Fixation of the Oxford Unicompartmental Knee Replacement

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Abstract

The Oxford Unicompartmental Knee Replacement (UKR) is a commonly performed procedure, with a good clinical outcome at 15 years, however, radiolucent lines are commonly found beneath the tibial tray. With the projected increase in knee arthroplasty, particularly in younger patients, implant longevity is of paramount importance. The aim of this thesis is to understand how fixation is achieved with the Oxford UKR and how it can be improved.

A histological study demonstrated that in the presence of a radiolucent line the tibial bone-cement interface is made up of a combination of direct bony contact, fibrocartilage and fibrous tissue. The radiolucency is more marked when there is more soft tissue. However in all cases there is some direct bony contact.

Cemented and cementless fixation was compared in a randomised controlled study using radiostereometric analysis and fluoroscopic imaging of the interfaces. In the first year the cementless tibial component subsided on average 0.28 mm and had an increased posterior slope of 0.40°, whereas the cemented component only subsided 0.09 mm, with a 0.10° increase in slope. In the second year both components had very little further subsidence (mean<0.05 mm) and no increase in posterior slope. In the second year a single cementless tibial component subsided greater than 0.15 mm, whereas four cemented components, all with radiolucencies, subsided more than 0.15 mm. At two years the cemented components had a significantly higher prevalence of radiolucency (62% v 29%), with 24% having a complete radiolucency, whereas no cementless components had a complete radiolucency.

Two designs of lateral UKR were also compared. These had a flat tibial component that predominantly transmits compressive loading, and a domed component that also transmits shear. There was a lower prevalence of radiolucency in the domed tibia (13% v 60%), even though there was a similar amount of migration as the cemented medial tibial component.

In conclusion radiolucent lines, both partial and complete, are common with cemented components, and may, in part, be a result of compressive loading. They are associated with good long-term results and direct bone cement contact indicating satisfactory fixation. However, they are also associated with increased migration and soft tissue at the interface suggesting that the fixation, although satisfactory, is suboptimal. The cementless components had no complete radiolucencies and low levels of migration in the second year. This suggests that bone ingrowth and secure fixation occurs reliably, and therefore that cementless fixation may be better than cemented for the Oxford UKR.

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Abbreviations

ACL	Anterior cruciate ligament
FTCL	Full thickness cartilage loss
HA	Hydroxyapaptite
LCL	Lateral collateral ligament
MB-RSA	Model-based radiostereometric analysis
MCL	Medial collateral ligament
MTPM	Maximum total point motion
NJR	National joint registry
OA	Osteoarthritis
OKS	Oxford knee score
OUKR	Oxford unicompartmental knee replacement
PE	Polyethylene
PFJ	Patellofemoral joint
PMMA	Polymethylmethacrylate cement
PROMs	Patient reported outcome measures
PTCL	Partial thickness cartilage loss
RL	Radiolucency
RLL	Radiolucent line
RSA	Radiostereometric analysis
TKR	Total knee replacement
UKR	Unicompartmental knee replacement

1 Introduction

The focus of this thesis is fixation in knee arthroplasty, with particular emphasis on radiolucency around the components. Knee arthroplasty is a common operation and is likely to become more common, with an aging population who wish to remain active for longer. Long term outcome of arthroplasty is dependent on many factors, some related to the patient and some related to the surgery. This work attempts to identify what happens at the component/bone interface, why it happens, and which surgical factors can be controlled to manipulate it.

1.1 Osteoarthritis of the Knee

The accepted definition of osteoarthritis (OA) by the World Health Organisation in the document "Global burden of osteoarthritis in the year 2000"[1] was suggested by the Subcommittee on Osteoarthritis of the American College of Rheumatology Diagnostic and Therapeutic Criteria Committee: "A heterogeneous group of conditions that lead to joint symptoms and signs which are associated with defective integrity of articular cartilage, in addition to related changes in the underlying bone at the joint margins"[2]. The diagnosis can be based on patient history and clinical examination as well as radiographic imaging. There are numerous scoring systems to describe the radiographic changes seen in a joint with osteoarthritis. The most commonly used are the Kellgren & Lawrence[3] and the Altman[2,4] scores. Osteoarthritis (OA) of the knee is a major challenge for modern healthcare. It affects about 10% of the Western population over 55 years of age with a quarter of those being severely disabled[5]. The knee joint can be affected in numerous ways, with the

most common pattern of arthritis involving the medial tibio-femoral compartment, followed by the patello-femoral compartment and then a combination of the two[6]. Isolated lateral compartment osteoarthritis is less common, but that compartment's involvement is more commonly seen as progression from medial/patello-femoral sided disease (tricompartmental pattern). The impact of knee osteoarthritis can be severe, with significant disability resulting. The risk of disability from knee OA alone is of a similar magnitude as that due to cardiac disease and greater than that from any other medical disorder in the elderly[7]. Although there are numerous non-operative interventions available for knee OA (weight loss, exercise programmes, analgesics, intra-articular injections and orthotics) the mainstay of treatment for intractable disease is arthroplasty.

1.2 Knee Arthroplasty

The European league against Rheumatism (EULAR) recommendations made in 2003 included the common non-operative interventions mentioned above, but concluded that knee arthroplasty was effective in those with severe knee OA[8]. A survey performed by EULAR of orthopaedic surgeons found that the two common indicators to consider surgical intervention were daily pain and radiographic evidence of joint space loss.

As the prevalence of knee OA is so high it is unsurprising that knee arthroplasty is a very commonly performed procedure in the western world. However, the rate at which the number of procedures is increasing is higher than might be expected. Kurtz et al published predictions of the increase in hip and knee arthroplasties until 2030[9]. This paper highlighted the current workload and the likely increases in primary and revision arthroplasty requirement, in particular a predicted growth of

673% in primary total knee replacement (TKR) and 174% in primary total hip replacement (THR) between 2005 and 2030. The New Zealand joint registry has reported a doubling in the number of TKRs performed in the last ten years[10] and the Swedish register noted a similar increase between 1995 and 2005[11]. Between the National Joint Registry (NJR) for England and Wales publishing their 6th annual report in 2009[12] and their 8th report in 2011[13], there was an increase of 12% for both THR and TKR. There were 39,750 primary total hip replacements and 45,135 primary knee replacements (both total and unicompartmental) in 2008 with an increase to 44,504 and 50,522 respectively in 2010. Although the number of primary procedures being performed is important it is interesting to note that there is a similar increase in the number of revision procedures. The number of revision arthroplasties performed in England in 2008, according to the NJR, was 5,391 for hip replacement and 3,317 for knee replacement. There was a 22% increase to 6,567 THRs and a 28% increase to 4,254 TKRs over the subsequent two years. The greater number of hip revisions is probably related to the increased number of hip replacements being performed historically when compared to knee replacements, but with knee replacements overtaking hips as the more common operation, combined with a slightly higher failure rate in knees, it can be assumed that the situation will be reversed in the near future. This assumption is supported by the work of Kurtz (albeit based on the USA model of healthcare) with hip revisions increasing by 137% over twenty-five years but an increase of 601% in knee revisions over the same time period. It is likely that the UK can expect a similar increase in arthroplasty requirement. Therefore the development of an implant that has extremely long survival, while providing an acceptable level of function, will have a significant effect on the number of revision operations required. This obviously has pronounced economic and healthcare provision benefits.

1.3 Fixation in Total Knee Replacement

Cemented fixation in knee arthroplasty has become prevalent and is the accepted standard. However, despite this status, it has numerous disadvantages, namely; infection risk, longevity in the young, loss of bone stock, fat embolism secondary to pressurisation and difficulty in revision. The majority of the orthopaedic literature regarding fixation in knee arthroplasty consists of case series, with follow up often less than ten years. A further compounding issue is that many large series are from the designer of the implant and are often better than the results reported elsewhere. There are some reports comparing fixation methods, but the best data available regarding survivorship as a feature of fixation is from the joint registries. The latest figures from the NJR show that the revision rate for cemented TKR is 3.8% and for cementless TKR is 4.8% at seven years[13]. There are other factors that affect survivorship, for example, those patients receiving a cemented TKR below the age of 60 have a three fold chance of failure by seven years when compared to patients older than 60 (7.5% v 2.6%). There is also a slightly increased chance of death in the immediate period after surgery in patients who have a cemented TKR. The Swedish register now reports so few cementless TKRs that meaningful comparisons between fixation methods is not possible[11]. The reduction in cementless TKR is a result of the poor outcomes up to 1994, with the cementless tibia being of particular concern.

It is, therefore, understandable that the cementless alternative to cemented TKR has struggled to gain widespread acceptance due to worse historical results, particularly with regard to longevity. However, the desire to persist in designing cementless

knee arthroplasty remains, as the theoretical benefits of a successful design over a cemented implant are considerable. Also, with a greater number of younger patients receiving knee arthroplasty surgery, and the results for cemented TKR in the young so poor, the need for an improved solution for that age group is considerable. The path to a successful cementless knee replacement is littered with failures and it is important to take heed of previous innovations, as often the solving of one problem leads to another[14-17].

1.3.1 Cementless Total Knee Replacement

The first cementless knees were implanted in the 1940s and 50s, with initially the femoral component and then the tibial component being developed. Campbell[18] reported his preliminary results with cementless femoral implants after Smith-Petersen had described the use of the Mold arthroplasty in the hip[19]. Subsequently, McKeever and Elliot reported their results with a tibial insert[20]. These implants allowed for one side of the joint to be cementless but maintained a cemented element on the opposite side. One of the first total cementless designs was by Freeman and named after the two centres at which it was designed, Imperial College and London Hospital (ICLH). This was first implanted in April 1970, with a series from 1971 of 71 joints reported in 1977[21]. Other designs which were developed and marketed over the next two decades included those by Kodama-Yamamoto, the Low Contact Stress (Depuy, Warsaw, IN) in 1978, the Porous Coated Anatomic (PCA) (Howmedica, Rutherford, NJ) in 1980, the Anatomic Total Knee (DePuy, Warsaw, IN) in 1980, the Ortholoc I (Wright Medical Technology, Arlington, TN) in 1982, the Tricon-M (Smith & Nephew, Memphis, TN) in 1983, the Miller-Galante I (Zimmer, Warsaw, IN) in 1983, the Anatomic Graduated Component (Biomet, Warsaw, IN) in 1984, the Press Fit Condylar (Depuy, Warsaw, IN) in 1985, the Natural Knee

(Intermedics, Austin, TX) in 1985 and the Genesis I (Smith and Nephew, Memphis, TN) in 1988. The advent of this number of different implants suggests that the wish to have a well functioning, reliable, cementless TKR is high, but there are numerous design issues that are difficult to surmount.

1.3.1.1 Cementless Prosthesis Design

Obviously the design problems specific to cementless implants are related to the implant-bone interface. The initial designs such as the ICLH had a tibial insert made totally of polyethylene (PE) with pegs for fixation. However, time showed that a polyethylene-bone interface did not give consistently good fixation[22]. The later designs mentioned above developed a metal backed tray, with the subsequent development of central stems of differing lengths and screw fixation. Hydroxyapatite coating, particularly of the tibial stem, has become more common.

The femoral side has caused fewer problems for designers, probably due to the shape and good press fit achievable. However, the tibial component has proved problematic, with the majority of aseptic loosening occurring on this side of the joint.

1.3.1.2 All-Polyethylene Tibial Insert

A study of the all polyethylene tibial insert used in the ICLH knee was reported by Blaha in 1982[23]. A comparison was made of the tibial component either with cement or as a cementless implant. Follow up was between one and four years. The findings supported the use of the cementless implantation, although obviously with such a short follow up period the authors were prudent in expressly stating the need for longer follow up. A report on the Tricon-P all PE tibial implant was produced by

Laskin in 1991[24]. This also showed that a cementless tibial PE implant could produce good clinical results, over a slightly longer follow up period of seven years. The problem of subsidence was mentioned, although the correlation between radiographic evidence and clinical symptoms was unclear.

Collier in 1991[25] studied the pattern of wear from failed PE tibial inserts in cementless knee arthroplasty and also, using finite element analysis, contact stress in new inserts. All the popular implants of the time, including the LCS, Miller-Galante I and II, the Natural knee, Ortholoc III and PCA I and II, were tested, using a medium size for consistency. The results showed that the less congruent designs had higher contact stresses, which was associated with greater wear, particularly in thinner inserts.

1.3.1.3 Porous Coating

Whiteside reported in 1995[26] that the design of the porous coating had an effect on radiolucency surrounding the tibial stem, which he attributed to polyethylene debris induced osteolysis. The Ortholoc II implant with total porous coating on the underside of the tibial tray did not allow polyethylene particles to migrate to the central stem, unlike the underside of the Ortholoc Modular implant which had smooth metal bridges between the screw holes and central stem. The two modular implants revised for loosening showed PE debris down the length of the central stem.

1.3.1.4 Hydroxyapatite Coating

Hydroxyapatite (HA) is a compound which is similar to bone mineral, sharing the same chemical formula. It can be used independently or associated with a porous

coating. It can be applied to existing prostheses. Akizuki reported in 2003 a study of thirty-two knees with a seven year follow up[27]. The normal Miller-Galante II knee was coated with hydroxyapatite-tricalcium phosphate and then implanted in the normal manner. The follow up suggested a good clinical and radiographic result with sound early fixation. Unfortunately, without comparison to the same implant lacking the HA coating, the results do not demonstrate the benefit of the additional HA, only that the implant in that configuration gives acceptable results.

Onsten *et al* published an interesting Radiostereometric Analysis (RSA) study looking at HA coating, porous coating and standard cementing with the PFC knee[28]. With migration measured using the RSA technique as the end point the paper showed that the porous coated knee had a statistically significant increase in migration compared with either the HA coated or standard cemented implant. There was no significant difference between HA coating and cementation.

1.3.1.5 Screw Fixation

In 1990 Miura published a study of cadaveric tibiae which had the tibial component from The Ortholoc II design applied with or without the addition of either four cortex piercing cancellous screws, or a polymethylmethacrylate (PMMA) sleeve to the tibial stem, or both[29]. The tibiae were then subjected to mechanical cyclical loading. The addition of the screws and sleeve did not affect the overall amount of micromotion at the tibial tray/bone interface, but together they had a significant reduction on lift-off of the tray from the cut tibial surface. The conclusion was that although micromotion was not diminished, it was the nature and direction of the movement which was altered, allowing for a better initial contact surface between the tibial tray and bone.

Whiteside reported in 1994 that four screws placed through the tibial tray produced a statistically significant decrease in the presence of either partial or total radiolucent lines beneath the tray[30]. It was concluded that, as previous studies had shown a clinical benefit from screw fixation of the tibial tray, better longevity may be due to the reduction in radiolucency. The report also stated that only two of 5758 screws developed radiolucent lines and there were no cases of osteolysis. Although the paper mentioned the non-fluoroscopic method for assessing radiolucent lines beneath the tray, it assumed that the rate at which lines were missed would be equal for both the screw and the non-screw methods. The mean length of follow up of the screw fixation group was 3.7 years, which is short. These flaws, in addition to the lack of a clinical end point, diminish any conclusions which could be drawn from this work.

Lewis in 1995 examined the change in peri-screw or sub-tibial tray radiolucency between initial postoperative radiographs and those taken at four years[17]. The results showed that there was significant progression of radiolucency over time. There was also a suggestion that as the peri-screw lucencies worsened that amount of sub-tibial tray lucency also increased, to the point of failure. However, the numbers of this occurrence were small. The likely cause of these radiolucencies and osteolytic areas was polyethylene debris passing beneath the insert and down the screw holes. Although the follow up period was not significantly longer than in Whiteside's work there does seem to be a discrepancy between the reported frequency of both radiolucency and obvious osteolysis.

Gejo in 2002 presented a study of the NexGen knee which was HA coated on the undersurface of the tibial component compared to a standard NexGen implant fixed with screws[31]. The results at one year showed a marked reduction in the presence of radiolucency beneath the tibial tray. The authors suggested that the HA coating

provided a good initial fixation and, therefore, this implant could provide an answer to the problems of cementless fixation. This is an unsubstantiated claim as the follow up was very short and no clinical outcome was demonstrated.

The use of screws for fixation has been extensively studied, but there is no clear evidence that their use provides a significant benefit and there is a likely association with increased sub-tibial tray osteolysis from transported PE debris.

1.3.1.6 Tibial Stem

The use of a tibial stem to provide a means of stabilising cementless implants has been shown to be effective. Volz in 1987 used paired cadaveric tibiae to test the stability and micromotion in various implant designs[14]. The AMK design with a central stem and four peripherally placed cancellous screws provided the most stability. The Whiteside implant which also had a central stem, but no screw fixation, provided stability similar to the Miller-Galante implant that had just screw fixation. The PCA implant with neither a central stem nor four screws, but two lateral fixation pegs, had the most movement. The conclusion was that a tibial stem provided good support, probably by reducing tray lift-off, which is associated with subsidence.

Kim in 1990 reported that the addition of a central stem to the PCA component resulted in good results at five years. Although this study did not contain comparison to other implants the lack of significant subsidence amongst the patients with the central stem addition suggests increased stability due to the central stem.

Albrektsson performed an RSA study on the addition of a metal backing and tibial stem to the Freeman-Samuelson implant[32]. The amount of inducible displacement

and progressive micromotion were reduced with the addition of the stem and metal backing. It is impossible, however, to establish from the results how much of the improvement is attributable to the stem and how much to the metal backing. It was not stated whether the metal tray was porous or HA coated.

In contrast to the support for a tibial stem, Stern *et al* reported in 1997 that the addition of either a short or long central tibial stem to the Ortholoc cementless implant did not result in improved initial fixation[33].

The debate on the use of a tibial stem seems to be related to the need for initial stability to allow bony in growth and long term stability. If too much micromotion is allowed then there can be a significant decrease in the amount of bony in growth, which has an effect on subsidence and migration. There appears to be no clear cut evidence on whether the addition of a tibial stem reduces micromotion enough, consistently, to allow good initial fixation.

1.3.1.7 Clinical Outcome

Cementless fixation in knee arthroplasty has failed to become widespread as the results obtained have not compared favourably with cemented fixation. However, as implant and fixation design have improved the gap between the two has lessened. The most important outcome measures are objective scores and revision rates. The revision rate is related to the level of deep infection, loosening and persistent pain, among other variables.

1.3.1.8 Longevity

The main aim of knee arthroplasty is to give prolonged pain relief. Therefore studies designed to assess the survivorship of an implant are important. It is difficult to establish the true life expectancy of an implant for many reasons. Patient follow up over a long period of time is difficult. Patients die or move away from the area of study, resulting in diminishing study numbers. A great deal of published research in this field is sub-optimal due to a short follow up period. It is also important to only consider strong endpoints. Often papers use a subjective score to assess a "good" outcome as opposed to a "poor" one. The increasing use of scoring systems such as the Oxford Knee Score (OKS) or the Hospital for Special Surgery (HSS) knee score have provided some measure of subjective assessment, as well as an ability to compare between studies.

A good example of the need for a long follow up period is provided by the papers by Duffy[34] in 1998 and Rand[35] in 1991. They are reports of the same study of the PFC knee at 2.8 years and ten years of follow up. The study directly compared the use of a cemented PFC knee to a cementless PFC knee. The initial results were very similar, although the cementless implant had a higher initial complication rate, mostly attributable to polyethylene wear on the metal backed patella implant. However the ten year results showed that the survival rate for the cementless PFC was 72% compared with 94% for the cemented version. The conclusion is that initial good results can be misleading as the rate of failure can be significantly different for implants.

The same PFC prosthesis was studied and the results published by McCaskie in 1998[36] and Khaw[37] in 2002. This study was also a comparison between the cemented and cementless versions of the implant. However, in this study the

differences in survivorship were the same, at just over 95%. Comparing the studies is difficult as the second study had increased numbers as they continued to recruit patients. The follow up period was also as short as 2.4 years, the longest being 13 years. The ten year survivorship was a statistically estimated result as the mean follow up was only 7.4 years. Therefore, the papers demonstrate the value of careful follow up, which can give encouraging results, but conclusion can be difficult until a sufficient true follow up period is achieved.

A further pair of papers on a different implant were produced by Hofmann that looked at the cementless Natural knee system[38,39], but this was not compared to a cemented prosthesis. The initial two to four year results showed good survivorship and clinical outcomes. The later study, which included the original patients, plus some new patients, had a follow up of ten to fourteen years. The quoted ten year survivorship was 93.4%, this used revision or radiographic evidence of loosening as end points. This result has a good length of follow up, but it is difficult to assess it against results for cemented TKRs as it was performed by one surgeon using an implant that only comes as a cementless version.

A report of the PCA knee by Moran[40] in 1991 showed that the five year survival of this cementless implant was 84%, which then dropped to 77% a year later. The paper made the interesting point that their initial two year data compared well with previously published reports by other authors using the same implant. But after this period the rate of failure increased markedly. This highlights the need for good longer term follow-up as early data can be misleading.

A short term follow up study by Nielsen[41] over three years published in 1992 showed the importance of regular assessment. The overall results were good but they identified undersizing of the tibial component as the main cause of early failure.

1.3.1.9 Difficult Patient Groups

One of the desired benefits of using cementless implants is a reduced operating time, which has implications when considering joint arthroplasty on difficult patients. These patients include those who are obese, diabetic or immunosupressed.

Hungerford compared obese patients and non-obese patients who had undergone cementless knee arthroplasty (PCA) between two and 11 years previously[42]. Although the numbers were relatively small (50 knees in each group) the results showed clearly that obese patients were not more likely to require revision. It was interesting to note that, although the soft tissue envelope can be a problem in obese patients, there were no revisions for infection. There was also a suggestion that the obese patients had worse clinical scores, but the results were not statistically significant. The conclusion was that a cementless prosthesis can be used in obese patients, and the results are similar to those obtained with cemented implants. There is not, however, any evidence in the literature comparing cemented and cementless TKR in obese patients.

Stuchain published data in 1991 regarding 53 cementless implants in patients with inflammatory arthritis requiring immunosuppressive medication, that the paper regarded as resulting in poor bone quality[43]. The medium term results (2 to 6.4 years) showed that survivorship was adequate, comparable to cemented implants, and that further study should be undertaken. Schroder[44] also reported, in 1996, results of 51 AGC knees in patients with rheumatoid arthritis, with a medium term follow up of five to seven years. There was only one case requiring revision, suggesting that it is a reasonable choice for this group of patients. There is no report

in the literature comparing cementless implants with cemented in these patients. The results shown above, therefore, suggest that cementless implants are usable in rheumatoid patients, but there is no long term data available. This may be because each study uses relatively small numbers, which will have increasing drop out with increasing years, resulting in cohorts too small for analysis.

1.4 Unicompartmental Knee Replacement

Unicompartmental knee replacement prostheses were introduced in the 1970s, although they were initially used as bicompartmental replacements as an alternative to TKR. There was a wide range of implants available, varying in much the same way as TKR components at the time; single and multiple radii femoral components, and both all-polyethylene and metal-backed tibial components. Initial reports demonstrated mixed results, with most studies being designer series or from a single surgeon[45-49]. It was these mixed results that limited the impact on orthopaedic practice with a strong reliance on TKR. There has been a debate between advocates of UKR and those with preference for TKR regarding the correct indications for both initial implantation and revision. This antipathy for UKR was perhaps compounded by the variety of unicompartmental prostheses available. The Oxford UKR, introduced by Goodfellow and O'Connor in the mid 1970s, differed from other implants, both uni- or tri-compartmental, by having a fully congruent, mobile polyethylene bearing. Although designed to reduce polyethylene wear and tibial component loosening by reducing contact stress between the components, it had an increased rate of bearing dislocation compared with fixed bearing devices. It was this increased early complication rate that led Lewold to report on the results of the Swedish knee registry showing that the Oxford UKR had an early complication rate twice that of the fixed bearing Marmor prosthesis[50]. However, the use of revision

rate has been a point of contention in the argument against UKR. The Oxford group highlighted, in an Annotation in the British Journal of Bone and Joint Surgery, that revision rate is an unrealistic measure of success when comparing total with unicompartmental replacement[51]. Using registry data they showed that a poorly performing UKR, as judged by the Oxford Knee Score (OKS), was six times more likely to be revised than an equally poorly performing TKR. This view was supported by Engh in his review of the current approach to the use of UKR[52].

1.4.1 Cemented Fixation in UKR

Despite the variation in design for the first UKRs they all used cement for fixation. In common with TKR prostheses, the femoral components benefited from fitting to the prepared femoral condyle and hence had a geometric advantage. In contrast, the single compartment tibial components not only had the problem of fitting to the flat surface of the prepared tibial plateau, like those of TKRs, but their reduced size gave less room for additional fixation designs such as pegs or keels. The great advantage of cement fixation in UKR, in addition to its ease of use and availability, was it's flexibility, being usable with almost any design. Cement was also used for UKR as the results in TKR were good. The initial results for UKR in the late 1970s and early 1980s showed that the main causes of failure were related to fixation, but also cementing errors. More recently the results from cemented UKR had been good, with many groups reporting over 90% survival at 10 years[53-55]. Survivorship at 15 years is less often reported, with results ranging between 87.5% and 95%[56,57]. However, those results are not supported by the NJR, again highlighting the difficulty in applying the results from specialist centres to the general orthopaedic population. The registry states UKR has a revision rate at seven years of 16.6%, much higher than that for TKR, with loosening of the tibial component as a major cause of failure.

The registry does not differentiate between cemented and cementless UKR, however, the majority of cases would be cemented as cementless UKR is relatively uncommon, with only a few centres performing the procedure. As with cemented TKR, cemented UKR is the standard procedure, but there is scope for results to be improved. This, combined with the need for a better long term solution for younger patients, means the search for an effective cementless alternative continues.

1.4.2 Cementless Fixation in UKR

Cementless fixation in unicompartmental knee replacement is a developing field with advances in implant design and fixation surfaces. Although there have been cementless options in unicompartmental replacement available for nearly 20 years, the operation has not become widespread. Cemented fixation is used in the majority of UKR procedures, with good clinical results. However, there is a concern over the suitability of cemented fixation in the younger, high-demand, patient. Cementing in UKR is difficult and cementing errors, such as cement loose bodies, are common and may cause failure. In addition, the slow development and general acceptance of cementless UKR may be in part due to poor results from early designs. The use of cementless fixation in UKR is likely to increase with the aim of long-term biological fixation being a realistic goal. The important factors for success in cementless UKR surgery are likely to be the same as for any arthroplasty surgery: adherence to appropriate surgical indications, use of a well designed implant and meticulous surgical technique.

1.4.2.1 Rationale

The development of cementless UKR has mirrored that of TKR, with the use of

porous coatings, with and without hydroxyapatite, and, in some designs, the addition of cancellous screw augmentation. All designs have utilised a keel on the tibial component, although the shape, size and orientation have shown considerable variation. The femoral component has usually mirrored the cemented equivalent for each design, although those femoral designs with a single peg had a second peg added for rotational stability.

One of the first advocates of cementless UKR was Jean-Alain Epinette[58] who designed and developed a hydroxyapatite coated tibial component. This component differed from most designs by employing a horizontal keel that slotted beneath the tibial spines, thus maintaining bone stock beneath the tibial tray. In addition there were cancellous screws to augment the initial fixation. Whiteside further highlighted the importance of initial stability in 1990, with a cadaveric *in vitro* study demonstrating the additional stability provided by cancellous screws in a unicompartmental tibial component, compared with a posteriorly angled peg[59].

Cementless fixation has many potential advantages over the more commonly used cemented fixation. In hip arthroplasty cementless fixation has become ever more popular, whereas cementless total knee arthroplasty has remained less popular, particularly with regard to the tibial component. This is probably due to the increased difficulty in obtaining good initial fixation with a mostly flat tibial component resting on a flat tibial plateau. Although cementation provides an adequate fixation method in most cases, the potential side-effects and complications ensured perseverance with the development of cementless fixation. The disadvantages of cement use include possible thermal damage to the bony surfaces, an increased operative time and the risk of cementing errors such as loose cement bodies or incorrect seating. Cementless fixation avoids these problems and has the advantage of preserving tibial bone, as well as the theoretical potential of very long term biological fixation.

However, cementless fixation in total knee arthroplasty has struggled to gain widespread acceptance due to some poor early results, with a particular risk of failure of ingrowth.

The use of cementless fixation in UKR has mainly been used in the few centres that are strong advocates of unicompartmental surgery. The latest reports from the Australian and New Zealand joint registries show that cementless UKR accounts for 11% and 6% of all UKR procedures respectively[10,60]. The Swedish register reported that all the UKRs performed in 2009 had both components cemented[11]. Neither the National Joint Registry in England and Wales nor the Canadian registry give information regarding fixation method for UKR[13,61].

A great deal of the literature regarding cementless TKR highlights loosening of the tibial component as a major contributor to the higher failure rate compared to cemented fixation. The tibial component in TKR is subjected to compression through the medial plateau, as the majority of weight bearing is through the medial side of the knee with physiological eccentric loading, with tension, or lift-off, in the lateral compartment. It is this lift-off that is a cause of loosening and hence failure of fixation. In medial UKR, and particularly with a mobile bearing, all of the force is compressive, without the corresponding lift-off associated with a tibial component over both plateaux. Therefore, theoretically, a UKR is an ideal implant to use cementless fixation.

Although the presence of thin, non-progressive, radiolucent lines has long been recognised in knee arthroplasty, with no associated increase in failure rate, the exact cause and effect of them is still unknown. There is, however, a perception that a radiolucent line is indicative of sub-optimal fixation. The incidence of radiolucency differs beneath different implants, suggesting that the mechanical environment is

important in their development. Forsythe *et al*[62] reported an incidence of over 50% with the cementless Whiteside Ortholoc II UKR, whereas Pandit *et al*[63] reported that just 7% of cementless Oxford tibial components had a partial radiolucency, with none having a full radiolucency. There is also a reported increase in incidence of radiolucent lines with cemented Oxford components compared to the cementless version[63]. There is no clear consensus on the role or importance of thin (≤1 mm), stable, so called "physiological" radiolucent lines, although there is evidence that they are not associated with either loosening or a decrease in clinical outcome scores. However, the greatly reduced incidence in cementless UKR is encouraging and suggests good bony fixation. The Oxford UKR is particularly suited to cementless fixation because of the fully mobile bearing. The bearing movement causes a marked reduction in shear forces being transmitted through the tibial tray and, therefore, the tray is mostly subjected to compression. This is an almost ideal mechanical environment for cementless fixation.

Radiostereometric analysis (RSA) studies of cementless fixation in TKR have shown a consistent pattern of migration, which differs from cemented fixation. Cemented components usually demonstrate early migration, but the magnitude is small and stability is achieved by two years. In contrast, cementless components usually migrate a larger amount in the first few months before stabilising. Onsten and Carlsson demonstrated a reduction in the movement between one and two years post operatively with the addition of a layer of hydroxyapatite to a porous coated PFC tibial component[64,65]. Likewise, Regner demonstrated the reduction in maximum total point movement at five years in the Freeman-Samuelson TKR tibial component with the addition of hydroxyapatite to the undersurface[66].

1.4.2.2 Indications

The indications for UKR are controversial and vary according to the surgeon's philosophy. In Oxford, the view is that there should be full thickness cartilage loss on both the medial tibial plateau and femoral condyle (bone-on-bone osteoarthritis), any intra-articular varus deformity should be correctable and the anterior cruciate ligament (ACL) should be intact. Patello-femoral joint damage is ignored unless there is severe damage laterally. Cartilage damage on the lateral femoral condyle is permissible provided there is full thickness cartilage present on a valgus stress radiograph and there is no full thickness loss centrally. Full thickness damage on the medial side of the lateral femoral condyle is not a contraindication[67]. Age, gender, activity level or Body Mass Index (BMI) are not considered to be contraindications. These indications are routine for both cemented and cementless Oxford UKR. Bontemps also recommends that the indications for cemented and cementless UKR are the same, however, due to cost saving, he favours cemented fixation in the elderly[68].

The suitability of cementless UKR in cases of osteonecrosis or areas of bone loss is less easily described. The consensus in the Oxford group is that if the knee is suitable for cemented UKR once the bony surfaces are prepared then cementless UKR is also indicated. The rationale for this is based on evidence that total bony ingrowth is not required to maintain implant stability and therefore if the bony surface can support the implant then either fixation method is acceptable. Epinette's group demonstrated implant stability in cementless UKR when the amount of bony contact between tibia and component was between 38-52% [58].

1.4.2.3 Post Surgical Follow Up

The standard post-operative rehabilitation regimen for both cemented and cementless UKR is used. Patients are allowed to weight-bear once comfortable, usually on the first post-operative day. The patient is discharged when mobile on crutches and can safely negotiate stairs. In Oxford there is no difference in time to discharge between cemented and cementless UKR. Patients are advised to mobilise as comfort allows and are warned that it may take many months for the soreness, stiffness and swelling to settle.

Before discharge patients have routine radiographs with the anteroposterior view taken parallel to the tibial tray, allowing assessment of the component-bone interface. The lateral view is perpendicular to the femoral component allowing assessment of bony contact around each peg. Using carefully screened radiographs enables proper evaluation of the interfaces and allows comparison with subsequent radiographs. The accuracy of detecting radiolucent lines, and hence assessment of whether they are progressive, is dependent on the reproducible acquisition of radiographs. The incidence of radiolucent lines beneath the cemented tibial component in Oxford UKR is approximately 62%[69]. However, the incidence in cementless Oxford UKR is markedly reduced at one year with only 7% having a partial radiolucency and none having a complete radiolucency[63]. Radiographs taken in the first few days after surgery sometimes demonstrate a thin radiolucent line beneath the tibial tray. This is indicative of the tray not being fully seated at the time of surgery. However, with normal post-operative rehabilitation the radiolucent line disappears and the tray becomes securely seated on the tibial plateau (Figure 1-1).

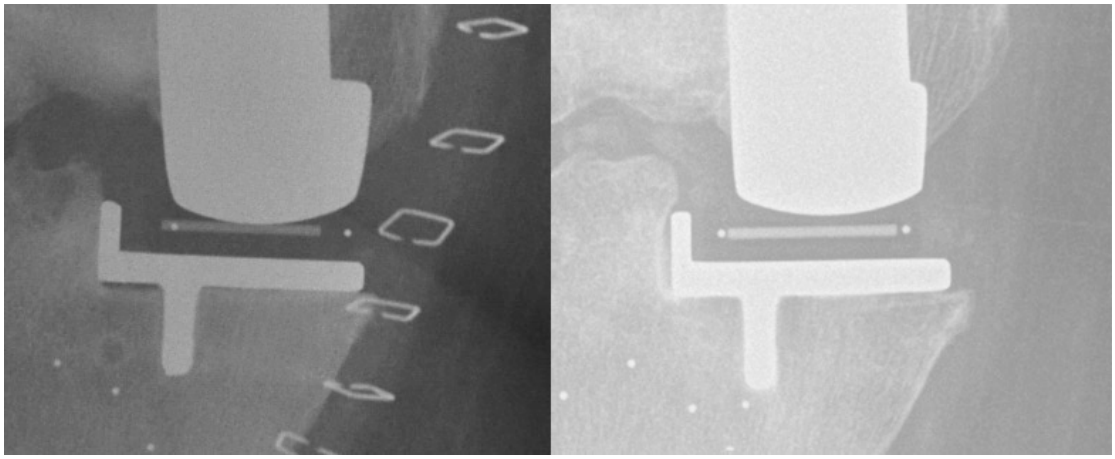

Figure 1-1 A cementless tibial component of an Oxford Unicompartmental Knee replacement not correctly seated post-operatively (left) but seated correctly at one year (right).

1.4.2.4 Clinical Outcome

Clinical results of cementless UKR are not commonly reported, and those reports evident in the literature are usually short series. A single randomised controlled trial of cemented versus cementless UKR in Oxford has shown no difference in clinical outcome, and a reduced incidence of radiolucency with cementless fixation, at two years[70]. There have also been reports that contribute to the base of knowledge in UKR fixation, with lessons being learned and improvements made. A report from Keblish in 2004 regarding the LCS mobile bearing UKR highlights the reasonable clinical results obtainable, but again shows that there are concerns regarding cementless fixation as all the failures of fixation in the study were in the cementless group[71]. The Porous Coated Anatomic UKR had initial success, both using cemented and cementless fixation methods. However, Bernasek described an increased number of failures due to fixation in the early post-operative period with fibrous tissue forming at the implant/bone interface[72] in the cementless components.

Lindstrand reported good results initially with the same implant, but then showed a deterioration between four and eight years post-operatively[73,74]. Although, the study

included both cemented and cementless components and the failures described in the mid-term were mostly related to extreme polyethylene wear. This demonstrates the difficulty in obtaining long term follow up on UKR fixed without cement. Epinette has provided perhaps the best mid to long-term follow up of a cementless UKR[75]. At a minimum follow up of five years, with a maximum of thirteen years, there were no failures of fixation in 125 hydroxyapatite coated Unix knee replacements. Radiographs obtained 14 years after surgery show that excellent fixation without the development of radiolucencies can be achieved. The results of the available published reports are summarised in Table 1-1. The data presented demonstrate the need for further studies with longer follow up in addition to focus on particular patient groups, such as the young with high demand.

Author (Implant, year)	**Number**	**Length of Follow-up**	**Failure due to cement-less fixation**	**Failure due to other reasons**	**Success Rate**	**Comments**
Bernasek [72] (PCA, 1988)	28 (26 medial, 2 lateral)	Minimum 2 years	4	2 (1 lateral progression, 1 patellar impingement)	22/28	
Magnussen [76] (PCA, 1990)	51 (42 medial, 9 lateral)	Minimum 2 years	0	1 (lateral progression)	50/51	
Forsythe [62] (Ortholoc, 2000)	57 (All medial)	1-8 years (mean 3.3)	1	0	56/57	5 had loose beads with significant radiolucencies
Keblish [71] (LCS, 2004)	127 (additional 50 cemented included in paper)	5-19 years	6	Not available as paper includes cemented UKR	Not available as paper includes cemented UKR	27 of 177 total UKR (cemented included) revised for bearing wear
Lecuire [77] (Alpina, 2008)	120 (108 medial, 12 lateral)	Mean 6.5 years	2	8 (3 lateral progression, 4 bearing fracture, 1 bearing wear)	110/120	Cementless failures revised early at 6 and 7 months.
Epinette [75] (Unix, 2008)	125 (111 medial, 14 lateral)	5-13 years	0	2 (1 ACL deficiency, 1 lateral progression)	123/125	2/125 had peri-screw osteolysis, but no component loosening
Pandit [63] (Oxford, 2009)	30 (All medial)	Minimum 1 year	0	0	30/30	Reduced radiolucencies compared to cemented Oxford UKR (RCT)

Table 1-1 Summary of published papers on cementless unicompartmental knee replacement.

1.4.2.5 Overview

At present cementless UKR is still an unproven long-term treatment for single compartment osteoarthritis. However, the majority of reported failures are due to either inherent problems with design or progression in another compartment, rather than the fixation method. Although due regard for the short to mid-term follow-up must be made, recent results show an encouraging future for cementless UKR.

1.5 Measuring Outcome

The most common outcome measurement used in knee arthroplasty is survivorship, as already evidenced by the use in national registers and being a common end-point in study reports. However, the use of revision as an end-point has several drawbacks. Firstly, revision is related not only to the clinical indications, such as continuing pain, loosening, wear and infection, but also surgical factors such as ease of revision. At one end of the spectrum there may be an implant that can fail, but revision is not possible or extremely difficult, resulting in close to 100% survivorship. At the other end of the spectrum there may be an implant that is very easy to revise with an excellent chance of good outcome, and thus may be revised for a "weaker" indication as the benefit outweighs the risk. In reality all implants fall between these two extremes. This, however, highlights the need to consider other end-points, such as patient reported outcomes (PROMs) or radiographic surrogates of failure. The commonest outcome score for knee replacement is the American Knee Society Score, which uses patient reported outcome but also uses surgeon measured variables such as alignment and range of movement[78]. The most common score that is patient reported only is the Oxford Knee Score[79], comprising 12 questions with a maximum score of 48 and a minimum of 0. The use of these scores can allow

comparison between treatments, such as between UKR and TKR[80] or to assess technical aspects of a procedure, such as component alignment, on outcome[81].

1.6 Radiostereometric Analysis

The initial theory of identifying the position in space of an object using twin radiographs was first described by Davidson and Hedley in 1897[82]. But it was the work of Goran Selvik, as part of his PhD at the University of Lund, Sweden, in 1972, that first led to the development of a system that was applicable to orthopaedics[83]. Selvik's Roentgen Stereogrammetric Analysis (RSA) system was an advance on previous work, introducing radio-opaque metallic marker pins or spheres, a calibration frame containing further metallic markers and utilising the theories of rigid body kinematics[83]. It was these advances that resulted in RSA becoming a powerful tool in the measurement of migration and implant stability in orthopaedics. Initially, the method was used almost exclusively in Scandinavia but has subsequently been used throughout the world. With the expansion of centres outside of Scandinavia using the technique the name was simplified to Radiostereometric Analysis, with the same abbreviation.

A review by Karrholm, Gill and Valstar, three current leading advocates of RSA, provides a thorough history of the development of RSA and demonstrates the difficulties faced while developing a complex system[84]. As computing power has increased it has simplified the whole process of RSA. Initially, developed plain radiographs had to be digitised manually and each marker individually identified. With the advent of digital radiology and automated marker identification analysis of each set of radiographs has been cut from several hours to as few as ten minutes. With automation the possible bias or error of human subjectivity is removed. The

development of model-based RSA (MB-RSA), that utilises computer aided design models rather than implants with additional markers, has made RSA easier to perform and has the advantage of studying non-modified implants.

As the accuracy and usability of the system developed it became possible to perform useful clinical trials. One of the first effective applications of RSA was on skeletal growth. Aronsson and Hansson described the longitudinal growth of the fibula in children with hormonal deficiencies[85]. Bylander also used RSA effectively to demonstrate the effect of physeal stapling on growth arrest in children in leg length discrepancy surgery[86]. Karrholm further extended the application of RSA in bone growth by showing the effect of fractures around the paediatric ankle on growth and subsequent alignment[87]. An obvious extension of the previous work centred on bone healing following fracture or osteotomies. Magyar evaluated high-tibial osteotomies, opening-wedge *versus* closing-wedge, using RSA and demonstrated an increased correction with the closing-wedge osteotomy[88]. Some further studies focused on spinal conditions such as lumbosacral fusion or advancement of spondylolistheses. Olsson collaborated with Selvik to assess the stability and progression of posterolateral fusion in the lumbar spine[89,90] and more recently Halldin investigated the effect of discectomy on segmental movement of the adjacent vertebrae[91]. While the initial investigations were often based on bone growth or bony movement, subsequent studies included the evaluation of ligamentous function. Edixhoven performed a cadaveric study to show that anterior drawer of the anterior cruciate ligament (ACL) could be measured using RSA[92] and Karrholm did further work demonstrating that displacement of the ACL could be measured in all three dimsensions[93].

1.6.1 RSA in Joint Arthroplasty

It is the study of total joint arthroplasty where RSA has had the biggest impact. While initial studies focused on movement, or migration, of the implants subsequent studies have diversified into looking at wear of the components. The quest for greater accuracy has driven advances in RSA, particularly in image acquisition and data processing. There are many components of arthroplasty surgery that may affect the longevity of an implant, from the design of the components and hence the subsequent forces through the implant/bone interface, to the method of fixation, or the way in which the bony surfaces are prepared. There have been several episodes in orthopaedics where initial clinical results suggest an implant or cement will be successful in the long term, only for subsequent catastrophic failure[94-98]. It can be a difficult clinical problem to identify those implants at risk, with problems often not evident until several years after implantation. The national joint registries can provide an earlier insight in to potential problems, but are still limited by the need for years of follow up. Therefore, there is a need for a method that can detect the potential for failure as soon as possible after implantation. Leif Ryd, over a period of three decades, has produced the most influential work regarding knee arthroplasty and RSA as he first identified early micromotion as a predictor for failure[99,100]. His thesis work followed several different designs of knee arthroplasty, implanted in either a cemented or cementless fashion, over a period of several years. Both migration and the amount of inducible movement resulting from an external force were measured. The work showed that regardless of design or fixation method progressive early migration (continuing after the first post-operative year) was a strong indicator of failure[99]. While the initial premise had strong evidence to support it, it was not until at least ten years had passed that the updated data showed that those implants that were originally “stable” proceeded to remain well functioning with no indication for revision, whereas those that were “at risk” were shown to indeed

require revision within ten years or were performing less well clinically[100]. This theory of using RSA to measure migration, and using progressive migration as a predictor of failure, can be used to perform early surveillance of new implants, while in addition it can also be used to evaluate existing implants used in new ways, for example through an alternative surgical approach[101]. An example of early surveillance is well demonstrated by Simpson *et al* in the study of the Furlong JRI femoral stem [102]. The original stem had very good clinical results confirmed over many years of follow up[103], however, finite element analysis of the stem suggested that improvements could be made on the stem design. This did not translate to *in vivo* where it was shown that the new design had less initial stability on average and one stem was "at risk" with continuing migration at two years. This study also highlighted the need for further research in to RSA and joint arthroplasty as although a potential problem was identified it was not possible to provide an absolute value of migration over which failure is likely to occur. This concurred with the previous work of Ryd that suggested that it is the progression of migration rather than the absolute values that can indicate failure. This does, however, introduce an intrinsic difficultly when performing an RSA study and then interpreting the results. For example, the Exeter femoral stem is a polished, tapered design that is intended to subside into the cement mantle providing excellent long term results. There has, however, been conflicting evidence in the literature regarding which cement to use (low *versus* high viscosity) with differing clinical results. A RSA study by Glyn-Jones showed that there was no difference in migration between cement groups with subsidence and rotation into valgus evident with both types of cement[104]. Therefore, it may be that the clinical results are dependent on other variables than those assumed.

The use of RSA in arthroplasty also increases our understanding of how implants behave and give a further insight in to the mechanics of implant/cement/bone interaction[105].

There are several technical considerations when using RSA in assessment of arthroplasty. The tantalum markers must be securely fixed in bone to provide a rigid body reference, against which migration of the implant can be calculated. Markers that are not securely fixed may move, thus reducing the number of markers available for analysis or resulting in inaccurate results. The distribution of markers is important, with avoidance of co-planar markers required to decrease the condition number, which is an indicator of the quality of marker spread, with a low number indicating good spread of the markers allowing more accurate measurement of migration[106]. In contrast, a large condition number is indicative of a weak spread of markers that may yield inaccurate migration results. It has been recommended that the condition number should be below 100 to provide an acceptable level of accuracy[107].

1.6.2 RSA in Knee Arthroplasty for Fixation

Fixation is the most investigated variable when looking at knee arthroplasty, with cementless fixation being a particular focus. Clinical reports of TKR outcome often do not include the type of cement used, but Nilsson has shown that the type of cement can have an effect on migration, with different types having grossly different migration profiles[108]. Indeed, that study showed the increased amount of migration with Boneloc cement (Biomet, Warsaw, USA) and predicted failure, which was subsequently shown by the national registries. However, with the clinical results of cemented fixation being better than cementless there has been a focus on whether migration is different between the two fixation methods. Nilsson studied cemented versus cementless fixation in tibial components showing that there was no difference between the two groups[109]. A further study from the same group showed a similar

finding in femoral components[110]. It is the latest work from the group however that is most interesting, with a randomised controlled trial showing that although cementless implants move more by three months they then become stable, with the cemented group continuing to migrate at two years[111]. However, Carlsson demonstrated that cemented fixation provides greater stability rather than cementless fixation, and a further finding of a difference between cementless fixation methods (hydroxyapatite versus porous coating)[64]. Further insight into the migration profiles of cementless implants has been provided by numerous studies[66,112,113]. Hydroxyapatite has been shown to stabilise components with both less migration and less inducible motion than porous coated implants. Hilding further showed that those cementless implants that are felt to be failing have increased inducible motion[112]. Further work by Albrektsson demonstrated that the addition of a tibial stem to an existing cementless tray provided greater stability and less inducible movement[32]. Whilst Henricson found that a mobile bearing implant did not produce less migration, as might be expected, than a fixed bearing implant, the pattern of migration differed, with increased subsidence with the mobile bearing and increased lift-off with the fixed bearing[114]. This suggests that although the overall migration was not different the forces through the tibial components were different between bearing types.

Very little has been published using RSA to evaluate UKR. Carlsson showed that the minimally invasive approach available to UKR had no increase in migration when compared to the standard open approach[115]. Although, with several studies showing excellent clinical outcome with the minimally invasive approach, it would be unexpected to see a difference in migration.

1.6.3 RSA in Prediction of Loosening

While the above mentioned studies often found a difference in migration or inducible movement between fixation methods, whether cemented or cementless, they did not give a threshold above which a particular component was near certain to fail. This highlights one of the inherent limitations of RSA. The majority of the papers cited used the work of Leif Ryd when determining whether an implant was "failing". The threshold of 200 μm of translation in the second post-operative year was used, based on the extensive work by Ryd, that included both TKR and UKR, with cemented and cementless fixation. The strength of the work was based on the length of the follow up and the number of implants. Follow up was greater than 10 years, which meant that there were a larger number of failures than with shorter follow up. With a greater number of failures the amount of migration required to predict failure is more accurately estimated. The number of implants included also gave a better insight into the normal migration profile, with cementless components migrating more than cemented, with increased subsidence and tipping into varus.

However, there is a weakness to the study, which is the variety of fixation and the number of different implants. Hence, using 200 μm as a predictor of failure may be inaccurate for certain implants or fixation types but there is little data from other studies to provide another estimate of failure.

An attempt to provide an assessment of initial stability and to find a threshold for failure obtainable intra-operatively was performed by Fukuoka *et al* [116]. A RSA study of the Kyocera Osaka City University Knee Replacement with cementless tibial components and cemented femoral components was performed. The tibial component had an HA coated central stem and four screws for initial fixation. The study assessed initial stability under a 20 kg load intra-operatively and then followed

up with RSA to assess micromovement over a two year period. The results indicate a correlation between initial stability and a reduction in micromovement over time. This study also suggested, as previously noted above, that movement progresses for six months and then stops. The study found that less than 200 μm of inducible movement after implantation was associated with less than 200 μm of migration in the second post-operative year.

A further consideration is the regular change in an implant's design by the manufacturer, either as a response to clinical results or to incorporate new technology. As has been shown above, migration or failure is often individual to a particular implant, which implies that even subtle changes to an implant can have profound effects on its migration and thus survivorship.

1.7 Radiolucency (RL)

1.7.1 Prevalence

The reported prevalence of radiolucency in knee arthroplasty is dependent on many factors; geometry of the implant, alignment of the radiographs and duration of follow up. The presence of radiolucency around components is well known, but the reason for the appearance is unknown. It is generally accepted that thin lines, that show no signs of progression, are benign[117]. However, those areas of radiolucency that get larger, or change in nature, have been associated with implant failure. Unfortunately, there is no standardised way of describing a radiolucency; it is an "all or nothing" phenomenon. Commonly only size is described and usually in a single dimension, namely depth. There is rarely description of the density, merely that it is less dense than the surrounding bone or implant (± cement).

Several studies have reported a prevalence of around 10% for radiolucent lines beneath a tibial component in TKR[118-120]. However, Ecker *et al* highlighted the importance of radiographic alignment in assessment of radiolucency[121]. In the series they reported for total condylar replacement they found a prevalence of 65%, but a further radiographic cadaveric study found that if the x-ray beam was rotated by more than 5°, or off centre by 2.5 cm, then a 1 mm radiolucency would be missed. Ritter *el al* also demonstrated that preparation of the cut bone surface before cementation affects radiolucent line formation, with high volume and high pressure irrigation reducing the prevalence[122].

It would appear from the literature that the reported prevalence of radiolucency in UKR is higher, often above 30%[69,123,124]. This may be a reflection of the ease with which radiographs can be aligned due to the smaller nature of the implants, or that the mechanical environment is different from TKR and a true difference in prevalence exists.

1.7.2 Effect of Fixation Method

Radiolucency has been recognised in both cemented and cementless fixation. Although the possible hypotheses for radiolucency formation depends on the fixation method, for example failure of ingrowth with porous coating or bony death from the heat of cement polymerisation, the prevalence shows the same variability for both methods. This suggests that some factors responsible for RL formation may be common to both methods and that the prevalence is highly related to the quality of the radiographs.

Vince demonstrated that about half of cemented TKRs had a partial RL area beneath the tibial component, and only those with a complete RL became loose[125]. This is in contrast to Tibrewal's study of the Oxford UKR that showed complete RLs are not related to loosening, but that it is important to see a sclerotic line beneath the radiolucency, which suggests equilibrium has been reached[126]. While many authors have stated that non-progressive radiolucency is common, and no cause for concern, Smith highlighted an association between stable radiolucencies that became progressive in association with increased polyethylene wear[127]. It was hypothesised that the thin radiolucency provided an easy avenue through which polyethylene debris could pass.

Kim *et al*[128] studied the incidence of osteolysis around the PCA implant using seven year follow up data of sixty knees. Although none of the implants became loose requiring revision the rate of tibial osteolysis was 90%. An 80% rate of osteolysis around the patellar implant was also noted, with six patellae requiring revision. The conclusion of the authors was that the cementless implants allowed significant amounts of polyethylene debris to reach the bone-implant interface.

Also using the PCA implant, Mont reported in 1995 a study designed to establish the effect of malalignment on aseptic loosening[15]. Thirty cases of aseptic loosening, with associated radiolucent lines, were matched to thirty well functioning implants. The aim of the study was to establish a single or combination of factors that could then predict the likelihood of aseptic loosening. Unfortunately the study was under-powered and did not allow a statistically significant difference to become apparent. Also, as the authors stated, the number of variable combinations, with regard alignment in the three planes, mean that identifying which are most relevant to loosening is very difficult.

Sorrels *et al* in 2004 looked at the bicruciate sacrificing porous coated LCS implant[129]. The study was primarily looking at survivorship and was a follow-up study of between five and 12 years but also looked at the presence of radiolucent lines, particularly beneath the tibial tray. Only one knee out of 528 was revised for aseptic loosening. It was noted that the presence of a radiolucent line was deemed to be non-progressive and those which measured greater than 2 mm, the upper sized group of lucencies, were not associated with loosening. This puts the emphasis on progression of a radiolucency, rather than its actual size.

The available evidence seems to suggest that the cause of aseptic loosening in cementless knee arthroplasty is unclear. It is apparent that initial stability is required to prevent significant micromovement. But the amount of movement required allowing effective bony integration, as opposed excess movement to allow loosening, is unknown. There is also doubt over the significance of radiolucent lines, and therefore radiographic studies are unreliable in attempting to find predictive markers of likely aseptic loosening and therefore implant failure.

1.7.3 Histology of the Radiolucent Line

Although radiolucencies are commonly seen at the interface of both total and unicompartmental knee replacement (TKR and UKR) they tend to be better visualised on the tibial rather than the femoral side. This is primarily due to the geometry of the tibial component, with most having a flat tibial plateau with either a peg or keel. In contrast, the femoral component often has a complex internal geometry that obscures the implant/cement/bone interface. For a radiolucency to be well seen there has to be a large, flat interface which is not obscured and the x-ray beam has to be parallel to the interface. With many TKRs a wide keel obscures the

interface and radiolucencies are not seen. The Oxford UKR has a large, flat tibial plateau and a keel that has straight, flat edges which does not obscure any radiolucency. It is, therefore, ideal to use as an implant to investigate the presence of radiolucency at the implant/cement/bone interface.

A further limiting factor regarding the correct identification of a radiolucency around an implant is the orientation of the radiographic beam. If standard radiographs are taken, which are not usually parallel to the interface, then radiolucencies are rarely seen. The optimum method to reliably align the x-ray beam parallel to the interface is to use an image intensifier. The incidence of radiolucencies on screened radiographs under the Oxford tibial component varies from about 40 to 100%[126,130,131], in contrast with standard radiographs where it is 0% to 20%[132-134]. The incidence of radiolucencies in total knee replacement is well documented with similarly high rates of 60-70% reported[135,136]. In addition, it has been suggested that the preparation of the tibial surface and the cementing technique can have an effect on the incidence of radiolucency in TKR[122] and UKR[137].

Although accurate detection of a radiolucency is important, it is the evaluation and classification that can alter patient management. Radiolucency around an implant has traditionally been interpreted as a sign of implant loosening. Ritter has reported on several series of cemented hip implants that radiolucencies are present around femoral stems and acetabular cups and that even thin RLLs can be associated with loosening[138,139]. Lonner reported on the significance of radiolucency beneath the tibial component in TKR, reporting on the initial clinical presentation of implant loosening and found that 80% of aseptic failures had a complete radiolucency[140]. Goodfellow et al[117] described two different types of radiolucency. The commonest type is the radiolucent line (RLL), which is usually 1 mm or less thick and has a sclerotic margin. It tends to develop and consolidate during the first and second

post-operative years and thereafter does not progress. It is common and not associated with significant problems and is, therefore, termed a *physiological* radiolucency[141]. In contrast, when there is loosening or infection the radiolucencies tend to be more than 2 mm thick, progressive and without a sclerotic margin. These have been called *pathological* radiolucencies.

As discussed above the radiographic appearances of radiolucent lines have long been known, but the composition of the tissue in the radiolucency has been studied in much less depth. One of the main limiting factors when comparing studies on RLLs from a radiographic perspective is the "all or nothing" nature of the identification. Nearly all studies rely on experienced investigators looking at a radiograph and deciding whether a RLL exists. Measurement is limited to depth and, on occasion, extent/width. Therefore, all RLLs are treated as the same entity, with classification based solely on depth and progression of depth. However, logic would suggest that they are not a single homogenous entity but are the radiographic manifestation of a spectrum of responses to multiple factors. These include patient factors as diverse as bone healing potential, immune response, pre-operative bone density, activity levels and Body Mass Index (BMI) or surgical factors including the quality of the bone preparation, alignment of cuts and component implantation as well as soft tissue balancing. These patient and surgical factors then act in combination to provide a widely differing mechanical environment for the components between patients.

If the composition of the tissue in the RLLs were accurately characterised it would lead to better understanding of potential causes of their heterogenicity. Tibrewal *et al* [126] have previously described the histology obtained from a single biopsy of the cement-bone interface of securely fixed tibial components revised for recurrent bearing dislocation. The radiolucency was composed of fibrocartilaginous

connective tissue with a sclerotic margin beneath made of a thick lamella of bone. It has been hypothesised that the development of the sclerotic line is due to an increase in stress in the bone beneath the soft tissue present in a RLL[142-145]. Ryd and Linder reported the histology of the interface in three patients after revision of the Marmor unicompartmental knee replacement[146]. This was found to be either fibrous tissue or fibrocartilage which they felt was consistent with their findings of initial migration but stable fixation, as measured by radiostereometric analysis. Even though the presence of a physiological radiolucent line is not associated with an inferior clinical outcome[69], the appearance often causes concern, particularly if the patient has continuing pain. It is, therefore, important to identify the constitution of the tissues in the radiolucent line in order to understand why they occur and their significance.

1.8 Summary of Current Knowledge

It is clear that knee arthroplasty is an operation that is regularly performed and the demand is going to increase. It is also evident that survival is not optimal. Therefore more work is required to find solutions for the different failure mechanisms. Fixation is poorly understood, and while the traditional method of cementation provides reasonable survival, it has undesirable complications. It is also probable that cemented fixation is unlikely to reliably provide very long term survival in those patients requiring their implants to last greater than 30 years.

Radiolucencies associated with knee arthroplasty components are poorly understood. It is unclear why they form in some patients and not others, what they are composed of and what is their effect on very long term survival. Studies have shown that the incidence of radiolucency is variable, strongly suggesting that their

development is multi-factorial, with both patient and surgical factors playing a role.

1.9 Scope of Thesis

This thesis is concerned with fixation in the Oxford Unicompartmental Knee Replacement, with particular emphasis on the formation of radiolucency around the components. A radiolucency has both a histological and radiographic component. It is not clear from which tissues different types of radiolucencies are composed, and what effect that composition has on the radiographic appearance. By studying a series of retrieval specimens the aim is to characterise the histological composition of the radiolucent areas, and assess whether there is an association between the composition and the radiographic appearance. Once the composition has been established further novel research should be focused towards identifying those factors, or combination of factors, that predispose to the development of radiolucency.

The majority of existing studies are retrospective, trying to establish causative factors from a cohort of patients who have received a particular intervention. An alternative approach is to develop a series of prospective studies that control known variables and investigate the development of radiolucency. Although patient factors are important it is difficult to control those variables in a single pathology cohort, such as those patients with gonarthrosis, where the disease can be so heterogenic. However, it is possible to control the surgical factors, the most important of which are mechanical: fixation, alignment and kinematics. In order to study these surgical factors it is important to control as many other variables as possible. Therefore, study of a single implant, that has cemented and cementless fixation options without change in implant design, and is commonly used, is desirable. The Oxford UKR is

ideal for a study of this kind as it has an identical surgical technique regardless of fixation method. It is then important to use the gold standard method, if possible, for measurement of the chosen variable, in this case implant migration. The most established method, and that with the highest level of acuracy, for study of implant fixation and migration is RSA. However, RSA has not been used previously with the Oxford UKR and therefore it is not known whether the current systems are accurate enough. In addition it is desirable to use non-modified implants and therefore model-based RSA should be used. A series of experiments has been designed by which the accuracy and repeatability of MB-RSA with the Oxford UKR can be assessed. Once the level of accuracy of the MB-RSA system is established it is then possible to design a study looking at the migration profile of both cemented and cementless OUKR. It has been shown that radiolucency is uncommon with cementless fixation, and very common when cement is used. Therefore, a randomised controlled trial has been set-up to look at the migration patterns of the two fixation methods. In addition, regular radiographs will be acquired to correlate the formation of a radiolucency with an individual pattern of migration.

While fixation of an implant, and subsequent radiolucency development, may be dependent on the fixation method used, there are other factors to consider. A further avenue of study regards the availability of a lateral Oxford UKR that has a different geometry, and therefore has different forces acting across the implant/cement/bone interface. Anecdotal evidence suggests that when the lateral tibial component of the OUKR was changed from flat to domed the incidence of radiolucency reduced. If this is true then it strongly suggests that alteration of the loading pattern of the cement/bone interface alters the likelihood of a radiolucency forming. Therefore, one may expect a difference in the incidence of radiolucency beneath the flat and domed tibial component in lateral OUKR. By looking at an existing series of flat OUKRs, and then by looking at a subsequent series of domed OUKRs by the same set of

surgeons, it will be possible to quantify the incidence of radiolucency in the two groups. It will also be possible to further assess the radiographs to see if there are any differences in implantation (for example, increased posterior slope or coronal alignment) and whether this accounts for any difference in radiolucency incidence. The continuation of this work involves further RSA investigation into the migration of the cemented domed tibial component. It would be assumed that the forces through the tibia would be compressive in a flat tray, and a combination of compressive and shear in a domed tray. This will give insight in to the migrational profile that protects against, or predisposes to, the formation of a radiolucent area.

In summary this thesis will:

- Establish the histological composition of radiolucency in the Oxford UKR.
- Validate the use of Model-based RSA for evaluation of the Oxford UKR.
- Characterise the migration profiles of cemented and cementless Oxford UKR in a randomised controlled trial.
- Investigate whether implant migration is associated with the formation of a radiolucency.
- Establish the prevalence of radiolucency in differing loading environments (flat *versus* domed lateral Oxford UKR).
- Characterise the migration profile of the lateral Oxford UKR and its association with radiolucency formation.

2 Histology of the Bone-Cement Interface in Retrieved Oxford Unicompartmental Knee Replacement

2.1 Introduction

While the radiological existence of radiolucency, particularly beneath the tibial component in knee arthroplasty, is well described in the orthopaedic literature there is very little on the tissue composition. It is not known whether there is bone resorption, in the manner of osteolysis as seen in the reaction to polyethylene debris, or change in the tissue secondary to either a mechanical or biological factor. It is likely that the cause is multi-factorial which means a large number of specimens are required. Unfortunately, samples are only available at revision and, therefore, in depth study of the radiolucent area with many variables standardised is difficult.

The aim of this study is to identify both the type and distribution of tissue at the cement-bone interface of a well fixed UKR. The secondary aim is to assess whether there exists a correlation between the presence of soft tissue at the cement-bone interface and the presence of radiolucent lines beneath the tibial tray.

2.2 Patient Selection

The main requirement of this investigation was for a securely fixed tibial component and the underlying cement/bone interface. Therefore, ten patients who were undergoing revision of an Oxford UKR for reasons other than component loosening were recruited. The patient demographics and reason for revision were collected

(Table 2-1). Seven patients were revised in the Nuffield Orthopaedic Centre, Oxford and three in Skovde, Sweden.

Case	Gender	Age at initial surgery	Indication	Side	Compartment	Time *in situ* (years)	Reason for Revision
1	F	52	OA	Right	Lateral	19	Medial progression
2	F	43	RA	Right	Lateral	19	Bearing dislocation
3	F	66	OA	Left	Medial	12	Lateral progression
4	F	58	OA	Left	Medial	10	Lateral progression
5	F	74	OA	Left	Medial	7	Lateral progression
6	F	73	OA	Right	Medial	7	Lateral progression
7	M	70	OA	Left	Medial	7	Loose femoral component
8	F	66	OA	Right	Medial	6	Lateral progression
9	F	67	OA	Right	Medial	2	Continuing pain
10	F	66	OA	Right	Medial	1	Bearing dislocation

Table 2-1 Patient demographics and reason for revision for the ten retrieved tibial components.

The mean age at index surgery was 62.5 years (range 43 to 70 years, SD 9.1 years). There were nine females and a single male patient. All original operations were primary Oxford UKR and the mean time *in situ* was nine years (range 1 to 19 years, SD 6.2 years), with eight implants being revised after a minimum of six years. Most patients (60%) were revised for disease progression in the contra-lateral tibiofemoral compartment with the remainder revised for bearing dislocation (20%), unexplained pain (10%) or a loose femoral component (10%).

2.3 Retrieval Technique

The tibial tray was confirmed to be securely fixed to the tibia at revision by the operating surgeon. The proximal tibia beneath the tibial component was fully exposed. Removal of the implant and bone directly beneath the tibial component was only performed If it was clinically appropriate and the bone loss would not result in unnecessary augmentation during the revision procedure. A saw cut was made through the anterior tibia below the level of the inferior margin of the keel. The saw cut was directed posteriorly beneath the tibial component, cutting the posterior and medial cortices. A vertical saw cut was made level with the vertical wall, extended inferiorly to meet the new horizontal cut. The tibial tray was then removed with the cement mantle and underlying bone *en bloc*. Care was taken to maintain the cement/bone interface and to prevent fragmentation.

2.4 Radiographic Evaluation

The pre-revision screened radiographs of the UKR *in situ* were assessed using a standardised technique (Figure 2-1A). The area beneath the tibial tray was divided into three regions, (Figure 2-1B), lateral to the keel (A), medial to the keel (B) and far medial (C). A lateral compartment specimen had the medial/lateral regions reversed. Therefore a right lateral compartment specimen was treated as if it were a left medial for consistency. Each region was deemed to have a radiolucency if greater than 50% of the region had a radiolucent zone. Using the classification of Goodfellow, a radiolucency thinner than 1 mm was deemed to be physiological, indicative of stable fixation, and if greater than 1 mm was deemed pathological, indicative of loosening[117].

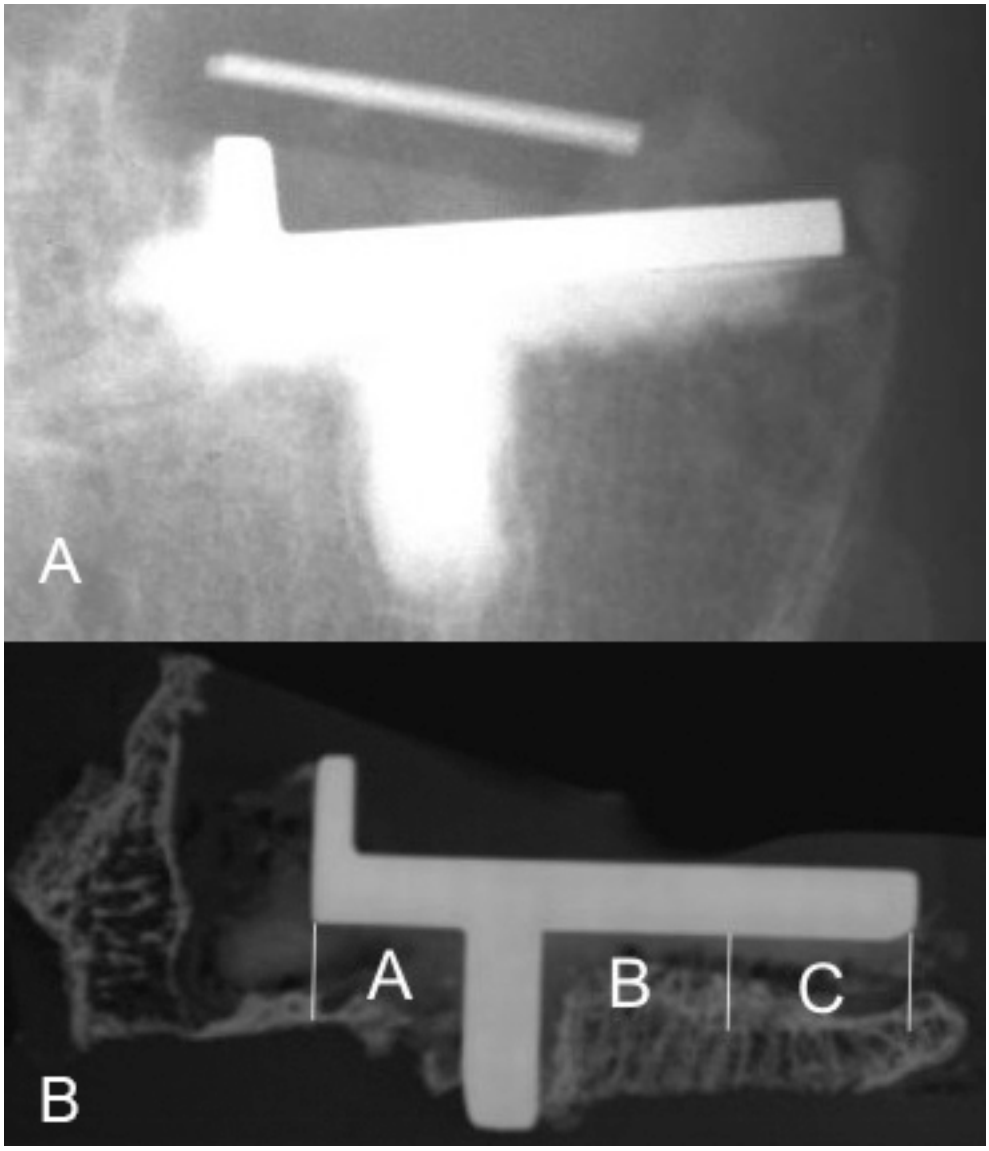

Figure 2-1A The pre-revision radiograph for a patient revised for mobile bearing dislocation. Figure 2-1B A section radiograph, of the same patient after retrieval and preparation of the tibial component, for assessment of radiolucency, with three regions: lateral to the keel (A), medial to the keel (B) and far medial (C). Medial and lateral descriptions were reversed for lateral compartment samples.

2.5 Sample preparation

The *en bloc* specimens, consisting of tibial component, bone and interface, were sent to the Royal National Orthopaedic Hospital, London for preparation and analysis by Professor Gordon Blunn. Each specimen was fixed in formaldehyde solution, dehydrated in serial dilutions of alcohol and three changes of absolute alcohol before being de-fatted in 50:50 alcohol:ether. They were then immersed in a 50:50 solution

of acrylic resin and absolute alcohol followed by concentrated acrylic resin solution. Once the specimens were embedded they were cut in the coronal plane into 5 mm slices using a water cooled 200 μm diamond band saw (EXAKT GMBH, Norderstedt, Germany).

2.6 Radiology

The Individual sections obtained for histological analysis were radiographed before staining. This then provided a series of sectioned radiographs (Figure 2.1B), the composite of which was equivalent to the pre-revision radiograph. This enabled assessment of whether a radiolucent area was evident throughout the interface, or whether a small area of radiolucency could be missed if other sections contained bone in that region and the composite radiograph therefore had the appearance of bone being present. Each section's radiograph was assessed for radiolucency using the same regional method as for the pre-revision radiographs. Each section was assessed by two observers independently and the intra-class correlation for inter-observer error was established.

2.7 Histology

Each cut section was glued to a Perspex slide using cyanoacrylate glue, polished to a depth of 150 μm and prepared for staining (Figure 2-2).

Figure 2-2 Polished section of a retrieved and sliced tibial component. The section has undergone radiography and has been prepared with a pre-stain.

The specimens were stained with Toluidine Blue and Paragon Stain (Sigma-Aldrich Ltd, Gillingham, UK). The slides were assessed histologically and the type of tissue that was most present at each 1 mm increment along the medio-lateral axis of the cement-tibial interface documented (Figure 2-3).

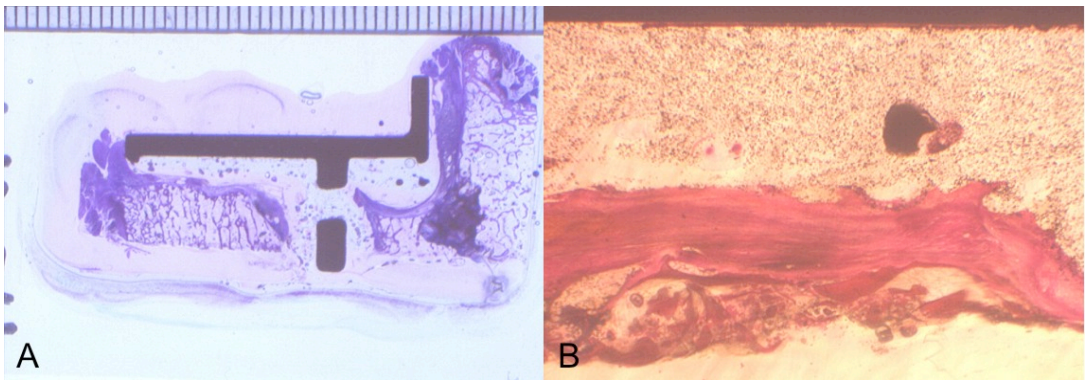

Figure 2-3A A fixed and stained section of a retrieved tibial component that has been fully prepared showing cement beneath the tibial tray and in the keel hole and the 1 mm ruler above the specimen. B) A magnified (x10) section of the same specimen from below the tibial tray showing the implant-cement-tissue interface.

The number of sections varied due to tray size (larger size = greater number of sections) and the number of 1 mm increments across a single section varied due to the varying width of the tibial tray at different points. Therefore, the total number of incremental samples was greater for larger trays. The percentage surface area of the interface for each tissue type was then calculated by dividing the total number of incremental samples containing the tissue by the total number. Tissues were classified as bone, fibrocartilage, fibrous tissue or granulation tissue based on the majority tissue type in each millimetre section. In addition to identifying the tissue type, the thickness of each soft tissue was measured for each incremental sample. The sum of all the thickness measurements was calculated for each tissue type to give the total thickness. The total thickness was then divided by the surface area of each tissue type (number of incremental samples) giving the mean thickness.

2.8 Analysis of Results: Graphical Representation

Once the samples had been fully assessed histologically, the data were analysed using a custom routine written in Matlab version 7.0 (The MathWorks Inc. Natick, USA) to map the distribution of each tissue type beneath each tibial tray and cement mantle. This generated a graphical representation of the tissue type directly in contact with the cement mantle and the distribution of the various tissue types beneath the tray.

2.9 Statistical analysis

The distribution of tissue percentages were assessed using frequency histograms and were non-normally distributed. In addition, tissue thickness was categorised and

was treated as an ordinal variable. Therefore non-parametric statistical tests were used with correlation coefficients being calculated using Spearman's rank correlation test. Reliability between two independent observers for assessment of radiolucency was tested using the intraclass correlation coefficient (ICC). All statistical analysis was performed using SPSS version 18 (IBM, New York, USA).

2.10 Results

2.10.1 Radiology

All of the patients had pre-revision radiographs available for assessment of radiolucency. Of those radiographs there were three with no radiolucent regions, four with a partial radiolucency (1 both sides of the keel, 2 medial to keel and 1 far medial) and three with a complete radiolucency in all zones. All radiolucencies were 1 mm thick or less with a well defined sclerotic margin. The distribution of radiolucency for each region on the sectioned radiographs showed variation from lateral to medial (Table 2-2). There was a radiolucent region in 22% of specimens lateral to the keel (region A), 36% medial to the keel (region B) and 48% in the far medial region (region C).

	Radiolucency (Pre-revision)			Radiolucency % (Sectioned)		
Case	Region A	Region B	Region C	Region A	Region B	Region C
1	Yes	Yes	Yes	0	25	25
2	No	No	Yes	0	25	100
3	Yes	Yes	Yes	90	90	90
4	No	Yes	No	17	83	17
5	No	No	No	0	0	0
6	No	No	No	25	0	25
7	Yes	Yes	Yes	60	80	100
8	No	Yes	No	33	55	77
9	No	No	No	17	33	50
10	Yes	Yes	No	0	50	0

Table 2-2 Presence of radiolucency in each region for the pre-revision radiographs from all retrieved tibial components. For the sectioned radiographs the figures presented are percentages which are calculated as the number of sections in which a radiolucency is present divided by the total number of sections.

The presence of radiolucency on the sectioned radiographs showed a strong inverse correlation with the percentage of bone (ρ=-0.755, p = 0.012). There was a moderate correlation with the percentage of fibrocartilage present (ρ=0.411) and a weaker correlation with the percentage of fibrous tissue (ρ=0.265), but neither correlation was statistically significant (p=0.239 and p=0.460 respectively). There was, however, a strong correlation between the percentage of soft tissue and presence of radiolucency (ρ=0.767, p = 0.010),

ICC between observers for assessment of radiolucency on the sectioned radiographs was 0.713.

2.10.2 Histology

The percentage of tibial tray surface area with cement-bone contact had a median of 52.5% (range 19% to 95%). Fibrocartilage was more common than fibrous tissue with a median of 27% (0%-49%) compared with 14% (0%-48%) for fibrous tissue. The individual distribution of different tissues beneath each tibial tray showed marked variability (Figure 2-4).

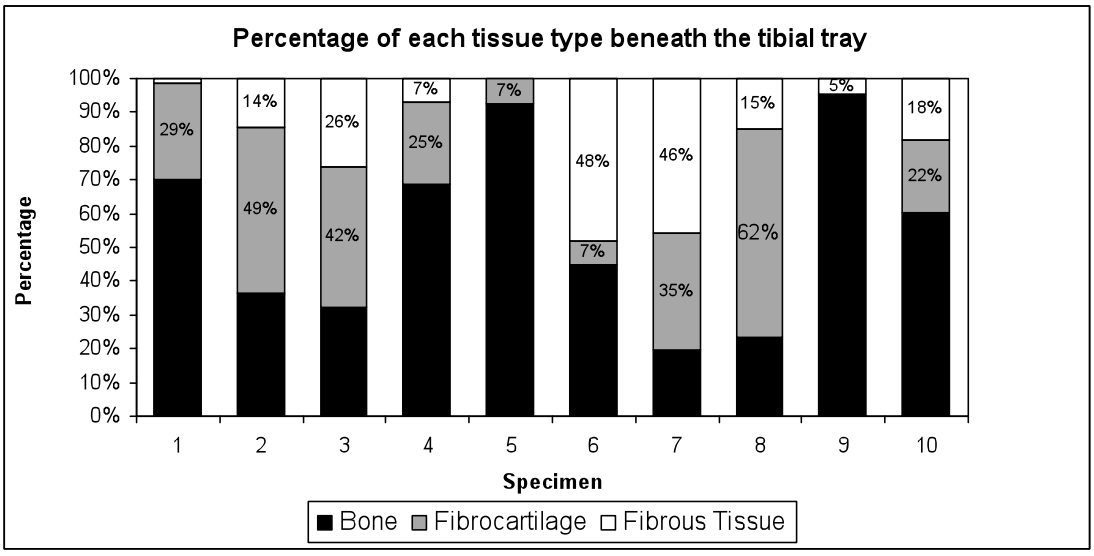

Figure 2-4 Percentage of each tissue type beneath the tibial tray for each retrieved tibial component.

Eight of the specimens had both fibrocartilage and fibrous tissue present, in differing proportions as shown, with one specimen each having only one tissue type in addition to bone. Of note, these latter two cases were those specimens that had the greatest percentage of bone beneath them. Three of 10 specimens showed evidence of bone remodelling (specimens 2, 8 and 10) and four had evidence of wear particles and macrophage activity (specimens 1, 2 ,6 and 7). As mentioned above all specimens had areas of bone/cement contact (19-95%) and there was interdigitation of cement evident in each case (Figure 2-5). The distribution of tissue

beneath each tray directly in contact with either cement or the implant did not show a consistent pattern and no single area, for example medial to the keel, showed a predisposition towards a single tissue type. Three examples are shown to demonstrate the distribution of tissue when there is a large, moderate and small amount of bone (Figure 2-6). It was also evident that individual tissue types often developed in multiple areas beneath each tibial tray, rather than in a single continuous area.

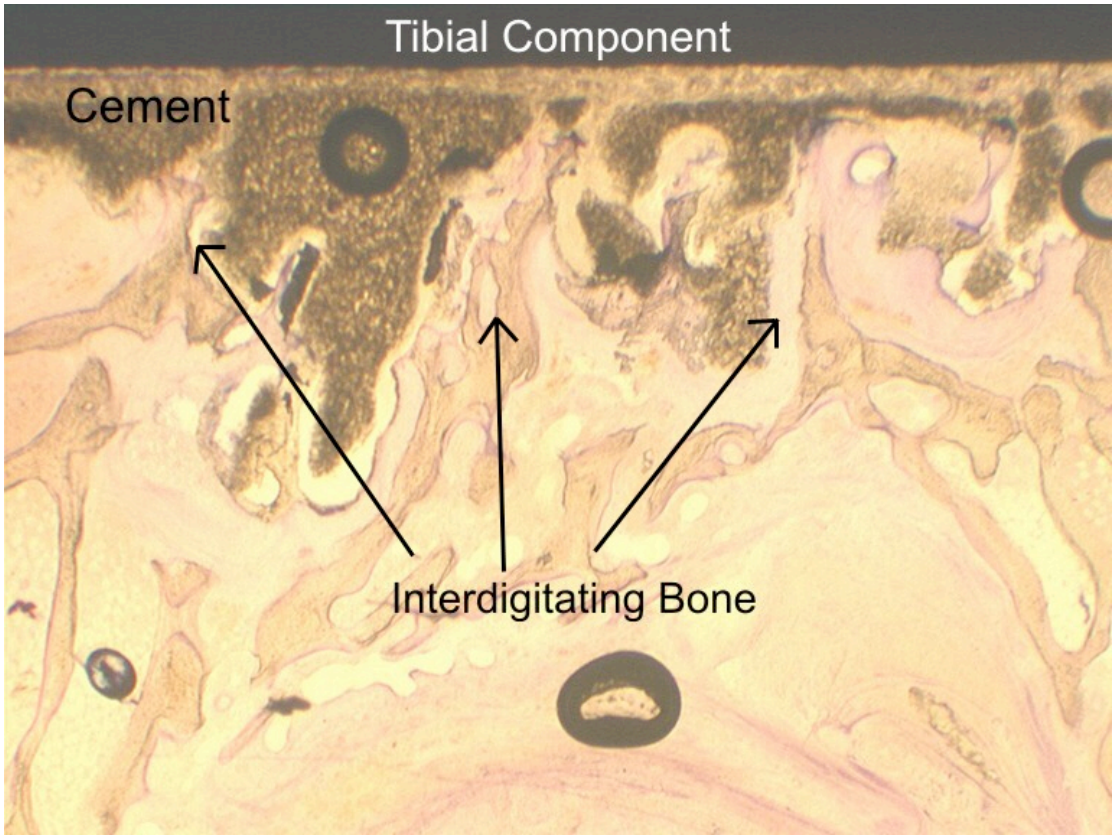

Figure 2-5 Magnified histological specimen of a sectioned and stained tibial component showing interdigitation of bone and cement at the interface below the tibial component.

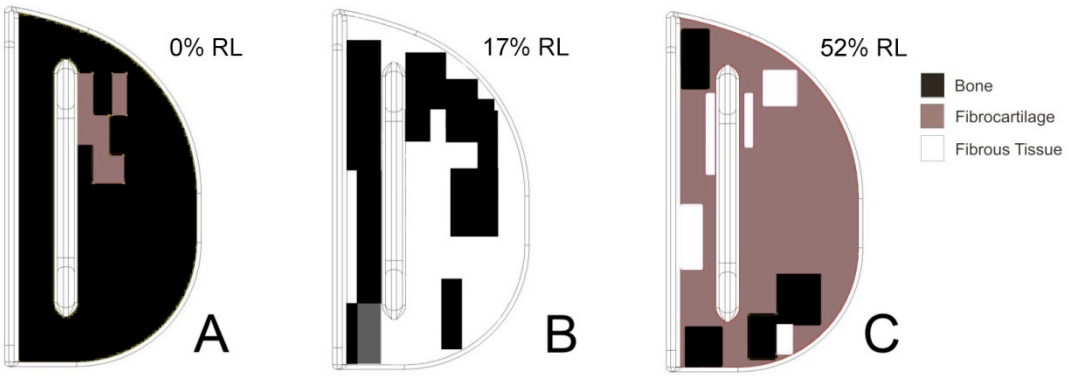

Figure 2-6 Diagrammatic representation of the distribution of each tissue type directly beneath either cement or the implant in three example trays; Case 5 (A) demonstrates almost full bony contact. Case 6 (B) demonstrates moderate bony contact and random distribution of fibrous tissue with a small amount of fibrocartilage posteriorly. Case 8 (C) shows small areas of bony contact with patches of fibrous tissue throughout predominant fibrocartilage. The amount of radiolucency present beneath each specimen is also shown.

The maximum thickness observed for soft tissue in any specimen was 3.5 mm. The mean thickness for soft tissue in all specimens was 0.73 mm (range 0.13 mm to 1.56 mm). For all specimens the percentage of bone showed a strong inverse correlation with the maximum thickness of soft tissue present between the cement and bone (ρ=-0.762, p=0.010) (Figure 2-7).

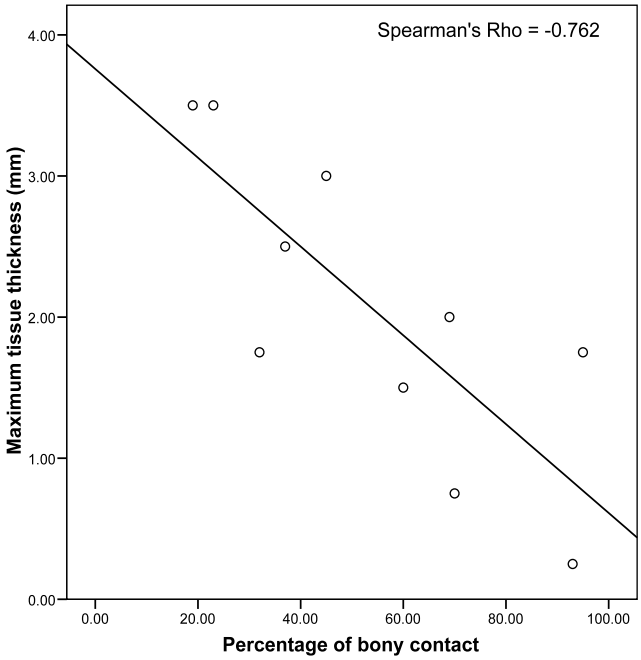

Figure 2-7 Scatterplot with line of best fit showing the negative correlation between the percentage of bone at the cement tissue interface beneath each retrieved tibial component and the maximum thickness of soft tissue present at the interface.

There was no correlation between the percentage of bone and the number of years the implant was *in situ* (ρ=0.265, p=0.460).

2.11 Summary of Results

- The radiolucent lines were all less than 1 mm, therefore they were deemed to be physiological, indicating implant stability, which was subsequently confirmed at revision.
- The amount of radiolucency at the interface is inversely related to the presence of bone and directly related to the presence of soft tissue. This adds to the evidence that radiolucencies are a manifestation of soft tissue at the interface.
- This study has shown for the first time that a radiolucency is not a manifestation of a complete layer of soft tissue but of a mixture of bone and

soft tissue. A possible reason that a radiolucency often appears so lucent, despite containing bone, is that it lies between the implant and a radiodense line which occurs at the margin of the soft tissue.

- The histological appearance of the interface with a radiolucent line is the same regardless of time *in situ* suggesting that the interface remains stable, with development within the first post-operative year. In areas where there is a contact between cement and bone, there is evidence of interdigitation of cement into the bone, and this probably occurred at the time of operation. It is, therefore, likely that the soft tissue appears at the interface because the bone is resorbed and replaced. The bone resorption probably occurs because it is damaged by both surgical trauma and the heat of polymerisation of the cement.
- Whether the resorbed bone is replaced by new bone, fibrocartilage or fibrous tissue will depend on a number of factors. The most important factor is likely to be the mechanical loading, in particular the amount, the type and how soon it is applied in the postoperative period[143,144]. Under the tibial plateau with the Oxford knee, the loading is primarily compressive because of the mobile bearing and this is likely to generate fibrocartilage. This theory is based on the study of canine models that have shown soft tissue at the interface is organised to withstand compressive loads[147].
- Polyethylene debris is known to stimulate bone resorption[148], and was seen in some cases in the interfacial tissue. However, the only cases in which it was seen were those that had been implanted for at least seven years. As RLLs form in the first year they cannot be caused by the polyethylene debris. In view of the fact that the RLLs remain stable for many years the low levels of polyethylene debris associated with the Oxford knee does not seem to affect them in the long-term.

- In conclusion, this study demonstrates that whether there is no radiolucency or a partial or complete radiolucency beneath the Oxford UKR tibial component there is likely some direct contact between cement and bone. In the areas where there is direct contact the cement interdigitation with the bone suggests that the interface is stable and not loose.

2.12 Discussion

The histological composition of RLLs beneath well fixed tibial components in Oxford UKR has previously been unknown. While the presence of thin, non-progressive RLLs beneath the tibial component are well recognised, their significance with regard fixation is poorly understood. The amount of radiolucency at the interface is inversely related to the presence of bone and directly related to the presence of soft tissue. This confirms that RLL are a manifestation of soft tissue at the interface. This study has, however, shown for the first time that a RLL is not a manifestation of a complete layer of soft tissue but of a mixture of bone and soft tissue. The reason a RLL often appears so lucent, despite containing bone, is that it lies between the implant and a radiodense line that occurs at the margin of the soft tissue.

The observation that there is bone within the radiolucency is important because it explains a number of clinical observations. Inexperienced surgeons may consider a tibial component with a RLL to be loose and, if there is associated pain, may revise it. At operation they find it to be secure. The reason it is secure is that there is bone at the interface, and as shown in this study there is interdigitation of cement within the bone (Figure 2-6). RLL have been shown in the acetabulum to predict long term loosening[138] yet around the Oxford UKR this does not seem to be the case. In addition, the observation that the histological appearance of the interface with a

radiolucent line is the same regardless of time *in situ* suggests that the interface remains stable.

It is unclear why RLLs appear. In areas where there is a contact between cement and bone there is evidence of interdigitation of cement into the bone, and this probably occurred at the time of operation. However, it has been recently suggested that resorption of the interdigitating trabeculae could be driven by alteration of the load across an interface as suggested by a μCT study of the cement/bone interface in TKR[149]. It is, therefore, likely that the soft tissue appears at the interface because the bone is resorbed and replaced. The bone resorption may occur because it is damaged by both surgical trauma and the heat of polymerisation of cement, although implant micromotion has been suggested as the cause of the sclerotic line often seen beneath[142]. Whether the resorbed bone is replaced by new bone, fibrocartilage or fibrous tissue will depend on a number of factors. The most important factor is likely to be the mechanical loading, in particular the amount, the type and how soon it is applied in the postoperative period. With the Oxford knee the loading under the tibial plateau is primarily compressive because of the mobile bearing and this is likely to generate fibrocartilage. This theory is based on the study of canine models that have shown soft tissue at the interface is organised to withstand compressive loads[147].

Polyethylene debris is known to stimulate bone resorption[148], and was seen in some cases in the interfacial tissue. However the only cases in which it was seen were those that had been implanted for at least seven years. As RLL form in the first year they cannot be caused by the polyethylene debris. In view of the fact that the RLL remain stable for many years the low levels of polyethylene debris associated with the Oxford knee over the long term[150,151] does not seem to cause progression of the radiolucent zones.

In conclusion, this study demonstrates that whether there is no radiolucency or a partial or complete radiolucency beneath the Oxford UKR tibial component there is always some direct contact between cement and bone. In the areas where there is direct contact the cement interdigitation with the bone demonstrates that the interface is stable and not loose.

In order to improve fixation in knee arthroplasty, and thus improve implant survival, further study should be directed towards identifying those factors that predispose to the formation of different tissue types. It is not known what determines the type of tissue formed at the interface. It may be that the migration of the tibial component has an effect on the type of tissue formed. For example, an implant that has very good initial stability may proceed to have a high percentage of bone at the interface, whereas an implant that takes time to stabilise may develop a greater percentage of soft tissue at the interface. Therefore, it would be useful to measure the effect of movement on the formation of radiolucency. The most accurate method available is radiostereometric analysis (RSA). Model-based RSA provides an effective system to measure migration in knee replacement. However, this model-based method has not been validated for use in OUKR. Therefore, a RSA system needs to be validated to ensure it is capable of detecting small migrations that may lead to radiolucent lines.

3 Validation of Model-based RSA with Unicompartmental Knee Replacement

3.1 Introduction

RSA in joint arthroplasty has been developed over the last four decades and steady advances in accuracy and usability have been made. The use of digital radiographs and increases in computing power have led to a dramatic reduction in the time required to analyse each set of stereoradiographs. However, it is important when designing a study to have a sound knowledge of the accuracy and reliability of a system as applied to the implant under investigation. It is perhaps not unreasonable to accept the accuracy stated by the producers of each RSA system, but that may lead to problems. The two main issues are: firstly, that the stated accuracy may only be applicable to the implant used in the accuracy tests, and secondly, that the migration of the new implant being studied may be less than the resolution limit of the system. A potential further issue relates to the set-up of radiograph acquisition, including the manufacture and set-up of the calibration object as well as the radiographic equipment for image capture and processing. The first issue, implant-dependent accuracy, may be underestimated. Many knee arthroplasty implants are based on a similar design, with only small differences in contour and peg or keel design. However, it is not clearly understood how these subtle differences may affect accuracy in RSA. When considering an RSA study of the Oxford UKR it is especially important to establish the correct accuracy and repeatability. Unicompartmental implants are considerably smaller than total knee implants, thus a small error in, say, pose estimation, may be proportionally bigger. In addition, the femoral component has a large articular surface that is part of a sphere and therefore

pose-estimation in particular may be sensitive to error.

This study investigates both the tibial and femoral components of the Oxford UKR in a model-based RSA system, to establish the accuracy and repeatability. Guidelines for assessing and reporting accuracy and repeatability have been published by a consensus group of RSA experts and have been followed in this work[107]. The two most important aspects of validation are accuracy, the ability to detect a true difference, and precision (sometimes termed repeatability), the ability to return the same result when repeat analysis is performed.

3.2 Model-based RSA

The RSA system used in Oxford for knee arthroplasty is that developed by Medis Specials in Leiden (Model-based RSA, version 3.21) by Bart Kaptein and Edward Valstar[152]. While traditionally software designed for RSA was immensely powerful it often lacked a user-friendly interface and its usability was often limited because of this. The Medis Specials software runs on a Windows PC and is designed for ease of usability as well as maintaining the high levels of engineering rigour expected in an RSA system. The main difference between the current software compared with traditional RSA software is the model-based nature. The original RSA technique relied on specially adapted implants that had additional marker balls fixed to them. The disadvantages of the system were the reliance on markers to estimate implant position, and hence the need for radiographs that showed the markers clearly, and that the measured migration was that of a modified, albeit only slightly, implant. Logistically there was also the problem of only being able to include a patient in a study if the modified implants were available. It is extremely expensive to have an entire range of sizes available of modified implants. The software has been validated

for the Model-based RSA using standard implants that are not modified and do not have markers attached. Computer aided design (CAD) models are instead used to pose estimate the position of the implant in the three dimensional space. The CAD models use the implant manufacturer's reference files for production of the implant. Therefore the CAD model has dimensions that are usually in the middle of the range of tolerance during the manufacturing process. An initial concern over the use of model-based RSA was related to the accuracy of the models compared to the implanted components. Reverse engineered (RE) models can be produced using laser scanned data from actual implants. Work by Kaptein et al has shown that although the RE models result in a slightly improved pose estimation compared to the generic CAD models the difference is unlikely to be of clinical significance[152]. As it is both time-consuming and costly, with sterilisation having to occur after scanning, to scan each component before implantation the CAD model-based system has become accepted. The model-based software has been validated with the Interax total knee prosthesis (Stryker Howmedica Osteonics Corp., Rutherfort, USA) and the femoral component of Profix total knee prosthesis (Smith & Nephew, Memphis, USA). It has not previously been validated for any unicompartmental prosthesis.

The Oxford UKR has both advantages and disadvantages for use in a model-based RSA system. The main advantage is that both components have a small manufacturing tolerance and therefore the CAD models provide an accurate representation of each implanted component. In addition, the tibial component has a series of straight edges that provide reliable reference points for pose estimation. In contrast, the femoral component has a large proportion of its contour consisting of a portion of a sphere. This potentially decreases the accuracy of pose estimation. Valstar has shown that hand polishing of an implant, and thus small variations in surface finish, can have an affect on pose estimation and subsequent accuracy[153]. A disadvantage of both components relates to their small size. Accurate pose

estimation relies on accurate edge detection of the actual contour on each radiograph. A small component takes up a smaller number of pixels, thus decreasing the accuracy of edge detection. The pose estimation algorithms used in the Model-based system have been validated[154].

3.3 Validation of *in-vitro* Precision

The initial test of RSA software is the inherent "system" error, i.e. that error that occurs due to the way the system calculates the various aspects of each analysis. The accepted method as described by Valstar *et al* is the double exposure method[107]. Previous validation experiments have assessed precision with repeat small translations[155] or multiple repeat stereoradiographs of the same set up with no translation applied. In view of the recommendations of the consensus group and that a repeat *in-vivo* experiment can only use the double exposure method, this was the method chosen for this experiment.

A phantom was constructed using a SawBones model of the knee joint (Medium left knee no. 1107, Sawbones Europe AB, Malmo, Sweden) with an Oxford UKR inserted in the routine surgical manner using standard instrumentation[117] (Figure 3-1).

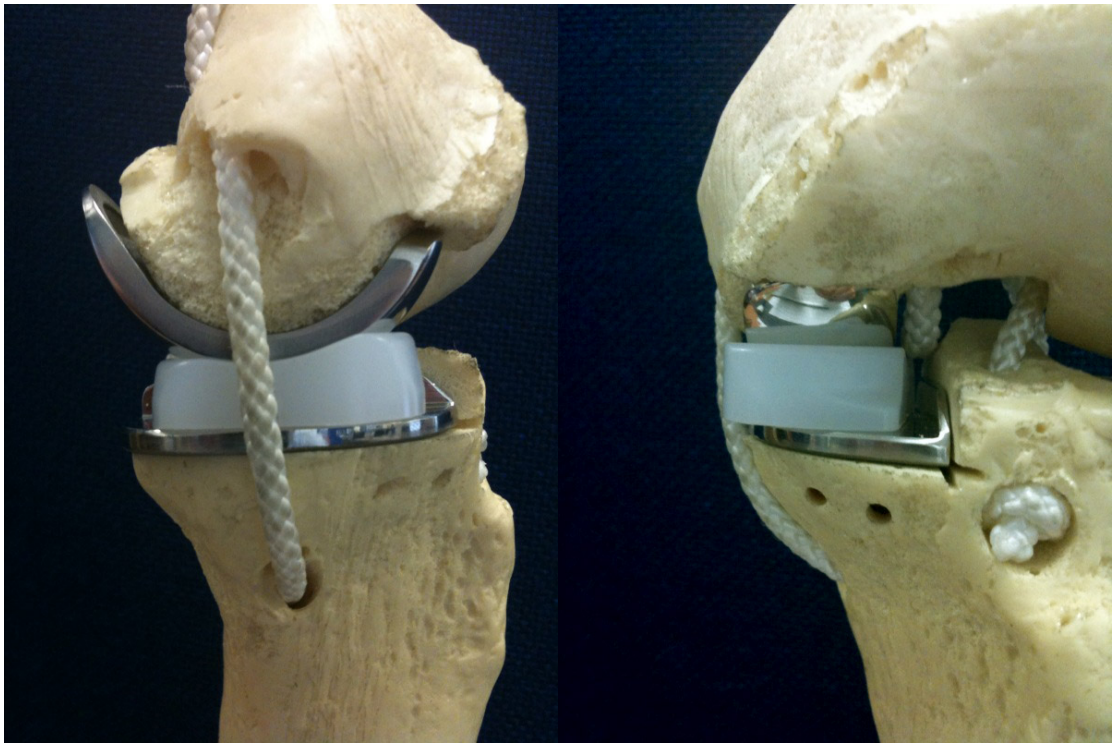

Figure 3-1 A phantom with a standard medial Oxford UKR, small femoral component and size A tibial component, implanted into a Sawbones model.

Tantalum markers were introduced into the phantom, after pre-drilling, to give a condition number of 15 for the femoral component and 40 for the tibial component. The small size of proximal tibia was the limiting factor for marker distribution, and hence a lower condition number could not be achieved (Figure 3-2).

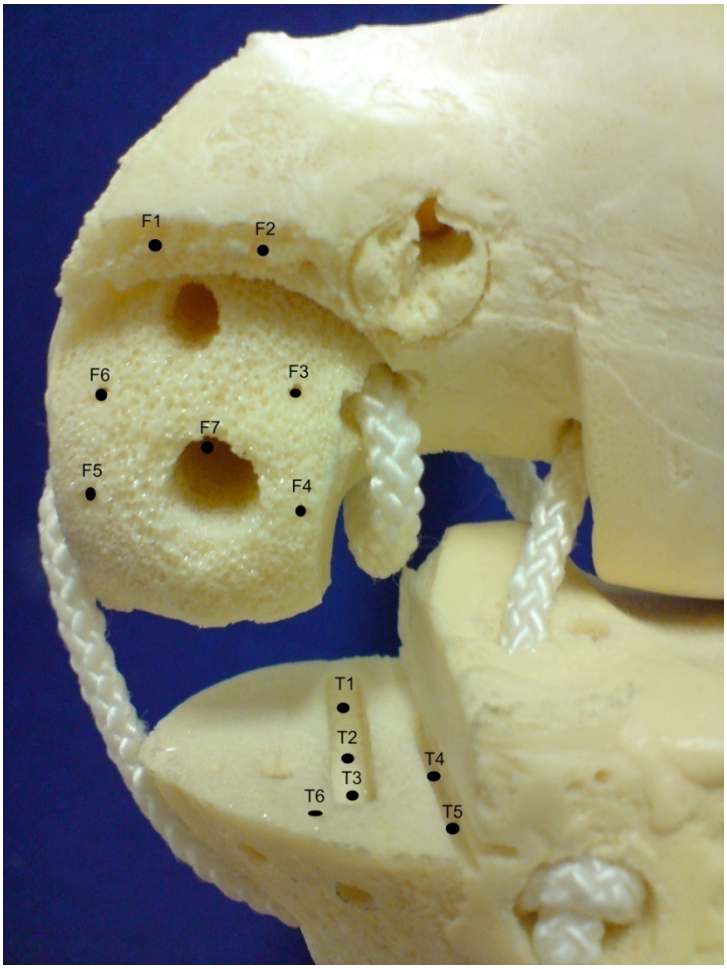

Figure 3-2 A phantom that has been prepared for implantation of a medial Oxford UKR. The placement positions for each of the 0.8 mm tantalum marker balls are shown. Advantage is taken of the peg hole in the femur and the keel slot in the tibia to gain depth of marker ball implantation.

The phantom was placed in the calibration object in the normal anatomical position as though standing in a normal weight-bearing position. A medium femoral component and a size C tibial component were used as they are in the middle of the available range for clinical use. Each phantom underwent eight double exposures after removal from the set-up and then return, to simulate clinical use with repeat attendances at follow up. The radiographs were taken using two Roentgen tubes (Siemens AX, Siemens UK, Camberley, UK and GE AMX 4, GE Healthcare, Little Chalfont, UK) set 1.5 m from the Computerised Radiography (CR) plates (Kodak DirectView 975 cassettes, 35 x 43 cm, Eastman Kodak Company, Rochester, New York, USA) and angled at 60°, perpendicular to the CR plates. Exposure parameters

were set at 76 kV and 16 mAs. CR plates were read on a Kodak DirectView CR975 (Kodak Ltd, Hemel Hempstead, UK) and the digital images produced in 12-bit grayscale DICOM format with a resolution of 2048 x 2500 pixels.

The images were analysed using both CAD models provided by the implant manufacturer and reverse engineered models provided by scanning the implants used (3D Scantech, Coventry, UK). Pose estimation error is the mean error between the actual component edge on the radiograph and the virtual edge of the superimposed component edge from the model. Rigid body error (RBE) is the mean distance between the position of a marker on the initial image and its position on a subsequent image. A large RBE indicates that either the markers are moving within the bone, or the image acquisition was sub-optimal with movement artifact. Migration was calculated for each of the three cardinal axes (*x, y, z*) and rotations around each of those axes (R*x*, R*y*, R*z*). All values for pose estimation error, rigid body error and translational migration are given in millimetres. Rotational migrations are given in degrees.

In addition, the images were analysed by two observers, independently, to assess the interobserver reliability using intra-class correlation.

3.4 Results

All stereoradiographs were acceptable for analysis. Model-based RSA software version 3.21 was used throughout.

3.4.1 Pose Estimation

The CAD models had a mean error for femoral and tibial components of 0.21 mm (SD 0.006 mm) and 0.14 mm (SD 0.011 mm) respectively. In contrast, the reverse engineered models had improved pose estimation errors of 0.19 mm (SD 0.02 mm) and 0.17 mm (SD 0.019 mm) for the femoral and tibial components respectively.

3.4.2 Rigid Body Error

The rigid body error (RBE) for the femoral component was 0.015 mm (sd 0.008 mm) when using both the CAD and RE models. For the tibial component the RBE for both CAD and RE models was 0.018 mm (sd 0.012 mm). As the estimation of rigid body error is independent of the models used it is reassuring that the values are consistent between the two groups.

3.4.3 Migration

There was little difference between the results for the CAD models and those that were reverse engineered (Table 3.1).

	X	***Y***	***Z***	**R*x***	**Ry**	**R*z***
CAD	0.04 (0.12)	0.00 (0.01)	0.03 (0.06)	-0.13 (0.14)	0.02 (0.16)	0.33 (1.09)
RE	-0.01 (0.03)	-0.02 (0.04)	0.01 (0.02)	-0.03 (0.08)	-0.02 (0.09)	0.04 (0.49)

Table 3-1 Mean translations in mm and rotations in degrees (standard deviation) between the two exposures for the femoral component for each of the three axes for the CAD and Reverse Engineered models.

The full results for each double exposure for the tibial component are presented in Appendix 3.1. In contrast to the femoral component the tibial component had the lowest level of precision in R*x* and opposed to Rz, but the overall level of precision was very high (Table 3.2).

	X	***Y***	***Z***	**R*x***	**R*y***	**R*z***
CAD	0.00 (0.02)	0.00 (0.02)	0.01 (0.04)	-0.01 (0.04)	0.10 (0.23)	-0.08 (0.14)
RE	0.00 (0.03)	0.00 (0.02)	0.00 (0.02)	0.05 (0.10)	0.16 (0.29)	-0.03 (0.10)

Table 3-2 Mean translations in mm and rotations in degrees (standard deviation) between the two exposures for the tibial component for each of the three axes for the CAD and Reverse Engineered models.

3.5 Measurement of Effect of Placement within the Calibration Frame

The method described above to test the precision of the system is an ideal situation,

with control over rigid body marker placement and the phantom centralised in the calibration frame. However, when a patient attends for repeat stereoradiographs they do not stand in exactly the same position as their previous attendance. This is particularly pronounced in obese patients where centralisation of a small implant within a large soft tissue envelope can be difficult. Therefore, it was necessary to assess whether moving a component to different positions within the calibration frame has an effect on the precision of the system.

3.5.1 Materials and Methods

The phantom was placed in an initial position in the calibration frame and baseline stereoradiographs acquired. Four subsequent sets of stereoradiographs were obtained with the phantom moved in such a way that its outline was on the periphery of the images. Each repeat set of stereoradiographs was treated as a double exposure to the initial stereoradiograph with the phantom centred.

3.5.2 Results

The precision was very high for each translation, with the lowest precision for the out-of-plane *z*-axis. The rotations were slightly less precise with the lowest precision for rotation around the out-of-plane *z*-axis (Table 3-3).

X	***Y***	***Z***	**R*x***	**R*y***	**R*z***
0.02	0.09	-0.13	0.22	0.22	0.85
(0.23)	(0.12)	(0.13)	(0.12)	(0.26)	(0.74)

Table 3-3 Mean results for translations in mm and rotations in degrees (standard deviation) for the three axes for gross movements of the entire phantom within the calibration frame.

3.6 Validation of Accuracy

Previous studies have shown that stable components in knee arthroplasty migrate between 0 and 2.0 mm over two years, with the majority migrating less than 0.5 mm[66,100,112,115]. The amount of migration depends on the method of fixation as well as surgical and patient factors. There is no amount of migration that has been identified as the minimum clinically significant amount. However, it is desirable to be able to detect migrations as small as 0.1 mm as the studies mentioned above often report translations as low as 200 μm at the first follow up radiograph that is commonly only three months post-operatively. It is also important to be able to measure small migrations as Ryd stated in his thesis that translations of 200 μm in the second post-operative year can be indicative of loosening[99]. The amount of rotation that would be clinically significant, and therefore the level one would wish to detect, is less easily identified. This is in part due to the forces applied through different designs of prosthesis, with some fixed bearing, highly congruent designs having large amounts of shear, and the mobile fully congruent bearing of the OUKR having little shear, with the forces applied to the tibial tray being almost completely compression. Each particular design is therefore going to produce rotation in a different axis, depending on the vector of force through the tibial component and the fixation design. Therefore, it is desirable to be able to detect a small amount of rotation in the most likely direction of migration, but also to detect larger rotations that may be associated with failure.

3.6.1 Materials and Method

A custom-made phantom was manufactured to contain a series of rigid body markers, a translation stage and the ability to rigidly fix a changeable component

(femoral or tibial). A rigid perspex block was drilled with a 0.8 mm drill bit and a single 0.8 mm tantalum marker ball placed in the bottom of each drilled column. These marker balls (n=8) provided the rigid body reference markers. It is recognised that the condition number can affect the analysis of implant movement and hence should be minimised, with an upper limit of 150 being acceptable[107]. For this experiment the condition number was minimised by designing a rigid body with a wide distribution of markers in a non-co-linear fashion. Hence, the condition number for all the following experiments was 9.6. The translation stage (7T38XYZ, Standa Ltd, Vilnius, Lithuania) was rigidly fixed to the perspex block to provide the gold standard measurement of component translation with an accuracy of 0.005 mm. Rigidly connected to the translation stage was a perspex stage upon which the component could be fixed. Therefore, as the perspex stage was moved using the translation stage all component movement was relative to the fixed rigid body markers. The entire construct was designed to fit within the calibration frame in the standard RSA setup in use at the Nuffield Orthopaedic Centre (Figure 3.3).

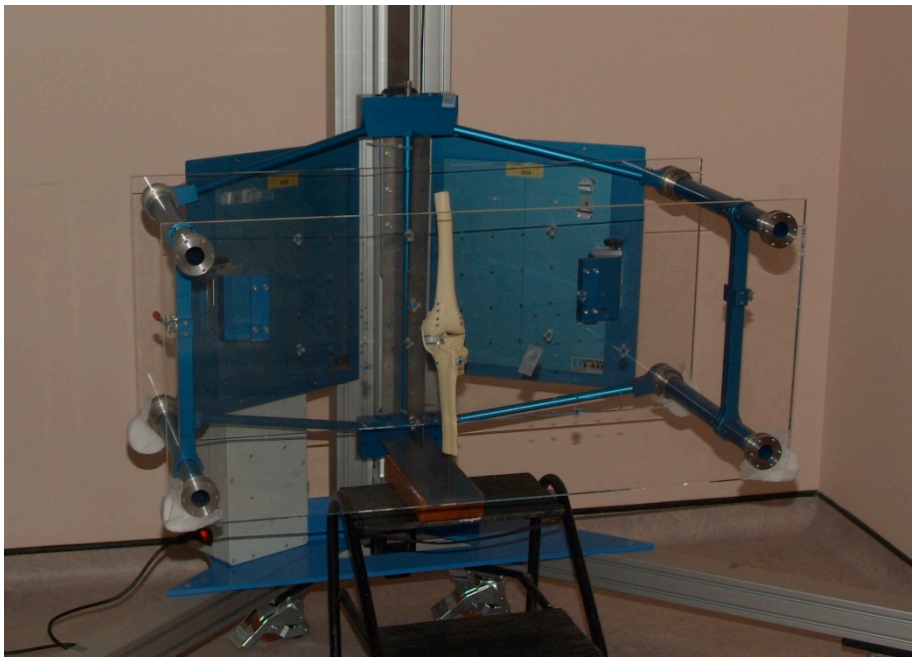

Figure 3-3 The standard calibration frame used for all RSA studies at the Nuffield Orthopaedic Centre. The patient, or in this case phantom, stands within the calibration frame. The radiographic cassettes are held securely in an upright position behind the calibration frame.

All radiographs were obtained in an identical manner as the previous experiment.

3.6.2 Translation Distances

Both the femoral and tibial components were studied individually. Each component underwent five consecutive translations of 0.1 mm (micro distance) and was then translated a further five times a distance of 1.0 mm (macro distance) resulting in a total translation of 5.5 mm in each of the three axes (total 30 translations).

3.6.3 Rotational Distances

As with for the translations each component was studied individually. Each component was attached to the same rig and an initial set of stereoradiographs acquired. A series of rotations was then applied in sequence; 0.2° three times, then 0.5° three times, and finally 1.0° three times. Thus, each component was rotated through a total of 5.1° during nine rotations. The femoral component was tested for rotation around the *x*- and *y*-axes and not the *z*-axis. The tight fixation of the peg and the *z*-axis being perpendicular to the arc of movement of the knee means that rotation around that plane is very unlikely to occur, and failure in that direction is not seen clinically. The tibial component was tested in the *x*- and *z*-axes as the long keel and vertical wall would prevent rotation around the *y*-axis.

3.6.4 Results

The pose estimation error for the femoral component was 0.22 mm (SD 0.006 mm)

and for the tibial component was 0.18 mm (SD 0.004 mm). These results are not significantly different from the previous experiment and indicate that the images obtained are suitable for use in an accuracy experiment. All images acquired were used and all eight rigid body markers were identified in each image, thus the lowest condition number available of 9.6 was used in each analysis.

3.6.4.1 Femoral Migration

Accuracy for measuring translation of the femoral component was overall very high, with the out-of-plane z-axis showing the lowest, but still acceptable, level of accuracy (Table 3.4).

	X	***Y***	***Z***
Micro (0.1 mm)	-0.05 (0.04)	-0.02 (0.02)	-0.12 (0.11)
Macro (1.0 mm)	0.04 (0.09)	0.02 (0.02)	-0.20 (0.19)

Table 3-4 Mean difference, in mm (standard deviation), between the actual translation (micromotion stage) and the measured translation (RSA) of the femoral component for each of the three cardinal axes. The results for the micro and macro movements are shown.

It is likely that the small difference in accuracy in the *z*-axis between migration magnitude is not significant. These results are perhaps better represented by a boxplot of the overall translation (micro and macro combined) where it can be appreciated that the in-plane *y*-axis has the highest accuracy and the mid out-of-plane *x*-axis has a level of accuracy between that of the other axes. (Figure 3-4) It

can also be appreciated that the *x* and *y* axes have accuracy centred on zero, whereas the *z*-axis error is biased towards a posterior translation.

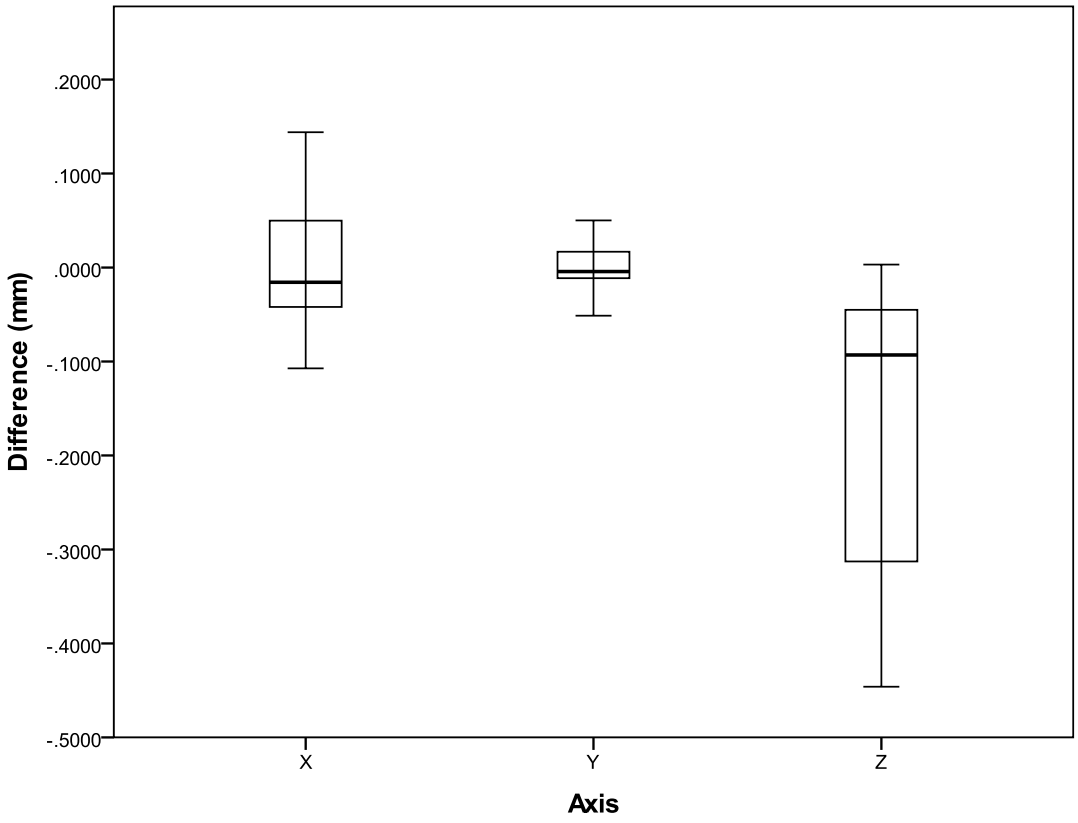

Figure 3-4 Boxplot (median, interquartile range and range) showing the difference between the actual translation and the measured translation of the femoral component accuracy for each axis.

3.6.4.2 Tibial migration

Analysis of translation of the tibial component was also consistent, but differed from the femoral component results as the out-of-plane z-axis had an improved level of accuracy for micro movements, but a similar level for the macro movements. In similarity with the femoral component, the results for the x- and y-axes were centred around close to zero, but there was a bias towards forward migration in the z-axis.

	X	***Y***	***Z***
Micro (0.1 mm)	-0.05 (0.01)	0.02 (0.01)	0.00 (0.03)
Macro (1.0 mm)	0.04 (0.05)	0.04 (0.01)	-0.14 (0.22)

Table 3-5 Mean difference, in mm (standard deviation), between the actual translation (micromotion stage) and the measured translation (RSA) of the tibial component for each of the three cardinal axes. The results for the micro and macro movements are shown.

The boxplot of combined accuracy for the tibial component highlights two points.

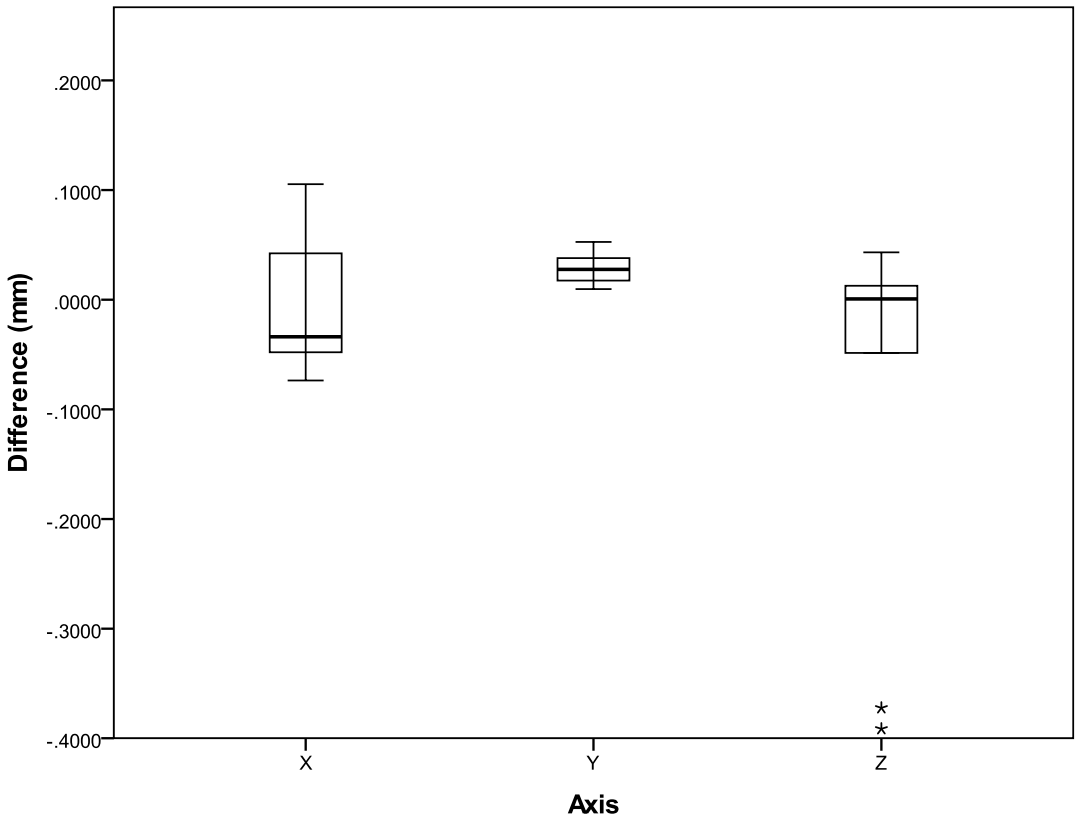

Figure 3-5 Boxplot (median, interquartile range and range) showing the difference between the actual translation and the measured translation of the tibial component accuracy for each axis.

Firstly, as expected, the *y*-axis has the highest accuracy, followed by the *x*-axis and then the *z*-axis, with the accuracy close to the zero line. The second point, in contrast to the results for the femoral component, is that the level of accuracy for the *z*-axis is potentially very high, with the overall accuracy reduced due to two extreme outliers (values greater than three times the inter-quartile range from the median). This also explains the difference in z-axis accuracy between migration magnitudes as both outliers occurred in the 1.0 mm group. In reality it is likely that the level of accuracy independent of migration size.

3.6.4.3 Femoral Rotation

Accuracy for the femoral component was good overall but showed some variation. Rotation around the *x*-axis was slightly less accurate than for the *y*-axis and there was no single amount of rotation for which the accuracy was highest between the two axes (Table 3-6).

	0.2°	0.5°	1.0°
R*x*	0.357 (0.126)	1.209 (0.469)	0.072 (0.224)
R*y*	0.151 (0.183)	0.095 (0.111)	0.541 (0.099)

Table 3-6 Mean difference, in degrees (standard deviation), between the measured and actual rotation for the different magnitudes of rotation for the femoral component rotation accuracy (degrees).

3.6.4.4 Tibial Rotation

Accuracy for tibial rotation was very good for small increments (0.2°), and moderate for medium and large increments (0.5° and 1.0°). The results for the rotations around the *x*-axis were considerably better than for rotations around the *z*-axis (Table 3-7).

	0.2°	0.5°	1.0°
R*x*	-0.003 (0.035)	-0.423 (0.335)	-0.355 (0.492)
R*z*	-0.117 (0.013)	-0.296 (0.912)	-2.060 (0.987)

Table 3-7 Mean difference, in degrees (standard deviation), between the measured and actual rotation for the different magnitudes of rotation for the tibial component rotation accuracy (degrees).

3.7 Validation of *in-vivo* Precision

The gold standard method to measure in-vivo precision, as described by the expert consensus group, is to perform double exposures of patients with knee replacements implanted [107]. The main difference between in-vitro and in-vivo measurement is the addition of the soft tissue envelope surrounding the knee replacement. Obviously this is more marked in obese patients. Normally knee radiographs are acquired to demonstrate the bony anatomy, but also to allow assessment of the soft tissues to be made. When RSA radiographs are acquired it is routine to use a higher dose of radiation to reduce the soft tissue shadow and highlight both the metal implants and the tantalum markers. However, it is not acceptable to give patients doses that are so high as to completely eliminate the soft tissue shadow. Therefore, there is always a degree of image degradation, particularly around the small rigid body markers.

3.7.1 Patients and Methods

Five patients who had undergone surgery to implant a standard Oxford UKR and had RSA marker balls inserted underwent routine stereoradiographs and then a second set to provide a double exposure. All patients had arthroplasty surgery for

osteoarthritis. The patients stood in the calibration frame in a normal double leg weight-bearing stance. Images were acquired as previously described and all images were analysed in the standard DICOM format.

3.7.2 Results

The mean condition number for the femoral components was 53. There was consistency across all migrations, with a high level of precision for the translations but less precision for the rotations, particularly in R*x* (Table 3-8).

	x	***y***	***z***	**R*x***	**R*y***	**R*z***	**MTPM**
Mean	0.01	-0.04	0.06	0.17	-0.02	-0.04	0.27
SD	0.11	0.08	0.10	0.26	0.42	0.48	0.07

Table 3-8 Mean migration between double exposures for the femoral component, in mm for translations and degrees for rotations, with standard deviation.

The mean condition number for the tibial components was 32. In contrast to the femoral component there was a higher level of precision for the rotations than the translations, but all were highly precise (Table 3-9).

	x	***y***	***z***	**R*x***	**R*y***	**R*z***	**MTPM**
Mean	-0.01	0.01	-0.07	0.00	-0.01	0.00	0.20
SD	0.10	0.07	0.15	0.06	0.06	0.06	0.09

Table 3-9 Mean migration between double exposures for the tibial component, in mm for translations and degrees for rotations, with standard deviation.

3.8 Summary of Results

- Reverse engineered Models provide slightly improved precision compared with CAD models, but the CAD models provide an acceptable level of accuracy.
- Non-centralisation of the object within the calibration frame results in a reduction in precision, with the *z*-axis being most affected, however, the reduction is small.
- Micro migrations of 0.1 mm are accurately measured for both the femoral and tibial components.
- Macro movements of 1.0 mm are accurately, albeit less so than for smaller movements, measured for both femoral and tibial components.
- Accuracy is lowest in the out of plane *z*-axis and highest in the cranial-caudal *y*-axis.
- Accuracy of rotation is best in the x-axis, with poorer accuracy in the out-of-plane *z*-axis for the tibial component.
- In-vivo double exposures demonstrate that a high level of accuracy is achieved and the model-based RSA system is suitable for assessment of UKR.
- Overall accuracy can be summarised, using the standard deviation of migration differences, as:

Femur					Tibia				
X	*Y*	*Z*	R*x*	R*y*	*X*	*Y*	*Z*	R*x*	R*z*
0.08	0.03	0.15	0.58	0.32	0.06	0.01	0.16	0.36	0.78

3.9 Discussion

Validation of any measuring system is important in order to understand the results produced and to establish whether they are accurate enough to be of use. When a system claims very high levels of accuracy, that validation is even more important, as a small change in accuracy can produce a different result of significant magnitude. RSA has established a position as the gold standard for measuring orthopaedic implant migration. However, the high levels of accuracy reported are often based on marker-based systems. Model-based systems are easier to use, enable the evaluation of non-modified implants and are thus cheaper. Several of the studies mentioned previously have demonstrated that model-based RSA can be accurate enough for evaluation of orthopaedic implants clinically. However, the Oxford UKR, using significantly smaller implants than with TKR and being inserted through a minimally invasive approach providing reduced access to the bony surfaces, provides an individual challenge to RSA. There is nothing in the English literature validating the use of model-based RSA in UKR and therefore, this work provides the first evaluation.

The initial experiment for in-vitro precision provides evidence that CAD models are precise enough to be used in clinical trials. This has significant implications regarding cost and the efficiency of running a clinical trial. If a study required the use of reverse engineered implants then there would be a significant increase in cost. Each implant to be implanted would have to be scanned before sterilisation. Potentially, only patients who would be likely to require a common size of implant could be recruited to prevent having to have all sizes of implants scanned. In addition, it would be likely that only a single patient could be recruited each day of surgery to prevent having to have multiple implants of the same size available.

However, the results show that CAD models offer a very similar level of precision, thus negating the requirement for scanning. This means that a clinical trial can recruit patients regardless of size of knee joint or whether they are having surgery on the same day as others recruited.

The level of precision with regard to migration demonstrated by the phantom experiment was equally encouraging. As expected, the lowest level of precision for translation of both the femoral and tibial component was in the out-of-plane *z*-axis, with both the *x*- and *y*-axes providing very high levels of precision. In contrast, the lowest precision for rotation differed between components. The femoral component had lowest precision with rotation around the *z*-axis whereas the tibial component had lowest precision for rotation around the *y*-axis. What is interesting with these findings is that the lowest precision for each component was for rotation around the axis that caused rotation of the longest dimension of the component. This, perhaps, is intuitive, as a small rotation of the shortest dimension causes a proportionally bigger translation than the same rotation of the longest dimension. Regardless of the relative level of precision between axes it can be seen that the lowest level is still acceptable for clinical use and provides evidence that small deviations of a small component can still be precisely detected by model-based RSA.

The final in-vitro precision experiment to identify the effect of moving the components within the calibration object was required before accuracy experiments could begin. The initial experiments were all in ideal conditions, with the phantom centralised in the calibration object. However, when a patient attends for radiographs it is often very difficult for the radiographer to place the components contained within the knee accurately in the centre of the calibration object. This is particularly important with obese patients as their soft tissue coverage makes identification of the underlying joint even more difficult. However, the results demonstrate that although there is a

reduction in precision when the UKR is on the edge of the calibration object the level is still high enough to be of use clinically. This enables the recruitment of all patients undergoing UKR, rather than just those who have a low body mass index (BMI) and would therefore provide an easier knee joint on which to obtain acceptable stereoradiographs.

While the precision of model-based RSA used with UKR has been demonstrated it is important to assess accuracy. The use of a highly accurate micrometer provided an ideal standard against which to compare the model-based RSA system. It enabled the assessment of both small translations that may be expected clinically as well as larger translations that may be expected in the failing implant. The initial consideration was over what magnitude of translation to measure. A pragmatic approach was taken, with a very small translation of 100 μm chosen as it is half the 200 μm shown by Ryd to be indicative of impending failure in the second post-operative year. The figure of 200 μm quoted by Ryd was based on the migrations of different TKR implants. However, it is not known what amount of migration is associated with failure in the Oxford UKR. Therefore, in order for the system to be useful in detecting a potential failing implant it has to be accurate when measuring potentially significant migrations. The larger 1.0 mm migration was chosen based on the observation that physiological radiolucencies are less than 1.0 mm in depth and therefore migrations of larger than this may be associated with thicker radiolucencies. The results demonstrate that a very high level of accuracy is possible with the smaller migrations, and only a minor decrease in accuracy is possible with the larger migrations. This is relevant clinically as it shows that the model-based RSA system is able to detect accurately migrations that one may expect in-vivo.

Accuracy for rotation is lower than for translation. For the tibial component, accuracy of rotation around the *x*- and *z*-axes was tested. Rotation around these axes is clinically manifested as a change in posterior slope (*x*-axis) and valgus/varus tilt (*z*-axis). Both of these migrations are clinically relevant as it is recognised that excess posterior slope or varus inclination can increase stress on the cancellous bone and lead to failure[156]. The level of accuracy, though lower for the *z*-axis, is acceptable to detect subtle changes in slope in either plane and thus be useful in identifying those components at risk of failure.

The final experiment, *in-vivo* precision, is important to ensure that the theoretical accuracy of a system is translatable into the clinical environment. The results *in-vivo* did not reach the very high levels of precision of the *in-vitro* phantom, but this would be expected as there is image degradation due to the overlying soft tissue. The results do demonstrate however, that a high enough level of precision is attainable *in-vivo*.

In conclusion, the series of experiments in this work demonstrate that the RSA system currently in use in Oxford would allow the accurate assessment of migration of the Oxford UKR in clinical trials. Furthermore, the use of CAD models would not compromise the accuracy or precision of the studies, enabling all patients available to be recruited, regardless of size or number.

4 Randomised Controlled Trial of Cemented versus Cementless Oxford Unicompartmental Knee Replacement

4.1 Introduction

The Oxford UKR has a long history using cemented fixation and a much shorter history using cementless fixation. This study was performed before general release of the cementless components. The cementless OUKR was first used in Oxford in 2005 after development in the preceding few years. Specific instrumentation was developed to prepare the tibial surface correctly, with a narrower keel slot, and to aid implantation. During clinical follow-up it has been reported that radiolucency develops in approximately two thirds of cemented OUKR[69], but that the prevalence in cementless OUKR is greatly reduced at one year[63]. The presence of radiolucency beneath the cemented components may suggest sub-optimal fixation. The reduction in the prevalence of radiolucency beneath the cementless tibial component has been maintained into the second post-operative year[70], which suggests that there may be a high percentage of bony ingrowth and thus stable fixation. It is not known why there is a difference in radiolucency prevalence between the two fixation methods. As discussed previously, there may be patient specific, surgeon specific and biomechanical reasons for the difference.

A significant advantage of using the Oxford UKR in a study such as this is that the cemented and cementless implants are essentially the same and the technique for implantation is identical, barring the obvious need for cementation in the cemented components, and thus confounders are minimised. Furthermore, the patients who receive each implant are from the same cohort as the indications are identical.

Therefore the OUKR is ideally suited to a study designed to measure migration of knee replacement using different types of fixation and identify those patients that go on to develop radiolucencies. This will then allow any association between migration and the development of radiolucency to be identified.

4.2 Study Design

4.2.1 Overview

The study was designed as a single-blinded randomised controlled trial of two types of fixation in Oxford UKR. The two types of fixation under investigation were standard PMMA cement and hydroxyapatite coated porous titanium. The study had two elements, clinical and radiological. The clinical part of the study used the Oxford Knee Score (OKS)[79,157] that was assessed annually (Appendix 1). The radiological part of this work used the model-based RSA system described and validated in Chapter 3 to assess component migration and fluoroscopically screened imaging to assess the development of radiolucency or osteopaenia. . The study was approved by the Oxfordshire Ethics Committee (C02.101).

4.2.2 Patient Selection

All patients undergoing medial OUKR at the Nuffield Orthopaedic Centre were considered for the study. Exclusion criteria were: previous surgery on the knee (excluding arthroscopy), age greater than 80 years and an American Society of Anaesthetists (ASA) score greater than three. The upper age limit was used to increase the likelihood that a recruited patient would be able to attend for extended

follow up. Patients who were entered into the study provided informed consent and understood they had an equal chance of receiving either a cemented or cementless UKR. A further, logistical, consideration was that each patient had to be close geographically to Oxford as previous experience of the department has shown a high drop out rate for patients who live out of the catchment area. Therefore, tertiary referrals were not recruited. Patients were recruited and consented in the pre-admission clinic, one to two weeks prior to surgery. Confirmation of consent was obtained on the morning of surgery. A power calculation was performed using the accuracy established in Chapter 3 and the requirement to detect a difference of 200 μm. Sixteen patients were required in each group. Additional patients were recruited to ensure there were adequate radiographs for analysis after two years of follow-up.

4.2.3 Randomisation

Block randomisation using sealed envelopes was used with blocks of ten containing five of each fixation type. Block randomisation was used to ensure an even distribution of patients with each fixation method. The operating surgeon was always unaware of the contents of each envelope, even when it was the final in each block. The patients were not stratified according to either age or sex. Once patients had an arthrotomy performed and suitability for UKR confirmed the envelope was opened. No patient received a different fixation type to that which they were allocated.

4.2.4 Implants

All components used in the study were standard Phase 3 Oxford UKR (Figure 4-1 and Figure 4-2). In all cemented cases CMW1 Gentamicin impregnated cement (Depuy International Ltd, Leeds, UK) was used according to the manufacturer's

instructions. For the cementless components each was examined prior to insertion to ensure the porous titanium had a complete covering of hydroxyapatite and was then implanted according to the manufacturer's recommended surgical technique.

Figure 4-1 Clinical photograph showing the undersurface of the hydroxyapatite coated titanium mesh on the cementless femoral component (left) and the uncoated cemented femoral component (right). The cementless component has two pegs while the cemented component has one and all pegs are uncoated. The main peg of the cementless component is oversized to provide a tight initial fit.

Figure 4-2 Clinical photograph showing the undersurface of the hydroxyapatite coated titanium mesh of the cementless tibial component (left) and the uncoated cemented tibial component (right).

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4.2.5 Surgical Technique

Surgery was performed by one of four specialist knee surgeons (DWM, AJP, CAFD, WFMJ) with extensive experience of the OUKR. Operative findings for each case were recorded, including: anterior cruciate ligament (ACL), patello-femoral joint, lateral compartment and medial compartment. The normal operative technique was followed in all cases. A medial para-medial incision and medial para-patellar approach was used. Tibial preparation used an extra-medullary tibial guide which was aligned horizontally to cut just beneath the tibial defect. The vertical tibial saw cut was placed just medial to the apex of the medial tibial spine and directed towards the hip joint or anterior superior iliac spine (ASIS). The saw blade was stopped about 1 mm above the guide so as not to damage the bone supporting the implant. The horizontal cut was made with a 7° posterior slope, taking care not to damage the medial collateral ligament (MCL).

The position of the femoral component was determined using a femoral drill guide. Bone was removed progressively from the distal femur until the flexion and extension gaps were balanced.

A meniscectomy was performed, preserving a small rim medially to protect the MCL from the implant. Bone and cartilage was removed anterior and posterior to the implant to prevent impingement. A slot for the tibial keel was fashioned using a "toothbrush" saw specific to the fixation used (Oxford Knee Resection Procedure Three Pack, Synvasive Technologies Inc, Reno, USA). A trial reduction was undertaken with the definitive trial components to ensure they seated fully, did not impinge and functioned satisfactorily. The definitive implants were then impacted until secure.

4.2.6 Insertion of Marker Balls

Tantalum marker balls with a diameter of 0.8 mm were used to provide the rigid body. The marker balls were inserted after tibial and femoral preparation was complete. The optimal position of the marker balls had been established previously (Figure 3-2). Each set of markers was inserted in the predetermined positions using a pre-loaded ball injector (RS-M 08, Tilly Medical Products, Lund, Sweden). Seven balls were inserted in the femur and six in the tibia.

4.2.7 RSA Stereoradiographs

All stereoradiographs were obtained with the patient standing in a normal two leg stance. The radiographs were taken post-operatively, when the patient was able to stand safely, usually day one or two post-operatively. Subsequent radiographs were taken at 3, 6, 12 and 24 months. Each pair of radiographs were assessed by the research radiographer and repeated if the calibration markers or rigid body markers were not visible. The standard calibration frame was used for all images. The radiographs were taken using two Roentgen tubes (Siemens AX, Siemens UK, Camberley, UK and GE AMX 4, GE Healthcare, Little Chalfont, UK) each set 1.5 m from the Computerised Radiography (CR) plates (Kodak DirectView 975 cassettes, 35 x 43 cm, Kodak Ltd, Hemel Hempstead, UK) and angled at 60°, perpendicular to the CR plates. Exposure parameters were initially set at 76 kV and 16 mAs, and adjusted depending on body habitus. CR plates were read on a Kodak DirectView CR975 (Kodak Ltd, Hemel Hempstead, UK) and the digital images produced in 12 bit greyscale DICOM format with a resolution of 2048 x 2500 pixels.

4.2.8 Screened Radiographs

All patients underwent standard post-operative radiography to ensure adequate implantation of components. Subsequently, each patient had screened fluoroscopy images obtained when they attended for their 6, 12 and 24 month RSA appointments. All radiographs were obtained using (Siemens SMS-AX, Siemens UK, Camberley, UK) and digital images in DICOM format produced (1024 x 1024 pixels). Each image was analysed for radiolucency, as well as for osteopaenia. The standard zonal method for assessment of radiolucency was used [117] (Figure 4-3 and Figure 4-4).

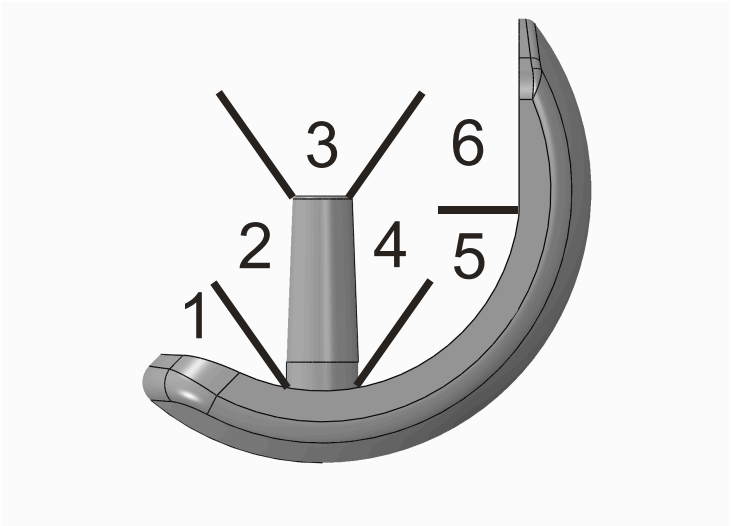

Figure 4-3 A schematic representation (lateral view) of a femoral component with six zones marked. The assessment of radiolucency beneath the femoral component is divided between these zones.

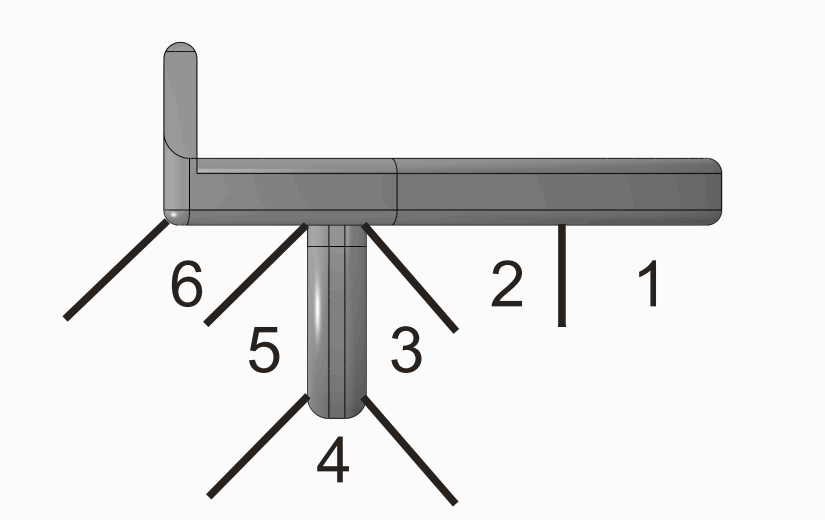

Figure 4-4 A schematic representation (anteroposterior view) of a tibial component with six zones marked. The assessment of radiolucency beneath the tibial component is divided between these zones.

4.3 Analysis

All RSA analysis was performed using Model-based RSA Software version 3.21 (Medis Specials, Leiden, The Netherlands). All analyses were performed by one operator (BK). Inter-observer variability was assessed using intra-class correlation.

4.3.1 RSA Calibration

Calibration was performed following automated detection of the fiducial and control markers and the manual addition of undetected markers. The automated algorithm could be adjusted for minimum and maximum radii of controls to optimise marker identification. The mean error for each set of calibration markers for the two radiographs was calculated. This was commonly necessary when markers overlapped other metallic objects such as the implants. In a correctly obtained radiograph calibration could be optimised until the mean error was less than the upper limit for the calibration box (Table 4-1).

Markers	Number detectable	Maximum mean error
Left Fiducial	20	0.200
Left Control	25	0.700
Right Fiducial	20	0.200
Right Control	25	1.100

Table 4-1. Maximum acceptable mean error (mm) for identification of calibration markers when calibrating each set of stereoradiographs for assessment using model-based RSA.

4.3.2 Edge Detection

The contour of each implant was detected using an automated Canny edge detection algorithm[158]. The region of interest (ROI) was adjusted to include only a single component. Edges could be selected and deselected as required, particularly with overlapping components. Thresholds for pixel gradient could be adjusted to optimise implant contour identification. Each implant had the maximal available amount of contour selected (Figure 4-5).

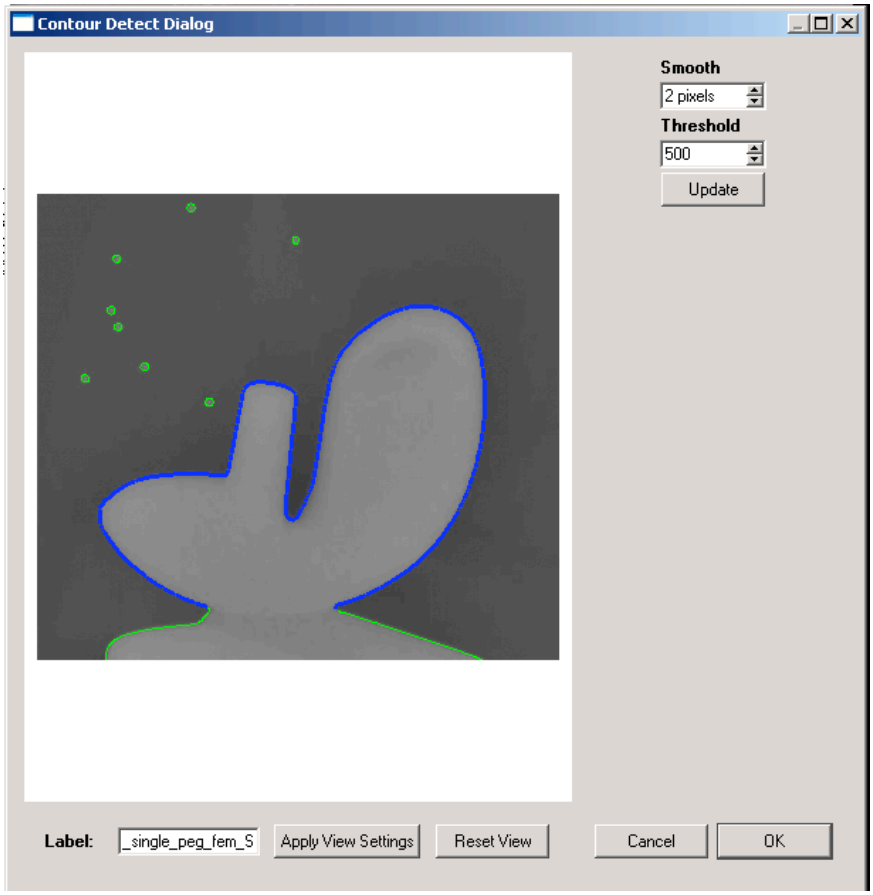

Figure 4-5 The actual contour of the femoral component is selected (blue line). A small area partially overlaps the tibial component and is not selected. The selection can be optimised by altering the shown parameters to further identify edges.

4.3.3 Pose Estimation

Each analysis used CAD models that matched the implanted components. Matching the virtual contour generated by projecting the CAD model into the image space with the detected (component) contour was performed using a fully automated downhill slope algorithm. The contours were matched using 100% of the available contours. The algorithm minimises the mean difference in distance between the two contours, with the value given in millimetres. Although the mean difference does not have a direction it does give a magnitude. Therefore, it can be used to ensure there were no large errors in pose estimation. Data from the phantom experiments showed that a maximal mean difference of 0.30 mm is acceptable for the femoral component and

0.20 mm for the tibial component.

4.3.4 Migration

All migration calculations were performed using the co-ordinates from the calibration frame. Translations were calculated for each of the three axes (*x,y,z* in millimetres). The *x* axis is medial-lateral, the *y* axis is superior-inferior and the *z* axis is anterior-posterior. Rotations about each of the axes (in degrees) were also calculated. As the migration or rotation of each component was calculated with reference to the calibration frame, the calculations had to be corrected to give the correct migration relative to the anatomical side (Table 4-2 and Table 4-3). For example, a positive migration along the *x* axis for a right sided component would be a medial translation, but a lateral translation for a left sided component. All results were converted to be as for a right sided implant to allow comparison across the cohort. At each time point a t-test was performed to see if there had been significant migration for each fixation type in each direction, as well as between fixation types.

	Right		**Left**	
	+ve	**-ve**	**+ve**	**-ve**
X	Medial	Lateral	Lateral	Medial
Y	Superior	Inferior	Superior	Inferior
Z	Anterior	Posterior	Anterior	Posterior
R*x*	Increased flexion	Decreased flexion	Increased flexion	Decreased flexion
R*y*	Internal rotation	External rotation	External rotation	Internal rotation
R*z*	Valgus	Varus	Varus	Valgus

Table 4-2 Clinical description of the migrations for the femoral component for each side. For analysis the left sided component results were transformed to right sided migrations.

	Right		Left	
	+ve	**-ve**	**+ve**	**-ve**
X	Medial	Lateral	Lateral	Medial
Y	Superior	Inferior	Superior	Inferior
Z	Anterior	Posterior	Anterior	Posterior
R*x*	Reduced Slope	Increased Slope	Reduced Slope	Increased Slope
R*y*	Internal	External	External	Internal
R*z*	Valgus	Varus	Varus	Valgus

Table 4-3 Clinical description of the migrations for the tibial component for each side. For analysis the left sided component results were transformed to right sided migrations.

For the femoral component migration in all directions was analysed, along with maximum total point motion (MTPM). In particular, the rotation about the *y*-axis was investigated further, both individually and as a relation to MTPM, as the femoral peg is parallel with that axis and therefore is the most likely direction of migration.

For the tibial component all directions of migration and MTPM were analysed. The most important direction of migration was subsidence, decrease in the *y*-axis, and further analysis, including the relation to MTPM, was performed.

For both components a further analysis was performed for all translations and rotations between the first and second post-operative year.

4.3.5 Timing

Patients had stereoradiographs taken post-operatively, within one week in most

cases. Subsequent radiographs were taken at 3, 6, 12 and 24 months. Radiographs were taken within two weeks of each scheduled time point. Clinical evaluation with the Oxford Knee Score was performed pre-operatively and at annual review. OKS was collected by a research physiotherapist pre-operatively and either the physiotherapist or radiographer at the annual review. The score was calculated using the new method, with a minimum of 0 and a maximum, indicating asymptomatic knee function, of 48[157]. When considering the outcome scores it is important to consider whether any patient or surgical factors have an influence. Some care must be taken over interpretation as although the study is well powered for migration using RSA, assessment of factors influencing outcome often have higher numbers.

4.3.6 Assessment of Radiolucency

All screened radiographs were assessed for radiolucency using the previously described zonal method (Figure 4-3 and Figure 4-4). Note was also made of whether a sclerotic line was evident beneath an area of radiolucency.

4.4 Results

4.4.1 Patient Recruitment and Demographics

Forty-seven patients were recruited, provided informed consent and were randomised to receive either a cemented or cementless Phase 3 Oxford UKR. Although the inclusion criteria allowed for all diagnoses for which an OUKR is indicated, all patients had a primary diagnosis of osteoarthritis. There were no

patients with either post-traumatic arthritis or osteonecrosis. One patient suffered a bearing dislocation and subsequent infection following bearing exchange. A further patient died four months post operatively. These patients were both withdrawn from the study. A full breakdown of the number recruited and subsequently analysed is presented as a CONSORT diagram[159] (Figure 4-6).

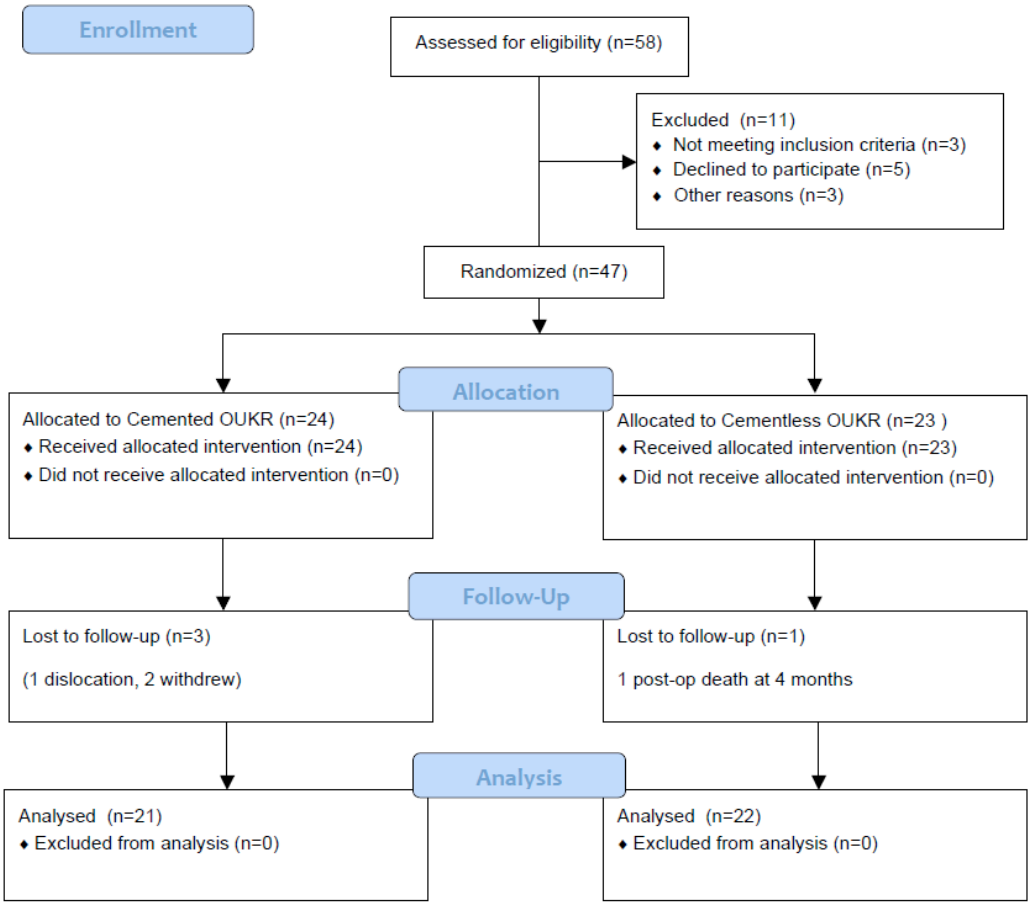

Figure 4-6 CONSORT diagram of recruitment for the study randomised controlled trial of cemented *versus* cementless Oxford unicompartmental knee replacement.

22 patients received a cementless OUKR and 21 received a cemented OUKR. The demographics are shown in Table 4-4.

	Cemented (n=21)	Cementless (n=22)
Age (years, SD)	65.4 (8.8)	67.6 (7.6)
Sex (Male:Female)	10:11	13:9
Side (right:left)	13:8	13:9

Table 4-4 Patient demographics for both the cemented and cementless patients. There was a similar distribution of ages and sides but a slight preponderance of males in the cementless group.

4.4.2 Operative Findings

All patients fulfilled the standard indications for OUKR. All had full thickness cartilage loss in the medial compartment, an intact ACL, no full thickness loss on the lateral facet of the patella and no significant cartilage damage on the weight-bearing portion of the lateral compartment (Table 4-5).

		Cemented	Cementless
ACL	Normal	10	7
	Synovial thinning	3	4
	Longitudinal splits	6	10
	Friable and fragmented	1	0
Patella (Medial facet)	Normal	6	7
	Superficial	6	5
	PTCL	5	4
	FTCL	3	5
Patella (lateral facet)	Normal	11	10
	Superficial	7	6
	PTCL	2	5
	FTCL	0	0
Trochlea	Normal	6	5
	Superficial	5	4
	PTCL	7	8
	FTCL	2	4
Lateral Compartment (weight bearing)	Normal	14	17
	Superficial	6	4
	PTCL	0	0
	FTCL	0	0
Lateral Compartment (non-weight bearing)	Normal	15	13
	Superficial	5	6
	PTCL	0	0
	FTCL	0	2

Table 4-5 Intra-operative findings for the ACL and articular surfaces of all three compartments for all study patients. The findings were assessed in a standardised manner by the operating surgery before proceeding with OUKR.

There was no significant difference in the state of the ACL between fixation methods ($p = 0.449$, Chi Squared).

4.4.3 Implant Demographics

The full range of femoral and tibial sizes were used. The three femoral sizes were

used in roughly equal numbers. The most common sizes of tibial component were in the middle of the range. The thinner bearings were used more often, with the thickest three bearing sizes (7-9) never used (Table 4-6).

		Cemented	Cementless
Femoral Component	Small	9	9
	Medium	6	7
	Large	6	6
Tibial Component	A	3	2
	B	3	5
	C	9	7
	D	2	1
	E	2	6
	F	2	1
Bearing	3	3	6
	4	10	14
	5	6	2
	6	2	0

Table 4-6 Implant demographics between fixation methods. As there were both male and female patients in the study there is the expected distribution of implant sizes across the entire range available..

4.4.4 RSA results

All patients had all stereoradiographs analysed. The tibial rigid body markers were more consistently seen than those for the femoral component. Subsequently, there was loss of stereoradiographs suitable for analysis of the femoral component more often than for the tibial component (Table 4-7)

		Cemented (n=21)	Cementless (n=22)
Femoral Component	3 months	19	21
	6 months	19	21
	12 months	18	20
	24 months	20	21
Tibial Component	3 months	21	22
	6 months	20	22
	12 months	20	22
	24 months	20	21

Table 4-7 Number of stereoradiographs suitable for analysis at each time point.

The condition number was assessed for each set of stereoradiographs. No set of rigid body markers had a condition number of over 95. The mean condition number for both femoral and tibial markers at the different time points (3,6,12 and 24 months) was between 35 and 51, with a standard deviation ranging between 9 and 21. Therefore, no set of stereoradiographs was discarded for an excessively high condition number.

4.4.4.1 Femoral component migration

There was no significant difference in migration in any direction between types of fixation by two years (Table 4-8, Table 4-9, Table 4-10 and Table 4-11).

		X	*Y*	*Z*	R*x*	R*y*	R*z*
Cemented	Mean	0.05	-0.17	0.14	0.19	0.10	-0.10
	Standard Deviation	0.40	0.25	0.33	0.47	0.74	0.95
	p-value	0.71	0.01	0.12	0.17	0.57	0.61
Cementless	Mean	-0.01	-0.10	0.26	0.22	0.26	-0.16
	Standard Deviation	0.36	0.34	0.48	0.95	0.55	0.89
	p-value	0.90	0.19	0.02	0.30	0.04	0.43
p-value cemented v cementless		0.65	0.44	0.38	0.91	0.46	0.85

Table 4-8 Mean migration, with standard deviation, for the femoral component at three months for all translations and rotations. P-value for each fixation method against zero migration. P-value then given between the two fixation methods. All p-values calculated using T-test.

		X	*Y*	*Z*	R*x*	R*y*	R*z*
Cemented	Mean	0.05	-0.02	0.16	0.27	0.05	0.19
	Standard Deviation	0.28	0.39	0.29	0.81	0.62	0.76
	p-value	0.41	0.80	0.02	0.30	0.04	0.43
Cementless	Mean	-0.12	-0.11	0.24	0.04	0.48	-0.11
	Standard Deviation	0.31	0.26	0.39	0.56	0.79	0.90
	p-value	0.10	0.08	0.01	0.78	0.01	0.60
p-value cemented v cementless		0.08	0.42	0.48	0.30	0.07	0.27

Table 4-9 Mean migration, with standard deviation, for the femoral component at six months for all translations and rotations. P-value for each fixation method against zero migration. P-value then given between the two fixation methods. All p-values calculated using T-test.

		X	***Y***	***Z***	**R*x***	**R*y***	**R*z***
Cemented	Mean	0.05	-0.12	0.24	0.16	-0.05	0.25
	Standard Deviation	0.28	0.25	0.32	0.65	0.63	0.80
	p-value	0.43	0.07	0.01	0.30	0.32	0.19
Cementless	Mean	-0.18	-0.12	0.26	0.22	0.24	-0.26
	Standard Deviation	0.28	0.24	0.31	0.57	0.52	0.93
	p-value	0.01	0.04	0.00	0.10	0.05	0.23
p-value cemented v cementless		0.01	0.99	0.89	0.78	0.07	0.08

Table 4-10 Mean migration, with standard deviation, for the femoral component at one year for all translations and rotations. P-value for each fixation method against zero migration. P-value then given between the two fixation methods. All p-values calculated using T-test.

		X	***Y***	***Z***	**R*x***	**R*y***	**R*z***
Cemented	Mean	0.03	-0.05	0.22	0.23	0.32	-0.06
	Standard Deviation	0.34	0.32	0.42	0.68	0.52	0.75
	p-value	0.71	0.56	0.04	0.18	0.75	0.74
Cementless	Mean	-0.05	-0.04	0.21	0.20	0.23	0.00
	Standard Deviation	0.53	0.27	0.23	0.54	0.52	1.28
	p-value	0.68	0.57	0.00	0.12	0.07	0.99
p-value cemented v cementless		0.59	0.91	0.91	0.89	0.64	0.86

Table 4-11 Mean migration, with standard deviation, for the femoral component at two years for all translations and rotations. P-value for each fixation method against zero migration. P-value then given between the two fixation methods. All p-values calculated using T-test.

Of note, the single significant difference observed, in the *x*-axis at one year, returned to no significance at two years. There was a small difference in the migration profile between the two fixation types. Both fixation types had significant migration anteriorly

along the *z*-axis, but the cementless femoral component also had a significant amount of rotation around the *y*-axis.

Analysing the MTPM showed no difference between the two fixation methods, with no increase between three months and two years (Figure 4-7).

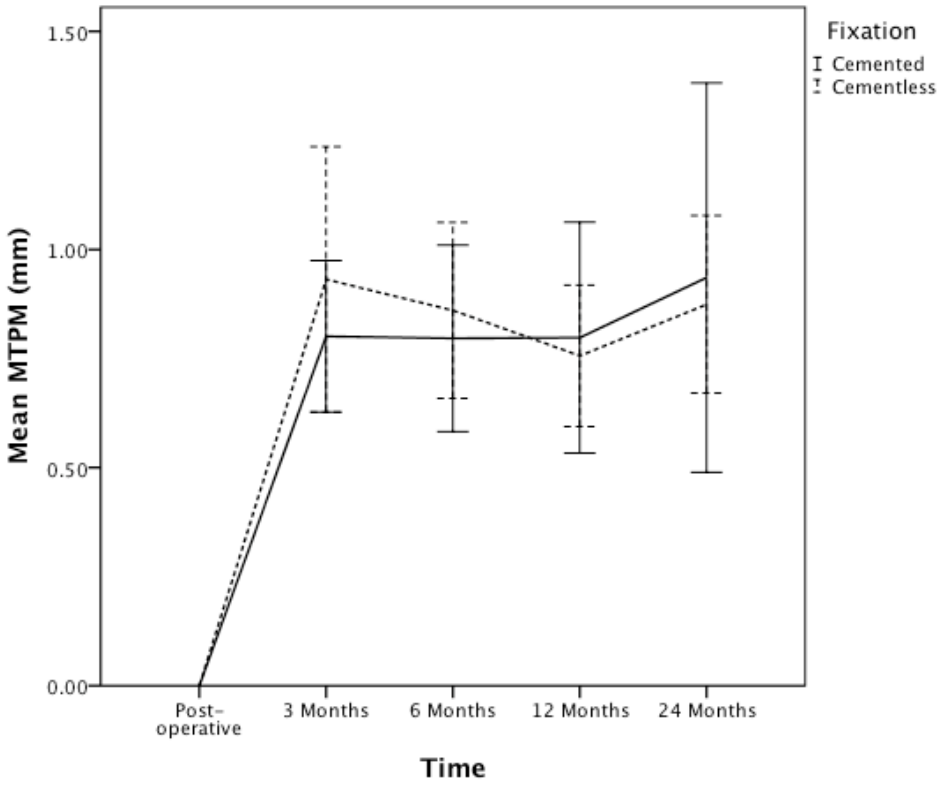

Figure 4-7 Mean MTPM for the femoral component, with 95% confidence intervals, at each follow-up point for both fixation types.

Rotation around the *y*-axis is relevant for the femoral component, as the single peg in the cemented component and the dual pegs in the cementless component are parallel with the axis and therefore rotational instability would be manifest as an increase in R*y*. Further analysis demonstrates that MTPM for the cemented femoral component is not associated (R^2 = 0.015) with rotation around the *y*-axis. The lack of an association is also evident with the cementless component (R^2 = 0.001) (Figure 4-8).

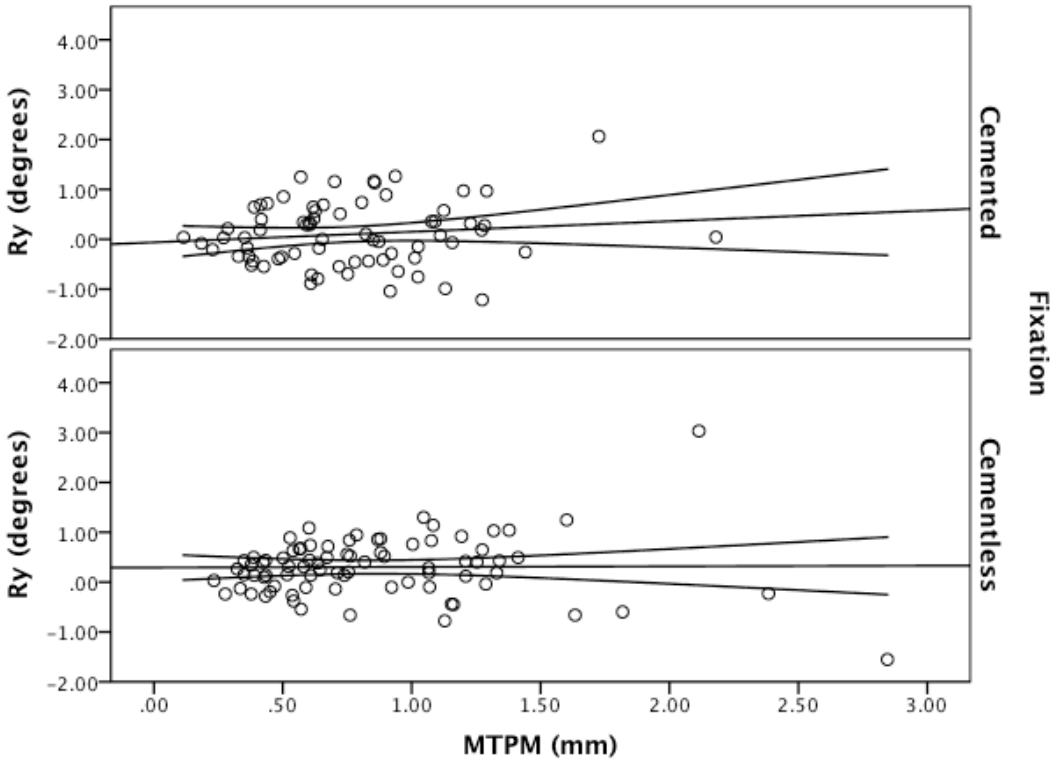

Figure 4-8 MTPM as a function of Ry for the femoral component (linear association with 95% confidence intervals).

Analysis of migration between the first and second post-operative year demonstrated a single significant migration, in the cemented component, with an increase in internal rotation (Table 4-12). The cementless component did not significantly migrate in any direction. There were seven cemented components that internally rotated greater than 0.5° and a two cementless component that externally rotated greater than 0.5°. The cemented components had a mean MTPM of 0.48 mm with four components having greater than 0.5 mm of MTPM. In contrast, the cementless components had a mean of 0.51 mm with seven components having greater than 0.5 mm of MTPM.

		X	*Y*	*Z*	R*x*	R*y*	R*z*
Cemented	Mean	-0.10	0.02	0.00	0.00	0.49	-0.24
	Standard Deviation	0.24	0.17	0.14	0.30	0.57	0.74
	p-value	0.15	0.67	0.89	0.97	0.01	0.24
Cementless	Mean	-0.08	0.06	-0.10	0.03	-0.10	0.14
	Standard Deviation	0.25	0.16	0.20	0.31	0.47	0.54
	p-value	0.18	0.13	0.05	0.66	0.36	0.28
p-value cemented v cementless		0.86	0.51	0.14	0.74	0.00	0.10

Table 4-12 Mean migration, with standard deviation, for all translations and rotations of the femoral component between the first and second post-operative years for both fixation types. The single significant migration was for the cemented femoral component around the *y*-axis.

4.4.4.2 Tibial Component migration

The cemented components showed significant subsidence (0.13 mm) at two years, but no other significant migration. The cementless component also subsided, but with a greater magnitude (0.34 mm), combined with an increase in posterior slope of 0.40°. The subsidence in the cemented components was slow and gradual over two years, whereas in contrast, the cementless components had marked subsidence by three months with only a small increase subsequently (Table 4-13, Table 4-14, Table 4-15 and 4-16).

		X	*Y*	*Z*	R*x*	R*y*	R*z*
Cemented	Mean	0.08	-0.10	-0.02	-0.09	-0.08	-0.10
	Standard Deviation	0.28	0.17	0.26	0.50	0.46	0.68
	p-value	0.22	0.02	0.72	0.44	0.45	0.50
Cementless	Mean	-0.09	-0.23	-0.03	-0.48	0.05	0.36
	Standard Deviation	0.22	0.18	0.20	0.88	0.63	0.70
	p-value	0.07	0.00	0.51	0.02	0.69	0.03
p-value cemented v cementless		0.04	0.02	0.90	0.08	0.44	0.03

Table 4-13 Mean migration, with standard deviation, for the tibial component at three months for all translations and rotations. P-value for each fixation method against zero migration. P-value then given between the two fixation methods. All p-values calculated using T-test.

		X	*Y*	*Z*	R*x*	R*y*	R*z*
Cemented	Mean	-0.06	-0.06	-0.05	-0.25	0.07	0.15
	Standard Deviation	0.19	0.18	0.30	0.65	0.36	0.98
	p-value	0.15	0.13	0.46	0.10	0.40	0.51
Cementless	Mean	-0.02	-0.28	-0.03	-0.46	0.12	0.33
	Standard Deviation	0.23	0.17	0.13	0.78	0.58	0.71
	p-value	0.62	0.00	0.27	0.01	0.36	0.04
p-value cemented v cementless		0.56	0.00	0.80	0.35	0.75	0.50

Table 4-14 Mean migration, with standard deviation, for the tibial component at six months for all translations and rotations. P-value for each fixation method against zero migration. P-value then given between the two fixation methods. All p-values calculated using T-test.

		X	*Y*	*Z*	R*x*	R*y*	R*z*
Cemented	Mean	0.01	-0.09	0.00	-0.10	-0.02	-0.29
	Standard Deviation	0.24	0.19	0.26	0.70	0.45	0.67
	p-value	0.91	0.04	0.95	0.53	0.82	0.06
Cementless	Mean	-0.04	-0.28	-0.01	-0.38	0.16	0.10
	Standard Deviation	0.21	0.19	0.15	0.73	0.54	0.63
	p-value	0.37	0.00	0.86	0.02	0.17	0.44
p-value cemented v cementless		0.51	0.00	0.88	0.22	0.23	0.05

Table 4-15 Mean migration, with standard deviation, for the tibial component at one year for all translations and rotations. P-value for each fixation method against zero migration. P-value then given between the two fixation methods. All p-values calculated using T-test.

		X	*Y*	*Z*	R*x*	R*y*	R*z*
Cemented	Mean	0.06	-0.13	0.03	-0.17	0.03	-0.31
	Standard Deviation	0.26	0.23	0.22	0.69	0.44	0.68
	p-value	0.28	0.02	0.51	0.30	0.74	0.06
Cementless	Mean	0.01	-0.34	-0.02	-0.40	0.24	-0.01
	Standard Deviation	0.19	0.23	0.16	0.76	0.61	0.60
	p-value	0.82	0.00	0.66	0.02	0.09	0.91
p-value cemented v cementless		0.44	0.01	0.42	0.31	0.23	0.15

Table 4-16 Mean migration, with standard deviation, for the tibial component at two years for all translations and rotations. P-value for each fixation method against zero migration. P-value then given between the two fixation methods. All p-values calculated using T-test.

The difference in subsidence between types of fixation was significant at three months and was maintained throughout each time period (Figure 4-9). There was no significant difference in migration in any other direction. There was a marked difference in migration profile between fixation types for the tibial component. With the exception of subsidence in the y-axis at three months the cemented components had no significant movement in any direction. In contrast, the cementless tibial

component had significant subsidence (*y*-axis) and increase in posterior slope (R*x*) that was seen at three months and was maintained at each further time point.

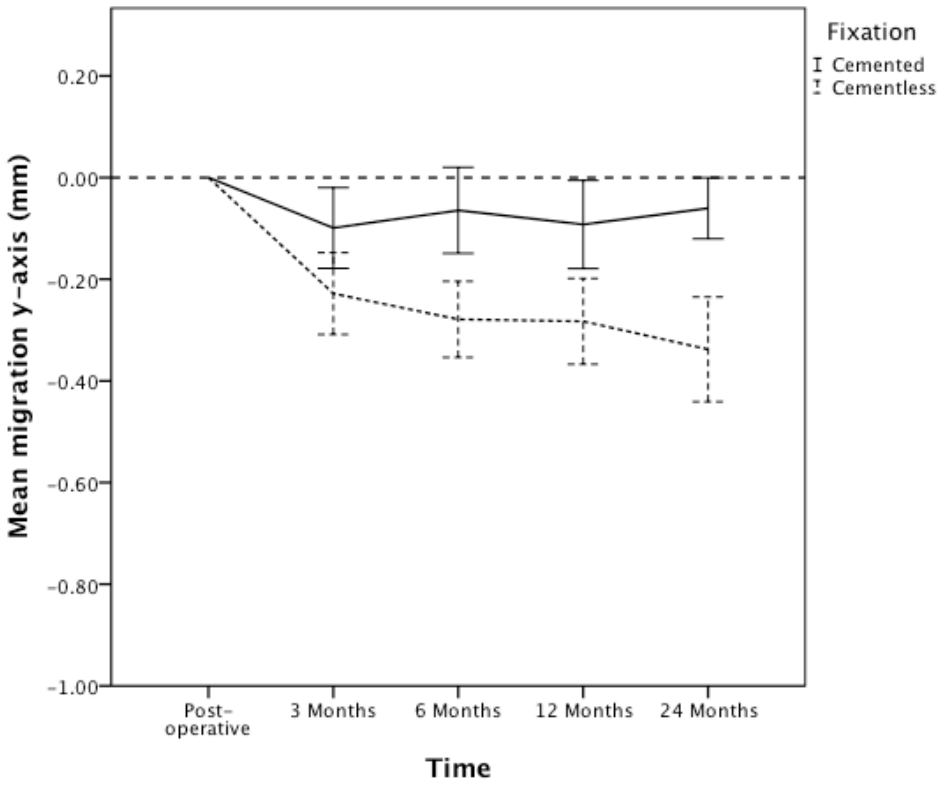

Figure 4-9 Mean migration in the y-axis for the tibial component (cemented: solid line, cementless: dashed line) with 95% confidence intervals.

A different presentation of the data, using boxplots, shows that there is a single outlier in the cemented group that becomes an extreme outlier with time (Figure 4-10).

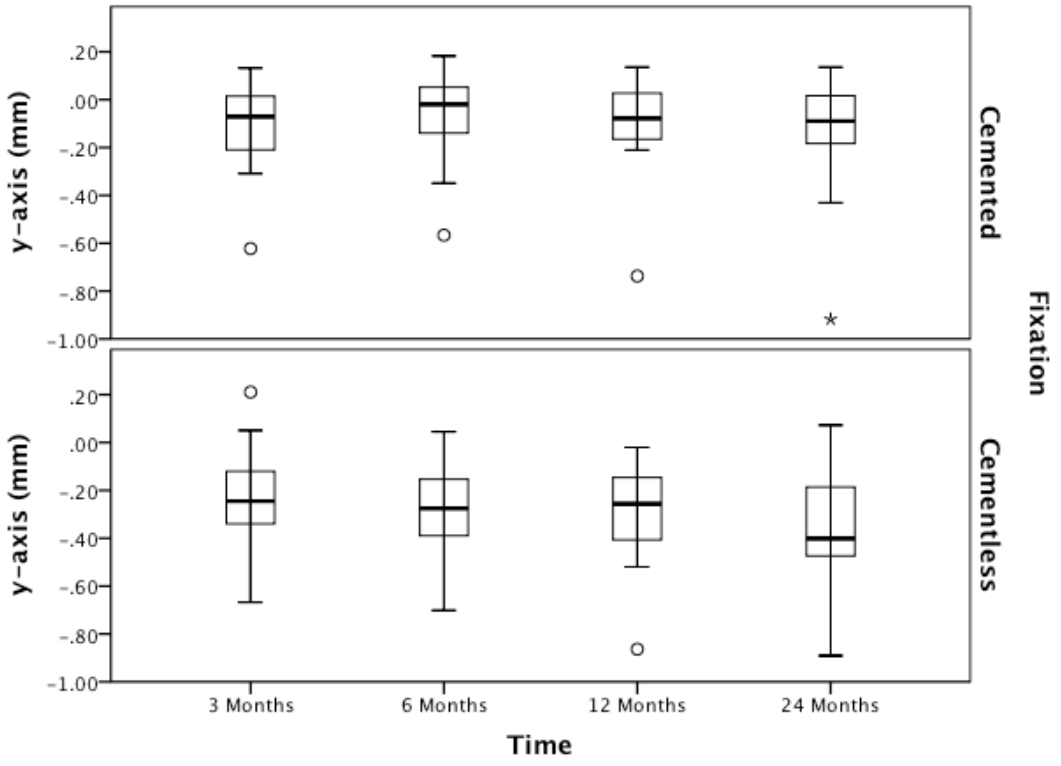

Figure 4-10 Boxplots for tibial subsidence over time (median, inter-quartile range and range for each box and whisker, circle for outlier (>1.5 IQR from the box) and asterisk for extreme outlier (>3 IQR from the box)).

There was also a significant difference in the x-axis and rotation around the z-axis at three months, but this was not maintained for the further time periods.

Although there was a significant difference in subsidence between fixation methods this did not significantly affect the MTPM, with no difference at any time point (Figure 4.11). However, the MTPM for the cementless components was consistently greater than those for the cemented components.

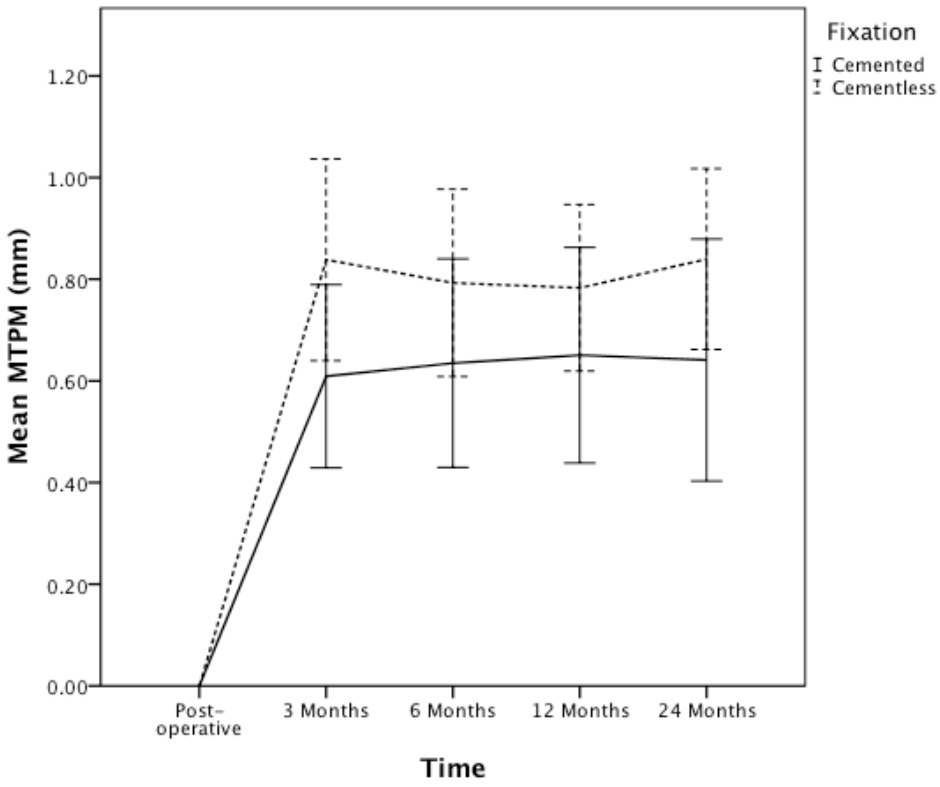

Figure 4-11 Mean MTPM at each time point for the tibial component with 95% confidence intervals.

The cementless components had both a greater mean subsidence (*y*-axis migration) and MTPM, but the association between the two was only weak (R^2 = 0.279). The association between subsidence and MTPM was slightly greater for the cemented components (R^2 = 0.366). A scattergraph demonstrates that more points are clustered around zero for the cemented component than the cementless component, but also highlights the number of outliers in the cemented group (Figure 4-12).

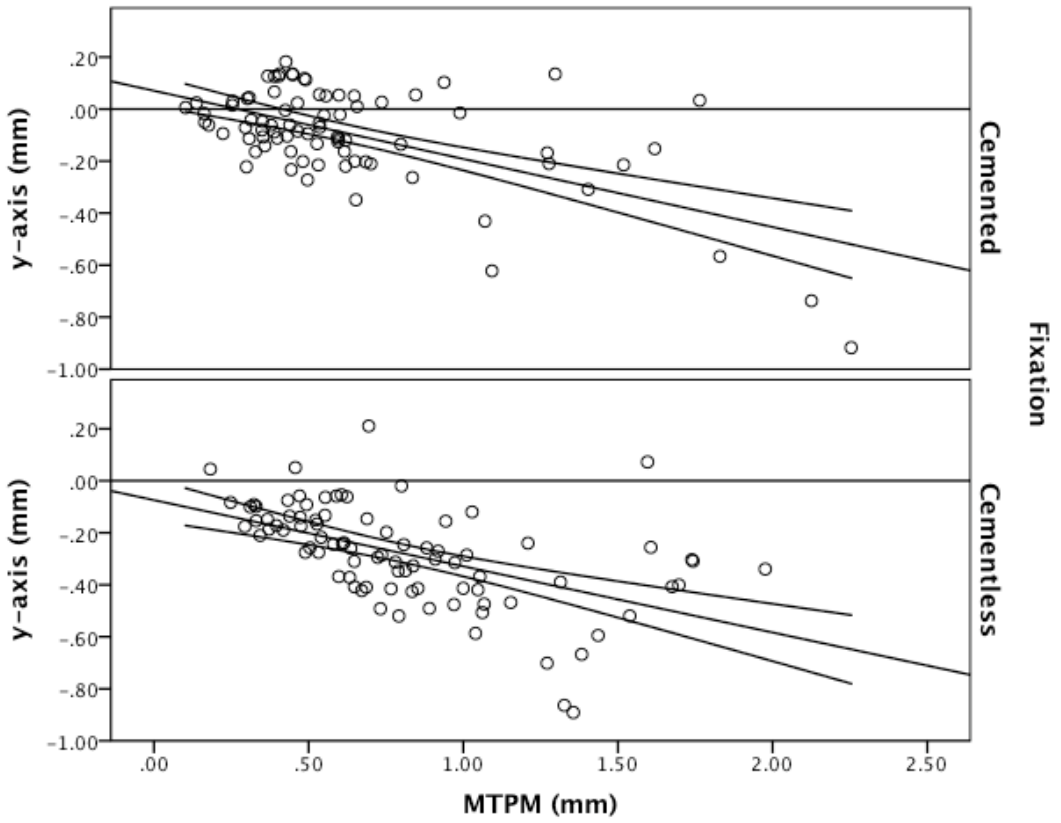

Figure 4-12 The association between y-axis migration and MTPM for the tibial component (linear association with 95% confidence intervals).

Analysis of migration between the first and second operative years demonstrated there was no significant difference between cemented and cementless fixation. However, both fixation types had a small amount of subsidence, which in the case of the cementless components was combined with a small increase in component varus.

		X	Y	Z	Rx	Ry	Rz
Cemented	Mean	0.07	-0.05	0.03	-0.01	-0.05	-0.07
	Standard Deviation	0.16	0.09	0.11	0.21	0.28	0.35
	p-value	0.08	0.04	0.29	0.86	0.42	0.36
Cementless	Mean	0.07	-0.04	0.02	0.03	-0.01	-0.18
	Standard Deviation	0.16	0.08	0.12	0.19	0.28	0.29
	p-value	0.07	0.03	0.53	0.47	0.92	0.01
p-value cemented v cementless		0.99	0.79	0.77	0.52	0.61	0.28

Table 4-17 Mean migration, with standard deviation, for all translations and rotations of the tibial component between the first and second post-operative years for both fixation types. Both fixation types had a significant subsidence and the cementless component also had an increase in component varus.

Four cemented components had greater than 0.15 mm of subsidence whereas only a single cementless component had the same amount. Both fixation types had a mean MTPM of 0.33 mm and four cemented and two cementless components had a MTPM of greater than 0.5 mm.

4.4.5 Clinical Outcome

All OKS questionnaires were completed in entirety with no loss of data collection. There was no significant difference between the scores, or change in scores, at any time point. (Table 4-18).

	Cemented	Cementless	p-value
Pre-operative	23.76 (13-37)	23.68 (12-36)	0.968
One year post-operative	39.95 (20-47)	41.27 (28-48)	0.526
Two years post-operative	38.35 (20-47)	41.52 (24-48)	0.197
Change pre-op to one year	16.19 (0-29)	17.14 (4-34)	0.677
Change one year to two years	-1.55 (-15-11)	0.48 (-14-11)	0.272

Table 4-18 Oxford Knee Scores for all patients in the study for the two fixation groups. Scores are 0-48 with 48 indicating best outcome.

For the cemented group there was no correlation between patient age and OKS either pre-operatively or at one or two years post-operatively (Pearson correlation 0.083, 0.152 and 0.165 respectively). However, in the cementless group there was a statistically significant correlation (Pearson correlation 0.487, $p = 0.021$) between age and pre-operative score. This correlation weakens and loses significance with the post-operative scores. For the patients receiving cemented components there was no correlation between OKS at two years and the size of the implanted components. There was also no correlation between final OKS and MTPM of either component. These results are similar for the cementless components, with no correlation between outcome at two years and either implant sizes or MTPM of either component. In addition, there is no correlation between tibial subsidence and outcome in either the cemented or cementless group.

4.4.6 Assessment of Radiolucency

All radiographs taken at one and two years postoperatively were assessed. No radiographs were rejected from analysis as all were correctly aligned. A single patient in the cementless group became unwell and did not attend her appointment at two years.

There were no radiolucencies around any femoral component in either group. There were several radiolucencies beneath the tibial component (Table 4-19).

	Cemented		Cementless	
	One year	**Two years**	**One year**	**Two years**
Full	2	5	1	0
Partial	11	8	7	6
None	8	8	14	15

Table 4-19 Number of full and partial radiolucencies beneath the tibial component at each follow up point for both fixation types.

The overall percentage of patients with a radiolucency in the cemented group was 62% at two years, compared to 29% for the cementless group, which was a significant difference (Chi squared, p = 0.017). The result for the cemented group is comparable to the prevalence previously reported by the same surgeons[69], whereas the prevalence for the cementless group is higher than that previously reported[63]. Of the cementless partial RLs at two years all were most evident in zone 6 as this was the only area that had a small sclerotic line beneath the radiolucent area (Figure 4-13).

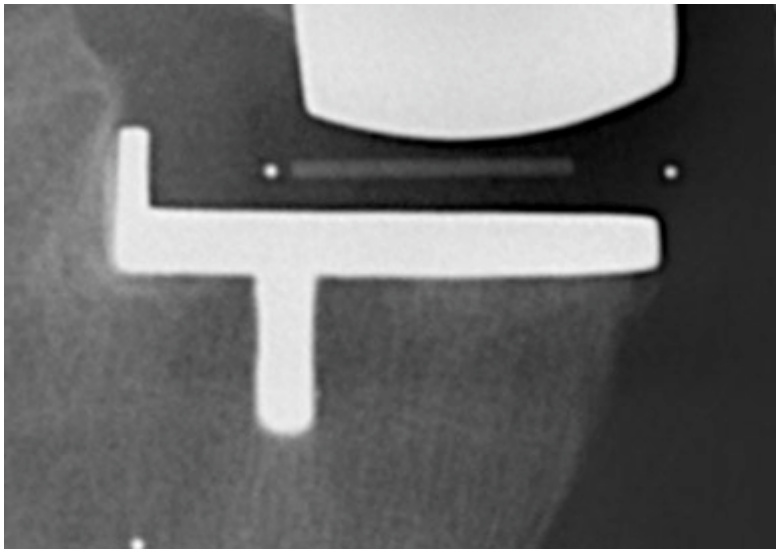

Figure 4-13 An example of a partial radiolucency, in zone 6, beneath a cementless tibial component.

A sclerotic line was not seen under any radiolucent area other than in zone 6 (Figure 4-4) in the cementless group. This contrasts with the observation in the cemented group that all the radiolucencies had a sclerotic line associated with them, regardless of in which zone they occurred (Figure 4-14).

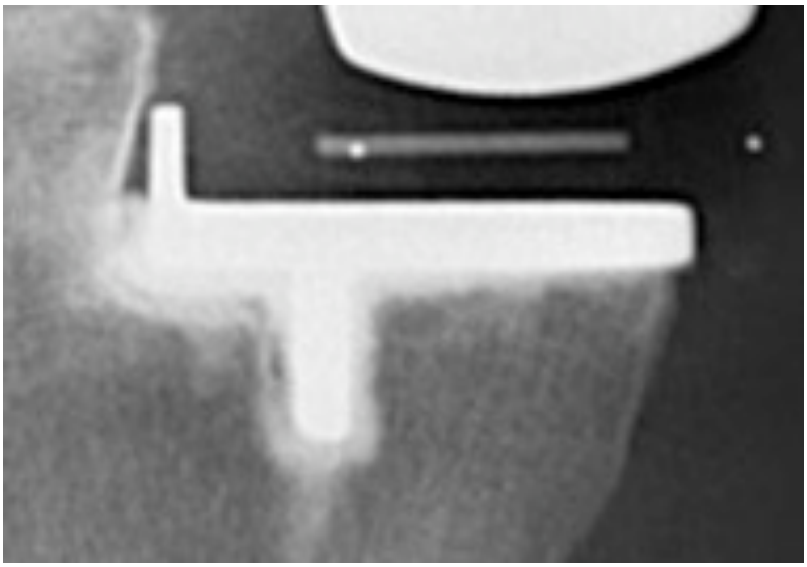

Figure 4-14 A partial radiolucency beneath a cemented tibial component with a sclerotic line in zones 4-7.

A further observation in the cementless group regarded the evolution of radiolucent areas. Several patients had additional imaging at six months post-operatively and in the cementless group the earlier radiographs often showed an isolated radiolucent ring around the tip of the keel that resolved by one year (Figure 4-15).

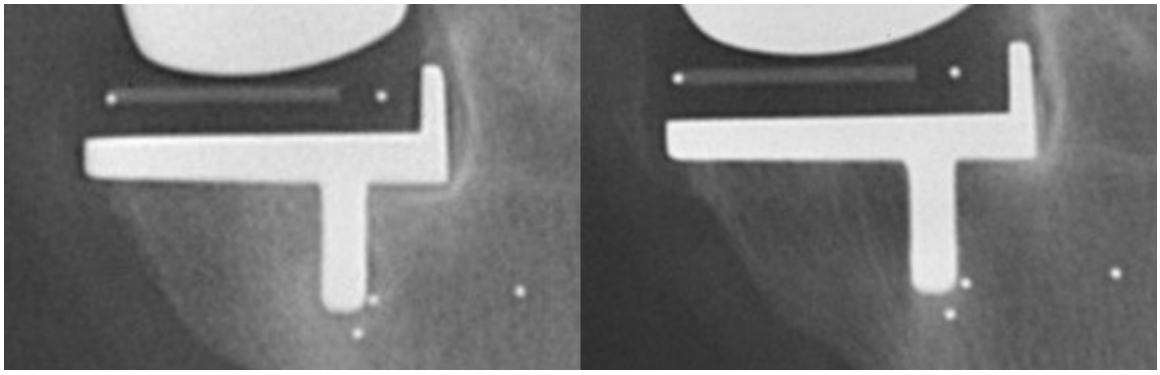

Figure 4-15 The radiograph on the left, at six months, shows a radiolucency around the keel and in zone 6, with the radiograph on the right, at one year, showing resolution of the peri-keel radiolucency and reduction of the radiolucency in zone 6.

4.4.7 Migration and radiolucency

There was no correlation between MTPM and the presence of radiolucency for either fixation type (Figure 4-16).

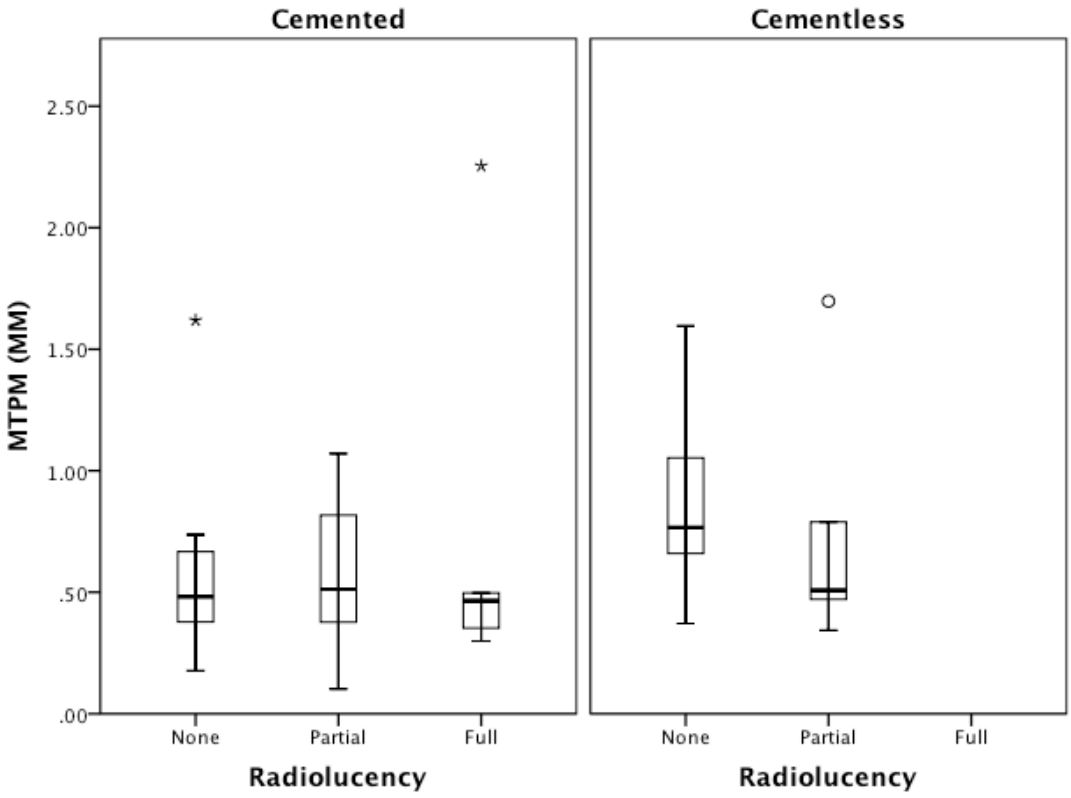

Figure 4-16 Boxplot of MTPM for each type of radiolucency for both cemented and cementless fixation for the tibial component.

However, an association between subsidence (*y*-axis migration) and the development of a radiolucency showed an interesting contrast between fixation types. Cemented tibial components had a moderate association, approaching significance, between increasing subsidence and the presence of a radiolucency (Pearson's correlation 0.405, p = 0.076), whereas subsidence had a moderate inverse correlation with the development of a radiolucency in the cementless group (Pearson's correlation 0.367, p = 0.102). The mean subsidence for the cemented component increased from no radiolucency through to full radiolucency. In contrast, there was greater subsidence in those cementless components that had no radiolucency (Figure 4-17).

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	Cemented			Cementless		
	None	**Partial**	**Full**	**None**	**Partial**	**Full**
MTPM	0.62 (0.47)	0.57 (0.31)	0.77 (0.83)	0.89 (0.34)	0.72 (0.50)	N/A
Y-axis	-0.04 (0.12)	-0.10 (0.18)	-0.29 (0.36)	-0.39 (0.24)	-0.21 (0.14)	N/A

Figure 4-17 Mean migration for MTPM and y-axis (SD) for each type of radiolucency for the two fixation types.

4.5 Summary of Results

- There was no difference in patient demographics between the two groups.
- The operative findings were similar in each group, with all patients having an intact ACL.
- The femoral component had a significant amount of anterior migration (*z*-axis), by three months for the cementless component and six months for the cemented component.
- There was no difference between fixation types in migration of the femoral component, in any direction, at two years.
- There was a significant increase in internal rotation of the cemented femoral component between the first and second post-operative years. No significant migration was seen in the cementless component in the same time period.
- Tibial migration showed a difference between groups for subsidence, with the cementless group showing greater subsidence and increase of posterior

slope, established at three months, but not for any other direction of migration or MTPM.

- Both tibial components demonstrated a small increase in subsidence between the first and second post-operative years. The cementless tibial component also had an increase in component varus. There was no difference between the two fixation types for any migration in the time period.
- There was no difference in clinical outcome between groups at two years.
- No radiolucencies were seen beneath the femoral component in either group.
- There was a difference in the prevalence of radiolucency beneath the tibial component, with an increased prevalence beneath cemented components.
- There was a moderate correlation between subsidence and the presence of a radiolucency. However, the correlation was for increased prevalence of radiolucency with increased subsidence in the cemented group but decreased prevalence of radiolucency with increased subsidence in the cementless group.

4.6 Discussion

The aim of randomisation is to stop the introduction of bias, and to eliminate the effect of any extraneous factor, such as age or sex. With the accuracy of RSA it is possible to have sufficient power to detect a small change in migration such that only a small number of patients are required. This can, however, allow patient related factors to take an effect as randomisation does not equalise the confounders before all the patients are recruited. It is reassuring then that this study has no difference between groups for patient demographics and although there is a preponderance of right-sided operations the proportion is almost identical in each group. There are certain variables that have not been measured, such as bone density or specific co-morbidities such as diabetes, but it is assumed that by recruiting routine patients with

osteoarthritis who have a low ASA then the numbers in each group are sufficient to equalise those factors.

A further consideration is the operative findings, particularly the state of the anterior cruciate ligament. It is well known that ACL deficient knees have a higher incidence of failure[160]. All patients had an intact ACL, although the single patient who had a friable and fragmented ligament could, perhaps, be assumed to have a non-functioning ACL. However, that patient actually had a lower MTPM than the group mean, although a partial radiolucency was present, and an OKS at two years of 47. The other operative findings were well balanced between groups which is of importance when considering the outcome measures, as it may be that, for example, patients with worse damage to their patello-femoral joint may have a decreased OKS due to those questions related to anterior knee function.

The main purpose of this study is to investigate whether there is a difference in migration between the two types of fixation and whether any difference in migration is related to the development of radiolucency. The femoral components did not migrate much (MTPM less than 1 mm) and the pattern of migration was very similar between the two groups. As expected overall there was no movement in the *x*- or *y*-axes, but there was a small amount (0.2 mm) in the *z*-axis, which is in the plane of flexion-extension and is therefore the most likely to occur through normal loading and movement of the joint. It may have been expected that some of the cementless components would migrate superiorly as the patient increased loading if the component had not been seated properly. However, only four patients had positive migration in the y-axis greater than 0.2 mm suggesting that the components were seated correctly at the time of surgery. There may also have been concern that the cementless femoral component, which relies on an interference fit for its initial stability would be prone to movement, particularly rotation around the y-axis which is

nearly parallel to the peg. The second peg was added to counteract rotation and succeeded in doing so, with the magnitude of rotation around the y-axis similar in each group. The significant difference in R*y* between the first and second post-operative years may be explained by the addition of the second peg in the cementless component. The cemented component had a significant increase in internal rotation in that time period, whereas the cementless component had very little movement in external rotation. By the second year the components would expect to be seated and firmly fixed. If, however, there is still a considerable force applied to the femoral component tending to cause internal rotation, it may be that the second peg is able to resist the force, whereas the cement-bone interface is not. A study of single and two peg cemented femoral components may be useful to further establish whether an additional peg is protective to internal rotation.

The absence of any radiolucencies of the femoral component was in keeping with previous studies that have demonstrated that femoral radiolucencies are uncommon. It should be highlighted that due to the geometry of the femoral component it is possible that a small radiolucency, particularly around the peg, may be difficult to see. This work highlights that the amount of migration seen clinically, combined with the forces across the component/cement/bone interfaces, does not predispose to the formation of radiolucency. This may be unsurprising when the shape of the component/bone interface is considered. The underside of the femoral component is a portion of a sphere and fully congruent with the femoral condyle that is prepared with a mill to be the same spherical portion. Therefore, translation in any axis results in the same relative movement of one sphere on another. The same is true of rotation, with the added factor that the congruency between the two surfaces does not change. It is, therefore, reasonable to assume that within the amount of migration seen clinically that the interface does not undergo sufficient force transmission to stimulate a change from bone to soft tissue.

The main difference in migration of the tibial component between the two fixation types was in the y-axis, manifested as subsidence. The cemented tibial component appeared to have very little subsidence at three months, which had only slight progression over the subsequent time points. This is to be expected as the cement used is designed as a grout, rather than an adhesive and provides interdigitation between the component and the bone. As the cement achieves its final shape intraoperatively any significant subsequent subsidence would have to be the result of collapse of either the cement structure, which would cause loss of fixation, or the underlying bone. In contrast, the cementless components subsided significantly more by three months but stabilised over the subsequent time points. Between the first and second post-operative year there was a small significant increase in subsidence for both fixation types of approximately 0.05 mm. Although the cementless group had greater subsidence overall at two years it is important to note that only a single component subsided more than 0.15 mm in the second year, in contrast to the cemented group where four components subsided greater than 0.15 mm. This further emphasises that the cementless tibial component has increased early subsidence but stabilises by the end of the first post-operative year. The cemented components that subsided more than 0.15 mm in the second year all had associated radiolucencies and hence suggests that the underlying soft tissue is a manifestation of lack of stability.

The results for the cemented component highlight the potential difficulty in analysing a group in its entirety. If an arbitrary cut off of a MTPM greater than 1 mm is taken, forming two groups for each fixation type, then subsidence at two years shows a marked difference between groups for the cemented tibial component, but not for the cementless component (Table 4-20). Thus, the cemented group may contain implants that are stable, the majority, and those that are loose. However, without

survival data it is not possible to establish a level of migration that is definitely indicative of impending failure.

	MTPM	X	Y	Z	Rx	Ry	Rz
Cemented	< 1 (n=17)	0.03	-0.06	0.01	-0.05	0.13	-0.27
	>1 (n=3)	0.24	-0.50	0.14	-0.85	-0.50	-0.49
	All (n=20)	0.06	-0.13	0.03	-0.17	0.03	-0.31
	p-value >1 v <1	0.23	0.00	0.37	0.06	0.02	0.62
Cementless	< 1 (n=15)	0.04	-0.28	-0.02	-0.12	0.09	0.04
	>1 (n=6)	-0.07	-0.48	0.00	-1.10	0.59	-0.16
	All (n=21)	0.01	-0.34	-0.02	-0.40	0.24	-0.01
	p-value >1 v <1	0.24	0.07	0.81	0.00	0.09	0.51

Table 4-20 Migration at two years for the tibial component with results divided based on MTPM of greater or less than 1 mm, for both fixation types.

It would seem that the increased subsidence of the cementless components did not have an effect on clinical outcome and, interestingly, appeared to have a trend towards being protective against the development of radiolucency. It has been suggested that initially the cementless component is sometimes not seated properly, perhaps because the operating surgeon is wary of using too much force and causing a plateau fracture, but subsides subsequently[63]. It may be that this is what is observed in this study, particularly when the subsidence is seen between the initial radiograph and the first follow-up point with no further significant subsidence.

In contrast to the femoral component the geometry of the tibial component means that migration of the tibial tray in the *x*- or *z*-axis will cause shear at the component/bone interface, whereas migration in the *y*-axis (subsidence clinically) will result in increased compression. Rotation in the *x*- or *z*-axis will result in

compression at the interface where the component is moving inferiorly, but tension at the opposite end of the component. In contrast rotation around the y-axis will result in shear at the interface beneath the tray, but compression/tension at each side of the keel. Therefore, a different combination of migrations can result in different forces across the interface.

Looking at the boxplots of tibial subsidence (Figure 4-10) it is obvious there is a single case in the cemented group that is initially an outlier and then an extreme outlier. Using Ryd's categorisation of continuous migration this patient is likely to fail within the next ten years. This patient also highlights the difficulty in clinically identifying patients who are likely to fail. This patient had a pre-operative OKS of 24, which improved to 45 by one year and then subsequently to 47 by two years. The subsidence by two years was 0.91 mm, with a significant increase in posterior slope, 2.86°, and a MTPM of 2.25 mm. The radiographs demonstrated a full radiolucency (Figure 4-18).

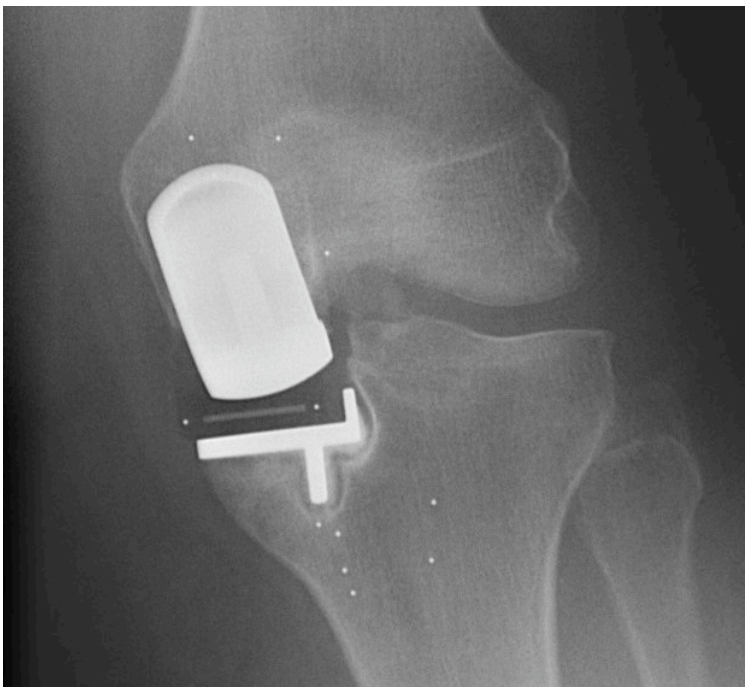


Figure 4-18 Radiograph at 6 months of a patient with a continuously migrating tibial component.

The radiolucency was less than two millimetres thick with a sclerotic line laterally but not medially, which would make it difficult to classify as either physiological or pathological. Two contrasting explanations present themselves, firstly, that a continuously migrating component is going to fail over the next few years, as predicted using Ryd's criteria. Alternatively, the unique mechanical environment of the OUKR, with a mobile bearing and thus nearly all the force across the interface being compressive, will dictate that the soft tissue and the dense sclerotic bone will provide a stable platform and the migration will stop.

There are two observations regarding the radiolucencies beneath the cementless tibial components. The first is the absence of a sclerotic line beneath the partial radiolucencies with the exception of zone 6. This suggests that there may be a different cause for the formation of a radiolucent area depending on where it occurs. In zone 6, rotation around the *z*-axis, increasing component valgus, would cause an increase in compression, with a corresponding increase in tension in zones 1 and 2. Zone 3 would have a smaller increase in compression, with tension in zone 5 and shear in zone 4. Therefore, the larger increase in compression in zone 6, as opposed to the different forces in other zones, is likely to be the cause of bony resorption and replacement with soft tissue with an underlying line of dense sclerotic bone. In reality however it is likely that a combination of migration, rather than isolated rotation around the z-axis causes the required pattern of force to create a sclerotic line beneath a radiolucency. The second observation regards the appearance of a radiolucency around the tip of the keel, without extension to the tray. This has not been identified before under the cemented component. The lack of proximal extension suggests that the radiolucency must be due to compression, caused by subsidence or increase in posterior slope, as rotation would cause the entire keel to move. A possible explanation for an increase in compression at the tip

of the keel is the inadequate clearance of the cut bone during preparation of the keel slot. If the slot has debris at the base then improper seating of the tibial component would occur, even with adequate force applied. This has previously been observed in the post-operative radiograph. Thus, the majority of weight-bearing force would be through the relatively small keel tip, with a large associated increase in force in the small area of underlying bone. This bone would then be resorbed due to the extreme compression, following the Utah paradigm of Woolf's law[161], allowing the component to subside. Once subsidence had occurred to the point that weight was borne throughout the tray on the prepared tibial surface rather than just the keel tip, the force beneath the keel would return to normal and bony ingrowth to the hydroxyapatite surface could occur. The postulated theory about slow subsidence of the cementless components may explain why there is an apparent inverse correlation between subsidence and the formation of radiolucency. The large forces transmitted across the tibial component may cause the underlying bone to be resorbed, thus accommodating the component. In contrast, it may be that with the cemented components the force applied to the underlying tibia is within a range that causes resorption of bone and subsequent development of soft tissue. Thus, there is rapid stabilisation and no further stimulus for differentiation, explaining why physiological radiolucencies do not progress.

The main limitation of this study is the number of patients with a full radiolucency. The study was powered to detect a difference of 200 μm in migration between types of fixation, and thus assess likelihood of failure using short-term data. However, the presence of a full radiolucency in cemented OUKR is felt to be an indicator of sub-optimal fixation and therefore it is desirable to have many patients with a full radiolucency to study. The number of full radiolucencies present in the cemented group was slightly less than might be expected (approximately one third of all

cemented OUKR are reported to have a full radiolucency[69]). More full radiolucencies may have allowed more accurate analysis of those migratory factors that were associated with their development. A second limitation relates to interpretation of the results regarding clinical outcome, the relationship between radiolucency and subsidence and those implants that migrated more than 0.15 mm in the second post-operative year. The study was powered to detect a migration difference at two years of 200 μm and, therefore, some caution is required when analysing results of other outcomes. However, the results highlight some potential patterns that would benefit from further study.

5 The Effect of Tibial Component Shape on the Development of Radiolucency

5.1 Introduction

The original Oxford lateral compartment replacement was identical to the medial device. Indeed, Goodfellow and O'Connor initially designed the Oxford UKR to be used as a bicompartmental replacement[162,163]. Although the original results were promising, with good restoration of function and reduction of pain[164], the lateral compartment replacements had an unacceptably high bearing dislocation rate[165]. The original lateral replacement used the same bearing as the medial side but was changed to have a higher posterior lip to attempt a reduction in dislocation rate. This change in bearing was coupled with a modified surgical technique (lateral parapatellar approach and division of popliteus) to further prevent dislocation. This brought down the dislocation rate from 10% to 5%, which was still unacceptably high. Therefore a modification was made to the tibial component. The native lateral tibial plateau is convex rather than flat. The new tibial component was also concave, with a radius of curvature similar to the normal knee. This further change, combined with the improved surgical technique reduced the dislocation further to an acceptable 1.7%[166].

The sagittal plane kinematics, expressed as the patellar tendon angle, of a knee that has been replaced with a flat mobile bearing replacement are unchanged compared to a native knee[167]. This similar kinematic profile was maintained when the domed tibial component was introduced, but with an increased flexion range when compared to the flat component[168]. Therefore, it would appear that the introduction of the domed tibial component greatly reduced one problem, dislocation, and allowed more

normal knee kinematics with improved deep knee flexion due to the bearing moving posteriorly without tightening the knee.

Although not formally reported in the literature it has been anecdotally noted that the prevalence of radiolucency beneath the tibial tray, either flat or domed, in the lateral compartment is less than in the medial compartment[169]. As both the indications for surgery and surgical technique are similar, as well as the patient cohort for each implant being the same it would suggest the reason for the difference in development of radiolucency is mechanical. The two compartments have different kinematic profiles and although the forces going through the tibial component are nearly entirely compressive, each mobile bearing has a different excursion. The lateral compartment bearing moves more posteriorly, almost off the back of the tibial component. This posterior movement is even more marked with the domed component. The increased posterior movement would result in tensive forces at the anterior of the flat tray and an anteriorly directed shear force in the domed tray. A second consideration is the reduced weight bearing through the lateral compartment compared with the medial compartment[170], even when there is a valgus deformity that is seen in lateral compartment osteoarthritis [171].

Further mechanical factors have not been identified that may result in reduction in prevalence of radiolucency in the lateral compartment following arthroplasty. This chapter aims to establish the true prevalence of radiolucency in both flat and domed lateral compartment arthroplasty and to evaluate whether component alignment, limb alignment or surgical errors are associated with the development of radiolucency.

5.2 Study Design

The study was designed as a retrospective comparative study between two cohorts of patients; those who had received a flat lateral UKR and those who had received a domed lateral UKR, in a single specialist centre. The primary outcome measure was prevalence of radiolucency beneath the tibial component.

5.2.1 Patient Selection

The database of patients undergoing lateral compartment UKR at the Nuffield Orthopaedic Centre has been running since November 1999. All patients operated on by Prof. Murray, Mr Dodd or Prof. Price had full demographic details and intra-operative findings entered. As well as patient demographics, pre-operative and post-operative Oxford Knee Scores (OKS) and Tegner[172] scores at one year were recorded. The Tegner activity score is a surrogate marker for the number of cycles a joint is put through as it is an assessment of a patient's activity level. The score is between one and ten, from basic daily activity to participation in sports to an international level. All patients receiving a lateral compartment UKR were included, with no exemption for age, sex or previous surgery. This is to give as true a prevalence of radiolucency as possible in "all comers". Surgical technique was unchanged between groups, with the components implanted to recreate the normal anatomy and to allow insertion of a bearing of appropriate thickness in extension. All components were cemented.

5.2.2 Radiology

All patients had post-operative radiographs before discharge from hospital. The radiographs were aligned, as previously described, to be parallel to the tibial tray. This enabled accurate assessment of the tibial tray/cement/bone interface. Patients then underwent repeat radiology annually. Those radiographs that were incorrectly aligned were discarded.

5.2.3 Radiograph Acquisition

All radiographs were assessed in a standardised manner by two assessors, independently of each other. Images were acquired either by scanning printed hard copies, from before the introduction of PACS (Patient Archiving and Communication System), or from the export facility in PACS. All images were in jpeg format and exported or scanned in 72 dpi to the appropriate resolution to capture the entire image (no less than 1024 x 1024). All images were corrected for magnification by circle fitting to the femoral component using a customised Matlab routine (courtesy of Hans Gray). This enabled accurate measurement regardless of radiographic magnification.

5.2.4 Radiographic Assessment Parameters

Assessment of radiolucency was in the same manner as previously described (Figure 4-4) adapted for the lateral compartment where zone 1 is most lateral through to zone 6 which is medial beneath the tibial tray. Prevalence of radiolucency could then be established.

Limb alignment was calculated using ImageJ (Image processing and analysis in Java, National Institute of Health, USA) on the available AP knee radiographs. Long leg views were not available but the work by Colebatch et al demonstrates the reliability of using standard AP knee radiographs[173]. The centre of the most proximal femoral diaphysis and most distal tibial diaphysis was established and the angle subtended between those points and a central point between the tibial spines taken as the limb alignment. A line parallel with the underside of the tibial tray was established using the same Matlab routine that scaled the radiographs. A perpendicular was then dropped from the centre of the femoral component to the tibial tray. Where this intersected with the tray gave the centre of the bearing and thus an estimation of whether the bearing was impinging on the vertical wall (Figure 5-1). A value of >0.5 indicates the bearing is laterally placed and a value <0.5 indicates the bearing is medially placed and thus at risk of wall impingement.

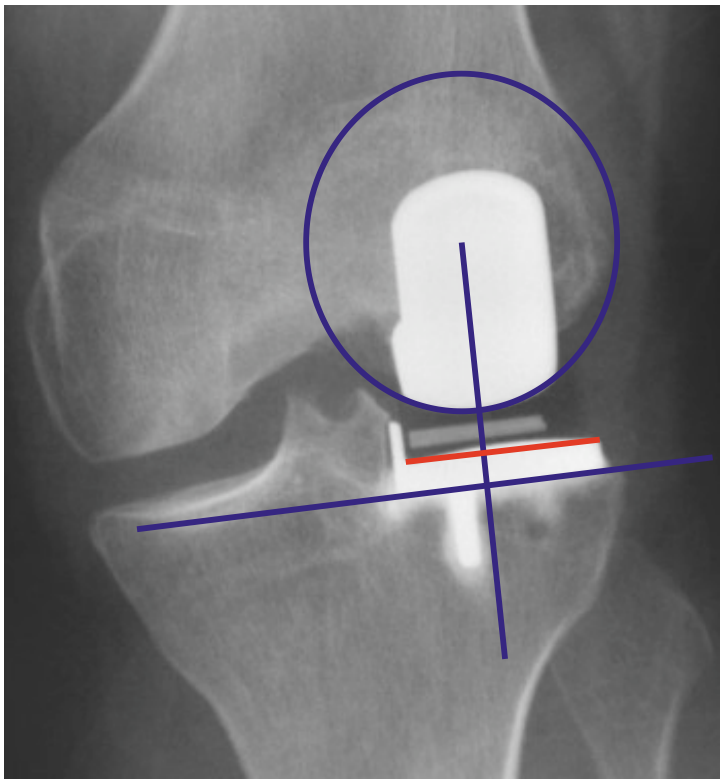


Figure 5-1. The method for calculating the centre of the bearing, a perpendicular dropped from the centre of the femoral component to a line parallel with the tibial tray (this example demonstrating wall impingement).

Further assessments on the AP radiographs included the depth of the initial vertical saw cut and the depth of the horizontal cut beneath the tibial spines (Figure 5-2).

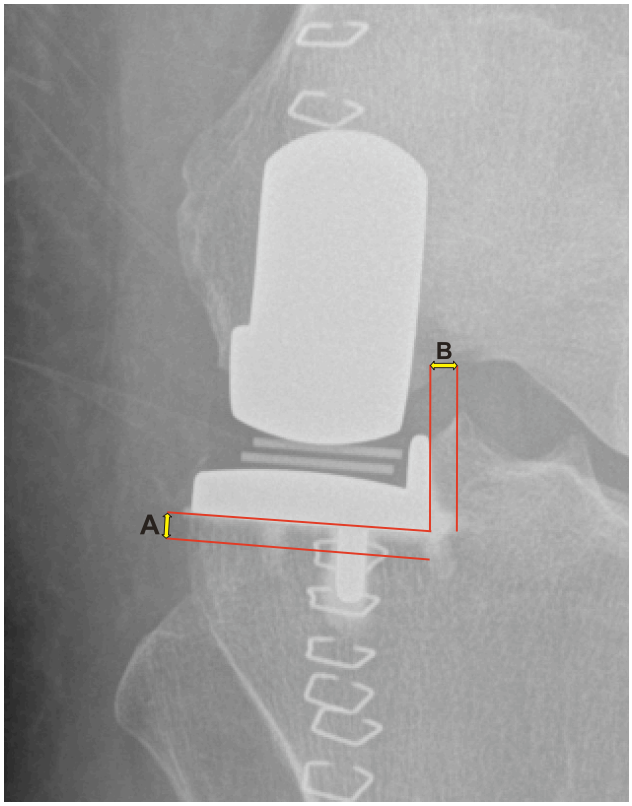


Figure 5-2 Diagram demonstrating the measurement of the vertical saw cut depth (A) and the depth of the horizontal saw cut beneath the tibial spines (B).

A further measurement was taken of the clearance between the anterior part of the femoral component and the bone of the condyle. In full extension the bearing can impinge on the anterior bone, which causes an increased rate of polyethylene wear and thus is a possible cause of both radiolucency secondary to osteolysis and thus implant failure[150,151].

5.3 Results

Sixty-one patients received a flat lateral Oxford UKR between November 1999 and August 2004. 199 patients received a domed lateral Oxford UKR between August 2004 and September 2009. Of those patients, 42 flat and 146 domed implants had acceptable radiographs both post-operatively and after at least one year. There were similar demographics for both types of tibial component with a greater number of right sided joints being replaced and more female patients undergoing surgery (Chi-squared, p=0.669 and 0.207 respectively), however there was a significant difference in age between groups (t-test, p=0.036) (Table 5-1).

	Flat (n=40)	**Domed (n=146)**
Mean Age (range)	57.1 (38.6 – 77.7)	62.2 (31.7-84.9)
Side (R:L)	25:15	99:47
Sex (M:F)	16:24	44:102

Table 5-1 Patient demographics for both the flat and domed lateral tibial components. The flat component had a significantly lower mean age but a similar preponderance for right knees and female patients.

5.3.1 Prevalence of Radiolucency

There was a significant difference in prevalence of both partial and full radiolucencies beneath the two types of tibial tray (Chi squared, p<0.001) with proportionally more radiolucencies of both types present with the flat tibial component (Table 5-2).

	Flat	Domed
No Radiolucency (%)	16 (40%)	127 (87%)
Partial Radiolucency (%)	21 (53%)	14 (10%)
Full Radiolucency (%)	3 (7%)	5 (3%)

Table 5-2 Prevalence of radiolucency between the flat and domed lateral tibial component There was a significant decrease in the prevalence of radiolucency in the domed lateral component.

Further investigation of the flat tibial component demonstrated that none of the measured variables were significantly different between those patients with a radiolucency (either partial or full) and those without a radiolucency (Table 5-3).

	No Radiolucency (n=16)	Partial Radiolucency (n=21)	Full Radiolucency (n=3)	p-value
Age	57.5 (10.6)	57.9 (10.2)	49.0 (13.2)	0.389
Alignment	177.1 (2.6)	176.4 (2.2)	175.2 (1.7)	0.411
Bearing position	0.40 (0.04)	0.40 (0.04)	0.41 (0.04)	0.827
Vertical saw cut	2.91 (1.29)	2.85 (1.82)	1.30 (1.21)	0.271
Horizontal saw cut	1.95 (1.02)	1.89 (1.45)	2.20 (1.97)	0.931
Anterior impingement	3.44 (1.90)	3.61 (2.71)	4.87 (2.14)	0.638

Table 5-3 Mean (SD) values for each variable for no, partial and full radiolucency in the flat lateral tibial component. p-value calculated using ANOVA.

Analysis of the radiographic parameters for the domed tibial component demonstrated that there was no significant difference for any variable between those patients with a radiolucency and those without (Table 5-4).

	No Radiolucency (n=127)	**Partial Radiolucency (n=14)**	**Full Radiolucency (n=5)**	**p-value**
Age (years)	58.0 (18.1)	61.9 (21.1)	71.6 (9.8)	0.217
Alignment (degrees)	174.7 (2.7)	175.5 (2.6)	177.3 (2.1)	0.071
Bearing position (ratio)	0.52 (0.05)	0.52 (0.04)	0.52 (0.05)	0.469
Vertical saw cut (mm)	1.67 (0.91)	1.52 (1.16)	1.78 (0.84)	0.836
Horizontal saw cut (mm)	2.25 (1.10)	1.85 (1.45)	1.80 (1.26)	0.400
Anterior impingement	5.28 (2.42)	5.74 (2.08)	6.92 (1.56)	0.356

Table 5-4 Mean (SD) values for each variable for no, partial and full radiolucency in the domed lateral tibial component. P-value calculated using ANOVA.

5.3.2 Surgical Parameters between Tibial Components

There was a significant difference between tibial component types for limb alignment, bearing position, vertical saw cut and clearance of the anterior condyle ($p<0.001$ for

all variables). There was no difference for the horizontal saw cut depth (p=0.219) (Table 5-5).

	Flat (n=40)	Domed (n=146)
Alignment (degrees)	176.6 (2.4)	174.8 (2.7)
Bearing position (ratio)	0.40 (0.04)	0.52 (0.05)
Vertical saw cut (mm)	2.76 (1.61)	1.66 (0.92)
Horizontal saw cut (mm)	1.94 (1.30)	2.20 (1.14)
Anterior clearance (mm)	3.64 (2.35)	5.37 (2.39)

Table 5-5 Mean (SD) for measured surgical parameters for the two types of lateral tibial component.

5.3.3 Outcome

For all patients there was no difference in OKS either pre-operatively or at one year for the two types of tibial component (Table 5-6). There was a difference in the improvement of the OKS between pre-operatively and at one year.

	Flat (n=40)	Domed (n=146)	p-value
Pre-operative OKS	22.7 (4 to 39)	22.9 (5 to 40)	0.930
One year OKS	35.6 (7 to 48)	38.9 (13 to 48)	0.067
Change in OKS	11.8 (9.7)	15.8 (8.7)	0.032

Table 5-6 Oxford Knee Scores pre-operatively and at one year for the two types of tibial component.

There was no difference in either pre-operative OKS (p=0.520) or OKS at one year (p=0.719) between those patients with a radiolucency and those without a

radiolucency in the flat tibial component group. Similarly, there was no difference in the OKS at either time point (p=0.643 and 0.522) for the domed tibial component (Table 5-7).

		No Radiolucency	Radiolucency
Flat Tibial Component	Pre-operative OKS	21.6 (4.8)	23.5 (9.6)
	One Year OKS	34.8 (10.4)	36.1 (11.5)
Domed Tibial Component	Pre-operative OKS	23.0 (7.8)	21.8 (10.3)
	One Year OKS	38.9 (8.8)	37.4 (9.1)

Table 5-7 Mean (SD) scores for both types of tibial component pre-operatively and at one year dependent on whether a radiolucency was present or not.

There was no difference in Tegner score between the two types of tibial component (flat mean 3.00, domed mean 2.73, p=0.183). There was also no difference in Tegner score depending on whether a radiolucency was present or not for the flat component (p=0.723) or the domed component (p=0.440) (Table 5-8).

	No Radiolucency	Radiolucency
Flat Tibial Component	2.93 (0.96)	3.05 (0.97)
Domed Tibial Component	2.76 (0.96)	2.53 (1.64)

Table 5-8 Mean Tegner activity scores (sd) for both types of tibial component depending on the presence or absence of radiolucency beneath the tibial component.

5.4 Summary of Results

- There is a significant difference in the prevalence of radiolucency beneath the flat and domed tibial components, with over a four-fold increase in the flat tibial component.
- Age, limb alignment or position of the bearing do not affect the prevalence of radiolucency for either type of tibial component.
- Surgical saw cut errors for tibial preparation are not associated with the development of radiolucency but there is a significant difference between types of tibial component.
- There is no difference in outcome at one year between patients with or without a radiolucency.

5.5 Discussion

The difference in prevalence of radiolucency between the two types of tibial component is significant. The patient cohort for both types of tibial component is the same, i.e. those patients with isolated lateral compartment osteoarthritis with symptoms severe enough to warrant arthroplasty, and the demographics of those patients, except age, are also the same in each group. Furthermore, with the exception of the tibial component itself, the surgical procedure, including the cementation technique, was unchanged between groups. Therefore it is reasonable to assume that the difference in prevalence is related to the change in implant geometry and, thus, the kinematics.

Although none of the surgical parameters were individually associated with the development of radiolucency there are some unexpected observations. With little

difference in surgical technique it is surprising that four of the five surgical parameters showed a significant difference between components. The differences may be explained by the surgical learning curve. There have been significantly more procedures performed in the last five years compared with the previous five. Therefore each surgeon has been performing over three times as many lateral UKRs in any given time frame for the domed component compared to the flat component. All of the differences were an improvement in the domed group suggesting that the surgeons were subtly modifying their technique to try and improve outcome. For example, leaving the patient in greater valgus reduces the risk of progression of OA in the medial compartment and increasing the gap between the femoral component and the anterior condyle reduced the risk of bearing impingement. This is manifested as improved outcome, with a significantly increased change in OKS between pre-operatively and at one year. The increase in OKS at one year is probably due to less pain as the lateral collateral ligament is no longer too tight in flexion with the posterior movement of the bearing.

It is also interesting to note that outcome was not affected by the presence of radiolucency, which is in keeping with the work on the medial compartment OUKR[69]. This further supports the suggestion that a thin, non-progressive radiolucency is the radiological manifestation of a stable construct and is important in the lateral compartment where bearing movement is greater than that in the medial compartment.

The main weakness of this study is the relative lack of flat tibial components to study compared to domed components. Although there are enough flat components to allow comparison, equal groups would provide stronger data. The concern over increased bearing dislocation with the flat tibial component restricted its use. It may also explain the difference in patient age between flat and domed components. The

mean age for the flat component was 57.1 years, which is young for knee arthroplasty. With concern over dislocation it may have been decided that those patients of older age may benefit from TKR for single compartment disease rather than accept the risk of dislocation. With the advent of the domed component, and the theoretical reduction in dislocation risk, those patients who previously would have had a TKR instead received a UKR.

A potential hypothesis for the reduction in radiolucency beneath the domed tibial component is suggested by studying the femoral component. It has long been known, anecdotally[169], that there is a different prevalence of radiolucency between the cemented femoral and tibial components, a finding which is supported by the findings from chapter 4. It has been hypothesised that the femoral component, due to its shape, hides a thin radiolucency. However, the screened images are aligned with the main curvature of the component and the cement pocket is filled with cement, therefore the interface between cement and bone should be visible. Therefore, there is truly a very low prevalence of radiolucency beneath the femoral component. A hypothesis is that the vector of force applied to the component changes as the knee moves through a range of motion. In full extension there is force applied perpendicularly to the interface at the anterior portion of the component, whilst in full flexion there is the same force applied to the posterior portion of the component. This observation may explain the reduction in radiolucency with the domed tibial component. It, like the femoral component, is a partial sphere, although with a significantly greater radius. The bearing moves around the circumference of the tibial component applying a force vector that changes when the knee moves through a range of motion. The movement is less than for the femoral component, but greater than for the flat tibial component. This may explain why the prevalence of radiolucency lies between that of the femoral component and the flat tibial component. An avenue of further study would focus on

movement of the domed tibial component, and in particular whether the domed bearing causes increased micromovement. The movement is likely to be translation anteriorly, secondary to the effect of a shear force, and rotation around the *x-axis*, secondary to the increased posterior movement of the domed bearing. A RSA study of the domed lateral UKR would allow assessment of those potential migrations and their effect on the development of radiolucency.

6 Lateral Unicompartmental Knee Replacement: Introduction of Shear

6.1 Introduction

Isolated lateral compartment disease is less common than on the medial side. However, it still presents approximately 10% of all unicompartmental knee replacement surgery. It is commonly performed using the same prosthesis as on the medial side. Results using a variety of prostheses in lateral unicompartmental replacement have been acceptable[165,174,175]. The reasons for failure are similar to medial surgery with progression in the other compartments and loosening of the components. With regard to the Oxford Lateral UKR, an additional failure mode was evident: dislocation of the mobile bearing. Gunther reported a dislocation rate of 10%, with the majority occurring early after implantation[165]. After recognition of the increased dislocation rate both the surgical technique and bearing design were modified. The bearing was altered to increase the amount of entrapment, and hence increase the amount of distraction between the femoral condyle and tibial plateau required to allow dislocation of the bearing. A study by Robinson et al identified further contributory surgical factors that could increase the chance of dislocation, with the most important factor being an increased tibial varus[176].

There are two common surgical factors that can affect alignment and cause an increased varus deformity. Firstly, putting in a bearing that is too thick and, secondly, making a horizontal tibial cut of insufficient depth without sufficient removal of bone from the femur. Both surgical errors have the effect of stretching the lateral collateral ligament (LCL) and raising the lateral joint line. In contrast to the medial collateral ligament (MCL), which is the same length through a full range of movement of the knee, the LCL is tight in knee extension but lax in knee flexion. Therefore, if the

lateral compartment is "overstuffed" through either of the aforementioned methods the LCL is stretched in full extension. This then permanently lengthens the ligament and allows an even greater level of laxity when in flexion. It is this increased laxity that presumably predisposes to bearing dislocation. This is particularly important when considering the amount of laxity evident in a normal lateral compartment. Tokuhara et al demonstrated the difference in the amount of joint opening between the medial and lateral compartments under varus and valgus stress[177]. The results showed the lateral compartment opened a mean of 6.7 mm under varus stress compared with 2.1 mm medially under valgus stress. Therefore the amount of opening is often greater than the entrapment of the mobile bearing. With the addition of a stretched LCL it can be appreciated why the dislocation rate was so high.

6.2 Oxford Domed Lateral UKR

The domed tibial component of the Oxford UKR used in the lateral compartment was developed to further reduce the dislocation rate, but also has potential kinematic advantages over the flat component. Although the convex lateral tibial plateau is polyradial Baré et al showed, using cadaveric specimens, that a lateral compartment component with a radius of 75 mm allowed a full range of movement up to 160° while maintaining the kinematics of a normal knee[178]. This was confirmed when van Duren et al performed an *in vivo* study of implanted lateral UKRs and found the domed tibial component provided a greater range of movement when loaded compared to the original flat lateral prosthesis and had near normal kinematics[168]. The clinical results of the new design regarding dislocation are encouraging with the primary dislocation rate at 0% and the secondary dislocation rate of 1.7%[166]. Although the results are for short to mid-term follow-up dislocation is most often an early problem[179] and it is likely that that the dislocation rate will not increase significantly with longer follow-up.

6.2.1 Change in Loading with the Domed Tibial Tray

The forces at the interface between the original flat tibial tray used in the lateral unicompartmental replacement and the proximal tibia were almost all compressive. The mobile bearing had some posterior movement in flexion that may have produced some tension in the anterior portion of the component. In contrast, the domed component allows a greater posterior movement of the bearing. This increased movement, coupled with the domed tray may have two effects. Firstly, the potential for tension in the anterior portion of the tray may be increased. Secondly, the vector of the compressive force will be altered, thus introducing some shear in addition to the normal compression (Figure 6-1).

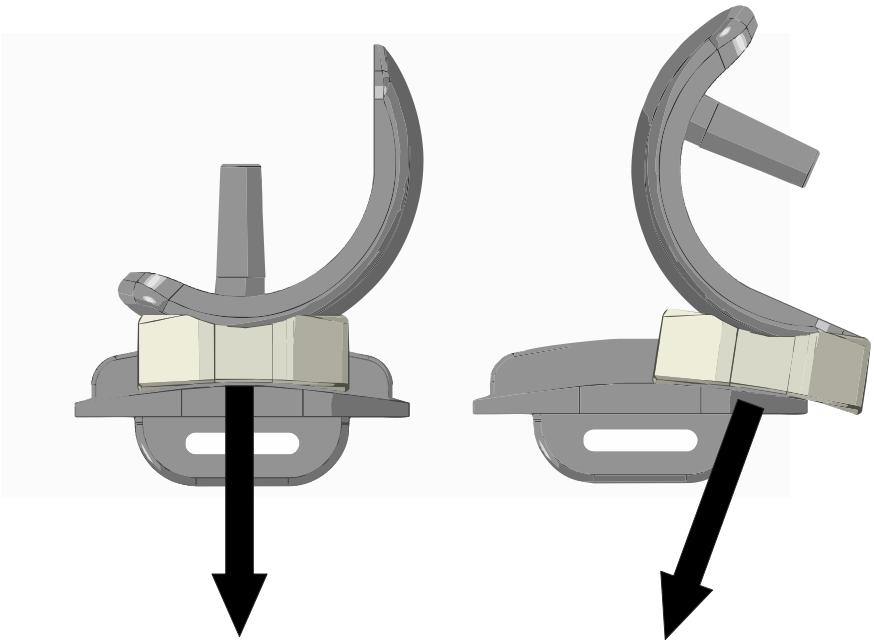


Figure 6-1 Change in force vector with flexion in the domed tibial component.

These additional forces may also result in a different pattern of migration of the domed component, with increased anterior translation or posterior slope.

6.2.2 Domed Lateral UKR and Radiolucency

As has been shown in the previous chapter the addition of the domed tibial component reduces the prevalence of radiolucency compared with the flat lateral tibial component. The prevalence of the domed component is also lower than the flat medial tibial tray. As the patient cohort is the same between groups and the method of fixation, cementation, is the same, it is logical that the different forces across the component/cement/bone interface are the cause of the different bony response to unicompartmental replacement. Chapter 4 demonstrated that implants with different patterns of migration have a different prevalence of radiolucency, with those implants that migrate further, albeit only a small amount, provoking a different response from the underlying bone, and hence a lower tendency to form soft tissue at the interface. The potential increase in anterior tension and shear across the whole interface with the domed component may be the reason for change in the prevalence of radiolucency. Therefore, it is important to establish the migration pattern of the domed components to assess whether the change in radiolucency is due to force transmission with or without component movement. As radiolucencies are known to develop within the first year following implantation, and do not progress if physiological, it can be assumed that it is the initial movement that is most important.

6.3 Study Design

6.3.1 Overview

A prospective cohort study was designed with the primary aim to characterise the migration pattern of the cemented domed lateral OUKR. The secondary aim was to see whether a change in migration is related to the presence of radiolucency.

6.3.2 Patient Selection

All patients undergoing lateral UKR for isolated lateral compartment osteoarthritis at the Nuffield Orthopaedic Centre under the care of Prof Murray, Mr Dodd, Mr Jackson or Prof Price were invited to participate. Exclusion criteria were previous surgery to the affected knee (excluding arthroscopy +/- menisectomy), previous intra-articular infection or ASA > 3. Patients over the age of 75 were not invited to prevent an unacceptably high drop out rate. Informed consent was obtained. The study was approved by the Oxfordshire Ethics Committee (09/H0605/13).

Patient demographic data were collected on all patients as well as the intra-operative findings for the affected compartment along with the ACL and the contralateral and patellofemoral compartments. Implant sizes were noted. The standard indications were followed, where patients received a UKR if they had a functioning ACL and had only mild cartilage damage in the other compartments.

6.3.3 Surgical Technique

All procedures were performed by one of four specialist knee surgeons with extensive experience of the device, as well as a full understanding of the principles of implantation. The principles behind lateral UKR differ considerably from those of the medial compartment. Medial UKR aims to replace the worn articular surfaces and restore ligamentous balance. The methods for balancing ligamentous tension are explained in full in Chapter 4. With the lateral compartment ligamentous balance cannot be achieved due to the laxity of the LCL in flexion. Therefore, the principle of restoring the normal anatomy and placing the articular surfaces of the components in the position of the pre-disease joint articular surfaces is employed. The aim is to

have the chosen bearing just gripped in extension but loose in flexion. This enables the bearing to move normally and provide a full range of movement while not increasing the risk of dislocation. The standard components were used. There are four sizes of tibial component (A – D) and three sizes of femoral component (small – large). Bearings, which are biconcave, were available in the same sizes as for medial UKR (3-9). Both the femoral and tibial components were cemented in standard fashion.

6.3.4 Insertion of Rigid Body Markers

The same pattern of rigid marker distribution was used in the lateral compartment as previously described in the medial compartment, with the femur having markers in each peg hole, in the intramedullary canal and anterior to the component. The tibia had markers beneath the keel slot and in to the opposite plateau. This ensured an easily repeatable distribution. The same pre-loaded ball injector (RS-M 08, Tilly Medical Products, Lund, Sweden) was used.

6.3.5 Post-operative Regimen

All patients were able to fully weight-bear as soon as they had adequate quadriceps control. There was no restriction on range of movement exercises and straight leg raising was encouraged.

6.3.6 Radiology

6.3.6.1 Radiostereometric Analysis

RSA stereoradiographs were obtained in the standard fashion using the same equipment as described in chapter 3. Each patient was radiographed standing in a normal double leg stance. Stereoradiographs were obtained post-operatively when weight-bearing could be tolerated and then at 3, 6, and 12 months. All RSA was performed using version 3.21 of the Medis Specials model based RSA software. The original DICOM images were used in all analyses. A single operator analysed all images and collected all of the migration data. Migration data was obtained in the routine fashion, with translations along the three axes and rotations around each of the axes. Maximum Total Point Motion (MTPM) was also calculated.

6.3.6.2 Fluoroscopy

Screened fluoroscopic films were obtained post-operatively, at three months and at one year when the patient attended for stereoradiograph acquisition. Fluoroscopic screening of the domed tibia is more difficult than with the flat component. The flat component allows easy assessment of the correct beam angle and rotation required. However, the domed tray does not allow easy assessment of the correct beam angle as it is difficult to judge when the domed upper surface is thinnest.

Each radiograph was assessed for radiolucency in the standard manner. The femoral component has six zones (Figure 4-3) and the tibial component seven zones, with only the weight bearing six zones assessed (Figure 4-4). For the lateral component the zones are reversed, with zone 1 being most lateral. This is to ensure consistency with the medial component. Zone 7, the non-weight-bearing zone was

disregarded. If any of the zones 1-6 had a radiolucency this was classified as partial. If all six zones were included the radiolucency was classified as full.

6.4 Data Analysis

Patient demographics were analysed to ensure a reasonable cohort was recruited with no significant difference from a cohort of cemented medial UKRs.

Intra-operative findings were also analysed to ensure there were no patients outside the standard indications, with particular emphasis on the state of the ACL. Implant demographics were recorded.

All translations and rotations were compared to those of the cemented medial components to allow analysis of whether the altered kinematics results in a different migratory pattern. However, the migration of greatest interest was forward translation (+ve *z*-axis) and increased posterior slope (-ve R*x*) as well as MTPM for overall migration. These particular migration parameters were also assessed against the presence of radiolucency as determined from the screened radiographs. Further analysis was performed on those stereoradiographs of those patients with full radiolucencies with the migration between three months and one year compared to those patients with no radiolucency.

All statistical analysis was performed using SPSS ver 18 (IBM, New York, USA).

6.5 Results

6.5.1 Patient Demographics

There were sixteen patients recruited who all received a standard cemented domed lateral UKR. The patient demographics showed there was a preponderance of female patients but an expected age distribution and an equal number of right and left joints (Table 6-1).

	Lateral UKRs (n=16)
Age (years, SD)	60.4 (10.7)
Sex (male:Female)	3:13
Side (right:left)	8:8

Table 6-1 Patient demographics for the domed lateral OUKR cohort. There was a preponderance of female patients but an equal distribution of sides.

6.5.2 Intra-operative Findings

The majority of patients had either a normal ACL or some synovial thinning, but all had a functioning ACL (Table 6-2). It was more common to find some patella femoral joint cartilage damage than not, but the damage was, in the main, superficial. None of the patients recruited had intra-operative findings that would count as a contra-indication to the routine use of the implant.

		Cemented Lateral OUKR
ACL	Normal	9
	Synovial thinning	5
	Longitudinal splits	2
	Friable and fragmented	0
Patella (Medial facet)	Normal	6
	Superficial	8
	PTCL	2
	FTCL	0
Patella (lateral facet)	Normal	6
	Superficial	8
	PTCL	2
	FTCL	0
Trochlea	Normal	5
	Superficial	7
	PTCL	4
	FTCL	0
Medial Compartment (femoral condyle)	Normal	6
	Superficial	7
	PTCL	3
	FTCL	0

Table 6-2 Intra-operative findings for all study patients receiving a domed lateral OUKR. Findings were determined by the operatibg surgeon using a standardised system of assessment.

6.5.3 Implant Demographics

An expected range of implants was used, with a preponderance of smaller implants than compared to medial UKR due to the lateral condyle and plateau being smaller in most patients (Table 6-3).

		Cemented Lateral OUKR
Femoral Component	Small	12
	Medium	3
	Large	1
Tibial Component	A	3
	B	8
	C	4
	D	1
Bearing	3	1
	4	4
	5	8
	6	3

Table 6-3 Implant demographics for all patients receiving a domed lateral OUKR in the cohort. There was a range of sizes used, as expected with male and female patients.

6.5.4 RSA results

6.5.4.1 Femoral Component Migration

There is a small amount of movement by three months with no further migration at

one year. There is no single direction of movement that predominates, with most migrations within the accuracy of the system, although there is some rotation in Rx, which is in line with the natural movement of the joint (Table 6-4). The only significant difference from zero migration was anteriorly in the *z*-axis ($p<0.05$ at all time points).

		X	***Y***	***Z***	**R*x***	**R*y***	**R*z***	**MTPM**
Three months	Mean	0.09	-0.10	0.20	0.06	-0.09	0.00	0.71
	Standard Deviation	0.26	0.30	0.27	0.56	0.72	0.81	0.22
	p-value	0.22	0.22	0.01	0.67	0.64	0.99	
Six months	Mean	0.05	-0.11	0.19	0.24	-0.08	-0.18	0.81
	Standard Deviation	0.44	0.24	0.24	0.67	0.83	1.11	0.34
	p-value	0.67	0.10	0.01	0.42	0.07	0.02	
One year	Mean	-0.02	-0.11	0.16	0.35	0.24	-0.13	0.77
	Standard Deviation	0.29	0.29	0.27	0.69	0.87	0.89	0.35
	p-value	0.79	0.20	0.04	0.08	0.31	0.60	

Table 6-4 Migration for the femoral component at each time point (mm for translations and degrees for rotations), P-value shown for calculated migration against zero migration, t-test.

The migration was nearly identical to that of the cemented femoral component in the medial compartment with no statistical difference for migration in any direction.

6.5.4.2 Tibial Component Migration

The tibial component had less overall migration than the femoral component and also stabilised by three months. There was no single direction of migration that predominated and in particular there was no subsidence and no significant increase of posterior slope (Table 6-5). There were three significant findings compared to zero migration. Firstly in the *y*-axis, with a slight increase at one year. Secondly, with increased internal rotation, R*y*, at three months that was maintained at one year. Thirdly, there was an increase in component varus at three months, also maintained at one year.

		X	***Y***	***Z***	**R*x***	**R*y***	**R*z***	**MTPM**
Three months	Mean	-0.04	0.02	0.01	-0.15	-0.23	-0.29	0.51
	Standard Deviation	0.19	0.17	0.14	0.49	0.46	0.43	0.21
	p-value	0.46	0.63	0.74	0.28	0.02	0.04	
Six months	Mean	-0.06	0.01	0.01	-0.07	-0.28	-0.22	0.48
	Standard Deviation	0.21	0.11	0.12	0.36	0.58	0.54	0.21
	p-value	0.30	0.83	0.63	0.50	0.08	0.13	
One year	Mean	-0.11	0.05	-0.02	-0.21	-0.31	-0.30	0.55
	Standard Deviation	0.27	0.09	0.12	0.44	0.50	0.49	0.23
	p-value	0.11	0.04	0.42	0.07	0.02	0.03	

Table 6-5 Migration for the lateral domed tibial component at each time point (mm for translations and degrees for rotations), P-value shown for calculated migration against zero migration, t-test.

The migration was nearly identical to that of the cemented tibial component in the medial compartment with no statistical difference for migration in any direction.

Importantly, there was no difference in MTPM (Figure 6-2), anterior translation in the *z*-axis (Figure 6-3) or increase in posterior tibial slope (rotation around the *x*-axis) (Figure 6-4).

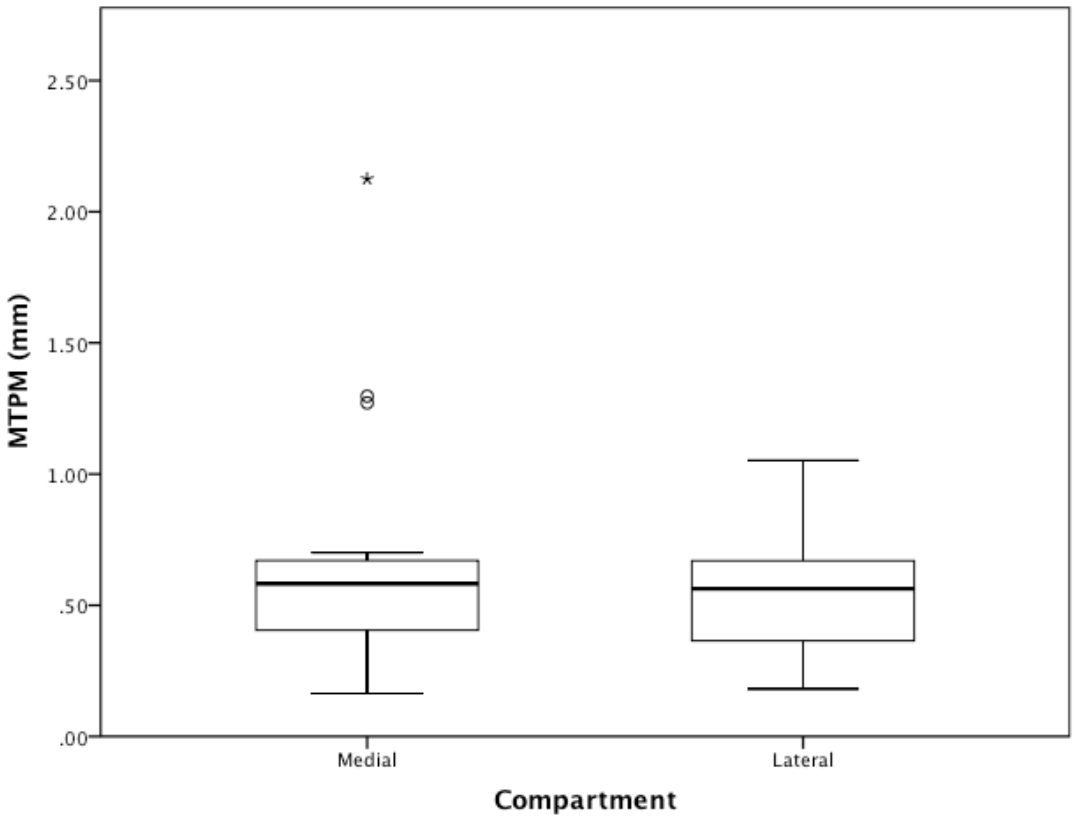


Figure 6-2 A boxplot showing the Maximum Total Point Motion for the medial and lateral cemented tibial components. The medial component has three outliers, whereas the lateral domed component has none.

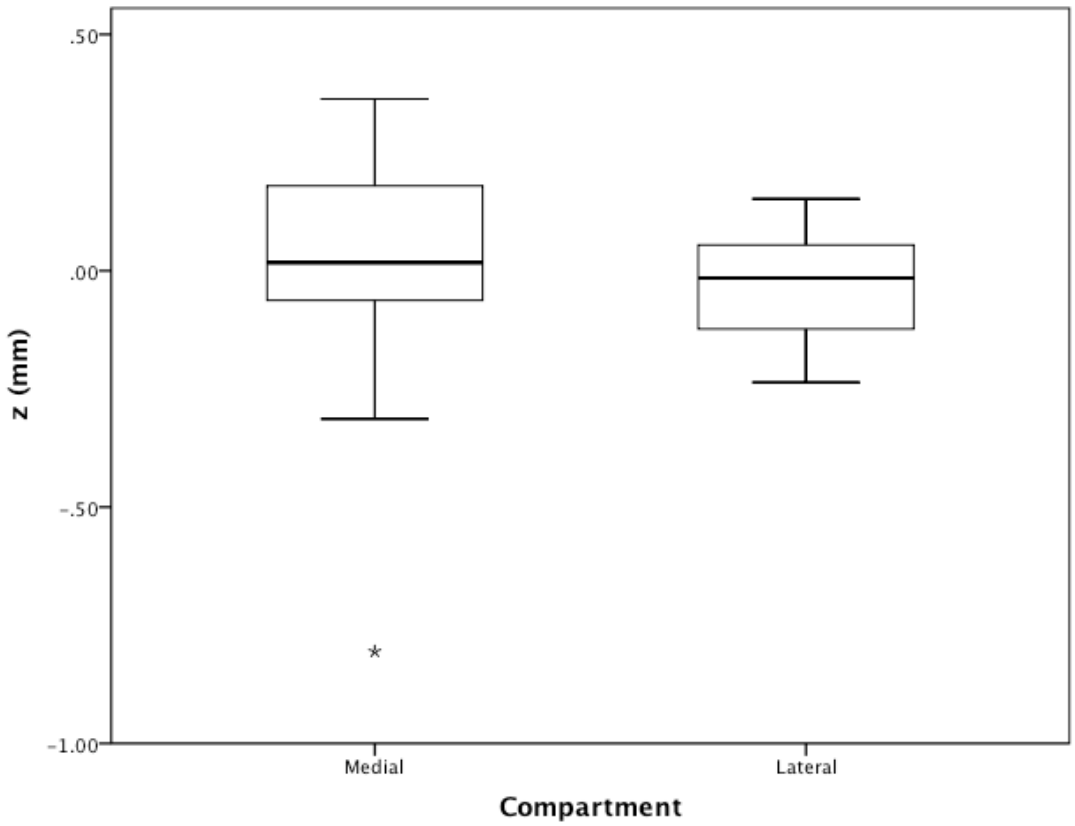


Figure 6-3 A boxplot showing the translation in the z-axis for the medial and lateral tibial components. The medial component has a single outlier. The lateral domed component has no outliers and a median in a tighter range than the medial component.

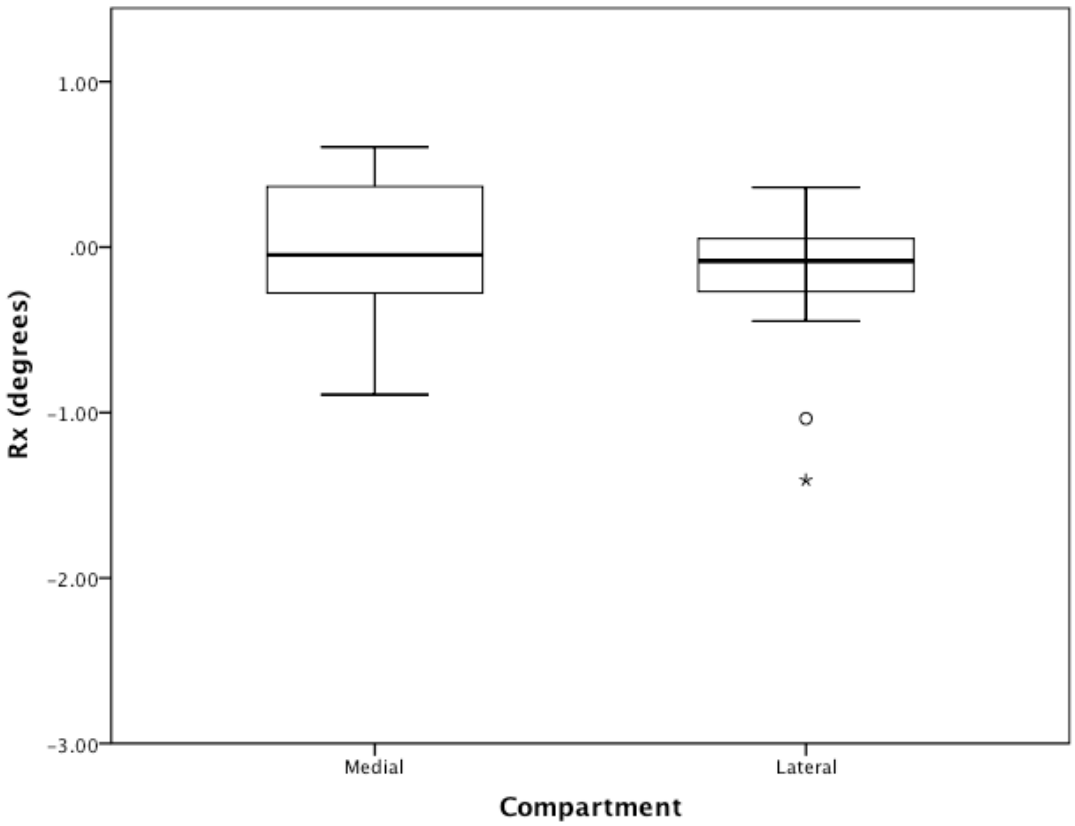


Figure 6-4 A boxplot showing rotation around the x-axis for the medial and lateral cemented tibial components. The medial component has a single outlier, in contrast to the domed lateral component that has two outliers. The medians are similar at close to zero.

6.5.5 Clinical Outcome

The OKS both pre- and post-operatively were in keeping with scores for the entire cohort of patients receiving a domed lateral UKR at the Nuffield Orthopaedic Centre. When comparing to medial cemented OUKR there is no significant difference at either time point or in change of score between pre-operatively and at one year (Table 6-6).

	Cemented Lateral OUKR	Cemented Medial OUKR
Pre-operative	21.4 (7-27)	23.76 (13-37)
One year post-operative	41.3 (32-48)	39.95 (20-47)
Change pre-op to one year	19.8 (12-34)	16.19 (0-29)

Table 6-6 Oxford Knee Scores for medial and Lateral OUKR assessed pre-operatively and at one year. The mean score (range) is given.

6.5.6 Assessment of Radiolucency

A single patient missed their screened radiographs, although had RSA stereoradiographs taken, at three months. All attended for their one year radiographs.

There were two radiolucencies seen around the femoral components at one year, both in zone 6 (see Chapter 4). One of which was apparent at three months. There was no associated sclerotic line. There were no radiolucencies around the femoral peg.

There were no radiolucencies seen on the post-operative radiographs beneath the tibial tray. All radiographs demonstrated good cement penetration. There were five full radiolucencies at one year, two of which were evident at three months, with the other three progressing from partial radiolucencies at three months (Table 6-7).

	Three months (n=15)	One year (n=16)
None	10	10
Partial	3	1
Full	2	5

Table 6-7 Prevalence of radiolucency in domed lateral UKR at three months and at one year post-operatively.

There was a sclerotic line evident in each case, suggesting a physiological radiolucency and hence stability (Figure 6-5).

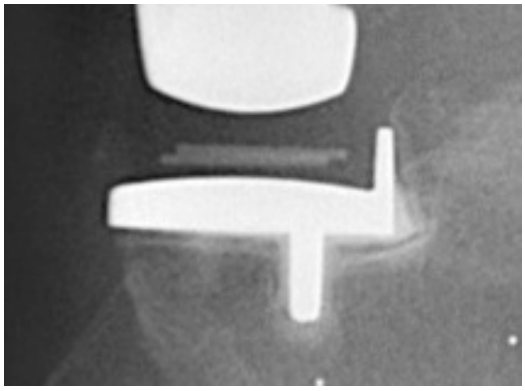


Figure 6-5 An example of a full radiolucency with a sclerotic line in a cemented domed lateral UKR. The sclerotic line is clearly seen beneath the tray and around the keel.

There was a single partial radiolucency at one year, which was not evident at three months, that was at the tip of the keel (Figure 6-6).

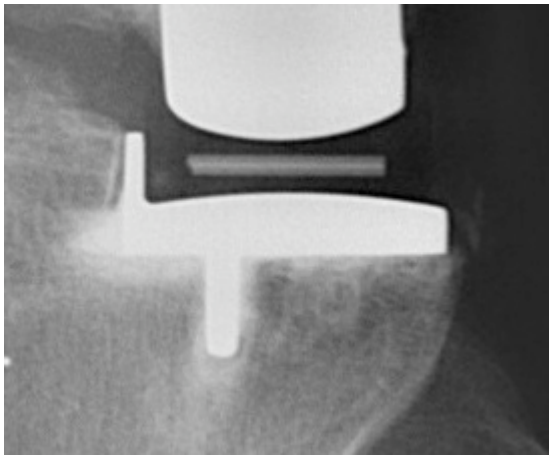


Figure 6-6 An example of a partial radiolucency (peri-keel) beneath a cemented domed lateral UKR. A sclerotic line is seen around the tip, with no radiolucency beneath the tray itself.

6.5.7 Migration and radiolucency

There were five patients who developed full radiolucencies beneath the tibia and ten patients who developed no radiolucency. Those patients with a full radiolucency had no increased translation in the z-axis, but did demonstrate a significant increase in both posterior slope and MTPM (Table 6-8)

	z	**R*x***	**MTPM**
No Radiolucency	0.00 (0.12)	-0.05 (0.20)	0.48 (0.17)
Full Radiolucency	-0.09 (0.10)	-0.60 (0.61)	0.72 (0.25)
p-value	0.156	0.020	0.046

Table 6-8 Mean migration (SD) for the *z*-axis and rotation around the *x*-axis between those patients with no radiolucency and those patients with a full radiolucency at one year. The difference in MTPM is also shown. There is no significant difference for the *z*-axis but there is for rotation around the *x*-axis and MTPM.

The migration between three months and one year for those patients with a full radiolucency was not significantly different from those with no radiolucency (Table 6-9).

		***z*-axis**	**R*x***	**MTPM**
No Radiolucency	mean	-0.02	-0.01	0.53
	SD	0.10	0.35	0.20
Full Radiolucency	mean	0.05	0.07	0.56
	SD	0.11	0.65	0.18
p-value		0.22	0.75	0.81

Table 6-9 Migration between three months and one year for the *z*-axis, rotation around the *x*-axis and MTPM for those patients with either no or a full radiolucency. There was no difference for any measurement.

6.6 Summary of results

- The patient cohort in this study was a reasonable representation of the larger cohort of patients receiving domed lateral UKR.
- All patients had a functioning ACL which is important to ensure they have near normal kinematics following UKR surgery.
- The femoral component had little migration, with stability by three months. The most migration occurred in R*x*, consistent with the normal movement in the knee.
- The only direction of significant migration for the femoral component was anteriorly along the z-axis.
- The tibial component migrated less than the femoral component with stability achieved by three months. In particular, there was no subsidence or increase in posterior slope.

- There was however a small increase in internal rotation and component varus at three months, maintained at one year.
- Clinically, there was a good improvement in OKS, with no significant difference to the medial scores.
- There were two partial radiolucencies in zone 6 beneath the femoral component.
- There were five full radiolucencies beneath the tibial component and a single peri-keel partial radiolucency.
- Those tibial components that had a full radiolucency demonstrated a significant increase in posterior slope and MTPM. But there was no increase in migration compared to those with no radiolucency after three months.

6.7 Discussion

The patient demographics were consistent with the overall cohort of patients receiving a lateral OUKR. All of the patients recruited satisfied the standard indications for lateral OUKR, with a functioning ACL and no significant cartilage damage in other compartments. Therefore, the results are likely to be applicable to the general population.

Overall, stability was achieved by three months for both the femoral and tibial components. There was no single direction of migration that was excessive for either component, although there were some significant migrations, albeit small, for both components. The femoral component migrated anteriorly which may be explained by the force applied to the component in deep knee flexion (Figure 6-1). The force applied to the tibial component in any position will result in an equal reactive force applied to the femoral component. In extension the femoral component has force

applied perpendicularly with the maximal surface area of cement mantle and in the direction of the single peg. In contrast, in deep flexion the vector of force is almost perpendicular to the peg and parallel to the cement. Cement is resistant to compression but less so to shear. Therefore, the femoral component is more susceptible to anterior migration than an increase in compression resulting in superior migration. The tibial component migration of increased internal rotation and varus is less obviously explained. It is possible that the kinematics of the lateral compartment cause the bearing to move in such a way that there is eccentric loading on the tibial component, resulting in an increased load against the vertical wall anteriorly. This increased load of the anteromedial region of the tibial component may lead to the migration seen.

The rotation of the femoral component around the *x*-axis is to be expected as it is parallel with the normal movement of the joint. There is slightly more rotation around the *x*-axis than was seen in the medial femoral component at one year (medial 0.16° v lateral 0.35°). This may be explained by the different kinematics in the two compartments. The medial femoral condyle rotates around a small area on the tibial plateau (R*y*) as well as flexing (R*x*), whereas the lateral femoral condyle has almost isolated flexion (R*x*).

There were an unexpected number of full radiolucencies beneath the tibial component which enabled assessment of the associated migration. Those patients that developed full radiolucencies all had evidence of radiolucency by three months. As previously discussed, an increase in posterior slope or anterior translation may be expected with the change in geometry and the high flexion achieved in the lateral compartment. Therefore, it is not surprising that those patients with a full radiolucency had an increase in posterior slope that also resulted in a greater MTPM. However, as demonstrated, there was no difference in migration between three

months and one year. The radiolucency in each case was evident by three months, suggesting that the initial fixation was sub-optimal but that the resorption of bone and replacement by soft tissue, thus providing a stable construct, was achieved by three months. There is no clear indication why some patients did not achieve good initial fixation and hence developed a full radiolucency.

In an ideal world a randomised controlled trial would have been constructed to assess the difference in both migration and the development of radiolucency between flat and domed components. However, as the flat component had an unacceptably high dislocation rate, despite the altered surgical technique, it is no longer implanted.

In conclusion, the domed lateral OUKR reaches stability by three months, even if there is increase of the posterior tibial slope and a radiolucency develops beneath the tibial component.

7 Discussion

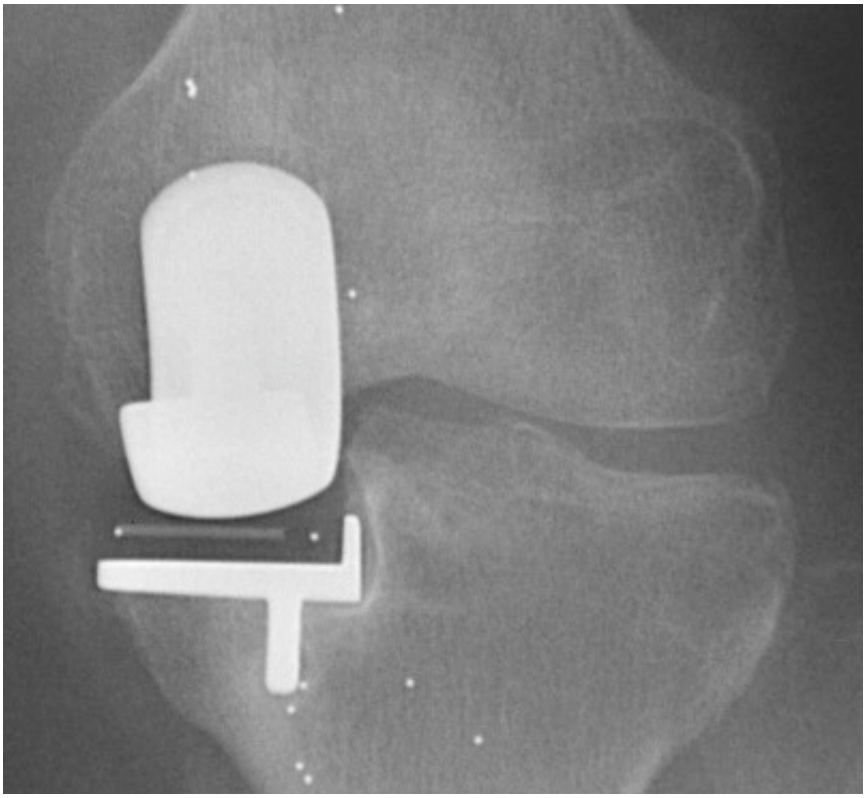
The main findings of this work advance the understanding of fixation in unicompartmental knee replacements. The presence of radiolucency beneath the components has been a cause of concern, particularly with regard fixation in the long term. However, even when a full radiolucency is evident, there is bone present between the tibia and cement beneath an OUKR tibial component. This explains the observation in cohort studies that a tibial component has a good clinical outcome, despite the presence of a full radiolucency.

While the long-term outcome of cemented OUKR is known, the same cannot be said of cementless OUKR. Historically, cementless knee arthroplasty has had poorer results when compared to cemented arthroplasty. The OUKR is particularly suited to cementless fixation, with the mobile bearing eliminating shear and resulting in nearly exclusive compressive forces across the implant/bone interface. Although the forces are almost exclusively compressive the type of fixation in the OUKR tibial component affects the migration profile of the implant. Cemented fixation results in little migration with stability by three months, in keeping with clinical observation. Cementless fixation results in early subsidence, within three months, but with little increase by two years. This is also in keeping with clinical observation, although only short-term results are available. The finding that there is little significant increase in migration between the first and second post-operative years suggests that both fixation methods achieve stability. However, the direction of the migration provides some insight into the effect of the forces on each component. The increase in internal rotation of the one-peg cemented femoral component, compared to no significant migration of the two-peg cementless femoral component, suggests that as

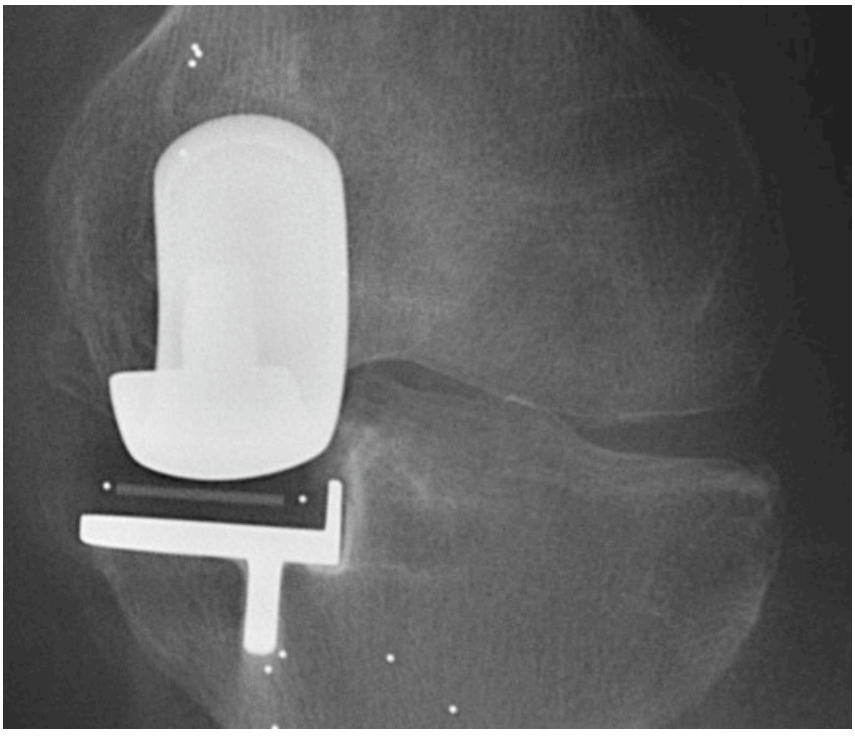
the components stabilise the forces acting on them also alter. This suggests an explanation as to why there is little internal rotation by one year, but then there is a significant increase. The tibial component has a slightly different profile of movement over time. There is initial subsidence, that reduces but continues, in the second post-operative year. For the cemented component the subsidence is the only direction of migration and the magnitude is small. The cementless component, however, has subsidence, of greater magnitude than the cemented tibia, in combination with an increase in posterior slope. There is also an initial increase in component valgus, which corrects over the first two years back to neutral. It is this combination of migrations that potentially explains some of the radiographic observations. An example patient illustrates the point. A female who had a cementless medial OUKR with the following migrations compared to the post-operative stereoradiographs:

	Subsidence	**Posterior slope**	**Valgus**
Three months	0.4 mm	0.8°	2.1°
Six months	0.4 mm	2.8°	1.2°
One year	0.4 mm	2.8°	0.6°
Two years	0.4 mm	2.8°	0.2°

With a radiograph at six months showing a radiolucency beneath the lateral tray and around the tip of the keel:



With resolution of the radiolucency around the keel and reduction of the radiolucency beneath the lateral tray by two years:



The combination of rapid subsidence, rotation into valgus and increase in posterior slope would result in the tip of the keel having the largest motion and hence an

associated radiolucency. The increase in posterior slope may be explained by not seating the component correctly at the time of surgery, but the increase in component valgus is unlikely to be due to incorrect seating as the anterior portion can be visualised and is seen to be seated at the time of surgery. Therefore, in order for the component to fall into valgus either the underlying bone needs to collapse or be replaced by soft tissue to allow the component movement, or the medial edge needs to lift off. As there is no lucency medially suggesting lift-off it is likely that the bone beneath the lateral portion of the tibial tray had been replaced by soft tissue, seen as radiolucency on the plain film. In addition, this patient had a pre-operative OKS of 25 and scores of 43 and 46 at one and two years respectively, suggesting that the migration in the second post-operative year does not cause symptoms.

The presence of a full radiolucency beneath a cemented tibial component is associated with an increase in migration, although as shown previously, not necessarily related to lack of stability. The main component of the migration is subsidence. Conversely, subsidence in cementless components is mildly protective against radiolucency. Therefore, subsidence per se is not the cause of radiolucency but rather the cemented components subside secondary to the formation of radiolucency. This further highlights that the two fixation types subside due to different reasons and that it can be incorrect to apply a single figure of migration as cause for concern regardless of implant type/design.

Different loading patterns result in a different prevalence of radiolucency formation. The prevalence of radiolucency is 60% with purely compressive force (flat lateral tibial component), whereas the addition of shear and more posterior bearing movement resulted in a significant reduction in radiolucency to 13%. Initially this may perhaps be counter-intuitive, as it could be assumed that there is greater migration with the introduction of greater bearing movement and an altered vector of

force. However, it has been shown above that increased initial migration does not necessarily compromise fixation and result in the formation of radiolucency.

The variable most likely to cause the development of a radiolucency is the preparation of the cut surface, i.e. a flat surface gives proper support for the component and there is little initial inducible micromotion, whereas an uneven surface would allow more inducible micromotion. This may explain the observation that there are very few radiolucencies beneath the femoral component. The femoral component surface is prepared with a mill that is simple to use and provides a consistent, even surface. In contrast, the tibial surface is prepared using an oscillating saw and changes in bone density or user error can result in an uneven surface. Therefore, it is very likely that there is little inducible micromotion beneath the femoral component and considerably more beneath the tibial component.

A further consideration is the vector of force between the component±cement and the underlying bone. The femoral component has a changing vector of force as the knee moves through a range of movement as the component rotates on top of the bearing. Whereas, the tibial component has a far smaller change in force vector as the bearing slides over the tibial tray maintaining a compressive force. This may also explain further the observation that the domed tibial tray has reduced radiolucency, with a proportionally larger bearing movement than the flat tray and therefore an increased change in the force vector between extension and flexion.

In conclusion, the OUKR achieves stable fixation regardless of whether cement or hydroxyapatite is used. The formation of radiolucency beneath the tibial component is related to initial stability, but does not represent a failing component as some bone is always present at the interface. Changes in the force applied to the tibial

component reduces the prevalence of radiolucency but the mechanism for this is not understood.

7.1 Limitations

There are numerous inherent problems when studying a particular implant used in clinical practice. One problem is the availability of the patients who fulfill the requirements of a study and are willing to participate. This is particularly a problem in a tertiary referral centre where patients often travel considerable distances for surgery and are not able to return for regular follow-up. A further problem regards the surgical experience, which by its nature, varies with time. Several of the studies in this work used patients on whom routine operations had been performed by experienced surgeons. A limited number of surgeons were used to try and reduce the number of operator-dependent variables, but those variables cannot be eradicated completely. An example would be the impaction of a cementless tibial tray, where the amount of force applied is balanced between enough to seat the component securely and too little to cause a plateau fracture.

A further limitation regards the assessment of radiolucency. Only standard radiographs (anteroposterior and lateral) are available and therefore, the assessment of whether a radiolucency is present or not is based on a 2D image and is binary. A system is needed that can quantify a radiolucency, either in terms of density or area, that can accurately measure progression.

7.2 Further Work

The main focus of continued investigation should be along several avenues:

Firstly, the initial fixation of any method is very important and is very difficult to assess. RSA should be used to assess the initial position of an implant before weight-bearing has started and then at short regular time intervals (perhaps weekly) to assess whether very early migration is associated with radiolucency. This study should be coupled with assessment of inducible movement, again particularly in the early period, to assess whether absolute or relative initial stability is required for optimum fixation.

Secondly, a method of quantifying radiolucency needs to be developed to enable a more rigorous investigation of the causative factors, as well as providing a useful clinical tool.

Thirdly, accurate characterisation of the implant (±cement)/bone interface is required. It is not known if the difference in material stiffness between the implant and the underlying bone has an effect on radiolucency formation. This is relevant in patients in whom there is low bone density.

Appendices

Appendix 1. Oxford Knee Score

Oxford Knee Score[1]

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

[1] 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

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