

# Metal-on-Metal: Questions & Answers

### What are the benefits of metal-on-metal hip replacement?

Cobalt Chrome alloy has been used since the 1930's for a multitude of orthopaedic applications. Due to its relatively high hardness, high stiffness and resistance to damage, Cobalt Chromium alloy has widespread use in modern day orthopaedics as a bearing surface especially in joint arthroplasty. It is commonly used in such applications as total and uni knee femoral components, spinal implants, total hip arthroplasty femoral heads articulating against polyethylene, and metal-on-metal total hips including hip resurfacing.

Due to its material properties Cobalt Chrome can be used to produce very thin metallic devices without the risk of fracture. This makes it attractive for use in hip arthroplasty for active patients to produce bone conserving implants while maximising the size of bearing diameter to reduce the risk of dislocation. With the current technology, other materials used in total hip arthroplasty, such as ceramics and polyethylene, cannot practically be manufactured into anatomically relevant implant sizes without sacrificing acetabular bone stock or increasing their risk of fracture. Well functioning metal-on-metal hip replacements also have the potential to produce very low amounts of wear compared to metal on polyethylene implants.

Cobalt chrome implants are known to release metal ions within the body. Although metal-on-metal hip replacements have been used for over 40 years investigations are being carried out into any long term clinical implications.

### What causes metal ions in the body?

Cobalt, chromium and molybdenum, which are the major constituents of the alloy used in artificial hip devices, are natural essential trace elements for humans and are found in the water supply and food. Cobalt is part of vitamin B12. Chromium facilitates insulin activity and is essential for the energy functions of the cell. Molybdenum is also essential for several cellular functions. Being essential elements there is an efficient continuous renal mechanism to get rid of much of the excess.

Measurable metal ion levels are present in the blood and urine of subjects with no artificial metal devices in the body. When artificial hip or knee devices are used, the circulating levels of these metal ions increase initially and then slightly reduce, but do not return to the levels that existed before the operation.

### Is there a 'normal' level of metal ions?

There are measurable levels of metal ions in the urine and blood of all humans. In general they are of the order of 1 part per billion or less.

### Are there set safety levels?

Although safe levels have been prescribed in Industrial Occupational Health settings, these are not directly applicable to patients with artificial hip devices. In one study of hip failures researchers found that serum chromium levels of 17 parts per billion (ppb) and serum cobalt levels of 19 ppb are unsafe and fail with excess wear and metal staining of tissues<sup>1</sup> and more recently reported that a majority of patients with well-functioning hips had a serum cobalt level of less than 4 ppb and a chromium level of less than 5 ppb<sup>2</sup>.

### What is the impact on the patient of metal ions in the body?

Metal-on-metal hip devices have been in use for over forty years. Since these devices are being increasingly used in young patients who are more active and are going to retain these devices over a longer life, there are concerns relating to potential unknown adverse effects. Although there are studies which show chromosome changes in association with increased metal ion levels, such changes have been seen in patients with different types of artificial hip and knee devices including metal-on-polyethylene and ceramic bearing devices. Scandinavian studies have shown no increase in the incidence of cancer in a group of patients with metal-on-metal devices followed up for over thirty years.

Recent studies show that some metal-on-metal devices are likely to release more metal ions and fail quicker because of suboptimal materials<sup>3</sup> and design<sup>4</sup>. Surgeon experience and positioning of the implants also has an effect on the release of metal ions.

### What is ALVAL?

ALVAL or 'Aseptic Lymphocytic Vasculitis and Associated Lesions' is thought to be a localized lymphocytic driven hypersensitivity immune response to particulate or metal ion/protein complexes produced from metallic implants<sup>5</sup>. Exact incidence is thought to be extremely rare but does not appear to correlate to basic preoperative metal sensitivity tests.

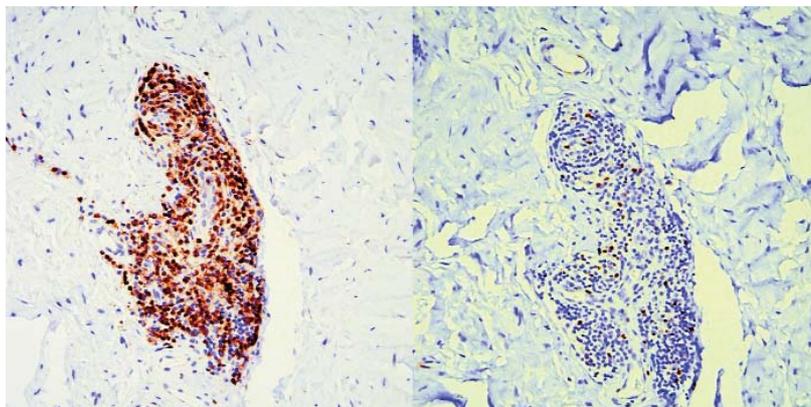


Figure 1 - Histological sections showing perivascular agglomerated infiltrates of CD3 and activated T Lymphocytes (stained brown) in retrieved capsular tissue of a patient with metal sensitivity post metal-on-metal hip replacement

### What is a pseudo tumour?

The term pseudotumor has not been clearly defined. Some patients with artificial hip devices experience pain or discomfort associated with a solid mass or a fluid-filled cavity with surrounding muscle, soft tissue and bone destruction. The device then has to be revised. These have been found in association with different types of bearings made of metal, polyethylene and ceramics, both in hips and knees.

### Is there an established link between metal ions and pseudo tumours?

There is growing evidence that a majority of these pseudotumors are associated with excessive wear, most commonly due to improper positioning of the components. There may be a very small percentage of patients who develop pseudotumors in the presence of expected levels of wear. These may be related to the patient being hypersensitive (allergic) to one or the other metals in the bearing. Patients with a known history of allergy to metallic objects such as costume jewellery need to be carefully assessed before the hip operation to determine if they have a true reaction to any of the different metals present in the alloy.

### What metals are we talking about?

Cobalt, chromium and molybdenum are the major constituents of the alloy used in artificial hip devices. In addition there are very small quantities of nickel, silicon, carbon and a few other substances. A subject can have a reaction to any one of these metals or combinations thereof.

### What is the history of metal ions for the BHR<sup>®</sup> System?

The BHR system has one of the longest track records with respect to ongoing serial metal ion assessments in patients following device implantation<sup>6,7</sup>. The results consistently show a period of increased cobalt and chromium levels in urine and blood, over the first 6 months to 2 years after the procedure<sup>8</sup>. Following this there is a gradual reduction in the ion levels over the subsequent years although they do not reach pre-operative levels. When the components are implanted improperly then there is a potential for excess wear<sup>9</sup>. However the BHR has been found to be more forgiving towards component malposition than some other competitive devices<sup>10</sup>.

### What effect does clearance, head size and activity have on metal ion release?

Femoral head size and patient activity have been shown to have no statistical effect on metal ion output<sup>11,12,13</sup>. Low clearance has been shown to reduce wear of a metal-on-metal device in laboratory studies but has produced little if any proven benefit clinically, with variables such as cup design and cup deflection appearing to play a larger role<sup>14,15</sup>.



Figure 2 - CT scan of a pelvis in a conventional metal-on-polyethylene total hip showing a space occupying mass. Biopsy needle can be seen on the top left.



Figure 3 - AP X-Ray of the pelvis in conventional metal-on-polyethylene hip showing eccentric wear of the liner.

### What about other S&N products?

Recent studies on patients with the Birmingham large diameter total hip replacements have shown urine and blood levels which are comparable to those with the BHR<sup>16</sup>. In orthopaedic implants with non metal-on-metal articulations metal ions released from other orthopaedic devices is expected to be low.

### Why is everyone so concerned all of a sudden?

Although metal-on-metal hip devices have been in use for more than four decades, their usage has increased significantly in the past ten years. During the last three years there have been reports from some centres of pseudotumor-related failures. Furthermore it has been shown that these patients when they are revised have a worse outcome than those who were revised for other reasons. In some centres the high incidence has been due to edge loading which implies poor component positioning<sup>17</sup> and in some centres<sup>18,19</sup> a particular device has been found to be responsible for the high incidence of failures. There have been other reports which have suggested when a favourable device was used and implanted well these failures are extremely rare.

### What is the impact of implant angle?

There is growing evidence that excessive metal ion levels and a majority of pseudotumors are associated with excessive wear<sup>17</sup>, most commonly due to improper positioning of the components<sup>9,20</sup>. When the ball and especially the socket (cup) are not properly positioned then the cup starts wearing at the edge in an excessive manner, in a manner similar to running an automobile engine without oil. The excess wear leads to high metal ion levels and potentially to pseudotumors. Studies performed on components from one centre showed that all components revised for a pseudotumor showed signs of edge wear which signifies component malpositioning<sup>17</sup>. No pseudotumor developed in a component which did not show edge loading. This proves that the implant position has a profound impact on the success or failure of a resurfacing device.

### What is the impact of surgical technique?

Hip resurfacing is potentially more difficult to perform than a total hip replacement. Implanting the resurfacing components in the correct position is of paramount importance. Therefore adequate surgeon training and proper surgical technique have an impact on the long-term success or failures of these devices. The recommended acetabular component position for the BHR device is between 40-45 deg inclination and 15-20 deg anteversion for longevity of the bearing.

### When revising a resurfacing femoral component to a modular head for femoral neck fracture, is it acceptable to leave a well fixed BHR cup in-situ?

If the acetabular component is well positioned, well fixed and undamaged it is totally acceptable to leave the cup in-situ. Tested in hip simulators a new run in phase is seen on the modular femoral head, while the acetabular component functions similarly as a pre-run in device<sup>21</sup>.

### Why do small sized components and women have a higher risk of revision in hip resurfacing?

In 2009 the Australian registry cited that components of less than 50mm in femoral head implant diameter produced a higher risk of cumulative revision in hip resurfacing<sup>22</sup>. Due to the majority of female patients being under 50mm in femoral head size this culminates in a higher revision rate than in male patients.

A recent single site study demonstrated that although female patients initially may appear to have a greater risk of revision, this increased risk is related to differences in the femoral component size and thus is only indirectly related to female gender. It was shown that the most common reason for failure in smaller sized components is neck of femur fracture or femoral head collapse with 56% (14/25) of aseptic revisions in femoral head sizes under 50mm femoral head implant diameter being undertaken for these reasons<sup>23</sup>.

Close attention should be paid to avoid notching of the femoral neck during the surgical procedure, or varus malposition of the femoral component, which have been shown to increase the risk of femoral neck fracture<sup>24</sup>. In addition, depending on bone quality and surgeons discretion, post operative precautions may be employed for women undergoing resurfacing to reduce the potential for femoral neck fracture.

### Globally published clinical results of the BHR system.

Author	Site	n	Survival	Follow Up (years)
Daniel <i>et al.</i> JBJS, 2004 <sup>25</sup>	Birmingham, UK	446	99.8%	4
De Smet. Hip Intl, 2005 <sup>26</sup>	Ghent	200	99.5%	1.5
Treacy <i>et al.</i> JBJS, 2005 <sup>27</sup>	Birmingham, UK	144	99.0%	5
Pollard <i>et al.</i> JBJS, 2006 <sup>28</sup>	Bristol, UK	54	94.0%	6
Hing <i>et al.</i> JBJS, 2007 <sup>29</sup>	Melbourne, Aus	230	99.1%	5
Nishi <i>et al.</i> JOA, 2007 <sup>30</sup>	Osaka, Japan	50	96.0%	5
Steffen <i>et al.</i> JBJS, 2008 <sup>31</sup>	Oxford, UK	610	95.1%	7
Heilpern <i>et al.</i> JBJS, 2008 <sup>32</sup>	Kent & Sussex, UK	110	96.3%	6
Kahn <i>et al.</i> JOA, 2009 <sup>33</sup>	Global, 8 Countries 58 surgeons	653	95.7%	8
McBryde <i>et al.</i> JBJS, 2010 <sup>23</sup>	Birmingham, UK 10 surgeons	2123	97.5%	5
Madhu <i>et al.</i> JOA, 2010 <sup>34</sup>	Hull, UK	117	91.5%	7
Australian Joint Registry 2009 <sup>35</sup>	Australia	8427	95.0%	8
Oswestry Registry <sup>36</sup>	Global - 16 Countries 18 Surgeons	518	95.4%	10

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