Combined Meeting:
Australian Knee Society, &
Australian Arthroplasty Society
October 7, 2005
Bunker Bay, Australia

Alternative Bearings in TKA:

Oxinium (Oxidized Zirconium)
--The Science behind the Ceramic--

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CoCr TKA Surface Roughens

(Levesque et al., ORS 1998)

- Thirteen consecutively retrieved CoCr clinical components
- All condyles had scratches, some oblique to articulation
- Condyle roughness increased, especially the peaks

Scratches on Retrieved Condyles

Geography of a Scratch

<table>
<thead>
<tr>
<th>Non-Implanted</th>
<th>Retrieved (Cemented)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Profile (Ra)</td>
<td>Mean Peak (Rpm)</td>
</tr>
</tbody>
</table>
Cobalt Chrome
Oxinium
Roughening Increases Wear

(Fisher et al., Proc IME, 1995)

- “...a single scratch 2 μm deep (with 1 μm adjacent peak height) on a metal counterface can cause a dramatic increase in the wear rate of UHMWPE”

- How do metal bearing surfaces roughen?
  - Abrasive wear (scratching by hard particles)
  - Oxidative wear (shearing of sliding surface)
Limited Alternatives to CoCr

- **Hardened Metals (ion implanted; diffusion hardened)**
  - Benefit inferior to ceramics and short-lived at best

- **Ceramic Coatings (titanium nitride; diamond)**
  - Limited durability, especially if damaged

- **Monolithic Ceramics (zirconia; alumina)**
  - Risk for brittle fracture
  - Not available commercially
Oxinium (Oxidized Zirconium)

- **Capability**
  - Reduce polyethylene wear by using a low-friction counterface that resists roughening and avoids brittle fracture

- **Method**
  - Form a ceramic surface on a metallic zirconium alloy by oxygen diffusion
Materials

- **Metallic element** -- Zirconium
  - Same family as titanium; very biocompatible

- **Metallic alloy** by combining with Niobium -- Zr-2.5Nb
  - Niobium and oxygen strengthen zirconium

- Oxidize to form **ceramic** -- Zirconia (zirconium oxide)
  - Low-friction and resists roughening
  - Brittle; low fracture toughness
Two Highly Biocompatible Metals

97.5% Zirconium
+ 2.5% Niobium
+ Oxygen and Heat
= Oxinium

<table>
<thead>
<tr>
<th>IV B</th>
<th>V B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ti</td>
<td>V</td>
</tr>
<tr>
<td>22</td>
<td>23</td>
</tr>
<tr>
<td>47.90</td>
<td>50.94</td>
</tr>
<tr>
<td>Titanium</td>
<td>Vanadium</td>
</tr>
<tr>
<td>4.5</td>
<td>5.96</td>
</tr>
<tr>
<td>3130 (Ar) 3d² 4s²</td>
<td>3530 (Ar) 3d³ 4s²</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Zr</th>
<th>Nb</th>
</tr>
</thead>
<tbody>
<tr>
<td>40</td>
<td>41</td>
</tr>
<tr>
<td>91.22</td>
<td>92.91</td>
</tr>
<tr>
<td>Zirconium</td>
<td>Niobium</td>
</tr>
<tr>
<td>6.4</td>
<td>8.4</td>
</tr>
<tr>
<td>3580 (Kr) 4d² 5s²</td>
<td>3300 (Kr) 4d⁴ 5s</td>
</tr>
</tbody>
</table>

Oxinium--Science Behind the Ceramic
Oxidation Process

- Wrought zirconium alloy component is heated in air
- Metal surface transforms to ceramic; not a coating
- Ceramic oxide is uniformly about 5 μm thick

Air
500°C

Oxygen
Diffusion
Original Surface

Ceramic Oxide

Oxygen Enriched Metal

Metal Substrate
Hardness
(Long et al., SFB 1998)

- Oxidized Zirconium surface is over twice as hard as CoCr.
- Underlying oxygen-rich zone promotes adherence to substrate.

![Graph showing Nano-Hardness (GPa) vs. Depth From Oxide Surface (µm) for Cast CoCr and Oxidized Zirconium.]
Polyethylene Wear against Oxinium
(Spector et al., AAOS 2001)

Using knee simulator, Oxinium reduced PE wear rate by 85% with fewer particles

- Three femorals each for 6M cycles of physiological motion
- Polyethylene wear measured by weight-loss and by particle analysis

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**Graphs:**
- Mean Tibial Wear (mm³)
- Aggregate Wear Rate (mm³/Mcycle)
- PE Wear Particles (relative number)

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Oxinium--Science Behind the Ceramic
Abrasion Resistance
(Hunter and Long, WBC 2000)

- Oxinium reduced abrasion against bone cement by over 4900X
- Oxidized Zirconium post-test roughness was over 160X less
  - 10 million cycle pin-on-disk test represents 10 years of cement debris in joint
Why Low Wear?

Lower Friction reduces adhesive wear

- Lower coefficient = increased sliding efficiency which may reduce wear
- Oxinium coefficient of friction is 1/2 that of cobalt chrome
Damage Tolerance
(Hunter, SFB 2001)

- Ceramic oxide surface adheres even if damaged by:
  - Punching crater through oxide, with adjacent heaving-up of substrate (hardness test)
  - Abrading bone cement pin for 10 Mcycle across line milled through oxide (modified abrasion test)
**Strength**

**(Tsai et al., SFB 2001)**

- Ox. Zirconium device strength is equivalent to CoCr
  - Supported 4.4 kN (1000 lbf) in 10 Mcycle fatigue test
  - Physiological worst-case: single condyle, no bone support, full flexion
Stress Shielding

- Ox. Zirconium is less stiff than CoCr; less stress shielding of bone
  - Simulated load of 6X body weight in full flexion
  - Stresses in cement remain below the minimum fatigue strength
Zirconium is one of five most biocompatible metals:
- Other four metals: niobium, titanium, tantalum, and platinum
- Based on self-passivation and lack of biological function

Alloy biocompatibility confirmed per ASTM F748:
- Cytotoxicity (L929 MEM Mouse Fibroblast)
- Sensitization (Kligman Maximization)
- Genotoxicity (Ames Mutagenicity and Mouse Micronucleus Assay)
- Implantation (Rabbit 90-Day Intramuscular and Rabbit 6-Month Transcortical)
- Intracutaneous Reactivity (Rabbit Intracutaneous Injection)
- Acute Toxicity (Mouse Systemic Injection and Rabbit Pyrogenicity)
- Haemocompatibility (Rabbit Hemolysis)
Zirconium is one of five most biocompatible metals

- Other four metals: niobium, titanium, tantalum, and platinum
- Based on self-passivation and lack of biological function
Metal Sensitivity

- Reports of metal hypersensitivity (especially nickel)
- Very low impurity content in Oxidized Zirconium
- Maximum specified impurity levels in alloys:
  - CoCrMo: 1% nickel
  - Ti-6Al-4V: 0.1% nickel
  - Zr-2.5Nb: Not detectable (0.0035% nickel)
Summary

- Less Polyethylene Wear Than CoCr
  - Harder Material
  - More Resistant to Scratching / Roughening Than CoCr
  - Less Friction Than CoCr

- Excellent Biocompatibility

- Strength of Metal; Tribology of Ceramic
And That’s about as Good as it Gets!

Thank-you!

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