The non-invasive measurement of knee kinematics in normal, osteoarthritic and prosthetic knees

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

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Abstract

Total knee arthroplasty (TKA) is the most widely performed intervention for end-stage osteoarthritis (OA) but in spite of limitations in surgical techniques, alignment measurements and clinical outcomes, the expectations of an active, aging population continue to increase. The aim of this thesis was to develop and validate a non-invasive kinematic assessment tool to improve the measurement of knee alignment and ligament laxity.

An intra-operative infrared tracking system was adapted for non-invasive use through the development of external mountings that enabled alignment measurements to be made supine, standing and following manual collateral stress. Coronal and sagittal plane mechanical femorotibial (MFT) angle measurement was validated to a precision of approximately ±1° by comparison to a custom made leg model, a flexible electrogoniometer and through repeatability measurements on 30 asymptomatic volunteers. Assessment of coronal laxity was quantified and standardised by controlling lever arm, applied manual load and knee flexion angle. Thirty one patients with end-stage OA were assessed before, during and six weeks following TKA and comparisons were made between invasive and non-invasive MFT angles and between supine and standing conditions.

For osteoarthritic knees, varus and valgus angular displacements were greater intra-operatively in comparison to pre-operative non-invasive measurements, whereas invasive and non-invasive stress angles for prosthetic knees showed less variation. From supine to bi-pedal stance, MFT angles most frequently changed to relative varus and extension for all knee types suggesting that soft tissue restraints may be more important than rigid bony or prosthetic architecture for controlling this weight-bearing alignment change.

The development of a non-invasive infrared (IR) system enabled knee alignment to be quantified as a dynamic parameter in comparison to current static assessment techniques such as radiographs. The generation of subject-specific kinematic profiles could help with the surgical planning and post-operative follow-up of patients undergoing alignment dependent procedures such as TKA.

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Peer revieved publications from this thesis

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Glossary

Term/abbreviation	Definition
ACL	Anterior cruciate ligament
Abduction	Movement which draws a limb away from the sagittal plane of the body
Adduction	Movement which brings a part of the anatomy closer to the sagittal plane of the body
AKS(S)	American Knee Society (Score)
Anterior	Front
AP	Antero-posterior
Arthrodesis	The artificial induction of joint ossification between two bones via surgery
ASIS	Anterior superior iliac spine; anatomical landmark that refers to the anterior extremity of the iliac crest of the pelvis
ASTM International	American Society for Testing and Materials International
BMI	Body mass index; body weight (kg) divided by square of height (m^2)
CAOS	Computer-assisted orthopaedic surgery
CAS	Computer-assisted surgery
CI	Confidence interval
Coronal plane	Vertical plane that divides the body into anterior and posterior sections
CT scan	Computed tomography scan
DAQ system	Data acquisition system
Diaphysis	Mid section (shaft) of a long bone
Distal	Away from a point of origin or attachment
EG	Electrogoniometer
EM	Electromagnetic
Extension	Movement that increases the angle between the bones of the limb at a joint

FAA	Femoral anatomical axis
FAD	Force application device
Femoral epicondyle	Bony protrusions located on the medial (medial epicondyle) and lateral (lateral epicondyle) sides of the distal end of the femur
FFD	Fixed flexion deformity
Flexion	Movement that decreases the angle between the bones of the limb at a joint
FMA	Femoral mechanical axis
FM anatomical angle	Femoral mechanical anatomical angle
FM angle	Femoral mechanical angle
FOM	Field of measurement
Goniometer	Instrument that measures angles
Greater trochanter	Large, irregular, quadrilateral eminence on the lateral aspect of the proximal femur
GUI	Graphical user interface
HAQ	Health assessment questionnaire
HJC	Hip joint centre
HTO	High tibial osteotomy
Hyperextension	Extension of a joint beyond the normal range. With respect to the knee joint in this study it is extension beyond a sagittal MFT angle of 0°
Hypoplasia	Underdevelopment or incomplete development of a tissue or an organ
In-vitro	Procedure performed in a controlled environment rather than a living organism
In-vivo	Occurring or carried out in a living organism
IR	Infrared
IM	Intramedullary
K/L grade	Kellgren and Lawrence grade
Lateral	Pertaining to a side, away from the midline of the body or a

	structure
LCL	Lateral collateral ligament; rounded, narrow ligament located on the lateral aspect of the knee
LED	Light emitting diode
MA	Mechanical axis
Malleolus	Bony prominence on either side of the ankle. Medial malleolus is the medial surface of the lower end of the tibia, lateral malleolus is the lower extremity of the fibula
MCL	Medial collateral ligament; broad, flat, membranous band on the medial aspect of the knee
Medial	Pertaining to, situated in, or oriented toward the midline of the body or a structure
MFT angle	Mechanical femorotibial angle
MRI scan	Magnetic resonance imaging scan
NSAIDS	Non-steroidal anti-inflammatory drugs
OA	Osteoarthritis
OKS	Oxford knee score
Osteotomy	Surgical procedure whereby a bone is cut to shorten, lengthen or change its alignment
Osteophyte	Bony outgrowth or protuberance
Patellofemoral joint	Articulation between the underside of the patella and the groove within the distal femur
PCL	Posterior cruciate ligament
Posterior	Back
Procurvatum	Angular deformity, usually of a long bone, in which the distal part is angulated posteriorly, so that the apex of the angle is anterior
Proximal	Nearest to a point of origin or attachment
Pubic symphysis	Midline cartilaginous joint uniting the left and right pubic bones at the anterior aspect of the pelvis
Recurvatum	Angular deformity, usually of a long bone, in which the distal part is angulated anteriorly, so that the apex of the angle is

	posterior
	Hyperextension (with regards to the knee joint)
RMS	Root mean square
RSA	Roentgen stereophotogrammetric analysis
Sagittal plane	Vertical plane which passes from front to rear dividing the body into right and left sections
SD	Standard deviation
SF-36	Short form-36
SPSS	Statistical Package for the Social Sciences
Subchondral	Below the cartilage
Supine	Lying
TAA	Tibial anatomical axis
THA	Total hip arthroplasty
Tibial Plateau	Proximal articular surface of the tibia consisting of the medial tibial plateau and the lateral tibial plateau
Tibial Plafond	Distal articular surface of the tibia
TKA	Total knee arthroplasty
TMA	Tibial mechanical axis
Transverse plane	Horizontal plane that divides the body into superior and inferior parts. It is perpendicular to the coronal and sagittal planes
UKA	Unicompartmental knee arthoplasty
Valgus	Outward angulation of the distal segment of a bone or joint
Varus	Inward angulation of the distal segment of a bone or joint
WOMAC	Western Ontario and McMaster Universities Arthritis Index

1 Introduction

1.1 Background

Osteoarthritis (OA) is a highly variable chronic disorder which severely influences health-related quality of life [Jones et al. 2000]. The knee is the most commonly involved joint and is estimated to affect approximately 10% of the population over 55 years of age [Peterson, 1996], with symptoms ranging from mild pain to complete loss of function. In the past, when conservative therapies failed, interventions such as mechanical realignment (osteotomy) or joint fusion (arthrodesis) represented the basics of surgical management, leaving many patients with end-stage OA of the knee significantly disabled. The introduction of total knee arthroplasty (TKA) in the early 1970s represented a new era in the management of advanced OA, and over the past few decades has evolved as a valid, reliable and cost-effective treatment [Liang et al. 1986]. There are now more than 90,000 TKAs performed annually in the United Kingdom [National Joint Registry for England and Wales, 7th Annual Report 2010, Scottish Arthroplasty Project Annual Report 2010], with this number expected to steadily increase in line with an expanding elderly population [Nilsdotter et al. 2009]. In spite of advances in the design of implants, along with improved instrumentation and surgical techniques, the fundamental goals of TKA have remained largely unchanged since the 1970s [Townley 1985]. These include correct alignment of the knee with balancing of the surrounding soft tissues in order to achieve a pain-free, well-functioning joint with good long-term implant survival [Freeman et al. 1978, Insall et al. 1985, Ranawat et al. 1993, Vince et al. 1989].

In spite of extensive research to establish normal alignment values in asymptomatic subjects [Cooke et al. 1997, Glimet et al. 1979 & 1980, Hsu et al. 1990, Moreland et al. 1987], as well as attempts to quantify the relationship between malalignment and OA pathogenesis [Cerejo et al. 2002, Cicuttini et al. 2004, Sharma et al. 2001, Tanamas et al. 2009], our understanding of static knee alignment remains poor. There are reported variations of up to ±5° in the mechanical coronal (frontal) alignment of asymptomatic subjects [Cooke et al. 1997, Glimet et al. 1979 & 1980, Hsu et al. 1990, Moreland et al. 1987] and potential changes between supine (lying) and standing conditions are not well documented. Despite a lack of standardised data, alignment measurements are fundamental to the surgical management of osteoarthritic knees. Restoring the coronal mechanical femorotibial (MFT) angle of the lower limb to 0° is a common intra-operative target with deviation beyond 0°±3° widely associated with reduced implant survival [Bargren et al. 1983, Jeffrey et al. 1991, Lotke and Ecker, 1977, Ritter et al. 1994] and poorer knee function [Oswald et al. 1993, Wasielewski et al. 1994]. However, TKA implants are positioned on supine limbs and then routinely measured post-operatively with standing x-rays. In addition to a potential weight-bearing change of alignment, radiographic limb-positioning errors may occur as a result of rotation or flexion of the knee [Krackow et al. 1990b, Siu et al. 1991, Swanson et al. 2000]. This may account for discrepancies between intra-operative alignment measurements and post-operative radiographs [Yaffe et al. 2008] as well as reports of post-operative coronal limb alignment exceeding 0°±3° in up to 30% of cases using conventional techniques [Mahaluxmivala et al. 2001, Peterson et al. 1988].

By comparison to the coronal plane, sagittal (lateral) alignment has been studied relatively little. However, knee extension deformities in TKA can lead to poorer functional outcomes and so a generally accepted supine intraoperative target is the restoration of full passive extension [Bellemans et al. 2006, Ritter et al. 2007]. Subsequent post-operative assessment is then routinely performed by subjective visual estimation or manual goniometry often in a supine position in spite of knee extension problems occurring during weight-bearing activities [Perry et al. 1975].

As well as correcting malalignment, it is generally accepted that the restraining soft tissues should be balanced during TKA surgery so as to work synergistically with the knee implant and provide increased stability, optimal range of motion and ultimately reduce implant wear [Freeman et al. 1986]. In general, the collateral ligament complexes control varus and valgus stability and assessment of their laxity by application of manual stress is a fundamental yet subjective component of many soft tissue management techniques in TKA surgery. Attempts have been made to categorise soft tissue laxity, such as Krackow’s classification of medial ligament tightness [Krackow 1990a] but this assumes that all clinicians have similar examination methods and are able to reliably judge knee alignment. However, human assessment of angles is poor [Edwards et al. 2004] and this has led to quantitative adjuncts such as stress radiographs [LaPrade et al. 2008] and the more recent introduction of optical and electromagnetic tracking systems for intra-operative use. This technology has provided surgeons with quantitative measurement tools that permit real time assessment of knee alignment, passive range of motion and ligament laxity [Bathis et al. 2004, Chauhan et al. 2004b, Stulberg et al. 2002]. The systems have high levels of precision and can achieve angular and distance measurements of within 1° or 1mm respectively [Haaker et al. 2005, Stockl et al. 2004]. As well as improving the positional accuracy of TKA implants, this technology can help to guide the extent of any surgical releases performed on restraining soft tissues in order to give a balanced knee [Hakki et al. 2009, Jenny et al. 2004, Picard et al. 2007b, Saragaglia et al. 2006, Unitt et al. 2008]. At present however, these quantitative measurement techniques have restricted scope due to their reliance on the rigid bony fixation of trackers and so the pre- and post-operative assessment of knee joints relies on subjective clinical evaluation along with static radiographic measurements. Adapting this technology for non-invasive patient assessment is potentially challenging due to the soft tissue artefacts associated with the external mounting of trackers. Previous investigations to quantify the movement of external marker sets relative to underlying bones have reported large potential errors and questioned the value of these methods for accurate kinematic analysis [Sangeux et al. 2006, Stagni et al. 2005]. Non-invasive tracking technology is therefore currently unavailable in this context.

1.2 Project rationale

There are clear knowledge gaps as well as limitations in current techniques with regards to assessment of knee alignment and quantification of soft tissues. In spite of this, patient expectations following TKA surgery are increasing in accordance with the functional demands of an active aging population [Lingard et al. 2006]. Recent data from the National Joint Registry for England and Wales revealed a one year post-operative dissatisfaction rate of 18.2% [Baker et al. 2007]. In addition, patient outcomes with regards to physical function have been shown to be considerably poorer than those concerning reduction of pain [Nilsdotter et al. 2009] and overall patient-reported satisfaction rates are less than for total hip arthroplasty (THA) [Bachmeier et al. 2001, Beverland 2010]. With an increasing number of procedures, along with a discrepancy between expectation and outcome, there is a definite need to improve knowledge of knee kinematics and re-evaluate the key principles of TKA.

Adapting intra-operative tracking technology for clinical use has the potential to enhance the pre-operative planning and post-operative follow up of patients undergoing TKA with respect to limb alignment and soft tissue balancing. Non-invasive measurements of knee alignment could be made when supine and standing which could help to define the relationship between the two measurement conditions. With regards to TKA, this could overcome the fact that implants are designed to function in weight-bearing conditions but are positioned in supine patients with no muscle tone.

Furthermore, the ability to measure angular displacements following an applied stress to the knee joint could provide quantitative information on the restraining properties of the supporting soft tissue structures. Standardisation of the subjective variables of physical assessment could make more widespread use of this quantitative data. Preoperative kinematic assessment could ultimately define patient-specific surgical goals with subsequent verification at different postoperative stages of recovery. This may ultimately lead to a reassessment of the technical aims of TKA and support recent evidence that has challenged the use of an arbitrary figure of 3° to define the limits of acceptable alignment [Parratte et al. 2010]. Targets based on subject-specific kinematics may prove to be more appropriate.

1.3 Aims

The aims of this thesis are as follows:

- Develop and validate a non-invasive kinematic assessment tool for dynamic measurement of knee alignment and soft tissue laxity
- Quantify and subsequently standardise the assessment of collateral knee laxity
- Measure dynamic alignment of normal, osteoarthritic and prosthetic knees
- Determine the relationship of knee kinematics to measurement conditions

2 Literature review

This review provides background information on the normal functional anatomy, kinematics and alignment of the knee joint and outlines the pathophysiology of OA along with subsequent management options. The principles of TKA are detailed with particular relevance to component alignment and balancing of the supporting soft tissues. Traditional instrumentation techniques and more recent intra-operative measurement technologies that rely on tracker fixation to bone are described. The limitations of this technology and currently available non-invasive techniques for measuring alignment and laxity are detailed providing the rationale for further work in this field.

2.1 Knee joint

The knee (Figure 2.1) is a synovial joint consisting of two articulations: the femorotibial joint between the distal end of the femur and the proximal end of the tibia, and the patellofemoral joint between the distal femur and posterior aspect of the patella. The femorotibial joint, comprised of a medial and lateral compartment, is a load bearing joint located between the two longest lever arms in the body. In addition to coping with activities such as walking, running, bending and jumping, it also works in conjunction with the hip and ankle joints, assisting in static erect posture. Therefore the knee joint needs to offer stability and weight support, in addition to having considerable mobility. Not surprisingly it is one of the most commonly injured joints in the human body and is highly susceptible to the development of OA.

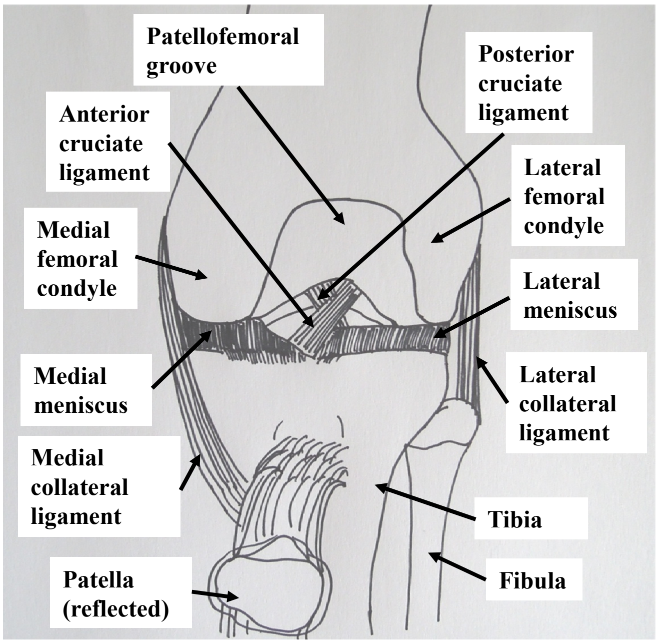


Figure 2.1 Knee joint (left) bony anatomy and main supporting soft tissues

2.1.1 Bone geometry

The femur and tibia usually meet at an angle of between 5° and 12° valgus owing to the convergence of the femur towards the midline relative to the vertical tibia. The distal femur bears two rounded articular surfaces covered by hyaline cartilage, the medial and lateral condyles, covered by hyaline cartilage, which articulate with the respective condyles on the tibia. They are joined anteriorly to form the patellar articular surface and are separated posteriorly by a deep intercondylar fossa. The condyles are almost in line with the front of the femoral shaft, but they project posteriorly beyond the shaft in a J-shape, which is of significance in movement of the joint. The medial condyle is larger, more curved and projects further posteriorly than the lateral condyle which accounts for the valgus angle between the femur and the tibia. The sides of the condyles each bear a projection called the medial and lateral epicondyles.

The proximal tibia is oval-shaped and projects backwards with regards the longitudinal axis of the tibia. It is sloped posteriorly at an angle of around 5° to 8°. The expanded upper end of the tibia forms two surfaces covered with articular cartilage, the medial plateau and the lateral plateau, which articulate with the corresponding femoral condyle. They are separated by the intercondylar eminence, the fixation point of both the anterior and posterior cruciate ligaments. The lateral articular area is slightly convex and is smaller than the concave medial area. The medial and lateral fibrocartilaginous menisci increase and deepen the contact surface between the femoral and tibial condyles, provide more stability and transmit up to around 50% of the tibiofemoral force during knee movement [Walker and Erkman 1975].

2.1.2 Range of movement and kinematics

Movement of the femorotibial articulation can occur in the longitudinal, anteroposterior (AP) and mediolateral (ML) geometric planes and in each of these, the tibia can translate or rotate with respect to the femur. This results in the paired motions of flexion-extension, varus-valgus rotation, internal-external rotation, AP translation, ML translation and compression-distraction. The latter two motions are minimal and so are not detailed below.

2.1.2.1 Flexion-extension

Although the knee joint is not a pure hinged joint, the predominant movement is rotation within the sagittal plane (flexion-extension). Flexion is produced mainly by the hamstring muscles, consisting of the semimembranosus, semitendinosus and biceps femoris, along with assistance from the two heads of gastrocnemius, and is generally limited by calf and thigh contact. The quadriceps femoris, consisting of rectus femoris, vastus lateralis, vastus intermedius and vastus medialis, acts through the ligamentum patellae to form the extensor mechanism. Extension is limited mainly as a result of the cruciate and collateral ligaments becoming taut and the menisci compressed and at this point the joint is normally slightly hyperextended. The arc of flexion-extension is dependent on a number of individual characteristics such as body habitus, degree of generalised laxity and sex. Typical maximum extension ranges from a few degrees of flexion to 20° of hyperextension, whilst maximum flexion varies between 125° to 165° [Sheldon, 1994]. In a normal American population typical values have been reported as 3° to 4° of hyperextension to 140° of flexion [Sheldon, 1994] but this can vary significantly. Rowe et al. (2000)

used flexible electrogoniometry to measure the flexion-extension angles of the knee utilised during a range of functional activities of daily living. The study concluded that most activities could be accomplished with a joint excursion of 110° of flexion.

The principle of the femoral condyles translating backwards during flexion is termed 'rollback', and its exact mechanism remains controversial. Early theories described a simplistic mechanism that involved a combination of rolling and sliding of the femoral condyles on the tibial plateau as a result of a rigid four-bar linkage provided by the cruciate ligaments. Support for this theory stemmed from the principle that flexion and extension do not occur about a fixed transverse axis of rotation but rather about a constantly changing centre of rotation (polycentric rotation) [Fick 1904, Frain et al. 1984]. When plotted, the path of this changing centre of rotation describes a J-shaped curve with a subsequent backwards movement of the femoral condyles with respect to the tibia. More recent studies however have suggested that only the lateral condyle rolls back during flexion as a consequence of femoral external rotation [Pinskerova et al. 2004]. Pinskerova (2004) demonstrated on both cadaver and living weight-bearing and non-weight-bearing knees that the medial femoral condyle did not seem to rollback with flexion. Instead it was the 'contact point' between the femur and the tibia that translated posteriorly rather than a relative point of rotation (termed the flexion facet centre) on the medial condyle which had no translation.

2.1.2.2 Varus-valgus rotation

Frontal plane rotation of the tibia on the femur (varus-valgus) is dependent on the general ligament laxity of the individual, amount of knee flexion and magnitude of applied load during testing. Minimal varus-valgus laxity occurs in full knee extension due to the relatively locked position of the tibia relative to the femur. Maximum laxity occurs at approximately 30° and is often measured in terms of joint line distraction [Sheldon, 1994]. With a valgus stress at 30° of knee flexion, medial femorotibial joint opening averages 4mm (range 0 to 10mm) according to American Academy of Orthopaedic Surgeons data [Sheldon, 1994]. With the same degree of flexion, varus stress results in an average of 6mm (range 2 to 14mm) of lateral joint opening according to the same source. These measurements are often based on radiographically measured distances of joint space opening [LaPrade et al. 2008, Moore et al. 1976, Wijdicks et al. 2010]. Alternatively, varus-valgus rotation can be quantified as an angular displacement which has been measured using a variety of different techniques. As a consequence of potential measurement errors, normal angular laxity values can vary substantially between studies. The measurement of varus-valgus knee laxity is further discussed in Section 2.6.3

2.1.2.3 Antero-posterior translation

The AP translation of the tibia on the femur in a healthy knee is again largely dependent on overall ligament laxity and the degree of knee flexion at the time of measurement. To a lesser extent it also depends on the amount of internal or external rotation. The AP translation of the tibia on the femur is again minimal in full extension as a consequence of the screw home mechanism (Section 2.1.2.4). Anterior translation of the tibia is greatest at around 30° of knee flexion due to the anterior restraints being at their most lax. In this position, anterior translation can vary from 2 to 10mm in individuals without ligament pathology [Sheldon, 1994]. As flexion increases the anterior laxity diminishes, particularly beyond 90°. Posterior translation is greatest at 90° of flexion and can vary in magnitude from 0 to 6mm [Sheldon, 1994]. As well as knee position, the amount of measured translation is dependent on the applied load. With control of these variables, most individuals should have a left to right AP laxity difference of 2mm or less [Sheldon, 1994].

2.1.2.4 Internal-external rotation

The complex rotational motion of the femorotibial joint during flexion-extension is mainly the result of the contour of the femoral and tibial condyles. The difference in size and curvature of the two femoral condyles results in a greater medial condyle joint surface compared to the lateral side. As a consequence, there is a difference in the backward role of the condyles during flexion leading to a greater backwards movement of the lateral condyle compared to medial side and internal rotation of the tibia with respect to the femur when the knee is flexed beyond 30°. Conversely, from full flexion to extension, the tibia externally rotates with respect to the femur. During the last few degrees of knee extension the external rotation of the tibia results in tightening of the ACL and PCL. This locks the femorotibial joint in a very stable position and is termed the screw home mechanism.

2.1.3 Passive restraints

The main stability of the knee joint is provided by the passive soft tissue restraints, with contribution to a lesser extent from the bony architecture of the femur, tibia and patella, and the dynamic activity of the surrounding muscles. The relative contribution of the passive restraints is dependent on the movement resisted and the position of the knee at the time of an applied load.

2.1.3.1 Varus

The lateral collateral ligament (LCL) is a strong rounded ligament extending from the lateral femoral epicondyle to the head of the fibula, with no attachment to the lateral meniscus. It is the primary restraint to varus angular displacement of the knee in all positions of knee flexion except for full extension. In this position, previous in-vitro testing has shown the posterior capsule to be the main resisting structure to an applied varus load [Markolf et al. 1976]. The anterior cruciate ligament (ACL) acts as a secondary restraint and its contribution can be differentiated into two functional bundles: anteromedial and posterolateral. The anteromedial fibres have greater tension in flexion whereas the posterolateral bundle is tighter in extension. The posterior cruciate ligament (PCL) also provides secondary restraint.

2.1.3.2 Valgus

The medial collateral ligament (MCL) is a broad, flattened ligament extending from the medial femoral epicondyle to the medial aspect of the proximal tibia. A short deep portion extends as a thickening in the capsule to the medial meniscus. The superficial portion of the MCL is the primary restraint to an applied valgus load in all degrees of knee flexion. In full extension, in-vitro testing has shown a significant reduction of between 50-60% of valgus stiffness on sectioning of the superficial MCL [Markolf et al. 1976]. The posteromedial capsular structures are tight in full extension but offer less resistance to valgus stress beyond 30° of flexion when they slacken [Sheldon, 1994]. The ACL and PCL act as secondary restraints to valgus force.

2.1.3.3 Antero-posterior translation

The predominant primary restraint to anterior translation of the tibia relative to the femur is the anteromedial bundle of the ACL in flexion and the posterolateral bundle of the ACL in extension. Other contributing secondary restraints are the iliotibial band, medial and lateral joint capsule, MCL, LCL and menisci. The primary restraint to posterior translation is the posterior cruciate ligament (PCL) with secondary contribution from the LCL [Ramachandran, 2007].

2.1.3.4 Internal-external rotation

The primary restraint to internal rotation of the tibia on the femur is the superficial and deep MCL with secondary restraint provided by the ACL. The LCL and posterolateral capsule are the primary restraints to external rotation with a lesser contribution from the PCL [Sheldon, 1994].

2.2 Lower limb alignment

Alignment is a relative, three-dimensional concept that requires clear definitions in order to establish both normal and abnormal conditions. There are two main considerations when evaluating alignment of the knee: axial alignment of the lower limb and joint line orientation. This requires the simplification of the complex morphology of bones and joints in order to define relevant axes and angles.

2.2.1 Definitions

Axes are applicable to any longitudinal projection of a bone but for practical purposes are only routinely measured in the coronal and sagittal planes which are the standard projections taken with lower limb X-rays. This represents a limitation of routine clinical practice due to the potential for limb mal-positioning when taking radiographs [Siu et al. 1991, Wright et al. 1991] leading to measurement errors when defining axes.

The femoral and tibial axes can be described in either anatomical or mechanical terms. In general, the mechanical axis (MA) of a long bone is a line drawn from the centre of the proximal joint to the centre of the distal joint. Therefore the MA is always a straight line in both the coronal and sagittal planes for the femur and tibia. The anatomical axis (AA) of a long bone is its mid-diaphyseal line, which can be determined by a line connecting two mid-cortical points at two different levels. As a consequence, the AA cannot always be represented by a single line for bones that are not straight.

The following axes and angles are commonly used for defining lower limb alignment [Maquet 1977, Moreland et al. 1987] and these are illustrated for the coronal plane in Figure 2.2

2.2.1.1 Lower limb mechanical axis (MA)

This is defined as a line drawn between the centre of the femoral head and the centre of the ankle and is the weight-bearing axis of the lower limb. The MA is a representation of the normal line of action of the ground reaction force exerted on the knee joint when standing on one leg [Maquet 1977, Cooke et al. 2007].

2.2.1.2 Femoral mechanical axis (FMA)

This is represented by a line drawn from the centre of the femoral head to the femoral centre of the knee.

2.2.1.3 Femoral anatomical axis (FAA)

The anatomical axis of the femur is the mid-diaphyseal axis of the femoral shaft. In the coronal plane, when extended distally it generally intersects the knee joint line 1cm medial to the joint centre and when extended proximally it usually passes through the piriformis fossa just medial to the medial cortex of the greater trochanter [Paley 2002].

2.2.1.4 Femoral mechanical (FM) anatomical angle

This is the difference between the anatomical and mechanical axes of the femur in the coronal plane and is measured by the angle they from as they intersect at the femoral knee centre. For a western population of normal healthy adults the mean and SD of FM anatomical angles has been measured as 5.8±1.9° [Hsu et al. 1990]. This is a similar result to studies examining subjects of Chinese origin with reported mean FM anatomical angles of 5.1±0.9° [Wang et al. 2010] and 5.7±1.0° [Tang et al. 2000].

2.2.1.5 Tibial mechanical axis (TMA)

The mechanical axis of the tibia is a line drawn from the tibial knee centre to the centre of the ankle.

2.2.1.6 Tibial anatomical axis (TAA)

This is the mid-diaphyseal axis of the tibial shaft and in relation to the TMA runs parallel and slightly medial by a few millimetres.

2.2.1.7 Mechanical femorotibial (MFT) angle

The MFT angle is formed by the intersection of the femoral and tibial mechanical axes. In the coronal plane it defines whether a knee is neutral, varus (bowlegged) or valgus (knock-kneed) aligned (Figure 2.6). In the sagittal plane it is a more dynamic measurement that constantly changes in accordance with the degree of knee flexion.

2.2.1.8 Femoral mechanical (FM) angle

In the coronal plane, this is the angle formed by the intersection of the femoral mechanical axis and a line tangent to the distal femoral condyles which defines the orientation of the femoral articular surface with respect to the FMA. There is no standardised nomenclature for measuring deviations from a perpendicular (90°) joint line which can be measured as either greater or less than 90°. However, it is common to measure from the lateral side of the joint as illustrated in Figure 2.2. Several studies have shown that the distal femoral joint surface is slightly valgus with respect to the FMA (Table 2.1). Although the values range from around 84° to 94°, approximately 95% of controls have a valgus FM angle [Picard 2007].

In the sagittal plane the distal femoral condyles are curved and therefore the FM angle cannot be routinely defined in this plane.

2.2.1.9 Tibial mechanical (TM) angle

This is the angle formed by the intersection of the tibial mechanical axis and a line tangent to the joint surface of the tibial plateau. The mean angle is in varus (Table

2.1) corresponding to the valgus angulation of the distal femoral joint line. Therefore the native joint line deviates by approximately 3° from the MA in the coronal plane. Krackow (1983) reported that this 3° varus obliquity allows the knee to maintain an optimal parallel orientation to the ground during normal bipedal stance and gait, which would otherwise result in relative joint line valgus.

In the sagittal plane the TM angle is a measure of the natural posterior slope of the proximal tibia. The angle between the joint surface and the TMA is often measured posteriorly which defines an angle <90° as having a posterior slope. Using plain radiographs, Paley et al. (1994) reported the mean and SD for normal subjects as 80±3.5°. This was similar to studies by Meister et al. (1998), who measured 79.7±1.8°, and Matsuda et al. (1999), who used magnetic resonance imaging to measure the sagittal TAA with respect to both the medial (79.3±5°) and lateral (82±4°) tibial plateaus.

Table 2.1 Distal femoral and proximal tibial knee joint orientation as reported by different authors

Date	Authors	FM angle mean ± SD (°)	TM angle mean ± SD (°)
1994	Chao et al	88.1±3.2	92.5±2.6
1994	Cooke et al	86.0±2.1	93.3±2.3
1994	Paley et al	87.8±1.6	92.8±1.5

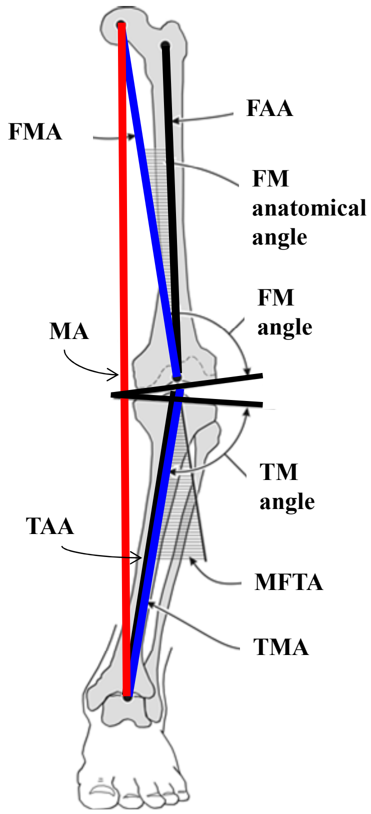


Figure 2.2 Commonly used lower limb alignment parameters in the coronal plane

2.2.2 Coronal plane

Lower limb alignment is most often considered in the coronal plane and frequently relies on radiographic detection of the necessary anatomical landmarks. In clinical practice, the standard method for obtaining the hip, knee and ankle centres and measuring overall alignment is the long-leg weight bearing radiograph. This relies on the definition and subsequent manual detection of "true" joint centres measured on 2-dimensional radiographs (discussed below). Furthermore the projected angles may not represent true lower limb alignment due to limb positioning errors [Brouwer et al. 2007a, Hunt et al. 2006].

2.2.2.1 Hip centre

This is normally taken to be the centre of the femoral head which can be determined using a template with concentric (Mose) circles (Figure 2.3).

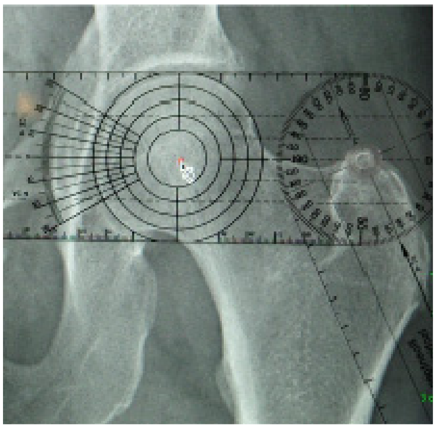


Figure 2.3 Template with concentric circles for radiographic estimation of femoral head centre

2.2.2.2 Knee centre

There is no universally accepted single point for definition of the knee joint centre with commonly used measurements illustrated in Figure 2.4. Moreland et al. (1987) performed standardised lower limb radiographs on 25 healthy volunteers and found these points to be within five millimetres of each other in a medio-lateral direction with the recommendation of a visually-selected mid-point.

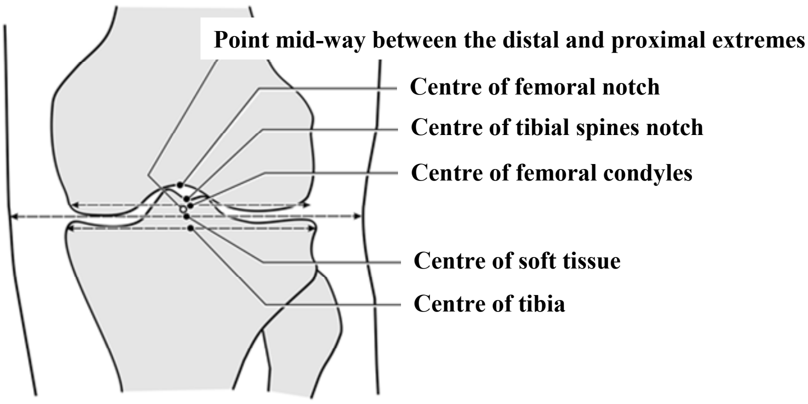


Figure 2.4 Commonly described methods of determining knee joint centre (black points) with visual estimation of "true" centre (white point) [Moreland et al. 1987]

2.2.2.3 Ankle centre

Commonly measured radiographic points to define the centre of the ankle joint are illustrated in Figure 2.5. These points are consistently within two to three millimetres of each other horizontally as reported by Moreland et al. (1987). The ankle joint centre can be represented as the mid-point of the three measured points.

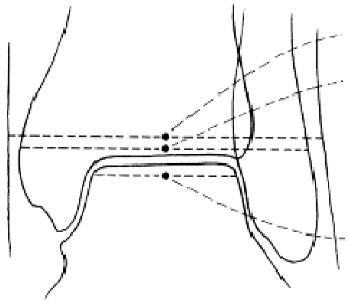


Figure 2.5 Commonly used radiographic measurements of ankle joint centre showing minimal ML variation of located points [Moreland et al. 1987]

2.2.2.4 Alignment

The relative orientation of the various lower limb axes can be used to determine coronal knee alignment in stance. From a functional perspective it is standard practice to use the mechanical measurements in order to define alignment as neutral, varus or valgus (Figure 2.6).

As a convention the MFT angle can be expressed as a displacement from 180° and so the MFT angle is 0° in neutral alignment [Cooke et al. 2007]. At this point the FMA and TMA are colinear and lie along the lower limb MA. In neutral alignment, the MA passes through the centre of the knee with the load distributed in varying proportions between the medial and lateral compartments. Maquet (1977) concluded that the knee joint force was evenly distributed, whereas Johnston et al. (1980) noted that 62% passed through the medial compartment. According to Hsu et al. (1990), an even greater proportion (75%) of the force passes through the medial compartment due to an imbalance in favour of the lever-arm force of body-weight against the counter-acting muscular forces during a single leg stance.

2.2.2.4.1 Varus

In varus malalignment the knee joint centre is lateral to the MA which creates an adduction moment and greater relative loading of the medial compartment when weight-bearing. A varus MFT angle is commonly defined as a negative angular displacement from 180° i.e. the angle between the FMA and TMA is <180° when using the convention of measuring from the medial side of the joint (Figure 2.6).

2.2.2.4.2 Valgus

In valgus malalignment the knee joint centre is medial to the MA resulting in an abduction moment and greater relative lateral compartment loading during weight-bearing activities. A valgus MFT angle can be defined as a positive angular displacement from 180° i.e. the angle between the FMA and TMA is >180° when using the convention of measuring from the medial side of the joint (Figure 2.6).

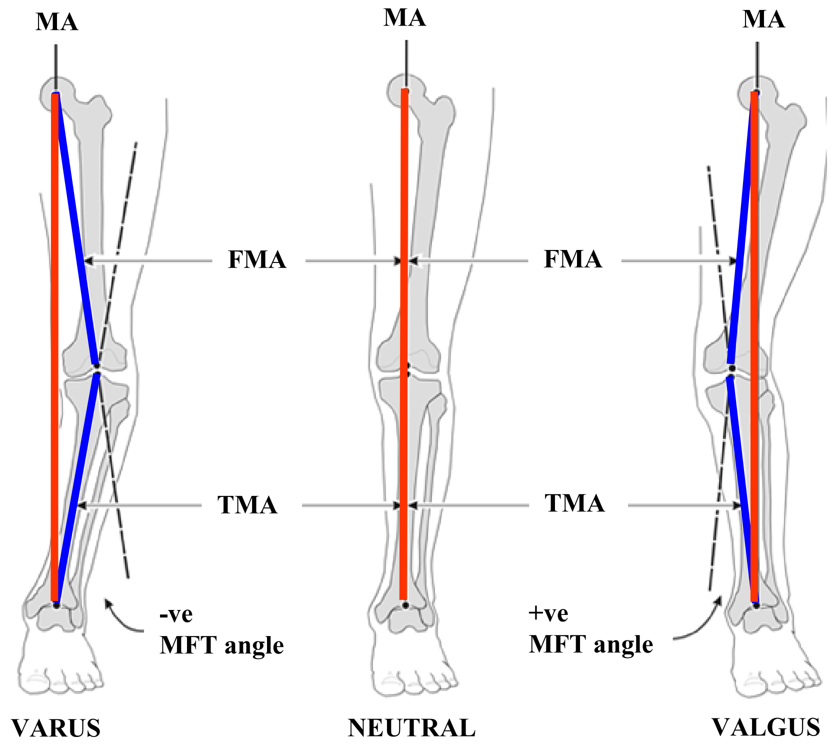


Figure 2.6 Neutral, varus and valgus coronal lower limb alignment as defined by the position of the knee centre relative to the MA

Several alignment studies using long-leg radiographs have been performed in an attempt to establish “normal” coronal standing alignment values in adult subjects with asymptomatic knees (Table 2.2). The overall mean MFT angle ranged from 2.2° of varus to 0.2° of valgus with similar standard deviations (SD) for each trial of between 2.2° and 2.9°. Therefore in spite of the mean coronal alignment being close to neutral, there is a large overall spread of values ranging from 5° varus to 5° valgus for the healthy adult population.

Most of the studies examined potential differences between sex and some categorised subjects according to age. Hsu et al. (1990) compared younger (age 25-40 years) with older (age 41-60 years) adults and found no difference between the two groups. This was a similar finding to the other studies comparing different age groups [Chao et al. 1994, Cooke et al. 1997, Wang et al. 2010]. Glimet et al (1979, 1980) assessed healthy controls over the age of 65 years whereas Moreland et al. (1987) and Tang et al. (2000) only included young adults with a mean age of 30 years and a range 21 to 31 years respectively. For both these latter studies the mean MFT angle was relatively more varus in comparison to the older subjects evaluated by Glimet et al. (1979, 1980). The presence of other confounding variables between the studies, such as race of subjects, prevents any firm conclusion being drawn with respect to age. However, given the findings of Hsu et al. (1990), Chao et al. (1994), Cooke et al. (1997) and Wang et al. (2010), and the overall similarity between the MFT angle measurements for all the studies, it is likely that age does not influence knee alignment in the healthy adult population. With regard to sex, the combined data suggests that female knee alignment is relatively more valgus than for males. This observation is supported by Wang et al. (2010) who found a statistical difference between the male and female subjects evaluated. However, this was the only study that reported a statistical sex difference.

Potential racial differences were reported by Tang et al. (2000) who compared the MFT angle measurements from Chinese subjects with similar age and sex-matched groups of white Caucasians from the studies by Moreland et al. (1987) and Hsu et al. (1990). For male subjects, there was no difference, but for females there was a statistical difference in MFT angle between the coronal alignment measurements of Tang et al. (2000) and Hsu et al. (1990).

The standing coronal alignment of asymptomatic knees is highly variable, with potential differences as a result of sex or racial origin. Therefore, as previously noted by Insall (1993), one should be cautious in defining what is "normal".

Table 2.2 Weight-bearing long-leg radiographic studies of coronal lower limb alignment in healthy adult populations, sub-divided by sex where possible. N=number of subjects

Date	Authors	N	Sex	MFT angle (°)	SD
1979	Glimet et al.	50	F	0	2.9
1980	Glimet et al.	50	M	-0.7	2.5
1987	Moreland et al.	25	M	-1.3	2.0
1990	Hsu et al.	120	Both	-1.2	2.2
1994	Chao et al.	127	Both	-1.2	2.2
1997	Cooke et al.	67	F	-0.5	2.8
		52	M	-1.6	2.8
2000	Tang et al.	25	F	-2.2	2.5
		25	M	-2.2	2.7
2010	Wang et al.	50	F	0.2	2.5
		50	M	-0.7	2.3

2.2.3 Sagittal plane

There is little information available regarding the weight-bearing sagittal mechanical axis of the lower extremity of normal subjects which may be due to the technical difficulty associated with obtaining an adequate full length lateral radiograph [Sparmann et al. 2003]. Similar to the coronal plane, the overall and segmental sagittal mechanical axes can be defined with reference to hip, knee and ankle centres.

2.2.3.1 Femoral mechanical axis

The FMA in the sagittal plane can be defined as a line from the femoral head centre to the femoral knee centre. Radiographic estimation of the latter requires a true lateral film with perfect overlapping of the femoral condyles. Subsequent definition of femoral knee joint centre remains controversial with no universally accepted single point. Two commonly described points result in a mean difference of 3° between the measured FMA [Chung et al. 2009]. The first is a point 1cm anterior to the end of Blumensaat's line (line extending through the intercondylar notch on lateral knee radiograph) [Brattstrom, 1970] and the second is a point 65% posterior on the line between the anterior cortex and the most prominent point of the posterior medial femoral condyle [Picard 2007] (Figure 2.7).

Due to the anterior bowing of the femur, the FAA follows a curved mid-diaphyseal and cannot be represented as a single straight line.

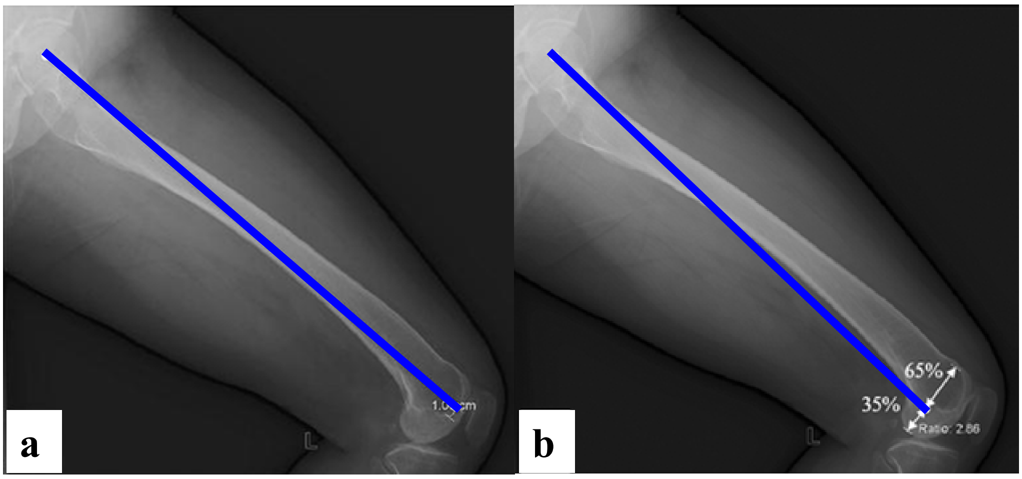


Figure 2.7 Sagittal FMA based on femoral knee centre a) 1cm anterior to the end of Blumensaat's line, and b) 65% posterior on line between anterior femoral cortex and posterior medial condyle

2.2.3.2 Tibial mechanical axis

The sagittal TMA can be defined as a line connecting the tibial knee and ankle joint centres (Figure 2.8). The tibial knee centre is often taken as the mid-point of the tibial plateau as measured on a true lateral radiograph [Han et al. 2008]. The distal point can be defined radiographically as the mid-point of the tibial plafond [Han et al. 2008] or the talar centre, determined by manually fitting a circle that incorporates a sector of the joint surface [Magerkurth et al. 2006] (Figure 2.9). From a practical point of view there is an insignificant difference between the two points for the purpose of defining an axis. In a radiographic study of 100 subjects, Magerkurth et al. (2006) measured the AP position of the talar centre with reference to the tibial anatomical axis which was found to be a mean distance of 1.7mm (range -3mm to 8mm) anterior to the TAA. It is also worth noting that the sagittal TAA, defined as a line connecting the upper and lower mid-points of the shaft, closely approximates to the TMA. Han et al. (2008) performed 133 axial computed tomographic (CT) tibial images, which were reconstructed using 3-dimensional software, and found that the TMA and TAA differed by a mean ± SD of 0.8±0.67°.

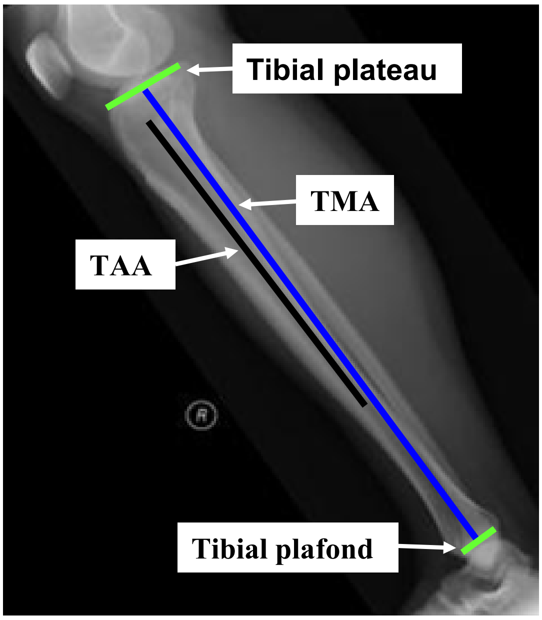


Figure 2.8 Lateral radiograph of the tibia showing a standard method of defining the TMA, which closely approximates to the TAA

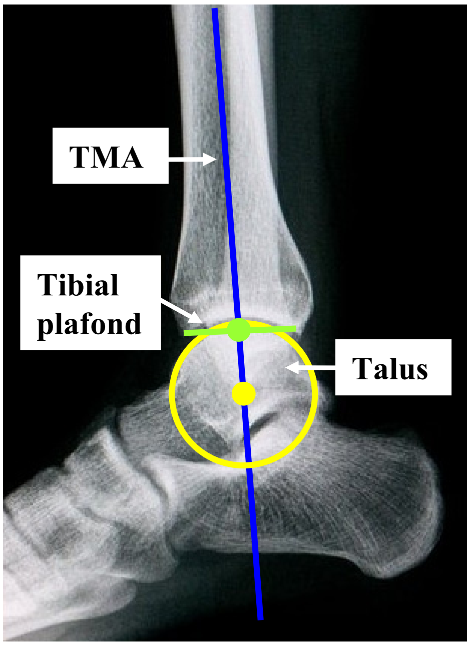


Figure 2.9 Two commonly used methods for determining distal TMA point. The centre of the talus (yellow point) has minimal AP variation from the TMA in comparison to the tibial plafond centre (green point)

2.2.3.3 Alignment

The sagittal weight-bearing axis can be represented as a line drawn from the centre of the femoral head to the centre of the ankle joint, as previously defined. The relationship of the MA to the rotational centre of the knee joint centre in the sagittal plane is dependent on the degree of flexion [Minoda et al. 2008]. Knee flexion angle therefore directly influences sagittal alignment which is a more dynamic parameter than for the coronal plane, where there is no functional range of motion. This can enable compensation for sagittal malalignment deformities such as recurvatum and procurvatum of the tibia.

When the FMA and TMA are colinear the sagittal alignment is 0°. Flexion from this position is normally defined as a positive angle and hyperextension is negative (Figure 2.10). When the flexion angle is 0°, the MA lies slightly anterior to the rotational knee joint centre [Minoda et al. 2008, Paley et al. 1994, Sugama et al. 2010] creating an extension moment that is balanced by the passive restraints of the posterior capsuloligamentous structures. With the knee “locked” in hyperextension, the MA passes even more anterior to the joint centre allowing the quadriceps muscle to relax during bi-pedal stance. If the knee cannot extend to a sufficient degree, the MA will lie posterior to the rotational joint centre and create an external flexion moment. To maintain a static standing position in this situation requires continuous contraction of the quadriceps muscle. The greater the degree of fixed flexion deformity, the greater the amount of work required by the quadriceps muscle to keep the knee extended.

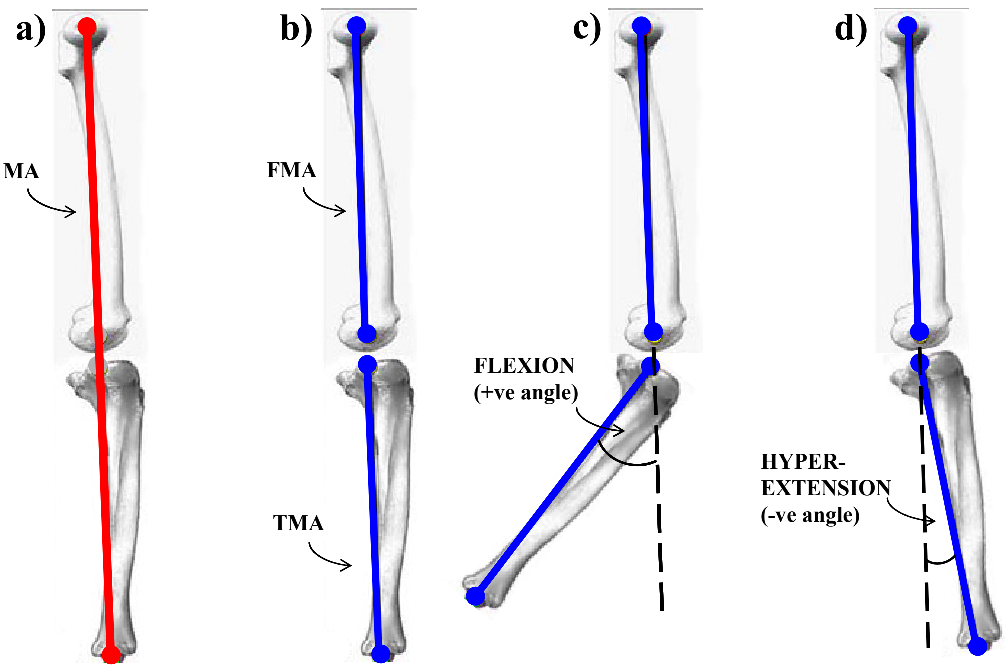


Figure 2.10 Sagittal plane alignment parameters and variation with knee flexion; a) mechanical weight-bearing axis, b) 0° of mechanical knee alignment, c) knee flexion denoted by +ve angle, c) hyperextension denoted by –ve angle

2.3 Osteoarthritis

2.3.1 Epidemiology

Osteoarthritis (OA) is the most common of all joint diseases and the knee is the most frequent large joint to be affected [Oliveria et al. 1995]. Approximately 25% of people over the age of 55 years have had knee pain on most days in a month over the past year [Peat et al. 2001], with an overall lifetime risk of symptomatic knee OA estimated at almost 1 in 2 [Murphy et al. 2008]. The natural history is highly variable, with the disease improving or remaining stable in some patients, but gradually worsening in others. It is a major cause of impaired mobility in the elderly which can prevent engagement in normal activities of daily living [Guccione et al. 1994]. With the expanding elderly population, the prevalence of OA is expected to increase, and it is anticipated that it will become the fourth leading cause of disability in the next few decades [Tanamas et al. 2009]. In addition to increasing age, risk factors include female sex, obesity, and previous knee injury or surgery [Felson 2003, Felson 2006].

2.3.2 Pathology

In spite of the frequency of OA, the exact aetiology remains obscure. Pathologically, it is characterised by fissuring and erosive lesions of hyaline cartilage progressing to more severe cartilage destruction as the disease advances. In addition to cartilage loss, there is sclerosis of the subchondral bone, cyst formation, and bony remodelling (osteophytes) at the margins of the joint (Figure 2.11). This can lead to capsular stretching and in some patients, inflammation of the joint synovium (synovitis). The distribution of OA is non-uniform and often localised to only one part of a joint. Focal areas of loss of cartilage can increase focal stress across the joint, leading to further loss. With a large enough area of cartilage loss or with remodelling of bone at the margins, the joint becomes tilted with potential malalignment developing. This is the greatest risk factor for structural deterioration of the joint since it further increases the degree of focal loading [Sharma et al. 2001].

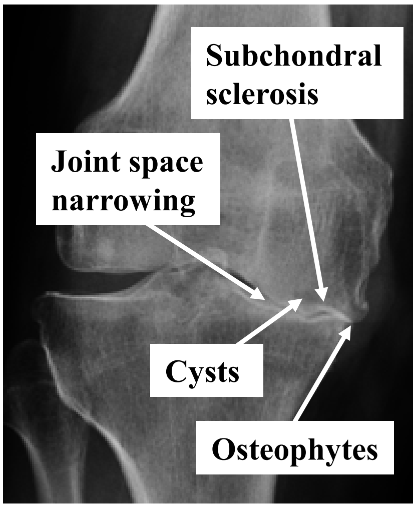


Figure 2.11 AP knee radiograph showing common features of OA

2.3.3 Diagnosis

Although the clinical picture is well-documented, there are large variations in the frequency and severity of knee OA symptoms including pain, stiffness, swelling, deformity and loss of function. Pain is usually activity-related and often precipitated by climbing stairs, getting out of a chair and walking long distances. Physical examination is a key component in the assessment of knee OA with many different potential signs. These include joint line tenderness, swelling, inflammation, reduced range of movement, abnormal gait, crepitus, weakness, instability and mal-alignment. Cushnaghan et al. (1990) found significant intra- and inter-observer variation in the detection of many commonly used physical signs for diagnosing OA of the knee. To potentially improve the reliability of physical examination, Cibere et al. (2004) implemented a strict standardisation protocol for a total of 42 physical signs and examination techniques, and reported reliable detection for 32 of them. However there was poor reliability for assessing medial and lateral joint laxity at 30° of knee flexion which the authors attributed to the subjective nature of quantifying "instability". This limitation of manually evaluating ligament tightness is particularly relevant to patients undergoing TKA as it is a technique often used to determine the need for an intra-operative soft tissue release [Mihalko et al. 2003, Whiteside 2002] (Section 2.4.5.1.4). The authors reported "adequate" reliability for the assessment of range of motion and alignment using inspection and manual goniometry. However no absolute values were given for the level of agreement between clinicians which was assessed as “adequate” on the basis of a reliability coefficient. In contrast, other studies have reported large variations in the assessment of both range of motion [Cushnaghan et al. 1990] and alignment [Markolf et al. 1976], drawing a similar conclusion that humans are poor at assessing angles [Edwards et al. 2004].

In conjunction with history and physical examination, radiographic evaluation is frequently performed in the assessment of patients with OA of the knee. The well recognised x-ray features (Figure 2.11) can help support the clinical diagnosis and provide a measure of OA severity. The radiological classification described by Kellgren and Lawrence (K/L) (1957) is the most widely used system to identify and grade the severity of OA (Table 2.3).

Table 2.3 Kellgren and Lawrence radiographic classification of knee OA

K/L grade	Radiographic features
0	Definite absence of x-ray changes
1	Doubtful narrowing of joint space and possible osteophytic lipping
2	Definite osteophytes and possible narrowing of joint space
3	Moderate multiple osteophytes, definite narrowing of joint space and some sclerosis and possible deformity of bone ends
4	Large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone ends

These criteria were adopted by the World Health Organisation (WHO) as the standard for epidemiological studies of OA [Kellgren et al. 1963]. However, in spite of more than 50 years of use, there is still widespread disagreement amongst investigators as to the optimum format of defining and interpreting the grades, with several variations described [Sciphof et al. 2008]. Whilst alternative imaging modalities, such as magnetic resonance imaging (MRI), can reveal OA changes [Bhattacharyya et al. 2003], it is likely that radiographic classification will remain the gold standard for quantifying OA for many years to come. However, in view of the poor correlation between clinical and radiographic findings [Hannan et al. 2000], patient management should ultimately be dictated by the severity of symptoms.

In addition to diagnosing and grading OA, radiographic imaging of the entire lower limb (long-leg radiograph) can also be used to assess joint malalignment. In spite of potential limb positioning errors, exposure of the pelvis to ionising radiation and the limited availability of this resource, long-leg radiographs are the current recommended gold standard investigation for assessing malalignment [Cooke et al. 2007].

2.3.4 Malalignment

Malalignment in the frontal plane is a frequent manifestation of knee OA due to asymmetrical wear of the medial (varus) or lateral compartments (valgus). When the knee is malaligned in the varus direction, the mechanical axis of the lower limb passes medial to the rotational knee centre, creating an adduction moment that increases the forces through the medial compartment when weight-bearing [Andriacchi, 1994]. Valgus malalignment results in a more laterally positioned ground reaction force vector and subsequently increased forces across the lateral tibiofemoral compartment (Figure 2.12).

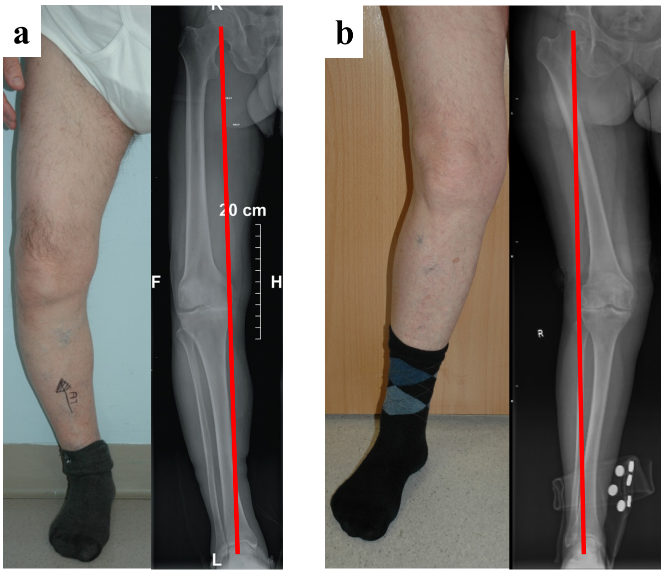


Figure 2.12 Clinical and radiological a) varus (MA medial to knee joint centre) and b) valgus (MA lateral to knee joint centre) malalignment secondary to OA

Medial OA is more common than lateral compartment disease [Ledingham et al. 1993] and subsequently, varus malalignment is the more frequent deformity affecting 53-76% of individuals with knee OA [Cahue et al. 2004, Cooke et al. 1994, Felson et al. 2004]. Natural history studies of primary knee OA have provided strong evidence that knee malalignment is an independent risk factor for OA knee progression [Cerejo et al. 2002, Cicuttini et al. 2004, Sharma et al. 2001, Tanamas et al. 2009]. Sharma et al. (2001) studied 230 individuals with knee OA and measured long-leg radiographic alignment and joint space distances at baseline and at 18 months. Varus malalignment at baseline was associated with a 4-fold increase in the risk of subsequent radiographic medial compartment narrowing at 18 months. Valgus malalignment at baseline resulted in an even greater risk of progressive lateral compartment narrowing of almost 5-fold. In addition to radiographic progression of the disease, the study also reported a greater functional decline from baseline to 18 months in patients with malalignment of more than 5° varus or valgus compared to those within these limits. Malalignment also mediates the effect of obesity on disease progression, whereby the detrimental effect of a high body mass index (BMI) appears only to be limited to patients with at least a moderate degree of malalignment [Felson et al. 2004].

Most studies investigating coronal knee malalignment have only been in the context of OA disease progression. However, in a large multicentre cohort study involving 2958 knees (1752 participants) without evidence of OA, Sharma et al. (2010) investigated the effect of varus and valgus malalignment on the incident risk of the disease. Short-leg knee and long-leg x-rays were performed at baseline for K/L grading of OA and lower limb alignment measurement respectively. Further knee radiographs were performed at 30 months for repeat grading of OA. Compartmental gap measurements were performed on baseline and follow-up radiographs for subjects with initial evidence of OA (K/L ≥2), as a measure of disease progression. The study found that in knees with OA, coronal malalignment increased the risk of progression in the biomechanically stressed compartment, confirming the findings of previous studies. In addition the study concluded that varus (defined as ≤-2°) but not valgus (defined as ≥2°) alignment was found to increase the risk of incident tibiofemoral OA, a finding that can potentially be explained from a mechanical perspective. The magnitude of the adduction moment that occurs during stance phase, even in neutrally-aligned knees, is increased with varus alignment resulting in even greater loads through the medial compartment [Hurwitz et al. 2002]. However, even although valgus alignment results in higher lateral compartment peak pressures during weight-bearing [Bruns et al. 1993], the medial compartment continues to bear proportionately more load until valgus is more severe [Harrington, 1983]. This difference between varus and valgus alignment was in agreement with a similar study by Brouwer et al. (2007) who radiographically evaluated 2664 knees (1501 participants) at baseline and at a mean follow-up of 6.6 years. In comparison to normal alignment, valgus was associated with a borderline significant increase in development of OA, and varus alignment was associated with a more significant 2-fold increased risk. However, a major limitation of this study was the use of short-leg radiographs to measure alignment based on the anatomical femorotibial angle. Previous evidence has demonstrated a poor correlation between short-leg and long-leg radiographs [van Raaija et al. 2009]. The potential discrepancy between knee radiographs and "true" mechanical alignment may explain the conflicting findings of another similar study by Hunter et al. (2007) who reported that knee alignment did not predict incident OA. Instead of a risk factor, malalignment was described as a marker of both disease severity and progression. The validity of the results can again be questioned on the basis that inaccurate short-leg knee radiographs were used to define alignment.

In spite of the limitations of the above studies, it is reasonable to conclude that both varus and valgus malalignment are independent risk factors for progression of medial and lateral compartment OA respectively. With regards to incidence risk it is perhaps less clear as to whether malalignment precedes the onset of OA or whether it occurs as a consequence of the disease. However, in view of the fact that OA is an irreversible disease of increasing prevalence [Woolf and Pfleger, 2003] and significant economic burden [Murphy et al. 2008], strategies to quantify the risk of its development or progression should be pursued. This may enable intervention at an earlier stage and postpone the need for more definitive intervention, particularly for varus knees.

2.3.5 Management

The treatment of knee OA involves alleviating pain, restoring mechanical malalignment and addressing any manifestations of joint instability. Management strategies can be broadly divided into non-operative (pharmacological and non-pharmacological) and operative strategies.

2.3.5.1 Pharmacological treatment

For relief of pain, the most widely recommended analgesics are non-steroidal anti-inflammatory drugs (NSAIDs) and acetaminophen, both of which have proven efficacy in comparison to placebo [Zhang et al. 2007a, Zhang et al. 2007b]. Although NSAIDs have modest analgesic superiority to acetaminophen [Pincus et al. 2001], they have potential for gastrointestinal complications which may require administration of a lower dose or the addition of a gastroprotecive agent such as a proton-pump inhibitor. An alternative strategy to decrease potential gastric toxicity is the use of cyclooxygenase-2 (COX-2) inhibitors, although evidence of potential increased cardiovascular risks has limited their use [Fitzgerald, 2004]. Opiate analgesic agents can be effective in controlling pain but side effects such as dizziness, nausea and vomiting, along with dependence are concerns. Glucosamine and chondriotin are commonly used oral therapies with minimal side effects but very little proven clinical benefit in patients with knee OA [Samson et al. 2007].

Intra-articular injections can potentially avoid the systemic side effects of oral regimes. Corticosteroid injections have been shown to be effective in the short term, between one and three weeks, but have diminishing efficacy beyond this [Bellamy et al. 2006]. Injections of hyaluronic acid, which is thought to augment the viscous properties of the articular compartment (viscosupplementation), have become more accepted as a treatment for knee OA over the past decade. Statistically significant efficacy has been reported in comparison to placebo but this clinical benefit is only modest and may be the result of publication bias [Lo et al. 2003].

2.3.5.2 Non-pharmacological treatment

There are many non-pharmacological interventions that aim to address the common manifestations of knee OA. Low-impact aerobic exercise can decrease pain and improve joint function [Ettinger et al. 1997], particularly if it trains muscles for normal daily activites. Isokinetic exercises (resisted flexion or extension of knee) can also reduce pain and improve stability by strengthening the supporting muscles [Baker et al. 2001] and, although the clinical importance of these effects cannot be accurately determined, the low cost and likely additional health benefits support their recommendation.

In view of the fact that the knee is a load-bearing joint (typically up to six times body weight), methods of reducing cartilage impact loading, such as a walking stick, are commonly adopted. Weight loss has been shown to improve function and, in combination with exercise, reduce pain [Messier et al. 2004]. For patients with predominant medial or lateral OA, attempts can be made to offload the affected compartment by use of an external brace. A varus or valgus directing brace is applied with the intent to alter a valgus or varus malaligned knee respectively. A systematic review of the use of valgus braces amongst patients with medial compartment OA found only limited evidence to support their use [Brouwer et al. 2008], with no evidence to support the use of a varus brace. Other methods of correcting malalignment across the knee include the use of wedged insoles or footwear orthotics. In medial OA and varus alignment, a shoe wedge that is thicker laterally is designed to move the lower limb mechanical axis laterally during walking. Although this footwear modification can decrease varus malalignment [Kerrigan et al. 2002], evidence from a randomised trial showed no difference in pain reduction compared with a neutral insert [Maillefert et al. 2001].

2.3.5.3 Operative treatment

When conservative therapy fails to control symptoms then operative intervention is normally indicated as a more definitive treatment. The type of procedure is dependent on patient factors and the nature of the OA. Localised articular cartilage defects can cause significant impairment, particularly in young active adults, and there are a variety of interventions to address the problem. Bone-marrow stimulation techniques such as abrasion arthroplasty, drilling and microfracture attempt to induce the formation of fibrocartilage repair tissue [Steadman et al. 2002]. Although promising short term results have been achieved, the clinical durability of the repair tissue and the clinical improvement declines over time [Knutsen et al. 2007]. An alternative approach involves restoration techniques such as osteochondral autograft or allograft which attempt to replace the defect with either host or donor cartilage respectively. Both these techniques have proven short-term and long-term success with clinical outcomes related to patient-specific and defect-specific factors [Harris et al. 2010].

For more generalised primary OA, arthroscopic washout and debridement is sometimes performed for attempted short-term relief of symptoms. However, a systematic review that included three randomised controlled trials concluded that arthroscopy had no clinical benefit and hence no role in the treatment of symptomatic OA of the knee [Laupattarakasem et al. 2008].

More definitive intervention generally requires the operative fusion, realignment or replacement of an osteoarthritic joint. Joint fusion (arthrodesis) can successfully alleviate pain but with obvious functional limitations. It is therefore largely historical for the primary treatment of knee OA, and its current indication is mainly as a salvage procedure for failed TKA [Lai et al. 1998].

Realignment surgery (osteotomy) aims to transfer the mechanical axis of the lower limb away from the arthritic load-bearing region of the joint, and is considered an option for more active patients with unicompartmental OA. One systematic review examined various osteotomy surgical techniques and concluded that there was limited evidence for its efficacy [Brouwer et al. 2007b]. However, conflicting evidence from a case series [Dahl et al. 2005] and a randomised controlled trial [Adili et al. 2002] demonstrated statistically significant and clinically important improvements in pain, function and stiffness following valgus tibial osteotomy.

Unicompartmental knee arthroplasty (UKA) is an alternative option to osteotomy when OA involves only one compartment, and is most commonly performed on the medial side. Over the past decade the popularity of UKA has increased [Willis-Owen et al. 2009] with proponents of this procedure citing preservation of uninvolved soft tissue and bone, rapid recovery and maintenance of normal knee kinematics as reasons for its use [Newman et al. 1998]. Although there is debate regarding the indications and contraindications [Murray et al. 1998], the generally accepted requirements for UKA include; (1) pre-operatively correctable varus or valgus deformity back to a more neutral alignment, (2) functional ACL, (3) minimum of 90° flexion, (4) flexion contracture of less than 10-15°, (5), no significant OA in the other compartments, and (6) non-inflammatory arthritis. The diagnosis of unicompartmental OA and the decision to perform a UKA is normally made on the basis of patient history, physical examination along with radiographic findings. In particular, the assessment of coronal and sagittal mechanical alignment forms an important part of the assessment. Varus or valgus malalignment that is judged to be manually incorrectable pre-operatively usually indicates a rigid deformity that cannot be adequately balanced with a UKA. In this circumstance, if a UKA is performed, the implant may be overstressed with a greater risk of early failure [Gulati et al. 2009]. Conversely, over-correction of a deformity can result in progressive OA in the adjacent compartment with early failure within the first five years after insertion [Weale et al. 2000].

Assessments of coronal malalignment and knee flexion generally rely on clinician estimates of MFT angles and so are susceptible to human measurement errors [Edwards et al. 2004, Markolf et al. 1976]. Stress radiographs can be used as an adjunct to clinical examination for a more quantitative measure of deformity correction and to identify any collapse of the adjacent “normal” knee compartment. However, radiographic techniques for measuring tibiofemoral gap distances and mechanical alignment, even with long-leg radiographs, are prone to errors (Section 2.6.1). Computer-assisted surgery (Section 2.5) can enable accurate intra-operative real-time assessment of limb alignment, including angular displacement with manual stress, and therefore should diminish the risk of overcorrection or undercorrection. Although this technology can more reliably achieve a desired MFT angle [Keene et al. 2006], the optimal coronal alignment following medial UKA has yet to be determined, with some surgeons regarding it as primarily a ligament-balancing procedure. Furthermore, this measurement tool is not available in a clinical setting and therefore cannot help with pre-operative planning or determining the suitability of a patient for this procedure.

Patient selection has been shown to be a crucial factor for the success of this procedure in combination with surgical expertise and can result in good long term results being achieved [Murray et al. 1998, Svard et al. 2001]. However, with limited objective measurement tools, appropriate patient selection for UKA can be difficult and may account for concerns regarding early failures [Fehring et al. 2010, Furnes et al. 2007, Heck et al. 1993]. A ten-year report from the Norwegian Arthroplasty Register concluded that survival of cemented UKA was inferior to that of cemented TKA in all age-categories with a relative risk of revision of 2 [Furnes et al. 2007]. Data from the Swedish Knee Arthroplasty Register echoed this concern and reported poorer survivorship of UKA compared to TKA [Lidgren et al. 2003]. However, the use of revision rate as an outcome measure should be interpreted with caution as there may be a lower threshold for revising UKAs to TKAs in patients who are typically younger, more active and potentially less tolerant of knee pain [Goodfellow et al. 2010]. Revision rates from joint registry data may therefore not provide a reliable means of comparing the success of these two implants. Nonetheless, in patients with unicompartmental OA, the potential advantages of UKA should be weighed up against the risks of early failure, and every effort made to ensure appropriate patient selection. In the absence of reliable preoperative and intraoperative measurement tools, recognition of contraindications may not always be possible.

2.4 Total knee arthroplasty (TKA)

In spite of a relatively short history, primary TKA is now firmly established as a safe, predictable and reproducible procedure. Its success depends on several factors, including appropriate patient selection and follow-up, prosthesis design and surgical technique with particular regards to alignment of the leg and balancing of the soft tissues that support the knee [Hungerford et al. 1985, Insall et al. 1985].

The first attempts at knee replacement surgery were by Gluck more than 100 years ago [Munzinger et al. 2004], which resulted in early failure, mainly as a result of inadequate sterilization techniques. It was not until the 1950s that TKA became more widely used. Early designs were constrained hinge joints, such as the Shiers (1954) and Walldius (1957) metal-on-metal hinge arthroplasties, and were implanted press-fit as bone cement was not available. They lasted several years before loosening as a result of significant constraint and poor fixation. The rigid axis also led to large amounts of metal wear which further contributed to the early failure. It soon became recognised that a fixed axis knee bearing should be avoided and this led to the development of condylar replacements which were conceived by several groups during the late 1960s and early 1970s.

2.4.1 Condylar TKA

The term "condylar total knee arthroplasty" can be defined as a knee resurfacing implant that consists of a single-piece femoral component covering both medial and lateral condyles and a single-piece tibial component resurfacing both medial and lateral tibial plateaus [Robinson, 2005] (Figure 2.13). This enabled resurfacing of the distal femur and proximal tibia with implants that resembled the natural knee, with constraint provided by the supporting ligaments. In general there were two distinct approaches to the challenge of creating a condylar TKA with stability, longevity and adequate range of motion. The first was an anatomical one involving implants that preserved most or all of the constraining soft tissues of the knee with fixed implant surfaces that avoided conflict with these constraints [Yamamoto, 1979]. The second approach was based on a functional one and attempted to simplify knee mechanics by resecting cruciate ligaments or designing movable joint surfaces to avoid conflict with the kinematics resulting from the soft tissues. One of the earliest examples based on this approach was the Freeman-Swanson knee prosthesis [Freeman et al. 1973] with many other innovators working on similar ideas throughout the 1970s. Although the two different approaches led to varying designs, the common goal of recreating optimal knee function led to more similarities than differences and reflected the on-going evolution of the understanding of knee kinematics.

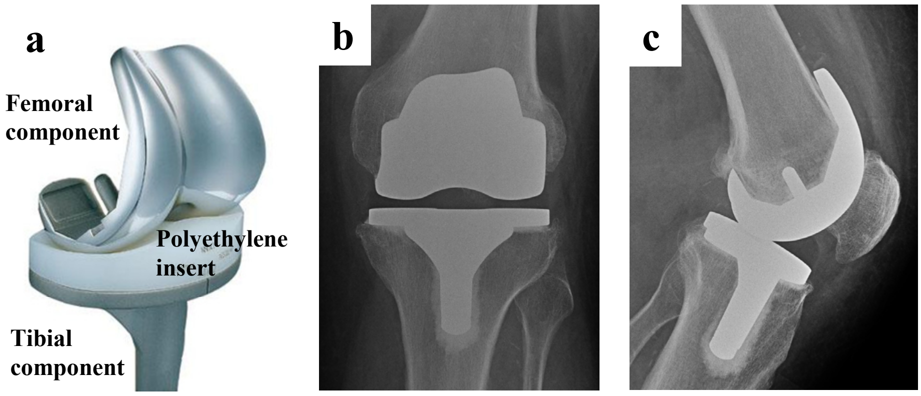


Figure 2.13 **a)** Condylar TKA components and post-operative b) AP and c) lateral radiographs of implant in-situ

2.4.1.1 Design compromise

Although there are many different examples of condylar TKA in current use, they are all conceptually similar in design. The conformity of the implants and subsequent degree of constraint is often determined by whether the posterior cruciate ligament (PCL) is retained or sacrificed. PCL-retaining implants have low conformity with a round-on-flat design and this is thought to more closely replicate knee kinematics by permitting femoral rollback. This has been reported to improve passive range of motion and the mechanical efficiency of the supporting knee muscles [Andriacchi and Galante, 1988]. However this belief is controversial, with evidence suggesting that the PCL does not function in the same way as a normal knee [Misra et al. 2003] and therefore should be resected. Freeman et al. (1977) described several advantages of PCL resection including deformity correction, enhanced exposure of the proximal tibia and ease of balancing the collateral ligaments. Furthermore the low conformity associated with PCL-retaining TKA designs can in theory lead to areas of high contact stress resulting in greater polyethylene wear [Pagnano et al. 1998]. PCL-substituting TKAs have increased conformity in both the sagittal and coronal planes overcoming the problems associated with high contact stresses. However this increased constraint can result in greater forces being transmitted to the bone-cement-implant interface with a potentially increased risk of loosening [Insall et al. 1982]. Therefore condylar design is a compromise between constraint (less contact stress) and achieving more normal knee kinematics (higher contact stress). Whatever the prosthetic model implanted, the ultimate and shared goal is a stable, well-aligned TKA that will provide the best longevity current materials can offer.

2.4.2 TKA alignment

Alignment is a relative term that is defined with respect to an axis or a plane (Section 2.2). In TKA there are two separate concepts of alignment, that of the implants and that of the lower limb as a whole. With regards to the implant, alignment is normally controlled in coronal, sagittal and transverse planes. Of these, the coronal and sagittal planes are the most important determinants of overall mechanical limb alignment and will be discussed in more detail.

2.4.2.1 Coronal plane

There is widespread agreement that in the coronal plane both the femoral and the tibial components should be placed perpendicular to the mechanical axis of the bones [Jeffery et al. 1991, Lotke and Ecker, 1977]. If this is achieved the MFT angle will be 0° and will result in the mechanical axis of the limb passing through the centre of the component. In contrast to normal knees (Section 2.2.2.4), where there is a variation in coronal alignment, restoring the MFT angle of the lower limb to 0° in prosthetic knees is aimed at preventing uneven varus-valgus contact pressure on the polyethylene and potential early failure [Moreland, 1987, Wasielewski et al. 1994]. Deviation beyond 0°±3° is thought to diminish implant durability and support for this post-operative target window is based on both in-vitro and in-vivo (clinical) evidence.

A cadaveric study by Werner et al. (2005) examined several biomechanical consequences of poor coronal tibial component alignment with the application of extension and simulated gait loads. Tibial malposition of greater than 3° varus or valgus was found to significantly alter pressure distribution and load between medial and lateral compartments during static loading and simulation of gait cycle. A similar finding was demonstrated by Green et al. (2002) who evaluated the proximal tibial strain of cemented TKA components during mechanical loading with three times body weight on fourteen paired fresh-frozen cadaver tibiae. For implants in 5° varus, there was a statistically increased area of highly concentrated strain in comparison to neutral alignment where the strain was almost equal on medial and lateral sides. The neutral tibiae revealed no significant increase in medial strain even when 75% of the load was placed on the medial side. The increased medial strain observed in varus tibiae was consistent with the overload of cancellous bone found by Bartel et al. (1982) in a finite element model of eccentric tibial loading. D'Lima et al. (2001a) also used finite element modelling to assess polyethylene contact stresses with different degrees of tibiofemoral conformity and alignment. Single condyle loading significantly increased mean and peak tibiofemoral contact stresses in both low, and to a lesser extent, high conformity conditions. The same authors [D'Lima et al. 2001b] performed a knee wear simulator study and found that 3° of varus malalignment significantly affected the quantity and surface distribution of polyethylene wear in comparison to neutral.

In-vitro evidence therefore is supportive of neutrally aligned TKA components with particular recognition of avoiding varus.

In contrast to the more controlled environment of in-vitro biomechanical tests, the clinical effects of TKA positioning are more difficult to quantify. In the absence of infection, a commonly used outcome measure is mechanical failure of implants leading to revision as a result of polyethylene wear, component loosening, instability, malalignment, extensor mechanism dysfunction or patellofemoral problems [Berend et al. 2004, Sharkey et al. 2002, Windsor et al. 1989]. However the use of revision rate as a measure of implant failure may not be entirely valid due to the fact that well-functioning knee replacements may lead to higher patient activity levels in comparison to poorly functioning implants that are mal-positioned. This could paradoxically result in worse survivorship for "good" knees.

The combination of tibial and femoral component orientation relative to the MA determines the post-operative MFT angle which is normally used to define overall TKA alignment (Figure 2.14). Pioneers of modern total condylar knee replacements, such as Freeman and Insall, recognized as far back as the 1970s that alignment was an important factor for wear patterns and subsequent survival of TKA components [Freeman et al. 1978, Insall et al. 1979]. This view was reinforced by Lotke and

Ecker (1977) who reviewed a series of 76 of their geometric TKA implants comparing early clinical results with radiographic positioning. A statistically significant positive correlation between a good clinical result and a well positioned prosthesis was reported and four out of the five instances of mechanical failure were in varus-positioned tibial components. However this study was performed between 1972 and 1974, a time when TKA was in its infancy prior to modern cementation techniques. Furthermore, the radiographic measurement of alignment was made with short-leg films so was prone to errors [Bonnici and Allen, 1991], and the measurement of clinical outcome was with a non-validated scoring system. This was also the case with other TKA survivorship studies around this time. Bargren et al. (1983) evaluated the Freeman-Swanson TKA between 1971 and 1975 and reported failure rates of 67% for varus knee prostheses versus 29% for knee prostheses in a neutral position. The study used only short-leg radiographs and a limited definition of a satisfactory outcome based on an improved range of movement, better function and less pain compared with the pre-operative state. Ranawat and Boachie-Adjei (1988) looked at TKA survivorship in 87 consecutive patients (112 knees) with a follow-up period of up to 11 years. A more reliable clinical scoring system was used (Hospital for Special Surgery knee disability score sheet) [Insall et al. 1979], but alignment measurements were again limited by the use of short-leg x-rays.

In spite of the drawbacks of early evaluations of malalignment, there were many subsequent studies that addressed these early limitations and reported similar findings that coronal malpositioning can lead to early loosening, increased polyethylene wear and poor overall function. Jeffrey et al. (1991) reviewed a series of 115 early condylar knee replacements from 1976 to 1981 with between 8 and 12 years of follow-up. This study used long-leg radiographs for all pre-operative and post-operative measurements in addition to the use of a recognised scoring system [Aichroth et al. 1978] to correlate clinical outcome with alignment. In spite of long-leg radiographs still being prone to measurement errors associated with lower limb positioning [Krackow et al. 1990b, Siu et al. 1991, Swanson et al. 2000], the study provided strong evidence that deviation of mechanical alignment beyond 0°±3° can result in poor implant survival. Components that were outwith this range had a 24% incidence of aseptic loosening at a median of 8 years compared with 3% aseptic loosening for components within a range of 0°±3°. Ritter et al. (1994) performed a survival analysis on 351 PCL-retaining TKAs up to 13 years post-operative follow up. Most of the reported failures were in varus-aligned knees with a smaller proportion in the neutral-aligned group and none in the valgus group. This led to the conclusion that surgeons should aim to align TKA implants in neutral or slight valgus. Additional evidence has supported the recommendation that varus alignment of the tibial component should be avoided. Aglietti and Buzzi (1988) evaluated 85 posteriorly stablised TKA implants, with an average follow up of 5 years, and found that any tibial component with a varus tilt of more than 2° had a considerably greater occurrence of radiolucent lines. They also concluded that optimal fixation of the tibial component occurred when it was positioned perpendicular to the tibial mechanical axis. More recent work by Berend et al. (2004) looking at 3152 TKAs also reported increased failure associated with varus tibial component alignment but in this study the threshold was more than 3°. However these findings are again limited by the use of short-leg radiographs to define tibial alignment, with the potential degree of measurement error invalidating the suggestion of specific varus malalignment limits. Nonetheless, the higher failure rates associated with varus aligned tibial components are consistent with the findings of several in-vitro studies detailed above as well as evidence provided by retrieval analysis of polyethylene tibial inserts during revision surgery showing a higher incidence of medial wear patterns [Wasielewski et al. 1994].

The collective evidence to date supports the widely held view that coronal alignment is important for the longevity of TKA implants but it is perhaps not strong enough to support the specific limits of 0°±3°. This was highlighted in a recent study by Parratte et al. (2010) looking at the 15 year implant survival rate following 398 modern TKAs performed between 1985 and 1990. Long-leg radiographs were used to define post-operative limb alignment as being in either a mechanically aligned group (0°±3°) or an outlier group (>3°). A mechanically aligned TKA did not confer an advantage in terms of survival with revision for any reason as the end point. In particular the two groups showed no difference in rates of mechanical failure, aseptic loosening or radiographic wear as measured end points. This survivorship study also questioned the quality of the clinical evidence supporting a post-operative alignment target of 0°±3° and suggested that this range may be too broad and imprecise to apply to every patient. In a review article, Sikorski (2008) shared the view that there is no good reason to believe that 3° represents a definitive value for the acceptability of alignment. However, neither Sikorski (2008) nor Parratte et al. (2010) could propose an alternative ideal post-operative limb alignment value acknowledging that, in the absence of additional data, an MFT angle of 0° should remain the current standard for comparison if other targets are introduced. Therefore a continued aim is to orientate both the femoral and tibial component perpendicular to the lower limb MA in order to achieve this neutral alignment.

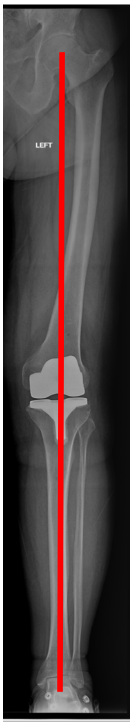


Figure 2.14 TKA positioned with coronal MFT angle of 0° as measured by weight-bearing long-leg radiograph

2.4.2.2 Sagittal plane

In contrast to the coronal plane, sagittal alignment of TKA components has not been studied as thoroughly [Yoo et al. 2008], but is kinematically important as the majority of motion occurs in this plane. In the coronal plane, orientation of components is routinely measured with respect to the well-defined weight-bearing MA of the lower limb. However the sagittal plane does not have an equivalent to the fixed coronal MA as a result of the load bearing axis changing instantly with the degree of knee flexion (Section 2.2.3). Several axes have been suggested but there has been no universal agreement for either tibial or femoral component sagittal orientation [Chung et al. 2009, Han et al. 2008, Yoo et al. 2008].

For the tibial component, the degree of posterior slope is important as it affects the biomechanics of both the tibiofemoral and patellofemoral joints, and can influence the success of a TKA procedure [Han et al. 2008]. There is a variation between different implants for the recommended “ideal” posterior slope on the basis of the geometric design of the prosthesis and whether the PCL is retained or substituted. However the lack of consensus by researchers and manufacturers regarding the reference axis makes it difficult to know what to aim for intra-operatively and how to subsequently measure it. Ewald (1989) recommended a cut perpendicular to the tibial MA and used a component that did not incorporate a slope. Insall et al. (1979) also recommended a perpendicular cut but, obtained a 7° posterior slope through the tilting of the tibial prosthesis. Townley (1985) used an implant without any posterior tilt but aimed to perform a cut between 6° and 9°. Hoffman et al. (1991) used a more patient-specific approach and varied the tibial cut according to the pre-operative posterior slope.

In addition to the variations of the target tibial cut, there are several different vertical tibial axes and depending on which is used, the measured posterior slope may change by up to 5° [Han et al. 2008]. Of the different axes described, several authors believe that the tibial MA, defined as a line from the centre of the proximal tibial plateau to the centre of the distal tibial plafond (Section 2.2.3.2), may be the ideal reference [Genin et al. 1993, Han et al. 2008]. This measurement, along with the tibial slope, can be obtained from conventional plain radiographs but with limited reproducibility due to rotational artefacts [Lonner et al. 1996]. Therefore any discussion regarding tibial slope should firstly define the reference axis used and acknowledge the limitations based on potential measurement errors.

Similar to the tibial component, femoral implant positioning is limited by a lack of standardised reference axes, with few studies exploring the clinical implications of malpositioning in the sagittal plane. However, femoral component positioning in this plane can influence the kinematics of a TKA in several ways. If the component is overly flexed relative to the sagittal FMA then it can limit knee extension or lead to increased polyethylene wear in posterior-stabilised implants due to impingement between the anterior part of the insert and the anterior margin of the intercondylar box [Puloski et al. 2001]. If the prosthesis is overly extended then there is a risk of creating a notch in the anterior femoral cortex when making the bone cuts, with increased risk of subsequent supracondylar fracture [Ritter et al. 2005]. The definition of excessive flexion or extension is clearly a relative term that is dependent on a measured axis. References based on the anatomy of the femoral shaft are limited as a result of the natural and variable anterior bowing of this long bone, which prevents the MA from being represented by a single intra-medullary line (Section 2.2.1.2). This is a particular problem with conventional instrumentation that relies on the direction of the alignment rod within the femoral shaft (Section 2.4.4).

Component positioning relative to the femoral MA can overcome the variable anatomy of the bowed femur but is again limited by lack of agreement of its precise definition, especially with regards to the femoral knee centre. Therefore in spite of computer-assisted technology (Section 2.5) enabling its intra-operative measurement, the sagittal femoral MA has been defined using different landmarks and target component alignment in previous studies has varied widely from 0° to 5° [Chung et al. 2009]. Outwith the operating theatre, the clinical measurement is again limited by the errors associated with plain radiographs.

2.4.3 Supine vs. weight-bearing alignment measurements

In addition to the errors associated with radiographic measurements, even with gold-standard long-leg films (Section 2.6.1), a further limitation of TKA alignment targets is the potential discrepancy between supine and weight-bearing conditions. This is a fundamental problem as the intra-operative measurement of alignment during knee surgery is performed on patients who are supine, with subsequent validation using weight-bearing radiographs. This standard practice makes the assumption that mechanical knee alignment is the same for both lying and standing conditions. However knee alignment is not a fixed parameter and has potential for angular displacement following the application of varus-valgus loads. In this situation alignment is a dynamic measurement that is affected by the restraining properties of the supporting soft tissues in addition to the bony congruency of the tibiofemoral joint. In addition there is also the potential influence of muscular tone in standing subjects which is absent in anaesthetised patients during surgical procedures.

The dynamic nature of coronal knee alignment has been recognised in several studies. Edholm et al. (1976) performed an orthoradiographic study on healthy subjects and found that the potential change in MFT angle between supine and standing conditions was affected by the degree of collateral knee instability. Sanfridsson et al. (1996) noted relatively more varus alignment during one-legged stance compared to two-legged stance due to the greater adduction moment forcing the knee into varus when standing on one leg. Brouwer et al. (2003) investigated the relationship between supine and standing knee alignment for subjects with medial OA and varus malalignment. Lying and weight-bearing (single-leg stance) long-leg radiographs performed on 20 subjects demonstrated a mean difference of 2° relative varus when standing. The degree of collateral laxity was also measured and was found to show no correlation with degree of MFT angle. However the grading system used [Insall et al. 1976] was highly subjective and so the validity of this finding can be questioned.

With regards to prosthetic knees, there is limited information regarding the relationship between intra-operative supine and post-operative standing measurements of alignment which may be due to the previous absence of a reliable intra-operative measurement tool. Attempts to assess knee alignment intra-operatively have mainly involved fluoroscopy and have been shown to have significant potential for error [Sabharwal and Zhao, 2008]. Computer-assisted technology (Section 2.5) has provided surgeons with more accurate intra-operative measurement tools that permit real time assessment of lower limb alignment [Bathis et al. 2004, Chauhan et al. 2004b, Stulberg et al 2002]. These systems have high levels of precision and can achieve angular measurements of within 1° [Haaker et al. 2005]. Yaffe et al. (2008) utilised this technology and assessed the relationship between supine navigation and standing radiographic measurements of limb alignment for patients undergoing computer-assisted TKA. The authors reported a discrepancy between the two assessment techniques, with pre-operative radiographic and pre-implant navigation measurements varying as much as 12° and post-implant navigation and post-operative radiographic measurements differing by up to 8°. The findings from this study were used to highlight the potential inaccuracy of radiographic measurements rather than recognise that the discrepancy between the two systems may be largely the result of the difference between the supine and standing conditions.

There are clear knowledge gaps on the subject of knee alignment and an improved understanding of the relationship between supine and weight-bearing conditions may be important for the monitoring of patients with OA, the subsequent planning of surgical interventions and the assessment of treatment outcomes. This may ultimately lead to a reassessment of the surgical goals of TKA.

2.4.4 Conventional TKA instrumentation

2.4.4.1 Alignment

In spite of limited clinical evidence, a common alignment target is the establishment of a joint line perpendicular to the lower limb coronal MA (Section 2.4.2.1). Current traditional instrumentation approaches to establishing proper orientation of distal femoral and proximal tibial cuts involve either intramedullary (IM) or extramedullary alignment rods (Figure 2.15).

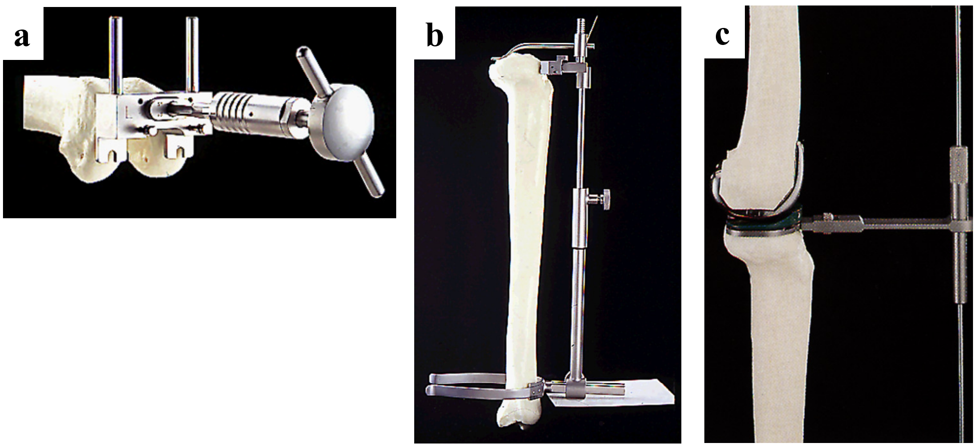


Figure 2.15 a) Femoral IM, b) tibial extramedullary and c) overall lower limb manual alignment guides

For tibial axial alignment an extramedullary jig is most frequently used with the aim of aligning the centre of the knee to the centre of the ankle. This relies on the identification of external anatomical landmarks in order to estimate the joint centre and align the cutting jig in the desired position. Erroneous medial or lateral placement at the ankle can lead to valgus or varus error respectively. Teter et al. (1995) reported that 8% of tibial cuts were malaligned by more than 4º in the coronal plane when an EM alignment guide was used. In the sagittal plane, the AP position of the guide at the ankle is normally used to determine the angle of the proximal tibial cut and is entirely dependent on human judgement.

For the femur, an IM alignment rod is the most widely used method for making the distal bone cuts due to the difficulty of aligning an extramedullary guide parallel to the shaft of the bone. In the coronal plane, the cutting block used to make the distal cut is orientated at a pre-determined valgus angle relative to the femoral shaft to achieve a cut that is aimed at being perpendicular to the MA. This valgus resection angle can be either fixed at a specific value for all patients, typically around 6º valgus, or based on a patient-specific radiographic measurement of the femoral mechanical (FM) anatomical angle (Section 2.2.1.4). The use of a fixed angle assumes little or no variation in the FM anatomical angle between different individuals but suitability of this practice can be challenged. Desme et al. (2006) reported a difference between the FM anatomical angles of varus and valgus osteoarthritic knees which were radiographically measured as 6.3º (SD 1.3º) and 4.7º (SD 1.4º) respectively. The use of a variable resection angle based on a pre-operative x-ray may increase the chance of achieving the desired distal femoral cut but is still subject to radiographic errors. In addition, execution of the pre-operative plan relies on the IM guide achieving the desired position within the femoral canal which in turn can depend on the identification of the correct entry point. A misplaced point of entry can result in the direction of the rod being significantly different from the true overall axis of the femur. In a cadaveric study, Mihalko et al. (2005) clearly demonstrated that entry point deviation of just 5mm anteriorly or posteriorly may result in a significant change in the sagittal femoral MA. Other studies have shown considerable variability of femoral coronal alignment using intramedullary instrumentation due to differences in canal diameter and more medial or lateral entry points [Nuno-Siebrecht et al. 2000, Reed and Gollish 1997].

In spite of improvements in the design and usability of mechanical alignment jigs, even the most elaborate systems are dependent on the knowledge and experience of the operating surgeon [Feng et al. 1994] and ultimately rely on visual inspection to confirm the accuracy of implant orientation and limb alignment.

2.4.5 Soft tissue management

The concept of "ligament balance" was described in the early years of knee arthroplasty surgery [Freeman et al. 1977, Insall et al. 1979] and since then the basic principles have remained largely unchanged. Along with correct alignment, ligament balance is believed to be a major component of TKA surgery and is an important requirement for a successful outcome. This view is supported by several clinical studies that have illustrated the detrimental effects of imbalance on both short term function [Unitt et al. 2008] and long term survival of implants [Sambatakakis et al. 1991, Wasielewski et al. 1994, Windsor et al. 1989].

In simplistic terms a knee with OA may have supporting ligaments that are either contracted or stretched. The surgical goal of achieving a balanced joint is based on the assumption that there should be a uniform tension around the entire knee and that this should be maintained throughout the range of flexion and extension [Sikorski 2008]. However there is very little objective evidence to support this belief and, in the native knee, it has been shown that tensions may not be symmetrical [Okazaki et al. 2006, Yoo et al. 2006].

In TKA surgery, the concepts of alignment and soft tissue balance are closely related and have a complex interaction. Component orientation in any plane can affect the joint gap and subsequent tension of the supporting tissues and for simplification, balancing of the knee is considered primarily in the coronal and sagittal planes.

2.4.5.1 Coronal plane

In the coronal plane options exist for balancing deformities from skin incision to final prosthetic implantation and depend on both the type of deformity and its severity.

2.4.5.1.1 Varus deformity

Predominant medial compartment OA is more common than lateral compartment disease and as a result varus malalignment is a more frequent deformity than valgus [Deakin et al. 2011]. Surgical planning often commences in the outpatient clinic when the patient is first assessed. Clinical and radiographic assessment of the deformity along with an estimate of whether this is "correctable", "partially-correctable" or "fixed" [Krackow 1990a] can influence the choice of surgical approach and predict the likely need for any soft tissue releases. For the varus knee the standard approach is medial parapatellar. Following this, either the soft tissues are released if they are judged to be tight or the bone cuts are performed first as this can alter the surrounding soft tissue tension and potentially avoid the need for any release [Whiteside et al. 2000]. If it is deemed necessary to perform a release then the surgical technique has been acknowledged as technically demanding [Whiteside et al. 2000] involving ligaments whose restraining properties vary in accordance with the degree of knee flexion [Grood et al. 1981, Markolf et al. 1976, Noyes et al. 1980]. In addition, the contracture and stretching of the supporting structures that occurs in osteoarthritic knees can effect the tension of the ligaments unequally during flexion and extension [Whiteside et al. 2000]. Therefore the surgical technique of balancing the collateral soft tissue structures is different for these two knee positions and will be mainly considered in extension in this thesis.

In addition to the subjective nature of judging whether ligaments are tight or lax, there are also many different soft tissue release sequences described in the literature [Engh 2003, Krackow and Mihalko 1999, Matsueda et al. 1999, Whiteside et al. 2000, Winemaker 2002]. However, in general terms they all follow the same logical principles involving the release of restraining tissues on the medial aspect of the knee in a progressive sequence that leads to increased angular displacement with either a manual stress or an instrumented gap-balancing tool. A common release order is deep MCL, posteromedial corner with attachment of semimembranosus, superficial MCL and PCL [Ramachandran, 2007]. Ideally the release should be performed in a controlled and predictable sequence leading to small incremental changes in medial laxity until the deformity is deemed to be adequately corrected. It is important to avoid over correction of the deformity which may result in instability of the knee joint and the requirement for a more constrained implant.

2.4.5.1.2 Valgus deformity

TKA surgery on valgus-aligned knees is widely acknowledged as being more technically demanding than varus knees. Fixed valgus contractures are often associated with additional deformities such as flexion contractures, femoro-tibial malrotation, hypoplasia of the lateral femoral condyle and subluxation of the patella [Munzinger et al. 2004]. In addition, valgus knee deformities are more common in patients with rheumatoid arthritis where the bone quality is often poor. Nonetheless, the principles of achieving deformity correction are the same as for varus knees and involve a sequential approach to the release of the restraining structures on the lateral aspect of the knee. In valgus knees this often begins with a lateral retinacular approach which provides a more direct access to the structures that require potential release. However, many surgeons still prefer to use a medial approach as they may be more familiar with this. Following exposure of the joint a common order of release, described by Insall et al. (1979), is as follows: lateral capsule, iliotibial band (tight in extension), popliteus (tight in flexion), LCL, intermuscular septum and lateral head of gastrocnemius muscle.

2.4.5.1.3 Soft-tissue release and clinical outcome

There is a general lack of data correlating soft tissue release with TKA outcome which may be largely due to the subjective nature of knee laxity assessment. It is assumed that a ‘well-balanced’ knee will perform better than one that is imbalanced and it has been reported that post-operative instability is often caused by poor ligament balancing [Takahashi et al. 1997]. Some authors suggest that a small degree of imbalance may be tolerable providing the knee is well-aligned [Moreland, 1988]. Unfortunately, most methods for defining knee laxity are subjective and measuring outcomes specific to ligament behaviour is difficult.

Instability is often considered an objective clinical finding and has been reported as the amount of joint opening following an applied load. Some scoring systems, such as the American Knee Society (AKS) clinical rating system [Insall et al. 1989], include a measure of stability based on the degree of mediolateral angulation following a varus-valgus load. Song et al. (2007) examined stability after TKA, comparing computer-assisted and conventional techniques, and reported no differences. However, their measure of stability was varus-valgus laxity in extension using stress radiographs with no indication of patient-reported outcomes. Unitt et al. (2008) used intra-operative force measurements to define balance (±3° angulation) and compared this with different outcome measures. Knees that were considered imbalanced in extension had significantly worse AKS clinical rating knee scores (measured by clinician) at 12 months post-operatively. However, the AKS clinical rating functional score (reported by patient) showed no difference suggesting that the patient perception of knee function does not necessarily correlate with objective stability. It is perhaps more appropriate, therefore, to consider instability as a patient-reported outcome as a 'lax' knee may not always be reported as feeling unstable. Conversely a knee that is considered 'tight' with minimal laxity may well feel unstable to the patient due to the knee 'buckling' as a result of other causes such as pain, quadriceps muscle weakness or patellar mal-tracking [Vince et al. 2006]. This highlights the fact that patients tend not to describe 'instability' as a symptom. Instead the clinician is required to decide whether the patient's symptoms represent true instability. Furthermore there are numerous causes of a knee feeling unstable, with collateral ligament imbalance representing one of many.

2.4.5.1.4 Frequency and extent of soft tissue release

In spite of a general absence of quantitative data it is generally considered that knees which are too "tight" may lead to patient dissatisfaction due to limited range of motion [van Damme et al. 2005], and have a higher risk of accelerated wear of the components [Engh, 2003]. This may account for the view that soft tissue release should be performed on all TKA procedures [Nagamine et al. 2004]. However, the surgical release of soft tissues is associated with a number of potential complications. Increased frequency of post-operative haematoma, wound complications and the subsequent risk of infection were reported by Kumar and Dorr (1997). Molloy et al.

(2004) reported that extensive soft tissue releases during TKA for valgus knees led to increased post-operative bleeding and prolonged hospital stays. Extensive release can also change the position of the joint line, impact on extensor mechanism function and therefore compromise clinical outcome [Martin and Whiteside, 1990]. In addition, a poorly judged excessive release may result in an unduly “lax” knee that may fare badly as a result of instability [Zalzal et al. 2004].

A generally accepted surgical aim therefore is for “some” coronal laxity, but this decision remains subjective and is often based on the “feel” of the surgeon. This is highlighted by the wide variation in the reported frequency of soft tissue release. Nagamine et al. (2004) suggested a release rate of 100%, whereas Whiteside et al. (2000) and Engh (2003) found it was only required in 76% and 50% of cases respectively. These high release rates may reflect the finding by Okazaki et al. (2006) that slight amounts of increased laxity can be tolerated following TKA surgery and so, in the absence of an objective measurement, it may be better to over-release rather than under-release.

The availability of instrumented gap-balancing devices and computer-assisted technology (Section 2.5.4) has provided surgeons with more quantitative methods of assessing laxity intra-operatively. Classic gap-balancing techniques simply involved spacer blocks to measure soft tissue tension [Insall et al. 1985] or laminar spreaders which enabled a comparison between medial and lateral joint spaces based on the degree to which they opened the gaps. More sophisticated designs incorporated scales to measure the amount of gap distraction [Unitt et al. 2008, Winemaker 2002] or force sensing devices to determine the force applied. The simultaneous use of CAS technology has proven to be a valuable adjunct to gap balancing devices with a growing number of specific software programs incorporated into the workflow of the navigation system. A drawback with these balancing techniques, even with computer-assistance, is the general requirement for the patella to be everted which has been shown to have a significant effect on the distribution of load between compartments. Crottet et al. (2007) found that 25% of the contact force induced by the patellar load was transferred to the lateral compartment following eversion and a similar finding was reported by Luring et al. (2005).

As an alternative to gap-balancing tools, varus and valgus stress manoeuvres can be used to apply loads to the supporting ligaments which do not require patellar eversion. Picard et al. (2007b) used manual stress and resultant computer-assisted angular measurements to determine whether a release should be performed and reported an overall release rate of 25% for a series of TKAs on varus knees. Hakki et al. (2009) used a similar method to achieve a release rate of 11%. In spite of the use of computer technology there was still the requirement to define a “well-balanced” knee based on a manually-applied load and this may account for the variation in release rates. In addition, although there were no reports of adverse outcomes due to excessively “tight” knees, neither study was able to show that avoiding a soft tissue release improved patient outcome.

2.4.5.2 Sagittal plane

Given that the majority of knee motion occurs in the sagittal plane, the concept of soft tissue restraints is different to that in the coronal plane. Maximum knee flexion may be limited by factors such as pain and swelling secondary to OA, and is poorly correlated with patient satisfaction [Miner et al. 2003]. At the other end of the arc of motion, the degree of knee extension is more influenced by the restraining soft tissues. If the knee is unable to be fully extended passively then it is deemed to have a fixed flexion deformity (FFD). This is a recognised complication of TKA surgery as pain and functional knee scores are more likely to be diminished than if knee extension was normal [Ritter et al. 2007]. This may be due to the fact that optimal knee function requires maximal knee extension [Bellemans et al. 2006] (Section 2.2.3.3). A residual flexion contracture can increase energy cost and decrease velocity during ambulation [Perry et al. 1975, Tew and Foster 1987]. Ritter et al. (2007) described a grading system based on the measured degree of deformity and this is often used to quantify FFD severity (Table 2.4).

Table 2.4 Classification of flexion contraction deformities [Ritter et al. 2007]

Degree of deformity	Flexion contracture range
Recurvatum	10° hyperextension and greater
Normal	9° hyperextension to 5°
Moderate	6° to 19°
Severe	20° and greater

The presence of an FFD is usually the combination of abnormalities in bony anatomy leading to impingement, in addition to soft tissue contractures [Bellemans et al. 2006]. Patients with longstanding OA, particularly with severe pain, may have a chronic tendency to assume the most comfortable position of the knee which is often with a degree of flexion in order to avoid painful extension. This can lead to secondary contractures of the posterior and collateral soft tissues resulting in a more marked FFD.

During TKA surgery it is generally believed that restoration of full passive extension should be attempted although there is evidence that a residual FFD may improve over time [Aderinto et al. 2005, Lam et al. 2003]. As is the case for coronal deformity, there are several specific surgical algorithms for managing FFD during TKA surgery. In general terms surgical correction is based on a combination of cutting more bone from the distal femur and proximal tibia to increase the extension gap, soft tissue release and precise component positioning [Mihalko and Whiteside 2003]. The soft tissues requiring release will often depend on the coronal deformity as FFD usually occurs in combination with varus or valgus malalignment. In general, once the bony cuts have been made and the appropriate collateral releases have been performed if necessary, if the knee is still unable to extend adequately then the posterior capsule may require release [Bellemans et al. 2006, Mihalko and Whiteside 2003].

2.4.5.2.1 Limitations of conventional techniques

The intra-operative judgement of FFD correction is based on an estimate of the knee flexion angle which is known to be unreliable (Section 5.3.3). Subsequent post-operative assessment is then routinely performed by visual estimation or manual goniometry with potential for significant intraobserver and interobserver error [Cushnaghan et al. 1990, Edwards et al. 2004]. Patients are often measured supine even although knee extension problems tend to occur during weight-bearing activities [Perry et al. 1975]. In spite of the inaccuracies of measuring sagittal alignment, Ritter et al. (2007) classified the severity of FFD on the basis of precise angular measurements (Table 2.4). The combination of measurement errors for classifying grade of FFD, lack of accurate intraoperative measurement tools, variations in classifying surgical release (often in combination with collateral deformities) and the potential improvement of FFD over time, make it difficult to correlate sagittal soft tissue management with outcome.

The use of computer assisted technology can overcome one of these limitations and provide an accurate real-time measurement of sagittal alignment. This can determine whether an intra-operative target in the sagittal plane (usually a sagittal MFT angle of 0°) has been obtained rather than relying on a visual estimate. However this technology is not available outwith the operating theatre and so can not help to identify the presence of FFD in a clinical setting.

2.4.6 Measuring outcome

The two basic aims of a TKA for end-stage osteoarthritis are relief of pain and restoration of function. Unfortunately, quantifying these outcomes by means of an objective scoring system has proven to be difficult with numerous rating systems described but very little consensus amongst surgeons about which one to use. In a systematic review of the orthopaedic literature, Drake et al. (1994) identified 34 different knee scoring systems that had been used up until then, most of which had not been validated. As far back as the 1970s, however, the requirement for a reliable assessment tool for joint arthroplasty was recognised when Kettelkamp and Thompson (1975) identified desirable criteria for such a system. This included the use of important measurable knee characteristics, avoidance of assigning arbitrary point values, the use of easily quantifiable clinical variables, the ability to relate points scored to clinical results and simplicity. More than 30 years on from this there is no universally accepted gold-standard measurement tool.

In simple terms, an outcome system for TKA should provide objective parameters that can be measured in a reproducible manner by independent observers. The system should be applicable before and after surgery to determine the level of benefit from the intervention and should enable comparisons to be made between different implants, techniques or patient groups [Davies, 2002]. The term "responsiveness" denotes the ability of a test to detect changes over a period of time [Wright and Feinstein, 1992], and is considered crucial for determining patient benefit. Tests that are highly responsive are more likely to have the ability to detect small differences in patient outcome. This feature is often used to measure the performance of an outcome system, which in turn can be focussed on different aspects of patient care.

The American Knee Society Score (AKSS) [Insall et al. 1989] and the Oxford Knee Score (OKS) [Dawson et al. 1998] are the most commonly used and widely accepted scoring systems in the United Kingdom for TKA [Medalla et al. 2009]. The AKSS is a dual rating system that is subdivided into a knee score that only rates the knee itself and a functional score that assesses walking and stair-climbing ability. This was designed to eliminate the problem of a declining score with age associated with general deterioration of the patient, which had been a problem with the preceding Hospital for Special Surgery Rating System [Ranawat and Shine, 1973].

The OKS is a subjective patient-derived 12-item questionnaire providing a measure of patient assessment of their TKA outcome (Appendix 1). There are five questions relating to the measurement of pain and seven to the assessment of function. The questionnaire was developed from patient interviews and validated against two generic health scales, the Short Form-36 [Ware JE Jr and Sherbourne CD, 1992] and Health Assessment Questionnaire (HAQ) [Fries et al. 1982]. Its original intent was for use in large randomised controlled trials for patients undergoing TKA to assess pain and function of the knee solely from the patients' viewpoint. It was designed to be short, practical, reliable, valid and sensitive to clinically important change and therefore be more accurate than other patient-based measures, such as the SF-36 or the Arthritis Impact Measurement Scale [Meenan et al. 1980]. These scales have been previously criticised for their length, difficulty in completion, unresponsiveness and lack of relevance for use in patients undergoing joint replacements [Fitzpatrick et al. 1992]. The simplicity of the OKS was therefore designed to encourage its widespread use as a recommended disease-specific tool for assessing TKA outcomes [Davies, 2002]. Initially, each question was scored from 1 to 5, with 1 representing the least pre-operative symptoms or the best post-operative outcome. The scores from each question were added so the overall score was from 12 to 60, with 12 being the best outcome. However, since then many surgeons have found this scale to be unintuitive which has led to a change in the numerical score assigned to each question. The newer recommended system scores each question from 0 to 4, with 4 being the best outcome. This method, when summed, produces overall scores running from 0 to 48, with 48 being the best outcome. Conversion from the 60-12 system to the newer 0-48 system and vice versa requires subtraction of the score from 60. To avoid confusion when reporting TKA outcomes, it is recommended that the method of scoring is always stated [Murray et al. 2007].

Both the AKS and OKS systems have been rigorously tested for reliability and validity [Davies, 2002] and a recent study reported a good correlation between the two [Reddy et al. 2011]. The greater emphasis centred on patient self-reported outcomes has supported the use of the OKS scoring system [Dawson et al. 1998]. When compared with the AKSS, SF-36 and HAQ, the OKS has fared favourably in terms of reproducibility, internal consistency, validity and responsiveness [Whitehouse et al. 2005]. However limitations of the OKS have been reported such as potential redundancy of some of the questions as well as difficulty completing the score, raising concerns about clarity and validity [Whitehouse et al. 2005]. This has led to the suggestion that where detailed assessment of outcome is required, the Oxford Knee Score may not be ideal when patients are left to complete this questionnaire unassisted [Whitehouse et al. 2005]. Furthermore, there are no published population normals for the scale, and so what constitutes a good score may be based mainly on clinical experience rather than an absolute numerical value. It has therefore been recommended that categorisation of scores should be avoided until large international data sets have been analysed [Murray et al. 2007].

In general there are reported limitations with all commonly used clinical scoring systems. However, with an increasing number of TKA procedures, along with a discrepancy between expectation and outcome [Lingard et al. 2006], there is a potential need to re-evaluate and improve current post-operative assessment. Weiss et al. (2002) proposed an individualised functional assessment which aimed to define the specific demands of each patient and then characterise the perceived limitations after knee replacement. This highlights the fact that in spite of TKA surgery providing effective pain relief, many patients still experience significant difficulty in performing activities regarded as important, such as squatting, kneeling and gardening. Miner et al. (2003) acknowledged that many scoring systems are incomplete and therefore suggested that combining measures, for example a joint-specific measure with a global health measure, may be more appropriate.

A simpler approach was described by Beverland (2010), based on an impression that TKA patients at the author's institution were not as happy as those undergoing total hip arthroplasty (THA) in spite of excellent 10-year survivorship. This hypothesis was tested and subsequently supported by the development of a simple 4-point score (Table 2.5) for measuring patient satisfaction. Using this system, there were found to be more "unhappy" knees than "very happy" ones. In contrast, for patients following THA, 55% were "very happy" compared to only 1% who were "never happy". Therefore, patients who underwent THA were almost 14 times more likely to be "very happy" when compared to patients undergoing TKA. The results emphasised the need to re-address the many potential factors that determine TKA outcome including surgical technique and patient expectations. In addition, the proposed scoring system provided a fundamental measurement of TKA success based on whether patients were "happy" and may be a useful adjunct to other conventional outcome rating measures.

Table 2.5 Scoring system for measuring patient satisfaction [Beverland, 2010]

Score	Level of satisfaction
1	Very happy - patient will feel they have a "forgotten joint" that feels normal
2	Happy
3	OK but not perfect
4	Never happy - frequently worse than preoperatively

2.5 Computer-assisted orthopaedic surgery (CAOS)

The term Computer Assisted Orthopaedic Surgery (CAOS) refers to an expanding list of technologies known by several different names such as computer-assisted surgery (CAS), medical robotics, computer integrated surgery, image-guided surgery and surgical navigation [DiGioia et al. 2004]. In simple terms CAOS can be regarded as a technique of using a computer to help orthopaedic surgeons plan and carry out surgical acts. The overall goal is to achieve improved surgical, clinical and functional results which have a smaller distribution around an ideal mean with elimination of unsatisfactory outliers (Figure 2.16) [Picard 2007].

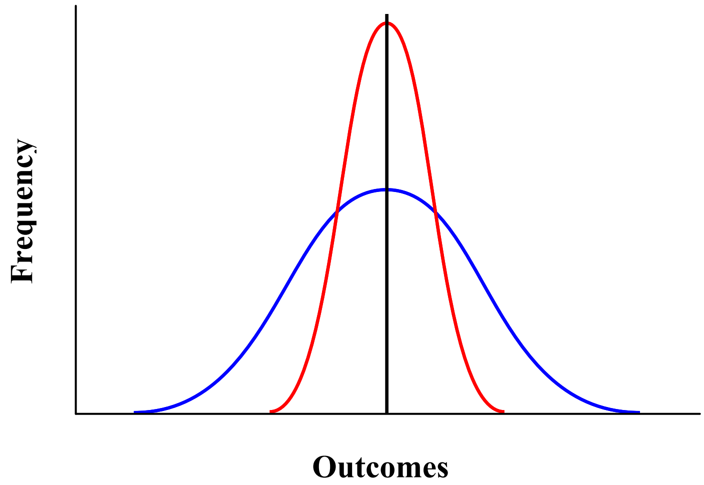


Figure 2.16 CAOS expectation (red curve) compared with current surgical results (blue curve)

2.5.1 History

Computer-assisted technology to optimise surgical performance was first introduced by neurosurgeons performing stereotactic biopsies, where high degrees of accuracy are required to avoid damaging vital areas of the brain. They utilised CT scans to determine the desired placement of a biopsy needle probe. This technology progressed through the 1980s and naturally evolved to the spine as a consequence of most neurosurgeons also performing spine surgery. This was the first application of computer-assisted surgery in orthopaedics and the first published work in this field involved a passive robot evaluating surgical correction of a scoliotic spine [DiGioia et al. 2004]. Other notable innovators were craniofacial surgeons who recognised the obvious potential of bone for generating preoperative computer models. This is due to its inherent rigidity and consistency of location in comparison to the brain which is a soft tissue. Computer graphics allowed surgeons to create reusable three-dimensional models for simulation of bone transformations. This approach evolved into the use of computer assisted design/computer assisted manufacturing (CAD/CAM) and computer surgical template concepts in orthopaedic surgery. Murphy et al (1986) were one of the first to publish work on CAD/CAM in orthopaedic surgery. This team generated a pre-operative 3D reconstruction of a dysplastic hip to determine the parameters of an implant which was then designed and machined using a computer. This concept of custom design continued through the late 1980s and was followed by the development of robotic assistive systems. These systems provided assistance with tasks such as bone cavity preparation in total hip replacement and actual cuts in TKA (active robots) or with other roles such as retraction or cutting jig positioning (semi-active). Soon after the introduction of these systems, the concept of 'navigation' systems was developed and introduced into surgical practice.

2.5.2 Navigation

Navigation systems augment mechanical instrumentation by permitting intra-operative real-time tracking of surgical tools and patient anatomy [Stulberg et al. 2002]. Whilst many attempts have been made to classify CAOS systems overall [Picard 2007], orthopaedic surgical navigation tends to fall into two main categories, image-based or image-less. A third category is introduced if the image-based system is sub-divided into pre-operative or intra-operative.

2.5.2.1 Image-based systems

Pre-operative image-based navigation relies on matching digital images (usually CT) to available bony landmarks which then directs optically guided surgical tools and implants into the desired anatomical position. The main disadvantages of CT scan guided systems are additional radiation, time and costs. Intra-operative image-based navigation refers to the concept of using fluoroscopic images to guide the placement of TKA components, although prior to this it had been used for other procedures such as positioning of anterior cruciate ligament grafts [Banks et al. 1998] or pedical screw fixation in spine surgery [Foley and Smith 1996].

2.5.2.2 Image-free systems

Image-free navigation uses information from direct measurement of anatomical landmarks and from calculating limb kinematics from relative bone movements. There are several basic components of commercially available systems.

2.5.2.2.1 Trackers

Trackers (also called “rigid bodies”) are fundamental elements of an image-free navigation system. They require stable fixation throughout the duration of a surgical procedure and this is achieved by attaching them to bone with screws (Figure 2.17). Both infrared (IR) and electromagnetic technology are used commercially. IR trackers can be further sub-divided according to the source of light emission.

Figure 2.17 Bi-cortical fixation screws for rigid attachment of trackers to bone

For active trackers, light emitting diodes send out light pulses that are registered by IR-only light sensors. This requires the power to be provided by the tracker, either via an electrical cable or batteries. Potential drawbacks therefore are the possibility of the wires getting caught and displacing the trackers or the extra weight of the batteries that may also increase the likelihood of movement. Active cameras on the other hand emit IR light from a ring surrounding each lens and use retro-reflective balls or discs as targets on the rigid bodies to mirror this light back to the lens. This method of tracking, also known as “semi-passive”, eliminates the need for batteries or wires as a power supply which may improve stability and usability. On the other hand, the retro-reflective coatings can suffer accuracy degradation when handled and so may require periodic replacement.

The use of a fully passive tracking system could potentially overcome some of the limitations of IR tracking. Fully passive systems use available visible light to observe targets in the same way as humans do without the need for IR light. Tracked target objects are marked with a visible pattern of a specific geometric design that is detected by standard video lenses and sensors. There are no fully passive commercial navigation systems in current use in orthopaedic surgery.

Regardless of the source or type of light, the above systems require the trackers to be continually visible to the localiser in order to be located spatially. This potential drawback is avoided with the use of electromagnetic (EM) tracking, with an EM transmitter in place of a light source. However, the accuracy of these systems can be affected by interference from nearby metallic objects, which is a potential problem in operating theatres [DiGioia et al. 2005].

2.5.2.2.2 Localiser

A localiser is able to determine the spatial position of several trackers with a high degree of accuracy. IR localisers detect signals (either reflected or from light emitting diodes) from trackers which enable it to calculate its position in space. Optical systems consist of two or three cameras which function like a pair of binoculars. As a result there is a variable field of measurement (FOM) and a variable degree of accuracy depending on the distance between the localiser and the tracker [Picard 2007]. In addition there are potential line-of-sight issues between the camera and trackers, and the potential for cameras to become confused by other light sources [DiGioia et al. 2005]. EM localisers do not have these drawbacks but are sensitive to the presence of nearby metallic objects as previously mentioned.

2.5.2.2.3 Pointer

A pointer (or "probe") is typically in the form of a pen and is used for locating anatomical landmarks. The handle has an attached tracker and the rigid tip of the stylus is in a constant, pre-calibrated position relative to this. Point localisation can be achieved to an accuracy of within 1mm [Haaker et al. 2005]

2.5.2.2.4 Central control unit and computer

This controls the switching sequence of the IR emitters of each active tracker and the succession of the flashes is then sensed by the corresponding localiser. The control unit is able to determine the exact position of each emitter and therefore that of every tracker. The computer coordinates all the components of the system as a whole.

2.5.2.2.5 Remote control of system

The control of the system can be achieved through the use of either a foot pedal or a manual trigger. This enables the registration of anatomical landmarks and navigation through the workflow without the intervention of an operating room technician.

2.5.2.2.6 Graphical workflow

Graphical representation of anatomical images is used to guide the surgeon as to the appropriate action to perform at specific stages of an operation. Anatomical landmarks and joints are illustrated when they require positional localisation and calculation of their rotational centre respectively. Real-time images are used to guide surgical manoeuvres, such as making bone cuts, and enable immediate validation of actions.

2.5.3 Alignment

A fundamental goal of computer-assisted technology is to increase the precision of knee arthroplasty component positioning in order to more reliably achieve a target MFT angle. In the coronal plane this is commonly accepted as 0°±3°, although some would challenge this limit (Section 2.4.2.1). In comparison to traditional instrumentation techniques, CAOS technology can lead to improved implant positioning and lower limb alignment as measured by long leg radiographs or CT scans [Bathis et al. 2004, Chauhan et al. 2004b, Matziolis et al. 2007, Sparmann et al. 2003]. In a prospective randomised trial of 240 TKA patients, Sparmann et al. (2003) demonstrated that the use of an image-free navigation system resulted in a statistically significant reduction in the number of positional outliers in comparison to manual instrumentation techniques. All the alignment parameters measured in both coronal and sagittal planes, with the exception of the sagittal tibial MA, were improved with the use of a navigation system. However the authors did acknowledge the potential positioning errors of 2° to 3° associated with the use of long leg radiographs. Bathis et al. (2004) conducted a similar prospective evaluation involving two unselected groups of 80 patients each undergoing primary TKA. In the computer-assisted group, 96% of patients were within the target coronal MFT angle range of 0°±3° in comparison to only 78% in the conventional instrumentation group, and this difference was statistically significant. There was also a more consistent achievement of the target femoral component position in the coronal plane using navigation, but there was no difference in the sagittal plane and for the tibial component there were no positional differences in either of the planes for the two techniques. Again, this study acknowledged potential measurement errors associated with long leg radiographic measurements. Chauhan et al. (2004a) recognised these limitations and developed a quantitative CT-based assessment of alignment (the Perth CT protocol) which was designed to provide a more reliable assessment of post-operative TKA positioning. A prospective study was then performed involving 70 consecutive patients undergoing TKA who were randomly assigned to either a computer-assisted or conventional jig-based group [Chauhan et al. 2004b]. Seven out of the 8 measured alignment parameters (including overall coronal limb alignment) were statistically improved with the use of navigation. Matziolis et al. (2007) also used post-operative CT scans to show a reduction in outliers with the use of computer-assisted techniques in comparison to conventional TKA. However there was no difference in rotational alignment of the tibial component reflecting the fact this was still largely dependent on landmark identification by the surgeon.

Not all of the evidence regarding component positioning and lower limb alignment is in support of the use of computer-assisted technology. Kim et al. (2009) performed sequential simultaneous bilateral knee replacements on 160 patients (320 knees), where one side was performed using image-free navigation and the other was replaced conventionally with traditional instrumentation. Both radiographic and CT images were used to quantify positioning. The authors reported that the use of computer-assisted techniques did not result in more accurate implant positioning, and the only statistical difference between the two groups was a longer operating time using navigation. However, when looking closely at all the radiographic parameters, the results in the CAOS group were superior to those in the standard group with differences in achieving target component orientation ranging from around 40% (outliers >3° in tibial sagittal plane) to 100% (outliers >3° in tibial coronal plane). Therefore in spite of not being significant according to the statistical methods used, the result indicated a strong trend in favour of CAOS. Furthermore, the surgeons may have benefitted from the augmented feedback from the navigation system leading to improved judgement of alignment using traditional instrumentation. This potential training effect was acknowledged by Stulberg et al. (2006) who, in a follow-up study to an initial experience of using navigation [Stulberg et al. 2002], reported similar alignment results between conventional and computer-assisted techniques. This was attributed to the real-time feedback provided by the navigation system which may have subsequently benefitted the surgeon when using conventional techniques.

Although some studies showed no improvements in TKA alignment using CAOS technology, most of the evidence is strongly in favour of the benefits of navigation, particularly for achieving a target MFT angle. A meta-analysis by Bauwens et al. (2007) aimed to explore the evidence in relation to precision of component placement with navigated TKA. The review included 11 randomised controlled trials and reported that navigation reduced the relative risk of ≥3° of malalignment by 25%. In spite of this finding the authors concluded that navigation showed no “meaningful” clinical advantage over conventional knee arthroplasty on the basis of radiographic end-points. This statement was based on the view that marginal improvements in limb alignment may not equate to functional benefits.

2.5.4 Soft tissue management

Computer-assisted surgical systems have provided surgeons with intra-operative quantitative measurement tools that permit real time assessment of lower limb kinematics with permanent access to a mechanical axis reference [Bathis et al. 2004, Chauhan et al. 2004b, Stulberg et al 2002]. These systems have high levels of precision and can achieve angular and tibiofemoral gap measurements of within 1° or 1mm respectively [Haaker et al. 2005, Stockl et al. 2004]. This has led to the development of quantitative soft tissue balancing algorithms which are often based on the resultant MFT angle deviation following the application of a varus or valgus stress. Luring et al. (2006) used a CT-free navigation system to quantify the effects of sequentially releasing the medial soft tissue structures of fresh cadavers. Several intra-operative in-vivo studies have confirmed the reliability of CAOS systems for enabling quantitative decisions to be made with respect to soft tissue balancing [Hakki et al. 2009, Jenny et al. 2004, Picard et al. 2007a, Saragaglia et al. 2006, Unitt et al. 2008]. Unfortunately, many of these techniques involved a manual surgeon-applied stress and therefore may be limited by lack of force standardisation. This could potentially explain the difference in the derived values of the varus and valgus stress angles between studies and suggests that these algorithms may only at best be surgeon-specific. Hakki et al. (2009) defined a balanced TKA in extension as having a unidirectional deflection arc of ≤2° from neutral alignment or a total arc of ≤4°. This was reported as having been achieved in all cases with a mean post-operative medial/lateral unidirectional deflection of 1.43°. Pre-operatively a release was only performed if any varus or valgus deformity could not be corrected to 0°, which resulted in an overall release rate of 10.75%. Saragaglia et al. (2006) used the same definition of a balanced TKA but had a different threshold for performing a release with cases of 3° or even 5° of under-correction on manual stress having no release. In spite of this, the overall collateral release rate was 17.3%, which was closer to the rate of 25% reported by Picard et al. (2007b). In this study, the stress angle values for performing a release were derived from an initial cohort whereby the navigation system was used as a measurement tool to quantify the technique of an experienced knee surgeon. The post-implant mean varus and valgus deflection arcs were 3.5° and 2.1° respectively which were more in agreement with a study of 526 knee replacements by Unitt et al. (2008) where balance was defined as a range between 3° varus and 3° valgus. Some authors may consider this as too lax but these values were comparable to normal knee controls as found by Okazaki et al. (2006) with a mean varus stress of 4.9° and mean valgus stress of 2.4°. These different quantitative algorithms highlight the need to define ‘normal’ knee laxity to help determine what the surgeon should aim for when performing computer-assisted TKA. This clearly requires standardised techniques in order to allow more useful comparisons between different sets of data.

Therefore, computer-assisted technology may enhance soft tissue management by quantifying the "balance" of the knee and potentially avoiding excessive releases, but there are limitations. In addition these techniques are invasive and therefore cannot be used in a clinical setting.

2.5.5 Functional outcome

Whilst it may be reasonable to assume that a well-aligned and well-balanced TKA is likely to function better than one that is poorly positioned, this is not always reflected in commonly used outcome rating systems. Spencer et al. (2007) reported the clinical follow-up to a prospective study comparing computer-assisted and conventional knee replacements [Chauhan et al. 2004b]. At two years there was no significant difference in knee "function", as measured by several scoring systems (Knee Society Score, WOMAC, SF-36 survey, Oxford Knee Score), patient satisfaction or incidence of anterior knee pain, in spite of more accurate alignment in the computer navigated group. However, this apparent lack of correlation between accuracy and function may not have been justified by the evidence presented by Chauhan et al. (2004b) which compared two groups of total knee replacements inserted in substantially different positions with regard to the posterior slope of the tibial components. It also raised the issue of how clinical outcomes should be measured. Traditional scoring systems such as WOMAC and Oxford Knee Scores may not detect functional benefits that could exist with more accurately aligned components.

Dillon et al. (2007) used gait analysis to compare computer-navigated and conventional TKA patients with normal control subjects. When performing a number of trials ranging from level walking to stair climbing, the navigated group had higher functional knee flexion values compared with the conventional group and was statistically more similar to the control knees. However, there was no indication of the measured amount of total knee flexion or whether the navigated patients had better clinical outcomes from scoring systems. Some authors would even question the importance of knee flexion as an outcome measure. Miner et al. (2003) found only a modest correlation between knee range of motion and WOMAC function, and concluded that the latter was the strongest determinant of patient satisfaction following TKA. Knee flexion did not appear to influence either satisfaction or perceived improvement in quality of life.

It appears that there are no reliable methods for quantifying knee “function” as an outcome measure and no clear relationship between currently used measures of function and clinical outcome.

2.5.6 Technical validation

The increasing use of navigation systems, particularly in knee arthroplasty, has been supported by randomised clinical trials that demonstrate a more consistent final position of implanted devices compared with conventional instrumentation techniques [Bathis et al. 2004, Chauhan et al. 2004b, Matziolis et al. 2007, Sparmann et al. 2003]. In these trials the comparison of navigated data to hip-knee-ankle radiographs or computerised tomography (CT) scans represents a form of clinical validation [DiGioia et al. 2005] that uses the orientation of the components to measure accuracy and hence validate systems. At present most of the available data supporting CAOS systems relates to the clinically measured positional accuracy of an implanted device compared with the planned or ideal position.

Unfortunately there are many potential sources of error in the whole surgical process that may lead to sub-optimal clinical performance of a computer system. These include surgeon errors when collecting anatomical and kinematic data [Robinson et al. 2006, Spencer et al. 2006], tracking inaccuracies, particularly inadvertent intra-operative tracker movement [Mayr et al. 2006] and errors associated with post-operative radiological measurements of implant position [Kalteis et al. 2006, Siu et al. 1991]. Furthermore, implant positioning may not be an appropriate measure of “clinical outcome” as it does not provide any information on knee “function” (Section 2.5.5).

In comparison to clinical validation, technical accuracy relates to the performance of the overall system or its individual components (subsystems) without the introduction of these unquantified variations or errors. For optical tracking systems, for example, one of the most basic functions is the accurate three-dimensional location of a point in space. There are no published guidelines for reporting accuracy and the only technical information available is that provided by the manufacturers. This makes it difficult to know the relative contribution of each source of error to the final outcome, which is an important consideration when adapting CAOS technology to new areas of orthopaedics. Having only clinical data to guide potential users limits direct comparisons between complete systems or subsystems.

To address this problem a group of surgeons, academics and product manufacturers involved in the use and development of CAOS systems met with members of the American Society for Testing and Materials (ASTM) International, one of the largest standards-developing organisations in the world. They drafted a set of standards for measuring and reporting basic static performance of computer aided surgical systems under defined conditions [Bach et al. 2007], but plans to make these widely available were abandoned.

In summary, whilst computer-assisted technology can improve the accuracy of TKA component positioning and provide a quantitative measure of assessing soft tissues, this has not yet equated to a significant difference in clinical outcome as measured by current assessment methods. The lack of a reliable, objective measure of TKA function could be an important reason why the expected clinical benefits of CAOS have not been widely reported. In addition, the absence of guidelines for independently measuring the technical performance of CAOS technology, limits the comparison of data between clinical trials involving different systems.

2.6 Measurement techniques

2.6.1 Imaging modalities

The standard measurement of knee alignment often relies on clinical evaluation in conjunction with radiographs that centre on the knee joint. However, human assessment of angles is known to be inaccurate [Edwards et al. 2004] and the use of knee radiographs has been found to be a poor prediction of mechanical lower limb alignment [van Raaija et al. 2009], especially in the presence of proximal femoral or distal tibial bone deformity [Cooke et al. 1997] or with the limb rotated. Lonner et al. (1996) made a synthetic lower limb model that included a TKA and performed a series of short view radiographs at varying degrees of knee flexion and lower limb rotation. With only 10° of flexion, there was a statistically significant variation of more than 4° in measured anatomical alignment between 20° external rotation and 25° internal rotation. Therefore the role of short view radiographs in assessing lower limb alignment for planning intervention strategies and for post-operative evaluation may be limited. Full-length hip-knee-ankle radiographs have therefore been increasingly adopted to provide more reliable pre- and post-operative information and are widely considered the gold standard for measuring knee alignment [Cooke et al. 2007]. In spite of enabling measurement of the mechanical femorotibial (MFT) angle these radiographs are also susceptible to limb positioning errors with apparent variations in alignment produced as a result of knee flexion or rotation [Krackow et al. 1990b]. Brouwer et al. (2007a) performed long-leg anteroposterior (AP) radiographs on a cadaveric lower limb and found that rotation without flexion had little effect on measured MFT angle, whereas simultaneous knee flexion and rotation caused significant changes in projected angles. In a clinical study, Hunt et al. (2006) performed long-leg radiographs in three different positions of rotation on 10 patients (19 lower limbs) presenting to an acute orthopaedic clinic. In comparison to the defined neutral postion, internal foot rotation resulted in significantly less varus and external rotation resulted in significantly greater radiographic varus alignment. Although these studies highlighted the importance of standardised positioning, radiographers may have difficulty in correctly achieving a position of within 10° of the neutral position in the majority of clinical settings [Wright et al. 1991]. Controlling lower limb positioning may be achievable by standardised approaches with normal subjects [Cooke et al. 1997, Siu et al. 1991], but may not be possible in obese patients or those with extremity deforming OA who often have flexion or rotation deformities. In addition to patient factors, human error during the process of radiographic alignment measurement may be an additional source of variability [Yaffe et al. 2008].

The errors associated with radiographic measurements can therefore challenge the validity of studies that use X-rays to quantify small changes in limb alignment. This is particularly relevant in TKA surgery where patients are routinely assessed post-operatively at a time when they may not have regained full knee extension [McGrory et al. 2002].

Computed tomography (CT) imaging can overcome the positional artefacts of plain radiographs by providing a 3D evaluation of lower limb anatomy and a more accurate measurement of MFT angles [Chauhan et al. 2004a]. However, alignment cannot be measured in a functional (weight-bearing) situation as subjects are required to be supine. Further drawbacks of both CT and long-leg radiographic imaging modalities include limited availability, exposure of the pelvis to ionising radiation and the lack of normal physiological control data from populations not typically exposed to them such as children and non-arthritic subjects with knee ligament injuries. Magnetic resonance imaging (MRI) is a commonly used investigation for assessing soft tissue structure but can also be used to measure lower limb alignment. Although images are routinely obtained in the supine position, the recent development of upright MRI scanners has allowed weight-bearing knee assessments to be made [Nicholson et al. 2010]. However, this technology is still largely experimental and not routinely available for clinical use. In addition, the artefacts caused by metallic TKA implants limits the use of MRI in arthroplasty assessments [White and Buckwalter 2002].

As an alternative to imaging, several clinical measures of alignment have been reported in the literature. Techniques include direct visual estimation of alignment along with measurement adjuncts such as calipers, manual goniometers and plumb-line methods [Hinman et al. 2006, Kraus et al. 2005]. These methods are inexpensive, avoid radiation exposure and are relatively quick to perform with instant measurement results. However the reported errors are potentially too large for use in planning and follow-up of surgical interventions such as replacement arthroplasty and corrective osteotomy where higher levels of accuracy are often required [Hinman et al. 2006].

2.6.2 Non-invasive tracking technology and external landmarks

In contrast to the clinic situation, a number of new technologies using IR tracking have been introduced intra-operatively to provide surgeons with quantitative measurement tools that permit real time assessment of lower limb kinematics (Section 2.5.2). Adapting this technology for non-invasive patient assessment is challenging due to the inability to directly palpate a landmark or rigidly secure a tracker to bone. The challenge of overcoming these soft tissue artefacts has been extensively researched in the field of biomechanics, particularly with respect to the hip joint which is deep-seated within the groin region and has no easily palpable surface anatomy. However, measurement of the MFT angle requires the localisation of the HJC (Section 2.2.1.7) and so non-invasive systems should have the ability to accurately determine this.

2.6.2.1 Hip joint centre location

Several investigators have attempted to estimate HJC relative to external bony landmarks based mainly on anthropometric studies of human cadaveric pelvises [Andriacchi et al. 1980, Bell et al. 1989, Seidel et al. 1995, Tylkowski et al. 1982]. This is frequently referred to as the “predictive method” of locating joint centres. Andriacchi et al. (1980) estimated that the HJC would lie 1.5-2cm distal to the midpoint of a line between the anterior superior iliac spine (ASIS) and the pubic symphysis in a frontal plane projection and directly medial to the greater trochanter in the sagittal plane. Tylkowski et al. (1982) took a different approach based on pelvic proportions and predicted that the HJC would lie 11% of the inter-ASIS distance medially, 12% distally and 21% posteriorly to the ASIS. Bell et al. (1990) compared these two methods on live subjects and concluded that neither was particularly accurate with overall three-dimensional errors of 3.61cm (Andriacchi et al. 1980] and 1.90cm [Tylkowski et al. 1982]. However, combining these two approaches improved the accuracy to within 1.07cm. Seidel et al. (1995) further investigated the relationship between HJC and selected aspects of pelvic geometry on human cadaveric pelvises. This study proposed a similar method to Bell et al. (1989) for location of the HJC along the mediolateral axis as 14% of pelvic width (SD 3%) relative to the ASIS. However their correlation analysis revealed that the HJC could be further optimised by including height and depth parameters as well as pelvic width. They proposed the location of HJC along the anteroposterior axis as 34% of pelvic depth (SD 2%) and 79% of pelvic height (SD 5%) along the superoinferior axis relative to the ASIS. Unfortunately the validation of Bell’s cadaveric work was based on a small sample of adult males without addressing potential variations of gender, age, race or anthropomorphic traits which may necessitate more population-specific regression equations. In addition, the use of cadavers or selected volunteers to validate HJC prediction methods may have over-estimated the accuracy of this method and failed to represent the true difficulty of palpating anatomical landmarks. However, this can present a challenge even to the most experienced clinician, with a wide range of intra and inter-observer errors reported for pelvic landmark identification [Spencer et al. 2006].

A potential means of avoiding the errors associated with external landmark identification is to use the movement of a joint to calculate its “functional” centre. This is of particular relevance to the hip joint as it is a tightly fitting ball-and-socket, enabling estimation of its rotational centre and overcoming the fact that it is located far away from palpable bony landmarks. This is often referred to as the “functional method” and is the standard computer-assisted intra-operative technique of determining HJC which avoids the need for surgical exposure of the hip. In the context of non-invasive measurement, there have been many different approaches described in the past. One of the earliest functional hip joint motion studies was by Johnston and Smidt (1969) using an electrogoniometer assembly attached proximally to a leather belt around the pelvis and distally secured around the thigh using elastic straps. This set up allowed freedom of motion in all directions which was recorded by changes in current through each of three potentiometers. Sixteen subjects underwent two sets of walking trials and the range of difference between the hip motion measurements was from 0° to 4°. Although the authors recognised the problem of soft tissue interposition between the straps and bone, this experiment proved that it was possible to determine a reliable model for the hip joint using functional methods.

Subsequent to this, most studies have involved the optoelectronic tracking of marker clusters located either directly or through some kind of fixture to the skin surface. The position and orientation of the external markers could then be assumed as the position and orientation of the underlying bone in spite of not being rigidly associated with it [Cappozzo et al. 1996]. Bell et al. (1990) attached spherical reflective skin markers to seven volunteers directly over the location of particular anatomical landmarks around the pelvis, greater trochanter (proximal femur) and lateral epicondyle. A Vicon motion analysis system (Vicon Motion Systems Ltd, Oxford, UK) continuously tracked the markers as the subjects sequentially flexed, extended and abducted the right hip. The epicondylar marker locations were least squares fit to a sphere whose centre defined the HJC as being the centre of femoral rotation in the pelvic reference frame. Although repeated trials were reproducible to within around 2cm, the average distance of the functionally located HJC from the reference HJC was 3.79cm with errors of up to 6.53cm. However, the reference HJC was defined using two oblique 2D radiographs and so was prone to measurement errors (Section 2.6.1). Furthermore, there were potential errors associated with anatomical landmark identification for placement of the reflective skin markers as previously discussed. In addition, the subsequent tracked rotational movements were active, involving potential movement of the external markers as a result of underlying muscle contraction.

Leardini et al. (1999) performed a similar study but used roentgen stereophotogrammetric analysis (RSA) to more accurately define the true HJC. In spite of the hip movements being active, the subjects were instructed to avoid internal or external rotation as this was felt to minimise potential soft tissue artefacts. In this study the functional method used was reported as estimating HJC location to within an average root mean square (RMS) distance of 13mm. In spite of these encouraging results, subsequent investigations to quantify the relative movement of external marker sets relative to underlying bones have reported large potential errors and questioned the value of these methods for accurate kinematic analysis [Sangeux et al. 2006, Stagni et al. 2005].

2.6.2.2 Soft tissue artefacts

Stagni et al. (2005) combined 3D fluoroscopy and stereophotogrammetry to quantify soft tissue artefacts during a variety of different functional activities. Two subjects, who had previously undergone TKA, were assessed and the soft tissue artefacts were quantified as the motion of a grid of retroreflective markers attached to the thigh and shank with respect to the underlying bones. The skin marker trajectory was found to be as high as 31mm for the thigh and 21 mm for the shank leading to the conclusion that these large errors could nullify the usefulness of using external markers for motion analysis. Again however, this involved active movement and was limited by the evaluation of only two subjects. Sangeux et al. (2006) used an alternative imaging technique (MRI) to quantify the relative 3D movement of external marker sets in relation to underlying bone. In this study, in-vivo kinematic analysis of the knee was based on external markers attached to the thigh and shank of 11 volunteers who were positioned supine on an MRI table. Although the study did not involve gait, knee extension was performed against the constraint of two elastic bands and therefore muscle contraction. This may have accounted for the large relative movement of the marker sets with respect to underlying bone (up to 22mm in translation and 15° in rotation). An alternative method for quantifying skin movement artefact has been through the use of intra-cortical pins. Both Fuller et al. (1997) and Benoit et al. (2006) compared knee kinematics using skin-mounted and pin-mounted markers. Both studies involved various movement activities including gait and both reported that external marker data are inappropriate for representing the motion of the underlying bones. A potential limitation of this method was the possible alteration of skin motion as a result of the intra-cortical pins [Stagni et al. 2005].

Regardless of the limitations of these studies, it appears that in the context of active lower limb kinematic measurments, skin mounted marker arrays do not track movements of the underlying bone very well. Mündermann et al. (2008) minimised these potential movement artefacts by measuring static standing lower limb alignment with position capture and skin markers along with external anatomical landmarks. The reliance on anthropometric measurements to predict joint centre location may have accounted for only a moderate correlation (R^2=0.544) with corresponding long-leg radiographs and a discrepancy of more than 5.3° for 10% of cases in an experimental set-up not readily adaptable to an out-patient clinic.

The current evidence would suggest that there are no reliable tracking systems for non-invasively quantifying knee alignment in the context of pre-operative surgical planning and post-operative follow up of alignment-dependent surgical procedures such as TKA.

2.6.3 Quantifying knee laxity

Clinical laxity tests are frequently used for soft tissue balancing in TKA and for assessing knee ligament injuries. Current routine methods are highly subjective with respect to examination technique, magnitude of clinician-applied load and assessment of joint displacement.

For collateral ligament injuries, scoring systems to grade severity are often based on millimetres of perceived joint opening with applied manual stress [Hefti et al. 1993, Petermann et al. 1993, Wijdicks et al. 2010]. The level of resolution required for this may exceed normal levels of human judgement and account for the frequent disparity between laxity examinations and true in-vivo joint function [Noyes et al. 1980]. Although soft tissues can be directly evaluated by MRI, only static anatomical information is provided with potential to underestimate the extent of any injury [Jacobson et al. 2006].

In TKA, assessment of laxity is a routine component of many soft tissue balancing techniques and is often used to determine the need for a soft tissue release [Mihalko et al. 2003, Whiteside 2002]. The decision to perform such a release and its extent is often based on the clinical judgement of whether a deformity is deemed ‘correctable’ when the knee is stressed (Section 2.4.5.1.4). Attempts have been made to categorise collateral laxity, for example Krackow’s classification of medial ligament tightness [Krackow et al. 1990b], but this assumes that all clinicians have similar examination methods and are able to reliably judge knee alignment. However, there may be wide variation in the resultant angular deviation of a knee joint following a clinician-applied load [Clarke et al. 2009]. In addition, human assessment of angles is known to be poor [Edwards et al. 2004] and the accuracy of alignment estimates under these circumstances may be no better than the order of ±5° [Markolf et al. 1976]. This has led to more quantitative adjuncts for measuring knee joint laxity and attempts to standardise applied load.

2.6.3.1 Stress radiographs

Radiographs taken whilst applying a load to the knee have been mainly used in the context of ligament injuries. Moore et al. (1976), evaluated patients with previous unilateral tibial plateau fractures with comparison to the uninjured contralateral knee.

The so-called clear space concept described by Martin (1960) was used which involved the radiographic measurement of the distance between opposing subchondral plates of the compartment spanned by the collateral ligament in question. The apparent laxity was determined from the difference between the gap measurements before and after an applied stress. Although leg position was standardised during the clinical examination, the magnitude of the applied load was not with no assessment of the repeatability of the technique.

More recent work by LaPrade et al. (2008) used a similar technique for assessing fibular collateral ligament and postero-lateral knee injuries but with a standardised 12-Nm moment in addition to a clinician-applied varus stress. In spite of this being an in-vitro, cadaveric study the authors concluded that this was a clinically-applicable technique and advocated that differences in radiographically measured gap opening of between 1 and 2 mm could determine injury severity. However, this degree of error could potentially be seen with small rotational variations in knee position [Siu et al. 1991] or magnification factors if the distance of the leg from the X-ray cassette was not controlled. Furthermore there was no measure of intra- or inter-observer variation for the magnitude of the clinician-applied load.

2.6.3.2 Instrumented measurement devices

An alternative approach to non-invasively measuring knee joint laxity involves the use of specially designed mechanical devices incorporating goniometers. Laxity can then be defined as the angular deviation recorded after varus-valgus load is applied [Sharma et al. 1999]. Early cadaveric work dating back to the 1940s was limited by the lack of standardisation of forces and moments applied with relatively inaccurate manual measurement tools to record the resultant displacement [Brantigan and Voshell, 1941]. Markolf et al. (1976) addressed these limitations and performed a more quantitative in-vitro cadaveric study. Special instrumented handles were used to record the forces and torques applied manually during the examination procedure. The resultant varus-valgus angulation data was electronically recorded by a specially designed three-dimensional goniometer linkage which allowed the knee joint to be maintained at a specific degree of flexion.

Adapting an instrumented method for the in-vivo, non-invasive quantification of knee joint laxity is challenging. Van der Esch et al. (2006) acknowledged that measuring coronal knee laxity in a clinical setting equates to measuring small differences in angular deviations, requiring a reproducible, highly precise method. Their approach was the construction of a measurement chair with an attachment to support the lower limb of the subject with five specific fixation points relative to the knee joint line. An electronic meter to record angular deviation was positioned in line with the varus-valgus rotation axis and a load was applied in a standardised manner. In spite of this set up, along with a clear experimental protocol, they concluded that laxity measurements were of limited use in clinical practice due to considerable measurement error. In particular inter-rater reliability was considerably lower than intra-rater reliability although there was the suggestion that training of observers improved repeatability.

A similar set-up was utilised by Sharma et al. (1999) consisting of a bench on which the subject sat and an attached low-friction track to support the leg with a hand-held dynamometer to apply a fixed load. The investigators recognised the importance of patient relaxation with the tests being performed in ‘a calming environment’ along with careful monitoring of any pain responses. This resulted in reasonable within- and between-session repeatability. Unfortunately the set-up was fairly impractical for clinical use and could only measure overall laxity as it could not reliably determine a neutral alignment point.

A less cumbersome device was the commercially available Genucom Knee Analysis System (Faro Medical Technologies Inc, Montreal, Canada). This instrumented measurement tool was utilised in several knee laxity studies in the 1990s investigating the effects of osteoarthritis and rheumatoid arthritis on ligament behaviour [Brage et al. 1994, Wada et al. 1996]. An electrogoniometer with six degrees of freedom was attached to the leg, and forces (displayed on a TV monitor) were manually applied to the tibia whilst the thigh was held in a fixed position. A soft tissue compensation protocol was developed to limit the motions of the femur and only tests with involuntary tibial or femoral rotations of <5° were accepted. To overcome potential problems of inter-rater reliability the tests were only valid if they were performed by a single licensed Genucom examiner. This resulted in single observer repeatability within reasonable limits, with coefficients of variation (ratio of standard deviation to the mean) ranging from 4 to 13%. This system did not find any widespread clinical use and was therefore discontinued.

In summary, neither the radiographic techniques nor experimental models described have been successfully implemented into routine clinical practice due to issues of accuracy and practicality. Therefore, despite the limitations of current manual knee laxity examination, this remains the primary means of assessing soft tissues in TKA and diagnosing ligament injuries. However with the growing physical demands of TKA patients [Nilsdotter et al. 2009] and the high incidence of soft tissue knee injuries [American Academy of Orthopaedic Surgeons: Common knee injuries, 2007], there is a potential role for improving the evaluation of knee laxity.

2.6.3.3 Measurement of applied load

To make widespread use of measured knee joint laxity, regardless of how it is recorded, requires an accurate method of standardising the applied forces and moments. In simplistic terms, the force application can be through a device that measures either a compressive or tensile load. Basic tensile methods include weight-pulley systems where specified loads are applied to a leg attachment at a set distance from the knee joint [Markolf et al. 1976, van der Esch et al. 2006] or spring-loaded strain gauges to apply a tensile force to the tibia with the femur immobilised [Wilson et al. 2010]. More modern designs use force transducers of which there are several different types of varying complexity. Strain gauge load cells are an example of an elastic device and are the most common type of force transducer. They consist of an elastic element to which a number of electrical resistance strain gauges are attached. The shape and modulus of elasticity of the element determines the resultant output (strain) following an applied force (stress) along a clearly defined axis. Several cadaveric studies have utilised strain gauge load cells with digital indicators to apply standardised varus-valgus moments to the knee joint [LaPrade et al. 2008, van Damme et al. 2005]. The use of cadaveric specimens permits direct attachment of the strain gauge to bone with accurate measurement of the applied load.

In contrast to tensile measurement of applied force, some devices are designed to measure force through pressure, the simplest being hydraulic or pneumatic load cells.

These devices contain a chamber filled with either a liquid or air which has a pre-load pressure. Application of a load increases the fluid or air pressure which is measured by a pressure transducer or displayed on a pressure gauge. Strain gauge load cells can also be configured to measure compression with the appropriate elastic element. The most commonly used is a foil strain gauge which is employed in the majority of precision load cells. Other examples include semiconductor, thin-film and wire strain gauges. D'Lima et al. (2005, 2007) utilised a force transducer to measure intra-articular compressive forces on the tibial component of knee replacements. Initial in-vitro testing confirmed the accuracy of a prototype [Kaufman et al. 1996] prior to implantation of the first 'e-Knee' which consisted of a total knee prosthesis containing load cells, a microtransmitter and an antenna [Morris et al. 2001]. A similar device that measures knee joint moments and forces was developed by Crottet et al. (2005) and evaluated on cadaveric specimens. This enabled the effects of different degrees of soft tissue release and of patellar eversion to be biomechanically quantified [Crottet et al. 2007]. Pressure-sensitive film is an alternative method for measuring varus-valgus stress-distribution patterns in tibiofemoral joints and this was utilised by Takahashi et al. (1997) with good reproducibility.

2.6.3.4 Manual force application

From the point of view of clinician-applied varus-valgus loads, however, a force measuring device should consider the way in which patients are examined. Typically, a manual force is applied to the distal aspect of the tibia whilst the thigh is stabilised with the other hand. Therefore to incorporate a force transducer into a routine clinical assessment ideally requires a manual, compressive device that does not alter the examination technique. Whilst there are no reports of such a device specifically developed for measuring collateral knee laxity, there are reports of devices for measuring manual contact forces. Van Zoest et al. (2002) recognised the importance of manual techniques in disciplines such as chiropractic and osteopathy and developed a hand-held measurement system for three-dimensional contact force measurement. This incorporated a 3D piezoelectric force transducer, which works on the principle that certain crystalline materials form electrical charges when a force is applied to them. The three-dimensionality of the system was considered to be a better representation of human contact as it could take into account any shear forces. Although this prototype had limitations, such as a contact area that was too large, it was felt to have potential for developing the manual force perception and force delivering skills of student practitioners by providing a quantitative feedback tool. Harms and Bader (1997) investigated the variability of forces applied by therapists during spinal mobilisation procedures. They constructed an instrumented mobilisation coach incorporating six load cells linked to a computer to enable measurement of the magnitude and direction of applied forces. In spite of standardising the manipulation technique, there was a large variation in the forces used by different therapists, ranging from 63 to 347N. This highlights the subjective nature of clinical examination.

2.7 Summary

The knee is a load bearing joint that is frequently affected by OA, a chronic disorder of increasing prevalence in an expanding population of elderly and functionally demanding patients [Lingard et al. 2006, Nilsdotter et al. 2009]. In addition to pain and swelling, malalignment in the coronal plane is a common manifestation of this condition due to asymmetrical wear of the medial (varus) and lateral (valgus) tibiofemoral compartments. In the sagittal plane, OA can lead to a decreased functional arc of motion due to loss of terminal extension and reduced maximum flexion. For end-stage disease, TKA represents the gold standard of surgical intervention when conservative management has failed, with more than 90,000 performed annually in the UK alone [National Joint Registry for England and Wales, 7^{th} Annual Report 2010, Scottish Arthroplasty Project Annual Report 2010]. In spite of previously reported coronal MFT angle variations of up to ±5° for asymptomatic individuals [Cooke et al. 1997, Glimet et al. 1979 & 1980, Hsu et al. 1990, Moreland et al. 1987], the most common alignment target for prosthetic knees is 0°, with wide acknowledgement that deviation of more than ±3° from this target can reduce implant survivorship [Bargren et al. 1983, Jeffrey et al. 1991, Lotke and Ecker, 1977, Ritter et al. 1994]. In order to minimise the risk of being outside this desired range, surgeons frequently use alignment jigs when performing knee replacements on patients who are in a supine position with exposed knee joints and no muscle tone. However, to subsequently verify the implant position, patients are routinely assessed post-operatively with standing radiographs under conditions that were different from when the implants were inserted. In spite of some reports that supine to standing variation may exist for healthy subjects, potential differences between the two conditions have not been widely documented. Furthermore, for osteoarthritic and prosthetic knees, there is no reliable information regarding the relationship between intra-operative supine and corresponding pre- and post-operative measurements of both supine and standing coronal MFT angles.

In comparison to the coronal plane, sagittal alignment has been studied relatively little in spite of recognition that knee extension deformities in TKA can lead to poorer functional outcomes in comparison to knee joints with full passive extension [Ritter et al. 2007]. A generally accepted intra-operative target is the correction of any flexion deformities to a sagittal MFT angle of 0°. Subsequent post-operative assessment is then routinely performed by visual estimation or manual goniometric measurements that have significant potential for observer error [Cushnaghan et al. 1990, Edwards et al. 2004]. Patients are often assessed in the supine position in spite of knee extension problems being more frequently associated with weight-bearing activities [Perry et al. 1975].

In addition to correcting malalignment during TKA surgery, it is generally accepted that the soft tissues restraining the knee should be neither too “tight” nor too “lax” and should be symmetrically “balanced” [Freeman et al. 1986]. In the coronal plane, the collateral ligaments are the main structures controlling varus and valgus stability and assessment of their laxity by application of manual stress is a fundamental component of many soft tissue management techniques. In spite of attempts to categorise the perceived coronal laxity of the knee [Krackow 1990a], this remains a subjective assessment that may vary between clinicians due to potential differences in examination technique, applied manual load and judgement of the resultant displacement of the joint. To overcome this in the clinical setting, stress radiographs have provided a more objective assessment of knee laxity [La Prade et al. 2008], but this involves ionising radiation, strict control of limb position and potential errors associated with tibiofemoral gap opening measurements.

The intra-operative use of computer-assisted technology has provided surgeons with a measurement tool that is accurate to within 1° and 1mm [Haaker et al. 2005, Stockl et al. 2004]. In addition to improving the consistency of TKA implant placement, these quantitative devices can provide a more objective measurement of knee laxity based on changes in MFT angle with applied load and can help to guide the extent of any surgical releases performed to give a “balanced” joint [Hakki et al. 2009, Jenny et al. 2004, Picard et al. 2007b, Saragaglia et al. 2006, Unitt et al. 2008]. This technology is currently limited to intra-operative use as it requires rigid fixation of trackers to bone and it is therefore unknown how the kinematic measurements obtained on supine, atonic lower limbs relate to pre-operative and post-operative conditions. Adapting this technology for non-invasive patient assessment is potentially challenging due to the soft tissue artefacts associated with the external mounting of trackers. Previous investigations to quantify the movement of skin-mounted marker sets relative to underlying bones during active movement have reported large errors [Sangeux et al. 2006, Stagni et al. 2005] raising doubts as to the suitability of tracking devices for non-invasive kinematic analysis.

2.8 Aims

Based on limitations in current measurement techniques and clear knowledge gaps on the subject of knee alignment and coronal laxity, this thesis has several aims. The first is to develop and validate a non-invasive kinematic assessment tool to enable dynamic measurement of knee alignment. This will require the technical evaluation of a suitable tracking system by measurement of positional localisation accuracy prior to adaptation of the system for non-invasive use. To quantify the soft tissue artefacts associated with external mounting of trackers, comparison will be made with a rigid leg model designed to represent optimum testing conditions. Further validation of the system will be performed by repeated assessments on healthy volunteers and this will also provide a database of normal knee kinematics.

Following the validation of a non-invasive tracking system for measuring knee alignment under different conditions, the next aim is to standardise the assessment of collateral knee laxity to ensure that the MFT angles with applied stress are obtained in a reproducible manner. This will require measurement and subsequent control of several parameters that may influence the degree of angular displacement during clinical assessment, including knee flexion angles, hand positioning of the examining clinician and measurement of applied load. Validation of the non-invasive system for accurately recording knee flexion will be achieved by comparison to a commercially available flexible electrogoniometer. The measurement of applied manual load will require the design and manufacture of a force application device with the goal of incorporating this into a routine clinical manoeuvre for assessing laxity. The lever arm will be measured using the non-invasive system to determine the perpendicular distance from the applied manual force to the rotational knee centre.

The final aim is to assess the knee kinematics of patients with osteoarthritic and prosthetic knees. This will be achieved by undertaking a clinical trial involving the recruitment of patients with symptomatic end-stage OA due to undergo TKA surgery. Assessments of MFT angle under different conditions will be made pre-operatively, intra-operatively and post-operatively. With regards to coronal lower limb alignment, the intra-operative assessment of MFT angles on anaesthetised subjects will provide a direct comparison with those obtained non-invasively and enable quantification of muscle tone and soft tissue artefacts. In addition, the relationship between supine intra-operative and standing post-operative MFT angles (both radiographic and non-invasively determined) will be explored to investigate any discrepancies between these measurements conditions. The pre-, intra- and post-operative assessment of collateral knee laxity will be compared in order to quantify the effect of surgical exposure and muscular tone on the resultant MFT angular displacements. Finally, the effect of weight-bearing on coronal and sagittal alignment will be evaluated for osteoarthritic (pre-operative) and prosthetic (post-operative) knees with the additional comparison of normal (volunteer) subjects.

The quantitative kinematic data from the clinical trial will determine whether the common surgical goals of TKA surgery with regards to alignment and soft tissue balancing require reassessment.

3 Development and validation of a non-invasive measurement tool

This chapter reports the selection, technical validation and non-invasive adaptation of an optical tracking system. The design and manufacture of a standardised measurement tool is detailed along with the positional accuracy testing of two potential systems. The non-invasive adaptation of the selected system is then described prior to quantification of the soft tissue artefacts associated with the external mounting of trackers. The design and manufacture of a rigid leg model, representing optimum testing conditions, and its comparison to measurements on a volunteer are reported. Further validation of the system is then detailed by repeated assessments on healthy subjects, whilst the mean values for the MFT angles are discussed along with the kinematic data for osteoarthritic and prosthetic knees in Chapter 5.

3.1 Selection of optical tracking system

The two key functions of optical trackers are the detection of the tracked object within the field of measurement of the sensor, and the subsequent measurement of its location and orientation. Optical localisers perform these functions by observing targets on the tracked objects from multiple angles of view and then triangulating the line of sight to the targets to calculate their location. The 3D locations of at least 3 targets are needed to determine the orientation of the tracked object relative to the camera. CAOS systems in current use have reported distance measurement accuracy of within 1mm [Stockl et al. 2004]. Accurate tracking technology was therefore fundamental to the development of a non-invasive measurement tool. Two potential systems were selected for evaluation; one based on infrared (IR) and the other on visible light.

3.1.1 Infrared system

The Polaris camera (Northern Digital Inc, Waterloo, ON, Canada) with corresponding active IR trackers from the OrthoPilot® navigation system (OrthoPilot®, BBraun Aesculap, Tuttlingen, Germany) was chosen due to its current surgical use. This is an active system (Section 2.5.2.2.1) where the trackers consist of an array of IR light-emitting diodes (LEDs) enabling detection by the optical localiser.

The specific sequence of IR pulses is used to distinguish between more than one tracker within the measurement field. The power is supplied through an electrical cable which avoids the need for the additional weight of batteries. This was considered a potentially important factor for subsequent non-invasive mounting. The trackers are attached to fixation pins or surgical tools by a coupling mechanism.

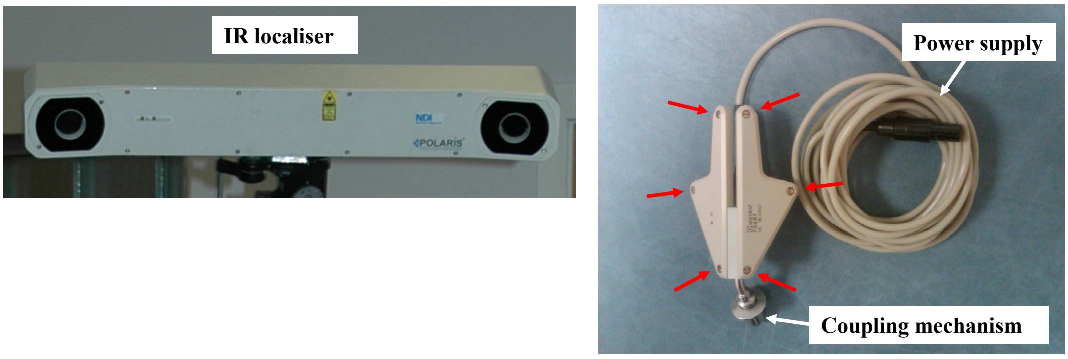


Figure 3.1 Localiser with corresponding active tracker with IR LEDs (red arrows)

3.1.2 Visible light system

The MicronTracker (Claron Technology Inc, Toronto, ON, Canada) fully passive visible light camera was selected based on its small size (case dimensions 172x57x57mm). This degree of portability was considered a major potential advantage given the aim of developing a system for use in a clinical setting where space can be limited.

This system used visible light and the tracking of a target was based on the detection of markers with visible geometric patterns. Specific areas on a marker required correct recognition in each of the images obtained by the two sensors. Once a marker pattern was identified in the two images, the exact 3D position of its target point could be calculated by triangulating the two projection lines associated with the two image positions in which the target sensor was observed.

The design of the rigid body was based on the IR tracker from the OrthoPilot® system but without the requirement for LEDs or a power supply. Therefore the coupling device mechanism was the same for both systems being evaluated. To complement its size and weight, the corresponding software was installed on a laptop computer and the entire system was contained in a portable case.

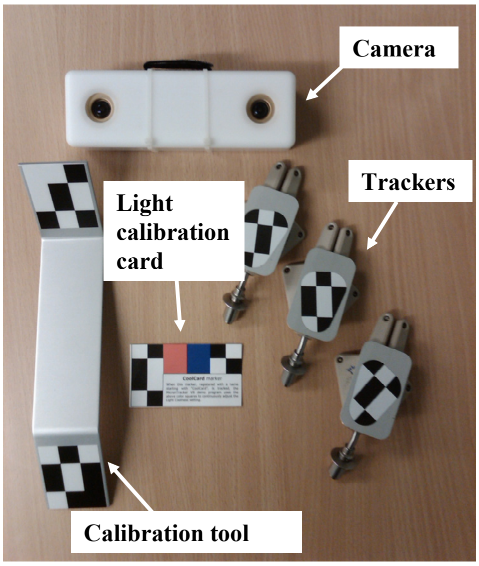


Figure 3.2 Visible light optical tracking system

3.1.2.1 Calibration

To exclude any potential degradation of accuracy as a result of environmental stresses or rough handling during transportation, a series of steps was undertaken to optimise the performance of the tracking system.

The camera was calibrated using the "R-Fine" application of the MicronTracker software which was designed for verifying and, if necessary, restoring the accuracy of the camera. This operated by detecting a two-faceted marker mounted on an S-shaped tool. The tool was held in a series of different orientations within the measurement volume as guided by the on-screen images and the variability of measurements of known length was used to quantify the degree of any distortion of the calibrated space. The multiple measurements of the tool were then used to optimally adjust the calibration model of the camera in order to reduce the length variability and eliminate any distortion effects. Following this process, the system indicated an 85% improvement in the accuracy of the camera from 1.6mm to 0.22mm root mean squared (RMS) error.

The reliance on visible light required the degree of "light coolness" to be measured. This property represented the overall balance between the light intensities along the continuum from blue (cool) to red (hot) ends of the visible spectrum. The MicronTracker software contained correction algorithms that automatically compensated for any changes in light coolness following the display of a marker card within the field of measurement.

3.2 Positional accuracy

Measuring the positional accuracy of a tracking system required the use of a standardised measurement object (phantom) calibrated to a suitable level of precision. In the absence of a commercially-available phantom or a published guideline for reporting accuracy, the proposed ASTM International draft standard [Bach et al. 2007] (Section 2.5.6) was obtained and its recommendations used to design a custom model.

3.2.1 Design of phantom model

Scaled manufacturing drawings were produced (Dr AH Deakin) based on a design over three levels (Figure 3.3). This consisted of a 150x150x20mm base plate and two additional levels including a single 30º slope.

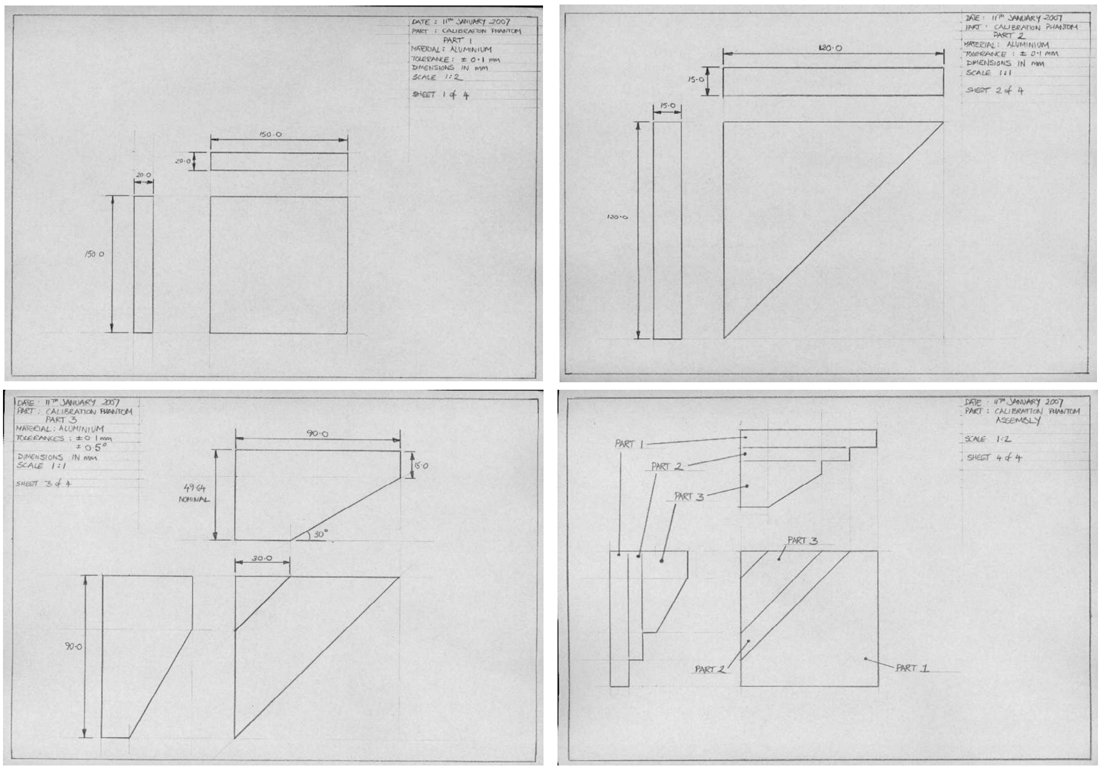


Figure 3.3 Manufacturing drawings for phantom

The final model was machined (Mr J Gillan) from a single billet of marine grade aluminium alloy 6082-T6, chosen for its dimensional stability, using a vertical computer numerical controlled (CNC) milling machine. This created a 3D surface on which 21 co-ordinates for 21 points were given at a variety of known locations (Figure 3.4). The holes were drilled with a Ø0.8mm 60º BS0 centre drill to a depth of 1.2mm, with chamfers of Ø1.0mm, designed to accommodate the 1.2 mm diameter ball-nosed tip of the pointer to be used, allowing the tip to fit into the hole and remain at the same position in space at all orientations of the pointer.

A Perspex base unit with three different sites of rigid tracker attachment was made to hold the phantom and provide its reference base (Figure 3.4). This avoided the need to directly modify the phantom itself, which could have resulted in the potential loss of its structural accuracy. It also allowed different fixation pins (secured in position by grub screws) and corresponding trackers to be attached permitting the evaluation and comparison of different systems. As a consequence of this modularity the precise locations of the points on the phantom relative to the origin of the attached rigid body were unknown and so repeatability was assessed for single point location. However the distance between points was known and so relative point to point accuracy could be evaluated.

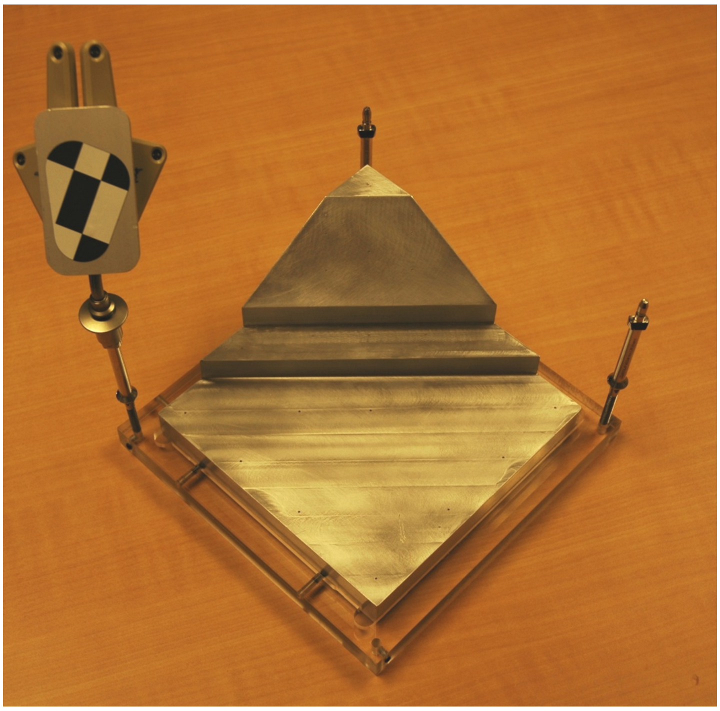


Figure 3.4 Phantom model with base unit and removable tracker pins for rigid body attachment

3.2.2 Methods

Software from the OrthoPilot® system was appropriately modified by BBraun Aesculap to allow repeated single point measurements for use with both of the tracking systems.

3.2.2.1 Apparatus set-up

The phantom was positioned within the optimum working range for each camera and in the centre of the measurement volume. This was approximately 2m for each system as indicated by the on-screen distance measurement. The fixed tracker generated an orthogonal xyz coordinate system, which seen from the camera made x horizontal, y depth (distance away from the camera) and z vertical (Figure 3.5).

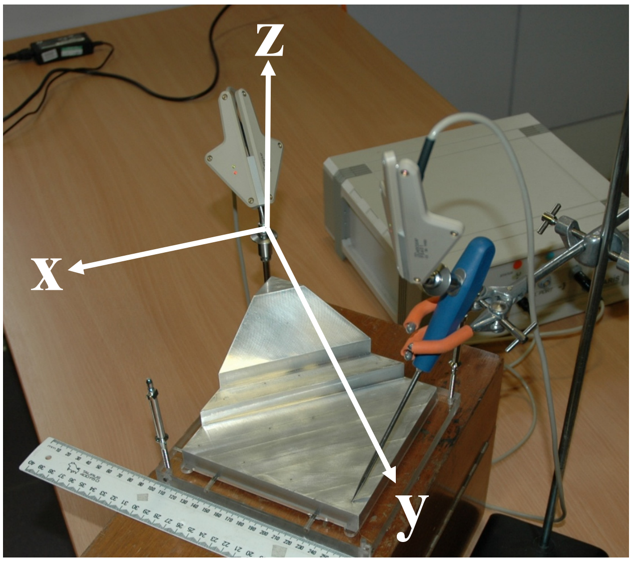


Figure 3.5 Apparatus set-up during clamped pointer trial illustrating the xyz coordinate system as viewed by the camera

3.2.2.2 Distance measurements

Two users with surgical navigation experience independently collected the same 10 points in sequence which provided nine length measurements between 50-130mm. The pointer was held by one hand and a foot pedal was used to register each point in a similar manner to that employed intra-operatively for anatomical landmark registration. This was repeated three times to give a total of 54 measurements. The distances between points as measured by the tracking systems were calculated and compared to the known absolute distances. The mean and range of error were calculated as a measure of accuracy, given that the comparative distances on the phantom model were taken to be the true measurements.

3.2.2.3 Single point repeatability

Due to the tracker interface being detachable the exact location of each point relative to the tracker was unknown and so repeatability (representing precision) was used for single point detection. In order to measure tracking precision under optimum conditions, the pointer was held securely by a clamp so that its tip remained in a fixed position in the point to be measured. This point was then registered 20 times in succession using the foot pedal and a total of five sets of trials were performed.

Between trials the pointer was removed and then re-clamped in the appropriate position.

The measurements were then repeated with the aim of quantifying the human movement artefacts associated with holding the pointer. In addition to the two clinicians used for distance measurements, a third observer with no surgical or CAOS experience was used. The three observers performed the measurements on two occasions using one and two-handed pointer grips with the aim of holding the pointer as still as possible. For each trial, the same point used for the clamped trials was registered 20 times in succession whilst holding the tip in the hole.

For each set of 20 measurements, a best-fit sphere was determined for the minimum size required to encompass all of the points. The sphere diameter was used to represent the maximum three-dimensional error for registration of the same point. The x, y and z coordinates for each point were examined separately and the spread of values represented as box plots to demonstrate the relative contributions of each axis to the overall three dimensional error and the intra-observer and inter-observer variation within and between each trial respectively.

3.2.3 Results

3.2.3.1 Distance measurements

For the linear distance measurements (Table 3.1), the IR system had a mean error of 0.4mm with an overall range of error of 2.3mm (-0.8 to 1.5mm). In comparison, the visible light system produced errors of up to 6mm. As a consequence of this unacceptable level of inaccuracy, the measurement of single point repeatability was not performed with the visible light system.

Table 3.1 Distance measurement errors for both IR and visible light tracking systems

	Distance measurement	
System	**Mean error (mm)**	**Range (mm)**
IR	0.4	-0.8 to 1.5
Visible light	3.4	1.5 to 6.2

3.2.3.2 Single point repeatability

Observers 1 and 2 (with prior CAOS experience) produced similar results for both single and two-handed pointer grips with sphere diameters of approximately 2.5mm required to encompass all the points (Table 3.2). Measurements obtained by observer 3 (novice with no navigation experience) showed inconsistencies and attempts to improve pointer stability with two hands led to an unexpected increase in the best-fit sphere diameter from 1.4 to 4.1mm.

Table 3.2 Minimum sphere diameters required to contain points in space for clamped trials and for observers of different experience (single and two-handed grips)

Trial (20 points each)	Mean centre x	Mean centre y	Mean centre z	Minimum sphere diameter (mm)
Clamp 1	-2.8	211.2	-80.1	0.3
Clamp 2	-2.1	212.3	-79.7	0.2
Clamp 3	-2.7	210.8	-79.8	0.2
Clamp 4	-2.2	211.1	-79.4	0.3
Clamp 5	-1.9	211.4	-79.3	0.3
Clamps combined (1-5)	-2.4	211.6	-79.7	1.8
Observer 1 (single hand)	-2.4	212.4	-80.1	2.3
Observer 1 (2 hands)	-2.1	211.7	-80.2	2.6
Observer 2 (single hand)	-2.2	211.8	-79.7	2.5
Observer 2 (2 hands)	-2.7	212.0	-80.1	2.6
Observer 3 (single hand)	-3.0	210.9	-80.2	1.4
Observer 3 (2 hands)	-2.5	211.7	-80.1	4.1

By comparison, the results obtained with the pointer clamped were considerably more precise and contained within spheres of 0.2-0.3mm diameter. However, when the pointer was removed and re-clamped the centre of the best-fit sphere for each trial varied in its location. This resulted in the cumulative error of the five clamp trials being significantly higher than each separate trial with a sphere of almost 2mm diameter required to encompass all 100 points.

The relative error of each axis is illustrated in the box plots (Figure 3.6). The z axis, which represented the vertical axis relative to the tracker, had the least amount of overall variation whereas the largest spread of values was seen with the y-axis, representing distance from the camera.

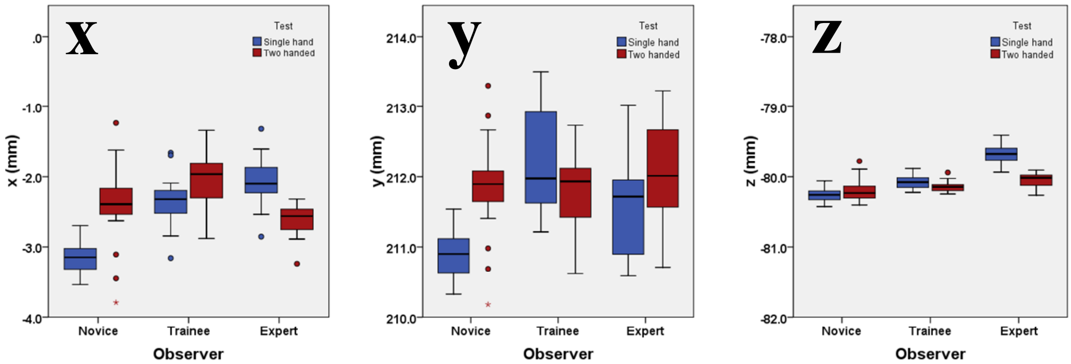


Figure 3.6 Box plots of location of points in space for each axis showing intra-observer and inter-observer variations for single-handed (blue) and two-handed (red) pointer grips (one increment on vertical axis = 1mm)

3.2.3.3 Summary

Positional testing demonstrated considerable levels of error for a visible light tracking system, but verified the accuracy and precision of a commercially available IR system which was selected for subsequent non-invasive adaptation. The results also highlighted the importance of holding the pointer as still as possible during point registration, although the precision of the system under optimum conditions could not be replicated with a manual grip.

3.3 Non-invasive adaptation of IR system

The normal intra-operative use of the IR system relies on rigid tracker fixation via pins inserted into bone in order to create a stable frame of reference for subsequent kinematic and anatomical landmark registration of the lower limb. Following this, the resultant MFT angle can be displayed in real-time providing a quantitative measurement of alignment (Section 2.5.2.2). The major challenge of adapting this technology for non-invasive use was the minimisation of potential soft tissue movement artefacts, requiring a stable method of tracker mounting to the appropriate lower limb regions.

3.3.1 Methods

3.3.1.1 External tracker mountings

Tracker mountings were required for the distal thigh and proximal calf regions corresponding to the normal sites of fixation for the femur and tibia trackers. For standard intra-operative practice, the system uses a 20 mm wide rubber strap to secure a metal tracker attachment base plate to the dorsum of the foot but this appeared to be insufficient for use around the thigh or calf regions in view of its size and degree of extensibility. Therefore an alternative material was selected; standard strength elastic webbing (542, E&E Accessories, UK), which was broader (45mm) and less extensible than the rubber strap. To accommodate a range of thigh and calf diameters, a variety of lengths were made with a sequence of eyelets at either end to connect to the tracker mounting plates and enable further adjustment of strap size (Figure 3.7). Attachment of the base plates was trialled on a volunteer at different locations and with varying degrees of tightness. The most stable positions appeared to be at the distal quadriceps musculo-tendinous junction for the thigh and at the point of maximal calf circumference, with base plate “hooked” over tibial crest, for the lower leg (Figure 3.7).

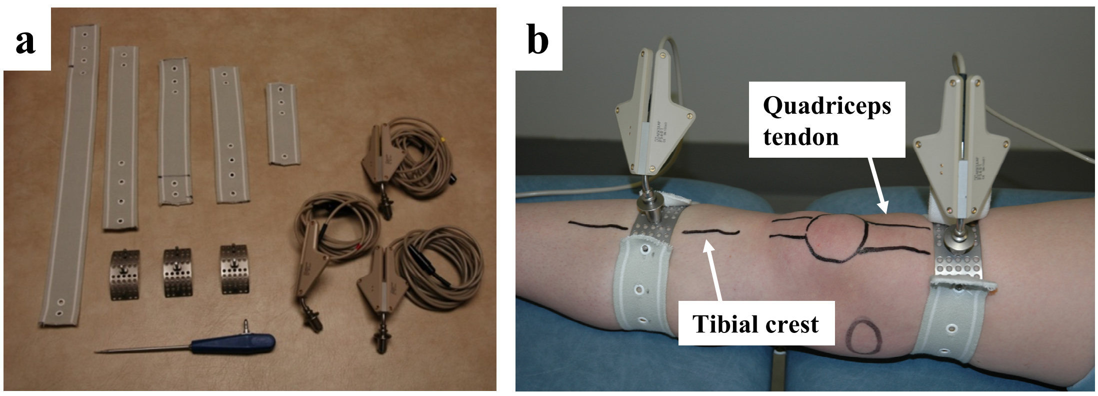


Figure 3.7 a) Straps and metal base plates for non-invasive mounting of trackers, b) mounted on right leg of volunteer

3.3.1.2 Rigid tracker mounting model

In order to quantify the soft tissue artefacts of the external mountings, a metal lower limb model was designed and manufactured to provide comparative optimum conditions for measuring knee alignment (Figure 3.8). This consisted of metal rods representing a femur, tibia and a foot with rigidly attached tracker mounts and mechanical hip, knee and ankle joints with the required range of movement for registration of their rotational centres. The knee and ankle were extended laterally to provide points representing the femoral epicondyles and ankle malleoli respectively. These anatomical points were required by the OrthoPilot® software as a means of verifying the kinematic joint centres [Picard 2007] and for the lower limb model were only necessary in order to advance the workflow of the software used.

Figure 3.8 Lower limb model with rigid tracker mountings

3.3.1.3 Tracker stability testing

To assess tracker stability, the repeatability of coronal knee alignment measurement for both the leg model and for the right lower limb of a slim, female volunteer (body mass index of 19) was determined. High tibial osteotomy (HTO) software

(Orthopilot® HTO v1.5, BBraun Aesculap, Tuttlingen, Germany) was used for kinematic determination of hip, knee and ankle centres and resultant determination of coronal MFT angles. Coronal alignment was defined with varus negative and valgus positive, whilst sagittal alignment was defined with hyperextension negative and flexion positive.

Following attachment of the trackers, the volunteer was asked to relax whilst lying supine on an examination couch. This was to minimise any muscle contractions and ensure that all movements were passive. The registration process followed that which would be employed intra-operatively in the normal use of the software (Figure 3.9). It began with the identification of the kinematic centre of the hip joint which required a slow, controlled circumduction of the thigh. The manoeuvre was performed in this manner to avoid moving the pelvis and subsequently altering the location of the rotational centre of the femoral head. If there was excessive movement of the pelvis or the trackers, then this could have resulted in a wider, "non-spherical" spread of acquired HJC points that was outwith the required precision of the system [Picard 2007]. This would result in rejection of the HJC acquisition and the instruction to repeat the circumduction manoeuvre until the spread of measured points was within the required threshold. The kinematic ankle centre was determined next by attaching a tracker to the dorsum of the foot and then dorsi-flexing and plantar-flexing the ankle. The broader strap was used in favour of the standard rubber strap as it appeared to hold the base plate more securely. The rotational centre of the knee joint was then acquired by flexing and extending the knee between 0 and 90° as well as rotating the tibia on the femur at 90° of flexion.

Hip **Ankle** **Knee**

Figure 3.9 Graphical guidance for kinematic acquisition of joint centres

Following a single registration, 20 consecutive MFT angle recordings were made with the rigid leg model stationary and with the volunteer instructed to remain as still as possible. The full registration process was then repeated a further 20 times on 13 different days to quantify additional soft tissue artefacts associated with removal and re-attachment of the trackers. Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) version 17 (SPSS Inc., Chicago, IL, USA) and F tests were used for comparison of the variances of the repeated data sets.

3.3.1.4 Volunteer repeatability

All experimental procedures were approved by the University of Strathclyde Ethics Committee and, after giving written informed consent, 30 volunteers were recruited (19 males and 11 females) with a mean age of 41 years (range 20-65) and a mean body mass index (BMI) of 26 (range 19-34). Participants confirmed no acute knee symptoms and no history of joint replacement. Basic demographic data were recorded prior to assessment of the right lower limb. Two kinematic registration processes were performed using the appropriate passive clinical manoeuvres described above. After each registration, the immediate coronal and sagittal alignments in full extension were recorded with the lower limb supported at the heel and the subject told to relax. Following this, coronal and sagittal alignment was measured with subjects asked to assume their normal bipedal stance. Returning the participant to the supine position, the coronal and sagittal alignment measurements were then performed twice and subsequent to this five manual stresses were applied to the knee joint by a single clinician to determine varus and valgus angular displacements. During these stress manoeuvres, the knee was held between 0° and 5° of flexion as indicated by the on-screen measurement of sagittal MFT angle. If the knee could not extend to 0° then the stress measurements were performed within a 5° window of flexion from the maximum extension angle. Following this, the coronal and sagittal alignment measurements were finally repeated twice again. Thus five supine coronal and sagittal MFT angles were determined, before and after standing and before and twice after five bouts of varus-valgus stressing. The clinician was blinded to all the recorded alignment measurements except for the initial supine coronal MFT angle following registration. Occasionally, this measurement after the second registration did not agree to within 2° of the first registration and if this occurred, the registration process was repeated. The limit of 2° was based on the acceptance of a small anticipated loss of accuracy due to soft tissue artefacts in comparison to the reported 1° accuracy for invasive use [Haaker et al. 2005]. The volunteer testing protocol and data collection form are shown in Appendix 2a and Appendix 2b respectively.

The mean difference and 95% limits of agreement [Bland & Altman, 1986] of supine coronal MFT angles taken consecutively, before and after standing and following collateral stress within each trial were measured. This was used as an indirect measure of any intra-registration tracker movement that may have occurred during manipulation of the lower limb or from the subject actively moving between supine and standing positions. The mean difference and 95% agreement limits were also used to assess inter-registration agreement of MFT angles measured supine, standing and following applied collateral stress. Bland-Altman plots were generated for all the comparative data sets. When more than one measurement of a variable was taken within a trial the median value was used.

3.3.2 Results

3.3.2.1 Tracker Stability

Comparison of the rigid and non-invasive mounts is shown in Table 3.3 and in box plots (Figure 3.10). Note that the y-axis of the box plots shows the distribution of measurements in relation to the "difference" from the mean rather than the actual mean values presented in the corresponding table. Consecutive readings of coronal alignment following a single registration demonstrated standard deviations of 0.07° and 0.13° for the rigid leg model and volunteer respectively and the variances were found to be statistically different ($p<0.01$) using an F-test. For multiple registrations the overall range was 1° larger for the non-invasive volunteer mounting but the SD was still less than 1° for both tracker mounting methods with no statistically significant difference in the variance of the groups.

Table 3.3 The mean and standard deviation (SD) of each set of tests was used to compare the difference in repeatability of the rigid model and the non-invasive tracker mounting (measurements in degrees)

	Single registration		**Multiple registrations**	
	Leg Model: Rigid mounting	**Volunteer: Non-invasive mounting**	**Leg Model: Rigid mounting**	**Volunteer: Non-invasive mounting**
n	20	20	20	20
Mean (SD)	2.1 (0.07)	1.4 (0.13)	1.6 (0.5)	1.5 (0.7)
range	2.0 – 2.3	1.1 – 1.6	0.9 – 2.8	0.3 – 2.5
F Test	p = 0.008		p =0.34	

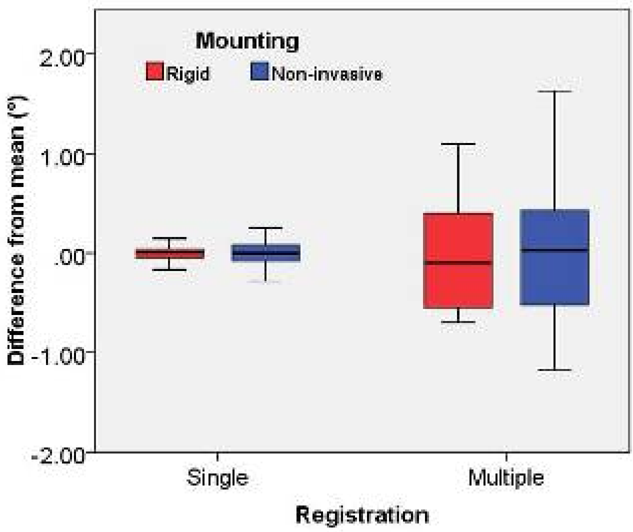


Figure 3.10 Box plots showing the distribution of coronal MFT angles following single and multiple registrations for rigid and non-invasive tracker mountings.

3.3.2.2 Repeatability

The alignment characteristics of the overall cohort and the male and female groups are shown in Table 3.4.

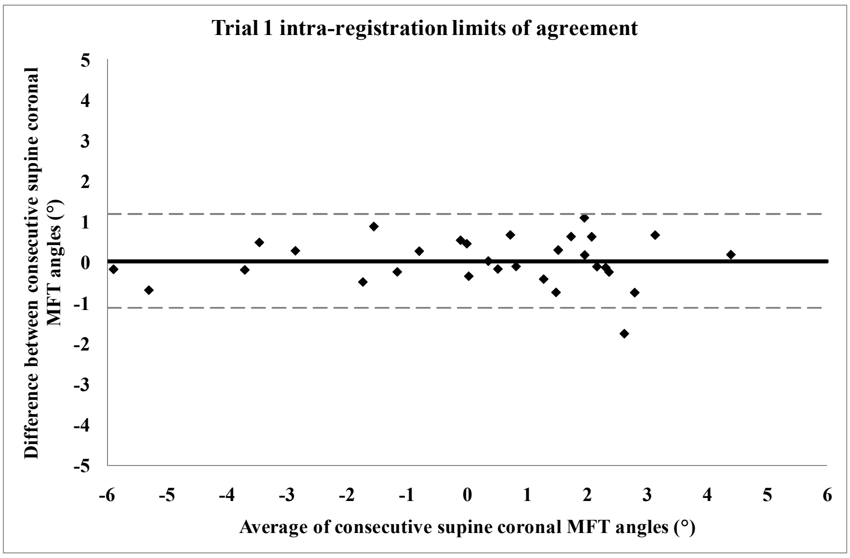
Table 3.4 Alignment characteristics of volunteer group

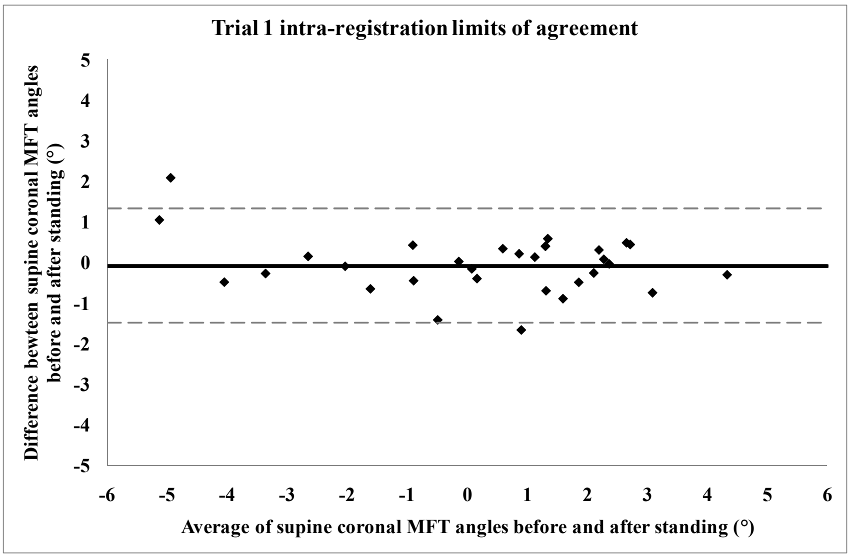
Measurement condition	MFT angle (°) mean ± SD		
	Overall (n=30)	Male (n=19)	Female (n=11)
Supine coronal	0.1±2.5	-0.7±2.7	1.0±1.9
Supine sagittal	-1.7±3.3	-1.3±3.6	-2.0±2.2
Change with varus stress	-3.8±1.2	-3.8±1.3	-3.6±1.5
Change with valgus stress	3.4±1.2	3.5±1.2	3.6±1.2
Standing coronal	-1.1±3.7	-1.5±3.8	-0.3±3.6
Standing sagittal	-5.5±4.9	-5.5±4.9	-5.0±5.2

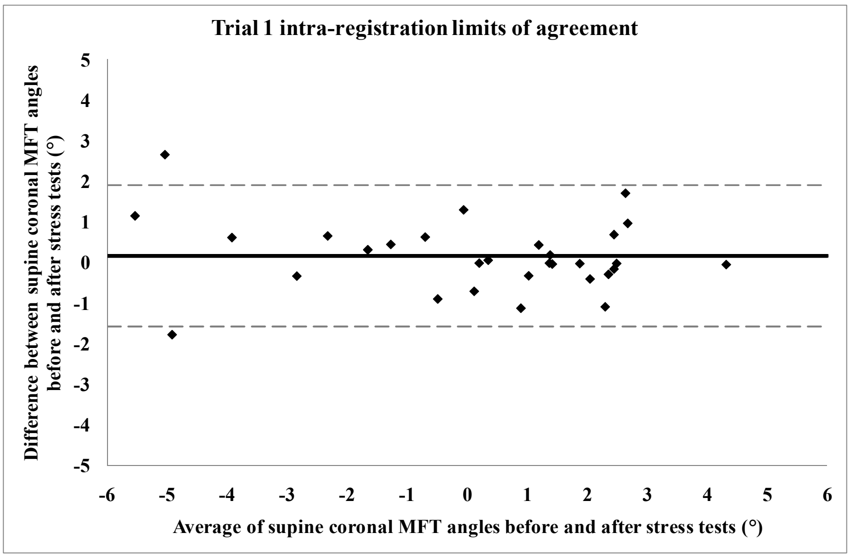
The intra-registration agreement of MFT angle measurements is shown for each of the two sets of registrations in Table 3.5. The corresponding Bland-Altman plots are shown in Figure 3.11. Repeat coronal alignment readings with the volunteer lower limbs stationary agreed to within almost ±1° for both the first and second registrations. For the first registration there was an approximate ±0.5° loss of repeatability for coronal alignment measured before and after collateral stress manoeuvres and a less significant loss of ±0.2° following stance trials. These small losses in coronal MFT angle repeatability were not seen for the second registration with a consistent agreement of approximately ±1°. Sagittal alignment measurements were less repeatable overall by an approximate factor of two and were generally no more precise for consecutive stationary readings.

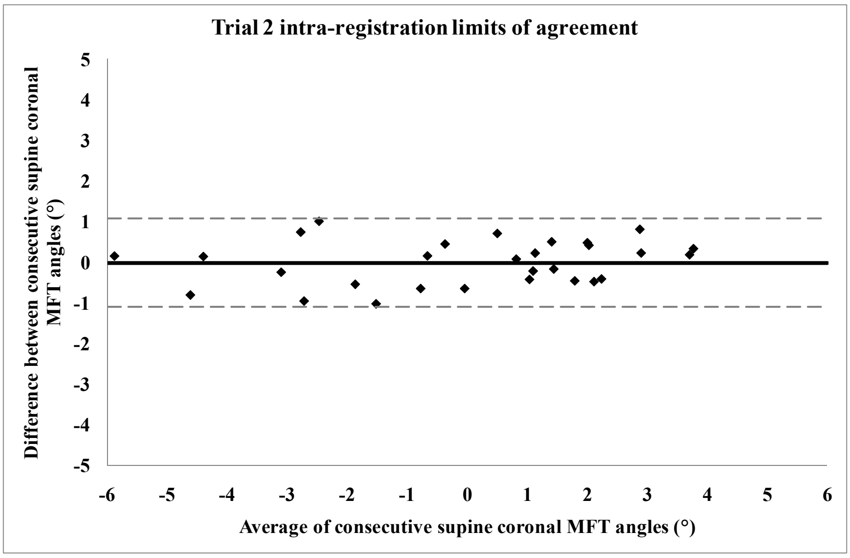
Table 3.5 Mean difference and 95% limits of agreement of repeat supine alignment measurements in extension with leg stationary and before and after both standing and collateral stress manoeuvres (measurements in degrees)

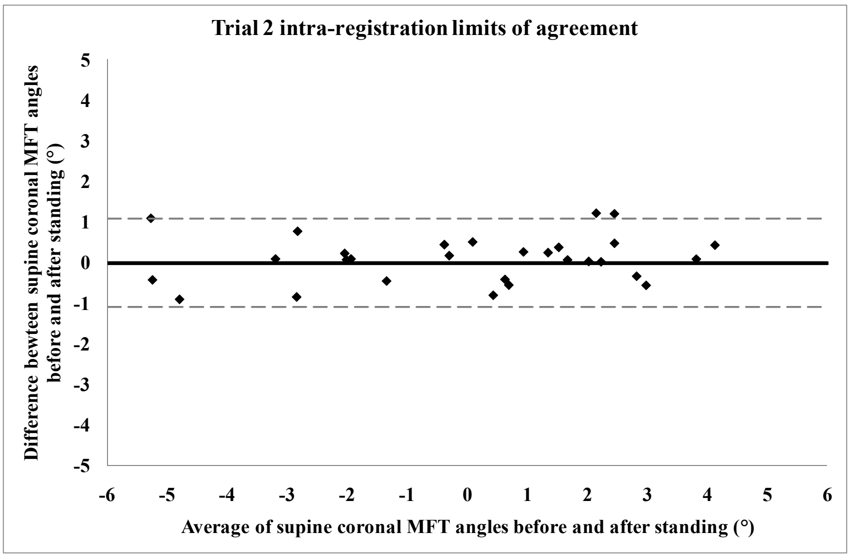
	Registration 1		Registration 2	
	Mean difference	**±1.96SD**	**Mean difference**	**±1.96SD**
Coronal MFT angle consecutive	0.03	1.2	-0.02	1.1
Coronal MFT angle before and after stance	-0.1	1.4	0.07	1.1
Coronal MFT angle before and after stress	0.2	1.7	0.2	1.0
Sagittal MFT angle consecutive	0.2	2.2	-0.1	2.1
Sagittal MFT angle before and after stance	0.5	2.8	0.7	2.6
Sagittal MFT angle before and after stress	-0.3	2.2	-0.9	1.7

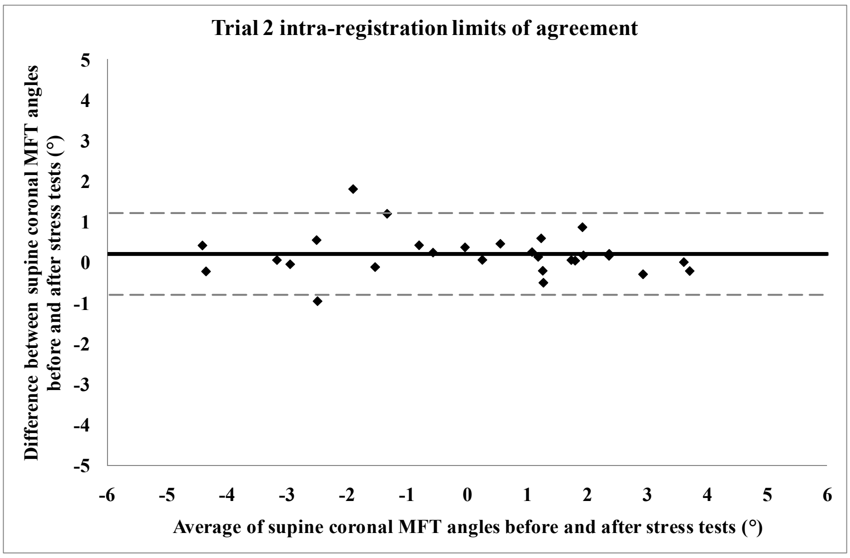


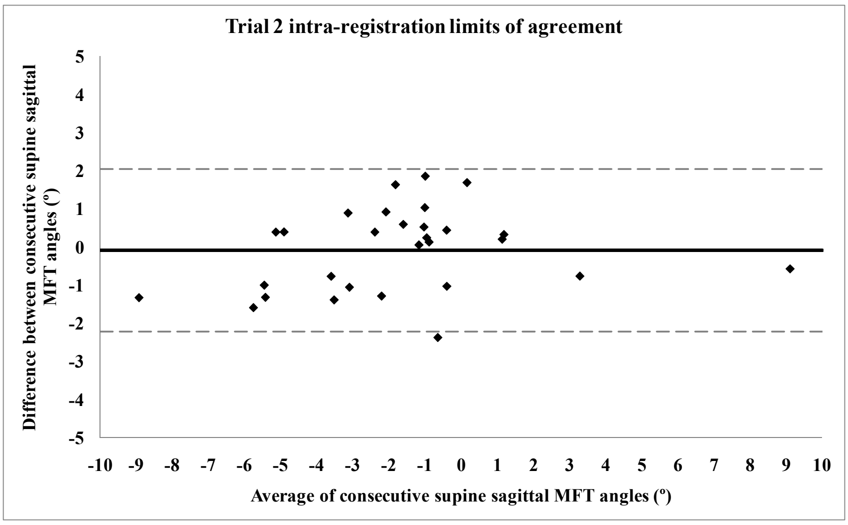

Trial 1 intra-registration limits of agreement
Difference bewteen supine coronal MFT angles before and after standing (°)
Average of supine coronal MFT angles before and after standing (°)
5
4
3
2
1
0
-1
-2
-3
-4
-5
-6
-5
-4
-3
-2
-1
0
1
2
3
4
5
6

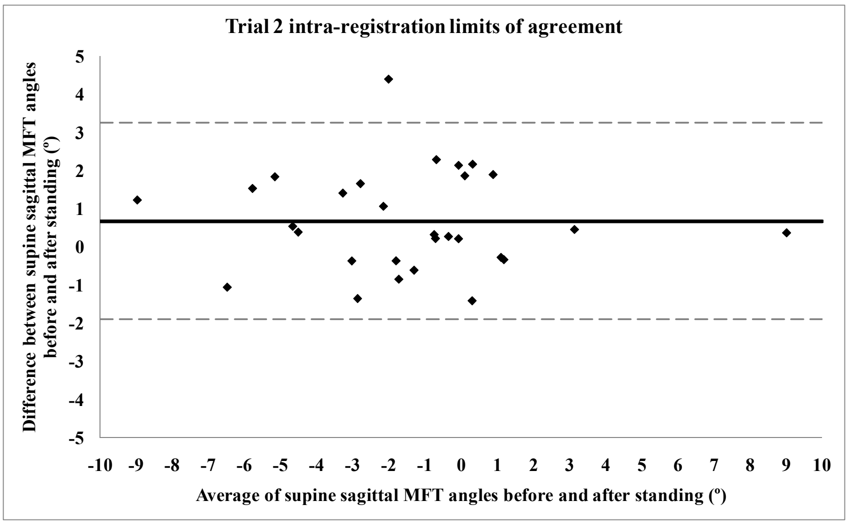

Trial 1 intra-registration limits of agreement
Difference between supine coronal MFT angles before and after stress tests (°)
Average of supine coronal MFT angles before and after stress tests (°)
5
4
3
2
1
0
-1
-2
-3
-4
-5
-6
-5
-4
-3
-2
-1
0
1
2
3
4
5
6


Trial 2 intra-registration limits of agreement
Difference between consecutive supine coronal MFT angles (°)
Average of consecutive supine coronal MFT angles (°)
5
4
3
2
1
0
-1
-2
-3
-4
-5
-6
-5
-4
-3
-2
-1
0
1
2
3
4
5
6


Trial 2 intra-registration limits of agreement
Difference bewteen supine coronal MFT angles before and after standing (°)
Average of supine coronal MFT angles before and after standing (°)


Trial 2 intra-registration limits of agreement
Difference between supine coronal MFT angles before and after stress tests (°)
Average of supine coronal MFT angles before and after stress tests (°)


Trial 2 intra-registration limits of agreement
Difference between consecutive supine sagittal MFT angles (°)
Average of consecutive supine sagittal MFT angles (°)



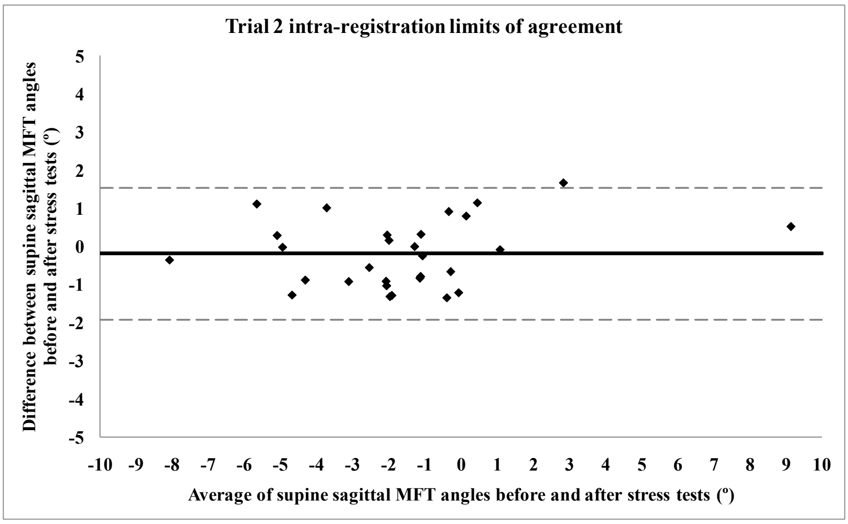


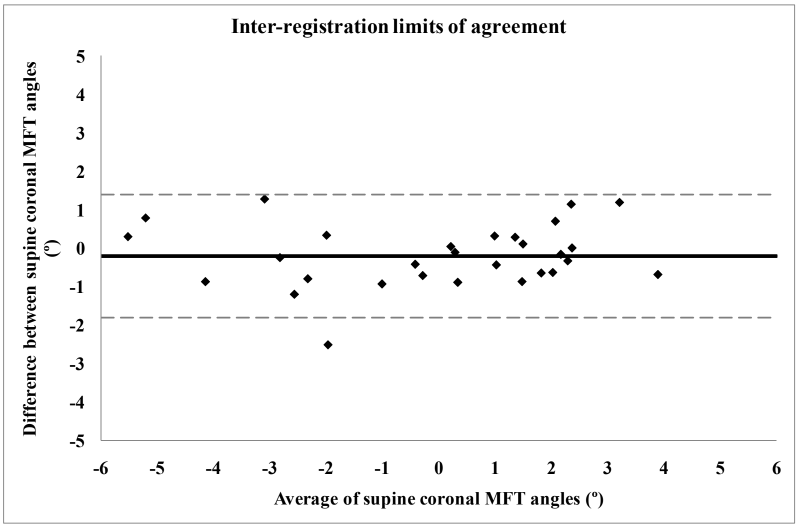
Figure 3.11 Bland-Altman plots showing intra-registration limits of agreement for trials 1 and 2

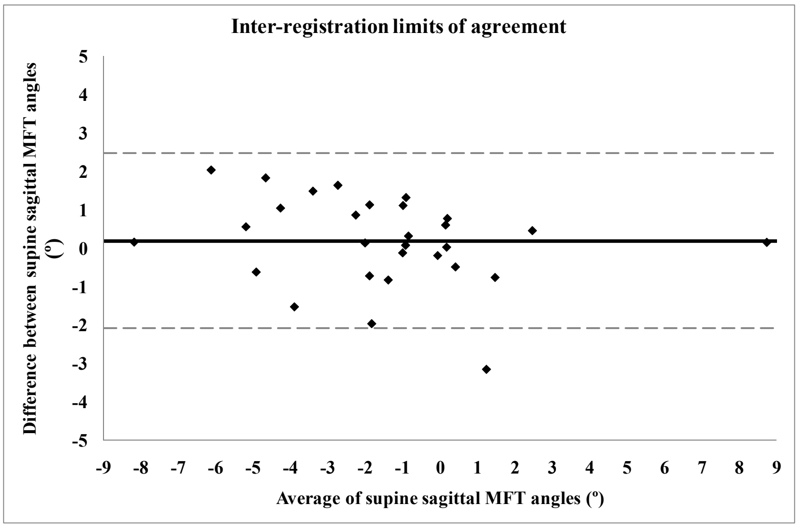
The agreement between the two registrations (Table 3.6) indicated a repeatability of approximately ±1° for all the supine alignment measurements including change with applied stress. On three occasions, a third registration process was required to obtain two consecutive registrations with a difference in supine coronal MFT angle of 2° or less.

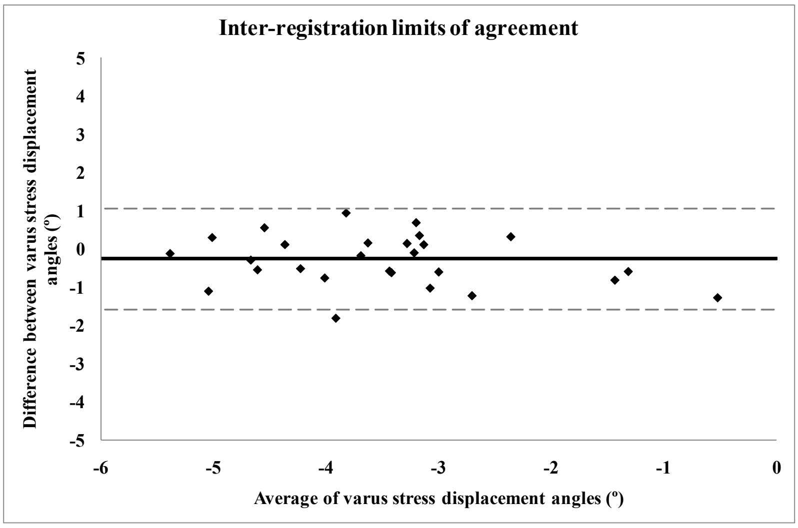
Standing alignment measurements showed less agreement for both coronal (±3°) and sagittal (±5°) MFT angles. These results are illustrated in Bland-Altman plots (Figure 3.12).

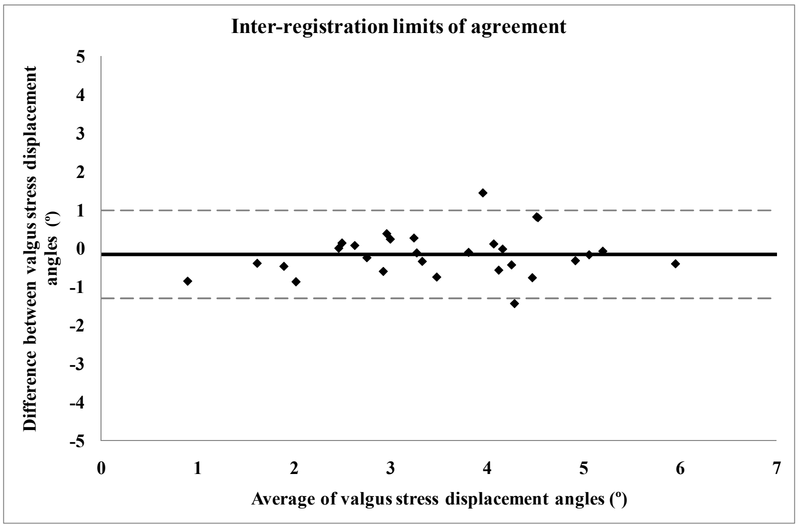
Table 3.6 Inter-registration agreement of supine and standing coronal and sagittal MFT angles, and relative change following varus-valgus stress (measurements in degrees**)**

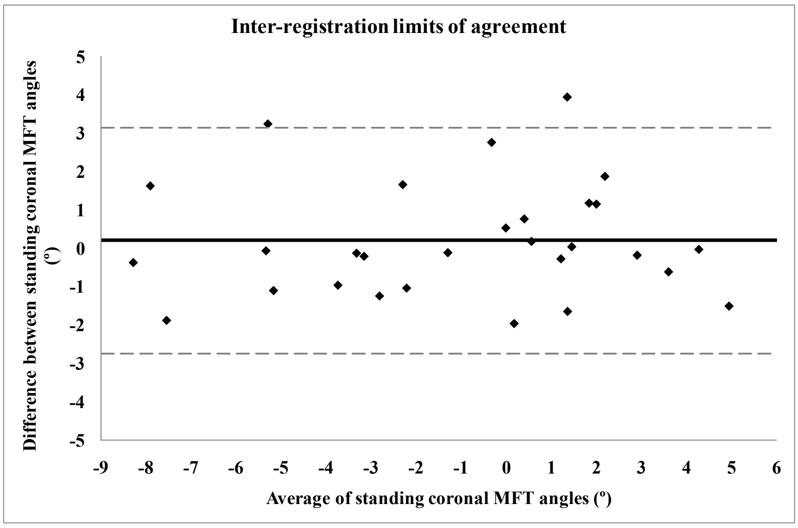
MFT angle	Mean difference	±1.96SD
Supine coronal	-0.2	1.6
Supine sagittal	0.2	2.3
Coronal change with varus stress	-0.3	1.3
Coronal change with valgus stress	-0.2	1.1
Standing coronal	0.2	2.9
Standing sagittal	0.1	5.0






Inter-registration limits of agreement
Difference between varus stress displacement angles (°)
Average of varus stress displacement angles (°)
5
4
3
2
1
0
-1
-2
-3
-4
-5
-6
-5
-4
-3
-2
-1
0


Inter-registration limits of agreement
Difference between valgus stress displacement angles (°)
Average of valgus stress displacement angles (°)
5
4
3
2
1
0
-1
-2
-3
-4
-5
0
1
2
3
4
5
6
7


Inter-registration limits of agreement
Difference between standing coronal MFT angles (°)
Average of standing coronal MFT angles (°)
5
4
3
2
1
0
-1
-2
-3
-4
-5
-9
-8
-7
-6
-5
-4
-3
-2
-1
0
1
2
3
4
5
6

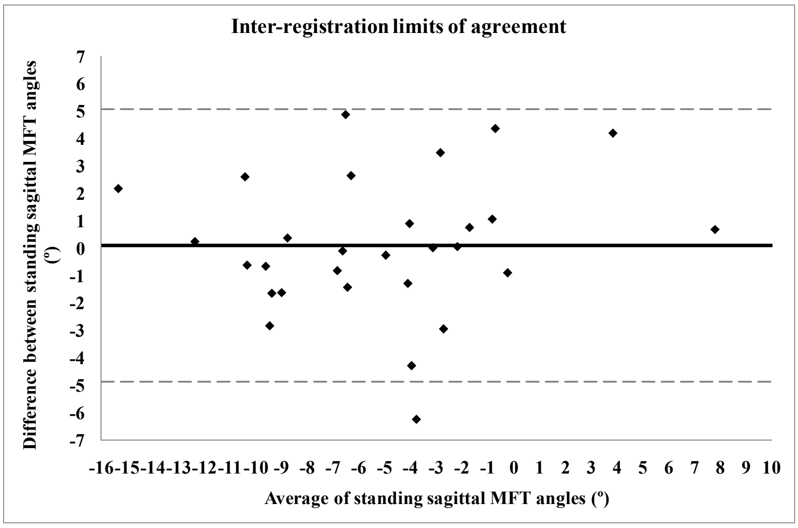


Figure 3.12 Bland-Altman plots showing inter-registration limits of agreement between trials 1 and 2

3.3.2.3 Summary

In comparison to rigid attachment, the non-invasive mounting of trackers resulted in an approximate 1° loss of coronal MFT angle repeatability as a result of soft tissue artefacts. This degree of error was reflected in the intra-registration and inter-registration 95% agreement limits for coronal alignment, which were approximately ±1° and ±1.5° respectively. In spite of a potential variation in applied manual load, this level of repeatability was maintained for coronal alignment change with varus and valgus stress. For supine unstressed measurements, the intra-registration and inter-registration agreement limits for sagittal MFT angles were less precise by up to 1°. The inter-registration standing measurements were less repeatable overall, particularly for the sagittal MFT angle.

3.4 Discussion of system validation

3.4.1 Positional accuracy

For optical tracking systems, one of the most basic functions is the accurate three-dimensional location of a point in space. It was therefore essential to confirm the accuracy of this parameter for the two systems being evaluated prior to subsequent non-invasive adaptation of the trackers. For commercially available systems, the positional accuracy with a rigid frame of reference is often quoted as approximately 1mm [Stockl et al. 2004], but there are few independent reports validating this figure. The guidelines proposed by ASTM International [Bach et al. 2007], led to the development of a test phantom and a simple, standardised method of measuring positional accuracy. This enabled the independent validation of the tracking performance of an IR system used in a commercially available navigation system. With the pointer clamped, the precision was well within the expected range of 1mm for each trial. However clamp re-application resulted in significantly less overall precision for the five trials with variation of the sphere centres and a larger cumulative error. This loss of precision may have been due to variations in tracker position between trials as changes in marker orientation can potentially affect accuracy [Maletsky et al. 2007].

Human movement artefacts introduced a surprising loss of accuracy by a factor of almost ten. This was in spite of optimal test conditions and attempts to hold the pointer as still as possible. Operator experience may also contribute to accuracy of point registration with less consistent results for a novice operator who produced both the largest and smallest sphere diameters. By comparison, the experienced operators produced more consistent results similar to the combined clamp trials but still significantly less precise than the individual clamped measurements.

For the visible light optical system, the magnitude of the point localisation error was considered unacceptable for further development as it was well beyond the desired 1mm range in spite of undergoing a thorough re-calibration process that claimed to have improved the measurement error to within this limit. This highlights the importance of independent accuracy testing which enabled identification of this error at an early stage and avoided any further development or clinical evaluation from being undertaken.

For the end user of a CAOS system, clinical outcome measures such as post-operative limb alignment and implant positioning may be more relevant compared to reports on technical accuracy. However, the degree of point registration accuracy required for different surgical steps may be an important consideration as small errors in locating landmarks can lead to significant errors of anatomical reference frames. For example in TKA, a 7mm anteroposterior error in identifying one of the femoral epicondyles could correspond to approximately 5° of rotational error in the transverse plane [Siston et al. 2007]. Potential errors such as this, along with inconsistent anatomical landmark identification [Robinson et al. 2006] may help to explain why some studies have failed to demonstrate a clinical advantage of CAOS systems over traditional instrumentation techniques [Lützner et al. 2008, Spencer et al. 2007].

3.4.2 Non-invasive adaptation of IR system

The stability of the IR tracker mountings permitted non-invasive kinematic measurement of knee alignment. For a single volunteer, the non-invasive attachments compared well with the rigid mountings of the leg model. The variance of volunteer measurements for repeated consecutive MFT angles on one registration was statistically greater than that of the rigidly fixed mounting but this difference was of doubtful clinical significance given that both set-ups were well within a precision of 1°. For repeated registrations, the SD of the non-invasive mounting was a third higher than the leg model but the actual range was only 1° larger with no statistical difference between the two. This result was perhaps surprising given that the leg model had a rigid hinge for a knee joint with no collateral movement and therefore a more consistent MFT angle. The only minor source of variation between trials on different days was the coupling mechanism between the trackers and fixation screws. In comparison, the volunteer straps would not have been identically applied in terms of both position and tightness. Furthermore, the small amount of natural collateral laxity of the volunteer knee could potentially have resulted in real differences in alignment on different days.

3.4.3 Volunteer repeatability

Further evaluation of the non-invasive tracker mountings was provided by repeatability of alignment measurements on multiple volunteers. The mean values of the MFT angles (Table 3.4) are subsequently discussed in conjunction with osteoarthritic and prosthetic knees in Chapter 5.

Following registration, the lower limb coronal and sagittal MFT angles could be repeatedly measured in real-time permitting an intra-registration assessment of tracker stability following stance and varus-valgus stress. These limb movements could have potentially modified tracker position but qualitatively they appeared stable throughout and remained in position for the duration of the measurements with no complaints of discomfort. This observation of stability was reflected in the results for consecutive coronal MFT angle measurements in comparison to those taken before and after stance and collateral stress of the knee. All repeatability was within levels of clinical relevance. For sagittal alignment the measurements were less repeatable overall within both sets of registrations with the poorest limits of agreement of up to almost ±3° seen before and after stance. However this may reflect a true difference in sagittal MFT angles rather than a change in tracker position. Some volunteers were noted to have poor relaxation which often improved throughout the course of the assessment with less resistance to full extension from the hamstring muscles. This resulted in a tendency for knees to become more extended towards the end of the trials which could potentially explain the greater variation in sagittal measurements in comparison to coronal MFT angles which were less likely to be affected by muscle tone.

The 95% limits of agreement between the two sets of registrations ranged from approximately ±1° to ±1.5° for all the supine coronal MFT angles including change with applied stress. For the initial supine coronal alignment measurements only three gave inconsistent results that required repetition. All repetitions were acceptable. Therefore although the registration process was open to error it was an infrequent occurrence and a simple repeat protocol enabled it to be identified every time.

The potential variation in applied manual load to the knee did not result in the loss of repeatability that would perhaps have been anticipated. This may be explained by the consistency of the clinician performing the collateral stress manoeuvres [Clarke et al. 2009] which may have shown greater inter-observer variation if different examiners were assessed. Standing alignment measurements showed less agreement for both coronal (±3°) and sagittal (±5°) MFT angles. This may have represented a true difference in alignment as a result of stance variation between trials as volunteers were only instructed to stand as normal rather than to assume a position of maximum extension with their knees “locked” straight. Therefore the variation in standing knee extension angle could have been due to this lack of control of limb position. In comparison, the supine measurements were performed in a more reproducible manner by supporting the lower limb under the heel and this was reflected in the narrower agreement limits illustrated with Bland-Altman plots. The ±5° scale of the y-axis (except for standing sagittal measurements) was chosen to reflect typical repeatability of other methods of assessing both sagittal [Edwards et al. 2004] and coronal [Mündermann et al. 2008] knee alignment including human variations of joint angle estimation [Markolf et al. 1976]. However it should be noted that considerably greater intra-observer estimates of knee flexion and extension angles have been reported with critical differences between measurements of 7.1° to 21.4° [Cushnaghan et al. 1990].

The use of externally mounted markers and a motion capture system was not an entirely novel approach to measuring lower limb alignment. Mündermann [2008] used this technology to measure static mechanical lower limb alignment but reported only a moderate correlation (R^2=0.544) with the corresponding long-leg radiographs and a discrepancy of more than 5.3° for 10% of cases. However, the hip, knee and ankle joint centres were determined from anthropometric measurements which are widely accepted as being inaccurate, particularly for the hip joint [Bell et al. 1990, Hicks and Richards 2005, Leardini et al. 1999, McGibbon et al. 1997]. The experimental set up in terms of anatomical landmark identification, marker placement, positioning of multiple cameras and data capture analysis also presented several limitations as a clinically adaptable measurement tool. In contrast, the system developed in this study consisted of a single portable camera unit with corresponding IR trackers that should be secure and visible but without the requirement of specific anatomical placement. The kinematic registration process was approximately five minutes with on-screen guidance for performing simple joint movements to determine their rotational centres. The subsequent MFT angle was generated from kinematic data alone without the potential associated errors of anatomical landmark registration [Robinson et al. 2006]. Hip joint centre location errors were minimised by a software algorithm that rejected the points in space acquired during thigh circumduction if their spread was too large or the distribution was non-spherical [Picard 2007]. The passive movements for kinematic registration were therefore required to be slow and controlled, which contrasts to other studies of functional joint centre determination using active movements or gait [Sangeux et al. 2006, Stagni et al. 2005].

The immediate generation of real-time on-screen coronal and sagittal MFT angles presented a number of potential advantages over other measurement systems. Firstly it enabled dynamic measurements of alignment to be made following applied stress or weight bearing with immediate visualisation of angular displacement. The ability to measure the resultant change in coronal MFT angle from a supine resting position following application of collateral stress has a potential clinical application for improving the measurement of relative varus and valgus knee laxity. Current methods are either subjective [Krackow 1990a], or rely on adjuncts such as X-ray measurements of tibiofemoral gap opening [LaPrade et al. 2008] which are prone to potential radiographic errors associated with limb positioning [Krackow et al. 1990b, Siu et al. 1991]. For weight-bearing conditions, the measurements did not require strict rotational control of the lower limb and the coronal MFT angle was recorded with the associated knee flexion angle. This IR system could therefore potentially offer a viable alternative to long-leg radiographs whilst also overcoming some of the previously discussed limitations.

The methodology for validation of the system had its limitations. The measurements were made by a single clinician involved in the development of the system without an assessment of inter-observer variation. The true volunteer knee alignments were unknown and so validation of the measurement tool was based on repeatability rather than comparison to a measurement standard. However, the IR measurement system is validated for use with rigid tracker attachments. It could therefore be inferred that repeatable measurements are also accurate, as for measurements to be repeatable, soft tissue artefacts must be minimal. In addition, it could be argued that the acknowledged long-leg radiographic gold standard has more potential variation [Siu et al. 1991] than the IR system which raises doubts as to whether x-rays are a suitable reference standard. Although there were several obese subjects, there were none who were morbidly obese and no subject reported discomfort when performing the necessary kinematic manoeuvres. The registration process may have been less reliable in a typically more obese osteoarthritic population [Amin et al. 2006, Dowsey et al. 2010] with potential pain on joint movement. This was subsequently addressed in the clinical trial (Section 5.1.2).

In summary, a non-invasive tool for measuring coronal and sagittal knee alignment under a number of dynamic, real-time conditions was developed and validated. This tool was used to quantify the kinematics of normal knees, both alignment and laxity. The portability of the system offers potential as an out-patient assessment tool and provides an alternative to long-leg radiographs without exposure to radiation. The measurement of supine, standing and stress alignment on both asymptomatic and osteoarthritic subjects may help to further our understanding of the complex kinematics of the knee.

4 Standardising collateral knee laxity assessment

The validation testing demonstrated that the non-invasive IR system was repeatable to approximately ±1° for supine MFT angle measurments, including varus and valgus stress. Therefore the clinical manoeuvre for testing collateral laxity appeared to be as consistent as the resolution of the IR measurement of angular displacement. This consistency may have been the result of a single clinician performing all the stress measurements on healthy knees, so quantifying this technique was important for more widespread clinical use. Standardising clinical examination could ensure that the non-invasive IR data was obtained in the same way, enabling a more direct inter-observer comparison of stress measurements. In addition, if there was scope to improve the consistency of measurements it was preferable to do this prior to assessment of osteoarthritic knees (Chapter 5).

The development of a quantitative assessment technique of coronal knee laxity for incorporation into current routine practice requires accurate standardisation of several parameters. The knee flexion angle should be determined and then maintained during the testing to minimise the potential positional variation in ligament restraining properties [Grood et al. 1981, Markolf et al. 1976, Noyes et al. 1980]. The hand positioning of the examining clinician should correspond to a measured lever arm, defined as the perpendicular distance of the applied force from the rotational knee centre. Accurate measurement of this manual force is then required to calculate the moment applied to the knee joint. Finally, the resultant displacement of the tibia with respect to the femur should be quantified as a measure of ligament laxity.

This chapter reports the measurement and subsequent control of these parameters. Validation of the non-invasive system for accurately recording knee flexion was achieved by comparison to a commercially available flexible electrogoniometer. The measurement of applied manual load required the design and manufacture of a force application device with the goal of incorporating this into a routine clinical manoeuvre for assessing laxity. The lever arm was measured using the non-invasive system to determine the perpendicular distance from the applied manual force to the rotational knee centre. Finally, the change in coronal MFT angle following applied varus and valgus loads was used to measure collateral joint laxity.

4.1 Methods

4.1.1 Knee flexion

The validation of the non-invasive system for assessing coronal knee laxity was based on repeatability measurements within the range of 0° to 5° of flexion. To further verify the IR measurement system for the precise control of flexion within this range, comparison was made with a validated flexible electrogoniometer (EG) (Biometrics Ltd, Cwmfelinfach, Gwent, UK) [Rowe et al. 2001]. In addition to measuring flexion angles with the knee extended, the flexible EG also provided a means of comparing sagittal alignment measurements throughout the entire arc of flexion. Validation of the IR system for recording maximum flexion could then enable measurement of this parameter for patients with OA, before and after TKA.

The right lower limb of a female volunteer (age 37, body mass index 19) was set up for the simultaneous use of both systems (Figure 4.1). The two end plates of the EG were attached to the lateral side of the leg using double sided medical tape with one end plate distal and the other proximal to the knee joint centre. The device was aligned along the estimated neutral mechanical axis of the hip-knee-ankle joint centres with the lower limb in full extension. The IR trackers were then attached over the top of the EG end plates using the extensible straps and metal base plates. Mechanical lower limb alignment was then measured using the kinematic registration process of the IR system and the knee positioned and recorded in 0° of flexion according to the on-screen display. This provided the ‘zero’ point for the EG with synchronisation of the two systems performed at the start of each trial.

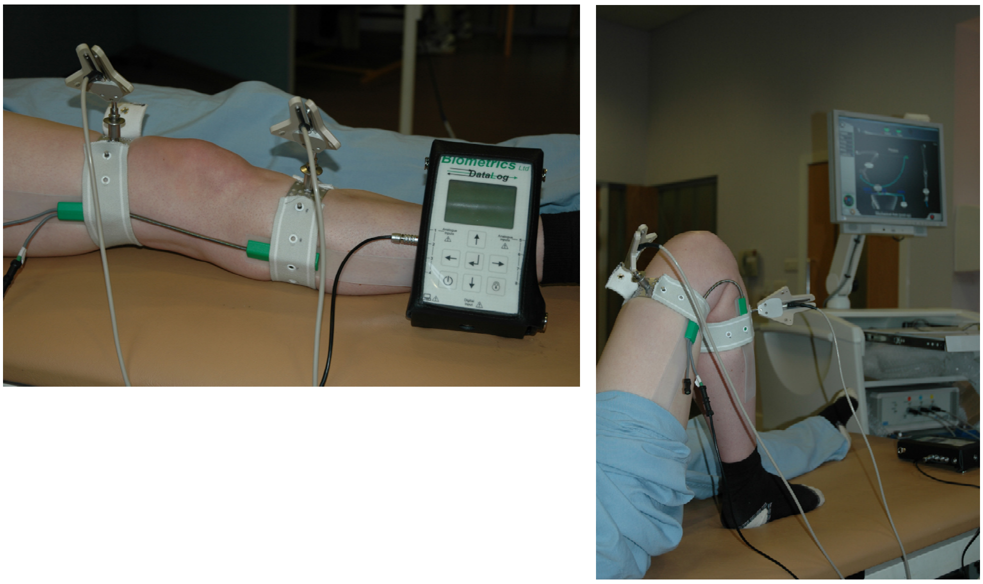


Figure 4.1 Simultaneous attachment of flexible EG and non-invasive IR trackers to volunteer lower limb with knee in extension and maximum recorded flexion (130°)

The knee was then passively flexed and held as stable as possible in 1° increments, as indicated by the IR system, and the precise angle at each point registered simultaneously by each system. After reaching 10° of flexion the knee was subsequently flexed in 10° increments up to a maximum of 130°. The trial was performed three times and the EG zeroed at the start of each set of measurements.

4.1.2 Moment arm

The moment arm was determined by the position of the clinician's hands during laxity assessment. The planned position of the manual force application was directly over the medial (valgus) or lateral (varus) ankle malleolus with the supporting hand placed over the medial (varus) or lateral (valgus) femoral epicondyle. The direction of application of the force was assumed to be in the coronal plane and perpendicular to the mechanical axis of the tibia. Thus the moment arm was the distance from the ankle centre to the rotational knee centre, which could be determined from the kinematic registration process of the non-invasive IR tracking system as the kinematic registrations identified the three-dimensional location of the rotational knee and ankle centres. To validate the repeatability of the system for knee centre to ankle centre measurement, 20 separate registrations were performed by a single clinician on both the leg model with rigidly fixed tracker mounting pins (Section 3.3.1.2) and the right lower limb of a female volunteer (age 37, body mass index 19) with the IR trackers removed and re-applied each time. The kinematic registrations identified the xyz coordinates of the rotational knee ($x_1y_1z_1$) and ankle ($x_2y_2z_2$) centres with respect to the same reference (tibial tracker). This enabled calculation of the moment arm as $\sqrt{(dx^2 + dy^2 + dz^2)}$, where $dx=x_1-x_2$; $dy=y_1- y_2$; $dz=z_1- z_2$. The previous paired volunteer registrations (Section 3.3.1.4) provided an additional 30 subjects for assessing moment arm repeatability.

4.1.3 Applied force and moment

4.1.3.1 Design and development of a force application device

The main goals of the hand-held force application device (FAD) were incorporation into routine clinical knee examination and accuracy of measurement. The design was based on a right-angled shell with a view to orthogonally mounting two transducers. Several prototypes were made out of cardboard in order to select the most appropriate geometry and dimensions for ease of manual use. The selected dimensions of the first working prototype (Figure 4.2) were 120x75mm for each of the two rectangular sections of the external shell. This was required to be stiff and light and so 3mm thick aluminium was chosen. For measuring force, two six degree of freedom Nano-25 force and torque sensors (ATI Industrial Automation, Apex, NC, USA) were chosen for their accuracy and small size. They were positioned orthogonally via the mounting adapters to the shell. The centre of each transducer was positioned 45mm from the end and 27.5mm from each of the sides of the rectangular sections of the shell. For contact with the ankle, two 80x60mm rectangular plates of 3mm aluminium were made and then attached to the tool adapter surfaces of the transducers. The inner patient contact surface then required a deformable material to avoid potential discomfort or skin damage. Expanded cross-linked polyurethane foam (Pe-Lite Medium – 5mm thickness) was selected and secured to the plates with strong adhesive. This internal aspect was designed to accommodate the ankle region with one contact surface acting as a leg support and the other being applied to either the medial or lateral malleolus during force application. The original design drawing and orientation of the xyz axes of each transducer are shown in Appendix 4.

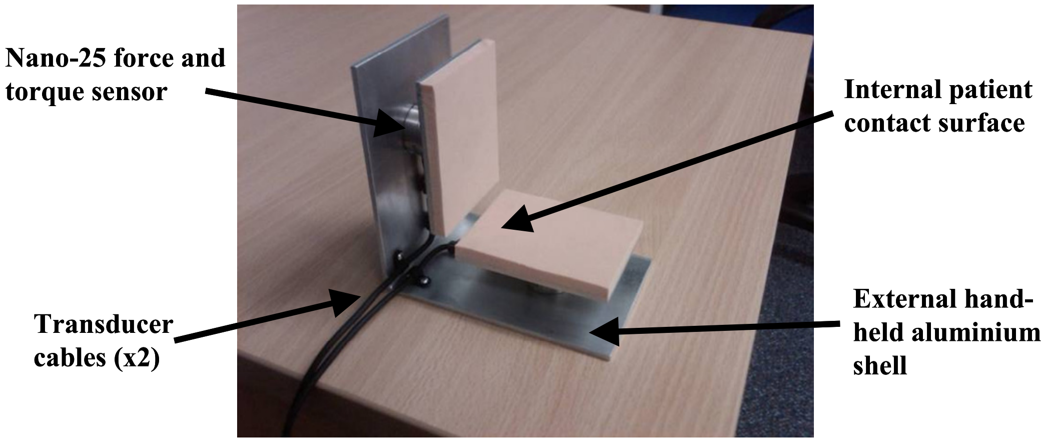


Figure 4.2 FAD working prototype

The two transducers were connected via an analogue to digital Data Acquisition (DAQ) board (NI USB-6229 M Series, National Instruments, Austin TX, USA) to a personal computer. LabView software (National Instruments, Austin TX, USA) was used to create a graphical user interface (GUI) to display the force data (work done by Dr AH Deakin). During the planned clinical application of the FAD it was anticipated that most of the compressive loading would be along a single axis (Fz) but to account for variations in orientation and shear forces on the other transducer, the GUI was configured to display the resultant of the three force channels (Fx, Fy, Fz) for each transducer ($\sqrt{(Fx^2+Fy^2+Fz^2)}$).

To ensure that there was no significant loss of transducer accuracy following incorporation into the FAD, incremental compressive loading in three orientations (Appendix) was performed using an Instron 5800R uniaxial testing machine (Instron® Ltd, High Wycombe, Bucks, UK) fitted with a 100N load cell (accuracy 0.1% full scale, 0.1N). Loading was performed in 5N increments from 0 up to 40N.

This upper limit was based on the maximum anticipated load to the knee not exceeding 12Nm, the subject tolerance limit often quoted in other studies measuring laxity [LaPrade et al. 2008, Sharma et al. 1999, van der Esch et al. 2006]. The rate of loading was 10N/s (i.e. each load step applied over 0.5 seconds) and the load was maintained for 10 seconds for each increment. This was felt to represent a typical amount of time for performing a stress manoeuvre in routine clinical practice. Testing was initially performed with a load applied directly along the z-axis and roughly estimated to be centred over the nanotransducer (Figure 4.3). It was then repeated to look at loading two axes (Fz and Fx; Fz and Fy) simultaneously by applying a load at 45°. This was done via a metal plate made of 3mm aluminium which fitted over the polyurethane and was designed and manufactured to use along with a 45° block. The FAD was held in a 45° V-block for this testing (Figure 5b). The Instron force data was recorded simultaneously via the DAQ board to allow comparisons with the transducer force outputs.

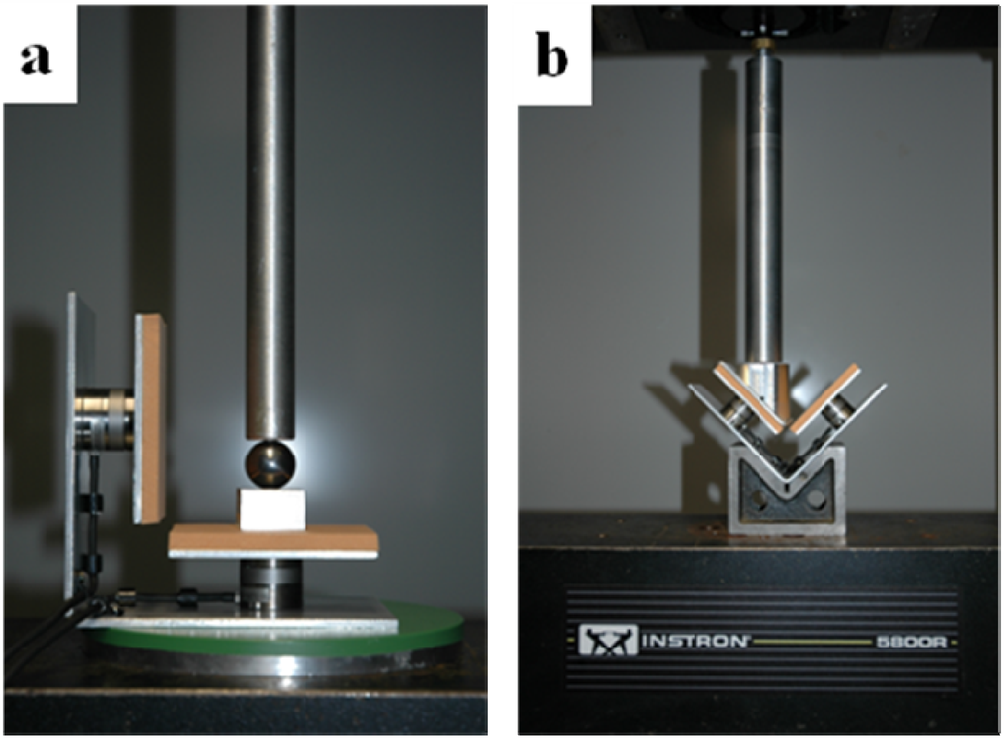


Figure 4.3 Loading the FAD (a) perpendicular to Fz and (b) at 45° angle using a V-block and custom made metal plate

4.1.3.2 Modification of FAD

Following the compressive load testing, the FAD was ergonomically modified prior to subject testing. The dimensions of each of the sides of the external shell were reduced to 100x55mm and the corners were rounded off to provide a more comfortable fit in the palm of the examiner. The internal patient-contact surface was contoured to improve the support of the ankle (Figure 4.4)

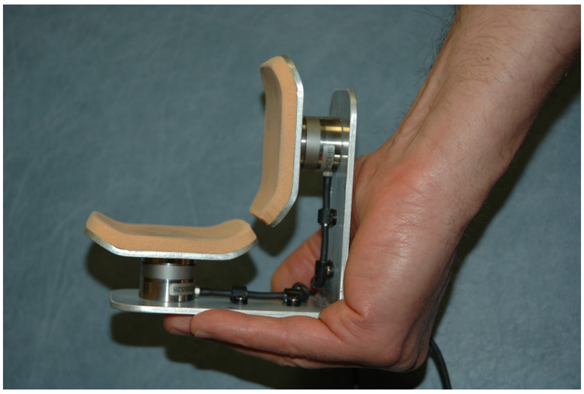


Figure 4.4 FAD prototype with ergonomic modifications

4.1.4 Measurement of applied moment

Following initial validation of the manual device, the GUI was modified (by Dr AH Deakin) to display in real-time the applied force, subject-specific lever arm (from IR system) and the calculated resultant moment. The FAD was then used as measuring device to determine the magnitude of the applied moments during routine clinical examination. Two clinicians (a consultant and a trainee orthopaedic surgeon) performed 10 varus and valgus stress manoeuvres on the right knees of two volunteers (female of BMI 19, male of BMI 27) using the standardised manual positioning previously described (Section 4.1.2). The FAD was held in the right palm during the application of clinically-judged maximum varus and valgus loads with the knee in extension. The clinicians were blinded to the moment reading displayed by the GUI. The mean applied moment and range of measurements for each set of manoeuvres were calculated to determine a target limit for the FAD as a control device.

4.1.5 Control of applied moment

The GUI was further modified (by Dr AH Deakin) to display the moment as an ascending bar with the option of selecting a colour change as it reached pre-determined limits. An "approaching target" and an "at target" limit were incorporated (Figure 4.5). To further supplement this visual warning, an intermittent auditory signal was programmed to sound at the same limits and this provided the examiner with the option of remaining visually focussed on the examination technique.

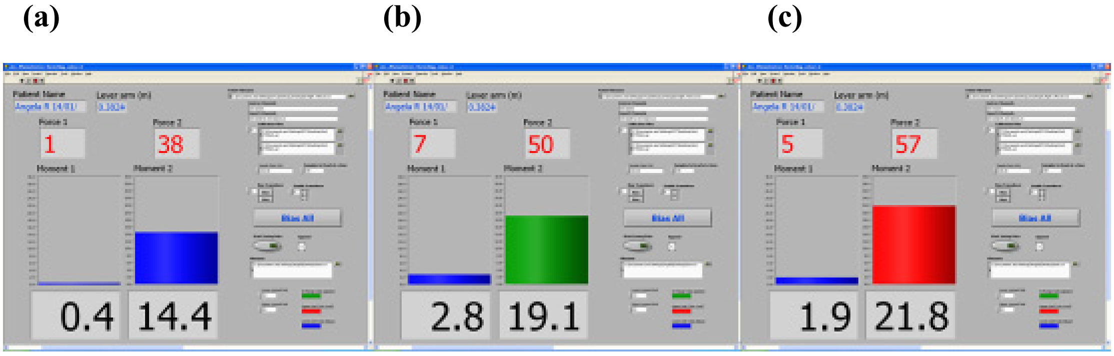


Figure 4.5 Customised LabView graphical displays illustrating the colour transition for a chosen target of 20 Nm with "approaching" limit of 18 Nm a) moment below first threshold b) moment above first threshold but below second c) moment above second threshold.

Three clinicians (two consultant orthopaedic surgeons and one trainee orthopaedic surgeon) were then instructed to perform six varus and valgus knee laxity examinations on a single volunteer with the aim of applying a consistent moment of 18 Nm as indicated by the FAD. This target moment was based on the results obtained from using the FAD as a measurement device (Section 4.2.4). An "approaching" limit of 16Nm was selected. The applied moment was continuously recorded enabling a measurement of any overshoot of the target moment. The technique was standardised as before but with an additional aim of maintaining the knee between 0° and 5° of flexion (target of 2°), as indicated by the IR tracking system. The clinicians were blinded to the corresponding laxity measurements for each applied moment.

4.1.6 Statistics

Analysis was completed using Excel 2007 (Microsoft Corp, Redmond, WA, USA). Agreement between measurements (different systems or paired repeated data) was assessed using the Bland-Altman method [Bland & Altman, 1986], with mean difference and limits of agreement for the difference calculated. Comparison of variance between groups was made using the F Test with $p<0.05$ considered statistically significant. To summarise results for non-parametric data, median and range were used whereas for parametric data mean and SD were used.

4.2 Results

4.2.1 Knee flexion

The mean differences and 95% limits of agreement between the flexible EG and non-invasive IR tracking systems for incremental 1° angles up to 10°, and incremental 10° angles up to 100° and 130° of flexion are shown in Table 4.1. Bland-Altman plots are shown in Figure 4.6.

Table 4.1 Mean difference and 95% limits of agreement between the two measurement systems for varying ranges and increments of knee flexion

	0° - 10°		**0° - 100°**		**0° - 130°**	
	Mean difference	**±1.96SD**	**Mean difference**	**±1.96SD**	**Mean difference**	**±1.96SD**
Trial 1	-0.4	±0.9	-1.0	±1.8	-0.3	±4.4
Trial 2	-0.8	±0.8	-0.2	±1.0	0.4	±3.3
Trial 3	0.0	±0.7	-0.1	±0.8	0.5	±3.3
Overall	-0.2	±0.8	-0.4	±1.5	0.2	±3.7

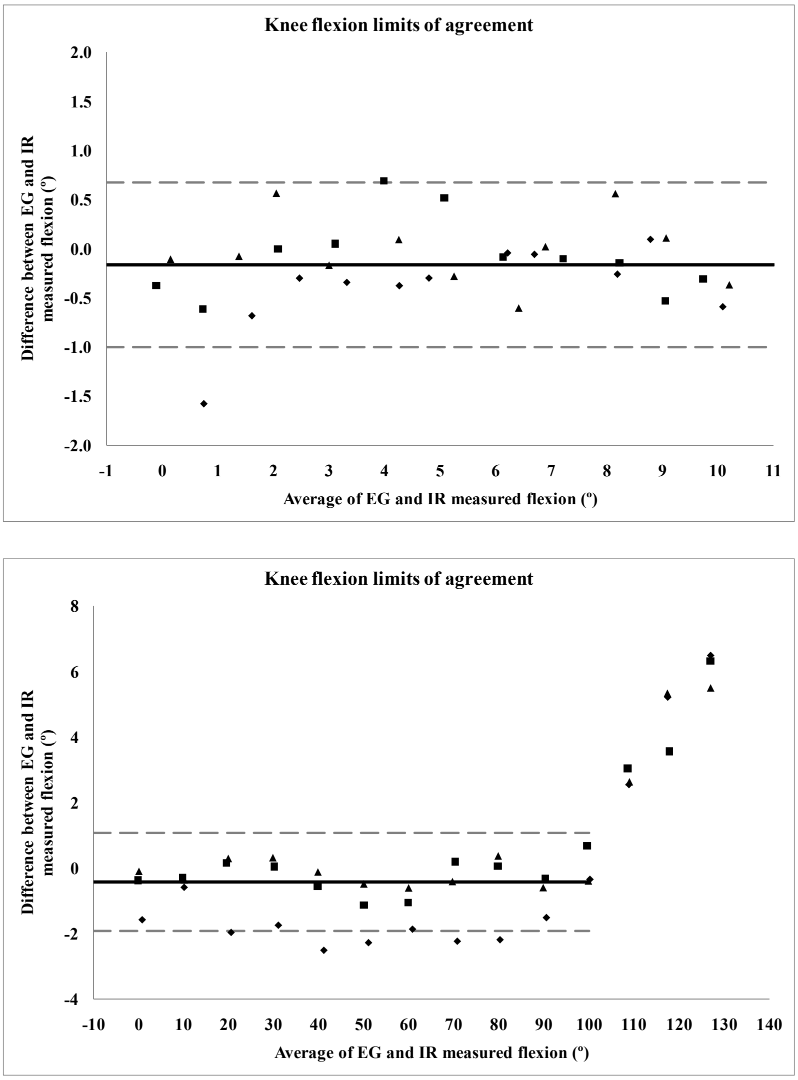


Figure 4.6 Limits of agreement for IR and EG measured flexion angles. Symbols indicate different trials (♦trial 1, ■ trial 2, ▲trial 3)

For 1° increments up to 10°, the two systems agreed to within ±1°. For measurements up to 100° of flexion, the data from all three trials had an overall agreement of approximately ±2° (trial 1) and ±1° (trials 2 and 3). Beyond this there was a consistent discrepancy between the two systems with relatively lower angles recorded by the EG. For trial 1 there was a large discrepancy for the initial ‘zero’ measurement of almost 2° and this difference seems to have remained constant throughout the 10° increments.

4.2.2 Moment arm

Repeated moment arm calculations using the leg model produced a standard deviation of 1.5mm, while on a single volunteer the standard deviation was 4.8mm. This difference of variance was statistically significant ($p<0.001$). For the paired volunteer measurements the mean and limits of agreement for the difference was 1.5±13mm, with the Bland-Altman plot (Figure 4.7) illustrating that most agreed to within 10mm (≤ 3% of leg length).

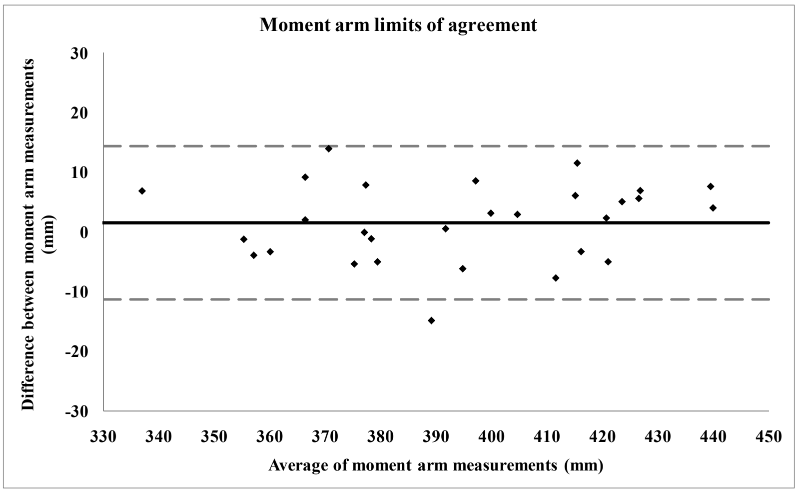


Figure 4.7 Limits of agreement for volunteer moment arm measurements

4.2.3 Applied force

Despite greater noise, possibly due to a poor earth connection, the output signals from the FAD closely correlated to those of the Instron testing machine. A typical trace is shown in Figure 4.8. The results showed that incorporation of the nano-transducers into the FAD had not adversely affected the magnitude of their force measurements.

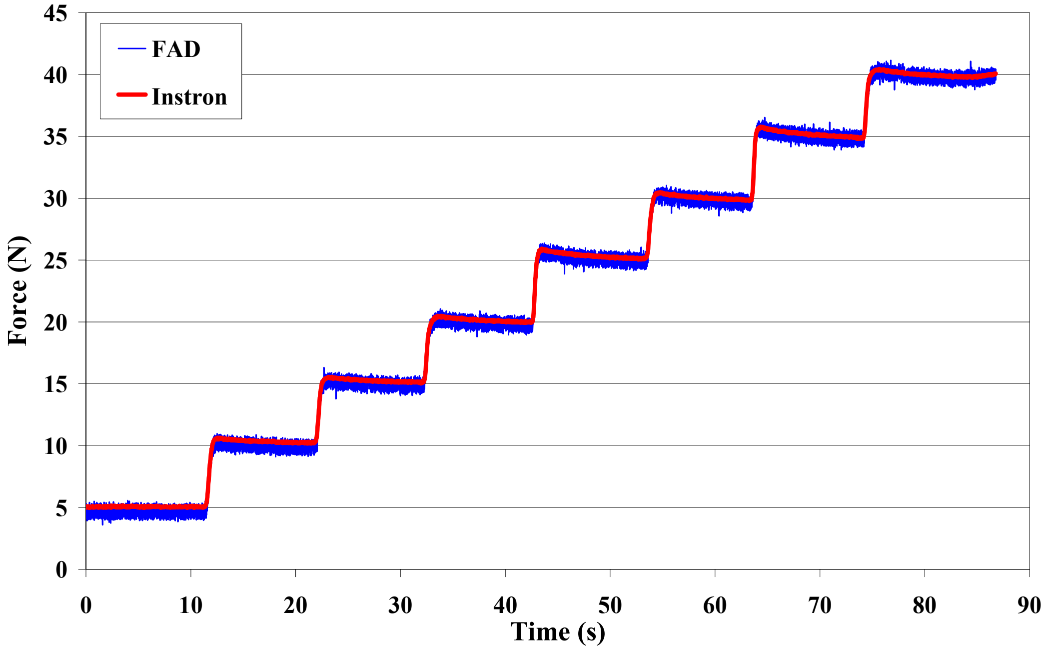


Figure 4.8 Simultaneous force output trace from the FAD (blue) and Instron (red) for 5N incremental compressive loads up to 40N

4.2.4 Measurement of applied moment

The mean overall applied moment was 22Nm (range 13 – 33) (Table 4.2). The mean moment for volunteer 1 was 19Nm (range 12 – 32) and based on this result, the standardised moment to be applied during subsequent varus and valgus stress testing of this subject was chosen to be 18 Nm.

Table 4.2 Mean and range of moments recorded by the FAD for repeated volunteer measurements

Volunteer	**Applied moment (Nm) median [range]**			
	Clinician 1		**Clinician 2**	
	Varus (n=10)	**Valgus (n=10)**	**Varus (n=10)**	**Valgus (n=10)**
1	20 [18 – 23]	15 [12 – 17]	27 [24 – 32]	16 [13 – 21]
2	30 [27 – 33]	19 [15 – 23]	33 [29 – 36]	20 [17 – 24]

4.2.5 Control of applied moment

The measured results for three clinicians during application of a target 18Nm moment are shown in Table 4.3. The overshoot ranged from 0 to 3.5Nm, with an overall mean value of 1.3Nm.

Table 4.3 Median and range of moments (recorded by the FAD) and corresponding mean angular displacements (measured by IR system) for repeated laxity tests on single volunteer (median and mean values rounded to nearest degree)

Clinician	Median moment [range] (Nm)		Mean laxity ± SD (°)	
	Varus (n=6)	Valgus (n=6)	Varus (n=6)	Valgus (n=6)
1	19 [18.8-19.9]	19 [18.3-20.1]	5 ± 1.1	3 ± 0.2
2	20 [18.0-21.5]	20 [19.1-20.3]	4 ± 0.8	3 ± 0.7
3	19 [18.4-19.1]	19 [18.3-19.1]	5 ± 0.3	3 ± 0.4

4.3 Discussion

The assessment of collateral knee laxity by application of varus and valgus stress is an important clinical manoeuvre for evaluating ligament injuries and a fundamental component of many TKA soft tissue management techniques. This aspect of the project aimed to overcome the subjective nature of current routine methods of assessment and develop a repeatable, objective stress test for incorporation into standard clinical practice. To achieve this required the accurate measurement and control of several variables that could impact on the moment applied to the knee.

4.3.1 Knee flexion

It was important to measure and maintain the flexion angle of the knee as this determines the orientation and material properties of its collateral restraints [Grood et al. 1981, Markolf et al. 1976]. The non-invasive IR technology used in this study provided a real-time display of sagittal alignment with measurements up to 100° agreeing to within ±1.5° of those obtained with a validated flexible electrogoniometer [Rowe et al. 2001]. This level of precision was far greater than human estimates of knee flexion where levels of intra-observer variation can reach 20° [Cushnaghan et al. 1990]. Beyond 100° there was less agreement between the measurements with relatively less knee flexion recorded by the flexible EG. This discrepancy was consistent between the three trials and became increasingly greater with each 10° increment beyond 100°.

Although the EG is a validated device for measuring knee flexion, a previous validation study measuring knee angles of up to 90° predicted that angles greater than this would be less accurate [Piriyaprasarth et al. 2008]. Rowe et al. (2001) noted that abduction or adduction of the flexible EG in combination with increasing flexion was potentially associated with substantial measurement errors. In addition, the attachment of the EG end-plates with double-sided tape was more likely to have slipped with increasing flexion [Piriyaprasarth et al. 2008]. It was therefore possible that the measurement difference between the two systems was a result of electrogoniometric errors rather than the IR system. In addition to its accuracy, the IR system could define the true position of knee flexion in comparison to the flexible EG, which would normally rely on an initial estimate of 0° as its starting point. Furthermore, the external mounting of IR trackers may not have been as user dependent as the more precise positioning of the flexible EG.

4.3.2 Applied moment

With control of knee flexion it was then necessary to standardise the clinical examination technique in order to define a moment arm. This involved careful hand positioning according to the surface anatomy, with the distance between the knee and ankle centres used to calculate the lever arm of the applied moment. The variation of repeated measurements on a single volunteer (SD ±4.8mm) compared well to the variation due to the system precision as measured by a leg model with rigid tracker mountings (SD ±1.5mm). Although this difference was statistically significant it represented only a small loss of accuracy from soft tissue artefacts. Further to this the measurement of this distance was repeatable to ±13mm when performed on 30 volunteers. Therefore the technique may be more accurate than currently available routine methods of leg length assessment such as a measuring tape or radiographs.

To standardise the moment required the control of the applied force. Much of the previous work in this area has relied on invasive access to the knee through either the use of cadavers or intra-operative studies in the context of TKA where gap-balancing devices have helped to quantify the amount of force application. Classic techniques involve spacer blocks as a surrogate measure of soft tissue tension [Insall et al. 1985] or laminar spreaders which enable a comparison between medial and lateral joint spaces both in flexion and extension. More sophisticated designs incorporated scales to measure the amount of gap distraction [Unitt et al. 2008, Winemaker 2002] or force sensing devices to determine the applied load. D'Lima et al. (2005, 2007) utilised a force transducer to measure intra-articular compressive forces on the tibial component of knee replacements and a similar device that measured knee joint moments and forces was developed and evaluated in-vitro by Crottet et al. (2005). The use of cadaveric specimens has permitted direct attachment of strain gauges to bone with accurate measurement of the applied moment-load. Methods of applying standardised varus-valgus moments to the knee joint have ranged from basic weight-pulley systems [Markolf et al. 1976, van der Esch et al. 2006] to digital strain gauges [LaPrade et al. 2008, van Damme et al. 2005].

Most non-invasive in-vivo studies that have sought to standardise varus and valgus loads to the knee have involved cumbersome experimental set-ups that are not readily adaptable to a clinical setting. Sharma et al. (1999) developed a bench with an attached low-friction track to support the leg and a hand-held dynamometer to apply a fixed load. Van der Esch et al. (2006) constructed a measurement chair with a lower limb attachment consisting of five specific fixation points relative to the knee joint line, an electronic meter to record angular deviation and a weight-pulley system to deliver a standardised load. In addition to the impracticalities of these set-ups the laxity measurements were of limited use in clinical practice due to considerable intra- and inter-observer measurement error.

From the point of view of clinicians, however, a force measuring device should consider the way in which patients are normally examined. The FAD designed in this study allowed the incorporation of commercial transducers without affecting the magnitude of their force measurements. In particular the deformation of internal patient contact surface (polyurethane pad) did not result in a measureable change in the transmitted loads. The design allowed the FAD to be incorporated into a routine clinical assessment with minimal alteration of examination technique. Whilst there are no descriptions of any similar devices for measuring collateral knee laxity, there are reports of measurement tools for recording manual contact forces. Van Zoest et al. (2002) recognised the importance of manual techniques in disciplines such as chiropractic and osteopathy and developed a palm-held force measurement system for improving the manual perception and force delivering skills of student practitioners. Harms and Bader (1997) investigated the variability of forces applied by therapists during spinal mobilisation procedures through the construction of an instrumented mobilisation coach that could measure the magnitude and direction of applied forces. In spite of standardising the manipulation technique, there was a large variation in the forces used by different therapists, ranging from 63 to 347N. In comparison, the varus and valgus knee moments recorded by the FAD in this study were more consistent for the two clinicians assessed, with a range of measurements from 13 to 33Nm for a total of 80 stress manoeuvres. This may reflect a more perceptible endpoint for the constraining soft tissues of the knee [Markolf et al. 1976], in contrast to the underlying tissues around the spine which may not provide obvious feedback when applying a manual compressive force. The mean recorded moment of 19Nm did not produce any discomfort in the particular individual tested despite being higher than the 12Nm upper subject-tolerance limit that is often used in other studies [La Prade et al. 2008, Sharma et al. 1999, van der Esch et al. 2006,]. This may have been due to the short duration of the stress manoeuvres compared to the more sustained loads in these experimental studies.

Following its use as a measurement tool, the FAD was utilised as a control device through the design of a GUI which provided a repeatable method of applying a pre-determined moment. The visual and auditory warning systems were effective in preventing significant overshoot of the selected threshold, with a mean of 1.3Nm. This indicated that it could satisfactorily be used as a control device.

4.3.3 Knee laxity measurement

For each applied varus and valgus load, the corresponding coronal angular displacement of the knee from its resting position, was used to quantify laxity. The repeated sets of measurements by three clinicians had similar mean values, and the standard deviations, ranging from ±0.2° to ±1.1°, may have been due to the actual variations in applied moment but may also have been a result of the ±1° accuracy of the non-invasive IR tracking technology [Chapter 3]. However, this represented a significantly higher degree of precision than the likely ±5° human error in estimation of alignment [Markolf et al. 1976]. The system also has a number of potential advantages over alternative non-invasive laxity assessments. The radiographic measurement of joint space opening has been widely reported [LaPrade et al. 2008, Moore et al. 1976, Wijdicks et al. 2010], but drawbacks include the use of ionising radiation and the requirement for meticulous control of lower limb positioning. The grading of collateral ligament injury severity on the basis of a 1-2mm difference in gap opening [LaPrade et al. 2008] could potentially be compromised by small rotational and sagittal variations in knee position [Krackow et al. 1990b, Siu et al. 1991]. An alternative approach to measuring laxity involves the use of specially designed mechanical devices incorporating goniometers. Early cadaveric work was limited by inaccurate manual measurement tools to record the resultant displacement following an applied load [Brantigan and Voshell, 1941]. Markolf et al. (1976) addressed these limitations by using a specially designed three-dimensional goniometer linkage which allowed the knee joint to be maintained at a specific degree of flexion whilst electronically recording the resultant varus-valgus angulation. Unfortunately, in-vivo adaptation of goniometers has generally involved cumbersome experimental set-ups which, as with previously described force application technology, are not practical for routine clinical use.

Although some of the disadvantages of other systems have been addressed, the measurement tool developed in this part of the project also had limitations. For the manually applied force, it was assumed that the loading of the transducers within the FAD was perpendicular to the tibial mechanical axis in the coronal plane. However, in spite of careful positioning of the device, the true orientation of the resultant force vector was unknown. Using the IR tracking system to give the real-time orientation of the FAD relative to the defined tibial moment arm could potentially overcome this. During laxity testing, although the auditory warning system enabled clinicians to remain more focussed on examination technique, there was still the requirement to use the on-screen display of flexion to control knee position. The use of a device to hold the knee in a specified degree of flexion, such as a wedge in the popliteal fossa, or the use of an image overlay [Moody et al. 2002] could remove the requirement to look at a computer screen during clinical examination.

4.4 Conclusions

In spite of the potential limitations of the system, the manual technique of coronal knee laxity assessment was successfully quantified and standardised for the limited number of subjects and clinicians evaluated. This resulted in a narrow range of laxity measurements within the accuracy limits of the IR system. Minimising the subjective variables of clinical examination with a more repeatable, quantitative technique could improve current knowledge of soft tissue knee behaviour. This may lead to improved balancing techniques in TKA through quantification of knee laxity before, during and after surgery enabling a more widespread use of single surgeon-derived algorithms [Hakki et al. 2009, Picard et al. 2007b, Saragaglia et al. 2006]. There is a potential role in the management of collateral ligament injuries with regard to more reliable initial diagnosis and severity grading as well as more targeted recovery and rehabilitation. Standardised data from healthy, injured and osteoarthritic knees could improve knowledge of normal and abnormal knee kinematics and lead to more objective treatment algorithms. Finally, as this augmented learning can be incorporated into traditional examination techniques, the ability to quantify the technique of senior clinicians may help to enhance the perceptive skills of more junior trainees who do not have the benefit of experience.

5 Clinical trial

The non-invasive adaptation of IR tracking technology (Chapter 3) resulted in approximately 1° loss of precision due to soft tissue artefacts in addition to the reported ±1° accuracy of the system [Haaker et al. 2005]. However the validation was based on the assessment of healthy volunteers with asymptomatic knees that may not have been representative of an older population with end-stage OA. The assessment of patients presented an additional challenge for a number of reasons. Osteoarthritic subjects were more likely to have pain on passive manipulation of the knee which could potentially compromise the initial registration and subsequent measurement of varus and valgus stress angles. Secure mounting of trackers may be more difficult to achieve in patients with poor skin quality, lower limb oedema or high BMIs. Post-operatively, in spite of an anticipated improvement in symptoms, there may still be pain and stiffness associated with the surgical procedure at the routine 6 week follow-up stage. Again this may hamper the registration process and restrict the assessment of collateral laxity.

This chapter reports a trial involving the recruitment of patients with symptomatic end-stage OA due to undergo TKA surgery. Further validation of the non-invasive IR system was performed on subjects with arthritic and prosthetic knees. Assessments of MFT angles under different conditions were made pre-operatively, intra-operatively and post-operatively enabling a number of comparisons to be made. The difference between intra-operative and non-invasive MFT angles provided an indirect measurement of the effect of muscle tone and surgical exposure on both unstressed alignment and angular displacement with applied varus and valgus loads. The effect of weight-bearing on coronal and sagittal alignment was evaluated for osteoarthritic (pre-operative) and prosthetic (post-operative) knees with the additional comparison of normal (volunteer) subjects (Chapter 3). In addition, the relationship between supine intra-operative and standing post-operative MFT angles (both radiographic and IR-measured) was explored. Clinical outcomes were also recorded and routine goniometer-measured TKA flexion angles were compared to those obtained with the IR system in order to assess the accuracy of current practice.

5.1 Methods

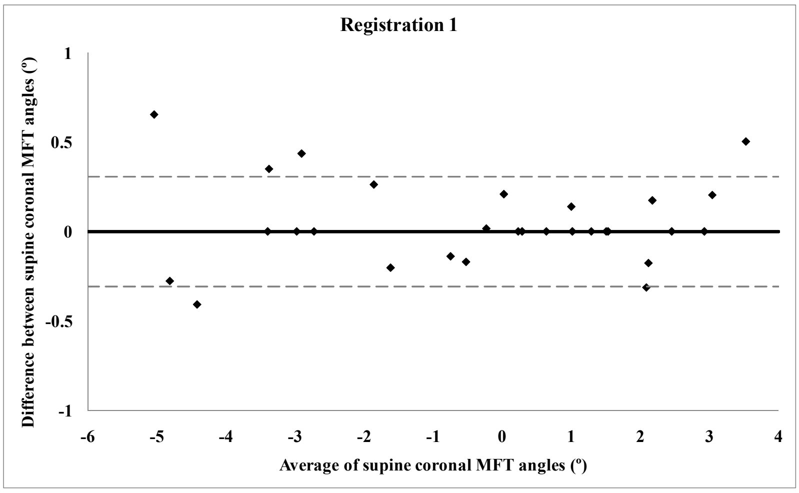
5.1.1 Development of methodology

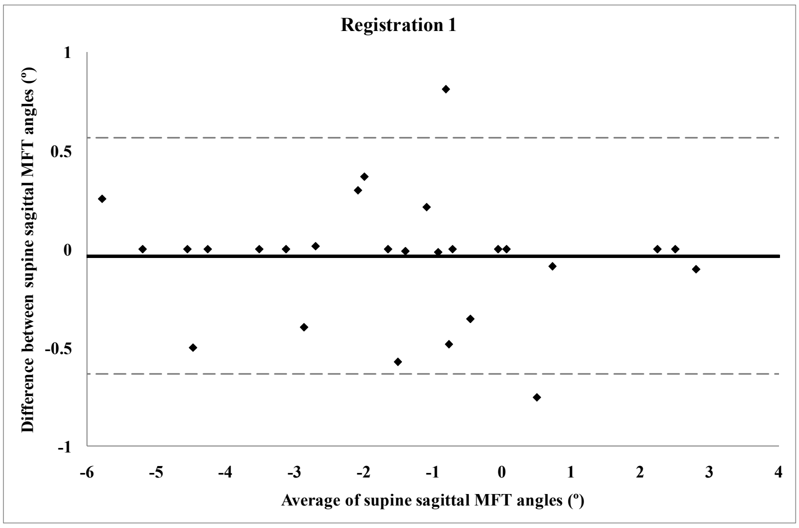
5.1.1.1 Repeated measurement protocol

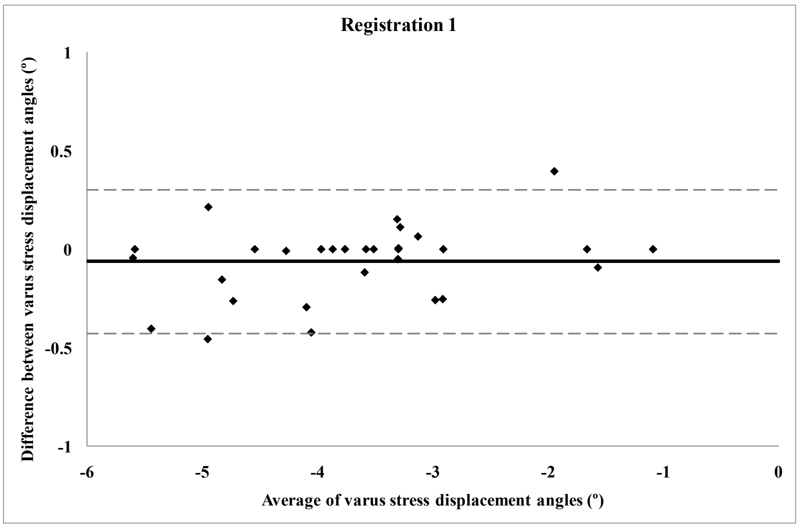
The volunteer validation of the IR system was based on a protocol that used the median of five measurements for all the supine MFT angles, which was intended to minimise the effect of a less stable tracker mounting in comparison to rigid fixation. For assessing patients with symptomatic knees, it was desirable to reduce the number of evaluations providing this did not compromise the repeatability of the IR system. Therefore a comparison was made between the use of either three measurements or five measurements to obtain the median MFT angles from the collected volunteer data. The median of the first three measurements was used for this purpose and compared with the median value from five using mean differences and Bland-Altman limits of agreement (Table 5.1). The table and corresponding Bland-Altman plots (Figure 5.1) demonstrated differences of between ±0.3° and ±0.8° for the two sets of measurements. These differences were felt to be clinically insignificant as 95% of the data spread fell within the 1° inherent accuracy of the IR system, and this supported the use of three repeat measurements instead of five. In addition to reducing the number of supine measurements, it was felt necessary to increase the standing alignment assessments from one to three. This resulted in a protocol that used the median of three alignment assessments to define the MFT angle for each measurement condition.

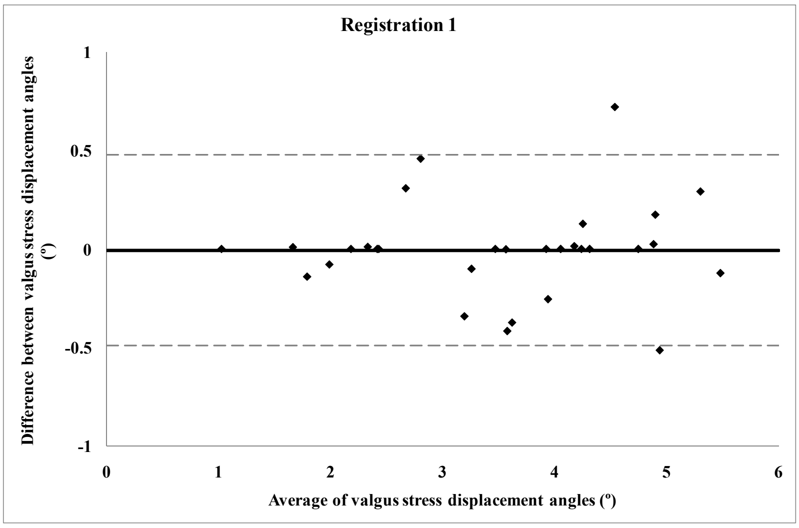
Table 5.1 Mean difference and 95% limits of agreement for volunteer MFT angles comparing data obtained with either three or five repeated measurements

MFT angle condition	Trial 1		Trial 2	
	Mean difference (°)	±1.96SD	Mean difference (°)	±1.96SD
Supine coronal	0.0	0.3	0.0	0.5
Supine sagittal	0.0	0.6	0.1	0.5
Varus stress	-0.1	0.4	-0.2	0.8
Valgus stress	0.0	0.5	-0.1	0.6

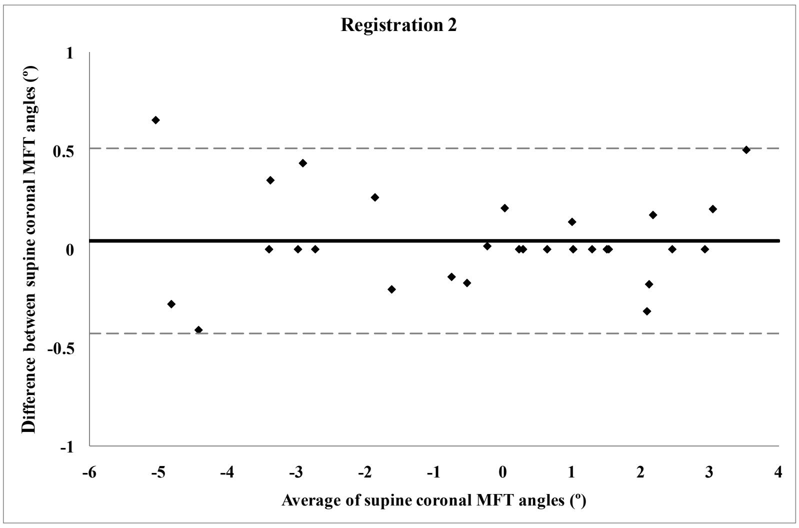

Registration 1
Difference between supine coronal MFT angles (°)
1
0.5
0
-0.5
-1
-6
-5
-4
-3
-2
-1
0
1
2
3
4
Average of supine coronal MFT angles (°)


Registration 1
Difference between supine sagittal MFT angles (°)
1
0.5
0
-0.5
-1
-6
-5
-4
-3
-2
-1
0
1
2
3
4
Average of supine sagittal MFT angles (°)

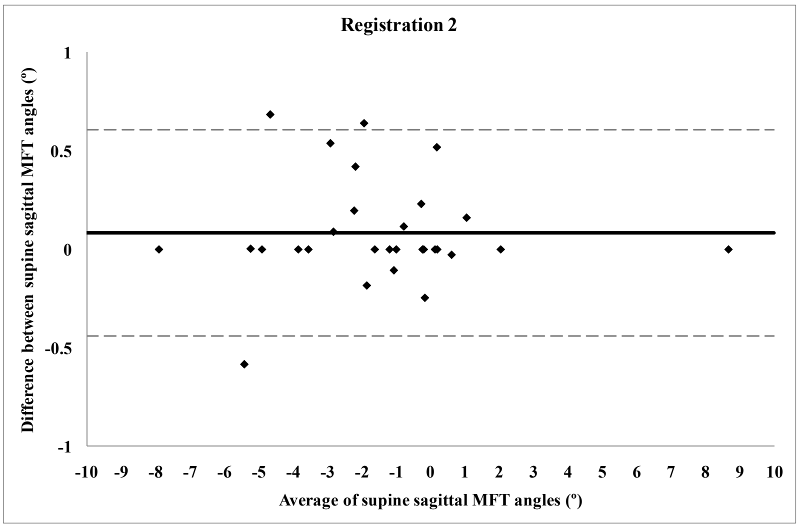

Registration 1
Difference between varus stress displacement angles (°)
1
0.5
0
-0.5
-1
-6
-5
-4
-3
-2
-1
0
Average of varus stress displacement angles (°)



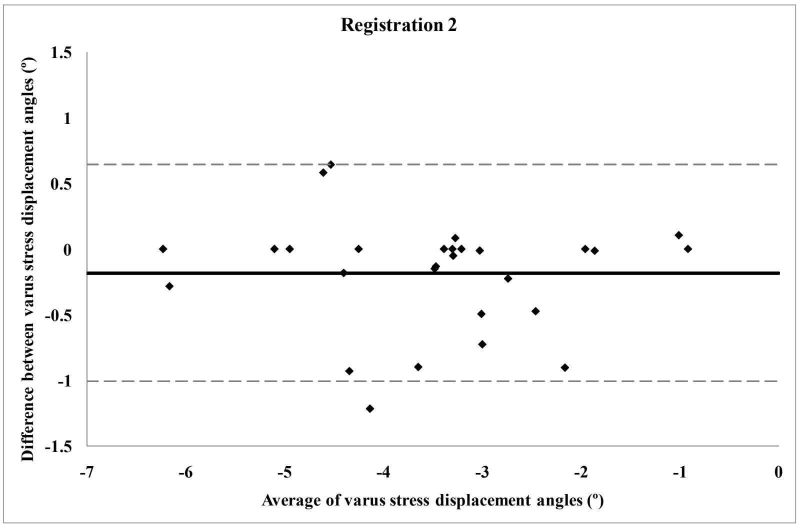
Registration 1
Difference between valgus stress displacement angles (°)
Average of valgus stress displacement angles (°)
1
0.5
0
-0.5
-1
0
1
2
3
4
5
6



Registration 2
Difference between supine coronal MFT angles (°)
Average of supine coronal MFT angles (°)
1
0.5
0
-0.5
-1
-6
-5
-4
-3
-2
-1
0
1
2
3
4



Registration 2
Difference between supine sagittal MFT angles (°)
Average of supine sagittal MFT angles (°)
1
0.5
0
-0.5
-1
-10
-9
-8
-7
-6
-5
-4
-3
-2
-1
0
1
2
3
4
5
6
7
8
9
10



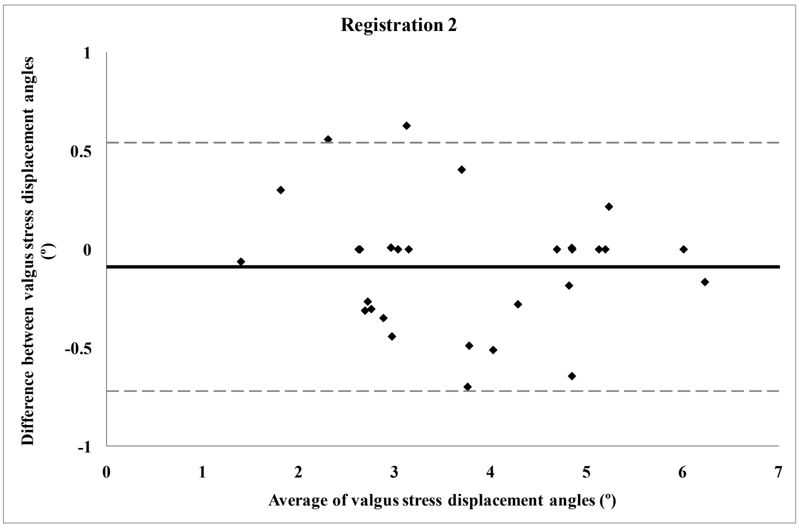


Figure 5.1 Limits of agreement for volunteer MFT angles comparing 5 with 3 consecutive measurements

5.1.1.2 Standardising laxity assessment

The development of a force measuring device (Section 4.1.3.1) had been based on the requirement for a repeatable method of obtaining stress measurement. However, the varus and valgus MFT angles obtained by a single observer during assessment of volunteers were repeatable to within the ±1° resolution of the non-invasive system. As a consequence of this degree of intra-observer repeatability, it was decided to use a single clinician to obtain all measurements and avoid the additional time associated with the use of the FAD. Also, the device requires further development to better determine the applied moment. This could potentially be achieved by registration of the FAD with the IR system, which was out with the scope of this thesis.

Therefore although the FAD had been successfully incorporated into the assessment of knee laxity for three clinicians (Section 4.2.5) it could not sufficiently improve upon the consistency of the stress angles to justify its inclusion in the protocol.

5.1.2 Patients

Local ethical approval was obtained from the West of Scotland Research Ethics Committee (WOS REC-2) for the clinical trial. Thirty one subjects were recruited (18 males and 13 females) with a mean age of 66 years (range 51-82) and a mean body mass index (BMI) of 33 (range 23-43). Eighteen right knees and 13 left knees were assessed. All were due to undergo primary TKA under the care of two different consultant surgeons who routinely used the OrthoPilot® navigation system.

The kinematic assessments for the clinical trial were all performed by the author.

5.1.2.1 Pre-operative assessment

At the pre-operative clinic the standard assessment included a full history, physical examination, Oxford knee score (Appendix 1) and a weight-bearing long-leg radiograph (Section 5.1.3). For the OKS the 60 (worst score) to 12 (best score) scale was used (Section 2.4.6). In addition to this routine assessment and after providing written informed consent, the patients underwent assessment using the non-invasive IR system. They were positioned supine on a height-adjustable examination couch with adequate exposure of the lower limb to be assessed. Trackers were then secured as firmly as possible to the distal thigh and proximal calf regions in the positions previously described (Section 3.3.1.3). With the subject instructed to relax, a full kinematic registration was performed using the workflow of the high tibial osteotomy (HTO) software (Section 3.3.1.3) and the coronal and sagittal MFT angles were recorded with the lower limb held up by supporting under the heel. With the trackers remaining in position, a second registration was performed and the mechanical knee alignment in extension was again recorded. If the coronal measurements from the two registrations disagreed by more than 2°, a subsequent registration was performed until agreement was within the ≤2° limit. When agreement was obtained a second measurement of coronal and sagittal alignment in maximum extension was recorded.

Following this, varus and valgus manual stress manoeuvres were performed using the previously described technique (Section 4.1.2). The target knee position during stress testing was a sagittal MFT angle of 2° or 2° of flexion relative to the maximum extension if there was a fixed flexion deformity of the knee. The magnitude of the applied stress was based on the perception of having reached an end point (i.e. no further angular displacement possible with manual load) or until the patient indicated discomfort. The on-screen display of angular displacement was covered up during testing.

The patient was then asked to assume a normal stance with the knees as "straight" as possible. After the weight-bearing MFT angles had been recorded the patient was returned to the supine position and the sequence of varus-valgus stress followed by bipedal stance was repeated twice.

Finally the lower limb was again supported under the heel and the coronal and sagittal MFT angles recorded, followed by a measurement of maximum passive knee flexion. Following initial agreement of registration, this provided three supine coronal and sagittal MFT angles in maximum extension, three coronal MFT angular displacements with varus-valgus stress and three coronal and sagittal MFT angles in bipedal stance. In addition there was a single measurement of the maximum passive knee flexion angle.

5.1.2.2 Intra-operative assessment

The TKA procedures were performed by one of two consultant orthopaedic surgeons using the OrthoPilot® image-free navigation system. The mechanical lower limb alignment target with the knee extended was 0° in both the coronal and sagittal planes. All implants were cemented PCL-retaining Columbus (BBraun Aesculap, Tuttlingen, Germany) condylar knee replacements. The knee joint was exposed using either a medial or lateral approach (Section 2.4.5.1) and following this, IR trackers were secured to the distal femur and proximal tibia using bone fixation screws. The registration process using the TKA software (Orthopilot® TKA v4.3, BBraun

Aesculap, Tuttlingen, Germany) was similar to that of the HTO workflow used non-invasively but with more anatomical points which were directly palpable as a result of the surgical exposure. Although these points provided additional information for orientation of the bone cutting blocks, it was the the rotational centres of the hip, knee and ankle joints that were used to define the coronal and sagittal MFT angles in exactly the same manner as the non-invasive system.

With the registration process completed the lower limb was held in maximum passive extension by supporting under the heel and the sagittal and coronal alignment recorded. Following this a single varus-valgus stress manoeuvre to a perceived end point was performed with recording of the resultant coronal angular displacement. For this, the knee was maintained at a target MFT angle of 2° or at 2° of flexion relative to the maximum extension if there was a fixed flexion deformity of the knee. Repeated stress manoeuvres were not performed intra-operatively due to the greater stability of the trackers in comparison to the non-invasive measurements which used a repeated measures protocol.

The remainder of the TKA procedure was routine and the extent of any soft tissue release was documented. Following final cementation of the implants, but prior to closure of the surgical incision, the coronal and sagittal MFT angles in full extension were recorded and a single varus-valgus stress manoeuvre performed whilst maintaining the knee in a target flexion angle of 2°. The maximum flexion angle was also recorded by supporting the thigh and passively allowing gravity to flex the knee.

5.1.2.3 Post-operative assessment

The patients were post-operatively assessed at an out-patient clinic six weeks following surgery where the non-invasive measurement protocol was identical to that used in the pre-operative assessment (Section 5.1.2.1).

Routine assessment was undertaken by arthroplasty outcome practitioners. In addition to clinical evaluation, the assessment included a weight-bearing long-leg radiograph (Section 5.1.3), an Oxford knee score (Appendix 1) and a simple 4-point satisfaction question similar to that used by Beverland (2010) (Figure 5.2). Any surgical complications were also noted. Passive range of knee motion was measured using a manual goniometer and this was recorded for comparison with the IR measurements.

How satisfied are you with your surgery?	
Very satisfied	□
Satisfied	□
Unsure	□
Dissatisfied	□

Figure 5.2 Post-operative TKA satisfaction question

5.1.3 Radiographic measurements

The standard method of taking the long-leg radiographs in the institution where the clinical trial was performed was an antero-posterior view of the knee joint including hip and ankle. Patients assumed a bi-pedal stance with a standard distance of 180cm in front of the x-ray source tube (GE Definium 8000). Their feet were rotated internally by 5° with the aim of bringing the intercondylar line parallel to the plane of the detector and potentially avoiding a mal-rotated radiographic image.

The coronal MFT angle was measured from digital images on Picture Archiving and Communications System (PACS) (Kodak, Carestream PACS Client, version 10.0) by a single independent observer not involved in the work using a defined protocol (Section 2.2.2). The MFT angle was taken as the angle between three points: the centre of the head of femur using Mose circles; for the knee centre, the midpoint of a line joining the distal femoral notch centre and the centre of the upper tibial surface and for the ankle centre, the midpoint of the superior talar margin was selected. The difference of the angle value from 180° was calculated and given a positive value for valgus deformities and a negative value for varus deformities.

5.1.4 Data analysis

Statistical analysis was completed using Excel 2007 (Microsoft Corp, Redmond, WA, USA) and SPSS 17.0 (SPSS Inc., Chicago, IL, USA).

5.1.4.1 Clinical outcomes

Differences in pre-operative and six week post-operative Oxford knee scores were calculated and the mean (95% CI) ± SD of the change was used as a measure of the overall clinical outcome of the group.

5.1.4.2 Repeatability of measures

To further validate the non-invasive system for measuring osteoarthritic (pre-operative) and prosthetic (post-operative) knees, the difference in initial supine coronal and sagittal MFT angles between registrations was assessed using Bland-Altman limits of agreement. Intra-registration variation of the repeated MFT angles following collateral stress and with bipedal stance was assessed using repeatability coefficients, representing the range within which 95% of the differences would be expected to lie [Bland and Altman, 1986]. The within-subject SD (S_W) of each set of measurements was used to calculate the repeatability coefficient using the formula; Repeatability coefficient = $1.96 \times \sqrt{2}\, S_W$.

5.1.4.3 Measurement of knee flexion

Comparison was made between the IR and clinical measurements of post-operative flexion angles with knees positioned in maximum flexion and extension. Data for extension were categorised into none, moderate and severe postoperative fixed flexion deformity (FFD) as per Ritter et al. (2007) (Table 2.4). Agreement in FFD classification between the two methods was assessed using the Kappa statistic.

5.1.4.4 Variation between alignment conditions and subject groups

Data was assessed for normality and paired t-tests were used to assess changes in alignment between different measurement conditions for osteoarthritic and prosthetic knees. For alignment change from lying to standing, data from healthy knees (Section 3.3.2.2) were also analysed.

To measure the combined effect of muscular relaxation due to anaesthetic and the initial surgical exposure, comparison was made between non-invasive pre- and post-operative supine MFT angles and the corresponding invasive pre- and post-implant measurements. The same comparisons were made for coronal MFT angles following varus and valgus stress manoeuvres. The pre- and post-operative radiographic coronal alignment measurements were compared to the corresponding weight-bearing IR measurements. In addition, the radiographic alignment was compared with the invasive intra-operative MFT angles as both of these are validated measurement tools.

The change in coronal and sagittal MFT angles from lying to standing was assessed for asymptmatic, osteoarthritic and TKA groups. To quantify the change in three dimensions, vector plots of the ankle centre displacement relative to the knee centre were produced in the transverse plane using Matlab (MathWorks Inc, Natick, MA, USA) (work done by Dr PE Riches). The displacements were determined as fractions of tibial length rather than absolute distance measurements in order to normalise the displacements. The origin of the vector was the supine position of the ankle centre relative to the knee centre and the end of the vector was the position after weight-bearing. Therefore the starting point was dependent on the initial coronal and sagittal alignment of the subject. To provide a clearer representation of the relative supine to standing alignment change, and for comparing groups, the displacements were also plotted from a common point of origin regardless of initial alignment.

5.2 Results

5.2.1 Patient cohort

Thirty one subjects were recruited out of a possible 35 consecutive patients scheduled to undergo TKA surgery. Three patients were excluded as they were not due to attend routine follow-up for geographic reasons. One patient did not speak English and so was unable to provide informed consent in the absence of an interpreter. Medical co-morbidities that could have potentially compromised the registration process included three patients with lower limb lymphoedema that restricted the secure attachment of trackers, five patients with morbid obesity

(BMI>40) and one patient with Parkinsonian tremor and unsteady gait. However, assessment was completed on all pre-operative patients following recruitment, so there were no exclusions.

Intra-operatively, all patients except one had medial approaches to the knee. Four patients had soft tissue releases performed as previously defined (Section 2.4.5.1); a moderate and an extensive medial release, an extensive lateral release including epicondylar osteotomy, and a selective posterior release. There were no recorded operative complications although one patient required repeat registration due to loosening of a femoral tracker pin. For intra-operative data collection, one patient had no measurements in the computer file due to an error in the data recording process. A second patient had no varus-valgus stress measurements due to the unavailability of the observer to perform the manoeuvres.

Post-operatively, four patients were treated with oral antibiotics for superficial surgical site infections and two had minor stitch abscesses, all of which resolved. There was one case of deep infection requiring washout and exchange of the polyethylene tibial insert leading to exclusion of this patient from the trial.

Overall, there were complete IR measurement data sets for 31 patients pre-operatively, 29 intra-operatively and 30 post-operatively. For comparison of intra-operative and post-operative varus-valgus stress, the exclusion and missing data resulted in 28 paired measurements.

For routine clinical evaluations, the Oxford knee score was completed by all patients pre-operatively and by 29 patients post-operatively due to one patient being excluded and one missing data collection form. This resulted in 29 paired measurements of pre-operative and post-operative change in score. The satisfaction question (Figure 5.2) was completed by only 28 patients because of the excluded patient, a missing data collection form and follow-up of a patient at an alternative clinic due to a wound problem which later resolved. Post-operative flexion angles were obtained on all patients except for the excluded subject, resulting in 30 comparative measurements.

5.2.2 Clinical outcomes

The mean (95% CI)±SD pre-operative and six week post-operative Oxford knee score was 44(42,46)±6 and 28(26,31)±7 respectively, and the mean (95% CI)±SD improvement was 15(12,18)±8. Only one patient had a pre-operative to post-operative decline in score and was “unsure” as to the level of satisfaction. The distribution of the scores is represented as box plots (Figure 5.3) and the level of patient-reported satisfaction is shown in Table 5.2.

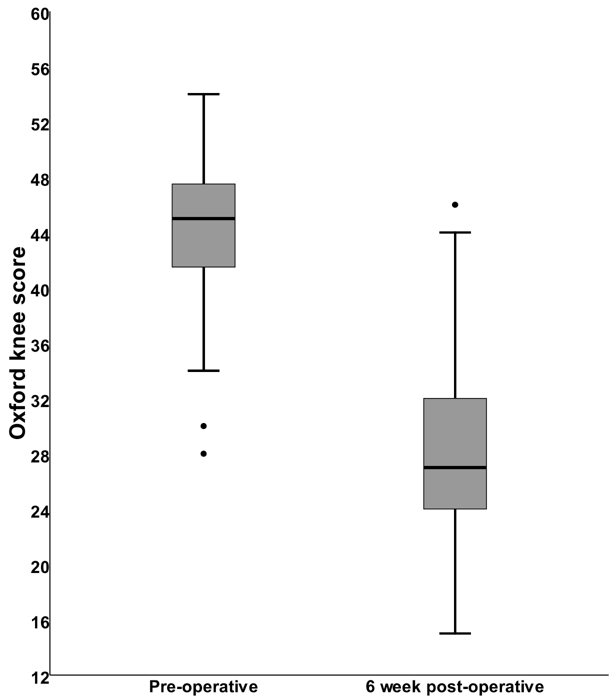


Figure 5.3 Box plots (median, IQ range, minimum and maximum values) showing change in distribution of Oxford knee score (60-12 scale) following TKA

Table 5.2 Patient-reported satisfaction level following TKA

Six week post-operative TKA satisfaction	
Very satisfied	18
Satisfied	9
Unsure	1
Dissatisfied	0

5.2.3 Repeatability of measures

The non-invasive measurement process was successfully completed on all pre- and post-operative patients assessed. The alignment characteristics of these two groups are shown in Table 5.3 and the coronal measurements are illustrated in Figure 5.4.

Table 5.3 Alignment characteristics of pre-operative (OA) and post-operative (TKA) patients as measured with non-invasive IR system

Measurement condition	MFT angle mean(95%CI)±SD (°)	
	OA (n=31)	**TKA (n=30)**
Supine coronal	-2.5(-4.6,-0.4)±5.7	-0.7(-1.2,-0.1)±1.4
Supine sagittal	7.7(5.1,10.4)±7.1	6.7(4.8,8.7)±5.1
Change with varus stress	-3.8(-4.4,-3.3)±1.5	-4.3(-4.8,-3.9)±1.1
Change with valgus stress	3.3(2.7,3.9)±1.6	2.8(2.5,3.1)±0.8
Standing coronal	-3.6(-5.8,-1.4)±6.0	-2.5(-3.3,-1.8)±2.0
Standing sagittal	1.8(-1.0,4.6)±7.7	1.1(-1.8,4.0)±7.6

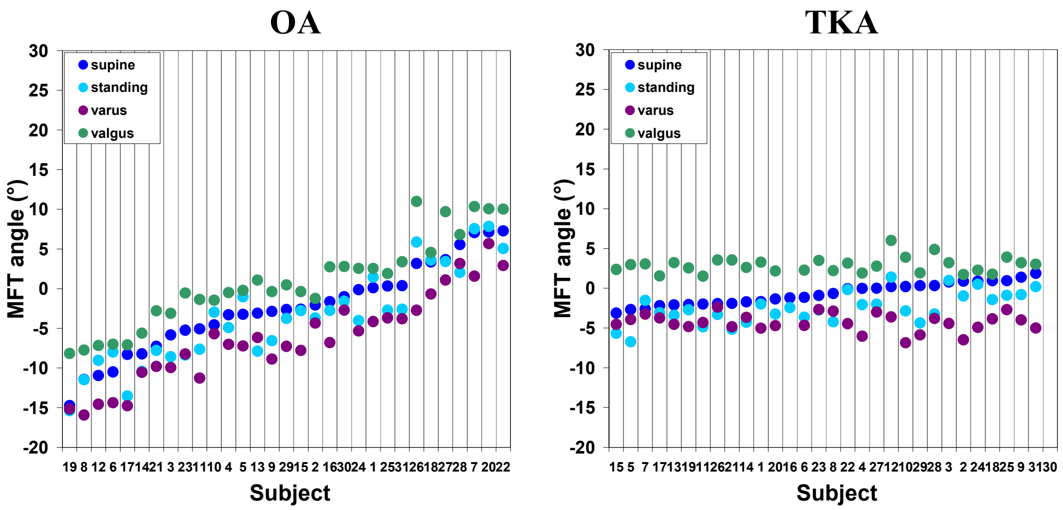


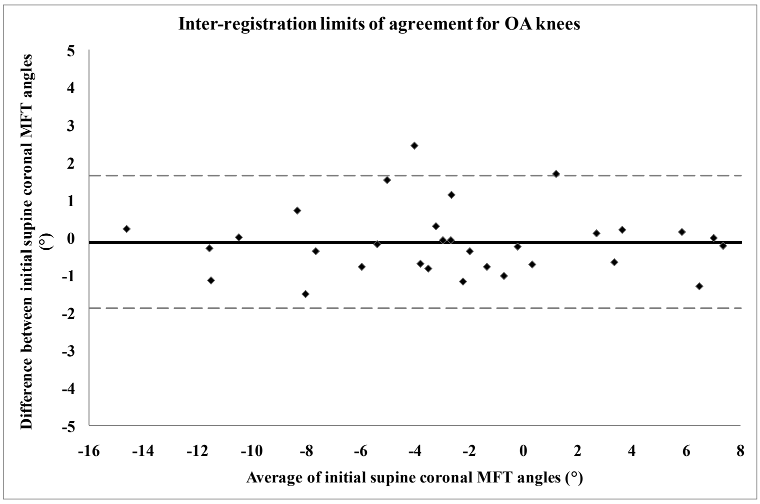
Figure 5.4 Coronal alignment characteristics of subjects before (OA) and after knee replacement (TKA) measured supine, standing and with varus-valgus stress

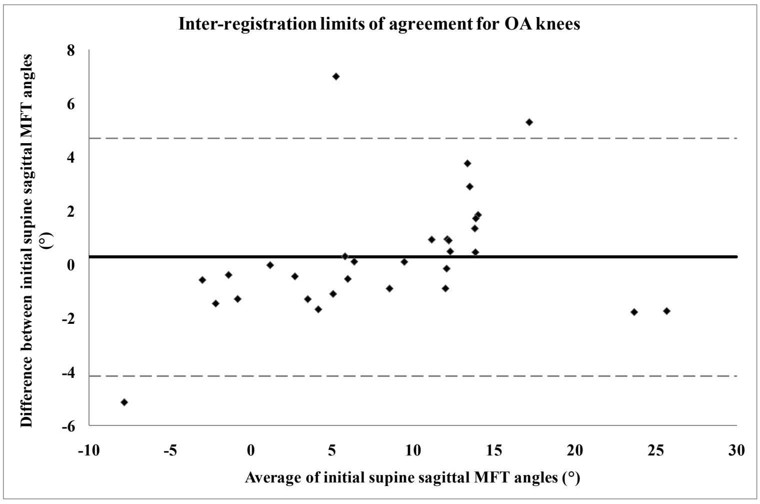
The inter- and intra-registration limits of agreement are shown in Table 5.4 and in corresponding Bland-Altman plots (Figure 5.5). On three occasions pre-operatively, a third registration process was required to obtain two registrations with a difference in supine coronal MFT angle of 2° or less. Post-operatively, the initial supine coronal MFT angles agreed to within 2° for all registrations and so no repetitions were required. Sagittal alignment was more variable, particularly for OA knees, with ±4.4° agreement between registrations. Sagittal inter-registration agreement improved by 1° for knees following TKA, to ±3.3°.

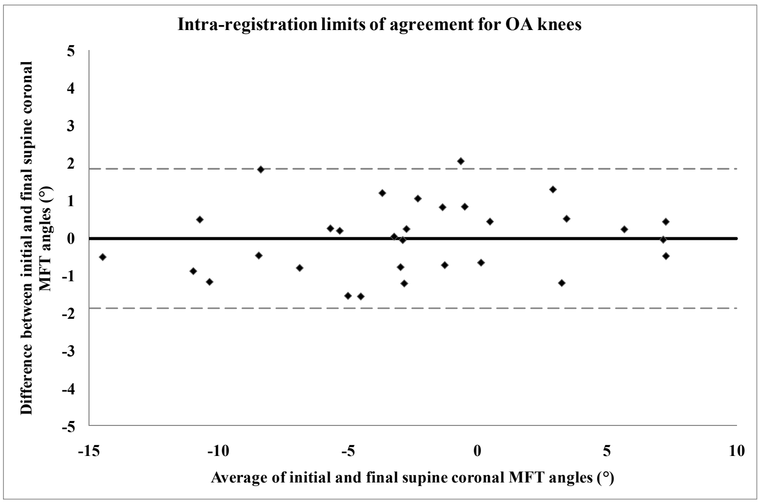
The intra-registration agreement for coronal MFT angles was within ±2° for osteoarthritic knees and almost ±1° following TKA. The sagittal alignment measurements were significantly less consistent, particularly for pre-operative patients, with agreement limits of ±6.9°. The final intra-registration sagittal MFT angles were relatively more extended compared to the initial measurements for both OA and TKA groups with mean differences of -2.5° and -2.3° respectively.

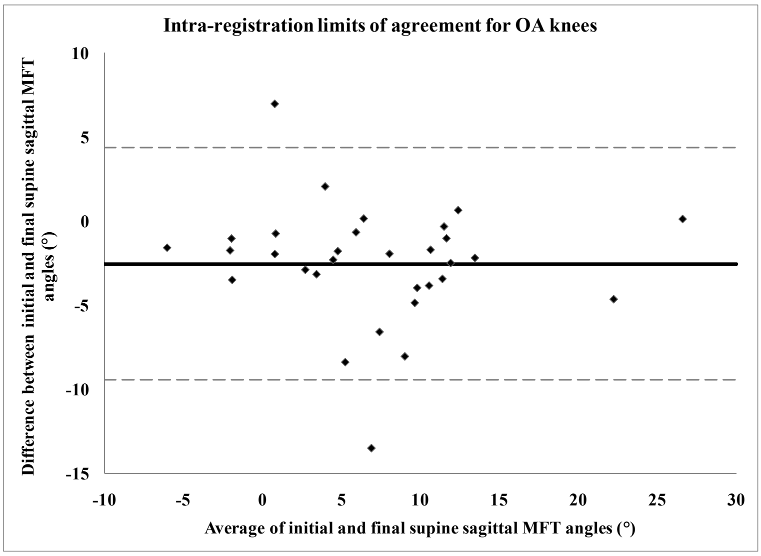
Table 5.4 Inter- and intra-registration agreement limits of supine MFT angles for pre-operative (OA) and post-operative (TKA) patient groups

MFT angle comparison (°)	Mean difference±1.96SD	
	OA (n=31)	TKA (n=30)
Initial coronal between registrations	-0.1±1.8	0.0±1.6
Initial sagittal between registrations	0.3±4.4	0.6±3.3
Initial and final coronal within registration	0.0±1.8	0.1±1.2
Initial and final sagittal within registration	-2.5±6.9	-2.3±3.8


Inter-registration limits of agreement for OA knees
Difference between initial supine coronal MFT angles (°)
Average of initial supine coronal MFT angles (°)
5
4
3
2
1
0
-1
-2
-3
-4
-5
-16
-14
-12
-10
-8
-6
-4
-2
0
2
4
6
8


Inter-registration limits of agreement for OA knees
Difference between initial supine sagittal MFT angles (°)
Average of initial supine sagittal MFT angles (°)
8
6
4
2
0
-2
-4
-6
-10
-5
0
5
10
15
20
25
30


Intra-registration limits of agreement for OA knees
Difference between initial and final supine coronal MFT angles (°)
Average of initial and final supine coronal MFT angles (°)
5
4
3
2
1
0
-1
-2
-3
-4
-5
-15
-10
-5
0
5
10


Intra-registration limits of agreement for OA knees
Difference between initial and final supine sagittal MFT angles (°)
Average of initial and final supine sagittal MFT angles (°)
10
5
0
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-15
-10
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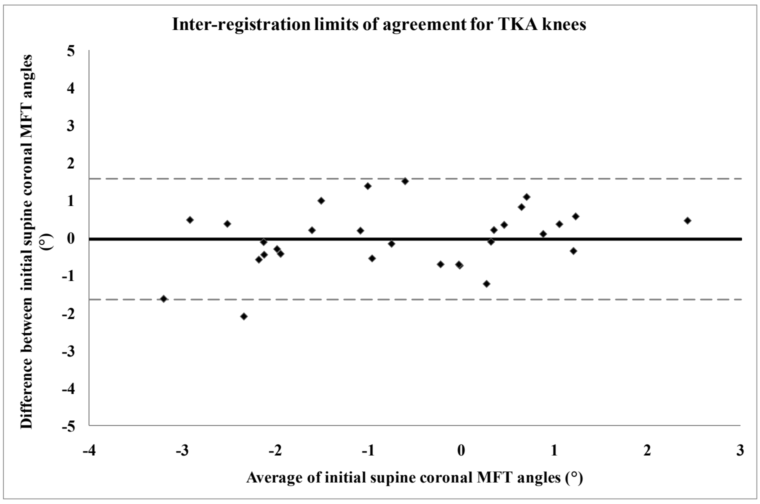
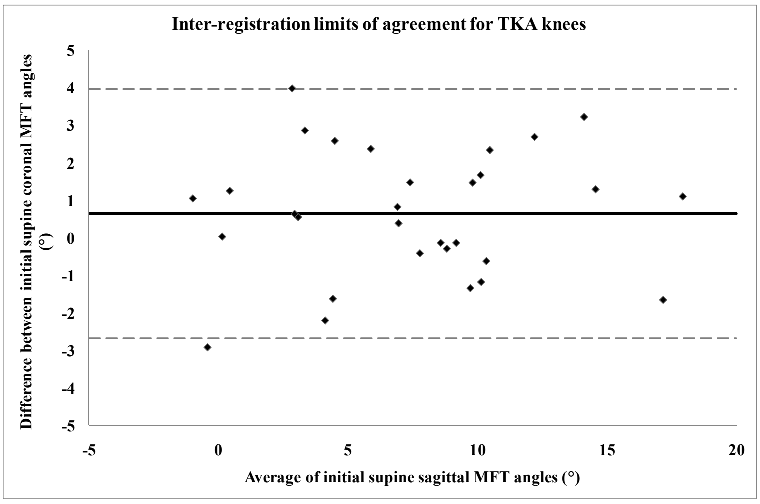
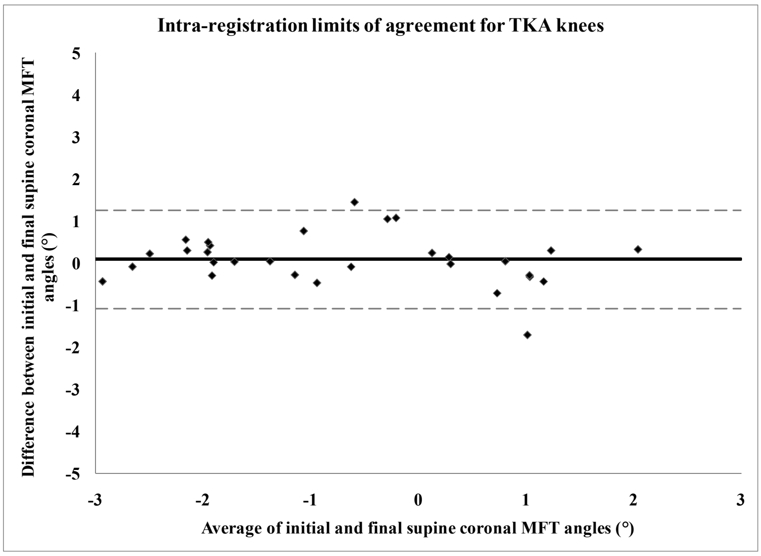
0
5
10
15
20
25
30


Inter-registration limits of agreement for TKA knees
Difference between initial supine coronal MFT angles (°)
Average of initial supine coronal MFT angles (°)
5
4
3
2
1
0
-1
-2
-3
-4
-5
-4
-3
-2
-1
0
1
2
3


Inter-registration limits of agreement for TKA knees
Difference between initial supine coronal MFT angles (°)
Average of initial supine sagittal MFT angles (°)
5
4
3
2
1
0
-1
-2
-3
-4
-5
-5
0
5
10
15
20



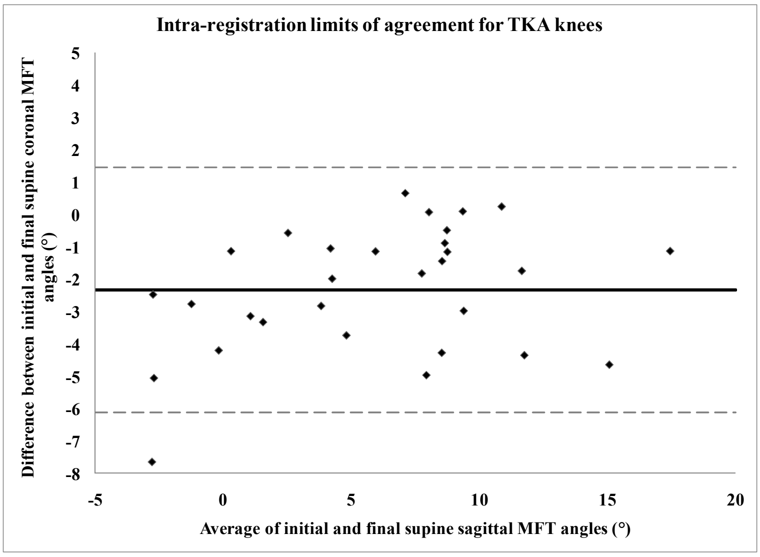


Figure 5.5 Pre- and post-operative inter- and intra-registration limits of agreement

Intra-registration variation of the repeated MFT angles following collateral stress and with bipedal stance is shown in Table 5.5. The repeatability coefficients for pre- and post-operative stress measurements were all within 2°. The standing coronal alignment was also repeatable to within 2° for osteoarthritic and prosthetic knees, whereas the standing sagittal measurements showed greater variation of almost 5° for both groups.

Table 5.5 Intra-registration variation of repeated varus-valgus stress and standing alignment measurements

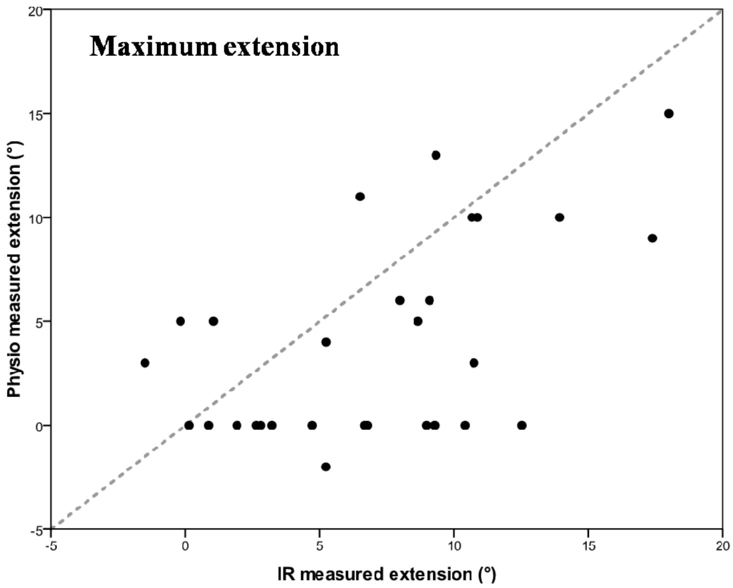
MFT angle measurement condition (°)	Repeatability coefficient	
	OA (n=31)	**TKA (n=30)**
Coronal change with varus stress	1.3	1.7
Coronal change with valgus stress	1.3	1.9
Standing coronal alignment	1.8	1.5
Standing sagittal alignment	4.7	4.5

5.2.4 Measurement of knee flexion

There was only moderate agreement between the goniometer and IR measurements (κ=0.44), with disagreement in nine cases all being patients with FFDs that were not identified clinically (Table 5.6). Agreement between the two measurement techniques is shown in plots of one method against the other (Figure 5.6) and illustrates a tendency for clinical measurements of knee flexion to be underestimates, especially in the extended position.

Table 5.6 Classification of measured angles into FFD categories for both measurements

<table>
<tr><th colspan="3" rowspan="3"></th><th colspan="3">IR</th></tr>
<tr><th colspan="3">Grade of FFD</th></tr>
<tr><th>None ≤5°</th><th>Moderate 6°≤19°</th><th>Severe 20°≤50°</th></tr>
<tr><td rowspan="3">Clinical</td><td rowspan="3">Grade of FFD</td><td>None ≤5°</td><td>12</td><td>9</td><td>0</td></tr>
<tr><td>Moderate 6°≤19°</td><td>0</td><td>9</td><td>0</td></tr>
<tr><td>Severe 20°≤50°</td><td>0</td><td>0</td><td>0</td></tr>
</table>



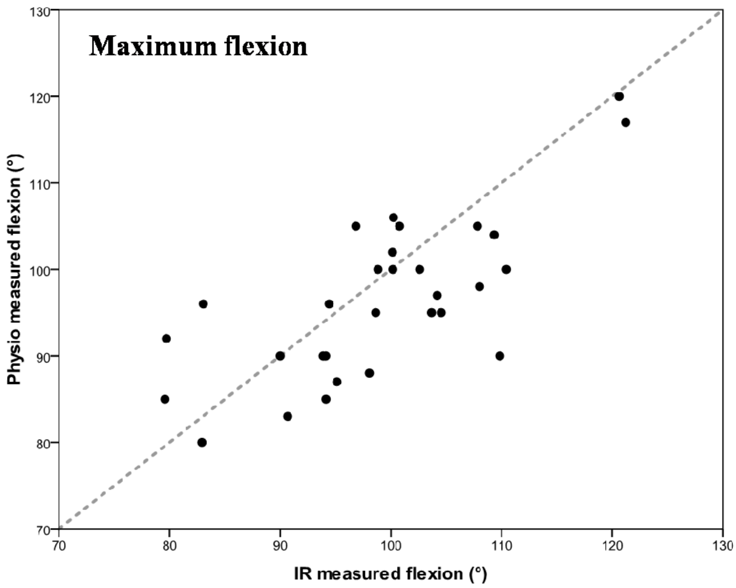


Figure 5.6 IR vs. physiotherapist measured knee flexion with manual goniometer in fully extended and fully flexed positions. The dotted lines represent absolute agreement between two measurements and so points below the line show clinical under-estimation and points above show clinical over-estimation of angles

5.2.5 Variation between alignment conditions and subject groups

Comparison of non-invasive and intra-operative alignment measurements is shown in Table 5.7. For osteoarthritic knees, the mean coronal MFT angle was similar between the non-invasive and invasive measurements with a small difference of 0.5°. The standard deviations were the same for both measurement conditions and the value of ±5.7° reflected the wide range of malalignment due to osteoarthritis. The mean coronal alignment for the non-invasive and invasive TKA groups was also similar and differed by only 0.5°; this difference was not statistically significant. The standard deviations of these two measurement conditions were also similar and within ±1.5°. For the supine sagittal MFT angles there was a significant difference between non-invasive and invasive measurement conditions for both osteoarthritic and prosthetic knees. For the osteoarthritic knees, the invasive intra-operative measurements were in greater relative extension by a mean of -5.2° in comparison to the pre-operative measurements. The post-TKA invasive measurements had an even greater tendency (-7.2°) to more extension in comparison to the non-invasive post-operative clinical measurements.

Table 5.7 Comparison of non-invasive and invasive supine alignment measurements for pre-operative (OA) and post-operative (TKA) patient groups

		mean(95%CI)±SD	
		OA (n=31)	**TKA (n=29)**
Supine coronal MFT angle (°)	**Non-invasive**	-2.5(-4.6,-0.4)±5.7	-0.7(-1.2,-0.1)±1.4
	Invasive	-2.0(-4.0,0.2)±5.7	-0.2(-0.6,0.2)±1.1
	Difference	0.5(-0.5,1.5)±2.8	0.5(-0.1,1.0)±1.4
	p value	0.3	0.08
Supine sagittal MFT angle (°)	**Non-invasive**	7.7(5.1,10.4)±7.1	6.7(4.8,8.7)±5.1
	Invasive	2.5(-0.3,5.3)±7.7	-0.5(-1.8,0.7)±3.3
	Difference	-5.2(-6.8,-3.7)±4.3	-7.2(-9.0,-5.4)±4.7
	p value	<0.001	<0.001

Comparison of non-invasive and invasive coronal laxity measurements is shown in Table 5.8 and illustrated in Figure 5.7. For osteoarthritic knees, both varus and valgus stress manoeuvres resulted in greater angular displacements for the invasive measurements and the mean differences in comparison to the non-invasive measurement conditions were statistically significant. For the prosthetic knees, the valgus angular displacements were statistically greater for the invasive intra-operative measurements but for varus angular displacement the two measurement conditions were statistically similar with a mean difference of 0.3°.

Table 5.8 Comparison of non-invasive and invasive coronal laxity for pre-operative (OA) and post-operative (TKA) patient groups

		mean(95%CI)±SD	
		OA (n=30)	**TKA (n=28)**
Varus angular displacement (°)	**Non-invasive**	-3.8(-4.4,-3.3)±1.5	-4.3(-4.8,-3.9)±1.1
	Invasive	-5.3(-6.3,-4.5)±2.2	-4.1(-4.6,-3.5)±1.4
	Difference	-1.5(-2.4,-0.6)±2.4	0.3(-0.3,0.8)±1.4
	p value	0.002	0.3
Valgus angular displacement (°)	**Non-invasive**	3.3(2.7,3.9)±1.6	2.8(2.5,3.1)±0.8
	Invasive	5.0(4.4,5.5)±1.6	3.7(3.2,4.2)±1.3
	Difference	1.6(1.1,2.2)±1.6	0.9(0.4,1.4)±1.3
	p value	<0.001	0.002

Radiographic and IR-measured coronal MFT angles are compared in

Table 5.9. Pre-operatively, the non-invasive standing alignment differed from the long leg radiographic alignment with a statistically significant mean difference of 1.8° relative valgus for the radiographs. The post-operative TKA non-invasive standing measurements were also statistically different to the radiographic measurements with an even greater degree of relative valgus of 2.9° measured by the radiographs. Comparison of the supine invasive intra-operative measurements with

the corresponding weight bearing radiographs showed smaller mean differences of within 1° for OA and prosthetic knees.

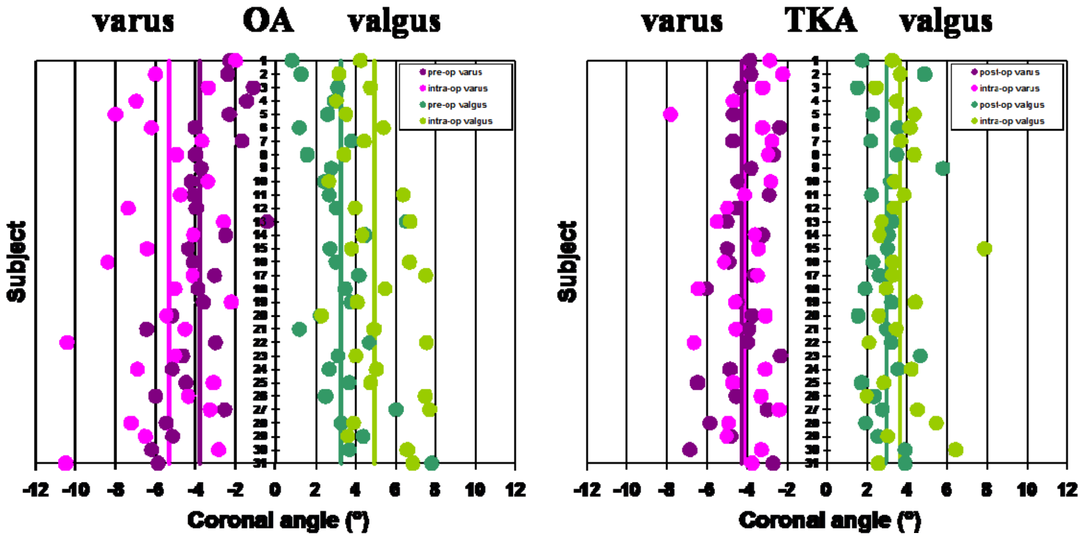


Figure 5.7 Comparison of non-invasive varus (dark purple) and valgus (dark green) stress angles with corresponding invasive varus (light purple) and valgus (light green) measurements for OA and TKA knees. The coloured solid lines represent the mean values for each measurement condition

Table 5.9 Comparison of radiographic alignment with non-invasive and invasive measurements for pre-operative (OA) and post-operative (TKA) patient groups

		mean(95%CI)±SD	
		OA (n=31)	**TKA (n=29)**
Coronal MFT angle (°)	**Non-invasive standing**	-3.6(-5.8,-1.4)±6.0	-2.5(-3.3,-1.8)±2.0
	Radiograph	-1.7(-4.6,1.1)±7.8	0.4(-0.7,1.5)±3.0
	Difference	1.8(0.3,3.3)±4.1	2.9(1.6,4.2)±3.3
	p value	0.02	<0.001
Coronal MFT angle (°)	**Invasive supine**	-2.0(-4.0,0.2)±5.7	-0.2(-0.6,0.2)±1.1
	Radiograph	-1.7(-4.6,1.1)±7.8	0.4(-0.7,1.5)±3.0
	Difference	0.2(-0.7,1.6)±3.7	0.6(-0.5,1.6)±2.7
	p value	0.8	0.3

For comparison of the supine and standing alignment measurements, the asymptomatic group was included (Table 5.10). In the coronal plane, the mean standing MFT angles were statistically more varus compared to supine measurements for asymptomatic, osteoarthritic and prosthetic knees. The greatest mean difference was seen with the TKA group with almost 2° of relative varus. In the sagittal plane, all three groups had a strong statistical tendency towards more relative hyperextension from supine to standing. The combined overall weight-bearing change to relative varus and hyperextension can be seen in graphs (Figure 5.8 and Figure 5.9) and vector plots (Figure 5.10 and Figure 5.11).

Table 5.10 Comparison of mean alignment for each group between supine and standing

		mean(95%CI)±SD		
		Control (n=30)	**OA (n=31)**	**TKA (n=29)**
Coronal MFT angle (°)	**Supine**	0.1(-0.8, 1.1)±2.5	-2.5(-4.6,-0.4)±5.7	-0.7(-1.2,-0.1)±1.4
	Stand	-1.1(-2.4,0.3)±3.7	-3.6(-5.8,-1.4)±6.0	-2.5(-3.3,-1.8)±2.0
	Diff	-1.2(-1.8,-0.5)±1.8	-1.1(-1.9,-0.3)±2.2	-1.9(-2.4,-1.3)±1.4
	p value	0.001	0.009	<0.001
Sagittal MFT angle (°)	**Supine**	-1.7(-2.9,-0.5)±3.3	7.7(5.1,10.4)±7.1	6.7(4.8,8.7)±5.1
	Stand	-5.5(-7.3,-3.6)±4.9	1.8(-1.0,4.6)±7.7	1.1(-1.8,4.0)±7.6
	Diff	-3.8(-5.4,-2.2)±4.3	-5.9(-8.0,-3.9)±5.6	-5.6(-7.3,-4.0)±4.3
	p value	<0.001	<0.001	<0.001

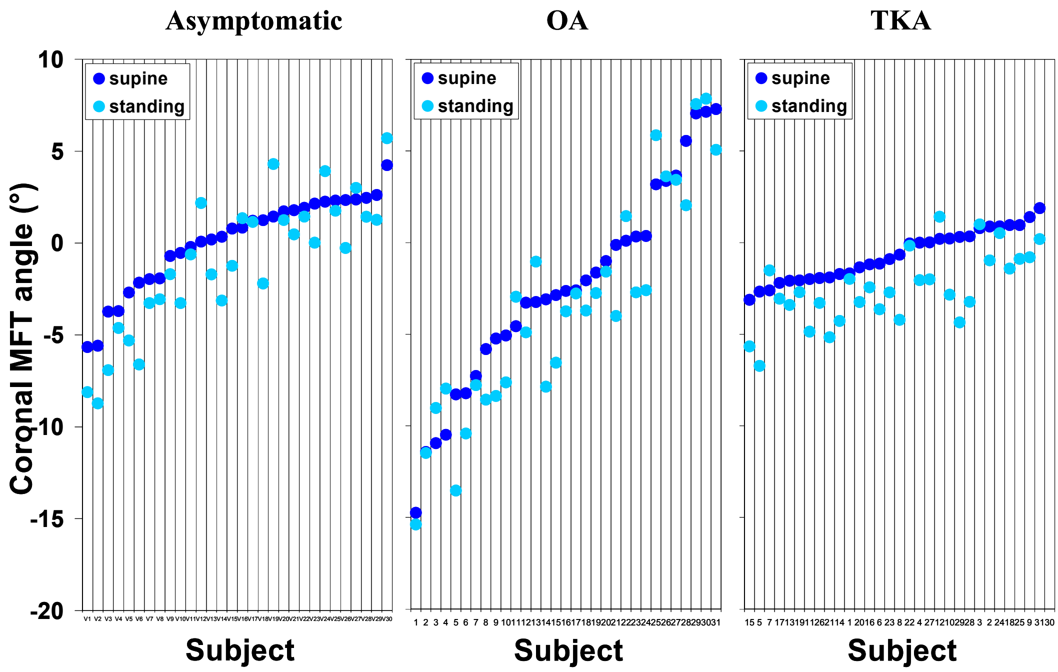


Figure 5.8 Coronal MFT angles (°) supine (dark blue) and standing (light blue) for all subjects in each group illustrating trend to relative varus

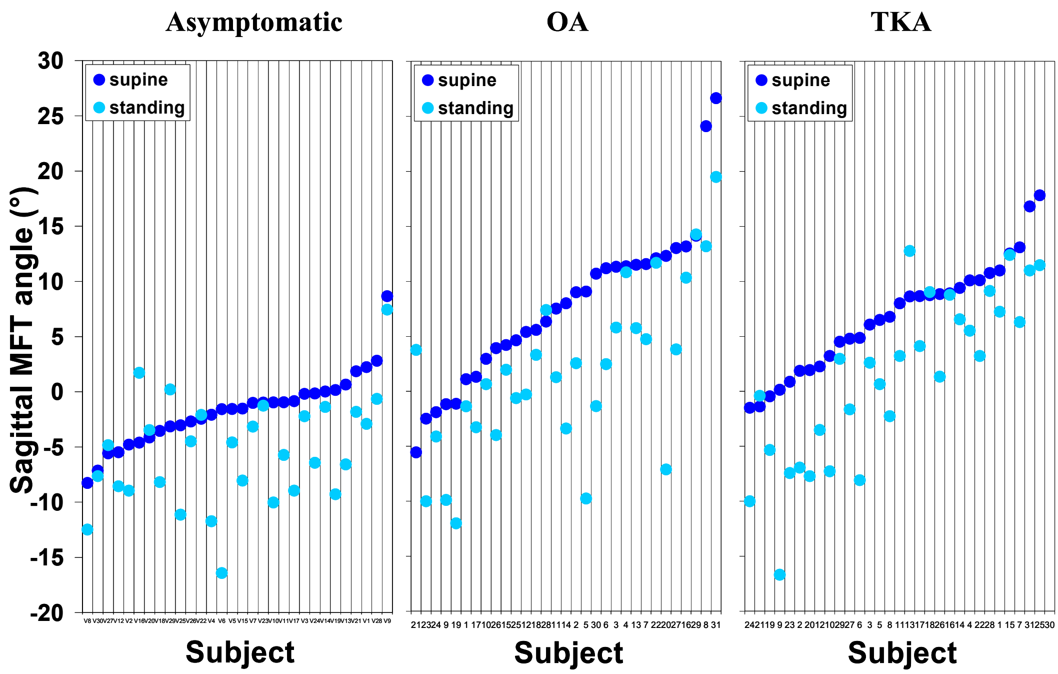


Figure 5.9 Sagittal MFT angles (°) supine (dark blue) and standing (light blue) for all subjects in each group illustrating trend to relative extension

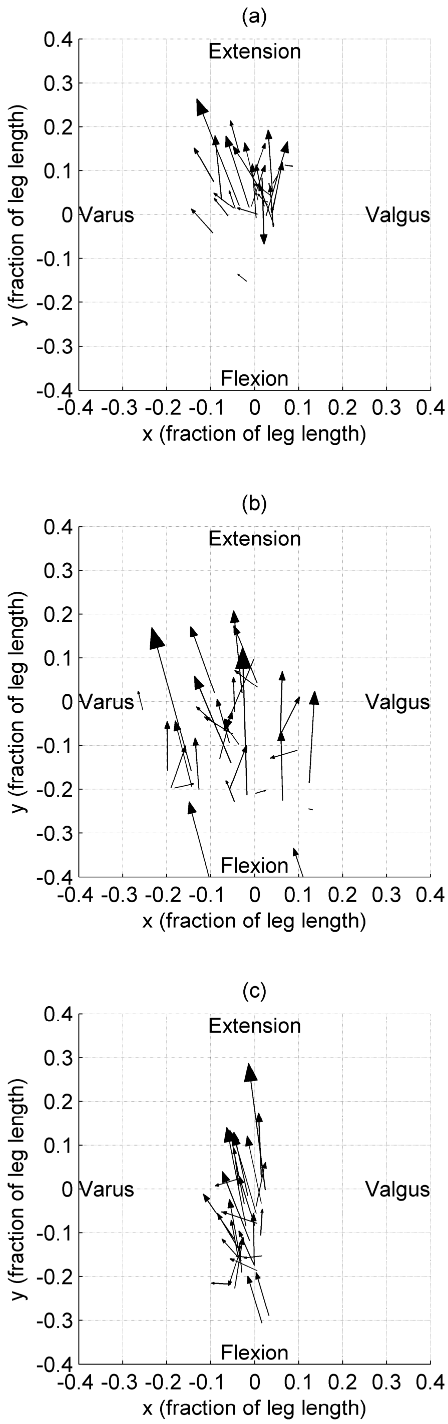


Figure 5.10 Combined coronal and sagittal displacement of ankle centre with respect to knee centre from supine to standing for a) asymptomatic, b) OA and c) TKA knees

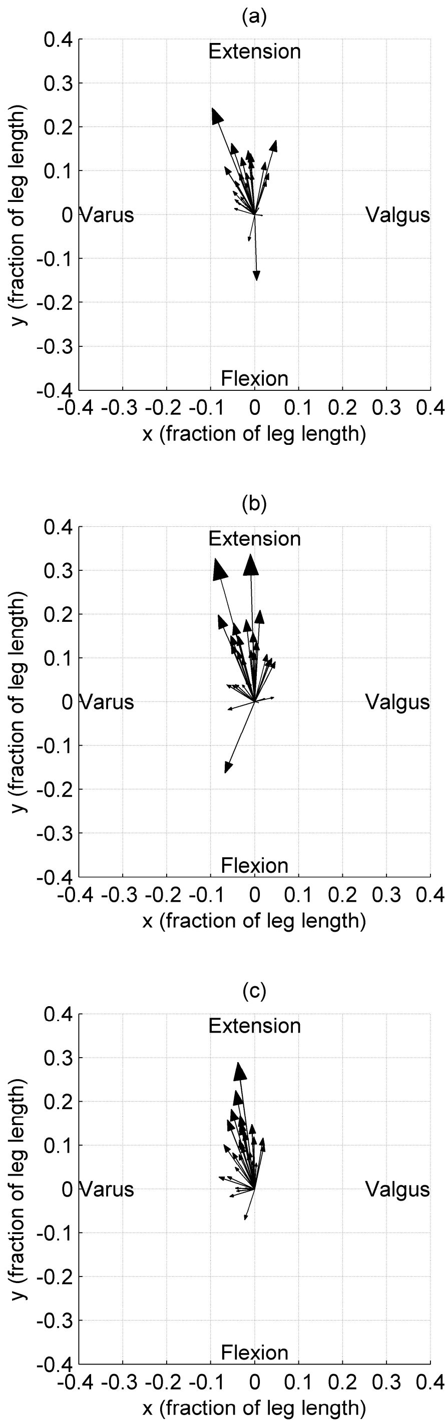


Figure 5.11 Relative ankle centre displacement with respect to knee centre from supine to standing for a) asymptomatic, b) OA and c) TKA knees

5.3 Discussion

5.3.1 Clinical outcomes

Following TKA, all patients except for one had an improvement in their Oxford knee score (OKS) when routinely assessed at six weeks. With regards to the post-operative mean score, there are currently no published systems of categorisation of the OKS due to potential variation from one population to another [Murray et al. 2007]. Baker et al. (2007) provided useful comparative data by measuring the OKS one year following TKA for 8231 patients in addition to asking whether they were satisfied, unsure or unsatisfied with their operation. The mean OKS of 25.0 (60-12 scale) from this large National Joint Registry study was marginally better than the mean score of 28.3 from the smaller patient cohort in this study. However, direct comparison cannot be made due to differences in the follow up period and potential for improvement in outcome scores up to one year following TKA [Gosens et al. 2005]. It may be more appropriate to use the change in OKS following TKA as a measure of outcome given that pre-operative baseline levels of pain and function have been shown to be the single best predictors of pain and function after joint replacement [Fortin et al. 1999]. Unfortunately the study by Baker et al. (2007) did not collect pre-operative knee scores and so this information was not available for comparison. With regards to satisfaction, Baker et al. (2007) reported that 81.8% of patients were "satisfied", 11.2% were "unsure" and 7% indicated they were "not satisfied" one year following TKA. A longer term follow up study from the Swedish Arthroplasty Register [Robertsson et al. 2000] reported remarkably similar satisfaction rates, with 81% of the 25000 TKA patients "satisfied", 8% "dissatisfied" and 11% "undecided". These results were also similar to those of Beverland (2010), who used a different scale for assessing satisfaction (Table 2.5) to evaluate 465 patients at a minimum follow up of 10 years. The results showed that 4% were "very happy", 81% were "happy", 8% were "OK but not perfect", and 7% were "never happy", which again are in agreement with those reported by the larger joint registry studies.

In comparison to recent published outcome data, all patients in this study apart from one were either satisfied or very satisfied (Table 5.2). This level of satisfaction, therefore, was not in keeping with recent larger outcome studies. However, it is difficult to make direct comparisons due to the variation in the follow up period and a level of expectation at six weeks that may not have been as high as that at one year or beyond. It has been shown previously that patient education can alter patient expectation [Mancusso et al. 2008], and so the detailed pre-operative information provided to patients in this study may have led to a more realistic expectation of outcome six weeks following knee replacement. A further reason for patients showing higher satisfaction rates than may be anticipated from other outcome studies was the involvement in a clinical trial. This resulted in additional time spent with patients before and after surgery, with a comprehensive description of the TKA procedure as part of the process of obtaining informed consent. Finally, it is worth noting that there is debate as to how satisfaction can be measured and to what extent it can be used to assess clinical outcome [Aspinal et al. 2003]. It has been shown that closed questions which ask directly about satisfaction levels are more likely to produce answers that are positive in comparison to open-ended questions [Carr-Hill, 1992]. This may account for the discrepancy between the high proportion of very satisfied patients in this study compared with the overall spread of the six week Oxford knee scores.

Regardless of the potential limitations of scoring systems, the clinical outcomes of the patient cohort compared favourably with the reported outcomes from other larger trials.

5.3.2 Repeatability of measures

In spite of patient factors such as obesity, poor skin quality and pain, all registrations were successfully completed with no exclusions due to an inability to perform the necessary rotational manoeuvres. In particular, hip joint centre registrations could have potentially been rejected if the acquired cluster of points was too scattered or non-spherical (Section 3.3.1.3). The limits of agreement for the initial coronal MFT angles between registrations were similar for both osteoarthritic (1.8°) and prosthetic knees (1.6°). This degree of variation was similar to the asymptomatic volunteer group (Table 3.6) in spite of patient co-morbidities and the fact that the inter-registration limits of agreement for the volunteer cohort were based on the median of five measurements, whereas the OA and TKA measurements were based on the single initial coronal MFT angle. For the sagittal measurements however, the limits of agreement were approximately 3° greater for the osteoarthritic group and 2° greater for the TKA group in comparison to the volunteer cohort. This wider variation in comparison to coronal measurements may be related to the more dynamic nature of sagittal alignment that can be influenced by the patient. In particular patients may have a tendency to resist forced extension which can be painful in osteoarthritic knees and at six weeks following TKA.

Once the registration process had been completed the intra-registration variation of the coronal MFT angles was similar to the asymptomatic volunteer measurements. For patient measurements the initial and final MFT angles were taken before and after a combination of standing and varus-valgus stress manoeuvres. In contrast, the asymptomatic volunteer intra-registration measurements were assessed both before and after stance and before and after collateral stress with limits of agreement ranging from 1.0° to 1.7°. By comparison, the pre-operative intra-registration coronal measurements showed agreement of 1.8°, and for the TKA group the limits of agreement were even more consistent at 1.2°. The results suggest that regardless of the type of knee being assessed, once a successful registration has been performed the non-invasive trackers show a consistent stability following stress manoeuvres or stance. The relative stability of the coronal TKA measurements, particularly in comparison to the osteoarthritic knees within the same patients, may be related to the increased congruency of the implants in comparison to a native knee joint. Although the implants were PCL-retaining, which attempts to preserve normal knee kinematics (Section 2.4.1.1), the congruency of the tibio-femoral articulation was greater for the prosthetic knees which all used highly congruent “deep dish” polyethylene tibial inserts.

The sagittal MFT angles showed considerably more intra-registration variation in comparison to the asymptomatic volunteer group. The volunteer sagittal MFT angles taken before and after both stance and varus-valgus stress had limits of agreement varying from approximately 2° to 3°. By comparison, the OA and TKA agreement limits were 6.9° and 3.8° respectively. It was observed however that patients tended to become more relaxed throughout the course of the assessment with less active resistance to full extension. This observation was reflected in the mean difference of more than 2° relative extension from initial to final intra-registration sagittal MFT angles. This was a similar trend to the asymptomatic volunteer measurements although the magnitude of the mean difference was greater for the patients, most likely a consequence of the higher initial sagittal MFT angles. The stability of the externally mounted trackers was reaffirmed by the intra-registration variation of repeated varus-valgus stress and standing alignment measurements. The repeatability coefficients of all the coronal alignment measurements were within 2° for osteoarthritic and prosthetic knees, with values ranging from 1.3° to 1.9°. The sagittal standing MFT angles showed intra-registration variation of almost 5°, again reflecting the fact that this is a more dynamic alignment parameter that can be directly influenced by how people stand.

5.3.3 Measurement of knee flexion

When assessing knee flexion following joint arthroplasty, manual goniometric measurements provided a poor estimate of the range when compared to the more accurate non-invasive system. When the knee was held in maximum flexion observers could either underestimate or overestimate the true angle. However when the knee was held in extension there was a tendency to predominantly underestimate which may lead to underreporting of both the frequency and magnitude of fixed flexion deformities (FFD). At six weeks following TKA, 18 patients had a moderate FFD as identified by the IR system, only half of which were identified by goniometer measurement alone. Edwards et al. (2004) compared both visual and manual goniometry measurements of the knee in maximum flexion with a lateral radiograph and found most errors involved an underestimate of true flexion. Edwards et al. (2004) concluded that it was safer to underestimate knee flexion angle as it would result in higher detection rate of cases with poor knee flexion. In contrast however, underestimation while in extension may be less desirable as it can fail to detect FFD which may have benefited from intervention had they been identified. It is known that residual flexion contractures can increase energy cost and decrease velocity during ambulation [Perry et al. 1975, Tew and Foster 1987] with pain and functional knee scores more likely to be reduced [Ritter et al. 2007]. Recognition and early detection are therefore important. The use of more accurate systems to identify and measure FFD may lead to more timely intervention and therefore to potentially improved outcomes.

5.3.4 Comparison of invasive and non-invasive alignment

The invasive OA and TKA supine coronal MFT angles were more valgus than the corresponding non-invasive measurements by a mean difference of 0.5°. This trend, although not statistically significant, may have represented the effect of the surgical exposure of the knee. Except for one case, knees were all approached from the medial side with potential for slightly more valgus alignment due to loss of some medial constraint. The effect of surgical exposure of the knee on coronal alignment has not been previously documented which may be related to the absence of an accurate non-invasive measurement tool. Although computer-assisted technology has enabled accurate intra-operative measurements of alignment, fixation of the trackers to bone requires the knee joint to be exposed. The use of non-invasive tracker attachments has therefore provided an indirect measurement of the effect of surgical exposure on mechanical lower limb alignment. The non-invasive and invasive measurement conditions also varied with respect to muscle tone. It is not clear whether the slight relative valgus in the non-invasive group was related to the presence of muscular tone.

Although there was a small difference between the mean coronal alignment measurements for the non-invasive and invasive conditions, the post-implant MFT angles were all within the target alignment range of 0°±3° for both measurement conditions. Therefore in spite of the potential effect of muscle tone and surgical exposure, the target coronal alignment that was achieved intra-operatively in the supine position was maintained at the six week follow up assessment.

In contrast to the coronal measurements, the sagittal MFT angles were significantly different for clinical and operative conditions. For osteoarthritic knees the sagittal MFT angles were more extended intra-operatively by a mean difference of 5.2°, most likely due to the absence of muscle tone. In the clinical setting, muscular contraction could have potentially restricted the amount of knee extension if this was painful. The removal of this muscular inhibition along with exposure of the knee resulted in a more extended intra-operative position. This was a similar finding in the TKA group, with an even greater degree of relative hyperextension for the invasive measurements. Therefore in spite of surgically correcting the pre-operative fixed flexion contractures in order to achieve sagittal MFT angles close to 0°, at the six week post-operative stage most patients were unable to achieve this degree of extension in the clinical setting. The mean post-operative maximum extension angle of 6.7° was only 1° more extended than the pre-operative osteoarthritic measurements. In addition to the potential effect of muscular inhibition of knee extension, the TKA patients may have adopted the position that they had been accustomed to prior to surgery. However, it is likely that this level of flexion deformity following TKA would improve over time as reported in previous studies [Aderinto et al. 2005, Lam et al. 2003].

5.3.5 Coronal laxity

For osteoarthritic knees, varus and valgus angular displacements were statistically greater intra-operatively by mean values of 1.5° and 1.6° respectively in comparison to non-invasive measurements. During pre-operative clinical assessment, the limiting factor during stress testing was often the discomfort of the manoeuvre rather than the perception of a definitive end-point. Muscular inhibition during stress testing was absent intra-operatively which most likely accounted for the greater overall mean values of the invasive measurements. Therefore the presence of muscle tone in the clinical setting resulted in a mean of 1.5° less angular displacement than would be expected intra-operatively for both varus and valgus stress manoeuvres. Hence the overall medio-lateral laxity of osteoarthritic knees was around 3° greater in patients who were anaesthetised. The effect of the medial exposure of the knee may have influenced the degree of valgus angular displacement, although the magnitude of the difference between non-invasive and invasive measurements was the same for both medial and lateral laxity. Coronal angular displacement following applied manual stress can form the basis of decision-making algorithms to determine the requirement for any soft tissue release during TKA surgery [Hakki et al. 2009, Jenny et al. 2004, Picard et al. 2007b, Saragaglia et al. 2006, Unitt et al. 2008]. Stress measurements obtained pre-operatively could therefore be expected to underestimate the degree of intra-operative varus and valgus angular displacements by an average of approximately 1.5° and so the thresholds should be adjusted accordingly in the future development of non-invasive soft tissue balancing algorithms to enable matching with intra-operative values.

Following TKA, the valgus stress angulation was statistically greater intra-operatively than non-invasively by a mean of 0.9°. This was a similar trend to that of osteoarthritic knees, but with less mean difference between the two measurement conditions. For varus angular displacement, however, there was no significant difference between non-invasive and invasive measurements. The mean difference between the two groups was only 0.3° with the greater angular measurements in the non-invasive group. This suggests that the difference between the intra-operative and post-operative valgus stress measurements was not the result of pain inhibition as this same trend would have then been expected for the varus stress angles had this been the case. The results suggest that the intra-operative varus laxity is likely to be the same when measured at the six week post-operative stage. However the intra-operative valgus laxity may be around 1° less when measured at six weeks. This could be due to the effect of wound closure with contraction of the medial tissues as part of the normal acute healing process [Hardy, 1989].

The low rate of medial soft tissue releases was based on the fact that most varus deformities were manually reducible to a coronal MFT angle of within 2° of neutral alignment or beyond, indicating that bony cuts alone were considered sufficient to balance the collateral restraints [Picard et al. 2007b]. If more soft tissue releases had been performed then the valgus angular displacement angles would have potentially been greater post-operatively which may have resulted in a similar medial and lateral laxity. However, whilst techniques have been described which aim for a symmetrical “balance” of coronal laxity [Insall et al. 1985, Whiteside et al. 2000, Winemaker 2002], there is no clear rationale for this. Markolf et al. (1976) performed a quantitative in vitro study of knee laxity by measuring the relative contributions of the supporting structures. However, in the absence of a reliable unstressed alignment angle, only the overall laxity was measured. Van Damme et al. (2005) used a similar test model and applied standardised moment loads of 9.8Nm to 12 cadaver knees, before and after TKA, and quantified relative varus-valgus coronal laxity as the amount of fluoroscopically measured joint space opening. The applied loads resulted in similar medial and lateral gap increases for both normal and prosthetic knees. However these findings may not represent true in-vivo knee laxity due to potential variation in the mechanical properties of the soft tissues of cadaveric knees. Furthermore, the repeatability of the loading method was not reported and the TKA technique, including the extent of any soft tissue releases, was not documented. These factors could have influenced the degree of medio-lateral knee laxity.

To overcome the limitations of using cadaveric knees, several clinical studies have been performed. Heesterbeek et al. (2008) measured knee laxity in 30 healthy subjects of mean age 62 (SD 6.4) years using a custom made stress device to apply 15Nm varus-valgus loads. Measured differences between neutral and varus-valgus stress radiographs were used to calculate angular displacement. In extension, the mean varus laxity was 2.8° (SD 1.3) and the mean valgus laxity was 2.3° (SD 0.8). In comparison to these laxity measurements, the healthy controls evaluated in this study had a mean varus laxity of 3.8° (SD 1.2) and a mean valgus laxity of 3.4° (SD 1.2) (Table 3.4), representing approximately 1° greater mean angular displacements. This may have been due to a difference in the magnitude of the applied load which was measured at approximately 19Nm in this study (Section 4.2.4) compared to 15Nm used by Heesterbeek et al. (2008). The difference in the mean age of the subjects assessed was also a potential variable. In spite of the variation between the magnitudes of the varus-valgus laxity measurements, the mean varus laxity was marginally higher by a similar amount (0.5°) in both studies. However, these differences were of doubtful clinical significance as they were beyond the sensitivity of both the non-invasive and radiographic measurement systems.

Okazaki et al. (2006) reported a more significant asymmetry of medio-lateral laxity in normal knees. Varus and valgus stress measurements were made on fifty asymptomatic knees and in extension the mean angle was 4.9° in varus stress and 2.4° in valgus stress. In spite of the potential errors associated with radiographic measurements, these angular displacements were similar to the post-operative non-invasive measurements in this study and suggest that the TKA laxity was comparable to normal knees. However, the "extended" knee position involved 10° of flexion which may have altered the restraining properties of the collateral structures in comparison to a more extended position [Grood et al. 1981, Markolf et al. 1976, Noyes et al. 1980], with potential to influence the angular displacements. The effect of knee flexion on stress angles was further highlighted by a similar study by Yoo et al. (2006) involving measurements on 100 healthy subjects. A custom made laxity device was used to quantify angular displacement following application of manual stress with the knee in 20° of flexion. This resulted in a mean varus laxity of 7° and a mean valgus laxity of 4.1° and suggested that increasing knee flexion may result in a greater relative increase in varus stress angle and hence a greater degree of varus-valgus asymmetry.

In contrast to clinical evaluations that predominantly rely on radiographic measurement of laxity, the use of computer-assisted technology intra-operatively has enabled a more direct recording of angular displacement. Jenny (2010) measured coronal plane knee laxity using image-free navigation in patients undergoing ACL reconstruction. Apart from isolated tears of the ACL, the 20 patients evaluated were deemed to have had no pathological laxity and no associated meniscal lesions. Following the application of manual stress by a single surgeon, the mean varus angular displacement in extension was 4.1±1.9° and the mean valgus angular displacement was 3.6±1.2°. These values were very similar to the post implant intra-operative TKA stress angles in this study with both sets of measurements obtained under similar conditions on anaesthetised patients. In spite of potential variation in magnitude of applied manual stress, this similarity between prosthetic and normal physiological laxity supports the intra-operative decisions made for these patients (independent of this study) to avoid medial releases for most cases.

5.3.5.1 How much laxity should surgeons aim for?

In TKA surgery, it is widely recognised that soft tissue management is an important factor for achieving a satisfactory clinical outcome [Freeman et al. 1977, Insall et al. 1979, Ranawat et al. 1993, Vince et al. 1989]. However there are no accepted laxity values to aim for intra-operatively and without the use of accurate measurement techniques, such as CAOS systems, the assessment of the soft tissues remains highly subjective. It is generally acknowledged that a TKA implanted “too tightly” should be avoided due to potential limitation in range of motion leading to poorer patient satisfaction [van Damme et al. 2005]. On the other hand, a prosthesis that is implanted “too loosely” may result in symptoms of instability [Zalzal et al. 2004] and again this may compromise patient outcome.

In the absence of quantitative data correlating soft tissue laxity with TKA outcome, the question of what to aim for intra-operatively has not been previously answered with strong supporting evidence. Unitt et al. (2008) used a calibrated distraction device to measure change in coronal knee angulation with applied load. Optimum knee laxity was defined as symmetrical angular displacements between -3° and +3° during gap distraction, and a lax knee was defined as measurements outside the ±3° range. “Balanced” knees with optimum laxity according to the defined criteria were associated with a statistically greater improvement in the American Knee Society clinical rating score [Insall et al. 1989] but no difference in the Oxford knee score was found. However, no specific angular measurements were obtained and the definition of a desired amount of laxity was based on values being within a range. Furthermore, there were five different surgeons using the balancer instrument with no measure of inter-observer or intra-observer repeatability. Therefore the conclusion that a “balanced” knee improves short term outcome in TKA was not strongly supported by the data presented.

Picard et al. (2007b) used navigation to measure relative angular displacement following manually applied varus and valgus load pre-implant and post-implant during TKA. The mean varus stress angle in extension was 3.5° and the mean valgus stress angle was 2.1°. The authors concluded that these values constituted a well-balanced knee based on similarities with the values obtained by Okazaki et al. (2006). However, the varus stress angle of 3.5° was almost 1.5° less than the mean angle obtained by Okazaki et al. (2006) for healthy controls. The measurements by Picard et al. (2007b) were obtained by a single surgeon with no standardisation of the applied load or measure of the degree of repeatability of the manual stress technique. There were also no clinical outcome measures supporting the degree of laxity obtained intra-operatively and this limitation was acknowledged by the authors.

Hakki et al. (2009) used a similar navigation measurement technique to that of Picard et al. (2007b) to quantify collateral laxity in extension by the degree of angular displacement following applied manual load. The mean unidirectional post-TKA varus-valgus deflection arc in extension was only 1.4°, which was less than the degree of laxity reported by other studies. In spite of this, however, the authors used their data to define a stable, balanced knee as having a total coronal deflection arc of ≤4°. The study did not report on any varus-valgus asymmetry and the use of single-surgeon stress measurements limited any direct comparisons with other studies in the absence of validation of the repeatability of the stress manoeuvres. It was therefore possible that the amount of load applied to the knee was less than that in other studies. Alternatively the knees may have been considered "too tight" by other surgeons, particularly in view of the results of this clinical study which showed that valgus angular displacement was likely to be less at the six week follow up clinic. Table 5.11 provides a summary of the studies discussed in relation to coronal knee laxity.

Table 5.11 Studies measuring coronal knee laxity

Date	Authors	N	Mean varus laxity	Mean valgus laxiy	Knee type	Knee position
2006	Yoo et al.	100	7°	4.1°	Normal	20° flexed
2006	Okazaki et al.	50	4.9°	2.4°	Normal	10° flexed
2007	Picard et al.	81	3.5°	2.1°	TKA	Extension
2008	Heesterbeek et al.	30	2.8°	2.3°	Normal	Extension
2009	Hakki et al.	93	1.4°	1.4°	TKA	Extension
2010	Jenny et al.	20	4.1°	3.6°	ACL injury	Extension

The non-invasive IR system developed in this study has provided new information on the relationship between intra-operative and post-operative TKA laxity measurements. The amount of varus angular displacement was not statistically different between the measurement conditions, whereas the mean valgus angular displacement was only 1° less when measured six weeks post-operatively. The TKA angular displacements were similar to the asymptomatic control values in this study (Table 3.4) as well as the previously reported normal physiological values in other studies [Jenny 2010, Okazaki et al. 2006]. For patients due to undergo TKA, non-invasive measurements obtained on the contralateral knee (if asymptomatic) or at an earlier stage in the patient's life prior to the onset of OA, could provide a subject-specific target during surgery. Alternatively, the mean coronal laxity (4° of varus and 4° of valgus) achieved during TKA surgery in this study can be considered a reasonable target when using quantitative techniques that enable accurate measurement of angular displacement. Furthermore, these intra-operative stress angles are likely to be similar to the six week post-operative measurements providing a standardised examination technique is used.

5.3.6 Radiographic and IR-measured coronal alignment

Long-leg radiographic measurements are widely considered to be an effective method for assessing lower limb alignment [Cooke et al. 2007], and so comparison was made between this method and the non-invasive IR standing measurements obtained under the same weight-bearing conditions. For osteoarthritic knees the mean coronal MFT angle measured radiographically was almost 2° more valgus than the non-invasive standing measurements. However, the SD of this difference was 4.1° indicating significant disagreement between the two measurement techniques. This discrepancy continued for post-operative TKA measurements with an even greater mean difference of almost 3° relative valgus reported by the radiographs. Although long-leg x-rays can be quite accurate in a controlled setting in normal subjects with minimal deformity [Cooke et al. 2007], when the required positional conditions are not met, then large measurement errors can occur (Section 2.6.1). In particular, with extremity-deforming OA or at an early stage following TKA, when patients are more likely to have fixed flexion contractures, variation in lower limb rotation can lead to large apparent errors in coronal alignment [Brouwer et al. 2007a]. Therefore, whilst comparison has been made to a recognised method for assessing knee alignment it cannot be assumed that the discrepancy between the two measurement systems is purely a result of errors associated with the IR system.

Yaffe et al. (2008) evaluated the relationship between long-leg radiographic and navigation alignment measurements before and after TKA and reported large discrepancies between the two techniques. The difference between pre-operative radiographs and intra-operative navigation measurements was as much as 12°, and the difference between the post-operative radiographs and navigation measurements was up to 8°. The study reported that radiographs had a tendency to over-estimate the degree of varus which was in contrast to the findings of this study. However, Yaffe et al. (2008) acknowledged that a major limitation of their study was the difference in weight-bearing conditions for obtaining the alignment measurements. Overall however there were both relative varus and valgus discrepancies between the two techniques. The authors also noted that radiographic results exhibited a greater range and variability than the navigation coronal MFT angular measurements. This was a similar finding to both the pre-operative and post-operative measurements in this study with almost 2° higher SD for OA knees and 1° higher SD for prosthetic knees for the radiographic measurements. This higher degree of variation, particularly for the TKA group where the knees were more likely to be aligned closer to a MFT angle of 0°, suggests that the radiographs may be less accurate than the IR system. This could potentially be explained by the fact that the IR system did not require stringent positional control of the lower limb and was potentially less prone to knee flexion and limb rotational errors. When comparing the intra-operative invasive supine measurements with the corresponding radiographic coronal MFT angles, the mean differences for both OA and prosthetic knees were minimal and well within 1°. However the SD of the differences of almost 4° for osteoarthritic knees and almost 3° for the TKA group highlighted the degree of potential variation between the two systems. In keeping with the findings of Yaffe et al. (2008) the range of variability of the navigation data was less than the corresponding weight-bearing radiographs by approximately 2°. This again suggests that the x-rays may be the less accurate measurement technique even when considering that the weight-bearing status was different during alignment measurement.

5.3.7 Comparison of supine and standing alignment measurements

5.3.7.1 Coronal plane

For the control group the mean coronal MFT angle in the supine position was 0.1° which changed to a mean value of -1.1° during bi-pedal stance. In comparison to previous radiographic evaluations of weight-bearing alignment in healthy individuals (Table 2.2), the mean varus angulation was similar, with other studies reporting overall values between 0° and -2°. The SD of the volunteer measurements of 3.7° was larger than the spread of alignment values reported by other studies of between 2° and 3°. However, the supine measurements from the control group had less variation with a SD of 2.5°. The mean supine and standing coronal MFT angles for the OA group were -2.5° and -3.6° respectively, which was in keeping with the expected predominance of varus deformities in an osteoarthritic population. The SD of 6° was indicative of the larger variation of coronal deformity as a result of the osteoarthritic process in comparison to healthy knees. For the TKA group, the mean (SD) supine alignment of -0.7° (1.4°) represented an accomplishment of the intra-operative alignment target of a coronal MFT angle to 0°±3°. However, the mean standing coronal MFT angle of -2.5° was closer to the varus end of this target window and the SD of 2° indicated that there were several patients with measurements of more than 3° of varus and therefore outwith this range when weight-bearing.

For all three groups, the relative mean changes to varus of between 1° and 2° were all statistically significant. Figure 5.8 provides a graphical illustration of the relative change to varus, which was of similar magnitude for each group. It can been seen that the osteoarthritic group had a greater range of coronal deformities, but in spite of this, the magnitude of the relative varus change was similar to both the asymptomatic and TKA groups. Furthermore, the relative change to varus was unaffected by the degree of initial supine coronal MFT angle. Therefore, the results suggested that for the range of deformity measured, the effect of weight-bearing was not dependent on the magnitude of the supine coronal MFT angle. This challenges the findings reported by Yaffe et al. (2008) where there was a greater discrepancy between supine navigation measurements and standing long-leg radiographs for patients with larger deformities. The authors postulated that this may have been partly due to the greater effect of weight-bearing on more malaligned limbs.

Specogna et al. (2007) used long-leg radiographs to quantify the effect of weight-bearing status on coronal knee alignment in patients with varus OA. Subjects were measured supine, during double-limb standing (approximately 50% weight-bearing) and during single-limb standing (>90% weight-bearing). There were statistically significant changes in the mean alignment of -1.6° from supine to bi-pedal stance and -1.6° from double-limb stance to single-limb stance. Therefore the overall mean difference from supine to single-limb stance was -3.2°. This supports the finding that weight-bearing status affects the degree of coronal lower limb alignment for varus knees. The magnitude of the change from supine to double-limb stance of -1.6° reported by Specogna et al. (2007) was similar to the mean difference of -1.1° in this study. However, the authors did not report any differences between the magnitudes of the alignment change from supine to standing with respect to the degree of malalignment. In spite of this the authors hypothesised that the weight-bearing effect on alignment may be associated with the degree of deformity as a potential result of collateral ligament insufficiency and pseudo-laxity which may exist on more severe cases of extremity-deforming OA. Although it is possible that more extreme degrees of coronal malalignment may result in larger discrepancies between supine to standing, there were too few patients with large coronal deformities to investigate this relationship further. Therefore larger numbers of subjects with more extreme malalignment would be necessary to determine whether there is an angular limit beyond which the supporting collateral knee ligaments undergo a change in restraining properties and behave in a less predictable manner than the results have shown. Indeed, the restraining properties of the soft tissues were similar for all the knees evaluated in this study, regardless of whether the knee joint was healthy, osteoarthritic or prosthetic.

Brouwer et al. (2003) also reported a change in coronal alignment from supine to standing in subjects with varus OA, measured with long-leg radiographs. The mean difference of 2° varus was similar to the findings of Specogna et al. (2007) and of this study, and again there was no correlation between the magnitude of deformity and the varus change with weight-bearing. Furthermore, Brouwer et al. (2007), found no association between the grade of collateral ligamentous laxity and the standing coronal MFT angle. This supports the belief that the restraining collateral structures of the knee behave in a constant and predictable manner within a certain range of coronal alignment. The results of both Specogna et al. (2007) and Brouwer et al. (2003) are in agreement with the results of this study, but are limited by the potential measurement errors associated with the use of long-leg radiographs (Section 2.6.1). The radiographic evaluations only provided static two-dimensional measurements with no consideration of potential change in sagittal alignment as later discussed (Section 5.3.7.2).

Kendoff et al. (2008) recognised the potential limitations of radiographic measurements and performed a cadaveric study using navigation measurements to quantify the effect of weight-bearing. A custom mechanical load apparatus was developed to simulate varying amounts of weight-bearing conditions in the supine position with predetermined axial loads applied through the foot. The amount of load represented either a quarter, a half or full body weight. The cadaveric lower limbs were incrementally loaded with no intervention and following coronal alignment correction with valgus tibial osteotomies of 2.5°, 5° and 7.5°. In addition, loading was performed for each alignment condition with either no medial collateral ligament release, partial release or complete release, and the magnitude of the alignment change was measured. The application of one-half body weight (equivalent to double-limb stance) to intact limbs resulted in an average deviation of 0.5° of varus, and although this was of slightly less magnitude to the changes reported for the in-vivo evaluations previously discussed, it still supports the finding that weight-bearing leads to relative varus. For loading of the intact cadaveric limbs and for varying degrees of corrected alignment with valgus tibial osteotomy, the magnitude of the angular displacement was related to the magnitude of the applied load. However, for the same applied load there were no significant differences between the relative changes in alignment according to the baseline coronal MFT angles. This again supports the view that the restraining properties of the collateral ligaments appear to be unaffected by the underlying knee joint alignment. Furthermore, partial release of the MCL did not reduce the restraining properties for the range of coronal alignment assessed and at all magnitudes of applied load. The only statistical reduction in restraining properties resulted from complete release of the MCL. This finding may account for the similarities between the supine to standing alignment changes for the patients in this study before and after TKA given that the majority of patients had no soft tissue releases.

Although the studies by Specogna et al. (2007) and Brouwer et al. (2003) reported similar findings to this study, they were limited by the use of static, two-dimensional radiographs that did not take into account any associated changes in knee flexion angle from supine to weight-bearing. The use of navigation technology by Kendoff et al. (2008) permitted measurement of any associated sagittal change in mechanical alignment during simulated weight-bearing but the use of cadavers in addition to simulated rather than actual stance limits the application of the findings to the clinical situation. The authors acknowledged these limitations and highlighted the current inability to use image-free navigation technology outwith the operating theatre. Therefore the associated sagittal plane measurements in this study have provided new in-vivo data not previously reported.

5.3.7.2 Sagittal plane

The mean supine sagittal MFT angle for the asymptomatic group was -1.7° representing a small amount of hyperextension that could be expected in a normal population (Section 2.1.2.1). From supine to standing, the mean change in sagittal alignment of almost 4° of relative extension may be representative of the normal passive, energy-preserving mechanism of stance. By hyperextending the knee joint, the weight-bearing sagittal MA can be transferred anterior to the rotational centre of the knee resulting in passive stretching of the posterior structures and subsequent reduction in the need for active muscular contraction when standing (Section 2.2.3.3). In contrast to weight-bearing, the supine measurements were obtained by raising the lower limb by the heel without forcing the knee into more extension and stretching the posterior soft tissue structures.

For patients with OA, the mean supine maximum passive extension angle was almost 8° of fixed flexion. In contrast to the control group there was a much larger range of sagittal MFT angles as indicated by the SD of 7.1°, but most patients were unable to achieve full extension. When standing however, the mean sagittal MFT angle was closer to 0° with a mean overall change in alignment of almost 6° relative extension. Therefore several patients were able to achieve more normal extension when standing, with an even greater relative change from supine in comparison to the control group. At six weeks following TKA, the same patient group had similar supine and standing sagittal alignment angles compared with the pre-operative measurements. In spite of correcting the pre-operative FFDs intra-operatively to a mean sagittal MFT angle of around 0°, when assessed at an early post-operative stage patients had resumed similar measurements to those obtained pre-operatively. This may have represented the more dynamic nature of sagittal alignment which can be influenced by pain and associated muscular contraction (Section 2.2.3.3). The similarities between the patients with OA and at an early stage following TKA are illustrated in Figure 5.9. However, the TKA group may progress to alignment values closer to the control group, as it has been shown that over time the degree of FFD following TKA can improve [Aderinto et al. 2005, Lam et al. 2003].

Similar to the weight-bearing change in the coronal plane, the magnitude of the relative difference from supine to standing was not related to the degree of initial flexion angle. The greater relative change for the pre-operative and post-operative knees in comparison to the control group may have been related to the differing weight-bearing instructions. The volunteers were asked to stand “normally” whereas the patients were instructed to stand with their knees “as straight as possible.” This again highlights the dynamic nature of sagittal plane alignment which may be more appropriate to quantify in association with the corresponding coronal MFT angle.

5.3.7.3 Combined coronal and sagittal change

Knee alignment is routinely quantified in two separate planes which are often considered independently. This method of assessment may be due to the long-standing, widespread use of radiographs for evaluating the musculoskeletal system where images are obtained separately in the anteroposterior and mediolateral planes and are dependent on accurate lower limb positioning. Measurement of alignment in the coronal plane, therefore, is normally made without any reference to the corresponding alignment in the sagittal plane and vice versa. The IR technology developed in this study has provided real time measurements of simultaneous coronal and sagittal MFT angles that are independent of limb position. The use of vector plots (Figure 5.10, Figure 5.11) has resulted in quantification of the combined coronal and sagittal alignment change from lying to standing as a single displacement vector, representing the overall effect of weight-bearing on the tibiofemoral joint. In practical terms the vectors provide three-dimensional measurements of alignment change as any displacement of the ankle centre relative to the knee centre in the craniocaudal direction would be minimal.

In comparison to the control group, it can be seen that the osteoarthritic group had a larger spread of vectors representing the greater range of malalignment. Following TKA, the spread of vectors along the varus-valgus axis was significantly less, representing the intra-operative goal of restoring the MFT angle to 0°. However, there remained a larger variation along the flexion-extension axis, similar to the pre-operative knees and the possible reasons for this have been previously discussed (Section 5.3.7.2).

For the three groups, although there was variation in the origin and magnitude of the displacement vectors, the directions illustrate the combined trend of relative varus and extension for most subjects, regardless of the initial supine knee alignment. The relative displacement, independent of initial alignment, demonstrates this similar overall trend more clearly and suggests that the degree of underlying knee deformity may not be an important contributing factor for this weight-bearing effect. Therefore the soft tissues restraining the tibiofemoral joint may have a greater influence on the dynamic nature of knee alignment between lying and standing conditions. This is a significant finding that highlights the importance of quantifying soft tissue behaviour, particularly when planning, performing and evaluating alignment-dependent surgical interventions of the knee.

6 Overall discussion and further work

Assessments of knee alignment and laxity are important aspects of many areas of clinical practice and biomechanical research. However, current routine methods of measuring knee kinematics may be limited by the inaccuracies and static nature of the techniques available [Section 2.6]. In contrast to the clinical setting, the utilisation of tracking technology for intra-operative patient use has provided surgeons with quantitative measurement tools that permit real time assessment of knee kinematics [Bathis et al. 2004, Chauhan et al. 2004b, Stulberg et al. 2002]. In its current commercial from, this technology has relied on rigid bony fixation of trackers and has only provided data for supine patients with absent muscle tone and an exposed knee joint during TKA surgery. The adaptation of tracking technology for non-invasive clinical assessment has been limited by the extent of the potential movement artefacts associated with the underlying soft tissues [Sangeux et al. 2006, Stagni et al. 2005]. This has raised doubts as to the suitability of tracked external marker sets for accurate evaluation of knee joint alignment and soft tissue laxity.

6.1 Development and validation of non-invasive measurement tool

The initial aim of this thesis was to adapt a tracking system for non-invasive use by developing a stable method for the external mounting of trackers. The first step in this process was to select the appropriate tracking technology, and so the static performance of two available systems was evaluated by measuring their localisation accuracy. This was achieved by designing and manufacturing a test phantom model which enabled single point repeatability and distance measurements to be assessed. Positional testing verified the sub-millimetre accuracy and precision of an IR tracking system under optimal test conditions but demonstrated distance measurement errors of up to 6mm for a visible light tracking system which were considered too large.

Phantom testing therefore served as an important initial step in the adaptation of a tracking system for non-invasive use as it prevented any further work from being undertaken on a system that was considered too inaccurate. It also enabled the claimed accuracy of an IR system to be verified independently, although comparison of clamped versus manually held pointer measurements highlighted the potential for human error to be introduced, with an almost ten-fold loss of precision. This result was surprising given that the pointer was held as still as possible during manual testing, and the ball-nosed tip was accommodated in the phantom holes in such a way that orientation should not have affected the location of the tip centre. The evaluation of relative error of each axis revealed that the y axis, representing distance from the camera, had the largest variation of measurements. Interestingly, the manufacturer of this camera claimed to be aware of the errors associated with detection of depth and the model evaluated in this thesis has been superseded by an apparently more accurate IR localiser. Nonetheless, the accuracy levels of within 2mm for the system evaluated were considered appropriate.

With a suitable tracking system selected, the next step was to achieve secure non-invasive lower limb attachments for the trackers. The use of a relatively broad, extensible material in a variety of different lengths along with a curved metal base plate provided an apparently stable set-up for mounting the trackers when trialled on a volunteer. As a consequence of not knowing the “true” coronal MFT angle of the volunteer, soft tissue artefacts during kinematic registration were indirectly measured by comparing the variance of repeated measurements with those obtained under optimum conditions. This was achieved by designing and manufacturing a lower limb model consisting of mechanical hip, knee and ankle joints connected by metal rods with rigidly attached tracker mounts. In comparison to rigid attachment the non-invasive mounting of trackers resulted in a small loss of repeatability as a result of soft tissue artefacts. The small standard deviation of 0.1° for consecutive alignment readings following a single registration on the volunteer leg highlighted the stability of the tracker mounts in the absence of any active or passive limb movement. For repeated registrations, requiring reattachment of the trackers on each occasion, the range of MFT angle measurements was 1° greater than the leg model and this difference was not statistically significant. This was a surprising result given that the leg model had a rigid hinge for a knee joint with no collateral movement and therefore a more consistent MFT angle. The only minor source of variation between trials on different days was the coupling mechanism between the trackers and fixation screws. In comparison, the volunteer straps would not have been identically applied in terms of both position and tightness. Furthermore, the small amount of natural collateral laxity of the volunteer knee could potentially have resulted in real differences in alignment on different days.

To overcome the fact that these results were obtained with a single, slim volunteer further evaluation of the non-invasive tracker mountings was provided by the assessment of 30 healthy subjects with a range of BMI from 19-34. In addition to measuring supine knee alignment at rest, both coronal and sagittal MFT angles were obtained during bipedal stance and following varus and valgus stress. Measurement of supine alignment before and after these measurement conditions was taken as an indirect measurement of any tracker movement. In spite of the greater potential for tracker movement during the conditional measurements, the repeatability of the coronal MFT angles was approximately ±1°, including change with applied stress. In spite of the range of BMI and the subjects having had no prior exposure to the kinematic registration procedure, the initial agreement between the two sets of registrations was outwith the required 2° limit for only three subjects. In these instances all repetitions were acceptable. Therefore although there were some cases of disagreement beyond 2°, this was an infrequent occurrence and a simple repeat protocol enabled the required agreement to be obtained for all cases. The results for the sagittal measurements were less consistent but this most likely reflected the dynamic nature of alignment in this plane. In comparison to coronal alignment, which is a more fixed parameter, flexion angle can be directly influenced by contraction of the muscles that cross the knee joint.

The repeatability of the coronal measurements for different subjects and different measurement conditions represents an achievement of the primary aim of this thesis, which was to adapt a tracking system for non-invasive use. The rigid leg model could be taken as a representation of the standard intra-operative use of computer-assisted technology with bony tracker fixation. Therefore using the same technology non-invasively appeared to lose only 1° of accuracy. These results are of importance as they represent a new accurate method of assessing lower limb alignment. The immediate generation of real-time on-screen coronal and sagittal MFT angles has a number of potential advantages over current measurement systems. It allows dynamic measurements of alignment to be made following applied stress or under weight bearing conditions, with immediate visualisation of angular displacement. The ability to measure the resultant change in coronal MFT angle following application of varus-valgus stress has a potential clinical application for improving the measurement of collateral knee laxity which is an important parameter for soft tissue balancing in knee arthroplasty and for evaluating ligament injuries. Current methods are either subjective [Krackow 1990a] or rely on X-ray measurements of tibiofemoral gap opening [LaPrade et al. 2008], which are prone to radiographic errors associated with limb positioning [Krackow et al. 1990b, Siu et al. 1991] and involve exposure to ionising radiation. For weight bearing conditions, the measurement did not require strict rotational control of the lower limb and the measured coronal MFT angle was recorded with the associated knee flexion.

This non-invasive IR technology therefore could potentially offer a superior alternative to long leg radiographs with comparable or even superior levels of accuracy. The potential advantages offered by CAOS technology intraoperatively could be realised in a clinical setting. The level of precision achieved with this non-invasive system was greater than previous studies that have looked at externally mounted markers in motion capture systems to measure lower limb alignment. Important contributing factors to the levels of accuracy achieved in this study may have been the passive nature of the clinical manoeuvres required to obtain the rotational joint centres necessary for measurement of MFT angles along with adequate subject relaxation.

Further work could lead to more direct assessment of the effect of muscle tone on tracker stability. One potential avenue for future research is the assessment of anaesthetised patients using the non-invasive tracker mounts for comparison of those obtained in the pre-operative clinic. Alternatively, patients with lower limb external fixation devices may offer a valuable opportunity to indirectly fix trackers to bone in a clinical setting for comparison with a non-invasive set-up. Additionally, further optimisation of the tracker mounts as well as reduction in the size and weight of trackers may lead to even greater levels of accuracy. However, in spite of potential for improvement, the system developed in its current form can provide clinically relevant real-time measurements of alignment under a number of different conditions and may help to further understanding of knee joint alignment.

6.2 Standardising collateral knee laxity assessment

The assessment of collateral knee laxity by application of varus and valgus stress is an important clinical manoeuvre for evaluation of ligament injuries and a fundamental component of soft tissue balancing in knee arthroplasty. Coronal MFT angular measurements with the knee stressed are potentially more variable than with standing measurements or in the supine resting position. For the validation of the non-invasive IR system, all measurements were obtained by a single observer and therefore to enable other clinicians to obtain data in a comparable manner, the aim of this aspect of the project was to quantify and subsequently standardise the clinical assessment of collateral knee laxity. This was achieved by the accurate measurement and subsequent control of positional variables that could impact on the load applied to the knee, in addition to using the non-invasive IR system to measure the resultant laxity.

Firstly it was important to measure and maintain the flexion angle of the knee during stress testing as it has previously been shown that the orientation and material properties of its collateral restraints can be affected by flexion [Grood et al. 1981, Markolf et al. 1976]. Validation of this parameter was achieved by comparison to a flexible electrogoniometer with measurements agreeing to within ±1.5° up to 100° of flexion. In addition to verifying the accuracy in comparison to a validated measurement device, the IR system had the advantage of not requiring an estimate of 'neutral' sagittal alignment and the attachment of trackers may not have been as user-dependent as the electrogoniometer.

With control of knee flexion angle it was then necessary to standardise the applied moment, requiring measurement of force and lever arm. The definition of a lever arm involved standardisation of clinical examination technique which required careful hand positioning according to surface anatomy. This was defined as the distance between the knee and ankle centres, and measurement of this was found to be repeatable to ±13mm when performed on 29 volunteers. In addition, the variation of repeated distance measurements on a single volunteer was only approximately 3mm greater than the mechanical leg model previously described. In spite of this small loss of precision as a result of soft tissue artefacts, the technique may have been more accurate than currently available routine methods of leg length assessment such as a measurement tape or radiographs.

With the ability to repeatedly measure a lever arm it was then necessary to measure and subsequently control the applied force. In contrast to previous work that has endeavoured to standardise the load applied to the knee using cumbersome experimental set-ups [Sharma et al. 1999, van der Esch et al. 2006], the aim was to develop a hand-held device that could be easily incorporated into routine clinical assessment with minimal alteration of examination technique. The design of the FAD reflected this goal and when used initially as a measurement device, the varus and valgus knee moments recorded by two clinicians performing a total of 80 stress manoeuvres were within a relatively narrow range of 13-33Nm. This contrasted to a study by van Zoest et al. (2002) where a palm-held force measurement system was used to standardise the manipulation technique of student chiropractic practitioners, with large variation in the forces measured ranging from 63N to 347N. Following its use as a measurement tool, the FAD was utilised as a control device through the design of a graphical user interface which provided a repeatable method of applying a pre-determined moment. The mean overshoot of 1.3Nm (range 0-3.5Nm), highlighted the effectiveness of the warning system for applying a manual load.

For each applied varus and valgus load, the corresponding coronal angular displacement of the knee from its resting position was used to quantify laxity. Repeated measurements by three clinicians had similar mean values and the standard deviation of the MFT angles, ranging from ±0.2° to ±1.1°, may have been largely the result of the ±1° accuracy of the IR tracking technology. Therefore the resolution of the non-invasive system may have been the limiting factor to more accurate quantification of laxity and although measurements with the FAD were no more precise than the judgement of the clinicians, additional information relating to applied load could improve current knowledge of soft tissue knee behaviour. This could lead to optimisation of balancing techniques in knee arthroplasty through quantification of knee laxity before, during and after surgery enabling a more widespread use of single surgeon-derived algorithms [Hakki et al. 2009, Picard et al. 2007b, Saragaglia et al. 2006]. Further work into the relationship between applied load and resultant laxity has a potential role in the management of collateral ligament injuries with regard to more reliable initial diagnosis, severity grading and assessment of recovery. The repeatability of all the components of knee laxity assessment suggests a potential training role for this technology which could be used to enhance the perceptive skills of more junior trainees who may not have the benefit of experience.

In spite of successfully quantifying and standardising the manual technique of coronal knee laxity assessment for the limited number of subjects and clinicians evaluated, there were components of this aspect of the project requiring further work. For the manually applied force, it was assumed that the loading of the transducers within the FAD was perpendicular to the tibial mechanical axis in the coronal plane. However, in spite of careful positioning of the device, the true orientation of the resultant force vector was unknown. Real-time tracking of FAD orientation relative to the defined tibial moment arm could potentially overcome this. Work continues on this aspect of the project, with a view to tracking the FAD in real time in order to ascertain the true orientation of the resultant force vector. The application of the FAD was not therefore included within the subsequent clinical trial.

6.3 Clinical trial

The validation of the non-invasive system on healthy volunteers indicated an approximately 1° loss of precision due to soft tissue artefacts in comparison to the accuracy of the system using rigid fixation (i.e. within 1°) [Haaker et al. 2005]. The assessment of patients with end stage osteoarthritis presented a greater challenge for a number of reasons. The subjects had painful knees with potential for exacerbation during the passive manipulation required for the registration process and during varus and valgus stress. Mounting of trackers in a secure manner was potentially more difficult to achieve due to a higher proportion of subjects with obesity, more fragile skin and lower limb oedema. Post-operatively, in spite of arthritic knees having been replaced with prosthetic implants, it was typical for some residual pain and stiffness associated with the surgical procedure to be present at the six week follow-up stage. The initial objective of the clinical trial was to further validate the system under more challenging conditions. Similar to the volunteer trial, repeatability of measurements was used as an indirect measurement of system accuracy. Two complete kinematic registrations were performed for each patient pre- and post-operatively and providing the initial supine coronal MFT angles agreed to within 2°, a total of three measurements were then obtained for each measurement condition. In spite of the potential difficulties posed by the patient population, all registrations were successfully completed with no exclusions due to an inability to perform the necessary rotational manoeuvres. Furthermore, the limits of agreement for the initial coronal MFT angles between registrations for both osteoarthritic and prosthetic knees were similar to the volunteer measurements.

For the sagittal measurements, the inter-registration agreement between the pre- and post-operative patients was greater than the volunteer cohort by up to 3°. As discussed previously this was most likely related to the more dynamic nature of sagittal alignment that could be influenced by the patient, particularly in the presence of pain. When the registration process had been completed the intra-registration variation of the coronal MFT angles was similar to the asymptomatic measurements with limits of agreement ranging from between 1° and 2°. These results suggest that regardless of the type of knee being evaluated, once a successful registration has been performed, the externally mounted trackers show a consistent stability for assessing alignment at rest following stress manoeuvres or stance.

The repeatability of the non-invasive IR system for the patient population, in addition to the asymptomatic population represented an accomplishment of the primary goal of this project, which was to adapt tracking technology for non-invasive use. Overall there were 61 subjects assessed with 30 patients having an additional assessment following a knee replacement. The consistent level of repeatability of within 2° provides convincing evidence of the stability of the system developed. Although validation of the measurement tool was based on repeatability rather than comparison to a measurement standard, the IR system is validated for use with rigid tracker attachments and it can therefore be inferred that repeatable measurements are also accurate as for measurements to be repeatable soft tissue artefacts must be minimal.

In addition it could be argued that the acknowledged long-leg radiographic gold standard had more potential variation than the IR system and that disagreement between measurements may not have reflected true inaccuracies.

Validation of the IR system and the patient cohort enabled a number of measurement conditions to be evaluated with a degree of accuracy that has not been previously available. For instance, knee flexion measurements are frequently performed in an out-patient clinic and form the basis of several clinical outcome scoring systems. Visual estimates of knee flexion angle along with adjuncts such as manual goniometers are the most widely used routine method of post-operative measurement. The patients in this study were routinely assessed by arthroplasty practitioners and this included assessment of maximal knee flexion as well as flexion angle with the knee fully extended. The simultaneous IR measurements enabled an investigation of the degree of accuracy of the experienced arthroplasty practitioners performing these measurements and revealed a tendency to underestimate flexion angles. In the context of detecting fixed flexion deformities it was therefore of significance that visual estimates of knee flexion may sometimes have failed to identify this and prevented potential intervention at an early stage.

The successful acquisition of kinematic data for normal, osteoarthritic and prosthetic knees enabled several important comparisons to be made for different measurement conditions. For the patients with end stage osteoarthritis, the use of intra-operative image-free navigation presented a valuable opportunity to compare the measurement of invasive and non-invasive supine alignment on the same subjects. The use of a single observer to obtain these measurements ensured that the alignment data were obtained in a consistent manner. The vast majority of knee replacements were performed using a medial approach which may have explained why the mean difference for the corresponding non-invasive measurements of both osteoarthritic and prosthetic knees was a small amount (0.5°) of valgus. Although these differences were statistically insignificant and were within the measurement resolution of the IR system, they are the first quantitative measurements that provide any information on the effect of absent muscle tone and knee joint exposure on lower limb mechanical alignment.

The measurement of the relative change in coronal MFT angle with varus and valgus stress enabled comparisons to be made between invasive and non-invasive conditions of both osteoarthritic and prosthetic knees. This was of particular importance given that the standard pre-operative clinical practice involves an assessment of ligament “tightness” as a predictor of whether surgical release will be necessary during subsequent TKA. This objective measurement is often repeated at follow-up to determine the degree of laxity of a knee replacement. Intra-operative computer assisted technology has led to quantitative algorithms that help surgeons to decide whether surgical release should be performed [Hakki et al. 2009, Jenny et al. 2004, Picard et al. 2007b, Saragaglia et al. 2006, Unitt et al. 2008]. For osteoarthritic knees, varus and valgus angular displacements were statistically greater intra-operatively by mean values of approximately 1.5° in comparison to non-invasive measurements. This difference was most likely due to the removal of muscular inhibition during stress testing in the out-patient clinic. Therefore the presence of muscle tone resulted in a mean of 1.5° less angular displacement than would be expected intra-operatively for both varus and valgus stress manoeuvres and so measurements obtained pre-operatively can therefore be expected to underestimate the degree of intra-operative varus and valgus angular displacement by approximately 1.5°. This information could help the future development of non-invasive soft tissue balancing algorithms to adjust the thresholds accordingly in order to match pre-operative with intra-operative values. Furthermore it could also help to determine the surgical approach to the knee. In particular, with valgus knees that are deemed to be “uncorrectable” with manual varus stress, some surgeons would opt for a lateral approach. The use of quantitative measurements pre-operatively could provide a more accurate prediction of whether a valgus deformity is correctable and potentially avoid the need for an approach that is considered more technically demanding [Fiddian et al. 1998].

In comparison to osteoarthritic knees, there was less difference between invasive and non-invasive measurements of coronal knee laxity for prosthetic knees. For valgus stress, the intra-operative measurements were statistically greater than those obtained six weeks post-operatively by a mean of approximately 1°. This difference may have been due to the fact that most knees were exposed through a medial approach with subsequent contraction of the tissues as part of the normal acute wound healing process [Hardy, 1989]. With maturation of the scar tissue it may be the case that the medial restraining soft tissues relax over time and result in more similar angular displacements to those obtained intra-operatively. Assessment at a later stage post-operatively could verify this. The varus stress angles were similar for invasive and non-invasive measurements which contrasts to the differences observed with osteoarthritic knees. This information may be of significant value to knee arthroplasty surgeons as it provides new data regarding the relationship between intra-operative and post-operative laxity measurements. The question of how much laxity to aim for during TKA surgery has not been reliably answered due to lack of appropriate non-invasive measurement tools. Therefore although coronal laxity can be quantified intra-operatively through the use of computer-assisted techniques, it has not been possible to determine how these measurements correlate to the post-operative setting. Surgeons therefore have not known whether knees have a tendency to “tighten” or “loosen” post-operatively in comparison to when they are implanted. This has been a major limitation for studies that have reported the development of intra-operative soft tissue balancing techniques based on computer-assisted angular measurements [Hakki et al. 2009, Jenny et al. 2004, Picard et al. 2007b, Saragaglia et al. 2006, Unitt et al. 2008], as the values may only be applicable to anaesthetised patients with exposed knee joints. The information provided by this study suggests that varus laxity is likely to be similar in the early post-operative period for prosthetic knees, and valgus laxity may be reduced by approximately 1°. Further measurements at a later stage could confirm whether this trend persists. Most of the osteoarthritic knees evaluated were varus malaligned and had medial approaches during TKA surgery. Further work looking at a larger range of coronal deformities, with more valgus malalignment, could provide more information on the relationship between invasive and non-invasive measurements for different knee subtypes. However, in the absence of this data, it would be reasonable to assume that the amount of overall coronal knee laxity desired post-operatively is likely to be similar to the amount measured intra-operatively post-implantation, with a potential small (1°) reduction in valgus stress angle.

Long-leg radiographic measurements are widely considered to be an accurate method for assessing lower limb alignment, but discrepancies have been reported between intra-operative navigation alignment and X-ray measurements [Yaffe et al. 2008]. The disagreement between the two techniques was mainly attributed to lower limb positioning errors associated with X-rays, particularly in the presence of knee flexion [Krackow et al. 1990b, Siu et al. 1991, Swanson et al. 2000]. However, a fundamental limitation of the navigation versus radiographic measurements was the difference in weight-bearing status of the subjects. Non-invasive adaptation of IR technology enabled a more appropriate comparison to be made with long-leg radiographs as both sets of measurements were obtained under similar weight-bearing conditions. In spite of this similarity, there were large discrepancies between the two systems, suggesting that the positional errors associated with radiographic measurements were likely to be a major factor in the disagreement.

The IR-measured sagittal data showed that most patients had fixed flexion deformities pre-operatively and at six weeks post-operatively, highlighting the fact that radiographic measurements would have been more susceptible to lower limb positioning errors. For clinicians using long-leg radiographs to quantify TKA alignment, it may be advisable to obtain measurements at a later post-operative stage when there are likely to be less knee flexion deformities [Aderinto et al. 2005, Lam et al. 2003]. For pre-operative osteoarthritic knees however this remains a problem as the presence of an FFD cannot be expected to change over time. The results of this study therefore highlight the potential limitations of X-rays for quantifying knee alignment. With the IR system, representation of alignment as several “conditional” measurements in both the coronal and sagittal planes illustrates the fact that knee alignment can be considered a dynamic parameter. In contrast, the single coronal value for radiographic MFT angles is more of a “snap-shot” of alignment under one measurement condition at one instant in time with no associated sagittal angular data. Representing knee alignment as a dynamic parameter using non-invasive IR technology may lead to a new definition of “knee alignment” and may provide a new gold standard assessment technique that is less prone to positioning errors and has the additional advantage of avoiding radiation exposure.

The knee is a load-bearing joint and its alignment is therefore normally assessed in the standing position. However surgical interventions such as TKA are performed on supine limbs with the components placed in the desired target position using either traditional or computer-assisted guidance systems. Limbs are then re-evaluated radiographically in the standing position which serves as a measure of whether the desired intra-operative alignment targets have been achieved. Potential differences between anaesthetised and awake patients, along with radiographic measurement errors, have meant that the relationship between supine and standing knee alignment is poorly understood. Therefore an important aim of this study was to investigate this relationship for patients with osteoarthritis, before and after TKA. In addition, the assessment of a control group provided a comparison with healthy knee kinematics.

In the coronal plane there was a relative change of 1° to 2° of varus from supine to bi-pedal stance, regardless of the type of knee evaluated and the magnitude of the initial deformity. This finding suggests that the soft tissue restraints may be more important than the rigid bony or prosthetic architecture for controlling this weight-bearing alignment change. Although previous radiographic studies have reported a similar finding [Brouwer et al. 2003, Specogna et al. 2007] they may be limited by the potential measurement errors associated with the use of long leg X-rays (section 2.6.1). The use of IR technology to quantify the effect of stance has only been previously performed on cadaveric lower limbs using simulated rather than actual weight bearing conditions. This study represents the first in-vivo data utilising IR technology to quantify the effect of weight bearing on the femorotibial joint.

The relative change to varus is an important consideration when performing alignment dependent procedures, such as TKA, on supine patients with a target MFT angle window. For TKA this has widely been accepted as 0±3° which could result in 'outliers' if the supine coronal MFT angle is close to the -3° varus limit of the window. This may explain the historical recommendation by Insall et al. (1985) to position components in slight valgus in order to potentially avoid the more frequent early failures observed in varus-aligned prosthetic knees. The results of this study would therefore support the recommendation of a target intra-operative MFT angle of 0° or slight valgus to avoid a change to a significant degree of varus alignment (beyond -3°) during weight bearing which may lead to unbalanced mechanical loading and subsequent premature failure of implants. The similar trend to relative varus for different knee types suggests that the mechanical properties of the collateral soft tissues remain unaffected by the process of osteoarthritis and following the surgical intervention of TKA. Future work to quantify the weight bearing effect of more severe coronal deformities may help to determine whether there is a limit beyond which the structural properties of ligaments change.

In comparison to radiographic weight bearing measurements, the IR system had the advantage of measuring the corresponding sagittal MFT angles from lying to standing. As for the coronal plane, the effect of weight bearing was similar for all knee types evaluated. From lying to standing there was a statistically significant trend to relative extension ranging from a mean of 4° for healthy knees to approximately 6° for osteoarthritic knees before and after TKA, and the magnitude of the difference appeared to be unrelated to the degree of initial flexion angle. This trend to relative extension may represent an attempt to transfer the weight bearing sagittal mechanical axis more anterior with respect to the centre of knee rotation and reduce the need for active muscular contraction when standing.

The findings of this study in the sagittal plane provide important information for surgeons performing TKA procedures. In spite of correcting flexion deformities intra-operatively, there may be a tendency for patients to resume the pre-operative sagittal MFT alignment in extension at the early follow-up stage. Although this can improve over time [Aderinto et al. 2005, Lam et al. 2003], it is important to provide patients with range of movement targets that address knee extension as well as flexion angles and when assessing maximum extension this should be performed weight bearing. With respect to intra-operative TKA alignment targets in the presence of FFD, it may not be necessary to perform extensive soft tissue releases in order to achieve a sagittal MFT angle of 0° when standing. Conversely, intra-operative hyperextension due to excessive bony cuts or soft tissue releases may be further exacerbated during weight-bearing and so should potentially be avoided.

The change in knee alignment from lying to standing is relevant to TKA surgery in both coronal and sagittal planes and so it may be more appropriate to consider a combination of the two when quantifying this change. The generation of vector plots represented a novel method of measuring the overall effect of weight-bearing on the tibiofemoral joint and a more graphical illustration of the similarities between different subjects and different knee types. The information provided by a single displacement vector could provide a patient-specific target during alignment-dependent procedures such as TKA. However in the absence of these measurements it is reasonable to assume that most subjects will tend to more varus and extension when standing. When combining the coronal and sagittal weight-bearing data with laxity measurements, it is clear that knee alignment is a more dynamic, three-dimensional parameter than the single MFT angle represented by radiographs.

6.4 Summary

The initial aims of this thesis (Section 1.3) were all accomplished. A tool for measuring knee kinematics was developed through the non-invasive adaption of IR tracking technology. This was subsequently validated and resulted in a device that could assess real-time knee alignment in coronal and sagittal planes.

To minimise potential variation when measuring MFT angles with applied varus and valgus stress, assessment of coronal laxity was quantified and standardised by controlling lever arm, applied manual load and knee flexion angle.

Measurement of knee alignment was performed supine, with collateral stress and during bipedal stance for normal, osteoarthritic and prosthetic knees. Comparative intra-operative measurements were obtained for osteoarthritic and prosthetic knees using a commercial navigation system. For both knee types, supine coronal invasive measurements were more valgus than intra-operative values but this difference was not statistically significant. In contrast supine sagittal MFT angles were significantly different, with the intra-operative measurements being in greater relative extension. For MFT angular displacement with applied collateral stress, OA knees were more lax when measured intra-operatively in comparison to measurements obtained non-invasively. For prosthetic knees only valgus angular displacements were more lax intra-operatively, with varus stress measurements similar for both invasive and non-invasive conditions. From supine to bi-pedal stance, MFT angles most frequently changed to relative varus and extension for all knee types suggesting that soft tissue restraints may be more important than rigid bony or prosthetic architecture for controlling this weight-bearing alignment change.

6.5 Conclusions

The non-invasive IR system developed and validated in this thesis offers a new definition of 'knee alignment' and represents an improved method of measuring this parameter with considerable potential to enhance current knowledge of knee kinematics. The assessment technique has numerous clinical applications ranging from the quantification of ligament injuries to the planning and follow-up of TKA patients. Continued measurement of asymptomatic individuals could help to determine the relative risk of injury and the development of OA with potential for intervention at an earlier stage. For those requiring surgical management, subject-specific kinematic profiles could affect the choice of procedure and the way it is performed. In addition it could help measure patient outcome and monitor post-operative progress. With patient expectation increasing and surgical success rates remaining relatively static, this non-invasive, kinematic IR assessment technique may provide a new avenue for progress.

References

No authors listed (2007), American Academy of Orthopaedic Surgeons: Common knee injuries (2007). Available at: http://orthoinfo.aaos.org/topic.cfm?topic=A00325. Accessed November 30, 2010

No authors listed (2010) National Joint Registry for England and Wales, 7th Annual Report:27

No authors listed (2010) Scottish Arthroplasty Project Annual Report 2010:5

Aderinto J, Brenkel IJ, P Chan (2005) National history of fixed flexion deformity following total knee replacement, *J Bone Joint Surg Br*;87-B:934-936

Adili A, Bhandari M, Giffin R, Whately C, Kwok DC (2002) Valgus high tibial osteotomy. Comparison between an Ilizarov and a Coventry wedge technique for the treatment of medial compartment osteoarthritis of the knee, *Knee Surg Sports Traumatol Arthrosc*;10(3):169-176

Aglietti P and Buzzi R (1988) Posteriorly stabilized total-condylar knee replacement: Three to eight years' follow-up of 85 knees, *J Bone Joint Surg*;70B:211-216

Aichroth P, Freeman MAR, Smillie IS, Souter WA (1978) A knee function assessment chart, *J Bone Joint Surg Br*;60-B:308-309

Amin AK, Patton JT, Cook RE, Brenkel IJ (2006) Does obesity influence the clinical outcome at five years following total knee replacement for osteoarthritis? *J Bone Joint Surg Br*;88(3):335-340

Andriacchi TP (1994) Dynamics of knee alignment, *Orthop Clin North Am*;25:395-403

Andriacchi TP, Anderson GBJ, Fermier RW, Stern D, Galante JO (1980) A study of lower-limb mechanics during stair-climbing, *J Bone Joint Surg*;62-A:749-757

Andriacchi TP and Galante JO (1988) Retention of the posterior cruciate in total knee arthroplasty, *J Arthroplasty*;Suppl 3:S13-S19

Aspinal F, Addington-Hall J, Higginson IJ (2003) Using satisfaction to measure the quality of palliative care: a review of the literature, *J Adv Nurs*;42:324-339

Bach JM, DiGioia AM, Jaramaz B, Mor AB (2007) Standard Practice for Measurement of Positional Accuracy Computer Assisted Surgical Systems, ASTM International (Draft)

Bachmeier CJM, March LM, Cross MJ, Lapsley HM, Tribe KL, Courtenay BG, Brooks PM (2001) A comparison of outcomes in osteoarthritis patients undergoing total hip and knee replacement surgery, *Osteoarthritis and Cartilage*;9(2):137-146

Baker KR, Nelson ME, Felson DT, Layne JE, Sarno R, Roubenoff R (2001) The efficacy of home based progressive strength training in older adults with knee osteoarthritis: a randomized controlled trial, *J Rheumatol*;28:1655-1665

Baker PN, van der Meulen JH, Lewsey J, Gregg PJ, National Joint Registry for England and Wales (2007) The role of pain and function in determining patient satisfaction after total knee replacement. Data from the National Joint Registry for England and Wales, *J Bone Joint Surg Br*;89(7):893-900

Banks AZ, Klos TVS, Habets RJE, Banks SA, Devilee RJJ, Cook FF (1998) Computer assistance in arthroscopic anterior cruciate ligament reconstruction, *Clin Orthop Rel Res*; 354:65-69

Bargren JH, Blaha JD, Freeman MAR (1983) Alignment in total knee arthroplasty: correlated biomechanical and clinical investigations, *Clin Orthop*;173:178-83

Bartel DL, Burstein AH, Santavicca EA, Insall JN (1982) Performance of the tibial component in total knee replacement, *J Bone Joint Surg Am*;64:1026

Bathis H, Perlick L, Tingart M, Luring C, Zurakowski D, Grifka J (2004) Alignment in total knee arthroplasty: comparison of computer-assisted surgery with the conventional technique, *J Bone Joint Surg Br*;86-B:682-687

Bauwens K, Matthes G, Wich M, Gebhard F, Hanson B, Ekkernkamp A, Stengel D (2007) Navigated total knee replacement: a meta-analysis, *J Bone Joint Surg Am*;89-A(2):261-269

Bell AL, Brand RA, Pederson DR (1989) Prediction of hip joint center location from external landmarks, *Hum Mvmt*;8:3-16

Bell AL, Pederson DR, Brand RA (1990) A comparison of the accuracy of several hip center location prediction methods, *J Biomechanics*;23(6):617-621

Bellamy N, Campbell J, Robinson V, Gee T, Bourne R, Wells G (2006) Intraarticular corticosteroid for treatment of osteoarthritis of the knee, *Cochrane Database Syst Rev*;(2):CD005328

Bellemans J, Vandenneuker H, Victor J, Vanlauwe J (2006) Flexion contracture in total knee arthroplasty, *Clin Orthop Relat Res*;452:78-82

Benoit DL, Ramsey DK, Lamontagne M, Xu L, Wretenberg P, Renström P (2006) Effect of skin movement artefact on knee kinematics during gait and cutting motions measured in vivo, *Gait & Posture*;24:152-164

Berend ME, Ritter MA, Meding JB, Faris PM, Keating EM, Redelman R, Faris GW, Davis KE (2004) Tibial component failure mechanisms in total knee arthroplasty, *Clinl Orthop Relat Res*;428:26-34

Beverland D (2010) Patient satisfaction following TKA: Bless them all! *Orthopedics*;33(9):657. doi: 10.3928/01477447-20100722-23

Bhattacharyya T, Gale D, Dewire P, Totterman S, Gale ME, McLaughlin S, Einhorn TA, Felson DT (2003) The clinical importance of meniscal tears demonstrated by magnetic resonance imaging in osteoarthritis of the knee, *J Bone Joint Surg Am*;85:4-9

Bland JM, Altman DG (1986) Statistical methods for assessing agreement between two methods of clinical measurement, *Lancet*;1:307-310

Bonnici AV and Allen PR (1991) Comparison of long leg and simple knee radiographs in assessment of knees prior to surgery, *J Bone Joint Surg [Br]*;73-B Suppl I:65

Brage ME, Draganich LF, Pottenger LA, Curran JJ (1994) Knee laxity in symptomatic osteoarthritis, *Clin Orthop Relat Res*;304:184-189

Brantigan OC and Voshell AF (1941) The mechanics of the ligaments and menisci of the knee joint, *J Bone Joint Surg*;23:44-66

Brattstrom H (1970) Patella alta in non-dislocating knee joints, *Acta Orthop Scand*;41:578-588

Brouwer GM, van Tol AW, Bergink AP, Belo JN, Bernsen RMD, Reijman M, Pols HAP, Bierma-Zeinstra SMA (2007) Association between valgus and varus alignment and the development and progression of radiographic osteoarthritis of the knee, *Arthritis Rheum*;56(4):1204-1211

Brouwer RW, Jakma TS, Verhagen AP, Verhaar JA, Bierma-Zeinstra SM (2008) Braces and orthoses for treating osteoarthritis of the knee, *Cochrane Database Syst Rev*;(1)

Brouwer RW, Jakma TS, Brouwer KH, Verhaar JA (2007a) Pitfalls in determining knee alignment: a radiographic cadaver study, *J Knee Surg*;20:210-215

Brouwer RW, Jakma TSC, Bierma-Zeinstra SMA, Ginai AZ, Verhaar JAN (2003) The whole leg radiograph, Standing versus supine for determining axial alignment, *Acta Orthop Scand*;74(5):565-568

Brouwer RW, Raaij van TM, Bierma-Zeinstra SM, Verhagen AP, Jakma TS, Verhaar JA (2007b) Osteotomy for treating knee osteoarthritis, *Cochrane Database Syst Rev*;(3)

Bruns J, Volkmer M, Luessenhop S (1993) Pressure distribution at the knee joint. Influence of varus and valgus deviation without and with ligament dissection, *Arch Orthop Trauma Surg*;113:12-19

Cahue S, Dunlop D, Hayes K, Song J, Torres L, Sharma L (2004) Varus-valgus alignment in the progression of patellofemoral osteoarthritis, *Arthritis Rheum*;50:2184-2190

Cappozzo A, Catani F, Leardini A, Benedetti MG, Della Croce U (1996) Position and orientation in space of bones during movement: experimental artefacts, *Clin Biomech*;11(2):90-100

Carr-Hill RA (1992) The measurement of patient satisfaction, *J Public Health Med*;14:236-249

Cerejo R, Dunlop DD, Cahue S, Channin D, Song J, Sharma L (2002) The influence of alignment on risk of knee osteoarthritis progression according to baseline stage of disease, *Arthritis Rheum*;46(10):2632-2636

Chao EY, Neluheni EV, Hsu RW, Paley D (1994) Biomechanics of malalignment, *Orthop Clin North Am*;25:379-386

Chauhan SK, Clark GW, Lloyd S, Scott RG, Breidahl W, Sikorski JM (2004a) Computer-assisted total knee replacement: a controlled cadaver study using a multi-parameter quantitative CT assessment of alignment (the Perth CT Protocol), *J Bone Joint Surg Br*;86-B:818-823

Chauhan SK, Scott RG, Breidahl W, Beaver RJ (2004b) Computer-assisted knee arthroplasty versus a conventional jig-based technique: a randomized, prospective trial, *J Bone Joint Surg Br*;86-B:372-377

Chung BJ, Kang YG, Chang CB, Kim SJ, Kim TK (2009) Differences between sagittal femoral mechanical and distal reference axes should be considered in navigated TKA, *Clin Orthop Rel Res*;467:2403-2413

Cibere J, Bellamy N, Thorne A, Esdaile JM, McGorm KJ, Chalmers A, Huang S, Peloso P, Shojania K, Singer J, Wong H, Kopec J (2004) Reliability of the knee examination in osteoarthritis: effect of standardisation, *Arthritis Rheum*;50(2):458-468

Cicuttini F, Wluka A, Hankin J, Wang Y (2004) Longitudinal study of the relationship between knee angle and tibiofemoral cartilage volume in subjects with knee osteoarthritis, *Rheumatology*;43:321-324

Clarke JV, Deakin AH, Nicol AC, Picard F (2009) Varus and Valgus Stress of the Knee Joint: Does a Reliable End-Point Exist? In *Proceedings of the IMechE- Knee Arthroplasty: From Early Intervention to Revision*, London, UK

Cooke TD, Li J, Scudamore RA (1994) Radiographic assessment of bony contributions to knee deformity, *Orthop Clin North Am*;25:387-393

Cooke D, Scudamore A, Li J, Wyss U, Bryant T, Costigan P (1997) Axial lower-limb alignment: comparison of knee geometry in normal volunteers and osteoarthritis patients, *Osteoarthritis Cartilage*;5:39-47

Cooke TD, Sled EA, Scudamore RA (2007) Frontal plane knee alignment: a call for standardized measurement, *J Rheumatol*;34:1796-1801

Crottet D, Kowal J, Sarfert SA, Maeder T, Bleuler H, Nolte LP, Dürselen L (2007) Ligament balancing in TKA: evaluation of a force-sensing device and the influence of patellar eversion and ligament release, *J Biomech*;40(8):1709-1715

Crottet D, Maeder T, Fritschy D, Bleuler H, Nolte LP, Pappas IP (2005) Development of a force amplitude- and location-sensing device to improve the ligament balancing procedure in TKA, IEEE Transactions on Biomedical Engineering;52(9):1609-1611

Cushnaghan J, Cooper C, Dieppe P, Kirwan J, McAlindon T, McCrae F (1990) Clinical assessment of osteoarthritis of the knee, *Ann Rheum Dis*;49:768-770

Dahl A, Toksvig-Larsen S, Roos EM (2005) A 2-year prospective study of patient-relevant outcomes in patients operated on for knee osteoarthritis with tibial osteotomy, *BMC Musculoskelet Discord*;6:18

Davies AP (2002) Rating systems for total knee replacement, *The Knee*;9:261-266

Dawson J, Fitzpatrick R, Murray D, Carr A (1998) Questionnaire on the perceptions of patients about total knee replacement, *J Bone Joint Surg Br*;80-B:63-69

Deakin AH, Basanagoudar PL, Nunag P, Johnston AT, Sarungi M (2011) Natural distribution of the femoral mechanical-anatomical angle in an osteoarthritic population and its relevance to total knee arthroplasty, *The Knee, In press (doi:10.1016/j.knee.2011.02.001)*

Desme D, Galand-Desme S, Besse J-L, Henner J, Moyen B, Leart J-L (2006) Analyse segmentaire de la deformation frontale dans les gonarthroses femoro-tibiales lateralisees, *Rev de Chir Ortho*;92:673-679 (in French)

DiGioia AM, Mor AB, Jaramaz B, Bach JM (2005) Accuracy and validation for surgical navigation systems, *AAOS Bulletin*;Volume 53,No. 5

DiGioia AM, Jaramaz B, Picard F, Nolte LP (Eds) (2004) *Computer and robotic assisted knee and hip surgery*, Oxford University Press, New York, USA

Dillon JM, Clarke JV, Nicol AC, Picard F (2007) Assessment of dynamic total knee arthroplasty function by two different surgical techniques (computer assisted and traditional instrumentation) using gait analysis, *Journal of Biomechanics*; 40 (Supplement 2): S589

D'Lima DD, Chen PC, Colwell CW Jnr (2001a) Polyethylene contact stresses, articular congruity and knee alignment, *Clin Orthop Relat Res*;392:232-238

D'Lima DD, Hermida JC, Chen PC, Colwell CW Jnr (2001b) Polyethylene wear and variations in knee kinematics, *Clin Orthop Relat Res*;392:124-130

D'Lima DD, Townsend CP, Arms SW, Morris BA, Colwell CW (2005) An implantable telemetry device to measure intra-articular tibial forces, *J Biomech*;38:299-304

D'Lima DD, Patil S, Steklov N, Colwell CW Jr (2007) Dynamic intraoperative ligament balancing for total knee arthroplasty, *Clin Orthop Relat Res*;463:208-212

Dowsey MM, Liew D, Stoney JD, Choong PF (2010) The impact of pre-operative obesity on weight change and outcome in total knee replacement: a prospective study of 529 consecutive patients, *J Bone Joint Surg Br*;92(4):513-520

Drake BG, Callahan CM, Dittus RS, Wright JG (1994) Global rating systems used in assessing knee arthroplasty outcomes, *J Arthroplasty*;9:409-417

Edholm P, Lindahl O, Lindholm B, Myrmerts R, Olsson KE, Wennberg E (1976) Knee instability. An orthoradiographic study, *Acta Orthop Scand*;47(6):658-663

Edwards JZ, Greene KA, Davis RS, Kovacik MW, Noe DA, Askew MJ (2004) Measuring flexion in knee arthroplasty patients, *J Arthroplasty*;19(3):369-372

Engh GA (2003) The difficult knee. Severe varus and valgus, *Clin Orthop Relat Res*; 416:58

Ettinger WH Jr, **Burns R**, **Messier SP**, **Applegate W**, **Rejeski WJ**, **Morgan T**, **Shumaker S**, **Berry MJ**, **O'Toole M**, **Monu J**, **Craven T** (1997) A randomized trial comparing aerobic exercise and resistance exercise with a health education program in older adults with knee osteoarthritis: the Fitness Arthritis and Seniors Trial (FAST), *JAMA*;277:25-31

Ewald FC (1989) The knee society total knee arthroplasty roentgenographic evaluation and scoring system, *Clin Orthop*;248:9-12

Fehring TK, Odum SM, Masonis JL, Springer BD (2010) Early failures in unicondylar arthroplasty, *Orthopaedics*;33(1):11

Felson DT (2003) Epidemiology of osteoarthritis. In: Brandt KD, Doherty M, Lohmander LS, eds. *Osteoarthritis*. Oxford, England: Oxford University Press:9-16

Felson DT (2006) Osteoarthritis of the knee, N Engl J Med;354:841-848

Felson DT, Goggins J, Niu J, Zhang Y, Hunter DJ (2004) The effect of body weight on progression of knee osteoarthritis is dependent on alignment, *Arthritis Rheum*;50:3904-3909

Feng EL, Stulberg SD, Wixson RL (1994) Progressive subluxation and polyethylene wear in total in total knee replacements with flat articular surfaces, *Clin Orthop;*229:60-71

Fick R (1904) Anatomie der Gerkenke. In : Von Bardelenben K. Handbuch der anatomie des menschen. Bd 2, S367, Jena, Fisher.

Fiddian NJ, Blakeway C, Kumar A (1998) Replacement arthroplasty of the valgus knee: a modified lateral capsular approach with repositioning of vastus lateralis, *J Bone Joint Surg Br*;80-B:859-861

Fitzgerald GA (2004) Coxibs and cardiovascular disease, *N Engl J Med*;351:1709-1711

Fitzpatrick R, Fletcher A, Gore S, Jones D, Spiegelhalter D, Cox D (1992) Quality of life measure in health care: I. Applications and issues in assessment, *BMJ*;305:1074-1077

Foley KT and Smith MM (1996) Image guided spine surgery, *Neurosurg Clin North Am*;7:171-186

Fortin PR, Clarke AE, Joseph L, Liang MH, Tanzer M, Ferland D, Phillips C, Partridge AJ, Bélisle P, Fossel AH, Mahomed N, Sledge CB, Katz JN (1999) Outcomes of total knee and hip replacement: preoperative functional status predicts outcomes at six months after surgery, *Arthritis Rheum*;42:1722-1728

Frain P, Fontaine C, D'Hondt D (1984) Contraintes du genou par dérangement ménisco-ligamentaire. Etude de l'articulation condylo-tibiale interne. Méthode cinématique expérimentale, *Rev. Chir. Orthop*;70:361-369

Freeman MA, Swanson SAV, Todd RC (1973) Total replacement of the knee using the Freeman-Swanson knee prosthesis, *Clin Orthop Relat Res*;94:153-170

Freeman MA, Todd RC, Bamert P, Day WH (1978) ICLH arthroplasty of the knee: 1968-1977, *J Bone Joint Surg Br*;60-B:339-44

Freeman MAR, Insall J, Besser W, Walker PS, Hallel T (1977) Excision of the cruciate ligaments in total knee replacement, *Clin Orthop*;126:207

Freeman MAR, Samuelson KM, Levack B, DeAlencar PGC (1986) Knee arthroplasty at the London Hospital, *Clin Orthop Relat Res*;205:12-20

Fries JF, Spitz PW, Young DY (1982) The dimensions of health outcomes: the health assessment questionnaire, disability and pain scales, *J Rheumatol*;9:789-793

Fuller J, Liu LJ, Murphy MC, Mann RW (1997) A comparison of lower-extremity skeletal kinematics measured using skin- and pin-mounted markers, *Human Movement Science*;16:219-242

Furnes O, Espehaug B, Lie SA, Vollset SE, Engesaeter LB, Havelin LI (2007) Failure mechanisms after unicompartmental and tricompartmental primary knee replacement with Cement, *J Bone Joint Surgery Am*;89:519-525

Genin P, Weill G, Julliard R (1993) The tibial slope. Proposal for a measurement method, *J Radiol*;74(1):27-33

Glimet T, Massé JP, Ryckewaert A (1980) Etude radiologique des genoux indolores de 50 hommes de plus de 65 ans. I. Téléradiographie de face en station debout, *J Radiol*;61, 8-9:509-510

Glimet T, Massé JP, Ryckewaert A (1979) Etude radiologique des genoux indolores de 50 femmes de plus de 65 ans. 1re partie : éléradiographie de face en station debout, *Rev Rhum;*46:589-592

Goodfellow JW, O'Connor JJ, Murray DW (2010) A critique of revision rate as an outcome measure: re-interpretation of knee joint registry data, *J Bone Joint Surg Br*;92-B;1628-1631

Gosens T, Hoefnagels NH, de Vet RC, Dhert WJ, van Langelaan EJ, Bulstra SK, Geesink RG (2005) The "Oxford Heup Score": the translation and validation of a questionnaire into Dutch to evaluate the results of total hip arthroplasty, *Acta Orthop*;76:204-211

Green GV, Berend KR, Berend ME, Glisson RR, Vail TP (2002) The effects of varus tibial alignment on proximal tibial surface strain in total knee arthroplasty, *J Arthroplasty*;17(8):1033-1039

Grood ES, Noyes FR, Butler DL, Suntay WJ (1981) Ligamentous and capsular restraints preventing straight medial and lateral laxity in intact human cadaver knees, *J Bone Joint Surg Am*;63:1257-1269

Guccione AA, Felson DT, Anderson JJ, Anthony JM, Zhang Y, Wilson PW, Kelly-Hayes M, Wolf PA, Kreger BE, Kannel WB (1994) The effects of specific medical conditions on the functional limitations of elders in the Framingham Study, *Am J Public Health*;84:351-358

Gulati A, Pandit H, Jenkins C, Chau R, Dodd CA, Murray DW (2009) The effect of leg alignment on the outcome of unicompartmental knee replacement, *J Bone Joint Surg Br*;91(4):469-474

Haaker RG, Stockheim M, Kamp M, Proff G, Breitenfelder J, Ottersbach A (2005) Computer-assisted navigation increases precision of component placement in total knee arthroplasty, *Clin Orthop Relat Res*;433:152–159

Hakki S, Coleman S, Saleh K, Bilota VJ, Hakki A (2009) Navigational predictors in determining the necessity for collateral ligament release in total knee replacement, *J Bone Joint Surg [Br]*;91-B:1178-1182

Han HS, Chang CB, Seong SC, Lee S, Lee MC (2008) Evaluation of anatomic references for tibial sagittal alignment in total knee arthroplasty, *Knee Surg Sports Traumatol Arthrosc*;16:373-377

Hannan MT, Felson DT, Pincus T (2000) Analysis of the discordance between radiographic changes and knee pain in osteoarthritis of the knee, *J Rheumatol*;27:1513-1517

Hardy MA (1989) The biology of scar formation, *Phys Ther*;69:1014-1024

Harrington IJ (1983) Static and dynamic loading patterns in knee joints with deformities, *J Bone Joint Surg Am*;65:247-259

Harris JD, Siston RA, Pan X, Flanigan DC (2010) Autologous chondrocyte implantation: a systematic review, *J Bone Joint Surg Am*;92-A:2220-2233

Harms MC, Bader DL (1997) Variability of forces applied by experienced therapists during spinal mobilization, *Clin Biomech*;12(6):393-399

Heck DA, Marmor L, Gibson A, Rougraff BT (1993) Unicompartmental knee arthroplasty: a multicenter investigation with long-term follow-up evaluation, *Clin Orthop*;286:154-159

Heesterbeek PJ, Verdonschot N, Wymenga AB (2008) In vivo knee laxity in flexion and extension: a radiographic study in 30 older healthy subjects, *Knee*;15(1):45-49

Hefti F, Müller W, Jakob RP, Stäubli HU (1993) Evaluation of knee ligament injuries with the IKDC form, *Knee Surg Sports Traumatol Arthrosc*;1(3-4):226-34

Hicks JL and Richards JG (2005) Clinical applicability of using spherical fitting to find hip joint centres, *Gait & Posture*;22:138-145

Hinman RS, May RL, Crossley KM (2006) Is there an alternative to the full-leg radiograph for determining knee joint alignment in osteoarthritis? *Arthritis Care & Research*;55:306–313

Hofmann AA, Bachus KN, Wyatt RW (1991) Effect of the tibial cut on subsidence following total knee arthroplasty, *Clin. Orthop*;269:63-69

Hsu RWW, Himeno S, Coventry MB, Chao EYS (1990) Normal axial alignment of the lower extremity and load-bearing distribution at the knee, *Clin Orthop*;255:215-227

Hungerford DS, Krackow KA (1985) Total joint arthroplasty of the knee, *Clin Orthop Relat Res*;192:23-33

Hunt MA, Fowler PJ, Birmingham TB, Jenkyn TR, Griffin JR (2006) Foot rotational effects on radiographic measures of lower limb alignment, *Can J Surg*;49:401-406

Hunter DJ, Niu J, Felson DT, Harvey WF, Gross KD, McCree P, Aliabadi P, Sack B, Zhang Y (2007) Knee alignment does not predict incident osteoarthritis: the Framingham Osteoarthritis Study, *Arthritis Rheum*;56(4):1212-1218

Hurwitz DE, Ryals AB, Case JP, Block JA, Andriacchi TP (2002) The knee adduction moment during gait in subjects with knee osteoarthritis is more closely correlated with static alignment than radiographic disease severity, toe out angle and pain, *J Orthop Res*;20:101-107

Insall JN (1993) Surgical techniques and instrumentation in total knee arthroplasty. *Surgery of the Knee*. Ed. 2, vol.2, pp 739-804. New York, Churchhill Livingston

Insall JN, Binazzi R, Soudry M, Mestriner LA (1985) Total knee arthroplasty, *Clin Orthop*;192:13-22

Insall JN, Dorr LD, Scott RD, Scott WN (1989) Rationale of the Knee Society clinical rating system, *Clin Orthop Relat Res*;248:13-14

Insall JN, Lachiewicz PF, Burstein A (1982) The posterior stabilised condylar prosthesis: a modification of total condylar design. Two to four year clinical experience, *J Bone Joint Surg Am*;64-A:1317

Insall JN, Ranawat CS, Aglietti P, Shine J (1976) A comparison of four models of total knee-replacement prostheses, *J Bone Joint Surg Am*;58(6):754-765

Insall JN, Scott WN, Ranawat CS (1979) The total condylar prosthesis: a report of two hundred and twenty cases, *J Bone Joint Surg Am*;61-A:173-180

Jacobson KE and Chi FS (2006) Evaluation and treatment of medial collateral ligament and medial-sided injuries of the knee, *Sports Med Arthrosc*;14(2):58-66

Jeffrey RS, Morris RW, Denham RA (1991) Coronal alignment after total knee replacement, *J Bone Joint Surg Br*;73:709-714

Jenny JY (2010) Coronal plane knee laxity measurement: Is computer-assisted navigation useful? *Orthop Traumatol Surg Res*;96(5):583-588

Jenny JY, Boeri C, Picard F, Leitner F (2004) Reproducibility of intra-operative measurement of the mechanical axes of the lower limb during total knee replacement with a non-imaged based navigation system, *Computer Aided Surg*;9(4):161-166

Johnston F, Leitl S, Waugh W (1980) The distribution of load across the knee. A comparison of static and dynamic measurements, *J Bone Joint Surg Br*;62B(3):346-249

Johnston RC and Smidt GL (1969) Measurement of hip-joint motion during walking. Evaluation of an electrogoniometric method, *J Bone Joint Surg*;51A(6):1083-1094

Jones CA, Voaklander DC, Johnston DW, Suarez-Almazor ME (2000) Health related quality of life outcomes after total hip and knee arthroplasties in a community based population, *J Rheumatol*;27(7):1745-1752

Kalteis T, Handel M, Herold T, Perlick L, Paetzel C, Grifka J (2006) Position of the acetabular cup - accuracy of radiographic calculation compared to CT-based measurement, *Eur J Radiol*;58:294-300

Kaufman KR, Kovacevic N, Irby SE, Colwell CW (1996) Instrumented implant for measuring tibiofemoral forces, *J Biomech*;29:667-671

Keene G, Simpson D, Kalairajah Y (2006) Limb alignment in computer-assisted minimally-invasive unicompartmental knee replacement, *J Bone Joint Surg Br*;88-B:44-48

Kellgren JH and Lawrence JS (1957) Radiological assessment of osteo-arthrosis, *Ann Rheum Dis*;16:494-502

Kellgren JH, Jeffrey MR, Ball J (1963) *The epidemiology of chronic rheumatism. Atlas of standard radiographs of arthritis.* Oxford, UK: Blackwell Scientific Publications, 1963:vii-11

Kendoff D, Board TN, Citak M, Gardner MJ, Hankemeier S, Ostermeier S, Krettek C, Hüfner T (2008) Navigated lower limb axis measurements: influence of mechanical weight-bearing simulation, *J Orthop Res*;26:553-561

Kerrigan DC, Lelas JL, Goggins J, Merriman GJ, Kaplan RJ, Felson DT (2002) Effectiveness of a lateral-wedge insole on knee varus torque in patients with knee osteoarthritis, *Arch Phys Med Rehabil*;83:889-893

Kettelkamp DB and Thompson C (1975) Development of a knee scoring scale, *Clin Orthop Relat Res*;107:93-99

Kim YH, Kim JS, Choi Y, Kwon OR (2009) Computer-assisted surgical navigation does not improve the alignment and orientation of the components in total knee arthroplasty, *J Bone Joint Surg Am*;91:14-19

Knutsen G, Drogset JO, Engebretsen L, Grøntvedt T, Isaksen V, Ludvigsen TC, Roberts S, Solheim E, Strand T, Johansen O (2007) A randomized trial comparing autologous chondrocyte implantation with microfracture. Findings at 5 years, *J Bone Joint Surg Am*;89:2105-2112

Krackow KA (1983) Approaches to planning lower extremity alignment for total knee arthroplasty and osteotomy about the knee, *Adv Orthop Surg*;7:69-88

Krackow KA (1990a) Varus deformity. *The technique of total knee arthroplasty*, pp 317-340, CO Mosby Company, St Louis, Missouri

Krackow KA and Mihalko WM (1999) The effect of medial release on flexion and extension gaps in cadaveric knees: implications for soft tissue balancing in total knee arthroplasty, *Am J Knee Surg*;12:222

Krackow KA, Pepe CL, Galloway EJA (1990b) A mathematical analysis of the effect of flexion and rotation on apparent varus/valgus alignment at the knee, *Orthopaedics*;13(8):861-8

Kraus VB, Vail TP, Worrell T and McDaniel G (2005) A comparative assessment of alignment angle of the knee by radiographic and physical examination methods, *Arthritis & Rheumatism*;52:1730–1735

Kumar PJ and Dorr LD (1997) Severe malalignment and soft tissue imbalance in total knee arthroplasty, *Am J Knee Surg*;10:36-41

Lai K, Shen W, Yang C (1998) Arthrodesis with a short Huckstep nail as a salvage procedure for failed total knee arthroplasty, *J Bone Joint Surg Am*;80:380-388

Lam LO, Swift S, Shakespeare D (2003) Fixed flexion deformity and flexion after knee arthroplasty. What happens in the first 12 months after surgery and can a poor outcome be predicted? *Knee*;10(2):181-185

LaPrade RF, Heikes C, Bakker AJ, Jakobsen RB (2008) The Reproducibility and Repeatability of Varus Stress Radiographs in the Assessment of Isolated Fibular Collateral Ligament and Grade-III Posterolateral Knee Injuries. An in Vitro Biomechanical Study, *J Bone Joint Surg Am*;90:2069-2076

Laupattarakasem W, Laopaiboon M, Laupattarakasem P, Sumananont C (2008) Arthroscopic debridement for knee osteoarthritis, *Cochrane Database Syst Rev*;(1):CD005118

Leardini A, Cappozzo A, Catani F, Toksvig-Larsen S, Petitto A, Sforza V, Cassanelli G, Giannini S (1999) Validation of a functional method for the estimation of hip joint centre location, *J Biomech*;32:99-103

Ledingham J, Regan M, Jones A, Doherty M (1993) Radiographic patterns and associations of osteoarthritis of the knee in patients referred to hospital, *Ann Rheum Dis*;52:520-526

Liang MH, Cullen KR, Larson E, Thompson MS, Schwartz JA, Fossel AH, Roberts WN, Sledge CB (1986) Cost-effectiveness of total joint arthroplasty in osteoarthritis, *Arthritis Rheum*;29:937-43

Lidgren L, Knutson K, Robertsson O (2003) Swedish knee arthroplasty register, *Annual Report* http://www.ort.lu.se/knee

Lingard EA, Sledge CB, Learmonth ID, Kinemax Outcomes Group (2006) Patient expectations regarding total knee arthroplasty: differences among the United States, United Kingdom, and Australia, *J Bone Joint Surg Am*;88-A(6):1201-1207

Lo GH, LaValley M, McAlindon T, Felson DT (2003) Intra-articular hyaluronic acid in treatment of knee osteoarthritis: a meta-analysis, *JAMA*;290:3115-3121

Lonner JH, Laird MT, Stuchin SA (1996) Effect of rotation and knee flexion on radiographic alignment in total knee arthroplasties, *Clin Orthop Relat Res*;331:102-106

Lotke PA, Ecker ML (1977) Influence of positioning of prosthesis in total knee replacement, *J Bone Joint Surg Am*;59-A:77-79

Lüring C, Hüfner T, Kendoff D, Perlick L, Bäthis H, Grifka J (2005) Influence of everted and subluxed patella in ligament balancing. In *Proceedings of the Fifth Annual Meeting of CAOS-International*, Helsinki, Finland, 2005

Lüring C, Hüfner T, Perlick L, Bäthis H, Krettek C, Grifka J (2006) The effectiveness of sequential medial soft tissue release on coronal alignment in total knee arthroplasty using a computer navigation model, *J Arthoplasty*;21(3):428-434

Lützner J, Krummenauer F, Wolf C, Günther K-P, Kirschner S (2008)**,** Computer-assisted and conventional total knee replacement: A comparative, prospective, randomised study with radiological and CT evaluation, *J Bone Joint Surg Br*;90-B:1039-44

Magerkurth O, Knupp M, Ledermann H, Hintermann B (2006) Evaluation of hindfoot dimensions: a radiological study, *Foot Ankle Int*;27(8):612-616

Mahaluxmivala J, Bankes MJ, Nicolai P, Aldam CJH, Allen PW (2001) The effect of surgeon experience on component positioning in 673 press fit condylar posterior cruciate-sacrificing total knee arthroplasties, *J Arthroplasty*;16:635-640

Maillefert JF, Hudry C, Baron G, Kieffert P, Bourgeois P, Lechevalier D, Coutaux A, Dougados M (2001) Laterally elevated wedged insoles in the treatment of medial knee osteoarthritis: a prospective randomized controlled study, *Osteoarthritis Cartilage*;9:738-745

Maletsky LP, Sun J, Morton NA (2007) Accuracy of an optical active-marker system to track the relative motion of rigid bodies, *J Biomech*;40:682-685

Mancuso CA, Graziano S, Briskie LM, Peterson MG, Pellicci PM, Salvati EA, Sculco TP (2008) Randomized trials to modify patients' preoperative expectations of hip and knee arthoplasties, *Clin Orthop Relat Res*;466(2):424-431

Markolf KL, Mensch JS, Amstutz HC (1976) Stiffness and laxity of the knee– the contributions of the supporting structures, *J Bone Joint Surg Am;*58-A:583-594

Martin AF (1960) The pathomechanics of the knee joint 1.The medial collateral ligament and lateral tibial plateau fractures, *J Bone Joint Surg Am;*42:13-22

Martin JW and Whiteside LA (1990) The influence of joint line position on knee stability after condylar knee arthroplasty, *Clin Orthop*;259:146-156

Matsuda S, Miura H, Nagamine R, Urabe K, Ikenoue T, Okazaki K, Iwamoto Y (1999) Posterior tibial slope in the normal and varus knee, *Am J Knee Surg*;12:165-168

Matsueda M, Gengerke TR, Murphy M Lew WD, Gustilo RB (1999) Soft tissue release in total knee arthroplasty. Cadaver study using knees without deformities, *Clin Orthop*;366:264

Matziolis G , Krocker D, Weiss U, Tohtz S, Perka C (2007) A Prospective, Randomized Study of Computer-Assisted and Conventional Total Knee Arthroplasty. Three-Dimensional Evaluation of Implant Alignment and Rotation, *J Bone Joint Surg Am;*89-A:236-243

Maquet PGJ (1977) *Biomechanics of the knee*. Berlin, Springer-Verlag.

Mayr E, Moctezuma de la Barrera J-L, Eller G, Bach C, Nogler M (2006) The effect of fixation and location on the stability of the markers in navigated total hip arthroplasty : a cadaver study, *J Bone Joint Surg [Br]*;88-B:168-72

McGibbon CA, Riley PO, Krebs DE (1997) Comparison of hip centre estimation using in-vivo and ex-vivo measurements from the same subject, *Clin Biomech*; 12(7/8):491-495

McGrory JE, Trousdale RT, Pagnano MW, Nigbur M (2002) Preoperative hip to ankle radiographs in total knee arthroplasty, *Clin Orthop Relat Res*;404:196-202

Medalla GA, Moonot P, Peel T, Kalairajah Y, Field RE (2009) Cost-benefit comparison of the Oxford knee score and the American knee society score in measuring outcome of total knee arthroplasty, *J Arthroplasty*;24-4;652-656

Meenan R, Gertman P, Mason J (1980) Measuring health status in arthritis: the arthritis impact measurement scales, *Arthritis Rheum*;23:146-152

Meister K, Talley MC, Horodyski MB, Indelicato PA, Hartzel JS, Batts J (1998) Caudal slope of the tibia and its relationship to noncontact injuries to the ACL, *Am J Knee Surg*;11:217-219

Messier SP, Loeser RF, Miller GD, Morgan TM, Rejeski WJ, Sevick MA, Ettinger WH Jr, Pahor M, Williamson JD (2004) Exercise and dietary weight loss in overweight and obese older adults with knee osteoarthritis: the Arthritis, Diet, and Activity Promotion Trial, *Arthritis Rheum*;50:1501-1510

Mihalko WM, Boyle J, Clark LD, Krackow KA (2005) The variability of intramedullary alignment of the femoral component during total knee arthroplasty, *J Arthroplasty*;20(1):25-28

Mihalko WM, Whiteside LA, Krackow KA (2003) Comparison of ligament-balancing techniques during total knee arthroplasty, *J Bone Joint Surg Am*;85-A(Suppl. 4):132-135

Mihalko WM and Whiteside LA (2003) Bone resection and ligament treatment for flexion contracture in knee arthroplasty, *Clin Orthop Relat Res*;406:141-147

Miner AL, Lingard EA, Wright EA, Sledge CB, Katz JN, Kinemax Outcomes Group (2003) Knee range of motion after total knee arthroplasty: how important is this an outcome measure? *J Arthroplasty*;18(3):286-294

Minoda Y, Kobayashi A, Iwaki H, Sugama R, Iwakiri K, Kadoya Y, Ohashi H, Takaoka K (2008) Sagittal alignment of the lower extremity while standing in Japanese males, *Arch Orthop Trauma Surg*;128:435-442

Misra AN, Hussain MRA, Fiddian NJ, Newton G (2003) The role of the posterior cruciate ligament in total knee replacement, *J Bone Joint Surg Br*;85-B(3):389-392

Molloy DO, Mockford BJ, Wilson RK, Beverland DE (2004) Blood loss following soft tissue release in total knee arthroplasty of the valgus knee, *J Bone Joint Surg Br*;87-B:156

Moody JE, Nikou C, Picard F, Levison T, Jaramaz B, DiGioia AM, Reverte CF (2002) Computer-integrated anterior cruciate ligament reconstruction system, *J Bone Joint Surg Am*;84:S99-S101

Moore TM, Meyers MH, Harvey JP (1976) Collateral ligament laxity of the knee. Long-term comparison between plateau fractures and normal, *J Bone Joint Surg Am*;58-A:594-598

Moreland JR (1988) Mechanisms of failure in total knee arthroplasty, *Clin Orthop Relat Res*;226:49-64

Moreland JR, Bassett LW, Hanker GJ (1987) Radiographic analysis of the axial alignment of the lower extremity, *J Bone Joint Surg Am*;69-A:745-749

Morris BA, D'Lima DD, Slamin J, Kovacevic N, Arms SW, Townsend CP, Colwell CW (2001) e-Knee: evolution of the electronic knee prosthesis, *J Bone Joint Surg Am*;83-A(suppl. 2, part 1):62-66

Mündermann A, Dyrby CO, Andriacchi TP (2008) A comparison of measuring mechanical axis alignment using three-dimensional position capture with skin markers and radiographic measurements in patients with bilateral medial compartment knee osteoarthritis, *The Knee*;15:480-485

Munzinger UK, Boldt JG, Keblish PA (eds) (2004) *Primary Knee Arthroplasty*, Springer-Verlag Berlin Heidelberg New York

Murphy L, Schwartz TA, Helmick CG, Renner JB, Tudor G, Koch G, Dragomir A, Kalsbeek WD, Luta G, Jordan JM (2008) Lifetime risk of symptomatic knee osteoarthritis, *Arthritis Rheum*;59(9):1207-1213

Murphy SB, Kijewski PK, Simon SR, Chandler HP, Griffin PP, Reilly DT, Penenberg BL, Landy MM (1986) Computer-aided simulation, analysis and design in orthopaedic surgery, *Orthop Clin N Am*;17(4):637-649

Murray DW, Fitzpatrick R, Rogers K, Pandit H, Beard DJ, Carr AJ, Dawson J (2007) The use of Oxford hip and knee scores, *J Bone Joint Surg Br*;89-B:1010-1014

Murray DW, Goodfellow JW, O'Connor JJ (1998) The Oxford medial unicompartmental arthroplasty: a ten year survival study, *J Bone Joint Surg Br*;80-6:983-989

Nagamine R, Kondo K, Ikemura S Shiranita A, Nakashima S, Hara T, Ihara H, Sugioka Y (2004) Distal femoral cut perpendicular to the mechanical axis may induce varus instability in flexion in medical osteoarthritic knees with varus deformity in total knee arthroplasty: a pitfall of the navigation system, *J Orthop Sci*;9:555-559

Newman JH, Ackroyd CE, Shah NA (1998) Unicompartmental or total knee replacement? Five-year results of a prospective, randomised trial of 102 osteoarthritic knees with unicompartmental arthritis, *J Bone Joint Surg Br*;80(5):862-865

Nicholson JA, Sutherland AG, Smith FW, Kawasaki T (2010) Upright MRI in kinematic assessment of the ACL-deficient knee, *Knee*, doi:10.1016/j.knee.2010.11.008

Nilsdotter AK, Toksvig-Larsen S, Roos EM (2009) Knee arthroplasty: are patients' expectations fulfilled? A prospective study of pain and function in 102 patients with 5-year follow-up, *Acta Orthop*;80(1):55–61

Noyes FR, Grood ES, Butler DL, Raterman L (1980) Knee Ligament Tests: What Do They Really Mean? *Physical Therapy*;60(12):1578-1581

Nuno-Siebrecht N, Tanzer M, Bobyn JD (2000) Potential errors in axial alignment using intramedullary instrumentation for total knee arthroplasty, J Arthroplasty;15:228-230

Okazaki K, Miura H, Matsuda S, Takeuchi N, Mawatari T, Hashizume M, Iwamoto Y (2006) Asymmetry of mediolateral laxity of the normal knee, *J Orthop Sci*;11(3):264-266

Oliveria SA, Felson DT, Reed JI, Cirillo PA, Walker AM (1995) Incidence of symptomatic hand, hip, and knee osteoarthritis among patients in a health maintenance organisation, *Arthritis Rheum*;38:1134-1141

Oswald MH, Jakob RP, Schneider E, Hoogewoud HM (1993) Radiological analysis of normal axial alignment of femur and tibia in view of total knee arthroplasty, *J Arthroplasty*;8:419-426

Pagnano MW, Cushner FD, Scott WN (1998) Role of the posterior cruciate ligament in total knee arthroplasty, *Acad Orthop Surg*;6:176-187

Paley D (2002) *Principles of deformity correction*. Berlin, Germany: Springer-Verlag

Paley D, Herzenberg JE, Tetsworth K, McKie J, Bhave A (1994) Deformity planning for frontal and sagittal plane corrective osteotomies, *Orthop Clin North Am*;25:425-465

Parratte S, Pagnano MW, Trousdale RT, Berry DJ (2010) Effect of postoperative mechanical axis alignment on the fifteen-year survival of modern, cemented total knee replacements, *J Bone Joint Surg Am*;92:2143-9

Peat G, McCarney R, Croft P (2001) Knee pain and osteoarthritis in older adults: a review of community burden and current use of primary health care, *Ann Rheum Dis*;60:91-7

Perry J, Antonelli D, Ford W (1975) Analysis of knee joint forces during flexed knee stance, *J Bone Joint Surg Am*;57:961-7

Petermann J, von Garrel T, Gotzen L (1993) Non-operative treatment of acute medial collateral ligament lesions of the knee joint. *Knee Surg, Sports Traumatol, Arthroscopy*;1:93-96

Petersen TL, Engh GA (1988) Radiographic assessment of knee alignment after total knee arthroplasty*, J Arthroplasty*;3:67-72

Petersson IF (1996) Occurrence of osteoarthritis of the peripheral joints in European populations, *Ann Rheum Dis*;55:659-61

Picard F (2007) *Computer Assisted Orthopaedics: The Image Free Concept*. Berlin, Germany: Pro BUSINESS GmbH

Picard F, Deakin AH, Clarke JV, Dillon JM, Gregori A (2007a) Using Navigation Intraoperative Measurements Narrows Range of Outcomes in TKA, *Clin Orth Relat Res*;463:50-57

Picard F, Deakin AH, Clarke JV, Dillon JM, Kinninmonth AW (2007b) A quantitative method of effective soft tissue management for varus knees in total knee replacement surgery using navigational techniques, *Proc. IMechE Part H: J Engineering in Medicine*;221(7):763-772

Pincus T, Koch GG, Sokka T, Lefkowith J, Wolfe F, Jordan JM, Luta G, Callahan LF, Wang X, Schwartz T, Abramson SB, Caldwell JR, Harrell RA, Kremer JM, Lautzenheiser RL, Markenson JA, Schnitzer TJ, Weaver A, Cummins P, Wilson A, Morant S, Fort J (2001) A randomized, double-blind, crossover clinical trial of diclofenac plus misoprostol versus acetaminophen in patients with osteoarthritis of the hip or knee, *Arthritis Rheum*;44:1587-1598

Pinskerova V, Johal P, Nakagawa S, Sosna A, Williams A, Gedroyc W, Freeman MA (2004) Does the femur roll-back with flexion? *J Bone Joint Surg Br*;86(6):925-931

Piriyaprasarth P, Morris ME, Winter A, Bialocerkowski AE (2008) The reliability of knee joint position testing using electrogoniometry, *BMC Musculoskeletal Disorders*;doi:10.1186/1471-2474-9-6

Puloski SK, McCalden RW, MacDonald SJ, Rorabeck CH, Bourne RB (2001) Tibial post wear in posterior stablized total knee arthroplasty; an unrecognized source of polyethylene debris, *J Bone Joint Surg Am*;83:390-397

Ramachandran M (Ed) (2007) *Basic Orthopaedic Sciences: The Stanmore Guide*. Hodder Arnold Publication, London, UK

Ranawat CS, Boachie-Adjei O (1988) Survivorship analysis and results of total condylar knee arthroplasty, *Clin Orthop*;226:6-13

Ranawat CS, Flynn WF Jr, Saddler S, Hansraj KK, Maynard MJ (1993) Long-term results of the total condylar arthroplasty: a 15 year survivorship study, *Clin Orthop*;286:94-102

Ranawat CS, Shine JJ (1973) Duo-condylar total knee arthroplasty, *Clin Orthop Relat Res*;94:185-195

Reddy KI, Johnston LR, Wang W, Abboud RJ (2011) Does the Oxford knee score complement, concur, or contradict the American Knee Society score? *J Arthroplasty*;26(5):714-720

Reed SC, Gollish J (1997) The accuracy of femoral intramedullary guides in total knee arthroplasty*, J Arthroplasty*;12(6):677-682

Ritter MA, Faris PM, Keating EM, Meding JB (1994) Post-operative alignment of total knee replacement: its effect on survival, *Clin Orthop*;299:153-156

Ritter MA, Lutgring JD, Davis KE, Berend ME, Pierson JL, Meneghini RM (2007) The role of flexion contracture on outcomes in primary total knee arthroplasty, *J Arthroplasty*;22(8):1092-6

Ritter MA, Thong AE, Keating EM, Faris PM, Meding JB, Berend ME, Pierson JL, Davis KE (2005) The effect of femoral notching during total knee arthroplasty on the prevalence of postoperative femoral fractures and on clinical outcome, *J Bone Joint Surg Am*;87:2411-2414

Robertsson O, Dunbar M, Pehrsson T, Knutson K, Lidgren L (2000) Patient satisfaction after knee arthroplasty: a report on 27,372 knees operated on between 1981 and 1995 in Sweden, *Acta Orthop Scand*;71:262-267

Robinson M, Eckhoff DG, Reinig KD, Bagur MM, Bach JM (2006) Variability of landmark identification in total knee arthroplasty, *Clin Orthop Relat Res*; 442:57-62

Robinson RP (2005) The early innovators of today's resurfacing condylar knees, *J Arthroplasty*;20(1 Suppl 1):2-26

Rowe PJ, Myles CM, Hillmann SJ, Hazlewood ME (2001) Validation of flexible electrogoniometry as a measure of joint kinematics, *Physiotherapy*;87:9:479-488

Rowe PJ, Myles CM, Walker C, Nutton R (2000) Knee joint kinematics in gait and other functional activities measured using flexible electrgoniometry: how much knee motion is sufficient for normal daily life? *Gait & Posture*;12:143-155

Sabharwal S and Zhao C (2008) Assessment of lower limb alignment: supine fluoroscopy compared with a standing full-length radiograph, *J Bone Joint Surg Am*;90:43-51

Sambatakakis A, Wilton TJ, Newton G (1991) Radiographic sign of persistent soft-tissue imbalance after knee replacement, *J Bone Joint Surg Br*;73-B:751-756

Samson DJ, Grant MD, Ratko TA, Bonnell CJ, Ziegler KM, Aronson N (2007) Treatment of Primary and Secondary Osteoarthritis of the Knee, Rockville, MD*: Agency for Healthcare Research and Quality*;157

Sanfridsson J, Ryd L, Eklund K, Kouvaras Y, Johnsson K (1996) Angular configuration of the knee. Comparison of conventional measurements and the QUESTOR Precision Radiography system, *Acta Radiol*;37(5):633-638

Sangeux M, Marin F, Charleux F, Dürselen L, Ho Ba Tho MC (2006) Quantification of the 3D relative movement of external marker sets vs. bones based on magnetic resonance imaging, *Clin Biomech*;21:984-991

Saragaglia D, Chaussard C, Rubens-Duval B (2006) Navigation as a predictor of tissue release during 90 cases of computer assisted total knee arthroplasty, *Orthopaedics*;29(10 Suppl):137-139

Schiphof D, Boers M, Bierma-Zeinstra SMA (2008) Differences in descriptions of Kellgren and Lawrence grades of knee osteoarthritis, *Ann Rheum Dis*;67:1034-1036

Seidel GK, Marchinda DM, Dijkers M, Soutas-Little RW (1995) Hip joint center location from palpable bony landmarks – a cadaver study, *J Biomechanics*; 28(8):995-998

Sharkey PF, Hozack WJ, Rothman RH, Shastri S, Jacoby SM (2002) Why are total knee arthroplasties failing today? *Clin Orthop Relat Res*;404:7-13

Sharma L, Song J, Dunlop D, Felson D, Lewis CE, Segal N, Torner J, Cooke TDV, Hietpas J, Lynch J, Nevitt M (2010) Varus and valgus alignment and incident and progressive knee osteoarthritis, *Ann Rheum Dis* doi:10.1136/ard.2010.129742

Sharma L, Song J, Felson DT, Cahue S, Shamiyeh E, Dunlop DD (2001) The role of knee alignment in disease progression and functional decline in knee osteoarthritis, *JAMA*;286:188-95

Sharma L, Congron L, Felson DT, Dunlop DD, Kirwan-Mellis G, Hayes KW, Weinrach D, Buchanan T (1999) Laxity in healthy and osteoarthritic knees, *Arthritis Rheum*;42:861-870

Sheldon SR (Ed) (1994) *Orthopaedic Basic Science*. American Academy of Orthopaedic Surgeons, 1994

Sikorski JM (2008) Alignment in total knee replacement, *J Bone Joint Surg Br*;90(9): 1121-1127

Shiers LGP (1954) Arthroplasty of the knee, *J Bone Joint Surg Br*;36-B:553-560

Siston RA, Giori NJ, Goodman SB, Delp SL (2007) Surgical navigation for total knee arthroplasty: A perspective, *J Biomech*;40:728-735

Siu D, Cooke TD, Broekhoven LD, Lam M, Fisher B, Saunders G, Challis TW (1991) A standardised technique for lower limb radiography. Practice, applications, and error analysis, *Invest Radiol*;26(1):71-77

Song EK, Seon JK, Yoon TR, Park SJ, Cho SG, Yim JH (2007) Comparative study of stability after total knee arthroplasties between navigation system and conventional techniques, *J Arthroplasty*:22(8):1107-1111

Sparmann M, Wolke B, Czupalla H, Banzer D, Zink A (2003) Positioning of total knee arthroplasty with and without navigation support: a prospective, randomized study, *J Bone Joint Surg Br*;85-B:830-835

Specogna AV, Birmingham TB, Hunt MA, Jones IC, Jenkyn TR, Fowler PJ, Giffin JR (2007) Radiographic measures of knee alignment in patients with varus gonarthrosis: effect of weightbearing status and associations with dynamic joint load, *Am J Sports Med*;35(1):65-70

Spencer JMF, Day RE, Sloan KE, Beaver RJ (2006) Computer navigation of the acetabular component: a cadaver reliability study, *J Bone Joint Surg [Br]*;88-B:972-5

Spencer JM, Chauhan SK, Sloan K, Taylor A, Beaver RJ (2007) Computer navigation versus conventional total knee replacement: no difference in functional results at two years, *J Bone Joint Surg Br*;89-B(4):477-480

Stagni R, Fantozzi S, Cappello A, Leardini A (2005) Quantification of soft tissue artefact in motion analysis by combining 3D fluoroscopy and stereophotogrammetry: a study on two subjects, *Clin Biomech*;20:320-329

Steadman JR, Rodkey WG, Briggs KK (2002) Microfracture to treat full-thickness chondral defects: surgical techniques, rehabilitation, and outcomes, *J Knee Surg*;15:170-176

Stulberg DS, Loan P, Sarin V (2002) Computer-assisted navigation in total knee replacement: results of an initial experience in thirty-five patients, *J Bone Joint Surg Am*;84-A:90-98

Stulberg DS, Yaffe MA, Koo SS (2006) Computer-assisted surgery versus manual total knee arthroplasty: a case-controlled study, *J Bone Joint Surg Am*;88:47-54

Stockl B, Nogler M, Rosiek R, Fischer M, Krismer M, Kessler O (2004) Navigation improves accuracy of rotational alignment in total knee arthroplasty, *Clin Orthop Relat Res*;426:180–186

Sugama R, Minoda Y, Kobayashi A, Iwaki H, Ikebuchi M, Hashimoto Y, Takaoka K, Nakamura H (2010) Sagittal alignment of the lower extremity while standing in females, *Knee Surg Sports Traumatol Arthrosc*; DOI: 10.1007/s00167-010-1137-x

Svard UC and Price AJ (2001) Oxford medial unicompartmental knee arthroplasty. A survival analysis of an independent series, *J Bone Surg Br*; 83-2:191-194

Swanson KE, Stocks GW, Warren PD, Hazel MR, Janssen HF (2000) Does axial limb rotation affect the alignment measurements in deformed limbs? *Clin Orthop Relat Res*;371:246-52

Takahashi T, Wada Y, Yamamoto H (1997) Soft-tissue balancing with pressure distribution during total knee arthroplasty, *J Bone Joint Surg [Br]*;79-B:235-239

Tanamas S, Hanna FS, Cicuttini FM, Wluka AE, Berry P, Urquhart DM (2009) Does knee malalignment increase the risk of development and progression of knee osteoarthritis? A systematic review*, Arthritis Rheum*;61(4):459-467

Tang WM, Zhu YH, Chiu KY (2000) Axial alignment of the lower extremity in Chinese adults, *J Bone Joint Surg Am*;82A:1603-1608

Teter KE, Bergman D, Colwell CW (1995) Accuracy of intramedullary versus extramedullary tibial alignment cutting systems in total knee arthroplasty, *Clin Orthop*;321:106-110

Tew M, Foster IW (1987) Effect of knee replacement on flexion deformity, *J Bone Joint Surg Br*; 69:395

Townley CO (1985) The anatomic total knee resurfacing arthroplasty, *Clin Orthop Relat Res*;192:82-96

Tylkowski CM, Simon SR, Mansour JM (1982) Internal rotation gait in spastic cerebral palsy in the hip. *Proceedings of the 10th open scientific meeting of the Hip Society* (edited by Nelson JP);89-125. Mosby, St. Louis

Unitt L, Sambatakakis A, Johnstone D, Briggs TWR (2008) Short-term outcome in total knee replacement after soft-tissue release and balancing, *J Bone Joint Surg [Br]*;90-B:159-165

van Damme G, Defoort K, Ducoulombier Y, Van Glabbeek F, Bellemans J, Victor J (2005) What should the surgeon aim for when performing computer-assisted total knee arthroplasty? *J Bone Joint Surg Am*;87-A(suppl. 2):52-58

van der Esch M, Steultjens M, Ostelo RWJG, Harlaar J, Dekker J (2006) Reproducibility of instrumented knee joint laxity measurement in healthy subjects *Rheumatology*;45:595-599

van Raaija TM, Brouwerc RW, Reijmana M, Bierma-Zeinstrab SMA, Verhaara JAN (2009) Conventional knee films hamper accurate knee alignment determination in patients with varus osteoarthritis of the knee, *The Knee*;16(2):109-111

van Zoest GGJM, van den Berg HTCM, Holtkamp FC (2002) Three-dimensionality of contact forces during clinical manual examination and treatment: a new measuring system, *Clin Biomech*;17:719-722

Vince KG, Abdeen A, Sugimori T (2006) The unstable total knee arthroplasty: causes and cures, *J Arthroplasty*:21(4, suppl. 1):44-49

Vince KG, Insall JN, Kelly MA (1989) The total condylar prosthesis: 10-12 year results of a cemented knee replacement, *J Bone Joint Surg Br*;71-B:793-797

Wada M, Imura S, Baba H, Shimada S (1996) Knee laxity in patients with osteoarthritis and rheumatoid arthritis, *Br J Rheumatol*;35:560-563

Walldius B (1957) Arthroplasty of the knee using an endoprosthesis, *Acta Orthop Scand*;Suppl 24

Walker PS, Erkman MJ (1975) The role of menisci in force transmission across the knee, *Clin Orthop*;109:184-192

Wang Y, Zeng Y, Dai K, Zhu Z, Xie L (2010) Normal lower-extremity alignment parameters in healthy southern Chinese adults as a guide in total knee arthroplasty, *J Arthroplasty*;25:563-570

Ware JE Jr, Sherbourne CD (1992) The MOS 36-item short-form health survey (SF-36): 1. Conceptual framework and item selection, *Med Care*;30:473-483

Wasielewski RC, Galante JO, Leighty R, Natarajan RN, Rosenberg AG (1994) Wear patterns on retrieved polyethylene tibial inserts and their relationship to technical considerations during total knee arthroplasty, *Clin Orthop*;299:31-43

Weale AE, Murray DW, Baines J, Newman JH (2000) Radiological changes five years after unicompartmental knee replacement, *The Journal of Bone and Joint Surgery*;82-B(7):996-1000

Weiss JM, Noble PC, Conditt MA, Kohl HW, Roberts S, Cook KF, Gordon MJ, Mathis KB (2002) What functional activities are important to patients with knee replacements, *Clin Orthop Relat Res*;404:172-188

Werner FW, Ayers DC, Maletsky LP, Rullkoetter PJ (2005) The effect of valgus/varus malalignment on load distribution in total knee replacements, *J Biomech*;38:349-355

White LM and Buckwalter KA (2002) Technical considerations: CT and MR imaging in the postoperative orthopaedic patient, *Semin Musculoskelet Radiol*;6:5-17

Whitehouse SL, Blom AW, Taylor AH, Pattison GTR, Bannister GC (2005) The Oxford knee score; problems and pitfalls, *The Knee*;12:287-291

Whiteside LA (2002) Soft tissue balancing, *J Arthroplasty*;17(4)(suppl. 1):67-72

Whiteside LA, Saeki K, Mihalko WM (2000) Functional medial ligament balancing in total knee arthroplasty, *Clin Orthop*;380:45

Wijdicks CA, Griffith CJ, Johansen S, Engebretsen L, LaPrade RF (2010) Injuries to the medial collateral ligament and associated medial structures of the knee, *J Bone Joint Surg Am*;92-A:1266-1280

Willis-Owen CA, Brust K, Alsop H, Miraldo M, Cobb JP (2009) Unicondylar knee arthroplasty in the UK National Health Service: an analysis of candidacy, outcome and cost efficacy, *Knee*;16-6:473-478

Wilson W, Deakin AH, Wearing SC, Payne AP, Picard F (2010) Computer-assisted measurements of coronal knee joint laxity in-vitro are related to low stress behaviour rather than structural properties of the collateral ligaments, in *Proceedings of 10th Annual Meeting of CAOS-International*, Paris, France

Windsor RE, Scuderi GR, Moran MC, Insall JN (1989) Mechanisms of failure of the femoral and tibial components in total knee arthroplasty, *Clin Orthop* 248;15-19

Winemaker MJ (2002) Perfect balance in total knee arthroplasty: the elusive compromise, *J Arthroplasty*;17(1):2-10

Woolf AD and Pfleger B (2003) Burden of major musculoskeletal conditions [review], *Bull World Health Organ*;81:646-656

Wright JG, Feinstein AR (1992) Improving the reliability of orthopaedic measurements, *J Bone Joint Surg Br*;74B:287-291

Wright JG, Treble N, Feinstein AR (1991) Measurement of lower limb alignment using long radiographs, *J Bone Joint Surg Br*;73:721-723

Yaffe MA, Koo SS, Stulberg SD (2008) Radiographic and navigation measurements of TKA limb alignment do not correlate, *Clin Orthop Relat Res*;466:2736-44

Yamamoto S (1979) Total knee replacement with the Kodama-Yamamoto knee prosthesis, *Clin Orthop*;145:60

Yoo JC, Ahn JH, Sung KS, Wang JH, Lee SH, Bae SW, Ahn YJ (2006) Measurement and comparison of the difference in normal medial and lateral knee joint opening, *Knee Surg Sports Traumatol Arthrosc*;14:1238-1244

Yoo JH, Chang CB, Shin KS, Seong SC, Kim TK (2008) Anatomical references to assess the posterior tibial slope in total knee arthroplasty: a comparison of 5 anatomical axes, *J Arthroplasty*;23(4):586-592

Zalzal P, Papini M, Petruccelli D, de Beer J, Winemaker MJ (2004) An in vivo biomechanical analysis of the soft-tissue envelope of osteoarthritic knees, *J Arthroplasty*;19:217-223

Zhang W, Moskowitz RW, Nuki G, Abramson S, Altman RD, Arden N, Bierma-Zeinstra S, Brandt KD, Croft P, Doherty M, Dougados M, Hochberg M, Hunter DJ, Kwoh K, Lohmander LS, Tugwell P (2007a) OARSI recommendations for the management of hip and knee osteoarthritis, Part I: Critical appraisal of existing treatment guidelines and systematic review of current research evidence, *Osteoarthritis Cartilage*;15:981-1000

Zhang W, Moskowitz RW, Nuki G, Abramson S, Altman RD, Arden N, Bierma-Zeinstra S, Brandt KD, Croft P, Doherty M, Dougados M, Hochberg M, Hunter DJ, Kwoh K, Lohmander LS, Tugwell P (2007b) OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines, *Osteoarthritis Cartilage*;16:137-162

Appendix 1 – Oxford Knee Score

OXFORD KNEE SCORE

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

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

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

- None ☐
- Very mild ☐
- Mild ☐
- Moderate ☐
- Severe ☐

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

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

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

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

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

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

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

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

PTO

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

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

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

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

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

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

9.Has pain interfered with your usual daily work?

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

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

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

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

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

12.Could you walk down a flight of stairs?

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

Patients Signature…………………………………………….……………….DATE……………..

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

GJNH January 2010

Appendix 2 – Test protocols

a) Volunteer testing protocol

The non-invasive measurement of lower limb kinematics
Volunteer testing protocol

- Signed informed consent obtained – number assigned
- Volunteer information
  - Height
  - Weight
  - Age
  - Sex
  - Side
  - Thigh girth
  - Calf girth
  - Muscularity
  - Leg hair
  - Beighton Hypermobility Score
  - Knee trauma history
- Shorts worn (provided if necessary)
- Supine on examination coach
- Orthopilot with HTO software used – volunteer number entered into system
- Polaris camera two metres from trackers
- Thigh and tibia straps tightly applied
- HTO registration 1
  - Screen 1 MFT angle in full extension
  - Screen 2 Nil
  - Screen 3 Standing alignment in extension (two legs)

  Data erase and alignment data covered on screen

  - Screen 1 MFT angle in full extension
  - Screen 2 Nil
  - Screen 3 MFT angle in full extension

  Data erase and alignment data covered on screen

  - Screen 1 MFT angle in 0°
  - Screen 2 Varus-valgus stress - standard technique (0 - 5° flexion)
  - Screen 3 MFT angle in extension

  Data erase and then repeat varus-valgus stress x5
- HTO registration 2
  - Screen 1 MFT angle in full extension
  - Screen 2 Nil
  - Screen 3 Standing alignment in extension (two legs)

  Data erase and alignment data covered on screen

  - Screen 1 MFT angle in full extension
  - Screen 2 Nil
  - Screen 3 MFT angle in full extension

  Data erase and alignment data covered on screen

  - Screen 1 MFT angle in 0°
  - Screen 2 Varus-valgus stress - standard technique (0 - 5° flexion)
  - Screen 3 MFT angle in extension

  Data erase and then repeat varus-valgus stress x5
- Repeat test if agreement between initial MFT angles >2°

b) Volunteer data collection form

Study title:
Assessment of a non-invasive knee laxity measurement technique

University of Strathclyde Glasgow

Date:

Volunteer number:

Height (m): Weight (kg): Sex: M / F

Side tested: Left / Right

Thigh girth (cm): Calf girth (cm):

Muscularity: Leg hair:

Broughton Hypermobility Score:

Knee Trauma History:

Registration 1

Time start: Time finish:
Attempts at HJC registration:
Initial MFTA (°):
Notes:

Orthopilot file name:

Registration 2

Time start: Time finish:
Attempts at HJC registration:
Initial MFTA (°):
Notes:

Orthopilot file name:

Registration 3

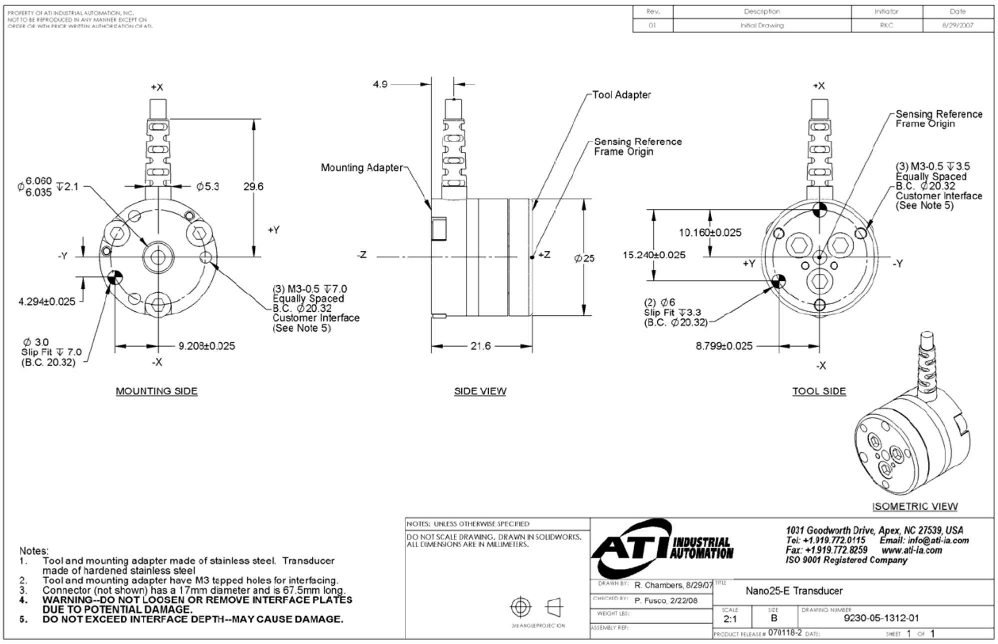
Time start: Time finish:
Attempts at HJC registration:
Initial MFTA (°):
Notes:

Orthopilot file name:

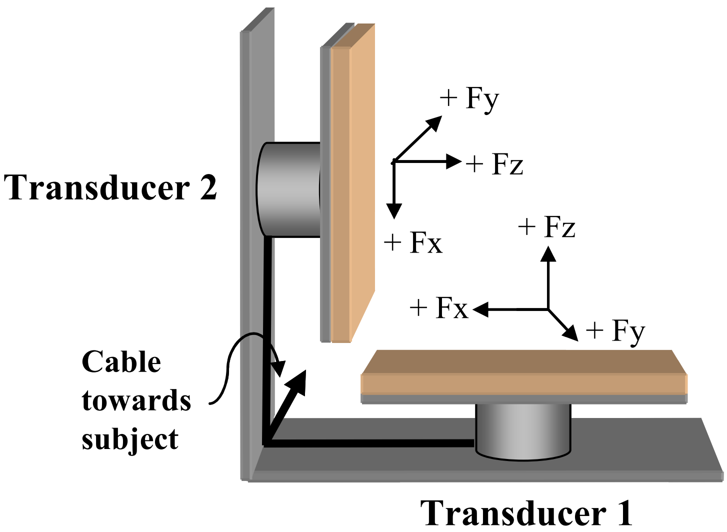
Version 1.0
UEC0910/06

Appendix 3 – Nanotransducer and FAD orientations

a) Definition of nanotransducer xyz axes



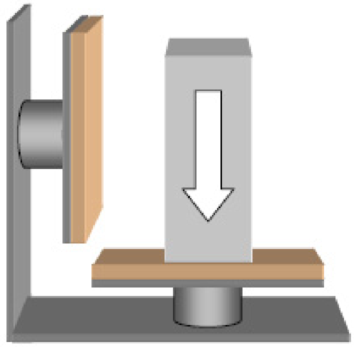
b) Orientation of nanotransducers within FAD



c) FAD orientation during Instron loading

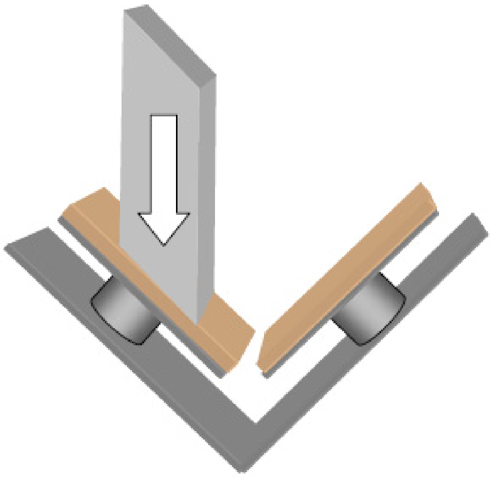
Position 1

- Load applied in z axis only
- 90° block attached to load cell perpendicular to polyurethane contact plate



Position 2

- Load applied in x and z axes
- 45° block attached to load cell
- Device rotated 45° around longitudinal axis from position 1



Position 3

- Load applied in y and z axes
- 45° block attached to load cell
- Device rotated 45° around transverse axis from position 1