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

AUTHORS

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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 ($S_a = 0.093 \mu m \pm 0.014$) and
25 for the retrieved CoCr femoral components ($S_a = 0.065 \mu m \pm 0.005$) were significantly
26 greater ($p<0.05$) than the roughness values for the as-manufactured femoral
27 components (OxZr $S_a = 0.061 \mu m \pm 0.004$ and CoCr $S_a = 0.042 \mu m \pm 0.003$). 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
measurements of the two materials is in contrast to previous topographical reports. Further analysis of retrieved OxZr TKRs is recommended so that a fuller appreciation of their benefits and limitations be obtained.

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

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

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

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

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

Non-contacting profilometry is a preferable method of surface roughness measurement as it is not limited by errors induced by the physical profile of the stylus.
and potential damage to the sample as the stylus drags across the surface [23]. Heyse et al [22] used non-contacting profilometry to compare the roughness measurements of as-manufactured OxZr and CoCr femoral components and 10 retrieved OxZr and CoCr femoral components. The overall roughness for the retrieved CoCr implants was 83% greater than that of the retrieved OxZr implants and, in agreement with Brandt et al [21], the as-manufactured CoCr femoral component had a lower surface roughness than the as-manufactured OxZr femoral component. In contrast to Brandt et al, the retrieved OxZr components measured by Heyse et al had a significantly greater surface roughness than the as-manufactured OxZr component.

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

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

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

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

2.1 Qualitative and semi-quantitative damage assessment

A macroscopic visual assessment of damage was performed for each retrieved femoral component. A Mitutoyo QuickScope vision measuring system with a x25 magnification (x50 lens and x0.5 zoom) was used to perform the semi-quantitative Hood analysis technique [24] and a surface damage score was calculated for the
articulating surface of each PE component. The articulating surface of the PE component was divided into sections and a grade assigned for each section corresponding to the estimated percentage area covered by 7 damage modes (surface deformation, pitting, embedded debris, scratching, burnishing, abrasion and delamination). The sum of the grades for each damage mode in each section gives the PE damage score with the maximum possible being 210.

2.2 Non-contacting profilometry

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

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

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

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

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

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

The mean $S_a$ values for the as-manufactured OxZr femoral component ($S_a = 0.061 \mu m \pm 0.004$), the as-manufactured CoCr component ($S_a = 0.042 \mu m \pm 0.003$) and the retrieved OxZr femoral components ($S_a = 0.093 \mu m \pm 0.014$) are comparable to the mean $S_a$ values reported by Heyse et al [22] for an as-manufactured OxZr femoral component ($S_a = 0.05 \mu m \pm 0.00$), an as-manufactured CoCr femoral component ($S_a = 0.04 \mu m \pm 0.01$) and retrieved OxZr femoral components ($S_a = 0.15 \mu m \pm 0.39$). However, the mean $S_a$ value for the retrieved CoCr femoral components ($S_a = 0.065 \mu m \pm 0.005$) is much lower than that reported by Heyse et al ($S_a = 0.21 \mu m \pm 0.21$). In contrast to the data presented by both Brandt et al [21] and Heyse et al [22], no difference was found between the surface roughness measurements for the retrieved OxZr femoral components and the retrieved CoCr femoral components.

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

The mean $S_a$ and $S_q$ were significantly less for the as-manufactured CoCr femoral component than for the as-manufactured OxZr femoral component which has been
Simulator studies report that the PE wear rate increases with increasing counter-face surface roughness [5, 13, 14] and so it would be expected that the rougher as-manufactured OxZr component would result in a greater PE wear rate than the as-manufactured CoCr component. However, the results from this study show that both OxZr and CoCr femoral components roughen after time in vivo (minimum time in vivo in this study is 35 months) and that there is no difference between the surface roughness parameters of the retrieved OxZr and CoCr femoral components. Kim et al [19] reported that the PE wear particles from CoCr TKRs were not different in weight, size or shape than those from OxZr TKRs which would be expected if the femoral components of both materials roughened to the same extent after a period of time in vivo. The results in this study and in Kim et al [19] support the findings that report no clinical difference between TKRs with OxZr femoral components and TKRs with CoCr femoral components at the 10 year follow up period [12, 17, 18].

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

In TKR, PE wear and failure due to debris related aseptic loosening and osteolysis is influenced by multiple contributing factors that are a combination of surgeon, patient and implant variables [29, 30]. Surface roughness of the femoral component is just one of these factors and differentiating out individual effects continues to be
challenging. Data from retrieval studies can add to the long-term clinical follow-up studies and *in vitro* wear analyses to help provide a clearer understanding of the interdependencies influencing wear *in vivo*.

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

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

We thank Smith & Nephew and DePuy Synthes for providing as-manufactured femoral components.

COMPETING INTERESTS

Author, DJW has received monies from Stryker with regards to lecturing not related to this work; author JH has received monies from Zimmer Biomet and Stryker for education not related to this work; and, author TJJ has received monies paid to Newcastle University for expert testimony not related to this work. All other authors certify that she or he has no commercial associations (e.g consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article.

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ETHICAL COMMITTEE REVIEW STATEMENT

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


FIGURE LEGEND

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

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

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

Figure 4: A retrieved PE component from an OxZr TKR.
Table 1. Patient and Implant Variables

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

<table>
<thead>
<tr>
<th></th>
<th>As-manufactured OxZr femoral component (n = 30, 1 component x 30 points)</th>
<th>Retrieved OxZr femoral components (n = 90, 3 components x 30 points per component)</th>
<th>As-manufactured CoCr femoral component (n = 30, 1 component x 30 points)</th>
<th>Retrieved CoCr femoral components (n = 90, 3 components x 30 points per component)</th>
<th>p-value 1 OxZr As-manufactured vs Retrieved</th>
<th>p-value 2 CoCr As-manufactured vs Retrieved</th>
<th>p-value 3 Retrieved OxZr vs Retrieved CoCr</th>
<th>p-value 4 As-manufactured OxZr vs As-manufactured CoCr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean $S_a$ (µm)</td>
<td>0.061 (±0.004)</td>
<td>0.093 (± 0.014)</td>
<td>0.042 (± 0.003)</td>
<td>0.065 (±0.005)</td>
<td>0.033</td>
<td>&lt;0.001</td>
<td>0.059</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mean $S_f$ (µm)</td>
<td>0.087 (± 0.005)</td>
<td>0.129 (± 0.017)</td>
<td>0.061 (± 0.004)</td>
<td>0.097 (±0.006)</td>
<td>0.021</td>
<td>&lt;0.001</td>
<td>0.079</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mean $S_p$ (µm)</td>
<td>0.632 (± 0.035)</td>
<td>0.758 (±0.045)</td>
<td>0.636 (± 0.042)</td>
<td>0.762 (±0.056)</td>
<td>0.029</td>
<td>0.075</td>
<td>0.960</td>
<td>0.937</td>
</tr>
<tr>
<td>Mean $S_r$ (µm)</td>
<td>-0.613 (± 0.028)</td>
<td>-1.000 (± 0.078)</td>
<td>-0.831 (± 0.211)</td>
<td>-1.145 (±0.087)</td>
<td>&lt;0.001</td>
<td>0.178</td>
<td>0.218</td>
<td>0.314</td>
</tr>
<tr>
<td>Mean $S_z$ (µm)</td>
<td>1.245 (± 0.053)</td>
<td>1.758 (±0.115)</td>
<td>1.467 (± 0.222)</td>
<td>1.918 (±0.112)</td>
<td>&lt;0.001</td>
<td>0.077</td>
<td>0.322</td>
<td>0.337</td>
</tr>
<tr>
<td>Mean $S_k$</td>
<td>0.6194 (± 0.105)</td>
<td>0.118 (±0.129)</td>
<td>0.806 (± 0.515)</td>
<td>-0.466 (±0.345)</td>
<td>0.003</td>
<td>0.045</td>
<td>0.116</td>
<td>0.725</td>
</tr>
</tbody>
</table>

* The mean value ± standard error is given for each surface roughness parameter. P-value 1 corresponds to the difference between the results for the retrieved OxZr femoral 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 components and the as-manufactured CoCr femoral component. P-value 3 corresponds to the difference between the results for retrieved OxZr femoral components compared 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-manufactured CoCr femoral component.
Figure 1.
Figure 2.
Figure 3.