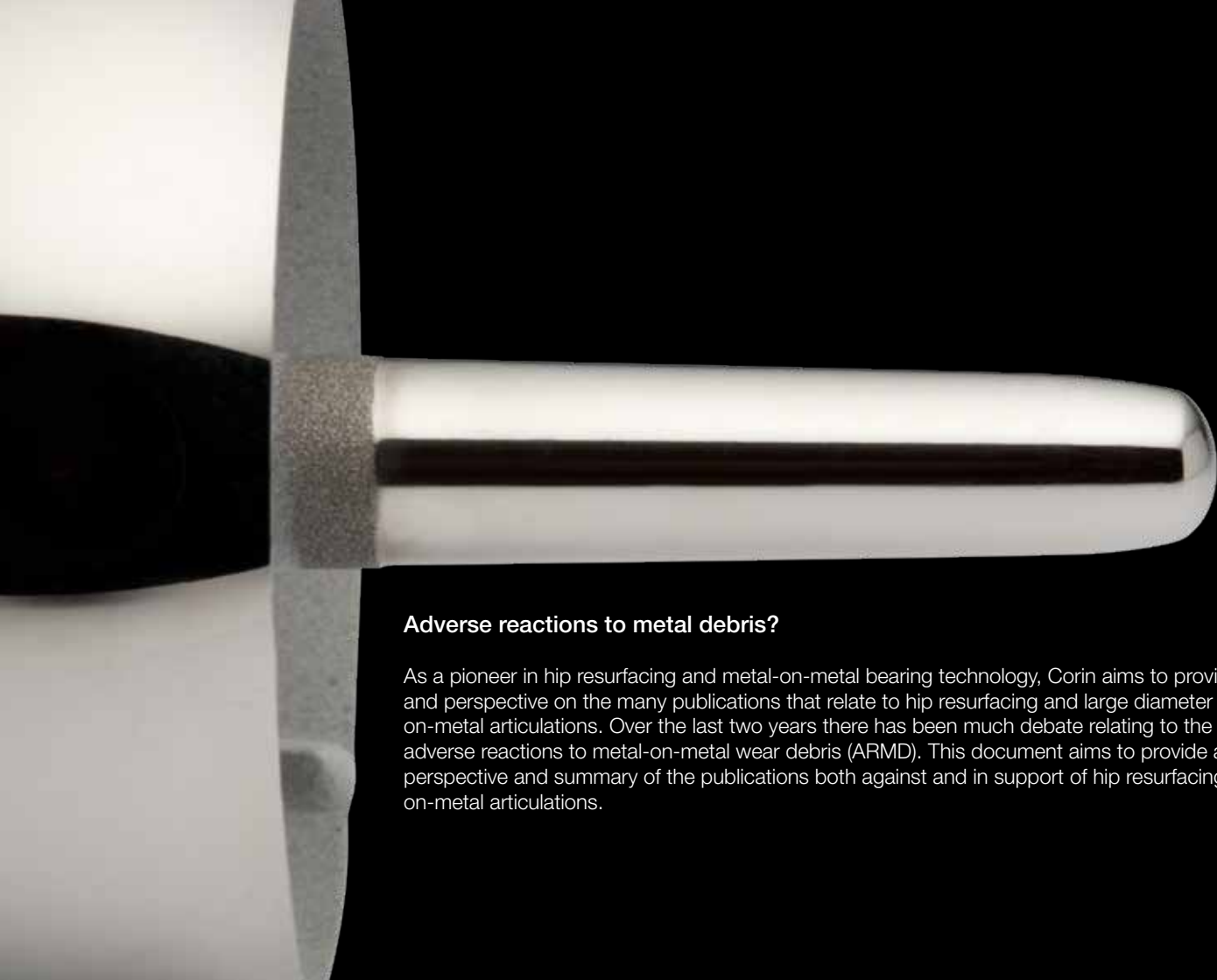




Corin

Metal-on-Metal
A clinical overview



Adverse reactions to metal debris?

As a pioneer in hip resurfacing and metal-on-metal bearing technology, Corin aims to provide clarity and perspective on the many publications that relate to hip resurfacing and large diameter metal-on-metal articulations. Over the last two years there has been much debate relating to the subject of adverse reactions to metal-on-metal wear debris (ARMD). This document aims to provide a balanced perspective and summary of the publications both against and in support of hip resurfacing and metal-on-metal articulations.

Introduction

Prior to the development of third generation metal-on-metal articulations, there was no viable long-term, bone conserving solution for challenging, active patients. The addition of this technology revolutionised the treatment of this patient group.

Third generation metal-on-metal hip resurfacings and large diameter metal-on-metal total hip replacements (THRs) have been available for over ten years. The published data shows a high survivorship for young, active patients treated with these articulations.

A number of series and joint registries show:

- 94.0% survivorship at 7 years¹
- 95.7% survivorship at 8 years²
- 96.4% survivorship at 8 years³

The most prevalent risk of failure in hip resurfacing has previously been identified as femoral neck fracture⁴, which tends to be an early failure mode (15 weeks post-operatively) and the risk is greatly reduced by correct patient selection and surgical technique⁵.

As the follow-up period increases for metal-on-metal hip resurfacing, some of the literature points to later complications associated with pain, fluid surrounding the joint (described as large sterile effusion of the hip), microscopic necrosis and metallosis⁶. These symptoms are described as adverse reactions to metal debris (ARMD)⁶.

This review discusses ARMD, the associated risk factors, the impact of implant design and the clinical results of metal-on-metal hip resurfacing.





ARMD literature

A series of papers have been published from a group of surgeons in Oxford (UK) that discuss the issue of 'pseudotumours'^{7,8,9,10}. Pandit *et al.*⁷ reported on 17 patients (20 hips) from a cohort of more than 1300 patients (Oxford patients and tertiary referrals) who presented with symptoms termed 'pseudotumours' described as soft tissue masses. The cause of these masses was not clearly determined (a weak correlation between the incidence and cup inclination was noted). However, the group extrapolated their data to predict that approximately 1% of all patients receiving a metal-on-metal hip resurfacing would develop a pseudotumour within 5 years. Although the authors state that pseudotumours have not been observed in conventional total hip replacement, the term in fact dates back to 1987 and has previously been associated with metal-on-polyethylene hips and methylmethacrylate found in bone cement¹¹.

In the second paper published by the Oxford group, Grammatopoulos *et al.*⁸ stated that the increased wear responsible for pseudotumours is probably as a result of edge loading or impingement interfering with the lubrication or destroying the congruency of the articulation. They also stated 'it is becoming evident that considerable care is needed in the positioning of these devices' within the Lewinnek safe zone. In a further paper Glyn-Jones *et al.*⁹ discussed the risk factors for inflammatory pseudotumour formation following hip resurfacing. This paper, identified the risk of revision associated with pseudotumours as 4% for all patients at 8 years, and 0.5% for men at 8 years.

Risk factors for revision

Glyn-Jones *et al.*⁹ described the risk factors as female gender, small component size, age and a diagnosis of dysplasia. The incidence is not associated to implant type according to the authors. The Cormet Hip Resurfacing (Corin), Birmingham Hip Replacement (BHR) (Smith & Nephew), Conserve Plus (Wright Medical) and Recap (Biomet) systems were used in the study. They stated that gender and age have a significant independent effect. The paper concludes females could be at a higher risk due to the increased prevalence of allergies to jewellery and/or the increased range of motion and therefore increased impingement and wear. A small bearing may also be a contributing factor as the incidence of hydrodynamic lubrication may be diminished or the superior cover of the implant reduced. A diagnosis of dysplasia may also increase the risk of misalignment, leading to impingement and wear. The Oxford group advise caution when indicating a resurfacing for a female especially those under 40 years old, however they stated it remains a good option for young men.

It has been noted that some patients have presented with an ARMD without component malpositioning^{9,12}. The wear of metal-on-metal hip resurfacings is multi-factorial and implant position (abduction and anteversion), component size and activity levels may have an effect. In a separate series, Hart *et al.* discussed a cohort of patients with metal-on-metal hip resurfacings revised for unexplained pain. In this series a high proportion of patients revised had a component positioned outside the Lewinnek safe zone¹² (13 out of 16 patients). This paper concluded that the increased incidence of metal debris due to component malpositioning and the risk of impingement due to reduced head-neck ratio are associated with revision of metal-on-metal hip resurfacings. Hart

*et al.*¹³ have also presented the threshold for metal sensitivity and specificity of high blood metal ions in predicting failure as 7ppb, they recommend monitoring patients with metal ion levels greater than this.

Nargol *et al.*⁶ discussed ARMD and stated that without exception the literature reports an increased incidence of these problems in women. This paper concludes that patients with smaller component size, sub-optimal orientation and design of the component are factors which make the patients more susceptible to wear and therefore possibly at a higher risk due to the increase in generation of metal debris. They also concluded that females may be at risk due to higher acetabular inclination, anteversion, smaller joint size, increasing the risk of posterior impingement and micro-separation leading to higher wear of the bearing.

In addition to female gender, small component size and higher abduction angles, Ollivere *et al.*¹⁴ report that an additional risk factor for revision due to ARMD is a high BMI leading to difficulty in positioning the cup in the correct orientation.

The importance of patient selection was previously highlighted by Stulberg *et al.*⁴ during the Cormet IDE study. Female gender, component size and a lower pre-operative Harris Hip Score were found to be significant risk factors for revision. If the patient indicated had multiple risk factors compared to none or one, the data showed the patient is more likely to require a revision.

Implant design

It has become evident that in addition to the points noted above, implant design also plays an important role in the success of hip resurfacing. Nargol *et al.*⁶ discussed the impact of a lower subtended angle in the cup design and its effect on the potential for edge loading leading to high wear. The ASR design (DePuy) subtends to an angle of 151° for a 52mm acetabular component⁶ whereas Cormet hip resurfacing has an increased arc of coverage of 163° which results in a decreased risk of edge loading and wear. This demonstrates the need for the greater arc of coverage seen in third generation hip resurfacings such as Cormet. In addition, Angadji *et al.* showed that the metallurgy of the Cormet device may protect the device from excessive wear at high angles¹⁵.

Kwon *et al.*¹⁰ from the Oxford group analysed eight resurfacing components revised for pseudotumours and found they had increased wear and edge loading. They concluded “our findings are the first direct evidence that pseudotumours are associated with increased wear at the metal-on-metal articulation. Furthermore, edge loading with the loss of fluid-film lubrication may be an important mechanism for the generation of wear in patients with a pseudotumour”.

This further supports the importance of arc of coverage in resurfacing and large diameter metal-on-metal components.

Cormet clinical results

In contrast to the above, there are three large cohorts of patients who have received a Cormet hip resurfacing. All the cohorts are multi-centre and show a very small number of ARMD cases.

In the first cohort, 4 of 1743 hips (0.22%) were revised due to metallosis or ALVAL¹⁶. In this group of 1515 patients, the average age was 54 years (20-89 years) and the majority had a pre-operative diagnosis of osteoarthritis (92%) with the remainder made up of a variety of AVN, inflammatory arthropathies and post-traumatic cases. The cohort consisted of 921 males and 594 females.

In the second cohort, the patients had a Cormet hip resurfacing implanted under an FDA approved investigational device exemption (IDE) study and there is 1 reported ARMD case (0.08%) from 1183 patients¹⁷.

From the second cohort, Gross *et al.*¹⁸ recently presented at the American Academy of Orthopaedic Surgeons (AAOS) meeting, the results of the Cormet hip resurfacing in 329 patients (373 hips) showed a survivorship of 94% at 8 years with no revisions due to ARMD.

Beaule *et al.*¹⁹ also presented a cohort of 3432 hip resurfacings (8.5% Cormet hip resurfacings) implanted in nine Canadian centres. They reported an ARMD incidence of 0.09% (3 cases) at a follow-up of 3.4 years. They concluded that there were a small number of patients in high risk categories resulting in excellent outcomes and minimal risk of pseudotumours.



The original
metal-on-metal hip resurfacing



Over 20 years' expertise in metal-on-metal hip resurfacing

1989 Vision...

Corin begins development of the first metal-on-metal hip resurfacing

1991 Origin...

The first implantation of the Corin McMinn Hip Resurfacing

1997 Evolution...

Corin Cormet Hip Resurfacing is launched

2004 Innovation...

First fully cementless resurfacing becomes available, removing all cement from the procedure

Conclusion

The literature concludes that a number of factors influence the success of metal-on-metal hip resurfacings and THRs. It is important the following are considered when selecting and implanting Cormet hip resurfacing or an Optimom large diameter metal head with a Cormet resurfacing acetabular component.

- **Patient selection:** do not implant in contra-indicated patients such as women of child bearing age as stated in the IFU. When indicating a patient, consideration should be given to the bone quality, component size and diagnosis of the patient.
- **Component positioning:** ensure the acetabular components are implanted with a maximum inclination of 45° and 10-15° of anteversion to minimise the potential of edge loading leading to increased metal wear debris.

In conclusion, Corin believes metal-on-metal hip resurfacing remains a safe and effective surgical intervention for well-indicated patients and **Cormet continues to form an important part of our continuum of care in hip replacements.**

2007 Expansion...

Cormet is launched in the USA by Stryker Orthopaedics

2008 Progression...

2mm incremental heads become available, allowing greater intra-operative flexibility

2009 Celebration...

Corin celebrates 20 years of metal-on-metal hip resurfacing innovation

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Hip continuum of care



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