

Management of Patients with Metal on Metal Hip Implants

Medsafe and the New Zealand Orthopaedic Association (NZOA) (www.NZOA.org.nz) support the advice to healthcare professionals issued by the UK Medicines and Healthcare Products Regulatory Agency (MHRA) on the management of patients implanted with metal on metal hip replacements.

Issue

The majority of patients who receive a metal on metal hip replacement do well with the implant and are thought to be at low risk of developing serious problems. A small number of patients implanted with metal on metal hip replacements may develop a metal debris problem that can lead to a progressive soft tissue reaction in proximity to the joint. The metal debris problem does not occur in every patient but in some patients it occurs through the build-up of microscopic metal debris through wear at the articular surface of the joint. The issue may be monitored through a heightened level of trace amounts of the metals cobalt and chromium in the blood of a patient. Early revision surgery of poorly performing hip replacements is likely to lead to a better outcome of revision surgery.

Action

The attached table developed by the MHRA details the management of patients with implanted metal on metal hip replacements. This management plan is supported by both Medsafe and NZOA and can be used as a set of guidelines or a protocol on how to manage patients with metal on metal implants. Where appropriate a revision of the implant should be completed as early as possible.

The types of replacement are divided into four groups:

- MoM hip resurfacing implants
- MoM total hip replacements with head diameter <36mm
- MoM total hip replacements with head diameter =36mm
- DePuy ASRTM hip replacements comprising:
 - ASRTM acetabular cups for hip resurfacing arthroplasty or total hip replacement
 - ASRTM surface replacement heads for hip resurfacing arthroplasty
 - ASRTM XL femoral heads for total hip replacement.

The table has recommendations for patients who are symptomatic and also those who are asymptomatic.

Importantly all patients with implanted with a metal on metal implant that has a large diameter head (36 mm or greater) will require annual follow-up for the life of the implant.

Medsafe and the NZOA are providing this advice to you so that healthcare professionals can provide consistent advice to patients that seek consultations regarding their implanted hip replacement.

Appendix

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

	MoM hip resurfacing (no stem)		Stemmed MoM total hip replacements – femoral head diameter <36mm		Stemmed MoM total hip replacements – femoral head diameter ≥36mm		DePuy ASR™ hip replacements (all types)	
	Symptomatic patients	Asymptomatic patients	Symptomatic patients	Asymptomatic patients	Symptomatic patients	Asymptomatic patients	Symptomatic Patients	Asymptomatic patients
Patient follow-up	Annually for the life of the implant	According to local protocols	Annually for the life of the implant	According to local protocols	Annually for the life of the implant	Annually for the life of the implant	Annually for the life of the implant	Annually for the life of the implant
Imaging: MARS MRI or ultrasound	Recommended in all cases	No - unless concern exists for cohort or patient becomes symptomatic	Recommended in all cases	No - unless concern exists for cohort or patient becomes symptomatic	Recommended in all cases	Recommended if blood metal ion levels rising	Recommended in all cases	Recommended in all cases
1st blood metal ion level test	Yes	No - unless concern exists for cohort or patient becomes symptomatic	Yes	No - unless concern exists for cohort or patient becomes symptomatic	Yes	Yes	Yes	Yes
Results of 1st blood metal ion level test	<i>Blood metal ion level >7ppb indicates potential for soft tissue reaction</i>		<i>Blood metal ion level >7ppb indicates potential for soft tissue reaction</i>		<i>Blood metal ion level >7ppb indicates potential for soft tissue reaction</i>	<i>If blood metal ion level >7ppb then second blood test required 3 months later</i>	<i>Blood metal ion level >7ppb indicates potential for soft tissue reaction</i>	<i>If blood metal ion level >7ppb then second blood test required 3 months later</i>
2nd blood metal ion level test	Yes - 3 months after 1 st blood test if result was >7ppb		Yes - 3 months after 1 st blood test if result was >7ppb		Yes - 3 months after 1 st blood test if result was >7ppb	Yes - 3 months after 1 st blood test if result was >7ppb	Yes - 3 months after 1 st blood test if result was >7ppb	Yes - 3 months after 1 st blood test if result was >7ppb
Results of 2nd blood metal ion level test	<i>Blood metal ion level >7ppb indicates potential for soft tissue reaction especially if greater than previously</i>		<i>Blood metal ion level >7ppb indicates potential for soft tissue reaction especially if greater than previously</i>		<i>Blood metal ion level >7ppb indicates potential for soft tissue reaction especially if greater than previously</i>	<i>If blood metal ion levels rising - further investigation required including imaging</i>	<i>Blood metal ion level >7ppb indicates potential for soft tissue reaction especially if greater than previously</i>	<i>Blood metal ion level rising indicates potential for soft tissue reaction</i>
Consider need for revision	If imaging is abnormal and/or blood metal ion levels rising		If imaging is abnormal and/or blood metal ion levels rising		If imaging is abnormal and/or blood metal ion levels rising	If imaging is abnormal and/or blood metal ion levels rising	If imaging is abnormal and/or blood metal ion levels rising	If imaging is abnormal and/or blood metal ion levels rising

Notes and guidance on next page

Table was updated on 27 August 2012

Table footnotes:

- Blood metal ion testing to be in whole blood
- 7 parts per billion (ppb) equals 119 nmol/L cobalt or 134.5 nmol/L chromium

Guidance notes:

- On the basis of current knowledge, this chart has been produced as a guide to the management of these patients. It will not necessarily cover all clinical situations and each patient must be judged individually.
- MARS MRI scans (or ultrasound scans) should carry more weight in decision making than blood ion levels alone.
- Patients with muscle or bone damage on MARS MRI are those of most concern. A fluid collection alone around the joint in an asymptomatic patient, unless it is very large can be safely observed with interval scanning.
- Local symptoms include pain and limping.