Metal on metal implants: where are we now and what should happen next?

Hip replacement has transformed the lives of countless patients but there have been repeated episodes of unacceptable rates of failure from changes to implant design. This editorial examines the most recent of these and suggests methods of minimizing this in the future.

History of metal on metal hip replacement

Cobalt chrome metal hip implants were first used in the 1930s and were the bearing surface of all total hip replacement throughout the 1950s. The cemented metal on metal McKee-Farrar from Norwich was the first reliable hip replacement in the early 1960s when Charnley was developing the metal on high density polyethylene bearing that has been the most widely used since. With metal on polyethylene bearings, patients over 62 years of age are more likely to die with their original prosthesis in place than undergo revision but the converse occurs in male patients under 50 years (Wainwright et al, 2011). This young population poses the major unsolved problem in hip replacement.

Complications of metal on metal hip replacement

The metal on metal McKee-Farrar (August et al, 1986) survived as well as the metal on polyethylene Charnley for 13 years but there were case reports (Jones et al, 1975) of widespread periarticular tissue necrosis associated with both a lymphocytic and histiocytic response.

Modern metal on metal hip resurfacing

In the late 1980s, McMinn (2009) noted the negligible wear of a series of uncemented metal on metal ring prostheses in the follow-up clinics of the Royal Orthopaedic Hospital, Birmingham. In contrast to metal on polyethylene hips, there was no wear or destruction of bone around the joint. McMinn then adopted the high carbide cobalt chrome metal on metal Ring bearing surface as a resurfacing to avoid the wear that young patients generated in metal on polyethylene bearings and to spare their femora for revision should the resurfacing fail.

The introduction of this was even more rigorous than Charnley. The implant was only supplied to selected surgeons who had been personally trained by the inventor. Clinical fellows were sent to assist with surgeons' early cases. A register was set up in an independent university department which ensured that follow up was carried out and reported. The Birmingham hip resurfacing is technically demanding. The femoral neck fractures in 1–2% during a learning curve of 30 cases, but in the hands not only of the inventor but also in a number of imitating units (Holland et al, 2012) survivorship after 10 years in the young male population was significantly better than with metal on polyethylene bearings. A further advantage was that the large bearing rarely dislocated.

Further developments

Three problems emerged. The device was marketed as being suitable for patients wishing to continue sporting activity and acquired designer status for patients aspiring to active lifestyles, extending the indications for the procedure. This resulted in the implantation of the prosthesis into women in their late 50s. Many implant companies extended their portfolio of prostheses to include metal on metal implants of different design and material to the Birmingham hip resurfacing and surgeons fearful of dislocation used the large diameter bearing as a total hip replacement with the aim of avoiding neck fracture, enhancing stability and reducing wear (Bolland et al, 2011).

It became apparent that metal on metal bearings wore excessively in the smaller sizes implanted in females. The new designs did not have the clinical history of the bearing surface of the Birmingham hip resurfacing and the performance of all of them was inferior, some with failure rates four times greater. The Anatomic Surface Replacement was withdrawn and the manufacturer is funding revision surgery resulting from failures of the device and facing class action litigation. A fresh problem emerged from the metal on metal hip replacements as the fixation of the modular heads to the morse taper on the stem was inadequate, creating wear, metal debris and periarticular tissue destruction.

Medical device alert

A medical device alert was issued by the Medicine and Healthcare Products Regulatory Agency on 28 February 2012 recommending annual review of all metal on metal implants for 5 years and that symptomatic patients and those at risk from suspect implants be investigated.

This has created huge anxiety in patients who were promised a well-functioning implant with enhanced longevity, even in those with well-functioning hips. A small proportion will have to undergo revision, the results of which are inferior to primary hip arthroplasty and significantly so if there is extensive necrosis of muscle and bone around the joint.

Where are we now?

Metal on metal hip resurfacing in patients under 55 years of age using the Birmingham hip resurfacing has been more successful than metal on plastic joints in a number of independent units and there is a continuing indication for metal on metal implants especially in males of this age.

What should happen next?

The question arises as to how to minimize such tragedies in the future as, under existing arrangements, they have happened before in hip replacement and will do so again if there is no change in the regula-

tion of new implants. A stepwise introduction of new implants was proposed over a decade ago but has not been adopted (Malchau, 2000).

Companies manufacturing prostheses do so to return profit and inevitably explore avenues to enhance this. This includes their having a complete range of prostheses to offer to the surgeons who purchase them. Most of these prostheses are modified versions of well-tried implants, have no clinical record and are usually worse than the prostheses they imitate. Apparently minor changes to the surface finish or shape of a hip replacement can turn an excellent implant into a hazard.

Lessons from the past

The original polished stainless steel Charnley stem was broadened to prevent fracture and when a low cost version manufactured in softer titanium with a rough surface finish (3M Capital) was released in the early 1990s, the revision rate was as high as 28% within 2 years when the original device was 1% per annum.

Regulation of new devices

The regulation of devices in both North America and Europe allows marketing of new prostheses if they are 'substantially equivalent' to existing ones. New hip implants can gain access to the European Union market on the basis of a literature review rather than clinical data. The United States Food and Drug Administration is more demanding than Europe but still allowed the Anatomic Surface Replacement onto the market and almost three quarters of their withdrawn devices are admitted under the 'substantial equivalence' route. Compliance with current regulations does not prevent untried hip prostheses from gaining access to the market and fails to protect the public from the potential hazards associated with some of them.

The future

A fresh approach beyond compliance with current regulations is required and is being explored. New implants should not be introduced to widen the portfolios of prosthesis manufacturers but only if they address a clinical need not met by existing devices. They should be implanted in a limited number of patients, followed annually for 5 years and then be released only if they are better than the existing standard treatment. This is likely to limit the breadth of the implant portfolios offered by industry and increase the cost of development but should better protect the patients for whom they are designed. BJHM

KEY POINTS

- Metal on metal hip replacements have been used successfully for over 50 years.
- Metal on metal wear particles can cause extensive tissue necrosis.
- Metal on metal resurfacings differ greatly in their outcomes.
- One metal on metal resurfacing gives excellent results in young males.
- Metal on metal hip replacements wear at the junction of the head and stem.
- The most severe failures have come from implants imitating the original.
- Regulations for introducing untried implants should be strengthened.

Gordon Bannister
Professor of Orthopaedic Surgery
University of Bristol
Consultant Orthopaedic Surgeon
North Bristol NHS Trust
Avon Orthopaedic Centre
Southmead Hospital
Bristol BS10 5NB
(gordon-bannister@tiscali.co.uk)

August AC, Aldam CH, Pynsent PB (1986) The McKee-Farrar hip arthroplasty. A long-term study. *J Bone Joint Surg Br* **68**(4): 520–7

Bolland BJ, Culliford DJ, Langton DJ, Millington JP, Arden NK, Latham JM (2011) High failure rates with a large-diameter hybrid metal-on-metal total hip replacement: clinical, radiological and retrieval analysis. *J Bone Joint Surg Br* **93**(5): 608–15

Holland JP, Langton DJ, Hashmi M (2012) Ten-year clinical, radiological and metal ion analysis of the Birmingham Hip Resurfacing: from a single, non-designer surgeon. *J Bone Joint Surg Br* **94**(4): 471–6

Jones DA, Lucas HK, O'Driscoll M, Price CH, Wibberley B (1975) Cobalt toxicity after McKee hip arthroplasty. *J Bone Joint Surg Br* **57**(3): 289–96

McMinn DJW, ed (2009) *Modern Hip Resurfacing.* Springer-Verlag, London: 1–41

Malchau H (2000) Introducing new technology: a stepwise algorithm. *Spine (Phila Pa 1976)* **25**(3): 285

Wainwright C, Theis JC, Garneti N, Melloh M (2011) Age at hip or knee joint replacement surgery predicts likelihood of revision surgery. *J Bone Joint Surg Br* **93**(10): 1411–15