Factors Associated with Trunnionosis in the Metal-on-Metal Pinnacle Hip

Harry S. Hothi[1], Antti Eskelinen[2], Reshid Berber[1], Olli Lainiala[2], Teemu Moilanen[2], John A. Skinner[1], Alister J. Hart[1]

1. Institute of Orthopaedics and Musculoskeletal Science, University College London and the Royal National Orthopaedic Hospital, Stanmore, United Kingdom
2. The Coxa Hospital for Joint Replacement, Tampere, Finland

Corresponding Author:
Harry S. Hothi
Institute of Orthopaedics and Musculoskeletal Science (University College London)
Royal National Orthopaedic Hospital, Brockley Hill, Stanmore, Middlesex, HA7 4LP
United Kingdom, Phone: +44 (0) 208 909 5825, Fax: +44 (0) 208 954 8560
Email: h.hothi@ucl.ac.uk

Abstract

Background

Trunnionosis of the tapered head-stem junction of total hip replacements (THRs), either through corrosion or mechanical wear, has been implicated in early implant failure. Retrieval analysis of large numbers of failed implants can help us better understand the factors that influence damage at this interface.

Methods

In this study we examined 120 retrieved total hip replacements (THR) of one bearing design, the 36mm diameter metal-on-metal (MOM) DePuy Pinnacle, that had been paired with 3 different stems. We measured material loss of the bearing and head-trunnion taper surfaces and collected clinical and component data for each case. We then used multiple linear regression analysis to determine which factors influenced the rate of taper material loss.

Results

We found four significant variables: (1) longer time to revision ($p=0.004$), (2) the use of a 12/14 taper for the head-trunnion junction ($p<0.001$), (3) decreased bearing surface wear ($p=0.003$) and (4) vertical femoral offset ($p=0.05$). These together explained 29% of the variability in taper material loss.

Conclusions

Our most important finding is the effect of trunnion design. Of the three types studied we found that S-ROM design was the most successful at minimising trunnionosis.

Keywords: Taper, Material Loss, Corrosion, Retrieval, Metal-on-Metal

Introduction

Numerous reports have demonstrated that a significant amount of material can be lost from the taper junction of large diameter ($\geq$36mm) total hip replacements (THRs) as a result of fretting or corrosion [1-4]. This process is commonly referred to as trunnionosis however the mechanisms of this are poorly understood.

Retrieval studies investigating large numbers of failed components have the ability to identify the surgical, implant and patient factors associated with high taper material loss [5]. For instance, previous studies have suggested that the paring of dissimilar alloys, i.e. a titanium stem with a cobalt-chromium head, can increase the risk of galvanic corrosion at the taper junction [6].

A recent in vitro study has suggested that smoother and longer trunnions are associated with less mechanically assisted corrosion (MAC) [7]. It is vital that retrieval studies confirm or refute these findings since in vitro studies did not predict the highly variable in vivo rates of bearing surface wear of metal-on-metal (MOM) hips.

The Pinnacle (DePuy) was one of the most commonly implanted MOM hips in the world and was typically paired with a Corail, Summit or S-ROM stem. It has been demonstrated that the Corail and Summit have a similar trunnion surface topography that is rougher than that of the S-ROM [8], which is also longer.

Furthermore an understanding of all other factors associated with increased taper material loss may assist clinical surveillance of implants through risk stratification and facilitate improved future designs. Therefore in this study we used multiple linear regression statistics to identify those factors that are associated with material loss at the head taper of a hip of a single design.

Methods

This was a retrieval study involving 120 MOM Pinnacle hips that had been consecutively received at our centre. Analysis was performed on a total of 360 different surfaces, consisting of the cup bearing, head bearing and head taper surface for each hip. All hips consisted of a 36mm femoral head and had been retrieved from 50 male and 70 female patients with a median age of 62 years (26-75) and a median time to revision of 73.5 months (12-128). The median pre-revision whole blood cobalt and chromium metal ion levels were 6.9 (0.60-97.40) and 3.7 (0.50-90.00) respectively; the median Co/Cr ratio was 1.95 (0-10.20). The reasons for revision were unexplained pain confirmed as adverse reaction to metal debris (ARMD) post-revision (n=115), infection (n=2), femoral loosening (n=1), malposition (n=1) and recurrent dislocations (n=1).

The hips had been paired with three different stem designs: Corail (n=61), Summit (n=42) and S-ROM (n=17) however only 16 stems were retrieved. All three stem designs were made of a forged titanium alloy (TiAl6V4) and used a cementless fixation. The trunnions of the Corail and Summit stems had the same diameter (12/14), comparable angle (5.6°), flexural rigidity (162.25 Nm^2 and 160.54 Nm^2 respectively), and comparable length and surface topography. The trunnion of the S-ROM stem was however longer and smoother [8], had a smaller diameter (11/13), greater angle (6°) and lower flexural rigidity (108.98 Nm^2), Figure 1. The S-ROM stem also has a greater degree of modularity with the addition of an adjustable proximal sleeve.

Pre-revision X-rays were obtained for each hip in order to measure the position of the implant; the median acetabular inclination was 45° (24-68) and the median horizontal and vertical femoral offsets were 43mm (28-59) and 76mm (52-98) respectively.

***Visual Assessment of Corrosion**:*

The severity of corrosion of each of the retrieved head taper surfaces was determined through macroscopic inspection and with the aid of a Leica M50 microscope [Leica Microsystems, Germany] at up to 40x magnification. A well-published scoring system [1] was used to grade each taper with a score of between 1 (no corrosion) and 4 (severe corrosion); this method has previously been demonstrated as being both repeatable and reproducible [2]. Corrosion scoring was conducted by a single examiner experienced in retrieval analysis. We repeated this corrosion scoring for the 16 stem trunnions that were available in this study.

***Measurement of Bearing Surface Material Loss**:*

A Zeiss Prismo (Carl Zeiss Ltd, Rugby, UK) coordinate measuring machine (CMM) was used to measure the volume of material loss at the cup and head bearing surfaces of the retrieved hips. A 2mm ruby stylus was translated along 400 polar scan lines on each surface, using previously published protocols [9], to record up to 30,000 data points. The raw data was analysed using an iterative least square fitting method and regions of material loss were mapped by comparing with the unworn geometry of the bearing surface. These wear maps were also used to determine if edge wear of the cup had occurred.

***Measurement of Head Taper Material Loss**:*

A Talyrond 365 (Taylor Hobson, Leicester, UK) roundness-measuring machine was used to measure the volume of material loss at the internal taper surface of each femoral head. Using previously published protocols [10], a 5µm diamond stylus was used to take a series of 180 vertical traces along the axis of the taper surface. These traces were combined to create a rectangular surface from which worn and unworn regions were identified and volumetric material loss calculated. Due to insufficient numbers of retrieved stems available we did not consider material loss at the stem trunnion in this study, however it has previously been shown that material loss at the trunnion is negligible [10] as the CoCr head taper is preferentially worn over the softer titanium stem.

Factors Included in the Multiple Regression Analysis

We calculated the association between 10 variables and the extent of corrosion and annual material loss rate at the taper; this was calculated by dividing the total volume of material loss by time in vivo and normalising to the equivalent of 1 year. These variables were identified through review of the current literature as factors known or likely to affect the mechanical properties of the head-stem junction, or those that were found to be directly associated with clinical performance. These factors were: (1) time to revision [1, 11, 12], (2) stem design [13, 14], (3) combined bearing surface wear rate [15], (4) cup inclination [16], (5) the presence of edge wearing [15, 17], (6) taper engagement length, (7) patient age, (8) patient gender, (9) horizontal femoral offset and (10) vertical femoral offset. Due to incompleteness of associated data for 12 implants, our final statistical models included 108 implants.

Statistical Analysis:

The outcome variable taper material loss rate was found to have a right skewed distribution. Therefore, a log transformation was performed prior to the analysis. Due to a number of zero loss rate values, a small constant of 0.2 was applied before the transformation (this chosen as the smallest value to produce an approximately normal distribution).

The analysis was performed using linear regression and was performed in two stages. Firstly, the separate association between each variable and the taper material loss rate was examined in a series of univariable analyses. Subsequently a multivariable analysis was performed to examine the joint association between the factors and taper material loss rate. A backwards selection procedure was used to retain only the statistically significant variables in the final model.

To make the regression results more interpretable, the regression coefficients were back-transformed, and expressed as the percentage change in taper material loss rate.

We confirm that all investigations were conducted in conformity with ethical principles of research, that informed consent for participation in the study was obtained and that institutional approval of the human protocol for this investigation was obtained.

Results

The median rate of volumetric material loss at the head taper was 0.23mm^3/year (0mm^3/year - 3.45mm^3/year). The median rate of volumetric wear from the combined bearing surfaces (cup and head) was significantly higher ($p<0.001$), with a median rate of 3.38mm^3/year (0mm^3/year - 62.12mm^3/year), Figure 2. We found evidence of corrosion on all head taper surfaces; the mean taper corrosion score was 3.25 (2-4). The head tapers with Corail and Summit stems showed visual evidence of imprinting of the trunnion fully inside the head taper whilst the tapers with S-ROM trunnions visually appeared to have engaged fully up to the edge of the taper surface.

The stem trunnions presented evidence of minimal surface changes with a median corrosion score of 1 (1-2).

Initially the separate association between each variable and taper material loss rate was examined in a series of univariable analyses, Table 1. As the outcome was given a log transformation, the results are reported in the form of a percent change, with 95% confidence intervals. For continuous variables (time to revision, inclination, age, femoral offset and total bearing wear rate) these represent the percentage change in the taper material loss rate for a one-unit increase in that factor (other sized increases are reported when one-unit was a small amount). For the categorical variables (stem design, edge wear, gender and engagement length) these give the percentage difference in the taper material loss rate between categories. P-values indicating the significance of each variable are also reported, as are R^2 values indicating the proportion of variation in the outcome explained by each factor.

The taper wear rate appeared to be significantly associated individually with time to revision ($p<0.001$), stem design ($p<0.001$), total bearing wear rate ($p=0.01$), taper engagement length ($p=0.004$), and horizontal ($p=0.02$) and vertical femoral offset ($p=0.01$).

Time to revision was positively associated with taper material loss rate (R^2=11.1%). A one-year increase in time to revision resulted in a 14% increase in predicted taper wear rate. The relationship between the two variables is shown in Figure 3, which shows the individual data points as well as the fitted regression line.

There was no significant difference in taper wear rate compared between using a Corail or Summit stem ($p=0.938$), which had median wear rates of 0.36mm^3/year (0mm^3/year - 3.45mm^3/year) and 0.35m m^3/year (0mm^3/year - 2.46mm^3/year) respectively. The hips with the S-ROM stem design had a median wear rate of 0.06mm^3/year (0mm^3/year - 0.52mm^3/year) and was significantly lower than the taper wear rates of the other two designs ($p=0.001$), Figure 4.

Total bearing wear rate (R^2 = 57.3%, p = 0.005) and taper engagement length (R^2 = 7%, p = 0.006) were both individually negatively associated with taper wear rate. A 5-unit increase in total bearing wear rate resulted in a 11% reduction in predicted taper wear rate, whilst patients with a taper engagement length of approximately 14mm had half the wear of those with a length of approximately 10mm. The results for total bearing wear rate are shown in Figure 5.

The second stage in the analysis examined the variables jointly in a multivariable analysis. Due to collinearity between taper engagement length and stem design only one could be included in the multivariable analysis. Taper engagement length was excluded from the model because stem design provided additional information. A backwards selection approach was used to retain only those factors associated with the taper wear rate, Table 2.

The multivariable analysis suggested some evidence that: (1) time to revision, (2) stem design (3) total bearing rate and (4) vertical femoral offset were independently associated with taper wear rate. The result for vertical femoral offset was only of borderline significance, and was retained in the final model. After adjusting for these variables there was no longer any effect of horizontal femoral offset upon the outcome. This is probably due to the high correlation with vertical femoral offset in that it makes sense that only one of the femoral offset variables would be selected in the multivariable regression.

The multivariable analysis gave an R^2 value of 29%. This suggests that just under a third of the variation in taper wear rate can be attributed to the variables in the final model. This leaves two-thirds of variation attributable to other sources.

Discussion

We conducted the first large-scale investigation of the head stem taper junction of retrieved Pinnacle MOM hips. After analysing the effect of 10 different variables we found that four of these showed a significant effect on taper material loss: time to revision, stem design, vertical femoral offset and total bearing rate. Our multivariable analysis showed that these four variables together accounted for approximately one-third of the variation in taper material loss rate in this study. The most interesting result was that of the effect of stem design. We found that the use of the S-ROM stem trunnion led to significantly less trunnionosis compared to the Corail and Summit stems. In comparison to these two stem designs, the S-ROM trunnion is: (1) narrower, (2) longer, (3) has a smoother surface topography, (4) wider trunnion angle and (5) lower flexural rigidity.

It is difficult to separate out the multiple design differences amongst hip tapers, including within our collection of retrieved hips. Therefore, by including only one design (Pinnacle) with one head size (36mm), we have been able to eliminate these variables as confounding factors in our analysis, thereby more clearly demonstrating the potential effect of other variables. However, it is important to note that our models are unable to explain two-thirds of the variability in the taper material loss. This is due to unknown influencing factors not being included in the current study and may include variables such as patient activity; efforts should be made in future studies to capture as many additional patient related data as possible.

The Corail and Summit stems have threaded trunnion surfaces that were originally created for use with ceramic heads but often have been paired with metal heads. Additionally both of these designs have a wider (12/14) short taper referred to by the manufacturer as the 'Articuleze Mini Taper' (AMT). In contrast, the trunnion of the S-ROM stem is notably longer, thinner (11/13) and is also unthreaded; Munir et al. [8] reported that the average surface roughness (S_a) of the S-ROM trunnion is up to 10 times smaller than that of the Corail and Summit.

In the current study, the median taper material loss rate with the longer, smoother 11/13 trunnions was 6 times smaller than the tapers that had used the shorter, rougher 12/14 trunnions. Visual macroscopic analysis suggested that the 12/14 trunnions were seated fully inside the taper such that the trunnion base was positioned beyond the taper opening. This position may have increased the susceptibility of the trunnion toggling within the taper, leading to regions of elevated contact stresses localised at opposing ends of the trunnion. The 11/13 trunnions however were engaged up to the boundary of the taper opening (with the exception of scalloped regions of the S-ROM design) thereby minimising this toggling risk. Furthermore, the greater contact area associated with the longer, smoother 11/13 trunnions is likely to have reduced contact stresses and therefore the extent of fretting-corrosion. It is hypothesised that a greater concentration of forces with a smaller contact area of the 12/14 trunnions may be such that the fracture strains of the oxidised layer on the taper surface are exceeded and therefore the corrosion and material loss mechanism accelerated. Our retrieval findings support the in vitro study conclusions made by Panagiotidou et al. [7] who observed greater degradation of the passive taper surface film when rough trunnions were used than with smooth. This study also concluded that a reduced contact area due to the use of shorter trunnions led to higher concentrations of bending moment forces at this junction. It should be noted however that variations in head neck length, particularly between hips of different designs, may explain some of the taper damage variations seen in other large retrieval studies. It is speculated that the higher frictional torque associated with large diameter bearings is transmitted along the taper junction and is a contributing factor to corrosion and material loss at this interface [18]. In this study we examined hips with a single head size of 36mm and found that there was a negative association between bearing surface wear rate and taper wear rate. This suggests that increasing bearing frictional torque was not a direct contributor to increasing material loss at the tapers of the implants in this study. This finding is counter-intuitive to what has previously been reported and may due to a single head size highlighting other reasons for bearing material loss which may normally be masked by the effect of increasing frictional torque with increasing head sizes.

The significant association between taper wear rate and time to revision suggests that once the damage mechanism begins at the junction, the rate of material loss accelerates over time. The combination of a suboptimal trunnion design and high frictional torque from the large MOM bearing may lead to an environment in which the oxidised layer on the CoCr taper surface is removed at a higher rate than it can re-passivate, therefore resulting in a continued attack and removal of the bulk alloy.

Conclusions

This retrieval study used a large number of MOM implants of a single design (DePuy Pinnacle) to investigate the factors associated with material loss at the head-stem taper junction. Our multiple regression models revealed four significant factors: (1) time to revision, (2) combined bearing surface wear rate, (3) vertical femoral offset and (4) stem design. These factors account for approximately one-third of the variability in taper wear rate; further work is required to identify those factors which account for the remaining unknown variability

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Variable	Category	% Change (95% CI)	P-value	R^2 (%)
Gender	Female Male	0 13% (-19%, 59%)	0.47	0.5
Age (**)	-	1% (-20%, 28%)	0.91	0.0
Time to revision (years)	-	14% (7%, 22%)	**<0.001**	11.1
Stem Design	Corail S-ROM Summit	0 -49% (-69%, -17%) 3% (-28%, 47%)	**<0.001**	7.5
Total Bearing Wear Rate (*)	-	-11% (-18%, -4%)	**0.005**	7.3
Inclination (**)	-	9% (-13%, 36%)	0.45	0.6
Horizontal Femoral Offset (*)	-	17% (2%, 33%)	**0.02**	5.6
Vertical Femoral Offset (**)	-	24% (5%, 46%)	**0.01**	6.8
Edgewear	No Yes	0 -23% (-46%, 9%)	0.14	2.1
Taper Engagement Length (mm)	10 14	0 -50% (-69%, -18%)	**0.006**	7.0

(*) % Changes given for a 5-unit increase in predictor variable
(**) % Changes given for a 10-unit increase in predictor variable

Table 1: Summary of initial univariable analysis

Model	Variable	Group	Ratio (95% CI)	P-value	R^2 (%) (#)
1	Time to revision (years)	-	11% (%3, 20%)	0.005	29.3
	Stem Design	Corail S-ROM Summit	0 -50% (-70%, -18%) -1% (-31%, 43%)	0.02	
	Bearing wear rate (*)	-	-10% (-17%, -3%)	0.003	
	Vertical Offset (**)	-	16% (-1%, 35%)	0.05	

(*) % Changes given for a 5-unit increase in predictor variable
(**) % Changes given for a 10-unit increase in predictor variable
(#) R^2 for the model as a whole

Table 2: Summary of final multivariable model

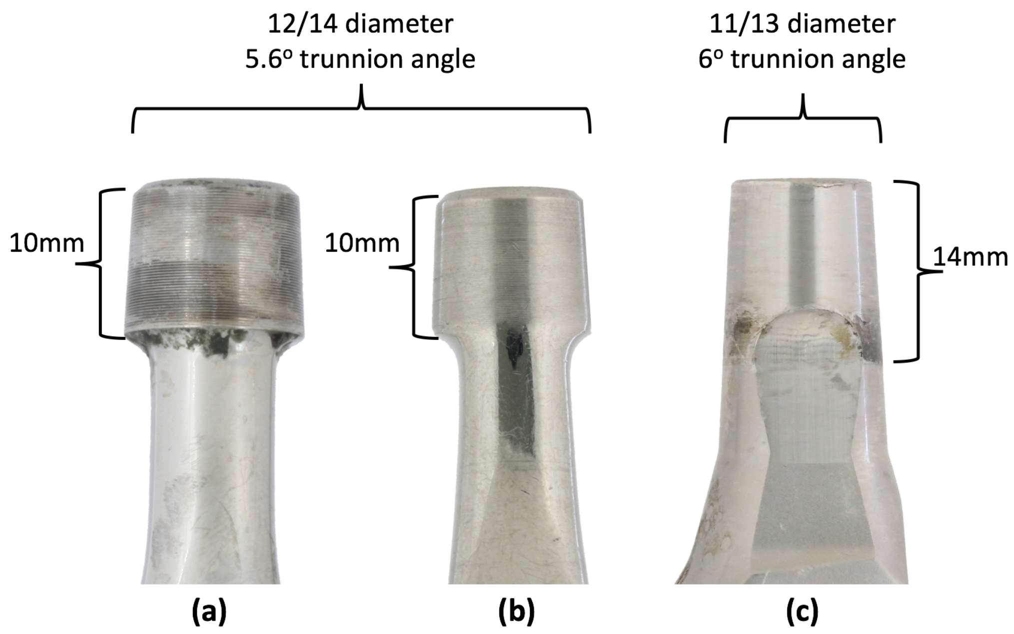

Figure 1: Trunnion dimensions of the **(a)** Corail, **(b)** Summit and **(c)** S-ROM stems

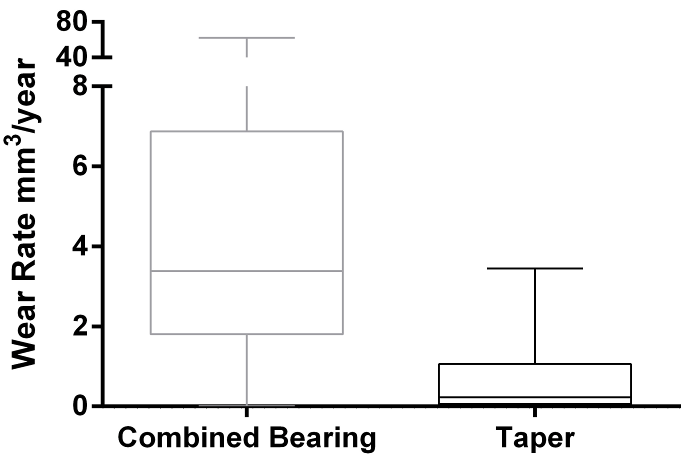

Figure 2: Measured wear rates at the bearing and taper surfaces

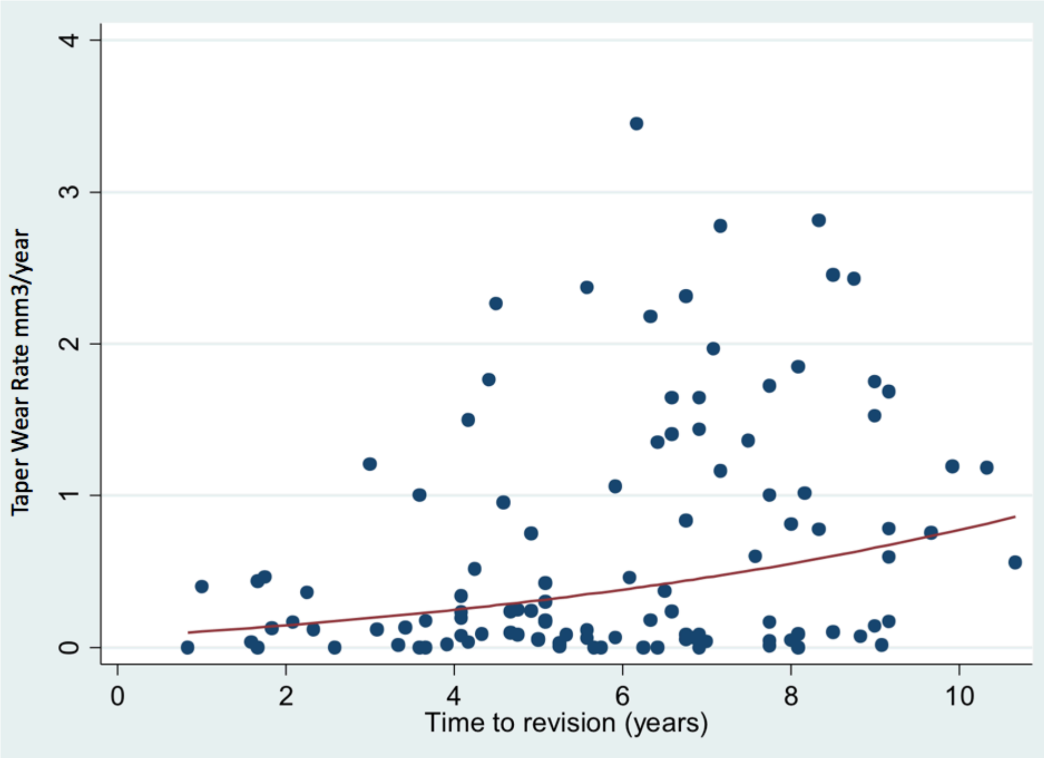

Figure 3: Plot of time to revision against taper material loss rate

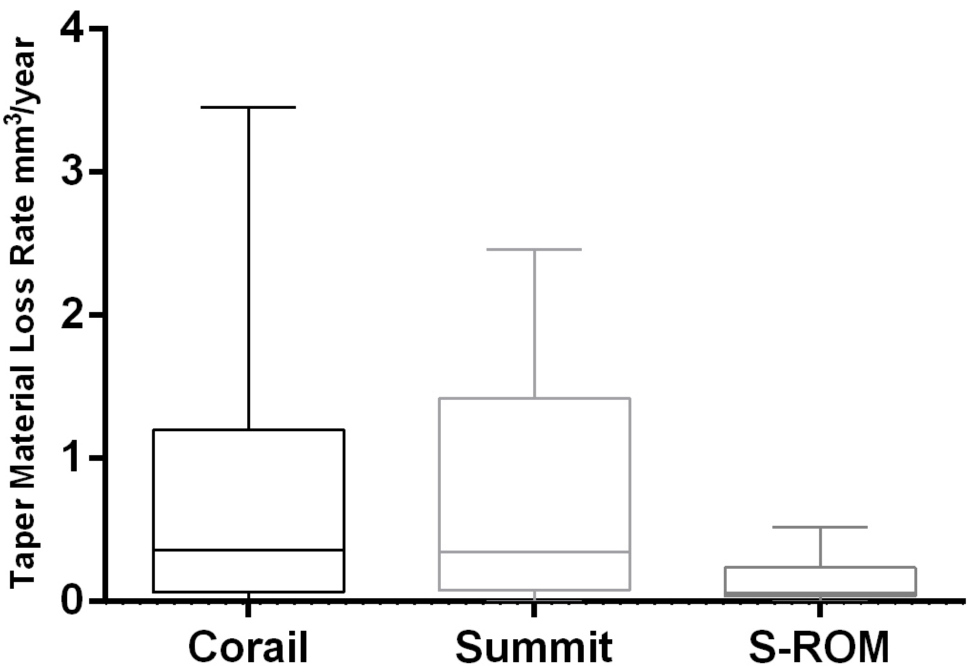

Figure 4: Differences in taper material loss rates between the three different stem designs

loss rate

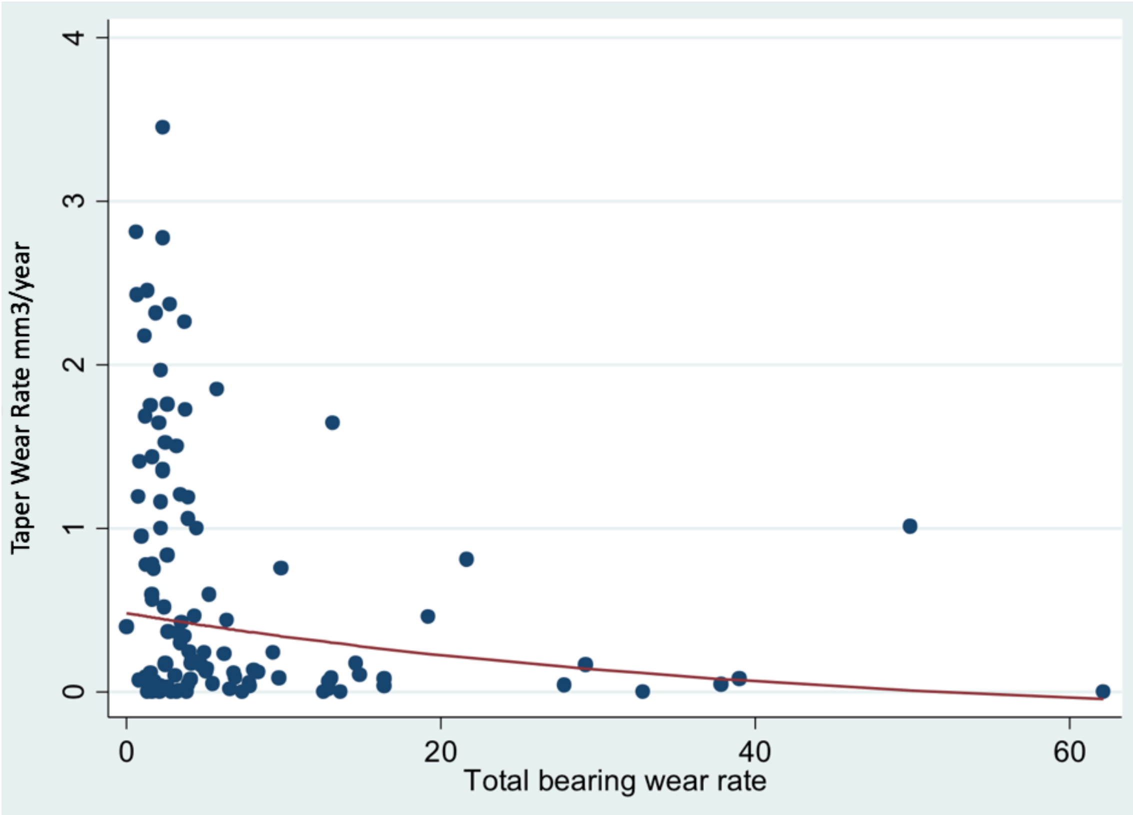

Figure 5: Plot of total bearing wear rate against taper material loss rate