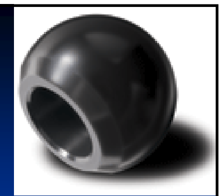
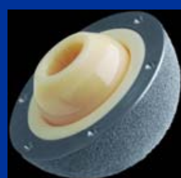



Materials for Joint Arthroplasty

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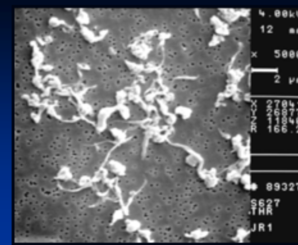
Introduction

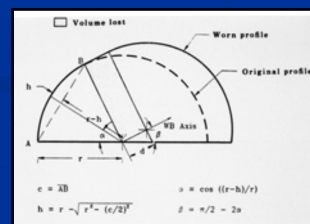
Midterm Failure of total joints is due to

- **Osteolysis**
- **? Cement disease**
- **? Particulate disease**
- **Biologic response to micron size particulate debris**

The Osteolysis Threshold

- Volumetric wear determines the number of particles and the "biological burden"
- All Charnley sockets with >5mm linear penetration are loose - a wear volume of about $1000mm^3$
- All hips with a wear volume of $>1000mm^3$ at 10 years had osteolysis
- Hips with wear rate of $<40mm^3/yr$ (0.13mm/yr) at low risk for osteolysis at 10 years; 25 years to get to $1000mm^3$





Kabo et al. 1993

Improvements

- Component metallurgy
- Component design
- Cementation techniques
- Cementless fixation
- Bearing surfaces

Decreasing Polyethylene Debris

Improve polyethylene processing

- Decrease free – radical generation
- Sterilize in absence of air
- Cross-linking improves wear properties
  - May effect mechanical properties

Decreasing Polyethylene Debris

Alternative bearing surfaces

- Ceramic on polyethylene
- Oxinium on polyethylene
- Ceramic on ceramic
- Metal on metal
- Metal on ceramic?

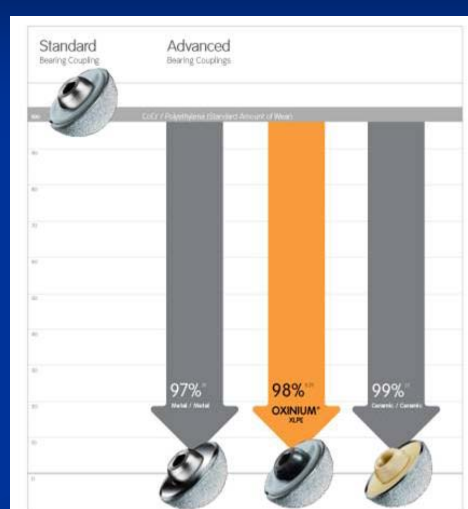
Alternative Bearing Advantages

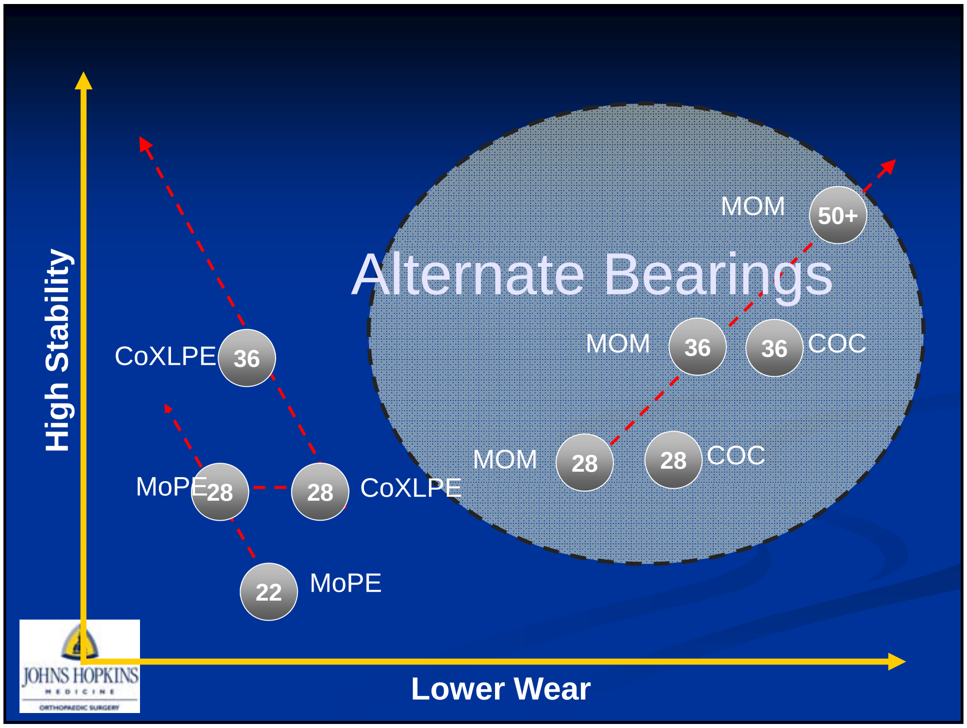
- Reduced wear particle production?
  - Reduce/eliminate osteolysis?
- Use of larger femoral heads
  - Increase joint stability
- Removal of polyethylene from system

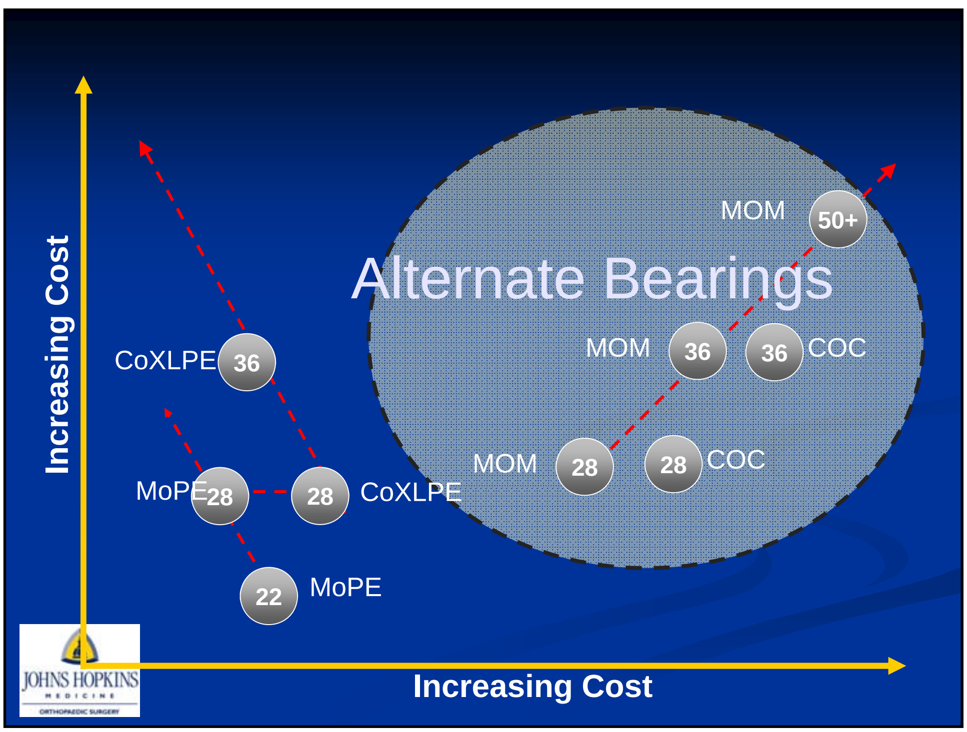
The question remains, will any of these increase the long term survival of the implant?

Advanced Bearings

- Advanced bearings wear 25 to 100 times less than standard implants.
- May produce a higher total number of particles
  - Usually much smaller and may be more biologically active




High Stability
Lower Wear
Alternate Bearings
MOM 50+
MOM 36
36 COC
CoXLPE 36
MOM 28
28 COC
MoPE 28
28 CoXLPE
22 MoPE
JOHNS HOPKINS
MEDICINE
ORTHOPAEDIC SURGERY


Increasing Cost
Increasing Cost
Alternate Bearings
MOM 50+
MOM 36
36 COC
CoXLPE 36
MOM 28
28 COC
MoPE 28
28 CoXLPE
22 MoPE
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Alternative Bearing Issues

- Benefit/Cost ratio
  - Favors use in younger and/or high demand patients
    - Return to work force at a higher activity level?
    - May eliminate need for revision?
- Each type of bearing has its own set of concerns and potential problems

Historical Bearings

- Cobalt Chrome femoral head on Teflon bearing
  - 300 total hips performed by Sir Charles Charnley
  - All failed quickly
- Early metal on metal designs
  - Poor manufacturing and poor fixation
  - A small percentage had long term survival >30 years
- Titanium on polyethylene
  - Very high wear rate and revision rate
  - Still offered by Biomet as an option for metal allergic patients undergoing a knee replacement (please avoid using this)

Cross-linked Poly:

Retrievals: Good results on wear . . .
But not a bullet-proof solution.

- Consider the mechanical properties
- Consider the free radical

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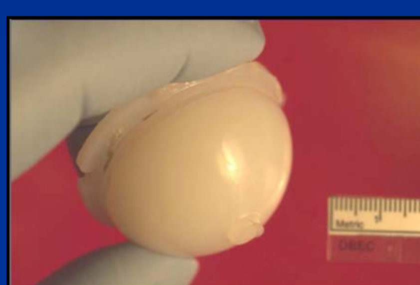
Longevity Crosslinked Liners

59 YO Female 5'-6" 200 lbs
Moderately active



Primary 52 OD / 32 ID
7 mo.

Revision 56 OD / 32 ID
27 mo.

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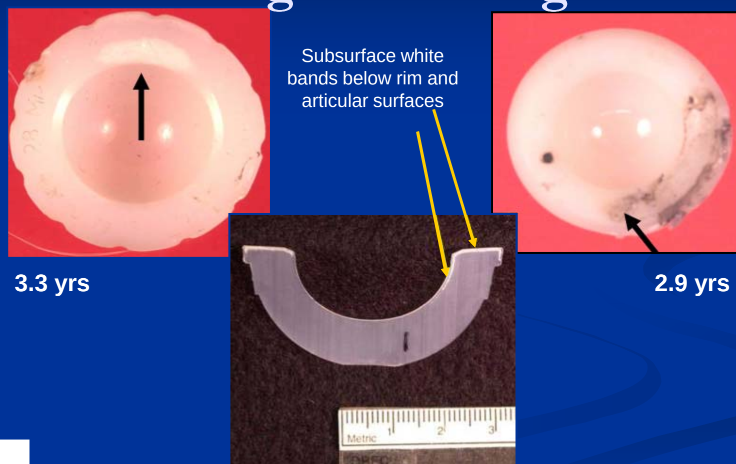
l, In Press, JBJS; Tower et al, 2006, AAOS)

Crossfire Retrievals Show Oxidation and Fatigue Cracking



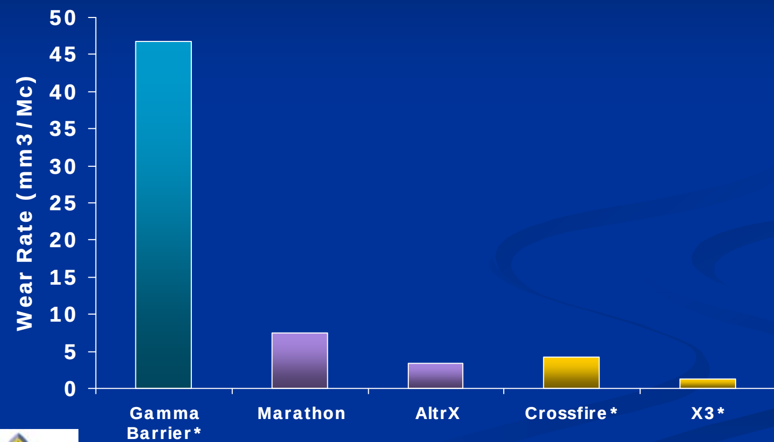
al, In Press, JBJS)

Commercial Crosslinked Materials

Supplier	Tradename	Joint	Resin	Radiation Source	Dose	Stabilization Process	Sterilization
Biomet	ArCom XL	Hip	1050	Gamma	5.0	Mechanical anneal	ETO
DePuy	Marathon®	Hip	1050	Gamma	5.0	Remelt	GP
	Sigma™ Crosslink	Knee	1020	Gamma	5.0	Remelt	GP
	AltrX	Hip	1020	Gamma	7.5	Remelt	GP
Smith & Nephew	XLPE	Hip, Knee	1050	Gamma	10.0	Remelt	ETO
Stryker	Crossfire®	Hip, Knee	1050	Gamma	10.5	Thermal anneal	Gamma
	X3™	Hip, Knee	1020	Gamma	9.0 (Sequential)	Sequential thermal anneal	GP
Zim	Prolong™	Knee	1050	E-beam	6.5	Remelt	GP
	Longevity® / Durasul®	Hip	1050	E-beam	10.0 / 9.5	Remelt	GP/ ETO

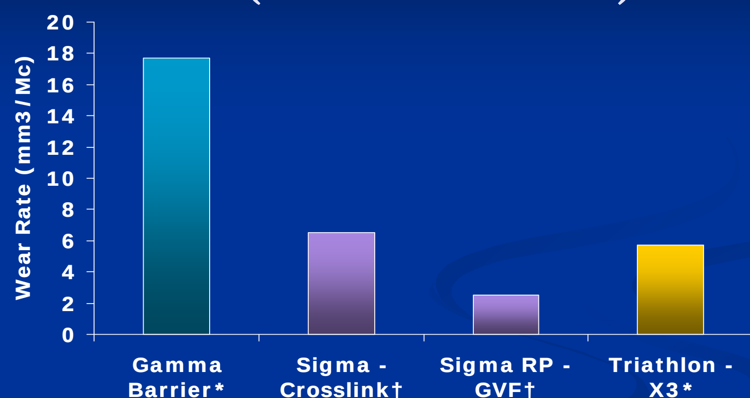
Mechanical anneal: polyethylene is mechanically deformed
Remelt: polyethylene is heated above its melting point (>140ºC)
Thermal anneal: polyethylene is heated but the temperature does not exceed the melting point (<135ºC)
(Wright Medical and Exatech also have received approval for crosslinked UHMWPE products.)

Reported Hip Simulator Wear Rates (Biomet's Data)



Wear rates are published values. They were not run under identical conditions and therefore are not directly comparable.
*Essner, A; et.al.; 51st Annual Meeting of the Orthopaedic Research Society, Poster 0830.

Reported Knee Simulator Wear Rates (Biomet's Data)



Kinematic conditions: Normal High High Normal

Wear rates are published values. They were not run under identical conditions and therefore are not directly comparable.
*Stryker Advertisement from JBJS, 88A(6), June 2006, Adv. 42, ref. 4.
†DePuy internal test reports: Crosslinked results in WR030058 and GVF results in WR05167

Ceramic Heads

- Biocompatible (highly oxidized material)
- Smooth (high density)
- Scratch resistant (hardness)
- Improved wetability (chemistry) and lubricity (friction)
- Lower wear rates

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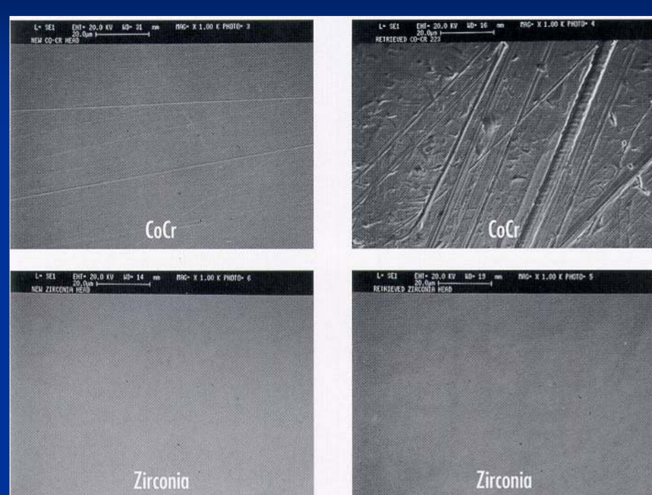
Scratch Resistance

CoCr

Zirconia



New Heads **Retrieved Heads**

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Ceramic Head Issues

- Cost/Benefit ratio
- Limited Head neck sizes
- Early fractures due to:
  - Material quality
  - Morse taper design
    - angle, roughness, tolerances
  - Quality control

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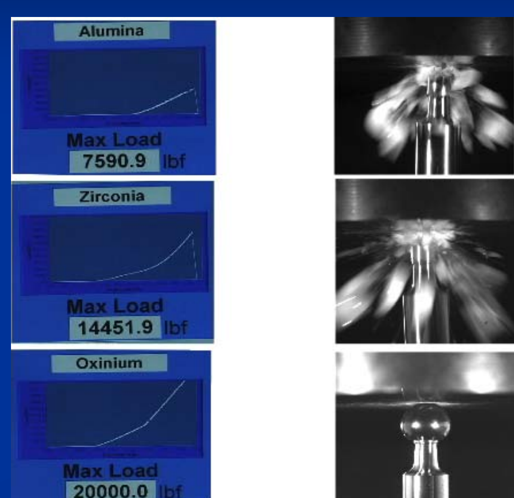
Ceramic Risks – Myths?

- Ceramic heads don't fracture often, but when they do it is catastrophic
- Ceramic debris can remain in the joint and can ruin future revisions



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How is the material improved?

- Improved raw material (fewer impurities)
- Grain size optimization
- Proof testing
- Understanding of Morse taper importance

**All major companies sold ceramic heads that they knew had defects and were substandard.

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Clinical Studies with Ceramic Fractures

- Difficult to establish rate
- Two early manufacturers highest failure rate
- Suboptimal Morse taper designs
- Major manufacturers: <1% for 80's and on
- Current quality even better (<0.5%?)
- Compare with revision for osteolysis

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Ceramic-on-Ceramic

- Alumina on alumina
- Zirconia on zirconia seems to have poor performance
- Lowest wear rates (100 times less than ceramic-on-polyethylene)

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First Generation Ceramic-Ceramic

- Lack of porous coating on cup
- Reduced motion to impingement
- Poor stem design for in-growth

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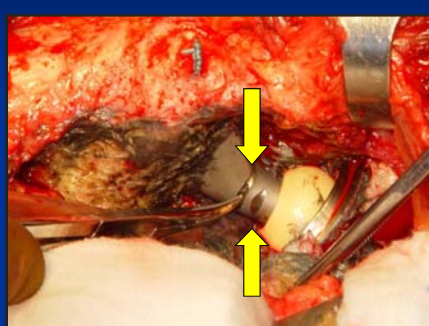
A failed ceramic-on-ceramic total hip arthroplasty is shown in the figure. What is the predominant factor contributing to the failure?

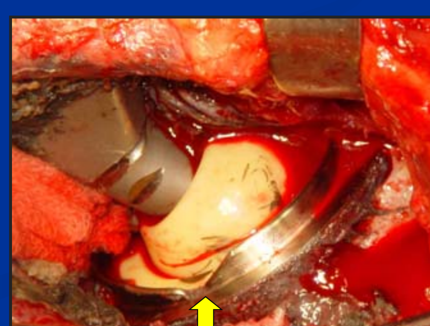
1. Poor quality ceramic material
2. Unfavorable head/neck ration
3. Nonmetal-backed acetabular component
4. Third-body debris
5. Impact loading

Ceramic on Ceramic



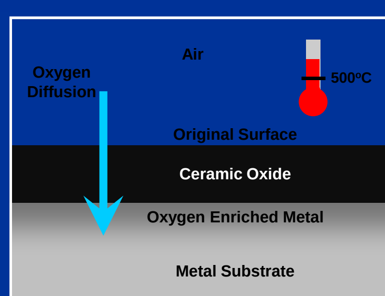
High squeak rates up to 25% !

Impingement wear



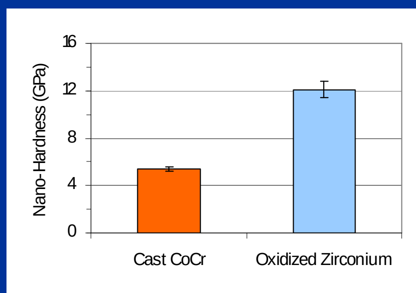
OXINIUM/XLPE

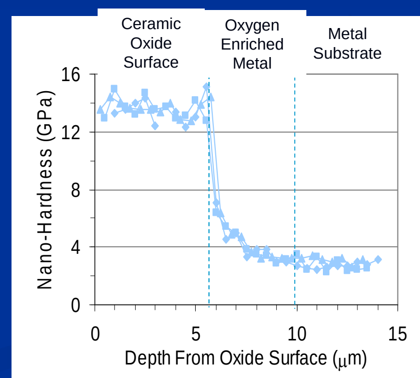
Surface Transformation – Not a Coating



Twice as Hard as Cobalt Chrome

- Oxygen enrichment aids adherence to substrate

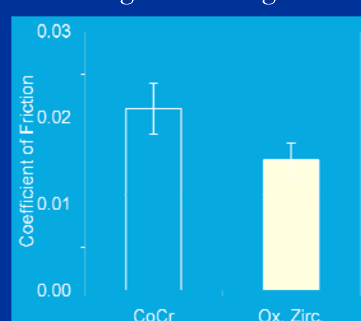




Long et al., SFB 1998

Half the Coefficient of Friction vs. CoCr

- Slides with less resistance:
  - Against polyethylene*
  - Against cartilage**

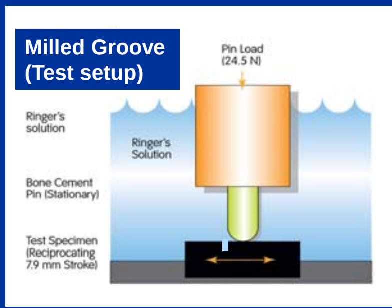


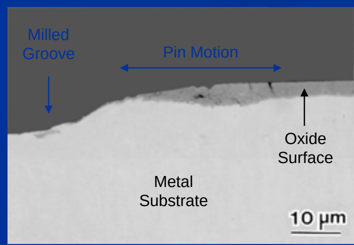
*Poggie et al., ASTM STP 1145

**Patel and Spector, Biomaterials 1997

Damage Tolerance

- Ceramic surface does not chip or break even with a groove milled through the surface





Hunter and Long, WBC 2000

Wear of metal-on-metal articulations in total hip arthroplasty is characterized by which of the following findings?

1. Fewer number of particles/wear volume compared with ceramic/ceramic bearings
2. Increased incidence of cancer secondary to higher serum metal levels
3. Rapidly declining levels of serum metal levels following hip arthroplasty
4. Ionically charged wear particles
5. Lower in vitro wear rates compared with ceramic/ceramic bearings

Metal-on-Metal Articulations

Pros

- Wear rates are low
- Rarely osteolysis
- Unbreakable
- Larger diameters favorable

Cons

- Elevated metal ion levels
- May cause allergic reaction
- Possible organ toxicity
- Cancer risk may be elevated

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Metal-on-Metal Articulations

Larger Diameter Bearings

- Wear decreases with increased diameter
- Lubrication improves with higher sliding velocity
- Rom is improved due to head neck ratio
- Stable

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Metal-on-Metal

- Early failures
- Due to suboptimal stem and bearing designs
- New designs promise very low wear rates
- Concerns with metal sensitivity
- Increased cancer level issue – metal ions found at distant sites

Metal-on-Metal Articulations

Unbreakable

- No significant wear
- No history of bearing fracture
- Scratches are self-healing

Metal-on-Metal Articulations

The Facts About Ion Release

1. **Co &Cr Release from Bearing**
2. **Measured in ppb (µg/l)**
3. **History of M-o-M > 40 Yrs**
   - Risk of allergic reaction
   - No identified risk of cancer
   - No identified risk of toxicity
4. Risk of ion complications low
5. **Less risk than that of Hip Revision?**

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Norwegian Registry Study Look at Cancer with M/M

Visuri et al., CORR 1996

- Combined cancer and THA registries
- 968 M/M at 15.7 yrs f/up
- 1831 M/P at 12.5 yrs f/up
- Both groups had lower levels than expected
- M/M had higher cancer levels than M/P

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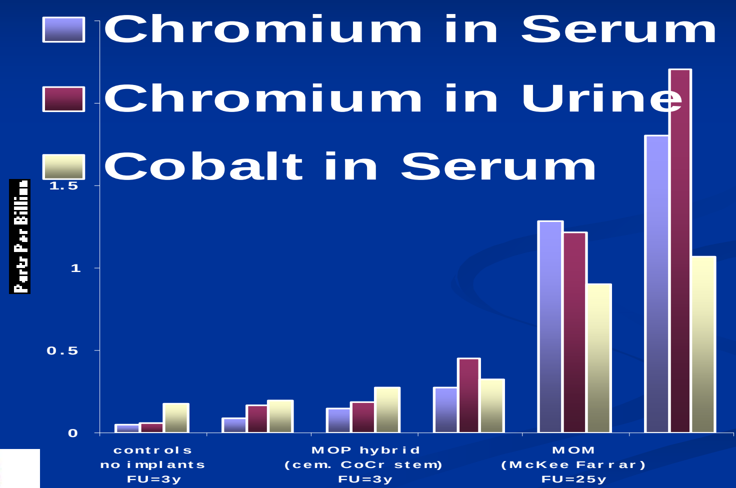
Mean Ion Levels in THA



(NEED REFERENCE)

Metal-Metal Devices

Name	M²A		Metasul	Lineage	Ultamet	
Size (mm)	28/32	38	28	28/32/36	28	36, 40, 44
Material	CoCr	CoCr	CoCr	CoCr	CoCr	CoCr
Processing	Lo C Wrought	Cast	Hi C Wrought	Cast	Hi C Forged	Hi C Forged
Diametral Clearance (µm)	50-150	50-150	90-140	60/?/?	40-80	80-120
Head Roughness (µm)	0.09	0.09	0.03*	?	< 0.01	< 0.01
Cup Roughness [illegible]m)	0.05	0.05	0.01*	?	< 0.01	< 0.01
[illegible]M (°)	126/132	154	115	120/127/132	146	Up to 159

* Average

Comparative Ion Levels

Comparison of Mean Serum Cobalt Levels

	Median µg/L[1]	In-Vivo Year
Metasul® [2,8]	1.1	1
Sikomet-SM21® [3,9]	1.5	1
M2A™ [4,10]	1.55	5
Ultima® [5,11]	1.3	1.6
Birmingham™ [6,11]	2.1	1.3
Cormet® [7,11]	3	1.3
Ultamet® [12]	0.66	1

References
1. Sample Method : Serum except Sikomet-SM21 (Whole Blood) 2. METASUL™ is a registered trademark of Zimmer, Inc. 3. Sikomet-SM21is a registered trademark of Sikov Medizintechnik, GmbH. 4. M2A-38 and M2A-Magnum are a trademark of Biomet Orthopaedics, Inc. 5. ULTIMA® and Ultamet® are registered trademarks of Depuy Orthopaedics, Inc. 6. Birmingham is a trademark [illegible]ephew 7. Cormet is a registered trademark of Corin Group PLC. 8. W. Brodner,et al., Elevated serum cobalt with metal-on-m[illegible]culating surfaces. J Bone Joint Surg Br 79 (1997), p. 316 9. Schaffer et al. Increased blood cobalt and chromium after total [illegible]acement. J Toxicol 1999 10. Rasquinha, et al. Serum metal levels and bearing surfaces in total hip arthroplasty. J Arthroplasty 21(6 Suppl 2):47-52, 2006 11. M.T. Clarke,et al, Levels of metal ions after small and large-diameter metal-on-metal hip [illegible] J Bone Joint Surg Br 85 (2003), p. 913 12. Data on file at DePuy Orthopaedics, Inc. (2007)

Clinical Concerns

- The biologic response to metal debris and metal ions
- Are they detrimental ?

Biological Response

- Four major considerations
  - Inflammatory response → **osteolysis**
  - Hypersensitivity → **allergic reaction**
  - Cytotoxicity → **cell death**
  - Carcinogenicity → **cancer**

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Biological Response

- **Inflammatory response**
  - Less inflammatory than metal-polyethylene
- **Hypersensitivity**
  - Avoid patients with known sensitivities
- **Cytotoxicity**
  - **Effect on clinical outcome unknown**
- **Carcinogenicity**
  - No correlation between cancer and THA

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Biological Response

- Four major considerations
  - Inflammatory response
  - Hypersensitivity
  - Cytotoxicity
  - Carcinogenicity

} Benefit-to-risk assessment By patient & surgeon

Reported Metal on Metal Concerns

- ALVAL (aseptic, lymphocytic vasculitis and associated lesions)
- Psudotumor
- Metal ions cross the placenta

**Occurs mostly in women, not reported in men.

- Metal ions are excreted via the kidney