INDEPENDENT PREDICTORS OF IMPLANT FAILURE UP TO 7.5 YEARS FOLLOWING 35 386 SINGLE-BRAND CEMENTLESS HIP REPLACEMENTS
A Retrospective Cohort Study using National Joint Registry Data

Simon S Jameson, MRCS[1]

Paul Baker, MSc FRCS (Tr&Orth)[1]

James Mason, DPhil MSc BSc (Hons)[2]

Monika Rymaszewska, MRCS[3]

Paul J Gregg, FRCS Ed (Orth)[4,5]

David J Deehan, MD MSc FRCS (Tr&Orth)[6]

Mike R Reed, MD FRCS (Tr&Orth)[7]

From:

The School of Medicine and Health, Durham University, UK

[1]Research Fellow
[4]Vice Chairman
The National Joint Registry for England and Wales

[2]Professor of Health Economics
School of Medicine and Health, Durham University, Queen's Campus, University Boulevard, Stockton-on-Tees, TS17 6BH, UK

[3]Specialty Registrar, Trauma and Orthopaedics
Northern Deanery Training Programme, UK

[5]Consultant Orthopaedic Surgeon
The James Cook University Hospital, Marton Road, Middlesbrough, TS4 3BW, UK

[6]Consultant Orthopaedic Surgeon
Newcastle Hospitals NHS Foundation Trust, Freeman Road, High Heaton, Newcastle upon Tyne, NE7 7DN, UK

[7]Consultant Orthopaedic Surgeon
Northumbria Healthcare NHS Foundation Trust, Woodhorn Lane, Ashington, Northumberland, NE63 9JJ, UK

Corresponding Author:
Simon Jameson
2 Ashville Avenue, Eaglescliffe, Stockton-on-Tees, TS16 9AX, UK
Tel: +44 7812603112 / Email: simonjameson@doctors.org.uk

Abstract

The popularity of cementless total hip replacements (THR) has surpassed cemented replacements in England and Wales. This retrospective cohort study records survival time to revision following primary cementless THR with the commonest brand combination (accounting for almost a third of all cementless THRs), and explores risk factors independently associated with failure, using data from the National Joint Registry for England and Wales (NJR). Patients with osteoarthritis who had a Depuy Corail/Pinnacle THR implanted between the establishment of the registry in 2003 and 31st December 2010 were included within analyses (35,386 procedures). Cox proportional hazard models were used to analyse the extent to which risk of revision was related to patient, surgeon and implant covariates. Overall 5-year revision was 2.4%. In the final adjusted model, we found that revision risk was significantly higher in patients implanted with metal-on-metal (MoM, Hazard ratio (HR)=1.93, $p<0.001$) and ceramic-on-ceramic (CoC, HR=1.55, $p=0.003$) compared to the best performing bearing (metal-on-polyethylene). Revision risk was also greater for smaller femoral stems (sizes 8 to 10, HR=1.82, $p<0.001$) when compared to mid-range sizes. In secondary analysis of only patients where body mass index (BMI) data were available (17 166), BMI $\geq 30 kg/m^2$ significantly increased revision risk (HR 1.55, $p=0.002$). The influence of bearing on revision risk remained significant (MoM: HR=2.19, $p<0.001$, CoC: HR=2.09, $p=0.001$). Risk of revision was independent of age, gender, head size and offset, shell, liner and stem type, and surgeon characteristics. We found significant differences in implant failure between bearing surfaces and femoral component size after adjustment for a range of covariates in a large cohort of single-brand cementless THRs. In this study of procedures performed since 2003, hard bearings had significantly higher revision rates, but we found no evidence that head size had an effect. Patient characteristics, such as BMI and ASA grade, also influence survival of cementless implants.

Introduction

Cementless total hip replacements (THRs) were introduced in the 1970s in an attempt to improve implant survival in younger patients (1). Advances in implant technology and engineering capability have led to an increase in the available implant options, including cementless fixation type, head size, bearing surface material and design philosophy. Manufacturers of cementless implants currently offer varying head sizes, in an attempt to decrease risk of dislocation (2-4) and increase range of movement (5), and a range of 'hard' bearings (metal-on-metal [MoM], ceramic-on-ceramic [CoC], ceramic-on-metal [CoM]), which can reduce wear (6) and may prolong implant survival. Longevity is crucial for the younger arthroplasty patient who requires a functioning hip joint for many decades.

However, it may be incorrect to assume that all implant options perform to the expected requirements, that all patients will experience a similar benefit, or that all surgeons will have the necessary skills and experience to implant successfully. Previous registry analyses, where implants types are grouped based on fixation or brand, fail to adjust for many of these factors, and may therefore be limited in their interpretation.

Cementless implants are used in the majority of THRs in Australia (7). Although national registry data does not currently exist for the US and other large international markets, the pattern of use may be similar. In 2005, only 22% of 56 350 THRs in England and Wales were cementless. However, by 2009 their popularity surpassed cemented THR, and the trend persists (43% of 68 907 procedures in 2010, compared with 36% cemented) (8). Despite this, there remains a lack of evidence for their superiority. According to the National Joint Registry for England and Wales (NJR), the unadjusted 5-year revision for cementless implants is twice that of cemented THR (8).

The aim of this study was to explore factors that may affect the risk of revision in a national cohort of patients undergoing a single type of cementless THR, using data from the NJR (9). Each brand of implant has a range of parameters that may influence the risk of failure over time. These parameters are not all comparable across brands e.g. in the liner types used. Thus to explore the determinants of failure it was appropriate to the limit the analysis to the most common cementless brand, and in simplistic analysis the best performing (8).

Methods

Data

The NJR collects data on patients, surgeons and implants performed in the private and public sector (National Health Service, NHS) in England and Wales. According to the NJR 8th Annual Report, the commonest brand combination of cementless THR used is the Corail stem/Pinnacle cup (DePuy Ltd, Leeds, United Kingdom), accounting for 31.2% of all cementless THRs (40 879 of 130 920) since the establishment of the registry in 2003 (8). The Corail femoral stem is a fully hydroxyapatite (HA) coated non-porous forged titanium alloy stem and comprises a proximal trapezoid cross section proximally and quadrangular cross section distally, with a polished, low profile neck and a 12/14 taper ('Articul/eze'). It is available in a range of sizes (6 to 20), neck offsets (standard, 'Lateralised Coxa Vara', and 'High Offset') and can be used with or without a collar. The Pinnacle cup system comprises a 180° titanium shell with coating options including 'Porocoat' (titanium sintered beads), 'Duofix' (Porocoat with an HA coating) and 'Gription' (high friction porous surface). The shell accepts polyethylene ('Enduron' standard polyethylene or 'Marathon' highly cross-linked polyethylene), ceramic ('Biolox Delta') and metal liners ('Ultamet'). It is available in acetabular sizes 38 to 66mm and the shell comes in four varieties: solid backed '100', spiked solid back '300', the 3-hole 'Sector', and a 'Multi-hole'. Data were extracted for all Corail/Pinnacle THRs performed and submitted to the NJR until 31st December 2010 with the primary diagnosis of osteoarthritis (OA). As several options were used rarely (determined as less than 200 occasions across the study period), these were excluded from analyses. A summary of inclusion criteria is shown in Figure 1.

Covariate categories previously thought to have a influence on revision risk (patient age at time of procedure, gender, co-morbidity score, body mass index (BMI), stem size, cup shell type and coating, bearing surface materials and head size) (10-14) were included in these analyses, with American Society of Anaesthesiology (ASA) grade taken to be a surrogate for co-morbidity score. We also examined the influence of stem design, combined offset (stem+head+liner) and primary surgeon characteristics. Covariates used are summarised in Table 1.

In order for an implant to have been recorded as revised (where one implant is exchanged for another, or removed as part of a staged procedure) on the NJR dataset, a complete record of the revision procedure (including side of operation) is linked to the original index procedure by matching unique patient identifiers. A number of causes of revision can be recorded for each operation. Where multiple reasons for revision were cited, all except pain have been recorded here. Should infection or periprosthetic fracture have been recorded, these individually were taken to be the only reason. Pain was only taken as a cause when no other reason was provided. Due to multiple reporting for individual procedures, the sum of causes is greater than 100%.

Statistical analysis

Age, stem size, consultant volume were analysed as categorical data (informed by spread of the data) because of the greater clinical relevance when making group comparisons. As available head sizes differ across bearing surfaces, these were partitioned into two groups (<36mm and ≥36mm) in order to ensure all sizes and bearings were represented within the model. Bearing surface categories were initially partitioned based on head and liner combination, including presence of posterior lip and type (standard or highly cross-linked) for the polyethylene group. As the femoral offset can be adjusted according to the type of stem, head and polyethylene liner, a combination of these values (based on manufacturers figures (15, 16)) were used to calculate combined offset for each hip.

To explore the influence of covariates the most common category was generally used as the reference: for example, mid-range stem size group was used as the baseline against which all other stem size groups were compared. Similarly, for bearings, the most commonly used standard (polyethylene acetabular liner) bearing was metal-on-polyethylene (MoP). Exceptions to this were age (where the youngest group was used as the baseline), head size (where the smallest head sizes were used), combined offset (where the standard/smaller ‘plus’ offsets were used) and consultant volume (where the highest volume group was used).

A revision procedure was considered to be the ‘failure event’, where time between index procedure and revision measured joint survival. Survival times for patients who had not undergone revision were censored at the study census date (31st December 2010). Kaplan-Meier survival charts were generated to display visual differences in unadjusted covariates. The log-rank (Mantel-Cox) test was used to perform paired comparisons between each of the covariates using the pair-wise over strata method. An adjusted significance threshold is provided (Bonferroni-correction method) to account for multiple testing. Covariate categories with significant influences are presented, with life tables to describe numbers within each covariate category entering each year of the study.

Cox proportional hazard models were used to assess the extent to which the timing of revision could be explained in terms of the measured patient, surgeon and implant covariates. Results are presented as HRs with 99% confidence intervals (CI): ratios greater than one indicate that risk is higher when compared with the reference covariate category. Due to the statistical methods employed, and the large population size, only covariates fitting models with $p<0.01$ were considered significant influences, to reduce the risk of Type 1 error.

Life tables were produced to report unadjusted one-, three-, and five-year revision rates (with 99% CIs estimated using the normal approximation) for each bearing, and for all 35 386 procedures included in the study. Survival was not reported if number entering a year was less than 5% of the original total in that particular bearing group.

Results

Of 35 386 primary procedures, the majority were performed in females (20 166, 57.0%), of ASA ≤2 (31 286, 88.4%) and of 75 years or less (28 497, 80.5%); the mean age at implantation was 66 years old. There were 17 166 (48.5%) procedures with complete BMI data; of the procedures with data, the majority were less than 30kg/m^2 (10 553, 57.9%). The majority of stems used were mid-range sizes (11-13: 20 774, 58.7%) and collarless (24 404, 69.0%). The commonest cup shell was a HA-coated cluster-hole (16 071, 45.4%). The commonest single type of bearing was CoC (10 540, 29.8%); MoM accounted for 27.5% (9736) of implants, and MoP accounted for (9242, 26.1%). The majority of polyethylene bearings were highly cross-linked without a posterior lip (5876, 16.6%) and most were 28mm (10162, 28.7%) (appendix 1). Just over half of all head sizes were 36mm or larger (19 344, 54.7%) and the combined offset was between zero and 10mm in the majority (27 677, 78.2%). In total, 21463 hard bearings were used, of which 18005 (50.9%) were 36mm (appendix 1). In 79% the consultant performing the procedure completed ≥51 Corail Pinnacle THRs over the study period (27 901 procedures). Patients were under the care of 854 different consultants in 301 different surgical units and, in most cases, the consultant performed the operation (29 954, 84.6%). Demographics are shown in Table 2. There were 1690 (4.8%) procedures with greater than five completed years of follow-up.

Reasons for revision

Four hundred and forty-eight patients had undergone a revision procedure by the census date. The most common reason was dislocation (108 revisions, 24.1% of all revisions). Aseptic component loosening/lysis accounted for 94 cases (21.0%), followed by infection (69, 15.4%), malalignment (51, 11.4%) and peri-prosthetic fracture (47, 10.5%). Revision data are summarised in Table 3.

Implant revision model

In simple (univariable) analysis, the following categories influenced implant revision risk: BMI (p=0.001), bearing (p<0.001) (Figure 2), femoral stem size (p<0.001) (Figure 3) and head size (p=0.001) (Table 4). There was a trend towards ASA grade influencing revision risk (p=0.014). Type of polyethylene (standard and highly cross-linked) and presence of a posterior lip were not found to be significant influences on implant survival: these covariates were therefore merged into one common polyethylene liner category to improve model efficiency. BMI was a significant influence but was unavailable in 51.5% of procedures and, as imputation may be unreliable with large amounts of missing data, we chose to present the final adjusted model in two ways: firstly, by removing BMI from the model and presenting adjusted results for the entire population, and secondly, using only those procedures (17 166) where a valid BMI was available.

After risk adjustment for the entire study population, following removal of BMI from the model, MoM (HR=1.93, 99% CI: 1.36 to 2.73, p<0.001) and CoC (HR=1.55, 99% CI: 1.07 to 2.26, p=0.003) bearings, and small femoral stem sizes (8-10: HR=1.82, 99% CI: 1.40 to 2.37, p<0.001) were independent influences associated with revision. There was a trend towards higher revision with a large stem (≥14, HR=1.43, 99% CI: 0.98 to 2.07, p=0.014) and ASA ≥3 (HR=1.39, 99% CI 0.99 to 1.96, p=0.013). Risk of revision for ceramic-on-polyethylene (CoP) bearings was not significantly different to MoP (HR=1.33, 99% CI: 0.83 to 2.12, p=0.123) (Table 4).

After risk adjustment with BMI included (17 166 patients), bearing (p=0.001) and stem size (p=0.002) categories remained significant influences on risk of revision. ASA grade was no longer selected in the final model. Despite the smaller numbers, the influence of individual bearing types on revision risk was similar to the entire population model (MoM: HR=2.19, 99% CI: 1.29 to 3.72, p<0.001, CoC: HR=2.09, 99% CI: 1.21 to 3.63, p=0.001), validating model estimates on the larger population, without adjustment for BMI. Small femoral stem sizes remained a significant influence (HR=1.82, 95% CI: 1.40 to 2.37, p=<0.001) but the large size category was not present in the final model (Table 5). Spearman's rank correlation coefficient between ASA grade and BMI for 17 166 patients (with recorded BMI) was 0.177 (2-tailed significance of p<0.001), indicating a weakly positive correlation and possible explanation for the role of these covariates in the entire and BMI-subset models.

Risk of revision was independent of age, gender, stem design, cup shell type, head size, combined offset, operating surgeon grade and consultant volume.

Revision rates

The overall 5-year revision rate was 2.41% (99% CI 2.02 to 2.79) for the entire study population. By bearing surface, five-year revision rates were 1.36% (99% CI 0.90 to 1.83) for MoP, 1.76% (99% CI 0.99 to 2.53) for CoP, 2.05% (99% CI 1.47 to 2.62) for CoC and 3.47% (99% CI 2.63 to 4.31) for MoM (Table 6).

For patients with a valid BMI, overall 1-, 3- and 5-year results were similar to the entire population. Although risk of 5-year revision with MoP and MoM bearings was higher in patients with BMI ≥30kg/m^2 (BMI <30kg/m^2: MoP 0.85%, MoM 3.70%, BMI ≥30kg/m^2: MoP 1.61%, MoM 5.01%), CIs were wide because of small numbers (Table 7).

Discussion

This retrospective cohort study provides the largest, in-depth analysis of a single brand combination of cementless THRs to date. Significantly greater revision rates following THR were independently associated with hard bearings (MoM, CoC) and small femoral stem sizes (sizes 8-10), after risk adjustment. These findings are clinically important as they identify modifiable parameters in the control of the operating surgeon. BMI was also a significant predictor of revision in those procedures with valid data. Other implant factors, including head size, did not significantly influence revision in this analysis.

Whilst this study reports a large, single brand combination analysis, we accept that there are limitations in its interpretation. The revision rates described in this study are limited to short-term data only (with a maximum follow-up of 7.5 years). The relative rates at which particular implants require revision may change with further follow-up. Revision is taken as a surrogate marker of implant failure, as other endpoints are unavailable in this dataset. This does not take into account patients living with a painful hip, or those awaiting revision at the time of censoring (17). Nor does it take into account any functional benefit (if any) of different implant components. Incomplete BMI data might lead to confounded findings when BMI is excluded from models, but sensitivity analyses including and excluding BMI provide similar findings. There was a weak positive correlation between ASA grade and BMI, which may explain the presence of ASA grade in the final, entire population model (when BMI was excluded). The study design is observational and thus vulnerable to omitted variables, which may have confounded our findings. For example, we lack radiographic data, which could potentially explain some early failures. However, similarities between the unadjusted and adjusted models, robustness under different model fitting assumptions, and time independence support the stability of estimates.

All MoM hip replacement bearings are currently of concern and, despite the large numbers implanted and the cost involved, the Medicines and Healthcare products Regulatory Agency (MHRA) have recently recommended yearly follow-up in all of these patients (18). After performing a systematic review of the literature on hip implant bearings, Sedrakyan at al found that MoM bearings provided no superiority in outcome scores in comparison studies with MoP bearings, but were associated with significantly higher risk of revision (after risk adjusting) in over 720 000 hip replacements drawn from registry data world-wide (19). An in-depth analysis of NJR data by Smith et al supports these poorer findings with MoM of all head sizes (20). Given the reports from independent centres and the risks associated with MoM bearings (metal ion levels, excessive bearing and taper wear, soft tissue destruction, possible systemic complications) (21), combined with the poorer survival reported here from the commonest cementless hip system combination used in England and Wales, we question the role of these bearings in modern hip arthroplasty.

Ceramic-on-ceramic bearings have previously been shown to have higher revision rates due to dislocation when compared with MoP in over 100 000 THRs from the Australian registry (22). Despite significantly poorer survival when compared with MoP in the mid-term analysis presented here, CoC bearings may ultimately provide greater longevity, without the concerns associated with MoM. Therefore, CoC may have a role in younger patients, but longer-term data is required.

CoM bearings have only been available for a short time and numbers are small; it is important to note that although the hazard ratio for the CoM group was consistent with the other hard bearings, there were no significant differences when compared with MoP due to the wide confidence intervals. As CoM is thought to offer some benefits over MoM, we felt the inclusion of this bearing was important (despite the limited data available).

CoP bearings did not significantly influence revision risk compared to MoP. Whilst the 5-year revision rate for the entire group of Corail/Pinnacle THRs was 2.41% in this study, MoP bearings reduced the revision rate to only 1.36%. Of note, the 5-year all-cause revision rate following the commonest cemented THR (Exeter V40 stem/Contemporary cup, Stryker Howmedica International, London, United Kingdom, 37 995 procedures) is 0.92%, according to the NJR 8th Annual Report (8). Bearings, rather than fixation method, may explain much of the differences in revision rates across registry data.

The influence of femoral stem size may result from inadequate press-fit or poor bone quality but, without more data, our study cannot explain this fully. While it may be difficult to assess preoperatively, patients requiring smaller Corail stems may be less suitable for cementless implants. A trend towards higher revision in very large implants was also seen, but disappeared when BMI was included in the model, suggesting it may be high BMI rather than large stem size which is associated with failure. The finding of higher revision in patients with a BMI over 30kg/m^2 is logical and an important one, given an apparent year-on-year increase in average BMI values within the arthroplasty population (8). It should also be considered as an important covariate in future similar analyses, and further effort should be made to increase BMI data compliance when collecting joint registry data.

Risk of revision was independent of age and gender, despite the previous reports of poorer outcomes in young, male patients after THR (10). Although head size has been found to influence implant revision across a range of implants (20), we failed to find an association in this analysis. Type of polyethylene (standard or highly cross-linked) did not influence revision risk in standard bearings, but longer-term analyses are needed. Although we did not find surgical volume to influence the risk of revision, there are limitations associated with this analysis; a surgeon's volume prior to the study period is unknown and their use of other types of hip replacement performed over the same period was not analysed (a high volume hip surgeon performing a small number of Corail/Pinnacle THRs may potentially be more successful than an occasional hip surgeon performing solely Corail/Pinnacles).

The commonest primary reason for revision was dislocation (24.1%); infection accounted for only 15.4% of revisions. As expected with mid-term data, the number of implants revised for aseptic loosening/lysis (20.0%) was low. The quality of recording of reasons for revision should be improved to consistently list primary and secondary causes; currently multiple causes of failure may be described, without any clear primary cause being identified. In-depth scrutiny of high-risk subsets is needed, and prospective studies of cause of revision combined with explant analysis will be of benefit.

In summary, bearing surfaces, femoral component sizes and patient BMI influenced implant survival in a large cohort of single-brand cementless THRs. Hard bearings had significantly higher revision rates. This study demonstrates that multiple factors can influence revision risk; registry data analyses may mislead if they fail to adjust for all relevant covariates when comparing across brands and types. For surgeons using cementless THR, this data may help guide their practice. Findings may also provide a useful reference for comparison with future analyses comparing implant types.

Word count: 3778

Acknowledgements

We thank the patients and staff of all the hospitals in England and Wales who have contributed data to the National Joint Registry. We are grateful to the Healthcare Quality Improvement Partnership (HQIP), the NJR steering committee and the staff at the NJR centre for facilitating this work.

Conflict of Interests Statement

The National Joint Registry for England and Wales is funded through a levy raised on the sale of hip and knee replacement implants. The cost of the levy is set by the NJR Steering Committee. The NJR Steering Committee is responsible for data collection. This work was funded by a fellowship from the National Joint Registry. The authors have conformed to the NJR's standard protocol for data access and publication. The views expressed represent those of the authors and do not necessarily reflect those of the National Joint Register Steering committee or the Health Quality Improvement Partnership (HQIP) who do not vouch for how the information is presented.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References

1. Charnley J, Cupic Z. The nine and ten year results of the low-friction arthroplasty of the hip. Clin Orthop Relat Res. 1973 Sep(95):9-25.
2. Jameson SS, Lees D, James P, Serrano-Pedraza I, Partington PF, Muller SD, et al. Lower rates of dislocation with increased femoral head size after primary total hip replacement: a five-year analysis of NHS patients in England. J Bone Joint Surg Br. 2011 Jul;93(7):876-80.
3. Berry DJ, von Knoch M, Schleck CD, Harmsen WS. Effect of femoral head diameter and operative approach on risk of dislocation after primary total hip arthroplasty. J Bone Joint Surg Am. 2005 Nov;87(11):2456-63.
4. Bystrom S, Espehaug B, Furnes O, Havelin LI. Femoral head size is a risk factor for total hip luxation: a study of 42,987 primary hip arthroplasties from the Norwegian Arthroplasty Register. Acta Orthop Scand. 2003 Oct;74(5):514-24.
5. Chandler DR, Glousman R, Hull D, McGuire PJ, Kim IS, Clarke IC, et al. Prosthetic hip range of motion and impingement. The effects of head and neck geometry. Clin Orthop Relat Res. 1982 Jun(166):284-91.
6. Santavirta S, Bohler M, Harris WH, Konttinen YT, Lappalainen R, Muratoglu O, et al. Alternative materials to improve total hip replacement tribology. Acta Orthop Scand. 2003 Aug;74(4):380-8.
7. Australian-National-Joint-Registry. Annual Report. 2011.
8. National-Joint-Registry. National Joint Registry for England and Wales 8th Annual Report. 2011.
9. National-Joint-Registry. 2011 [29/10/2011]; Available from: http://www.njrcentre.org.uk/njrcentre/default.aspx.
10. Roder C, Bach B, Berry DJ, Eggli S, Langenhahn R, Busato A. Obesity, age, sex, diagnosis, and fixation mode differently affect early cup failure in total hip arthroplasty: a matched case-control study of 4420 patients. J Bone Joint Surg Am. 2010 Aug 18;92(10):1954-63.
11. Hallan G, Lie SA, Havelin LI. High wear rates and extensive osteolysis in 3 types of uncemented total hip arthroplasty: a review of the PCA, the Harris Galante and the Profile/Tri-Lock Plus arthroplasties with a minimum of 12 years median follow-up in 96 hips. Acta Orthop. 2006 Aug;77(4):575-84.
12. Howard JL, Kremers HM, Loechler YA, Schleck CD, Harmsen WS, Berry DJ, et al. Comparative survival of uncemented acetabular components following primary total hip arthroplasty. J Bone Joint Surg Am. 2011 Sep 7;93(17):1597-604.
13. Stilling M, Rahbek O, Soballe K. Inferior survival of hydroxyapatite versus titanium-coated cups at 15 years. Clin Orthop Relat Res. 2009 Nov;467(11):2872-9.
14. Johnsen SP, Sorensen HT, Lucht U, Soballe K, Overgaard S, Pedersen AB. Patient-related predictors of implant failure after primary total hip replacement in the initial, short- and long-terms. A nationwide Danish follow-up study including 36,984 patients. J Bone Joint Surg Br. 2006 Oct;88(10):1303-8.
15. Depuy-Orthopaedics-Ltd. Corail Surgical Technique. 2011 [23/03/2012]; Available from: http://www.depuy.com/sites/default/files/products/files/0612-82-501r5%20SCRN%20(2)_0.pdf.
16. Depuy-Orthopaedics-Ltd. Pinnacle Acetabular System Surgical Technique. 2011.
17. Wylde V, Blom AW. The failure of survivorship. J Bone Joint Surg Br. 2011 May;93(5):569-70.
18. Medicines-and-Healthcare-products-Regulatory-Agency. Medical Device Alert: All metal-on-metal (MoM) hip replacements (MDA/2012/008). 2011 [21/03/2012]; Available

from:
http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON143782.
19. Sedrakyan A, Normand SL, Dabic S, Jacobs S, Graves S, Marinac-Dabic D. Comparative assessment of implantable hip devices with different bearing surfaces: systematic appraisal of evidence. BMJ. 2011;343:d7434.
20. Smith AJ, Dieppe P, Vernon K, Porter M, Blom AW. Failure rates of stemmed metal-on-metal hip replacements: analysis of data from the National Joint Registry of England and Wales. Lancet. 2012 Mar 12.
21. Haddad FS, Thakrar RR, Hart AJ, Skinner JA, Nargol AV, Nolan JF, et al. Metal-on-metal bearings: the evidence so far. J Bone Joint Surg Br. 2011 May;93(5):572-9.
22. Sexton SA, Walter WL, Jackson MP, De Steiger R, Stanford T. Ceramic-on-ceramic bearing surface and risk of revision due to dislocation after primary total hip replacement. J Bone Joint Surg Br. 2009 Nov;91(11):1448-53.

Figure 1. Flow chart describing the inclusion criteria for this study

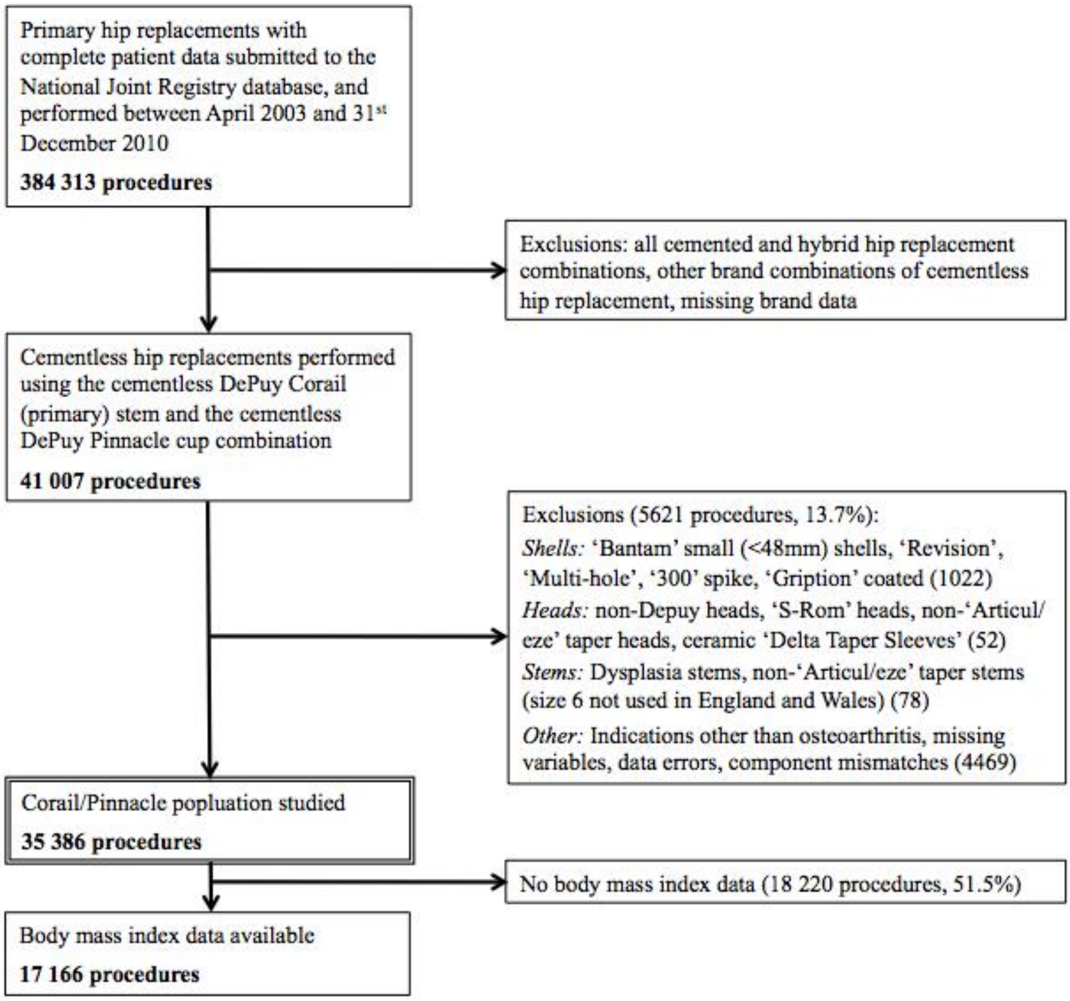
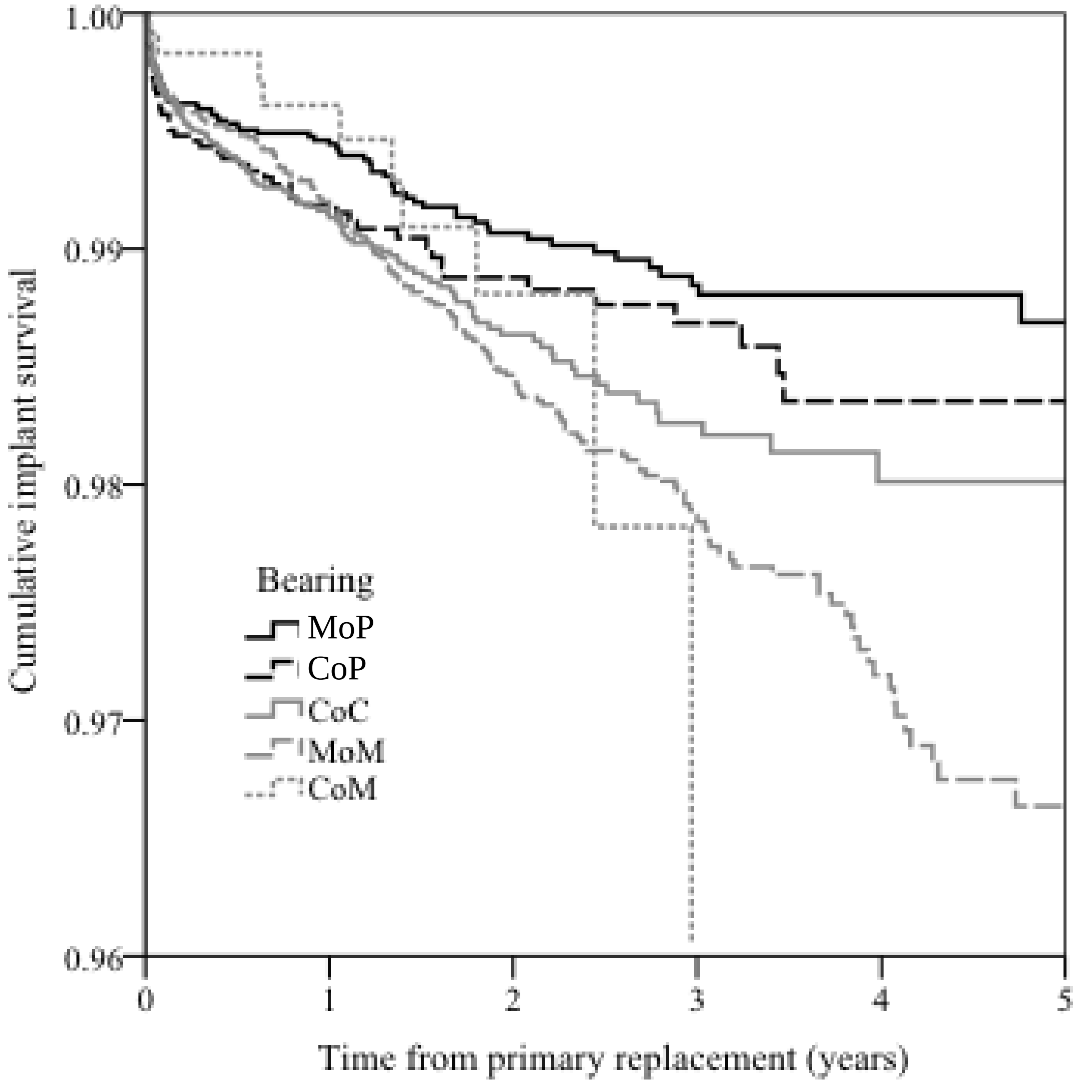


Figure 2. Kaplan Meier: unadjusted cumulative implant survival of Corail Pinnacle cementless hip replacements by bearing
(MoP – metal-on-polyethylene, CoP - ceramic-on-polyethylene, CoC – ceramic-on-ceramic, MoM – metal-on-metal, CoM – ceramic-on-metal, England and Wales, 2003-2010)



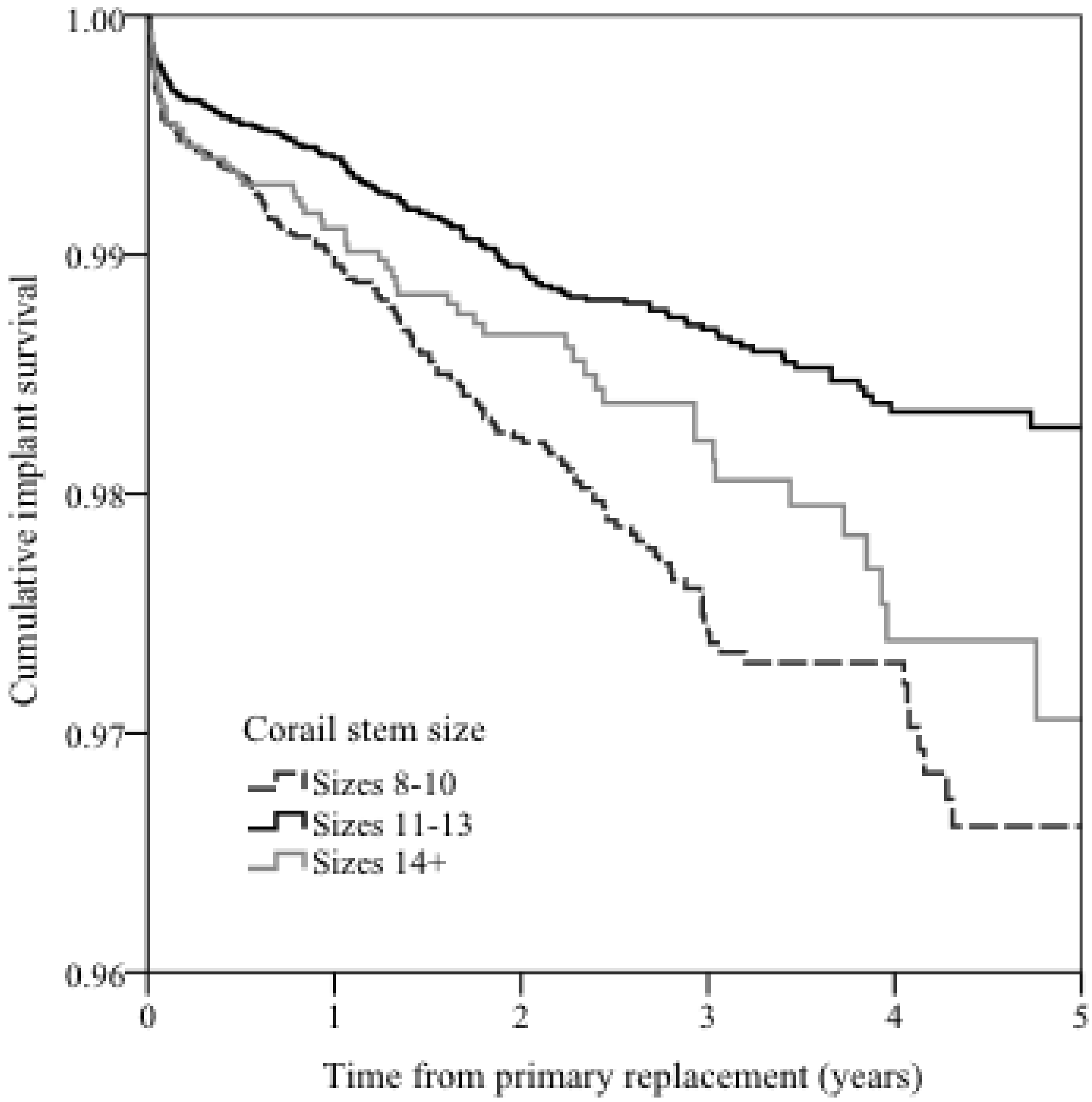
Life table showing numbers at risk in each year

Brand	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
MoP	9242	6211	4066	2513	1489	640
CoP	4681	3077	1938	1148	520	167
CoC	10540	6587	3816	1877	772	289
MoM	9736	8689	6370	3781	1733	592
CoM	1187	711	238	28	8	2

Log rank (Mantel-Cox)	MoP	CoP	CoC	CoM	MoM
MoP (p-value)	-	0.160	0.006	0.321	<0.001
CoP	0.160	-	0.398	0.800	0.024
CoC	0.006	0.398	-	0.819	0.101
CoM	0.321	0.800	0.819	-	0.685
MoM	<0.001	0.024	0.101	0.685	-

Bonferroni-corrected significance threshold p=0.001

Figure 3. Kaplan Meier: unadjusted cumulative implant survival of Corail Pinnacle cementless hip replacements by Corail stem size
(England and Wales, 2003-2010)



Life table showing numbers at risk each year

Femoral size	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
8-10	10229	7221	4616	2532	1133	431
11-13	20897	14976	9771	5613	2769	1043
≥14	4260	3078	2041	1202	620	216

Log rank (Mantel-Cox)	Sizes 8-10	Sizes 11-13	Sizes ≥14
Sizes 8-10 (p-value)	-	<0.001	0.132
Sizes 11-13	<0.001	-	0.011
Sizes ≥14	0.132	0.011	-

Bonferroni-corrected significance threshold p=0.003

Table 1. Covariates used in the event analyses

Category	Variable type	Covariate
Age	Ordinal	≤60 years 61-75 ≥76
Gender	Binary	Female Male
ASA grade	Ordinal	Grade 1/2 Grade ≥3
Body mass index	Ordinal	$<30kg/m^2$ $\geq30kg/m^2$
Stem size	Ordinal	8-10 11-13 ≥14
Stem design	Nominal	Collarless Collared
Cup shell type	Nominal	Solid HA coated Solid, non-HA Cluster-hole HA Cluster-hole, non-HA
Bearing	Nominal	Metal-on-PE Metal-on-PE, posterior lip Metal-on-XLPE Metal-on-XLPE, posterior lip Ceramic-on-PE Ceramic on-PE, posterior lip Ceramic-on-XLPE Ceramic on-XLPE, posterior lip Ceramic-on-ceramic Ceramic-on-metal Metal-on-metal
Head size	Ordinal	28/32mm ≥36mm
Combined offset	Ordinal	Low (0-4mm) Medium (5-10mm) High (≥11mm) Minus
Primary surgeon	Binary	Consultant Other
Consultant volume	Ordinal	Low (≤50 cases throughout study period) Medium (51-300) High (≥301)

ASA – American Society of Anaesthesiologists, BMI – body mass index, kg – kilogram, m – metre, mm – millimetre, HA – hydroxyapatite, PE - standard polyethylene, XLPE – highly cross-linked polyethylene

Table 2. Demographics of Corail Pinnacle cementless hip replacement patients (England and Wales, 2003-2010)

	n=35 386	
Age, mean years (SD)	66.3	(10.0)
≤60, n (%)	8835	(25.0)
61-75	19 662	(55.6)
≥76	6889	(19.5)
Gender		
Female	20 166	(57.0)
Male	15 220	(43.0)
ASA grade		
1/2	31 286	(88.4)
≥3	4100	(11.6)
Body mass index, mean kg/m^2 (SD)	28.8	(5.3)*
<30kg/m^2, n (%)	10 553	(29.8)
≥30kg/m^2	6613	(18.7)
No data	18 220	(51.5)
Stem size		
8-10	10 168	(28.7)
11-13	20 774	(58.7)
≥14	4444	(12.6)
Stem design		
Collarless	24 404	(69.0)
Collared	10 982	(31.0)
Cup shell type		
Solid HA coated	7496	(21.2)
Solid, non-HA	2805	(7.9)
Cluster-hole HA	16 071	(45.4)
Cluster-hole, non-HA	9014	(25.5)
Bearing		
Metal-on-polyethylene (all)	9242	(26.1)
Standard polyethylene	*3892*	*(11.0)*
Standard lipped polyethylene	*453*	*(1.3)*
XL polyethylene	*4198*	*(11.9)*
XL lipped polyethylene	*699*	*(2.0)*
Ceramic-on-polyethylene (all)	4681	(13.2)
Standard polyethylene	*1742*	*(4.9)*
Standard lipped polyethylene	*406*	*(1.1)*
XL polyethylene	*1678*	*(4.7)*
XL lipped polyethylene	*855*	*(2.4)*
Ceramic-on-ceramic	10 540	(29.8)
Ceramic-on-metal	1187	(3.4) 9736
Metal-on-metal	(27.5)	
Head size		
28/32mm	16 042	(45.3)
≥36mm	19 344	(54.7)
Combined offset category		
Low (0-4mm)	11 770	(33.2)
Medium (5-10mm)	15 907	(45.0)
High (≥11mm)	5977	(16.9)
Minus	1732	(4.9)
Primary surgeon		
Consultant	29 954	(84.6)
Other	5432	(15.4)
Number of consultants (n)	854	
Consultant volume		
Mean volume (range), SD	242 (1 to 1208), 275	
Low (≤50 cases over study period)	7485	(21.2)

Medium (51-300)	17 902	(50.6)
High (≥301)	9999	(28.3)
Number of surgical units (n)	301	

SD – standard deviation, * - based on 17 166 patients, HA – hydroxyapatite, XL – highly cross-linked

Table 3. Reason recorded for revision following Corail Pinnacle cementless hip replacement (England and Wales, 2003-2010)

	Revision (n=448)
Dislocation, n (%)	108 (24.1)
All aseptic component loosening/lysis	94 (21.0)
Stem only	*64 (14.3)*
Cup only	*20 (4.5)*
Both	*10 (2.2)*
Infection	69 (15.4)
All malalignments	51 (11.4)
Stem only	*20 (4.5)*
Cup only	*28 (6.3)*
Both	*3 (0.7)*
Periprosthetic stem fracture	47 (10.5)
Soft tissue reaction / ‘Metallosis’	31 (6.9)
Unexplained pain	22 (4.9)
All implant fractures	20 (4.5)
Stem only	*7 (1.6)*
Cup only	*13 (2.9)*
Dissociation of liner	10 (2.2)
Liner wear	5 (1.1)
‘Stem subsidence’	3 (0.7)
Other	28 (6.3)

Table 4. Independent predictors of revision following entire series of 35 386 cementless Corail Pinnacle hip replacements: simple and multi-variable Cox regressions (Body mass index excluded, England and Wales, 2003-2010)

Covariate	**Simple analysis**			**Multi-variable analysis**		
	HR	**99% CI**	**P value**	**HR**	**99% CI**	**P value**
Gender						
Female	-					
Male	1.03	0.81-1.32	0.725			
Age						
Category			0.796			
≤60	-					
61-75	0.94	0.70-1.25	0.553			
≥76	0.92	0.63-1.33	0.559			
ASA grade						
1/2	-			-		
≥3	1.38	0.98-1.94	0.014	1.39	0.99-1.96	0.013
Stem size						
Category			<0.001			<0.001
8-10	1.79	1.38-2.33	<0.001	1.82	1.40-2.37	<0.001
11-13	-			-		
≥14	1.44	0.99-2.09	0.012	1.43	0.98-2.07	0.014
Stem design						
Collarless	-					
Collared	1.05	0.80-1.37	0.670			
Cup shell type						
Category			0.354			
Solid, HA coated	0.82	0.59-1.15	0.128			
Solid, non-HA	1.10	0.69-1.75	0.591			
Cluster, HA coated	-					
Cluster, non-HA	0.92	0.68-1.24	0.447			
Bearing						
Category			<0.001			<0.001
Metal-on-poly.	-			-		
Ceramic-on-poly.	1.32	0.82-2.11	0.135	1.33	0.83-2.12	0.123
Ceramic-on-ceramic	1.54	1.06-2.25	0.003	1.55	1.07-2.26	0.003
Ceramic-on-metal	1.47	0.64-3.37	0.237	1.45	0.63-3.33	0.253
Metal-on-metal	1.92	1.36-2.72	<0.001	1.93	1.36-2.73	<0.001
Head size						
28/32mm	-					
≥36mm	1.38	1.07-1.77	0.001			
Combined offset						
Category			0.352			
Low	-					
Medium	1.05	0.79-1.40	0.639			
High	1.23	0.86-1.76	0.136			
Minus	1.30	0.76-2.21	0.213			
Operator						
Consultant	-					
Other	0.84	0.59-1.20	0.206			
Consultant volume						
Category			0.230			
Low (≤50)	1.02	0.73-1.43	0.869			
Medium (51-300)	0.86	0.65-1.13	0.152			
High (≥301)	-					

HR – hazards ratio, CI – confidence intervals, ASA – American Society of Anaesthesiologists, HA – hydroxyapatite,

Table 5. Independent predictors of revision following cementless Corail Pinnacle hip replacements based on 17 166 patients with valid Body Mass Index data: simple and multi-variable Cox regressions (England and Wales, 2003-2010)

Covariate	Simple analysis			Multi-variable analysis*		
	HR	99% CI	P value	HR	99% CI	P value
Gender						
Female	-					
Male	1.03	0.81-1.32	0.725			
Age						
Category			0.796			
≤60	-					
61-75	0.94	0.70-1.25	0.553			
≥76	0.92	0.63-1.33	0.559			
ASA grade						
1/2	-					
≥3	1.38	0.98-1.94	0.014			
Body mass index						
<30kg/m^2	-			-		
≥30kg/m^2	1.58	1.11-2.26	0.001	1.55	1.08-2.22	0.002
Stem size						
Category			<0.001			0.002
8-10	1.79	1.38-2.33	<0.001	1.70	1.16-2.51	<0.001
11-13	-			-		
≥14	1.44	0.99-2.09	0.012	1.44	0.83-2.49	0.092
Stem design						
Collarless	-					
Collared	1.05	0.80-1.37	0.670			
Cup shell type						
Category			0.354			
Solid, HA coated	0.82	0.59-1.15	0.128			
Solid, non-HA	1.10	0.69-1.75	0.591			
Cluster, HA coated	-					
Cluster, non-HA	0.92	0.68-1.24	0.447			
Bearing						
Category			<0.001			0.001
Metal-on-poly.	-			-		
Ceramic-on-poly.	1.32	0.82-2.11	0.135	1.36	0.69-2.68	0.242
Ceramic-on-ceramic	1.54	1.06-2.25	0.003	2.09	1.21-3.63	0.001
Ceramic-on-metal	1.47	0.64-3.37	0.237	1.31	0.45-3.83	0.514
Metal-on-metal	1.92	1.36-2.72	<0.001	2.19	1.29-3.72	<0.001
Head size						
28/32mm	-					
≥36mm	1.38	1.07-1.77	0.001			
Combined offset						
Category			0.352			
Low	-					
Medium	1.05	0.79-1.40	0.639			
High	1.23	0.86-1.76	0.136			
Minus	1.30	0.76-2.21	0.213			
Operator						
Consultant	-					
Other	0.84	0.59-1.20	0.206			
Consultant volume						
Category			0.230			
Low (≤50)	1.02	0.73-1.43	0.869			
Medium (51-300)	0.86	0.65-1.13	0.152			
High (≥301)	-					

HR – hazards ratio, CI – confidence intervals, ASA – American Society of Anaesthesiologists, HA – hydroxyapatite

Table 6. Revision rates following entire series of Corail Pinnacle hip replacements by bearing, and overall (99% confidence intervals) (England and Wales, 2003-2010)

	Revision rates by bearing					**Overall revision rates**
	MoP	**CoP**	**CoC**	**CoM**	**MoM**	
1-year	0.61% (0.38-0.83)	0.90% (0.51-1.29)	0.93% (0.66-1.20)	0.42% (0.00-0.96)	0.82% (0.58-1.06)	0.79% (0.66-0.93)
3-year	1.22% (0.84-1.60)	1.41% (0.85-1.97)	1.82% (1.35-2.29)	3.46% (0.01-6.91)	2.17% (1.72-2.61)	1.77% (1.53-2.01)
5-year	1.36% (0.90-1.83)	1.76% (0.99-2.53)	2.05% (1.47-2.62)	-	3.47% (2.63-4.31)	2.41% (2.02-2.79)
Total number	9242	4681	10540	1187	9736	35386

MoP – metal-on-polyethylene, CoP – ceramic-on-polyethylene, CoC – ceramic-on-ceramic, CoM – ceramic-on-metal, MoM – metal-on-metal

Table 7. Revision rates following Corail Pinnacle by bearing in patients with body mass index (BMI) data (17 166 patients), and overall
(99% confidence intervals, England and Wales, 2003-2010)

	Revision rates by bearing					**Overall revision rates**
	MoP	**CoP**	**CoC**	**CoM**	**MoM**	
1-year						
All	**0.63% (0.30-0.97)**	**0.86% (0.34-1.38)**	**1.33% (0.84-1.82)**	**0.29% (0.00-0.83)**	**0.95% (0.55-1.35)**	**0.92% (0.71-1.13)**
BMI <30kg/m²	*0.50% (0.13-0.88)*	*0.84% (0.19-1.49)*	*1.00% (0.45-1.54)*	*0.23% (0.00-0.83)*	*0.76% (0.30-1.22)*	*0.73% (0.50-0.97)*
BMI≥30kg/m²	*0.86% (0.22-1.49)*	*0.90% (0.03-1.77)*	*1.84% (0.94-2.75)*	*0.40% (0.00-1.42)*	*1.25% (0.52-1.99)*	*1.22% (0.83-1.60)*
3-year						
All	**1.13% (0.60-1.66)**	**1.59% (0.68-2.50)**	**2.27% (1.35-3.19)**	**3.29% (0.00-7.39)**	**2.61% (1.77-3.46)**	**2.03% (1.61-2.44)**
BMI <30kg/m²	*0.85% (0.25-1.45)*	*1.58% (0.39-2.78)*	*1.75% (0.65-2.85)*	*2.82% (0.00-7.47)*	*2.19% (1.24-3.13)*	*1.66% (1.18-2.14)*
BMI≥30kg/m²	*1.61% (0.60-2.62)*	*1.58% (0.25-2.92)*	*3.06% (1.47-4.65)*	*4.11% (0.0-11.91)*	*3.34% (1.73-4.95)*	*2.63% (1.85-3.40)*
5-year						
All	**1.13% (0.60-1.66)**	**1.59% (0.68-2.50)**	-	-	**4.17% (2.32-6.02)**	**2.68% (1.91-3.45)**
BMI <30kg/m²	*0.85% (0.25-1.45)*	*1.58% (0.39-2.78)*			*3.70% (1.60-5.80)*	*2.25% (1.37-3.13)*
BMI≥30kg/m²	*1.61% (0.60-2.62)*	*1.58% (0.25-2.92)*			*5.01% (1.38-8.64)*	*3.41% (1.92-4.89)*
Total number	4763	2612	4827	836	4128	17 166

MoP – metal-on-polyethylene, CoP – ceramic-on-polyethylene, CoC – ceramic-on-ceramic, CoM – ceramic-on-metal, MoM – metal-on-metal

Supplementary material

When treated as continuous covariates both age (HR=1.00, 99% CI 0.99 to 1.01, p=0.543) and consultant volume (HR=1.00, 99% CI 0.99 to 1.00, p=0.232) were not significant influences on univariable analysis.

In order to improve efficiency of the final statistical models, where no differences were found within subcategories (e.g. different polyethylene liners) during preliminary modelling, a decision was taken to combine these. The reliability of the models was explored by alternative stepwise procedures using the likelihood ratio test. Covariates found not to be statistically significant were excluded from the model, based on statistical entry ($p<0.05$) and rejection ($p>0.10$) criteria. The same covariates were fitted forward and reverse stepwise to ensure findings were not qualitatively affected in the final model, with any inconsistency reported. The final model was re-evaluated as a directly entered model (non-stepwise) to provide unconditional estimates, and was assessed by exploring 2-way interactions between covariates and for the constant proportionality over time assumption. In addition, baseline entry and rejection criteria for the model were reduced to $p<0.01$ and $p>0.05$ respectively to test covariate selection within the model. All models were fitted using SPSS version 19.0 (SPSS Inc, IBM Corporation, Armonk, New York).

Tests for interaction (multiplicative) between covariates and for time-dependency were not statistically significant. Forward and reverse stepwise model construction and varying significance thresholds led to the same final model when BMI was included. When BMI was removed from the analysis, forward stepwise construction (but not backward) failed to select ASA grade when thresholds for inclusion were reduced.

Spearman's rank correlation coefficient was calculated for ASA and BMI in order to explain the role of these covariates in the entire model and the BMI-subset model.

Appendix 1. Breakdown of Corail/Pinnacle THRs used, by bearing and head size (England and Wales, 2003-2010)

	Usage, n (%)					*Overall*
	MoP	**CoP**	**CoC**	**CoM**	**MoM**	
28mm	7242 (20.5)	2920 (8.3)	2042 (5.8)	43 (0.1)	359 (1.0)	12606 (35.6)
32mm	1520 (4.3)	1212 (3.4)	704 (2.0)	0	0	3436 (9.7)
36mm	472 (1.3)	544 (1.5)	7794 (22.0)	1144 (3.2)	9067 (25.6)	19021 (53.8)
40mm	7 (0.0)	3 (0.0)	0	0	269 (0.8)	279 (0.8)
44mm	1 (0.0)	2 (0.0)	0	0	41 (0.1)	44 (0.1)
Total number	9242 (26.1)	4681 (13.2)	10540 (29.8)	1187 (3.4)	9736 (27.5)	35386

MoP – metal-on-polyethylene, CoP – ceramic-on-polyethylene, CoC – ceramic-on-ceramic, CoM – ceramic-on-metal, MoM – metal-on-metal, BMI – body mass index