

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

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26 **Abstract**

27 Background

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

32

33 Methods

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

39

40 Results

41 We found four significant variables: (1) longer time to revision ($p=0.004$), (2) the use of a
42 12/14 taper for the head-trunnion junction ($p<0.001$), (3) decreased bearing surface wear
43 ($p=0.003$) and (4) vertical femoral offset ($p=0.05$). These together explained 29% of the
44 variability in taper material loss.

45

46 Conclusions

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

49

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

51 **Introduction**

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

56

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

62

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

67

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

72

73 Furthermore an understanding of all other factors associated with increased taper material
74 loss may assist clinical surveillance of implants through risk stratification and facilitate
75 improved future designs. Therefore in this study we used multiple linear regression statistics

76 to identify those factors that are associated with material loss at the head taper of a hip of a
77 single design.

78

79 **Methods**

80 This was a retrieval study involving 120 MOM Pinnacle hips that had been consecutively
81 received at our centre. Analysis was performed on a total of 360 different surfaces, consisting
82 of the cup bearing, head bearing and head taper surface for each hip. All hips consisted of a
83 36mm femoral head and had been retrieved from 50 male and 70 female patients with a
84 median age of 62 years (26-75) and a median time to revision of 73.5 months (12-128). The
85 median pre-revision whole blood cobalt and chromium metal ion levels were 6.9 (0.60-97.40)
86 and 3.7 (0.50-90.00) respectively; the median Co/Cr ratio was 1.95 (0-10.20). The reasons
87 for revision were unexplained pain confirmed as adverse reaction to metal debris (ARMD)
88 post-revision (n=115), infection (n=2), femoral loosening (n=1), malposition (n=1) and
89 recurrent dislocations (n=1).

90 The hips had been paired with three different stem designs: Corail (n=61), Summit (n=42)
91 and S-ROM (n=17) however only 16 stems were retrieved. All three stem designs were made
92 of a forged titanium alloy (TiAl6V4) and used a cementless fixation. The trunnions of the
93 Corail and Summit stems had the same diameter (12/14), comparable angle (5.6°), flexural
94 rigidity (162.25 Nm² and 160.54 Nm² respectively), and comparable length and surface
95 topography. The trunnion of the S-ROM stem was however longer and smoother [8], had a
96 smaller diameter (11/13), greater angle (6°) and lower flexural rigidity (108.98 Nm²), Figure
97 1. The S-ROM stem also has a greater degree of modularity with the addition of an adjustable
98 proximal sleeve.

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

102

103 ***Visual Assessment of Corrosion:***

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

111

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

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

120

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

122 A Talyrond 365 (Taylor Hobson, Leicester, UK) roundness-measuring machine was used to
123 measure the volume of material loss at the internal taper surface of each femoral head. Using

124 previously published protocols [10], a 5 μ m diamond stylus was used to take a series of 180
125 vertical traces along the axis of the taper surface. These traces were combined to create a
126 rectangular surface from which worn and unworn regions were identified and volumetric
127 material loss calculated. Due to insufficient numbers of retrieved stems available we did not
128 consider material loss at the stem trunnion in this study, however it has previously been
129 shown that material loss at the trunnion is negligible [10] as the CoCr head taper is
130 preferentially worn over the softer titanium stem.

131

132 ***Factors Included in the Multiple Regression Analysis***

133 We calculated the association between 10 variables and the extent of corrosion and annual
134 material loss rate at the taper; this was calculated by dividing the total volume of material loss
135 by time in vivo and normalising to the equivalent of 1 year. These variables were identified
136 through review of the current literature as factors known or likely to affect the mechanical
137 properties of the head-stem junction, or those that were found to be directly associated with
138 clinical performance. These factors were: (1) time to revision [1, 11, 12], (2) stem design [13,
139 14], (3) combined bearing surface wear rate [15], (4) cup inclination [16], (5) the presence of
140 edge wearing [15, 17], (6) taper engagement length, (7) patient age, (8) patient gender, (9)
141 horizontal femoral offset and (10) vertical femoral offset. Due to incompleteness of
142 associated data for 12 implants, our final statistical models included 108 implants.

143

144 ***Statistical Analysis:***

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

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

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

157

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

161

162 **Results**

163 The median rate of volumetric material loss at the head taper was $0.23\text{mm}^3/\text{year}$ ($0\text{mm}^3/\text{year}$ -
164 $3.45\text{mm}^3/\text{year}$). The median rate of volumetric wear from the combined bearing surfaces (cup
165 and head) was significantly higher ($p<0.001$), with a median rate of $3.38\text{mm}^3/\text{year}$
166 ($0\text{mm}^3/\text{year}$ - $62.12\text{mm}^3/\text{year}$), Figure 2. We found evidence of corrosion on all head taper
167 surfaces; the mean taper corrosion score was 3.25 (2-4). The head tapers with Corail and
168 Summit stems showed visual evidence of imprinting of the trunnion fully inside the head
169 taper whilst the tapers with S-ROM trunnions visually appeared to have engaged fully up to
170 the edge of the taper surface.

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

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

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

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

190 There was no significant difference in taper wear rate compared between using a Corail or
191 Summit stem ($p = 0.938$), which had median wear rates of $0.36 \text{ mm}^3/\text{year}$ ($0 \text{ mm}^3/\text{year} -$
192 $3.45 \text{ mm}^3/\text{year}$) and $0.35 \text{ mm}^3/\text{year}$ ($0 \text{ mm}^3/\text{year} - 2.46 \text{ mm}^3/\text{year}$) respectively. The hips with
193 the S-ROM stem design had a median wear rate of $0.06 \text{ mm}^3/\text{year}$ ($0 \text{ mm}^3/\text{year} -$
194 $0.52 \text{ mm}^3/\text{year}$) and was significantly lower than the taper wear rates of the other two designs
195 ($p = 0.001$), Figure 4.

196 Total bearing wear rate ($R^2 = 57.3\%$, $p = 0.005$) and taper engagement length ($R^2 = 7\%$, $p =$
197 0.006) were both individually negatively associated with taper wear rate. A 5-unit increase in

198 total bearing wear rate resulted in a 11% reduction in predicted taper wear rate, whilst
199 patients with a taper engagement length of approximately 14mm had half the wear of those
200 with a length of approximately 10mm. The results for total bearing wear rate are shown in
201 Figure 5.

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

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

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

217

218

219 **Discussion**

220 We conducted the first large-scale investigation of the head stem taper junction of retrieved
221 Pinnacle MOM hips. After analysing the effect of 10 different variables we found that four of
222 these showed a significant effect on taper material loss: time to revision, stem design, vertical

223 femoral offset and total bearing rate. Our multivariable analysis showed that these four
224 variables together accounted for approximately one-third of the variation in taper material
225 loss rate in this study. The most interesting result was that of the effect of stem design. We
226 found that the use of the S-ROM stem trunnion led to significantly less trunnionosis
227 compared to the Corail and Summit stems. In comparison to these two stem designs, the S-
228 ROM trunnion is: (1) narrower, (2) longer, (3) has a smoother surface topography, (4) wider
229 trunnion angle and (5) lower flexural rigidity.

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

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

245 In the current study, the median taper material loss rate with the longer, smoother 11/13
246 trunnions was 6 times smaller than the tapers that had used the shorter, rougher 12/14
247 trunnions. Visual macroscopic analysis suggested that the 12/14 trunnions were seated fully

248 inside the taper such that the trunnion base was positioned beyond the taper opening. This
249 position may have increased the susceptibility of the trunnion toggling within the taper,
250 leading to regions of elevated contact stresses localised at opposing ends of the trunnion. The
251 11/13 trunnions however were engaged up to the boundary of the taper opening (with the
252 exception of scalloped regions of the S-ROM design) thereby minimising this toggling risk.
253 Furthermore, the greater contact area associated with the longer, smoother 11/13 trunnions is
254 likely to have reduced contact stresses and therefore the extent of fretting-corrosion. It is
255 hypothesised that a greater concentration of forces with a smaller contact area of the 12/14
256 trunnions may be such that the fracture strains of the oxidised layer on the taper surface are
257 exceeded and therefore the corrosion and material loss mechanism accelerated. Our retrieval
258 findings support the in vitro study conclusions made by Panagiotidou et al. [7] who observed
259 greater degradation of the passive taper surface film when rough trunnions were used than
260 with smooth. This study also concluded that a reduced contact area due to the use of shorter
261 trunnions led to higher concentrations of bending moment forces at this junction. It should be
262 noted however that variations in head neck length, particularly between hips of different
263 designs, may explain some of the taper damage variations seen in other large retrieval studies.
264 It is speculated that the higher frictional torque associated with large diameter bearings is
265 transmitted along the taper junction and is a contributing factor to corrosion and material loss
266 at this interface [18]. In this study we examined hips with a single head size of 36mm and
267 found that there was a negative association between bearing surface wear rate and taper wear
268 rate. This suggests that increasing bearing frictional torque was not a direct contributor to
269 increasing material loss at the tapers of the implants in this study. This finding is counter-
270 intuitive to what has previously been reported and may due to a single head size highlighting
271 other reasons for bearing material loss which may normally be masked by the effect of
272 increasing frictional torque with increasing head sizes.

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

279

280 **Conclusions**

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

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Variable	Category	% Change (95% CI)	P-value	R ² (%)
Gender	Female	0	0.47	0.5
	Male	13% (-19%, 59%)		
Age (**)	-	1% (-20%, 28%)	0.91	0.0
Time to revision (years)	-	14% (7%, 22%)	<0.001	11.1
Stem Design	Corail	0	<0.001	7.5
	S-ROM	-49% (-69%, -17%)		
	Summit	3% (-28%, 47%)		
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	0	0.14	2.1
	Yes	-23% (-46%, 9%)		
Taper Engagement Length (mm)	10	0	0.006	7.0
	14	-50% (-69%, -18%)		

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

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

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377 **Table 1:** Summary of initial univariable analysis

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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	0	0.02	
		S-ROM	-50% (-70%, -18%)		
		Summit	-1% (-31%, 43%)		
Bearing wear rate (*)	-	-10% (-17%, -3%)	0.003		
Vertical Offset (**)	-	16% (-1%, 35%)	0.05		

388 (*) % Changes given for a 5-unit increase in predictor variable
389 (**) % Changes given for a 10-unit increase in predictor variable
390 (#) R² for the model as a whole

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392 **Table 2:** Summary of final multivariable model

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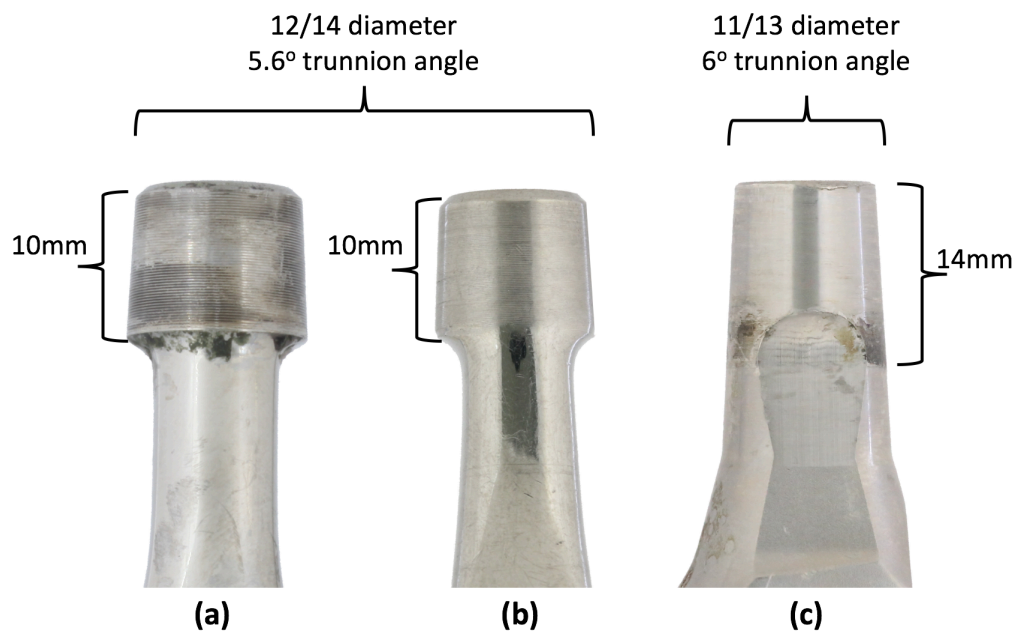
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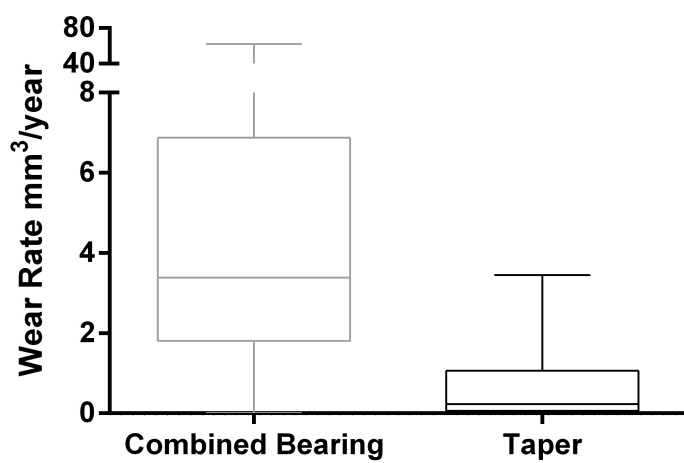


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410 **Figure 1:** Trunnion dimensions of the (a) Corail, (b) Summit and (c) S-ROM stems

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

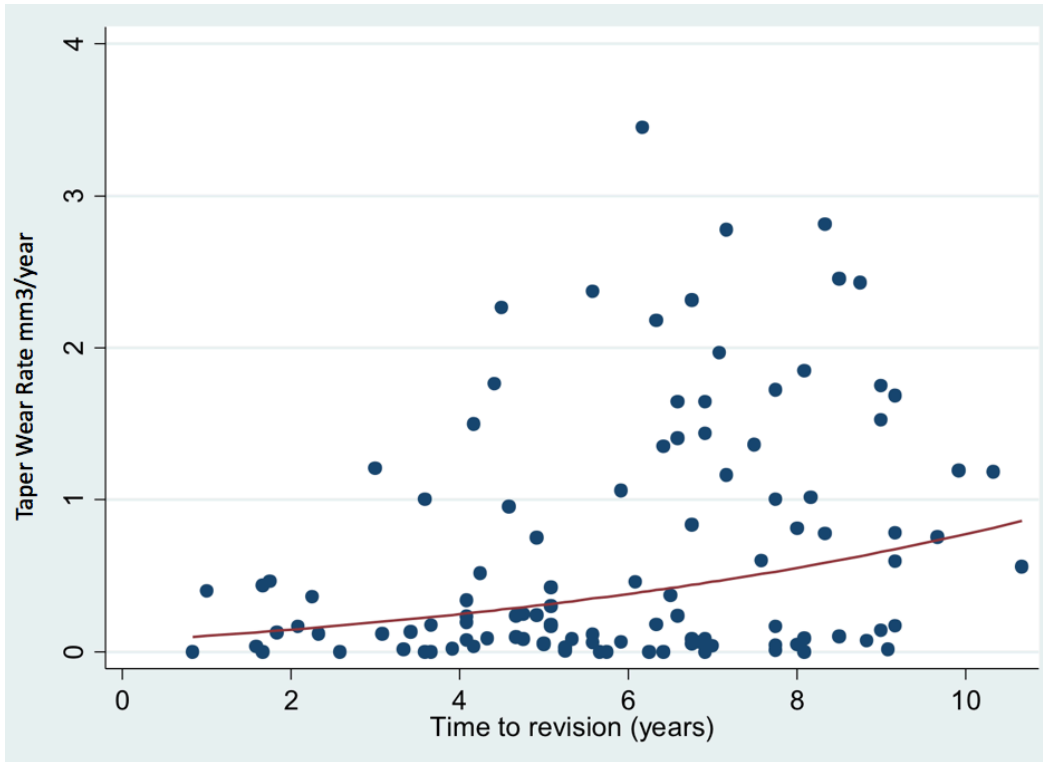
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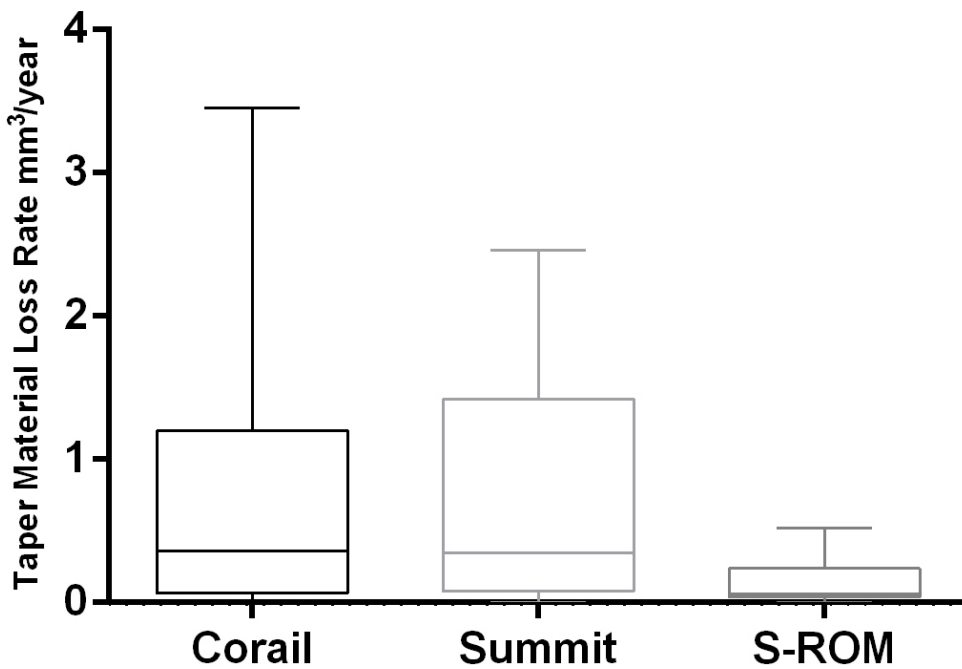
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421 **Figure 3:** Plot of time to revision against taper material loss rate

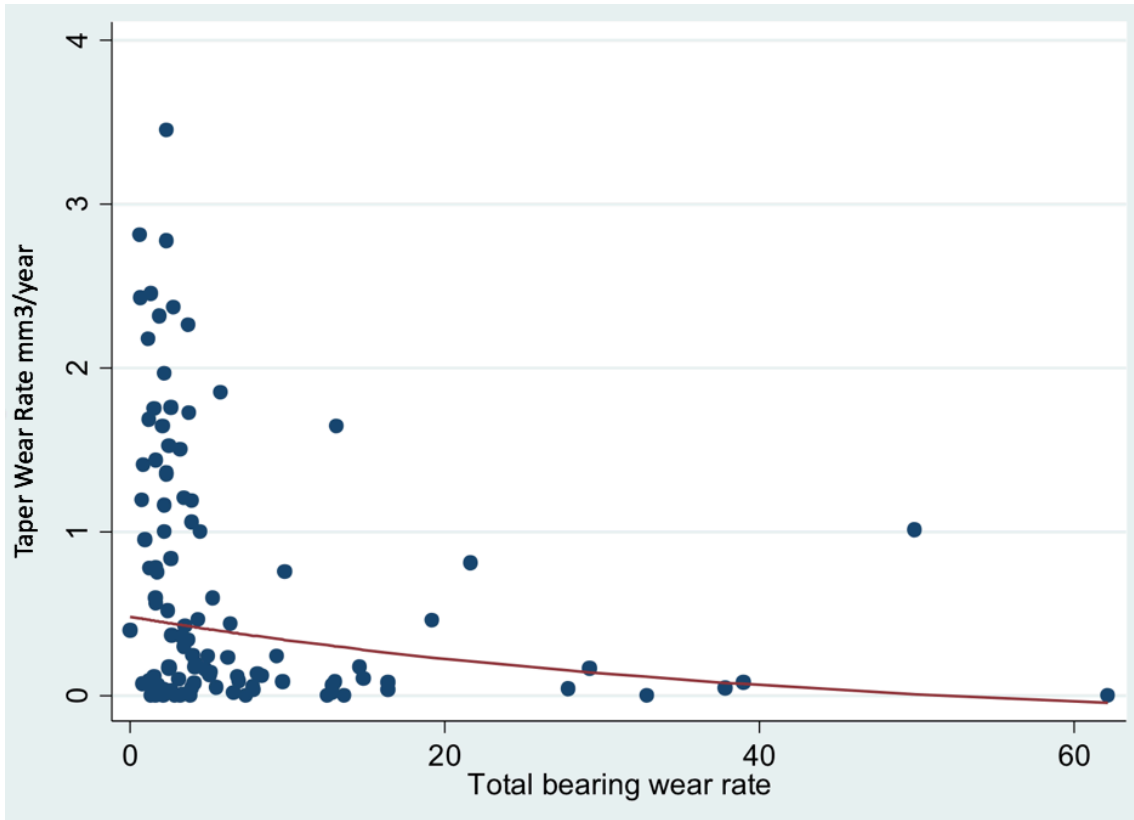
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424 **Figure 4:** Differences in taper material loss rates between the three different stem designs

425 loss rate



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

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