## 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 BioLoc 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 (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 FESEM 1530.
- Three images were generated at 10k, 20k, 30k, 50k, 70k, 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).
- Seven comparable samples (GUR1050 UHMWPE sterilised by 2.5MV gamma irradiation in air) were digested for direct comparison [4].
- Measurements from all the filters were combined to generate size and area distributions.
- Seven comparable samples (GUR1050 UHMWPE sterilised by 2.5MV/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.

## Results

### Wear:
- CFR-PEEK wear exhibited a step-like wear behavior as previously reported [5].
- **Mean wear rate:** 0.30 ± 0.07 mm³/Mc 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 (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 FESEM 1530.
- Three images were generated at 10k, 20k, 30k, 50k, 70k, 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).
- Seven comparable samples (GUR1050 UHMWPE sterilised by 2.5MV/gamma radiation in air) were digested for direct comparison [4].
- Measurements from all the filters were combined to generate size and area distributions.
- Seven comparable samples (GUR1050 UHMWPE sterilised by 2.5MV/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.

### Wear particles:
- **Demonstrated flake, fibril and granule morphologies** (Figure 1) predominantly less than 100nm in size (12-31µm).
- **Significantly greater volumes of PEEK wear particles** (p<0.05) were observed in the 0.1-1.0 µm size range (Figure 2b) whilst significantly greater volumes of UHMWPE wear particles were observed in the 10.0> µm size range (Figure 2b).

## 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±0.07mm³/Mc) suggesting it is unlikely that the functional volume concentration of particles would reach high enough levels to cause osteolysis.**

## References

- [1] Ingham and Fisher Biomaterials 2005

## Financial Disclosure

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