A matched comparison of revision rates of cemented Oxford Unicompartmental Knee Replacements with Single and Twin Peg femoral components, based on data from the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man

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Background and purpose — Registries report high revision rates after unicompartmental knee replacement (UKR) due, in part, to aseptic loosening. In an attempt to improve Oxford UKR femoral component fixation a new design was introduced with a Twin rather than a Single peg. We used the National Joint Registry (NJR) to compare the 5-year outcomes of the Single and Twin Peg cemented Oxford UKRs.

Patients and methods — We performed a retrospective observational study using NJR data on propensity score matched Single and Twin Peg UKRs (matched for patient, implant and surgical factors). Data on 2,834 Single Peg and 2,834 Twin Peg were analyzed. Cumulative implant survival was calculated using the Kaplan–Meier method and comparisons between groups performed using Cox regression models.

Results — In the matched cohort, the mean follow up for both Single and Twin Peg UKRs was 3.3 (SD 2) and 3.4 years (SD 2) respectively. The 5-year cumulative implant survival rates for Single Peg and Twin Peg were 94.8% (95% CI 93.6–95.8) and 96.2% (CI 95.1–97.1) respectively. Implant revision rates were statistically significantly lower in the Twin Peg (hazard ratio [HR] = 0.74; p = 0.04). The revision rate for femoral component aseptic loosening decreased significantly (p = 0.03) from 0.4% (n = 11) with the Single Peg to 0.1% (n = 3) with the Twin Peg. The revision rate for pain decreased significantly (p = 0.01) from 0.8% (n = 23) with the Single Peg to 0.3% (n = 9) with the Twin Peg. No other reasons for revision had significant differences in revision rates.

Interpretation — The revision rate for the cemented Twin Peg Oxford UKR was 26% less than the Single Peg Oxford UKR. This was mainly because the revision rates for femoral loosening and pain were halved. This suggests that the Twin Peg component should be used in preference to the Single Peg design.
The Twin Peg cemented femoral component was introduced in 2003 but has only been widely used since 2009 (Figure 1) (White et al. 2015). A cementless version of the Twin Peg component was also introduced at a similar time. The Twin Peg cemented component is used with the same cemented tibial component and polyethylene bearing as the Single Peg component. We are not aware of any direct comparative clinical studies of Single Peg and Twin Peg cemented femoral components.

The National Joint Registry for England, Wales, Northern Ireland and Isle of Man (NJR) is the largest replacement registry (National Joint Registry 2018). We used NJR data to compare the revision rate and mechanisms of implant failure, in particular femoral component aseptic loosening, following cemented medial Oxford UKRs using Single and Twin Peg femoral components.

Patients and methods

We performed a retrospective observational study using the NJR database after NJR Research Sub-Committee approval (National Joint Registry 2018). Data collected by the NJR includes patient, implant, and surgical information. The database has excellent linkability to subsequent revision surgery and is also linked to the Office of National Statistics, which provides mortality data.

Anonymized patient data were extracted from the NJR, which included all primary Oxford UKRs implanted between January 1, 2009 and December 31, 2017 (n = 41,593). After data cleaning there were 20,692 medial cemented Oxford UKRs (17,855 Single Peg and 2,837 Twin Peg) eligible for study inclusion (Figure 2).

The study exposure was the peg design (Single vs. Twin Peg). Given the potential for factors other than peg design to affect the revision rate (Prempeh and Cherry 2008, Selby et al. 2012, Judge et al. 2013, Elmallah et al. 2015, Lim et al. 2015, Bayliss et al. 2017, Hosaka et al. 2017, Picard et al. 2018, Mohammad et al. 2020b) we a priori matched the Single and Twin Peg UKRs for multiple known confounders using propensity scores. Logistic regression was used to generate a propensity score representing the probability that a patient received a Twin Peg UKR. These propensity scores were generated from patient demographics, surgical factors, and implant factors. Specifically, factors used for matching were: age, sex, primary diagnosis, unilateral/bilateral UKRs, ASA grade, chemical thromboprophylaxis, mechanical thromboprophylaxis, year of surgery, operating surgeon grade, surgeon caseload, surgical approach, operating technique and implant component sizes (Table 1). Surgeon caseload was defined as the average number of UKRs done per calendar year by the operating surgeon and stratified into low (<10 cases/year), medium (10 to <30 cases/year) and high volume (≥30 cases/year) as described previously (Mohammad et al. 2020a). BMI was not used for matching given it had a significant proportion of missing data. However, our data demonstrate that BMI was well balanced between groups and our approach is similar to previous studies using NJR data (Matharu et al. 2017, Mohammad et al. 2020a).

We matched using a 1:1 ratio on the logit of the propensity score with a 0.02-SD calliper width. We used greedy matching without replacement, which has superior performance for estimating treatment effects (Austin 2009). Standardized mean differences (SMDs) were examined both before and after matching to assess for any covariate imbalance between the different peg design groups, with SMDs of 10% or more considered suggestive of imbalance (Austin 2009). After matching, 5,668 UKRs (2,834 Single Peg and 2,834 Twin Peg UKRs) were included for analysis.

Statistics

Outcomes of interest were: (1) implant survival and (2) indications for revision surgery, particularly femoral component aseptic loosening. Cumulative survival was determined using the Kaplan–Meier method. The endpoint for implant survival was revision surgery (any addition, removal, or exchange of implant component). Implant survival was compared between the Single and Twin Peg groups, using Cox regression models, with the proportional hazards assumptions assessed and satisfied in all analyses. Additionally, to account for clustering within the matched cohort, a robust variance estimator was used in regression models. Univariable and adjusted models were also assessed. The adjusted models included covariates with residual imbalance after matching (SMD of 10% or more) (Austin 2009). A multi-level frailty model was tested in regression models to adjust for patient clustering within surgeons. The proportional chi-squared test with Yate’s correction or 2-sided Fisher’s exact test was used to compare the indications for revision surgery between groups. The latter was used only when either group had an expected frequency of under 5.
The NJR database allows for revisions for UKRs with any aseptic loosening to be analyzed and also for aseptic loosening by each component involved (e.g., femoral or tibial component). The primary analysis was of revision for aseptic femoral loosening. Aseptic tibial loosening and overall loosening rates were also analyzed as there were some cases of combined tibial and femoral loosening.

All statistical analyses were performed using Stata (Version 15.1; StataCorp, College Station, TX, USA) except propensity score matching, which was performed using R (Version 3.4.0; R Foundation for Statistical Computing, Vienna, Austria). P-values of < 0.05 were considered significant, with 95% confidence intervals (CI) presented.

**Ethics, funding, and potential conflicts of interest**

This study was based entirely on existing patient records acquired during routine clinical care and thus did not require ethical approval. This project was fully approved by the NJR Research Sub Committee. Zimmer Biomet provided funding for the research but were not involved in the study.

**Results**

The matched cohort included 5,668 Oxford UKRs, with 2,834 Single Peg UKRs and 2,834 Twin Peg UKRs. The mean age at surgery was 65 years (SD 10), with 51% of the cohort being female. The mean BMI was 30 (SD 10), with 51% of the cohort being overweight.

### Table 1. Patient and surgical factors. Values are number (%) unless otherwise specified

| Covariate | Unmatched cohort | Matched cohort |
|-----------|------------------|----------------|
|           | Single Peg | Twin Peg | SMD | Single Peg | Twin Peg | SMD |
| Sex       |            |           |     |            |           |     |
| Female    | 8,454 (47) | 1,431 (50) | 1,441 (51) | 1,428 (50) | 0.06 | 0.099 |
| Male      | 9,401 (53) | 1,406 (50) | 1,393 (49) | 1,406 (50) | 0.01 | 0.03 |
| Age at surgery | 65 (10) | 65 (10) | 65 (10) | 65 (10) | 0.02 | 0.01 |
| mean (SD) | 13,159 | 1,868 | 2,165 | 1,865 | 0.04 | 0.03 |
| Primary diagnosis | 17,676 | 1,797 (99) | 1,799 (99) | 1,794 (99) | 0.04 | 0.02 |
| Year of surgery | 2018 (8) | 2,182 (8) | 2,182 (8) | 2,182 (8) | 0.05 | 0.05 |
| Surgeon caseload | 3,344 (19) | 488 (17) | 483 (17) | 488 (17) | 0.4 | 0.06 |
| VTEP— mechanical | 10,447 (59) | 2,020 (71) | 2,972 (70) | 2,017 (71) | 0.06 | 0.003 |
| ASA grade | 1,426 (8) | 208 (7) | 240 (8) | 208 (7) | 0.08 | 0.003 |
| LMWH (± other) | 4,731 (26) | 590 (21) | 593 (21) | 590 (21) | 0.03 | 0.03 |
| VTEP— chemical | 1,833 (9) | 475 (17) | 520 (18) | 475 (17) | 0.03 | 0.03 |
| Year of surgery | 7,266 (41) | 893 (31) | 915 (32) | 892 (31) | 0.04 | 0.04 |
| Minimal invasive surgery | 16,283 (91) | 2,513 (89) | 2,536 (89) | 2,511 (89) | 0.01 | 0.01 |
| Femoral component size | 16,462 (92) | 2,656 (94) | 2,668 (94) | 2,653 (94) | 0.06 | 0.02 |
| Small | 4,076 (23) | 796 (28) | 788 (28) | 793 (28) | 0.3 | 0.04 |
| Medium | 9,536 (53) | 1,451 (51) | 1,462 (52) | 1,451 (51) | 0.1 | 0.03 |
| Extra large | 4,170 (23) | 582 (21) | 577 (20) | 582 (21) | 0.07 | 0.02 |
| Tibial component size | 4,151 (23) | 607 (21) | 607 (21) | 607 (21) | 0.09 | 0.02 |
| Small | 4,076 (23) | 796 (28) | 788 (28) | 793 (28) | 0.3 | 0.04 |
| Medium | 9,536 (53) | 1,451 (51) | 1,462 (52) | 1,451 (51) | 0.1 | 0.03 |
| Extra large | 4,170 (23) | 582 (21) | 577 (20) | 582 (21) | 0.07 | 0.02 |
| Bearing size | 43 (0.2) | 6 (0.2) | 4 (0.1) | 6 (0.2) | 0.02 | 0.02 |
| Extra small | 4,076 (23) | 796 (28) | 788 (28) | 793 (28) | 0.3 | 0.04 |
| Medium | 9,536 (53) | 1,451 (51) | 1,462 (52) | 1,451 (51) | 0.1 | 0.03 |
| Extra large | 4,170 (23) | 582 (21) | 577 (20) | 582 (21) | 0.07 | 0.02 |
| AA | 83 (0.5) | 11 (0.4) | 12 (0.4) | 11 (0.4) | 0.09 | 0.02 |
| A | 2,109 (12) | 399 (14) | 382 (14) | 397 (14) | 0.1 | 0.03 |
| B | 4,151 (23) | 607 (21) | 607 (21) | 607 (21) | 0.09 | 0.02 |
| C | 5,071 (28) | 798 (28) | 809 (28) | 798 (28) | 0.09 | 0.02 |
| D | 4,120 (23) | 636 (22) | 642 (23) | 636 (22) | 0.09 | 0.02 |
| E | 1,871 (11) | 294 (10) | 286 (10) | 293 (10) | 0.1 | 0.03 |
| F | 450 (3) | 92 (3) | 89 (3) | 92 (3) | 0.02 | 0.02 |
| Bone graft used | 3,972 (22) | 635 (22) | 652 (23) | 635 (22) | 0.04 | 0.04 |
| OA = osteoarthritis, SD = standard deviation, SMD = standardized mean difference, UKR = unicompartmental knee replacement, VTEP = venous thromboembolism prophylaxis.
In the matched cohort, the mean follow-up for both Single and Twin Peg UKRs was 3.3 (SD 2) and 3.4 years (SD 2) respectively. In total 176 knees underwent revision surgery: 102 (3.6%) Single Peg UKRs and 74 (2.6%) Twin Peg UKRs. The 5-year cumulative all-cause implant survival rates were 94.8% (CI 93.6–95.8) for Single Peg UKRs and 96.2% (CI 95.1–97.1) for Twin Peg UKRs (Figure 3). The difference in cumulative revision rates between Twin Peg and Single Peg UKRs was statistically significant (HR = 0.74, p = 0.04).

The most common reasons for revision in the Single Peg group were osteoarthritis progression (n = 26, 0.9%), pain (n = 23, 0.8%), and aseptic loosening (n = 18, 0.6%) (Table 2). In the Twin Peg UKR group the most common reasons for revision were osteoarthritis progression (n = 25, 0.9%), aseptic loosening (n = 14, 0.5%), and pain (n = 9, 0.3%) (see Table 2). There was a statistically significant (p = 0.01) difference in the revision rate for pain between the Single Peg (n = 23, 0.8%) and the Twin Peg (n = 9, 0.3%). The revision rate for femoral component aseptic loosening was significantly lower (p = 0.03) in the Twin Peg group (n = 3, 0.1%) compared with the Single Peg group (n = 11, 0.4%). However, there was no statistically significant change in the revision rate for aseptic loosening overall (Twin Peg n = 14, 0.5%; Single Peg n = 18, 0.6%; p = 0.5) or tibial component loosening (Twin Peg n = 12, 0.4%; Single Peg n = 10, 0.4%; p = 0.7).

### Discussion

This is the first formal comparative observational clinical study of Single and Twin Peg cemented medial Oxford UKR femoral components. We found that the 5-year survival improved from 94.8% with the Single Peg to 96.2% with the Twin Peg and the overall revision rate decreased by 26% (p = 0.04). The main reason for this was that the revision rate for femoral component aseptic loosening (0.4% to 0.1%) and pain (0.8% to 0.3%) more than halved with the Twin Peg component. The Twin Peg was not associated with a significant increase in revision rate for any reason. This suggests that the Twin Peg femoral component is a safer component than the Single Peg.

The Twin Peg femoral component was introduced primarily to decrease the rate of femoral loosening. Our study has shown that it has reduced the rate of femoral component loosening from 11/2,834 with the Single Peg to 3/2,834 with the Twin Peg. As the incidence of loosening is low there is some uncertainty about the magnitude of the decrease but it is approximately three-quarters and it is certainly not increased. This suggests that it has improved fixation and has achieved its design aim.

The Twin Peg component was also associated with a halving in the revision rate for pain. There are various possible reasons for this. Surgeons are able to record more than 1 reason for revision, so some revisions for pain may have been cases of...
The main limitation of this study is the short follow up of the Twin Peg component. Additionally, the work is based on Registry data and therefore the only outcome measure is revision. However, studies of Single (Luscombe et al. 2007, Pandit et al. 2011) and Twin Peg (White et al. 2015, Lum et al. 2016) cohorts appear to report equivalent functional outcomes. Additionally, revision reasons in the NJR are those recorded at the time of surgery even if these subsequently change. Registries can underreport revisions although there is no reason to believe this would differ between the groups. Another limitation is that, despite matching, there is potential residual confounding and matching can reduce generalizability. However, virtually all Twin Peg cases were matched, which improves generalizability. Following matching the only variable with appreciable imbalance was the year of primary surgery, which is important as technique and instrumentation improved with time. However, there were no differences in our findings when we adjusted the regression models for year of primary surgery. There was a substantial proportion of BMI data missing so we did not match on BMI. However, the BMI was well balanced between groups.

In summary, this propensity-matched registry-based study found the risk of revision of the cemented Oxford UKR was 26% less with the Twin Peg femoral component compared with the Single Peg. This was primarily because the revision rates for femoral component loosening and pain more than halved. The Twin Peg was not associated with a significant increase in revision rate for any reason. This suggests that the cemented Twin Peg femoral component should be used instead of the Single Peg design.
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