Title: The variation in taper surface roughness for a single design effects the wear rate in total hip arthroplasty

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Abstract8

Material loss from the head-stem taper junction of total hip arthroplasty (THA) is implicated in adverse reactions to metal debris (ARMD); the mechanisms for this are multi-factorial. We investigated the relationship between the roughness of the 'as manufactured' taper surface and the wear rate from this junction. 50 retrieved Pinnacle metal-on-metal (MOM) bearings paired with a Corail stem were included in the study. Multivariable statistical analysis was performed to determine the influence of taper roughness on material loss rate after controlling for other confounding surgical, implant and patient factors. The surface roughness of the 'as manufactured' head taper surface was associated with the rate of material loss from this surface. Four of eighteen roughness variables taken from ISO 4287 and ISO 13565-2 were significant: The Reduced Peak Height (Rpk, the protruding peaks above the core) (p=0.004), Material Ratio 1 (Mr1, the ratio of the protruding peaks above the core) (p=0.002), Area of the Peak Region (A1, the area of the Abbott-Curve that contains the peaks from the profile) (p=0.003) and the Skewness (Rsk, the asymmetry of the height distribution corresponding to the height or depth of surface features) (p=0.03). We found a large variability in the measured values with a median (range) of 0.50 (0.05-2.98), 11.98 (0.46-39.98), 30.89 (0.15-581.00) and 0.04 (-0.73-0.84) respectively. A one-unit increase in Rpk was associated with a 73% increase in the taper wear rate. The variability of 'as manufactured' surface roughness has a significant effect on taper material loss.

Keywords:8

Hip;8Retrieval;8Taper;8Wear;8Corrosion8

Introduction

Material lost from the head-stem taper junction of total hip arthroplasty (THA) is implicated in adverse tissue reactions, leading to early implant failure [1]. This impacts on the future performance of all implants that have a junction between CoCr and Titanium components such as the 1.5 million hips implanted annually, spinal implants [2] and knee implants [3].

Material loss may be due to corrosion, mechanical wear or a combination of the two mechanisms and is influenced by multiple surgical, implant and patient factors. Surgical factors may include impaction force of the head [4], implant factors may relate to head diameter and head length [5] while patient factors are largely unknown.

Creating a seal between the head taper and trunnion is an important engineering principle to reduce corrosion at the junction by preventing fluid ingress and micro-motion. It is speculated that variations in the tolerances and surface finish of the taper will have an affect on the function of this junction but this has not been investigated by independent research on current designs.

We aimed to investigate the relationship between the unengaged / 'as manufactured' taper surface on wear rate of the engaged taper surface Our objectives were 1) to quantify the roughness of the unengaged / as-manufactured taper surfaces and 2) relate these findings to taper material loss from the engaged taper surface and clinical and implant data.

Materials and Methods –

The study was approved by the institutional review board.

Patients (Table 1)

Between 2008 and 2015 we collected 130 failed metal-on-metal (MOM) THAs of a single design (modular Pinnacle; DePuy, Warsaw, Indiana) that had been combined with one of three stem designs (Corail, Summit and S-ROM, all constructed from titanium alloy ($TiAl_6V_4$)). The Pinnacle MOM bearing consists of a press-fit titanium acetabular shell with a cobalt-chromium liner articulating with a CoCr head. From these, 50 met our inclusion criteria: (1) single head bearing diameter (36mm); (2) paired with one stem design (Corail); (3) in situ for a minimum of 12 months; and (4) minimum of 1.5mm of unengaged taper surface. The retrievals were obtained from 30 women and 20 men. The median age at the time of implantation was 61 years (range 35-73 years) with a median time to revision of 67.5 months (range 19-124 months).

Cup inclination angle, and stem vertical and horizontal offsets were calculated using plain radiographs by an experienced orthopaedic surgeon. The reason for revision in all cases was unexplained pain (n=50) and was confirmed by the revising surgeon as being due to an adverse reaction to metal debris (ARMD). We received 8 stems with the bearings in this study. The head lengths ranged from -2.0 - +12.0. The Corail stem is a titanium alloy ($TiAl_6V_4$) hydroxyapatite coated un-cemented stem with a 12/14 ARTICUL/EZE Mini Taper (AMT) (fig 1).

Measurement of Head Taper Material Loss

Measurement of the volume of material loss at each of the head taper surfaces was undertaken using a roundness-measuring machine (RMM) (Talyrond 365, Taylor Hobson, Leicester, UK) using previously published methods [6]. A series of 180 vertical traces were taken along the axis of the taper surface using a 5μm diamond stylus. These were combined to form a rectangular surface from which unworn regions were identified and the volume of material loss in worn regions calculated.

Measurement of Bearing Surface Material Loss

The volume of material loss at the cup and head bearing surfaces was measured using a Zeiss Prismo (Carl Zeiss Ltd, Rugby, UK) coordinate measuring machine (CMM). A 2mm ruby stylus was translated along 400 polar scan lines on the surface to record up to 30,000 unique data points using previously published measurement protocols. An iterative least square fitting method was used to analyze the raw data to map regions of material loss by comparing with the unworn geometry of the bearing [7].

Roughness Parameters of 'As Manufactured' Head Taper Surface and Stem Trunnion The roughness parameters of the 'as manufactured' taper surface and were obtained using 4 vertical traces that were taken at 90 degree increments of the head taper using the RMM from the unworn region of the head taper. Use of the traces and visual analysis of the component showed the unengaged area of the head. If ≥1.5mm of the head had not been engaged this met the inclusion criteria (fig 2). 1.5mm of the unengaged surface was then extracted and a list of parameters (ISO 4287 and ISO 13565-2 taken from ISO 4288:1996(en)) were produced using TalyMap 7 software (Taylor Hobson, Leicester, UK) (table 2). This was repeated for all 4 of the extracted traces and the results averaged. The same method was used on the stem trunnions to obtain the roughness values for use as a comparative group.

Statistical Analysis

All analyses were performed using Stata (version 13.1; StataCorp) and a significance level was 0.05. The outcome variable in all analyses was the taper wear rate which was calculated as the total wear volume divided by the time in situ. Due to the continuous nature of the outcome, all analysis was performed using linear regression. An examination of the distribution of the values for this outcome suggested that it was heavily positively skewed. As a result, the variable was given a log transformation, and all analysis was performed on the transformed scale. Due to there being some zero values, a small constant was added to all values before the log transformation.

Analysis 1: Clinical and Implant data

Analysis 1 examined how sets of possible variables that have been previously shown to influence taper wear rate were associated with the outcome (Time to revision, Bearing wear rate, Inclination, Horizontal / Vertical offset, Edge wear, Head length) [8-10].

Analysis 2: Roughness Parameters of the 'As Manufactured' Taper Surface - Univariate

Analyses 2 looked at each roughness parameter separately in a univariate analysis. Firstly, the association with taper wear rate was examined without allowing for any other variables. Subsequently adjustments were made for possible confounding variables found to be significantly associated with taper wear rate from analysis 1.

Analysis 3: R oughness Parameters of the 'As Manufactured' Taper Surface - Multivariable

Analysis 3 examined the joint association between the roughness parameters and taper wear rate in a multivariable analysis. Before the main analysis was performed, the collinearity between predictor variables was examined. This is present where there are strong associations between predictor variables, and can cause problems with model fitting. This was assessed using variance inflation factors (VIFs), with a VIF of 10 or higher considered evidence of collinearity. Where two or more factors were found to be collinear, only one factor was included in the multivariable analysis. The factors were chosen based on the functional characteristics of the roughness parameters and the relationship between them. A backwards selection of the roughness parameters was made, with the aim of retaining only those parameters found to be statistically significant in the final model. All of the roughness parameters were adjusted for time to revision, bearing wear rate and head offset. Rsk ratios were reported for a 0.1-unit increase, Rmr was reported for a 10-unit increase, Mr1 and Mr2 were reported for a 5-unit increase and A1 and A2 were analyzed on a log scale (base 10).

Results

Taper and Bearing Wear Rate

The taper wear rates for the tested components ranged from 0 - 3.45 mm^3/year with a median of 0.27mm^3/year. The bearing wear rates for the tested components ranged from 0.87 – 62.12 mm^3/year with a median of 3.59 mm^3/year. (Table 3)

Roughness Parameters

The median of the roughness parameters (range) for the ‘as manufactured’ taper surface were - Rc 2.79 (0.52-11.33), Rt 3.47 (1.09-12.40), Ra 0.79 (0.16-3.19), Rq 0.89 (0.20-3.72), Rsk 0.04 (-0.73-0.84), Rku 2.05 (1.40-3.29), Rmr 24.80 (5.71-97.48), Rdc 1.88 (0.36-7.69), Rk 2.06 (0.61-6.33), Rpk 0.50 (0.05-2.98), Rvk 0.37 (0.10-7.32), Mr1 11.98 (0.46-39.98), Mr2 91.84 (59.13-99.00), A1 30.89 (0.15-581.00) A2 17.41 (0.67-1130.00) (Table 4).

The median of the roughness parameters (range) for the 8 retrieved stem trunnions were - Rc 7.26 (4.89-8.95), Rt 7.61 (2.20-8.90), Ra 1.89 (1.34-2.61), Rq 2.17 (0.94-2.63), Rsk 0.62 (0.21-2.56), Rku 2.22 (1.73-8.63), Rmr 10.30 (4.79-12.78), Rdc 4.20 (3.10-5.08), Rk 5.17 (3.98-6.07), Rpk 3.22 (0.14-5.68), Rvk 0.18 (0.05-34.07), Mr1 26.43 (18.80-98.93), Mr2 99.09 (94.73-984.33), A1 1.64 (0.15-10.87) (Table 5).

Statistical Analysis

Analysis 1: Clinical and Implant data (Table 6)

The results suggested that of the possible confounding variables, only time to revision (p=0.004), bearing wear rate (p=<0.001) and head offset (p=0.02) were significantly associated with taper wear rate, a greater time to revision and greater head offset was associated with a higher wear rate. A one-year increase in revision time was associated with a 24% increase in taper wear rate, whilst a one-unit increase in head offset was associated with an 11% increase in wear rate. Conversely, bearing wear rates was negatively correlated with taper wear rate. A one-unit increase in bearing wear rate on the log scale (equivalent to a 10-fold increase in bearing wear rate) was associated with four-fold reduction in taper wear rate.

Analysis 2: Roughness Parameters of the 'As Manufactured' Taper Surface - Univariate (Table 7)

These indicated that a number of the roughness parameters were significantly associated with taper wear rate. The parameters Rsk (p=0.02 / p=0.03), Rpk (p=<0.001 / p=0.004), MR1 (p=0.001 / p=0.002) and A1 (p=0.002 / p=0.003) were significant both before and after adjusting for the potentially confounding variables. Additionally, Rp (p=0.006 / p=0.11), Rt (p=0.01 / p=0.38) and Rmr (p=0.009 / p=0.15) were significant in the unadjusted analysis, but lost significance after adjustment for the three potentially confounding variables.

With the exception of Rmr, the remaining significant parameters had ratios over 1, suggesting that higher values of each parameter were associated with a greater degree of taper wear rate. Rmr had a ratio below 1 (ratio 0.91 95% CI: 0.81, 1.03), suggested higher values were associated with a less taper wear rate and the effects of each roughness parameter upon the outcome were typically reduced after adjustments for the potential confounding factors (time to revision, bearing wear rate and head offset).

Analysis 3: Roughness parameters of the 'As Manufactured' Taper Surface - Multivariable

Examinations of collinearity between variables suggested that a large number of parameters were collinear. As a result, two different multivariable analyses were performed, one including Rpk (and omitting Mr1), and a second including Mr1 (and omitting Rpk). For each analysis, a backwards selection procedure was performed to examine the factors associated with the taper wear rate.

When Rpk was included in the analysis, this was found to be the only significant roughness parameter. As this was the only roughness parameter in the final model, the size of effect was equivalent to that seen in the earlier analysis. That is a ratio for a one-unit increase of 1.73 (95% CI: 1.21, 2.49); $p=0.004$. This suggests that a one-unit increase in Rpk was associated with a 73% increase in wear rate.

When Mr1 was included in the analysis, this was found to be the only significant roughness parameter. As only Mr1 was significant (of the roughness parameters), the size of effect for this variable was equivalent to that from the earlier analysis. That is a ratio for a five-unit increase of 1.21 (95% CI: 1.07, 1.36); $p=0.002$. This suggests that a 5-unit increase in Mr1 was associated with a 21% increase in wear rate.

The R2 values from the multivariable analysis was 48% when Rpk was included, and 53% when Mr1 was included This value compares to an R2 value of 42% when just the known risk factors (time to revision, bearing wear rate and head offset) were included

Discussion

We examined the surface topography of the ‘as manufactured’ female head taper of the Pinnacle MOM bearing. We found that (1) there was a large variability in the surface roughness of these tapers and (2) this variability had a significant effect on the volume of material lost at the taper junction. After controlling for known confounding surgical, implant and patient factors, our multivariable statistical analysis revealed that a one-unit increase in the roughness parameter Rpk was associated with a 73% increase in the taper wear rate.

Our results are of clinical significance due to the growing evidence that material released from the head-stem junction, due to mechanical wear and/or corrosion, plays a role in implant failure due to adverse tissue reactions. Retrieval analysis of a large number of implants of a single design can help us understand the surgical, implant and patient factors that influence the rate of material released from this junction.

Previous studies have reported on the importance of stem trunnion design and topography, with the length, diameter and roughness shown to influence taper wear rate [11, 12]. Head size, head length and offset have also been implicated in material loss differences however the influence of the head taper counter-face has not been fully explored.

The large variability in the surface finish that we found in this study was surprising; our measurements revealed that the difference between the maximum and minimum values for the surface roughness parameters was as high as 3873-fold. The relationship between increasing taper surface roughness and material loss draws parallels with previously reported studies investigating roughness of the stem trunnion surface [11, 13]. Indeed, we found some head tapers in the current study with measured Ra values that were greater than that reported for 'rough' trunnions in a previous experimental study (range 2.73–2.79µm) with the highest Ra of 'as manufactured' head taper in our study being 3.19µm. This is also higher than the largest value of the 8 retrieved Corail trunnions we tested (max 2.61µm) (fig 4).

The four roughness parameters that were found to be significant predictors of material loss are associated with the peaks of the surface (Rpk), the area of the material that contains these peaks (A1), the ratio of the peaks when compared to the rest of the material (M1) and the degree of asymmetry of the surface height distribution (Rsk). These all related to the size and density of the asperities and therefore the mechanical interactions that occur at the interface (fig 5).

We suggest a mechanism whereby the distribution of high peaks across the taper surface prevents full sealing of the taper junction at the trunnion-taper interface, allowing fluid ingress at the junction, increasing micro-motion as the peaks are worn down (fig 6) and initiating a mechanism of mechanically assisted crevice corrosion (MACC) in addition to galvanic corrosion.

This process may be further exacerbated by the already ‘rough’ topography of the Corail AMT trunnions used with the bearings in this study as shown in Table 6. A recent in-vitro study analyzing the AMT trunnion engagement on the Pinnacle CoCr head has shown a maximum of 20% of the available trunnion surface engages the head, even at the highest impaction force used in the experiment with only the threads making contact with the taper, further reducing the contact area while increasing the contact stresses and allowing channels for fluid [14].

The results of our study correspond with a previous in-vitro study that looked at the influence of roughness parameters on wear; this study found that Rpk was one of the most predominate surface features that influenced the wear rate of polyethylene against a harder steel counter face [15]. Rpk is a characteristic that represents the highest peaks on the profile and in engine components are quickly worn away, however, in hydraulic and aerospace applications that require a watertight seal having a high Rpk prevents this by leaving gaps in the interface. Aerospace and hydraulic seal literature states that the surface profile of the material must have extremely low Rpk to create an effective, watertight and long lasting seal [16, 17].

Clinical relevance

The metal-on-metal DePuy Pinnacle was one of the most widely used MOM hip worldwide with a combination of a titanium Corail femoral stem on a CoCr head; the knowledge gained in this study will help surgeons manage patients with this implant design.

Limitations

As with all retrieval studies, the tested components are failed implants that have been revised and therefore we are unable to compare these to well functioning implants. We have also not been able to calculate the sample size or power needed for this study, as this is the first to look into this subject. While it is possible that a lack of power may have influenced the results, the data we provided could be used in future studies as a base for power calculations and comparison.

Conclusion

We have shown that the surface finish of the head taper of a commonly used total hip replacement of a single design has a large variability in its measured roughness; our multivariable analysis has identified 4 roughness parameters that significantly influence the volume of material lost from the taper junction: Rpk, A1, M1 and Rsk. We suggest that manufacturers ensure that the tapers have as plateaued a surface as possible to allow a good seal on the trunnion to minimize fluid ingress and micro-motion.

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Figure 1 –

The Pinnacle metal-on-metal components with Corail stem (DePuy, Warsaw, Indiana), which were used in all analyzed cases. (a) Press-fit titanium acetabular shell (b) Cobalt-chromium liner (c) Cobalt-chromium head (d) Corail un-cemented femoral stem

Figure 2 –

Diagram showing the possible areas that the ‘as manufactured’ surface data was taken. Red area denotes the trunnion engagement within the femoral head (a) ≥1.5mm of ‘as manufactured’ surface available at both proximal and distal region of head, (b) ≥1.5mm of ‘as manufactured’ surface available at proximal region of head, (c) ≥ 1.5mm of ‘as manufactured’ surface available at distal region of head, (d) ≥ 1.5mm of ‘as manufactured’ surface not available and therefore did not satisfy inclusion criteria

Figure 3 –

The Pinnacle head taper was (a) measured with a RMM (arrow showing the stylus in contact with the taper) (b) generated a wear map showing the ‘as manufactured’ (bi) and worn region of the head taper (bii) from which (c) the ‘as manufactured’ and worn regions can be identified using a 2D extracted trace (19.5mm) of the taper and (d) 1.5mm of the ‘as manufactured’ surface extracted. (e) Schematic showing the trace with labeling of the features observed

Figure 4 –

Schematic showing the difference in surface roughness of the taper against the ridged AMT trunnion. (a) High surface roughness causing a gap in the junction interface and high stress points leading to micro-motion and a route for fluid ingress. (ai) Single thread at distal end of the AMT trunnion against the head taper with blue arrow showing route for fluid ingress. (b) Low surface roughness allowing a tighter fit and therefore minimizing the fluid ingress and micro-motion. (bi) Single thread at distal end of AMT trunnion against head taper with blue arrow showing smaller gap for fluid ingress.

Figure 5 - Diagram showing an example of a primary trace and how it is used to construct the Abbott-Curve from which ISO 13565-2 parameters are generated. Rpk, A1 and Mr1 can clearly be visualized as the characteristics of the material that lie in the peak region and Rvk, A2 and Mr2 the valley region. For an effective seal at the interface peaks in the Rpk region should be minimized with a high density of the surface in the Rk region. This would result in the material ratio showing low Rpk, A1 and Mr1 values.

Figure 6 –

Schematic showing the difference in surface roughness of the taper against the ridged AMT trunnion. (a) High surface roughness causing a gap in the junction interface and high stress points leading to micro-motion and a route for fluid ingress. (ai) Bottom 3 ridges at distal end of the AMT trunnion against the head taper with blue arrow showing route for fluid ingress. (b) Low surface roughness allowing a tighter fit and therefore minimizing the fluid ingress and micro-motion. (bi) Bottom 3 ridges at distal end of AMT trunnion against head taper with blue arrow showing smaller gap for fluid ingress.

Table 1 – Demographic, Surgical and Orientation Data

	Number	Median	Range
Gender (Male : Female)	20 : 30		
Age at Primary Surgery (years)		61	35-73
Time to Revision (months)		67.5	19-124
Femoral Head Diameter (mm)		36	36
Angle of Acetabular Inclination (deg)		45.4	24.5-68.6
Vertical Offset (mm)		77.3	55.1-98.2
Horizontal Offset (mm)		44.8	28.1-56.9
Head Length (mm)		+5	-2-+12

Table 2 – Combined Parameters, Units and Description for ISO 4287 and ISO 13565-2

Parameter	Unit	Description
Rp	µm	Maximum Peak Height – The highest peak in the profile
Rv	µm	Maximum Valley depth – The deepest valley in the profile
Rz	µm	Ten-spot Average Roughness – Average of the 5 highest peaks and 5 deepest valleys in the profile
Rc	µm	Mean Height of the Roughness Profile Elements – The mean height of irregularities on the profile
Rt	µm	Maximum Height of the Profile – The height between the highest peak and the deepest valley in the profile
Ra	µm	Arithmetic Average Roughness – Average of the all the peaks and valleys in the profile
Rq	µm	Geometric Average Roughness – The standard deviation of height distribution providing the same information as Ra
Rsk	No Unit	Skewness – The asymmetry of height distribution. Positive values correspond to high peaks on a regular surface, negative values correspond to pores and scratches on the surface.
Rku	No Unit	Kurtosis – The shape / sharpness of the frequency distribution curve
Rmr	%	Material Ratio – The length of the bearing surface at a set depth below the highest peak
Rdc	µm	Material Ratio at a Given Depth – The height difference between two levels of a given material ratio (Rmr)
Rk	µm	Core Roughness – The surface that will maintain the load throughout the life of the component
Rpk	µm	Reduced Peak Height – The protruding peaks above the core
Rvk	µm	Reduced Valley Depth – The valleys that will retain fluid or worn out material
Mr1	%	Material Ratio 1 – The ratio of peaks that sit above the core
Mr2	%	Material Ratio 2 – The ratio of valleys the sit below the core
A1	$\mu m^2/mm$	Area of the Peak region – The area of the Abbott-Curve that contains the peaks from the profile
A2	$\mu m^2/mm$	Area of the Valley region – The area of the Abbott-Curve that contains the valleys from the profile

Table 3 - Total Bearing and Taper Wear Rates

	Bearing Wear Rate (mm^3 / year)	**Taper Wear Rate (mm^3 / year)**
Minimum	0.87	0.00
25% Percentile	2.28	0.05
Median	3.59	0.27
75% Percentile	7.48	1.20
Maximum	62.12	3.45

Table 4 –

Variations in the 'as manufactured' taper surface roughness parameters

	Minimum	25% Percentile	Median	75% Percentile	Maximum
Rc	0.52	1.48	2.79	4.66	11.33
Rt	1.09	2.23	3.47	5.66	12.40
Ra	0.16	0.39	0.79	1.36	3.19
Rq	0.20	0.47	0.89	1.66	3.72
Rsk	-0.73	-0.31	0.04	0.35	0.84
Rku	1.40	1.73	2.05	2.34	3.29
Rmr	5.71	15.43	24.80	44.88	97.48
Rdc	0.36	0.88	1.88	3.03	7.69
Rk	0.61	1.30	2.06	3.95	6.33
Rpk	0.05	0.24	0.50	1.06	2.98
Rvk	0.10	0.22	0.37	0.66	7.32
Mr1	0.46	5.99	11.98	21.89	39.98
Mr2	59.13	84.53	91.84	95.79	99.00
A1	0.15	7.12	30.89	140.10	581.00
A2	0.67	5.67	17.41	48.79	1130.00

Table 5 –

Variations in the stem trunnion surface roughness parameters

	Minimum	25% Percentile	Median	75% Percentile	Maximum
Rc	4.89	6.65	7.26	8.26	8.95
Rt	2.20	6.17	7.61	8.28	8.90
Ra	1.34	1.76	1.89	2.23	2.61
Rq	0.94	1.72	2.17	2.40	2.63
Rsk	0.21	0.48	0.62	0.75	2.56
Rku	1.73	2.09	2.22	2.35	8.63
Rmr	4.79	8.09	10.30	11.71	12.78
Rdc	3.10	4.17	4.20	4.87	5.08
Rk	3.98	4.28	5.17	6.01	6.07
Rpk	0.14	1.18	3.22	4.61	5.68
Rvk	0.05	0.07	0.18	0.30	34.07
Mr1	18.80	21.91	26.43	35.98	98.93
Mr2	94.73	97.98	99.09	99.54	984.33
A1	0.70	203.71	379.63	656.56	1069.25
A2	0.15	0.38	1.64	4.88	10.87

Table 6 – Analysis of covariates on taper wear rate

	Number	Ratio (95% CI)	p-value
Gender	50	0.81 (0.42, 1.58)	0.54
Age (**)	42	1.11 (0.72, 1.71)	0.63
Time to revision (years)	50	1.24 (1.07, 1.42)	**0.004**
Bearing wear rate (#)	50	0.23 (0.12, 0.46)	**<0.001**
Inclination (**)	41	1.12 (0.75, 1.66)	0.58
Horizontal offset (*)	41	1.10 (0.86, 1.40)	0.46
Vertical offset (**)	41	1.19 (0.83, 1.70)	0.33
Edge wear	50	0.74 (0.36, 1.51)	0.40
Head Length	50	1.11 (1.02, 1.22)	**0.02**

(*) Ratio reported for a 5-unit increase
(**) Ratio reported for a 10-unit increase
(#) Variable analysed on log scale (base 10)

Table 7 – Analysis of roughness parameters on taper wear rate with both unadjusted and adjusted for covariates

Variable	Unadjusted Ratio (95% CI)	Unadjusted p-value	Adjusted (+) Ratio (95% CI)	Adjusted (+) p-value
Rp	1.51 (1.13, 2.00)	**0.006**	1.25 (0.95, 1.64)	0.11
Rv	1.17 (0.92, 1.47)	0.19	1.02 (0.84, 1.25)	0.82
Rz	1.14 (1.00, 1.30)	0.05	1.05 (0.93, 1.18)	0.41
Rc	1.14 (0.99, 1.31)	0.06	1.05 (0.92, 1.19)	0.50
Rt	1.14 (1.01, 1.29)	**0.01**	1.05 (0.94, 1.17)	0.38
Ra	1.53 (0.97, 2.39)	0.06	1.15 (0.76, 1.76)	0.49
Rq	1.46 (0.98, 2.18)	0.06	1.14 (0.79, 1.65)	0.48
Rsk (^)	1.11 (1.02, 1.20)	**0.02**	1.08 (1.01, 1.15)	**0.03**
Rku	0.89 (0.40, 1.94)	0.76	1.41 (0.70, 2.84)	0.32
Rmr (^^^)	0.83 (0.73, 0.95)	**0.009**	0.91 (0.81, 1.03)	0.15
Rdc	1.18 (0.98, 1.42)	0.07	1.06 (0.89, 1.26)	0.51
Rk	1.20 (0.98, 1.47)	0.08	1.08 (0.90, 1.30)	0.39
Rpk	2.30 (1.54, 3.42)	**<0.001**	1.73 (1.21, 2.49)	**0.004**
Rvk	0.97 (0.76, 1.25)	0.83	0.90 (0.74, 1.10)	0.31
Mr1 (^^)	1.28 (1.11, 1.48)	**0.001**	1.21 (1.07, 1.36)	**0.002**
Mr2 (^^)	1.10 (0.93, 1.30)	0.25	1.14 (1.00, 1.30)	0.05
A1 (#)	1.85 (1.26, 2.69)	**0.002**	1.62 (1.19, 2.19)	**0.003**
A2 (#)	0.88 (0.57, 1.35)	0.54	0.80 (0.57, 1.12)	0.19

(+) Adjusted for Time to revision, Bearing wear rate and Head offset
(^) Ratio reported for a 0.1-unit increase
(^^) Ratio reported for a 5-unit increase
(^^^) Ratio reported for a 10-unit increase
(#) Variable analysed on log scale (base 10)

Figure – 1

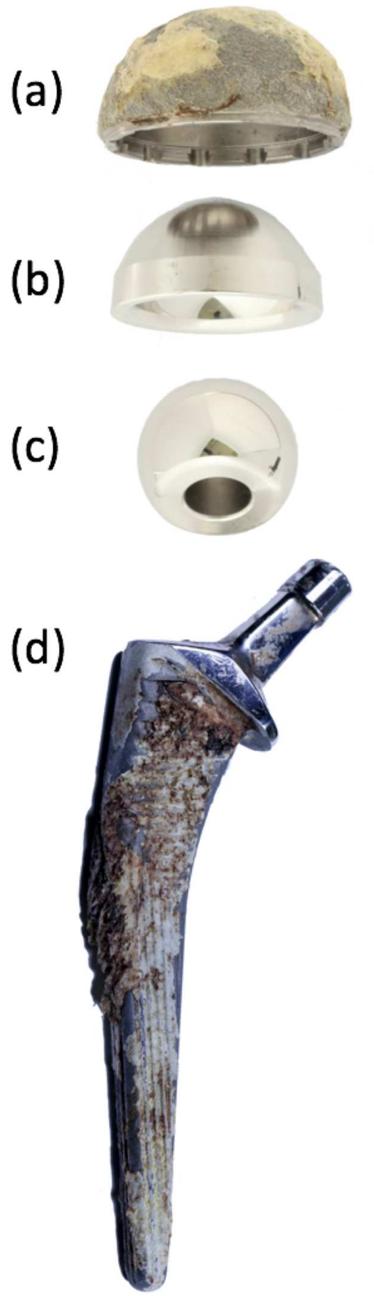

Figure 2 –

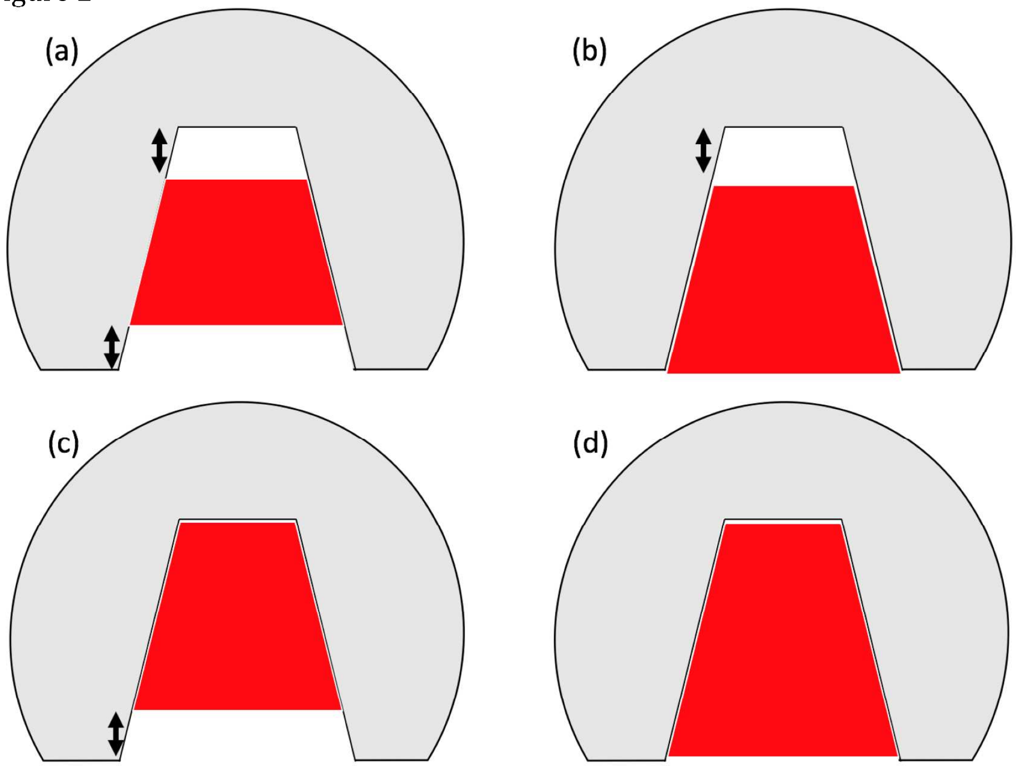

Figure 3 –

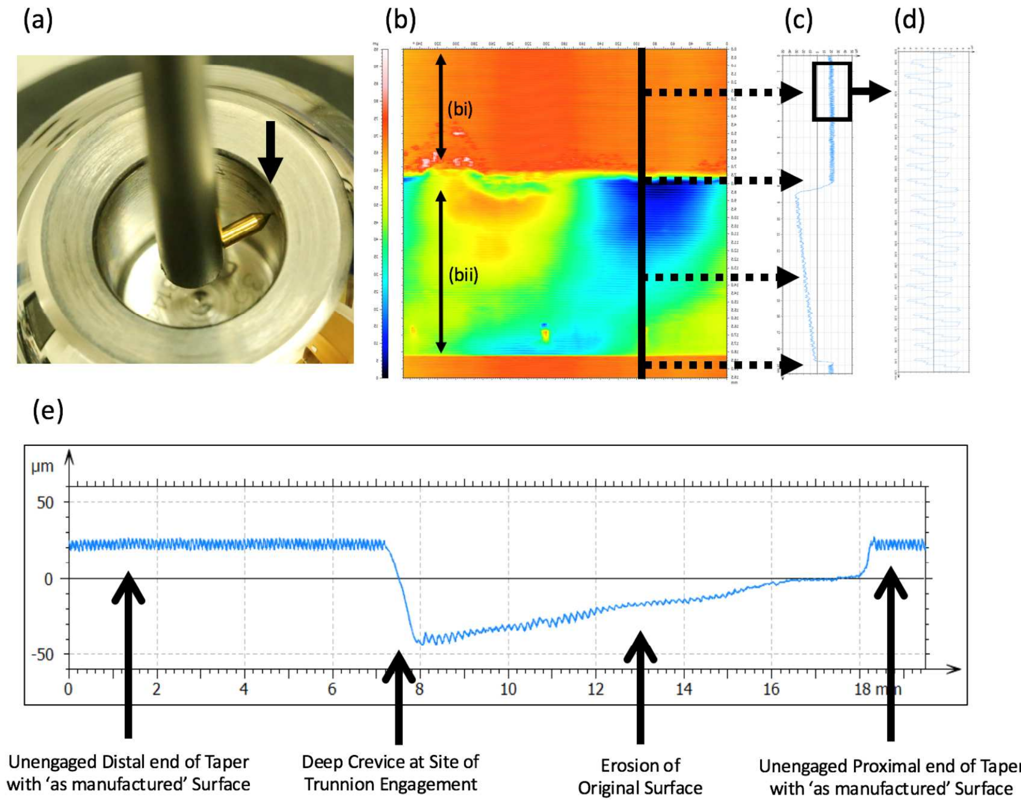
(a)
(b)
(c)
(d)
(bi)
(bii)
(e)
µm
50
0
-50
0
2
4
6
8
10
12
14
16
18 mm
Unengaged Distal end of Taper with 'as manufactured' Surface
Deep Crevice at Site of Trunnion Engagement
Erosion of Original Surface
Unengaged Proximal end of Taper with 'as manufactured' Surface

Figure 4 –

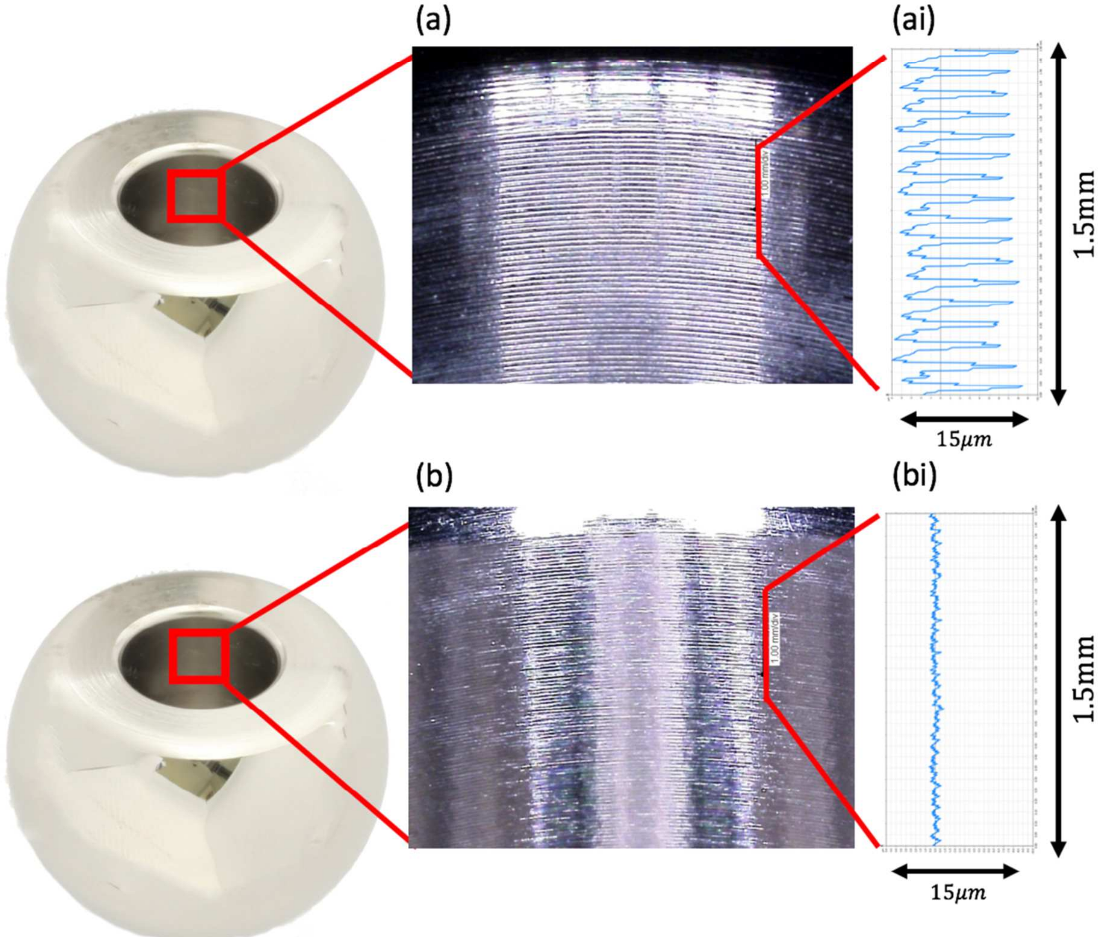

Figure 5 –

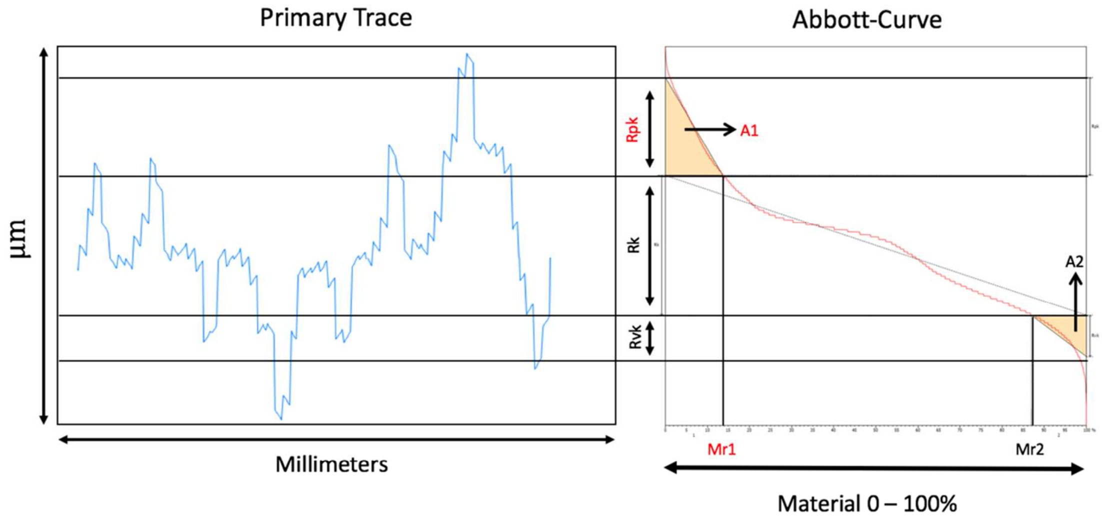
Primary Trace
µm
Millimeters
Abbott-Curve
Rpk
A1
Rk
A2
Rvk
Mr1
Mr2
Material 0 – 100%

Figure 6 –