

**NHS Implant Analysis Service Annual Conference  
The Catalyst Building, Newcastle City Centre  
25th November 2024**

**Summary document**

*Each year, around 20,000 people in the UK suffer through painful revision surgery to replace implants for joints such as hip and knee. This isn't just a burden on patients, but also on the NHS, which incurs millions of pounds in additional surgery costs and litigation fees.*

*Yet, once the surgery is complete, around 95% of implants are simply thrown away.*

*By studying retrieved joint implants, we can gain crucial information about what leads to implant failure, similar to how black box flight recorders help us understand aircraft accidents.*

*At this conference, we'll be sharing insights from the physical analysis of retrieved implants and discussing them together in a dynamic setting so that we can improve the safety of patients undergoing joint replacement procedures in the future.*

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## Take home messages

### ***Joint replacement surgery***

- Joint replacements are one of the success stories of modern surgery

### ***Joint replacement failures***

- Joint failures are costly, with both economic and psychological effects

- Joint revisions cost up to £30,000 each
- Joint failure has major impacts on patients' lives
- Litigation can affect surgeon's careers
- Abnormal wear creates metal debris – this leads to aseptic lymphocyte-dominant vasculitis-associated lesion (ALVAL), soft tissue destruction
- ALVAL is seen in some patients and not others
  - There is a variety of patient factors involved
  - There may be links to increased levels of metal ions in the blood
- There have been manufacturing issues with some implants
  - These should be picked up by QA/QC, but this does not always seem to happen
- The companies developing the joints (including Capital hip, ASR hip, Pinnacle hip and NexGen knee) have not always acknowledged the issues and have blamed surgeons
  - Work by surgeons fed into withdrawals of a number of implants

### **Registries**

- The National Joint Registry was created to pick up issues with joints – however, data lag from annual publication, camouflage, where results are hidden by joint variants, and not being able to view the data including and excluding specific characteristics has resulted in issues being reported late
  - NJR data reporting is improving
- The Orthopaedic Data Evaluation Panel awards benchmarks based on manufacturers data
  - Beyond Compliance assesses and monitors new devices

### **Explant analysis**

- Explant analysis uses a variety of techniques to look at abnormal wear and other issues
  - Can determine mechanism and severity of failure, to trigger withdrawal of poorly performing implants more quickly and improve future implant design, thereby reducing the costs associated with revisions
  - Can protect patients, surgeons and hospitals
  - Can support litigation
  - Needs implants to be collected
  - Analysts don't always see the implants that have functioned well
  - Needs to be carried out independently
  - The data is valuable – the reporting should be clear and transparent
- Explant analysis is supported by the MHRA
- The independent sector is looking into involvement in implant analysis
- The NHS Implant Analysis Service works with the independent company ExplantLab
  - Explants are removed, shipped to the lab, analysed and reports returned to surgeons
  - Provides High volume screening service (£199) or full detailed report service (£495)
  - Provides valuable data – but needs high numbers of both successful and failed implants
  - Cost can be an issue

- IAS funding could be too much for individual trusts
  - Could be a mixed model of commercial and central NHS funding
  - Could focus on certain groups of implants

## **Session 1**

### ***Joint replacement: one of the great success stories of modern surgery: Tom Joyce, School of Engineering, Newcastle University, UK***

- Before joint replacement, there was no effective treatment for joint failure and the chronic pain could lead to suicide
- Hip replacements were the operation of the 20<sup>th</sup> Century, with survival rates of 83% at 20 years and revision rates are <5% at 10 years
- The knee replacement is the most common joint replacement worldwide, followed by hips and shoulder joint
- Joint replacements vary in complexity, and there have been advances in materials and design features

### ***What have we learnt since the ASR disaster: Tony Nargol, North Tees Hospital, Teesside, UK***

#### ***The ASR hip***

- 2017: Three reports of milky yellow fluid without infection – aseptic lymphocyte-dominant vasculitis-associated lesion (ALVAL) with soft tissue destruction and hips that failed prematurely
  - Adverse reaction to metal debris as a result of abnormal bearing wear and female head taper wear
- The failure rate of 49% at six years in the North Tees area – DePuy said it only happened in the North Tees hospital
- After meeting with the Medicines and Healthcare products Regulatory Agency (MHRA), ASR was recalled worldwide in 2010

#### ***The DePuy Corail Pinnacle MoM***

- Failures caused by abnormal bearing wear and abnormal female head taper wear inside the head, releasing metal debris
- Went to the MHRA in 2012 with blood metal ion data, explant analysis and a single hospital series of patients
- NJR included multiple variants and a failure rate of 2.29%; later separation of the results showed the outlier

#### ***The NexGen knee***

- X-ray changes seen; explant analysis detected abnormal wear

- NJR did not show an issue as it was camouflaged within many generations of NexGen products

### *The role of the National Joint Registry in joint recalls*

- NJR is published September each year, making it up to a year out of date
- Initially it only looked at primary implants, not revisions – reporting for all cases became mandatory in 2011

### *Data from advertising*

- Data used in advertising isn't always backed up by science

### *Explant analysis*

- Testing sufficient numbers provides early indication of problems

## ***NJR – past and present: Simon Jameson, Consultant Hip and Knee Surgeon, University Hospitals Tees, UK***

### *The 3M Capital Cemented Hip System*

- Marketed in the UK between 1991 and 1997; data hid the poorer performance of the modular flanged variant
- The NJR was created as a registry could have identified the issue sooner

### *NJR history*

- The data is improving over time, from creation in 2003 to 4 million procedures recorded in 2024

### *Current NJR output*

- Annual Report, Annual Clinical Report, Clinical Level Reports, Implant costs – at trust and individual level, Surgeon profiles

### *Challenges*

- More data is always wanted
- Data quality challenges
- Camouflage – results hidden by multiple versions of the same product

## ***The Southampton experience of large MoM heads on stems: Jeremy Latham, Metal Hips Research Group, Southampton, UK***

- Used large heads on stems – high failure rates, loosening of stem, erosion, fluid in the hip, dead bone in the socket and stem, dead tissue associated with increased wear and evidence of corrosion on the surface of the stem leading to fractures
- The Metal Hips Research Group shared experience, started retrieval analysis
- Faced 10 years of litigation, accused of breach of duty, almost lost indemnity cover, no support from manufacturers

- Traumatic process

## ***ODEP, BC, MDR & ORP! – Keith Tucker, Chair of ODEP and the Beyond Compliance advisory group, UK***

### ***ODEP***

- The Orthopaedic Data Evaluation Panel (ODEP) was set up in 2003 by NICE after the 3M Capital Hip issues
- Awards benchmarks based on submitted data from manufacturers
  - The data includes the revision rate and why revisions have been made
- Ratings are based on brands and product codes to reduce camouflage

### ***Beyond Compliance***

- NJR/ODEP did not pick up ASR or MoM quickly or react adequately
- MHRA asked ODEP to assess and monitor new devices – created Beyond Compliance in 2012 to support the safe and stepwise introduction of new or modified implantable medical devices

### ***Medical Device Regulation (MDR)***

- Introduced in 2017, requires clinical investigations for new and legacy devices
- Has resulted in some legacy devices being taken off the market
- ODEP wants to collect similar data

### ***Outcome registries programme (ORP)***

- Recommends that new devices should be monitored, and that implants in patients should be in a registry

## ***One Bad Apple? My experience with the NexGen – Chris Jack, consultant trauma and orthopaedic surgeon, University Hospital Southampton, UK***

- Used the NexGen PS implant with patella resurfacing
  - Saw a lot of revisions, but no impact from patient or surgeon factors
  - 87% of the revisions were from aseptic loosening of the tibia
- Zimmer Biomet reps said that there was no issue
- Was told by the NJR that his revision was too high
  - The NJR had noted an issue with the NexGen knee in 2015 (level one outlier) – if it had been withdrawn then, there could have been different outcomes for patients and surgeons
- The joint was recalled in 2022 - different combinations had camouflaged the issue
- The NJR needs better data, and needs to share concerns and inform surgeons about issues with implants
- Remember the patients – they just want to get on with their lives

### ***Session 1 discussion***

- The NJR won't prevent problem implants coming onto the market, but it will reduce their impact
- The issues with the 3M Capital hip were picked up in 1999 but not in high enough numbers to be persuasive
- Companies can put similar products onto the market – the equivalence rationale is now much tighter
- The EU/UK Medical Device Regulations (MDR) is putting a greater scrutiny on compatibility
- The NJR needs to be able to have sets of data with and without specific implants to show how devices are used at specific institutions
- Changes in devices can be large or subtle – for example sterilisation differences to the polyethylene in a joint – but these mean that the joint is not the same as the original one

### **Session 2**

#### ***Explant analysis of spinal rods from children with scoliosis – Tom Joyce, Professor of Orthopaedic Engineering, School of Engineering, Newcastle University, UK***

- In November 2012, the House of Commons Science & Technology Committee recommended that “explanted joints should be analysed, and subsequent data generated should be reported to the NJR and published”

#### ***The MAGEC spinal growing rod***

- Explant analysis of over 200 rods showed wearing, seal issues and other problems
- Used from 2014 – MHRA investigations led to suspension of the CE mark in 2020 and withdrawal in the UK

#### ***Revised version: MAGEC X***

- Explant analysis of the new version showed metallosis and issues with the sealing mechanism
- There has been no NICE recommendation for MAGEC since 2020

#### ***Explant analysis: How and why – David Langton, Founder & Chief Scientific Officer, ExplantLab, Newcastle, UK***

##### ***Why and how***

- Explant analysis can inform implant development
- Understanding how much material is worn away, and the rate and location of the wear
- Uses visual analysis and surface profilometry; wear can also be assessed by testing blood levels

- However, one key issue is cost – ExplantLab has worked to reduce labour costs and increase the number of explants that can be analysed

### *Funding sources*

- British Orthopaedic Association (BOA)
- Carrying out medicolegal consultations for patients
- FDA
- Arthroplasty for Arthritis
- Private investment
- UK government
- Implant Analysis Service

### ***A revision surgeon's lifetime experience of implant retrieval: Why it is important – Richard Beaver, consultant surgeon, Royal Perth Hospital, Perth, Western Australia***

- Can only identify implant failings if the implants are collected and analysed
- Registries help both surgeons and manufacturers
- Retrieval labs don't always see the implants that have functioned well
- Analysis should be carried out by independent labs with independent funding, using standardised equipment

### ***Insights from a government administered retrieval unit – Moreica Pabbruwe, Assistant Professor, CITRA – Bioengineering Health Technology Management Unit, East Metropolitan Health Service, Perth, Western Australia***

- Implant failures are caused by implant, patient factors and surgical factors
- Implant retrieval analysis goals are to determine mechanism and severity of failures, and identify optimal or successful design criteria for future implants
- In case studies from CITRA, implant analysis has helped with the selection of ideal combinations of components, the impact of patient factors, better design of implants and better matching of implants to specific patients

### ***Challenges and benefits of retrieval analysis***

- Challenges to implant retrieval analysis include lack of well-functioning comparators, low numbers, lack of standardisation
- Benefits include
  - Identifying design, materials and manufacturing issues early
  - Costs savings through avoiding revisions
  - Better patient safety
- Collaboration supports better retrieval analysis

## Session 3

### ***The NHS Implant Analysis Service – Sue Waller, Clinical Nurse Specialist at North Tees and Hartlepool NHS Foundation Trust, UK<sup>1</sup> & David Langton, Founder & Chief Scientific Officer, ExplantLab, Newcastle, UK***

- The aim is to keep it independent and reduce bias
  - Work with ExplantLab, which has provided the expertise, knowledge and facilities
- Used by trusts across England

#### ***Why is it important?***

- Reports offer learning and discussion opportunities for surgeons
- Trend analysis with an early warning system can improve patient outcomes
- If implants are thrown away it's hard to make a difference for the future

#### ***How it works***

- Explants are removed, shipped from hospital to lab and decontaminated
- Analysis carried out and report emailed to surgeon
- High volume screening service (£199) or full detailed report service (£495)

### ***IAS: Data handling – David Langton, Founder & Chief Scientific Officer, ExplantLab, Newcastle, UK***

- Patient consent is needed so that data can be shared for scientific education, to help manufacturers, and for regulators
- Patient information is important for context
- Ideally, data sets should combine explant data, NJR data, in vivo data and genetics
- Routine analysis provides valuable data
- Measuring old devices is useful for comparison with new ones
- Costs can be an issue, but clinical waste disposal can be costly and failing devices cost the NHS a lot
- The IAS needs support to make it a global service for all devices, not just orthopaedics, along with a multidisciplinary advisory board

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<sup>1</sup> Sue Waller is employed by North Tees and Hartlepool NHS Foundation Trust (NTHFT) and is contracted to work on the NHS Implant Analysis Service provided by NTH Solutions, NTHFT's subsidiary

***Explant analysis and our MDTs – Raghu Sidaginamale, Consultant Trauma and Orthopaedic Surgeon, Hip & Knee arthroplasty, North Tees and Hartlepool NHS Foundation Trust, UK***

- The NHS Implant Analysis Service and the collaborative efforts of MDTs play a vital role in improving orthopaedic care and improving outcomes for patients
- Every private and NHS centre should get involved in IAS
- Large numbers of explants are needed – whether a success or a failure – and full clinical details support data interpretation
- Case studies showed the role of explant analysis on failed implants

***Evidence of time dependent degradation of polypropylene surgical mesh explanted – Nicholas Farr, School of Chemical, Materials and Biological Engineering, University of Sheffield, UK***

- The team developed methods of analysing vaginal mesh implanted in sheep models
  - Observed mesh degrading – cracks and crazes in mesh, formation of particles, changes in stiffness
- Evolving research techniques can provide insights into biomaterial characterisation
- Implant analysis needs to know
  - What analysis should be undertaken
  - How hazard analysis techniques can be used

## **Session 4**

***Explant analysis, AI and genetics – David Langton, Founder & Chief Scientific Officer, ExplantLab, Newcastle, UK***

- The demand for hip and knee replacements is forecast to double as the population ages and obesity levels rise – more surgery means more revisions required
- Several thousand different designs of joint replacements have been available for UK surgeons over the last 15 years.
- Levels of chronic pain following joint replacement remain at approximately 10-20%
- Immune responses limit the long-term survival of joint replacements

***Developing and predicting ALVAL***

- Some patients develop ALVAL – the same material debris can provoke different immune responses in different patients
  - Certain patient characteristics promote the development of ALVAL, whereas some patients are relatively resistant to developing the condition
- Knee surgeons do not routinely request examination of tissues to look for ALVAL
  - Approx 30% of failed TKRs show signs of ALVAL, with the ALVAL grade correlating with pain levels
- Blood Co and Cr concentrations may frequently be elevated in patients with TKRs – but little data have been published

- 15% of patients of European descent have genetic variants which are associated with a significant increased risk of ALVAL type reactivity to CoCr
  - 15% of patients who receive CoCr implants as part of knee replacements have chronic pain
  - Alternatives are provided for hip replacements but disregarded for knee replacements
- In the ArthroGenex study, there were:
  - Increased levels of titanium ions in all revision cases
  - Genetic links to pain with elevated Ti levels; not the CoCr risk alleles
- Explant analysis can help to understand disease processes and develop diagnostic tests

## Session 5

### Manufacturers Q&A

#### *Question: Is there value in autopsy analysis?*

- Seems logical – can reduce mistakes
- Retrieval needs to be independent, with multidisciplinary support

#### *Question: With up to 40% of retrievals being out of spec, is there a QA problem?*

- Should be picked up by internal and external audits
- Can't be as bad as this

#### *Question: Are issues a regulatory thing or should they be picked up by the QMS?*

- QMS is important, but there should also be internal auditing – these should work together
- New implants should be analysed as well as explants

#### *Question: Should implant analysis be part of post-market clinical follow up? Or made a legal requirement?*

- Yes – but who would manage it and fund it?

### *Audience comment*

I spent 10 years looking at manufacturing problems – I've seen things on production lines that people don't want to tell anyone senior about. I have seen FDA reports where UK things have been noted as wrong but not reported to the MHRA. These issues can be hidden. Some are retested to get them off the production line. Some companies are not even measuring.

#### *Question: Should implant analysis be internal or external?*

- Both internal and external
- External and independent

- Retrieval labs should be consistent and audited

**Question: There is no guidance for allergies**

- This is a developing area
- We need to get organisations to acknowledge hypersensitivity
- Instructions for use (IFU) may just talk about 'allergy' as a blanket comment
- It's hard to change an IFU. I'm concerned that we are taking allergies too far
- Surgeons should check – so we need to alert the surgeons

## **Session 6**

**Revision TKR and its Associated Costs – Jacky Ping Hei Cheng,  
Trauma and Orthopaedics Surgeon, University Hospital  
Southampton NHS Foundation Trust, UK**

- Revision surgeries are more costly than primary procedures
- Based on implant cost, operative time recorded, length of stay, bed cost per day and operating theatre cost per day, the average cost per patient is £15,638
- Additional costs could increase this to £30,000

**Explant analysis in the private sector – Debbie Dobbs, Executive  
Director, Circle Health Group, UK**

- The independent sector needs to:
  - Consider the risks and benefits of getting on board with new research
  - Look at the opportunities that can be offered to patients depending on payor type
  - See what the commercial or financial slant is
  - Encourage support/dispel myths
    - Does this conflict with income generation?
  - Consider whether to get involved or leave it to the NHS
  - Decide whether to wait until the research is proven

## **Session 7**

**Implant failure: My story – Sharon Craddock, patient**

- Primary total knee replacement with NexGen in both knees 2017/2018
  - Grateful for two new knees, but was still in pain and on inflammatory drugs
  - Had stomach and haemoglobin issues and had to come off anti-inflammatories
- Revision total knee replacement in both knees 2021
  - First revision in 2021 – left knee
    - Had to reduce working hours, became anxious about crowds
    - Anxious about the revision outcome

- Needed IV iron and repair to femur
- Second revision in 2023
  - Had allergic adverse reaction to glue and dressings, and a skin infection
- Impacts
  - No day without pain
  - Had to make changes at home, change car
  - Can't do long walks any more – even gardening is hard
  - Ongoing pain – now potentially unrevisable
  - Has affected freedom and self-confidence
  - Had a lot of time off work

### ***The MHRA perspective on implant retrieval analysis and its role in patient safety – Rebecca Owens, Medicines & Healthcare products Regulatory Agency, UK***

- One of the key elements of the medical device regulations is post-market surveillance to ensure long-term safety

#### ***Manufacturer's responsibilities***

- Review experience in post-production phase, investigate complaints and identify trends/signals
- Identify non-compliance and opportunities for improvements, make corrective and preventive actions
- Update clinical evaluation with post-market surveillance data
- Carry out continuous risk management to ensure that benefits outweigh risks
- Report adverse incidents and field safety corrective actions to MHRA, issue field safety notices to users

#### ***MHRA's responsibilities***

- Signal detection
  - Adverse incident reports, real-world data, engagement, risk prioritisation
- Assessment
  - Review of all data sources, engagement, expert advice, benefit-risk evaluation assessment
- Communication
  - National Patient Safety Alerts, Devices Safety Information (DSI), engagement, expert advice
- Impact assessment and signal detection
  - Engagement, adverse incident reports, real world data, lessons learned

#### ***Signal assessment and benefit risk evaluation***

- Explant analysis could help towards corrective action, gain additional information and strengthen a signal of concern alongside other data sources

### ***Retrieval analysis and post-market surveillance***

- Linking to the NJR would provide a better view of issues
- The MHRA can only take action when it is notified of issues
- To be important for post-market surveillance, retrieval analysis needs:
  - A national reach
  - Maximum engagement with stakeholders including manufacturers
  - Early notification for signals
  - Linked clinical data and minimum agreed data sets
  - Integration into robust manufacturer PMS systems
- It can:
  - Assist with identification of issues sooner
  - Build a better understanding of how different devices, brands and variants perform relative to one another
  - Improve both current and future patient outcomes and to increase patient safety

### ***Legal implications of explant analysis - Catherine Slattery and Natalie Truman, Associate Solicitors, IrwinMitchell, UK***

#### ***Legal test for product liability***

- The Consumer Protection Act 1987 states that a product is 'defective' if the safety of the product is 'not such as persons generally are entitled to expect.'
- The claim must be within 10 years of the product leaving the factory/going into circulation, even if the implant is on the shelf for some time before use, and cannot be extended

#### ***Investigation of claims***

- Information required includes:
  - Medical records/radiology from the hospital and GP
  - History from claimant – background and personal impact
  - Independent expert evidence
  - Explant analysis – including clinical evidence and trauma
    - Can provide evidence as to why the implant failed
  - Disclosure from manufacturer – rarely provided voluntarily; may need court intervention
  - Testing evidence in conference with Counsel
- Patient and surgical factors need to be considered, as manufacturers may argue that surgeons with high revision rates are outliers, or that patients have a propensity to certain outcomes

#### ***Use of explant analysis in practice – Pinnacle MoM group litigation***

- The Court decided that the propensity to shed metal debris was not a defect
- The claimants relied heavily on statistics arguing that that the cumulative revision rate for the prosthesis at 10 years post-implantation was materially higher than comparators, but the court accepted DuPuy's argument that statistics were unreliable:

- NJR had missing data, included a number of outlying surgeons, and conflated a number of variants (camouflage)
- MHRA guidance following the withdrawal of a different type of MoM prosthesis resulted in enhanced surveillance, increasing the number of revisions
- Media reporting had an impact on revision rates
- Reliance on epidemiological data requires caution
  - Can identify trends, but cannot prove causation
  - Needs expert analysis
- Identifying a unique mechanism of failure through explant analysis can help to avoid this problem, and may be more attractive to the courts