

When technology fails patients

Nanoparticles as a result of medical device failure



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Context

In 2010, two hip prosthesis designs, called ASR™, were taken off the market after having been implanted into nearly 100,000 patients. The reason: increased failure rates related to a range of adverse reactions to metal debris (Langton et al. 2010) which are likely to be the cause of widespread health problems.



Patients are asked to trust medical and clinical sciences. Imagine the disappointment, fear and impact when medical interventions go wrong, leaving greater (including social) damage than they were intended to address in the first place.

1. Engineering Background

The replacement of diseased hip joints with artificial hips is *the* outstanding success in orthopaedics in the 20th century (Skinner & Kay 2011). Millions of these replacements have been implanted world-wide, delivering in most cases pain-relief and mobility to patients. Artificial hip joints replace the body's own worn and diseased hip joint.

Metal-on-metal joints

Metal-on-metal hip replacements had, until very recently, been seen to offer improved mobility and longer *in vivo* lifetime especially for younger people in their 30s to 50s.

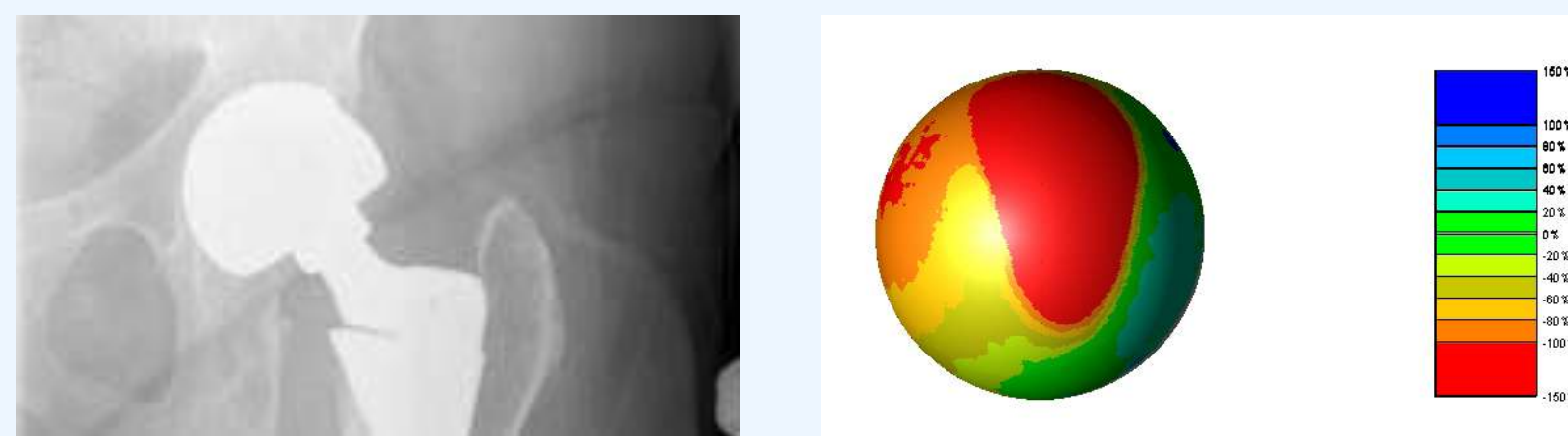


However, a number of these metal-on-metal designs have failed earlier and in more patients than expected. In the ASR™ case, the wear of the prosthesis tends to be faster and more encompassing than anticipated.

This has led to the release of large amounts of Cobalt and Chromium nanoparticles into patients' bodies.

2. Nanoparticles from devices

Both Chromium (Cr) and Cobalt (Co) nanoparticles are extremely reactive; they can cause damage to the DNA repair mechanism. (Hartwig et al. 2003). Their release is caused by greater wear of the articulating surfaces.



Femoral neck fractures, pseudotumors, lesions and metallosis are symptoms of the heightened release of these nanoparticles into human tissue and blood.

Whilst many physicians tend to wait until symptoms become apparent, increased Cr/Co levels in blood and serum are strong indicators for adverse effects even when the patient remains otherwise asymptomatic (no pain, mobile) for many years (Langton et al. 2009).

Despite clinical assumptions that after the removal of worn hip replacements the level of Cr and Co ions in the tissue and blood will decrease, widespread uncertainty about the long-term impacts of nanoparticles on the human body exists, but also real anxiety about illness, disability and livelihood.

3. Rationale of this project

Patients are concerned and confused about the impact and effect of the nanoparticles in their bodies. The lack of a unified approach to responding to increased levels of ions, as well as the use of three (!) units of measurements, aggravate the situation.

Over the last three decades, trust in science has eroded: BSE, GMO, grey goo and climate change debates show that whilst citizens are required to become more science-savvy, science, industry and policy seem to ignore or overlook the concerns of the publics. The case of ASR™ shows the potential danger of a similar trajectory developing in medicine.

A range of governance and practice questions are raised by the ASR™ case, and voiced by patients: in how far are medical devices clinically tested before their introduction to the market – specifically their life cycle? Why has the regulation of medical devices not prevented this failure? And what is the role of the surgeon's knowledge and limits of obligation?

4. Project Objectives

The New England Journal of Medicine has branded the ASR™ recall a “public health nightmare”. However, the needs and concerns of patients and their families are often not heard, or taken into account.

Taking a patient-centred approach, we will document and report their experiences, expectations and concerns in order to expand the discourse. We seek to open up underlying narratives that accompany the failure of medical devices, and the uncertainty of patients and practitioners about understanding, and dealing with, nanoparticles in the human body.

Our goals are:

- Record and document patients' experiences with failed hip replacements and *in vivo* nanoparticle release
- Support patients in the North-East of England in developing links with other stakeholders in the UK, Europe and the world
- Bring together engineers, Third Sector and Industry representatives with patients to discuss the 'lessons learned' from ASR™



5. Methods & Outcomes

Co-enquiry principles (Reason 2002) will inform this patient-centred project, supported by a range of public dialogue opportunities:

- Website and Twitter
- Public talks and Q&A events
- A dedicated regional patient-centred workshop

Outcomes will be available publicly on the website as film clips, DVDs, and mini posters.

Funding

This project is funded through an EPSRC Impact Award to further the research undertaken at Newcastle University by Dr Thomas Joyce.

Reading: Barry (2001) *Athlone Press*; Curfman (2011) *N Engl J Med* **365**;11; Hartwig et al (2003) *Toxicology* **193**(1-2); Irwin (2001) *Pub Underst Sci* **10**(1); Langton et al (2010) *J Bone Joint Surg (Br)* **92-B**; Reason (2002) *Syst Pract Act Res* **15**(3); Skinner & Kay (2011) *BMJ* **342**; The Royal College of Surgeons (2001).