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

Methods:

Explanted 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 components received at the NRR which were used in Pinnacle MoM systems.

Female taper surface analysis

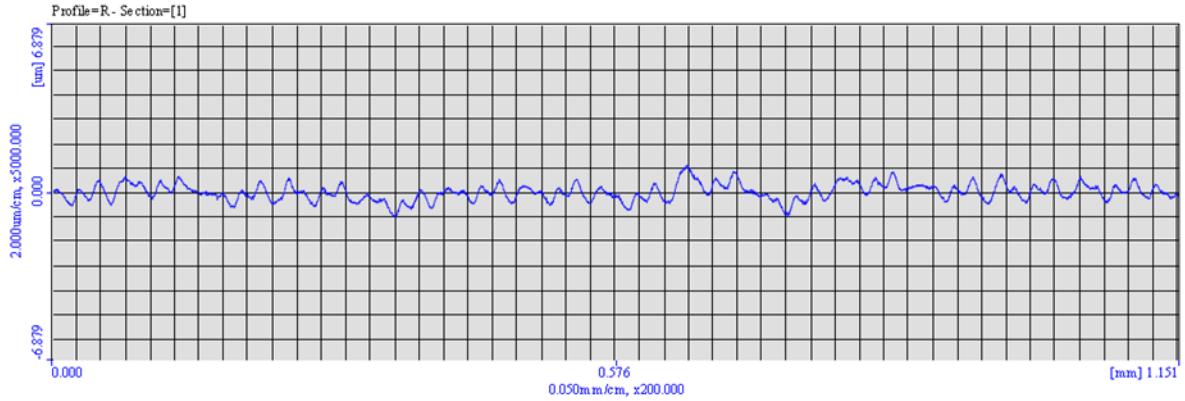
A multiple regression model was constructed in an attempt to explain the variation in volumetric wear of the female taper surface. The variables under investigation were: duration in vivo; femoral head offset; Rpk (all logged values) and stem type (SROM versus Corail).

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.

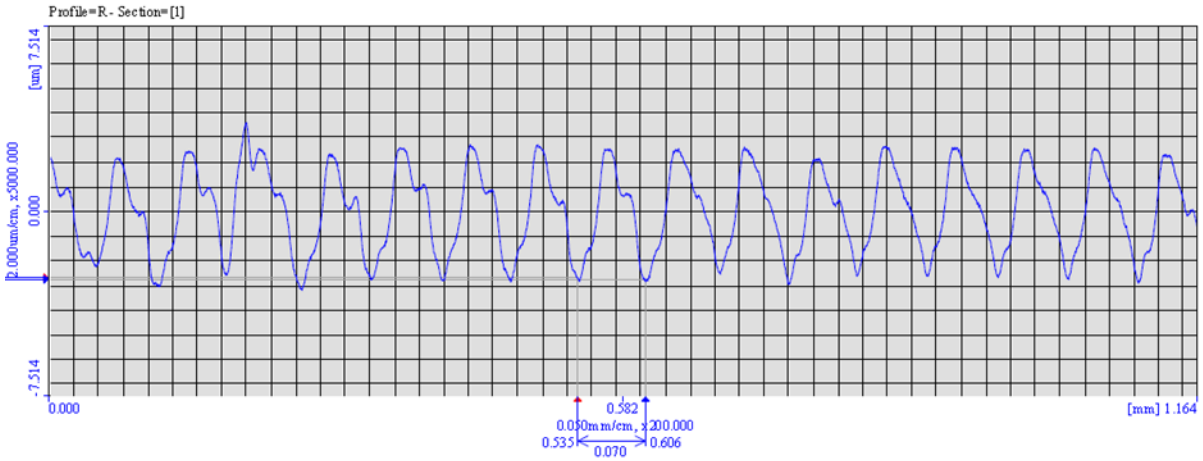
Source	t	Pr > |t|	Lower bound (95%)	Upper bound (95%)
Duration in vivo	2.718	0.008	0.002	0.013
Head offset	3.176	0.002	0.022	0.095
Rpk	3.384	0.001	0.054	0.207
Corail stem	3.892	0.000	0.258	0.797

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.*

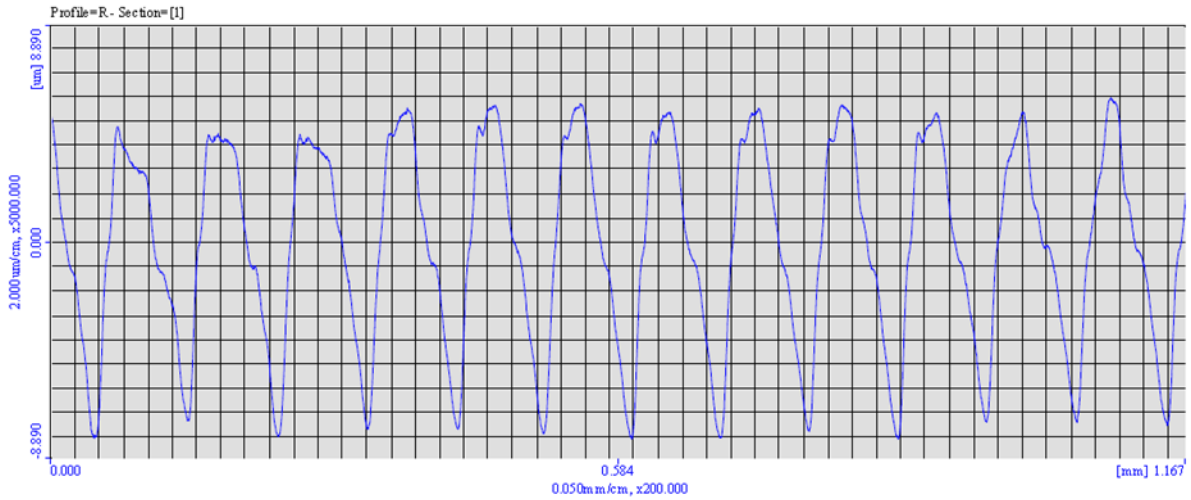
Appendix 1 figure 1: Profilometry trace of unworn surface of female taper surface of an Articuleze head implanted in 2008. Rpk = 0.310, Ra = 0.261. Note that all profilometry traces shown in figures 1 2 and 3 are presented at the same scale. In the explanted components in this study, approximately 25% of Articuleze and Ultamet heads were found to have the following surface profile:



Appendix 2 figure 2: Profilometry trace of unworn surface of the female taper surface of an Articuleze 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 the unworn female taper surface of an Ultamet head implanted in 2006. Ra = 3.158, Rpk = 2.369. This head trace is typical of those with the largest 25% Rpk values.



Dimensional Assessment of Bearing Diameters

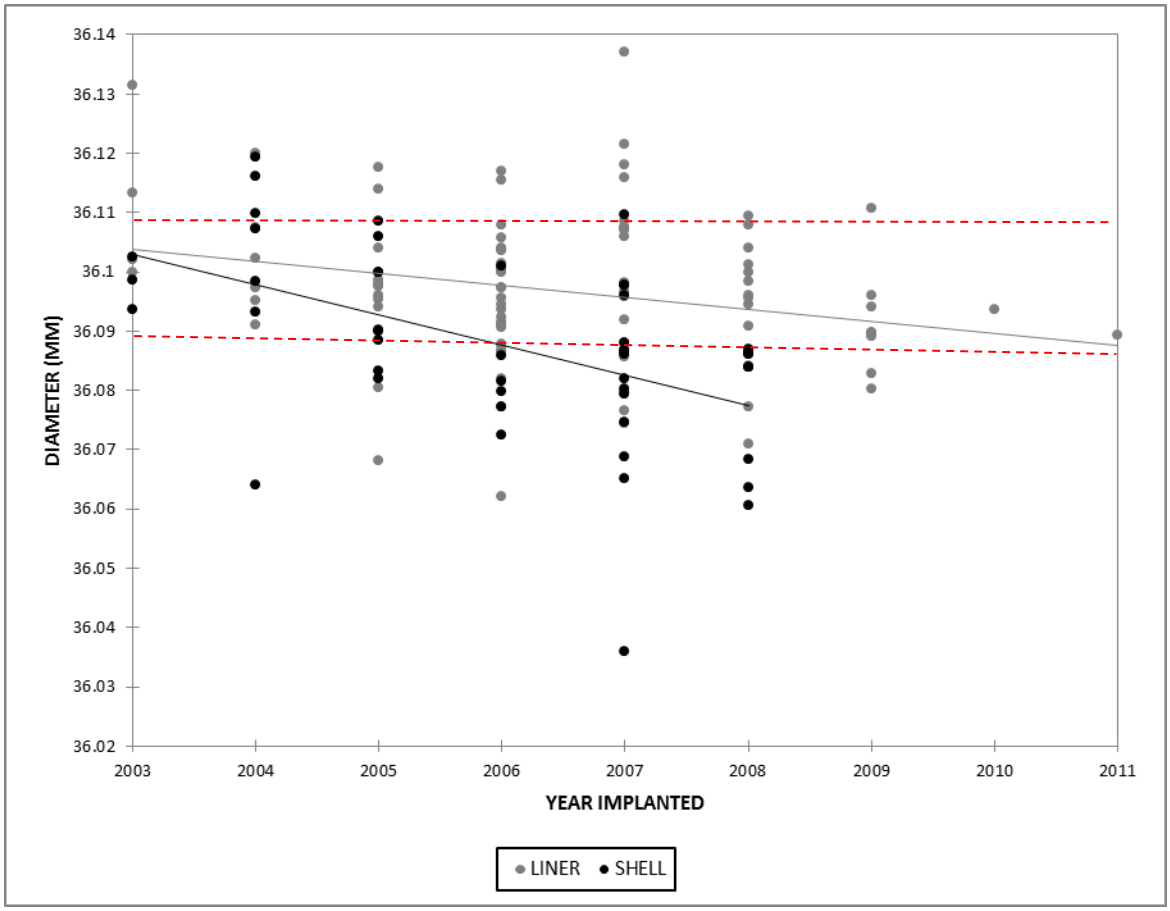
Note: "date of implantation" is a reliable indicator of date of manufacture (correlation of 0.90 with lot number). As liners that are not extracted from shells during explanation do not allow the lot number to be visualised, date of implantation was therefore used as the continuous variable as a surrogate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

Liners:

For this analysis, all explanted MoM Pinnacle devices received at Newcastle University and North Tees Explant centre were included. There were a total of 144 explanted liners. 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):



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 ($p<0.001$).

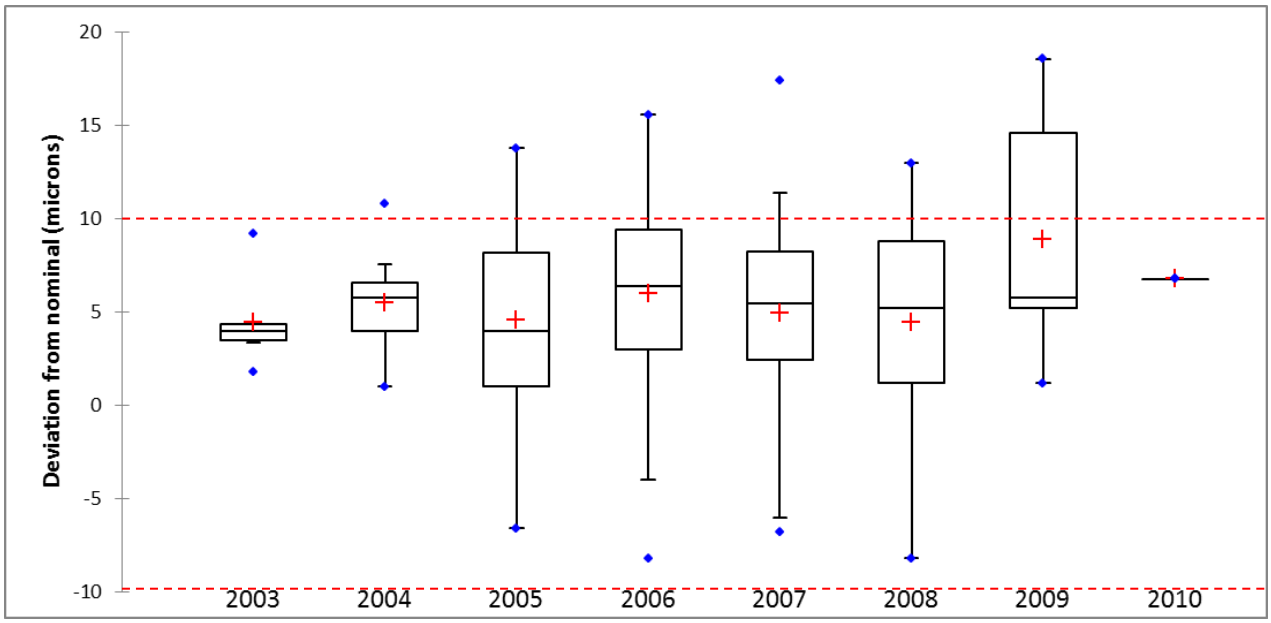
Source	t	Pr > |t|	Lower bound (95%)	Upper bound (95%)
Shell size	-0.669	0.505	-0.211	0.104
Year implanted	-4.895	< 0.0001	-0.550	-0.233
Liner extracted	4.892	< 0.0001	0.221	0.520

Femoral heads

147 heads (Ultamet and Articuleze) 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 diameters tended to be larger with more recent date of implantation (rank correlation 0.240 $p = 0.005$).

Year of implantation	Number of explanted femoral 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.



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 of components?

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.(1) 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.(2)

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 Reinisch et al(3) wrote in the 2003: “The initial radii of the heads and the inserts were assessed from the unworn areas.” Other available literature on the subject includes that from Morlock et al(4) and De Haan et al.(5) The unworn surface is routinely used not only to calculate wear but also the starting diametrical clearance of the devices – a key facet of this paper. We have published work on bearing diameters and wear volumes a number of papers which have been widely cited.(6-11)

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

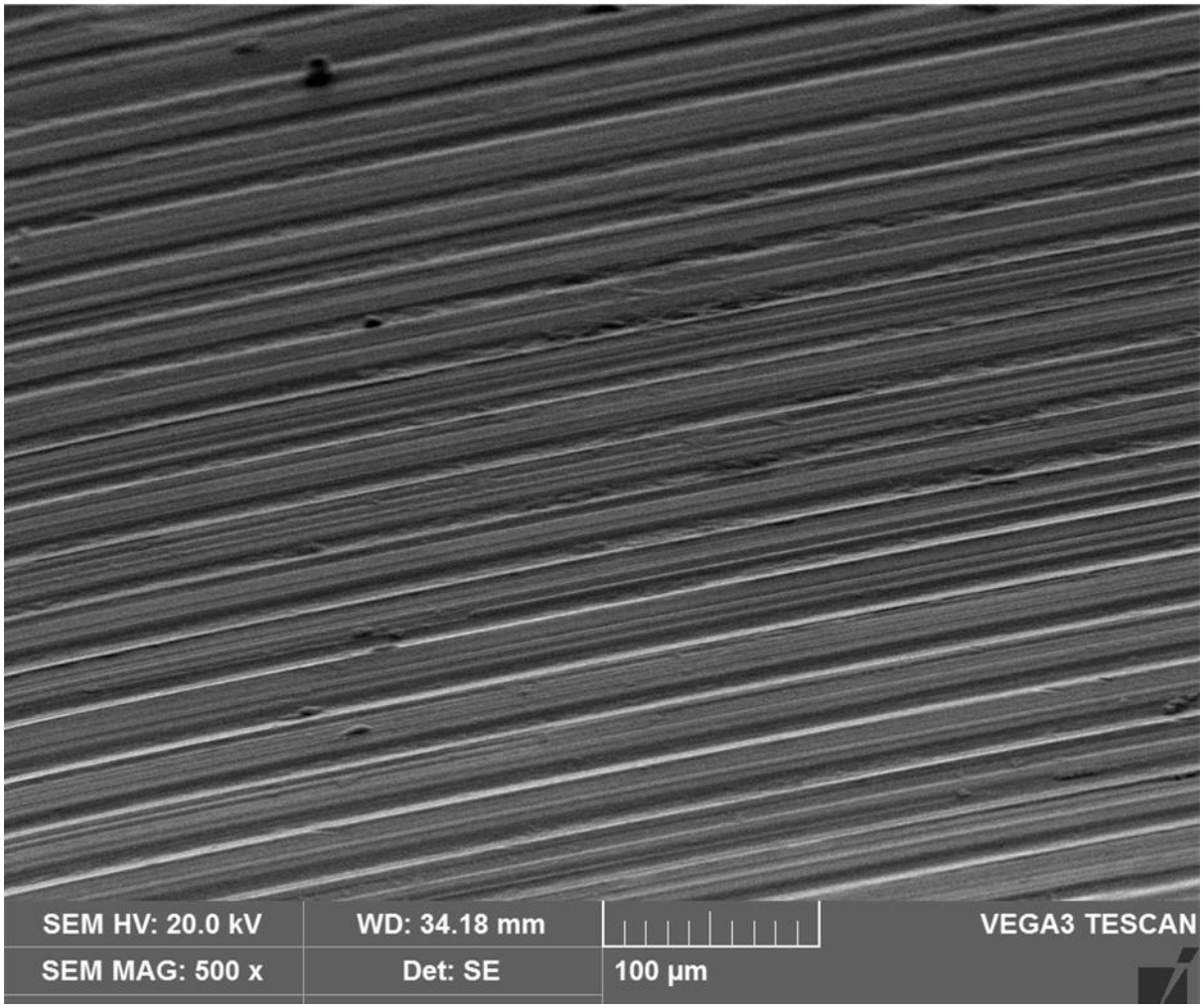
We, along with several other authors have noted that it is possible in most cases to identify the unworn, as manufactured of the female taper surface. This is because the modern male taper trunnion (as is the case with the Corail stem used in this study) has a 10mm engagement length. The engagement length 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 previous publications.(9)

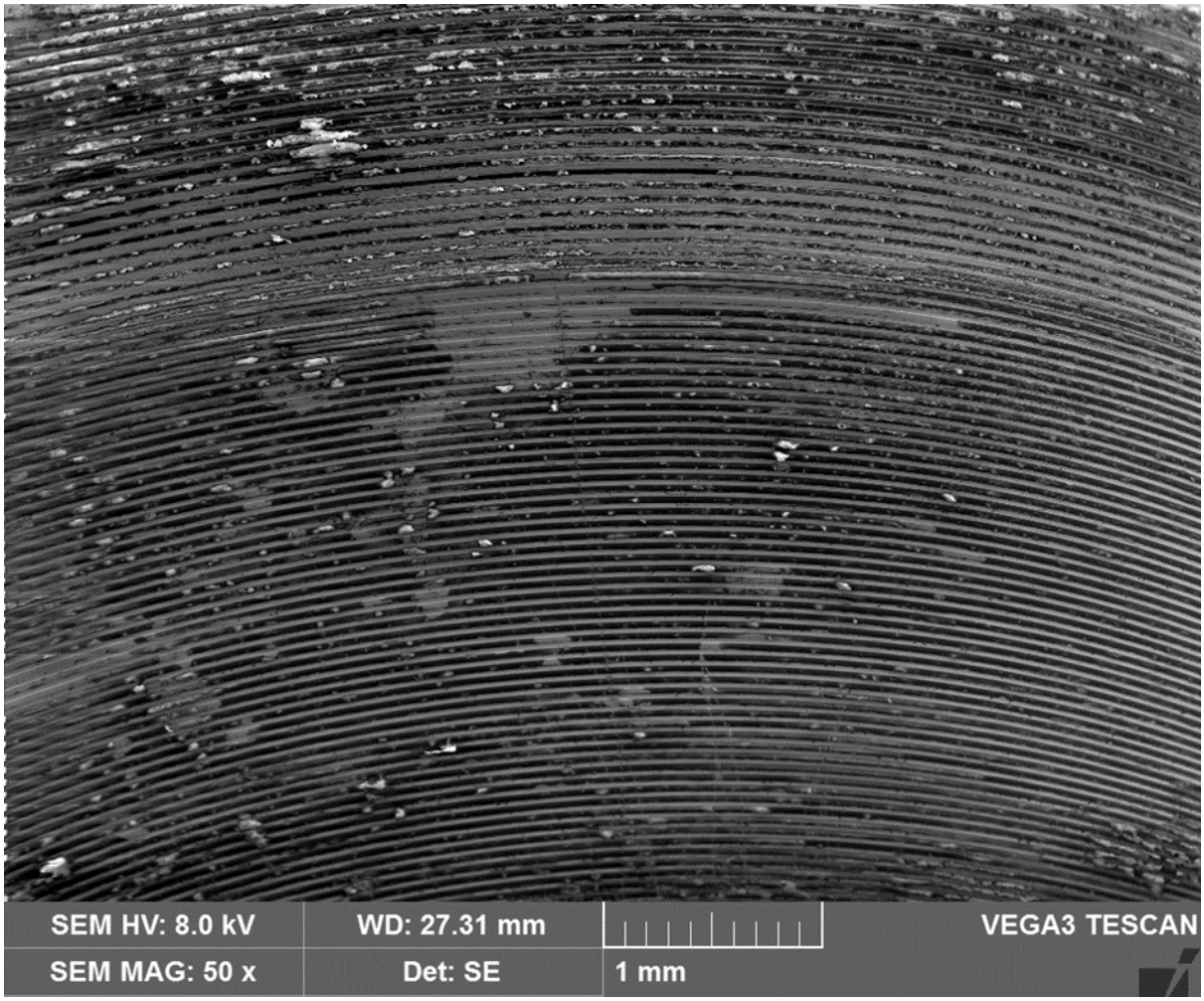
We are not alone in describing this preservation of the as manufactured surface. Other authors have also described volumetric techniques which, by definition, require that the unworn surface be successfully identified:

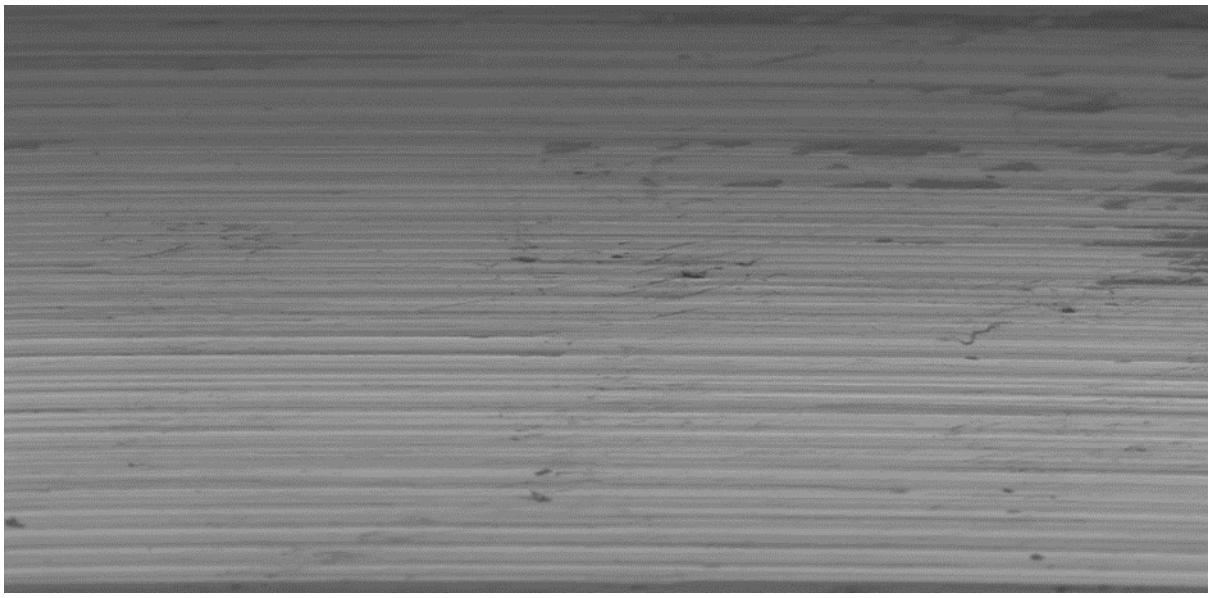
In “Characterisation of the oxide film on the taper interface from retrieved large diameter metal on polymer modular total hip replacements” by Cook et al, the authors note in figure 1b that “the distal end of the taper shows original machining marks”.(12)

In “Material Loss at the Taper Junction of Retrieved Large Head Metal-on-Metal Total Hip Replacements” by Hart et al(13) the authors state in figure 1 that they “assessed volumetric material loss using reference to the unworn surface”.

Below are typical images obtained from explanted components which clearly demonstrate preservation of the as manufactured taper surface.


SEM HV: 20.0 kV
WD: 34.18 mm
VEGA3 TESCAN
SEM MAG: 500 x
Det: SE
100 µm

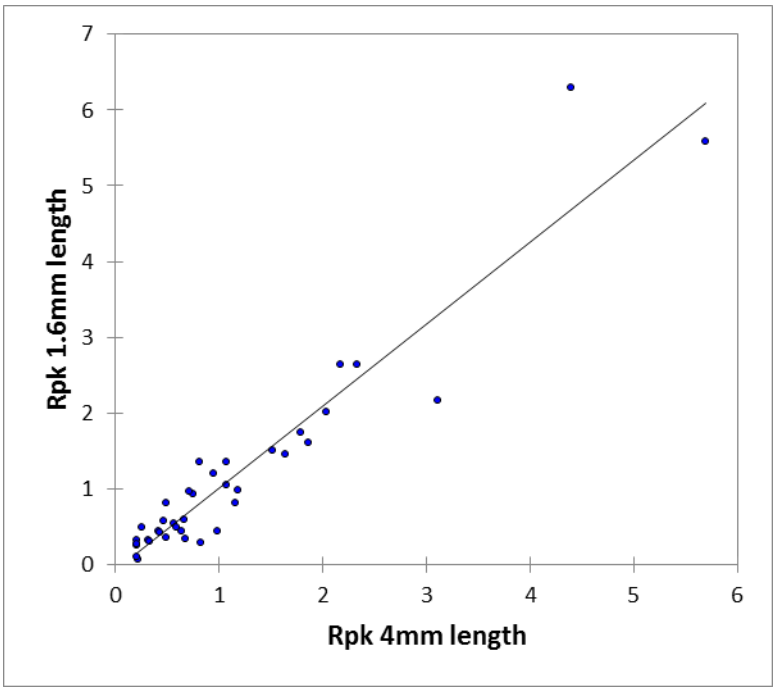

SEM HV: 8.0 kV
WD: 27.31 mm
VEGA3 TESCAN
SEM MAG: 50 x
Det: SE
1 mm

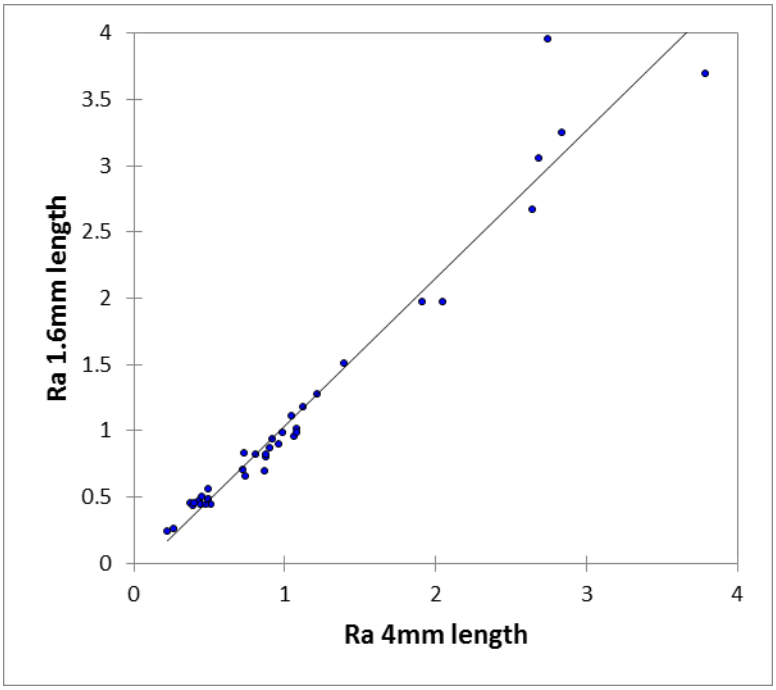


Surface Roughness of the As Manufactured Taper Surface – Assessment:

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 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*") 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.

The comparison study included the first 35 Ultamet and Articuleze 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:





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.

1. Sieber HP, Rieker CB, Kottig P. Analysis of 118 second-generation metal-on-metal retrieved hip implants. J Bone Joint Surg Br. 1999;81(1):46-50.
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11. Langton DJ, Joyce TJ, Jameson SS, Lord J, Van Orsouw M, Holland JP, et al. Adverse reaction to metal debris following hip resurfacing: the influence of component type, orientation and volumetric wear. J Bone Joint Surg Br. 2011;93(2):164-71.
12. Zeng P, Rainforth WM, Cook RB. 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.
13. Matthies AK, Racasan R, Bills P, Blunt L, Cro S, Panagiotidou A. Material loss at the taper junction of retrieved large head metal-on-metal total hip replacements. J Orthop Res. 2013;31.