

# International Comparative Evaluation of Knee Replacement with Fixed or Mobile Non-Posterior-Stabilized Implants

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**Background:** Mobile-bearing total knee prostheses were designed to reduce wear and improve implant survivorship following total knee arthroplasty. However, the benefit of mobile-bearing total knee arthroplasty remains unproven. Both mobile-bearing and fixed-bearing total knee arthroplasty implants are available in posterior-stabilized and non-posterior-stabilized designs. With the latter, the implant does not recreate the function of the posterior cruciate ligament (PCL) with a posterior-stabilizing cam mechanism. The purpose of the present study was to compare mobile-bearing, non-posterior-stabilized devices with fixed-bearing, non-posterior-stabilized devices used in total knee arthroplasty through a novel multinational study design.

**Methods:** Through the use of a distributed health data network, primary total knee arthroplasties performed for osteoarthritis from 2001 to 2010 were identified from six national and regional total joint arthroplasty registries. Multivariate meta-analysis was performed with use of linear mixed models, with the primary outcome of interest being revision for any reason. Survival probabilities and their standard errors were extracted from each registry for each unique combination of the covariates.

**Results:** A total of 319,616 patients (60% female) underwent non-posterior-stabilized total knee arthroplasty. A fixed-bearing, non-posterior-stabilized design was used in 258,190 (81%) of the knees and a mobile-bearing, non-posterior-stabilized design in 61,426 (19%) of the knees. Sixty-nine percent of the patients who received a fixed-bearing implant were over sixty-five years of age, compared with 63% of those who received a mobile-bearing implant. Mobile-bearing designs had a higher risk of revision, with a hazard ratio of 1.43 (95% confidence interval, 1.36 to 1.51;  $p < 0.001$ ).

**Conclusions:** Previous comparisons of mobile-bearing and fixed-bearing total knee arthroplasty outcomes have been inconclusive. The current study utilized an advanced, harmonized distributed analysis of six national and regional joint-replacement registries. To our knowledge, it is the largest analysis of mobile-bearing total knee arthroplasty to date. Mobile-bearing, non-posterior-stabilized designs presented a greater risk of failure than was found for fixed-bearing, non-posterior-stabilized designs. Caution should be used in the selection of the mobile-bearing non-posterior-stabilized design for total knee replacement.

Mobile-bearing total knee prostheses were developed to reduce wear of articular bearing surfaces following total knee arthroplasty. To our knowledge, no clinical study has demonstrated the superiority of mobile-bearing compared with conventional fixed-bearing total knee arthroplasty, but the promise of wear reduction has led to continued interest in mobile-

bearing total knee replacement. The LCS (Low Contact Stress, DePuy Synthes), the original mobile-bearing total knee arthroplasty implant, has been used in patients worldwide since 1977<sup>1</sup>.

Reports are conflicting regarding the revision rate associated with the LCS implant<sup>2,3</sup>. Prior studies have not demonstrated the superiority of mobile-bearing compared with fixed-bearing

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TABLE I Included Implants by Registry, Age, Sex, Fixation, and Patella Resurfacing\*

	Registry (No. [%])					
	U.S., KP	Australia	Italy, E-R	Sweden	Norway	Spain, C
<b>Fixed non-PS</b>						
Age in yr						
<45	102 (0.7)	671 (0.5)	13 (0.2)	247 (0.3)	58 (0.4)	4 (0)
45-55	1343 (9)	9319 (6.9)	119 (2.1)	3980 (5.1)	670 (4.6)	56 (0.5)
56-65	4634 (30.9)	34,801 (25.9)	786 (13.9)	19,242 (24.5)	3430 (23.8)	719 (6.8)
>65	8904 (59.4)	89,369 (66.6)	4731 (83.7)	54,976 (70.1)	10,258 (71.2)	9758 (92.6)
Sex						
Male	5573 (37.2)	57,330 (42.7)	1464 (25.9)	31,357 (40)	4657 (32.3)	2885 (27.4)
Female	9410 (62.8)	76,830 (57.3)	4185 (74.1)	47,088 (60)	9759 (67.7)	7652 (72.6)
Fixation						
Uncemented	627 (4.2)	32,401 (24.2)	619 (11)	1042 (1.3)	385 (2.7)	594 (5.6)
Hybrid	1828 (12.2)	40,572 (30.2)	278 (4.9)	49 (0.1)	1926 (13.4)	3511 (33.3)
Cemented	12,528 (83.6)	61,187 (45.6)	4752 (84.1)	77,354 (98.6)	12,105 (84)	6432 (61)
Patella resurfacing						
No resurfacing	608 (4.1)	78,553 (58.6)	5457 (96.6)	73,639 (93.9)	13,785 (95.6)	7536 (71.5)
Resurfacing	14,375 (95.9)	55,607 (41.4)	192 (3.4)	4806 (6.1)	631 (4.4)	3001 (28.5)
<b>Mobile non-PS</b>						
Age in yr						
<45	26 (1.4)	309 (0.6)	6 (0.2)	14 (2)	34 (0.4)	0 (0)
45-55	377 (20.9)	4012 (8.4)	60 (2.1)	145 (20.9)	469 (5.6)	1 (1.1)
56-65	937 (52.1)	13,552 (28.5)	432 (14.9)	360 (51.8)	1957 (23.4)	5 (5.6)
>65	460 (25.6)	29,703 (62.4)	2410 (82.9)	176 (25.3)	5898 (70.6)	83 (93.3)
Sex						
Male	792 (44)	20,672 (43.5)	777 (26.7)	318 (45.8)	2656 (31.8)	27 (30.3)
Female	1008 (56)	26,904 (56.5)	2131 (73.3)	377 (54.2)	5702 (68.2)	62 (69.7)
Fixation						
Uncemented	248 (13.8)	23,507 (49.4)	153 (5.3)	0 (0)	507 (6.1)	27 (30.3)
Hybrid	433 (24.1)	11,464 (24.1)	434 (14.9)	0 (0)	651 (7.8)	2 (2.2)
Cemented	1119 (62.2)	12,605 (26.5)	2321 (79.8)	695 (100)	7200 (86.1)	60 (67.4)
Patella resurfacing						
No resurfacing	58 (3.2)	31,998 (67.3)	2816 (96.8)	667 (96)	8089 (96.8)	81 (91)
Resurfacing	1742 (96.8)	15,578 (32.7)	92 (3.2)	28 (4)	269 (3.2)	8 (9)

\*Non-PS = non-posterior-stabilized, KP = Kaiser Permanente, E-R = Emilia-Romagna region, and C = Catalan region.

total knee arthroplasty, despite the increased cost associated with mobile-bearing implants<sup>4</sup>. The LCS implant was identified as a risk factor for revision of primary total knee arthroplasty in some studies<sup>3,5</sup>, but not in other studies<sup>6,7</sup>.

Mobile-bearing total knee arthroplasty implants are available in posterior-stabilized and non-posterior-stabilized design options. With the latter, the implant does not recreate the function of the posterior cruciate ligament (PCL) with a posterior-stabilizing cam mechanism. The LCS is an example of a mobile-bearing, non-posterior-stabilized implant. Fixed-bearing total knee implants are also available in posterior-stabilized and non-posterior-stabilized designs.

The specific aim of this study was to compare the implant survivorship of mobile-bearing, non-posterior-stabilized total knee arthroplasty with that of fixed-bearing, non-posterior-stabilized total knee arthroplasty. A multiregistry, collaborative approach was utilized to increase the sample size and for greater generalizability of the practices of surgeons globally.

### Materials and Methods

A distributed health data network was developed by the International Consortium of Orthopaedic Registries (ICOR) and used in this study to reduce barriers to participation (e.g., involving data security, privacy, proprietary information, and legal issues) relative to an approach involving a centralized data warehouse<sup>8-10</sup>. A distributed health data network is a decentralized model that

TABLE II Fixed-Effects Model\*

	Hazard Ratio (95% CI)	P Value
Time in yr		
0 to 1	Ref.	
1 to 2	9.76 (8.38-11.37)	<0.001
2 to 3	18.94 (16.23-22.09)	<0.001
3 to 4	24.35 (20.86-28.42)	<0.001
4 to 5	28.30 (24.24-33.04)	<0.001
5 to 6	31.34 (26.84-36.60)	<0.001
6 to 7	34.06 (29.15-39.78)	<0.001
7 to 8	36.73 (31.44-42.92)	<0.001
8 to 9	39.17 (33.50-45.80)	<0.001
9 to 10	43.94 (37.34-51.70)	<0.001
Sex		
Male	Ref.	
Female	0.91 (0.87-0.95)	<0.001
Age in yr		
>65	Ref.	
≤65	0.56 (0.53-0.58)	<0.001
Patella resurfacing		
No	Ref.	
Patella resurfaced	0.84 (0.79-0.88)	<0.001
Fixation		
Cemented	Ref.	
Uncemented	1.13 (1.06-1.20)	0.002
Hybrid	0.99 (0.94-1.06)	0.867
Fixed registry effects†	—	—
Implant design		
Fixed non-posterior-stabilized	Ref.	
Mobile non-posterior-stabilized	1.43 (1.36-1.51)	<0.001

\*Results are based on an iterative solution that updates the residual covariances until convergence. Confidence intervals (CIs) are based on a Z distribution. The estimated intercept was  $-6.417$  (standard error, 0.085). †Fixed registry effects were included in this model, but the results are omitted from this table because a precondition of data sharing was no reporting of comparisons between registries.

allows secure storage and analysis of data from multiple registries<sup>11</sup>. Generally, the data from each registry are standardized and provided at the level of aggregation that is most suitable for the detailed analysis of interest. The aggregated data are combined across registries<sup>12</sup>.

The first step undertaken in developing the research network was to evaluate the variation in international practice. All interested registries participated in decision-making on key variables to be included for analytic purposes. Next, each contributing registry provided data depicting the mean values and proportions of patient and procedure-related characteristics. Six national and regional registries (Kaiser Permanente in the U.S., Swedish Knee Registry, the Emilia-Romagna region in Italy, the Catalan region in Spain, Norway, and Australia) formed the basis of the study collaboration.

The study compared mobile-bearing with fixed-bearing non-posterior-stabilized total knee arthroplasty. The study included only osteoarthritis patients

who had undergone total knee procedures from 2001 to 2010 and excluded posterior-stabilized knees, and constrained and hinged devices, as well as reverse hybrid fixation (cemented femur and cementless tibial components). The outcome of interest was time to first revision for any reason. The distribution of implants by registry and by age, sex, fixation, and patella resurfacing characteristics is shown in Table I.

### Statistical Analyses

Multivariate meta-analysis was performed with use of linear mixed models, with survival probability as the unit of analysis<sup>13</sup>. The models estimated the residual covariances with the precise method reported previously<sup>14</sup>, and implemented a transformation<sup>15-17</sup> to ensure that the models could be fit with existing SAS software (SAS Institute). Survival probabilities and their standard errors were extracted from each registry for each unique combination of the covariates (for example, patella resurfacing, implant fixation, and age) at each distinct event time. Each unique combination was grouped into yearly time intervals, with only the earliest observation in each interval retained.

We fitted two models, one that treated the registries as a set of fixed effects and the other that treated them as random effects. Both models included an intercept, fixed versus mobile-bearing, age, sex, fixation, resurfacing, piecewise constant function of time, residual variance fixed at 1, and either random effects for intercept and fixed versus mobile-bearing, or fixed registry effects. Although the random-effects model offers some inferential advantage for combining studies<sup>18,19</sup>, with the limited numbers of contributing registries, the estimated between-registry variation in the random-effects model can be quite inaccurate. Further, the absence of randomization for mobility and stabilization groups could lead to confounding due to registry-level effects. The random-effects model does not address this issue, but the fixed-effects model does<sup>20,21</sup>. Therefore, preference would be given to interpretation of the fixed-effects model, particularly if the parameter estimates are substantially different in the fixed-effects model compared with those in the random-effects model<sup>20,21</sup>.

The results of the fixed-effects model are presented below and in Table II, and the results of the random-effects model are included in the Appendix. SAS version 9.2 was used for all analyses. Additional details regarding the model fitting are given in the Appendix.

TABLE III Commonly Used Total Knee Arthroplasty Implants Included in Analysis

Design	Implant
Fixed-bearing, non-posterior-stabilized	NexGen (Zimmer)
	P.F.C. Sigma (DePuy Synthes)
	Genesis II (Smith & Nephew)
	Profix (Smith & Nephew)
	Scorpio (Stryker)
	Vanguard (Biomet)
	AGC (Anatomic Graduated Component; Biomet)
	Tricon (Smith & Nephew)
	ADVANCE (Wright Medical)
	Mobile-bearing, non-posterior-stabilized
P.F.C. Sigma Rotating Platform (DePuy Synthes)	
RBK (Global Orthopaedic Technology)	
TC-Plus Solution (Smith & Nephew)	
Total Articulating Cementless Knee (Waldemar Link)	
Rotaglide (Corin Medical)	

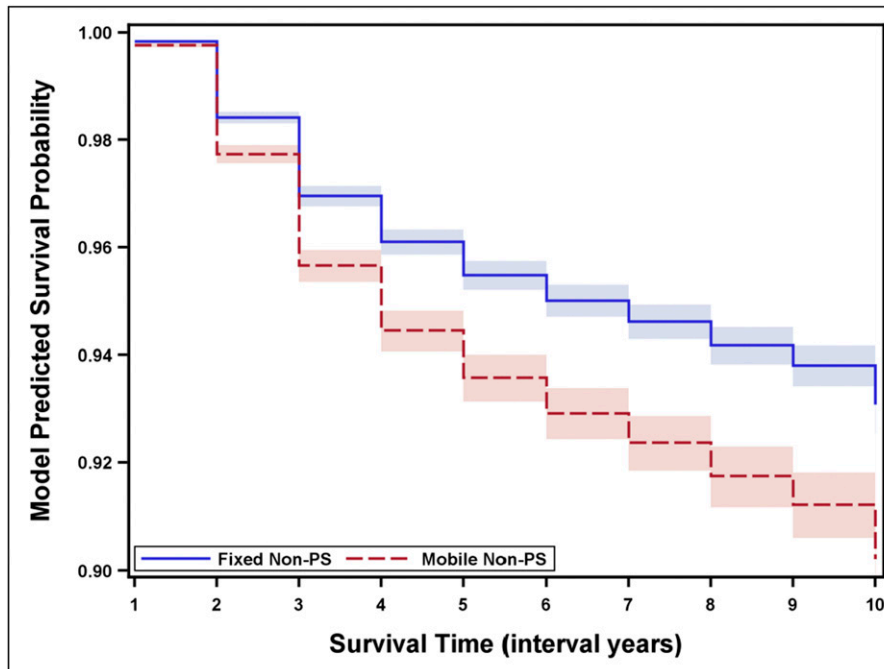


Fig. 1  
Model-predicted survival probability. The x-axis values of 1 to 10 correspond to the interval years (zero to one through nine to ten years). The graphs depict the fixed-effects model, results of which are also shown in Table II. Confidence intervals (shaded areas) are based on a Z distribution. Non-PS = non-posterior-stabilized.

## Results

A total of 319,616 patients (60% female) who received non-posterior-stabilized knee implants were included in the study. In 258,190 (81%) of the knees, a fixed-bearing design was used, and in 61,426 (19%) of the knees, a mobile-bearing design was used. Sixty-nine percent of the patients who received the fixed-bearing implants were over sixty-five years of age, compared with 63% of those who received the mobile-bearing implants. Five-year revision rates varied across the six participating registries, ranging from 1.8% to 3.5%. Distribution of implants by registry and by age, sex, fixation, and resurfacing characteristics is shown in Table I.

The most commonly used mobile-bearing and fixed-bearing total knee implants included in the analysis are presented in Table III. The majority of the mobile-bearing implants were rotating-platform designs.

Interpretation of the results focuses on the fixed-effects model, with the results of the random-effects model presented in the Appendix. We were unable to detect a significant effect for a two-way interaction between prosthesis and either: time, age, sex, patella resurfacing, or fixation. The overall effect was a hazard ratio (HR) of 1.43 (95% confidence interval [CI], 1.36 to 1.51;  $p < 0.001$ ), indicating greater risk of revision for mobile-bearing knee implants. However, in the first year, the magnitude of this effect was higher (HR, 1.90 [95% CI, 1.39 to 2.61];  $p < 0.001$ ), than in the subsequent nine years (HR, 1.43 [95% CI, 1.36 to 1.51];  $p < 0.001$ ). The findings from the fixed-effects model without a time interaction effect are depicted in Table II. Figure 1 depicts the model-predicted survival for fixed and mobile

non-posterior-stabilized implants according to the fixed-effects model.

## Discussion

In this multiregistry analysis, mobile-bearing, non-posterior-stabilized total knee arthroplasty was identified as a risk factor for revision. Combining data elements among the registries, much like in a prospective multicenter study, increased the sample size and thereby improved precision and statistical power, which is particularly important for rare events such as revisions. Challenges to data sharing among multiple registries were managed with a decentralized data warehouse with sharing of aggregate-level data, leading to an unprecedented collaboration among six joint-replacement registries located in different countries.

The LCS implant was the first commercially available mobile-bearing total knee arthroplasty implant and continues to be used by orthopaedic surgeons worldwide. In addition to the LCS implant, other mobile-bearing, non-posterior-stabilized designs are commercially available, and many of these were included in the current analysis. The surgical implantation of the LCS design entails resection of the PCL without incorporating a cam mechanism. Most commercially available fixed-bearing total knee arthroplasties in the U.S. recreate the function of the PCL using a cam mechanism, but non-posterior-stabilized versions do exist. These designs incorporate a raised anterior lip of the tibial insert. The current study indicated, in the absence of a posterior-stabilizing cam mechanism, increased risk of revision following mobile-bearing compared with fixed-bearing total knee arthroplasty.

TABLE IV Random-Effects Model\*

	Hazard Ratio (95% CI)	P Value
Time in yr		
0 to 1	Ref.	
1 to 2	9.77 (8.38-11.38)	<0.001
2 to 3	18.95 (16.24-22.12)	<0.001
3 to 4	24.37 (20.88-28.46)	<0.001
4 to 5	28.34 (24.26-33.09)	<0.001
5 to 6	31.38 (26.86-36.65)	<0.001
6 to 7	33.91 (29.02-39.61)	<0.001
7 to 8	36.77 (31.46-42.98)	<0.001
8 to 9	39.22 (33.53-45.88)	<0.001
9 to 10	44.00 (37.38-51.80)	<0.001
Sex		
Male	Ref.	
Female	0.91 (0.87-0.95)	<0.001
Age in yr		
>65	Ref.	
≤65	0.56 (0.54-0.58)	<0.001
Patella resurfacing		
No	Ref.	
Patella resurfaced	0.84 (0.79-0.88)	<0.001
Fixation		
Cemented	Ref.	
Uncemented	1.12 (1.05-1.19)	<0.001
Hybrid	0.99 (0.93-1.06)	0.862
Implant design		
Fixed non-posterior-stabilized	Ref.	
Mobile non-posterior-stabilized	1.45 (1.08-1.93)	0.024

\*Results are based on an iterative solution that updates the residual covariances until convergence. The model is estimated with use of restricted maximum likelihood (REML). Our simulations indicated that an optimal strategy for confidence interval (CI) construction in the presence of random effects was to use  $t_{K-1}$  for fixed parameters with corresponding random effects, and to use  $t_{n-p}$  otherwise. This is the approach taken in the construction of the CIs and p values reported in this table. The estimated intercept was  $-6.233$  (standard error, 0.134), the random effect intercept was 0.065 (standard error, 0.043), and the random effect for implant design was 0.039 (standard error, 0.050).

Different results have been reported for mobile-bearing total knee arthroplasty implants<sup>22-25</sup>. A well-conducted prospective, randomized trial did not show any significant differences between mobile-bearing and fixed-bearing total knee arthroplasty regarding function but was not large enough to look at revision occurrence<sup>6</sup>. One meta-analysis found similar functional outcomes<sup>2</sup>, and another, a lower rate of revision associated with mobile-bearing total knee arthroplasty<sup>7</sup>. However, analysis of the Kaiser Permanente total joint registry determined that the adjusted revision risk of the LCS implant was two times higher than that for fixed-bearing total knee replacements<sup>5</sup>. In the 2011 annual report of the Australian Orthopaedic Association registry, the ten-year cumulative percent revision for the LCS was 7.4 (95% CI, 6.4 to 8.7) compared with 2.7 (95% CI, 2.1 to 3.5) for the NexGen CR, a fixed-bearing implant<sup>26</sup>. Similarly, a Norwegian study identified the LCS and LCS Complete implants

as having a six to seven-times higher risk for tibial component loosening compared with fixed-bearing total knee implants<sup>3</sup>.

To our knowledge, our study was more powerful than any previous investigation, and its major strength was the inclusion of the largest sample size of mobile-bearing and fixed-bearing total knee replacements reported to date. While understanding the reasons for reoperation is important, the implant survivorship itself is a very valuable outcome from the patient perspective. One limitation of this study is that mobile-bearing total knee arthroplasties are performed much less frequently than are fixed-bearing total knee arthroplasties. Mobile-bearing total knee arthroplasties represent 1.2% to 30% of the volume of primary total knee arthroplasty in annual reports of total knee registries. Hence, patient selection for mobile-bearing or fixed-bearing total knee arthroplasty might be based on factors other than surgeon preference, with some potential of selection bias.

In conclusion, non-posterior-stabilized, mobile-bearing total knee arthroplasty was identified as a revision risk factor for primary total knee arthroplasty in a unique international collaboration of six joint-replacement registries. Although this observation was clear, the results should not be extrapolated to all mobile-bearing total knee arthroplasties, as there are other designs of mobile-bearing implants, including those that incorporate a cam mechanism. Despite challenges of data sharing among large institutions, the methodology utilized in the collaboration of multiple registries in this study can be replicated for other clinical research questions.

### Appendix—Details of the Model Fitting

For the models described, we chose to retain observations with a standard error of  $<0.025$ , given simulations indicating increased bias, increased root-mean-squared error, and poorer coverage when observations with greater degrees of imprecision (resulting from sparse data for certain covariate combinations) were retained. This particular threshold was based on both the simulation results and a sensitivity analysis of the effect on model parameters when various levels of restriction (0.05, 0.025, 0.0125) were applied.

The fixed-effects model was based on the random-effects model selected. For the random-effects model, we initially considered interactions with time in our model. The interaction terms were based on intervals of time: zero to one year through nine to ten years. A likelihood ratio test using maximum likelihood estimation found insufficient evidence of improvement as a result of including the interaction of prosthesis and time in the model,  $\chi^2(9) = 14.37$ ,  $p = 0.110$ . Examination of the point estimates suggested a more parsimonious specification of time for the interaction, (zero to one year versus one to ten years). However, this failed to reach significance as well,  $\chi^2(1) = 3.24$ ,  $p = 0.072$ . As an exploratory measure, we also examined whether there was evidence of a two-way interaction between prosthesis and either: resurfacing, fixation, age, or sex. A global test of all of these two-way interactions indicated no evidence of an effect,  $\chi^2(5) = 5.74$ ,  $p = 0.332$ . ■

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