Bad Bearings:

THE DEVOLUTION OF HIP REPLACEMENT IN AMERICA 1970-2014

Stephen S. Tower, M.D.
Orthopedic Surgeon
Affiliated Professor University of Alaska
President of the Alaska Arthroplasty Initiative

DISCLOSURES

Industry ***Legal Work*** ***No***

Alaska Arthroplasty Initiative
$50,000 Grant
Providence Alaska Medical Center

Explant Analysis $1000

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

Efficacy Safety And Value

Revision surgery 50-100K

Un-Proven parts 15K
"Space Suits" and Laminar flow 1K (increase infections 3X)

Cost, Complexity, and Complications

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

BY MARK B. COVENTRY, M.D.*, ROBERT D. BECKENBAUGH, M.D.*, DECLAN R. NOLAN, M.B., B. CH.*, AND DUANE M. ILSTRUP, M.S.*, ROCHESTER, MINNESOTA

From the Mayo Clinic and Mayo Foundation, Rochester

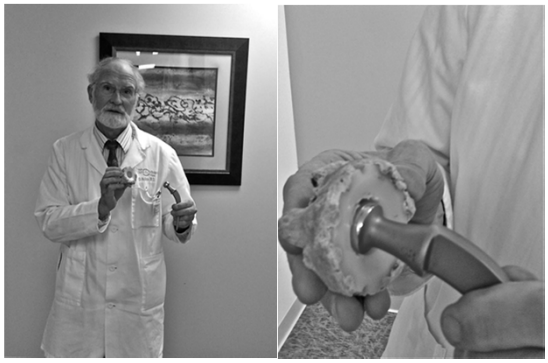
Mayo Clinic first 2000 Charnley Hips 1969-1971

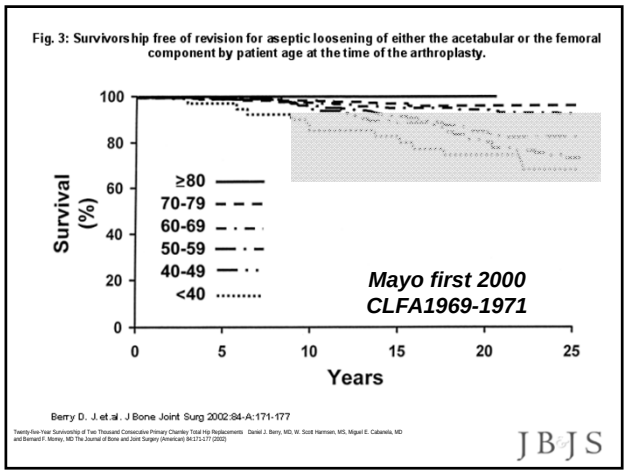
Dr. Declan Nolan 1970

Failure rate 1% per year patients < 50

0% per year patients > 70 years

Dr. Declan Nolan 2011





The Holy Grail of Hip Replacement

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

1970 Predicate Simplicity

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

5 Year Revision Rates

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

4 million Americans at Risk:
Unexpected Failure Mechanisms

Periprosthetic Metallosis
Hypercobaltemia
Pseudotumors
Cobaltism
from Hip Replacements with Chrome-Cobalt Components

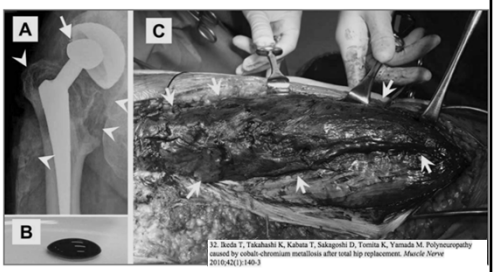
At-risk populations USA

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)

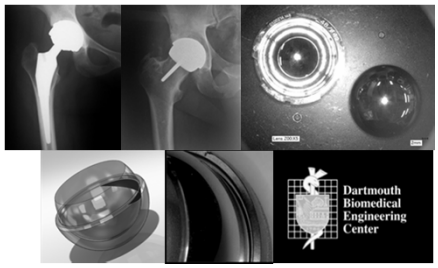
Systematic Literature Review of 2318 publications we found 9 cases of cobaltism from CoM wear



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)

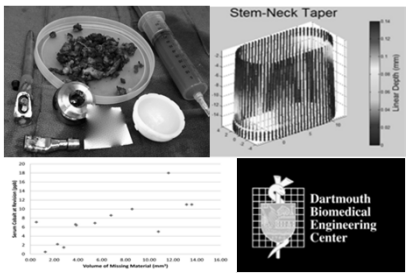
Systematic Literature Review of 2318 publications we found 25 cases of cobaltism from MoM wear



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

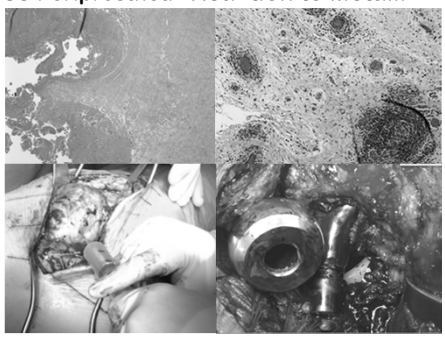
Taper Corrosion (3,000,000)

Recently recognized cause of APRMD and Hypercobaltemia. Most hips done past 20 years at risk. Cobaltism yet to be reported.



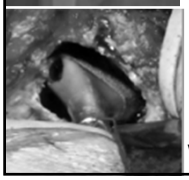
Periprosthetic Metallosis: Minimal
Pseudotumors: Common but sometimes asymptomatic
Hypercobaltemia: Minimal to Moderate < 1-20 ppb
Cobaltism: Tinnitus, Disordered Mood and Sleep, Cognitive Dysfunction, Anorexia, Diastolic Dysfunction, common (Alaska)

Pseudotumor
AKA **APRMD**
Adverse Periprosthetic Reaction to Metallic Debris

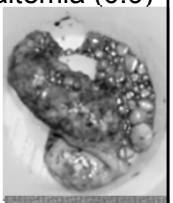


Osteolysis, Pseudotumor, Sciatica

Minimal Metallosis and 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 (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 ?

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 doi:10.2106/JBJS.J.00125

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

Joshua J. Jacobs, MD*
Rush University Medical Center, Chicago, Illinois

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

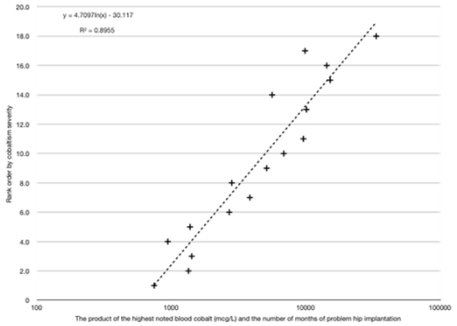
TABLE IV MoM 'High' Risk Group

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

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.



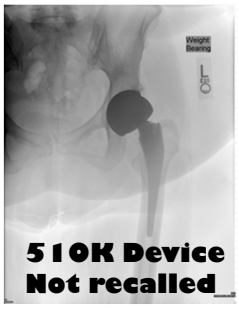
Alaskan Rejuvenate Series Recalled Implant

30 revised of about 70 at risk
Median [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-Rejuvenate Series Taper Corrosion Hips

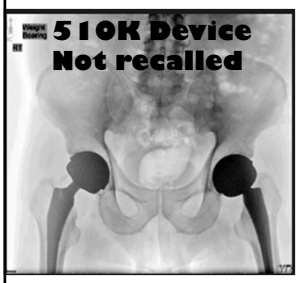
6 revised of about 20,000 at risk
Median [BCo] = 4 PPB
5 with reversible Cobaltism?
Mean latency to illness 5 years
Mean latency to revision 7 years
Population at risk *NOT* systematically screened

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

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

Rejuvenate Implanted 8/2010

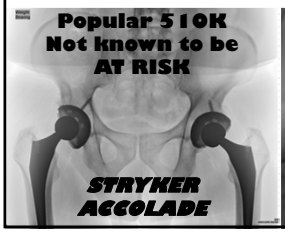
20 months later:
progressive fatigue, poor sleep, nausea, weight loss from 140 to120 pounds, deafness, myalgia, cognitive decline, arrythmia and diastolic dysfunction
B[Co] = 11 PPB

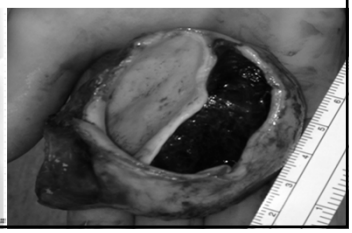
RECALLED 7/2012 (at 23 months)

Explanted after 33 months

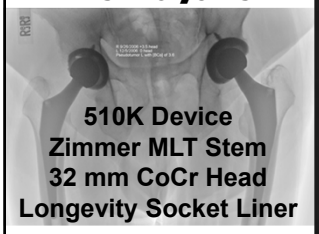
4 Million at Risk?!

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

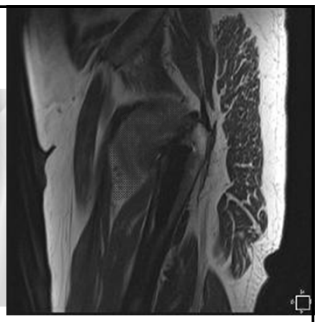




CoCr-on-Plastic MOST POPULAR HIP USA Past 20 years

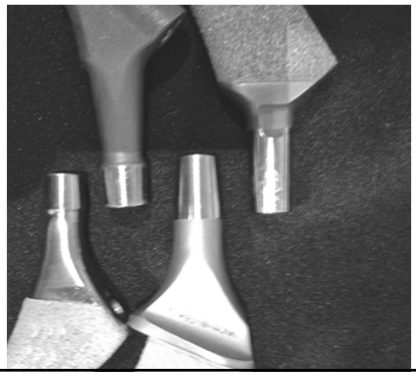


510K Device
Zimmer MLT Stem
32 mm CoCr Head
Longevity Socket Liner



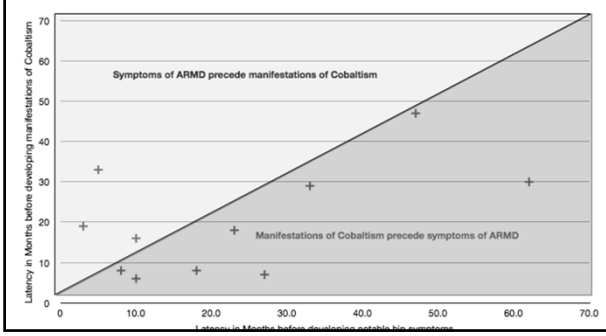
66 year-old med-mal attorney
4 months of left groin pain
8 years post implant
[BCo] of 4 PPB

Altered Stem-Head Tapers

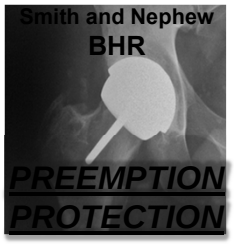


510K

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

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

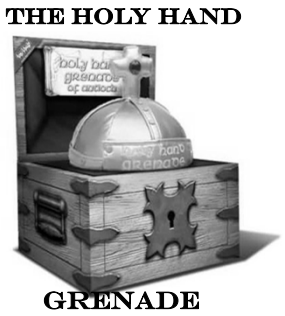
New Hips: 1980-2010 Evolution

Marketing
or
Science ?

More Stable
Less Wear (mm)^3
Lasts longer – no
Saves bone - no
Easier Revision-no

Unexpected Toxicity

Proving Non-inferiority Of New Hips



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

Hip Replacement Costs USA
12K – 120K JAMA 2/2013

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Efficacy Safety And Value

Cost, Complexity, and Complications