



Withdrawal of DePuy ASR Resurfacing and XL metal on metal bearings – Information for and Advice to Surgeons from the British Hip Society and the British Orthopaedic Association

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The ASR Device has now been withdrawn due to adverse results and higher than expected revision rates on the UK NJR and Australian Registries. The revision rate at 5 years in the NJR is 12% for ASR Resurfacing and 13% for Stemmed ASR Components. The British Hip Society and British Orthopaedic Association suggest that the following may aid patient care.

All patients with these components should be identified and should be informed that they have a hip replacement device that has been withdrawn, and that they are now under the umbrella of close clinical follow up and surveillance.

Some form of follow up should be performed at least annually and patients should be given contact information so that they can be reviewed quickly should they have worsening pain or deteriorating clinical function associated with the hip implant. Follow up should continue for the life of the implant, until more data is available.

At present it is felt that no specific investigations are required in the absence of pain and with implants that are performing well apart from regular follow-up. However x-rays that show that the components have come to lie in a position associated with high wear will need to be followed up more closely.

With a painful implant, further investigations should be performed. Other causes of pain such as infection, loosening of components, soft tissue / psoas impingement, fracture, osteonecrosis, referred pain from the spine, pelvis or adnexae should be excluded and this will require a history and clinical examination.

Blood Cobalt and Chromium ions should be measured as these are an indicator of surface wear. They are usually surprisingly low in well functioning components. The MHRA has suggested that levels of either Cobalt or Chromium above 7ppb ($\mu\text{g/l}$ or ng/ml) may be significant. Below this level significant soft tissue reaction and tissue damage is less likely and there seems to be a lower risk of implant failure. Above this level, patients will require closer observation and may require revision if clinically indicated. There is no evidence that above a certain metal ion concentration, revision must be performed. However, the higher the level the more concerned one becomes.

The other useful investigation is cross sectional imaging, either MRI with metal artefact reduction sequences (MARS) or ultrasound. These are both operator dependent but are capable of giving clear images of fluid collections or solid lesions ('pseudotumour') around the hip. A link on the BHS and BOA websites will be available to provide further information on protocols, points of contact and examples of common findings.

It is still thought that significant soft tissue reactions are unlikely in the absence of pain. Some asymptomatic patients may seek further reassurance, in such cases blood ion levels and imaging may be performed but caution should be exercised in acting on the findings in the asymptomatic patient. It is recommended if the tests are abnormal then more frequent follow-up should be instituted with the tests repeated at intervals (2 – 6 months). If the patient remains asymptomatic but the tests become progressively more abnormal, revision surgery may need to be considered.

The decision on when to advise revision surgery remains clinical. It is thought that worsening or severe pain, rising metal ions or increasing size of cystic or solid mass are concerning and may require revision surgery. There is increasing evidence that solid masses are more concerning than cystic ones. There is also evidence that cystic masses are found adjacent to well functioning hips. Research and audit will improve future guidance in this area.

Revision surgery may be challenging in the presence of pseudotumour, often requiring difficult debridements and reconstructions. It is considered important to do a thorough debridement of the abnormal tissue akin to the treatment of infection. MRI and / or CT should be performed preoperatively as lesional tissue may extend within the pelvis. Surgery should be performed by experienced revision surgeons and may require onward referral to a tertiary centre.

In the case of an asymptomatic joint with normal investigations, (if investigations have been performed), then yearly follow up is all that is indicated and the treating surgeon should arrange this, though the patient should be advised to report back urgently should symptoms develop in the interim.

In all other cases it is suggested that surgeons managing these cases obtains a second opinion from another experienced revision surgeon to confirm and support the appropriateness of the treatment plan, which may either be watchful waiting in the presence of equivocal symptoms or equivocal abnormal investigation; or the decision to intervene and revise the hip. Retrieved implants at revision surgery should be retained and sent to an independent assessment facility for investigation. The patient needs to be informed that the implant has been retained and where it is, should it be required later as evidence for legal proceedings

If you are asked to send patient data or imaging to any commercial company, the commercial company needs to get the patients written consent in every case. Doing so may have legal implications for the patient and this needs to be explained to the patient if consent is sought for whatever reason.

Decision Tree

1. Identify patients with ASR Implants (medical or hospitals records or via National Joint Registry).

2. Contact patients and explain they are under close follow-up and they should contact Depuy (by calling patient contact number on 01908 302195 or 0800 279 4865 9am - 5pm Mon-Fri).

3. Arrange out patient consultation:

If asymptomatic with normal examination and satisfactory x-rays follow up in one year.

If asymptomatic with normal examination but x-rays show components may have come to lie in a position associated with high wear perform blood ion levels and/or imaging.

If tests normal follow up in 2-6 months and repeat tests.

If tests equivocal repeat after 2-6 months* (if deteriorating consider revision).

If tests are abnormal strongly consider revision*.

If asymptomatic with normal examination and satisfactory x-rays but patient worried wanting reassurance about their hip consider doing blood ions and/or imaging:

If tests normal follow up in one year.

If tests equivocal repeat after 2-6 months* (if deteriorating consider revision).

If tests are grossly abnormal consider revision*.

If symptomatic exclude other causes of pain and do blood ions and/or imaging:

If symptoms mild but tests normal repeat follow up and tests in 2–6 months*.

If symptoms mild but tests abnormal consider revision*.

If symptoms are severe or worsening but tests normal consider revision*.

If symptoms are severe or worsening and tests abnormal strongly consider revision*.

Notes

* Treatment decisions should be confirmed with an (another) experienced revision surgeon. It is important that the patient receives the best possible advice under these difficult and evolving circumstances. The decision-making and the performance of subsequent revision may come under close scrutiny. All revision cases should be logged with the NJR with patient consent. The NJR is independent and will be able prospectively to audit the cases and the situation as it develops.

Patients should have open access to return to clinic at any time if symptoms deteriorate.

Revision surgery may be complex and should only be undertaken by experienced revision surgeons.

Revision should be performed expeditiously when indicated to avoid progressive tissue damage.

Blood ion tests need to be performed by accredited laboratory (MHRA guidance MDA/2010/069).

Ultrasound or MARS MRI scans need to be performed by a department experienced in MoM imaging.

Implants retrieved should be sent to an independent laboratory with patient's knowledge.

Information should not be sent to a commercial company without patient consent .

Depuy will provide funding for follow up, investigations and revision surgery if indicated.

This guidance represents best current practice to protect patients but may change with experience.

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