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[A comparative surface topographical analysis of explanted total knee replacement prostheses: Oxidised zirconium vs cobalt chromium femoral components.](#)

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1 TITLE PAGE

2 A comparative surface topographical analysis of explanted Total Knee Replacement  
3 prostheses: Oxidised Zirconium vs Cobalt Chromium femoral components

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12

13 ABSTRACT

14 It has been proposed that an increased surface roughness of the femoral components  
15 of Total Knee Replacements (TKRs) may be a contributing factor to the accelerated  
16 wear of the polyethylene (PE) bearing and ultimately prosthesis failure. Oxidised  
17 Zirconium was introduced to the orthopaedic market in an attempt to reduce PE wear  
18 associated failures and increase the longevity of the prosthesis.

19 In this study, non-contacting profilometry was used to measure the surface roughness  
20 of the femoral components of 6 retrieved TKRs (3 Oxidised Zirconium (OxZr) and 3  
21 Cobalt Chromium alloy (CoCr) femoral components) and 2 as-manufactured femoral  
22 components (1 OxZr and 1 CoCr). A semi-quantitative method was used to analyse  
23 the damage on the retrieved PE components.

24 The  $S_a$  values for the retrieved OxZr femoral components ( $S_a = 0.093\mu\text{m} \pm 0.014$ ) and  
25 for the retrieved CoCr femoral components ( $S_a = 0.065\mu\text{m} \pm 0.005$ ) were significantly  
26 greater ( $p < 0.05$ ) than the roughness values for the as-manufactured femoral  
27 components (OxZr  $S_a = 0.061\mu\text{m} \pm 0.004$  and CoCr  $S_a = 0.042\mu\text{m} \pm 0.003$ ). No  
28 significant difference was seen between the surface roughness parameters of the  
29 retrieved OxZr and retrieved CoCr femoral components. There was no difference  
30 between the PE component damage scores for the retrieved OxZr TKRs compared to  
31 the retrieved CoCr TKRs.

32 These results agree with other studies that both OxZr and CoCr femoral components  
33 roughen during time *in vivo* but the lack of difference between the surface roughness

34 measurements of the two materials is in contrast to previous topographical reports.  
35 Further analysis of retrieved OxZr TKRs is recommended so that a fuller appreciation  
36 of their benefits and limitations be obtained.

37 **Keywords:** Total Knee Replacement; retrieval; Oxidised Zirconium (OxZr); surface  
38 roughness; profilometry.

39

40 1. INTRODUCTION

41 Total Knee Replacement (TKR<sup>\*</sup>) offers improved mobility and pain relief for many  
42 people suffering with the debilitating disease of osteoarthritis [1-4]. In the longer-  
43 term, wear of the polyethylene (PE) component and PE wear-debris associated  
44 problems continue to limit TKR longevity. The 2016 Australian Orthopaedic  
45 Association National Joint Replacement Registry (AOANJRR) [1] and the National  
46 Joint Registry (NJR) Annual Report for England, Wales, Northern Ireland and the Isle  
47 of Man [3] both cite aseptic loosening as the main reason for TKR revision at 10  
48 years and beyond. Whilst there are many factors that influence PE wear within TKR,  
49 an increased surface roughness of the counter-face femoral component has been  
50 reported as one of the causative mechanisms of accelerated PE wear [5-10].

51 In 2004, Oxidised Zirconium (OxZr) (a surface-modified metal comprising a uniform  
52 ceramic surface with a gradual transition from ceramic oxide to substrate metal alloy)  
53 was introduced for TKR femoral components in an attempt to reduce PE wear  
54 associated failures [11, 12]. With a greater surface hardness and wettability than  
55 cobalt-chromium alloy (CoCr) [13], OxZr femoral components should theoretically  
56 lead to the reduction of PE wear. While *in-vitro* wear testing of OxZr TKRs has  
57 shown significant wear reduction when compared to CoCr TKRs [13-15], the 10-year  
58 clinical follow-up reviews reported no difference in survivorship or patient-reported

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\* List of Abbreviations: Total Knee Replacement (TKR); polyethylene (PE); Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR); National Joint Registry (NJR) Oxidised Zirconium (OxZr); Cobalt Chromium (CoCr); Body Mass Index (BMI); Anterior – posterior (AP).

59 outcome measures [16-19]. Further, the revision rates reported in both the NJR and  
60 the AOANJRR for Genesis II Oxinium are higher at 12 years than that of the standard  
61 CoCr Genesis II [1, 3]. Vertullo et al [20] analysed data presented in the 2016  
62 AOANJR report [1] and concluded that OxZr femoral components did not reduce  
63 revision rates compared with the same CoCr femoral components across all age  
64 groups.

65 While laboratory simulation can provide important data, the analysis of retrieved  
66 TKR components provides invaluable insights into the *in-vivo* tribological  
67 performance of the prostheses. Two previous retrieval studies [21, 22] reported on the  
68 measurement of roughness parameters of as-manufactured and retrieved OxZr and  
69 CoCr femoral components. Using contact profilometry, Brandt et al [21] analysed the  
70 surface damage of 26 pairs of retrieved OxZr and CoCr TKRs. All roughness  
71 parameters were found to be significantly lower on an as-manufactured CoCr femoral  
72 component when compared to retrieved CoCr femoral components but no significant  
73 difference was found between the roughness parameters measured on an as-  
74 manufactured OxZr femoral component compared to retrieved OxZr femoral  
75 components. The surface roughness parameters for the as-manufactured CoCr  
76 femoral component were significantly lower than for the as-manufactured OxZr  
77 femoral component, however there was no significant difference between the results  
78 for the retrieved CoCr femoral components and the retrieved OxZr femoral  
79 components.

80 Non-contacting profilometry is a preferable method of surface roughness  
81 measurement as it is not limited by errors induced by the physical profile of the stylus

82 and potential damage to the sample as the stylus drags across the surface [23]. Heyse  
83 et al [22] used non-contacting profilometry to compare the roughness measurements  
84 of as-manufactured OxZr and CoCr femoral components and 10 retrieved OxZr and  
85 CoCr femoral components. The overall roughness for the retrieved CoCr implants  
86 was 83% greater than that of the retrieved OxZr implants and, in agreement with  
87 Brandt et al [21], the as-manufactured CoCr femoral component had a lower surface  
88 roughness than the as-manufactured OxZr femoral component. In contrast to Brandt  
89 et al, the retrieved OxZr components measured by Heyse et al had a significantly  
90 greater surface roughness than the as-manufactured OxZr component.

91 Gascoyne et al [16] used observer damage scoring and microcomputed tomography to  
92 quantify the damage observed on the articular surface of the PE inserts from the same  
93 cohort used by Brandt et al [21]. No significant difference was found between the PE  
94 damage of the two groups.

95 The purpose of this study was to use non-contacting profilometry to investigate the *in*  
96 *vivo* changes in surface roughness of OxZr TKRs and CoCr TKRs in order to add to  
97 the limited literature available on this topic. It was hypothesised that both OxZr and  
98 CoCr femoral components will roughen *in vivo* when comparing retrieved to as-  
99 manufactured prostheses; further, the extent of the roughening would be greater on  
100 retrieved CoCr femoral components compared with retrieved OxZr femoral  
101 components.

102

103 2. MATERIALS & METHODS

104 Ethical approval was obtained for the retrieval of 6 explanted TKRs (3 with OxZr and  
105 3 with CoCr femoral components) from the Freeman Hospital, Newcastle upon Tyne,  
106 UK. All prostheses were implanted with cemented fixation with modular fixed PE  
107 bearings. The 3 retrieved CoCr TKRs (DePuy PFC Sigma Bicondylar) were selected  
108 to match the OxZr TKRs (3 Smith & Nephew Oxinium TKRs – 2 Genesis II; 1  
109 Legion) based on time *in vivo*. The mean time *in vivo* for the OxZr retrievals was 58  
110 ( $\pm 24.8$ ) months and 47 ( $\pm 14.3$ ) months for the CoCr retrievals. The mean BMI for the  
111 OxZr retrievals was 30.2 ( $\pm 3.3$ ) and 33.4 ( $\pm 5.4$ ) for the CoCr retrievals; the mean age  
112 at primary surgery was 51 ( $\pm 14.0$ ) years for the OxZr prostheses and 60 ( $\pm 8.5$ ) years  
113 for the CoCr prostheses. The patient and implant variables are shown in Table 1.

114 An as-manufactured Smith & Nephew Genesis II Oxinium femoral component and an  
115 as-manufactured DePuy PFC Sigma Bicondylar femoral component were available  
116 for analysis. Before the commencement of any analyses, all retrieved explanted  
117 components were sterilised in formaldehyde solution for at least 48 hours, rinsed with  
118 water and air-dried.

119 2.1 Qualitative and semi-quantitative damage assessment

120 A macroscopic visual assessment of damage was performed for each retrieved  
121 femoral component. A Mitutoyo QuickScope vision measuring system with a x25  
122 magnification (x50 lens and x0.5 zoom) was used to perform the semi-quantitative  
123 Hood analysis technique [24] and a surface damage score was calculated for the



124 articulating surface of each PE component. The articulating surface of the PE  
125 component was divided into sections and a grade assigned for each section  
126 corresponding to the estimated percentage area covered by 7 damage modes (surface  
127 deformation, pitting, embedded debris, scratching, burnishing, abrasion and  
128 delamination). The sum of the grades for each damage mode in each section gives the  
129 PE damage score with the maximum possible being 210.

## 130 2.2 Non-contacting profilometry

131 Surface roughness measurements for the retrieved and the as-manufactured femoral  
132 components were performed on a Zygo NewView 5000 non-contacting white light  
133 interferometric profilometer as used in previous explant studies [25-27]. The x10 lens  
134 was used with a x2 zoom, giving an area of view of 317 x 238  $\mu\text{m}$ . The Zygo has a  
135 vertical resolution of greater than 1 nm. Measurements were taken of mean surface  
136 roughness  $S_a$  (the mean of the variation in peaks and valleys from the centreline of the  
137 sampling area), root-mean-square surface roughness  $S_q$  (the root-mean-square of the  
138 variation in peaks and valleys from the centreline of the sampling area), maximum  
139 peak height  $S_p$ , maximum valley depth  $S_v$ , peak to valley  $S_z$  (sum of the maximum  
140 peak height and the maximum valley depth of the sampling area) and surface  
141 skewness  $S_{sk}$  (the symmetry of the profile about the mean line) [28]. Fifteen  
142 measurements were taken at approximately  $30^0$  flexion on each femoral condyle (see  
143 Figure 1).

144 2.3 Statistical Analysis

145 Statistical software programme Minitab® 17 was used to perform two-sample  
146 Student's t-tests to compare the roughness measurement results. A p-value of <0.05  
147 was considered to show significant difference. Sample sizes for the roughness values  
148 were n=30 and n=90 for the as-manufactured and retrieved components respectively.  
149 Normality was not checked as the sample sizes were great enough for the tests to be  
150 accurate for non-normal data.

151

152 3. RESULTS

153 Macroscopic visual assessment showed the damage to the retrieved OxZr femoral  
154 components to be minimal but there were obvious scratches in the anterior –posterior  
155 (AP) direction; the retrieved CoCr femoral components showed light to moderate  
156 scratching also in the AP direction.

157 The roughness parameters,  $S_a$ ,  $S_q$ ,  $S_z$  and  $S_p$  were greater, and  $S_v$  and  $S_{sk}$  were more  
158 negative, for the retrieved than for the as-manufactured for both OxZr and CoCr  
159 femoral components. There were no significant differences between any of the  
160 surface roughness parameters measured on the retrieved OxZr femoral components  
161 compared to those measured on the retrieved CoCr femoral components (see Table 2  
162 and Figures 2 and 3). The  $S_a$  and  $S_q$  were both significantly greater ( $p < 0.001$ ) for the  
163 as-manufactured OxZr femoral component than for the as-manufactured CoCr  
164 femoral component.

165 All six of the retrieved PE components displayed *in vivo* damage with burnishing  
166 being the most prevalent damage mode observed; there was no embedded debris or  
167 delamination detected. Figure 4 shows a retrieved PE component with an area of  
168 burnishing and a pit approximately 1mm in size. The Hood damage scores are given  
169 in Table 1.

170

171 4. DISCUSSION

172 The results show that both OxZr and CoCr femoral components roughen *in vivo*  
173 which is in agreement with other reports of retrieved TKRs components [22, 27].  
174 Further, in agreement with Scholes et al [27], femoral component roughening does  
175 not appear to be correlated to length of time *in vivo*.

176 The mean  $S_a$  values for the as-manufactured OxZr femoral component ( $S_a = 0.061\mu\text{m}$   
177  $\pm 0.004$ ), the as-manufactured CoCr component ( $S_a = 0.042\mu\text{m} \pm 0.003$ ) and the  
178 retrieved OxZr femoral components ( $S_a = 0.093\mu\text{m} \pm 0.014$ ) are comparable to the  
179 mean  $S_a$  values reported by Heyse et al [22] for an as-manufactured OxZr femoral  
180 component ( $S_a = 0.05\mu\text{m} \pm 0.00$ ), an as-manufactured CoCr femoral component ( $S_a =$   
181  $0.04\mu\text{m} \pm 0.01$ ) and retrieved OxZr femoral components ( $S_a = 0.15\mu\text{m} \pm 0.39$ ).

182 However, the mean  $S_a$  value for the retrieved CoCr femoral components ( $S_a =$   
183  $0.065\mu\text{m} \pm 0.005$ ) is much lower than that reported by Heyse et al ( $S_a = 0.21\mu\text{m}$   
184  $\pm 0.21$ ). In contrast to the data presented by both Brandt et al [21] and Heyse et al  
185 [22], no difference was found between the surface roughness measurements for the  
186 retrieved OxZr femoral components and the retrieved CoCr femoral components.

187 When reviewing these results, it must be considered that the as-manufactured and  
188 retrieved CoCr femoral components used in this study are a different design to those  
189 reported on by Brandt et al and Heyse et al which may go towards explaining the  
190 differences seen.

191 The mean  $S_a$  and  $S_q$  were significantly less for the as-manufactured CoCr femoral  
192 component than for the as-manufactured OxZr femoral component which has been

193 reported previously [21, 22]. Simulator studies report that the PE wear rate increases  
194 with increasing counter-face surface roughness [5, 13, 14] and so it would be  
195 expected that the rougher as-manufactured OxZr component would result in a greater  
196 PE wear rate than the as-manufactured CoCr component. However, the results from  
197 this study show that both OxZr and CoCr femoral components roughen after time *in*  
198 *vivo* (minimum time *in vivo* in this study is 35 months) and that there is no difference  
199 between the surface roughness parameters of the retrieved OxZr and CoCr femoral  
200 components. Kim et al [19] reported that the PE wear particles from CoCr TKRs were  
201 not different in weight, size or shape than those from OxZr TKRs which would be  
202 expected if the femoral components of both materials roughened to the same extent  
203 after a period of time *in vivo*. The results in this study and in Kim et al [19] support  
204 the findings that report no clinical difference between TKRs with OxZr femoral  
205 components and TKRs with CoCr femoral components at the 10 year follow up  
206 period [12, 17, 18].

207 All the retrieved PE components were observed to have undergone *in vivo* damage  
208 but there was no noticeable difference between the damage observed on the OxZr  
209 TKRs compared with the CoCr TKRs. There was no relationship found between the  
210 Hood scoring system of the PE component damage and the femoral component  
211 roughness measurements. These results match those presented in a recent study [16].

212 In TKR, PE wear and failure due to debris related aseptic loosening and osteolysis is  
213 influenced by multiple contributing factors that are a combination of surgeon, patient  
214 and implant variables [29, 30]. Surface roughness of the femoral component is just  
215 one of these factors and differentiating out individual effects continues to be

216 challenging. Data from retrieval studies can add to the long-term clinical follow-up  
217 studies and *in vitro* wear analyses to help provide a clearer understanding of the  
218 interdependencies influencing wear *in vivo*.

219 It is acknowledged that this study is limited by the small number of retrieved OxZr  
220 TKRs that were available for analysis. However, there is a limited literature on  
221 retrieved OxZr TKRs and the recent history of orthopedics has shown the vital role  
222 that explant analysis can provide in understanding why some implants fail [31]. There  
223 are inherent limitations associated with the analysis of ‘failed’ prostheses as opposed  
224 to those which are still *in vivo* and may be functioning ‘well’. However, such ‘failed’  
225 implants have arguably undergone the truest test of all in the human body, and this  
226 unique data should be shared. The surface roughness data of this retrieval study  
227 contributes to the current literature within this area [16, 20-22, 27]. In time, with  
228 longer clinical follow-up periods reported in arthroplasty registries and the further  
229 analysis of more explanted samples, the benefits and limitations of OxZr femoral  
230 components may become clearer. Ultimately the aim of the interdisciplinary  
231 evaluation of retrieved prostheses is to lead to future improvements in TKRs and a  
232 concomitant reduction of failures.

233 .  
234

235 5. CONCLUSIONS

236 Both OxZr and CoCr femoral components show increased surface roughness  
237 parameters following time *in vivo*. No significant difference was seen between the  
238 surface roughness parameters of the retrieved OxZr and CoCr femoral components.  
239 Further analysis of retrieved OxZr TKRs is recommended so that a fuller appreciation  
240 of their benefits and limitations be obtained.

241

242

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245    femoral components.

246            COMPETING INTERESTS

247    Author, DJW has received monies from Stryker with regards to lecturing not related  
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251    certify that she or he has no commercial associations (e.g consultancies, stock  
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258            ETHICAL COMMITTEE REVIEW STATEMENT

259    This study is approved by Ethical Committee Review REC 09/H0906/72.



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386

387 FIGURE LEGEND

388 Figure 1: Profilometer measurements were taken at approximately 30° flexion in the  
389 boxed areas as shown on this femoral component

390 Figure 2: Surface roughness parameters  $S_a$ ,  $S_q$  and  $S_p$  measured on as-manufactured  
391 OxZr and CoCr femoral components and retrieved OxZr and CoCr femoral  
392 components.

393 Figure 3: Surface roughness parameters  $S_v$ ,  $S_z$  and  $S_{sk}$  measured on as-manufactured  
394 OxZr and CoCr femoral components and retrieved OxZr and CoCr femoral  
395 components.

396 Figure 4: A retrieved PE component from an OxZr TKR

397 Table 1. Patient and Implant Variables

<b>Implant No.</b>	<b>Make &amp; Model of retrieved prosthesis</b>	<b>Gender</b>	<b>Side</b>	<b>BMI</b>	<b>Indication for primary surgery</b>	<b>Indication for Revision</b>	<b>Time <i>In Vivo</i> (Months)</b>	<b>Age at implantation of retrieved prosthesis</b>	<b>PE Articular Surface Hood Damage Score</b>
1	S&N Genesis II Oxinium	Female	Right	28.4	Osteoarthritis	Pain / Hypermobility	40 months	37 years	22
2	S&N Genesis II Oxinium	Male	Right	28.2	First revision of primary TKR indicated for osteoarthritis.	Instability	86 months	51 years	35
3	S&N Legion Oxinium	Male	Left	34	Osteoarthritis	Chronic infection and instability / Pain	47 months	65 years	44
4	DePuy PFC Sigma	Female	Right	33	Osteoarthritis	Component malalignment	44 months	50 years	25
5	DePuy PFC Sigma	Male	Left	28.3	Osteoarthritis	Component malalignment	35 months	66 years	15
6	DePuy PFC Sigma	Female	Left	39	Osteoarthritis	Instability / Pain	63 months	63 years	33

400 Table 2. Femoral component surface roughness measurements

	As-manufactured OxZr femoral component (n = 30, 1 component x 30 points)	Retrieved OxZr femoral components (n = 90, 3 components x 30 points per component)	As-manufactured CoCr femoral component (n = 30, 1 component x 30 points)	Retrieved CoCr femoral components (n = 90, 3 components x 30 points per component)	p-value 1 OxZr As-manufactured vs Retrieved	p-value 2 CoCr As-manufactured vs Retrieved	p-value 3 Retrieved OxZr vs Retrieved CoCr	p-value 4 As-manufactured OxZr vs As-manufactured CoCr
Mean $S_a$ ( $\mu\text{m}$ )	0.061 ( $\pm 0.004$ )	0.093 ( $\pm 0.014$ )	0.042 ( $\pm 0.003$ )	0.065 ( $\pm 0.005$ )	0.033	<0.001	0.059	<0.001
Mean $S_q$ ( $\mu\text{m}$ )	0.087 ( $\pm 0.005$ )	0.129 ( $\pm 0.017$ )	0.061 ( $\pm 0.004$ )	0.097 ( $\pm 0.006$ )	0.021	<0.001	0.079	<0.001
Mean $S_p$ ( $\mu\text{m}$ )	0.632 ( $\pm 0.035$ )	0.758 ( $\pm 0.045$ )	0.636 ( $\pm 0.042$ )	0.762 ( $\pm 0.056$ )	0.029	0.075	0.960	0.937
Mean $S_v$ ( $\mu\text{m}$ )	-0.613 ( $\pm 0.028$ )	-1.000 ( $\pm 0.078$ )	-0.831 ( $\pm 0.211$ )	-1.145 ( $\pm 0.087$ )	<0.001	0.178	0.218	0.314
Mean $S_z$ ( $\mu\text{m}$ )	1.245 ( $\pm 0.053$ )	1.758 ( $\pm 0.115$ )	1.467 ( $\pm 0.222$ )	1.918 ( $\pm 0.112$ )	<0.001	0.077	0.322	0.337
Mean $S_{sk}$	0.6194 ( $\pm 0.105$ )	0.118 ( $\pm 0.129$ )	0.806 ( $\pm 0.515$ )	-0.466 ( $\pm 0.345$ )	0.003	0.045	0.116	0.725

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402 \* The mean value  $\pm$  standard error is given for each surface roughness parameter. P-value 1 corresponds to the difference between the results for the retrieved OxZr femoral  
 403 components compared to those for the as-manufactured OxZr femoral component. P-value 2 corresponds to the difference between the results for the retrieved CoCr femoral  
 404 components and the as-manufactured CoCr femoral component. P-value 3 corresponds to the difference between the results for retrieved OxZr femoral components compared  
 405 to those for retrieved CoCr femoral components. P-value 4 corresponds to the difference between the results for the as-manufactured OxZr femoral component and the as-  
 406 manufactured CoCr femoral component

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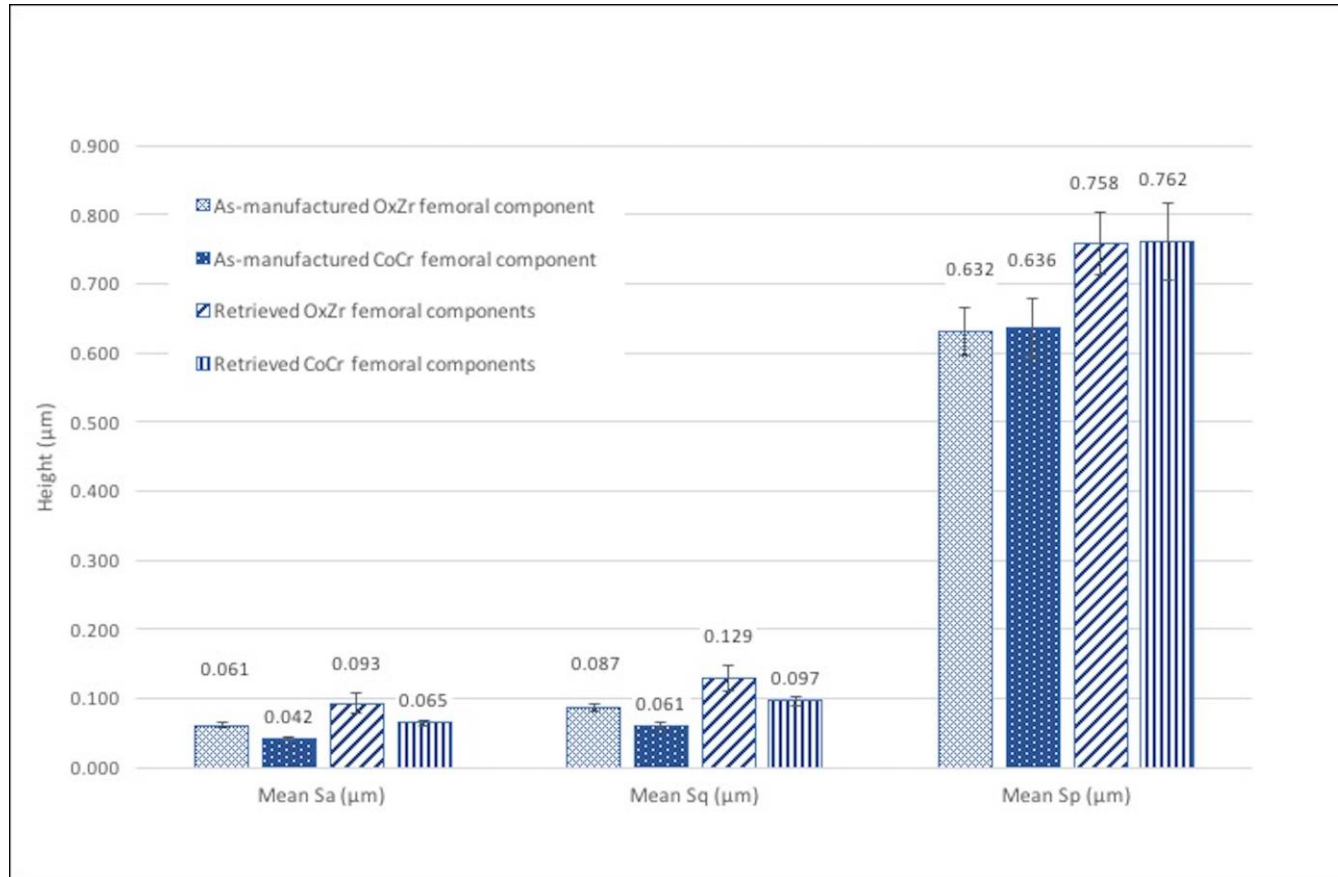
408 Figure 1.



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411 Figure 2.

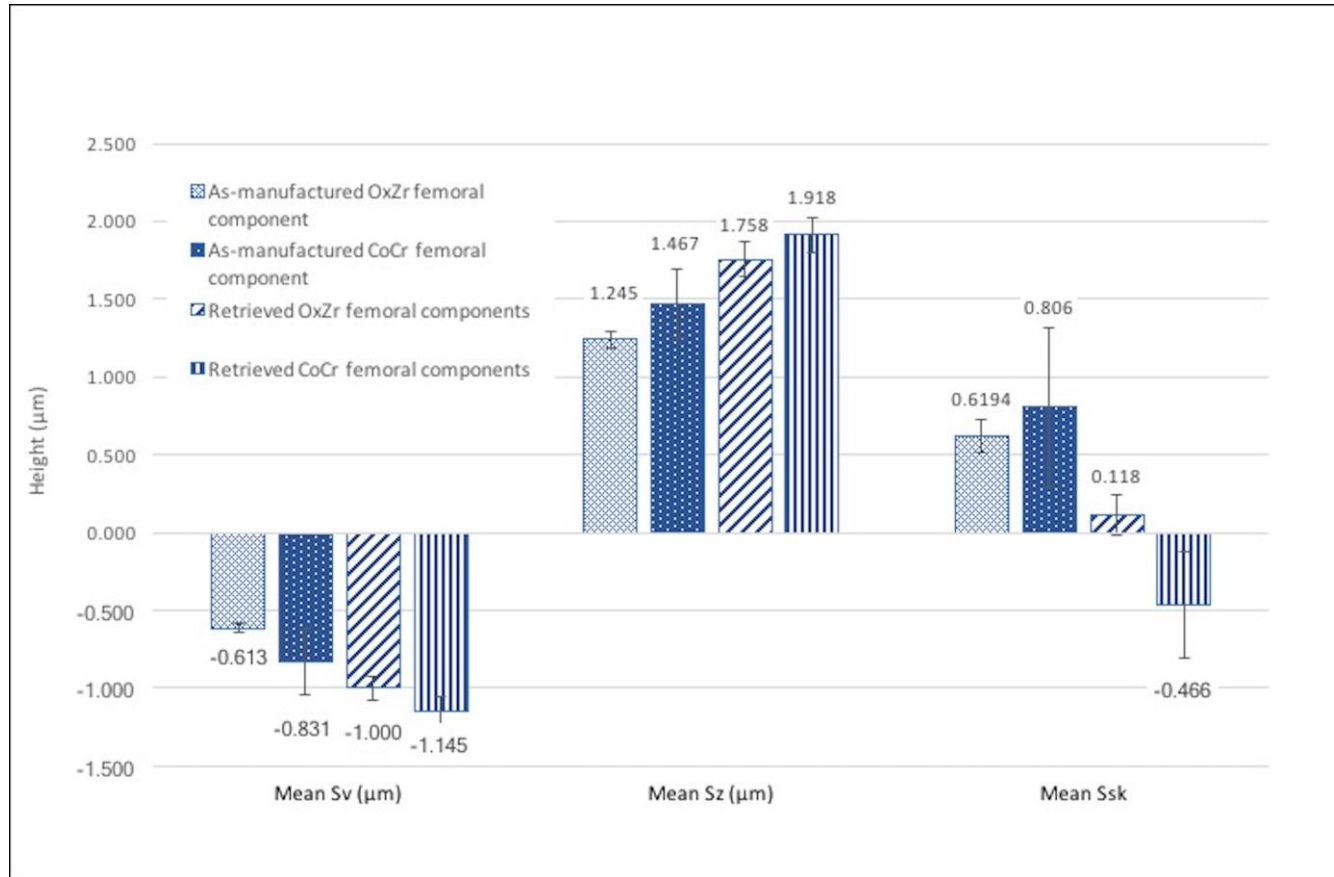


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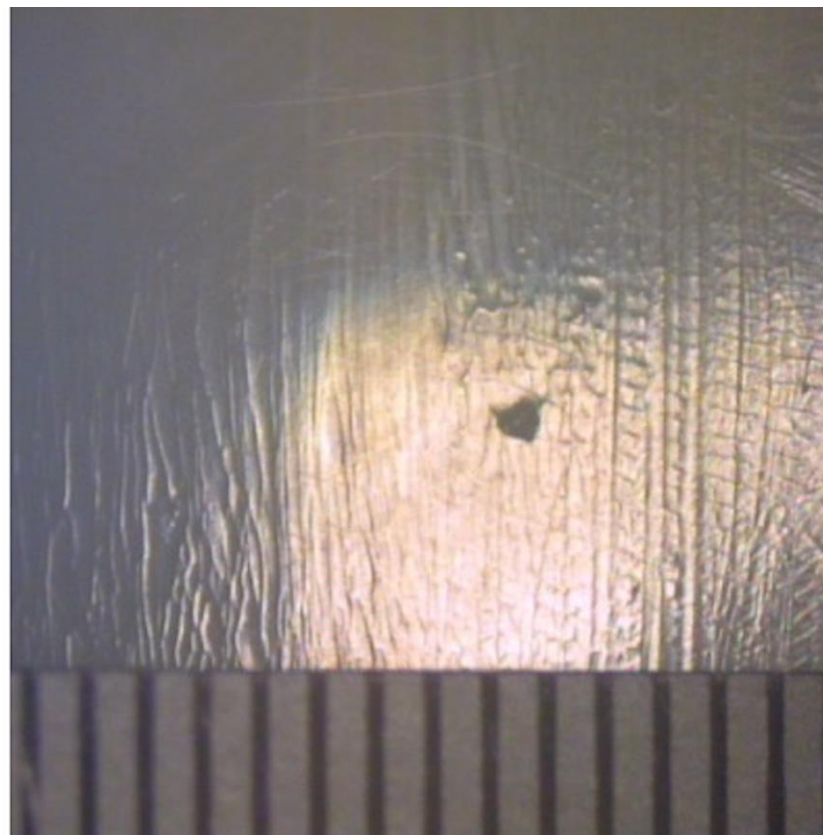
414 Figure 3.



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417 Figure 4.



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