Medical Engineering and Physics 50 (2017) 59–64

Contents lists available at ScienceDirect

Medical Engineering and Physics

journal homepage: www.elsevier.com/locate/medengphy

A comparative surface topographical analysis of explanted total knee replacement prostheses: Oxidised zirconium *vs* cobalt chromium femoral components

Emma Kennard[a,*], Susan C. Scholes[a], Raghavendra Sidaginamale[a], Rajkumar Gangadharan[b], David J. Weir[b], James Holland[b], David Deehan[b], Thomas J. Joyce[a]

[a] *Bioengineering Group, School of Engineering, Newcastle University, Stephenson Building, NE1 7RU Newcastle upon Tyne, England, United Kingdom*
[b] *Freeman Hospital, NE1 7DN Newcastle upon Tyne, England, United Kingdom*

ARTICLE INFO

Article history:
Received 30 January 2017
Revised 7 September 2017
Accepted 2 October 2017

Keywords:
Total knee replacement
Retrieval
Oxidised zirconium (OxZr)
Surface roughness
Profilometry

ABSTRACT

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

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

The S_a values for the retrieved OxZr femoral components ($S_a = 0.093$ µm ± 0.014) and for the retrieved CoCr femoral components ($S_a = 0.065$ µm ± 0.005) were significantly greater ($p < .05$) than the roughness values for the as-manufactured femoral components (OxZr $S_a = 0.061$ µm ± 0.004 and CoCr $S_a = 0.042$ µm ± 0.003). No significant difference was seen between the surface roughness parameters of the retrieved OxZr and retrieved CoCr femoral components. There was no difference between the PE component damage scores for the retrieved OxZr TKRs compared to the retrieved CoCr TKRs.

These results agree with other studies that both OxZr and CoCr femoral components 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.

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 outcome measures [16–19]. Further, the revision rates reported in both the NJR and the AOANJRR for Genesis II

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

* Corresponding author.
E-mail address: e.kennard@newcastle.ac.uk (E. Kennard).

https://doi.org/10.1016/j.medengphy.2017.10.003
1350-4533/

Table 1
Patient and implant variables.

Implant no.	Make & model of retrieved prosthesis	Gender	Side	BMI	Indication for primary surgery	Indication for revision	Time *In Vivo* (Months)	Age at implantation of retrieved prosthesis	PE articular surface hood damage score
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

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 prostheses. 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 micro-computed 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 hypothesized 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 ($\pm$24.8) months and 47 ($\pm$14.3) months for the CoCr retrievals. The mean BMI for the OxZr retrievals was 30.2 ($\pm$ 3.3) and 33.4 ($\pm$5.4) for the CoCr retrievals; the mean age at primary surgery was 51 ($\pm$14.0) years for the OxZr prostheses and 60 ($\pm$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 $\times$25 magnification ($\times$50 lens and $\times$0.5 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 $\times$10