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

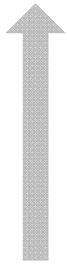
No economic COI

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

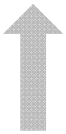
Cemented MoP $6000
Cemented CoP $8000
Hybrid MoP $10000
Un-cemented MoP $12000
Un-cemented CoC $16000
MoM Resurfacing $10000
MoM THA $14000



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



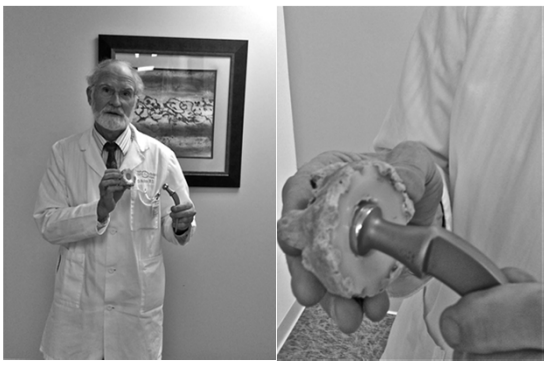
Efficacy Safety And Value

Un-Proven parts 15K

Cost, Complexity, and Complications

Revision surgery 50-100K

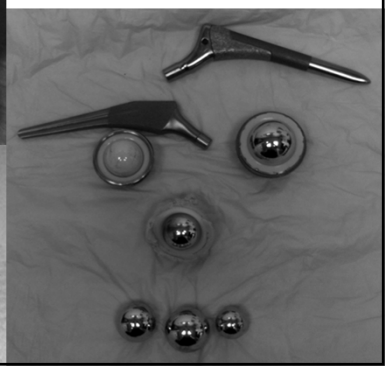
Dr. Declan Nolan 2011



The Holy Grail of Hip Replacement

Lasts Forever
Instant recovery
Pain free
Stable
No activity limits
<u>Not poison the patient</u>

510 K Devices



1970 Predicate Simplicity

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

5 Year Revision Rates

Predicate Charnley THA 1970s <u>2-3%</u>

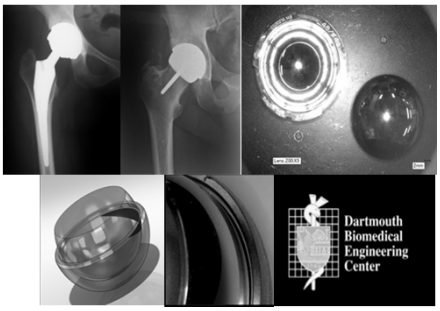
PMA Metal-on-Metal Resurfacing 15% (5x)

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

510K Modular Neck THA 44% (22x)

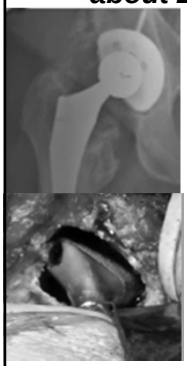
2010 Wear of chrome-cobalt hip implants ½-1 million Americans at risk

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 PPB

10 with reversible Cobaltism?

Mean latency to illness 2 years
Mean latency to revision 3 years

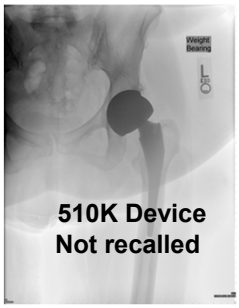
Patients not systematically screened

Alaskan Non-Rejuvenate Series Taper Corrosion

6 revised of about 1000 at risk Median [BCo] = 4 PPB
5 with reversible Cobaltism?
Mean latency to illness 5 years
Mean latency to revision 7 years

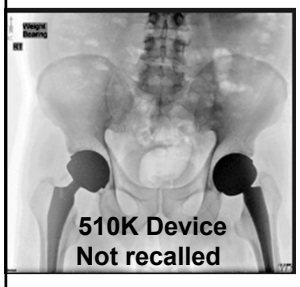
Population at risk not systematically screened

Cobaltism Awareness:
Systematic Monitoring of Patients with MoM Hips Indicated



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

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

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

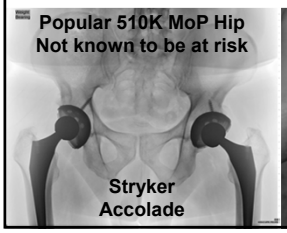
Rejuvenate Implanted 8/2010

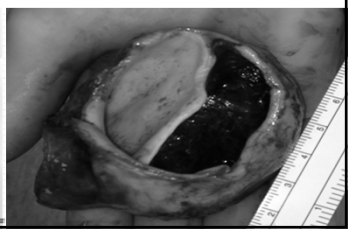
20 months later:
progressive fatigue, poor sleep, nausea, weight loss from 140 to120 pounds, deafness, myalgia, cognitive decline, arrhythmia and diastolic dysfunction
B[Co] = 11 PPB

Recalled 7/2012 (at 23 months)
Explanted after 33 months

Population at risk 2 million

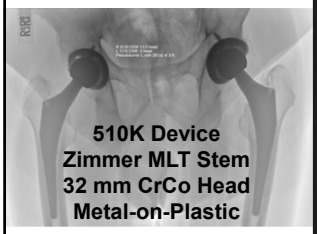
56 y/o male: 6 and 3 years s/p
32 mm CrCo-on-Plastic non-Rejuvenate Stryker Hips
Several months left groin pain: [BCo] = 4 PPB
Admitted to CCU post screening ECHO for acute asymptomatic proximal aortic dissection

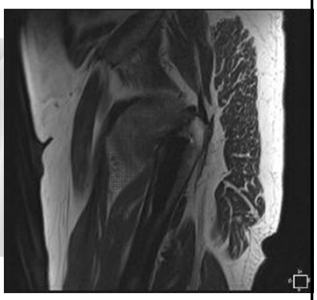




Metal-on-Plastic Bearing

Chrome-Cobalt modular ball on Ti Alloy Stem





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

Pathophysiology of Periprosthetic and Systemic Toxicity of Chrome-Cobalt Metallosis

Periprosthetic
Immune
Cytotoxic

Systemic
Immune
Cytotoxic

Periprosthetic Consequences of Immune Response to Chrome-Cobalt Metallosis

Type IV Hypersensitivity
Periprosthetic Lymphocyte Infiltrates
Solid and Cystic Pseudotumors
leading to
Tissue damage
Hip instability
Weakness
Prosthetic loosening
Compression of Neurovascular structures
Generally Painful

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

Systemic Consequences of Immune Response to Chrome-Cobalt Metallosis

Systemic Immune Response
leading to
Pseudo septic syndrome

Lymphocyte Mutation
possibly resulting in
Lymphoma and Lymphocytic Leukemia

Systemic Consequences of Chrome-Cobalt Related Cytotoxicity
Toxic Progeria

Oxidative Stress and Mitochondrial Toxicity
leading to
Death or Dysfunction of Highly Metabolic Cells
resulting in
Audio-vestibular and Optic Dysfunction
Peripheral Neuropathy
Cardiomyopathy
Cognitive and Affective Dysfunction
Generalized Constitutional Decline
Thyropathy

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

Efficacy Safety And Value

Cost, Complexity, and Complications

References on Thumb-drive

- Alaskan Case reports (AK EPI BULL) (JBJS)
- A Systematic Review of the Literature of Systemic Arthroprosthetic Cobaltism (Gessner, Steck, Woebler, Tower)
- APC case reports cardiomyopathy (Allen and Machado)
- APC case reports multiple organ (Dahms and "House")
- APC case reports neurologic (Rizzetti "Loss of Sight and Sound")
- Cobalt Cardiomyopathy (Seghizzi)
- Cobalt Neurotoxicity (Catalani general, Prentice MRI brain changes HRA)
- Chrome-cobalt debris immunology (Willert, Hallub)
- Monitoring guidelines (Alaska Medicine, NPS Australia)
- Toxicology of chrome-cobalt debris (Simonsen, Gill)

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.