Summaries from the
Advanced Bearing Surfaces Seminars
Held in Cape Town and Sandton, South Africa on 24 and 25 October 2012

“At Smith & Nephew we take great pride not only in what we do, but how we do it.”
I was involved in the Smith and Nephew advanced bearing surfaces in hip arthroplasty seminar as faculty chairman and in compiling the academic program. This meeting is significant for a number of reasons. It is not only a clinical meeting but includes plenty of the scientific basis for the clinical decisions orthopaedic arthroplasty surgeons make on a daily basis. Also the bearing surface is not a solved problem despite all the excellent options we have available including metal-on-metal, ceramic-on-ceramic and- metal, oxinium or ceramic on cross-linked polyethylene. The in-depth discussion and debate took us closer to solving the bearing surface problem especially when it comes to the young and active, patients with problematic morphology like dysplasia and diagnoses that traditionally have a poor prognosis with arthroplasty like avascular necrosis. We also examined what the future possibly holds in terms of oxinium on oxinium and combinations of ceramics and metal.

It was a privilege to work with a distinguished faculty comprising of some top hip surgeons from South Africa and around the world and eminent material scientists. The surgeons in the faculty were Profs. Robert Bourne (Canada) and Rajesh Malhotra (India); Drs. Robert McLennan Smith and Lipalo Mokete. The materials scientists were Dr. Gordon Hunter (USA) and Tim Band (UK). The talks were of high quality and the content relevant. The meeting was truly interactive with good panel discussion, debate and contributions from the delegates. It was certainly a very interesting, useful and worthwhile meeting.
Tim Band, United Kingdom
Since 2004 Tim has held the position of Global Director Advanced Bearing Systems for Smith & Nephew. In this role he manages Advanced Bearing Systems global business including Design, Development, Manufacturing, Logistics, Quality Regulatory and Marketing disciplines with overall responsibility for P&L. Tim is a regular contributor to Scientific Journals and has contributed chapters to Modern Hip Resurfacing, Edited by Derek McMinn, Aug 2007 and Adult Hip (Third Edition) Metal on Metal Articulations 2012.

Dr Rob McLennan-Smith, South Africa
Dr McLennan-Smith is an orthopaedic surgeon in private practice based at Westville hospital, Durban. He is a recognised Birmingham Hip resurfacing specialist who regularly participates in surgeon training. He has undertaken five international clinical trials and is a frequent speaker at local and international arthroplasty meetings. Dr McLennan-Smith specialises in total Hip Arthroplasty, revision Hip Arthroplasty, total Knee Arthroplasty and revision Knee Arthroplasty.
Dr McLennan-Smith is president-elect of the South African Arthroplasty Association and was a member of the SAOA Congress Committee, holding the Trade Portfolio.

Dr Bob Bourne, Canada
Dr Bourne is a Professor of Surgery at the University of Western Ontario. Although retired from clinical practice, he is still devoted to teaching and research. Dr Bourne has over 200 peer-reviewed publications to his credit. Dr Bourne is a past President of the Canadian Orthopaedic Association (2005-06) and the Hip Society (1998-99) and he was President of the Knee Society in 2011. Dr Bourne is actively involved with both clinical and basic science research. His primary interests are clinical trials, musculoskeletal imaging, wear studies, retrieval analyses and analysis of large data sets (i.e. Canadian Joint Replacement Registry).

Prof Rajesh Malhotra, India
Dr Rajesh Malhotra is Professor, Department of Orthopaedics AIIMS (All India Institute of Medical Sciences) New Delhi, which, in 2012, became the first centre in the country to introduce computer assisted total hip replacement. More than 65,000 total hip replacement procedures are performed annually in India and most of the patients needing hip replacement in India are young with greater risk of one or more revision surgeries in future. Prof Malhotra is a dedicated teacher and mentor with special interest in Joint Replacement Arthroplasty, Bone Banking, Osteoporosis and Paediatric Orthopaedics. He has authored 70 articles in peer-reviewed journals and contributed chapters to THE YEAR BOOK OF DIAGNOSTIC RADIOLOGY (1993) and THE YEAR BOOK OF ORTHOPEDICS (2003).

Dr Adriaan van Huyssteen, South Africa
Dr Adriaan van Huyssteen, is a Consultant Orthopaedic Hip and Knee Surgeon in Private Practice, Panorama MediClinic, Cape Town and works as visiting locum Consultant Orthopaedic Surgeon at the Royal Hospital Haslar, Portsmouth NHS Trust, England once a year. He is a founding member of the South African Society for Hip Arthroscopy and undertakes a variety of mentoring and training roles. He completed a Clinical Research Fellowship in Advanced Hip Surgery at the Avon Orthopaedic Centre, Southmead Hospital, Bristol and spent a year as a clinical fellow (specialist registrar level) at the Bristol Royal Infirmary and the Avon Orthopaedic Centre. Dr van Huyssteen has had many papers published in peer reviewed journals and has presented widely. He is currently involved in research relating to: the use of TMT in acetabular revision surgery, and hip replacement using large metal-on-metal bearing surfaces.
Dr Lipalo Mokete, South Africa
Dr Lipalo Mokete is Consultant Orthopaedic Surgeon at Charlotte Maxeke Johannesburg Academic Hospital. He is a lecturer in Orthopaedics at the University of the Witwatersrand and completed two fellowships: Lower Limb Arthroplasty Surgery – University of Western Ontario, Canada (2006) and Lower Limb Arthroplasty Surgery – Wits University / Johannesburg Hospital (2005). He contributed to a chapter entitled Noise Emissions in Total Hip Replacements, with an Emphasis on Ceramic-on-Ceramic and Ceramic-on-Metal Bearings and Different Articular Sizes. Tribology in Total Hip Arthroplasty, K Knahr (ed.) 2011 and has presented at a number of Arthroplasty and Orthopaedic meetings.

Dr Gordon Hunter, USA
Dr Hunter started his career in aviation engineering. In 1996 he joined Smith & Nephew where he has held the position of Group Manager, Materials Quality and Strategic Manufacturing since 2007. His role encompasses managing quality control of materials used in orthopaedic implants and instruments: assisting development and implementation of new materials and processes for orthopaedic implants; working on hard bearing surface, bone ingrowth surface, polyethylene, and powder metal technologies; and providing technology support for OXINIUM oxidized zirconium joint replacement prostheses. He earned the title “Dr Ox” for leading the development and initial commercial implementation of oxidized zirconium products for which he was awarded an ASMI Engineering Materials Achievement in 2005. Dr Hunter has developed twelve patents on oxidized zirconium technology and five patents on hearth melting techniques. He has published articles on biomaterials testing and metal processing in over fifty journals.

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Decline in use of metal on metal bearings

There has been a significant decline in the use of metal on metal bearings. It has been dramatic over the last four years, driven by the description of AVAL tumours by the David-Murray group in Oxford and the ASR experience. It has been catastrophic over the past 6 months following a leak of preliminary information from Patrick Case’s group in Bristol on a speculated increase in bladder cancer as a result of raised metal ions in the urine. This resulted in scare stories in the medical and popular press. Then we had the withdrawal of the large diameter MoM THR which added to the attrition. This created a perfect storm for metal on metal. To quote Mr Tracey, one of the designers of the Birmingham hip: “we have reached a catastrophic crossover of inconclusive research into the mainstream press, and it’s not been good for patients; it’s not been good for surgeons and it’s not been good for the medical profession”.

The leak of information from Bristol was from a study which was unsupported by large epidemiological analysis (unlike studies by Visuri, Jim Holland and authors of the NJR in the UK). This led to sensationalistic headlines in the tabloids and was even proliferated in the British Medical Journal with headlines such as: “How safe are metal on metal implants” and culminated in a news broadcast of an interview with the head of the MHRA in the UK entitled “New Hip Replacement Fails and Poisons and is not tested.” The president of the British Orthopaedic Association put out a statement saying that there was no verified evidence that metal on metal hip replacement increase risk of cancer and that it would be unwise to remove these replacements based only on the risk of cancer. This started to balance the media reports but the damage was already done.

Joint Registry Data

The UK National Joint Registry shows that in 2006, Resurfacing represented nearly 10% of all primary hips in the UK but usage declined over the past 2 years to around 2 or 3% for both Resurfacing and modular heads for MoM bearings. Nearly half the resurfacing patients are in the fit and healthy patient category; the average age for a hip resurfacing patient is 6 years younger than the average Arthroplasty patient. This makes comparisons of outcomes between bearing surfaces difficult since the resurfacing category has the most high demand patients.

A paper published in the British Medical Journal, called: “Mortality and Implant Revision Rates of hip Arthroplasty in Patients with Osteoarthritis”, showed that the mortality rate over a 6 year period was significantly lower for patients receiving a BHR™ than those receiving a cemented hip. This was a registry based cohort study, where thousands of patients were considered and the analysis accounted for patient’s age, gender and preoperative health scores. This is also true in the Australian Joint registry when adjustments are made for age and gender.

When Mr McMinn introduced the MoM hip resurfacing in the 1980’s, the primary objective was to provide at least 10 symptom free years of joint function, so that when patients reached the age of 65 or older they were suitable for a conventional total hip Arthroplasty. Excellent outcomes can be achieved by:

- correct patient selection
- good surgical technique
- optimal implant positioning
- optimised implant design

Optimised device design is multifactorial. It involves:

1. The bearing material and it’s metallurgy;
   - Successful implants were all made from high carbon cobalt chrome with no post-casting thermal treatment
2. Diametric clearance
   - Well performing resurfacing implants all have a gap of 200 - 250 microns between the femoral and acetabular components
   - Deformation occurs regularly during impaction; if this deformation reduces the diametric clearance, the bearing will be starved of fluid which will lead to increased friction and wear.
3. The articulation angle or bearing surface arch, also known as the subtend angle
   - The optimal subtend angle is between 100 & 166 degrees
   - No hip resurfacing device has a true hemispherical 180 degree articulation and some devices have an insertion mechanism with a locking mechanism inside the rim, creating a smaller arc of articulation.
4. Fixation – this is particularly important on the acetabular side because modification of the material microstructure during the porous coating process will affect performance.
The first Birmingham Hip Resurfacing was implanted in July 1997. It is enjoying its 15th year of clinical use and there have been over 150,000 procedures carried out around the world. The joint registries provide excellent clinical evidence.

The 2011 Australian Joint Registry shows a 7% revision rate at 10 years. This is all patients, all pathologies and all learning curves. The 2012 registry has a 0.4% change in survivorship.

The UK Joint Registry shows a 95% survivorship at 7 years.

In 2006 there were 18 different hip resurfacing devices on the market. Poor performing implants did not have the optimal design features

- The Cormet 2000 device has a titanium vacuum spray which requires thermal treatment of the cup.
- The Conserve Plus Cup from Wright medical has an attachment which requires multiple thermal treatments for the material to bond
- The Durom Device had a clearance very close to the limits of deformation experienced in vivo
- The ASR had different microstructure on the head compared to the cup as a consequence of post-casting treatment of the cup as well as low diametric clearance, but perhaps its biggest design flaw was the reduced sub-end angle

Peer Review for BHR

There is an extensive list of peer reviewed publications supporting the BHR device which have reported on short medium and now long term results for the device, from a truly global population of authors from the UK, Europe and Australia. Some of the cohorts are extremely large and the quoted survivorships are excellent.

To summarize all the data, nearly 13,5 thousand patients with nearly 2 million observed lives have been reported in that group. This accounts for nearly 10% of all BHRs implanted, excluding those included in the registries. The average follow-up of these studies is nearly 8 years and survivorship exceeds 95%. A subset of that group of nearly 9,5 thousand patients and 700,000 observed years reports on a follow-up of 10 years. This is about 6% of all BHRs implanted, with a survivorship of 95%. BHR is one of the most reported orthopaedic devices in history.

The Australian National Joint registry reports that the survivorship for total hip replacement in males under 65 is 92% at 10 years. At the 10 year time point, in males under 55 and males between 65 & 55 there is a spike that starts at 9 to 10 years. The data in the same registry for BHR for the same patient cohort shows the survivorship in men under 65 with osteoarthritis is 96% at 10 years, with a flattening of the cumulative revision rate between 8 & 10 years, instead of the spike seen in total hips.

### Table HI78: Yearly Cumulative Percent Revision of Primary Total Resurfacing Hip Replacement

<table>
<thead>
<tr>
<th>Head Component</th>
<th>Acetabular Component</th>
<th>1 Yr</th>
<th>3 Yrs</th>
<th>5 Yrs</th>
<th>7 Yrs</th>
<th>10 Yrs</th>
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<tbody>
<tr>
<td>ASR</td>
<td>ASR</td>
<td>3.3</td>
<td>5.9</td>
<td>10.5</td>
<td>13.0</td>
<td>17.9</td>
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<tr>
<td>Adept</td>
<td>Adept</td>
<td>1.2</td>
<td>1.9</td>
<td>3.5</td>
<td>5.0</td>
<td>6.3</td>
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<tr>
<td>BHR</td>
<td>BHR</td>
<td>1.5</td>
<td>2.5</td>
<td>3.5</td>
<td>5.0</td>
<td>6.3</td>
</tr>
<tr>
<td>Bionik</td>
<td>Bionik</td>
<td>3.8</td>
<td>10.0</td>
<td>11.1</td>
<td>11.1</td>
<td>11.1</td>
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<tr>
<td>Conmet</td>
<td>Conmet</td>
<td>2.0</td>
<td>4.5</td>
<td>6.2</td>
<td>11.1</td>
<td>16.1</td>
</tr>
<tr>
<td>Conmet 2000 HAP Coated</td>
<td>Conmet</td>
<td>2.5</td>
<td>4.8</td>
<td>7.4</td>
<td>9.6</td>
<td>13.1</td>
</tr>
<tr>
<td>Durom</td>
<td>Durom</td>
<td>3.1</td>
<td>5.4</td>
<td>7.3</td>
<td>9.6</td>
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</tr>
<tr>
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<tr>
<td>Mitch IRH</td>
<td>Mitch IRH</td>
<td>1.3</td>
<td>2.2</td>
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</tr>
<tr>
<td>Recap</td>
<td>Recap</td>
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<td>6.3</td>
<td>10.7</td>
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<tr>
<td>Other (6)</td>
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<td>5.6</td>
<td>8.9</td>
<td>10.4</td>
<td>12.7</td>
<td>18.9</td>
</tr>
</tbody>
</table>

Note: Only prostheses with over 100 procedures have been listed.

Australian Registry results for BHR, Males under 65 years of age September 1999 – December 2010
Source: Data has been sourced from the Australian Orthopaedic National Joint replacement Registry Annual Report. Adelaide: AOA; 2011. Tables have been reproduced in exact and complete form.
Large diameter metal on metal bearings for Total hip replacements

The British Hip Society (BHS) met in Spring 2012 and a number of surgeons presented a series on large diameter metal on metal hips, and as a consequence the BHS advised that metal on metal hip replacements using a bearing of 36mm or above should not be performed, they also said (quite a way down the paper) that the advice did not apply to resurfacing.

The Australian NJR shows that the ASR large diameter metal on metal hip had a revision rate of 44% at 7 years; the UK NJR shows that the BHR from Smith & Nephew (as of February 2012 this was nearly 3,5 thousand patients) had a survivorship of over 92% at 8 years which satisfies the NICE guidelines for hip replacements. If you take the Birmingham Modular heads on Smith & Nephew stems the situation improves to nearly 94%

In addition to implant choice the other keys to a successful outcome for a resurfaced hip are:

1. Component positioning
   - Acetabular inclination in the transverse plan must be 40-45 degrees
   - In the sagittal plane inclination must be between 10-15 degrees
   - In the coronal plane it must be 10-15 degrees
   NB: femoral neck antversion must be taken into account. The combined antversion of femoral neck and acetabulum must not exceed 45 degrees in order to avoid edge wear

2. Patient selection
   - Avoid small female patients; Acetabular components less than 46mm and patients with dysplasia

In conclusion

Generic metal-on-metal bearings have the worst results; however the BHR provides superior clinical results for males under the age of 65 with osteoarthritis. Registry results and peer reviewed articles demonstrate the reproducibility of the procedure amongst all surgeons but there are risks. The original design objective for the BHR was to provide at least 10 symptom free years of joint function has been met and the BHR is the most appropriate choice for young active male patients but public perception seems to be the problem.
BHR° Picking the right patient and techniques
Dr Rob McLennan-Smith

Initial Indications
- Proximal femoral deformity
- Young patients
- High activity level
- AVN
- Any patient with adequate bone stock

AVN - high failure rate with traditional THA
- 116 patients with SRA since 2001
- 2 patients have progressed to fracture
- BMHR a better option?

Proof that life doesn’t end after a hip replacement
64 Year old patient. Photo taken approaching Everest Base Camp, Nov 2008. Right hip resurfacing op 2 ½ years previously

Many surface Replacement systems developed on the back of the BHR success
"Any major change to the basic BHR design is likely to cause problems and the more changes, the greater the probability”  Mr Derek McMinn.

The Durom Cup
- Smoother surface – failure of ingrowth in USA lead to recall
- Equatorial circumferential sharp fins required forceful impaction
- Can’t change cup position once impacted
- Low radial clearance
- High incidence of binding
- 2 mm wider at the rim than the dome
- Plasma spray fixation surface required near perfect contact
- Recall in 2008

Du Puy Hip Implant Recall
- August 2010 - The largest recall in the history of Orthopaedics
- 97 000 patients worldwide
- Design flaw – low arc of cover due to the inserter cut out
- Low radial clearance necessitates a low inclination angle to get fluid bearing.
- ASR is very vulnerable to malplacement
Experience so far – 2001 – 2010

BHR = 126 Cormet = 2
ASR = 571 (revision rate 5.4%)

Post ASR recall 8/2010
- BHR = 120

Current Indications
- Physiologically young patients
- High activity level anticipated
- Good foreseeable bone quality
- Men only

BHR in females
- Ligamentous laxity
- Greater ROM
- Smaller size
- Increased acetabular/femoral anteversion
- Increased lumbar lordosis
- Narrower femoral necks
- All leads to edge loading

Contraindications
- Elderly
- Inactive
- Ligamentous hyperlaxity
- Osteoporotic potential – females steroid usage
- Small size < 50mm head
- Abnormal proximal femoral anatomy
- Femoral head/neck cysts
- Femoral anteverision
- Narrow neck
- Varus neck
- LLD > 3 cm

Surgical Approach
- Changed from Harding to Posterior for SRA
- Gl. max release in large / tight patients
- Circumferential capsulotomy essential

The Best Hip Options at Present

BHR in active men
Increased risk in women patients with small hip cup sizes
Ceramic/Ceramic non-cemented in women of child bearing age.
Cemented MOP/COP > 75 yrs or osteopaenic

The inclination/ Version Jig
High dislocation potential patients?
Be careful of inclination
20 degrees anteverision
45 degrees inclination.
Aim for 35-40

Surgical Tip
Positioning the patient -essential to stabilise pelvis for version
BMHR™ - Filling the void
Prof Rajesh Malhotra

Metal on Metal
There is a place for Metal-on-Metal if bone preservation and physiological bone loading to prevent further bone loss, are one’s priorities. Metal-on-Metal failures are due to improper implants (not all implants are the same), improper technique and improper patient selection. Considering these factors will ensure that the implant performs well. Why Metal on Metal? Younger active patients may outlive their implants and they will require a revision later in life and larger heads have advantages in terms of stability and the femoral side lends itself to revision.

BHR Survivorship
Resurfacing has had its own evolution - from the polyethylene to the Metal-on-Metal. When the third generation Metal-on-Metal arrived in the form of BHR it was shown to be very successful (over 160,000 implanted worldwide), with evidence that designer and non-designer centers have done very well in respect of survival.

The BHR results have shown that primarily in younger patients with osteoarthritis, one achieves very good survival (predictably), but survival data of patient’s avascular necrosis drops the survival data. The Birmingham group showed if the vascular necrosis cases where removed from the results the BHR survivorship was equal to or better than standard implants. So AVN was impacting the results.

On the Australian Registry less than 10% of patients have AVN. In India (high incidence of AVN in young patients, average age 30-35) up to 40% of patients have their hips replaced due to AVN. AVN therefore remains the problem.

Note: primary osteoarthritis is very different from AVN. If you place an implant on bad bone – even if it is grafted, survival of the bone is the issue. In addition all types of hip replacements do worse for AVN than they do for the other etiologies. In addition patients may still be consuming alcohol or taking steroids, which does not help the case.

Introduction of BMHR
Therefore a device was needed with the benefits of resurfacing, and that is not resurfacing in the true sense. When BMHR was introduced, it introduced a new resection level. Bad bone could be removed but bone conservation remained the key when operating in young patients. There is no violation of the intramedullary femoral canal, a compressive load is transmitted to the medial calcaneous in the native femur, the visual stop ensures that the impact is not further than required. An added advantage is that if one was doing a BHR and found that the bone underneath was not good quality; one extra step allows one to use BMHR. It doesn’t add much operating time (a few minutes), due to using a different jig for cutting the head off as opposed to the usual one for BHR.

Indications for BMHR
Any patient who would benefit from resurfacing, but can’t have it done for either technical or anatomical reasons e.g. young patients with avascular necrosis, large femoral head cysts, young patients with deformed anatomy, Perthes osteoarthritis, slipped capital Epiphysis deformity, dysplasia with head or cup mismatch and previous fractured neck of the femur.

Contraindications
Contraindications general for prosthetic hip Arthroplasty, recent active infection, vascular deficiency, weak hip muscles, the skeletally immature, poor medical condition.

Note: one cannot correct severe leg length discrepancies or severe anatomical abnormalities, there must be sufficient bone to support the device, cysts should not extend into the neck, the femoral neck blood supply should not be compromised, and the head/neck offset must be restored.
Are all ceramics equal?

Dr Gordon Hunter

The answer is NO, but before we start to talk about ceramics we have to take a look at the counterface: Polyethylene wear. There are 3 factors that drive polyethylene wear:

- Fatigue wear - Polyethylene is made more brittle by gamma sterilisation. No company still uses gamma sterilisation.
- Adhesive wear - Due to friction and results in pulling of the polyethylene surface as the femoral head slides over it.
- Abrasive wear – Wear caused by peaks in the hard surface.

Cobalt chrome is a fantastic material which works and will continue to work very well, but it is not perfect. One of the areas of concern is that it is prone to roughening. Metal is ductile so when a hard particle ploughs the surface you end up with a valley with peaks on either side. It is these peaks that lead to increased abrasive wear of the polyethylene.

What is a ceramic?

This is where ceramics come in. Different disciplines have different definitions of a ceramic. For orthopaedics a ceramic is a compound that includes a metallic element and a non-metallic element. Metallic elements are to the left of the periodic table and want to give up an electron. Non-metals are to the right of the periodic table and want to accept an electron. If you put them together they share an electron and this creates a very strong bond, as a result these materials are hard, rigid and non-conductive and non-reactive. This is the basic characteristic of a ceramic.

The first ceramics were introduced in the 1970s. These early ceramics were made from an alumina compound but these failed because there were pits in the material which reduced the fracture toughness of the device. Prozr Zirconia heads were introduced in the late 1980s. The crystalline structure of Zirconia, unlike Alumina changes shape as it cools after being heated. When it cools from 110 degrees centigrade there is a 5% volume increase in the material, causing the crystals to shift or shear. This is called monoclinic phase. Adding Yttria to the ceramic stabilisers the high temperature phase so that the material can cool to room temperature without becoming monoclinic. If the ceramic subsequently cracks, the phase transformation is triggered and this will squeeze the crack shut, giving zirconia a much better toughness than alumina. Unfortunately Zirconia did not live up to its promise. The material is compromised by water and heat which interferes with the Yttria and in the fluid environment can trigger the transformation. Once 25% of the material is in the monoclinic phase cracks appear on the surface and crystal grains pop out of the surface. This leads to increase abrasive wear. In addition zirconia is a very good insulator so it keeps heat at the interface, causing the polyethylene to warm and soften which increases wear. As a result the entire industry has moved away from Zirconia Ceramic.

In the 1990s Biolox improved alumina by reducing the grain size through a heat-pressing process. This reduced the porosity and improved the toughness. This was branded Biolox Forte and most white ceramics seen today are this material. Biolox then developed a ceramic matrix composite consisting of 82% alumina with 17% stabilised zirconia and a bit of chromium and strontium. They branded this material Biolox delta. If a crack develops in a biolox delta implant it will run until it encounters a zirconia grain which then transforms, expanding to close the gap. Because most of the composite is alumina it is more stable but alumina is softer than zirconia so the chromium is added for hardness. The chromium gives Biolox delta its distinctive pink colour. The strontium oxide produces platelet like structures which divert any cracks in the material. This composite therefore has increased fracture risk, increase burst strength and allows for more size options and applications such as ceramic liners and femoral components for knees. Time will tell if Biolox delta lives up to its promise, and if the Zirconia which makes up 17% of the matrix will stay stable. There are a lot of lab tests to support it but we are starting to see clinical evidence of the zirconia at the surface of biolox delta implants transforming. This had not caused any failure but could increase polyethylene wear. McMinn has seen an increase in strontium and chromium in blood samples taken from Biolox delta patients. While it is possible, although unlikely that the chromium could come from another source, the only source of strontium in these patients is the biolox delta ceramic fracture of a ceramic femoral head which remains a concern. This is very, very rare, but when it does happen, it loads the joint with very hard, sharp particles which are almost impossible to remove completely. They also lead to damage of the stem taper which may necessitate replacing the stem.
The problem with metal on polyethylene and ceramic on polyethylene, even cross-linked polyethylene, is that it still wears which leads to osteolysis. Ceramic-on-ceramic fracture, even with the improved ceramics, there are case reports of fractures. Metal-on-metal has the issues associated with the metal ion release such as AVAL and hypersensitivity to metal, ion toxicity and groin pain.

**Studies**
In 2001, Firkin et al published an article on ceramic-on-metal study done in a hip simulator. They showed that the wear rate of articulating couples is inversely proportional to the hardness of the bearing material. Therefore 2 dissimilar bearing couples will have reduced adhesive wear. 28mm BioLox Forte ceramic head on a high carbon wrought CoCr alloy cup was mounted in a physiological hip simulator. At 5 million cycles the wear rate of the Ceramic on metal construct was significantly less than that for Metal-on-metal; there was no bedding in effect; the particles generated by the ceramic-on-metal were significantly smaller than the metal on metal wear particles. Other hip simulator studies on Ceramic-on-metal with different ceramics have been published. All show significantly lower wear in Ceramic-on-metal compared to Metal-on-metal but not compared to Ceramic on ceramic. There is lower friction in Ceramic-on-metal compared to metal-on-metal which results in lower metal ion release in ceramic-on-metal compared to metal-on-metal. In addition, fracture is not an issue; the use of large heads with a smaller cup (36mm in a 50mm cup) is possible. Therefore ceramic-on-metal appears to be the ideal bearing surface.

An In vitro study was conducted at Johannesburg Hospital comparing four different bearing surfaces: Ceramic-on-ceramic; Ceramic-on-polyethylene; Metal-on-metal and Ceramic-on-metal. These results were compared to in vitro work out of Leeds University. The results showed increased wear in all bearing surfaces; however Ceramic-on-metal coupling had the lowest wear and no stripe wear. The blood levels of Cobalt and chromium at 6months were lowest in the ceramic-on-metal and highest in the metal-on-metal. At 12 months the chromium levels remained low but the Cobalt levels were only slightly (but not significantly) lower in the Ceramic-on-metal compared to ceramic-on-ceramic.

In June 2011 The FDA approved ceramic-on-metal (Pinnacle CoMplete System from J&J dePuy) on the basis of a 2 year randomised control trial that was done in North America. The study compared 194 patients with Ceramic-on-metal implants to 196 patients with metal-on-metal. At 2 years, 2 ceramic-on-metal implants and 3 metal-on-metal implants had been revised.

**Results**
Ceramic-on-metal implants were implanted from 2007 in the UK, by 2010, 1% of all uncemented bearings were ceramic on metal but by 2011 usage had declined to 0.4%. The same registry shows that at 2 years, ceramic-on-metal did just as well as ceramic-on-poly but at 3 years the revision rate increases to 2.9% which is almost the same a metal-on-metal. The reason for failure for ceramic-on-metal implants is predominantly aseptic loosening. Revision for pain, lysis, and periprosthetic fracture are comparable to ceramic on polyethylene but aseptic loosening is almost as high as metal-on-metal.

**In Conclusion**
Ceramic-on-metal couplings have significantly lower friction than metal-on-metal bearings, which leads to lower wear and fewer metal ions being produced. Circulating blood levels of metal ion in ceramic-on-metal bearings are less than metal on-metal. However, the sizes of the particles produced by ceramic-on-metal are significantly smaller than metal-on-metal particles, which leads to increased biological response and possible allergic reactions.

Finally a metal head should never be coupled with a ceramic cup because this leads to catastrophic wear. There is a temptation in the revision of a ceramic-on-ceramic hip replacement with a wear fixed cup and ceramic liner. If there is damage to the trunion it is tempting to use a metal head with the ceramic liner because using a ceramic head on a damaged trunion increased the risk of fracture of the ceramic head. In these situations it is advisable to revise the stem.
Oxinium™ – the science
Dr Gordon Hunter

What is Oxinium? How is it made, why is it made, and what are its advantages?

Osteolysis in the hip is a major concern in orthopaedic surgery. Sharky et al conducted a NICE study categorizing the reasons for early and late knee revisions; using 2 to 3 years as the guiding line. Infections were the key reason for early revisions and are often related to both patient and surgical factors. Late stage revisions were dominated by polyethylene wear, loosening caused by osteolysis, and instability initiated by changes of the geometry of the polyethylene components. These are important factors in long-term implant survivorship especially in high demand patients i.e. young, active, heavy, and those with a biological sensitivity to polyethylene and metal ions.

Historically delamination of polyethylene is a key issue, which was solved by eliminating gamma sterilization and using ethylene oxide fumigation. Adhesive and abrasive wear is an issue and younger, larger patients want to go back to being active as soon as possible.

Cobalt chrome as a bearing surface has limitations: it roughens over time which increases wear and releases metal ions. Alternatives have been sought for many decades and included fusion hardening the cobalt chrome heads. This improvement was short-lived, still released metal ions and was inferior to ceramics. Ceramics are hardwearing and do not release metal ions, but the crystals are monolithic in structure and can shatter when stressed or exposed to a direct impact.

Coating a metal surface with a ceramic like Titanium Nitride, (second in hardness only to a diamond), improves hardness but not shear resistance. This coating is inhomogeneous, has metal nodules and pores and is laid down perpendicular to the surface. The surface can therefore be rubbed off with a bone cement pin in a million cycles and once exposed, hard particles float around in the joint, which can now attack the unprotected exposed metal.

Zirconium metal, (the same family as titanium on the periodic table), can be alloyed with a small amount of Niobium to produce a highly biocompatible metal without impurities such as cobalt, chrome, nickel, titanium or aluminum. The metal is then diffusion hardened to further improve wear resistance and longevity. By heating the surface of the metal, oxygen diffuses into the surface, and saturates it with oxygen. As the oxygen concentration in the surface increases it starts to move into the crystal lattice sites within the metal, which causes a spontaneous transformation from Zirconium metal, to Zirconium oxide or zirconia. This transforms the metal into a ceramic like state about 5 microns thick. Under the ceramic layer there is an enriched metal layer, which acts as a transition layer between the ceramic surface and the underlying metal and Oxinium is created.

This ceramic oxide now covers the entire surface of the metal, and it has all the benefits but none of the negatives of a ceramic bearing surface. Therefore any other bearing surface such as polyethylene or any soft tissue is in contact with a smooth ceramic-like like bearing surface.

How does Oxinium perform?
As the load on the material is increased it starts to bend and flex, just like metal. If it was a true ceramic or any other metal oxide it would either break, or peel away, or flake off from the surface (like rust off iron).

However Zirconium is one of the very few metals where the oxide remains attached under these conditions.

Baking bread is a good analogy. As one bakes dough in an oven, the surface hardens, and a crust develops, and there is a transition between and the hard crust and the soft interior. It is all still one material and in the case of Zirconium, it’s a composite of ceramic like material at the surface with a metal on the inside.
The reason for its strength and ductility is that the individual zirconium crystals are ten times smaller than the crystals of monolithic ceramics. Zirconium crystals are oriented perpendicular to the surface and they are self-supporting. They are also interlaced, which makes them very hard to pull apart and they resist the formation of cracks. In addition this interlacing occurs between the ceramic and the metal as well, so that too is very well locked in place. Although the individual crystals are brittle, they are extremely small and the boundaries allow a small amount of movement. Therefore as the metal flexes, the ceramic surface can flex and it effectively becomes ductile. When a crush test is performed on a ceramic head it will burst, but oxidized zirconium does not. Referring to damaged tapers a Zirconium oxide head was tested by squashing it on its side, and under 10 tons of pressure it become oval but did not crack. This makes the material very unusual.

As an example if one conducts a fatigue test on an oxinium knee implant by applying 4500 pounds of pressure on the condyle it will bend, as cobalt chrome would, but it won’t shatter like a ceramic would. Also if more pressure is applied past a certain point, the zirconium oxide can’t withstand that much deformation; and cracks will start to form. It will still feel smooth; but ones finger will be able to detect the small cracks. This means that the surface oxide is actually more firmly attached to the metal than to itself. If it breaks or cracks, the oxide remains attached to the metal underneath. That gives it superior damage tolerance. The process of oxidization also coats the entire surface of the implant i.e. all the grooves and cams. It therefore has the same geometry as cobalt chrome components; they are interchangeable in surgery, and are applied with the same surgical techniques and instruments. To test the hardness of the zirconium oxide coating a bone cement pin was rubbed over a zirconium oxide disc for 10 million cycles without affecting the oxide coating. In fact the wear track became smoother which will reduce friction and abrasive wear on a polyethylene implant. It is also more wettable than metal surfaces which will also reduce friction. All these factors are a major improvement when compared with the 1 million cycle test performed on a Titanium nitride disc.

If cobalt chrome is tested in this way a wear track appears in the disc and 4900 times more material is removed (which is 160 times rougher than oxinium).

Studies
In a Scripps Institute study a simulator test was performed on polyethylene to measure the loss in cubic millimeters per million cycles under normal kinematics polyethylene on cobalt chrome polyethylene showed 42% more wear when compared to the oxinium components. Once the amount of rotation was increased the difference in polyethylene wear between cobalt chrome and oxinium was up by 61%.

In Clemens’s study the femoral components were tumbled in an abrasive to get as rough as one would expect to see in normal implant retrievals. It was found that oxinium is much more resistant to abrasive wear. Depending on the tests conducted on hips, knees, with or without abrasives, with different types of kinematics, one finds a difference between 40 and 90% in the volumetric wear rate, when comparing cobalt chrome with oxinium. It also seems that as one increases the aggressiveness of the tests, the relative performance of oxidized zirconium improves in comparison with the cobalt chrome. This is very relevant where one is concerned with the wear rates, especially in high demand patients or in patients with metal ion problems. Oxinium shows improved performance in these patients when compared to metal implants made from either nickel, cobalt and chrome.

Taper junction corrosion, has recently received much more focus, especially in the larger heads, both metal on metal, and on metal on poly. n tests conducted that accelerate these conditions corrosion can be generated and cobalt chrome is very sensitive to these conditions. Oxidized zirconium actually acts as a galvanic protection against corrosion on the stems; whether they are stainless steel or titanium. Unlike zinc, the oxidized zirconium doesn’t ionize, but it strengthens the oxide, and continues to bias the stem to prevent corrosion.

Survivorship
Oxidized zirconium knees have now been implanted for almost 15 years and total hips for over 10 years. Formal studies on oxinium implants have now been running for 5 to 6 years and are showing equivalence with traditional implants. This is to be expected because in this short time frame one wouldn’t expect to see much difference with the well-performing conventional materials. As the registries reach 10 to 15 years and where survivorship issues are going to become more important and relevant, it is expected that the oxinium implants will show improved survivorships.

In conclusion, oxinium is a metal device; it is strong, durable, not brittle but wears like a ceramic, is smoother, resists roughening, has less friction, produces less abrasive wear, and has better lubrication properties. One can improve its design, offer a surgeon all the surgical flexibility he has with metals, and also offer excellent biocompatibility with the reduced potential for metal allergies.
Changes in implant design

Changes in implant design have improved the performance of crosslinked polyethylene. Early crosslinked implants fractured because they were too thin, either because large head sizes in smaller cups require a thin liner or the locking mechanism was on the periphery of the cup where the liner is thinnest. Smith & Nephew have moved the locking mechanism inside the cup in the R3 which protects the locking mechanism from the slight weakening caused by crosslinking the polyethylene. We reviewed 150 revision cases of Cobalt chrome femoral heads and we verified the damage to the femora heads. Then we looked at a series of cases that were revised for recurring dislocations with both cobalt chrome and Oxinium. Implants from both groups were damaged from running over the edge of the cup and then pulled back in. These damaged heads were placed in a wear simulator. The Oxinium was like pristine cobalt chrome because, if you scratch cobalt chrome, there is a build-up of metal on either side of the scratch but in Oxinium you get the valleys but not the peaks which is why wear with the damaged Oxinium heads was not evident.

I started using Oxinium on crosslinked polyethylene in 2001. The first patient was 47 years old and the 10 year post-op Xray looks as good as it did the day it was implanted. We have followed up a number of patients now for 10 years and they have no detectable wear in our different 2D and 3D wear measurements.

Verilast technology seems to be the best available bearing surface, combining a fracture resistant ceramisied metal with a wear resistant polyethylene. It shows the lowest wear rate in vitro, there is no risk of fracture and no squeaking and the Australian registry shows the excellent results.

Wear rates in hip replacements

In the last decade the highest growth in hip replacements has been in males between 45 & 54 years old. Young male patients have the most wear. Most people in advantage communities live for about 85 years, so we have an increasing number of active noncompliant male patients expecting their implant to last more than 20 years.

Component position, even simply antversion of the acetabular cup affects wear rates. There is a substantial increase in wear rates of acetabular cups that are placed in over 45 degrees of antversion when using conventional polyethylene.

There is a direct correlation between wear and damage to the femoral heads. Metal femoral heads scratch in vivo and scratches on the femoral head lead to increased wear. Issues with hard-on-hard bearing surfaces especially metal-on-metal mean that most surgeons have reverted to using polyethylene with either metal or ceramic in more patients in the past few years. Verilast is the combination of a scratch resistant ceramisied metal head with crosslinked polyethylene cup. The results of this are illustrated in the Australian registry results where the highest revisions rate is for metal-on-metal and the lowest is for Oxinium.

The 2011 Australian registry includes the addition of a new category of bearing surface “Ceramicised Metal/Polyethylene”. The only product to fall into this category is Verilast. Summary of Ceramicised Metal / Polyethylene data:

- Lowest revisions per 100 observation years of all bearing types at 7 years: 0.48 (0.39, 0.58) revisions/100 Obs. Yrs.
- Highest survivorship of all bearing categories at 7 years: 97.8%
Clinical benefits in knees?
Crosslinked polyethylene implants have clinical benefits on hips, but this has not yet been proven in knees. So scientists are trying to apply what they’ve learned in hips, and apply it to knees. Knee wear is an issue, and the original problem was gamma sterilization. This issue has been solved but there is still the problem of abrasive and adhesive wear which can be addressed by changing the polyethylene. Polyethylenes are long chains of carbon, all wound together, about 1mm long, with crystalline parts that bind them together – in simplest terms they look like a plate of spaghetti. These strands are cohesive and tough and if they are struck they won’t crack into pieces. One can rub it and it will resist adhesion, although occasionally a strand will be pulled out. Radiation further changes the structure, and creates reactive ends, which bind with each other and create an interlinked interconnected network structure which is very good at resisting adhesive wear. This is called crosslinked polyethylene and the amount of crosslinking is a function of radiation dosage i.e. the greater the radiation the greater the adhesive wear properties. But as one increases the radiation, the strength of the material and its ability to withstand impact decreases, so there is a trade-off. So for knees, the compromise is that one uses 7.5 megarads to create the cross linked polyethylene. That gives it strength combined with excellent wear properties. It is then stabilized, to prevent the production of free radicals that can interact with oxygen and degrade the product over time.

When exposed to torture tests, (knee back in full flection, applying stress on both the posterior aspect of the articular surface and the anterior part of the locking mechanism) there were no signs of cracking. The mechanical properties were therefore very good for this type of application. Furthermore the wear in cubic millimeters per million cycles was measured in a knee simulator test (a million cycles is equivalent to about one year’s wear in a typical patient) and showed a 73% reduction in volumetric wear in the cross-linked knee: which is very significant. But a cobalt chrome surface will roughen over time, and this affects the wear rate of cross-linked polyethylene. All the benefits of crosslinking polyethylene at 7.5 megaRads is undone if it is combined with a cobalt chrome surface. Therefore as one increases the demand of cross-linked polyethylene it behaves more and more like conventional polyethylene; which is the opposite of what is required for high demand patients.

Verilast Technology for knees
To overcome this problem one can combine oxidized zirconium, with cross-linked polyethylene radiated to 5 megarads, which will produce a 94% reduction in wear. If the oxidized zirconium is roughened the results unexpectedly further improve. This technology which operates synergistically is called Verilast. The Oxinium keeps the abrasive conditions and the lubrication issues under control, and allows the cross-linked polyethylene to maximize its ability of resisting adhesive wear. Verilast technology for knees: An Oxinium femoral component and the XLPE component specifically designed for knees exhibiting low wear characteristics.

In a 5 million cycle test for a younger patient (equivalent about 3 years use) Verilast technology showed a 98% reduction in wear compared to conventional technology. In another test data was collected after 45 million cycles (31 years of use) and showed a 81% reduction in wear. The FDA has allowed Smith&Nephew to use the 30 year wear performance claim, which applies to Legion CR and PS, and in Europe it includes Genesis II CR and PS. This is not a guarantee or warrantee, but it means under normal conditions, this knee should last 30 years in terms of wear performance. Oxinium in hips were put to the same test; and wear rates versus conventional technology was significantly better i.e. a 98% reduction. Verilast, the combination of the Oxinium material, with XLPE specifically designed for knees or hips, has very low wear characteristics.

VERILAST® Technology in the LEGION® Primary Knee System was tested for 30 years of simulated wear performance
Global Trends: What does the future hold?
Prof Bob Bourne

Global arthroplasty trends
Primary total hip arthroplasty rates vary from 50 to 130 per 100,000 patients in the population (0.05 – 0.13%). The huge variation may be due to ethnicity, for example European countries or countries such as North America and Australia where a large proportion of the population are of European descent, have a higher rate of joint replacements, however osteoarthritis is not common in Indian and Chinese people, therefore joint replacements in these countries is relatively low, this may also be due to lack of access to treatment or education. In Canada about 80 total hips are done for 100,000 of the population. This includes Primaries and Revisions. There is a higher incidence of women with THA than men, which may be because women have a longer life expectancy than men.

In the past decade there has been a 140% increase in the number of knees performed. Knees are growing at a much faster rate than hips, the number of knee procedures performed per annum over took the number of hips in the late 1990’s. At least a third of patients receiving a joint replacement in Canada are under 65 years of age. This is also the case in Australia.

Fixation
There is a trend towards cementless fixation. The number of cemented implants is declining in usage while hybrids are plateauing, but cementless procedures are growing. In Canada and Australia, about 70% of all hips are cementless and about 26% are hybrid so cementing the acetabulum is almost a lost art. This does not make it right, but it has been the trend over the last decade.

Outcomes
Patients with a diagnosis of Osteoarthritis generally have the lowest revision rate, but there is a move towards doing total hips on femoral neck fractures. Studies suggest that there are better outcomes, but there is a higher failure rate and a higher mortality rate in these patients compared to osteoarthritis patients.

Causes of Failure
Data from Canada and Australian Joint registries show that most failures, especially those that occur in the second decade (around 14-15 years), are related to wear. Not surprisingly, younger patients have the highest revision rates, and these are the patients who need the advanced bearing solutions that we have debated in our previous talks. In every registry, Swedish, Canadian, Australian and New Zealand show that males have a higher revision rate than females. Cemented implants in patients under 55 have the highest revision rates, even in Sweden where 96% of total hips are cemented stems. Similarly in the 55-64 age groups, cemented stems do not perform well. However, with patients over 75, the reverse is true, cementless fixation has the highest revision rate.

Modular necks have almost twice the revision rate to monolithic stems. This may be because a number of these stems are being done by surgeons wanting to use a mini approach which compromises the outcome. In addition, some of the modular necks were made of Titanium whereas the CoCr necks appear to perform better. Bearing couples has been debated earlier.

Verilast™
Smith & Nephew are very excited about the results of Verilast, but this data will only be really useful at 20 years, since wear is not really an issue at eight years. It is very promising but it is not conclusive. It is interesting that Ceramic on crosslinked poly does not do as well as Verilast; it may be the surgical approach, the implants used, patient selection or all of these issues. This is something that the international registry group is looking at.

In the large head category, metal-on-metal total hips have the highest revision rates, while crosslinked (modified) polyethylene has the lowest revision rate, but the results are not as dramatic in the registry as the lab results suggest. The lab results showed a 89% reduction in wear using crosslinked polyethylene, whereas clinical studies only measure 40% reduction in wear.
Predictions

Knee replacements will continue to grow faster than hip replacements despite patient satisfaction following knee replacement being 80% compared to 95% for hip replacement patients. Surgeons will continue to perform total hips on patients with 20-40 year life expectancies. This means that there is constant push for new developments to improve the longevity of the implant. It is therefore very important that any new products are introduced to the market in a responsible manner and only after robust preclinical testing. The trend towards cementless fixation will continue, particularly for patients under 65.

Until the issues of hard-on-hard bearings have been resolved low friction arthroplasty with modified or crosslinked polyethylene will remain the implant of choice. 90% of all countries are using crosslinked polyethylene. The counter face, whether metal, ceramic or Oxinium will depend on the patients age and activity level, and the debate of which is the best will only be answered when there is sufficient long term data. The optimal crosslinking method has still not been resolved. We are onto our 3rd generation of crosslinked polyethylene and we do not have 20 year data on the first generation. We need to be careful that we don’t keep changing the product before we are able to obtain long term results, or we will not be able to work out what works and what doesn’t.

The use of registries will grow, but a means to encourage or force surgeons to submit their data needs to be implemented. Voluntary contribution does not work; one idea is that the hospital will not get paid unless the data is submitted another is that the hospital that does the primary procedure has to pay for the revision. This last suggestion will encourage the head of department to hire the best surgeons; use the best nurses and facilities available and use the best performing implant. There are other issues such as the strategies to reduce costs since hip and knees have been identified as high cost; high risk procedure. There is a lot of pressure to reduce costs, and we need to stay involved, we cannot leave it to the administrators to make the decisions for us.

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As leaders in our Industry sectors, we at Smith & Nephew believe we should also be leaders in education. Every year thousands of health care professionals benefit from our skills development programmes.
A stack of evidence to support BHR®

The BHR system is the only resurfacing device with over 10 years clinical data published by multiple authors in peer reviewed journals which comprehensively demonstrate outstanding clinical results and functional outcomes.

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