

Biological impact of BIOLOX[®] *delta*

Generating clinically-relevant ceramic particulate wear debris in vitro is a technically challenging process due to the inherent low wear rates of modern ceramics for TJA.

So far, the size, morphology and biological responses of modern composite ceramic for arthroplasty were not investigated. This was made possible by developing innovative wear particle generation, isolation and characterization methods.

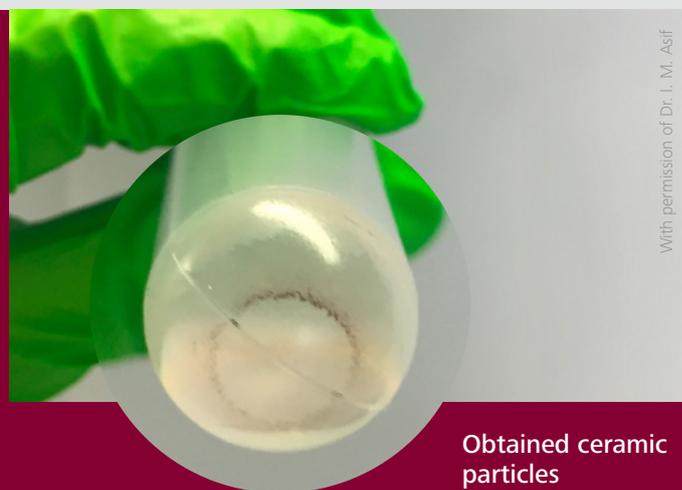
Joanne Tipper and her group at the Leeds University investigated the characteristics and biological activity of powder particles and clinically-relevant wear particles, both from BIOLOX[®] *delta* zirconia toughened alumina ceramics.

The clinically-relevant BIOLOX[®] *delta* wear particles were produced in a hip simulator under extremely severe edge loading conditions. The biological impact of the ceramic particles was assessed using human blood cells from healthy persons. No cytotoxic effects were observed at clinically relevant concentrations. Further the BIOLOX[®] *delta* particles failed to stimulate an inflammatory response in terms of TNF- α release and did not cause any significant DNA damage or oxidative stress at clinically relevant concentrations.

Very high doses of particles may stimulate the biological responses. But this is very unlikely to be achieved in the real setting due to the extremely high wear and scratch resistance of BIOLOX[®] *delta*. These findings allowed the researchers to conclude that BIOLOX[®] *delta* particles have a low biological impact, which may enhance long-term clinical performance.

The wear particles were assessed in terms of:

- Cytotoxicity
- Inflammation
- Genotoxicity
- Oxidative stress



Obtained ceramic particles

With permission of Dr. I. M. Asif



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Biological impact of BIOLOX[®]delta (continued)

Figure 1

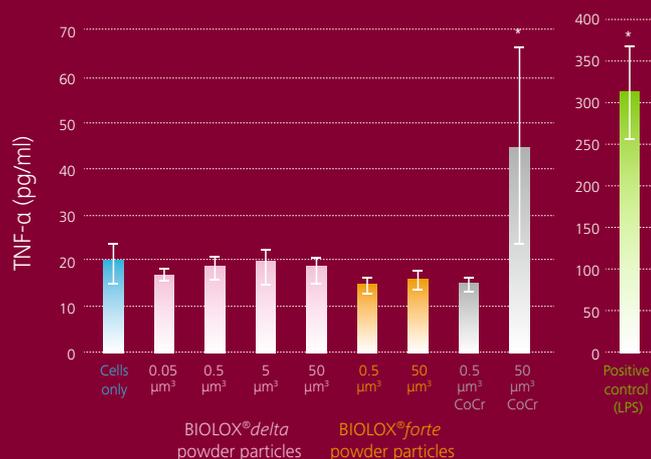
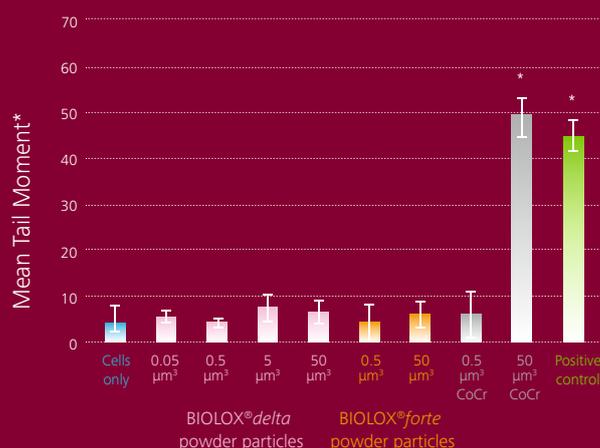


Figure 2



*Index of induced DNA damage (Comet Assay)

The experimental approaches demonstrated that BIOLOX[®]delta powder particles do not cause enhanced release of immune-mediators (such as TNF-α) in contrast to CoCr particles (fig. 1).

In contrast to CoCr particles, BIOLOX[®]delta powder particles do not exhibit genotoxic effects, thus do not cause any DNA damage, again highlighting the excellent biocompatibility and the inertness of ceramics even in its particulate form (fig. 2).



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