Complications of Wear or Corrosion of Chrome-Cobalt Hip Implants

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Disclosures

Index Case of Arthroprosthetic Cobaltism 2006-2009

Author of Index Case Reports
AK State Epi, Alaska Medicine, JBJS 2010

Board Member Health Watch USA

No economic COI
Where are we going?
21st Century Cures Act

Reduction of level of evidence to antidotal!
Past House, pending in Senate
Structural FDA weaknesses.
Legislated FDA weaknesses.
Disregard for costs of new technology.
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 – 80K JAMA 2/2013

Retrospective Study $ 0.01 per implant
Implant Registration $50 per implant
Explant Analysis 1K
Generic Parts 5K

Efficacy
Safety
And Value

Un-Proven parts 15K

Revision surgery 50-100K

Cost, Complexity, and Complications
The Holy Grail of Hip Replacement

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

Pre-Market Approved Devices

510 K Devices
1970
Predicate Simplicity

2 Parts
3 Materials
Plastic
Stainless Steel
Cement

2010 – 510 K 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%

PMA Metal-on-Metal Resurfacing 15% (5x)

510K Metal-on-Metal THA 44% (22x)

510K Modular Neck THA 44% (22x)
2010 Wear of chrome-cobalt hip implants ½-1 million Americans at risk

Systematic Literature Review of 2318 publications we found 25 cases of cobaltism from wear of CrCo hip implants

A Systematic Review of Systemic Cobaltism after Wear or Corrosion of Chrome-Cobalt Hip Implants
BD Gessner, T Steck, E Woelber, SS Tower Journal Public Safety June 2015 Open Access
2015 *Taper Corrosion of CrCo Components about 2 million Americans at risk*

Osteolysis, Pseudotumor, Sciatica

56 YO active male, 6 years post THA.

Popular non-recalled Stryker 32 mm MoP 510K hip.

Osteolysis detected with surveillance XR.

Minimal Metallosis and Hypercobaltemia (0.9)
Monitoring Hip Patients at Risk

**Blood or Urine Cobalt (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 likely more toxic than that produced by abrasive wear.

Urine levels generally 3-5X Blood Levels
Alaskan Rejuvenate Series
Recalled Implant Taper Corrosion

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 Revised MoM Series

**Metal-on-Metal Wear**

- 35 revised of < 100 at risk Median
  \[ [BCo] = 40 \text{ PPB} \]
- 10 with reversible Cobaltism?
- Mean latency to illness 2 years
- Mean latency to revision 3 years

**Patients not systematically screened**
Alaskan Non-Rejuvenenate Series

Taper Corrosion

6 revised of about 1000 at risk Median $[\text{BCo}] = 4 \text{ PPB}$

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

40 y/o nurse, 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

510K Device
Not recalled
Cobaltism Awareness:
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, lowest DBS setting

510K Device
Not recalled
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

\[ \text{B[Co]} = 11 \text{ PPB} \]

Recalled 7/2012 (at 23 months)
Explanted after 33 months
Population at risk 2 million

56 y/o male: 6 and 3 years s/p 32 mm CrCo-on-Plastic non-Rejuvenate Stryker Hips
Several months left groin pain: \([BCo] = 4\) PPB
Admitted to CCU post screening ECHO for acute asymptomatic proximal aortic dissection

Popular 510K MoP Hip
Not known to be at risk

Stryker Accolade
66 year-old attorney, 4 months of left groin pain
8 years post implant, [BCo] of 4 PPB
A Systematic Review of Systemic Cobaltism after Wear or Corrosion of Chrome-Cobalt Hip Implants

BD Gessner, T Steck, E Woelber, SS Tower  Journal Public Safety  June 2015 Open Access

25 Cases Identified

Toxic Progeria
84% Hip Symptoms
75% cranial or peripheral nerve dysfunction
72% diastolic or systolic cardiomyopathy
72% constitutional decline
32% mood or cognitive dysfunction
48% thyropathy

Mean BCo 324 (20-1000)

Illness Severity correlated with BCo
Reversibility Noted in non-fatal cases
Periprosthetic Consequences of Chrome-Cobalt Metallosis

Pseudotumors
and
Necrosis of Capsule, Tendons
and Bone
leading to
Hip Instability
Weakness
Prosthetic loosening
can be
Painful or Painless
New Hips: 1980-2010 Evolution

Larger Heads
More Parts
Unproved material
Unproved design
Unanticipated modes of failure

Science or Marketing Driven?
Complications of Hip Implant
Chrome-Cobalt
Wear & Corrosion

Unexpected
Long Latency
Significant
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

For non-recalled Hips Companies profit from sale of both primary and revision Implants
Monitoring Patients with at-risk hips for hip tissue complications

Annual **Blood** or **Urine** Cobalt Level

- > 1 (3) some wear or corrosion likely
- > 3 (9) increasing risk of problems cross-sectional imaging even if no symptoms at hip.

**Hip Symptoms** (regardless of Cobalt levels)

- Plain Radiographs
- Cross-sectional imaging
Monitoring Patients with at-risk hips for Cobaltism

Annual **Blood** or **Urine** Cobalt Level

- > 1 (3) some wear or corrosion likely
- > 3 (9) increasing risk of problems cross-sectional imaging even if no symptoms at hip.

Through neurologic, cardio-vascular, psychiatric, and constitutional ROS.

Positive ROS for Cobaltism

- Base-line audiogram, echocardiogram.
- Neuro-cognitive testing
Treatment of patients with Hypercobaltemia, Cobaltism, or Hip Complications

**Blood cobalt 3-10 no symptoms**
- Baseline cross-sectional imaging of the hip
- Baseline audiogram, echocardiogram.
- Baseline neurocognitive testing
- Every 6 months repeat neurologic, cardio-vascular, psychiatric, and constitutional ROS and urine and whole blood cobalt level.

**Blood cobalt > 10 or Cobaltism or Tissue Damage at the Hip**
- Consider Revision Surgery if patient fit of major operative procedure
- Chelation might be considered if patient is unfit for major surgery
Hip Replacement Costs USA
12K – 120K JAMA 2/2013

Retrospective Study $ 0.01 per implant

Implant Registration $50 per implant

Explant Analysis 1-2K per Explant

Generic Parts 5K

New unproven expensive implants 10-20K premium leads to Revision Surgery 50-150K

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