OUTCOME AFTER MEDIAL UNICOMPARTMENTAL KNEE REPLACEMENT



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ABSTRACT

Outcome after medial unicompartmental knee replacement

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St Cross College — **Trinity term 2013**

Medial Oxford unicompartmental knee replacement (UKR) is an established and successful treatment for patients with antero-medial knee osteoarthritis. However, following the operation some patients have pain which compromises their functional outcome. The aims of this thesis were to determine the incidence of pain, to identify the patient, disease and surgical risk factors associated with this pain and to try and understand why it occurs. The clinical studies were performed using patients operated on by experienced surgeons.

The incidence of post-operative severe pain was 3% at six weeks and 2% at one year and the incidence remained unchanged at subsequent follow ups. The overall incidence of pain has reduced over the years. In patients who had UKR between 1998 and 2001, the incidence of severe pain was 5%; this reduced to 2.3% for the period between 2008 and 2011. As the indications have not changed, the improvement is probably due to modifications in the surgical technique and due to improvements in instrumentation. Patients with severe pain at the final follow up had a worse neuropathic pain score, and the patients with possible pre-operative neuropathic pain achieved significantly worse outcome.

To explore the effect of disease severity on outcome, matched cohorts of patients with partial thickness cartilage loss (PTCL), bone-on-bone and bone loss were compared. All those with bone-on-bone and bone loss did well, whereas 20% of those with PTCL did not benefit from the surgery; 7% had severe pain and 17% had pain related complications.

Although component and leg alignment, and component overhang have a profound effect on the outcome of total knee replacement (TKR), their effect on the outcome of the Oxford UKR are not known. It was found that malalignment in the coronal or sagittal planes of the femoral component within ±10° and of the tibial component within ±5° did not compromise the outcome. Leg alignment was not related to outcome even though 18% were in 5° varus and 8% were in 10° varus. In contrast, tibial component overhang ≥3 mm compromised the outcome and 21% of these patients continue to suffer from pain.

The presence of radiolucent lines (RLL) following a joint replacement is usually deemed to be indicative, or predictive, of loosening. 63% of Oxford UKRs were found to have RLL under the tibial component. No correlation was found between RLL and outcome, particularly pain.

It has been suggested that post-operative pain, which is commonly antero-medial over the proximal tibia, may be related to bone overload. This was explored using the finite element (FE) analysis. Following implantation of the Oxford UKR, the strains in the antero-medial region doubled. Various implantation, loading and alignment variables were studied and the findings correlated with the clinical studies, suggesting that high strain is an important cause of pain. With time, the bone will remodel, so the strains will decrease but individual differences in the remodeling threshold may explain resolution of symptoms in some, but not in all, patients.

In conclusion, this work has shown that following the Oxford UKR, pain is a rare but important complication. The chance of pain can be decreased by operating only on patients with bone-on-bone arthritis and taking care with the surgical technique. Bone overload is likely to be an important cause of pain, and further modification to the implant or technique, such as achieving fixation of the tibial component vertical wall to bone, may further decrease the incidence of pain.

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ABBREVIATIONS

ACL	Anterior cruciate ligament
AKSS	American Knee Society Score
AKSS-F	Functional AKSS
AKSS-O	Objective AKSS
ANOVA	One-way analyses of variance
AP	Antero-posterior
ASIS	Anterior Superior Iliac Spine
AVN	Avascular necrosis
BE	Bone exposed
BL	Bone loss
BMI	Body mass index
CT	Computer Tomography
dof	Degrees of freedom
DXA	Dual-energy X-ray absorptiometry
FE	Finite element
FS	Function score
FTA	Femoro-tibial angle
FTCL	Full thickness cartilage loss
HKA	Hip-knee-ankle
HTO	High tibial osteotomy
ICC	Intraclass correlation coefficient
ICOAP	Intermittent and Constant Osteoarthritis Pain
ICOAP-C	Intermittent and Constant Osteoarthritis Pain-Constant
ICOAP-I	Intermittent and Constant Osteoarthritis Pain-Intermittent
IT	Ilio-tibial band
JSN	Joint space narrowing
Lat	Lateral
LCL	Lateral collateral ligament
MCL	Medial collateral ligament
MRI	Magnetic resonance imaging
NJR	National Joint Register
OA	Osteoarthritis
OKS	Oxford Knee Score
PCL	Posterior cruciate ligament
PET	Positron Emission Tomography
PROMs	Patient reported outcome measures
PS	Pain score
PTCL	Partial thickness cartilage loss
RLL	Radiolucent lines
ROM	Range of motion
RSA	Radiostereometric analysis
SED	Strain energy density
SONK	Spontaneous osteonecrosis of the knee
SRM	Standardised response mean
TKR	Total knee replacement
UKR	Unicompartmental knee replacement
VMS	von Mises strains
3D	Three dimensional

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1. INTRODUCTION

1.1 Relevant knee anatomy

The knee is the largest synovial joint of the human body, comprising three functional components: patello-femoral, medial tibio-femoral and lateral tibio-femoral joints. The manner in which the proximal tibia and distal femur articulate with each other not only allow hinge movement (flexion/extension), but also permit rotation[1]. Various factors contribute to knee joint stability which include the shape of the articulating bones and the static and dynamic restraint provided by the ligaments and muscles crossing it[2]. In addition, there is a thick fibrous capsule encasing the whole of the joint.

The bony structures of the proximal tibia, distal femur and patella are quite unique. The medial femoral condyle, being larger, extends distally on antero-posterior (AP) radiographs. The lateral femoral condyle, easily identified by a groove for the popliteus tendon on lateral (Lat) radiographs[3], is much smaller in all dimensions. The medial tibial plateau is oval and concave while the lateral tibial plateau is circular and convex[2]. As a result of the smaller size of the lateral compartment in both AP and proximo-distal planes, the medial femoral condyle rotates on the tibia and also translates to some extent in the AP plane during the range of motion (ROM)[1]. Conversely, the lateral femoral condyle translates freely in the AP plane with very little rotation permitted around a transverse axis[4]. The patello-femoral joint contributes to the knee stability primarily due to its role in the extensor mechanism [2].

The medial and lateral menisci, enhance the conformity of the tibio-femoral joints and assist in rotation of the knee[1]. They also help in load transmission[5-7]. Both menisci move posteriorly as the knee flexes but the medial meniscus moves less (approximately 5.1 mm) than the lateral meniscus (11.2 mm)[1]. The anterior and

posterior horns of each menisci also move differently with knee flexion, thereby maintaining the conformity of the tibio-femoral articulated surfaces during the knee ROM[8,9].

Four ligaments are crucial in maintaining the knee joint stability. These are the anterior cruciate ligament (ACL), the posterior cruciate ligament (PCL), the medial collateral ligament (MCL) and the lateral collateral ligament (LCL). The primary function of the ACL is to prevent the anterior translation of the tibia on the femur but it is also a secondary restraint to internal rotation, varus, valgus and hyperextension[8,10-14]. The PCL prevents posterior translation of the tibia on the femur. Besides this, it also acts as a secondary restraint to varus, valgus and external rotation[8,9,11,12]. The MCL has a superficial and a deep portion[1,13], with the superficial portion contributing the most to the knee stability[15]. Throughout the knee ROM, the MCL prevents tibial valgus, as well as external rotation. Its role is even more crucial during knee flexion because the posterior capsule is relaxed during that time[1]. The lateral stability of the knee is conferred by the LCL and the ilio-tibial (IT) band, both of which act as restraints to varus throughout the ROM[16-18].

1.2 Terminology of leg alignment

1.2.1 Anatomical axis

The line drawn along the shaft of the femur passing through the centre of knee to the centre of the ankle is called the femoro-tibial angle (FTA) (Figure 1-1). In other words, this is a line joining the anatomic axis of the femur with the anatomic axis of the tibia[19]. It is the most commonly used measurement of axial alignment during clinical assessment of the knee. The average FTA is about 178° in men, 176° in Asian women and 174° in white women[20,21] (range 171° to 183°).

1.2.2 Mechanical axis

The line drawn from the centre of the femoral head to the centre of the ankle joint is called the mechanical axis of the lower limb. This is considered to be more accurate in defining the force transmission across the knee joint and in the majority of cases[19,22] it passes through the medial tibio-femoral compartment, about 5–10 mm from the centre of the knee while standing[19,22]. This is also called the load bearing axis[23]. This is different from the mechanical axis of the femur which is formed by the line connecting the centre of the femoral head to the centre of the knee and the mechanical axis of the tibia which is formed by the line connecting the centre of the knee to the centre of the tibiotalar joint[19]. The angle formed between the mechanical axis of the femur and the tibia is called the hip-knee-ankle angle which is just short of 180° in normal knees[19,21] (Figure 1-1).

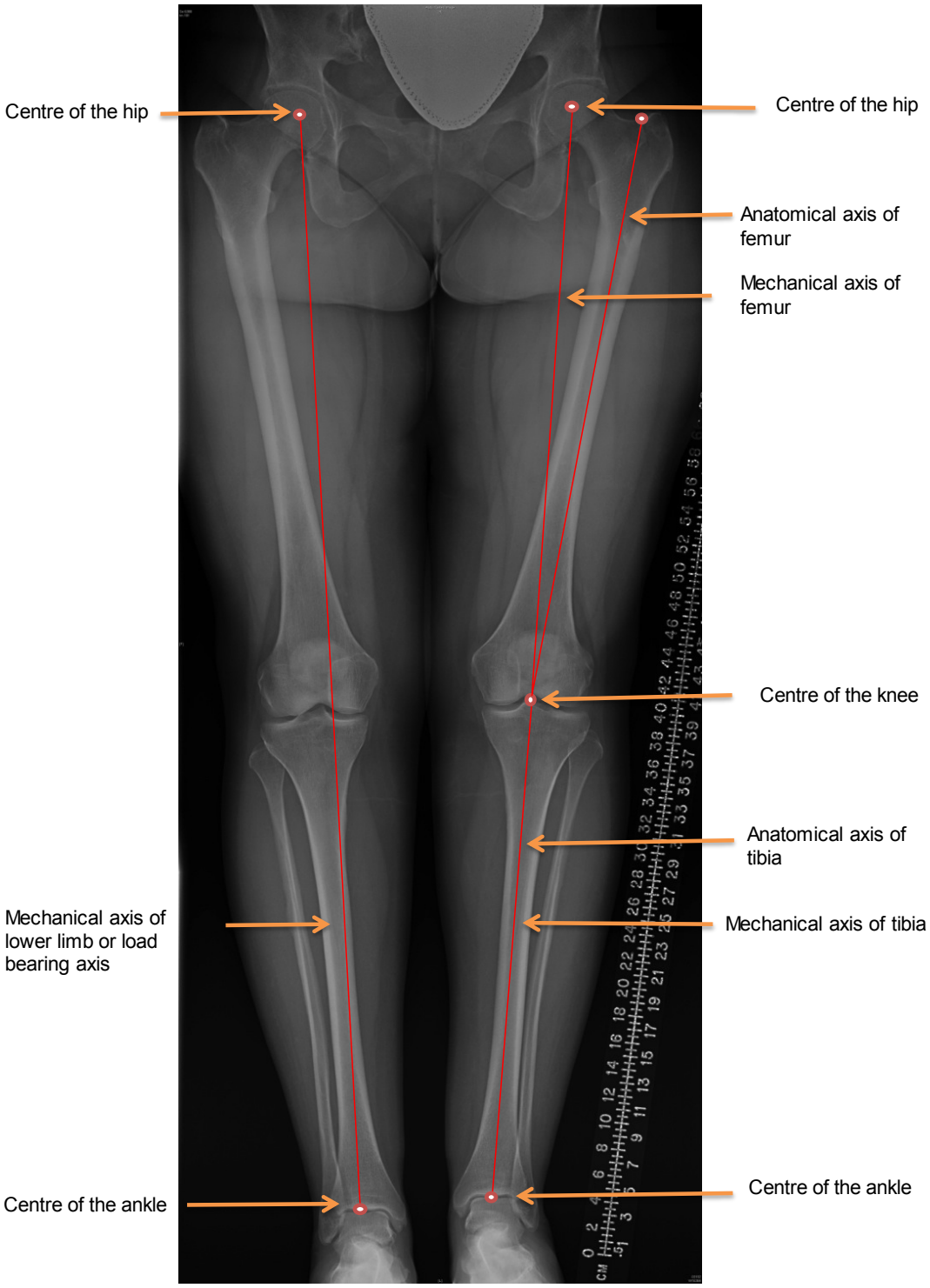


Figure 1-1: Mechanical and anatomical axes of the knee

1.3 Kinematics and kinetics of the knee

1.3.1 Kinematics

Kinematics is the description of relative motion of a body or system of bodies without consideration of the forces involved. With regards to the knee, the kinematics

describes the relative motion of femur, tibia and patella involved in two interdependent articulations; the tibio-femoral and the patello-femoral joints[24].

1.3.2 Kinetics

Kinetics is the analysis of the forces and moments which are involved in producing the movements of free bodies in space[24].

Knee kinematics and kinetics have been a subject of discussion since their first description by Giovanni Borelli (1608–1679), who is often described as the 'father of biomechanics[25]. One important breakthrough came when Zuppinger[26] postulated the presence of a 'four-bar linkage' mechanism in the knee based on a radiographic study. He suggested that cruciate ligaments may act as 'guiding' rather than as 'restraining' structures and this can only happen if both the cruciates remain tense throughout flexion. The cruciate ligaments form the two crossed bars and the femur and the tibia form the other two bars[27] (Figure 1-2).

A unique characteristic of the 'four-bar linkage' model is that the length of each of the four bars remains constant but the angle between each bar can change. This allows the lower leg to rotate. The cross-over point moves as the joint goes from flexion to extension so that the knee does not have a fixed point of rotation[27,28].

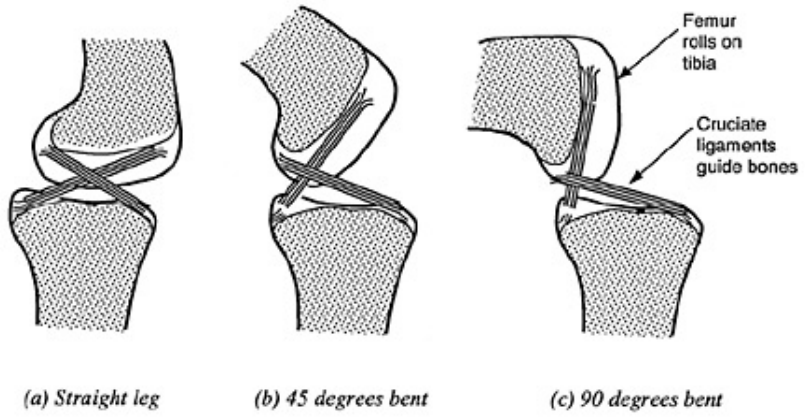


Figure 1-2: Four bar linkage model of the cruciate ligaments[28]

The 'four-bar linkage' model has been extensively studied and used for mathematical modelling studies of the knee[29-32]. The critics of this model say that it has many potential weaknesses[33]. Since the model is based on findings of cadaveric studies, two-dimensional radiographs, and computer based mathematical models, many approximations have been made. Furthermore, the authors have assumed that linkages are rigid while in real life, the cruciate ligaments are extensible under the influence of muscle forces and external loads[24].

Another view of knee kinematics came when Iwaki *et al*.[34] used magnetic resonance imaging (MRI) to determine the shapes of the articular surfaces and their relative movements in six unloaded cadaveric knees. The authors approximated the medial condyle of the femur to be composed of the arcs of two circles while the lateral femoral condyle was approximated to be composed almost entirely of a single circular facet. Similarly, the medial tibial plateau was approximated to be like two angled flats and laterally the tibia was approximated to be roughly flat. Although the authors found some antero-posterior movement in the medial femoral condyle, they simplified this to assume there was none. On the lateral side, the authors concluded that the femur tends to roll backwards with flexion which contributes to internal

rotation of the tibia around a medial axis with flexion. The same group undertook further studies when the living knee was loaded up to a knee flexion of 90°[35] and then with active knee flexion from 90° to 133° and passive knee flexion to 162°[36]. There was 4 mm backward movement of the medial femoral condyle and a 15 mm backward movement of the lateral femoral condyle, which caused internal rotation of the tibia at extreme flexion (162°) and caused the lateral femoral condyle to lie posterior to the tibia.

These three papers provided a simplified explanation of knee kinematics and generated further research on this controversial topic. In 2004, Williams and Logan[33] studied weight bearing tibio-femoral motion using an open MRI scanner and instead divided the range of motion at the knee into three arcs: the screw-home arc (0° to 20°), the functional active arc (20° to 120°) and the passive deep flexion arc (120° to high flexion) based on anatomy of distal femur and tibial plateau. A recent publication[37] based on an anatomical study, MRI and previously published cryosections, further described the tibio-femoral joint movement. Between 120° and 160° knee flexion, the medial femoral condyle initially moves posteriorly (5 mm) and then rises up on the posterior horn of the medial meniscus. There is limited flexion beyond this range because the posterior horn of the medial meniscus is compressed in a synovial recess between the femur and the tibia. The lateral femoral condyle, however, rolls back over the posterior tibia along with the posterior horn of the lateral meniscus at 160° knee flexion. This study concluded that hyperflexion is a separate arc and as such it is difficult to design an implant for total knee replacement (TKR) which will allow physiological movement from 0° degrees to 160°.

1.4 Osteoarthritis of the knee

Osteoarthritis (OA) is a progressive condition affecting the synovial joints

characterised by focal areas of articular cartilage loss, thickening of the joint capsule and associated bone hypertrophy manifesting as osteophytes/subchondral bone sclerosis[38,39]. It is one of the leading causes of disability worldwide[40]. The hip and knee joints are most commonly affected. The main symptom is pain[41] and besides pain, it also causes inability to perform activities of daily living[42,43] and impaired quality of life[44].

Various classification systems have been proposed to grade the severity of OA. The most commonly quoted classification in the literature is the Ahlbäck classification, based on the loss of subchondral bone on conventional radiographs[45]. Another classification proposed by Kellegren and Lawrence[46] divided OA into five grades. The similarities and differences between the two are shown in Table 1-1[47] :

Ahlback grade	**Ahlback definition**	**Kellegran and Lawrence grade**	**Kellegran and Lawrence definition**
		Grade 1 'Doubtful'	Minute osteophyte, doubtful significance
		Grade 2 'Minimal'	Definite osteophyte, unimpaired joint space
Grade I	Joint space narrowing (joint space <3mm)	Grade 3 'Moderate'	Moderate diminution of joint space
Grade II	Joint space obliteration	Grade 4 'Severe'	Joint space greatly impaired with sclerosis of subchondral bone
Grade III	Minor bone attrition (0-5 mm)	Grade 4 'Severe'	Joint space greatly impaired with sclerosis of subchondral bone
Grade IV	Moderate bone attrition (5-10 mm)	Grade 4 'Severe'	Joint space greatly impaired with sclerosis of subchondral bone
Grade V	Severe bone attrition (>10 mm)	Grade 4 'Severe'	Joint space greatly impaired with sclerosis of subchondral bone

Table 1-1: Comparison of Ahlback with Kellegren and Lawrence grading of osteoarthritis[47]

Altman *et al.*[48] described a scoring system based on screening radiographs. Tibio-femoral compartments were assessed for joint space narrowing (JSN) and

osteophytes on a 4-point scale (0–3) and sclerosis was assessed on a 2-point scale (0–1). A total score of 2 in any compartment meant presence of radiographic OA[49].

Each of these grading methods has its shortcomings. Moreover, they have poor inter-observer and intra-observer reproducibility[47,50]. Therefore, despite extensive epidemiological and clinical research there is no consensus on the best classification criteria to define knee OA[51]. A correlation, however, exists between the degree of radiographic changes and the degree of pain and other symptoms[52].

The aetiology and pathogenesis of OA is different in the lateral and medial compartments of the knee due to the difference in the relative contribution of mechanical and constitutional factors. Several studies have suggested more anterior wear in medial knee OA compared to more posterior wear in lateral knee OA[53-55].

The concept of antero-medial OA was first described by White *et al*.[56] based on a prospective study of medial tibial plateaus excised during unicompartmental knee replacement (UKR). The resected tibial plateaus were divided into four equal zones from front to back. The antero-central zone was found to be the most commonly affected and the lesions seldom extended to the posterior zone. Harman *et al.*[57] assessed the size and location of articular cartilage wear from varus and valgus osteoarthritic tibial plateaus resected during TKR. They found that ACL deficient varus plateaus had significantly larger wear areas, which were located more posterior on the medial plateau. In contrast, ACL intact, as well as deficient, valgus tibial plateaus had wear areas located posterior to the centre of the lateral plateau. These observations provided insight into the altered knee mechanics in osteoarthritic knees.

1.5 Treatment of osteoarthritis

The aim of treatment of OA is pain control and minimising disability[58]. Various measures can be tried such as life style modification, education, weight loss, physiotherapy and regular exercise in addition to pain relief medications[59]. Off-loading braces have been tried with some success in the early stages of unicompartmental OA[60]. However, the brace was not effective in obese patients. The results from a prospective randomised multi-centre trial[61] indicate that an off-loading brace produces very small effects. Furthermore, patient compliance may be an issue.

If non-operative measures have not produced satisfactory pain relief, a variety of surgical options are considered ranging from arthroscopic lavage, high tibial osteotomy (HTO), distal femoral osteotomy, UKR, and TKR to arthrodesis.

With regards to OA, knee arthroscopy is used mainly for diagnostic purposes. A randomised placebo-controlled trial of patients with knee OA undergoing arthroscopic lavage/debridement demonstrated no significant improvement in outcome compared to a placebo procedure[62]. A more recent randomised control trial performed to analyse the role of arthroscopic surgery in patients with moderate-to-severe knee OA demonstrated that there was no additional benefit of knee arthroscopy when compared to optimised physical and medical therapy[63]. Knee arthrodesis is rarely performed and its main use is as a salvage procedure in patients with uncontrollable prosthetic joint infection[64].

HTO still has some role in the treatment of a unicompartmental disease, especially in patients who are young and more active. The aim of the surgery is to realign the mechanical axis and thereby off-load the medial compartment. With correct patient selection and precise surgical technique, up to 85% 20-year survivorship has been

noted[65] although the Finnish registry data based on 3195 knees demonstrated a survival of 89% at five years and 73% at ten years[66]. A meta-analysis comparing the medial opening-wedge and lateral closing-wedge HTO revealed no difference in any clinical outcome, functional score or complications between the groups[67].

Another definitive treatment for OA is to surgically replace the diseased articular cartilage through joint replacement surgery; which can either be unicompartmental or total. In UKR, only the diseased medial or lateral tibio-femoral compartments or an isolated patello-femoral joint is replaced. In TKR, both medial and lateral tibio-femoral joints are replaced with or without resurfacing of the patella. In the United Kingdom, TKR is currently performed in more than 90% of cases presenting with knee arthritis mirroring similar findings in other countries[68]. The TKR component design allows either preservation of the PCL (cruciate retaining) or its sacrifice and substitution (posterior stabilised)[24].

Although HTO and UKR are used for similar pathologies, the types of patients operated upon tend to be different; with those for HTO being very young and active and having mild disease without bone-on-bone and a marked deformity[69]. The literature does not clearly demonstrate the efficacy of the one treatment over the other[70] as they tend to be used in different people. A prospective randomised controlled trial[71] was performed in elderly patients which compared the clinical outcomes of patients treated with HTO compared to that with UKR. With UKR, the predicted survivorship was 82% at five years and 77% at 10 years; whereas, with HTO, this was 78% and 60% respectively. However, none of the differences reported in the study were statistically significant. A meta-analysis[72] comparing the two treatment methods demonstrated that patients with UKR had higher ratio for an excellent outcome (odds ratio: 2.43, $p<0.001$) and lower risk of revision (odds ratio: 0.47) and complications (odds ratio:0.24) than HTO.

Various types of UKRs have been tried and tested over the years. The first published evidence came in 1958 when MacIntosh[73] used the Vitallium tibial plateau prosthesis. It provided good pain relief but there were early failures due to implant migration. McKeever, later on, tried to solve the problem by adding a keel to the tibial plateau[74]. The short and intermediate follow up results of these two implants have been noted to have good results in 70% to 90% of patients[75,76].

1.5.1 Fixed bearing designs

The introduction of Marmor's modular hemiarthroplasty[77] in 1970 and successful use of St. Georg Sled prosthesis[78] marked the beginning of a new era. These employed a fixed polyethylene bearing and a polycentric femoral component. Some initial studies showed good results[79,80] but there were other studies which reported a less favourable outcome[81,82]. Consequently, the interest in UKRs began to decline. In spite of this, fixed bearing UKRs are still being used with some studies quoting a survival rate of 89.8% for the medial Sled at 15 years[83] and 98% for Miller-Galante implants at 10 years[84]. Parratte *et al.*[85] reported a 12% revision rate at a mean follow-up of 17 years (range: 15–21 years) and the same group reported 80% survival rate at a mean follow-up of 20 years (range: 15–21 years)[86].

1.5.2 Mobile bearing designs

Goodfellow and O'Connor were the first to introduce the concept of a mobile bearing or meniscal bearing. It was first used as a bicompartmental device and the prosthesis comprised a spherical femoral component which articulated with a fully congruent and unconstrained, mobile tibial polyethylene insert[29]. The stability of the knee was dependent on intact cruciate and collateral ligaments. The results[87] were less satisfactory than TKR and 5% prosthesis failed and 6% were revised at a follow up of two to six years. The results were, however, were good overall if the ACL was intact.

Out of the first 100 operations, there were no failures in patients with intact ACL. It was observed that with an intact ACL the disease was usually unicompartmental, so the use of the prosthesis was abandoned in its bicompartmental form.

The prosthesis was first used in a patient as a unicompartmental device in 1982[88] with good results. The stability and alignment was restored in all, and the pain was relieved in 96% patients. The status of the ACL was found to be the most important contributor towards a good outcome with 4.8% failure rate in patients with intact ACL compared to 16.2% in patients without an ACL ($p<0.02$). The role of the ACL in maintaining the sagittal plane stability after meniscal bearing UKRs was further confirmed by an *in-vivo* study which demonstrated that ACL deficient UKRs had significantly larger anterior displacement compared to those with intact ACL[89].

1.6 Oxford UKR

In 1976, Goodfellow and O'Connor identified four principles which should guide the design of any prostheses designed to replace diseased or worn articular surfaces[29]:

1) The components should allow movement between articulating bones without limitation. In the case of the knee, they should allow rollback as well as sliding.
2) Only compressive stresses are exerted on the peri-articular bone.
3) The cruciate and collateral ligaments are restored to their natural tension, providing stability to the otherwise unconstrained implants.
4) The contact areas are sufficiently large so as to maintain the contact pressure under load at a level that prosthetic materials can withstand.

The spherical femoral component and a fully congruent unconstrained mobile bearing of the Oxford UKR (Figure 1-3) exert less shearing stress on the implant/bone interface. The intact cruciate and collateral ligaments enhance stability and allow normal mobility by preserving the knee kinematics[90].



Figure 1-3: Design of Oxford UKR

The design of the articulation of the Oxford UKR has not changed much since its introduction in 1976; but there have been several changes to the fixation surfaces, instrumentation and method of implantation[90], especially with the advent of the minimally invasive surgical approach[91,92].

The use of UKR instead of TKR offers many advantages. The knee function is more physiological[93] and this has been confirmed by *ex-vivo*[94,95] and *in-vivo* studies[96,97]. UKR allows rapid recovery[98], the hospital stay is much shorter (1.4 days versus 2.2 days)[99] and patients are better able to descend stairs[100]. There is decreased risk of thromboembolic events[101] and less requirement for blood transfusion[102,103]. Furthermore, it preserves better range of motion at the knee[104] and revision surgery is usually easier[105,106]. The latter has been questioned in some recent studies[107].

Most studies have reported a good survival rate for Oxford UKR, ranging from 92% to 100% at 10 years[108-110]. An independent series has demonstrated a 20 year

survivorship of 92% and more than 90% had good or excellent clinical results at 10 years, using the Hospital for Special Surgery (HSS) knee score criteria[111]. Some studies have, however, reported a less successful outcome[112-114] with a survival rate as low as 74%. Robertsson *et al.* analysed the data from the Swedish Knee Arthroplasty Register from 1986 to 1995 and found approximately a three-fold increase in cumulative revision rates for the Oxford UKR in centres which performed fewer than 23 implantations a year[115].

The success of Oxford UKR relies on appropriate selection of patients. It is important that the disease is confined to only the medial tibio-femoral compartment of the knee at the time of implantation. The condition of patello-femoral joint has always been controversial. Some authors believe that correction of varus deformity will improve patella tracking and hence the condition of the patellar articular surface is not as important[116-118]. A more recent study suggested that provided there is no bone loss and grooving on the lateral facet of patella, the articular cartilage damage to the patello-femoral joint does not compromise the functional outcome after Oxford UKR[119].

Full thickness cartilage loss in the lateral compartment is an absolute contraindication for medial UKR but some damage to the medial side of the lateral femoral condyle is often seen due to impingement by the tibial spine. This is not considered a contraindication for Oxford UKR[120]. Another contraindication for UKR is poor function of the ACL, as there is a risk that it will lead to premature failure of implanted components[118,121]. This is again not an absolute contraindication as an *in-vivo* study has shown normal restoration of kinematics in ten patients after combined ACL reconstruction and Oxford UKR[122,123]. A recent clinical study has confirmed that patients with an ACL deficiency and Oxford UKR had no difference in survivorship compared to the patients with intact ACL[122,123], although follow up was relatively

short. In 1989, Kozinn and Scott[124] proposed that UKR should be not be performed in patients with weight > 82 kg, age < 60 years, heavy manual workers or those who had an exposed bone in the patello-femoral joint or chondrocalcinosis. There is evidence that these contraindications may be unnecessary for the Oxford UKR[125].

The progression of the disease to the lateral compartment is considered to be a major problem with medial UKR, as 5% of patients in a study performed by Squire *et al.*[126] needed revision surgery due to disease progression. Conversely, a study by Ackroyd *et al.* using St George Sled prosthesis showed that only 2.2% of UKRs were revised by 10 years because of disease progression in either the lateral or patellofemoral compartments[127]. A prospective study on 1000 patients with Oxford UKR demonstrated that the progression of arthritis in the lateral compartment accounted for revision surgery in 0.9% of patients[128].

1.7 Assessing outcome after knee replacement

There are various ways to assess the outcome after a knee joint replacement. These mainly include: survival analysis, outcome scores and radiological assessments. Various computational modelling approaches such as the use of finite element (FE) analysis, radiostereometric analysis (RSA) and kinematic assessment have also been described.

1.7.1 Survival analysis

Survival analysis is a method that is used to assess the chance of an implant surviving for a particular length of time. It is especially useful when analysing data from patients with different lengths of follow-up as it allows cases to be entered and withdrawn from a trial at any stage and for whatever reason such as loss to follow up

or death[129]. There are number of confounding factors affecting the survival analysis such as small numbers, loss to follow up and the definition of failure[129,130].

Several definitions of failure have been used in the literature with each one generating a different survival rate[131]. Revision arthroplasty is the most widely used end-point as it is easy to identify and is reproducible. However, it is not without its shortcomings; the revision surgery may be delayed or even postponed either due to surgeon or patient factors. To eliminate this bias, it has been suggested that more than one definition of failure should be analysed which could include: revision rates, development of severe pain or pain as bad as pre-operative state, and occurrence of radiological signs of loosening[129].

1.7.2 Outcome scores

The objective of survival analysis is to provide information about the implant longevity but it is recognised that some patients suffer with pain and have poor function despite the survival of the implant[132]. It is therefore rational to assess the implant success using clinical parameters, such as pain and function. An assessment of change from one clinical state to another, generally following either an intervention or passage of time is involved in measuring outcomes. The information is gathered at two specified time points and the magnitude of change occurring during this time interval is taken as the effect of a certain treatment[133].

A variety of scoring systems are available to assess the outcome of knee replacements. They can either be completed by the surgeon or by the patient and generally fall into one of the three categories: generic, disease specific and joint specific. The score most commonly used by surgeons or independent observers to assess the outcome of knee replacement is the American Knee Society Score (AKSS) (Appendix 1). This was produced by the Knee Society[139] and is divided into

'objective' and 'functional' scores with a potential maximum score of 100 points in each section. The objective AKSS (AKSS-O) is based on assessment of pain, range of motion and stability at the knee and there are deductions for deformities at the knee. The functional AKSS (AKSS-F) is based on the patients' ability to walk and climb stairs and there are deductions for using walking aids. Although, the AKSS was modified in 2011, the older version was used for the purpose of this thesis to ensure direct comparison between datasets because some data had already been collected using the old version. The most common patient-centred score used to assess the outcome after knee replacements is the Oxford Knee Score (OKS) (Appendix 2) which is a cumulative score based on twelve questions, each scoring from 0-4, with a minimum score of zero (worse outcome) and maximum score of 48 (best outcome)[140,141].

The scores completed by the surgeons have certain shortcomings which include: high risk of detection bias[134] and inability to take account of the patient's perspective[135]. The conventional knee scores filled by operating surgeons have been shown to be inaccurate, unreliable and have poor reproducibility[136,137]. This problem can be overcome to some extent by utilising an independent observer[134]. However, patient based questionnaires are limited in that patients may find it difficult to differentiate between the true pain of a failing joint replacement and referred pain due to pathology in other joints. A study on 141 patients awaiting hip or lumbar spine surgery, with no known knee problems, reported that only 11% had the maximum OKS and the mean OKS was significantly lower than the score obtained from patients with TKR[138].

1.7.3 Radiological assessment

Radiological assessment mainly comprises plain AP and Lat radiographs of the knee and a vast array of information can be obtained from their accurate assessment. For

instance, a failing prosthesis can usually be identified. It is essential to obtain radiographs with the x-ray beams parallel to the joint replacement component surfaces, to accurately measure the alignment and reduce parallax error. Some other parameters that can be measured include the anatomical and mechanical axis of the leg, radiolucency, overhanging or underhanging components or the progression of arthritis in the retained compartments. This list is not exhaustive and various computer programs have been developed to further help with radiological assessments[142].

1.8 Failure of joint replacements

There are many reasons why joint replacements fail but as mentioned in Section 1.7.1, the definition of failure is subject to controversy. Some of the mechanisms by which knee replacements can fail include; aseptic loosening, osteolysis, implant failure/dislocation, septic loosening and wear.

1.8.1 Aseptic loosening

The term aseptic loosening is used to denote loosening of an implant without infection. In TKR, it is more commonly seen under the tibial component or around the patella and is rare under the femoral component. Femoral and tibial loosening may occur with UKR. It is difficult to diagnose femoral loosening on standard radiographs and a flexion-extension screened lateral view may be needed[143]. The twin peg Oxford UKR has been suggested as an alternative for surgeons who are concerned over the risk of femoral loosening with the single peg Oxford UKR[144].

1.8.2 Osteolysis

In TKR and fixed bearing UKR, the osteolytic defects under the tibial or the femoral component are generally thought to represent a response secondary to wear debris.

In mobile bearing UKR, physiological radiolucent lines (RLL) are commonly seen under the tibial component of Oxford UKR. They may represent a response to compressive load[145] but RLL are rarely observed with cementless implants[146].

1.8.3 Implant failure

Implant failure after UKR could occur due to bearing dislocation or component failure. The Oxford UKR, which has a mobile bearing, has been shown to have 0.6% rate of bearing dislocation in series of 1000 patients operated using a minimally invasive approach[128]. This incidence used to be higher with Phase 1 implants (2.5%) when the femur was prepared using a saw. With the introduction of a guided power mill for Phase 2 and Phase 3 implants, the incidence has reduced (0.5% and 0.2% respectively)[147,148]. The polyethylene bearing can fracture with an estimated incidence of 0.35% for Phase 3 with a marker wire, and 0% for Phase 3 without the posterior marker wire[149]. The incidence of implant fractures and breakage is decreasing due to continuous improvement in design and manufacturing techniques.

1.8.4 Septic loosening

Unlike aseptic loosening, septic loosening is a result of a deep joint infection. In TKR, the rate of infection is higher in patients with rheumatoid arthritis (4.4%) compared to 1.7% in patients with OA[150]. The incidence in UKR is less than half of that in TKR[128]. Various general factors help in reducing the risk of infection such as; good surgical technique, antibiotics and vertical laminar flow in operating theatres[151]. In relation to UKR, the specific factors may include the minimally invasive surgical technique.

1.8.5 Wear

Polyethylene wear is recognised as a major cause of failure of joint replacements[152,153]. There are two types of polyethylene wear seen in TKR and modular fixed UKR: articular and under-surface wear. Articular wear is thought to

occur due to the high contact stress exerted by the round femoral component against the flat bearing. A more conforming polyethylene bearing can reduce the contact stresses and hence may reduce this type of wear. Under-surface wear occurs at the interface between the polyethylene bearing and the metallic tibial base plate, and can be exacerbated by modular fixation.

The Oxford UKR has a spherical femoral component and a fully congruent unconstrained mobile bearing thereby offering a theoretical advantage of reduction in both types of wear. A retrieval study of 47 bearings (mean time to revision: 8.4 years) has shown a mean rate of linear penetration of 0.07 mm/year with the Oxford UKR[154]. The annual mean wear rate of the Phase 2 bearings have been reported to be significantly less than that of Phase 1 bearings (Phase 2: 0.02 mm/year, Phase 1: 0.07 mm/year)[155]. This correlates well with a previous clinical study where the thickness of bearing used at implantation was shown to have no influence on the 10-year survival[156] and a more recent study where none of the patients were revised for polyethylene wear[128]. In contrast, the average linear wear rates in TKR are quite high (0.127 mm/year)[157].

1.9 Revision of Oxford UKR

A review of the New Zealand Joint Registry[158] from January 1999 to December 2012 stated that there were 445 revisions out of the 6621 UKRs (6.7%) that were performed. A further 42 patients had a second revision, five patients had a third revision and one patient had a fourth revision. Three hundred and seventy four of these 445 (84%) patients were revised to TKRs. Of the patients who were revised, 38.4% (171 patients) were revised for pain. The other common reasons for revision included aseptic loosening of the tibial (22.5%) or femoral (14.6%) components, bearing dislocation (9.2%), progression of disease (7.4%) and deep infection (3.6%).

The less common reasons for revision were: tibial fracture, wear, impingement, implant breakage, failure and fractured femur.

A review of the United Kingdom National Joint Registry[159] reveals that there were 1572 revisions out of total 35749 registered Oxford medial UKRs (3.9%) from April 2003 to December 2010. The most common cause of revision was loosening (30%) followed by unexplained pain (23%). The other causes of revision included dislocation of the bearing (9%), infection (6%), malalignment (5%) and progression of disease on the lateral side (4%). The revision rates at five years for unexplained pain was 1.6% for UKR compared to 0.2% for TKR ($p<0.001$).

The data published by the Australian Orthopaedic Association National Joint Replacement Registry[160] on 1948 primary UKR revisions reveals a slightly different picture. The main causes for revision were aseptic loosening (50%), progression of disease (17%), unexplained pain (12%), infection (5%) and patello-femoral pain (<1%). A few other unlisted causes contributed to 14% of revision surgeries.

Wynn Jones *et al.*[161] retrospectively reviewed 1165 primary medial UKRs performed from January 1996 to December 2008 to examine the cause of revision. They also included patients who had the primary operation elsewhere but were revised at their hospital; 89 revisions were identified from January 2002 to February 2008. Nine patients were revised to another UKR. Eighty were revised to a TKR. Eleven per cent of patients were revised for an unexplained pain. The other causes of revision included femoral component loosening (40%), tibial component loosening (16%), bearing dislocation (16%) and progression of lateral disease in 11%. A primary Oxford UKR bearing thickness of greater than 6 mm was associated with an increased likelihood of requiring revision components.

Revision surgery, as mentioned in section 1.7.1, may not be the best outcome measure when comparing different implants[162]. This is evident from the New Zealand Joint Registry data, which publishes both clinical outcomes (OKS) as well as revision rates. The UKR had a better knee score than TKR but there were three times more revisions with UKR. This was due to the fact that the sensitivity of the revision rate to clinical failure was different for UKR compared to TKR. Only about 12% of TKRs were revised in patients with OKS < 20 points compared to about 63% of UKRs.

If revision surgery is taken as a primary end point then there is huge variability in the reported literature. Some studies suggest survival rate after Oxford UKR as high as 100%[188] and as low as 75%[114]. The reason for this variation is not known but this may be related to the volume of cases performed at different centres. The Oxford group[128] has reported 96% survival rate based on 1000 phase 3 Oxford UKR patients.

1.10 Pain after Oxford UKR

Some patients after UKR continue to experience pain post-operatively[159,163]. The issue of pain is not unique to the Oxford UKR; pain has also been reported after other types of UKR[164] and is more common after a TKR[165] than after a UKR. The pain can be disabling, often increases on weight bearing and can compromise the functional outcome. Sometimes it is worse than the pre-operative pain. The problem is compounded when some of these patients have no untoward finding upon clinical examination or the radiographs. The aetiology of unexplained pain is multifactorial but some studies indicate that it may be due to local bone overload, particularly in the case of antero-medial pain over the tibia[166,167], which is further influenced by the implant position, applied load, development of RLL and material properties of the bone.

The exact incidence and natural history of this pain is not known. The factors contributing to pain and poor function after UKR could be categorised into pre-operative, intra-operative or post-operative factors. The pre-operative factors include selection of patients outside of the operative indications for instance those who already have a disease in the lateral compartment or those where knee pain is a result of pathology elsewhere else and there is less severe OA in the medial compartment. There is some evidence[168] following TKR or total hip replacement that patients tend to experience high pain post-operatively if they have less severe radiographic OA pre-operatively. Intra-operative factors mainly include the surgical technique, appropriate component size, leg alignment, component alignment and the restoration of knee kinematics. The post-operative factors may be related to abnormally high strain in the proximal tibia following UKR implantation.

Painful UKR is associated with patient dissatisfaction and often leads to revision surgery[158,160]. Early revision for pain is not always necessary as the pain can settle over a period of time[169]. Furthermore, the revision surgery does not always improve pain especially if the cause of pain is unexplained[170].

1.11 Aims of this thesis

As mentioned in section 1.7.1 and section 1.9, revision surgery is not considered to be the best outcome measure to assess the results of Oxford UKR. Some patients suffer with pain and have poor function despite the survival of the implant[132]. Furthermore, National Joint Registry data confirms unexplained pain as one of the most common indications for patients undergoing revision surgery after UKR[158-160]. The aims of this thesis are, therefore, to define the incidence, natural history, clinical impact and patho-mechanism of pain observed post-operatively in some patients

following Oxford UKR. There will be a particular focus on identifying factors that influence the clinical and radiological outcomes and are associated with pain and poor function. In order to explore whether pain is related to local bone overload, the stresses and strains in the proximal tibia will be studied using FE analysis and the effect of altering various parameters that could affect these will be analysed.

This work aims to advance our understanding of factors that cause poor outcome after UKRs and to help in reducing the incidence of post-operative pain, associated dissatisfaction and unnecessary revisions. Although this thesis is focused on the Oxford UKR, the findings could be applied to other types of knee replacements.

1.11.1 Incidence and natural history of pain after UKR

The aim of this study is to analyse the incidence of pain after Oxford UKR and its progression with time. The study will also evaluate whether the incidence has changed over the years (Chapter 2).

1.11.2 Factors contributing to pain and poor function

These can be broadly classified into three categories: severity of disease, surgical technique and quality of fixation.

1.11.2.1 Severity of disease

The study will analyse how the severity of OA in the medial compartment affects the clinical outcome after UKR. The proportion of patients who are considered not to have benefited substantially from surgery will also be analysed (increase in OKS ≤ 6) (Chapter 3).

1.11.2.2 Surgical technique

Many surgical errors may contribute to post-operative pain. These include problems

with component alignment, leg alignment and component overhang.

1.11.2.2.1 Effect of component alignment

This study will focus on analysing the component alignment after Oxford UKR in coronal and sagittal planes. The relationship between the interval groups for each of the femoral and tibial parameters and the five-year OKS, change in OKS (Δ OKS), Pain Score and the number of regions with RL will be analysed (Chapter 4).

1.11.2.2.2 Effect of leg alignment

A new method of measuring leg alignment clinically will be developed for this study and its accuracy and repeatability will be described. The effect of the post-operative leg alignment after Oxford UKR on clinical and radiological outcomes will be analysed (Chapter 5).

1.11.2.2.3 Effect of tibial component size

This study will analyse the effect of overhanging and underhanging tibial components on clinical and radiological outcomes after Oxford UKR, so as to develop evidence-based guidelines on the intra-operative selection of tibial component sizes (Chapter 6).

1.11.2.3 Quality of fixation

The study will establish the incidence, aetiology and clinical significance of RLL observed after Oxford UKR in some patients; in particular whether they are related to pain and poor function. Various factors that could contribute to radiolucency will be analysed (Chapter 7).

1.11.3 Bone overload as a cause of pain

A fully validated finite element model of the proximal tibia will be utilised for this study[171,172]. Various alignment and loading parameters that could affect the antero-medial tibial strain will be analysed. The results will then be compared with the clinical outcome studies (as mentioned above) to analyse whether or not bone overload is related to post-operative pain (Chapter 8).

2. INCIDENCE AND NATURAL HISTORY OF PAIN AFTER OXFORD UKR

2.1 Introduction

Persistent knee pain is a significant cause of dissatisfaction after a knee replacement. With TKR, nearly 20% of patients are not satisfied with the outcome at one year, and at 10 years less than 10% of patients are "very happy"[165].

The incidence of persistent pain after UKR is not known and is debated. Some individual studies have reported an incidence as low as 1%[173] and as high as 50%[163]. The national joint registers (NJR) provide some evidence of the clinical impact of pain after UKR. The New Zealand Joint Register[158] recently published a 13 year report demonstrating that pain was the cause in 38% of UKR revisions. The data from the NJR of England and Wales suggest that 23% of UKRs revised were for pain[159]. The NJR uses revision as a primary end point, which has been questioned in recent publications[132,162]. There has been no large prospective study to look at the incidence of pain after UKR. The natural history of this pain, its aetiology and its impact on long-term outcome is also not known.

2.2 Methods

Over the past 13 years, all patients undergoing Oxford UKR under care of two senior surgeons at the Nuffield Orthopaedic Centre, Oxford have been prospectively followed. Pre-operative clinical data and follow up clinical data at 1 year, 2 years, 5 years and 10 years have been obtained. The clinical assessment includes documentation of detailed OKS[140,141], AKSS-O and AKSS-F[139] and Tegner activity score[174]. A record is kept of any complications encountered including the presence of persistent pain, its location, severity and duration. In addition, all patients have

regular radiographic assessments. The demographic and intra-operative data (Appendix 3) are also collected.

The OKS ranges between 0 and 48, with 48 being the best[141]. The pain score (PS) is deduced from the OKS[100,175] comprising of questions 1, 4, 5, 8 and 9, which are all directly related to patients' perception of pain. The best clinical outcome is represented by the highest score, with the maximum attainable pain score being 20. The rest of questions form the function score (FS). Changes in OKS and PS (∆ OKS and ∆ PS respectively), relative to the pre-operative value, are recorded at each follow up.

2.2.1 The incidence of pain and its natural progression

The cohort of 1101 patients with cemented medial Oxford UKR was used to analyse the incidence and progression of pain as demonstrated by the response to question number 1 of the OKS, which determines the severity of pain in the knee during the last four weeks. '0' represents severe pain and '4' represents no pain. The percentage of patients complaining of severe pain was analysed at pre-operative state and at one year and final follow up intervals. The total value and the change in OKS and PS were also analysed to demonstrate the improvement in functional outcome and pain respectively, after Oxford UKR. The response of the patients to question number 1 of OKS was determined and analysed over the 10 year period to estimate the natural history and progression of severe pain after Oxford UKR. The pre-operative data was available on 697 patients. Therefore the change in scores was calculated in these patients only.

The above data will provide a valuable insight into the long-term incidence, prevalence and progression of pain following Oxford UKR. This, however, does not convey any information about the incidence during the early post-operative period.

To address this problem and to identify the incidence and prevalence of pain within the early months after surgery, another set of data was analysed. This comprised 180 patients, who in addition to having their pre-operative and one year detailed OKS, also had OKS recorded at six weeks following the surgery. These patients attended the ward discharge clinic run by physiotherapists, who routinely collect OKS at each clinic attendance.

2.2.2 The change in the incidence of pain with time

The popularity of Oxford UKR has increased in recent years[68]. It is hypothesised that as surgeons accumulate more experience and get accustomed to the design and implantation philosophy of Oxford UKR, their learning curve improves and patients achieve better outcome. To analyse whether the incidence of pain has changed over the years, two groups of 120 patients each were identified from the whole cohort.

(a) 'Old' group: initial cohort of 120 patients who had surgery from 1998-2001.

(b) ' New' group: recent cohort of 120 patients who had surgery from 2008-2011.

The groups were matched for age, gender, pre-operative OKS and pre-operative PS and the patients with less than one year follow up were excluded.

2.2.3 Detailed analysis of patients with pain at final follow up

Patients with the response of '0' to question number 1 of OKS, indicating severe pain at final follow up were identified (n=26), and a detailed analysis was undertaken to identify any factors that are associated with pain and poor outcome. This included an analysis of various patient related, surgeon related and implant-related factors that

have a direct, or indirect, effect on the functional outcome; in particular whether there was a mechanical cause of post-operative pain.

2.2.4 Outcome assessment using pain specific questionnaires

A consecutive series of 107 patients undergoing Oxford UKR were analysed pre-operatively and at one year-post operatively. In addition to the detailed OKS, ∆ OKS, PS and ∆PS; specific pain scores like painDETECT (Appendix 4) and Intermittent and Constant Osteoarthritis Pain[176] (ICOAP) (Appendix 5) were also collected. The painDETECT was devised to identify the difference between the neuropathic pain and nociceptive pain[177]. It is composed of questions about the graduation of pain, pain course pattern and radiation of pain. The maximum possible score is 38 and the minimum possible score is -1. A score ≤ 12 suggests that a neuropathic component is unlikely (< 15%), while a score ≥ 19 strongly suggests that there is a neuropathic component (> 90%). Between these two values, the result is uncertain[177]. The ICOAP score was originally developed for analysing joint pain after OA, but it has also been validated for use in hip and knee arthroplasty[176]. It comprises of 11 questions each ranging from 0-4. The first five questions measure the constant pain (ICOAP-C) and the next six questions measure the intermittent pain (ICOAP-I). The best score is 0 and the worst score is 44.

For the purpose of this study and comparative analysis, the ICOAP and painDETECT scores were standardised from 0 to 100 with higher scores representing a better outcome. The standardised response means (SRM's) were also calculated. This is calculated by dividing the mean change in score by standard deviation of the change in score. The SRM is a measure of responsiveness, where a higher score indicates an increased ability of a scoring system to detect change in a given patient group undergoing treatment that is expected to generate a change in their symptoms[178].

The patients complaining of moderate to severe pain at one year follow up (as measured by their response to question number 1 of OKS) were compared with the rest of patients for differences in ICOAP and painDETECT to identify any differences in characteristics of pain or pre-operative variables between the two groups.

To analyse whether the patients with unlikely pre-operative neuropathic pain (painDETECT score ≤ 12) achieve a different outcome compared to the patients where neuropathic pain is likely or uncertain (painDETECT score >12), these two groups of patients were matched for their pre-operative OKS, PS, response to question number 1 of OKS, and ICOAP score. The two groups were analysed for differences in their outcome measures.

2.2.5 Statistical analysis

Analyses were carried out with the statistical package SPSS for Windows (V.18, Chicago, Il, USA). The data was analysed for normalcy using visual inspection of histograms with normal curves, Shapiro-Wilk and Kolmogorov-Smirnov tests, where applicable. Non parametric analysis was performed using the Mann-Whitney U test for comparison between the two groups. For continuous data, Student's t-tests were used for two groups of variables and one-way analyses of variance (ANOVA) for more than two groups, followed by post-hoc Tukey analysis. For categorical data, Pearson's Chi-square test was used with statistical significance reached by a p-value of <0.05.

2.3 Results

2.3.1 Incidence of pain and its natural history

There was no significant difference ($p=0.234$ and 0.547 respectively) between the pre-operative OKS and one year OKS of the small group (180 patients) with six

weeks follow up compared to the larger cohort (>1100 patients). The data from these two studies was combined to identify the difference in the incidence of severe pain pre-operatively and at six weeks, one year and final follow up intervals.

At an average follow up of 4.05 years (SD: 2.4, range 1 to 12 years), the data shows that patients have the greatest increase in OKS during the first six weeks but keep improving until one year after the surgery. Their clinical scores then reach a plateau and there is little change (<1%) between the first year and their final follow up (Table 2-1, Figure 2-1, 2-2 and 2-3).

Scores	Mean	SD	Number of patients
Pre OKS	22.9	7.8	697
Pre PS	8.0	3.3	697
Pre OKS1	0.7	0.6	697
6 wk OKS	33.8	7.6	180
6 wk Δ OKS	10.9	1.0	180
6 wk PS	13.2	3.7	180
6 wk Δ PS	5.2	4.9	180
6 wk OKS1	2.2	1.0	180
6 wk Δ OKS1	1.5	1.2	180
1 yr OKS	40.4	7.7	1101
1 yr Δ OKS	17.5	11.7	697
1yr PS	16.7	3.8	1101
1 yr Δ PS	8.7	5.2	697
1 yr OKS1	3.0	1.1	1101
1 yr Δ OKS1	2.3	1.2	697
Final OKS	40.5	8.0	1101
Final Δ OKS	17.6	11.7	697
Final PS	16.8	3.9	1101
Final Δ PS	8.8	5.1	697
Final OKS1	3.0	1.1	1101
Final Δ OKS1	2.3	1.2	697

Table 2-1: Mean and standard deviation of clinical scores in patients with Oxford UKR. 'Final' refers to the functional outcome at the final follow up

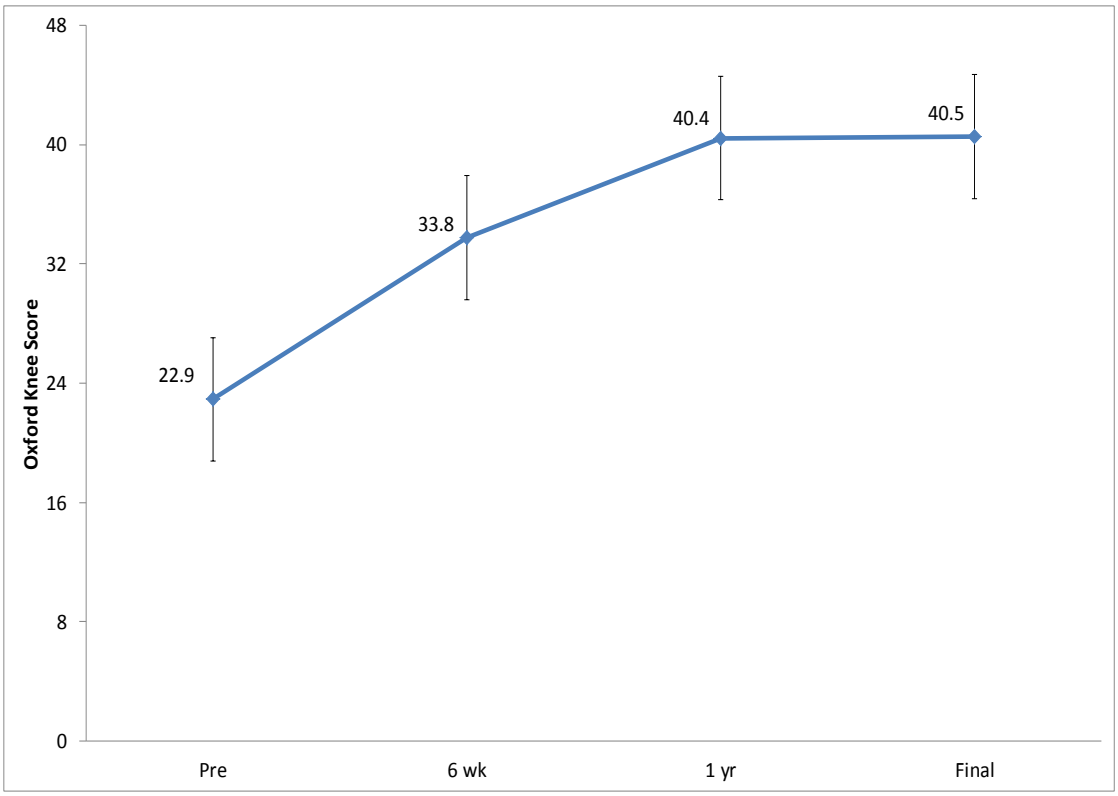


Figure 2-1: Mean OKS and the change in OKS from the pre-operative state to final follow up (range 1-12 years) (error bars represent standard errors)

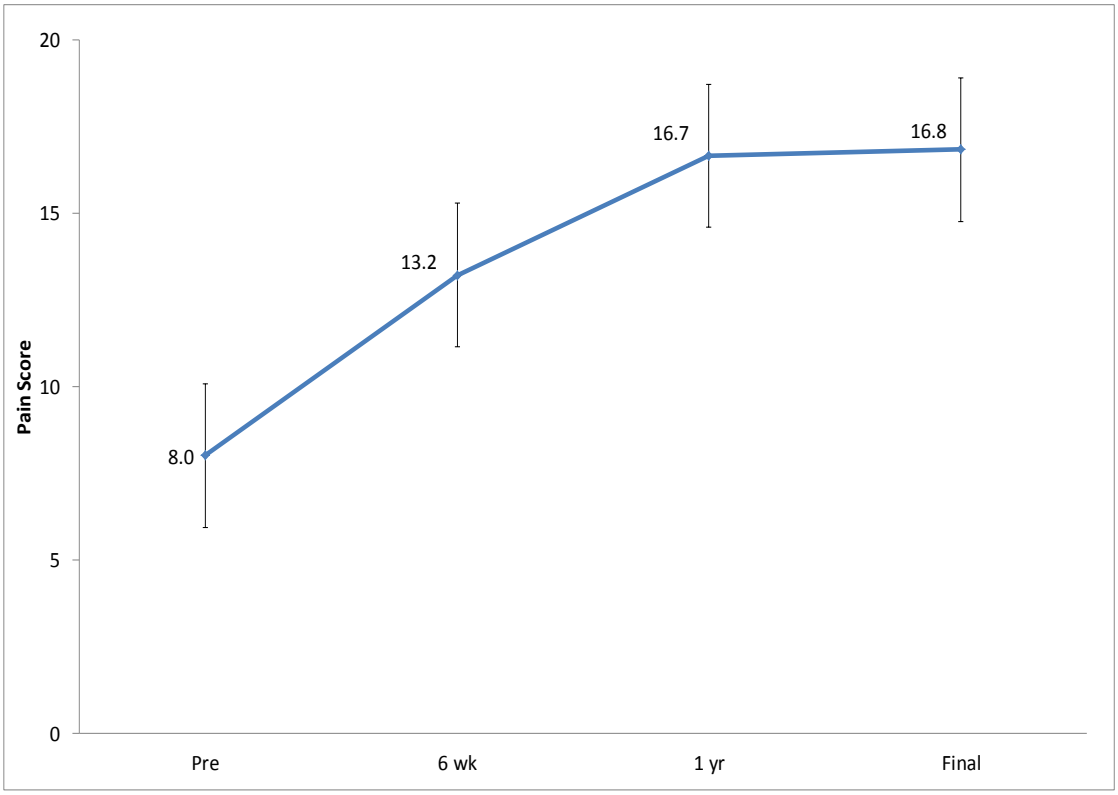


Figure 2-2: Mean PS and the change in PS from the pre-operative state to final follow up (range 1-12 years) (error bars represent standard errors)

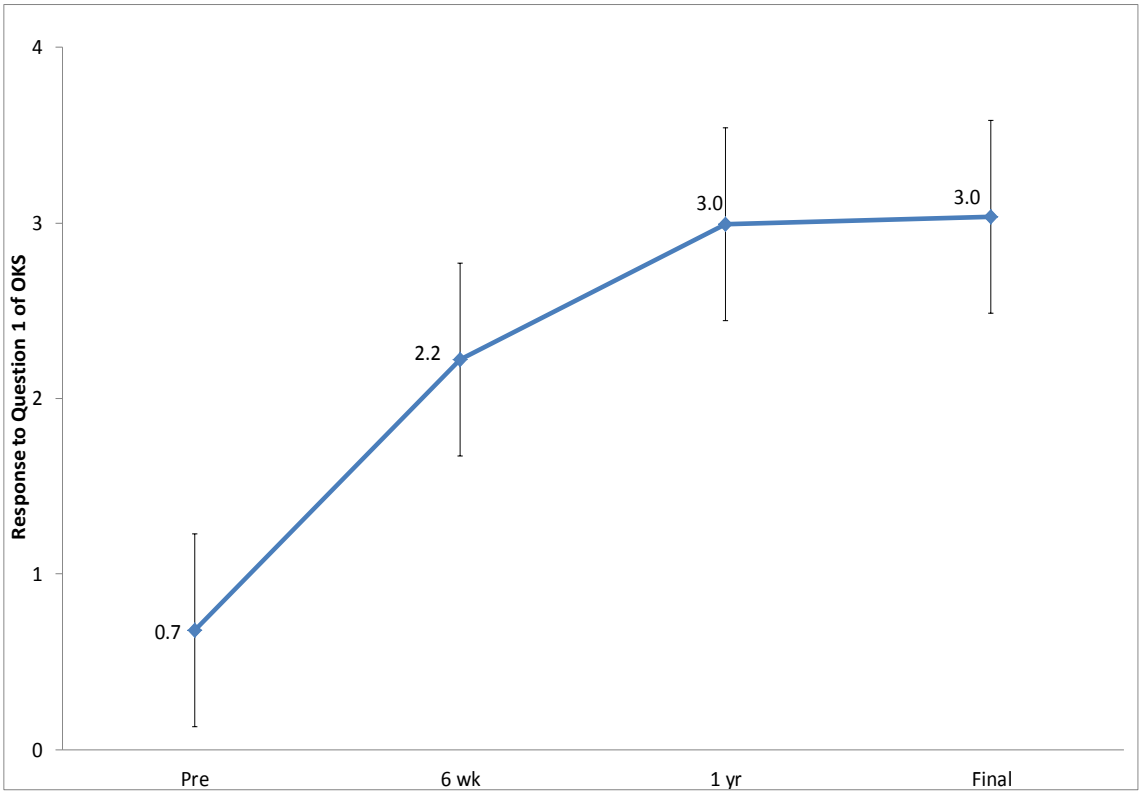


Figure 2-3: Mean response to question number 1 of OKS and the change in this response from the pre-operative state to final follow up (error bars represent standard errors)

The percentage of patients complaining of severe pain was based on their response to question number 1. Before the surgery, 41.5% had severe pain. The incidence reduced to 2.8% at 6 weeks and 2.1% at one year follow up (Table 2-2). There was little change in the incidence of severe pain between the first year and final follow up (2.2%).

Response to question number 1 of OKS	Pre-op	6 weeks	1 year	Final follow up
0 (severe pain)	41.5	2.8	2.1	2.2
1 (moderate pain)	49.1	26.1	12.8	11.3
2 (mild pain)	9.5	28.9	13.3	13.1
3 (very mild pain)	0	30.6	27.6	27.5
4 (no pain)	0	11.7	44.2	45.9

Table 2-2: Percentage of patients with their responses to question number 1 of OKS

2.3.2 The change in the incidence of pain with time

The 'Old' and 'New' groups were matched for pre-operative outcome scores and the demographic variables like age and gender were comparable (Table 2-3). The 'New' group of patients had significantly better Δ OKS compared to the 'Old' group. The OKS, PS, Δ PS and OKS1 were also better in the 'New' group but these were not statistically significant (Table 2-3).

Groups	**Old**		**New**		**Significance**
Gender (number)	**Males**	**Females**	**Males**	**Females**	
	52	68	54	66	0.791
Age (years)	**Mean**	**SD**	**Mean**	**SD**	
	67.0	9.5	65.8	10.5	0.091
Scores	**Mean**	**SD**	**Mean**	**SD**	
Pre OKS	20.7	9.5	20.9	5.5	0.339
Pre PS	7.1	3.1	7.3	2.8	0.360
Final OKS	38.0	10.0	41.1	6.7	0.078
Final Δ OKS	17.2	8.9	20.1	7.1	**0.044**
Final PS	16.0	4.5	17.1	3.7	0.079
Final Δ PS	8.8	4.3	9.8	4.0	0.130
Final OKS1	2.9	1.2	3.1	1.1	0.137
Final Δ OKS1	2.5	1.2	2.5	1.1	0.564

Table 2-3: Mean and standard deviation of clinical scores of Old and New group of patients with Oxford UKR when the groups were matched for pre-operative OKS, PS, response to question number 1 and age

The 'New' group of patients had significantly less incidence of severe pain compared to the 'Old' group. The incidence has decreased from 5% at final follow up in the 'Old' group to 2.3% at final follow up in the 'New' group (p=0.03).

2.3.3 Detailed analysis of patients with pain at final follow up

A total of 26 patients were identified, out of the whole cohort, who had severe pain at their final follow up, as determined by their response to question number 1 of OKS. Their detailed analysis was undertaken (Table 2-4). Three patients were revised. One was for progression of arthritis, one was for tibial component loosening and the third patient was revised to a TKR in South Africa; however the cause of revision is unknown.

	Mean	SD
Age (years)	64.5	11.2
Height (cm)	166.1	8.6
Weight (kg)	79.8	16.7
Gender	73% females, 27% males	
ACL status	58% Normal, 24% Synovial damage, 18% Longitudinal splits	
Involved femur	Partial thickness cartilage loss 5%, Full thickness cartilage loss 15%, Bone loss/exposed 80%	
Involved tibia	Partial thickness cartilage loss 5%, Full thickness cartilage loss 10%, Bone loss/exposed 85%	
Surgeon	CAFD 65%, DWM 35%	
Femoral component size	Small 39%, Medium 48%, Large 13%	
Tibial component (smallest to largest)	A 0%, B 10%, C 57%, D 29%, E 4%	
Bearing thickness	3mm 25%, 4mm 50%, 5mm 12%, 6mm 8%, 7mm 5%	
Pre OKS	16.4	6.4
Pre PS	5.5	2.5
Final OKS	18.2	9.2
Final PS	5.4	3.5
Final ΔOKS	0.6	8.9
Final ΔPS	-0.6	3.0

Table 2-4 Detailed analysis of patients with severe pain at final follow up

A mechanical cause of post-operative pain was identified in 9 patients (35%), but no obvious abnormality in either of the pre-operative, intra-operative or post-operative factors was found in the rest of the patients.

2.3.4 Outcome assessment using pain specific questionnaires

The raw and the standardised scores (Table 2-5 and Table 2-6) demonstrate that all the outcome scores improve after the surgery. The question 1 of OKS had the highest SRM (1.87) and the painDETECT score had the lowest (0.7).

Scores	Baseline	12 Months	Change	SRM
OKS	24.8, (9.5), 25	41.0, (7.0), 43	14.2, (10.0), 14	1.60
PS	8.6, (4.0), 8	17.0, (3.4), 18	8.4, (4.5), 8	1.83
FS	16.1, (5.8), 16	23.9, (3.9), 25	7.8, (5.8), 8	1.33
OKS 1	0.8, (0.7), 1	3.0, (1.0), 3	2.2, (1.1), 2	1.87
ICOAP	18.9, (8.4), 19	4.7, (7.0), 2	14.2, (10.0), 14	1.40
ICOAP-C	7.9, (5.5), 9	1.4, (3.0), 0	6.5, (5.5), 6	1.18
ICOAP-I	10.9, (5.5), 12	3.2, (4.3), 2	7.6, (6.9), 9	1.10
painDETECT	9.6, (6.3), 9	5.0, (5.4), 4	4.5, (6.5), 4	0.70

Table 2-5: Mean (standard deviation) and median of various outcome scores

Standardised Scores	Baseline	12 Months	Change
OKS	51.7, (19.8), 52.0	85.5, (14.7), 89.5	33.7, (21.0), 33.3
PS	43.3, (20.1), 40	85.3, (17.1), 90	42.0, (22.9), 40
FS	57.7, (20.8), 57.1	85.6, (14.0), 89.2	27.9, (20.9), 28.5
OKS 1	21.2, (18.4, 25	76.1, (25.5), 75	54.9, (29.2), 50
ICOAP	56.9, (19.2), 56.8	89.2, (16.1), 95.4	32.2, (22.9), 31.8
ICOAP-C	60.1, (27.4), 55	92.7, (15.3), 100	32.5, (27.5), 30
ICOAP-I	54.2, (23.1), 50	86.2, (17.9), 91.6	32.0, (28.8), 37.5
painDETECT	72.5, (18.2), 74.2	85.5, (15.5), 88.5	13.0, (18.6), 11.4

Table 2-6: Standardised mean (standard deviation) and median of various outcome scores

The patients complaining of moderate or severe pain at one year had a significantly higher (Table 2-7) mean pre-operative painDETECT score (13.8, suggesting a possibility of neuropathic pain), compared to the rest of the patients (9.0, suggesting that neuropathic pain is unlikely). In addition to the OKS, PS and FS, this group of patients also had worse ICOAP and painDETECT scores at one year follow up.

Groups	Patients with moderate or severe pain at one year		Patients with no, very mild or mild pain at one year		Significance
Scores	**Mean**	**SD**	**Mean**	**SD**	
Pre OKS	21.0	10	25.2	9.4	0.160
Pre PS	6.7	3.5	8.8	4.0	0.092
Pre FS	14.2	6.6	16.3	5.7	0.256
Pre OKS1	0.4	0.5	0.9	0.7	0.060
Pre ICOAP	20.0	7.4	18.8	8.5	0.640
Pre ICOAP-C	10.3	6.3	7.7	5.3	0.128
Pre ICOAP-I	9.7	6.9	11.1	5.4	0.432
painDETECT	13.8	9.2	9.0	5.7	**0.017**
1 yr OKS	28.2	11.1	42.5	4.6	**<0.001**
1 yr Δ OKS	3.1	11.7	15.4	9.1	**0.002**
1yr PS	10.7	4.5	17.7	2.3	**<0.001**
1 yr Δ PS	4.0	4.2	8 9	4.3	**0.001**
1 yr FS	17.5	6.8	24.7	2.6	**<0.001**
1 yr Δ FS	3.2	6.4	8.3	5.5	**0.006**
1 yr OKS1	0.8	0.4	3.3	0.7	**<0.001**
1 yr Δ OKS1	0.3	0.6	2.4	1.0	**<0.001**
1 yr ICOAP	16.9	12.2	3.3	4.6	**<0.001**
1 yr Δ ICOAP	3.1	11.7	15.4	9.1	**<0.001**
1 yr ICOAP-C	6.7	5.6	0.85	1.9	**<0.001**
1 yr Δ ICOAP-C	3.6	6.1	6.8	2.0	0.067
1 yr ICOAP-I	10.1	6.7	2.5	3.1	**<0.001**
1 yr Δ ICOAP –I	-0.4	9.4	8.6	5.9	**<0.001**
1 yr painDETECT	13.6	8.6	4.0	3.9	**<0.001**
1 yr Δ painDETECT	0.1	7.1	4.9	6.2	**0.020**

Table 2-7: Mean and standard deviation of various outcome scores in patients with moderate or severe pain (OKS Q1 ≤1) (n=11) compared with patients who do not have moderate or severe pain (OKS Q1 >1) at one year follow up (n=96)

The matched group of patients with likely or probable pre-operative neuropathic pain (painDETECT score > 12) achieved significantly less improvement in scores at one year compared to the rest of the patients (Table 2-8).

Groups	**Unlikely pre-operative neuropathic pain**		**Uncertain or likely pre-operative neuropathic pain**		**Significance**
Scores	**Mean**	**SD**	**Mean**	**SD**	
Pre OKS	21.7	4.7	21.3	8.2	0.834
Pre PS	7.5	2.2	7.2	3.2	0.682
Pre FS	14.1	2.9	14.0	5.2	0.952
Pre OKS1	0.7	0.6	0.7	0.7	0.848
Pre ICOAP	21	6.5	21	7.9	1.0
1 yr OKS	42.6	4.2	37.6	10.6	0.316
1 yr Δ OKS	20.9	4.6	16.3	11.0	**0.038**
1yr PS	17.9	2.3	15.6	4.9	0.130
1 yr Δ PS	10.3	2.4	8.3	5.0	**0.050**
1 yr FS	24.7	2.4	22.0	5.8	0.205
1 yr Δ FS	10.6	2.8	7.9	6.3	**0.042**
1 yr OKS1	3.2	0.8	2.7	1.3	0.238
1 yr Δ OKS1	2.5	1.0	2.0	1.3	**0.048**

Table 2-8: Mean and standard deviation of various outcome scores in a matched group of patients with possible or likely neuropathic pain (painDETECT score >12) and those with unlikely neuropathic pain (painDETECT score ≤ 12) (n=30 in each group)

2.4 Discussion

The actual incidence of pain following Oxford UKR is not clearly established. A study by Kim *et al.*[173] prospectively analysed 560 knees and found the incidence of persistent unexplained medial knee pain following Oxford UKR to be 1%. These assessments were performed at various time points and it is not clear from the paper, at which point the incidence of pain was recorded. The results are comparable to the

present study where the incidence of severe pain at one year and final follow up was about 2%.

The other end of the spectrum is a study by Edmondson *et al.* who studied patients with a minimum of three years follow up[163] and found medial knee discomfort to be present in 22 of their 40 patients (55%). These patients correspondingly had a low OKS (<37). The authors identified a few factors which could contribute to medial joint discomfort such as: impingement; an overhanging tibial component; errors in cementing; aseptic loosening of the femur or tibia; soft tissue irritation (MCL, Pes Anserinus); and neuroma formation. The fundamental weakness of this study was its retrospective design involving a small cohort. Furthermore, the study group only performed a few UKRs annually and it is well established that surgeons who perform less than one UKR per month achieve poor functional outcomes[162,179].

The current prospective study has a large cohort and demonstrates that knee pain improves rapidly after Oxford UKR. The incidence of severe pain, as demonstrated by the response to question number 1 of the OKS, is 3% at six weeks and 2% at one year. Thereafter, it does not change and remains at 2% until the last functional outcome. There is a much higher incidence of unexplained pain after TKR. A postal questionnaire sent to 9417 patients with TKR identified from the NJR data of England and Wales, demonstrates an incidence of persistent knee pain to be 19.8% at a minimum of 12 months following surgery[165]. This was assessed using individual responses to questions forming the OKS.

An important element of this study was to analyse the difference in distribution of OKS, PS and the incidence of severe pain following UKR in the ‘New’ group compared to the ‘Old’ group. The final outcome was better in the ‘New’ group. There are number of factors that could contribute to this, for instance an improvement in the

instrumentation of Oxford UKR and modification of the surgical technique. In addition, there is a better awareness of pre-operative and intra-operative patient related, implant-related and surgical factors that influence the functional outcome after Oxford UKR.

The instrumentation and the technique of cemented Oxford UKR have changed since its first introduction. The sagittal cut of tibia is now made just medial to the apex of the medial tibial spine. This is more lateral compared to the earlier years when it was placed lateral to the medial tibial condyle. Furthermore, the horizontal tibial cut is made higher. In addition, a toothbrush saw has been introduced (Figure 2-6) in place of the previously used flat sagittal saw. This prevents deep cuts when preparing the tibial keel slot. Furthermore, the surgical technique has been optimised allowing better alignment and position of implanted components.



Figure 2-4: Toothbrush saw and the previously used sagittal saw for cutting out a tibial keel slot (images courtesy of Biomet Oxford UKR surgical technique manual[180])

Nerhus *et al.*[181] recently performed a prospective multi-centre study involving 96 knees to analyse how patient reported outcome measures (PROMs), like OKS, change with time following Oxford UKR. A particular emphasis was laid on patients' self-reported pain and their daily function during the study period. The study found that although the OKS continued to improve until two years after surgery (Figure 2-5), there was only a small change seen after the first six months of surgery. The findings are consistent with this larger study of 1101 patients, which demonstrates that most patients plateau at about one year after surgery. Between one year and the last

functional assessment, there was very little change in patient reported outcome measures of both the present study and that of Nerhus *et al.*[181]. This effect is manifested in not just the pain specific questions (OKS 1 and PS) but also in the absolute and change in OKS, which relates to the overall functional outcome.

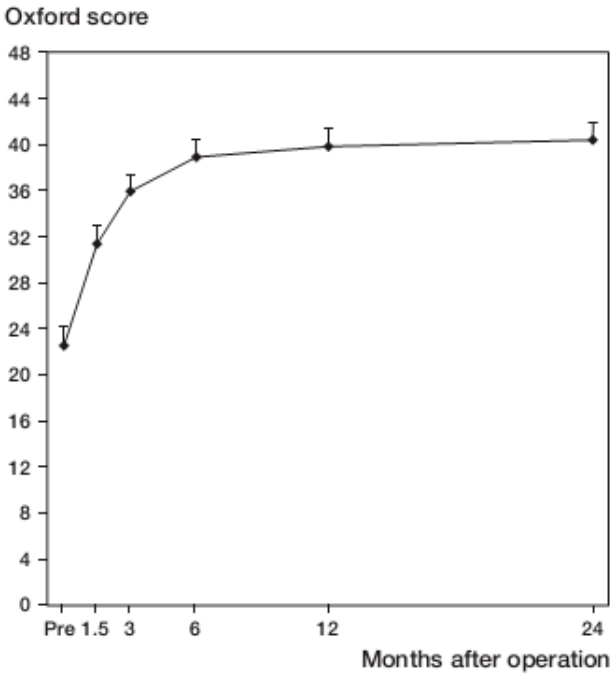


Figure 2-5: Change in OKS over 24 months[181]

It is interesting to note that subjective assessment of patient function using PROMs (OKS in this study) demonstrate ongoing improvement. The present study shows an improvement up to one year following the surgery but Nerhus *et al.*[181] demonstrated improvement up to two years post-operatively. This difference could partly be due to the fact the NJR data collates data from several centres and hence is unable to eliminate the effect of confounding factors like pre-operative patient selection, surgeon's surgical technique and experience and the post-operative rehabilitation programme. The clinician-based scores (like AKSS) do not demonstrate any significant improvement after six months[181]. This emphasises the importance of measuring the patient's own experience of disability using self-reported questionnaires following a joint replacement surgery. Another study, however, demonstrates that AKSS continue to improve up to 3 years after Oxford UKR[173].

Dieppe *et al.*[182] studied a group of patients (n=21) who complained of unexplained knee pain of at least 6 months duration, after Oxford UKR. The authors categorised them into three distinct groups depending on their primary pain symptom, characteristics of pain and their examination findings. These were: Pain of mechanical origin (33.3%); Neuropathic-like pain (33.3%); and Infero-medial UKR pain (33.3%). All patients with neuropathic pain were females. The study group recognised a particular group of patients who had a distinct infero-medial pain, which radiated to the front of the tibia and concluded that this might be related to increased intra-osseous pressure below the tibial implant. They were however unable to explain why certain patients develop, or are more susceptible to, this pain. The study was also unable to identify any factors, which may aid in the pre-operative identification of such patients. The current study also identified a mechanical cause of pain in 35% of patients such as an overhang, partial thickness cartilage loss (PTCL), pathological radiolucency and tibial component malalignment. No obvious cause could be determined in the rest of the patients.

It is not surprising to note that all outcome measures including OKS, ICOAP and painDETECT improve after surgery; however OKS1 and PS had the highest SRMs with standardised changes of about 55% and 42% respectively. On the other hand, painDETECT score, with the lowest SRM, only changed by 13% and ICOAP by 32%. This implies that OKS1 and PS are more valuable in detecting the change in outcome between the pre-operative and follow-up states than the ICOAP and painDETECT scores. The low SRM of ICOAP compared to other pain scores has already been established[176], however there has been no previous study comparing the OKS with ICOAP or with the painDETECT score.

Patients with likely or probable pre-operative neuropathic pain achieved a significantly worse outcome compared to the rest of the patients. Furthermore, the patients with moderate or severe pain at one year had significantly worse pre-operative painDETECT scores. Based on numbers too small to make firm conclusions, it is apparent that the use of the painDETECT score helps to some extent in identifying patients who will not do well after Oxford UKR. It is, however, not clear whether it is the best screening measure for such purpose; further research is needed to clarify this issue.

The major strength of this study is that it is a prospective study with a large cohort (>1100 patients). The detailed individual responses to the 12 questions forming the OKS were available, thereby allowing an accurate estimation of PS and incidence of severe post-operative pain as assessed by the response to question number 1 of the OKS. In addition, the availability of ICOAP and pain DETECT scores allowed comparison with the components of OKS for analysis of patients complaining of post-operative pain.

This study has some limitations. Although absolute and detailed OKS were available for all, the pre-operative OKS and one year OKS was missing in some patients. The calculation of Δ OKS and Δ PS was therefore carried on a smaller cohort (n=697). Nevertheless, there was a sufficient sample size, allowing meaningful statistical analysis. Although, the ‘New’ and the ‘Old’ groups were matched for various pre-operative and demographic variables, it is possible that there were some other confounding variables within the groups, which were not fully eliminated. Furthermore, this study did not analyse why the patients in the ‘Old’ group had a less satisfactory outcome compared to the ‘New’ group. This is because the main aim of this study was to analyse the incidence and the natural history of pain following UKR and whether this has changed over the years

2.5 Summary

This study demonstrates that the functional outcome of Oxford UKR has improved over the last 10 years and there are number of factors that may contribute to this effect. The incidence of severe pain after Oxford UKR is 3% at six weeks and 2% at one year and at a medium-term follow up. Patients with probable pre-operative neuropathic pain tend to do badly after Oxford UKR. There are number of other possible reasons why patients after UKR could have pain and hence a poor functional outcome. These factors will be fully analysed later in this dissertation.

3. THE SEVERITY OF ARTHRITIS AFFECTING THE OUTCOME AFTER OXFORD UKR[183]

3.1 Introduction

The successful outcome of UKR can only be achieved consistently if the implant is used for appropriate indications. The most common indication for UKR is medial compartment OA[184]. Although there is considerable debate about the suitable indications and contraindications[108,124], the surgeons who originally designed the Oxford UKR have always strongly recommended that UKR should only be performed on patients with medial OA if there is full thickness cartilage loss (FTCL)[108,185]. This recommendation, however, is based on anecdotal evidence that patients with pain following UKR frequently have pre-operative radiographs demonstrating only partial loss of the medial joint space.

Despite the recommendation that the Oxford UKR should only be implanted if there is bone-on-bone articulation in the affected compartment[185], the surgery is sometimes performed in patients with partial thickness cartilage loss (PTCL). It is not known whether such patients achieve equivalent outcome compared to patients with FTCL and how the severity of arthritis affects the functional outcome.

3.2 Methods

3.2.1 Patient selection

From the prospectively collected data as described in section 2.2, patients undergoing UKR with a primary diagnosis of degenerative OA were included in the study. Patients with other causes such as avascular necrosis (AVN) were excluded. In addition to clinical and radiographic data, intra-operative surgical findings were recorded in a systematic fashion on a standardised operation form. Intra-operatively,

the state of the medial and lateral compartment, the patello-femoral joint and the ACL were assessed. On this form, the state of the articular cartilage on the medial tibial and femoral condyles was classified into seven grades (Table 3-1):

Grade	Articular cartilage damage
1	normal
2	superficial damage
3	partial thickness cartilage loss
4	focal full thickness cartilage loss
5	extensive (>2 cm^2) full thickness cartilage loss
6	bone loss <5mm thick
7	bone loss >5mm thick

Table 3-1: Degree of articular cartilage damage as recorded on the standardised form

From the articular damage grade, a group of patients with PTCL were identified. This group consisted of all the patients who had a grade 3 or lower lesion on either the medial tibial or femoral condyle (but not necessarily both). Having identified these patients (n=29), they were matched for age, gender, pre-operative OKS and follow up period to two other groups; the bone exposed (BE) group and the bone loss (BL) group. In the BE group (n=29), there was FTCL but no bone loss (grade 4 or 5) on both the medial tibial and femoral condyles. In the BL group (n=29), there was bone loss (grade 6 or 7) on both the medial tibial and femoral condyles. The outcome of these three groups was compared.

Of the patients in the PTCL group, 7 out of the 29 knees had PTCL on both the femur as well as the tibia; the remaining 22 had PTCL on one side and FTCL on the other (21 with BE, one with BL). All patients satisfied the recommended indications[108,185] for the Oxford UKR except for the status of the medial compartment. Thus they all had full thickness cartilage laterally and functioning ACL and MCL[185].

3.2.2 Assessment

All patients underwent a standard post-operative rehabilitation programme and were assessed pre-operatively and at regular intervals and post-operatively by an independent physiotherapist in a dedicated research clinic. For this study, the pre-operative data and the clinical data at the latest follow-up was used for analysis. The clinical outcome was assessed using the OKS. Complications and revisions were also recorded.

The primary outcome measure was the ΔOKS from the pre-operative value to the final follow-up value. The groups were also compared for total OKS and the proportion of patients that were considered not to have benefited substantially from surgery. A patient was considered not to have benefited substantially from surgery if ΔOKS ≤ 6[140].

3.2.3 Statistical Analysis

A non-parametric analysis of the scores from each group was performed with the Kruskal-Wallis test. Pearson's chi-square test was used for categorical data. Significant differences were demonstrated by a $p<0.05$[186]. All analysis was carried out using the statistical package SPSS for Windows (Version 16.0, Chicago, IL, USA).

3.3 Results

There was no statistically significant difference between the three groups in terms of age, gender or time to follow up (Table 3-2).

	PTCL	BE	BL	Significance
Number of patients	29	29	29	
Age (years)	62 (SD:10.4) [40-82]	60 (SD:8.5) [40-81]	63 (SD:11.9) [41-81]	0.313
Gender Male	12	13	12	0.893
Female	17	16	17	
Follow up (years)	2.1 (SD:1.0)	2.1 (SD:1.1)	2.1(SD:1.3)	0.454

Table 3-2: Demographic and pre-operative variables between the groups (PTCL, BE and BL)

PTCL Group: The mean pre-operative OKS was 21.6 (SD: 7.7, range: 10 to 39) which improved to 36.4 (SD: 9.9, range: 12 to 48) at the last follow-up (Table 3-3). The mean change in OKS was 14.8 (SD 11.2, range: -9 to 38). Four out of 29 patients developed complications, all of which were related to pain: one had an ultrasound guided injection; one had an arthroscopy; one had a manipulation under anaesthetic for pain and stiffness; and one developed chronic regional pain syndrome which was treated conservatively. None of the radiographs at the last follow up showed any evidence of infection, component loosening or progression of arthritis.

BE Group: The mean pre-operative OKS was 21.7 (SD: 5.6, range: 12 to 33) which improved to a mean OKS of 43.1 (SD: 3.9, range: 36 to 48) at the time of last follow-up (Table 3-3). The mean change in OKS was 21.4 (SD 5.6, range: 9 to 30). One patient complained of pain at two year follow up. No other patients developed any complications or needed any further surgery. None of the radiographs at the last follow up showed any evidence of infection, component loosening or progression of arthritis.

BL Group: The mean pre-operative OKS was 20.8 (SD: 7.2, range 7 to 34) which improved to 42.6 (SD: 4.6, range: 33 to 48) (Table 3-3). The mean change in OKS was 21.8 (SD 6.8, range: 7 to 33). None of the patients developed any complications or needed further surgery. None of the radiographs at the last follow up showed any evidence of infection, component loosening or progression of arthritis.

Groups	**OKS (SD)**		
	Pre-op	**Follow up**	**Change**
PTCL	21.6 (7.7)	36.4 (9.9)	14.8 (11.2)
BE	21.7 (5.6)	43.1 (3.9)	21.4 (5.6)
BL	20.8 (7.2)	42.6 (4.6)	21.8 (6.8)
p-value	0.65	<0.001	<0.01

Table 3-3: Oxford Knee Scores for the three groups (PTCL, BE and BL)

There was no statistically significant difference in pre-operative OKS between the three groups. There was no difference between the BE or BL groups at any stage. The improvement in the mean OKS in both the BE and BL group was greater than in the PTCL group (45% and 47% increased, respectively) and the difference was statistically significant ($p < 0.01$), (Table 3-3). Similarly the BE and the BL group had a significantly ($p < 0.001$) higher total OKS at final review compared with the PTCL group. The variability in the OKS at last follow up was substantially higher in the PTCL group than in the other two groups (Figures 3-1 & 3-2). The outcome was consistently better in the BE and BL groups but not in the PTCL group (Figure 3-3).

The proportion of patients (6/29 = 21%) that did not achieve substantial benefit from surgery ($\Delta OKS \leq 6$) was significantly higher ($p=0.04$) in the PTCL group than in the BE (0/29) or the BL (0/29) groups.

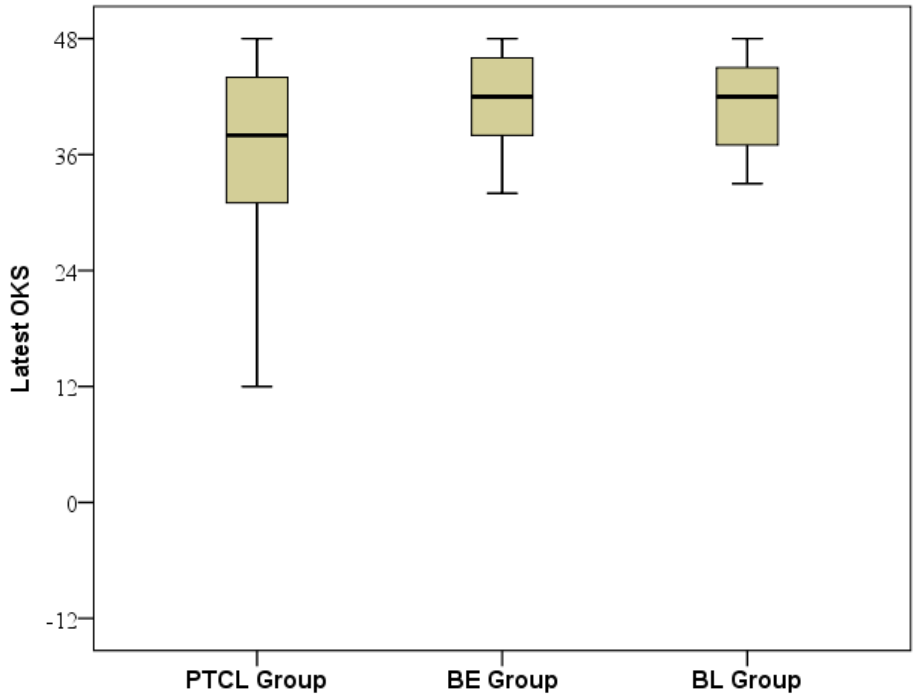


Figure 3-1: Box and whisker plot showing OKS at the last follow up for the three groups (PTCL, BE and BL)

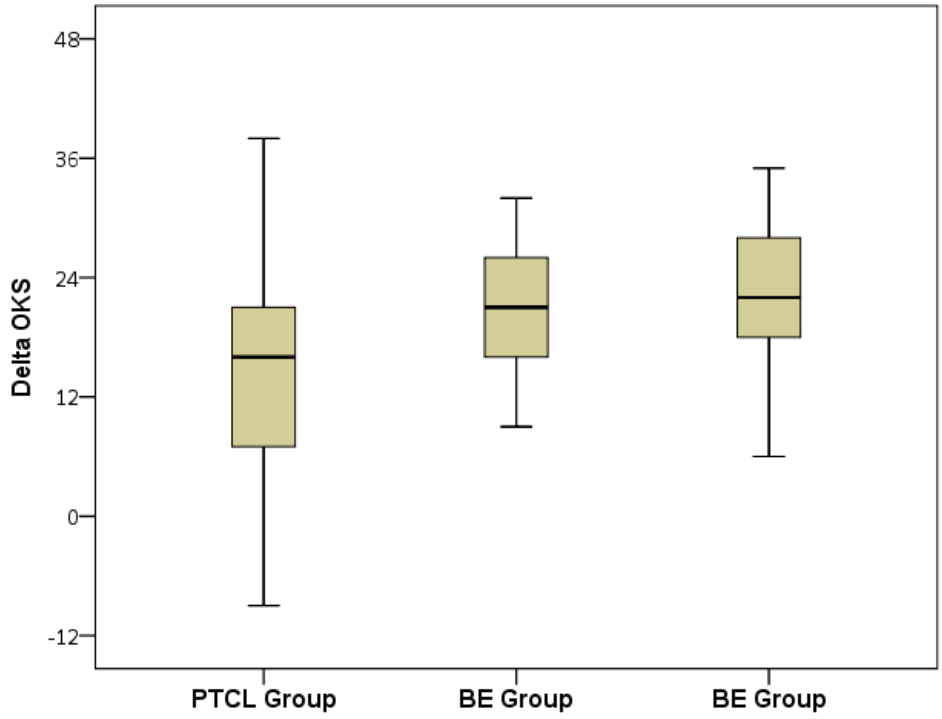


Figure 3-2: Box and whisker plot showing change in OKS for the three groups (PTCL, BE and BL)

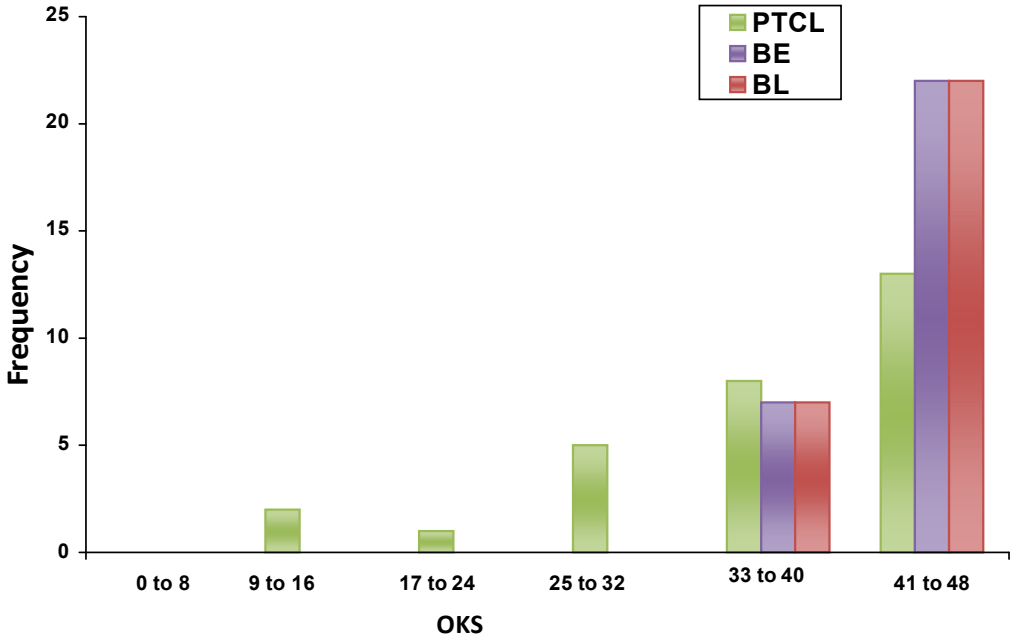


Figure 3-3: Bar chart showing distribution of the OKS at last follow up in the three groups (PTCL, BE and BL)

The mean OKS for the patients with PTCL on both sides was 31 (range: 18 to 46) and for those with PTCL on one side was 38 (range: 12 to 48). Three out of seven with PTCL on both sides did not have substantial improvement, whereas three out of 29 with PTCL on one side did not have substantial improvement.

3.4 Discussion

In the past decade the popularity of Oxford UKR has increased[187]. The reasons for this include: the introduction of reliable instrumentation for implantation through a small incision with minimal disturbance of the extensor mechanism, resulting in rapid recovery and decreased morbidity[98]. In addition, the publication of good long term results from a number of centres[108-110,188] and short term evidence demonstrating high levels of function due to normal kinematics and proprioception as a result of a functioning cruciate mechanism[189] has also contributed to the increasing usage of Oxford UKR.

The most common indication for Oxford UKR is antero-medial OA. The traditional method to quantify the severity of medial OA is with the Kellgren and Lawrence assessment of AP radiographs[46,190]. PTCL is scored as Grade 1 or 2, whereas FTCL is Grade 3 or 4. If a radiograph is of good quality and there is FTCL, then there will be bone-on-bone articulation. If there is PTCL on a radiograph, there may or may not be bone-on-bone articulation; so further assessment is required. This can include: standing weight bearing or standing flexed weight bearing (Rosenberg) radiographs[191]; varus stress radiographs with the knee flexed at 20 degrees[185] or arthroscopy. The recommendations from the manufacturers are that Oxford UKR surgery should only be performed if bone-on-bone articulation is demonstrated by one of these techniques[108,185].

As the understanding of medial compartment OA has grown, the indications for UKR have broadened[192,193]. Similarly, the expectations of patients and their general practitioners have changed. Patients want smaller incisions, shorter hospital stays and earlier achievement of functional goals[194,195]. In general, it is believed that UKR helps to achieve these goals if performed at the correct time, especially before the OA has progressed too far. This can sometimes cause early referral and a demanding patient who wishes to have a UKR for symptoms that may not be particularly severe (senior supervisor's personal experience).

There are many patients with severe pain and limited function, who have extensive and substantial cartilage damage in the medial compartment but who do not have bone-on-bone articulation. Typically, radiographs of these patients show the presence of PTCL rather than FTCL. If these patients continue to have severe symptoms despite conservative and arthroscopic interventions, the next logical therapeutic intervention would be a HTO or joint replacement.

If a surgeon is persuaded into replacing a joint, despite there not being bone-on-bone articulation, the surgeon will want to do the most bone conserving operation. As these patients tend to be young and active with high expectations, the surgeon may select the Oxford UKR as it is known to work well in young active patients (with bone-on-bone articulation)[194]. As a result, despite the recommendation that the Oxford UKR should only be implanted in patients with bone-on-bone articulation, some are implanted in patients with PTCL[196].

The results confirm that patients do well following Oxford UKR, provided there was bone-on-bone articulation of the joint. The outcome was found to be equally good whether there was bone exposed or bone loss. However, in patients with PTCL, the change in OKS was approximately 50% reduced. The difference in scores between those with PTCL and those with bone-on-bone articulation was both statistically significant and clinically important (7 OKS points). The distribution of the data (Figure 3-3) suggests that patients with PTCL tend to do worse than those with bone-on-bone articulation; in addition, about 20% of the PTCL group had no benefit from the surgery ($\Delta OKS \leq 6$). A subgroup analysis (based on numbers that are too small for firm conclusions) suggests that with less severe damage, the results are even more unpredictable: with PTCL on both the femur and the tibia about 50% have no benefit from surgery.

It seems counter intuitive that following Oxford UKR, patients have a worse outcome if they have mild rather than moderate or severe OA. There are at least two possible reasons for this observation. Firstly, the patients with PTCL may have higher expectations and a lower tolerance to pain so are less likely to be satisfied. Secondly, as cartilage does not have a nerve supply[197], it is possible that the origin of the knee pain is due to pathology elsewhere. Post mortem studies of asymptomatic knees

have shown a high incidence of partial thickness cartilage damage in the medial compartment confirming that this is usually not a source of pain[198]. When a patient with PTCL presents to a clinician, it is difficult to confirm the exact origin of the pain even if great care is taken to rule out pain referred from other sources. It is therefore likely that the reason why 20% of patients with PTCL did not benefit from surgery was that their pain was not arising from the articular cartilage in the medial compartment of the knee. As an example, hip OA is known to cause pain around the knee in 47% of patients[199].

Revision of UKR, particularly in patients with no mechanical problems, is usually straight forward and requires only standard primary TKR components[106]. As a result many patients who initially had UKR for PTCL may undergo revision to a TKR and in turn many may continue to have poor outcome. This sequence of events may explain in part some of the observations made by national registers that the incidence of revision for pain is higher in UKR than TKR and that revisions of UKR to primary TKR have worse results than primary TKR[68,107,159]. An association between a lower pre-operative grade of radiographic OA (Kellegren-Lawrence <3) and a high incidence of pain post-operatively, has already been established for TKR[168].

The recommendation that patients with medial OA should only have a UKR if they have bone-on-bone articulation should therefore be strengthened, because now there is evidence that about 20% of these patients do not benefit from the surgery. The converse, however, is that about 80% of patients with PTCL do achieve satisfactory outcome (ΔOKS >6). Currently there is no method of predicting which patients will benefit and which will not after Oxford UKR. There is a need for such a method, as there are many patients with knee pain and medial compartment PTCL. It is rare to have FTCL loss on one side and PTCL loss on the other side, except in the case of spontaneous osteonecrosis of the knee (SONK) or AVN, in which the

unaffected bone in the involved compartment may be relatively normal. In the case of SONK, Oxford UKR is not contraindicated[185]. In actual fact, the results of Oxford UKR in these conditions are comparable to that for OA[200,201].

The results of Oxford UKR depend on careful selection of patients. There are a number of possible investigations that might predict outcome post-operatively. For example a good result might be predicted by a hot spot on bone scanning, subchondral change on MRI scanning, or a positive response to an intra-articular injection. Often, good quality AP and Lat plain radiographs provide valuable information. Niinimäki *et al.*[196] studied pre-operative standing weight bearing radiographs in 113 knees taken in extension and found the re-operation rate to be six times higher when the thickness of the pre-operative medial joint space was >2 mm and eight times higher when the thickness of the pre-operative medial space was >40% of the thickness of the lateral space. Further research is needed to assess these and other techniques.

3.5 Summary

Patients undergoing medial UKR reliably achieve excellent clinical outcome only if the criterion of the pre-operative presence of FTCL in the medial compartment is met. Patients with PTCL have a less predictable outcome and a higher proportion do not benefit from their surgery. The surgeon should be very careful when suggesting Oxford UKR to such patients.

4. THE EFFECT OF COMPONENT ALIGNMENT ON CLINICAL AND RADIOLOGICAL OUTCOMES AFTER OXFORD UKR[202]

4.1 Introduction

Ever since the minimally invasive approach for Oxford UKR was described[203], there has been a debate over the accuracy of implantation of UKR components[98,204,205]. Although the recovery time and the hospital stay has considerably reduced[98], many surgical landmarks are obscured during the operation and hence intra-operative orientation and positioning of the components can be difficult[206]. In addition, the surgery is technically demanding[207].

The manufacturer[180] has recommended arbitrary guidelines for component positioning which are not evidence based. Furthermore, it is not known whether malalignment of Oxford UKR components affects the functional outcome and contributes to pain and poor function. The aim of this chapter is to examine the influence of component alignment on outcome and to assess acceptable ranges of alignment.

4.2 Patient selection

The data was gathered prospectively and patients who underwent primary UKR from January 1998 to March 2002 were identified. Only patients with isolated OA of the medial compartment of the knee, confirmed at the time of the surgery, were included. Patients were excluded if AP and Lat radiographs were not available or there was less than five years of clinical follow up.

Oxford UKR performed in a total cohort of 183 patients met the selection criteria; 155 patients had unilateral implantation and 28 had bilateral implantation. There were 82 males (95 knees) and 101 females (116 knees) in the study, comprising a total of 211 knees. The mean age at surgery was 66.3 years (SD: 9.4 years, range: 36.1–85.7 years), the mean body mass index (BMI) was 28.1 (SD: 4.9, range: 14.9–44.2). The mean follow-up was 5.2 years (SD: 0.6 years, range: 4.0 to 7.9 years). The operations were carried out by two senior orthopaedic consultants in the hospital, using cemented Phase 3 Oxford UKR components (Biomet UK Healthcare Ltd, Swindon, UK) with the minimally invasive approach.

All 211 knees with AP and Lat radiographs and five year clinical follow up were included for the assessment of their component alignment. Out of these 211 knees, only 164 knees had screened radiographs with radiographic beam parallel to the tibial component, thereby allowing an accurate assessment of tibial component size and radiolucency underneath the tibial component. The knees that were excluded for radiographic analysis had the X-ray beam excessively rotated relative to the components (Figure 4-1). These radiographs were identified by comparing the width of the vertical tibial wall on the radiographs with the actual width of the tibial component. The radiographs were deemed to be ‘perfectly aligned’ if this measurement was within ± 5% of the actual tibial component vertical wall width. None of the patients from the entire cohort of 211 was lost to follow up or was revised due to tibial component loosening.



Figure 4-1: A poorly aligned radiograph which was excluded from the radiographic study

4.2.1 Clinical assessment

The main outcome measure was the total OKS (0-48). In addition to the absolute value of OKS, the change in OKS (Δ OKS), PS (0-20) and the change in PS (Δ PS) at five year follow up were also calculated.

4.2.2 Radiological assessment

AP and Lat radiographic images were scanned digitally at 300 dpi resolution and converted to JPEG format (Epson Expression 1640XL scanner with Transparency Unit, Epson, California, USA) for further evaluation. The magnification was calculated by comparing the radius of curvature of the spherical femoral component on the digital image, with the known implant size that was used during the surgery.

On AP views, the varus/valgus alignments of the femoral and tibial components were measured relative to the long axis of the tibia, which was defined as a line drawn from the centre of the knee along the medullary canal of the tibia[205] (Figure 4-2).

On lateral views, flexion/extension of the femoral component was measured relative to the posterior femoral cortex, and for the tibial component, relative to the posterior tibial cortex (Figure 4-3).

Neutral was considered to be 0º for femoral valgus/varus and flexion/extension, and for tibial valgus/varus. Varus was considered negative and valgus was considered positive. A 7º posterior-inferior tilt of the tibial component was taken as neutral[185], as this is the average slope of the tibial plateau. Any tibial component tilt more than 7º was considered positive and any tilt less than 7º was considered negative. All measurements were made using Image J (version 1.46), a java based image processing program (National Institute of Health, USA).

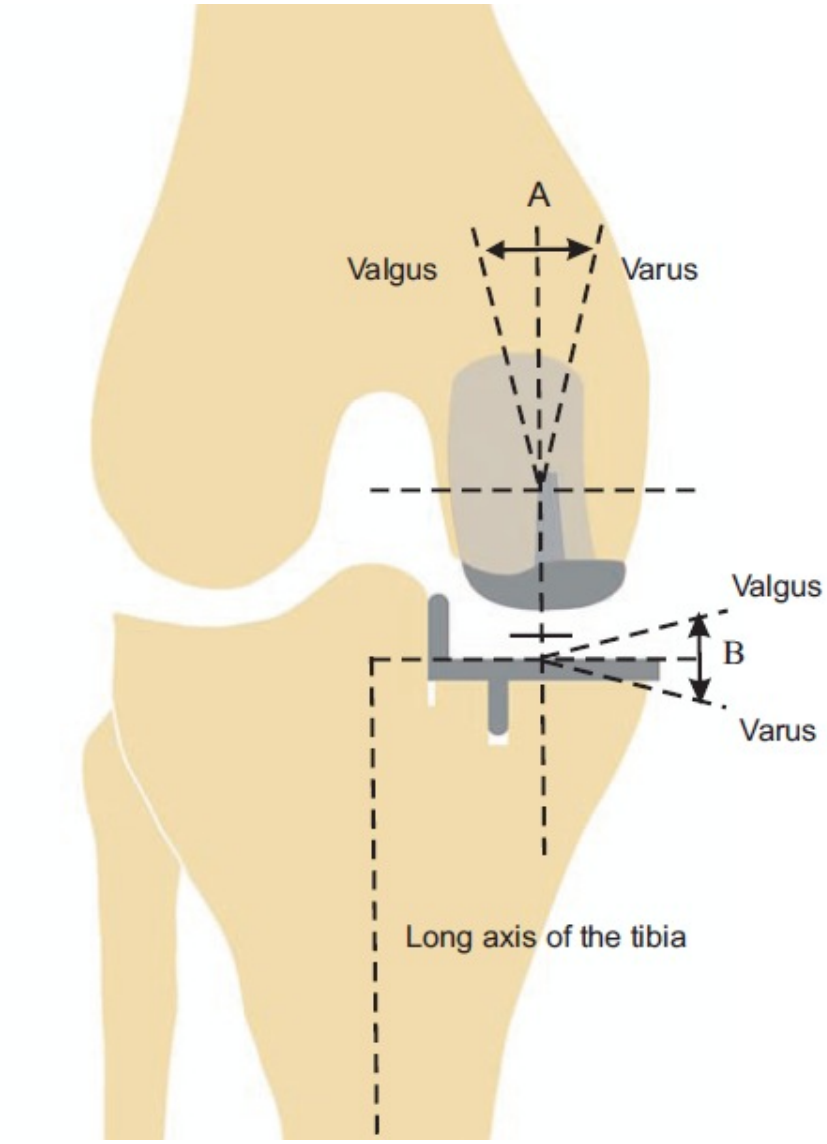


Figure 4-2: Measurement of coronal alignment of components

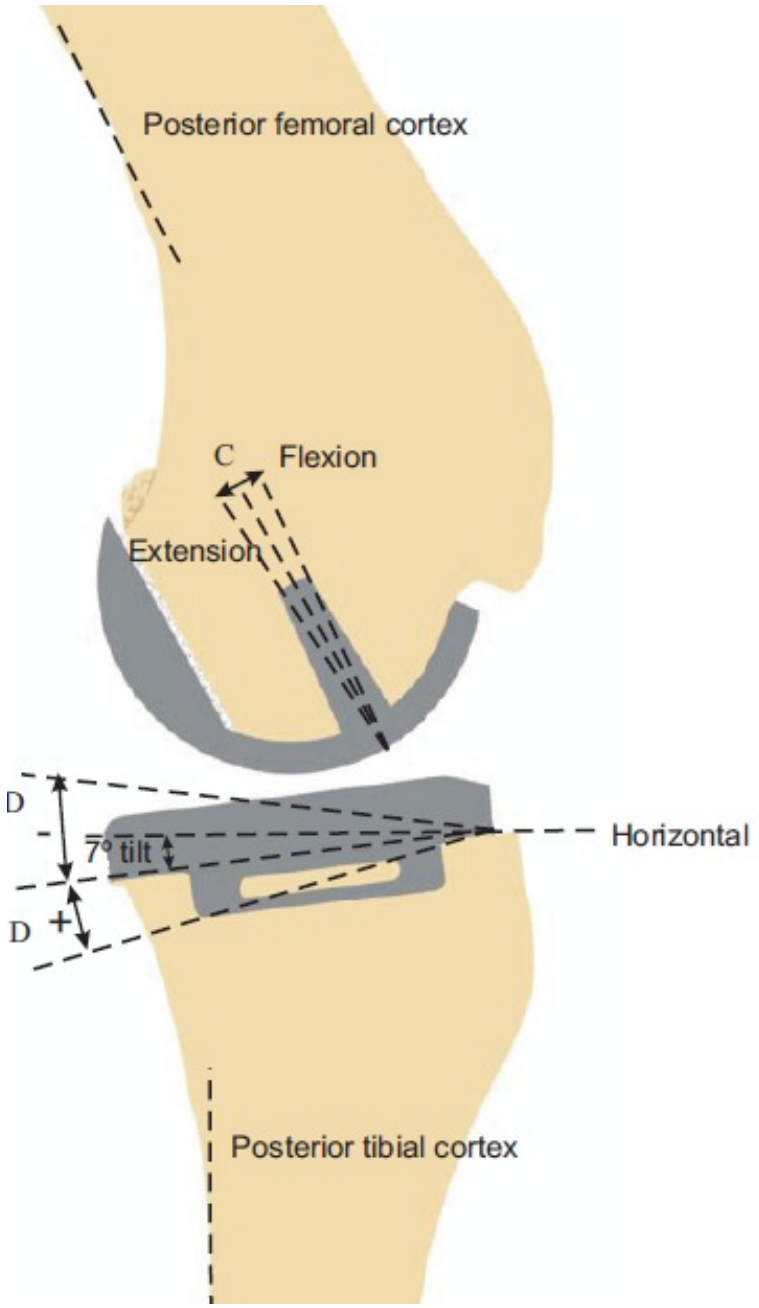


Figure 4-3: Measurement of sagittal alignment of components

The images were also checked for regions of radiolucency (RL) around the tibial component. The area under the tibial implant was divided into six regions[145] and the presence of RL recorded for each region (Figure 4-4).

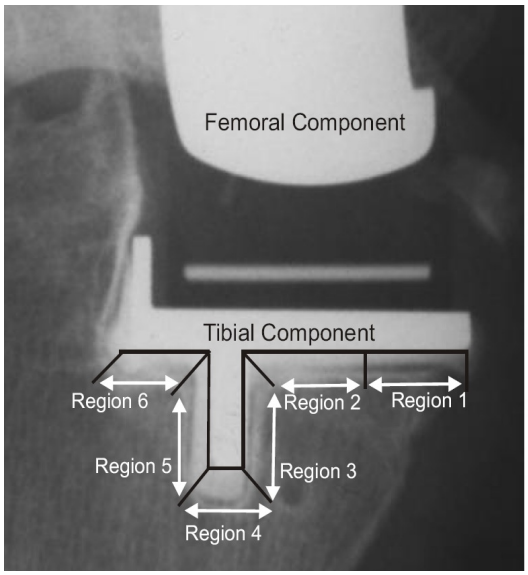


Figure 4-4: Definition of the regions of radiolucency under the tibial component

Radiographic magnification was determined by comparing the apparent radius of curvature in the femoral component on the digital image to the implant size obtained from the operative data. Since the articulating surface of the femoral component of Oxford UKR is spherical, any femoral tilting does not alter the measured radius of the femoral component on the radiographs. The digital images were scrutinised for RL around the implanted tibial tray. Where RL was detected, measurements of the length and width of each radiolucent area was made, using custom software written (courtesy H Gray) in Matlab (v.7.0, Mathworks, Newton, MA, USA).

4.2.3 Analysis

For each parameter measured, components that deviated from neutral were grouped at consecutive 2.5º intervals. The relationship between the interval groups for each of the femoral and tibial parameters and the five year OKS, Δ OKS, PS and the number of regions with RL was analysed. The data was not normally distributed. Non parametric analysis was therefore performed using the Kruskal-Wallis test for comparison between the groups. The Pearson Chi-squared test was used for comparison between the groups and the RL regions.

The distribution of the data was used to identify the common range of alignment for each of the alignment parameters. To ensure every alignment interval within the implanted range was acceptable, the outcomes of those at the extremes of the range were compared with the remainder.

A significant difference was demonstrated by a p-value < 0.05. All analyses were carried out using the statistical package SPSS for Windows (v.18.0, Chicago, IL, USA). The images were assessed by two independent observers. Inter-observer reliability was assessed when two observers measured the alignment in 20 knees. The intraclass correlation coefficient (ICC)[208] was calculated using a two-way mixed model, with a statistical significance set at 95%. The differences between the measurements of the two observers were calculated (Mean 0.6º, SD 0.25) giving an accuracy (2SD) of 0.5º. The ICC was 0.91.

4.3 Results

The average OKS was 40.3 (SD: 8.2, range 12 to 48). The presence or absence of radiolucencies was assessed in 164 radiographs, which were perfectly aligned. There were no cases with femoral radiolucencies and 101 knees (62%) had radiolucencies under the tibial components. These were all radiolucent lines of one milimetere thickness or less and all had sclerotic margins.

4.3.1 Valgus/varus of femur

Ninety percent of the components were between 8.4º varus and 5.1º valgus. The mean position was 1.4° varus (SD: 4.0, range: 8.9º valgus to 12.5º varus) (Figure 4-5, Table 4-1). There was no significant difference in the OKS (p=0.672) (Figure 4-6), ΔOKS (p=0.544), PS (p=0.342), Δ PS (p=0.237) or the number of regions with RL (p=0.696), between the groups of varying varus/valgus femoral angle.

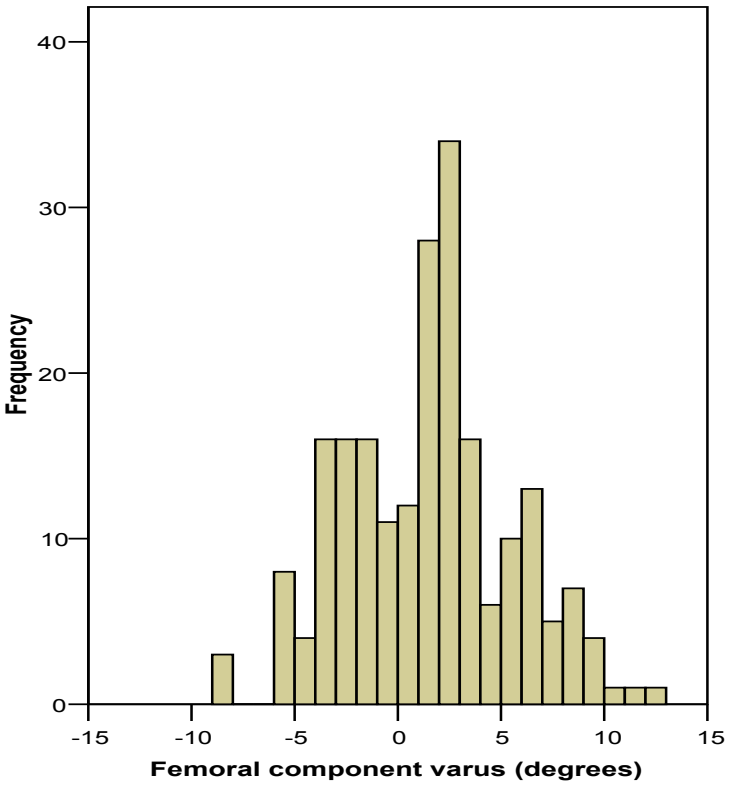


Figure 4-5: Histogram showing the varus alignment of the femoral component (Valgus=Negative, Varus=Positive)

The manufacturer's recommended range of alignment from 10º varus to 10º of valgus was achieved in 98.6% of cases. The OKS for the extreme intervals within this range (± 7.5º to ± 10º, Mean: 41.8, SD: 7.8, n: 14) was not significantly (p=0.242) different from the other intervals (-7.5º to 7.5º, mean: 40.2, SD: 8.2, n: 194). The incidence of RL was also not different between the groups (p= 0.184).

	5 yr OKS		RL	
Femur varus	**N**	**Mean ± SD**	**N**	**Percentage with radiolucency (%)**
-10 to -7.5 degrees	3	37.3 ± 15.1	2	50
-7.5 to -5.0 degrees	8	38.6 ± 9.4	6	67
-5.0 to -2.5 degrees	25	42.4 ± 6.3	17	53
-2.5 to 0 degrees	38	39.9 ± 7.5	29	62
0 to 2.5 degrees	65	40.2 ± 8.2	54	54
2.5 to 5.0 degrees	31	40.6 ± 8.8	24	67
5 to 7.5 degrees	27	38.5 ± 9.6	21	71
7.5 to 10 degrees	11	43.7 ± 3.6	8	87
10 to 12.5 degrees	3	38.3 ± 16.7	3	67
Total	211	40.3 ± 8.2	164	62

Table 4-1: OKS and number (N) of regions with RL at 5 years following surgery for groups of varying varus position of the femoral component (Valgus=Negative, Varus=Positive)

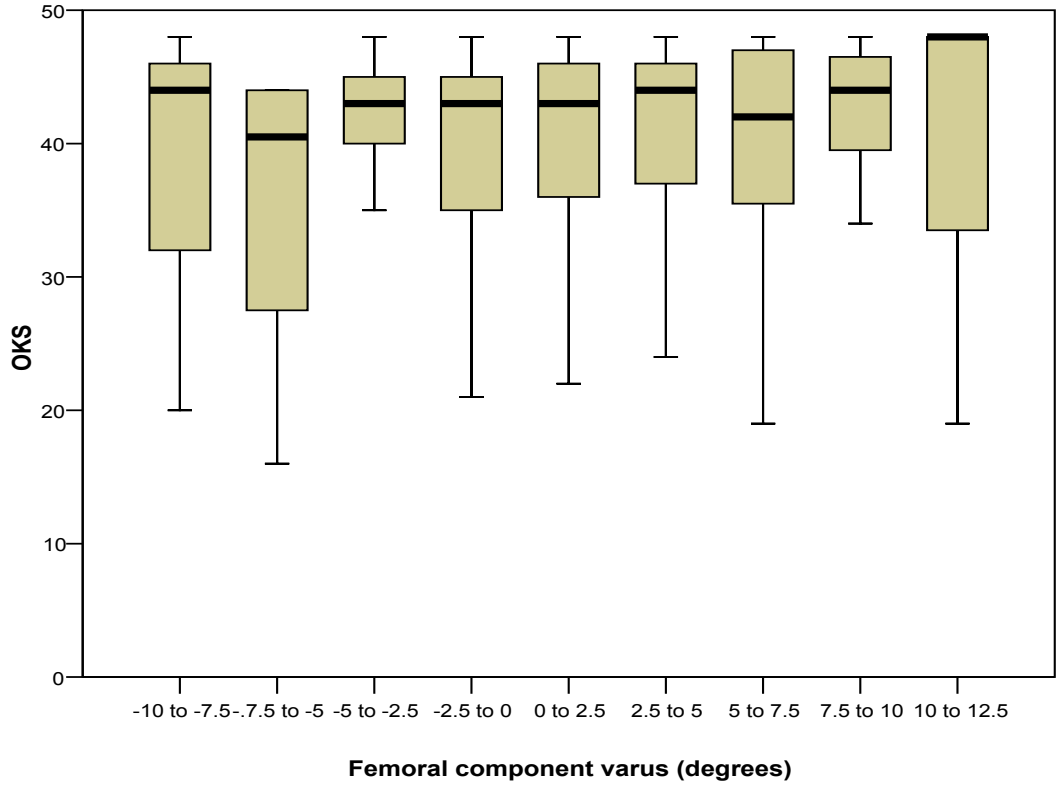


Figure 4-6: Box plot showing the 5 year OKS for different groups of varus alignment of the femoral component (Valgus=Negative, Varus=Positive)

4.3.2 Flexion/extension of femur

Ninety percent of the components were between 7.4º extension and 6.6º flexion. The mean position was 0.8º extension (SD: 4.3, range: 9.9º extension to 9.6º flexion) (Figure 4-7, Table 4-2). There was no significant difference in the OKS (p=0.503) (Figure 4-8), ΔOKS (p=0.232), ΔPS (p=0.573), PS (0.223) or the number of regions with RL p=0.639), between the groups.

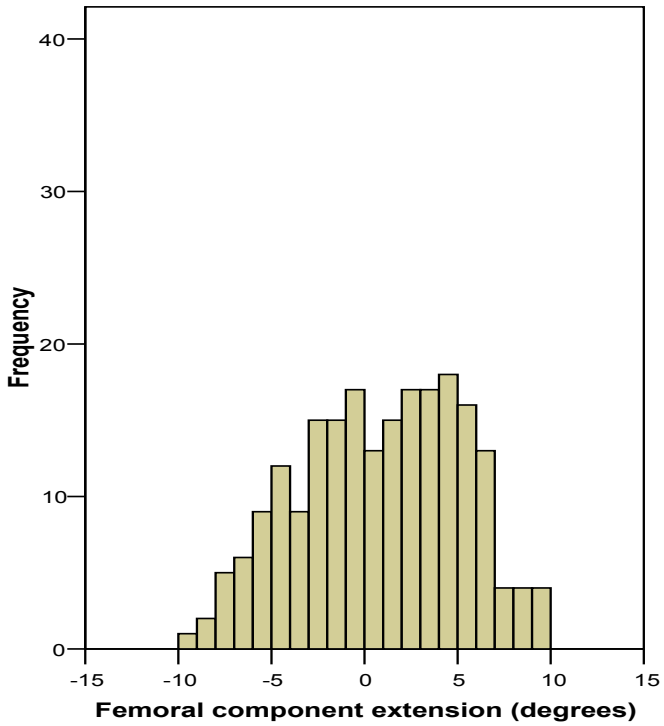


Figure 4-7: Histogram showing the extension alignment of the femoral component (Flexion=Negative, Extension=Positive)

All patients achieved the manufacturer's recommended range of alignment from 10º flexion to 10º extension. The OKS for the extreme intervals within this range (flexion/extension intervals −10° to −7.5° and 7.5° to 10°, mean OKS: 41.4, SD: 8.0, n=13) was not significantly (p=0.445) different from the other intervals (flexion/extension between−7.5° and 7.5°, Mean OKS: 40.2, SD: 8.3, n: 198). There was no difference in the incidence of RL (p=0.216) between the groups.

	5 yr OKS		RL	
Femur extension	**N**	**Mean ± SD**	**N**	**Percentage with radiolucency (%)**
-10 to -7.5 degrees	5	45.4 ± 3.0	4	50
-7.5 to -5.0 degrees	18	41.1 ± 4.9	14	57
-5.0 to -2.5 degrees	28	41.1 ± 6.3	22	55
-2.5 to 0 degrees	40	39.5 ± 8.4	31	69
0 to 2.5 degrees	35	42.4 ± 6.2	25	72
2.5 to 5.0 degrees	45	37.8 ± 11.6	34	59
5 to 7.5 degrees	32	40.9 ± 6.8	26	61
7.5 to 10 degrees	8	38.9 ± 9.3	8	37
Total	211	40.3 ± 8.2	164	62

Table 4-2: OKS and number (N) of regions with RL at 5 years following surgery for groups of varying extension position of the femoral component (Flexion=Negative, Extension=Positive)

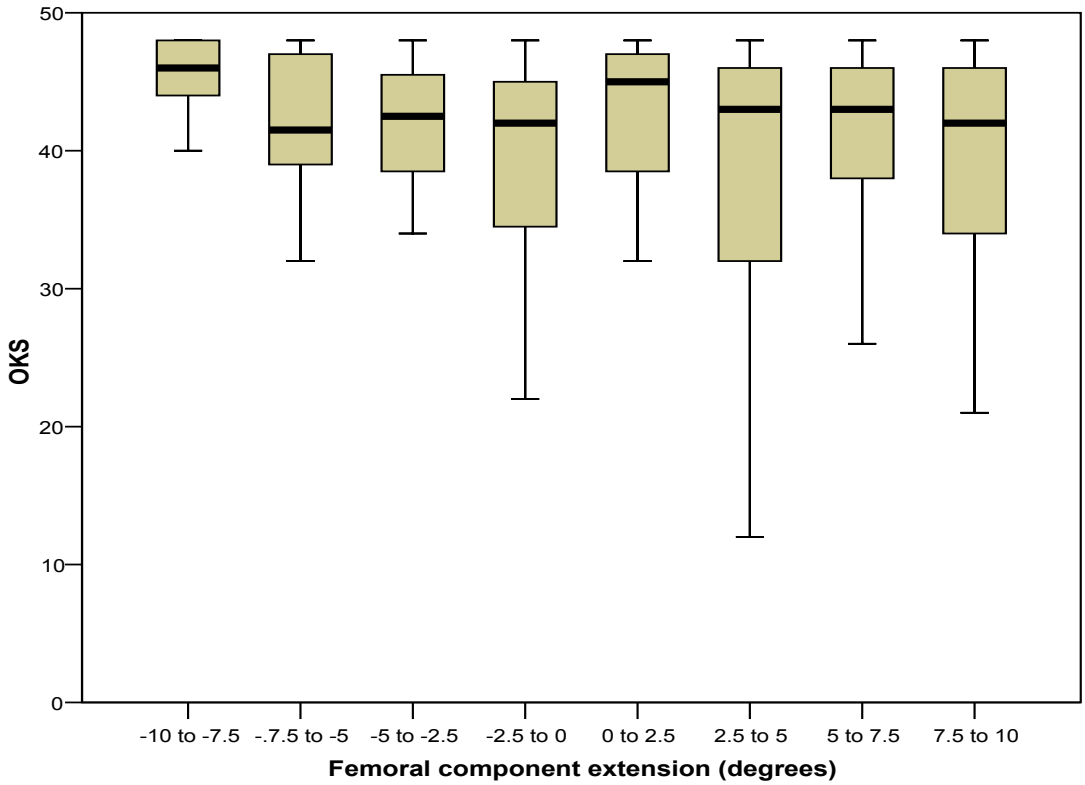


Figure 4-8: Box plot showing the 5 year OKS for different groups of extension alignment of the femoral component (Flexion=Negative, Extension=Positive)

4.3.3 Valgus/varus of tibia

Ninety percent of the components were between 1.3° valgus and 5.3° varus. The mean position was 2.1° varus (SD: 2.1, range: 4.2º valgus to 6.1° varus) (Figure 4-9, Table 4-3). There was no significant difference in the OKS (p=0.421) (Figure 4-10), ΔOKS (p=0.676), ΔPS (p=0.153), PS (p=0.124) or the number of regions with RL (p=0.307), between the groups.

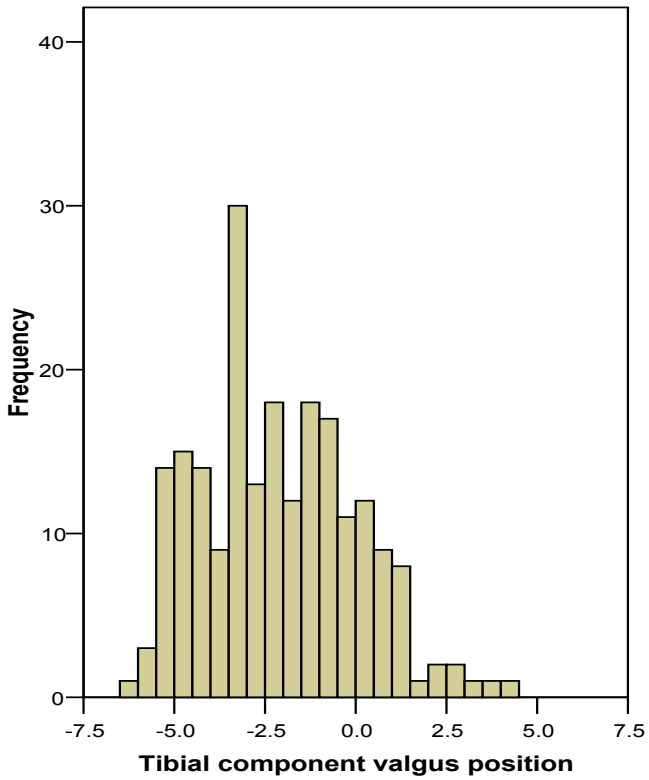


Figure 4-9: Histogram showing the valgus alignment of the tibial component (Varus=Negative, Valgus=Positive)

The recommended range of alignment from 5° varus to 5° of valgus was achieved in 91.5% patients. The OKS for the extreme intervals within this range (varus/valgus intervals −5° to −2.5° and 2.5° to 5°, mean OKS: 39.7, SD: 8.9, n=85) was not significantly (p=0.327) different from the inner range (varus/valgus between−2.5°and 2.5°, mean OKS: 41.0, SD: 7.7, n=108). The incidence of RL (p=0.573) was also not different between the extreme and inner ranges.

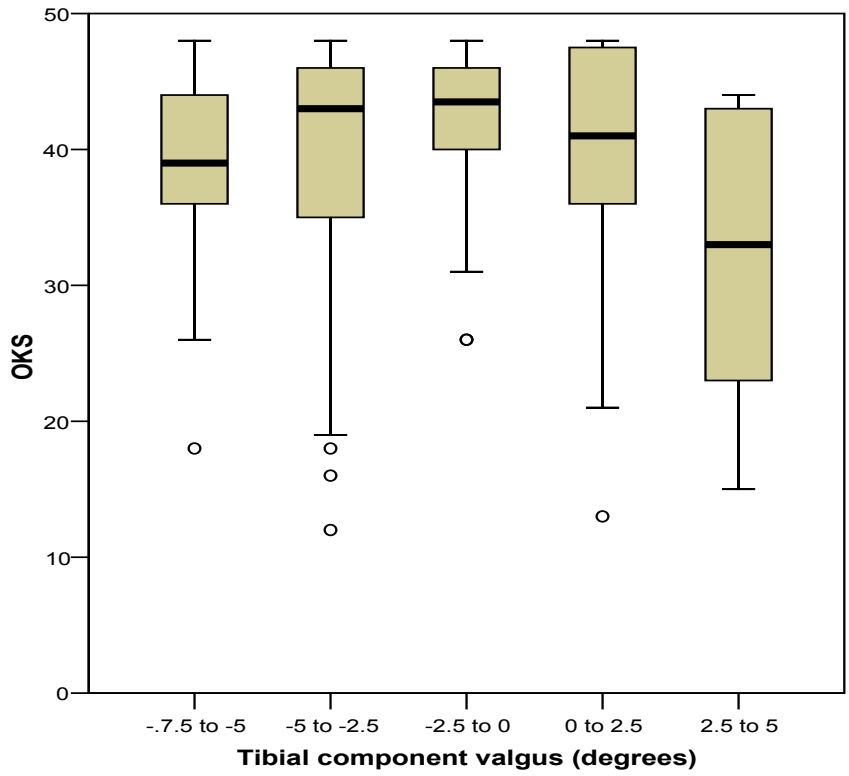


Figure 4-10: Box plot showing the 5 year OKS for different groups of valgus alignment of the tibial component (Varus=Negative, Valgus=Positive)

	5 yr OKS		RL	
Tibia valgus	**N**	**Mean ± SD**	**N**	**Percentage with radiolucency (%)**
-7.5 to -5.0 degrees	18	38.9 ± 7.6	15	67
-5.0 to -2.5 degrees	80	39.5 ± 9.1	65	65
-2.5 to 0 degrees	76	41.7 ± 6.9	58	64
0 to 2.5 degrees	32	39.4 ± 9.3	22	41
2.5 to 5.0 degrees	5	41.8 ± 4.6	4	75
Total	211	40.3 ± 8.2	164	62

Table 4-3: OKS and number (N) of regions with RL at 5 years following surgery for groups of varying valgus position of the tibial component (Varus=Negative, Valgus=Positive)

4.3.4 Superior/inferior tilt of tibia

Ninety percent of the components were between 3.3° inferior and 5.1° superior tilt. The mean position was 1.9° superior tilt (SD: 2.7, range: 6.2° superior to 6.1° inferior tilt) (Figure 4-11, Table 4-4). There was no significant difference in the OKS

(p=0.572) (Figure 4-12), ΔOKS (p=0.498), ΔPS (p=0.238), PS (p=0.175) or the number of regions with RL (p=0.542), between the groups.

The recommended range of alignment from 5° superior to 5° of inferior tilt was achieved in 92.4% patients. The OKS for the extreme intervals within this range (superior/inferior tilt intervals −5° to −2.5° and 2.5° to 5°, mean OKS: 40.1, SD: 8.4, n=96) was not significantly (p=0.777) different from those in the inner range (superior/inferior tilt between −2.5° to 2.5°, OKS Mean: 40.8, SD: 7.7, n=99). There was also no difference in the incidence of RL (p=0.399) between the extreme and inner ranges.

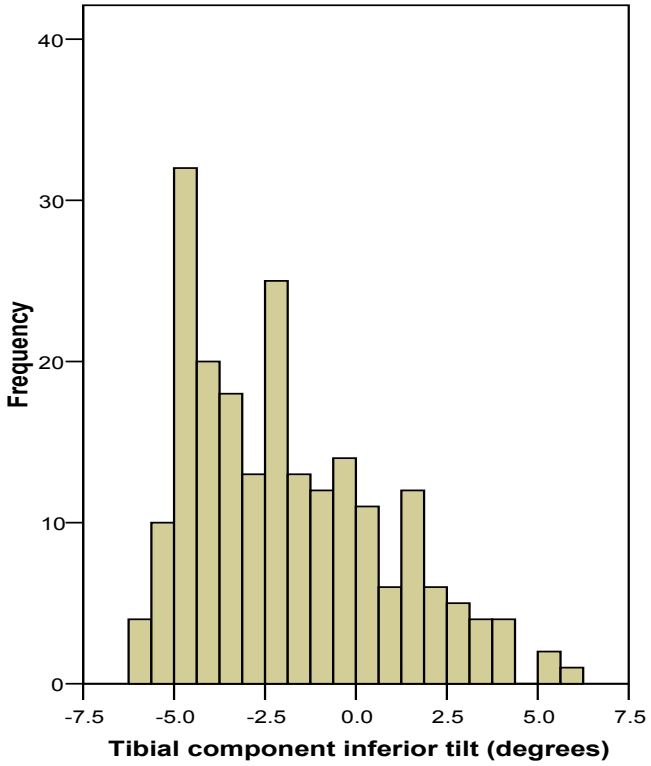


Figure 4-11: Histogram showing the inferior tilt of the tibial component (Superior=Negative, Inferior=Positive)

	5 yr OKS		RL	
Tibia inferior tilt	**N**	**Mean ± SD**	**N**	**Percentage with radiolucency (%)**
-7.5 to -5.0 degrees	13	37.4 ± 11.2	11	64
-5.0 to -2.5 degrees	83	39.8 ± 8.5	68	66
-2.5 to 0 degrees	64	41.6 ± 7.0	50	54
0 to 2.5 degrees	35	39.5 ± 8.6	26	62
2.5 to 5.0 degrees	13	42.0 ± 8.2	8	75
5 to 7.5 degrees	3	42.7 ± 5.9	1	0
Total	211	40.3 ± 8.2	164	62

Table 4-4: OKS and number (N) of regions with RL at 5 years following surgery for groups of varying inferior tilt position of the tibial component (Superior=Negative, Inferior=Positive)

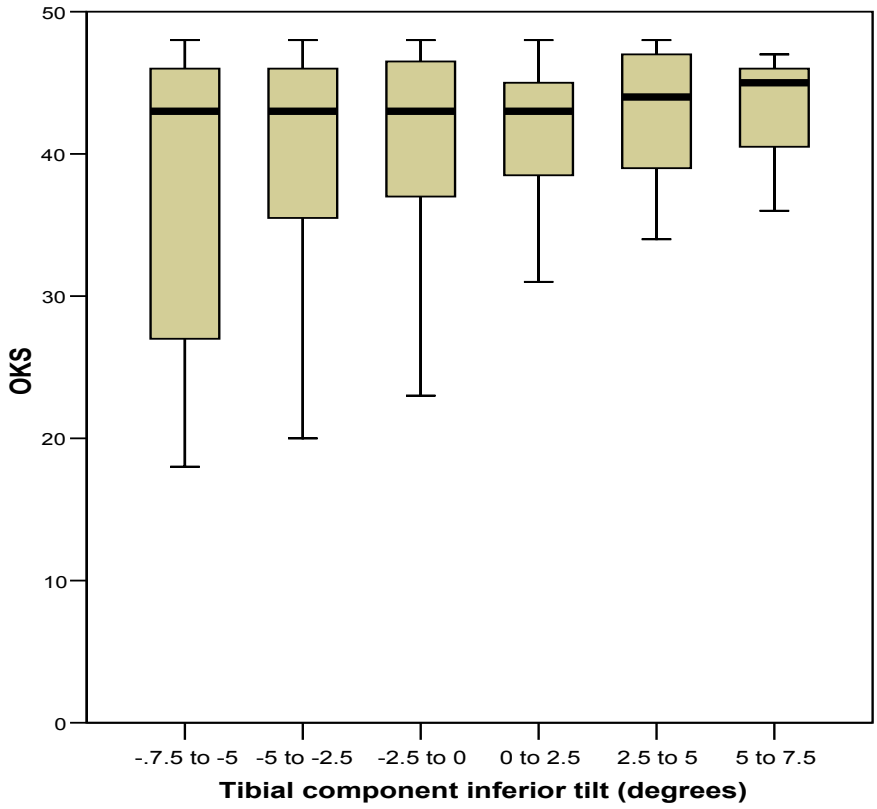


Figure 4-12: Box plot showing the 5 year OKS for different groups of inferior tilt of the tibial component (Superior=Negative, Inferior=Positive)

4.4 Discussion

The component alignment after a knee replacement has always been a subject of discussion. It is often believed that TKR allows better component positioning and limb alignment compared with UKR[209]. The concern is that the minimally invasive approach reduces access to many surgical landmarks and a constant pressure from the patella on the implanting instruments may lead to incorrect placement of the components[210]. There are many studies reported in the literature[98,206,211] about the functional outcomes following UKR but very few studies have assessed the impact of component alignment on clinical and radiological outcomes. Cool *et. al.*[210] performed a survivorship analysis on 50 UKRs (average follow up: 3.7 years) and observed that 70% of femoral components and all tibial components were within the recommended range. Swienckowski *et al*.[212] concluded that patients with 9° of posterior tibial slope had the best clinical scores and the outcome deteriorated with excessive (>11°) or inadequate (< 8°) posterior slope. Shakespeare *et al.*[205] studied the accuracy of implantation of components in the Oxford UKR and found that all femoral components were within the recommended range for varus/valgus but tibial components were inserted in slight varus (mean 1.8°). The posterior slope of the tibial components was within the recommended limits by the manufacturer.

Common malalignments following UKR include varus or valgus of the femoral or tibial components, and variations in tibial slope and femoral flexion[205]. It has been argued that provided the orientation of knee components is within a certain range, the effect on the mechanics of the knee will be negligible[116,205]. Furthermore, the design of the Oxford prosthesis has a theoretical advantage in that malalignment of the femoral and tibial components is more forgiving than in other prostheses. This is because the articulating surface of the femoral component is spherical, preserving equal contact stresses to the polyethylene bearing, even if rotated relative to the tibia, thus

compensating for deviations in alignment[185]. The manufacturer has recommended arbitrary guidelines which are not evidence-based. There are therefore two important unanswered questions: 1) what is the acceptable limit of component alignment after Oxford UKR? and 2) does it matter if the Oxford UKR components are maligned in the coronal or sagittal plane?

This study demonstrates that in patients with Oxford UKR performed though a minimally invasive approach, in 99% of cases the femoral components are implanted between ±10° varus/valgus and flexion/extension and 92% of cases have tibial components between ±5° varus/valgus and superior/inferior tilt. It also shows that within this range, the orientation of the components does not affect the functional outcome as measured by the OKS and RL at five years. Therefore the component alignment within this range is acceptable and the manufacturer's guidelines, although arbitrary and not evidence-based, are still valid. The mean tibial slope was 2° superior tilt; this was probably due to the fact that the tibial component was implanted relative to the anterior tibial cortex and the radiographic measurement was taken with respect to the posterior tibial cortex.

The studies of implant alignment in TKR reveal that acceptable limits are very narrow[213,214]. The primary reason for wide acceptable limits with UKR and the narrow limits with TKR may be because component alignment is related to leg alignment with TKR, but not with UKR. With TKR, a few degrees of component malalignment will cause enough abnormality in leg alignment to cause failure[213,214]. In contrast, with UKR, leg alignment depends on component thickness rather than alignment. For the Oxford UKR, the bearing thickness is selected to restore ligament tension to normal, thereby restoring normal pre-disease alignment[185].

It is emphasised that the Oxford UKR is a mobile bearing device, which has a completely different design and philosophy than the fixed bearing UKR (see section 1-5). The results of this study therefore cannot be extrapolated to fixed bearing devices. With a fixed bearing UKR, although the acceptable range of alignment is larger than for TKR[79], it is not as large as for the Oxford UKR. This is because, with fixed bearing devices, there is a risk of edge loading and rapid wear[79]. In contrast, the Oxford UKR has a spherical femoral component and a conforming bearing with a very large surface area (about 6 cm^2)[215], so malalignment, even if it is quite substantial, will not result in high contact stresses and rapid wear[185]. Furthermore, with a fixed bearing UKR, it has been shown that tibial slope outside the range of 8° to 11° is associated with a worse outcome[212]. The Oxford UKR does not demonstrate this. This difference may be the result of different instrumentation. With the Oxford UKR, the tibial slope and flexion gap are defined by the initial tibial cut. Bone is then progressively removed from the distal femur until the flexion and extension gaps are equal[185]. Thus, with this instrumentation, whatever the tibial slope, the gaps will be equal. In contrast, if the femoral component is applied anatomically, the tibial slope will affect the flexion-extension balance.

The follow up period used in this study was five years, at which time the OKS will give an accurate picture of the pain experienced and the functional limitations during everyday activities. It does not, however, predict whether there will be a long term failure. To address this, RL was also assessed and compared between the groups. RL around the implanted tibial component is a common finding following UKR, with an incidence ranging from 32-96%[145]. While pathological RL is associated with poor clinical outcome and may even lead to revision surgery, physiological RL, which is far more common, does not seem to be associated with poorer clinical outcome. The results of this study confirm this finding as none of the patients had pathological RL. The radiolucencies were all one millimetre or less thick and all had a sclerotic margin,

indicating that they were all physiological and, therefore, not suggestive or predictive of loosening[185]. No relationship was found between the alignment parameters and the incidence of RL.

The aetiology for RL remains unclear. It was previously thought that varus/valgus mal-alignments of the tibial component may cause RL owing to uneven load distribution on the affected tibia. It is possible that a substantial malalignment of the femoral component could achieve this; however no such cases were found in our cohort. More recently there has been a suggestion[216] of an association between RL and excessive postero-inferior tilt of the tibial component (>13º). The findings of this study do not support these suggestions; however no tibial component implanted at >13º was identified in our cohort. A greater cohort size would be required to allow for a fair comparison.

Besides loosening, other important failure modes are; wear, disease progression to lateral OA, and dislocation. The Oxford UKR has a fully congruent mobile bearing, so as explained above, wear is minimal even in cases of malalignment[215]. Disease progression to the lateral compartment is thought to relate to leg alignment, which is independent of component alignment for UKR[217,218]. There were no dislocations in this series so it is not possible to assess the influence of alignment on dislocation. However, it is unlikely to have an effect, as within the proposed range, component alignment is not related to bearing entrapment.

The study has several weaknesses inherent in any clinical and radiological analysis. Only 211 UKRs were assessed; this number is less than other reported series of intermediate/long term outcomes of Oxford UKR, however a power analysis[219] revealed that the sample size was adequate for meaningful statistical analysis. Furthermore, although clinical follow-up was available for all, radiographs accurate

enough to assess the interface were available for only 164 patients. Sample size evaluation using Altman's nomogram[219] revealed that this smaller cohort size was also adequate to identify differences between the groups.

Another limitation of the study is that full-length radiographs were not available for measuring component alignment. This was addressed by referencing the available bone cortices to the angles of interest. Though not perfect, this gives a sufficiently accurate reading of the true alignment angles[220] and the same method has been used by other authors[205,206,210]. Moreover, as the acceptable range of component alignment is so large, short radiographs are probably accurate enough. The lack of sufficiently sized cohort outside the recommended range also prevented more meaningful assessment into the effects of breaching those criteria limits. This probably does not matter as this study and others[205] have observed that it is relatively easy to position the components within the recommended range, despite the limited exposure of a minimally invasive approach.

The use of computer-aided systems has been advocated[221-223] to improve the precision of implantation of UKR. Perlick *et al.*[221] demonstrated that 90% of patients, having UKR, were in the range of 4-0º varus (mechanical axis) with the computer-aided surgery as compared to 70% in the conventional group. Another study[223] showed a significant increase in the rate of the prosthesis implanted in the desired angular range with the use of navigation system. However, in both of these studies, there was a significant increase in the operation time (19 and 20 minutes respectively). This study suggests that the majority of components implanted using the minimally invasive approach lie within the recommended range of position and the clinical and radiological outcome is not compromised for implants lying within or just outside of this range. As the acceptable range is wide and can be achieved with

manual instruments, navigation does not seem to be necessary for obtaining satisfactory implant position with Oxford UKR.

4.5 Summary

The results of this study demonstrate that the majority of surgically implanted Phase 3 Oxford UKRs, using a minimally invasive approach, lie within the recommended range of position and that there seems to be no significant difference in OKS or radiolucency for implants lying within or just outside of this range. This study also shows that there is no evidence to revise the current recommended range of component positioning for the Oxford UKR. For the Oxford UKR, which is particularly forgiving, femoral malalignment of up to 10° is compatible with good clinical and radiological outcomes. For tibial components, up to 5° of malalignment is acceptable.

5. THE EFFECT OF LEG ALIGNMENT ON CLINCAL AND RADIOLOGICAL OUTCOMES AFTER OXFORD UKR[224]

5.1 Introduction

After TKR, leg alignment is critical with malalignment increasing the risk of failure[225-228]. The situation is generally thought to be similar after medial UKR[140,218,229-234] although Larsson *et al.*[79] suggested that minor malalignment does not significantly influence the outcome, whereas marked post-operative deformity does. Even if the poor alignment does not compromise the initial post-operative result, it is believed that the long term result will be affected[218]. There is, however, no consensus about the ideal post-operative leg alignment after Oxford UKR and how it should be measured.

This chapter describes the accuracy and repeatability of a new clinical method of measuring the leg alignment. After validating this new method, it explores the relationship between the leg alignment after Oxford UKR and clinical and radiological outcomes at five years post-operatively.

5.1 Patient selection

Out of the 164 knees with five year clinical follow up and 'perfectly aligned' radiographs allowing for assessment of radiolucency (Section 4.2), 160 knees had data on leg alignment, which were analysed for this study. There were 72 knees in males, 88 knees in females and the mean age at surgery was 65.7 years (SD: 8.9). Patients were assessed clinically and radiologically and for this study, pre-operative and five year data was used.

5.1.1 Clinical assessment

The clinical outcome was assessed using the OKS, AKSS-F, AKSS-O and the Tegner score. As mentioned in section 2.2 and shown in Appendix 1, the AKSS[139] is completed by clinicians and consists of two scores, Objective and Functional, ranging from 0 to 100 points each (with 100 points being the best score). The AKSS-O score includes data on pain, range of motion (ROM), stability, alignment, flexion contracture and extension lag of the knee. A 125° ROM at the knee is given a maximum of 25 points and for each 5° loss of ROM, one point is deducted. 5-10° valgus is considered as the normal alignment and 3 points are deducted for each degree of malalignment.

For this study, the AKSS-O was analysed with and without these deductions. The AKSS-F score allocates points for walking distance and stair climbing ability and makes deductions for the use of a walking aid. The Tegner activity scale[174] assesses activity on a range from 0 to 10. An activity of 10 corresponds to participation in competitive sports at elite level and an activity level of 0 is assigned if a person is on sick leave or receiving disability benefits because of knee problems.

The AKSS is open to observer bias; so patients were assessed independently by physiotherapists. A part of the AKSS-O is an assessment of leg alignment. There are, however, no guidelines as to how this assessment should be made. However, as 5º to 10º of valgus is deemed normal, the anatomical rather than mechanical alignment should be assessed (Section 1.2). The only landmark around the hip that can be reliably identified, and is approximately the anatomical axis of the femur, is the Anterior Superior Iliac Spine (ASIS). Therefore, a new method was developed for this study and the angle between the ASIS, the centre of the knee and the centre of the ankle was measured to assess the leg alignment. To do this accurately, a goniometer with a magnified scale and extendable arms was used.

The measurements of leg alignment were made with the patient standing (Figure 5-1). The centre of the ankle, the knee and the ASIS were identified by direct palpation. The goniometer hinge axis was placed over the centre of the knee and the ends of the extendable arms placed over the ASIS and the centre of the ankle. The alignment was then measured using the magnified scale to the nearest degree.

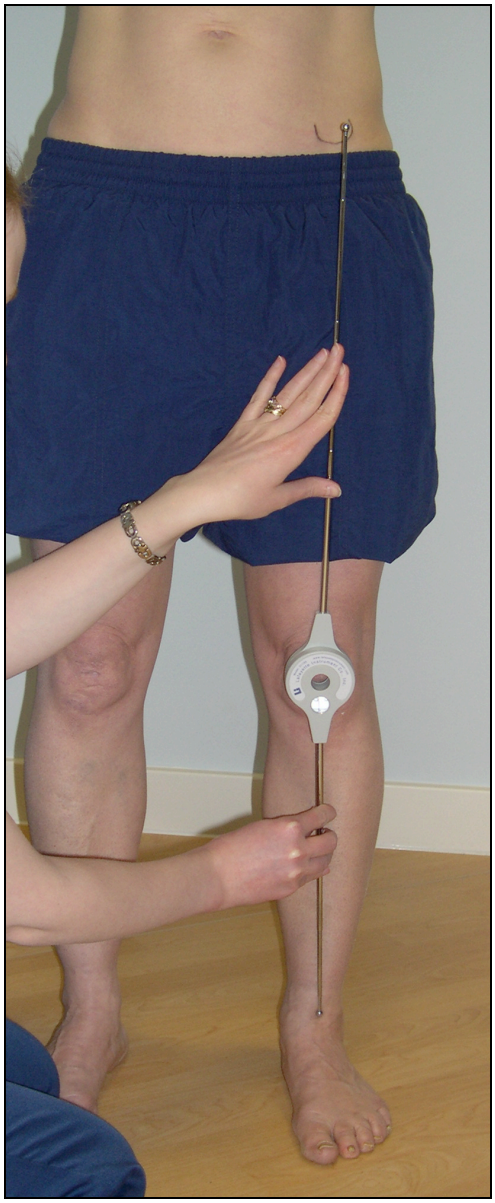


Figure 5-1: Measurement of leg alignment using goniometer with extendable arms

5.1.2 Reliability of leg alignment measurements

The reliability of the new method of clinical alignment measurement was assessed in two ways: a) measurement of inter-observer errors to assess the repeatability and b) comparison with radiological assessment of leg alignment to assess the accuracy of the clinical method.

To assess the inter-observer reliability, two observers independently measured the alignment of 53 patients. This demonstrated a mean difference of 0.7º between the two measurements and a 2.5° SD[235]. The maximum difference was 5° which occurred in a very obese patient. The ICC was calculated in the same manner as described in section 4.2.3 and was 0.89[208].

To assess the accuracy of the measurement, 20 long leg alignment radiographs were studied. On these, the angle between the anatomical axis passing from the centre of the knee along the femoral diaphysis and the line from the centre of the knee to the ASIS was measured (Figure 5-2). This was measured as 0.8° (SD: 0.5°, range 0.1° to 1.4°). Therefore, the new method of measuring leg alignment was able to assess the anatomic leg alignment with an accuracy of a few degrees.

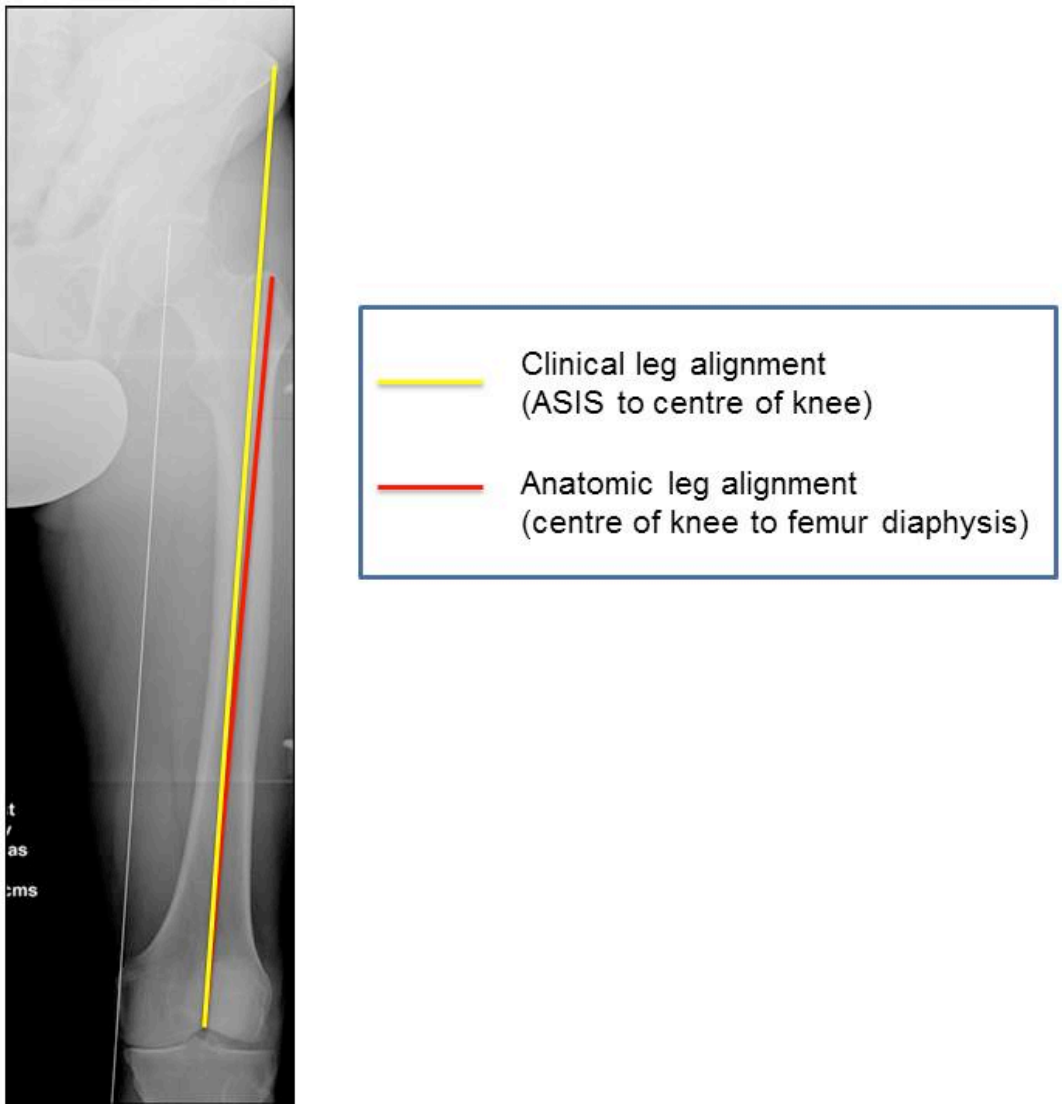


Figure 5-2: Assessment of accuracy of new method for measuring clinical leg alignment by comparing with anatomical leg alignment

5.1.3 Radiological analysis

The five-year post-operative radiographic assessment of the knee was made using fluoroscopic guidance with the patient supine and the images were analysed for regions of radiolucency around the tibial component (Section 4.2.2). The progression of arthritis to the lateral compartment and component subsidence were also analysed.

5.1.4 Data analysis

The knees were subdivided into four groups according to the AKSS[139] alignment

criteria:

1. Neutral: Physiological 5-10° valgus (normal alignment) (n=116)
2. Mild varus: 0 to 4° valgus (n=29)
3. Marked varus: >0° varus (n=13)
4. Valgus: >10° valgus (n=2)

As there were only two patients in the valgus group (>10º valgus), no further analysis of these was undertaken. In the primary analysis, comparisons were made between the three remaining groups in terms of both absolute and change in the OKS, AKSS (Total, Objective and Functional) and Tegner scale at five years following surgery. For secondary analysis, the three groups were compared in the same manner but no deductions were made to the Total and AKSS-O as a result of post-operative leg alignment. The three groups were also compared for the presence of radiolucent lines (RLL) to analyse the difference in the quality of fixation.

5.1.5 Statistical Analysis

The data was not normally distributed. The Kruskal-Wallis test was therefore used to perform non-parametric analyses between the groups and the scores. For comparison with the RL regions, Pearson's Chi-square test was used. A significant difference was demonstrated by a p-value<0.05. All analyses were carried out using the statistical package SPSS for Windows (v.18.0, Chicago, IL, USA).

5.2 Results

There were 116 knees (73%) with neutral alignment (5-10º valgus), 29 knees (18%) with mild varus (0 to 4º valgus) and 13 with marked varus (>0º varus) (Table 5-1).

		Neutral Valgus (5-10º)	Mild varus Valgus (0- 4º)	Marked varus Varus (>0º)	Significance
Number of patients		116	29	13	
Age (years) [Range]		66.9 (SD:9) [43.1-84.4]	61.6 (SD:8) [48.2-78.5]	64.4 (SD:9) [54.3-88.0]	**0.013**
Gender	Male	45	16	9	**0.048**
	Female	71	13	4	

Table 5-1: Details of patients in the three groups

The OKS increased significantly (p=0.03) with increasing varus (Table 5-2, Figure 5-3). The change in OKS, the AKSS-F and the Tegner score had a similar trend with increasing varus being associated with improving function (Table 5-2, Figures 5-4 and 5-5). However, for none of these scores was the trend statistically significant. The only scores which did not show this trend were the Total and AKSS-O. These scores were significantly (p <0.001) worse with increasing varus. However, the difference disappeared if the three point deduction for each degree of malalignment was removed.

	Neutral Valgus (5-10º)	Mild varus Valgus (0 - 4º)	Marked varus Varus (>0º)	Significance
5 yr OKS	40 (SD:9) [12-48]	42 (SD:5) [32-48]	45 (SD:4) [32-48]	**0.027**
5 yr Δ OKS	22 (SD:9) [-2-42]	23 (SD:9) [9-43]	24 (SD:5) [18-33]	0.789
AKSS-Total	176 (SD:27) [86-200]	164 (SD:25) [105-195]	162 (SD:20) [119-180]	**0.001**
AKSS-Total Without deduction	176 (SD:27) [86-200]	175 (SD:24) [114-200]	187 (SD:17) [149-200]	0.410
AKSS-Objective	94 (SD:10) [54-100]	77 (SD:15) [34-94]	70 (SD:13) [39-82]	**< 0.001**
AKSS-Objective Without deduction	94 (SD:10) [54-100]	89 (SD:14) [49-100]	94 (SD:8) [69-100]	0.209
AKSS-Function	83 (SD: 21) [0-100]	86 (SD:15) [55-100]	92 (SD:13) [60-100]	0.419
Tenger activity scale	2.8 (SD:1) [1-8]	3.0 (SD:1) [1-8]	3.1 (SD:1) [2-6]	0.561

Table 5-2: Means (standard deviations) of follow up clinical scores/scale in different groups

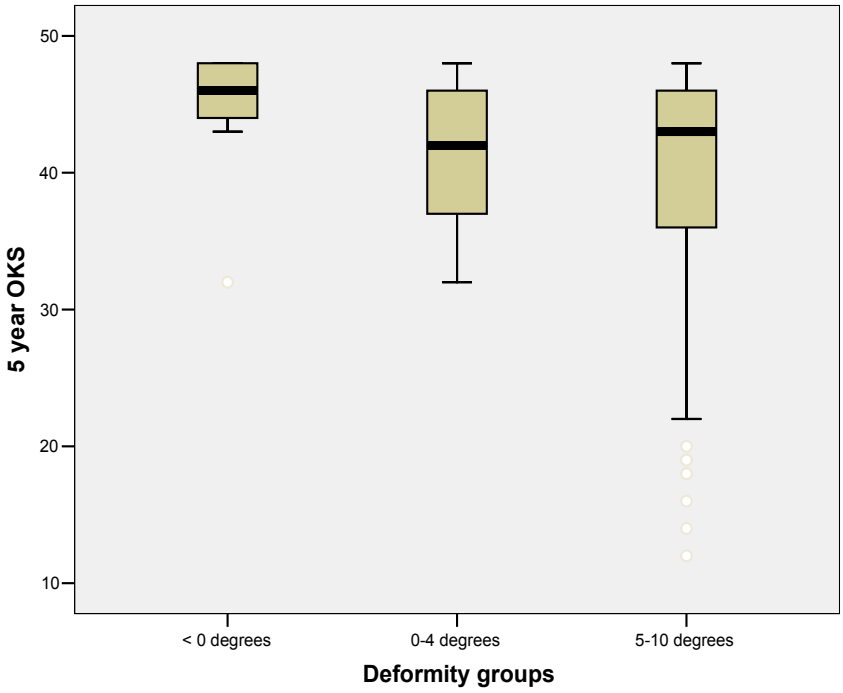


Figure 5-3: Box plots showing distribution of OKS between the three groups

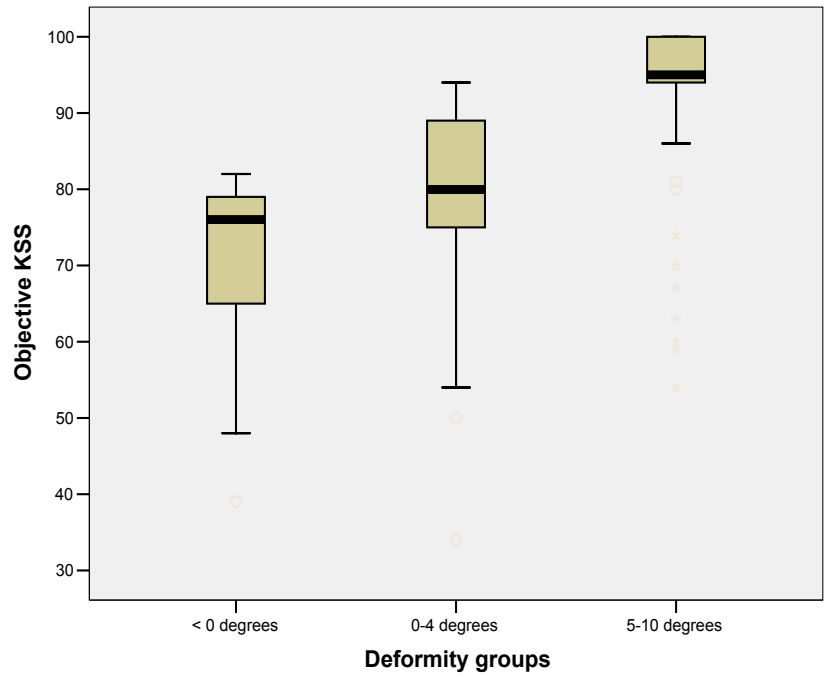


Figure 5-4: Box plots showing distribution of AKSS-O between the three groups

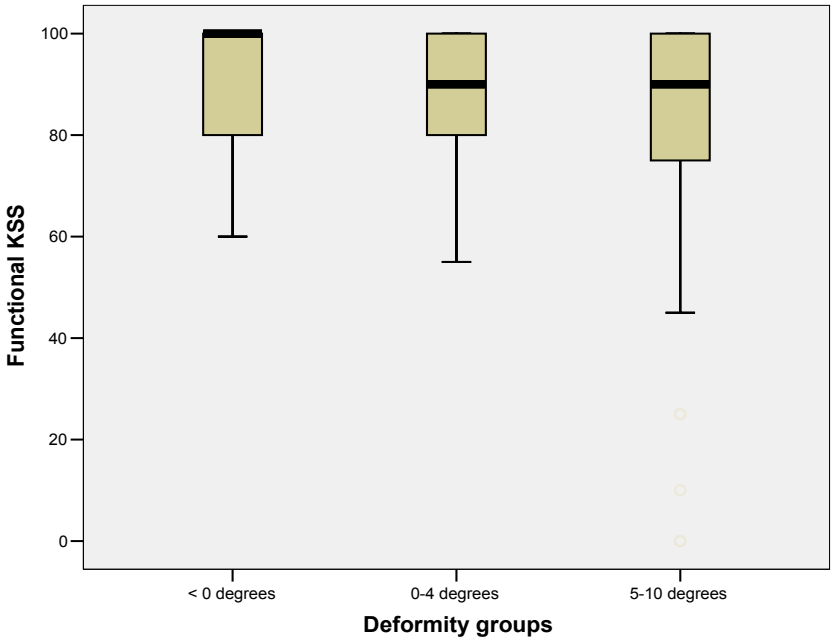


Figure 5-5: Box plots showing distribution of AKSS-F between the three groups

No significant difference was found in the incidence of five year RLL under the tibial component for different groups (Table 5-4). All the observed radiolucencies were physiological and there were no femoral radiolucencies.

Radiolucency	Neutral Valgus (5-10º)	Mild varus Valgus (0 - 4º)	Marked varus Varus (>0º)	Significance
None	50	12	5	0.935
Observed	66	17	8	

Table 5-3: Radiolucency under the tibial component for different groups

5.3 Discussion

Just like the anatomic alignment after TKR, the final alignment after medial UKR is considered to be a factor which may affect the long term success of the operation[140,218,229-231,233,234,236]. It is thought that post-operative residual deformity could alter the distribution of weight medio-laterally[228] and may lead to early polyethylene wear, poor functional results, and a high revision rate. The limb alignment with Oxford UKR (or any mobile bearing UKR) is directly related to the amount of bone excised and the thickness of the bearing/implant used[185,205]. This study shows that following Oxford UKR, 73% of knees were neutrally aligned, 18% were in mild varus (0 - 4º) and 8% were in marked varus (>0º). With TKR, it would be unacceptable to have such a high incidence of varus as this is associated with an unsatisfactory functional outcome and an increased failure rate from loosening and wear[228,237].

In general, alignment after a knee replacement is largely dependent on three factors; the amount of bone resected, the thickness of the tibial component implanted and the amount of passive correction achievable at the time of the surgery[231]. Various authors[108,140,218,233,234] have recommended under correction of the knee deformity during Oxford UKR because over correction increases the risk of failure due to

progression of the disease to the lateral compartment. However, undercorrecting the deformity increases the load medially, and so may result in loosening or accelerated wear of the polyethylene[140,218].

The goals of limb alignment and implant position are slightly different for mobile bearing UKR than for fixed bearing UKR and TKR. The indications ensure that the Oxford UKR is used only when the ligaments are functionally normal. The aim of the surgery is to restore the knee kinematics to normal. As the ligaments are functionally normal, they are never released. Ligament balance is restored by accurately positioning the femoral component and ligament tension is restored by inserting an appropriate thickness of bearing[185]. As ligament tension is restored to normal, the intra-articular deformity secondary to arthritis is corrected. However, there is an extra-articular deformity, which is usually tibia vara. This is not corrected, so after the operation these patients should end up with their pre-disease varus leg alignment restored. Therefore, the patients with varus alignment of 5º or 10º post-operatively would have had 5º or 10º of varus before they developed arthritis, caused by 5º or 10º of tibia vara.

This effect has been observed by other authors as well[236,238]. Mullaji *et al.*[238] studied limb alignment in Oxford UKRs (n=121) using HKA and demonstrated an average improvement of 4.9° from the pre-operative value. 75% of knees had a neutral alignment (177° ± 3°) while 14% had excessive varus (<174°) and 11% had valgus (>180°). The pre-operative HKA was found to be the major predictor of post-operative HKA because the limbs with pre-operative varus tended to remain in varus while the limbs with lesser pre-operative varus deformity had a tendency to go into valgus post-operatively. Another study[236] analysed leg alignment using standing 3-foot radiographs (n=63) before and after surgery and measured the FTA and the location of the mechanical axis. The patients were divided into two groups: the first group had 23 knees with unilateral surgery and a normal opposite side, and the

second group had 21 knees with bilateral simultaneous surgery. There was no difference between the groups in either the FTA or the mechanical axis. The study confirmed that the soft tissue balancing technique for Oxford UKR should allow restoration of leg alignment to the pre-disease state.

The surgical technique[185] for Oxford UKR recommends that the soft tissue tension after component implantation should be adequate enough to prevent the joint from subluxation or dislocation. Therefore, the operating surgeons have a natural tendency to implant the largest possible bearing, as it feels more stable; but implanting a bearing which is larger than required overcorrects the deformity and leads to valgus knee alignment. As a result, the load on the lateral compartment is increased, predisposing the knee to late degenerative arthritis[236,239]. On the other hand, implanting a bearing that is smaller than the required size increases tension in the medial compartment and has the potential to cause excessive polyethylene wear and limit movement[239]. None of the patients examined in this study had progression of arthritis to the lateral compartment, or needed revision up to five years after surgery. This might not be sufficient time to observe these complications and this is why this study also analysed radiolucency which provides some indication of the quality of fixation and can predict some long-term failure. There was no significant difference in the incidence of radiolucency between the groups.

This study demonstrates that about 25% of patients have varus alignment after Oxford UKR, but this does not compromise the clinical outcome at five years as assessed by the 5-year OKS and ΔOKS (p=0.027 and 0.789 respectively). In actual fact, patients with marked varus (varus >0º) had a slightly better 5 year OKS and Δ OKS as compared to the other groups. It is not known why this pattern was observed. One possible reason could be that patients in mild and marked varus groups were significantly younger (p=0.010) compared to patients in the neutral group (normal alignment). Also, there were more men in mild varus and marked

varus groups compared to the neutral group (Table 5-1). Another possible reason could be that varus provides a functional advantage. There is some anecdotal evidence to support this, such as the observation that football players have a high incidence of varus[240]. Further evidence that varus malalignment does not compromise the long term outcome is that although 25% of the Oxford UKRs examined in this study were in varus, the failure rate at 20 years is less than 10%[109]. Whatever the explanation, these results indicate that varus does not compromise the functional outcome.

If AKSS is used to assess the clinical outcome of the same cohort of patients, then the results are completely different. This study demonstrates that patients with mild and marked varus have significantly reduced Total and AKSS-O ($p=0.001$ respectively). This is, however, not perceived by the patients because the ability of patients to perform specific activities as assessed by the Tegner activity scale was not statistically different between the groups ($p=0.561$). Furthermore, the OKS which offers the advantage of using the patients' subjective assessment of the knee giving a more accurate picture of the pain experienced and the functional limitations in daily activities[140] was also better in patients with varus ($p=0.027$). With the OKS, questionnaires are completed by the same patient before and after surgery, compared to an investigator-led questionnaire where the clinician may vary at different time points. It is surprising that there was a highly significant decrease in the Total and AKSS-O with increasing varus. As this decrease disappeared when the 3 point deduction for each degree of malalignment was removed, it is likely that the decrease was a result of this deduction.

Detailed analysis of the marked varus group makes it clear that the deduction is inappropriate for mobile bearing UKR. None of the patients in this group had excellent AKSS-O, yet they had the highest OKS, 75% had excellent AKSS-F, and 92% had excellent AKSS-O without deduction. This somewhat arbitrary deduction

may be appropriate for TKR, but it does not seem to be justified for UKR. As 25% of UKR patients are in varus, UKR patients will have worse AKSS scores than TKR patients, even if they have a similar or better functional outcome.

The range of motion achieved by the patients was also analysed and compared to the clinical scores. No significant difference was demonstrated in the Total, AKSS-O and AKSS-F (p=0.216, 0.324 and 0.273 respectively). The OKS at five years, however, showed a significant improvement as the ROM improved (p=0.04). This could possibly be explained by the fact that, in the AKSS, a maximum of 25 points are awarded for a ROM ≥125º and any subsequent improvement in the ROM does not earn extra points. This is acceptable for TKR, as most patients[241-243] would not achieve ROM up to 125º, but may not be appropriate for UKR. In UKR, patients[244] have been shown to achieve flexion up to 135º. In this series, about 30% patients had ROM above 125º. Therefore, the version of AKSS used in this thesis is not a reliable tool for assessing the outcome of UKR.

The radiological outcome was assessed by the presence of RLL beneath the tibial component. There was no statistical difference (p= 0.520) in the incidence of RL for varying leg alignment. RL around the implanted tibial component is a common finding following UKR, with an incidence[145] ranging from 32-96%. Goodfellow et al.[185] classified these into physiological and pathological types depending on criteria such as RL thickness, progression, and the presence of sclerotic lines. While pathological RL is associated with a poor clinical outcome and may even lead to revision surgery, physiological RL is far more common and does not seem to be associated with poorer clinical outcome. This study confirms this finding, as no patients in this study had pathological RL. Furthermore, as the incidence of RL was the same in each group and as the mobile bearing Oxford UKR is highly resistant to wear[215], varus malalignment is unlikely to increase the failure rate from wear or loosening.

One reason why surgeons are concerned about varus malalignment after knee replacement is that this leads to failure of TKR as a result of component loosening and wear[228,237]. A biomechanical analysis explains why varus causes problems after TKR but not after UKR. If a TKR is in varus there will be eccentric loading[245,246]; this will result in component rocking with tension at the implant-bone interface of the non-loading component. Bone cement and the cement-bone interface tends to fail under tension; this results in loosening[247]. A FE study confirms that the maximum contact stresses in the bone increase by nearly 150% with a varus tilt of only 5°[248]. With UKR, whatever the alignment of the leg, the centre of the force on the tibial component is likely to be near the centre[185]. Therefore, the bone-implant interface will be compressed and there should be no loosening. A further concern is that if the leg is in varus, the loading on the UKR components will increase. Although this may be the case in extension, this is unlikely to be a problem as the overall loads are relatively low[249]. The very high loads occur when the knee is flexed, for example getting out of a chair[249]. In flexion, the majority of loads are generated by the Quadriceps muscle. As the patellar tendon is roughly central between the compartments, the forces generated in the components will not be influenced greatly by malalignment.

This study does not demonstrate that alignment after UKR does not matter. In contrast, it demonstrates that the leg alignment should be returned to the pre-disease state. If the pre-disease alignment is not restored, the outcome is likely to be compromised. For example, if the deep fibres of a normal MCL are released, either deliberately in an attempt to achieve a straight leg in a patient with tibia vara or accidentally during tibial preparation, this will result in overcorrection of the intra-articular deformity. This in-turn will result in altered knee kinematics and an increased risk of bearing dislocation, poor function and failure[185].

The main limitation of this study is that the leg alignment was measured clinically rather than with long leg radiographs. The routine assessment of AKSS requires a clinical measurement of alignment. As there is no documented reliable method for measuring leg alignment clinically, this study developed a new technique by using a long arm goniometer with a magnified scale to measure the angle between the ASIS, knee and ankle. The technique is accurate to within a few degrees and can reliably categorise alignment into 5º intervals. This was the required level of accuracy for this study. Furthermore, as explained in section 4.1.2, the clinical alignment was comparable to radiological alignment with an error of 0.8º. Another limitation of the study was the unavailability of pre-operative clinical leg alignment data. This information would have helped to confirm the restoration of the leg alignment to the pre-disease state following Oxford UKR.

5.4 Summary

Following Oxford UKR, about 25% of patients have varus leg alignment. This study indicates that does not compromise their outcome. Varus alignment is a result of the surgical technique which corrects the intra-articular deformity caused by arthritis, and leaves the extra-articular deformity caused by tibia vara. In contrast, ligament releases designed to correct an extra-articular deformity may compromise the outcome. The version of AKSS used in the study was shown to not be a reliable tool for assessing the outcome of UKR, as the deductions for malalignment in the Objective score are not justified following UKR. It was found that clinical leg alignment could be measured to an accuracy of a few degrees using a long arm goniometer with a magnified scale referenced off the ASIS, the knee and the ankle; this alternative novel measurement technique could negate the need of long leg radiographs when assessing leg alignment.

6. THE EFFECT OF TIBIAL COMPONENT SIZE ON CLINICAL AND RADIOLOGICAL OUTCOMES AFTER OXFORD UKR[169]

6.1 Introduction

An optimally implanted UKR tibial component would be one that is flush with the corresponding edges of the tibia. This is often not possible, partly because the tibial component may not be of the ideal shape[250] and also because there may not be sufficient component increments provided by the manufacturers. In such situations the operating surgeon needs to know whether it is best to tend towards component overhang with an increased risk of soft tissue irritation and pain[251,252] or underhang with an increased risk of subsidence[253].

The width of Oxford UKR tibial implants increase in 2 mm increments. The manufacturer has suggested that an appropriate component size is one that reaches the medial cortex or overhangs slightly[180]. However, there is currently no study to substantiate this recommendation or quantify the extent of an acceptable overhang. The aim of this study was to assess the effect of overhang and underhang of tibial components on the clinical and radiological outcomes after Oxford UKR. This will help in developing evidence-based guidelines on the intra-operative selection of appropriate tibial component size.

6.2 Methods

6.2.1 Patient selection

Out of the 164 knees with five year clinical follow up and 'perfectly aligned' radiographs allowing for assessment of radiolucency and tibial component size (Section 4.2), 163 knees (134 patients) were analysed in this study. The patients

were selected based on the criteria that they had clinical scores and radiographs pre-operatively, one year post-operatively and five years post-operatively. One patient did not have a one year follow up, so was excluded. The operations were carried out by two senior surgeons using the standard surgical technique and indications for the cemented Phase 3 Oxford UKR[185]. The surgeon's aim was for the tibial component to be aligned with the tibial margin or to overhang up to 2 mm.

6.2.2 Radiological assessment

The post-operative radiographs were obtained as described in section 4.2.2 and were adjusted for magnification. All measurements were made using custom image processing software (courtesy H Gray) written in Matlab (v.7.0, Mathworks, Newton, MA, USA). The distance between the medial edge of the tibial component and the furthest medial point of the proximal tibia directly underneath the implant was measured, which quantified the medial tibial component overhang or underhang in millimetres (Figure 6- 1).

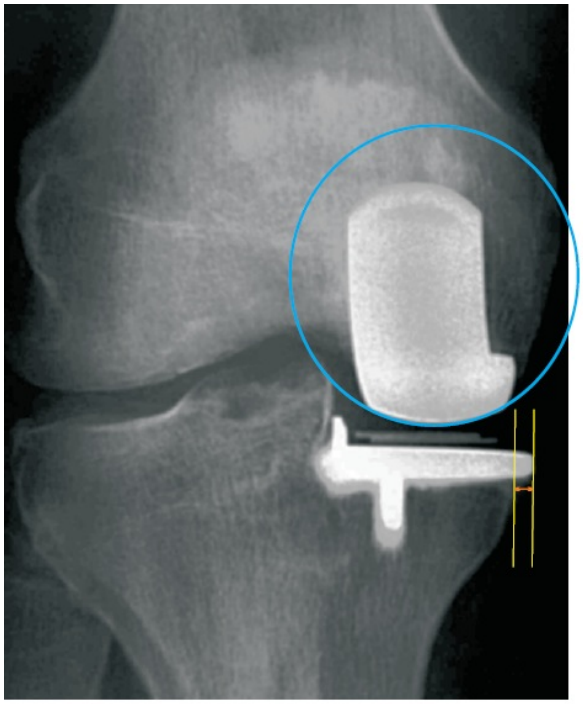


Figure 6-1: Illustration of the measurement of tibial component overhang. Blue circle represents the circular fit to the femoral component for calibration. The arrow depicts the tibial component overhang

6.2.3 Clinical assessment

The clinical outcome was assessed using the total OKS (0-48). In addition to the absolute value of OKS, ∆ OKS, PS and ∆PS were also calculated.

The knees were divided into four component overhang/underhang groups (Table 6-1).

Group	Criteria
Minor overhang	Perfectly aligned tibial components and overhanging up to 3 mm
Major overhang	Tibial components with overhang of 3 mm or more
Minor underhang	Tibial components with up to 3 mm of underhang
Major underhang	Tibial components with underhang of 3 mm or more

Table 6-1: Overhang groups

There were 112 in the 'minor overhang' group, 14 in the 'major overhang' group, 35 in the 'minor underhang' group and two in the 'major underhang' group. Since, there were only two patients in the 'major underhang' group, these were not analysed statistically. Their mean five-year OKS and ∆OKS were 44 and 25.5 respectively and PS and ∆ PS were 19 and 15 respectively. There were 75 male and 86 female knees in the rest of the groups. The mean age at surgery was 66.4 years (SD: 8.9, range 45.2 – 85.7).

The knees were also divided into those in which the bearings would be likely to overhang (bearing width +1 mm greater than the width of the flat part of tibial tray) and those in which bearing overhang was unlikely (bearing width +1 mm is less than the tibial tray width) and the results were compared between the groups.

6.2.4 Analysis

The groups were compared with patient demographics and component size. In the primary analysis, comparisons were made between the three component size groups in terms of both absolute and change in the OKS and PS at year one and five following surgery.

In the secondary analysis, the incidence of overhang with the narrowest component (26 mm wide) was compared with the incidence with the larger components. This analysis was undertaken to determine whether the smaller tibial components were more likely to overhang. The two bearing groups; those that did overhang, and those that did not, were also compared in terms of clinical outcome measures.

The Kruskal–Wallis statistical test was used to compare the continuous demographic variables (age and BMI) and the outcome scores between the three tibial component size groups; differences between two group pairs was examined using the Mann–Whitney U test. The Chi-squared test was used to examine the categorical demographic data (gender and side) between the groups and to analyse the relationship between component size and tibial overhang. Statistical difference was considered to be true for a p-value <0.05. All analyses were carried out using the statistical package SPSS for Windows (v.18.0, Chicago, IL, USA).

6.2.5 Inter-observer variability

Inter-observer errors in the measurement of tibial component overhang were assessed using measurements from two independent observers of 20 radiographs. The differences between the measurements of the two observers were calculated (mean 0.4 mm, SD 0.2) giving an accuracy of the measurements (2SD) of 0.4 mm. The ICC was 0.96 and was calculated as described in section 4.2.3.

6.3 Results

Of the 163 knees, only six (3.7%) were deemed to have a "perfectly" fitting tibial component where the medial most part of the tibial tray was flush with the medial tibial cortex.

The groups were well matched for age, height, weight, BMI, side of operations, pre-operative OKS and pain score (Tables 6-2 and 6-3). The smallest width tibial components were twice as likely to overhang when compared to the larger components (p<0.001).

	Minor underhang (< 0mm)	**Minor overhang (0 to <3mm)**	**Major overhang (≥ 3mm)**	**Total**	**Significance**
Number of patients Male Female	35 19 16	112 52 60	14 4 10	161 75 86	0.605
Left **Right**	16 19	60 52	5 9	81 80	0.666
Age at Surgery (years)	65.2 (SD: 8.3)	66.1 (SD: 9.0)	71.4 (SD: 8.9)	66.4 (SD: 8.9)	0.997
Height (m)	1.7 (SD: 0.1)	1.7 (SD: 0.1)	1.7 (SD: 0.1)	1.7 (SD: 0.1)	0.515
Weight (kg)	79.6 (SD: 15.3)	79.3 (SD: 13.8)	73.6 (SD: 11.9)	78.9 (SD: 14.0)	0.464
BMI	26.1 ± 3.3	28.1 ± 4.9	27.3 ± 2.3	27.2 ± 3.5	0.132
Smallest width components (26 mm)	14 (19%)	49 (68%)	9 (13%)	72	**0.001**
Tibial trays with width > 26 mm	21 (24%)	63 (70%)	5 (6%)	89	

Table 6-2: Demographic variables and other factors between the groups

	Minor underhang (<0 mm)	Minor overhang (0 to 3 mm)	Major overhang (≥ 3 mm)	Significance
OKS (Pre-Op)	19 (SD:9)	19 (SD:8)	19 (SD:10)	0.952
1 yr OKS	38 (SD:10)	39 (SD:10)	36 (SD:11)	0.519
1 yr ∆ OKS	21 (SD:10)	20 (SD:11)	14 (SD:11)	0.244
5 yr OKS	40 (SD:9)	41 (SD:7)	31 (SD:11)	**0.001**
5 yr ∆ OKS	21 (SD:8)	23 (SD:10)	11 (SD:9)	**0.001**
PS (Pre-Op)	7 (SD:4)	6 (SD:4)	7 (SD:4)	0.616
1 yr PS	16 (SD:4)	17 (SD:4)	15 (SD:5)	0.408
1 yr ∆ PS	9 (SD:4)	10 (SD:5)	8 (SD:6)	0.278
5 yr PS	16 (SD:4)	17 (SD:4)	13 (SD:5)	**0.001**
5 yr ∆ PS	9 (SD:4)	11 (SD:5)	6 (SD:4)	**0.008**

Table 6-3: Follow up clinical scores at various time points between the groups

One year after surgery, although there was a trend for a lower absolute and change in OKS and PS in the 'major overhang' group when compared to the other two groups, it was not significant (Table 6-3 and Figure 6-2). By five years; the 'major overhang' group had a significantly lower ∆OKS (p=0.021 *vs.* 'underhang', and p=0.001 *vs.* 'minor overhang' group) and total OKS (p=0.002 *vs.* 'underhang', and p=0.001 *vs.* 'minor overhang' group).

The ∆PS was significantly lower for the 'major overhang' group when compared to the 'minor overhang' (p=0.012), but not when compared to the 'minor underhang' group (p=0.211). At five years, total PS was significantly lower in the 'major overhang' group (p=0.014 *vs.* 'underhang', and p=0.001 *vs.* 'minor overhang' group). There was no significant difference between the 'underhang' and the 'minor overhang' groups at any stage.

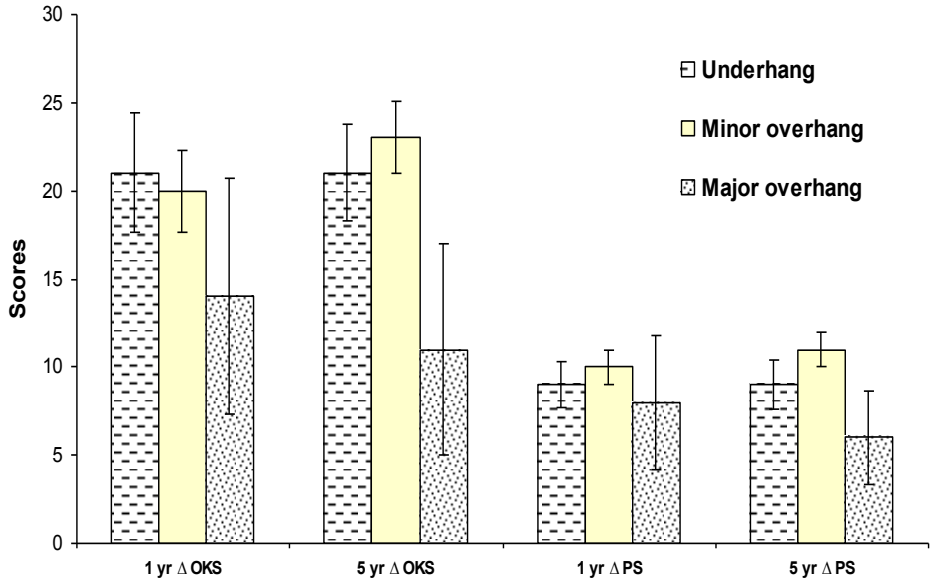


Figure 6-2: One and five year change in the OKS compared with pre-operative evaluation for components implanted with varying degrees of overhang (error bars represent 95% CI)

The analysis of the bearing sizes revealed that none of the bearings were wider than the tibial trays (Table 6-4). However, 25% (42 out of 161) bearings (highlighted in Table 6-4) were about the same width as the tibial trays, so they were likely to overhang by a small amount. There was no statistical difference between the bearings likely to overhang and those unlikely to overhang in terms of one year ΔOKS and ΔPS (p= 0.728 and 0.779 respectively), and five year ΔOKS and ΔPS (p= 0.547 and 0.347 respectively).

Tibial size and width of the flat part	Bearing size and width			
	Small (22 mm)	**Medium (24 mm)**	**Large (26 mm)**	**XL (28 mm)**
A and B (24 mm)	40	33	0	0
C (26 mm)	3	36	8	0
D (28 mm)	0	16	15	1
E (30 mm)	0	2	7	1

Table 6-4: Comparison of the size of the tibial tray with the size of bearings implanted

6.4 Discussion

Appropriate sizing of the tibial component is essential for optimising proximal tibial bone coverage and load transmission in TKR[254,255]. If the implant is too small and inadequately supported, it will subside and loosen[253]. Conversely, if it is too large the overhang may cause soft tissue irritation and pain[252]. The strongest bone in the proximal tibial plateau is the cortex, this should therefore be covered by the implant[255-257]. Tibial component sizing is even more critical for UKR than for TKR, as although the load may be halved, the amount of bone support is less than a half, and there is insufficient room for a large stem.

The study provides evidence that a good medium term clinical outcome score can be achieved after Oxford UKR with tibial component overhang, provided that it is less than 3 mm. Excessive overhang of 3 mm or more, however, is associated with a significantly reduced clinical outcome at five years after surgery. The OKS at five years was substantially lower (10 points) with an overhang of ≥3 mm compared with the 'minor overhang' and 'underhang' groups. It would therefore be advised that the

optimum surgical technique must ensure that component overhang does not exceed 3 mm.

There was no statistical difference between the clinical scores of the 'minor underhang' and the 'minor overhang' groups. The cause for concern with an underhanging tray is that the load is transmitted primarily through the relatively weak cancellous bone rather than the stronger cortical bone[253]. Studies have shown that this may increase the risk of tibial component subsidence[253] and loosening. However, as the incidence of tibial loosening is very low[128], the numbers of patients in this study were insufficient to identify an increase in loosening rate.

In this study, only 4% of the patients had a tibial component which was flush with the medial cortex; this indicates that in the majority of cases, there is not an available component of the ideal size or shape. In these cases, the surgeon has to decide whether to select a component size that will overhang or underhang. As there is a risk of subsidence and hence loosening with components that underhang, it is perhaps better that a tibial component is implanted perfectly or with a small overhang. The Oxford tibial components are manufactured in 2 mm width increments; therefore the surgeon should be able to implant a component that is either flush or overhangs by up to 2 mm.

Another important and clinically relevant observation from this study is that about two-thirds of components that were found to overhang by 3 mm or more were the smallest width components available. It could be hypothesised that in majority of these cases, excessive overhang was the result of the smallest width component available being too large. Therefore, based on this finding the manufacturer should consider introducing an even narrower component or the surgeon should make the vertical cut more lateral.

In terms of the change in clinical scores, it is of interest that in most cases, improvement continued beyond one year after UKR surgery. Although the majority of the improvement in clinical scores for the 'minor underhang' and the 'minor overhang' groups occurred in the first year, from one to five years there was a further increase of approximately 10% (p=0.040). In contrast, in the 'major overhang' group, between one and five years, there was a reduction in the OKS. Because of this, the difference between the scores in the groups did not reach statistical significance at one year, but did at five years post-operatively. This has important clinical implications. The majority of UKR patients can be told that although the majority of their improvement will occur during the first year, that there will be a small additional improvement thereafter. In contrast, patients with an overhang of 3 mm or more, particularly if they have symptoms related to the overhang, cannot be reassured that their symptoms will improve after one year. In actual fact, they should probably be warned that their symptoms might worsen.

With a mobile bearing UKR, there is a concern; not only that an overhanging tibial component might irritate the soft tissues, but also that the overhanging bearing would do the same (senior supervisor's personal opinion). This study found that 25% of the bearings were likely to overhang the tibial component. This, like a small amount of tibial overhang, did not compromise the outcome. Neither of the bearings had a large amount of overhang.

The exact mechanism by which an overhanging tibial component causes pain and leads to a poor functional outcome remains unknown. Various hypotheses have been proposed. One possibility[252] is that the overhanging tibial component causes irritation of MCL or Pes Anserinus bursitis. This has been supported by a recent cadaveric mechanical study[251] which investigated the loads in the MCL for different levels of

tibial component overhang after UKR. Up to 2 mm overhang was shown not to demonstrate a statistically significant difference in MCL load compared to the baseline data; the MCL load however increased significantly with 4 and 6 mm overhang models. This correlates well with the current study as this study demonstrates that up to 3 mm overhang does not compromise the clinical outcome but any overhang more than 3 mm significantly reduces the post-operative OKS.

Another possible mechanism that could explain the poor functional outcome with overhanging tibial components could be related to excessive bone strains in the proximal tibia. Simpson *et al.*[167] used a validated FE model to investigate the effect of underhanging and overhanging Oxford UKR tibial components on surface proximal tibial bone strains. The authors found that the mean von Mises strains increased by 17% with a 3 mm overhang and 30% with a 6 mm overhang. The underhanging components resulted in a reduction of mean von Mises strains. However, the model simulated overhang and underhang by altering the position of vertical cut rather than implanting an incorrect tibial tray size; which is a more common clinical reason for underhang or overhang (anecdotal evidence).

There are other clinical studies that correlate tibial component overhang with clinical outcome after UKR. Some studies[252] have mentioned medial overhang as the cause of persistent ongoing pain after TKR but a more recent study[258] which was specifically undertaken to identify the incidence and effect of tibial component overhang on functional outcomes after TKR has disputed this. McArthur *et al.*[258] found no association between the degree of tibial overhang and the OKS. However, patients with isolated medial overhang were found to have a lower mean OKS (33.2) compared to patients with isolated lateral overhang (mean OKS 36.8); although this was not statistically significant.

The present study focusses on overhang of the Oxford UKR; however, the conclusions are likely to be relevant to other UKR systems provided that the soft tissues are handled in the same manner. When preparing the medial compartment prior to implantation, adequate care should be taken to leave some soft tissues medially so that the implant does not irritate the medial collateral ligament. In particular, a small cuff of medial meniscus and the coronary ligaments should be left behind[185].

The study has several limitations. Although pre-defined landmark points were specified to ensure the reliability of the implant measurements, there were subjective elements in selecting and determining the edges of the bone and implants. Furthermore, radiographic overexposure distorted implant borders on some images, whilst underexposure obliterated the medial tibial bone border. Contrast adjustment using computer software provided a partial solution to this issue, but only for images with adequate quality in the first instance. Nevertheless, the ICC between two observers was high. Although the majority of the knees (70%) had a minor overhang, the number with major overhang (3 mm or more) was small. This was not unexpected as the aim of the surgery was to achieve minimal overhang. As a result, the power of the study was low (80%) with a risk of type II error. This was, however, of little consequence as a significant difference between the groups was found.

6.5 Summary

This study demonstrates the effect of excessive medial tibial component overhang in UKR on clinical outcome. Significantly worse OKS and PS were associated with 3 mm or more medial overhang of the tibial component. Although trays with an underhang or overhang of less than 3 mm have a similar outcome, there is a known risk of loosening with underhanging components[257]. It would therefore be

recommended that tibial components are implanted which are either flush with the medial cortex or with only a minor overhang.

7. THE EFFECT OF RADIOLUCENT LINES (RLL) UNDER THE TIBIAL COMPONENT ON CLINICAL AND RADIOLOGICAL OUTCOMES AFTER OXFORD UKR[259]

7.1 Introduction

Radiolucencies are dark areas, sometimes observed around implanted metal components on radiographs. They are usually found at the bone-cement interface of cemented components or between the implant and the adjacent bone in cases of cementless components. Their presence on radiographs following a hip or knee replacement has often been associated with loosening[260]. A high incidence of RLL, however, is observed in post-operative radiographs following the Oxford UKR[145,244,261]. Despite RLL being very common, their aetiology is not known. Although a number of hypotheses have been proposed, none have been established. In order to gain insight into the aetiology of RLL, it is necessary to determine if they are related to any patient factors (such as BMI and activity level) or surgical factors (such as the state of the ACL and component alignment) or the post-operative factors (such as leg alignment). The study was designed to establish the incidence, aetiology and clinical outcome for RLL observed after Oxford UKR; in particular whether they are related to unexplained post-operative pain.

7.2 Methods

7.2.1 Patient selection

Out of the original cohort of the 164 knees with 'perfectly aligned' radiographs and five year clinical follow up (Section 4.2.2), 161 knees in 138 patients were analysed in the study. Three knees were excluded due to inadequate demographic and intra-operative data. The patients were evaluated clinically and radiographically, pre-operatively and at five years following surgery.

7.2.2 Radiological assessment

The radiographs were obtained and radiolucencies were analysed in accordance with the technique described in section 4.2.2. The area under the tibial tray was divided into six regions and in each region, the presence or absence of RL and the thickness of the RLL were recorded (Figure 4-4). Radiolucencies beside the vertical wall were not assessed as this is not a site where the component is fixed and no cement is placed there.

7.2.3 Clinical assessment

The primary outcome measures were the OKS, PS, AKSS–O, AKSS-F and Tegner activity scale, as described in section 4.2. Changes in these scores, relative to the pre-operative value, were also calculated at five years post-operatively.

7.2.4 Analysis

In order to determine which factors were related to RLL, the distribution of RLL in each patient was classified in three ways:

(a) The presence or absence of RLL

(b) Complete RLL (all six tibial regions with RLL), partial RLL (1 – 5 regions with RLL), and no RLL.
(c) The number of regions with RLL.

The relationship between RLL categorisation and the following were then analysed:

(a) Pre-operative variables such as age at the time of surgery, BMI, gender and pre-operative clinical scores.
(b) Intra-operative factors such as the operating consultant and the ACL status.
(c) Follow up clinical scores as well as the respective changes in the scores over the five years.

Mann-Whitney U and Kruskal-Wallis tests were used for analysis of the non-parametric data. Categorical data was analysed using Chi-squared test. Analyses were carried out with the statistical package SPSS for Windows (V.18.0, Chicago, Il, USA). Statistical significance was denoted by a p-value of <0.05.

7.2.5 Inter-observer variability

To assess the intra- and inter-observer variability, repeated measurements in a subgroup of patients were made by two researchers. None of the researchers had performed the surgery and the X-ray analysis was conducted blinded to the clinical scores. The ICC for both intra- and inter-observer average data were greater than 0.98 ($p<0.01$).

7.3 Results

Of the 161 knees in the study, 101 (62%) were found to have RLL under the Oxford UKR tibial component on radiographs at five years postoperatively. None of the

radiolucencies were greater than one millimetre thick and all had a sclerotic margin. Forty-nine (30%) knees had complete RLL involving all six zones, 52 (32%) had partial and 60 (38%) had no RLL.

7.3.1 RLL vs. No-RLL

The demographics of the patients in the RLL and No-RLL groups were comparable (Table 7-1). The groups were well matched and there was no statistically significant difference in the pre-operative criteria: age at surgery, BMI or gender between the RLL and No-RLL group.

	No-RLL (n= 60, 38%)	**RLL** (n= 101, 62%)	**Significance**
Age (years)	64.3 ± 7.7 (49.5-80.0)	67.1 ± 9.5 (45.3-85.7)	0.223
Gender (Female)	36	52	0.289
(Male)	24	49	
BMI	26.9 ± 4.9 (14.9 – 42.9)	27.8 ± 4.3 (20.9 - 44.2)	0.385
Pre-operative Scores:			
OKS	19 ± 8 (6-42)	19 ± 8 (3-38)	0.945
AKSS-O	35 ± 10 (10-47)	35 ± 8 (15-48)	0.918
AKSS-F	50 ± 10 (30-65)	51 ± 11 (25-70)	0.528
Tegner	2 ± 1 (1-3)	2 ± 0 (1-3)	0.287
5 Year Follow-up Scores:			
5 yr OKS	40 ± 8 (12-48)	40 ± 9 (14-48)	0.212
5 yr AKSS-O	89 ± 13 (45-100)	89 ± 14 (30-104)	0.545
5 yr AKSS-F	86 ± 17 (25-100)	86 ± 18 (0-100)	0.256
5 yr Tegner	3 ± 1 (1-6)	3 ± 1 (1-8)	0.221
Pain scores:			
5 yr OKS Q1,4,5,8,9	17 ± 4 (5-20)	16 ± 4 (3-20)	0.258
5 yr AKS Q1	10 ± 5 (1-19)	10 ± 5 (2-19)	0.212
5 Year Change in Scores:			
ΔOKS	21 ± 11 (3-42)	22 ± 10 (4-46)	0.655
Pain scores:			
5 yr ΔOKS Q1,4,5,8,9	5 ± 1 (2-6)	5 ± 1 (1-6)	0.228

Table 7-1: Demographics and scores in the two groups (RLL and No-RLL). The values indicate mean +/- SD and range

There was no difference between the two groups in terms of the operating surgeon, ACL status, or the degree of post-operative residual varus/valgus leg alignment (Table 7-2). The differences in clinical scores, including the pain scores, between the groups were also insignificant.

	No-RLL	RLL
ACL grade (Chi-Square p-value = 0.256)		
Normal	46	76
Synovial damage	9	17
Longitudinal Splits	4	8
Friable & fragmented	1	0
Absent	0	0
Absent and reconstructed	0	0
Valgus/varus Deformity (Chi-Square p-value = 0.935)		
Varus <0 degrees	4	6
Valgus (0-4 degrees)	17	25
Normal (5-10 degrees)	39	68
Valgus (>10 degrees)	0	2

Table 7-2: Degree of ACL damage and clinical deformity in the two groups (RLL and No-RLL)

7.3.2 No, Partial and Complete RLL

No statistical significance was found in any of the variables when the groups were subdivided into the no, partial and complete radiolucency categories (Table 7-3 and 7-4).

	No-RLL (n= 60, 38%)	**Partial RLL** (n=52)	**Complete RLL** (n= 49)	**Significance**
Age (years)	64.3 ± 7.7 (49.5-80.0)	67.7 ± 9.4 (49.4-85.7)	66.4 ±9.5 (45.3-84.1)	0.358
Gender (Female)	36	28	24	0.528
(Male)	24	24	25	
BMI	26.9 ± 4.9 (14.9 - 42.9)	27.8 ± 4.6 (20.9 - 44.2)	27.9 ± 4.0 (22 - 39.7)	0.625
Pre-operative Scores:				
OKS	19 ± 8 (6-42)	19 ± 8 (4-35)	19 ± 9 (3-38)	0.969
AKSS-O	35 ± 10 (10-47)	36 ± 8 (15-48)	33 ± 8 (20-48)	0.514
AKSS-F	50 ± 10 (30-65)	50 ± 11 (25-70)	53 ± 10 (35-70)	0.522
Tegner	2 ± 1 (1-3)	2 ± 0 (1-3)	2 ± 1 (1-3)	0.233
5 Year Follow-up Scores:				
5 yr OKS	40 ± 8 (12-48)	40 ± 9 (16-48)	39 ± 9 (14-48)	0.565
5 yr AKSS-O	89 ± 13 (45-100)	89 ± 13 (30-104)	88 ± 14 (30-104)	0.454
5 yr AKSS-F	86 ± 17 (25-100)	87 ± 14 (45-100)	84 ± 21 (0-100)	0.652
Tegner	3 ± 1 (1-6)	3 ± 1 (1-8)	3 ± 1 (1-6)	0.611
Pain scores:				
5 yr OKS Q1,4,5,8,9	17 ± 4 (5-20)	16 ± 4 (3-20)	17 ± 4 (5-20)	0.395
AKS(5) Q1	10 ± 5 (1-19)	11 ± 5 (0-19)	11 ± 5 (0-19)	0.256
5 Year Change in Scores:				
ΔOKS	21 ± 11 (3-42)	22 ± 9 (4-37)	22 ± 10 (4-46)	0.912
Pain scores:				
5 yr ΔOKS Q1,4,5,8,9	5 ± 1 (2-6)	5 ± 1 (1-6)	5 ± 1 (1-6)	0.732

Table 7-3: Demographics and scores in the three groups (Partial, Complete and No-RLL)

	No-RLL	Partial RLL	Complete RLL
ACL grade (Chi-Square p-value = 0.256)			
Normal	46	40	36
Synovial damage	9	8	9
Longitudinal Splits	4	4	4
Friable & fragmented	1	0	0
Absent	0	0	0
Absent and reconstructed	0	0	0
Valgus/varus Deformity (Chi-Square p-value = 0.935)			
Varus <0 degrees	4	4	2
Valgus (0-4 degrees)	17	11	14
Normal (5-10 degrees)	39	35	33
Valgus (>10 degrees)	0	2	0

Table 7-4: Degree of ACL damage and clinical deformity in the three groups (Partial RLL, Complete RLL and No-RLL)

7.3.3 Regions with RLL

No statistical significance was found in the incidence of radiolucent regions under the tibial component between the No-RLL, partial-RLL and complete-RLL groups. RLL were most commonly seen in region 6 (49%) followed by region 1 (48%). The average width of a RLL was 0.73 mm (SD: 0.36) and there was no significant difference in the width of RLL seen in the different regions (p=0.231).

7.4 Discussion

Goodfellow *et al.* subdivided radiolucencies observed under the tibial component of Oxford UKR into two distinct subtypes[185]. The commonest type is the physiological radiolucency, which is often called RLL. This develops during the first post-operative year and thereafter consolidates, but does not progress. The RLL are narrow and usually are one millimetre thick but can be up to two millimetres. They are well defined and are surrounded by a radio dense sclerotic line. In contrast, the rarer type of radiolucency is the pathological radiolucency which is associated with loosening or

infection. They are progressive, poorly defined, more than two millimetres thick and without the presence of a radio dense line (Figure 7-1).

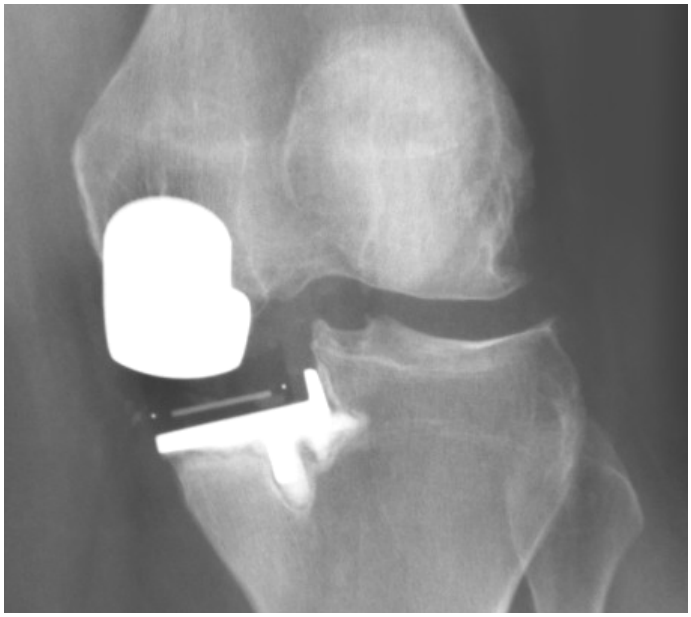


Figure 7-1: Radiograph showing a pathological radiolucency under the tibial component of the Oxford UKR

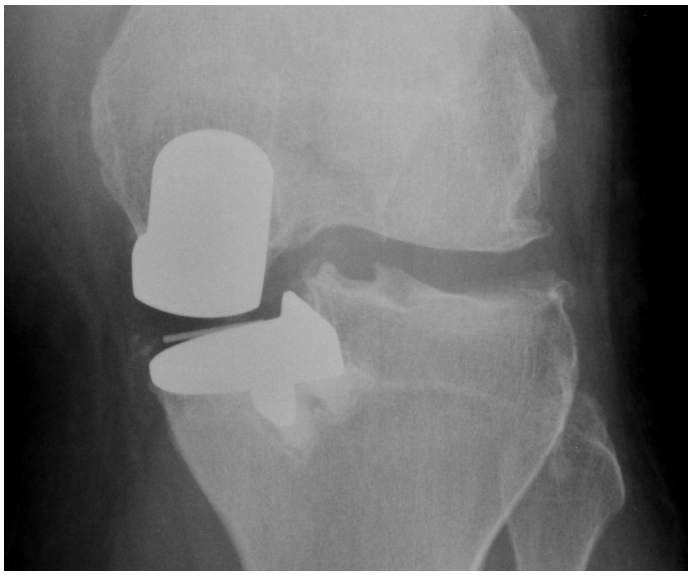
Physiological radiolucencies are commonly observed after Oxford UKR. *Tibrewal et al.* detected an incidence of 96% partial or complete RLL around the tibial components in 80 knees from 78 patients with the Oxford meniscal knee replacement implants[145]. This study confirms that RLL under the tibial component following Oxford UKR are common. One third of cases had complete RLL, one third had partial and one third had none. The majority of Oxford UKR tibial components have RLL at one year, yet the clinical data demonstrates that at 10 and even 20 years the incidence of loosening is very low[108,156]. This indicates that RLL are neither associated with, nor predictive of loosening. Despite this many surgeons feel that if a patient has pain and a RLL on the radiograph then the pain is related to the RLL. There is therefore a tendency to convert these cases to TKR. In order to determine whether pain is

caused by RLL, it is necessary to determine, in a large study, if RLL and symptoms are related.

The incidence of RLL can depend on how the radiographs are taken. If an image intensifier is used and the x-ray beam is adjusted until it is parallel to the interface then RLL are commonly seen (Figure 7-2a and 7-2b)[185]. Conversely with standard radiographs, which are not taken parallel to the interface, any radiolucent material is obscured by the implant so RLL cannot be visualised[262]. Tibrewal *et al*.[145], who were the first to report a high incidence of RLL for the Oxford UKR, studied a group of patients who had undergone bicondylar knee replacements[145]. The high incidence was attributed primarily to the fluoroscopically aligned radiographic technique used for the post-operative assessment of the implant. This study only used fluoroscopically screened radiographs following Oxford UKR and confirms that with accurately aligned radiographs, there is a high incidence of RLL. It was also observed that a RLL seen during screening will disappear if the fluoroscope is tipped just two degrees (Figure 7-2a and 7-2b) so the precision with which screened x-rays are taken will also influence the incidence of RLL.



7-2 a: Screened radiograph showing radiolucency



7-2 b: Standard radiograph of the same patient not showing the radiolucency

Figure 7-2: Pair of radiographs, one screened (a) and one standard (b), of the same patient showing that RLL is not always visible on standard x-rays. The standard X-ray was taken on the same day as the screened X-ray with two degrees tilt of the image intensifier (copyright Oxford University Press)[185]

The use of fluoroscopic aligned radiographs is not a very common practice in the UK. Kalra *et al*.[263] conducted a telephonic survey of 110 hospitals in the UK and found

that no hospital other than the Nuffield Orthopaedic Centre, Oxford acquired radiographs under fluoroscopic guidance. All other hospitals used standard weight-bearing AP and cross-table lateral radiographs in the follow-up of UKR. The intra- and inter-observer reliability, and the sensitivity and specificity of the measurements from standard radiographs were assessed. Their results demonstrated that the standard radiographs were 63.6% sensitive and 94.4% specific for tibial RLL and 63.9% sensitive and 72.7% specific for femoral RLLs. Screened radiographs were not taken, so equivalent values for fluoroscopy-guided radiographs are unknown.

None of the factors that are thought to influence implant fixation were found to be significantly associated with the presence or distribution of RLL in this study. In particular, patient related factors, such as BMI and activity level (Tegner score) which influence the load transmitted by the knee and which are thought to influence loosening of UKR[166] were not related to RLL. Similarly, surgery related factors such as residual varus or ACL damage, which are also thought to increase the likelihood of loosening, did not relate to RLL. It therefore remains unclear what factors are likely to lead to RLL.

Many theories have been proposed to explain the underlying aetiology of RLL. Thermal necrosis due to the heat of polymerisation of cement and the resulting bone resorption has been suggested, as in the case of hip replacement[264]. Some studies have reported a higher incidence of tibial RLL in cementless UKR compared with cemented UKR, which may disprove the theory[265]; however, not all studies agree[146,266]. There is some evidence[267,268] that pulse lavage can decrease the incidence of RLL suggesting that cementing technique may be of importance. The possibility of micromotion causing local osteonecrosis and fibrocartilage tissue formation leading to RLL has also been considered[269]. However, Rea *et al.* found no

correlation between RLL and micro motion of the tibial component using RSA, despite having a 75% incidence of RLL[270].

Another suggested theory is that RLL formation is a response to load[271]. A recent study by Gray *et al.*[272] used a validated 3D FEA model to identify the cause of radiolucency and sclerotic lines observed underneath the tibial components of Oxford UKR. The authors observed that the mean von Mises stress of the elements in the bone adjoining the radiolucent zone with a sclerotic line was higher when it was assumed that adaptive remodelling (1.43 MPa) occurred due to regular loading. In contrast, when no remodelling was modelled, the mean von Mises stress was low (0.69 MPa).

As this study was performed on patients with an Oxford UKR, it is not clear whether the findings could be extrapolated to other UKR devices or TKR. Although metal-backed fixed bearing UKR are similar in many ways to the Oxford UKR, the load transmission is not identical[273]. As previously mentioned, with a mobile bearing, the load at the interface in the Oxford UKR is predominantly compressive. With a fixed bearing UKR, particularly if the polyethylene is worn, shear stress may occur at the interface in addition to compression. These shear stresses may affect RLL formation in a different way. The interface loading with TKR is very different to UKR because of the deep stem and because the loads can be eccentric, causing tipping. It is therefore unlikely that the findings from the study will apply to TKR.

With the Oxford UKR, as a result of the mobile bearing, all the loads (except those related to friction) transmitted to the tibial bone-cement interface are compressive. Gray *et al.* suggested that the sclerotic margin of RLL forms first as a fibrocartilage at the interface, then develops into a new subchondral bone in response to mechanical loading[272]. Li *et al*. found that there was a lower incidence of RLL in mobile bearing

implants than fixed[274]; fixed UKR components have a more concentrated load position as they are not conforming, this change in load profile may have influenced RLL position.

Simpson *et al.*[275] used FEA to determine the cause of physiological radiolucency. The authors analysed AP radiographs of 20 cemented and 20 cementless Oxford UKRs and defined Zone 7 as the region parallel to the vertical wall of the tibial component. All forty radiographs were found to have radiolucency in Zone 7. The FEA study revealed this region had 80% less strain energy density (SED), 63% less maximum tensile stress and 52% less maximum compressive stress compared to the intact tibia. This phenomenon was observed both in the cemented and cementless models. The authors suggested that this reduction could send a signal for adaptive bone remodelling and the bone resorption will continue until the equilibrium state is reached. The high incidence of RL in Zone 6 in the present study could partly be due to the same process, but this was not analysed in the current study.

A recent study performed by Kendrick *et al.*[269] studied the radiology and histology of retrieved specimens of 10 patients in whom a well fixed Oxford UKR was revised with a view to identify the type and distribution of tissue at the cement–bone interface. The authors observed that 52% (median) of tibial tray surface area had a cement–bone contact. The rest of the area had either fibrocartilage (median 27%) or fibrous tissue (median 14%). A strong inverse correlation was found between the percentage of cement–bone contact and the presence of radiolucency. In the current radiographic study, about two-thirds of the radiographs had some evidence of radiolucency under the tibial component.

Clinically the most important finding of this study was that there was no relationship between RLL or the extent of the RLL and outcome. In particular, patients with

complete RLL did not have more pain than those without RLL. This indicates that the underlying process responsible for the RLL does not necessarily cause pain. In other words, if a patient is being investigated for pain then physiological RLL should be ignored. This is a real clinical problem for surgeons that use standard, non-screened x-rays. These surgeons may formulate the view that RLL are rare. There is a danger that if as part of an investigation of a patient with post-operative pain, the radiographic beam of a standard radiograph happens to be aligned with the component and RLL are observed, such surgeons may decide to revise the UKR. It is therefore important that surgeons are made aware that physiological RLL are unlikely to be the cause of pain.

This study has some limitations. Firstly, femoral radiolucencies were not assessed; however no patient in the published data of first 1000 patients with Oxford UKR has been revised for loosening of the femoral component[128]. The incidence of femoral loosening was therefore considered sufficiently low to justify omission. Some authors[263] have, however, developed a method to categorise femoral radiolucencies based on lateral radiographs. Another limitation of the study is that although the radiographs were accurately aligned, some of them were not of good quality (either overexposed or underexposed) which made measurement and detection of radiolucency difficult. Adjustment of the contrast and brightness helped to overcome this issue.

7.5 Summary

This study demonstrates that under the tibial component of the Oxford UKR, complete RLL are seen in one third of patients, partial RLL in one third and no RLL in one third. The frequency of RLL does not seem to relate to patient (such as age, BMI, gender, activity level) or operative (such as ACL status or alignment) factors.

Therefore, it remains unclear why RLL occur. No relationship was found between RLL and outcome, particularly pain. Therefore, physiological RLL are not likely to be a source of pain and can be ignored when investigating patients who have post-operative pain, although they should be monitored to ensure that RLL do not progress with time.

8. BONE OVERLOAD AS A CAUSE OF PAIN

8.1 Introduction

It has been hypothesised in several studies that there is an excessive strain in the proximal tibia following UKR implantation and this may be related to unexplained pain and hence a poor functional outcome[166,167,276]. It is not possible to measure these strains clinically using non-invasive techniques and cadaveric studies are not practical when exploring numerous variables which may affect these strains. The use of finite element analysis (FEA) provides a balanced solution. Not only does the FEA allow an accurate estimation of these strains based on validated models, but also there is flexibility to alter various loading and alignment parameters in a relatively short time and at a reduced cost. Furthermore, the effect of each parameter can be assessed individually by keeping the rest of the boundary conditions and loading parameters unchanged.

The aim of this study was to compare various parameters that could affect the proximal tibial bone strain after UKR implantation using the FE method. The other objectives were to determine the clinical significance of proximal tibial bone strain and analyse whether the FEA could predict trends observed clinically.

8.2 Finite Element Analysis

FEA, a computer based numerical method, is commonly used for solving difficult engineering and mathematical problems. It offers a distinct advantage over analytical and experimental methods for analysing objects with complex geometries, loading conditions and material properties[277]. FEA can solve complicated simulations at great speed, has a significantly reduced cost compared with experimental methods and

has the advantage, clinically, of being able to assess or predict a mechanical scenario non-invasively.

The basic principle of FEA is to reduce a continuous object into many smaller elements for which individual mechanical calculations are achievable; these multiple achievable calculations can then be solved for the whole object[278]. The elements are connected to each other at nodes and each element is assigned a known material property (such as elastic modulus and Poisson's ratio), which determines how it responds to certain loading parameters and boundary conditions. Linear elastic material models assume each element behaves like a spring and follows Hooke's law, which states that the spring elongation is directly proportional to the load applied[279].

Force = Stiffness X change in length

or

$$\boldsymbol{F} = k\,\boldsymbol{x}$$

where 'k' is the stiffness matrix of the spring and x is the change in length

The calculations are therefore performed at each node simultaneously by inverting the stiffness matrix and results of these calculations then represent the behaviour of the entire structure in terms of displacement.

Bone, with heterogeneous material properties and a complex 3D geometry, has been analysed using FEA since 1972[280]. With the advancement in computing power, the orthopaedic applications of FEA have been extended to the analysis of joint replacements[166,281,282], fracture healing[283-285], fracture fixation devices[286] and bone remodelling[287,288] and many more.

From the nodal displacement, a number of outputs can be generated but the most commonly used are the stresses and strains. The Von Mises criterion is a formula which often used to calculate equivalent equivalent stress or strain respectively[289].

Broadly, FEA consists of following three steps[277]:

Pre-processing: This step includes making three-dimensional (3D) models, generating the mesh (dividing the entire structure into multiple elements), and applying loading and boundary conditions and the material properties.

Processing or simulation: During this step, the model is solved by carrying out various matrix formulations, inversions and multiplications.

Post-processing: The results are viewed and analysed during this step.

A detailed description of these steps with particular reference to this study is given below.

8.2.1 Constructing 3D geometric models

One of the challenges for any FEA study is to obtain accurate 3D geometry of the constituent parts. The whole analysis will yield erroneous results if the 3D models are not representative. The 3D geometry of each UKR tibial component used in this study was obtained from the manufacturers (Biomet UK Healthcare Ltd, Swindon, UK).

The 3D profile of the bone can be obtained in two ways. One method is to use surface digitisation which involves directly inputting the coordinates of the geometric surface into a computer[290]. The second method, which is more commonly used, is to use medical imaging techniques like Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) to produce multiple 2D images of an object in different

cross sections. These 2D images are then reconstructed using image segmentation software to produce a 3D model. It is imperative that the scanner has a sufficiently high resolution to create a sufficiently representative 3D model.

For the purpose of this study, a previously obtained CT scan (HiSpeed CT/I, GE Medical Systems, USA) of cadaveric tibia (male donor, age 60 years, height 178 cm, weight 82 kg, left side) was used (courtesy of H Gray)[291]. The CT dataset was then used to create 3D surface models through image segmentation using MIMICS software (Materialise, version 2010 x64, Leuven, Belgium). These were then imported into Solidworks Software (version 2011 x64, Waltham, MA, USA) which was used for making cuts in the proximal tibia and inserting the geometric model of the Oxford UKR tibial tray (Figure 8-1).

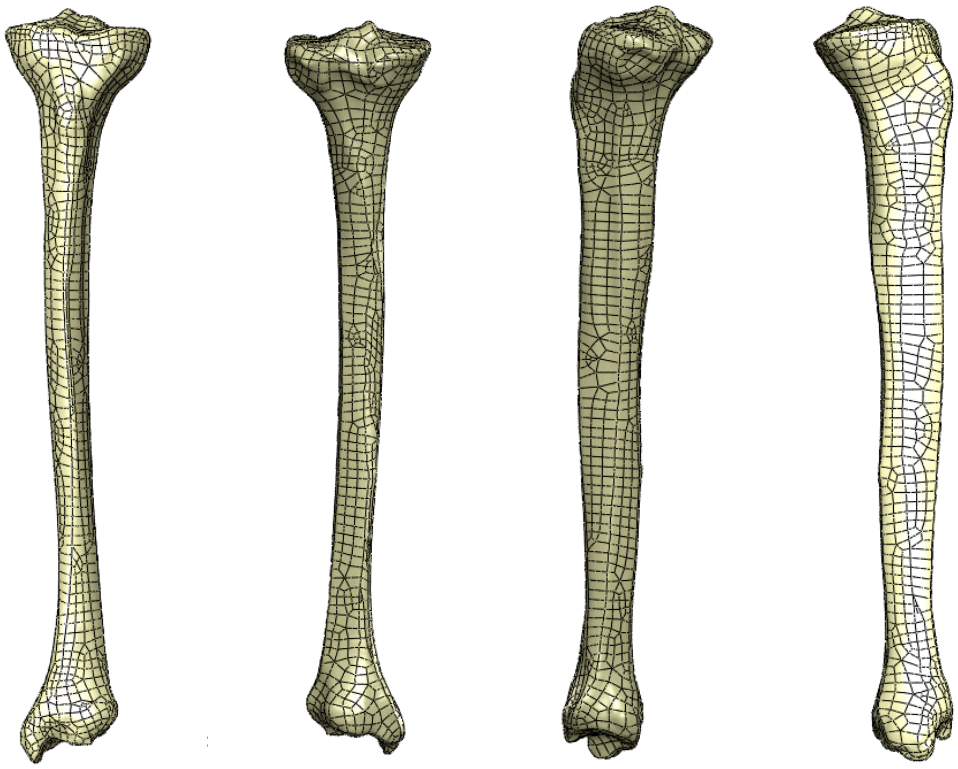


Figure 8-1: 3D model of the whole tibia imported into Solidworks

The tibial mechanical axis was defined so it could be used a reference for making cuts in the proximal tibia to later insert the Oxford UKR tibial component and for applying the correct loading conditions. The proximal point of the tibial axis was the centre of the knee, which was determined by a method described by Cobb *et al.*[292]. Visually best fit circles were drawn on the proximal medial and lateral tibial plateau. The midpoint of the line joining the centres of these circles was taken as the centre of the knee (Figure 8-2).

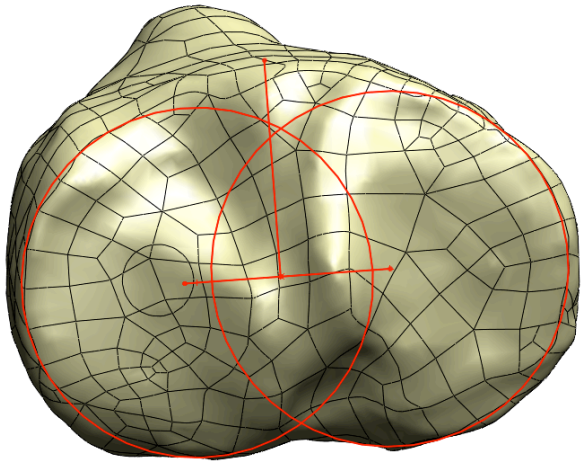


Figure 8-2: Proximal tibial surface showing the centre of the knee as determined by the midpoint of the line joining the centres of medial and lateral tibial plateau circles

The distal part of the mechanical axis was the centre of the ankle which was determined using the described by Yoshioka *et al.*[293]. Two diagonals were drawn from the corners of the weight-bearing area of the distal articular surface of the tibia and the centre of the ankle was taken as the intersection point between these diagonals (Figure 8-3).

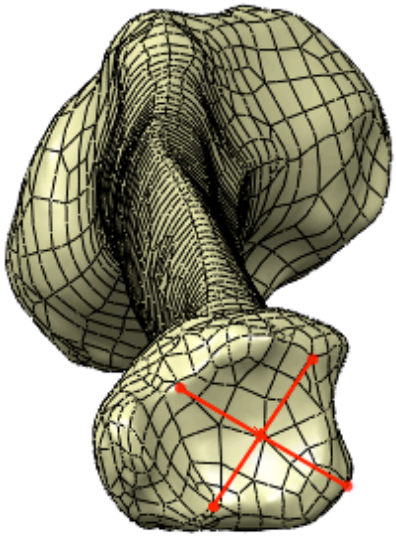


Figure 8-3: Distal tibial articular surface showing the centre of ankle as an intersection of two diagonals

The mechanical axis was marked as a line joining the centre of the knee and centre of the ankle (Figure 8-4). In the tibia, the mechanical axis generally corresponds to the anatomical axis[19].

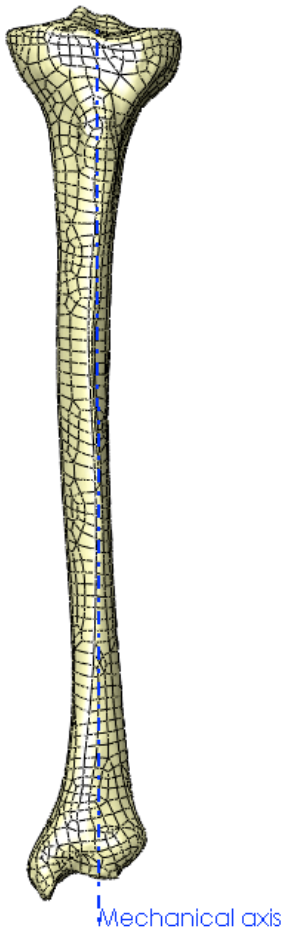


Figure 8-4: Full length tibia demonstrating the mechanical axis

A reduced model measuring 75 mm from the tibial plateau was created as this was the main area of interest where patients most commonly complain of pain (Figure 8-5).

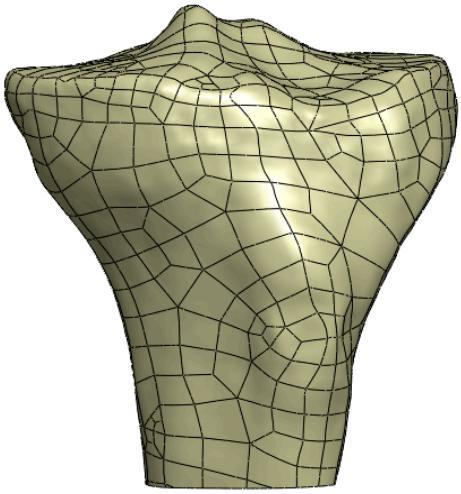


Figure 8-5: Reduced 75 mm model of the proximal tibia which was used to make cuts to implant the Oxford UKR tibial component

A neutral model with a well aligned tibial component was first created. Various planes were drawn on the 3D model as templates for making bone cuts: the tibial slope plane, the mechanical axis plane and the distal tibial articular plane. The horizontal and sagittal cuts were then made in accordance with the surgical guidelines[185]. The recommended sagittal cut in the neutrally aligned model was positioned just medial to the insertion site of the ACL on the tibial spine and parallel to the tibial mechanical axis. The recommended horizontal cut was the one which was 4 mm from the tibial slope plane and perpendicular to the sagittal cut and parallel to the tibial slope plane (Figure 8-6).

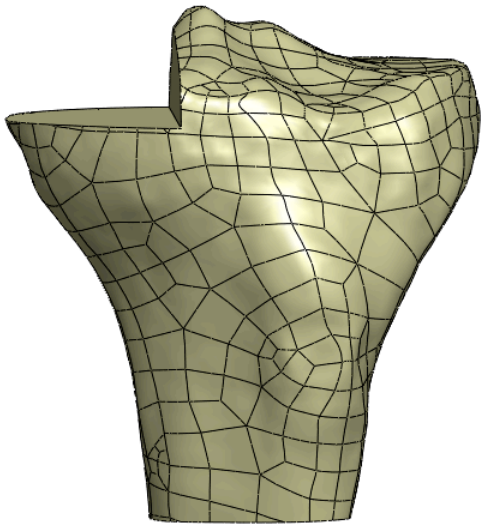


Figure 8-6: Proximal tibia with ideal horizontal and sagittal cuts

The geometry of an appropriately sized tibial component was used to position the keel slot on the horizontal cut surface (Figure 8-7). In this model, a Size C tibial tray was found to avoid overhanging or underhanging of the tibial component.

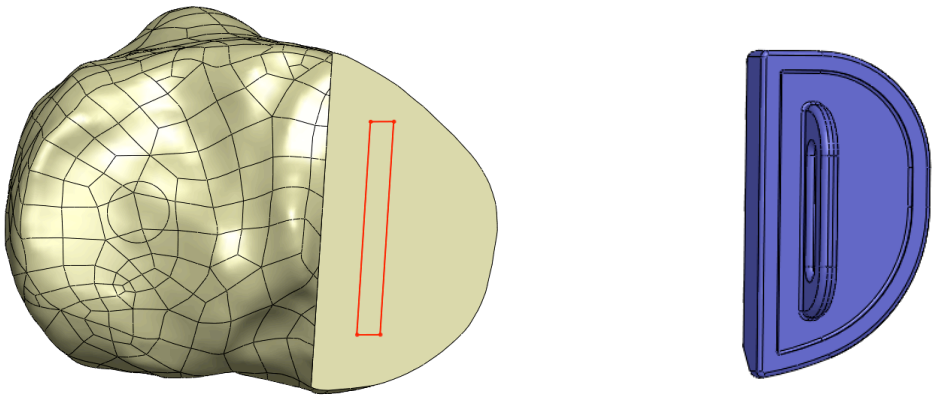


Figure 8-7: Sketch of the left side Size C tibial tray keel slot on the horizontal cut surface

The tibial keel slot was then prepared on the 3D model (Figure 8-8).

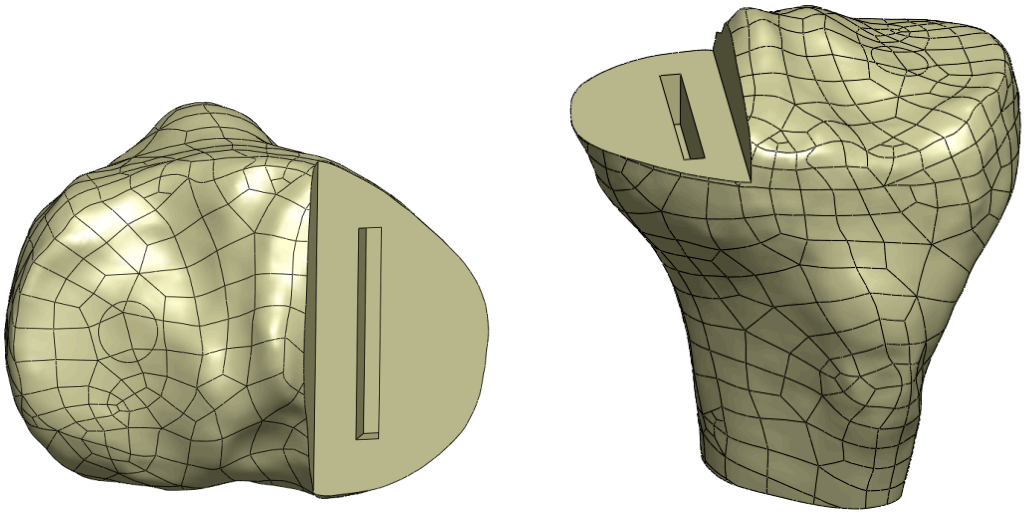


Figure 8-8: Keel slot prepared on the proximal tibia and the model was ready for implanting the tibial component

A rectangular area (Test area) was marked on the antero-medial surface of the 3D proximal tibial model. This area has been shown in some previous studies[166,167] to demonstrate a high tibial bone strain after UKR. The proximal length of the rectangle was 13.6 mm below the horizontal cut surface [167](Figure 8-9).

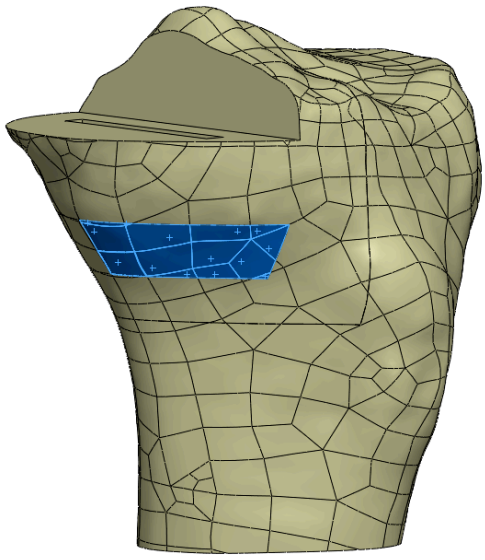


Figure 8-9: Test area on the antermedial surface of proximal tibia which was used for strain comparisons between different models

An assembly was then made by inserting a tibial component into the prepared 3D model of the proximal tibia (Figure 8-10). A one millimetre space was defined between the central part of the tibial component and the upper surface of proximal tibia, which was filled up with cement. No cement was modelled between the lateral vertical wall of the tibial component and the medial vertical wall of the proximal tibial saggital cut, in accordance with the surgical technique[185].

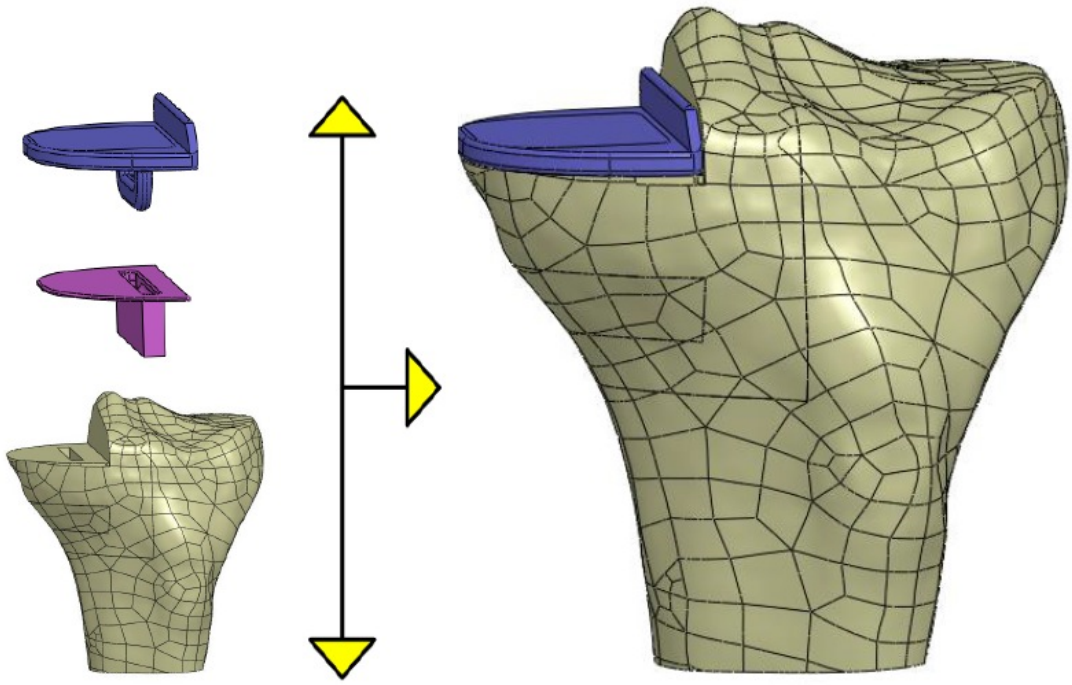


Figure 8-10: A 3D model assembly of the neutrally aligned tibial component showing the three constituent parts: proximal tibia, bone cement and tibial component

The cement pocket was within the outer rim of the lower surface of the tibial component (Figure 8-11). This outer rim of the tibial component was therefore in contact with the proximal tibial horizontal cut surface. This study is different to the majority of the published literature on the Oxford UKR[166,167] because the cement is constrained to be within the cement pocket and this therefore better represents the surgical technique[185].

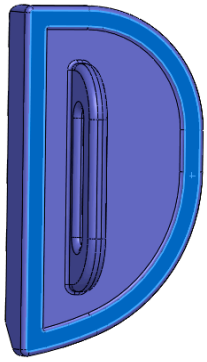


Figure 8-11: 3D geometric model of the under surface of the tibial tray demonstrating the outer rim which was in contact with the proximal tibia (highlighted in blue). There was no cement mantle between this surface and the proximal tibia

The three constituent parts of the 3D model assembly were imported to Abaqus CAE Software (version 6.9.3, Providence, Rhode Island, USA) for meshing and applying boundary conditions.

8.2.2 Mesh convergence

In any FEA study, choosing the correct type of elements and the density of the mesh is essential to get reproducible, accurate data. A less refined mesh may not give representative results. On the other hand, a mesh which is highly dense will no doubt improve the accuracy of results, but at the cost of exponentially increasing the computer processing time[294]. There is often a stage whereby any further increase in mesh refinement only changes the results by a small margin but the amount of time taken to solve the model increases exponentially. This point is called mesh convergence and is said to have been reached if the results meet the required accuracy.

The process of finding that stage generally involves going through a few steps:

1) The models are created and analysed using a random mesh size with reasonable number of elements.
2) The model is then re-analysed with a finer mesh and the results are compared with the previous mesh density.
3) The mesh density is then increased again and the model analysed iteratively until the results converge satisfactorily.

In this study, the mesh density was assigned using different sizes of global seeds ranging from 1-6 mm; the smaller the size of the global seeds, the larger the number of nodes and the finer the mesh (Table 8-1) (Figure 8-12).

Average size of global seeds (mm)	Number of nodes in the Test area
1.00	1409
1.50	652
1.75	507
2.00	427
2.50	272
3.00	233
4.00	160
5.00	119
6.00	101

Table 8-1: Number of nodes in the 'Test' area when different sizes of global seeds were used to mesh the 3D tibial model

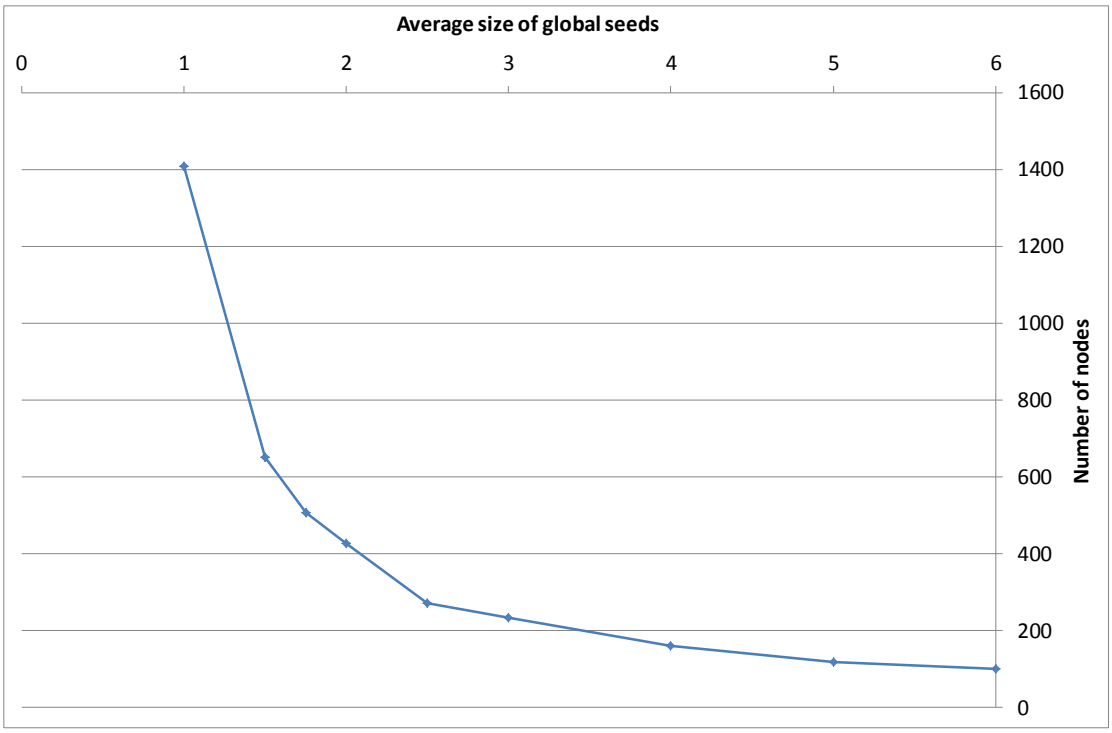


Figure 8-12: The relationship of mesh size with the number of nodes

The mean and median von Mises strains (VMS) in the Test area (Figure 8-13) were used for performing the mesh convergence study and different mesh sizes were analysed. Less than a 5% change in the median or mean VMS with progressively smaller mesh sizes was used to define convergence and therefore was taken as the desired accuracy of the model. The nodes converged at a global seed size of 2 mm (number of nodes: 427) as there was < 5% change in the median and <2% change in the mean VMS beyond this level (Figure 8-14). Therefore, for this study, a global size of 2 mm seeds was used for meshing the tibia (Figure 8-15).

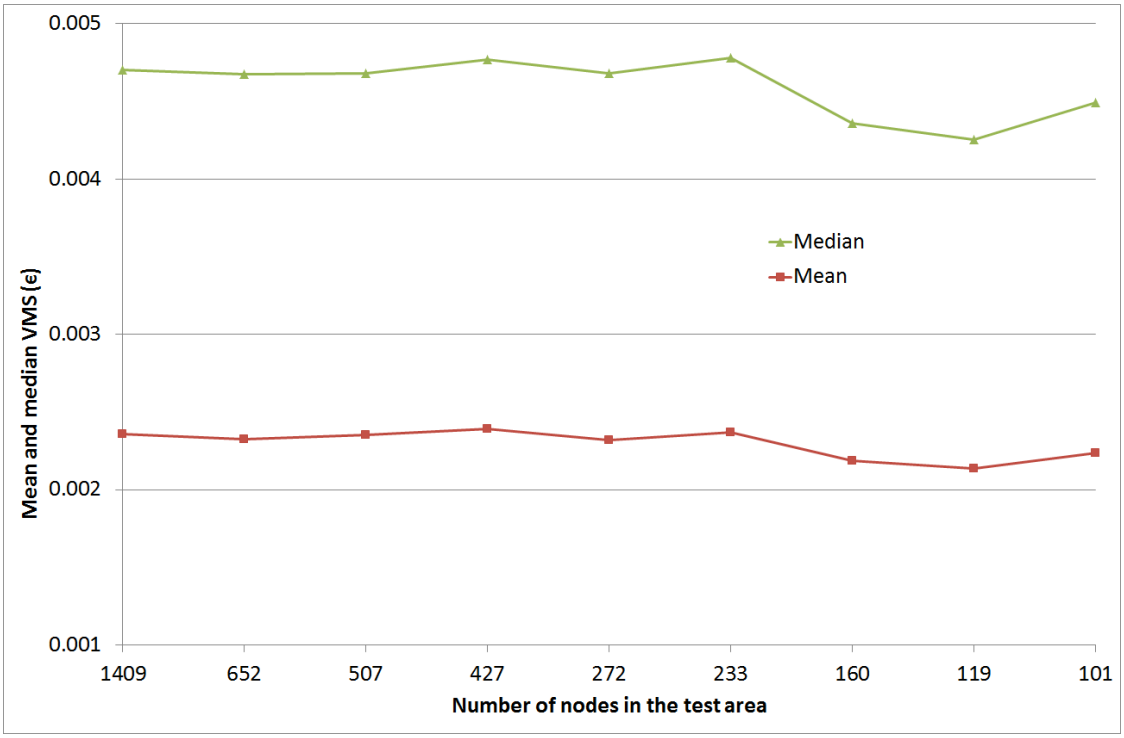


Figure 8-13: Mean and median VMS in the test areas plotted against the number of nodes in the model demonstrating <5% change in the median VMS and <2% change in the mean VMS from the global seed size 2 mm onwards

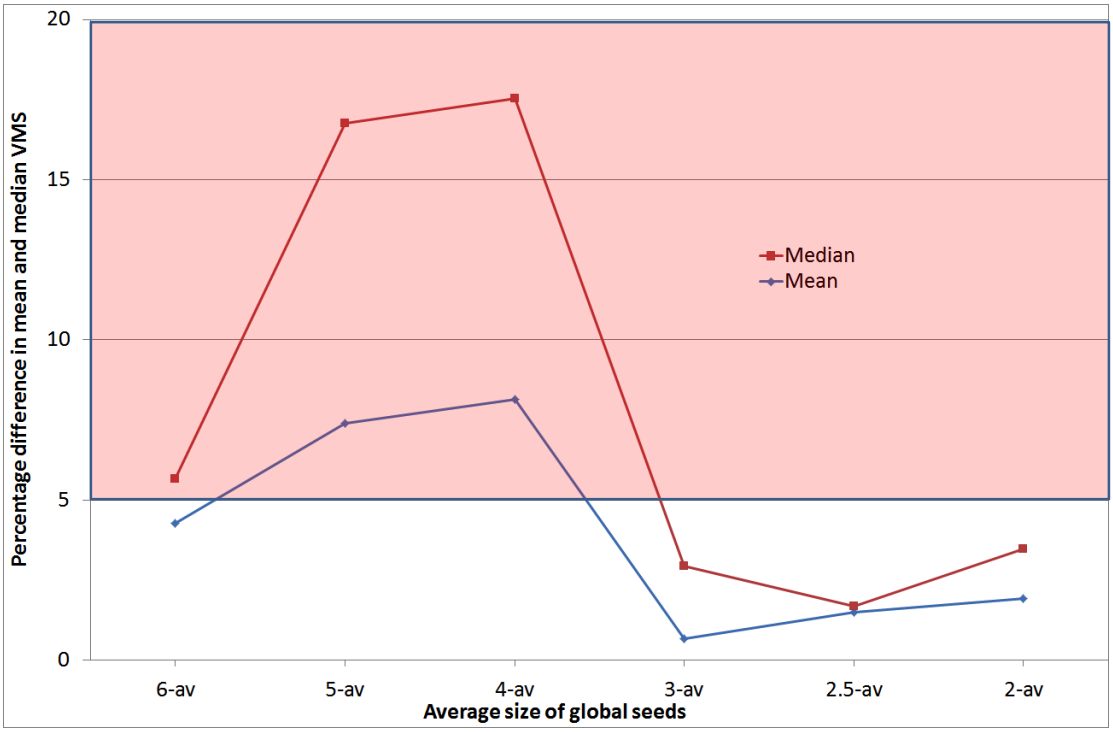


Figure 8-14: Percentage difference in the mean and median VMS between gradually reducing approximate size of global seeds. The red area was beyond the acceptable limits of accuracy

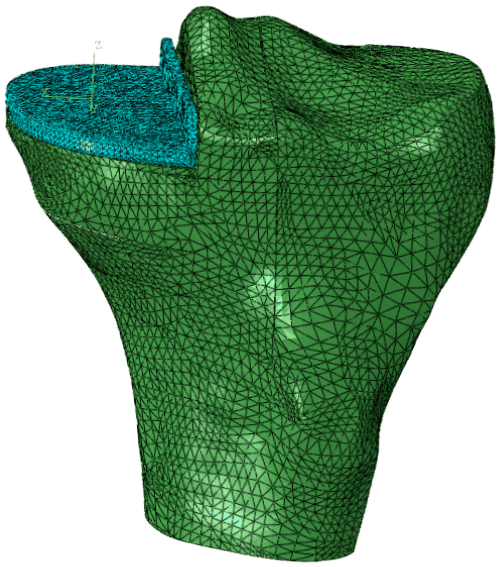


Figure 8-15: 3D model of proximal tibia with implanted UKR after meshing in Abaqus

8.2.3 Assigning material properties

Once the proximal tibia was meshed in Abaqus, the material properties were assigned to the bone (Figure 8-16) using MIMICS software. The material assignment methodology has been previously validated[171] and is based on orthotropic material properties derived (courtesy H Gray) from the CT Hounsfield units in accordance with the relationships established by Rho *et al.*[295]. One of 400 material properties was assigned to each element in the bone. The tibial component, made up of cast cobalt-chromium-molybdenum alloy, was modelled as a linear isotropic elastic material with a Young's modulus of 195000 MPa[296] and a Poisson's ratio of 0.3[297]. The bone cement was also assigned linear isotopic material properties with a Young's modulus of 1940 MPa[296] and a Poisson's ratio of 0.3[298].



Figure 8-16: 3D model of a neutrally aligned tibial component in the proximal tibia after assigning various material properties. Different colours demonstrate different material properties of the elements

8.2.4 Boundary conditions

The published *in vivo* motion and axial tibial load data collected from a patient performing treadmill gait, measured using video fluoroscopy and an instrumented tibial component, was used to apply load in the FE models. The step-up activity (two times the body weight medially and 1.5 times the body weight laterally[249]) was modelled as it has been shown to correlate better with the clinical outcome measures[299]. The medial load was applied to the tibial component using an analytical field method described by Pegg *et al*.[276]. On the lateral tibial plateau, the load was applied in a circular area (10 mm diameter) in the centre, along the mechanical axis of the tibia. The lower end of the tibia in the proximal tibial model was rigidly constrained. The contact surfaces between the lower end of the tibial component and the upper end of cement (bone-cement interface) and between the lower end of the cement and upper end of the proximal tibia (cement-bone interface) were modelled as tie constraints – this is where was no movement was permitted between tied

nodes (Figure 8-17). Only the step up activity was modelled in the current study, as this corresponded to the flexion angle (35°) which demonstrated the maximum load[249].

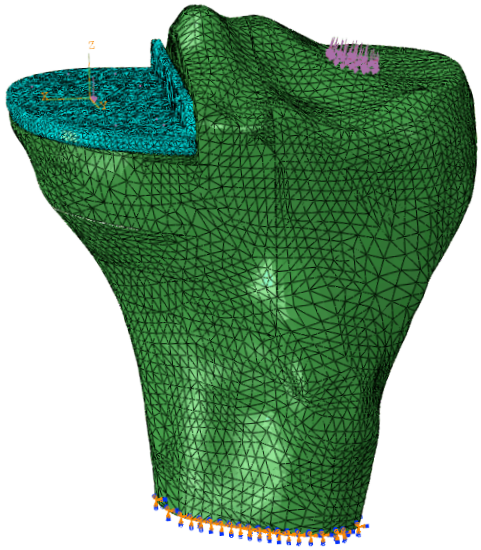


Figure 8-17: Neutrally aligned model with the loads applied on the medial and lateral tibial plateau and a fixed lower end

8.3 Analysis

8.3.1 Model verification

The primary outcome measure was the mean VMS within the pre-defined Test area on the antero-medial cortical surface of the proximal tibia (Figure 8-9). The area was chosen based on clinical observations and previously reported clinical studies[163] which suggest this area to be the commonest location where patients perceive pain. The mesh in this region was consistent between models with varying implantation and alignment parameters, thus allowing comparison between different FE models. The assessment of strain in this region to examine tibial pain has been previously reported in the literature[167,276].

The reduced proximal tibial model was validated against the full-length tibia model to ensure the length change did not affect the results. To perform this, an experiment

was conducted to analyse whether the reduction in the model size, from the full length to 75 mm, influenced the strains in the proximal tibia. The mean VMS in the test area in the full length tibial model with neutrally implanted UKR was 2120 με (SD 939 με). This was not significantly different (p=0.232) from the reduced neutrally implanted UKR model (2019 με, SD 946 με). As no significant difference was found, this reduced proximal tibial was used for all the remaining analyses.

8.3.2 Model application

To analyse the effect of Oxford UKR implantation on proximal tibial bone strain, the strains on the neutrally aligned model were compared with the strains on the intact tibia (non-implanted model) when the same boundary conditions and loading parameters were applied. The effect of the neutrally implanted tibial component without keel slot was also analysed to determine whether the position of the keel slot influenced these strains. During the surgical implantation of the Oxford UKR, cement is not applied to the vertical wall of tibia[185]. An experiment was conducted to analyse whether bonding the lateral surface of the vertical wall of the tibial tray with the medial surface of the proximal tibial sagittal cut, influences the proximal tibial bone strain.

The following other variants in the implant alignment and position were modelled: alignment parameters, overhang and underhang parameters and loading parameters.

8.3.2.1 Alignment parameters

A total of eight varus-valgus malalignments of the tibial tray in the coronal and sagittal planes were modelled, up to 5 degrees at 2.5 degree increments. These were:

- 2.5 degrees varus
- 2.5 degrees valgus
- 2.5 degrees superior tilt
- 2.5 degrees inferior tilt
- 5 degrees varus
- 5 degrees varus
- 5 degrees valgus
- 5 degrees superior tilt
- 5 degrees inferior tilt

These angles were chosen to allow direct comparison with the clinical study as detailed in Chapter 4. For creating the varus-valgus models, the tibial tray was rotated around the base of the vertical wall; for creating superior-inferior tilt models, the tibial tray was rotated round the anterior edge of the tibial tray. The position of the femoral component was not changed and the load was applied in the centre of the tibial component in all the models.

8.3.2.2 Overhang or underhang parameters

The overhang of the tibial component was modelled in two ways:

a) Altered sagittal cut: The tibial sagittal cut was placed increasingly medially at one millimetre increments to generate four overhang models.

- 1 mm overhang
- 2 mm overhang
- 3 mm overhang
- 4 mm overhang

b) Incorrectly sized tibial component: The best fitting tibial component, based on visual inspection, was a Size C tibial tray which had no overhang or underhang.

- Size A and B trays were used to create two 'Underhang' models (2 mm and 4 mm underhang, respectively).
- Size D and E trays were used to create two 'Overhang' models (2 mm and 4 mm overhang, respectively).
- Size E tray without the keel slot was also modelled to analyse whether the position of the keel slot in an overhanging tibial component influenced the results.

It was not possible to implant the Size F tibial tray into the model as the keel slot of Size F tibial tray was larger than the tibia itself. Implanting the Size F tibial tray caused the tibial keel slot to penetrate the posterior cortex.

8.3.2.3 Loading parameters

In the Oxford UKR, the load is transmitted from the centre of the femoral component to the centre of the bearing to the tibial tray. In the neutrally aligned model, the load was applied to the centre of the tibial component. Any malpositioning of the femoral component alters the load positioning on the tibial component. The effect of a malpositioned femoral component was simulated by altering the point where this load was applied. Six models were created:

- 10 mm anterior load
- 10 mm posterior load

- 10 mm medial load
- 10 mm lateral load
- 5 mm medial load
- 5 mm lateral load

8.3.3 Statistical analysis

The data was found not to be normally distributed. Non-parametric analyses using the Mann-Whitney U and Kruskal-Wallis tests were performed for comparison of the VMS between the models. Statistical significance was taken at the 5% level ($p < 0.05$). All statistical analyses in this study were carried out using SPSS for Windows (v.18.0, Chicago, IL, USA).

8.4 Results

The mean and median VMS in the Test area of the intact tibial model was 1010 με and 984 με respectively. The implantation of the tibial component in a neutral position resulted in a statistically significant ($p<0.001$) increase in strain. The mean VMS increased to almost double (2019 με) and the median VMS increased to more than double (2090 με), compared to the intact model. The maximum VMS was observed on the antero-medial aspect of the proximal tibia (Figure 8-18).

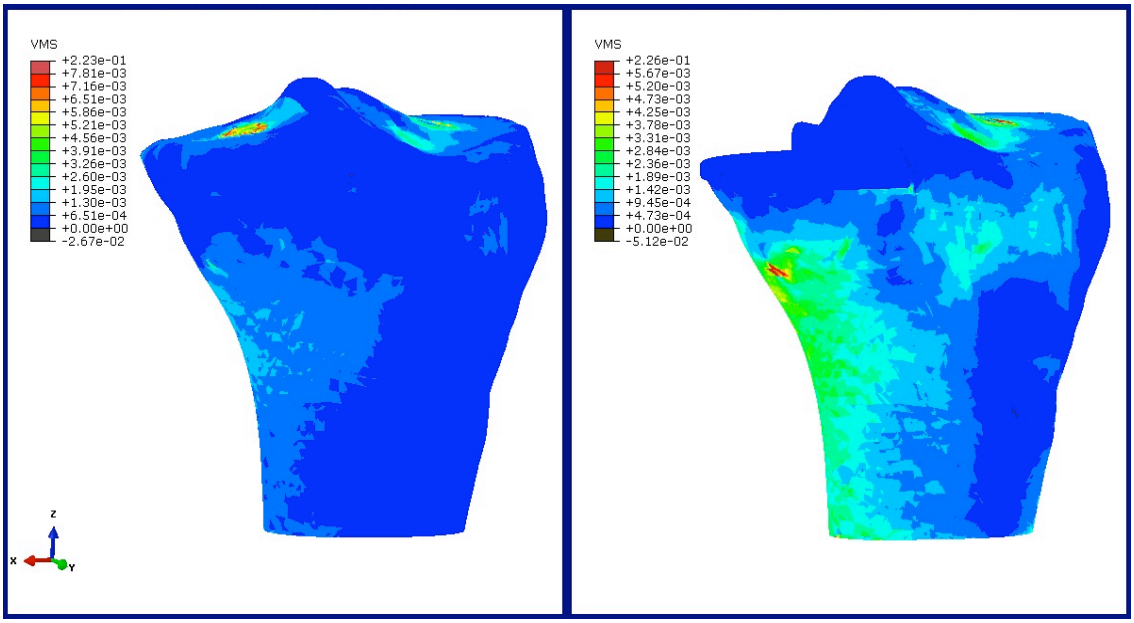


Figure 8-18: VMS in the neutrally implanted model compared to the intact model

When the implanted model was sectioned in the coronal plane, an increased region of strain was found along the keel slot (Figure 8-19).

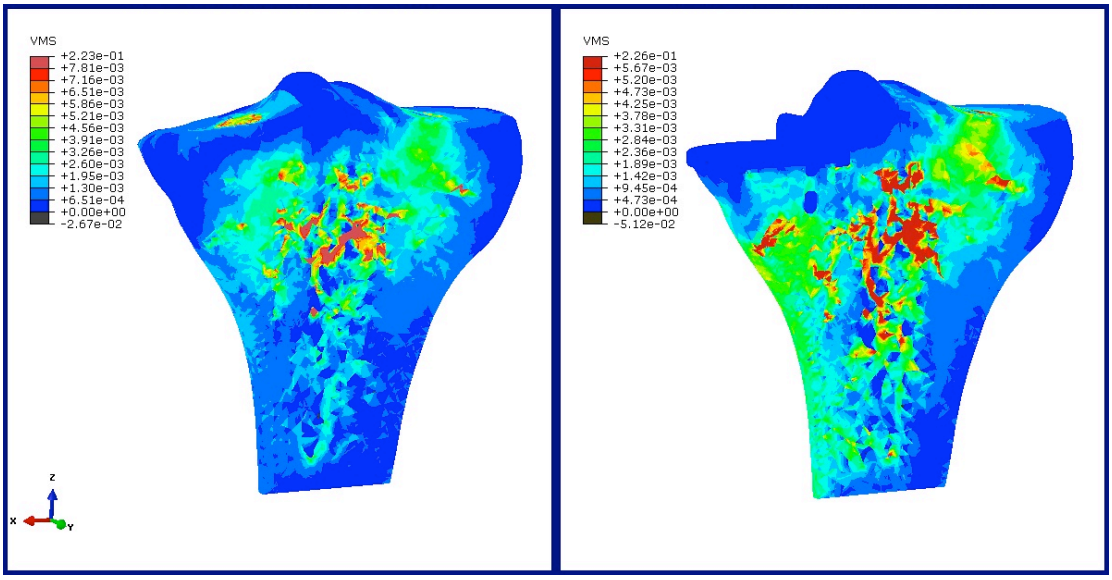


Figure 8-19: Coronal section of the neutrally aligned model and the intact model demonstrating increased VMS along the cortical surface and the keel slot in the implanted model

When the lateral wall of the tibial component was rigidly bonded with the medial wall of the tibial sagittal cut, there was 16% reduction in the VMS ($p<0.01$) in the Test area. There was a 5% reduction in the VMS when the keel slot of the neutrally implanted tibial component was removed, which was not statistically significant ($p=0.205$) (Figure 8-20) (Appendix 7-1).

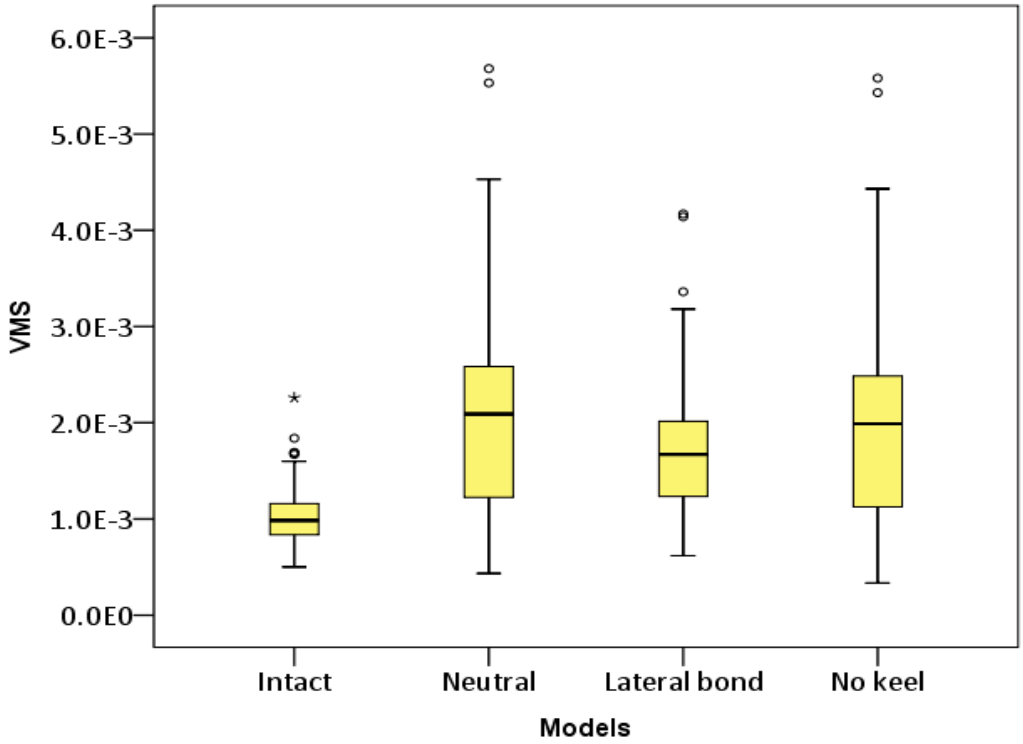


Figure 8-20: Box and whisker plots demonstrating the mean VMS on the 'Test' area in the intact tibia, neutrally implanted, laterally bonded and neutrally implanted with no keel models

8.4.1 Alignment models

In all the alignment models, increased strain was observed on the antero-medial tibial surface compared to the neutrally implanted model. There was, however, very little change in the mean or median VMS with the coronal or the sagittal plane malalignment of the Oxford UKR tibial component, as compared to the neutrally implanted model (Appendix 7-2) (Figure 8-21).

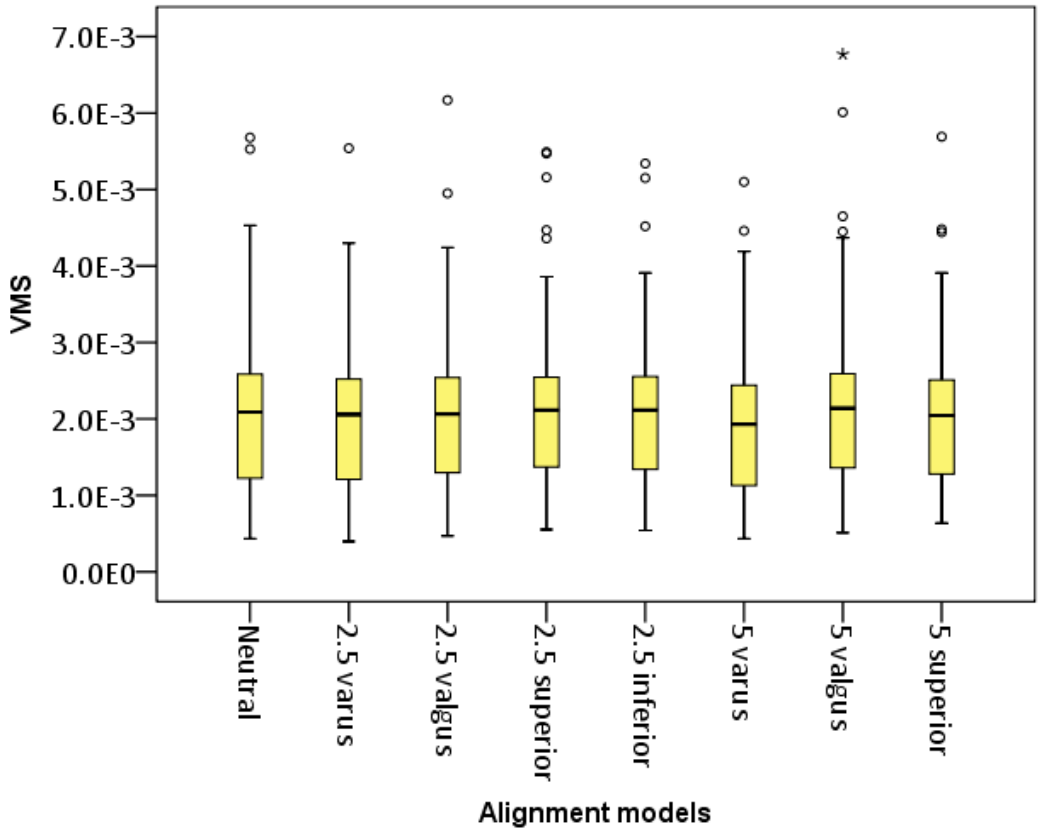


Figure 8-21: Box and whisker plots demonstrating the mean VMS on the test surface in various alignment models compared to the neutral model

The percentage change in the mean VMS in the Test area amongst various alignment models compared to the neutral model was less than 10% (Figure 8-22), which was not statistically significant (p=0.36).

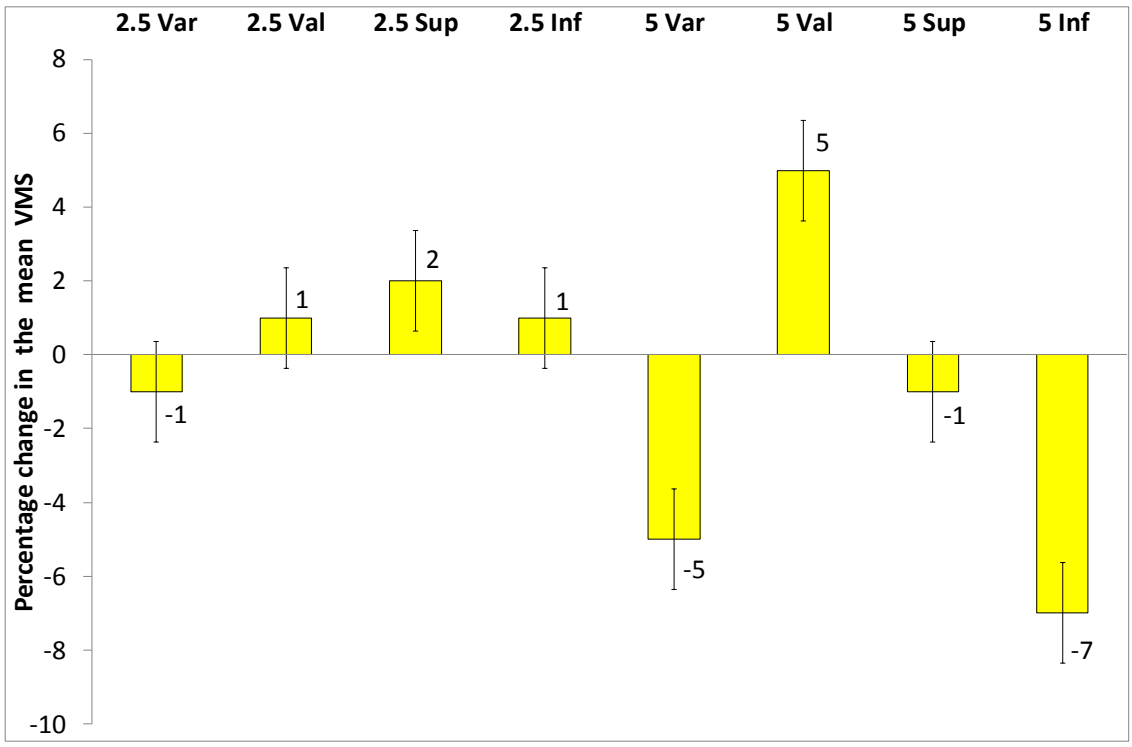


Figure 8-22: Percentage change in the mean VMS between various alignment models compared to the neutrally implanted model (error bars represent standard errors)

8.4.2 Overhang models

8.4.2.1 Altered sagittal cut

The mean and median VMS on the proximal tibia gradually increased when the overhang was increased by altering the tibial sagittal cut (Appendix 7-3).

The difference in VMS between the neutral model and the model with 1 mm overhang was not significant (p-=0.77) but the differences in VMS between the neutral model and the models with 2 mm, 3 mm and 4 mm overhang were statistically significant (p<0.001 respectively) (Figure 8-23).

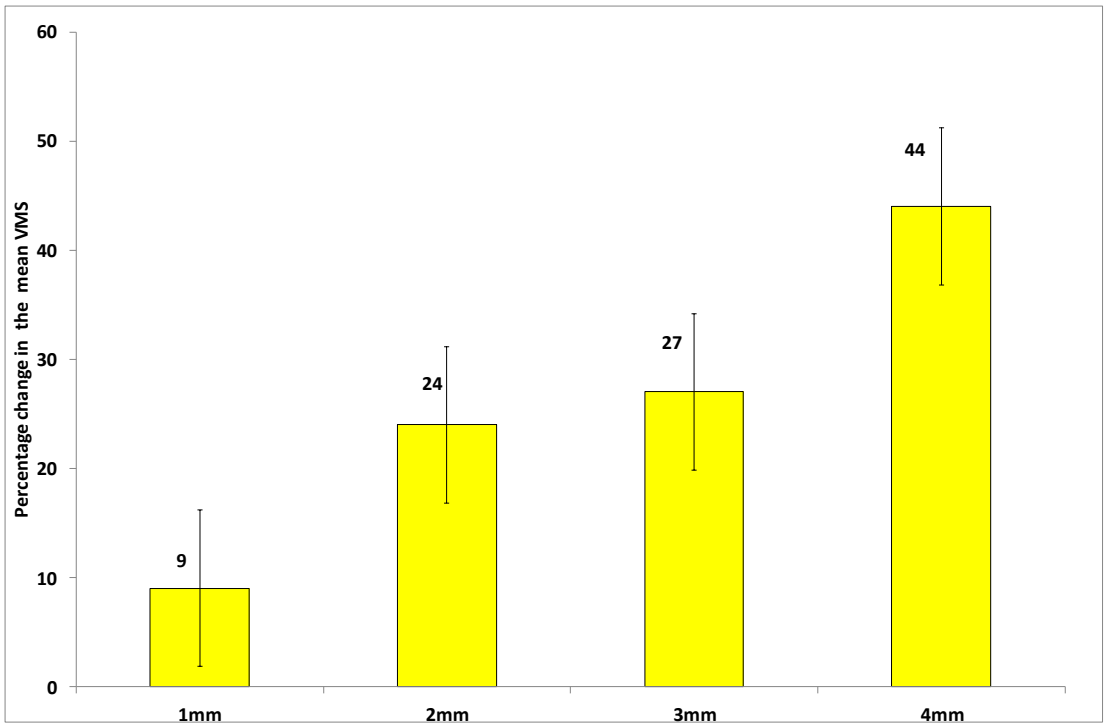


Figure 8-23: Percentage change in the mean VMS between various overhang models, created by altering the tibial sagittal cut, compared to the neutrally implanted model (error bars represent standard errors)

8.4.2.2 Incorrect size tibial component

In the neutrally aligned model, the Size C tibial tray was implanted and was deemed to be the 'perfect fit', with no overhang or underhang. When the Size A and B trays were implanted, there was a decrease in the mean and median VMS on the proximal tibia. Conversely, Size D and E trays were overhanging and resulted in an increase in the mean and median VMS (Appendix 7-4).

The underhanging size A and B trays had significantly lower mean VMS compared to the neutral model ($p < 0.001$ and $p < 0.01$, respectively). Implanting the Size D tray did not change the VMS significantly ($p=0.08$) but an overhanging Size E tray resulted in significant increase in the VMS on the antero-medial tibia ($p<0.001$) (Figure 8-24). When the same Size E tray was implanted without the keel slot, there was only a 5% increase in the proximal tibial strain compared to the neutral model, which was not statistically significant ($p=0.27$).

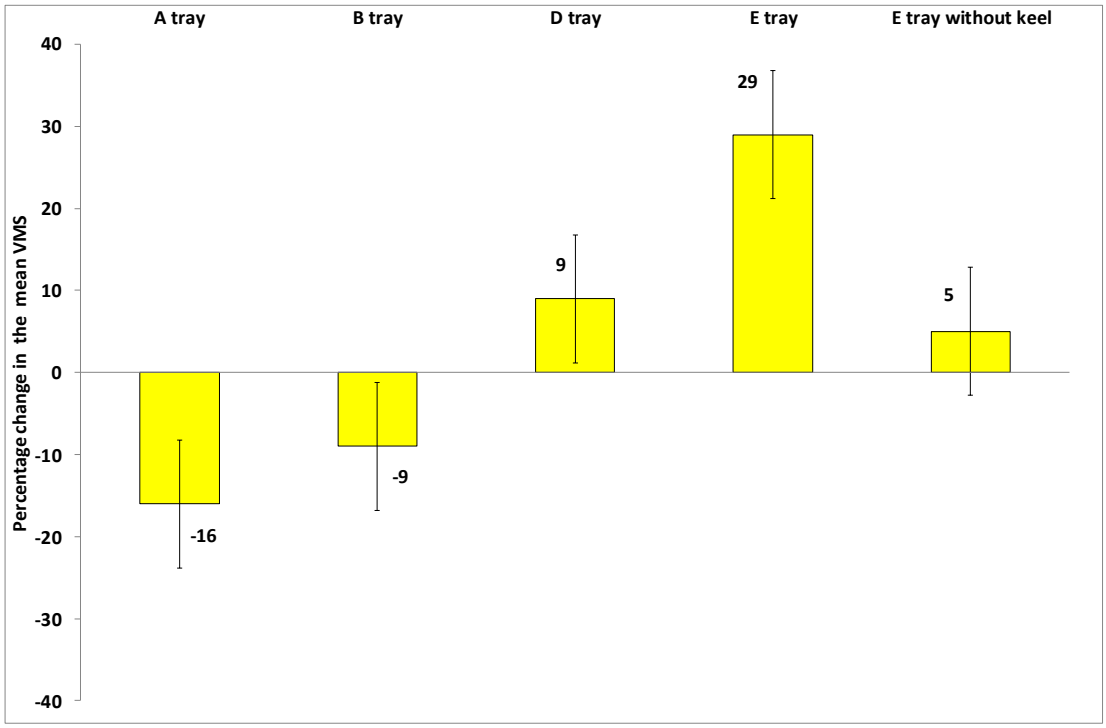


Figure 8-24: Percentage change in the mean VMS between various overhang models, created by implanting the incorrect size tibial component, compared to the neutrally implanted model (error bars represent standard errors)

8.4.2.3 Altered loading parameters

When the point of load application on the tibial component was altered to model the effect of the malposition of the femoral component, the 5 mm and 10 mm medial load positions significantly increased the VMS strains in the proximal tibia ($p < 0.01$ and $p < 0.01$ respectively). The 5 mm and 10 mm lateral load positions, however, significantly decreased the VMS strains on the proximal tibia ($p = 0.05$ and $p < 0.01$ respectively). The 10 mm anterior load position increased, and 10 mm posterior load position decreased the VMS ($p < 0.01$ and $p < 0.01$ respectively) (Appendix 7-5) (Figure 8-25).

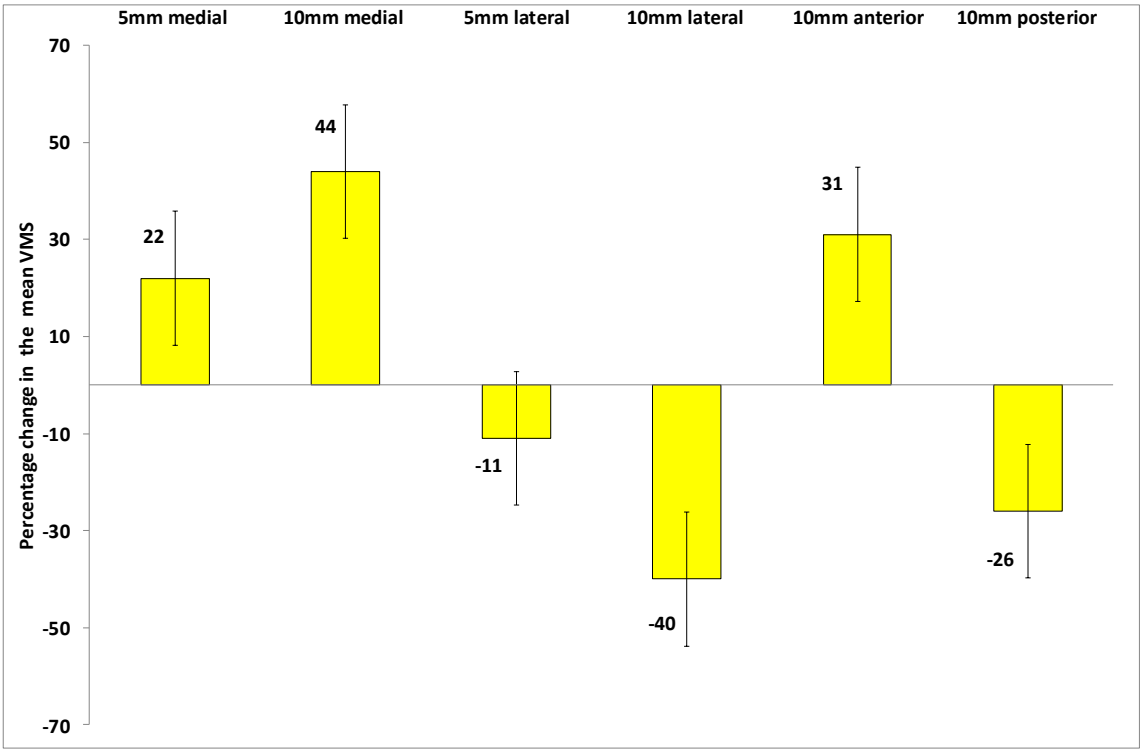


Figure 8-25: Percentage change in the mean VMS between various models created by altering the loading parameters, compared to the neutrally implanted model (error bars represent standard errors)

8.5 Discussion

8.5.1 Previous FE studies

The use of FEA to determine bone stress in the proximal tibia following UKR has been reported previously. Iesaka *et al.* used a simple 2D model of the proximal tibia to determine the effects of the tibial component coronal plane inclination on the contact pressure at the implant–bone interface[300]. Their results were different to the current study because the stress concentration at the proximal medial diaphyseal cortex gradually increased as the inclination changed from valgus to varus. As a result, the authors suggested that it is preferable to have a slight valgus inclination of the tibial component rather than varus or neutral inclination. The study had a number of shortcomings which include the use of a very simplistic 2D model, and arbitrary division of the proximal tibia into cortical, subchondral, metaphyseal cancellous and diaphyseal cancellous bones for assignment of material properties. Furthermore, the

authors have not mentioned whether they performed the mesh convergence study or not.

The same unit later modified the model and created a more accurate 3D geometry and assigned material properties directly from the CT data to simulate the inhomogeneous distribution of cancellous bone properties. The results were similar to their previous study[300] and in addition to recommending a slight valgus alignment the authors suggested avoiding excessive posterior slope to the tibial component. No validation was, however, performed for either of these studies. In addition a fixed bearing UKR system was assessed. Although these studies provide very useful information, the results are not directly comparable to the present study. The current study is based on the Oxford UKR which is a mobile bearing device and has a completely different design and fundamental principles. The difference in surgical cuts and the loading parameters are expected to also produce a different pattern of stresses and strains on the proximal tibia.

Simpson *et al.*[166,167] correlated increased proximal tibial strain following Oxford UKR implantation with unexplained pain and analysed the effect of various component sizes, loading and alignment parameters. Although the authors utilised a validated FE model[171], no details were given as to how the cuts were made on the proximal tibia for UKR implantation, which could potentially have a huge effect on the strain distribution. Furthermore, bone cement was modelled as one millimetre distal extension of the tibial component, which is known not to occur clinically; a more realistic 'cement pocket' was used in the present study. Nevertheless, the authors provided important insight into proximal tibial bone strain after Oxford UKR implantation and concluded that provided the bone remodels progressively, unexplained pain related to increased proximal tibial strain should cease in 12

months. If there is degenerative bone remodelling and/or increased micro-damage, as may be the case in some patients, pain can have tendency to become chronic[167].

Various other FEA studies have been conducted on the Oxford UKR: to analyse kinematic changes and cartilage damage potential in the retained compartment following implantation[301]; to understand the aetiology and significance of sclerotic and radiolucent lines seen on follow up radiographs in some patients[272]; and to evaluate the effect of various factors such as muscle forces, loading position and changes in gait pattern on the proximal tibial bone strain[276]. Some authors have calculated strain energy density (SED) using FEA and have used this to predict adaptive bone remodelling[166,302] following an implantation. With time, the bone remodelling has the potential to reduce bone strain through increasing density and elastic modulus, which may explain why pain tends to settle down in some patients over time. It is difficult to know why pain does not settle in all patients but it could be related to remodelling thresholds, which may vary.

8.5.2 Correlation of the current FE study with the clinical studies

This study demonstrates that after Oxford UKR, even when implanted in a perfect alignment and with no overhang or underhang, the mean and median proximal tibial VMS would be twice as high as the intact tibia model. Other authors[166,167] have also analysed the strains in the same area but have found them to be 48% higher after neutral implantation. This variation could be due to the fact that the test area used in the other studies was not exactly the same (although similar). Furthermore, the 3D model and the cement pocket used in the current study were created differently compared to the other studies. The present model, however, was more anatomical and is therefore thought to better estimate these strains.

When a mechanical bond was introduced between the lateral wall of the tibial component and the adjacent tibial vertical wall, the antero-medial bone strains reduced by 16%. This reduction is similar to results from a previously reported study[166]. This is most relevant for cementless components where it may be possible to introduce porous or hydroxyapatite coating to augment such fixation. With cemented Oxford UKR, even if the cement is applied to the vertical wall of the tibial component, it is unlikely to perform well due to the presence of shearing and tensile forces at the cement-bone or cement-implant interface[166]. The results of this study implies that if such a bond could be achieved then the strains in the proximal tibia could be substantially lowered, thereby potentially decreasing the chance of developing antero-medial knee pain. The tibial component implanted without a keel slot did not change the proximal tibial bone strains significantly which indirectly implies that if the keel slot is made in accordance with the recommended guidelines[185], the proximal tibial bone strain is not significantly altered.

The design of the Oxford prosthesis has the advantage that the precise rotational alignment of the femoral component is not considered to be a prerequisite for implant longevity[29,116]. This is because the spherical femoral component transfers equal stresses to the polyethylene bearing, even if the component is rotated in the frontal or sagittal plane[303]. Malalignment of the tibial component however, may not be as well tolerated[304,206]. In the present mechanical study, increased strain was observed on the antero-medial tibial surface in all the alignment models compared to the neutrally implanted model. There was, however, no significant change in either the mean or median VMS with the coronal or the sagittal plane malalignment of the Oxford UKR tibial component up to 5°, compared to the neutrally implanted model. This finding correlates well with the clinical study (Chapter 4) which demonstrated that 92% of implanted tibial components were between ±5° varus/valgus and superior/inferior tilt

and that within this range the orientation of the components did not significantly affect the functional outcome, as measured by the OKS and RL at five years.

The sagittal cut in the neutral model was made just medial to the footprint of the ACL, as recommended by the surgical technique[185]. Any further lateral position of this cut would damage the fibres of the ACL. When the tibial tray overhang was modelled by moving the vertical cut medially, the mean and median VMS on the proximal tibia gradually increased. A 3 mm overhang increased strains by 27% and a 4 mm overhang increased strains by 44%, both of which were statistically significant ($p<0.001$ respectively). The clinical study (Chapter 6) also demonstrated that overhang ≥3 mm was associated with poor outcome at five years post-operatively. This group of patients had significantly worse OKS, Δ OKS, PS and Δ PS compared to the other groups. One millimetre overhang due to the altered vertical cut increased the bone strain by 9% only, which was not statistically significant. This is similar to the clinical study where the 'minor overhang' group achieved good medium term clinical outcome score. Two millimetres overhang, however, increased the bone strain by 24% ($p<0.001$) but clinically was not found to significantly compromise the functional outcome. The current study did not take into account the effect of bone remodelling which may partly explain why the results are different.

There is a belief amongst the senior surgeons at the Nuffield Orthopaedic Centre that as the learning curve has reached a plateau and the instrumentation for the Oxford UKR has improved, the sagittal cut of the tibia is being perfomed more lateral compared with earlier procedures. This may explain the fact that the 'New' group (a recent cohort of 120 patients who had surgery from 2008-2011) achieved better functional outcome compared with the 'Old' group (initial cohort of 120 patients who had surgery from 1998-2001) when compared for OKS, Δ OKS, PS, Δ PS, OKS1 and Δ OKS1 (Chapter 2).

When overhang was modelled by implanting a larger tibial component instead of the appropriately sized tibial tray, the mean and median VMS increased. This increase (9%) was not significant when the Size D tray was implanted but was significant when the Size E tray was implanted (29%). The significant increase in bone strain with the Size E tray correlates with the findings of the clinical study (Chapter 6), where an overhang ≥3 mm (Size E tray in this study) significantly affected the functional outcome and led to a poor OKS and PS. On the contrary, an overhang <3mm (Size D tray in this stay) did not compromise the final clinical outcome. The underhanging Size A and B tibial trays caused a significant reduction in VMS over the proximal tibia. Clinically, implanting undersized tibial trays did not compromise the functional outcome (Chapter 6) but there is a risk of tibial component subsidence and loosening with an underhanging tray since the load is not transmitted through the stronger cortical bone but primarily through the relatively weak cancellous bone[253]. It is thought, from these results, that the position of the keel slot in the implanted tibial component is the main factor which can affect the tibial strains. This is evident from the fact the there was only 5% increase in the mean VMS when the Size E tray was implanted without a keel slot.

With the Oxford UKR, load is transmitted from the centre of the femoral component to the centre of the bearing and then to the tibial component. The unconstrained mobile bearing moves freely[185] and the position of the femoral component determines the bearing position. The medio-lateral or antero-posterior position of the femoral component, therefore, affects the load vector by altering the position of the bearing on the tibial component. The mean VMS increased significantly when the load was applied 5 mm and 10 mm medially (22% and 44% respectively) and decreased significantly when the load was applied 5 mm and 10 mm laterally (11% and 40% respectively). As 10 mm medial position of the femoral component may however be

quite extreme and may not be commonly implanted, as the femoral component (and possibly the bearing too) will impinge against the soft tissues with such implantation.

Clinically, it is not possible to implant a femoral component in either a 5 mm or 10 mm lateral position because in these positions, the bearing will impinge against the tibial vertical wall. Medial positioning of the femoral component, however, should be avoided as the results demonstrated a significant increase in the proximal tibial bone strain when femoral component was moved beyond 5 mm. Anterior positioning of the femoral component increased and posterior positioning decreased the mean VMS in the proximal tibia. These results are different from the FE study performed by Pegg *et al*.[276], where the authors reported significant increases in the VMS with both anterior and posterior loading positions. The chosen area of interest, however, extended both anteriorly and posteriorly over the proximal medial tibia in their study compared to the present study, where the strains were tested only over the antero-medial tibial surface.

Due to the spherical nature of the femoral component, malalignment of up to 10° in either the coronal or sagittal plane has been shown not to affect the clinical or radiological outcome (Chapter 4). Small *et al.*[305] conducted an *in vitro* biomechanical study to quantify the strain on the tibial metaphyseal surface after varying the sagittal slope, resection depth, rotation and medial shift following Oxford UKR implantation. The authors demonstrated that tibial component rotation had the least overall influence in tibial loading of all factors examined. The most balanced strain response to loading following UKR was exhibited by the Oxford UKR with minimal distal resection, most lateral positioning, neutral component rotation, and 3° of slope (from mechanical axis). The effect of rotation of tibial components on proximal tibial bone strains was not analysed in the present study.

The mechanism behind how increased bone stress/strain causes pain after UKR implantation is not known, but several authors[166,172] have observed an association between the location of high bone strain and where patients complain of pain. The causal link between the two, however, has not been found. Skeletal pain has a very complex aetio-pathogenesis and transmission pathway. It is not just the periosteum that has a nerve supply[306-308] the bone marrow and the mineralised bone are also innervated by sensory and sympathetic nerve fibres. The periosteum, however, has the greatest density of neurons[306] making it very sensitive. This may explain why some UKR patients achieve a temporary relief (anecdotal evidence) of antero-medial knee pain following a local anaesthetic injection into the anserine bursa, which is very closely connected to the periosteum. Increased tibial strain might result in physical damage thereby impacting the sensory and sympathetic innervation of the marrow, mineralized bone, and the periosteum. These nerve fibres might play a unique but coordinated role in the generation of skeletal pain[306].

The current FE model has not analysed the reason or the effect of RLL on proximal tibial bone strain. Gray *et al*.[272] created a 3D FE model of proximal tibia implanted with Oxford UKR to simulate one year of *in vivo* post implant remodelling. The authors suggested that the sclerotic region under the RLL had higher mean von Mises stress when remodelling was assumed, which implies that commonly observed RLL under the tibial component generated increase stress on the underlying bone. The clinical study, however, found that was no relationship between RLL and outcome, particularly pain (Chapter 7). Simpson *et al.*[166] correlated the increase in SED (area under the stress-strain curve) in the region adjacent to the tibial tray to be the cause of radiolucency.

The aim of the Oxford UKR is to correct the intra-articular deformity only. Any extra-articular deformity such as tibia vara is not corrected. The ligament balance is

restored by the position of the femoral component and the appropriate bearing thickness[185]; both of which help in restoring the knee kinematics to normal. It is reasonable to assume that as long as the leg alignment is restored to the pre-disease state, the load distribution in a kinematically restored and ligamentously balanced Oxford UKR would be no different from the native knee. Furthermore, it has been shown by a clinical study (Chapter 5) that the leg alignment after UKR does not affect the clinical or radiological outcome Therefore, the effect of leg alignment after Oxford UKR on the proximal tibial bone strain was not modelled. In addition, there are practical limitations in modelling the effect of leg alignment. The present study did not have an articulated femoral component in the 3D model, the presence of which is essential for changing the load characteristics occurring as a result of alteration in the leg alignment.

This study's findings indicated that the increased bone strain after Oxford UKR is due to the combined effect of the position of the femoral component as well as the tibial component. The position of the femoral component affects the load vector while the position of the tibial component (in particular the position of the keel slot) influences the availability of the bony support underneath. The position of the femur was not changed in the neutral and the alignment models and in all cases, the load was applied to the centre of the tibial component. With overhang models due to the altered sagittal cut, the femoral component (and hence the applied load) was positioned increasingly medially. Any increase in proximal tibial bone strain was therefore mainly due to the position of the femoral component. Conversely, in overhang models due to the incorrect size tibial components, the load vector was not changed. The keel slot, however, was placed increasingly medially with incremental sizes of the tibial components. The significant increase in the proximal strain observed with Size E tibial component was therefore mainly contributed by the tibial

component. When the same Size E component was implanted without the keel, the strain decreased significantly.

8.5.3 Limitations

This study has several limitations some of which are inherent with any FE study such as the difficulty in creating a material model sufficiently complex to simulate accurately the biological behaviour of the bone in response to physiological loading. Another important limitation is that only one tibia was modelled in the study. The CT scan provided grayscale values which were used to calculate material properties; clearly this and the patient specific geometry has an implication on the strain values and having more tibiae would have improved the understanding of material property distribution and anatomical effects would have been more representative. The FE model used in the study was, however, validated and the same material property definitions have also been used by other authors[167,171,276]. Furthermore, since the current study is a comparative analysis of the proximal tibial bone strain amongst different models (all of which use the same material properties), this limitation may affect the magnitude of strain, but the trends and comparisons will be valid.

8.6 Summary

This study provides evidence that following implantation of an Oxford UKR, the strains in the proximal tibia are markedly increased. The similarity of the FEA study with the clinical studies suggests that pain after Oxford UKR could be as a result of increased proximal tibial bone strain. By applying physiological, kinematic and loading conditions to a validated FE model of the implanted tibia, it was possible to investigate the effect of various implantation, loading and alignment parameters. This increased strain may be the cause of persistent post-operative pain. With the passage of time, the bone is likely to remodel but individual differences in the

remodelling threshold may explain resolution of symptoms in some, but not all, patients. Avoiding factors that lead to increased proximal tibial bone strain, compared to the neutral model, has a huge potential in reducing the incidence of pain and poor function after UKR implantation.

9. CONCLUSIONS, LIMITATIONS AND FUTURE WORK

9.1 Conclusions

9.1.1 Clinical studies

- The incidence of severe pain after Oxford UKR is 3% at six weeks and 2% at one year and at a medium-term follow up. The overall incidence of severe pain has reduced over the years which could be due to the combined effect of the modification of surgical technique, improvements in instrumentation and better awareness of factors leading to an unsatisfactory outcome.

- The use of the ICOAP score, on its own, does not give any additional information than that provided by the OKS. Question number 1 of the OKS and the PS, with the highest SRMs, are the most sensitive scores, when analysing patients with post-operative pain.

- Patients who have a high probability of pre-operative neuropathic pain (as assessed by the painDETECT score) tend to do badly after the operation. Similarly, some patients with moderate or severe pain at the final follow up have a worse pre-operative neuropathic pain score. The routine use of painDETECT score in pre-operative assessment of patients waiting for Oxford UKR might help in identifying patients with high neuropathic component.

- The results of Oxford UKR depend on careful selection of patients. Patients with less severe arthritis in the medial compartment have a less predictable outcome and a higher proportion do not benefit from their surgery. The

recommendation that patients with medial OA should only have a UKR if they have bone-on-bone articulation should be strictly followed.

- There is no evidence to revise the current recommended range of component positioning for the Oxford UKR: femoral component malalignment of up to 10º and tibial component malalignment up to 5º is compatible with good clinical and radiological outcomes. The majority of surgically implanted Phase 3 Oxford UKRs, using a minimally invasive approach, lie within the recommended range, suggesting that the minimally invasive approach does not reduce the accuracy of implanting an Oxford UKR.

- Leg alignment after Oxford UKR should be returned to the pre-disease state. If the pre-disease alignment is not restored, the outcome is likely to be compromised. A quarter of patients have varus leg alignment after Oxford UKR which does not compromise the clinical and radiological outcome.

- Appropriate tibial component sizing is critical for UKR. Medial overhang ≥ 3 mm significantly causes worse OKS and PS. Although knees with an underhang or overhang < 3 mm have a similar outcome, there is risk of tibial component subsidence and loosening with underhanging components and hence it is better avoided.

- Radiolucent lines are commonly observed after UKR. No statistically significant relationship was found between the presence and extent of the RLL and outcome. In particular, patients with complete RLL did not have more pain than those without. Therefore, if a patient complains of pain following UKR and has a RLL visible on a radiograph, it should not be assumed that the source of pain is the radiolucency.

9.1.2 FE study

- After Oxford UKR, the mean and median proximal tibial strains are twice as high as the intact tibia model, even when the components are implanted in perfect alignment, with no overhang or underhang.

- When a mechanical bond is introduced between the lateral wall of the tibial component and the adjacent tibial vertical wall, the antero-medial bone strains reduce by one-sixth. Achieving such a bond has potential to decrease the chance of developing antero-medial knee pain.

- There is no significant change in bone strain when the Oxford UKR tibial component is malaligned in the coronal or the sagittal plane by up to 5°, compared with a neutrally implanted component.

- The strains on the proximal tibia gradually increase when the tibial tray overhang is modelled by moving the vertical cut medially. Overhanging components due to a malpositioned sagittal cut should therefore be avoided.

- Undersized/underhanging tibial components significantly decrease proximal tibial bone strain, but overhanging oversized components result in a significant increase in the antero-medial tibial strain. This is likely to be due to the position of the keel slot.

- The position of the femoral component affects the point of load application on the tibial component. The medial and anterior loading positions significantly increased the strains in the proximal tibia and should be avoided.

- The similarity of the FEA study with the clinical studies suggests that pain after Oxford UKR could be a result of increased proximal tibial bone strain. With the passage of time, the bone is likely to remodel but individual differences in the remodelling threshold may explain resolution of symptoms in some, but not all, patients.

9.2 Limitations

In addition to specific limitations mentioned in individual chapters, there are some general limitations to consider; most of which are inherent in any clinical and radiological analyses. The Oxford UKR surgeries were performed by two senior surgeons. Since both of them are faculty members on Oxford UKR instructional courses, strict guidelines were followed with regards to patient selection, intra-operative surgical technique and the post-operative rehabilitation programme. Consequently, there were not many patients who had a bad outcome or who had Oxford UKRs implanted at extreme of alignments or tibial component sizes. Furthermore, physiological radiolucency was carefully interpreted in the follow up radiographs and there were no unnecessary revisions. Though good for the patients, this meant that some of the studies had a smaller sample size for outliers, which made it difficult to perform robust statistical tests. The results from the surgery performed by other surgeons might vary.

The sample size was not same in all the clinical studies and some of them had a low power. This was because some patients had missing data on certain parameters and not all patients had adequately aligned screened radiographs. The logistics of scheduling follow-up appointments with independent assessors also resulted in some missed appointments. Although this is less of a limitation in the studies where there

was a statistical significance, there is a risk of type II error in some studies. In addition, some of the patients enrolled into this study had their surgery more than 10 years ago but only five year follow-up data was used (which was the latest follow-up data available at the time of the analysis). It is possible that their clinical picture has changed between five years and 10 years post-operatively, which was not taken into account.

9.3 Future work

9.3.1 Clinical studies

- This study is performed on Oxford UKR, which has a fully congruent mobile bearing. Although the design philosophy and mechanics of mobile bearing UKRs are very different from fixed bearing UKRs and TKRs, it would be very interesting to compare their results not only in terms of clinical and radiological outcomes, but also with regards to the effect of various loading and implantation parameters on the proximal tibial bone strain.

- Since the results of the Oxford UKR are unpredictable in patients with PTCL, a number of possible investigations might help to identify patients who will or will not do well post-operatively. For example, a good result might be predicted by increased uptake on bone scanning, subchondral change on MRI scanning, or a positive response to an intra-articular injection. Further research is needed to assess these and other techniques.

- Patients with neuropathic pain pose a difficult management problem. The use of painDETECT score might help in identification of such patients pre-operatively and such patients might need to be counselled differently. Similarly, patients with post-operative neuropathic pain might benefit from an expert opinion by the pain specialists and prescription of medications that

control neuropathic pain such as gabapentin. Further research is needed to explore measures to predict pre-operative and control post-operative neuropathic pain.

9.3.2 FE study

- The mechanism behind how increased bone stress and strain cause pain after UKR implantation is not known. An *in vivo* or in *vitro* study should be conducted to analyse this relationship and test proposed theories. A clinical study using radio-isotopes such as bone scan, Dual-energy X-ray absorptiometry (DXA), Positron Emission Tomography (PET) scans could help in determining the biological activity in the proximal tibial following UKR implantation.

- Bisphoshonates, which are often prescribed to correct an imbalance between osteoblast-mediated bone formation and osteoclast-mediated bone resorption, might help in modification of proximal tibial bone strain after UKR. Further research is needed to explore their role in management of patients with post-operative pain.

- A number of tibiae could be scanned to improve the understanding of material property distributions and further increase the accuracy of the model. The differences between male and female tibiae could be analysed which could help in understanding how difference in proximal tibial morphology affects the bone strain explaining and why females tend to have more post-operative pain.

- The current FE model could be further improved by taking into effect all the muscle forces acting on the knee and creating a material model which will

simulate the biological behaviour of the bone in response to physiological loading.

- The effect of other alignment, implantation and the loading parameters could be studied. This may include studying the effect of rotational malalignment, increasing the limits of coronal/sagittal plane malalignment and analysing the strains on the proximal tibia over the entire gait cycle.

PUBLISHED PEER-REVIEWED PAPERS (related to this work)

The incidence of physiological radiolucency following the oxford unicompartmental knee replacement and its relationship to outcome
A Gulati, R Chau, H Pandit, A J Price, CAF Dodd, DW Murray
J Bone Joint Surg Br. 2009 Jul; 91(7):896-902

Influence of component alignment on outcomes for unicompartmental knee arthroplasty
A Gulati, R Chau, DJ Simpson, CAF Dodd, HS Gill, DW Murray
Knee. 2009 Jun; 16(3):196-9. Epub 2008 Nov 29

The effect of leg alignment on the outcome of unicompartmental knee replacement
A Gulati, H Pandit, C Jenkins, R Chau, CAF Dodd, DW Murray
J Bone Joint Surg Br. 2009 Apr; 91(4):469-74

Unicompartmental knee replacement for patients with partial thickness cartilage loss in the affected compartment
H Pandit, **A Gulati**, C Jenkins, K Barker, AJ Price, CA Dodd, DW Murray
Knee. 2011 Jun; 18(3):168-71. Epub 2010 Jun 2

Tibial overhang in unicompartmental knee replacement: functional outcome
R Chau, **A Gulati**, HG Pandit, DJ Beard, AJ Price, CAF Dodd, HS Gill, DW Murray
Knee. 2009 Oct; 16(5):310-3. Epub 2009 Feb 1

Elevated proximal tibial strains following unicompartmental knee replacement- A possible cause of pain
DJ Simpson, AJ Price, **A Gulati**, DW Murray, HS Gill
Med Eng Phys. 2009 Sep; 31(7):752-7. Epub 2009 Mar 10

PRESENTATIONS (related to this work)

Radiolucency following the Oxford unicompartmental knee arthroplasty: associative factors and effects on outcome scores
Annual meeting of British Association for Surgery of the Knee, Oxford, Mar 2010

Medial unicompartmental knee replacement for partial thickness cartilage damage: Functional results
77th Annual Meeting of the American Academy of Orthopaedic Surgeons, New Orleans, Mar 2010

Influence of tibial component size in unicompartmental knee replacement on functional outcomes
76th Annual Meeting of the American Academy of Orthopaedic Surgeons, Las Vegas, Feb 2009

An acceptable limit of tibial component overhang in the Oxford Unicompartmental Knee Arthroplasty
Annual meeting of Br Association for Surgery of Knee, Bournemouth, Apr 2008

Malalignment after unicompartmental arthroplasty: Does it matter**?**
Annual meeting of Br Association for Surgery of Knee, Bournemouth, Apr 2008

Unicompartmental Knee Arthroplasty: Impact of component position on clinical and radiological outcomes
75th Annual Meeting of the American Academy of Orthopaedic Surgeons, San Francisco, Mar 2008

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APPENDICES

Appendix 1: American Knee Society Score

Appendix 2: Oxford Knee Score

Appendix 3: ICOAP

Appendix 4: PainDETECT

Appendix 5: Tegner activity scale

Appendix 6: Intra-operative UKR form

Appendix 7: VMS data in various alignment, overhang and loading models

Appendix 1-AKSS

PART B (American Knee Soc. Score): For Doctor/Clinician to Complete

DIAGNOSIS: **Date:**

Evaluator (Surname) ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ **Centre:**

Pain	points
None	50
Mild or Occasional	45
Mild - Stairs only	40
Mild Walking and Stairs	30
Moderate - Occasional	20
Moderate - Continual	10
Severe	0

Stability: (maximum movt in any position)			
AP	*points*	*Med-lat*	*points*
< 5 mm	10	<5°	15
5-10 mm	5	6-9°	10
>10 mm	0	10-14°	5
		15°	0

ROM	
degrees	points
≥125	25
120	24
115	23
110	22
105	21
100	20
95	19
90	18
85	17
80	16
75	15
70	14
65	13

degrees	points
60	12
55	11
50	10
45	9
40	8
35	7
30	6
25	5
20	4
15	3
10	2
5	1
0	0

Extension: ☐☐ Maximum Flexion ☐☐☐

subtotal ☐☐☐/100

Flexion contracture:		Extension Lag		Alignment	
	points		points	ASIS – Knee - Ankle	points
0	0	0	0	5-10°Valgus (normal)	0
5-9°	2	0-9°	5	0-4°Valgus	10
10-15°	5	10-20°	10	11- 15°Valgus	10
16-20°	10	>20°	15	Other	20
>20°	15			Measurement	degrees
				Note varus / valgus	

DEDUCTIONS (minus)

Deductions Total

/50

Knee Score

/100

JNCTION SCORE

Walking		Stairs		Support (deductions)	
	points		points		points
Unlimited	50	normal	50	Stick	5
500m-1km	40	down with rail	40	2 sticks	10
100-500m	30	up & down with rail	30	crutches/walker	20
<100m	20	unable down	15		
Housebound	10	unable	0		
Unable	0				

Function Total

/100

COMMENTS & CHARNLEY ABC:

A: knee only B: other joints C: systemic illness

Please file safely in patient notes

PhysioResearch11/02/03MK4

Appendix2: OKS

Oxford Knee Assessment - PART A: FOR PATIENT

Date: ☐☐/☐☐/☐☐

Op date: : ☐☐/☐☐/☐☐

Patient Name & no. (Sticky Label)

PROBLEMS WITH YOUR KNEE

During the past 4 weeks.....

● tick one box for every question

1

During the past 4 weeks.....

How would you describe the pain you usually have from your knee?

None	Very mild	Mild	Moderate	Severe
❒4	❒3	❒2	❒1	❒0

2

During the past 4 weeks.....

Have you had any trouble with washing and drying yourself (all over) because of your knee?

No trouble at all	Very little trouble	Moderate trouble	Extreme difficulty	Impossible to do
❒4	❒3	❒2	❒1	❒0

3

During the past 4 weeks.....

Have you had any trouble getting in and out of a car or using public transport because of your knee? (whichever you would tend to use)

No trouble at all	Very little trouble	Moderate trouble	Extreme difficulty	Impossible to do
❒4	❒3	❒2	❒1	❒0

4

During the past 4 weeks.....

For how long have you been able to walk before pain from your knee becomes **severe**? *(with or without a stick)*

No pain/more than 30 mins	16 to 30 mins	5 to 15 mins	Around the house only	Not at all - pain severe when walking
❒4	❒3	❒2	❒1	❒0

5

During the past 4 weeks.....

After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your knee?

Not at all painful	Slightly painful	Moderately painful	Very painful	Unbearable
❒4	❒3	❒2	❒1	❒0

PLEASE TURN OVER

Oxford Knee Score© Department of Public Health, Institute of Health Sciences, Old Road, Oxford OX3 7LF (Dawson et al 1998)

6	***During the past 4 weeks*****.....**				
	Have you been limping when walking, <u>because of your knee</u>?				
	Rarely/never	Sometimes, or just at first	Often, not just at first	Most of the time	All of the time
	❒4	❒3	❒2	❒1	❒0
7	***During the past 4 weeks*****.....**				
	Could you kneel down and get up again afterwards?				
	Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
	❒4	❒3	❒2	❒1	❒0
8	***During the past 4 weeks*****.....**				
	Have you been troubled by <u>pain from your knee</u> in bed at night?				
	No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
	❒4	❒3	❒2	❒1	❒0
9	***During the past 4 weeks*****.....**				
	How much has <u>pain from your knee</u> interfered with your usual work *(including housework)*?				
	Not at all	A little bit	Moderately	Greatly	Totally
	❒4	❒3	❒2	❒1	❒0
10	***During the past 4 weeks*****.....**				
	Have you felt that your knee might suddenly 'give way' or let you down?				
	Rarely/never	Sometimes, or just at first	Often, not just at first	Most of the time	All of the time
	❒4	❒3	❒2	❒1	❒0
11	***During the past 4 weeks*****.....**				
	Could you do the household shopping <u>on your own</u>?				
	Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
	❒4	❒3	❒2	❒1	❒0
12	***During the past 4 weeks*****.....**				
	Could you walk down one flight of stairs?				
	Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
	❒4	❒3	❒2	❒1	❒0

TOTAL SCORE /48

Appendix 3: Operative data form for Oxford UKR

Oxford Unicompartmental Knee Studies

Data Collection Package

Murray / Dodd / Price /Jackson

I. DATE: _____ **II. Side: RIGHT / LEFT**

III. Med / Lat **IV. Cemented / Cementless**

V. Assessment Time: Pre 1 2 3 4 5 6 7 8 9 10 11 12 13 14

VI. Patient Information:
Please place sticky label here:
Name _____
Hospital Number _____ **Tel No.**_____
_____ **D.O.B.** _____

VII. Height: in cm: _____ **VIII. Weight:** in Kg: _____

IX. Radiology: Yes / No Date:_____

X. Comment:
1. Opposite knee asymptomatic
2. Opposite knee symptomatic
3. Opposite knee has had a successful uni knee.
4. Opposite knee has had a problematic uni knee.
5. Opposite knee has had a successful TKR.
6. Opposite knee has had a problematic TKR.
7. Other comment.

XI. Location of Pain around knee: pre-op only (can be more than one)
____Anterior ____Medial ____Lateral ____General

XII. Post-Op Goals: 1. _____ **2.** _____

XIII. Achieved Post-Op Goals

1.	No trouble at all	Very little trouble	Moderate trouble	Extreme difficulty	Impossible
2.	No trouble at all	Very little trouble	Moderate trouble	Extreme difficulty	Impossible

Comment: _____

XIV. Patient Rating Excellent Good Fair Poor
Therapist Rating Excellent Good Fair Poor

Appendix 4: PainDETECT

painDETECT™

PAIN QUESTIONNAIRE

Date: Patient: Last name: First name:

How would you assess your pain **now**, at this moment?

0 1 2 3 4 5 6 7 8 9 10

none max.

How strong was the **strongest** pain during the past 4 weeks?

0 1 2 3 4 5 6 7 8 9 10

none max.

How strong was the pain during the past 4 weeks **on average**?

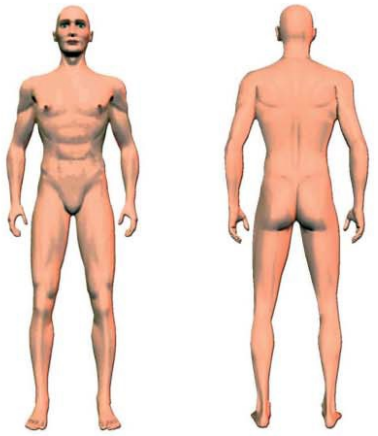
0 1 2 3 4 5 6 7 8 9 10

none max.

Mark the picture that best describes the course of your pain:

- **Persistent pain with slight fluctuations** ☐
- **Persistent pain with pain attacks** ☐
- **Pain attacks without pain between them** ☐
- **Pain attacks with pain between them** ☐

Please mark your **main area of pain**



Does your pain radiate to other regions of your body? yes ☐ no ☐

If yes, please draw the direction in which the pain radiates.

Do you suffer from a burning sensation (e.g., stinging nettles) in the marked areas?

never ☐ hardly noticed ☐ slightly ☐ moderately ☐ strongly ☐ very strongly ☐

Do you have a tingling or prickling sensation in the area of your pain (like crawling ants or electrical tingling)?

never ☐ hardly noticed ☐ slightly ☐ moderately ☐ strongly ☐ very strongly ☐

Is light touching (clothing, a blanket) in this area painful?

never ☐ hardly noticed ☐ slightly ☐ moderately ☐ strongly ☐ very strongly ☐

Do you have sudden pain attacks in the area of your pain, like electric shocks?

never ☐ hardly noticed ☐ slightly ☐ moderately ☐ strongly ☐ very strongly ☐

Is cold or heat (bath water) in this area occasionally painful?

never ☐ hardly noticed ☐ slightly ☐ moderately ☐ strongly ☐ very strongly ☐

Do you suffer from a sensation of numbness in the areas that you marked?

never ☐ hardly noticed ☐ slightly ☐ moderately ☐ strongly ☐ very strongly ☐

Does slight pressure in this area, e.g., with a finger, trigger pain?

never ☐ hardly noticed ☐ slightly ☐ moderately ☐ strongly ☐ very strongly ☐

(To be filled out by the physician)

never	hardly noticed	slightly	moderately	strongly	very strongly
☐ x 0 = 0	☐ x 1 = ☐	☐ x 2 = ☐☐	☐ x 3 = ☐☐	☐ x 4 = ☐☐	☐ x 5 = ☐☐

Total score ☐☐ **out of 35**

R. Freynhagen, R. Baron, U. Gockel, T.R. Tölle, Current Medical Research and Opinion vol 22 (10) 2006; 1911-1920 ©Pfizer Pharma GmbH 2006

Appendix 5: ICOAP

A Measure of Intermittent and Constant Osteoarthritis Pain, ICOAP: KNEE Version

People have told us that they experience different kinds of pain (including aching or discomfort) in their knee. To get a better sense of the different types of knee pain you may experience, we would like to ask you about any "constant pain" (pain you have all the time) separately from any pain that you may experience less often, that is, "pain that comes and goes". The following questions will ask you about the pain that you have experienced in your knee in the PAST WEEK. Please answer ALL questions.

A) CONSTANT PAIN

For each of the following questions, please select the response that best describes, on average, your *constant knee pain* in the PAST WEEK.

1. **In the past week, how intense has your *constant knee pain* been?**

☐0	☐1	☐2	☐3	☐4
Not at all/ No constant knee pain	Mildly	Moderately	Severely	Extremely

2. **In the past week, how much has your *constant knee pain* affected your sleep?**

☐0	☐1	☐2	☐3	☐4
Not at all/ No constant knee pain	Mildly	Moderately	Severely	Extremely

3. **In the past week, how much has your *constant knee pain* affected your overall quality of life?**

☐0	☐1	☐2	☐3	☐4
Not at all/ No constant knee pain	Mildly	Moderately	Severely	Extremely

4. **In the past week, how frustrated or annoyed have you been by your *constant knee pain?***

☐0	☐1	☐2	☐3	☐4
Not at all/ No constant knee pain	Mildly	Moderately	Severely	Extremely

5. **In the past week, how upset or worried have you been by your *constant knee pain*?**

☐0	☐1	☐2	☐3	☐4
Not at all/ No constant knee pain	Mildly	Moderately	Severely	Extremely

B) PAIN THAT COMES AND GOES

For each of the following questions, please select the response that best describes your *knee pain that comes and goes*, *on average,* in the PAST WEEK.

6. In the past week, how intense has your most severe *knee pain that comes and goes* been?

☐0	☐1	☐2	☐3	☐4
Not at all/ No knee pain that comes and goes	Mildly	Moderately	Severely	Extremely

7. In the past week, how frequently has this *knee pain that comes and goes* occurred?

☐0	☐1	☐2	☐3	☐4
Never/ No knee pain that comes and goes	Rarely	Sometimes	Often	Very Often

8. In the past week, how much has your *knee pain that comes and goes* affected your sleep?

☐0	☐1	☐2	☐3	☐4
Not at all/ No knee pain that comes and goes	Mildly	Moderately	Severely	Extremely

9. In the past week, how much has your *knee pain that comes and goes* affected your overall quality of life?

☐0	☐1	☐2	☐3	☐4
Not at all/ No knee pain that comes and goes	Mildly	Moderately	Severely	Extremely

10. In the past week, how frustrated or annoyed have you been by your *knee pain that comes and goes*?

☐0	☐1	☐2	☐3	☐4
Not at all/ No knee pain that comes and goes	Mildly	Moderately	Severely	Extremely

11. In the past week, how upset or worried have you been by your *knee pain that comes and goes*?

☐0	☐1	☐2	☐3	☐4
Not at all/ No knee pain that comes and goes	Mildly	Moderately	Severely	Extremely

THANK YOU!

Appendix 6: Tegner activity scale

Please circle the number, which best describes the activity you are able to do.

TEGNER ACTIVITY SCORE	
10	**Competitive Sports**: soccer – National & International Elite
9	**Competitive Sports**: soccer – lower divisions, ice hockey, wresting, and gymnastics
8	**Competitive Sports**: bandy, squash/badminton, athletics (jumping etc.), downhill skiing
7	**Competitive Sports**: tennis, athletics (running), motocross, speedway, handball, basketball **Recreational Sports**: soccer, badminton, ice hockey, squash, athletics (jogging), cross-country.
6	**Recreational Sports**: tennis, badminton, handball, basketball, downhill skiing, jogging at least 5 times a week
5	**Work**: heavy labour (building, forestry) **Competitive Sports**: (cycling/cross-country skiing) **Recreational Sports**: (jogging on uneven grounds at least 2 times a week)
4	**Work**: moderate heavy labour eg. truck driving, heavy domestic work **Recreational Sports**: cycling, cross-country skiing, jogging on even ground at least 2 times a week
3	**Work**: light labour eg. nursing **Competitive and recreational sports**: swimming, walking in forest possible
2	**Work**: light labour Walking on uneven ground possible but walking in forest impossible
1	**Work**: sedentary work, walking on even ground possible
0	**Sick Leave / Disability** pension due to knee problems

Appendix 7: VMS data in various alignment, overhang and loading models

Appendix 7-1: Mean, median and SD of VMS in intact tibia, neutrally implanted, laterally bonded and neutrally implanted with no keel models

	Mean	Median	SD	Significance
Intact	1.010E-03	9.845E-04	2.648E-04	-
Neutral	2.019E-03	2.090E-03	9.461E-04	<0.001
Lateral bond	1.691E-03	1.670E-03	5.996E-04	<0.001
No keel	1.919E-03	1.990E-03	9.461E-04	<0.001

Appendix 7-2: Mean, median and SD of VMS in various alignment models compared to the intact and neutrally implanted model

	Mean	Median	SD	Significance
Intact	1.010E-03	9.845E-04	2.648E-04	-
Neutral	2.019E-03	2.090E-03	9.461E-04	<0.001
2.5 varus	1.992E-03	2.060E-03	9.507E-04	<0.01
2.5 valgus	2.049E-03	2.065E-03	9.521E-04	<0.001
2.5 superior	2.066E-03	2.115E-03	8.895E-04	<0.001
2.5 inferior	2.041E-03	2.115E-03	8.559E-04	<0.001
5 varus	1.908E-03	1.930E-03	9.349E-04	<0.001
5 valgus	2.124E-03	2.140E-03	9.805E-04	<0.001
5 superior	2.003E-03	2.045E-03	8.588E-04	<0.001
5 inferior	1.880E-03	1.920E-03	8.593E-04	<0.001

Appendix 7-3: VMS in overhang models, created by altering the tibial sagittal cut, compared to the neutrally implanted model

	Mean	Median	SD	Significance
Neutral	2.019E-03	2.090E-03	9.461E-04	-
1 mm medial sagittal cut	2.200E-03	2.230E-03	1.115E-03	0.77
2 mm medial sagittal cut	2.505E-03	2.530E-03	1.319E-03	<0.001
3 mm medial sagittal cut	2.556E-03	2.610E-03	1.446E-03	<0.001
4 mm medial sagittal cut	2.913E-03	2.950E-03	1.666E-03	<0.001

Appendix 7-4: VMS in overhang models, created by implanting an undersized or oversized tibial component, compared to the neutrally implanted model

	Mean	Median	SD	Significance
A tray	1.706E-03	1.660E-03	8.607E-04	<0.001
B tray	1.829E-03	1.870E-03	8.768E-04	<0.001
C tray (Neutral)	2.019E-03	2.090E-03	9.461E-04	-
D tray	2.200E-03	2.230E-03	1.115E-03	0.08
E tray	2.600E-03	2.630E-03	1.115E-03	<0.001
E tray without keel	2.125E-03	2.160E-03	1.025E-03	0.27

Appendix 7-5: VMS in models created by altering the loading parameters

	Mean	Median	SD	Significance
Neutral	2.019E-03	2.090E-03	9.461E-04	-
5 mm medial load	2.461E-03	2.510E-03	1.298E-03	<0.001
10 mm medial load	2.901E-03	2.910E-03	1.656E-03	<0.001
5 mm lateral load	1.817E-03	1.809E-03	1.115E-03	0.05
10 mm lateral load	1.217E-03	1.190E-03	3.206E-04	<0.001
10 mm anterior load	2.655E-03	2.730E-03	9.119E-04	<0.001
10 mm posterior load	1.500E-03	1.430E-03	8.900E-04	<0.001