Ontario
Health Quality Ontario
Qualité des services
de santé Ontario

OHTAC Recommendation: Metal-on-Metal Hip Resurfacing Arthroplasty

Ontario Health Technology Advisory Committee

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Background

An evidence-based analysis was conducted by Health Quality Ontario to answer the following research questions concerning metal-on-metal (MOM) hip resurfacing arthroplasty (HRA):

- Is the revision rate of MOM HRA using different implants lower than the benchmark set by the National Institute of Clinical Excellence (NICE)?
- What are the biological effects and consequent clinical significance of exposure to high levels of metal ions and metal debris?

Clinical Need

Total hip arthroplasty (THA) is one of the most commonly performed operations and has long been considered the treatment of choice for advanced osteoarthritis of the hip in older patients. This procedure has a high success rate and has consistently provided good outcomes in terms of joint function and the risk for revision in this patient population.

In younger people, MOM HRA has been advocated as an option for the treatment of degenerative hip disease. The primary goal of MOM HRA is to buy time until an age at which conventional THA would be suitable for the patient. Younger and more active people have higher expectations with respect to the use of their joints and it is perceived that MOM HRA results in a greater range of motion and would better suit the active lifestyle of younger people who place additional stress on their prostheses and for a longer period of time.

The aim of MOM HRA is to preserve the proximal femoral bone and to restore the normal anatomy and biomechanics of the joint. In this technique, a metal cap is placed on the femoral head to cover the damaged surface of the bone, and a metal cup is placed in the acetabulum. Surgeons who are in favour of the technique point to the advantages of conserving the femoral bone stock and the reduced risk of dislocation due to the large diameter of the components. However, MOM HRA is technically demanding and there is a learning curve associated with this procedure. Since retention of the proximal femoral bone limits operative access to the socket, it increases component placement errors and creates a weak spot that results in early or late failures.

The Technology

The current third generation of MOM HRA implants consists of a cemented femoral component and a press-fit acetabular component. The implants for MOM HRA are made of cobalt-chromium alloy, which can be a source of metal ions in patients receiving these implants.

Currently, the following MOM HRA implants are licensed in Canada:

- Birmingham Hip Resurfacing (Smith & Nephew Orthopaedics Ltd, Memphis, Tennessee)
- ConservePlus (Wright Medical Technology Inc, Arlington, Tennessee)
- Cormet (Corin Ltd, Cirencester, Gloucestershire)
- Durom (Zimmer Inc, Warsaw, Indiana)
- ReCap (Biomet Orthopedics, Warsaw, Indiana)

The Articular Surface Replacement implant (Depuy International Ltd, Leeds, Yorkshire) was originally issued a license by Health Canada, which was subsequently cancelled in November 2010 due to a high rate of revision for MOM HRA with this implant reported by the national registries.

Summary of OHTAC Findings

- There have been long-term follow-up studies for MOM HRA with 3 implants (Birmingham Hip Resurfacing, ConservePlus, and Cormet). The revision rates for MOM HRA with these implants appear to meet the NICE criteria for a revision rate of 10% or less at 10 years. Metal-on-metal HRA with the ReCap implant had excellent outcomes at a mean follow-up of 2.9 years. One randomized controlled trial with a mean follow-up of 4.7 years compared the revision rate for MOM HRA using the Durom implant and THA, and reported a higher revision rate for MOM HRA with the Durom implant than for THA, but the observed difference was not statistically significant. One implant (Articular Surface Replacement) failed to meet the NICE criteria.

- Several criteria must be met in order for MOM HRA to be successful. These include the careful selection of patients and surgeons having appropriate surgical skills and adequate training. There is a learning curve associated with MOM HRA and it has been shown that malpositioning of the acetabular component results in an increased rate of wear of the implant and failure of MOM HRA. In addition, a smaller component size has also been shown to be associated with increased metal wear and risk of failure.

- The ideal patients for MOM HRA are young male patients with end stage hip osteoarthritis, good bone quality, and proper anatomy around the affected joint.

- The potential complications of MOM HRA are high cobalt and chromium ion levels in the blood and urine of patients, and periprosthetic reactions to wear particles described in the literature as adverse reactions to metal debris. This term includes pseudotumors, aseptic lymphocytic vasculitis–associated lesions, and metal sensitivity. The precise biological pathway that leads to these reactions is still unknown. Risk factors for development of pseudotumors have been reported as: being a female, especially being a female aged less than 40 years, small component size, and hip dysplasia. The incidence of symptomatic pseudotumors in Canadian academic centres is reported as 0.1%.

- Normal renal functioning is required to excrete the excess metals produced by the MOM implant; therefore, MOM bearings are contraindicated in patients with abnormal renal function.

- Studies have shown an increase in chromosomal aberrations in patients with MOM articulations, but the clinical implications of this effect and their long-term consequences are still unknown. Epidemiological studies have shown that patients who underwent MOM HRA did not have an overall increase in mortality or risk of cancer.

- There is insufficient clinical data to confirm the teratogenicity of MOM implants in humans. However, since cobalt and chromium can pass the placental barrier, non-MOM bearing surfaces have been recommended for women at childbearing ages who require hip arthroplasty.

OHTAC Recommendations

In considering the findings from the literature search and from consultations with experts in the field, OHTAC made the following recommendations:

- Metal-on-metal HRA is a reasonable treatment option for osteoarthritis patients who meet the appropriate criteria.[1]

- Metal-on-metal HRA should only be performed by surgeons who have appropriate training and who have acquired a high level of experience by performing a high annual volume of THAs and MOM HRAs.[2]

- There is evidence of increased cobalt and chromium levels in the blood and urine of patients who receive MOM HRA; however, there is no conclusive evidence that exposure to high metal ion levels has harmful biological consequences. As such, OHTAC recommends that patients receiving these implants be informed of the potential for exposure to metal ions, and that the adverse effects and long-term implications of elevated metal ion exposure in patients who receive these implants are not known at this time.

- Since cobalt and chromium can pass the placental barrier, OHTAC recommends that non-MOM bearing surfaces be used in women of childbearing ages who require hip arthroplasty.

[1] Expert opinion informed us that the appropriate criteria for patient selection are: male patients under 60 years of age with osteoarthritis, good bone quality, no significant acetabular deformity, and a large diameter femoral head to accommodate a femoral component of 50 mm or larger. Selection of female patients for this procedure requires very careful consideration.

[2] Expert opinion informed us that the appropriate volume is considered to be performing at least 100 THAs and at least 20 HRAs per year.