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MEDICAL DEVICE Alert

Safety of metal-on-metal hip implants

Metal-on-metal (MoM) hip implants were widely used globally when they were first introduced into the market. However, concerns over the safety of such devices have led to a decline in their use. For example, a higher rate of premature failure was observed for the DePuy Articular Surface Replacement (ASR) hip systems. This led to their worldwide recall in 2010. The objective of this article is to highlight the safety issues concerning MoM hip implants, as well as to encourage reporting of their adverse events (AEs) to facilitate HSA's monitoring of their safety and performance in the local population.

Hip implants

A hip implant consists of three key components, namely the femoral stem, the femoral head , and the acetabular cup. It can be made of various combinations of materials (e.g., MoM, metal-on-polyethylene, ceramic-on-polyethylene, ceramic-on-ceramic) and is used either for total hip replacement (THR) or hip resurfacing procedures (Figure 1). In a hip resurfacing procedure, only the upper surface of the head of the femur is replaced. Hip resurfacing procedures currently only use MoM combinations, and are typically used in younger adults as they tend to have stronger bones.

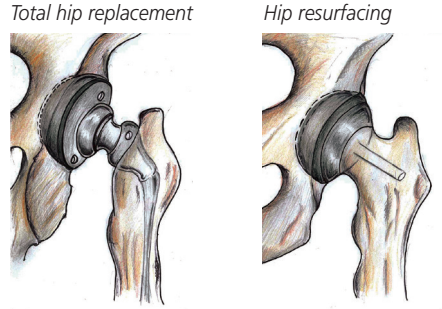

Figure 1: Illustration of MoM total hip replacement and hip resurfacing systems

MoM hip implants provide the ability to use larger diameter femoral head sizes compared to other combinations of articulating materials. These sizes more closely mimic natural anatomy and may reduce the incidence of post-operative dislocation.

Safety issues unique to MoM hip implants

General risks associated with hip implants include device wear, infection and dislocation from malpositioning of prosthesis. Device wear is the primary cause of premature failure in hip prostheses. Although device wear is experienced with all hip implants over time, it presents unique risks for MoM implants due to the possible release of metal particles (cobalt and chromium ions) from MoM articulation, causing local inflammatory responses and damage to tissues surrounding the implant and joint. This is termed as "adverse local tissue reaction (ALTR)" or "adverse reaction to metal debris". Patients with progressing ALTR may be considered for earlier revision surgery to prevent extensive damage to bone, muscles and nerves.[1] Device wear in MoM implants may also lead to systemic toxicity from the release of metal ions into the bloodstream.[2]

Risk factors which may attribute to increased risk of device wear or soft tissue reactions include female patients, patients with components not aligned optimally, increased activity, patients who are severely overweight and patients with bilateral implants.[3] Revision rates have also been found to be influenced by femoral head sizes; large-diameter THR and small-diameter hip resurfacing implants have demonstrated higher failure rates.[4] Another factor which influences revision rates is the brand of prosthesis. For instance, the 10-year revision probability of the ASR system is reported at 30.36%, compared to the Birmingham Hip Resurfacing (BHR) system at 9.04%.[5]

Revision surgery is the main risk outcome for MoM hip implants. According to the National Joint Registry for England and Wales' (NJREW) 2014 Annual Report, the estimated probability of revision for MoM bearings (uncemented) and resurfacing MoM at 10 years are 21.92% and 13.01%, respectively.[5] The UK National Institute for Clinical Excellence (NICE) has recommended that prostheses for THR and resurfacing arthroplasty be considered as treatment options for people with end-stage arthritis of the hip only if the prostheses have rates (or projected rates) of revision of 5% or less at 10 years.[6]

Example of a recent FSCA related to MoM hip implants

In January 2015, Smith & Nephew Orthopaedics Ltd initiated an update to the Instructions for Use (IFU) for the BHR System to include warnings on risk factors that could increase the risk of early revision surgery. These factors included being female, femoral head diameter ≤ 48mm, aged 65 or older, avascular necrosis, and congenital dysplasia.

Subsequently, the company recalled all lots of BHR System with femoral head diameter ≤ 46mm (and their corresponding acetabular cup components), and contraindicated the use of BHR in all female patients. This was due to data from NJREW indicating that revision rates associated with the female gender and smaller femoral heads sizes exceeded the current revision rate benchmark established by NICE. The company also updated the IFU to warn against considering patients, who from plain radiograph pre-operative templating appear to require 48mm femoral head, as candidates for BHR implantation.

All relevant healthcare professionals were informed of the above safety issues through the dissemination of Dear Healthcare Professional Letters in February and July 2015.[7] Physicians were advised the following:

- Maintain routine follow-up protocol for patients who have undergone hip resurfacing arthroplasty
- Patients who experience symptoms including limited mobility, pain, swelling, enlarged bursae, pseudotumours, tissue masses, fluid collections, or local build-up of excessive metal particles or metal hypersensitivity, may require revision surgery, with attendant risks and the potential for impaired function
- The need for any additional follow-up, including the necessity for diagnostic imaging and blood tests, should be determined on a case-by-case basis following detailed assessment of the patients' clinical circumstances

Local situation and call for reporting

To date, HSA has received nine local AEs related to MoM hip implants, all of which were associated with ASR hip systems. The AEs reported included pain and mobility issues. All patients received revision surgeries as a corrective measure.

HSA continues to actively monitor the safety and performance of MoM hip implants supplied in Singapore. It also keeps a close watch on the international developments. To facilitate the local surveillance of MoM hip implants, HSA encourages the return of any explanted MoM device to its local authorised registrant for further device analysis by the manufacturer. Healthcare professionals are also strongly encouraged to report any AEs related to MoM system to the Vigilance and Compliance Branch at *Tel: +65 6866 3538*, *Fax: +65 6478 9069*, or report online at *http://www.hsa.gov.sg/ae_online*.

References

1 http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241604.htm

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3 http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2012/15835a-eng.php

4 https://aoanjrr.dmac.adelaide.edu.au/documents/10180/172286/Annual%20Report%202014

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6 https://www.nice.org.uk/guidance/ta304

7 http://www.hsa.gov.sg/DHCPL

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