**Implant alignment following Total knee arthroplasty: a quality indicator for the intra-operative performance of the operating team.**

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# Declaration

This thesis is submitted to the University of Warwick in support of my application for the degree of MD. It has been compiled solely by me and has not been submitted in any previous application for any degree.

Parts of the work presented in this this has been presented and published in the following conferences and peer review journals:

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The work presented (including data generated and data analysis) was carried out by me except in the cases outlined below:

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# Abbreviations

| | |
|---|---|
| 6DoF | Six degrees of freedom |
| ACL | Anterior cruciate ligaments |
| aFCA | Axial femoral component axis |
| AHRQ | Agency for healthcare research and quality |
| ANOVA | Analysis of variance |
| ANTS | Non-technical skills for Anesthetist |
| aTCA | Axial tibial component axis |
| BMI | Body mass index |
| CAD | Computer assisted design |
| CAS | Computer assisted surgery |
| cFAA | Coronal femoral anatomical axis |
| cFCA | Coronal femoral component axis |
| CRM | Crew resource management |
| CT | Computerised tomography |
| cTAA | Coronal tibial anatomical axis |
| cTCA | Coronal tibial component axis |
| cTFaA | Coronal tibio-femoral anatomical axis |
| cTFmA | Coronal tibio-femoral mechanical axis |
| df | Degree of freedom |
| DoH | Department of Health |
| EPOC | Explicit professional oral communication observation tool |
| EQ5D | EuroQol |
| FMA | Femoral mechanical axis |
| FMA | Femoral mechanical axis |
| FsEA | Femoral surgical epicondylar axis |
| FTMRA | Femorotibial components mismatch rotational angle |
| GCP | Good clinical practice |
| GRRAS | Guidelines for reporting reliability and agreement studies |
| HF | Human factors specialist |
| HSS | Hospital for special surgery score |
| ICC | Interclass correlation |
| K-W | Kolmogorov-Smirnov test |
| KSS | Knee Society Score |
| LLMA | Overall lower limb mechanical axes |
| LLR | Long leg radiograph |
| NHS | National Health System |
| NICE | Institute for clinical excellence |
| NIHR | National institute for Health and research |
| NHSLA | National Health System Litigation Authority |
| NOTTS | Non-technical skills for surgeons |

| | |
|---|---|
| NPSA | National patient safety agency |
| NRLS | National Reporting and Learning System |
| OA | Osteoarthritis |
| OKS | Oxford knee score |
| OSTAS | Objective structured assessment of technical skills |
| OTAS | Observational teamwork assessment for surgery |
| Oxford NOTECHS | Oxford non-technical score |
| Oxford NOTECHS II | Oxford non-technical score II |
| PACS | Picture archiving and communicating system |
| PCL | Posterior cruciate ligament |
| PRISMA | Preferred Reporting Items for Systematic Reviews and Meta-Analysis. |
| PROMS | Patient reported outcome measures |
| QALY | Quality adjusted life |
| r | Parson's correlation coefficient |
| RA | Rheumatoid arthritis |
| RCT | Randomised controlled trials |
| ROM | Range of movement |
| S-W | Shapiro-Wilk test |
| S3 | Safer surgical services study |
| SEIPS | Systems Engineering Initiative for Patient Safety |
| SF36 | Short Form 36 |
| sFAA | Sagittal femoral anatomical axis |
| sFCA | Sagittal femoral component axis |
| SLR | Short leg radiograph |
| SOP | Standard operating procedure |
| SPLINTS | Scrub practitioners List of Intraoperative Non-technical Skills System. |
| sTAA | Sagittal tibial anatomical axis |
| sTCA | Sagittal tibial component axis |
| sTFA | Sagittal tibio-femoral axis |
| TKA | Total knee arthroplasty |
| TMA | Tibial mechanical axis |
| TPS | TOYOTA production system |
| TRA | Tibial component rotational angle |
| TTA | Tibial tuberosity axis |
| UK | United Kingdom |
| US | United States of America |
| VAS | Visual analogue scale |
| VDU | Virtual Display Unit |
| WOMAC | Western Ontario and McMaster Universities Arthritis Index |

# Abstract

Evidence of inadvertent patient harm due to healthcare staff errors - both within the NHS and in other healthcare providers worldwide - prompted regulator-led changes to eliminate such distressing incidents to patients and medical staff alike. Surgical disciplines, including orthopaedic surgery, became a focus of attention given the scale of the problem within operating theatres.

Orthopaedic theatres are an example of a complex working environment that has been likened to an airplane cockpit whereby the delivery of unsafe and low quality service can lead to highly significant consequences. Around 32.6% of all surgical patient safety incidents reported by the NPSA are related to orthopaedics. Evidence suggests that harm incidents are influenced by the surgical team's non-technical skills, and can occur through an unpredicted combination of small, seemingly innocuous everyday events. It is also suggested that non-technical factors including the non-technical skills of the operating team can influence the technical tasks during surgery.

In elective orthopaedic surgery, one important technical task during TKA surgery is achieving a neutral limb alignment making it a suitable surrogate for technical success and quality indicator for intra-operative performance. The impact of malalignment on patient outcomes is not fully understood. A systematic review of the literature demonstrated that although malalignment appears to associate with poor procedure outcomes however, the evidence in the literature to support this conclusion is subject to several limitations. There is also variability in the assessment methods qualities and

a checklist to assess the radiological assessment methods is presented. Malalignment on the coronal plane is regarded as the most significant in determining long term implant survival. A novel X-ray method using custom made jig and trigonometry principles designed during this thesis has demonstrated higher agreement with CT scan than the commonly used conventional short leg X-rays in assessing coronal malalignment; (95% Limits of agreement = -3.616867 to 3.616867 for novel technique versus -6.333201 to 5.754254 for conventional short leg X-rays).

In order to explore the relationship between non-technical factors and technical success, successive TKAs were observed to collect data on surgical team's non-technical performance and the number of unwanted events. 3D malalignment was assessed using a low dose CT. Parson's correlation and regression analysis showed that better overall limb alignment following TKA correlates significantly with better intra-operative non-technical skills measured using the Oxford NOTECHS II score (r=-0.407, p=0.01), and not with eventless procedures (measured by the glitch count). The surgical teams' non-technical skills play a significant role in the team's ability to carry out technical tasks. If we are to provide optimal patient care we need to invest in improving non-technical skills in the theatre.

# Chapter 1 Introduction

## 1.1 Thesis aims and objectives

The aim of this thesis is to explore the association between technical success in the operating theatre and the non-technical skills and aspects of the surgical team and surgery in the operating theatres through achieving the following objectives:

a) Explore the notion of patient harm within the NHS and discuss the differences between the person-focused and the system approach to patient safety.

b) Identify a suitable environment for conducting the research questions proposed in this thesis.

c) Detailed description of malalignment following TKA surgery as a measure of technical success and to explore the most appropriate radiological method for the assessment of malalignment following TKA.

    i. Present a novel radiological method for the assessment of TKA malalignment on the coronal plane.

d) Perform a systematic review of the literature exploring the impact implant and/or limb malalignment following TKA surgery on patient outcomes.

e) Perform a real time observational study in the elective orthopaedics theatres exploring the association between Oxford NOTECHS II score and Glitch count (measures of non-technical skills and surgical process) and malalignment of TKA.

## 1.2 **Safety in the National Health System (NHS)**

The National Health Service (NHS) is "*the biggest single experiment in social service that the world has ever seen undertaken.*" Aneurin Bevan (1948)

In the UK, healthcare is provided primarily by the NHS. Since the time of its establishment in 1948, the central principle of this hugely ambitious system was to provide good health care to all [1, 2]. In its constitution, the NHS aspires to the highest standards of excellence and professionalism, and to the provision of high-quality care that is effective, patient-focused, and safe [3].

### 1.2.1 Insight into the problem of safety in the NHS

Safe care refers to the process of preventing harm to patients; harm can be in the form of physical or psychological injury, suffering, disability or death. The prevention of harm is best described by the National Patient Safety Agency (NPSA) as '*the process which involves the identification and management of patient-related risks, the reporting and analysis of harm-related incidents, the capacity to learn from and follow-up on these incidents, and the implementation of solutions to minimise the risk of them recurring'* [4].

Over a decade ago, health care providers in the NHS, and worldwide, were faced with damning evidence concerning the safety levels of care provided in the health care systems. Reports emerged from the US [5-7], Australia [8], Canada [9], and the UK [10] indicating that patients seeking medical attention were subjected to harm not from their underlying diseases rather unintentionally from the same people providing the necessary care needed within the health care systems. Surgical specialties and the operating theatre in particular, have been the focus of attention as it is reportedly where most patient harm occurs [5, 7, 11].

In light of this evidence, the UK health care government authority, the Department of Health (DoH), published a milestone report “An organisation with a memory” [12] detailing the extent of the problem. In its report it was evident that the true scale of the problem was unclear. The report conceded that safety incidents are likely to be under-reported or simply unnoticed by investigators due to the inadequacy of medical notes documentation [13]. In spite of this potential underestimation, the approximate rate of adverse events resulting in patient harm was around 10% of admissions [10, 12, 14, 15], which, at the time of these reports, were between 300,000 to 1.4 million events per year. In addition, over 6,600 adverse incidents involving medical devices were reported to the Medical Devices Agency in 1999, including 87 deaths and 345 serious injuries [12]. The financial consequences were equally major; around £400 million in clinical litigation settlements and an estimated cost of £2 billion a year in additional hospital stays alone [12]. In 2013/14, the National Health System Litigation Authority (NHSLA) made payments approximately totalling £1.2 billion in clinical litigation settlements across all of its schemes [16].

More recently, evidence from the notorious Mid Staffordshire hospital investigation revealed that the patient safety problems continue to exist. The Francis report [17] concluded that patient safety features high amongst other lapses in care provided to patients in this trust.  This report was further supplemented by the National Advisory Group on the Safety of Patients in England's report "A promise to learn- a commitment to act; Improving the Safety of Patients in England" highlighting several problem areas predisposing to patient safety failings and that the problem is likely to exist throughout the NHS trusts [18]. The recent reports have also triggered a further response from the UK government in renewing and reaffirming its commitment to the values of the NHS set out in its Constitution with a commitment to enhancing patient care and patient safety. These reports also stressed the fact that the NHS as an organisation is a world leading establishment with many strengths that should be celebrated and that these shortfalls are present in most health systems.

The impact of suboptimal care on patient outcomes is widely recognised [19-21]. There is the potential for distressing physical and emotional consequences to patient and their families. The magnitude of these distressing events can be clearly seen in the case studies presented in the DoH and Francis reports [12, 17]. Equally, such incidents can impact on the medical staff involved resulting in emotional distress and loss of morale [22].

### 1.2.2 Similarities with other industries & the transfer of knowledge

Before long, it became clear that the safety concerns in the health care are not unique to the industry. Other industries such as, aviation, offshore oil industry, and the nuclear industry have suffered comparable challenges in the past.  Moreover, these industries share similarities with health care in the ways of: tasks complexity, the diverse range of human skills required within operating teams, and the integrated role of technology. Similar to health care and more so to the operating room, these industries are regarded as high risk industries where the delivery of low quality service can lead to tragic consequences as seen in the airlines database of disasters [23], list of deadliest oil rig accidents [24], and database of nuclear reactor safety incidents [25]. As a result, these industries have invested significant time and money to develop safety management systems [26] and equip their teams with the right tools and skills [27] to achieve the desired high standards and to reduce adverse events.

The similarities discussed above have created an opportunity for healthcare as an industry to learn from the experiences of these industries. Research in the field of safety and human error in industries such as aviation is undeniably more advanced and refined. Their current safety records are far superior to that of healthcare. The organisational attitude to safety, the safety management systems such as, the extensive use of standard operative procedures and the crew resource management (CRM) programme [27] (details below) are some of the main reason for their success over the past five decades. In the centre of these activities is the realisation that humans are prone to errors, and team members must develop the necessary skills in order to stop threats propagating into accidents. These skills will be one of the main areas of focus of this thesis.

### 1.2.3 Identified issues to date

The realisation of the extent of the problem of safety in healthcare has resulted in patient-safety becoming a primary focus for the health authorities. This resulted in a change of direction in tackling the problem of patient harm in the NHS. The DoH initiated safety campaigns [4] and set up several bodies specifically designed to tackle the issue. The results, based on lessons learnt from other industries and the available research, were to target key areas that were deemed necessary in reducing patient harm including:

1. Creating a safe and open culture; a culture where the health organisation is aware of the potential for things to go wrong. Both the shop-floor staff and the senior management are able to acknowledge mistakes, learn from them, share the information openly, and take action to put things right when an incident happens.
2. Incident reporting; setting up a mechanism for reporting and analysing safety related incidents in a non-punitive manner.
3. Learning from mistakes; it is equally important that the causes behind safety related incidents are explored and the lessons learnt implemented to prevent the same incidents from happening again; which is a key finding of several reports investigating patient harm related incidents.
4. Systems approach to safety; (described in detail below), this approach recognises that the majority of patient harm from safety related incidents are

not solitary actions of individuals, but rather are from inadequate and suboptimal systems that these individuals are interacting with.

### 1.2.4 Systems approach to patient safety

Efforts to investigate and analyse adverse events and poor outcomes have been dominated by a wide spread 'blame and shame' culture. Human errors and individual underperformances have predominately been the outcome of these investigations; usually after retrospective analysis of case notes without appreciating the biased benefit of hindsight. This can be described as a person-centred approach to patient safety. More recently, a different approach has been providing more understanding of the role of humans and systems in the patient-related adverse incidents; the systems approach to safety.

A systems approach to safety is a philosophy that sees human errors as a consequence of inadequate components of the system [28, 29]. A holistic theory recognising that working systems in organisations such as health care are made up of complex processes put together creating the components of the system. These complex processes are inherently weak and are embedded with latent failures that predispose the humans working within them to err. This approach has become a major contribution to the understanding of patient harm and adverse events. It is probably one of the most important lessons the health care has learnt from other high-risk industries.

The system theory of threat and error is eloquently described in James Reason's model as 'holes in the Swiss cheese' [28] (Figure 1-1). In this model, in-row layers of Swiss cheese demonstrate the working processes including the safety measures and defences built into an organisation. Latent failures or inherent weaknesses in the system are represented by the holes in the layer of Swiss cheese. In the recently developed version of the model, these layers are constantly in motion, representing the day to day changeable nature of these processes including the latent failures embedded within them. Similar to real life scenarios, many potential adverse events might pass through one or two layers of safety, but be captured by the next. An adverse event, referred to as an 'Accident' in this model, occurs when a series of in-line failures (holes) combine to allow the advancement of an event, referred to as 'Hazard', across all layers. The last layer of cheese in this model represents the role of humans at the sharp end. Human actions and subsequent errors are described as the active failures and have been subdivided into slips, lapses, mistakes or procedural violations.

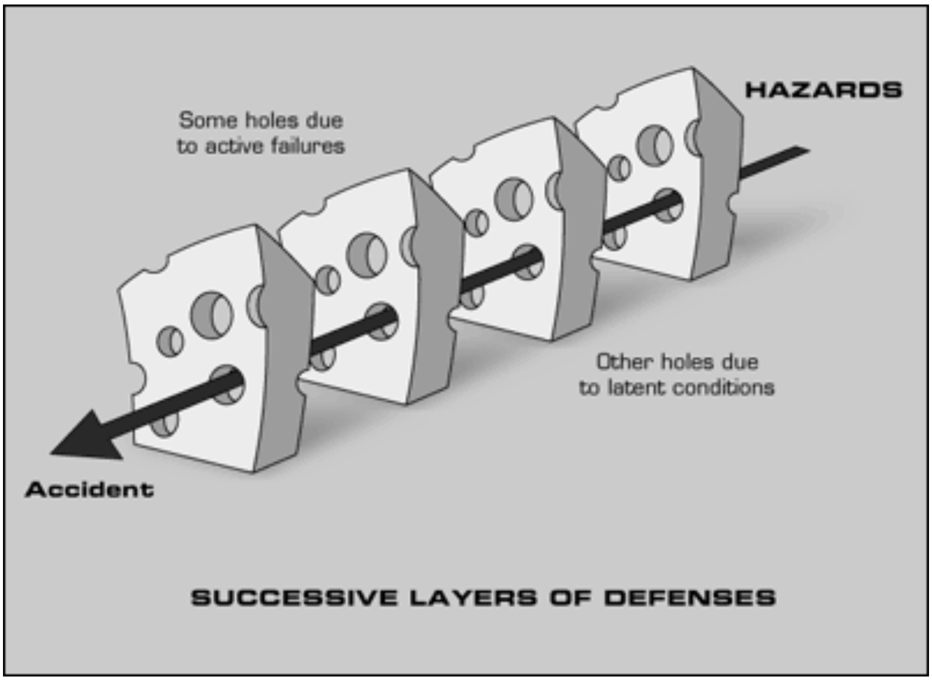



*Figure 1-1: Swiss cheese model by James Reason [28]*

When applying the Swiss cheese model to the health care system, it is evident that latent failures exist within safety process measures. Harm often appears to occur mostly through a sequence of small, seemingly innocuous everyday events that combine unpredictably to affect the patient [30]. Organisational complexity, high-technology equipment and the lack of systematic communications and staff teamwork training have been highlighted as issues and inherent weakness in the safety processes which create the grounds for errors and harm to patients in the healthcare. This has been most demonstrated by observational studies conducted in high risk surgery theatres such as, paediatric cardiac surgery, where serious safety and quality issues have associated with the accumulation of small observable process deviations or non-operative undesirable events [30, 31].

A variety of other theoretical models and frameworks have been proposed to help classify, understand and analyse the causes of error and patient-harm related events in healthcare. One model that helps understand the role of interacting systems resulting in adverse events is the Systems Engineering Initiative for Patient Safety (SEIPS) Model described by Carayon et al [32] (Figure 1-2). In this model, the application of human factors, systems engineering concepts and methods help understand the complexity of process the health care industry face. The discipline of human factors in healthcare is concerned with '*enhancing clinical performance through an understanding of the effects of teamwork, tasks, equipment, workspace, culture, organisation on human behaviour and abilities, and application of that knowledge in clinical settings*' [33]. This model analyses the human's interactions with four key aspects of a work system: task, environment, organisation, and technology, thus acknowledging five dimensions contributing to risk and error.

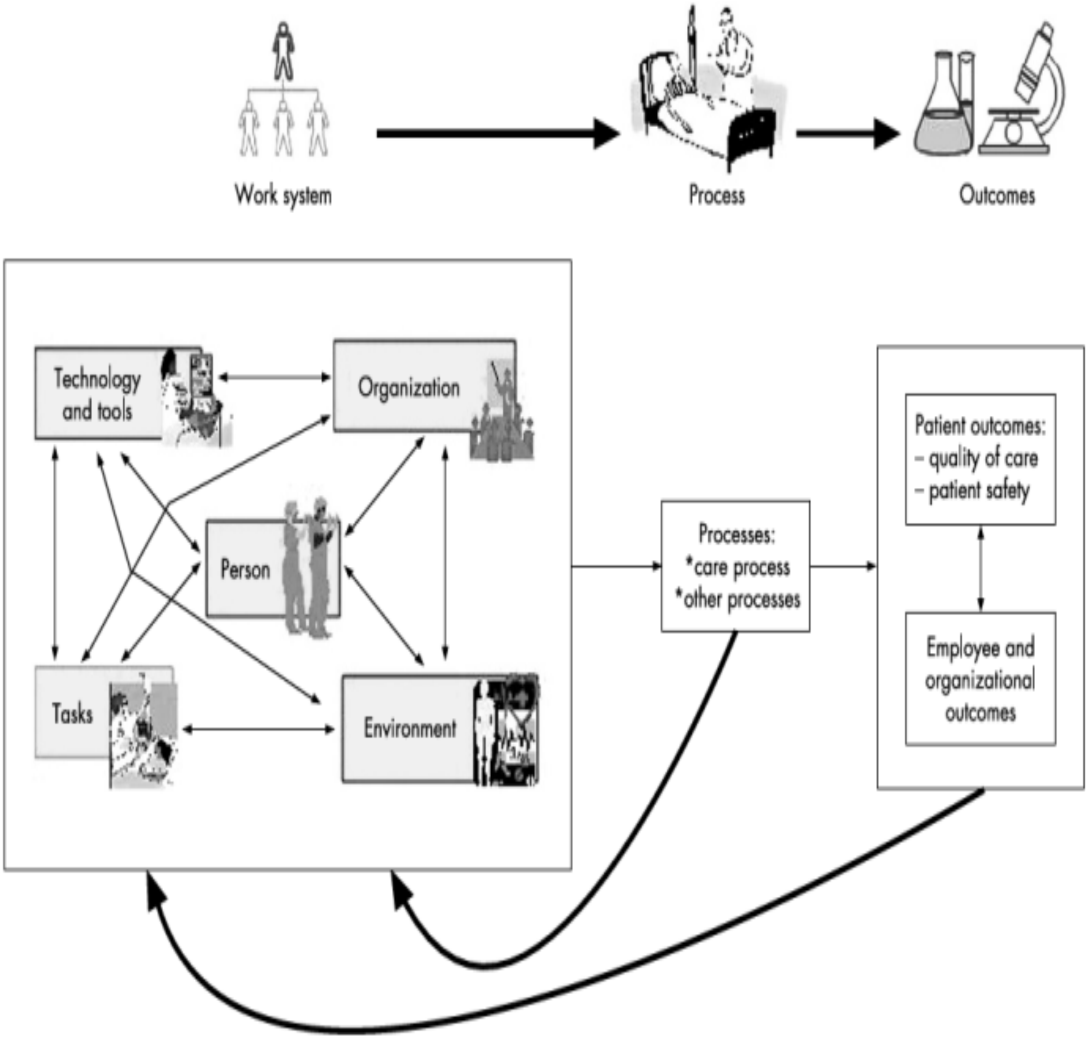



*Figure 1-2: Systems Engineering Initiative for Patient Safety (SEIPS) model of work system and patient safety [32]*

Another model described by McCulloch et al [34] argues that the components which most influence safety are the culture, technology and system in the workplace, as described in their 3D model of influences on patient safety and risk (Figure 1-3). The significance of this simple but comprehensive model is that it is data-driven and supported by testing on observation of real instances. Where the Reason model recognises only the potential for different weaknesses in the system to coincide, the

3D model acknowledges that such features may interact with each other in many different ways, both helpful and harmful, as represented by the double-headed arrows in the diagram. The 3D model is explicitly designed to focus on safety influences at the micro-system (ward or operating theatre) level.

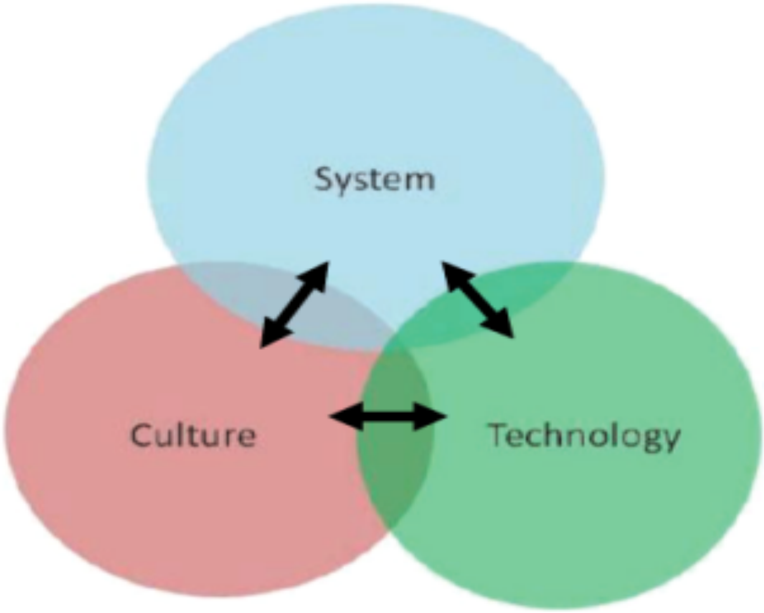



*Figure 1-3: The 3D model of influences on patient safety and risk [34]*

In contrast, Lawton et al [35] produced their wide-ranging framework of contributory factors to patient safety incidents within hospital settings. It represented a summary of the empirical evidence in the area using the existing evidence to develop a clearly defined and hierarchically ordered framework that describes contributory factors from the sharp end to latent.

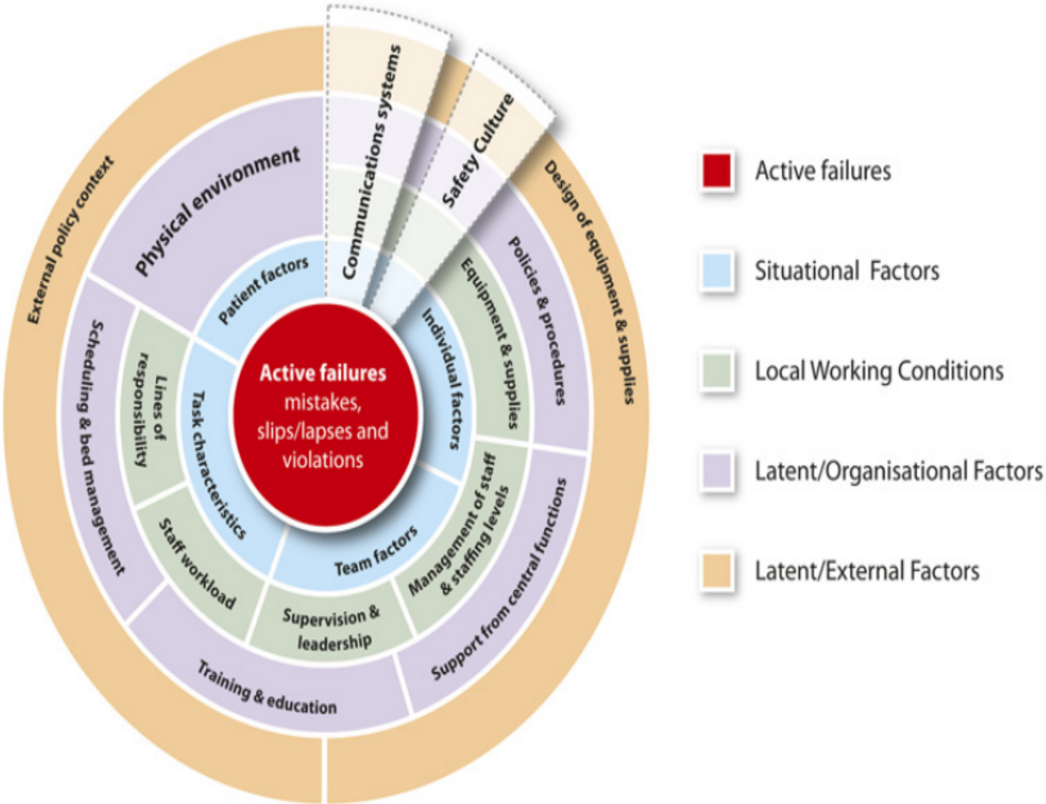



*Figure 1-4: The Yorkshire contributory factors framework [35]*

The key message shared in these models and frameworks is that human error is nothing but one link in the chain of events within a vulnerable system that leads to a patient harm-related incident. If efforts to rectify this problem stop at identifying these individuals and subjecting them to disciplinary actions, i.e. blaming and shaming them, then a valuable opportunity to make the healthcare systems better and more resilient has been missed. This would also leave the working process within the system unchanged and vulnerable for a similar error to occur, a likelihood which has been clearly demonstrated in the literature with around 50% of harm incidents being reoccurrences [4].

#### 1.2.4.1 Safety improvement interventions in healthcare

The benefit of adopting a systems approach to safety does not stop at identifying the root causes behind adverse events or understanding the course of events in the run up to a patient harm incident. Instead, a systems approach provides the basis on which any changes or interventions to improve patient safety in health care can be designed. A variety of interventions are currently available each targeting different aspect of healthcare. Based on the targeted improvement, these interventions can be loosely grouped into: Teamwork and communication interventions inspired by the aviation model Crew Resource Management (CRM) for example the work presented by McCulloch and Catchpole [36, 37], process improvement intervention such as Lean Production adopted from the manufacturing sector for example the work presented by Kreckler et al. [38], and organisational culture intervention as seen in the work presented by Morello et al. [39].

Understanding the relationship between humans and the work environment will be the starting point for any successful intervention in the health system. These interventions must avoid the commonly practiced ‘reactive’ attempts to address isolated aspects of the system in response to an event or accident, or the initiatives that target one aspect of care in order to meet management targets in a top-to-bottom fashion. Instead, a ‘proactive’ approach with a data driven assessment of systems and processes led by the people operating these processes followed by a more holistic intervention programmes directed simultaneously at people, teams, tasks, workplaces and institutions must be adopted. This will allow an opportunity for designing a robust system free of latent failures across a wide range of processes.

#### 1.2.4.1.1 Team's non-technical skills training interventions

A team is a group of people with a full set of complementary skills required to complete a common task, job, or project. In the operating room, the operating team consist of several members from different disciplines including, anaesthesia, nursing, and specialty surgery. Together, they are responsible for the patient care and safety. Non-technical skills are the generic behavioural skills that strengthen the team members' technical ability to perform tasks [36]. Essential non-technical skills can be structured into several dimensions based on the experience developed in the field of aviation [40]. These include leadership and management skills, teamwork and cooperation, problem solving and decision making, situation awareness, and communications and interactions skills. The role of the non-technical skills has increasingly become evident in enhancing patient safety. Smits et al [41] found human safety behaviours to contribute to 61% of the adverse events. Teamwork-related issues cause the most stress inducing events to surgeons during surgery [42]. There is a widespread belief that healthcare team's effectiveness can be improved by improving non-technical skills such as, undertaking specific training to improve interpersonal interaction and communication [37].

In aviation, the team's cognitive or non-technical skills training is integrated in the crew member's training; referred to as Crew Resource Management (CRM). CRM can broadly be defined as the utilisation of all available human, informational, and equipment resources toward the effective performance of a safe and efficient flight. CRM is an active process by crew members to identify significant threats to an operation, and to develop, communicate, and carry out a plan to avoid or mitigate each threat. CRM reflects the application of human factors knowledge to the special case of crews and their interactions [27]. This error management model has been adapted for use in the clinical environment. The application of non-technical skills training has resulted in improvement in staff attitudes to safety, team non-technical performance, and reduced error rates both in the operative field and outside it [36, 43-45].

However, there remain many unanswered questions; what is the mechanism by which non-technical skills failures result in patient harm? Which domains of non-technical skills have the biggest impact on team's technical performance? What aspects of technical performance are most affected by non-technical skills? Therefore, for the success of non-technical skills focused interventions, a clearer understanding of the complex and interdependent relationships between non-technical skills and technical performance is required.

#### 1.2.4.1.2 Surgical process redesign approach and interventions

In a complex system such as healthcare, processes are designed to facilitate the progression of patients through the various departments in the system from identification to final outcome, ideally discharge with a clean bill of health. This may involve multiple small scale individual processes such as investigations, receiving medication or surgery all of which work together to achieve the target outcome. These processes govern the way staff perform their jobs and deliver their services. It is therefore intuitive to assume that systems with superior processes perform better than others resulting in better patient outcomes. In this thesis, the surgical process of interest is the orthopaedic operation within the theatre environment. This refers to the patient's journey between entering and exiting the operating room. In this context, an optimum process is seen as the smooth, uninterrupted, and natural progression or flow of the surgical procedure.

Evidence from observational studies in high risk operation such paediatric cardiac surgery [30] has shown that deviations and disruptions to the surgical process during an operation can result in patient harm. These seemingly insignificant events in isolation are believed to impede the surgical team's ability to deal with more significant events effectively and are often ignored or managed on *ad hoc* basis by members of the team however (as shown in Reason's Swiss cheese model) these latent failures can accumulate and escalate to more significant threat to patient safety. In this thesis, these events are referred to as 'Glitches' and part of the work an investigation into the relationship between 'Glitches' and patient safety is undertaken.

Redesigning processes as a strategy to reduce process 'Glitches' and improve efficiency in the complex working environments is a common practice in the car manufacturing industries. This can be best demonstrated in TOYOTA car manufacturing plants and the

TOYOTA production system (TPS) where the Lean philosophy is applied. Lean is the term used to describe a set of concepts that utilises principles aiming to reduce waste and improve productivity. These are customised to local requirements to achieve '*kaizen*' (Japanese for a process of contentious improvement; Kai meaning change and Zen meaning good) and involves a continuous process of procedures re-evaluation to reduce unnecessary steps and streamline processes, redesign the work environment to be more clutter free, bringing into the open process problems to allow targeted and multidisciplinary solutions, and deliver a customer-focused service. The popularity of this philosophy has increased and attracted the attention of rivals within the car manufacturing industry such as Rolls Royce and various other industries including the giant supermarket Tesco. This indicates that this philosophy may also play a significant role in improving working environment in other large and complex industries such as the NHS.

With the popularity of the system theory gaining momentum in healthcare, it was inevitable that existing process would be examined and attempts of system redesign emerge [32]. Studies were able to show advantage in applying Lean principles in healthcare and improve the system impacting positively on patient journey within a ward setting [46]. The majority of these studies have interventions designed in collaboration with experts in the field of Lean. These experts have the advantage of being external to the system and therefore have a fresh perspective on the problems that may appear as the norm for individuals within the system. One of the main challenges for these interventions is the ability to demonstrate a measurable change that is clinically relevant to the staff and their patients' outcomes.

#### 1.2.4.2 Application in the operating theatres

In hospitals, the operating theatre provides a challenging and complex environment. This can be attributed to many factors including: the nature of the tasks involved, the range of human skills required within an operating team, and the role of technology. These elements have been identified in other high-risk environments such as aviation. Similarities in the working environment between high-risk industries and healthcare have been suggested. For example, the operating room has been likened to an airplane cockpit and a nuclear power station control room, and it is these similarities that became the bases for applying the tools developed in other industries in healthcare.

Because the operating theatre has become a focus of attention, many studies have been conducted investigating the levels of patient safety within this work environment. These studies, mainly observational, have focused on the non-technical aspects of surgery. Observers have either been from medical or human factors backgrounds and have collected real time data. Different parameters of these non-technical processes were analysed by different groups of researchers. A group of studies focused on the role of the team's non-technical skills. These studies gained motivation from the success of non-technical skills training such as, CRM in the aviation industry. Various adaptations of the aviation designed scales and observational tools for use in the operating theatres to facilitate data collection were used; one example that is used in this thesis is Oxford non-technical skills scale (NOTECHS) [47]. These studies went on to highlight the role of staff teamwork skills, communication failures [48, 49], information sharing [50], and cultural and hierarchal barriers in increasing the risk of errors.

Other studies focused on the impact of non-surgical events during the course of surgery on the process of surgery such as interruptions [51], noise [52], and distractions [53]. These studies were influenced by the results of analysing patient harm-related incidents suggesting the presence of co-incidental accumulation of a number of minor failures prior to an adverse event. Other non-technical aspects of surgical performance including dealing with fatigue, stress, and seeking performance feedback have also been described [54]. These studies have provided a variety of models to identify and categorise these events; for example the Glitch counting methods [55] used in this thesis. The significance of these models is that they provide researchers with methods to analyse unwanted events in the surgical process and help shape the interventions designed to eliminate them.

#### 1.2.4.3 Choosing a suitable technical outcome measure

While there are a considerable number of studies that have analysed adverse events during surgery in the operating theatres, few studies assessed the influence of non-technical performance on technical outcomes. Studies investigated for an association between the two, have usually focused on crude technical outcomes such as survival rates. Patient safety in surgery has moved beyond survival rates and is now considered in a wide range of surgical outcomes including complication rates, quality of life outcomes, and readmission rates. There is also a need to incorporate other outcomes directly related to technical success. For example, in Orthopaedics surgery, as will be discussed below, certain technical aspects such as alignment of implants in knee arthroplasty, are an important procedural goal and can potentially influence patient outcomes following surgery. Several aspects must be considered when identifying a suitable patient-related technical outcome measure for this research. For the purposes of this thesis, the outcome measure must demonstrate evidence that it measures what it claims to measure i.e. validity, it must produce results that are reproducible and internally consistent i.e. reliability, and it needs to be clinically appropriate and relevant in answering the research question.

Although the precise extent remains unclear, evidence suggests that certain aspects of non-technical performance can enhance or, if absent, contribute to the deterioration of technical performance [45]. There appears to be a need to understand the interaction between non-technical performance and outcome in terms of technical performance. This is very important because this has the potential to improve patient safety within the theatre environment. So far, within orthopaedics there is little research that has directly addressed this gap of knowledge. Therefore this work will provide the most comprehensive evidence to inform this highly important field. The main goal of this work is to address the question: Is there an association between non-technical aspects of surgery and technical outcomes?

## 1.3 Orthopaedics surgery: a multidisciplinary and complex speciality

Orthopaedic theatres are a good example of a complex working environment. Orthopaedic surgery, which is the treatment of bone and joint disease such as osteoarthritis, back pain, congenital deformities, fractures and all various musculoskeletal injuries, can be loosely divided into trauma and elective surgery. Trauma surgery deals with musculoskeletal pathologies requiring surgical interventions mostly resulting from acute injury or trauma such as fractures. Elective surgery deals with other non-acute and usually less urgent causes such as knee osteoarthritis requiring TKA. An important distinction between the two is the time pressure and urgency to operate. Elective surgery is usually planned-in-advance surgery and is relatively more predictable in comparison to trauma surgery. Similar to other surgical specialties, elective orthopaedics involves multidisciplinary teams working together to deliver optimum patient care. During an operation, the team members are constantly managing a wide range of tasks. In orthopaedics, teams are also regularly dealing with changing tools and technology in a field where reliance on highly specialised equipment is a prominent feature. These characteristics potentially make elective orthopaedics an environment susceptible to errors. Evidence for this is noted in the NPSA's National Reporting and Learning System (NRLS) were 900 000 errors have recently been reported and over 3 million reported overall. The database has revealed that a high proportion of all surgical patient safety incidents within the NHS are related to the specialty of orthopaedics and trauma (32.6%) [56]. Analysis of the NHSLA between 2005 and 2010 revealed 515 (11.2%) relating to orthopaedics identified from the 4609 in the NHSLA database, of these 298 (58%) involving total knee replacements (TKRs) [16]. In the light of this evidence, it seems pertinent to conduct patient safety focused research in the field of elective orthopaedics. In addition, a number of operations in elective orthopaedics, such as TKA, have a fairly standardised surgical process that would create a suitable environment for measuring the effects of interventions, in particular, ones that involve a system redesign.

## 1.3.1 Total knee Arthroplasty (TKA)

### 1.3.1.1 The Knee: structure, embryology and function

The human knee joint (Articulatio Genu) is the largest synovial joint in the body with its main articulation between the femoral and tibial condyles. Although formerly described as a hinge-joint, it is a complex joint with 3 articulations; two condyloid joints between each femoral condyle and its corresponding tibial condyle; and a third between the patella and the femur [57].

The movements at the knee joint are flexion and extension, and, in certain positions of the joint, internal and external rotation. The main difference in movements compared to those in a typical hinge-joint such as the elbow are that (a) the axis around which motion takes place is not a fixed one, but shifts forward during extension and backward during flexion; (b) the commencement of flexion and the end of extension are accompanied by rotatory movements associated with the fixation of the limb in a position of great stability [57].

The knee joint orientation, limb axes, and alignment are important factors during the planning knee operations such as TKA. Details of these are presented later in the thesis

### 1.3.1.2 Arthritis of the knee

The knee is one of the joints most frequently affected with arthritis [58, 59]. Pathologically, arthritis is a joint disease generally characterised by structural damage to the articular cartilage associated with new bone formation (osteophytosis), changes to the subchondral bone (both sclerosis and cysts formation), thickening to the joint capsule, and a varying degree of synovitis [60]. The X-ray appearance of these changes seen on the weight bearing images of the knee help confirm the diagnosis [61, 62]. The clinical manifestations of this syndrome include joint pain, varying degree of functional limitation, and reduced quality of life [63, 64]. However, there is a poor link between changes on X-rays and symptoms [64]. In fact, it is not uncommon for patients to have no symptoms despite evidence of structural damage to cartilage and significant radiological evidence of arthritis. The commonest form of knee arthritis is osteoarthritis (OA) [58, 65]. The cause for the majority of knee osteoarthritis is unknown and is called idiopathic or primary. There is a strong hereditary component with an unclear genetic predisposition mechanism [60, 66]. Other causes of knee arthritis include inflammatory diseases; e.g. Rheumatoid arthritis (RA). Management of knee arthritis requires a holistic approach to patient care and surgery, such as TKA, is typically reserved until other non-operative treatments fail to provide adequate relief of symptoms [64].

### 1.3.1.3 TKA: Features and advancement to date

TKA is an elective surgical intervention designed for the treatment of end-stage knee arthritis. Although there are many variations of the procedure, generally speaking, TKA aims to replace the weight bearing surfaces of the knee, in particular, the medial and lateral tibio-femoral compartments.

Historically, the first attempts to replace the knee surfaces date back to the 1860 [67]. At the time, soft tissue of various origins was interposed within the knee joint surfaces with or without bone resection. Since then, this procedure has evolved dramatically and many designs have been developed [68-71]. In 1973 the total condylar knee was first produced [72, 73]. It involved replacing the weight bearing parts of the joint surfaces with non-connected artificial component. This successful design would become the basis of most modern implants available in the current market.

The main features of a total condylar TKA implant include a round ended, metal-based femoral component articulating with a congruent tibial component. The tibial component can either be completely polyethylene or metal-based base with a polyethylene inserts mounted on it (Figure 1-5).

*Figure 1-5: An example of TKA design (Nexgen, Zimmer ®) [74]*

The design provides larger contact areas between the components, and with a central eminence on the tibia, to allow joint movements while achieving medial-to-lateral stability and reducing contact stress. In some cases the patella is also replaced with a polyethylene component. Other important TKA design features include the degree of constraint. Several types are currently available such as unconstrained, semi-constrained, and fully constrained or hinged. The most commonly used, the unconstrained design, can either be cruciate retaining or cruciate sacrificing. Another categorisation incorporating current available deigns would be:

1. Cruciate retaining.
2. Medial pivot.
3. Posterior stabilising using a posterior peg.
4. Hinged components with a rotating platform.
5. Pure hinge.

The differences between the different designs and the biomechanical consequences are not within the remit of this thesis. However, only non-constraint designs were considered for this thesis. This is because constrained implants are usually inserted in the presence of a loss of bone stock making it difficult to assess alignment both intra- and postoperatively.

#### 1.3.1.4 TKA is a large volume operation with variable outcome

TKA is one of the most commonly performed orthopaedic procedures. In the UK, a steady rise in the number of procedures over the past five years reaching over 77,000 in the year 2013 in England & Wales [75]. In addition, the prevalence of degenerative joint arthritis is expected to increase as more of us reach an advance in age. Consequently, it is estimated that there will be a sharp rise in the number of patients requiring TKA in the future [76].

Pain relief, improved function, greater patient satisfaction, and implant longevity are measures of a successful outcome. TKA is considered an effective procedure in the majority of patients, with the bulk of published results reporting a 'good' or 'excellent' outcome in approximately 80%- 90% of patients [77-80]. National registries and various studies have also demonstrated survivorship analysis with over 95% survival of TKA reported in the range of 10 to 15 years [75, 81, 82].

While the majority of TKA surgery has shown good or excellent long term results, as many as 20% of patients 1 year remain unsatisfied with outcome [83-87]. Achieving adequate pain relief, meeting pre-operative patient expectation, better functional outcomes, and hospital experience are the most significant predictors of satisfaction following TKA [79, 83-85, 87-89].

Regardless of the outcome measure chosen, the success or failure of the procedure has been attributed to a number of factors including: patient-related factors such as pre-operative functional state [90, 91], procedural-related factors and surgeon's experience [92-97], the choice of implants [80, 98], as well as outcome measures related factors [99-101]. It is apparent that there remains a difficulty in knowing for whom the procedure is less effective and which factors help or hinder effectiveness.

The variability in TKA outcomes has a wider implication if the size of investment made by the NHS towards this procedure is considered. A TKA cost the NHS an average of £7458 per patient [102]. Furthermore, if an implant fails, a revision TKA has further financial costs without considering the increased health risks to patients. Based on the gain in quality-adjusted life (QALY) [103], both primary and revision procedures are below the £20,000 to £30,000 /QALY range that the National Institute for Health and Clinical Excellence (NICE) considers cost-effective [103]. As the NHS expenditure is squeezed due to the challenging financial situation, it is imperative for health intervention such as TKA to be cost effective and deliver adequate outcomes.

### 1.3.2 The technical considerations of TKA

Technically, several challenges must be overcome to produce an acceptable TKA result. A detailed account of a the technical steps during a TKA procedure is presented later in this thesis, though, these can be summarised into the main areas:

- Appropriate bony cuts
- Adequate soft tissue balance
- Compatibility between tibio-femoral articulation and the quadriceps mechanism
- Satisfactory fixation of prosthesis
- Perfect alignment
- Good wound management.

The surgeon's objectives are to create appropriate bony cuts, maintaining the joint line at the appropriate level, and achieve compatibility between the joint articulation and the quadriceps mechanism including the patella. The soft tissues around the knee must be adequately balance to produce sufficient tension without restriction to the knee range of motion or excessive compression on the polyethylene. And finally, for the mechanically-aligned TKA, which is the sole method of TKA included in this thesis, it is important to align the implants perfectly on the three planes; coronal or frontal, sagittal or lateral, and axial planes, resulting in a neutrally aligned limb.

Another more recent philosophy for TKA implantation is the kinematically aligned TKA [104, 105]. Kinematic alignment aims to replicate the patient's pre-existing anatomy rather than create a 180° limb axis. By placing the femoral component so that its transverse axis coincides with the primary transverse axis in the femur about which the tibia flexes and extends. With the removal of osteophytes the original ligament balance can be restored and the tibial component is placed with a longitudinal axis perpendicular to the transverse axis in the femur. For the purposes of this thesis, the term TKA will be used to describe mechanically-aligned TKA unless specifically stated.

#### 1.3.2.1 Alignment and TKA

Alignment following a TKA refers to two distinct but somewhat related concepts; these are the overall limb alignment, also referred to in the literature as the limb mechanical axis, and the TKA implants' alignment. Implant components are positioned on the appropriate bone relative to each other and/or in relation to a group of theoretical planes and axes (discussed below). Although these two alignment concepts should be treated separately, they are interconnected. In fact, the final implant alignment is one of the major determining factors of the overall limb alignment. As a result, malalignment errors in any one parameter of alignment can result in an alteration to the other parameters.

During TKA, limb and implant alignment are both planned and achieved utilising specialised equipment 'jigs' that relies on several anatomical landmarks to position. After accessing the joint, the surgeon positions the specifically designed jigs along the bones axes and uses the saw to make the bony cuts. When making these bone cuts, the surgeon takes into account the severity of bone loss and the condition of the soft tissues around the joint. The bone cuts are made to accommodate the implants chosen by the surgeon after a series of checks and trials. The implants are then fixed directly or more commonly using bone cement - when using cemented implants - onto the respective bones. The ultimate goal of these well-rehearsed procedural processes and surgical steps is to produce a neutrally aligned limb with a mechanical axis of 180° and no rotational mismatch between the components.

### 1.3.3 The assessment of TKA alignment post-operatively

The assessment of alignment following a TKA can be done using several methods. The more effective and most commonly used method is using radiological techniques. Similar principles are applied for the assessment of alignment as those to the construction of alignment during surgery. The same anatomical landmarks can be identified radiologically and can aid the accurate assessment (within 1°) of alignment parameters. In the literature, several terms have been interchangeably used to describe the various parameters of alignment. In this section, the concept of alignment is broken down into its main components, in order to identify taxonomy for this thesis.

The relevant anatomical landmarks seen on the radiological images are utilised to establish the axes on the various planes. These axes are then used to calculate the components position in relation to the bones. Although this may appear straightforward, many factors may cause systematic errors during the assessment of alignment, significantly, the modality of radiological technique and the referencing system used. For these reasons, inconsistency in describing malalignment has been identified in the literature. Prior to describing the various methods available for measuring alignment following TKA, a detailed discussion of the concept of alignment including the workings and boundaries of its radiological assessment is presented.

### 1.3.3.1 Anatomical Planes

Both overall limb alignment and components alignment are controlled on three anatomical planes; these are the coronal, sagittal, and axial planes. The coronal or frontal plane is the plane running through the centre of the limb from side to side dividing it into a front and back section (Figure 1-6). Malalignment on this plane can result in a valgus (outward deviation of the distal segment of the bone/joint relative to the body) or varus deformities (inward deviation of the distal segment of the bone/joint relative to the body). The sagittal or lateral plane is a vertical plane running through the limb from front to back dividing it into right and left sections (Figure 1-6). Malalignment in this plane results in a flexion or extension deformity (forward or backward deviation of the distal segment of the bone/joint relative to the body respectively). Finally, the axial or transverse plane is the horizontal plane running through the limb dividing it to proximal and distal sections (Figure 1-6). Malalignment on this plane results in internal or external rotational deformity.

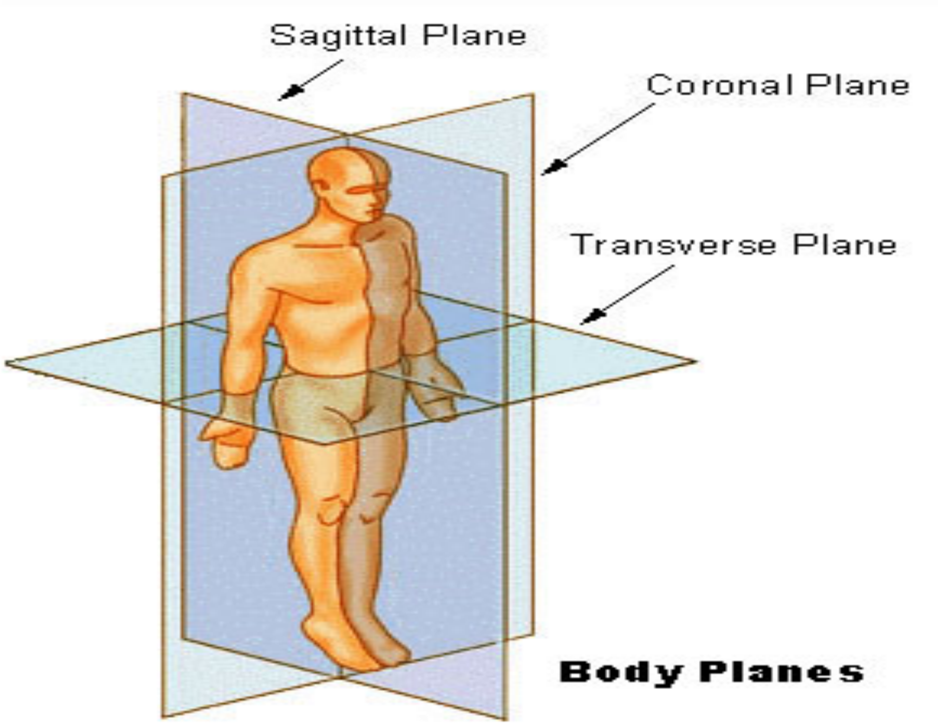



*Figure 1-6: Body planes*

### 1.3.3.2 Anatomical landmarks

When considering TKA alignment, several key anatomical landmarks must be identified, most importantly, the centre of the femoral head, the centre of the knee, and the centre of the ankle. Establishing the location of these landmarks aids the restoration of alignment during surgery. Equally important, these anatomical landmarks are used in the radiological assessment of alignment following surgery. In the literature, various methods and systems have been used to identify these landmarks [106-108]. The anatomical landmarks that are used for the assessment of alignment following TKA, and are of interest to this thesis, are illustrated in Figure 1-7.

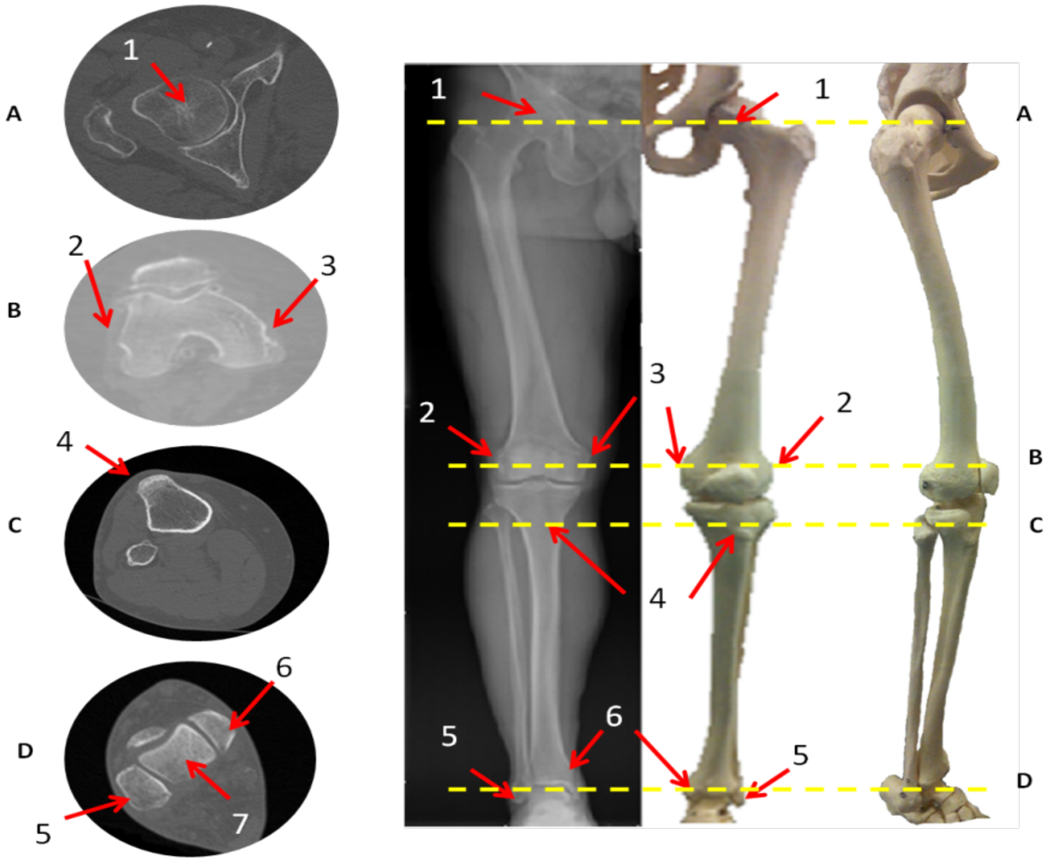



*Figure 1-7: Hybrid figure showing anatomical landmarks on a radiological image and saw bone skeleton of the lower limb*

Yellow dotted lines are cross sections with the CT scan appearance at each level on the left. 1= Femoral head, 2= Lateral femoral epicondyle, 3= Medial femoral epicondyle, 4= Tibial tuberosity, 5= Ankle lateral malleolus, 6= Ankle medial malleolus, 7= Ankle Talar dome.

i. **The centre of the femoral head** can be identified radiologically using a Mose hip template [109] or, more recently, using computer software on digital images of the femoral head. In both methods, the centre of a best-fit circle positioned within the cortex of the widest part of the femoral head on two different planes represents the centre of the femoral head Figure 1-8

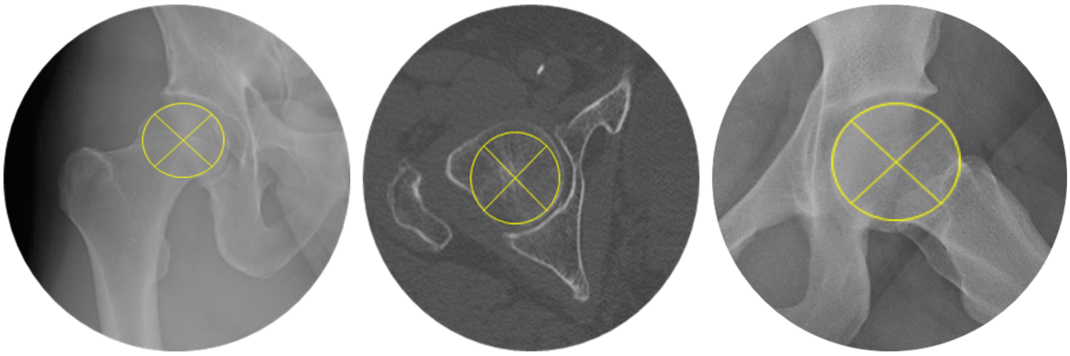



*Figure 1-8: Identifying the centre of the femoral head using a best fit circle on all three planes; plain X-rays for the coronal and sagittal views of the hip joint, and CT slice image through the largest part of the femoral head for axial view.*

ii. **The centre of the knee** is more challenging to identify; more so when assessing radiological images of TKA. Anatomically, the knee joint is considered a modified hinge joint. Due to the effect of the cruciate ligaments in the native knee, the centre of the joint is seen to alter on the sagittal plane as the femora glides posteriorly on the fixed tibia during the range of motion from extension to flexion [110, 111]. Also, in a load bearing knee, when progressively squatting from extension, there is very little translation on the medial side of the knee compared to the lateral side resulting in longitudinal rotation with the medial compartment being the centre of rotation [111]. In a total condylar knee replacement, the femoral component in majority of systems is seen to glide anteriorly relative the fixed tibia during the range of motion. Other newer designs have a single radius of curvature to mimic the native knee kinematics and have less translation. This phenomenon creates a variable centre point around which the knee joint moves during the different range of motion. Radiologically, the centre of the knee has commonly been assessed with the knee static and in full extension. This centre is designed to aid with the assessment of static alignment. Out of the five centres identified by Moerland et al [112] on radiological images, most authors [113-116] identify the deepest part of the femoral notch, the Anterior Cruciate Ligament (ACL) femoral insertion, as the centre of the native knee. As for images of TKA, the centre of the knee joint is the point of intersection between the anatomical femoral axis (below) and the line joining the distal ends of the femoral component condyles on the coronal plane [117-120] (Figure 1-9), the intersection between the anatomical femoral axis and the distal femoral component edge sagittally [117, 118, 120] (Figure 1-9), and the centre of a line joining the femoral component pegs transferred distally to the level of the femoral component distal edges on axial images [121] (Figure 1-9).

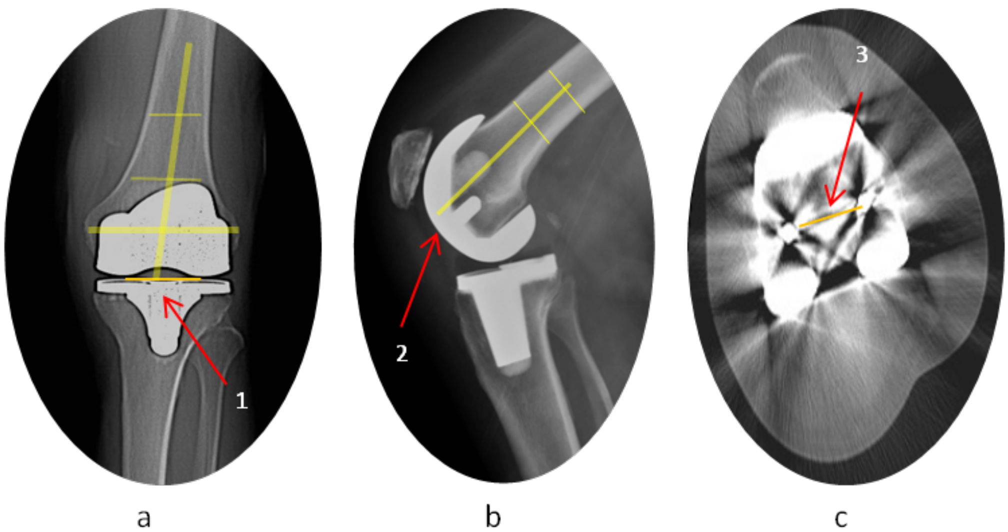



*Figure 1-9: the centre of the knee (1: Coronal; 2: Sagittal; 3: Axial)*

iii. **The centre of the ankle.** The ankle joint is the articulation between the distal tibia (tibia plafond), the distal fibula, and the dome of the talus. The superior talar dome is entirely covered through its articulation with the tibia plafond. The true centre of the ankle is the centre of the talus [57]. This can be identified radiologically as the midpoint of a line across the talus at the level of the superior talar dome on coronal images of the ankle and the centre of the best fit circle within the talus cortex on the most proximal axial slice (Figure 1-10).

*Figure 1-10: The centre of the ankle*

Other anatomical landmarks that will aid in the identification of alignment parameters include:

iv. **The medial and lateral epicondyles**; the medial epicondyle is a large convex eminence to which the tibial collateral ligament of the knee-joint is attached. The lateral epicondyle, smaller and less prominent than the medial, gives attachment to the fibular collateral ligament of the knee-joint [57] (Figure 1-7).

v. **The tibial tuberosity**; a large narrow oblong elevation which gives attachment to the ligamentum patellae. It is the lower aspect of a triangular area regarded as the continuation of the anterior surfaces of the tibial condyles with one another [57] (Figure 1-7).

#### 1.3.3.3 Axes

An axis in anatomy is a theoretical line connecting two anatomical points. It can be a line about which a geometric body part rotates or may be conceived to rotate; for example, the knee flexion and extension around the femoral transepicondylar axis [122], or it can be a positional reference; for example, the femoral anatomical axis running through the centre of the femoral medullary canal [106]. When assessing TKA alignment, several axes are identified:

#### 1.3.3.4 Mechanical Axes

In orthopaedic terms, a mechanical axis is a straight line connecting two joint centres [106]. Three longitudinal mechanical axes can be identified in the lower limb. These are: the **overall lower limb mechanical axis (LLMA)**, the **femoral mechanical axis (FMA)** and the **tibial mechanical axis (TMA)**. The orientations of these axes in the standing position will determine the limb alignment [123].

The LLMA is the straight line starting in the centre of the hip joint, passing through or around the knee joint, and ending at the centre of the ankle joint (Figure 1-11). On radiological images of a weight bearing, non-rotated, and fully extended lower limb, the LLMA can be plotted by drawing a line connecting a point in the centre of the femoral head to a point in the centre of the ankle joint on both the coronal and sagittal views. Similarly, the FMA is the line connecting a point in the centre of the femoral head to a point in the centre of the knee, and the TMA is the line connecting the centre of the knee to the centre of the ankle (Figure 1-11).

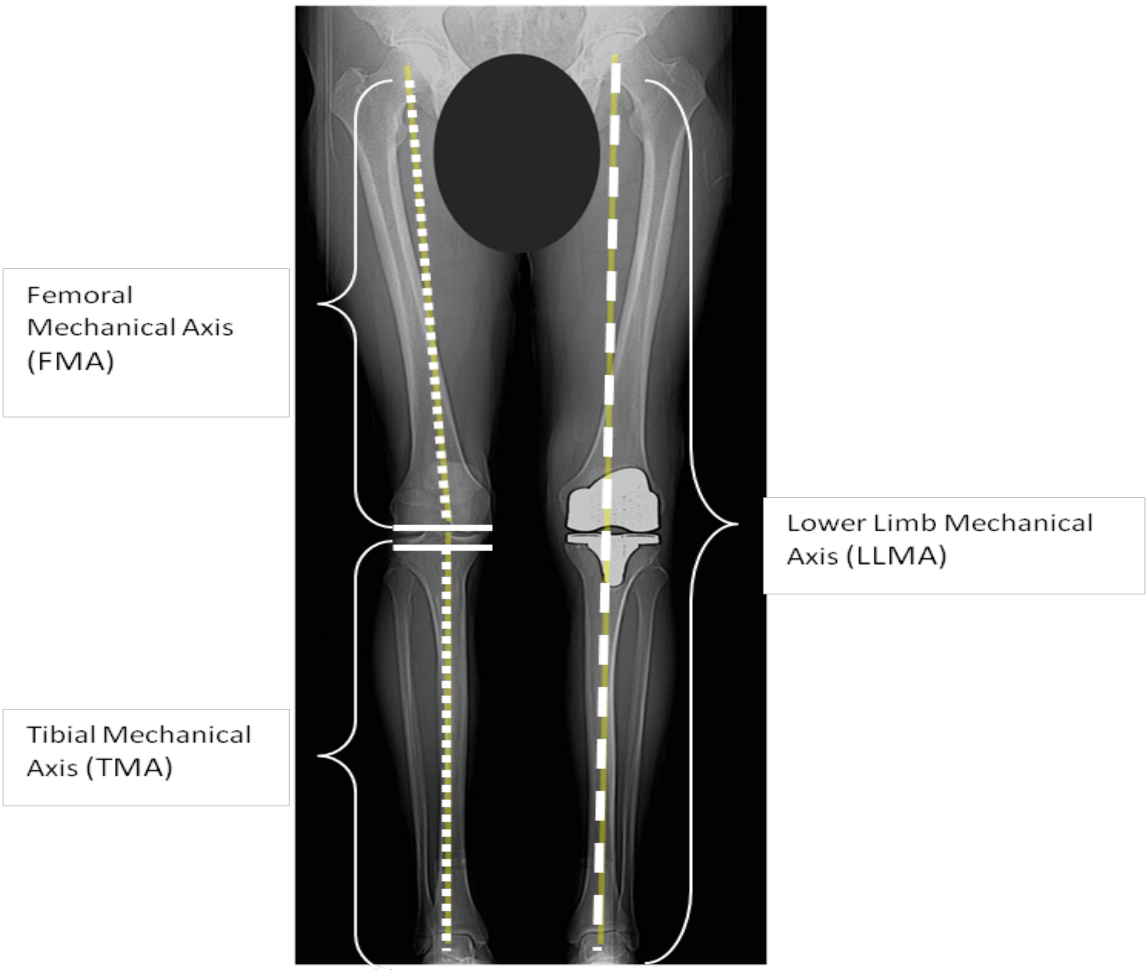



*Figure 1-11: The coronal Axes of the lower limb*

For total condylar and mechanically aligned TKA, both the femoral and the tibial components should be implanted along the LLMA [92, 124-131]. If successful, and with adequate soft tissue balance and if there are no extra articular deformities, this will produce a neutral mechanical axis of the limb, which runs through the centre of the knee. Any deviation from the centre of the knee on the coronal axis indicates a limb malalignment or a deformity such as valgus and varus limb deformities. Deviations from the centre of the knee along the sagittal axis indicate a flexion or extension deformities. In the restored and neutrally aligned limb following TKA surgery, the LLMA will overlap the mechanical axes of the femur (FMA) and tibia (TMA) on the coronal plane.

#### 1.3.3.5 Anatomical Axes

While it is ideal to position implants along the mechanical axis in a conventional mechanically aligned TKA [92, 119, 124, 126, 127, 132], surgeons rely on anatomical landmarks and axes for alignment orientation intra-operatively [74, 133]. Similarly, anatomical axes can be used for the radiological assessment of alignment following TKA. Unlike the mechanical axes, a considerable number of anatomical axes have been described in the literature. One of the main reasons for the abundance of these reference systems is the low reliability in any one system [125]. This can be due to normal anatomical variability [106-108], changes secondary to arthritis making the identification of anatomical landmarks difficult, and the complexity of identifying alignment on any one plane [134]. The majority of authors conceded that it is wise to be familiar with more than one system during both surgery and subsequent radiological assessment. Yoshioka et al [106] used cadaveric femora to describe femoral anatomical axes and angular measurements which are still used as references for aligning implants in TKA surgery. Oswald et al [135] described anatomical femoral axes on radiological images, and introduced the distal femoral axis which corresponded with the femoral intra-medullary guide rod's  position during conventional TKA. Jenny et al [136] found small differences radiologically between the different sagittal axes such as, the distal cortical axis and the distal femoral anatomical axis. On the other hand, around 4° to 6° differences were noted by other reports [113, 137].  Yoo et al [138] compared five radiologically identified tibial anatomical axes on the sagittal plane used for the assessment of tibial slope and found considerable similarities between systems. The greatest variability noted was between the systems of femoral [139, 140] and tibial [94, 107, 140] axial rotational axes.

For the purposes of this thesis, the anatomical axes considered are the coronal femoral anatomical axis (cFAA), coronal tibial anatomical axes (cTAA), the sagittal femoral anatomical axis (sFAA), and sagittal tibial anatomical axes on the sagittal planes (sTAA). The anatomical axial axes considered included the femoral surgical epicondylar axis (FsEA) and the tibial tubercular axis (TTA); both of which have been described in the procedural instruction manual and have widely been reported as the reference axes of choice for TKA rotation alignment [125, 140-142]. The rational for using these axes is that these anatomical axes are the axes used by the current project recruited cohort of surgeons to align implants during TKA surgery:

i. **The coronal femoral anatomical axis (cFAA).** The cFAA is the straight line through the centre of the intramedullary canal of the femur. On radiological images of the femur, the coronal femoral anatomical axis (cFAA) can be identified by connecting two points in the centre of the medullary canal, one in the proximal and the other in the distal parts of the bone (Figure 1-12).

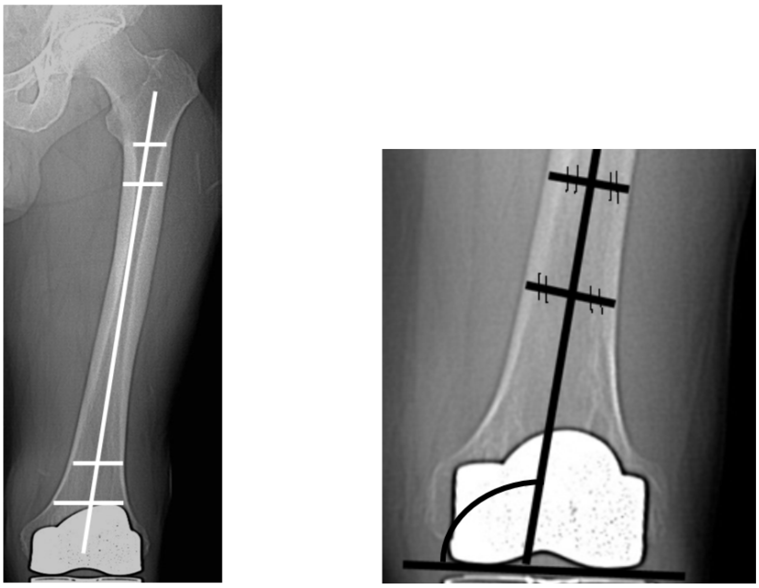


*Figure 1-12: Plotting the coronal femoral anatomical axis cFAA*

ii. **The sagittal femoral anatomical axis (sFAA).** On the sagittal plane, due to the natural femoral bow, the sFAA can be plotted by connecting two points in the centre of the medullary canal of the distal part of the femur around 10 cm proximal to the femoral intercondylar notch [113, 117, 136, 143] on sagittal images of the femur (Figure 1-13).

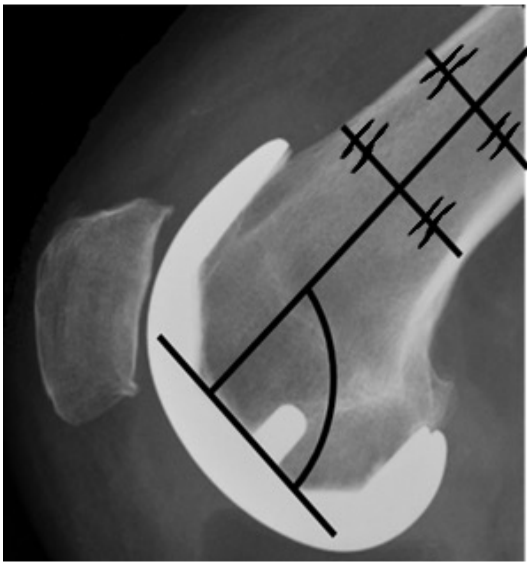


*Figure 1-13 : Plotting the sagittal femoral anatomical axis sFAA*

The ideal femoral component position is perpendicular to the femoral mechanical axes (FMA). During TKA surgery, the femoral jig is placed along the FAA using an intramedullary rod. The cFAA is estimated to be at a 6° angle relative to the FMA [112, 123, 143-145]. The positioning of femoral component relative to the anatomical axis on the coronal plane is achieved by setting the femoral cutting jig in 6° valgus relative to the intramedullary femoral rod. The correct sagittal positioning of the femoral component is more demanding. The distal sFAA is normally parallel to the FMA [136]. The anterior femoral cortical line [146] (Figure 1-14), is another axis guide used to position the femoral implant relative to the sagittal plane and help avoid femoral notching (a complication encountered when the femoral component is in an abnormally extension position and indenting the femoral anterior cortex). The surgeon aims to position the component perpendicular to the intramedullary rod and further checks position relative to the anterior femoral cortical line, which is ideally parallel to the sFAA. For the purposes of this work, the assessment of alignment on the sagittal plane will be relative to the sFAA as this is directly linked to intramedullary rod used for implant positioning.

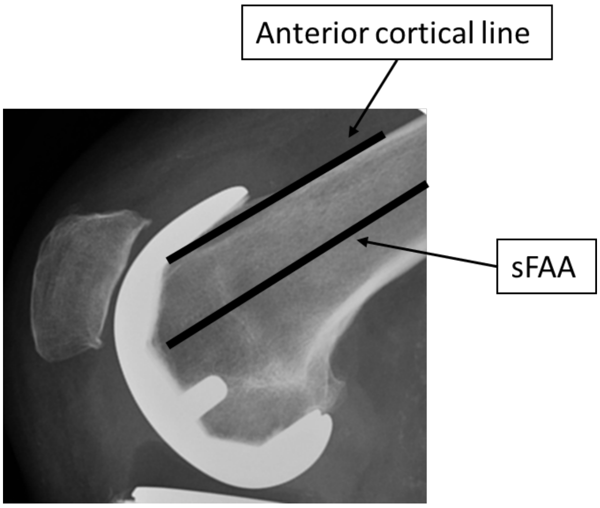



*Figure 1-14: Position of the anterior cortical line*

iii. **The Tibial Anatomical axis (TAA)**; similarly, TAA is the straight line through the centre of the intramedullary canal of the tibia bone in coronal and sagittal planes [138, 143] (Figure 1-15). During surgery, the tibial extramedullary or intramedullary jigs are placed along this axis. The tibial implant is positioned relative to the anatomical axis which, in a normally shaped tibia, is also parallel to the mechanical axis of the bone [138].

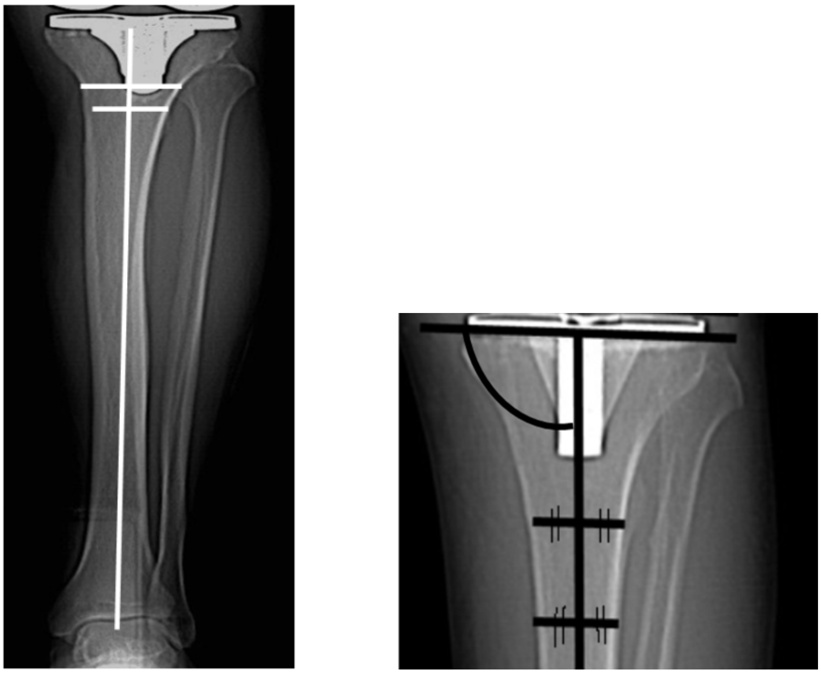


*Figure 1-15: Plotting the tibial anatomical/ mechanical axis*

iv. **The femoral surgical epicondylar axis (FsEA)** is a line connecting the sulcus of the medial epicondyle and the most prominent point of the lateral epicondyle on the distal femur (Figure 1-16). As well as being the anatomical axis, the FsEA is also regarded by several investigators as the mechanical axis around which knee flexion-extension movement occurs [122, 147-149] and the standard axis for establishing femoral component rotation [150-152]. It is shown that normal patellar tracking, less patello-femoral shear forces, and minimised tibio-femoral wear motions were identified when the rotational alignment was set parallel to the FsEA [150], making it an ideal axis for the assessment of femoral component rotational alignment. When deciding the femoral component axial rotation during surgery, several other anatomical structures and axes have been described and can be utilised by the surgeon. These include the posterior femoral condyles or the posterior condylar axis [153], the antero-posterior axis (Whiteside's line) [154], and the anterior femoral axis [155]. These have been shown to be inconsistent [152, 155, 156], likely due to deformation in the anatomy secondary to the disease process of arthritis for which the surgery is indicated. The main reason for choosing the FsEA axis for the assessment of alignment in this thesis is that other anatomical landmarks and axes will not be reliably visible on post-operative images of TKA due to the bone cuts made during surgery.

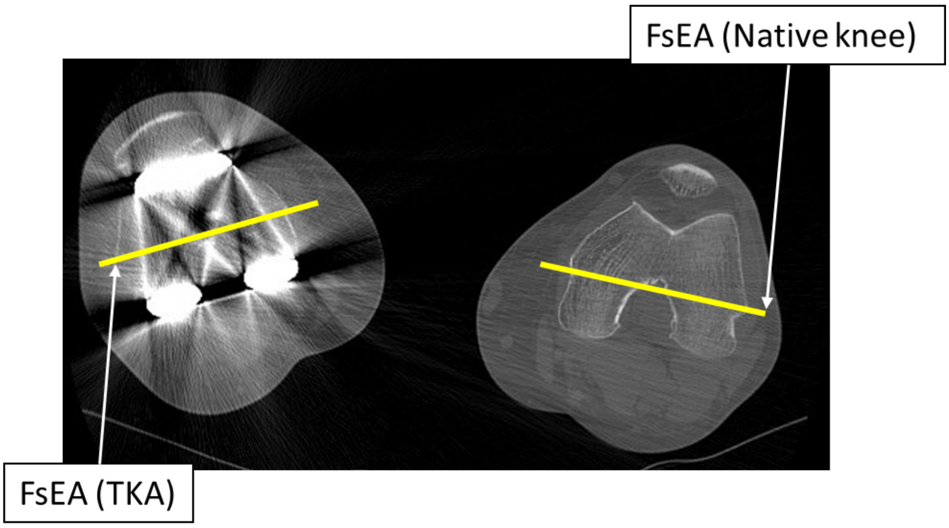



*Figure 1-16: The FsEA as seen on CT scan at the level of the most prominent lateral femoral condyle*

v. **The Tibial tubercular axis (TTA).** Unlike the femoral component, there is no standard for tibia component rotational alignment [157]. Several reference anatomic landmarks and axes are used to align the tibial have been utilised during surgery. These include the femoral component rotation using the sFEA

[107, 158, 159], the medial 1/3 of the tibial tubercle [152, 159, 160], patellar tendon [107, 161], the posterior cruciate ligament (PCL) attachment [107, 161], the mid-sulcus axis (the line medial to tibia tubercle going through the mid-sulcus of the tibial spines) [162], transverse axis of the tibia [152, 159], posterior tibial condylar axis [159, 163]. Others include the ankle malleolar axis [107], and axis of the second metatarsal of the foot [107]. Due to this abundance of reference points, the reported tibial rotation malalignment has been large [164]. Out of these landmarks and axes, the TTA was selected in this thesis for the assessment of post-operative alignment. This is because the TTA was used by the surgeons performing the TKA in the cohort of patients recruited for the study. Surgeons would select the best fitting tibial component size and align the component's anteroposterior axis (described below) in line with the medial tibia tubercle creating the axis between the centre of the component and the tibia tubercle. On radiological images, TTA is plotted by connecting the geometrical centre of the proximal tibia to the medial 1/3 of the tibial tuberosity [94, 141] (Figure 1-17). The geometric centre of the proximal tibial is identified using the centre of a best fit circle within the cortex of the bone just below the implant base in a TKA, or the tibia plateau in a native joint. This point is then transposed distally to the axial image at the level of the tibial tuberosity and connected to the identified point on the tuberosity. The tibial implant axial rotation can then be assessed relative to this axis. To achieve this, implant axes are identified.

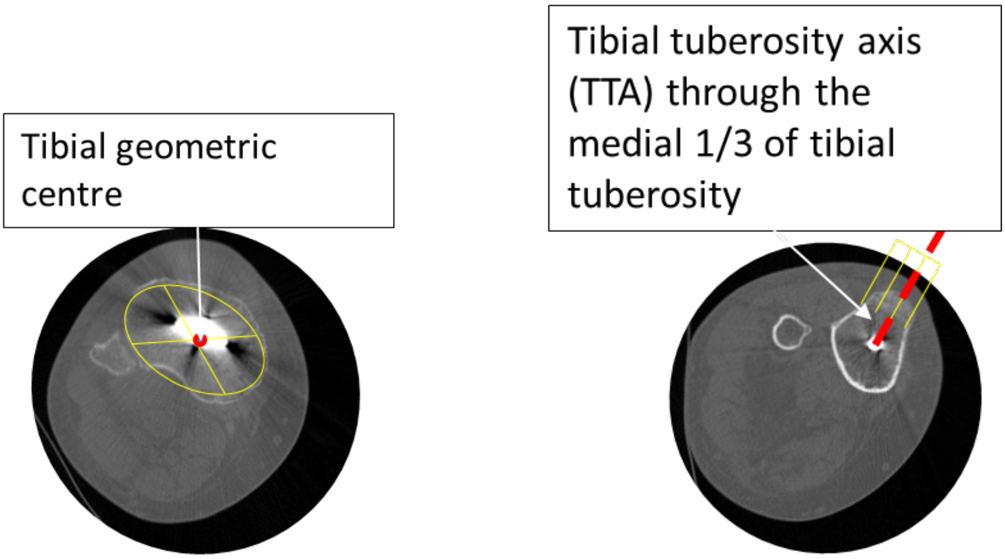



*Figure 1-17: CT scan series showing the tibial tubercular axis TAA (white)*

### 1.3.3.6 TKA implants Axes

This refers to axes of the two main TKA components; the femoral and the tibial components. No attempts have been made to assess the alignment of patellofemoral joint in this thesis as almost all TKAs performed in the department and subsequently recruited in this thesis studies were done without replacing the patella (patellar resurfacing).

Due to the geometrical shape of the TKA implants, the component axes can be identified using different landmarks on the silhouette of its components radiological images. On the coronal plane, the **coronal femoral component axis (cFCA)** can be identified by plotting a horizontal line connecting the most distal points on both condyles of the femoral component (Figure 1-18). This is then used to assess the femoral component's valgus/varus malalignment relative to the cFAA.

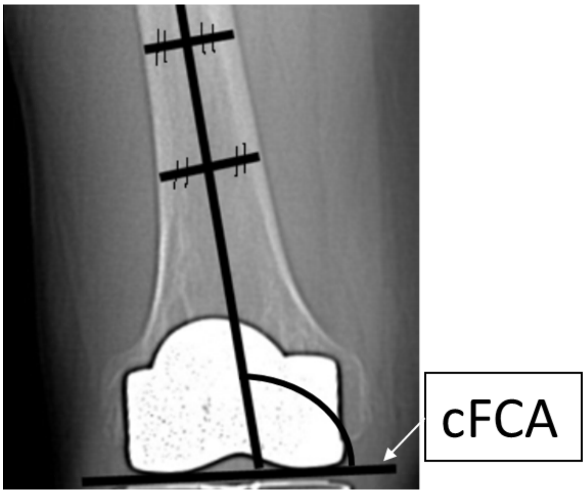



*Figure 1-18: Coronal femoral component axis (cFCA)*

The **sagittal femoral component axis (sFCA)** can be identified by plotting a horizontal line along the flat sections of the front, base, or pegs of the femoral component on the sagittal plane (Figure 1-19). This is then used to assess the femoral component's flexion/extension malalignment relative to the sFAA.

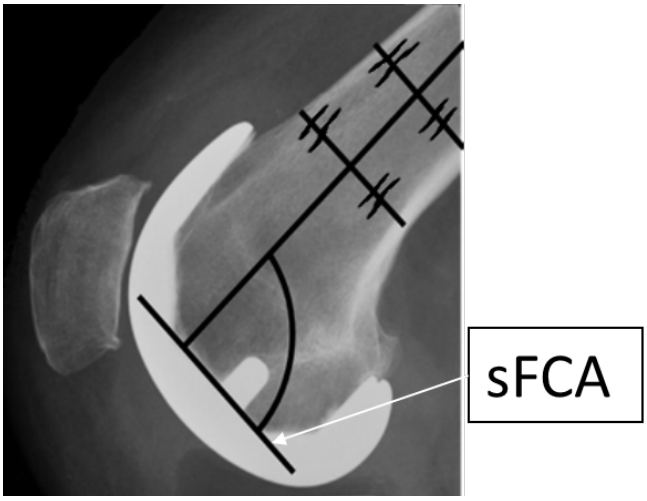



*Figure 1-19: Sagittal femoral component axis (sFCA)*

To identify the **femoral component's axial axis (aFCA)**, one of three lines can be plotted; a horizontal line through the centres of the femoral component's pegs, a horizontal line along the flat surfaces of the posterior aspect of the femoral condyles, and the horizontal line along the flat base surface of the anterior aspect of the femoral component (Figure 1-20). Either of these axes can be used to assess the femoral component's external/internal rotational malalignment relative to the FsEA.

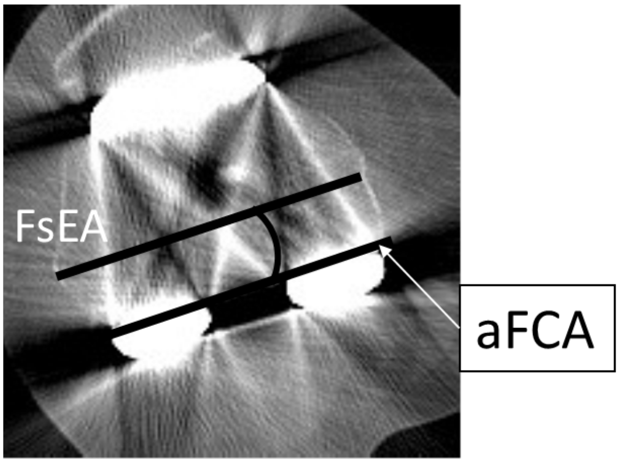



*Figure 1-20: Axial femoral component axis (aFCA)*

Similarly, the **coronal tibial component axis (cTCA)** is the horizontal line along the base of the tibial component plate on the coronal plane (Figure 1-21). This is used to assess for component valgus/varus malalignment.

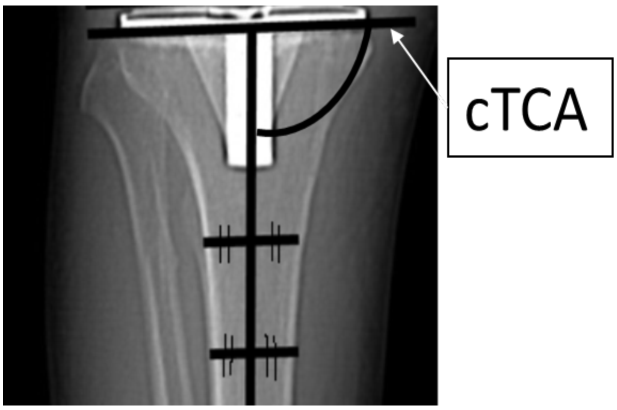



*Figure 1-21: Coronal tibial component axis*

The **sagittal tibial component axis (sTCA)** is the horizontal line along the tibial component base plate on the sagittal plane (Figure 1-22). This is used to assess for tibial slope alignment.

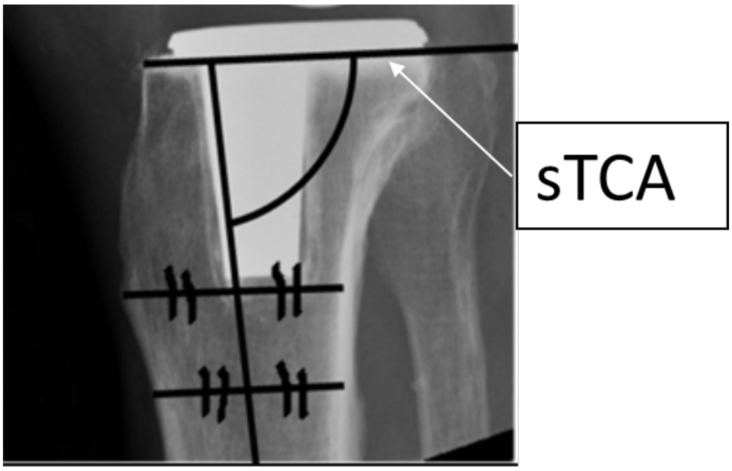



*Figure 1-22: Sagittal tibial component axis (sTCA)*

Finally, the **axial tibial component axis (aTCA)** is the horizontal line along the flat posterior aspect of the tibial plate on the axial plane (Figure 1-23). This is used to assess for component internal/external rotational alignment.

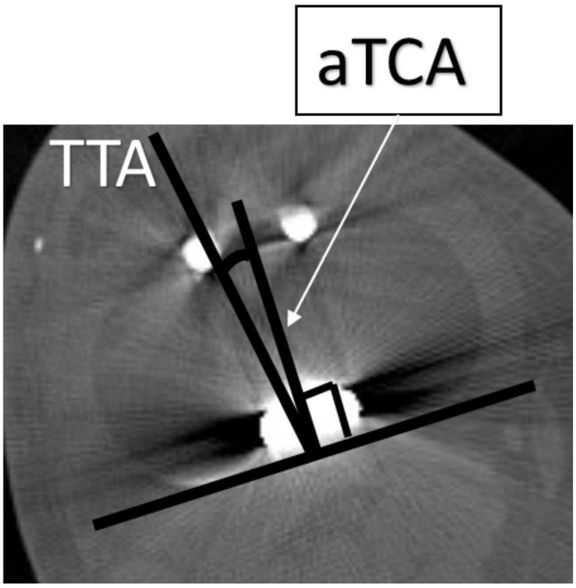



*Figure 1-23: Axial tibial component axis (aTCA)*

The component's axes will be determined based on the position of the implant. This position can be altered within the six degrees of freedom.

### 1.3.3.7 Six degrees of freedom (6DoF)

In the context of TKA alignment (6DoF) refers to the freedom of movement of implants (femoral and/or tibial component) in the three-dimensional space. Relative to the bones, the TKA components can either translate along the perpendicular axes; forward/backward, up/down, and/or medial/lateral, or rotate about the perpendicular axes; internal/external rotation, flexion/extension tilt, and/or valgus/varus tilt (Figure 1-24).

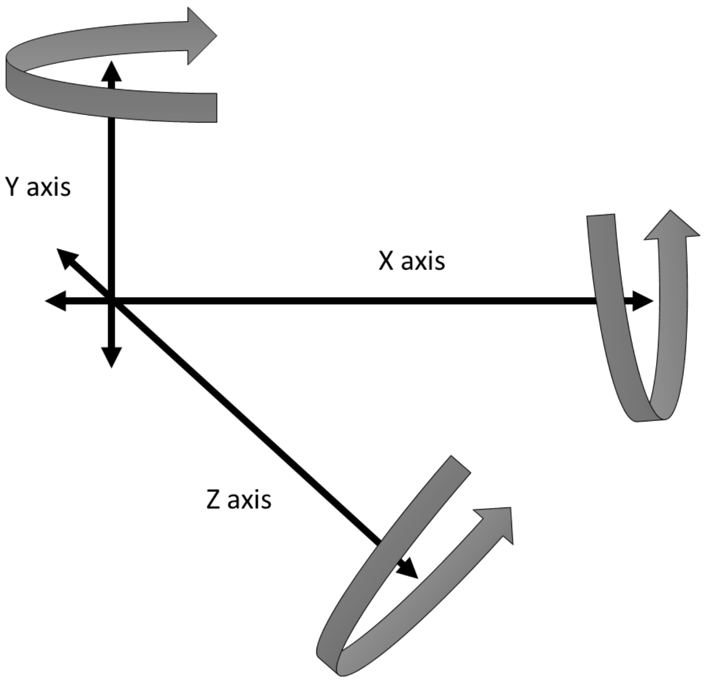



*Figure 1-24: 6DoF*

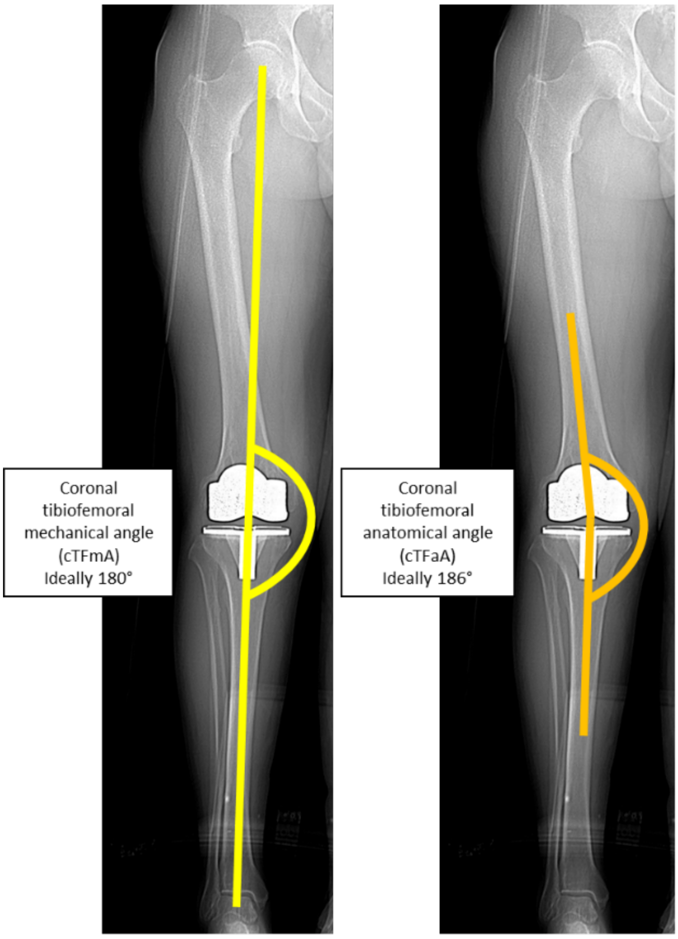
Although translation malalignment of components can result in complications such as incorrect joint line level and overhanging of components relative to the bones resulting in soft tissue irritation, the malalignment parameters of interest to this thesis are these resulting from rotation about the components perpendicular axes (internal/external rotation, flexion/extension tilt, and/or valgus/varus tilt).

### 1.3.3.8 Alignment Angles

Alignment angles are the angles at which the TKA implants are positioned relative to the bones. These are identified by measuring the angles resulting from the intersection of relevant implant and bone axes. These axes, identified using the anatomical landmarks described above, are relative to the three planes; coronal, sagittal and axial.

On radiological images of the lower limb, the alignment angles can be measured using simple geometry principles. Using computer software or a pencil and goniometer, the relevant angles were calculated.

Based on the TKA system used, a set of ideal alignment angles suggested by the manufacturer are provided for optimum TKA performance [74, 133, 165] as well as the Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System [143, 166]. When assessing post-operative alignment, most studies in the literature allow a 2 or 3 degrees error range before malalignment is considered. This range is entirely arbitrary and is based on the assumption that factors such as pin stability, cutting blade oscillations and the hardness of bone can all induce deflections of 1 or 2 degrees [167]. There is a wide variability in the literature regarding the reporting and description of TKA malalignment. Therefore, all alignment angles in this thesis are reported using a 180° system [168]. The alignment angles, which can be identified on radiological images of the lower limb following TKA, are described in the table and figures below (Table 1-1 and


Coronal tibiofemoral mechanical angle (cTFmA) Ideally 180°
Coronal tibiofemoral anatomical angle (cTFaA) Ideally 186°

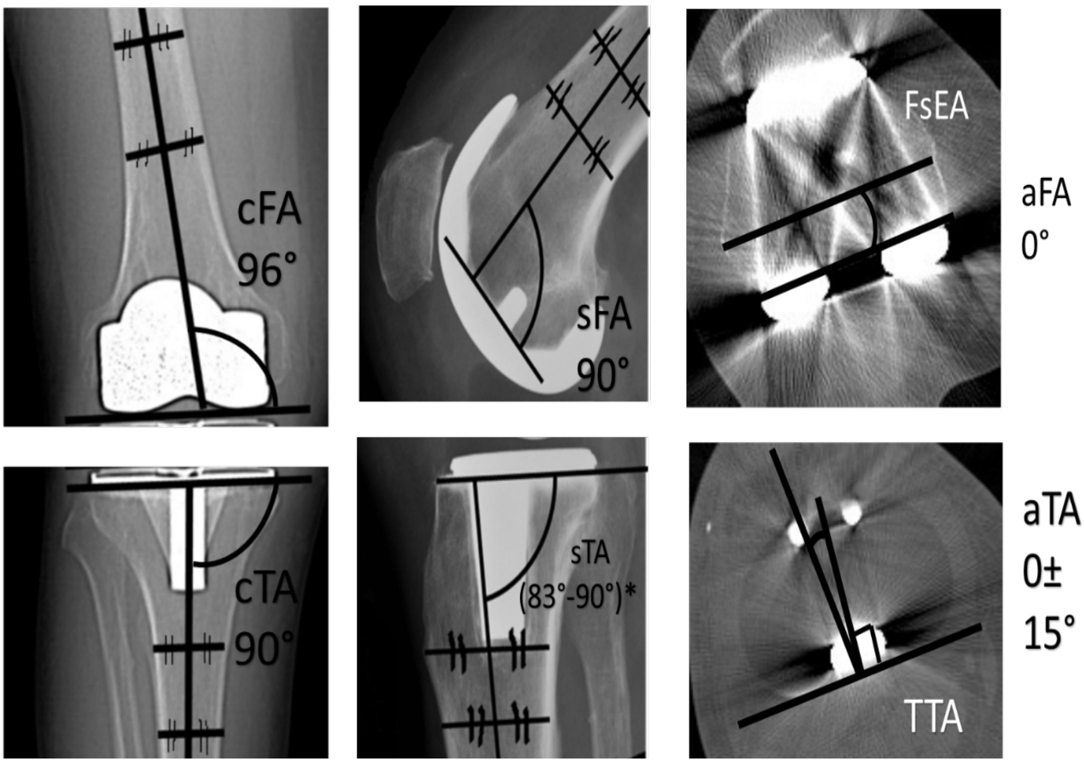

cFA 96°
sFA 90°
FsEA
aFA 0°
cTA 90°
sTA (83°-90°)*
aTA 0± 15°
TTA

Figure 1-25).

*Table 1-1: Alignment angles identified on radiological images showing the ideal values*

| | | Femoral component Axis (FCA) | Tibial Component Axis (TCA) | Components Axes |
|---|---|---|---|---|
| **Coronal plane** | **Femoral Anatomical Axis (cFAA)** | Coronal femoral-component anatomical angle (cFaA)<br>α angle*<br>Ideal angle= 96° | | Tibio-femoral Anatomical angle (cTFaA)<br>Ideal angle= 186° |
| | **Tibial Anatomical Axis (cTAA)** | | Coronal Tibial-component anatomical angle (cTaA) β angle*<br>Ideal angle= 90° | |
| | **Femoral Mechanical Axis (cFMA)** | Coronal femoral-component mechanical angle (cFmA)<br>Ideal angle= 90° | | Tibio-femoral Mechanical angle (cTFmA)<br>Ideal angle= 180° |
| | **Tibial Mechanical Axis (cTMA)** | | Coronal Tibial-component mechanical angle (cTmA) β angle*<br>Ideal angle= 90° | |
| **Sagittal plane** | **Femoral Anatomical Axis (sFAA)** | Sagittal femoral-component anatomical angle (sFA)<br>γ angle*<br>Ideal angle= 90° | | |
| | **Tibial Anatomical Axis (sTAA)** | | Sagittal Tibial-component anatomical angle (sTaA) δ angle*<br>Ideal angle= 83°-90°† | |
| | **Femoral Mechanical Axis (sFMA)** | Sagittal femoral-component mechanical angle (sFA)<br>Ideal angle= 90° | | Tibio-femoral angle (sTFA)<br>Ideal angle= 180° |
| | **Tibial Mechanical Axis (sTAA)** | | Sagittal Tibial-component mechanical angle (sTmA)<br>Ideal angle= 83°-90°† | |
| **Axial plane** | **Femoral epicondylar Axis (aFTA)** | Femoral component Rotation angle (FRA)<br>Ideal angle= 0° | | Femoro-tibial components mismatch rotational angle (FTMRA)<br>Ideal angle= 0° |
| | **Tibial Tubercular Axis (aTTA)** | | Tibial component Rotation angle (TRA) Ideal angle= 0-15° [149] | |

*** Based on The Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System [143]**
**†TKA System specific**

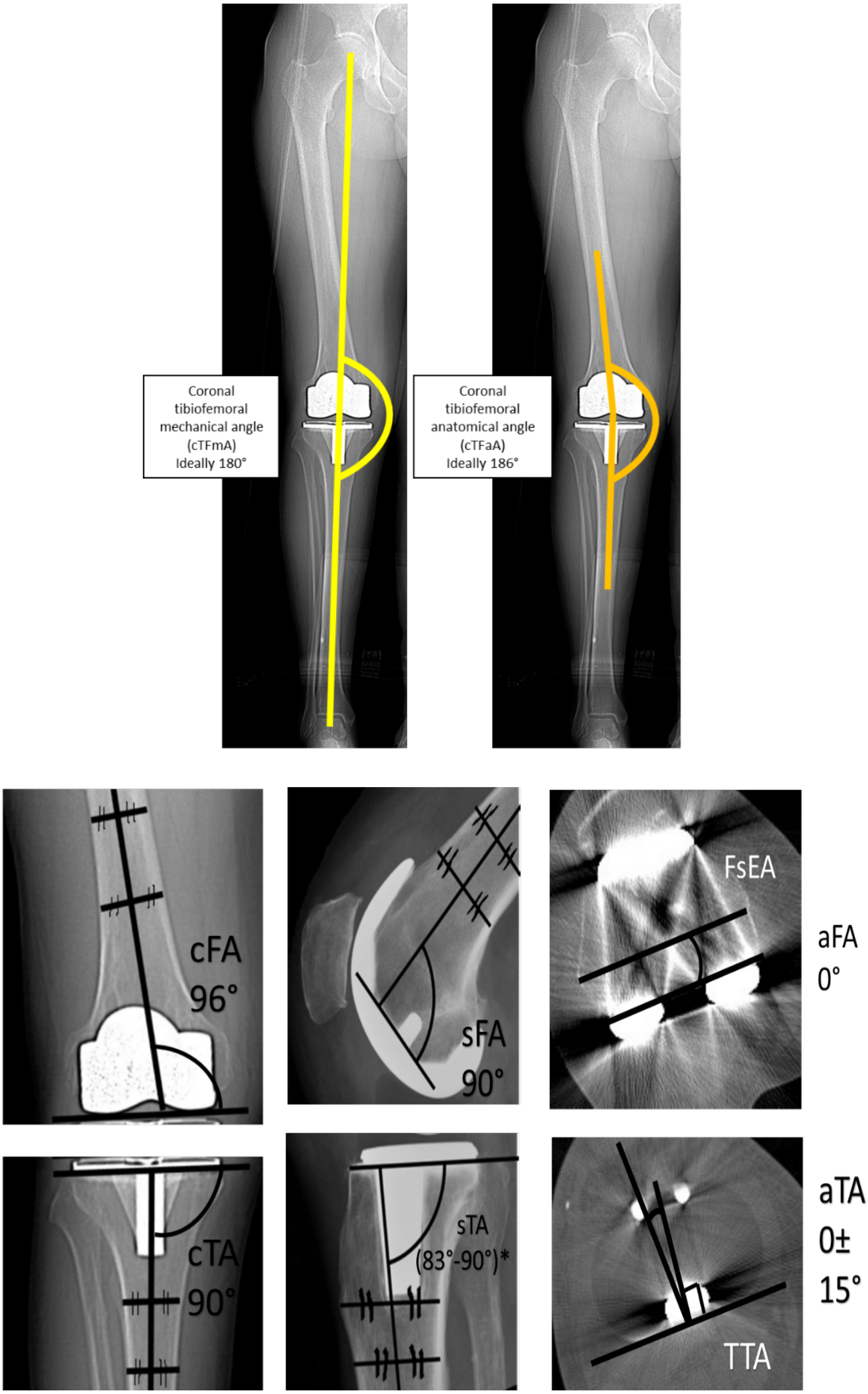



*Figure 1-25: Alignment angles identified on radiological images showing the ideal values*

### 1.3.4 Malalignment following TKA

Amongst the various contributing factors to the success of TKA, procedural factors are mainly concerned with the surgical team's techniques, operative decisions, choices, and doings [98]. Many investigators have examined the large number of factors that fall under the umbrella of procedural factors [89, 92-96]. This is not surprising once we consider that procedural factors, unlike many other factors, can be influenced by modifying the surgeon's and/or surgical team's decisions and performance. Improvement in these factors may subsequently impact positively on patient outcomes.

One outcome that is likely to be influenced by procedural factors is the alignment following TKA. Implant and/or limb malalignment is one of the important aspects of the operation that many consider to negatively influence outcomes following TKA such as, functional outcomes, post-operative complications, and revision rates [92, 94, 95, 124, 129, 169, 170].

There are several modes of failure that lead to reduced implant longevity or revision surgery in TKA. These include, as shown by Bozie et al [171] using a US nationwide inpatient sample: Infection (25.2%), mechanical or aseptic loosening (16.1%), implant breakage (9.7%), dislocation (7.1%), periprosthetic osteolysis (3.2%), bearing surface wear or poly wear (4.9%), periprosthetic fractures (1.5%), and other mechanical complications (15.4%). Of these failure modes, in particular mechanical related failures, malalignment of either components or limb may be a significant contributory factor. One explanation is that malalignment can result in abnormal polyethylene stress [172, 173] that can result in an increase in polyethylene debris which can lead to aseptic loosening, a common cause of implant failure resulting in revision surgery [174, 175].

Revision attributed to malalignment is reported to amount to as many as 37% of overall TKA failures [92, 124-126, 128, 169, 170, 176]. In addition, it accounts for around 50% of early failures due to instability and failure of fixation [92, 124, 129, 169, 170, 177]. Similarly, malalignment has been linked to poor functional outcomes [95, 178, 179] and worse patient reported outcomes (PROMS) [119, 180]. On the other hand, others argue that the consequences of malalignment are likely to be small if any [116, 181]. The argument put forward is that the freedom of movement between components in new total condylar designs can accommodate for some malalignment. Furthermore, the philosophy of total condylar TKA and the restoration of limb alignment to 180° mechanical axis have recently been questioned. This is because the limb alignment for the majority of normal individuals is in fact not in a neutral 180° alignment [182]. Thus, restoring the limb to this position might not benefit all patients. In one study [183], cohorts with better post-operative alignment did not show better clinical results. This has led surgeons to explore other avenues such as custom made cutting blocks [184] where alignment, amongst other decisions, is tailored to the patient's anatomy based on pre-operative radiological images. This may prove to be the start of a significant shift in the TKA design, however, the initial reports for this practice has not demonstrated an advantage when compared to conventional total condylar designs [185]. What is unclear is a unified definition of normal alignment and the accepted parameters of alignment and what level of malalignment result in worse outcomes. These areas will be further explored with a systematic review of the literature is conducted to identify the impact of malalignment on patient outcomes (**Error! Reference source not found.**), and a literature review to identify the methods of assessing alignment following TKA surgery (Chapter 2).

While it is not yet fully clear whether patient outcomes and satisfaction is directly influenced by the accuracy of implants or limb alignment, modern total condylar knee arthroplasty implants are designed to align within specific parameters as recommended by implant manufacturers [74, 133, 165] TKA procedures recruited for this thesis were all modern total condylar implants and have been designed to be aligned specifically within certain parameters to restore overall limb alignment to a neutral 180° mechanical axis. Surgeons in this cohort have set out to achieve these targets and therefore malalignment will be assessed relative to these parameters. On this basis, malalignment of implants and/or limb following TKA was chosen as a proxy for the technical success and a measure of how accurate the surgical team were in achieving their targets.

### 1.3.5 Improving TKA alignment

Attempts to achieve better components and/or overall limb alignment during TKA have been widely reported. The inconsistency in TKA alignment has commonly been attributed to surgeon’s performance. Hence, improvement has focused on improving surgeon's technical skills. Most significantly, the use of computer assisted surgery. This technology utilises real time assessment of implants' position relative to the bones through the use of imaging such as, computerised tomography (CT), or the use of sensors attached to specific parts of the limb. The surgeon can immediately assess the orientation and position of implants and adjusts accordingly to achieve the target alignment. Although this technology has been shown to be successful in reducing the outliers in terms of malalignment outcomes [186-188], it has some drawbacks, in particular, cost effectiveness in low volume centres and increased operative time and no improvement in patient-reported outcome measures (PROMs) [189-191].

### 1.3.6 A system approach to TKA malalignment

The link between surgeon performance and achieving technical targets is of significant importance to this work. Given the heavily standardised steps during TKA surgery, it is natural to assume that better alignment in TKA can be achieved if the surgical team was able to execute tasks more effectively. During the process of dealing with a harm related incident, a person-focused approach would single out an individual or a group of individuals as the sole source of error and is to blame due to lack of certain required skills. In the NHS, medical staff follow well-structured training and assessment programmes prior to employment in healthcare. For surgeons this means demonstrating competencies in both knowledge and skills required to perform the procedure independently. Also, evidence from harm-related incidents show that errors do occur to experienced and technically competent team members which discredits the theory of the bad apple within the establishment [12]. Therefore, for the purposes of this thesis and from a system's approach point of view, it is not a question of whether the surgical team possesses the technical capability to perform the procedure rather the team's ability to achieve what is expected of them technically. Key questions are: how can the surgical team achieve their maximum technical potential and perform their tasks adequately? And what are the factors that can hinder this?

As discussed above, evidence suggests the presence of other non-technical factors that can influence outcome. The non-technical performance and skills of the surgical team being an important factor that can affect technical skills. Also, deviations and disruptions to the surgical process during an operation can result in poor outcomes. We also believe that technical fidelity is improved by systems redesign and/or better non-technical skills within the operating team; therefore this work will set out to study the effects of non-technical outcomes within the theatre environment on technical outcomes related to surgery and patients. Specifically, the association between the surgical team's non-technical skills and/or the flow of the surgical process and malalignment as a technical following TKA.

# Chapter 2 The impact of malalignment following total knee replacement on patient outcome: A systematic review of the literature.

## 2.1 Declaration

Parts of the work presented in this chapter has been published in the following peer review journals:

6. Does malalignment affect patient reported outcomes following total knee arthroplasty: a systematic review of the literature. Mohammed Hadi et al., SpringerPlus (2016) 5:1201. DOI 10.1186/s40064-016-2790-4.
7. Does malalignment affect revision rate in total knee replacements: a systematic review of the literature. Mohammed Hadi et al., Hadi et al. SpringerPlus (2015) 4:835. DOI 10.1186/s40064-015-1604-4

## 2.2 Introduction

As discussed earlier in Chapter 1, the success of TKA surgery is multi-factorial. Malalignment of implants and/or limb following TKA surgery has been associated with poor functional outcomes, post-operative complications (dislocation, aseptic loosening), and increased revision rates [92, 94, 95, 124, 129, 169, 170]. All parameters of TKA alignment have been implicated but a considerable number of studies have asserted the importance of achieving a perfect limb mechanical axis within (±3°) [92, 124, 145]. Evidence of increased polyethylene-insert wear in finite module analysis

[176] and in simulated cadaveric studies with maligned implants [129] allude to a theoretical basis for poor outcomes.

This view however has been challenged. The evidence linking poor outcomes to malalignment routinely quoted in the literature is largely historic, based on studies that have examined older and most likely inferior implant designs, some of which have already been discontinued, and may have applied poor radiological techniques in their assessment method of alignment [124]. More doubt arose from studies comparing the outcomes of conventional to computer assisted TKA [192, 193]. Computer-assisted technology is more consistent at achieving better alignment by reducing outliers but little evidence of clinical advantage has been identified [192, 193]. Of note, the majority of these studies did not investigate the association between malalignment and outcome *per se*. Instead, they carried out a head to head comparison between the two techniques and attributed the change in patient outcomes to the difference in malalignment. This may seem plausible given the computer-assisted surgery's (CAS) ability in achieving better alignment. On the other hand, with reports showing averages of around 18% [194] and up to 48% [195] malalignment in the CAS groups, coupled with underpowered studies and potential confounders, this association is questioned. Also the choice of target for ideal alignment has been challenged by proponents of kinematically aligned TKA. As discussed earlier in this thesis, kinematic alignment aims to place the femoral component so that its transverse axis coincides with the primary transverse axis in the femur. With the removal of osteophytes the original ligament balance can be restored and the tibial component is placed with a longitudinal axis perpendicular to the transverse axis in the femur and not perpendicular to the mechanical axis of the tibial.

Nonetheless, achieving neutral alignment relative to the mechanical axes remains the commonly performed procedure amongst most orthopaedic surgeons and is recommended by knee systems manufacturers for mechanically aligned TKA [74, 133, 165].

It is clear that more evidence on the association between outcome and malalignment following TKA is necessary given this conflicting evidence and the scale of this procedure. Efforts to review the evidence on this issue are faced with a number of challenges:

1. Malalignment is, intuitively, an undesirable result. For example, it would be unethical to randomise patients in an RCT into two groups based on how well alignment is planned. It is therefore reasonable to infer that studies assessing the impact of malalignment on patient outcome are unlikely to be experimental, and the association sought would be the by product of a different study focus. An example of this can be seen in some RCT studies comparing conventional to CAS. Thus, the bulk of evidence on the association between malalignment and outcome is likely to come from observational studies. As a result, a careful analysis of study quality has to be made and an awareness of the potential of systemic bias maintained when comparing studies.

2. Another challenge is the variety in both clinical and radiological outcome measures described and reported in the literature. Alignment, as discussed in Chapter 1, is a 3D concept. As many as 13 different parameters of alignment can be assessed. This inevitably results in heterogeneous data especially with more studies focusing on individual parameters of malalignment.

To investigate the role of alignment in TKA surgery, this Chapter has been designed to examine the impact of malalignment on patient outcome in a systematic fashion. To collate best available evidence, a systematic review with clearly stated objectives and an explicit, reproducible methodology is presented.

## 2.3 Aim

The aim of this systematic review was to collate and analyse the available evidence on the association between malalignment following TKA surgery and patient-related clinical outcomes.

## 2.4 Methods

This review followed the guidelines described in the Agency for Healthcare Research and Quality (AHRQ) criteria [196] and PRISMA Statement for reporting systematic reviews [197]. The review has been registered, and a protocol published on the PROSPERO database for systematic reviews website [198].

### 2.4.1 Research question

In patients undergoing primary total condylar knee replacement is radiologically assessed malalignment, associated with changes in patient-reported outcomes, complications, and implant longevity?

### 2.4.2 Search strategy

A computerised literature search of the relevant databases was carried out including:

- Medical Literature Analysis and Retrieval System Online, Bethesda, Maryland, USA (MEDLINE) 2000-2014,
- Cumulative Index to Nursing and Allied Health Literature, Glendale, California USA (CINHAL) 2000-2014,
- Excerpta Medica Database, Amsterdam, the Netherlands (EMBASE) 2000-2014.

A broad search using MeSH terms “knee”, “replacement”, “alignment” and “outcome” was adopted. This was intended to identify all English-language studies published from 2000 through to 2014. A decision not to search for earlier publications was made to avoid the inclusion of studies with potentially poor implant designs and poor radiological assessment methods. A detailed search strategy for each database is provided, (Appendix - 7, Appendix - 8, Appendix - 8). The last search was performed on September 2014. In addition, a manual search of bibliographies of all eligible and other relevant publications was undertaken.

Using a multistage assessment method [80], two investigators reviewed the titles and abstracts to identify and retrieve all articles relevant to our research questions. A final independent review of the retrieved articles was undertaken to ensure their compliance with the inclusion criteria. Any disagreement was resolved by consensus of all three primary reviewers.

### 2.4.3 Criteria for considering studies in the review

#### 2.4.3.1 Types of studies

All study designs were considered for inclusion in this review. This included both observational and experimental designs.

A meta-analysis of RCTs may be seen to deliver the strongest evidence when investigating the outcome of an intervention. If the research question is concerned with aetiological hypotheses such as detecting an association between an exposure and an outcome, or a potential risk in a large population, similar to the current research question, then observational studies, such as cohort studies [199] are more appropriate and likely to be the dominant design.

There is a clear risk with synthesis of data from such studies. Confounding and selection bias often distort the findings from observational studies and there is a danger that meta-analyses of observational data produce very precise but equally spurious results [200]. Therefore, the principles of systematic reviews including the publication of a study protocol, a broad and complete literature search, and an objective studies selection process and data extraction in a reproducible and objective fashion, has been undertaken.

#### 2.4.3.2 Types of participants

All patients who have undergone an elective primary TKA for the treatment of knee arthritis (primary and secondary arthritis) and have had at least a 6 months follow-up were considered. Studies with unique patient demographics such as high BMI and pre-operative varus deformities were not excluded, but measures to highlight the potential confounding factors were taken.

#### 2.4.3.3 Types of operations

All open procedures using a total condylar knee replacement and all described approaches, by means of CAS or conventional techniques using both extra medullary and intramedullary jigs were considered. Other variations taken into account during the analysis included: the use of cement, cementing techniques, whether the cruciate ligament was retained or sacrificed, and the resurfacing of the patellae.

#### 2.4.3.4 Types of Radiological outcome measure

All radiological alignment assessment methods and parameters described were included.

#### 2.4.3.5 Types of patient-related outcome measures

On the basis that the objective of TKA surgery is to relieve pain, restore function, and improve quality of life, all patient-reported outcome measures assessing for any of the above were considered. Other outcomes including functional outcomes as well as evidence on implant durability were included. Outcome measures must have been validated for use in patients with knee arthritis and TKA.

Patient-related clinical outcome measures can be broadly grouped into the following categories:

1. Generic quality of life outcomes such as the EQ5D [201] and SF36 [202], and disease specific quality of life outcomes like WOMAC [203].
2. Knee specific functional outcome measures; both patient and assessor reported outcomes, such as the Knee Society Score (KSS) [143], the Oxford Knee Score(OKS) [204, 205], and range of motion (ROM).
3. Other clinical outcome measures assessing patient morbidity and mortality such as revision rates.

The KSS - which is the most widely used outcome measure during the period of interest for this systematic review - is divided into knee score and function score. The knee score is based on the assessment of pain, range of motion, stability and alignment of the leg. The function score is based on activities of daily living such as walking and climbing stairs. For each, a maximum score of 100 points is awarded. A main criticism of the scale is that it is completed by the assessor which may result in assessor bias. In response to these criticisms, a revised knee society scoring system has recently been developed [206] and validated [206] for measuring outcomes in TKR. The popularity of this scoring system is likely due to the inclusion of range of motion and alignment measurements as part of the assessment, which are relevant aspects of TKA. The Knee Society pain and function scores demonstrated moderate to strong correlations with the corresponding pain and function domains of the WOMAC and SF-36 [207]. All things considered, a decision was made to add the KSS total and/or function score to the list of patient reported outcome measures when reporting the results of this review.

In recent years there has been a gradual and widespread adoption of PROMS following TKA surgery. These are seen to be less subject to the biases with examiner reported outcome measures [208]. These outcome measures of interest to this review however, it is likely that PROMS will only feature in more recent publications identified.

### 2.4.4 Exclusion criteria

Studies included data on revision knee operations, unicompartmental knee replacement, non-condylar implants (such as hinged prosthesis), and studies that have not provided adequate and explicit information on the correlation analysis between outcomes of interest were excluded.

### 2.4.5 Data extraction

Two reviewers independently recorded details from each eligible study on the data extraction form (Appendix - 9). The extracted data included study demographic and quality characteristics, procedure information, implant details, and relevant outcome data on post-operative alignment that correlated with patient-related clinical outcomes. Any disagreements were discussed between the reviewers and settled by consensus. Where necessary the authors were contacted for any further information or missing data.

### 2.4.6 Quality assessment of included studies

Two reviewers independently assessed the methodological qualities of each of the included studies. As mentioned above, the variety in the methodological designs of eligible studies have presented this review with several challenges in particular the assessment of studies' qualities.

Quality assessment, also referred to as the assessment of risk of bias, is part of the process of evaluating the strength of a body of evidence. Studies are examined for the presence of systematic errors that can bias the true effects of the exposure evaluated. A judgement is made on the finding's trustworthiness based on the design, conduct, and reporting of the study [196] . The assessment is made using specific scales of which a variety is available.

There is currently no consensus amongst the research groups on the best tool to use. The AHRQ advocates using tools, *"specifically designed for use in systematic reviews and have demonstrated acceptable validity and reliability, or show transparency in how assessments are made by providing explicit support for each assessment, specifically address items related to risk of bias (internal validity), and preferably are based on empirical evidence of bias"* [196].

With that in mind, a different assessment tool was used for each methodological study design of the eligible studies. RCT were assessed using the AHRQ design-specific scale [196] (Appendix - 10) for selection bias (randomisation procedure and allocation concealment), performance bias (risk of unintended exposure), attrition bias (numbers of patients lost during follow-up), detection bias (length of follow-up, validity of outcomes, and blinding), and reporting bias (all potential outcomes reported). Case control and Cohort studies were assessed using the Ottawa-Newcastle score [209] (Appendix - 11, Appendix - 12). This scale allows a semi-quantitative assessment of study quality on three dimensions: selection, comparability, and, depending on the study type, outcome for cohort studies or exposure for case-control studies. Case series were assessed using the AHRQ design-specific scale [196] (Appendix - 13) for patient selection, outcome assessment, the identification of cofounders, and adequacy of follow up. Based on the results of the assessment, each study was graded as 'low risk', 'high risk, or as 'unclear risk' for any evidence of bias.

### 2.4.7 Statistical Analysis

A formal meta-analysis of the primary outcome was not deemed useful due to the variety and inconsistency in reporting outcomes. Instead a qualitative assessment with a narrative description of the evidence was undertaken.

### 2.4.8 Sensitivity assessment

Studies were further evaluated based on the quality of their radiological methods for assessing alignment. Studies applying radiological methods with low risk of bias were analysed independently. The evaluation was done using a 'five question' flowchart that is further discussed in detail in Chapter 3 of this thesis (Figure 2-1).

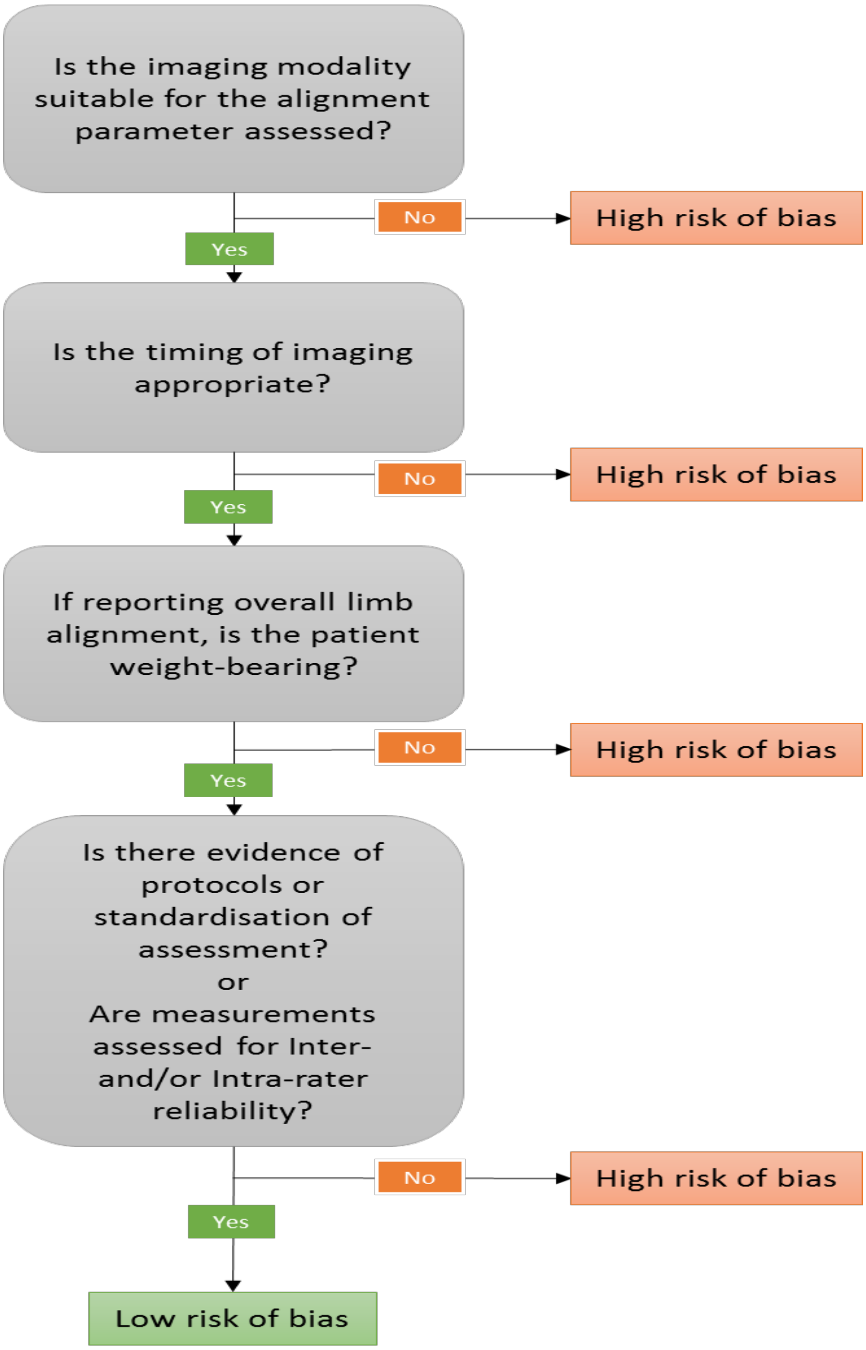



*Figure 2-1: Flowchart for evaluating the quality of radiological methods used for assessing alignment following a TKA*

## 2.5 Results

### 2.5.1 Search results

The initial search of the three databases returned 2793 citations, of which 1719 were considered for screening. One hundred and eighty nine studies were selected for manuscript review stage. Most studies were excluded at the title and abstract screening stage (n=2604), the main two reasons for exclusions were duplication and the lack of outcome of interest. Details of the study selection process are described in diagram below. (Figure 2-2)

A total of 25 studies [94, 95, 105, 115, 116, 118, 119, 126-128, 178-180, 193, 210-221] fulfilled the systematic review inclusion criteria and were eligible for inclusion. These included five RCTs [119, 212, 216, 217, 220], nine Case control studies [94, 115, 116, 179, 180, 193, 213, 215, 219], and 11 case series [95, 105, 118, 126-128, 178, 211, 214, 218, 221]. Two RCTs [119, 217] were the 1 year and 5 year follow-up results respectively for the same cohort of patients. A decision to include them separately was made to investigate for a difference in short and long term outcomes. All studies apart from one [221] were from single centres; seven studies were from North America [105, 116, 126-128, 179, 215], 13 studies from Europe [94, 115, 118, 178, 180, 193, 211-214, 216, 218, 219], four studies from Australia [95, 119, 217, 220], and one study from Asia [221]. Eighteen studies had declared receiving no funds or sponsorship from any commercial or industry related organisation. Further characteristics of eligible studies are described in Table **2**-**1**, Continued: Table 2-2, and Continued: Table 2-3.

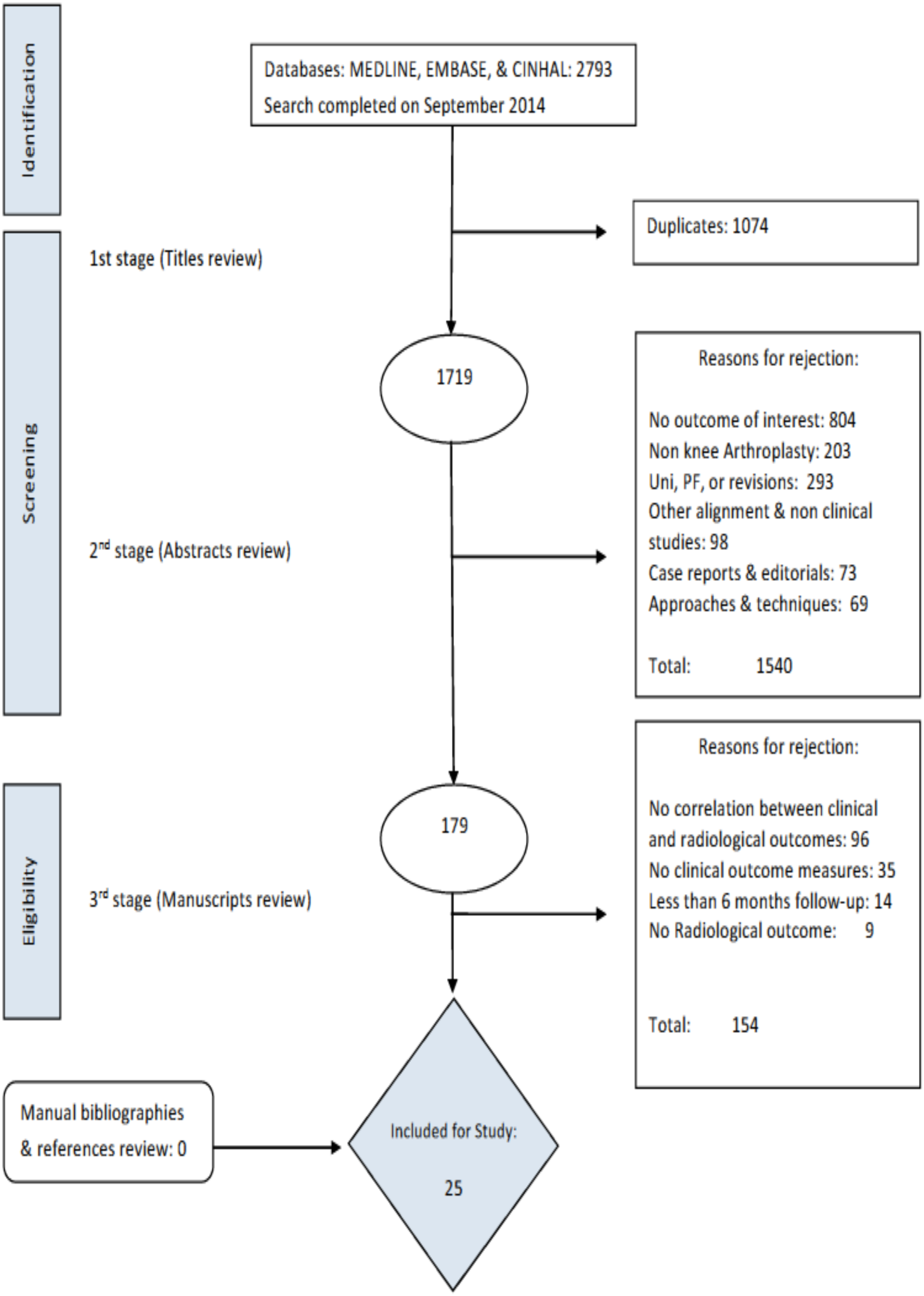



*Figure 2-2: Flow diagram showing the studies selection process*

*Table 2-1:* ***Eligible studies' characteristics***

| Author | Design | Sample size knee (patients) | Follow up Mean/ (Range) | lost to follow-up knee (patients) | final study sample size knee (patients) |
|---|---|---|---|---|---|
| **Aglietti et al 2007 [178]** | case series | 64 (72) | 8 yrs ( 5–12) | 19 (15) | 53 (48) |
| **Bach et al 2009 [211]** | case series | 113 (105) | 10.8 yrs (2–17) | (7) No adequate data | ? (98) |
| **Bankes et al 2003 [118]** | case series | 198 (194) | 6.5yrs (4.5-9.5) | None/ database study | 198 (194) |
| **Barrack et al 2001 [179]** | case control | 16 (13) + 14(11) within series of 118 (89) | 5.7 yrs | 2 (2) control did not consent | 14 (case) vs. 14 (control) |
| **Bell et al 2012 [219]** | case control | 60 with pain versus 67 control | 2.4 yrs versus 1 yrs | 6 cases & 11 control | 56 in each group |
| **Berend et al 2004 [126]** | case series | 8598 (5535) from database | 5 yrs (2-14.2) | | 3152 (2125) 41 tibial failures analysed |
| **Blakeney et al 2013 [220]** | RCT | 107 | 3.9 yrs (2.6-5.9) | 5 died, 11 lost | 93 analysed |
| **Bonner et al 2011 [115]** | case control | 501 (396) from database | 9.8 yrs (?-15) | 184 (died before last review but survival data included in analysis) | 458 TKRs (362) Cases (Aligned) 372 vs. Control (Malaligned) 86 |
| **Choong et al 2009 [119]** | RCT | 120 (?) | 1 yrs | 9 (5 refused, 4 Lost to follow up) | 111 (?) |
| **Czurda et al 2010 [180]** | case control | 19 cases (painful), 19 controls from a cohort of 330 | 2.2 yrs (1.6-3.5) | None | 38 (38) |

*Continued: Table 2-2: Eligible studies' characteristics*

| Author | Design | Sample size knee (patients) | Follow up Mean/ | Author | Design |
|---|---|---|---|---|---|
| **Fang et al 2009 [127]** | case series | 6070 (3992) from database | 6.6yrs (2-22.5) | 1118 (28.0%) patients died | 3 groups: well aligned n=4236, varus n=1222, valgus n=819 |
| **Gøthesen et al 2014 [216]** | RTC | 12 pilot study then 192 (randomised) | 1 yr | 19 | 87 Conv vs 88 CAS |
| **Howell et al 2013 [105]** | case series | 101 | 6-9 months | 1 | 100 |
| **Huang et al 2012 [217]** | RTC | 115 | 5 yrs | 25 | 44 Conv. versus 46 CAS |
| **Kim et al 2013 [221]** | case series | 3150 (1747) | 15.8 yrs (11-18) | 30 Excluded (infection and fractures), 102 lost | 3048 (1696) |
| **Longstaff et al 2009 [95]** | case series | 159 (?) | 1 yrs | 9 complications + 4 Lost fu | 146 (?) |
| **Lutzner et al 2010 [212]** | RCT | 80 (?) | 1.8 yrs | 7 (?) | 73 (?) |
| **Magnussen et al 2011 [213]** | case control | 608 knees with preoperative varus OA (?) | 4.7 yrs (2-19.8) | 55 (excluded) | 553(511), divided into three groups based on postoperative FTMA |
| **Matziolis et al 2010 [193]** | case control | 218 (184) | (5-10 yrs) | Database | group A: 25 cases (largest varus axial malalignment), group B: 25 controls |

*Continued: Table 2-3: Eligible studies' characteristics*

| Author | Design | Sample size knee (patients) | Follow up Mean/ (Range) | lost to follow-up knee (patients) | final study sample size knee (patients) |
|---|---|---|---|---|---|
| **Morgan et al 2007 [214]** | case series | 197 (153) | 9 yrs | None mentioned | 197 (153) |
| **Nicoll et al 2010 [94]** | case control | 61(60) painful, 26 control from a series of 740 | > 1 yr | 23 (?) | 39 (38) case, 26 (?) control |
| **Parratte et al 2010 [116]** | case control | 417 (295) | minimal 15 yr | 19(15) | mechanically aligned group : 292 vs. outlier group: 106 |
| **Rienmüller et al [218]** | case series | 219 | 5 yrs | 5 (4) died, 4 lost to f/u, 10 infection , 1 arthrofibrosis | 204 (193) |
| **Ritter et al 2011 [128]** | case series | 9483 (?) | 7.6 ± 3.8 yrs (2 to 22.5) | 482 lost to follow-up, 2204 <2 years follow-up, 727 no alignment recorded, 1118 patients died. | 6079 (?) |
| **Stulberg et al 2008 [215]** | case control | 51 (58) | 2.5 yrs | 6 (6) | 52 (45) |

## 2.5.2 Quality Assessment' of eligible studies

Variable methodological qualities in the included studies were identified. A detailed quality assessment for each of the eligible studies is described in Table 2-4, Table 2-5, and Table 2-6. The studies are presented in order of the highest level of evidence based on study design.

*Table 2-4: Quality assessment for RCTs*

| | Quality assessment | | | | | | | | | Judgment on risk of bias |
|---|---|---|---|---|---|---|---|---|---|---|
| **Authors** | Was the allocation sequence generated adequately? | Was the allocation of treatment adequately concealed? | Did researchers rule out any unintended exposure that might bias results? | Were participants analysed within the groups they were originally assigned to? | Was the length of follow-up different between the groups? | Were the outcome assessors blinded to the intervention or exposure status of participants? | Were the potential outcomes pre-specified by the researchers? | If attrition was a concern were missing data handled appropriately? | Were outcomes assessed using valid and reliable measures across all study participants? | |
| **Blakeney et al 2013 [220]** | Yes | No | Yes | Yes | No | No | Yes | Yes | Yes | Low risk |
| **Choong et al 2009 [119]** | Yes | No | Yes | Yes | No | No | Yes | Yes | Yes | Low risk |
| **Huang et al 2012 [217]** | Yes | No | Yes | Yes | No | No | Yes | Yes | Yes | Low risk |
| **Lutzner et al 2010 [212]** | Yes | No | Yes | Yes | No | No | Yes | Yes | Yes | Low risk |
| **Gøthesen et al 2014 [216]** | Yes | Yes | Yes | Yes | No | Yes | Yes | Yes | Yes | Low risk |

*Table 2-5: Quality assessment for cohort and case control studies*

| Author | Quality assessment | | | | | | | | | Judgment on risk of bias |
|---|---|---|---|---|---|---|---|---|---|---|
| | Is the case definition adequate? | Representativeness of the cases | Selection of Controls | Definition of Controls | Comparability of cases and controls on basis of design or | Ascertainment of exposure | Same method of ascertainment for cases and controls | Non-Response rate | Total Newcastle Ottawa Scale (possible 9 starts) | |
| **Barrack et al 2001 [179]** | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | 8* | Low risk |
| **Bell et al 2012 [219]** | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | 8* | Low risk |
| **Bonner et al 2011 [115]** | Yes | Yes | Yes | Yes | Yes | No | Yes | Yes | 7* | Low risk |
| **Czurda et al 2010 [180]** | Yes | Yes | Yes | Yes | Yes | No | Yes | Yes | 7* | Low risk |
| **Magnussen et al 2011 [213]** | Yes | Yes | Yes | Yes | Yes | No | Yes | Yes | 7* | Low risk |
| **Matziolis et al 2010 [193]** | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | 8* | Low risk |
| **Nicoll et al 2010 [94]** | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | 8* | Low risk |
| **Parratte et al 2010 [116]** | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | 8* | Low risk |
| **Stulberg et al 2008 [215]** | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | 8* | Low risk |

*Table 2-6: Quality assessment for case series*

| | Quality assessment | | | | Judgment on risk of bias |
|---|---|---|---|---|---|
| **Author** | Consecutive selection of patients? | Were outcomes measured in an objective way? | Were known confounders identified and appropriately controlled for? | Was follow-up of patients sufficiently long and complete? | Judgment on risk of bias |
| **Aglietti et al 2007 [178]** | Yes | ? | No | Yes | High risk/ unclear risk |
| **Bach et al 2009 [211]** | Yes | ? | No | Yes | High risk/ unclear risk |
| **Bankes et al 2003 [118]** | Yes | Yes | No | Yes | Low risk |
| **Berend et al 2004 [126]** | Yes | Yes | Yes | Yes | Low risk |
| **Fang et al 2009 [127]** | Yes | Yes | Yes | Yes | Low risk |
| **Howell et al 2013 [105]** | ? | Yes | Yes | Yes | Low risk /unclear risk |
| **Kim et al 2013 [221]** | Yes | No | Yes | Yes | Low risk |
| **Longstaff et al 2009 [95]** | Yes | Yes | Yes | Yes | Low risk |
| **Morgan et al 2007 [214]** | ? | Yes | No | Yes | High risk/ unclear risk |
| **Rienmüller et al [218]** | Yes | ? | No | Yes | High risk/ unclear risk |
| **Ritter et al 2011 [128]** | Yes | Yes | Yes | Yes | Low risk |

### 2.5.3 Studies results

The grand total of patients recruited in the studies was 21,828. The details of studies are described under the following heading:

#### 2.5.3.1 Participants

Minimal patient baseline characteristics were reported. The majority of studies included patients whom were eligible for primary TKA surgery. Three studies' cohorts were selected based on their pre-operative characteristics: One study [178] only recruited patients with a preoperative valgus knee deformity, the aim was to describe a technical step in the procedure that was applicable to these types of patients. The other study [118] recruited two groups of patients to reduce heterogeneity; preoperative varus knee deformity secondary to osteoarthritis (OA) and preoperative valgus knee deformity secondary to Rheumatoid arthritis (RA). The final study [213], selected only patients with preoperative varus knee deformities to assess the effects of residual varus on patient outcome.

#### 2.5.3.2 Implant choices

All but seven studies [119, 180, 212, 215-217, 220] exclusively used conventional techniques for implanting the knee replacement components. Five studies [178, 180, 212, 218, 221] used a tibial rotating platforms component in all of their patients. Patella arthroplasty or resurfacing was part of the operative procedure in three studies [116, 118, 213], formed the bulk of patients operated (102 out of a total sample size of 111 patients) in one study [119], formed a statistically non-significant difference in percentages for both cases and controls in one study [94], and was randomised as part of an RCT in another study [179].

#### 2.5.3.3 Surgical techniques

The posterior cruciate ligament was sacrificed in 3766 knees as part of the procedure in four studies [178, 213, 219, 221], retained in 18 studies, and not stated in four studies [115, 116, 126, 220]. In two studies [95, 119] the operative plan was to preserve the posterior cruciate ligament, where, five patients out of a sample size of 146 and 15 out of a sample size of 111 respectively had their operation plan altered and the cruciate ligaments sacrificed due to intra operative findings. Except for two studies [115, 180], all studies used cemented implants only. One study [105] used kinematic-aligned knee technique. The main difference to a mechanically-aligned knee technique is the utilisation of the articular surface of the femoral condyle and not the transvers epicondylar axis as the intraoperative morphologic reference for the transverse axes of the femur [105].

### 2.5.4 Details of outcomes measures

#### 2.5.4.1 Alignment outcomes

Ten parameters of alignment were identified. For each of the femoral and tibial components, alignment was assessed on the coronal or frontal plane, the sagittal or lateral plane, and the axial plane resulting in three groups of alignment parameters for both components. On the coronal plane, the femoral component was assessed in relation to the anatomical and mechanical axes resulting in another parameter. The coronal tibio-femoral angle in relation to the overall limb mechanical and anatomical axes and both components axial rotational angles (combined or mismatch) amount to the remainder. Chapter 1 discusses in detail the parameters of alignment; a summary of these parameters is presented in the table below (Table 2-7).

*Table 2-7: Summary of the radiological alignment parameters*

| | | **Femoral component** | **Tibial Component** | **Both** |
|---|---|---|---|---|
| **Coronal plane** | Anatomical Axis | Coronal femoral-component anatomical angle (cFaA).<br>α angle* | Coronal Tibial-component angle (cTaA)<br>β angle* | Tibio-femoral angle (cTFaA) |
| | Mechanical Axis | Coronal femoral-component mechanical angle (cFmA) | | Tibio-femoral angle (cTFmA) |
| **Sagittal plane** | | Sagittal femoral-component angle (sFA)<br>γ angle* | Sagittal Tibial-component angle (sTA)<br>δ angle* | |
| **Axial plane** | | Femoral component Rotation angle (aFRA) | Tibial component Rotation angle (aTRA) | Femorotibial-components combined or mismatch rotational angles (aFTCRA, aFTMRA) |

*** Based on The Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System [143]**

Malalignment was described as a percentage of patients or knees aligned within ±3° and/or ±2° of the optimal position. These arbitrary figures are designed to account for potential errors from the saw blade vibration and jig migration with some authors setting more stringent criteria for malalignment (±2°) than others (±3°). The details of the optimal angles are described in Chapter 2. Alignment of the limb's coronal overall alignment both anatomical (cTFaA) and/or mechanical axis (cTFmA) was assessed in all but three study [95, 218, 219].

A considerable amount of variability in the method of assessing alignment between studies has been identified. The main differences were: inconsistent use of protocols to control for limb position; the use of different radiological modalities including computerised tomography (CT) and plain X-rays; changeable patient weight bearing status; and variability in the timing of imaging ranging from immediate post-operative [214] to latest follow-up 12 years following surgery [128]. Details of the radiological methods assessment and alignment data are presented in Table 2-8 and Table 2-9.

*Table 2-8: Studies radiological methods quality assessment*

| | Modality of imaging | Timing of imaging | Weight bearing | Protocol/ standardisation | Rater reliability assessment | Outcome |
|---|---|---|---|---|---|---|
| **Aglietti et al 2007 [178]** | LLR | Latest follow up | Yes | Stress to assess varus-valgus stability | No | High Risk |
| **Bach et al 2009 [211]** | SLR | at follow up | No | Standardised | No Experienced radiologist | High Risk |
| **Bankes et al 2003 [118]** | SLR | 3 & 12 month follow up | Yes | Standardised supine & Lat, knee full extension. | N | Low Risk |
| **Barrack et al 2001 [179]** | CT, LLR | at latest follow up | Yes | U | N o | High Risk |
| **Bell et al 2012 [219]** | CT | 26 months | N o | U | MSK radiologist | High Risk |
| **Berend et al 2004 [126]** | SLR | at follow up (? included) | Yes | U | No | High Risk |
| **Bonner et al 2011 [115]** | LLR | 6 months | Yes | Standardised | No Single observer | Low Risk |
| **Blakeney et al 2013 [220]** | CT (3D), LLR | 3 months | No | Standardised | No | Low Risk |
| **Choong et al 2009 [119]** | CT , LLR | 6 weeks | Yes | Standardised with jig | No | Low Risk |
| **Czurda et al 2010 [180]** | CT, LLR | at 1st follow up | Yes | fluoroscopy first | No radiologist | Low Risk |

| | Modality of imaging | Timing of imaging | Weight bearing | Protocol/ standardisation | Rater reliability assessment | Outcome |
|---|---|---|---|---|---|---|
| **Fang et al 2009 [127]** | SLR | Varied (? included) | Yes | Yes | No | High Risk |
| **Gøthesen et al 2014 [216]** | CT, LLR | 3 months | Yes | Yes | No | Low Risk |
| **Howell et al 2013 [105]** | CT | 2 days | No | Yes | No | Low Risk |
| **Huang et al 2012 [217]** | CT , LLR | 6 weeks | Yes | Standardised with jig | No | Low Risk |
| **Kim et al 2013 [221]** | CT, LLR | 1 week | No | Yes | Yes | Low Risk |
| **Longstaff et al 2009 [95]** | CT | 6 months | No | Yes Perth's protocol | Yes | Low Risk |
| **Lutzner et al 2010 [212]** | CT, LLR | 18-32 months | Yes | U | No | High Risk |
| **Magnussen et al 2011 [213]** | LLR | Follow up (varied) | Yes | Yes Routine for Database | Yes | High Risk |
| **Matziolis et al 2010 [193]** | LLR | Latest follow up | Yes | Yes | Yes | High Risk |
| **Morgan et al 2007[214]** | LLR | Immediate post op | Yes | Yes | No | Low Risk |
| **Nicoll et al 2010 [94]** | CT, SLR | at least one year after TKR | No | U | No Senior author | High Risk |
| **Parratte et al 2010 [116]** | LLR | 2-3 month post op | Yes | Yes Standardised protocol | Yes | Low Risk |
| **Rienmüller et al [218]** | LLR, Axial XR | 5 years | No | Yes | Yes | High Risk |
| **Ritter et al 2011 [128]** | SLR | latest follow up | No | U | No | High Risk |
| **Stulberg et al 2008 [215]** | LLR, SLR, Navigation system | 4 weeks and 2 years | Yes | Yes Navigation system | No | Low Risk |

**CT= computerised tomography, LLR= Long leg radiograph, SLR= Short leg radiograph, U=Unknown**

*Table 2-9: Alignment Data of included studies*

| | PA/ Coronal tibial (beta) angle | Lat/ Sagittal Tibial angle | PA/ Coronal femoral (alpha) angle | Lat/ Sagittal femoral angle | Anatomical Axis (Tibio-femoral anatomical angle) | Mechanical Axis (Tibio-femoral mechanical angle) | Femoral component Rotation | Tibial Component Rotation | Combined/Mismatch |
|---|---|---|---|---|---|---|---|---|---|
| **Aglietti et al 2007 [178]** | NE | NE | NE | NE | NE | 69% within 2° of neutral alignment.<br>9% Varus within 5°.<br>11% Valgus within 5°.<br>4% varus greater than 5°. | NE | NE | NE |
| **Bach et al 2009 [211]** | 86.8°<br>(74-91)<br><br>n=92 (93.8%) within normal range (NS) | 86.3° flexion (76 flex - 96 ext)<br><br>n=51 (52%) within normal range (NS) | 96.2°<br>(90-112)<br><br>n=98 (100%) within normal range(NS) | 4.6 flexion<br>(0-18 flex)<br><br>n=47 (47.9%) within normal range (NS) | 4.1° valgus<br>(6-12 valgus)<br><br>n=48 (48.9%) within normal range(NS) | NE | NE | NE | NE |
| **Bankes et al 2003 [118]** | 88.23 +/-1.81(SD)<br><br>19.2% <87°,<br><br>0.5%>93° | 89.67+/-1.96(SD) | 96.04+/-2.94 (SD)<br><br>11.6% <94°,<br><br>0.5%>100° | 4.05+/-1.21(SD) | 4.28 +/-3.56 (SD)<br><br>64.6% Perfect<br><br>31.4% <4°,<br><br>4% >10° | NE | NE | NE | NE |
| **Barrack et al 2001 [179]** | Case: Mean 0.6 varus Range (1.9 varus –1.4 valgus)<br><br>Control: Mean 0.3 varus Range (1.6 varus–1.8 valgus)<br>(p NS) | NE | Case: Mean 5.2 valgus Range: (3.9 valgus –7.4 valgus)<br><br>Control: 5.6 valgus Range: (3.8 valgus–7.6 valgus)<br>(p NS) | NE | NE | Case: Mean 4.6 valgus Range: (3.1 –7.1 )<br><br>Control: Mean: 5.3 valgus Range: (3.5–7.3)<br>(p NS) | Case: Mean 1.5 ER Range: (5 IR–7 ER)<br><br>Control: Mean 2.2 ER Range: (4 IR–9 ER)<br>(p NS) | Case: Mean 6.2 IR Range:(15 IR – 6 ER)<br><br>Control: Mean 0.4 IR Range: (8 IR–12 ER)<br>(p 0.012) | Case: Mean 4.7 IR Range:(17 IR–4 ER)<br><br>Control: Mean 2.6 ER Range: (4 IR–14 ER)<br>(p 0.0035) |
| **Bell et al 2012 [219]** | NE | NE | NE | NE | NE | NE | Control: 3.9° ER (5.7) [7.9° IR to 9.3° ER]<br>vs<br>Cases: 2.3° IR (4.6) [19.5° IR to 6.3° ER]<br>difference: 6.2° p=0.002 | Control : 5.8° ER (11.7) [16.8° IR to 15.8° ER]<br>vs<br>cases 3.4° IR (8.5) [19.6° IR to 18.0° ER]<br>difference: 8.9° p=0.001 | Combined: Control 8.7° ER (14.8) [16.1° IR to 23.7° ER] vs Cases 7.1° IR (9.3) [27.2° IR to 13.6° ER] 15.8° p=0.001<br>Mismatch: Control 5.6° ER (11.6) [17.7° IR to 18.6° ER] vs cases 1.2° IR [19.5° IR to 22.0° ER], difference: 6.8° p=0.002 |
| **Berend et al 2004 [126]** | Evaluated but not reported | NE | Evaluated but not reported | NE | Mean 3.6° valgus for whole cohort.<br>vs<br>1.6° for failure group | NE | NE | NE | NE |

*Continued Table 2-9: Alignment Data of included studies*

| | PA/ Coronal tibial (beta) angle | Lat/ Sagittal Tibial angle | PA/ Coronal femoral (alpha) angle | Lat/ Sagittal femoral angle | Anatomical Axis (Tibio-femoral anatomical angle) | Mechanical Axis (Tibio-femoral mechanical angle) | Femoral component Rotation | Tibial Component Rotation | Combined/Mismatch |
|---|---|---|---|---|---|---|---|---|---|
| **Blakeney et al 2013 [220]** | NE | NE | NE | NE | NE | Within 3° (n=74)<br>vs<br>>3° (n=32) | NE | NE | NE |
| **Bonner et al 2011 [115]** | NE | NE | NE | NE | NE | 81% aligned within 3° | NE | NE | NE |
| **Choong et al 2009 [119]** | NE | NE | NE | NE | NE | Conv. Mean: -1.41 SD 3.39<br>vs<br>CAS Mean: -0.60 SD 2.40 | NE | NE | NE |
| **Czurda et al 2010 [180]** | NE | No data<br>(2˚cut off) | NE | No data<br>(3˚cut off) | NE | No data<br>(3˚cut off) | No data<br>(3˚cut off) | NE | NE |
| **Fang et al 2009 [127]** | Mean: 90.4°<br>(±2.1°) | NE | NE | NE | Mean 4.8° (±2.5°) valgus.<br>n=4236 (69%) within normal range (2.4-7.2) | NE | NE | NE | NE |
| **Gøthesen et al 2014 [216]** | Evaluated but not reported | Evaluated but not reported | Evaluated but not reported | Evaluated but not reported | Evaluated but not reported | Evaluated but not reported | Evaluated but not reported | Evaluated but not reported | Evaluated but not reported |
| **Howell et al 2013 [105]** | (+/- 0) In range n=4 vs Outliers (n=96) | NE | NE | NE | (-2.5 to -7.4)<br>In range (n=57)<br>vs<br>Outliers (varus n=41, valgus n=2) | (+/- 3)<br>In range (n=93)<br>vs<br>Outliers (varus n=6, valgus n=1) | NE | NE | mismatch (+/- 10) In range (n=98) vs outliers (n=2) |
| **Huang et al 2012 [217]** | NE | NE | NE | NE | NE | Within 3° (n=69)<br>vs<br>>3° (n=21) | NE | NE | NE |
| **Kim et al 2013 [221]** | Normal 90°<br>(n=2,168) | Normal<br>(n=2,495) (0–7°) | Neutral (n=2858)<br>(2.0–8.0° valgus) | Neutral<br>(n=1,735) (0–3°) | (3–7.5° valgus ) | NE | Normal (n=2,490)<br>(2–5° ER) | Normal<br>(n=2,490)<br>(2–5° ER) | NE |
| **Longstaff et al 2009 [95]** | n=33 good<br>(±2°)<br><br>n=13 bad | n=95 good<br>(+1 to +5)<br><br>n=51 bad | n=122 good<br>(±2°)<br><br>n=24 bad | n=90 good<br>(±2°)<br><br>n=56 bad<br>(±3°),(>5) | NE | Evaluated but not reported | n=92 good<br>(±2°)<br><br>n=54 bad | Evaluated but not reported | n=68 good<br>(±2°)<br><br>n=78 bad<br>(±3), (>5) |
| **Lutzner et al 2010 [212]** | NE | NE | NE | NE | NE | Evaluated but not reported | NE | NE | (n=63) KSS Function score <10° mismatch 70 (+/- 10), improvement of 15 (+/- 15)<br>vs.<br>(n=9) KSS Function >10° mismatch 50 (-12+20), improvement -5 -(3+5) |

*Continued Table 2-9: Alignment Data of included studies*

| | PA/ Coronal tibial (beta) angle | Lat/ Sagittal Tibial angle | PA/ Coronal femoral (alpha) angle | Lat/ Sagittal femoral angle | Anatomical Axis (Tibio-femoral anatomical angle) | Mechanical Axis (Tibio-femoral mechanical angle) | Femoral component Rotation | Tibial Component Rotation | Combined/Mismatch |
|---|---|---|---|---|---|---|---|---|---|
| **Magnussen et al 2011 [213]** | 84.7° ± 3.7° | NE | 90.2° ± 2.7° | NE | NE | 170.2° ± 4.4° | NE | NE | NE |
| **Matziolis et al 2010 [193]** | Cases: 1.8° +/- 1.9°,<br><br>Control -0.3° +/- 1.4° | NE | Cases 4.2° +/- 1.4°<br>Vs<br>Control 0.1° +/- 1.4° | NE | NE | Cases 6.3° +/- 2.0°<br>vs<br>Control 0° +/-1.2° | NE | NE | NE |
| **Morgan et al 2007[214]** | NE | NE | NE | NE | Neutral (4-9°, n=73)<br>Varus (n=66)<br>Valgus (n=58) | NE | NE | NE | NE |
| **Nicoll et al 2010 [94]** | painful: 0.4° of varus (2.5°) outliers 5<br>vs<br>painless: 0.2° varus (2.7°) outliers 4<br>(NS) | painful: 7.3° of posterior slope (2.5°)<br>vs<br>painless 7.2° posterior slope (2.3°)<br>(NS) | painful :6.6° of valgus (2.7°) outliers 4<br>vs<br>painless 6.6° valgus (2.0°) outliers 2<br>(NS) | painful: 0.2° of flexion (3.0°)<br>vs<br>painless: 0.4° of flexion (3.3°) | painful: 5.7° of valgus (2.9°) outliers: 9<br>vs<br>painless: 6.3° of valgus (2.3°) outliers 4<br>(NS) | NE | Painful: Mean: 2.0 IR Range: (8.8 IR - 3.9ER)<br>vs<br>Pain free: Mean 0.8 IR Range(5.9 IR - 6.8ER) | Painful: Mean 4.3 IR Range : (25.4IR - 13.9ER)<br>vs<br>Pain free Mean 2.2 ER Range (8.5 IR- 18.2 ER) | Combined rotation; Painful Mean 8.0 IR Range (25.6 IR- 22.1ER) vs. Pain free Mean 1.3 ER Range: (10.7 IR- 14.3 ER) (p0.001)<br>Mismatch rotation; Painful Mean 2.6 IR Range (25.6 IR- 21.1 ER) vs. Pain free 3.1 ER Range (10.3 IR - 22.1ER) |
| **Parratte et al 2010 [116]** | 90° ± 2.1 (79 to 96) | NE | ? 90° ± 1.9 (80 to 99) | NE | NE | 180° ± 2.8 (172 to 189 ) | NE | NE | NE |
| **Rienmüller et al [218]** | NE | NE | NE | NE | NE | NE | n=96 within ±3°<br>vs<br>n=108 outliers.<br>Mean 2.8°(±3.4°)<br>Range 6° ER - 15° IR | NE | NE |
| **Ritter et al 2011 [128]** | Neutral defined as any angle > or = 90. Neutral in 81.9% | NE | Neutral defined as any angle ≥8 valgus. 91.6% neutral. | NE | Neutral defined as 2.5 to 7.4<br>71% neutral. | NE | NE | NE | NE |
| **Stulberg et al 2008 [215]** | NE | -2.93 (2.219) | NE | 1.73 (0.961) | NE | 0.56 ± 1.0(-1-3) | NE | NE | NE |

### 2.5.4.2 Patient-related clinical outcomes

The patient-related clinical outcomes identified in this review included both PROMs and investigator-led assessment outcome measures. These included: KSS; Hospital for Special Surgery Score (HSS); WOMAC; SF-12; SF-36; EQ5D; patellofemoral symptoms score; Nottingham health profile; Visual analogue scale (VAS); post-operative length of stay; blood loss; complications; and revision rates. Of the 25 studies, the KSS was the predominately used outcome measure reported in 15 studies [94, 95, 118, 119, 178-180, 193, 211-213, 215-218] . Revision rate was the sole outcome measure in seven studies [115, 116, 126-128, 214, 221].

## 2.5.5 The association between malalignment and patient-related outcomes

Where reported, both malalignment and patient-related outcome data were incomplete and were measured at different time points. As a result, pooling quantitative analyses were not possible. Instead, a descriptive analysis with narrative and qualitative assessment of the evidence is presented. Details of the association between malalignment and outcomes are presented below:

### 2.5.5.1 Malalignment and patient reported outcomes

Of the 18 studies examining patient reported outcomes including quality of life and functional outcomes relative to malalignment, 12 studies (67%) [94, 95, 119, 178-180, 212, 213, 216, 217, 219, 220] demonstrated an association between malalignment in one or more parameter of alignment and a worse patient reported outcome. Details in Table 2-10 and Continued table **2**-**11**.

When evaluating the evidence based on the quality of radiological methods used for assessing alignment using the quality of radiological methods checklist, only nine studies [95, 105, 118, 119, 180, 213, 215-217, 220] applied radiological methods with a low or medium risk of bias. Of these, six studies (67%) [95, 119, 180, 216, 217, 220] identified worse patient reported outcome with malalignment (Figure 2-3).

#### 2.5.5.2 Malalignment and revision rates

Revision rate was the outcome measure in eight studies. Four studies (50%) [126-128, 221] demonstrated an association between a malalignment in one or more parameter and an increased revision rate. Details in Table 2-12

When evaluating the evidence based on the quality of radiological methods used for assessing alignment using the quality of radiological methods checklist, four studies applied radiological methods with low risk when assessing alignment, only one study (25%) [221] identified worse revision rate with malalignment (Figure 2-3).

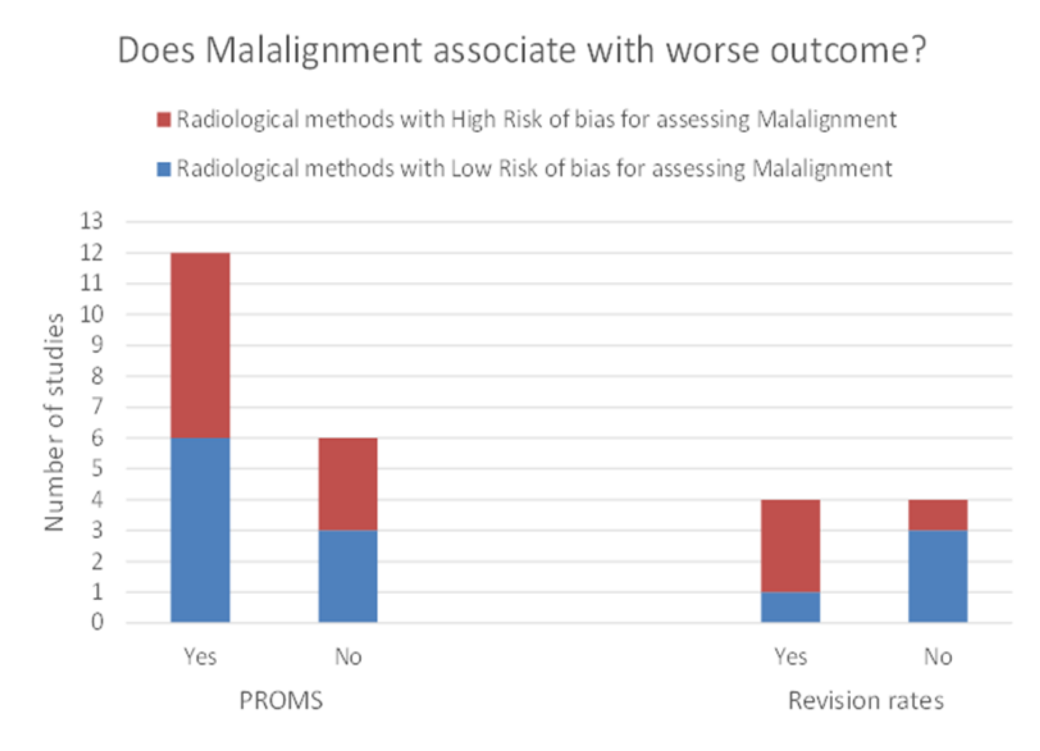



*Figure 2-3: Bar chart showing the association between malalignment and outcome*

### 2.5.5.3 Parameters of malalignment and patient outcomes

When each parameter of malalignment was evaluated individually for association with worse outcomes, apart from aTRA, aCRA with PROMS and cTFaA with revision rates, the number of studies showing an association with worse outcome with malalignment parameters was smaller (Figure 2-4).

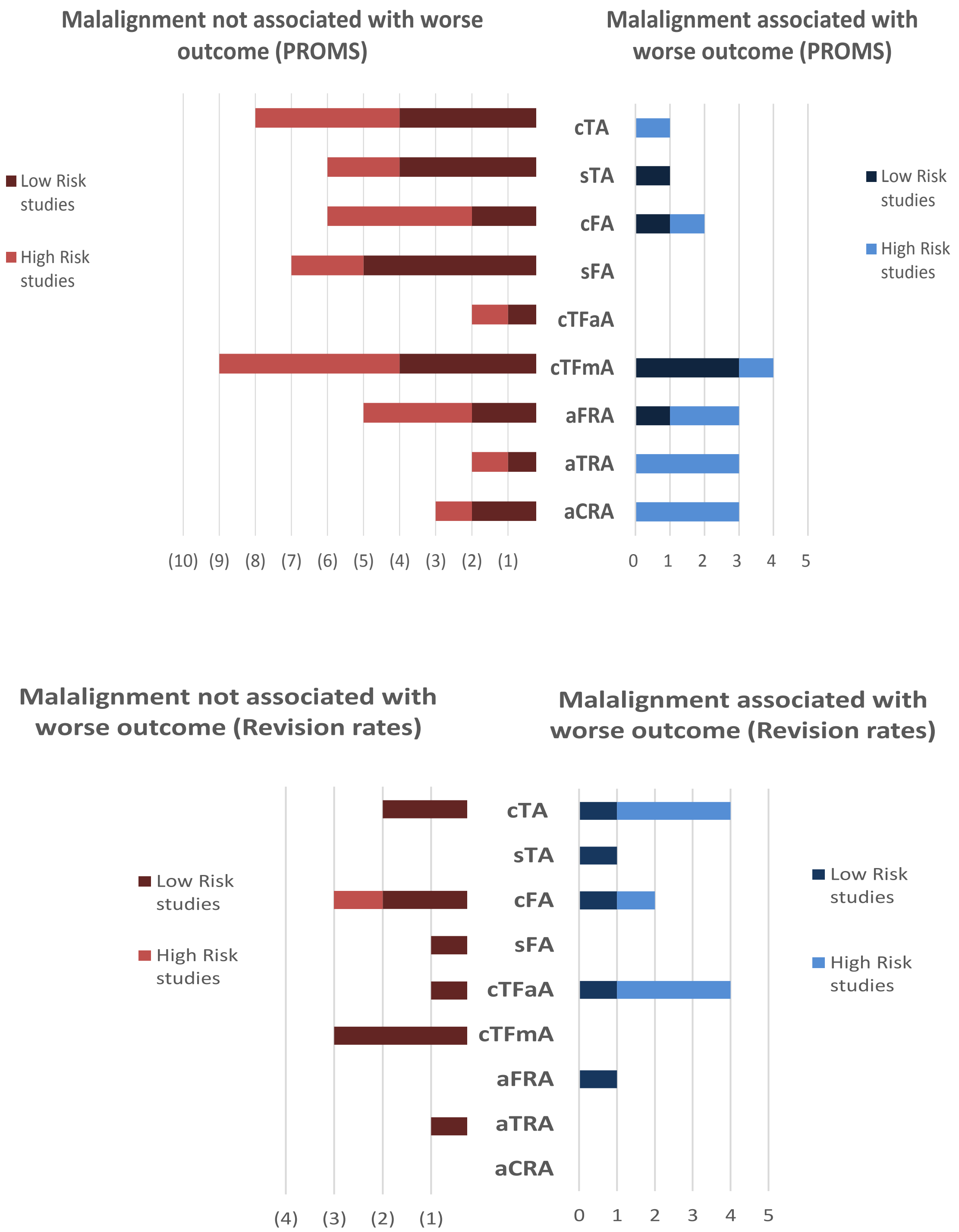



*Figure 2-4: Chart showing the associated malalignment parameter with outcomes*

The number of studies (x-axis) and association identified for each parameter of alignment described (y-axis).

cTFaA= coronal Tibiofemoral anatomical angle, cTFmA= coronal Tibiofemoral mechanical angle, cTA= coronal Tibial angle, sTA= sagittal Tibial angle, cFA= coronal Femoral angle, sFA= sagittal Femoral angle, aFRA= axial Femoral rotational angle, aTRA= axial Tibial rotational angle, aCRA= Combined/ mismatch rotational angle

*Table 2-10: The association between malalignment and patient-reported outcomes. Summary of results*

| Author | Radiological assessment quality | 'Risk of Bias' assessment | Parameter of Alignment assessed | Patient-related outcome assessed | Any statistical significant association between malalignment & worse outcome? | Details of the association identified |
|---|---|---|---|---|---|---|
| **Aglietti et al 2007 [178]** | High Risk | unclear risk | cTFmA | KSS (clinical) HSS patellar score | Yes | Lower functional scores in patients with overall varus alignment |
| **Bach et al 2009 [211]** | High Risk | unclear risk | cTFaA, cTA, sTA, cFA, sFA | KSS<br>HSS<br>Bristol score<br>Nottingham health profile | No | No significant correlation was found between implant alignment and the mean clinical score outcomes. |
| **Bankes et al 2003 [118]** | Low Risk | Low risk | cTFaA, cTA, sTA, cFA, sFA | KSS | No | No difference in functional outcome between in-range aligned implants and outliers. |
| **Barrack et al 2001 [179]** | High Risk | Low risk | cTFmA, cTA, cFA, aFRA, aTRA, aCRA | KSS<br>VAS<br>Patella-femoral symptoms questionnaire | Yes | Tibial component rotation and combined component rotation were correlated with lower KSS (clinical) and the presence of anterior knee pain. |
| **Bell et al 2012 [219]** | High Risk | Low risk | aFRA, aTRA, aCRA | OKS, VAS, ROM | Yes | There was a significant difference between the two cohorts with increased numbers of patients in the painful cohort with excessively internally rotated tibial (p=0.0003) and femoral (p=0.014) components and with internally rotated combined component (p=0.0003) and mismatched component rotations (p=0.0001). |
| **Blakeney et al 2013 [220]** | Low Risk | Low risk | cTFmA | SF-12, OKS | Yes | There was a significant improvement in the OKS when mechanical axis was within ±3° of neutral.<br>There were no statistically significant differences seen in the MCS and PCS components of the SF-12. |
| **Choong et al 2009 [119]** | Low Risk | Low risk | cTFmA | KSS<br>SF-12<br>Blood loss<br>Length of stay<br>complications | Yes | At 12 months, the total KSS score was significantly better in patients with a mechanical axis within 3° of neutral compared to those greater than 3°.<br>The SF-12 physical and mental scores were significantly better for patients with a mechanical axis within 3° of neutral. |
| **Czurda et al 2010 [180]** | Low Risk | Low risk | cTFmA, sTA, sFA, aFRA | WOMAC<br>KSS | Yes | Rotational malalignment had a sevenfold higher probability of suffering from post-operative pain.<br>No statistically significant relationship between post-operative pain and implant malalignment in terms of the mechanical axis, flexion of the femoral component, the dorsal slope. |
| **Gøthesen et al 2014 [216]** | Low Risk | Low risk | cTFmA, cTA, cFA, aFRA, aTRA, aCRA | KSS, KOOS, EQ-5D, VAS, ROM | Yes | Tibial posterior slope < 1°, or an anterior slope, had worse KSS scores and VAS at one year follow-up.<br>Outliers of the other angles measured did not show any statistically significant differences in functional results compared with the well-aligned knees. |

*Continued table 2-11: The association between malalignment and patient-reported outcomes. Summary of results*

| Author | Radiological assessment quality | 'Risk of Bias' assessment | Parameter of Alignment assessed | Patient-related outcome assessed | Any statistical significant association between malalignment & worse outcome? | Details of the association identified |
|---|---|---|---|---|---|---|
| **Howell et al 2013 [105]** | Low Risk | Unclear risk | cTA, cTFmA, aCRA | WOMAC, OKS | No | There was no difference in function scores between in-range aligned implants and outlier. |
| **Huang et al 2012 [217]** | Low Risk | Low risk | cTFmA | KSS<br>SF-12 | Yes | IKS score remained significantly better for patients with a mechanical axis within 3° at 5 years.<br>SF-12 score significantly higher than patients greater than 3°.<br>There was a decline in SF12-MCS for the group whose alignment was greater than 3° at 12 and 24 months and again at 5 years. |
| **Longstaff et al 2009 [95]** | Low Risk | Low risk | cTA, sTA, cFA, sFA, aFRA, aCRA<br><br>Cumulative score of malalignment | KSS<br>Length of stay | Yes | Good coronal femoral alignment had a better functional outcome at 1 year compared to the badly aligned<br>Good sagittal or rotational femoral alignment and coronal tibial and sagittal tibial alignment demonstrated a trend to better function at 1 year (Both NS).<br>Patients with a cumulative error score of less than 6° had a significantly better functional outcome at 1 year than those with greater alignment errors (NS).<br>The postoperative hospital stay in patients with this low cumulative error score was 2 days shorter than their badly aligned counterparts (P =0.001). |
| **Lutzner et al 2010 [212]** | High Risk | Low risk | cTFmA, aFRA, aTRA, aCRA | EuroQol<br>KSS | Yes | Mismatch between femoral and tibial >10° component was associated with lower KSS (function) scores<br>The postoperative femoral or tibial rotational alignment of the components alone had no influence on the functional outcome. |
| **Magnussen et al 2011 [213]** | High Risk | Low risk | cTFmA, cTA, cFA | KSS<br>revision rates | Yes | Lower KSS score with varus tibial component, lower KSS score with valgus femoral component. |
| **Matziolis et al 2010 [193]** | High Risk | Low risk | cTFmA, cTA, cFA | KSS<br>WOMAC SF36<br>ROM | No | No difference in any outcome between malaligned and aligned groups |
| **Nicoll et al 2010 [94]** | High Risk | Low risk | cTFaA, cTA, sTA, cFA, sFA, aFRA, aTRA, aCRA | KSS<br>VAS | Yes | Painful group there were more cases with femoral internal rotation over 6° and tibial internal rotation of 9°.<br>No other difference between groups in other alignment parameters |
| **Rienmüller et al [218]** | High Risk | Unclear risk | aFRA | KSS, ROM | No | No statistically significant difference could be seen in relation to KSS (knee score [KS] and function score [FS]) or range of motion |
| **Stulberg et al 2008 [215]** | Low Risk | Low risk | cTFmA, sTA, sFA | KSS<br>ROM<br>Flexion contractures | No | No association with KSS for any measure of alignment<br>Increased postoperative mechanical axis deviation associated with the presence and magnitude of flexion contractures |

**cTFmA= coronal tibiofemoral mechanical angle, cTFaA= coronal tibiofemoral anatomical angle, cTA= coronal tibial angle, sTA= sagittal tibial angle, cFA= coronal femoral angle, sFA= sagittal femoral angle, aFRA= axial femoral rotational angle, aTRA= axial tibial rotational angle, CRA= Combined/ mismatch rotational angle.**
**KSS= Knee society score, OKS= Oxford knee score, VAS= Visual analogue scale, ROM= Range of motion, HSS= Hospital for special surgery score.**

*Table 2-12: The association between malalignment and revision. Summary of results*

| Author | Radiological assessment quality | 'Risk of Bias' assessment | Parameter of Alignment assessed | Outcome assessed | Any association between malalignment & worse outcome | Details of association identified |
|---|---|---|---|---|---|---|
| **Berend et al 2004 [126]** | High Risk | Low risk | cTFaA, cTA, cFA | Tibial implant survival | Yes | Failure associated with:<br>Varus tibial component alignment > 3° (Hazard Ratio 17.2, p < 0.0001).<br>Overall varus limb alignment.<br>Femoral component valgus in the face of tibial varus reduced the risk of failure, but was not fully protective. |
| **Bonner et al 2011 [115]** | Low Risk | Low risk | cTFmA | Revision rate | No | No difference in revision rate |
| **Fang et al 2009 [127]** | High Risk | Low risk | cTFaA, cTA | Revision rate | Yes | Revision rate lower for neutral group (0.5%) compared to varus group (1.8%) (P = .0017) and valgus group (1.5%) (P=.0028). The failure rate was equally low for each degree within the neutral alignment group, which includes a range of approximately 5° (2.4°-7.2°).<br>At 20 years, survival rate was 99%, compared to 95% for the varus group and 97% for the valgus group<br>6.9 times increased risk of failure by medial tibial collapse in varus knees compared to properly aligned<br>3.7 times increased risk of failure due to instability compared to normal aligned knees (P = .02).<br>Varus tibial alignment was found to be only associated with a 2.8 times increased risk of failure by medial tibial collapse (odds ratio, 3.0; P=.04), compared to a 6.9 times risk for tibial collapse based on overall varus alignment (P <.0001). |
| **Kim et al 2013 [221]** | Low Risk | Low risk | cTA, sTA, cFA, sFA, cTFaA, aFRA, aTRA, aCRA | Revision rate | Yes | Risk factors for revision are overall anatomical knee alignment less than 3° valgus, coronal, alignment of the femoral component less than 2.0° valgus, flexion of the femoral component greater than 3°, coronal alignment of the tibial component less than 90°, sagittal alignment of the tibial component less than 0° or greater than 7° slope, and external rotational alignment of the femoral and tibial components less than 2° |
| **Magnussen et al 2011 [213]** | High Risk | Low risk | cTFmA, cTA, cFA | Revision rate KSS | No | No diff in IKS or revision in patients with neutral (within 3°) or varus residual overall limb alignment. |
| **Morgan et al 2007[214]** | Low Risk | unclear risk | cTFaA, | Revision rate | No | No association between malalignment and revision rate |
| **Parratte et al 2010 [116]** | Low Risk | Low risk | cTFmA, cTA, cFA | Revision rate | No | No difference in revision rate |
| **Ritter et al 2011 [128]** | High Risk | High risk | cTFaA, cTA, cFA, | Revision rate | Yes | Varus tibial malalignment and valgus femoral malalignment associated with revision.<br>Correction of varus or valgus malalignment of the first implanted component by placement of the second component to attain neutral tibio-femoral alignment was associated with a failure rate of 3.2% (p = 0.4922) for varus tibial malalignment and 7.8% (p = 0.0082) for valgus femoral malalignment. |

**cTFaA= coronal Tibiofemoral anatomical angle, cTFmA= coronal Tibiofemoral mechanical angle, cTA= coronal Tibial angle, sTA= sagittal Tibial angle, cFA= coronal Femoral angle, sFA= sagittal Femoral angle, aFRA= axial Femoral rotational angle, aTRA= axial Tibial rotational angle, aCRA= axial Combined/ mismatch rotational angle**

## 2.6 **Discussion & conclusions**

The impact of malalignment following TKA surgery on patient-related outcomes has been debated since the early years of this procedure's conception. Design improvement, technology advancement, and increased patient demands and expectations are some of the factors that have swayed views on this issue. This systematic review has examined the latest evidence on the association between TKA implant and overall limb malalignment following TKA surgery and patient-related outcomes.

The main findings of this review were that 67% (total n=9) of the studies with 'Low risk' radiological assessment methods have found a statistically significant association between one or more parameter of malalignment and PROMS, whereas only 25% (n=1) found a similar association with revisions rates. This association was less evident when the malalignment parameters were evaluated individually for any association with outcomes. We found that malalignment in the mechanical axis was not associated with worsening PROMs score disagreeing with the view that mechanical axis alignment is important for patient outcome.

The relationship between malalignment and both patient reported outcomes and/or revision rates has attracted much attention in the orthopaedic literature. Many studies have failed to address this in a consistent manner. Fifty three articles were excluded from this review because, even though the authors did report descriptive assessments of both malalignment and functional outcomes, they did not report any associations between the two sets using statistical analyses. This is an important finding in itself, for two reasons. First, it may highlight publication bias if correlational analyses were not reported due to non-significant findings. Second, it highlights significant variability in reporting across studies, rendering cross-study comparisons difficult. Therefore, with a view toward improving the standard of the evidence base, we advocate that both descriptive and correlational analyses be provided for any study jointly assessing malalignment and functional outcomes.

Seven studies in this review used CAS. This is relatively small given the popularity of this technique and its consistency at achieving better alignment [186-188]. It would be reasonable to assume that studies reporting CAS outcomes would provide data on the association between alignment and outcome. The literature suggests that CAS studies are usually under-powered for subanalysis of aligned vs malaligned and therefore not reported [222]. The outcomes of CAS vs conventional techniques must not be confused with the outcomes of well-aligned and malaligned knees.

Another important finding was the lack of consistency in the way different studies assessed alignment following TKA surgery. It is this finding that makes a more formal analysis impossible and has to be improved in the future. There is a clear need for a standardised method of reporting alignment following TKA. In order to analyse the evidence based on its radiological assessment merits, a checklist has been devised to quality assess the radiological methods used in each of the eligible studies. This checklist consisted of five questions exploring the following key aspects: the suitability of the imaging modality used, the timing of the imaging, the patient's weight bearing status at the time of imaging, standardisation of acquired images, and evidence of rater reliability when assessing the images for alignment. Further details are described in Chapter 3 of this thesis.

One of the main strengths of this review was in the systematic fashion it was conducted and the adherence with guidelines available on systematic reviews published by one of the major research groups AHRQ. The strength of the evidence presented relies on the strengths and weaknesses of the included studies of which several were identified:

1. The parameters of malalignment were poorly defined. Studies presented malalignment data either in terms of deviation from the leg axis in the arithmetic mean or as two groups of 'Aligned' vs.' Malaligned' or ' in range' vs. 'Outliers'. While the majority of studies applied a ± 3° range around a perfect alignment measurement, some studies had a more stringent criterion applying a ± 2° range. In applying this narrow range, Longstaff et al [95] found better functional outcomes with good coronal femoral alignment and only a trend to better function at 1 year on patients with 'good' coronal tibial, sagittal tibial, and sagittal femoral alignment.
2. A number of studies restricted their analysis to one or two parameters of alignment. This approach is problematic given the relative interconnection between the alignment components in a TKA. Berend et al [126] found the

effect of malalignment in one implant moderated by the alignment of the other. Ritter et al. [128] concluded that correction of the alignment of the second component in order to produce an overall neutrally aligned knee replacement when the first component has been malaligned may increase the risk of failure. These findings suggest a complex interplay between all measures of alignment in both the tibial and the femoral components that cannot be simplified to conventional definitions of “malaligned” or “aligned”.

3. A number of studies had relatively small sample sizes and were predisposed to a type II error. The non-significant differences obtained here are due to the small numbers in the sample. Matziolis et al [193] found varus malalignment not to influence outcome on a sample of 50 patients divided into two groups, while Morgan et al [214] had only six revisions in his sample looking at the association between malalignment and revision rates.
4. In our opinion, the main limitation in the evidence analysed was in the methods of assessing alignment, in particular, the timing of assessment. Ritter et al [128] retrospectively analysed 9483 patients operated on between 1983 and 2006 and found failure most likely to occur with tibial component malalignment. The radiological data used in their analysis were obtained at the time of latest follow-up ranging between 2 to 22.5 years following surgery. Barrack et al [179] found tibial component rotation and combined components rotation to be associated with lower KSS. The CT scans were performed on a matched 14 cases with knee pain, total 28 patients, after the onset of symptoms with an average of 5.5 years after operation.

The characteristics of the patient-related clinical outcome measures used by the studies included in this review may have contributed to the quality of the evidence presented. Revision rate as an outcome measure might not be a good representation of implant failure. The decision to revise an implant is subject to the surgeons' endorsement that might be determined by other, patient-related and non-patient-related, factors. On the other hand, some quality-of-life outcomes can suffer from ceiling effects, which can result in abolishing the advantage of perfectly aligned implants in comparison to those with mild degree of malalignment. The KSS is a regularly used functional score and most commonly identified in this review is subject to assessor bias.

In conclusion, based on the current best available data, malalignment appears to be associated with procedure outcomes. The evidence available in the literature to support this conclusion is subject to several limitations. These limitations are mainly related to the methods of assessing alignment and the characteristics of the outcome measures used. Larger longitudinal studies with a standardised, robust method for assessing alignment, and better reporting of outcomes are required. Now that more reliable methods of assessing patient reported outcome are available we expect that better reporting will occur in the future.  The results of this systematic review confirm the relevance and importance of alignment during TKA. The knowledge gained from this and the previous Chapter have contributed to and provided clear rationale for use of malalignment following TKA as a surrogate for technical success of this procedure.

This would help frame the research question proposed in Chapter 4 to test the thesis's main hypothesis.

# Chapter 3 Malalignment following TKA surgery: A literature review of the radiological assessment methods, and the development of new radiological technique for the assessment of coronal alignment.

As discussed in Chapter 1, the assessment of alignment following a TKA can be performed by various methods, most commonly using radiological assessment techniques. Other methods such as, computer assisted surgery (CAS) technology, with or without radiological imaging, can provide instant measurements of alignment during the operation. Alignment can also be measured directly by means of performing a physical examination of the limbs using a goniometer (an instrument used to measure angles). With advancing imaging technology, many radiological assessment techniques, with variable properties and reliabilities, are now available.

In Chapter 4 of this thesis, a study investigating the association between malalignment following TKA surgery and non-technical outcomes during surgery is presented. In order to establish the most suitable method of assessing malalignment, the main objective of this chapter is to identify the most suitable radiological method for the assessment of alignment following TKA. Section 2 of this chapter, an agreement and reliability study for a novel method using custom made jig and trigonometry principles for the assessment of coronal alignment is presented.

## 3.1 Literature review on the current radiological methods for assessing alignment parameters following TKA surgery.

The use of imaging following TKA is an important tool for investigating unsuccessful TKAs and post-operative complications [223, 224]. There are currently numerous refined imaging modalities with various properties available. The choice of modality is primarily dictated by the pathology investigated. The information extracted from image interpretation depends on the inherent limitations of the physical processes creating and displaying the radiological images. Hence it is important to identify the most appropriate method of imaging for each pathology. For the assessment of malalignment following TKA surgery, a successful radiological modality would be one capable of producing a geometrical image of the knee and/or limb that resembles reality.  Different radiological modalities are currently available, these can be summarised in order of the complexity of image acquisition in the diagram below (Figure 3-1).

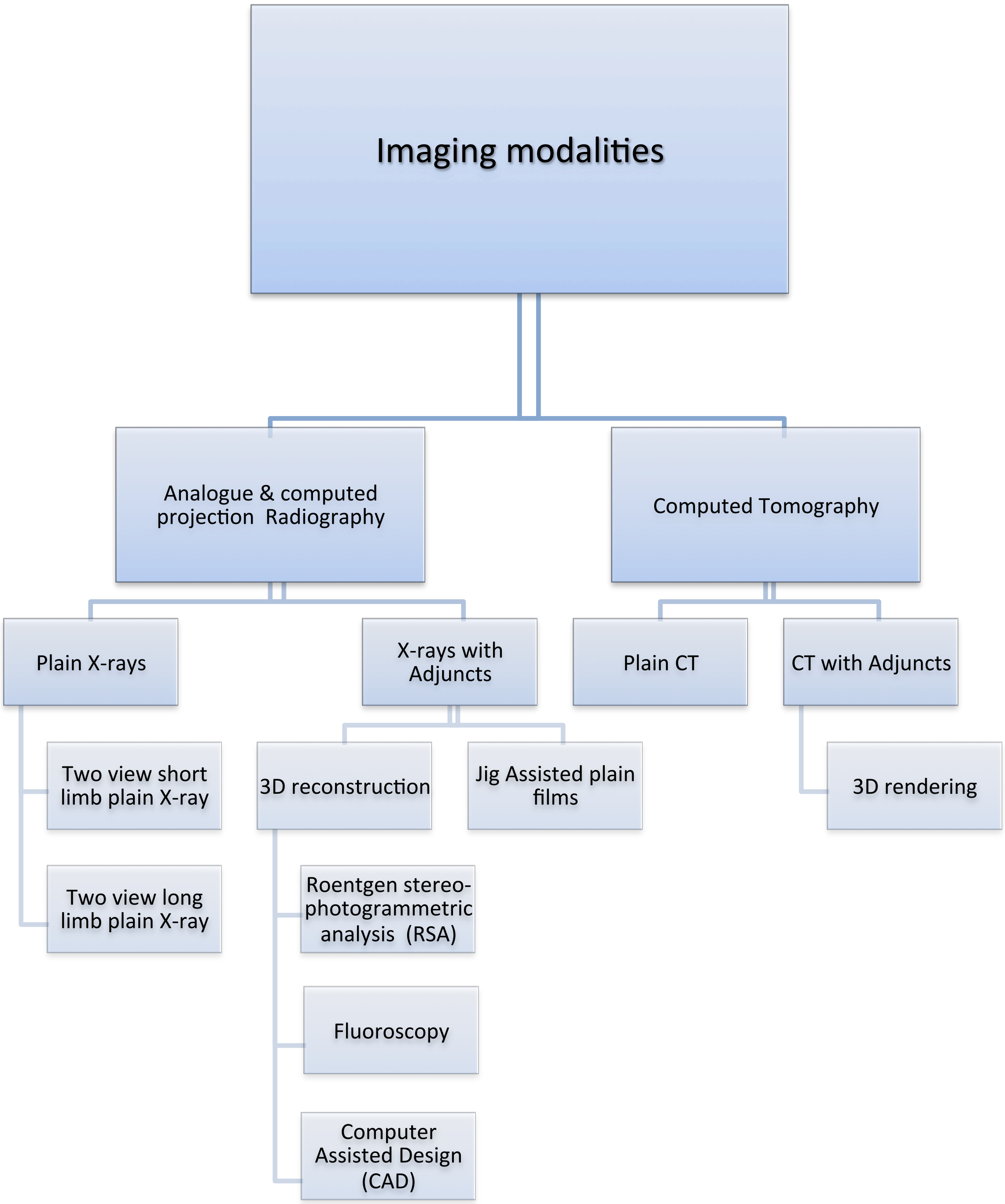



*Figure 3-1: Imaging modalities for the assessment of Alignment following TKA*

### 3.1.1 Analogue & computed projection radiography (Plain X-rays)

Historically analogue and recently computed projection radiography (plain X-rays) is one of the most common methods used for the radiological assessment and follow-up of a TKA [225, 226]. It refers to the use of projection electromagnetic radiation (X-ray) to create images. X-rays are emitted from the X-ray tube after a high atomic number heavy metal element such as, Tungsten, is bombarded with an accelerated high voltage electrons. The X-ray photons pass through the body, and finally, hit the recording device (detector) in different intensities based on tissue attenuation. The result, is a two dimensional image of body structures superimposed on each other. The main difference between analogue and computed projection radiography is the physical make and material used for recording the images and the subsequent image extraction process. In computed radiography, X-rays are trapped on a phosphor storage device that requires light (laser) input to release the trapped energy. The images are created as a matrix of pixels and stored in a binary format and can be displayed and manipulated digitally on a computer screen. Analogue radiography, which was rapidly superseded by digital or computed radiography, uses silver based photographic emulsion and a multi-stage film development process to create a hard copy film.

In terms of TKA alignment assessment, two sizes of plain X-rays have been reported in the literature; short and long leg X-rays. **Short leg X-rays**, typically showing 10-15 cm above and below the knee joint, have been used in the assessment of TKA since the early days of the procedure [227]. **Long leg X-rays**, acquires an image of the hip, knee and ankle on one film, and is widely considered the method of choice for the assessment of coronal alignment following TKA [112, 115, 116, 178, 193, 214, 228]. The key difference between the two modalities is in the geometry of the image produced. In the case of ‘short film X-rays’, the X-rays are emitted from a fixed-point approximately 100 cm away from the subject. As the rays diverge the image is magnified. With ‘long leg X-rays’, pencil beams reduce the magnification effect because X-rays are projected from multiple points along the limb.

The assessment of TKA alignment using X-rays is an integral aspect of the operation’s evaluation and is described in the Roentographic Knee Society Scoring System [143, 166]. On the other hand, the reliability of this method has been questioned. Lonner et al [229], and more recently Radtke et al [230], both highlighted the impact of limb rotation during X-ray acquisition on the resultant 2-dimenssional (2D) image. They showed a significant difference when assessing the same malalignment angle in various limb rotational positions Figure 3-2 shows a 3-dimenssional (3D) geometric model, created using computer Assisted Design Software (Auto CAD), with an implanted tibial component in an exaggerated malalignment of 20° valgus. The model is rotated around its longitudinal axis in 5° increments. The angle created between the tibial implant longitudinal axis and the tibial bone longitudinal axis is calculated each time on the 2D slices representing a plain X-ray. As the rotation of the model increases, the angle, initially calculated to be 20°, appears to decrease in size to about 14° confirming the findings (Figure 3-2).

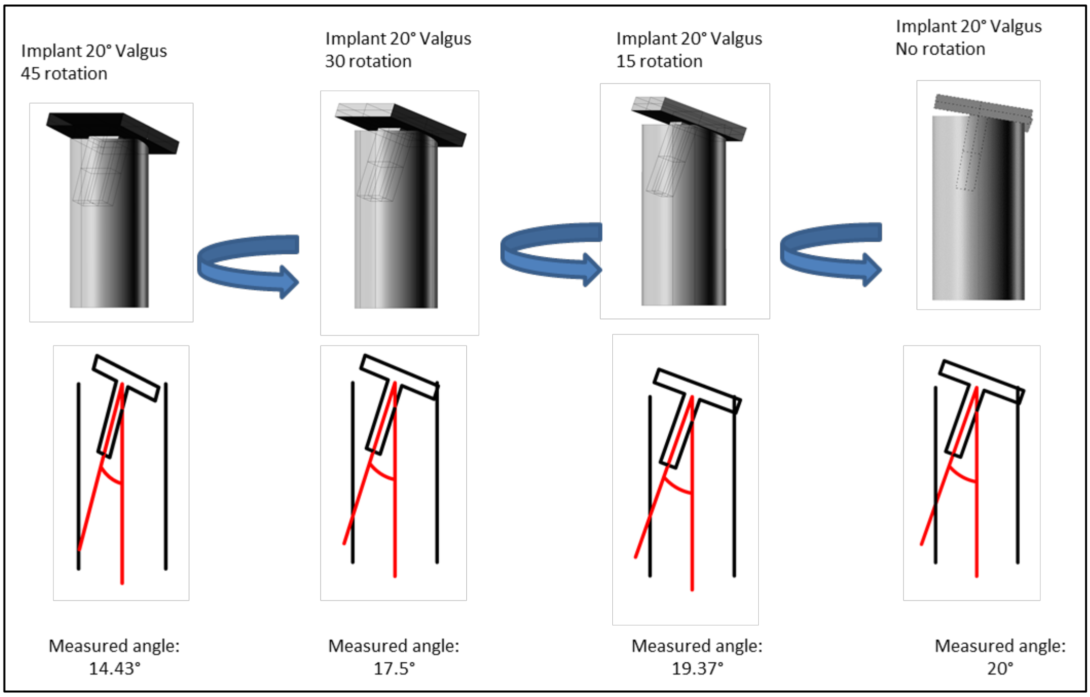



*Figure 3-2: CAD Model showing the change in 2D angle measurement secondary to the model's 3D incremental rotation*

Another drawback to plain X-rays is the inability to assess all parameters of alignment such as axial rotational alignment angles. The lower limb mechanical axis (described above) cannot be accurately plotted on Short leg X-rays as the hip and ankle joints are not part of the image. Instead, investigators [118, 124, 126-128, 211] estimated its position relative to the anatomical axes of 6 degrees valgus.

These limitations have inspired researchers to develop new techniques and methods using various **adjuncts** to improve the reliability of the plain X-ray.

Prakash et al [231] took advantage of the digital imaging technology and reported on a software that automatically assesses alignment by detecting the bone-soft tissue difference in grey-level gradients. Although this reduces the human error in terms of image interpretation, errors as a result of limb positioning at time of image acquisition remain unaffected. One approach to prevent leg rotation was to control its position through the use of standard procedures [232] or specifically designed jigs [233]. The work of Cook et al [123, 233] has demonstrated the benefit of using jigs for the assessment of limb alignment. The principles described were only applied to patients with knee arthritis and not TKA patients and were not tested for the assessment of component malalignment. No evidence has been identified in the literature of the use of jigs during plain X-rays for the assessment of TKA malalignment.

A different approach was to calculate the component's alignment parameters and accounting for any rotation mathematically. Analysing the geometrical relationship of the TKA component's pegs on a radiographic image of a phantom model, Eckhoff et al [234] was able to calculate the rotation alignment of both the femoral and tibial components using a lateral view plain radiographs. His method was later modified using **Fluoroscopy** in order to capture the direction of rotation [235]. Despite a good inter-rater reliability, two main disadvantages were reported; the method was limited to implants with pegs only, and a high rate of inaccuracies in the measurement were noted when the images were acquired with the knee in a flexed position.

More recently, with the help of computer analyses, **3D reconstruction** has become more popular [236-240]. Sato et al [237] used two X-ray machines, at a 60° angle, and a camera calibration system to calculate the relative distances and orientations of components,  Varshney et al [238]used multiple X-ray images to reconstruct a 3D model of implants relative to the bones and each other.  Lai et al [239] and then his colleagues Syu et al [241]used **roentgen stereophotogrammetric** model  analysis with the help of CAD technology to analyse the components' silhouette and reverse engineer 3-planar alignment relative to the saw bones used - Roentgen stereophotgrammetry is a technique to obtain 3D measurements from a radiograph. This technique was described back in the 1970s by Selvik [242]. The marker-based system involved the implantation of tantalum markers around the object being imaged which can be used as reference points to calculate the implant's orientation on the radiological images. This can be achieved manually using mathematical equations [242] or automatically using computer software [243]. The major drawback of using markers when compared to the new model-based system using CAD is the need for a cumbersome and specific surgical setup during the preparation process [236].

Generally speaking, these techniques aim to provide spatial information similar to that provided by computerised tomography with less cost and radiation as shown below.

### 3.1.2 Computerised tomography (CT)

**CT**, originally known as computed axial tomography (CAT scan), is an X-ray imaging technique that produces cross sectional views of the body. The main advantage of this technology is in its ability to provide information on depth relevant anatomical structures compared to plane X-rays. In addition to axial views, CT scans provide profile images of the whole body called "scout" views. In terms of TKA alignment, these images are comparable to long leg X-rays and can be used for the assessment of mechanical, anatomical, and component axes. During a CT scan, patients lie flat on the scanner table while the tube and detectors rotate 360° around them. X-rays are produced continuously passing through the patient and then captured by the numerous sub-millimetres detectors. The modern scanners are able to scan axially and move the table at the same time. This creates a 'spiral' volumetric acquisition that can be reconstructed to represent either a 3D volume or contiguous 2D slices of that 3D volume. With improved reconstruction algorithms in the newest machines, this technology is now capable of providing very detailed 3D images.

Several methods to assess TKA alignment following surgery have been described in the literature. Assessments on 2D axial slices from earlier CT scanners were initially used and are more widely reported. The key difference between these reported methods was in the choice of referencing system used when identifying the relevant anatomical axes. Berger et al [149, 244] described his methods of assessing the femoral component axial alignment relative to femoral surgical epicondylar axis; Nicoll et al [94] used the tibial geometric axis to calculate tibial implant rotation, and Chauhan et al [114] described their protocol for the assessment of most alignment parameters; the Perth's protocol. With all of these techniques, the alignment angles of interest were calculated in a 2D fashion on three planes; coronal, sagittal, and axial. Matziolis et al [245] took full advantage of the CT's 3D ability. His method involved identifying relevant anatomical landmarks on CT scan images to identify bone axes. Using these landmarks, the spatial positions of the components were each identified by one vector. The angles between the components and limb axes, also represented by vectors, were then mathematically calculated. This method of 3D CT reconstruction was shown to be more reliable than two dimensional techniques in the assessment of alignment parameters following TKA [246].

One of the main criticisms of CT is the increased radiation exposure to patients in comparison to X-rays. The effective dose from the CT scan has been estimated as 3mSv while that of an X-ray of an extremity is 0.001mSv. 3mSv is equivalent to 400 days of background radiation, i.e. the radiation dose we are all exposed to during normal day-to-day living. Currently published risk estimates suggest that a dose of 3mSv represents an additional life time fatal cancer risk of approximately 1 in 7 000 [247]. Henckel et al [248] addressed this issue and presented their low-dose CT protocol, Imperial Knee Protocol, reducing the effective dose received down to the equivalent of one long leg radiograph. Another factor to be considered when assessing alignment is the patient's weight bearing status at time of imaging. Another limitation to CT is that patients are non-weight bearing at time of imaging. This may potentially impact on the lower limb alignment as the kinematics of the weight bearing knee are different to that with no load [249, 250]. This is likely the result of the interaction between the loaded knee joint and ligaments during the range of motion [111]. CT scans with axial loading have been reported in the literature for the assessment of spinal [251] and foot [252] pathologies, however and at the time of this work, none has been reported for the assessment of TKA post-operative alignment.

### 3.1.3 The reporting of malalignment following TKA surgery

The reporting of alignment following TKA is a demanding task. As discussed earlier, both assessing and subsequently reporting alignment requires an understanding of the anatomy and physiology of the lower limb both pre and post TKA. There are a large number of reference systems, and a considerable amount of overlap in techniques used by different investigators. This problem is compounded by a lack of consistency amongst researchers in terms of describing alignment parameters. There is a clear need for uniformity in the assessment methods and terminology used; a finding that has been evident in the published literature. To fully understand the impact of malalignment on the outcome of TKA, a valid, reliable, reproducible, and safe method of assessment is required.

Clearly, there are inherent limitations with radiographic techniques that must be considered when assessing alignment following TKA.  Factors including soft tissue conditions and patient positioning, human error in measuring alignment due to imprecise landmark identification contribute to the imprecision of this modality. Therefor a method for assessing the quality of studies reporting malalignment following TKA surgery that has been developed for this thesis is presented below.

### 3.1.4 Quality assessment of radiological studies reporting malalignment following TKA surgery.

Several factors must be considered when reviewing published evidence on malalignment following TKA surgery. In the literature, various limitations to radiological assessment of alignment methods have frequently been highlighted. Prior to this work, no method for assessing the quality of radiological techniques in studies reporting on malalignment following TKA has been described. A method of radiological quality assessment has been developed for this thesis using a flowchart assessment technique. This method is modelled on the limitations already discussed above. A diagram of the flowchart with five scoring questions is presented below. These questions in the flow chart are:

i. Type of imaging modalities: The suitability of the selected modality for the alignment parameter of interest. The rationale for this is that different information can be provided from different modalities. As discussed above, CT scans are superior at assessing axial rotation alignment due to its ability to provide information on depth and deliver axial slices around the knee [244] when compared to plain film X-rays. An overall limb alignment is better assessed on a whole leg radiograph compared to a short film radiographs [233]. Mathematically reverse engineering implant alignment and estimating mechanical axes based on their relationship to anatomical axes are potential sources of error. This item is regarded as an absolute qualifying factor when applying the quality assessment method. Studies with unsuitable imaging modality for the alignment parameter of interest regarded as high risk for bias.

ii. The timing of the imaging; is another absolute qualifying factor. The timing of image acquisition following surgery is important in understanding the association between malalignment and outcome of surgery. For example, malaligned components seen on X-ray images several years following surgery can be the result of implant migration not component malalignment at time of surgery [253]. A 0.5 mm implant migration is acceptable within the first 12 months of surgery but up to 1.6 mm can be seen [254]. Migration can accelerate and worsen malalignment and therefore, it is important to assess implant position in timely fashion in order to identify malalignment at the time of surgery. For the purposes of this thesis, early post-operative images would be best for assessing malalignment, a cut off time of one year following surgery was decided as most follow-up programs will have follow-up X-ray films at 1 year following surgery.

iii. Patient position during imaging; the effect of soft tissue balance following TKA surgery can alter the limb alignment which is most visible during stressing manoeuvre in particular weight bearing [111]. When assessing for overall limb alignment, weight bearing becomes another absolute factor to be meet otherwise the study is regarded as high risk.

iv. Protocols are necessary to ensure consistency in producing comparable images for different patients and in the assessment of images. These protocols will govern the methods used for image acquisition based on the modality used; for example the distance from X-ray tube to patient when using plain X-rays to control magnification of images, the use of equipment and jigs as a the method for controlling rotation of the limb, and the body area, slice thickness, and acquisition time when using CT scanning to ensure relevant anatomy is included in the scan.

v. Inter- and intra-rater reliability; studies need to demonstrate the reliability of the assessment method used.

As shown in the flow chart below, studies are only regarded as low risk of bias for radiological assessment if they progress through the chart with an answer ‘yes’ to the questions.

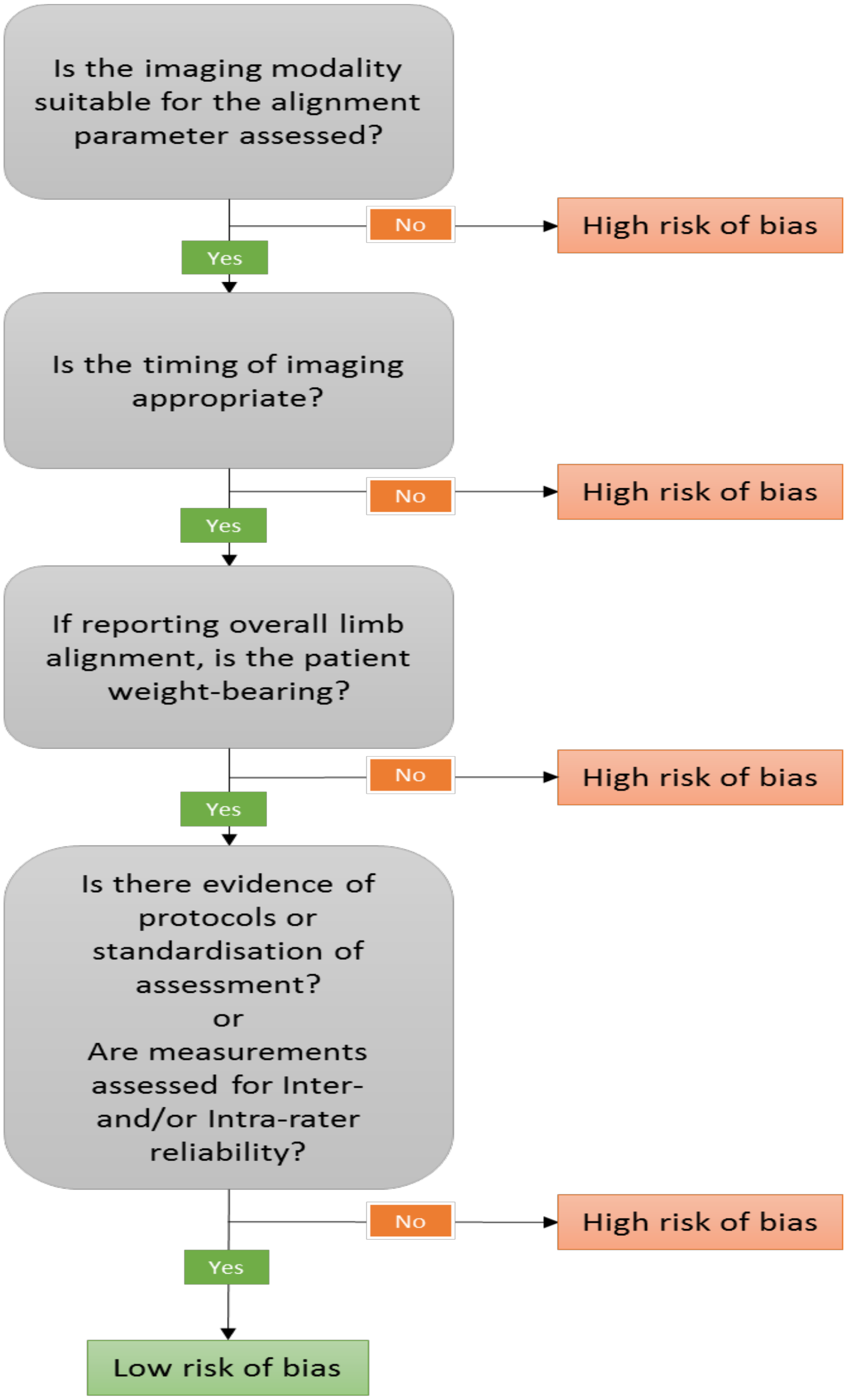



*Figure 3-3: Flow chart for evaluating the quality of radiological methods used for assessing and reporting alignment following a TKA*

### 3.1.5 Conclusion

Alignment following TKA surgery is a multidimensional concept. When using conventional mechanically aligned total condylar TKA systems, surgeons will strive to achieve a set of ideal alignment angles. There are numerous anatomical reference points and axes that are used to establish the alignment of both components and limb during TKA surgery. Several factors may play a part in achieving these set targets most of which are controlled by the surgical team such as making the appropriate bone cuts and balancing the soft tissues around the knee. Another factor that was not discussed in detail is whether there are any deformities around the knee prior to surgery. This will require further attention from the surgeon with a tailored approach to surgery however, for the majority of cases the principles remain the same in achieving a neutral overall limb alignment.

There are a variety of radiological modalities for the assessment of alignment following TKA. As technology advances and image acquisition improves more reliable information will be available. The choice of modality must ultimately be made according to the parameter of malalignment being investigated with the least radiation exposure to patient. Radiological images need to be acquired in a timely fashion to identify malalignment at time of surgery. The process of image acquisition should be controlled to factors such as weight bearing status and limb rotation to minimise error in assessment. Lastly, demonstrate adequate inter- and intra- rater reliability.

Currently, there is a lack of consistency in assessing and subsequently reporting malalignment in the literature.  There is a clear need to scrutinise evidence on the basis on its radiological assessment methods. Therefore, a method for assessing the quality of studies based on their radiological assessment methods for malalignment following TKA surgery has been developed and presented. The lack of consistency in assessing malalignment will inevitably result in a lack of understanding of the full impact of malalignment on outcomes following TKA. Chapter 2 of this thesis is systematic review of the literature designed to investigate the effect of malalignment following TKA surgery on patient outcomes.

Finally, the aim of this Chapter was to establish the most suitable radiological method for assessing alignment that will be used for the main study in this thesis (Chapter 4). Given that the precise assessment of post-operative alignment of interest included the overall lower limb alignment and implants alignment across all three planes, it was decided that CT scan would be the modality of choice. A modified protocol was devised to reduce the radiation dose by skipping sections of the leg during CT scanning while maintaining limb integrity on the digital images to allow the correct identification of the relevant anatomical landmarks, axes, and the implants position relative to them and each other.

## 3.2 The assessment of coronal component alignment following TKA surgery: an agreement and reliability study for a novel method using custom made jig and trigonometry principles

### 3.2.1 Introduction

Achieving perfect coronal alignment is one requirement towards a successful TKA. Several authors have recognised coronal plane malalignment as one of the most important factors determining the long-term prosthesis survival [124, 126-128, 169, 170, 217]. Therefore, it is imperative to identify patients with malalignment in a timely fashion if adequate management is to be arranged. Above, an account of the various modalities available for the assessment of coronal malalignment following TKA is presented.

Despite the presence of very refined radiological techniques, such as CT scanning, short film plain X-rays remain the commonest modality of radiological assessment post TKA surgery. It is not surprising given that X-rays are widely available, cheap, and expose patients to a relatively small radiation dose. As discussed above, short film X-rays are unreliable in assessing the implant alignment following a TKA [229, 230, 233, 255]. The 2 dimensional image produced is influenced by the position of the X-ray beam source and the patient's orientation, in particular, limb rotation [229, 230]. Several attempts to overcome these limitations have been reported with variable success. These included standardising the position of limbs during image acquisition using surface anatomy landmarks [232], and 3D image reconstruction using multi-view images [238] or camera calibration systems [237].

Rheumatology is another discipline where the assessment of lower limb alignment is necessary. Similarly, short film plain X-rays commonly provide this information necessary for monitoring the progression of knee arthritis. Radiological studies investigating rheumatoid arthritis of the knee have reported X-rays techniques capable of producing more reliable images when assessing limb alignment. Their method involves positioning the patient with the knee in a semi-flexed position resembling that of skier descending down a slope (Schuss position views). The primary purpose of this position is to enhance joint space appearance on X-rays to allow for better assessment of the loss of joint space as a consequence of knee arthritis. Through standardising the patient’s knee position in a controlled environment, these techniques were able to demonstrate validity and excellent inter-rater agreement when assessing anatomical axes of the femur and tibia comparable to other assessment modalities such as long leg X-rays [233, 256, 257].

Given that implant alignment can be assessed relative to the anatomical axes, we hypothesised that these concepts and techniques can be successfully replicated for TKA patients.  Thus, the aim of this study is to report a new radiological X-ray technique with the aid of jigs and standard operating procedures (SOP) (See Appendix B) on patients following TKA surgery. No evidence of similar study or the use of Jigs on patient following TKA surgery has been identified. Based on the Guidelines for Reporting Reliability and Agreement Studies (GRRAS) [258], an agreement and reliability study for the assessment of component alignment on the coronal plane in patients following TKA between the new X-ray methods and CT scan images is presented.

### 3.2.2 Methods

#### 3.2.2.1 Research question

Can jig-assisted X-rays of the knee in the semi-flexed position (Schuss position) following TKA generate reproducible images of the knee and allow reliable assessment of TKA implants alignment in the coronal plane when compared to CT scan?

#### 3.2.2.2 Pilot study using Saw Bones®

Prior to the main clinical study for this section, a preliminary pilot study was also carried out to assess the face validity of this new technique. This involved the use of saw bones (Sawbones®, Inc. Vashon Island, WA) to create three Nexgen (Zimmer Inc, Warsaw, IN) TKA models. The implants were positioned by an orthopaedic consultant using similar TKA equipment and setting the jigs accordingly, to create the following:

- A neutral knee model with the femoral component at 6° valgus to the cFAA and the tibia at 90° to the cTAA. (cTFaA = 186°)
- A model with an exaggerated valgus knee deformity
- A model with an exaggerated varus knee deformity

A CT scan of each model was taken to check the angle achieved (Figure 3-4) then X-rayed according to the new protocol in a semi-flexed position. The positioning of models proved difficult in particular the degree of knee flexion because in the Schuss views method, as will be discussed in detail below, the patient is weight-bearing and the degree of knee flexion is based on the size of the leg and foot. The degree of flexion will in turn decide the degree of X-ray tube inclination.  Therefore, two sets of X-rays were acquired for each model (10° knee flexion with 10° X-ray tube inclination and 20° knee flexion and 20° X-ray tube inclination). The images were reviewed by two researchers with experience in using the measurement tools on PACS (picture archiving and communication system). Component alignment was assessed relative to the anatomical axes of the bones. The two aims for this study were achieved; firstly to identify the deformity correctly on the images, and secondly to calculate the cTFaA to within 5 degrees of the true angle on the three models by both assessors (Table 3-1).

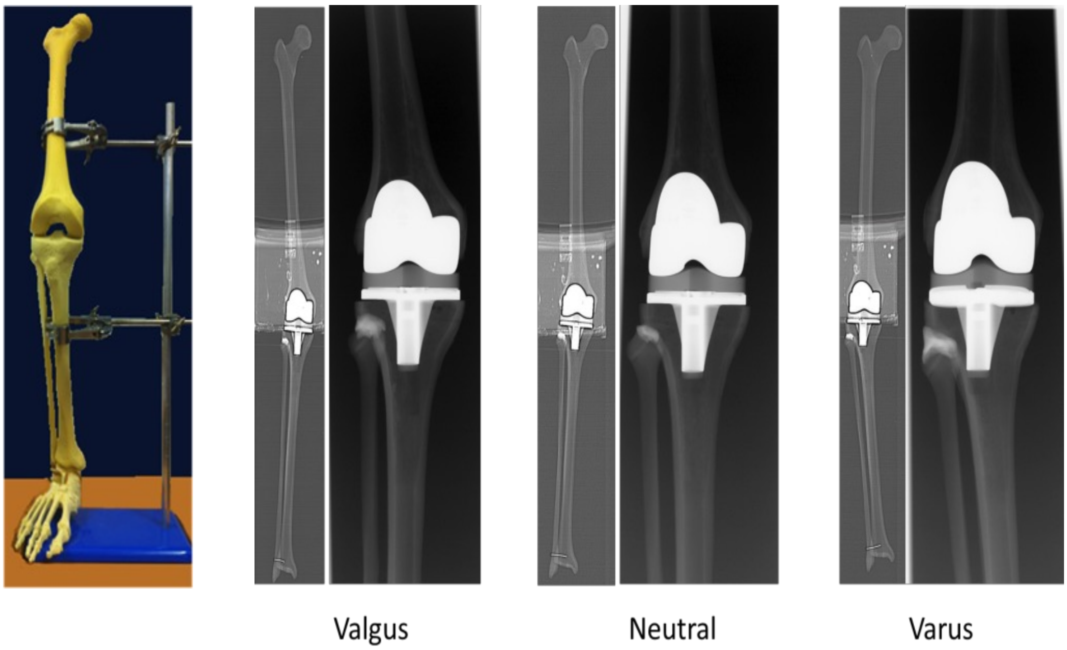



*Figure 3-4: (Left) Saw-bones model in a semi-flexed position. (Right) CT and X-rays in Schuss position of 3 different Saw-bone models in neutral, varus and valgus knee positions*

*Table 3-1: Results of the saw bones pilot study showing the deformity correctly identified and the cTFaA measured to within 5° in all models*

| Model | Flexion-inclination angle | cTFaA angle (CT) | Deformity identified (both assessors) | Radiological angle Assessor 1 | Radiological angle Assessor 2 |
|---|---|---|---|---|---|
| **Neutral knee** | 10-10 | 185 | Yes | 182 | 183 |
| | 20-20 | 185 | Yes | 185 | 183 |
| **Valgus knee** | 10-10 | 190 | Yes | 190 | 189 |
| | 20-20 | 190 | Yes | 191 | 190 |
| **Varus knee** | 10-10 | 173 | Yes | 173 | 174 |
| | 20-20 | 173 | Yes | 172 | 173 |

#### 3.2.2.3 Study settings and patient selection

Recruitment to this study was performed as part of the main recruitment process for the study in Chapter 4 of this thesis. All patients who agreed to take part in the other study and subsequently underwent a lower limb alignment CT scan were also invited to this study. This took place during the 6 weeks follow-up visit following TKA surgery. All images would be acquired on the same day. If the patients agreed to take part, their immediate post-operative short leg films would be retrieved from PACS for use in the analysis of the current study. Ethical approval was obtained for this study (Oxford A REC 09/H0604/39) Appendix 15.

#### 3.2.2.4 New semi-flexed (Schuss position) X-ray protocol

This X-ray method is a modification of the Lyon Schuss X-rays view previously reported for knee joint space visualisation [257, 259, 260]. All X-rays were acquired at 6 weeks following surgery. Short leg X-rays of the knee were performed with patient weight bearing, heels 10 cm apart, feet 10 degrees external rotation, and both knees semi-flexed. A custom-made prototype jig was designed to achieve the required patient position. The jig was designed so the patient's toes are in line with X-ray detector base and the knee in contact with the centre of the X-ray film. The jig was positioned according to the side being X-rayed and moved front to back according to the patient's foot size in line with various axes placed on the floor (Figure 3-5 A, B).

Participants were first, asked to stand on the jig and place both heels along the back and middle jig edges; this would position the heels 10 cm apart and feet 10 degrees in external rotation (Figure 3-5 C). Secondly, patients flexed both their knees until contact with the X-ray detector was achieved. The X-ray detector would be moved up and down until the knee contact is with the centre. Finally, patients leaned forward until the anterior aspects of both thighs were in full contact with the X-ray detector (Figure 3-5 D).

Applying trigonometry principles (described below), the X-ray tube inclination angle was adjusted according to the patient's leg length (length from superior patellar edge to floor) and foot size. From a fixed tube-to detector distance of 100 cm, the X-ray tube was elevated or lowered until the X-ray central beam - represented by a laser marker - was pointing at the posterior knee crease. The X-ray tube window was enlarged to include at least 10 cm above and below the knee joint. The participants were asked to hold position while X-rays are acquired.

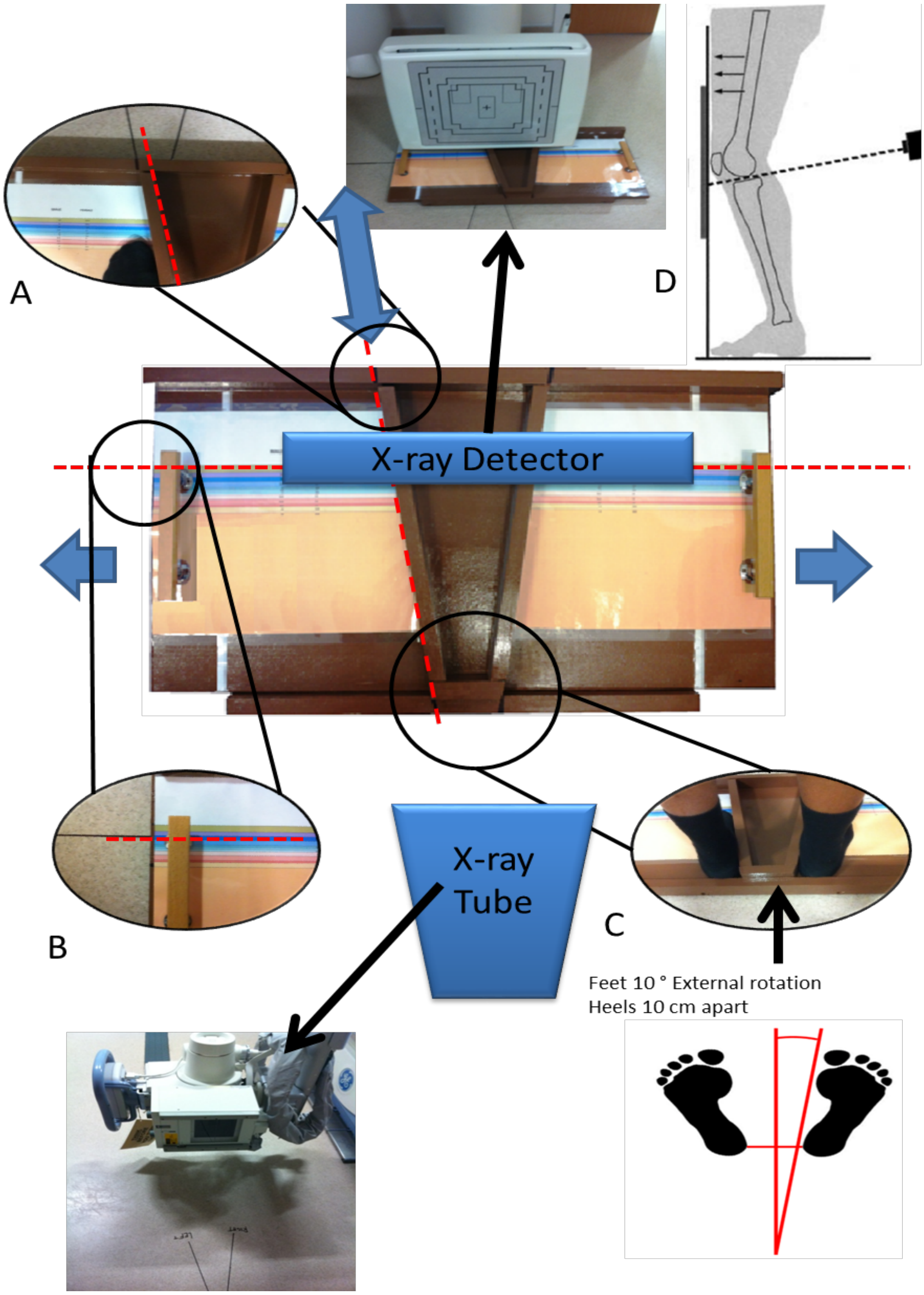



*Figure 3-5: Prototype Jig positioning for a LEFT knee X-ray.*

*A. Jig moved sideways until aligned with oblique floor axis based on limb side being X-rayed. B. Jig moved front and back until horizontal axis is aligned with foot size colour line. Blue arrows show the direction the jig can be moved for positioning. Red dotted lines show the floor markings used for jig positioning. C. Patient feet positioned along the back and middle jig edges. D. Thigh position against X-ray detector [257].*

### 3.2.2.5 Measuring the X-ray inclination angle using trigonometry principles

A method to calculate the X-ray inclination angle was developed using trigonometry principles. A schematic diagram below demonstrates the method (Figure 3-6 and Appendix - 1).

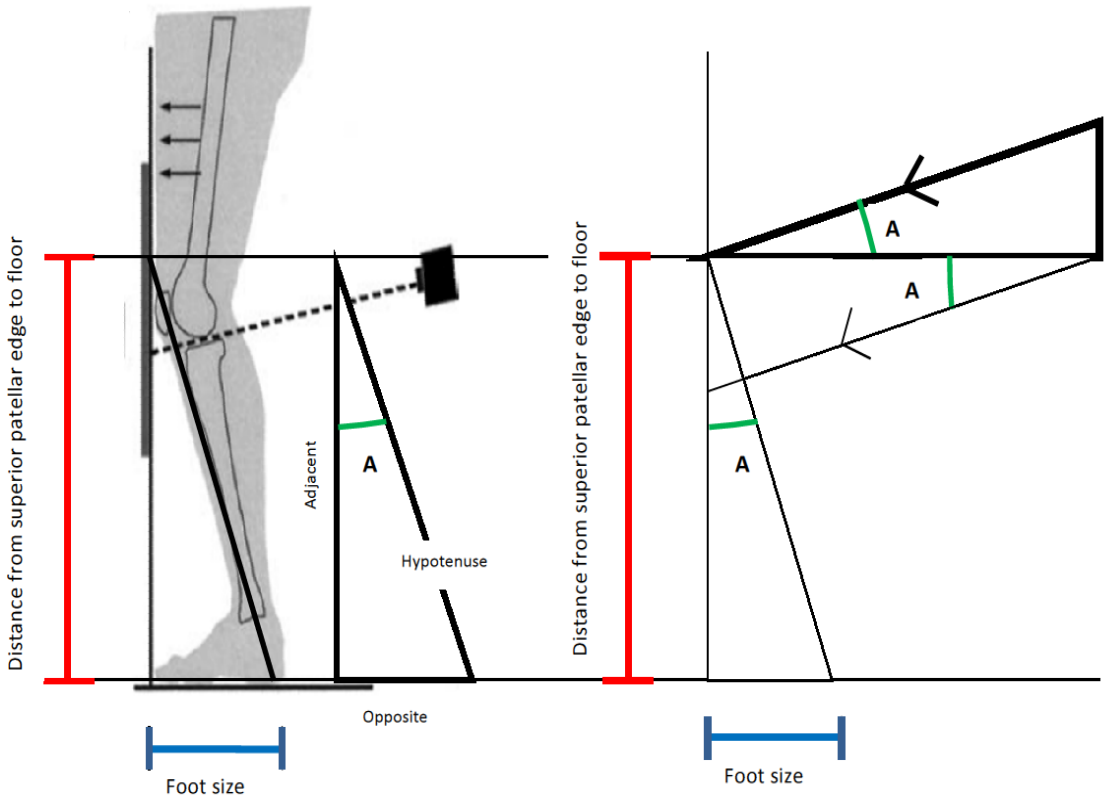



*Figure 3-6: Schematic diagram showing the inclination angle calculations using trigonometry principles*

To calculate angle A, two measurements were acquired from each individual; foot size and the distance from the superior patellar edge to floor both in centimetres. These two measurements will form the two sides of the right angle triangle; the adjacent and opposite. The measurements are then fed into the following equation:

$A° = \tan^{-1}$ (opposite/adjacent)

∴ Inclination angle° = $\tan^{-1}$ (foot size / distance from the supra-patellar edge to floor) – tibia slope angle (7°)

The feet size measurements were modelled on the commercially available Mondopoint system of feet sizing (Appendix - 2). The distance from the supra-patellar edge to floor was measured using a ruler prior to the X-ray acquisition. A chart with a range of feet sizes plotted against a range of distances from floor to supra-patellar edge was designed to assist with the calculation of the X-ray inclination angle (Appendix - 3 and Appendix - 4). This value was then provided to the radiographer acquiring the image to set the X-ray machine accordingly.

The inclination angle will determine the position of the X-ray tube so that the X-ray beam runs parallel to the tibial component's metal flat base. The majority of tibial implant will be implanted with a 5°-7° posterior slope. The inclination of the X-ray tube will take this into account and the error due to the posterior slope either minimised or mitigated. Another advantage is producing a less distorted image with a more defined bone-implant interface both allowing more accurate assessment of implant position relative to bony anatomical axes. However, not all implants require a posterior slope. Constrained implants tend to be rotating platform with a zero degree slope. Other implants have a posterior sloping poly insert built in. In these instances the degree of sloping will be set to zero when calculating the angle.

Because the novelty of the technique, and despite providing an SOP (Appendix - 5), patient positioning was performed under my supervision to ensure the protocol was implemented accurately.

#### 3.2.2.6 CT scan protocol

Scans were performed according to the departmental lower limb alignment CT protocol with patients in a supine position. A multi-slice CT scanner captured contiguous slices from the hip acetabular roof to the ankle talar dome. Three dimensional rendered images were then used for the assessment of alignment parameters. Further details of the CT scan protocol used are described in Chapter 4.

#### 3.2.2.7 Routine short leg radiographs

These were performed according to the departmental protocol at our hospital. Short leg radiographs were performed during the immediate post-operative period. For the coronal images, patients were supine with knees fully extended as pain allows. Positioning the big toe vertically upwards controlled rotation, and sagittal views were performed with the patient on their side and the knee rotated outwards.

#### 3.2.2.8 Alignment parameters assessed

The parameters of interest were the components alignment angles assessed on the coronal plane; the coronal femoral-component angle (cFCA) and the coronal tibial component angle (cTCA). Both cFCA and cTCA were assessed relative the corresponding femoral and tibial bone coronal anatomical axes. All assessments were performed on computerized images by applying digital measurement tool using PACS. Details of alignment angles parameters are presented in section 1 of this Chapter.

#### 3.2.2.9 Statistical analysis

Various statistical approaches can be used when performing reliability and agreement measurement. The researcher's choice can be influenced by different factors such as, study design, data types, and approach to error. The popularity of reliability and agreement studies in the research medical field is a reflection of the abundance and common practice of comparing medical instruments [261]. Intraclass correlation coefficient (ICC) based on analysis of variance (ANOVA) has been frequently applied for measuring the reliability of continuous scales. Shrout and Fleiss [262] advocated the use of ICC for agreement studies were an ICC value of 1 indicates perfect reliability, 0.81–1 very good reliability, 0.61-0.80 good reliability, 0.41 to 0.60 moderate and < 0.40 poor reliability [258]. ICC was used for the assessment of Inter-rater and Intra-rater reliability in this study.

As for how well a new test is performing compared to a standard, ICC has been shown to be inappropriate for agreement studies by Bland and Altman [263]. They argued that correlation only measures the strength of linear association between variables not agreement. They proposed a new method known as the Bland–Altman method which calculates the mean difference between two methods of measurement (the 'bias'), and 95% limits of agreement as the mean difference 2 standard deviations (2 SD) or more precisely (1.96SD). They present the data in a commonly known Bland-Altman plot. It is expected that the 95% limits include 95% of differences between the two measurement methods. If the limits of agreement are narrow then there is sufficient confidence in the new method.

The Bland-Altman method was used in this study because the main focus of this study was to investigate whether the novel X-ray measurements are in more agreement with the CT scan measurement being the gold standard than conventional short leg X-rays. Two separate plots were used to calculate the agreement between the novel method with CT and conventional short leg X-rays with CT. The limits of agreement for both methods were presented for comparison. A positive result would be a narrower limits of agreement for the novel method compared to conventional short leg X-rays. The assessments using both methods were completed by two assessors. Assessor 1 made 2 sets of assessments at two different time points more than 3 weeks apart in random order. A third set of measurements were made in conjunction with assessor 2 and were identified by consensus, the measurements from set 3 were used for the agreement analysis. This was because the agreement study was a non-pragmatic study so errors of measurements are as little as possible.

Analysis was performed using SPSS 22.0 statistical software (SPSS Inc, Chicago, Illinois, U.S.A.).

### 3.2.3 Results

Twenty patients following TKA with a total of 20 knees were recruited for this study. These patients agreed to take part from a group of 57 patients who were enrolled in the other studies of this thesis. Descriptive data summary is presented in the table below. Agreement between novel X-ray method (Schuss position) was higher with the 95% Limits of agreement = -3.616867 to 3.616867 while the 95% Limits of agreement = -6.333201 to 5.754254 for conventional short leg X-rays. Details of each agreement analysis are presented in the respective plots below. The ICCs for inter-rater and intra-rater reliability was 0.853 and 0.938 respectively.

*Table 3-2: Descriptive analysis of agreement study coronal alignment on CT scan versus Schuss position and conventional X-rays*

| | Component | Number | Mean | 95% CI | |
|---|---|---|---|---|---|
| **CT** | Femur | 19 | 93.7 | 92.5 | 95.0 |
| | Tibia | 19 | 88.8 | 87.8 | 89.3 |
| **Schuss position** | Femur | 19 | 93.2 | 92.2 | 94.1 |
| | Tibia | 19 | 89.4 | 88.5 | 90.3 |
| **Conventional X-rays** | Femur | 19 | 94.3 | 93.3 | 95.2 |
| | Tibia | 19 | 88.9 | 87.4 | 90.4 |

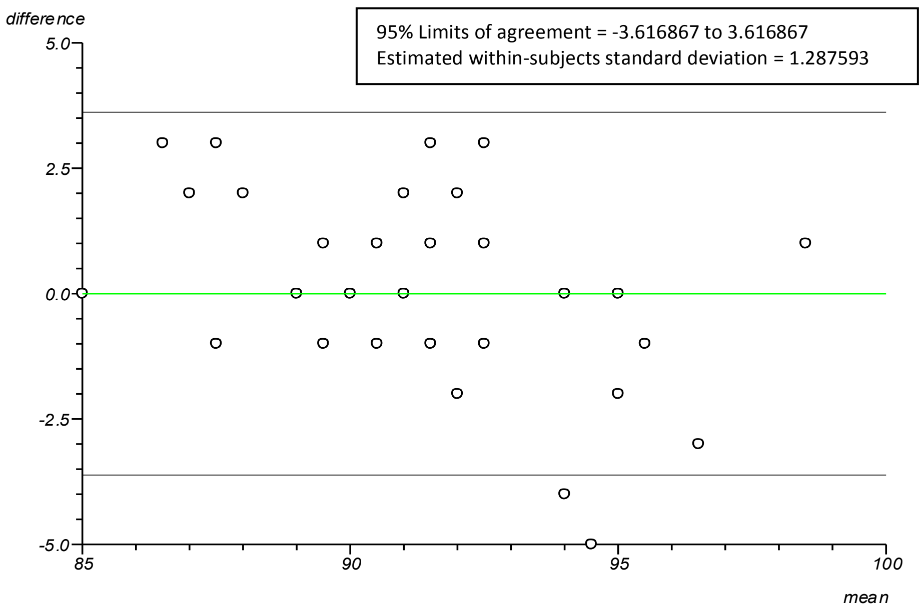



*Figure 3-7: Bland-Altman 95% Limits of agreement plot graph for Schuss position X-ray method with CT*

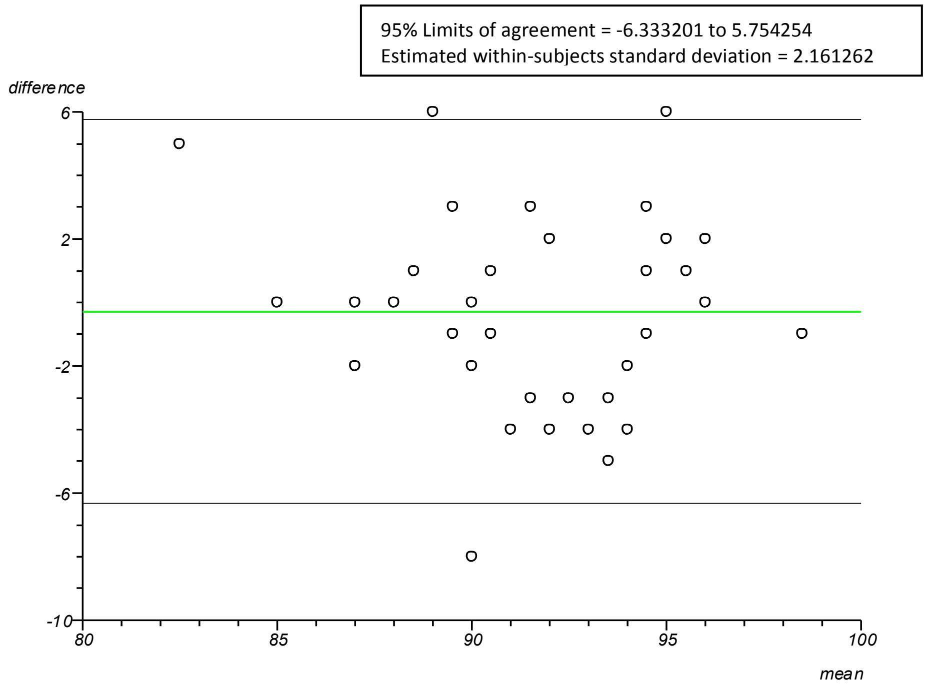



*Figure 3-8: Bland-Altman 95% Limits of agreement plot graph for conventional short leg X-ray method with CT*

## 3.2.4 Discussion

The main finding of this study is that when assessing coronal malalignment following TKA, this novel X-ray method using custom made jig and trigonometry principles has demonstrated higher agreement with CT scan than the commonly used conventional short leg X-rays. The novel X-ray technique described in this study is therefore a more precise method for the assessment of coronal alignment following TKA surgery than conventional X-ray techniques. This is significant because coronal alignment is regarded by many as one of the most important factors determining the long-term prosthesis survival [124, 126-128, 169, 170, 217].

The use of X-rays images for the assessment of alignment following TKA surgery has repeatedly been criticised [229, 230, 264, 265]. Accurate measurements are subject to error due to the variation in limb rotation and magnification. Despite this problem, X-rays remain the routine post-operative method of assessment while other modalities such as CT scan are, and rightly so, reserved for investigating patients with complications owing to the extra cost and radiation incurred. Therefore the assessment of alignment has been unreliable and this may have contributed to the gap in knowledge and the lack of understanding of the relationship between malalignment and patient outcomes [125]. Developing means that can improve the accuracy of assessment on plain X-rays is therefore relevant to TKA surgery follow-up.

Other described X-ray techniques in the literature have used tomography-like techniques where multiple X-ray beams were simultaneously projected and used computer software to analyse images making. These techniques are more time consuming, expensive, and use more radiation in comparison with this technique. Also, to our knowledge this the first study that uses both a jig and applies trigonometry principles for X-ray inclination angle when assessing alignment in TKA.

The main strengths to this technique include the standardisation of the knee position that can be replicated using the custom made jigs and in particular, the use of trigonometry to calculate X-ray inclination angle which are important factors for an adequate X-ray image. This allowed for rotation and magnification control when acquiring the images. CT scan images were used as a comparator in this study, which is regarded as standard for assessing alignment following TKA surgery.

An important aspect in this technique is its ability to alter the X-rays inclination angle based on the patient's anatomy (leg length and foot size) and more significantly in TKA surgery, the tibial slope. Conventionally the X-ray beam will run perpendicular to the extended knee. Different TKA systems have different slope angles, which results in image the image being distorted with may lead to error in measurements. Applying this method the calculated angle will allow the X-ray beam to run along the implant bone interface and reduce image distortion from implants.

Several challenges were encountered during this study. Routine short leg X-rays are performed with the patients lying down in our department therefore, positioning the patients for the Schuss view required guidance for both patients and radiographers. Simple modifications in the form of creating grid lines on the floor of the existing X-ray room were made to place the jig in the correct position. More ease and improvement in the process can be achieved if a purpose built setup existed and improvement to the jig's positioning apparatus were made. Also, patients would have found maintaining the Schuss position easier if they had support equipment to use such as, wall mounted handles.

There are other limitations; this technique is designed to assess the component's coronal alignment only. It is a small study, containing information from only 20 knees. However, the strength of the ICC values gives some confidence that the findings are more widely applicable. The images were not validated using a standard such as digitised phantoms, which would have given more support to the conclusion. This research is for applied clinical practice, from which the images were obtained, so the data obtained have clinical relevance.

Another potential pitfall that was not assessed in this study included the imaging of patients with extra-articular rotational deformities such as external tibia torsion. A fixed foot positioning would likely rotate the knee relative to the leg and result in a rotated image of the knee worsening any deformity in these patients and therefore this method would not be suitable without tailored modification.

X-rays are a cheap, readily available, and relatively safe technique for the assessment of alignment following TKA provided the images produced are suitable for the assessment. This has been demonstrated in this study when compared to CT scan images. This technique can provide an opportunity for the assessment of alignment following TKA to be performed on a bigger scale during follow-up. In addition, the trigonometry principles used to calculate the X-ray inclination angle can be applied to other X-ray studies such as joint space assessment in patient with rheumatoid arthritis and in TKA and Uni-knee replacement for implant-bone interface assessment for the assessment of loosening.

Based on this study's findings, the use of jig assisted with trigonometry X-ray technique after TKR will help reduce measurement errors of components on the coronal plane compared to routine X-rays. This method is fit for the purpose of describing the position and orientation of the components and this technique will enable the surgeon to describe the accuracy of placement of the components with more confidence and without the need to resort to high doses of radiation.

# Chapter 4 The association between malalignment following TKA and the team's non-technical skills and/or surgical process related events

## 4.1 Declaration

Parts of the work presented in this chapter has been published in peer review journals and presented in the following meetings:

1. Can good non-technical skills during surgery improve patient outcomes? A prospective observational study. M. Hadi, D. Griffin, P. McCulloch presented at the ASGBI International Surgical Congress Harrogate, 29th April to 2nd May 2014.
2. Evaluation of surgical team performance in elective operative theatres. Mohammed Hadi. ASiT Conference on 16-17 April 2011, UK
3. Evaluation of surgical team performance in elective operative theatres. Mohammed Hadi. International journal of surgery 2011 (volume 9 issue 7 Page 538 DOI: 10.1016/j.ijsu.2011.07.216)

## 4.2 Introduction

As previously discussed in this thesis, the success of TKA is multi-factorial [92, 94, 95, 169]. The systematic review in Chapter 2 demonstrated that limb malalignment following TKA is an important factor in achieving better patient outcomes (PROM and Revision rates). Alignment, as shown in Chapter 1, is the product of a set of procedural steps and processes, performed by the surgeon and their team during the operation.

Using a battery of tools and specifically designed equipment, the surgical team fixes the TKA components onto the patient's femur and tibia bones to achieve the desired, and typically, pre-planned implant position. Along with implant positioning, the surgeon corrects any pre-existing knee deformity while maintaining adequate soft tissue tension across the joint during the full range of movements of the knee. This is achieved by adjusting the soft tissues and ligaments surrounding the knee and choosing the correct size implants. This requires the surgeon to make a series of decisions based on several procedural and patient-related findings and the use of a series of trials before committing to the final components. The operation is carried out by the surgeon while managing, collaborating and interacting with team members including the scrub nurses, circulating nurses, and anaesthetist to ensure the patient's safety and facilitate the smooth progress of surgery.

Achieving the desired alignment is therefore a key procedural goal in TKA. The degree of limb malalignment and that of the components, which can both be evaluated radiologically as discussed in Chapter 1, can therefore be considered as a suitable surrogate for the team's success in achieving this key procedural goal. The majority of attempts to improve alignment during TKA surgery have focused on advancing the surgeon's technical ability to position the components. A good example of this is illustrated in the development and use of CAS. This technology provides real time representation of the patient's anatomy on a Virtual Display Unit (VDU) with computer-aided feedback demonstrating the ideal position of implants. The surgeon then adjusts bone cuts and soft tissue releases accordingly. The technology has had inconsistent results, is considered expensive, slow, and requires specialised training [266-268].

Theatre based observational studies, discussed in Chapter 1, have identified other factors that may contribute to the outcome of a surgical procedure. These factors are focused on non-technical aspects of the surgery such as a team's non-technical skills and the smoothness of the surgical process. The surgical team's poor non-technical skills have been identified as a potential cause for surgical errors and worse quality of care [30, 44]. Indepth analyses of patient harm incidents such as, operative complications and poor outcomes show the presence of seemingly minor events or failures during the process of an operation prior to the occurrence of an adverse event [30, 31]. Both of these findings suggest that a well-functioning team with good non-technical skills working in a smooth operating environment can aid the surgeon and team to execute the required tasks effectively and more accurately.

It is therefore reasonable to infer that during TKA, correct implant and limb alignment as an operative goal is influenced by the surgeon and team's ability to make correct decisions based on intra-operative findings and utilising their non-technical skills such as situation awareness, problem solving, and decision making skills. This outcome may also be influenced by the team's ability to carry out the surgical procedural steps in a smooth and event-free environment. Therefore, an investigation is carried out into the relationships between the surgical team's non-technical skills, the smoothness of the surgical process, and the post-operative alignment as an indicator of operation's quality .

## 4.3 **Methods**

### 4.3.1 Research question

In patients undergoing elective TKA, are the surgical team's non-technical skills measured by the Oxford Non-technical Scale (Oxford NOTECHS II) [269] and/or smoothness of the surgical process measured by the 'Glitch rates' [55] associated with changes in implant or limb alignment assessed radiologically following surgery?

### 4.3.2 Study design

To answer the research question, a prospective cohort observational study design was adopted. Based on most standard systems of classifications, observational studies are considered inferior to RCTs in terms of the level of the evidence they provide. However, observational studies are an appropriate design for research questions aimed at identification of potential risk factors in a large population [270]. In this context, team non-technical skills and quality of surgical process can both be viewed as possible risk factors for malalignment. Methodologically, it is reasonable to investigate observationally whether a hypothesised relationship such as this appears to exist, before proceeding to an RCT of measures designed to ameliorate or eliminate the risk factors if deemed appropriate. The nature of this research study, particularly the risk factors being investigated, requires a prospective method of data collection. Therefore a cohort study is the most appropriate study design for investigating the relationships that has been hypothesised at this stage in the development of the evidence.

### 4.3.3 Study variables and outcome measure

Details of this study's outcome measures including the rationale and methods applied to collect them will be discussed in the next sections. The outcome measures include:

#### 4.3.3.1 Primary outcome measures

- Explanatory variables

a) Team' s Oxford NOTECHS II score

b) Average Glitch count per hour of operating

- Response variables

a) Overall limb malalignment

#### 4.3.3.2Secondary outcome measures

- Explanatory variables

a) Sub-team Oxford NOTECHS II score (e.g. Surgeon, Scrub nurse, anaesthetics)

b) Average number of glitches per hour per phase of operation (e.g. between skin incision and closure)

c) Average number of glitches per hour of operating within specific categories (e.g. Distractions)

- Response variables

a) Individual malalignment parameters (e.g. cFA, cTA)

b) Grouped malalignment parameter (e.g. total degrees of malalignment of all components)

### 4.3.4 Study Setting

This thesis study was nested within but carried out independently alongside a multi-centre interventional controlled time series project called Safer Delivery of Surgical Services (S3). The S3 project was funded by the National Institute for Health and Research (NIHR) Programme Grants for Applied Research and aimed to evaluate approaches to improvement in patient safety and quality of care in surgical settings. The main objective of the S3 project was to test the efficacy of various types of industrial developed strategies and interventions when applied to different groups of surgical theatre teams (Table 4-1). Various surgical disciplines including orthopaedics were included in three UK hospital theatre departments. This study collected teamwork, process and outcome data from a large prospective cohort of joint replacement operations from several different locations, providing an excellent dataset for this thesis cohort study. The details of involved theatres are described in Table 4-2.

*Table 4-1: Types of interventions applied by the S3 project*

| Intervention | Details |
|---|---|
| **Teamwork training:** | A training package based on the aviation Crew Resource Management training model. CRM concepts and principles included:<br>1. Flattened hierarchy i.e. all team members regardless of seniority can voice concerns and challenge decisions.<br>2. 'Sterile cockpit' concept i.e. Time periods when all non-essential tasks and communication are suspended while important procedures are performed.<br>3. Briefing, debriefing and checklists, to counteract the natural human fallibility with the aim of reducing error, improving safety, and enhancing job satisfaction. |
| **Standard operating procedures (SOP):** | The development of formalised work systems with a highly standardised approach to tasks, characterised by a standard method and regular checks to ensure it is followed. Deviation from the standard method remains permissible, but needs to be justified by specific circumstances. SOPs are developed by involving the theatre team in a detailed analysis of their work processes during a selection of common operations. |
| **Lean:** | This is a quality improvement methodology from the automotive industry that has been applied widely in health care. The 5 principles of lean applied included: 5S (a radical reorganisation and tidying of the workspace), process mapping, error visibility, whole-staff engagement, and Plan-Do-Check-Act (PDCA) cycle use. |

*Table 4-2: Details of theatres involved in S3 project*

| | Site A | Site B | Site C |
|---|---|---|---|
| **Hospital type** | University teaching hospital and a satellite elective unit | Specialist elective unit | District general hospital |
| **Case mix (S3 Control)** | Elective orthopaedics | Elective orthopaedics | Elective General and Vascular |
| **Case mix (S3 Active)** | Elective and Emergency trauma and orthopaedics | Elective orthopaedics and Plastic Surgery | Elective orthopaedics |
| **Types of interventions** | TT & SOP<br>vs<br>Lean<br>vs<br>control | SOP<br>vs<br>Lean & TT<br>vs<br>control | TT<br>vs<br>control |
| **TT: Teamwork Training, SOP: standard operating procedure training<br>Further details on the intervention is described in table 4-1.** | | | |

The S3 study hypothesised that surgical teams that undergo the described interventions (Active group), demonstrate better non-technical skills and lead operations with fewer unwanted events compared to teams with no intervention (Control group). This would translate as safer care to patients with reduced morbidity and mortality. The study also hypothesised that the change in both the level of non-technical skills and the rate of unwanted events would be dependent on the type of interventions trained. These hypotheses are based on the proposition that teamwork training will provide team members with necessary co-operative skills that would enhance overall team technical performance, while other interventions such as, standard operating procedures (SOP) and Lean are designed to address directly the inbuilt flaws and failures in the surgical process itself that may lead to errors.

Therefore, this study provided a situation where different theatre teams can be expected to show varied levels of performances in terms of non-technical skills and smoothness of the surgical process. This is a desirable situation in terms of the research question studied for this thesis as the extension of the normal variance in performance that is expected to arise after training would likely to tip the balance of the signal-to-noise ratio in favour of the signal, and make detection of a relationship easier

### 4.3.5 Ethical considerations

Ethics Committee approval was obtained for this study (Oxford A REC 09/H0604/39) .Due to the study settings, several ethical protocols were predetermined as part of the S3 project. These protocols were designed to address the various ethical concerns for such study. Firstly, protocol for theatre team members. Before the start of any intra-operative observations, all theatre team members were to be informed of the study and asked to provide a written consent. To make the consent process as efficient as possible, a meeting with theatre teams was set up prior to the study start date. All staff members were provided with information on the ongoing studies and were offered an opportunity to ask questions. An information pack, including a consent form, was also given to take home and to return at a later date. Staff members who did not attend the meeting were approached individually and the same was provided. Others such as, students, company representatives, and visiting surgeons who have entered theatres without previous knowledge of the ongoing observations were approached as soon as it was feasibly possible and the information was provided. All staff members were given the opportunity to opt out at any time during the study. In operations where any staff member did not consent, no observations took place. If a decision to opt out was made after the start of data collection, the observations would have been stopped, the data pack destroyed, and the case excluded. However, during the period of the study, no such instances occurred.

The second ethical consideration and protocol revolved around the patient's involvement in the study. There were two issues to address; one involved the patients undergoing surgery during data collection for this and the S3 studies, and the other involved the patients taking part in the subsequent radiological assessment for this study. For the former, and due to minimal interaction with patients, the only ethical requirement set by the ethics committee was to provide patients with information sheets explaining the nature of the study. This was done on the day of operation as soon as possible and prior to induction of anaesthesia. At that point, patients were given the option to decline taking part, in which case no observations would take place. During the period of the study, no such instances occurred. For the subset of TKA patients eligible for the current study, a consent form was required for a series of radiological studies to assess postoperative alignment. In these instances, patients were sent information packs including consent forms via the post prior to their 6 weeks follow up appointments. During the follow-up appointment, a clinical research fellow (MH) with appropriate training and Good Clinical Practice (GCP) credentials completed the patient's consent forms with them. Patients were given the option to decline participation at which point the case was excluded from the current study.

All data was recorded anonymously. Each case had a unique identification number that matched with a hospital identification number. Data were initially recorded on paper packs (Appendix 14: Example of theatre Data collection pack [272]), which were transferred as soon as possible to an electronic web-based database specifically designed for the S3 study. This database was securely hosted on the host university server. Access to the database was restricted to the research personnel via the intranet. The paper packs were then securely stored on university campus during the period of the study.

Radiological and patient related outcome data were treated as medical records and were kept on the hospital's secure servers. Access to this information was only permitted to clinical staff with the necessary credentials.

### 4.3.6 Case selection

Both primary and revision TKA operations were recruited for this study. The TKA cases studied were from two sites (university Hospital Coventry and Warwick and St Cross Hospital, Rugby). The two sites had two different types of interventions (teamwork training and Lean intervention) during the process of collecting data.  Two other Orthopaedic sites were involved in the S3 study (Nuffield Orthopaedic Centre, Oxford and Kettering General Hospital, Kettering) but did not provide patients for this alignment study. Opportunity sampling from targeted operating lists that fulfilled the following criteria:

- Lists in which the surgical team was enrolled in either the ‘Active’ or ‘Control’ arms of the S3 study.
- Lists with the highest proportion of TKA.
- No exclusions were made based on the number, grade or level of experience of the teams involved in each operation.

Potential operating lists for observation were identified few days in advance via contacting Surgeon’s secretaries. This allowed the observation teams to plan observations accordingly. The main limiting factor for observations was the logistics around both surgical and research team’s working timetables and annual leave holidays. Overall, whilst it was not possible to observe consecutive TKA procedures for logistic reasons, a large representative convenience sample was collected.

### 4.3.7 Total knee arthroplasty operative techniques

All TKA were comparable in terms of operative techniques. The dissimilarities were dictated by the two different TKA system used (NexGen® Complete Knee Solution Legacy System by Zimmer® and Vanguard® Complete Knee System by Biomet®). The operation details can be divided into 3 high level tasks:

- Joint access: A 15-20 cm vertical median skin incision was used. Following soft tissue dissection, a medial para-patellar approach was utilized to allow access to the joint.
- Joint replacement procedure: All surgeons started femoral preparation first. This involved introducing the femoral intramedullary guide jig through the

femoral intercondylar notch area along the femoral anatomical axis. The entry point for the jig was around 1cm anterior to the PCL femoral attachment. The distal femoral bone cut was performed avoiding any flexion/extension deformities relative to the sagittal plane. On the coronal plane, the femoral jig was set with a 6 degrees valgus angle in order to align the component's horizontal axis perpendicular to the mechanical axis. The Femoral component was then sized and its rotational alignment orientated by setting the jig in 3°external rotation relative to the posterior condylar axis and aligning it along the surgical epicondylar axis which was identified intra-operatively both visually and by palpation. All femoral bone cuts were made using the relevant cutting guides. Next, the tibial preparation was carried out. The cutting blocks were positioned perpendicular to the tibial mechanical axis using an extra-medullary jig. The tibial mechanical axis was identified by palpating for the tibia shaft proximally, and assessing the centre of the ankle joint position distally by palpating for both ankle malleoli. The slope of the proximal tibial bone cut was adjusted according to the knee system used (Nexgen® knee system required the surgeon to make a slope cut of around 7° while the Vangard® knee system had an inbuilt slope and required no slope bone cuts). For orientating the tibial rotation, surgeons positioned the tibial implant relative to the tibial tuberosity axis first. Identifying the tibial tuberosity axis was achieved using the tibial tuberosity as a landmark and aligning the tibial component's anteroposterior axis in line with it. Then the surgeon would perform a knee flexion/extension manoeuvre using the trial implants allowing the tibial plate to rotate slightly if necessary to ensure no implants mismatch on the axial plane. The tibia keel cuts were then made and the implant orientation was marked with a diathermy prior to the component being cemented in this final position. Implants position, soft tissue balance, range of joint movement, and overall limb alignment were checked, and adjusted if necessary, during the trailing phase. In all cases, both implants were cemented and no patella was resurfaced.

- Soft tissue and skin closure: a layer by layer closure was performed.

### 4.3.8 Theatre Observations

The intra-operative data collected for this study (details are shown below), were the same data collected for the S3 project. The theatre observation methods applied in this study were an evolved version of the observational methods described in earlier studies that have preceded the S3 study by our research team members of the S3 project [43, 44, 47]. The details of which are:

#### 4.3.8.1 The observation team

Six researchers with either a clinical or human factors (HF) background made up the observation team. Two out of the three clinical observers were surgical trainees and had at least 2 years of NHS experience in surgical theatre environments. The other clinical observer was an experienced anaesthetic nurse practitioner. HF observers were qualified in HF with varied experience in health care, aviation, military and human performance measurements. HF in health care is best defined as the discipline concerned with "*Enhancing clinical performance through an understanding of the* *effects of teamwork, tasks, equipment, workspace, culture, organisation on human behaviour and abilities, and application of that knowledge in clinical settings."* [271] Direct observations were conducted by observers, one clinical and one HF, during each operation.

Prior to data collection, all observers underwent a 2 month period of targeted training. HF observers were provided with operative technical knowledge using video recordings of operations, text books and familiarisation sessions in real theatre environment. Clinical observers received intensive training in the principles of human factors and its application to healthcare. All observers were trained in team evaluation techniques used in this study: Oxford non-technical skills scale II (Oxford NOTECHS II) and Glitch counting; details below.

#### 4.3.8.2 Intra-operative observational Data collected

For each case, data was documented in a specially designed collection pack (Appendix 14 Example of theatre Data collection pack [272]). The packs were process maps designed by the clinical observers, and included a step-by-step guide to the procedure being observed [272]. The process maps were tested over several weeks to provide a "standard" process. Data collection would commence from the time the patient entered the operating theatre via the anaesthetic room till exit to the recovery bay. The data collection was limited to the operating room, however, observers asked staff members for further information to fill any gaps in the observations when appropriate. The intra-operative data collected included the following:

#### 4.3.8.3 The surgical team's non-technical skills

As discussed in Chapter 1, the surgical team's non-technical skills are the generic behavioural skills that strengthen the team member's technical ability to perform the task. These include; leadership and management skills, team work and cooperation, problem solving and decision making, situation awareness, and communications and interactions skills. To be able to collect data on these non-technical skills, a specifically designed scale called the Oxford NOTECHS II was used.

#### 4.3.8.4 The Oxford non-technical skills scale II (Oxford NOTECHS II)

Several methods have been developed for measuring non-technical skills in the operating theatre, some focused on whole team performance such as OTAS [273], Oxford NOTECHS [47], OSTAS [274], and EPOC [275], while others focused on sub-team performance such as ANTS [276], NOTSS [277] and SPLINTS [278]. The one used in the current study, Oxford NOTECHs II scale, has its origins in the aviation industry. It was developed from an earlier version [47] which in turn was based on scales developed for use in cockpit crew teamwork training and assessments. Adaptations, that ensured its successful usability in the operating theatres, were made based on a process involving task analyses and input from a safety expert panel that included human factors scientists, anaesthetists, different speciality surgeons, and aviation training experts [47, 279].

The Oxford NOTECHS II has been structured along the four behavioural dimensions: leadership and management (L&M); teamwork and cooperation (T&C); problem solving and decision-making (PS & DM); and situation awareness (SA). A list of behavioural markers was used to aid the observers in identifying the relevant behavioural dimension Table 4-3.

*Table 4-3: Oxford NOTECHS II behavioural markers [47]*

| | |
|---|---|
| **Leadership and management** | |
| **Leadership** | Involves/reflects on suggestions/ visible/ accessible/ inspires/ motivates/ coaches |
| **Maintenance of standards** | Subscribes to standards/ monitors compliance to standards/ intervenes if deviation/ deviates with team approval/ demonstrates desire to achieve high standards |
| **Planning and preparation** | Team participation in planning/ plan is shared/ understanding confirmed/ projects/ changes in consultation |
| **Workload management** | Distributes tasks/ monitors/ reviews/ tasks are prioritised/ allots adequate time/ responds to stress |
| **Authority and assertiveness** | Advocates position/ values team input/ takes control/ persistent/ appropriate assertiveness |
| **Teamwork and cooperation** | |
| **Team building/ maintaining** | Relaxed/ supportive/ open/ inclusive/ polite/ friendly/ use of humour/ does not compete |
| **Support of others** | Helps others/ offers assistance/ gives feedback |
| **Understanding team needs** | Listens to others/ recognises ability of team/ condition of others considered/ gives personal feedback |
| **Conflict solving** | Keeps calm in conflicts/ suggests conflict solutions/ concentrates on what is right |
| **Problem-solving and decision-making** | |
| **Definition and diagnosis** | Uses all resources/ analytical decision-making/ reviews factors with team |
| **Option generation** | Suggests alternative options/ asks for options/ reviews outcomes/ confirms options |
| **Risk assessment** | Estimates risks/ considers risk in terms of team capabilities/ estimates patient outcome |
| **Outcome review** | Reviews outcomes/ reviews new options/ objective, constructive and timely reviews/ makes time for review/ seeks feedback from others/ conducts post treatment review |
| **Situation awareness** | |
| **Notice** | Considers all team elements/ asks for or shares information/ aware of available of resources/ encourages vigilance/ checks and reports changes in team/ requests reports/ updates |
| **Understand** | Knows capabilities/ cross-checks above/ shares mental models/ speaks up when unsure/ updates other team members/ discusses team constraints |
| **Think ahead** | Identifies future problems/ discusses contingencies/ anticipates requirements |

Based on intra-operative observation, a score from 1-8 is awarded to each of the sub-team (Surgeon's team, Anaesthetist's team, Nursing Scrub team) on each of the behavioural dimensions. Because surgical teams are expected to maintain an effective level of safety during surgery, a baseline score of six was used to anchor the observations. If sub-teams consistently maintained an effective level of safety and teamwork, this score remained unchanged. Any change in behaviour that would either enhance or degrade safety levels would be reflected on the score. Behavioural markers were incorporated to aid the observers in the assessment process [47] . The scores are anchored to the categories in Table 4-4.

*Table 4-4: Oxford NOTECHs II scoring paradigm [269]*

| Score | Consistency | Behavioural descriptors |
|---|---|---|
| **1** | Consistent | Behaviour compromises patient safety and effective team work |
| **2** | Inconsistent | |
| **3** | Consistent | Behaviour in other conditions could directly compromise patient safety and effective team work |
| **4** | Inconsistent | |
| **5** | Inconsistent | Behaviour maintains an effective level of patient safety and teamwork |
| **6** | Consistent | |
| **7** | Inconsistent | Behaviour enhances patient safety and effective teamwork |
| **8** | Consistent | |

Another aspect of the Oxford NOTECHS II scale is the ability to assess the whole operating team as a unit as well as the sub-teams described earlier. The sub-scores can reflect each sub-teams' non-technical skills separate to the other members of the team within the whole operating theatres [47].

The primary measure for the purposes of this study is the whole team score (Team's Oxford NOTECHS II score). A sub-analyses are conducted with sub-teams' scores and the combined surgical and scrub sub-teams Oxford NOTECHS II scores only. This is made on the assumption that the anaesthetic team's input, although clearly essential as part of an operating team towards patient safety as a whole, is less influential in achieving better alignment following TKA given their lack of direct input technically towards this surgical goal.

To assess for observational competency and Oxford NOTECHs II reliability amongst observers, independent dual observations of elective orthopaedic operations across multiple sites were conducted.  The observers, both individually and in pairs, performed observations on 20 cases with an expert observer. Inter-rater agreement of overall and sub-team Oxford NOTECHs II scores were evaluated using the rWG(J)  test [280].

#### 4.3.8.5 Surgical process ("the flow of an operation")

*"The ability to manage errors and unexpected events during the surgical procedures is a sign of clinical excellence"* [281].

As discussed in Chapter 1, deviation and disruption to the surgical process (glitches) can make the surgical team ability less effective. Identifying these glitches is likely to be instrumental in improving patient safety within the operating theatres. Several methods have been described in the literature for identifying unwanted events in the operating theatre during surgery [28, 44, 282-284]. For the current study, to capture these glitches the following method was used:

#### 4.3.8.6 Measuring the surgical process: 'Glitch Count'

The method used was referred to as 'glitch counting'. In this method glitches are defined as *"deviations from the recognised process with the potential to reduce its quality or speed, including interruptions, omissions and changes, whether or not these actually affected the outcome of the procedure"* [55].

When observed, the details surrounding each identified glitch were noted down with the corresponding time and conclusion. It was therefore possible to cluster glitches based on the time of their occurrences; for example, before skin incision, between skin incision and start or end of implant fixation, between skin incision and wound closure, etc.

Following each case, the observers would categorise the glitches based on the observed circumstances into one of 12 categories Table 4-5**Error! Reference source not found.** These categories were developed by the research team based on knowledge acquired from previous research [30] and other reported classification systems [283-285]. The process required the research team members to group the glitches on the bases of their qualitative similarities and the potential of aiding and highlighting possible solutions [55].

A process of segregating glitches based on several qualitative factors was conducted to aid the correlation analysis. Initially glitch categories were divided into two groups: ‘relevant’ and ‘non-relevant’. This was achieved using the Delphi process [286] by different members within the S3 research group.  The team involved:

1. S3 chief investigator; Professor and General Surgery consultant (PM);
2. S3 principle investigator in a satellite hospital Professor and Orthopaedic surgery consultant (DG);
3. Senior Researcher and HF expert (KC);
4. Senior Researcher and Lean expert (SN);
5. Two clinical research fellows and surgical trainee (MH, ER);
6. Two research associates and HF experts (SP, LM).

The researchers were asked to predict the relationship between Oxford NOTECHS II scores, the 13 glitch sub-categories, and outcomes [55]. The process was completed in two rounds. Initially, team members ranked the likelihood of correlation of each glitches category with Oxford NOTECHS II, then the glitches categories association with malalignment. The identified relevant glitch categories were then each correlated with the explanatory variables in a sub-analysis.  The timing of glitches was then used for segregating the glitches. Glitches between skin incision and end of implant cementation time would likely to have a greater impact on alignment than glitches before start of surgery or after the implants are fixed. Therefore these glitches were included for analyses. Finally, a separate analysis was performed between malalignment and a subset of glitches deemed relevant to implant positioning. Identifying implant positioning-relevant glitches was achieved by a further review of each glitch within the already identified relevant groups and occurred within the skin incision and end of cementation time frame and was seen to be relevant after exploring the circumstances around each glitch. This was a subjective assessment aimed at further interrogating the relationship between malalignment and very targeted group of glitches.

As a result, an exploratory matrix of sub-analyses was performed and the sets of glitches identified for the analysis were:

- The average glitches per hour of operating for the total sample of observed glitches for the whole operation.
- The average glitches per hour of operating for the total sample of observed glitches excluding those before skin incision and after the fixation of implants.
- The average glitches per hour of operating for the sample of observed glitches within each individual relevant category for the whole operation.
- The average glitches per hour of operating for the sample of observed glitches within each individual relevant category excluding those before skin incision and after the fixation of implants.
- The average glitches per hour of operating for the sample of observed relevant glitches only.

To test the reliability of the categorisation process, observers categorised a random sample of 50 glitches from the S3 database. Cohen's Kappa was used as a measure of inter-rater reliability.

*Table 4-5: Glitch categories*

| Glitch Category | Definition | Examples |
|---|---|---|
| **Absence** | Absence of theatre staff member, when required | Circulating nurse not available to get equipment |
| **Communication** | Difficulties in communication among team members | Repeat requests; incorrect terminology; misinterpretations |
| **Distractions** | Anything causing distraction from task | Phone calls/bleeps; loud music requiring to be turned down |
| **Environment** | Faulty or poorly maintained environment | Theatre doors stuck open |
| **Equipment related** | Issues arising from equipment design or faulty or poorly maintained equipment | Compatibility problems with different implant systems; equipment blockage<br>Battery depleted during use; blunt equipment |
| **Health & Safety** | Any observed physical risk to personnel | Mask violations; food/drink in theatre |
| **Patient related** | Events that occur due to unique patient factors and not related to other categories | Difficulty in extracting previous implants, unexpected anatomically related surgical difficulty and anaphylaxis |
| **Planning & Preparation** | Instances that may otherwise been avoided with appropriate prior planning and preparation | Insufficient equipment resources; staffing levels; training |
| **Process Deviation** | Incomplete or re-ordered completion of standard tasks | Unnecessary equipment opened |
| **Slips** | Psychomotor errors | Dropped instruments |
| **Training** | Events related to training of a team member | Consultant corrects assistant's operating technique |
| **Workspace** | Equipment or theatre layout issues | De-sterilising of equipment/scrubbed staff on environment |

### 4.3.9 Radiological data collection

All eligible patients that agreed to take part in this study had a radiological assessment of their post-operative alignment. The malalignment parameters of interest for this study as well as the methods used to assess these parameters radiologically are described in detail in Chapter 1. A summary is presented below:

#### 4.3.9.1 Imaging Modality

The modality of choice for this study was CT. CT is widely used for the assessment of limb alignment and implant position following TKA and the rationale for selecting this modality is discussed in Chapter 3. Using CT, the coordinates of relevant anatomical structures seen on images were identified from the raw data. The coordinates were then used to construct a geometric module of the limb then calculate the relevant malalignment angles mathematically.

#### 4.3.9.2 Timing of the scan

Scanning patients commenced after the immediate post-operative swelling and pain subsided. Post-operative swelling can potentially result in knee flexion deformity which can in turn distort the overall limb alignment measurements. The scans were arranged during the first follow up review clinic around 6 weeks following surgery. For some patients the scans were delayed due to varied follow-up arrangements however, all scans were performed within 1 year following surgery. This time limit was decided so that any malalignment identified would be secondary to errors of component implantation reducing the possibility of it being attributed to bone collapse or implant migration [287].

#### 4.3.9.3 Imaging Protocol

Scans were performed by a senior radiographer according to the departmental lower limb alignment CT protocol at the University Hospital Coventry and Warwickshire. Patients were positioned supine with both legs extended and were internally rotated until the patellae faced upwards. A multi-slice spiral CT scanner captured 1.25 mm contiguous slices from the hip acetabular roof to the ankle talar dome.

To minimise radiation exposure, a low dose CT scanning protocol was adopted [248]. The CT axial slices skipped a section of the femoral and tibial bone shafts while maintaining structural image continuity of the limb.

#### 4.3.9.4 Radiological alignment assessment protocol

A multistage assessment method was performed:

Stage 1: using PACS, the relevant anatomical and component landmarks for each scan were identified on the cross sectional slice images Figure 4-1. The coordinates of these landmarks were then documented in an “x,y,z” format on an excel file.

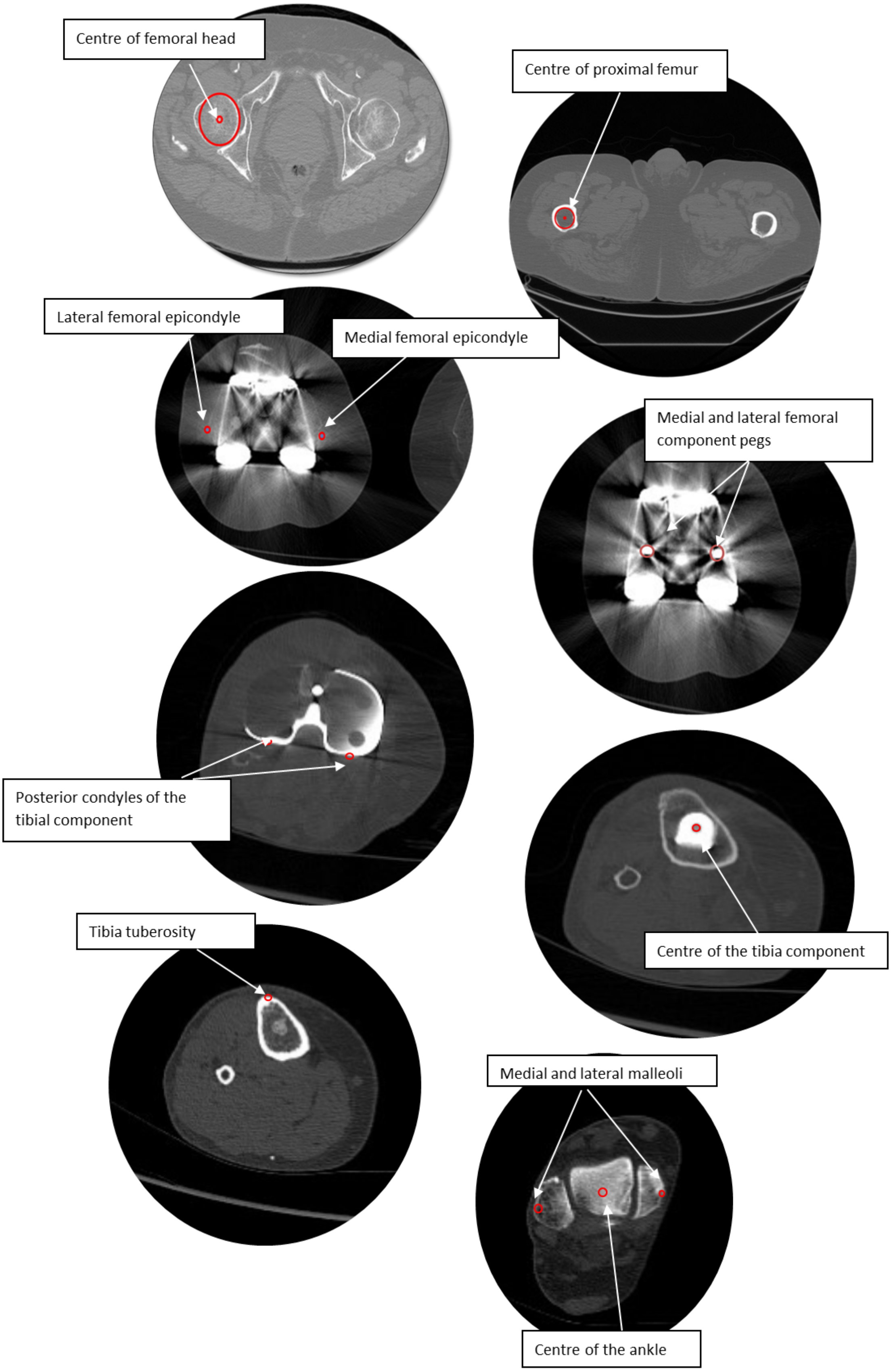



*Figure 4-1: Radiological landmarks identified on CT for the assessment of alignment.*

Stage 2: using Microsoft Excel software, the coordinates were used to plot axes that represented the anatomical and component axes. These axes were then used to calculate the malalignment angles.

### 4.3.9.5 Alignment parameters assessed

The alignment angles of interest and the methods for assessing these parameters have been discussed in Chapter 1. A summary of these angles are presented in Table 4-6. The alignment angles were grouped into two groups; Group 1 included cTFmA and aTFMA, and group 2 included cFaA, cTA, sFA, sTA, aFRA, and aTRA. The distinction between the groups was based on the difference in the set of surgical tasks required to achieve each of these angles by the operative team.

Group 1 alignment parameters are the angles involving both TKA components (femoral and tibial component). Both angles reflect the relationship between the two components on the various planes as an end result of the procedure; cTFmA being a measure of the overall coronal limb alignment and aTFMA is the overall rotational joint profile. As well as a gross technical error, the non-technical element resulting in malalignment in this group is likely to be in areas such as lack of situation awareness (e.g. failing to recognise wrong soft tissue balance), or an error of judgment (e.g. incorrect sizing of implants or not correcting for extra-articular deformities). A satisfactory alignment in this group is likely to require the team demonstrating adequate awareness, problem solving, and judgment skills, which are measurable using the Oxford NOTECHS II scale. As discussed in Chapter 1, no overall sagittal alignment is currently described for mechanically aligned TKA. Instead, a surgeon relies on the anatomical landmarks and axes of each the femur and tibia bones individually to position the components on the sagittal plane and therefore no overall sagittal tibio-femoral mechanical alignment (sTFmA) feature in this group.

Group 2 is the malalignment of each component relative to their anatomical axis. These are the femoral and tibial components on all three planes. Alignment in this group is reliant on the surgeon's technical accuracy in positioning the implant, which involves making the correct bony cuts and subsequent fixation of the components. This technical task is highly dependent on the equipment and jigs designed for this task. Therefore, alignment of these components is likely to be influenced by the reliability of the tools and equipment utilised and the smoothness of the surgical process, which can be evaluated using the glitch count outcome measure.

*Table 4-6: Alignment parameters and angles on which malalignment can be identified*

| | **Group 1**<br>**Overall Outcome Malalignment angles** | | **Group 2**<br>**Individual component Malalignment angles** | |
|---|---|---|---|---|
| | Both components | | Femoral component | Tibial Component |
| **Coronal plane** | Coronal Tibio-femoral mechanical angle (cTFmA) (180°) | | Coronal femoral-component anatomical angle (cFaA). (96°) | Coronal Tibial-component angle (cTA) (90°) |
| **Sagittal plane** | | | Sagittal femoral-component angle (sFA) (90°) | Sagittal Tibial-component angle (sTA) (90°/83°)† |
| **Axial plane** | | Tibio-femoral components rotational mismatch angles (aTFMA) (0°) | Femoral component Rotation angle (FRA) (0°) | Tibial component Rotation angle (TRA) (0±15°) |

**† Based on which TKA system used**

### 4.3.9.6 The scoring of malalignment

Several malalignment scores were calculated. Malalignment of the cTFmA (overall limb alignment) is the primary alignment parameter outcome used for analysis. As discussed in previous chapters, the cTFmA is the most widely assessed parameter of alignment in the literature for the mechanically aligned knees and is a suitable representation of malalignment following this type of TKA surgery. Malalignment was calculated in degrees by subtracting the measured angle from its ideal value (180°).

A series of sub-analyses were performed that involved the grouping of multiple alignment parameters based on the two groups described above. Similarly the errors in alignment were calculated for each individual parameter assessed within the group by subtracting the measured angle from its ideal value. A scoring system based on an adaptation of that described by Sikorski for malalignment following revision TKA [167] was used for this study. A malalignment score was calculated by summing all individual error values into a single score. For each case, two malalignment scores were calculated, one for each group of alignment parameters described above; Malalignment score 1 and malalignment score 2 respectively. Below is an example of how malalignment scores were calculated Table 4-7.

*Table 4-7: Example showing the malalignment scoring system*

| | **Group 1** | | | **Group 2** | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Both components | | Malalignment Score 1 | Femoral Component | | | Tibial Component | | | Malalignment Score 2 |
| | cTFmA | aTFMA | | cFaA | sFA | FRA | cTA | sTA | TRA | |
| **Ideal angle** | 180° | 0° | | 96° | 90° | 0° | 90° | 83°/ 90°* | 10°- 20° | |
| **Actual angle** | 178° | 6° | | 94° | 89° | 5° | 90° | 83° | 21° | |
| **Error** | 2 | 6 | 8 | 2 | 1 | 5 | 0 | 0 | 1 | 9 |

*** Two possible ideal angles based on the TKA system used**

### 4.3.9.7 Inter- Intra- rater reliability of assessment.

Two-way mixed measures Intraclass Correlation Coefficient (ICC) was used for reliability statistics. Two assessors (clinical orthopaedic researcher (MH) and a radiologist (AA)) measured a randomly selected set of angles (n=50) to assess for inter-rater reliability. Another set of measurements was made 6 weeks later by MH to assess for intra-rater reliability. Both assessors had previous experience in assessing alignment following a TKA. For calibration, both observers initially performed dual assessment on a set of TKA images prior to independent data collection. All assessors were blinded to identifying patient details, alignment parameters targets set by the surgeon, and the intra-operative findings. The inter- and intra- observer reliability was excellent (ICC of 0.946 and 0.850 respectively).

## 4.3.10 Sample size

From the onset of this study and after acquiring statistical advice, it was apparent that the sample size would be pragmatic. Any attempts to identify a certain figure would be unfruitful as there are no useful published data on the subject of interest that might help us to make a sample size estimate. Therefore the goal was to recruit the maximum number of cases during the period of study (December 2011-December 2012). This was dictated by 3 main factors:

- The number of TKA operations performed in the hospital by the participating teams.
- Issues revolving logistics and access to theatres to perform the observations during the study period
- The consenting of patients to undergo radiological imaging.

### 4.3.11 Statistical plan

SPSS 22.0 statistical software (SPSS Inc, Chicago, Illinois, U.S.A.) was used for the statistical analyses. The descriptive data were presented either as mean (M), percentage (%), range (R) or 95 per cent confidence interval (95% CI). Normally distributed continuous data were analysed using Pearson's coefficient for correlation. A Simple linear regression was performed to predict the relationship between correlated variables. The independent variables were screened for any violation of assumptions prior to analysis for outliers (on a box plot), linearity (on a scatterplot), normality (using Shapiro-Wilk and Kolmogorov-Smirnov), and homogeneity of variance (using Levene's test). The log transformation of data was used if a potential skew in the data was observed. The correlation coefficient (r), equations derived from the regression analysis, and the percentage of variance the regression accounted for ($r^2$) are reported. The strength and direction of the correlation coefficient was made based on Dancey and Reidy's categorisation [288]. When investigating the association of the primary variables, a p-value <0.05 was considered to be statistically significant. For the analysis of secondary variables, a p-value of <0.01 was set to adjust for multiple testing using the Bonferroni correction technique [289].

## 4.4 **Results**

### 4.4.1 Descriptive statistics

#### 4.4.1.1 TKA Operations

During the period of theatre observation, December 2010 to November 2011, a total of 57 patients underwent TKA under the care of the consultants taking part in the S3 study (49 primary TKA, 8 revisions TKA; 5 revision of partial knee arthroplasty to total arthroplasty, 1 revision secondary to infection, and 2 revisions to aseptic loosening).

All patients were then approached to take part in the present study and undergo a CT scan for the assessment of alignment. A total of 18 cases were completely excluded for the following reasons:

- 2 cases declined taking part to avoid another journey to hospital.
- 1 case could not attend as she was caring for a sick relative.
- 1 case declined in fear of extra radiation in light of the Fukushima disaster [290].
- 12 cases declined having a CT scan without providing a reason.
- 2 cases left the department before the CT scan was performed due to the waiting time.

Three cases had an incomplete CT sequence due to operator error resulting in some missing data on the axial plane. These cases were excluded in some of the analysis and this was highlighted in the number value.

Thirty-nine patients made up the case sample included in this study. A total of 11 surgeons performed the operations using one of the two TKA systems:

- (75%, n=29) NexGen® Complete Knee Solution Legacy® with Knee Fixed Bearing Knee by Zimmer®
- (25%, n=10) Vanguard® Complete Knee System with Fixed Bearing by BioMet®

A total of 90 hours of intra-operative theatre observations time were made. Average case length was 138 minutes (95% CI: 122-154; R: 89 -285 minutes). Average time between patient entering theatres and starting skin incision was 13 minutes while the average time between component cementation and patient leaving theatres was 21 minutes. The average time between skin incision and the end of component cementation was 108 minutes (95% CI: 92-125; R: 59 – 255 minutes).

### 4.4.1.2 Oxford NOTECHS II

The average team Oxford NOTECHS II score was 77 out of a possible 96; (95% CI 75-79; R: 60-94). The distribution of data is presented in histogram below Figure 4-2. Details of sub-team Oxford NOTECHS II are shown in Table 4-8

The Oxford NOTECHS II inter-rater reliability analysis showed excellent agreement amongst the observers rWG(J) range 0.84 to 0.98, where 1.0 = perfect agreement. [280].

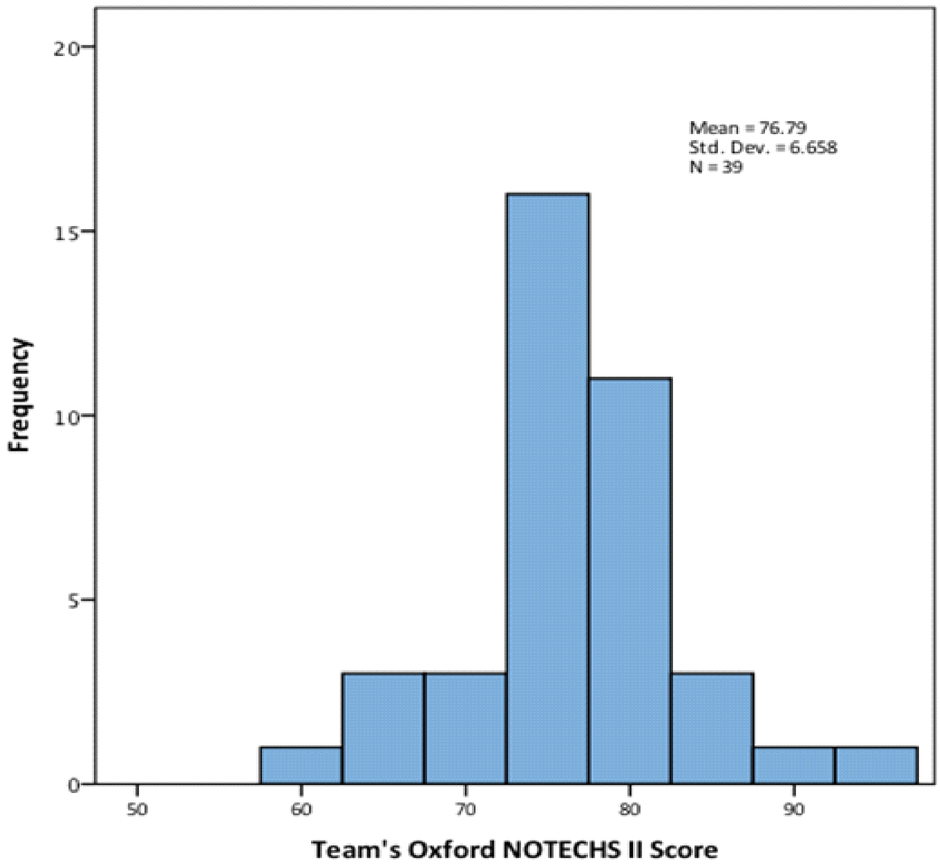



*Figure 4-2: Oxford NOTECHS II Scores distribution of data*

*Table 4-8: Sub-team Oxford NOTECHS II scores*

| Oxford NOTECHS II | Maximum possible Score | Mean | 95% CI | | Range | |
|---|---|---|---|---|---|---|
| **Whole Team** | 96 | 77 | 75 | 79 | 60 | 94 |
| **Surgical Sub-team** | 32 | 26 | 26 | 27 | 20 | 32 |
| **Scrub Sub-teams** | 32 | 25 | 24 | 26 | 19 | 31 |
| **Anaesthetic Sub-team** | 32 | 25 | 24 | 26 | 18 | 32 |

### 4.4.1.3 Glitches

A total of 511 glitches were observed. Due to the variable operating time, the average number of glitches per hour of operating was used for the primary study analysis; the distribution of log data is presented in histogram below Figure 4-3. A breakdown of the glitch categories and frequency of each is demonstrated in Figure 4-4.

The reliability of the glitch categorisation was good between the four observers (0.70, 95% CI 0.66 to 0.75).

The result of the Delphi exercise revealed that the relevant glitches categories are: Distractions glitches, planning & preparation, equipment related, process deviations, absence, and communication glitches.

A total of 321 glitches were excluded for the sub-analysis involving malalignment-relevant only glitches. The reasons for exclusion were:

- Glitches occurring prior to skin incision (n=72)
- Glitches occurring after the end of implants fixation (n=33)
- ‘Non-relevant’ glitch categories:
- Slips (n=59)
- Health & Safety (n=36)
- Training (n=12)
- Work space (n=4)
- Patient related (n=2)
- Environment (n=0)
- Glitches from relevant categories however not perceived to directly impact on implant positioning (n=103).

The remaining glitches (n=190) included: distractions accounted for 79 glitches; Planning & Preparation, Equipment related, process related, absence, and communication glitches made up the rest (n=111).

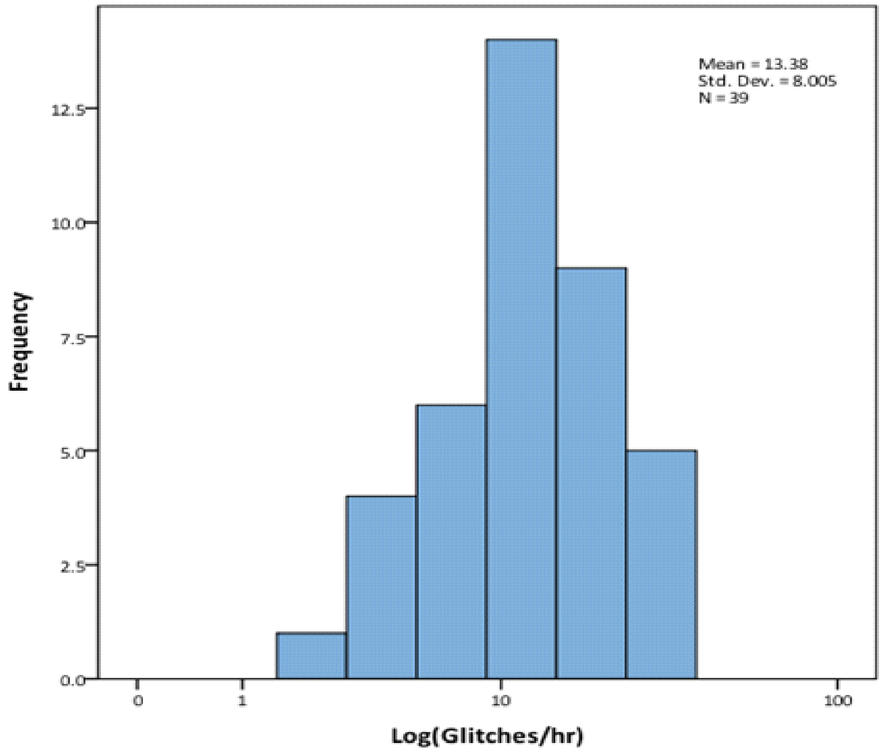



*Figure 4-3: Glitches distribution of data*

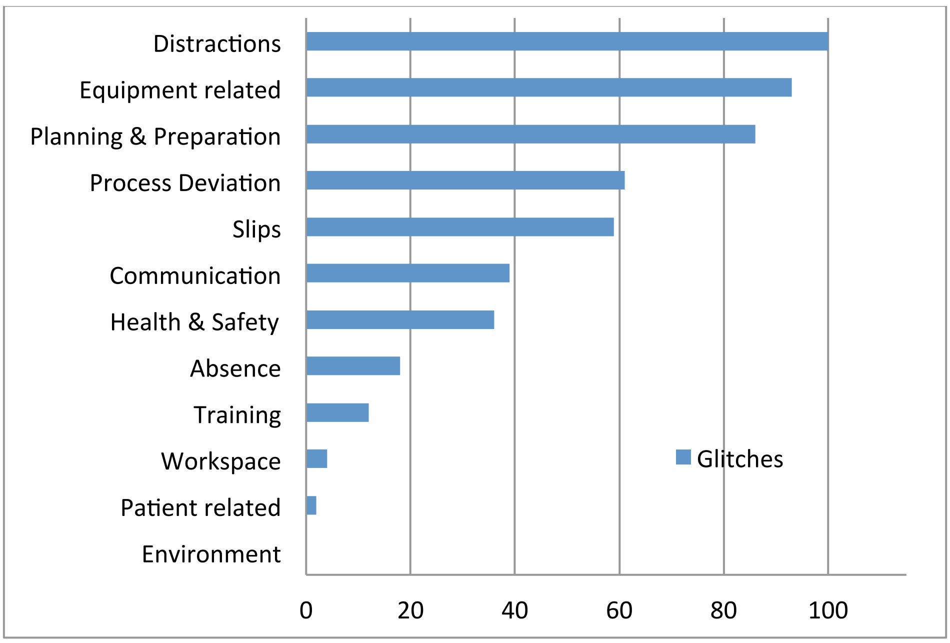



*Figure 4-4: Breakdown of overall glitches with frequencies of each category*

### 4.4.1.4 Radiological malalignment

#### 4.4.1.4.1 Overall Limb Alignment (Coronal tibio-femoral angle (cTFmA))

The mean cTFmA is 180° (179-182; 95% CI). Twenty one cases (53%) were well aligned within +/-2°. The distribution of alignment in degrees is presented in the histogram below (Figure 4-5). The error or the absolute difference to the ideal angle is presented in degrees in the histogram below (Figure 4-6)

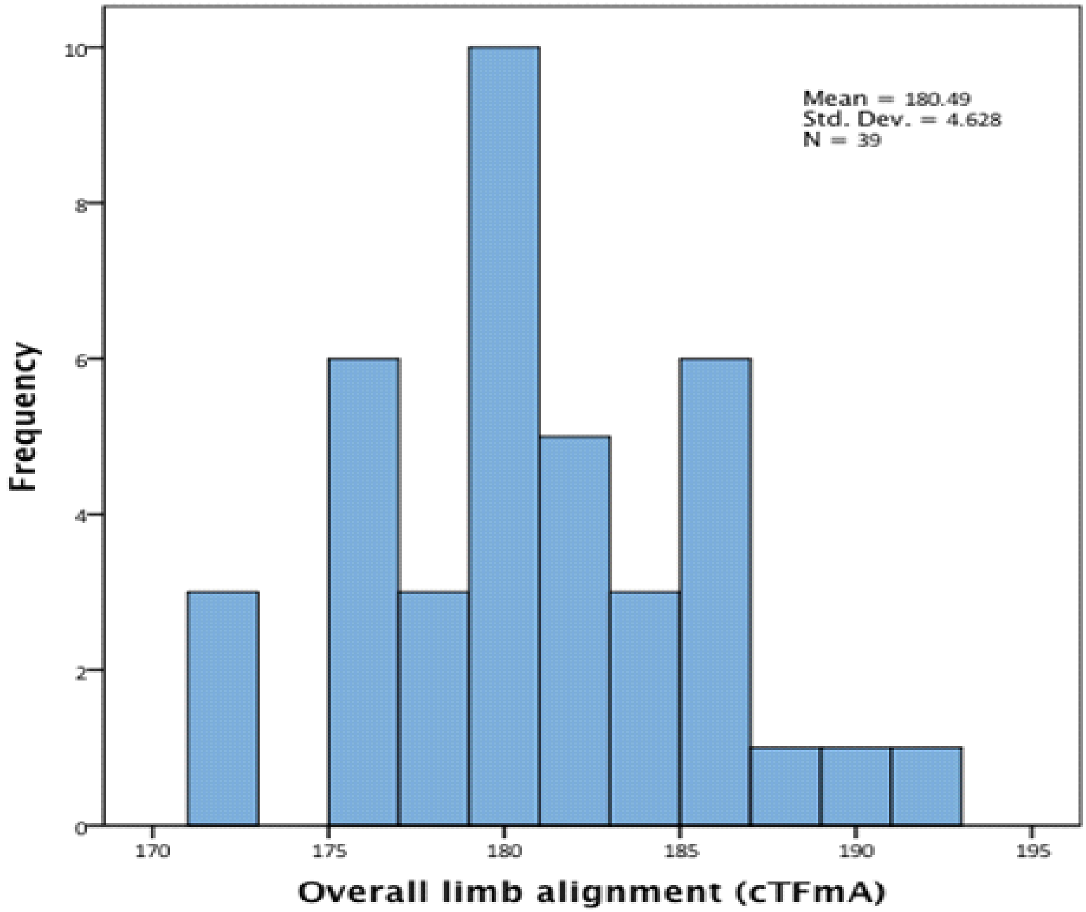



*Figure 4-5: Overall limb alignment data distribution*

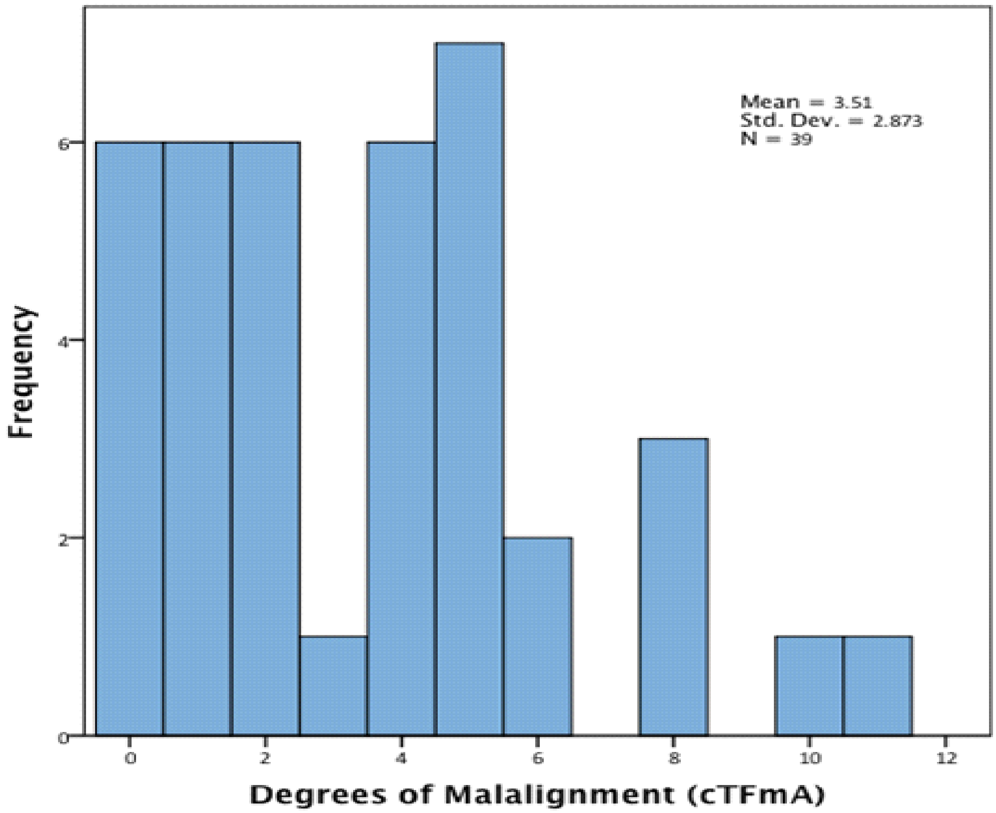



*Figure 4-6: Histogram showing the distribution of data for Degrees of Malalignment (cTFmA)*

### 4.4.1.4.2 Malalignment score 1

This score was the sum of errors in the cTFmA (M=3.6; 95% CI= 2.6-4.5; SD=2.8; n=38) and the rotational mismatch between the femoral and tibia components (aTFMA) (M=3.6; 95% CI= 2.6-5.0; SD 3.6; n=38). The mean Malalignment score 1 was 7.4 (6.0-8.8; 95% CI). The histogram below shows the distribution of data Figure 4-7.

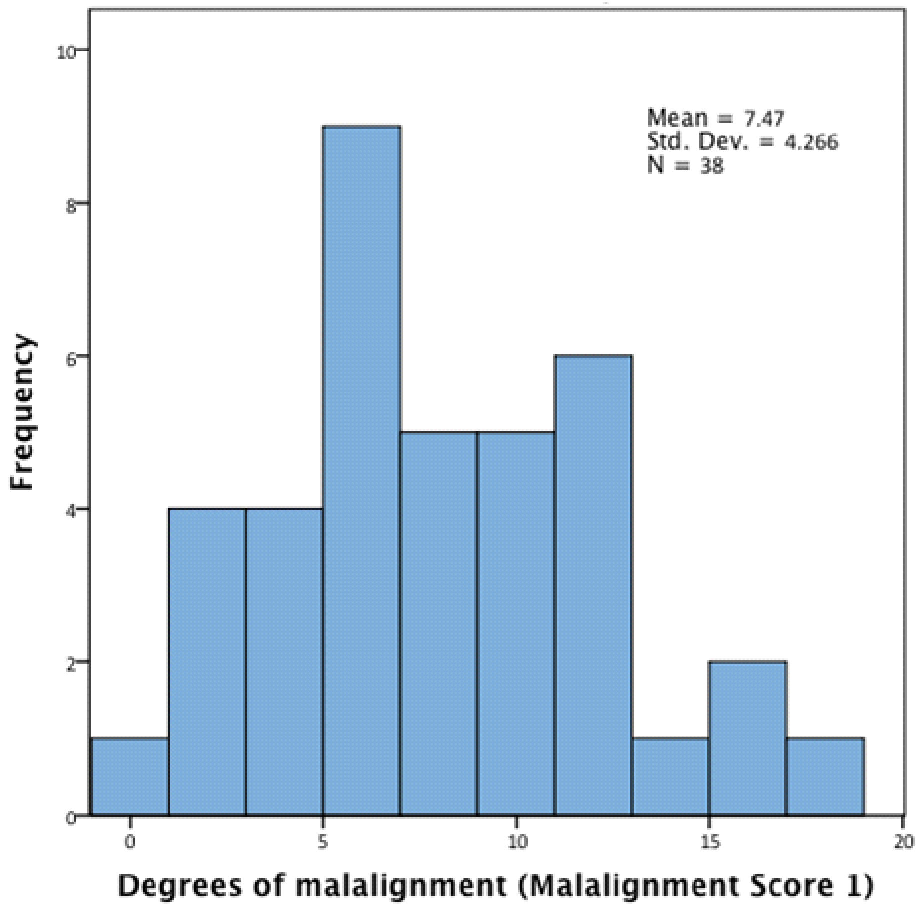



*Figure 4-7: Histogram showing data distribution for Malalignment Score 1*

### 4.4.1.4.3 Malalignment score 2

The Malalignment score 2 (M= 18.1, 95% CI= 15.4-20.8) (Figure 4-8), was the sum of errors in the cTA (M= 3.9, 95% CI= 2.9-4.9, SD 2.9), cFA (M=2.6; 95% CI= 1.9-3.4; SD=2.1), sTA (M= 3.3, 95% CI= 2.5-4.1, SD 2.3), sFA (M= 3.4; 95% CI= 2.3-4.4; SD=3.1), aTA (M=2.2, 95% CI= , and aFA (M= 3.6, 95% CI 2.6-4.7, SD 3.0). The distribution of alignment data for the individual parameters of the femoral and tibial component are presented in Figure 4-9 and Figure 4-10 respectively.

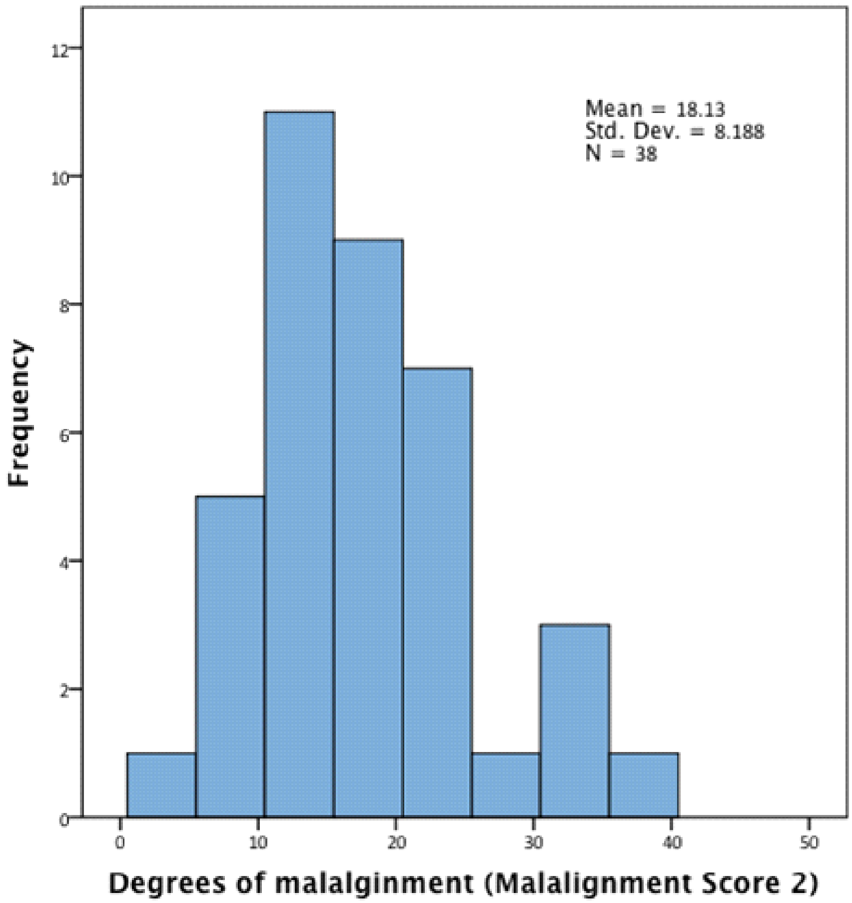



*Figure 4-8: Histogram showing data distribution for Malalignment Score 2*

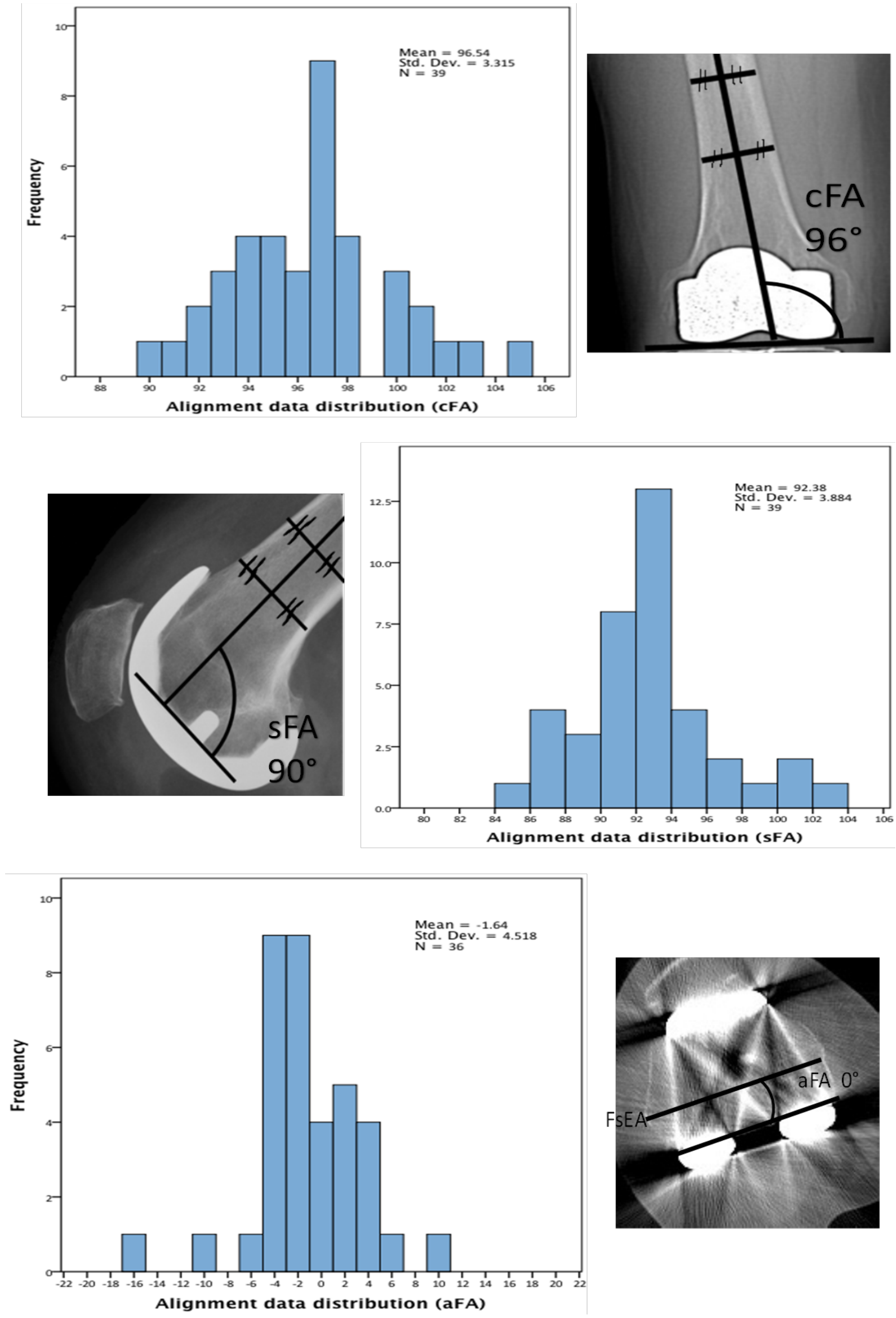



*Figure 4-9: Top row: Histogram showing the distribution of alignment data of the coronal Femoral Angle (cFA) shown on adjacent X-ray image. Middle row: Histogram showing the distribution of alignment data of the sagittal Femoral Angle (sFA) shown on adjacent X-ray*

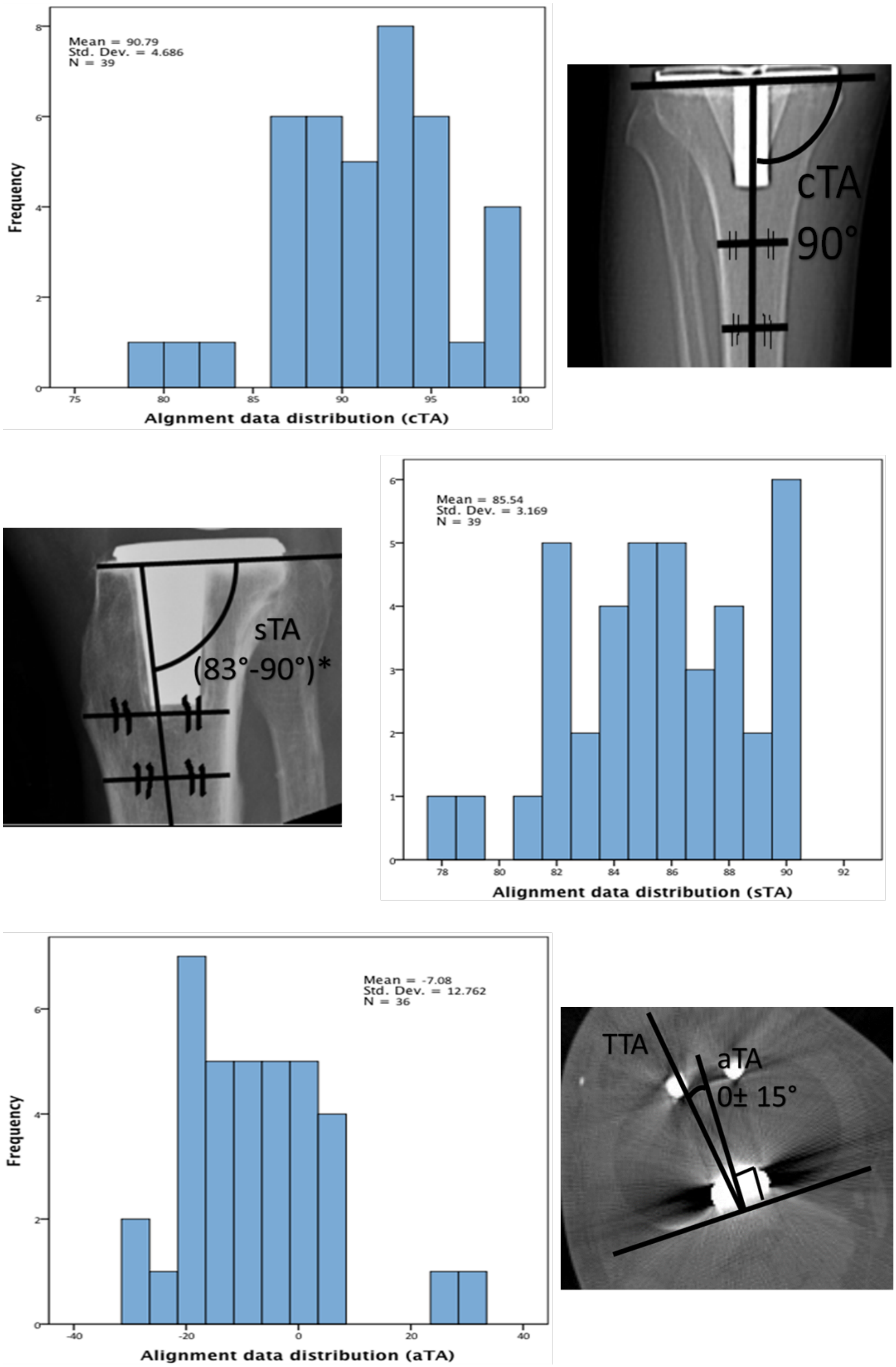



*Figure 4-10: Top row: Histogram showing the distribution of alignment data of the coronal tibial Angle (cTA) shown on adjacent X-ray image. Middle row: Histogram showing the distribution of alignment data of the sagittal tibial Angle (sTA) shown on adjacent X-ray*

### 4.4.2 Analytic statistics

The independent variables (Oxford NOTECHS II, Average Glitches/hr of operating, overall limb malalignment, malalignment Score 1, and malalignment Score 2) were assessed for any violation of assumptions prior to any parametric analysis:

- Cases with missing data of any outcome measure were excluded.
- No significant outliers identified on the data box plots.
- Reasonable assumption of Linearity as seen in the scatter plots.
- The assumption for normality was reasonable as demonstrated in histograms and statistically for:

  Oxford NOTECHS II (S-W= 0.969, df= 38, p=0.356; K-S= 0.145, df= 38, p= 0.078),

  Average glitches/hr of operating (S-W=0.967, df= 38, p=0.316; K-S= 0.133, df=38, p=0.088)

  Overall limb alignment (cTFmA) (S-W= 0.975, df= 39, p= 0.528; K-S= 0.106, df= 39, p=0.20)

  Malalignment score 1 (S-W= 0.973, df=38, p=0.467; K-S=0.109, df=38, p=0.200),

  Malalignment score 2 (S-W=0.959, df=36, p=0.201; K-S=0.117, df=36, p=0.200).

  (S-W: Shapiro-Wilk test; K-W: Kolmogorov-Smirnov test, df: Degree of freedom.)
- Levene test on data split based on side of surgery provided evidence of homogeneity of variance for Oxford NOTECHS II (p=0.332), average glitches/hr of operating (p=0.783), error to overall limb malalignment (p=0.185),

malalignment score 1 (p=0.795), and malalignment score 2 (p=0.836), and supplemented by the relatively random display of points on scatter plots.

#### 4.4.2.1 Correlation analysis between the overall limb alignment and Oxford NOTECHS II score.

A Pearson product-moment correlation coefficient (r) was computed to assess the relationship between error to overall limb alignment (cTFmA) and Oxford NOTECHS II. There was a negative correlation between the two variables, r = -0.407, n = 39, p = 0.01. Overall, there was a moderate, negative correlation between Oxford NOTECHS II and overall limb malalignment. A simple linear regression analysis was conducted to determine if overall limb alignment (response variable) could be predicted from Oxford NOTECHS II Score (explanatory variable). The null hypothesis tested being that r=0. The $r^2$ value suggests that approximately 17% of the variation in the overall limb Malalignment error can be attributed to variation of Oxford NOTECHS II. The unstandardized slope (-0.18) is statistically significantly different from 0 (t= -2.7, df=38, p=0.01); with every 5 points decrease in Oxford NOTECHS II, overall limb malalignment error increase by about 1 degree. A scatterplot (Figure 4-11) and a simple regression analysis table of coefficients and confidence intervals (Table 4-9) are presented below.

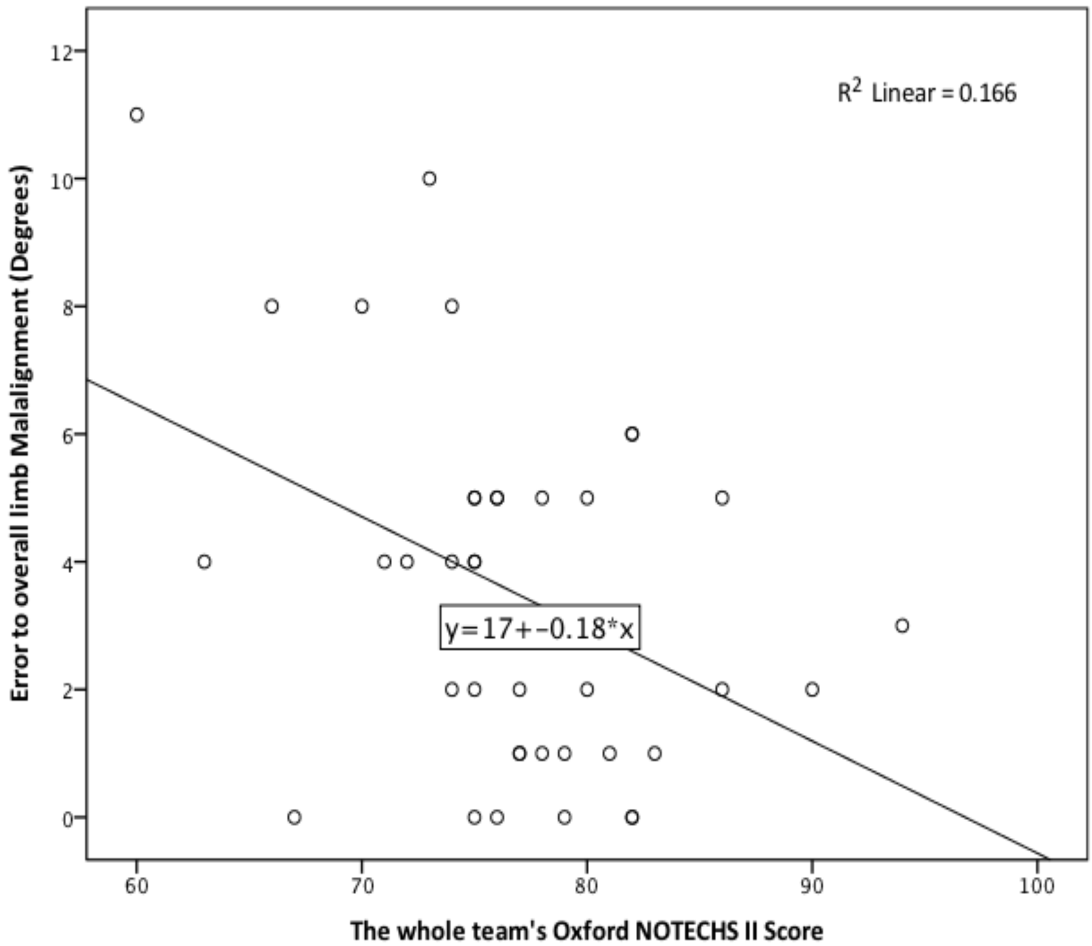



*Figure 4-11: Scatter plot of the whole team's Oxford NOTECHS II and Error to overall limb malalignment with a linear line through the data points*

*Table 4-9: Table of Coefficients for linear regression model (Oxford NOTECHS II and Overall limb malalignment error)*

| Model | | Unstandardized Coefficients | | Standardized Coefficients | t | Sig. | 95% Confidence Interval for B | |
|---|---|---|---|---|---|---|---|---|
| | | B | Std. Error | Beta | | | Lower Bound | Upper Bound |
| 1 | (Constant) | 17.004 | 4.995 | | 3.404 | .002 | 6.882 | 27.125 |
| | Oxf NOTECHS II | -0.176 | 0.065 | -0.407 | -2.711 | 0.010 | -0.307 | -0.045 |

Dependent Variable: Error to overall limb Malalignment

### 4.4.2.2 Correlation analysis between the overall limb alignment and Glitches during surgery

The computed Pearson's r to assess the relationship between error to overall limb alignment (cTFmA) and average glitches/hr of operating showed that there was a non-significant weak positive correlation between the two variables (glitches and error in overall limb malalignment), r = 0.094, n = 38, p = 0.575.

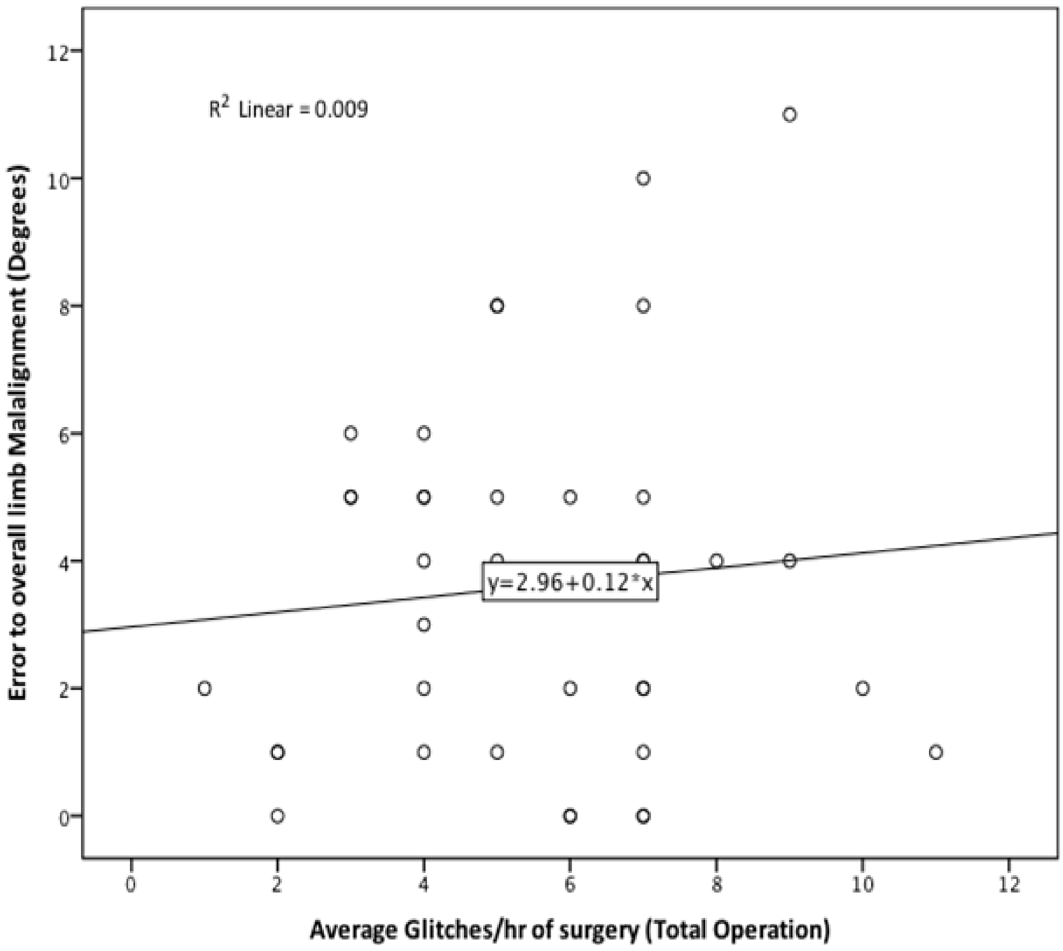



*Figure 4-12: Scatter plot of the average glitches/hr of surgery and Error to overall limb malalignment with a linear line through the data points*

### 4.4.2.3 Relationship between Oxford NOTECHS II sub-scores and malalignment scores.

For this sub-analyses, a correlation statistics was made between the Oxford NOTECHS II whole team's score and sub-scores (Surgical sub-team, Scrub nurse sub-team, Anaesthetics sub-team, and the combined surgical and scrub nurse sub-teams) and Malalignment score 1. This showed a moderate negative correlation between whole team's (r=-0.391), the surgical sub-team (r=-0.360), the scrub nurse sub-team (r=0.388), and the combined surgical and scrub nurse combined scores (r=-0.384) and Malalignment score 1. The correlation is statistically significant at a p-value of 0.05, however only approaching significance at the Bonferroni adjusted p-value of 0.01. Although a negative weak correlation between anaesthetic sub-team and Malalignment score 1 was identified (r=-0.258), this did not reach statistical significance. The details of the results are shown in table below (Table 4-10).

*Table 4-10: Showing the Pearson Correlation matrix between Oxford NOTECHS II whole team and sub-teams scores and Malalignment score 1*

| | | Malalignment Score 1 |
|---|---|---|
| Whole Team's Oxford NOTECHS II Score | Pearson Correlation | -0.391* |
| | Sig. (2-tailed) | 0.015 |
| | N | 38 |
| Surgeon sub-team's Oxford NOTECHS II Score | Pearson Correlation | -0.360* |
| | Sig. (2-tailed) | 0.026 |
| | N | 38 |
| Scrub Nurses sub-team's Oxford NOTECHS II Score | Pearson Correlation | -0.388* |
| | Sig. (2-tailed) | 0.016 |
| | N | 38 |
| Anesthetics sub-team's Oxford NOTECHS II Score | Pearson Correlation | -0.258 |
| | Sig. (2-tailed) | 0.119 |
| | N | 38 |
| Surgeons & Scrub Nurse sub-teams' Oxford NOTECHS II Score | Pearson Correlation | -0.384* |
| | Sig. (2-tailed) | 0.017 |
| | N | 38 |

* Statistical significance at p=0.05, however not significant at Bonferroni adjusted p-value 0.01

#### 4.4.2.4 Relationship between glitch relevant categories and subgroups and malalignment scores

The exploratory sub-analyses correlation matrix between relevant glitches categories and malalignment parameters (overall limb malalignment and malalignment score 2) showed that only distractions type glitches between skin incision and end of implant fixation times demonstrated a positive moderate correlation with overall limb malalignment however this approached statistical significance but did not reach the adjusted p-value of <0.01 ($r=0.362$, $df=38$, $p=0.26$). All other categories of glitches categories had weak and non-significant correlation coefficients.

As for the sub-analyses involving the three sub-sets of glitches (Average glitches/hr of operating for the full length of surgery, average glitches/hr of operating between skin incision and end of implant fixation time, and average alignment-relevant only glitches/hr of operating) and malalignment score 2, all but the average relevant glitches/hr of surgery between skin incision and end of implant fixation time variable showed a reverse (negative) correlation. Again, all of the correlation coefficients were weak and none reached statistical significance. Results of this sub-analysis are displayed in table below (Table 4-11).

*Table 4-11 Pearson Correlation matrix between Glitches and Malalignment score 2*

| | | | Malalignment Score 2 |
|---|---|---|---|
| Total operation time | Average Total Glitches | Pearson Correlation | -0.275 |
| | | Sig. (2-tailed) | 0.094 |
| | | N | 38 |
| | Average Relevant Glitches | Pearson Correlation | -0.135 |
| | | Sig. (2-tailed) | 0.420 |
| | | N | 38 |
| Skin incision to implant fixation time | Average Total Glitches | Pearson Correlation | -0.077 |
| | | Sig. (2-tailed) | 0.645 |
| | | N | 38 |
| | Average Relevant Glitches | Pearson Correlation | 0.121 |
| | | Sig. (2-tailed) | 0.468 |
| | | N | 38 |

No statistically significant results at Bonferroni adjusted p-value 0.01

## 4.5 **Discussion**

### 4.5.1 Summary of Findings

#### 4.5.1.1 Oxford NOTECHS II

The main finding in this study is that better intra-operative non-technical skills measured using the Oxford NOTECHS II score correlated significantly with better overall limb alignment following TKA (r=-0.407, n=39, p=0.01). The correlation between non-technical skills and malalignment was further noted when assessing the correlation between team and sub-teams' Oxford NOTECHS II scores (excluding the anaesthetic sub-team score) with Malalignment score 1 – sum of malalignment errors of the combined component mechanical alignment and axial mismatch (cTFmA and aTFMA). This correlation however approached but did not reach the statistical significance for the adjusted p-value of <0.01 for multiple testing (r=-0.391, p=0.015;

r=-0.360, p=0.026; r=-0.388, p=0.016; r=-0.384, p=0.017 for malalignment score 1 with the whole team's Oxford NOTECHS II scores, the surgeon sub-team's Oxford NOTECHS II score, the scrub nurse sub-team Oxford NOTECHS II score, and the surgeon and scrub nurse combined sub-team's Oxford NOTECHS II scores respectively). A linear regression analysis to determine if overall limb malalignment (response variable) could be predicted from Oxford NOTECHS II score (explanatory variable) suggested that approximately 17% of the variation in the overall limb malalignment error can be attributed to variation of Oxford NOTECHS II. The unstandardized slope (-0.18) is statistically significant and with every 5 points decrease in the team's Oxford NOTECHS II score, there is a 1 degree increase in overall limb malalignment error. This supports the notion of better surgical team's non-technical skills in the operating theatre leads to better outcome.

### 4.5.1.2 Glitch count

The other main finding is that this study did not demonstrate a statistically meaningful correlation between glitches and overall malalignment (r = 0.094, n = 38, p = 0.575) or any sub-sets of glitches and malalignment score 2 – sum of three planer component malalignment relative to anatomical axes (cFA, sFA, aFA, cTA, sTA, and aTA). Distraction type glitches - defined as anything causing distraction from task such as phone calls, bleeps, loud music requiring being turned down - showed a moderate positive correlation with overall limb malalignment however this correlation approached but did not reach statistical significance (r=0.362, df=38, p=0.26).

### 4.5.2 Strengths and limitations compared with other studies

The key aim of this study was to address a gap in the literature on the relationship between non-technical aspects of surgery including non-technical skills and the smoothness of the surgical process in theatres and patient related technical outcomes. This is the first study to address this gap utilising malalignment following TKA in elective orthopaedic surgery as a predictor and a measure of technical success. Previous studies investigating the link between non-technical and technical outcomes in theatres utilised a variety of technical predictive factors. In one study [282], these included dexterity parameters such as time to complete the task/operation, economy of motion, tool movement smoothness, instrument smoothness, hand movement, instrument path length, gesture proficiency, and hand motion efficiency. Other studies measured the quality of the technical performance either by counting the number of technical errors and evaluating the impact of these errors on the standard technique or used procedural technical global rating scales according to checklists of surgical steps for each procedure such as the objective structured assessment of technical skill (OSATS) [291]. Other assessment tools described in the literature to capture quality of technical performance included mortality and morbidity and complication rates [50]. Although these outcome measures are undoubtedly relevant in terms of assessing technical performance they do not directly measure technical or patient-related final outcomes. They also may be subjective, non-specific, and difficult to assess given the variety of surgical techniques described for certain surgical procedures.

One of the main strengths of this study is in the type and quality of technical outcome utilised to address the question on the relationship between non-technical and technical aspect of surgery. Malalignment following TKA is pertinent to the correct execution of the procedure technically [74, 133], is linked to outcome following TKA surgery, and can be reliably measured radiologically [292] making it an ideal outcome measure for this study and research in elective orthopaedic theatres.

For the standard mechanically-aligned TKA, there is a set of target alignment parameters required to achieve by the surgeon during the operation. These parameters are designed to deliver a mechanically aligned lower limb at 180°. The targets are achieved by the surgeon using a battery of equipment and specialised jigs. Any malalignment is a clear indication of a missed target. The importance of achieving this target alignment can be appreciated from the popular use of CAS TKA surgery.

It is conceded that there is currently no consensuses on whether better aligned knee result in better patient outcomes. As shown in this thesis systematic review (Chapter 2) the evidence to support the notion of malalignment resulting in poor patient outcome is subject to many limitation. Nevertheless, the surgeons strive to align TKA implants to achieve a mechanically aligned lower limb at 180° making malalignment following TKA surgery a significant predictive factor for the success of TKA surgery and an ideal outcome measure for this study.

The radiological methods for assessment of malalignment in this study were designed following a detailed literature search (Chapter 3). CT was the radiological instrument of choice as it provides more geometric information in particular in relation to axial alignment [114, 245, 266, 292]. As with the method described by Kim et al [266], the x, y, z location of the relevant anatomical landmarks are identified using the CT scans raw data of the whole limb. These relevant anatomical landmarks were then used to calculate mathematically limb and implant alignment. This method reduces the risk of making measurement errors as it eliminates the need to plot lines manually on images to calculate intersection angles. Similar to their findings, the inter- and intra- observer reliability were both excellent (ICC of 0.946 and 0.850 respectively).

This study's findings shows a clear advantage of demonstrating better non-technical skills in the operating theatre, a notion already popular in the field of safety research. However, this is a correlational observation study and cannot establish a cause-and-effect relationship between good non-technical skills in theatres and better technical outcomes. This study's finding supports the findings of several other studies. A recent systematic review by Hull et al [45] of studies in simulation environment and real life theatres in a variety of surgical disciplines including paediatric cardiac surgery concluded that non-technical skills of theatre team members do have an effect on their technical performances. In other studies, poor non-technical skills in theatres (especially in situational awareness among surgeons) were shown to have a negative impact on patient outcome as demonstrated by higher rate of technical errors [43, 293]. Another important finding was the lack of a statistically significant correlation between the anaesthetic sub-team scores and malalignment. This is however to be expected as TKA is an elective procedure routinely performed on relatively healthier patients which provide smaller change to anaesthetist during surgery when compared to paediatric cardiac surgery as an example. This may manifest itself as less variability in the anaesthetic team's performance during the observed operations, which may have made the relationship between the variables undetectable.

As for the distraction glitches within the surgical process, several studies have shown that distraction specific glitches in the operating theatres are prevalent and can impact negatively on safety outcomes [294-296]. Sevdalis et al showed a link to deterioration in intra-operative patient safety checks [53]. Persoon et al [297] concluded that distractions could be disturbing and impact negatively on performance as shown by interviewing the operating team members. This study has also demonstrated that these type of glitches when occurring during the critical operating time (between skin incision and end of implant cementation) correlate with worse technical outcomes although this was approaching but did not reach statistical significance for the adjusted p value.

This study did not demonstrate a correlation between malalignment and increased average glitches or subsets of glitches. On the face of it, it appears that these events, in their totality, did not hamper the technical performance.  Although these results do contradict previous findings suggesting that glitches impede team performance and contribute to errors in surgery [30, 44, 283], other studies have found a similar finding and an absence of a significant relationship [298].  This important finding highlights some issues:

Firstly, this finding may be the result of the nature of both the operations studied and that of the glitches observed. Many see the impact of glitches on the surgical process and ultimately on patient outcome, resulting from their ability to reduce the capacity of the theatre teams to identify and compensate for more serious and unavoidable incidents that can occur during surgery. Eliminating these seemingly insignificant glitches will results in an event free progress of an operation and reserve the team's coping capacity for the management of serious issues in particular, during high-risk operations or if the team non-technical performance is ineffective [44]. Woods et al [299] describes the dynamic escalation principle where the greater the trouble in the underlying process or the higher the tempo of operations, the greater demand for cognitive activity and coordination which may ultimately bring out the penalties of poor support for work. Elective orthopaedic surgery in general and TKA in particular are regarded as high volume but low risk. The impact of increased glitches on surgical outcomes may be neutralised by the fact that team members were able to compensate for such events and maintain their performance in these types of operations due to the lack of significant trouble. It is however undoubtedly true that team members are regularly making trade-offs when dealing these increasing demands. Clearly there is a limit to what individuals and teams may adapt to.

As for the nature of glitches experienced, Yue-Yung Hu et al. [300] presented a conceptual model in which glitches may be regarded as safety compromises, which may be partially or fully recoverable and suggests their effects may also be additive, accumulating until a threshold for harm is reached. Glitches are likely to have a complex non-linear effect on the surgical process and consequently on patient outcome. This observation may therefore hold the answer to why different studies have demonstrated variable results. It is reasonable to infer that the glitches observed in this sample study did not cross the threshold level - which can be relatively high in the field of elective orthopaedic surgery in comparison to paediatric cardiothoracic surgery as shown by Catchpole et al [30].

Secondly, there is an inherent difficulty with the technique of error counting (in this study referred as glitches) as eloquently explained by S. Dekker [301] who argues that the process of counting errors during, for example a surgical procedure, is a form of structural analysis that incorrectly assumes cause and consequence. The focus being to minimise risk through reducing the measurable effect of these counted errors. The researchers of such models can always find supportive arguments with further refining. In his paper Dekker [301] conceded that an alternative theory is difficult to propose. However, he reported that *"health practitioners should actively engage operational and organizational conditions, and realise that safety cultures are not cultures without errors, and consider safety as a dynamic, interactive, communicative act that is created as people conduct work, construct discourse and rationality around it, and gather experiences from it."*

A definite position cannot be made based on the glitch related results in this study. It is clear that further analysis of the glitch categories and complex statistical models are required to identify which types of glitches have the most impact and which category of glitches are more relevant for different types of operation. The study's sample size and power must also be considered when interpreting the results of the sub-analysis.

Similar to many reports in this field, this study was observational and utilised a prospective method for data collection. A significant advantage is this study collected real time intra-operative team and process performance data in real theatre environment by two independent observers. An independent dual observation of a theatre environment is logistically a challenging and costly task when compared to single observer. In the literature, many studies have advocated single observer techniques however, the multiple demands of a theatre environment may require more attention than a single observer can provide. This is clearly demonstrated in our research group's (S3) publication [55], that showed between 40% and 75% of the total glitches were observed by a single observer. There was also a difference in the categories each observer collected highlighting the importance and advantage of having observers with different but relevant backgrounds in these type of studies; clinical and HF. Simulation offers an enormous opportunity to examine how team and system improvements can be made in high risk situations without threatening patients however simulation is not quite like real life; and errors usually do not lead to adverse outcomes. Therefore data presented in this study are closely related to what actually occurred in the clinical settings.

Other limitations to this study include its vulnerability to observer bias and the Hawthorne effect. Questions regarding the importance of this phenomenon which describes an alteration in the participants' behaviour when aware of being observed are raised [302]. The Hawthorne effect is unavoidable in this type of observational study. Evidence from the larger sample set for the S3 study show the same patterns of glitches were repeated by teams after longer exposure to observation, suggesting that the Hawthorne effect was not prominent [55]. Data collectors were aware of the study hypothesis, however, non-technical outcomes (Oxford NOTECHS II and Glitches) and technical outcomes (Malalignment) were analysed separately with all identifying data being concealed during the period of analysis.

The data set in this study is relatively small with a total of 39 knees included. Albeit the correlations identified were statistically significant. The analysis did not account for other aspects of the operation that may influence technical outcome such as surgical complexity, patient factors, severity of pre-operative malalignment. Also, it was not possible to conclude which behaviours were most important or whether their influence varied by operative stage. The importance of non-technical outcomes would undoubtedly become more significant if the technical challenge is greater or present at a critical part of the operation; a much larger sample would be needed to demonstrate such a finding.

In this study sample, 53% of patients were within 2 degrees of neutral when assessing the coronal mechanical axis (coronal tibiofemoral angle). This was worse compared to other studies such as Anderson et al [303] (70%) and Mizu-uchi et al [117] (71%). Although the different technical ability among different surgeons may account for the difference in technical outcome, this is most likely due to the fact that this study included multiple surgeons of different level of experience within a teaching hospital environment using different knee systems, and both primary and revision surgery. It also reflects the fact that this was a true cohort study of real surgical experience, rather than a focused study of a particular issue carried out by experts with a focus on measuring the achievement of results as near to technically optimal as possible. All lead surgeons included were NHS consultants with arthroplasty experience.

Several challenges were encountered when identifying the target alignment; in particular, the tibial component rotation alignment. Tibia component rotational alignment can be achieved surgically using two different methods. Firstly, using the tibia tuberosity as a reference point, secondly, allow the implant to take its own position by flexing and extending the knee while trialling implants. Intra-operatively, surgeons apply both techniques to ensure that the tibia component alignment is adequately placed. To account for this, the rotational alignment margin of error is relatively large compared to the femoral rotational alignment. Therefore, the tibia rotation errors in this study are likely to be a conservative estimate. This may have contributed to the fact that the analyses involving rotational malalignment did not have a large impact on the final study result or direction. There is a strong argument to exclude axial alignment parameters in similar future studies and replace CT scan as the radiological assessment tool of choice with the novel method using trigonometry and jigs in the Schuss position described in (**Error! Reference source not found.**) of this hesis. This will have the advantage of reducing cost, radiation exposure, and will ease recruitment thus increasing sample sizes.

Another challenge when assessing alignment was the effect of soft tissue balancing during TKA. A surgeon relies on the anatomical axes to create the bony cuts required for a TKA. To achieve the target neutral mechanical axis, a significant amount of soft tissue adjustment is made. Anecdotally, some surgeons will class this operation as a soft tissue operation rather than a bony one. This aspect of the operation is not directly assessed in this thesis. When addressing this issue two groups of malalignment were generated; one to account for the errors in bony cuts only (malalignment score 2) and the other to account for the overall result including the soft tissues (malalignment score 1). Noteworthy, in some cases there was a high number of errors in score 2 while maintaining a low score in error score 1 and vice versa. This may suggest that some surgeons intentionally made "errors" in the bony cuts to achieve adequate overall alignment or failed to correct the soft tissue adequately resulting in a malaligned limb. Although both demonstrate a clear limitation to the technical outcome used in this study, they are also a significant limitation to the philosophy of the mechanically knee and/or the tools used for this type of operation. Again, these issues highlight the significance of both better technical and better non-technical skills of the surgical team in delivering a technical targets such as implant position.

In the literature, a 2 degrees or 3 degrees malalignment margin is repeatedly quoted when assessing for TKA alignment. This arbitrary figure is used to account for the errors made due the use of the saw blade during surgery [125]. In this study, errors in degrees were calculated relative to the target perfect value. This was decided primarily because this study is designed to measure the size of errors made regardless of the cause including those due the equipment's fit for purpose properties.

Fundamentally, these study findings do not demonstrate that patients are at harm from malalignment following TKA due to poor non-technical skills or interrupted surgical process. Instead it shows that operative targets were less likely to be achieved suggesting a worsening in the technical outcomes due to the worsening of non-technical aspect of surgery.

### 4.5.3 Conclusions

Implant alignment following TKA surgery is a quality indicator for intra-operative performance of the operating team. The surgical teams' non-technical skills measured by the Oxford NOTECHS II play a significant role in the team's ability to carry out technical tasks. Glitches within the surgical process in this study did not impact on the technical outcome; this is likely due to the nature of elective orthopaedic surgery theatres. Distraction glitches were the most detrimental on technical outcome. Developing an intervention solely based on these findings would not be straightforward. The investments in improving team's non-technical skills will likely help surgical teams achieve their surgical targets thus improving patient outcomes and providing a safer environment for patients.

# Chapter 5 **Discussions & Conclusions**

## 5.1 **Summary of new findings**

The NHS, UK's main health care provider, is an inspired, professional, and ambitious establishment that provides essential healthcare to millions. Evidence of inadvertent patient harm due to healthcare staff errors - both within the NHS and in other healthcare providers worldwide - prompted a regulator-led changes to eliminate such distressing incidents to patients and medical staff alike. Surgical disciplines, including orthopaedic surgery, became a focus of attention given the scale of the problem within operating theatres. The transfer of knowledge from other industries including the aviation, nuclear, and military industries, as well as the expertise of Human Factors specialists, helped enhance our understanding of the problem. A key argument highlighted in Chapter 1 is that humans make errors as a consequence of inadequate system components within which they work. Healthcare organizations would need to ditch the commonly practiced individual blame-and-shame methods when dealing with errors and adopt a more holistic strategy; a systems approach. By improving the processes within the healthcare system and by equipping the teams with adequate non-technical team working skills, errors are reduced and patient safety and outcomes are enhanced.

To help further our understanding of these errors during surgical operations, researchers focused their attention on developing assessment methods and tools specifically designed for use in the operating theatres. Studies were then able to identify an inconsistency in the level of non-technical skills demonstrated by operating teams.  Also, closer observation and in depth analysis of the operating processes where patient harm has been reported revealed the presence of seemingly insignificant events prior to the occurrence of an error in theatres. Both of these findings led to the postulation that certain aspects of the surgical team's non-technical performance in the operating theatres can enhance, or if absent contribute to the deterioration of the team's technical performance. However, there remains a need to establish clear evidence on the interaction between non-technical performance and technical outcomes. So far, within orthopaedic theatres there is no research that has addressed this knowledge gap using specific patient related outcomes. Thus, this work has been conducted to bridge this gap and provide the most comprehensive evidence to inform this highly important field.

In Chapter 1, a discussion is presented on the suitability of elective orthopaedic theatres in general and TKA in particular for conducting this research highlighting the complex, high volume, multidisciplinary, and equipment-reliant nature of this surgical field. Also, a description of the non-technical assessments measure utilised for this research; the Oxford NOTECHS II for the assessment of team's non-technical skills and glitch count to assess the smoothness of the surgical process. Both of these outcome measures were developed and applied by our research group while conducting the S3 project alongside but independently of this thesis research. The S3 was a project testing the efficacy of various types of industrial developed strategies and interventions when applied to different groups of surgical theatre teams in improving the team's non-technical performance. This provided a situation where different theatre teams were expected to show varied levels of performances in terms of non-technical skills and smoothness of the surgical process. This was identified as a desirable situation in terms of this thesis as the extension of the normal variance in performance that is expected to arise after training would likely to tip the balance of the signal-to-noise ratio in favour of the signal, and make detection of a relationship easier.

The next issue to address in this thesis was identifying a suitable technical outcome that would provide a surrogate for technical success. Having explored the procedural steps of a modern condylar and mechanically aligned TKA in Chapters 1 and 4, post-operative malalignment was investigated for suitability as an outcome measure. Achieving the correct implant and limb alignment following surgery is considered as a significant procedural requirement and is recommended by the implant manufacturers confirming its validity as an outcome measure for technical success. In Chapter 1 of this thesis, further exploration of the concept of malalignment was undertaken to provide a definition and taxonomy used in this thesis and to be applied in future research. In Chapter 3, analysis of the various available radiological tools was also performed and a rationale for applying CT scan as the method of choice for this research is presented citing the additional axial information provided when compared to plain X-rays and its rater reliability for the assessment of malalignment. In addition, a novel X-ray technique for assessing coronal alignment following TKA surgery (regarded by many orthopaedic surgeons as the most important alignment parameter) was developed during this thesis. This method uses plain X-rays with the aid of jigs and simple geometry to assess coronal overall limb malalignment. It is a standardised, more readily available, cheap, and has less radiation exposure when compared to CT. Malalignment assessment using this novel technique also demonstrated superior agreement with the assessment of malalignment on CT scan images when compared to routine X-rays suggesting it is a viable option to replace routine X-rays in day-to-day clinical practice as well as replacing CT scan in similar future research. Finally, to assess for clinical relevance and appropriateness of malalignment following TKA, a systematic review of the literature was conducted in Chapter 2 to determine its impact on patient related outcomes. The results of which showed that although evident when examining the most robust published studies, there was a significant limitation in the evidence supporting the notion that malalignment results in worse patient reported outcomes and/or worse implant longevity. The main limitation identified in the literature was the predominant bias in the radiological assessment methods applied for assessing alignment. Therefore, guidelines for assessing the studies' risk of bias in a flowchart format was developed and utilised to aid in scrutinising the evidence during this thesis.

In light of the above findings and because delivering 180° neutral alignment is a the surgical target for the whole cohort of orthopaedic surgeons using mechanically aligned TKA and recruited during this research, post-operative malalignment was deemed a suitable technical outcome measure to answer the main research question in this thesis: In patients undergoing elective TKA, are the surgical team's non-technical skills measured by the Oxford Non-technical Scale (Oxford NOTECHS II) and/or smoothness of the surgical process measured by the 'Glitch rates' associated with changes in implant or limb alignment assessed radiologically following surgery?

Chapter 4 of this thesis focused on conducting the experiment to answer the above question. A cohort study was presented as the most suitable study design to address the question of identifying potential risk factors in a large population. A correlation and a regression analysis would provide the statistical evidence and the strength of relationship between the explanatory and response variables. The data on non-technical aspects of surgery was provided following a lengthy real time independent dual observation of TKA procedures in two different sites by a team of clinical and human factors experts. The primary explanatory variable for Oxford NOTECHS II was presented as the total team's score; this included the surgical sub-team, scrub nurse sub-team, and anaesthetic sub-team. The non-technical domains assessed were:

- Leadership and management
- Teamwork and cooperation
- Problem solving and decision-making
- Situation awareness

Due to the properties of the Oxford NOTECHS II scale, a variety of secondary scores based on individual sub-team's scores were available to use in sub-analyses. Similarly, the primary explanatory variable for glitches was the average glitches per hour of surgery of all glitch categories. These were:

- Absence
- Communication
- Distractions
- Environment
- Equipment related
- Health and safety
- Patient related
- Planning and preparation
- Process deviation
- Slips
- Training
- Workspace.

Exclusions of glitches based on category, time of occurrence, and relevance to malalignment created additional sub-sets of glitches that were then used in sub-analyses. Overall limb alignment was the primary response variable while the sum of different alignment parameters - based on the procedural tasks and potential non-technical skills involved – made up the different malalignment scores that would be used in the secondary sub-analyses.

An interesting mixture of positive and negative correlations was identified. The main finding of this research was that better intra-operative non-technical skills measured using the Oxford NOTECHS II score correlates significantly with better overall limb alignment following TKA. The sub-analyses reinforced this correlation between the surgical and scrub nurse sub-teams' scores and malalignment. Both of these findings support an already popular belief that poor surgical team's non-technical skills during surgery can result in worse patient outcomes. It also supports the notion that investment in improving team's non-technical skills can improve patient outcomes and provide a safer environment for patients. An understandable but still interesting finding was the lack of correlation between anaesthetic sub-team's non-technical skill scores and malalignment in this study. This finding highlights an apparent difference in the level of demand placed on anaesthetists during elective TKA in comparison to other acute surgical disciplines such as paediatric cardiac surgery.

The other main finding of this research was that this study did not demonstrate a meaningful correlation between glitches and malalignment. A finding, which on the face of it may appear negative, is plausible given the nature of the surgical process in elective TKA as well as the stage of our understanding of glitches and their interaction with the surgical process. As with other research in the area, distraction glitches had the most detriment on the outcome and had a moderate correlation with post-operative malalignment however this did not reach statistical significance.

This study has addressed a knowledge gap in the current understanding of the relationship between non-technical aspects of surgery and patient related technical outcomes. It is the first study to utilise malalignment following TKA in elective orthopaedic surgery as a predictor and a measure of technical success.

## 5.2 Implications and future direction

The relationship between non-technical aspects during a surgical procedure and technical outcomes of the operation is not fully understood. Although the surgical team's non-technical performance and the surgical process have both been widely explored by researchers, the impact of it on technical performance is not fully known. There are clearly many variables contributing to this and these need to be clarified. This research has achieved its primary aim of addressing the research question on the relationship between non-technical aspects of surgery measured using Oxford NOTECHS II and glitch counting, and malalignment as technical outcome related to TKA surgery in the elective orthopaedic operating theatres.

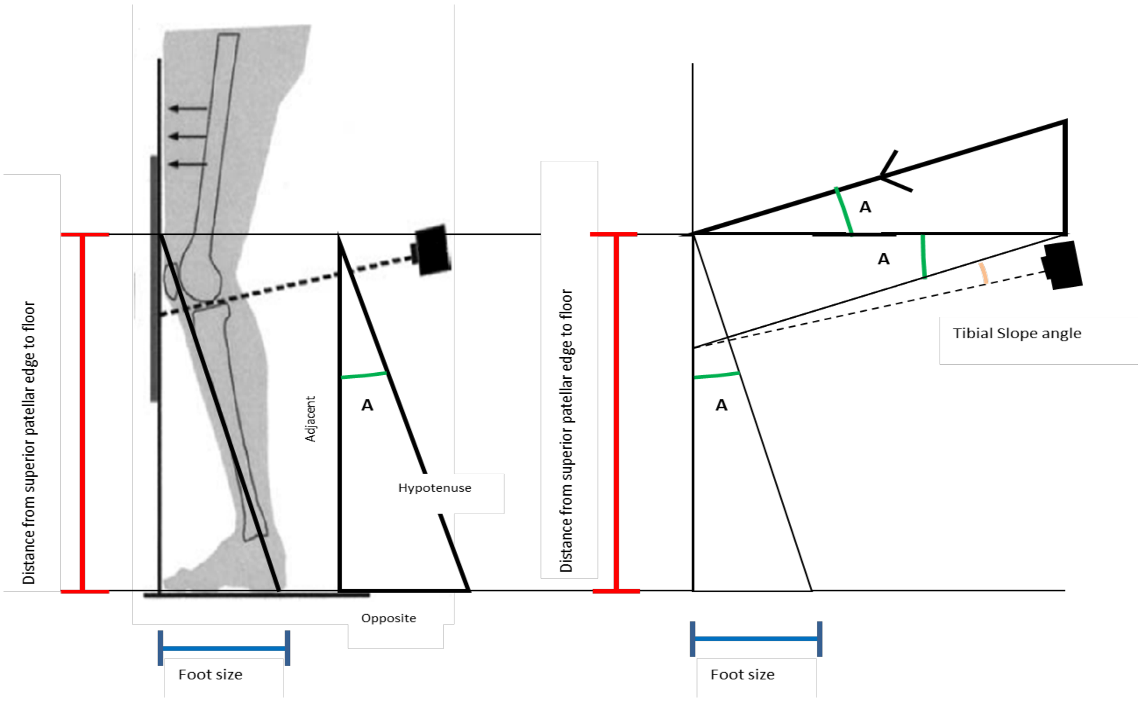
Many new questions emerged during the process of resolving this research's questions. A natural development to this research is to expand the data pool in order to identify the correlation between non-technical skills domains and glitches subcategories with technical outcomes. There is a strong argument based on the findings of this research and on the experience gained during this thesis for a lengthier more focused approach to the research question proposed. A single observer with adequate clinical and human factors experience collecting non-technical data from multiple sites for a longer period of time would enable the collection of more data from a larger number of operations. This would replace the more logistically cumbersome dual observations method. The results of this study can aid with sample size calculation to identify a precise number of operations needed. Thus, enough power can be generated to allow sub-categories analysis and shed more light on the impact of different aspects of the non-technical data collected such as, the glitch category that has the most detriment on the surgical process or the non-technical skill domain that can enhance the team's performance. The overall limb malalignment would be selected as the sole technical outcome. This can be achieved by using the novel X-ray assessment method presented in Chapter 3 of this thesis. The advantages being less radiation exposure to patients, less impact on patient convenience and therefore more patient compliance, and finally reducing research cost and time spent on CT scanning. The analysis of these variables would provide further valuable evidence on the associations between non-technical aspects of surgery and technical outcomes.

Another application of the Oxford NOTECHS II and Glitch count is in the assessment and training of healthcare providers in the operating theatres. In the current UK national move towards competency-based curricula for postgraduate medical education, theatre observations and non-technical assessment tools can be valuable in both the assessment and as training aids for trainees. In contrast to the nontechnical skills for surgeons (NOTSS) which currently being used for surgeons, the Oxford NOTECHS II can be used for the assessment of the entire operating team including the nursing and anaesthetic teams. Non-technical skills can change from the informally acquired skill by trainees through apprenticeship and observation to one of active knowledge acquisition with behavioural change.

Finally, Researchers must continue to challenge our understanding of how to deliver a safe environment to our patients. The relationship between humans, environment, systems, equipment, and management must be repeatedly examined. As more research discovers more means to scrutinize our systems, our understanding of the flaws and traps is enhanced, and our strategies for remedies are improved. The improvement of surgical safety must continue to be at the forefront of current research, as this will result not only in keeping patients safe during what is likely to be one of their most vulnerable times but also, in an improved workplace environment for NHS staff where staff can feel safe in the knowledge that a robust system is in place.

# Appendices

*Appendix - 1: Trigonometry for Schuss view X-ray beam inclination measurements*




**Tan A = opposite/adjacent**

**A (degrees) = tan $^{-1}$ (opposite/adjacent)**

**Angle A = foot size (cm) / distance from the supra-patellar edge to floor (cm)**

**X-ray Caudal inclination Angle = Angle A – TKR Tibial Slope Angle (7$^{o}$)**

*Appendix - 2: Foot size conversion chart*

| Adult foot size conversion chart | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| System | | Sizes | | | | | | | | | | | |
| Europe | | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 | 46 |
| U.K. | Male | 3 | 4 | 4.5 | 5.5 | 6.5 | 7 | 7.5 | 8 | 8.5 | 10 | 11 | 12 |
| | Female | 2.5 | 3.5 | 4 | 5 | 6 | 6.5 | 7 | 7.5 | 8 | 9.5 | 10.5 | 11.5 |
| Australia | Male | 3 | 4 | 4.5 | 5.5 | 6.5 | 7 | 7.5 | 8 | 8.5 | 10 | 11 | 12 |
| | Female | 3.5 | 4.5 | 5 | 6 | 7 | 7.5 | 8 | 8.5 | 9 | 10.5 | 11.5 | 12.5 |
| U.S. & Canada | Male | 3.5 | 4.5 | 5 | 6 | 7 | 7.5 | 8 | 8.5 | 9 | 10.5 | 11.5 | 12.5 |
| | Female | 5 | 6 | 6.5 | 7.5 | 8.5 | 9 | 9.5 | 10 | 10.5 | 12 | 13 | 14 |
| centimetres | | 22.8 | 23.5 | 23.8 | 24.5 | 25.1 | 25.4 | 25.7 | 26 | 26.7 | 27.3 | 27.9 | 28.6 |

*Appendix - 3: Chart for calculating the inclination angle*

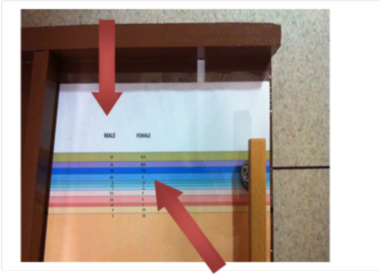
| CM | 22.8 | 23.5 | 23.8 | 24.5 | 25.1 | 25.4 | 25.7 | 26 | 26.7 | 27.3 | 27.9 | 28.6 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 25 | 42 | 43 | 44 | 44 | 45 | 45 | 46 | 46 | 47 | 48 | 48 | 49 |
| 25.5 | 42 | 43 | 43 | 44 | 45 | 45 | 45 | 46 | 46 | 47 | 48 | 48 |
| 26 | 41 | 42 | 42 | 43 | 44 | 44 | 45 | 45 | 46 | 46 | 47 | 48 |
| 26.5 | 41 | 42 | 42 | 43 | 43 | 44 | 44 | 44 | 45 | 46 | 46 | 47 |
| 27 | 40 | 41 | 41 | 42 | 43 | 43 | 44 | 44 | 45 | 45 | 46 | 47 |
| 27.5 | 40 | 41 | 41 | 42 | 42 | 43 | 43 | 43 | 44 | 45 | 45 | 46 |
| 28 | 39 | 40 | 40 | 41 | 42 | 42 | 43 | 43 | 44 | 44 | 45 | 46 |
| 28.5 | 39 | 40 | 40 | 41 | 41 | 42 | 42 | 42 | 43 | 44 | 44 | 45 |
| 29 | 38 | 39 | 39 | 40 | 41 | 41 | 42 | 42 | 43 | 43 | 44 | 45 |
| 29.5 | 38 | 39 | 39 | 40 | 40 | 41 | 41 | 41 | 42 | 43 | 43 | 44 |
| 30 | 37 | 38 | 38 | 39 | 40 | 40 | 41 | 41 | 42 | 42 | 43 | 44 |
| 30.5 | 37 | 38 | 38 | 39 | 39 | 40 | 40 | 40 | 41 | 42 | 42 | 43 |
| 31 | 36 | 37 | 38 | 38 | 39 | 39 | 40 | 40 | 41 | 41 | 42 | 43 |
| 31.5 | 36 | 37 | 37 | 38 | 39 | 39 | 39 | 40 | 40 | 41 | 42 | 42 |
| 32 | 35 | 36 | 37 | 37 | 38 | 38 | 39 | 39 | 40 | 40 | 41 | 42 |
| 32.5 | 35 | 36 | 36 | 37 | 38 | 38 | 38 | 39 | 39 | 40 | 41 | 41 |
| 33 | 35 | 35 | 36 | 37 | 37 | 38 | 38 | 38 | 39 | 40 | 40 | 41 |
| 33.5 | 34 | 35 | 35 | 36 | 37 | 37 | 37 | 38 | 39 | 39 | 40 | 40 |
| 34 | 34 | 35 | 35 | 36 | 36 | 37 | 37 | 37 | 38 | 39 | 39 | 40 |
| 34.5 | 33 | 34 | 35 | 35 | 36 | 36 | 37 | 37 | 38 | 38 | 39 | 40 |
| 35 | 33 | 34 | 34 | 35 | 36 | 36 | 36 | 37 | 37 | 38 | 39 | 39 |
| 35.5 | 33 | 34 | 34 | 35 | 35 | 36 | 36 | 36 | 37 | 38 | 38 | 39 |
| 36 | 32 | 33 | 33 | 34 | 35 | 35 | 36 | 36 | 37 | 37 | 38 | 38 |
| 36.5 | 32 | 33 | 33 | 34 | 35 | 35 | 35 | 35 | 36 | 37 | 37 | 38 |
| 37 | 32 | 32 | 33 | 34 | 34 | 34 | 35 | 35 | 36 | 36 | 37 | 38 |
| 37.5 | 31 | 32 | 32 | 33 | 34 | 34 | 34 | 35 | 35 | 36 | 37 | 37 |
| 38 | 31 | 32 | 32 | 33 | 33 | 34 | 34 | 34 | 35 | 36 | 36 | 37 |
| 38.5 | 31 | 31 | 32 | 32 | 33 | 33 | 34 | 34 | 35 | 35 | 36 | 37 |
| 39 | 30 | 31 | 31 | 32 | 33 | 33 | 33 | 34 | 34 | 35 | 36 | 36 |
| 39.5 | 30 | 31 | 31 | 32 | 32 | 33 | 33 | 33 | 34 | 35 | 35 | 36 |
| 40 | 30 | 30 | 31 | 31 | 32 | 32 | 33 | 33 | 34 | 34 | 35 | 36 |
| 40.5 | 29 | 30 | 30 | 31 | 32 | 32 | 32 | 33 | 33 | 34 | 35 | 35 |
| 41 | 29 | 30 | 30 | 31 | 31 | 32 | 32 | 32 | 33 | 34 | 34 | 35 |
| 41.5 | 29 | 30 | 30 | 31 | 31 | 31 | 32 | 32 | 33 | 33 | 34 | 35 |
| 42 | 28 | 29 | 30 | 30 | 31 | 31 | 31 | 32 | 32 | 33 | 34 | 34 |
| 42.5 | 28 | 29 | 29 | 30 | 31 | 31 | 31 | 31 | 32 | 33 | 33 | 34 |
| 43 | 28 | 29 | 29 | 30 | 30 | 31 | 31 | 31 | 32 | 32 | 33 | 34 |
| 43.5 | 28 | 28 | 29 | 29 | 30 | 30 | 31 | 31 | 32 | 32 | 33 | 33 |
| 44 | 27 | 28 | 28 | 29 | 30 | 30 | 30 | 31 | 31 | 32 | 32 | 33 |
| 44.5 | 27 | 28 | 28 | 29 | 29 | 30 | 30 | 30 | 31 | 32 | 32 | 33 |
| 45 | 27 | 28 | 28 | 29 | 29 | 29 | 30 | 30 | 31 | 31 | 32 | 32 |
| 45.5 | 27 | 27 | 28 | 28 | 29 | 29 | 29 | 30 | 30 | 31 | 32 | 32 |
| 46 | 26 | 27 | 27 | 28 | 29 | 29 | 29 | 29 | 30 | 31 | 31 | 32 |
| 46.5 | 26 | 27 | 27 | 28 | 28 | 29 | 29 | 29 | 30 | 30 | 31 | 32 |
| 47 | 26 | 27 | 27 | 28 | 28 | 28 | 29 | 29 | 30 | 30 | 31 | 31 |
| 47.5 | 26 | 26 | 27 | 27 | 28 | 28 | 28 | 29 | 29 | 30 | 30 | 31 |
| 48 | 25 | 26 | 26 | 27 | 28 | 28 | 28 | 28 | 29 | 30 | 30 | 31 |
| 48.5 | 25 | 26 | 26 | 27 | 27 | 28 | 28 | 28 | 29 | 29 | 30 | 31 |
| 49 | 25 | 26 | 26 | 27 | 27 | 27 | 28 | 28 | 29 | 29 | 30 | 30 |
| 49.5 | 25 | 25 | 26 | 26 | 27 | 27 | 27 | 28 | 28 | 29 | 29 | 30 |
| 50 | 25 | 25 | 25 | 26 | 27 | 27 | 27 | 27 | 28 | 29 | 29 | 30 |

*Appendix - 4: Chart for calculating the inclination angle*

| UK FOOT SIZE | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MALE | | 3 | 4 | 4.5 | 5.5 | 6.5 | 7 | 7.5 | 8 | 8.5 | 10 | 11 | 12 |
| FEMALE | | 2.5 | 3.5 | 4 | 5 | 6 | 6.5 | 7 | 7.5 | 8 | 9.5 | 11 | 12 |
| cm | | 22.8 | 23.5 | 23.8 | 24.5 | 25.1 | 25.4 | 25.7 | 26 | 26.7 | 27.3 | 27.9 | 28.6 |
| Tibia Size in cm | 25 | 35 | 36 | 37 | 37 | 38 | 38 | 39 | 39 | 40 | 41 | 41 | 42 |
| | 26 | 34 | 35 | 35 | 36 | 37 | 37 | 38 | 38 | 39 | 39 | 40 | 41 |
| | 27 | 33 | 34 | 34 | 35 | 36 | 36 | 37 | 37 | 38 | 38 | 39 | 40 |
| | 28 | 32 | 33 | 33 | 34 | 35 | 35 | 36 | 36 | 37 | 37 | 38 | 39 |
| | 29 | 31 | 32 | 32 | 33 | 34 | 34 | 35 | 35 | 36 | 36 | 37 | 38 |
| | 30 | 30 | 31 | 31 | 32 | 33 | 33 | 34 | 34 | 35 | 35 | 36 | 37 |
| | 31 | 29 | 30 | 31 | 31 | 32 | 32 | 33 | 33 | 34 | 34 | 35 | 36 |
| | 32 | 28 | 29 | 30 | 30 | 31 | 31 | 32 | 32 | 33 | 33 | 34 | 35 |
| | 33 | 28 | 28 | 29 | 30 | 30 | 31 | 31 | 31 | 32 | 33 | 33 | 34 |
| | 34 | 27 | 28 | 28 | 29 | 29 | 30 | 30 | 30 | 31 | 32 | 32 | 33 |
| | 35 | 26 | 27 | 27 | 28 | 29 | 29 | 29 | 30 | 30 | 31 | 32 | 32 |
| | 36 | 25 | 26 | 26 | 27 | 28 | 28 | 29 | 29 | 30 | 30 | 31 | 31 |
| | 37 | 25 | 25 | 26 | 27 | 27 | 27 | 28 | 28 | 29 | 29 | 30 | 31 |
| | 38 | 24 | 25 | 25 | 26 | 26 | 27 | 27 | 27 | 28 | 29 | 29 | 30 |
| | 39 | 23 | 24 | 24 | 25 | 26 | 26 | 26 | 27 | 27 | 28 | 29 | 29 |
| | 40 | 23 | 23 | 24 | 24 | 25 | 25 | 26 | 26 | 27 | 27 | 28 | 29 |
| | 41 | 22 | 23 | 23 | 24 | 24 | 25 | 25 | 25 | 26 | 27 | 27 | 28 |
| | 42 | 21 | 22 | 23 | 23 | 24 | 24 | 24 | 25 | 25 | 26 | 27 | 27 |
| | 43 | 21 | 22 | 22 | 23 | 23 | 24 | 24 | 24 | 25 | 25 | 26 | 27 |
| | 44 | 20 | 21 | 21 | 22 | 23 | 23 | 23 | 24 | 24 | 25 | 25 | 26 |
| | 45 | 20 | 21 | 21 | 22 | 22 | 22 | 23 | 23 | 24 | 24 | 25 | 25 |
| | 46 | 19 | 20 | 20 | 21 | 22 | 22 | 22 | 22 | 23 | 24 | 24 | 25 |
| | 47 | 19 | 20 | 20 | 21 | 21 | 21 | 22 | 22 | 23 | 23 | 24 | 24 |
| | 48 | 18 | 19 | 19 | 20 | 21 | 21 | 21 | 21 | 22 | 23 | 23 | 24 |
| | 49 | 18 | 19 | 19 | 20 | 20 | 20 | 21 | 21 | 22 | 22 | 23 | 23 |
| | 50 | 18 | 18 | 18 | 19 | 20 | 20 | 20 | 20 | 21 | 22 | 22 | 23 |
| | 51 | 17 | 18 | 18 | 19 | 19 | 19 | 20 | 20 | 21 | 21 | 22 | 22 |
| | 52 | 17 | 17 | 18 | 18 | 19 | 19 | 19 | 20 | 20 | 21 | 21 | 22 |
| | 53 | 16 | 17 | 17 | 18 | 18 | 19 | 19 | 19 | 20 | 20 | 21 | 21 |
| | 54 | 16 | 17 | 17 | 17 | 18 | 18 | 18 | 19 | 19 | 20 | 20 | 21 |
| | 55 | 16 | 16 | 16 | 17 | 18 | 18 | 18 | 18 | 19 | 19 | 20 | 20 |
| | 56 | 15 | 16 | 16 | 17 | 17 | 17 | 18 | 18 | 18 | 19 | 19 | 20 |

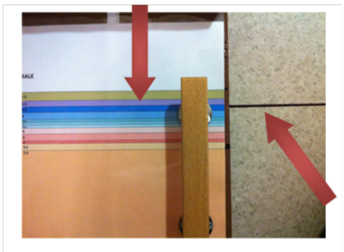
*Appendix - 5: Schuss Views X-rays SOP.*

# User Guidelines for the S3 Project Schuss View X-rays



1. **Check for the request form for the following details:**
    a. "Trial study Schuss views"
    b. Foot size
    c. X-ray tube inclination angle.

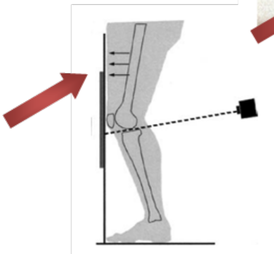
2. **Position the Foot jig in the correct position:**
    a. Align the black line on the jig corresponding to the foot size and gender with the horizontal black line on the floor.



    b. Align the top and bottom marks on the jig with correct side oblique line on the floor. (For example: During a right knee x-ray, align the right sided top and bottom marks on the jig with the right sided oblique line on the floor).

3. **Position the Tube angle:**
    a. Using the provided Angle on the form.

4. **Position the patient:**
    a. Ask patients to remove shoes and any clothes items that may cover the knees.
    b. Ask the patient to stand on the jig with both heels flush against the rear piece.
    c. Ask the patients to flex both knees
    d. Ask patients lean both thighs flush against the detector.



5. **Position the Detector:**
    a. Raise or lower the detector to centre through the crease of the knee.
    b. Increase the widow size to x-ray distal 1/3 of femur and 1/3 of the proximal tibia.

6. **Label x-ray as "S3 view**

*Appendix - 6: MEDLINE search strategy*

1 exp Knee Prosthesis/ or exp Arthroplasty, Replacement, Knee/ or total knee arthroplasty.mp.

2 exp Arthroplasty, Replacement, Knee/ or exp Knee Prosthesis/ or knee replacement.mp.

3 1 or 2

4 Alignment.mp.

5 exp Bone Malalignment/ or malalignment.mp.

6 misalignment.mp.

7 4 or 5 or 6

8 outcome measures.mp. or exp "Outcome Assessment (Health Care)"/

9 patient satisfaction.mp. or exp Patient Satisfaction/

10 exp "Quality of Life"/ or exp Treatment Outcome/ or exp "Outcome Assessment (Health care)"/ or exp Patient Satisfaction/ or patient reported outcomes.mp. or exp Questionnaires/

11 self report.mp. or exp Self Report/

12 patient participation.mp. or exp Patient Participation/

13 oxford knee score.mp.

14 exp "Severity of Illness Index"/ or WOMAC.mp.

15 exp "Range of Motion, Articular"/ or knee function.mp.

16 exp Intraoperative Complications/ or exp Postoperative Complications/ or complications.mp.

17 knee society score.mp.

18 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17

19 3 and 7 and 18

*Appendix - 7: EMBASE search strategy*

**1 knee replacement.mp. or exp knee arthroplasty/**

**2 knee arthroplasty.mp. or exp knee arthroplasty/**

**3 1 or 2**

**4 alignment.mp.**

**5 misalignment.mp.**

**6 malalignment.mp.**

**7 4 or 5 or 6**

**8 exp "quality of life"/ or exp outcome assessment/ or outcome measures.mp. or exp treatment outcome/ or exp outcomes research/**

**9 patient satisfaction.mp. or exp patient satisfaction/**

**10 quality of life.mp. or exp "quality of life"/**

**11 self report.mp. or exp self report/**

**12 exp patient participation/ or patient participation.mp.**

**13 exp rating scale/ or oxford knee score.mp. or exp scoring system/**

**14 exp functional assessment/ or exp questionnaire/ or exp pain assessment/ or WOMAC.mp.**

**15 exp follow up/ or knee function.mp. or exp health status/ or exp knee function/**

**16 range of motion.mp. or exp joint mobility/ or exp "range of motion"/**

**17 exp peroperative complication/ or exp perioperative complication/ or exp postoperative complication/ or complications.mp. or exp complication/**

**18 knee society score.mp.**

**19 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18**

**20 3 and 7 and 19**

**S4 S1 and S2 and S3**

**S3 (MH "Outcome Assessment") OR (MH "Outcomes (Health Care)+") OR (MH "Treatment Outcomes+") OR "outcome measures" OR (MH "Arthritis Impact Measurement Scales") OR "outcome assesment" OR (MH "Patient Satisfaction") OR "patient satisfaction" OR (MH "Personal Satisfaction+") OR (MH "Quality of Life+") OR "quality of life" OR (MH "Quality Assessment+") OR "treatment outcome" OR "patient reported outcomes" OR (MH "Self Report") OR "self report" OR (MH "Self Assessment") OR "oxford knee score" OR "WOMAC**

**S2 “alignment" OR "malalignment" OR "misalignment"**

**S1 (MH "Arthroplasty, Replacement, Knee+") OR "total knee replacement" OR "total knee arthroplasty"**

*Appendix - 9: Systematic review data collection form*

| Author | Year of Publication | Journal | Design | Length of Follow up Mean/(Range) | Sample size knee (patients) | lost to follow-up knee (patients) | final study sample size knee (patients) | Operative Method | Implant Details | Imaging Method | Time of imaging |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | |

| Clinical outcome(s) | | | Results | Implant alignment Data | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Tibia | | femur | | | | Axial | | |
| PROM | other | Revision | | PA/ Coronal (beta) | Lat/ Sagittal | PA/ Coronal (alpha) | Lat/ Sagittal | Anatomical Tibofemoral angle | Mechanical Tibiofemoral angle | Femoral component Rotation | Tibial Component Rotation | Combined |
| | | | | | | | | | | | | |

| Assessment of Studies quality | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Statistical Analysis | Level of evidence (Oxford) | Case Series | | | | | Case control & Cohort studies | RCT | | | | | | | | |
| | | Consecutive selection of patients? | Were outcomes measured in an objective way? | Were known confounders identified and appropriately controlled for? | Was follow-up of patients sufficiently long and complete? | Assessment total | Newcastle Ottawa Scale | Was assignment of treatment described as random? | Was method of randomisation well described & appropriate? | Was the method really random? | Was allocation concealed & concealment method described? | Was study described as double blind? | Who was blinded? | Was method of blinding adequately described? | Were withdrawals stated? | SCORE on Jadad sale |
| | | | | | | | | | | | | | | | | |

| Notes |
|---|
| |

*Appendix - 10: AHRQ quality assessment scale for RCTs*

| **Quality assessment for RCTs** | Judgment on risk of bias (Y/N) |
|---|---|
| Was the allocation sequence generated adequately? | |
| Was the allocation of treatment adequately concealed? | |
| Did researchers rule out any unintended exposure that might bias results? | |
| Were participants analysed within the groups they were originally assigned to? | |
| Was the length of follow-up different between the groups? | |
| Were the outcome assessors blinded to the intervention or exposure status of participants? | |
| Were the potential outcomes pre-specified by the researchers? | |
| Are all pre-specified outcomes reported? | |
| If attrition was a concern were missing data handled appropriately? | |
| Were outcomes assessed using valid and reliable measures across all study participants? | |
| Good studies = have most/all of the relevant quality items, Fair studies = have some of the relevant quality items, Poor studies = have few of the relevant quality items (but sufficient value to include for further review). | |

**NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE**
**CASE CONTROL STUDIES**

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Exposure categories. A maximum of two stars can be given for Comparability.

## Selection

1) Is the case definition adequate?
   a) yes, with independent validation ✸
   b) yes, eg record linkage or based on self reports
   c) no description

2) Representativeness of the cases
   a) consecutive or obviously representative series of cases ✸
   b) potential for selection biases or not stated

3) Selection of Controls
   a) community controls ✸
   b) hospital controls
   c) no description

4) Definition of Controls
   a) no history of disease (endpoint) ✸
   b) no description of source

## Comparability

1) Comparability of cases and controls on the basis of the design or analysis
   a) study controls for _______________ (Select the most important factor.) ✸
   b) study controls for any additional factor ✸ (This criteria could be modified to indicate specific control for a second important factor.)

## Exposure

1) Ascertainment of exposure
   a) secure record (eg surgical records) ✸
   b) structured interview where blind to case/control status ✸
   c) interview not blinded to case/control status
   d) written self report or medical record only
   e) no description

2) Same method of ascertainment for cases and controls
   a) yes ✸
   b) no

3) Non-Response rate
   a) same rate for both groups ✸
   b) non respondents described
   c) rate different and no designation

**NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE**
**COHORT STUDIES**

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

## Selection

1) Representativeness of the exposed cohort
   a) truly representative of the average _______________ (describe) in the community ✸
   b) somewhat representative of the average ______________ in the community ✸
   c) selected group of users eg nurses, volunteers
   d) no description of the derivation of the cohort

2) Selection of the non exposed cohort
   a) drawn from the same community as the exposed cohort ✸
   b) drawn from a different source
   c) no description of the derivation of the non exposed cohort

3) Ascertainment of exposure
   a) secure record (eg surgical records) ✸
   b) structured interview ✸
   c) written self report
   d) no description

4) Demonstration that outcome of interest was not present at start of study
   a) yes ✸
   b) no

## Comparability

1) Comparability of cohorts on the basis of the design or analysis
   a) study controls for _____________ (select the most important factor) ✸
   b) study controls for any additional factor ✸ (This criteria could be modified to indicate specific control for a second important factor.)

## Outcome

1) Assessment of outcome
   a) independent blind assessment ✸
   b) record linkage ✸
   c) self report
   d) no description

2) Was follow-up long enough for outcomes to occur
   a) yes (select an adequate follow up period for outcome of interest) ✸
   b) no

3) Adequacy of follow up of cohorts
   a) complete follow up - all subjects accounted for ✸
   b) subjects lost to follow up unlikely to introduce bias - small number lost - > ____ % (select an adequate %) follow up, or description provided of those lost) ✸
   c) follow up rate < ____% (select an adequate %) and no description of those lost
   d) no statement

*Appendix - 13: AHRQ quality assessment scale for case series*

| Quality assessment for case series | Judgment on risk of bias (Y/N) |
|---|---|
| Consecutive selection of patients? | |
| Were outcomes measured in an objective way? | |
| Were known confounders identified and appropriately controlled for? | |
| Was follow-up of patients sufficiently long and complete? | |
| For these studies it would be reasonable to consider the presence of all or 3 factors = Good (low risk), only 2 factors = Fair, and only 1 factor = either Poor (high risk) or of insufficient quality (unclear risk). | |

## *Appendix 14: Example of theatre Data collection pack* [272]

**V4** 20/10/10

**SAFER SURGICAL SERVICES**
**TOTAL KNEE REPLACEMENT CASE SUMMARY SHEET**

**PRIVATE & CONFIDENTIAL**

If found, please return to:

E.Robertson or L. Morgan
Nuffield Department of Surgical Sciences
Level 6
John Radcliffe Hospital
Oxford
OX3 9DU

**V4** 20/10/10

**Pre-operative questions to the Operating Surgeon**

1. On a scale of 0 – 100, how confident are you that this patient will have a satisfactory long-term result?
   a. Pre-operative: ________________
2. On a scale of 0 – 100, how confident are you that this patient will have an uncomplicated post operative course?
   a. Pre-operative:________________
3. How would you rate the difficulty of this operation? Average Above Average Difficult
4. Any other relevant information?

**V4** 20/10/10

Date: ____/____/____ Theatre number ________

Site: NOC UHCW KGH RUGBY

Observer: ER LM MH SP KC Second Observer: ER LM MH SP KC N/A

Operation listed: LEFT RIGHT ________________ Operation performed: LEFT RIGHT________________

Order on list: ___/___ Order performed: ___/___ Reason for change: ____________

**Database Code**: ____________________ MALE FEMALE

1st surgeon ________________ Anaesthetist ________________ Scrub nurse ________________

2nd surgeon ________________ ODA/P ________________ Circ. Nurse ________________

Sales rep ________________ Others ________________________________________

Staff training during case: Y / N

Surgeons Anaesthetists ODA Scrub Nurse Circulating Nurse

**V4** 20/10/10

**PRE AND POST LIST BRIEFING**

Pre-list briefing: Y / N Lead by: Anaesthetist Circulating Nurse Scrub Nurse Surgeon

Debriefing: Y / N Lead by: Anaesthetist Circulating Nurse Scrub Nurse Surgeon

**In Theatre**

**Anaesthetic Administered**

GA Epidural Spinal Regional Anaesthesia ( Femoral or Sciatic ) Local Anaesthetic

TEDS on: Y / N ASA: 1 2 3 4 Antibiotics given: Y / N

**V4** 20/10/10

1. **Preoperative Preparation (In Anaesthetic room)**
   a. Leg shaved
   b. Velband wrapped around tourniquet site
   c. Tourniquet put on
   d. Crepe over tourniquet
   e. Operating table side supports configured
   f. Gamgee placed between brace and skin
   g. Sandbag placed at foot to keep at 90°
   h. Patient prepared for tx to theatre

**V4** 20/10/10

2. **Pre-Op Preparation (In Theatre)**
   a. **PATIENT IN TO THEATRE** [ : ]
   b. Vetilation configured
   c. Monitoring configured
   d. Skin prepped
   e. Someone at end of bed holds foot off the table
   f. Prep of knee up to tourniquet
   g. Paper sheet placed on bed
   h. 'U' drape with sticky stuck to skin blocking off tourniquet from rest of leg
   i. Foot placed in to next drape which is wrapped round foot
   j. Stocking style drape pulled over the foot up to the knee
   k. Hole cut in stocking drape
   l. Skin adhesive drape attached over knee
   m. Second 'u' drape
   n. Last drape layer placed - leg put through hole in drape
   o. *Change of gloves*

**V4** 20/10/10

3. **Scrub Team Preparation**
   a. Skin Instruments set up
   b. Monopolar plugged in
   c. Suction connected
   d. Light handles on
   e. **WHO CHECKLIST (GO TO PAGE 8)**

4. **Tourniquet**
   a. Leg elevated, tourniquet inflated
   b. **TIME** [ : ] and pressure noted on preparation board

**TIME OUT** (To be read out loud)

**Before start of surgical intervention**
**for example, skin incision**

**Have all team members introduced themselves by name and role?**
☐ Yes

**Surgeon, Anaesthetist and Registered Practitioner verbally confirm:**
☐ What is the patient's name?
☐ What procedure, site and position are planned?

**Anticipated critical events**
**Surgeon:**
☐ How much blood loss is anticipated?
☐ Are there any specific equipment requirements or special investigations?
☐ Are there any critical or unexpected steps you want the team to know about?
**Anaesthetist:**
☐ Are there any patient specific concerns?
☐ What is the patient's ASA grade?
☐ What monitoring equipment and other specific levels of support are required, for example blood?
**Nurse/ODP:**
☐ Has the sterility of the instrumentation been confirmed (including indicator results)?
☐ Are there any equipment issues or concerns?

**Has the surgical site infection (SSI) bundle been undertaken?**
☐ Yes/not applicable
- Antibiotic prophylaxis within the last 60 minutes
- Patient warming
- Hair removal
- Glycaemic control

**Has VTE prophylaxis been undertaken?**
☐ Yes/not applicable

**Is essential imaging displayed?**
☐ Yes/not applicable

**V4** 20/10/10

3.e.1. Content (information communicated?) Y / N
3.e.2. Audience (all team present?) Y / N
3.e.3. Participation (active?) Y / N
*3.e.4. Completion (all 3 sections completed?) Y / N*
3.e.5. Lead by: Anaesthetist Circulating Nurse Scrub Nurse Surgeon
3.e.6. TEDS on: Y / N
3.e.7. ASA: 1 2 3 4
3.e.8 Antibiotics given: Y / N

8

**V4** 20/10/10

**SOFT TISSUE PREPARATION**

5. **Incision & Access**
   a. **Surgeon confirms OK to start**
   b. **FIRST INCISION** [ : ]
   c. Through subcutaneous fat **(DO OXFORD NOTECHS NOW (pg10))**
   d. Control of bleeding, possibly with electrocautery
   e. Through patellofemoral ligament
   f. Suction (joint fluid)
   g. Straighten the knee, hold the patella and reflect it laterally, then knee back to 90°
   h. Dissect any loose tissue (meniscous/ACL/fat behind patellofemoral ligament)

**V4** 20/10/10

**Oxford NOTECHS**

| | | Surgical Team | Anaesthetic Team | Nursing Team |
|---|---|---|---|---|
| Leadership & management | Leadership<br>Maintenance of standards<br>Planning and preparation<br>Workload management<br>Authority & Assertiveness | | | |
| Teamwork & cooperation | Team building/maintaining<br>Support of others<br>Understanding team needs<br>Conflict solving | | | |
| Problem solving & decision making | Definition & diagnosis<br>Option generation<br>Risk assessment<br>Outcome review | | | |
| Situation awareness | Notice<br>Understand<br>Think ahead | | | |

| 1 consistent | 2 inconsistent | 3 consistent | 4 inconsistent | 5 inconsistent | 6 consistent | 7 inconsistent | 8 consistent |
|---|---|---|---|---|---|---|---|
| Behaviour compromises patient safety and effective teamwork | | Behaviour in other conditions could directly compromise patient safety and effective teamwork | | Behaviour maintains an effective level of patient safety and teamwork | | Behaviour enhances patient safety and teamwork, a model for all other teams | |

# *Appendix 24: Example of theatre Data collection pack* [272] Continued

V4 20/10/10

**Bony Preparation**

**6. Femoral** (Femoral **FIRST** ▯ Tibial **FIRST** ▯)

a. Find the intercondylar midpoint
b. Drill up the femur
c. Insert intramedullary guide rod up the femur
d. Place the cutting guide on rod
e. Pin cutting block in place
f. Use 'angel wing' to check depth of cut
g. Remove intramedullary rod
h. **DISTAL FEMORAL CUT: TIME WHEN SAWING STARTS** [ : ]
i. Femoral cutting guide removed
j. Femur lifted away from tibia to remove excess tissue
k. Treatment area tidied with nibblers
l. Femoral sizing guide centred on prepared surface
m. Stylus used to check and fix position
n. Rotational alignment determined & femoral sizing noted
o. Holes drilled through block to permit secure attachment of cutting block then femoral sizing guide removed
p. 2nd cutting block selected (based on femoral size)
q. 2nd chamfer cutting block secured with pins
r. Assistant surgeon holds cutting block firmly and protects soft tissues with 'legs'
s. **SECOND FEMORAL CUT: TIME WHEN SAWING STARTS** [ : ]
t. Treatment area tidied with 'nibblers'

V4 20/10/10

**7. Tibial Preparation**

a. 'Fag' instrument used to pull the tibia anterior to the femur
b. 2 'legs' Used to protect the medial and lateral collateral ligaments
c. *Intramedullary* guidance (drill down tibia, intramedullary rod inserted)
d. *Extramedullary* guidance (grip placed round the ankle to secure the measurement, surgeon checks rod is 2 finger breadths from shin)
e. Jig placed on anterior cortex of tibia
f. Angel wing check of level of cut
g. Nail or screw in place
h. Intra/extramedullary guides removed
i. 'fag' and 'legs' kept in place to protect the ligaments
j. **TIBIAL CUT** [ : ]
k. Cutting block removed
l. Cut tidied with nibblers
m. Scrub nurse sizes the tibia depending upon the cut wafer
n. Keel punch tibial trial inserted
o. Correct orientation is ensured with guidance rod (from tibial trail to ankle joint)
p. Pinned in place
q. Keel punch performed

V4 20/10/10

**8. Trial of Prosthesis**

a. Insert the femoral and tibial trial prostheses and impact
b. Insertion of trial spacer
c. Checks no hyper extension of knee (straighten the knee)
d. Check balance medially/laterally (bent knee does not open up when stressed medially or laterally)
e. **Once everyone happy, sizes confirmed and requested from the store**

**9. Preparing the prosthetics**

a. Wash the knee with saline and dry with swabs
b. **Circulating nurse checks size of both prostheses with Scrub Nurse and Surgeon**
c. **Team changes gloves**
*d. The surgeon may drill small holes in the tibia or femur (sclerotic bone)*
e. Dry cement ingredient added to mixing bowl

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**10. Cementing Process**

a. **WET PART ADDED** [ : ]
b. Circulating Nurse starts wall clock, Scrub nurse mixes cement
c. Once mixed, scrub nurse hands surgeon cement
d. **"CEMENTING NOW" Y/N**
e. Surgeon places layer of cement on tibial plateau
f. Prosthesis is inserted, impacted and excess is cleared
g. Scrub nurse or Surgeon place cement on femoral prosthesis
h. Surgeon puts cement on the femur then lines up the prosthesis, impacts and excess cleared
i. Surgeon inserts trial spacer and puts leg out to length to pressurise the cement until it is set
j. Spacer removed once cement set
k. **Spacer size confirmed by surgeon**
l. Obtained by circulating nurse and checked by scrub nurse and surgeon
m. Opened & placed on tibial component & possibly pinned

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**11. Final Check & wound closure**

a. Final check that the knee is balanced (hyperextended/straight/lateral/medial movement)
*b.* ***TOURNIQUET MAY BE LET DOWN*** [ : ]
c. Tissues are cleaned with sterile saline solution
d. **2 members conduct the counts aloud, and in unison**
e. Verbal confirmation of the success of the count
*f. Drain inserted and connected to vacuum container*

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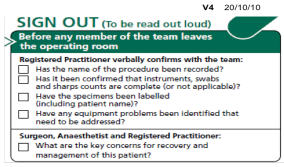
**12. Closure**

a. Closure of the patellofemoral ligament with thick vicryl
b. Closure of Subcuticular layer and skin
c. **DO OXFORD NOTECHS NOW (pg 16)**
d. Skin is closed
e. Opsite to wound and dressing to drain site
f. Velband, crepe and tape around knee
g. **TOURNIQUET MAY BE LET DOWN** [ : ]
h. **TRANSFER OUT OF THEATRE** [ : ]
i. "Monopolar site intact"
j. **WHO CHECKOUT**


SIGN OUT (To be read out loud)
Before any member of the team leaves the operating room
Registered Practitioner verbally confirms with the team:
☐ Has the name of the procedure been recorded?
☐ Has it been confirmed that instruments, swabs and sharps counts are complete (or not applicable)?
☐ Have the specimens been labelled (including patient name)?
☐ Have any equipment problems been identified that need to be addressed?
Surgeon, Anaesthetist and Registered Practitioner:
☐ What are the key concerns for recovery and management of this patient?

| | | |
|---|---|---|
| 12.j.1 | Content (information communicated?) | Y / N |
| 12.j.2. | Audience (all team present?) | Y / N |
| 12.j.3. | Participation (active?) | Y / N |
| *12.j.4.* | *Completion (all 3 sections completed?)* | *Y / N* |
| 12.j.5. | Lead by: Anaesthetist, Circulating Nurse, Scrub Nurse, Surgeon | |

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**Oxford NOTECHS**

| | | Surgical Team | Anaesthetic Team | Nursing Team |
|---|---|---|---|---|
| Leadership & management | Leadership<br>Maintenance of standards<br>Planning and preparation<br>Workload management<br>Authority & Assertiveness | | | |
| Teamwork & cooperation | Team building/maintaining<br>Support of others<br>Understanding team needs<br>Conflict solving | | | |
| Problem solving & decision making | Definition & diagnosis<br>Option generation<br>Risk assessment<br>Outcome review | | | |
| Situation awareness | Notice<br>Understand<br>Think ahead | | | |

| 1 consistent | 2 inconsistent | 3 consistent | 4 inconsistent | 5 inconsistent | 6 consistent | 7 inconsistent | 8 consistent |
|---|---|---|---|---|---|---|---|
| Behaviour compromises patient safety and effective teamwork | | Behaviour in other conditions could directly compromise patient safety and effective teamwork | | Behaviour maintains an effective level of patient safety and teamwork | | Behaviour enhances patient safety and teamwork, a model for all other teams | |

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**13. Handover to Recovery**

a. Anaesthetist delivers patient to bed space
b. Recovery nurse ready & available for receipt of patient
c. **SET UP OF MONIOTORING** [ : ]
d. Handover of information
  i. Patient details
  ii. Allergies
  iii. Operation details
  iv. Anaesthetic details
  v. Analgesia plan
  vi. Post operative plan
  vii. Infusion pumps are checked for correct functioning
  viii. Opportunity for questions
e. Drains are located safely & on suction
f. **HANDOVER FINISHED** [ : ]

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**14. Post-Operative questions to the Operating Surgeon**

a. On a scale of 0 – 100, how confident are you that this patient will have a satisfactory long-term result?
  i. Post operative (within one hour of finishing): ________________

b. On a scale of 0 – 100, how confident are you that this patient will have an uncomplicated post operative course?
  i. Post operative (within one hour of finishing):________________

c. Were you aware of any technical problems with this operation?

d. Do you feel that there were any slips, errors or mistakes in the procedure?

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26 April 2011

Mr Peter McCulloch
Reader in Surgery
University of Oxford
Nuffield Department of Surgery
6th Floor, John Radcliffe Hospital
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OX3 9DU

Dear Mr McCulloch

| | |
|---|---|
| **Study title:** | **An industrial quality improvement approach to patient safety in surgery** |
| **REC reference:** | **09/H0604/39** |
| **Amendment number:** | **Modified Substantial amendment 5- 20.4.11** |
| **Amendment date:** | **20 April 2011** |

Thank you for submitting the above amendment, which was received on 20 April 2011. It is noted that this is a modification of an amendment previously rejected by the Committee (our letter of 20 April 2011 refers).

The modified amendment has been considered on behalf of the Committee by the Chair.

**Ethical opinion**

The Chair was content that the requested change (addition of a sentence in the PIS to state "an additional x-ray of the same knee on the same day" will take place, was added).

I am pleased to confirm that the Committee has given a favourable ethical opinion of the modified amendment on the basis described in the notice of amendment form and supporting documentation.

**Approved documents**

The documents reviewed and approved are:

| Document | Version | Date |
|---|---|---|
| Substantial Amendment letter Dr Sarah Wayte 25/03/2011 | | 25 March 2011 |
| Participant Consent Form: Participant Consent Form - CT Scan | 1.1 | 20 April 2011 |
| Participant Information Sheet: Participant Information Sheet - CT Scan | 1.1 | 20 April 2011 |
| Modified Amendment | Modified Substantial | 20 April 2011 |

| | | |
|---|---|---|
| | amendment 5- 20.4.11 | |
| Covering Letter | | 20 April 2011 |

**R&D approval**

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

**Statement of compliance**

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

| **09/H0604/39:** | **Please quote this number on all correspondence** |
|---|---|

Yours sincerely

Smacpherson.

pp **Dr Karen Melham**
**Chair**

E-mail: scsha.oxfordreca@nhs.net
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