**FACTORS INFLUENCING REVISION RISK FOLLOWING 15,740 SINGLE-BRAND HYBRID HIP REPLACEMENTS**
**A Retrospective Cohort Study from a National Joint Registry**


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**Abstract**

*This retrospective cohort study of a National Joint Registry data examines survival time to revision following the commonest brand of primary hybrid THR, exploring risk factors independently associated with failure. Overall 5-year revision was 1.56%. In the final adjusted model, revision risk was significantly higher with standard polyethylene (PE) liners (metal-on-PE: hazard ratio (HR)=2.52, p=0.005, ceramic-on-PE: HR=2.99, p=0.025) when compared to metal-on-highly-cross-linked (XL) PE. Risk of revision with ceramic-on-ceramic bearings was borderline significant (HR=1.86, p=0.061). A significant interaction between age and acetabular shell type (solid or multi-hole) was found (p=0.022), suggesting that solid shells performed significantly better in younger patients. In summary, we found there were significant differences in implant failure between different bearing surfaces and shell types after adjusting for a range of covariates.*

Running title: Factors influencing revision risk following 15,740 single-brand hybrid hip replacements

Key words: hybrid total hip replacement, bearings, revision, acetabular shell

## Introduction

Primary cemented total hip replacement (THR) has good medium- to long-term implant survival across national joint registries and meta-analyses globally (1-8). However, for younger patients with higher demands, a cemented polyethylene cup may fail at a greater rate, and may not provide sufficient longevity. Hybrid THRs, where a cemented stem is coupled with a cementless cup, may an attractive option in these patients. Cementless modular acetabular components allow the use of a range of bearing surfaces in combination with larger head sizes. When these implants were examined in patients under 70 years in England and Wales, the National Joint Registry (NJR) found that hybrid THRs had equivalent 5-year revision rates when compared to cemented implants, and superior revision rates when compared to cementless implants in females (7). In addition, Australian registry data for patients aged 50 to 64 years has demonstrated superior results with hybrid implants compared to both cemented and cementless implants (8). In 2010, 16% of 68 907 THRs in England and Wales were hybrid procedures (7).

National registry data allows independent analyses of large volumes of procedures over an entire population. However, there are limitations to these analyses. Despite the numerous implant options and materials used, many registries analyse implants using simple discriminators, such as fixation type, when in reality no two brands of implants are alike, and assumptions of similarity may be misplaced.

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 combination of hybrid 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. acetabular shell type.

Thus, to explore the determinants of failure it was appropriate to the limit the analysis to the most common hybrid brand combination recorded on the NJR (7).

## Materials and methods

### *Design*

A retrospective cohort study was conducted to assess patient level NJR data for survival time to revision for the commonest brand of primary hybrid THR.

### *Data*

The NJR has assimilated data on patients, surgeons and implants performed in both the private and public sector (National Health Service, NHS) in England and Wales since 2003. According to the NJR 8th Annual Report, the commonest brand combination of hybrid THR used in England and Wales since 2003 features the Stryker Exeter V40 hip and Trident socket (Stryker Orthopaedics, Mahwah, New Jersey, United States), accounting for 33.0% of all hybrid THRs (18 358 of 55 551) (7). The Exeter V40 femoral stem is a polished, double tapered, collarless stainless steel design with a 'V40' taper and a hollow distal centraliser to allow subsidence for compressive loading throughout the cement mantle. It is available in a range of stem widths (0 to 5), offsets (30mm to 56mm) and lengths (short: 104 to 134mm, standard: 158mm, and 'long stem' options: 200mm to 260mm). The Trident Acetabular System is an uncemented modular cup manufactured from hydroxyapatite (HA) coated porous titanium (non-HA coated Trident cups are not available in the United Kingdom). Liner options include standard polyethylene (PE), highly cross-linked (XL) PE (first generation: 'Crossfire', and second generation: 'X3'), alumina ceramic, and constrained. The shells are available as a press-fit no-hole ('Solid-back') type, or in multi-hole ('5-hole', 'Cluster-hole (3-hole)' and 'Multi-hole') form, allowing supplementary fixation with acetabular screws. Two types of shell geometry are manufactured: 'Hemispherical' and Peripheral self-locking' (PSL, or rim-fitting). Femoral heads are available in stainless steel ('Orthinox': 22, 26, 28, 30, 32, and 36mm), cobalt-chrome ('Vitallium': 28, 32, 36, 40, and

44mm) and ceramic (‘Alumina’ 28, 32, and 36mm). Three brands of cement have been used with these components: ‘Palacos’ (three manufacturers: Heraeus Holding GmbH, Hanau, Germany; Schering-Plough Corporation, Kenilworth, New Jersey, USA; Biomet Inc., Warsaw, Indiana, USA), ‘CMW’ (DePuy Orthopaedics Inc., Warsaw, Indiana, USA) and ‘Simplex’ (Stryker Corporation, Kalamazoo, Michigan, USA). Palacos and CMW are available as high and low viscosity, and all brands have plain or antibiotic impregnated versions. Data were extracted for all Exeter/Trident THRs performed and submitted to the NJR until 31st December 2010 with the primary diagnosis of osteoarthritis (OA). As several options were used rarely, these were excluded from analyses. A summary of inclusion criteria is shown in Figure 1.

Covariate categories thought to have an influence on revision risk were patient age at time of procedure, gender, co-morbidity score, body mass index (BMI), stem size, bearing surface material and head size (10-12). American Society of Anaesthesiology (ASA) grade was used as a surrogate for co-morbidity. We also examined the influence of head offset, acetabular shell type and primary surgeon characteristics. Covariates used are summarised in Table 1.

For an implant to have been recorded as revised (where one implant is exchanged for another, or removed as part of a staged procedure), a complete record of the revision procedure (including side of operation) must be linked to the original index procedure by matching the unique patient identifier. A number of causes of revision can be recorded for each operation; these were interpreted hierarchically for infection and peri-prosthetic fracture, pre-selecting in that order. Pain was only taken as the primary cause when no other reason was provided.

***Statistical analysis***

Continuous and discrete continuous covariates (age, head offset, consultant volume) were analysed as categorical data (informed by spread of the data) because of the greater clinical relevance when making group comparisons. Preliminary analysis of age as a continuous variable is also reported. To explore the influence of covariates the most common category was generally used as the baseline case: for example, 32mm heads were used as the baseline against which all other head sizes were compared. Exceptions to this were age (where the youngest group was used as the baseline), consultant volume (where the highest volume group was used) and bearing (where the type most commonly used in 2010 was used).

A revision procedure was considered to be a 'failure event', where the time between the index procedure and revision was the measure of 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. 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 Hazard ratios (HRs) with 95% confidence intervals (CI): ratios greater than one indicate that risk is higher when compared with the reference covariate category. Covariates fitting models with $p<0.05$ were considered significant influences.

Life tables were produced to report unadjusted one-, three-, and five-year revision rates (with 95% CIs estimated using the normal approximation) for each shell type and bearing in patients ≤75 years. Survival was not reported if number entering the first year was less than 500, or number entering any subsequent year was less than 5% of the original number entering in that group.

## Results

Of 15 740 primary procedures, the majority were performed in females (9573, 60.8%), with ASA ≤2 (13 693, 87.0%) and 75 years of age or less (11 764, 74.7%); the mean age at implantation was 68 years old. There were 6641 (42.2%) procedures with complete BMI data; of the procedures with data, the majority were less than 30kg/m$^2$ (4638, 69.8%). The most commonly used stem was 44mm offset (8627, 54.8%) and taper sizes ≤2 (14 255, 90.6%) accounted for the majority. A standard neck offset (63.4%, 9986) and a 32mm diameter (45.4%, 7153) were the most commonly used heads. The commonest cup design was a PSL multi-hole (10 497, 66.7%) and only 33.3% (5243) relied on press-fit fixation with a solid-back shell. Over the entire study, the commonest bearing was ceramic-on-ceramic (CoC, 6144, 39.0%). However, during 2010 this was metal-on-XLPE (MoXLPE). Palacos high viscosity antibiotic impregnated (52.5%, 8264) was most commonly used to cement the stem. The procedure was performed through a posterior approach in 67.5% of cases (10 620). In most cases the consultant performed the procedure (12 886, 81.9%). Medium- or high-volume Exeter/Trident hybrid arthroplasty surgeons (≥51 cases over study period) accounted for 70.8% (11 147) of procedures. Patients were under the care of 575 different consultants in 239 different surgical units. Demographics are shown in Table 2 and bearing use by year in Table 3.

### *Reasons for revision*

One hundred and forty-one patients had undergone a revision procedure by the census date. The most common reason was infection (38 revisions, 27.0% of all revisions). Reason for revision was determined to be dislocation in 36 cases (25.5%), followed by aseptic component loosening/lysis (33, 23.4%), malalignment (18, 12.8%) and peri-prosthetic fracture (17, 12.1%). Revision for dissociation of liner occurred in seven patients (5.0%), five of which were ceramic liners (3.5%). Revision data are summarised in Table 4.

***Associations with implant revision***

In simple (univariable) regression analysis, age ($p=0.033$), bearing ($p=0.050$, Figure 2), shell type ($p=0.024$, Figure 3), and surgical approach ($p=0.036$) influenced implant revision risk (Table 5). Although bearing category was on the threshold of significance, several individual bearings had $p<0.05$. Brand of cement, shell geometry and type of femoral head metal (stainless steel or cobalt-chrome) were not found to be significant influences for survival: these covariates were therefore merged into common categories. First- (‘Crossfire’) and second-generation (‘X3’) XLPE liners were combined into one group, as the ‘Crossfire’ liner was used rarely.

After risk adjustment, procedures performed using standard PE liners (metal-on-PE bearings: HR=2.64, 95% CI 1.39 to 4.99, $p=0.003$, ceramic-on-PE: HR=3.07, 95% CI 1.18 to 8.00, $p=0.022$) and CoC bearings (HR=1.93, 95% CI 1.00 to 3.69, $p=0.049$) were associated with significantly higher revision rates when compared with procedures using a MoXLPE bearing. Procedures employing multi-hole acetabular shells (HR=1.70, 95% CI 1.16 to 2.48, $p=0.006$) had a greater risk of revision compared with solid-back shells. Older patients (≥76 years) were associated with a lower revision risk (HR=0.46, 95% CI 0.25 to 0.83, $p=0.010$) compared to patients ≤60 years (Table 5). After risk adjusting, surgical approach was not selected for the final model.

When covariates were tested for multiplicative relations a significant interaction between age group and shell type was found ($p=0.022$). Bearing category remained significant ($p=0.048$)

but age group and shell type as individual covariates no longer met the inclusion criteria for the model.  This suggests that lower risk of revision in patients ≥76 years was associated with multi-hole shells and lower risk of revision in patients ≤60 was associated with solid-back shells (Table 6).  In this model, CoC bearings were not associated with significantly higher revision, although this was marginal (HR=1.86, 95% CI 0.97 to 3.56, p=0.061).

Revision risk was independent of gender, ASA grade, stem characteristics, head size, neck offset, cement type, operator grade and consultant experience.

***Revision rates***

The overall five-year revision rate was 1.56% (95% CI 1.23 to 1.89) for the entire study population.  In patients ≤75 years, five-year revision rates for solid-back shells were 1.21% (95% CI 0.67 to 1.76) compared with 2.07% (95% CI 1.52 to 2.62) for multi-holes (Table 7). Three-year revision rates for bearing and shell type indicate the use of a MoXLPE bearing with a solid-back shell may ultimately have the lowest revision rate, although there were no statistically significant differences across these small groups.

**Discussion**

This retrospective cohort study provides the largest, in-depth analysis of a single brand combination of hybrid THRs. Significantly greater revision rates were associated with bearing surface material and shell type after risk adjustment. These findings identify modifiable parameters in the control of the operating surgeon. Other potentially modifiable factors, including surgical approach and femoral head size, were not found to significantly influence revision.

Whilst these data are the largest to date reporting a single brand combination analysis of hybrid THRs, we accept that there are limitations in its interpretation. The revision rates described in this study are limited to mid-term data only (the earliest implanted was 2003). The relative rates at which particular implants require revision may change with further follow-up and more informative data. In addition, the highly cross-linked PE in this system has only been used in considerable numbers since 2007, limiting comparisons across bearings. Revision is a hard end-point and may be considered a surrogate marker of implant failure, as other endpoints are unavailable. This does not take into account patients living with a painful hip, or those awaiting revision at the time of censoring (13). Furthermore, revision procedures may be missed by the NJR due to compliance and linkage issues, but these should affect all groups equally. The study design is observational and thus vulnerable to omitted variables, which may have confounded our findings. Information regarding duration and severity of symptoms, radiographic appearance and activity levels prior to and following the procedure were not available. However, similarities between the unadjusted and adjusted models, robustness under different model fitting assumptions, and time independence support the stability of estimates.

Highly cross-linked polyethylene has improved resistance to wear compared to standard PE, resulting in generation of fewer wear particles (14). A meta-analysis of ongoing clinical trials found XLPE liners exhibited reduced radiological wear and osteolysis at a mean follow-up of 5.1 years (1.8 to 9.0) compared to standard PE. Although there was no difference in revision rates between the types of PE, concerns regarding early failures attributable to brittleness of the XLPE were unfounded (15). A mid- to long-term implant survival analysis of almost 9000 primary procedures from the Mayo clinic using thirteen different cementless cup systems found improved survival (although not statistically significant) with XLPE liners compared to standard PE liners (16). This current study is the first to identify an implant survival benefit of XLPE liners within a single acetabular system, albeit using short- to mid-term data.

Ceramic-on-ceramic bearings have good mid- to long-term survival data (17). It is anticipated that a low wearing CoC bearing should provide adequate longevity for the young, active patient. However, there are concerns regarding higher risks of dislocation (18), fracture and squeaking (17). This current study has identified that MoXLP is currently (marginally) outperforming CoC in the Trident system. However, CoC and MoXLPE bearings may have equivalent survival in patients aged ≤60 years. CoC bearings may ultimately provide greater longevity in younger patients, but longer-term data is required.

The use of the multi-hole shell option allows supplementary screw fixation of the cup, rather than reliance on press-fit alone. The decision to use a multi-hole shell may be explained by: inadequate press-fit of the trial/solid shell; anatomical factors (e.g. wall defects) precluding the use of cemented cups or press-fit components without screw augmentation; or the operating surgeon’s normal practice. From the data presented here, multi-hole shells are associated with higher revision in younger patients, but possibly lower revision in older patients. Although we have no data on screw usage, it is assumed that a (more expensive) multi-hole shell would be used in conjunction with screws in the majority of cases, to supplement inadequate press-fit. This potentially poorer method of fixation, the reduced surface area for bony in-growth, or wear debris migrating through the holes, may contribute to the higher revision seen in these multi-hole shells in younger patients. Conversely, in older patients with poorer bone quality, reliance on press-fit alone may not be adequate in any patients, and supplementary fixation with screws may provide greater fixation. Of note, no difference in revision was found between PSL and Hemispherical shells.

Previous reports have shown that increasing age is associated with lower revision rates after cemented THR (10, 19). We found an interaction with shell type, which may explain the lower revision rates in older patients in this study. However, it is important to remember that patients ≥76 years have lower functional demands, and fewer patients requiring revision surgery will be fit enough in this age group, limiting the conclusions that can be drawn when patient reported functional and general health data are unavailable. Furthermore, 10-year patient survival following THR performed in older patients (aged ≥80 years) is less than 25% according to Norwegian Registry data (20). The literature reports no superiority of cementless over cemented cups at ten years (21) and, given costs are generally higher than cemented, we question the cost-effectiveness of the use of cementless cups in 3976 (25%) patients ≥76 years in this current analysis.

As expected, the overall revision presented here at five years 1.56% (95% CI 1.23 to 1.89) was similar to reports from the NJR 8$^{th}$ AR for 18 358 Exeter V40/Trident THRs (1.69%, 95% CI 1.39 to 2.07) (7). However, revision at five years when the commonest bearing

(CoC) was used in combination with a solid-back shell in patients ≤75 years was only 1.13% (95% CI 0.43 to 1.83). Although the follow-up time is shorter, the data presented here suggests that MoXLPE, in combination with a solid shell has even lower revision. Overall revision, as described in the analyses of brands alone in the NJR 8$^{th}$ Annual Report, is therefore skewed by longer follow-up data from poorer performing components (historical higher use of standard PE). Components that are now most commonly used in current practice (MoXLPE, CoC bearings) have lower revision rates than those reported by the NJR.

Increasing femoral head size is thought to contribute to lower dislocation (22) and revision (11). However, in this study there were no differences in revision rates across head sizes. Of note, surgical approach did not influence revision after adjustment for other factors. Although BMI appeared to have an influence on the model, with the degree of missing data it was felt that excluding this parameter was the most appropriate solution. Efforts to improve BMI recording to allow for appropriate adjustment in future explanatory analysis are required.

The commonest primary reason for revision was infection (27.0%); dislocation accounted for 25.5% of revisions. This study reports mid-term data: as expected, only a small number of implants (23.4%) were revised for aseptic loosening/lysis. Excluding dislocation, cup related failures (aseptic loosening/lysis, malalignment, dissociation of liner, and liner wear) were cited in 39.7% (56) of revisions, compared with 9.9% (14) for stems. Of note, previous concerns regarding high rates of mal-seating of the Trident ceramic liners (8 to 16.4% of all procedures) (23, 24) do not appear to translate into liner dissociation and subsequent revision procedures (3.5% of revisions were attributable to ceramic liner dissociations in this series).

In summary, there were significant differences in implant failure between bearing surface materials and acetabular shell fixation types, after adjustment for a range of covariates in a large cohort of single-brand hybrid THRs. In this study, standard polyethylene liners and multi-hole Trident shells were associated with significantly higher revision rates overall. Metal-on-highly-cross-linked polyethylene in a shell with no holes appears to be the best choice in patients ≤75 years, in short- to medium-term analysis of this popular hybrid brand combination. CoC bearings may have a role in the youngest patients.  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 hybrid THR, the findings presented may help guide their practice. Findings may also provide a useful reference for comparison with future analyses comparing implant types.

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**Table 1**. Final 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 ≤2, Grade ≥3 |
| Body mass index | Ordinal | <30kg/m$^2$, ≥30kg/m$^2$ |
| Stem offset | Ordinal | 35mm, 37.5mm, 44mm, 50mm |
| Stem taper | Ordinal | ≤2, ≥3 |
| Head size | Ordinal | 28mm, 32mm, ≥36mm |
| Neck offset | Ordinal | Standard, 'Plus' head, 'Minus' head |
| Shell design | Nominal | Solid-back, Multi-/cluster-hole |
| Bearing | Nominal | Metal-on-standard polyethylene (PE)<br>Metal-on-highly-cross-linked (XL) PE<br>Ceramic-on-standard PE<br>Ceramic-on-XLPE<br>Ceramic-on-ceramic |
| Cement type | Nominal | Palacos high viscosity antibiotic impregnated, Simplex P antibiotic impregnated, Other |
| Surgical approach | Nominal | Posterior, Anterolateral, Other |
| Year of procedure | Continuous | 2003 to 2010 |
| Primary surgeon | Binary | Consultant, Other |
| Consultant Exeter/Trident volume | Ordinal | Low (≤50 cases throughout study period), Medium (51-200), High (≥201) |

ASA – American Society of Anaesthesiologists, kg – kilogram, m – metre, mm – millimetre

**Table 2**. Demographics of Exeter V40/Trident hybrid hip replacements (England and Wales, 2003-2010)

| | **n=15 740** |
|---|---|
| *Age*, mean years (SD, range) | 67.5(10.7, 15-102) |
| ≤60, n (%) | 3535 (22.5) |
| 61-75 | 8229 (52.3) |
| ≥76 | 3976 (25.3) |
| *Gender* | |
| Female | 9573 (60.8) |
| Male | 6167 (39.2) |
| *ASA grade* | |
| 1/2 | 13 693 (87.0) |
| ≥3 | 2047 (13.0) |
| *Body mass index*, mean $kg/m^2$ (SD) | 28.4 (5.3)* |
| <30$kg/m^2$, n (%) | 4638 (29.5) |
| ≥30$kg/m^2$ | 2003 (12.7) |
| No data | 9099 (57.8) |
| *Stem offset* | |
| 35.5mm | 1186 (7.5) |
| 37.5mm | 5135 (32.6) |
| 44mm | 8627 (54.8) |
| 50mm | 792 (5.0) |
| *Stem taper* | |
| ≤2 | 14 255 (90.6) |
| ≥3 | 1485 (9.4) |
| *Head size* | |
| 28mm | 4764 (30.3) |
| 32mm | 7153 (45.4) |
| ≥36mm | 3823 (24.3) |
| *Neck offset* | |
| Standard (0) | 9986 (63.4) |
| Plus (+4mm to +8mm) | 2534 (16.1) |
| Minus (-2.7mm to – 5mm) | 3220 (20.5) |
| *Shell design* | |
| Solid back | 5243 (33.3) |
| *PSL* | *3882 (24.7)* |
| *Hemispherical* | *1361 (8.6)* |
| Multi-hole | 10 497 (66.7) |
| *PSL* | *6934 (44.1)* |
| *Hemispherical* | *3563 (22.6)* |
| *Bearing* | |
| Metal-on-standard polyethylene (PE) | 4265 (27.1) |
| Metal-on-highly cross-linked (XL) PE | 3829 (24.3) |
| *Stainless steel-on-XLPE* | *1661 (10.6)* |
| *Cobalt-chrome-on-XLPE* | *2168 (13.8)* |
| Ceramic-on-standard PE | 354 (2.2) |
| Ceramic-on-XLPE | 1148 (7.3) |
| Ceramic-on-ceramic | 6144 (39.0) |
| *Cement* | |
| Palacos high viscosity antibiotic impregnated | 8264 (52.5) |
| Simplex P antibiotic impregnated | 5530 (35.1) |
| Other | 1484 (9.4) |
| Missing | 462 (2.9) |
| *Surgical approach* | |
| Posterior | 10 620 (67.5) |
| Anterolateral | 4662 (29.6) |
| Other | 319 (2.0) |
| Missing data | 139 (0.9) |

| | | |
|---|---|---|
| *Year of procedure* | | |
| 2003 | 74 | (0.5) |
| 2004 | 376 | (2.4) |
| 2005 | 1125 | (7.1) |
| 2006 | 1755 | (11.1) |
| 2007 | 2590 | (16.5) |
| 2008 | 2867 | (18.2) |
| 2009 | 3610 | (22.9) |
| 2010 | 3343 | (21.2) |
| *Primary surgeon* | | |
| Consultant | 12 886 | (81.9) |
| Other | 2854 | (18.1) |
| *Number of consultants* (n) | 575 | |
| *Consultant Exeter/Trident volume* | | |
| Low (≤50 cases over study period) | 4593 | (29.2) |
| Medium (51-200) | 6969 | (44.3) |
| High (≥201) | 4178 | (26.5) |
| *Number of surgical units* (n) | 239 | |

SD – standard deviation, * - based on 6641 procedures

**Table 3**. Bearings used for Exeter v40/Trident hybrid hip replacements, by year (England and Wales, 2003-2010)

| Year | Bearing | | | | |
|---|---|---|---|---|---|
| | **MoXLP** | **MoSP** | **CoSP** | **CoXLP** | **CoC** |
| 2003, n (%) | 0 (0) | 26 (35.1) | 5 (6.8) | 0 (0) | 43 (58.1) |
| 2004 | 1 (0.3) | 140 (37.2) | 28 (7.4) | 0 (0) | 207 (55.1) |
| 2005 | 6 (0.5) | 453 (40.3) | 62 (5.5) | 1 (0.1) | 603 (53.6) |
| 2006 | 25 (1.4) | 785 (44.7) | 88 (5.0) | 10 (0.6) | 847 (48.3) |
| 2007 | 383 (14.8) | 956 (36.9) | 56 (2.2) | 65 (2.5) | 1130 (43.6) |
| 2008 | 782 (27.3) | 671 (23.4) | 40 (1.4) | 242 (8.4) | 1132 (39.5) |
| 2009 | 1292 (25.8) | 666 (18.4) | 45 (1.2) | 425 (11.8) | 1182 (32.7) |
| 2010 | 1340 (40.1) | 568 (17.0) | 30 (0.9) | 405 (12.1) | 1000 (29.9) |
| *Total* | *3829 (24.3)* | *4265 (27.1)* | *354 (2.2)* | *1148 (7.3)* | *6144 (39.0)* |

MoXLP – metal-on-cross-linked polyethylene, MoSP – metal-on-standard polyethylene, CoSP – ceramic-on-standard polyethylene, CoXLP – ceramic-on-cross-linked polyethylene, CoC – ceramic-on-ceramic

**Table 4**. Reasons recorded for revision following Exeter V40/Trident hybrid hip replacement (England and Wales, 2003-2010)

| | **Revision (n=141)** |
|---|---|
| Infection, n (%) | **38 (27.0)** |
| Dislocation | **36 (25.5)** |
| All aseptic component loosening/lysis | **33 (23.4)** |
| *Stem only* | *4 (2.8)* |
| *Cup only* | *23 (16.3)* |
| *Both* | *6 (4.3)* |
| All malalignments | **18 (12.8)** |
| *Stem only* | *3 (2.1)* |
| *Cup only* | *14 (9.9)* |
| *Both* | *1 (0.7)* |
| Periprosthetic fracture | **17 (12.1)** |
| *Stem only* | *13 (9.2)* |
| *Cup only* | *4 (2.8)* |
| Dissociation of liner | **7 (5.0)** |
| All implant fractures | **6 (4.3)** |
| *Stem only* | *4 (2.8)* |
| *Cup only* | *2 (1.4)* |
| Unexplained pain | **8 (5.7)** |
| Liner wear | **5 (3.5)** |
| Other | **5 (3.5)** |

**Table 5**. Independent predictors of revision following 15 740 Exeter/Trident hybrid hip replacements: simple and multivariable Cox regressions
(England and Wales, 2003-2010)

| **Covariate** | **Simple analysis** | | | **Multivariable analysis** | | |
|---|---|---|---|---|---|---|
| | **HR** | **95% CI** | **P value** | **HR** | **95% CI** | **P value** |
| *Gender* | | | | | | |
| Female | 1 | | | | | |
| Male | 1.04 | 0.74-1.45 | 0.829 | | | |
| *Age* | | | | | | |
| Category | | | 0.033 | | | 0.037 |
| ≤60 years | 1 | | | 1 | | |
| 61-75 | 0.79 | 0.54-1.14 | 0.201 | 0.75 | 0.50-1.11 | 0.148 |
| ≥76 | 0.50 | 0.30-0.84 | 0.009 | 0.46 | 0.25-0.83 | 0.010 |
| *ASA grade* | | | | | | |
| 1/2 | 1 | | | | | |
| ≥3 | 1.08 | 0.66-1.77 | 0.766 | | | |
| *Stem offset* | | | | | | |
| Category | | | 0.613 | | | |
| 35.5mm | 0.73 | 0.34-1.59 | 0.429 | | | |
| 37.5mm | 1.01 | 0.70-1.46 | 0.943 | | | |
| 44mm | 1 | | | | | |
| 50mm | 1.38 | 0.74-2.60 | 0.316 | | | |
| *Stem taper* | | | | | | |
| ≤2 | 1 | | | | | |
| ≥3 | 0.63 | 0.32-1.24 | 0.180 | | | |
| *Head size* | | | | | | |
| Category | | | 0.152 | | | |
| 28mm | 1.28 | 0.89-1.84 | 0.176 | | | |
| 32mm | 1 | | | | | |
| ≥36mm | 0.82 | 0.51-1.33 | 0.421 | | | |
| *Neck offset* | | | | | | |
| Category | | | 0.139 | | | |
| Standard | 1 | | | | | |
| Plus | 1.38 | 0.89-2.15 | 0.152 | | | |
| Minus | 1.41 | 0.95-2.10 | 0.085 | | | |
| *Bearing* | | | | | | |
| Category | | | 0.050 | | | 0.035 |
| Metal-on-XLPE | 1 | | | 1 | | |
| Metal-on-standard PE | 2.46 | 1.30-4.65 | 0.006 | 2.64 | 1.39-4.99 | 0.003 |
| Ceramic-on-standard PE | 3.51 | 1.37-9.00 | 0.009 | 3.07 | 1.18-8.00 | 0.022 |
| Ceramic-on-XLPE | 1.98 | 0.78-5.04 | 0.150 | 1.86 | 0.72-4.77 | 0.198 |
| Ceramic-on-ceramic | 2.29 | 1.23-4.26 | 0.009 | 1.93 | 1.00-3.69 | 0.049 |
| *Shell* | | | | | | |
| Solid back | 1 | | | 1 | | |
| Multi-hole | 1.54 | 1.06-2.24 | 0.024 | 1.70 | 1.16-2.48 | 0.006 |
| *Cement* | | | | | | |
| Category | | | 0.169 | | | |
| Palacos HV antibiotic | 1 | | | | | |
| *Simplex P antibiotic* | 0.97 | 0.67-1.41 | 0.876 | | | |
| *Other* | 1.55 | 0.95-2.52 | 0.082 | | | |
| *Surgical approach* | | | | | | |
| Category | | | 0.036 | | | |
| Posterior | 1 | | | | | |
| Antero-lateral | 1.53 | 1.09-2.15 | 0.015 | | | |
| Other | 0.51 | 0.07-3.63 | 0.497 | | | |
| *Year of procedure* | 1.06 | 0.94-1.19 | 0.341 | | | |
| *Operator* | | | | | | |
| Consultant | 1 | | | | | |
| Other | 1.28 | 0.85-1.91 | 0.237 | | | |

| | | | |
|---|---|---|---|
| *Consultant Exeter/Trident volume* | | | |
| Category | | | 0.273 |
| Low (≤50) | 1.14 | 0.71-1.83 | 0.597 |
| Medium (51-200) | 1.40 | 0.91-2.13 | 0.130 |
| High (≥201) | 1 | | |

HR – hazards ratio, CI – confidence intervals, ASA – American Society of Anaesthesiologists, XLPE – highly cross-linked polyethylene, PE – polyethylene

**Table 6**. Revision following 15 740 Exeter/Trident hybrid hip replacements: Multivariable Cox regressions with multiplicative interaction of age and shell type (England and Wales, 2003-2010)

| **Covariate** | **Multivariable analysis** | | |
|---|---|---|---|
| | **HR** | **95% CI** | **P value** |
| *Age* | | | |
| Category | | | 0.330 |
| ≤60 years | 1 | | |
| 61-75 | 0.79 | 0.49-1.25 | 0.307 |
| ≥76 | 0.62 | 0.33-1.17 | 0.141 |
| *Bearing* | | | |
| Category | | | 0.048 |
| Metal-on-XLPE | 1 | | |
| Metal-on-standard PE | 2.52 | 1.33-4.78 | 0.005 |
| Ceramic-on-standard PE | 2.99 | 1.50-7.78 | 0.025 |
| Ceramic-on-XLPE | 1.74 | 0.68-4.45 | 0.252 |
| Ceramic-on-ceramic | 1.86 | 0.97-3.56 | 0.061 |
| *Shell* | | | |
| Solid back | 1 | | |
| Multi-hole | 1.37 | 0.91-2.07 | 0.135 |
| *Age*shell* | | | |
| Category | | | 0.022 |
| ≤60 years | 1 | | |
| 61-75 | 0.80 | 0.33-1.94 | 0.628 |
| ≥76 | 0.23 | 0.08-0.70 | 0.010 |

HR – hazards ratio, CI – confidence intervals, ASA – American Society of Anaesthesiologists, XLPE – highly cross-linked polyethylene, PE – polyethylene

**Table 7**. Revision rates following Exeter/Trident hybrid hip replacement by bearing and shell type in patients ≤75 years (95% confidence intervals) (England and Wales, 2003-2010)

| | **Revision rates by bearing** | | | | **Overall revision rates** |
|---|---|---|---|---|---|
| | **MoXLP** | **MoSP** | **CoXLP** | **CoC** | |
| **1-year** | | | | | |
| **All** | **0.33% (0.07-0.60)** | **0.73% (0.39-1.08)** | **0.65% (0.08-1.21)** | **0.54% (0.35-0.74)** | **0.57% (0.43-0.71)** |
| *Solid shell* | *0.24% (0.00-0.72)* | *0.79% (0.21-1.37)* | - - | *0.25% (0.03-0.46)* | *0.40% (0.20-0.59)* |
| *Multi-hole shell* | *0.36% (0.05-0.68)* | *0.70% (0.27-1.13)* | *0.67% (0.00-1.42)* | *0.73% (0.44-1.02)* | *0.67% (0.47-0.86)* |
| **3-year** | | | | | |
| **All** | **0.72% (0.26-1.18)** | **1.36% (0.87-1.86)** | **1.49% (0.10-2.87)** | **1.10% (0.79-1.41)** | **1.14% (0.92-1.37)** |
| *Solid shell* | *0.24% (0.00-0.72)* | *1.35% (0.55-2.16)* | - - | *0.42% (0.13-0.71)* | *0.64% (0.37-0.91)* |
| *Multi-hole shell* | *0.86% (0.28-1.44)* | *1.37% (0.74-2.00)* | *2.15% (0.00-4.51)* | *1.57% (1.08-2.06)* | *1.46% (1.13-1.79)* |
| **5-year** | | | | | |
| **All** | - - | **2.01% (1.25-2.78)** | - - | **1.66% (1.15-2.16)** | **1.74% (1.35-2.13)** |
| *Solid shell* | - - | *1.78% (0.63-2.92)* | - - | *1.13% (0.43-1.83)* | *1.21% (0.67-1.76)* |
| *Multi-hole shell* | - - | *2.17% (1.14-3.19)* | - - | *1.99% (1.30-2.67)* | *2.07% (1.52-2.62)* |
| *Total number* | | | | | |
| **All** | **2193** | **2476** | **937** | **5831** | **11 764** |
| *Solid shell* | *504* | *957* | *375* | *2202* | *4180* |
| *Multi-hole shell* | *1689* | *1519* | *562* | *3629* | *7584* |

Inadequate numbers of CoSP for analysis.

For sub-analysis of data, where numbers were inadequate no figures are reported.

**Figure 1**. Flow chart describing the procedures included

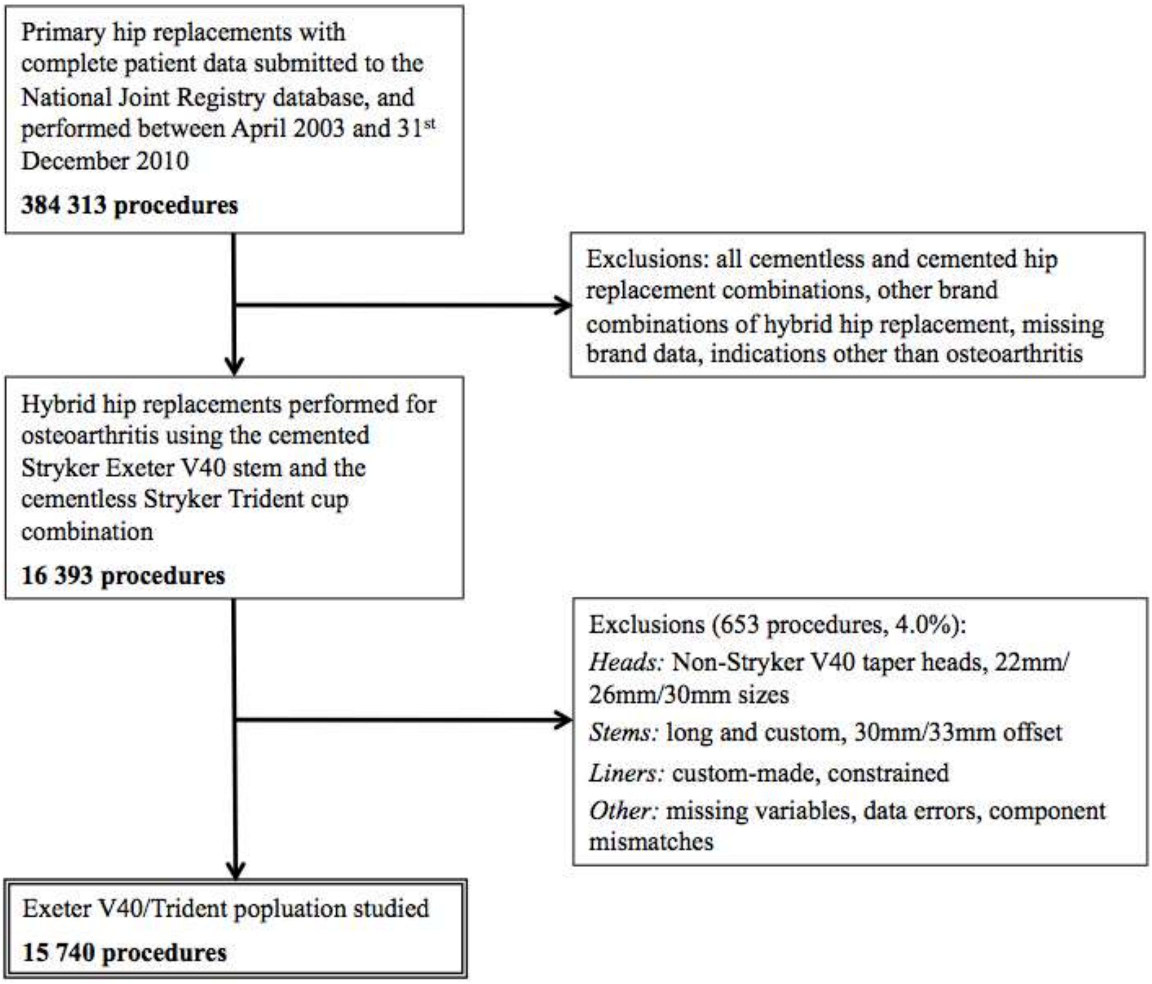
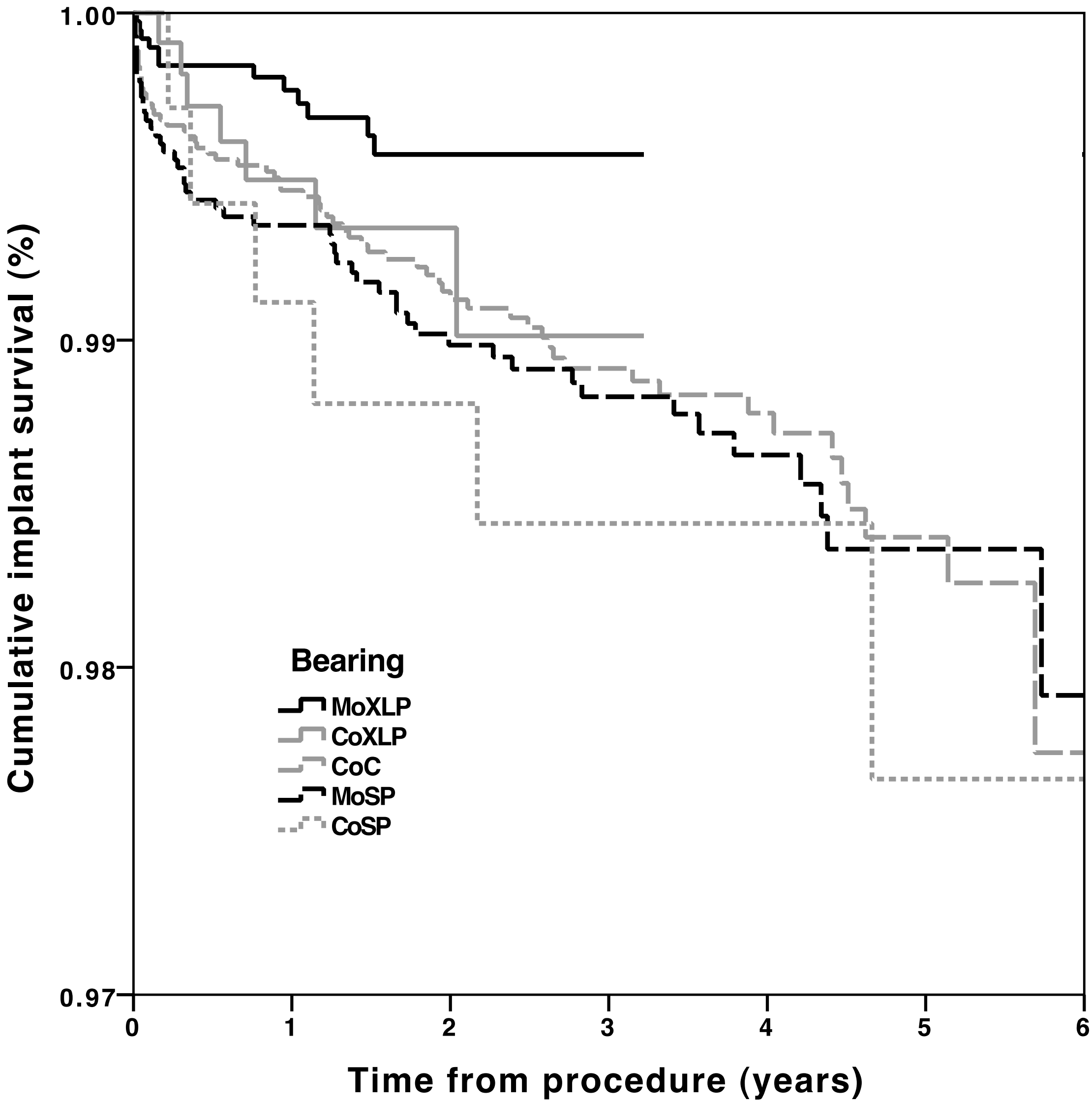


**Figure 2.** Kaplan Meier: unadjusted cumulative implant survival of Exeter V40/Trident by bearing (England and Wales, 2003-2010)

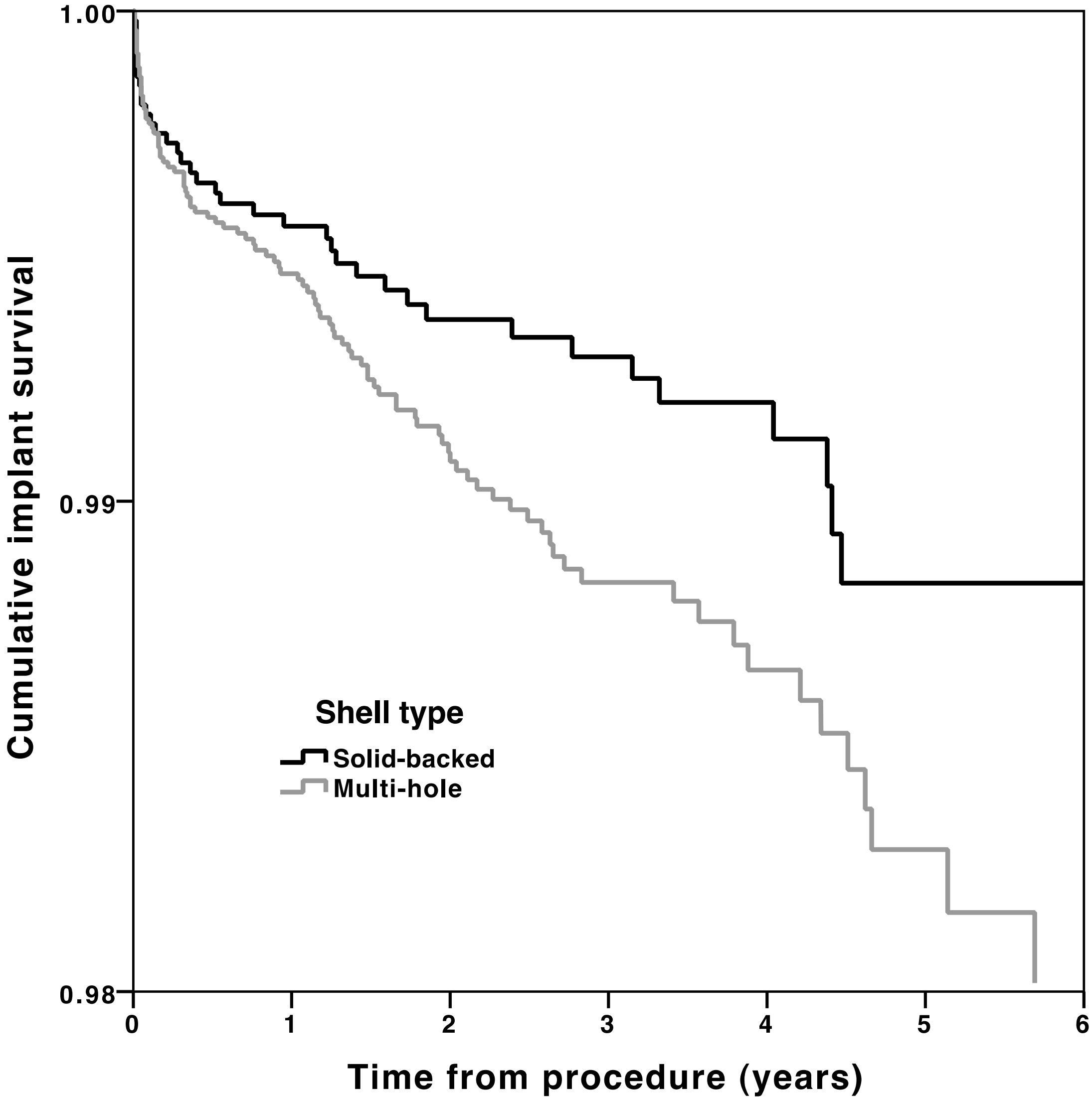



| Log rank (Mantel-Cox) | MoXLP | MoSP | CoSP | CoXLP | CoC |
|---|---|---|---|---|---|
| **MoXLP (p-value)** | - | 0.003 | 0.015 | 0.149 | 0.010 |
| **MoSP** | 0.003 | - | 0.368 | 0.521 | 0.706 |
| **CoSP** | 0.015 | 0.368 | - | 0.399 | 0.296 |
| **CoXLP** | 0.149 | 0.521 | 0.399 | - | 0.798 |
| **CoC** | 0.010 | 0.706 | 0.296 | 0.798 | - |

Life table showing numbers at risk in each year

| Cup design | Year 0 | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
|---|---|---|---|---|---|---|
| **MoXLP** | 3829 | 2452 | 1146 | 395 | 30 | 7 |
| **MoSP** | 4265 | 3618 | 2911 | 2196 | 1276 | 554 |
| **CoSP** | 354 | 320 | 274 | 232 | 175 | 91 |
| **CoXLP** | 1148 | 728 | 305 | 72 | 8 | 1 |
| **CoC** | 6144 | 5100 | 3885 | 2753 | 1637 | 814 |

**Figure 3.** Kaplan Meier: unadjusted cumulative implant survival of Exeter V40/Trident by shell type (England and Wales, 2003-2010)




| Log rank (Mantel-Cox) | Solid | Multi-hole |
|---|---|---|
| **Solid-back shell (p-value)** | - | 0.023 |
| **Multi-hole shell** | 0.023 | - |

Life table showing numbers at risk each year

| Shell type | Year 0 | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
|---|---|---|---|---|---|---|
| **Solid-back shell** | 5243 | 4187 | 3098 | 2413 | 1343 | 597 |
| **Multi-hole shell** | 10497 | 8031 | 5423 | 3235 | 1783 | 870 |

**Supplementary material**

The reliability of the Cox model 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 order to improve efficiency of the final models, where no differences were found within subcategories (e.g. shell geometry type) during preliminary modelling, these were combined. All models were fitted using SPSS version 19.0 (SPSS Inc, IBM Corporation, Armonk, New York).

On univariable analysis, age as a continuous covariate was a significant influence (HR=0.98, 95% CI 0.96 to 1.00, p=0.016). We therefore created separate multivariable models to test age selection (as continuous or categorical data). As a continuous covariate, age did not affect selection within the model, nor the influence of the other significant covariates (multi-hole shell: HR=1.69, MoSP bearing: HR=2.65, CoSP: HR=3.15, CoXLP: HR=1.89, CoC: HR=1.94). The final model was therefore reported with age using categorical data.

High BMI ($\geq$30kg/m$^2$) was associated with an increased risk of revision compared to BMI <30kg/m$^2$ on univariable analysis ($\geq$30kg/m$^2$: HR=2.03, 95% CI 1.15 to 3.58, p=0.015). This inclusion of BMI in the preliminary multivariable modelling resulted in the loss of 58% of available procedures from the analysis, and while the HRs for individual bearings where not qualitatively affected by this, shell type and age were not selected within the model (supplementary Table 1).  This substantial data loss was accompanied by stepwise selection instability, and so BMI was therefore removed from the final analysis.

Tests for time-dependency of covariates were not statistically significant. Forward and reverse stepwise model construction led to the same final model.

**Supplementary Table 1**. Independent predictors of revision following 15 740 Exeter/Trident hybrid hip replacements, including body mass index data: simple and multivariable Cox regressions (England and Wales, 2003-2010)

| Covariate | Simple analysis | | | Multivariable analysis* | | |
|---|---|---|---|---|---|---|
| | **HR** | **95% CI** | **P value** | **HR** | **95% CI** | **P value** |
| *Gender* | | | | | | |
| Female | 1 | | | | | |
| Male | 1.04 | 0.74-1.45 | 0.829 | | | |
| *Age* | | | | | | |
| Category | | | 0.033 | | | |
| ≤60 | 1 | | | | | |
| 61-75 | 0.79 | 0.54-1.14 | 0.201 | | | |
| ≥76 | 0.50 | 0.30-0.84 | 0.009 | | | |
| *ASA grade* | | | | | | |
| 1/2 | 1 | | | | | |
| ≥3 | 1.08 | 0.66-1.77 | 0.766 | | | |
| *Body mass index* | | | | | | |
| <30kg/m$^2$ | 1 | | | 1 | | |
| ≥30kg/m$^2$ | 2.03 | 1.15-3.58 | 0.015 | 2.00 | 1.13-3.54 | 0.017 |
| *Stem offset* | | | | | | |
| Category | | | 0.613 | | | |
| 35.5mm | 0.73 | 0.34-1.59 | 0.429 | | | |
| 37.5mm | 1.01 | 0.70-1.46 | 0.943 | | | |
| 44mm | 1 | | | | | |
| 50mm | 1.38 | 0.74-2.60 | 0.316 | | | |
| *Stem taper* | | | | | | |
| ≤2 | 1 | | | | | |
| ≥3 | 0.63 | 0.32-1.24 | 0.180 | | | |
| *Head size* | | | | | | |
| Category | | | 0.152 | | | |
| 28mm | 1.28 | 0.89-1.84 | 0.176 | | | |
| 32mm | 1 | | | | | |
| ≥36mm | 0.82 | 0.51-1.33 | 0.421 | | | |
| *Neck offset* | | | | | | |
| Category | | | 0.139 | | | |
| Standard | 1 | | | | | |
| Plus | 1.38 | 0.89-2.15 | 0.152 | | | |
| Minus | 1.41 | 0.95-2.10 | 0.085 | | | |
| *Bearing* | | | | | | |
| Category | | | 0.050 | | | 0.159 |
| Metal-on-XLPE | 1 | | | 1 | | |
| Metal-on-standard PE | 2.46 | 1.30-4.65 | 0.006 | 1.97 | 0.71-5.45 | 0.194 |
| Ceramic-on-standard PE | 3.51 | 1.37-9.00 | 0.009 | 5.44 | 1.08-27.36 | 0.040 |
| Ceramic-on-XLPE | 1.98 | 0.78-5.04 | 0.150 | 3.16 | 1.02-9.81 | 0.046 |
| Ceramic-on-ceramic | 2.29 | 1.23-4.26 | 0.009 | 2.50 | 1.02-6.15 | 0.046 |
| *Shell* | | | | | | |
| Solid back | 1 | | | | | |
| Multi-hole | 1.54 | 1.06-2.24 | 0.024 | | | |
| *Cement* | | | | | | |
| Category | | | 0.169 | | | |
| Palacos HV antibiotic | 1 | | | | | |
| *Simplex P antibiotic* | 0.97 | 0.67-1.41 | 0.876 | | | |
| *Other* | 1.55 | 0.95-2.52 | 0.082 | | | |
| *Surgical approach* | | | | | | |
| Category | | | 0.036 | | | |
| Posterior | 1 | | | | | |
| Anterolateral | 1.53 | 1.09-2.15 | 0.015 | | | |
| Other | 0.51 | 0.07-3.63 | 0.497 | | | |
| *Year of procedure* | 1.06 | 0.94-1.19 | 0.341 | | | |

| | | | |
|---|---|---|---|
| *Operator* | | | |
| Consultant | 1 | | |
| Other | 1.28 | 0.85-1.91 | 0.237 |
| *Consultant Exeter/Trident volume* | | | |
| Category | | | 0.273 |
| Low (≤50) | 1.14 | 0.71-1.83 | 0.597 |
| Medium (51-200) | 1.40 | 0.91-2.13 | 0.130 |
| High (≥201) | 1 | | |

HR – hazards ratio, CI – confidence intervals, ASA – American Society of Anaesthesiologists, XLPE – highly cross-linked polyethylene, PE – polyethylene, *based on 6637 procedures with body mass index data