Bad Bearings:  
**THE DEVOLUTION OF HIP REPLACEMENT IN AMERICA 1970-2014**

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**DISCLOSURES**

- Industry: No  
- Legal Work: No  
- Alaska Arthroplasty Initiative: $50,000 Grant  
  Providence Alaska Medical Center

**Marketing trumps science and value**  
**NICE Report**

- Cemented MoP $6000  
- Cemented CoP $8000  
- Hybrid MoP $10000  
- Un-cemented MoP $12000  
- Un-cemented CoC $16000  
- MoM Resurfacing $10000  
- MoM THA $14000

**Hip Replacement Costs USA**

- **12K - 120K JAMA 2/2013**
  - Retrospective Study $ 0.01 per implant  
  - Implant Registration $50 per implant  
  - Explant Analysis 1K  
  - Generic Parts 5K

- **Revision surgery 50-100K**
  - Un-Proven parts 15K  
  - “Space Suits” and Laminar flow  
  - 1K (increase infections 3X)

**Efficacy**  
- Safety  
- And  
- Value

**Safety And Value**

- Cost, Complexity, and Complications

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**2,012 Total Hip Arthroplasties: A Study of Postoperative Course and Early Complications**

- By Mark R. Coventry, M.D., *1*  
  - Robert E. Hochberg, M.D., *2*  
  - Declan Nolan, M.D., *1*  
  - Charles W. Radin, M.D., *1*  
  - Debra M. Struebel, M.D., *1*  

- Mayo Clinic  
  - first 2000  
  - Charnley Hips 1969-1971

- Failure rate  
  - 1% per year patients < 50  
  - 0% per year patients > 70 years

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*From the Mayo Clinic and Mayo Foundation, Rochester*
The Holy Grail of Hip Replacement

Lasts Forever
Instant recovery
Pain free
Stable
No activity limits
Not poison the patient

501K Devices

1970
Predicate Simplicity

2 Parts
3 Materials
Plastic
Stainless
Steel
Cement

2010 – 510K Evolution
Modularity, Complexity,
Unproven Bearing Couples

7 parts
5 junctions
Metal-on-Metal Bearing
Multiple Alloys
Multiple Surface Treatments

5 Year Revision Rates

Predicate Charnley THA 1970s 2-3%
510K Metal-on-Metal THA (ASR) 44% (22X)
510K Modular Neck THA
MoP or CoP Rejuvenate 44% (22X)
PMA Metal-on-Metal Resurfacing
Conserve Plus 10% (5X)
BHR 4% (2X)
**Periprosthetic Metallosis**

**Hypercobaltemia**

**Pseudotumors**

**Cobaltism**

from Hip Replacements with Chrome-Cobalt Components

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**At-risk populations USA**

**Ceramic-on-Metal Wear (1000s)**

**Metal-on-Metal Wear (1,000,000)**

**Taper Corrosion (3,000,000)**

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**Ceramic-on-Metal wear (1000s)**

Systematic Literature Review of 2318 publications we found 9 cases of cobaltism from CoM wear

**Metal-on-Metal wear (1,000,000)**

Systematic Literature Review of 2318 publications we found 25 cases of cobaltism from MoM wear

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**Taper Corrosion (3,000,000)**

Recently recognized cause of APRMD and Hypercobaltemia. Most hips done past 20 years at risk. Cobaltism yet to be reported.
Osteolysis, Pseudotumor, Sciatica
Minimal Metallosis and Hypercobaltemia (0.9)

56 YO active male
6 years post THA
Popular non-recalled Stryker 32 mm MoP
510K hip
No perceived problem with the hip
Osteolysis detected with surveillance XR

Monitoring Hip Patients at Risk
Blood Cobalt Level (PBB)

- 0.2 normal, > 1.0 excess exposure (PBB)
- 1 small ball Metal-on-Metal THA
- 2-3 large ball Metal-on-Metal HR or THA
- 2-10 APRMD, subclinical and mild cobaltism
- 11-100 subclinical, mild, and moderate cobaltism
- 101-300 moderate to severe cobaltism
- 301-1000 extreme manifestations, DEATH (1 case)

Cobalt debris from corrosion more toxic at the hip and systemically than from wear?

Cobaltism Awareness - December 2010

Arthroprosthetic Cobaltism: Neurological and Cardiac Manifestations in Two Patients with Metal-on-Metal Arthroplasty: A Case Report
Stephen S. Tower
J Bone Joint Surg Am, published online Oct 29, 2010
Access the most recent version at the J.BJS.org site.

Commentary and Perspective on
"Arthroprosthetic Cobaltism: Neurological and Cardiac Manifestations in Two Patients with Metal-on-Metal Arthroplasty, A Case Report" by Stephen S. Tower, MD
Johns Hopkins Medical Center, Baltimore, MD

The report is unusual because of the rarity of the occurrence of metal-induced systemic complications in patients with total hip replacement and the fact that the author was one of the patients. As millions of patients worldwide have undergone total hip replacement, these cases represent rare events indeed.

Cobaltism Awareness January 2014 JBJS

Alaskan MoM Hip Series
35 revised of < 100 at risk Median [BCo] = 40 PPB
10 with reversible Cobaltism?
Mean latency to illness 2 years
Mean latency to revision 3 years
Population at risk NOT systematically screened

Cobaltism: Severity relates to the degree and duration of cobaltemia literature review, wear cases.
**Alaskan Rejuvenate Series**

**Recalled Implant**

30 revised of about 70 at risk
Median \([\text{BCo}] = 4\) PPB
10 with reversible Cobaltism?
Mean latency to illness 2 years
Mean latency to revision 3 years
Population at risk systematically screened

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**Alaskan Non-Rejuvenate Series**

**Taper Corrosion Hips**

6 revised of about 20,000 at risk
Median \([\text{BCo}] = 4\) PPB
5 with reversible Cobaltism?
Mean latency to illness 5 years
Mean latency to revision 7 years
Population at risk NOT systematically screened

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**Cobaltism Awareness: Systematic Monitoring of Patients with MoM Hips Indicated**

Young patient, missed 2 annual follow-ups but saw surgeon socially
1-2 times a week
\([\text{BCo}] = 63\) ppb
Reversible Neurocobaltism with 48 months of surplus morbidity

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**Cobaltism Awareness: Severe Cobaltism may precede Hip Symptoms**

46 y.o. Pilot F/H PD
2009 Biomet “Magnum” MoM Hips
42 months max DBS & Drugs
Onset of hip pain \([\text{BCo}] = 116\) PPB
Hips Revised to Ceramic-on-Plastic
2 months post revision \([\text{BCo}] = 0.7\)
12 months post-op off DBS & Drugs
2 years post-op off Drugs, min DBA

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**Cobaltism Awareness: Systematic Monitoring of Patients at Risk for Taper Corrosion Indicated**

Rejuvenate Implanted 8/2010
20 months later:
progressive fatigue, poor sleep,
nausea, weight loss from 140 to 120 pounds, deafness, myalgia, cognitive decline, arrhythmia and diastolic dysfunction
\([\text{BCo}] = 11\) PPB
RECALLED 7/2012 (at 23 months)
Explanted after 33 months

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**4 Million at Risk?!**

56 yo male: 6 and 3 years s/p
32 mm CoCr-on-Plastic non-Revujenate Styker Hips
Several months left groin pain: \([\text{BCo}] = 4\) PPB
Admitted to CCU post screening ECHO for acute asymptomatic proximal aortic dissection

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66 year-old med-mal attorney
4 months of left groin pain
8 years post implant
[BCo] of 4 PPB

Cobaltism may precede Hip Symptoms
Alaskan MoM Series

Patients with modular Chrome-Cobalt Components may require systematic monitoring of cobalt levels!

- Annual [BCo]: > 1 ppb is significant hypercobaltemia
- Cross-sectional imaging indicated any at risk patient with hip symptoms and for asymptomatic patients with B[Co] > 2.9 ppb
- Consider Revision
  - [BCo] > 10 pbb
  - Any systemic manifestations c/w cobaltism and B[Co] > 3 ppb
  - Hip symptoms and pseudo-tumor

New Hips: 1980-2010 Evolution
More Stable
Less Wear (mm)$^3$
Lasts longer – no
Saves bone - no
Easier Revision-no
Marketing or Science?

Extreme Hypercobaltemia and Cobaltism
Not Rare in Patients Implanted with PMA
HIP RESURFACING DEVICES

Implanted for 36 Months
Blood Cobalt Level 322 PPB
Same as NEJM case that needed heart transplant
Proving Non-inferiority Of New Hips

THE HOLY HAND

GRENADA

Prospective
10 year Study of a thousand hips blinded with controls by un-invested Investigators

Joint Registries

Retrospective
Comprehensive practice review with explant analysis

Tribology & Corrosion

Unexpected
Long Latency
Significant

Summer 2010 Regulatory Response

➢ CDC Atlanta
  • “Let’s Circulate this Nationwide”

➢ FDA Washington DC
  • “No, medical devices our our turf”
  • Dr. Tower is not an expert

FDA’s Criteria for Expertise
  Industry Consultant or
  Furthered by Orthopedic Professional Organization

Primary Hips USA

➢ 270,000 per year
  • $30,000 Basic
  • $60,000 (Bells Whistles)
  • 10 Billion $ a year

95% 510K unproven implants

Revision Hip Replacement USA

50,000 per year
$50-100k each
$2.5 Billion yearly

Metal-Metal hip surplus ten year costs: 10.6 Billion Dollars

➢ One Million MoM Implanted
  • $5K increased primary implant costs
  • Excess ten year revision rate 10-50%
  • $60K revision cost
  • 10% 5 year revision rate of revisions
  • $1000 + yearly serum monitoring costs
What went Wrong?

• Conflict of Interest?
  • Premarket
  • Market
  • Regulation
  • Professional spheres
  • Post Market

Cost of Metal-Metal Debacle USA

A Billion Dollars per year
Design Surgeons of the ASR paid about $20 Million

Cost of 510K Debacle USA?
Ten Billion Dollars per year

Solutions

• An NTSB approach to premature total joint failures
• Regional registries that employ explant analysis to determine the “probable cause” of failures
• Identification of “Canary in the Cage” early sentinel implant failures
• Non-conflicted analysis of new technologies
• Regulatory reform mandating use of proven, less expensive implants for most all

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