Bad Bearings:

THE DEVOLUTION OF HIP REPLACEMENT IN AMERICA
1970-2014

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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

Safety And Value
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

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

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From the Mayo Clinic and Mayo Foundation, Rochester

Mayo Clinic first 2000 Charnley Hips 1969-1971
Dr. Declan Nolan 1970

Failure rate 1% per year patients < 50
0% per year patients > 70 years
Dr. Declan Nolan 2011
Fig. 3: Survivorship free of revision for aseptic loosening of either the acetabular or the femoral component by patient age at the time of the arthroplasty.

Survival (%)

Years

≥80
70-79
60-69
50-59
40-49
<40

Mayo first 2000
CLFA1969-1971

The Holy Grail of Hip Replacement

- Lasts Forever
- Instant recovery
- Pain free
- Stable
- No activity limits
- Not poison the patient
501 K Devices

Antecedent Device

Pre-Market Approved Devices
1970
Predicate
Simplicity

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

2 Parts
3 Materials
Plastic
Stainless
Steel
Cement

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)
4 million Americans at Risk: Unexpected Failure Mechanisms

Periprosthetic Metallosis

Hypercobaltemia

Pseudotumors

Cobaltism

from Hip Replacements with Chrome-Cobalt Components
At-risk populations USA

Ceramic-on-Metal Wear (1000s)
Metal-on-Metal Wear (1,000,000)
Taper Corrosion (3,000,000)

Metallosis: Pseudotumors
Hypercobaltemia: Cobaltism
Ceramic-on-Metal wear (1000s)

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

Periprosthetic Metallosis: Extreme
Pseudotumors: Asymptomatic in several cases

Hypercobaltemia: Extreme 400-1000 ppb

Cobaltism: Deafness, Blindness, Dementia, Peripheral Neuropathy, Hypothyroidism, Cardiomyopathy
Metal-on-Metal wear (1,000,000)

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

Periprosthetic Metallosis: Moderate
Pseudotumors: Common but sometimes asymptomatic
Hypercobaltemia: Moderate to Severe 16-398 ppb
Cobaltism: Tinnitus, Disordered Mood and Sleep, Cognitive Dysfunction, Anorexia, Patchy Retinopathy, Cardiomyopathy
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.

Periprosthetic Metallosis: Minimal
Pseudotumors: Common but sometimes asymptomatic
Hypercobaltemia: Minimal to Moderate < 1-20 ppb
Cobaltism: Tinnitus, Disordered Mood and Sleep, Cognitive Dysfunction, Anorexia, Diastolic Dysfunction, common (Alaska)
Pseudotumor
AKA APRMD
Adverse Periprosthetic Reaction to Metallic Debris
Osteolysis, Pseudotumor, Sciatica
Minimal Metallosis and Hypercobaltaltemia (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 (Industry)
• 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 that from wear?
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.
## TABLE IV MoM ‘High’ Risk Group

<table>
<thead>
<tr>
<th>‘High’ Risk Group Stratification</th>
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<tbody>
<tr>
<td>Patient factors</td>
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<tr>
<td>Female with dysplasia (for hip resurfacing)</td>
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<tr>
<td>Patient with high activity level</td>
</tr>
<tr>
<td>Symptoms</td>
</tr>
<tr>
<td>Symptomatic</td>
</tr>
<tr>
<td>Severe local hip and/or mechanical symptoms</td>
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<tr>
<td>Systemic symptoms</td>
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<tr>
<td>Clinical examination</td>
</tr>
<tr>
<td>Change in gait (i.e., limp)</td>
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<tr>
<td>Abductor weakness</td>
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<tr>
<td>Swelling</td>
</tr>
<tr>
<td>Systemic symptoms</td>
</tr>
<tr>
<td>Implant type</td>
</tr>
<tr>
<td>Large-diameter femoral head (≥36 mm) modular or nonmodular MoM THA</td>
</tr>
<tr>
<td>Recalled MoM implant</td>
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<tr>
<td>Radiographs (2 views ± serial for comparison when available)</td>
</tr>
<tr>
<td>Suboptimal acetabular cup orientation</td>
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<tr>
<td>Implant osteolysis/loosening</td>
</tr>
<tr>
<td>Infection work-up (ESR, CRP, ± hip aspiration)</td>
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<tr>
<td>Within normal limits</td>
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<tr>
<td>Metal ion level test</td>
</tr>
<tr>
<td>High (&gt;10 ppb)</td>
</tr>
<tr>
<td>Cross-sectional imaging (MARS MRI; ultrasound or CT when MRI contraindicated or MARS protocol not available)</td>
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<tr>
<td>Presence of abnormal tissue reactions with involvement of surrounding muscles and/or bone</td>
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<tr>
<td>Solid lesions</td>
</tr>
<tr>
<td>Cystic lesions with thickened wall</td>
</tr>
<tr>
<td>Mixed solid and cystic lesions</td>
</tr>
<tr>
<td>Treatment recommendation</td>
</tr>
<tr>
<td>Consider revision surgery</td>
</tr>
</tbody>
</table>
Alaskan MoM Hip Series

35 revised of < 100 at risk Median

\[ [\text{BCo}] = 40 \text{ PPB} \]

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.

\[ y = 4.7097 \ln(x) - 30.117 \]

\[ R^2 = 0.8955 \]

The product of the highest noted blood cobalt (mcg/L) and the number of months of problem hip implantation
Alaskan Rejuvenate Series
Recalled Implant

30 revised of about 70 at risk
Median \([BCo]\) = 4 PPB
10 with reversible Cobaltism?
Mean latency to illness 2 years
Mean latency to revision 3 years
Population at risk systematically screened
Alaskan Non-Rejuvenenate Series
Taper Corrosion Hips

6 revised of about 20,000 at risk

Median [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
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

[BCo] = 63 ppb
Reversible Neurocobaltism with 48 months of surplus morbidity
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 $B[Co] = 116$ PPB
Hips Revised to Ceramic-on-Plastic
2 months post revision $B[Co] = 0.7$
12 months post-op off DBS & Drugs
2 years post-op off Drugs, min DBA

510K Device
Not recalled
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

B[Co] = 11 PPB

RECALLED 7/2012 (at 23 months)

Explanted after 33 months
56 yo male: 6 and 3 years s/p 32 mm CoCr-on-Plastic non-Revujenate Styker Hips
Several months left groin pain: [BCo] = 4 PPB
Admitted to CCU post screening ECHO for acute asymptomatic proximal aortic dissection

Popular 510K Not known to be AT RISK

STRYKER ACCOLADE
66 year-old med-mal attorney

4 months of left groin pain

8 years post implant

[BCo] of 4 PPB
Altered Stem-Head Tapers
Cobaltism may precede Hip Symptoms
Alaskan MoM Series
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

Smith and Nephew BHR
PREEMPTION PROTECTION
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 ppb

  • 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?
Proving Non-inferiority Of New Hips

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

Joint Registries

Prospective

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
Operational Budget $350,000 a year
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