Ceramic-on-Ceramic THR’s

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Bearing Surface Choices

**Head**
- Metal
- Ceramic
  - Alumina
  - Zirconia

**Cup**
- Polyethylene
  - Standard polyethylene
  - Cross-linked polyethylene
  - Highly cross-linked polyethylene
- Metal
- Alumina
Metal-Poly—The Gold Standard

- Developed by Sir John Charnley (U.K.) in the late 1960’s
- Has withstood the test of time
- Many long-term studies with excellent survivals in appropriate patients
- Wear rates 0.1-0.2mm/year
## Charnley Long-term Results (metal-poly)

<table>
<thead>
<tr>
<th>Author</th>
<th>Age</th>
<th>Follow-up</th>
<th>Results</th>
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<tbody>
<tr>
<td>Callaghan, JBJS, 2000</td>
<td>Mean 65 yrs</td>
<td>Minimum 25 yrs</td>
<td>3% femoral revision</td>
</tr>
<tr>
<td>Wroblewski, JBJS, 1999</td>
<td>Mean 43 yrs</td>
<td>20-30 yrs</td>
<td>2.8% femoral revision</td>
</tr>
<tr>
<td>Schulte, Johnston, JBJS, 1993</td>
<td>Mean 65 yrs</td>
<td>Minimum 20 yrs</td>
<td>2% femoral revision</td>
</tr>
<tr>
<td>Kavanagh, J Arthroplasty, 1994</td>
<td>Mean 64 yrs</td>
<td>Minimum 20 yrs</td>
<td>16% <em>overall</em> revision rate</td>
</tr>
<tr>
<td>Callaghan, JBJS, 1998</td>
<td>&lt; 50 yrs</td>
<td>20-25 yrs</td>
<td>13% femoral failure rate</td>
</tr>
</tbody>
</table>
Ceramic-Polyethylene

- Choices are Alumina vs Zirconia
  - Alumina
    - Harder surface
    - Better tribological properties ("rubbing" properties—friction/lubrication/wear)
  - Zirconia
    - Lower modulus of elasticity (less "stiffness")
    - Twice the toughness & fracture strength
  - Generally ½ the poly wear rate of metal-poly
Ceramic-Poly Long-Term Results

  - 64 ceramic-poly THA’s
  - All Charnley-Muller stems, cemented poly cups
  - 32 mm heads
  - 17-21 year f/u
  - 20 year survival = 79%
  - Linear poly wear = 0.034 mm/year

  - 97 ceramic-poly THA’s
  - Minimum 10 year f/u
  - 15 year femoral survival = 92%
  - Linear poly wear = 0.15 mm/year
Alumina vs Zirconia

- Each has benefits
  - Better wear characteristics than zirconia
  - Zirconia more fracture resistant
  - But modern alumina has improved strength
  - Less wear against polyethylene—0.04 vs 0.08mm/year (Hernigou, AAOS, 2000)
  - Zirconia recall (2001)
Zirconia Head Recall

- August 14, 2001, St. Gobain DesMarquest recalled nine specific production batches of its zirconia ceramic femoral heads
- Root cause was in their manufacturing process
Highly Crosslinked PE

- **First examples**
  - 1971 - Oonishi (Japan)
    - 40 times the gamma radiation used to sterilize PE
  - 1978 – Grobbelaar
    - Radiation and chemical treatments
  - 1986 – Wroblewski
    - Chemical treatments

- **Today, most require e-beam treatment or 5-10 mRad gamma radiation (compared to 2.5 mRad for gamma sterilization)**
Highly Crosslinked PE

- Early examples used very different techniques that today’s highly crosslinked PE
- Contemporary concerns center on the decreased fatigue and tensile strength - these deficiencies could result in catastrophic failures
  - Most concerning in non-congruous articulations (TKA’s) or roughened counter-surfaces
  - Less concerning in congruous articulations (THA’s)
- Short-term experience only with modern XLPE’s
- Commercially available
  - Zimmer/Centerpulse/DePuy/S&N/Stryker-Howmedica
Metal-Metal

- First examples
  - 1959 - Sivash prosthesis
    (Dr. Sivash, Russia)
  - 1964 - Moore prosthesis
    (Dr. Ring, UK)
  - 1965 - McKee-Farrar prosthesis
    (Dr. McKee, UK)
Early examples lacked sufficient manufacturing tolerances and many failed rapidly, however, some survived for 20+ years.

Contemporary concerns center on ion release and possible carcinogenic effects:
- High levels of Co and Cr in serum and urine (esp during “running in” phase)
- Chromosomal damage
- ?Link to some malignancies

Commerically available:
- Wright/Encore/Centerpulse
Ceramic-Ceramic

- Early examples
  - 1969 – France (Boutin)
  - 1974 – CeramTec (Germany)
  - Early 1980’s -- Mittelmeier (Autophor) –U.S. (Smith & Nephew)
    - Failures due to:
      - Lack of fixation
      - Neck impingement
    - However, minimal wear
Ceramic-Ceramic Today

- 2 companies received FDA approval Feb 3, 2003
  - Wright Medical
  - Stryker/Howmedica/Osteonics
- Encore approved 2004
- Several others will likely receive FDA approval in 2005
- All ceramics manufactured by CeramTec (Germany)
Stryker/Howmedica/Osteonics
Trident® Cup

- Ceramic inlay inset into metal shell to prevent neck/ceramic impingement
- Concern over metal-metal impingement
  - Wear debris/osteolysis
  - Notching of neck; neck fracture
  - Additional modular interface
  - Reduced range of motion
Wright Medical Lineage® Cup

- Ceramic not inset into metal shell
- Some concern over neck/ceramic impingement
  - Ceramic chipping and fracture
    - 3rd body wear
    - Ceramic failure
  - ?notching of neck
Plus Orthopedics MPF Cup

- Manufactured by Intraplant Medical Products
- Ceramic or polyethylene inserts
  - Recent re-design allows thicker poly (GII)
- Plasma sprayed
- Flattened dome allows optimum press fit
Ceramic-Ceramic Wear Rates

- Retrievals have shown very low wear
  - Hundreds (thousands) of times less linear wear than conventional polyethylene (1000-2000x)—depending on study
- Very favorable tribological properties
  - Smooth surface
  - Wettable
  - Hard surface
Ceramics – Hardness

- Extremely hard surfaces – hard to scratch, surface stays relatively pristine
Ceramic-Ceramic Wear Reduction

- Improved implantation techniques
  - Avoid vertical cup placement
  - Avoid neck impingement (3rd body debris)
- Avoidance of small heads
- Improved manufacturing tolerances
Linear Wear Rates

(200x lower linear wear than metal-poly)
Volumetric Wear Rates

(<1000x volumetric wear than metal-poly)
Concern: Ceramic Fracture

- **Causes**
  - Poor manufacturing techniques with older components
  - Neck/insert impingement
    - Design problems
    - Surgical technique
  - Trauma

- **Damage to stem taper and acetabular shell**
  - Due to extreme hardness of alumina
  - Usually requires revision to metal head/poly insert, or revision of femoral component
Fewer Ceramic Fractures Today

- Improved Strength due to
  - Better designs
    - Larger heads
    - No skirts
    - Grooved trunnions
  - Decrease in grain size and void reduction
  - Better manufacturing tolerances
- 100% proof testing
Ceramics – Technical Aspects

- Grain size and void reduction

Alumina ca. 1980

Alumina Biolox (forte)
FDA Strength Standard for Ceramic Heads = 46kN

- Break Strength (kN):
  - Ceramic Bearing: 46 kN
  - Hip stem: 16 kN
  - Femur: 9.5 kN
  - 4X Body Weight: 3.1 kN
Burst Strengths of Alumina Ceramics

(1 kN = 225 lbs)

- **Biolox**
- **Biolox Forte**
- **Biolox Delta**
Ceramics – Strength Testing

- **Heads**
  - 100% proof testing – heads tested prior to packaging
  - Subjected to burst pressures that will destroy the head if any defects are present in the head
  - Prior to proof testing fracture rate was \(= 0.02\%\) with \(~2\) million implantations

- **Inserts**
  - Crush strength of 18,000 lbs
Clinical Reports of Ceramic Fracture

- Sedel, 2003 Hip Society Meeting, New Orleans
  - 1977 - 2001
    - 3300 ceramic-ceramic THA’s
    - 1200 ceramic-poly THA’s
  - 13 fractures (8 heads, 5 liners)
    - 13/7800 = 0.17% (0.25% from multiple studies)
    - 3 due to trauma
    - 2 early on (weaker alumina)
    - 2 due to design flaw
    - 3 related to recent design change (now corrected)
Sedel, Treatment of Ceramic Fractures

- 8 diagnosed immediately, revised to new ceramic component
- 1 revised to metal head due to damage to trunnion
- 4 complete revisions
Willmann, Clin Orthop, 2000
(Report of CeramTec Alumina Heads)

- 2.5 million alumina femoral heads implanted to date
  - Published fracture rates 0% after 1990 to 13.4% prior to 1990
    (highest rates in poorly manufactured ceramics by companies no longer in business)

- 3 generations of Ceramtec aluminas
  - 1st generation: 0.026% fracture rate
  - 2nd generation: 0.014% fracture rate
  - 3rd generation: 0.004% fracture rate
    - = Biolox Forte
    - Since 1994
    - All HIP, laser marked, proof tested

- Best estimate: 1/10,000 modern ceramic components will fracture
## CeramTec Ceramics Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Alumina</th>
<th>BIOLOX®</th>
<th>BIOLOX® forte</th>
</tr>
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<tbody>
<tr>
<td>Strength</td>
<td>400</td>
<td>500</td>
<td>580</td>
</tr>
<tr>
<td>Structure</td>
<td>&lt; 4.5</td>
<td>&lt; 3.2</td>
<td>&lt; 1.8</td>
</tr>
<tr>
<td>Density (g/cm³)</td>
<td>3.94</td>
<td>3.96</td>
<td>3.98</td>
</tr>
<tr>
<td>Laser-engraved</td>
<td>?</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>HIPped</td>
<td>?</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Proof-tested</td>
<td>?</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>100% control</td>
<td>?</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Suited for BIOLOX® forte/</td>
<td>?</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>BIOLOX® forte configurations</td>
<td></td>
<td></td>
<td></td>
</tr>
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</table>

? = unknown  + = yes  - = no
Importance of Component Positioning

- Imperative to avoid cup malpositioning
  - Vertical placement leads to high stress concentration, debris generation, and 3rd body/runaway wear
  - Correct version imperative to avoid impingement in flexion or extension
    - Impingement can lead to chipping of the liner, 3rd body wear
    - Damage to the metal neck can lead to 3rd body generation, neck weakening/fracture
Ceramics – Clinical Studies

- Long-term studies
  - Hamadouche, Sedel, et al, JBJS, 2002
    - 118 consecutive ceramic-ceramic THA’s (Ceraver Osteal)
    - 80% cemented, 20% cementless
    - Minimum f/u = 18.5 years
    - Wear undetectable by XR
    - 10 cases with osteolysis
    - No ceramic fracture
**Mittelmeier (Autophor) Results**

- **Jazrawi, et al., J Arthroplasty, 1999**
  - 60 THA’s
  - Mean 12.7 year f/u
  - Mean age 45.2 years
  - Mean wear rate = 0.016mm/year

- **Garcia-Cimbrelo, et al, J Arthroplasty, 1996**
  - 83 THA’s
  - Mean 12.3 year f/u
  - Mean age 47.5 years
  - No significant radiographic wear

- All failures due to poor design, loosening
Does Every Patient Need Ceramic-Ceramic?

- Many good long-term metal-poly and ceramic-poly studies showing excellent results
  - Best results in older, sedentary patients
  - Poorer results in young, active, or heavy patients
- Cost also an issue
  - Most hospitals will not allow use of ceramics in every patient due to expense
Later THA Results—Improved Cement Technique
(metal or ceramic heads)

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<td>Barrack, JBJS, 1992</td>
<td>18-50 yrs</td>
<td>10-14.8 yrs</td>
<td>2% radiographic femoral failure rate, 0 revisions</td>
</tr>
<tr>
<td>Schmalzried, JBJS, 1993</td>
<td>23-83 yrs</td>
<td>5-8 yrs</td>
<td>1% femoral failure rate</td>
</tr>
<tr>
<td>Mulroy, JBJS, 1990</td>
<td>20-84 yrs</td>
<td>10-12.7 yrs</td>
<td>3% radiographic femoral failure rate</td>
</tr>
<tr>
<td>Russotti, CORR, 1988</td>
<td>22-90 yrs</td>
<td>5-7 yrs</td>
<td>0 revisions, 90% excellent clinical results</td>
</tr>
<tr>
<td>Oishi, Colwell, JBJS, 1994</td>
<td>41-92 yrs</td>
<td>6-8 yrs</td>
<td>0 radiographic failures, 97% good/excellent results, 1 revision</td>
</tr>
<tr>
<td>Ballard, Johnston, JBJS, 1994</td>
<td>18-49 yrs</td>
<td>10-15 yrs</td>
<td>12% femoral failure rate, 5% femoral revisions (young pts)</td>
</tr>
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General Guidelines

- Use what is necessary to obtain necessary lifespan of implant for patient
  - <60 years old: Ceramic-ceramic
  - 60-65 years old: Ceramic-X-linked poly
  - 65-70 years old: Ceramic-poly
  - >70 years old: Metal-poly
Summary

- Ceramics have become reliable, safe, low-wearing bearing surfaces
- But, they are not completely without problems
- And, not every patient needs a ceramic-ceramic total hip
- Only through further research and comparison to other bearing surfaces will we know the future role of ceramics in THA
Thank-You

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