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Title: Evidence-based indications for mobile-bearing unicompartmental knee replacement in a consecutive cohort of 1000 knees.

Abstract

Background:

The indications for unicompartmental knee replacement (UKR) remain controversial. Previously recommended contra-indications include: age under 60years, weight 180lb (82kg) or over, patients undertaking heavy labour, chondrocalcinosis, and exposed bone in the patellofemoral joint. This study explores whether these contra-indications are valid in mobile-bearing UKR.

Methods:

Using a prospective series of 1000 consecutive medial UKR in which the reported contra-indications were not applied, the functional outcome and survival in patients with or without contra-indications were compared.

Results:

Of the 1000 consecutive UKR (818 patients) 68% (678 knees) would be considered contra-indicated based on published contra-indications. At a mean follow-up of ten-years (5 to 17) there was no difference in American Knee Society Objective Scores (AKSS-O) ($p=0.05$) or Oxford Knee Score (OKS) ($p=0.08$) between groups. However, knees with contra-indications had significantly ($p=0.02$) fewer poor outcomes and significantly better AKS Functional Scores (AKSS-F) ($p<0.001$) and Tegner Activity Scores ($p<0.001$). At fifteen-years no difference in implant survival ($p=0.33$) was observed.

The 3% of UKR performed in young males (age<60) weighing 180lb or over with high activity levels, who have been reported to have poor outcomes after fixed-bearing UKR, had significantly better AKSS-F ($p<0.001$), OKS ($p=0.01$) and Tegner Activity Score ($p<0.001$) at ten-years. No difference in AKSS-O ($p=0.54$) at ten-years or implant survival at fifteen-years ($p=0.75$) was seen.

Conclusion:

This large case series provides evidence that patients with the previously reported contra-indications do as well as, or even better than, those without contra-indications. Therefore these contra-indications should not apply to mobile-bearing UKR.

Keywords: Unicompartmental knee replacement; patient selection; clinical outcomes; implant survival

Level of Evidence: Level IV

Introduction

Unicompartmental knee replacement (UKR) has significant patient benefits over total knee replacement (TKR) including improved functional outcomes and significantly lower morbidity and mortality[1]. Despite the benefits of UKR it remains relatively underutilised and this in part is due to controversies in the indications. In their seminal paper on UKR Kozinn and Scott highlighted the benefits of UKR including retained normal knee kinematics and proprioception, improved range of movement, preserved bone stock and, in the case of failure, ability to revise to a primary TKR[2]. However to optimise outcomes, primarily based on their experience with a fixed-bearing device, they advised strict patient and disease criteria for the procedure[2].

The Oxford UKR (Zimmer Biomet, Warsaw, Indiana, USA) employs a fully congruous freely mobile-bearing articulating with a spherical femur and a flat tibia. In contrast to the indications proposed by Kozinn and Scott, the indications used for the Oxford UKR lie solely with the pathoanatomy of the disease[3]. The Oxford medial UKR is indicated for the treatment of anteromedial osteoarthritis (AMOA) and spontaneous osteonecrosis of the knee (SONK)[3]. In AMOA there should be 1) bone-on-bone arthritis in the medial compartment 2) retained full thickness cartilage in the lateral compartment, best visualised on a valgus stress X-ray 3) a functionally normal medial collateral ligament (MCL) and 4) a functionally normal anterior cruciate ligament (ACL)[4]. The status of the patellofemoral joint (PFJ), with the exception of bone loss with grooving laterally, is not considered a contra-indication to Oxford UKR.

When the contra-indications to UKR as proposed by Kozinn and Scott are applied to the knee replacement population it has been reported that around 6% of patients may be considered appropriate for UKR, whereas using the criteria for Oxford UKR up to half of patients may be eligible[5, 6].

In a recent publication we have demonstrated a survival of 91% at 15years with 81% of patients achieving good or excellent functional outcomes as assessed by AKSS at ten-years following UKR using the indications for Oxford UKR, which in our practice is satisfied in over 50% of cases needing knee replacement[7]. The primary purpose of this study is to investigate

whether applying previously published contra-indications as advised by Kozinn and Scott and others influences fifteen-year survival and ten-year functional outcomes in 1000 consecutive cemented mobile-bearing UKRs. The secondary purpose is to perform subgroup analysis to assess the outcomes of mobile-bearing UKR performed in young, heavy, highly active males, who have been reported to have poor outcomes after fixed-bearing UKR[8].

Patients and Methods

Details of this cohort have been published previously[7]. In summary, between June 1998 and March 2009 1000 consecutive Oxford UKRs were performed in 818 patients via a minimally invasive approach by [redacted] with all patients meeting the recommended indications for UKR as described by Goodfellow et al.[3]. The mean age at the time of operation was 66 (range 32 to 88) with 48% of the patients being male (393 patients) and 52% female (425 patients).

Outcome assessments were performed by a research physiotherapist independent of the clinical team using a standard protocol of clinical review with functional assessment pre-operatively and at one, five, seven, ten, twelve and fifteen-years. Functional outcomes were assessed using the: AKSS-O, AKSS-F, OKS, and Tegner Activity Score[9-11]. In addition the AKSS-O was calculated without performing deductions for alignment, as unlike TKR, the Oxford UKR aims to restore pre-disease alignment not achieve neutral alignment[12]. All patients, with the exception of four lost to follow up in the first year, were contacted in the previous 18months to ascertain the current functional status of their knee and incidence of re-operations. Where patients had died, information about the status of their knee and further operations was obtained from primary and secondary care records as well as the patient's relatives where appropriate. Any complications and reoperations were carefully recorded and analysed.

Patients were classified into subgroups based on each of the previously proposed contra-indications to UKR: younger than 60years, weight 180lb (82kg) or more, high levels of activity, chondrocalcinosis and exposed bone in the PFJ. High activity level was classified as a Tegner activity score of 5 or above at any stage after surgery as this incorporates: heavy labour (e.g. building/forestry) and/or competitive sports (e.g. cycling/cross-country skiing) and/or recreational sports (jogging on uneven ground at least twice a week).

This study was approved by the local ethics committee who confirmed that the clinical follow up 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.

Statistical Analysis

A power calculation was performed using the minimally clinically important difference reported for OKS [13]. Using the Altman nomogram for a power of 80% at a significance level of 0.05 and using a standard deviation of 8, a sample size of 80 patients is required to detect a clinically important difference between groups. Due to differences in the number of knees in each group, with knees with reported contraindications typically having fewer knees than those without, it was established that a minimum of 20 knees in the smaller cohort was required to for the study to have adequate power [14].

Functional outcomes and implant survival were compared between groups based on whether patients had any, or none, of the published contra-indications, and on the presence, or absence, of each of the individual published contra-indications. An additional subgroup of young males (age<60) weighing 180lb or more with a high activity level, who have been reported to have poor outcomes after fixed-bearing UKR, was compared to the outcomes of knees not in this group.

Functional outcomes were compared at 10years using non-parametric tests (Kruskal-Wallis). Differences in categorical functional outcomes were assessed using a Ch-Squared test. Survival was assessed using life-table analysis with confidence intervals (CI) calculated using the method described by Peto et al.[15]. Survival was compared using the log-rank test. A broad definition of failure was used with failure defined as any implant-related re-operation, which included any re-operations in which components were removed, changed, in which the mobile-bearings were replaced for dislocation, and any re-operations in which new components were inserted. Statistical significance was defined as $p<0.05$.

Results

The mean follow up was 10.3years (range 5.3 to 16.6) with 516 knees having a minimum ten-year follow up and 60 knees a minimum fifteen-year follow-up. All patients were followed up for a minimum of five-years with the exception of those who were lost to follow up (4), died (44), underwent revision (23) or withdrew from the study due to poor health (10). In all patients that died the status of the implant at death was known. None of the patients who withdrew from the study had revisions.

Overall 81% of knees in this cohort, 86% without deductions for alignment, achieved good or excellent outcomes using AKSS-O criteria at ten-years with a fifteen-year survival of 91% (95%CI, 83 - 98%)[7].

Contra-indicated vs ideal

Over two-thirds of knees (68%, 678knees) were considered contra-indicated for UKR based on the previously reported contraindications of: age under 60years, weight 180lb or over, high activity levels, chondrocalcinosis, and evidence of exposed bone in the PFJ. Pre-operatively no difference in AKSS-O (p=0.79), AKSS-F (p=0.15), OKS (p=0.86) was seen between contra-indicated and ideal knees with contra-indicated knees having higher Tegner Activity scores (p=0.01).

At ten-years no difference in AKSS-O or OKS was detected between contra-indicated and ideal knees, however contra-indicated knees had significantly better AKSS-F and Tegner Activity scores than ideal knees. Table 1. Figure 1 & 2. At ten-years, 7% of contra-indicated knees had poor outcomes (AKSS-O <60) whereas 18% of ideal knees had poor outcomes. The difference was statistically significant (p=0.02). Figure 3A.

When AKSS-O is calculated without performing deductions for alignment, as this does not influence outcomes following mobile-bearing UKR, at 10years in contra-indicated knees the mean AKSS-O was 89.3 (SD 15) with 87% of knees achieving a good or excellent outcome, compared to ideal knees where the mean AKSS-O was 86.4 (SD 16) with 82% achieving good

or excellent outcomes. If deductions for alignment are excluded the previously observed difference in percentage of knees reporting poor outcomes at ten-years is not observed, (5% contra-indicated vs 7% ideal; p=0.22), suggesting that the poor results assessed using AKSS-O in the ideal knees are a result of alignment which has not been demonstrated to influence long term outcome or survival following mobile-bearing UKR. Figure 3B.

No difference in time to failure, mechanism of failure or implant survival was found between contra-indicated and ideal knees at fifteen-years. Table 1. Figure 4.

Effect of age

A quarter of the UKR in this series (25%, 245knees) were implanted in patients aged under 60years, with this group having a mean age of 54years (range 33 to 60). Pre-operatively no difference in AKSS-O (p=0.31), AKSS-F (p=0.07), OKS (p=0.47) or Tegner Activity score (p=0.07) was seen between those aged under 60 and those aged 60 years and older.

At ten-year follow up patients aged under 60years at the time of operation had significantly better AKSS-F, OKS and Tegner Activity scores than those patients who did not meet these criteria. Table 1. No difference in AKSS-O was seen. No difference in categorical functional outcomes was seen between groups (p=0.34) with 83% (88% excluding deductions for alignment) of knees in patients aged under 60 obtaining good or excellent results, compared to 81% (85% excluding deductions for alignment) in patients aged 60years or over. No difference in in time to failure, mechanism of failure or fifteen-year implant survival was seen between groups. Table 1.

Effect of weight

Almost half of the UKR in this series (45%, 449knees) were implanted in patients who weighted 180lb or greater. The mean weight in this group was 209lb (range 180 to 408). Pre-operatively no difference in AKSS-O (p=0.73), AKSS-F (p=0.12) or OKS (p=0.74) was seen between groups with the pre-operative Tegner Activity Scale was found to be significantly higher in those who weighed 180lb or greater (p=0.01).

At ten-year follow up no difference in AKSS-O, AKSS-F or OKS was seen between those who weighed 180lb or greater and those that did not with Tegner Activity scores remaining higher in those than those patients who weighed 180lb or greater. Table 1. No difference in categorical functional outcomes between groups was seen at ten-years (p=0.31) with 85% (88% excluding deductions for alignment) of knees in patients weighing 180lb or greater obtained good or excellent results compared to 78% (85% excluding deductions for alignment) in those patients who weighed under 180lb.

No difference in time to failure, mechanism of failure or fifteen-year implant survival was seen between groups. Table 1.

Effect of activity level

Ten percent of the UKR in this series (96knees) were implanted in patients who reported high activity, a Tegner Activity Score of ≥5, post-operatively. The mean Tegner Activity Score in the high activity group was 5.4 (range 5 to 8) with pre-operatively the high activity group reporting significantly higher AKSS-F (p<0.001), OKS (p=0.02) and Tegner Activity scores (p<0.001) with no difference in AKSS-O (p=0.34) between groups detected.

At ten-year follow up the high activity group had better AKSS-F, OKS and Tegner Activity scores, however no difference in AKSS-O scores were seen compared to those patients that did not report high activity. Table 1. No difference in categorical functional outcomes was seen between groups at ten-years (p=0.34) with 84% (86% excluding deductions for alignment) of knees in high activity patients obtained good or excellent results compared to 81% (86% excluding deductions for alignment) in patients not in this group.

No difference in time to failure, mechanism of failure, or fifteen-year implant survival was seen between groups. Table 1.

Effect of chondrocalcinosis

Thirteen percent of the UKR in this series (126knees) were implanted in patients with evidence of chondrocalcinosis. Pre-operatively no difference in AKSS-O (p=0.12), AKSS-F (p=0.11) or

OKS (p=0.69) was seen between those knees with or without chondrocalcinosis however those with chondrocalcinosis reported worse Tegner Activity scores (p=0.03).

At ten-year follow up no difference in activity scores was seen between groups with no difference in categorical functional outcomes seen (p=0.46). Table 1. In knees with chondrocalcinosis 83% (90% excluding deductions for alignment) achieved good or excellent results, compared to 81% (86% excluding deductions for alignment) of knees without chondrocalcinosis.

No difference in time to failure, mechanism of failure, or fifteen-year implant survival was seen between groups. Table 1.

Effect of patellofemoral joint disease

Sixteen percent of the UKR in this series (158knees) were implanted in patients with exposed bone in the PFJ. Pre-operatively no difference in AKSS-O (p=0.51), AKSS-F (p=0.38), OKS (p=0.26) or Tegner Activity scores (p=0.86) was seen between those knees with exposed bone and those without.

At ten-year follow up no difference in outcome scores or in categorical functional outcomes was seen between those knees with exposed bone at the PFJ and those without (p=0.38). Table 1. In knees with exposed bone in the PFJ 85% (88% excluding deductions for alignment) obtained good or excellent results, compared to 81% (86% excluding deductions for alignment) of knees without exposed bone at the PFJ.

No difference in time to failure, mechanism of failure, or fifteen-year implant survival was seen between groups. Table 1.

Compound Assessment: Young males (age<60) weighing 180lb or more with high activity levels

Three percent of UKR in this series (28knees) were performed in young males (age<60) weighing 180lb or more with high activity levels. Pre-operatively this group reported higher

AKSS-F ($p=0.02$), OKS ($p=0.003$) and Tegner Activity scores ($p<0.001$) than knees not in this group with no difference in AKSS-O ($p=0.06$).

At ten-years young males weighing more than 180lb with high activity level reported significantly ($p<0.001$) higher AKSS-F, OKS and Tegner Activity scores compared to knees not in this group with no difference in AKSS-O. Table 1. No difference in categorical functional outcomes was seen at ten-years between groups ($p=0.22$) with 89% (94% excluding deductions for alignment) of knees in young males weighing more than 180lb with high activity level obtaining good or excellent results, compared to 81% (85% excluding deductions for alignment) of knees not in this group.

No difference in time to failure, mechanism of failure, or fifteen-year implant survival was seen between groups. Table 1.

Discussion

Overall 68% (678) of knees had one or more contraindication to UKR according to the previously published literature with this study finding no evidence that these published contraindications should be applied to mobile-bearing UKR. At ten-year follow up, 85% of knees (87% without deductions for alignment) that would be considered contraindicated for UKR had good or excellent outcomes using AKSS-O criteria. This contra-indicated group reported significantly better AKSS-F and OKS scores compared to those knees considered ideal candidates and had significantly fewer poor results. Additionally no difference in time to failure, mechanism of failure, or implant survival at fifteen-years was observed between the groups.

For each of the previously published contra-indications to UKR (age <60years, weight ≥180lb, heavy labour or activity, chondrocalcinosis and exposed bone in the PFJ) ten-year functional outcomes were equal, or superior in those knees with contra-indications compared to those knees considered ideal. Additionally for each of the contra-indications no difference in implant survival at fifteen-years was seen compared to ideal candidates providing strong evidence that mobile-bearing should not be restricted in these cases.

One of the reasons that patient selection guidelines were introduced was that, based on the experience with fixed-bearing UKR, it was noted that some patients groups had poor outcomes[8]. One such group is young males (age<60) weighing 180lb or greater with a high activity level which in this series of mobile-bearing UKR we found to have better results than of knees not in this group with no difference in implant survival at fifteen-years.

Previous shorter term studies have also shown that patients treated with the mobile-bearing UKR that have the proposed contra-indications have similar functional outcomes and survival as those considered ideal[16, 17]. This study has however shown that patients with contra-indications actually have better results. Therefore applying the contra-indications will worsen outcomes overall as UKR will not be carried out in the patients who have the potential to attain best results from it. Why in this study patient with contra-indications actually had better results

is unclear as aside from those with high activity levels no difference in pre-operative AKSS-O was seen between groups. For some patients for example those under 60 years or over 180lb (who tended to be younger) this may relate to a higher potential to achieve optimum functional outcomes, for others including those with PFJ disease, the improved outcomes may relate to restoring the native knee kinematics.

The indications for the Oxford knee are based on patho-anatomy and if a patient has anteromedial OA or medial osteonecrosis it is recommend that a UKR should be implanted. These indications are satisfied in 50% or more cases that need knee replacement and during the study period around 60% of all primary knee replacements performed were UKR. This would have been reduced to under 20% if the contra-indications were used[5, 18]. Additionally, further reductions in UKR utilisation would be seen if there was a requirement for focal medial pain which many consider to be important, even though it has been shown to be unnecessary as it does not influence the outcome[19]. If surgeons do small numbers of UKR or have UKR utilisation of less than 20% data from the National Joint Registry has shown the failure rate increases[20]. This further supports the recommendation that if surgeons want to use mobile-bearing UKR they should base their indications on the pathoanatomy and ignore the contra-indications proposed by Kozinn and Scott[21-26].

The strengths of this study are that it is a consecutive series with long-term, comprehensive, clinical follow up. The limitations are that is that this is a designer series and the results observed may not be representative, however similar results have been published at independent centres at shorter follow up providing further support for using broad indications for mobile-bearing UKR[22-25, 27]. A further limitation is that, whilst all comparisons were appropriately powered, larger subgroups of patients, with more data at longer term follow up would increase the confidence in the observations made.

Conclusion

This study provides long-term evidence that for mobile-bearing UKR the indications should be based on the patho-anatomy of the disease, as proposed by Goodfellow et al. and does not support the contra-indications proposed by Kozinn and Scott and others[2, 3]. Indeed patients with the contra-indications do better than those without.

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Figure Legends

Figure 1: Bar Chart showing mean AKSS-Objective, AKSS-Objective excluding deductions for alignment and AKSS-Functional Score by year of follow-up based on the presence or absence of the published contraindications to UKR: age <60 years, weight ≥180lb, high activity, chondrocalcinosis, and exposed bone in the patellofemoral joint.

Figure 2: Bar Chart showing mean OKS by year of follow-up based on the presence or absence of the published contraindications to UKR: age <60 years, weight ≥180lb, high activity, chondrocalcinosis, and exposed bone in the patellofemoral joint.

Figure 3: A: AKSS – Objective categorical outcomes with (A) and without (B) deductions for alignment at ten years based on the presence or absence of the published contraindications to UKR: age <60 years, weight >180lb, high activity, chondrocalcinosis, and exposed bone in the patellofemoral joint. There were significantly fewer poor outcomes in contra-indicated knees compared with ideal knees (A: p=0.02), however this effect is not seen once deductions for alignment (which does not influence outcome following mobile-bearing UKR) are excluded (B: p=0.22).

Figure 4: Survival analysis based on the presence or absence of the published contraindications to UKR: age <60 years, weight >180lb, high activity, chondrocalcinosis, and exposed bone in the patellofemoral joint.