The Articular Surface Replacement (ASR™) artificial hip joint

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1st October 2011

FUNDED BY

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A caveat

- I am not a medical doctor
- I am not an orthopaedic surgeon
- I cannot give medical advice
- But I have 18 years of medical engineering experience
- And have been studying the ASR and other metal-on-metal hips since late 2007

Overview

- Total hip replacement (THR)
- Metal-on-metal THR and hip resurfacings
- The DePuy ASR™ hip
- Research at Newcastle University and clinical data from orthopaedic colleagues
- Lessons from THR history - Capital 3M and Sulzer hips

The Lancet 2007

The operation of the century: total hip replacement

Ian D Learmonth, Claire Young, Cecil Rorabeck

Lancet 2007; 370: 1508–19
Published Online
March 29, 2007
DOI:10.1016/S0140-6736(07)60457-7

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In the 1960s, total hip replacement revolutionised management of elderly patients crippled with arthritis, with very good long-term results. Today, young patients present for hip-replacement surgery hoping to restore their quality of life, which typically includes physically demanding activities. Advances in bioengineering technology have driven development of hip prostheses. Both cemented and uncemented hips can provide durable fixation. Better materials and design have allowed use of large-bore bearings, which provide an increased range of motion with enhanced stability and very low wear. Minimally invasive surgery limits soft-tissue damage and facilitates accelerated discharge and rehabilitation. Short-term objectives must not compromise long-term performance. Computer-assisted surgery will contribute to reproducible and accurate placement of implants. Universal economic constraints in healthcare services dictate that further developments in total hip replacement will be governed by their cost-effectiveness.

- '*Charnley LFA: a worldwide retrospective review at 15 to 20 years*' (Older, J Arthroplasty, 2002, 675-680). 83% survival rate at 20 years
- UK National Joint Registry (NJR) 2011 - 97% survival rate at 7 years (cemented hips)

Total Hip Replacement (THR) history

- 66k+ primary THR fitted in UK in 2009-10
- Metal-on-polyethylene THR fail due to wear
- Younger, more active patients wear their prosthesis out
- How to reduce the wear?
- Metal-on-metal (MOM) THR
- Metal is Cobalt Chromium (CoCr) alloy

Modern MoM THR

- 100 fold reduction in wear claimed
- Volumetric wear was reduced
- But metal wear particle size is smaller, typically 1000x smaller than plastic wear particles
- Actual numbers of CoCr particles higher than UHMWPE
- Potential danger from metal particles?
- In US, 35% of THR were MoM (Bozic, 2009, JBJS)

Metal-on-Metal Resurfacing THR

- Initial trials in 1990s
- Birmingham Hip Resurfacing (BHR)
- Aimed at younger, more active patients

- Claims that bone stock is preserved and increased range of motion provided
- Should give low wear and improved lubrication

Metal-on-metal resurfacing of the hip in patients under the age of 55 years with osteoarthritis

J. Daniel,
P. B. Pynsent,
D. J. W. McMinn

From The Birmingham Nuffield Hospital and the Royal Orthopaedic Hospital, Birmingham, England

The results of conventional hip replacement in young patients with osteoarthritis have not been encouraging even with improvements in the techniques of fixation and in the bearing surfaces. Modern metal-on-metal hip resurfacing was introduced as a less invasive method of joint reconstruction for this particular group.

This is a series of 446 hip resurfacings (384 patients) performed by one of the authors (DJWM) using cemented femoral components and hydroxyapatite-coated uncemented acetabular components with a maximum follow-up of 8.2 years (mean 3.3). Their survival rate, Oxford hip scores and activity levels are reviewed.

Six patients died due to unrelated causes. There was one revision (0.02%) out of 440 hips. The mean Oxford score of the surviving 439 hips is 13.5. None of the patients were told to change their activities at work or leisure; 31% of the men with unilateral resurfacings and 28% with bilateral resurfacings were involved in jobs that they considered heavy or moderately heavy; 92% of men with unilateral hip resurfacings and 87% of the whole group participate in leisure-time sporting activity.

The extremely low rate of failure in spite of the resumption of high level occupational and leisure activities provides early evidence of the suitability of this procedure for young and active patients with arthritis.

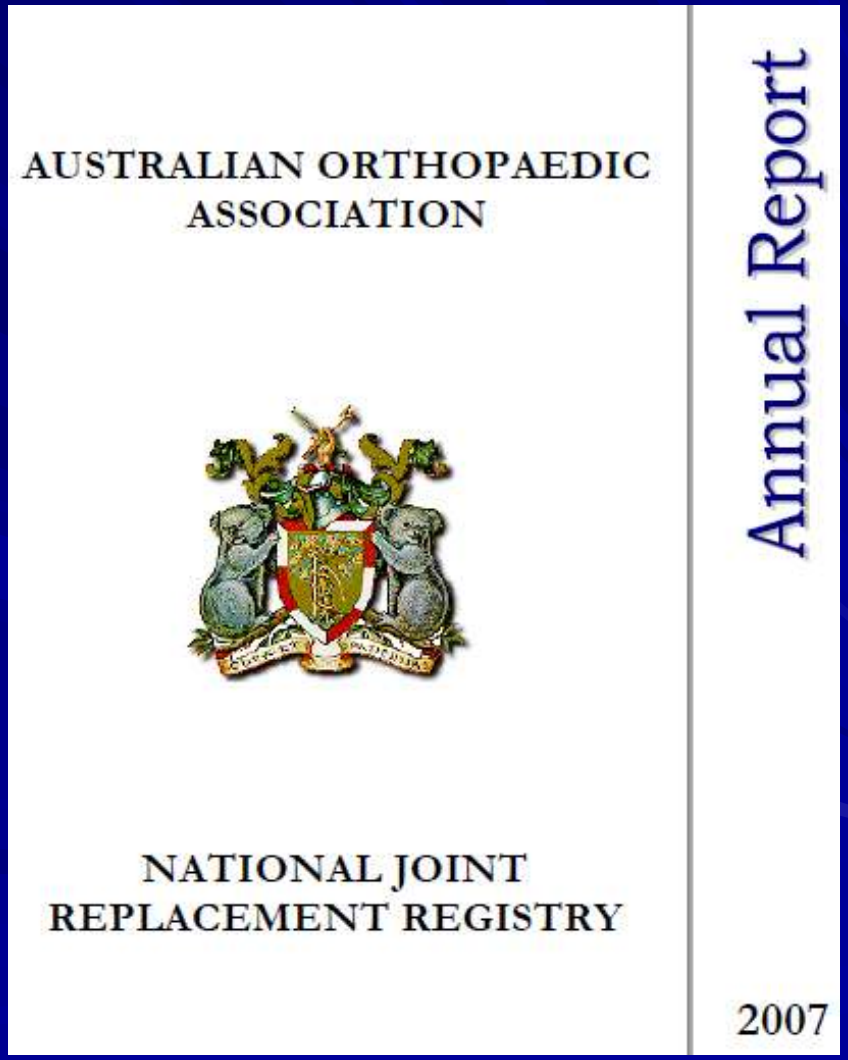
- Daniel et al, 2004, JBJS (UK) 177-84
- One revision (0.02%) out of 440 hips
- Suitable ‘for young and active patients with arthritis’

DePuy ASR™ – a history

- De Puy ASR™ introduced 2003 smaller diametral clearance, sub-hemispheric cup, compared with BHR
- Available in resurfacing (except in US)
- And in large diameter head total hip replacement ‘XL’
- The acetabular cup is identical in both designs

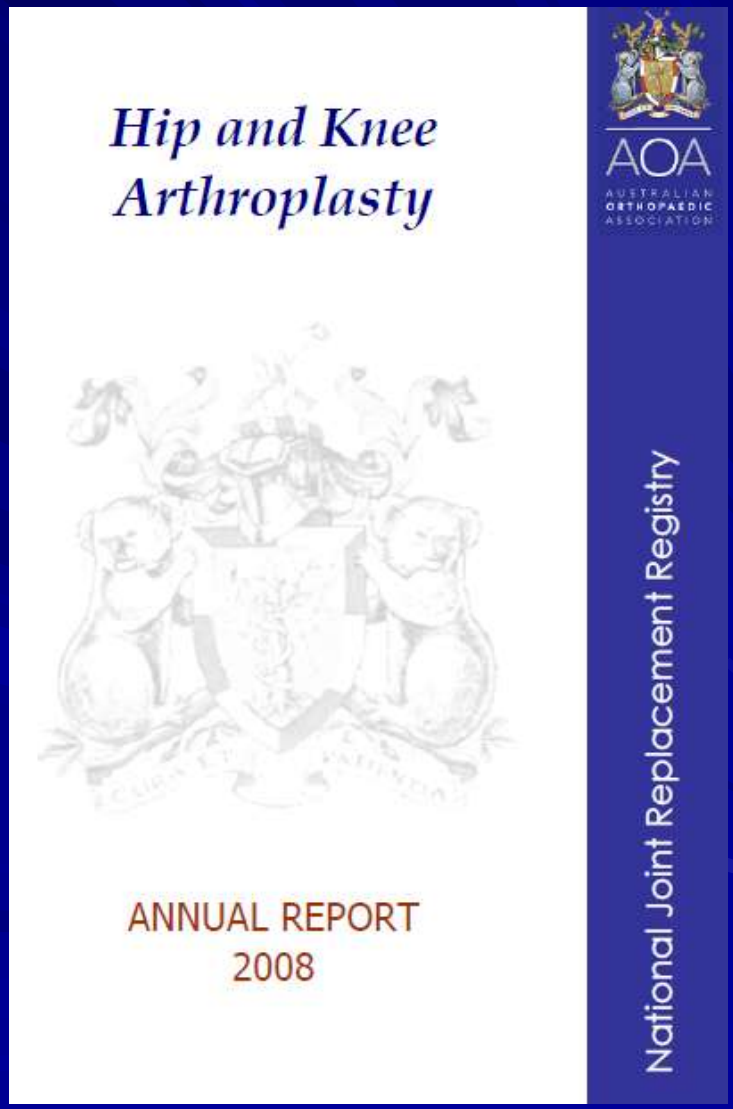
DePuy ASR™ – a troubled history

- 2007 Australian Joint Registry “The ASR has twice the risk of revision compared to all other resurfacing procedures”



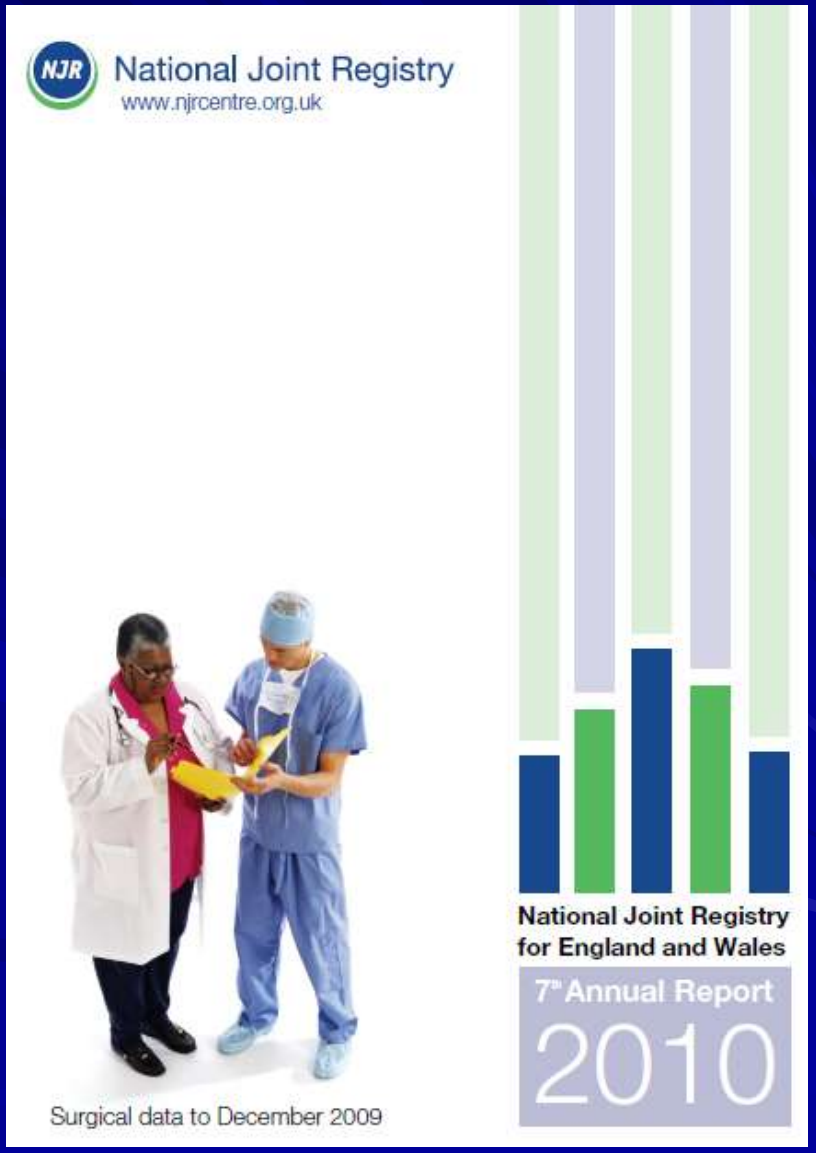
DePuy ASR™ – a troubled history

- 2008 Australian Joint Registry “The three year cumulative percent revision for BHR is 2.5% and for ASR is 6.0%”
- 2009 Australian Joint Registry “The eight year cumulative percent revision of the BHR is 5.0%. The five year cumulative percent revision for the ASR is 8.7%”



DePuy ASR™ – a troubled history

- 2009 National Joint Registry “The lowest three year revision rate was seen for the BHR (3.3%) and the highest for the ASR (7.5%)”
- 2010 NJR “the BHR had a five year revision rate of 4.3% (3.8% to 4.9%). The ASR had a five year revision rate of 12.0% (9.3% to 15.4%)”



ASR™ - Recent timeline (1)

- December 2009, DePuy withdraws ASR™ from Australian market
- 3 March 2010, New York Times article “Concerns over ‘metal-on-metal’ hip implants”
- 6 March 2010, DePuy issues warning letter to US surgeons about failure rates of ASR™ acetabular cups
- 18 April 2010, Sunday Times article “Tumour fear over metal hip replacements”
- 22 April 2010, UK Medicines and Healthcare products Regulatory Agency (MHRA) issues a Medical Device Alert for all MoM implants

ASR™ - Recent timeline (2)

- 26 Aug 2010, DePuy withdraw ASR™ worldwide, quoting NJR revision rates of 12% and 13%
- 10 March 2011, British Orthopaedic Association and British Hip Society press release mentions revision rates of up to 49% at 6 years for the ASR™ XL
- 15 March 2011, Head of DePuy Orthopaedics to step down
- May 2011 – TV programmes: Channel 4 *Despatches*; BBC *The One Show*; ABC (Australia) *Four Corners*
- 15 Sept 2011, New York Times “Metal hips failing fast” (NJR 2011 data – 29% revision rate ASR™ XL)

RESEARCH AT NEWCASTLE UNIVERSITY/ UNIVERSITY HOSPITAL OF NORTH TEES

Examination of failed and retrieved ASR™ hip prostheses

Linked with clinical expertise at University Hospital of North Tees, UK

SOME OF OUR SCIENTIFIC PUBLICATIONS

The effect of component size and orientation on the concentrations of metal ions after resurfacing arthroplasty of the hip

D. J. Langton,
S. S. Jameson,
T. J. Joyce,
J. Webb,
A. V. F. Nargol

From the University Hospital of North Tees, Stockton-on-Tees, England

Increased concentrations of metal ions after metal-on-metal resurfacing arthroplasty of the hip remain a concern. Although there has been no proven link to long-term health problems or early prosthetic failure, variables associated with high metal ion concentrations should be identified and, if possible, corrected. Our study provides data on metal ion levels from a series of 76 consecutive patients (76 hips) after resurfacing arthroplasty with the Articular Surface Replacement. Chromium and cobalt ion concentrations in the whole blood of patients with smaller (≤ 51 mm) femoral components were significantly higher than in those with the larger (≥ 53 mm) components ($p < 0.01$). Ion concentrations in the former group were significantly related to the inclination ($p = 0.01$) and anteversion ($p = 0.01$) of the acetabular component. The same relationships were not significant in the patients with larger femoral components ($p = 0.61$ and $p = 0.49$, respectively). Accurate positioning of the acetabular component intra-operatively is essential in order to reduce the concentration of metal ions in the blood after hip resurfacing arthroplasty with the Articular Surface Replacement implant.

JBJS (UK) Sept 2008, 1143-1151

For DePuy ASR™ hip resurfacings ion levels linked to acetabular cup size and position

Tribological analysis of failed resurfacing hip prostheses and comparison with clinical data

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The manuscript was received on 21 July 2008 and was accepted after revision for publication on 8 January 2009.

DOI: 10.1243/13506501JET484

J Engineering Tribology, 2009, 317-323

Abstract: Metal-on-metal resurfacing hip prostheses offer potential benefits over total hip replacement for younger and more active patients. Although some reported clinical results of resurfacing hip prostheses are excellent, other outcomes are less positive. To aid with understanding the balance of benefits related to these devices, analysis of failed resurfacing prostheses can contribute critical insights. However, because these implants are so new there are relatively few such prostheses available for independent *ex vivo* analysis. From a single-surgeon clinical cohort, a number of failed resurfacing hip prostheses were obtained and studied. It was found that roughness values of the articulating surfaces had increased so that the theoretical lubrication regime would shift from the fluid film to the boundary. In turn, this would likely result in increased wear from the articulating surfaces. High ion levels were seen in the patients from whom the explants were obtained, thus supporting the hypothesis that wear was linked with failure of the explanted hip resurfacing prostheses.

Keywords: metal-on-metal, cobalt chrome, hip resurfacing, hip prostheses, explant

Failed ASR™ resurfacing hips had roughened in the body

Blood metal ion concentrations after hip resurfacing arthroplasty

A COMPARATIVE STUDY OF ARTICULAR SURFACE REPLACEMENT AND BIRMINGHAM HIP RESURFACING ARTHROPLASTIES

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There have been no large comparative studies of the blood levels of metal ions after implantation of commercially available hip resurfacing devices which have taken into account the effects of femoral size and inclination and anteversion of the acetabular component. We present the results in 90 patients with unilateral articular surface replacement (ASR) hip resurfacings (mean time to blood sampling 26 months) and 70 patients with unilateral Birmingham Hip Resurfacing (BHR) implants (mean time 47 months).

The whole blood and serum chromium (Cr) and cobalt (Co) concentrations were inversely related to the size of the femoral component in both groups ($p < 0.05$). Cr and Co were more strongly influenced by the position of the acetabular component in the case of the ASR, with an increase in metal ions observed at inclinations > 45° and anteversion angles of < 10° and > 20°. These levels were only increased in the BHR group when the acetabular component was implanted with an inclination > 55°.

A significant relationship was identified between the anteversion of the BHR acetabular component and the levels of Cr and Co ($p < 0.05$ for Co), with an increase observed at anteversion angles < 10° and > 20°. The median whole blood and serum Cr concentrations of the male ASR patients were significantly lower than those of the BHR men ($p < 0.001$). This indicates that reduced diametral clearance may equate to a reduction in metal ion concentrations in larger joints with satisfactory orientation of the acetabular component.

JBJS (UK)
Oct 2009

Contact Patch to Rim (CPR) distance – ASR™ cups more sensitive to position than BHR. An explanation for differences in clinical results

Early failure of metal-on-metal bearings in hip resurfacing and large-diameter total hip replacement

A CONSEQUENCE OF EXCESS WEAR

JBJS (UK) Jan 2010

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N. J. Hallab,
S. Natu,
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From North Tees and Hartlepool NHS Trust, Stockton-on-Tees and Centre for Rehabilitation, Newcastle University, Newcastle upon

Early failure associated with adverse reactions to metal debris is an emerging problem after hip resurfacing but the exact mechanism is unclear. We analysed our entire series of 660 metal-on-metal resurfacings (Articular Surface Replacement (ASR) and Birmingham Hip Resurfacing (BHR)) and large-bearing ASR total hip replacements, to establish associations with metal debris-related failures. Clinical and radiological outcomes, metal ion levels, explant studies and lymphocyte transformation tests were performed. A total of 17 patients (3.4%) were identified (all ASR bearings) with adverse reactions to metal debris, for which revision was required. This group had significantly smaller components, significantly higher acetabular component anteversion, and significantly higher whole concentrations of blood and joint chromium and cobalt ions than asymptomatic patients did (all $p < 0.001$). Post-revision lymphocyte transformation tests on this group showed no reactivity to chromium or cobalt ions. Explants from these revisions had greater surface wear than retrievals for uncomplicated fractures. The absence of adverse reactions to metal debris in patients with well-positioned implants usually implies high component wear.

Adverse Reaction to Metal Debris (ARMD) – an umbrella term to describe joint failures associated with pain, a large sterile effusion of the hip and/or macroscopic necrosis/metallosis

■ HIP

JBJS Feb 2011

Adverse reaction to metal debris following hip resurfacing

THE INFLUENCE OF COMPONENT TYPE, ORIENTATION AND VOLUMETRIC WEAR

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J. Lord,
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From Newcastle University and University Hospital of North Tees, Newcastle-upon-Tyne, United

We sought to establish the incidence of joint failure secondary to adverse reaction to metal debris (ARMD) following metal-on-metal hip resurfacing in a large, three surgeon, multicentre study involving 4226 hips with a follow-up of 10 to 142 months. Three implants were studied: the Articular Surface Replacement; the Birmingham Hip Resurfacing; and the Conserve Plus. Retrieved implants underwent analysis using a co-ordinate measuring machine to determine volumetric wear. There were 58 failures associated with ARMD. The median chromium and cobalt concentrations in the failed group were significantly higher than in the control group ($p < 0.001$). Survival analysis showed a failure rate in the patients with Articular Surface Replacement of 9.8% at five years, compared with < 1% at five years for the Conserve Plus and 1.5% at ten years for the Birmingham Hip Resurfacing. Two ARMD patients had relatively low wear of the retrieved components. Increased wear from the metal-on-metal bearing surface was associated with an increased rate of failure secondary to ARMD. However, the extent of tissue destruction at revision surgery did not appear to be dose-related to the volumetric wear.

Adverse Reaction to Metal Debris (ARMD) – 4,226 hips, follow up 10 to 142 months, ASR™ performs far worse than BHR or Conserve Plus

Tribology International 44 (2011) 517–522

Contents lists available at ScienceDirect

Tribology International

journal homepage: www.elsevier.com/locate/triboint

A study of the wear of explanted metal-on-metal resurfacing hip prostheses

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ARTICLE INFO

Article history:
Received 30 September 2009
Received in revised form
16 March 2010
Accepted 12 April 2010
Available online 20 April 2010

Keywords:
Failure
Metal wear
Wear measurement

ABSTRACT

Due to their recent introduction there are few studies of retrieved resurfacing hip prostheses. Nine such components associated with groin pain in patients, and five associated with early fracture of the femur, were obtained and analysed using a roundness measuring machine. While the 'fracture' components showed no more than 3 μm out of roundness, components associated with groin pain showed between 15 and 92 μm out of roundness values. These latter results indicate wear and correlated with high metal ion levels in these patients, therefore the groin pain was likely associated with an adverse reaction to excessive metal wear debris.

Retrieved ASR™ hip prostheses, from patients who had groin pain, show high wear

■ HIP

Accelerating failure rate of the ASR total hip replacement

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From the University Hospital of North Tees, Stockton, United Kingdom

There is widespread concern regarding the incidence of adverse soft-tissue reactions after metal-on-metal (MoM) hip replacement. Recent National Joint Registry data have shown clear differences in the rates of failure of different designs of hip resurfacing. Our aim was to update the failure rates related to metal debris for the Articular Surface Replacement (ASR). A total of 505 of these were implanted.

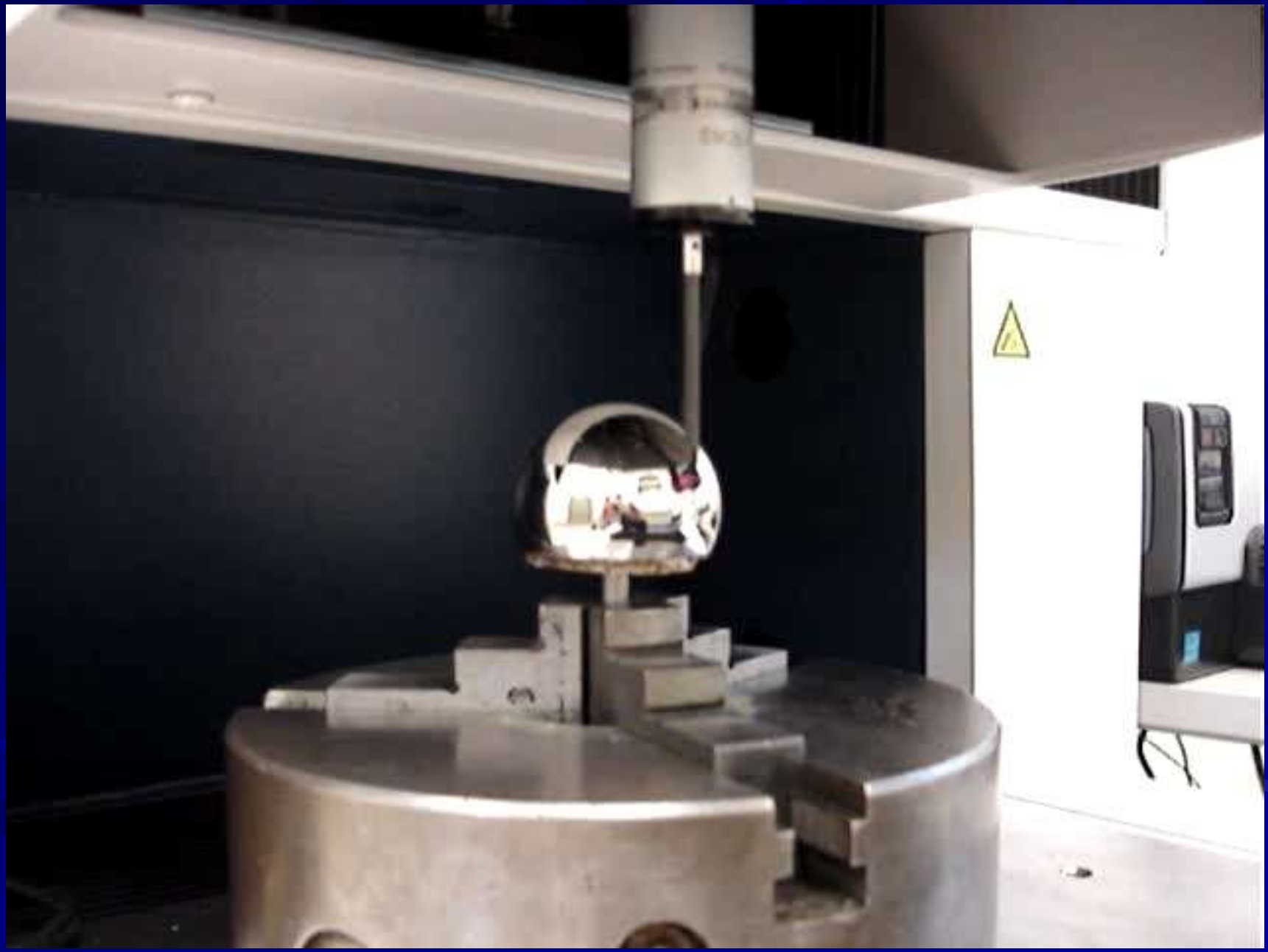
Kaplan-Meier analysis showed a failure rate of 25% at six years for the ASR resurfacing and of 48.8% for the ASR total hip replacement (THR). Of 257 patients with a minimum follow-up of two years, 67 (26.1%) had a serum cobalt concentration which was greater than 7 µg/l. Co-ordinate measuring machine analysis of revised components showed that all patients suffering adverse tissue reactions in the resurfacing group had abnormal wear of the bearing surfaces. Six THR patients had relatively low rates of articular wear, but were found to have considerable damage at the trunion-taper interface. Our results suggest that wear at the modular junction is an important factor in the development of adverse tissue reactions after implantation of a large-diameter MoM THR.

JBJS August 2011

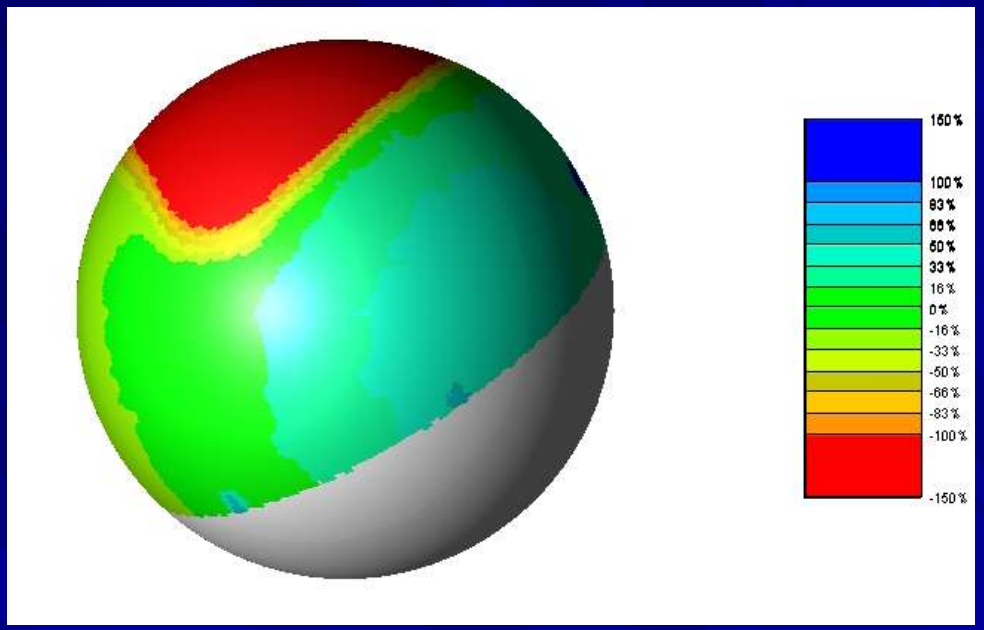
BIOENGINEERING ANALYSIS OF RETRIEVED HIP PROSTHESES

Mitutoyo LEGEX322 Co-ordinate Measuring Machine (CMM)

- We measure wear
- Wear is a volume
- CMM recommended by international standards for measurement of wear in hip prostheses (ISO14242-2)
- State-of-the-art LEGEX 322 has an accuracy of 0.8μm

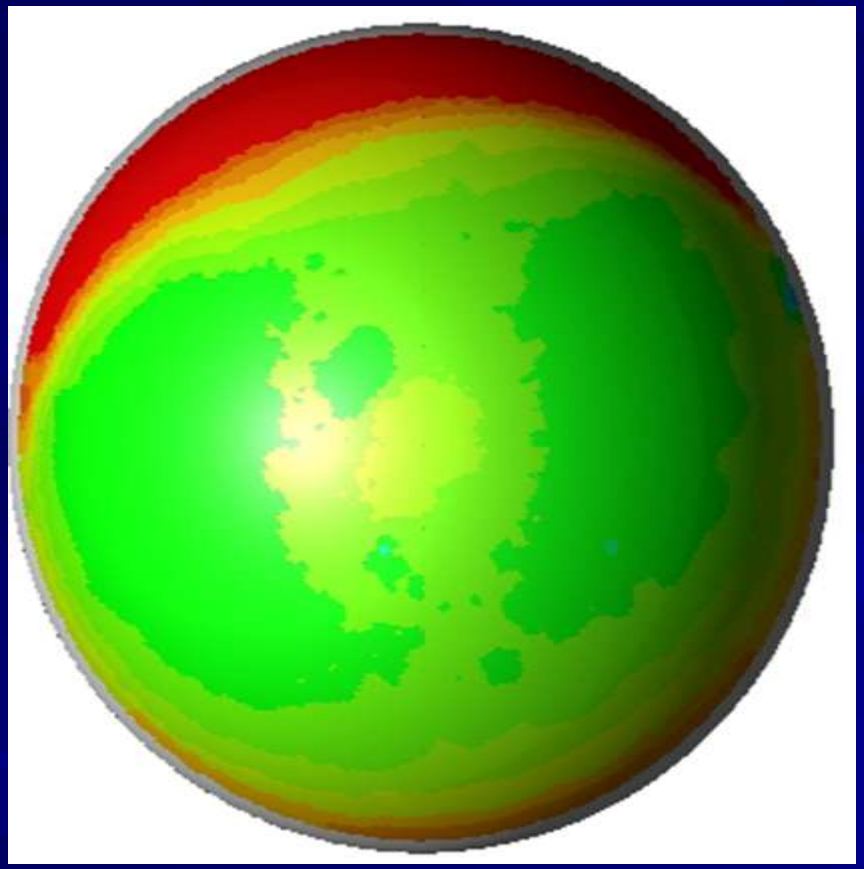


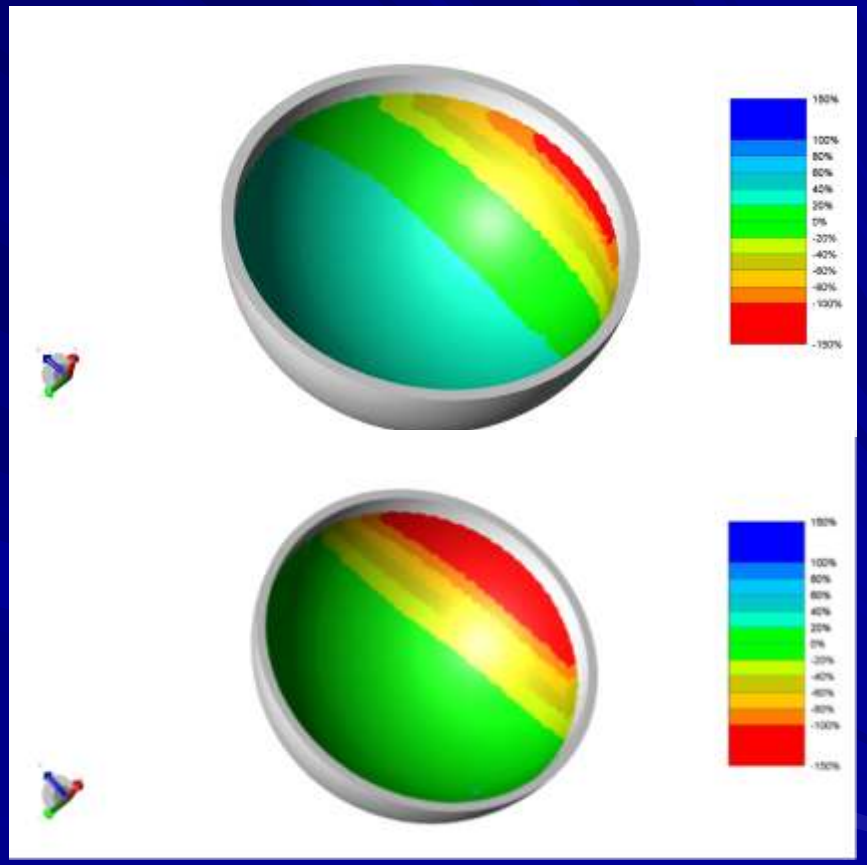
ARMD ASR™ head late fracture



- 64 yr old male, femoral fracture at 4 years
- 50.5mm dia, inclination 59°, anteversion 31°
- Red area shows at least 20µm of wear, wear volume from head 134mm^3

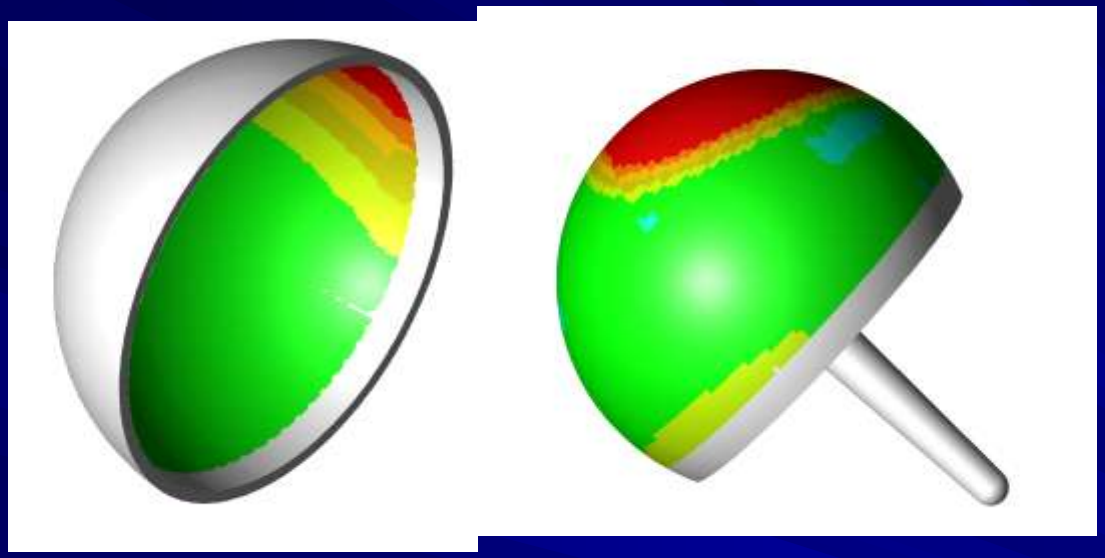
Explant analysis – ASR™ cups

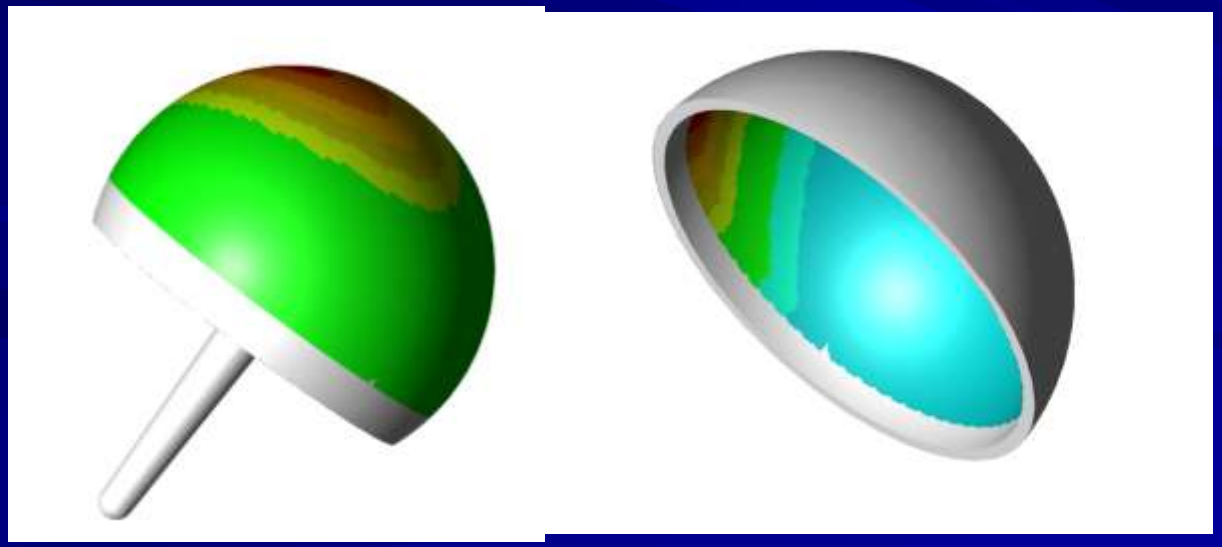




Wear at edge of cups – ‘rim wear’ commonly seen

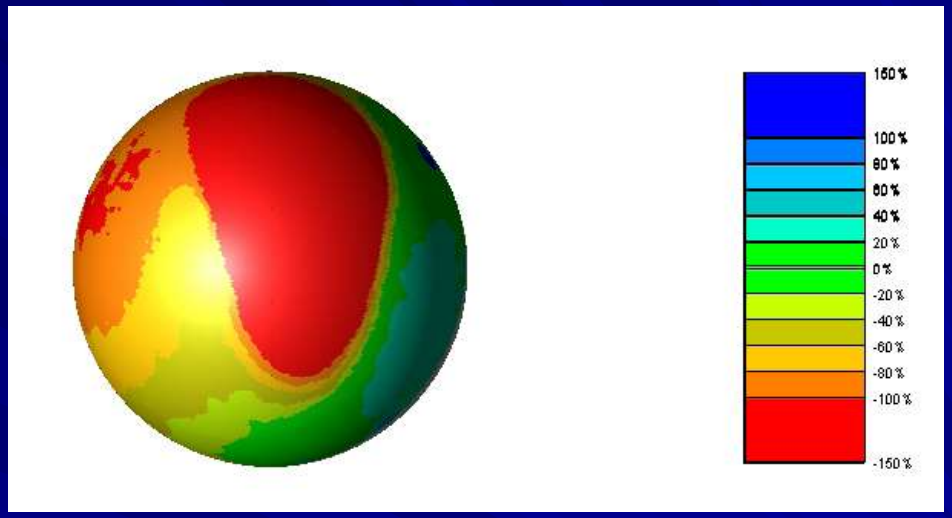
Failed ASR™ head and cup pairs





Common factor – ‘rim wear’ at edge of cup. Associated with cups fitted at high inclination and/or anteversion angles

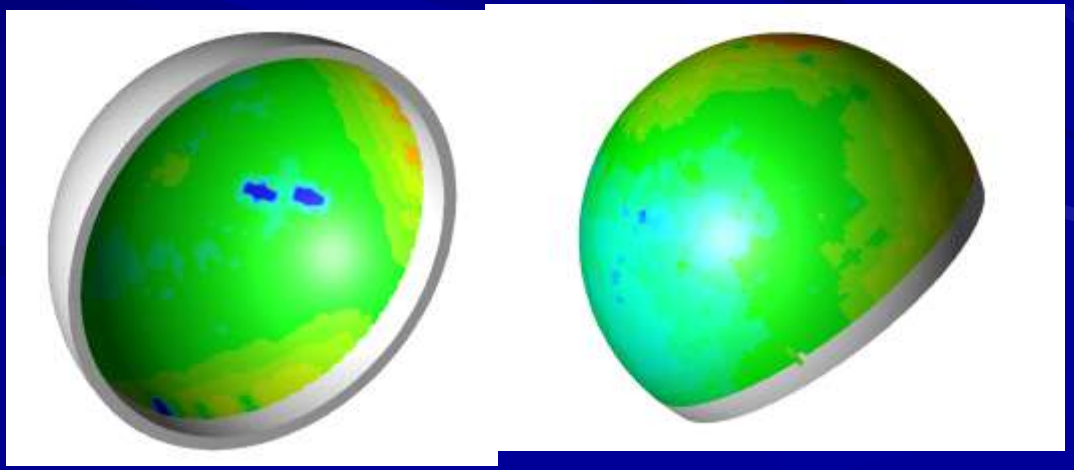
ARMD ASR™ XL femoral head



- Female patient, ASR™, failure at 35 months
- 45.5mm diameter, inclination 60°, anteversion 31°: Co 32.2µg/L, Cr 22.0µg/L
- Red area shows at least 20µm of wear depth, wear volume from head 20.2mm^3

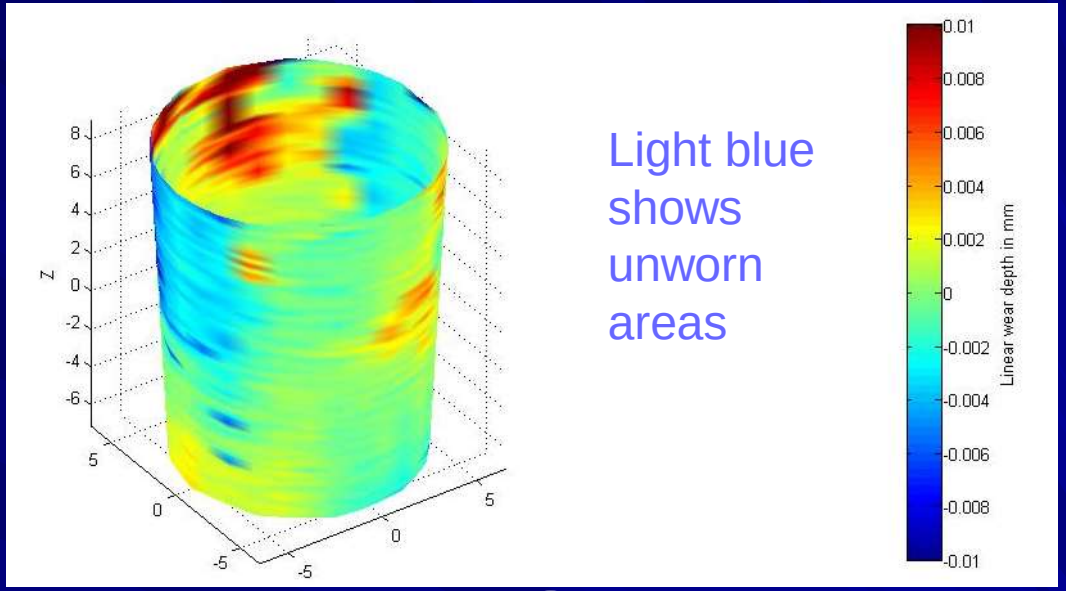
Case study

- Female patient, ASR™ XL
- Cup inclination good, ions low
- Revision at 21 months
- Joint effusion and severe tissue destruction
- Attribute failure to metal allergy?
- Total bearing surface wear <2mm^3



Look elsewhere on the ASR™ XL

- Wear at the taper junction
- We use our CMM to measure taper wear
- Example - 0.7mm^3 taper volume loss; maximum wear depth 39 microns
- Enough to cause failure and tissue destruction in this patient



Failure rates of Mr Nargol's cohort of 505 ASR™

- 418 ASR™ resurfacing: 25% revision rate at 6 yrs
- 87 ASR™ XL total hip replacement: 49% revision rate at 6 yrs
- Failure rates even higher if UK guidance of >7µg/l metal ion levels taken
- Compares with 3% revision rate at 7 yrs from (UK) National Joint Register 2011 for conventional cemented total hip replacements

Langton et al, JBJS (UK), 2011, 93B, 8, 1011-1016

The national picture – not just ASR

- NJR 2010 - for resurfacing prostheses the five year revision rate was 6.3% (5.7% to 7.0%)
- For large head metal-on-metal (LHMoM) five year revision rate was 7.8% (6.6% to 9.3%)
- NJR 2011 – resurfacing at 11.8% at seven years
- LHMoM 13.6% at seven years

Clinical Results – Metal Ions

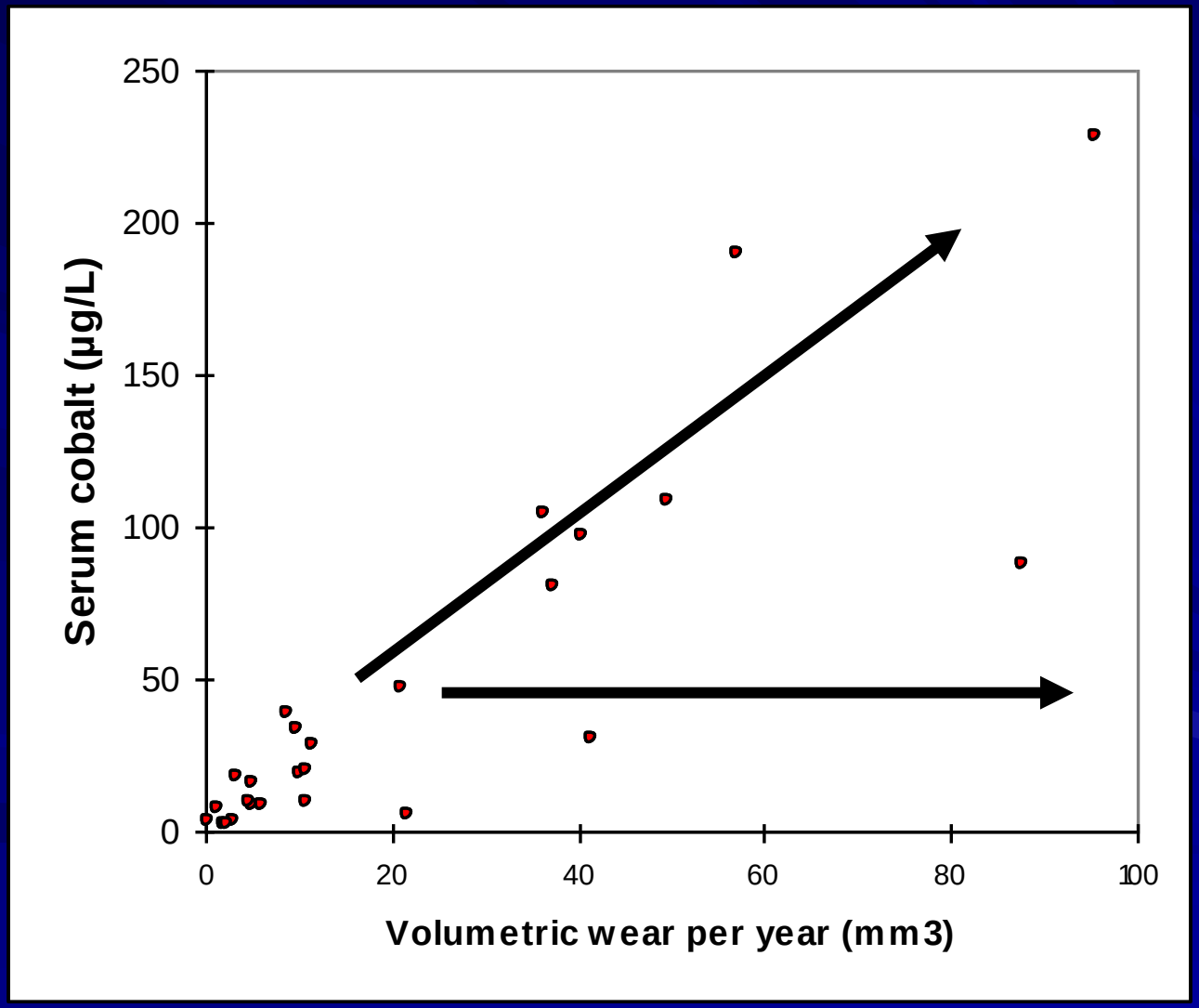
Current guidelines MDA-2010-069

For patients presenting with symptoms of abnormal pain, limping, swelling around the hip, deteriorating hip function or radiological abnormality:

- consider measuring cobalt and chromium ion levels in whole blood and/or performing cross sectional imaging including MRI or ultrasound scan
- in line with MDA/2010/033, if metal ion levels in whole blood are elevated above 120 nmol/L (cobalt) or 135 nmol/L (chromium) [ie seven parts per billion (ppb) for either metal ion], a second test should be performed three months after the first in order to identify patients who require closer surveillance, which may include cross sectional imaging
- if MRI or ultrasound scan reveals soft tissue reactions, fluid collections or tissue masses then consider revision surgery.

7ppb = 7 microgrammes per litre (µg/l)

Metal ions = wear



“The cobalt ladder”

1µg/L

Physiological

2µg/L

Patients with hip resurfacings (upper normal):

5µg/L

Abnormal wear

>10µg/L

60% show ARMD within 3 years

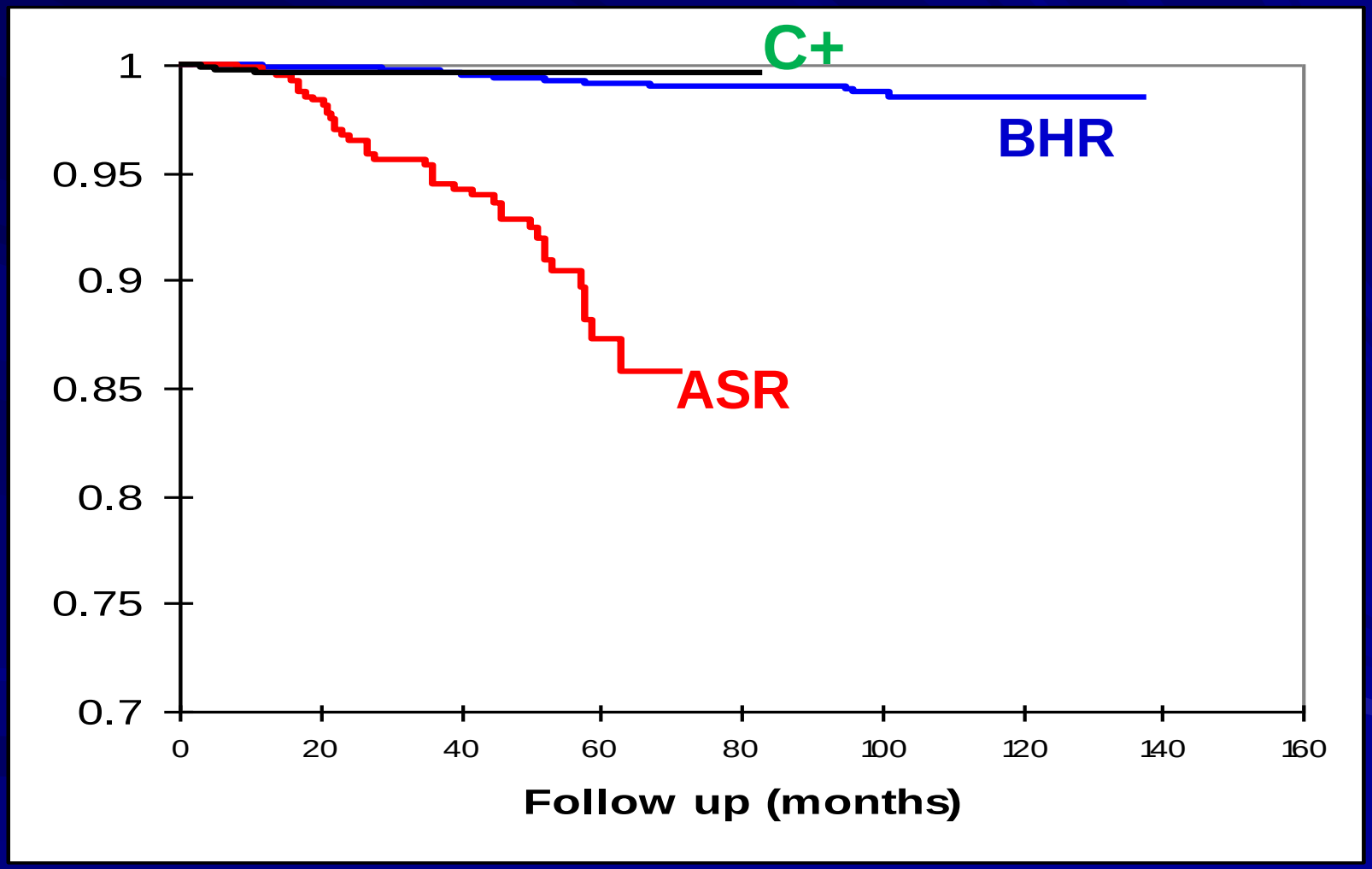
20µg/L

Metalosis

Variables influencing metal ion concentrations in hip resurfacings

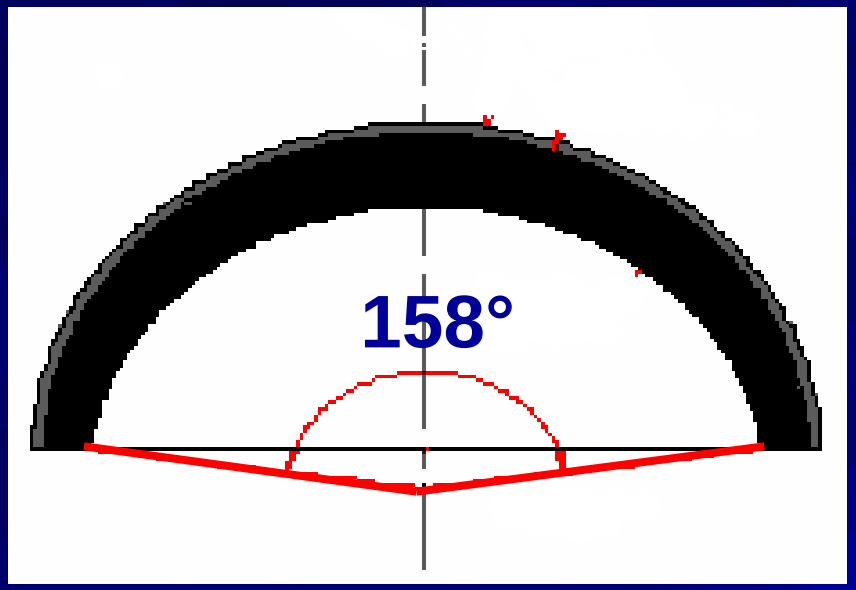
- The device
- Bearing diameter
- Cup orientation

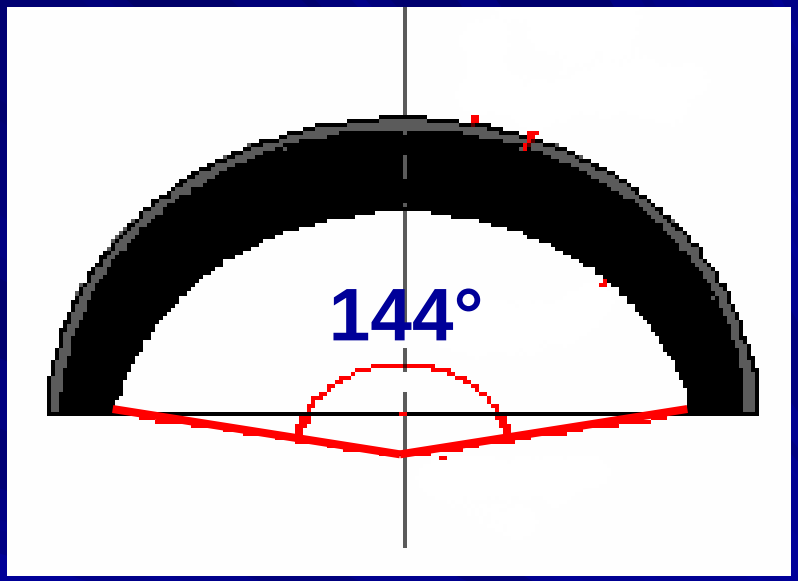
Are all hip resurfacings the same? (multi-centre study of 4,226 hips)



Langton et al, JBJS (UK), Feb 2011, 93B, 164-171

What explains these differences?





BHR

ASR

Conserve Plus coverage 163°

Failures by bearing diameter

- Bearing diameter is the diameter of the femoral head component
- For ASR resurfacings, small diameters fail more quickly (one of the reasons why more failures are seen in women – women tend to have smaller pelvises than men)
- For ASR XL THR failures occur at all diameters – metal wear debris arises from the articulating surface and/or the taper junction

Factors for revision at North Tees

1. Pain
2. Blood chromium and cobalt
3. Scan
4. Aspiration
   - Volume of fluid
   - Hip metal ion levels

Lessons from THR history

Device	Number implanted	Impact
Capital 3M hip (1998)	5,000	Introduction of National Joint Registry
Sulzer hip (2001)	21,000	$1.2 billion – end of Sulzer Medica
De Puy ASR™ (2010)	96,000	?????

The Articular Surface Replacement (ASR™) artificial hip joint

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1st October 2011

FUNDED BY

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