April 16, 2012

Dear Dr. Carome,

We read with interest the comments attributed to you by Deborah Cohen in her piece in the British Medical Journal on the 28th of February 2012, that "this is one very large uncontrolled experiment exposing millions of patients to an unknown risk." These comments are being quoted as first principles by the newspapers and law firms around the world. The comments have been widely reported in the lay press and have caused massive patient alarm and helped bring the profession of orthopaedic surgery, the regulatory bodies, the medical device industry and the operation of hip replacement into disrepute.

The earliest successful total hip replacements (THRs) which were introduced into clinical usage by McKee in 1960 were made of cobalt-chrome metal-on-metal bearings. It was only a few years later in 1962 that Sir John Charnley started using metal on ultrahigh molecular weight polyethylene bearings in what are today termed conventional total hip replacements.

The Swedish National Hip Arthroplasty Register in its report in 2000 noted that in young patients (men and women under the age of 55 years with osteoarthritis) the performance of conventional hip replacements was dismal with a 19% implant failure rate at 10 years and a 67% failure rate at 16 years. In contrast the performance of conventional total hip replacements in older patients is very satisfactory. There was therefore a need to develop more robust implant types for use in younger more active patients. We have been involved in that development and one of us is the co-designer of the Birmingham Hip Resurfacing (BHR).

Our results with the BHR in patients under the age of 55 years with osteoarthritis show less than 2% implant failure at 10 years and < 3% failure at 14.5 years. Very promising results have been reported with the BHR from other sources and from national joint registers in predominantly young patients. Of course we acknowledge that the BHR with its high clearance, metallurgy and acetabular coverage is strongly based on the successful first generation metal-on-metal devices used since 1960. This is no surprise as our development of the BHR started with a detailed forensic analysis of the first generation MoM implants. This was specifically performed to ensure that key bearing characteristics were faithfully transferred to the BHR so that a new bearing experiment was not initiated.
In a few patients still alive with long term historic MoM devices the metal ion levels are not significantly different to our BHR patients with 12+ year followup. This shows that patients with BHR devices do not have a greater metal ion exposure compared to the historic MoM devices.

Newer devices such as Johnson-Johnson’s ASR and Zimmer’s Durom with their low radial clearance and other bearing characteristics have no basis in history and these resurfacings have shown high failure rates, in some cases up to 25% failure at 7 years. The ASR XL15 16 17 and Durom MoM Total Hip Replacements also have high failure rates, in particular they appear to fail with head-neck taper failures as a major issue. It has been shown that the deformation of the ASR and Durom cups during cup implantation exceeds the initial clearance and leads to clamping between the head and the cup. This can lead to high frictional torque at the bearing being transmitted to the taper junctions eventually leading to taper failures. Accelerated cup loosening in these low clearance MoM THRs is also a feature.

Our experience with MoM Total Hip Replacements using BHR cups and modular heads on stems show 98% implant survival at 10 years and no observed head-neck taper failures. Analysis of the NJR (England and Wales National Joint Register) results of Smith & Nephew stems with a BHR cup show a failure rate superior to the NICE (National Institute of Clinical and Health Excellence) guidelines. Before beginning to use the BHR MoM Total Hip Replacements, we performed Metasul small diameter MoM THR’s. These implants also have had excellent survival and metal ion levels no different to the BHR.

The BHR is made of cobalt-chrome alloy, which contains about 28% chromium, 6% molybdenum around 1% different trace materials and the rest (around 65%) cobalt, a material that has been in use in hip arthroplasty as Vitallium since 1938. With your expertise in renal medicine you would agree that these are essential trace elements with deficiency states described for each of them, that there is a renal clearance mechanism for these metals and that they are not nephrotoxic at the clinically relevant levels.

However there has been concern that these ions can cause chromosome and DNA changes with potential carcinogenic effects. For the last two decades the Bristol Implant Research Centre in the United Kingdom has been on a mission to establish a link between implant materials and early markers of cancer. In a cross-sectional study they analysed chromosome changes in a group of patients at the time of revision arthroplasty (revision of predominantly metal on polyethylene replacements). They then compared the results with tests from controls presenting for primary arthroplasty. The Bristol study showed that there is an increase of translocations and aneuploidy in the study group, and that there were differences between cobalt-chrome and titanium-containing implants.

The same Centre then performed a longitudinal study on patients with metal-on-metal (MoM) hip replacements but found that the increase of chromosome aberrations in these patients was not as great as that previously reported for the metal-on-polyethylene prostheses in the cross-sectional study mentioned above. No significant relationship was found between the chromosome changes and the blood levels of cobalt.
or chromium. Studies from the same centre also demonstrate that ceramic-ceramic bearing replacements also show similar chromosome changes in the peripheral blood. All three of these studies were performed in the same laboratory using the same techniques by the same team. Therefore chromosome changes in patients with MoM bearings are no greater than those with either M-PE or ceramic-ceramic bearings. On the basis of chromosome changes, the risk of carcinogenesis should be no greater in MoM bearings as compared to the other bearings.

Fairly extensive long term studies have been conducted and published on the effects of these metals in patients with metal-on-metal hip arthroplasties and compared to patients with metal-on-polyethylene hip arthroplasties and with the general population.

Anyone interested in hard evidence in the world literature will find the published life work of Prof Visuri and colleagues in Finland. They studied more than 2000 patients with hip replacements over 30 years and compared their causes of death with the general population. The patients included 579 who had metal-on-metal (MoM) THR's and 1585 who had metal-on-polyethylene (MPE) THR's, providing exposure risk of over 36000 person-years in patients with hip replacements. Patient records from the general population were used as controls.

They found that there was no significant increase in cancer rates or in organ system failure rates with the exception that those with conventional hip replacements had a higher likelihood of dying from Alzheimers disease (Table 1). This was after 30 years and although not in a randomized controlled trial setup, the effects were compared to those with metal-on-polyethylene hip replacements and to the general population. They also studied the site-specific incidence of cancer and found no increase in the different cancers as compared to the general population.

Table 1

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<th>Prevalence of Metal on Metal Total Hip Replacements</th>
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general population

Conventional Total Hip Replacements

as compared to the

general population

Metal on Metal Total Hip Replacements

compared to

Conventional Total Hip Replacements

Cancer

No difference

Decreased in MPE

Slight decrease in the MPE group in the first 20 years. No difference thereafter

Cardiovascular Diseases

1st decade, decreased in MoM

2nd decade: Equal

Increased thereafter
1st decade, decreased in MPE

2nd decade: Equal

Increased thereafter

No difference

Diabetes mellitus

Slightly decreased in MoM group

Decreased in MPE group

No difference

Alzheimer’s Disease

No difference

Increased in MPE

Decreased in MoM
Respiratory Diseases

Decreased in MoM

Decreased in MPE
during the first 20 years.

Increased thereafter

Decreased in the MPE group during the first 20yrs.

No difference thereafter
The effect of hip resurfacings and different replacements on the incidence of cancer has also been studied in the large England and Wales National Joint Register in a recent publication in the British Medical Journal, where the data from nearly 300,000 hip replacements were independently analysed. They conclude that, despite the theoretical risks, we did not find a link between metal-on-metal hip replacements (either stemmed or resurfacing) and increased incidence of cancer diagnosis. They also state that a comparison of one year observed diagnosis rates with expected rates showed that men and women with all types of hip replacement were less likely to receive a diagnosis of cancer than an age and sex matched general population. Patients with metal-on-metal bearing surfaces had lower observed incidence rates than those with other bearing surfaces, with a particularly low rate in younger patients in the resurfacing metal-on-metal group. Furthermore, our models indicated that patients undergoing resurfacing procedures were less likely than those with alternative bearings to get a diagnosis of prostate cancer, haematological cancers, or any cancer and had a lower risk of death. This was after they had adjusted for age, gender, diagnosis, preoperative health status and comorbidities at the time of operation using flexible parametric analysis.

At this practice we have been performing metal-on-metal resurfacing and total hip replacements for the past twenty one years. On our website we have the testimonials of patients who have enjoyed the benefits of hip resurfacing for over twenty years and a woman who underwent a metal-on-metal total hip replacement over forty years ago, and continues to benefit from it. You can watch her story at http://www.youtube.com/watch?v=KqQAnDJKqhU.

We would appreciate if you could explain which part of our practice is a large uncontrolled experiment.

Yours sincerely,
Joseph Daniel FRCS MS(Orth)
Director of Research
McMinn Centre

Derek McMinn MD FRCS
Consultant Orthopaedic Surgeon
McMinn Centre

Cc to:
Rt Hon Andrew Lansley MP, Secretary of State for Health
Rt Hon Stephen Dorrell MP, Chairman of the Health Select Committee
Professor Sir Kent Woods, Chief Executive, MHRA
Christy Foreman, Director, Office of Device Evaluation, FDA
Michelle Bolek, FDA
Laura Powers-Freeling, Chairman, National Joint Register
Professor Norman Williams, President, Royal College of Surgeons
Mr Joe Dias, President, British Orthopaedic Association
Mr Gordon Bannister, President, British Hip Society
Mr Mike Frazzette, President, Advanced Surgical Devices Division, Smith & Nephew
Dr Andy Weymann MD, Medical Director, Smith & Nephew
Mr Tim Band, Global Director Advanced Bearing Systems, Smith & Nephew
Dr Fiona Godlee, Editor, British Medical Journal
Dr Deborah Cohen, Investigations Editor, British Medical Journal
Mr John Witherow, Editor, The Sunday Times
Mr Meirion Jones, Producer, BBC Newsnight
Vicky Marlow, Patient Support Group, Hip Resurfacing Site

The references below can be downloaded at http://www.mcminncentre.co.uk/bhr-resources.html


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