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

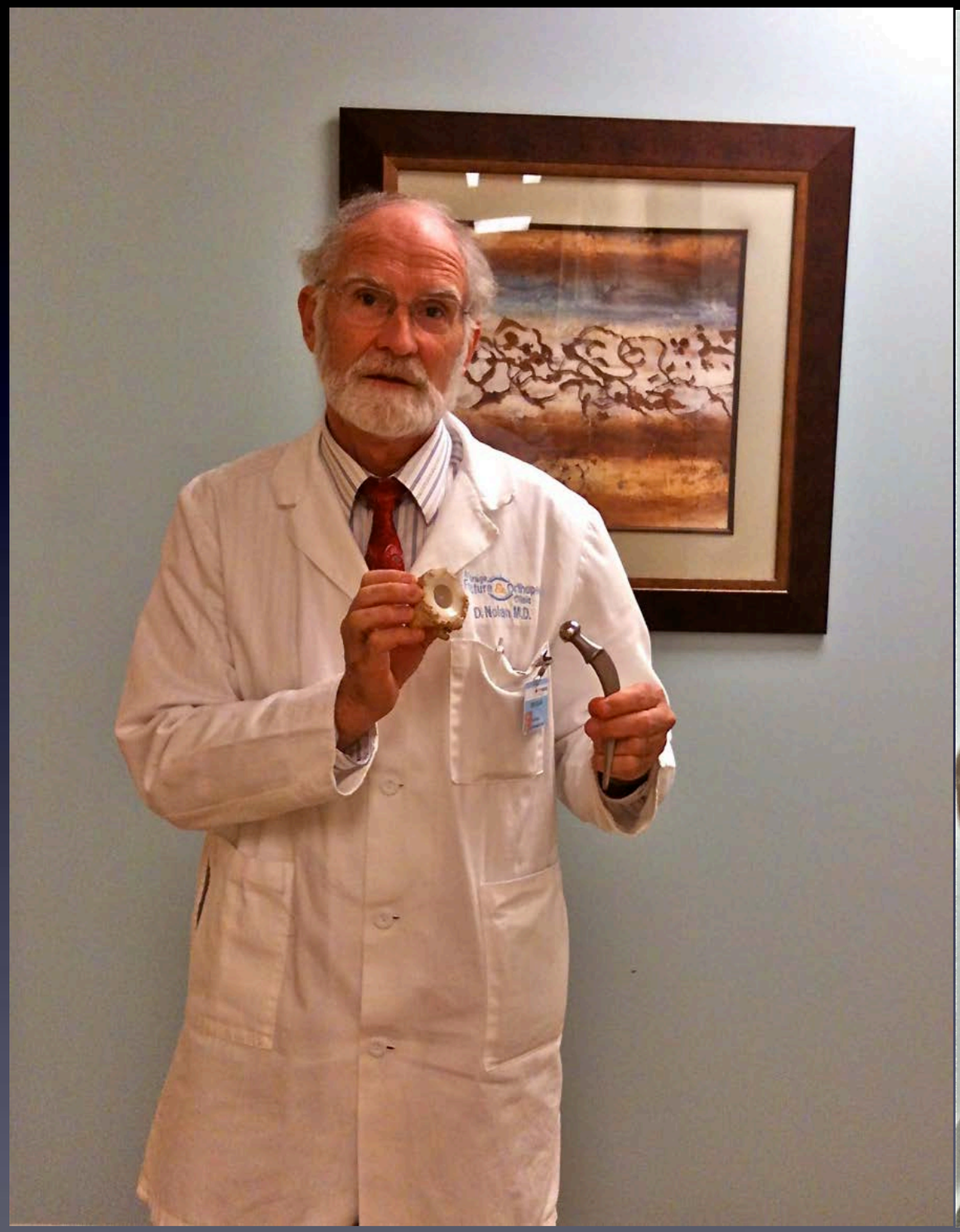
Efficacy Safety And Value

Un-Proven parts 15K

Cost, Complexity, and Complications

Revision surgery 50-100K

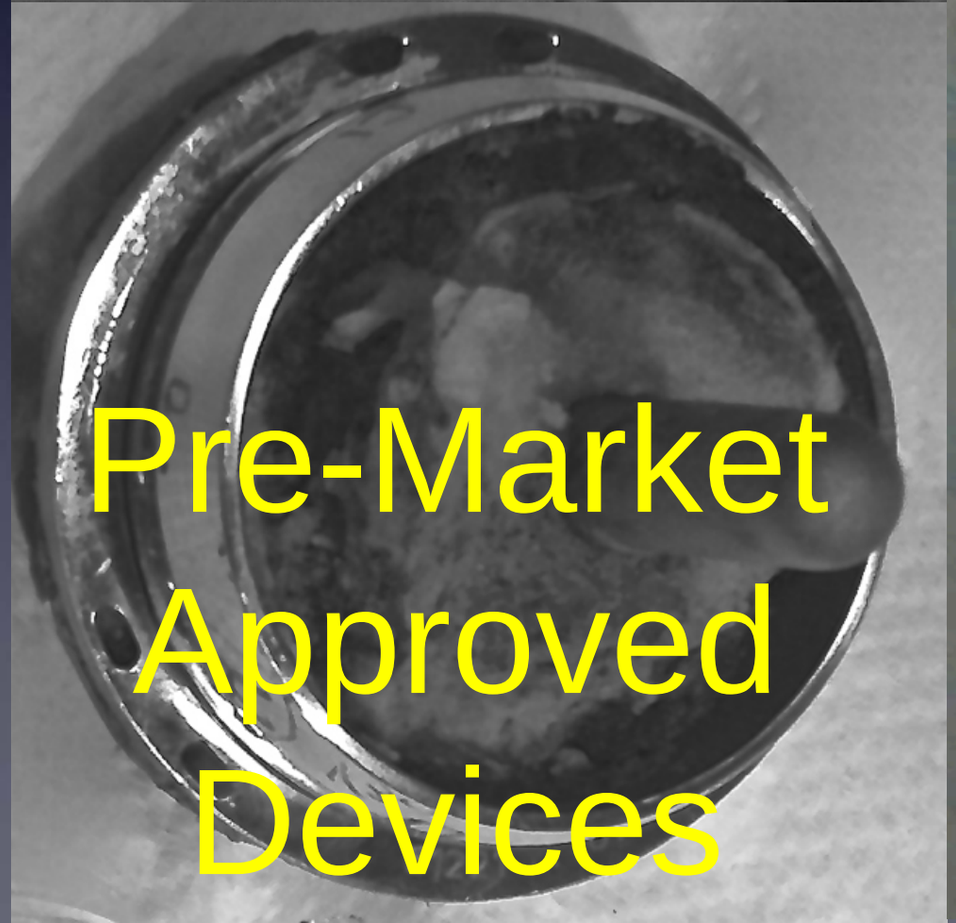
Dr. Declan Nolan 2011



The Holy Grail of Hip Replacement

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

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%

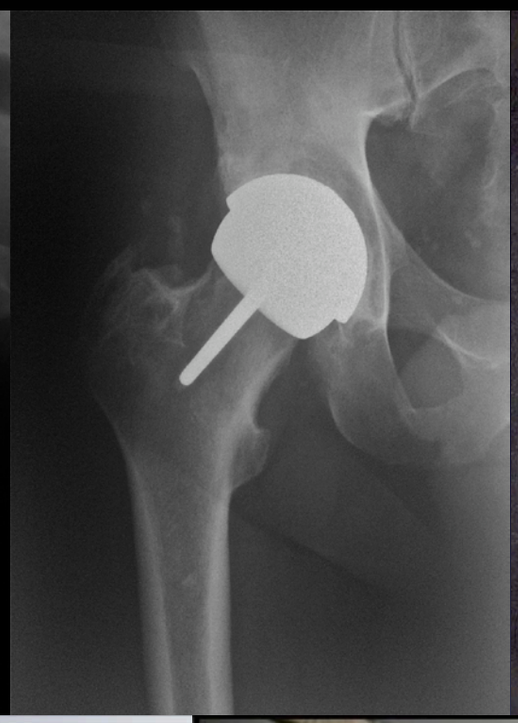
PMA Metal-on-Metal Resurfacing 15% (5x)

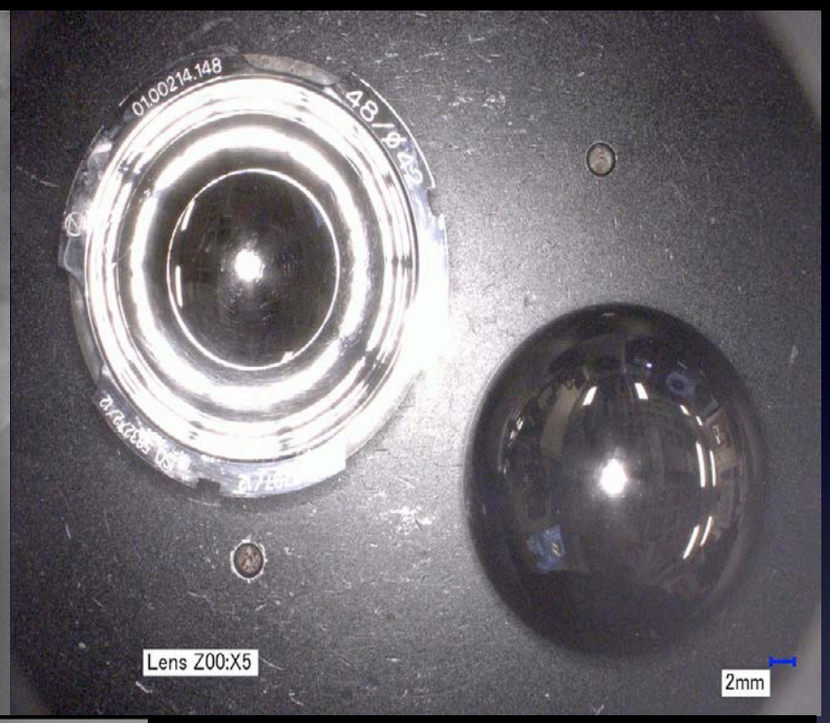
510K Metal-on-Metal THA 44% (22x)

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 PPB

10 with reversible Cobaltism?

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

Patients <u>not systematically</u> screened

Alaskan Non-Rejuvenate Series
Taper Corrosion

6 revised of about 1000 at risk Median [BCo] = 4 PPB

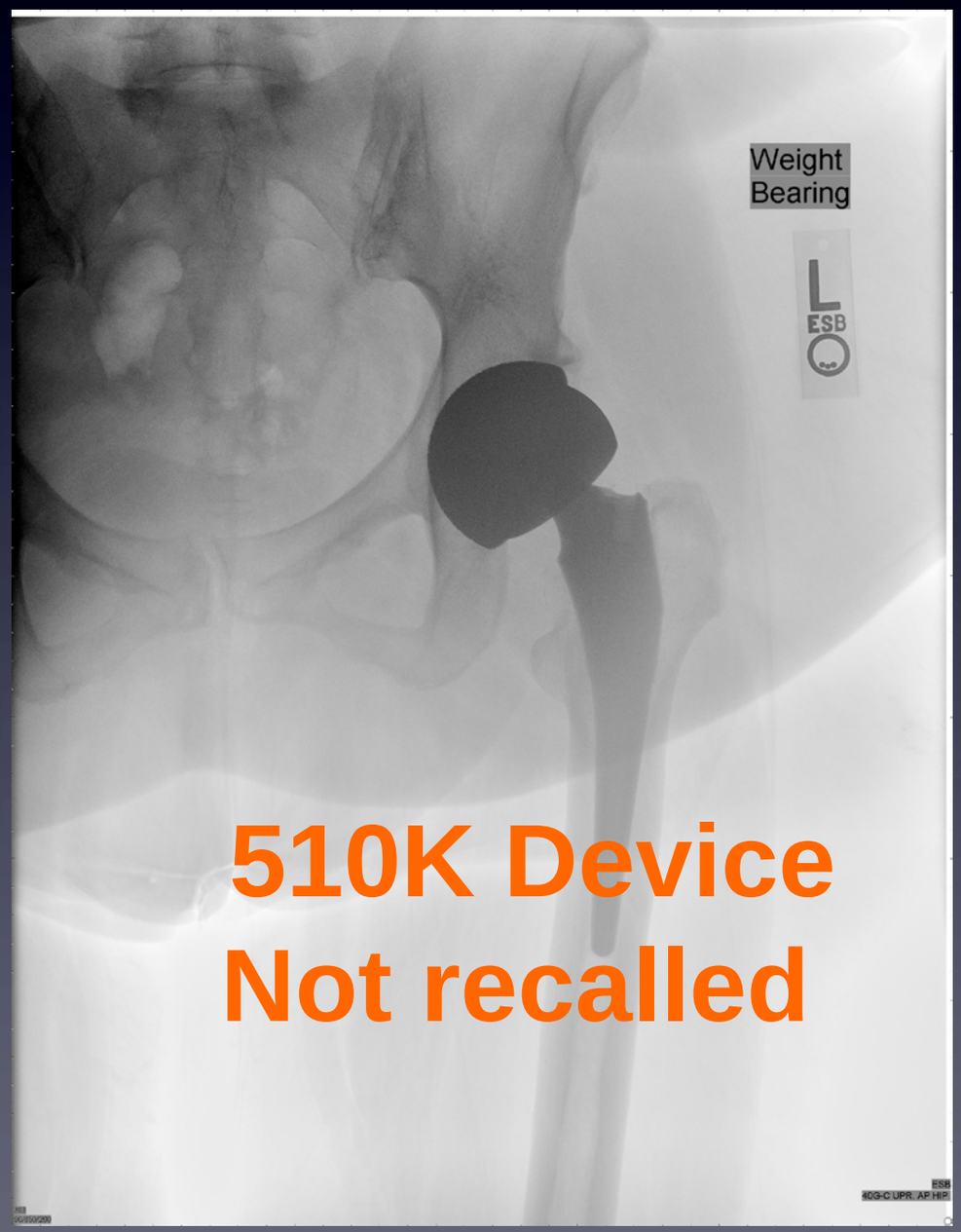
5 with reversible Cobaltism?

Mean latency to illness 5 years

Mean latency to revision 7 years

Population at risk <u>not systematically</u> screened

Cobaltism Awareness:
Systematic Monitoring of Patients with MoM Hips Indicated



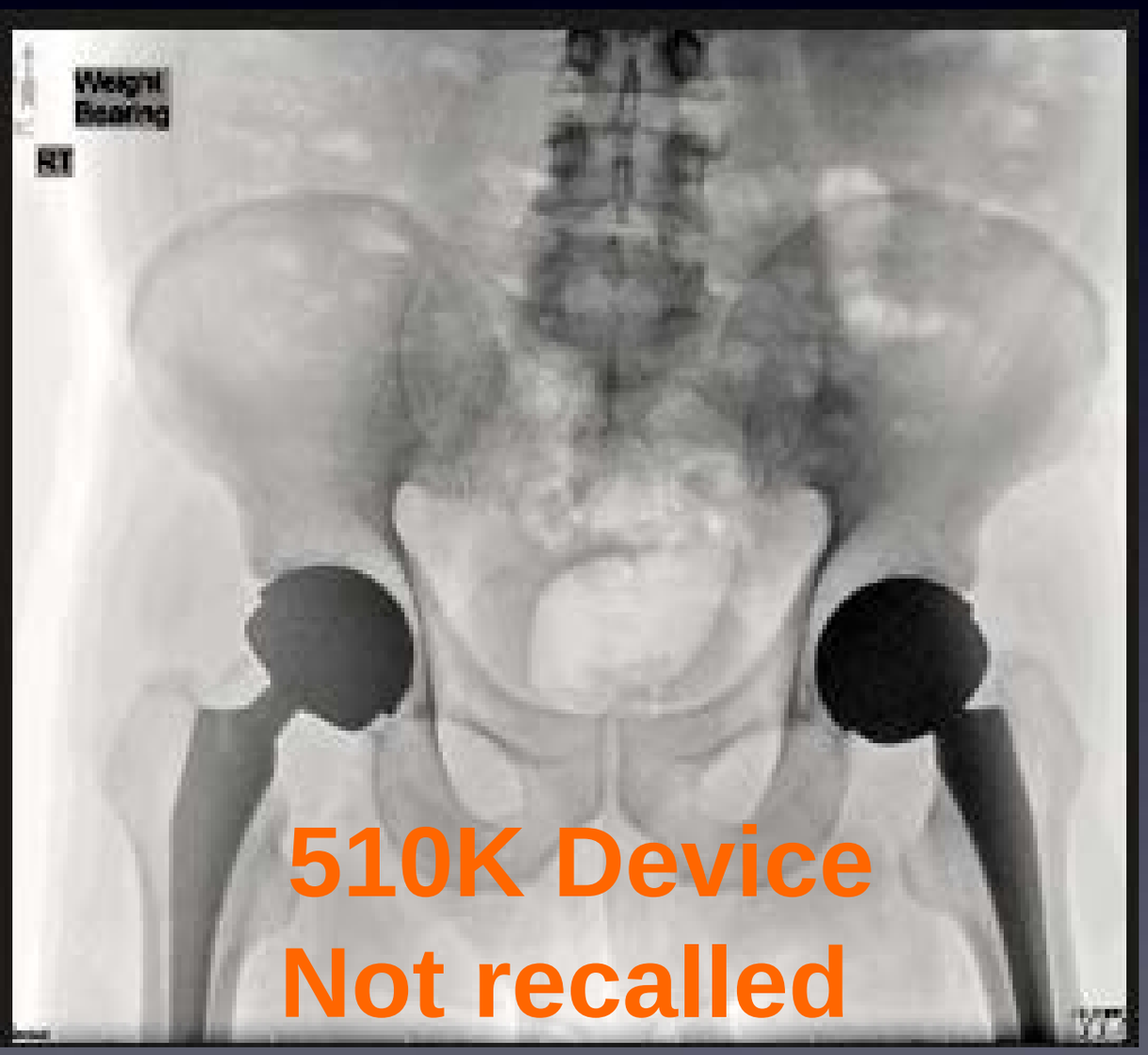
510K Device
Not recalled

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

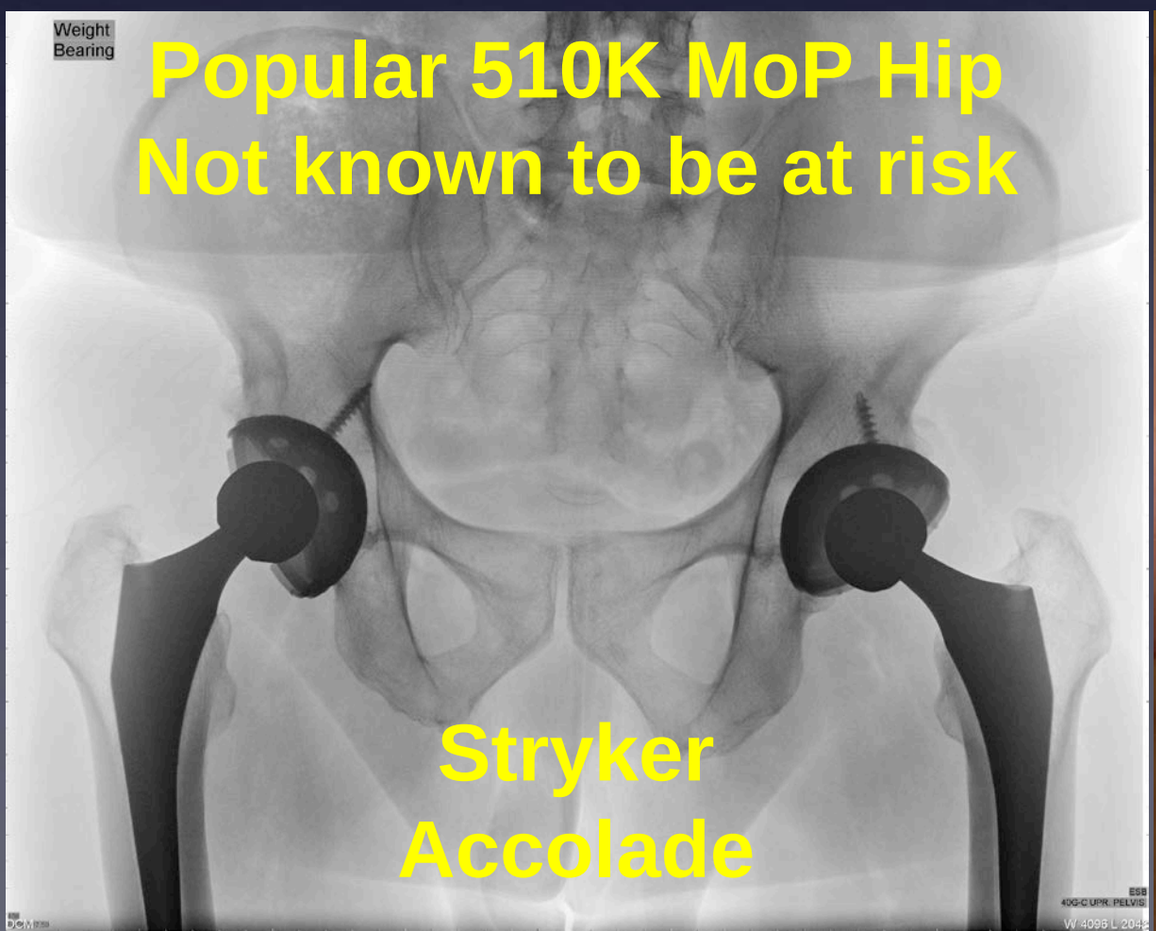
Rejuvenate Implanted 8/2010

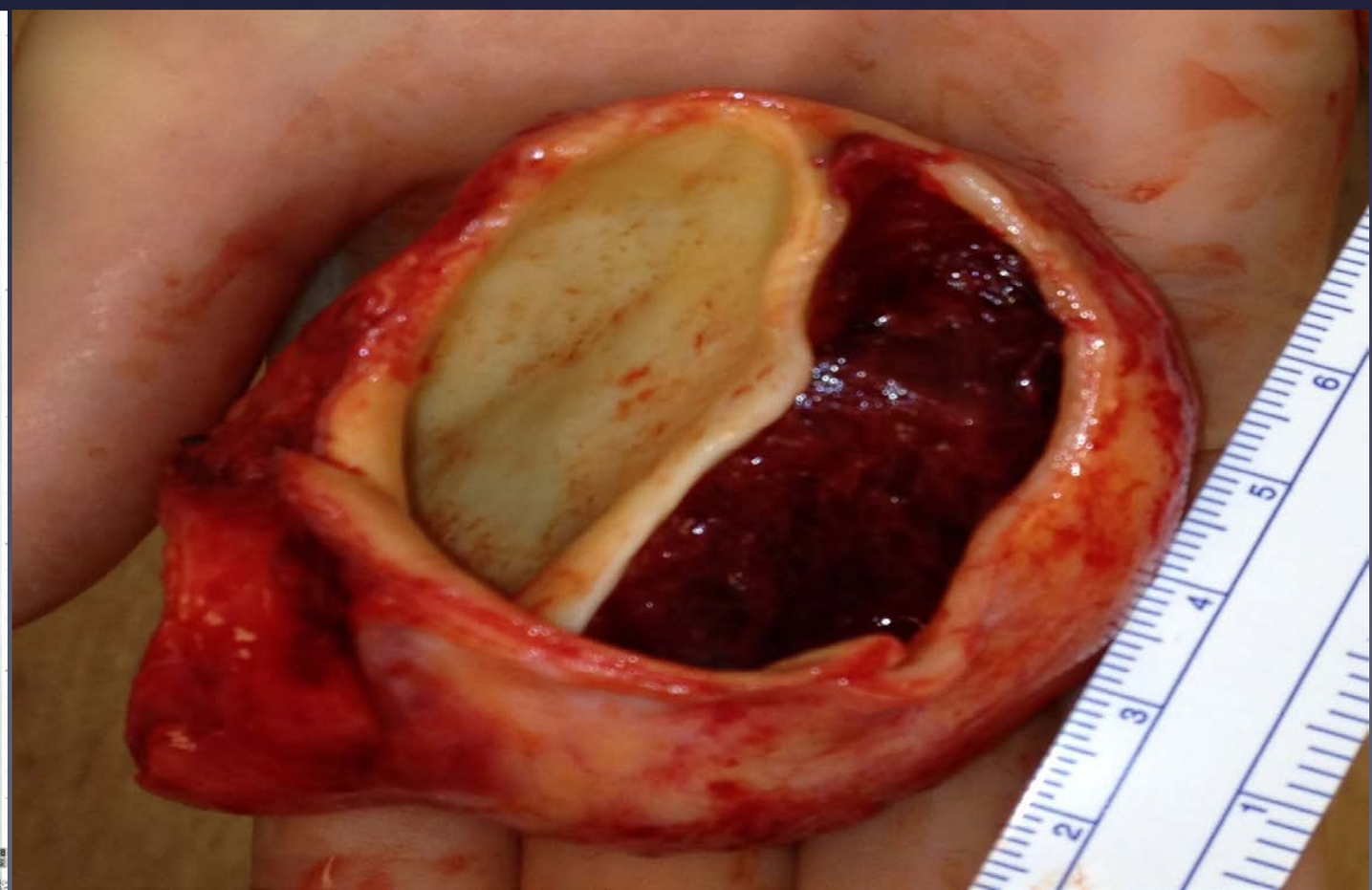
20 months later:
progressive fatigue, poor sleep, nausea, weight loss from 140 to120 pounds, deafness, myalgia, cognitive decline, arrhythmia and diastolic dysfunction
B[Co] = 11 PPB

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

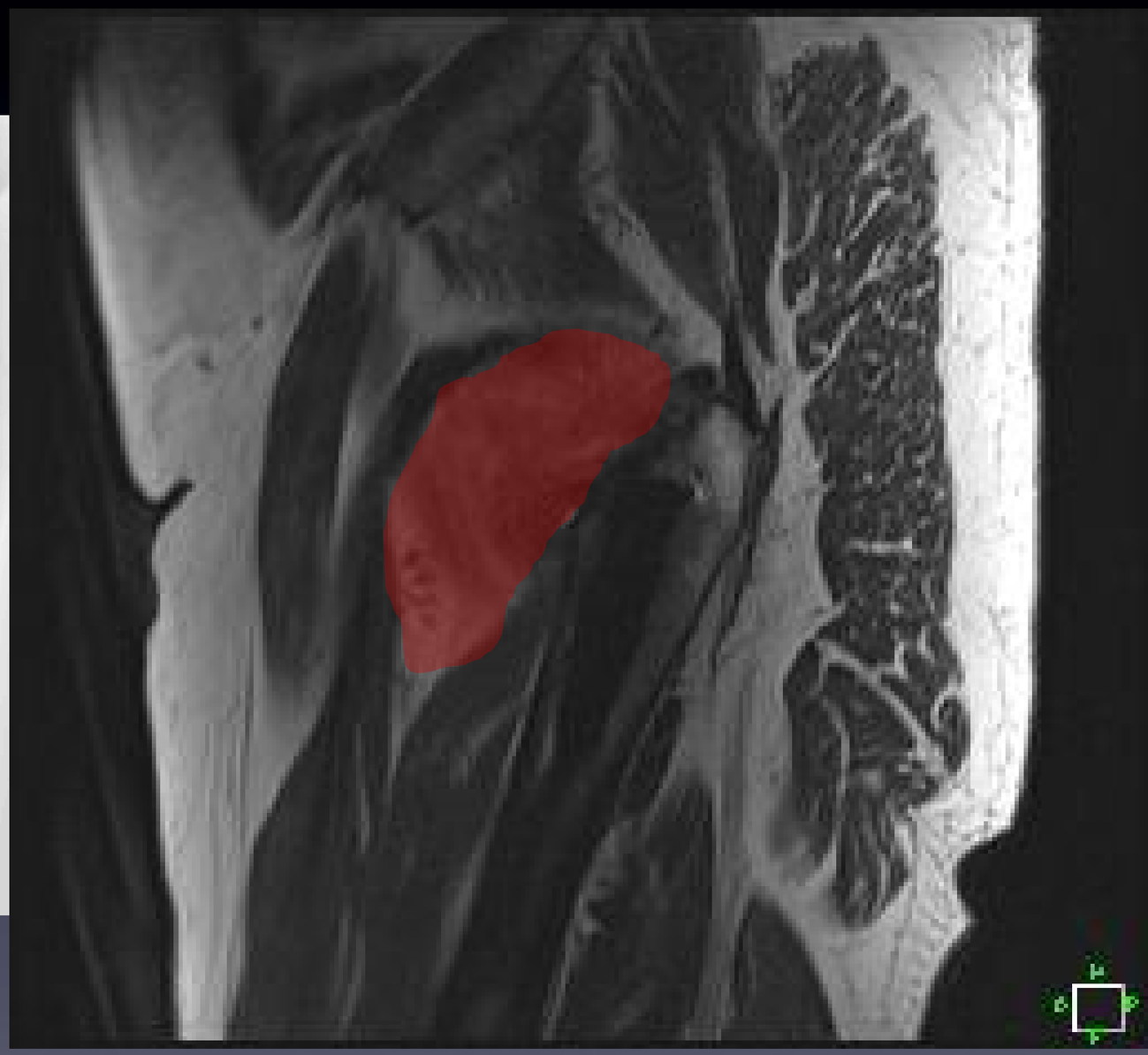




Metal-on-Plastic Bearing

Chrome-Cobalt modular ball on Ti Alloy Stem

510K Device
Zimmer MLT Stem
32 mm CrCo Head
Metal-on-Plastic



66 year-old attorney, 4 months of left groin pain

8 years post implant, [BCo] of 4 PPB

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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

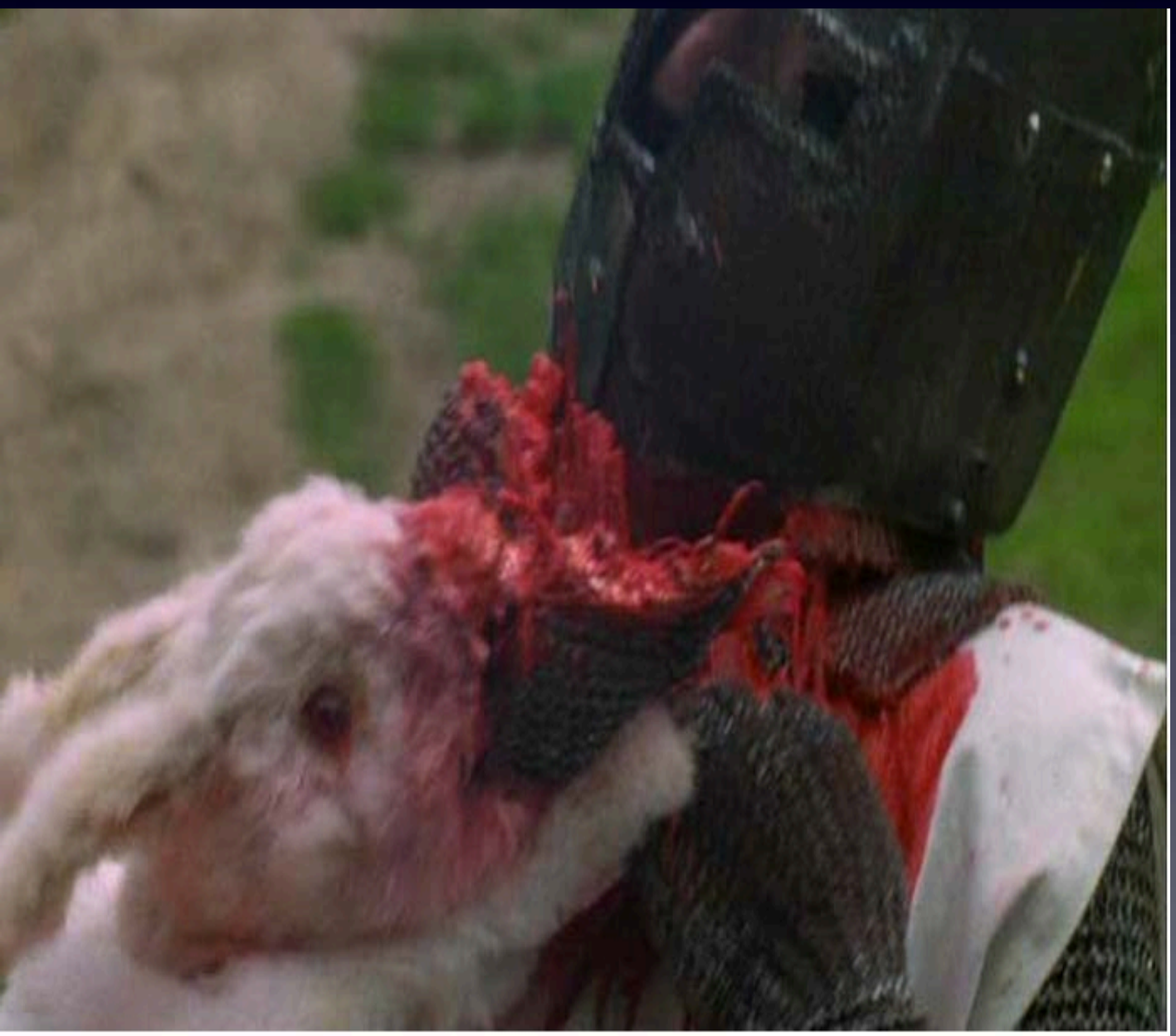
Unproved material

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

Dartmouth Biomedical Engineering Center

DBEC CREW MoM
AAOS 2012

THAYER SCHOOL OF ENGINEERING DARTMOUTH COLLEGE

Cost Explant Analysis 1-2K

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

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.