FIXATION OF THE CEMENTLESS OXFORD UNICOMPARTMENTAL KNEE REPLACEMENT

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ABSTRACT

Fixation of the cementless Oxford Unicompartmental Knee Replacement
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The Oxford Unicompartmental Knee Replacement (OUKR) is an effective treatment for symptomatic end-stage anteromedial osteoarthritis. In contrast with data from specialist centres, the National Joint Registries suggest a higher revision rate than total knee replacement. The cementless version of the OUKR was introduced to prevent cementation errors, improve fixation, reduce the incidence of radiolucent lines and ultimately reduce the discrepancy between the results of specialist centres and National Joint Registries. There are, however, anecdotal reports of tibial plateau fractures with cementless fixation. The aim of this thesis was to assess the clinical outcome and key biomechanical aspects of the fixation of the cementless OUKR.

A systematic review demonstrated that modern cementless unicompartmental knee replacements (UKRs) are safe and effective.

The cementless OUKR had a 10-year survival of 97% and 88% good or excellent clinical results in a prospective, consecutive case series of 1000 cases from two centres.

The primary stability of the cementless OUKR relies on the interference fit. The 5-year results of a randomised controlled trial using radiostereometric analysis demonstrated that cementless components are as stable as cemented. Although sufficient in providing component stability, the interference fit could be excessive increasing the risk of fracture. A biomechanical test was carried out to study the effect of interference on the force required to implant the tibial component (push-in force) and the fixation strength (pull-out force). The results demonstrated that a reduction of the interference up to 50% significantly reduces the force required to implant the components without affecting their primary stability.

In conclusion, the cementless fixation of the OUKR is safe and effective, with excellent long-term survival. The stability of cementless components is reliable and at least as good as that of the cemented implant. However, the interference fit around the tibial component is excessive. A reduced interference fit could decrease the risk of fracture without affecting the stability of the components.

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CONTENTS

List of abbreviations

AMOA: Anteromedial Osteoarthritis

CI: Confidence intervals

HA: Hydroxyapatite

KSS: Knee Society Score

N.R.: Not reported

NSAIDs: Nonsteroidal anti-inflammatory drugs

OA: Osteoarthritis

OKS: Oxford Knee Score

OUKR: Oxford Unicompartmental Knee Replacement

PFJ: Patellofemoral joint

RCT: Randomised Controlled Trial

RLs: Radiolucent lines

RSA: Radiostereometric Analysis

SD: Standard Deviation

TKR: Total Knee Replacement

UKR: Unicompartmental Knee Replacement

CHAPTER 1

INTRODUCTION

Knee osteoarthritis

Osteoarthritis (OA) is considered the most common joint disorder in the world and the most frequent source of pain, loss of function and disability in the elderly [1, 2]. In a European population over 65 years, the prevalence of clinically evident OA in any joint was 30.4%. In 19% of the cases the OA involved the knee, which is the most frequently affected joint [2]. In a study on the Framingham cohort, the radiographic evidence of knee OA was 27% in patients younger than 70 years, and 44% in patients older than 80 years [3]. Clinical manifestations include pain, joint stiffness, progressive deformity, joint instability and crepitus. The radiographic features include cartilage loss with consequent joint space narrowing (or complete obliteration), presence of osteophytes, subchondral sclerosis and cyst formation. Different degrees of synovitis, degeneration of ligaments and menisci and muscular atrophy are usually associated [4].

OA has a multifactorial aetiology, resulting from the intricate interaction between mechanical, cellular and biochemical factors. A wide set of risk factors can predispose to the development of OA. These include systemic risk factors, such as age, gender, genetic susceptibility, ethnicity, obesity, diet and bone metabolism, and local risk factors, such as muscle strength, activity, injuries and limb alignment [5].

Early OA can be treated conservatively with painkillers, NSAIDs, intra-articular injections and physiotherapy. However, the only definitive treatment for symptomatic end stage knee OA is partial (unicompartmental) or total knee replacement (TKR) [4]. Knee OA can affect the entire joint, but it is often limited to one compartment. In a cross-sectional study on knee radiographs of more than 5000 patients with either symptomatic knee OA, or at high risk of disease, joint space narrowing was encountered in the medial compartment in about 30% of cases and in the lateral compartment in 8% of cases. Bi-compartmental joint space narrowing was detected in about 2% of cases, whilst the rest of individuals did not present joint space narrowing [6]. These results are consistent with those reported by Ahlback in the 1960s on patients with symptomatic knee OA [7]. Furthermore, long follow-up studies on untreated patients showed that even if progressive, in most cases OA tends to remain limited to the compartment initially affected [8].

Anteromedial osteoarthritis

In 1991, White et al. described a specific pattern of OA defined "anteromedial osteoarthritis" [9]. This definition includes those knees in which OA affects mainly the medial compartment of the joint (Figure 1.1). The erosion on the tibial side is limited to the anterior portion, with preserved cartilage on the posterior aspect. The anterior cruciate ligament (ACL) is functionally intact, and the medial collateral ligament (MCL) length is maintained. The posterior capsule is generally shortened, causing a variable degree of flexion deformity. The lateral compartment is preserved, even though some cartilage fibrillation can be present. Clinically, AMOA is characterised by pain during standing and walking, which is relieved in the seating

position. The varus deformity is not correctable when the knee is fully extended. However, the intra-articular varus deformity can be corrected with the knee at 20 degrees of flexion, and corrects spontaneously around 90 degrees of flexion.

The ACL plays a primary role in the development of this condition, by maintaining the physiological roll-back of the femur on the tibia during knee flexion. Consequently, the posteromedial tibial cartilage is preserved. The varus deformity in extension derives from cartilage loss on the distal portion of the femoral condyle and on the anteromedial portion of tibia. Around 90 degrees of flexion, the preserved cartilage on the posterior aspect of the femoral condyle and the posteromedial tibial plateau get in contact correcting the intra-articular varus deformity and preventing the MCL from shortening.

A tear of the ACL can lead to a progressive degeneration of the posterior portion of the tibial plateau, with consequent shortening of the MCL and progression of OA to the other compartments of the knee [10].

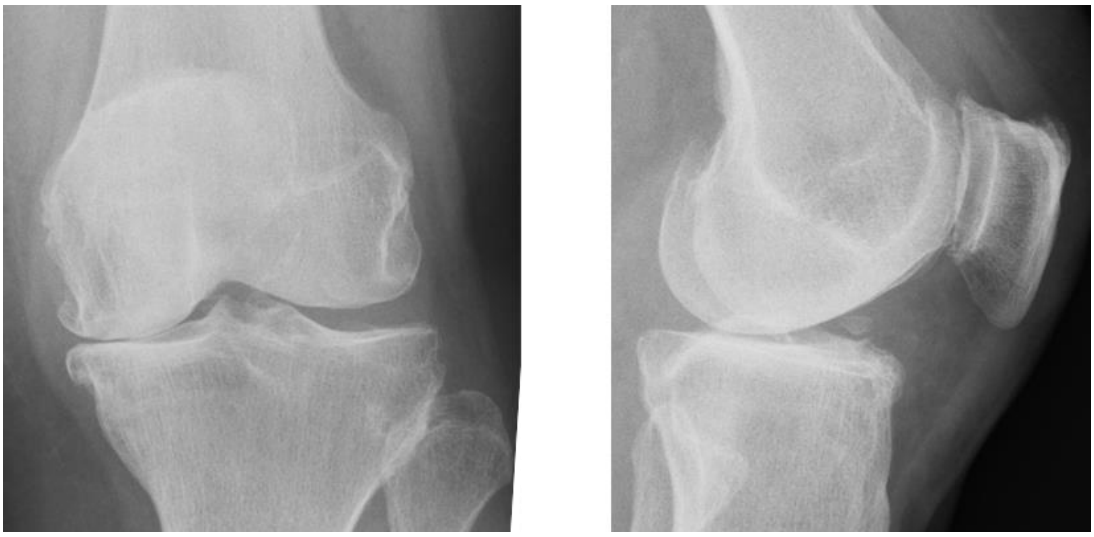

Figure 1.1. Anteroposterior and lateral x-ray of the knee showing AMOA.

Unicompartmental knee replacement and the "Oxford knee"

McKeever and MacIntosh first proposed the theory of unicompartmental knee replacement (UKR) in the 1950s, with the introduction of a metallic component that was used to replace the tibial surface [11]. The results of these procedures were unfortunate, with a high incidence of complications and poor functional results.

The first modern unicompartmental designs, the "St. Georg" and the "Marmor Knee", were introduced in 1969 and 1972, respectively [12]. Both presented a polyradial metallic femoral component and a flat tibial component made of polyethylene. Initially, the results were controversial. Wear and polyethylene deformation were the biggest problems, which led to the introduction of metal-backed tibial component [13].

In the 1970s and 1980s, the understanding of OA as a pathology of the entire joint and the rising interest towards total knee replacement led to a fervent development of these implants. In contrast, UKRs had limited diffusion and innovation, so that some of the implants that are nowadays still in use are almost unchanged [14].

In 1974, John Goodfellow and John O'Connor introduced the "Oxford Knee", characterised by a metal femoral component with a spherical articular surface, a flat tibial component and an interposed polyethylene mobile bearing (Figure 1.2). The mobile bearing unconstrained and shaped to be fully congruent at both the femoral and tibial interfaces. This unique design aimed to minimise wear and allow unrestricted movements of the joint that were guided by soft tissues. All these features are unchanged on the current version of the prostheses. Initially the "Oxford Knee" was used as a bi-compartmental knee replacement. Since 1982, following the observation that OA was often limited to the medial compartment, the "Oxford Knee" is used as a unicompartmental knee replacement [14].

Figure 1.2. The Phase 1 OUKR

Indications for the Oxford medial UKR

Symptomatic AMOA with severe cartilage loss in the affected compartment and radiographic evidence of bone-on-bone disease is the primary indication for the Oxford UKR [14]. Cartilage in the weight bearing portion of the lateral compartment should be preserved. However, grade 1 cartilage damage, marginal osteophytosis and a cartilage ulcer on the medial border of the lateral condyle are frequently encountered and do not represent a contraindication. The intra-articular deformity should be correctable with the knee at 20 degrees of flexion. The cruciate ligament should be functionally intact. In selected cases of ACL deficient knees, a simultaneous reconstruction of the ACL can be performed. The knee should be able to flex at least to 110 degrees.

Patellofemoral OA is not considered a contraindication for OUKR, unless there is a severe involvement of the lateral facet with bone loss or grooving. Age, level of activity, obesity and chondrocalcinosis are not considered contraindications [15]. Inflammatory diseases and previous high tibial osteotomies are considered contraindications.

Results of UKRs

Interest in UKR progressively increased over the last twenty years. Several studies report excellent long-term survival and clinical outcome, both in independent and designers case series [16-22].

The clinical results of UKRs and TKRs are comparable, with more excellent results obtained with UKRs [23]. Furthermore, a study on over 100,000 matched patients from the National Joint Registry of England and Wales has demonstrated that the incidence of severe medical complications and mortality is significantly lower in UKRs than TKRs [24]. Consequently, UKR is an advantageous procedure for patients meeting the recommended indications. It has been estimated that about 50% of patients requiring knee replacement surgery could be a candidate for UKR [15, 25]; on average, less than 10% of these patients are treated with unicompartmental knee replacement in current clinical practice.

Despite the excellent results reported by several studies, the NJR data show that the revision and re-operation rates are up to three times higher for UKRs than TKRs, also when patients are matched [24].

The discrepancy between case series from specialist centres and National Joint Registries is likely to be an expression of the higher susceptibility of the UKR to revision, misdiagnosis of implant loosening and relatively limited experience of orthopaedic surgeons with regards to this procedure [26].

Rationale for cementless fixation

According to the National Joint Registry of England and Wales, the most common causes of revision of unicompartmental knee replacements are aseptic loosening and

unexplained pain. Revisions that are performed for erroneous diagnosis of loosening caused by any reason fall in the first category. The second category includes a vast and heterogeneous range of problems, including cementation errors such as the presence of protruding cement or loose bodies.

Radiolucent lines are common in cemented UKRs, usually being observed in about 2/3 of the tibial components [27]. Physiological radiolucent lines are detected in well-functioning implants and do not affect the clinical outcome or correlate with loosening or failure [28] (Figure 1.3). However, these findings have been correlated with the presence of a fibrocartilagineous tissue layer at the bone-prosthesis interface, suggesting a suboptimal fixation [29].

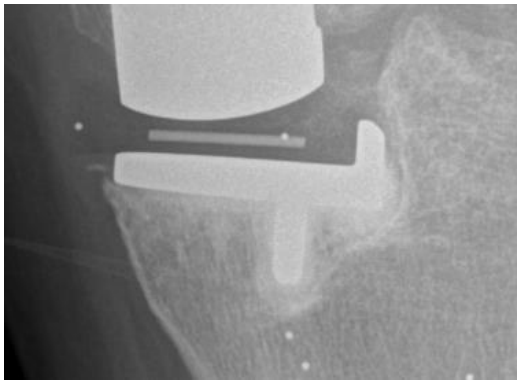

Figure 1.3. Complete RL around a cemented tibial component.

The detection of radiolucent lines (RLs) is a frequent cause of misdiagnosis of loosening, especially when associated with unexplained pain.

The cementless version of the Oxford knee (OUKR) was introduced in 2004, as an alternative to cemented fixation to reduce the incidence of RLs, avoid cementation errors, improve fixation and ultimately reduce the discrepancy between the results of specialist centres and National Joint Registries.

Cementless fixation in unicompartmental knee replacement

Cementless fixation in TKR has been widely investigated since the introduction of the first cementless knees in the early 1970s [30]. Despite early conflicting results, recent evidence showed encouraging outcomes and survival of modern implants [31].

In contrast, cementless fixation in UKR has not been extensively studied. Even if cementless options have been available for over 20 years, poor results of the first cementless UKRs contributed to limit the widespread acceptance of this alternative method of fixation [32-38].

In the last ten years, several specialist centres reported the results of cementless UKRs with randomised controlled trials and case series, showing excellent clinical outcome and survival and some advantages over cemented implants [18, 19, 27, 39-41]. These include a significantly lower incidence of RLs [19, 27], avoidance of cementation errors and faster surgical time [16, 27].

The cementless OUKR

The cementless OUKR implant is similar to the widely used cemented OUKR but has modifications to facilitate cementless fixation [27]. The cement pockets on both components are filled with porous titanium and the surfaces that are in contact with bone are coated with calcium hydroxyapatite (HA). The vertical tibial wall is not considered weight bearing and is not coated with titanium, although it is coated with hydroxyapatite (Figure 1.4). The porous plasma spray coating upon the cementless OUKR is produced by the deposition of Ti-6Al-4V alloy powder upon the surface of the components, the thickness of this coating complies with the requirements of the FDA and has a total coating thickness of between 500 and 1,500 microns. The femoral

component extends a further 17 degrees anteriorly to allow implantation in a flexed position, and has two HA-coated cylindrical pegs for press-fit fixation and to confer rotational stability. The femoral component is implanted in 5 to 10 degrees of flexion and the slot for the tibial keel is narrower than the cemented in order to provide a good initial press-fit.

The primary stability of the cementless OUKR relies on the interference fit (or press-fit), which is the fixation between two parts that is generated by friction after they have been pushed together.

Figure 1.4. The cementless OUKR

Relevant evidence on the cementless OUKR

Since its introduction, the cementless Oxford UKR has been the most used and studied cementless unicompartmental knee worldwide.

In 2009, Pandit et al. published the results of a RCT comparing the cemented and cementless versions of the OUKR in 62 patients, reporting a significantly lower incidence of RLs underneath the tibial component in the cementless group (7% vs 75%) at one year of follow-up. The clinical outcome was similar for both groups [27]. The five-years results of the same cohort of patients confirmed the lower incidence of RLs in the cementless group (7% vs 67%). There was no significant difference in the Oxford Knee Score. However, the Knee Society functional score revealed better results in the cementless group ($p = 0.003$) [27]. The authors concluded that cementless fixation provides an improved fixation at five years, with comparable or superior clinical outcome. Furthermore, surgical time was significantly lower for the cementless operations.

In 2013, Liddle et al. presented the results of a prospective multicentre series including 1000 OUKRs. There were no tibial or femoral loosenings, and the overall complication rate was comparable to cemented fixation ($p = 0.87$). Survival was 97.2% at six years. However, only 27% of patients had a follow-up beyond one year [19].

In 2015, Kendrick et al. published the two-year results of a RCT comparing the component migration of cemented and cementless OUKR with radiostereometric analysis (RSA). There was no significant difference in the migration of femoral components in the cemented and cementless groups. Both presented an anterior migration of 0.2 mm in the first year and none in the second year. The cementless tibial components subsided significantly more than cemented components in the first year (mean 0.28 mm vs. 0.09 mm, $p < 0.001$). However, there was no difference in the second year (both 0.05 mm, $p=0.92$). This difference was expected, since cemented components reach their definitive fixation just after implantation, while cementless

components seat or bed-in before biological fixation occurs. The authors concluded that cementless fixation is “at least as good, if not better than, that of cemented devices” [39].

Possible complications of cementless fixation

So far, there is no evidence of specific complication of the cementless version of the OUKR. However, studies on large cohorts of patient with sufficient follow-up are required to draw definitive conclusions.

There are anecdotal reports of surgeons who have a higher incidence of fractures in cementless implants. A cadaver study reported that lower loads were required to cause a fracture in the cementless OUKR [42]. Perioperative medial condyle fracture is a rare but known complication of cemented UKRs. The aetiology of fracture is multifactorial. Technical errors such as a deep tibial resection, a medialised positioning of the tibial component, the damage of the posterior cortical bone and the use of a heavy hammer are known risk factors. Furthermore, the risk seems higher in specific subset of patients such as the Asian population, in which the size and morphology of the proximal tibia can predispose to fracturing of the medial condyle.

The design and surgical technique of the cemented and cementless OUKR are very similar. The press-fit fixation of the tibial component and the interference generated around the keel of the implant is probably the most relevant difference. The forces acting on the bone during the implantation and the impaction on the component could initiate a fracture or cause bone damage, which can eventually result in a fracture after weight bearing is initiated. Indeed, most of the fractures are diagnosed intraoperatively

or in the first four to eight weeks after surgery, when patients increase mobilisation and weight bearing.

The interference fit around the tibial component of the cementless OUKR is unclear. An insufficient interference fit would cause loosening and instability, while an excessive interference would cause trabecular bone damage and increase the risk of fracture. So far, there are no data about the ideal range of interference for the OUKR.

Scope of this thesis

Some aspects of the cementless OUKR are still unclear, such as mid- and long-term survival, quality of fixation, suitability of the procedure in specific subgroups of patients and specific complications connected to fixation, implant design and surgical technique.

The scope of this thesis is to analyse the clinical results of the cementless Oxford knee and to study its fixation.

Chapter two presents a systematic review of the current evidence on all modern cemented UKRs, focusing on survival, clinical outcome and mode of failure and complications.

The third chapter reports the 10-year survival and clinical outcome of the first 1000 consecutive cementless OUKR implanted in two institutions. The results of the radiographic analysis of a subgroup of patients with a minimum follow-up of 5 years is also reported.

Chapter four reports the 5-year results of a randomised controlled trial with radiostereometric analysis (RSA), focusing on the quality of cementless fixation.

The fifth chapter presents the results of a biomechanical test that studied the fixation of the tibial component and the effect of the interference fit around the tibial keel on the force required to implant the components and on the fixation strength.

Finally, the studies are drawn together in the Discussion chapter and possibilities for Further Work are set out.

CHAPTER 2

CEMENTLESS FIXATION IN MEDIAL UNICOMPARTMENTAL KNEE REPLACEMENT: A SYSTEMATIC REVIEW

Introduction

Unicompartmental knee replacement (UKR) is an effective treatment for anteromedial osteoarthritis of the knee. As for total knee replacement (TKR), cementation is still considered the standard method of fixation for UKR. Cementless fixation in TKR has been widely investigated. Despite early conflicting results, recent evidence showed encouraging outcome and survival of modern implants [31, 43].

In contrast, the experience of cementless fixation in UKR is still limited. Even if cementless options have been available for over 20 years, the poor results of the first cementless UKRs contributed to limit the widespread acceptance of this alternative method of fixation [32-38]. In the last ten years several specialist centres have reported the results of cementless UKRs with randomised controlled trials and case series, showing excellent clinical outcome and survival and some advantages over cemented implants[18, 19, 27, 39-41]. These include faster surgical time and avoidance of cementation errors, which can cause impingement and/or accelerated wear, leading to early failures. In addition, the incidence of radiolucencies around the tibial component is significantly reduced in cementless UKRs [27]. However, some aspects still need to be analysed, including possible complications, causes of failure, clinical outcome, long-term survival and the suitability of cementless fixation in specific patient groups.

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This systematic review presents the current evidence on cementless medial UKR, with emphasis on (1) clinical outcome, (2) failures and revisions, (3) implant survival and (4) complications encountered.

This is the first systematic review comprehensively reporting the results of modern cementless UKRs.

Materials and Methods

This systematic review has been registered with PROSPERO (http://www.crd.york.ac.uk/PROSPERO) on the 20th November 2015 (protocol number: CRD42015029477).

The research question was formulated according to the PICO (Patients, Intervention, Comparative, Outcome) approach [44] as follows: (P) patient with unicompartmental OA; (I) cementless medial UKR; (C) not comparative; (O) clinical outcome, failures, revisions, implant survival and complications. Two independent reviewers performed a systematic review of the literature according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. The following database were comprehensively searched: PubMed, Cochrane, MEDLINE, CINAHL, Embase, and Google Scholar. Different combinations of the keywords “unicompartmental”, “unicondylar”, “partial knee replacement” and “UKR” were combined with each of the keywords “uncemented”, “cementless” and “survival”, “complications”, “outcome”. In addition, a hand-search of the bibliography of relevant studies was performed. The last search was performed on the 28th November 2015. All articles published in English on peer-reviewed journals were considered. Duplicate references were discarded.

To be included, a study needed to meet at least one of the following inclusion criteria: (1) report the outcome with a validated scoring system, (2) report failures and revisions and (3) cumulative survival. Studies with a mean follow-up shorter than two years, studies on experimental implants, literature reviews, case reports, studies on animals, cadavers or in vitro, biomechanical reports, technical notes and letters to editors were excluded. Studies including both cementless and cemented implants or medial and lateral UKRs were included only if the outcome measures, failure rate and/or survival were reported separately and clearly. If two or more studies reported on the same group of patients only the most recent study was included. Studies before 2000 or reporting on old implant designs (such as the PCA) were excluded from the present review, since their poor results have been correlated with an obsolete design and/or recognised materials issues, and significantly differ from those of modern UKRs.

There was complete agreement between the reviewers regarding inclusion and exclusion in all cases. All the abstract of studies meeting the inclusion criteria were independently evaluated, and full-text of relevant papers were retrieved and carefully assessed to confirm eligibility.

Data extraction was then performed independently to reduce the risk of bias. In case of discrepancy, the data extraction was repeated and discussed.

Revision was defined as the exchange or addition of a new component in the knee.

The parameter “revision per 100 observed component years” [45, 46] was used to compare the revision rates of individual studies with different follow-up.

The risk of bias of each study has been assessed with the MINORS score [47], a methodological index for evaluation of non-randomised studies, and a further scoring system based on the presence of the primary outcomes of this systematic review (A =

clearly reported, B = non reported or unclear) and the number of cases included (A > 100, B = 51-99, C < 50). This modified version of the method previously reported by de Vos-Kerkhof et al. [48] was used to adjust the assessment of the risk of bias to number of patients included in the studies and the clarity in reporting the primary outcome measures of this review. Studies with a MINORS score over 80% were considered at low risk of bias. Studies with a MINORS score lower than 70% were considered at high risk of bias, except for those with three or more "A" in the second scoring system. Results are reported in Table 2.1.

Table 2.1. Risk of bias of the studies included in the review

Study	MINORS	Score 2				Bias Risk
		Clinical outcome	Failures	Survival	Number of cases	
Akan et al. 2013	16/24	A	A	B	A	Low
Forsythe et al. 2000	7/16	A	A	B	B	High
Hall et al. 2013	11/16	A	A	A	B	Low
Hooper et al. 2015	12/16	A	A	A	A	Low
Jeer et al. 2004	11/16	A	A	A	B	Low
Kendrick et al. 2015	23/24	A	B	B	C	Low
Lecuire et al. 2014	11/16	A	A	A	B	Low
Pandit et al. 2013	24/24	A	A	B	C	Low
Pandit et al. 2015	13/16	A	A	A	A	Low
Schlueter-Brust et al. 2014	9/16	B	A	A	B	High

Results

Literature search

The literature search resulted in a total of 63 references. After abstract evaluation, 47 papers were discarded because of duplication (12) or off-topic (35). After full-text

retrieval and evaluation, three further papers were excluded from the study because they failed to meet the inclusion criteria or reported incomplete data. Three further papers [17, 19, 27] were discarded because the results of the same cohort of patients have been subsequently reported with longer follow-up. Ten papers were included in the final systematic review. Two of these studies were randomised controlled trials (RCTs) [39, 41], two prospective consecutive case series [18, 49] and three retrospective case series [16, 50, 51]. Three further studies were case series, without clear reporting of data collection method [52-54]. The PRISMA flowchart is reported in Figure 2.1.

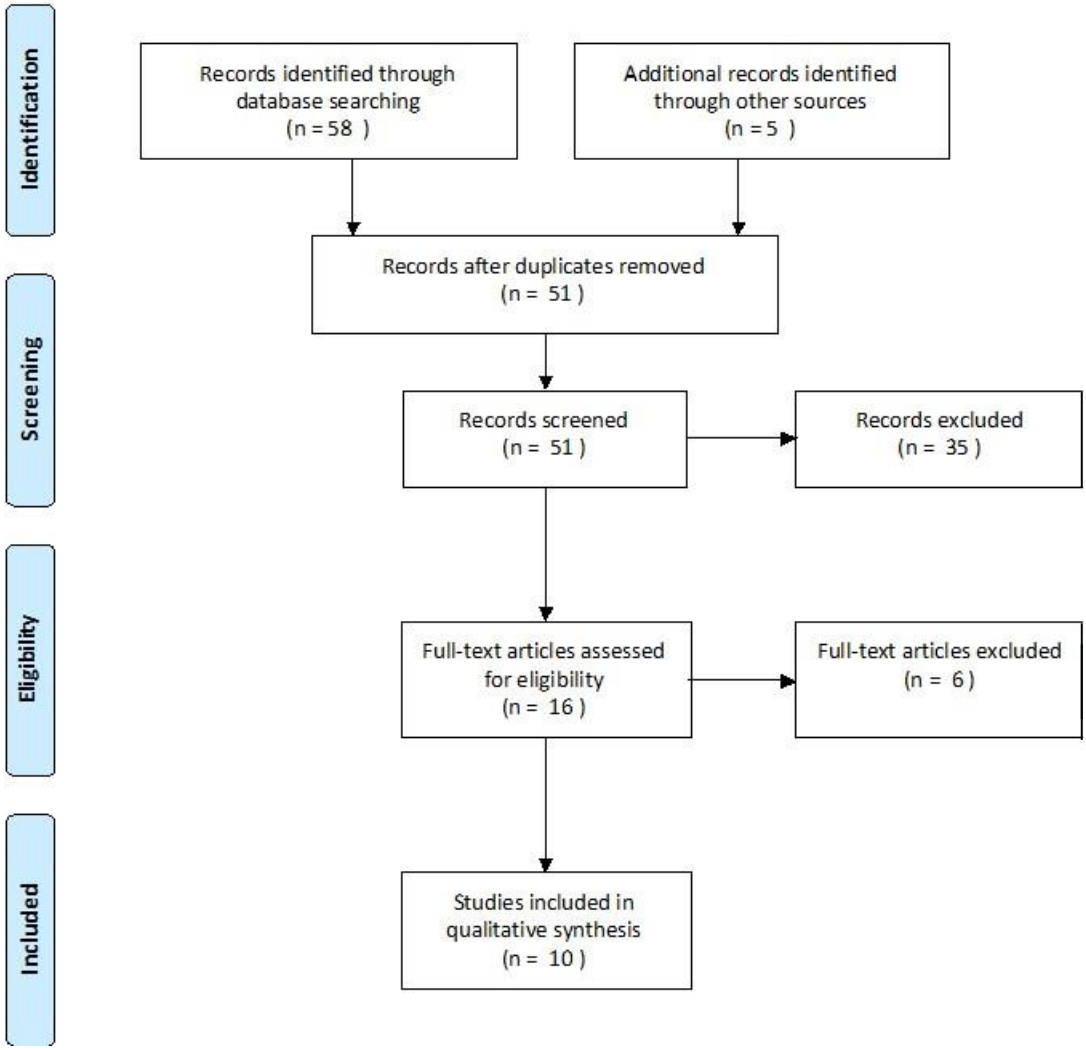

Figure 2.1. PRISMA flow diagram.

Clinical outcome

Seven out of 10 studies [16, 18, 39, 41, 49-51] reported the clinical outcome using the Oxford Knee Score (OKS). Overall, the mean OKS showed an excellent outcome (score > 41) in four studies, and a good outcome (34 to 41) in three (Table 2.2). Four studies [16, 41, 49, 53] reported the clinical outcome using the Knee Society Score (KSS), as detailed in Table 2.3. All of them reported a good or excellent mean postoperative score according to the KSS criteria [55].

Table 2.2. Studies reporting postoperative Oxford Knee Score.

Study	**Study design**	**Implant**	**Cases**	**Follow-up, years** *(range)*	**Age** *(range)*	**M/F**	**Pre-op. OKS** *(SD, range)*	**Post-op. OKS** *(SD, range)*
Akan et al. 2013	n.r., consecutive	OUKR	122	2.5 (2-3)	64.9 (35-79)	11/104	20.9 (6.2, n.r.)	41.1 (6.0, n.r.)
Hall et al. 2013	Retrospective	Unix	85	10 (8-13)	60-90	37/28	n.r.	38 (n.r., 12-48)
Hooper et al. 2015	Prospective, consecutive	OUKR	147	5	63.6 (39-86)	81/45	22.9 (8.4, 2 - 44)	42.4 (6.5, 18 - 48)
Jeer et al. 2004	n.r., consecutive	LCS UKR system	66	5.9 (5.1–6.6)	69 (54.4–87.4)	26/26	20.5 (n.r., 13–32)	37.0 (n.r., 17– 48)
Kendrick et al. 2015	RCT	OUKR	22	2	67.6 (49.1 - 81.6)	13/9	23.68 (n.r., 12 - 36)	41.52 (n.r., 24 - 48)
Pandit et al. 2013	RCT	OUKR	30	5	63.8 (45-82)	16/14	21.1 (6.1, n.r.)	39.4 (9.9, n.r.)
Pandit et al. 2015	Prospective, consecutive	OUKR	512	3.4 (1.0-10.2)	65.1 (35 - 94)	299/221	27 (9, n.r.)	43 (7, n.r.)

n.r. = not reported

Table 2.3. Studies reporting preoperative and postoperative KSS.

Study	Study design	Implant	n	Follow-up years *(range)*	Age *(range)*	M/F	Pre-op. KSS *(SD, range)*	Post-op. KSS *(SD, range)*
Akan et al. 2013	Retrosp., consecutive	OUKR	122	2.5 (2-3)	64.9 (35-79)	11/104	Obj. 43.8 (9.2, n.r.) Fun. 59.0 (11.6, n.r.) Total: 102.8 (14.8, n.r.)	Obj. 87.6 (10.2, n.r.) Fun. 90.2 (6.5, n.r.) Total: 177.8 (12.1, n.r.)
Lecuire et al. 2014	n.r., consecutive	Alpina	65	11 (10-13)	71.8 (50-80)	18/47	Obj.: n.r. Func.: n.r. Total: 119.3 (16.8, n.r.)	Obj.: n.r. Func.: n.r. Total: 171.4 (25.3, n.r.)
Pandit et al. 2013	RCT	OUKR	30	5 (5)	63.8 (45-82)	16/14	Obj.: 41.6 (11.1, n.r.) Func.: 60.3 (13.8, n.r.) Total: 101.9 (17.7, n.r.)	Obj.: 78.8 (14.0, n.r.) Func.: 92.0 (12.7, n.r.) Total: 170.8 (18.9, n.r.)
Pandit et al. 2015	Prospective, consecutive	OUKR	512	3.4 (1.0-10.2)	65.1 (35 - 94)	299/221	Obj.: 52 (20, n.r.) Func.: 71 (17 n.r.) Total: 123 (n.r.)	Obj.: 81 (13, n.r.) Func.: 86 (16, n.r.) Total: 167 (n.r.)

n.r. = not reported

Failures and revisions

All the studies reported the number and details of failures and revisions, summarised in Table 2.4.

There were 48 revisions in 1199 cases, with an overall revision rate of 0.8 per 100 observed component years (range 0 - 2.0). The mean follow-up ranged from 2 to 11 years (median 5 years). The number of revisions per 100 observed component years for each study is reported in Table 2.5.

Table 2.4. Causes of failure and revision surgeries.

Study	Implant	MB/ FB	Cases *(n)*	Mean FUP *(range)*	Revisions	Causes of failure; reoperation *(time after primary UKR)*
Akan et al. 2013	OUKR	MB	122	2.5 (2-3)	6	2 Unexplained pain; 2 TKR (n.r.) 3 Bearing dislocation;1 b. exchange, 2 TKR (n.r.) 1 Tibial plateau fracture; 1 TKR (n.r.)
Forsythe et al. 2000	Whiteside Ortholoc	FB	72	3.4 (1-8)	5	1 Persistent pain; 1 TKR (7.5) 3 Tibial condyle fracture; 3 ORIF (intra-op.) 1 Femoral condyle fracture; 1 ORIF (intra-op.)
Hall et al. 2013	Unix	FB	85	10 (8-13)	7	4 Aseptic loosening (tibial comp.); 4 TKR (n.r.) 1 Infection; 1 TKR (n.r.) 2 OA progression; 2 TKR (n.r.)
Hooper et al. 2015	OUKR	MB	147	5	6	1 Early loosening of tibia; 1 TKR (12m) 1 Lateral and PFJ OA progression; TKR (8y) 2 Bearing dislocations; 1 bearing exchance (16m), 1 ACLR + bearing exchange (n.r.) 2 Late onset of RA; 2 lateral UKRs (4y)
Jeer et al. 2004	LCS UKR system	MB	66	5.9 (5.1–6.6)	5	2 Lateral OA progression (overcorrection); 2 TKR (5.3, 5.4); 1 Tibial plateau fracture; TKR (2w) 2 Unexplained pain; 2 TKR (11m, 23m)
Kendrick et al. 2015	OUKR	MB	22	2	0	
Lecuire et al. 2014	Alpina	FB	65	11 (10-13)	11	2 Lateral OA progression; 2 TKR (1y. 7y) 1 Unexplained pain; 1 TKR (8y) 1 ACL tear; 1 TKR (9y) 3 PE fractures; 3 revision UKR (4y, 5y, 5y) 4 PE wear; 4 PE exchange (2-6y)
Pandit et al. 2013	OUKR	MB	30	5	0	
Pandit et al. 2015	OUKR	MB	512	3.4 (1.0-10.2)	6	4 OA progression; 2 lateral UKR (4y, 4.2y), 1 PFJR (2.1y), 1 TKR (6.9y) 2 Bearing dislocation; 2 bearing exchange (1.8y, 2.3y)
Schlueter-Brust et al. 2014	AMC/Uni glide	MB	78	10	2	1 Aseptic loosening (tibia); 1 tibial component revised (2.8y) 1 Bearing dislocation; 1 bearing exchange (6.5y)
	Total		**1199**		**48**	

MB: mobile bearing, FB: Fixed bearing

Table 2.5. Revisions per 100 observed component years.

Study	Implant	Cases	Revisions	Mean FUP	Observed components years	Revisions per 100 observed component years
Akan et al. 2013	OUKR	122	6	2.5	305	2.0
Forsythe et al. 2000	Whiteside Ortholoc	72	5	3.4	245	2.0
Hall et al. 2013	Unix	85	7	10	850	0.8
Hooper et al. 2015	OUKR	147	6	5	735	0.8
Jeer et al. 2004	LCS UKR system	66	5	5.9	389	1.3
Kendrick et al. 2015	OUKR	22	0	2	44	0
Lecuire et al. 2014	Alpina	65	11	11	715	1.5
Pandit et al. 2013	OUKR	30	0	5	150	0
Pandit et al. 2015	OUKR	512	6	3.4	1741	0.3
Schlueter-Brust et al. 2014	AMC/Uniglide	78	2	10	780	0.3
Total		**1199**	**48**		**5954**	**0.8**

The most common cause of failure was progression of osteoarthritis (OA) in retained compartments (n=11, 0.9%), followed by bearing dislocation, which occurred in 8 cases (0.7%). Six cases failed for loosening of the tibial component (0.4%). In one of these cases, the authors identified a surgical technique error during implantation, with incomplete seating of the component [18].

Seven failures were caused by wear or polyethylene fracture, all in fixed bearing devices. In total, these complications occurred in 3.2% of cases treated with a fixed bearing device.

The incidence of each cause of failure is reported in Table 2.6.

The most common revision surgery was TKR, performed in 25 cases (52%), followed by exchange of polyethylene bearing (wear or dislocation) in 9 cases (19%) and addition of a further unicompartmental implant in 5 cases (10%).

Table 2.6. Causes of failure, incidence and incidence rate.

Cause	Incidence	Incidence rate *(in percentage)*	Comments
OA progression	11	0.9	
Bearing dislocations	8	0.7	All mobile bearings
Other	7	0.6	
Unexplained pain	6	0.5	
Loosening	6	0.5	All tibial components
Tibial plateau fracture	5	0.4	
Wear	4	0.3	All fixed bearings
Infection	1	0.1	

Overall survival

Eight studies reported the overall survival (Table 2.7). Three studies reported the 5-year cumulative survival of the cementless OUKR, ranging from 98.7% and 100%. The Unix and the AMC/Uniglide (Corin, Cirencester, UK) showed a 10-year survival of 92% and 97.4% respectively. Hall et al. [50] reported a significant reduction of survival for the Unix at 12 years; however, only a small number of patients were at

risk at that stage. The 13-year survival of the Alpina (Biomet, Bridgend, UK) was 88%.

Table 2.7. Overall survival.

Study	Implant	Cases	Mean follow-up	Overall survival
Hall et al. 2013	Unix	85	10	92% at 10 years (34 at risk); 76% at 12 years (11 at risk)
Hooper et al. 2015	OUKR	147	5	98.7% at 5 years (136 at risk)
Jeer et al. 2004	LCS UKR system	66	5.9	89.7% at 5 years (n.r.)
Kendrick et al. 2015	OUKR	22	2	100% at 2 years (22 at risk)
Lecuire et al. 2014	Alpina	65	11	88% at 13 years (n.r)
Pandit et al. 2013	OUKR	30	5	100% at 5 years (28 at risk)
Pandit et al. 2015	OUKR	512	3.4	98.7% at 5 years (57 at risk)
Schlueter-Brust et al. 2014	AMC/Uniglide	78	10	97.4% at 10 years (n.r.)

Studies comparing cemented and cementless versions of the same implant

Three studies compared the cementless and cemented version of the OUKR [16, 39, 41]. Two are randomised controlled trials, and one a retrospective observational study. In the first RCT on 62 patients with 5-year follow-up, Pandit et al. [41] reported no significant difference in any outcome measure between the cemented and cementless groups, except for a superior AKSS functional score and a significantly lower incidence of radiolucencies in the cementless group. Furthermore, surgical time was significantly shorter in the cementless group.

In the second RCT, Kendrick et al. [39] compared the migration of components of cemented and cementless OUKR with Radiostereometric analysis (RSA) at 2 years of follow-up. The authors concluded that the cementless fixation is as good as that of cemented OUKR. The study confirmed a significantly lower incidence of RLs in the cementless components. There was no significant difference in the OKS between the two groups.

The third study comparing the cemented and cementless versions of the OUKR was a retrospective observational study on 263 cases, 141 of which were cemented and 122 cementless. The mean follow-up was 42 months in the cemented group and 30 months in the cementless group. The clinical results and survival showed no significant difference between the two groups. The surgical time was shorter in the cementless group [16].

Discussion

The most relevant finding of this review is that cementless fixation is effective and safe in all patients in whom it was used. Cementless fixation has many advantages,

including shorter surgical time, avoidance of cementation errors, lower incidence of radiolucent lines and reliable fixation. None of the studies suggested any specific contraindications to use of cementless fixation.

Cementation is an adequate fixation method for UKR, and is considered the standard technique. However, aseptic loosening, misinterpretation of radiolucent lines (RLs) and cementation errors are among the most common causes of failure of cemented implants, with a consequent increase in the cumulative revision rate as evident from National Joint Registries [19]. The advantages of cementless fixation could improve the outcome of UKRs and reduce the discrepancy between the results of specialist centres and National Joint Registries.

UKRs are more suitable for cementless fixation than TKRs, as the mechanical environment at the bone-implant interface is very different. In UKR the loads under the tibial component are mainly compressive, both when the loads across the knee are central or eccentric. Furthermore, UKR have no tibio-femoral constraints, which are responsible for significant shear stress and tilting. Especially in mobile bearing UKR, shear forces are minimal [25]. Like TKR, cementless options for UKR include porous coating, hydroxyapatite coating, screw fixation and modified implant design.

In 1988, Lindstrand first published results of randomised trial comparing cemented and cementless PCA (Porous Coated Anatomic) unicompartmental implant in 93 knees with follow-up ranging from 1 to 4 years, reporting satisfactory results and no cases of loosening in neither group [35]. In 1990, Magnussen et al. published a case series reporting the results of 51 PCA cementless unicompartmental knees, with satisfactory results in 90% of patients and no failures due to component loosening at a final follow-up ranging from 24 to 40 months [38]. However, in a follow-up extension

(4 to 8 years) of the PCA study group, Linstrand [36] reported 9 failures (7 cemented, 2 uncemented) with 6 revisions for loosening of the femoral component (2), tibial component (2), or both components (l), and polyethylene wear (1). All revised tibial components showed polyethylene wear and the weight-bearing radiographs revealed major polyethylene wear in an additional 14 knees, revealing a relevant problem of the PCA implant, confirmed by further studies [56]. Swank et al. reported in 1993, the results of a small series containing both cemented and cementless UKRs showing slightly better results for the cementless implants, although the overall results were poor with 12% failure at 4 years with an high rate of polyethylene wear [57]. These studies on early cementless UKRs were excluded from the present review, since the controversial and often poor results have been clearly ascribed to materials and design issues.

The studies included in this review report the results of modern cementless designs. All the studies reported good or excellent results for cementless UKRs. Three studies compared the clinical outcome of cementless and cemented UKRs. Outcome measures resulted comparable for the two groups in all the studies, except for a superior functional KSS reported by Pandit et al. [41]. However, most of these studies are probably underpowered to identify a relevant difference in the clinical outcome. Further randomised controlled trials or case-control studies are needed to draw definitive conclusions.

The cumulative incidence of complications and revisions is comparable to that reported in similar studies on cemented UKRs [20, 58]. In a review analysing the causes of failure of the Oxford UKR Kim et al. [58] reported an overall failure rate of 4.5% with a median follow-up of 5.6 years (range 0.1–11). Considering only the

studies on the cementless OUKR, the overall failure rate was 2.1% with a median follow-up of 3.4 years (range 1-10.2). The lower incidence of failure could be partially justified by the shorter follow-up of the cementless OUKR. A longer follow-up is needed to compare the results and draw definitive conclusion.

Loosening of the tibial component occurred in six cases (0.5%), one of which was considered a surgical error by the authors. This confirms the reliability of cementless fixation in UKR.

There is an unfounded perception that cementless fixation is not suitable for all patients, for example old age or patients with osteoporosis [59]. Some of the authors may tend to offer cementless fixation to different cohorts of patients, such as younger population. However, none of the studies mentioned different indications for cementless fixation, considered parameters such old age or poor bone quality as exclusion criteria or performed a formal preoperative assessment of bone quality (e.g. using DEXA scan). Nevertheless, the incidence of complications related to bone quality and or fixation was not more frequent than that reported for cemented implants.

Medial tibial condyle fracture is an uncommon but well-recognised complication of cemented and cementless UKR [60, 61]. However, some surgeons are concerned about a higher incidence of fractures in cementless implants. The total incidence of tibial plateau fractures in this review was 0.4%. Kim reported an overall incidence of 0.2% in cemented OUKR [58]. Most of the fractures occurred intra-operatively or in the early post-operative weeks; therefore, the different length of follow-up should not significantly influence the comparison between these two studies. Even if the available data do not permit a formal statistical comparison, the incidence of fractures in cementless UKRs seems higher than previously reported for cemented implants. The

cause is likely to be multifactorial, combining the risk factors previously described for the cemented UKR [42, 62] with a higher push in force required for the interference-fit. The role of the interference fit of the tibial component of the OUKR will be discussed in the fifth chapter of this thesis. The introduction of most of the cementless devices is recent and the majority of the case series inevitably include surgeries performed at the beginning of surgeons' learning curve. This limit has been discussed by some of the authors, and must be taken into account as it may have increased the incidence of such complications. However, considering only cementless OUKR the overall incidence of fractures was 0.1%, which is similar to the rate reported by Kim for the cemented version of the implant. The risk of fracture can be reduced by strict adherence to surgical technique, adequate clearing of peg and keel slots, avoidance of damage to the posterior cortical bone and delicate impaction using a small hammer.

The 5-year (98.7% to 100%) and 10-year (92% to 97.4%) survival rates reported in these studies are excellent.

The study by Jeer et al. reported a 90% survival of the LCS UKR system with 6 years of follow-up. However, four out of the six failures reported in this study were considered as technical errors, and all occurred at the beginning of the learning curve with the new implant. The survival rates reported for cementless implants are comparable to those published for similar cohorts of cemented UKRs [20, 22].

The overall rate of revisions per 100 observed component years was 0.8, ranging from 0 to 2.0. This is based on the assumption that the revision rate is constant, and does not take into account that there may be a high early revision rate. Consequently, this tends to over-estimate the revision rate in short term follow-up studies. However, it is helpful when comparing studies with different lengths of follow-up [45].

The number of cementless UKRs reported in National Joint Registries is still small, and usually reported cumulatively with cemented UKRs. However, the 2015 report of the New Zealand Joint Registry contains a significant number of cementless UKRs, with separate reporting of revision rate. The revision rate for cementless UKR was 0.67/100 components-year (95% CI: 0.49 – 0.90), while the revision rate for cemented UKR was 1.33/100 components-year (95% CI: 1.23 – 1.44) [63]. According to these data, the revision rate of cementless implants appears significantly lower.

The vast majority of cementless implants in the New Zealand Registry are OUKRs. Similarly, in the studies included in this review the cementless OUKR was used in most cases (833/1199, 70%). Therefore, the results of this specific design had a strong influence on the overall conclusions; in contrast, the evidence supporting the use of other cementless devices is weaker. The design of cementless implants appears to be critical in achieving stability and reliable fixation. Consequently, detailed studies are necessary prior to the introduction of new cementless devices into clinical practice, and after the introduction careful follow-up is required.

This study has some limitations. First, except for the two randomised controlled trials, most of the included studies are case series with a low level of evidence (level IV). Two of the studies that have been included have a poor MINORS score and have been considered at high risk of bias. The clinical outcome has been reported in a reasonably homogeneous manner, mainly with the OKS and KSS scores. However, there is a significant variation in the follow-up length and the incompleteness of some of the data does not permit a formal statistical analysis of the results. Most of the studies reported the results with a mid-term follow-up. The difference between implant designs represents a further source of variability. In addition, there is a possible risk of

publication bias, with the tendency to publish good results and neglect poor results. The data from National Joint Registries can only partially compensate this problem, since they involve further limitations such us underreporting of re-operations, revisions and intraoperative complications [64].

Conclusions

Cementless fixation is a safe and effective alternative to cementation in medial unicompartmental knee replacement. Clinical outcome, failures, reoperation rate and survival are similar to those reported for cemented implants. The advantages of cementless fixation include lower incidence of radiolucent lines, avoidance of cementation errors and faster surgical time.

The results of this systematic review suggest that cementless UKRs can be safely used in the clinical practice.

CHAPTER 3

TEN YEAR SURVIVAL OF THE CEMENTLESS OUKR [2]

Introduction

The cementless version of the Oxford knee (OUKR) was introduced in 2004, as an alternative to cemented fixation to limit cementation errors, improve fixation, reduce the incidence of RLs and ultimately reduce the discrepancy between the results of specialist centres and National Joint Registries.

Two randomised controlled trials have compared the clinical results and migration pattern of cementless and cemented OUKR on a limited number of patients (n = 62, n = 43) [27, 39]. The clinical results were comparable, with superior functional scores in the cementless implants. Although the cementless tibial components showed more migration in the first year, there was no difference in second year migration suggesting that cementless fixation was as good as cemented. Both studies demonstrated a lower incidence of radiolucencies in the cementless components. Failures and complications of the OUKR are infrequent. Therefore, the sample size of both the trials was too small to compare complications or identify possible contraindications for cementless fixation. Successively, a multicentre study on 1000 cases demonstrated an acceptable level of complications and no additional contraindication compared to cemented fixation [19]. However, the study had a short-term clinical and radiographic follow-up. We recently analysed a prospective case series describing the outcome of the first 512 cementless OUKRs implanted by two designer surgeons and followed up

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independently with the aim to determine the complication rate, the clinical outcome and the mid-term survival. The study had a mean follow-up of 3.4 years, with 120 cases having a minimum follow-up of 5 years. The results of this study have been previously published [49] and will be in part reported in this chapter.

The short- and mid-term studies suggest that the cementless OUKR is a safe and reproducible treatment for patients with end-stage anteromedial osteoarthritis [16, 18-20, 41, 49]. So far, however, there are no data on long-term outcome of the implant.

This prospective, multicentre case series is the first to report the long-term survival and complications of the cementless OUKR on a cohort of 1000 consecutive cases. The 5-year radiographic analysis of a subset of patients from the designer case series is also reported in this chapter.

Materials and Methods

Multicentre case series with 10-year follow-up

Between June 2004 and December 2011, 1000 consecutive medial cementless Oxford UKRs (865 patients) were performed in two institutions by nine surgeons. Patients were prospectively identified and independently followed-up in dedicated clinics.

All the cases fulfilled the recommended indications by Goodfellow et al. [14]; anteromedial osteoarthritis (AMOA) was the most common primary diagnosis (995 cases), followed by avascular necrosis (5 cases). Age, level of activity, BMI, chondrocalcinosis or patello-femoral OA (except for severe grade OA of lateral facet with bone loss or grooving) were not considered contraindications.

Patients who had undergone previous anterior cruciate ligament reconstruction or high tibial osteotomy were excluded from the study.

All procedures were performed through a minimally invasive approach, as previously described in the literature [25].

The cementless OUKR was used in all cases. Surgical findings were registered using established terminology on a standard form, reporting the status of the ACL, grade of cartilage damage (both in the affected and retained compartments) and implant sizes. Early mobilisation within pain limits and full weight-bearing as tolerated were encouraged. All patients were treated with a standard rehabilitation protocol.

Patients were assessed pre-operatively and at 1, 2, 5, 7 and 10 years after surgery. The clinical outcome was measured using the Oxford Knee Score (OKS), a validated patient-based questionnaire ranging from 0 (worst outcome) to 48 (best outcome) [65]. Eventual complications or further surgeries were recorded at each follow-up appointment. Patients who were unable to attend follow-up were contacted by post or telephone to obtain the OKS [66] and relevant clinical information.

Revision was defined as exchange or addition of a new component in the knee. Survival was determined with life table analysis.

The clinical and radiological follow-up of these patients formed part of routine assessment and therefore does not need formal ethical approval. Consent was taken from all patients for involvement in this study, including consent to use data from medical records and radiographs.

Five-year radiographic analysis

A subgroup of 106 patients from the designer group had a radiographic follow-up at 5 years. Aligned post-operative radiographs were obtained either using an image intensifier or a digital radiographic system. The radiographic beam for the AP

radiographs was aligned parallel with the tibial component and for the lateral radiographs was perpendicular to the femoral component as previously described [28]. All the five year follow-up radiographs were assessed and compared with the postoperative radiographs, looking for progression of osteoarthritis in the lateral compartment and patella-femoral joint, the presence and extent of radiolucency and evidence of component subsidence. All the assessments were performed by two independent observers. For descriptive purposes, the interface under the tibial implant was divided into three areas: zone A medial to the keel, zone B surrounding the keel and zone C lateral to the keel. The interface lateral to the vertical wall was not studied, as it is non-weight-bearing. The presence of radiolucencies was classified as absent, partial or complete for each area of the interface under the tibial component. When present, the maximum thickness of radiolucencies was measured using the femoral implant to calibrate the images.

Results

One thousand cementless OUKR were implanted in 865 patients. There were 730 unilateral procedures and 270 bilateral procedures, of which 158 were simultaneous and 112 staged. Of the 865 patients, 478 (55%) were men and 387 (45%) women. The mean age at the time of operation was 66 years (35-94).

The primary indication was anteromedial osteoarthritis in 995 cases and avascular necrosis in 5 cases.

Sixty-five patients (6.5%) were lost at follow-up during the study, 38 of which had a clinical score over one year of follow-up. Forty-two patients (4%) deceased for unrelated causes. The mean follow-up of patients that were not deceased, revised or

lost to follow-up was 7.0 years (SD 1.5, range 4.7 – 12.1), with 858 cases having a minimum follow-up of 5 years.

Survival

Considering revisions for any cause, the survival at 10 years of follow-up was 97% (CI 95%: 93.1-100%) (figure 3.1) with 87 patients at risk in the tenth year (Table 3.1). In the worst-case scenario, in which all patients lost to follow-up were considered to be failures, the ten-year cumulative survival rate using implant-related operation as the definition of failure was 89% (95% CI 78.4 to 99.6).

Table 3.1. Life table with the point of failure defined as the exchange or addition of a new component in the knee.component

Follow-up (yrs)	***Number at start***	***Revised***	***Withdrawn***	***Lost to FU***	***Dead***	***At Risk***	***Annual Failure***	***Survival***	***95% CI***	***95% CI***
0 to 1	1000	5	21	18	3	990	0.005	99.5	99.1	99.9
1 to 2	974	7	14	11	3	967	0.007	98.8	98.1	99.5
2 to 3	953	3	22	12	10	942	0.003	98.5	97.7	99.2
3 to 4	928	3	10	2	8	923	0.003	98.1	97.3	99.0
4 to 5	915	4	49	6	10	891	0.004	97.7	96.7	98.7
5 to 6	862	1	242	10	6	741	0.001	97.6	96.5	98.7
6 to 7	619	1	242	3	1	498	0.002	97.4	96.0	98.8
7 to 8	376	0	175	2	0	289	0.000	97.4	95.5	99.2
8 to 9	201	1	76	1	0	163	0.006	96.8	94.1	99.4
9 to 10	124	0	74	0	1	87	0.000	96.8	93.1	100.4
10 to 11	50	0	40	0	0	30	0.000	96.8	90.6	103.0
11 to 12	10	0	9	0	0	6	0.000	96.8	82.2	111.3

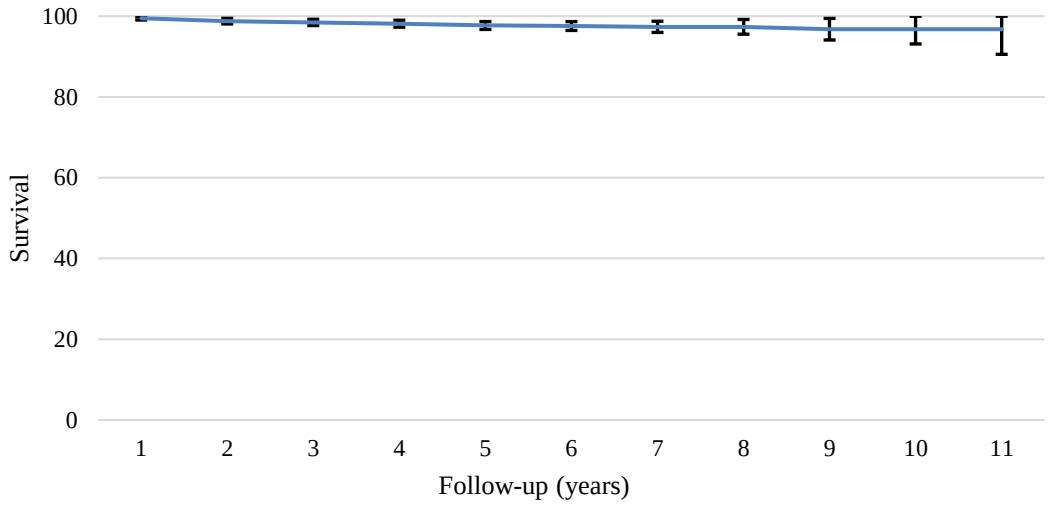


Figure 3.1. Survival curve (95% confidence intervals)

Re-operations

Twenty-five cases (2.5%) needed revision surgery, defined either as the exchange of an existing component or the addition of a new component (Table 3.2).

Table 3.2. Cause, incidence, timing and treatment of failures

	N	***%***	***Mean time after op. (years)***	***Treatment***
OA progression	11	1.1	3.8	TKR: 5 UKR: 6
Bearing dislocation	8	0.8	1.9	BE: 7 ACLR + BE: 1
Tibial loosening	2	0.2	0.9	TKR: 2
Fracture	2	0.2	0.2	TKR: 2
Pain	2	0.2	3.8	TKR: 2
Infection	0	0	0	-
	Total: *25*	*2.5*	**Mean:** *2.7 years*	

The most common reason for revision was progression of arthritis in the retained compartment, occurred in 11 cases (1.1%), at a mean of 4 years after primary surgery. The lateral compartment was involved in 9 cases, in three of which a concomitant degeneration of the patello-femoral joint was recorded. Out of these 9 cases, 4 were revised to TKR and 4 with the addition of a lateral UKR. One last case was treated by simultaneous addition of a lateral UKR, PFJR and ACL reconstruction 18 months after primary surgery. Two of these revisions were performed in the same patient, who originally underwent a bilateral procedure. She was subsequently diagnosed with late onset rheumatoid arthritis and developed OA in the lateral compartment bilaterally, revised with the addition of a lateral UKR three years after the index procedure. Two patients underwent revision with the diagnosis of OA progression in the PFJ. Both of them were treated in other institutions. In the first case the symptoms (pain 2 years after index procedure) were ascribed to OA progression in the PFJ and patient underwent revision with addition of a PFJ replacement. However, the patient's x-rays showed a preserved PFJ joint space. In these circumstances, we would have performed an arthroscopy before proceeding to a revision surgery. The patient died about three years after revision surgery for unrelated causes. We do not have clinical and radiographic information about the second patient, who underwent revision to TKR about 5 years after index procedure.

The second most common reason for revision was bearing dislocation, which occurred in 6 cases (0.6%) at a mean of 2 years after surgery. All these cases were treated with insertion of a new bearing. Two further patients had a bearing dislocation which occurred secondary to a traumatic ACL tear. One of them was treated with and ACL reconstruction and bearing upsize by 1 mm. He had an uneventful recovery with an

OKS of 43 at the last follow-up. The second case was treated by bearing upsize only. He recovered well and his OKS was 48 at the last follow-up.

There were two tibial fractures, both diagnosed post-operatively. Both underwent revision to TKR one month and two months after index procedure, respectively.

Two failures were due to tibial component loosening. In both cases patient presented pain and progressive radiolucency underneath the tibial component. Revision to TKR was performed respectively 8 and 12 months after surgery. In the latter case, the tibial component was inadequately impacted at operation and failed to settle with weight bearing.

Two further patients required revision to TKR for persistent pain. The first case underwent surgery two years after the primary operation. In this case, the operation did not reveal any obvious cause to justify the symptoms. The second case, which underwent revision after 5 years, showed impingement caused by tibial component overhang.

Finally, two patients with superficial infection needed washout without component exchange, therefore not counting as revisions. A further patient underwent an arthroscopy for recurrent haemarthroses. There were no revisions caused by deep infection.

Clinical outcome

The mean OKS improved from 23.2 (SD 7.9) to 41.7 (SD 6.8) at one year of follow-up ($p < 0.001$). The mean OKS was 41.8 (SD 7.1) at 5 years, 42.7 (SD 6.9) at 7 years and 41.7 (SD 6.8) at 10 years (Figure 3.2). There was no significant difference between the postoperative follow-up scores.

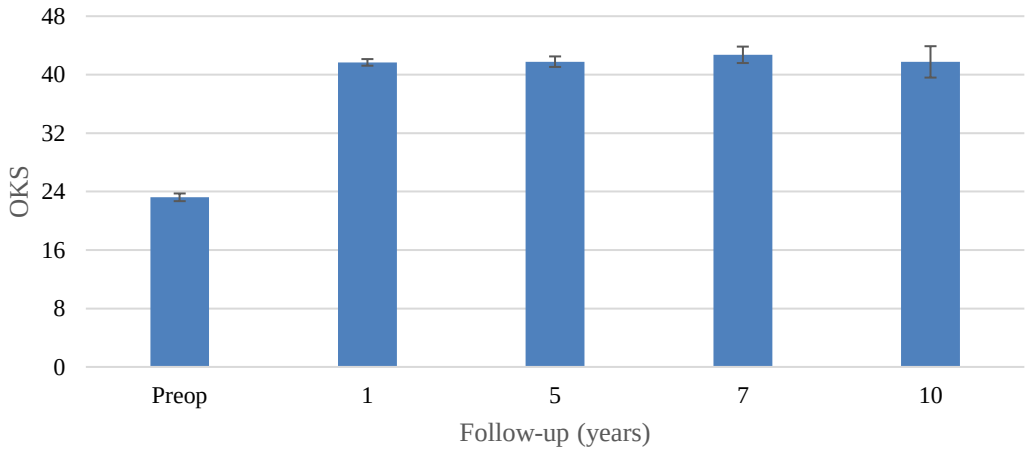


Figure 3.2. Clinical outcome (Oxford Knee Score), 95% confidence intervals

Radiographic analysis

Out of the 106 knees from the designer series with complete 5-year radiographic follow-up, none showed any evidence of loosening of either the femoral or tibial component. There was no significant progression of the arthritis in the retained compartments and none of the cases showed presence of complete physiological or pathological radiolucencies. Partial radiolucent lines were seen in 12 knees (11%). The intra- and inter-observer reliability was > 0.9. The mean thickness of radiolucencies in these patients was 1.3 mm (range 0.5-2.3, SD = 0.5).

When available, the postoperative, 2-years and 5-years follow-up radiographies were compared. This was possible in 93 cases. In nine cases small RLs visible in postoperative radiographs underneath the tibial component laterally to the keel, disappeared in subsequent follow-up radiographs. These findings are likely to be a manifestation of progressive seating of the component in the first months after surgery, as previously reported in RSA studies on cementless OUKR [39]. One tibial component had a valgus subsidence of 5.2 degrees at 2 years. This patient also had a radiolucency in zone C, but no radiolucencies in the other zones underneath the tibial

component. The clinical results were satisfactory (OKS = 40, AKSS functional = 90) and the patient had no further complications.

Discussion

This multicentre, prospective case series includes mixed cases from the designers and from an independent high-volume centre. Considering all causes of failure, the 10-year survival of the cementless OUKR was 97%, suggesting that the good mid-term results of the procedure are maintained on long-term follow-up.

This study confirms that there are no specific complications of cementless OUKR on a large cohort of patients.

The primary outcome of this study was the analysis of the long-term survival and modes of failure of the cementless OUKR. Further work will include a long-term radiographic analysis, focusing on the incidence of RLs, implant migration and progression of OA in the retained compartment. Nevertheless, this chapter reports the 5-year radiographic analysis of a subgroup of patients from the designer case series.

Survival, clinical outcome and number of failures are similar to those previously reported in a similar study on the cemented OUKR [20]. In both the studies, the two most common causes of failure were progression of OA in the retained compartments and bearing dislocation, with a similar incidence between the two fixation methods.

In contrast, failures caused by unexplained pain were higher in the cemented case series (6 vs 2), even though the difference is not statistically significant (p=0.32). One explanation is the possible impingement caused by protruding cement or the presence of loose fragments in cemented implants.

Two failures in this series were caused by tibial component loosening 8 and 12 months after the index procedure, respectively. In one case, the tibial component was inadequately impacted and failed to seat with weigh bearing, developing progressive RLs and pain. It could be argued that this case does not represent a failure of the fixation, but a surgical error. The second case was completely seated after the operation, but developed progressive RLs and pain and was revised 12 months after the index procedure. Even considering both cases as loosening, the incidence of failures for tibial component loosening is similar to that previously reported for the cemented OUKR, confirming the long-term reliability of cementless fixation.

There were two tibial plateau fractures, both diagnosed in the first two postoperative months. Both these cases occurred at the beginning of the learning curve of two of the surgeons with the cementless implant. Considering that this study includes the first cementless OUKR ever implanted, the incidence of this complication is still really low. This suggests that strict adherence to the surgical technique and avoidance of technical errors can prevent this complication.

There were no revisions caused by infection. This data differs with that previously reported for the cemented OUKR, in which five cases were revised for infection or suspicion of infection ($p=0.03$). The shorter surgical time is a possible explanation, even though we are not able to assess the influence of other factors such as a different antibiotic prophylaxis or surgical preparation. Further studies are needed to draw definitive conclusions.

The radiographic analysis of a subgroup of cases with minimum follow-up of 5 years from the designers series has been previously published [49]. None of the knees showed evidence of complete radiolucencies or pathological radiolucencies. Partial

radiolucent lines were identified in 11% of the knees. The remaining 89% had no radiolucent lines. Most radiolucencies were hardly visible. The thickest radiolucency was 2.3 mm in zone C (Figure 3.3). This is unlikely to be of any concern as there was secure fixation around and medial to the keel (zones A&B) and the patient had a good clinical outcome (OKS 40).

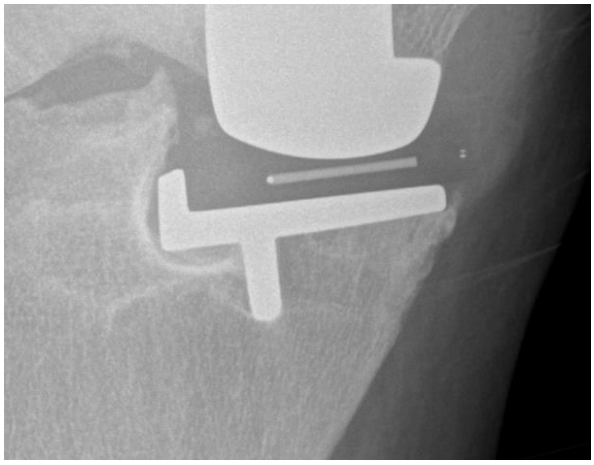


Figure 3.3: Biggest RL noticed in zone C, measuring 2.3 mm.

The reduced incidence of complete radiolucent lines compared to the cemented components could eventually improve the results of the OUKR in the national joint registries by limiting the number of unnecessary revisions caused by misdiagnosis of loosening.

Five patients in the study had cementless OUKR for spontaneous osteonecrosis (SONK). None of these cases required revision or had evidence of component loosening or subsidence. Although the numbers are too small to draw definitive conclusions, the results are encouraging.

Many surgeons have reservations about use of cementless UKR, particularly in patients who are old, have poor bone quality or history of osteoporosis [59]. Some

authors advocate the need of a preoperative assessment of bone density [67]. In the first 500 cementless OUKRs implanted by the designers, one third of patients (34%) were 70 years or older and 8% were older than 80 years at the time of the operation. In neither of these subgroups were there cases of implant subsidence or loosening, confirming that use of cementless Oxford is safe in the elderly [49].

This is the first study reporting the 10-year survival and clinical results of the cementless OUKR on a large cohort of patients from two high-volume centres.

This study has some limitations. First, a complete radiographic analysis at 10 years has not been performed, yet. The long-term assessment of the x-rays will be fundamental to identify possible evidence of implant-related issue that could be asymptomatic or not detected with the clinical assessment. However, the 5-year results of the radiographic analysis of a subset of patients from the designer series confirmed a lower incidence of radiolucent lines and no specific complications of cementless fixation.

Both centres involved in this study are specialist centres with extensive experience on the OUKR and its cementless version. Therefore, these are possibly the best results that can be obtained with this procedure.

Conclusions

The cementless OUKR is a safe and reliable procedure for treatment of anteromedial OA, showing excellent clinical outcome and survival at 10-years follow-up. The re-operation rate is similar to that previously reported for the cemented version of the implant in high volume centres. The radiographic results at 5-years showed a reduced incidence of RLs compared to that previously reported for cementless implants.

CHAPTER 4

FIVE-YEAR RESULTS OF A RANDOMISED CONTROLLED TRIAL OF CEMENTED *VERSUS* CEMENTLESS OXFORD UNICOMPARTMENTAL KNEE REPLACEMENT USING RADIOSTEREOMETRIC ANALYSIS

Introduction

The results presented in the previous chapters confirmed that the cementless OUKR has excellent clinical results and survival. However, the introduction of a new implant, as well as the modification of an existing design, is a complex process that requires caution and extensive study before exposing a large number of patients at risk. About six years ago, a randomised controlled trial was initiated to compare the cementless fixation of the OUKR to the standard cemented fixation using radiostereometric analysis (RSA), and thereby to ensure that the fixation of the new device, the cementless, was as good as the existing cemented.

RSA is a true three-dimensional radiographic method to measure the motion between an implant related to the host bone. It was introduced in 1974 by Selvik [68], and initially used predominantly in Scandinavia. Subsequently, it has been used throughout the world mainly for the assessment of joint replacements. Being highly accurate, RSA requires a small number of patients per group in a RCT. Previous studies showed that continuous implant migration after the first post-operative year is a good predictor of long term loosening [69, 70]. For these reasons, a randomised controlled trial using RSA has been suggested as the best way to compare a new implant to what is considered the standard [71].

In 2015, Kendrick et al. published the two-year results of this randomised controlled trial, which suggested that the fixation of the cementless tibial component is as good as the cemented component [39]. The cemented tibial component had minimal subsidence at three months (0.10 mm, p=0.21), which had progressed slightly at two years (0.13 mm, p=0.12). In contrast, the cementless components had a significant subsidence during the first three months (0.23 mm, p<0.001), and only slight further progression over the subsequent time points. The difference is to be expected, since the cemented components achieve their final fixation and stability intra-operatively, whereas cementless component can seat or bed-in before secondary fixation occurs.

A recent Cochrane meta-analysis on RSA studies comparing cemented versus cementless fixation in total knee replacement has reported that cemented tibial components have a smaller displacement than cementless components after two years. However, the cementless components have a significantly lower risk of future aseptic loosening with a 16% absolute risk difference between groups [31]. Furthermore, previous studies have suggested the possible role of polyethylene debris in the loosening of cementless prosthetic components, which could became apparent on a long-term follow-up [72]. Consequently, the extension of the follow-up of this study beyond two years is important.

This chapter presents the five-year results of a randomised controlled trial comparing the migration of the cementless and cemented OUKR using RSA.

Materials and Methods

A consecutive series of patients who were due to undergo OUKR for medial compartment osteoarthritis were invited to participate in the study. Patient older than

80 years, with an American Society of Anesthesiologists (ASA) score greater than three or having had previous open surgery or anterior cruciate ligament reconstruction on the same knee were excluded from the study. After enrolment and assessment for eligibility, 47 patients gave their consent and were included in the study. All the operations were performed by one of four experienced surgeons at the Nuffield Orthopaedic Centre, Oxford. Block randomisation with closed envelopes was performed once patients had undergone arthrotomy and suitability for OUKR was confirmed. Intra-operative evaluation of the ACL and all three compartments was recorded. All patients fulfilled the recommended indication for OUKR [14]. All cases were performed through a minimally invasive approach. All components used in the study were standard Phase 3 Oxford UKR (Biomet, Bridgend, UK). 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 that there was good layer of porous titanium and that this had a complete covering of hydroxyapatite and was then implanted according to the recommended surgical technique. To provide a reference rigid body for RSA, seven tantalum marker balls with a diameter of 0.8 mm were inserted in the femur and six in the tibia after bone resections were performed. Each set of markers was inserted in predetermined positions using a pre-loaded ball injector (RS-M 08, Tilly Medical Products, Lund, Sweden). The condition number, which is a measure of how well spaced the markers are (where a lower number indicates a better spread of markers with improved accuracy), was calculated for each set of stereo-radiographs. It has been suggested that for large joints a condition number below 100 achieves reliable results [70].

Patients underwent weight-bearing stereoradiographs post-operatively and at three, six, 12, 24 and 60 months after the operation. All stereoradiographs were obtained with the patient standing within a calibration frame in a normal two-legged stance. Additional screened radiographs were obtained using fluoroscopy, with the x-ray beam aligned to the tibial tray so as to provide the best image of the bone-implant interface. All stereoradiographs were analysed using model-based RSA (ver 3.21, Medis Specials, Leiden, The Netherlands) (Figure 4.1).

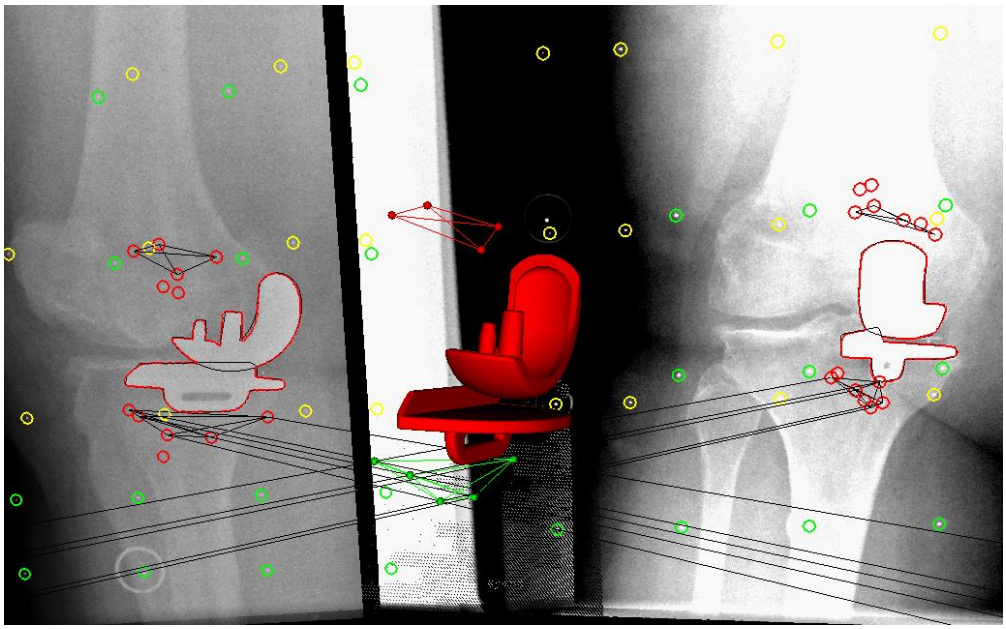


Figure 4. 1. Model base RSA.

Computer aided design models for all implant sizes were provided by the manufacturer (Biomet, Bridgend, UK). All translations were measured in millimeters and rotations in degrees. Migrations for left sided components were converted to those for a right-sided component for analysis of direction of movement as well as magnitude. Table 4.1 describes in clinical terms the migration or rotation of the components on each axis. Figure 4.2 shows the valgus and varus migration of the tibial component.

Migrations at each time point were compared to zero migration as well as between fixation groups.

Table 4.1: Clinical description of migration or rotation for femoral and tibial components using three axes.

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

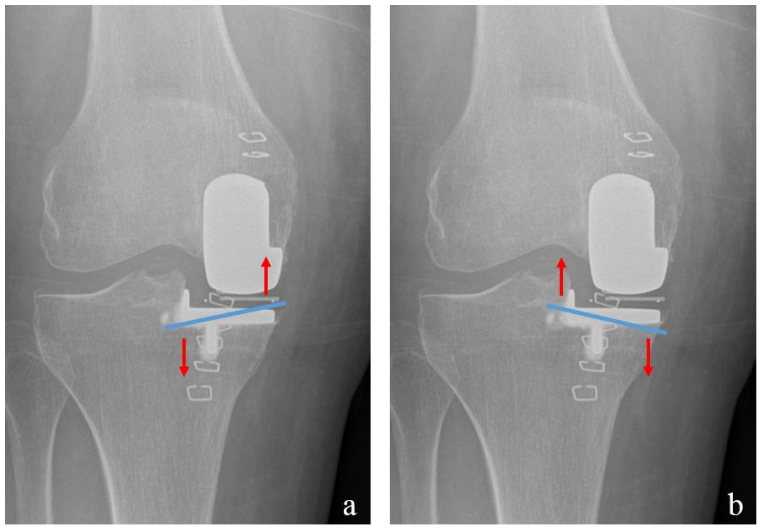


Figure 4.2: Diagram showing valgus (a) and varus (b) migration of the tibial component.

The Oxford Knee Score was obtained at annual review when each patient attended for radiographs [73].

A power calculation to detect a 0.2 mm difference in migration with a power of 80% and a significance of 0.05 required 16 patients in each group. Forty-seven patients were recruited to allow for loss to follow up or unusable stereoradiographs. All RSA calculations were conducted following the recommendations of an expert group[70]. The study was approved by the Regional Ethics Committee (C02.101).

Statistical analysis

Wilcoxon rank sum test was used for migration against zero, Mann–Whitney for migration between fixation methods and t-test for comparison of clinical outcome. The Chi-squared test was used to compare categorical variables between the groups. All values are expressed as means unless stated otherwise. Statistical significance was set at $p<0.05$. Statistical analysis was performed using PASW Satistics version 22.0 (SPSS Inc, Chicago, USA).

Results

Of the 47 patients initially included in the study, 24 were allocated in the cemented group and 23 in the cementless group. At the five-year follow-up, 5 patients had withdrawn the study, two patients had died and one patient in the cemented group had a bearing dislocation. Thirty-nine patients were available for analysis, 19 in the cemented group and 20 in the cementless group. The two groups had homogeneous age, gender, laterality and preoperative OKS as reported in Table 4.2.

Table 4.2: Distribution of patients and characteristics of the two groups.

	Cemented	Cementless	p
Cases	19	20	-
Age	65 (49-79, SD: 9)	67 (49-79, SD: 7)	0.48
M:F	8:11	11:9	0.42
Right:Left	11:8	12:8	0.58
Pre-op OKS	24 (13-37, SD: 6)	24 (12-36, SD: 7)	0.98

Femoral migration

At five years, the femoral component showed a significant mean anterior migration (z-axis) of about 0.20 mm (SD 0.19) in the cemented group and 0.14 mm (SD 0.31) in the cementless group, without significant difference between the two groups (p = 0.79). The anterior migration was significant at all time points (3, 6, 12, 24 and 60 months) when compared to zero migration, without a significant difference between the two groups (Tables 4.3 and 4.4). The anterior migration occurred almost entirely in the first three months and remained stable up to five years (Figure 4.3).

The cemented femoral component showed an inferior migration of 0.16 mm (SD 0.19) at five years. Although this was significant when compared to zero migration, it was not significantly different between the groups and did not progress after the first year.

Occasional significant differences were encountered between cemented and cementless components, although none of them was persistent at the five years follow-up.

The femoral component showed no significant migration in any other direction at five years, and no difference between cemented and cementless components. There was no significant migration on any axis after the first year.

Table 4.3. Mean femoral migration for each axis (mm) or rotation around an axis (degrees) at each time point (SD, p-value when mean compared to zero migration (Wilcoxon rank))

	Cemented					**Cementless**				
	Follow-up (months)									
	12	**24**	**60**	**12-24**	**24-60**	**12**	**24**	**60**	**12-24**	**24-60**
X	0.05 (0.28, 0.47)	0.03 (0.34, 0.80)	0.10 (0.35, 0.21)	-0.10 (0.24, 0.15)	-0.16 (0.31, 0.19)	-0.18 (0.28, 0.01)	-0.05 (0.53, 0.33)	-0.02 (0.46, 0.41)	-0.08 (0.25, 0.18)	0.07 (0.23, 0.20)
Y	-0.12 (0.25, 0.01)	-0.05 (0.32, 0.46)	-0.16 (0.19, 0.005)	0.02 (0.17, 0.67)	-0.01 (0.18, 0.19)	-0.12 (0.24, 0.06)	-0.04 (0.27, 0.69)	-0.07 (0.29, 0.33)	0.06 (0.16, 0.13)	-0.06 (0.21, 0.15)
Z	0.24 (0.32, 0.01)	0.22 (0.42, 0.03)	0.20 (0.30, 0.02)	0.00 (0.14, 0.89)	0.02 (0.24, 0.78)	0.26 (0.31, 0.00)	0.21 (0.23, 0.00)	0.14 (0.31, 0.04)	-0.10 (0.20, 0.05)	0.03 (0.21, 0.49)
Rx	0.16 (0.65, 0.40)	0.23 (0.68, 0.18)	0.16 (0.54, 0.33)	0.00 (0.30, 0.97)	-0.05 (0.50, 0.87)	0.22 (0.57, 0.04)	0.20 (0.54, 0.16)	0.35 (0.44, 0.01)	0.03 (0.31, 0.66)	0.04 (0.42, 0.99)
Ry	-0.05 (0.63, 0.45)	0.32 (0.52, 0.15)	-0.34 (2.07, 0.98)	0.49 (0.57, 0.01)	0.11 (0.75, 0.87)	0.24 (0.52, 0.05)	0.23 (0.52, 0.11)	0.29 (0.79, 0.19)	-0.10 (0.47, 0.36)	0.11 (0.37, 0.24)
Rz	0.25 (0.80, 0.17)	-0.06 (0.75, 0.69)	0.25 (0.88, 0.25)	-0.24 (0.74, 0.24)	-0.11 (0.87, 0.73)	-0.26 (0.93, 0.11)	0.00 (1.28, 0.81)	-0.17 (1.14, 0.44)	0.14 (0.54, 0.28)	-0.11 (0.79, 0.39)

Table 4.4. P-value for migration in each axis or rotation around an axis between cemented and cementless fixation for the femoral component at each time point (Mann-Whitney U).

	12 months	24 months	60 months	12 - 24 months	24 – 60 months
X	0.02	0.18	0.15	0.94	0.12
Y	0.57	0.91	0.45	0.94	0.39
Z	0.75	0.60	0.79	0.20	0.54
Rx	0.54	0.91	0.21	1.00	0.81
Ry	0.08	0.89	0.27	0.00	0.66
Rz	0.03	0.86	0.14	0.18	0.73

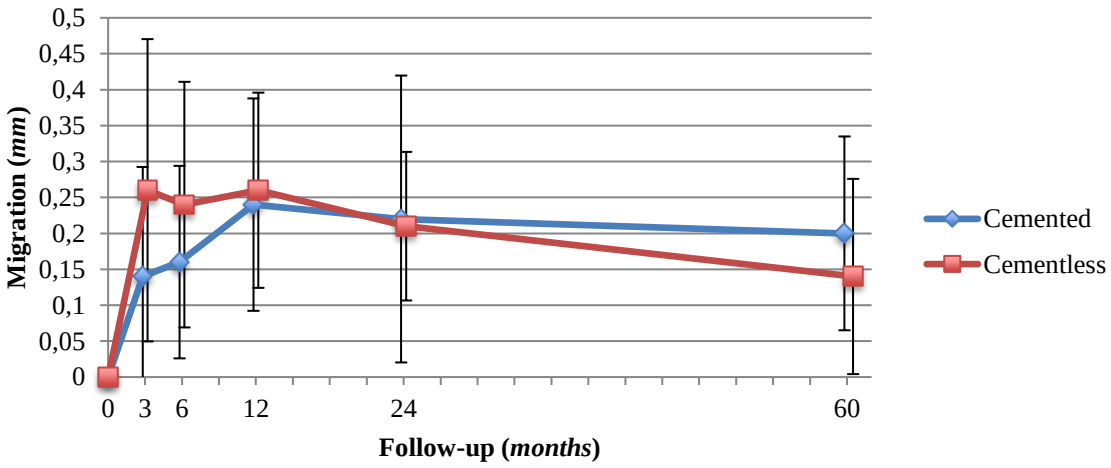


Figure 4.3: Mean migration in the z-axes (anterior migration) of the femoral component in the cemented and cementless groups with 95% confidence intervals.

Tibial migration

The tibial component showed a significant difference in the distal migration in the first year, where the cemented components subsided by 0.09 mm (SD 0.19) and the cementless components by 0.28 mm (SD 0.19) ($p<0.01$). In the second year, both groups showed a small but significant distal migration of 0.05 mm and 0.04 mm for the cemented and cementless groups, respectively (Figure 4.4). There was no further distal migration in either group after the second year (Table 4.5 and 4.6).

The cemented tibial component tipped into a mean varus of 0.29 degrees (SD 0.67) by 12 months (Rz axis). The varus subsidence was 0.45 degrees by 5 years (SD 0.80, $p = 0.01$), although the progression after the second year was not statistically significant. On the same axis, the cementless components initially showed a valgus subsidence of 0.33 degrees (SD 0.71, $p = 0.04$) at 6 months. There was no significant difference at the subsequent time points compared to zero migration, although there was a minimal but significant varus subsidence in the 12-24 and 24-60 months intervals, which led the components in 0.13 degrees of varus (SD 0.68, $p = 0.5$) at five years.

After the second year, there was no significant migration or rotation in any other direction in either group.

Table 4.5. Mean tibial migration for each axis (mm) or rotation around an axis (degrees) at each time point (SD, p-value when mean compared to zero migration (Wilcoxon rank)).

	Cemented					Cementless				
	Follow-up (months)									
	12	**24**	**60**	**12-24**	**24-60**	**12**	**24**	**60**	**12-24**	**24-60**
X	0.01 (0.24, 0.91)	0.06 (0.26, 0.37)	0.03 (0.22, 0.42)	0.07 (0.16, 0.08)	-0.12 (0.25, 0.07)	-0.04 (0.21, 0.57)	0.01 (0.19, 0.61)	-0.03 (0.21, 0.68)	0.07 (0.16, 0.07)	-0.03 (0.14, 0.35)
Y	-0.09 (0.19, 0.28)	-0.13 (0.23, 0.12)	-0.14 (0.29, 0.01)	-0.05 (0.09, 0.04)	-0.02 (0.11, 0.49)	-0.28 (0.19, 0.00)	-0.34 (0.23, 0.00)	-0.28 (0.19, 0.00)	-0.04 (0.08, 0.03)	-0.01 (0.07, 0.77)
Z	0.00 (0.26, 0.48)	0.03 (0.22, 0.48)	0.01 (0.31, 0.57)	0.03 (0.11, 0.29)	-0.03 (0.14, 0.26)	-0.01 (0.15, 0.53)	-0.02 (0.16, 0.16)	0.00 (0.11, 0.88)	0.02 (0.12, 0.53)	-0.02 (0.12, 0.79)
Rx	-0.10 (0.70, 0.94)	-0.17 (0.69, 0.43)	-0.34 (1.19, 0.13)	-0.01 (0.21, 0.86)	-0.08 (0.56, 1.00)	-0.38 (0.73, 0.02)	-0.40 (0.76, 0.02)	-0.28 (0.80, 0.22)	0.03 (0.19, 0.47)	0.04 (0.18, 0.65)
Ry	-0.02 (0.45, 0.79)	0.03 (0.44, 0.26)	0.07 (0.40, 0.36)	-0.05 (0.28, 0.42)	0.05 (0.48, 0.90)	0.16 (0.54, 0.18)	0.24 (0.61, 0.19)	0.28 (0.47, 0.04)	-0.01 (0.28, 0.92)	0.04 (0.29, 0.31)
Rz	-0.29 (0.67, 0.01)	-0.31 (0.68, 0.04)	-0.45 (0.80, 0.01)	-0.07 (0.35, 0.36)	-0.11 (0.34, 0.24)	0.10 (0.63, 0.34)	-0.01 (0.60, 0.93)	-0.13 (0.68, 0.50)	-0.18 (0.29, 0.01)	-0.27 (0.15, 0.00)

Table 4.6. P-value for migration in each axis or rotation around an axis between cemented and cementless fixation for the tibial component at each time point (Mann-Whitney U).

	12 months	**24 months**	**60 months**	**12-24 months**	**24 – 60 months**
X	0.55	0.68	0.48	0.98	0.44
Y	0.00	0.00	0.003	0.92	0.50
Z	0.43	0.19	0.65	0.73	0.38
Rx	0.11	0.14	0.95	0.43	0.69
Ry	0.27	0.65	0.28	0.62	0.70
Rz	0.01	0.19	0.21	0.28	0.04

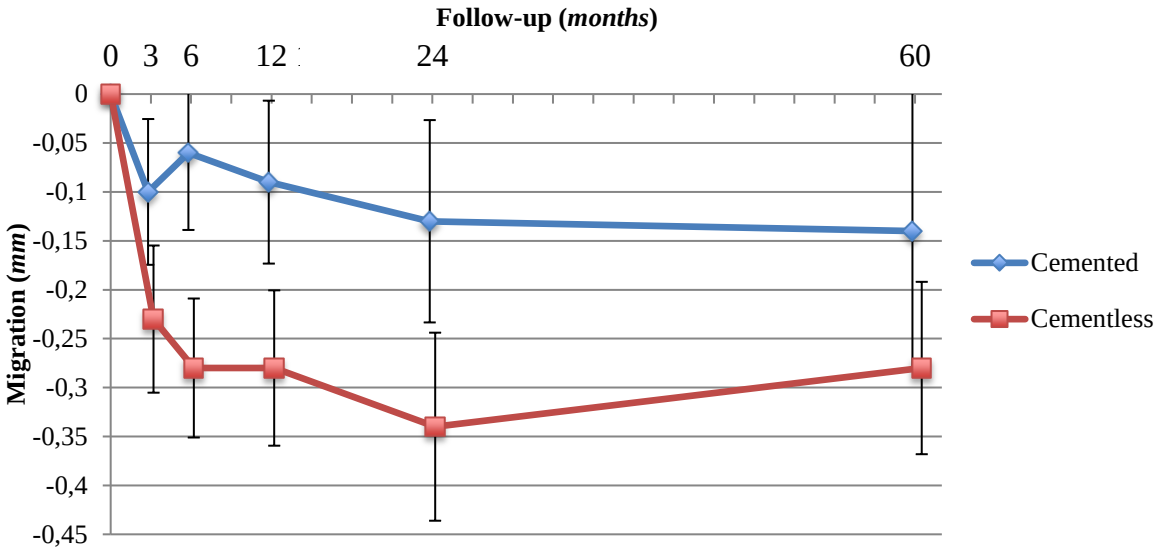


Figure 4.4: Mean migration in the y-axes (subsidence) of the tibial component in the cemented and cementless groups with 95% confidence intervals.

Radiological assessment

Five-years radiographs were available for 18 patients in the cemented group and 19 patients in the cementless group. All the x-rays were correctly aligned and allowed a satisfactory evaluation of the bone-implant interface of the tibial component.

There were 7 radiolucent lines on 18 patients in the cemented group (37%) and one on 19 patients in the cementless group (5%) at five years. There were no complete radiolucencies around the cementless components, while one case in the cemented group presented a complete radiolucent line (Figure 4.5a and 4.5b). This difference was statistically significant ($p = 0.01$).

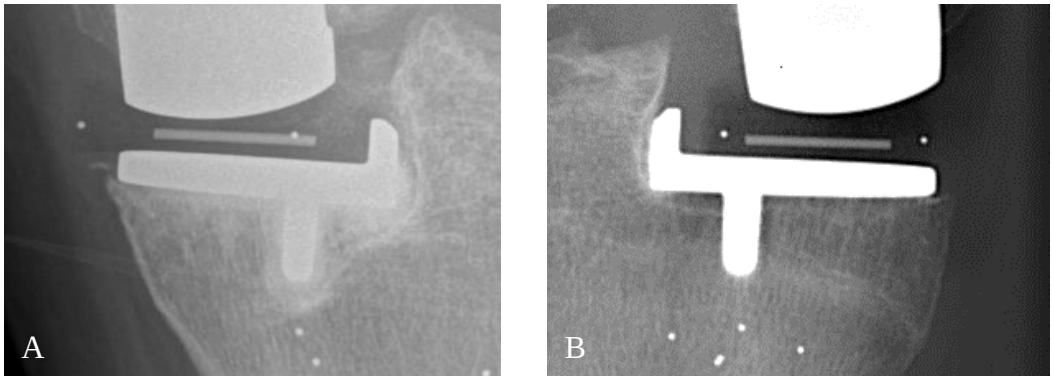


Fig. 4.5a and 4.5b. Complete radiolucent line around a cemented tibial component (a); small partial radiolucent line around a cementless tibial component (b).

Clinical outcome

At five years, the mean OKS was 37 (SD 12) in the cemented group and 41 (SD 7) in the cementless group. This difference was not significant ($p = 0.26$).

Discussion

The two-year results of this randomised controlled trial have suggested that cementless fixation is as good as cementation [39].

Despite the relevance of the second year migration as a predictor of long term loosening [69], the previous experience on cementless fixation in total knee replacement emphasizes the importance to extend the follow-up of this study beyond two years. Furthermore, there was some ongoing migration between one and two years and it is important to know what has happened to this.

At five-years, the anterior migration of the femoral components was stabilised in both groups. After the first year, there was no significant migration of the femoral

component in any direction. There was no difference between the cemented and cementless components.

The tibial components were stable in both groups after the second year. The only exception is represented by a minimal varus subsidence (z-axis) of 0.27 degrees of the cementless components in the interval between two and five years. Nonetheless, there was no significant migration on the z-axis at five years when compared to zero migration. This data is difficult to interpret. The measured migration is around one tenth of degree per year, which is near the accuracy of the system. Even if confirmed, this amount of migration would be clinically irrelevant. In contrast, the cemented components showed a varus subsidence of 0.45 degrees at five years ($p = 0.01$), which occurred almost entirely in the first year, without further progression.

At five years, the mean subsidence of cemented tibial components was 0.14 mm (SD 0.29), whereas cementless components subsided a mean of 0.28 mm (SD 0.19). The difference in subsidence occurred almost entirely during the first three months, where the cementless component subsided a mean of 0.23 mm (SD 0.18) and the cemented components 0.10 mm (SD 0.17). This is difference is expected, as cement achieves its final shape intra-operatively and substantial subsidence would necessarily be the result of collapse of either the cement structure or the underlying bone and would imply a failure of the fixation. In contrast, cementless components can further seat, bed-in or adjust their position under the loading forces before secondary fixation occurs.

There was no significant migration or rotation in any other direction in either group, at any time point.

There were 7 radiolucent lines (6 partial, 1 complete) in the cemented group and one (partial) in the cementless group. The only partial RL in the cementless group was

hardly visible (Figure 4.4b) and many surgeons would not even consider it to be a radiolucent line. The incidence of RLs in this cohort of patient is lower than previously reported for similar cohorts of patients, both among the cemented and cementless groups. Interestingly, the number of RLs detected at five years in both groups is lower than that reported at two years. The assessment of the x-rays was performed in conjunction with the first author of the two-year evaluation, to rule out an inter-observer discrepancy. The different incidence of RLs could be related to a less accurate alignment of the radiographs. Even a small difference in the alignment of the beam can hide or reveal a radiolucent line. Despite the generally low incidence of RLs, the difference between the two groups was statistically significant and confirms the results of previous studies [19, 41, 49].

There was no significant difference in the mean OKS, which was 37 (SD 12) for the cemented group and 41 (SD 7) for the cementless group. However, this study is underpowered to detect a significant difference in the OKS, which does not represent the primary outcome measure of the study. It is interesting to note that in two separate RCTs, one in our institution and one in Denmark, cementless had a superior OKS than cemented OUKRs. If all the 150 patients included in these two studies were taken together, this difference would probably be statistically significant.

So far, none of the case series published on cementless OUKR identified specific complications related to the fixation, with the exception of a small number of cases in which the tibial component subsided in valgus, as previously reported [74]. Four out of the six cases reported a clinical improvement and radiological evidence of good fixation within the first post-operative year, while two were revised. Although the cause of this phenomenon is unclear, it was speculated that it could be the consequence

of the impingement of the mobile bearing against the lateral wall of the tibial tray in flexion with a consequent altered load, which forces the component to tilt. Careful adherence to the surgical technique should prevent this problem.

This is the first study comparing the stability of cemented and cementless OUKR components using RSA. Randomised controlled trials using RSA is considered the best way to compare the stability of a new implant to what is considered the gold standard [71]. In conjunction to the results of the case series presented previously [18, 19, 49], this study confirms the safety and efficacy and reliability of the fixation of the cementless OUKR.

This study has some limitations. First, the power analysis supported the inclusion of a small number of patients in the trial to detect a difference in migration. However, this number is too small to assess a difference in the clinical outcome and complications, which are rare with this implant. Furthermore, the nature of the study did not allow a blinded procedure. A prolonged follow-up of the study will be necessary to assess the long-term results of the cementless OUKR.

Conclusions

The five-year results of this randomised controlled trial confirm that the fixation of cementless components is at least as good as that of cemented components, with a lower incidence of radiolucent lines.

CHAPTER 5

OPTIMAL INTERFERENCE OF THE TIBIAL COMPONENT OF THE CEMENTLESS OXFORD UNICOMPARTMENTAL KNEE REPLACEMENT

Introduction

The primary stability of the cementless OUKR relies on the creation of an interference fit between the prosthetic components and the bone surfaces. Interference fit (or press fit) is the fixation between two parts that is generated by friction after they have been pushed together. For orthopaedic implants, interference is defined as the difference between the size of the implant and the size of the bone cavity into which the implant is pressed, and is measured in millimeters.

The ideal interference fit for orthopaedic implants is uncertain. A previous biomechanical study has suggested that the optimal interference for a peg in cancellous bone should range between 0.65 and 0.8 mm [75]. However, the optimal interference is likely to be influenced by implant design, friction coefficient of the surfaces, and the skeletal segment in which the implant is used. The optimal interference for the cementless OUKR is still unclear.

Insufficient interference would compromise the primary stability of the implant and might cause implant migration, loosening and failure. In contrast, excessive interference increases the assembly load required to seat the component which in turn generates stress in the bone, trabecular damage and increases the risk of fractures [76]. The randomised controlled trial presented in the third section of this thesis demonstrated that the stability of the cementless OUKR is reliable and at least as good

as the cemented, suggesting that the current interference is sufficient to ensure an adequate primary stability of the components.

However, a cadaver study has suggested that lower loads are required to cause a fracture in cementless compared to cemented OUKR tibial components [42], and there are anecdotal reports of surgeons who have a higher incidence of perioperative tibial plateau fractures with cementless fixation. Even though the reason for this is not clear, the interference around the keel of cementless components, which is the most relevant design difference with the cemented version of the implant, is likely to play a primary role.

While the current interference of the cementless tibial component is sufficient to ensure reliable stability, it may be unnecessarily high and increase the risk of perioperative tibial plateau fracture.

All the surfaces of the cementless OUKR components that are in contact with bone are coated with porous titanium and hydroxyapatite, which increase the friction and encourages bone ingrowth. The only exceptions are the femoral pegs, which are coated with hydroxyapatite only. The porous coating of the cementless OUKR is produced by the deposition of Ti-6Al-4V alloy powder upon the surface of the components. The thickness of this coating is different on different parts of the component.

The stability of the tibial component is ensured by the implantation of the keel of the component (Figure 5.1) in a slot prepared on the tibial bone resection. The keel is wider than the slot in the bone, and the difference in width between the keel and the slot produces an interference fit (or press-fit fixation).

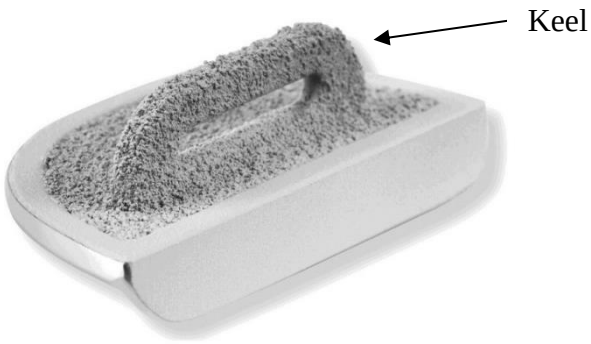
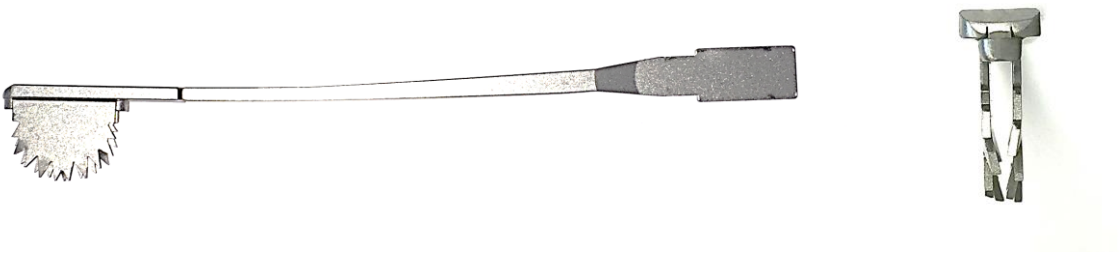


Figure 5.1. Inferior surface of the tibial component of the cementless OUKR with a porous titanium and hydroxyapatite coating.

The slot in the tibia into which the keel is pressed is prepared using a specific sawblade, called the "keel cut saw" (Synvasive Technology Inc., Reno, U.S.A.), which is used with a power tool (Figure 5.2).



a b

Figure 2. Lateral (a) and frontal (b) views of the "keel cut saw".

The keel cut saw is used through a slot in the tibial component template (Figure 5.3), which guides the saw and limits the anteroposterior extension of the slot (Figure 5.4).

Figure 5.3. The tibial template has a slot that guides the keel cut saw, limiting the anteroposterior and lateral movements and therefore contributing to determine the final size of the slot prepared in the bone.

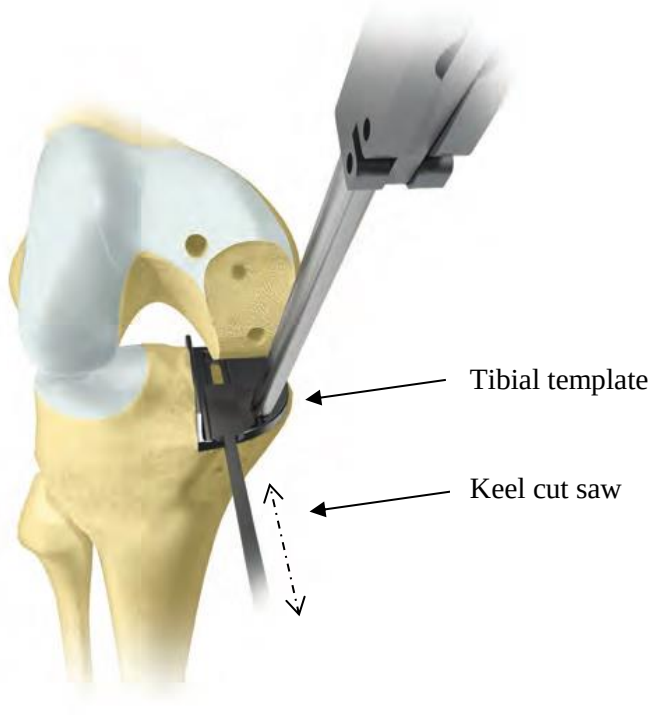


Figure 4. Tibial slot preparation: the keel cut saw is used through the slot on the tibial template, which guides the sawblade and limits the anteroposterior extension of the slot.

The size of the slot produced in the tibial bone has a certain amount of variability, which is related to the tolerance in the size of the instruments, the surgical technique and the bone quality. So far, there is no data on the size of the slot produced in the bone with this instrumentation. Consequently, the current interference fit around the keel of the tibial component is unclear.

An experiment was carried out with the aim of assessing the current interference fit of the cementless tibial component of the OUKR and identifying its optimal value. The force required to seat the component (push-in force), which is likely to be related to the risk of fracture, and the force required to remove the component (pull-out force), which is related to primary stability, have been measured.

Materials and methods

Keel measurement

The thickness of the keel of 12 standard, size "C" cementless tibial components was measured by two independent observers with a digital calliper (Sealey, Bury St. Edmunds, U.K.). Ten measurements were performed in ten different positions on the keel following a standardised sequence (Figure 5.5), to take into account the irregularity and non-homogeneous distribution of the coating. The thickness of each keel was estimated by the mean of the ten measurements.

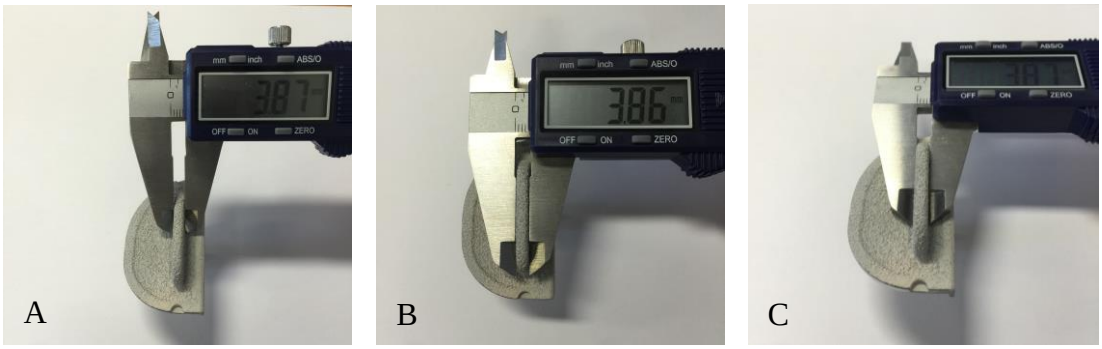


Figure 5.5: Measurement sequence: six measurements were taken in six random positions on the keel as shown in Figure 5A (moving from anterior to posterior). Two further measurements were taken in the positions shown in Figures 5B and 5C, which were repeated tilting the component by 180 degrees. Measurements were repeated by two independent observers.

Slot measurement

Six slots were prepared on a solid polyurethane foam (20 PCF, Sawbones, Malmo Sweden) with a standard keel cut saw (Synvasive Technology Inc., Reno, U.S.A.) through a standard size "C" tibial template (Biomet UK Ltd, Swindon, U.K.). Subsequently, each Sawbones block was cut in 2 mm thick sections perpendicular to the longitudinal axis of the slot with a band saw. The sections were numbered sequentially and photographed using a digital camera in a standardised fashion. The photographs were aligned using a digital alignment grid and shot at a fixed distance (13 cm) from the sample. A precision ruler was used as a reference for magnification. The width and depth of the slot were measured in each section using a digital software (Meazure, v 2.0.1 for Windows, C Thing Software) on a screen resolution of 1920 x 1080 pixels (96.0 px/in). The width of the ruler was measured in a position adjacent to the slot to assess the magnification.

The slot was divided in four portions from the top to the bottom and the width measured in each portion (w1 –w4). The maximum (d1) and minimum depth (d2) were also measured as shown in Figure 5.6.

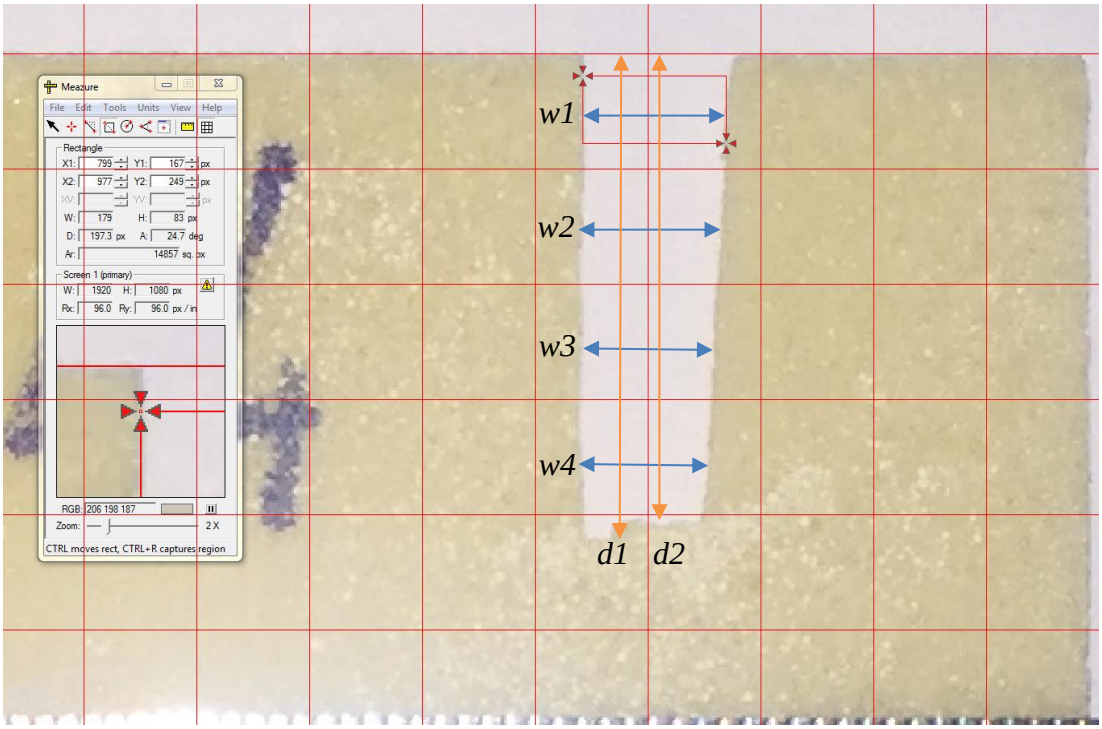


Figure 5.6. Measurement of a slot section. Each section is divided in four portions and the width of each portion is measured (w1, w2, w3 and w4). The minimum and maximum depth are also measured (d1, d2).

The sections including the most anterior and posterior portions of the slots, which were below 9.0 mm of maximum depth, were excluded. The measurements were repeated on 12 random sections, which have been photographed rotating the sample by 180 degrees to assess the reproducibility of the method.

Interference

Interference was defined as the difference in millimeters between the mean width of the keel and the mean width of the tibial slot (Figure 5.7).

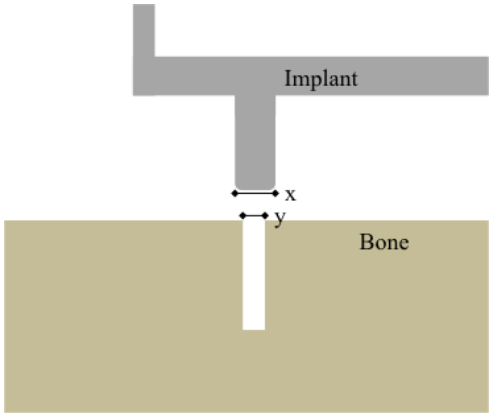


Figure 7. The interference is calculated as the difference between the size of the implant (*x*) and the size of the bone cavity in which it is pressed in (*y*) (*interference = x-y).*

Push-in and pull-out force measurement

A CNC machine (Hurco VM1) was used to cut slots in blocks of solid polyurethane foam (20 PCF, Sawbones, Malmo Sweden), which is the most widely used analogue for trabecular bone [77, 78]. The use of a CNC machine was preferred to the standard surgical instrumentation to prepare slots with different width (ranging from 2.0 to 3.8 mm) and obtain a specific nominal interference.

A custom-made boss was welded to the upper surface of twelve standard cementless size C Oxford UKR components by the company producing the implant (Biomet UK Ltd, Swindon, U.K.), to securely fasten the components to the materials testing machine.

A Dartec materials testing machine (HC10) was used to implant and extract the tibial components, at 0.01 mm/s, whilst measuring the push-in and pull-out forces.

Six components were used and each was implanted in 12 new slots with a range of interference of 0.1 mm to 1.9 mm. The length and depth of the slots were constant (39 mm and 14 mm, respectively) and exceeded the dimensions of the keel, to exclude the influence of the impingement on the bottom or with the anterior or posterior ends of the slot.

Each component was tested starting from the minimal interference to the maximal interference, to reduce the risk of damaging the porous coating on the components.

The experiment was repeated with six further tibial components on a cellular polyurethane foam block (15 PCF, Sawbones, Malmo Sweden), which is a more porous analogue for trabecular bone.

Statistical analysis

One-way ANOVA tests were performed to compare the push-in and pull-out forces between groups. The post-hoc analysis was carried out with the Bonferroni procedure. A paired T test was used to compare the repeated measurements of the slot width. Statistical significance was set at $p < 0.05$. Pearson's correlation test was performed to measure the inter-observer variability. All analyses were carried out using SPSS version 22.0 for Windows (SPSS Inc., Chicago, USA).

Results

Measurement of the keel of the cementless OUKR

The mean thickness of the tibial components was 3.87 mm (range 3.83 – 3.92) (Table 5.1). The intra-observer correlation was 0.82. There was no significant difference between the measurements performed by the two observers (p = 0.31).

Table 5.1. Mean thickness of the keel of each tibial component.

Component	Mean thickness (mm)	Range (mm)
A	3.88	3.73 - 4.02
B	3.83	3.73 - 3.93
C	3.88	3.83 - 3.94
D	3.83	3.75 - 3.91
E	3.92	3.80 - 4.08
F	3.92	3.81 - 4.06
G	3.87	3.77 - 4.02
H	3.85	3.79 - 3.97
I	3.84	3.73 - 3.92
L	3.85	3.72 - 3.93
M	3.92	3.81 - 4.09
N	3.83	3.74 - 3.96
Overall mean	**3.87**	**3.76 - 3.99**

Measurement of the slots

Ten sections were measured for each slot. The maximum width of the slots was measured in the most superficial portions (mean 2.93 mm, SD 0.08, range 2.77 – 3.1),

while the minimum width was registered in the deepest portions (mean 2.70 mm, SD 0.15, range 2.42 – 3.12). The maximum depth of the slots was 9.92 mm (SD 0.31, range 9.07 – 10.41) and the minimum depth 9.27 mm (SD 0.59, range 7.61 – 9.81). The mean width of the slots was 2.83 mm (SD 0.10). The measurements for each portion of the slot are reported in Table 5.2.

Table 5.2. Mean width for each portion of the slot in millimetres. W1 is the width of the most superficial portion of the slot, while w4 refers to the deepest part. D1 represents the maximum depth and d2 the minimum depth.

	Width (mm)				**Depth (mm)**	
	W1	**W2**	**W3**	**W4**	**D1**	**D2**
Mean	2.93	2.87	2.82	2.70	9.92	9.27
SD	0.08	0.12	0.12	0.15	0.31	0.59
Range	2.77 - 3.10	2.65 - 3.14	2.59 - 3.14	2.42 - 3.12	9.07 - 10.41	7.61 - 9.81

Current interference

The thickness of the keel varies in different portions of the slot because of the roughness of the surface and the non-homogeneous distribution of the porous coating. The mean of all measurements (3.87 mm) has been used to calculate the nominal interference for each slot, using to the following formula:

Keel thickness (3.87 mm) – slot width = interference

The current interference ranges from a minimum of 0.94 mm to a maximum of 1.17 mm in the different portions of the slot, with a mean value of 1.04 mm. However, considering the minimum and maximum width measured in the slot sections, the interference fit can range from a minimum of 0.73 mm to a maximum of 1.45 mm.

Push-in and pull-out measurement

In the solid polyurethane blocks (20 PCF), the push-in force progressively increased with increasing interference. With the maximum interference tested (1.9 mm) the push in force was 1852 N (SD 106). The pull-out force was related in a non-linear fashion to interference. The highest pull-out force (380 N, SD 24) was obtained with an interference of 0.7 mm, which required a push-in force of 925 N (SD 65). The pull out force decreased with higher interference.

For an interference ranging from 0.9 and 1.3 mm, which is similar to the current range, the push-in force oscillated between 1254 and 1456 N and the pull-out force between 167 and 317 N. Compared to this, interferences of 0.7 mm, 0.6 mm or 0.5 mm had push-in forces that were reduced by up to 45% ($p<0.001$) and comparable or superior pull-out forces ($p > 0.05$). The pull-out force progressively decreased with interference of 0.4 mm and less. The complete results are reported in Appendix 1 (Table A-1).

The one-way ANOVA revealed a significant difference between groups both for the push-in and the pull-out measurements ($p < 0.001$). The results of the post-hoc analysis are reported in table 5.3a and 5.3b.

Table 5.3a and 5.3b. Results of the post-hoc analysis. Significance was set as <0.01. There was a significant difference in push-in force between the current interference and the "ideal" range of interference (a). There was no difference in the pull-out between the 0.5, 0.6 and 0.7 slot. In contrast, the interference values in the "ideal range" showed a superior pull-out force compared to an interference of 1.1 and 1.3 mm (b).

a

			Current range		
	Interference		**0.9 mm**	**1.1 mm**	**1.3 mm**
		Push-in force (SD)	1254 N (43)	1363 N (90)	1456 N (53)
Ideal range	**0.5 mm**	803 N (74)	< 0.01	< 0.01	< 0.01
	0.6 mm	945 N (55)	< 0.01	< 0.01	< 0.01
	0.7 mm	925 N (65.2)	< 0.01	< 0.01	< 0.01

b

			Current range		
	Interference		**0.9 mm**	**1.1 mm**	**1.3 mm**
		Pull-out force (SD)	317 N (53)	194 N (51)	167 N (30)
Ideal range	**0.5 mm**	285 N (21)	1	< 0.01	< 0.01
	0.6 mm	341 N (27)	1	< 0.01	< 0.01
	0.7 mm	380 N (24)	0.1	< 0.01	< 0.01

With the more porous bone analogue, although the forces were lower, the relationship between interference and push in and pull out force were similar. Again, the pull out force decreased with higher interference. The pull-out force presented almost constant values for an interference ranging from 0.5 to 1.9 mm.

With the maximum interference tested (1.9 mm) the push in force was 1123 N (SD 242). The highest pull-out force was around 200 N, obtained with for all the value of interference ranging from 0.7 to 1.3 mm.

For the current range of interference, the push-in force varied between 595 and 835 N and the pull-out force between 196 and 199 N. Compared to this, interferences of 0.7 mm, 0.6 mm or 0.5 mm had push-in forces that were reduced by up to 47% ($p<0.001$) and comparable pull-out forces ($p > 0.05$). Also in the cellular block the pull-out force progressively decreased with interference of 0.4 mm and less. The complete results are reported in Appendix 1 (Table A-2). The results of the post-hoc analysis are reported in Table 5.4a and 5.4b.

Table 5.4a and 5.4b. Results of the post-hoc analysis. Significance was set as <0.01. There was a significant difference in push-in force between the current interference and the "ideal" range of interference (a). In contrast, there was no difference in the pull-out (b).

a

			Current range		
	Interference		**0.9 mm**	**1.1 mm**	**1.3 mm**
		Push-in force (SD)	595 N (26)	723 N (41)	835 N (68)
Ideal range	**0.5 mm**	357 N (34)	< 0.01	< 0.01	< 0.01
	0.6 mm	420 N (37)	0.11	< 0.01	< 0.01
	0.7 mm	467 N (79)	1	< 0.01	< 0.01

b

			Current range		
	Interference		**0.9 mm**	**1.1 mm**	**1.3 mm**
		Pull-out force (SD)	196 N (18)	200 N (20)	199 N (27)
Ideal range	**0.5 mm**	169 N (14)	1	0.96	1
	0.6 mm	185 N (19)	1	1	1
	0.7 mm	199 N (7)	1	1	1

The relation between push-in and pull-out forces with varying interference, in both testing materials, is reported in Figures 5.8 and 5.9.

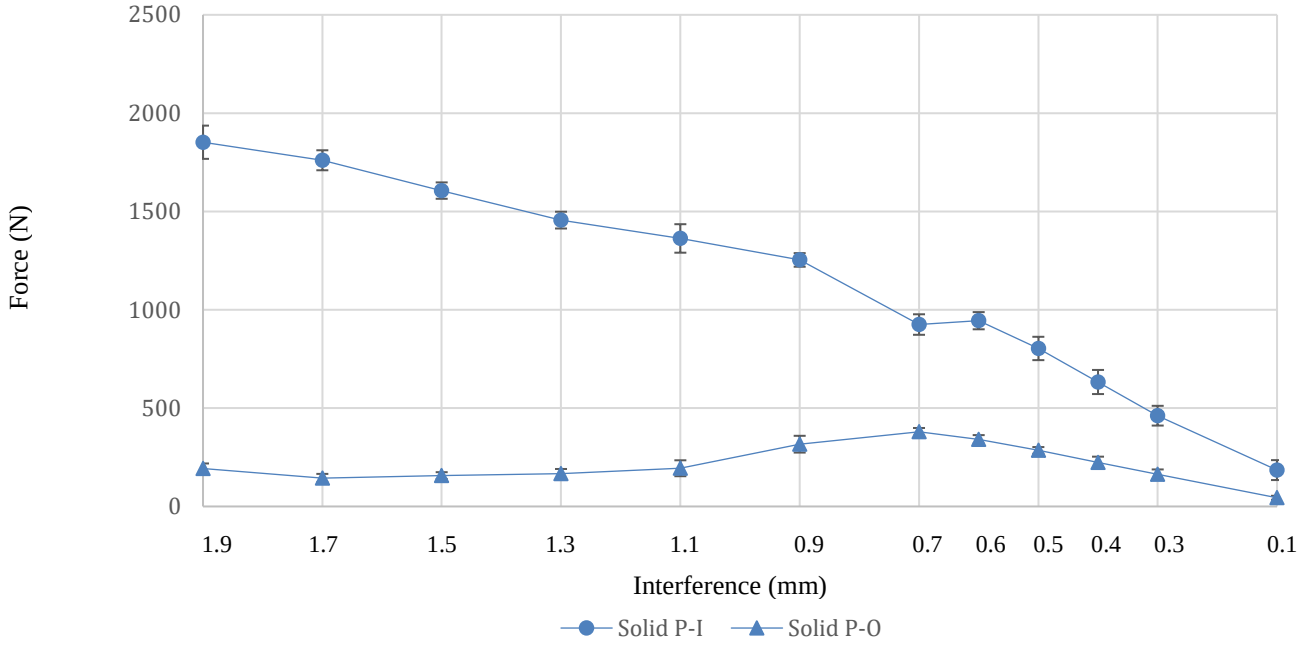


Figure 5.8. Mean push-in and pull-out value with varying interference for the solid testing material (20 PCF) (95% confidence intervals).

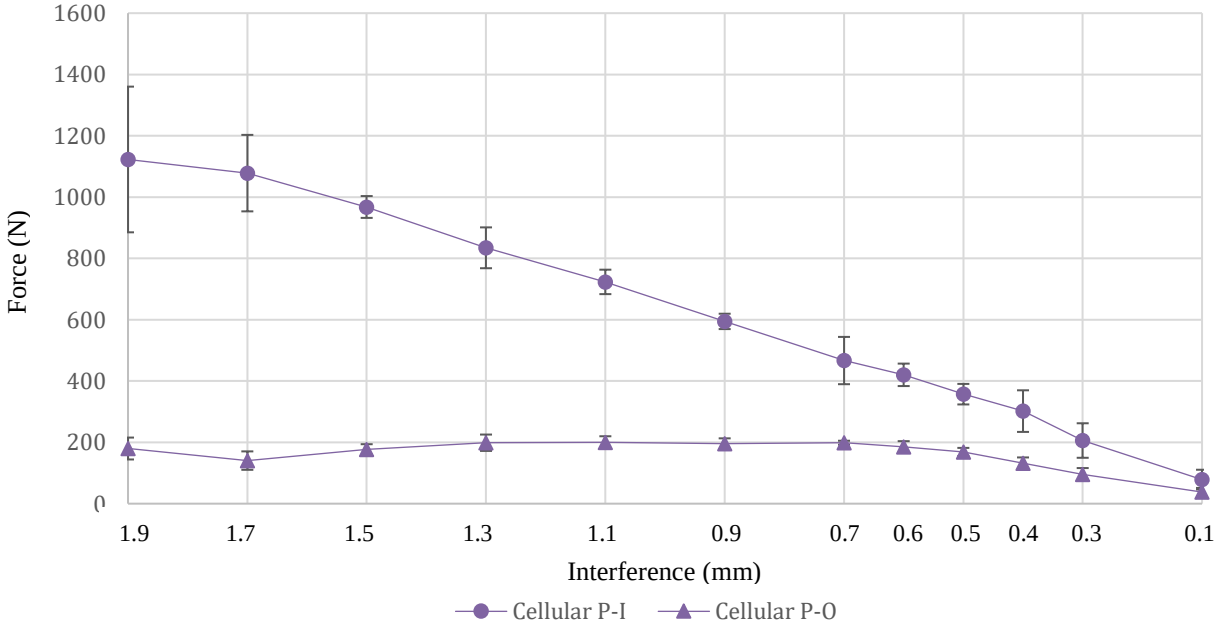


Figure 9: Mean push-in and pull-out value with varying interference for the cellular testing material (15 PCF) (95% confidence intervals).

Discussion

This biomechanical study suggests that decreasing the interference fit of the keel of the cementless OUKR would significantly decrease the push-in force required to seat the component, without diminishing the pull-out force and therefore ensuring the same level of primary stability.

There was an almost linear correlation between the nominal interference and the push-in force; the higher the interference the higher the push-in force. In contrast, there is a non-linear correlation between interference and the pull-out force. On the 20 PCF solid polyurethane blocks, the pull-out force resulted in almost constant for values of nominal interference ranging from 1.1 to 1.9 mm, with a median value of 167 N. It increased for values of interference ranging from 0.5 to 0.9 mm, reaching the peak value of 380 N for a nominal interference of 0.7 mm, and then progressively decreased for values of interference below 0.4 mm.

The interference that is achieved with the current implant design ranges from 0.9 to 1.3 mm. The variability in interference is caused by the irregularity in the geometries of both the porous coating and the bone slot. According to this study, the ideal nominal interference should be in the range between 0.5 and 0.7 mm. Compared to the current range (0.9 – 1.3 mm), this “ideal range” produces an equal or superior pull-out force, with a reduction in the push in force up to 45%. A very similar pattern of results were obtained using the cellular polyurethane blocks, which has different mechanical properties and friction coefficient.

The results are consistent with those reported by Berahamani et al. (2015) who demonstrated that beyond a certain interference the fixation strength does not increase, in a cadaveric study assessing the initial stability of pegs with different surface

morphologies. These findings were explained by excessive stresses during insertion that would cause damage to the bone and limit additional stability [75, 79].

Previous biomechanical studies on bone demonstrated that the permanent deformation of the testing material during implantation leads to an actual interference fit that is less than the nominal interference [76, 80]. The permanent trabecular bone deformation was higher for higher nominal interference, and occurred mainly during the push-in rather than the pull-out phase. The difference between the nominal interference and the effective interference that resulted was minimal for an interference of 0.3 mm, and increased with increased interference. The actual interference was around 30% of nominal interference for an interference of 0.9 mm [76].

The cementless keel cut saw is designed to create a slot that is narrower than the keel of the tibial component, to generate an interference fit that ensures primary stability of the component. During implantation of the tibial component the interaction of the keel with the walls of the slot generates a force normal to the walls of the slot. A previous biomechanical study has demonstrated that whilst the pull-out force is significantly lower than the push-in force, the normal forces on the bone are roughly equivalent to the push-in force [80]. It has been shown that these forces can cause fractures during implantation of prosthetic components [76, 81].

Medial tibial condyle fracture is an uncommon but well-known complication of cemented and cementless UKR [60, 61].

The aetiology of medial tibial plateau fractures is likely to be multifactorial. Several risk factors associated with the procedure have been described for cemented UKRs [25, 62, 82]. These include a deep resection, damage to the posterior cortical bone, a

medial vertical cut, more than one pin hole, and excessive impaction during implantation.

A cadaver study has suggested a reduced fracture load in cementless UKR compared to cemented tibial components [42], and some surgeons are concerned about a higher incidence of perioperative tibial plateau fractures with the use of cementless fixation. However, the systematic review on cementless fixation in UKR presented in this thesis did not reveal an increased incidence of fractures in cementless implants.

The design of the cementless OUKR tibial component is similar to the cemented version. The cement pockets are filled with porous titanium, produced by the deposition of Ti-6Al-4V alloy powder upon the surface of the components. All the surfaces that are in contact with bone are coated with calcium hydroxyapatite (HA) [49]. The instrumentation and surgical technique are the same of the cemented OUKR except for the fixation, which is ensured by interference fit in the cementless implant. All the risk factors and technical precautions described for the cemented OUKR are therefore applicable to the cementless OUKR. An excessive interference fit is a possible additional risk factor for medial tibial condyle fractures by causing a splitting force that can initiate a fracture or produce structural damage on the bone. This may subsequently propagate when weight bearing is initiated and eventually result in a fracture [76].

A high interference can make component implantation difficult. Incomplete seating of the tibial component is not uncommon, and does not represent a problem since components will seat spontaneously with weight bearing [39]. However, in such situation some surgeons may use an excessive force while hammering. Excessive hammering or the use of a heavy hammer are known risk factors for fractures [25].

The results of this study show that a reduced nominal interference would require a lower push-in force to seat the tibial component of the cementless OUKR, yet would achieve a similar or higher pull-out force. A reduced push-in force would produce less normal force on the bone and possibly limit the trabecular damage of the bone. Moreover, the impaction required to implant the component would be reduced. By limiting these problems, a lower nominal interference could reduce the risk of perioperative tibial condyle fracture.

This is the first study identifying the current and the ideal range of interference for the tibial component of cementless OUKR and assessing its correlation with push-in and pull-out forces.

The study suggests that the current nominal interference could be safely reduced.

This study has some limitations. First of all, tests were carried out on artificial bone. Even though the Sawbones blocks used are meant to resemble the bone properties, their biomechanical behaviour and friction coefficient will be inevitably different from human bone. However, a second testing material, having a different modulus and structure has been tested and found to have similar results. Future research will compare the optimal interference with current interference in animal or cadaveric bone, although neither of them provides a good representation of osteoarthritic bone. In this test we only considered the width of the slot. The length, depth and shape of the slot are likely to play an important role and will be studied in the future, as well as the possible interference fit generated between the wall of the tibial component and the sagittal bone cut. In this test, the tibial components were implanted with a constant displacement generated by a testing machine on a single axis. This significantly differs from the way the components are implanted in the clinical setting and could partially

affect the results. Finally, at this stage we could not formally correlate the risk of fracture with the nominal interference. All these aspect will be object of future research.

The final endpoint of this project will be an iteration of the surgical instrument and/or the tibial component, to improve the efficacy and safety of the procedure.

Conclusions

This study suggests that decreasing the interference fit of the keel of the cementless OUKR reduces the push-in force and can increase the fixation strength.

A lower interference fit may both improve primary fixation and decrease the risk of fracture.

CHAPTER 6

DISCUSSION

The results of this research project have helped improve the knowledge of cementless OUKR (indications, complications, long-term outcome) and the understanding of some of the biomechanical aspects of cementless fixation.

Despite the controversial history of cementless UKR, a systematic review of literature suggests that modern implants are safe and effective, with an overall revision rate of 0.8 per 100 observed component years (range 0 – 2.0). The survival reported for five different implants ranged between 90% and 100% at five years and between 92% and 97% at ten years. Although some surgeons may tend to offer cemented fixation to selected patients, none of the studies mentioned different patient selection criteria or considered parameters such as old age or poor bone quality as exclusion criteria. No formal preoperative assessment of bone quality was suggested by any of the studies. One of the limitations of the systematic review is that the majority of the studies (70%) reported on the cementless OUKR. Therefore, the results of this specific design had a significant influence on the overall conclusions. The OUKR is particularly suitable for cementless fixation, since virtually all the forces thorough the bone-implant interface are compressive. The history of cementless implants suggests that the design, materials and surgical technique are critical in achieving reliable results. Consequently, detailed studies are necessary prior to the introduction of new cementless devices in the clinical practice.

The analysis of the prospective case series confirmed that the cementless OUKR can be safely used in all patients with anteromedial osteoarthritis who meet the indication for UKR. The cementless fixation was offered to all the patients, despite old age or poor bone quality. The clinical outcome was good or excellent in 80% of cases. Considering all causes of failure, the five-year survival was 98%. None of the failures were related to the fixation of the implant. None of the available five-year radiographs (n = 106) showed evidence of complete radiolucencies or pathological radiolucencies, and 89% of cases showed no evidence of RLs. In contrast, the detection of "physiological" RLs is a common finding in cemented implant radiographies. Radiolucent lines have been correlated with the presence of some fibrocartilaginous tissue at the bone-prosthesis interface [29]. Even if physiological radiolucent lines are detected in well functioning implants and do not affect the clinical outcome or survival [28], they may be the manifestation of a sub-optimal fixation. Furthermore, RLs are a frequent cause of misdiagnosis of loosening, especially in low volume centres or less experienced hands.

A small group of patients had the cementless OUKR for spontaneous osteonecrosis (SONK) of the medial femoral condyle. The results were good in all the patients, with no evidence of subsidence or loosening of the components. Although the sample is too small to draw firm conclusions, these preliminary results suggest that cementless fixation can be safely used in patients with osteonecrosis. Future studies are needed to confirm these findings.

The preliminary results of the analysis of a cohort of 1000 consecutive cases from two centres demonstrated a 10-year survival of 97%. Twenty-five patients required a

revision operation. The nature and incidence of complications were similar to that reported for the cemented version of the implant in similar studies.

Except for the reduced incidence of RLs, the results of the cementless and cemented OUKR are similar in high volume centres. This is to be expected, since the misinterpretation or RLs, cementation errors and a lower threshold to revision are more common in low-volume centres and in the hands of less experienced surgeons.

In contrast, the advantages of the cementless fixation could positively influence the revision rate in the National Joint Registries, which includes cases from both high volume and low-volume centres and occasional users. Interestingly, the 2015 report of the New Zealand Joint Registry showed a significant reduction in the revision rate of the cementless OUKR, which was 0.67 per 100 component years (95% CI 0.49 – 0.90) compared to 1.33 per 100 component years (95%CI 1.23 – 1.44) of the cemented version. The 5-year survival was 98% for the cementless OUKR versus 93% for the cemented OUKR. Similar results are reported in the National Joint Registry of England and Wales. Data extracted in January 2016 revealed a revision rate of 0.77 and 1.32 per 100 component years for cementless and cemented OUKR, respectively. It is likely that the dramatic decrease in incidence of complete radiolucent lines from about one third in cemented components to zero in cementless contributes to this.

The two-year results of the randomised controlled trial comparing the cemented and cementless OUKR with radiostereometric analysis (RSA) have suggested that “for the Oxford UKR, cementless fixation is at least as good as, if not better than, cemented” [39]. Despite the relevance of the second year migration as a predictor of long term loosening [69], the previous experience on cementless fixation in total knee

replacement emphasizes the importance to extend the follow-up of this study beyond two years.

At five-years, the femoral components had stabilised in both groups without any evidence of further significant migration in any direction at any time point between 2 and 5 years. The tibial component showed no significant subsidence in both groups after the second year. The five-year results of this randomised controlled trial confirm that the fixation of cementless components is as good as that of cemented components, with a lower incidence of radiolucent lines.

The last section of this research project focussed on the interference around the cementless tibial component. The ideal interference of cementless orthopaedic implants is unclear, and likely to vary for different implant designs and bone segment in which the implant is used.

This is the first study to estimate the current interference fit of the cementless Oxford UKR and the lessons learnt will be useful in designing future implants and also provide guidance for change in instrumentation and/or surgical steps. The RSA study demonstrated a reliable stability of the cementless components, thus suggesting that the current interference fit provides sufficient fixation strength. However, a cadaveric study suggested a lower load to fracture of the cementless OUKR [42], and some surgeons are concerned of a higher incidence of perioperative medial tibial condyle fractures.

Medial tibial condyle fractures are a rare but known complication of medial unicompartmental knee replacement, both in cemented and cementless implants. Some technical errors, such as a deep resection, a medialised position of the tibial component, the damage of the posterior cortical bone and excessive impaction have

been identified as risk factors [25, 83]. Specific subsets of patients, such as the Asian population, seem to be more at risk because of the size and morphology of the proximal tibia. The strict adherence to the surgical technique can significantly reduce the risk of fracture, as suggested by the low incidence of this complication (0.002%) in the cohort of 1000 patients who underwent the operation in one of the two high volume centres. However, the interference around the tibial keel could cause trabecular bone damage and require strong impaction, eventually increasing the risk of fracture in the cementless OUKR.

A biomechanical test demonstrated that for the current level of interference the force required to implant the component is as high as 1500 N. Interestingly, a reduction of the interference would significantly decrease the push-in force required to seat the component, without diminishing the pull-out force and therefore ensuring the same level of primary stability.

The interference that is achieved with the current implant design ranges from 0.9 to 1.3 mm. According to the results of this study, the ideal nominal interference should be in the range between 0.5 and 0.7 mm. Compared to the current range, this “ideal range” produces an equal or superior pull-out force, with a reduction in the push in force up to 45%. In the clinical practice, the modification of the interference could make the tibial component easier to implant maintaining an optimal primary stability, reducing the risk of fracture. The main limitation of the biomechanical test on interference is the use of a testing material instead of animal or human bone. However, the use of testing material provided a controlled and reproducible experimental condition. This was fundamental due to the lack of preliminary data on the interference fit of the cementless OUKR. This study sets the basis for future experiments on bone.

If the results are confirmed in bone, a modification of the implant design or the instrumentation will be desirable to optimise the surgical procedure and the outcome of the operation.

CHAPTER 7

FURTHER WORK

Further analysis will be required to assess the long-term clinical outcome and consolidate the findings on long-term survival.

Similarly, the extension of the follow-up of the randomised controlled trial comparing the cemented and cementless OUKR with RSA is central to assess potential long-term advantages of biologic fixation.

Besides the repetition of the biomechanical test on bone, some other aspects such as the size and morphology of the extremities of the slot and the possible interference fit generated between the vertical wall of the tibial component and the tibial wall need to be evaluated. The bone morphology of the proximal tibia needs to be studied to identity possible patients that have an increased risk of fracture with cementless fixation.

The final aim of this research project will be an iteration of the design of the tibial component of the cementless OUKR to optimise fixation and reduce possible perioperative complications. An RSA study could be used to compare the migration pattern of the new design and the current tibial component.

APPENDICES

Appendix 1: Optimal interference of the tibial component of the cementless OUKR

Table A-1 Push-in and pull-out measurements on the solid polyurethane block (20 PCF)

Push-in (N)

	Component								
Interference	**1**	**2**	**3**	**4**	**5**	**6**	**Mean**	**SD**	**95% CI**
1.9	1758	1794	1779	1809	1971	2001	1852	105.6	1768 – 1937
1.7	1749	1733	1686	1767	1749	1877	1760	63.6	1709 – 1811
1.5	1598	1582	1537	1592	1639	1689	1606	52.1	1565 – 1648
1.3	1384	1456	1405	1490	1526	1476	1456	53.3	1413 – 1499
1.1	1364	1359	1204	1352	1470	1428	1363	90.6	1290 – 1435
0.9	1295	1298	1243	1272	1226	1187	1254	43.2	1219 – 1288
0.7	895	864	1022	990	908	871	925	65.2	873 – 977
0.6	917	884	1009	1006	895	956	945	54.6	901 – 988
0.5	801	703	885	888	742	801	803	74.2	744 – 863
0.4	562	580	727	733	591	604	633	76.6	572 – 694
0.3	466	443	538	531	389	403	462	62.7	411 – 512
0.1	247	261	171	202	117	112	185	63.4	134 – 236

Pull-out (N)

1.9	181	183	183	165	258	184	192	33.0	166 – 219
1.7	136	128	126	120	181	175	144	26.5	123 – 166
1.5	153	162	120	172	183	151	157	21.6	140 – 174
1.3	-	162	157	156	218	141	167	29.7	143 – 191
1.1	174	228	119	184	268	193	194	50.6	154 – 235
0.9	259	367	287	271	329	388	317	53.3	274 – 359
0.7	420	387	366	348	371	386	380	24.3	360 – 399
0.6	322	393	323	335	329	346	341	27.1	319 – 363
0.5	283	301	314	255	270	287	285	21.1	268 – 302
0.4	185	229	285	242	193	207	224	37.0	194 – 253
0.3	137	173	212	182	137	138	163	31.1	138 – 188
0.1	43	35	56	62	38	31	44	12.5	34 – 54

Table A-2. Push-in and pull-out measurements on the cellular polyurethane block (15 PCF).

Push-in (N)

	Component								
Interference	**1**	**2**	**3**	**4**	**5**	**6**	**Mean**	**SD**	**95% CI**
1.9	1579	1189	1012	1027	891	1039	1123	242.5	885 – 1360
1.7	1322	1009	1105	999	981	1055	1078	127.3	954 – 1203
1.5	993	898	998	980	973	966	968	36.3	932 – 1003
1.3	961	759	843	823	806	815	835	68.0	768 – 901
1.1	719	669	709	717	732	794	723	40.7	684 – 763
0.9	593	572	594	563	630	616	595	25.6	569 – 620
0.7	475	612	408	431	478	397	467	78.7	390 – 544
0.6	468	415	393	395	465	385	420	37.4	384 – 457
0.5	389	350	351	366	389	297	357	34.2	324 – 391
0.4	376	197	296	320	370	252	302	69.2	234 – 370
0.3	107	197	219	246	275	192	206	57.4	150 – 262
0.1	107	43	62	101	115	43	78	32.9	46 – 111

Pull-out (N)

1.9	208	234	183	147	139	168	180	36.4	144 – 216
1.7	164	176	157	109	135	101	140	30.7	110 – 171
1.5	193	176	164	171	158	202	177	17.0	161 – 194
1.3	197	222	219	147	206	201	199	27.2	172 – 225
1.1	180	214	202	177	197	230	200	20.2	180 – 220
0.9	211	210	196	174	174	209	196	17.7	178 – 213
0.7	207	203	189	201	198	194	199	6.6	192 – 205
0.6	214	190	174	174	196	161	185	19.2	166 – 204
0.5	184	168	176	164	175	145	169	13.5	155 – 182
0.4	147	101	145	138	144	118	132	18.9	114 – 151
0.3	57	101	112	112	105	87	95	21.1	75 – 116
0.1	57	24	35	53	32	26	38	13.7	24 – 51

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