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The Oxford medial unicompartmental knee replacement: the South African experience

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***Abstract (Structured; 250 Words Maximum)**

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Abstract

Background The Oxford Unicompartmental Knee Replacement (OUKR) is a successful treatment for end-stage, symptomatic anteromedial osteoarthritis. This study reports the results of a cohort of consecutive cemented and cementless medial OUKRs from an independent centre and aims to answer the following questions: what is the mid to long-term survival of OUKR in the hands of a non-designer surgeon? Are there any differences in the mid to long-term survival of cementless and cemented OUKR? Are the failure modes any different with the cementless and cemented OUKR?

Methods 1120 consecutive Oxford UKRs were implanted in a single centre for the recommended indications. Patients were prospectively identified and followed up. Survival of was calculated with revision as the end-point.

Results There were 522 cemented and 598 cementless implants. The mean follow-up was 8.3 years for cemented implants (range 0.5-17, SD 2.9) and 2.7 years (range 0.5-7, SD 1.8) for cementless implants. The OKS improved from a preoperative mean of 22 (SD 8.1) to 40 (SD 7.9) at the last follow-up ($p < 0.001$). There were 59 failures requiring revision surgery, with a 5.3% cumulative revision rate. The most common reason for failure was progression of osteoarthritis in the lateral compartment, occurred in 26 cases (2.3%). The life table analysis showed a cumulative 10-year survival of 91% (95% CI 87.3 – 95.2).

Conclusion The results of this prospective, consecutive case series from the African continent demonstrated that excellent results are achievable with the OUKR in independent centres if the correct indications and surgical technique are used.

Level of evidence IV.

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Keywords: Unicompartmental knee replacement, UKR, Cementless

Introduction

The Oxford Unicompartmental Knee Replacement (OUKR) is a successful treatment for end-stage, symptomatic anteromedial osteoarthritis of the knee (AMOA). Compared to total knee replacement (TKR), UKR is associated with significantly lower morbidity and mortality [1]. In addition, patients regain better range of movement, superior function and more natural feel of the knee [2,3]. However, data from the National Joint Registry of England and Wales reports a higher revision rate [1]. This contrasts with the results reported in several studies, which showed excellent long-term survival and clinical outcome [2,4-9]. Multiple factors hypothetically contribute to this discrepancy, including the susceptibility of UKR to revision, the use of heterogeneous indications and the unsuitability of survival as a comparison term between UKR and TKR [10]. A deeper analysis of registry data has revealed how usage, intended as the proportion of cases that are UKR in a surgeon's practice, influence the outcome of the procedure. Surgeons performing UKR in more than 20% of their knee arthroplasties achieve acceptable revision rates, and those who are around 50% achieve optimal results. In contrast, a usage below 20% results in a high revision rate [12]. This can explain the good results reported in big cohort studies and randomised controlled trials and their discrepancy with those reported in National Registries. However, most of this studies are from the designers and some authors have expressed concern regarding the reproducibility of such results in non-designer centres[11].

The OUKR has recently reached the 40th anniversary of its introduction in the clinical practice and is nowadays the most implanted partial knee replacement all over the world. The design underwent some modifications since is introduction. The Phase 3 represents the most recent version of the implant, which is still based on the same principles and key design features of the original implant without any changes made to the articular surfaces. Compared to the Phase 2, the Phase 3 had a new, less invasive instrumentation / surgical technique (minimally invasive surgical approach without patella eversion and without dislocating the tibio-femoral joint thereby preserving the extensor mechanism) and an increased range of component sizes. Cementation has been the only option for many years, before the introduction of a cementless version of the OUKR in 2004. Cementless fixation aimed to reduce the incidence of radiolucent lines, avoid cementation errors and introduce biological fixation [14,15], eventually reducing the discrepancy between the revision rate of National Joint Registries and high volume centres.

The most common failure modes of cemented OUKR include bearing dislocation, progression of osteoarthritis in the retained compartment and component loosening [16].

In spite of the perceived advantages of cementless OUKRs, there are some unique problems associated with their use such as valgus subsidence and higher fracture risk [17,18]. These need to be looked at in a big cohort and ideally the data should be compared with those of the cemented OUKRs to see if the overall implant survival and complications differ in cemented and cementless OUKR.

The designers have published the results of a RCT comparing the cemented with cementless OUKRs with 5-year follow-up. The study demonstrated no significant difference in any outcome measure, except for a

superior Knee Society functional score in the cementless group and a reduced incidence of radiolucent lines in cementless implants. There was no difference in complications among groups [3]. However, the sample size was small and the study was primarily set up to show equivalence in implant survival.
No long-term follow up data on large cohorts comparing cemented OUKRs with cementless OUKRs exist.

This study reports about a large, consecutive cohort of medial OUKRs from an independent centre from the African continent with the purpose of assessing the mid- to long-term clinical results in non-designer hands. It includes consecutive cohorts of both the cemented as well as cementless OUKRs and aims to answer the following questions: 1.What is the mid to long-term survival of OUKR in the hands of a non-designer surgeon? 2. Are there any differences in the mid to long-term survival of cementless OUKR as compared to cemented OUKR? 3. Are the failure modes any different with the cementless OUKR as compared to cemented OUKR in the hands of a non-designer surgeon?

Materials and methods

Between 2000 and 2016, 1120 Oxford UKRs were implanted in a single centre. All the procedures were cemented OUKRs until 2009, when the cementless fixation was progressively introduced. Between 2009 and 2013, both cemented and cementless OUKRs were implanted. The same indications were used for both fixation methods, and the decision between cemented and cementless did not rely on specific criteria. Cementation was discontinued after 2013. Overall, 522 implants were cemented and 598 were cementless.

The cementless OUKR is a modified version of the cemented implant [19]. 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 femoral component has two HA-coated cylindrical pegs for press-fit fixation and to confer rotational stability. The slot for the tibial keel is narrower than the cemented in order to provide press-fit fixation and ensure primary stability.

All the cases fulfilled the recommended indications by Goodfellow et al. [20]; osteoarthritis was the most common primary diagnosis (1088 cases), followed by avascular necrosis (32 cases – 24 in the cemented group and 8 in the cementless group). Age, level of activity, BMI, chondrocalcinosis or presence of patello-fermoral OA (except for severe grade OA of lateral facet with bone loss or grooving) were not considered contraindications [21]. Patients who had either friable fragmented or absent anterior cruciate ligament (ACL) or had undergone previous/simultaneous ACL reconstruction or previous high tibial osteotomy were excluded from the study.
All procedures were performed through a minimally invasive approach, as previously described[22].
All patients were treated with a standard rehabilitation protocol. Patients were allowed to fully weight-bear and early mobilisation was encouraged. Patients were prospectively identified and independently followed-up in dedicated clinics. All patients were consented to be involved in the study prior to their inclusion in the

study. The study was approved by the local Human Research Ethics Committee of the University of the Witwatersrand - Johannesburg (Protocol no: M1704114).

The clinical outcome was measured using the Oxford knee score (OKS), a validated patient-based questionnaire to assess function and pain after knee replacement surgery. The OKS ranges from 0 (worst outcome) to 48 (best outcome) [23].

Any complications encountered during or after surgery or further surgeries were recorded at each follow-up appointment.

Statistics

Mann-Whitney U tests were performed to compare the pre-operative and post-operative (most recent) OKS scores. Fisher's test was used to compare the incidence of component loosening between cemented and cementless implants. Statistical significance was set at $p < 0.05$.

The log rank test was used to compare the survival curves of cemented and cementless implants. All analyses were carried out using SPSS version 22.0 for Windows (SPSS Inc., Chicago, USA).

Revision was defined as exchange or addition of a new component in the knee. A life table analysis was performed to estimate the survival. The 95% confidence intervals (CI) were calculated using the method described by Peto et al. [24].

Results

Of the 1120 consecutive OUKRs included in this series, 522 were cemented and 598 were cementless. The mean age at the time of the operation was 65 years (range 31-94, SD 9). There were 573 males (51%), 232 in the cemented group and 341 in the cementless group.

The mean follow-up was 5.3 years (range 0.5 -17, SD 3.7), with 569 patients having a minimum follow-up of 5 years and 171 patients having a minimum follow-up of 10 years. The mean follow-up was 8.3 years for the cemented implants (range 0.5-17, SD 2.9) and 2.7 years (range 0.5-7, SD 1.8) for the cementless implants. The OKS improved from a preoperative mean of 22 (SD 8.1) to 40 (SD 7.9) at the last follow-up ($p < 0.001$).

There were 59 failures requiring revision surgery (40 in cemented implants and 19 in cementless implants), with a 5.3% cumulative revision rate. The most common reason for failure was progression of osteoarthritis in the lateral compartment, occurred in 26 (2.3%) cases. Four of these cases were treated with revision to total knee replacement, and the remaining with the addition of a lateral domed UKR. The second commonest cause of failure was bearing dislocation, occurred in 9 patients (0.8%). Six patients (0.5%) had a tibial plateau fracture, which was treated by open reduction and internal fixation in 4 cases and with revision to

TKR in two cases. All these cases were cementless UKRs and in women. Six other patients developed component loosening, 5 femoral (all in cemented cohort) and one tibial. Out of these 6 cases of component loosening, 3 were revised to TKR whilst in the remaining three cases the components were replaced by a cemented UKR component. Ten cases had a revision for other causes, as reported in Table 1. Two further cases were revised to TKR in other institutions for unknown reason. There were no revisions for infection or wear of the polyethylene.

There were additional 46 operations (25 in cemented implants and 21 in cementless implants) that were not considered revisions, since there was no addition or exchange of the existing prosthetic components. Thirty-eight of these reoperations were arthroscopies for lateral meniscal tear (n =20), debridement of the lateral compartment for lateral degeneration (n=8), haemarthrosis (n=2), large haematoma (n=2), synovitis (n=2), removal of a loose body (n=2, both cemented), removal of impingement (n=2) and washout of suspected infection (n=1). The remaining reoperations were manipulations under anaesthesia for postoperative stiffness (n=7).

The life table analysis showed a cumulative 10-year survival of 91% (95% CI 87.3 – 95.2) [Table 2]. There was no statistically significant difference between the 5-year survival of cemented and cementless components, which was 95.1 and 95.8, respectively (p=0.97) (Figure 1).

Discussion

The purpose of this prospective, consecutive case series was to evaluate the mid- to long-term results of medial OUKR in an independent centre. The results confirmed that good clinical outcome and survival can be achieved with the OUKR by a non-designer surgeon. These are the first results from the African continent and highlight the importance of proper patient selection and optimal surgical technique to achieve implant survival rates similar to the designer series. There was no difference in survival between the cemented and cementless versions of the implant. None of the failures were secondary to infection or wear of the polyethylene.

Several studies demonstrated that unicompartmental knee replacement is a successful treatment for symptomatic, end-stage anteromedial OA [2,4-9]. However, either these do not provide 10-year survival and/or number of cases in the cohort are relatively small. In addition, we are not aware of any other study which compares the survival of large cohorts of cemented and cementless OUKRs implanted by a non-designer surgeon.

The clinical results of UKRs and TKRs are comparable, with more excellent results (OKS >41) obtained with UKR even in multi-surgeon series as confirmed from the analyses of the Joint Registry data from New Zealand [25]. 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 [1]. 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 candidate to UKR [21,22]; on average, less than 10% of these patients are treated with partial knee replacement in current clinical practice across most of the countries. In our hands, we try and offer a patient a UKR whenever possible due to its safety and clinical effectiveness. No case of infection, implant survival not dissimilar to TKR, very low manipulation rates and low morbidity and mortality are key advantages of UKR in our 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. According to this data, if 100 patients receiving TKR received UKR instead, there would be about one fewer death and three more reoperations in the first 4 years after surgery [1]. The discrepancy in the survival rates between the NJR and high volume centres is controversial. It has been argued that the revision is not an objective measure when comparing UKR and TKR because of the higher susceptibility of UKR to revision [10]. On the other hand, some surgeons claim that the good results achieved in designer centres are not generally reproducible.

The results of this prospective, consecutive case series from the African subcontinent highlights following key messages. Impalnt survival of 91% at 10 years for all-cause revision is similar to other published large-data series. The 5-year survival was similar in cemented and cementless implants. No particular assessment technique was used to confirm the suitability of a patient for a cementless UKR. As primarily the forces transmitted are compressive, the implant works well with the cementless fixation and bone density or patient's age do not matter in the success or failure of a cementless fixation. Recent evidence suggests that the results of cementless and cemented OUKR are similar in high volume centres [3,26], in which technical errors, inappropriate indications and misinterpretations of RLs are uncommon. However, the 2015 report from the New Zealand Joint Registry reported a revision rate of 0.67 per 100 component years (95% CI 0.49 – 0.90) and 1.33 per 100 component years (95% CI 1.23 – 1.44) for cementless and cemented OUKR, respectively [25]. These results are encouraging and suggest that the cementless fixation is succeeding in its intended purpose.

The cumulative failure rate in this cohort was higher to that reported in a designer series of cemented OUKRs with similar follow-up (5.3% vs 2.9%). However, it was similar to that of mixed designer and independent cohorts studies with comparable follow-up [16]. The most common causes of failure were progression of OA in the retained compartments and bearing dislocation occurring in 2.3% and 0.8% of cases, respectively. Progression of arthritis in the retained lateral compartment is well documented after UKR. Overall the risk is low and no exact aetiology has been identified other than MCL damage at the time of primary UKR.

In this cohort there were no failures caused by infection. Only one patient in the cemented group required an arthroscopic debridement for suspected infection one month after the operation. The patient subsequently did well and is now in the tenth year of follow-up without any evidence of residual infection or impending implant failure.

In this series, there were 5 revisions caused by a failure of fixation. There were five cases of femoral component loosening, all in cemented implants, and one tibial component loosening in a cementless implant. The incidence of femoral loosening was significantly higher in the cemented group ($p = 0.03$). This data are consistent with those previously reported on single-peg cemented femur, which may provide a limited rotational stability. The introduction of twin peg femoral components resulted in a significant reduction of loosening [27]. In contrast, there was no significant difference in the incidence of tibial loosening between cemented and cementless fixation ($p = 0.4$), suggesting that cementless fixation is as reliable as cemented on the tibial side, providing better fixation on the femoral component. Further biomechanical research is needed to compare the component micromotion and rotational stability of cemented and cementless UKRs.

There were six tibial plateau fractures, all occurred in cementless implants and all in women. Medial tibial condyle fracture is a rare but recognised complication of cemented and cementless UKRs [28,29]. The aetiology of medial tibial plateau fractures is likely to be multifactorial. Several risk factors have been described for cemented UKRs [22,30,31], including 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 [18]. However, a systematic review on cementless fixation in UKR did not reveal an increased incidence of fractures in cementless implants. The instrumentation and surgical technique of the cementless OUKR are the same of the cemented version 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. However, the interference fit can represent an additional risk factor, causing trabecular bone damage and possibly initiating a fracture, making the cementless OUKR less forgiving to technical errors. It has been suggested that the strict adherence to the surgical technique should limit the incidence of this complication [32].

This study has some limitations. First, the lack of the radiographic analysis, which may cause an underestimation of specific complications such as the progression of OA in the retained compartments. Although all symptomatic patients were assessed, silent progression of lateral OA is a possibility and future failures may occur with time. Second, it is not a randomised controlled trial but a comparison of consecutive cohorts. Although this is the case, the number of cases available for FU are sufficiently large to draw meaningful conclusions.

One of the key strengths of this study is that it includes a consecutive series of large cohorts of both cemented and cementless OUKR, both performed with the same indications and recommended surgical technique by the same non-designer surgeon. The introduction of the cementless version of the OUKR aimed to reduce the incidence of radiolucent lines and avoid cementation errors [7], theoretically reducing the revision rate in National Joint Registries. Partial or complete radiolucencies are present in two thirds of cemented OUKRs [3]. The presence of "physiological" radiolucency does not affect the outcome or correlate with loosening or failure [33]. However, radiolucencies can be misinterpreted and lead to "unnecessary" revisions. Excess cement, presence of loose fragments or inadequate cement penetration can cause impingement, unexplained pain, loosening and accelerated wear. In our hands, we have seen significant reduction in the incidence of component loosening with the use of cementless implants. Although the fracture rates are significantly higher, we believe these should reduce in the coming years as we have learnt the nuances of the cementless system. All the fractures occurred in women and the tibial components were typically smaller. Ensuring the use of largest tibial size, avoidance of large hammer and accepting incomplete seating of the tibial component are key lessons for a surgeon when embarking on using the cementless implants.

Further research is needed to assess the potential long-term benefits of cementless fixation, as well as RCT to detect possible differences in the clinical outcome of cemented and cementless OUKRs. Commonest failure mode is progression of arthritis although the incidence is low. It will be useful to assess the factors contributing to progression of arthritis and establish mechanisms to rule out inflammatory osteoarthritis using pre-operative tests which can be reliably carried out.

In conclusion, the results of this prospective, consecutive case series from the African continent demonstrated that excellent results are achievable with the OUKR in independent centres if the correct indications and surgical technique are used.

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Figures (Number each one)
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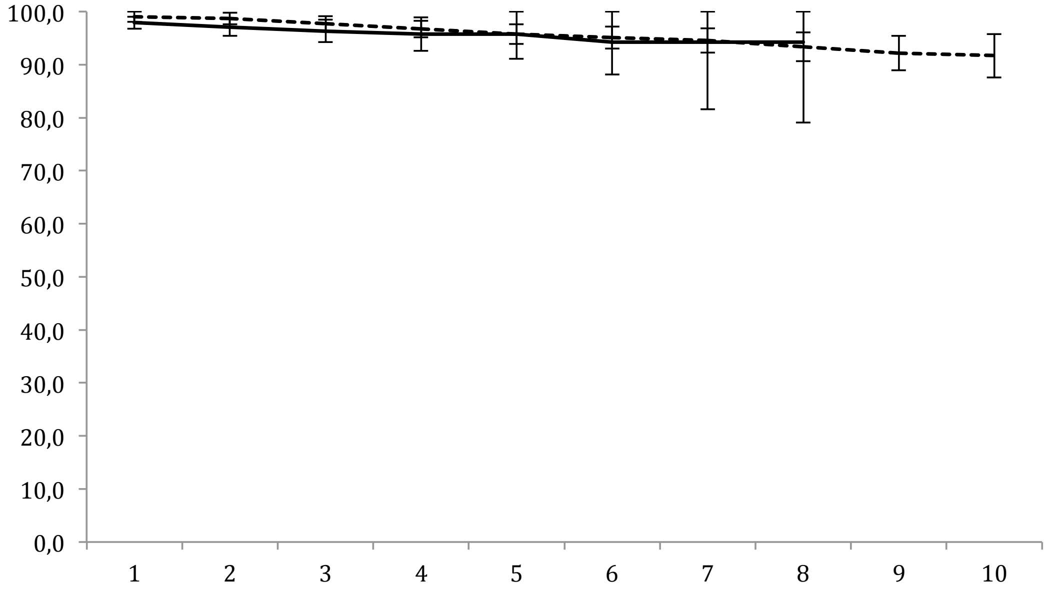

Figure 1. Survival curve of the cemented (dotted) and cementless (solid) OUKR

Tables (Number each one)

Table 1. Other causes of revision

Months since Op	**Reason for Revision**	**Complication Resolved How?**	**Primary Fixation**
5	Subsidence	Bearing upsize	Cementless
8	Synovitis secondary to inflammatory OA	Arthrotomy, synovectomy & bearing exchange	Cementless
9	AVN	Revision to TKR	Cemented
14	AVN Lateral	Addition of domed UKR	Cementless
25	Synovitis & Rhematoid Arthritis	Arthrotomy, synovectomy and bearing exchange	Cemented
29	Traumatic Peri-prosthetic femoral fracture	Revision to TKR	Cemented
30	Bearing Subluxation & Anterior Impingement	Removal of impingement and bearing exchange	Cementless
39	Unexplained pain	PFJ replacement and removal of impingement	Cementless
41	Subsidence	Bearing upsize	Cemented
104	Trauma and lateral compartment progression	Addition of domed UKR	Cemented

Table 2. Life table analysis

Follow Up (Yrs)	**Number at start**	**Revised**	**Withdrawn**	**Lost to FU**	**Dead**	**At Risk**	**Annual Failure**	**Annual Success**	**Survival**	**95% CI**	**95% CI**
0 to 1	1120	16	104	1	0	1068	0,015	0,985	98,5	97,8	99,2
1 to 2	1000	6	133	14	0	934	0,006	0,994	97,9	97,0	98,8
2 to 3	861	7	122	20	0	800	0,009	0,991	97,0	95,9	98,2
3 to 4	732	6	100	9	0	682	0,009	0,991	96,2	94,7	97,6
4 to 5	626	5	90	10	3	581	0,009	0,991	95,3	93,7	97,0
5 to 6	531	4	88	6	0	487	0,008	0,992	94,5	92,6	96,5
6 to 7	439	2	72	14	1	403	0,005	0,995	94,1	91,8	96,3
7 to 8	365	4	75	6	1	328	0,012	0,988	92,9	90,3	95,6
8 to 9	286	3	81	3	2	246	0,012	0,988	91,8	88,5	95,1
9 to 10	202	1	49	3	0	178	0,006	0,994	91,3	87,3	95,2
10 to 11	152	2	55	1	1	125	0,016	0,984	89,8	84,8	94,8