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Identifying failing implants

Over 100,000 hip replacements are performed annually in the NHS. Implants can fail, particularly in younger patients, and 8,000 need to be revised annually. Design innovations, such as hip resurfacing and stemmed metal-on-metal hip replacements, were introduced to improve longevity. These were quickly and widely adopted based on laboratory simulations, without long-term safety data.

What translational research was done?

Between 2003-2011, 31,000 stemmed metal-on-metal hip replacements and 32,000 metal-on-metal hip resurfacings were recorded in the National Joint Registry. Before 2012, more than 1 million of these prostheses were implanted worldwide.

We identified that evaluating innovations in orthopaedic surgery to ensure patient safety requires both patient population data to evaluate real-world results, and laboratory-based approaches to study the effects of wear debris from metal implants. We found that cobalt and chrome nanoparticles directly damaged DNA of human cells and caused indirect damage by signalling across barriers such as the placenta[1].

We were awarded the contract to analyse the National Joint Registry for England and Wales, the world's largest joint replacement registry. We established a research programme to **analyse over 400,000 hip replacements**.

This revealed catastrophically high failure rates in stemmed metal-on-metal hip replacements and in hip resurfacing in women, and that these were responsible for more than **8,000 excess revision** procedures, **costing over £100 million**[2,3].

This equates to more than **110,000 avoidable revisions worldwide**.

Translation into later phase research, clinical practice and patient benefit

Our research revolutionised clinical practice, **virtually ending the use of these implants in the UK** (13,630 in 2008 vs 466 in 2018) and worldwide (Australia 3,699 in 2008 vs 0 in 2018; Canada 1,207 in 2010 vs 0 in 2018).

The MHRA issued a Medical Device Alert, reinforced by the British Orthopaedic Association and British Hip Society, recommending against their use other than in exceptional circumstances and with targeted monitoring. The US Food and Drugs Administration now approves no stemmed metal-on-metal hip replacements and only two resurfacing systems.

The National Joint Registry was cited as a **"global exemplar"** of medical device registries by the Under Secretary of State for Health and Social Care in her report to Parliament (2020). Our work was **cited in a European Union Policy Report** and since September 2021, the European regulations on implantable medical devices has changed.

References

1. Parry et al., Biomaterials, 2010;DOI:10.1016/j.biomaterials.2010.02.038
2. Smith et al., Lancet, 2012;DOI:10.1016/S0140-6736(12)60353-5
3. Smith et al. Lancet , 2012;DOI:10.1016/S0140-6736(12)60989-1