Correspondence

We welcome letters to the Editor concerning articles which have recently been published. Such letters will be subject to the usual stages of selection and editing; where appropriate, the authors of the original article will be offered the opportunity to reply.

Letters should normally be under 300 words in length, double-spaced throughout, signed by all authors and fully referenced. The edited version will be returned for approval before publication.

$2.00 *J Bone Joint Surg [Br]* 2007;89-B:989-9.

Blood and urine metal ion levels in young and active patients after Birmingham hip resurfacing arthroplasty

Sir,

We read with interest the paper by Daniel et al[1] entitled "Blood and urine metal ions levels in young and active patients after Birmingham hip resurfacing arthroplasty: four-year results of a prospective longitudinal study." This paper presents the pre- and post-operative metal ion measurements of 26 patients who have undergone Birmingham Hip Resurfacing with 50 mm or 54 mm femoral components. While we acknowledge the science behind the measurement method used by the authors (urine and whole blood with HR-ICPMS), we would be interested in the authors' comments regarding the following issues.

It is unclear to the readership whether or not this cohort of 26 patients is representative of the entire cohort of patients who received metal ion analyses. If this is a subset which only involves 50 mm and 54 mm femoral components then this may not be representative and should not be considered as a baseline upon which other metal ion studies should reference themselves for comparative purposes. In selecting only 50 mm and 54 mm components they have probably included mainly, if not exclusively, men. Gender ratio is not reported in the paper. Women will very rarely need these implant sizes.

Gender and bearing diameter have a significant impact on patients' metal ion levels. Recently, we reported chromium and cobalt ion levels with the Durom (Zimmer, Warsaw, Indiana) in whole blood.[2] Our mean chromium and cobalt levels in whole blood for the whole group (men and women, all sizes) was 1.6 µg/L of chromium and 0.7 µg/L of cobalt. When splitting the group by gender, mean levels at one year were lower in men: 1.5 µg/L *versus* 1.9 µg/L for chromium and 0.6 µg/L *versus* 0.8 µg/L for cobalt ($p = 0.05$).

Using a similar selection process as Daniel et al[1] in their paper (limiting the results to 50 mm and 54 mm femoral components), the mean metal ion levels in our patients (24 men and 1 woman) were 1.4 µg/L of chromium and 0.6 µg/L of cobalt in whole blood at one year (25% reduction *versus* our whole cohort results). As a comparison, Daniel et al[1] reported 2.4 µg/L of chromium and 1.3 µg/L of cobalt with the Birmingham Hip Resurfacing.

As the study was a prospective study where pre-operative whole blood was collected (before the implant size was known) they could have reported the results of the whole cohort (all implant sizes). By doing so, they could have provided the readers a real baseline for further comparison.

While assessing the performance of a new implant or technique, the results should be presented for the whole cohort where the innovation will be used. In the case of hip resurfacing, males and females with good femoral bone stock, significant life expectancy, no metal allergy, unimpaired renal function, and with suitable anatomy for the procedure, are examples. Selecting subgroups based on diagnosis, implant size, or gender may not reflect the real performance of the device or technique. Hence we feel that the authors' conclusion that their results provide a baseline for comparison with other implants is not justified. For the moment, we can only use their data for comparison with patients with similar component diameters (50 mm and 54 mm).

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P-A. VENDITTOLI, MD, MSc, FRCS, Assistant Professor of Surgery
M. GANAPATHI, FRCS
M. LAVIGNE, MD, FRCS
Maisonneuve-Rosemont Hospital,
Department of Surgery,
Montreal University,
Montreal, Canada.

1. **Daniel J, Ziaee H, Pradhan C, Pynsent PB, McMinn DJW.** Blood and urine metal ion levels in young and active patients after Birmingham hip resurfacing arthroplasty: four-year results of a prospective longitudinal study. *J Bone Joint Surg [Br]* 2007;89-B:169-73.
2. **Vendittoli PA, Mottard S, Roy AG, Dupont C, Lavigne M.** Chromium and cobalt ion release following the Durom high carbon content, forged metal-on-metal surface replacement of the hip. *J Bone Joint Surg [Br]* 2007;89-B:441-8.

Author's reply:

Sir,

We that Dr Vendittoli and colleagues for their interest in our paper.

Our study is the first attempt at understanding *in vivo* metal release and systemic exposure in patients with modern metal-metal (MM) resurfacings through a prospective longitudinal assessment of the whole blood levels and daily output of cobalt and chromium. They suggest that we should not have used the inclusion criterion of selecting only two bearing diameters in our study. Including all sizes and genders is commendable, provided that adequate numbers of patients are recruited to represent every possible bearing, diameter and gender; and the temporal trend is assessed in each separately through adequately-sized cohorts. Inclusion criteria are designed to reduce confounding variability while allowing the sample to be representative of the larger population under investigation. It has been stated that metal release from surface corrosion is a function of surface area[1] and clearly bearings of different diameters will have differing contribution to overall metal ion production. Being *ad hoc* and unselective with

regard to this important variable would lead to unspecified numbers of subjects with each diameter and contribute to statistical confounding.

Our choice of the two sizes (50 mm and 54 mm bearings) was based on several observations. First, these two sizes are by far the most commonly used sizes and represent more than twice as many resurfacings as all other sizes put together in our centre (over 70% need one of these two sizes). Second, young men with unilateral hip osteoarthritis managed with resurfacing have been shown[2] to be the most active resurfacing group with 92% participating in sport and 62% participating in impact sport. Our purpose was to assess metal release in this extremely active patient group who are the worst-case scenario for metal ion release in correctly implanted devices. Furthermore, when attempting to assess timed excretion of metal in urine, patients need to collect urine in a specimen container without spillage or contamination and it is obvious that men are more efficient at complying with this task. They did not perform urine collection to assess 24-hour production of metal ions thus simplifying their study but reducing the overall scientific value of their work.

Moreover, in their study they instructed their patients not to engage in new, strenuous activities in the week before specimen collection. Being prescriptive with regards to activities in any form has the potential to make patients restrict regular activities, rendering the investigation less representative of the day-to-day conditions these bearings are subject to in real life, and may reduce the validity of their results. Our patients were asked to live their lives as normal and collect their specimens without any restriction of physical activity at all.

It appears to us that Vendittoli et al's arguments stem from their assumption that we have presented a subset of results selected from a larger cohort. We carefully designed this investigation as a prospective longitudinal study with the stated inclusion criteria, amongst others, of using only two femoral head sizes in men to ensure the study has sufficient power. After informed consent we collected urine and whole blood specimens from all men (who were templated and found likely to need 50 mm or 54 mm femoral components; and consented to participate in this long-term study) pre-operatively but discarded specimens from patients who did not receive the stated head sizes immediately after the operation.

In their letter, Vendittoli and colleagues select a subset of results from their publications. This *post facto* selection is unscientific and does not carry any relevance to the study. From an assessment of blood levels in a large (n = 152) cross-sectional group of men and women with unilateral Birmingham Hip Resurfacings (BHRs) with over five years follow-up we found no significant difference in either cobalt ($p > 0.1$) or chromium ($p > 0.05$) when men with 50 mm and 54 mm diameter bearings were compared with all other subjects. Neither was there a significant mean difference nor association between subjects with different bearing diameters or genders.

The other possibility is that the design difference between the components used in the two studies accounts for the differences found in the two centres. Vendittoli et al state that the Durom resurfacing implant produces higher metal ion blood levels in women compared with men and higher blood levels in small implants compared with large. Also they note that the radial clearance on the Durom is 75 μm. Since it is not otherwise stated, we have assumed that this clearance is held constant across the range of sizes. The BHR, on the other hand, has a decreasing clearance with decreasing head diameter with the ratio of diameter to clearance held constant across the range. The fact that the blood metal ions with the BHR do not differ in women compared with men and across the range of head sizes may merely reflect a constant lubrication regimen across the range of BHR sizes. With a constant clearance across the range of Durom head sizes, clearly the lubrication regimen will be less favourable in smaller sizes and this design difference may account for our differing perspectives.

In conclusion, we reiterate our assertion that our longitudinal metal ion study is carefully designed to minimise confounding factors and monitor *in vivo* metal ion release on a continuing time scale following implantation of a particular metal-metal resurfacing and forms a valid baseline for future studies.

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J. DANIEL, FRCS, Director of Research
H. ZIAEE, BSc(Hons)
C. PRADHAN, FRCS
P. B. PYNSENT, PhD
D. J. W. McMINN, FRCS
The McMinn Centre and the Royal Orthopaedic Hospital, Birmingham, UK.

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2. Daniel J, Pynsent PB, McMinn DJ. Metal-on-metal resurfacing of the hip in patients under the age of 55 years with osteoarthritis. *J Bone Joint Surg [Br]* 2004;86-B:177-84.