

**WORKSHOP**  
**Evaluation of Implant Failure: The Role of MRI and Retrieval  
Analysis**  
**(In Collaboration with The Hip Society)**

Organizers:  
Douglas E. Padgett, PhD  
Timothy M. Wright, PhD

Speakers:  
Mathias P.G. Bostrom, MD  
Hollis G. Potter, MD  
Timothy M. Wright, MD

## Clinical Evaluation and Workup of the Failed Implant

Mathias P.G. Bostrom, MD

EA Salvati Chair and Professor of Orthopaedic Surgery

Hospital For Special Surgery

New York NY

Total joint arthroplasty is a well documented successful intervention in the treatment of end stage arthritis. Predictable relief of pain and improvement in function has been demonstrated after both total hip and total knee arthroplasty. While short term complications such as infection, stiffness, and instability are well known, failures due to bearing related phenomena such as wear, osteolysis and loosening have historically been considered the long term sequelae of joint replacement.

Over the past decade, there has been an increasing incidence of unexplained pain following total joint arthroplasty especially following hip replacement. The first reports of this phenomena were in association with metal-on-metal bearings. Over the past several years, pain and altered function have also been identified in patients with traditional metal-on-polyethylene bearings.

There has been a wide variety of clinical symptoms in this cohort of patients. While pain is the most common presentation, instability, limp, weakness have all been described. In addition, extra-skeletal symptoms including rash, generalized fatigue and malaise have also been reported. The time to onset of these symptoms has presented from within the first year after surgery to as long as a decade following implantation.

The clinical evaluation includes:

- observation of gait
- assessment of range of motion, strength, balance
- survey of the surgical site assessing for erythema, rash, swelling

Thorough radiographic evaluation is mandatory and includes:

1. plain anteroposterior radiographs and lateral  
-assessment for bone resorption which is unusual after a short duration of implantation  
-implant loosening
2. Cross sectional imaging

-while ultrasound has been shown by some centers to be a good modality for imaging, metal artifact reduction sequence MRI or variants of this technique appear to be the most sensitive for soft tissue destruction as well as bone loss.

### Laboratory Evaluation

Standard laboratory evaluation should include screening labs to rule out infection.

This are:

- erythrocyte sedimentation rate
- C- reactive protein
- complete blood count with differential

With the knowledge of metal associated biologic reactions (adverse local tissue reaction), baseline metal ion levels should be obtained.

-Serum Cobalt, Chromium

-ratio of these 2 may be suggestive of source of the metal ions:

-concordant elevation of both Cobalt and Chromium may suggest bearing wear such as in a metal on metal implant

-preferential rise of Cobalt over Chromium has been associated with corrosion occurring from either a MOM bearing, a metal-metal shell interface or from the trunnion (head-neck taper junction)

### Additional studies:

-in instances where there is a suspicion for infection, aspiration of the joint is appropriate. Joint fluid should be sent for:

-cell count looking for polymorphonuclear leukocytes including differential. This should be performed manually to avoid spuriously elevated results.

-culture and sensitivity

-joint fluid metal ion analysis

Treatment of biologically driven adverse tissue reaction is guided by several factors:

-source of the problem such as trunnion or in the case of metal-on-metal articulation, the bearing

-integrity of fixation of the components

-appropriate position of the implants

#### Metal on Metal bearings

-Failed resurfacings are probably best treated by revising both the femoral and acetabular components. In some instances, it is possible to retain a resurfacing shell provided you can ensure:

-good fixation / alignment and compatible bearing

-Trunnion derived ALTR

Exchange of a metallic head (typically Cobalt-Chrome) to a ceramic ball with a titanium interface sleeve appears successful

-In instances of gross trunnion damage, it may be necessary to remove the femoral component.

#### [Corrosion at the head-neck taper as a cause for adverse local tissue reactions after total hip arthroplasty.](#)

**Cooper** HJ, **Della Valle** CJ, Berger RA, Tetreault M, Paprosky WG, Sporer SM, Jacobs JJ. J Bone Joint Surg Am. 2012 Sep 19;94(18):1655-61.

#### [What do we know about taper corrosion in total hip arthroplasty?](#)

Jacobs JJ, **Cooper** HJ, Urban RM, Wixson RL, **Della Valle** CJ. J Arthroplasty. 2014 Apr;29(4):668-9. doi: 10.1016/j.arth.2014.02.014. Epub 2014 Feb 18

#### [MRI, Retrieval Analysis, and Histologic Evaluation of Adverse Local Tissue Reaction in Metal-on-Polyethylene Total Hip Arthroplasty.](#)

Nodzo SR, **Esposito** CI, Potter HG, Ranawat CS, Wright TM, **Padgett** DE. J Arthroplasty. 2017 May;32(5):1647-1653. doi: 10.1016/j.arth.2016.11.046. Epub 2016 Dec 8

#### [Adverse local tissue reactions in metal-on-polyethylene total hip arthroplasty due to trunnion corrosion: the risk of misdiagnosis.](#)

Whitehouse MR, Endo M, Zachara S, Nielsen TO, Greidanus NV, Masri BA, **Garbuz DS**, Duncan CP. Bone Joint J. 2015 Aug;97-B(8):1024-30

**(MR) Imaging of Metallic Implants  
ORS 2018**

Hollis G. Potter, MD  
Chairman, Department of Radiology & Imaging  
The Coleman Chair, MRI Research  
Hospital for Special Surgery  
Professor of Radiology  
Weill Medical College of Cornell University

• **Adverse Reactions around Joint Replacements**

- J & J Depuy recall: ASR implant; Stryker Rejuvenate stem
- British MHRA press release 2012
- "... surgeons and doctors ... should annually monitor patients for the lifetime of their metal-on-metal total hip replacements..."
- FDA 522 Postmarket surveillance studies
  - CDRH issued 522 orders to all MOM total hip manufacturers on May 6, 2011: cross sectional imaging and serum ion levels
  - Current recommendations for Orthopaedic Surgeons:
    - Symptomatic patients: Diagnostic imaging and metal ion testing
  - June 2012 FDA Orthopaedic and Rehabilitation Devices Advisory Panel meeting: recommended **MRI with metal artifact reduction**
  - **BUT**: FDA has only approved 4 TJA devices that are labelled "MRI compatible"; data on implant heating is based largely on agarose phantoms without addressing effect of internal perfusion and external convection!
  - MRI is a safe and effective means by which to assess tissue reactions (Koff, Potter AJR 2014; 203:154-61)

• **Scanner Reported Whole Body SAR Values for TKA, THA and TSA**

Joint	Scanning Sequence, SAR Value (W/kg)	
	2D Fast Spin-Echo	MAVRIC SL
Total knee arthroplasty (n = 30) <sup>a</sup>	0.39 ± 0.64	0.20 ± 0.32
Total hip arthroplasty (n = 30) <sup>b</sup>	1.52 ± 0.33	0.93 ± 0.28
Total shoulder replacement (n = 30) <sup>c</sup>	1.14 ± 0.37	0.92 ± 0.24

Note—Data are mean ± SD. Protocols used are described in Table 1. All scanning was performed at 1.5 T.

MAVRIC SL = multiacquisition variable resonance image combination technique (GE Healthcare).

<sup>a</sup>Scanning was performed using an eight-channel transmit-receive lower extremity coil.

<sup>b</sup>Scanning was performed using an eight-channel receive-only cardiac coil.

<sup>c</sup>Scanning was performed using a three-channel phased-array receive-only coil.

Koff MF, Shah P, Potter HG. Clinical implementation of MRI of joint arthroplasty. *AJR Am J Roentgenol.* 2014 Jul;203(1):154-61.

• **Accuracy of MRI in detecting periacetabular osteolysis**

- *MRI Sensitivity = 95%*
  - *83 of 87 locations with lesions were correctly identified*
  - *Radiographs (current standard with oblique views) = 52%*
  - *CT (optimized) = 75%*
  - *For radiographs and CT, lesion detection was dependent on lesion location*
  - *MRI had consistently good sensitivity in all lesion locations*
- *MRI Specificity = 98%*
  - *48 of 49 locations having no lesions were correctly identified*
  - *X-Ray 96%; CT 100%*
- *Walde et al; CORR 2005; 437:138-144*

• **The cellular basis of osteolysis and ALTR**

- Osteolysis: nanoparticles of polyethylene (metal, ceramic) primarily target macrophages and osteoclast precursor cells
  - Results in up-regulation of proinflammatory signaling and inhibition of the protective actions of anti-osteoclastogenic cytokines such as interferon gamma
  - Up-regulation of osteoclasts and down-regulation of osteoblasts
  - Host response is variable– lies within SNPs (single nucleotide polymorphism) within the genome

- MOM constructs: two modes of adverse local tissue reaction (ALTR)
  - Cell mediated: DTH reaction driven by lymphocyte reaction resulting in local tissue damage and necrosis; avoid term “pseudotumor”; ALVAL histologic term/classification
  - Foreign body reaction due to metallic debris (increased risk with abnormal radiographic measurements)
- Tribocorrosion: corrosion (electrochemical reaction between slightly different metallic composites) and wear (mechanical degradation process due to offset geometry) around modular THA
  - May be modular neck head junction, modular stem or at trunnion

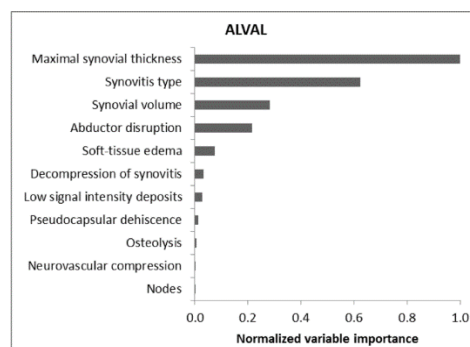
## MRI Predicts ALVAL and Tissue Damage in Metal-on-Metal Hip Arthroplasty

Danyal H. Nawabi MD, FRCS(Orth), Stephanie Gold BA,  
Steven Lyman PhD, Kara Fields MS, Douglas E. Padgett MD,  
Hollis G. Potter MD

- **Identify which MRI characteristics correlate to moderate to severe ( $\geq 5$ ) ALVAL score and degree of intraoperative damage**
  - **Correlate MRI with clinically and biologically relevant outcomes**
- 70 MOM hips in 68 pts with preoperative 1.5T GEHC MRI using an optimized protocol including the MAVRIC prototype
  - THA with diameter  $>38\text{mm}$ : (24 ASR, 8 BHR, 7 M2a-Magnum, 4 Durom, 3 Conserve Plus); RSA: 19 BHR, 2 Comet, 1 recap, 2 Conserve Plus; revised by 13 surgeons
- 13 MRI variables assessed including synovial volume and osteolysis
  - Coefficient of repeatability between two MR radiologists was  $0.25\text{cm}^3$  for osteolysis and  $1.8\text{cm}^3$  for synovitis (JBJS, JBJS(A) 2013; 95(10):895-902)
- All patients underwent revision arthroplasty with intraoperative assessment and tissue biopsy (loosening 11; malalignment 4; infection 1; **unexplained pain 54**) (*Nat J Reg of England and Wales*)

Sensitivity/specificity of **94%/87%** for ALVAL of  $\geq 5$  and **90%/86%** for predicting intraoperative damage

Random forest analysis demonstrates the normalized importance of MRI characteristics in predicting the presence of ALVAL and intraoperative tissue damage. Importance is normalized to the best predictor, assigned the value of 1.



- **ALTR around modular dual taper stems**

*Burge et al, Radiology 2015; 277:142-50*

- 54 hips in 50 pts underwent revision
- 13/54 (24%) **asymptomatic** revised based on MRI **alone**
- Synovial thickness 10mm (2-22mm)
- Multiple regression analysis: After adjusting for age and sex, every mm increase in synovial thickness was associated with a mean 0.3 increase in ALVAL score (95% confidence interval: 0.2, 0.4;  $P = 0.002$ ). No association was found between ALVAL and any other predictor of interest, including serum ion levels

- **Results: MRI vs Wear Analysis**

**Preliminary Significant Correlations (Spearman Rank)**

- MRI synovial thickness with visual damage at the femoral stem head trunnion ( $\rho = 0.48$ ,  $p = 0.004$ )
- MRI ALTR grade with visual damage of the femoral head taper ( $\rho = 0.20$ ,  $p = 0.014$ )
- MRI ALTR grade with visual damage of femoral stem in modular designs ( $\rho = 0.59$ ,  $p = 0.006$ )

- **MRI ALTR grade with femoral head volumetric wear ( $\rho = 0.93, p=0.001$ )**
- **MRI as a biomarker of ALTR**
  - Different synovial reactions were detected using MRI
    - Qualitative grading detect implant specific synovial response
    - ALTRs for mMOP > MOP, Polymeric for MOP > mMOP
    - Differences reflect variable host-mediated response to mount discernable synovitis pattern on MRI
    - MRI ALTR grade correlates to visual damage scores from retrieval analysis
    - Not all metallic deposits discernable on morphologic MRI scanning: require new methods
- **Tissue reactions on MRI**
  - Normal: flat, low signal intensity pseudocapsule with thin lining
  - Infection: laminated synovium with surrounding soft tissue edema
  - Polymeric: intermediate signal synovial deposits; osteolysis is common and typically of intermediate signal intensity
  - Metallosis: low signal intensity deposits in the soft tissue/bone (does not necessarily mean ALTR)
  - ALTR: tissue necrosis: fluid collection with THICK rind and poor definition with surrounding tissue; osteolysis less common
- **MRI in predictive of ALTR and tissue damage in THA**
  - MRI can be used as a screening tool to distinguish those patients with adverse local tissue reaction
  - MOST ACCURATE TEST TO DETECT ADVERSE SYNOVITIS AND BONE LOSS
  - ALTRs occurs with ALL bearing constructs in both symptomatic and asymptomatic patients
  - Maximum synovial thickness is highly correlated with a diagnosis of ALVAL in patients with a modular head-neck and neck-stem implant
  - MRI/US protocols must allow for thickness measurements to be clear
  - Radiographic measurements, clinical symptoms or serum ion levels alone do not predict the presence and extent of wear-induced synovitis
  - New phase contrast measurements may quantify metal burden in soft tissues

**The Role of Implant Retrieval in Evaluating Failed Implants**

*ORS Workshop on Evaluation of Implant Failure: The Role of MRI and Retrieval Analysis*

Timothy Wright, PhD

Director, Department of Biomechanics and F.M. Kirby Chair of Orthopaedic Biomechanics

Hospital for Special Surgery

Professor of Applied Biomechanics in Orthopaedics

Weill Medical College of Cornell University

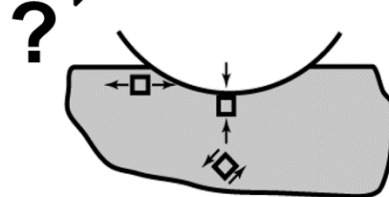
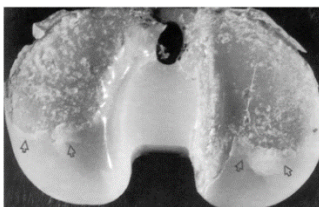
**Implant Retrieval Analysis**

- Mission Statement: assess the performance of orthopedic devices through observations and measurements made on components retrieved at revision surgery
- HSS Implant Retrieval System: now in its 41<sup>st</sup> year, a collection of more than 25,000 total joint components
- Though retrieval analysis is limited to “failed” implants, it is not failure analysis per se
- Retrieval analysis in isolation provides only limited value
  - Better to incorporate retrieval analysis into the total clinical picture (e.g., reason for implantation, length of implantation, component placement and orientation, reason for removal, pathology of surrounding tissues, advanced imaging)
  - Best to embed retrieval analysis into multidisciplinary arthroplasty research
  - Size matters: the bigger and more complete the system, the greater the power to explore surgical, material, and design factors affecting performance while accounting for confounding clinical and demographic factors

**Two examples of retrieval analysis applications**

- *Assessing the Performance of Bearing Materials*
  - Oxidation of conventional ultrahigh molecular weight polyethylene

**Observed Wear** ↔ **Stress State**



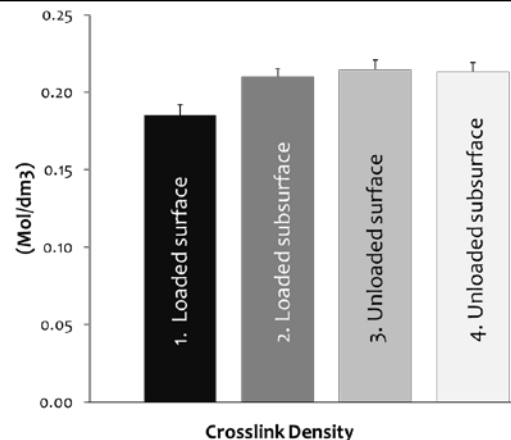
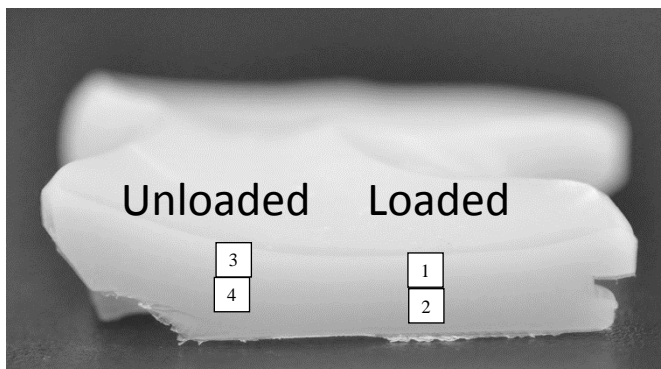
**High stresses, complex kinematics, large exposed surface**

- Highly cross-linked polyethylene
  - Increased crosslinking improves abrasive wear resistance
  - Accompanying thermal treatments reduce/eliminate free radicals, reducing oxidation
  - Nonetheless, retrieved components show oxidation and reduced crosslinks, especially in highly loaded, worn areas on knee components

**Crosslink Density Is Reduced and Oxidation Is Increased in Retrieved Highly Crosslinked Polyethylene TKA Tibial Inserts**

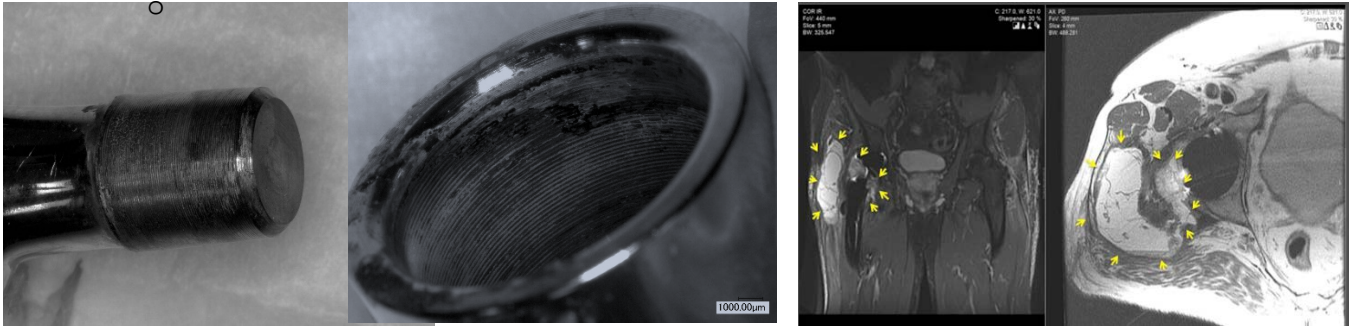
Tong Liu MD, Christina I. Esposito PhD, Jayme C. Burket PhD, Timothy M. Wright PhD

Clinical Orthopaedics and Related Research®  
A Publication of The Association of Bone and Joint Surgeons®



- **Tribocorrosion at Modular Connections**

- Mechanically assisted crevice corrosion between the femoral head and the stem

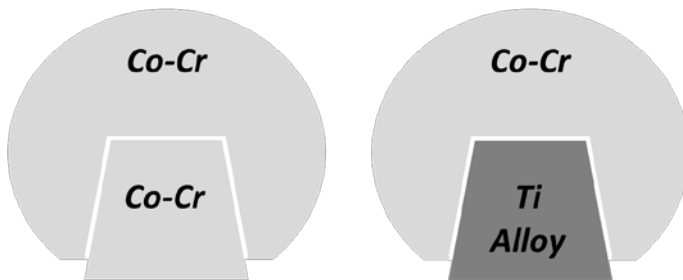


- Adverse local tissue reactions to corrosion debris regardless of bearing surface material

MRI, Retrieval Analysis, and Histologic Evaluation of Adverse Local Tissue Reaction in Metal-on-Polyethylene Total Hip Arthroplasty Scott R. Nodzo, MD <sup>a,\*</sup>, Christina I. Esposito, PhD <sup>b</sup>, Hollis G. Potter, MD <sup>c</sup>, Chitranjan S. Ranawat, MD <sup>a</sup>, Timothy M. Wright, PhD <sup>b</sup>, Douglas E. Padgett, MD <sup>a</sup>  
 The Journal of Arthroplasty

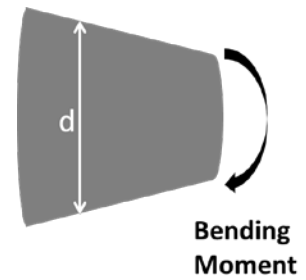
- Multifactorial problem, but certainly dependent on surface mechanics of the modular connection

**Head and stem materials**



*Greater fretting damage with Co-Cr against Ti Alloy connections, but Ti alloy is less prone to corrosion*

**Trunnion flexural rigidity**



V40 Tapers	Co-Cr (E = 241 GPa)	TMZF (E = 80 GPa)
Rigidity [Nm <sup>2</sup> ]	296 ± 24	96 ± 4
Diameter [mm]	12.6 ± 0.3	12.5 ± 0.1

PCA Tapers	Co-Cr (E = 241 GPa)
Rigidity [Nm <sup>2</sup> ]	386 ± 12
Diameter [mm]	13.4 ± 0.1