

<sup>1</sup>Christopher Brown, <sup>1</sup>Claire L Brockett, <sup>1</sup>Joanne Tipper, <sup>2</sup>Gemma John, <sup>1</sup>Sophie Williams, <sup>1</sup>John Fisher

<sup>1</sup>Institute of Medical and Biological Engineering, School of Mechanical Engineering University of Leeds, UK

<sup>2</sup>DePuy International, UK

Contact email: C.J.F.Brown@leeds.ac.uk

## Background

• Concerns regarding UHMWPE wear-debris induced osteolysis [1] have led to alternative materials being sought for total hip replacement. Carbon-fibre reinforced poly-ether ether ketone (CFR-PEEK) has shown reduced wear compared with conventional UHMWPE [2, 3]

• The aim of this study was to investigate the wear performance and wear debris generated by a novel ceramic-on-CFR-PEEK total hip replacement through an *in-vitro* wear study and compare these to wear results from CoCr-on-UHMWPE THR which have previously been reported [4].

## Materials & Methods

- Five 36mm diameter Biolog Delta heads were paired with ram-extruded CFR-PEEK cups
- Hip simulator testing was conducted for 10 million cycles (Mc) under standard conditions (Prosim hip simulator, SimSol, UK) [5], lubricant was 25% (v/v) bovine serum (with 0.03% (v/v) sodium azide)
- Lubricant was removed from simulator stations at 1Mc and wear particles were isolated using the protocol described in ISO 17853 [6]:
  - 10ml of serum lubricant was added to 40ml of hydrochloric acid (37%, v/v) and mixed at 50°C for 1 hour
  - 0.5ml of solution was added to 100ml of methanol
  - Final solution filtered through a 0.015µm filter and observed using a LEO FEGSEM 1530.
  - Three images were generated at 10k, 20k, 30k, 60k, 75k and 90k magnifications for each station and analysed using Image Pro Plus® software to measure maximum diameter and area of particles (at least n=150 particles). Fig 1.
  - Measurements from all the filters were combined to generate size and area distributions
- Seven comparable samples (GUR1050 UHMWPE sterilised by 2.5MRad gamma radiation in air) were digested for direct comparison [4]:
- Percentage data were arcsine transformed, means ± 95% confidence limits calculated. Transformed data were analysed by one-way ANOVA and minimum significant difference calculated using the T-method

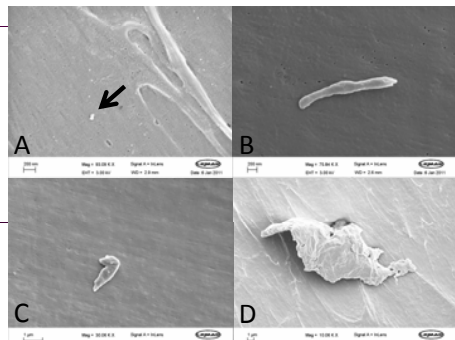


Figure 1: Scanning Electron Micrographs of Wear Particles Generated by Ceramic-on-CFR PEEK Hip Prosthesis in 25% (v/v) New Born Bovine Serum. Image Shows: Granules (A), Fibrils (B) and Flakes (C and D)

## Results

### Wear:

- CFR-PEEK wear exhibited a step-like wear behavior as previously reported [5]
- Mean wear rate:  $0.30 \pm 0.07 \text{ mm}^3/\text{Mc}$

### Wear particles

- Demonstrated flake, fibril and granule morphologies (Figure 1) predominantly less than 100nm in size (12nm–31µm) (Figure 2a)
- Mode of distribution for volumetric concentrations of particles as a function of size was in the 1-10µm size range (Figure 2b)
- Significantly higher numbers of UHMWPE wear particles ( $p < 0.05$ ) were observed in the  $10.0 > \mu\text{m}$  size range (Figure 2a).
- Significantly greater volumes of PEEK wear particles ( $p < 0.05$ ) were observed in the  $< 0.1 \mu\text{m}$  and  $0.1-1.0 \mu\text{m}$  size range (Figure 2b) whilst significantly greater volumes of UHMWPE wear particles were observed in the  $10.0 > \mu\text{m}$  size range (Figure 2b).

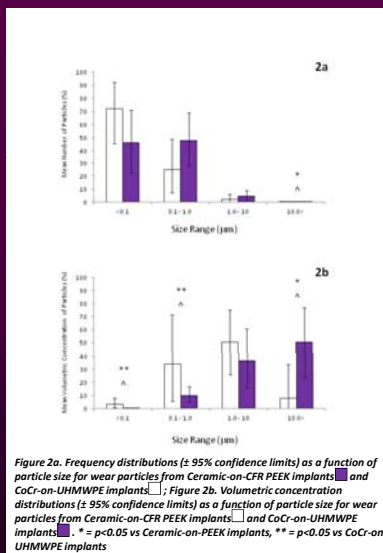


Figure 2a. Frequency distributions (± 95% confidence limits) as a function of particle size for wear particles from Ceramic-on-CFR PEEK implants (■) and CoCr-on-UHMWPE implants (■); Figure 2b. Volumetric concentration distributions (± 95% confidence limits) as a function of particle size for wear particles from Ceramic-on-CFR PEEK implants (■) and CoCr-on-UHMWPE implants (■). \* =  $p < 0.05$  vs Ceramic-on-PEEK implants, \*\* =  $p < 0.05$  vs CoCr-on-UHMWPE implants

## Discussion

- Comparison of PEEK and UHMWPE wear particles, revealed that the PEEK material produced greater numbers of nanoscale particles than the UHMWPE (70% vs 45%)
- Overall, similar numbers of submicrometre-sized particles were produced by both materials (>95% of particles) [4].
- The PEEK material generated significantly greater volumes of particles in the submicrometre and nanometre size ranges, indicating that the particles might be more biologically active than UHMWPE particles.
- However the wear rate of the CFR-PEEK cups was extremely low ( $0.30 \pm 0.07 \text{ mm}^3/\text{Mc}$ ) suggesting it is unlikely that the functional volume concentration of particles would reach high enough levels to cause osteolysis

## References

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- [3] Grupp *et al* Acta Biomaterialia 2010
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- [6] ISO 17853 Wear of implant materials – Polymer and metal wear particles – Isolation, characterisation and quantification. 2011

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## Financial Disclosure

CLB, SW and JF are paid consultants to DePuy International, UK, GJ is an employee of DePuy International, UK