Tribology and *ex vivo* analysis: hip and knee prostheses

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A clinical and engineering collaboration

Title / Author	Cited by	Year
Early failure of metal-on-metal bearings in hip resurfacing and large-diameter total hip replacement: A CONSEQUENCE OF EXCESS WEAR DJ Langton, SS Jameson, TJ Joyce, NJ Hallab, S Natu, AVF Nargol Journal of Bone & Joint Surgery, British Volume 92 (1), 38-46	234	2010
The effect of component size and orientation on the concentrations of metal ions after resurfacing arthroplasty of the hip DJ Langton, SS Jameson, TJ Joyce, J Webb, AVF Nargol Journal of Bone & Joint Surgery, British Volume 90 (9), 1143-1151	166	2008
Blood metal ion concentrations after hip resurfacing arthroplasty A COMPARATIVE STUDY OF ARTICULAR SURFACE REPLACEMENT AND BIRMINGHAM HIP RESURFACING ARTHROPLASTIES DJ Langton, AP Sprowson, TJ Joyce, M Reed, I Carluke, P Partington, AVF Nargol Journal of Bone & Joint Surgery, British Volume 91 (10), 1287-1295	106	2009
Adverse reaction to metal debris following hip resurfacing the influence of component type, orientation and volumetric wear DJ Langton, TJ Joyce, SS Jameson, J Lord, M Van Orsouw, JP Holland, AVF ... Journal of Bone & Joint Surgery, British Volume 93 (2), 164-171	90	2011
Accelerating failure rate of the ASR total hip replacement DJ Langton, SS Jameson, TJ Joyce, JN Gandhi, R Sidaginamale, P Mereddy, J ... Journal of Bone & Joint Surgery, British Volume 93 (8), 1011-1016	87	2011

Overview

- Tribology
- Why undertake *ex vivo* analysis
- Hip prostheses
- Knee prostheses

TRIBOLOGY

Tribology fundamentals

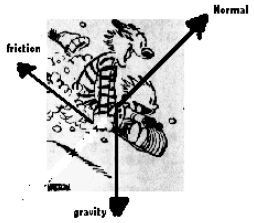
Jin et al, *Biotribology*, Current Orthopaedics, 2006, 20, 1, 32-40

Joyce, *Biopolymer Tribology*, in *Polymer Tribology*, Imperial College Press, 2009, 227-266

Definition of tribology

- Tribology, from the Greek *tribos* 'to rub'
- The science of interacting surfaces in relative motion, including friction, lubrication and wear
- Biotribology is this science related to the body
- Primarily synovial joints and replacement joints

Friction



Friction (1)

- Friction force is a resistance to motion
- With no lubricant:
  - Friction force is proportional to normal force F = μN
  - Friction is independent of velocity
  - Friction is independent of apparent contact area
  - Friction is dependent on real contact area (1 to 0.0001% of apparent contact area)

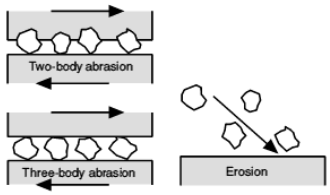
Friction (2)

- Friction force (F) = $F_{adhesion} + F_{ploughing}$

Due to chemical bonding at the asperity contacts

Due to breaking and deforming of one asperity by another

Wear



Wear (1)

- Wear is the progressive loss of material from a surface. Various wear regimes:
  - Adhesive – due to bonding
  - Abrasive – due to hard asperities
  - Fatigue – due to cyclic stresses
  - Erosive – due to relative motion with a fluid containing hard particles
  - Corrosive – due to chemical reactions

May occur singly or in combination

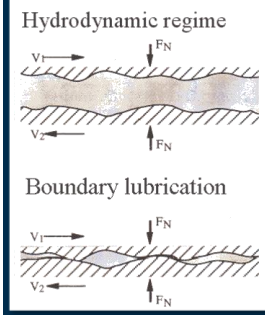
Wear (2)

- Wear can be measured as a depth, but volume is much better
- Generally wear volumes:
  - Increase with load
  - Increase with sliding distance
  - Increase with surface roughness
  - Decrease with surface hardness
- However, many other factors can be involved in the wear process

Lubrication

Adds a fluid film to separate surfaces

Lubrication regimes



- Indicated by lambda ratio, λ
- Hydrodynamic lubrication (λ>3)
- Mixed lubrication (1<λ<3)
- Boundary lubrication (λ<1)
- Metal-on-polyethylene implants operate under boundary lubrication

Calculation of lubrication regimes

$$\lambda = \frac{h_{min}}{\left[(R_{a1})^2 + (R_{a2})^2\right]^{1/2}} \qquad \frac{h_{min}}{R_x} = 2.80\left(\frac{\eta u}{E^* R_x}\right)^{0.65}\left(\frac{w}{E^* R_x^2}\right)^{-0.21}$$

- R_{a1} and R_{a2} are the surface roughness values of each component, h_{min} is the minimum effective film thickness, R_x is the equivalent radius (m), η is the viscosity of the lubricant (Pa s), u is the entraining velocity (m/s), E* is the equivalent elastic modulus (Pa), and w is the load (N)

$$\frac{1}{R_x} = \frac{1}{R_1} - \frac{1}{R_2} \qquad \frac{1}{E^*} = 0.5\left(\frac{1-\nu_1^2}{E_1} + \frac{1-\nu_2^2}{E_2}\right)$$

Calculation of lubrication regimes

Implant type	Dia. (mm)	Roughness, head and cup (nm Ra)	Lubrication regime (λ value)
Metal-on-polymer total hip replacement	28		
Metal-on-metal total hip replacement	28		
Metal-on-metal hip resurfacing	52		

Calculation of lubrication regimes

Implant type	Dia. (mm)	Roughness, head and cup (nm Ra)	Lubrication regime (λ value)
Metal-on-polymer total hip replacement	28	20, 1500	
Metal-on-metal total hip replacement	28	20, 20	
Metal-on-metal hip resurfacing	52	20, 20	

Calculation of lubrication regimes

Implant type	Dia. (mm)	Roughness, head and cup (nm Ra)	Lubrication regime (λ value)
Metal-on-polymer total hip replacement	28	20, 1500	Boundary lubrication (λ<1)
Metal-on-metal total hip replacement	28	20, 20	Mixed lubrication (1<λ<3)
Metal-on-metal hip resurfacing	52	20, 20	Fluid film lubrication (λ>3)

Different Hip Resurfacing Designs

Implant	Revision rate at 5 years
ASR	13.8%

Source: National Joint Registry for England and Wales 2012

Different Hip Resurfacing Designs

Implant	Revision rate at 5 years
ASR	13.8%
BHR	3.7%

Source: National Joint Registry for England and Wales 2012

Different Hip Resurfacing Designs

Implant	Revision rate at 5 years
ASR	13.8%
BHR	3.7%
Conserve +	8.5%

Source: National Joint Registry for England and Wales 2012

Different Hip Resurfacing Designs

Implant	Revision rate at 5 years
ASR	13.8%
BHR	3.7%
Conserve +	8.5%
Durom	6.0%

Source: National Joint Registry for England and Wales 2012

Why *ex vivo* analysis?

- To learn from failures to prevent future failures
- Patients get better implants
- Costs reduced due to fewer revision operations
- Failure could be due to:
- Design defect
- Poor surgical instruments/training
- Ensure the orthopaedic surgeon doesn't mistakenly get blamed

HIPS

The Lancet 2007

The operation of the century: total hip replacement

Ian D Learmonth, Claire Young, Cecil Rorabeck

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
- National Joint Registry (NJR) 2012 – 97.7% survival rate at 8 years (cemented hips)

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Mail on Sunday 24 Oct 2010

DePuy ASR™

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November 2011

- Australian Senate report
- "The committee is deeply disturbed by what appears to be tardiness on the part of JJM to act on known problems with these devices. Many people could have avoided considerable pain, suffering and diminished quality of life if the company had acted in a responsible manner"

The Senate

Community Affairs References Committee

The regulatory standards for the approval of medical devices in Australia

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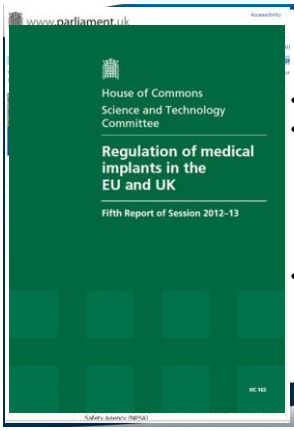
May/Nov 2012



- UK Government
- *"When things go wrong with implants it can ruin lives— as the complications with metal-on-metal hip replacements have sadly shown"*
- *"Much greater transparency is needed about the approval process"*

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2013

Monitoring the Introduction and Performance of a Joint Replacement: The United Kingdom Metal-on-Metal Alert

JBJS (US) 2011

Keith Tucker, FRCS, Paul Gregg, MD, FRCS, Peter Kay, FRCS, Martyn Porter, FRCS, Peter Howard, FRCS, Martin Pickford, PhD, and Crina Cacou, PhD

Investigation performed at the National Joint Registry of England and Wales

- "Data critical of the performance of the ASR were presented at numerous scientific meetings in 2008 and onward to the time of this writing, particularly at meetings of the British Hip Society (BHS) and the British Orthopaedic Association (BOA). This factor, rather than the MHRA alert in July 2010, almost certainly led to the subsequent drop in sales of that implant"

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Who criticised ASR in 2008?

- *Hip resurfacing in females – are we under-diagnosing metal hypersensitivity?* DJ Langton, SS Jameson, T Joyce, J Webb, AVF Nargol. British Hip Society, Norwich, February 2008
- *Analysis of ex vivo resurfacing hip prostheses and comparison with clinical data.* TJ Joyce, D Langton, S Jameson, AVF Nargol. British Orthopaedic Research Society, Manchester, June 2008
- *Analysis of failed metal-on-metal resurfacing hip prostheses.* TJ Joyce, DJ Langton, SS Jameson, AVF Nargol. Bath Biomechanics Symposium, Bath, 15 September 2008
- *Reducing exposure to metal ions following hip resurfacing: the importance of acetabular orientation*. DJ Langton, SS Jameson, TJ Joyce, J Webb and A V F Nargol. British Orthopaedic Association 2008 annual congress, Liverpool, September 2008
- *Early aseptic failure of large metal-on-metal hip arthroplasty – is metal sensitivity a consequence of excess wear?* DJ Langton, SS Jameson, TJ Joyce, J Webb, AVF Nargol. British Orthopaedic Association 2008 annual congress, Liverpool, September 2008

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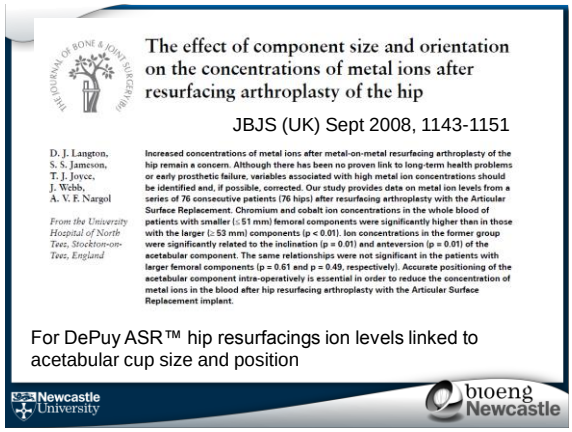

The effect of component size and orientation on the concentrations of metal ions after resurfacing arthroplasty of the hip

JBJS (UK) Sept 2008, 1143-1151

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.

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

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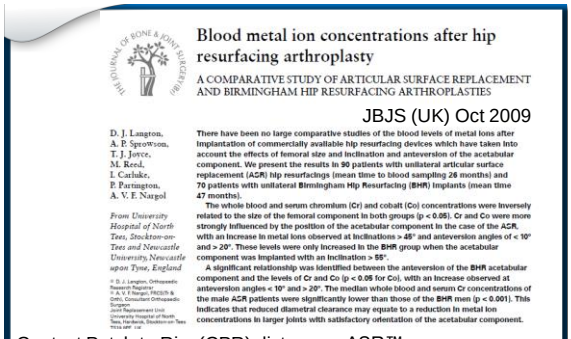

Blood metal ion concentrations after hip resurfacing arthroplasty

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

JBJS (UK) Oct 2009

D. J. Langton, A. P. Sprowson, T. J. Joyce, M. Reed, I. Carluke, P. Partington, A. V. F. Nargol

From University Hospital of North Tees, Stockton-on-Tees and Newcastle University, Newcastle upon Tyne, England

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.

Contact Patch to Rim (CPR) distance – ASR™ cups more sensitive to position than BHR: explains differences in clinical results

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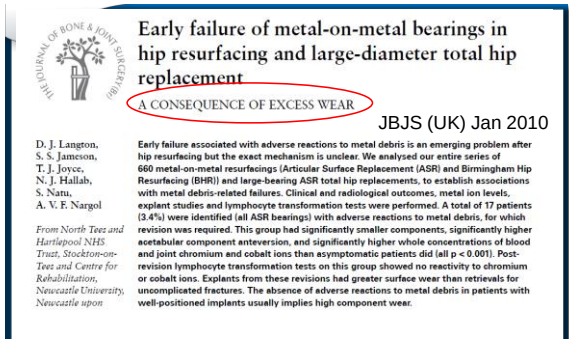

Early failure of metal-on-metal bearings in hip resurfacing and large-diameter total hip replacement

A CONSEQUENCE OF EXCESS WEAR

JBJS (UK) Jan 2010

D. J. Langton, S. S. Jameson, T. J. Joyce, N. J. Hallab, S. Natu, A. V. F. Nargol

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.

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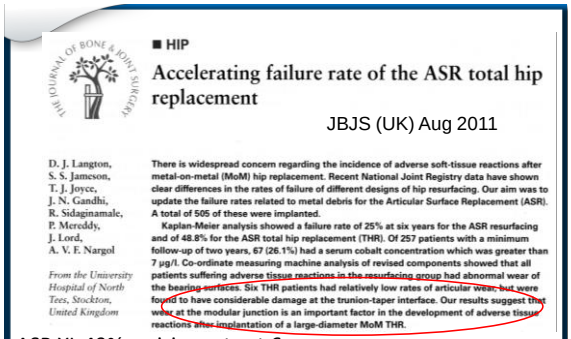

■ HIP

Accelerating failure rate of the ASR total hip replacement

JBJS (UK) Aug 2011

D. J. Langton, S. S. Jameson, T. J. Joyce, J. N. Gandhi, R. Sidaginamale, P. Mereddy, J. Lord, A. V. F. Nargol

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.

ASR XL 49% revision rate at 6 yrs

Identification of damage at taper interface

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■ HIP

Taper junction failure in large-diameter metal-on-metal bearings

D. J. Langton, R. Sidaginamale, J. K. Lord, A. V. F. Nargol, T. J. Joyce

From Newcastle University, Newcastle upon Tyne, United Kingdom

Objectives

An ongoing prospective study to investigate failing metal-on-metal hip prostheses was commenced at our centre in 2008. We report on the results of the analysis of the first consecutive 126 failed mated total hip prostheses from a single manufacturer.

Methods

Analysis was carried out using highly accurate coordinate measuring to calculate volumetric and linear rates of the articular bearing surfaces and also the surfaces of the taper junctions. The relationship between taper wear rates and a number of variables, including bearing diameter and orientation of the acetabular component, was investigated.

- Bone & Joint Research, 2012, 1, 4, 56-63
- Measurement of taper wear volumes

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SPECIAL ISSUE PAPER 317

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

T J Joyce[1*], D J Langton[2], S S Jameson[2], and A V F Nargol[2]
[1]Centre for Rehabilitation and Engineering Studies, School of Mechanical and Systems Engineering, Newcastle University, Newcastle upon Tyne, UK
[2]Joint Replacement Unit, University Hospital of North Tees, Hardwick, Stockton-on-Tees, UK

The manuscript was received on 21 July 2008 and was accepted after revision for publication on 8 January 2009.
DOI: 10.1243/13506501JET484

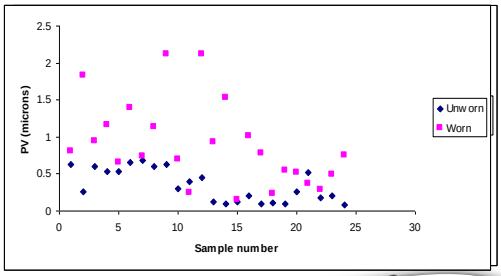
J Engineering Tribology, 2009, 317-323

Failed ASR™ resurfacing hips had roughened in the body

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

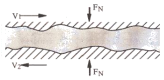
Roughness values: worn vs unworn areas of ASR™ femoral heads



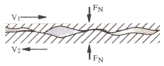
Summary of roughness results

- Typical changes 15nm Ra to 60nm Ra
- Results in change from hydro-dynamic to boundary lubrication
- In boundary lubrication, wear volume (V) is proportional to sliding distance (D)
- Hip resurfacings are large diameter, so wear could occur over a large sliding distance giving high wear volumes ....

Hydrodynamic regime

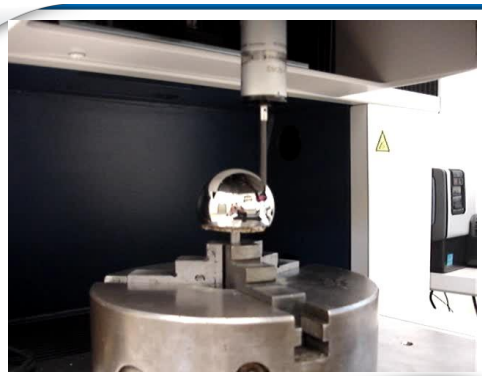


Boundary lubrication

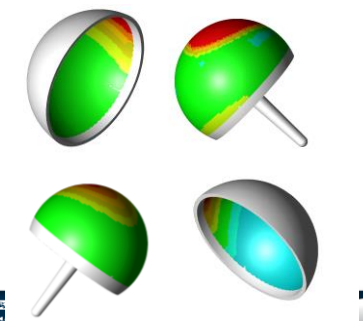


$V = KFD$

V = Volume lost (mm^3)
K = Wear factor ($x10^{-6} mm^3/Nm$)
F = Load (N)
D = Sliding distance (m)



Failed ASR™ resurfacings



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

Questions to you

- What is an acceptable wear rate *in vivo* for a metal-on-metal hip?
- How do you measure this wear *in vivo*?

Wear 272 (2011) 79–87

Contents lists available at ScienceDirect

Wear

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

Volumetric wear assessment of failed metal-on-metal hip resurfacing prostheses

J.K. Lord[a,*], D.J. Langton[a], A.V.F. Nargol[b], T.J. Joyce[a]

[a] School of Mechanical & Systems Engineering, Stephenson Building, Claremont Road, Newcastle University, Newcastle upon Tyne NE1 7RU, England, UK
[b] Joint Replacement Unit, University Hospital of North Tees, Hardwick Road, Stockton TS19 8PE, UK

- For ASR explants, average wear 18mm^3/year
- 3mm^3/year as 'tipping point' above which failure occurs

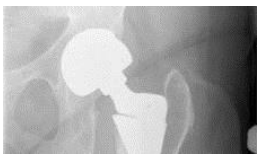
Could *in vitro* wear testing of the ASR identified high wear?

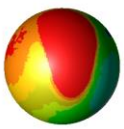
Tribology and Wear of Metal-on-Metal Hip Prostheses: Influence of Cup Angle and Head Position

Sophie Williams, Ian Leslie, Graham Isaac, Zhongmin Jin, Eileen Ingham and John Fisher
J Bone Joint Surg Am. 2008;90:111-117. doi:10.2106/JBJS.H.00485

- Small resurfacing ASR tested at 55° inclination by Leeds University/DePuy
- 9mm^3/million cycles wear (90x > large ASRs at 45°)
- Resurfacing patients do 1.9 million steps p.a.
- Average wear ASR resurfacing explants 18mm^3/year (Lord *et al*, Wear, 2011)
- Hip simulators can provide clinically relevant results

ASR™ XL femoral head

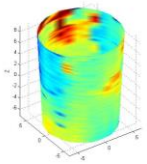




- Female patient, ASR™, failure at 35 months
- 45.5mm diameter, inclination 60°, anteversion 31°: Co 32.2µg/L, Cr 22.0µg/L
- Red area shows at least 20µm of wear depth, wear volume from head 20.2mm^3

Wear at taper junction ASR™ XL

- 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

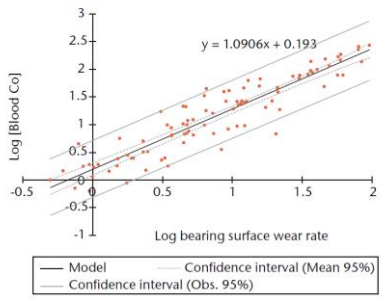


Light blue shows unworn areas

Langton et al, BJR, 2012, 56-63

A WORD ON IONS

Plot wear rate v blood Co



The 'cobalt ladder'

Whole blood Cobalt	Interpretation
<1µg/l	93% of population

The 'cobalt ladder'

Whole blood Cobalt	Interpretation
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<2µg/l	Values are near to background. Expected wear of MoM resurfacings

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>5.6µg/l	100% specific for abnormal wear
>10µg/l	Abnormal wear unequivocal

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4.5 to 5.6µg/l	High specificity for abnormal wear
>5.6µg/l	100% specific for abnormal wear
>10µg/l	Abnormal wear unequivocal
>20µg/l	Metal staining of the joint

Bone Joint Research, 2013, 2, 84-95

BJR

HIP

Blood metal ion testing is an effective screening tool to identify poorly performing metal-on-metal bearing surfaces

R. P. Sidaginamale, T. J. Joyce, J. K. Lord, R. Jefferson, P. G. Blain, A. V. F. Nargol, D. J. Langton

Objectives
The aims of this piece of work were to: 1) record the background concentrations of blood chromium (Cr) and cobalt (Co) concentrations in a large group of subjects; 2) to compare blood/serum Cr and Co concentrations with retrieved metal-on-metal (MoM) hip resurfacings; 3) to examine the distribution of Co and Cr in the serum and whole blood of patients with MoM hip arthroplasties; and 4) to further understand the partitioning of metal ions between the serum and whole blood fractions.

Open Access Research

BMJ open

The clinical implications of elevated blood metal ion concentrations in asymptomatic patients with MoM hip resurfacings: a cohort study

David J Langton, Raghavendra P Sidaginamale, Thomas J Joyce, Shonali Natu, Peter Blain, Robert Drysdale Jefferson, Stephen Rushton, Antoni V F Nargol

To cite: Langton DJ, Sidaginamale RP, Joyce TJ, *et al*. The clinical implications of elevated blood metal ion concentrations in asymptomatic patients with MoM hip resurfacings: a cohort study. *BMJ Open* 2013;**3**:e001541. doi:10.1136/bmjopen-2012-001541

ABSTRACT
Objective: To determine whether elevated blood cobalt (Co) concentrations are associated with early failure of metal-on-metal (MoM) hip resurfacings secondary to adverse reaction to metal debris (ARMD).
Design: Cohort study.
Setting: Single centre orthopaedic unit.
Participants: Following the identification of complications potentially related to metal wear debris, a blood metal ion screening programme was instigated

ARTICLE SUMMARY

Article focus

- Current Food and Drug Administration guidance for the management of patients with MoM hips states that 'the utility of routine screening of asymptomatic patients using blood metal ion testing has not been established.'
- This study sought to document the clinical course of asymptomatic patients with elevated

KNEES

Background

- Knee replacements are the most common joint replacement procedure in the UK and the world
- The number of operations increases every year and cannot solely be explained by an increasing and ageing population
- A proportion do fail, many of these are linked to wear particle induced osteolysis

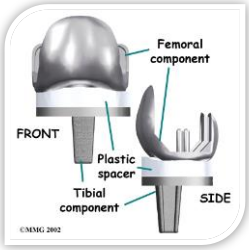
NJR 2012

National Joint Registry

Surgical data to 31st December 2011

- 84,643 knee joint replacement procedures in 2011
- Average patient age 68
- 56% female
- 98% osteoarthritis
- 5,137 revisions
- 6.1% revision burden

Total Knee Replacement (TKR) and Unicondylar



NJR 2012 – 91% TKR,
1% patello-femoral replacement,
8% unicondylar

93% fixed, 7% mobile

30% fixed, 70% mobile

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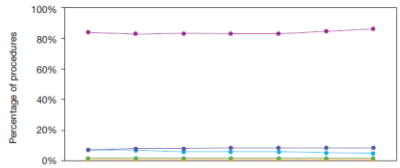
Figure 2.17

Type of primary knee replacement procedures undertaken between 2005 and 2011.



Year	2005	2006	2007	2008	2009	2010	2011
TKR using cement	84%	83%	83%	83%	83%	85%	86%
TKR not using cement	7%	7%	6%	6%	6%	5%	4%
TKR Hybrid	1%	1%	1%	1%	1%	<1%	<1%
Patello-femoral	1%	1%	1%	1%	1%	1%	1%
Unicondylar	7%	8%	8%	8%	8%	8%	8%
Number of procedures	59,385	62,327	73,523	77,624	78,832	81,042	79,516

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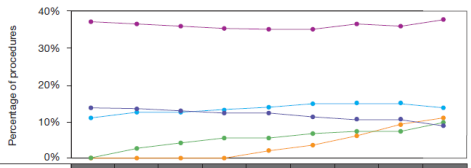
Figure 2.24

Top five total condylar knee brands, trends 2003 to 2011.



Year	2003	2004	2005	2006	2007	2008	2009	2010	2011
Number of components used	21,624	40,837	53,519	54,755	64,624	68,232	69,255	71,217	70,451

PFC Sigma — Nexgen — Triathlon — Genesis 2 — AGC

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NJR 2012

Figure 3.6

Risk of revision following primary knee replacement (cumulative hazard with 95% confidence intervals), by prosthesis type.

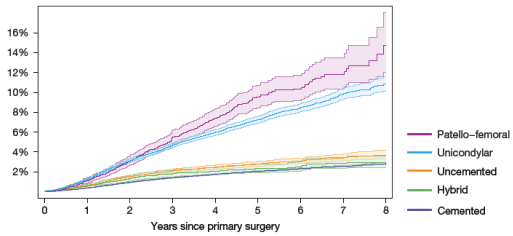

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Table 3.17 Estimated medium-term revision rates after primary knee replacement by fixation, constraint and bearing type (95% confidence intervals).

	Year 4	Year 5	Year 6	Year 7	Year 8
All cemented	1.74% (1.69-1.79)	2.04% (1.98-2.10)	2.30% (2.24-2.36)	2.55% (2.47-2.64)	2.82% (2.71-2.94)
Cemented, unconstrained, fixed	1.58% (1.52-1.64)	1.84% (1.77-1.91)	2.10% (2.02-2.19)	2.34% (2.24-2.44)	2.62% (2.48-2.77)
Cemented, unconstrained, mobile	2.25% (2.03-2.48)	2.56% (2.32-2.83)	2.73% (2.47-3.03)	2.92% (2.61-3.26)	3.13% (2.72-3.62)
Cemented, posterior-stabilised, fixed	1.87% (1.77-1.96)	2.25% (2.13-2.38)	2.52% (2.38-2.67)	2.79% (2.62-2.96)	3.09% (2.86-3.35)
Cemented, posterior-stabilised, mobile	2.60% (2.19-3.09)	2.94% (2.48-3.50)	3.43% (2.86-4.11)	3.63% (2.96-4.46)	3.63% (2.96-4.46)
All uncemented	2.45% (2.24-2.67)	2.78% (2.55-3.04)	3.09% (2.82-3.38)	3.44% (3.11-3.81)	3.69% (3.29-4.14)
All hybrid	2.03% (1.69-2.43)	2.30% (1.93-2.75)	2.49% (2.08-2.98)	2.84% (2.36-3.43)	2.95% (2.43-3.59)
Uncemented/hybrid, unconstrained, fixed	2.21% (1.97-2.47)	2.44% (2.18-2.74)	2.60% (2.31-2.92)	3.02% (2.65-3.44)	3.08% (2.69-3.53)
Uncemented/hybrid, unconstrained mobile	2.32% (2.04-2.63)	2.67% (2.35-3.03)	2.96% (2.60-3.37)	3.17% (2.77-3.64)	3.44% (2.91-4.07)
All unicondylar	5.90% (5.67-6.14)	7.24% (6.90-7.59)	8.46% (8.05-8.90)	9.64% (9.30-10.42)	10.62% (10.10-11.59)
Unicondylar, fixed	6.09% (5.52-6.73)	7.23% (6.55-7.98)	8.39% (7.57-9.31)	9.38% (8.35-10.54)	10.14% (8.84-11.63)
Unicondylar, mobile	5.98% (5.65-6.32)	7.32% (6.93-7.74)	8.55% (8.07-9.06)	10.04% (9.40-10.71)	11.06% (10.24-11.99)
All patello-femoral	7.40% (6.57-8.34)	9.51% (8.45-10.71)	10.36% (9.17-11.70)	11.81% (10.33-13.51)	14.70% (12.01-18.00)
Other/Unknown	3.70% (3.09-4.44)	4.24% (3.55-5.08)	4.72% (3.93-5.66)	5.42% (4.45-6.59)	6.02% (4.81-7.53)
All types	2.23% (2.18-2.29)	2.64% (2.58-2.70)	2.99% (2.92-3.07)	3.36% (3.27-3.45)	3.71% (3.59-3.84)

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Indications for knee revision surgery (NJR 2012 p103)

Aseptic loosening	**35%**
Pain	16%
Lysis	10%
Wear of PE component	10%
Instability	14%
Infection	23%
Malalignment	7%
Stiffness	5%
Progressive arthritis remaining	8%
Others	17%

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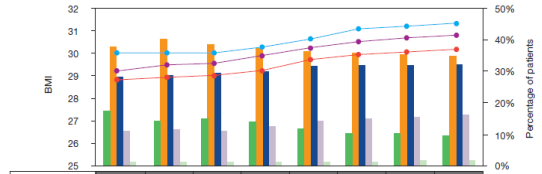
Australian Joint Registry 2012

Table KT6: Primary Total Knee Replacement by Reason for Revision

Reason for Revision	Number	Percent
Loosening/Lysis	2960	30.0
Infection	2145	21.7
Patellofemoral Pain	1339	13.6
Pain	886	9.0
Instability	577	5.8
Arthrofibrosis	376	3.8
Fracture	234	2.4
Malalignment	213	2.2
Patella Erosion	199	2.0
Incorrect Sizing	148	1.5
Wear Tibial Insert	140	1.4
Metal Sensitivity	130	1.3
Other	533	5.4
TOTAL	9880	100.0

But (1) Heavier patients

BMI for primary knee replacement patients between 2004 and 2011.

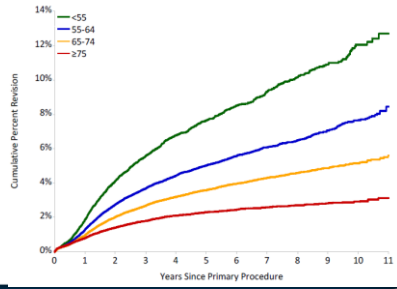


Year	2004	2005	2006	2007	2008	2009	2010	2011
Average BMI -all patients	29.25	29.45	29.53	29.85	30.28	30.54	30.66	30.82
Average BMI -female	30.02	29.96	29.97	30.32	30.72	31.04	31.15	31.34
Average BMI -male	28.78	28.92	28.97	29.25	29.7	29.89	30.04	30.16

But (2) Younger patients

- There has been a dramatic increase in the number of knees implanted in the 45-64 age group from 2000 to 2008
- Likely subject to more wear
- "the greater risk of implant failure in younger patients, coupled with longer remaining life expectancy in this age group, will combine to produce even higher rates of revision" (Losina 2012)

Australian Joint Registry 2012 Knee revision rates by patient age



Why *ex vivo* analysis of knee implants?

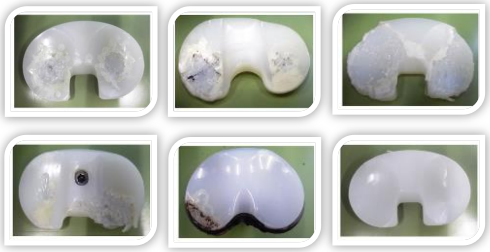
- There are no standard techniques to quantify *in vivo* wear rates and track the clinical performance of UHMWPE components in knee replacements
- The most effective way to evaluate the *in vivo* performance of UHMWPE continues to be the analysis of retrieved components from revision surgery or autopsy

How to undertake *ex-vivo* analysis of knee implants?

- Semi-quantitative Hood analysis of UHMWPE articulating and non-articulating surfaces
- Roughness and surface topography of femoral (metal) articulating surfaces
- Roughness and surface topography of articulating and backside of tibial UHMWPE insert
- Roughness and surface topography of (metal) tibial tray

Mitutoyo Quick Scope vision measuring microscope

Ex-Vivo Analysis UHMWPE



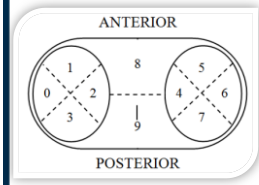
Selection of six retrieved Total Knee Replacement PE components with varying levels of macroscopic surface damage

Hood[1] Analysis: Surface Damage Modes

1. **Surface Deformation** - Areas where there is evidence of permanent deformation occurring on or around the articulating surface
2. **Pitting** - Depressions in the articulating surface
3. **Embedded Debris** - Recognised by a colour and/or texture difference
4. **Scratching** - Indented lines generally found in an anterior-posterior direction and the areas of wear
5. **Burnishing** - Areas that have become highly polished
6. **Abrasion** - Areas in which the UHMWPE has a shredded or tufted appearance
7. **Delamination** - Areas in which a large sheet of UHMWPE has been removed with evidence around the periphery of a subsurface failure mechanism occurring parallel to the articulating surface

1. Hood et al *JBiomedMatRes1983 Retrieval analysis of total knee prostheses: A method and its application to 48 total condylar prostheses*

Hood Analysis



- Tibial UHMWPE articulating surface divided into 10 sections
- In each section a score 0, 1, 2 or 3 is given for each surface damage mode
  - 0 = Damage mode not observed
  - 1 = Damage mode observed on <10%
  - 2 = Damage mode observed 10-50%
  - 3 = Damage mode observed >50%
- Total degradation score = sum of all surface damage mode scores for all 10 sections
- Maximum degradation score = 210 (i.e. 3 x 10 x 7 = 210)

Hood Analysis

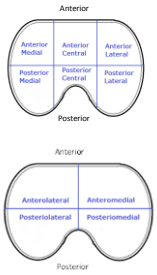
KXXX Hood Analysis	
Assessor:	A Other
Date:	xx/xx/xx

	0	1	2	3	4	5	6	7	8	9	
Surface Deformation											
Pitting											
Embedded Debris											
Scratching											
Burnishing											
Abrasion											
Delamination											
											TOTAL

Hood Analysis Limitations

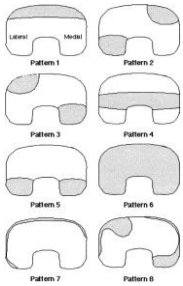
- Inter- and Intra- Observer variability
- Semi-quantitative
- Grade bands too broad?
- Total score gives no indication of location of wear

Backside wear



- Important as smaller, more reactive PE particles produced here (Conditt et al, 2005)
- Rao et al 2002, 6 sections + each of the 7 Hood damage modes, graded 0-3
- Conditt et al 2005, 4 sections

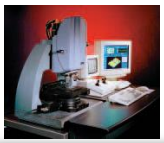
Backside wear



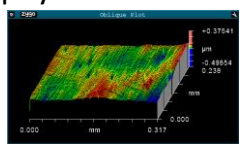
- Wasielewski et al (2004)
- Identification patterns for backside wear
- Same 7 damage modes are used as in the Hood analysis

Ex-vivo analysis: surface topography

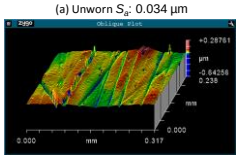
- Roughness and surface topography measurements are taken using a Zygo NewView 5000 non-contacting 3D profilometer
- Vertical resolution of better than one nanometre
- Measurements include
  - S_q – *Root Mean Squared Roughness*
  - S_a – *Average Roughness*
  - S_{sk} – *Roughness Skew*



Surface topography – femoral

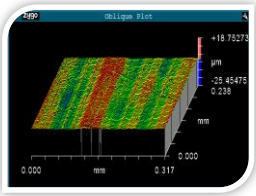


(a) Unworn S_a: 0.034 µm

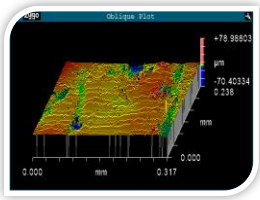


(b) Worn S_a: 0.324 µm

Ex-Vivo Analysis
Surface Topography - UHMWPE



(a)



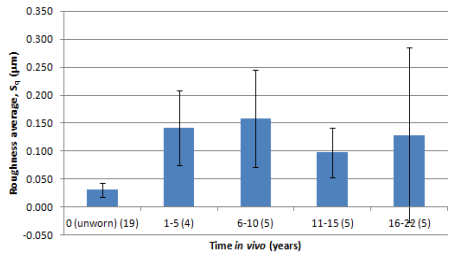
(b)

Surface topography of a UHMWPE Tibial component (a) un-worn area (S_a: 0.311 µm) and (b) worn area (S_a: 1.467 µm)

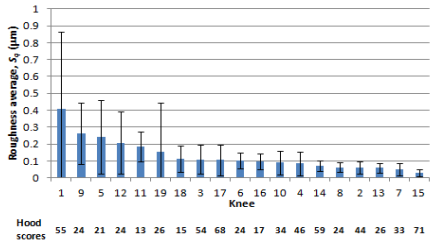
PILOT STUDY RESULTS (THANKS TO FREEMAN HOSPITAL FOR SUPPLY OF EXPLANTS)

Knee	Age at Revision	BMI	Sex	Right or Left	Time in vivo (years)	Cemented (C) or uncemented (U)	Knee Type	Indication for revision
1	81	27.5	M	R	20	U	Stryker Kinematic	Aseptic loosening
2	72	29.5	M	R	19	C	Smith and Nephew Genesis	Wear of UHMWPE, periprosthetic fracture
3	72	21.5	M	R	12	C	Stryker Kinemax	Infection
4	72	29.5	F	R	7	C	Plus Orthopaedics TC Plus	Wear of UHMWPE
5	56	28.5	M	R	7	C	Stryker Kinemax	Loosening
6	90	27	F	L	7	C	Biomet Maxim	Instability
7	55	26	M	R	22	C	Stryker Kinemax Plus	Infection
8	80	24	F	L	1	C	Biomet AGC V2 HPS	Instability, aseptic loosening, periprosthetic fracture
9	73	41.7	M	L	6	C	Biomet Dual Articular 2000	Infection
10	73	30	F	L	13	C	Stryker Kinemax	Wear of UHMWPE
11	77	25	M	R	2	C	DePuy Noiles S-ROM rotating hinge	Infection
12	79	31.5	M	R	5	C	DePuy PFC Sigma	Infection
13	85	NK	F	R	20	C	Biomet AGC V2 HPS	Tibial loosening
14	82	25	M	L	19	C	Stryker Kinematic	Aseptic loosening and wear
15	79	32.7	M	L	14	C	Stryker Kinemax	Aseptic loosening
16	79	NK	F	R	7	C	DePuy PFC Sigma	Infection
17	67	32	F	L	13	C	Stryker Kinemax	Wear of UHMWPE
18	67	38	M	R	3	C	DePuy PFC Sigma	Fixed flexion, tight anterior compartment
19	49	33	F	L	14	U	Exactech Optetrak	Tibial loosening

Roughness femoral v time in vivo

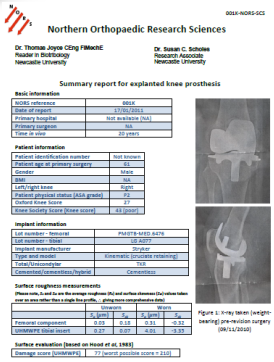


Roughness femoral v Hood score



Summary of pilot study results

- All femoral components were shown to be up to 11x rougher
- Mostly, this roughness was more apparent on the lateral condyle than the medial
- Increase in roughness occurred relatively soon after implantation


001K-NORS-SCS

Northern Orthopaedic Research Sciences

Dr. Thomas Joyce CEng FIMechE
Reader in Biotribology
Newcastle University

Dr. Susan C. Scholes
Research Associate
Newcastle University

Summary report for explanted knee prosthesis

Basic information

NORS reference	001K
Date of report	17/01/2011
Primary hospital	Not available (NA)
Primary surgeon	NA
Time in vivo	10 years

Patient information

Patient identification number	Not known
Patient age at primary surgery	61
Gender	Male
BMI	NA
Left/right knee	Right
Patient physical status (ASA grade)	P2
Oxford Knee Score	27
Knee Society Score (Knee score)	61 (poor)

Implant information

Lot number - femoral	PM1078-MED-8476
Lot number - tibial	LD A277
Implant manufacturer	Stryker
Type and model	Kinematic (cruciate retaining)
Total/Unicondylar	TKR
Cemented/cementless/hybrid	Cementless

Surface roughness measurements

(Please note, S_a used to see the average roughness (R_a) and surface skewness (S_{sk}) values taken over an area rather than a single line profile, ... giving more comprehensive data)

	Unworn		Worn	
	S_a [µm]	S_{sk}	S_a [µm]	S_{sk}
Femoral component	0.03	0.18	0.31	-0.32
UHMWPE tibial insert	0.27	0.07	0.01	-0.35

Figure 1: X-ray taken (weight-bearing) pre-revision surgery (09/11/2010)

Surface evaluation (based on Hood *et al*, 1983)

Damage score [UHMWPE]	77 (worst possible score = 210)

Results

Indication for revision surgery	Aseptic loosening [metalosis noted]
Suggested reason for failure	Surface observations suggest aseptic loosening due to wear particle induced osteolysis, along with fatigue failure indicated by delamination wear

- We continue to look at knee explants


Topographical analysis of the femoral components of ex vivo total knee replacements

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Materials in Medicine

Journal of Materials Science

- Examination of failed TKR

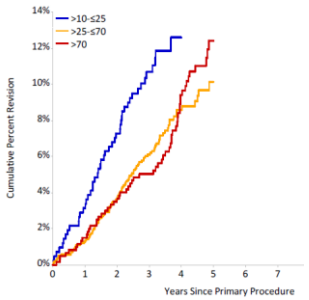
n.s.t.c.
Newcastle Surgical Training Centre

Freeman Hospital, Newcastle upon Tyne

DePuy LCS® Duofix™ knee

- Global revision rate 0.57%, higher in Australia, 1.34% revision rate (2009)
- DePuy recalled
- Willis-Owen, JBJS 2011, 8% revision rate
- "A complete explanation of the cause of this problem has not been made available by the manufacturer"
- Why not?

Australian Joint Registry 2012



- LCS Duofix knee
- By surgeon number of procedures/year
- >10-25: 10.7% revision rate at 3 yrs
- 26-70: 10.1% revision rate at 5 years
- >70: 12.4% revision rate at 5 years
- "2,614 procedures"

Overview

- Tribology
- Why undertake ex vivo analysis
- Hip prostheses
- Knee prostheses

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