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Increased risk of aseptic loosening for 43,525 rotating-platform vs. fixed-bearing total knee replacements
A Norwegian–Australian registry study, 2003–2014

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Background and purpose — Given similar functional outcomes with mobile and fixed bearings, a difference in survivorship may favor either. This study investigated the risk of aseptic loosening for the most used subtypes of mobile-bearing rotating-platform knees, in Norway and Australia.

Patients and methods — Primary TKRs reported to the Norwegian and Australian joint registries, between 2003 and 2014, were analyzed with aseptic loosening as primary end-point and all revisions as secondary end-point. We hypothesized that no difference would be found in the rate of revision between rotating-platform and the most used fixed-bearing TKRs, or between keeled and non-keeled tibia. Kaplan–Meier estimates and curves, and Cox regression relative risk estimates adjusted for age, sex, and diagnosis were used for comparison.

Results — The rotating-platform TKRs had an increased risk of revision for aseptic loosening compared with the most used fixed-bearing knees, in Norway (RR = 6.95% CI 4–8) and Australia (RR = 2.1, 95% CI 1.8–2.5). The risk of aseptic loosening as a reason for revision was highest in Norway compared with Australia (RR = 1.7, 95% CI 1.4–2.0). The keeled tibial component had the same risk of aseptic loosening as the non-keeled tibia (Australia). Fixation method and subtypes of the tibial components had no impact on the risk of aseptic loosening in these mobile-bearing knees.

Interpretation — The rotating-platform TKRs in this study appeared to have a higher risk of revision for aseptic loosening than the most used fixed-bearing TKRs.

The LCS complete implant, also called LCS MBT (Low Contact Stress Mobile Bearing Tray, DePuy, Warsaw, IN, USA), is a modified version of the classical tibial rotating platform introduced at the beginning of the century. In a previous report from the Norwegian Arthroplasty Register (NAR), the LCS MBT was found to have an increased risk of aseptic loosening, particularly on the tibial side (Gothesen et al. 2013). Despite the overall survival of these total knee replacements (TKRs) remaining acceptable, a 7-fold increased risk of tibial loosening was identified, prompting further investigations. A retrieval study suggested that the bonding between cement and implant had weakened due to a lower roughness of the cement–implant interface (Kutzner, personal communication). It has been suggested that other causes increasing the risk of aseptic loosening and osteolysis may include increased wear particle production related to the mobile-bearing design, or a difficult surgical technique (Huang et al. 2002). Recent reports from large registries have confirmed the higher risk of revision with a mobile-bearing design, and have advised caution when selecting such implants (Graves et al. 2014, Namba et al. 2014).

The mobile-bearing design was developed to reduce shear and tear forces and thereby reduce wear of the insert (Buechel and Pappas 1986). In addition, a mobile bearing is designed to be less rigid, and mechanically closer to a normal knee. Improved patellar tracking was claimed to be one of the advantages of this design. However, few independent investigators have been able to show improved function with this design (Ranawat et al. 2004, Lygre et al. 2010, Hofstede et al. 2015). If function is not improved and the revision rate increases, the use of mobile-bearing TKRs in standard knee replacement will be questionable.

Increased risk of mobile-bearing loosening appears to be a global issue. However, local variation including operative techniques, clinical and radiological interpretation of informa-
tion, different types of surface geometry, and design of the implants may be important factors leading to varying results. Previous registry studies do not provide much information about various subtypes and designs of mobile-bearing knees. The rotating-platform design is the most used mobile-bearing design; therefore, the aim of this study was to investigate this design in further detail. The most used subtypes of the rotating-platform design used in Australia and Norway were selected for comparison between and within countries using catalogue numbers to compare identical implants. Registry data from the Norwegian Arthroplasty Register (NAR) and the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) were analyzed. Our hypothesis was that the most used fixed-bearing TKRs, in Norway and Australia, had a lower risk of aseptic loosening than the most used mobile-bearing TKRs.

Patients and methods

The NAR has collected data on TKRs since 1994 and the AOANJRR since 1999. The AOANJRR had its first year of complete national registering in 2003. Hence, the study includes selections from complete datasets reported from 2003 to 2014. The completeness of the data collection in the NAR and AOANJRR is 96–99% (Furnes 2015, Graves 2015).

From the Norwegian registry 12,003 patients with rotating-platform TKRs, and 19,580 patients with fixed-bearing TKRs, were included (mean age 69 (SD 10), 36% men). From the Australian registry 31,522 patients with rotating-platform TKRs, and 48,173 patients with fixed-bearing TKRs (mean age 68 (SD 9), 45% men), were included. A prospective observational study was performed, and primary mobile-bearing LCS Complete (Low Contact Stress, DePuy, Warsaw, IN, USA) and PFC Sigma (Press Fit Condylar, DePuy, Leeds, UK) TKRs, with rotating platform, without patella resurfacing, were selected for analysis (Table 1, Figure 1). A non-keeled tibial component was used in 90% of cases in Norway and 49% in Australia (catalogue numbers 129431, 129432). The keeled version of the tibial component was used in 10% of cases in both countries (catalogue numbers 129433, 129434). The Duo-fix version was used in < 1% of cases in Norway and 41% in Australia (catalogue numbers 9003). Any type of fixation was included in the initial datasets.

| Study group mobile-bearing TKRs | Control group fixed-bearing TKRs | p-value a |
|---------------------------------|---------------------------------|-----------|
| Number                          | Norway 12,003                   | Australia 31,522 | Norway 19,580 | Australia 48,173 |
| Men (%)                         | 36                               | 45                  | 36              | 45                  |
| Age years (SD)                  | 68.7 (9.6)                      | 68.0 (9.3)          | 69.2 (9.7)      | 68.3 (9.2)          |
| Primary diagnosis (%)           | Primary osteoarthritis 91 98 | Other 9 2 | Primary osteoarthritis 89 99 | Other 11 1 |
| Fixation, n (%)                 | Cemented 9,615 (81)            | 5,999 (19)         | 14,732 (76)    | 21,425 (45)         |
|                                 | Cementless 1,362 (11)           | 18,377 (58)        | 1,062 (5)      | 10,126 (21)         |
|                                 | Hybrid (cemented tibia) 975 (8) | 6,767 (22)         | 3,674 (19)     | 16,551 (34)         |
|                                 | Hybrid (cementless tibia) 3 (0) | 379 (1)            | 22 (0)         | 71 (0)              |
|                                 | Missing 48                      | 0                  | 90             | 0                   |
| Mobile-bearing subtype tibia    | LCS Complete (MBT)              | 12,003             | 31,522         |
|                                 | No keel, n (%)                 | 10,764 (90)        | 15,415 (49)    |
|                                 | Keel, n (%)                    | 1,148 (10)         | 3,208 (10)     |
|                                 | Duo-fix, n (%)                 | 91 (0)             | 12,899 (41)    |
| Mobile-bearing subtype tibia    | AGC, n (%)                      | 1,622 (8)          |
|                                 | NexGen, n (%)                  | 5,347 (27)         | 16,609 (35)    |
|                                 | PFC Sigma, n (%)               | 9,231 (19)         |
|                                 | Profix, n (%)                  | 12,611 (65)        |
|                                 | Triathlon, n (%)               | 23,333 (46)        |
|                                 | Computer navigation, n (%)     | 1,684 (14)         | 2,384 (8)      | 1,722 (10)          | 11,286 (23) |

Study group: Mobile bearing knees with an LCS Complete tibial component catalogue numbers 12943 or 9003. Control group: 3 most used fixed-bearing, cruciate-retaining TKRs without patella resurfacing, in Norway and Australia.

a P-values are generated on the basis of differences between groups using chi-square test for sex and diagnosis, and independent samples t-test for age difference.

b LCS Complete (also called LCS MBT) and PFC Sigma have identical tibial components (cat. no: 1294-31/32 (no-keel) and 1294-33/34 (keel)). The Duo-fix version has cat. no: 9003. For simplicity this component is called LCS Complete in this paper.
sub-analyses, fixation of the tibial component was targeted. Fully cemented and hybrids with cemented tibial components were allocated to the cemented group, whereas fully cementless and hybrids with cementless tibial components were allocated to the cementless group. For controls, the 3 most used fixed-bearing TKRs (all fixations) in each country were selected (Norway: AGC (Anatomic and Universal, Biomet, Warsaw, IN, USA), NexGen (Zimmer, Warsaw, IN, USA), Profix (Smith & Nephew, Memphis, TN, USA). Australia: Triathlon (Stryker, Mahwah, NJ, USA), NexGen, PFC Sigma (fixed bearing)) (Table 1). Anonymized datasets from Norway and Australia, from the years 2003 to 2014, were merged by converting the respective variables into common variables, using the Australian hierarchy system for ranking of revision diagnoses (Graves 2015).

**Statistics**

The null hypothesis assumed a similar risk of revision for aseptic loosening when TKRs with a rotating-platform tibial component were compared with the most used fixed-bearing knees within the 2 countries, and similar outcome between the countries. Also, the results for the keeled vs. the non-keeled versions used within Australia were expected to be similar. Demographics were analyzed by descriptive analyses, using the chi-square test for categorical data (sex and diagnosis) and Student’s t-test for age difference. A reversed Kaplan–Meier (K–M) method was used to calculate the median follow-up time (Schemper and Smith 1996). Survivorship was calculated by the K–M method, and relative risk estimates (RR) were derived from a Cox multiple regression model with adjustments for age, sex, fixation, and diagnosis. The proportional hazards assumption of the Cox regression model was tested and considered to be satisfactory, except for a negligible divergence during the first 3 months of the Norwegian dataset (see Supplementary data). Survival curves were constructed by K–M estimates. Confidence intervals of 95% (CI) were reported. Tests were 2-sided and p-values < 0.05 were regarded as statistically significant.

The survival analyses were based on an assumption of non-informative censoring. The validity of this assumption could be debatable since knees in one treatment group could be more likely to be censored due to, for example, pain than knees in the other treatment group. To account for possible bias due to informative censoring we performed a sensitivity analysis to check whether our conclusions would be any different by using death and other revision reasons as competing risk factors (Fine and Gray). This sensitivity analysis did only marginally change our results and did not alter our conclusions (Andersen et al. 2012). SPSS® Statistics version 23 (IBM Corp, Armonk, NY, USA) was used for the statistical analyses.

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

Written consent from each patient is required for the collection of Norwegian data, according to a concession from the Norwegian Data Inspectorate issued September 15, 2014 (ref. no:03/00058-20/CGN). For Australian data, the patients have the opportunity to opt out; otherwise their data will be collected and managed by the AOANJRR, according to their obligations, as a Federal Quality Assurance activity. The first
Results

The selected study groups consisted of 43,525 mobile-bearing, non-posterior-stabilized, rotating-platform TKRs, without patella resurfacing, reported to the national joint replacement registries of Norway (n = 12,033) and Australia (n = 31,522) during the years 2003–2014 (Table 1, Figure 1). The most used subtype in both countries was the non-keeled version (Norway n = 10,764, Australia n = 15,415). Some keeled components were used in Norway (n = 1,148) and Australia (n = 3,208), and Duo-fix (intended for cementless fixation and no keel) was rarely used in Norway (n = 91) and often used in Australia (n = 12,899). For control groups, the 3 most used fixed-bearing CR TKRs, without patella resurfacing, were selected in Norway (n = 19,580) and Australia (n = 48,173, Figure 1, Table 1).

Survival estimates, aseptic loosening as end-point

The 10-year K–M survival estimates with aseptic loosening as endpoint showed a lower survival rate (%) for the mobile-bearing groups compared with the fixed-bearing groups (97.2 vs. 99.6 in Norway, and 98.2 vs. 99.0 in Australia) (Table 2 and 3, Figure 2).

Risk estimates, aseptic loosening as end-point

The adjusted Cox regression analysis estimating the risk of revision for aseptic loosening showed a 6-fold increased risk for the Norwegian study group compared with the country-specific control group, and a 2-fold increased risk for the Australian study group (Table 2). The risk of revision for aseptic loosening was higher in Norway compared with Australia (RR = 1.7) (Table 2, Figure 3).
Various fixation and design results, aseptic loosening as end-point

A sub-analysis of fixation technique showed that the cemented non-keeled tibias were at a higher risk in Norway than in Australia (RR = 2.4), whereas the cementless non-keeled tibias did not show any difference between countries. However, within Australia, the cementless non-keeled tibias had a statistically significantly higher risk for aseptic loosening than the cemented tibias (RR = 1.5, CI 1.0–2.0, p = 0.03) (see Table 2). For the keeled tibias there was a short follow-up (<1 year), and Duo-fix subtypes were few (n = 91) in Norway, hence a comparison with Australian data was not justified for these subtypes. However, within Australia these subtypes had a lower survival, similar to the non-keeled subtype, in comparison with the fixed-bearing group (keeled RR = 2.0, Duo-fix RR = 2.2) (Table 2). Within Australia there were no differences in survival rates for the 3 subtypes of the rotating platform (non-keeled, keeled (RR = 1.0) and Duo-fix (RR = 1.1), using non-keeled as reference (Table 2, Figure 4).

Risk of revision for any reason as end-point

However, when comparing rotating platform with fixed bearing, using revision for any reason as a secondary end-point, the risk was higher for the rotating-platform group in both countries (Norway, RR = 1.4, Australia, RR = 1.6), and the K–M overall survival estimates were higher in the fixed-bearing TKRs (Table 4). Subdividing into age categories and sex did not markedly change the results. The overall survival (all revisions included) showed almost identical K–M survival rates (Norway: 93%, Australia: 93.5), and Cox risk estimate (RR = 1.1), between countries (Table 4).

Discussion

We found an increased risk of aseptic loosening for the most used subtypes of rotating platforms in mobile TKR. In comparison with the most used fixed-bearing knees, the rotating-platform knees had an increased overall risk of revision (revision for any reason as end-point), largely due to an increased risk of aseptic loosening regardless of fixation or variations of the under-surface or stem (keel or no keel). The difference between rotating-platform and fixed-bearing knees, in relation to aseptic loosening as the endpoint, seemed to be greater in Norway than in Australia.
relative study between Norway and a US registry (Paxton et al. 2011). In the Australian study cohort, there were a higher proportion of males, and the average age was 0.7 years lower than in the Norwegian study cohort. These differences were almost identical in the control cohorts. Due to the strict longevity and revision cause perspective of this registry study, the clinical scores and functional status of the patients were not evaluated. Previous publications and reviews have addressed this issue (Hofstede et al. 2015), and the use of patient-related outcome scores in registries, as recently established by several registries, will add important information to our findings in the future.

One would generally expect younger males to have an elevated revision rate, hence these differences were adjusted for in the Cox regression analysis (Graves 2015). However, in this study the Australian patients (younger and more males) seemed to have a lower revision rate due to aseptic loosening, compared with the Norwegian patients. Consequently, a selection bias due to age and sex was unlikely. A revision diagnosis hierarchy, developed by the AOANJRR, was used to standardize the reporting of revision causes (Graves 2015). However, different distributions of reported revision causes were found in the 2 registries, implicating different traditions with respect to reporting (Table 5). Revisions due to pain as the only reason were more commonly reported in Australia, and most of these had a minor revision with insertion of a patellar button. Patella resurfacing is rarely performed in Norway as a primary pro-

### Table 3. 10-year K–M survival data for revision due to aseptic loosening for the control groups, i.e. the 3 most common fixed bearing implants in each country

| Country Group | Subgroup (Implant type) | Tibial fixation | Total (n) | Revised for aseptic loosening (n, %) | Median follow-up (years) | K–M survival 10 years (%, 95% CI) | At risk (n) |
|---------------|-------------------------|----------------|-----------|-------------------------------------|-------------------------|----------------------------------|------------|
| Norway Control | All                     | Any            | 19,580    | 51 (3)                              | 4.6                     | 99.6 (99.4–99.8)                  | 4,127      |
|               | Profix                  | Any            | 12,611    | 27 (2)                              | 5.7                     | 99.7 (99.5–99.9)                  | 3,401      |
|               | NexGen                  | Any            | 5,347     | 11 (2)                              | 1.2                     | 99.6 (99.4–99.8)                  | 952        |
|               | AGC                     | Any            | 1,622     | 13 (6)                              | 6.6                     | 99.0 (98.4–99.6)                  | 623        |
| Australia Control | All                     | Any            | 48,173    | 195 (4)                             | 3.4                     | 99.0 (98.8–99.2)                  | 1,170      |
|               | Triathlon               | Any            | 22,333    | 68 (3)                              | 3.1                     | 99.4 (99.2–99.6)                  | 1,726      |
|               | NexGen                  | Any            | 16,609    | 76 (5)                              | 3.3                     | 99.2 (99.0–99.4)                  | 1,459      |
|               | PFC Sigma               | fixed bearing  | 9,231     | 51 (6)                              | 4.9                     | 98.9 (98.5–99.3)                  | 793        |

### Table 4. 10-year K–M survival data and relative risk (RR) estimates by Cox regression analysis adjusting for age, sex, and preoperative diagnosis for revision due to any reason

| Country Group | Implant type | Tibial fixation | Total (n) | Revised for any reason (n, %) | Median follow-up (years) | K–M survival 10 years (%, 95% CI) | At risk (n) | Cox RR1 a | Cox RR2 |
|---------------|--------------|----------------|-----------|-----------------------------|-------------------------|----------------------------------|------------|-----------|---------|
| Australia Control | Fixed bearing | Any            | 48,173    | 1,071                       | 3.4                     | 95.9 (95.5–96.3)                  | 1,170      | 1 (ref.)  | 1 (ref.) |
| Study         | Mobile bearing| Any            | 31,522    | 1,403                       | 5.4                     | 93.5 (93.1–93.9)                  | 2,723      | 1 (ref.)  | 1.6 (1.5–1.7) |
| Norway Control | All          | Any            | 19,580    | 599                         | 4.6                     | 95.5 (95.1–95.9)                  | 1,737      | 1.2 (1.1–1.4) | 1 (ref.) |
| Study         | Mobile bearing| Any            | 12,003    | 495                         | 4.1                     | 93.0 (91.6–94.4)                  | 155        | 1.1 (1.0–1.2) | 1.4 (1.2–1.6) |

* Cox regression risk estimates of Norwegian study or control group with corresponding Australian study or control group as reference

### Table 5. Number of revisions (n) by country and specified revision diagnosis, for the non-keeled mobile-bearing LCS Complete, hierarchical order from top to bottom. Values are number and percent of revisions

| Revision diagnosis | Norway n = 10,763 | Australia n = 15,415 | Total n = 26,178 |
|--------------------|--------------------|----------------------|------------------|
| Not revised        | 10,290             | 14,929               | 25,219           |
| Total number revised| 473               | 486                  | 959              |
| Infection          | 115 (24)           | 78 (16)              | 193              |
| Malalignment       | 33 (7)             | 8 (2)                | 41               |
| Loosening/lysis    | 178 (38)           | 143 (29)             | 321              |
| Instability        | 47 (10)            | 21 (4)               | 68               |
| Pain only          | 52 (11)            | 122 (25)             | 174              |
| Other reasons      | 48 (10)            | 114 (24)             | 162              |
cEDURE (2%) (Furnes 2015), thus Norwegian surgeons may be more reluctant to revise with insertion of a patellar component (Leta et al. 2016). Consequently, traditions, teaching, culture, and health care systems might have impacted the way orthopedic surgeons reported their revision diagnoses. The larger difference between mobile-bearing and fixed-bearing knees observed in Norway might have been enforced by the good results of the most used fixed-bearing knees in the Norwegian control group. Laboratory findings of a higher roughness of the tibial under-surface of the Profix knee, widely used in Norway, may indicate that this knee was more resistant to aseptic loosening than the mobile-bearing knees studied (Kutzner et al. 2016).

Previous registry studies have reported increased revision rates for mobile-bearing implants (Graves et al. 2014, Namba et al. 2014), and aseptic loosening has been suggested as the major reason for the increased risk (Gothesen et al. 2013). Rotating-platform mobile bearing was found to have a better long-term outcome than the meniscal bearing (Buechel et al. 2001), leading to a wider use of this subtype. This subtype has been the most used subtype of mobile-bearing implants in both Norway and Australia in the last decade. The mobile-bearing knee was supposed to generate fewer shear forces than the fixed-bearing knees, and less polyethylene wear and osteolysis was expected (Buechel and Pappas 1986, O’Connor and Goodfellow 1996). In vitro studies supported this theory; however, this advantage could not be demonstrated in patients (Kim et al. 2010, Moskal et al. 2014). Furthermore, the mobile-bearing knee was designed to give better functional results by improving patellar tracking and reducing anterior knee pain. None of these benefits have been demonstrated in large independent trials or follow-up studies (Hanusch et al. 2010, Lampe et al. 2011, Mahoney et al. 2012, Breugem et al. 2014). Recently, the in vitro reduction of torque forces, demonstrated when using a rotating platform, has encouraged some surgeons to use this implant in younger patients with higher impact forces, and in revision operations using constrained implants for poor bone stock (White et al. 2014). However, if it does not stop subsiding it is a predictor for loosening. Whether these implants loosen because of debonding, failure to settle into the bone, or due to osteolysis is unknown.

A registry analysis like this cannot give the exact mechanisms behind the revision causes. However, registries are able to reveal weaknesses and trends, prompting further research and laboratory testing, as well as clinical trials. The increased risk of aseptic loosening in rotating-platform tibial components (LCS Complete and PFC Sigma, non-keeled, keeled, and Duo-fix, cemented and cementless), needs to be addressed. The subgroups to benefit from this particular implant require data evidence to support its suitability. However, fixed-bearing TKR seems to be a good and safe alternative.

In summary the mobile-bearing rotating-platform TKRs, including subtypes, have an increased risk of aseptic loosening leading to revision, compared with the most used fixed-bearing TKRs in Norway and Australia. Despite different reporting traditions in the 2 countries, the increased risk of aseptic loosening was still evident. In this registry study there was no supporting evidence that choosing a mobile-bearing rotating-platform TKR for patients was beneficial. For standard patients fixed-bearing TKR is the best option.

Supplementary data
Supplementary data are available in the online version of this article, http://dx.doi.org/10.1080/17453674.2017.1378533
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