

LETTERS

RESPONSE

DePuy Orthopaedics replies to Deborah Cohen

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We highlight some of the factual errors and omissions in Deborah Cohen's article on the safety of metal-on-metal (MoM) hip implants with regard to such hip implants in general and the DePuy ULTAMET implant in particular—one option used with the Pinnacle acetabular cup system.¹

All hip implants, irrespective of the materials used, are known to wear. Indeed, concern that debris from the wear of metal-on-polyethylene hip replacements caused bone damage rekindled interest in developing a new generation of MoM implants. Contrary to Cohen's suggestion, the potential for reactions to debris from the wear of MoM hip implants has been studied for over two decades. In February 2012 the Medicines and Healthcare Products Regulatory Agency (MHRA) said: "The majority of patients implanted with metal-on-metal hip replacements have well functioning hips and are thought to be at a low risk of developing serious problems."²

Cohen states that DePuy had been aware since 2008 of raised metal ion levels in people with ULTAMET MoM implants, implying that the company concealed this information. However, patients with MoM hip implants—and some with other bearing surfaces—have long been known to have "raised levels of ions." Data on previous generations of metal implants did not indicate clinical problems from these releases in well-functioning implants, some of which had been in place more than 15 years. She expresses alarm about levels of metal ions associated with the ULTAMET MoM implant, implying that a fifth of patients with "DePuy's flagship Pinnacle system" had blood metal ion levels above the 7 ppb cited in MHRA guidance. None of the three studies she cites supports this proposition.

Cohen focuses on the potential risk of cancer from MoM implants. However, in response to the media attention on this risk the British Orthopaedic Association and British Hip Society stated: "Currently there is no verified evidence that having a metal on metal hip replacement increases cancer risk."³ A subsequent *BMJ* research article comprising 40 576 patients with MoM hip implants showed "no evidence that metal-on-metal bearing surfaces were associated with an increased risk of any cancer diagnosis in the seven years after surgery."⁴

Taper corrosion in modular total hip replacement systems, irrespective of the bearing surfaces, has been reported over the years. Its clinical significance has not been established. Contrary to Cohen's assertion, DePuy's most commonly used tapers (12/14) have had the same angles and surface finishes since they were first introduced. Cohen also mistakenly asserts that current taper lengths were first introduced in 2004, but they were first used in 2001. Since 2001 DePuy has gradually adopted this taper specification on other stems. As Cohen notes, DePuy received complaints about taper corrosion from surgeons in Japan, but she does not say that the stems at issue used a particular taper first introduced in the mid-1980s. She also does not say that DePuy communicated with doctors in Japan in June 2011 in connection with its investigation, advising them not to use these stems in combination with certain MoM implants.

Cohen suggests that the current generation of MoM hip implants was introduced despite known risks and without a clear clinical need. This is not true. Early failures in the first generation of MoM implants were reported, but subsequent reviews showed that many of them were successful long term, with much lower wear than polyethylene systems. When concerns emerged about the damage caused by polyethylene debris, the orthopaedic community became interested in MoM bearings again. The other options at this stage were newer polyethylenes and ceramics that did not yet have long term clinical track records. Furthermore, MoM implants allowed larger femoral heads to be used, which lowers the risk of dislocation. Viewed in context, the reintroduction of MoM hip implants was a well-considered response.

DePuy monitors closely data related to ULTAMET MoM implants from many sources, including published and unpublished data from national joint registries, published papers, company sponsored clinical trials, and internal complaint data. Specifically, DePuy has conducted four separate studies that include patients with ULTAMET MoM implants with a head size ≥ 36 mm. The pooled results on 1076 hips (779 with more than two years of follow-up) show a 97% survival rate at 5 years, consistent with data from national joint registries.

In summary, Cohen's article is not a balanced presentation of the facts of MoM implants in general and DePuy's ULTAMET MoM implants in particular. Given the serious nature of the issues raised, a more balanced presentation would have been appropriate and more in keeping with the *BMJ*'s aim of "helping doctors make better decisions."

Competing interests: GI and SS are employees of DePuy Orthopaedics. For the full rapid response see www.bmj.com/content/344/bmj.e1410/rr/578762.

- 1 Cohen D. How safe are metal-on-metal hip implants? *BMJ* 2012;344:e1410. (28 February.)
- 2 Medicines and Healthcare products Regulatory Agency (MHRA). Metal-on-metal hip implants. 2012. www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice-M-T/Metal-on-met.
- 3 British Orthopaedic Society. BOA/BHS information to patients about newspaper reports on cancer and total hip replacements. www.boa.ac.uk/PI/Pages/Metal-on-Metal.aspx#CANCER%20REPORTS.
- 4 Smith AJ, Dieppe P, Porter M, Blom AW. Risk of cancer in first seven years after metal-on-metal hip replacement compared with other bearings and general population: linkage study between the National Joint Registry of England and Wales and hospital episode statistics. *BMJ* 2012;344:e2383. (3 April.)

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