



Bergiers S, Hothi HS, Henckel J, et al. Wear performance of retrieved metal-on-metal Pinnacle hip arthroplasties implanted before and after 2007. *Bone Joint Res* 2018;7:595-600.

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Sir,

A study on the effects of diametrical clearance with no diametrical clearance values. I have several concerns regarding the methodology and conclusions of this recently published study.¹ However, I do not want the attention of a reader of this correspondence to be distracted from the central issue.

This is an explant study which purports to examine the effect of changes in diametrical clearance *on the clinical performance of the Depuy Pinnacle Ultamet metal-on-metal device, yet the diametrical clearances have not been reported.*

As Bergiers et al have clearly read our work (the current paper is apparently based on our findings published in 2016, written in 2014²), the authors will be well aware that a significant percentage of components used in this hip system were manufactured outside of their required specifications and should not have left the factory.^{2,3} We also reported a statistically significant relationship between the batch number (i.e. the day of manufacture, engraved on all components) and an increasing trend towards non-conformance. Bergiers et al have simply ignored the date of manufacture in their analyses. Instead, they have chosen to examine the effect of *implantation* pre and post the year 2007. Quite what the relevance is of whether a device was implanted before or after 2007 in the study of manufacturing changes occurring circa 2006 is open for debate; components have a shelf life of five years.

The authors misleadingly state in their discussion that: "As with all retrieval studies, we do not know the as-manufactured dimensional state of the components prior to implantation and how this would have impacted the individual clearances of each implant." Yet, in the validation paper of the analytical techniques the authors rely on, they explicitly state that the accuracy of wear measurements is dependent on the ability to identify accurately the unworn (i.e. as-manufactured) geometry. Indeed, *the unworn dimensions of explants are given to micron-level accuracy.*⁴ The authors have actually reported volumetric wear values of bearings and tapers in multiple publications. Yet they have continually avoided reporting the clearance values.⁵⁻⁷ Interestingly, this is a consistent approach used by other Depuy-funded institutions.⁸

Finally, I note that the authors have used similar study methods to conclude that the articular surface replacement (ASR) does not wear at a greater rate than the Birmingham Hip Resurfacing,⁹ a finding which seems ever more incredible as the years go by, given the huge differences in revision rates between these two hip implants, as shown in multiple joint registries. And, in fact, Bergiers et al state that their “evidence raises doubts regarding the use of ‘revision rate’ and ‘time to revision’ as reliable indicators of implant performance, especially in the analysis of hips with large ranges of implantation dates”. Do the authors suggest, therefore, that perhaps we do not need joint registries? Or perhaps that the DePuy ASR, with its 50% revision rate and short time to revision, was actually a well-performing implant?

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Conflict of Interest: Expert witness for plaintiffs in ongoing metal-on-metal hip litigation. Qui tam whistleblower cases with United States government for fraudulent claims made by Depuy in marketing of Pinnacle product.