Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2017/018 Issued: 29 June 2017 at 14:30

All metal-on-metal (MoM) hip replacements: updated advice for follow-up of patients

Summary

MHRA is updating advice provided in MDA/2012/036, to assist the early detection of soft tissue reactions in patients implanted with metal-on-metal (MoM) hip replacements.

Action

1. Put updated systems in place for the follow-up and investigation of all patients implanted with MoM hip replacements.

2. Follow the patient management advice given in table 1* of the appendix in conjunction with the following guidance notes:

- MARS MRI scans or ultrasound scans should carry more weight in decision-making than isolated blood metal levels alone.
- Patients with muscle or bone damage shown on MARS MRI are those of most concern.
- An isolated fluid collection (unless very large) around the joint in an asymptomatic patient, can be observed with interval scanning and clinical review.
- Local symptoms may occur in otherwise well-functioning hips; these should be investigated for other causes.
- Rising blood metal levels may indicate potential for soft tissue reaction.
- After revision surgery, whole blood metal levels of chromium and/or cobalt are expected to fall and symptoms to improve. Persistent symptoms should be investigated for potential causes that include: failure of fixation, component loosening, infection and instability. If no cause is found, further blood metal level measurement and cross-sectional imaging should be considered.
- The advice in table 1 has been produced based on current knowledge, it will not necessarily cover all clinical situations. Each patient must be assessed individually.

* In all cases, the benefit of ionising radiation screening should be weighed against the risks from radiation exposure on an individual patient basis, in line with the requirements of The Ionising Radiation (Medical Exposure) Regulations 2000.

Action by

- Medical directors.
- Orthopaedic departments.
- Orthopaedic surgeons.
- Staff involved in the management of patients with joint replacement implants.

Deadlines for actions

Actions underway: 13 July 2017
Actions complete: 27 July 2017

.

Department of Health, Social Services and Public Safety www.dhsspsni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Problem / background

MHRA, in consultation with its independent Metal-on-Metal Expert Advisory Group (MoM EAG), has continued to monitor the performance of MoM hip joint articulations for the occurrence of soft tissue reaction associated with these devices. The majority of patients with MoM hip replacements currently have well-functioning hips. However, some patients will develop progressive soft tissue reactions to the wear debris associated with MoM articulations. Data from the 13th Annual Report of the National Joint Registry of England, Wales, Northern Ireland and the Isle of Man, published in 2016[1], continued to show a risk of adverse soft tissue reaction to particulate debris.

MHRA's clinical orthopaedic experts have also observed that soft tissue necrosis may occur in both asymptomatic and symptomatic patients, and believe early detection of these events should give a better revision outcome should this becomes necessary.

This advice also draws on information from:

- The British Hip Society on the follow up of patients given in the Primary Total Hip Replacement: A Guide to Good Practice, Nov 2012. This publication is also known as the Blue Book.[2]
- Orthopaedic Data Evaluation Panel (ODEP) device ratings. These ratings are based on the strength of the evidence presented by the manufacturer regarding their device.

There is no agreed threshold value for whole blood metal levels that either predicts outcome, or mandates revision. Decisions to revise are influenced by patient factors, blood metal levels, imaging findings, and implant type and position. Other patient specific factors may need to be considered when interpreting results for blood metal levels.

Measurements of cobalt or chromium blood levels should be carried out:

- in England, Northern Ireland or Wales, by laboratories participating in the Trace Elements External Quality Assessment Scheme (TEQAS) - www.sas-centre.org/
- in Scotland, by the Scottish Trace Element and Micronutrient Reference Laboratories - http://www.trace-elements.co.uk/

Note: The recommendations in this Medical Device Alert (MDA) **replace** the patient follow-up advice previously given in MDA/2012/036, MDA/2013/010, and MDA/2015/024.

This Medical Device Alert is being sent to GPs for information only, in case patients ask about the contents of this notice. GPs need take no further action on receipt of this alert

1) The National Joint Registry for England, Wales Northern Ireland and the Isle of Man, (2016); 13th Annual Report 2016, National Joint Registry for England, Wales Northern Ireland and the Isle of Man. Available: http://www.njrcentre.org.uk/njrcentre/Portals/0/Documents/England/Reports/13th%20Annual%20Report/07950%20NJR%20Annual%20Report%202016%20ONLINE%20REPORT.pdf Last accessed 28 June 2017

2) British Orthopaedic Association. (2012). Primary Total Hip Replacement: a guide to good practice. Available: https://www.britishhipsociety.com/uploaded/Blue%20Book%202012%20fsh%20nov%202012.pdf. Last accessed 28 June 2017.

Distribution

Trusts (NHS boards in Scotland)
CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Biochemists
- Clinical governance leads
- Fracture clinics
- Haematologists
- Medical physics departments
- MRI units, directors of
- Orthopaedic surgeons
- Outpatient clinics
- Physiotherapists
- Radiation & medical oncology departments
- Radiographers
- Radiologists
- Radiology departments
- Radiology directors

Public Health England
Directors for onward distribution to:

- Safety officers

NHS England area teams
CAS liaison officers for onward distribution to all relevant staff including:

- General practitioners
- General practice managers
- General practice nurses

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

- Adult placement
- Hospitals in the independent sector
- Independent treatment centres

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2017/018** or **2016/005/025/264/001**.

Technical aspects
Orthopaedic team, Devices Safety and Surveillance, MHRA
Tel: 020 3080 7080
Email: aic@mhra.gov.uk

Clinical aspects
Devices Clinical Team, MHRA
Tel: 020 3080 7274
Email: dct@mhra.gov.uk

Reporting adverse incidents in England
Through Yellow Card https://yellowcard.mhra.gov.uk/

Northern Ireland
Alerts in Northern Ireland are distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
CMO Group
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk
https://www.health-ni.gov.uk/niaic

Reporting adverse incidents in Northern Ireland

Please report directly to NIAIC using the forms on our website.

Scotland
Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

Reporting adverse incidents in Scotland

NHS Boards and Local Authorities in Scotland – report to Health Facilities Scotland.

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to Health Facilities Scotland.

Private facilities providing care to private clients report to the Care Inspectorate and MHRA.

Wales
Enquiries in Wales should be addressed to:
Healthcare Quality Division
Welsh Government

Tel: 02920 823 624 / 02920 825 510

Email: Haz-Aic@wales.gsi.gov.uk

Reporting adverse incidents in Wales

Report to MHRA through Yellow Card https://yellowcard.mhra.gov.uk/ and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).

Appendix

Table 1 - Management recommendations for patients with metal-on-metal hip replacement implants

Device implanted	**Hip resurfacing (no stem):** - female - male (femoral head diameter ≤48mm) - All DePuy ASR hip resurfacing devices **Stemmed total hip replacement (THR):** - femoral head diameter ≥36mm	**Hip resurfacing (no stem):** - male (femoral head diameter >48mm) **Stemmed total hip replacement (THR):** - femoral head diameter <36mm		
Patient and device group	**Symptomatic and asymptomatic**	**Symptomatic**	**Asymptomatic** • All stemmed THR • Resurfacing devices without 10A ODEP rating	**Asymptomatic** Resurfacing devices with 10A ODEP rating (Table 2)[5,6,7]
Frequency of follow-up after primary operation date	Annually while the device remains implanted.	Annually while the device remains implanted.	Annually for the first five years, two yearly to ten and three yearly thereafter	First year, once at seven years and three yearly thereafter
Questionnaire	Oxford Hip score assessment	Oxford Hip score assessment	Oxford Hip score assessment	Oxford Hip score assessment
Imaging	• MARS MRI or ultrasound recommended if negative change in Oxford Hip Score is observed and/or elevated/rising blood metal levels.	• MARS MRI or ultrasound in all cases	• Plain radiographs • MARS MRI or ultrasound recommended if negative change in Oxford Hip Score is observed and/or elevated/rising blood metal levels.	• Plain radiographs • MARS MRI or ultrasound recommended if negative change in Oxford Hip Score is observed and/or elevated/rising blood metal levels.
Blood Metal Level Test [1,2,3]	All patients.	All patients.	All patients.	All patients.
Consider need for revision [4]	If imaging is abnormal and/or blood metal levels rising, and/or hip related clinical function / Oxford hip score deteriorating	If imaging is abnormal and/or blood metal levels rising, and/or hip related clinical function / Oxford Hip Score deteriorating	If imaging is abnormal and/or blood metal levels rising, and/or hip related clinical function / Oxford Hip Score deteriorating	If imaging is abnormal and/or blood metal levels rising, and/or hip related clinical function / Oxford Hip Score deteriorating

Table footnotes:

1. Whole blood should be used to test for cobalt and chromium metal levels.

2. Whole blood metal levels ≥7ppb (119 nmol/L cobalt or 134.5 nmol/L chromium) in one or both metals, indicates the need for closer follow-up and cross-sectional imaging.
3. For stemmed total hip replacements, blood metal levels lower than 7ppb (119 nmol/L cobalt or 134.5 nmol/L chromium) may be associated with wear or corrosion at non-articulating surfaces.
4. Following revision, failure to see a fall in blood metal levels in patients with ongoing symptoms requires investigation.
5. The frequency of follow-up for asymptomatic male patients implanted with a 10A rated resurfacing device is in line with the British Hip Society (BHS) Blue Book Guidance on the follow-up for all total hip replacements.
6. A list of 10A ODEP rated hip resurfacing devices can be found in Table 2.
7. In circumstances where the ODEP rating of the device is unknown, the guidance for devices without 10A ODEP rating should be followed.

Table 2 – List of 10A ODEP rated metal-on-metal hip resurfacing devices

Supplier	Product	ODEP rating
MatOrtho	Adept Resurfacing Head (48-58mm)	10A
Smith & Nephew	Birmingham Hip Resurfacing Head (48–62mm)	10A*

The Orthopaedic Data Evaluation Panel (ODEP) consists of orthopaedic surgeons and non-clinical experts. The panel rate the strength of the evidence presented by the manufacturer regarding their device and awards an ODEP rating based on the evidence submitted.

ODEP ratings are subject to change.

The information provided in the table above was correct at the time of publication.

ODEP rated devices can be found at www.odep.org.uk