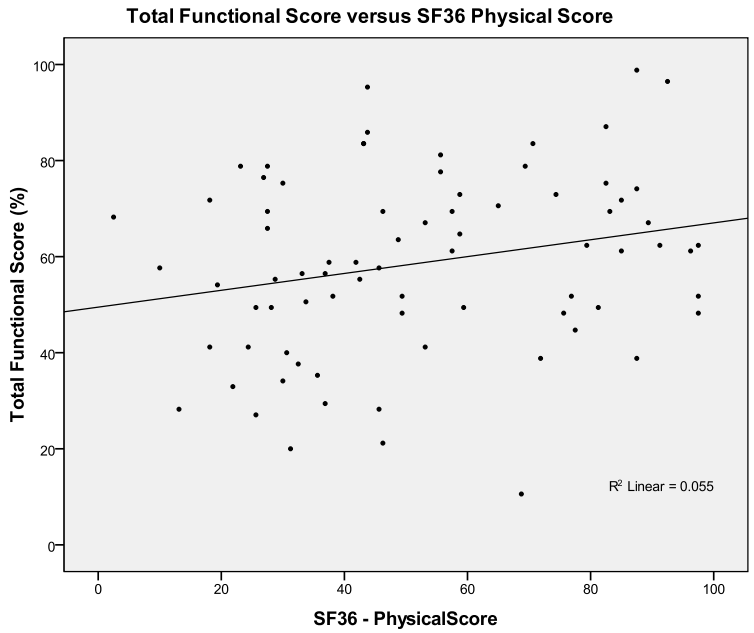


Figure 3.86 SF-36 Physical score versus Total Functional Score for all of the trial patients.

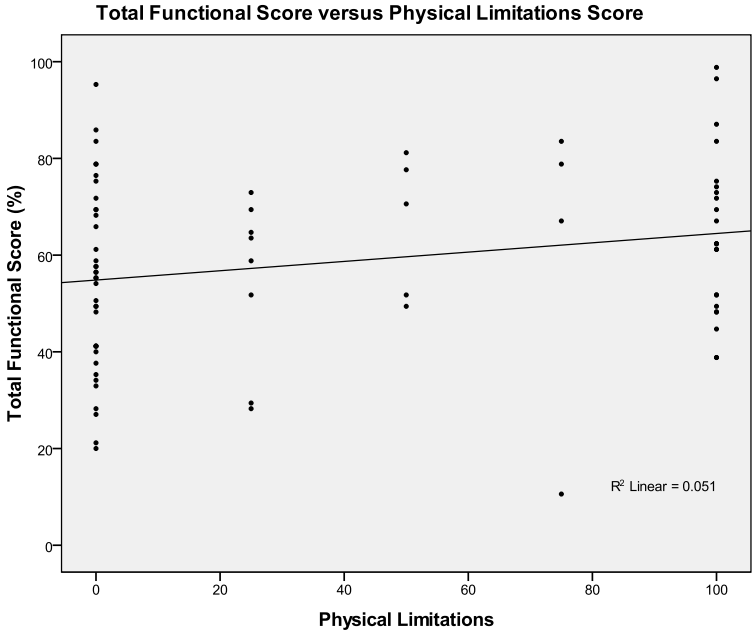


Figure 3.87 'Limitations due to physical health' score versus Total Functional Score for all of the trial patients.

Of the three plots (figure 3.85-3.87) the physical functioning score had the strongest correlation with the electrogoniometry Total Functional Score, r=0.344

(95% CI 0.13 to 0.53). The coefficient of determination was r^2=0.119. Therefore physical functioning score accounts for 12% of the Total Functional Score.

3.10 MULTIPLE REGRESSION: CLINICAL MEASURES AND FUNCTIONAL SCORE

Table 3.40 is a summary of all the clinical variables measured including questionnaire scores, hamstring and quadriceps moments, activity data and quality of life scores and the correlation values in relation to the Total Functional Score.

Table 3.40 Summary of r, r^2 and p values for each parameter and the Total Functional Score

	r	r^2	p
Passive ROM	0.503	0.253	**<0.001**
AKSS function	0.408	0.166	**<0.001**
Physical functioning	0.344	0.119	**0.002**
Oxford Function	-0.315	0.099	**0.008**
Hamstring moment	0.302	0.091	**0.008**
WOMAC -function	-0.294	0.086	**0.012**
WOMAC -pain	-0.269	0.072	**0.022**
Oxford	-0.261	0.068	**0.027**
SF36 - physical	0.234	0.055	**0.04**
WOMAC	-0.231	0.054	**0.043**
Quad moment	0.232	0.054	**0.044**
VAS	-0.229	0.053	**0.045**
Limitations due PH	0.226	0.051	**0.048**
WOMAC -stiffness	-0.216	0.047	0.066
Pain	0.197	0.039	0.086
Oxford Pain	-0.176	0.031	0.147
Social functioning	0.177	0.031	0.123
AKSS knee	0.155	0.024	0.207
Standing	-0.156	0.024	0.317
Sitting/lying	0.142	0.02	0.365
Patient Satisfaction	0.137	0.019	0.236
Energy/fatigue	0.129	0.017	0.262
SF36 -Mental	0.119	0.014	0.302
Walking	0.11	0.012	0.484
Limitations due EP	0.092	0.008	0.425
H/Q	-0.091	0.008	0.434
General health	0.054	0.003	0.64
No of Steps	-0.048	0.002	0.762
Emotional well being	-0.042	0.002	0.719

The variables in bold had a statistical significant correlation ($p<0.05$) with the Total Functional Score. However this test does not indicate the strength of the relationship. Correlation coefficient (r) indicates the strength of the association. The relationship was weak to moderate for all the variables in relation to the Total Functional Score, apart from the passive ROM measurement which had a strong correlation.

The parameters which were seen to have a significant correlation to the Total Functional Score were used in a multiple regression analysis (i.e. those in bold). The previously discussed model included passive ROM and the AKSS function score. This model was estimated to predict around 30% of the Total Functional Score.

This model was changed to include the next variable in the table, 'physical functioning' score. However, inclusion of this variable did not result in a significant increase in the adjusted r^2 value. The inclusion of the OKS function score or the hamstring moment also did not result in a significant increase in the adjusted r^2 value. Therefore the addition of these explanatory parameters to the regression model did not increase the clinical measures predictive response to the Total Functional Score. The model using passive ROM and the AKSS function score was concluded to have the highest predictive power for the Total Functional Score

3.11 RESULTS SUMMARY

In conclusion there were only minimal gait cycle differences identified between the two surgical groups. The functional outcome of the navigated TKA group was shown to be slightly improved compared to the conventional TKA group but this did not reach statistical significance. The electrogoniometry functional assessment did not show significant differences in terms of maximum, minimum and excursion knee joint angles for the 12 individual activities. However there were statistically significant differences recorded during the pre-swing phase of the level walking and slope walking activities. The mean knee joint angle was higher for the navigated group during 50-70% of the gait cycle for up slope, during 55-65% of the gait cycle for level walking and 54-64% of the gait cycle for down slope. These differences in walking cycles did not lead to a difference in the overall Total Functional Score which was calculated for each trial patient. Within both groups the

Total Functional Score varied greatly from 11 to 95 for the navigated group and 20-99 for the conventional group. The average score for the navigated group was 59 compared to the average score of 58 for the conventional group.

Post operative implant alignment has been previously studied and seen to be significantly improved in navigated TKA groups. The use of the computer to assist the surgeon during knee replacement surgery has been seen to decrease the variability of the alignment and therefore decrease the number of outliers within this group of patients. The most commonly quoted alignment parameter within literature is the mechanical axis alignment. The desired range is $+/-3^{o}$ of the neutral axis. In this study 94% of the navigated group compared to 81% of the conventional group where within this desired mechanical alignment range. Of the other alignment parameters measured, six out of eight resulted in an improved alignment in the navigated group. The frontal tibial alignment was the same for both groups with 97% of the patients' outcome alignment within the desired range. The sagittal tibial alignment was improved in the conventional group with 72% within the desired range compared to 71% of the navigated group.

The investigation into the possible relationship between function and alignment did not result in any strong correlations. The sagittal femoral and tibial alignments and the mechanical axis alignment were seen to have a quadratic relationship with function. For all of the alignment parameters studied there was no clear association between alignment errors (deviation in implantation outwith the desired range) and the overall Total Functional Score.

The electrogoniometry functional differences identified in the gait cycles were not seen to translate into differences in functional outcome calculated in clinical questionnaires. The subjective questionnaires did not show any significant differences between the two surgical groups in terms of function, pain or emotional well being. The activity levels of the two groups were also seen to show no significant differences.

Quadriceps and hamstring moments were seen to be significantly improved for the females in the navigated group. There were no differences between the males in the navigated and conventional groups. The differences in muscle strength maybe related to the improvements observed in the walking cycles in the navigated group.

Therefore the study resulted in minimal improvements in functional outcome and alignment of the prosthesis for the navigated TKA group compared to the conventional TKA group. Navigated TKA was associated with additional costs in the form of the navigation system. Therefore the cost of the intervention was increased and has to be weighted against the possible increase in quality adjusted life years (QALYs). From the results from the various clinical questionnaires recorded it was concluded that the health state of the two groups was similar and therefore at one year post operative there was no increase in QALYs for the navigated group. This study and previous studies in literature comparing navigated and conventional TKA have concluded that there was an improvement in the alignment of the implant. This in turn is expected to increase the longevity of the implant which would lead to an increase in the QALY. It is unknown whether the subtle functional improvements in the navigated group will lead to continuing good function and therefore result in a higher QALY value compared to the conventional TKA group.

Correlation analysis demonstrates the association of a variety of clinical questionnaire scores and the hamstring and quadriceps moment data with the objective electrogoniometry Total Functional Score. The correlation coefficient (r) for these variables ranged from 0.2 to 0.5 indicating the varying strength of the association. However the interpretation of the correlation coefficient is important and depends on context. Cohen's scale states that 0-0.1 indicates no correlation, 0.1-0.3 indicates a weak correlation, 0.3-0.5 indicates a moderate correlation and 0.5-1.0 indicates a strong correlation. However other scales are used to categorize the strength of the correlation. One such scale states that a correlation coefficient which is greater than 0.8 indicating a strong correlation and less than 0.5 indicates a weak relationship. The variables with a statistically significant association with the Total Functional Score using the Cohen scale have either a weak or moderate correlation apart from passive ROM which had a strong correlation.

The 95% CI range calculated for the variables were large, for example for the physical functioning score, 95% Confidence Interval 0.13 to 0.53. A correlation coefficient below r=0.32 for the trial sample size (n=77) gives a Confidence Interval range of r values which starts below r=0.1. Therefore the range of plausible values for this parameter enters the 'no correlation' part of the Cohen scale. Therefore the

only three variables with a 95% Confidence Interval range of correlation coefficients within the 'correlation' part of the Cohen scale were passive ROM, AKSS function score and the SF-36 physical functioning score. Electrogoniometry functional assessments give extensive kinematic data during daily activities. Objective functional assessments can only be completed on sub groups of complete populations. Therefore how well the routine clinic assessment can explain the patients overall function is important. From multiple regression it was concluded that the passive range of motion and the AKSS function score accounts for about 30% of the objectively measured electrogoniometry functional score. However this leaves 70% of the variance unexplained.

Although there was no major differences resulting from the two surgical interventions this set of data clearly indicates the ongoing limitations one year post operative seen in TKA patients compared to age matched 'normal' subjects. The electrogoniometry kinematic functional assessment showed that the TKA group were statistically significantly limited during a range of daily activities. The average maximum knee flexion angles for the TKA group had decreased by at least 10^{o} for level and ramp walking. The flexion angle used by the TKA group was also up to 25^{o} less than the 'normal' group for the stairs activities and 35^{o} less for the bath activities. The activity level for 'normal' age matched elderly was low where the group mean was 6500 steps/day. However this was greater than the TKA group mean which equalled 6300 steps/day. Health questionnaire scores (SF-36) for a 'normal' group were higher indicating better health compared to the TKA group. This therefore translates into higher QALYs as their 'health state' is improved compared to the TKA group due to generally less pain, and limitations due to physical and emotional health. This illustrates another difference in the state of health and function between a healthy elderly group and a TKA group.

In summary the navigated TKA group showed improved functional outcome in the electrogoniometry assessment and implant alignment. These improvements were not translated into differences in the clinical scores measured. The TKA patient group one year post operative continue to be functional limited compared to age matched 'normals'.

CHAPTER 4. DISCUSSION

4.1 INTRODUCTION

In the recent past there has been an increase in resources devoted to the development of navigation systems in orthopaedics. They are thought to provide the surgeon with a tool which will help achieve 'well' aligned TKA implants in a greater number of patients with greater implant longevity. The theory is that the current generation of navigation systems will improve the mechanical axis alignment in TKA which will promote implant durability and possibly have other clinical and functional benefits for the patient. Evidence exists that the navigation system can improve the consistency of the rotational alignment of the implants. The costs incurred from the navigation systems would therefore be off set by a reduction in the number of TKA revision surgeries required, an increase in patient satisfaction rates and better functional outcome. This thesis aimed to compare the functional outcome of electromagnetic navigated TKA with conventional TKA. Investigating a range of outcomes such as kinematics using electrogoniometry, daily activity levels recorded by an activity monitor (ActivPAL), hamstring and quadriceps moments and patient and clinical based questionnaires, allowed an extensive study to be completed.

Further to the functional assessment an in depth alignment study was completed using both CT scans and weight bearing double stance long leg radiographs taken 3 months after the surgery. Alignment is commonly used as a parameter to compare navigation and conventional TKA. Therefore it was important to include this parameter as it allows this study to be compared to studies within the literature.

Previously, the relationship between alignment and functional outcome has not been fully investigated and it is therefore not known whether alignment is a predictor of patient functional outcome. Previous studies have explored the possible effect alignment has on the longevity of the implant but this was not the purpose of the study. All implants from both groups were still in situ at the time of the one year follow up assessment.

Since resources' do not allow in depth assessments to be completed on all routine TKA patients it is important to understand the relationship between the

routine clinical outcome measures and the objective electrogoniometry functional measures which are studied in research trials. Regression allowed an analysis of the specific clinical measures which could be used to predict and explain the other objective measures, particularly the electrogoniometry data.

Implant survival rates can be used to assess the success of TKA as a surgical method and also the survivorships of differing implant designs. However survival rates do not provide information about the functional performance of the implant during its lifespan or patient satisfaction. The patient's everyday functional performance is an important factor in determining patient and surgeon satisfaction. There are in fact a number of critical factors in evaluating the success of TKA which include function, alignment, patient satisfaction and long term survival of the implant.

4.2 FUNCTIONAL ASSESSMENT COMPARING NAVIGATED AND CONVENTIONAL TKA

Total knee arthroplasty is becoming increasingly common within the younger adult population, i.e. younger than 65 years of age. This means that the functional demands on the implanted knee are likely to be different and in fact can be greater in this group as they may still be working and in some cases can be fairly active. Valuable functional assessments must be able to distinguish small differences and therefore be sensitive to changes within subject groups. Pain has a strong influence on subjective patient based questionnaires scores (PROMS) which means that they may not be sensitive to functional differences. Boonstra et al (2008) concluded that a functional knee test should be 'independent of pain (content validity)'. Therefore objective tests such as the sit to stand movement were seen to be suitable for 'initial assessment of global function' and the timed up and go test could be used as a biomechanical test to identify how the patient's knee function has been affected by disease or surgical procedure. To overcome the subjectivity and pain dominance of clinical scores, gait analysis can be used as an additional means of evaluation. Pain is a continuing issue with some patients and it can mask a good function score in questionnaires about daily living.

The consort diagram in figure 3.1 on page 143, illustrates the breakdown of the first 120 patients within this RCT. They are divided into two surgical groups. The diagram defines the size of the two groups which were then studied at the one year post operative functional assessment. Each surgical arm had 60 patients in it. From these groups of 60 patients, 38 navigated and 39 conventional patients completed the functional assessment. The patients excluded from the functional assessment had their data collected for the other trial outcome parameters such as the alignment study and clinical questionnaires. It is common to find osteoarthritis in multiple joints. This led to some of the patients (15 navigated and 12 conventional) having functional limitations which were unrelated to their operated knee joint. Therefore functional data from this set of patients if included, would skew the group data as their functional data would be dominated by the other diseased other joints. This is one of the drawbacks of functional testing related to a procedure on a specific joint rather than a disease or procedure which affects the whole body. The consort diagram also highlights the fact that from the group of TKA patients who completed the functional assessment there were 3 CT scans missing from each group. The availability of research scanners remains a problem and in these cases cancellations of the original appointment or a reluctance to have the scan caused the missing data.

The pre operative clinical questionnaire scores were used to compare the two surgical groups. The clinical scores recorded by the trial patients prior to their operation were varied within the two groups. The range of function scores recorded for the navigated and conventional groups were; AKSS function score, 15-100 and 5-80 respectively. The health status scores recorded for the navigated and conventional group range was; SF 36 mental score 23-90 and 24-94 respectively. The pain levels were recorded within the Oxford Knee Scores and the AKSS knee score. Both of these questionnaire scores were shown to vary greatly between TKA patients; navigated OKS 24-52, AKSS 25-84 and conventional OKS 27-52, AKSS 24-82. Therefore pre operative scores were patient dependant, and in fact it is possible that the patients on the TKA waiting list are at varying stages of osteoarthritis progression. However the mean clinical scores for the two surgical groups were comparable and showed that the groups were clinically similar. The group was also comparable with osteoarthritis groups in literature. The mean total AKSS for the 77

trial patients was 96 points out of a maximum of 200 points. The AKSS scores recorded within studies in literature, ranged from a mean of 72 points to 116 points(Decking R et al., 2005, Liebensteiner M.C et al., 2008, Senden R et al., Available online 3 September 2010, Spencer J.M et al., 2007, Stulberg S.D et al., 2006). The score of 96 is therefore indicative of a typical OA population.

It has already been noted that some patients in this trial from both of the surgical groups were not suitable for the complete functional assessment and were therefore excluded from it. However it was also found that within the group of patients who were eligible for the electrogoniometry functional assessment, there were a few who did not complete all of the activities. The activities included in the functional assessment vary in the level of difficulty. For activities such as, ascent and descent of stairs there were two different gait patterns recorded. The patients who found these activities difficult used a method which limited the knee joint flexion required. These patients walked up and down the stairs one step at a time. It was also seen that three patients did not complete the slope activity as they could not walk far enough to complete the 10 minute circuit. This was a clear indicator of a limited functional ability. Only about one third of the trial patients completed the bath activity. This was the most difficult task in the circuit and involved high knee flexion angles to bend the lower limb to clear the edge of the bath tub. It was found that the majority of patients did not use a bath in their homes. Therefore not being able to complete the bath activity did not impact their everyday life and they did not feel functional limited. Some of the patients used a shower within a bath, and therefore had to be able to step in, but did not attempt to sit down in the bath tub. The bath activity required the patient to be confident that they could complete the task. In some cases it was likely that they could have accomplished the task as they had a good ROM. However some patients were not willing to attempt it for fear of being stuck in the bath. At home they avoided sitting in a bath and also sitting on the floor for housework tasks. It takes a lot of upper body strength to push yourself up to get out of a bath. One method used in this task was to turn over and kneel first before standing. Kneeling was another task which many patients avoided although for the most part these patients did not have pain when they knelt on there operated knee joint.

Functional outcome of conventional TKA patients has previously been investigated using electrogoniometry (Myles C.M et al., 2006, Myles C.M et al., 2002) and gait analysis (Wilson S.A et al., 1996) on varying sample sizes, n=16-50. These studies have analysed gait cycle patterns and range of flexion required during daily functional activities. Gait analysis has been used to investigate post operative function in TKA patients and also as a method of comparing knee implants. Betek et al (2011) studied the kinematics of walking, comparing conventional, navigated and minimally invasive navigated TKA with 15 patients in each group. Their gait analysis study did not show a significant difference in the rehabilitation time or in the maximum, minimum or excursion knee joint angles between the navigated and conventional groups during walking. However the sample size for each of the 3 surgical groups was relatively small. Extensive gait analysis studies have not been published to date where a range of functional tasks are investigated, and used as a method of comparison between navigated and conventional TKA groups.

The results from the thesis electrogoniometry functional assessment showed that there was patient variability within both of the surgical groups. Tables 3.4-3.6 (page 156-157) gives a summary of the mean maximum, minimum and excursion knee joint angles for each of the functional activities completed. They include the range of knee joint angles recorded as well as the standard deviation which indicates the degree of variability within the group. Variability was lowest during the level and slope walking tasks, SD=8^{o}, and highest in the out of bath task, SD=30. Therefore, there was a range of functional abilities within the TKA groups. This was highlighted through the range of Total Functional Scores recorded within the total TKA group (Total Functional Scores, navigated group (22-95), conventional group (24-99)). The total functional score did not correlate strongly with the patient's age (r=0.1). This means that increasing age did not directly lead to a decrease in patient's knee function. Instead, the variability in functional levels within this patient group was likely to be related to other factors such as weight, obesity and co morbidities. These factors are likely to affect the patient's daily function and activity level.

The mean function cycle for each of the functional tasks completed illustrated similar kinematic patterns between the two surgical groups. There were no statistically significant differences between the navigated and conventional TKA

group in terms of the maximum, minimum and excursion knee joint angle for any of the 12 daily activities completed during the functional assessment. There was also no statistical difference between the patients operated and non operated knee joint in terms of maximum knee flexion angle. The only difference in gait pattern was found in the down stairs task where the inclusion of 11 patients who walked 1 step at a time led to a decreased knee flexion angle during stance phase. Electrogoniometry is a sensitive kinematic measurement. A previous electrogoniometry study (Myles C.M et al., 2002) found that differences of around 5^{o} between the two time points indicated a significant difference in knee joint angles in a TKA group. The standard deviation calculated for each of the tasks was similar to those calculated for the two TKA groups within this thesis. For the sample size used in this study (n approx = 40) then it was calculated that a significant difference in the group mean values was 4.5^{o} for a standard deviation of 10^{o}. Therefore differences of approximately 5^{o} would give a significant statistical difference between the two surgical groups, but the exact value would depend on the variability of the flexion angles measured within the TKA group.

The maximum knee flexion angle for level walking was the same for both surgical groups (54^{o}). This kinematic data for level walking was similar to that reported by Hatfield (2011) at 1 year after surgery, and Wilson (1996) at 4 years post surgery. In comparison the mean maximum knee joint angle for level walking for normal age matched subjects is 67^{o} (Rowe P.J et al., 2000). The maximum flexion angle in the complete walking cycle corresponds to the maximum flexion angle during swing phase. There was also no significant difference in the maximum knee flexion angle during stance phase. Stance phase relates to the knee angles during the weight bearing section of the function, therefore it is an important parameter to investigate.

In this study the mean excursion knee joint angle for both stair ascent and descent for the navigated group was 72^{o}. The conventional group recorded a mean knee joint angle of 74^{o} for stair ascent and 69^{o} for the stair descent. In comparison the mean excursion knee joint angle for normal age matched subjects during stair ascent is 80^{o} and for stair descent is 79^{o} (Rowe P.J et al., 2000). Wilson (1996) also investigated stairs using a 5 camera VICON system, where the mean excursion for

the TKA group for stair ascent was 90^{o} and for stair descent was 88^{o}.This thesis group of trial patients had significantly lower mean knee joint angles than those in Wilson's study. The mean age of the thesis TKA patients were similar to the study by Wilson. However Wilson's study had only included 16 patients and they had excluded those patients who had recorded a Knee Society score below 'good' or 'excellent'. Therefore there was an element of bias in the patient selection. Another study (Myles C.M et al., 2002) recorded that the mean excursion knee joint angle for stair ascent in was 67^{o} and for stair descent was 65^{o} in a TKA patients group 18-24 months post operation. These results appear to differ from the thesis TKA group, however the minimum knee joint angle for ascent and descent stairs in Myles's study was about 10-11^{o}. This means that the maximum knee joint angle for stair ascent was 78^{o} and for stair descent it was 76^{o}. In comparison the minimum knee joint angle for this thesis TKA patient group for the stairs activity was about 4-5^{o}. Therefore they had a straighter lower limb during the stairs gait cycle. In fact the active maximum knee joint angle in this thesis and Myles study were similar. Therefore it can be concluded that the results for this activity can show variation between studies involving TKA patients. It has already been discussed that a few TKA patients in this thesis study completed the stairs activity one step at a time. This lowers the maximum knee joint angle recorded for this patient and in turn lowers the group mean. As this method was adopted by patients in both surgical groups then it was not an issue when comparing the two groups. However this may explain the differences between the thesis data and that recorded in studies in literature as they do not mention whether a different stair walking method was present in any of their patients, or if this was an exclusion from the literature studies.

The study by Myles et al (2002) used electrogoniometry therefore their methodology was comparable to this study. Myles et al (2002) completed the same set of functional activities 18-24 months post operation on a group of TKA patients. They recorded mean excursion knee joint angles for up and down slope which were comparable with this study (up slope; thesis=52^{o} Myles=51^{o} down slope; thesis 56^{o} Myles=57^{o}). However for the chair and bath activities Myles study reported lower mean knee flexion angles (for example low chair stand-sit; thesis=90^{o} Myles=73^{o}). The higher knee joint angles recorded for the low chair activity relates to the fact that

the chair in this study was lower (low chair height; thesis= Myles=380mm) and therefore increased the difficulty of the task and the increased knee flexion angle requirement to complete the activity successfully.

The maximum and excursion knee joint data from this thesis indicates that about 90^{o} ROM is required to successfully complete daily tasks such as level and slope walking, stair negotiation and sit to stand using both high and low chairs. To complete the bath activity a greater ROM was required.

Passive ROM was measured routinely in the outcomes clinic. However the relationship between this parameter and the active ROM which patients use in daily activities has not been explained. The passive ROM (Mean; navigated=115^{o}, conventional=115^{o}) was significantly greater than the ROM recorded during the active functional activities. The maximum active ROM measured was in the conventional group for the into bath task (105^{o}). The passive ROM was also significantly greater then the ROM measured during the active deep flexion (Mean; navigated=108^{o}, conventional=108^{o}). Deep flexion allowed a weighted measurement of ROM to be recorded. Deep flexion was an electrogoniometry activity where the patient while resting one foot on a step, bent into the knee joint. Passive ROM was measured using a manual goniometer while the patient lay on a clinic bed. Therefore active and passive ROM was measured with different equipment. There is the issue of whether the two different methodologies explain the differences in the ROM measured in that one task involves bending the lower limb while standing and the other bending the lower limb when lying down.

Manual goniometers have been used for years within clinics. Their accuracy relates to the user and how accurately it is aligned on the lower limb. The reliability and repeatability of this device to measure knee ROM has been reported in Clapper et al study (1988). It concluded that this was a reliable measurement through high intraclass correlation coefficients. Electrogoniometry has also been shown to be an accurate measurement system as seen through the validation study within this thesis and also a study by Rowe et al in 2001. The accuracy of this system again relates to the user and precise attachment of the equipment.

The results from the electrogoniometry functional assessment also showed that all of the activities except for the bath task produced a repeatable function pattern.

The repeatable pattern was recorded for the majority of the trial patients. There were minor differences between patients in the magnitude of the knee joint angles but the timing was similar between the TKA patients. This allows sections of the function cycle to be studied separately, such as stance and swing phase in gait. This means that analysis can be completed on sections of the functions as well as on the whole task.

Although the mean maximum and minimum knee joint angle for each of the functions reported no significant difference between the two surgical groups, there were statistically significant differences at other points in the function cycle. The navigated group recorded a statistically significant higher mean knee flexion angle between 55-65% of the level walking cycle. They also recorded a statistically significant higher knee flexion angles between 50-70% in the up slope walking cycle and finally between 54-64% of the down slope walking cycle. The time points where the differences occurred did not correlate with the maximum or minimum points on the cycle. In fact the differences were found during terminal stance, during the pre swing phase of the gait cycle. This can also be referred to as the 'push off' phase, where power is generated to advance the limb into swing phase so the knee joint quickly flexes to allow the foot to clear the ground. The navigated group illustrates an earlier, more vigorous push-off phase. This suggests an increase in power during push-off into swing phase to cause the increase in knee flexion angle. Winter et al (1990) reported that the power exerted by elderly subjects during 'push-off' was reduced when compared to a younger test group. This study suggests that the elderly subjects used a less vigorous push-off to try to reduce the 'potential for instability'. Therefore push-off appears to be linked to confidence in walking ability. Although the differences during push-off in our study are small they were statistically significant and suggest a trend toward a more normal gait cycle in the navigated group.

The stance phase for the navigated group, on average was a smaller percentage of the complete gait cycle. This means that a greater percentage of the function cycle was swing phase which was associated with single limb support. Single stance phase is avoided when subjects experience lower limb pain as it means that their complete body weight has to be supported through one knee joint. This means that when the

knee joint is painful such as in knee osteoarthritis there is a decrease in the percentage of the cycle which is swing phase (Landry S.C et al., 2007). Therefore if the navigated TKA group records an increase in the percentage of the gait cycle which is swing phase then this again indicates a trend towards a better, more normal function.

The electrogoniometry assessment was only completed at one time point, one year after surgery. This means that it is difficult to relate the data to a baseline function and analyse the difference in function before and after surgery. However previous work by Myles et al (2002) has shown that the difference in functional performance before and after surgery in a TKA group was minimal with an average of only a 2% improvement in knee motion between pre operation and 18-24 months post operation.

Pre and post operative clinical scores on the other hand indicate that there was a significant improvement in the TKA patients after surgery (pre-op; OXS=42 (SD 5.7), AKSS knee=47 (SD 15.2), AKSS function=49 (SD 15.8)) (post-op; OKS=26 (SD 8.6), AKSS knee=81 (SD 15.4), AKSS function=70 (SD 20.9)). Therefore the subjective scores improve significantly indicating a patient perceived improvement after surgery. These scores are highly influenced by pain levels. They therefore may indicate a decrease in pain and the fact that performing daily tasks is easier.

It is important to determine how improved this patient group is and whether they are similar to age matched healthy subjects. The post operative function data was therefore related to an age matched ‘normal’ group. This normal data had been collected from 40 elderly ‘normal’ subjects using electrogoniometry. The functional assessment methodology was the same as that used in the functional assessment in this study. This allowed the functional outcome of the TKA patient group to be compared with that of a healthy older adult group. An overall Total Functional Score was developed within this thesis based on this age matched group. It has not as yet been validated. An overall functional score allows all of the functional tasks to be grouped together to examine the overall functional ability. It also allowed the small differences between groups for each task to be grouped together to determine whether the differences in each activity would accumulate to a significant difference between the two surgical groups. The scoring system looked at marking each

functional activity out of five where the inability to complete a task was scored zero points and a good kinematic outcome, similar to that expected in healthy older adults was scored five points. The mean total functional score for the two groups was not statistically significantly different but the navigated group recorded a higher mean score. The total functional score allows patient performance with regards to a range of functional tasks to be compared between patients but also as a whole surgical group. Gait analysis generally focuses on individual tasks. However using the functional score the overall patient's performance was scored in relation to an age matched control group. It has been documented in the literature that there are continuing limitations within TKA patient groups' years after surgery (Myles C.M et al., 2002). The total functional score allows a quantitative difference in functional ability level to be calculated where 100 refers to the best score possible doing every task within one SD of normal. The 'normal' group average score was 88.7. A score of 0 would indicate that no functional tasks could be completed. Scores between 0-100 would indicate where on the scale the patient's functional outcome would lie.

Functional outcomes used to compare navigated and conventional TKA in the recent literature have been limited. The data has mostly been extracted from various questionnaires, many of which are patient based. Therefore the measures are subjective and the problems and errors which can be associated with them have been discussed. A few studies have included functional tasks and clinical scores completed by qualified clinicians which result in objective and more accurate data. However none of these studies completed a full kinematic study.

Therefore in conclusion there were minimal differences between the conventional and navigated TKA groups in terms of kinematics over a range of 12 functional activities. The significant differences between the groups were recorded during terminal stance phase during level and slope walking where the navigated group recorded higher knee joint angles. The navigated group also reported an increase in the percentage of the gait cycle which was swing phase. Therefore the navigated group indicated a trend towards improved gait and functional outcome. The mean total functional score which was based on all 12 of the functional activities was also higher for the navigated group however this was not statistically significant improvement.

4.3 CLINICAL MEASURES COMPARING NAVIGATED AND CONVENTIONAL TKA

Knee function can be quantified using performance based measures such as kinematic assessments. However the disadvantages to these types of assessments are that they are time consuming and require clinically trained personnel to collect and analyse the data. Therefore patient based scales or questionnaires are more commonly used to assess patient knee function and overall post surgical outcome. However the question is whether these are sensitive enough to detect small changes which can be recorded in objective tests such as the electrogoniometry assessment, or if the fact that they are subjective and influenced by pain which will limit their usefulness.

Questionnaires determine the patients' perception of their knee status which is important as it relates to how satisfied the patient is with the outcome. However pain has a strong influence on whether the patient was satisfied with the procedure and second to this will be their functional outcome. It is likely that if the patient has a painful knee then this will overshadow any good function they would report post operatively.

4.3.1 Clinical Questionnaires

This study concluded that there were no significant differences in the clinical questionnaire scores between the navigated and conventional TKA groups. The questionnaires included in this analysis were, the Oxford Knee Score, the AKSS, the WOMAC and the SF-36. The Oxford Knee Score was split into a function and pain score. The AKSS comprises a knee and function score. The SF-36 comprises a function and mental score. The WOMAC can be sub divided into a pain, stiffness and function score. The absence of significant differences between the two surgical groups were consistent with the results from studies by Spencer et al (2007), Kim et al (2009) Luring et al (2009), Molfetta et al (2008), Molfetta (2008) and Stulberg et al (2006). These studies reported no clinical difference between the surgical groups when they used various questionnaire scores as a method of comparison.

Spencer et al (2007) concluded that there was no difference functionally between their navigated and conventional TKA groups at a 2 year follow up

assessment. Previous to this study they had published data which concluded that the implant alignment in the navigated group had a statistically significant improvement. Their study did not find that the alignment improvement in this group led directly to a functional improvement in the short term. The functional outcome data collected was through patient based questionnaires, the SF-36, Oxford Knee Score and WOMAC and the clinically based Knee Society Score (AKSS). The AKSS functional score is subjective and completed by the patient. However the AKSS knee score includes objective measures such as the ROM, knee alignment and knee stability. The AKSS was recorded at 1 year post operation as well as at 2 years after surgery. The mean 1 year post operative AKSS in Spencer's study was 153.5 for the navigated group and 152.2 for the conventional group. This is comparable with this thesis study where the mean navigated score was 158 and the mean conventional score was 154. The remaining questionnaires were only recorded 2 years after the surgery. The Oxford Knee Scores at 2 years post operation were comparable to those recorded by the thesis TKA group at 1 year post operation (Spencer; navigated=27, conventional=20, Thesis; navigated=24, conventional=26). The SF-36 scores in Spencer's study at 2 years indicated better health and functional outcome than those recorded in this thesis study at 1 year post operation. For example in Spencer's study, the SF-36 'physical functioning' score for the navigated group was 56, and the conventional group was 60. For the Thesis TKA groups the SF-36 'physical functioning' score was 49 for the navigated group, and 47 for the conventional group. This suggests that TKA patient groups continue to improve between the first and second year post surgery. In addition to these questionnaires the patients completed the Bartlett Patellar pain questionnaire. This includes quadriceps strength, the ability to rise from a chair and stair climbing ability. This final questionnaire includes objective measures adding to the quality of the functional outcome data. Spencer's study supports the electrogoniometry data in this thesis as it had concluded that at this short term follow up there was no statistically significant differences between the two surgical groups in terms of sit to stand or during the ascend and descend stairs activity.

Another study comparing navigation and conventional TKA at 2 years post operation (Luring C et al., 2009) also used questionnaires, the WOMAC and the

AKSS. They also included objective measures such as range of motion, knee stability and isokinetic muscle strength. In this study the navigated group had better knee stability and range of motion scores but the difference was not statistically significant. The only parameter to be statistically significantly improved was the implant alignment.

The AKSS recorded for the two surgical groups in Kim's (2009) study gave mean values for Knee and Function scores which were about 10 points higher than this thesis data. For example the navigated group in Kim's study recorded a mean AKSS knee of 92, and a mean AKSS function of 83. In comparison in this thesis the TKA group reported a mean AKSS knee of 83, and a mean AKSS function of 75. This study had a longer follow up with a mean of 3.4 years. It is not known how long TKA patients take to reach the plateau of their functional outcome which means that they are likely to continue to improve past their one year clinical check up. In fact a study by van der Linden determined that TKA 'functional knee motion' continues to improve between their 2 study time points, 18-24 months and 7 years post operation.

Molfetta et al (2008) investigated functional outcome of a navigated and a conventional TKA group at five years after surgery. They again did not conclude that there was a significant difference between the two surgical groups. Their post operative evaluation had only included the clinically based AKSS and ROM. They concluded that the coronal alignment of the navigated group was significantly improved but the sagittal alignment was not different between the two groups. Therefore they found that coronal alignment improvements in the navigated group did not directly lead to an improved function. This study was a mid term study with a mean follow up of 5.4 years.

Stulberg at al (2006) compared a navigated and conventional TKA group in the short term, 1 and 6 months after surgery. They found no significant difference in terms of clinical or functional scores. They found less pain in the navigated group at 1 month but the difference had not been noted again at 6 months post operation. One thing to note about this study was that they had not found any improvement in the implant alignment when using navigation. Therefore they could not draw conclusions regarding the relationship between alignment and functional outcome. The two

groups were similar in terms of alignment therefore it would not be expected that a difference in function would be recorded.

This thesis compares two surgical groups using both objective electrogoniometry data and subjective clinical questionnaires. Many knee scores are in use and reported in literature as tools to evaluate TKA. They differ in reliability and responsiveness as they are mainly patient based. Gait analysis has the advantage of yielding reproducible objective data. It has been reported that the significant gait analysis parameters after TKA are 'maximum knee flexion during stance and swing, maximum hip extension and maximum ankle plantar flexion, stride length, double support phase and gait velocity' (Liebensteiner M.C et al., 2008). Therefore the important parameters to study in a TKA patient group cannot be recorded through questionnaire scores. The disadvantage of gait analysis is that it is a costly and a time consuming way of accessing post operative function. Therefore there is a need for clinical scores and clinical assessments which produce good objective representation of patients' functional outcome. The objective Total Functional Score from the electrogoniometry data was not shown to correlate strongly with any of the clinical questionnaire scores in this study. Passive range of motion had the strongest correlation with the objective score. Regression analysis showed that the combination of the ROM measurement and a functional clinical score such as the AKSS function score, could be used as predictors for the objective score. This combination of subjective scores allowed the greatest percentage of the objective score to be explained (r^2= 0.29). However this still predicted less than a third of the objectively measured function. Liebensteiner et al (2008) also investigated the correlation between functional outcome in TKA patients in terms of 'locomotion and the clinical knee scores'. If clinical questionnaires can give a true representation of the patients function then the time and money spent on objective data collection could be reduced. Liebensteiner et al (2008) did not find adequate correlations between the post operative clinical scores and gait analysis measurements. The only strong correlation was between 'max pelvic obliquity stance' and 'AKSS knee'. On the other hand the pre operative clinical scores showed a strong correlation with a number of gait analysis parameters. Therefore the questionnaire scores were found to 'adequately' assess the functional capacity of the TKA prior to their surgery but there

was no knee and function scores which was ‘recommended’ for post operative assessment. Therefore Liebensteiner’s study and this thesis agree that gait analysis assessments are required to investigate the functional ability of TKA patients in depth.

4.3.2 Health Questionnaire

Health and well being questionnaires are an essential part of post operative assessment as they investigate the patient perceived general health, function and emotional well being. Although it has been discussed that they do not record objective data they are important as they record the patients’ satisfaction and how they feel about their health situation. It has been discussed that pain may influence the recorded functional outcome leading to the impression that the patient has a poorer outcome than is perhaps measured in objective tests. Since the difficulty of activities relates greatly to the patients pain levels it is difficult to separate function and pain. The fact that a patient has the ability to complete functional tasks could be lost if they have pain, as they just avoid the activities which give them pain.

It was found that pain scores did not show a strong correlation with the objective functional outcome. However the VAS pain score did show a strong correlation with patient satisfaction ($r=0.6$) which agrees with literature (Kwon 2010). Continuing pain after TKA surgery therefore will have a strong influence on how patients rate the success of the operation. It will be less important that they can walk well and have a good kinematic outcome, if the pain limits the distance they can walk and the tasks they can perform. Therefore this indicates the first priority of the patient. However the success of the operation in the surgeon’s opinion will be based on different criteria, for example additional outcomes as well as the outcome pain levels. They will be interested in the alignment of the implant, the ROM and questionnaire scores.

There were no statistical differences between the two surgical groups in terms of the SF-36 health questionnaire. This questionnaire includes general health and emotional well being, along with pain and the possible limitations experienced due to physical health.

SF-36 scores have been reported within the literature. However it is difficult to find an age matched 'normal' group to compare with the TKA group as firstly the patient group in this study had a wide age range. The majority of the patients in the TKA group were around pensionable age with the mean age of 66 years old. Therefore using an elderly group would give the best comparison for this patient group. The age matched 'normal' group used for comparison was from Lyons et al (1994). This paper studied a group of subjects who were 65 and over. They were then grouped into various categories with reference to their medical history, for example whether they had a long standing disability. The healthy 'normal' group used as the baseline comparison reported no long standing disability; this was only 38% (81 subjects) of the studies participants. The other categories used to group participants within the study were, 'having seen their GP', 'admitted to hospital in last year' or 'attended an outpatient's clinic'. The age matched 'normal' group reported higher SF-36 scores than the trial patient group, indicating better health and function (SF-36 physical score; TKA group=52.7 and normal group=75.8, SF-36 mental score; TKA group=62.7 and normal group=82.3). When studying an elderly group they are likely to have an illness or medical complaint as seen by the fact that only 38% of Lyon's elderly population did not have a long standing illness.

The SF-36 physical and mental scores for this thesis patients' demonstrate a statically significant ($p<0.001$) improvement from the pre-operation scores (pre-op SF-36 physical score=35.2, mental score=47.5; post-op SF-36 physical score=52.7, mental score=62.7). The increase in SF-36 scores can be assumed to be related to the outcome of their knee arthroplasty surgery. Therefore they rate the improvement in their overall health state as positive. However these quality of life scores also illustrate the continuing limitations of the TKA group compared to the healthy elderly population.

In conclusion there was no difference in the health and well being scores recorded for the two surgical groups. Both TKA groups had a statistically significant improvement over the first year, but the patient group had a lower SF-36 than an age matched 'normal' group showing a continued limitation at this stage (1 year post operation). The SF-36 health scores did not correlate well with the objective total

functional score. Instead the SF-36 mental scores were moderately correlated with both the VAS pain scores (r=0.4) and the satisfaction rate (r=0.4).

4.4 ALIGNMENT STUDY COMPARING NAVIGATED AND CONVENTIONAL TKA

Navigation has been introduced as a method to increase the accuracy and the reproducibility of implantation of TKA prostheses. It has been documented that accurate mechanical axis alignment relates to longevity of the implant (Lotke P.A and Ecker M.L, 1977). Within literature there is a conflict as to whether there is in fact an improvement in the post operative implant alignment when using navigation systems. Many authors (Anderson K.C et al., 2005, Bäthis H et al., 2004, Bolognesi M and Hofmann A, 2005, Chauhan S.K et al., 2004b, Chin P.L et al., 2005, Decking R et al., 2005, Haaker R.G et al., 2005, Jenny J.Y et al., 2005, Sparmann M et al., 2003, Stockl B et al., 2004) have shown that navigation can lead to significant improvements in alignment and a reduction in the number of outliers recorded. However alignment studies comparing navigated and conventional TKA vary in the extent of the differences reported. Some studies report statistically significant improvements in all parameters studied (Anderson K.C et al., 2005). However other studies only report improvements in some of the analysed alignment parameters, for example Decking et al (2005) recorded statically significant improved mechanical axis alignment in the navigated group but no difference when comparing frontal femoral or tibial alignment or sagittal femoral or tibial alignment. In contrast Bathis et al (2004) found the only parameter to show no significant improvement in the computer assisted group was the frontal tibial alignment.

On the other hand some authors (Bauwens K et al., 2007, Kim Y.H et al., 2007, Kim Y.H et al., 2009, Lützner J et al., 2008, Stulberg S.D et al., 2006) have seen little difference between the two surgical groups in terms of alignment outcome.

There is a lack of consistency within literature as to the possible benefits with regards to alignment outcomes when using navigation systems. Two Meta analysis studies comparing navigated and conventional TKA outcomes also have conflicting conclusions. Mason et al (2007) indicated significant improvement in component orientation and mechanical axis alignment in the navigated groups when reviewing

29 studies. Whereas Bauwen et al (2007) reported that there was no statistically significant difference between the two surgical groups in terms of mechanical axis alignment based on analysis of 33 studies.

The next question would be to consider, what are the benefits of improved alignment? Are there alignment parameters which are more important and lead to benefits for the patient? Does the improved alignment lead to a reduction in post operative pain, an increase in dynamic function, an increase in ROM, an increase in the clinical scores or an increase in the longevity of the implant? It is hypnotised that correct alignment would lead to improvements in all of these areas but it has not been investigated in long term studies so that conclusions can be drawn.

Long term studies which relate alignment and longevity (Jeffery R.S et al., 1991, Parratte S et al., 2010) have differed in their findings. It is a popular belief that a correctly aligned knee implant in the coronal plane will increase the longevity of the implant, therefore delaying the need for additional surgery (Jeffery R.S et al., 1991). However Parratte et al (2010) did not find a significant increase in the survival rates in the 'well' aligned implant group. The knees in this study were 15 years post operation and had been implanted using conventional instrumentation. One of the issues with investigating survival rates or revision rates is that this does not always indicate the success rate of the implant as poorly functioning implants can remain in situ. There may be problems with some of these implants however due to medical or age related issues then further surgery is not recommended. Therefore it is likely that there will be implants which have not been revised but have problems which are included in the statistics regarding implant success and longevity. The other issue is that longevity of the knee implant is not likely to be only related to the coronal alignment. It is possible that sagittal and rotational alignments are important as well in the longevity of the TKA prosthesis. The other issue which may influence the outcome of the surgery is the soft tissue balance.

In this study the mechanical axis, the sagittal tibial alignment and the both the femoral and tibial rotational alignments did not record statistically significant improvements in the navigated TKA group. However for all but the sagittal tibial alignment the percentage of trial patients within the desired alignment range for the particular parameter was greater in the navigation group. Both surgical groups had

over 90% of correctly positioned femoral and tibial components in the frontal plane which suggests that some parameters can be successfully corrected by conventional instrumentation and do not require the additional support of a navigation system. Other parameters such as the femoral sagittal alignment appear to be more difficult and variable when using conventional methods. In this study the rotational outcome for both groups showed large variations. The navigation system was seen to improve the outcome of the rotational alignment but there was still a large spread of outcome alignments.

The proposed benefit of navigation is the reduction in the number of outliers within navigated TKA groups. In cases were the mean alignment outcome did not differ between navigated and conventional groups then the number of outliers was decreased in the navigated groups (Han H.S et al., 2006). In this thesis the range of alignment outcomes recorded by the navigated group was seen to be reduced in most parameters, for example in terms of the mechanical axis alignment the navigated group range was 4^{o} varus to 4^{o} valgus compared to the conventional group which was 6^{o} varus to 6^{o} valgus. This in itself is an improvement. The aimed 'desired range' is generally quoted as $+/-3^{o}$ of the neutral alignment. However aiming for neutral (0^{o}) does not take into consideration the patients' natural anatomy and the fact that in a pre diseased state their lower limb alignment may not have been neutral. In these cases it may not be appropriate to restore their knee to a neutral axis. However for some parameters the exact neutral alignment is unknown and can also depend on the implant used. The other issue is how wide the allowable range should be and if the effects are linear. Therefore do problems increase as the alignment error increases, or is there a cut off alignment were problems occur in the patients out with this target alignment. The target of 0^{o} $+/-3^{o}$ is a relatively broad and generic target which does not take patient specific differences into consideration. It is common practice to group patients into two groups, those within the desired range and an 'outlier' group. This means that a patient with an alignment of 4^{o} from neutral and one with a 7^{o} error alignment would be part of the same error group, with no distinction between the extent of the alignment error present. It is unknown whether the degree of error has an effect on longevity or functional outcome. Therefore it is not known precisely at which alignment error the occurrence of problems would begin. Parratte et al (2010)

defined a mechanically aligned knee as +/-3^{o} of the neutral mechanical axis, and the outlier group as any knee outwith this range. They did not report that there was an improvement in the longevity of the knees in the 'well' aligned group. Therefore they did not conclude that this mechanical axis alignment 'goal' was a way of 'predicting the durability of modern total knee arthroplasty implants'. They concluded that this neutral alignment was a reasonable target but that the 'dynamic impact of gait', the most commonly used functional activity, may mean that there is an alignment which would distribute the load better across the knee joint. Therefore if the ideal alignment is associated with 'dynamic gait pattern' then it is difficult to uses a specific neutral value, as it may be patient dependant.

The rotational alignments of the tibial and femoral component are highly important in avoiding increased ligament tension post operatively and patello femoral complications. Rotational malalignment has been correlated to the failure of the implant (Incavo S.J et al., 2007). Therefore it is generally thought of as one of the important parameters to correct. However it is seen as one of the most difficult in this study as seen through the large variation in measurements within both surgical groups. This may be due to the identification of the landmarks within the surgery. There may be errors within the registration process as small errors in the registration of each of the bony landmarks would result in incorrect data being processed within the navigation system.

One issue with rotation and all the alignment parameters is the accuracy of the measurement from the CT scan. Some of the slices in the CT scan are not clear due to metal artefact from the implant. The prosthesis appears on the scan as a bright white light and there adds to the difficulty in identifying bony landmarks for the analysis. Different methods of analysis can be identified within the literature, where different landmarks are used (Jazrawi L.M et al., 2000, Wong A.K.O et al., 2009). Therefore differences will probably exist between studies. Even when the same landmarks are used for the measurement there is an issue of the intra and inter observer reliability. This thesis showed good intra observer reliability for alignment analysis of CT scans (section 2.12) and inter observer reliability for both the long leg and CT scan measurements (section 2.11 and 2.13). The repeatability of the measurement is highly important when comparing patients and TKA groups'

outcomes especially when there was more than one observer. The absolute accuracy of the alignment measurements was unknown therefore the measurements from the observer with the most experience were taken as the 'true' valves for the inter observer reliability study.

There were variations reported in the mechanical axis alignment measured using long leg radiographs and CT scans. Therefore, the mechanical axis alignment was measured using two methodologies. It would be expected that the mechanical axis alignment measured using radiographs and CT scans would have a strong correlation. The two measurement methodologies resulted in two different sets of results which highlight the issue regarding comparing studies. Some of these discrepancies may result from the difference in weight bearing status when the measurement was taken. The long leg radiographs are weight bearing. A study investigating mechanical weight bearing simulation (Kendoff D et al., 2008) used 10 fresh cadavers with no detectable pathology of the knee joint found that the effect of 0.5 body weight through the intact knee joint could cause a deviation of 0.4^{o} in the mechanical axis. Since the forces across the knee joint while standing are higher than this, then the effect would be expected to be greater and therefore the possible differences between weight bearing and non weight bearing measurement could amount to a couple of degrees. Double limb standing and supine radiographs have also been reported to result in inconsistencies in patients with existing varus malalignment (double limb standing=-7.1^{o} +/-3.8^{o}, supine=-5.5^{o} +/-2.8^{o}) (Specogna A.V. et al., 2007). Therefore Specogna study found the average difference between measurements taken supine and double limb standing was 1.6^{o}, and the greatest spread of results was seen in the standing radiographs. Sabharwal et al (2008) found that an 'increase in BMI was associated with a greater magnitude of discrepancy' between the two measurement techniques, and hence BMI differences are a plausible explanation for the differences found for the mechanical axis alignment. The knee can also be unstable if correct ligament balancing has not been achieved. This means that when standing the lower limb and the knee joint can be forced into a malaligned position which is not as apparent while non weight bearing due to instability. The impact of this can be minimised by checking the poly gap which is the gap between

the metal distal femoral condyles and the metal tibial tray as this should be rectanglar.

Radiographs are also sensitive to flexion or rotation as these will distort the varus/valgus measurement on the 2D image. CT scans do not have this issue as it is an analysis of a 3D image. Standardized guidelines are used in radiology to minimise the errors in the measurements. Therefore the presence of rotational issues due to the patient not standing correctly was unknown within this patient group but should be minimal. For the patients in this study the ROM data was collected at each appointment, pre operation and 3 month and 1 year post operation. Therefore the ROM was measured at the same time point as the long leg radiographs (3 months). Of the 77 trial patients in the thesis 31 had a flexion contracture which varied from 2-23^{o} at 3 months post operation. Therefore there was the possibility of errors in a large proportion of the radiographs. Also pain will be a factor in whether the patient stands with their lower limbs straight. Even if they can straighten out their legs on a bed in the clinic it is unknown if directly related to the situation at the time of the radiograph. The Oxford Knee Scores, which includes pain questions, are still high at 3 months post operation as the patients are still recovering and undergoing rehabilitation. At one year post surgery it was reported that less trial patients had a flexion contracture (3 months=31; 12 months=18) and the Oxford Knee Scores were lower (3 months=29.8; 12 months=24.9), suggesting less pain. It may be that one year review clinics would be a better time point to measure the mechanical axis through radiographs, as the possibility of errors should be reduced.

The issue of lack of correlation between weight bearing and non weight bearing measurements was also raised in literature when investigating intra operative data output from navigation systems. The weak correlation (r^2=0.007) of post operative radiographic and navigation mechanical axis measurements has been reported (Yaffe M.A. et al., 2008). Stulberg et al (2002) found that the average discrepancy between the navigation intra operative data and the radiological measurement was 2.1^{o}. Choi et al (2011) found no outliers in the intra operative navigation data however when the same patients were analysed using post operative radiographs then there were as many as 20% outliers. The navigation system aims to implant the prosthesis in the correct alignment and orientation. If the system recorded

a malalignment then the protocol would suggest bone cuts and steps to be taken to correct the error. Therefore it is not surprising that the study found that the navigation intra operative data indicated no outliers. However 20% of the navigated knees were found to be malaligned on radiographs with regards to the mechanical axis. It is a concern that a number of the knees which have been well aligned as recorded by the navigation systems are then found to be in the 'outlier' group post operation. This study in fact found that there was no significant radiographic improvement in the navigated group for mechanical axis. The inherent limitations of radiographic measurements will exist for both the navigated and conventional groups. The navigation registration process is subject to inter surgeon variations in terms of bony landmark location.

Navigation systems have been shown to be a useful tool for accurately implanting knee joint prostheses. Many studies show that navigation improves post operative alignment which is thought to improve longevity of the implant. Stulberg has published two studies investigating navigation, 2002 and 2006. The earlier study found that the conventional instrumentation 'introduced consistent and significant error compared to computer assisted'. However this was not supported by the study in 2006. Navigation systems may have the potential as a training tool. They give the surgeon intra operative feedback which allows them to develop an understanding of the proper alignment which can be used in TKA with conventional instrumentation.

One of the possible issues with the results from the studies published in reference to TKA outcomes, is the fact that they are generally led by an experienced and skilled surgeon. Therefore as was found in this study the outlier groups for the measured alignment parameters are low, which may not be typical of every surgeon or hospital. These systems would be more likely to be cost effective in high volume hospitals, but they may not in fact significantly improve the outcome of the surgery particularly with experienced surgeons. Navigation may therefore be a benefit in hospitals where a low volume of TKAs are preformed as it would work as an additional tool for the inexperienced surgeon, or for those who do not regularly perform TKA. However there is then an issue of the cost effectiveness of the use of navigation in low volume hospitals.

4.5 CAN ALIGNMENT PREDICT FUNCTION?

This study showed that there was a trend towards better alignment of the knee implants in the navigated group with some of the parameters showing a significant improvement with the use of navigation. Both surgical groups contained a high percentage of well aligned knees. Therefore dividing the TKA patients in terms of correctly aligned knees and an 'outlier' group would mean that patients from both surgical groups would be in both of the alignment groups. There was a trend towards better function within the navigated group, but overall there was a large variation in the functional outcome of the TKA patients. A good mechanical axis alignment outcome is thought to correlate with the longevity of the implant. However the possible correlation between alignment and functional outcome has not been fully explored. Using all the trial patients as one TKA group the theory that a 'well' aligned knee joint would lead to a good functional outcome was investigated.

It is not well understood which alignment parameters influence post operative function. Therefore which alignment errors have a greater impact on functional outcome is unclear. Each alignment parameter measured was investigated for a possible correlation with each of the functional activities, as well as the objective Total Functional Score for each patient. Studies in literature have defined different 'desired' ranges such as $+/-3^{o}$ or $+/-2^{o}$. This means that an absolute cut off alignment is unknown. It is generally taken that an error of up to 3^{o} from the neutral alignment is acceptable. The other issue is whether the direction in which the error occurs is important, for example would a 5^{o} varus and 5^{o} valgus deviation give the same functional outcome or in fact lead to similar problems. For this reason the errors were not group together as 1^{o}, 2^{o}, 3^{o} and so on from neutral. If the analysis had been completed in this way then the influence of the error direction could not have been investigated.

The relationship between alignment and function would not be expected to be linear. Instead it is hypothesised that errors in both directions would lead to a decrease in functional outcome. This would therefore give a quadratic relationship with the neutral alignment relating to the peak functional outcome score. A weak quadratic relationship with the Total Functional Score was seen for the sagittal femoral and sagittal tibial alignments and the mechanical axis alignment recorded on

long leg radiographs. Both the sagittal femoral and mechanical axis scatter plots indicate that the best total functional score were found in patients with close to neutral alignment and that the score achieved decreased as the deviation recorded increased. Interpreting the sagittal tibial deviation was not as straight forward as the proposed neutral alignment did not to relate to the peak in the quadratic correlation curve. However it has to be noted that looking at the whole TKA group it was common for the tibial implant to have been implanted flatter than the proposed 7^{o} posterior slope. A 7^{o} posterior slope was taken as neutral as this was what the implant company had suggested. In fact in this study the best functional scores were seen in the patients with a 4-5^{o} posterior tibial slope.

For both the frontal femoral and frontal tibial parameters the number of patients in the outlier group was small. Within the desired alignment range the associated patient's Total Functional Score was highly variable. These plots showed that within the group of patients with a neutral alignment scores of between 20-100 points were achieved. Therefore in this case there was no direct relationship between a well aligned knee and post operative function.

Previous studies have reported a trend for better function and quality of life in groups of TKA patients with good alignment accuracy (Choong P.F et al., 2009, Longstaff L.M et al., 2009). Choong et al (2009) divided the TKA patients into two groups, those who were within 3^{o} of neutral mechanical axis alignment and those in the 'outlier' group. They found that there was no difference in the SF-12 mental score at 6 weeks, 3 months and 6 months, but there was a significant improvement at 12 months in the group within the 'desired range'. The SF-12 physical score was also seen to be improved in the 'desired range' group at 3 months, 6 months and 12 months. The International Knee Society score showed significant improvements at all the time points, 6 weeks, 3 months, 6 months and 12 months. Therefore they found a positive correlation between accurate mechanical axis alignment and good clinical scores. Longstaff et al classed their knees as good alignment if they were within 2^{o} of neutral. They found that good femoral coronal alignment lead to statistically significantly better function as measured through the AKSS. For the other five parameters measured, sagittal femoral and tibial rotation, femoral rotation and tibial coronal alignment there was a trend towards better function demonstrated,

which did not reach significance. The errors in each of the six alignment parameters mentioned were also added together to give a cumulative error score. It was reported that an error less than 6^{o} was associated with significantly better function.

The literature has grouped patients into 'well aligned' or 'outlier' groups. To investigate both the objective Total Functional Score and the subjective clinical scores in the same terms as the literature then the trial patients were also grouped into a 'well aligned' and an 'outlier' group. A two sample t test with a significance level of p=0.05 was used to compare the well aligned group with the poorly aligned group.

There were no significant differences between the Total Functional Score for the two groups in terms of the any of the alignment parameters studied. The satisfaction score for the frontal femoral 'well aligned' group was statistically significantly higher (p=0.02). The AKSS knee score was also higher in the 'well aligned' group, 83 points compared to 66. However this did not reach significance (p=0.068) as the sample size was small with only 2 patients within the outlier group. The number of patients within the 'outlier' groups for some of the alignment parameters was small. Although this means that the surgery was a success a small 'outlier' group limits the conclusions which can be drawn.

The 'outlier' group for the frontal tibial parameter also only consisted of data from 2 patients. These 2 outlier patients scored high in the SF-36 physical score, 'general health' score and 'limitations due to physical health' score and therefore the results in fact surprisingly suggested a trend to better clinical scores within the outlier group. This result is more likely to be due to the small group numbers and the short follow up. For these 2 outlier patients the error in alignment had not caused them any problems or limited their functional ability. It is unknown if this would change during a longer follow up.

The mechanical axis alignment measured from the CT scan showed that the 'well aligned' group had a statistically significantly higher Oxford Knee Score (p=0.03). The 'outlier' group contained 9 trial patients and scored a mean of 30 points compared to the 'well aligned' group whose mean score was 24 points.

Therefore the alignment outcomes showed a weak relationship with the objective and subjective function scores. In summary there were weak correlations found between the objective Total Functional Score and three alignment parameters;

the sagittal femoral and sagittal tibial alignment measured on the CT scans and the mechanical axis alignment measured on the long leg radiographs. The quadratic correlation results indicated that the neutral alignment related to better function with decreased function as the alignment errors increased. One of the main problems in drawing conclusions about the outlier groups was that because TKA is a successful operation then the number of patients in the 'outlier' groups was small. Small numbers of outlier patients meant only limited conclusions could be drawn about the error groups. When the patients were grouped into those within 3^{o} of neutral and those in the outlier group, then it was concluded that a good frontal femoral alignment led to a significant improvement in the satisfaction score and the 'well aligned' mechanical axis group reported significantly better Oxford Knee Scores. Therefore at the 1 year follow up there was a trend towards better function within the 'well aligned' group in terms of the clinical scores. However it was not recorded that a 'well aligned' knee group was associated with a good electrogoniometry Total Functional Score. The clinical significance in improved alignment accuracy may increase and become more apparent in mid to long term studies.

4.6 HAMSTRING AND QUADRICEPS MOMENT DATA

Patient expectations continue to increase as the knee arthroplasty population becomes younger. In general they desire more than just pain relief. Quadriceps function and strength are critical determinants of overall functional outcome. In fact patients with a better quadriceps strength recorded a 'more normal gait and improved ability to climb stairs' which in turn leads to better clinical scores (Berman 1991). TKA for the majority of patients results in a functional improvement and better gait pattern. However there are continuing kinematic and kinetic lower limb abnormalities. TKA patients at 2 years follow up have been reported to have only 83% quadriceps strength compared to their contra lateral knee (Berman A.T et al., 1991). The muscle balance around the knee joint is also important as imbalance can result in joint instability. TKA patients have reported signs of muscle weakness as a result of disuse atrophy prior to their surgery (Gur H and Cakin N, 2003).

In this study the patients repeated the quadriceps and hamstring measurements three times and an average was calculated. This allowed errors to be minimized. If

the results from any of the three trials were vastly different then they were rejected and additional measurements were recorded.

The navigated group had statistically significantly higher knee flexion and extension moments compared to the conventional group. The conventional group was made up of a larger percentage of females than the navigated group. There is an obvious difference in strength between genders. This gender ratio imbalance could explain the difference between the surgical groups. Therefore the navigated and conventional TKA groups had to be sub divided into males and females (navigated males=22 females=16; conventional males=19 females=20). There was no statistical difference between the two male surgical groups. However the navigated female group recorded a statistically higher quadriceps ($p=0.003$) and hamstring ($p=0.03$) moments. Luring et al (2009) also used isokinetic muscle force as an objective parameter for comparison of computer assisted and conventional TKA. In this case there was no recorded significant difference between the two surgical groups. However it was noted that the patient sample size was small. Their follow up time length was greater than this thesis study. However Luring commented on the fact that their study had a short term follow up (2 years) and they suggested that they would maybe see differences at a later stage, which may also be true of the male sub group within this thesis.

The improved muscle strength calculated in the navigated group would be expected to result in an improved functional outcome, and lead to an improved gait pattern. The navigated group did show some improvements during level and slope walking which indicated that their gait was closer to that of a ‘normal’ age matched subject. The specific differences were found during terminal stance and pre swing phase. It was noted that the knee flexion angle was higher in the navigated group. A better, more normal quadriceps and hamstring function would link directly to this improvement in knee flexion angles. During pre swing the knee rapidly flexes. This action is controlled by the hamstrings.

Therefore, the female navigated TKA group recorded significantly higher quadriceps and hamstring moments than the conventional group. It is likely that both groups would continue to show limitations in muscle strength compared to age matched normals. Physiotherapy in the initial period after surgery introduces

exercises which increase the strength of the muscles in the lower limb, which patients continue on their own when they leave the hospital Post surgical rehabilitation can lead to improvements over the first 12-18 months, however 'strength deficits' can be 'prolonged by adaptive functional habits' (Greene K.A and Schurman II J.R, 2008). Patients sometimes change their dynamic functional patterns prior to knee surgery so that they minimise pain. However these habits can continue after surgery limiting their progress. The extent of muscle atrophy due to inactivity prior to surgery also influences the possibility for the patient to regain muscle strength, to equal their contra lateral limb, and increase towards muscle strength levels found in 'normal' subjects.

4.7 ACTIVITY LEVEL DATA

There has been limited work completed into the activity level of TKA patients after surgery. Following surgery patients follow a rehabilitation programme consisting of various exercises to increase strength and range of motion. The length of the recovery period varies and can continue during first post operation year and in some patients longer. In this time the patients are encouraged to participate in mild exercise especially walking to help with their functional recovery. However the age range generally associated with TKA patients means that co morbidities are common and can greatly influence their activity level. One of the other issues commonly found within this patient group is the presence of symptomatic OA in other joints. If OA is present in other lower limb joints then this will impact there general activity level even if they do not have pain in the operated joint. In fact in these cases the patient will not get the benefit of their knee surgery until their pain is decreased in other arthritic joints.

It was concluded that there was no statistical difference in the activity levels of the navigated and conventional surgical groups. There was no significant difference in terms of the mean number of steps the two surgical groups took in a 24 hour period, the percentage of the day they spent standing, walking or sitting. However there was a great variation in the activity levels recorded by the TKA patients.

One disadvantage of the activity monitoring protocol used within this trial was that it only recorded the patient's activity for one 24 hour period. The patients were

asked to use a typical day. It was found that it was common for either the day after the clinic appointment or two days after the clinic appointment was used as their typical day. It is possible that for some of the patients their activity levels were similar each day, for example they have a routine such as walking the dog or going to the local shop everyday. However for others the day of the week will greatly affect how active they are. The final issue with using the day after the clinic appointment could be that this is an unusually quiet day as they have been to the hospital the previous day for their clinic appointment. Therefore it is possible that their day to day activity levels vary. Recording a week's activity data would be likely to give a better overall picture but may also increase the likelihood of a technical error in the data collection, and also a lower completion rate.

There was a large variation in the activity levels of the overall TKA group which was unrelated to either the surgical method or the outcome alignment of the surgery. The activity level was also not strongly correlated with age in this thesis study. A study by Bennett et al (2008) agrees with this finding as they reported no 'clear correlation between age and activity levels' at 10 years after hip replacement surgery. There was no strong correlation between the activity levels measured by the ActivPAL and either the objective electrogoniometry Total Functional Score or the subjective functional questionnaire scores. This suggests that in some cases the TKA patients have the capability to be functionally active but this does not necessary relate to what they do in daily living activities. Marker et al (2009) found that their activity score had a stronger correlation with the subjective AKSS function score than with the objective AKSS knee score. This agrees with the data in this thesis in that a weak correlation was found between the ActivPAL 'number of steps' and the AKSS function score. However there was a large variation in the activity level (number of steps) in patients with the same AKSS function score. The AKSS function score is a simple questionnaire only recording walking distance and ability to deal with stairs and if a walking aid was required. It therefore does not explain fully the patients activity levels or the activities they participate in. No correlation was found between the 'number of steps' and the AKSS knee score or the total Oxford Knee Score or the pain and function sub scores of the Oxford Knee Score.

Therefore functional ability measured through clinical questionnaires did not appear to strongly relate to whether the patient was active in daily living.

The ActivPAL records the number of steps in the day but it does not give any indication as to the impact level of the activity preformed. In fact activities such as running and cycling would be counted as steps and rated the same as walking even although the participation in these activities would indicate a greater functional ability. It would be an advantage to record the daily activities as well as the number of steps per 24 hours.

There was only a weak correlation between activity level (number of steps) and the VAS pain score (r=-0.25). This suggests that pain does not strongly influence whether the patient is active or not. Therefore a patient with a painful knee would not necessarily sit all day resting. Instead they would cope with the pain as they went about their daily activities.

In conclusion there was no difference between the activity levels of the two surgical groups. It was seen that there was a greatly varied activity level outcome which did not correlate strongly with alignment or functional scores. As activity level did not correlate well with function it is important to understand that patients with good functional scores and good post operation outcome may still not be active. There was only a weak correlation between activity level and pain scores (VAS) therefore it was not necessarily pain which limits this group of patients on a daily basis.

4.8 ICF: CAPACITY VERSUS CAPABILITY

The International Classification of Functioning, Disability and Health, or the ICF is WHO's (World Health Organisation) framework for measuring health and disability in the individual and the population. It focuses on the impact of health conditions on the individual rather than the cause of disability and therefore allows health and disability to be measured. This concept addresses that fact that disability is not only a medical dysfunction but that there is also a social aspect to disability. Therefore the impact of diseases such as osteoarthritis are not only pain and loss of function but the social aspect such as the loss of independence and freedom which can lead to an emotional impact such as depression. Health questionnaires such as

the SF-36 are therefore important in measuring this emotional impact on the subject's everyday life.

This thesis has discussed the fact that a good functional outcome does not appear to directly relate to an active daily life for TKA patients. There are various reasons for this such as, co morbidities resulting in limitations and behavioural habits. Patients have a mind set in their diseased state which after surgery may not change and therefore they do not increase their activity levels or change their lifestyles. Therefore they have not changed the expectations of their functional ability. The families can add to this problem as they continue to give the same support and therefore tasks which the patient could deal with are completed for them. The support is necessary before and immediately after surgery but in some cases the patients are capable after surgery but just not active.

The effect of disease and illness can be examined through the functional capacity of the individual which refers to the 'capability of the individual to perform tasks and activities that they find necessary or desirable in their lives'. Functional capability is measured by what the individual can do and in this study was demonstrated though the use of the electrogoniometry functional assessment. This was completed by the majority of TKA patients which indicated a high level of functional capability. The clinical scores also suggested that the patients were capable of being functionally active. Therefore it is possible that functional capability is not translated into the patient actually being functionally active. This means that there is a further issue to deal with. TKA patients, who have a good function post operatively, however do not always use this ability productively. Pain levels for most OA patients is reduced through surgery. However being active after surgery for some TKA patients would require a lifestyle change. For some patients the symptoms of OA have limited them but for others they may never have been an active person. Within the TKA group there will be different patient expectations and criteria to fulfil for a satisfactory outcome. Activity levels will also relate to the patients motivation and desire to be active after the surgery.

4.9 HEALTH ECONOMICS FOR NAVIGATION VERSUS CONVENTIONAL TKA

For all new technologies the economical cost implications have to be assessed. It is important to determine the costs and benefits of the introduction of the new technology. The question remains "are the clinical improvements for the TKA patient as a result of navigation systems worth the increased economic cost of the surgery?" At the moment only the potential cost effectiveness of navigation can be discussed as there is a lack of long term clinical data.

The implant used in both the conventional and navigated group was the same. However there are additional costs related to the surgical disposables and also the navigation system. The cost of purchasing the system can be as much as £50,000 and then there is the cost of maintaining the system. The surgical time for TKA was also increased when using navigation which related to an increase in theatre and staff time. The number of days spent in hospital was similar within the two surgical groups.

Navigation has been shown to be a successful tool for improving implant alignment and orientation. In the majority of studies navigation allows implantation to be more consistent. However whether the positioning of the TKA prosthesis is significantly improved is debatable as some studies have found good alignment results with both navigated and conventional TKA. The question is whether good alignment will directly impact the longevity of the implant and the patient functional outcome. Increased longevity of TKA implants directly impacts the revision rates. Revision TKA is a complicated procedure and a definite disadvantage to the patient due to the problems of additional surgery. It also has a cost implication for the NHS. From the Scottish Arthroplasty report (2009) there were 6884 primary TKA performed and 567 revision TKA procedures. From this report the revision rate at 1 year post operation was low at 0.7%. It increased to 2.1% for 3 year post operative TKA, and to 2.8% for 5 year post operative TKA. There was no data reported for long term TKA revision rates, for example 10 or 15 years. In the literature revision rates vary between studies but it is generally reported that TKA has a 92-94% survival rate at 10-12 years (Nafei A et al., 1996, Tayot O et al., 2001). For navigation to be cost effective then it would have to improve the revision rates, for

example decrease the 6% rates at 10 years by 2%. If the navigation system was used within a high volume hospital then it would also become more cost effective, if the results continued to show that the radiological outcomes were more consistent. Otherwise, if navigation does not reduce the probability of TKA revision then it will not prove to be cost effective.

Quality adjusted life years (QALYs) are sometimes used as a measure of the disease burden. It can be used to assess the value for money of the medical intervention. QALYs includes both the quality and quantity of years. Quality of life is scored in terms of five categories, mobility, pain, self care, anxiety/depression and usual activities. Each can be rated as no problems, some problems or major problems. A year of perfect health would be scored as 1. If health is impaired then the quality score decreases, for example some problems in each area would result in a score of 0.516. The quality score is then multiplied by the number of years lived at that health status. Therefore although TKA was not likely to increase the number of years a patient would live (quantity), it is expected to increase the 'quality' of the years lived. Therefore if the quality life score is increased by 0.25 for a continuous period of 10 years then the intervention would gain 2.5 QALY.

Patient satisfaction is a multifactoral issue which relates to pain and functional outcome and the QALY scale takes this into consideration. It is likely that for the majority of TKA patients, whether the surgery was completed using conventional methods or navigation, a gain in QALYs will result hence it is the long term difference in QALYs produced by navigation which is important. Since long term data is not available it is unknown whether navigation will result in a good outcome which will last for an increased number of years compared to conventional TKA, and therefore result in a QALY gain.

For the majority of TKA patients there is an increase in the quality of the years they live. The survival rates for knee replacements are high with the majority lasting for 10-15 years. This study has concluded that the functional outcome, pain levels and health status was similar in both the navigated and conventional TKA groups. This means the quality of life score would be the same. If the navigated TKA lasts longer then there would be a direct benefit for the patient in that the 'quality' score of the years lived remains high. This assessment was only at one year after surgery and

therefore longer follow ups are required. If problems occur later on, in either of the surgical groups such as increased pain or reduced mobility, then the ‘quality’ score of years lived will decrease.

Therefore, at one year after surgery little clinical or functional benefits have been recorded due to the use of navigation. Therefore at this early stage the increased costs of navigation in TKA have not been balanced by patient benefits or a reduction in revision rates. If the improved alignment in the navigated group results in improved function at a later follow up or increased longevity of the implant then the QALY gain would be higher within this group. Therefore navigation systems used in TKA would become cost effective.

Navigated surgery has led onto further technical advancements such as robotic controlled surgery. This technology has the potential benefits of increased accuracy as it aims to further improve alignment. The other potential benefits of this type of system would be the advancements in the cutting tools. By moving on from cutting blocks and saws then there is the potential for more accurate shapes to be cut from the bone, minimising the bone removed and also ensuring a more accurate fit for the implant. The continuing progression and advancement of technology in this field leads to increased costs for research and development but the technology has the aim of improving the surgical outcomes which would have a direct impact on the life of TKA patients.

4.10 TKA PATIENTS COMPARED TO AGE MATCHED NORMALS

Gait patterns change with age, for example, there is a noticeable decrease in gait velocity, cadence and stride length. The mean age of the TKA group was 66 years old and therefore this patient group is comparable to a ‘younger’ older adult group. Elderly walking cycles have been reported to show decreased swing phase peak flexion angles and they have been noted also to show a residual slight flexion at the end of swing instead of full extension as in the case of the younger adult group (Winter D.A. et al., 1990). Both these differences lead to a decrease in the range of motion during the gait for the elderly group. The older adults are screened carefully so that only the fit and healthy individuals are recruited (Winter D.A. et al., 1990).

This age group generally have underlying health issues which mean that as a comparison group they have superior health, function and clinical scores.

The electrogoniometry function cycles for the two TKA groups in this study were found to have the same kinematic pattern as age matched 'normal' subjects as reported by Rowe et al (2000). The 'normal' group data was from work carried out by Dr Marietta L. van der Linden in the school of Health Sciences in Queen Margaret University College under the supervision of Professor Philip J Rowe. The study recorded kinematic data from 40 aged matched normals during a similar electrogoniometry functional assessment as that completed by the TKA group in this thesis. The major difference between the patient group and the normal group was that the normal group recorded significantly higher knee flexion angles during the tasks for example for stairs ascent the mean maximum KJA for the 'normal' group=101^{o} compared to TKA group=77^{o} (section 3.3.5 page 210). This data agrees with that published to date where TKA patients record less ROM during walking activities than a control group (McClelland J.A et al., 2007). The TKA group produces less knee flexion during swing which results in a lower maximum flexion angle for the overall gait cycle. McClelland's study also stated that there was a reduction in the ROM during loading in TKA patients. This also agrees with the data in this study in that the stance phase ROM was seen to be smaller than that recorded by the age matched normal group. The significance of the small flexion angles during load transfer refers back to the contact surface area of the knee joint. The contact surface area decreases with increasing flexion angle. This therefore means that the pressure (force per area) increases with increasing knee flexion angle. Therefore one way for the patients to limit the magnitude of the pressure on the knee cartilage is to minimally flex the knee during the loading section of stance phase. This has been described as a method of reducing pain in the knee joint. The fact that OA patients' alter their gait is possibly a learnt phenomenon that will continue. Therefore the issue of an altered gait may continue in TKA patient groups even when pain is decreased.

Therefore the TKA patients in this study show functional limitations compared to 'normal' age matched subjects one year after TKA. These functional limitations were seen in the electrogoniometry assessment and also in the clinical questionnaires such as the SF-36.

4.11 ORTHOPEADIC CLINICAL ASSESSMENT

4.11.1 Present Clinical Assessment

At present the clinical assessment of outcomes routinely includes a patient based questionnaire (Oxford Knee Score), radiographs and ROM measurements. These assessment are conducted during routine clinics and do not include an in depth assessment and analysis as this would be too time consuming and too costly a practice. However this means that the analysis of the patient's functional outcome is limited. The present clinical assessments are focused on determining if healing and rehabilitation have progressed as expected in the first year, and whether there is any problems at that stage.

TKA aims to realign the lower limb and reduce Oxford Knee Scores which would indicate an improved function. There is no set target which means that the outcomes of the patients seen at their one year follow up appointment are varied as to their functional outcome. The patient satisfaction is used as an indication as to whether they are happy and can continue with there current treatment plan or if they are unhappy then a solution is investigated.

While it is useful to monitor patient progress for clinical decision making these limited evaluations would seem inadequate for research progression. Where research studies are in operation a more in depth and multi factorial assessment would appear to be warranted with objective and sensitive outcome measures such as those used in this study. Randomised controlled trials are expensive to perform and false negative results caused by poor outcome measures can have a detrimental impact on practice by leading to the rejection of good technology under the false impression that it does not improve practice. The use of poor outcomes measures means that to gain the same power in a study the sample size must be increased which leads to greater research costs, more assessments and the exposure of more participants to the risks associated with an unknown device or technique. A more cost effective, scientifically appropriate and ethical approach to research studies would be to use the highest level of measurement accuracy available so as to determine with power the outcome of a technique across a range of clinical issues using the minimum number of participants. In this study, group sizes of 40 were sufficient to find differences if they exist between surgical groups. Differences in the order of a few degrees were

reported, which is a level where the group differences begin to look clinically significant. However there was no difference between groups established.

4.11.2 Possible Changes for Future Clinical Practice

Although gait analysis using methods such as the flexible electrogoniometry and VICON systems which are important for research and for evaluating surgical interventions, it is not practical to carry out these kinds of assessments on every patient. Instead a large sub group has to be studied which will describe the larger TKA population.

Although the full electrogoniometry assessment cannot be completed with every patient it is important to use the best tools to describe the patient's functional outcome within the outcome clinics. It was concluded from the regression analysis within this study that the electrogoniometry Total Functional Score was best represented by measuring the passive ROM and recording a functional score from a clinical questionnaire. Unfortunately these two outcome measures only explained 30% of the objectively measured electrogoniometry score. The present functional scores are therefore limited in the data they record. There was no clinical score which strongly correlated with the objective electrogoniometry data. Therefore these kinematic studies continue to be required to fully investigate post operative TKA function.

The AKSS functional score which can be used to record post operative TKA function only records level walking and the ability to ascend and descend stairs. It also includes whether the patient requires an aid. It is expected that patients are capable of being active after their TKA surgery unless co morbidities affect their general health. Therefore a range of activities and daily functions should be included in the function questionnaire used. One such questionnaire which looks at a wide range of daily activities is the WOMAC. The function section of this questionnaire includes 17 questions ranging from standing to how difficult the patient finds heavy domestic tasks. The activities evaluated within the WOMAC are basic everyday activities; walking, stairs, sit to stand, lying and shopping. It would be expected that the majority of healthy TKA patients could manage these types of activities with little difficulty. A clear problem with this type of questionnaire is that although the

questions relate to the operated knee it is difficult to separate other medical problems while explaining the difficulty level of the task. Therefore it is difficult to isolate the effect of the operated joint in terms of function.

In some cases questionnaires such as the WOMAC investigate the patients' function fully. The main thing which is missing from these questionnaires is a section on sports and low to mid impact activities which patients return to within the first year after surgery. Many TKA patients find that they can return to their jobs, work in the garden, and play sports such as golf, lawn bowls, walking, hiking, swimming, skiing and cycling. The ability to take part in activities such as these indicates a functional outcome level beyond that measured in the simple clinical questionnaires; Oxford Knee Score and AKSS. This was sufficient when the main aim of TKA was pain relief within an elderly population who generally had a low activity level lifestyle. However as the TKA population becomes younger this is no longer the case. The functional expectations have increased and good function post operation is also a primary objective. Therefore, although high impact sports are not recommended after TKA it is generally accepted that mild to moderate level of exercise is actually beneficial. The relief of pain and improvement in function is expected to lead to an increase in exercise and an overall healthier lifestyle. Therefore there is a need for questionnaires to include an activity component which would differentiate between activity levels of those patients at the higher end of the scale, who can function normally with activities of daily living.

Since this project was initiated a High Activity Arthroplasty Score (HAAS) has been developed to assess the variations in functional outcome particularly in the high functioning knee and hip arthroplasty patients (Talbot S et al., 2010). When this score was used in large group (n=152) of young (40-66years old) knee and hip arthroplasty patients it was found that it resulted in a large range of scores which closely approximated to a normal distribution. This was compared to the distribution found in other scores used for example the Harris Hip Score (HHS) where the majority of the patients were grouped at the high end of the scale(Talbot S et al., 2010). Therefore the HAAS could distinguish between activity levels of the TKA patients throughout the full outcome range. The presence of the high functioning TKA patients is likely to increase as the TKA population becomes younger. It would

be sensible for the orthopaedic community to adopt this score alongside the established Oxford Knee Score or Harris Hip Score

Another important finding this study has identified is the fact that a good function measured through the objective electrogoniometry system did not strongly correlate with the activity level recorded in a typical 24 hour period. There were possible problems in recording only one 24 hour period rather than measuring a few days and averaging the results. This would have given a more accurate indication of the patient's daily activity level. The electrogoniometry data was based on kinematics and the score indicated how close to a 'normal' functional pattern the patient achieved during daily activities. The lack of a strong correlation suggests that a good kinematic functional outcome did not directly lead to an active lifestyle, in the same way that a poor kinematic functional outcome did not directly lead to a low activity level in daily life.

One of the limitations of the ActivPal is that it does not distinguish between steps in terms of impact and velocity. Therefore brisk walking is for example, recorded as general steps in the same as slow walking within the house is recorded as steps. Again the impact of the activity is not taken into consideration when determining the patient's activity level. This means that stairs and slope walking are rated the same as level walking. In this sense it would be advantageous to be able to record kinematics during this 24 hour period. From this kinematic data the particular functions could be identified from the differences in functional cycles and the maximum flexion angles required to complete the function. This sort of objective measuring device could again only be used on a sub group of the TKA population, but using a range of ages within the TKA population it would be possible to get a good, overall picture of the functional outcomes of TKA patients. From this it may be possible to understand better why the relationship between functional capacity and capability was not stronger with activity levels. Obviously for some of the patients in this population co morbidities play a significant role in limiting the benefit in function that results from their surgery, while for others psychosocial factors play a leading role.

It is important to look at the patients function and other medical conditions so as to explain the difference between capability and capacity but there are also social

and emotional issues which may influence the outcome of the surgery. The majority of TKA patients have suffered with severe OA for many years which means that they have gradually decreased their activity level as a result of pain in their joints. Therefore their lifestyles have adapted to their situation with knee OA and perhaps other lower limb problems. Therefore it would require a change in the mind set to change these lifestyle patterns and the belief that they are able to be more functionally active. Families also adapt over time, increasing the help they give to those who are functionally impaired. This habit continues during rehabilitation as it will be required. The issues occur when their help becomes counter productive as the TKA patients do not push themselves to do activities that in fact they are capable of completing.

Summary questionnaires although subjective are good for quick assessment within clinics. Questionnaires which lead to a better description of the functional level of the TKA patient and their activity levels would be beneficial for audit and clinical research analyses of this group especially as the age range of the TKA group widens and differences in post operative functional outcome becomes increasingly varied within the group. For the testing of new devices and the technology related to arthroplasty the use of a variety of objective outcome, measures high quality scientific measures of impairment, functional activity and participation (as seen in activity levels and quality of life) would seem both possible and warranted before such a device or technology is given approval and put on open release. Currently only the longevity, complication rate and toxicology are considered but in the future we should select those methods and procedures that also lead to better patient function and satisfaction. To do this we must expand out portfolio of outcome measures.

CHAPTER 5. CONCLUSION AND FUTURE WORK

5.1. CONCLUSION

This study has shown that Total Knee Arthroplasty is a successful surgical intervention for decreasing pain but less successful at restoring function at one year post operation. The post TKA group recorded improved clinical and functional scores compared to the pre operative assessment scores but less than 'normal' values.

The study aimed to compare an electromagnetic navigated TKA group with a conventional TKA group. Literature has reported no significant functional differences in short and mid term studies, using subjective questionnaires and clinical scores. This study was also a short term follow up. However it used electrogoniometry as an objective kinematics measurement system. One limitation of the study was that the electrogoniometry study was not completed prior to the surgery therefore there was no baseline data to compare the 1 year post operation data with. Knee kinematics of the two surgical groups was compared during 12 functional activities. Functional outcome was also recorded through muscle strength test, activity monitoring and clinical questionnaires. The conclusions of the functional assessment were:

- Electrogoniometry is a reliable and repeatable measure which can be used to study knee kinematics in Total Knee Arthroplasy patients.
- All of the functions (except in and out of a bath) recorded a repeatable functional pattern; therefore average cycles could be calculated for each patient and also for the two groups.
- There were no significant differences between the two groups in terms of the maximum, minimum and excursion knee joint angle during any of the 12 activities.
- The two groups showed no significant differences in terms of the stance phase maximum knee joint angle; this refers to the weight bearing phase of walking activities.
- The navigated group recorded a higher electrogoniometry Total Functional Score but it did not reach statistical significance.

- There was a statistically significant increase in knee joint angles recorded in the navigated group at the terminal stance/pre swing phase of level walking, up and down slope. The navigated group demonstrated a quicker, more powerful push off into swing phase.
- The female navigated group recorded a statistically significant increase in hamstring and quadriceps moments. This maybe related to the improved walking cycle seen in the navigated group. There was no difference between the male navigated and conventional group in terms of the hamstring and quadriceps moments.
- There was no significant difference between the two surgical groups in terms of activity level.
- There was no significant difference between the two surgical groups in terms of clinical scores, range of motion or health scores.

Within the literature it has been reported that navigation can lead to improved mechanical axis alignment. The consistency of the coronal, sagittal and rotational alignment is also thought to be superior in navigated TKA groups. However this theory is not supported by all comparison studies as some have concluded that the outcome alignments are similar in navigated and conventional groups. The conclusions from the alignment study were:

- The frontal femoral and sagittal femoral alignment demonstrated a statistically significant improvement in the navigated group
- The conventional TKA group demonstrated a statistically significant improvement in the frontal tibial alignment, but there was only one outlier in each surgical group.
- For all the alignment parameters, apart from the sagittal tibial alignment, the navigated group had a higher percentage of the group within the 'desired' range.

The relationship between alignment and functional outcome was investigated. The literature suggests that a 3^{o} error range from neutral alignment is acceptable for implant survival and represents a good alignment outcome. The degree of error which would be associated with functional problems is unknown. It was hypothesised that the relationship between alignment and function would be

quadratic, where increasing error in either direction would relate to a decreased function.

- The electrogoniometry Total Functional Score had a weak quadratic correlation with sagittal femoral, sagittal tibial and mechanical axis alignment, so confirming this hypothesis.
- From this correlation the most functional neutral sagittal tibial alignment was recorded at 4-5^{o} posterior slope rather than the 7^{o} which has been suggested by the implant company.

The literature has reported a trend to better function in 'well' aligned TKA groups. 'Well aligned' and 'outlier' groups were correlated with functional outcomes.

- The satisfaction score for the frontal femoral 'well aligned' group demonstrated a statistically significant improvement compared to the 'outlier' group.
- The AKSS knee score was improved in the frontal femoral 'well aligned' group but it did not reach significance.
- The CT mechanical axis 'well aligned' group demonstrated a statistically significant improvement in the Oxford Knee Score.

Regression analysis showed that 30% of the objective electrogoniometry Total Functional Score could be explained by recording passive ROM and a function questionnaire score. ROM and questionnaires are routinely used in outcome assessments. This suggests that objective gait analysis assessments are still essential in properly auditing different implants and surgical interventions. However the present outcome assessments do not record enough detailed functional information to select the best implant for function.

The present functional questionnaires do not include high impact activities of daily living and sports. This means that the extent of functional recovery cannot be properly reported as they suffer badly from ceiling effects. The TKA population now includes a range of ages. TKA patients now have different expectations pre operatively and the functional ability after surgery is varied. There is a need for methods to distinguish between patients within the 'good' function group. The activity level of the TKA patients within this study also varied greatly. It was seen to

have a weak correlation with pain scores, but little correlation with functional outcome. Therefore, the good functional outcome reported in some TKA patients was not then translated into an active lifestyle. Electrogoniometry can be used to measure kinematics of a range of functions. It shows the potential knee function restored to the patient to perform tasks. However it was reported that a 'good' knee kinematic outcome did not relate to the patients being active. Therefore patients' inactive lifestyles can be affected by many other physical, psychological and social factors and not directly related to problems in their knee joint. Electrogoniometry is therefore suitable as a primary outcome measure for assessing TKA implants and surgical techniques where as activity monitoring, QOL measures and satisfaction indicate more the success of rehabilitation and self care.

Despite the improvements in implant and surgical technique, TKA patients still had limited function compared to age match 'normal' subjects. Osteoarthritis commonly affects multiple joints and therefore can be associated with ongoing disability.

In conclusion, TKA was shown to be a successful surgical intervention for end stage osteoarthritis with about 90% of the trial patients being satisfied or very satisfied at their one year follow up assessment. Navigation was seen to result in some alignment improvements. The navigated group also showed trends towards better functional outcome. The cost effectiveness of navigation is unclear as long term data is unavailable at the present time. This surgical intervention would become cost effective in the long term if there was a reduction in revision rates, as well as patient health and functional benefits. The system also has the potential as a training tool as it allows alignment to be visualised with real time feedback. Therefore it is still unknown whether navigated TKA will lead to a functional improvement but in the short term the two groups appears to be similar with respect to function.

5.2. FUTURE WORK

The study will continue beyond the scope of this thesis. The 200 patients will be followed up for 10 years, therefore the mid to long term functional and clinical outcomes can be analysed. Further work would include completing the 1 year electrogoniometry assessment on all the trial patients. Increased numbers within the

‘alignment versus function’ study would allow the question of whether there is a relationship between these two parameters to be studied in depth. This study has collected data for many different parameters and there is a need for an in depth statistical analysis of the whole patient group when they reach 1 year.

Further work would also include validating the Total Functional Score and modifying it to include the activities which can be used to identify differences between normal and patient groups.

It was interesting to find that a ‘good’ knee kinematic outcome as measured through the electrogoniometry functional assessment did not strongly related to the patient’s activity level. Recording activity data for up to a week and investigating fully the activities and tasks which the TKA patients participate in after surgery would allow a better picture of the patient’s daily activity levels to be developed. Further work into the reasons why good functional outcome and activity is not strongly related is required.

There is scope for further work into the intra and inter observer reliability of radiographs and CT scans. These two methods of analysis are used to investigate alignment therefore it is important that there is a standard protocol so that the results are valid. These measurement systems also were found to result in different outcome alignments within this patient group. There is a need for further investigation into this issue as at the moment it is assumed that both measurement systems are accurate and valid for clinical use. However, if there are discrepancies between the two systems when measuring the same alignment parameter then this could be a cause for concern.

Conferences and Publications

ABSTRACTS IN PEER REVIEWED JOURNAL

J.R. Smith, P.J. Rowe, M. Blyth, B. Jones S-43 Does Navigated Total Knee Replacement Lead to an Improved Functional Outcome? Journal of Biomechanics. 2010;43(Suppl 1): S46-S47 Abstracts of the International Conference on Orthopaedic Biomechanics, Clinical Applications and Surgery (OBCAS)

ABSTRACTS IN PEER REVIEWED CONFERENCES

International Society of Biomechanics (ISB) – Brussels, Belgium July 2011

- Does accurate anatomical alignment result in a better clinical and functional outcome at 1 year after TKA? Abstract 1307
- Navigated versus conventional total knee arthroplasty. Are there improved gait kinematics or clinical benefits? Abstract 733

Computer Assisted Orthopedic Surgery (CAOS) – London, UK June 2011

- Navigated versus conventional Total Knee Arthroplasty. Are there improved gait kinematics or clinical benefits?

EFORT - Copenhagen, Denmark June 2011

- Free paper - Electromagnetic navigation versus conventional Total Knee Arthroplasty: Clinical improvements. Blyth, Mark / Jones, Bryn / Smith, Julie / Rowe, Phil

British Association for Surgery of the Knee (BASK) – Cardiff, Wales March 2011

- Clinical improvements with electromagnetic navigation versus conventional total knee arthroplasty. M Blyth, B Jones, J Smith, P Rowe

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ZIMMER (2011a) NexGen LPS Flex Zimmer, Inc.

ZIMMER (2011b) NexGen® Complete Knee Solution Legacy® Knee Posterior Stabilized (LPS) Zimmer, Inc.

APPENDICES

Appendix 1:

STUDY PROTOCOL

TITLE: A single centre, randomised, single-blind, parallel group study to compare the results of total knee surgery using conventional instrumentation versus the INAV electromagnetic computer navigation system.

Country: United Kingdom

Chief Investigator: Mr Mark Blyth FRCS (Ed) (Tr+Orth)

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Study Sponsor: Greater Glasgow Health Board
North Glasgow University Hospitals Division
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84 Castle Street, Glasgow, G4 0SF

Proposed start date: March 2007

Recruitment period: 18 months

PROTOCOL SYNOPSIS

Title: A single centre, randomised, single-blind, parallel group study to compare the results of total knee surgery using conventional instrumentation versus the INAV electromagnetic computer navigation system.

Rationale: Using the INAV electromagnetic computer navigation system, accuracy of implantation of total knee replacement in the coronal plane is thought to be possible to within 1 degree. Evidence from the current literature suggests that alignment errors exceeding 3 degrees are associated with early implant failure. The effects of these alignment errors on patients' functional outcome are unknown.

Objective: To compare the results of total knee replacement surgery using conventional instrumentation versus the INAV electromagnetic computer navigation system which has been developed to assist surgeons performing total knee replacement.

Study Population: A total of 300 patients with osteoarthritis of the knee who are suitable for a total knee replacement will be enrolled.

Study Design: A single centre, randomised, single blind controlled study. Patients will be randomised pre-operatively to conventional or INAV instrumentation. Patients will receive the standard post-operative follow-up treatment with the addition of a CT scan at 3 months to assess post-operative alignment. Long-term follow-up will continue at 1, 3, 5 and 10 years.

Study Endpoints:

Primary Efficacy:

- Implant positioning measured at 3 months post-operatively using 3D reconstruction CT scans and long leg x-rays.

Secondary Efficacy:

- Functional outcome at 1 year measured using electrogoniometry and Activpals
- Patient satisfaction and quality of life at 1,3,5 and 10 years using COPM and SF36 measures
- Clinical outcome scores (American Knee Society Score and Oxford Knee Score) at 3 months, 1, 3, 5 and 10 years
- Radiographic Outcome at 1,3,5,10 years
- Time to implant failure, defined as revision or intention to revise for any reason or progression of radiological lucent lines.

Safety:

- Post-operative complication rates
- Duration of operation
- Adverse events will be recorded and reported appropriately throughout the study to assess safety.

Investigation schedule:

Action	Pre-treatment	Treat-ment	3 months	1 year	3 years	5 years	10 years
Issue patient information leaflet	X						
Obtain written informed consent	X						
Medical history	X						
Radiographic examination / Long leg x-rays (LL)	X/LL	X	LL	X	X	X	X
Physical examination	X		X	X	X	X	X
Oxford/AKSS knee scores	X		X	X	X	X	X
Assign randomised treatment	X						
Surgical details		X					
CT scan for alignment			X				
Assess and record adverse events / interim history		X	X	X	X	X	X
Detailed Functional Assessment				X			
SF 36/ Canadian Occupational Performance Measure	X			X	X	X	X

1.0 INTRODUCTION:

The INAV electromagnetic computer navigation system was commercially launched in 2005. Computer navigation systems in surgery have been in use since the late 1990s with the first designs requiring preoperative mapping with computed tomography (CT) scanning. Although these systems were initially developed for neurosurgery, their use in Orthopaedics has steadily increased particularly in spine surgery.

A significant technological advance came however with the development of so-called imageless systems which rely on the use of 3D arrays and a process of registration to map the surgical field.

The first generation of these systems involved the use of optical arrays with direct line of sight between array and sensor required. Difficulties were encountered in maintaining this direct line of sight due to blood spillage on the optical array and the presence of surgical assistants. These difficulties have led to the development of an electromagnetic system where the optical arrays have been replaced with electromagnetic coils.

The advantage of all computer navigation systems is that they theoretically allow the surgeon to implant components with a high degree of accuracy. In total knee replacement surgery this means that alignment in the coronal plane can be achieved to within 1 degree of the neutral mechanical axis.

There is evidence from the literature to suggest that alignment errors in coronal plane exceeding 3 degrees from the neutral mechanical axis are associated with early implant failure thought to be associated with eccentric loading of the polyethylene tibial tray. The effects of these alignment errors on the patient's functional outcome are unknown. Earlier studies have demonstrated the reduction of outliers and the migration of the group towards the ideal 0 degrees when using optical navigation systems.

The effects of other alignment parameters, such as femoral and tibial rotation, on function and survivorship of joint replacements are poorly understood. This study aims to demonstrate a reduction in variance of alignment when using an electromagnetic navigation system and to quantify the surgical, clinical and functional benefits of such a reduction. We are unaware of other studies published using this or any other electromagnetic system.

While Clinical knee scores (KSS and Oxford scores) may reveal the success of the navigated procedure from a surgical view point they are relatively crude and insensitive outcome measures when related to patient function and satisfaction. It is therefore possible that navigated surgery may lead to important but subtle improvements in patient function which have a substantial impact on quality of life but which are not detected by the typical knee rating scores used to detect improved surgical outcome. Using knee scores alone increase the chances of making a type II error in which it would be concluded that no differences exist in patient outcome when in fact they do exist and are valuable to the patient but have not been captured by the clinical rating scale outcome measures deployed. By performing a scientific, precise, accurate and multi dimensional assessment of patient functional outcome and satisfaction it will be possible to determine the benefits (if any) of navigated versus non-navigated surgery for patient functional outcome. This data can be used

to inform health care service providers such as the UK NHS of the benefits to be gained for their patients in terms of functional outcome by investing in navigated surgery.

2.0 OBJECTIVES:

2.1 Primary Objective

To compare alignment in 2 groups of patients undergoing total knee replacement. In the first group bone cuts will be made using conventional instrumentation utilising intramedullary femoral and extramedullary tibial reference guides. In the second group the INAV navigation system will be used to determine femoral and tibial cuts. At 3 months post operation alignment and implant placement in both groups will be verified with long leg x-rays and 3D reconstruction CT scans.

2.2 Secondary Objectives

1. To compare the influence of the different treatment on the functional outcome. By carrying out a multi dimensional and full evaluation of the functional outcome at 1 year post-operation. The evaluation will be based on the recommendations of the WHO International Classification of Functioning, Disability and Health for the assessment of health technologies (the WHO ICF 2001 and previously the WHO ICIDH-2, 1998). See Appendix I for details.
2. To compare both groups of patients using clinical scoring systems (the American Knee Society and Oxford scores) both preoperatively and in the postoperative phase.
3. To compare the influence of the different treatment on the patient's satisfaction and quality of life (COPM, SF-36) both preoperatively and in the postoperative phase.
4. To compare time to implant failure, defined as revision or intention to revise for any reason or the progression of lucent lines seen at radiological follow-up.
5. To compare the complication rates between groups. Complications to be measured include superficial and deep infection, neural and vascular damage, bone fracture around the implant, early loosening of the implant, dislocation or fracture of the implant, excessive haemorrhage requiring reoperation, reoperation for any reason, thrombotic complications, post operative confusion and death.
6. To compare the operative times between the groups.

3.0 ENDPOINTS

3.1 Primary endpoint

The primary endpoint is the postoperative implant position. This will be measured in the coronal plane from the neutral mechanical axis at 3 months post-operation. In

addition measurements in the sagittal (ante-, retroversion) and the transversal plane (rotational alignment) of femoral and tibial components will be compared between the 2 study populations.

Secondary endpoints

1. Functional outcome measurements at one year detailed in Appendix 1.
2. Clinical scores (the American Knee Society and Oxford scores) at 3 months, 1, 3, 5 and 10 years post-operation.
3. Patient satisfaction and quality of life (COPM, SF-36) at 3 months, 1, 3, 5, 10 years post-operation.
4. Incidence of post-operative complication (i.e. superficial and deep infection, neural and vascular damage, bone fracture around the implant, loosening of the implant, dislocation or fracture of the implant, excessive haemorrhage requiring reoperation, reoperation for any reason, thrombotic complications, post operative confusion and death).
5. Time to implant failure, defined by revision or intention to revise for any reason or the progression of lucent lines seen at radiological follow-up.
6. Duration of the operation

4.0 INVESTIGATION DESIGN

Please refer to investigation schedule on page 4
This is a single centre, randomised, single blind controlled study. Patients will be randomised in a 1:1 manner to receive a total knee replacement for osteoarthritis implanted using either conventional or navigated techniques.
The study will continue until a total of 150 patients have been recruited to each group and followed up for 10 years post-treatment.
The primary analysis will take place once 3 month-follow-up data is available for all enrolled patients.

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5.0 DEVICES

The total knee replacement used in this study will be a Zimmer NexGen LPS-Flex design which is CE marked and in routine use in our hospital. All implant components will be cemented.

The INAV electromagnetic computer navigation device is CE marked for assisting Total Knee Replacement surgery and is also in routine use in our hospital.

6.0 RISK/BENEFIT ANALYSIS

The perceived benefit of using the INAV system is to allow for more accurate implantation of a total knee replacement when compared to conventional methods. As the intramedullary space of the femur is not violated it is possible there will be decreased bleeding and decreased fat embolism causing post operative confusion and pulmonary complications.
Risks of the INAV include the procedure taking slightly longer than a conventional surgery.
Risks common to both methods are those of total knee replacement in general. Any surgical procedure poses a potential risk and the procedures undertaken as part of this clinical investigation are no exception. There are known risks associated with the method of anaesthesia (general, local and epidural). In addition there are risks associated with a surgical procedure that involves a device, these include the following: damage to nervous and vascular tissue, infection, long term swelling, fracture of bone surrounding a device, loosening, dislocation or fracture of the device, haemorrhage, decreased range of motion or mobility deformity, allergic reaction to the device (including immunological reaction to device wear debris) and failure of the device to be incorporated into the body – this is not an exhaustive list. A comparison may require revision surgery, Very rarely a complication may prove fatal.
The anticipated benefits a patient will experience as a result of participating in this clinical evaluation include: reduction or relief of pain, restoration or improvement in range of motion and mobility, correction or improvement of disfiguring deformity and an improvement in their quality of life.
Subjects will be advised of the potential risks and benefits associated with this investigation verbally by the investigator and by writing in the form of the subject information leaflet which will be approved by the ethics committee.

7.0 STUDY POPULATION

7.1 Number of patients

A total of 300 patients meeting the inclusion and exclusion criteria will be enrolled from a single centre.

Recruitment in the study will cease once the target number of patients has been reached.

Only patients whom the Investigators believe can comply with the study procedures (i.e. visit schedule compliance and CT scan) should be entered into the study.

7.1 Inclusion Criteria

vii) Male or female subjects may be recruited to the evaluation.

viii) Subjects must be at least 18 years of age and there will be no maximum age limit. The subject's age must be considered suitable by the Investigator for a knee arthroplasty using either of the two systems available in the evaluation.

ix) Subjects, who are able to give voluntary, written informed consent to participate in this investigation and from whom consent has been obtained.

x) Subjects, who, in the opinion of the Investigator, are able to understand this investigation, co-operate with the investigation procedures and are willing to return to the hospital for all the required post-operative follow-ups.

xi) Subjects who require a knee arthroplasty for primary surgical management of idiopathic osteoarthritis.

xii) Subjects, who in the opinion of the Investigator, are considered to be suitable for treatment with a NexGen LPS-Flex total knee replacement.

7.2 Exclusion Criteria

xiv) Subjects who, in the opinion of the Investigator, have an existing condition that would compromise their participation and follow-up in the study.

xv) Subjects who require revision total knee arthroplasty surgery.

xvi) Subjects with any tibial deformity requiring tibial component augmentation.

xvii) Subjects whom, in the opinion of the Investigator, require a constrained prosthesis.

xviii) Subjects with inflammatory polyarthritis.

xix) Subjects with disorders of the feet, ankles, hips or spine causing significant abnormal gait or significant pain.

xx) Subjects with osteoarthritis of the contralateral knee causing significant abnormal gait or significant pain.

xxi) Subjects with a poorly functioning contralateral total knee replacement causing significant abnormal gait or significant pain. Subjects with a well functioning contralateral total knee replacement will not be excluded.

xxii) Subjects with neurological conditions affecting movement.

xxiii) Subjects with a pathology which, in the opinion of the Investigator, will adversely affect healing.

xxiv) Subjects with other disorders which, in the opinion of the Investigator, will/could impair rehabilitation.

xxv) Contra-indications for use of the device, as detailed in the package insert.

xxvi) Women who are pregnant.

xxvii) Subjects who are known drug or alcohol abusers or with psychological disorders that could effect follow-up care or treatment outcomes.

xxviii) Subjects who are currently involved in another clinical study with an investigational product.

xxix) Subjects who are currently involved in any injury litigation claims.

8.0 INVESTIGATIONAL PROCEDURES

An overview of the procedures each subject will undergo during the course of this investigation is contained in the Investigational Schedule at the front of this protocol and in more detail as follows:-

8.1 Screening **Evaluations**

8.1.1 Informed Consent

Subjects considered suitable for participation in this clinical investigation by the Investigator will be given a verbal explanation of the nature of their clinical condition, this investigation and follow-up requirements by the Investigator (or a designated deputy), and supplied with the subject information leaflet. Each subject will be allowed sufficient time to decide whether they wish to participate in this investigation. Any queries which subjects may have regarding this investigation will be addressed appropriately by the Investigator or another member of the investigative team at the hospital.

Subjects will be instructed that they are free to obtain further information from the Investigator at any time, that they are free to withdraw their consent and to discontinue their participation in the study at any time without prejudice.

If the subject is willing to participate in this investigation written informed consent will then be obtained. Written informed consent from the subject must be obtained before any of the screening procedures are performed.

8.1.2 Subject eligibility and identification

The patient details will be recorded on a patient log. If a patient fails any of the eligibility criteria for the evaluation, the patient will not be advanced any further into the evaluation. The failure of a patient to meet the eligibility criteria will be documented by the Investigator and filed with the signed consent form.

The Investigator will also inform the subject's General Practitioner (GP) in writing of the subject's participation in this investigation.

8.1.3 Randomisation

Patients will be randomised to receive a NexGen LPS-Flex design total knee replacement using either conventional or computer assisted surgical techniques once voluntary written informed consent has been obtained and it has been confirmed that the patient meets all of the eligibility criteria. Randomisation will be stratified by surgeon to eliminate bias.

8.1.4 Clinical Assessments

Each subject considered eligible for entry into this investigation will have the following information and procedures recorded at the pre-investigational examination:-

- Patient identification (initials and evaluation number)
- Demographics (date of birth, sex, weight, height)
- Concomitant medication
- Medical history (past and present)

The following baseline assessments will be performed (within 30 day prior to treatment):-

- Oxford Knee Score, American Knee Society Score, Short Form-36 (SF-36) and the Canadian Occupational Performance Measure (COPM)
- Radiographic Analysis incl. weighted long leg x-rays

8.2 Surgical Procedure

8.2.1. Subject pre-operative management

The pre-operative management of each subject enrolled in this clinical investigation will be as per the standard regime used at the investigation centre. Pre-operative management for the device to be used will be undertaken as per the normal clinical practice of the Investigator.

8.2.2. Anaesthesia

The method of anaesthesia used will be as per the standard clinical practice of the Investigator.

8.2.3. Procedure

The surgical technique/approach used in the clinical investigation will be as per the standard clinical practice of the Investigator. Devices and instruments supplied by Zimmer GmbH will be used in accordance with the manufacturer's instruction.

Any alteration to the standard clinical practice of the Investigator will be documented.

8.2.4. Intra-operative assessments

During the operative procedure an assessment will be performed and the following information will be recorded in the subject's case record form:

a. Subject identification
b. Date of surgery
c. Antibiotic prophylaxis
d. DVT prophylaxis
e. Pre operative visually assessed deformity in coronal and sagittal planes
f. Surgical approach used
g. Details of all devices and components used
h. Soft tissue balancing
i. Posterior cruciate ligament status
j. Cement use
k. Details of any problems or complications encountered
l. Time for the procedure
m. Tourniquet time
n. Surgeon name and grade
o. Pre-operative and post-operative alignment parameters as determined by the INAV system for the navigated group (see Appendix 2)

A patient Record Label for each device or component used during the procedure will be affixed to the patient's hospital notes and to the case record form.

8.3 Follow-Up Assessments

Subjects will be followed up as part of the clinical investigation at the following time points:-

3 months (± 14 days)
1 year (± 30 days)
3 years (± 30 days)
5 years (± 30 days)
10 years (± 30 days)
Every effort will be made to follow-up subjects within the time windows indicated.

The following assessments will be completed:-

1. Oxford Knee Score, American Knee society score, Short Form-36 (SF-36) and the Canadian Occupational Performance Measure (COPM) at each visit
2. Details of any post-operative problems or complications
3. CT scanning at 3 months.
4. Radiographic Analysis at each visit according to the Investigation schedule

8.4 Detailed Functional Assessment

Subjects will be reviewed at 1 year at the time of their follow-up assessment for detailed functional outcome data according to the protocol outline in Appendix 1.

8.5 Computerised Tomography

CT scanning of patients will be carried out at Glasgow Royal Infirmary to the following protocol:

Requires reconstruction of a model with 30 slices.
5 slices at the femoral neck and head
14 slices of the distal femur
8 slices of the proximal tibia
3 slices of the ankle
All slices at 3 mm intervals.
Brand
Reference
Tube: numerical sensors (1, 2, 4, 8, 16, 32)
Anticipated radiation dose:
Format for MOD: own brand format or Dicom 3.0
Capability to burn CD's in own format or Dicom 3.0
Type of software, capability for smooth rays (issue for acquisition with prosthesis /artefacts)
Analysis of the anonamised CT generated data will be carried out by Zimmer GmbH with independent validation at Glasgow Royal Infirmary.

8.6 Safety Assessments

8.6.1. Adverse event reporting

At each follow-up assessment details of any adverse event or adverse device effect reported by the subject will be recorded. Details to be recorded include the nature, onset, duration, severity, relationship to the operative procedure or device and outcome of the event.

The occurrence of adverse events (including new illnesses, worsening symptoms of coexisting diseases or additional symptoms) will be identified by spontaneous reports from the subject in response to a standard question (e.g. how have you been since your last visit?) or by clinical/radiological assessment.

According to the European Standard EN 540 for the Clinical Investigation of Medical Devices for Human Subjects, an adverse event is defined as ‘any undesirable clinical occurrence in a subject whether it is considered device related or not’. In addition, an adverse device effect, undesirable side effect, is defined as ‘a device related adverse event’.

An adverse event or an adverse device effect may be mild, moderate or severe and are usually unexpected. A severe adverse event or adverse device effect is defined as any experience that:

i) is fatal or life threatening;
ii) is permanently incapacitating or disabling;
iii) requires or prolongs in-patient hospitalisation because of a potential disability, danger to life or an intervention has been necessitated;
iv) causes foetal distress, foetal death or a congenital anomaly; or
v) results in malignancy.

The Chief Investigator will report adverse events to the Sponsor. Severe adverse events will be reported as they occur and within 1 week. If the adverse event is felt to be device related the chief investigator will also notify Zimmer GmbH.

8.7 END OF TRIAL

The trial is expected to end after the last 10 year assessment. Thus the end date will be expected to be May 2019.
The primary efficacy data will be reported once recruitment has stopped and 3-month CT data has been analysed.

9 STATISTICS AND DATA MANAGEMENT

9.1 Sample Size

A total of 300 subjects will be enrolled into the study (approximately 150 per treatment group).
Data from the literature [1-5] suggest that between 15% and 20% of patients undergoing knee replacement will have an alignment error of more that 3 degrees. Given that a reduction in this proportion of 10% would be considered to be of significance, with 80% power and a two-sided significance level of 0.05, the study will require 140 patients per group using the standard binomial test of two proportions and the tables in "Sample size tables for clinical studies" , Machin et al (2nd ed 1997, Blackwell Science). This will be increased to 150 per group to allow for dropouts.

9.2 Randomisation

Subjects will be randomised with equal probability to each treatment and treatment will be stratified by surgeon, to minimise bias. The randomisation list will be generated by an independent statistical centre and held off-site. Allocation of treatment will be carried out by telephone.

9.3 Efficacy Evaluations

9.3.1 Primary Efficacy Analysis

The primary analysis variable is the proportion of patients who are shown to have alignment error from the neutral mechanical axis greater than 3 degrees as demonstrated by long leg x-rays and CT scan at 3 months post-operation. A 95% confidence interval will be obtained for the difference in proportions from each of the two treatment groups.
Summary statistics, including 95% confidence intervals, will also be presented for the actual alignment errors in the two groups, although the study has not been powered on the basis of this measurement.

9.3.2 Secondary Efficacy Analysis

Functional outcome: See Appendix 1

Clinical Scores: Oxford scores and AKSS scores will be calculated and summarised preoperatively and at post-operative visits at 3 months and 1, 3, 5 and 10 years. The change in score at each time point will be presented and compared between the 2 groups.

Patients who complete the surgical phase but fail to complete follow-up postoperatively will be included in the analysis up to the point of last assessment.

Time to implant failure: the two groups will be compared using the log rank test.

9.4 Safety Evaluations

Summary statistics of post-operative complication rates and adverse events will be produced by treatment group and will undergo clinical review.

Summary statistics will be produced for the duration of operation for each treatment group and a 95% confidence interval for the difference in duration will be calculated.

9.5 Planned Interim Analysis

As an additional safety measure, an interim analysis will be conducted once 100 operations -50 in each group- have been performed and data from the 3 month follow-up CT scan is available. This has two aims:

i) To check the assumptions underlying the calculation of the sample size, hence providing the opportunity to revise the sample size if necessary; and
ii) To check the accuracy of the INAV operative measurements of coronal, sagittal and rotational alignment against the CT analysis.

A Data Monitoring Committee will be constituted to review the results of these analyses and guidelines for actions to be recommended following this review will be formulated in advance and documented in the Committee Charter. Actions to be recommended may include early termination of the study.

9.6 Data Management

Data will be collected on Case Report Forms (CRFs) and entered, verified and validated by an independent Contract Research Organisation using the appropriate level of quality assurance.

CT scan data will be anonamised and sent to Zimmer GmbH on compact disc for further, blinded analysis. Specifically, this will involve calculating a variety of angles between implants and bony landmarks on the CT scans. The results will be forwarded to the CRO for statistical analysis.

10 ETHICAL CONSIDERATIONS

10.1. Ethics Committee Approval

Prior to the initiation of this investigation, the Investigator will submit the protocol and any other documents as may be required to an appropriate Ethics Committee for review and approval. The Committee will be requested to provide a letter documenting approval of this investigation. The Investigator, and any other member of the investigative team, if a member of the Ethics Committee, must not participate in the decision making. A list of the members of the Ethics Committee reviewing this protocol will be requested.

The Ethics Committee approving the original protocol must be notified of, and give approval to, any significant changes to the protocol. The Chief Investigator must notify the Ethics Committee with 10 working days of the discovery of any severe adverse events or adverse device effects which occur during this investigation.

10.2. Informed Consent

Each subject will have the nature and the purpose of this investigation explained to them by the Investigator or another member of the investigative team at the hospital. Prior to entry into this investigation the subject must give voluntary, written informed consent to participate by signing the consent form. On the same occasion, the Investigator will also sign the informed consent form. Three copies of the consent form are to be made.

The original copy of the signed consent form will be kept in the investigator file at the study site. A copy will be kept in the patient/hospital notes and a further copy provided to the subject.

10.3. Confidentiality of Subject Records

Confidentiality of subject data will be maintained at all times. Subject anonymity will be guaranteed and all documentation relating to a subject (including radiographs and CT scans) will be kept in secure locations.

10.4. Declaration of Helsinki

This investigation will be conducted in accordance with the relevant articles of the Declaration of Helsinki as adopted by the 18th World Medical Authority in 1964 and as revised in Tokyo (1075), Venice (1983), Hong Kong (1989), South Africa (1996) and Scotland (2000).

10.5 GOOD CLINICAL PRACTICES

This investigation will be conducted in accordance with the principles of the European Standard EN540 'Clinical investigation of medical devices for human subjects'.

11 REGULATORY REQUIREMENTS

This clinical investigation is a post-marketing surveillance study to obtain additional data. The devices are CE marked products and cleared for sale by the appropriate Regulatory Authority in the country (ies) in which the PMS study is to be conducted. Hence, this investigation does not require submission to the MDS (or appropriate Regulatory Authority) for approval under the requirements of the Medical Devices Directive 93/42/EEC in the UK or to any other regulatory agency outside the UK.

12 STUDY TERMINATION

12.1. Subject Withdrawals from the Investigation

Any subject who wishes to withdraw from this investigation on his/her own accord and for whatever reason is entitled to do so without obligation and prejudice to further treatment. In addition, the Investigator may decide for reasons of medical prudence, to withdraw a subject. In either event, the Investigator will clearly document the date and reason(s) for the subject's withdrawal from this investigation in the CRF and should indicate whether or not he considers it was related to the device. The Investigator will also notify Zimmer GmbH of the subject's withdrawal.

12.2. Termination of the Clinical Investigation

Both the sponsor and the Chief Investigator reserve the right to terminate the study at any time. Should this be necessary, the procedures will be arranged on an individual study basis after review and consultation by both parties. In terminating the study, Zimmer GmbH and the Chief Investigator will assure that adequate consideration is given to the protection of the patient's interests, and the appropriate bodies such as the LREC/MRECs and Regulatory authorities are informed as appropriate.

13. References

1. Alignment in total knee arthroplasty: a comparison of computer-assisted surgery with the conventional technique J Bone Joint Surg Br. 2004 Jul;86(5):682-7.
2. Computer-Assisted Navigation Increases Precision of Component Placement in Total Knee Arthroplasty Clin Orthop Relat Res. 2005 Apr;(433):152-9.
3. Randomized Control Trial Comparing Radiographic Total Knee Arthroplasty Implant Placement Using Computer Navigation Versus Conventional Technique J Arthroplasty. 2005 Aug; 20(5):618-26.
4. Computer navigation versus standard instrumentation for TKA: a single-surgeon experience. Clin Orthop Relat Res. 2005 Nov; 440:162-9.
5. Leg axis after computer-navigated total knee arthroplasty: a prospective randomized trial comparing computer-navigated and manual implantation. J Arthroplasty. 2005 Apr; 20(3):282-8.

14. APPENDIX 1 (of Protocol)

Measurement protocol for the Functional ability, activity level and quality of life assessments

This proposal aims to carry out a multi dimensional and full evaluation of the functional outcome of the TKA clients at 1 year post operation in the two patient groups indicated above. The evaluation will be based on the recommendations of the WHO International Classification of Functioning, Disability and Health for the assessment of health technologies (the WHO ICF 2001 and previously the WHO ICIDH-2, 1998). In line with this framework our assessment will examine impairment, ability and participation as separate domains and then look at the associations between them.

1. Impairment

Passive and active flexion and passive and active extension of both knees will be measured with the subject lying in supine using a standard clinical manual protractor goniometer. For all manual goniometry measurements flexion will be recorded with a positive sign and extension with a negative sign. The active excursion available will be calculated by subtracting the extension value from the flexion value.

The patients will be asked to rate the pain they experience from the affected knee on a Visual Analogue Scale in the form of a 100 mm long horizontal line with the labels "no pain" (score of zero points) and "worst possible pain" (score of 100 points).

Additional data recorded will include WOMAC clinical rating scores, age, sex, height, weight, limb length, knee flexor strength and knee extensor strength.

2. Ability

2.1 Overview

In order to asses the patient's functional ability two sets of measures will be taken. The excursion of the knee will be measured during a range of functional activities including gait, stairs, ramp walking, rising to stand and sitting down, transfers into

and out of a bath and squatting using flexible electrogoniometry. The activity of the subjects in their daily life will be recorded using a system of Activity monitors called Activpals which will record the time spent lying, sitting, standing and walking and the number and timing of transfers between these states. This functional evaluation using electrogoniometry to assess 13 functional activities and Activpals to record a day's activity is the most in depth kinematic analysis of the functional outcome of TKR carried out by the scientific community to date and had been published by us in a series of journal articles in Orthopaedic, biomechanical and health science journals

2.2 Functional ability assessment

Two flexible electrogoniometers (M180, Penny and Giles Ltd, Blackwood, Gwent, UK) will be used to measure the flexion - extension angle of the knees with respect to time. The electrogoniometer consists of a central strain gauged flexible shim that runs the length of the device with two end plates attached to the shim. The resulting transducer is flexible in both anterior - posterior and medio-lateral directions and so does not have a specific centre of rotation. This is a major advantage over conventional potentiometer type electrogoniometers that require complex mechanical attachments and linkages to enable polycentric joint movement to occur.

The electrogoniometers will be attached to flexible plastic strips which will be adjusted to the length of the patients' shank or thigh. These plastic strips will be attached to the skin over the lateral boarder of the subject's leg using double-sided tape. One strip will be attached to the shank and one to the thigh. The device will therefore straddle the knee in the sagittal plane with the output of the device giving the flexion - extension angle of the knee.

Small, lightweight, thin profile, footswitches will be attached to the heel and 1st metatarsal area of the soles of both feet. These heel and toe switches will be wired in parallel so that pressing either switch registered as contact between the foot and the floor. In this configuration they can be used to indicate stance or swing of the limb. Both the electrogoniometers and footswitches will be connected via thin flexible cables to a small, lightweight, battery driven, data logger which will power the instruments and record the 4 channels of data (left knee flexion - extension, left foot contact, right knee flexion – extension, right foot contact) at 50 Hertz. . The zero datum for joint measurement will be the knee joint alignment exhibited during standing upright with the knees straight.

The cables and attachments will be held in place using broad, lightweight straps around the shank and thigh. The datalogger will be placed into a pocket on to a bib worn by the subject. The bib will be of a similar design to those worn during athletic events. Data from the datalogger will be downloaded to a portable PC computer using an interface cable between the datalogger and computer.

The subjects will be asked to perform 13 functional activities. All tasks will be performed at the subject's selected speed (free speed). The thirteen functions will be:
1. Level walking: level walking;
2. Ascend slope: ascent of a 5 degree slope;
3. Descend slope: descent of a 5 degree slope;

4. Ascend stairs: ascent of a 20 step flight of stairs (165mm riser, 280mm tread);
5. Descend stairs: descent of a 20 step flight of stairs (165mm riser, 280mm tread);
6. Sit down low chair: descent from standing into a low chair (380mm high);
7. Sit to stand low chair: ascent from a low chair to standing (380mm high);
8. Sit down standard chair: descent from standing into a standard chair (460mm high);
9. Sit to stand standard chair: ascent from a standard chair to standing (460mm high);
10. Into Bath: from standing alongside bath, step in and sit down (590mm high);
11. Out of bath: from sitting, stand up and step out to stand alongside bath (590mm high).
12. Getting down to a squatting position
13. Getting up from a squatting position

The data will be down loaded from the datalogger at the end of the circuit using the Penny and Giles software. The data will then exported to Excel for Windows and Matlab where all further data processing and analysis will be carried out including interpolation using a specially written Matlab program.

For each of the 13 activities a single cycle of the left and right legs will be identified from the data using the footswitch and electrogoniometer information. Where a number of cycles are available such as during gait and stair negotiation a cycle will be randomly selected from the middle of the data stream in order to avoid cycles during initiation or termination of the activity. Each cycle will then be interpolated to give the joint angle at 100 percentage points throughout the cycle. These standardised cycles will then be amalgamated for the group to give the mean knee joint angle for the group throughout the gait cycle. The upper and lower 95% confidence limits for the group which indicate the band which contains 95% of the normal group data will also be calculated for each percentage point. These bands indicate the inter subject variability in the data and give a “normal” band against which patients can be compared.

For each subject performing each function using each knee, the minimum knee joint angle used during the cycle and the maximum knee joint angle used during the cycle will be recorded. These two values indicate the range of joint motion required to perform the functional activity. In addition the excursion of the joint during the function will be calculated by subtracting the minimum value from the maximum values. The excursion indicates the amount of free knee joint angulation required to perform the task. Tables of minimum joint angle, maximum joint angle and joint excursion will be prepared in excel showing the average value for the normal and patient groups, as will tables of the standard deviation for flexion in each group and the maximum and minimum group values. The knee excursion used by each group on the left knee, the right knee and the mean of both knees will be compared and the mean, standard deviation and 95% confidence limits will be calculated for each activity.

2.2 Activity level assessment

The activity level of the subjects will be monitored during a full day of normal daily life using a system of activity monitoring called Activpal. This consists of a small lightweight box, about half the size of a match box which is attached to the thigh of the subject using sticky tape. This system records the activity of the subject as either lying, sitting, standing or walking continuously during up to 110 hours. The data can be down loaded to a computer at the end of the test session. The data can be used to indicate the total time spent in each activity, the number of transitions between different positions and the timing of the activities during the recording period. It therefore allows an in depth assessment of the subjects true levels of activity in life as indicated by their mobility.

3. Participation

Two measures of participation will be used, the Short Form-36 (SF-36) which reflects the patients health and well being and the Canadian Occupational Performance Measure (COPM) which is a patient generated outcome measure of the patients satisfaction with the functional outcome of the operation.

4. Statistical analysis

Appropriate summary statistics of minimum joint angle, maximum joint angle and joint excursion recorded during the various functional tasks will be prepared for the two treatment groups and for each activity. For each individual a total functional score will be calculated based on their performance over the range of functional tasks. This overall functional score will be compared between the two groups and also correlated with the implant alignment data.

Appendix 2:

North Glasgow University Hospitals NHS Trust

R&D Management Form

This NGT R&D Management Form (referred to as PART D in COREC guidelines) should be completed and submitted with Sections A, B, and C of your Ethics (COREC) application to the relevant R&D Office.

If ethics approval is not required please submit this form directly to the R&D Office with an explanatory letter.

Please ensure that you discuss clinical trials with the appropriate site pharmacist at least **six** weeks before commencement of the trial.

If you require any assistance in completing the form please contact the appropriate department:

Section 1	Research Office	See Below
Section 2	Pharmacy Department	See page 4 for details
	Finance Department	Joanne McCreath – 201 9706
		Elizabeth Stirling – 201 9748
		Brenda Colvin – 201 9705

R&D Department contact details:

NGT R&D Manager

Dr Caroline Connolly 0141 211 4599

caroline.connolly@northglasgow.scot.nhs.uk

	West Office	**East Office**
Commercial Research	Dr Gillian Martin	Mr Ross Nicol

Co-ordinators	0141 211 1813 gillian.martin@northglasgow.scot.nhs.uk	0141 211 4587 ross.nicol@northglasgowscot.nhs.uk
Academic Research	Dr. Judith Godden 0141 211 1817 judith.godden@northglasgow.scot.nhs.uk	Dr Fiona Graham 0141 211 0475 fiona.graham.gri@northglasgowscot.nhs.uk
Co-ordinators Assistants	Mrs Lorraine Reid 0141 211 6281 lorraine.reid.wg@northglasgow.scot.nhs.uk	Lesley Hickey 0141 211 1114 lesley.hickey@northglasgow.scot.nhs.uk
	Research Audit Facilitator Eileen McCafferty 0141 211 1813 eileen.mccafferty@northglasgow.scot.nhs.uk	**Data Co-ordinator** Kirsty Simpson 0141 232 0753 kirsty.simpson@northglasgow.scot.nhs.uk

West Research Office **Ground Floor, Room 9, Admin Building** **Western Infirmary** **Glasgow, G11 6NT**	**East Research Office** **Glasgow Royal Infirmary** **4th Floor Walton Building** **84 Castle Street** **Glasgow, G4 0SF**

This form may also be downloaded from the Trust website: www.ngt.org.uk/research

NORTH GLASGOW UNIVERSITY HOSPITALS NHS TRUST

R&D MANAGEMENT FORM

THIS FORM MUST BE TYPED.

Project Reference No. from REC (**same number as that on Part A of COREC Form**) 07/50704/6

SECTION 1: PROJECT DETAILS

1. Project Title

Conventional versus iNav^{TM} electromagnetic computer assisted total knee replacement.

2. Principal Research Question (in one sentence or as brief as possible)

To compare the alignment of the total knee replacements implanted using either iNav^{TM} electromagnetic computer assisted total knee replacement surgery versus

3. Full Name and Relevant Grade of All Investigators

Full Name (Title, First Name, Surname)	**Grade**	**Hospital & Department**	**Employ Org Trust/Uni/ Other**	**Do you have an Honorary NHS Contract?**	**Telephone No. / Email**
Mr Mark Blyth **(Principal Investigator)**	FRCS (Ed) (Tr+Orth)	GRI - Department of Trauma and Orthopaedics	NHS Greater Glasgow and Clyde		0141 211 4107 mark.blyth@northglasgow.scot.nhs.uk
Mr Neville Strick	FRACS (Orth)	GRI - Department of Trauma and Orthopaedics	NHS Greater Glasgow and Clyde		0141 211 4744 neville.strick@northglasgow.scot.nhs.uk
Mr Bryn Jones	FRCS (Tr+Orth)	GRI - Department of Trauma and Orthopaedics	NHS Greater Glasgow and Clyde		0141 211 4606 bryn.jones@northglasgow.scot.nhs.uk

Mr Angus MacLean	FRCS (Tr+Orth)	GRI - Department of Trauma and Orthopaedics	NHS Greater Glasgow and Clyde		0141 232 0911 angus.maclean@northglasgow.scot.nhs.uk
Mr Andrew Stark	FRCS Tr+Orth)	GRI - Department of Trauma and Orthopaedics	NHS Greater Glasgow and Clyde		0141 211 4420 andrew.stark@northglasgow.scot.nhs.uk
Mr Roland Ingram	FRCS (Tr+Orth)	GRI - Department of Trauma and Orthopaedics	NHS Greater Glasgow and Clyde		0141 211 4605 roland.ingram@northglasgow.scot.nhs.uk
Mr Andrew Brooksbank	FRCS (Tr+Orth)	GRI - Department of Trauma and Orthopaedics	NHS Greater Glasgow and Clyde		0141 211 5186 andrew.brooksbank@northglasgow.scot.nhs.uk
Professor Philip Rowe			Professor of Rehabilitation Science, Strathclyde University Head of the HealthQWest	Yes	0141 548 3032 philip.rowe@strath.ac.uk)
Miss Julie Smith			Strathclyde University	Yes	julesrs82@hotmail.com
Mr vivek padmanaabhan			Strathclyde University	Yes	vivek_vip2000@yahoo.co.in

4. Please indicate the NGT sites where the study will take place and the No. Subjects being recruited at each site

Sites	**GRI**	**STOBHILL**	**WESTERN**	**GARTNAVEL**	**DENTAL**	**OTHER (Please Specify)**	**TOTAL**
No. subjects	**300**						**300**

5. Source of sample group for NGT, e.g. PCT, clinic, other Trust

Orthopaedic Outpatient clinics at Glasgow Royal Infirmary

6. Proposed Start Date at NGT site (day/month/year)
…01/03/07…….

Proposed End Date at NGT site (day/month/year)
……01/09/18…….

7. Methodology/Study type (you may tick more than one)

Re-analysis of original data		Interviews	√	Before-after study	
Laboratory study		Randomised controlled trial	√	Case-control	
Case note review		Controlled trial without randomisation		Cohort observation	
Dose-finding study		Economic evaluation		Other (please specify	
Questionnaires	√	Cross-sectional study			

8. Activity Areas (please tick more than one if appropriate)

Cancer		**Renal & Urology**	
Vascular *(includes Respiratory; Diabetes; Stroke)*		**Infection & Inflammation** *(includes Laboratories; Bacteriology;*	
Ageing and Neurology *(includes Geriatric Medicine; Mental Health; Clinical Neurological Science; Anaesthetics;*		**Maternal, Neonatal & Developmental** *(includes Paediatric; Genetic Disease; Obstetrics & Gynaecology)*	
Orthopaedics, Muscle & Trauma *(includes Accident & Emergency; General Surgery; Rheumatology)*	√	**Healthcare & Diet** *(includes Nutrition; Nursing; PAMs; General Practice; Primary Care; Health Economics)*	
Dental *(includes Oral Surgery)*		**Skin** *(includes Dermatology; Burns; Plastic Surgery)*	
Gastroenterology, ENT & Ophthalmology		**Therapeutics & Devices** *(includes Pharmacology)*	

9. NHS Priority Areas (please tick)

Cancer		**CVD/Stroke**		**Mental Health**		**Public Health**			

10. Departmental Authorisation (COMMERCIAL STUDIES ONLY)
(Consultant, Head of Department or equivalent person within NGT giving authorisation to this study. This should **not** be someone in the study team)

Name	**Job Title**	**Department**	**Employed by**	**Tel. No. / email**

Departmental Authorisation Signature:-----------

SECTION 2: PHARMACY

PHARMACY (Non-commercial projects only. For commercial projects, the company will liaise with Pharmacy directly)

1. **Pharmaceutical aspects and the dispensing of drugs must be discussed with your local Pharmacy representative,**
   at least 6 weeks before commencing the study.

Site Pharmacists who may approve a clinical trial	Site		Contact No.
Eileen Conkie	Western Infirmary	Clinical Trials	Ext. 52756
Colin Rodden	Gartnavel General Hospital	Dispensary	Ext. 53319
Carla Forte	Beatson Oncology Centre	Oncology	Ext. 52740
Graham Conkie	Western Infirmary	Production	Ext. 52882
Elizabeth Douglas	Glasgow Royal Infirmary		Ext. 21188 /
Elizabeth Douglas	Dental Hospital and School	Dispensary/C	Ext. 21188 /
Steven Leadbetter	Glasgow Royal Infirmary	Aseptic Services	Ext 24265
Sally McKendrick	Glasgow Royal Infirmary	Oncology	Ext 24265
David Ross	Stobhill Hospital	Dispensary	Ext 13579

For further information, please contact Mrs F McMillan Clinical Governance Development Pharmacist: WIG Ext. 52706

2. All medicinal products to be administered as part of study:

	Drug 1	Drug 2	Drug 3	Drug 4
Generic Name				
Proprietary name				
Dosage form				
Strength				
Route				
Dosage & frequency				
Treatment Duration				

Standard Drug or Trial Drug (please indicate)				
Total (Standard + Trial) Drug Cost				

3. Authorised and signed on behalf of Pharmacy Department by:
(Please note that only staff detailed above may sign this section.)

	West Site	**East Site**
Name		
Job Title		
Signature		
Date		

SECTION 2: FINANCE

Definitions

Commercial: Where the study is fully funded & sponsored by a Pharmaceutical Company

Non-Commercial : Where the study is funded by charities, research councils or Trust Endowment Funds etc.

Is this project COMMERCIAL ☐ **NON-COMMERCIAL** √ ☐
(Please tick appropriate box)

Commercial Projects

If you have identified your project as Commercial you **do not** have to complete the Pharmacy and Finance Section.

You must contact either: - Dr Gillian Martin, (West Commercial Research Co-ordinator, on Tel. No. 0141 211 1813)

or Mr Ross Nicol (East Commercial Research Co-ordinator, on Tel. No. 0141 211 4587),

to provide details of the Clinical Research Associate.

Non-Commercial Projects

- ***Please contact Joanne McCreath / Elizabeth Stirling / Brenda Colvinn in the Finance Department, Trust Headquarters, if you have any queries (Tel No : 201 9706/ 9748 / 9705).***
- *No part of this form should be left blank - where no costs are incurred please state that there are no costs.*
- *This section **must** be signed by Head of Department/Clinical Director and any other heads of support department as required.*

1. Is this project being submitted for any internal or external funding? Yes / No

2. If yes, is the funding:

Research Council		**Charity**	
University		**Department of Health / NHS**	
Endowment fund		**Endowment fellowship**	

Other *(please state)*

Orthopaedic Implant Company - Zimmer GmbH
Sulzer Allee 8, 8404 Winterthur, Switzerland

3. Funding details

Source of external funding		**COSTS COVERED**	**Please indicate value**
Name of Funder / Funding Body	**Zimmer GmbH**	Staffing	**£140 000**

Funding – awarded/pending	**£71 000**	Facilities	**£**
Grant Ref. No.		Laboratory	**£**
Duration	**36 months (11x £26 000)**	Radiology	**£88,500 (300X£295)**
Proposed Start Date	**15 December 2006**	PAMS	**£**
Proposed End Date	**15 December 2009**	Drugs	**£**
Value	**£357'000**	Pharmacy Sundries	**£**
		Ethics Admin Charges	**£**
		Strathclyde University	**£72 000**
		Other	**£41 950**
		TOTAL	**£342,450**
Administered By			
North Glasgow University Hospitals NHS Trust			
Endowment (Greater Glasgow Health Board)	**GRI Orthopaedic Department Endowment Fund**		
University			
Other (Please State)			

4.Please provide details of any drugs, equipment etc being provided free for use in this study, including details of the donor.

We will continue to have the use of the INAV machine in the hospital free of charge

5. Costs summary

(a) Staffing

Please detail all staff involved in project regardless of employer / funder and indicate if new staff are required. Please indicate grade of staff if name of individual not yet known.

Name	Site	Employed by	Funded by	Estimated hours on project *per patient*
Julie Smith	**Strathclyde University**	**Strathclyde University**	**Strathclyde University**	**11 (40*52*3/300)**
Mr Vivek Padmanaabhan	**Strathclyde University**	**Strathclyde University**	**Strathclyde University**	**10**
Research Nurse	**GRI**	**Greater Glasgow Health Board**	**GRI Orthopaedic Department Endowment Fund**	**28 (40*52*4/300)**
Mark Blyth	**GRI**	**Greater Glasgow Health Board**	**Greater Glasgow Health Board**	**2**
Phil Rowe	**Strathclyde**	**Strathclyde University**	**Strathclyde University**	**1**

	University			

Note: Estimated hours per patient includes set up and hours involved on project. Set up time should include "thinking time"
along with preparation time for Ethics & Grant submissions.

(b) NHS Service support costs:
All NHS tests / samples taken beyond routine patient care should be listed below.
(Refer to Appendix 1 for list of signatories)

Laboratories	**Name of test**	**Volume *per patient***	**Authorised and signed by head of support department**
Biochemistry			
Haematology			
Pathology/Cytology			
Microbiology			
Virology			
Other			

Radiology / Cardiology	**Description**	**Volume *per***	**Authorised and signed by head of support department**
CT	**Lower Limb CT scan**	**1**	
MRI			
X RAY			
Ultrasound			
ECG			
EEG			
Endoscopy			
Other			
Theatre	**Description of procedure**	**Volume *per patient***	**Authorised and signed by head of support department**
In Patient Procedure			
Day Case Procedure			
Out Patient Procedure			

Other			

PAMs / other support	**Description**	**Total mins. *per patient***	**Authorised and signed by head of support department**
Dietetics			
Occupational			
Physiotherapy			
Speech Therapy			
Medical			
Library			
Other			

(c) Additional patient stays / visits

Type of Stay	**Clinic/Ward/Department Used**	**Length of Additional Stay/Attendance *per patient***
Inpatient		
Day case		
Outpatient		
Follow-up visits	Orthopaedic Clinics	30 min

Note: Use of accommodation to facilitate a trial, eg use of an outpatient clinic to screen patients, should be included above.

(d) Additional pharmacy costs

Please make clear how the drugs / sundries are being funded

Description	**Dosage *per patient***	**Unit cost**	**Total cost *per patient***

Please state any other financial implications, e.g. will patients be prescribed drugs from the Trust when they would normally receive them from their G.P. or another hospital? Will there be any drug costs at end of study?

(e) Will the trial patient population be recruited from other Health Board areas?
Yes / No

(e) Will the project patient population be recruited from other Health Board Areas?
yes

If yes, please provide details.
All patients that are seen on waiting list for knee surgery may be enrolled in study. There may be patients from outside our Health Board Area but this is unlikely as will only be routine knee replacement surgery performed under study

(f) **Supplies and equipment**

Please include purchase cost and running cost

Department	Item	Volume	Unit cost	Total cost

(g) **Additional costs not covered above**

Department	Item	Volume	Unit cost	Total cost
Stationary	Info Sheets, Consent,	3000	£0.10	£300
Postage	Letter to GP, Patient	900	£1	£900
Patient Travel	Taxi fare on request	150	£5	£750
Patient Meals				
Other	Projected data analysis costs/ data monitoring costs	1	£40 000	£40 000

6. Implications on patient care service and costs

(a) Will the project impact on waiting lists?
No

If yes, state how

(b) Are there any other implications on service costs as a result of this project?
No
If yes, please provide details

Note: Include here any savings that may result. If the project has implications on future service developments please describe the impact on treatment and costs / savings.

The hypothesis is that knee replacement surgery will be done better resulting in less revision surgery in the long term

7.Project authorisation by Clinical Director or Head of Department

I confirm that the above accurately represents the resources required for this project and that the project has my authorisation.

Name	Mr Lech Rymaszewski
Job title	Clinical Director
Department	Orthopaedics
Signature	
Date	

Appendix

List of Signatories

GRI

Biochemistry	Dr Andy Duncan
Pathology	Dr Anne-Marie McNicol
Bacteriology	Dr Grant MacKenzie
Haematology	Professor Isobel walker
CT	Dr Ian Stewart
MRI	Dr Eddie Leen
Other Radiology	Dr Allan Reid / Dr Martin Sambrook
ECG	
Nuclear Medicine	Dr. R Bessent
Microbiology:	Dr. J Hood

Stobhill

Radiology	Dr. I MacLeod
Nuclear Medicine	Dr. G Gillen
Biochemistry	Dr Beth Farish

Western / GGH

Biochemistry	Dr Richard Spooner
Haematology	Kathleen McIlwaine
Pathology	Robin Reid
Radiology	Dr. M Cowan
Immunology:	Dr. A Farrell (WIG)
Nuclear Medicine	Dr. T Hilditch
Virology	Dr. W Carman named on official list
Microbiology	Dr S Alcock (WIG) or Dr Gulen

Appendix 3:

Patient Information Sheet

Conventional versus iNav™ electromagnetic computer assisted total knee replacement.

Invitation to Patient:

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and discuss it with your surgeon, GP, friends and relatives if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

What is the purpose of the study?

The purpose of this study is to compare the alignment of the knee implant in two groups of patients undergoing total knee replacement. Patients will be randomly assigned to either group one (the control group), which will undergo surgery using conventional instrumentation as reference guides i.e. standard care. For the second group the surgery will use the iNav™ navigation system as a reference guide. The navigation system is a portable system which may result in an accuracy of the implantation of the total knee replacement to within 1 degree. Literature suggests that alignment errors exceeding 3 degrees are associated with early failure of the replaced joint. The study also aims to compare the influence of the different treatments on the functional outcome of the patients. Finally the outcome of the surgery for the two groups will be compared through a series of questionnaires looking at things like pain and mobility.

Why have I been chosen?

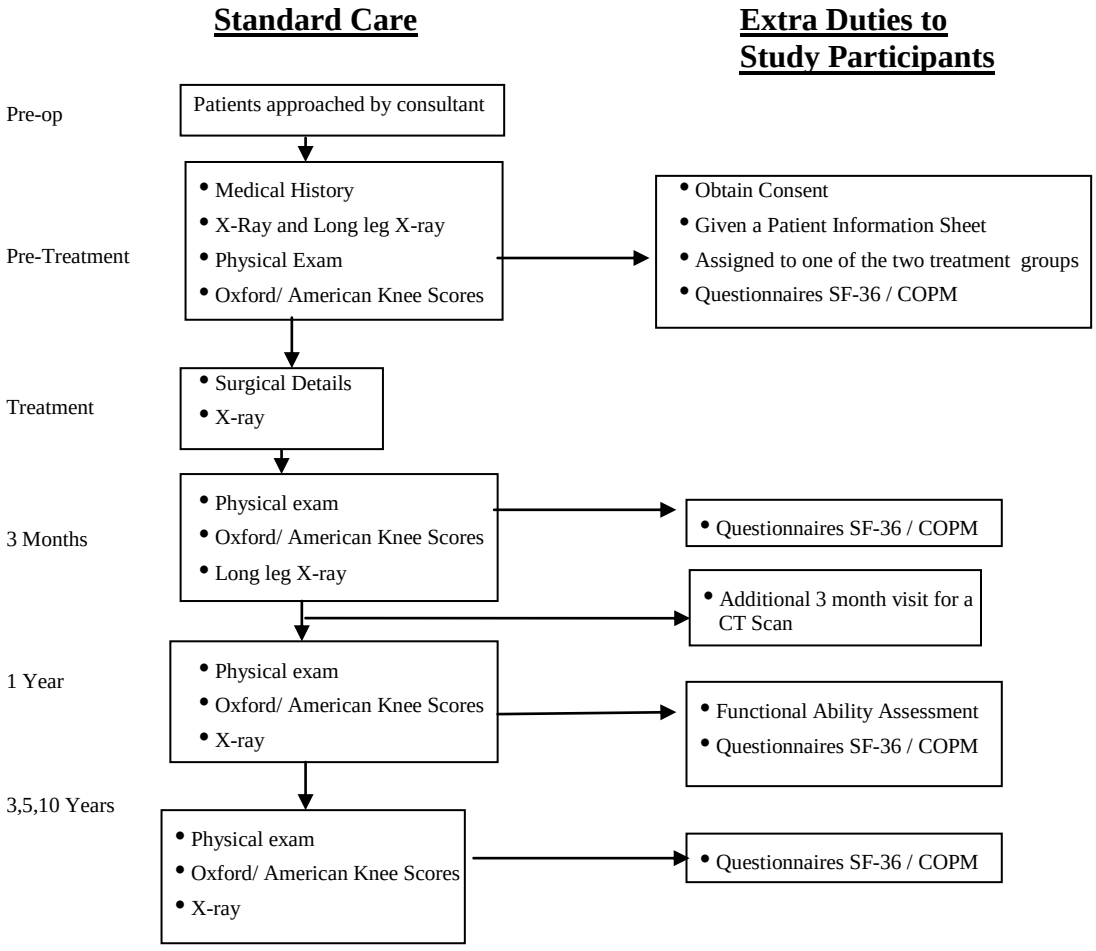
As you require a total knee replacement for osteoarthritis your consultant has identified you as a suitable candidate for this study. The study will include 300 patients (150 patients in each group).

Do I have to take part?

No. It is purely voluntary whether or not you decide to take part. If you decide to participate, you will be given this information to keep and asked to sign a consent form. You will still be free to withdraw at any time and without the need to give an explanation. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

If you decide to take part you will be randomly assigned to one of the two groups. This is a 'blind-trial' which simply means that you will not know which treatment group you are in. Both groups will receive very similar treatment to our current standard of care. The surgery and in patient stay will not be appreciably different to our current care. The only difference is the actual method used to help us place the knee replacement correctly. The chart below outlines all the details of the treatment and the timings of these visits. Patients not taking part in this study would also be required to attend follow up visits at these times as normal standard of care.



As mentioned in the flow chart, at each follow up visit you will be asked to complete a series of questionnaires.

- Oxford/AKSS knee scores which are clinical outcome questionnaires and routinely collected following total knee replacement surgery therefore are not additional to this study.
- 2 additional questionnaires - Short form 36 (SF-36) and the Canadian Occupational Performance Measure (COPM) which look at the patient's satisfaction and quality of life.

In addition to the above standard knee replacement care and follow up, at 3 months post-operation you will be asked to return to the Glasgow Royal Infirmary for a CT scan and x-ray of the operated leg. It should last approximately 30 minutes. This is a standard CT scan but, we do not routinely assess knee replacements this thoroughly and will thus give us valuable data.

At the one year post-operation visit a detailed functional ability assessment will be completed by research assistants from Strathclyde University. This assessment should take approximately 40 minutes at the Glasgow Royal Infirmary and will take place at the same time as your routine clinic appointment. This assessment consists of a series of measurements, questionnaires and activity monitoring.

The functional ability assessment uses measurement sensors, which will be attached across the outside border of both of your knees using sticky tape. These will measure the angle of the knee joint as you complete various tasks. The sensors will be attached to a datalogger. You will be wearing a bib with a pocket to carry the datalogger. The final part of the equipment is footswitches. These are flat sensors which are attached to your heel and toe and will record when your foot is in contact with the ground. You will only wear this equipment when you perform 13 functional activities (walking, ramp walking, stair negotiation, rising to and sitting to a standard and low chair, getting in an out of a bath and performing a deep squat). All tasks will be performed at your selected speed, a speed which you are comfortable with.

You will also be asked to wear an activity monitor called an Activpal for a day which will record the periods of the day which you sit, lie, walk and stand. The Activpal is a small lightweight box, about half the size of a match box and is attached to your thigh using sticky tape.

Overall you will therefore be asked to make one additional visit out with your normal treatment, for the CT scan at 3 months and have a longer assessment at 1 year post operation. Travel expenses will be provided for the additional visit.

What do I have to do?

You would be required to attend a CT scan at 3 months post-operation, complete a functional assessment at 1 year post-operation, and complete questionnaires at each visit.

What is the device which is being tested?

The device which is being tested is called iNav^{TM} and is a portable computer navigation system which has been in use since 2005. It has official market approval for being used clinically in the UK. Computer navigation systems in surgery have been used since the late 1990s. The technological advancement has come about with the development of imageless systems which can map the 3D surgical field. The advantage of computer navigation systems is that they could allow the surgeon to implant components with a higher degree of accuracy.

What are the alternatives for treatment?

The alternatives to the use of the iNav^{TM} navigated system for total knee replacement would be the use of conventional instrumentation to determine the reference points, which is the standard best practice. Conventional Instrumented Knee Surgery has been proven to be highly successful in removing pain and increasing patient function in the majority of individuals, but in some patients poor alignment of the implant can lead to difficulties.

What are the side effects of any treatment received when taking part?

The potential risks of total knee replacement are common to both methods, and any surgical procedure poses a potential risk. There are risks associated with the anaesthesia which are also common to both methods. The risk of using the iNav^{TM} system is that this procedure takes slightly longer than the conventional surgery. Although this device has been tested with a favourable outcome and is currently in use there is a small risk that it will not achieve the correct alignment. The potential side effects of total knee replacement will be explained fully to you by your surgeon as part of the operation consent process.

CT scans are taken at 3 months post operation would not routinely be taken. Therefore they pose a small but definite ionizing radiation risk that you would not otherwise have required.

CT dose is equivalent to 1 year background radiation and represents an additional risk of lifetime fatal cancer of 1 in 9200. In terms of comparative lifetime risk of death, it is similar to the lifetime risk of a fatal accident from commuting 2 hours/week by public transport (bus/train) for 25 years

What are the other possible disadvantages and risks of taking part?

The risks associated with the functional testing using the measurement equipment are minimal. You will be asked to perform a series of functional activities in and around the hospital (including walking, ramp walking, stair negotiation, rising to and sitting to a standard and low chair, getting in an out of a bath and performing a deep squat). The measurement devices will record the amount of flexion / extension present at the knee over time during each task. These devices and the associated attachment and evaluation protocols have been used by the investigators in a number of previous studies to investigate knee function during activities of daily life. There is no pain or discomfort associated with the equipment. The potential risks associated with this equipment are the risk of a slight reaction to the tape used to attach the sensors to the leg. There is a slight risk of falling while wearing the equipment due to the wires but these will be tucked away to minimise the chance of this and you will be supervised at all times by an investigator.

What are the possible benefits of taking part?

The perceived benefit of using the iNav^{TM} system is to allow for more accurate implantation of a total knee replacement when compared to conventional methods. As the femur bone is not violated it is possible there will be decreased bleeding and decreased fat embolism reducing the risk of post-operation complications.

It is anticipated that most patients will experience a reduction or relief of pain, restoration or improvement in the range of motion and mobility, correction or improvement of disfiguring deformity and an improvement in their quality of life. This is common to both methods.

What happens when the research study stops?

If the research study is stopped, you will be contacted and informed of this and given the reasons why. Your medical care will continue as per standard practice for patients who have undergone total knee replacement.

What if relevant new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your research doctor will tell you about it and discuss whether you want to or should continue in the study. If you decide not to carry on, your research doctor will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

Also on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue.

If the study is stopped for any reason, you will be told why, verbally and in writing, and your continuing care will be arranged.

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

You have the option to withdraw at any stage of the trial. If relevant data has already been collected i.e. through CT scans, questionnaires and functional assessment, this will continue to be analysed, and used in the outcomes of the study. If you do not wish any data to be used in this study then all data relating to you will be destroyed.

What if there is a problem?

If you have concern about any aspect of the study, you should ask to speak with one of the researchers who will do their best to answer your questions. Contact details are detailed at the end of the information sheet. 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.

If a serious event happens during or following the patients participation in the trial the details will be recorded. Any adverse events will be reported immediately to the appropriate regulatory authorities and necessary interventions will occur.

Will my taking part in this study be kept confidential?

Confidentiality of patient's data will be maintained at all times. Your name/address will be removed and you will be assigned a unique identification number. Your anonymity will be guaranteed and all documentation relating to you (including radiographs and CT scans) will be kept in secure locations.

If you join the study, the CT scan data collected for the study will be looked at by authorised people from the funding company, Zimmer GmbH. This data will be anonamised and sent on a compact disc. Some parts of your medical records and data collected may be looked at by authorised people from an independent Contract Research Organisation to verify and validate the data. All will have a duty of confidentiality to you as a patient and nothing that could reveal your identity will be disclosed outside the research site. The functional outcome data and questionnaires analysed by the Bioengineering Unit of Strathclyde University will have your name and address removed so that you cannot be recognised from it. The data collected will be stored on a secure IT System in the Glasgow Royal Infirmary and will be retained for 10 years after completion of the study (i.e. until September 2018).

Your GP will be notified of your participation in the trial, unless you specifically request that they are not told.

What will happen to the results of the research study?

The results of the study will be published. You will not be identified in any report/publication. You will be sent a letter informing you when the results are available and details of who to contact to obtain a copy.

Who has reviewed the study?

This study was given favourable ethical opinion for conduct in the NHS by the Glasgow Royal Infirmary LREC and the University of Strathclyde ethics committee.

Who is funding the research?

Zimmer GmbH,
Sulzer-Aller 8, CH – 8404 Winterthur
Switzerland

They are providing the funding to Greater Glasgow and Clyde Health Board as part of their surgical and research support programme for Orthopaedic services. From the trial if significant benefit is shown it is likely the use of the iNav system will become

standard practice in Greater Glasgow and Clyde Health Board and will also be adopted in other Orthopaedic services.

Who is organising the trial and contact details for further information?

Should you have any further questions or require any further information about the study you may contact the following person:

Mr Mark Blyth
Consultant Orthopaedic Surgeon
Department of Trauma and Orthopaedics
Glasgow Royal Infirmary
84 Castle Street
Glasgow
G4 0SF, UK
Tel: 0141 211 4107
Fax: 0141 211 5925

Thank you for considering taking the time to read this information and for considering participating in this study.
If you decide to take part in the study you will be given a copy of this information sheet and the signed consent form to keep.

Appendix 4:

Centre Number :
Study Number:
Patient Identification Number for this trial:

CONSENT FORM

Title of Project: Computerised Tomography validation of the INAV electromagnetic navigation system for total knee replacement.
Name of Researcher: Mr Mark Blyth (Consultant Orthopaedic Surgeon)

Please initial box

1. I confirm that I have read and understand the information sheet dated 22/02/07 (version 7) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. I understand also that I can ask to have my data withdrawn form the study at anytime. ☐

3. I understand that relevant sections of any of my medical notes and data collected during the study, may be looked at by responsible individuals from the research team (i.e. surgeon, research nurses and research assistants), from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in the research. I give permission for these individuals to have access to my records. ☐

4. I agree to my GP being informed of my participation in the study. ☐

5. I understand that confidentiality and anonymity are assured during and after the study has been completed. ☐

6. I agree to take part in the above study. ☐

_____

Name of Patient Date Signature

_____

Name of Person taking consent (if different from researcher) Date Signature

_____

Researcher Date Signature

(When completed, 1 for patient; 1 (original) for researcher site file; 1 to be kept in medical notes)

Appendix 5:

Orthopaedic department
Glasgow Royal Infirmary
Castle Street
G4 0SF

Date:

Dear Dr,

Patient name:
DOB:

The above named patient has been recruited to participate in a randomised control trial for total knee replacements. We are comparing conventional versus iNav^{TM} electromagnetic computer assisted total knee replacement. I have included a Patient Information Sheet for your information.

I am the Consultant Orthopaedic Surgeon organising the trial. If there are any queries or problems with this patient, or you have any questions regarding the study, please contact myself at:

Tel: 0141 211 4107
Fax: 0141 211 5925

Yours Sincerely,

Mr Mark Blyth
Consultant Orthopaedic Surgeon

Appendix 6:

Patient details

Patient name:	**Patient code:**
Date of test:	**Time of test:**
DOB:	**M/F**
Knee affected:	**Navigated / Conventional**
Consultant:	

Other joints

Contralateral Knee Normal / Affected

Left hip: Normal / Affected **Right hip:** Normal / Affected

Left foot/ankle: Normal / Affected **Right foot/ankle:** Normal / Affected

Spine: Normal / Affected

ActivPAL

Monitor Number ……..

Strength/Moment Calculation

Affected	**Contra-lateral**
Quad……	Quad…….
Hamstring…….	Hamstring……

Knee to Ankle (length) ……....

1 Year Post-op Functional Assessment: Electrogoniometry

Electrogoniometer number

Left…… right……

Channels

1	4	7
2	5	8
3	6	

Knee extension angle in standing (manual goniometer) - (flexion contracture is neg)

left……

right……..

	TECHNIQUE/COMMENTS
Single leg maximum flexion Most affected	Step height – High / Low
Single leg maximum flexion, contra lateral leg	Step height – High / Low
Walk	
Sit in low chair	Use armrest – No / Yes
Rise to stand from low chair	Use armrest – No / Yes
Sit in standard chair	Use armrest – No / Yes
Rise to stand from standard chair	Use armrest – No / Yes
Into bath	Leg 1st – Right / Left
Sit bath Stand from bath	

Out of bath	Leg 1st – Right / Left

Stairs Up	Stick R Stick L hand rail (L/R, balance/support):
Stairs Down	Stick R Stick L hand rail (L/R, balance/support)
Up slope	Stick R Stick L Other
Down slope	Stick R Stick L Other

Comments

Appendix 7:

Oxford Knee Score

Thank you for taking the time to help us better understand how your knee problem affects your daily life.
Please place a "X" in the box of the answer that best describes your knee:

1. **How would you describe the pain you usually have in your 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 at all	∀
Very little trouble	∀
Moderate trouble	∀
Extreme difficulty	∀
Impossible to do	∀

3. Have you had any trouble getting in and out of the car or using public transport because of your knee? (With or without a stick)

No trouble at all	∀
Very little trouble	∀
Moderate trouble	∀
Extreme difficulty	∀
Impossible to do	∀

4. For how long are you able to walk before the pain in your knee becomes s eve re? (With or without a stick)

No pain > 60 mins	∀
16-60 minutes	∀
5-15 minutes	∀
Around the house	∀
Not at all – severe on walking	∀

5. After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your knee?

Not at all painful	∀
Slightly painful	∀
Moderately painful	∀
Very painful	∀
Unbearable	∀

6. Have you been limping when walking, because of your knee?

Rarely/never	∀
Sometimes or just at first	∀
Often, not just at first	∀

Most of the time ∀
All of the time ∀

7. Could you kneel down and get up again afterwards?
Yes easily ∀.
With little difficulty ∀
With moderate difficulty ∀
With extreme difficulty ∀
No impossible ∀

8. Are you troubled by pain in your knee at night in bed?
Not at all ∀
Only one or two nights ∀
Some nights ∀
Most nights ∀
Every night ∀

9. How much has pain from your knee interfered with your usual work? (including housework)
Not at all ∀
A little bit ∀
Moderately ∀
Greatly ∀
Totally ∀

10. Have you felt that your knee might suddenly "give away" or let you down?
Rarely/never ∀
Sometimes or just at first ∀
Often, not just at first ∀
Most of the time ∀
All of the time ∀

11. Could you do household shopping on your own?
Yes easily ∀.
With little difficulty ∀
With moderate difficulty ∀
With extreme difficulty ∀
No impossible ∀

12. Could you walk down a flight of stairs?
Yes easily ∀.
With little difficulty ∀
With moderate difficulty ∀
With extreme difficulty ∀
No impossible ∀

Appendix 8:

WOMAC OSTEOARTHRITIS INDEX VERSION LK 3.1

You will be asked to indicate on this type of scale the amount of pain, stiffness or disability you have experienced **in the last 2 weeks.**

Please note that you are to complete the questionnaire with respect to your knee on which you will have/had surgery.
Think about this knee when answering the questionnaire. Indicate the severity of your pain, stiffness and physical disability that your feel is caused by arthritis in this knee.

PAIN

Think about the pain you felt in your knee due to your arthritis during the last 2 weeks

QUESTION How much pain do you have?

1. Walking on a flat surface

None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

2. Going up or down stairs

None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

3. At night while in bed, i.e. pain that disturbs your sleep.

None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

4. Sitting or lying

None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

5. Standing upright

None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

STIFFNESS

Think about the stiffness (not pain) you felt in your knee due to your arthritis during the last two weeks.

Stiffness is a sensation of **decreased** ease in moving your joint.

6. How **severe** is your stiffness **after first wakening** in the morning?

None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

7. How **severe** is your stiffness after sitting, lying or resting **later in the day?**

None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

DIFFICULTY PERFORMING DAILY ACTIVITIES

Think about the difficulty you had in doing the following daily physical activities due to arthritis in your knee during the last two weeks.
By this we mean **your ability to move around and look after yourself**.

QUESTION **What degree of difficulty do you have?**

8 Descending stairs.

None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

9. Ascending stairs.

None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

10. Rising from sitting

None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

11. Standing

None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

12. Bending to the floor

None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

13. Walking on a flat surface

None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

14. Getting in/out of car, or getting or on off a bus.

None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

15. Going shopping

None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

16. Putting on your socks or tights

None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

17. Rising from bed.

None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

18. Taking off your sock or tights.

None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

19. Lying in bed

None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

20. Getting in or out of the bath.

None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

21. Sitting

None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

22. Getting on or off the toilet

None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

23. Performing heavy domestic duties

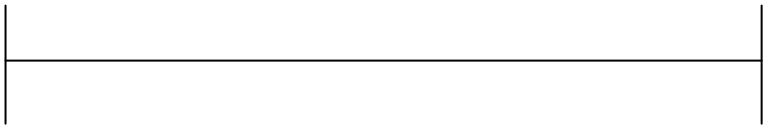
None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

24. Performing light domestic duties

None	Mild	Moderate	Severe	Extreme
∀	∀	∀	∀	∀

Pain intensity scale

Mark the line at the point which best corresponds to the intensity of the pain you have experienced in the last 48 hours.



LEAST possible pain **WORST possible pain**

****

Satisfaction with your knee replacement

How satisfied are you with your knee replacement?

Very unsatisfied	Unsatisfied	Don’t know	Satisfied	Very satisfied
∀	∀	∀	∀	∀

Appendix 9:

KNEE SOCIETY SCORE (Insall Modification - 1993)

This scoring system is the version of the knee score as modified by Dr. John Insall in 1993. The scoring system combines a relatively objective **Knee Score** that is based on the clinical parameters and a **Functional Score** based on how the patient perceives that the knee functions with specific activities.

The maximum Knee Score is 100 points and the maximum Functional Score is 100 points.

To calculate the two scores the answers to the questions and the findings on the examination are given a value based on the results. To obtain the Knee Score and the Functional Score the result of each question is totalled. Notice that some results are negative to denote that they are deductions to the score.

Pain	**50 (Maximum)**	
Walking		
None	35	
Mild or occasional	30	
Moderate	15	
Severe	0	
Stairs		
None	15	
Mild or occasional	10	
Moderate	5	
Severe	0	

R.O.M.	**25 (Maximum)**	

5^{o}= 1 point

Extension = ☐

Flexion = ☐

Excursion = ☐

Stability **25 (Maximum)** ☐

Medial/Lateral

0-5 mm	15
5-10 mm	10
> 10 mm	5

Anterior/Posterior

0-5 mm	10
5-10 mm	8
> 10 mm	5

Deductions

Extension lag

None	0
<4 degrees	-2
5-10 degrees	-5
>11 degrees	-10

Flexion Contracture

< 5 degrees	0
6-10 degrees	-3
11-20 degrees	-5
> 20 degrees	-10

Malalignment

5-10 degrees (5^o = -2 points)	0

Pain at rest

Mild	-5
Moderate	-10
Severe	-15
Symptomatic plus objective	0

(Now, total the scores to obtain the total Knee Score for the patient.)

Knee Score 100 (Maximum) = ☐

Function Score **Maximum (100)**

How does your knee affect your walking ability?

I can walk unlimited distances.	50
I can walk more than a kilometre	40
I can walk between 500 metres and a kilometre	30
I can walk less than 500 metres	20
I only walking indoors	10
I cannot walk at all.	0

How do you go up and down stairs?

Normal up and down.	50
Normal up, down with rail	40
Up and down with rail.	30
Up with rail; down unable	15
Unable	0

What type of support do you use when walking?

None	0
Cane/stick	-5
Two canes/sticks	-10
Crutches or walker	-20

Function Score 100 (Maximum) = ☐

Appendix 10:

Body Builder Marker File

!MKR#2
[Autolabel]

Pointer1
Pointer2

WST1
WST2
WST3
WST4

LTHI1
LTHI2
LTHI3
LTHI4

LSHIN1
LSHIN2
LSHIN3
LSHIN4

LCAL
LHMET1
LHMET5

LLMAL
LMMAL

RTHI1
RTHI2
RTHI3
RTHI4

RSHIN1
RSHIN2
RSHIN3
RSHIN4

RCAL
RHMET1
RHMET5

RLMAL
RMMAL

Pointer1,Pointer2

WST1,WST2
WST2,WST3
WST3,WST4
WST4,WST1

LHMET1,LHMET5
LHMET5,LCAL
LCAL,LHMET1

RHMET1,RHMET5
RHMET5,RCAL
RCAL,RHMET1

LSHIN1,LSHIN2
LSHIN2,LSHIN3
LSHIN3,LSHIN4
LSHIN4,LSHIN1

RSHIN1,RSHIN2
RSHIN2,RSHIN3
RSHIN3,RSHIN4
RSHIN4,RSHIN1

LTHI1,LTHI2
LTHI2,LTHI3
LTHI3,LTHI4
LTHI4,LTHI1

RTHI1,RTHI2
RTHI2,RTHI3
RTHI3,RTHI4
RTHI4,RTHI1

LLMAL,LMMAL

RLMAL,RMMAL

Waist
LeftThigh
RightThigh
LeftShin
RightShin
LeftFoot
RightFoot

Waist,LeftThigh
LeftThigh,LeftShin
LeftShin,LeftFoot
Waist,RightThigh
RightThigh,RightShin
RightShin,RightFoot

Waist=WST1,WST2,WST3,WST4

LeftThigh=LTHI1,LTHI2,LTHI3,LTHI4
RightThigh=RTHI1,RTHI2,RTHI3,RTHI4

LeftShin=LSHIN1,LSHIN2,LSHIN3,LSHIN4
RightShin=RSHIN1,RSHIN2,RSHIN3,RSHIN4

LeftFoot=LHMET1,LHMET5,LCAL
RightFoot=RHMET1,RHMET5,RCAL

[Virtual Points]

RLMAL
RMMAL
LLMAL
LMMAL

RCAL
RHMET1
RHMET5

LCAL
LHMET1
LHMET5

RASIS
LASIS
SACR

RMEF
RLEF
LMEF
LLEF

RHJC
RKJC
RAJC

LHJC
LKJC
LAJC

RHJC,RKJC
RKJC,RAJC

LHJC,LKJC
LKJC,LAJC

RHMET1,RHMET5
RHMET5,RCAL
RCAL,RHMET1

LHMET1,LHMET5
LHMET5,LCAL
LCAL,LHMET1

Waist1
RThigh
RShin
RFoot
LThigh
LShin
LFoot

[Calib points]

CalRMEF
CalRLEF
CalLMEF
CalLLEF
CalRASIS
CalLASIS
CalSACR

[Kinematics]

RKJCAngles
LKJCAngles

[Force Vectors]
P_ForcePlate1 Base of Plate1 Vector

F_ForcePlate1 Tip of Plate1 Vector

RKneeForce
LKneeForce

P_ForcePlate1, F_ForcePlate1

[Moments from model]

RKneeMoment
LKneeMoment

Appendix 11:

Body Builder Model File

```
{*Start of macro section*}
{*====================*}

macro SUBSTITUTE4(p1,p2,p3,p4)

{*Replaces any point missing from set of four fixed in a segment*}

s234 = [p3,p2-p3,p3-p4]
p1V = Average(p1/s234)*s234
s341 = [p4,p3-p4,p4-p1]
p2V = Average(p2/s341)*s341
s412 = [p1,p4-p1,p1-p2]
p3V = Average(p3/s412)*s412
s123 = [p2,p1-p2,p2-p3]
p4V = Average(p4/s123)*s123

p1 = p1 ? p1V
p2 = p2 ? p2V
p3 = p3 ? p3V
p4 = p4 ? p4V
endmacro


macro FORCEVECTOR(FP)
If ExistAtAll( FP )
        F_#FP = FP(1)
        M_#FP = FP(2)
        C_#FP = FP(3)
        if ( ABS ( F_#FP ) > 10 )
                P_#FP = C_#FP + { -M_#FP(2)/F_#FP(3), M_#FP(1)/F_#FP(3), -
C_#FP(3) }
        else
                P_#FP = C_#FP
        endif
        F_#FP = F_#FP + P_#FP
        OUTPUT ( P_#FP, F_#FP )
EndIf
endmacro


macro SEGVIS(Segment)
{*outputs a visual representaion of the segment to be viewed in the Workspace*}
{*0(Segment) is the origin of the segment*}
```

```
ORIGIN#Segment=O(segment)
AXISX#Segment={100,0,0}*Segment
AXISY#Segment={0,100,0}*Segment
AXISZ#Segment={0,0,100}*Segment
output(ORIGIN#Segment,AXISX#Segment,AXISY#Segment,AXISZ#Segment)
Endmacro


macro AXES(Segment)
{*Outputs the 3 orthogonal unit vectors for the segment in order that the rotation
matrices can be defined*}
{*This is for the animation package*}

X#Segment=1(Segment)
Y#Segment=2(Segment)
Z#Segment=3(Segment)
OUTPUT(X#Segment,Y#Segment,Z#Segment)
endmacro

macro ColeJCS(seg1,seg2,joint)
{*  Procedure to calculate the rotations about defined embedded axes using the joint
co-ordinate system.

References:Cole,G.K. et al (1993).  Application of the Joint Co-ordinate System
           to Three-dimensional Joint Attitude and Movement Representation : A
           Standardization Proposal.  Journal of Biomechanical Engineering.
           November 1993 : Vol 115 : pp 344-349

aEone,aEtwo,aEthree =unit vector describing the attitude of the 1st,2nd and 3rd axis
of
the joint co-ordinate system between the reference segment (seg1) and the target
segment
(seg2), relative to an inertial reference system.

If the axes of a body segment co-ordinate system are identified as an axis of Flexion,
a
Longitudinal axis and a Third axis, then Fone, Lone, Tone are unit vectors that
describe
the attitude of the Flexion, Longitudinal and Third axes respectively, in an inertial
reference system.

Input:     'seg1', 'seg2' describing the axes of the co-ordinate systems embedded in
each segment.
     Fone, Lone, Tone describe the flexion, longitudinal and third co-ordinate
     axes of the proximal segment.
     Ftwo, Ltwo, Ttwo describe the flexion, longitudinal and third co-ordinate
     axes of the distal segment.
```

'joint' is the name given to the joint at which the specified segments interact.

Output: Angles of rotation about axes aEone,aEtwo,aEthree, flexion, abduction and rotation
respectively. Counterclockwise rotations are chosen as positive*}

```
Fone=3(seg1)
Lone=2(seg1)
Tone=1(seg1)
Ftwo=3(seg2)
Ltwo=2(seg2)
Ttwo=1(seg2)


{*Defines e1 and e3*}
aEone=Fone
aEthree=Ltwo

{*Calculate the Vector or Cross Product between the Vectors*}
Va={2(aEthree)*3(aEone)-3(aEthree)*2(aEone),3(aEthree)*1(aEone)-
1(aEthree)*3(aEone),1(aEthree)*2(aEone)-2(aEthree)*1(aEone)}
Vb=DIST({2(aEone)*3(aEthree)-3(aEone)*2(aEthree),3(aEone)*1(aEthree)-
1(aEone)*3(aEthree),1(aEone)*2(aEthree)-2(aEone)*1(aEthree)},{0,0,0})
Vc={2(Va)*3(aEthree)-3(Va)*2(aEthree),3(Va)*1(aEthree)-
1(Va)*3(aEthree),1(Va)*2(aEthree)-2(Va)*1(aEthree)}

{*Calculate the Scalar or Dot Product between the Vectors*}
DPone=(1(Va)*1(Ttwo))+(2(Va)*2(Ttwo))+(3(Va)*3(Ttwo))
DPtwo=(1(Vc)*1(Ftwo))+(2(Vc)*2(Ftwo))+(3(Vc)*3(Ftwo))

{*Calculates A (AA) and then e2*}
IF DPone < 0 AND DPtwo > 0 THEN AA=-1 ELSE AA=1 ENDIF
aEtwo=(Va/Vb)*AA

{*Calculate the value of r.*}
Rone={2(Fone)*3(aEtwo)-3(Fone)*2(aEtwo),3(Fone)*1(aEtwo)-
1(Fone)*3(aEtwo),1(Fone)*2(aEtwo)-2(Fone)*1(aEtwo)}
Rtwo=DIST(Rone,{0,0,0})
r=Rone/Rtwo

{*Calculate the Scalar or Dot Product between the Vectors.*}
aEtwoTonedp=(1(aEtwo)*1(Tone))+(2(aEtwo)*2(Tone))+(3(aEtwo)*3(Tone))
aEtwoLonedp=(1(aEtwo)*1(Lone))+(2(aEtwo)*2(Lone))+(3(aEtwo)*3(Lone))
rLtwodp=(1(r)*1(Ltwo))+(2(r)*2(Ltwo))+(3(r)*3(Ltwo))
FoneLtwodp=(1(Fone)*1(Ltwo))+(2(Fone)*2(Ltwo))+(3(Fone)*3(Ltwo))
aEtwoTtwodp=(1(aEtwo)*1(Ttwo))+(2(aEtwo)*2(Ttwo))+(3(aEtwo)*3(Ttwo))
aEtwoFtwodp=(1(aEtwo)*1(Ftwo))+(2(aEtwo)*2(Ftwo))+(3(aEtwo)*3(Ftwo))
```

```
IF aEtwoLonedp >= 0 THEN aEtwoLonesign=1 ENDIF
IF aEtwoLonedp < 0 THEN aEtwoLonesign=-1 ENDIF
IF FoneLtwodp >= 0 THEN FoneLtwosign=1 ENDIF
IF FoneLtwodp < 0 THEN FoneLtwosign=-1 ENDIF
IF aEtwoFtwodp >= 0 THEN aEtwoFtwosign=1 ENDIF
IF aEtwoFtwodp < 0 THEN aEtwoFtwosign=-1 ENDIF

joint#Flex=(acos(aEtwoTonedp))*(aEtwoLonesign)
joint#Abd=(acos(rLtwodp))*(FoneLtwosign)
joint#Rot=(acos(aEtwoTtwodp))*(aEtwoFtwosign)
joint#angles=<joint#Flex,joint#Abd,joint#Rot>

OUTPUT(joint#angles)

joint#JCS=[joint,aEtwo,aEone,xyz]

ORIGIN#joint#jcs=0(joint#jcs)
XAXIS#joint#jcs=0(joint#jcs)+(1(joint#jcs)*100)
YAXIS#joint#jcs=0(joint#jcs)+(2(joint#jcs)*100)
ZAXIS#joint#jcs=0(joint#jcs)+(3(joint#jcs)*100)
OUTPUT(ORIGIN#joint#jcs,XAXIS#joint#jcs,YAXIS#joint#jcs,ZAXIS#joint#jcs)

ENDMACRO


macro POINTER(Anatomy,Segment)

{*Calculates the position of the end of the pointer for calibration in the technical
frame it belongs to*}
{*1st determine the "point" in the Global system and outputs it as point#Calib. Then
converts the point into*}
{*the appropriate technical reference frame and stores it as parameter
$%#point#Calib*}

unitPointer=((Pointer1-Pointer2)/DIST(Pointer1,Pointer2))
Anatomy#Calib=Pointer1+123*unitPointer
OUTPUT(Anatomy#Calib)
PARAM(Anatomy#Calib)
%#Anatomy#Calib=Anatomy#Calib/Segment
PARAM(%#Anatomy#Calib)
endmacro


MACRO DYNPOINTER (AnatPoint,Segment)
AnatPoint=%#AnatPoint#Calib*Segment
OUTPUT(AnatPoint)
PARAM(AnatPoint)
ENDMACRO
```

```
{*Macro for Dot Product*}
MACRO DotProduct (One,Two,DotProd)
	DotProd = (1(One)*1(Two)+2(One)*2(Two)+3(One)*3(Two))
ENDMACRO


{* Macro to do a cross product *}
MACRO CrossProduct ( First, Second, Result )
	Result = { First(2)*Second(3)-First(3)*Second(2),
	First(3)*Second(1)-First(1)*Second(3),
	First(1)*Second(2)-First(2)*Second(1)}
ENDMACRO


{*End of macro section*}


{*Anthropometric Data*}
{*==================*}
{*From DA Winter, Biomechanics and Motor Control of Human Movement*}


AnthropometricData
DefaultPelvis 0.142 0.865 0.5 0.3
DefaultFemur 0.1 0.567 0.323 0
DefaultTibia 0.0465 0.567 0.302 0
DefaultFoot 0.0195 0.5 0.475 0
EndAnthropometricData


{*Optional points are points which may not be present in every trial*}
{*=====================================================
=======*}

OptionalPoints(LHMET1,RHMET1,LHMET5,RHMET5,LCAL,RCAL)
OptionalPoints(LSHIN1,LSHIN2,LSHIN3,LSHIN4,RSHIN1,RSHIN2,RSHIN3,RS
HIN4)
OptionalPoints(LTHI1,LTHI2,LTHI3,LTHI4,RTHI1,RTHI2,RTHI3,RTHI4)
OptionalPoints(WST1,WST2,WST3,WST4)
OptionalPoints(LLMAL,LMMAL,RLMAL,RMMAL)
OptionalPoints(Pointer1,Pointer2)
OptionalPoints(RMEF,RLEF,LMEF,LLEF)
OptionalPoints(RASIS,LASIS,SACR)
OptionalPoints(CalRMEF,CalRLEF,CalLMEF,CalLLEF)
OptionalPoints(CalRASIS,CalLASIS,CalSACR)
```

```
{*Substitutes missing markers based on clusters of 4 markers*}
{*=========================================================*
}
SUBSTITUTE4(LSHIN1,LSHIN2,LSHIN3,LSHIN4)
SUBSTITUTE4(RSHIN1,RSHIN2,RSHIN3,RSHIN4)
SUBSTITUTE4(LTHI1,LTHI2,LTHI3,LTHI4)
SUBSTITUTE4(RTHI1,RTHI2,RTHI3,RTHI4)
SUBSTITUTE4(WST1,WST2,WST3,WST4)


{*Force Vectors*}
OptionalReactions ( ForcePlate1)
ForceVector(ForcePlate1)



{*Defines technical axis systems for the segments from the clusters*}
{*==================!====================*}
RThigh=[RTHI1,RTHI1-RTHI3,RTHI3-RTHI2,yxz]
LThigh=[LTHI1,LTHI1-LTHI3,LTHI2-LTHI3,yxz]
RShank=[RSHIN1,RSHIN1-RSHIN4,RSHIN2-RSHIN4,yxz]
LShank=[LSHIN2,LSHIN2-LSHIN3,LSHIN2-LSHIN4,yxz]
Waist1=[WST1,WST1-WST2,WST3-WST2,yxz]


{*Anatomical calibration from static/pointer trials*}
{*================================================*}

If $Static==1

{*For pointers*}
{* Will give parameter Anatomy#calib  *}



If EXIST(CalRMEF)
POINTER(RMEF,RThigh)
EndIf

If EXIST(CalRLEF)
POINTER(RLEF,RThigh)
EndIf


If EXIST(CalLMEF)
POINTER(LMEF,LThigh)
EndIf
```

```
If EXIST(CalLLEF)
POINTER(LLEF,LThigh)
EndIf


If EXIST(CalRASIS)
POINTER(RASIS,Waist1)
EndIf


If EXIST(CalLASIS)
POINTER(LASIS,Waist1)
EndIf


If EXIST(CalSACR)
POINTER(SACR,Waist1)
EndIf


{*%RMMAL=RMMAL/RShank*}
{*%LMMAL=LMMAL/LShank*}
{*%RLMAL=RLMAL/RShank*}
{*%LLMAL=LLMAL/LShank*}

{*PARAM (%LMMAL,%LLMAL,%RLMAL,%RMMAL)*}

EndIf


{*Dynamic trials*}
{*==============*}
If $Static==0

{*Anatomical frame definition*}

{*RMMAL=%RMMAL*RShank*}
{*RLMAL=%RLMAL*RShank*}
{*LMMAL=%LMMAL*LShank*}
{*LLMAL=%LLMAL*LShank*}

OUTPUT (RMMAL,RLMAL,LMMAL,LLMAL)


DYNPOINTER (RMEF, RThigh)
```

```
DYNPOINTER (LMEF, LThigh)

DYNPOINTER (RLEF, RThigh)

DYNPOINTER (LLEF, LThigh)

DYNPOINTER (RASIS, Waist1)

DYNPOINTER (LASIS, Waist1)

DYNPOINTER (SACR, Waist1)



{*Pelvis Segment*}
{*==============*}


midASIS=(LASIS+RASIS)/2
InterASISdist=DIST(LASIS,RASIS)

OUTPUT (midASIS)

Pelvis=[midASIS, RASIS-LASIS,SACR-midASIS, zyx, DefaultPelvis]
OUTPUT (midASIS, SACR)
PARAM (midASIS, SACR)



{*Hip Joint centre*}
{*===============*}

{*hip joint centre is 14%.30% and 19% from the interASIS distance*}
{*0.36 represents 50% from the ASIS less the 14%*}

%RHipOffsetFactor={-0.19,-0.3,0.36}
%LHipOffsetFactor={-0.19,-0.3,-0.36}


InterASISdist=DIST(LASIS,RASIS)
RHJC=(InterASISdist*%RHipOffsetFactor)*Pelvis
LHJC=(InterASISdist*%LHipOffsetFactor)*Pelvis

OUTPUT (RHJC,LHJC)
PARAM (RHJC,LHJC)


{*Hip Segment*}
```

```
{*===========*}


LHip=[LHJC,RASIS-LASIS,SACR-midASIS,zyx]
RHip=[RHJC,RASIS-LASIS,SACR-midASIS,zyx]


{*Thigh Segment*}
{*==================*}
{*Define joint centre first for origin of axis system, then create kinematic segment
axis definition. link in the anthro data*}


LKJC=(LLEF+LMEF)/2
RKJC=(RLEF+RMEF)/2

OUTPUT(LKJC,RKJC)
PARAM(LKJC,RKJC)


LFemur=[LKJC,LHJC-LKJC,LLEF-LMEF,yxz,DefaultFemur]
RFemur=[RKJC,RHJC-RKJC,RMEF-RLEF,yxz,DefaultFemur]



{*Shank Segment*}
{*=============*}


LAJC=(LMMAL+LLMAL)/2
RAJC=(RMMAL+RLMAL)/2

OUTPUT(LAJC,RAJC)
PARAM(LAJC,RAJC)

LTibia=[LAJC,LKJC-LAJC,LLMAL-LMMAL,yxz,DefaultTibia]
RTibia= [RAJC,RKJC-RAJC,RMMAL-RLMAL,yxz,DefaultTibia]




{* SEGVIS section*}
{*===============*}

SEGVIS(Pelvis)
SEGVIS(LHip)
SEGVIS(RHip)
SEGVIS(LFemur)
```

```
SEGVIS(RFemur)
SEGVIS(LTibia)
SEGVIS(RTibia)


{*KINEMATIC CALCULATIONS*}
{*====================*}

{*Euler angles for output into computer programme*}
GlobalPelvis=<Pelvis,1>
OUTPUT(GlobalPelvis)

{*RKneeAngles=<RFemur,RTibia,zyx>*}
{*LKneeAngles=<LFemur,LTibia,zyx>*}



{*OUTPUT(RKneeAngles)*}
{*OUTPUT(LKneeAngles)*}



{*Angles calculated using the floating axis method*}
ColeJCS(RFemur,RTibia,RKJC)
ColeJCS(LFemur,LTibia,LKJC)

{*corrects so that flexion, abduction and external rotation are positive*}
{*Order of angles is flexion, abd, ER*}

RKJCAngles=<-1(RKJCAngles),-2(RKJCAngles),-3(RKJCAngles)>
LKJCAngles=<-1(LKJCAngles),2(LKJCAngles),3(LKJCAngles)>

Output(RKJCAngles,LKJCAngles)


EndIF
{*Ends dynamic trials*}


{*KINETIC CALCULATIONS*}
{*====================*}

NN=$BODYMASS


{*Force Vectors*}
{*=============*}
OptionalReactions(ForcePlate1)
```

```
ForceVector(ForcePlate1)



{* Forces and Moments *}
{*====================*}

{* The correction makes so +ve moments tend to abduct, externally rotate and flex*}
{* These moments are external moments*}
{* Normalised to body mass *}


RKneeForce=1(REACTION(RTibia))/NN
RKneeMoment=2(REACTION(RTibia))/NN
RKneeMoment=RKneeMoment/(1000)
RKneeMoment = {-1(RKneeMoment),-2(RKneeMoment),3(RKneeMoment)}

LKneeForce=1(REACTION(LTibia))/NN
LKneeMoment=2(REACTION(LTibia))/NN
LKneeMoment=LKneeMoment/(1000)
LKneeMoment = {1(LKneeMoment),2(LKneeMoment),3(LKneeMoment)}

OUTPUT(RKneeForce,LKneeForce)
OUTPUT(RKneeMoment,LKneeMoment)

{*Ends dynamic trials*}
```

Appendix 12:

Example Body Builder Parameter File

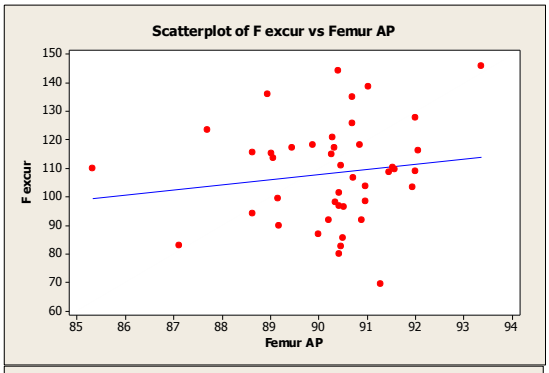
```
{*VICON BodyLanguage (tm)*}
{*copyright 1995,1996,1997 Oxford Metrics Ltd*}

{*parameters for use with Fullbody.MKR, Fullbody.mod*}


{*Marker diameter and joint widths*}
{*================================*}

      $Height = 1680
      $BODYMASS = 72
      $FootLength = 250

DistanceThreshold=500
```

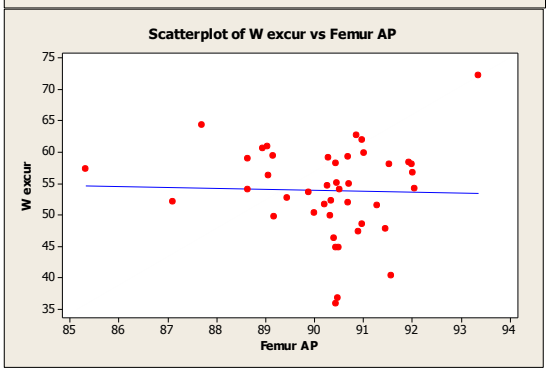
{* Output from file*}

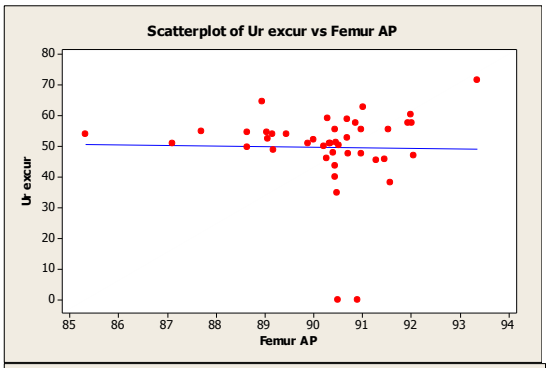
SACRCalib = {228.517,-53.8905,983.635}

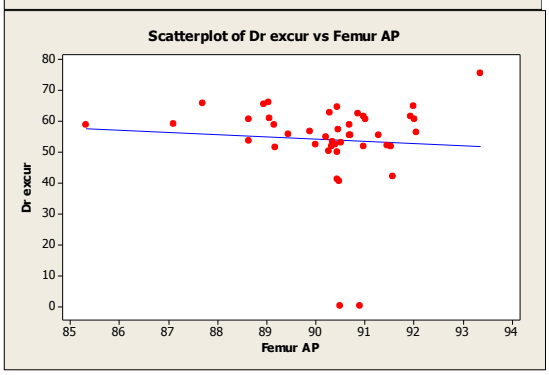
Appendix 15:

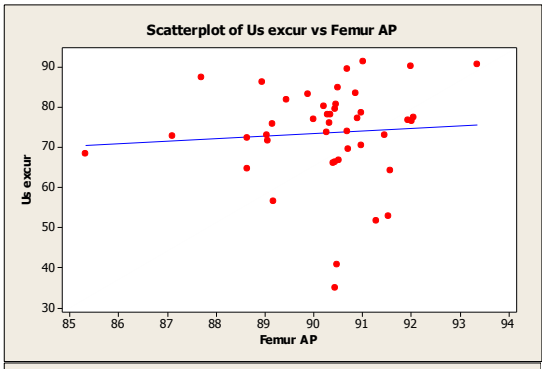
Frontal Femoral Alignment versus Electrogoniometry activities

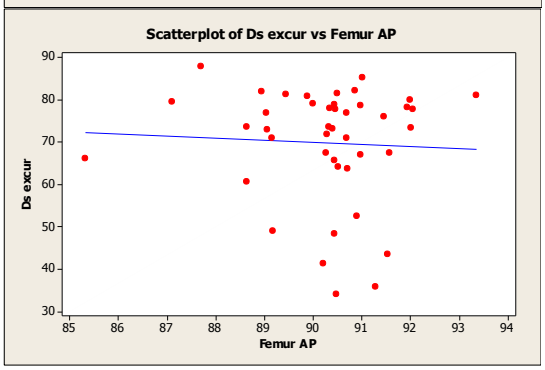


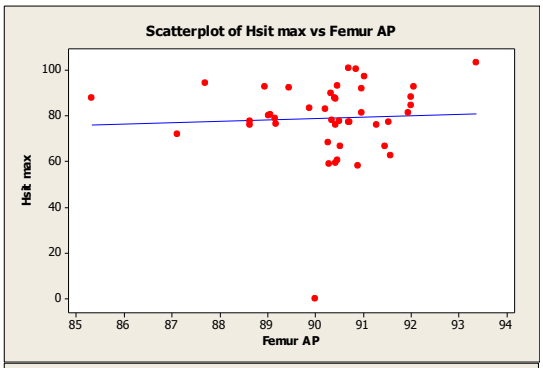


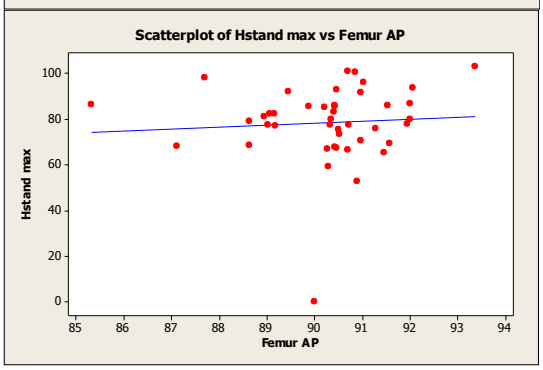


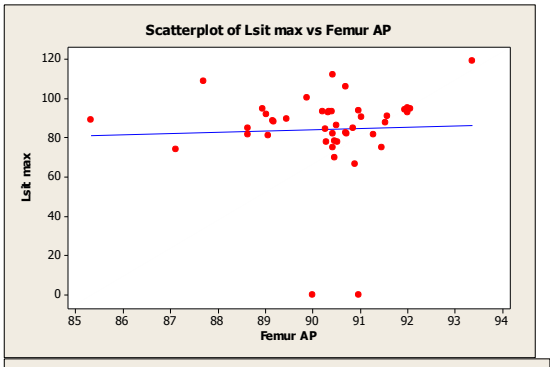


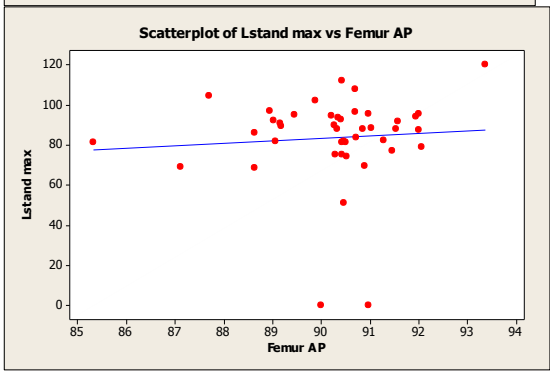

Scatterplot of Us excur vs Femur AP
Us excur
Femur AP
90
80
70
60
50
40
30
85
86
87
88
89
90
91
92
93
94


Scatterplot of Ds excur vs Femur AP
Ds excur
Femur AP
90
80
70
60
50
40
30
85
86
87
88
89
90
91
92
93
94


Scatterplot of Hsit max vs Femur AP
Hsit max
Femur AP
100
80
60
40
20
0
85
86
87
88
89
90
91
92
93
94


Scatterplot of Hstand max vs Femur AP
Hstand max
Femur AP
100
80
60
40
20
0
85
86
87
88
89
90
91
92
93
94


Scatterplot of Lsit max vs Femur AP
Lsit max
Femur AP
0
20
40
60
80
100
120
85
86
87
88
89
90
91
92
93
94


Scatterplot of Lstand max vs Femur AP
Lstand max
Femur AP
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20
40
60
80
100
120
85
86
87
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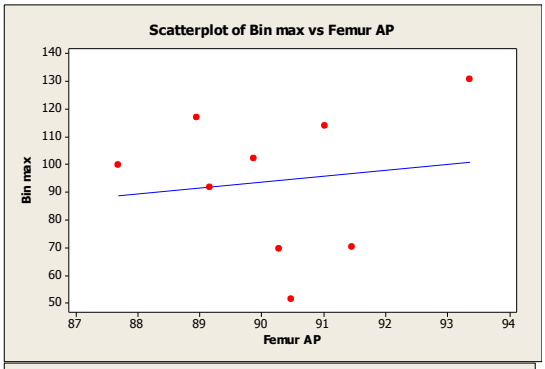
92
93
94


Scatterplot of Bin max vs Femur AP
Bin max
Femur AP
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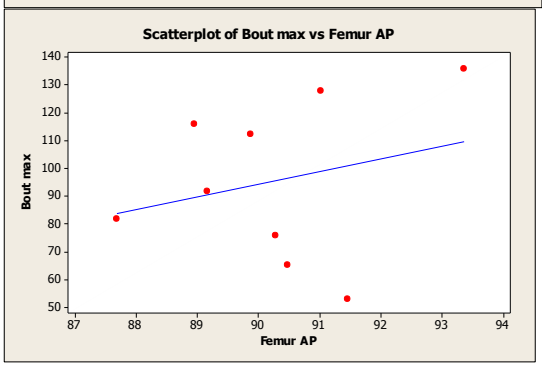
Scatterplot of Bout max vs Femur AP
Bout max
Femur AP
50
60
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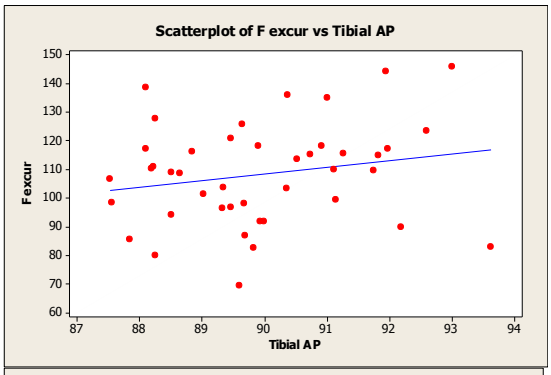
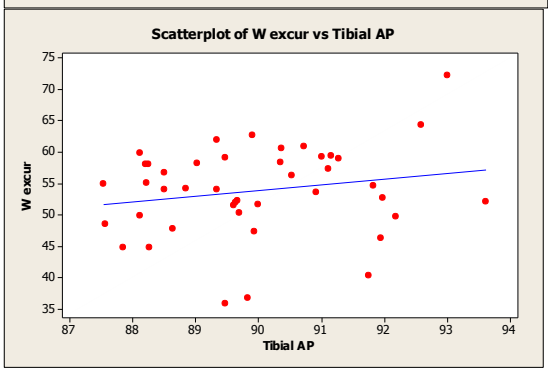
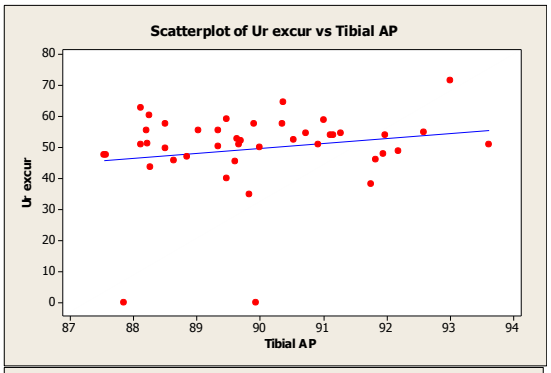
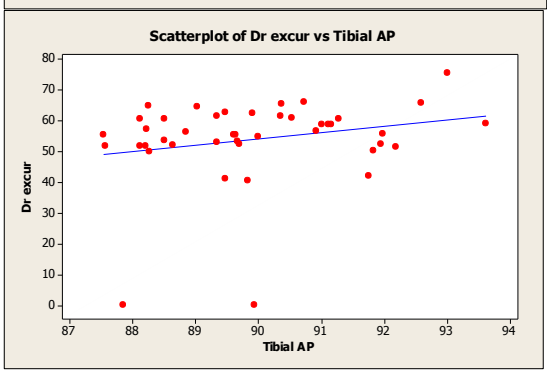
94

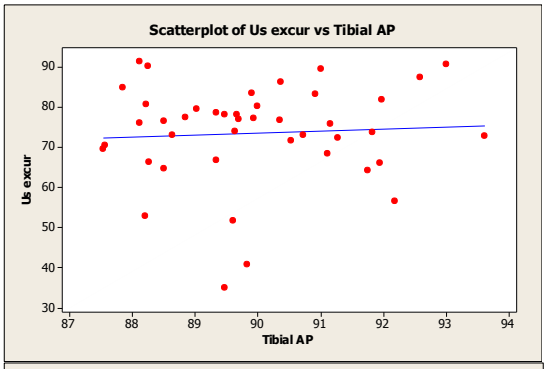
Femoral Tibial Alignment versus Electrogoniometry activities










Scatterplot of Us excur vs Tibial AP
Us excur
Tibial AP
90
80
70
60
50
40
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90
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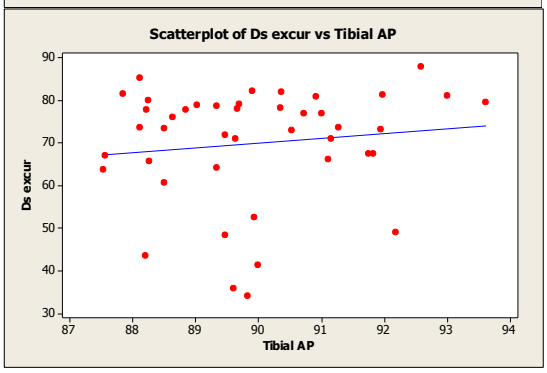
92
93
94


Scatterplot of Ds excur vs Tibial AP
Ds excur
Tibial AP
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80
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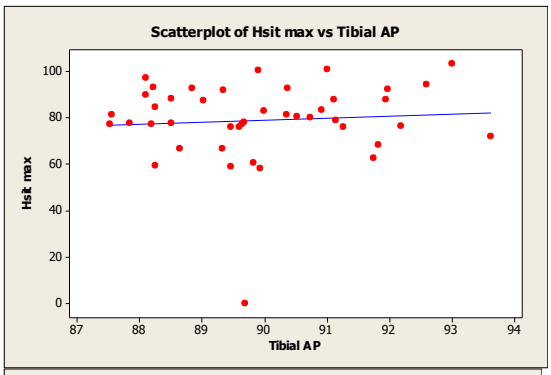
Scatterplot of Hsit max vs Tibial AP
Hsit max
Tibial AP
100
80
60
40
20
0
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88
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90
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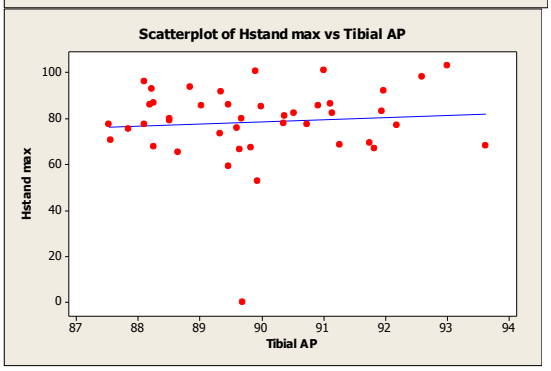
92
93
94


Scatterplot of Hstand max vs Tibial AP
Hstand max
Tibial AP
100
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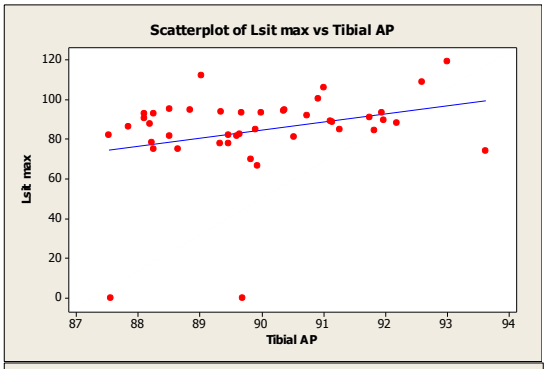
94


Scatterplot of Lsit max vs Tibial AP
Lsit max
Tibial AP
0
20
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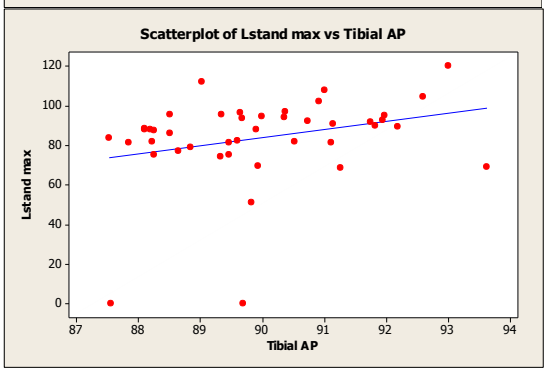
Scatterplot of Lstand max vs Tibial AP
Lstand max
Tibial AP
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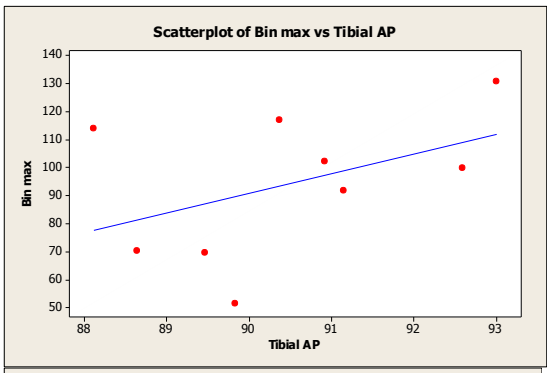
Scatterplot of Bin max vs Tibial AP
Bin max
Tibial AP
50
60
70
80
90
100
110
120
130
140
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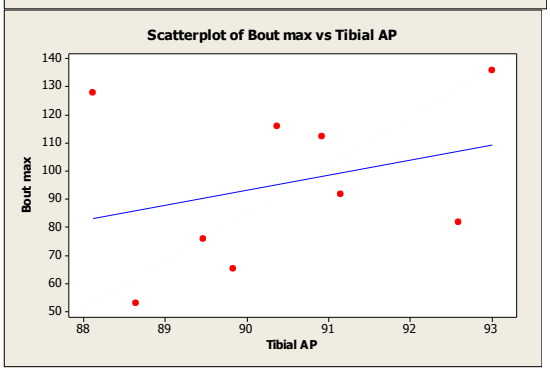
90
91
92
93


Scatterplot of Bout max vs Tibial AP
Bout max
Tibial AP
50
60
70
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100
110
120
130
140
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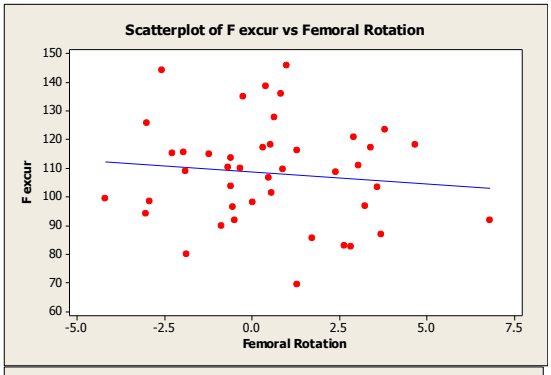
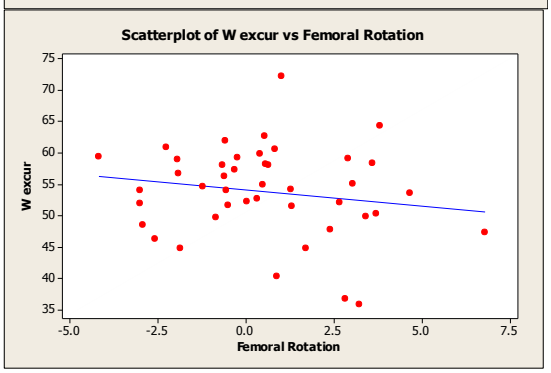
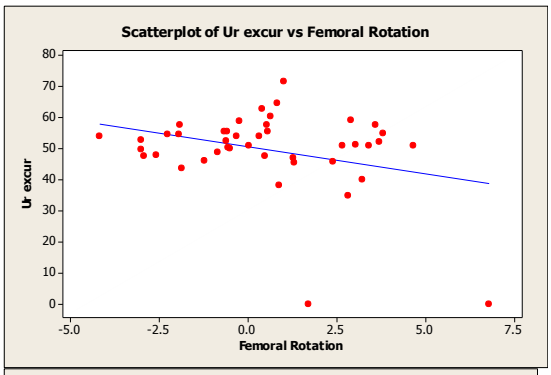
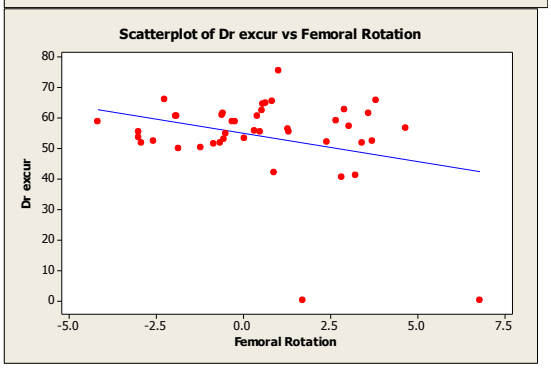
92
93

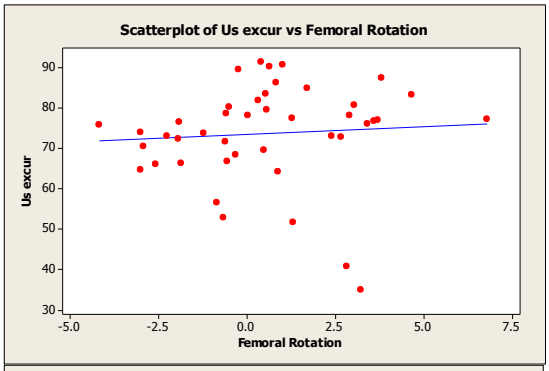
Femoral Rotational Alignment versus Electrogoniometry activities

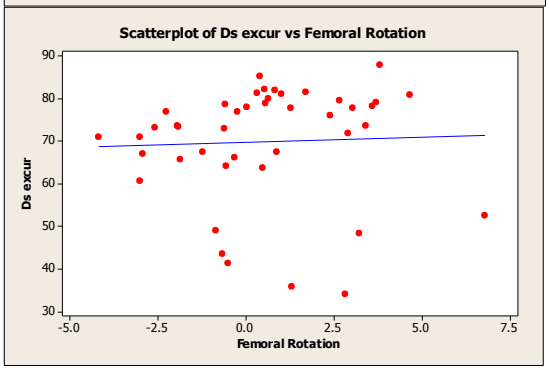









Scatterplot of Us excur vs Femoral Rotation
Us excur
Femoral Rotation
90
80
70
60
50
40
30
-5.0
-2.5
0.0
2.5
5.0
7.5


Scatterplot of Ds excur vs Femoral Rotation
Ds excur
Femoral Rotation
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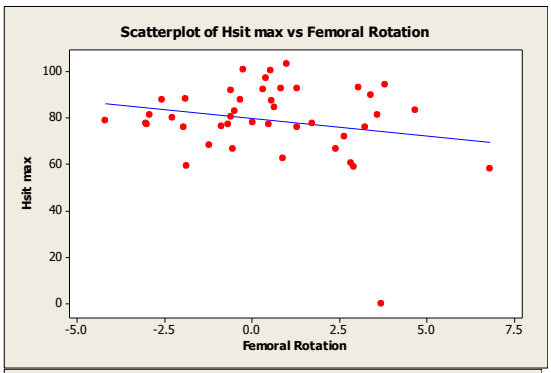
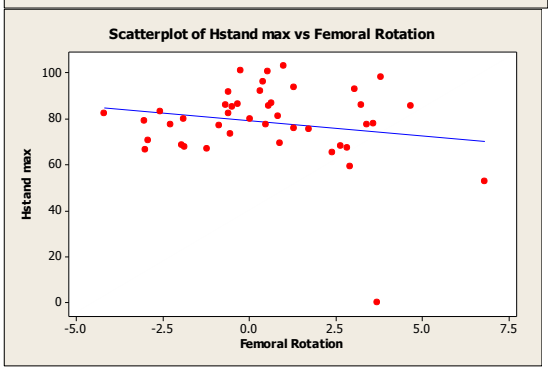
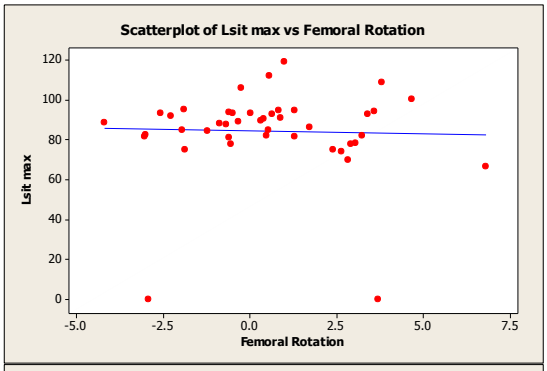
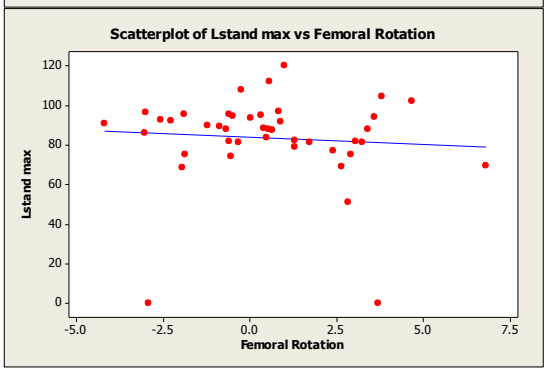
80
70
60
50
40
30
-5.0
-2.5
0.0
2.5
5.0
7.5


Scatterplot of Hsit max vs Femoral Rotation
Hsit max
Femoral Rotation
100
80
60
40
20
0
-5.0
-2.5
0.0
2.5
5.0
7.5


Scatterplot of Hstand max vs Femoral Rotation
Hstand max
Femoral Rotation
100
80
60
40
20
0
-5.0
-2.5
0.0
2.5
5.0
7.5


Scatterplot of Lsit max vs Femoral Rotation
Lsit max
Femoral Rotation
120
100
80
60
40
20
0
-5.0
-2.5
0.0
2.5
5.0
7.5


Scatterplot of Lstand max vs Femoral Rotation
Lstand max
Femoral Rotation
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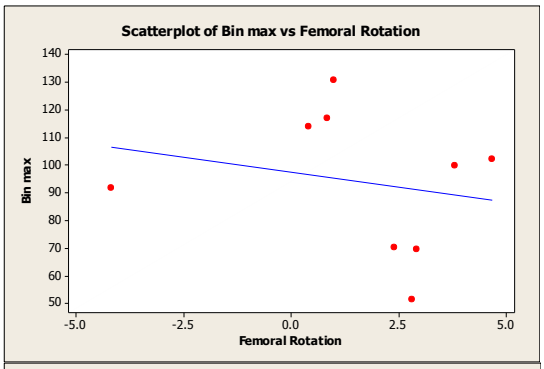
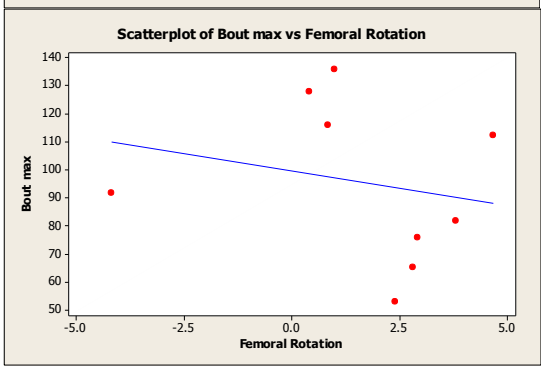
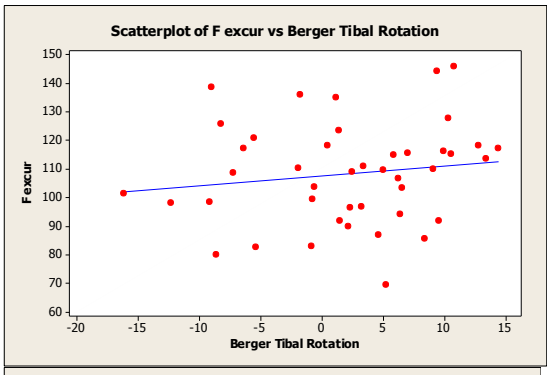
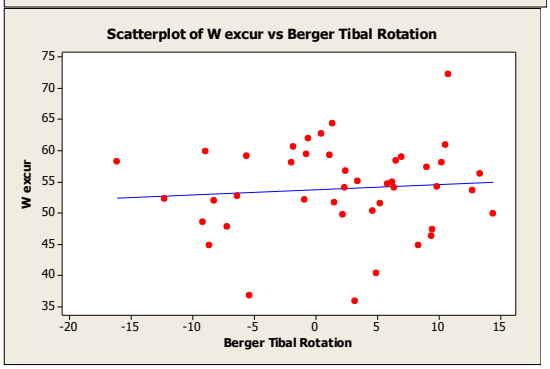
100
80
60
40
20
0
-5.0
-2.5
0.0
2.5
5.0
7.5

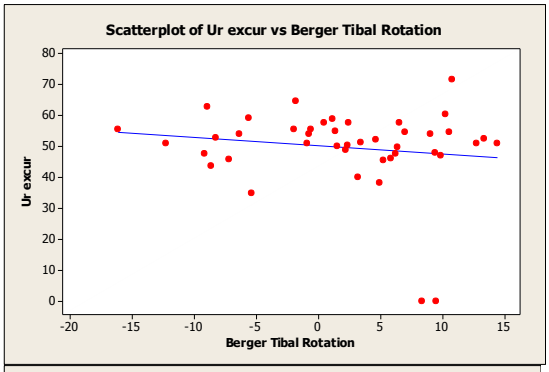

Scatterplot of Bin max vs Femoral Rotation
Bin max
Femoral Rotation
140
130
120
110
100
90
80
70
60
50
-5.0
-2.5
0.0
2.5
5.0

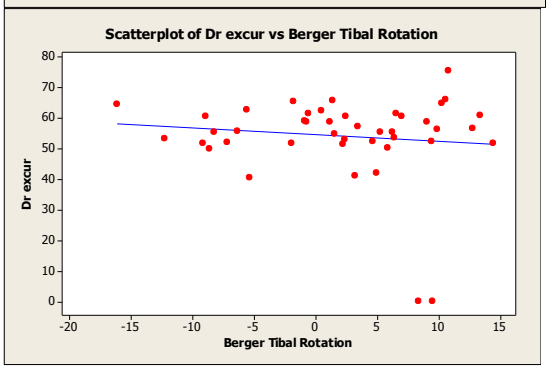

Scatterplot of Bout max vs Femoral Rotation
Bout max
Femoral Rotation
140
130
120
110
100
90
80
70
60
50
-5.0
-2.5
0.0
2.5
5.0

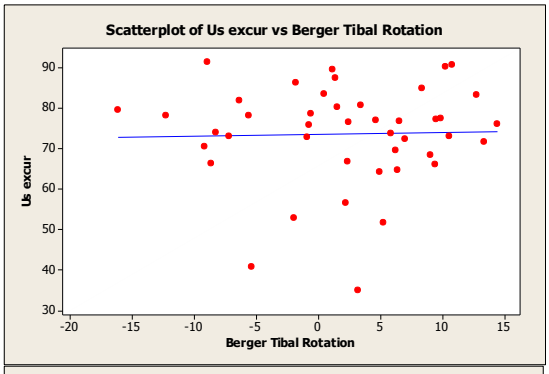
Tibial Rotational Alignment versus Electrogoniometry activities

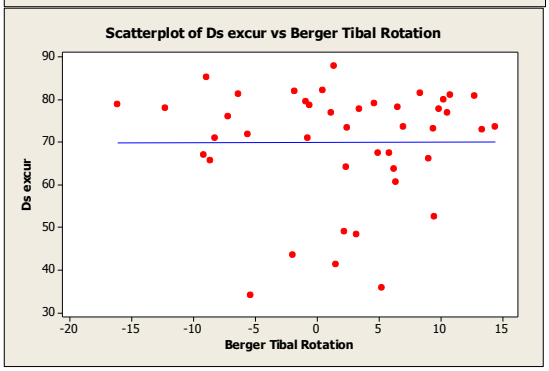


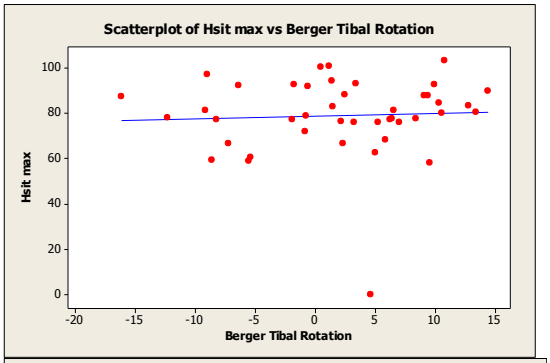


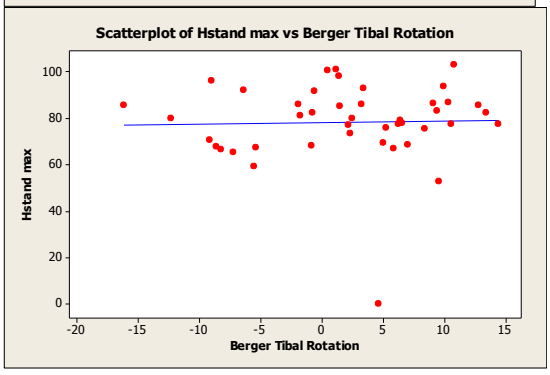


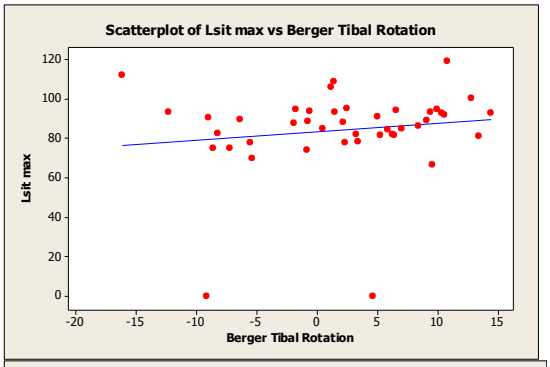


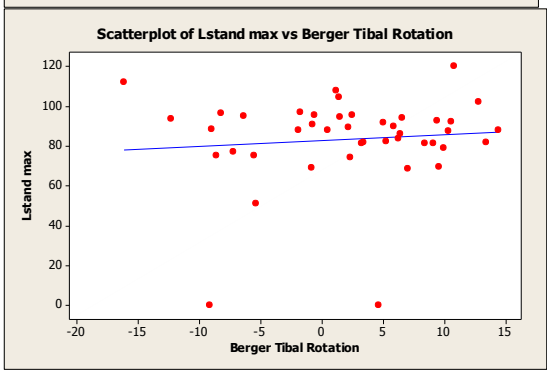

Scatterplot of Us excur vs Berger Tibal Rotation
Us excur
Berger Tibal Rotation

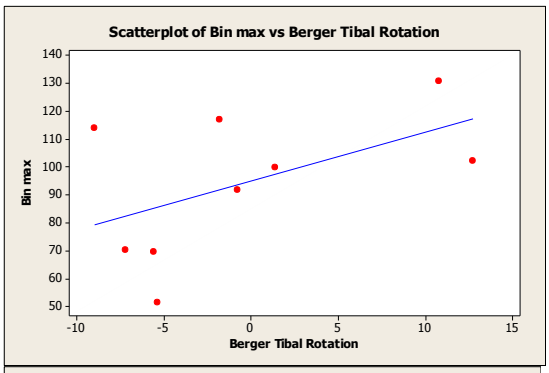

Scatterplot of Ds excur vs Berger Tibal Rotation
Ds excur
Berger Tibal Rotation

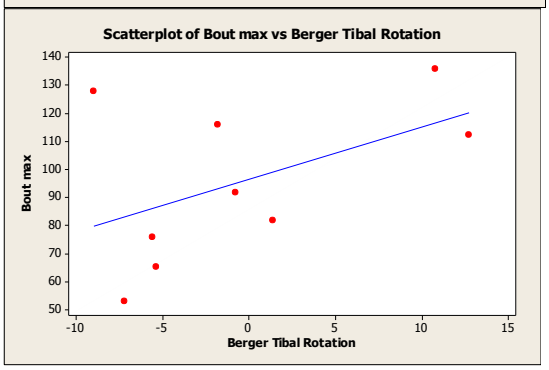

Scatterplot of Hsit max vs Berger Tibal Rotation
Hsit max
Berger Tibal Rotation


Scatterplot of Hstand max vs Berger Tibal Rotation
Hstand max
Berger Tibal Rotation


Scatterplot of Lsit max vs Berger Tibal Rotation
Lsit max
Berger Tibal Rotation


Scatterplot of Lstand max vs Berger Tibal Rotation
Lstand max
Berger Tibal Rotation


Scatterplot of Bin max vs Berger Tibal Rotation
Bin max
Berger Tibal Rotation


Scatterplot of Bout max vs Berger Tibal Rotation
Bout max
Berger Tibal Rotation