

***Cobalturia and Encephalopathy are
common in Patients with Contemporary Hip
Arthroplasties***

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Disclosures
(skin in the game)

Index Case of Arthroprosthetic Cobaltism 2006-2009

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

As surgeon has implanted about 1000 “AT RISK” hips

Board Member Health Watch USA

No economic COI

Arthroplasty [A]

Cobalt [C]

Encephalopathy [E]

Clinical Syndrome (REVERSABLE!)

- Fatigue
- Cognitive decline
- Disordered mood
- Motor and Sensory Dysfunction

Pathophysiology

- Suppression of brain metabolism

Imaging

- 18-F-FDG PET Brain scan

“at-risk-hip”

A hip replacement with any Chrome-Cobalt (CrCo) part

Regardless of bearing couple

- Metal-on-Metal (MoM) resurfacing and stemmed, CrCo Head and Socket
- Metal-on-Plastic (MoP) Modular CrCo Head
- Some Ceramic-on-Plastic designs with modular CrCo necks, stems, or sockets

Alaskan 101/57/25 Series

***Screened with Urine-Cobalt and
12 symptom inventory***

- 101 patients with an “**at-risk-hip**” screened over 30 months
- 57 Cobalt-Positive (Urine Cobalt > 0.9 ppb)
- 25 of 57 with confirmed Arthroplasty-Cobalt-Encephalopathy (ACE) by FDG-PET-Brain-Scan

12 symptom inventory

Incidence in the 25 + FPBS Patients

- Tremor (62%)
- Forgetfulness (57%)
- Fatigue (55%)
- Imbalance or Weakness (41%)
- Disordered Mood (32%)
- Disordered Sleep (32%)
- Generalized Pain (26%)
- Audiovestibular dysfunction (25%)
- Peripheral Neuropathy (18%)
- Executive Dysfunction (14%)
- Non-refractive Blindness (14 %)
- Weight loss > 10% body weight (9 %)

25 FPBS Patients

- Median B[Co] 4.1
- Median U[Co] 13
- Median U[Co]/B[Co] 3.8
- Median Age at Hip Replacement 59
- Median Duration of potential cobalt exposure 8.8 Years
- Median Latency to ACE symptoms 6.8 years
- Symptoms at hip producing systemically circulated Cobalt (64%)
- Median duration of ACE symptoms before hip symptoms 1 year

13 Revised FPBS Patients

- 9 followed greater than 6 months post-revision
- 7 of 9 resolved cobaltemia
- 5 of 7 improved neurologically
- 2 unimproved neurologically repeat FPBS worse
- 2 improved repeat FPBS, stable or improved.

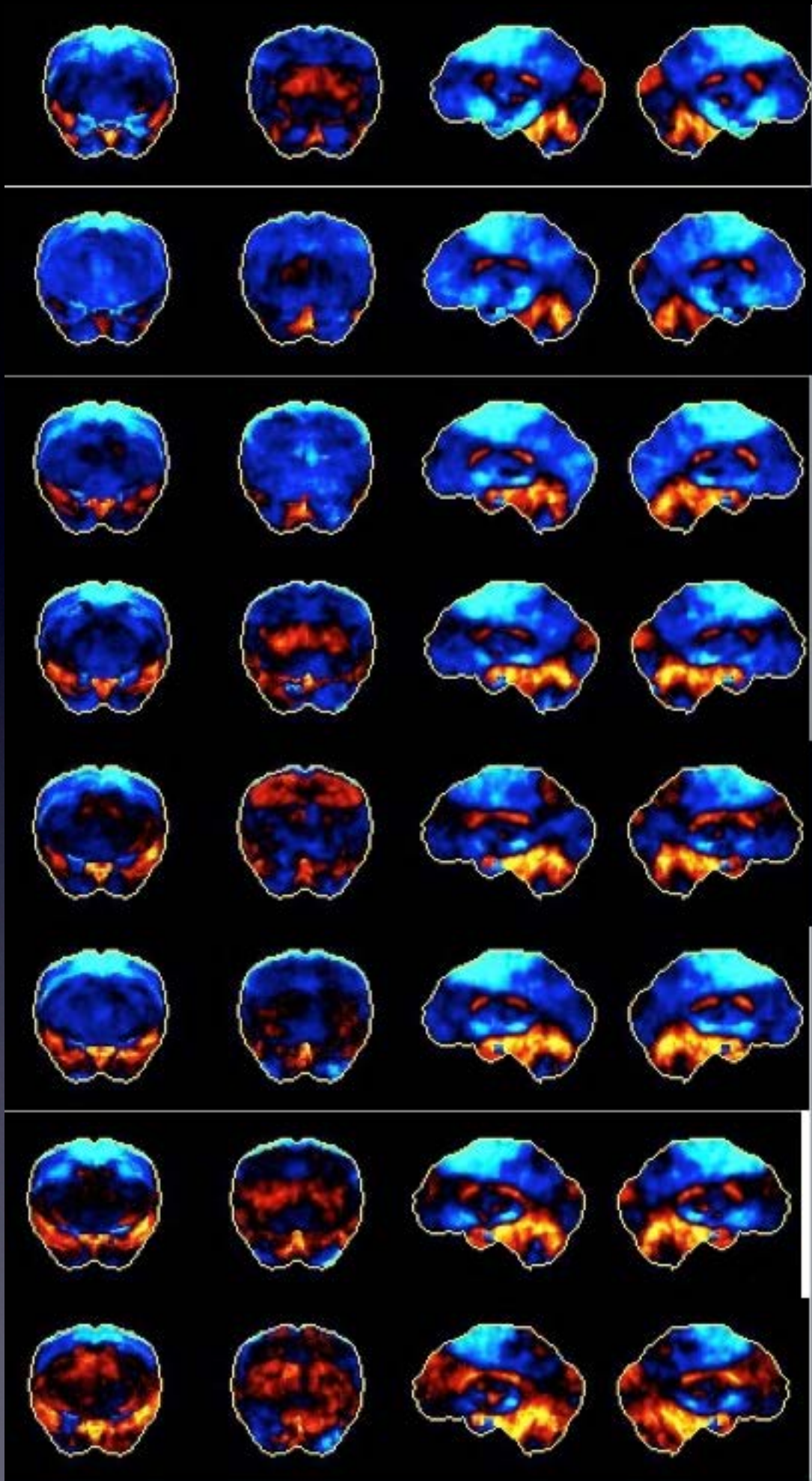
BLUE IS BAD

SEVERE HYPOMETABOLISM GENERALIZED and FOCAL

- MEDIAL TEMPORAL LOBES
- ANTERIOR CINGULATE GYRUS
- BASAL GANGLIA
- DISCRETE AREAS OF
 - FRONTAL
 - PARIENTAL
 - OCCIPITAL CORTICES

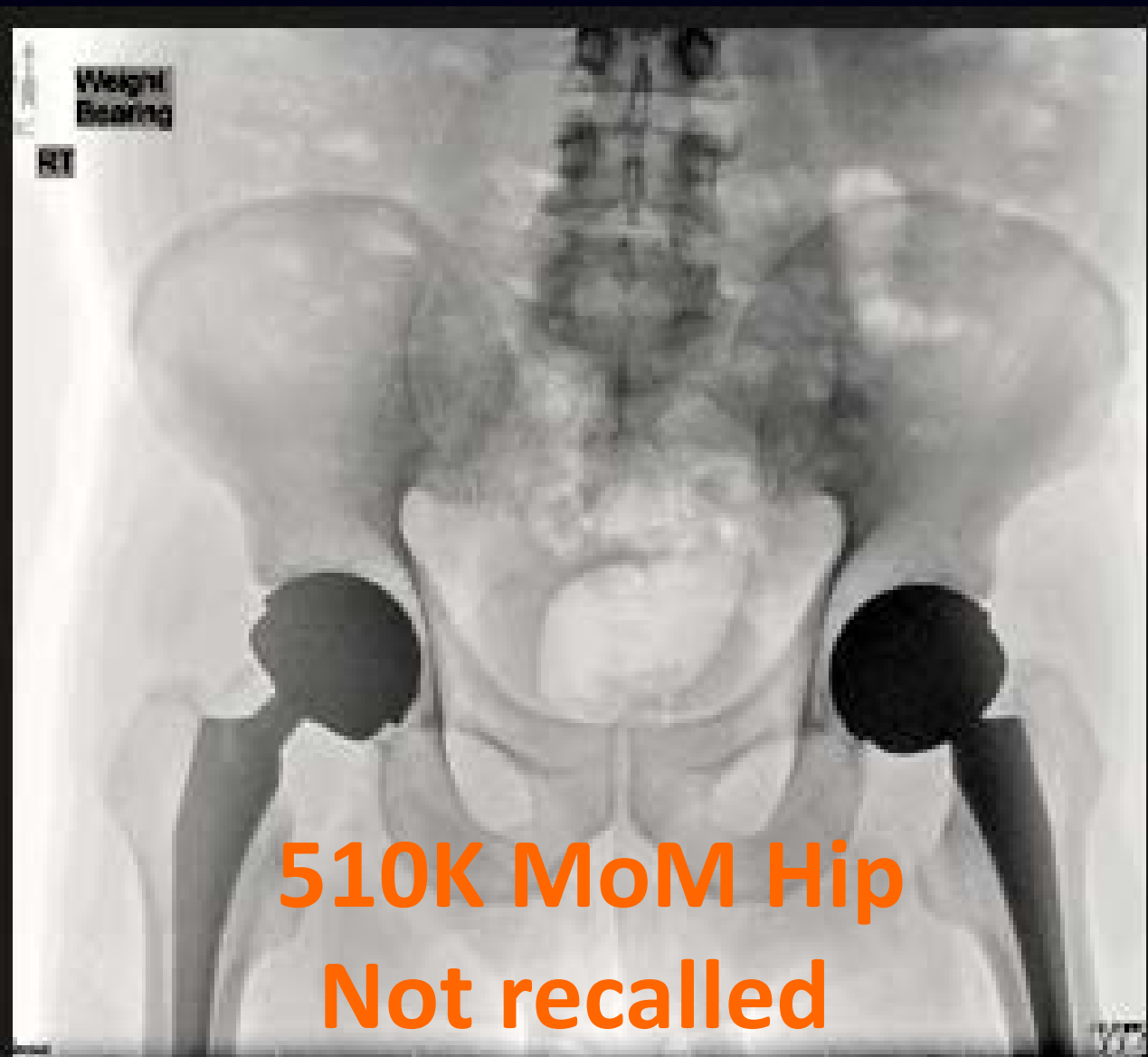
NEUROCOGNITIVE DEFICITS

- SHORT TERM MEMORY
- PROCESSING SPEED
- WORD FINDING DIFFICULTIES
- MOTOR SPEED
- FINE MOTOR COORDINATION
- DISORDERED MOOD
- FATIGUE AND DISORDERED SLEEP



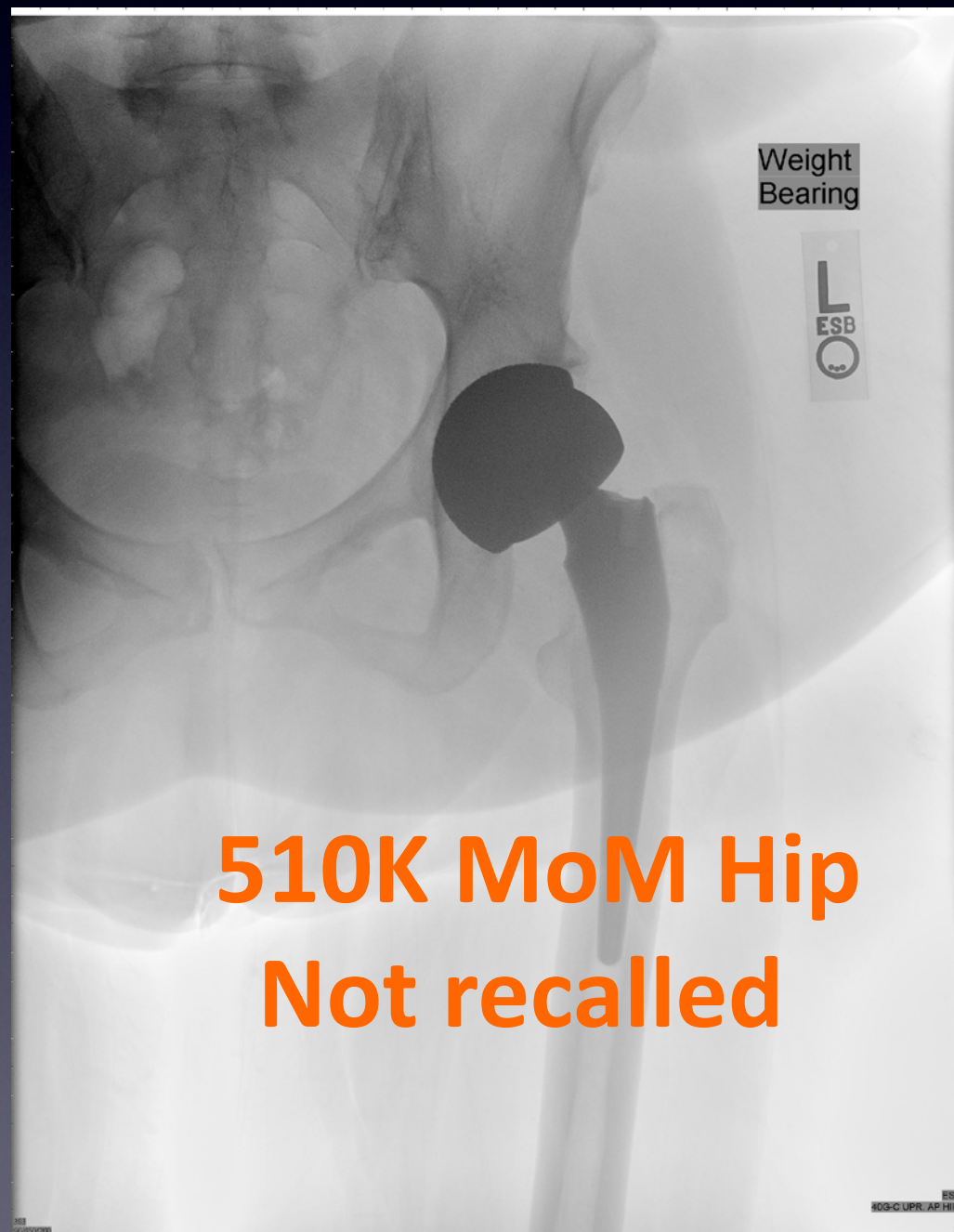
Cobaltism Awareness:

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 with Most
Hip Replacements Indicated



40 y/o nurse, missed 2
annual follow-ups but
saw surgeon
vocationally 1-2 times
a week
[BCo] = 63 ppb
Reversible
Neurocobaltism with 48
months of surplus
morbidity

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

Rejuvenate Implanted 8/2010
70 YO GENERALLY WELL WOMAN

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



510K
MoP Hip
RECALLED

Cobaltism Awareness: Systematic Monitoring of Most Patients with Replaced Hips Indicated

Stryker Accolade “fitted” 2006 for a 68 year-old
Professor

8 years later onset of progressive cognitive
decline, tremor, fatigue, incoordination, and

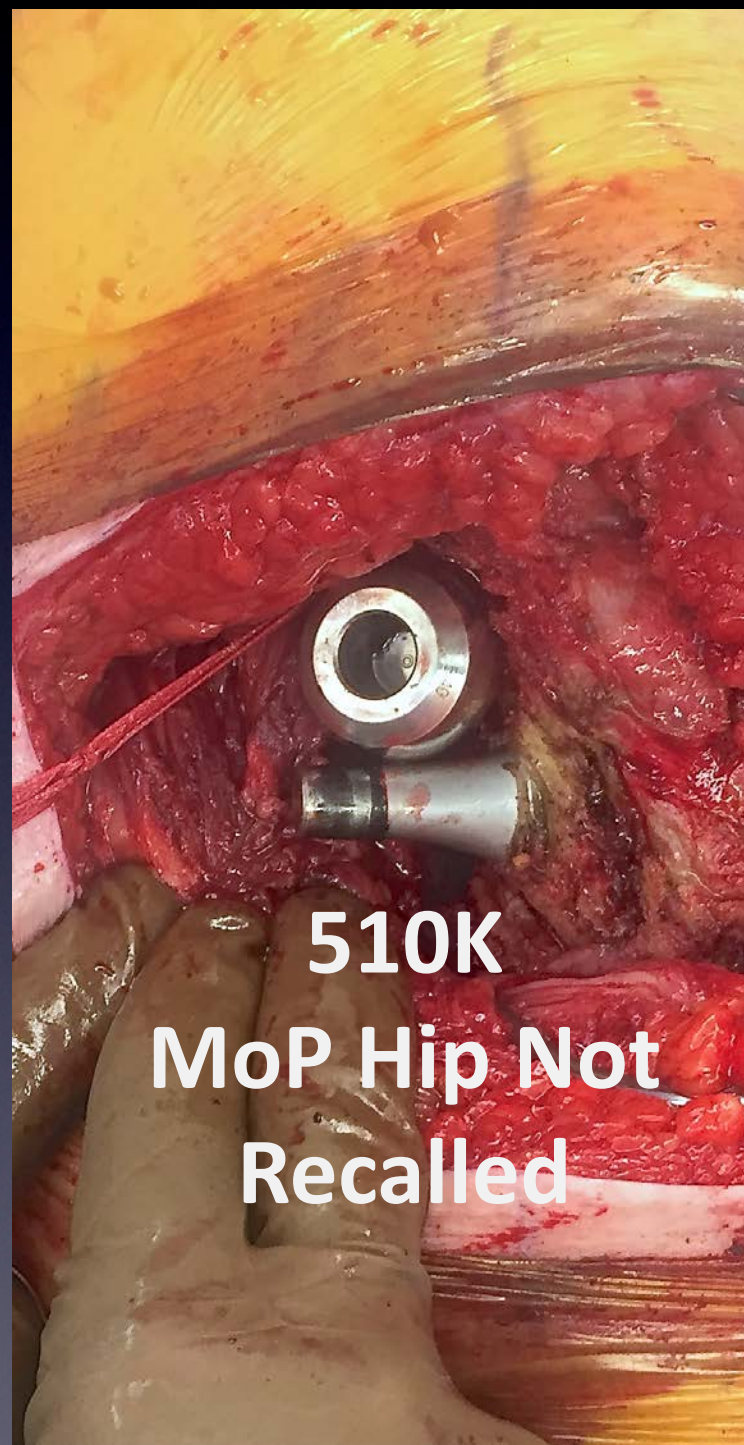
B[Co] = 5.8 PPB

U[Co] = 35 PPB

Joint Fluid [Co] = 1100 PPB

Neurocognitive testing unfit to drive due to
incoordination, reaction time, and judgment
issues. Revised 8/2016 patient now 78 YO.

“Silent Recall” V40 Taper CrCo heads 10/2016



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 Chrome-Cobalt Related Cytotoxicity Toxic Progeria

**Oxidative Stress and Mitochondrial Toxicity
leading to
Death or Dysfunction of Highly Metabolic Cells
resulting in
Mood and Sleep Disorders
Constitutional and Cognitive Decline
Motor-Sensory Neuropathy CNS & PNS
Audio-vestibular and Optic Dysfunction
Movement Disorders
Cardiomyopathy**

A Systematic Review of Systemic Cobaltism after Wear or Corrosion of Chrome-Cobalt Hip Implants

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

25 Cases Identified

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

Case Reports Arthro-Prosthetic-Cobaltism

Post Gessner cursory Literature Review

- 8 cases all with cardiomyopathy
- 3 of 8 died, 2 after hip revision, one before
- 3 heart transplants
- 1 patient ECMO
- 1 patient TPE and Dialysis
- 4 patients ventricular assist devices
- 1 patient with 7 month hospital stay for parental chelation therapy
- All survivors underwent hip revision

Case Series of clinical and subclinical APC

- **Green – 10 patient with failed MoM with Cognitive Decline, Depression and Anxiety**
- **Michet – Patients near Mayo Clinic 10 years post hip replacement more likely to die for accidents, poisonings, and dementia than patients without hip replacements**
- **Prentice – Patients with “well-functioning” MoM hip resurfacing (mean B[Co] 1.8) have MRI atrophy of basal ganglia and visual pathways and echocardiography cardiomyopathy compared to matched controls with MoP hips (mean B[Co] 0.3)**
- **Gilliam – Male AUS Vets with ASR MoM hips 3.8 times more likely to be hospitalized for Heart Failure than those with MoP hips.**

Monitoring Hip Patients at Risk

Blood or Urine Cobalt (PBB)

- **0.2 NORMAL**
- **1 BIOLOGIC EXPOSURE THRESHOLD (BET)**
- **> 1 MOST MoM, MOST MODULAR CrCo Modular Neck**
- **> 1 Many (10-33%) MODULAR CrCo Modular Head MoP Hips**
- **1-10 Pseudotumors, subclinical and mild COBALTISM**
- **11-100 subclinical, mild, and moderate COBALTISM**
- **101-300 moderate to severe COBALTISM**
- **301-1000 extreme COBALTISM (30 CR), DEATH (5 cases)**

Cobalt debris from corrosion a order of magnitude more toxic than that produced by abrasive wear.

Urine levels generally 3-5X Blood Levels

Monitoring Patients with at-risk hips for Cobaltism

Annual **Urine** Cobalt Level

- > **(0.9)** some wear or corrosion with increasing risk of problems systemically
 - **U[Co] > 0.9**
 - **B[Co]**
- 12 symptom inventory for ACE.
 - 2 or more ACE symptoms suggestive of ACE
- **U[Co] > 0.9** and 2 or more ACE symptoms
 - Consider FDG-PET-Brain-Scan

510 K Devices

Antecedent
Device

Pre-Market
Approved
Devices



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**

1970 Predicate Simplicity



**2 Parts
3 Materials
Plastic
Stainless Steel
Cement**

2016 – 510 K Evolution Modularity, Complexity, Unproven Bearing Couples



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

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**

Un-Proven parts 15K

Revision surgery 50-100K



**Efficacy
Safety
And
Value**



**Cost, Complexity,
and Complications**

5 Year Hip Revision Rates

Predicate Charnley 1970s 2-3%

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

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

510K Modular Neck THA 44% (22x)

510K Modular CrCo Head (1-5x)????

Where are we going?
21st Century Cures Act

**Reduction of level of evidence to
antidotal for introduction of new
medical devices!**

Past House, pending in Senate
Structural FDA weaknesses
Legislated FDA weaknesses
Disregard for costs of new technology

New Hips: 1980-2016 Evolution



Larger Heads

More Parts

Unproved materials

Unproved design

Unanticipated modes of failure

Market rather than Science Driven

The Holy Grail of Hip Replacement

Lasts Forever

Instant

recovery

Pain free

Stable

No activity

limits

Not poison

the patient



Proving Non-inferiority of New Hips

The Holy Hand Grenade
Of Empirical Science



Prospective

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

Joint Registries

Retrospective

Comprehensive practice
review with explant analysis

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

