Has the revision rate changed for 36 mm metal-on-metal total hip replacements with Pinnacle cups by year of implantation? An interrupted time-series analysis using data from the National Joint Registry for England and Wales

Abstract

Aims

To determine whether revision rates for metal-on-metal total hip replacements (MoM THRs) with Pinnacle cups varied by year of implantation, and compare these to revision rates for other MoM THR designs.

Methods

Data from the National Joint Registry included 36mm MoM THRs with Pinnacle cups implanted between 2003-2012 with at least 5-years follow-up (n=10,776), and a control group of other MoM THRs (n=13,817). The effect of implantation year on all-cause revision rates was assessed using Cox regression and interrupted time-series analysis.

Results

For Pinnacles, compared with hips implanted in 2004-2006, hips implanted in 2007-2012 had higher revision rates (hazard ratio (HR)=2.01; CI=1.57-2.57; p<0.001). For primaries performed after 2007, the number of revisions per 1000 implant-years at-risk significantly increased by 5.20 (CI=0.52-9.89; p=0.033) compared with pre-2007. In the control group, hips implanted in 2007-2012 also had higher revision rates (HR=1.77; CI=1.49-2.10; p<0.001), with revisions per 1000 implant-years for primaries performed after 2007 significantly increasing by 6.13 (CI=1.42-10.83; p=0.016).

Conclusion

Five-year revision rates were significantly increased in all primary MoM THRs implanted from 2007 onwards. Contrary to recent reports the finding was not specific to Pinnacles, and may be explained by increased surveillance and lowering of the revision threshold over time.

Introduction

Metal-on-metal total hip replacements (MoM THRs) are associated with high failure rates due to the release of cobalt and chromium from the bearing surface and/or the femoral head-stem taper junction.[1-6] There is now evidence to suggest that similar problems can also occur in patients without MoM bearing surfaces.[7] Worldwide authorities recommend MoM THR patients undergo regular surveillance to detect complications early.[8-10] The Pinnacle system (DePuy, Leeds, United Kingdom) represents one of the most commonly used MoM THR devices with approximately 180,000 implanted worldwide.[3, 11-13] High revision rates have been reported for MoM THRs with Pinnacle cups (subsequently referred to as Pinnacles) in registries[3, 11] and large single-centre studies.[12, 14-17]

Two recent studies together involving over 1,000 primary 36 mm Pinnacles (8.4% of all such implants within the National Joint Registry (NJR)) both reported that hips implanted from 2006 onwards had a significantly increased risk of failure compared with those implanted before 2006.[12, 17] Explant analysis also demonstrated that Pinnacles manufactured from 2006 onwards were increasingly likely to have lower clearance values than intended by the manufacturer.[12] It has been postulated that these previously unrecognised changes in the device manufacturing process may be responsible for the increased failure rates reported from 2006 onwards.[12, 17]

These observations are concerning and, if specific to Pinnacle cups, may require important changes to surveillance for Pinnacle patients.[8-10] Assessment of the effect of year of Pinnacle implantation on revision rates in a large unselected population would therefore be advisable. Although an initial review of Pinnacles recorded in the NJR did not show a higher revision rate for the batch numbers identified previously[12] compared to the others, it was suggested that this analysis would be repeated.[18]

This study aimed to validate the findings from the two recent Pinnacle cohorts using the NJR dataset and novel statistical methodology.[12, 17] We investigated whether five-year revision rates for 36 mm MoM THRs with Pinnacle cups, and for a control group of all other MoM THRs, were higher in primary hips implanted from 2007 onwards compared with those implanted pre-2007. Hips implanted from 2007 onwards were distinguished from earlier implantations as 2007 represented the first complete calendar year following the postulated changes in the Pinnacle clearance values.[12]

Patients and Methods

Study design and data source

We performed a retrospective observational cohort study using the NJR, which has recorded all hip replacements performed at hospitals in England and Wales since April 2003.[11] Unique patient identifiers allow linkage of primary procedures to any subsequent revisions where components were removed or exchanged. The NJR obtains data on time to death following arthroplasty from the Personal Demographics Service.

Participants, selection criteria, and implants

Anonymised patient data were extracted from the NJR up to and including 31st December 2015.[11] The dataset included all primary 36 mm MoM THRs with an uncemented Pinnacle acetabular component implanted with either a Corail (12/14 taper) or SROM (11/13 taper) stem (all components manufactured by DePuy). The last implantation was in August 2012. The Corail and SROM stems represented the two most commonly used femoral stems with Pinnacles, and were selected as these designs were studied previously.[12, 17] The final cohort for analysis included 11,826 primary 36mm Pinnacles. Both femoral components were uncemented titanium alloy stems, and were implanted with an Ultamet cobalt-chrome alloy liner, and either an Ultamet (SROM) or Articul/eze (Corail) cobalt-chrome alloy femoral head (all manufactured by DePuy). Further information about these components has been described.[12, 15, 19]

A control group of all other primary MoM THRs (>36 mm) implanted between 2003 and 2012 was extracted from the NJR (n=14,934). This group included all manufacturer designs apart from ASR MoM THRs (DePuy), and MoM THRs with Pinnacle cups. The control group therefore included a variety of manufacturer designs and femoral head sizes.

Exposures and outcomes

The exposure (intervention) of interest was the year of primary hip implantation, which was grouped as described. For all procedures the NJR collects data on patient demographics and the surgical procedure (age, gender, body mass index (BMI), American Society of Anesthesiologists (ASA) grade, indication, surgeon grade, and components implanted), which were adjusted for in our analysis.

The study outcome was all-cause revision surgery (removal or exchange of any primary arthroplasty component). Surgeons can record one or multiple indications when performing revisions, including infection, periprosthetic fracture, aseptic loosening, dislocation/subluxation, adverse soft tissue reaction to particulate debris (latter available since June 2008),[11] lysis, implant malalignment, implant wear, implant fracture, head/socket mismatch, liner dissociation, pain, and other.

Statistical analysis

All analyses were performed using Stata Version 13.1 (Lakeway Drive, Texas, USA), with a 5% level of significance and 95% confidence intervals (CI). Cumulative all-cause revision rates following primary Pinnacle arthroplasty were estimated using the Kaplan-Meier method. Hips not undergoing revision were censored on the study end date (31st December 2015), or at the time of death (if earlier). Revision rates were determined for the whole cohort, and also for a follow-up controlled cohort in Pinnacles only (referred to subsequently as the 5-year cohort). The 5-year cohort included all patients with the potential for at least 5-

years follow-up (hence by definition had their primary before 2011) with revision outcomes censored at 5-years from the date of primary operation in patients not undergoing revision or death within 5-years (Table 1).

Cox proportional hazards models (univariable and multivariable) were used to assess the effect of year of primary hip implantation on time to all-cause revision surgery in both the whole cohort (for Pinnacles) and the 5-year cohort (for both Pinnacles and other MoM THRs). Proportional hazards assumptions were assessed using Schoenfeld's residuals and satisfied. Multivariable models were adjusted for age, gender, BMI, ASA grade, indication, surgeon grade, femoral stem design, and bilateral MoM THRs.

For the 5-year cohort (for both Pinnacles and other MoM THRs), 5-year all-cause revision rates were calculated for each calendar year of implantation. The 5-year revision rate was calculated by dividing the total number of all-cause revisions by the total of the individual implant-years at risk in the 5-year cohort. The 5-year revision rate was expressed as the number of all-cause hip revisions per 1000 implant-years at risk.

Interrupted time-series analysis (longitudinal quasi-experimental design)[20] was used to assess the trends in six-monthly 5-year revision rates before 2007 and from 2007 onwards. This was performed for Pinnacles and other MoM THRs separately. Analyses were based on 6 pre-intervention data points (January 2004 to July 2006), and 8 post-intervention data points (January 2007 to July 2010). Segmented linear regression models were used to estimate changes in 5-year revision rates immediately after 2007. Controlling for baseline level and trend, the models estimate changes in levels and trends of rates after 2007. The regression model includes terms to estimate the pre-existing level for each rate in the first 6-months of the observation period (intercept), trend in the rate before the change in 2007, change in level of the rate after 2007, and change in trend after 2007. Regression diagnostics confirmed the underlying model assumptions, and that there was no evidence of serial autocorrelation (Durban-Watson test) and seasonality.[21]

Results

Whole Pinnacle cohort (11,826 hips)

All-cause revision surgery was performed in 1,190 (10.1%) hips at a mean time of 4.6 years (range 0.003-11.1 years) from arthroplasty. The commonest revision indication was adverse soft tissue reaction to particulate debris (48.6%) (Table 2). The mean follow-up time in 8,952 surviving non-revised hips was 7.7 years (3.4-12.6 years), with a mean time to death in 1,684 non-revised hips of 4.5 years (0.003-12.0 years). The cumulative all-cause 10-year revision rate was 15.2% (CI=14.2%-16.4%; 678 hips at risk at 10-years).

The association of the year of primary Pinnacle implantation on outcome was non-linear. This had the potential to violate the assumptions of the statistical analyses performed, including the requirement for a linear trend in the pre-2007 time period to undertake interrupted time series analysis. Specifically the few hips implanted in 2003 (n=48) had high revision rates (23.8% at 10-years), which were very different to the many other hips implanted before 2007. It was therefore necessary to group Pinnacle hips implanted in 2003 separately, to satisfy the model assumption of linearity. Pinnacles implanted in 2007-2012 had higher revision rates compared with those implanted in 2004-2006 (Hazard Ratio (HR)=1.21; CI=1.05-1.40; p=0.008) (Figure 1).

5-year Pinnacle cohort (10,776 hips)

In the 5-year cohort, 627 (5.8%) hips were revised for any indication at a mean time of 2.7 years (range 0.003-4.99 years) from arthroplasty (Table 1). The commonest revision indication was adverse soft tissue reaction to particulate debris (31.6%) (Table 2). The 5-year all-cause revision rate was 5.8% (CI=5.4%-6.3%).

5-year Pinnacle cohort: Cox regression analysis

Univariable analysis demonstrated that compared with primary Pinnacles implanted in 2004-2006, both hips implanted in 2007-2012 (HR=2.01; CI=1.57-2.57; p<0.001) and in 2003 (HR=4.57; CI=1.99-10.5; p<0.001) had significantly higher revision rates. Adjusting for all covariates (excluding BMI; n=10,776) in a multivariable model produced similar results: 2007-2012 (HR=2.22; CI=1.73-2.85; p<0.001) and 2003 (HR=2.44; CI=1.03-5.77; p=0.042). Adjusting for all co-variates (including BMI; n=4,446) in a multivariable model also produced similar results: 2007-2012 (HR=2.23; CI=1.42-3.51; p=0.001), with no hips in 2003 included due to missing BMI data. The inclusion of BMI in the model therefore did not change the findings.

As a sensitivity analysis, the multivariable model was repeated with the 1,345 Pinnacles implanted in 2006 excluded. This demonstrated that compared with primary Pinnacles implanted in 2004-2005, hips implanted in 2007-2012 continued to have significantly higher revision rates (HR=2.05; CI=1.46-2.87; p<0.001).

5-year Pinnacle cohort: Interrupted time-series analysis

For primary Pinnacles implanted between 2004 and 2010, the 5-year revision rate ranged from 5.74 (CI=2.39-13.8) all-cause hip revisions per 1000 implant-years at risk in 2004 to 14.6 (CI=12.6-17.0) all-cause hip revisions per 1000 implant-years at risk in 2009.

The interrupted time-series analysis assessed trends in the 5-year revision rate for primary Pinnacles implanted before 2007 and from 2007 onwards (Figure 2). For primary Pinnacles implanted before 2007 there was a non-significant downward trend in the 5-year revision rate over time ($p=0.773$). Immediately after 2007, the 5-year revision rate significantly increased by 5.20 (CI=0.52-9.89; $p=0.033$) compared with before 2007. For primary Pinnacles implanted from 2007 onwards there was a non-significant increasing trend in the 5-year revision rate ($p=0.450$), which demonstrated that the increase in revision rates occurring immediately after 2007 persisted in subsequent years.

5-year control group of all other MoM THRs (13,817 hips)

The 5-year control group included 13,817 other MoM THRs (Table 1), with 877 (6.3%) all-cause revisions at a mean time of 3.9 years (range 0.003-5.0 years) from arthroplasty.

Univariable Cox regression analysis demonstrated that compared with primary MoM THRs implanted in 2004-2006, primary MoM THRs implanted in 2007-2012 (HR=1.77; CI=1.49-2.10; $p<0.001$) had significantly higher revision rates. Adjusting for all covariates (excluding BMI; n=13,817) in a multivariable model produced similar results: 2007-2012 (HR=1.79; CI=1.51-2.13; $p<0.001$). Adjusting for all co-variates (including BMI; n=4,377) in a multivariable model produced similar results: 2007-2012 (HR=1.91; CI=1.23-2.98; $p=0.004$). The inclusion of BMI in the model therefore did not change the findings.

For primary MoM THRs implanted between 2004 and 2010, the 5-year revision rate ranged from 7.42 (CI=4.79-11.5) in 2005 to 17.8 (CI=15.1-21.0) in 2008. Interrupted time-series analysis demonstrated that primary MoM THRs implanted immediately before 2007 had a non-significant downward trend in the 5-year revision rate over time ($p=0.251$) (Figure 2). Immediately after 2007, the 5-year revision rate significantly increased by 6.13 (CI=1.42-10.83; $p=0.016$) compared with before 2007. For primary MoM THRs implanted from 2007 onwards there was a non-significant increasing trend in the 5-year revision rate ($p=0.241$), which demonstrated that the increase in revision rates occurring immediately after 2007 had persisted in subsequent years.

Discussion

Data from the world's largest arthroplasty registry demonstrated that all primary MoM THRs implanted from 2007 onwards had significantly higher five-year revision rates compared with those implanted before 2007. The finding was not specific to Pinnacle implants, and therefore does not currently support recent observations.[12, 17]

When assessing the effect of a time dependent variable (year of implantation) on revision rates it is necessary to control for the varying lengths of patient follow-up. In the 5-year cohort with a controlled follow-up time Pinnacles implanted from 2007-2012 had double the risk of revision compared with those implanted in 2004-2006, even when adjustment was made for potential confounders. The interrupted time-series analysis clearly demonstrated that immediately after 2007 there was a significant increase in revision rates for Pinnacles, with the 5-year revision rate almost doubling compared with Pinnacles implanted before 2007 (Figure 2). For primaries implanted from 2007 onwards there were no significant changes in subsequent revision rates, therefore the increase in revision rate occurring immediately after 2007 was sustained in future years. In isolation these observations support those from two recent studies.[12, 17] However analysis of a large control group of MoM THRs with non-Pinnacle cups was important to put the findings into context. This demonstrated that the findings for other MoM THRs implanted from 2007 onwards closely paralleled those in Pinnacles.

The universal increase in revision rates for all primary MoM THR designs implanted from 2007 onwards in a large registry cohort with controlled follow-up time is likely to be explained by more intensive patient surveillance in recent years as well as the progressive lowering of the threshold for performing revision. High revision rates for MoM THRs were first identified in ASR implants leading to a voluntary manufacturer recall and an alert from the Medical and Healthcare products Regulatory Agency (MHRA) in 2010.[1, 22] High revision rates were subsequently observed in other MoM THR designs.[2-4, 11] This led to another MHRA alert being issued in 2012, recommending that all patients with 36 mm or greater MoM THRs required a minimum of annual clinical surveillance, regardless of symptoms.[8] Some centres had routinely started investigating MoM THR patients earlier than 2012[12, 14] because of problems reported with hip resurfacings.[23, 24] Furthermore the poor short-term outcomes following MoM hip arthroplasty revision surgery performed for adverse reactions to metal debris (ARMD)[25, 26] led surgeons and worldwide regulatory authorities to widely recommend performing early revisions.[8-10, 25, 27] Surgeons subsequently adopted a lower threshold for performing revision surgery for ARMD in MoM hip arthroplasty patients, with evidence that this strategy can improve outcomes.[27, 28] It is important to recognise that as our study used a 5 year follow-up period from primary surgery, only the revision rates in the 2007 onwards group would have significantly been influenced by the increased surveillance and lowering of the revision threshold which largely occurred from 2012 onwards. It is also worth acknowledging that although the 2007 time point was of a-priori interest here, the data presented does also demonstrate a general trend of increasing revision rates with time for all MoM THRs recorded in the NJR (Figure 3). Regular patient surveillance, and lowering the revision threshold over time are again likely responsible for this.

A recent systematic review demonstrated that more intensive surveillance protocols (blood metal ions and cross-sectional imaging) were associated with the highest prevalence of ARMD revision surgery.[29] Given that most MoM THR patients will have undergone such intensive surveillance since 2012,[8] it would be expected that all primary MoM THRs implanted from 2007 onwards would have significantly higher 5-year revision rates compared with those implanted before 2007 that were not universally subjected to this follow-up. In addition to surveillance bias, the lowering of the threshold for performing revision has also been implicated in the increasing ARMD failure rates observed following MoM hip arthroplasty.[17, 30] A report on 1,429 hip resurfacings demonstrated that those implanted from 2007 onwards had a 2.4 times increased risk of ARMD revision compared with hip resurfacings implanted before 2007.[30] The present NJR findings in all MoM THRs supports recent observations in hip resurfacings.

Based on the current findings no changes to surveillance protocols for MoM THR patients are presently recommended.[8-10] However registries can underreport revisions,[31, 32] and they do not contain data on explant analyses. Hence if there truly was a widespread change in the Pinnacle manufacturing process that has the potential to influence revision rates, as suggested by implant retrievals,[12] then it may take time for this to be detected within the registry. Indeed it took some time for registries to detect problems with recalled ASR MoM hip arthroplasties.[8, 9, 11] Furthermore one study reported that the higher failure rates with more recent primary Pinnacles only became apparent between 4 and 8 years following arthroplasty.[17] This may not have been apparent in the present analysis because it was based on a cohort with 5-year follow-up. Therefore the NJR analysis should be repeated in future years to establish whether or not revision rates for Pinnacles implanted from 2007 onwards have substantially increased relative to other MoM THRs.

Study strengths include using a large unselected population (approximately 7% of all Pinnacles implanted worldwide),[12] which reduces the likelihood of sampling bias and increases generalisability of our findings. The large cohort ensures adequate statistical power when assessing revision rates in relation to year of primary MoM THR implantation. The

NJR uses linked data to capture revisions performed at different institutions, with almost complete compliance now reported.[11] This study was strengthened by having a large control group. Without this comparator group the findings would have been incorrectly interpreted.

Study limitations include using observational registry data, which means we cannot infer causality. However this work was undertaken specifically to assess whether the findings regarding year of implantation and failure rates were reproducible in a large population. Registries can also underreport arthroplasty failures, with a recent NJR implant retrieval validation study reporting that 23% of revisions performed were not on the NJR.[31, 32] Therefore our revision rates may be underestimated. Femoral component design was a potential confounder given that stem design usage with Pinnacles has varied over time (Appendix), and that the SROM has a higher revision rate compared with the Corail.[11] However femoral design was controlled for in the multivariable models, and did not change the findings. In line with worldwide usage,[2, 3, 11] small numbers of Pinnacles were implanted in 2003 and from 2011 onwards, therefore revision rates for these years could not be meaningfully assessed. Although revision rates have been reported per year of implantation this does not necessarily reflect year of manufacture. This may be most relevant in centres implanting smaller volumes.

Interrupted time-series analysis generally requires at least 8 pre-intervention and post-intervention data points,[33] and at least 100 observations at each time point,[34] to achieve an acceptable level of variability of the estimate at each time point. Whilst the number of observations available at each time point was high, we were limited by the number of pre-intervention time points. As it was not known exactly when potential changes in Pinnacle implant clearance occurred in 2006 it is possible that some implants with new clearance values were included in the pre-2007 group. This cut-off was chosen to ensure further power was not lost with the pre-intervention aspect of the time-series analysis. However it is clear that excluding the 2006 data points would not have changed the findings (Figures 2 and 3), which was confirmed in a multivariable model with 2006 Pinnacle implantations excluded. A fixed follow-up interval of five-years was chosen to reduce the bias when comparing revision rates between the Pinnacle and control groups, with similar methods being used previously.[17] However it is recognised that the revision rates by year of primary implantation in both the Kaplan Meier and interrupted time-series analyses will have been influenced by the external time dependent confounder of increased surveillance and lowering of the revision threshold in more recent years. This must be considered when interpreting our findings. It is also acknowledged that the control group was heterogeneous (included a variety of MoM THR implant designs and femoral head sizes) compared with the Pinnacle group. This was necessary to ensure adequate numbers for powering the study given the large Pinnacle group. However this is mitigated by all MoM THRs with 36 mm or larger femoral head sizes being treated differently from 2012 onwards, with increased surveillance and reduced thresholds for performing revision surgery. Finally, there is a potential for residual confounding in the analysis.

Conclusions

Data from the world's largest arthroplasty registry has demonstrated that five-year revision rates were significantly increased in all primary MoM THRs implanted from 2007 onwards compared with those implanted before 2007. The finding was not specific to Pinnacle implants, and therefore does not support recent concerns regarding potential changes in the Pinnacle device manufacturing process and higher revision rates in more recent years.[12, 1717] The observations in NJR data regarding the change in revision rates for all MoM THRs with time may be explained by more intensive patient surveillance and the progressive lowering of the threshold for performing revision surgery.

Take home message

Five-year revision rates were significantly increased in all primary MoM THRs implanted from 2007 onwards, and not just in Pinnacles. These observations may be explained by more intensive patient surveillance and the progressive lowering of the threshold for performing revision over time.

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Table 1 Demographics for patients receiving primary metal-on-metal total hip replacements

Covariate		Pinnacle 5-year cohort (10,776 hips)	Other MoM THR 5-year cohort (13,817 hips)
Gender	Female / Male	5,703 (52.9%) / 5,073 (47.1%)	6,640 (48.1%) / 7,177 (51.9%)
Age at primary	Mean (range) in years	65.4 (17 to 97)	60.9 (30 to 92)
Body mass index *	Mean (range) in kg/m^2	28.8 (16 to 60)	29.0 (16 to 60)
ASA grade	1 2 3 or above	1,953 (18.1%) 7,324 (68.0%) 1,499 (13.9%)	4,503 (32.6%) 8,233 (59.6%) 1,081 (7.8%)
Hip laterality	Unilateral / Bilateral MoM THR	9,076 (84.2%) / 1,700 (15.8%)	***
Year of primary	2003 2004 2005 2006 2007 2008 2009 2010 2011 2012	43 (0.4%) 178 (1.7%) 687 (6.4%) 1,345 (12.5%) 2,330 (21.6%) 2,826 (26.2%) 2,403 (22.3%) 961 (8.9%) ** **	227 (1.6%) 574 (4.2%) 1,276 (9.2%) 1,975 (14.3%) 3,016 (21.8%) 3,443 (24.9%) 2,191 (15.9%) 1,094 (7.9%) ** **
Year of primary (grouped)	2003 2004 to 2006 2007 to 2012	43 (0.4%) 2,210 (20.5%) 8,523 (79.1%)	227 (1.6%) 3,825 (27.7%) 9,765 (70.7%)
Hip diagnosis	Primary osteoarthritis / Other	10,222 (94.9%) / 554 (5.1%)	12,679 (91.8%) / 1,138 (8.2%)
Surgeon grade	Consultant / Other	9,019 (83.7%) / 1,757 (16.3%)	12,225 (88.5%) / 1,592 (11.5%)
Femoral stem	Corail / SROM	10,067 (93.4%) / 709 (6.6%)	****

ASA = American Society of Anesthesiologists; MoM THR = metal-on-metal total hip replacement

* Body mass index data was available for 4,446 hips (41.3%) in the Pinnacle cohort and 4,377 hips (31.7%) in the other MoM THR cohort.

** Data suppressed due to small count within the cell. The actual number was between 1 and 5.

******* Unable to determine hip laterality for this cohort given the dataset available.

******** Multiple implant combinations used so this information was not provided.

Table 2 Indications for all-cause revision surgery following 36mm metal-on-metal total hip replacement with Pinnacle cups

Indication for revision surgery	Number of revised hips with indication in whole cohort	Number of revised hips with indication in 5-year cohort
Adverse soft tissue reaction to particulate debris *	578 (48.6%)	198 (31.6%)
Pain	252 (21.2%)	153 (24.4%)
Aseptic loosening	202 (17.0%)	118 (18.8%)
Other	178 (15.0%)	122 (19.5%)
Dislocation / subluxation	96 (8.1%)	77 (12.3%)
Infection	93 (7.8%)	61 (9.7%)
Implant malalignment	76 (6.4%)	47 (7.5%)
Periprosthetic fracture	56 (4.7%)	32 (5.1%)
Lysis	46 (3.9%)	25 (4.0%)
Implant wear	44 (3.7%)	24 (3.8%)
Implant fracture	14 (1.2%)	9 (1.4%)
Head / Socket mismatch	8 (0.7%)	**

One or more indications may be selected for each hip undergoing revision.

A number of the revision indications (aseptic loosening; implant malalignment; periprosthetic fracture; lysis; implant fracture) can include a problem on either the femoral side or the acetabular side or both sides.

* Adverse soft tissue reaction to particulate debris was only introduced as a revision indication for surgeons to select from June 2008 onwards.

** Data suppressed due to small count within the cell. The actual number was between 1 and 5.

Appendix Table Femoral component design implantation over time for the whole Pinnacle cohort (11,826 hips)

Year of implantation	Corail stem	SROM stem
2003	2 (4.2%)	46 (95.8%)
2004	91 (48.2%)	98 (51.8%)
2005	649 (86.9%)	98 (13.1%)
2006	1,405 (95.6%)	64 (4.4%)
2007	2,404 (94.8%)	131 (5.2%)
2008	2,950 (95.9%)	126 (4.1%)
2009	2,454 (94.2%)	150 (5.8%)
2010	1,002 (94.8%)	55 (5.2%)
2011	91 (100%)	0 (0%)
2012	10 (100%)	0 (0%)

Percentages are for the number of specified femoral component designs implanted in each calendar year.

Figure legends

Figure 1 Cumulative all-cause revision rates following metal-on-metal total hip replacement with 36mm Pinnacle cups at up to 7-years following primary implantation for the whole cohort (11,826 hips)

95% confidence intervals have been omitted for clarity. The number of hips at risk at 7-years for each year primary implantation group were: 2003 = 34 hips; 2004-2006 =1,955 hips; 2007-2012 = 4,414 hips.

Figure 2 Trends in the 5-year all-cause revision rates at six-month intervals for 10,730 metal-on-metal total hip replacements with Pinnacle cups, and a control group of 13,817 other metal-on-metal total hip replacement designs.

The 5-year revision rate has been expressed as the number of all-cause hip revisions per 1000 implant-years at risk. Trends in 5-year revision rates were analysed using segmented linear regression. The year 2007 was chosen as the transition point given that this represents the first complete calendar year since potential changes in the Pinnacle manufacturing process were made.

Figure 3 Trends in the 5-year all-cause revision rates for all metal-on-metal total hip replacements with year of primary implantation.

The 5-year revision rate has been expressed as the number of all-cause hip revisions per 1000 implant-years at risk.