

# EVIDENCE IN ACTION

2007-2017: A decade of independent collaborative research in partnership with University College London and the Royal National Orthopaedic Hospital

# LIRC

London Implant Retrieval Centre



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# LIRC

London Implant Retrieval Centre

[www.lirc.co.uk](http://www.lirc.co.uk)

## We've shown the world the value of analysing the failed medical device

The effects of metal-on-metal (MOM) hip failure have impacted more than a million patients worldwide during the past decade, with widespread repercussions for the healthcare profession and implant manufacturing industry. Throughout this time, by analysing failed implants, London Implant Retrieval Centre (LIRC) has been gathering key evidence for the precise causes of failure.

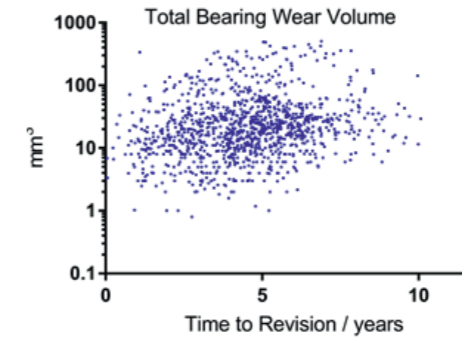
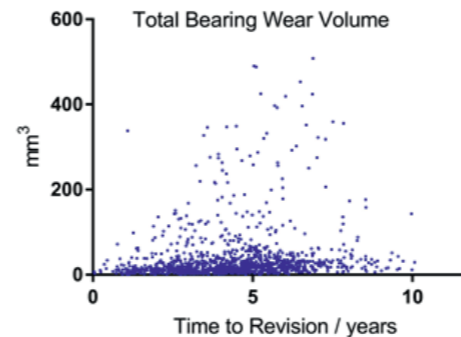
We began in 2007 when surgeons sent us failed implants to analyse. LIRC was the first global retrieval programme for failed hips and remains the world's leading source of analysis of failed orthopaedic implants. Our research has led to changes in understanding, practice and regulation of all metal-on-metal hip devices in the United States, United Kingdom and other countries worldwide.

Since 2012 LIRC has been the independent global retrieval centre for the analysis of the recalled DePuy (Johnson and Johnson) ASR hip, as part of an Anglo-American collaboration with John Vernon Luck, Sr., Orthopaedic Research Centre in Los Angeles, California. Since 2014 we have also been the

global retrieval centre for Stryker Corporation's Rejuvenate and ABG II implants.

This booklet explores our work during the past decade and the value of our evidence for patients, surgeons and manufacturers, as the MOM hip crisis continues to unfold.

### Data from the five-year Anglo-American worldwide ASR retrieval program



**Harry Hothi**

LEAD ENGINEER, LIRC

In the past ten years we've...

Collected **8,000** components

Published **130** PubMed journal papers

Been endorsed through major awards and prizes, and

**£5 MILLION** in funding

Shown at exhibitions attended by more than **350,000** medical professionals, and... **50,000** members of the public

### The London Implant Retrieval Centre is...

Enabling safer patient care

The world's leading source of analysis of failed orthopaedic implants

A partnership between surgeons, engineers, imaging scientists and healthcare professionals

Equipped with state-of-the-art measurement facilities

Based at the largest orthopaedic hospital in the UK

A dissemination force of more than 200 collaborators and 500 implant contributors from 27 countries

A source of insight for leading hospitals around the world

### Our impact is seen in...

**A BETTER QUALITY OF LIFE** for patients among the 1.5 million around the world with metal-on-metal hip replacements, with similar quality of life benefits expected for all hip, spine and knee implants.

**NEW TECHNIQUES** for managing patients hip replacements, such as levels of blood metal ions, the award winning MARS MRI protocol, and informing surgeons how to surgically correct the failed implant.

High-quality **EVIDENCE** that has helped manufacturers while supporting patient claims.

**GUIDANCE** for surgeons worldwide on which implants perform best.

**EDUCATIONAL RESOURCES** for surgeons in training, experienced hip surgeons, and patients wanting to know more about their implants.

## Evidence for safer design

Like a black-box flight recorder, a failed implant holds data that can reveal causes of failure – and how to prevent them. Our job is to unlock this data and make it useful. We work closely with patients to conduct forensic investigations into the failed implants, comparing our findings with those for well-functioning implants.

Through our reports, journal articles, public information resources and direct face-to-face advice, we help patients, hospitals, health improvement bodies and all other stakeholders to benefit from safer, better-informed and more innovative orthopaedic care.

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## A model for research impact

London Implant Retrieval Centre grew out of a simple research goal: to collect failed hip implants and investigate the causes of failure, so lessons can be learnt for future patients.

In practice this involves unraveling the complex relationship between surgical, implant and patient (S.I.P.) factors. In tackling this challenge, LIRC has pioneered a new, collaborative, interdisciplinary model for orthopaedic research funded through a consortium of orthopaedic manufacturers.

**"It is hoped that the London Implant Retrieval Centre... will serve as a model for the future."**

**Joshua Jacobs**

PREVIOUS PRESIDENT (2013) OF THE AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS

### How do we stay independent from our funders?

The money that pays for LIRC is provided strictly on terms that give us full freedom to investigate anything we choose, and to publish our findings. We've maintained this freedom from the start, when nine different manufacturers agreed to provide funds for us to set up. Like any independent laboratory, we have clear guidelines for impartiality, and if there's a potential conflict of interest we put special measures in place. For example, when looking at disputed cases we may conduct 'blind' tests and send our findings to all relevant parties.

## Advising

On the strength of the evidence we've gathered since 2007, we're able to provide expert opinion on key questions about hip and knee implants.

How can we make implants function as long as possible? What's the best way to position them in the body? Which designs perform best? And what activities should patients do and avoid? Our opinions benefit patients, implant manufacturers and legal bodies. By remaining independent and impartial we can support all parties in resolving failed implant issues.



## Reporting

We provide reports on failed hip replacements that help surgeons, patients, lawyers, manufacturers and healthcare regulators understand why the failure occurred.

By analysing the retrieved implant we provide evidence attributing failure to the relevant S.I.P. factors. We use state-of-the-art measurement machines that follow international standards. All of our methods are published in peer reviewed, international medical and engineering journals. We follow rigorous reporting principles that include validation via other laboratories, presentation to specialists and public critique.



## Research

Research drives us and our approach is practical, drawing upon world-class surgical and engineering expertise.

LIRC is based on a university hospital campus that is globally recognized as a leader in orthopaedics and implant research. We have published 130 PubMed journal papers, with one per month for the past 50 months, working with 150 co-authors. These have been cited by other researchers more than 1000 times.



# The impact of our research

The evidence we've gathered has directly affected UK and US health policy and led to changes in clinical practice, implant design, procedures for monitoring, management and safety, and approaches to care for 1.5 million MOM hip patients worldwide.

"Should I remove the well fixed, well-positioned and non-infected stem?"

Mr James Donaldson, Consultant Orthopaedic Surgeon, RNOH

"The evidence says yes in this instance because the Cro/Cr ratio is high and the stem could be corroded"

LIRC analysis of Zimmer CPT hip implants

## DIRECT IMPACTS: Practical guidance for surgeons...

Our evidence enables surgeons to make accurate, informed decisions in their daily work.

"Which stem design is best for minimising taper problems?"

Dr Antti Eskelinen, Consultant Orthopaedic Surgeon, Deputy Chief (Orthopaedics) and Head of Research at Coxa Hospital for Joint Replacement

"The evidence says longer, smoother trunnions are best"

LIRC comparison of DePuy S-ROM and Corail Stems for MOM pinnacle hip implants

"Does my patient have a component size mismatch?"

Mr Matthew Burwell, Consultant Orthopaedic Surgeon, Royal United Hospital, Bath

"The evidence says yes because the centres of rotation of the cup and head are not aligned on their 3D CT model"

LIRC analysis of all types of MOM hip implants

"Do I need to prepare time, equipment and patient consent for removal of this well-fixed, well-positioned, non-infected stem?"

Mr Richard Carrington, Consultant Orthopaedic Surgeon, RNOH

"The evidence says yes because this hip has a Ti stem/head junction and it is likely that the head will be inseparable"

LIRC analysis of Biomet Taperloc/Magnum hip implants

## INDIRECT IMPACTS: Wider benefits of our work

### A clear threshold for metal ions in the blood...

Our research identified a level of seven parts per billion as an important cut-off in the blood levels of metal ions between poor and well-functioning hips.

#### IMPACT:

This level has become a standard for clinical guidance globally. It was adopted by the MHRA (Medicines and Healthcare Products Regulatory Agency) in 2010 and NICE (the National Institute for Health and Care Excellence) in 2014, ruling out the use of most types of MOM implant in the UK. Meanwhile international health regulatory agencies and professional bodies have used the research to create their own recommendations.

### Simple and effective testing...

We've shown how MRI (Magnetic Resource Imaging) scans can be used to evaluate inflammation and muscle damage, by looking at the 'shadow' a metal implant causes in the tissue around it.

#### IMPACT:

Our findings have shaped a new testing procedure, set out in the award-winning MARS (Metal Artifact Reduction Sequence) MRI protocol, which has become routine in NHS hospitals. Use of this test has cut the number of unnecessary implant repair operations, while reducing the burden of care by getting patients back in action more quickly. The economic impact is far-reaching.

### Validating National Joint Registry (NJR) records...

The NJR has collected data on more than 1.8 million operations. We cross-checked this database with ours, to see if the NJR had accurately recorded the failed cases represented by our collected retrieved implants.

#### IMPACT:

Our audit revealed that only 40% of the cases for which we hold failed implants were actually being classed as failures in NJR annual reports. We also showed that NJR data quality has improved substantially over time: increasing by 50% between 5 and 10 years following the start of the NJR. The linkage of LIRC and NJR databases means that the NJR is the only joint replacement registry in the world to offer this kind of, "reference standard / indisputable" validation: the failed component with markings is the ultimate proof that an implant has been implanted and then removed.

The National Joint Registry is one of several major organisations that uses LIRC evidence to validate the accuracy of its data.

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## Standing by our evidence

We have published more than 130 PubMed journal papers. These publications have been scrutinized by professional bodies, experts and other stakeholders across a range of fields, subjecting our approach to a rigorous evaluation according to scientific principles of repeatability and reliability.

The MHRA (Medicines and Healthcare Products Regulatory Agency), the FDA (American Food and Drug Administration) National Joint Registry, ASTM (American Standards for Testing and Materials) and a range of other bodies use our findings as a means of validation, for cross-checking and corroborating their own data.

We assure the quality of our evidence in a variety of ways, including:

- working with a broad spectrum of industry partners
- consulting with our network of surgeons and engineers
- inter-laboratory collaboration
- in-house reliability and repeatability testing
- publication in peer review journals

We demonstrate the quality of our evidence through:

- measurement of inter and intra-observer errors
- intra-laboratory comparison
- papers from other labs showing similar results and conclusions



## Equipped for research

We have dedicated laboratories and offices, and full onsite provision for secure and tracked implant storage. Our lab space houses state-of-the-art measurement machines to quantify surface damage in all orthopaedic implants, such as the bearing and taper surfaces of hip replacements and the polyethylene components used in knee implants.

## Evidence worth sharing

We make an impact by raising awareness about causes, effects and wider issues associated with joint replacement. Our work is shared through a range of educational resources offered by charitable and regulatory organisations. We're been widely covered in the media, with features on BBC online and articles in the Daily Telegraph, Daily Mail and Guardian.

## The engineering dimension...

We work with engineers across a range of disciplines at University College London (UCL) — including Chemical and Mechanical Engineering, Medical Physics, Aspire Rehabilitation and Medical Image Computing.

We also collaborate with university engineering departments at Leeds, Huddersfield, Queen Mary and Hamburg, and Baylor College of Medicine, Texas.



## Understanding the ASR story

In 2011 DePuy launched a competition to find an independent body that could investigate causes of failure of its widely used ASR and ASR XL MOM hips. LIRC won the international award, launching a five-year, £5 million project to collect and analyse the implants, in collaboration with John Vernon Luck, Sr., Orthopaedic Research Centre in Los Angeles, California.

### A global challenge

90,000 ASR and ASR XLs metal-on-metal hips have been fitted to patients worldwide, but by 2010 the manufacturer DePuy decided to recall them, prompted by failure rates of up to 13% at five years after implantation. Failure can mean permanent injury and difficult corrective surgery. There was a clear need for patients, surgeons and manufacturers worldwide to understand the causes of failure.

### A strong body of evidence

Our analysis shows there are multiple causes of failure, with a wide spread of data for all parameters, including wear of the bearings, corrosion of the stems, and level of bone attachment to the cups. Other key findings are that high wear is not the only factor in early revision, and low metal ions are not necessarily an indicator of good hip functioning.

## An Anglo-American collaboration

LIRC was engaged to conduct an independent, objective analysis of failed ASR and ASR XL hips in all countries outside the USA, in parallel with John Vernon Luck, Sr., Orthopaedic Research Centre in Los Angeles, California, which was the centre for American cases. We used our network of hospitals across 29 countries to collect implants. Each was then decontaminated, anonymised and securely housed in our dedicated tracked storage facilities. Our analysis included bearing-wear measurement, detailed surface examination, ALVAL (aseptic lymphocytic vasculitis-associated lesions) to determine the severity of soft tissue changes, and taper corrosion grading.

## Far-reaching impacts

Our evidence influences clinical practices for better patient safety. The ASR project also showed what's possible: this was the largest study of recalled implants ever conducted. Given the sensitivity of each case, it was unclear at the outset whether a sufficient sample could be collected. Yet after five years we succeeded in collecting 1800 implants from 100 surgeons in 29 countries. As such the project proves the viability of this research model on a large scale.

## INTERNATIONAL COLLABORATORS



### Coxa Hospital for Joint Replacement

Tampere, Finland

The largest hospital in the Nordic countries to specialise exclusively in joint replacement operations, with services provided by more than 180 leading experts.



### HELIOS ENDO-Klinik

Hamburg-Berlin, Germany

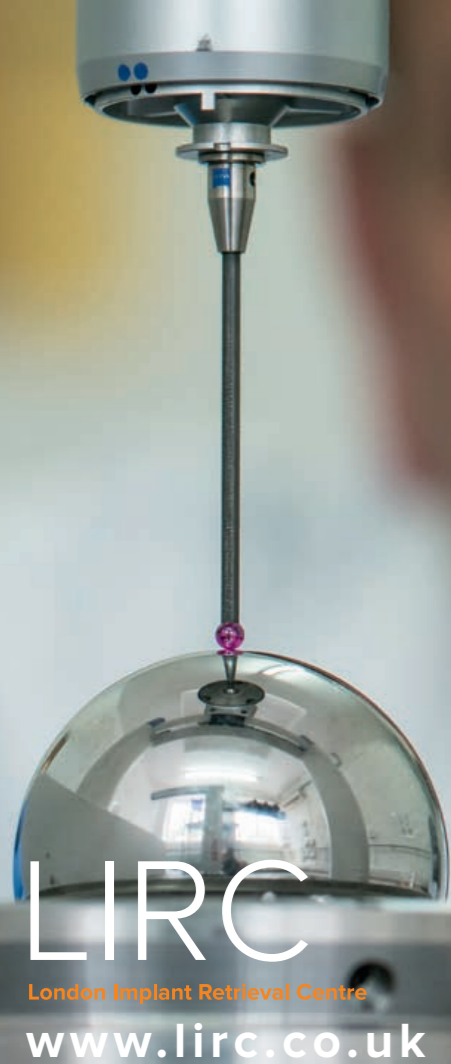
The largest hospital in Europe for the treatment of infected cases in orthopaedics, with more than 7,000 orthopaedic procedures performed annually.

### Kantonsspital Baselland

### Kantonsspital Baselland-Bruderholz

Basel, Switzerland

A leading establishment, providing medical care for around a quarter of a million people, while actively engaged in education, training, and pioneering new forms of medical care.



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## An expanding world

Our goal is to maximize the number of successful, high-performing implants for every patient — from every manufacturer. In this respect our work is precompetitive, expanding the market size for all, rather than market share for some. We work with a consortium of manufacturers, along with regulators and other key stakeholders.

### Beyond compliance

We work with Beyond Compliance to help enable safer innovation, supporting the development of new joint replacement technologies while at the same time protecting patients.

### MHRA

(Medicines and Healthcare Products Regulatory Agency).

The MHRA uses our findings as a means of validation, for cross-checking and corroborating their own data.

We do this against a backdrop of rising expectations about what technology can do when human joints fail. Patients want implants that last forever and enable active lifestyles, yet it remains hard to predict how an implant will behave over time. Our work is one part of an early warning system for complications following replacement surgery. Such measures won't predict the future, but as the market continues to expand we can help make sure that the suffering caused by widespread failure of MOM hips will never happen again.

### NJR

(National Joint Registry)

We help the NJR validate its reports by cross-checking NJR records with our own (see page 8).

## PEOPLE FIRST

LIRC exists above all to make sure hip replacements last as long as possible, and to make life better for those with painful implants.

**By working closely with patients we get to see how the evidence we gather makes a real difference.**



Nicola Niechcial

Nicola had revision surgery for a failed MOM hip in 2007. She says...

“Seven years down the line and I'm back to walking my beloved dogs, cycling to work every day, swimming and playing with my granddaughter; something

I never thought I'd be able to

contemplate. Sure, I still have the osteoarthritis in my other joints, and I know I'll probably have to face more surgery eventually, but the revision surgery has given me my life back, bought me so much more time, and made my other joint problems more bearable.”



We hold regular open days at LIRC, giving patients a chance to find out more about our work, give feedback, and share experiences with each other.

## Get information

Learn the types of orthopaedic implants, the anatomy of a hip or knee joint, and what to expect during and after surgery.

FIND OUT MORE AT: [lirc.co.uk/patient-information](http://lirc.co.uk/patient-information)

## Get involved

Visit us during one of our open days; help critique our research and information, and work with us to shape our plans for the future.

FIND OUT MORE AT: [lirc.co.uk/patient-involvement](http://lirc.co.uk/patient-involvement)

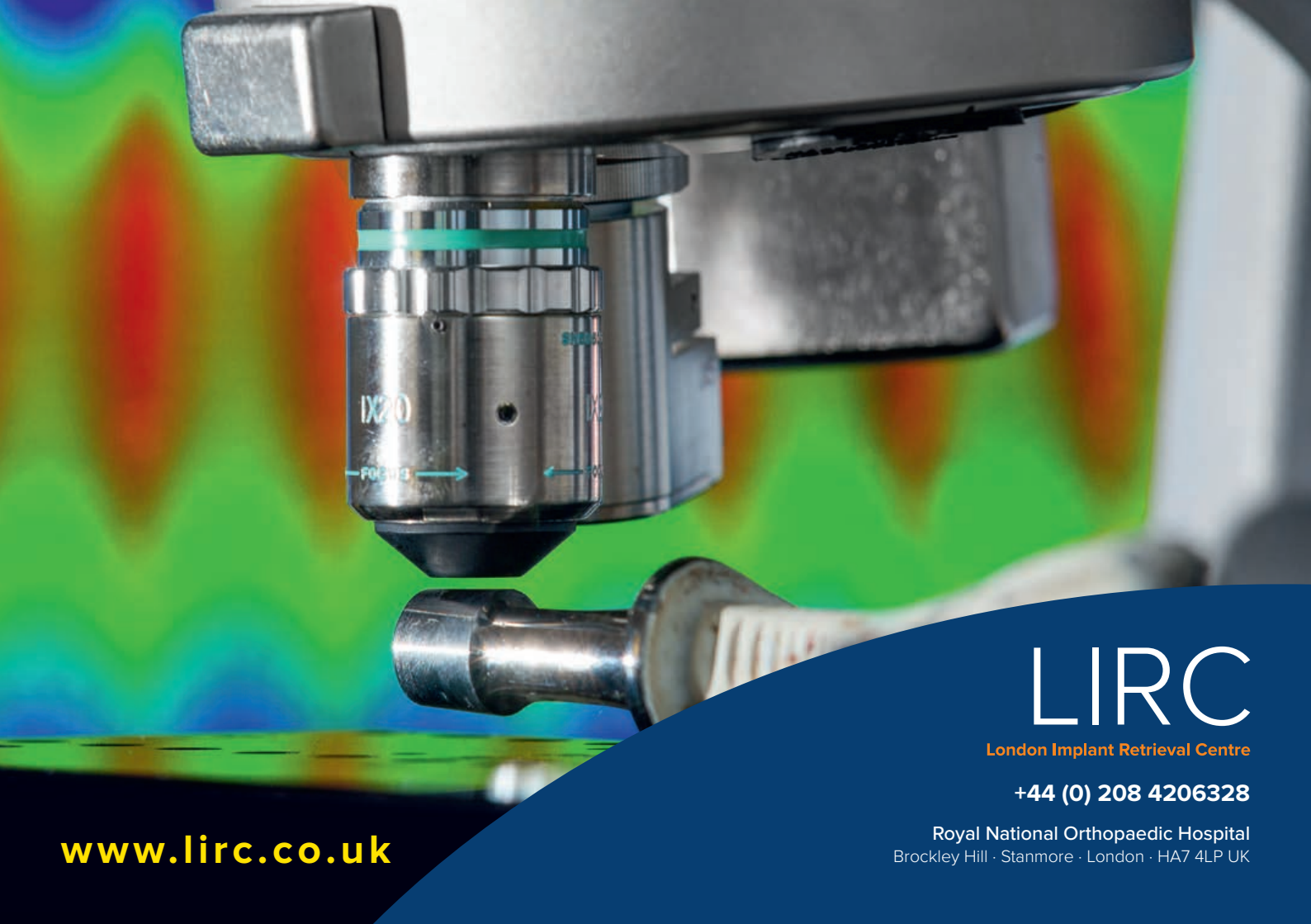
## Get in touch

The London Implant Retrieval Centre

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