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A RETROSPECTIVE COHORT STUDY OF THE PERFORMANCE OF THE PINNACLE METAL ON METAL (MOM) TOTAL HIP REPLACEMENT: A SINGLE CENTRE INVESTIGATION IN COMBINATION WITH THE FINDINGS OF A NATIONAL RETRIEVAL CENTRE

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A RETROSPECTIVE COHORT STUDY OF THE PERFORMANCE OF THE PINNACLE METAL ON METAL (MOM) TOTAL HIP REPLACEMENT: A SINGLE CENTRE INVESTIGATION IN COMBINATION WITH THE FINDINGS OF A NATIONAL RETRIEVAL CENTRE

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Abstract

Objectives: To determine risk factors for revision in patients implanted with a commonly used metal on metal (MoM) hip replacement.

Design: Retrospective cohort study in combination with a prospective national retrieval study (Northern Retrieval Registry (NRR)).

Setting: Single centre orthopaedic unit in combination with the NRR.

Participants: All patients implanted with a DePuy Pinnacle MoM hip prostheses by one of the senior authors were invited to attend for a review which included clinical examination, blood metal ion measurements, radiographs and targeted imaging. Explanted components underwent wear analysis using validated methodology and these results were compared to those obtained from the NRR.

Results: 488 Pinnacle hips were implanted into 434 patients (243 females and 191 males). Of these, 352 patients attended the MoM recall clinics. 55 patients had died during the study period. For the purposes of survival analysis, non-attendees were assumed to have well-functioning prostheses. The mean follow up of the cohort as a whole was 86 months. 65 Pinnacles were revised and two listed for revision. Prosthetic survival for the whole cohort was 84.3%(80.7-88.0) at 9 years The majority of explanted devices exhibited signs of taper junction failure. Risk factors for revision were bilateral MoM prostheses, smaller Pinnacle shell sizes, and implantation in 2006 and later years. A significant number of devices were found to be manufactured out of their specifications. This was confirmed with analysis of the wider data set from the NRR.

Conclusions: This device was found to have an unacceptably high revision rate. Bilateral Pinnacles, those implanted into female patients and Pinnacles implanted in later years were found to be at greater risk. A significant number of explanted Pinnacles were found to be manufactured with bearing diameters outside of the manufacturer’s stated tolerances. Our findings highlight the clinical importance of hitherto unrecognised variations in device production.

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Article Focus

While the use of MoM hip devices has declined dramatically in the last five years, hundreds of thousands remain in situ. Greater understanding of the mechanisms of prosthetic failure could enable management strategies to be developed in accordance with local resources as well as helping to avoid potential problems with future designs.

This study sought to determine the risks and reason for early revision of a device used in large numbers across the world.

Strengths of the study

This is the first study to combine the results of a patient cohort with those obtained from a retrieval registry in order to better understand the performance of a device.

Previous studies of this device have reported results from centres with several surgeons and have not examined the impact of shell size on prosthetic survival nor considered variations in manufacturing processes.

Limitations of the study

The patient cohort was followed up retrospectively, with thirty patients lost to follow up.

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Background

There is general acceptance that large diameter metal on metal (MoM) total hip arthroplasty (THA) has not lived up to clinical expectations.[1][2][3][4] Although the use of MoM hip devices has declined dramatically in the last five years,[4] hundreds of thousands remain in situ,[5] with the long term future uncertain. Greater understanding of the mechanisms of prosthetic failure would enable management strategies to be developed in accordance with local resources as well as helping to avoid potential problems with future designs.

Failures of MoM hip arthroplasty have been attributed to:

1. Device related factors (design)[7]

2. Device related factors (manufacturing)[8]

3. Surgical factors[9]

4. Host factors[10]

1. Device factors (design): Previous publications have shown that the DePuy (Warsaw, Indiana, USA) ASR Hip System (which employs an identical taper connection to the DePuy Pinnacle system with respect to the metallurgy and morphology and which also utilises similar low diametrical clearance technology) failed because of: a shallow acetabular component (low coverage arc) predisposing to edge wear;[11] metal debris release from the head neck taper junction;[12] and low diametrical clearance leading to an increased propensity to edge wear[13] and cup loosening[14].

2. Device factors (manufacturing): We have previously presented evidence from the Northern Retrieval Registry that a number of ASR and Pinnacle components were manufactured out of specification in terms of undersized cups and oversized heads, with Pinnacles manufactured post 2006 significantly more likely to have a clearance value lower than stated to regulators.[8]

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3. *Surgical factors:* Cup orientation has been shown to affect wear rates/metal ion release in MoM arthroplasty[9] and devices with lower coverage arcs and sharper articular rims are particularly sensitive to cup position.[15]

4. Host factors: Our previous investigations and clinical experience have shown that: adverse reaction to metal debris (ARMD) is more common in devices with abnormal wear[16] however soft tissue damage is more strongly related to lymphocyte dominated reactions than wear rates;[17] women appear to more readily mount a negative immune cascade than males when exposed to equivalent loads of debris;[18] debris from a failing taper junction appears to be associated with a more intense inflammatory response than an equivalent dose from the bearing surface;[19] devices with no excessive wear with associated ARMD are commonly found in patients with bilateral devices implying a process of sensitisation (unpublished data).

The aim of this study was to identify variables associated with early failure of the Pinnacle 36mm MoM system by a retrospective analysis of all patients implanted with this device by two experienced hip surgeons at our institution. After consideration of the above factors we hypothesized:

1. Overall failure rates would be higher in female patients, those who received bilateral prostheses and in Pinnacles implanted from 2006 onwards.

2. Failures related to excessive bearing surface wear would be commonest in patients implanted with the smallest sized Pinnacle shells (ie thinnest liners).

3. Failures related to taper failure would be more common than those related to excessive bearing wear.

4. Failures related to taper malfunction would be more commonly found in patients with patients with Corail stems due to the negative effect of a short, ridged male taper.[20][21][22]

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5. The Pinnacle system would be relatively resistant to the effects of cup position in terms of blood metal ion release due to its smoother rim and greater arc of cover conferring protection from edge wear. By extension, ARMD would, in general, be unrelated to cup position.

Patients, Implants and Methods

A full MoM hip recall was commenced at our centre in 2010 however from 2008 we had been acutely aware of the possibility of ARMD,[16] with blood metal ion testing and cross sectional imaging used routinely. All patients implanted with MoM hip prostheses were invited to attend for a clinical review during which patients were examined and assessed using a Harris Hip Score questionnaire. Patients were identified using all available records including NJR reports, operating theatre lists and DePuy sales records. All patients were offered blood tests for serum and whole blood chromium (Cr) and cobalt (Co) measurements using high resolution ICPMS. EBRA analysis of standing radiographs was performed as previously described.[23] From this total group of patients, all those with a 36mm MoM Pinnacle hip which had been used in conjunction with an SROM or Corail uncemented stem were identified. From this sub group, only those whose components had been implanted by either of the two senior authors of this paper (RKL and AVFN) were included in this study. RKL and AVFN are both specialist consultant lower limb arthroplasty surgeons. The use of the SROM was dependant on two factors - time and complexity of surgery. Prior to 2005, patients under 70 were considered for a MoM THR using an SROM. From 2005 onwards the Corail was increasingly used, with the SROM reserved for more complex cases where there were concerns over anatomy (development dysplasia/Perthes').

A general protocol was put in place based on our clinical experience: patients with pain/discomfort underwent ultrasound scanning irrespective of blood metal ion results; patients with no pain and blood Co concentrations > 4µg/l underwent ultrasound examination; patients with pain and

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excessive ions OR pain and a significant volume of fluid/solid mass on ultrasound patient underwent hip joint fluid aspiration (which was performed to measure joint fluid metal ion concentrations and to identify infection). The patient was considered for revision surgery based on all of the above parameters.

The Pinnacle MoM total hip arthroplasty system

The Pinnacle shell is a porous coated titanium (Ti) alloy shell which accommodates the Ultamet metal liner which is available in varying thicknesses. The liner and femoral head are wrought high carbon content alloys. The clearance for this bearing surface is stated as 100µm ± 20µm. In this patient cohort a standard 36mm bearing diameter was used. The 160° sub-hemispherical bearing surface does not vary with the thickness of the liner. The femoral head is manufactured in two forms: The 11/13 for use with the SROM stem and the 12/14 head which can be used with the Corail stem. Both stems are uncemented stems and from the same Ti alloy.

Explant analysis

Explanted Pinnacle femoral head, head tapers and acetabular liners underwent dimensional and volumetric wear analysis using previously described methodology. The accuracy of these techniques has been discussed in detail in previous publications.[24][25] The retrieved explants were designated as exhibiting: "bearing failure" if the combined mean volumetric wear rate of the head and cup was measured as equal to or greater than $2mm^3$ per year[26] and the maximum wear depths were measured at the edge of the cup (edge wear); "taper failure" if material loss from the female taper surface was greater than or equal to $0.5mm^3$ and the pattern of material loss showed hallmark asymmetric distribution with an obvious circumferential trough of wear (*figure 1*);[27] "mixed failure" if both of the above characteristics were present; or "no abnormal wear".

The Northern Retrieval Registry (NRR) explant database

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The NRR collects explanted devices from several major hospitals in the North of England on a routine basis. The Pinnacle devices in this collection underwent the same evaluation as described above in order to determine trends in manufacturing and factors associated with taper failure.

Survival analysis

Joints were censored as "failed" if they had been revised or the patient had been listed for revision surgery at the time of writing. Joint survival analysis of the cohort as a whole was conducted initially to determine the predicted nine year survival of the male and female cohorts using Kaplan Meier analysis. Cox proportional hazards modelling was then used to analyse the effect of sex, age, implantation pre or post 2006, bilaterality, liner size, surgeon and stem type on risk of revision. The model was used initially to determine the risk of early revision/intention to revise for all cause clinical failure. The model was then repeated to determine the risk of biomechanical failure as determined by the results of the explant analysis ie the risk of revision associated with "bearing failure" and risk of revision associated with "taper failure". As liners of size 50mm were only introduced from 2008 onwards, and as we were investigating the effect of early versus late implantation, there was a concern over data bias. Hazards modelling was conducted using data only of patients who were followed up for at least six years or whose joints had failed before 6 years, resulting in the removal of 51 patients.

Results

In total 488 Pinnacle hips were implanted into 434 patients (243 females and 191 males). Of these, 352 patients attended the MoM recall clinics. 55 patients had died during the study period. For the purposes of survival analysis, non-attendees were assumed to have well-functioning prostheses. The mean follow up of the cohort as a whole was 86 months (*table 1*).

Table 1 – Patient demographics.

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	Corail Pinnacles	SROM Pinnacles
Patients	307	127
Joints	347	141
M:F joints	140:207	67:74
Number with bilateral MoMs	61 (19.9%)	14 (11%)
Mean age in years	67	63
% with degenerative osteoarthritis (%)	86.7%	80%
Median shell size in mm (range)	52 (50 – 66)	54 (50 – 66)
% x rays available	82.9%	77.3%

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Median inclination angle (°) of acetabular component (range)	43.9 (26.1 – 61.9)	45.6 (26.0 - 65.6)
Median anteversion angle of the acetabular component in degrees	14.4 (0 – 47.3)	18.6 (4.6- 45.6)
Median (range) femoral head offset	5 (-2 – +12)	6 (0 – 9)

The early (pre 2006) and late implantation cohorts are shown in *table 2*.

Table 2 – Patient demographics of the early versus the late implantation cohort.

	Pre 2006 (early cohort)	**2006 onwards (late)**
Joints	141	347

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M:F joints	74:67	133:214
Number bilateral MoMs	21 (14.9%)	80 (22.7%)
Corail:SROM	42:98	303:42
Mean age in years	62	67
Median shell size in mm (range)	54 (52 – 66)	52 (50 – 66)
Predicted joint survival/survival at 8 years	97.5%	81.1% (76.7 - 85.5)

At the time of writing, 65 Pinnacles had been revised and two were listed for revision (*table 3*).

Table 3: Details of revision cases.

Total number of joints revised	65

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Number listed for revision	2		
Mean time to failure (months)	53 (11.5 – 112)		
	Failed	**Non failed**	**Significance**
Males versus females	16 : 51	191:230	<0.001
Bilateral versus unilateral	27:40	82:339	<0.001
Median age	66	68	0.052
Median shell size male	55	56	0.591
Median shell size female	52	52	0.146
Median (range) acetabular inclination (°)	42.8 (32.5 – 55.9)	44.6 (26 – 65.6)	0.086
Median (range) acetabular anteversion (°)	12.5 (1.8 -34.8)	16.2 (0 - 47.3)	0.002
Median (range) blood Cr unilaterals (μg/l)	5.73 (0.88 – 14.2)	4.580 (0.37 – 20.3)	< 0001
Median (range) blood Co unilaterals (μg/l)	5.64 (0.8 – 27.0)	1.74 (0.33 – 22.13)	< 0.001

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Median (range) blood Cr bilaterals (µg/l)	6.16 (0.80 – 18.4)	9.62 (0.47 – 26.3)	0.001
Median (range) blood Co bilaterals (µg/l)	8.55 (0.86 – 27.0)	3.20 (0.33 – 22.1)	< 0.001
	Unilaterals	**Bilaterals**	**Significance**
Median (range) bearing surface wear rates (mm^3 per year)	1.55 (0.23 - 6.69)	0.72 (0.23 – 7.43)	0.005
Median (range) combined wear rates* (mm^3 per year)	2.05mm3 per year (0.35 – 6.75)	1.23mm3 per year (0.29 – 8.13)	0.014
	SROM Pinnacles	**Corail Pinnacles**	**Significance**
Median (range) female taper wear rates (mm^3 per year)	0.06mm (0.02 – 0.50)	0.15 (0 – 2.16)	0.002

All but one of the revisions were carried out for ARMD, with one revision for a loose cup. Prosthetic survival rate for the cohort as a whole was 84.3% at 9 years (80.7-88.0).

Explant analysis

Volumetric wear rates of the bearing and female taper surfaces are listed in *table 3.* Taper wear was associated with a larger female taper angle and an increased femoral head offset. A multiple regression model using the complete NRR dataset (*appendix 1*) showed however that duration in vivo and surface finish of the male and female taper surfaces were the dominant variables

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associated with taper wear. *Appendix 1* also provides a detailed analysis of the change in bearing dimensions over time, again derived from the NRR dataset.

Hypothesis 1: Failure rates would be higher in female patients and in those who received bilateral prostheses and in Pinnacles implanted from 2006 onwards

Female hips, with a predicted survival of 79.2% (73.7 – 84.7) at nine years had a significantly higher failure rate than male hips at the same length of follow up (male survival 91.3% (87.1 -95.4)) (p = 0.001)(*figure 2*). However, there were only 33 bilateral male hips compared to 76 bilateral female hips. Pinnacles in patients with bilateral MoM hips had a significantly lower survival rate than in patients with unilateral Pinnacles ((73.2% (64.2 – 82.1) versus 87.7% (83.8 - 91.5)(p<0.001)) at nine years respectively. Cox proportional hazards model identified only the presence of bilateral joints and the late cohort as significant risk factors for all cause revision however there was a trend towards increased risk of revision with smaller shell sizes (*table 4*).

Table 4: Cox proportional hazards model results with joints censored initially for all cause revision, then for "bearing failure" and "taper failure".

Proportional hazards model for all cause revision				
	Pr > Chi^2	Hazard ratio	Lower 95% CI	Upper 95% CI
Bilaterality	**<0.001**	**2.408**	**1.478**	**3.925**
Shell size	0.070	0.862	0.733	1.012
Surgeon	0.950	0.966	0.559	1.669
Age	0.229	0.984	0.959	1.010
Male sex	0.167	1.619	0.818	3.205
Corail stem	0.136	1.596	0.864	2.950
Early cohort	**0.002**	**0.096**	**0.022**	**0.424**
Proportional hazards model for revision associated with bearing failure				
Bilaterality	0.272	1.606	0.690	3.739
Shell size	**0.034**	**0.755**	**0.582**	**0.979**

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Surgeon	0.567	0.782	0.337	1.815
Age	0.130	0.980	0.959	1.005
Male sex	0.918	0.942	0.690	2.967
SROM stem	0.866	0.901	0.266	3.045
Early cohort	**0.003**	**0.041**	**0.005**	**0.327**
Proportional hazards model for revision associated with taper failure				
Bilaterality	**0.009**	**2.869**	**1.290**	**6.295**
Shell size	0.530	0.936	0.760	1.152
Surgeon	0.793	0.888	0.366	2.154
Age	0.980	0.980	0.940	1.023
Male sex	0.401	0.615	0.198	1.910
SROM stem	0.45	1.523	0.505	4.593
Early cohort	**0.033**	**0.936**	**0.760**	**1.152**

With this analysis repeated using shell sizes as categorical variables, shell sizes 50 and 52mm were found to be significant risk factors for early revision. To confirm the legitimacy of this model, a log rank test was performed between bilateral (n=47) and unilateral females (n=85) Corail Pinnacles of the commonest female shell size (52mm). The survival rate of the bilateral Pinnacles was significantly lower (61.6% (47.0 – 76.2) versus 85.7% (77.7 – 93.6) at nine years (p = 0.001). As sex and shell size were clearly correlated, the impact of shell size versus sex was further investigated by including only patients with shell sizes 52 and 54mm (the shell sizes with the most even distribution of male and female patients). Sex and bilaterality were the other categorical variables. This analysis again found that a smaller shell size had a greater impact on prosthetic failure than patient sex (shell size 54mm hazard ratio 0.452(0.181-1.130)(p=0.089) versus male sex HR 0.790 p = 0.593. This analysis found again that the presence of bilateral MoM prostheses was the biggest risk factor (HR 2.357 p = 0.005).

*2. <u>Failures related to **bearing failure** would be commonest in patients with smaller shell sizes</u>*

Larger shell sizes and earlier implantation were associated with a significantly reduced risk of revision (*table 4* and *figure 3*).

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*3. Failures related to **taper failure** would be more common than those related to excessive bearing wear*

50 of the 65 (77%) failures involved taper failure. 32 failures (49%) involved bearing failure. Volumetric wear results obtained from bearing and taper surface analyses are listed in *table 2*. Analysis of wear rates of explants retrieved from patients with bilateral MoM prostheses revealed a significantly lower median wear rate from the CoCr surfaces than in those retrieved from unilateral patients (*table 2*).

4. Failures related to taper failure would be more commonly found in patients with Corail stems. The Corail stem was not significantly associated with a greater or lesser risk of taper failure than the SROM stem. Only the presence of bilateral MoM joints and later implantation date were associated with a greater risk of revision associated with taper failure (*table 4*).

5. The Pinnacle system would be relatively resistant to the effects of cup position and ARMD would, in general, be unrelated to cup position.

The statistical analysis is described in detail in *appendix 1*. The variable with the greatest power to explain the variation in blood Co and Cr was shell size (*figure 4*). Shell size, duration from primary procedure to venesection and cup angles of inclination and anteversion were found to explain approximately only 12% of the variation in the Cr metal ion results and only 5% of the variation in the Co results. Patients with cups placed in accordance with the Pinnacle surgical manual[28] (40-45° inclination and 10-20° of anteversion) had a median Co concentration higher than all other unilateral patients (1.89µg/l versus 1.69µg/l p =0.445) and a significantly lower survival rate (69.9% (49.3 – 89.7) versus 82.7% (78.4 – 87%)) at nine years. (Where x rays were unavailable for analysis cup position was assumed optimal in order to provide worst outcome scenario for this patient group).

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Discussion

While the exact number of Pinnacle implantations is not publicly known, a rough estimate can be extrapolated from the information from DePuy sales records released in the ongoing ASR litigation proceedings.[29] Approximately 93,000 ASRs were sold globally, with around 6,000 reported in the NJR of England and Wales. The 2014 Annual NJR Report lists 11,871 Pinnacle implantations. If England and Wales represent the same proportion of Pinnacle as ASR implantations then it is not unreasonable to suggest that the Pinnacle MoM system has been implanted into over 180,000 patients globally, making it the most commonly used large diameter MoM THR in the world.

There is a sharp contrast between the reported performance of the Pinnacle in North America compared to Europe (*table 5*) (TABLE OVERSIZED – SEE EXTRA FILE). It is not clear why this is, although examination of the literature reveals an American preference for the use of CoCr uncemented stems and a heavier financial influence from manufacturers in American studies.[30] There appears to be a stricter consensus guidance directed follow up in Europe following a more aggressive management stance from European regulators such as the MHRA.[31] Pinnacles in the American studies were also, in general, implanted earlier. This is the first study of its kind to combine clinical data, blood ion concentrations and explant analysis in an attempt to better understand the performance of this widely used device.

Up until recently, the existing work on the Pinnacle focused mainly on blood ion concentrations rather than survivorship. Engh et al reported on metal ion concentrations in patients implanted with 36mm Pinnacle devices and compared them to the results of patients with 28mm Pinnacles.[32] In their comparison of the two groups the authors noted “Although it is reassuring that the levels were not different, the question remains why the 36mm MoM ion levels were not lower.” Accepted

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tribological theory indicates that the larger 36mm bearing should exhibit lower bearing wear rates due to an improved lubricating regime.[33] The same surgical group subsequently studied the incidence of adverse local tissue reactions in their patients. They described a survivorship analysis of their 945 36mm Pinnacle hips which revealed a 1% chance at three years that tissue retrieved at revision consistent with a reaction to a MoM bearing would be identified.[34]

More recently, Barrett et al published the results of a multicentre investigation into the incidence of Pinnacle revision for ARMD.[30] Barrett et al surmised that "the short-term results…. represent good survivorship and a low incidence of ARMD at up to 5-year follow-up." We have reservations about these conclusions as radiographic evaluation of postoperative cup inclination was obtained in only 420 (54%) of the 779 patients and in only 6 of 7 revision cases.

The survival rate of the Pinnacle at our unit (84.3% at nine years) is consistent with recent studies by investigators who conducted more rigorous follow up in keeping with consensus guidelines.[1] Matharu et al described a cumulative survival rate of the Corail Pinnacle system at eight years of 88.9% (78.5-93.4).[35] Most recently, Lainiala et al reported an overall survival rate of 86% (82-90) at nine years with the Pinnacle used primarily in combination with the Summit CoCr stem.[36] Both groups noted a trend, albeit a non-significant one, towards an increased failure rate in female patients. Unfortunately neither of the studies examined the impact of shell size on prosthetic survival. The absence of shell size as a risk factor in a statistical analysis may have reduced the impact of other variables, most notably the presence of bilateral MoM joints. This may provide some explanation for the differing conclusions between authors. Matters are further complicated however by the use of all Ti alloy stems in Matharu et al's study and predominantly CoCr stems in Lainiala et al's.

In the current paper, Corail stems were associated with greater blood Co concentrations and greater taper wear rates than SROMs (*appendices 1 and 2*). However, this did not equate to an increase in taper failure identified on explant analysis or revision rate. This result is at odds with DePuy's own

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internal studies which found a five year revision rate of the Corail Pinnacle of 14.1% versus 4.78% for the SROM Pinnacle.[37] We have yet to identify evidence of mechanically assisted crevice corrosion [38] - the classical theory of taper failure – and thus do not believe that a CoCr on CoCr head stem combination protects from this mode of failure. Mixed metallurgy therefore should not entirely explain the difference in failure rates between the North American and European studies. Indeed the high failure rate reported in Lainiala et al's study involved mainly patients with CoCr on CoCr taper connections. Other factors appear to be more important than stem type in the success or failure of the Pinnacle device.

An important consideration in the failure of the Pinnacle is that of variation brought about by manufacturing processes. Using a large collection of Pinnacle devices obtained via the Northern Retrieval Registry, we have previously reported that a number of Pinnacles were produced with diametrical clearances outside of the manufacturers' stated tolerances.[8] Components produced from 2006 onwards appeared to be the most commonly affected (*figure 5* and *appendix 2*). Lower clearances render bearings vulnerable to clamping/lubricant starvation should the cups deflect greater than expected when press fit into the acetabulum.[39] Even in the absence of frank clamping, liner distortion can alter the tribological properties of the bearings leading to increased wear.[40] Squire et al showed that Pinnacle Ti shells undergo large dimensional changes when press fit into the acetabulum.[39] They demonstrated that shells of size 50mm, 52mm and 54mm have similar stiffnesses, yet the corresponding liners have walls which decrease in thickness as shell sizes decrease. Smaller diameter liners therefore would likely be the most vulnerable to deflection and this is something we have shown in a small unpublished study using sawbones. Liner deflection may well explain why smaller Pinnacle shell sizes were associated with higher blood ion concentrations (*figure 4*) and a higher failure rate (*figure 3*).

We observed great variation (apparently random, varying between batches) in the as manufactured surface finish of the female taper surfaces. Our unpublished work suggests that this surface finish, as

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is the case with male taper roughness, is a critical factor in material loss at this junction (*see appendix 2*). Without a large number of sterile implants from the different years of manufacture however it is currently impossible to know whether variation in taper surface finishes in and of itself explains the difference in failure rates between the patient cohorts pre and post 2006.

We did not identify a strong relationship between Pinnacle cup orientation and blood ion concentrations in this large data set and we can conclude definitively that failures in this series were not brought about by inaccurate acetabular cup placement. These results are consistent with Matharu et al's [35], Smith et al's [41] and Laniala et al's [36]. There was however a trend towards larger blood Co concentrations with longer follow up and in patients implanted with Corail stems. This was not the case with respect to Cr. Increased Co concentrations relative to Cr are indicative of taper failure - direct physical evidence of which was obtained from explant analysis. This confirmed that in 50% of the explants there was no excessive wear from the bearing surfaces, yet taper failure had occurred in 50 of 65 retrieved Pinnacles. The five year follow up study on 36mm Pinnacle metal ions by the Engh group[42] found changes similar to ours – a Co level that rises significantly over time in the absence of a corresponding change in Cr. We believe that the patients in Engh's cohort are experiencing the phenomena we describe in this paper.

The issue of progressive taper damage over time is disturbing as smaller amounts of taper debris are associated with greater tissue damage than equivalent doses from the bearing surfaces.[19]We have stated on multiple occasions that total metal dose itself does not explain variation in soft tissue damage/extent of ARMD observation at revision surgery.[17] In fact, in our experience, a patient implanted with a prosthesis experiencing extremely high rates of volumetric wear with massive concentrations of metal ions in the periprosthetic tissue develop extensive soft tissue injury relatively infrequently.[18] Soft tissue damage is often associated with heavy lymphocyte infiltration and it is likely the immune response that is integral to the development of tissue necrosis rather than a direct toxic insult.[17] It is likely therefore that debris released from taper junctions is more

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immunogenic. We also found that patients with bilateral joints were at significantly greater risk of developing ARMD. This observation is also compatible with the process of a patient becoming sensitised to excessive metal debris from a malfunctioning joint, with a negative immune cascade precipitated by small amounts of metal generated from a well-functioning joint.[16]

Female patients were at greater risk of early device failure. This is a finding reported on multiple occasions by multiple sources.[10] Unfortunately, despite the standardisation of the bearing diameters in this study, the shell sizes and thus thicknesses of the liners were a critical confounding variable. Indeed the Cox proportional hazard model described herein to analyse the risk of bearing failure found that liner size and/or earlier year of liner manufacture was a greater threat to prosthetic survival than patient sex. This analysis needs to be repeated, ideally with National Joint Registry statistics.

Finally, a significant number of patients were lost to follow up. We have assumed in our survival analyses that these patients are asymptomatic at present. This is a major assumption and joint survival rates reported herein are likely to represent "best outcome scenario".

In summary, in patient cohorts undergoing contemporary MoM follow up, the Pinnacle MoM device has a high mid-term failure rate, meaning tens of thousands of patients around the world are at risk of early revision surgery. Optimal cup orientation does not afford protection to the patient. Presence of bilateral MoM prostheses appears to increase the risk of joint failure. Other risk factors appear to be smaller shell sizes and female sex. Variations in manufacturing may play a significant role in prosthetic failure and we recommend further investigation using larger data sets. Taper failure appears to be time dependent and a rising Co level should alert the clinician.

Author contributions:

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David Langton: Contributed to the conception and design of the study, acquisition and interpretation of the data, wrote the initial draft of the paper and gave final approval of the manuscript.

Raghavendra Prasad Sidaginamale: Contributed to the conception and design of the study, acquisition and interpretation of the data, revision of the initial drafts of the paper and gave approval of the final manuscript.

Peter Avery: Contributed to the conception and design of the study, acquisition and interpretation of the data, revision of the initial drafts of the paper and gave approval of the final manuscript.

Sue Waller: Contributed to the conception and design of the study, acquisition and interpretation of the data, revision of the initial drafts of the paper and gave approval of the final manuscript.

Tank Ghanshyabhai: Contributed to the conception and design of the study, acquisition and interpretation of the data, revision of the initial drafts of the paper and gave approval of the final manuscript.

Nick Cooke: Contributed to the conception and design of the study, acquisition and interpretation of the data, revision of the initial drafts of the paper and gave approval of the final manuscript.

Rajesh Logishetty: Contributed to the conception and design of the study, acquisition and interpretation of the data, revision of the initial drafts of the paper and gave approval of the final manuscript.

Antoni Viraf Francis Nargol: Contributed to the conception and design of the study, acquisition and interpretation of the data, revision of the initial drafts of the paper and gave approval of the final manuscript.

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DJL, AVFN and NJC all are retained experts for plaintiffs in ongoing metal on metal litigation. All other authors have no competing interests.

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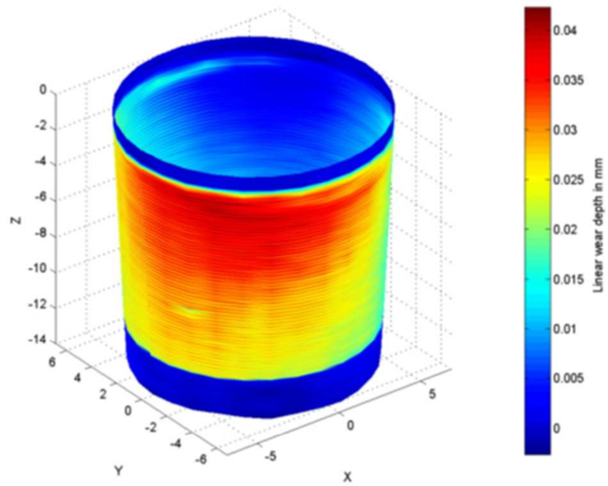

CMM generated wear map of a typical failed taper with a deep asymmetrical groove of wear corresponding to the base of the stem taper. In this case the Corail stem has imprinted its ridged form onto the female taper surface.
216x121mm (96 x 96 DPI)

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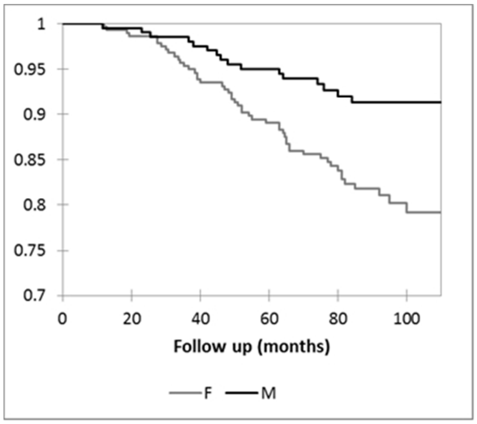

Kaplan Meier survival curve of male (M) and female (F) hips, all patients included in analysis.
216x121mm (96 x 96 DPI)

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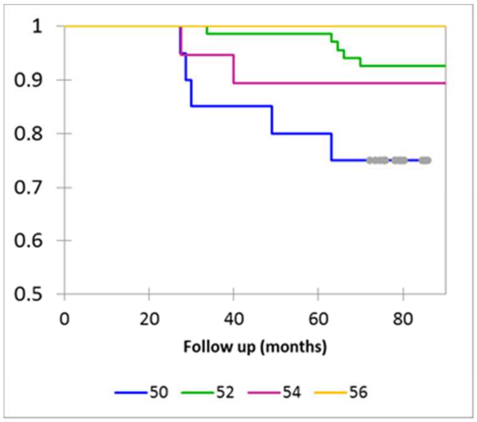

Kaplan Meier survival analysis of unilateral, female Corail Pinnacles split by shell size. All implantations from 2006 onwards. Size 50mm shell size was a significant risk factor compared to the other shells (hazard ratio 3.925 (1.925 – 12.374) (p = 0.020).
216x121mm (96 x 96 DPI)

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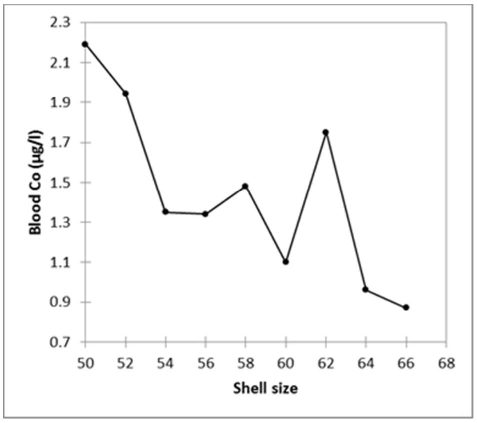

In this chart, unilateral patients were grouped according to shell sizes and the median Co concentration calculated and plotted.
216x121mm (96 x 96 DPI)

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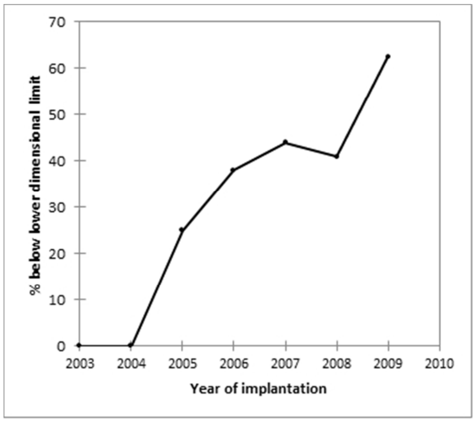

% of retrieved Pinnacle bearings which were measured to be below the lower tolerance limit for the diameter. All Pinnacle cups analysed to date at the Northern Retrieval Registry are included. Pre 2006 n = 41, 2006 onwards n = 106.
216x121mm (96 x 96 DPI)

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Appendix 1 - Blood metal ion concentrations

A total of 308 patients with unilateral prostheses gave blood samples for metal ion testing.

Male:female hips	129:179
Median (range) shell size in mm	52 (50 - 66)
Mean (range) age at primary	66 (40 -89)
Mean (range) time to venesection in months	52 (4 - 109)
Median (range) Co in µg/l	1.81(0.33 – 22.1)
Median (range) Cr in µg/l	4.82 (0.36 – 20.3)

All non-parametric data was log normalised. A multiple regression model was constructed in order to examine the effect of cup inclination/anteversion, shell size, duration from primary operation to venesection and stem type on blood Co and Cr concentrations in patients with a unilateral prosthesis.

The results of this analysis are shown below

For Co concentrations:

Source	t	Pr > |t|	Lower bound (95%)	Upper bound (95%)
Intercept	2.583	0.010	1.036	7.676
Log[inclination]	0.413	0.680	-0.546	0.836
Log[anteversion]	-1.758	0.080	-0.273	0.015
log [shell size]	-3.223	0.001	-4.709	-1.138
Log[duration]	3.129	0.002	0.174	0.765
Stem-CORAIL	2.798	0.006	0.046	0.267

Equation of the model: [Log]cobalt = 4.356 + 0.145*log[inclination]-0.128*log[anteversion]-2.923*log[shell size]+0.4696*log [duration]+0.1565*Stem-CORAIL

The resulting r squared value was 0.082 ($p < 0.001$) meaning that the regression model described herein only accounted for approximately 8% of the variation in Co concentrations. Smaller shell sizes, longer duration from primary to venesection, and Corail stems were significantly associated with greater Co concentrations.

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For Cr concentrations:

Source	t	Pr > |t|	Lower bound (95%)	Upper bound (95%)
Intercept	3.258	0.001	1.560	6.326
Log[inclination]	2.378	0.018	0.103	1.095
Log[anteversion]	-3.505	0.001	-0.288	-0.081
log [shell size]	-3.351	0.001	-3.463	-0.900
Log[duration]	-1.646	0.101	-0.389	0.035
Stem-CORAIL	0.412	0.681	-0.062	0.096

Equation of the model: Log[chromium] = 3.943+0.5992*log[inclination]-0.1842*[log anteversion]-2.1815*log[shell size]-0.1771*log [duration]+1.6538E-02*Stem-CORAIL

The resulting r squared value was 0.120 (p < 0.001) meaning that the regression model described herein accounted for approximately 12% of the variation in Cr concentrations. Smaller shell sizes, higher inclination angles and lower anteversion angles were significantly associated with greater Cr concentrations.

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Appendix 2: Explant analysis

Female taper surface analysis

A multiple regression model was constructed in an attempt to explain the variation in volumetric wear of the female taper surface. The variables under investigation were: duration in vivo; femoral head offset; Rpk (all logged values) and stem type (SROM versus Corail).

This model provided an explanation for approximately 43% of the variation in logged values of taper wear ($p<0.001$), with longer duration in vivo, the Corail stem, larger Rpk values and femoral head offset all associated with increased material loss from the femoral head taper surface.

Source	t	Pr > |t|	Lower bound (95%)	Upper bound (95%)
Duration in vivo	2.718	0.008	0.002	0.013
Head offset	3.176	0.002	0.022	0.095
Rpk	3.384	0.001	0.054	0.207
Corail stem	3.892	0.000	0.258	0.797

There was great variation in the surface roughness of the original as manufactured form of the female taper surface. This original surface is easily identified as in the majority of tapers there is a distal portion which lies beyond the trunnion engagement area. The Rpk value (the reduced peak height), which is the average height of the protruding peaks above the roughness core profile (in layman's terms is how "mountainous" a manufactured surface is) - was an important factor associated with material loss. *This manufacturing variation was apparently random and was not consistently linked to date of manufacture.*

Appendix 1 figure 1: Profilometry trace of unworn surface of female taper of Pinnacle head implanted in 2008. Rpk = 0.310, Ra = 0.261. Note that all profilometry traces shown in figures 1 2 and 3 are shown with the same scale. In the explanted components in this study, approximately 25% of Pinnacle 12/14 heads were found to have the following surface profile (all images which follow were taken at the same level of magnification):

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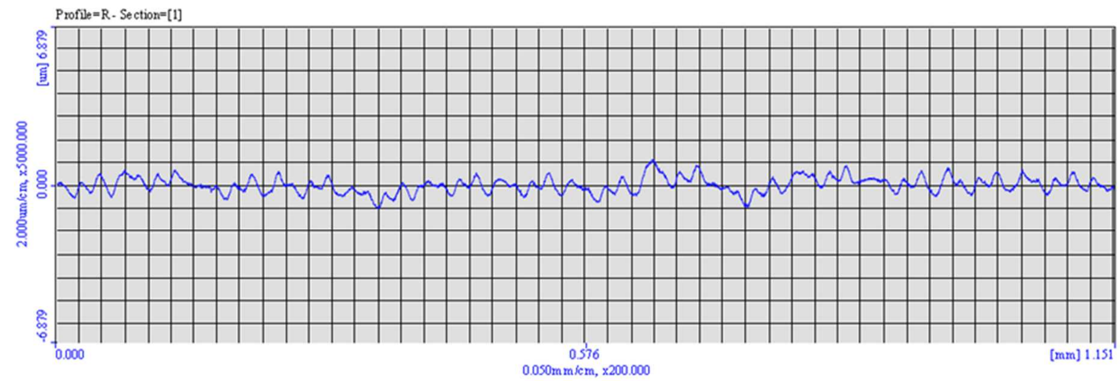
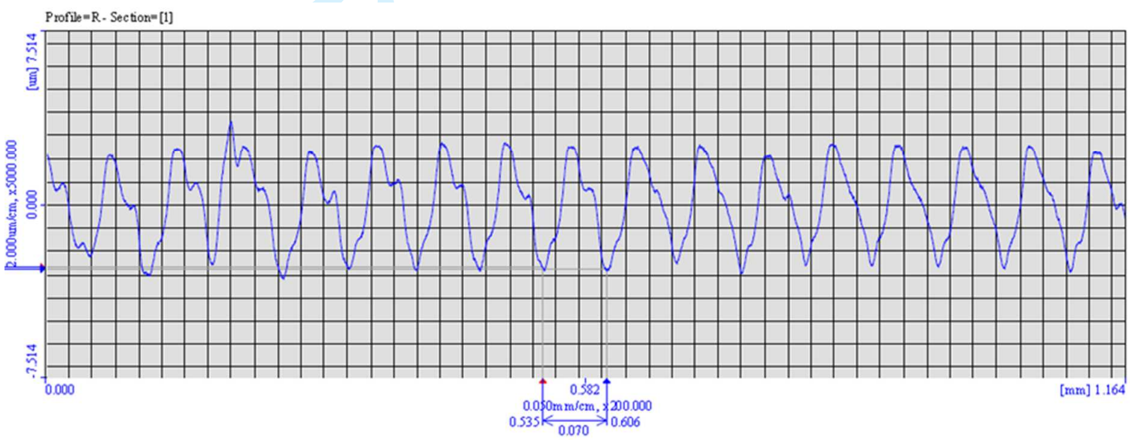
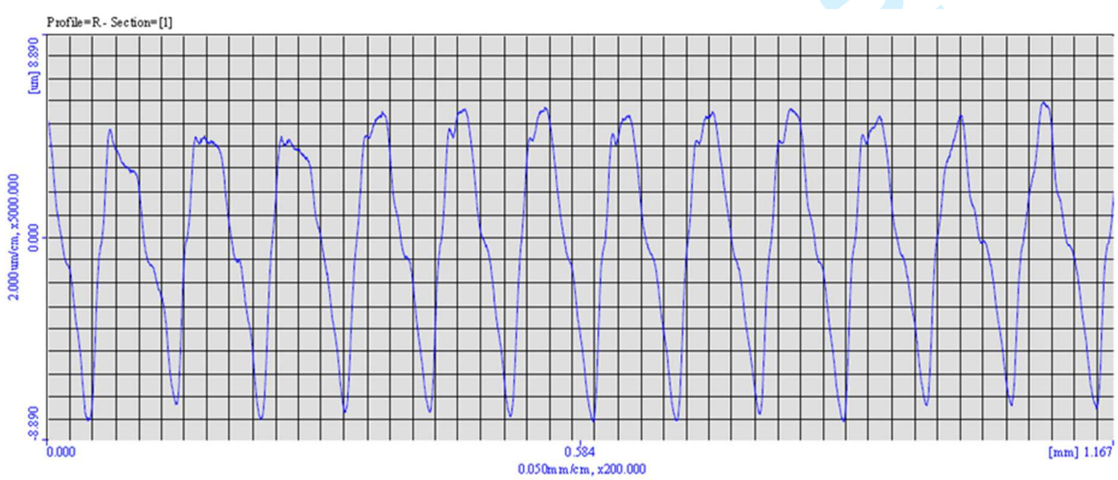


Appendix 2 figure 2: Profilometry trace of unworn surface of female taper of Pinnacle head implanted in 2006. Ra = 1.609, Rpk = 0.946. Approximately 25% of female tapers were finished in this way:



Appendix 3, figure 3: Profilometry trace of unworn surface of female taper of Pinnacle head implanted in 2006. Ra = 3.158, Rpk = 2.369. This head trace is typical of those with the largest 25% Rpk values.



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Dimensional Assessment of Bearing Diameters

Note: "date of implantation" is a reliable indicator of date of manufacture (correlation of 0.90 with lot number). As liners that are not extracted from shells during explanation do not allow the lot number to be visualised, date of implantation was therefore used as the continuous variable as a surrogate for the date of manufacture.

Liners:

For this analysis, all explanted Pinnacle devices received at Newcastle University and North Tees Explant centre were included. There were a total of 144 explanted Pinnacle cups. Cup diameters were non-normally distributed (p<0.001).

Year of implantation	Number of explanted liners	Number of explanted liners retrieved in shell
2003	4	3
2004	6	7
2005	11	9
2006	27	6
2007	21	14
2008	17	9
2009	8	0
2010	1	0
2011	1	0

It was apparent that there was trend towards smaller liner diameters with date of implantation, as can be seen in the chart below. The trend appeared to be exaggerated if the liner had been explanted still in its shell (red liners indicate upper and lower manufacturing tolerances):

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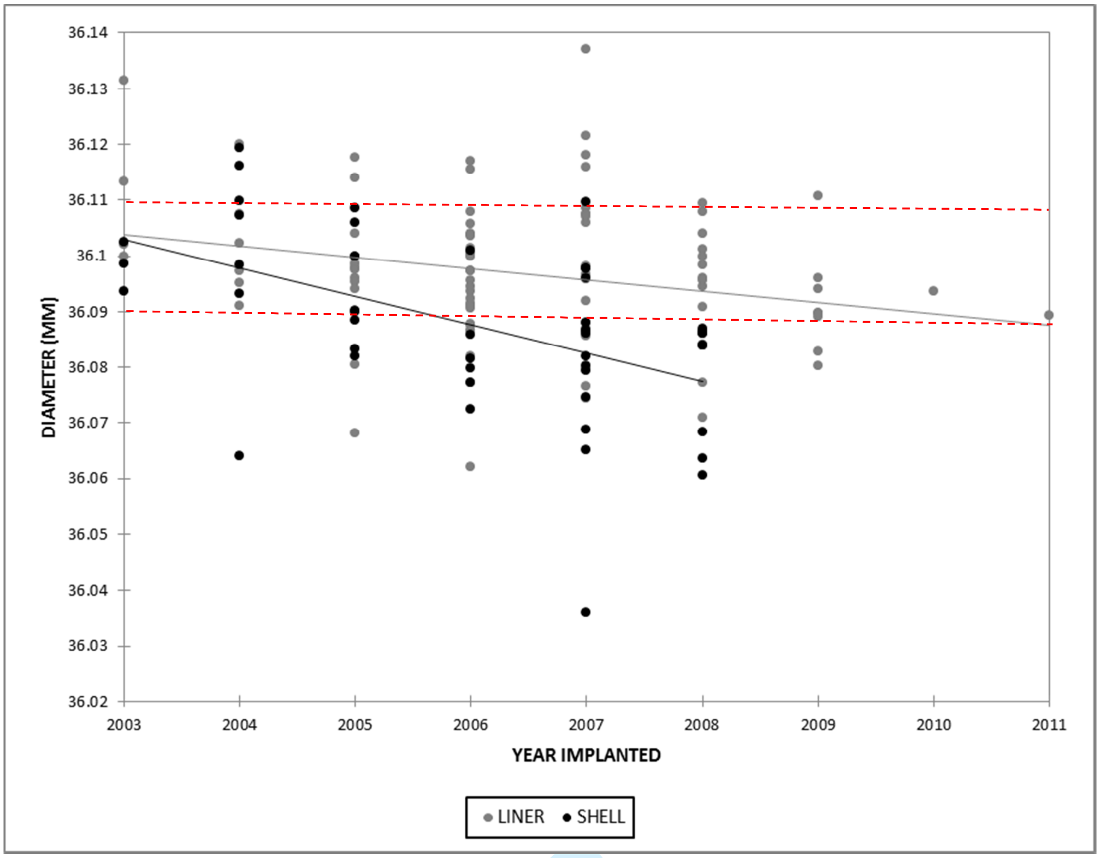

In order to investigate this relationship a multiple regression model was constructed. The year of implantation and shell size were the explanatory continuous variables and liner received in our out of its shell was the categorical variable. This model provided approximately 24% of the variation in the bearing surface, with later years of implantation and liner in shell significantly reducing the diameter (p<0.001).

Source	t	Pr > |t|	Lower bound (95%)	Upper bound (95%)
Shell size	-0.669	0.505	-0.211	0.104
Year implanted	-4.895	< 0.0001	-0.550	-0.233
Liner extracted	4.892	< 0.0001	0.221	0.520

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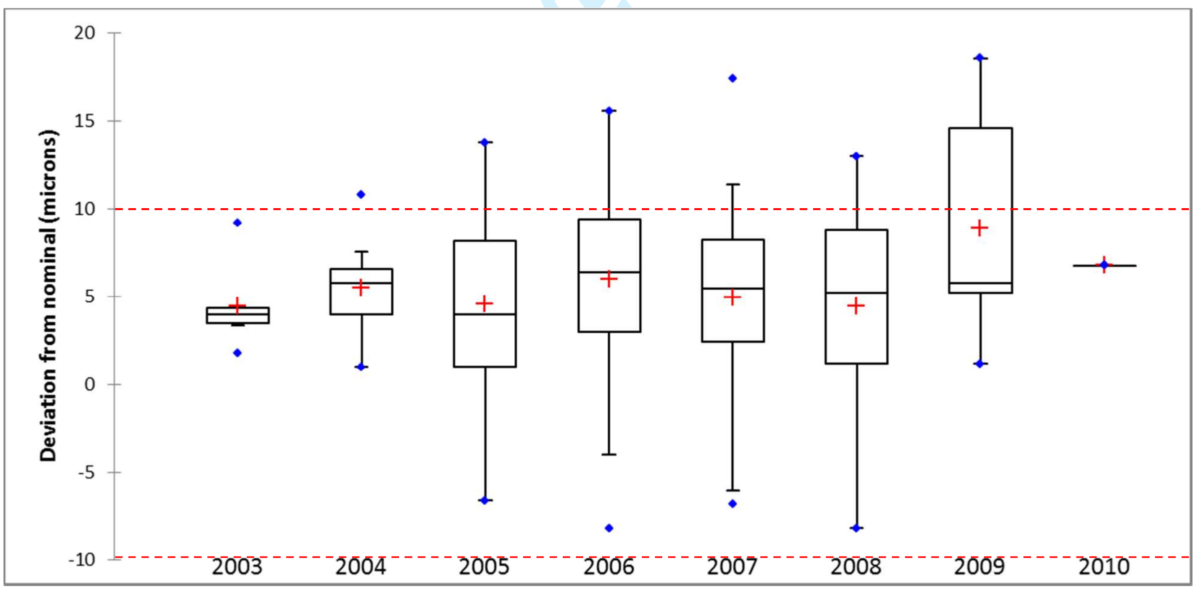
Femoral heads

147 Pinnacle heads were analysed. Head sizes were non-normally distributed (p<0.001) with a median diameter of 36.006 (6 microns larger than the nominal diameter of 36.000mm). Spearman rank correlation showed a significant positive trend towards increasing diameter with increasing lot number (ie Pinnacle diameters tended to be larger with more recent date of implantation (rank correlation 0.240 p = 0.005).

Year of implantation	Number of explanted Pinnacle heads
2003	6
2004	13
2005	20
2006	33
2007	40
2008	25
2009	9
2010	10

Below is a box and whisker chart which illustrates the deviation from nominal size in microns. The red lines indicate the upper and lower tolerance bands.



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Authors	Source	% 36mm diameter Pinnacles	Implantation date	Number of hips	Stems	Mean FU	Prospective	Blood Co > 5µg/l (%)	Survival	Risk factors (examined/positive)
Engh et al	USA	100%	2001-2002	131	AML/Prodigy (CoCr)	5 yrs	No	Not reported	98% at 5 yrs	Not examined
Engh et al	USA	100%	2003 -2005	32	AML/Prodigy (CoCr)	2 yrs (max)	Yes	Not reported	Not reported	Not examined
Antoniou et al[43]	Canada	100%	2005 - 2006	58	Prodigy (CoCr)	1yr	Yes	6.9%	Not reported	Not examined
Barrett et al	USA	98.8%	2001-2009	778	Endurance Prodigy Replica S-ROM AML Summit	4.2 yrs	Yes	Not reported	97% at 5 years	Not examined
Smith et al	Canada	Not reported	Not reported	16	Not reported	3.4 yrs	Yes	6.25%	Not reported	Not examined
Bernasek et al[44]	USA	86%	2001 - 2005	430	Summit (CoCr)	6.8yrs	No	Not reported	95.8% at 9 yrs	None
Liudahl et al[45]	USA	97%	2002 - 2006	169	Summit (CoCr)	4.7 yrs	Yes	Not reported	99.4% at 4 yrs	None
Matharu et al	Europe	97.6%	2004 -2010	578	Corail (Ti)	5 yrs	No	8.7% *above 7*	88.9 at 8 yrs	Sex p =0.053
Lainiala et al	Europe	100%	2002 -2010	430	Corail/SROM (Ti), Summit/Prodigy (CoCr)	7.5 yrs	No	16.1%	86% at 9 yrs	Gender;age;bilaterality;stem. Sex p =0.069
Langton et al	Europe	100%	2003 - 2009	488	Corail/SROM (Ti)	7.2 yrs	No	10.9%	84.3% at 9 yrs	Sex;age;stem;bilaterality;shell size;year of implantation

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A RETROSPECTIVE COHORT STUDY OF THE PERFORMANCE OF THE PINNACLE METAL ON METAL (MOM) TOTAL HIP REPLACEMENT: A SINGLE CENTRE INVESTIGATION IN COMBINATION WITH THE FINDINGS OF A NATIONAL RETRIEVAL CENTRE

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A RETROSPECTIVE COHORT STUDY OF THE PERFORMANCE OF THE PINNACLE METAL ON METAL (MOM) TOTAL HIP REPLACEMENT: A SINGLE CENTRE INVESTIGATION IN COMBINATION WITH THE FINDINGS OF A NATIONAL RETRIEVAL CENTRE

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Abstract

Objectives: To determine risk factors for revision in patients implanted with a commonly used metal on metal (MoM) hip replacement.

Design: Retrospective cohort study in combination with a prospective national retrieval study (Northern Retrieval Registry (NRR)).

Setting: Combined orthopaedic unit in combination with the NRR.

Participants: All patients implanted with a DePuy Pinnacle MoM hip prostheses by the two senior authors were invited to attend for a review which included clinical examination, blood metal ion measurements, radiographs and targeted imaging. Explanted components underwent wear analysis using validated methodology and these results were compared to those obtained from the NRR.

Results: 489 Pinnacle hips were implanted into 434 patients (243 females and 191 males). Of these, 352 patients attended the MoM recall clinics. 64 patients had died during the study period. For the purposes of survival analysis, non-attendees were assumed to have well-functioning prostheses. The mean follow up of the cohort as a whole was 89 months. 71 Pinnacles were revised. Prosthetic survival for the whole cohort was 83.6% (79.9-87.3) at 9 years. The majority of explanted devices exhibited signs of taper junction failure. Risk factors for revision were bilateral MoM prostheses, smaller Pinnacle liners, and implantation in 2006 and later years. A significant number of devices were found to be manufactured out of their specifications. This was confirmed with analysis of the wider data set from the NRR.

Conclusions: This device was found to have an unacceptably high revision rate. Bilateral Pinnacles, those implanted into female patients and Pinnacles implanted in later years were found to be at greater risk. A significant number of explanted Pinnacles were found to be manufactured with bearing diameters outside of the manufacturer's stated tolerances. Our findings highlight the clinical importance of hitherto unrecognised variations in device production.

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Article Focus

While the use of MoM hip devices has declined dramatically in the last five years, hundreds of thousands remain in situ. Greater understanding of the mechanisms of prosthetic failure could enable management strategies to be developed in accordance with local resources as well as helping to avoid potential problems with future designs.

This study sought to determine the risks and reason for early revision of a device used in large numbers across the world.

Strengths of the study

This is the first study to combine the results of a patient cohort with those obtained from a retrieval registry in order to better understand the performance of a device.

Previous studies of this device have reported results from centres with several surgeons and have not examined the impact of liner size on prosthetic survival nor considered variations in manufacturing processes.

Limitations of the study

The patient cohort was followed up retrospectively, with thirty patients lost to follow up.

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Background

There is general acceptance that large diameter metal on metal (MoM) total hip arthroplasty (THA) has not lived up to clinical expectations.[1][2][3][4] Although the use of MoM hip devices has declined dramatically in the last five years,[4] hundreds of thousands remain in situ,[5] with the long term future uncertain. Greater understanding of the mechanisms of prosthetic failure would enable management strategies to be developed in accordance with local resources as well as helping to avoid potential problems with future designs.

Failures of MoM hip arthroplasty have been attributed to:

1. Device related factors (design)[6,7]

2. Device related factors (manufacturing)[8]

3. Surgical factors[9]

4. Host factors[10]

1. Device factors (design): Previous publications have shown that the DePuy (Warsaw, Indiana, USA) ASR Hip System (which employs a similar taper connection to the DePuy Pinnacle system with respect to the metallurgy and morphology) failed because of: a shallow acetabular component (low coverage arc) predisposing to edge wear;[11] metal debris release from the head neck taper junction (figure 1);[12] and the same low diametrical clearance technology leading to an increased propensity to edge wear[13] and cup loosening[14]. Diametrical clearance is described in *figure 2.*

2. Device factors (manufacturing): The Northern Retrieval Registry (NRR), directed by one of the authors, analyses explanted devices from several major hospitals in the United Kingdom on a routine basis. During this analysis it was found that a number of Pinnacle devices were manufactured with lower diametrical clearances than was intended by the manufacturer. The rate of non-conformance appeared to increase over time, with Pinnacles manufactured from the year 2006 onwards

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significantly more likely to have a clearance value lower than stated to regulators. [15]These results are described in *figure 3* and in greater detail in Appendix 2.

3. *Surgical factors:* Cup orientation has been shown to affect wear rates/metal ion release in MoM arthroplasty[9] and devices with lower coverage arcs and sharper articular rims are particularly sensitive to cup position.[7]

4. Host factors: Our previous investigations and clinical experience have shown that: adverse reaction to metal debris (ARMD) is more common in devices with abnormal wear[16] however soft tissue damage is more strongly related to lymphocyte dominated reactions than wear rates;[17] women appear to more readily mount a negative immune cascade than males when exposed to equivalent loads of debris;[18] debris from a failing taper junction appears to be associated with a more intense inflammatory response than an equivalent dose from the bearing surface[19]. In our own experience, devices with no excessive wear with associated ARMD are commonly found in patients with bilateral devices implying a process of sensitisation.[20]

The aim of this study was to identify variables associated with early failure of the Pinnacle 36mm MoM system by a retrospective analysis of all patients implanted with this device by two experienced hip surgeons at our institution. After consideration of the above factors we hypothesized:

1. Overall failure rates would be higher in female patients, those who received bilateral prostheses and in Pinnacles implanted from 2006 onwards.

2. Failures related to excessive bearing surface wear would be commonest in patients implanted with the smallest sized Pinnacle shells (ie thinnest liners).

3. Failures related to taper failure would be more common than those related to excessive bearing wear.

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4. Failures related to taper malfunction would be more commonly found in patients with patients with Corail stems due to the negative effect of a short, ridged male taper.[21][22]

5. The Pinnacle system would be relatively resistant to the effects of cup position in terms of blood metal ion release due to its smoother rim and greater arc of cover conferring protection from edge wear. By extension, ARMD would, in general, be unrelated to cup position.

Patients, Implants and Methods

Patients implanted with a Pinnacle MoM hip prosthesis in our group of hospitals were identified using all available records including NJR reports, operating theatre lists and DePuy sales records. From this total group of patients, all those with a 36mm MoM Pinnacle hip which had been used in conjunction with an SROM or Corail uncemented stem were identified. From this sub group, only those whose components had been implanted by either of the two senior authors of this paper (RKL and AVFN) were included in this study (*figure 4*). RKL and AVFN are both specialist consultant lower limb arthroplasty surgeons. The use of the SROM stem was dependant on two factors - time and complexity of surgery. Prior to 2006, patients under 70 who were not suitable for resurfacing or patients of any age where there were concerns over anatomy (developmental dysplasia/Perthes'/SUFE/narrow femoral neck) were considered for a MoM THR using an SROM. The SROM has a modular junction which allows the surgeon to rotate the neck in order to compensate for variations in existing anatomy. From 2005 onwards the Corail was increasingly used, with the SROM reserved for the more complex cases. Operations were performed from 2003 to 2009 at two National Health Service (NHS) hospitals and one private unit. All bilateral replacements were performed sequentially. Patients were followed up annually in the NHS. At the private unit most patients were discharged after one year. From 2007 - 2011, as our awareness of ARMD began to increase[16], patients attending clinic who had developed symptoms were offered blood metal ion

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testing and ultrasound scanning if deemed necessary. From 2011 onwards, following general acceptance of widespread problems with MoM[1] a full recall of Pinnacle MoM patients was performed, which entailed Harris Hip Score evaluation, radiographs when necessary and routine testing of serum and whole blood chromium (Cr) and cobalt (Co) measurements using high resolution ICPMS. EBRA analysis of standing radiographs was performed as previously described[23].

A general protocol was put in place based on our clinical experience. This is described in *figure 5.* Ultrasound scans were performed by one senior musculoskeletal radiologist with extensive experience in the diagnosis of ARMD. Revision findings were recorded according to a gross scoring system we have previously used.[17] Likewise, histological findings were documented using previously published methods.[24]

The Pinnacle MoM total hip arthroplasty system

The Pinnacle shell is a porous coated titanium (Ti) alloy shell which accommodates the Ultamet metal liner which is available in varying thicknesses. The size of the implanted Pinnacle shell is largely dictated by the patient's anatomy. In this study, all patients received a standardised liner with a 36mm internal bearing surface. As shells become larger, because the mating liner is a standardised size, by necessity the wall of the liner must become thicker in order to press fit into the larger diameter shell (*figure 6*). The liner and femoral head are wrought high carbon content alloys. The clearance for this bearing surface is stated as 100µm ± 20µm. The 160° sub-hemispherical bearing surface does not vary with the thickness of the liner. The femoral head is manufactured in two forms: The 11/13 for use with the SROM stem and the 12/14 head which can be used with the Corail stem. Both stems are uncemented stems and from the same Ti alloy. The 11/13 head has a taper angle range of approximately 5.95 – 6.01 degrees. The equivalent range for the 12/14 head is 5.57 – 5.72 degrees.

Explant analysis

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Explanted Pinnacle femoral head, head tapers and acetabular liners underwent dimensional and volumetric wear analysis using previously described methodology. This was conducted by one of the authors (DJL) at Newcastle University and North Tees Explant Centre. The accuracy of these techniques has been discussed in detail in previous publications.[25] The retrieved explants were designated as exhibiting: "bearing failure" if the combined mean volumetric wear rate of the head and cup was measured as equal to or greater than $2mm^3$ per year[26] and the maximum wear depths were measured at the edge of the cup (edge wear); "taper failure" if material loss from the female taper surface was greater than or equal to $0.5mm^3$ and the pattern of material loss showed hallmark asymmetric distribution with an obvious circumferential trough of wear (*figure 1*);[27] "mixed failure" if both of the above characteristics were present; or "no abnormal wear".

The explant results presented in the main body of this paper represent only those derived from the failed prostheses of the patient group in this study. The results presented in *figure 2* and *Appendix 2* are generated from the pool of Pinnacle devices received at the NRR.

Survival analysis

Joints were censored as "failed" if they had been revised or the patient had been listed for revision surgery at the time of writing. Deceased patients were assumed to have a well-functioning joint at the time of death. Patient who were lost to follow up were also assumed to have well-functioning prostheses. Joint survival analysis of the cohort as a whole was conducted initially to determine the predicted nine year survival of the male and female cohorts using Kaplan Meier analysis. Differences in survival between groups were assessed for significance using the log rank test. Cox proportional hazards modelling was then used to analyse the effect of sex, age, implantation pre or post 2006, bilaterality, liner size, surgeon and stem type on risk of revision. The model was used initially to determine the risk of early revision for all cause clinical failure. The model was then repeated to

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determine the risk of biomechanical failure as determined by the results of the explant analysis ie the risk of revision associated with “bearing failure” and risk of revision associated with “taper failure”. As liners of size 50mm were only introduced from 2008 onwards, and as we were investigating the effect of early versus late implantation, there was a concern over data bias. Hazards modelling was therefore conducted using data only of patients who were followed up for at least six years or whose joints had failed before 6 years, resulting in the removal of 69 patients for all cause revision, 82 for revision in association with bearing failure and 90 for revision associated with taper failure (*figure 4*).

Ethics

Ethical approval for this study and the NRR data collection was given by the LREC County Durham and Tees Valley 2 under an extension of the existing project “The Assessment of Failed Hip Resurfacings” (reference number 09/H0905/41). It is hospital policy to consent patients prior to revision surgery for the storage and analysis of all explanted orthopaedic devices.

Results

In total 489 Pinnacle hips were implanted into 434 patients (243 females and 191 males). Of these, 352 patients attended the MoM recall clinics. 64 patients had died during the study period. For the purposes of survival analysis, non-attendees were assumed to have well-functioning prostheses. The mean follow up of the cohort as a whole was 89 months (*table 1*).

Table 1 – Patient demographics.

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	Corail Pinnacles	SROM Pinnacles
Patients	307	127
Joints	348	141
Surgeon 1 vs surgeon 2	254:94	120:21
M:F joints	140:208	67:74
Number with bilateral MoMs	87 (25.0%)	13 (9%)
Mean age in years	67	63
% with degenerative osteoarthritis (%)	86.7%	80%
Median liner size in mm (range)	52 (50 – 66)	54 (50 – 66)

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% x rays and HHS score available	82.9%	77.3%
Median inclination angle (°) of acetabular component (range)	43.9 (26.1 – 61.9)	45.6 (26.0 - 65.6)
Median anteversion angle of the acetabular component in degrees	14.4 (0 – 47.3)	18.6 (4.6 - 45.6)
Median (range) femoral head offset	5 (-2 – +12)	6 (0 – 9)

The early (pre 2006) and late implantation cohorts are shown in *table 2*.

Table 2 – Patient demographics of the early versus the late implantation cohort.

	Pre 2006 (early cohort)	2006 onwards (late)

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Joints	141	348
M:F joints	74:67	133:215
Number bilateral MoMs	21 (14.9%)	79 (22.7%)
Corail:SROM	44:97	304:44
Mean age in years	62	67
Median liner size in mm (range)	54 (52 – 66)	52 (50 – 66)
Predicted joint survival/survival at 8 years	94.1% (89.1 – 98.1)	81.1% (76.7 - 85.5)

At the time of writing, 71 Pinnacles had been revised (*table 3*).

Table 3: Details of revision cases. It can be seen that failed joints were more likely to have cups placed at lower angles of inclination and lower anteversion, though the positions in which they were placed would generally be regarded as acceptable. A full discussion of the implications of this finding

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is beyond the scope of this paper. It was a result however, which was in direct contrast to our previous findings with the ASR device.[15]

Total number of joints revised	71		
Mean time to failure (months)	52 (11.5 – 112)		
	Failed	**Non failed**	**Significance**
Males versus females	16 : 55	191:227	<0.001
Bilateral versus unilateral	24:47	76:342	<0.001
Median age	66	68	0.052
Median (range) HHS	66 (23 – 100)	91 (28 – 100)	<0.001
Median liner size male	55	56	0.591
Median liner size female	52	52	0.146
Median (range) acetabular inclination (°)	42.8 (32.5 – 55.9)	44.6 (26 – 65.6)	0.053
Median (range) acetabular	13.0 (1.8 - 34.8)	16.2 (0 - 47.3)	0.005

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anteversion (°)			
Median (range) blood Cr unilaterals (µg/l)	3.62 (0.88 – 26.2)	4.580 (0.37 – 20.3)	< 0.001
Median (range) blood Co unilaterals (µg/l)	3.62 (0.86 – 19.7)	1.48 (0.33 – 12.5)	< 0.001
Median (range) blood Cr bilaterals (µg/l)	9.72 (0.47 – 26.3)	6.15 (0.8 – 18.4)	0.001
Median (range) blood Co bilaterals (µg/l)	9.54 (1.42 – 27.0)	3.39 (0.33 – 22.1)	< 0.001
	Unilaterals	**Bilaterals**	**Significance**
Median (range) bearing surface wear rates (mm^3 per year)	1.92 (0.23 – 8.37)	0.88 (0.23 – 7.43)	0.007
Median (range) combined wear rates* (mm^3 per year)	2.19 (0.35 – 8.43)	1.57 (0.29 – 8.13)	0.038
	SROM Pinnacles	**Corail Pinnacles**	**Significance**
Median (range) female taper wear rates (mm^3 per year)	0.04 (0 – 0.50)	0.21 (0 – 2.20)	<0.001

All but one of the revisions were carried out for ARMD, with one revision for a loose cup. Prosthetic survival rate for the cohort as a whole was 83.6% (79.9-87.3) at 9 years. In only one case was no abnormal fluid identified at revision. In 53 cases (75%) copious amounts of fluid were found, and in

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32 (45%) it was noted to be under pressure or had fistulated through the capsule. Obvious damage to the abductor musculature was noted in 38 cases. Moderate to severe ALVAL was documented on examination of retrieved tissues in 36 cases (51%). In 13 cases (19%) histological findings were solely those of metallosis with no lymphocytic infiltration identified.

Explant analysis

Volumetric wear rates of the bearing and female taper surfaces are listed in *table 3.* Taper wear was associated with a female taper angle at the larger end of the device's tolerance band and an increased femoral head offset. A multiple regression model using the complete NRR dataset (*appendix 1*) showed however that duration in vivo and surface finish of the male and female taper surfaces were the dominant variables associated with taper wear. *Appendix 1* also provides a detailed analysis of the change in bearing dimensions over time, again derived from the NRR dataset.

Hypothesis 1: Failure rates would be higher in female patients and in those who received bilateral prostheses and in Pinnacles implanted from 2006 onwards

Female hips, with a predicted survival of 77.9% (72.2 – 83.6) at nine years had a significantly higher failure rate than male hips at the same length of follow up (male survival 91.4% (87.4 -95.5)) (p = 0.001)(*figure 7*). However, there were only 31 bilateral male hips compared to 69 bilateral female hips. Pinnacles in patients with bilateral MoM hips had a significantly lower survival rate than in patients with unilateral Pinnacles ((73.7% (64.4 – 82.9) versus 86.2% (82.2 - 90.2)(p<0.001)) at nine years respectively (*figure 8*). Cox proportional hazards model identified only the presence of bilateral joints and the late cohort as significant risk factors for all cause revision however there was a trend towards increasing risk of revision with smaller liner sizes (*table 4*).

Table 4: Cox proportional hazards model results with joints censored initially for all cause revision, then for "bearing failure" and "taper failure".

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Proportional hazards model for all cause revision (N=489)				
	Hazard ratio	Pr > Chi^2	Lower 95% CI	Upper 95% CI
Bilaterality	**2.408**	**<0.001**	**1.478**	**3.925**
liner size	0.862	0.070	0.733	1.012
Surgeon	0.966	0.950	0.559	1.669
Age	0.984	0.229	0.959	1.010
Male sex	1.619	0.167	0.818	3.205
Corail stem	1.596	0.136	0.864	2.950
Early cohort	**0.096**	**0.002**	**0.022**	**0.424**
Proportional hazards model for revision associated with bearing failure (N=407)				
Bilaterality	1.837	0.162	0.783	4.306
Liner size	**0.744**	**0.028**	**0.572**	**0.968**
Surgeon	0.742	0.498	0.337	1.815
Age	0.980	0.130	0.959	1.005
Male sex	0.922	0.889	0.690	2.967
SROM stem	0.901	0.866	0.266	3.045
Early cohort	**0.041**	**0.003**	**0.005**	**0.327**
Proportional hazards model for revision associated with taper failure (N=399)				
Bilaterality	**2.869**	**0.009**	**1.290**	**6.295**
Liner size	0.936	0.530	0.760	1.152
Surgeon	0.888	0.793	0.366	2.154
Age	0.980	0.980	0.940	1.023
Male sex	0.615	0.401	0.198	1.910
SROM stem	1.523	0.45	0.505	4.593
Early cohort	**0.936**	**0.033**	**0.760**	**1.152**

With this analysis repeated using liner sizes as categorical variables, liner sizes 50 and 52mm were found to be significant risk factors for early revision. To confirm the legitimacy of this model, a log rank test was performed between bilateral (n=45) and unilateral female (n=86) Corail Pinnacles of the commonest female liner size (52mm). The survival rate of the bilateral Pinnacles was significantly lower (63.1% (48.6 – 77.6) versus 84.9% (76.9 – 92.8) at eight years (p = 0.003). As sex and liner size were clearly correlated, the impact of liner size versus sex was further investigated by including only patients with unilateral joints with liner sizes 52 and 54mm (the liner sizes with the most even distribution of male and female patients). This analysis again found that a smaller liner size had a

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greater impact on prosthetic failure than patient sex (liner size 54mm hazard ratio 0.340(0.116-0.999)(p=0.050) versus male sex hazard ratio 1.082 (p = 0.859).

*2. Failures related to **bearing failure** would be commonest in patients with smaller liners*

Larger liners and earlier date of implantation were associated with a significantly reduced risk of revision (*table 4* and *figure 9*).

*3. Failures related to **taper failure** would be more common than those related to excessive bearing wear*

50 of the 71 (70%) failures involved taper failure. 34 failures (48%) involved bearing failure. Volumetric wear results obtained from bearing and taper surface analyses are listed in *table 2*. Analysis of wear rates of explants retrieved from patients with bilateral MoM prostheses revealed a significantly lower median wear rate from the CoCr surfaces than in those retrieved from unilateral patients (*table 2*).

4. Failures related to taper failure would be more commonly found in patients with Corail stems. The Corail stem was not significantly associated with a greater risk of taper failure than the SROM stem. Only the presence of bilateral MoM joints and later implantation date were associated with a greater risk of revision associated with taper failure (*table 4*).

5. The Pinnacle system would be relatively resistant to the effects of cup position and ARMD would, in general, be unrelated to cup position.

The statistical analysis is described in detail in *appendix 1*. The variable with the greatest power to explain the variation in blood Co and Cr was liner size (*figure 10*). Liner size, duration from primary procedure to venesection and cup angles of inclination and anteversion were found to explain approximately only 12% of the variation in the Cr metal ion results and only 5% of the variation in the Co results. Patients with cups placed in accordance with the latest version of the Pinnacle

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surgical manual[28] (40-45° inclination and 10-20° of anteversion) had a median Co concentration greater than all other unilateral patients (1.89µg/l versus 1.69µg/l p =0.445) and a significantly lower survival rate (69.9% (49.3 – 89.7) versus 82.7% (78.4 – 87%)) at nine years (where x rays were unavailable for analysis cup position was assumed optimal in order to provide the worst outcome scenario for this patient group).

Cumulative revision rates (for all cause revision) with numbers at risk in the various survival analyses described above are given in *Appendix 3*.

Discussion

While the exact number of Pinnacle implantations is not publicly known, a rough estimate can be extrapolated from the information from DePuy sales records released in the ongoing ASR litigation proceedings.[29] Approximately 93,000 ASRs were sold globally, with around 6,000 reported in the NJR of England and Wales. The 2014 Annual NJR Report lists 11,871 Pinnacle implantations. If England and Wales represent the same proportion of Pinnacle as ASR implantations then it is not unreasonable to suggest that the Pinnacle MoM system has been implanted into over 180,000 patients globally, making it the most commonly used large diameter MoM THR in the world.

There is a sharp contrast between the reported performance of the Pinnacle in North America compared to Europe (*table 5*). It is not clear why this is, although examination of the literature reveals an American preference for the use of CoCr uncemented stems and a heavier financial influence from manufacturers in American studies.[30] There appears to be a stricter consensus guidance directed follow up in Europe following a more aggressive management stance from European regulators such as the MHRA.[31] Pinnacles in the American studies were also, in general, implanted earlier. This is the first study of its kind to combine clinical data, blood ion concentrations and explant analysis in an attempt to better understand the performance of this widely used device.

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Authors	Source	% 36mm diameter Pinnacles	Implantation date	Number of hips	Stems	Mean FU	Prospective	Blood Co > 5µg/l (%)	Survival	Risk factors (examined/positive)
Engh et al	USA	100%	2001-2002	131	AML/Prodigy (CoCr)	5 yrs	No	Not reported	98% at 5 yrs	Not examined
Engh et al	USA	100%	2003 -2005	32	AML/Prodigy (CoCr)	2 yrs (max)	Yes	Not reported	Not reported	Not examined
Antoniou et al[43]	Canada	100%	2005 - 2006	58	Prodigy (CoCr)	1yr	Yes	6.9%	Not reported	Not examined
Barrett et al	USA	98.8%	2001-2009	778	Endurance Prodigy Replica S-ROM AML Summit	4.2 yrs	Yes	Not reported	97% at 5 years	Not examined
Smith et al	Canada	Not reported	Not reported	16	Not reported	3.4 yrs	Yes	6.25%	Not reported	Not examined
Bernasek et al[44]	USA	86%	2001 - 2005	430	Summit (Ti)	6.8yrs	No	Not reported	95.8% at 9 yrs	None
Liudahl et al[45]	USA	97%	2002 - 2006	169	Summit (Ti)	4.7 yrs	Yes	Not reported	99.4% at 4 yrs	None
Matharu et al	Europe	97.6%	2004 -2010	578	Corail (Ti)	5 yrs	No	8.7% *above 7*	88.9 at 8 yrs	Sex (p =0.053)
Lainiala et al	Europe	100%	2002 -2010	430	Corail/SROM/Summit (Ti), Prodigy (CoCr)	7.5 yrs	No	16.1%	86% at 9 yrs	Gender;age;bilaterality;stem. Sex (p =0.069)
Langton et al	Europe	100%	2003 - 2009	488	Corail/SROM (Ti)	7.2 yrs	No	10.9%	83.6% at 9 yrs	Sex;age;stem;bilaterality;liner size;year of implantation

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Up until recently, the existing work on the Pinnacle focused mainly on blood ion concentrations rather than survivorship. Engh et al reported on metal ion concentrations in patients implanted with 36mm Pinnacle devices and compared them to the results of patients with 28mm Pinnacles.[32] Accepted tribological theory indicates that the larger 36mm bearing should exhibit lower bearing wear rates due to an improved lubricating regime.[33] In their comparison of the two groups the authors noted: “Although it is reassuring that the levels were not different, the question remains why the 36mm MoM ion levels were not lower.” The same surgical group subsequently studied the incidence of adverse local tissue reactions in their patients. They described a survivorship analysis of their 945 36mm Pinnacle hips which revealed a 1% chance at three years that tissue retrieved at revision consistent with a reaction to a MoM bearing would be identified.[34]

More recently, Barrett et al published the results of a multicentre investigation into the incidence of Pinnacle revision for ARMD.[30] Barrett et al surmised that the results represented good survivorship and a low incidence of ARMD at up to five year follow-up. We have reservations about these conclusions as radiographic evaluation of postoperative cup inclination was obtained in only 420 (54%) of the 779 patients and in only 6 of 7 revision cases.

The survival rate of the Pinnacle at our unit (83.6% at nine years) is consistent with recent studies by investigators who conducted more rigorous follow up in keeping with consensus guidelines.[1] Matharu et al described a cumulative survival rate of the Corail Pinnacle system at eight years of 88.9% (78.5-93.4).[35] Most recently, Lainiala et al reported an overall survival rate of 86% (82-90) at nine years with the Pinnacle used primarily in combination with the Summit stem.[36] Both groups noted a trend, albeit a non-significant one, towards an increased failure rate in female patients. Unfortunately neither of the studies examined the impact of liner size on prosthetic survival. The absence of liner size as a risk factor in a statistical analysis may have reduced the impact of other

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variables, most notably the presence of bilateral MoM joints. This may provide some explanation for the differing conclusions between authors.

In the current paper, Corail stems were associated with greater blood Co concentrations and greater taper wear rates than SROMs (*appendices 1 and 2*). However, this did not equate to an increase in taper failure identified on explant analysis or revision rate. This result is at odds with DePuy's own internal studies which found a five year revision rate of the Corail Pinnacle of 14.1% versus 4.78% for the SROM Pinnacle.[37] We have yet to identify evidence of mechanically assisted crevice corrosion [38] - the classical theory of taper failure – and thus do not believe that a CoCr on CoCr head stem combination protects from this mode of failure. The use of mixed metallurgy hip systems therefore should not entirely explain the difference in failure rates between the North American and European studies. Other factors appear to be more important than stem type in the success or failure of the Pinnacle.

An important consideration in the failure of the Pinnacle is that of variation brought about by manufacturing processes. Using a large collection of Pinnacle devices obtained via the Northern Retrieval Registry, we have previously reported that a number of Pinnacles were produced with diametrical clearances outside of the manufacturers' stated tolerances.[8] Components produced from 2006 onwards appeared to be the most commonly affected (*figure 3* and *appendix 2*). Lower clearances render bearings vulnerable to clamping/lubricant starvation should the cups deflect greater than expected when press fit into the acetabulum.[39] Even in the absence of frank clamping, liner distortion can alter the tribological properties of the bearings leading to increased friction[40], which in turn renders a prosthesis susceptible to increased wear from the bearing or taper surfaces. Squire et al showed that Pinnacle Ti shells undergo large dimensional changes when press fit into the acetabulum.[39] They demonstrated that shells of size 50mm, 52mm and 54mm have similar stiffnesses, yet the corresponding liners have walls which decrease in thickness as shell sizes decrease. This can be seen clearly in *figure 6*. Smaller diameter liners therefore would likely be

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the most vulnerable to deflection and this is something we have shown in a small unpublished study using sawbones. Liner deflection may well explain why smaller Pinnacle liner sizes were associated with higher blood ion concentrations (*figure 10*) and a higher failure rate (*figure 9*).

We observed great variation (apparently random, varying between batches) in the as manufactured surface finish of the female taper surfaces. It appears that this surface finish, as is the case with male taper roughness, is a critical factor in material loss at this junction (*see appendix 2*). Without a large number of sterile implants from the different years of manufacture however it is currently impossible to know whether variation in taper surface finishes in and of itself explains the difference in failure rates between the patient cohorts pre and post 2006. At present there appears to be no clear relationship between date of manufacture and taper roughness. We therefore believe that the increased failure rate of the late cohort is more likely explained by the increasing tendency in later years to produce devices with very low clearances. This would have the knock on effect of placing the taper junction under greater stress from increased frictional forces generated from the bearing surfaces.

We did not identify a strong relationship between Pinnacle cup orientation and blood ion concentrations in this large data set and we can conclude definitively that failures in this series were not brought about by inaccurate acetabular cup placement. These results are consistent with Matharu et al's [35], Smith et al's [41] and Laniala et al's [36]. There was however a trend towards larger blood Co concentrations with longer follow up and in patients implanted with Corail stems. This was not the case with respect to Cr. Increased Co concentrations relative to Cr are indicative of taper failure - direct physical evidence of which was obtained from explant analysis. This confirmed that in 50% of the explants there was no excessive wear from the bearing surfaces, yet taper failure had occurred in 50 of 71 retrieved Pinnacles. The five year follow up study on 36mm Pinnacle metal ions by the Engh group[42] found changes similar to ours – a Co level that rises significantly over

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time in the absence of a corresponding change in Cr. We believe that the patients in Engh's cohort were experiencing the phenomena we describe in this paper.

The issue of progressive taper damage over time is disturbing as smaller amounts of taper debris are associated with greater tissue damage than equivalent doses from the bearing surfaces.[19]We have stated previously that total metal dose itself does not explain the variation in soft tissue damage/extent of ARMD observation at revision surgery.[17] In fact, in our experience, a patient implanted with a prosthesis experiencing extremely high rates of volumetric wear with massive concentrations of metal ions in the periprosthetic tissue develop extensive soft tissue injury relatively infrequently.[18] Soft tissue damage is often associated with heavy lymphocyte infiltration and it is likely the immune response that is integral to the development of tissue necrosis rather than a direct toxic insult.[17] It is likely therefore that debris released from taper junctions is more immunogenic. We also found that patients with bilateral joints were at significantly greater risk of developing ARMD. This observation is also compatible with the process of a patient becoming sensitised to excessive metal debris from a malfunctioning joint, with a negative immune cascade precipitated by small amounts of metal generated from a well-functioning joint.[20]

Female patients were at greater risk of early device failure. This is a finding reported on multiple occasions by multiple sources.[10] Unfortunately, despite the standardisation of the bearing diameters in this study, the shell sizes and thus thicknesses of the liners were a critical confounding variable. Indeed the Cox proportional hazard model described herein to analyse the risk of bearing failure found that liner size and/or earlier year of liner manufacture was a greater threat to prosthetic survival than patient sex. This analysis needs to be repeated, ideally with National Joint Registry statistics.

Finally, a significant number of patients were lost to follow up. We have assumed in our survival analyses that these patients are asymptomatic at present. This is a major assumption and joint survival rates reported herein are likely to represent "best outcome scenario".

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In summary, in patient cohorts undergoing contemporary MoM follow up, the Pinnacle MoM device has a high mid-term failure rate, meaning tens of thousands of patients around the world are at risk of early revision surgery. Optimal cup orientation does not afford protection to the patient. The presence of bilateral MoM prostheses appears to increase the risk of joint failure. Other risk factors appear to be smaller liner sizes and female sex. Variations in manufacturing may play a significant role in prosthetic failure and we recommend further investigation using larger data sets. Taper failure appears to be time dependent and a rising Co level should alert the clinician.

In general, however, the wear rates of the MoM bearing surfaces retrieved from patients in this series were low. Consistent with this observation we found that the clinical performance of unilateral Pinnacle hips produced before 2006 was extremely encouraging, providing some evidence that MoM technology can in certain circumstances be used successfully.

Author contributions:

David Langton: Contributed to the conception and design of the study, acquisition and interpretation of the data, wrote the initial draft of the paper and gave final approval of the manuscript.

Raghavendra Prasad Sidaginamale: Contributed to the conception and design of the study, acquisition and interpretation of the data, revision of the initial drafts of the paper and gave approval of the final manuscript.

Peter Avery: Contributed to the conception and design of the study, acquisition and interpretation of the data, revision of the initial drafts of the paper and gave approval of the final manuscript.

Sue Waller: Contributed to the conception and design of the study, acquisition and interpretation of the data, revision of the initial drafts of the paper and gave approval of the final manuscript.

Tank Ghanshyabhai: Contributed to the conception and design of the study, acquisition and interpretation of the data, revision of the initial drafts of the paper and gave approval of the final manuscript.

Nick Cooke: Contributed to the conception and design of the study, acquisition and interpretation of the data, revision of the initial drafts of the paper and gave approval of the final manuscript.

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Rajesh Logishetty: Contributed to the conception and design of the study, acquisition and interpretation of the data, revision of the initial drafts of the paper and gave approval of the final manuscript.

Antoni Viraf Francis Nargol: Contributed to the conception and design of the study, acquisition and interpretation of the data, revision of the initial drafts of the paper and gave approval of the final manuscript.

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Competing Interests:

DJL, AVFN and NJC all are retained experts for plaintiffs in ongoing metal on metal litigation. All other authors have no competing interests.

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Figure Legend

Figure 1: CMM generated wear map of a typical failed taper with a deep asymmetrical groove of wear corresponding to the base of the stem taper. In this case the Corail stem has imprinted its ridged form onto the female taper surface.

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Figure 2: A Pinnacle head and liner. The red arrows indicate the small gap between the head and the liner surface which is the “clearance”. Diametrical clearance is calculated by subtracting the diameter of the head from the diameter of the liner.

Figure 3. The diametrical clearances of all mated Pinnacle components (head and cup combinations) received at the NRR to present date. The red unbroken line represents the nominal target clearance with the outer broken red lines indicating the upper and lower tolerance bands. 5 out of the 43 (12%) hips implanted prior to 2006 were found to be below the lower tolerance band compared to 43 out of 118 (36%) implanted from 2006 onwards.

Figure 4. A flowchart to illustrate the subjects involved in the various survival analyses.

Figure 5. A flowchart to illustrate the investigation pathways for the subjects in the study.

Figure 6: The relationship between liner thickness and shell size. On the left the relatively thick liner of a 60mm prosthesis is seen in comparison with a 52mm liner. The head in both cases is the standard 36mm diameter component. As can be seen on the right, liner walls become progressively thicker as the liner size increases.

Figure 7. Kaplan Meier survival curves of male and female hips, all patients included in analysis, all cause revision.

Figure 8. Kaplan Meier survival curves of unilateral versus bilateral Pinnacle prostheses, all patients included in analysis, all cause revision.

Figure 9. Kaplan Meier survival curves for Pinnacle hips implanted into female patients belonging to the late cohort (all cause revision).

Figure 10: In this box and whisker chart, unilateral patients were grouped according to liner sizes and the blood Co distributions plotted (blood Co concentrations measured in µg/l).

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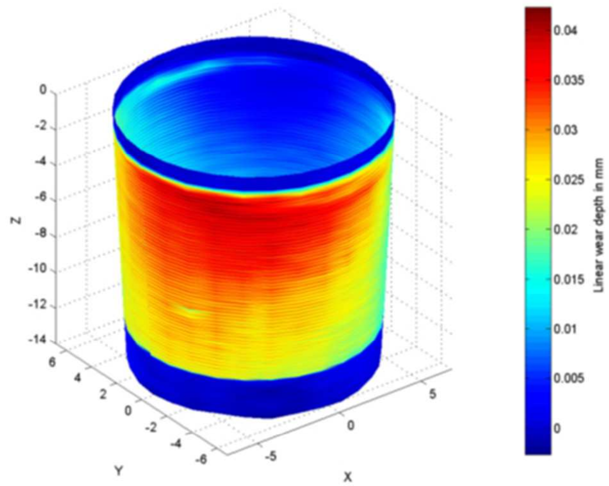

CMM generated wear map of a typical failed taper with a deep asymmetrical groove of wear corresponding to the base of the stem taper. In this case the Corail stem has imprinted its ridged form onto the female taper surface.
216x121mm (96 x 96 DPI)

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Figure 2: A Pinnacle head and liner. The red arrows indicate the small gap between the head and the liner surface which is the "clearance". Diametrical clearance is calculated by subtracting the diameter of the head from the diameter of the liner.
359x289mm (96 x 96 DPI)

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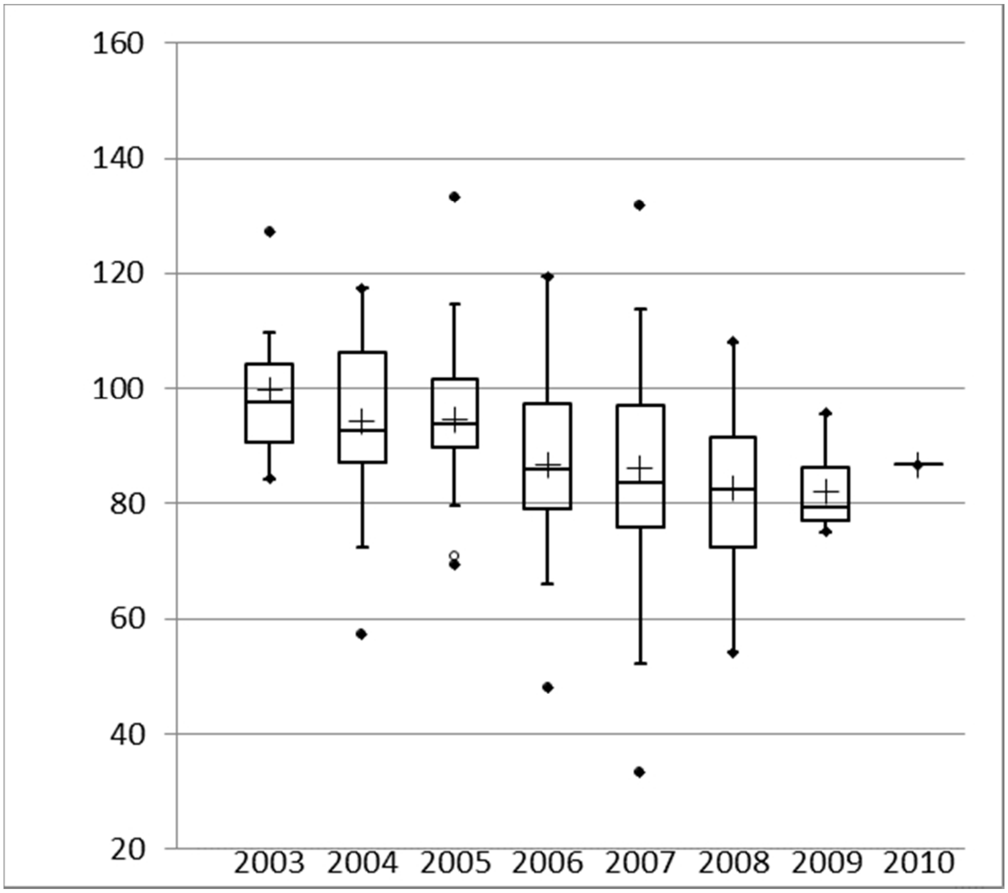

Figure 3. The diametrical clearances of all mated Pinnacle components (head and cup combinations) received at the NRR to present date. The red unbroken line represents the nominal target clearance with the outer broken red lines indicating the upper and lower tolerance bands. 5 out of the 43 (12%) hips implanted prior to 2006 were found to be below the lower tolerance band compared to 43 out of 118 (36%) implanted from 2006 onwards.

101x90mm (150 x 150 DPI)

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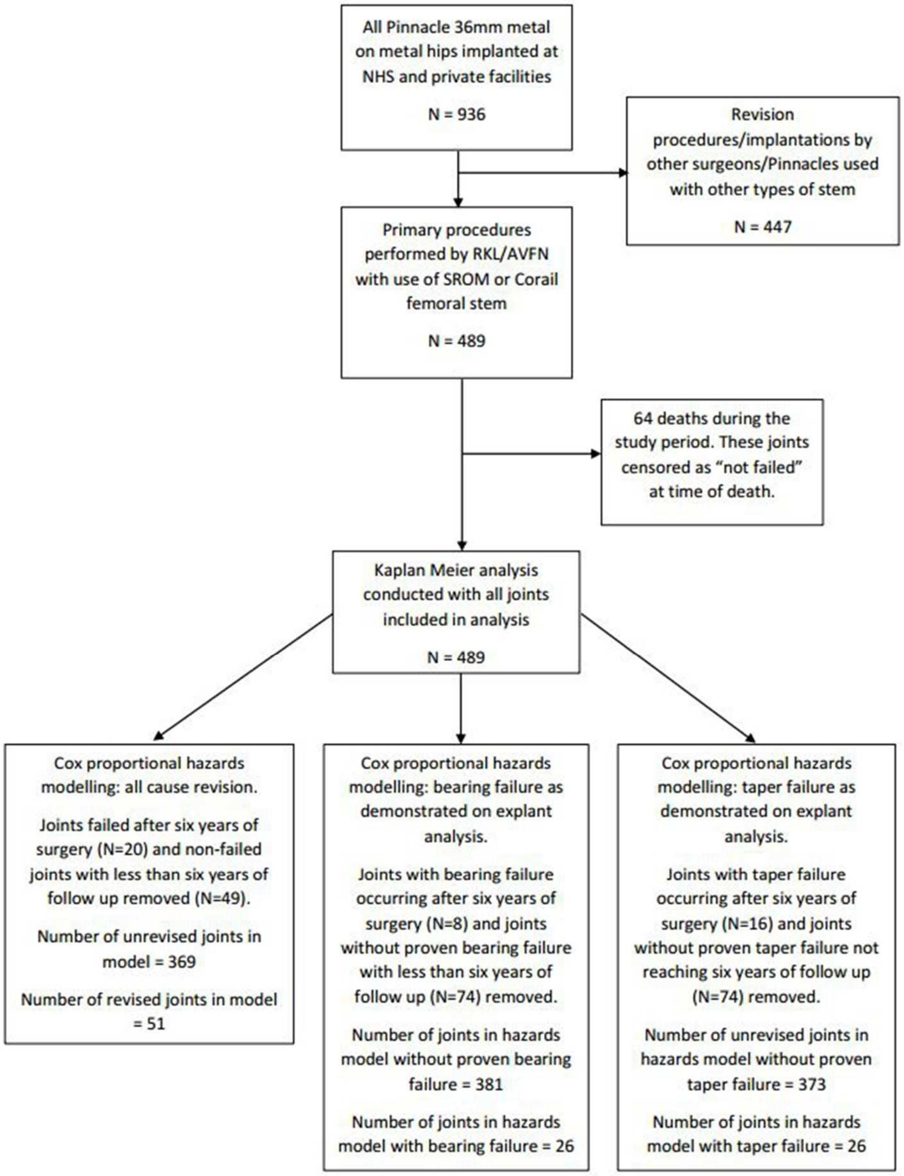

Figure 4. A flowchart to illustrate the subjects involved in the various survival analyses.
179x225mm (96 x 96 DPI)

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Figure 5. Investigation flow chart. There have been slight modifications to the management of patients over the study period. Metal Artefact Reduction Sequence (MARS) MRI is now becoming more frequently used. Patients are also now offered revision if blood Co concentrations are found to be greater than 25μg/l, irrespective of symptoms.

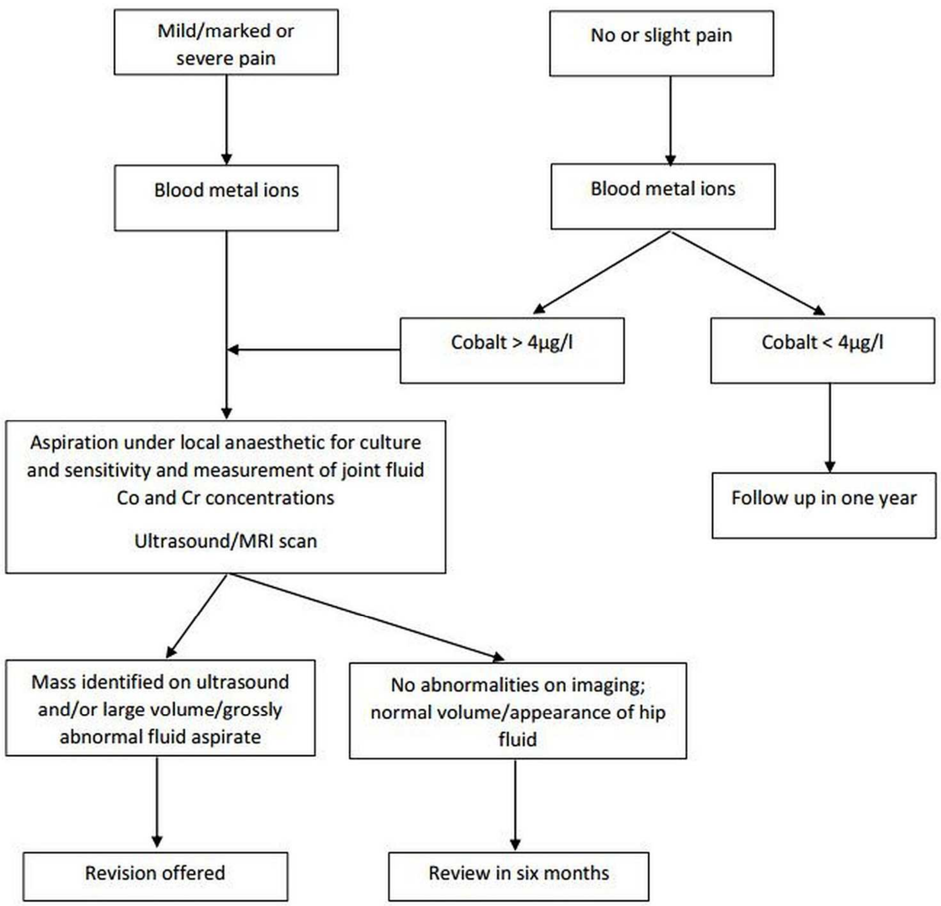

Figure 5. A flowchart to illustrate the investigation pathways for the subjects in the study.
182x196mm (300 x 300 DPI)

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Figure 6: The relationship between liner thickness and shell size. On the left the relatively thick liner of a 60mm prosthesis is seen in comparison with a 52mm liner. The head in both cases is the standard 36mm diameter component. As can be seen on the right, liner walls become progressively thicker as the liner size increases.
842x285mm (96 x 96 DPI)

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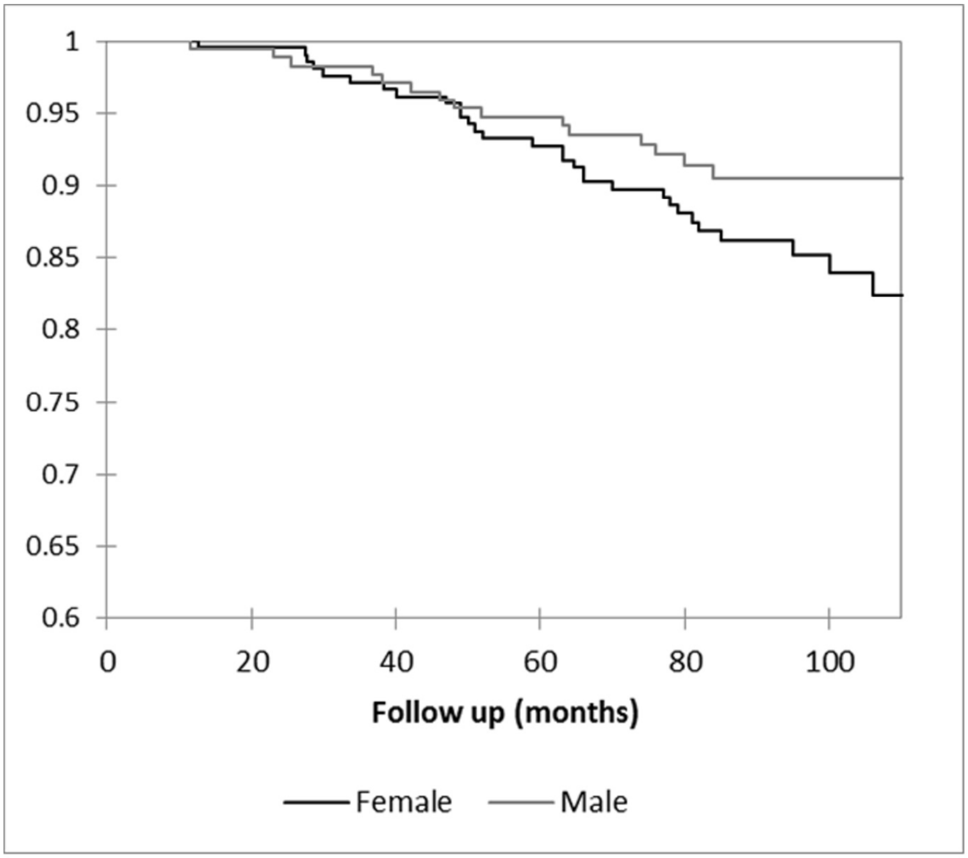

Figure 7. Kaplan Meier survival curves of male and female hips, all patients included in analysis, all cause revision.
376x330mm (96 x 96 DPI)

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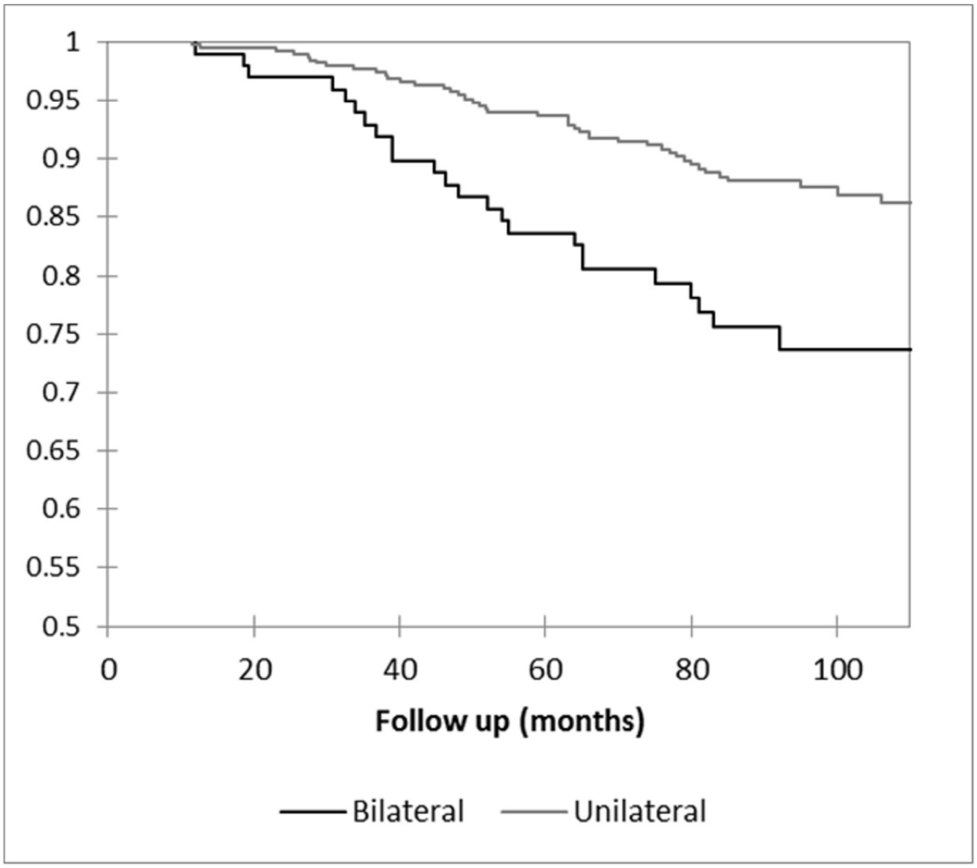

Figure 8. Kaplan Meier survival curves of unilateral versus bilateral Pinnacle prostheses, all patients included in analysis, all cause revision.
370x325mm (96 x 96 DPI)

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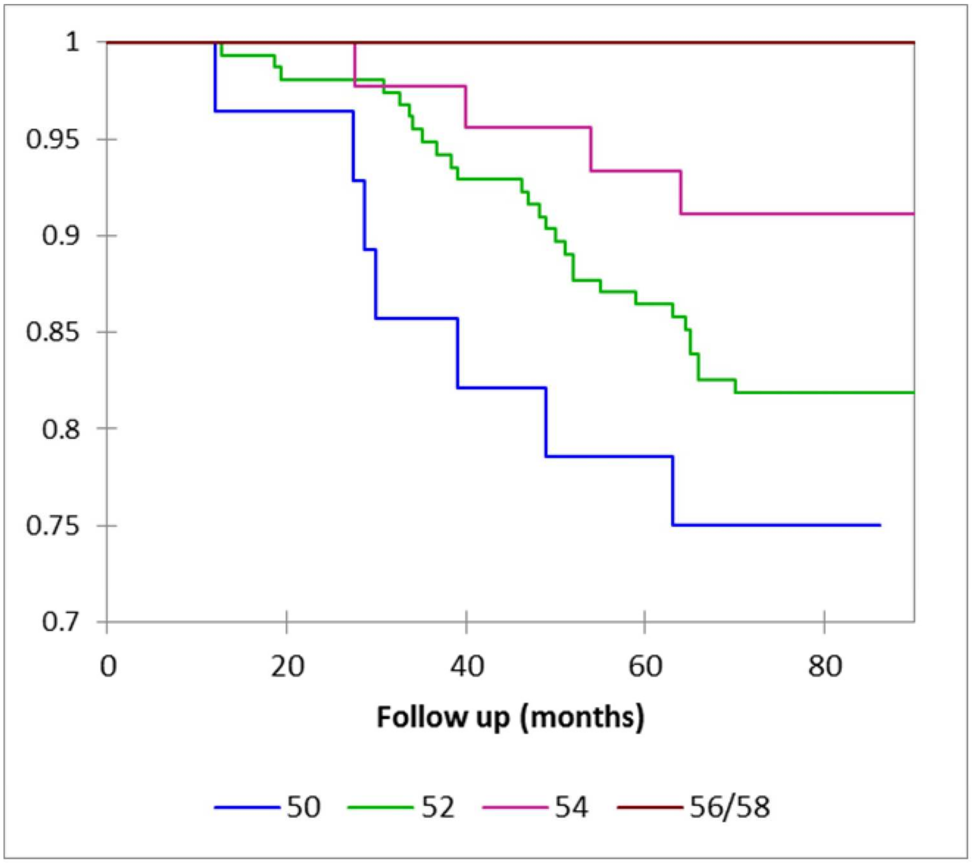

Figure 9. Kaplan Meier survival curves for Pinnacle hips implanted into female patients belonging to the late cohort (all cause revision).
359x316mm (96 x 96 DPI)

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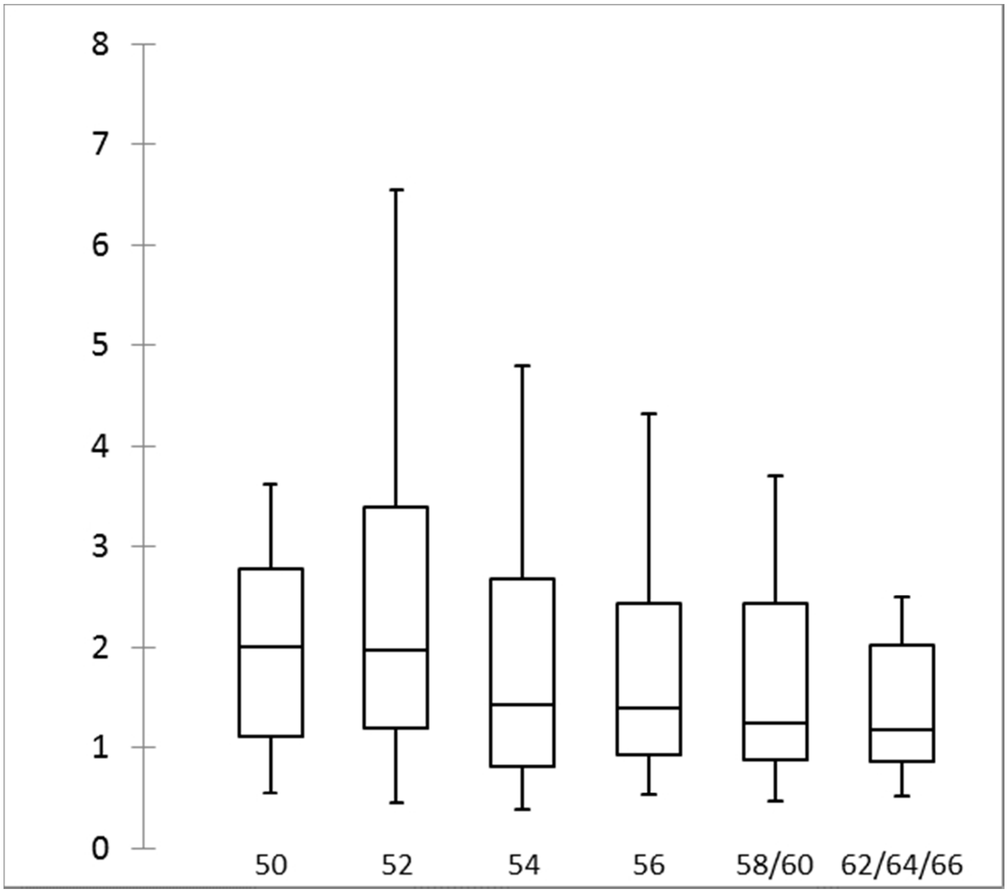

Figure 10: In this box and whisker chart, unilateral patients were grouped according to liner sizes and the blood Co distributions plotted (blood Co concentrations measured in µg/l).
101x90mm (150 x 150 DPI)

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Appendix 1 - Blood metal ion concentrations

A total of 308 patients with unilateral prostheses gave blood samples for metal ion testing.

Male:female hips	129:179
Median (range) shell size in mm	52 (50 - 66)
Mean (range) age at primary	66 (40 -89)
Mean (range) time to venesection in months	52 (4 - 109)
Median (range) Co in µg/l	1.81(0.33 – 22.1)
Median (range) Cr in µg/l	4.82 (0.36 – 20.3)

All non-parametric data was log normalised. A multiple regression model was constructed in order to examine the effect of cup inclination/anteversion, shell size, duration from primary operation to venesection and stem type on blood Co and Cr concentrations in patients with a unilateral prosthesis.

The results of this analysis are shown below

For Co concentrations:

Source	t	Pr > |t|	Lower bound (95%)	Upper bound (95%)
Intercept	2.583	0.010	1.036	7.676
Log[inclination]	0.413	0.680	-0.546	0.836
Log[anteversion]	-1.758	0.080	-0.273	0.015
log [shell size]	-3.223	0.001	-4.709	-1.138
Log[duration]	3.129	0.002	0.174	0.765
Stem-CORAIL	2.798	0.006	0.046	0.267

Equation of the model: [Log]cobalt = 4.356 + 0.145*log[inclination]-0.128*log[anteversion]-2.923*log[shell size]+0.4696*log [duration]+0.1565*Stem-CORAIL

The resulting r squared value was 0.082 ($p < 0.001$) meaning that the regression model described herein only accounted for approximately 8% of the variation in Co concentrations. Smaller shell sizes, longer duration from primary to venesection, and Corail stems were significantly associated with greater Co concentrations.

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For Cr concentrations:

Source	t	Pr > |t|	Lower bound (95%)	Upper bound (95%)
Intercept	3.258	0.001	1.560	6.326
Log[inclination]	2.378	0.018	0.103	1.095
Log[anteversion]	-3.505	0.001	-0.288	-0.081
log [shell size]	-3.351	0.001	-3.463	-0.900
Log[duration]	-1.646	0.101	-0.389	0.035
Stem-CORAIL	0.412	0.681	-0.062	0.096

Equation of the model: Log[chromium] = 3.943+0.5992*log[inclination]-0.1842*[log anteversion]-2.1815*log[shell size]-0.1771*log [duration]+1.6538E-02*Stem-CORAIL

The resulting r squared value was 0.120 (p < 0.001) meaning that the regression model described herein accounted for approximately 12% of the variation in Cr concentrations. Smaller shell sizes, higher inclination angles and lower anteversion angles were significantly associated with greater Cr concentrations.

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Appendix 2: Explant analysis from Explants Obtained Via the Northern Retrieval Registry

Methods:

Explanted Pinnacle femoral head, head tapers and acetabular liners underwent dimensional and volumetric wear analysis using previously described methodology. This was conducted by one of the authors (DJL) at Newcastle University and North Tees Explant Centre. The accuracy of these techniques has been discussed in detail in previous publications.[24][25] The results here include those of the failed explants in the manuscript in addition to all Pinnacle components received at the NRR.

Female taper surface analysis

A multiple regression model was constructed in an attempt to explain the variation in volumetric wear of the female taper surface. The variables under investigation were: duration in vivo; femoral head offset; Rpk (all logged values) and stem type (SROM versus Corail).

This model provided an explanation for approximately 43% of the variation in logged values of taper wear ($p<0.001$), with longer duration in vivo, the Corail stem, larger Rpk values and femoral head offset all associated with increased material loss from the femoral head taper surface.

Source	t	Pr > |t|	Lower bound (95%)	Upper bound (95%)
Duration in vivo	2.718	0.008	0.002	0.013
Head offset	3.176	0.002	0.022	0.095
Rpk	3.384	0.001	0.054	0.207
Corail stem	3.892	0.000	0.258	0.797

There was great variation in the surface roughness of the original as manufactured form of the female taper surface. This original surface is easily identified as in the majority of tapers there is a distal portion which lies beyond the trunnion engagement area. The Rpk value (the reduced peak height), which is the average height of the protruding peaks above the roughness core profile (in layman's terms is how "mountainous" a manufactured surface is) - was an important factor associated with material loss. *This manufacturing variation was apparently random and was not consistently linked to date of manufacture.*

Appendix 1 figure 1: Profilometry trace of unworn surface of female taper of Pinnacle head implanted in 2008. Rpk = 0.310, Ra = 0.261. Note that all profilometry traces shown in figures 1 2 and 3 are shown with the same scale. In the explanted components in this study, approximately 25% of Pinnacle 12/14 and 11/13 heads were found to have the following surface profile (all images which follow were taken at the same level of magnification):

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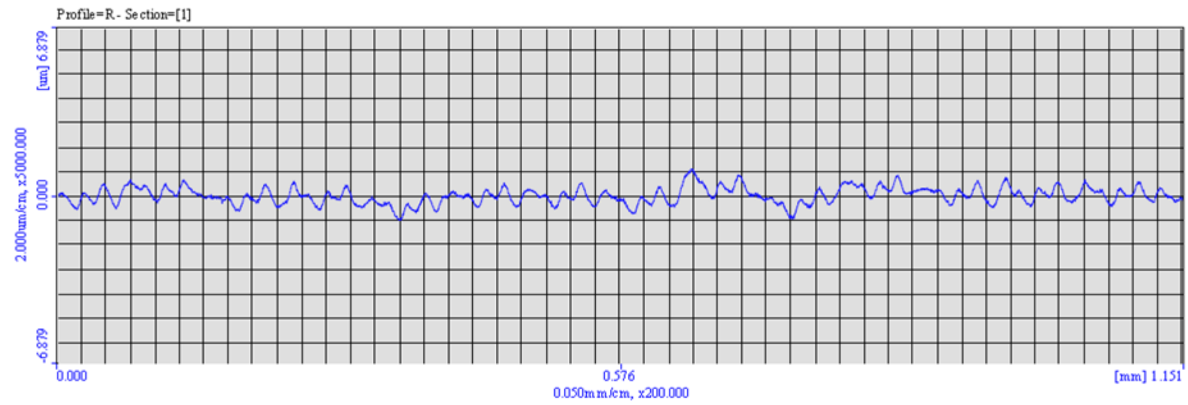
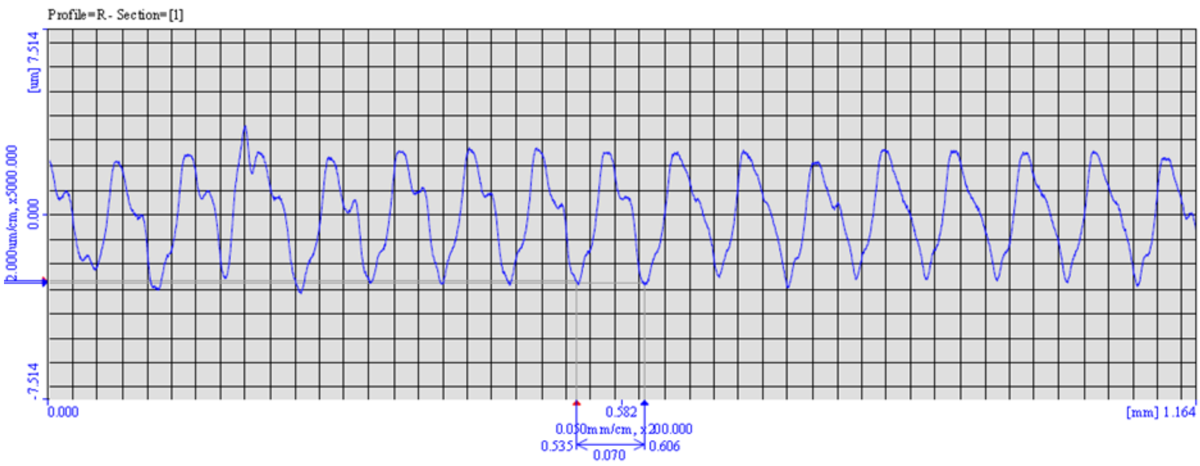


Appendix 2 figure 2: Profilometry trace of unworn surface of female taper of Pinnacle head implanted in 2006. Ra = 1.609, Rpk = 0.946. Approximately 25% of female tapers were finished in this way:



Appendix 3, figure 3: Profilometry trace of unworn surface of female taper of Pinnacle head implanted in 2006. Ra = 3.158, Rpk = 2.369. This head trace is typical of those with the largest 25% Rpk values.

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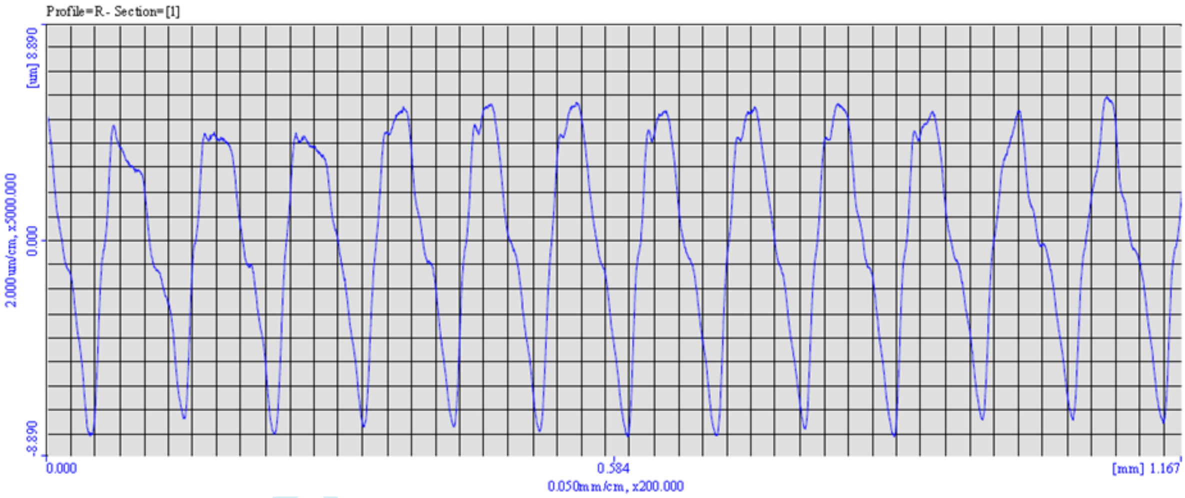

<u>**Dimensional Assessment of Bearing Diameters**</u>

Note: "date of implantation" is a reliable indicator of date of manufacture (correlation of 0.90 with lot number). As liners that are not extracted from shells during explanation do not allow the lot number to be visualised, date of implantation was therefore used as the continuous variable as a surrogate for the date of manufacture.

Liners:

For this analysis, all explanted Pinnacle devices received at Newcastle University and North Tees Explant centre were included. There were a total of 144 explanted Pinnacle cups. Cup diameters were non-normally distributed ($p<0.001$).

Year of implantation	Number of explanted liners	Number of explanted liners retrieved in shell
2003	4	3
2004	6	7
2005	11	9
2006	27	6
2007	21	14
2008	17	9
2009	8	0
2010	1	0
2011	1	0

It was apparent that there was trend towards smaller liner diameters with date of implantation, as can be seen in the chart below. The trend appeared to be exaggerated if the liner had been explanted still in its shell (red liners indicate upper and lower manufacturing tolerances):

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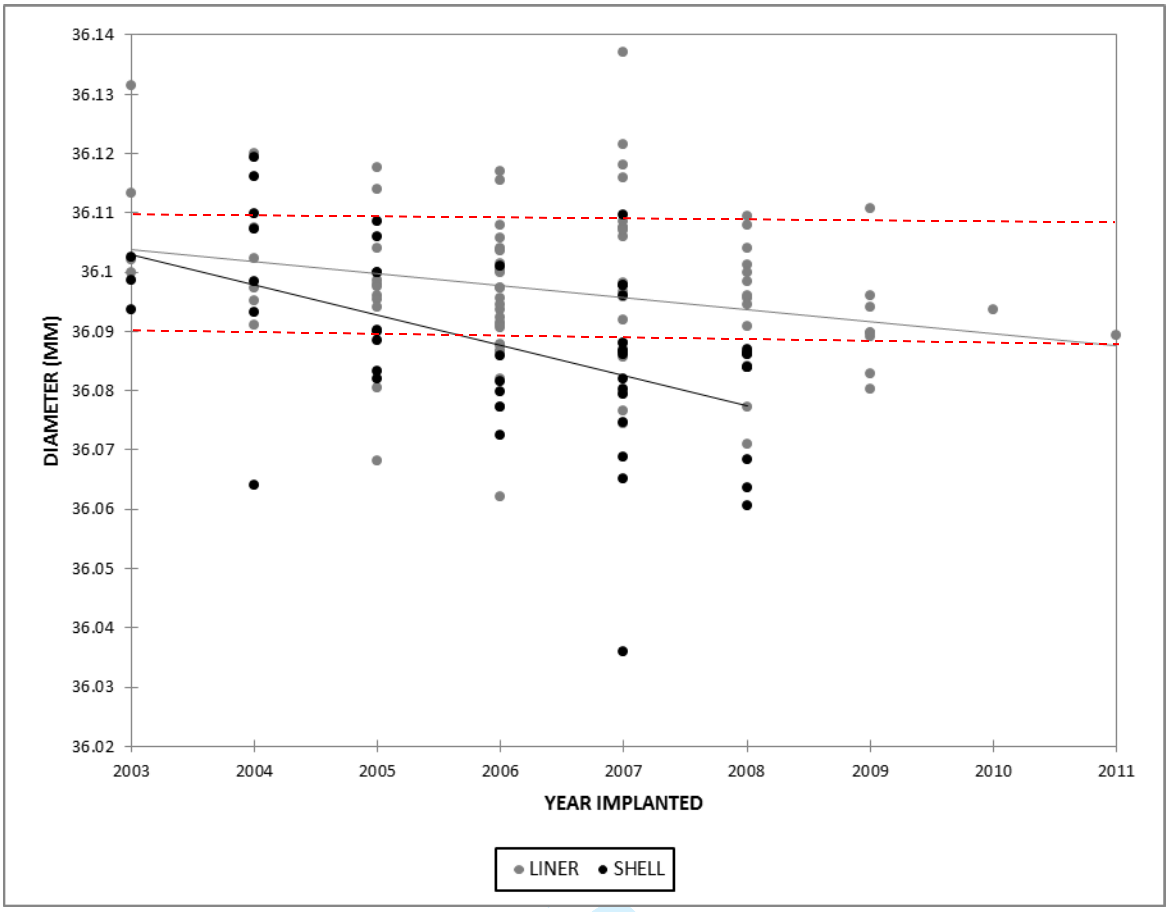

In order to investigate this relationship a multiple regression model was constructed. The year of implantation and shell size were the explanatory continuous variables and liner received in our out of its shell was the categorical variable. This model provided approximately 24% of the variation in the bearing surface, with later years of implantation and liner in shell significantly reducing the diameter (p<0.001).

Source	t	Pr > |t|	Lower bound (95%)	Upper bound (95%)
Shell size	-0.669	0.505	-0.211	0.104
Year implanted	-4.895	< 0.0001	-0.550	-0.233
Liner extracted	4.892	< 0.0001	0.221	0.520

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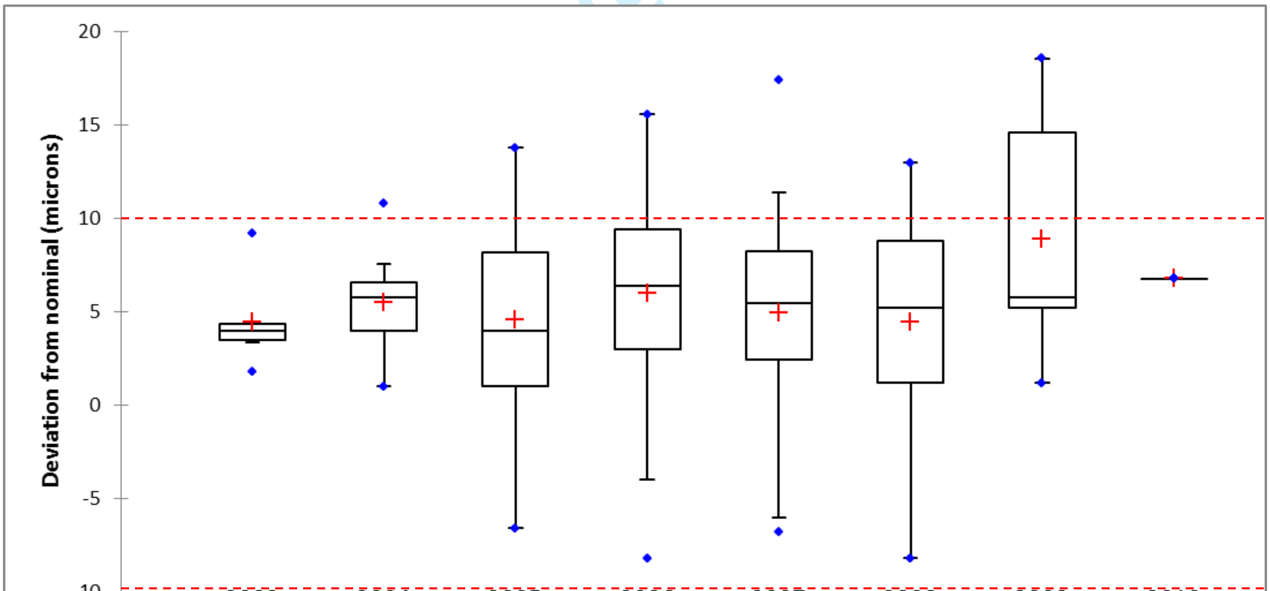
Femoral heads

147 Pinnacle heads were analysed. Head sizes were non-normally distributed ($p<0.001$) with a median diameter of 36.006 (6 microns larger than the nominal diameter of 36.000mm). Spearman rank correlation showed a significant positive trend towards increasing diameter with increasing lot number (ie Pinnacle diameters tended to be larger with more recent date of implantation (rank correlation 0.240 p = 0.005).

Year of implantation	Number of explanted Pinnacle heads
2003	6
2004	13
2005	20
2006	33
2007	40
2008	25
2009	9
2010	10

Below is a box and whisker chart which illustrates the deviation from nominal size in microns. The red lines indicate the upper and lower tolerance bands.



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Analysis of unused components

A total of ten unused liners and eight unused femoral heads were examined in a similar way to the explants. These components were obtained from theatre stocks and were sterile prior to examination.

The femoral head taper surface finishes showed identical findings in terms of variation in peak to peak distances and surface parameters such as Ra and Rpk. 4 out of 8 (50%) were found to have an Ra value greater than the roughness of the Ultima head – the device (0.6 microns) on which the Pinnacle was predicated.

Four of the eight femoral heads (50%) were found to be larger than the expected upper tolerance band.

Of the ten sterile liners, only one was found to be unquestionably within the expected size range. 4 out of the 10 (40%) were undersized and five were equivocal. It was noted that the liners were not perfectly spherical, showing small troughs at the pole and flaring at the rim.

Can explants be used to identify the original dimensions?

1. Bearing diameters

This has been successfully carried out for over 20 years. Sieber et al used techniques similar to our own to determine that in vivo volumetric wear rates of some MoM articulations can be as low as 0.3mm^3 per year (Analysis of 118 second-generation metal-on-metal retrieved hip implants. HP Sieber, CB Rieker, P. Köttig J Bone Joint Surg [Br] 1998;80-B:46-50).

This heavily cited paper is used to this today as solid evidence of the low wearing nature of MoM devices. Indeed, the designers of the Depuy ASR and Pinnacle hip systems frequently refer to this study, most notably in the paper "Isaac GH et al (2006) Development rationale for an articular surface replacement: a science based evolution. Proc Inst Mech Eng H 220(2):253–268".

Multiple other authors have published work involving calculations of wear rates – the very nature of which fundamentally depends on the ability to identify the unworn surface. As G. Reinisch et al wrote in the 2003: "The initial radii of the heads and the inserts were assessed from the unworn areas." (Biomaterials 24 (2003) 1081–1091).

The other available literature includes (by no means an exhaustive list):

Morlock MM et al (2008) Modes of implant failure after hip resurfacing: morphological and wear analysis of 267 retrieval specimens. J Bone Joint Surg Am 90(Suppl 3):89–95

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De Haan R et al (2008) Revision of metal-on-metal resurfacing arthroplasty of the hip: the influence of malpositioning of the components. J Bone Joint Surg Br 90(9):1158–1163.

The unworn surface is routinely used not only to calculate wear but also the starting diametrical clearance of the devices – a key facet of our paper.

We have published work on bearing diameters and wear volumes in the following papers which have been widely cited, and, too our knowledge without valid criticism:

Practical considerations for volumetric wear analysis of explanted hip arthroplasties. Langton DJ, Sidaginamale RP, Holland JP, Deehan D, Joyce TJ, Nargol AV, Meek RD, Lord JK. Bone Joint Res. 2014 Mar 13;3(3):60-8

Blood metal ion testing is an effective screening tool to identify poorly performing metal-on-metal bearing surfaces. Sidaginamale RP, Joyce TJ, Lord JK, Jefferson R, Blain PG, Nargol AV, Langton DJ. Bone Joint Res. 2013 May 16;2(5):84-95.

Taper junction failure in large-diameter metal-on-metal bearings. Langton DJ, Sidaginamale R, Lord JK, Nargol AV, Joyce TJ. Bone Joint Res. 2012 Apr 1;1(4):56-63.

Accelerating failure rate of the ASR total hip replacement. Langton DJ, Jameson SS, Joyce TJ, Gandhi JN, Sidaginamale R, Mereddy P, Lord J, Nargol AVF. J Bone Joint Surg Br. 2011 Aug;93(8):1011-6.

Reducing metal ion release following hip resurfacing arthroplasty. Langton DJ, Joyce TJ, Mangat N, Lord J, Van Orsouw M, De Smet K, Nargol AV. Orthop Clin North Am. 2011 Apr;42(2):169-80.

Adverse reaction to metal debris following hip resurfacing: the influence of component type, orientation and volumetric wear. Langton DJ, Joyce TJ, Jameson SS, Lord J, Van Orsouw M, Holland JP, Nargol AV, De Smet KA. J Bone Joint Surg Br. 2011 Feb;93(2):164-71.

Furthermore, of the authors of the current paper was invited to write a chapter on this subject in the Springer published textbook "Metal on metal: A Clinical Practicum", 2014 edited by Lynne C. Jones, A. Seth Greenwald and Warren O. Haggard (see screen shots below):

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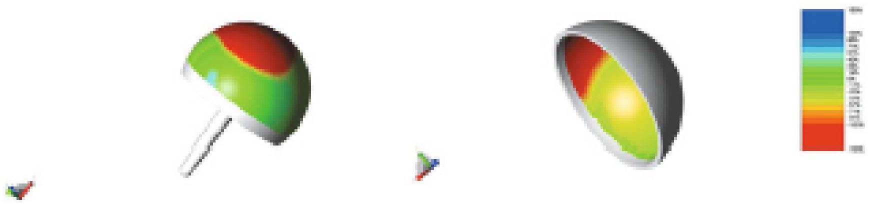

Fig. 5.1 Typical wear map of a failed hip resurfacing. *Red areas* indicate wear of greater than 10 µm. Volumetric wear rate was greater than 30 mm³/year in this case. Typically as is seen in cases of excessive bearing surface wear, blood Co concentration was 92 µg/L and Cr was 40 µg/L. Joint fluid levels showed the usual paradoxical concentration ratio associated with excessive bearing wear with Cr concentration of 11,000 µg/ and Co 4,500 µg/L. Gross metallosis and osteolysis was encountered at revision surgery though soft tissue necrosis was not extensive. Note that even with such elevated wear rates a large proportion of the bearing surface remains within the as-manufactured form (*green areas*)

Identifying Atypical Wear: Characterizing and Quantifying Wear

Please note that for the purposes of this chapter, "wear" is defined as material removal from metallic surfaces. In reality, the mechanisms leading to metal release are complex and involve interaction between friction and corrosion (tribocorrosion). It is legitimate to use the term "wear" as a catch-all term in this context as the elimination of friction between two components (the head and the cup for the bearing, the stem and head at the taper junction) would eliminate the vast majority of debris production.

Volumetric and linear wear analysis of retrieved MoM components has been performed since the 1990s [6]. According to the current literature, coordinate measuring machines (CMM) and Redlux are the most commonly used modalities to carry out these measurements [7, 8]. While a contacting probe is used in the former versus light waves in the latter, the fundamental principles are the same: the unworn surface is identified; a complete idealised surface is then generated based on this unworn surface and then compared to the areas where material has been lost. This can be done relatively easily due to two factors. Firstly, particularly in the most worn samples, maximum material loss occurs in discreet, localised areas of the head, cup and tapers. This phenomenon has been described by a number of authors after examination of explants and those taken from hip simulator studies [9, 10]. Large portions of the bearing and taper surfaces are thus left relatively undisturbed (Figs. 5.1 and 5.2). This begs the question: How is the unworn area identified? Advancements in manufacturing technology led to the reintroduction of MoM because components could now be produced which were much smoother and rounder than before. One of the critical principles underpinning the hope for the successful function of contemporary MoM arthroplasty was that these precision-manufactured components could harness a beneficial fluid film [11]. This enhanced lubrication would lead to a reduction in wear rates [12]. Manufacturing data confirms that heads, cups and tapers

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2. Surface roughness Assessment of the As Manufactured Taper Surface - is it preserved following explantation?:

We, along with several other authors have noted that it is possible in most cases to identify the unworn, as manufactured of the female taper surface. This is because the modern male taper trunnion (as is the case with the Corail stem used in this study) has a 10mm engagement length. The engagement length for the commonly used Pinnacle heads are over 20mm in length (for -2 offset heads) and 13mm for the less frequently used +8.5 offset heads. This means that there is a good proportion of the taper surface which does not engage with another metal surface. We have described this in detail in the JBJS Br (see image below):[i]

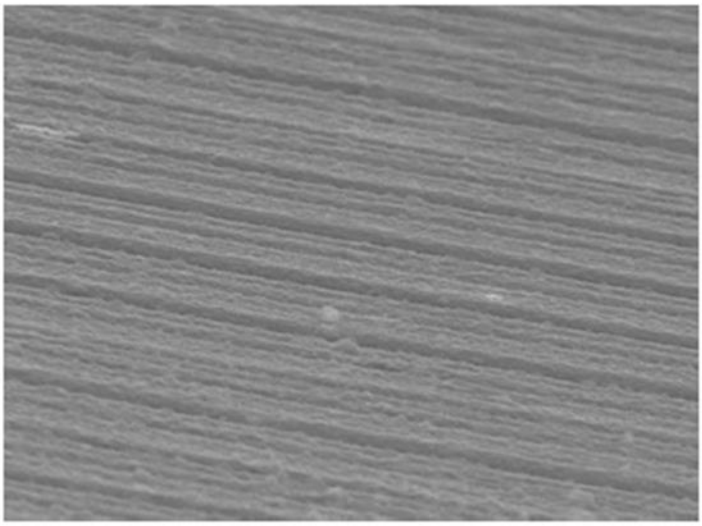

Fig. 4b

these areas there is marked abnormality of the taper surface with wear depths reaching 40 µm. Figure 4b – Scanning electron microscopy (SEM) image of the areas with no surface change. The manufacturing form has been retained and the elemental composition is as expected. Figure 4c – SEM image of the worn areas. The manufactured form has been lost and there are chromium, phosphate and titanium rich deposits (points 0 and

Images from an explanted ASR device were also published in the Bone and Joint Research Journal:[ii]

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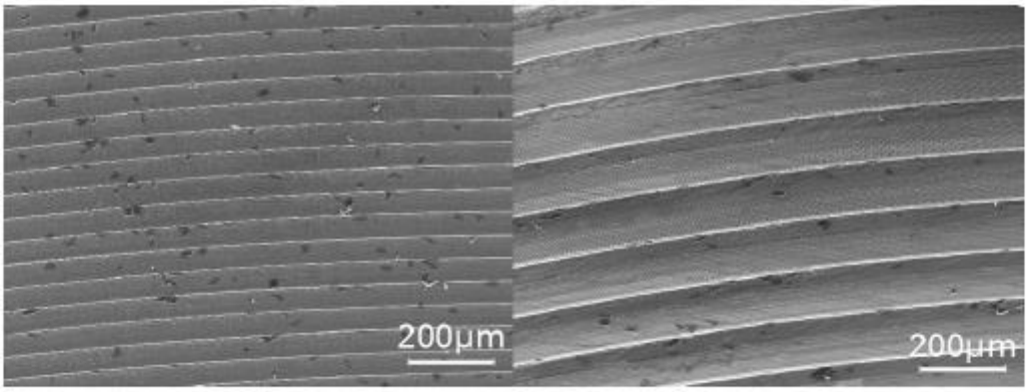

Fig. 4

Scanning electron microscopy (SEM) images of an area of unworn manufactured taper surface (left) and an area deeper in the same taper that shows the imprint of the machining grooves of the trunnion (right). Note: images are at the same level of magnification.

We are not alone in describing this preservation of the as manufactured surface. Other authors have also described volumetric techniques which, by definition, require that the unworn surface be successfully identified:

In “Characterisation of the oxide film on the taper interface from retrieved large diameter metal on polymer modular total hip replacements” by Cook et al, the authors note in figure 1b that “the distal end of the taper shows original machining marks”.[iii]

In “Material Loss at the Taper Junction of Retrieved Large Head Metal-on-Metal Total Hip Replacements” by Hart et al[iv] the authors state in figure 1 that they “assessed volumetric material loss using reference to the unworn surface”.

In the simulator study described in Blunn et al’s “Enhanced Wear and Corrosion in Modular Tapers in Total Hip Replacement Is Associated with the Contact Area and Surface Topography”[v] the authors showed with SEM and profilometry that the original machining marks were even present in the worn as well as the unworn areas.

Here are some other images of the obvious as manufactured surface identified on explanted components:

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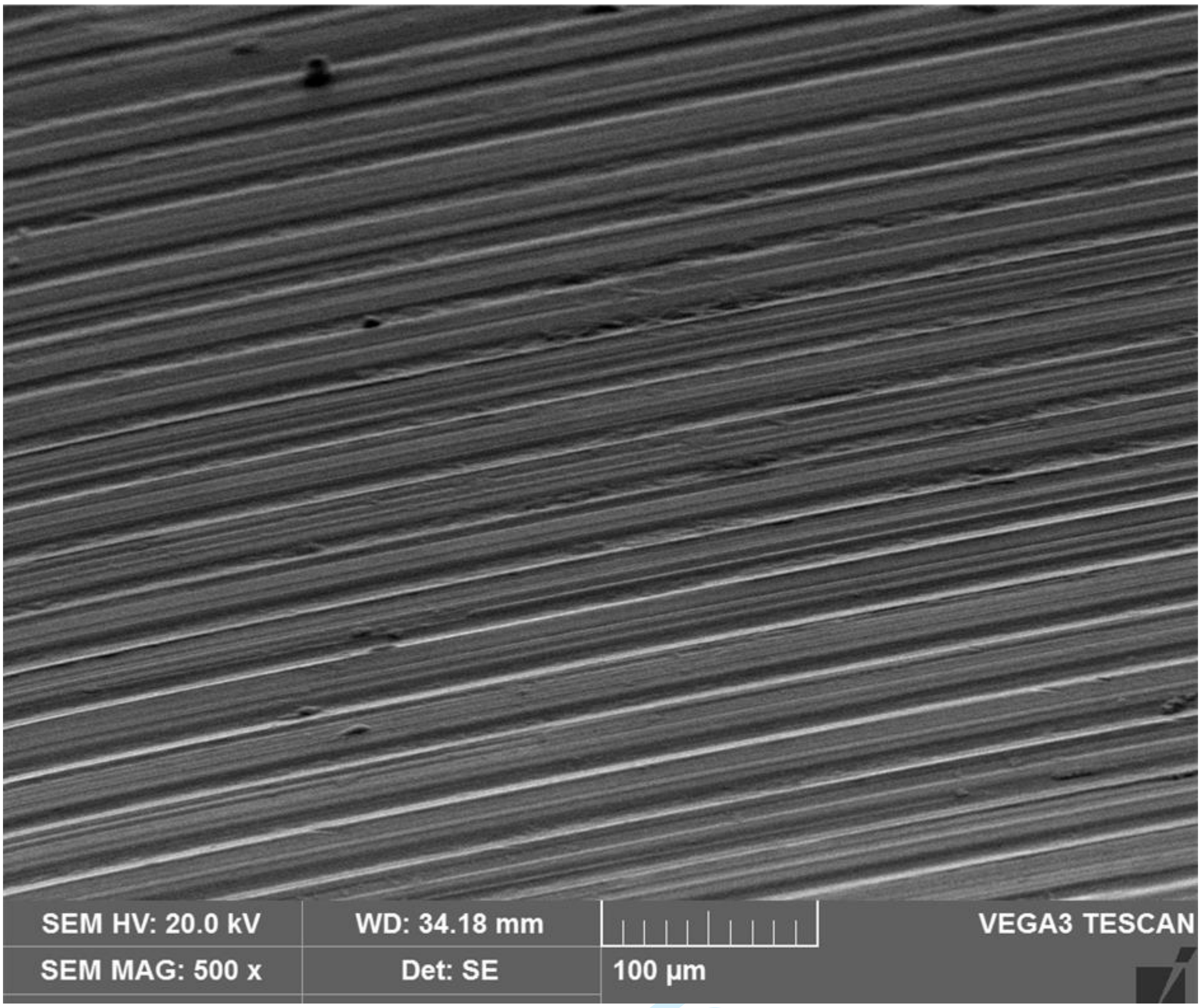

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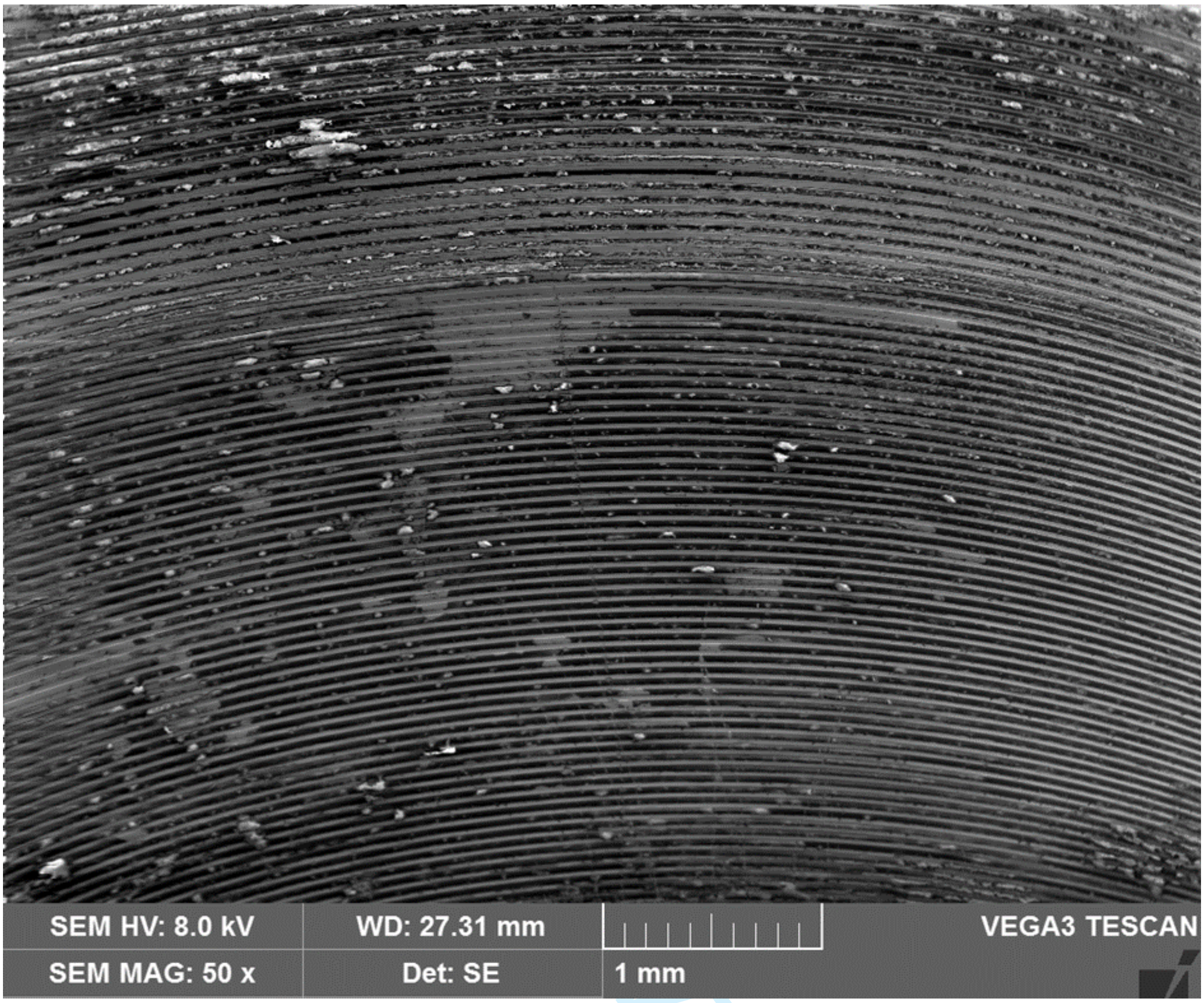

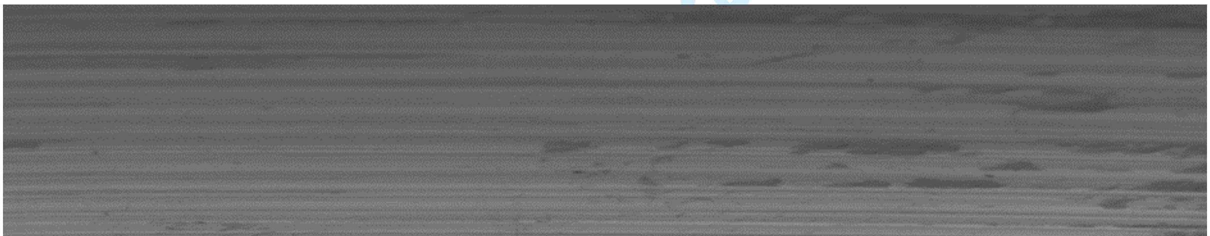

Surface Roughness of the As Manufactured Taper Surface – Assessment:

Surface roughness parameters depend on the periodicity of the measured surface, the sampling length and the evaluation length. We wanted to choose an appropriate measurement combination

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for the surfaces under investigation. Almost all (93 out of the 95) samples had preserved, unworn areas greater than 2mm in length which were free of debris. The as manufactured Ra value of the Pinnacle head taper should, according to publicly available manufacturing records be < 0.6 microns. It is unknown whether it should be periodic. However, during our measurements it became clear that a number of explants exhibited surfaces with much greater roughness values and with exaggerated periodic profiles. After consideration of *ISO standard 4288 Geometric Product Specification (GPS) — Surface texture — Profile method: Rules and procedures for the assessment of surface texture* it was felt most appropriate that ideally a 4mm evaluation length with sampling length of 0.8mm should be used. However, as noted above, a number of explants did not have a total 4mm length free of wear. Bearing this in mind, (*as well as the fact that some authors have noted the inherent complications with interpretation of Rsm- "The case of surface texture parameter RSm. P J Scott Meas. Sci. Technol. 17 (2006) 559–564"*)(see tables below extracted from ISO 4288) we conducted a comparison study of the difference between a reduced 1.6mm evaluation length (composed of two sets of 0.8mm sampling lengths) versus a 4mm evaluation length with the same sampling lengths.

Table 1 — Roughness sampling lengths for the measurement of *Ra*, *Rq*, *Rsk*, *Rku*, *RΔq* and curves and related parameters for non-periodic profiles
(for example ground profiles)

Ra µm	Roughness sampling length *lr* mm	Roughness evaluation length *ln* mm
(0,006) < *Ra* ≤ 0,02	0,08	0,4
(0,02) < *Ra* ≤ 0,1	0,25	1,25
0,1 < *Ra* ≤ 2	0,8	4
2 < *Ra* ≤ 10	2,5	12,5
10 < *Ra* ≤ 80	8	40

Table 2 — Roughness sampling lengths for the measurement of *Rz*, *Rv*, *Rp*, *Rc* and *Rt* of non-periodic profiles
(for example ground profiles)

Rz[a] *Rz*1max.[b] µm	Roughness sampling length *lr* mm	Roughness evaluation length *ln* mm
(0,025) < *Rz*, *Rz*1max. ≤ 0,1	0,08	0,4
0,1 < *Rz*, *Rz*1max. ≤ 0,5	0,25	1,25
0,5 < *Rz*, *Rz*1max. ≤ 10	0,8	4
10 < *Rz*, *Rz*1max. ≤ 50	2,5	12,5
50 < *Rz*, *Rz*1max. ≤ 200	8	40

[a] *Rz* is used when measuring *Rz*, *Rv*, *Rp*, *Rc* and *Rt*.
[b] *Rz*1max. is used only when measuring *Rz*1max., *Rv*1max., *Rp*1max. and *Rc*1max.

Table 3 — Roughness sampling length for the measurement of *R*-parameters of periodic profiles, and *RSm* of periodic and non-periodic profiles

RSm µm	Roughness sampling length *lr* mm	Roughness evaluation length *ln* mm
0,013 < *RSm* ≤ 0,04	0,08	0,4
0,04 < *RSm* ≤ 0,13	0,25	1,25
0,13 < *RSm* ≤ 0,4	0,8	4
0,4 < *RSm* ≤ 1,3	2,5	12,5
1,3 < *RSm* ≤ 4	8	40

The comparison study included the first 35 Pinnacle heads of -2 and 1.5 head offset (in order to ensure > 4mm of unworn surface to be measured).The results of this comparison study are shown here for Rpk (the main parameter under investigation) and Ra:

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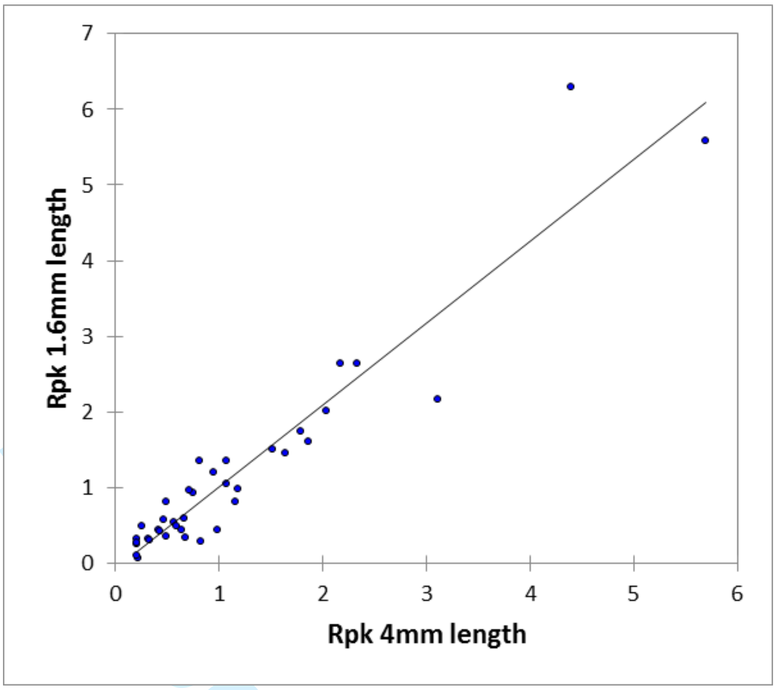

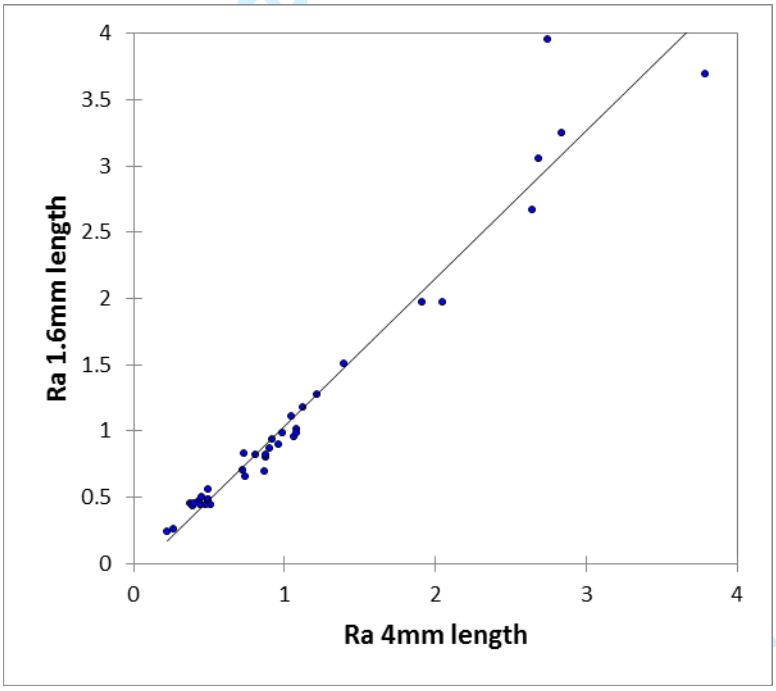

We found extremely good agreement between the two techniques, with both Ra and Rpk measurement correlations above 0.90 ($p < 0.001$). Bland Altman plots were constructed and deemed satisfactory for the purposes of the investigation.

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[i] Langton DJ, Jameson SS, Joyce TJ, Gandhi JN, Sidaginamale RP, Mereddy P, Lord J, Nargol AV. Accelerating failure rate of the ASR total hip replacement. *Journal of Bone and Joint Surg (Br)* 2011;93:1011-6.

[ii] Langton DJ, Sidaginamale RP, Lord J, Nargol AVF, Joyce TJ. Taper junction failure in large diameter metal on metal hip arthroplasty. *Bone and Joint Research.* 2012;4:56-63.

[iii] Zeng, Rainforth, Cook. Characterisation of the oxide film on the taper interface from retrieved large diameter metal on polymer modular total hip replacements. *Tribology International* 2015;89:86–96.

[iv] Matthies AK, Racasan R, Bills P, Blunt L, Cro S, Panagiotidou A, Blunn G, Skinner J, Hart AJ. Material loss at the taper junction of retrieved large head metal-on-metal total hip replacements. *J Orthop Res.* 2013;31:1677-85

[v] Panagiotidou A, Meswania J, Hua J, Muirhead-Allwood S, Hart A, Blunn G. Enhanced wear and corrosion in modular tapers in total hip replacement is associated with the contact area and surface topography. *J Orthop Res.* 2013;31:2032-9.

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Appendix 3: Survival Analysis

A comparison of the revision rates of the unilateral versus bilateral Pinnacle prostheses. All patients in the study were included in this analysis with revision for all causes included.

	Cumulative percentage probability of revision (95% CI) at:				
	Year 1	**Year 3**	**Year 5**	**Year 7**	**Year 9**
Bilateral	1.0 (0.1 – 7.0)	7.1 (3.5 – 14.5)	16.3 (10.4 – 25.6)	24.5 (17.1 – 35.1)	26.1 (18.5 – 37.5)
Number at risk	100	92	81	56	20
Unilateral	0.3 (0.1 – 2.1)	2.6 (1.2 – 4.5)	6.3 (4.3 – 9.4)	11.5 (8.6 - 15.4)	13.8 (10.4 – 18.4)
Number at risk	389	374	344	247	103

A comparison of the revision rates of the Pinnacle prostheses implanted into male and female patients. All patients in the study were included in this analysis with revision for all cause included.

	Cumulative percentage probability of revision (95% CI) at:				
	Year 1	**Year 3**	**Year 5**	**Year 7**	**Year 9**
Female	0.7 (0.2 – 2.8)	4.7 (2.7 – 7.9)	10.9 (7.8 – 15.3)	18.2 (14.1 – 23.6)	22.1 (17.1 – 28.6)
Number at risk	282	266	240	172	57
Male	0.5 (0.1 – 3.4)	2.0 (0.7 – 5.2)	5.0 (2.7 – 9.1)	8.6 (5.3 - 13.7)	8.6 (10.4 – 18.4)
Number at risk	207	199	185	130	103

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Kaplan-Meier estimates of the cumulative percentage probability of revision (95% CI) of Pinnacles implanted into female patients. All cause revision. As there was a shorter follow up with the size 50mm liners, joints failed after six years of surgery and unrevised joints with less than six years of follow up were removed.

	Cumulative percentage probability of revision (95% CI) at:				
	Year 1	**Year 3**	**Year 5**	**Year 7**	**Year 8**
Liner size 50	3.6 (0.5 – 24.5)	14.3 (5.8 – 35.4)	25.0 (13.2 – 47.5)	25.0 (13.2 – 47.5)	25.0 (13.2 – 47.5)
Number at risk	28	24	23	20	7
Liner size 52	0.6 (0.1 – 4.6)	5.2 (2.6 – 10.1)	13.5 (9.1 -20.2)	18.1 (12.9 – 25.3)	18.1 (12.9 – 25.3)
Number at risk	155	148	135	110	67
Liner size 54	0.0	4.4 (1.1 – 17.2)	8.9 (3.5 -22.7)	8.9 (3.5 -22.7)	8.9 (3.5 -22.7)
Number at risk	45	44	43	36	24
Liner size 56/58	0	0	0	0	0
Number at risk	17	17	17	16	9

Kaplan-Meier estimates of the cumulative percentage probability of revision (95% CI) of Pinnacles implanted into female and male patients belonging to the early and late cohorts. Survival curves top, with corresponding cumulative percentage probabilities bottom.

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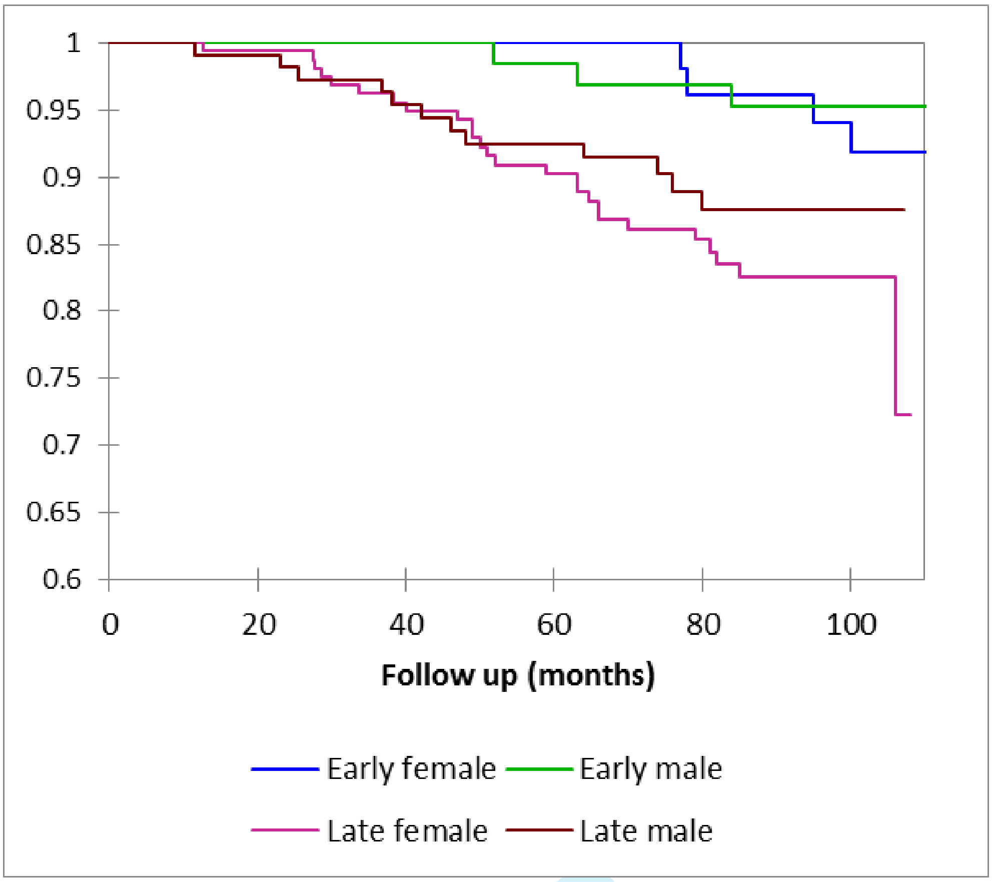

	Cumulative percentage probability of revision (95% CI) at:				
	Year 1	**Year 3**	**Year 5**	**Year 7**	**Year 8**
Early female cohort	0.0	0.0	0.0	3.9 (1 – 15.3)	8.1 (3.2 – 20.7)
Number at risk	53	53	53	49	46
Early male cohort	0.0	0.0	1.6 (0.2 – 11.1)	4.8 (1.6 – 14.4)	4.8 (1.6 – 14.4)
Number at risk	67	65	63	61	60
Late female cohort	0.0	4.4 (2.2 – 9.2)	9.8 (6.0 – 15.8)	16.5 (11.4 – 23.8)	17.4 (12.1 – 25.0)
Number at risk	160	152	152	90	35
Late male cohort	1.3 (0.1 – 6.5)	3.7 (1.4 – 9.6)	7.5 (3.8 – 14.6)	9.7 (5.4 – 17.6)	12.5 (7.3 – 21.4)

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Number at risk	109	105	95	75	17

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