Metal on Metal Vs Other Bearing Surfaces in Total Hip Replacement

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Introduction and review of evidence

Hip replacements are one of the most commonest orthopaedic procedures performed with over 50,000 performed annually (1). The earliest known hip replacement was done in 1891 using an ivory ball joint and nickel screws (2).

In a total hip replacement, the hip joint is replaced by an artificial prosthesis.

Osteoarthritis (OA) is the main indication for a hip replacement and this was the primary diagnosis in 94% of hip replacement operations in England during 2005 (2). Other indications include rheumatoid arthritis, avascular necrosis and hip fractures. Women outnumber men by a ratio of nearly 2:1 for the over 65 age group (3).

OA is the most common form of arthritis and is a syndrome characterised by joint pain and varying degrees of functional limitation and reduced quality of life (QoL) (9). Common peripheral sites affected are the knees, hips and hand (9). Structural changes to the joints may occur without any symptoms and may involve all joint tissues. Pathological changes that occur include loss of articular cartilage and osteophyte formation (new bone formation) at joint sites (9). The effects on society and at an individual level can be substantial. It costs the UK economy over 1% of its gross national product per year and 36 million lost working days amounting to over £3 billion loss (4).

The primary cause of OA is unknown. However, there are many secondary causes.

OA has numerous risk factors and these are split into three categories:

Genetic factors. This is thought to cause between 40-60% of hand, knee and hip OA (9).

Constitutional factors. This is ageing, female gender and obesity (9).

Biomechanical risk factors. This includes joint injury, occupation and reduced muscle strength (9).

Many of the risk factors can be reversible or avoidable and thus reduce the risk of OA developing.

Over 8 million people in the UK are affected by joint pain which may be attributed by OA (5). Most people over the age of 60 will have radiological evidence for it even though they may be asymptomatic (13).

X-rays can confirm the presence of changes which would aid in the diagnosis of OA. These would typically show loss of joint space, osteophytes, subchondral sclerosis, and subchondral cysts (6). Other investigations can include MRI and arthroscopy (13). The NICE guideline development group considered a working diagnosis if a patient had persistent joint pain that is worse with use, aged over 45 and morning stiffness lasting no more than half an hour (9).

All patients with OA should be assessed holistically. NICE recommends that before any pharmacological therapy is initiated, patients should be advised and educated on the physical measures that can be taken to prevent further OA. For obese patients, interventions that results in weight loss should be recommended (9).

Pharmacological intervention is aimed at reducing pain and patients should be offered paracetamol and/or topical NSAIDS. Patients could then be offered an oral NSAID with a proton pump inhibitor, COX-2 inhibitors or opioids. Intra-articular injections of corticosteroids have been found to be useful due to their anti-inflammatory effects (9).

Those patients who despite pharmacological intervention still experience symptoms that have a substantial effect on their QoL should be referred for joint replacement surgery (9).

OA of the hip has the worst outcome compared to the knees or hands as a significant number of people will need a hip replacement within 1 to 5 years. However some hips do heal spontaneously with improvements in radiographic appearances and symptoms (9).

Hip replacements can either be a total hip arthroplasty or a hemiarthroplasty.

Total hip arthroplasty involves replacement of the articular surfaces of the acetabulum and replacement of the femoral head and neck. During a resurfacing total hip arthroplasty, only the surface of the femoral head is replaced (11).

For a total hip arthroplasty indications include:

- Pain and disability due to degenerative osteoarthritis
or inflammatory arthritis where other non surgical methods have failed.

- Fracture of the proximal femur in particular the intra-capsular part of the neck (8).
- Young patients with osteoarthritis and good bone stock may be considered for a resurfacing total hip arthroplasty as this has the advantage of preserving the femoral neck for any future surgery when the patient outlives the prostheses (5).

A variety of prostheses are used and include metal, polyethylene and ceramic. Fixation methods include polymethylmethacrylate cement, screw fixation, cementless press fit and porous ingrowth fixation (9).

There are more than 60 prostheses available to the NHS with the costs varying greatly (5). Due to variation in prostheses design, they are classified into whether they are cemented, uncemented or hybrid (cemented stem with a cementless cup) (10). Approximately 90-95% of prostheses used in hip replacements are cemented (5). NICE recommends to use the best prostheses available which have a revision rate of 10% or less at 10 years (5).

Infection and loosening of the prostheses are the most serious common complications (11). However, the complication rate for hip replacements is around 1% (13). Furthermore, the 30 day mortality rate is about 0.5% (12).

Discussion

Metal on Metal (MoM) total hip resurfacing arthroplasty involves replacing the head of the femur with a metal surface and lining the acetabulum with a metal cup.

Tradition implants were made of metal and polyethylene (a plastic). The metals used include titanium, stainless steel and cobalt chrome. Implants are secured to the bone by either cementing them into place or press fitting them whereby new bone will form around the implant to secure it.

MoM implants use similar materials but have no polyethylene between the two metal implants. This type of implant does not wear as quickly as a traditional metal-plastic implant which wears at a rate of 0.1mm/year. MoM implants wear 10 times less at a rate of 0.01mm/year (13).

There are also newer ceramic on ceramic implants which are smoother and wear even less than the MoM implants. Although ceramic implants have been promising under laboratory conditions, there is a lack of long term evidence and concerns of the prostheses breaking. One study found that 28 out of 999 patients (2.7%) reported squeaking after their Ceramic hip replacement (14).

MoM implants have no polythene component and are therefore thought to be less likely to fail as they cannot be subject to loosening that conventional THRs undergo (due to polythene degradation).

Revision to a conventional THR in the case of failure of a MoM implant, is thought to be easier to perform as less femoral bone would have been removed in the original procedure. Furthermore outcomes are better when compared to a revision of a primary THR.

The United States FDA approved of the Pinnacle CoMplete Acetabular Hip System, the world’s first ceramic on metal hip replacement in 2011 which consists of a ceramic ball and metal socket (15). They based their approval on a two year RCT which found no difference between 194 patients who received the new ceramic on metal system and 196 in the in the MoM group. Only two patients required a revision in the ceramic on metal group compared to three in the MoM group.

The Pinnacle CoMplete Acetabular Hip System was manufactured by Depuy who also manufactured the ASR (articular surface replacement) MoM system which had to be recalled due to 13% of patients needing a revision within 5 years, more than twice the expected rate. This recall affected 93,000 people around the world who also had the implant.

The British Orthopaedic Association (BOA) in 2011 reported that large diameter MoM devices from other manufacturers showed similar results to the ASR XL MoM device (16). They found a higher than anticipated early failure rate. This ranged from a 21% revision rate at 4 years to 49% at 6 years for the ASR XL device. Similar devices had a revision or impending revision rate of 12-15 % at 5 years. Due to the high failure rates, the BOA recommended regular follow ups of patients with MoM prostheses for at least 5 years and probably for the life of the prostheses (18).

The Australian National Joint Replacement Registry (NJRR) noted large differences in the outcome of MoM prostheses. An acceptable rate of failure of hip prostheses is considered to be less than 1%/year. However the ASR prostheses revision rate was 6.5% at 3 years and 10.9% at 5 years when inserted as a resurfacing implant (17).

The NJRR found that in patients with a primary diagnosis of OA, 92% of MoM implants survived at seven years. RCTs comparing conventional THRs to MoM prostheses demonstrated favourable short term results. Furthermore survival estimates were 95.5% at 12 years.
MoM prostheses release a variety of metal ions into local tissue and general circulation of which chromium ions are the most widely reported. Increased levels of cobalt have been associated with neurological, cardiac and endocrine symptoms (18-20). Mao et al found that their patient's symptoms were related to their elevated cobalt levels, which declined significantly once their MoM prostheses were removed (21). One patient's cerebrospinal fluid (CSF) was found to contain both cobalt and chromium suggesting that they had crossed the blood brain barrier. Long term exposure to cobalt may also be associated with cancer (22). Concerns have also been raised of metal induced hypersensitivity reactions. One study analysing the tissue from 19 cases of failed MoM implants found infiltration of lymphocytes and plasma cells consistent with a hypersensitivity reaction (23). Joint effusions and tissue necrosis were also commonly seen (25).

One study comparing 107 MoM prostheses with 70 metal on polyethylene with an average follow up duration of 20 years observed a survival rate of 77% and 73% respectively with minimal osteolysis in the MoM group (24).

Another study with 105 MoM cases with a minimum follow up of 10 years found a 98.6% probability of survival with rare osteolysis and no ion related complications (25).

In 2010, the UK Medicines and Healthcare products Regulatory Agency issued a medical device alert on all MoM implants. They stated that a small number of patients had soft tissue reactions such as soft tissue necrosis due to wear debris associated with MoM prostheses. (26). To resolve the problem, an action plan was instigated for the follow up of patients at least annually for five years postoperatively. Patients with painful MoM implants are to have blood cobalt and chromium levels checked in addition to a MRI scan. Revision surgery was recommended if imaging revealed soft tissue reactions, fluid collections or tissue masses (28).

Conclusion

NICE recommends using the best prostheses that have a revision rate of less than 10% at 10 years (5). Furthermore the BOA recommends that the selection of prostheses for general use should be based on the evidence published from any National Joint Register (18). However the BOA says that prostheses with apparent good published results may have been modified subsequently by manufacturers and the prostheses used in the initial study trial may no longer be available. As some implants fail before 10 years and some after, patients should be followed up at year one, year five and every subsequent five years after surgery. This should include a history of any problems and both AP and lateral X-rays.

NICE recognises that the specific recommendations for the selection of a hip prostheses for a primary THR are difficult to construct due to a poor evidence base (5). Due to the lack of long term evidence for MoM prostheses, NICE recommends prostheses that have at least three years evidence (5).

MoM hip resurfacing arthroplasty has been recommended by NICE for people with advanced hip disease who are likely to outlive a traditional prostheses and who would have otherwise have had a traditional THR. Activity levels of patients should be taken into account when considering a hip resurfacing arthroplasty (5). Patients should also be advised about the long term safety and reliability of MoM hip resurfacing.

Due to increasing number of younger patients who require a hip replacement and increased patient expectations, there is a growing demand for a long lasting prostheses. The benefits of having a MoM prosthesis must be weighed against the disadvantages of hypersensitivity reactions, metal toxicity and failure rates. Newer bearings, although they may have a lower rate of wear, lack long term evidence to support them.

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