

Medico-legal reporting on hip resurfacing operations

Metal-on-metal (MoM) hip resurfacing was developed in the 1990s by surgeons in Birmingham, UK, as a surgical solution to the problem of osteoarthritis in younger, more active patients. Early results were promising and the procedure gained in popularity. However, adverse reports of soft-tissue reaction and failure started to appear from 2008 onwards. Surgeons may be asked to write medico-legal reports on the surgical aspects of an individual case for claimant lawyers or in defence for the NHSLA or indemnity insurers. The purpose of this article is to cover some of the aspects of the operation that may be considered in such medico-legal reports.

Our knowledge of failure mechanisms and contributory factors has improved during the last five years and so it is important that the report should consider knowledge available and accepted at the time of clinical interventions. Some of the important milestones may be of useful reference.^{1,2}

Traditional hip replacement in the young patient group has been associated with a higher failure rate compared with a more elderly population. The resurfacing operation offered the advantage of less femoral bone being removed at the primary operation and it was perceived that the MoM articulation would allow a greater activity level, with less wear, than with a more conventional bearing. Building on the success of the hip resurfacing, large bearing, MoM total hip replacement also became popular during the second half of the last decade. The reporting surgeon may wish to review the indications for the operation in each case to assess whether it was

appropriate to recommend a resurfacing rather than a conventional replacement.

Public, surgeon, industry and press enthusiasm fuelled its popularity and by 2006 resurfacing accounted for approximately 10% of the hip replacement procedures in the UK. In 2007 the Australian Joint Replacement Registry,³ and in 2008 the NJR for England and Wales,⁴ reported increased failure rates in female patients and in those over 65 years of age. It was presumed that these failures were mainly due to femoral neck fracture but other causes came to light.

In 2008 the Oxford group reported their experience of soft-tissue reaction seen in response to metal wear debris from hip resurfacing operations.⁵ The Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK received increasing reports of failure of MoM hips and issued an alert to surgeons in April 2010.⁶ Subsequent information from the NJR identified the ASR system (DePuy, Warsaw, Indiana, USA) as having a higher failure rate leading to a further

MHRA notice in May 2010.⁷ DePuy subsequently withdrew the ASR device from the market in August 2010 and offered a voluntary recall of this device. The MHRA has further recommended recall of all patients with hip resurfacing or total hip replacement with a MoM articulation.

Causes of failure include general risks of infection, loosening and dislocation, although the latter is generally considered to have a lower incidence in resurfacing compared with conventional replacement. Avascular necrosis of the femoral head was hotly debated on the introduction of MoM resurfacing. Experimental work suggested that the anterolateral surgical approach may reduce the risk of this compared with the posterior approach but surgeons have used a variety of approaches to the hip for resurfacing with no proven clinical adverse effect or benefit on the outcome of the resurfacing.

Risks specific to MoM resurfacing include femoral neck fracture which was recognised early on in the hip resurfacing experience.

Notching of the superior femoral neck and severe varus alignment of the femoral component are recognised as contributory technical factors. Severe osteoporosis was deemed to be a contraindication to the operation for this reason.

However, the main problem which led to the professional, regulatory and public concern was excessive wear of the components causing adverse reaction to metal debris (ARMD) locally in the soft tissues and bone of the hip, and a rise in blood cobalt and chromium ion levels. Some causes of this are likely to be implant related. The ASR had a shallower acetabular articular surface than other more successful designs which may have made it more prone to edge loading and wear. These are product liability issues and generally will be beyond the remit of an orthopaedic/hip surgeon and more in the field of bioengineers or orthopaedic researchers.

Implant position is within the remit of the surgeon, and review of the radiographs before and after surgery are important. The standard BHR (Smith & Nephew, London, UK) operative technique manual suggested that the acetabular component should be implanted in 45° of inclination and 20° of anteversion. However, appreciation of the effect of cup position on edge loading led to a refinement of this and this changed in 2005 to 15° to 20° of anteversion and 40° to 45° of inclination. In 2006 another manufacturer, Finsbury Orthopaedics Limited (Leatherhead, UK), recommended that the surgeon aim operatively for 30° to 35° inclination and 20° to 25° anteversion. There is now a known relationship between the angle of insertion and wear/metal ion blood levels, and both inclination and anteversion are important. There seems to be consensus

that inclination above 55° is associated with increased wear but what would be deemed an unacceptable implantation is difficult to define fully as inevitably there is a degree of normal surgical error which is reflected in most reported series. Allowing for intra-operative error of judgement, above 65° may be difficult to defend but the circumstances of an individual case such as high BMI, pelvic deformity, etc would need to be taken into consideration.

In addition to the well documented problems of ARMD, comment may need to be made on the biological effects of raised serum cobalt and chromium ion levels. Increased risk of cancer was cited as a possibility based on experimental laboratory work but NJR data have failed to show any increased risk to date. However, the registry is only ten years old and carcinogenic effects may take longer to become apparent. General toxic effects (thyroid, neurological, cardiac, etc) of cobalt and chromium ions are well documented in metal workers.² Causation may be difficult to prove and if there is concern about an individual case a report from an appropriate medical discipline should be considered.

The reported outcome after revision surgery for failed resurfacing when pseudotumour is present is worse than for standard revision hip replacement.⁸ The outcome of revision may be time dependent, with more extensive soft-tissue destruction after delayed diagnosis leading to a poorer outcome.

Providing a medico-legal report in such cases brings a number of surgical and product design aspects together for consideration. Cases in which the surgeon has performed the operation for the correct indications, in a technically

competent way and with appropriate follow-up will be relatively straightforward to defend from a surgical perspective. If these conditions have not been met, and the patient has suffered harm/revision, it may be much more difficult as the liability and causation may need to be jointly attributed to the surgeon and the product.

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