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Survival rates and causes of revision in cemented primary total knee replacement

A REPORT FROM THE NORWEGIAN ARTHROPLASTY REGISTER 1994–2009

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We evaluated the rates of survival and cause of revision of seven different brands of cemented primary total knee replacement (TKR) in the Norwegian Arthroplasty Register during the years 1994 to 2009. Revision for any cause, including resurfacing of the patella, was the primary endpoint. Specific causes of revision were secondary outcomes.

Three posterior cruciate-retaining (PCR) fixed modular-bearing TKRs, two fixed non-modular bearing PCR TKRs and two mobile-bearing posterior cruciate-sacrificing TKRs were investigated in a total of 17 782 primary TKRs. The median follow-up for the implants ranged from 1.8 to 6.9 years. Kaplan-Meier 10-year survival ranged from 89.5% to 95.3%. Cox's relative risk (RR) was calculated relative to the fixed modular-bearing Profix knee (the most frequently used TKR in Norway), and ranged from 1.1 to 2.6. The risk of revision for aseptic tibial loosening was higher in the mobile-bearing LCS Classic (RR 6.8 (95% confidence interval (CI) 3.8 to 12.1)), the LCS Complete (RR 7.7 (95% CI 4.1 to 14.4)), the fixed modular-bearing Duracon (RR 4.5 (95% CI 1.8 to 11.1)) and the fixed non-modular bearing AGC Universal TKR (RR 2.5 (95% CI 1.3 to 5.1)), compared with the Profix. These implants (except AGC Universal) also had an increased risk of revision for femoral loosening (RR 2.3 (95% CI 1.1 to 4.8), RR 3.7 (95% CI 1.6 to 8.9), and RR 3.4 (95% CI 1.1 to 11.0), respectively). These results suggest that aseptic loosening is related to design in TKR.

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The aim of this study was to investigate the rate of survival and causes of revision for seven brands of cemented primary total knee replacement (TKR) registered in the Norwegian Arthroplasty Register (NAR) between 1994 and 2009. The brands are currently and historically among the most commonly used both in Norway and around the world.[1,2] The study was limited to cemented implants without patellar resurfacing, and the data reflect the results of the average surgeon. We accept that pooling of data from many surgeons, with different experience, patient volumes and skills, may give good external validity but may also hide the effect of a learning curve and any positive effect that may be related to high volumes undertaken by some surgeons.

We also investigated whether survival was brand specific or related to particular types of design.

Patients and Methods

Data from patients registered in the NAR during this time were evaluated. The registration of hip replacements in the NAR started in 1987 and was expanded to include TKRs and the replacement of other joints in 1994.[3,4] The completeness of the registration was estimated by Espehaug et al[5] to be 99% of all primary TKRs and 97% of all revision procedures between 1999 and 2002. Any complete or partial removal/exchange of the implant, or insertion of a component (including a patellar component), was considered a revision procedure. The unique identification number of all Norwegian residents facilitates linking the revisions to the primary operations.

All TKRs were cemented and were inserted without patellar components. Differences between the designs were predominantly on the tibial side; two were mobile-bearing TKRs (LCS Classic and LCS Complete (DePuy, Warsaw, Indiana), both rotating platform), two were non-modular fixed bearing TKRs (AGC Universal and AGC Anatomic; both Biomet, Warsaw, Indiana), and three were modular fixed-bearing TKRs (Duracon; Stryker, Portage, Michigan; NexGen; Zimmer, Warsaw, Indiana; and Profix; Smith & Nephew, Memphis, Tennessee). The mobile-bearing TKRs were posterior cruciate ligament (PCL) sacrificing, and the others were PCL retaining.

Implant designs not in use after 2004, and those that were used in < 500 cases, were

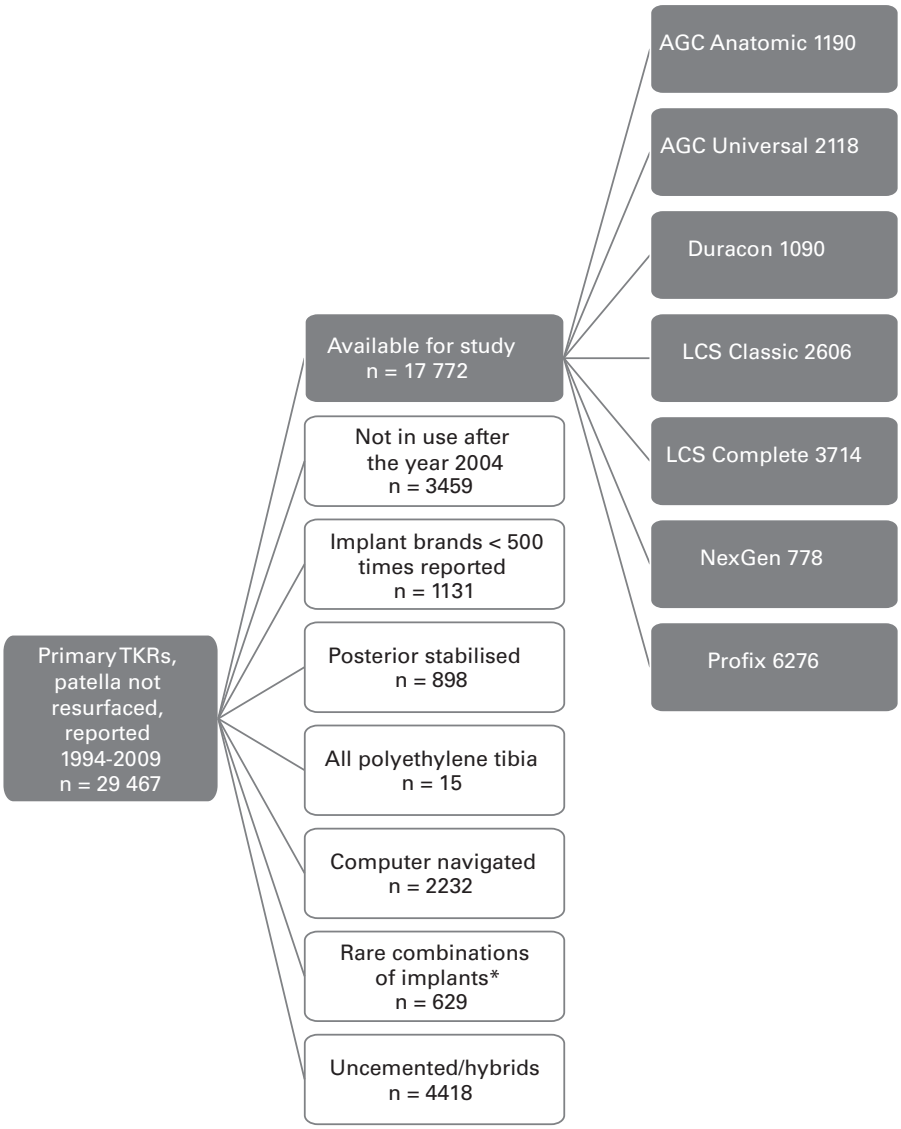

Fig. 1

Selection chart showing inclusions and exclusions of cases. There may be more than one exclusion criterion per case (* rare combinations of implants: Profix mobile-bearing (n = 12), AGC Dual (52), various combinations of LCS (n = 565); TKR, total knee replacement).

excluded (Fig. 1). TKRs introduced with computer-navigation were excluded because the technique was not widely used for the TKRs that were selected. Posterior-stabilised implants were excluded because of relatively low numbers (the Profix Conforming Plus was regarded as posterior stabilised). The inclusion criteria were met by 2118 AGC Universal, 1190 AGC Anatomic, 1090 Duracon, 778 NexGen, 6276 Profix, 2606 LCS Classic and 3714 LCS Complete TKRs.

Statistical analysis. Revision for any cause was the primary endpoint. Specific causes for revision and types of revision were secondary outcomes. Descriptive analyses were used to assess the baseline characteristics of the various brands (Table I). Information on deaths or emigrations up to 31 December 2009 was retrieved from the National Population Register. The survival times of unrevised TKRs were taken at the last date of observation (date of death or emigration, or 31 December 2009). Median follow-up was calculated with the reverse Kaplan–Meier method.[6] Unadjusted survival curves for the various brands were constructed using the Kaplan-Meier method, and stopped when < 50 knees remained at risk. Survival percentages after five and ten years' follow-up are reported. Cox's multiple regression model was used to calculate hazard rate ratios (RR), adjusted for potential confounding by age, gender, pre-operative diagnosis (osteoarthritis or other diagnoses) and previous knee surgery (yes/no). The RR estimates are presented with 95% confidence intervals (CI) and p-values reported relative to the Profix TKR, which was the most common

Table I. Demographic data (ACL, anterior cruciate ligament; PCL, posterior cruciate ligament)

	Implant						
Characteristic	**AGC Anatomic**	**AGC Universal**	**Duracon**	**LCS Complete**	**LCS Classic**	**NexGen**	**Profix**
Patients (n)	1190	2118	1090	3714	2606	778	6276
Male (n, %)	450 (*37.8*)	650 (*30.7*)	352 (*32.3*)	1219 (*32.8*)	718 (27.6)	273 (*35.1*)	1950 (*31.1*)
Right knee (n, %)	637 (*53.5*)	1149 (*54.2*)	596 (*54.7*)	2004 (*54.0*)	1437 (*55.1*)	394 (*50.6*)	3422 (*54.5*)
Mean (SD) age (yrs)	69.7 (9.1)	71.0 (9.2)	70.7 (9.3)	69.6 (9.6)	71.5 (9.0)	69.2 (10.5)	70.0 (10.0)
Age group (n, %)							
≤ 60 years	169 (*14.2*)	259 (*12.2*)	141 (*12.9*)	597 (*16.1*)	299 (*11.5*)	130 (*16.7*)	1015 (*16.2*)
61 to 70 years	393 (*33.0*)	575 (*27.1*)	330 (*30.3*)	1214 (*32.7*)	706 (*27.1*)	235 (*30.2*)	1846 (*29.4*)
71 to 80 years	492 (*41.3*)	962 (*45.4*)	446 (*40.9*)	1394 (*37.5*)	1174 (*45.0*)	316 (*40.6*)	2434 (*38.8*)
> 80 years	136 (*11.4*)	322 (*15.2*)	173 (*15.9*)	509 (*13.7*)	427 (*16.4*)	97 (*12.5*)	981 (*15.6*)
Diagnosis (n, %)							
Primary osteoarthritis	1062(*89.5*)	1832 (*86.9*)	950 (*87.5*)	3338 (*90.1*)	2268 (*87.4*)	674 (*86.7*)	5325 (*85.2*)
Other	124 (*10.5*)	276 (*13.1*)	136 (*12.5*)	366 (*9.9*)	328 (*12.6*)	103 (*13.3*)	928 (14.8)
Hospitals using this design (n)	11	29	18	35	30	19	40
Mean (SD) operation time (min)	85 (23)	96 (23)	98 (30)	97 (24)	101 (35)	105 (54)	92 (32)
Cement with antibiotics (n, %)	1187 (*99.7*)	2115 (*99.9*)	1089 (*99.9*)	3711 (*99.9*)	2592 (*99.5*)	778 (*100*)	6200 (*98.8*)
Patients with previous operations on the knee (n, %)	311 (*26.2*)	456 (*21.6*)	333 (*30.6*)	1128 (*30.4*)	688 (*26.4*)	205 (*26.4*)	1542 (*24.6*)
Intact ACL pre-operatively (n, %)	904 (*76.0*)	1664 (*78.8*)	792 (*73.3*)	2995 (*80.7*)	1940 (*74.6*)	542 (*69.7*)	5246 (*83.6*)
Intact PCL post-operatively (n, %)	1027 (*91.9*)	1950 (*96.3*)	911 (*87.7*)	250 (*6.9*)	353 (*13.9*)	649 (*95.2*)	5941 (*97.0*)

TKR in Norway in the last decade. A sub-analysis was performed to present the risk estimates of the category of design relative to fixed modular-bearing designs.

We tested the proportional hazards assumption of the Cox model based on scaled Schoenfeld residuals.[7,8] With revision for any reason as the endpoint, the assumption was found valid for the factors 'prosthesis brand' with the Profix implant as the reference brand ($p \geq 0.1$) and 'design category' with fixed modular bearing as the reference category ($p \geq 0.6$). Bilateral TKRs were included in the study. Although this might imply a violation of the assumption of independent observations in the survival analyses, studies have shown that the impact on statistical precision is minor for both hip[9] and knee replacements.[10]

PASW Statistics v18 (IBM SPSS, Armonk, New York) and R v2.13.0 (The R Foundation for Statistical Computing, http://www.R-project.org 2008) were used for the statistical analyses, and $p < 0.05$ was considered statistically significant.

The NAR has approval from the Norwegian Data Inspectorate to collect patient data on condition of written consent of the patient.

Results

The study groups did not differ markedly with respect to age, gender, laterality or diagnosis (Table I). The median follow-up ranged from 1.8 to 6.9 years depending on the implant (Table II).

The Cox's regression analyses and the Kaplan-Meier curves showed that the Duracon, LCS Classic, LCS Complete and AGC Universal brands had a higher risk of revision (RR 1.3 to 2.6) and a statistically significantly lower survival (89.5% to 94.0%) than the Profix TKR (95.3%) (Table II, Fig. 2). The NexGen and the AGC Anatomic TKR performed in a similar manner to the Profix. A sub-analysis of TKRs performed in the latest time period, after 2004, showed a higher risk of revision for the two mobile-bearing implants (RR 1.3 (95% CI 1.0 to 1.7)), but not for monobloc implants (RR 1.0 (95% CI 0.7 to 1.4)) compared with the fixed-bearing implants.

There was an increased risk of revision for aseptic tibial loosening in the LCS Classic, LCS Complete and the Duracon TKRs compared with the Profix (RR 6.8 (95% CI CI 3.8 to 12.1), RR 7.7 (95% CI 4.1 to 14.4) and RR 4.5 (95% CI 1.8 to 11.1), respectively) (Table III and Fig. 3a). These implants also had an increased risk of revision for aseptic femoral loosening (RR 2.3 (95% CI 1.1 to 4.8), RR 3.7 (95% CI 1.6 to 8.9) and RR 3.4 (95% CI 1.1 to 11.0), respectively) (Fig. 3b). Also, the AGC Universal TKR had an increased risk of revision for aseptic tibial loosening (RR 2.5 (95% CI 1.3 to 5.1)) compared with the Profix.

The risk of revision due to deep infection was higher for all TKRs except the LCS Classic, compared with the Profix (RR from 1.8 to 3.7). The risk of revision due to polyethylene wear and to malalignment was higher in the Duracon

Table II. Kaplan-Meier survival by implant brand of cemented primary total knee replacements without patellar resurfacing, reported to the Norwegian Arthroplasty Register between 1994 and 2009, with revision for all causes as the endpoint (CI, confidence interval)

				5 years		10 years			
Implant	Total (n)	Revised (n, %)	Median follow-up (yrs)	Survival (%, 95% CI)	At risk (n)	Survival (%, 95% CI)	At risk (n)	Relative risk (95% CI)*	p-value
Profix	6276	195 (*3.1*)	4.5	96.3 (95.7 to 96.9)	2575	95.3 (94.5 to 96.1)	51	1	
Duracon	1090	56 (*5.1*)	1.8	93.3 (91.1 to 95.5)	247	89.5 (86.1 to 92.9)	117	2.6 (1.9 to 3.4)	< 0.001
NexGen	778	25 (*3.2*)	3.2	94.7 (92.5 to 96.9)	159	-†	4	1.2 (0.8 to 1.9)	0.3
LCS Classic	2606	129 (*5.0*)	6.6	95.6 (94.8 to 96.4)	1898	94.0 (92.8 to 95.2)	261	1.3 (1.0 to 1.6)	0.017
LCS Complete	3714	102 (*2.7*)	1.9	94.9 (93.5 to 96.3)	61	-‡	0	1.5 (1.1 to 1.9)	0.002
AGC Universal	2118	121 (*5.7*)	6.9	94.7 (93.7 to 95.7)	1436	92.6 (91.2 to 94.0)	369	1.6 (1.3 to 2.0)	< 0.001
AGC Anatomic	1190	29 (*2.4*)	2.7	96.5 (95.1 to 97.9)	119	-§	0	1.1 (0.7 to 1.6)	0.7

* Cox regression with adjustment for age, gender, diagnosis and previous surgery
† last revision at 4.65 years
‡ last revision at 4.31 years
§ last revision at 3.89 years

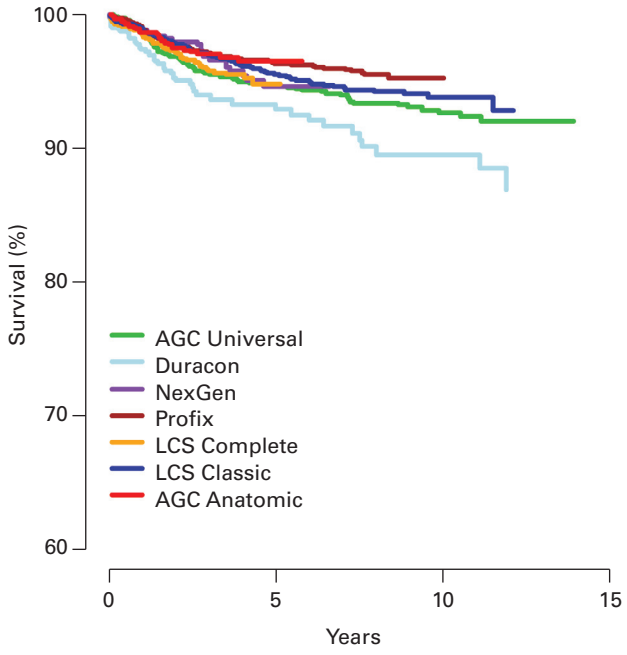

Fig. 2

Kaplan-Meier survival analysis of the various brands with revision for any reason as the endpoint.

TKRs (RR 16.6 (95% CI 4.9 to 56.7) and RR 8.7 (95% CI 3.7 to 20.4), respectively). However, the number of revisions for these reasons was low (n = 10 and n = 10, respectively). The LCS Classic had a higher risk of revision due to dislocation of the polyethylene (RR 3.7 (95% CI 1.2 to 11.1)). The AGC Universal had a higher risk of revision due to pain (RR 2.1 (95% CI 1.5 to 3.0)) and dislocation of the patella (RR 8.0 (95% CI 1.6 to 39.6)), whereas the LCS Complete and LCS Classic had a lower risk of revision due to pain as the only cause of revision (RR 0.4 (95% CI 0.2 to 0.8)). Insertion of a patellar component was the most frequent revision operation performed for pain.

Using the fixed modular-bearing category as the reference, for the three categories of design we found an increased risk of revision due to aseptic loosening of the tibial tray in the mobile-bearing (RR 4.8 (95% CI 3.2 to 7.3)) and the monobloc category (RR 1.9 (95% CI 1.1 to 3.3)). Aseptic loosening of the femoral component was more common in the mobile-bearing category (RR 2.5 (95% CI 1.4 to 4.4)). Further, we included only the most used subtypes of the implants in the analysis, but the results did not change.

In order to minimise the effect of a learning curve, we performed a sub-analysis that only included TKRs from hospitals having inserted > 100. The risk of revision for aseptic tibial loosening was still higher for the LCS Classic (RR 5.8 (95% CI 3.3 to 10.2) and the LCS Complete (RR 6.8 (95% CI 3.6 to 12.8)) compared with the Profix TKR. The type of cement did not influence survival. The mean operating time ranged from 85 minutes for the AGC Anatomic to 105 minutes for the NexGen TKR (Table I).

In order to preclude any time dependency, we analysed the one-year and five-year Kaplan-Meier overall survival rates and the Cox's regression hazard rate ratios. The differences in survival of the various brands did not change markedly over time (see Supplementary Material).

Discussion

The Duracon, LCS Classic, LCS Complete and AGC Universal brands had lower survival than the Profix, whereas the NexGen and AGC Anatomic TKRs did not. Increased risk of revision for aseptic loosening of the tibial and femoral components was the major reason for the inferior performance. The AGC Universal was more likely to be revised because of pain than the other brands, and LCS Complete and LCS Classic were less likely to be revised for this reason. The risk of revision for deep infection was higher for all brands, except the LCS Classic, than for the Profix.

The implants with a higher risk of aseptic loosening represent different design principles, so no common thread was apparent. For example, the fixed non-modular bearing AGC Universal was inferior to the Profix, but the AGC Anatomic was not.

Revision because of pain was rare with mobile-bearing implants, which is consistent with the theory that rotation of the mobile bearing improves patellar tracking.[11] The

Table III. Causes of revision by incidence and Cox's relative risk (RR) for cemented total knee replacements without patellar resurfacing reported to the Norwegian Arthroplasty Register between 1994 and 2009. There may be more than one cause of revision reported in each case. Statistically significant differences compared with the Profix implant, are marked with bold (CI, confidence interval)

	Implant						
Cause of revision	**Profix**	**Duracon**	**NexGen**	**LCS Complete**	**LCS Classic**	**AGC Universal**	**AGC Anatomic**
Incidence (n, %)							
Aseptic loosening (femur)	12 (*0.2*)	4 (*0.4*)	1 (*0.1*)	10 (*0.3*)	16 (*0.6*)	5 (*0.2*)	1 (*0.1*)
Aseptic loosening (tibia)	15 (*0.2*)	7 (*0.6*)	4 (*0.5*)	32 (*0.9*)	58 (*2.2*)	17 (*0.8*)	3 (*0.3*)
Dislocation (patella)	2 (*0.0*)	5 (*0.5*)	-	-	-	6 (*0.3*)	1 (*0.1*)
Dislocation (other)	5 (*0.1*)	-	-	1 (*0.0*)	9 (*0.3*)	1 (*0.0*)	-
Instability	31 (*0.5*)	11 (*1.0*)	5 (*0.6*)	10 (*0.3*)	13 (*0.5*)	15 (*0.7*)	5 (*0.4*)
Malalignment	12 (*0.2*)	10 (*0.9*)	2 (*0.3*)	5 (*0.1*)	13 (*0.5*)	4 (*0.2*)	2 (*0.2*)
Deep infection*	31 (*0.5*)	15 (*1.4*)	11 (*1.4*)	33 (*0.9*)	21 (*0.8*)	22 (*1.0*)	11 (*0.9*)
Fracture affecting implant	8 (*0.1*)	1 (*0.1*)	-	4 (*0.1*)	8 (*0.3*)	-	-
Pain†	68 (*1.1*)	3 (*0.3*)	3 (*0.4*)	11 (*0.3*)	14 (*0.5*)	51 (*2.4*)	7 (*0.6*)
Polyethylene wear	4 (*0.1*)	10 (*0.9*)	-	3 (*0.1*)	1 (*0.0*)	2 (*0.1*)	-
Stiffness	12 (*0.2*)	5 (*0.5*)	-	5 (*0.1*)	1 (*0.0*)	1 (*0.0*)	-
Other	27 (*0.4*)	10 (*0.9*)	1 (*0.1*)	11 (*0.3*)	7 (*0.3*)	7 (*0.3*)	-
RR (95% CI)							
Aseptic loosening (femur)	1	**3.4** (1.1 to 11.0)	0.9 (0.1 to 6.8)	**3.7** (1.6 to 8.9)	**2.3** (1.1 to 4.8)	0.8 (0.3 to 2.4)	0.8 (0.1 to 6.3)
Aseptic loosening (tibia)	1	**4.5** (1.8 to 11.1)	2.9 (0.9 to 8.6)	**7.7** (4.1 to 14.4)	**6.8** (3.8 to 12.1)	**2.5** (1.3 to 5.1)	1.7 (0.5 to 5.9)
Dislocation (patella)	1	**19.3** (3.7 to 100.3)	0	0	0	**8.0** (1.6 to 39.6)	3.1 (0.3 to 34.7)
Dislocation (other)	1	0	0	0.5 (0.1 to 4.0)	**3.7** (1.2 to 11.1)	0.5 (0.1 to 4.6)	0
Instability	1	**3.5** (1.7 to 7.0)	1.5 (0.6 to 3.8)	1.0 (0.5 to 2.1)	0.8 (0.4 to 1.6)	1.2 (0.7 to 2.3)	1.3 (0.5 to 3.3)
Malalignment	1	**8.7** (3.7 to 20.4)	1.8 (0.4 to 7.9)	1.4 (0.5 to 4.1)	2.1 (0.9 to 4.6)	0.9 (0.3 to 2.7)	1.4 (0.3 to 6.3)
Deep infection*	1	**3.7** (2.0 to 6.9)	**3.3** (1.6 to 6.5)	**2.6** (1.6 to 4.3)	1.4 (0.8 to 2.5)	**1.8** (1.1 to 3.2)	**2.4** (1.2 to 4.7)
Fracture affecting implant	1	0.8 (0.1 to 6.6)	0	1.2 (0.4 to 4.1)	1.9 (0.7 to 5.1)	0	0
Pain†	1	0.4 (0.1 to 1.4)	0.4 (0.1 to 1.3)	**0.4** (0.2 to 0.8)	**0.4** (0.2 to 0.8)	**2.1** (1.5 to 3.0)	0.7 (0.3 to 1.5)
Polyethylene wear	1	**16.6** (4.9 to 56.7)	0	4.0 (0.8 to 19.9)	0.3 (0.0 to 3.0)	0.8 (0.1 to 4.3)	0
Stiffness/Other	1	**3.7** (1.8 to 7.7)	0.3 (0.0 to 2.4)	1.1 (0.5 to 2.2)	0.6 (0.3 to 1.3)	0.8 (0.3 to 1.8)	0

* deep infection rules out aseptic loosening
† pain as the only cause of revision

AGC Anatomic, with right/left femoral components, has replaced the AGC Universal, and its good results are consistent with data from the Australian Arthroplasty Registry showing similar revision rates for monobloc and fixed-bearing TKRs after ten years.[2]

The risk of revision due to dislocation of the polyethylene bearing was higher for the LCS Classic than for the Profix, but not for the LCS Complete. In our study most of the mobile-bearing LCS TKRs sacrificed the PCL, whereas the fixed modular and fixed non-modular TKRs were PCL retaining (Table I).

This study focused on the causes of revision and found the highest risk of revision to be in the LCS TKRs, for both aseptic tibial and femoral loosening. Other studies have shown good survival and clinical results of mobile-bearing designs,[11-14] but these studies did not compare mobile with fixed bearings. The inferior results of the mobile-bearing TKRs in our study are consistent with data from the Australian Joint Replacement Registry[2] and from the Southern California Permanente Medical Group.[15,16]

The aim of the mobile-bearing design was to combine low constraint forces with low contact stresses, theoretically reducing polyethylene wear and aseptic loosening.[17] Early fixed-bearing designs had unsatisfactory function and range of movement, and it was claimed that the biomechanics of the mobile-bearing design were closer to those of a normal knee, and would improve function and longevity.[18] Dislocation of the polyethylene was a problem in the early years of the mobile-bearing TKR, but as the technique and instruments evolved, this complication became rare.[19] However, there is no strong evidence that any mobile-bearing design is superior to a fixed bearing with regard to pain, function, range of movement or failure rate.[20,21] It is claimed that wear of the polyethylene in the modular fixed bearing and the mobile bearing at the tibial interface may lead to peri-prosthetic osteolysis and loosening.[22,23] This so-called backside wear is eliminated in the fixed non-modular (monobloc) design, but the modularity option is lost. The monobloc design has excellent survival in several studies,[24-27] but most surgeons prefer the modular fixed bearing.

A retrieval study evaluating 48 mobile bearings concluded that wear was as severe as that in fixed modular-bearing designs.[28] Similar polyethylene wear was found for a mobile-bearing rotating platform and a fixed modular bearing in an *in vitro* study.[29] Another *in vitro* study, however, concluded that the wear rate of the fixed bearing was four times higher than for the rotating platform,[30] but in two meta-analyses no differences in the incidence of

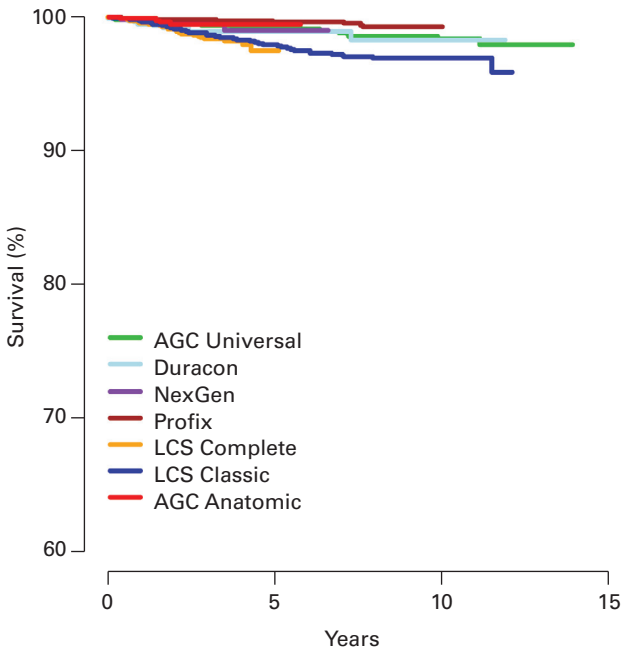

Fig. 3a

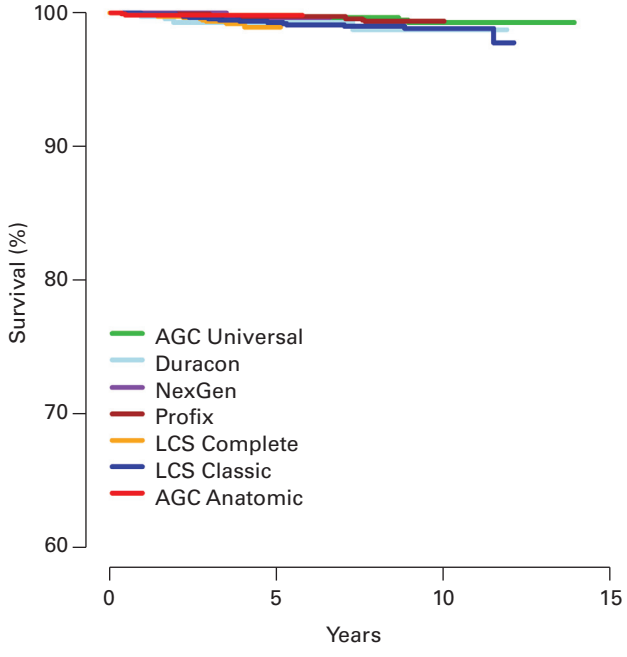

Fig. 3b

Kaplan-Meier survival analyses of the various brands with a) tibial and b) femoral loosening as the endpoint.

radiolucent lines or clinical outcome were found.[20,31] Recent reports from the NAR did not show differences in pain, function or survival for the LCS Classic, or survival for the LCS Complete, compared to the AGC Universal TKR.[32,33] Differences in geometry and undersurface texture in the two mobile-bearing TKRs might explain why they differ in outcome.[34] All the mobile-bearing TKRs in this study were 'no keel' subtypes, and there might have been less resistance to rotational forces with this design compared with those with a keel (Supplementary Material). The higher risk of revision for aseptic loosening of the tibial and femoral components in the LCS Classic and LCS Complete must be further investigated, focusing on wear and shear forces at the prosthesis–cement–bone interfaces.

The inferior results reported here for the Duracon TKR differ from those reported from the Australian Arthroplasty Register.[2] A possible explanation could be that in 2005 the Duracon TKR was introduced in one geographical region of Norway as a result of a tender process, and therefore the local surgeons were obliged to go through a learning process.

In conclusion, differences in the causes of revision were brand specific. The assumption that fixed modular-bearing implants are more at risk of loosening due to polyethylene wear than mobile-bearing designs was not supported by this study.

Supplementary material

A table detailing the use of subtypes of implants within each brand and two Kaplan-Meier survival curves showing cumulative survival at i) one and ii) five years are available with the electronic version of this article on our website www.bjj.boneandjoint.org.uk

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