


Open Public Hearing Orthopaedic and Rehabilitation Devices Panel

June 27-28, 2012

**One Patient's Metal on Metal Hip Implant Story
Updated – 2.3.2013**



WAPS

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MY STORY IN BRIEF

***2006-2007 Bilateral M-o-M Resurfacings**

M-o-M was declared to be the implant that would allow the highest level of activity and last the longest, possibly even my lifetime.

***2009 Revision of First Failed Implant**

No bony in-growth of the acetabular socket

Presence of metallosis

Damage to acetabulum required bone graft



MY STORY IN BRIEF

*2011 Revision Implant Fails

No bony in-growth with socket
Complicated revision surgery
Lengthy rehab
Loss of muscle strength, flexibility
and mobility

Remaining M-o-M is Symptomatic

THE COST OF FAILURE



- Invasive surgical procedures
- Protracted recoveries
- Loss of income
- Expensive medical bills
- Increased cost for insurance
- Loss of skilled work force
- Diminished health
- Diminished quality of life





THE SOLUTION HAS BECOME THE PROBLEM!

CoCr METAL ALLOYS AND BONE

Metal alloys undergo corrosion

- *Release metallic particles which ionize and disperse systemically
- *Enter the bloodstream and accumulate both in surrounding tissues and organs
- * Critical connective tissues are damaged and lost to resection



CoCr METAL ALLOYS AND BONE

Metal ions influence the biology of osteoblasts

- *Bone resorbing cells are activated
- *Mineralization of bone tissue is delayed

Significance of Elevated Blood Metal Ion Levels in Patients with Metal-on-Metal Prostheses: An Evaluation of Oxidative Stress Markers

Cathy Tkaczyk¹, Alain Petit², John Antoniou², David J. Zukor², Maryam Tabrizian¹ and Olga L. Huk^{*,2}

(Morais et al. 1998, Fernandes 1999)



CONCLUSIONS

- M-o-M implants cause great damage
- Bold action is necessary
- Responsibility rests with the
 - * FDA
 - * Medical organizations (AAOS)
 - * Congress

Failure to take decisive action to protect human life is unconscionable.



CONCLUSIONS

*There is no glory in being
the number one innovator
of failed devices!*

*Any financial advantages gained
for our economy by placing innovation
and quick to market approvals above
safety, is a wash-out on the patient end.*



RESPONSIBLE ACTIONS

Place patient safety first by

- Calling for the discontinuance of all M-o-M implants
- Strengthen the device approval process so that new devices are not approved based on devices known to have failure issues
- Implementing a Unique Device Identification system
- Developing a National Registry
- Requiring Pre-Market testing on all high risk devices



RESPONSIBLE ACTIONS

Place patient safety first by

- Adding further protections to inform, educate, & streamline flow of information to patient-victims
- Requiring full disclosure of risks and failure modes
- Posting national alerts to news agencies so the general public knows about levels of device failures & health damages.



UPDATED - 11.2012

**** 2007 M-o-M Implant Revised***

Diagnosis: Implant Failure, Osteolysis, Metallosis, Impingement, Implant cup was no longer round

2006-2012 – 5 Hip Replacements in 6 years

Loss of job and income

Diminished quality of life

High medical expenses

Compromised quality of health