Bearing Surface Options in Total Joint Replacement: The Experts Provide the Evidence.

Javad Parvizi, M.D., F.R.C.S.
President

A. Seth Greenwald, D.Phil.(Oxon)
Chairman, Scientific Committee

May 19–20, 2012
Las Vegas, Nevada
14th International BIOLOX® Symposium
Bearing Surface Options in Total Joint Replacement: The Experts Provide the Evidence.

COURSE DESCRIPTION

The growing use of hip and knee arthroplasty as a solution for degenerative joint disease has extended its domain to include younger, more active patients as well as the attending longevity of our senior population on a global basis. To accommodate this increasing in vivo requirement, a number of articulating bearing options have emerged coupled with continuous ongoing improvements that assure material durability and host acceptance. This symposium presents a contemporary view of clinical and laboratory experiences from a group of international orthopaedic surgeons and researchers involved in the achievement of these goals.

LEARNING OBJECTIVES

As a result of attending this symposium, each participant will be able to:

- Appreciate the evolution of contemporary bearing surface couples in hip and knee arthroplasty.
- Evaluate the early and long-term clinical outcomes as reported particular to material durability, biocompatibility within the in vivo host, and ultimately patient satisfaction and function.
- Identify post-surgical diagnostic indicators that assist patient intervention strategies when problems arise.
- Appreciate the complications that have emerged from the in vivo employ of contemporary bearing couples.
- Identify and discuss solutions for these complex problems where revision is an endpoint.

DISCLAIMER

The information in this educational activity is provided for general medical education purposes only and is not meant to substitute for the independent medical judgment of a physician relative to diagnostic and treatment options of a specific patient’s medical condition. The viewpoints expressed in this activity are those of the author/faculty. They do not represent an endorsement by the Current Concepts Institute or CeramTec. In no event will the Current Concepts Institute or CeramTec be liable for any decision made or action taken in reliance upon information provided through this activity.
14th International BIOLOX® Symposium

Bearing Surface Options in Total Joint Replacement: The Experts Provide the Evidence.

PROGRAM

SATURDAY, MAY 19, 2012

11:00 a.m. - 6:27 p.m.  Registration - Ironwood Ballroom 5
12:00 p.m. - 1:00 p.m.  Lunch - Juniper Ballroom 2
1:00 p.m. - 3:09 p.m.  General Sessions I & II - Juniper Ballroom 3
3:09 p.m. - 3:29 p.m.  Refreshments - Juniper Ballroom 2
3:29 p.m. - 6:27 p.m.  General Sessions III, IV, V & VI - Juniper Ballroom 3
6:27 p.m. - 8:30 p.m.  Reception - Ironwood Terrace

SUNDAY, MAY 20, 2012

7:00 a.m. - 2:45 p.m.  Registration - Ironwood Ballroom 5
7:00 a.m. - 8:00 a.m.  Buffet Breakfast - Juniper Ballroom 2
8:00 a.m. - 9:50 a.m.  General Sessions VII & VIII - Juniper Ballroom 3
9:50 a.m. - 10:10 a.m.  Refreshments - Juniper Ballroom 2
10:10 a.m. - 11:58 a.m.  General Sessions IX & X - Juniper Ballroom 3
11:58 a.m. - 12:50 p.m.  Lunch - Juniper Ballroom 2
12:50 p.m. - 2:45 p.m.  General Sessions XI & XII - Juniper Ballroom 3

ALL PARTICIPANTS ARE REQUIRED TO WEAR THEIR BADGE FOR ENTRANCE TO THE GENERAL SESSIONS AND FOOD FUNCTIONS.
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SATURDAY, MAY 19, 2012

12:00 p.m. Lunch

Opening Remarks:
1:00 Welcome Javad Parvizi, M.D., F.R.C.S.
1:05 #1 How Far Have We Come? Richard H. Rothman, M.D., Ph.D.

SESSION I John Fisher, Ph.D., C.B.E. & Michael Morlock, Ph.D.
The Bearing Surface Conundrum
1:25 #2 Bearing Surfaces for Joint Replacement Stuart P. Goodman, M.D., Ph.D.
1:33 #3 Evolution of Polyethylene Steven M. Kurtz, Ph.D.
1:41 #4 Evolution of Metal-Metal Bearings Justin Cobb, M.Ch.(Oxon), F.R.C.S.
1:49 #5 Evolution of Ceramics Robert Streicher, Ph.D.
1:57 #6 “Trunionitis”: A Cause for Concern? Aldo Toni, M.D.
2:05 Discussion

SESSION II Justin Cobb, M.Ch.(Oxon), F.R.C.S. & Atsushi Kusaba, M.D.
Assessment of Hip Wear
2:25 #7 In Vitro Measurement of Wear John Fisher, Ph.D., C.B.E.
2:33 #8 Patient Activity and Hip Wear Thomas P. Schmalzried, M.D.
2:41 #9 Wear Measurement of Hard Surfaces James P. Waddell, M.D., F.R.C.S.(C)
2:49 Discussion
3:09 Refreshment Break

SESSION III William J. Maloney III, M.D.
3:29 #10 Total Hip Arthroplasty Bearing Surface Problems: I Need Your Help! Fares S. Haddad, M.B., F.R.C.S.
Christian Hendrich, M.D.
Richard H. Rothman, M.D., Ph.D.
Aldo Toni, M.D.
William L. Walter, M.D., F.R.A.C.S., Ph.D.

SESSION IV Peter F. Sharkey, M.D. & Jun-Dong Chang, M.D., Ph.D.
When the Smoke Clears: What Do You Do?
4:09 #11 Bearing Surface Choice: A European Experience Gerald Pflüger, M.D.
4:17 #12 Bearing Surface Choice: An Asian Experience Kyung-Hoi Koo, M.D.
4:25 #13 Bearing Surface Choice: A South American Experience Luiz Sergio Marcelino Gomes, M.D., Ph.D.
4:33 #14 Bearing Surface Choice: A North American Experience Jonathan P. Garino, M.D.
4:41 Discussion
# 14th International BIOLOX® Symposium

**Bearing Surface Options in Total Joint Replacement: The Experts Provide the Evidence.**

## SESSION V

**James P. Waddell, M.D., F.R.C.S.(C) & Karl Knahr, M.D.**  

**Bearing Surface Problems in THA**

<table>
<thead>
<tr>
<th>Time</th>
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<th>Title</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>5:01</td>
<td>#15</td>
<td>The Causes of THA Failure</td>
<td>Fares S. Haddad, M.B., F.R.C.S.</td>
</tr>
<tr>
<td>5:09</td>
<td>#16</td>
<td>XLPE: As Good as it Seems?</td>
<td>Michael D. Ries, M.D.</td>
</tr>
<tr>
<td>5:17</td>
<td>#17</td>
<td>Ceramics: Breaking &amp; Squeaking?</td>
<td>William L. Walter, M.D., F.R.A.C.S., Ph.D.</td>
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<tr>
<td>5:25</td>
<td>#18</td>
<td>Metal on Metal: What a Mess?</td>
<td>Craig J. Della Valle, M.D.</td>
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<tr>
<td>5:33</td>
<td>#19</td>
<td>Resurfacing Hip Arthroplasty: Are the Issues Clear?</td>
<td>Thomas P. Schmalzried M.D.</td>
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<td>5:41</td>
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<td>Discussion</td>
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## SESSION VI

**A. Seth Greenwald, D.Phil.(Oxon) & Javad Parvizi, M.D., F.R.C.S.**  

**The BIOLOX® Research & Clinical Award Papers**

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<tr>
<td>6:01</td>
<td>#20</td>
<td>Roughness of Alumina-Ceramic Hip Bearings: Retrievals Compared to Autoclaved/Simulator Wear on Femoral Ball Heads</td>
<td>Ian C. Clarke, Ph.D.</td>
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<tr>
<td>6:09</td>
<td>#21</td>
<td>Peri-Implant Histology &amp; Cytokine Pattern in Metal Allergic Knee Arthroplasty – Patients with Improvement After Revision with Hypoallergenic Materials</td>
<td>Peter Thomas, M.D.</td>
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<td>6:17</td>
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<td>Discussion</td>
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<td>6:27</td>
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<td>Adjournment</td>
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## RECEPTION

6:27 – 8:30 p.m.  
Converse with the experts over cocktails.

## SUNDAY, MAY 20, 2012

**SESSION VII**  
**Thomas P. Schmalzried, M.D. & Aree Tanavalee, M.D.**  

**Bearing Surface Problems in TKA**

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<th>Time</th>
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<tbody>
<tr>
<td>8:00</td>
<td>#22</td>
<td>The Causes of TKA Failure</td>
<td>Peter F. Sharkey, M.D.</td>
</tr>
<tr>
<td>8:08</td>
<td>#23</td>
<td>The All Poly Tibia: When &amp; Why</td>
<td>Craig J. Della Valle, M.D.</td>
</tr>
<tr>
<td>8:16</td>
<td>#24</td>
<td>XLPE: Does it Serve a Noble Purpose?</td>
<td>Stuart P. Goodman, M.D., Ph.D.</td>
</tr>
<tr>
<td>8:32</td>
<td>#26</td>
<td>The All Ceramic Knee: A Possibility?</td>
<td>Wolfram Mittelmeier, M.D.</td>
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<td>8:40</td>
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<td>Discussion</td>
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## SESSION VIII

**Steven M. Kurtz, Ph.D. & Carsten Perka, M.D.**  

**Submitted Papers**

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<th>Time</th>
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<tbody>
<tr>
<td>9:00</td>
<td>#27</td>
<td>Cementless Metaphyseal-Fitting Anatomic Total Hip Arthroplasty with a Ceramic-on-Ceramic Bearing in Patients Thirty Years of Age or Younger</td>
<td>Young-Hoo Kim, M.D.</td>
</tr>
<tr>
<td>9:08</td>
<td>#28</td>
<td>THA Patients in Standing and Sitting Positions: A Prospective Evaluation of Ceramic &amp; Non-Ceramic Implants Using the Low Dose “Full Body” EOS Imaging System</td>
<td>Jean-Yves Lazennec, M.D.</td>
</tr>
<tr>
<td>9:16</td>
<td>#29</td>
<td>Metallosis in Metal on Metal PPF Total Hip Arthroplasties</td>
<td>Robert Legenstein, M.D.</td>
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<tr>
<td>9:24</td>
<td>#30</td>
<td>Revision Total Hip Arthroplasty Performed with an Alumina-on-Alumina Bearing Surface</td>
<td>Hee-Joong Kim, M.D.</td>
</tr>
<tr>
<td>9:32</td>
<td>#31</td>
<td>High Riding DDH Acetabular Side: What We Should Do if the Real Acetabulum is Too Small</td>
<td>Yonggang Zhou, M.D.</td>
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<td>9:40</td>
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<td>Discussion</td>
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<td>9:50</td>
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<td>Refreshment Break</td>
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SESSION IX  Donald S. Garbuz, M.D., F.R.C.S.(C) & Stephen B. Murphy, M.D.

**The Clinical Management of Hip Problems**

10:10 #32  Hip Instability  Karl Knahr, M.D.
10:18 #33  Metal on Metal: Ion Levels as an Intervention Strategy  Michael Morlock, Ph.D.
10:26 #34  Metal Hypersensitivity: Fiction or Reality?  Peter Thomas, M.D.
10:34 #35  Failed Metal on Metal: Full of Puss, Is it Infected?  Matthew S. Austin, M.D.
10:42 #36  Revising a Fractured Ceramic Bearing: Chip Shot  Jonathan P. Garino, M.D.
10:50 #37  Osteolysis: Graft or Revise?  Carsten Perka, M.D.
10:58  Discussion

SESSION X  Javad Parvizi, M.D., F.R.C.S.

11:18 #38  Total Knee Arthroplasty Problems: I Need Your Help!  Matthew S. Austin, M.D.
Jonathan P. Garino, M.D.
Wolfram Mittelmeier, M.D.
K. H. Sancheti, M.D.
Peter F. Sharkey, M.D.
11:58  Lunch

SESSION XI  Fares S. Haddad, M.B., F.R.C.S. & Luiz Sergio Marcelino Gomes, M.D., Ph.D.

**Clinical Decision Making & Outcomes**

12:50 #39  Measuring Outcomes: Tools of the Trade  Donald S. Garbuz, M.D., F.R.C.S.(C)
12:58 #40  Patient Activity after Arthroplasty: Do's & Don'ts  William L. Walter, M.D., F.R.A.C.S., Ph.D.
1:06 #41  Clinical Results in Young Patients  Stephen B. Murphy, M.D.
1:14 #42  Medium to Long Term Follow Up: An FDA Study  J. Wesley Mesko M.D.
1:22 #43  BIOLOX® delta: The Ceramic on Ceramic Experience  Raghu Raman, M.D.
1:30  Discussion

SESSION XII  Thomas S. Thornhill, M.D.

1:50 #44  Nightmare Cases  Craig J. Della Valle, M.D.
William J. Maloney III, M.D.
J. Wesley Mesko, M.D.
Carsten Perka, M.D.
Fritz Thorey, M.D.

Remains of the Day:

2:40  Bringing it All Together  A. Seth Greenwald, D.Phil.(Oxon)
2:45  Adjournment
14th International BIOLOX® Symposium
Bearing Surface Options in Total Joint Replacement: The Experts Provide the Evidence.

FACULTY

Matthew S. Austin, M.D., Rothman Institute, Philadelphia, Pennsylvania
Jun-Dong Chang, M.D., Ph.D., Hangang Sacred Heart Hospital, Seoul, South Korea
Ian C Clarke, Ph.D., DARF Implant Center, Colton, California
Justin Cobb, M.Ch.(Oxon), F.R.C.S., Imperial College, London, United Kingdom
Craig J. Della Valle, M.D., Rush University Medical Center, Chicago, Illinois
John Fisher, Ph.D., C.B.E., University of Leeds, Leeds, United Kingdom
Donald Garbuz, M.D., F.R.C.S.(C), University of British Columbia, Vancouver, British Columbia, Canada
Jonathan P. Garino, M.D., Pennsylvania Orthopedic Center, Malvern, Pennsylvania
Fares S. Haddad, M.B., F.R.C.S., Princess Grace Hospital, London, United Kingdom
Christian Hendrich, M.D., Orthopaedic Hospital Schloss Werneck, Werneck, Germany
Hee-Joong Kim, M.D., Seoul National University College of Medicine, Seoul, South Korea
Young-Hoo Kim, M.D., Ewha Womans University School of Medicine, Seoul, South Korea
Karl Knahr, M.D., Orthopaedic Hospital Vienna-Speising, Vienna, Austria
Kyung-Hoi Koo, M.D., Seoul National University Budang Hospital, Gyeonggi-do, South Korea
Steven M. Kurtz, Ph.D., Exponent, Philadelphia, Pennsylvania
Atsushi Kusaba, M.D., Ebina General Hospital, Kanagawa, Japan
Jean-Yves Lazennec, M.D., La Pitié Salpêtrière Hospital, Paris, France
Robert Legenstein, M.D., Orthopaedic Clinic Wiener Neustadt, Vienna, Austria
William J. Maloney III, M.D., Stanford University, Stanford, California
Luiz Sergio Marcelino Gomes, M.D., Ph.D., Pontifical Catholic University, Sao Paulo, Brazil
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Wolfram Mittelmeier, M.D., University of Rostock, Rostock, Germany
Michael Morlock, Ph.D., Hamburg University of Technology, Hamburg, Germany
Stephen B. Murphy, M.D., Tufts University, Boston, Massachusetts
Javad Parvizi, M.D., F.R.C.S., Rothman Institute, Philadelphia, Pennsylvania
Carsten Perka, M.D., Charité Hospital, Berlin, Germany
Gerald Pfuger, M.D., Evangelisches Krankenhaus, Vienna, Austria
Raghu Raman, M.D., Hull Royal Infirmary, Hull, United Kingdom
Michael D. Ries, M.D., UCSF Medical Center, San Francisco, California
Richard H. Rothman, M.D., Ph.D., Rothman Institute, Philadelphia, Pennsylvania
K.H. Sancheti, M.D., Sancheti Hospital, Pune, Maharashtra, India
Thomas P. Schmalzried, M.D., Joint Replacement Institute, Los Angeles, California
Peter F. Sharkey, M.D., Rothman Institute, Philadelphia, Pennsylvania
Robert Streicher, Ph.D., University of Insubria, Varese, Italy
Aree Tanavalee, M.D., Chulalongkorn Hospital, Bangkok, Thailand
Peter Thomas, M.D., Ludwig-Maximilians-University, Munich, Germany
Fritz Thorey, M.D., ATOS Clinic Heidelberg, Heidelberg, Germany
Thomas S. Thornhill, M.D., Harvard Medical School, Boston, Massachusetts
Aldo Toni, M.D., Rizzoli Orthopaedic Institute, Bologna, Italy
James P. Waddell, M.D., F.R.C.S.(C), St. Michael’s Hospital, Toronto, Ontario, Canada
William L. Walter, M.D., F.R.A.C.S., Ph.D., Sydney Hip & Knee Surgeons, Waverton, Australia
Yonggang Zhou, M.D., The General Hospital of Chinese People’s Liberation Army, Beijing, China
14th International BIOLOX® Symposium

Bearing Surface Options in Total Joint Replacement: The Experts Provide the Evidence.
At the present time total hip arthroplasty is arguably the most dependable and durable operation in the history of medicine. At several centers worldwide better than a 99% survivorship have been reported at 10 years. This spectacular track record brings with it not only the benefits of a powerful operation, but the responsibility that should bear heavily on the surgeon when he uses innovative and unproven technology.

At the present time innovation brings more risk than benefit and, therefore, the surgeon must clearly ask himself, “What problem is being solved?” by the new technology and most important what controlled Level I evidence is there that the technology is superior to our current modalities.

The discussion will cover implants, bearings, pain control, rehabilitation and SMART implants.

Twenty-five years ago I predicted that total hip replacements will be predominantly cementless and the architecture will embrace the tapered stem concept. These predictions have become manifest. Our Center has had three decades of experience with three iterations of tapered stems in over 15,000 patients. They have proven effective for the young osteoarthritic patient with good bone stock, the elderly octogenarian with poor bone stock, and the rheumatoid who also bears the burden of poor bone quality. At the end of 10 years the mechanical failure rate remains under 1% not only at our Center, but many centers worldwide.

In terms of bearings, there are no bad choices today. Our group almost exclusively uses highly crosslinked polyethylene on the socket side with either a delta ceramic or metal head. We rarely use all ceramics because of the frequency of squeaking. If one extrapolates the current tenure data on crosslinked polyethylene it may be that today’s hips will last 200 years. Wear rates have been demonstrated at 0.04 mm per year at the end of 10 years. This appears linear and does not accelerate.

Improved methods of pain control are one of the most dramatic developments in total hip replacement. By minimizing pain a program of rapid rehabilitation with early hospital discharge and rapid return to work has evolved. We frequently use perioperative joint injections and non-steroidal anti-inflammatory drugs rather than parenteral narcotics.

Finally, developments in the future will in all likelihood be biologic rather than mechanical. “SMART Implants” are an example of this type of technology in which the implant will respond to the needs of the patient whether it be sepsis, osteo-integration, or pain control.
Notes:
Bearing surfaces for total joint replacement (TJR) have taken on new significance, given that patients are living longer more active lives, and TJR has been extended to younger more energetic patients. Traditional metal-on-conventional polyethylene articulations have stood the test of time, however newer polyethylenes, metal-on-metal (MOM) and ceramic-on-ceramic (COC) bearings are currently being implanted. Intermediate term results for highly crosslinked polyethylene (HXLPE) for THR are impressive, with no reports of osteolysis to date. Proper implant position is crucial; with the use of larger femoral heads, edge loading has led to failure in thin implants with suboptimal position. For TKA, HXLPE is more controversial. There are no intermediate term results substantiating its use, and theoretical concerns about fatigue failure have been voiced. Newer Vitamin E doped polyethylenes hold great promise.

MOM implant bearings have become more controversial. A dramatic decrease in the use of MOM bearings has been reported in several registries. Concerns for this bearing couple include issues related to suboptimal design, and adverse effects of metallic by-products including cytotoxicity, DNA damage, metal hypersensitivity, hematopoietic abnormalities and trans-placental migration. Resurfacing arthroplasty with MOM bearings may be indicated for younger active male patients with normal anatomy. Wear from the trunion-head articulation in large MOM THR is a growing concern.

COC bearings are being used in younger active patients, especially in Europe and Asia. Fracture of the femoral head is rarely seen, however implant chipping, edge loading with striped wear and squeaking in small numbers of patients continue to be reported.
Notes:
Ultra-high molecular weight polyethylene, also known as UHMWPE, polyethylene or, simply, “poly,” has been an orthopaedic bearing material for total joint arthroplasties since the 1960s [1]. For three decades after its introduction by Charnley for metal-on-plastic low friction arthroplasty, advances in polyethylene technology were relatively modest. The development of highly crosslinked polyethylenes (HXLPEs) in the late 1990s ushered in a period of scientific growth and renewed interest in further optimizing and standardizing the polymer for hip and knee arthroplasty. Today the surgeon can choose between conventional gamma-inert or gas sterilized polyethylene, as well as 1st or 2nd generation HXLPEs for the hip and knee [1].

The first generation of HXLPEs was clinically introduced starting in 1998 to reduce wear and the incidence of revision resulting from osteolysis. A second motivation for developing these HXLPEs was to reduce oxidation, which had been associated with short-term clinical failures after gamma sterilization in air and long-term shelf aging in air. However, the strategies for achieving wear reduction and oxidation resistance varied among orthopaedic implant producers. One approach, known as annealing, involved a single thermal treatment below the crystalline melt transition in polyethylene to preserve crystallinity and mechanical properties. A second approach to polyethylene formulation, referred to as remelting, involved thermal treatment above the melt transition. A second generation of HXLPEs employing sequential annealing or Vitamin E for stabilization of the poly was clinically introduced starting in 2005.

Recently, a systematic review of the literature [2] was conducted to provide a concise overview of the major themes in polyethylene biomaterials, including the development of first-generation HXLPE. A systematic review also examined the radiographic wear data and incidence of osteolysis for first-generation HXLPE in hip and knee arthroplasty. Available evidence in 44 primary research studies uniformly supports elevated radiation crosslinking technology as an effective method to reduce femoral head penetration and osteolysis in total hip arthroplasty; however, the improvement in long-term survivorship remains to be demonstrated. Because only two studies reporting short-term clinical outcomes of HXLPEs in knee arthroplasty could be identified, it remains too early to perform a meta-analysis of the knee literature. Currently, too few clinical studies are available to systematically review the outcomes of second generation HXLPEs in either the hip or the knee.

Although the HXLPE is increasingly used in total hip arthroplasty, the conventional gamma-inert or gas sterilized poly is still widely used especially in the total knee arthroplasty due to improved polymer processing and packaging techniques. Current research is focusing in the development of polyethylene with optimally balanced properties that minimize wear while maximizing other equally important properties.

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Notes:
Evolution of Metal-Metal Bearings

Justin Cobb, M.Ch.(Oxon), F.R.C.S.

Introduction: Metal on metal hip resurfacing can provide outstanding and durable function for young men with hip disease, yet is also associated with unacceptable failure rates. This paper examines which variables are responsible, and how and why they evolved.

Material and methods: All metal on metal devices have been reviewed for the following characteristics: materials, surface finishes and coatings, device design, bearing design including nominal clearance, manufacturing tolerances. These have been correlated with laboratory and clinical results.

Results: Cobalt-Chrome alloys are the dominant material used in metal on metal bearings, with titanium offered by one manufacturer. Historically ‘as cast’ material was used by many manufacturers, while heat treatment for surface finish is also used successfully. Coating is available with titanium nitride or diamond like carbon, although clinical results are few and short term in the hip. Device design varies in both the thickness of wall of both components, the subtended angle of the socket, and the stem size. There is little variation in the subtended angle of the femoral component across all manufacturers. Nominal clearance of bearings varies, with one low clearance device being an outlier. Manufacturing tolerances are hard to find in published literature.

Conclusions: The bearing couple of metal on metal joints does vary significantly between manufacturers. The variations are principally in three areas: metallurgy, nominal clearance and component design. These variables, combined with surgeon error, may explain some of the unacceptable variability in outcome in women, and in some devices.
Notes:
Alumina Ceramic
Aluminum-Oxide Ceramic is a high strength and extremely hard material. Alpha alumina is bio-stable and practically insoluble in the body environment. Therefore, ageing or any systemic reaction in the human body with this ceramic is of no concern. Due to its chemico-physical structure it is hydrophilic allowing liquids to bound to and lubricate its surface.

First Generation Alumina Ceramic
Boutin introduced alumina ceramic components for articulation with itself for THA in 1970, followed by Mittelmeier and others. Problems observed were up to 0.5% fractures and run-away wear in case of edge contact. Nevertheless, the wear rate was in the range of 5 microns per year, much less than for any articulation with polyethylene cups and reaction to alumina wear particles is generally sparse and mostly benign.

Third Generation Alumina Ceramic
Significant improvements in material properties and quality had been made and the successful third generation of alumina has been introduced in 1995. It was a further evolution regarding material properties, manufacturing, quality control and design. Refinement of purity, grain size and manufacturing resulted in improved fracture rate (0.01%) and further increased its wear resistance.

Fourth Generation Alumina Ceramic
The latest evolution, introduced in 2003, was developed by adding Zirconia and secondary elements to alumina to further increase its toughness and reduce the fracture risk to 0.003%. This AMC (alumina matrix composite) reduced the wear rate further to 1-3 micron per year, even under adverse conditions. The combination of AMC vs. AMC is the lowest wearing articulation today for THA.
Fretting corrosion at the head taper junction is reported for retrieved stems with larger diameter heads (36-40 mm on 12-14 mm neck): 42% had severe to extreme severe taper corrosion and corrosion worsens with time, raising concerns for the future. (1)

Larger metal on metal heads may be connected to the stem by an adapter sleeve; more interfaces are then under loads. Comparing whole-blood Co ion levels (2) in patients with Durom (Zimmer, USA) total hip resurfacing vs Durom large-diameter-head THA with adapter sleeve (all made with Co-Cr alloy), 0.7 μg/L was detected for the former vs 2.2 μg/L for the latter at 12 months follow-up. Another report confirms this trend (3). Different adapter sleeve designs cause significantly different Co ions levels (4).

Factors involved with larger head adapters are: more friction at the articulating surface, increased torque at adapter-head interface, clearance, area of contact and surface roughness. The Australian Joint Registry (AJR) reports at 9 years cumulative revision rate for metal on metal THA ranging from 5.5% with ≤32 mm heads up to 12% for ≥36 mm heads. On the contrary the revision rate falls from 6% to 4%, when similar comparison is made with ceramic heads.

It is impossible to divide the ions produced by the bearing surface and adapter sleeve; the AJR reports the same revision rate for Zimmer Durom total resurfacing versus Zimmer Durom stemmed THA at 7 years. The adapter sleeve could add some more ions, but they could not be clinically relevant.

With large-ceramic-heads (≥40 mm diameter) a titanium adapter sleeve (called “Option” by CeramTec, D) gives less concern, because it tends to cold-weld to the stem neck (limiting debris formation) and makes a larger Ti-alloy-ceramic contact surface, increasing the 12-14 mm tapered neck diameters to 16-18 mm diameters of the adapter.

References:
1. Engh et al. Poster 068 AAOS 2012
14th International BIOLOX® Symposium

Bearing Surface Options in Total Joint Replacement: The Experts Provide the Evidence.

Notes:
**Introduction:** Current international standards require the wear of hip joint replacements to be determined preclinically under a standard walking cycle, with correctly positioned prostheses. This approach does not replicate the variation in wear rates or wear mechanisms found clinically. Over the last decade we have developed a Stratified Approach For Enhanced Reliability “SAFER” pre-clinical testing of joint replacements, which determines the effect of variations in surgical positioning, patient activities, patient populations and biomaterial stability on the wear of the prosthesis. The effect rotational and translational mal-positioning of components on the wear of ceramic on ceramic and metal on metal hip prostheses in in vitro simulations is reported in this study.

**Materials and Methods:** Our previous research has developed and validated hip simulation methods for adverse conditions for rotational and translational mal-positioning of Biolox Forte alumina ceramic on ceramic bearings. For ceramic bearings, translational mal-positioning, not rotational mal-positioning, leads to head wear on the rim of the acetabular cup and stripe wear on the head (Nevelos et al 2000, Fisher 2011). In this presentation the wear of Biolox Delta ceramic on ceramic and metal on metal bearings determined in vitro under adverse conditions is reported.

**Results:** Extremely low wear of Biolox Delta ceramic on ceramic bearings was found under standard walking conditions, < 0.05mm$^3$/million cycles. Increasing the cup inclination angle to 65°, did not increase wear or produce stripe wear. Translational mal-position (micro-separation) generated a small increase in wear to 0.13mm$^3$/million cycles with stripe wear on the head. The stripe wear of Biolox Delta was substantially less than found with Biolox Forte. For metal on metal bearings, standard walking cycle simulation produced wear rates of less than 1 mm$^3$/million cycles. Increasing the cup inclination angle to 60°, produced stripe wear of 3 mm$^3$/million cycles on the 28 mm full hemisphere cup and 5 mm$^3$/million cycles on the 39 mm sub hemisphere cups. It did not produce stripe wear on the 36 mm full hemisphere cups. Translational mal-position produced a substantial increase in stripe wear on all three bearings, with wear rates of 4 to 5 mm$^3$/million cycles on size 28 and 36 mm cups and 9 mm$^3$/million cycles on the sub hemispherical 39 mm cup.

**Conclusions:** Adverse condition simulation testing in vitro, showed lower wear for Biolox Delta ceramic compared to Biolox Forte ceramic. These adverse conditions in vitro simulation tests with both translational and rotational mal-position replicated the higher wear rates, stripe wear, rim loading wear mechanisms, wear particle distributions and failure mechanisms found clinically.

**References:**
The in vivo measurement of polyethylene wear is most commonly performed on antero-posterior (AP) radiographs. The actual measurement is of linear head penetration, which is a combination of creep (material deformation) and wear (removal of material). Charnley and Cupic (1) described the so-called uni-radiographic method as, “the narrowest measurement in the weight-bearing area is subtracted from the widest measurement in the non-weight-bearing zone, and the difference is then divided by two”. Charnley and Halley (2) described the so-called dual-radiographic method (with a reported accuracy of +/- 0.5 mm) where the position of the femoral head within the polyethylene liner was measured as above on initial postoperative radiographs and then the same measurements were made on follow up radiographs. The difference between the two measurements represents wear when corrected for magnification based on the known femoral head size. Linear regression analysis of wear measurements made over time can be used to separate true wear (removal of material) from creep (3).

The Livermore technique (4) uses a template of concentric circles and a caliper for identification of the shortest distance from the centre of the femoral head to the cement-prosthesis interface, to the nearest 0.1 mm. Magnification is adjusted from the known size of the femoral head. The difference between measurements made on follow up x-rays and the initial x-rays represents the amount of wear.

Shaver et al. (5) developed a digital edge-detection computer assisted technique. The margins of the femoral head and acetabular component were identified by evaluating gradients of grey-scale intensity on digitized images of radiographs. Martell et al. (6) described a computer-assisted technique based on edge detection and vector wear analysis for the determination of polyethylene wear on digital radiographs. They reported an accuracy of +/- 0.08 mm that compares favorably with the Livermore technique, which showed an accuracy of +/- 0.26 mm and +/- 0.25 mm using calipers and digitizing tablets, respectively. Digital assessment software continues to evolve with the goals of increased ease of use, accuracy, and reproducibility.

By incorporating measurements from digitized true lateral radiographs, three dimensional measurement techniques have been described by Devane et al in 1995 (7) and Martell et al. in 2003 (8). Martell et al. concluded that the 3-D method had greater demands for image acquisition, data storage, and analysis with only a 10% improvement in the detection of wear compared to 2D analysis. The relatively high frequency of poor quality lateral radiographs makes utilization of the 3-D method clinically challenging.

Radiostereometric Analysis (RSA) allows the spatial localization of rigid bodies relative to spherical markers made of Tantalum, which are inserted into the patient and/or attached to the prosthesis, and is considered to be the most accurate and precise method for measuring wear (9, 10). The patient is x-rayed from two angles simultaneously together with a reference cage, producing two radiographs. Three-dimensional coordinates can be reconstructed from the two projections. By comparison to a previous RSA examination, position changes between different
elements can be calculated. The requirement for specialized equipment and the implantation of Tantalum beads limits the use of this method to a small group of patients and research purposes. Various uses and mathematical algorithms have been developed, and advancements in computer programs and digital radiography continue to expand RSA capabilities.

Computed tomography (CT) measurements of polyethylene wear are promising, but infrequently used at this time due to practical issues.

References:

Notes:
Introduction: We conducted a prospective randomized controlled trial comparing the clinical and radiologic outcomes of ceramic-on-ceramic, cobalt chrome on ultra-high molecular weight polyethylene and cobalt chrome on highly cross-linked polyethylene bearing surfaces at a minimum of five years.

Materials & Methods: One hundred and two primary total hip replacements were performed in 91 patients (mean age 5.27 years, 19-64). Patients were randomized to receive one of the three bearing surfaces with 28 mm femoral heads. All patients were followed up to at least 60 months following surgery with outcome measures including WOMAC and SF-12. Radiologic assessment included implant position, evidence of osteolysis and measurement of linear wear.

Results: Ninety-seven hips in 87 patients were available for review at a minimum of five years. Two hips were revised (infection; periprosthetic fracture) leaving a total of 94 hips available. At five years there was no difference in the WOMAC or SF-12 scores. Three patients in the ceramic group reported squeaking. Radiologic evaluation revealed a mean annual wear rate in the ceramic group of 0.006 mm/yr, standard polyethylene of 1.51 mm/yr and cross-linked polyethylene of 0.59 mm/yr. ANOVA reveals these differences in wear rates to be significant between all three groups.

Conclusions: This paper confirms our previously published experience (1). While there was no difference in clinical outcome between the three groups, radiologically there was evidence of significant difference in wear rates.

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Bearing Surface Options in Total Joint Replacement: The Experts Provide the Evidence.

Notes:
More than a decade ago, three "new" bearing couples were introduced (or re-introduced) into the US market. These included metal on metal, ceramic on ceramic and highly cross-linked polyethylene. Now ten years later, we have a better understanding of the performance of these bearings in vivo. Early component failure has highlighted the importance of technique and the limitations of the bearing materials. Highly cross-linked polyethylene has performed well but because of socket design issues in combination with large femoral heads, the liners have occasionally fractured. Ceramic bearings, although much improved, can still fracture and occasionally squeak. Metal on metal bearings, especially large head metal on metal conventional total hip replacement and monoblock sockets have had the highest prevalence of failure. Mechanisms of failure have included failure of socket integration, adverse local tissue reactions (ALTR) and iliopsoas impingement.
Notes:
In a review of European THA wear couple preferences, it is crucial to define whether we are focusing on the geographical Europe, the former Western and Eastern Europe, the EU countries or the countries of the Euro-zone. In order to properly answer the question, we have reviewed data from several sources such as the registries of the United Kingdom, Italy, Sweden and Denmark as well as Eucomed data from 17 other European countries. A review of the data provided in these gives us an overall picture of the utilization of different wear couple materials in total hip arthroplasty:

The overall utilization in all 21 countries shows that 22% of the usage is conventional polyethylene inlays; 54% of the usage was for inlays of highly crosslinked polyethylene; 18% were ceramic inlays and 6% for metallic inlays. If we only look at the data from the EU countries the usage is almost identical. In the Euro zone, the usage is 33% for conventional polyethylene inlays; 39% for highly crosslinked polyethylene; 24% for ceramic and 4% for metal inlays.

On the femoral head side of the articulation, we find that in the 21 EU countries 62% of the wear couples used a metal femoral head and 38% used a ceramic femoral head. In the Euro-zone we find a distribution of 57% of metal and 43% of ceramic ball heads.

The numerous sorts of PE inlay makes it very difficult to determine the exact distribution of the ball heads and inlay relationship.

Different regional and country-specific outliers and the influence of the gross national product and health expenditure percentage on the various bearing couples will be discussed.
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Notes:
INTRODUCTION: In East Asia, femoral head osteonecrosis is a frequent disease of the hip. Patients are young with a mean age of 40 to 50 years. They frequently sit and squat on the floor. Conventional PE articulation was associated with high rates of excessive wear, osteolysis and loosening.

MATERIALS AND METHODS: We have used a contemporary ceramic articulation since 1998; 3rd generation ceramic between 1998 and 2008 and 4th generation ceramic since March 2008. We report the results of THA with use of the ceramic articulations.

RESULTS: Ceramic liner fracture occurred in 3.5% after the use of sandwich type ceramic liner and ceramic head fracture in 4.0% after the use of 28 mm short neck head ball. The 10 year survival of THA using 28 mm medium or long neck ceramic head was 100% without any fracture, without any wear and without any osteolysis. The ceramic bearings have superb outcomes in 10-year studies, and the results are better than any other bearings in young patients.

CONCLUSIONS: Ceramic fracture, squeak and stripe wear appeared as matters of concern in contemporary ceramic articulation. The ceramic fractures are caused by impingement the stem neck against the edge of metal shell or ceramic liner, subluxation and excessive edge-loading in inappropriate designs. The squeak occurs due to impingement generating metal debris, which enters the articular interface and causes a vibration. These problems can be prevented by proper implant design and accurate surgical technique to avoid impingement. The problem is inappropriate implant design not the ceramic material.
Notes:
The overall utilization of THA in South America is expected to increase substantially during the next decades due to the absolute increase in population, especially in the age group above 65 years. This specific population, which houses about 80% of all primary procedures, will nearly triple between 2000 and 2030. In this particular age group, metal-on-polyethylene still remains the bearing surface of choice for most surgeons worldwide, exceeding 50% of all primary hip replacement performed, either in South America or in the U.S.

The increased use of THA in the age group between 20 and 55 years is another concern in South America, because this particular population will present an absolute increase of about 70 million people between 2000 and 2030. Alternative bearings are the first choice for the younger and more active patients. In South America, ceramic-on-ceramic is the most frequently used bearing, exceeding 50% in Brazil and Argentina, whereas a metal-on-metal bearing is preferred in the U.S. (41.8%). However, some differences can be observed between different countries within South America, such as the very low utilization of metal-on-metal bearings in Brazil (4.3%), compared with Argentina (19.8%).

In South America most of the population is assisted by universal systems of health policies, which largely depend on public investments and impose a fixed reimbursement or tariff. These health system characteristics may lead to financial constraints, which limit the choice of alternative bearings based on the socioeconomic status, or may induce patient out-of-pocket expenses through a private health system.
Notes:
The selection of a bearing choice remains somewhat controversial in North America. The main reason for this controversy is the high level of success for both ceramic bearings as well as that of highly cross-linked polyethylene. While large head metal-on-metal systems, including resurfacing, were popular just a few years ago, complications related to metal-on-metal bearings have significantly reduced the enthusiasm. Ceramic bearings have enjoyed a high level of success in North America over the last decade since its approval. Multiple studies have been published illustrating that success. While there was some concern regarding squeaking, it remains a bit of a mystery in terms of causation. The advent of multi-bearing cups and questions regarding the long term durability of highly cross-linked polyethylene will continue to keep ceramic-ceramic bearings as a very viable option for younger and active patients.
Notes:
Total Hip Arthroplasty (THA) is a successful clinical intervention for patients with end-stage hip disease that has been performed for over 40 years with good functional outcomes. In the United Kingdom in 2011, over 79,000 procedures were performed and trends indicate that this is increasing annually (www.njrcentre.org.uk). However, the natural history of these implants is failure, with rates increasing as the interval from surgery increases. In spite of continual improvements in surgical technique and implant design, the burden of revision surgery is not decreasing; in the United States, there is a lifetime incidence of 18% for revision THA and the number of revision procedures is projected to double by the year 2026.

The etiology and rates of revision THA vary from country to country and depend on material and design related factors, surgical and biological factors. Bozic and colleagues demonstrated the leading causes of revision THA in the United States were instability and aseptic loosening, with all-component revision being the most common procedure performed. Results from the Swedish joint registry show aseptic loosening is the most common cause of revision THA. Labek and colleagues amalgamated data from several registries from around the world and demonstrated THA revision rates of 6% at 5 years post-surgery and 12 years post-surgery. Recently, Smith and colleagues (2012) demonstrated that revision rates for THA were highest for larger heads and metal-on-metal articulations and that aseptic loosening was the most common etiology.

This paper will summarize the indications for revision surgery in our unit and in the UK as a whole. Lessons learnt from our failures will trigger improvements in design and technique.
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Notes:
Highly crosslinked UHMWPE was introduced for use in THA over ten years ago and is now the most commonly used bearing surface in THA. In vitro studies and multiple in vivo clinical prospective randomized and RSA studies demonstrate consistent reductions in radiographic wear and osteolysis in comparison to “conventional” (gamma inert sterilized or gas sterilized) UHMWPE.

However, crosslinking also reduces the mechanical properties of UHMWPE and a small number of fractures of modular acetabular liners have occurred in vivo. The fractures typically initiate at sharp corners of the liner locking mechanism and are caused by edge loading or impingement. Modifications in implant design to reduce areas of unsupported UHMWPE above the rim of the shell and improve the geometry of the liner locking mechanism reduce stresses at the liner locking mechanism which should decrease the risk of fracture. Further, second and third generation highly crosslinked UHMWPE’s have been developed in an effort to retain greater mechanical properties of the material. Methods to reduce the effects of crosslinking on the loss of mechanical properties include a reduction in the irradiation dose, and annealing the irradiated material below the melting point, which retains a higher level of crystallinity and strength, but also leaves free radicals which can oxidize in vivo. Secondary processes (Vitamin E or sequential irradiation) have been used to reduce the free radical concentration and potential for oxidation. However clinical retrieval studies which demonstrate the amount of oxidation that may occur with these sub melt annealed and secondary treated crosslinked UHMWPE’s are not yet available.

Recent retrieval studies of highly crosslinked UHMWPE’s which were annealed above the melting temperature have demonstrated evidence of oxidation which would not have been expected to occur in vivo. Although highly crosslinked UHMWPE’s have been used successfully in large numbers of THA’s over the past ten years with excellent clinical results, further follow up is still necessary to determine the relative long term in vivo durability of these materials.

References:


Notes:
Introduction: Fifty-four alumina ceramic-on-ceramic bearings were retrieved at one center after a mean of 3.5 years (0.2 to 10.6). Six alumina bearings (0.15%) were retrieved for fracture of the ceramic head (all three were revision heads with titanium alloy adapter sleeves) or acetabular liner (3) after an average of 4 years. Three hips were revised for persistent squeaking during the stance phase of walking.

Materials and Methods: The femoral heads were measured using a non-contact optical coordinate measuring system (RedLux Artificial Hip Profiler, RedLux Ltd, Southampton, UK). The data was analyzed using 3-dimensional modeling software (RedLux Ltd, Southampton, UK) to find the volume of the wear on the femoral heads. The dimensions of the edge wear on the liners were measured manually.

Results: Forty-five out of fifty-four bearings (83%) had stripe wear after an average of 3.5 years. Posterior edge loading was found in the majority of these retrievals (59%). Anterosuperior edge loading occurred less often but produced a higher wear rate. Stripe wear on the femoral heads had a median volumetric wear rate of 0.2 mm³/year. The wear volume on the femoral heads corresponded to the width of edge wear on the matching liner. Anteversion of the acetabular component was found to be a more important determinant than inclination for wear in ceramic bearings.

Conclusions: Posterior edge loading may be considered to be a normal occurrence in ceramic-on-ceramic bearings with minimal clinical consequences. Edge loading should be defined as either anterosuperior or posterior, since each edge loading mechanism may result in different clinical complications.
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Notes:
Metal on metal (MOM) bearings have theoretical advantages including a hard bearing surface that resists “wear related” failures and the ability to use “jumbo” femoral heads to reduce the risk of dislocation. However, there has been appropriate concern based on a higher than expected rate of failure and the withdrawal of one device from the market.

Issues have included adverse local tissue reactions, failed ingrowth and corrosion related problems. It is important, however, to recognize that not all MOM bearings and cups are created equal with some designs fairing quite well. Further, the Australian Hip Registry suggests that MOM hip resurfacing outperforms conventional THA in males < 55 years old with a diagnosis of osteoarthritis.

When a patient with a MOM bearing presents with pain it is important to evaluate them in a systematic fashion. The first step is to “pretend” that they do not have a MOM bearing and evaluate them as if you would any other painful THA. This includes a careful history and physical examination, evaluation for extrinsic causes of hip pain and infection; it is important to recognize that purulent fluid around a hip may not mean infection and that if a manual synovial fluid white blood cell count may be required to get an accurate reading as cellular or metallic debris can lead to abnormally high readings. X-rays should be reviewed for evidence of loosening or osteolysis as well as component malposition which has been correlated with failure. An understanding of common modes of failure for specific implants is also helpful in determining the cause of pain.

Metal ion levels can potentially be helpful in diagnosing a bearing that is not performing correctly; it is important to understand however that strict “cut-off” values are probably an oversimplification and may not correlate with clinical important parameters such as soft tissue damage. Cross sectional imaging can also be helpful but is operator and equipment dependent. Hypersensitivity type reactions appear to be rarely implicated as a cause of failure but can be assessed using a “lymphocyte transformation” assay. The decision to intervene and revise a MOM THA can be a complex one and requires shared decision making between the patient and the physician. While it is important not to feel “pushed” into revising a MOM total hip, it is equally important to act early in cases where the bearing is not performing as expected to avoid soft tissue damage.

References:

Notes:
The efficacy of hip resurfacing arthroplasty has been demonstrated over the last 15 years utilizing metal-metal bearings. It is inappropriate to compare the outcomes of a procedure when surgeons are on the “learning curve” for that procedure - to those of a more established procedure. The results of hip resurfacing are consistently better in the hands of an experienced surgeon. It should be noted that national joint registry data includes hip resurfacings performed during surgeons’ learning curves, but not so much for total hips. Despite this bias, the 10 year survivorship of hip resurfacing in younger patients of relatively large stature with osteoarthritis is better than that of total hip replacement in the same demographic. Further, it is critical to distinguish between issues related to the hip resurfacing procedure and those related to metal-metal bearings.

The majority of complications associated with resurfacing, which include femoral neck fractures, accelerated wear, and adverse local tissue reactions (ALTR), are related to surgical technique / component position. Because of the relatively small head-to-neck ratio in resurfacing compared to modern total hips, the window for acceptable component position is smaller. There are two challenges with component positioning: 1) identifying the desired component positions for a specific patient, and 2) being able to reliably implant the components in those positions. In addition to intra-operative navigation, pre-operative imaging with CT or MRI and the application of so-called shape matching guides may improve the accuracy of femoral and acetabular component positioning.

The issue with hip resurfacing today is adverse local tissue reactions (ALTR) associated with cobalt chromium alloys. Bearing surface technology continues to evolve. A challenge for hip resurfacing is keeping the aggregate acetabular component thickness at or below 5mm (component outer diameter-to-inner diameter difference of 10mm or less) to conserve acetabular bone stock. There is limited experience with ceramic-ceramic hip resurfacing. The enthusiasm for the low wear potential and biocompatibility of these materials is tempered by the fracture risk in the young and active, predominantly male (larger), resurfacing patient. Ceramic-on-metal bearings for total hip (metallic acetabular component) demonstrate very low wear in simulator tests and have promising short-term clinical results. This bearing couple can be extended to hip resurfacing.

Modification of cobalt chromium bearing surfaces with ceramic-like coatings, such as chromium nitride, have the theoretical potential of lower wear and better biocompatibility without the fracture risk of a ceramic component. However, there are challenges in quality control of a production-level coating process and the risk of accelerated abrasive wear if the coating is defective, cracks or chips.

There is now more than 10 years of clinical experience with crosslinked polyethylenes documenting low wear and reduced osteolysis. The industry has slowly moved to thinner modular liners to accommodate larger femoral heads. The clinical results with heads >36mm has been favorable to date. Wear simulator data indicates lower wear with a thinner crosslinked polyethylene. At least one manufacturer already offers a modular acetabular system (for
total hips) with a nominal outer diameter-to-inner diameter difference of 10mm. A thin crosslinked polyethylene bearing may be extended to hip resurfacing when molded into a cementless fixation substrate.

References:


Notes:
Introduction: Ceramic hips have been used for over 30 years, both all-ceramic (COC) and ceramic/PE (CPE). Alumina has 40-year history whereas yttria-stabilized zirconia was abandoned due to adverse phase changes. An alumina-matrix composite (AMC) has now seen use for 10 years. There appears to be only 2 short-term clinical studies on AMC ceramics in this time, one documenting a fractured AMC ball. This study analyzed the clinical studies, simulator wear studies and retrieval studies representing ceramic bearings. The AMC explant cases were used to compare in vivo wear to those predicted in lab studies. The hypothesis was that the zirconia phase transformation would be mild, self-limiting and have no effect on the implant micro-finished surfaces of both simulator and explanted AMC bearings.

Methods:
1) Simulator micro-separation wear studies (5Mc) of non-aged and aged 36mm AMC balls, cups
2) Retrieval studies of explanted AMC balls and cups
3) Raman spectroscopy of zirconia phases in AMC balls
4) AFM and white-light interferometry study of surface changes AMC balls, cups
5) Wear map comparisons of simulator to explants
6) Linear and volumetric wear assessments by CMM for simulator and explants

Results: The monoclinic phase averaged 7% + 3.1% on the surfaces of as-received delta balls. The monoclinic content then increased linearly with autoclave time (1.2%/hr) and by 10 hours averaged a total of 19%. With further aging, the monoclinic increased but much more slowly to 22.6% by 30 hours. This long-term rate (0.18% per hour) was 6.7-fold reduced compared to the 10-hour rate, i.e. 84% of the total monoclinic content had been achieved by the 10-hour treatment.

The AFM roughness study revealed the details of the manufacturer’s ceramic polishing marks on as-received balls and showed that the as-received balls had a very low roughness averaging 3 nm. There was a gradual increase in ball roughness with autoclave time to 10-hour treatment but this was very small. With longer autoclave times, roughness increased very slowly. Depending on the autoclave hours the monoclinic content on control samples increased slightly from 3 nm to 4.5 nm average. Over all aging, the delta roughness represented an exceptionally fine polish of less than 5 nm.

With 5 million cycles in the hip simulator, overall wear-rates with 36mm aged delta/delta combinations (0.1 mm³ per million cycles) were indistinguishable from control delta bearings and same as in prior non-aged, simulator studies. The Raman profile of increasing monoclinic content with autoclave time remained intact at end of the wear study. It was noted that the non-wear and main-wear zones showed the same monoclinic at zero and 30 hours. After 5-million load cycles in the simulator, the roughness values in non-wear regions had increased very mildly.
from 3 nm controls (Ra = 4.9 nm) and could even be considered a mild environmental effect. Overall, monoclinic in non-wear zones showed mildly increasing and virtually linear trend to 30 hours (rate of 0.28% per hour; \( R = 0.95 \)) and achieved 17.9% monoclinic by 30 hours treatment. In the main-wear zone, the most monoclinic increase occurred up to 10 hours (12% up to 17%) and then showed only slight mild increase to 18.4% for 30 hour aging.

For stripe-wear zones, the Raman profile demonstrated that monoclinic phase behaved differently from non-wear and main-wear zones. Starting at a control value of 16.5% after simulator wear, the monoclinic content increased to 24.1% within 10 hours aging and some outliers approached 30%. With longer aging times, the simulator stripes showed a monoclinic content decreasing to 22.1% on average, thereby approaching that in non-wear and main-wear zones. The stripe-wear monoclinic increased at rate 0.76%/hr from zero to 10 hours; from 10 to 30 hours the monoclinic showed a decreasing rate of -0.1% /hr.

After simulator wear, the main-wear zone in delta control balls appeared marginally rougher at 5.9 nm, but the main change was the 21.2 nm roughness evident in stripe-wear zones. It was noted that with 5 hours of autoclave, there was little difference evident for all other treatments. From this time on, the autoclave controls and the non-wear regions averaged a very slight increase of 1.3 nm whereas the stripe wear averaged a decrease of 3.8 nm. Normalizing the roughness values to the non-worn controls showed that there was little difference evident with non-wear and main-wear zones. Only the stripe-wear zones showed a 4- to 7-fold elevation in roughness overall and this actually decreased with further autoclave aging. Thus an average roughness of 5 nm appeared an adequate overall description for the delta hip bearings.

Eight delta retrieval cases were prepared for comparison with the hip simulator study. Six had ceramic liners and two had UHMWPE liners, all with short follow-up times. The bearing surfaces generally featured highly-polished, surfaces that were marred only by ever present evidence of black metallic transfer. Thus visually identifying main-wear zones appeared impossible and even the labeling of stripe-wear zones could not made with any level of confidence. The monoclinic content in retrieved balls varied from 14.6% to 38.7%. Compared to non-wear zones, the monoclinic content in areas designated as main-wear and stripe-wear averaged 1.1- and 1.2-fold higher, respectively. However such differences were not statistically significant. There appeared to be no individual differences evident in the assessments of non-wear versus main-wear and stripe-wear zones. Retrievals with extremely different monoclinic trends showed little difference in roughness data. Only two retrievals appeared significantly higher than the others and the two delta-polyethylene combinations appeared little different from delta-delta combinations. This lack of zone differentiation may be due to the difficulty of identifying stripe wear on delta retrievals combined also with their short follow-up times. Thus overall an average roughness of 5 nm appeared an adequate overall description for the retrievals.

**Conclusion:** The continuing excellent AMZ bearing finish measured both in simulator studies and ex-vivo provided confirmation that the tetragonal to monoclinic phase had no detrimental effect. Indeed, the wear rates of aged versus non-aged AMZ bearings showed no difference in the severe microseparation wear tests. The zirconia transformation data showed almost identical results in the wear laboratory and in explants, with peak monoclinic appearing to stabilize at 30%. However the surprise was that the maximum in vivo transformation occurred very quickly, within 2 years duration. AMC balls and liners have been in use 5-10 years in some centers. Thus retrieval, clinical and laboratory studies provide new understanding of AMC ceramic bearings and offer confirmation of the superior bearing surface and the self-limiting transformation kinetics on the outermost ceramic surface.
PAPER #21  Peri-Implant Histology & Cytokine Pattern in Metal Allergic Knee Arthroplasty Patients with Improvement After Revision with Hypoallergenic Materials

Introduction: In knee arthroplasty patients with complications not explained by classical mechanisms like infection or malalignment/malposition the role of hypersensitivity to implant materials may be questioned. In 10 such patients – recruited from the Munich implant allergy outpatient clinic - with metal sensitisation and revision surgery a combined evaluation of peri-implant histology and cytokine expression, microbiology and of outcome after revision with alternative “hypoallergenic” materials was done.

Methods: Allergy diagnostic was patch test and lymphocyte transformation test (LTT); histology included immunophenotyping of T, B-cell and monocytic infiltrate together with assessing the interface/neosynovia reactivity pattern according to the classification of Morawietz&Krenn, RT-PCR-based cytokine analysis covered IFN-g, IL-1β, IL-2, IL-6, IL-8, IL-10, IL-17, TGFβ, TNFα. Separate tissue specimen were also processed for microbiology. As control, the same examinations were done upon revision in 5 individuals without metal allergy (patch test and LTT negative). WOMAC score was compared before and after revision with “hypoallergenic” arthroplasty (9x titanium-based/coated, 1x oxidinium).

Results: Metal sensitisation: patch test Ni+4/10, Co+3/10 Cr+1/10, in LTT Ni+8/10, Co+1/10. Histology: 3/10 patients showed foreign body /wear related reactivity (Type I), 7/10 showed the indeterminate type (type 4) low in cells /rich in collagen fibres - in 10/10 scattered partly dense T-lymphocytes were seen and no signs of infection. Cytokine expression patterns differed between the 2 groups (IFNy: 4/10 vs 0/5; TGFβ 8/10 vs 5/5; IL-8 8/10 vs 0/5; IL-6 6/10 vs 1/5, IL10 7/10 vs 5/5). There was no infection. Mean WOMAC was (preop) 40.4 +/-20.58 and (postop) 55.58 +/- 20.14. 9/10 patients improved their WOMAC score.

Conclusion: Metal allergy as mechanism of implant failure remains a controversial issue. However combined evaluation of allergy diagnostics, peri-implant histology and cytokine expression together with exclusion of infection and follow up after revision with “hypoallergenic” implant materials will help to better characterize patients with potential implant hypersensitivity.
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Notes:
TKA is generally considered a durable procedure with reported implant survivorship in many series of 90% or greater at 20 year follow-up. However, implant failure can occur through a variety of mechanisms including bearing surface and backside wear, polyethylene fracture and particulate generated osteolysis.

Implant design, polyethylene quality and manufacturing methods, third body wear debris, and patient specific factors have all been shown to influence the durability of the TKA bearing surface. This lecture will examine modes of TKA failure related to bearing surface issues, evaluate factors which may effect the longevity of the TKA bearing and explore newer and future technologies that could potentially lower the incidence of bearing related failure following TKA.
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Notes:
All polyethylene tibial components were used extensively in early TKA designs. Metal backed components were introduced as they were thought to both improve stress transfer to the proximal tibia (and thus theoretically decrease the risk of loosening) and allowed for modularity. Modularity is attractive as it allows for greater intra-operative flexibility (how many times do you decide to change your mind between the trial and final components?), are easier to implant and allow for isolated exchanges of the bearing surface for causes such as infection or a wear related failure. While rapidly accepted as standard for TKA, modularity is associated with negative features including increased cost of the implant itself and so-called “backside wear”. While backside wear is dependent on a number of different factors, in some designs it has lead to real problems and a higher than expected risk of revision.

Based on desires to both better control costs and decrease the impact of backside wear, there has been a resurgence of interest in using all polyethylene tibial components. A review of studies that have examined the results of using all polyethylene tibial components suggest that they are not “all created equal”. Total knees are complex systems and thus performance of these designs seems to be related to a number of different factors including the quality of the polyethylene and the conformity of the tibio-femoral articulation with more conforming articulations performing better than round on flat articulations. Thus, surgeons considering a change to this type of system must carefully consider the design of the TKA they favor and consider using a system with a prior track record of good performance prior to using this technique.

The literature is unclear on which patients are best suited to this technique. While all polyethylene tibial components are generally suggested for use in elderly, low demand non-obese patients it is unclear if younger patients may benefit equally from the potential advantages of an all polyethylene tibial component or if there are other factors such as patient weight, BMI or deformity that are compatible with the use of this technique.

References:

Wear of total knee arthroplasties (TKA) is still a major problem, especially because the age of patients undergoing TKA has decreased by approximately one decade. Wear is mainly due to adhesive/abrasive wear and fatigue. Although most implants are gamma sterilized and packaged in a non-oxygen containing environment, in vivo oxygenation after implantation still occurs. Cyclic loading produces high subsurface stresses and high peak loads. Edge loading and backside wear increase the particle burden in active patients.

Numerous cross-linked polyethylenes (XLPE) are currently available, but conventional polyethylene is still the “gold standard” in TKA. This is primarily because of concerns regarding suboptimal fatigue properties of XLPE. In vitro studies of polyethylenes that are gamma irradiated and re-melted, or have undergone sequential irradiation and annealing below the melt temperature have demonstrated decreased articular wear and delamination after 5-10 million cycles. Concerns of XLPE include smaller, potentially more biologically active polyethylene wear particles, reduced fracture toughness and reduced resistance to fatigue crack propagation. Few studies with sufficient follow-up are available for review. In one series with 5-8 years of follow-up, the XLPE for TKA was found to be efficacious and safe. Newer Vitamin E doped polyethylenes show great potential for decreased wear in the laboratory. These newer materials are currently undergoing clinical trials.
Notes:
Third body abrasives such as particles of bone, polymethylmethacrylate (PMMA), or porous coatings have been implicated as a cause of metal bearing counterface scratches that occur in vivo. The resultant increase in surface roughness is associated with an increase in UHMWPE wear. Cobalt chrome femoral heads used in total hip arthroplasty are forged alloys with greater hardness and scratch resistance than cast cobalt chrome. However, cobalt chrome femoral components used in total knee replacements are typically cast alloys which may leave them more susceptible to surface roughening. Scratches of the femoral condyles are frequently observed on clinically retrieved cobalt-chrome total knee femoral components.

Numerous approaches have been proposed for enhancing the abrasion resistance of metallic counterfaces including nitrogen ion implantation, thermally driven diffusion hardening, vapor deposition of an oxide surface, and transformation of the substrate metal surface into a ceramic layer. Oxidized zirconium is a material with a metal substrate with ceramic surface. Use of an oxidized zirconium counterface has been shown to effectively reduce TKA wear in vitro. Clinical retrieval studies also demonstrate less UHMWPE wear damage with a hardened scratch resistant counterface compared to cobalt chrome. Clinical radiographic studies have not demonstrated a clear superiority of one counterface material over another. However, for younger more active patients who could outlive the durability of their arthroplasty, use of a hardened scratch resistant counterface may reduce the risk of wear related failure.

Nickel which is contained in cobalt chrome implants is a potential source of metal allergy. The role of metal allergy in causing pain or failure after TKA is a relatively poorly understood. However, for patients with a clinical history of metal allergy and supportive allergy serologic testing, use of non reactive implant materials may be beneficial. Oxidized zirconium provides a variable alternative to cobalt chrome implants in order to avoid exposure to nickel in susceptible patients.
Total knee replacement (TKR) is a successful procedure in orthopaedic surgery. In order to further improve survival rates and obtain optimal clinical outcome with higher range of motion, improvements in fixation and wear couples as well as specific designs have been made. The worldwide circulation of ceramics in total hip replacement is justified through its extreme wear and corrosion resistance because of the excellent tribological properties and the absence of electrochemical reactions. Using these advantages, as well as finding a solution in cases of hypersensitivity against metallic implant materials, led to the development of total knee replacement systems with a ceramic components. However, ceramic materials are brittle and less resistant especially to impact load in comparison to metallic implants. This requires components with sufficient thickness on the tibial side, which can lead to increased bone loss. In particular, this may lead to inadequate stability and dislocation of the joint line. Furthermore, the tribological behavior of an all-ceramic total knee, i.e. the femoral and tibial component as well as the insert, is not clearly investigated so far. Therefore, all ceramic knee endoprostheses are not feasible at the moment. There is still a need for further development and adequate preclinical testing of all-ceramic implants. A major prerequisite should be the optimization of existing designs of the femoral ceramic component.
SESSION VIII  Submitted Papers

Steven M. Kurtz, Ph.D. & Carsten Perka, M.D. - Moderators

PAPER #27  
9:00 AM - 9:08 AM
Cementless Metaphyseal-Fitting Anatomic Total Hip Arthroplasty with a Ceramic-on-Ceramic Bearing in Patients Thirty Years of Age or Younger  
Young-Hoo Kim, M.D.

Introduction: The mid- or long-term studies on the current generation of cementless THA with alumina-on-alumina ceramic bearings in patients younger than 30 years of age are limited. The purpose of this study was to evaluate the mid-term results of the cementless metaphyseal-fitting anatomic total hip prosthesis in patients younger than 30 years of age.

Materials and Methods: We reviewed ninety-six patients (127 hips) who had a cementless THA when they were 30 years or younger at surgery. The most common diagnoses were osteonecrosis (54.3%) and DDH (20.5%). Demographic data, Harris hip score, WOMAC index and UCLA activity scores were recorded. Radiographic evaluation was used to determine implant fixation and osteolysis. The minimum follow-up was 10 years (mean, 14.6 years; range, 10 to 16 years).

Results: The mean preoperative Harris hip score, WOMAC score and UCLA activity score were 41 points, 66 points and 3 points, respectively. At final follow-up, the mean Harris hip score, WOMAC score and UCLA activity score were 95 points, 16 points and 8 points, respectively. No hip resulted in thigh pain after one year postoperatively. All of the femoral stems and all but one of the acetabular components were well-fixed at final follow-up. No hip exhibited squeaking, ceramic fracture, loosening, or osteolysis at final follow-up.

Conclusions: These results in patients 30 years of age or younger suggest that cementless metaphyseal-fitting anatomic total hip prosthesis with alumina-on-alumina ceramic bearing provides outstanding mild-term fixation and significant pain relief well into the second decade without osteolysis.
Introduction: Most radiographic analyses of THA patients are based on AP standing x-rays or lying CT scans. Recent literature points out the interest of standing and sitting. Pelvic tilt and sacral slope variations are relevant parameters for planification and navigation. The accuracy of the anterior pelvic plane measures is questionable due to the variations in the quality of lateral standing/sitting x-rays. Hip extension is a key factor in lumbo-pelvic balance; it has been suggested as a significant parameter in THA instability. Using conventional x-rays, it is impossible to evaluate simultaneously hip-spine relationships, THA position and the entire lower limb profile. EOS® is an innovative slot-scanning radiograph system allowing the simultaneous acquisition of 2 orthogonal images. This study reports the “functional” positions of 150 unilateral THA, including the lateral orientation of the cups and the testing of THA extension.

Methods: The following parameters were measured: sacral slope (SS), pelvic incidence and anterior pelvic plane (APP) (pelvic parameters), sagittal inclination (ASI), frontal inclination (AFI) and planar anteversion (ANT) (acetabular parameters). Variations of sagittal orientation of the cup were measured on lateral standing and sitting images. Pelvic extension ability was measured using a simple and reproducible protocol; the extension from the hips and from the spine were individualized. The non-implanted hips were the control group. Descriptive and multivariate analyses were performed for the different parameters.

Results: The mean doses for full body were 0.80 mGy ± 0.11 for standing and 0.94 mGy ± 0.21 for sitting. Pelvic incidence was 55.83° ± 11.4.

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The extension test has been conducted in all cases without technical limitation. Values for repeatability and reproducibility are less than 5°. In a control group without THA, hip extension is 13.5° (± 8.2°) and only 5.3° (± 9.3°) in THA patients. The spinal extension is 0.6° (± 7.0°) in controls and 2.7° (± 14.5°) in THA patients.

Conclusion: The EOS® slot-scanning technology offers a significant dose reduction benefits. Culmination of both the beams and detectors minimizes the scattered radiation, while considerably enhancing image quality and
avoiding the distortion induced by usual imager systems. The image quality is sufficient to allow a precise analysis of cup parameters even though patients’ thickness varies.

A global analysis of the whole body can be performed in the true standing and sitting positions. This study points out standing / sitting variations for pelvis and acetabulum orientations. We observed that the anterior pelvic plane is different from the vertical plane in half cases in standing position. The overall vision of the patients is an improvement to individualize the true hip extension or flexion, and to assess the impact of pelvic tilt. The EOS® imaging system provides new informations regarding the pelvic functional anatomy in THA patients with potential applications for the study of unstable cases and wear phenomena.
Metallosis in Metal on Metal PPF Total Hip Arthroplasties

9:16 AM - 9:24 AM

Robert Legenstein, M.D.

Introduction: The development of metallosis, (osteolytic bone reactions, fluid production, soft tissue necrosis) is a not commonly reported complication after THR. Cases of metallosis have been found following the use of second generation metal-on-metal hip replacements (Beaule et al. 2001). The exact reasons are unknown (Willert et al. 2000), but hypersensitivity reaction is favored ahead of toxic effects, immune defects and exogen causes (Thomas 2007). The purpose of our study was to analyze metallosis cases in the first consecutive year of metal-on-metal implantation. The phenomenon of metallosis occurred at an unpredictable time in situ and was often misinterpreted as a low grade infection.

Methods: In a retrospective study, we analyzed all 173 (102 women and 71 men) primary and single cementless PPF total hip replacements (STRATEC®) with metal-on-metal (low carbide 0.00-0.08% carbon content) articulation of 1995. One patient was lost to follow-up, 18 patients were deceased. The average age at the time of surgery was 63.3 years (range: 31 to 76 years). The mean duration of follow-up was 115 months (range: 64 to 149 months). Blood parameters, periarticular histology, and bacteriology and in 3 cases i.a. metal analyses were performed.

Results: Forty (23.1%) metallosis cases were observed. Revision was done in 29 (16.8%) patients: 3 femur fractures (1 with metallosis), 5 cases of infection and 21 cases of metallosis. The median HHS at follow-up was 95. Eighteen cases (10.4%) had clinical or radiological metallosis signs as follows: 6 patients (3.2%) had periprosthetic osteolysis and pain, 16 patients (9.2%) had osteolysis without pain and 9 patients (5.2%) had pain without osteolysis in the radiographs. Pain caused by metallosis typically occurred inguinal and at an average time of thirty months postoperatively (range: 5-58 months). Pain in the area of the trochanter major and at initial walking was concomitant. Dislocation was observed in 13 cases at an average time of 44 months with an average cup inclination of 48°. Out of 40 metallosis cases, 10 (25%, Ø 47°) dislocations were recorded. At revision surgery in the case of macroscopic metallosis, a smooth, slightly red to orange colored synovial membrane was found in the newly formed hip capsule. Extensive necrosis within this synovial membrane was observed and diffuse lymphoplasmacytic infiltrates were noted. In most cases the bursa ileopectinea was highly filled and in this synovia extremely elevated intra-articular metal levels from Cr 32 - 46095 μg/l and Co 30 - 67410 μg/l were detected.

Conclusion: The results of our analysis provide that the PPF total hip replacements with low carbide metal-on-metal articulation were not as satisfactory as those of the conventional polyethylene-on-ceramic articulation with a revision rate below 5% at 10 years follow-up. Since 2003 we do not implant or recommend metal-on-metal for total hip arthroplasty anymore. Close radiographic and computertomographic monitoring with high mark on typical osteolysis and exact clinical evaluation is recommended for all patients after total hip arthroplasty with metal-on-metal bearings. Symptoms are minimal and occur late. Low grade infections have to be identified and differentiated. Symptomless patients with severe osteolysis must be detected and head and inlay changes performed.
Introduction: The purpose of this study was to evaluate the outcomes of revision total hip arthroplasties (THAs) with a third-generation alumina-on-alumina bearing surface in patients with osteolysis.

Materials and Methods: Seventy consecutive revision THAs were performed in 67 patients with osteolysis between April 1998 and December 2000 using a cementless BiCONTACT®-PLASMACUP®SC revision implant incorporating a third-generation alumina-on-alumina bearing surface. Six hips in 6 patients were lost to follow-up, which was performed at a minimum of 7 years. The average age of the patients at the time of the index revision THA was 47 years.

Results: No implants had been re-revised nor was osteolysis detected at a mean of 9.8 years post-operatively. There was one case of stem loosening, but no cases with cup loosening. Fretting of the femoral neck was observed on radiographs of two hips. The average Harris hip score improved from 62 points prior to surgery to 90 points at the time of this review. Six hips were associated with an intermittent clicking sound, but no hips had squeaking. No ceramic femoral head or liner fractures occurred. Two surgical procedures were performed for an infection in a patient. With any re-operation or radiographic evidence of osteolysis or loosening as the end point, the 7-year survival rate was 96.9% (95% confidence interval, 90.8%-100%).

Conclusions: The alumina-on-alumina bearing surfaces used for cementless revision THAs in patients with osteolysis were found to produce encouraging clinical results and implant survival rates, with no detectable osteolysis at a minimum of 7 years post-operatively.
High Riding DDH Acetabular Side: What We Should Do if the Real Acetabulum is Too Small
Yonggang Zhou, M.D.

Introduction: Patients with high riding hip dislocation are relatively young and a durable bearing such as ceramic on ceramic should be used when THA is needed. But their undeveloped acetabuli are too small to accommodate the smallest ceramic cup, which is 46mm. So we want to develop a method to use a COC prosthesis for them without the need of construct bone graft.

Materials and Methods: Thirty-seven Crowe IV DDH patients' acetabular CT scan data were used to measure their acetabular dimensions to make sure if they can be reamed to 44mm. The result is negative, but we found the bone at posterior part is abundant. If we ream it posteriorly and inferiorly, we can ream it to 44mm. We tried this method in 32 patients (43 hips) between Jan 2007 and Oct 2010 with a mean 3.7 (range, 1.5 to 5.2 years) years follow-up. The mean age was 31.44 ± 7.86 (range, 22 to 49 years) years.

Results and Conclusions: The average height of the patients' acetabulum was 36.7±9.3mm, and the average width was 29.3±8.5mm. They are much smaller than 44mm. But if we ream the acetabulum posteriorly and inferiorly, we can make a 44mm socket to accommodate a 46mm cup. We also confirmed this method in patients. Forty-one hips (30 patients) of 43 hips (32 patients) were reamed to 44mm and had 46mm ceramic cup in. All cups and stems were stable. No patients required revision at the final follow up. The other two patients are only 132mm and 130mm high, respectively. We have to use 40mm cup with PE liner. So CoC bearing should be used and can be used in high riding DDH patients with our method.
14th International BIOLOX® Symposium

Bearing Surface Options in Total Joint Replacement: The Experts Provide the Evidence.

Notes:
Dislocation is a common complication following primary total hip arthroplasty (THA) in 2-4% and revision THA in 5-10%. The major number of dislocations occurs in the early postoperative phase. Risk factors can be related to patient attributes, specifics of surgical procedure and implant features. Patients of advanced age, female gender, neuromuscular disease, adipositas as well as non-compliant patients and revision THA are more likely to suffer from hip instability. Extreme cup positions, posterior approach, limited surgical experience and trochanteric avulsion are surgery related factors increasing dislocation risk. On the implant side a low head to neck ratio, short neck length, small head diameter and low offset stems bear a higher chance for hip instability. If dislocation occurs, thorough history of the dislocation mechanism as well as physical examination and radiographic assessment are inevitable to make the right therapeutical decisions. Treatment of choice for first time dislocations is non-surgical including closed reduction followed by immobilization in an abduction brace or plaster cast. In case of recurrent dislocation or incorrect implant position, surgical intervention should be carried out according to the etiology of instability. First line surgical options include trochanteric advancement, implant repositioning, implantation of a larger sized head or longer neck. Further options such as an elevated rim liner, constrained cup or bipolar and tripo lar arthroplasty proved to significantly lower the risk of dislocation. In case of trochanteric avulsion/pseudoarthrosis, refixation of the greater trochanter will solve the issue of abduction weakness.
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Notes:
Arthroplasty bearings articulating against PE have shown that minor increases of metal ion (Co, Cr, Ni, Mo, Mn, Ti) concentrations in blood or peri-prosthetic tissue, due to the unavoidable wear and corrosion of the metal components in the body, to be tolerable without any proven or known consequences (Pazzaglia et al., 1986). However, if the ion levels exceed a certain threshold, major biological responses are observed (Kwon et al., 2011). Consequently the determination of ion levels has become part of the standard diagnosis. A fixed “value” for the threshold and whether there is a direct relation between ion concentration and biological response are presently unknown.

Published threshold values are changing: In 2008, critical serum Cr-ion levels of >17 μg/l and serum Co-ion levels of >19 μg/l were associated more likely with metallosis (De et al., 2008). In 2011, the current levels were lowered to 7 μg/l by the MHRA. Since no critical blood or serum limits for exposed workers are available, sensitivity and specificity of a given threshold are investigated in clinical studies. A current study showed this threshold to present low sensitivity (57%) and specificity (64%) (Malek et al., 2012). Furthermore, nearly 50% of the patients undergoing revision exhibited ion concentrations below the threshold (Hart et al., 2012). Even so it is agreed that high ion levels are an indication for a problem, ion levels below the threshold should not be mistaken for a false sense of security.
Notes:
Metal Hypersensitivity: Fiction or Reality?

Peter Thomas, M.D.

Introduction: Upon osteosynthesis or arthroplasty some patients may develop complications that are not explained by common causes like infection or mechanical problems. Since cutaneous metal allergy is frequent in the general population (approx. 13% to Ni, 2% to Co and 1% to Cr), a metal implant hypersensitivity might be questioned as differential diagnosis. As we are running a special ambulatory for such patients, examples of characteristic findings will be presented and discussed in view of the corresponding literature.

Methods: To assess potential metal hypersensitivity, a combined approach of patch test (to prove metal allergy) and lymphocyte transformation test (LTT; to show metal sensitisation) was performed. If available also peri-implant histology was done. The latter included immunophenotyping of cellular infiltrate and if possible further RT-PCR-based cytokine analysis.

Results: In a first series of 239 patients with suspected intolerance reactions to metal implants 71 (29.7 %) were found to have metal allergy. LTT reactivity was predominantly found to Ni, but also to Co and Cr. Subsequently, in a series of 10 patients with metal allergy and peri-implant lymphocytic inflammation the outcome after revision with “hypoallergenic” implants was assessed and revealed amelioration / resolution of the symptoms. In analogy to published observations, we also observed among the patients with suspect of potential metal implant allergy clinical pictures like local or generalized eczema, urticaria, impaired wound or osseous healing, seroma formation and implant loosening.

Conclusions: The findings of reported studies and of our special ambulatory support a role of metal allergy in implant intolerance reactions. The diagnosis of implant allergy should be made on a case-by-case basis by a) excluding alternative symptom elicitors (in particular infection) and b) a combined approach of patch testing (eventually LTT) and peri-implant histology.
Notes:
Introduction: Metal-on-metal (MoM) bearings gained recent popularity in total hip arthroplasty (THA). However, reports of adverse local tissue reactions (ALTR) have led to increased focus surrounding the failures of this bearing surface. The purpose of this review is to highlight the literature regarding the clinical presentation of failed MoM THA and the difficulty in differentiating these cases from periprosthetic joint infection (PJI).

Methods: A PubMed literature search using MeSH terms “metal on metal” AND “hip” AND (“replacement” OR “arthroplasty”) AND (“reaction” OR “infection”) yielded 19 relevant articles from 2008-2012 regarding ALTR in THA. Included in these were 7 studies discussing MoM reactions and PJI.

Results: The most common symptom in patients with ALTR to MoM bearings was groin pain aggravated by weight bearing. Fever and elevated inflammatory markers were not uncommon in this population. Intraoperative presence of “creamy, milk-stained fluid” under high pressure was frequently encountered. Three studies found perivascular lymphocyte infiltration (PVLI) to be suggestive of metal hypersensitivity. However, two studies reported PVLI to be nonspecific for MoM failures. Serum metal ion levels were not reliable indicators of ALTR. Eight cases of PJI presenting concomitantly with ALTR have been reported and suggest that ALTR may predispose to PJI. Cultures may be the only identifiable characteristic distinguishing MoM reaction from PJI.

Discussion: Overall, the literature demonstrates few diagnostic differences between ALTR and PJI. Further methods need to be developed to differentiate ALTR from PJI in MoM bearings.
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Bearing Surface Options in Total Joint Replacement: The Experts Provide the Evidence.

Notes:
Fractures of ceramic bearings in total hip arthroplasty continue to decrease. There are several reasons for this, but revolve primarily around the shift to BioLox Delta and the increased use of larger ball head sizes. However, revising a fractured ceramic component can be potentially challenging depending on a number of circumstances. What a surgeon should do will depend on a number of factors and should be individualized for each patient. With that in mind, there are three main guidelines in dealing with this problem: revise the damaged metal component that held the now fracture ceramic part; remove as much of the synovium and as many of the fractured pieces as possible; restore the functional joint with a ceramic-ceramic bearing, if possible.
Osteolysis is defined as the process of progressive destruction of periprosthetic bony tissue, characterized on serial radiographs as progressive radiolucent lines and/or cavitation at the implant-bone or cement-bone interface. Osteolysis occurs with all kinds of bearings, frequently as a result of particulate debris. Sometimes additional osteopenia due to physiological aging and stress shielding can be observed. The resulting bone loss is a serious problem in revision total hip arthroplasty.

There are different treatment strategies for pelvic osteolysis with a well-fixed acetabular component after total hip arthroplasty (THA). These strategies include either the revision of the acetabular cup or the revision of the liner in combination with debridement of the osteolysis and bone grafting. The understanding of the underlying mechanism for debris generation is necessary. Debris generation depends on age, patient activity, quality of PE, fixation of the liner in the shell and the resulting extent of micromotion and design features of the shell (e.g. holes).

The ideal strategy depends on clinical symptoms, location of the osteolysis, progression of bone defects and stability of the implant. Conservative treatment is acceptable in a limited number of patients only, with low activity level, minor progression and higher age. Operative treatment is necessary in the majority of all cases.

The standard diagnostics include radiological imaging with different views (AP, lateral, oblique) and CT scans. In more and more cases, especially metal-metal bearings, additional MRI is necessary for proper diagnostics.

Treatment strategy depends on stability of the cup and implant contact to the host bone. All treatment strategies include the exchange of the debris generator (normally the liner and the head), the removal of granulation tissue from the osteolytic lesion and the reconstruction of the bone defect with an appropriate material (normally allogenic bone chips) with or without cup exchange. Although access to the osteolytic lesion is normally easier with the removal of the acetabular cup, additional significant bone loss, especially of the pelvic columns, is possible after cup removal. The risk of simple liner exchange and grafting of the bone lesion are progression of osteolysis, loosening and dislocation. So an exact treatment algorithm should be determined in advance. Only closed follow-up can prevent large osteolysis.

References:


Notes:
This session will involve discussion by the panel on some of the challenges of present day total knee arthroplasty. In particular we will discuss problems of metal-hypersensitivity, polyethylene wear and massive osteolysis, as well as fatigue fracture of highly crosslinked polyethylene.

The panel will be shown representative cases and asked to render opinion regarding potential etiology for failure and management plans.
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Bearing Surface Options in Total Joint Replacement: The Experts Provide the Evidence.

Notes:
Traditionally survivorship has been the gold standard by which we measure success after joint replacement surgery. Over the last decade it has become apparent that survivorship alone is an inadequate way to measure success of our interventions. In most studies patient-reported outcome measures (PROMs) have now been accepted as the standard by which to measure clinical outcomes. Today, most published articles include survivorship and PROMs. With the increasing use of PROMs numerous outcome measures have been developed.

Choosing the appropriate outcome measure will depend on the purpose. Joint registries usually use survivorship. However, simple outcome measures such as satisfaction have been used to differentiate predictors of success in some large registries.

In clinical studies in arthroplasty the most frequently used tools are WOMAC and Oxford 12. This presentation will highlight the advantages and disadvantages of these 2 frequently reported PROMs.

While these 2 outcome tools are commonly used, one major problem is the ceiling effect. This becomes especially problematic when these tools are used in young, active patients since many will hit the ceiling with these tools and any incremental benefit will be hard to demonstrate.

To overcome this problem of ceiling effect, new tools have been developed to address young patients undergoing arthroplasty and joint preservation surgery. A couple of these tools will be highlighted in this presentation.

While PROMs are certainly the best method to assess outcomes, objective tools still may play a role. Certainly in RCTs where PROMs may not be sensitive enough to pick up differences between 2 groups, objective tools may be useful. One example of these is the University College (London) Functional Clinical Assessment. This will be shown as an example.

Many tools are available for measuring outcomes. Choosing the right one will depend on the nature of the study be it a registry, RCT or office database.
**Introduction:** Post-operative instructions to patients and post-operative limitations on patient activities by the surgeon are intended to reduce the risk of both early and late complications. Early complications include periprosthetic fracture, loosening due to inadequate primary stability and dislocation. Late complications may include wear, breakage, periprosthetic fracture, and dislocation.

**Materials and Methods:** Our clinical database of over 10000 joint replacements including over 4000 ceramic-on-ceramic hip replacements records all early and late complications. Complications are assessed for patient demographics, activities related to the complication and implant variables.

**Results:** The commonest early complication requiring revision surgery is periprosthetic femoral fracture. Therefore all patients are asked to use crutches or a cane for 4 to 6 weeks after surgery. Revision surgery may require 6 weeks touch weight bearing or even bed rest if bone quality is very poor. Standard antidislocation precautions are recommended though dislocation is extremely rare. Patients are advised to return to tennis and golf at 3 months. In the case of resurfacing, patients are advised to wait 6 to 12 months before returning to surfing, skiing or other high impact sports to reduce the risk of femoral neck fracture.

We have observed only 6 ceramic breakages (3 acetabular liners in primary hips and 3 femoral heads in revision cases where the stem was retained) – none of these ceramic breakages were related to high impact activities. Therefore we place specific no restrictions on our patients based on bearing material.

**Conclusions:** Post-operative limitations are intended to mitigate risk of failure at the bone implant interface (periprosthetic fracture or loosening) and soft-tissue envelope (dislocation). We do not place limitations on our patients to protect the bearing from breakage as we feel this is not necessary.
Notes:
Young patients have been reported to have a higher risk of revision following total hip arthroplasty than older cohorts. This was attributed to the higher activity level which led to increased wear, osteolysis, and component fracture. We prospectively assessed the clinical results, wear and osteolysis, the incidence of squeaking, and the survivorship of ceramic on ceramic THA in patients younger than 50 years (mean age of 42 [18 – 50] years). The series included 425 THAs in 370 patients with 368 hips followed for a minimum of 2 years (mean 7.1 years, range 2 – 14 years). All patients received uncemented acetabular components with flush-mounted acetabular liners using an 18 degree taper. No osteolysis was observed in any uncemented construct. There was osteolysis around one loose cemented femoral component. The survivorship for reoperation for implant revision was 96.7%. There were only two acetabular liner fractures (0.47%) and one femoral head fracture (0.24%). Two of the three fractures involved a fall from a significant height. There were no hip dislocations. Five patients (1.17%) noted rare or occasional squeaking. None had reproducible squeaking. In summary, the current study shows that ceramic-on-ceramic THAs in the young patient population are extremely reliable with a very low revision rate and an absence of wear-induced osteolysis. In addition, it shows that both bearing fracture in this young patient population typically occurs with polytrauma and squeaking issues that have been raised relative to ceramic bearings occur very rarely with the flush-mounted ceramic liner design used in this study.
Notes:
Introduction: Ceramic on Ceramic (C-C) with a raised metallic edge acetabular design is a dependable bearing for total hip arthroplasty in the active person at a minimum of ten years.

Materials: A three center outcome report of an industry sponsored randomized controlled US IDE study initiated in 1996 that consisted of 349 hips. One hundred-forty one in a Biolox forte C-C group and 71 in a metal on poly (M-P) control group. 133 additional non randomized factory titanium clad ceramic acetabular liners mated with ceramic heads were added. Clinical and radiographic assessments made at greater than 10 years. The same tapered straight titanium stem with hydroxyapatite coating was used in all. A fourth center studied the radiographic findings of the same C-C hip design in those with ongoing aggressive physical activity at a similar time interval.

Methods: Annual x-ray and clinical visits were conducted up to 5 years with annual phone follow-up between 5-10 years and x-ray analysis at 10 years. Complications and adverse events were recorded.

Results: Osteolysis in C-C: 1.7%, M-P 19.4%. Revisions C-C: 2.6%, M-P 10.5%. Bearing related failures: C-C 2/349 liner fractures .5%, M-P 3/95 3.2%. Squeaking 1.6% non reproducible. Greater prevalence of incomplete radiolucent lines was identified in proximal stem zones in UCLA 9 and 10 activity patients than those with less activity. This did not translate into less patient activity over time or more discomfort.

Conclusions: Although utilization has decreased as there is growing confidence with crosslinked polyethylene, C-C is functioning well at greater than 10 years.
Notes:
Introduction: Bigger bearing couples are in vogue for the added advantage of improved function. Larger Metal on Metal bearings are being used with caution due to he perceived metal debris disease. The alternative 'Big Balls' remains the ceramic couple. To report the clinical, functional and radiological outcome of consecutive primary hip arthroplasties using large diameter (36mm and above) 4th generation ceramic bearing couples

Methods: We prospectively reviewed 519 consecutive primary THA using fully HAC coated acetabular shell and fully HAC coated stem (JRI Ltd) in 502 patients, with mean follow-up of 46 months. A Biolox-Delta ceramic liner with an 18 deg taper and Biolox-Delta ceramic head (36mm and 40mm) were used in all cases, which were performed in one institution by 3 surgeons. 12 were lost to follow-up. Clinical outcome was measured using Harris, Charnley Oxford, EuroQol EQ-5D scores. Radiographs were systematically analyzed for implant position, loosening, migration, osteolysis. Return to sports and hobbies were recorded.

Results: Mean age was 64.9 yrs (11-82 yrs). There were no dislocations. 50-62mm acetabular shells were used. 36 mm head was used in 92% of cases. No acetabular revisions were performed for aseptic loosening. Other re operations were for infection (1), peri-prosthetic fractures (1) and one ceramic liner fracture. The mean Harris and Oxford scores were 95 (88-97) and 14.1 (12-33) respectively. Harris and Oxford scores were 95 (88-97) and 14.1 (12-33), respectively. The Charnley score was 5.7 (5-6) for pain, 5.8 (4-6) for movement and 5.9 (4-6) for mobility. Mean time to return to recreational sports was 4.2 months. There was no migration of acetabular component. Acetabular radiolucencies were present around one shell. No acetabular liner wear was demonstrated in CT Scans. Mean inclination was 47.4 deg (37-65). Mean EQ-5D description scores and health thermometer scores were 0.84 (0.71-0.92) and 88 (66-96). With an end point of definite or probable loosening, the probability of survival was 100%. Overall survival with removal or repeat revision of either component for any reason as the end point was 99.1%.

Conclusion: The results of this study show an excellent clinical and functional outcome and support the use of a fully coated prosthesis with ceramic bearing couples. However, the issue of ceramic fracture does exist. We envisage to monitor and prospectively report the long-term outcome of this series of patients.
Notes:
This will be a case based interaction of hip and/or knee problems that are not "one of a kind cases" but will illustrate problems that could lead to "nightmares" for both patient and surgeon.

The faculty is an experienced group of clinically active arthroplasty surgeons.
14th International BIOLOX® Symposium
Bearing Surface Options in Total Joint Replacement: The Experts Provide the Evidence.

Notes:
National joint replacement registries have been established in several countries throughout the world including almost every English speaking country except the United States. When developed, operated and reported by orthopaedic surgeons, the data from national joint replacement registries has been used to improve outcome, identify poorly performing technology and generate research questions. In the United States, hip and knee replacement represent the single biggest expense for CMS. Failure is costly. Between 1997 and 2003, revision surgery accounted for approximately 19% of Medicare hip replacement expenditures and 8.2% of knee replacement expenditures. The ability of a national joint replacement registry to reduce the revision burden is well documented in Sweden. Through the process of continuous feedback to hospital centers and operating surgeons, the revision burden in Sweden has declined over the past two decades. In 1990, the revision burden for hips in Sweden was approximately 10% compared to 18% in the United States. Today, the revision burden for hips in Sweden is 8%. In the United States, it remains at approximately 18%. Similarly, the cumulative frequency of hip revision in Sweden has steadily declined from 10% at 11 years for cases done in 1979 to 4% at 11 years for cases done 1989. They attribute this in large part to the Swedish Hip Registry.

The need for a national joint replacement effort in the United States is obvious and is the impetus for this RFA. There are more than one million hip and knee replacements performed in the United States each year, an order of magnitude greater than any other country in world. Demand has increased steadily from 1990 to the present. The number of knee replacements alone is projected to grow by 673% to 3.48 million by the year 2030. Most new hip and knee replacement systems are introduced to the market via the 510k process. Little if any effective post-market surveillance occurs. Despite the fact that new hip and knee systems are designed, manufactured and implanted with the expectation that they are at least equivalent to existing products, problems can and do occur. Currently, there is no effective mechanism to identify poorly performing implant technologies or techniques. As a result, nationally we are performing a large clinical trial but neglecting to track outcomes. The outcome is that inferior technologies and techniques continue to be utilized longer than necessary and patients suffer.

There is a growing body of evidence to suggest that implant registries that generate real time survivorship curves can serve as a clinical trip wire for inferior technology. When sufficiently large numbers of procedures are tracked, patient and surgeon factors that impact outcome tend to evenly distributed across various implant designs. Implant technology then tends to dominate overall survivorship. Figure one is a socket survivorship data from a single institution for patients undergoing primary total hip replacement. Statistical analysis identifies outliers. Investigation of inferior performance and notification to key stakeholders can lead to correctional activity minimizing patient exposure enhancing patient safety and reducing overall costs.

The Australian Hip and Knee Registry is a relatively recent joint replacement registry that documents the impact collection of the minimum data set can have on informed decision making. Metal on metal hip resurfacing was
introduced in Australia in 1999. Analysis of the level one data demonstrated that at four years there was a significant increased risk of revision surgery for hip resurfacing compared to conventional total hip replacement. Further analysis demonstrated subgroups (elderly and women) that were at very high risk of failure. This information had an immediate impact on patient selection. Metal on metal hip resurfacing was introduced in the United States in 2006 through a controversial FDA approval. With approval came the requirement of post-market surveillance. These studies may be ongoing, but to my knowledge the information is not being presented to surgeons and patients. Within the past year, metal-metal hip replacements have been withdrawn from the US market based in part on data from international registries.

There are many documented examples where national joint registries have identified poorly performing technology. In Norway, they have identified inferior results as early as three years following market introduction. Several uncemented implant designs and two bone cements have been withdrawn from the market as a result. The Australian Joint Replacement Registry demonstrated inferior performance of a uni-compartmental knee spacer leading to market withdrawal. Interesting, that same implant is still sold in the United States.

Using level one data (minimum data set), implant registries can also distinguish between poorly performing technologies and technologies that are technically difficult to perform. The Swedish Knee Registry provides an excellent example. In this registry, the eight year survivorship of the Oxford UKR in the hands of high volume surgeons exceeded 92% compared to less than 82% with low volume surgeons. In contrast, the Endo Link UKR likely represented a technically more straightforward procedure. Overall survivorship was good and surgical volume has little impact on outcome. Finally, the PCA UKR during the time period reported documented inferior technology. This implant had poor survivorship regardless of surgical experience. This data can also be utilized to examine the learning curve associated with introduction of new technology.

As it relates to bearing surfaces, the registries tell us that metal on metal total hip replacement has the highest failure rates. However, it is important to sort out the reasons for failure. Certainly, local adverse tissue reactions are much more frequent with metal on metal hip replacements. However, other problems such as failure of monoblock sockets to osseointegrate or taper corrosion more commonly seen with large femoral heads also play a role. The registries tell us where problems may exist but rarely tell us why they exist.

Notes:
Program Evaluation

Please assist us in future course planning by completing the following evaluation. Please circle the number which best reflects your view of the following: (5= Excellent, 4=Very Good, 3=Good, 2=Fair, 1=Poor)

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**Learning Objectives**

This activity met its stated objectives.

I learned new knowledge and skills from this activity.

This activity is relevant to my professional role.

How can we improve the activity to make it more relevant to your professional practice?

**Suggestions for Future Activities/Topics**

In order to design future education that can help improve practice, we need to better understand your clinical challenges. Please respond to the following questions:

In what clinical areas do you feel the least prepared or most uncomfortable?

What patient problems need more attention or follow up?

Please list any topics for future activities that would assist you in your professional role:
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*Moderator