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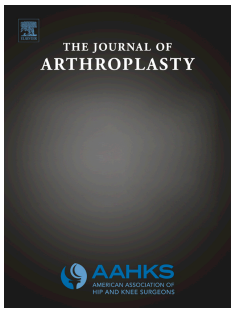

Mortality and Implant Survival with Simultaneous and Staged Bilateral Total Knee Arthroplasty Experience from the Australian Orthopaedic Association National Joint Replacement Registry

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Experience from the Australian Orthopaedic Association National Joint Replacement Registry

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Mortality and Implant Survival with Simultaneous and Staged Bilateral Total Knee Arthroplasty

Experience from the Australian Orthopaedic Association National Joint Replacement Registry

Abstract

Background: Total knee arthroplasty (TKA) is an effective procedure for relieving pain and restoring function in osteoarthritis, with a significant proportion of patients having severe disease bilaterally. However, although there are differences in patient selection criteria for bilateral procedures, there is no consensus regarding the optimal timing for bilateral TKA. The aim of this study is to compare rates, causes of revision and 30-day mortality between simultaneous and staged bilateral TKA using data from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR).

Methods: Data for over 36,000 bilateral TKAs was collected from September, 1999 to December, 2015. Rates and causes of revision and 30-day mortality rate were obtained for simultaneous bilateral and staged procedures with intervals of 1 day–6weeks, 6weeks–3months and 3months–6months. Yearly cumulative percent revision (CPR) or survival (CPS) with 95% confidence intervals calculated by the Kaplan-Meier method and adjusted hazard ratios were used for comparisons.

Results: There was no significant difference between revision rates or reasons for revision between staged bilateral and simultaneous TKA (HR 1.09 (95% CI 0.85-1.40; p=0.511) for 1day–6weeks, 0.93 (95% CI 0.77-1.14; p=0.494) for 6weeks–3months, and 1.10 (95% CI 0.98-1.23; p=0.115) for 3months–6months). The most common reasons for revision were loosening/lysis and infection. The 30-day mortality rates were lower in the 6weeks-3months group than simultaneous bilaterals (p=0.007).

Conclusion: This study demonstrates that simultaneous and staged bilateral TKA have similar rates of revision over the medium term but that 30-day mortality is reduced in the 6weeks-3months group.

Word count: 249/250

Keywords: Registry; primary: bilateral knees; mortality; survivorship; revision

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Introduction

Total knee arthroplasty (TKA) is a highly successful procedure for relieving pain and restoring function in severe osteoarthritis of the knee joints. The prevalence of bilateral knee osteoarthritis has been shown to be as high as 5% [1]. A number of studies have evaluated the need for a contralateral TKA after the first TKA. Ritter et al. [2] reported that when the contralateral knee was diagnosed with osteoarthritis at the time of the first TKA, the second TKA was required within 10 years in 37% of patients. Mont et al. [3] reported that 23% of patients scheduled for unilateral TKA had severe symptoms in the contralateral knee, and 93% underwent contralateral TKA within the follow-up time of the study (minimum of 5 years).

Controversies in timing of bilateral TKA for patients with arthritis in both knees are far from resolved. The safety of simultaneous bilateral TKA remains a concern [4-6]. There are reports of increased perioperative complications, including pulmonary embolism, deep vein thrombosis, cardiac, neurologic and wound complications, as well as intensive care unit admissions [7, 8]. There is no consensus in the literature as to whether this confers an increased risk of mortality [9-13]. There have been large institutional series reports that have shown that simultaneous bilateral TKA can be performed safely without increased peri-operative morbidity and mortality compared to staged bilateral TKA if a selective pre-operative screening process is used [14-16]. Same-day bilateral TKA has been reported to have benefits of decreased cost [17-19], improved recovery time [20], the use of a single anaesthetic [21], and equal functional outcomes [22].

In patients undergoing staged bilateral TKA, there is a wide range of reported recommended intervals between the first and second operation, ranging from 1 to 120 months [23-25]. The indications for staged TKA and the methods of choosing the first side for operation varied between studies [26, 27]. Many comparisons were aimed at the safety, perioperative complications and cost effectiveness of simultaneous versus staged bilateral TKA, while few studies had considered subsequent revision rates.

The aim of this study was to utilise data from the Australian Orthopaedic

Association National Joint Replacement Registry (AOANJRR) to investigate the implant survivorship and 30-day mortality of simultaneous bilateral TKA compared to staged bilateral TKA of various intervals.

Materials and Methods

The analysis for this study was undertaken by the AOANJRR. The AOANJRR is an Australian Federal Government-funded AOA initiative with the purpose of improving the care of patients undergoing joint arthroplasty, providing accurate demographic information, and establishing a reliable method of audit for both hospitals and individual surgeons [28, 29]. Data collection commenced in September 1999, with staged state-based implementation leading to full national data collection in mid-2002.

Registry data is obtained at the time of surgery and includes patient details, hospital, type of procedure, joint replaced, side, diagnosis, and component details. All public and private hospitals in Australia performing joint replacement surgery provide information to the Registry. Data is validated against State Health Department separation data and this enables the AOANJRR to have a complete dataset of all joint replacement surgery. The AOANJRR dataset is matched biannually to the Australian National Death Index (Australian Institute of Health and Welfare). This enables the AOANJRR to have a complete list of patients who have died and the date of their death.

The study period for this analysis was September 1, 1999 to December 31, 2015. The AOANJRR identified all bilateral primary TKA procedures undertaken for osteoarthritis (OA) within 6 months of the initial procedure. Bilateral TKA procedures were grouped into four categories: simultaneous (same-day), or staged bilateral TKA procedures with intervals of 1 day – 6 weeks, 6 weeks – 3 months and 3 months – 6 months, with numbers reported at patient level.

Analysis provided information on revision rates (as determined by the time to first revision of either knee from the time of second TKA), reasons for revision, cumulative incidence revision for the five most common reasons for revision, types of revision, and 30-day mortality after the second procedure . Further analysis by

age (over or under 65 years) and type of fixation (cement, cementless or hybrid) was undertaken. These analyses did not identify any differences to the overall data and have therefore not been included (data available upon request). ASA grade and BMI were available from the time they were added to the core dataset in 2012 and 2015 respectively.

Statistics

The Kaplan Meier method was used to determine cumulative percent revision (CPR) and cumulative percent survival (CPS). Unadjusted CPR values are reported with 95% confidence interval (CI). Revision (and mortality) rates were compared using Cox proportional hazards models, adjusting for age and sex. Tests were 2-tailed at the 5% level of significance. Descriptive analysis of reasons for revision and type of revision are also reported.

Results

There were 36,087 bilateral primary TKAs (72,174 knees) undertaken for OA with a maximum interval of six months between procedures during the study period. Specifically, there were 23,136 (64.1%) simultaneous bilateral TKA procedures and 12,951 staged bilateral TKA procedures (1,262 (3.5%) 1 day – 6 weeks, 2,638 (7.3%) 6 weeks–3 months, and 9,051 (25.1%) 3–6 months) (Table 1). Age, gender, ASA grade and BMI details for each group are shown in Table 1.

There was no significant difference in the rate of revision when the three different interval groups of staged bilateral TKA were compared to simultaneous bilateral TKA (1 day–6 weeks) HR= 1.09 (95% CI 0.85-1.40; p=0.511), (6 weeks–3 months) HR=0.93 (95% CI 0.77-1.14; p=0.494) and (3 month–6 months) HR=1.10 (95% CI 0.98-1.23; p=0.115). (Table 2, Figure 1).

In the simultaneous bilateral TKA group the most common reasons for revision were loosening/lysis (29.0%), infection (23.4%) and patellofemoral pain (11.3%). The reasons for revision were similar in the staged bilateral TKA groups (Table 3, Figure 2). There was no significant difference in the revision rates for loosening/lysis or infection when the three different interval groups of staged bilateral TKA were compared to simultaneous bilateral TKA (Table 4).

The most common type of revision for simultaneous bilateral TKA was a total revision (tibial and femoral components - 25.0%), insert only - 22.6% and patella only - 17.7%). The types of revision in the staged bilateral TKA groups were similar (Table 5).

The 30-day mortality (from second procedure) for the four groups of bilateral TKA procedures was 0.17% (simultaneous), 0.08% (1 day – 6 weeks), 0.04% (6 weeks – 3 months) and 0.07% (3 months – 6 months) (Table 6). For comparison, the 30-day mortality rate for all primary TKAs for OA is 0.13%. Overall, when combining all staged bilaterals (1 day – 6 months), the 30-day mortality was 0.06% which was significantly lower than the simultaneous bilateral group (p=0.0004). There was a significantly lower 30-day mortality rate in the staged 6 weeks to 3 months group than for the simultaneous bilaterals (OR 0.30 (95% CI 0.13 to 0.72), p=0.007). Although the 30-day mortality rates were also lower in the other staged groups than the simultaneous bilaterals, statistically there was no significant difference (1 day – 6 weeks; OR 0.46 (95% CI 0.06 to 3.33), p=0.441 and 3 months – 6 months, OR 0.19 (95% CI 0.03 to 1.39), p=0.103). Both age and ASA grade were significantly lower in the simultaneous bilateral group compared with all other groups (both p<0.001, chi-squared test).

Discussion

This study compared the revision rates, reasons for revision, types of revision and 30-day mortality of simultaneous bilateral TKA to the three groups of staged bilateral TKA of various intervals. There was no difference in revision rate, reasons for revision or types of revision. There was a significantly lower 30-day mortality rate in the 6 weeks – 3 months staged compared with the simultaneous bilateral groups.

The rate of revision between the groups in our study were similar, with no significant differences found between the simultaneous and different timed staged procedures.

However, our analysis shows a significantly lower 30-day mortality rate for staged 6 week – 3 months bilateral TKA despite the fact that the simultaneous bilateral

group was younger and fitter (according to ASA grade) than the other groups. It has been suggested that 30-day mortality rate provides the best measure of mortality related to TKA, as reporting of mortality beyond 30 days of the procedure may represent deaths not related to the operation [30]. Some studies have shown increased 30-day mortality rate for simultaneous bilateral TKA compared to staged bilateral TKA [31, 32] and unilateral TKA [30]. A number of more recent studies have shown no difference in 30-day mortality between simultaneous bilateral TKA and unilateral TKA [11, 13, 33, 34], which may correlate with improvement in surgical technique over time or better patient selection, although some had relatively small numbers.

In 2003, Ritter et al [25] found no significant difference among the three groups of simultaneous bilateral, staged bilateral, and unilateral TKA with respect to revision or mortality rates. The 10 year CPR for simultaneous bilateral, unilateral, and staged bilateral TKA groups was 98.3% (95% CI, 97.5% - 99.1%), 97.5% (95% CI, 95.4% - 99.6%), and 99.5% (95% CI, 98.6% - 100%), respectively. Our data of comparing simultaneous bilateral TKA and staged bilateral TKA of different durations echoes these findings of no significant difference in revision rates.

In a 1997 study on a larger group of Medicare patients, Ritter et al [31] compared a simultaneous bilateral TKA group (12,922 patients) with groups that had staged procedures within six weeks (4354 patients), six weeks - three months (4524 patients), three - six months (9829 patients), and six months - one year (31,401 patients). The simultaneous bilateral TKA group had the highest cumulative mortality rate at three months postoperatively (1.47%). At one year, the group that had the staged procedure within six weeks had the highest cumulative mortality rate (2.83%). By two years postoperatively, the cumulative mortality rates for all of the groups were similar. Neither the simultaneous nor the staged bilateral TKA had a mortality advantage over the others, and it was determined that the decision about whether to attempt simultaneous or staged bilateral TKA should be made on an individual basis by the patient and the physician. In 2001, Parvizi et al [30] investigated the mortality rate within thirty days after TKA in their entire patient cohort of 22,540 patients over a 28-year period (with 2,679 – 11.9%

bilateral cases). The mortality rate within 30 postoperative days after simultaneous bilateral TKA was significantly higher ($p < 0.002$) than that after unilateral TKA.

Previous studies have reported increased wound healing problems, and cardiopulmonary problems [35] following simultaneous bilateral TKA. There have also been reports of greater risk of complications and mortality associated with early staged bilateral TKA (within the same hospitalisation or within 3 months) [36, 37]. Experts participating in the Consensus Conference on Bilateral Total Knee Arthroplasty Group in 2013 [38], made a number of consensus statements. Most (81%) agreed that if a patient was not a suitable candidate for same-day bilateral TKA, then a second TKA should be scheduled for at least 3 months or later. The vast majority (96%) opposed the idea of staging within the same hospital admission. Our findings suggest that a delay of 6 weeks may be adequate to mitigate mortality risk.

Much has been discussed about perioperative complications that are associated with simultaneous bilateral TKA. Cardiac complications such as myocardial infarction, arrhythmias, and congestive cardiac failure are some of the common reported cardiac complications following simultaneous bilateral TKAs [23, 33, 39, 40]. The cause of this remains unclear; however, the rates of cardiac complication are reported to be higher in patients with pre-existing comorbid medical conditions and in elderly patients (>80 years). It can be postulated that the physiological stress imposed by the simultaneous procedure on this group of high-risk patients with presumed suboptimal cardiorespiratory reserve could be the cause of increased complications [41]. This may be attributed to longer length of hypotension secondary to spinal anaesthesia, larger fluid shifts, and potentially greater intraoperative hypoxia or anaemia during hospitalization.

The rates of intensive care unit admission are also reported to be higher with simultaneous bilateral procedures. This might be a reflection of the greater need for monitoring of cardiopulmonary parameters with this procedure, especially in elderly patients. In a study by Bullock et al [33], the rate of intensive care unit admission was observed to be 0.59% in the unilateral group and 3.9% in the bilateral group, with a relative risk of 6.61. Similarly, Ritter et al [31] reported that

the number of intensive care unit care days of simultaneous bilateral TKA were twice that in unilateral or staged groups.

The rates of blood transfusion in simultaneous bilateral TKA have also been found to be greater than those in unilateral arthroplasty groups, in varying degrees [34, 42-45].

A major strength of the study is the completeness and volume of bilateral procedures analysed. The revision rate of TKA is low; therefore, large numbers are required to have sufficient statistical power to enable a meaningful comparison. This is most easily achieved using data from a large registry. Although the numbers in the subgroups of staged bilateral TKAs are comparatively low, there is a good representation across all states/territories within Australia, with relatively high numbers of surgeons (more than 200 in each group) and hospitals (more than 100 in each group) represented in these groups [data not shown but available]. Most studies to date have compared safety, perioperative complications and cost of the surgeries of simultaneous bilateral TKA to staged bilateral TKA. To our knowledge, this represents the first study that has sufficient power to statistically compare revision rates.

The major limitations of this study are the potential for confounding and patient selection for bilateral surgery. The risk of revision may be impacted by multiple factors including age, gender, comorbidity, type of prosthesis, surgical expertise and the perceived risk versus benefit of undertaking a revision. While it is likely that some of these factors are equally distributed across groups, it is almost certain that patients chosen to have simultaneous bilateral TKA differ from the population having staged bilateral TKA, as indicated by the lower age and ASA grade. Although the analysis is adjusted for age and gender, more detailed patient demographic data were not analysed beyond age comparison of over and under 65s, fixation and comparison of age and ASA between groups. There is selection bias of patients undergoing simultaneous bilateral TKAs who are younger, healthier, and less medically comorbid. The simultaneous bilateral group would therefore be expected to have a *lower* 30-day mortality rate than any other group, rather than the contrary finding in our study with a higher mortality rate than all of the other

groups. The reasons for this contrary finding are not obvious from the data available on the Registry, particularly in relation to the lower 30-day mortality in the 6 week – 3 month group, and so a plausible explanation for this would be speculation on the authors' part. Further investigation to confirm this finding and explain it are therefore recommended. Other medical complications that do not lead to revision are also not recorded in the registry which limits the outcome used in the analysis to revision or death. There is also the likelihood that some intended bilateral patients died before the second side was performed, which would mean that the differential in 30-day mortality between the same day and staged bilaterals would be less pronounced. This may also partially account for the increased 30-day mortality rate in the unilateral TKA's. However, this is unlikely to account for the entire difference in mortality rate.

Conclusion

Although there is no difference in revision rates based on the interval of the second procedure for bilateral primary TKA undertaken within 6 months, the mortality is significantly lower when bilateral procedures are staged and lowest when the interval is 6 weeks to 3 months. In spite of being younger and fitter, the simultaneous bilateral TKAs have a measurably higher 30-day mortality risk than staged surgery, and surgeons and patients need to decide on a case-by-case basis whether the elevated risk of bilateral surgery is outweighed by patient-specific benefits. .

Ethics, funding and conflicts of interest

No ethical approval was required for this registry study. There were no external sources of funding and none of the authors had any conflicts of interests specifically for this project.

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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412

Table and Figure Legends

Table 1: Demographics for each group. Patient numbers are reported.

Table 2: Yearly Cumulative Percent Revision of Primary Total Knee Replacement (Primary Diagnosis OA) with all primary TKA for OA for comparison [46].

Table 3: Most Common Revision Diagnoses of Primary Total Knee Replacement (Primary Diagnosis OA).

Table 4: Hazard ratios (95% CIs) of revision rates for various staged interval bilaterals compared with simultaneous bilaterals (with p-values) with reasons for revision of loosening/lysis or infection.

Table 5: Type of Revision of Primary Total Knee Replacement (Primary Diagnosis OA).

Table 6: 30-day Mortality (Cumulative Percent Survival (CPS)) following Bilateral Primary Total Knee Replacements by Group (Primary Diagnosis OA).

Figure 1: Cumulative Percent Revision of Primary Total Knee Replacement (Primary Diagnosis OA)**.**

Figure 2: Cumulative Incidence Revision Diagnosis of Primary Total Knee Replacement (Primary Diagnosis OA)

Table 1: Demographics for each group. Patient numbers are reported.

	Bilateral Same Day	**Bilateral 1 day-6wks**	**Bilateral 6wks-3mths**	**Bilateral 3mths-6mths**
N	23136	1262	2638	9051
Gender				
Male	12449 (53.8%)	691 (54.8%)	1478 (56.0%)	4388 (48.5%)
Female	10687 (46.2%)	571 (45.2%)	1160 (44.0%)	4663 (51.5%)
Age				
<55	2284 (9.9%)	152 (12.0%)	241 (9.1%)	544 (6.0%)
55-64	8526 (36.9%)	481 (38.1%)	886 (33.6%)	2554 (28.2%)
65-74	8979 (38.8%)	420 (33.3%)	996 (37.8%)	3628 (40.1%)
≥75	3347 (14.5%)	209 (16.6%)	515 (19.5%)	2325 (25.7%)
ASA*				
N	7000	309	726	2069
1	777 (11.1%)	28 (9.1%)	41 (5.6%)	99 (4.8%)
2	4531 (64.7%)	185 (59.9%)	415 (57.2%)	1104 (53.4%)
3	1651 (23.6%)	93 (30.1%)	259 (35.7%)	842 (40.7%)
4	41 (0.6%)	3 (1.0%)	11 (1.5%)	24 (1.2%)
BMI*				
N	2626	127	245	535
Underweight	285 (10.9%)	12 (9.4%)	33 (13.5%)	69 (12.9%)
Normal	263 (10.0%)	6 (4.7%)	15 (6.1%)	45 (8.4%)
Pre-Obese	775 (29.5%)	44 (34.6%)	52 (21.2%)	140 (26.2%)
Obese Class 1	772 (29.4%)	28 (22.0%)	74 (30.2%)	106 (19.8%)
Obese Class 2	361 (13.7%)	20 (15.7%)	37 (15.1%)	98 (19.0%)
Obese Class 3	170 (6.5%)	17 (13.4%)	34 (13.9%)	77 (25.8%)

*ASA has only been recorded for procedures since 2012; BMI has only been recorded since 2015. ASA and BMI are based on the first procedure.

Table 2: Yearly Cumulative Percent Revision of Primary Total Knee Replacement (Primary Diagnosis OA) with all primary TKA for OA for comparison [46].

Group	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	7 Yrs	10 Yrs	13 Yrs
Bilateral same day	1028	23136	1.2 (1.1, 1.4)	3.1 (2.9, 3.3)	4.4 (4.1, 4.7)	5.6 (5.2, 6.0)	7.4 (6.9, 8.0)	9.9 (9.0, 10.8)
Bilateral 1 day–6 wk	65	1262	1.4 (0.9, 2.3)	4.0 (3.0, 5.3)	4.9 (3.7, 6.4)	6.0 (4.6, 7.8)	7.6 (5.7, 9.9)	10.5 (7.2, 15.3)
Bilateral 6wk–3mths	108	2638	1.3 (0.9, 1.8)	2.9 (2.3, 3.7)	4.2 (3.4, 5.2)	5.1 (4.1, 6.3)	6.6 (5.3, 8.2)	7.9 (6.2, 10.0)
Bilateral 3mths–6mths	411	9051	1.3 (1.1, 1.5)	3.3 (2.9, 3.7)	4.5 (4.0, 5.0)	5.6 (5.1, 6.3)	7.0 (6.3, 7.8)	9.0 (7.8, 10.3)
Total	**1612**	**36087**						
*All primary OA TKA**	*17213*	*482373 (knees)*	*1.0 (1.0, 1.1)*	*2.7 (2.7, 2.8)*	*3.6 (3.6, 3.7)*	*4.4 (4.3, 4.4)*	*5.3 (5.2, 5.4)*	*7.3 (7.1, 7.6)*

Note: *all bilateral procedures are reported at the patient level (i.e. one patient is two knees) and so risk of revision to either knee is higher than for a single knee (majority of primary OA TKA)

Table 3: Most Common Revision Diagnoses of Primary Total Knee Replacement (Primary Diagnosis OA).

	Bilateral Same Day			Bilateral 1day-6wks			Bilateral 6wks-3mths			Bilateral 3mths-6mths		
Revision Diagnosis	**N**	**% Revision**	**% Primary**	**N**	**% Revision**	**% Primary**	**N**	**% Revision**	**% Primary**	**N**	**% Revision**	**% Primary**
Loosening/Lysis	298	29.0	1.3	20	30.8	1.6	35	32.4	1.3	115	28.0	1.3
Infection	241	23.4	1.0	15	23.1	1.2	33	30.6	1.3	132	32.1	1.5
Patellofemoral Pain	171	16.6	0.7	11	16.9	0.9	14	13.0	0.4	57	13.8	0.7
Instability	69	6.7	0.3	1	1.5	0.1	5	4.6	0.2	26	6.3	0.3
Other	249	24.2	0.1	18	27.7	1.4	21	19.4	0.8	81	19.7	0.9
N Revision	**1028**	**100.0**	**4.4**	**65**	**100.0**	**5.2**	**108**	**100.0**	**4.1**	**411**	**100.0**	**4.5**
N Primary	**23136**			**1262**			**2638**			**9051**		

Table 4: Hazard ratios (95% CIs) of revision rates for various staged interval bilaterals compared with simultaneous bilaterals (with p-values) with reasons for revision of loosening/lysis or infection.

	Bilateral same day	
Staged interval	**Loosening/lysis**	**Infection**
1 day – 6 weeks	1.13 (0.72 to 1.78), p=0.586	1.13 (0.72 to 1.78), p=0.586
6 weeks – 3 months	1.04 (0.73 to 1.48), p=0.812	1.04 (0.73 to 1.48), p=0.812
3 months – 6 months	1.11 (0.90 to 1.38), p=0.327	1.11 (0.90 to 1.38), p=0.327

Table 5: Type of Revision of Primary Total Knee Replacement (Primary Diagnosis OA).

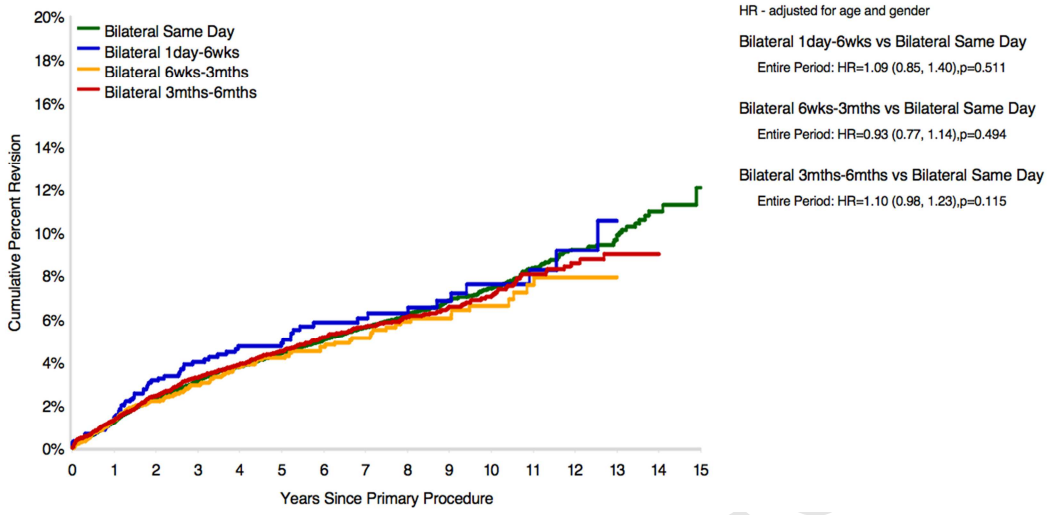
	Bilateral Same Day			Bilateral 1day-6wks			Bilateral 6wks-3mths			Bilateral 3mths-6mths		
Type of Revision	**N**	**% Revision**	**% Primary**	**N**	**% Revision**	**% Primary**	**N**	**% Revision**	**% Primary**	**N**	**% Revision**	**% Primary**
TKR (Tibial/Femoral)	257	25.0	1.1	23	35.4	1.8	31	28.7	1.2	91	22.1	1.0
Insert Only	232	22.6	1.0	12	18.5	1.0	24	22.2	0.9	109	26.5	1.2
Patella Only	182	17.7	0.8	13	20.0	1.0	22	20.4	0.8	63	15.3	0.7
Insert/Patella Patella Only	118	11.5	0.5	6	9.2	0.5	3	2.8	0.1	32	7.8	0.4
Tibial Component	100	9.7	0.4	4	6.2	0.3	12	11.1	0.5	51	12.4	0.6
Femoral Component	71	6.9	0.3	3	4.6	0.2	4	3.7	0.2	18	4.4	0.2
Cement Spacer	59	5.7	0.3	4	6.2	0.3	11	10.2	0.4	42	10.2	0.5
Removal of Prostheses	4	0.4	0.0				1	0.9	0.0	3	0.7	0.0
Insert Only Minor Components*	1	0.1	0.0									
Insert/Patella Insert Only*	1	0.1	0.0									
Minor Components	1	0.1	0.0							1	0.2	0.0
N Revision	**1028**	**100.0**	**4.4**	**65**	**100.0**	**5.2**	**108**	**100.0**	**4.1**	**411**	**100.0**	**4.5**
N Primary	**23136**			**1262**			**2638**			**9051**		

Note: *Same day primary bilateral patients revised on the same day. Both types of revision are listed.

Table 6: 30-day Mortality (Cumulative Percent Survival (CPS)) following Bilateral Primary Total Knee Replacements by Group (Primary Diagnosis OA).

Group	N Death (30 day)	N Patients	% 30-day Deaths	30-day CPS	Logistic regression (age/gender adjusted) p-value
Bilateral Same Day	40	23,136	0.17	99.9 (99.4, 100.0)	Reference
Bilateral 1day-6wks	1	1262	0.08	99.9 (99.9, 100.0)	p=0.441
Bilateral 6wks-3mths	1	2638	0.04	99.9 (99.7, 100.0)	p=0.007
Bilateral 3mths-6mths	6	9051	0.07	99.8 (99.8, 99.9)	p=0.103
All staged 1 day-6mths	*8*	*12,951*	*0.06*	*99.9 (99.8, 100.0)*	*p=0.0004*
TOTAL	**48**	**36,087**	**0.13**		
All primary OA TKA	*629*	*482,373 (knees)*	*0.13*	*99.9 (99.8, 99.9)*	*p=0.095*

Figure 1: Cumulative Percent Revision of Primary Total Knee Replacement (Primary Diagnosis OA).



Number at Risk	0 Yr	1 Yr	5 Yrs	8 Yrs	10 Yrs	13 Yrs	15 Yrs
Bilateral Same Day	23136	20028	10302	5358	3044	791	91
Bilateral 1day-6wks	1262	1109	626	349	196	50	9
Bilateral 6wks-3mths	2638	2285	1203	650	377	101	3
Bilateral 3mths-6mths	9051	7983	4339	2328	1331	301	17

Figure 2: Cumulative Incidence Revision Diagnosis of Primary Total Knee Replacement (Primary Diagnosis OA)