Institute of Medical & Biological Engineering

Successful Recovery of Ultra-low Volumes of Clinically Relevant Wear Particles Generated from the Latest Generation Composite Hip Replacements

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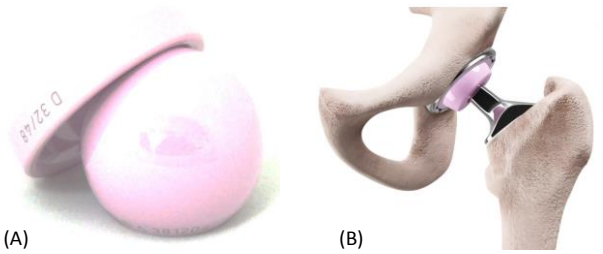
Introduction

Understanding wear particle characteristics and their biological activity is an essential step for the pre-clinical testing of joint replacements.

The characterisation of wear particles from the latest composite ceramic-on-ceramic (CoC) total hip replacements such as those using BIOLOX® Delta (CeramTec GmbH, Germany) (Fig. 1) has been particularly challenging, due to the limited sensitivity of current particle isolation methods [1-4].



(A) (B)

Fig. 1: BIOLOX® Delta (A) head and cup components and (B) in situ

The aims of this study were to optimise and validate a newly developed particle isolation method, which was subsequently applied to hip simulator lubricant for the isolation and characterisation of ultra-low volumes of clinically relevant composite ceramic wear particles.

Methods

Validation of novel method

Commercially obtained zirconia toughened alumina (ZTA) ceramic particles (5mm^3, 1mm^3, 0.5mm^3, 0.1mm^3 and 0.05mm^3), spiked in 25% (v/v) foetal bovine serum (FBS) were used to assess and validate the sensitivity of the novel particle isolation method [5] (Fig. 2) in terms of recovery rates.

Characterisation

The recovery rates were determined gravimetrically using pre-weighed glass vials and the ZTA particles were characterised before and after isolation in terms of their size and morphology, using cold-field emission gun scanning electron microscopy (CFE-SEM), EDX analysis and image analysis software.

Hip simulator serum

The validated method was subsequently applied to hip simulator lubricant (25% (v/v) FBS) with BIOLOX® Delta ceramic wear debris generated under severe edge loading conditions (0.1-1 mm^3/million cycles) [6].

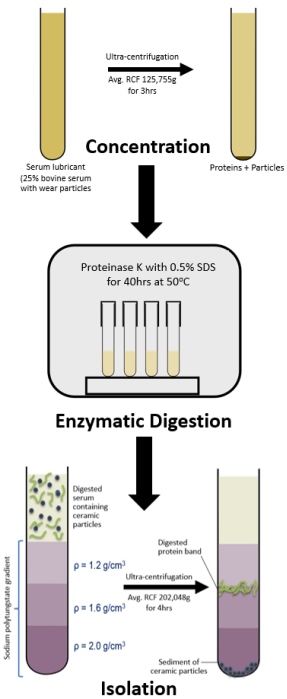


Fig. 2: Schematic of novel particle isolation method procedure.

Results & Discussion

This novel method of wear particle isolation demonstrated an average recovery of 93% for all the ZTA particle volumes tested (Fig. 5). The characteristics (size and morphology) of the ZTA particles was unaffected by the isolation process (p>0.05).

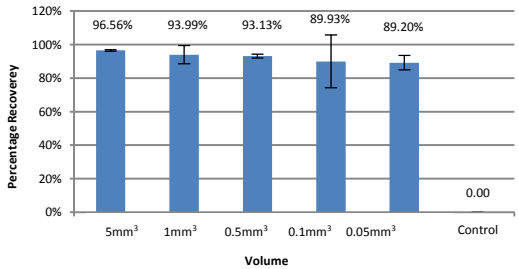


Fig 5: The recovery rates of the ZTA particles isolated using the newly developed method. The error bars show ±95% confidence limits.

The BIOLOX® Delta wear debris generated using a hip simulator were successfully recovered using the validated particle isolation method and revealed a bimodal size range (Fig. 6 & 7) i.e. large alumina particles; mode size of 1-2µm and small zirconia granular particles; mode size of 40-50nm.

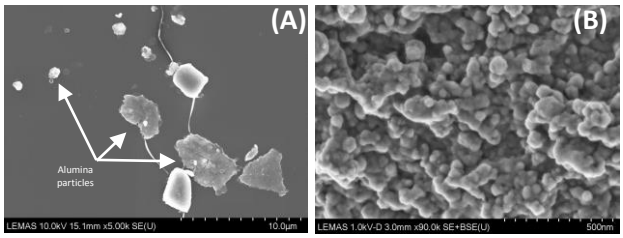


Fig. 6: CFE-SEM images of BIOLOX Delta (A) large micrometer alumina wear particles, and (B) small nano-scale zirconia particles recovered from hip simulator serum.

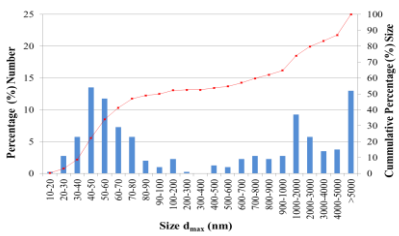


Fig 7: Figure 1: Frequency size distribution of recovered clinically relevant BIOLOX® Delta ceramic wear particles that were generated under edge loading conditions. Four hundred particles were analysed for both the large micrometer and small nano-scale particles.

The high sensitivity of this novel particle isolation method coupled with its effective removal of protein, allowed for the first time the successful recovery of wear particles generated from BIOLOX Delta CoC hip replacements.

Significance

- This work continues to increase our understanding of the characteristics of ceramic wear debris and the development of more biocompatible and longer lasting implants.
- The optimised method will be used as a preclinical testing tool to better understand the likely clinical performance of these materials in patients

References

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