*FDA Orthopaedic Rehabilitation Devices Panel*
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# Soft Tissue Imaging in Metal-on-Metal Total Hip Arthroplasty

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# Overview

- *What We Already Know*
- *What We Do Not Know*
- *What We Need to Know*
  - Current Research
  - Future Focus

# I. What We Already Know

# Modes of MoM Failures

- Loosening/lysis
- Dislocation
- Infection
- Fracture
- *Adverse Biological Reactions*
  - Systemic
  - Local

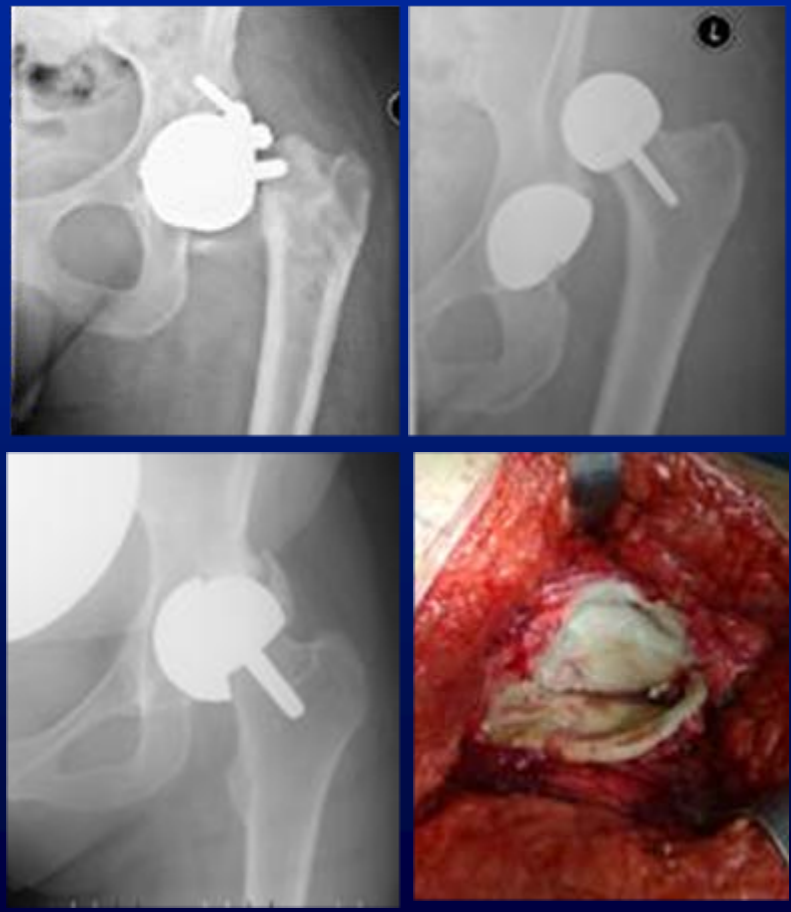


**Table.** Differential Diagnosis for the Painful MoM Hip Arthroplasty

| |
|---|
| **Extrinsic to the Hip** |
| Spine disease: stenosis, disc herniation, spondylolysis, or spondylolisthesis |
| Peripheral vascular disease |
| Complex regional pain syndrome |
| Psychologic disorder |
| Hernia (femoral, inguinal) |
| Peripheral nerve injury (eg, sciatic, femoral, meralgia paresthetica) |
| Malignancy or metastases |
| Metabolic bone disease (eg, Paget disease, osteomalacia) |
| **Intrinsic to the Hip** |
| Intracapsular/implant related |
| Infection |
| Loosening |
| Instability/subluxation |
| Periprosthetic fracture |
| Adverse soft tissue reaction/hypersensitivity |
| Extracapsular |
| Trochanteric bursitis |
| Iliopsoas tendonitis |

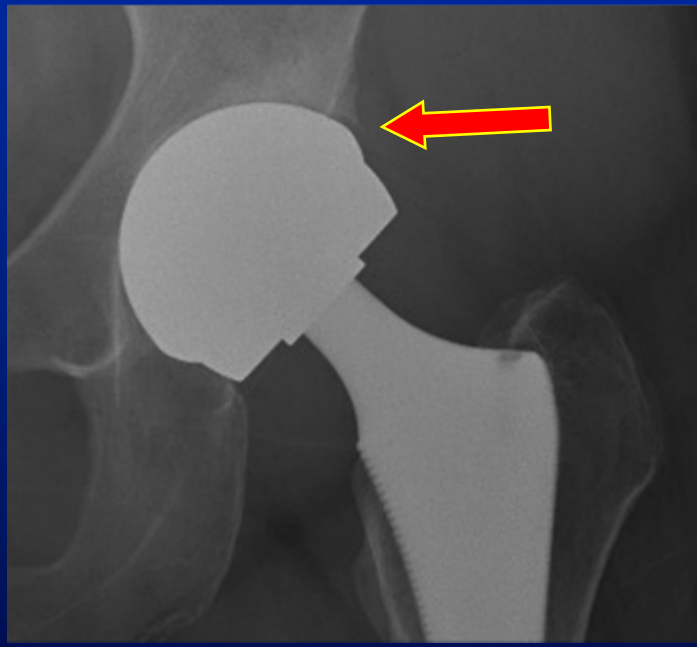
Kwon, Jacobs *et al*. JoA 2012

# How to Evaluate Painful MoM

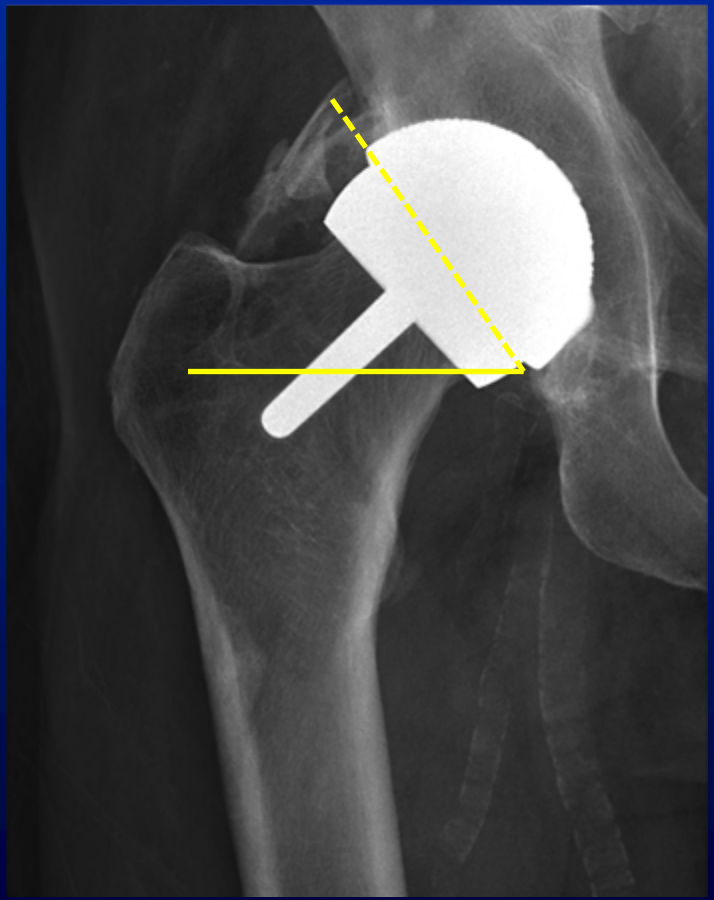
- Systematic Approach
- Clinical Hx and Physical Exam
- ESR/CRP/Joint Aspiration
- Cobalt and Chromium ion levels
- Imaging
  - Radiographs
  - CT
  - Ultrasound
  - MRI

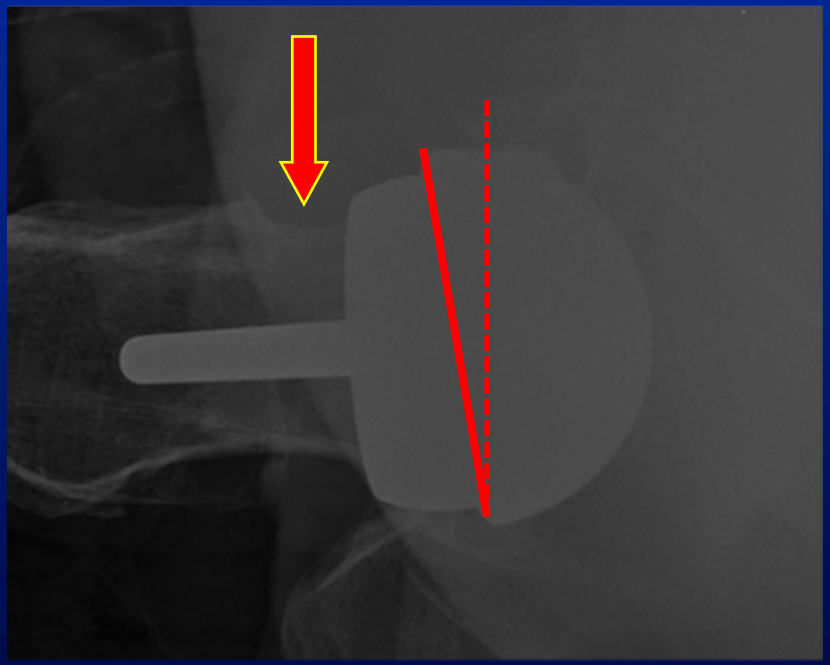
# Radiographs: Utility

- Serial films in 2 views
  - Identify implant class (modularity) and type
  - Implant positioning (correlates with wear)
  - Implant loosening
  - Osteolysis (Park JBJS 2005)
  - Fracture
- Information from XR often indicate the need for revision surgery



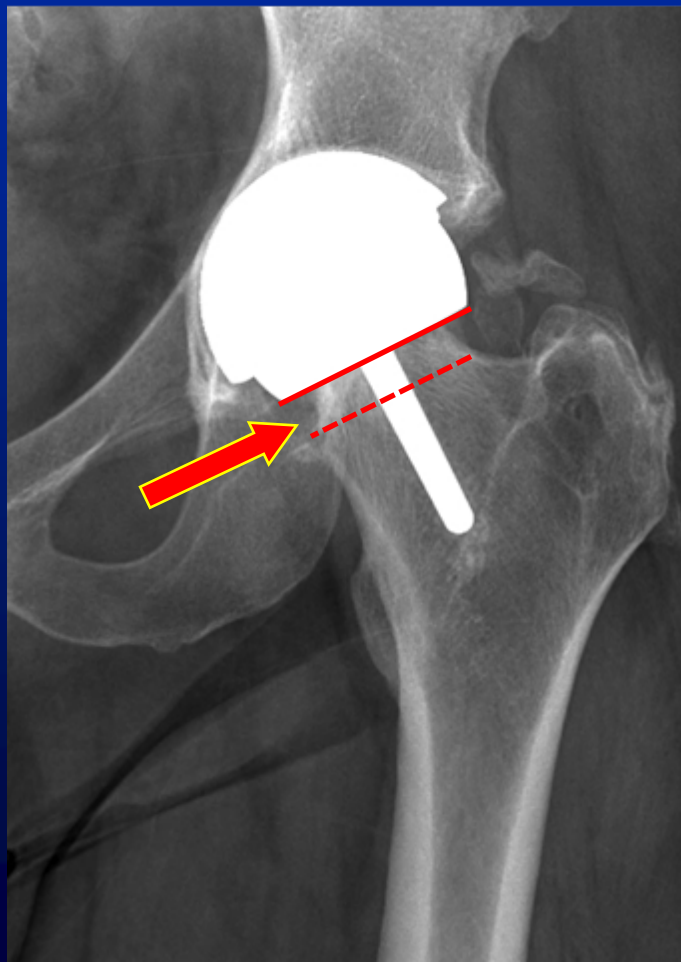
# Cup Orientation



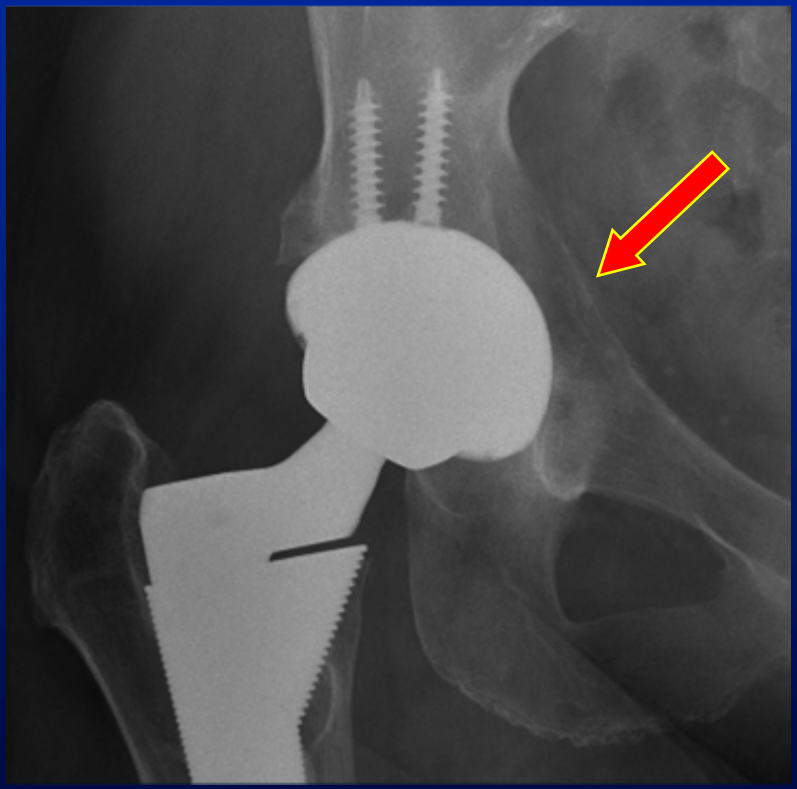


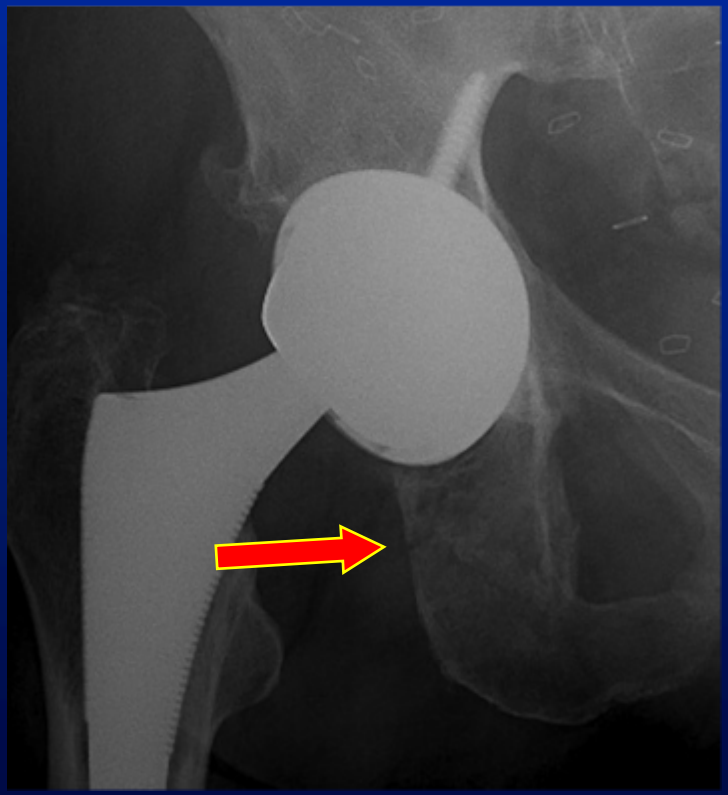
# Radiographs

- Femoral neck Narrowing
  - Common in asymptomatic (Hing *et al.* JBJS Br 2007)
  - Also associated with reactive mass (Grammatopoulos *et al.* JBJS Br 2010)



# Osteolysis



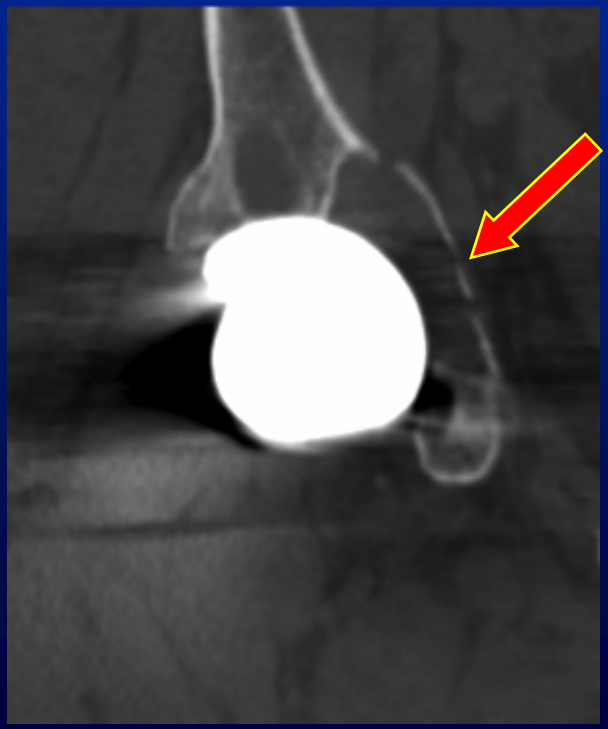


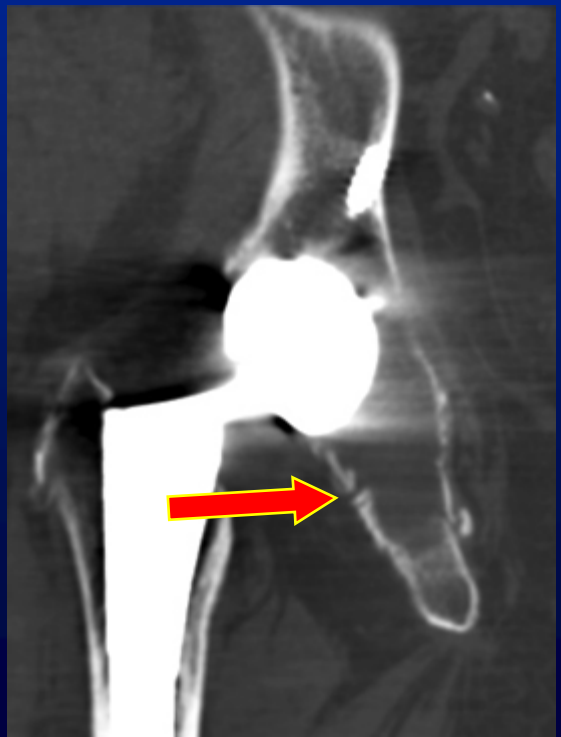
# Radiographs: Limitations

- Underestimate the presence and extent of osteolysis
- Failure to detect periprosthetic soft tissue complications

# Computed Tomography: Utility

- Useful in determining component alignment (3D)
- Provides bony details (osteolysis)





# CT: Limitations

- May delineate solid or cystic periprosthetic masses
- Relatively inferior soft tissue contrast
- Ionising radiation
- Bosker *et al.* Paper #303, AAOS 2012
  - Asymptomatic ‘Screened’ using CT
  - Prevalence 31%
  - No difference in clinical outcome scores

# Ultrasound: Utility

- Potential Advantages
  - Not affected by metal artifacts
  - Differentiate solid *vs.* cystic
  - Detects small lesions close to metal implants
  - Used to guide biopsy and injections (Iliopsoas injection and Hip joint aspiration)
  - No ionising radiation
  - Relative low costs
- Useful screenng tool

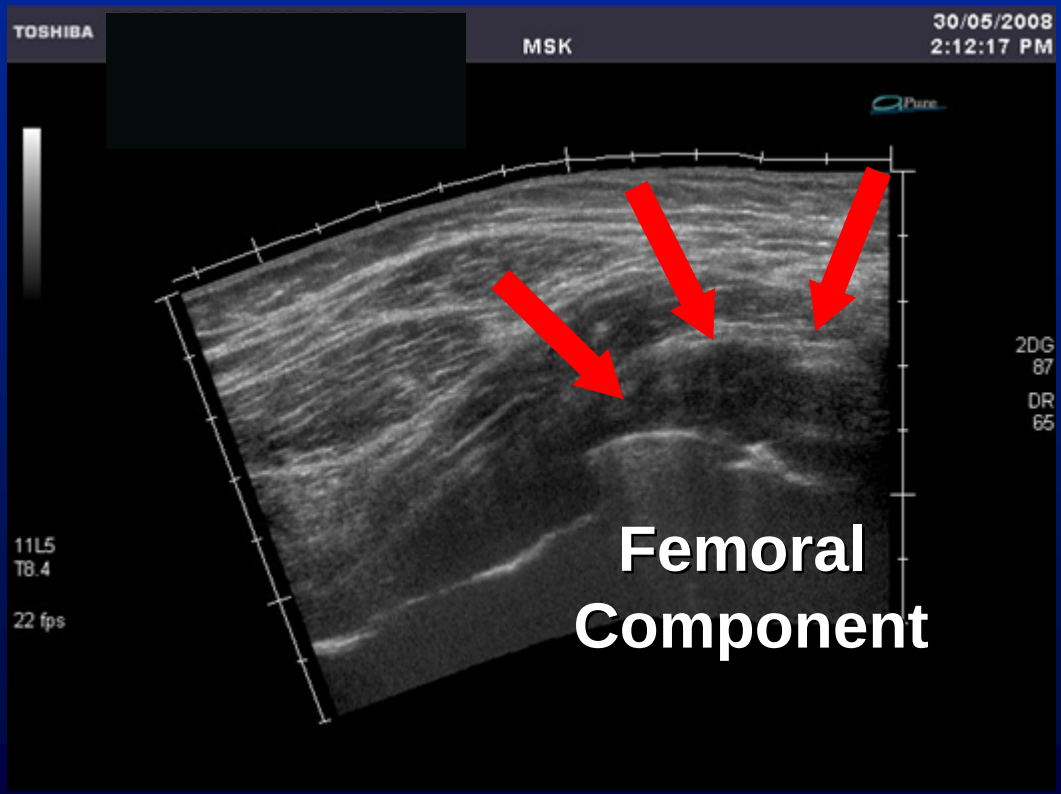
# US Screening of Pseudotumours

Kwon *et al*. JoA 2011

- N=201 consecutive MoMHRA
- Asymptomatic
- ‘Screened’ using US

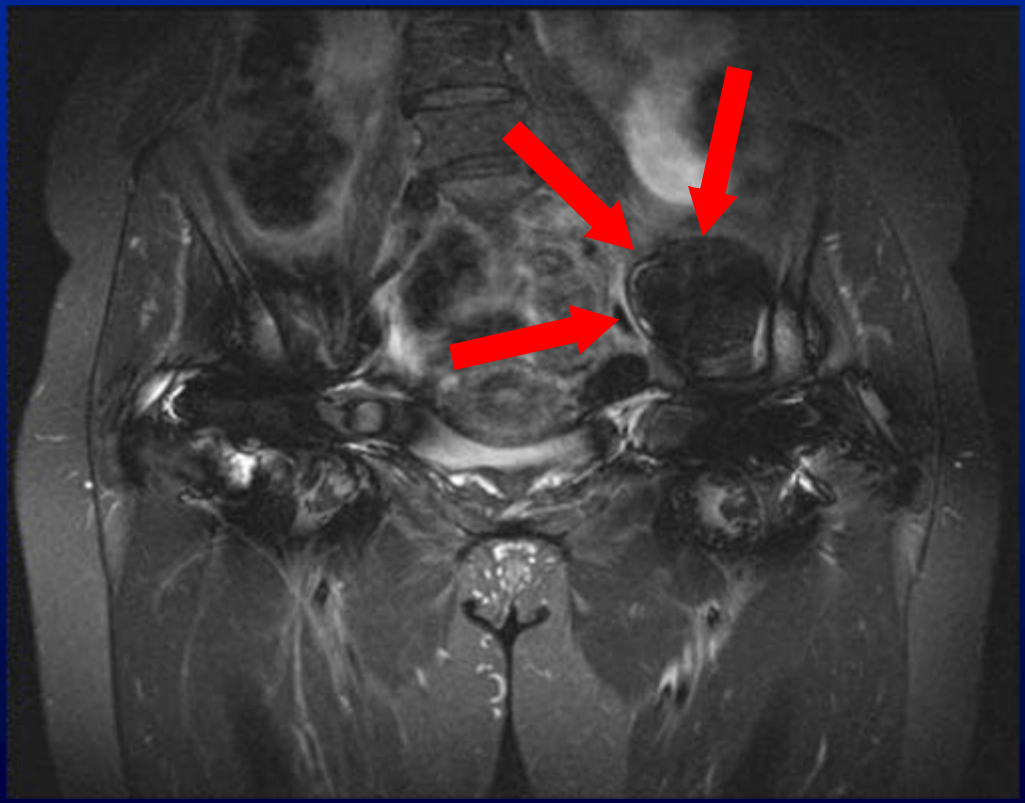
# Ultrasound

- Initial imaging modality



# MRI

- To assess the extent of identified masses



# ‘Asymptomatic’ Pseudotumours

- 4% Prevalence
  - 7 Patients (1M:6F) out of 158 patients
  - 6/7 Bilateral implants (1M:5F)
  - Both hips in 4/6
- Size ranges 2 × 1 × 2 cm to 8 × 7 × 8 cm

Kwon, Ostlere *et al*. JoA 2011

# US Screening of Pseudotumours

- Williams *et al*. JBJS Am 2012
  - N=73 Asymptomatic ‘Screened’ using US
  - Prevalence 27% MoM THA; 14% MoMHRA
- Nishi *et al*. JoA 2012
  - N=88 (46 HR + 42 Large head MoM THA)
  - 22% Abnormal Pattern
  - Associated with clinical symptoms

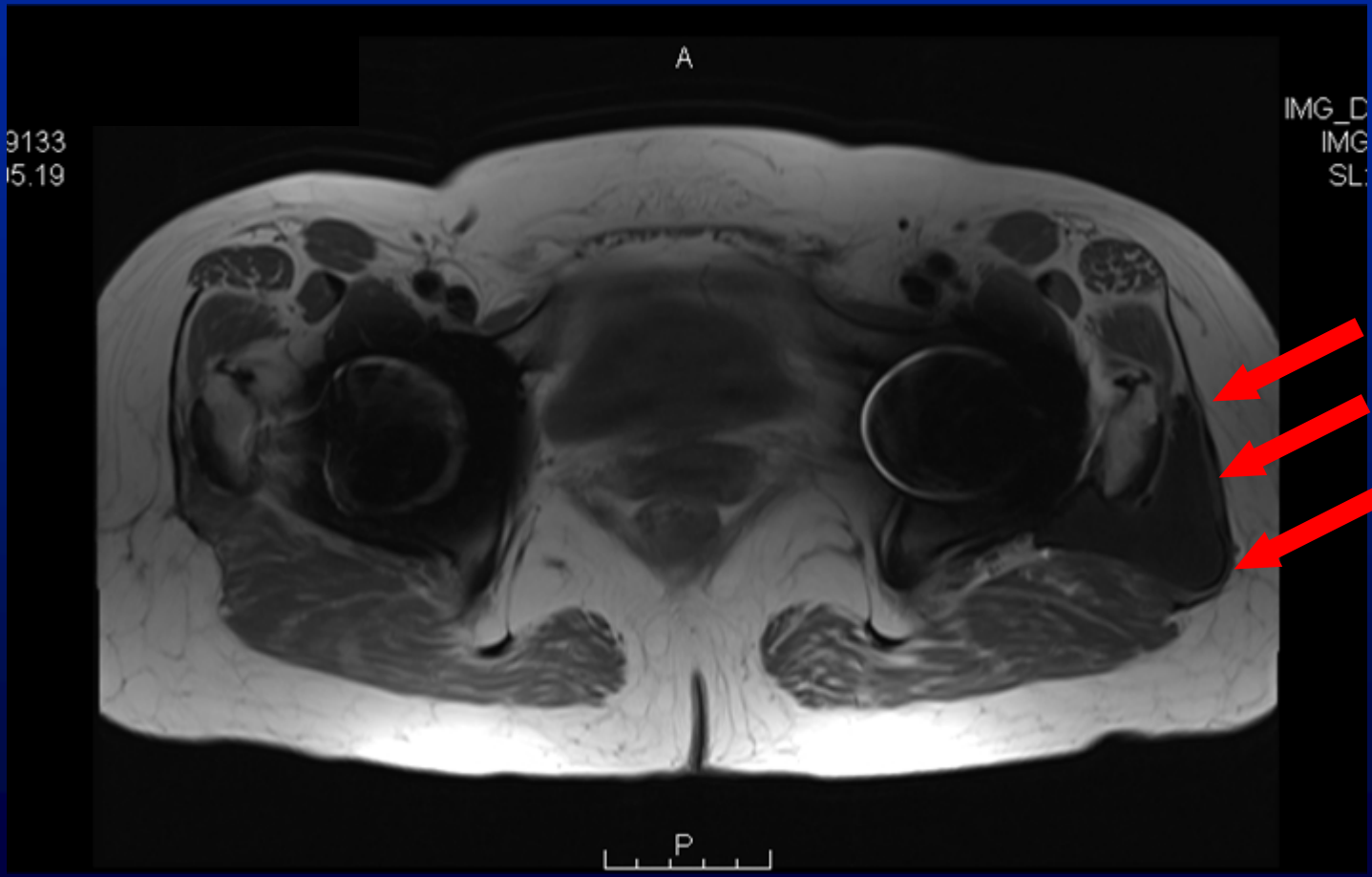
# Ultrasound: Limitations

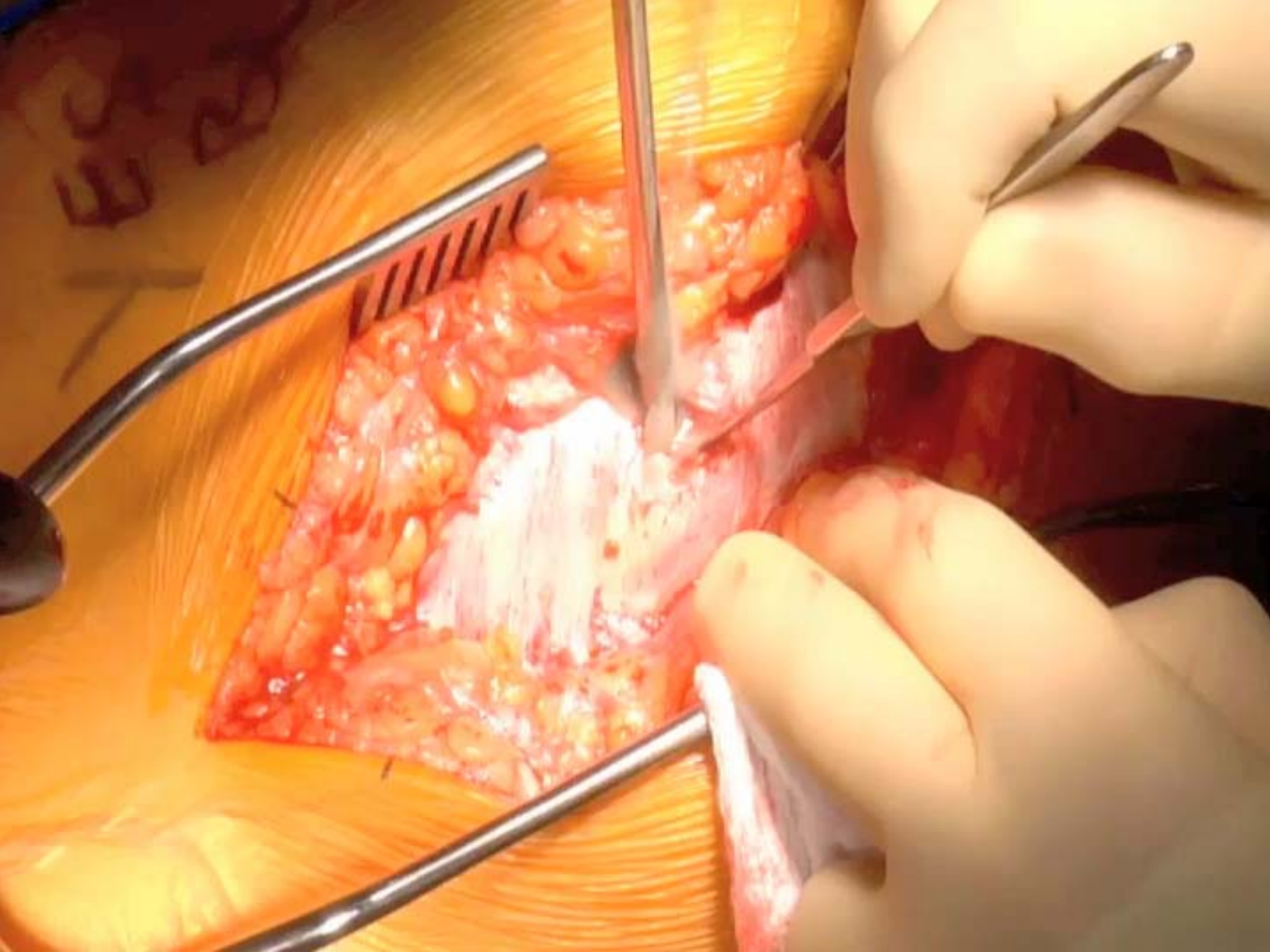
- Operator dependent
- Limited
  - Evaluating deep lesions
  - Defining anatomical extension
  - Evaluation of surrounding soft tissue envelope
  - Transmission based on patient factors

# MARS MRI

- **M**etal **A**rtifact **R**eduction **S**equence
  - Minimises metal artefact while maintaining image quality
- Image distortion reduction
  - Maximising bandwidth
  - View angle tilting
  - Fast or turbo spin echo pulse sequence
  - Avoid frequency selective fat suppression or gradient echo

# What Does It Look Like?





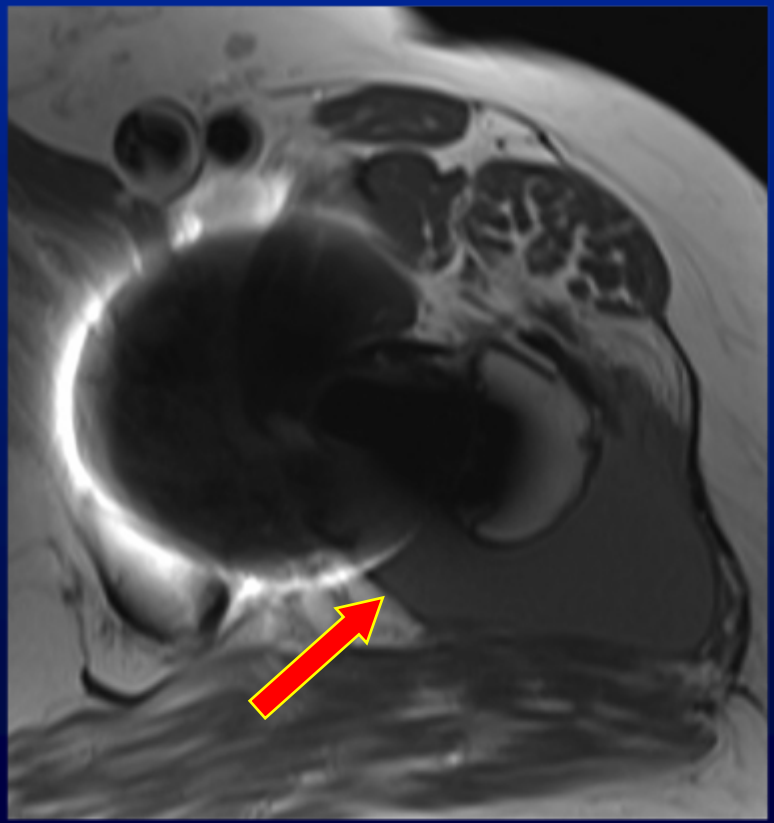
# MARS MRI: Utility

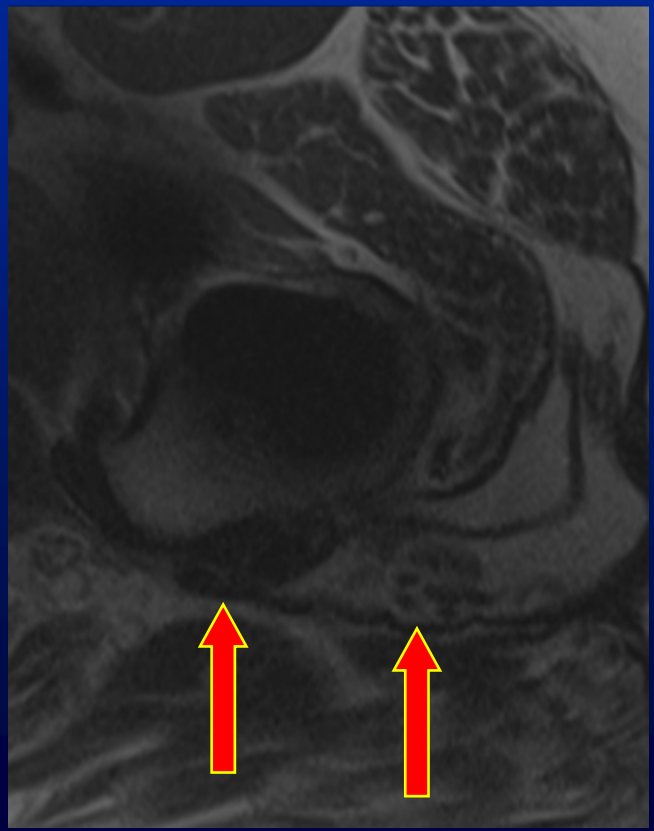
- Important cross-sectional imaging modality in detection of adverse local tissue reactions
  - Delineate anatomical extension of periprosthetic lesions
  - Detection of compression of juxtaposed neurovascular structures (important in pre-operative planning)
  - Evaluation of surrounding tissue envelope

Hayter *et al*. Orthop Clin N Am 2011

# MRI Anatomical Extension

- Reported as ‘Trochanteric Bursitis’ on US





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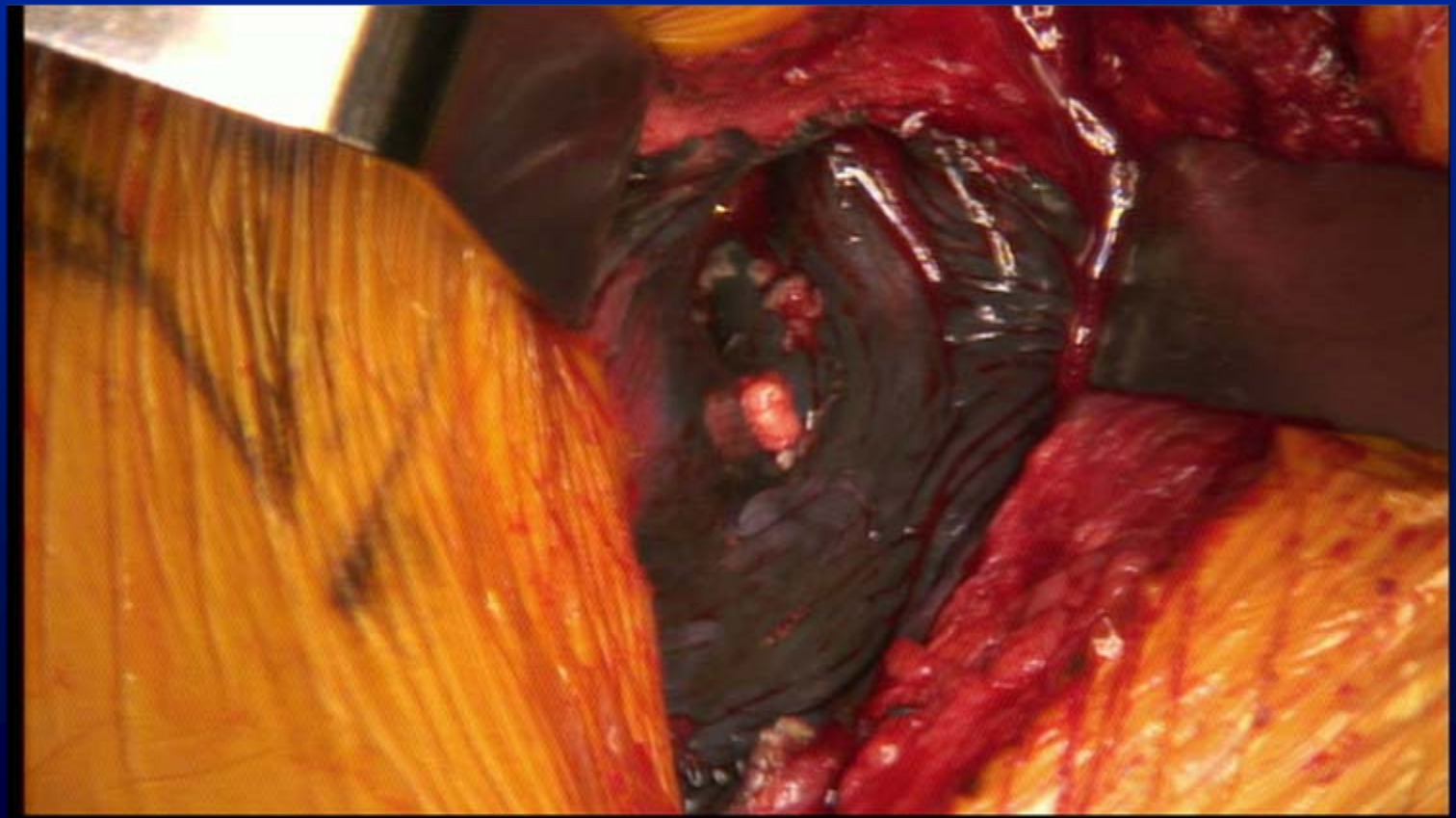
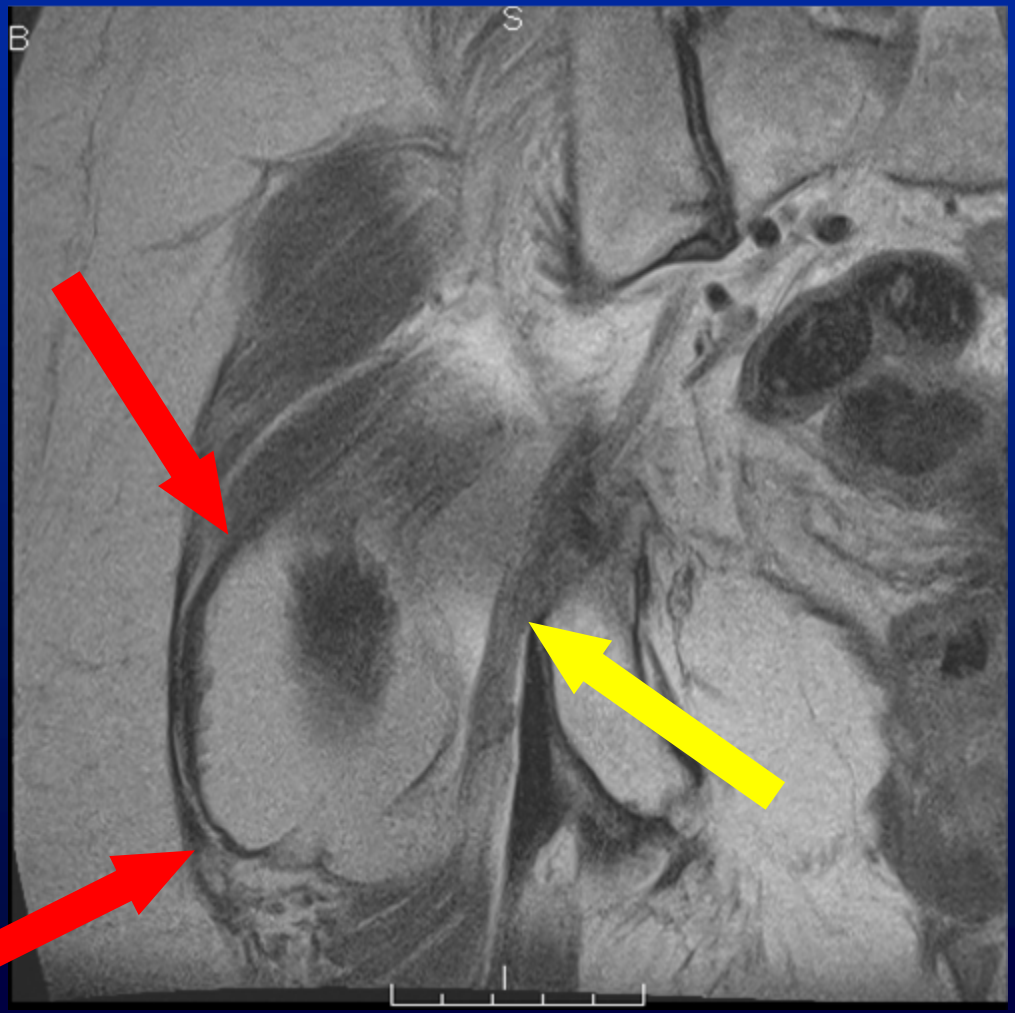
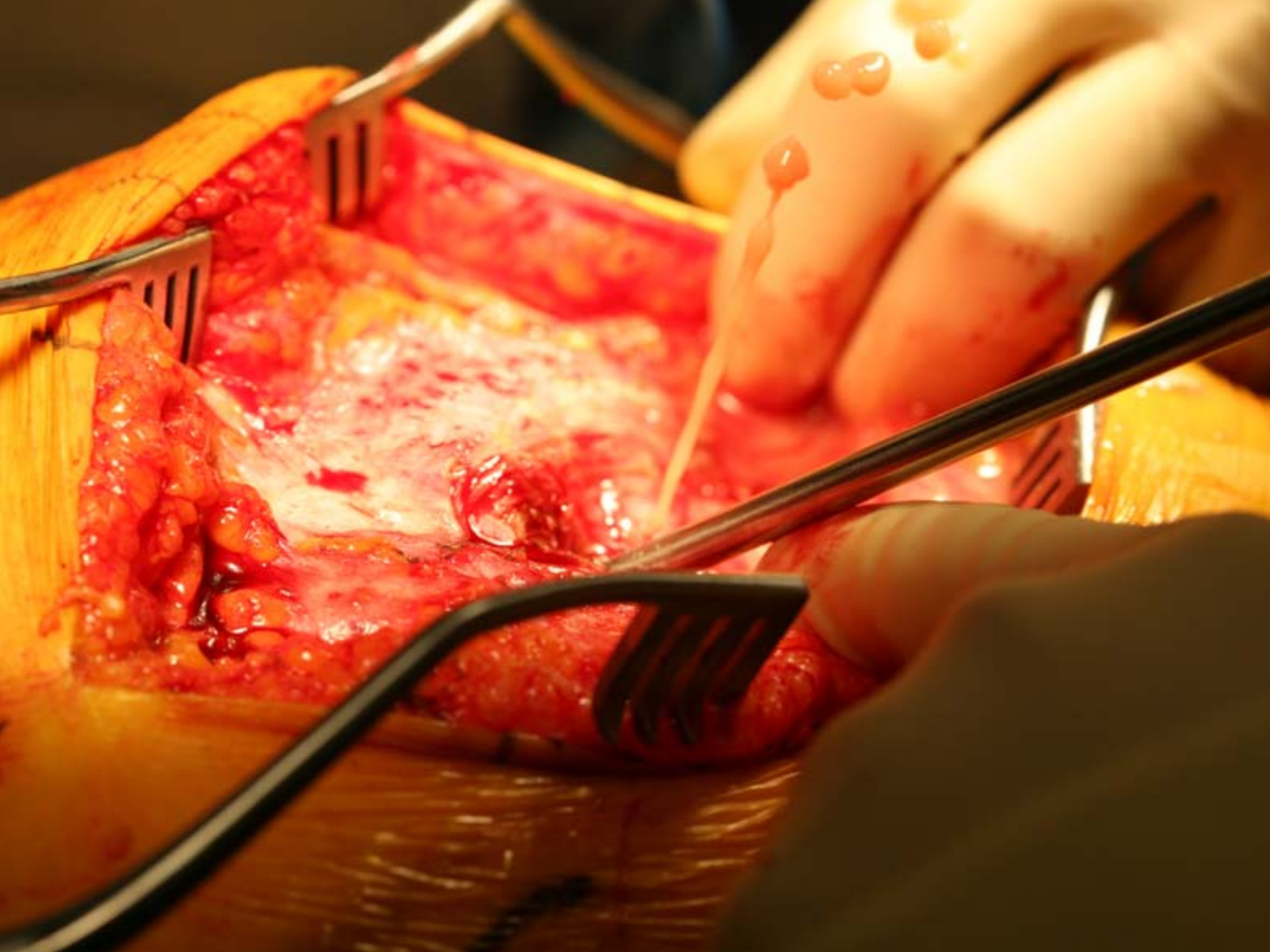
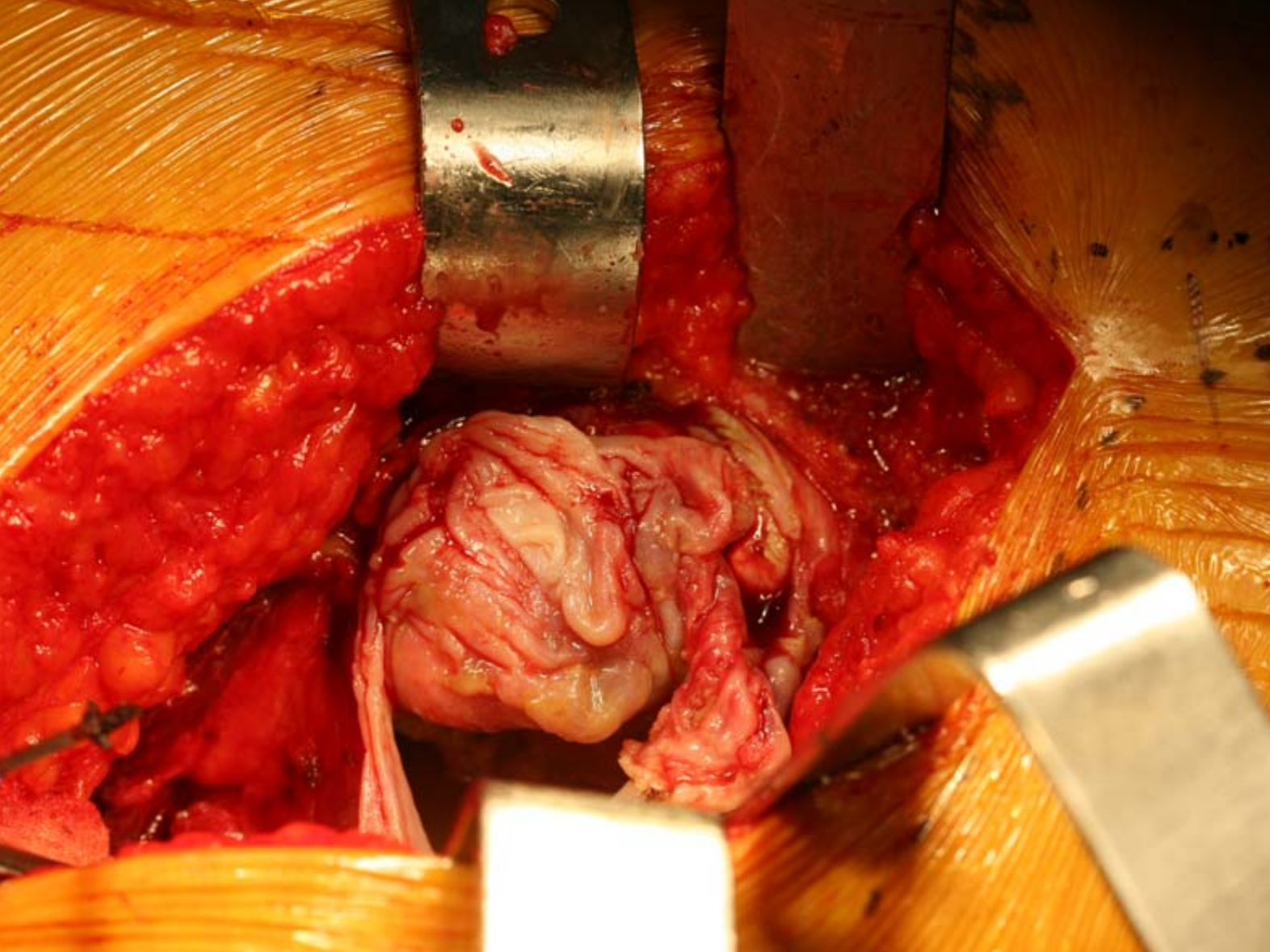


# MRI Neurovascular Structures







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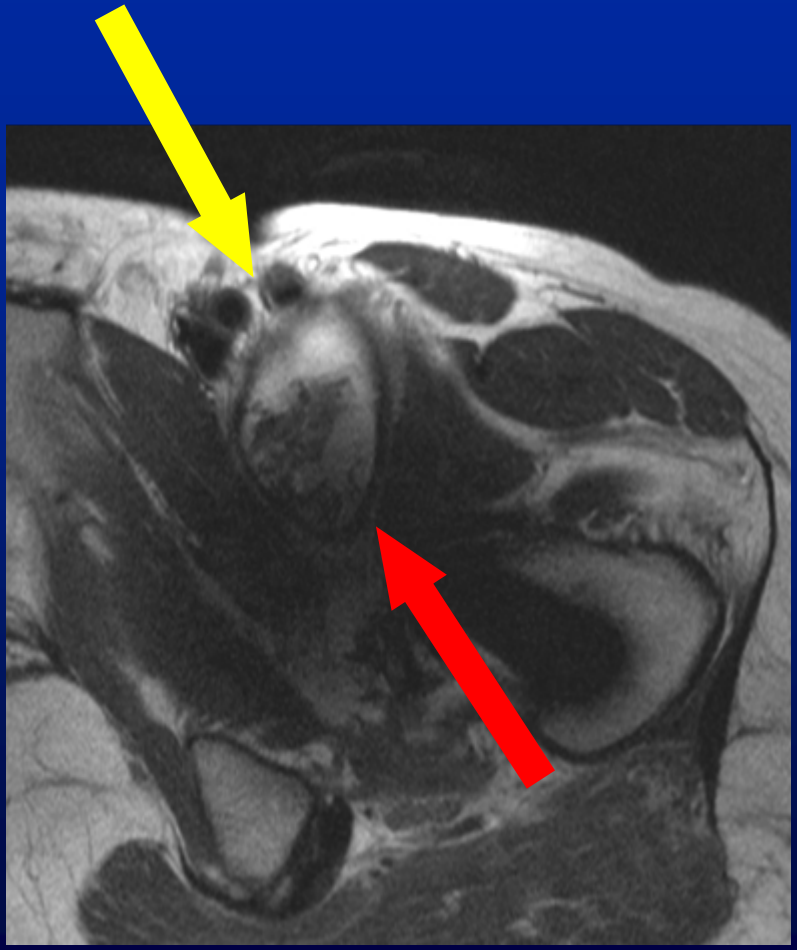
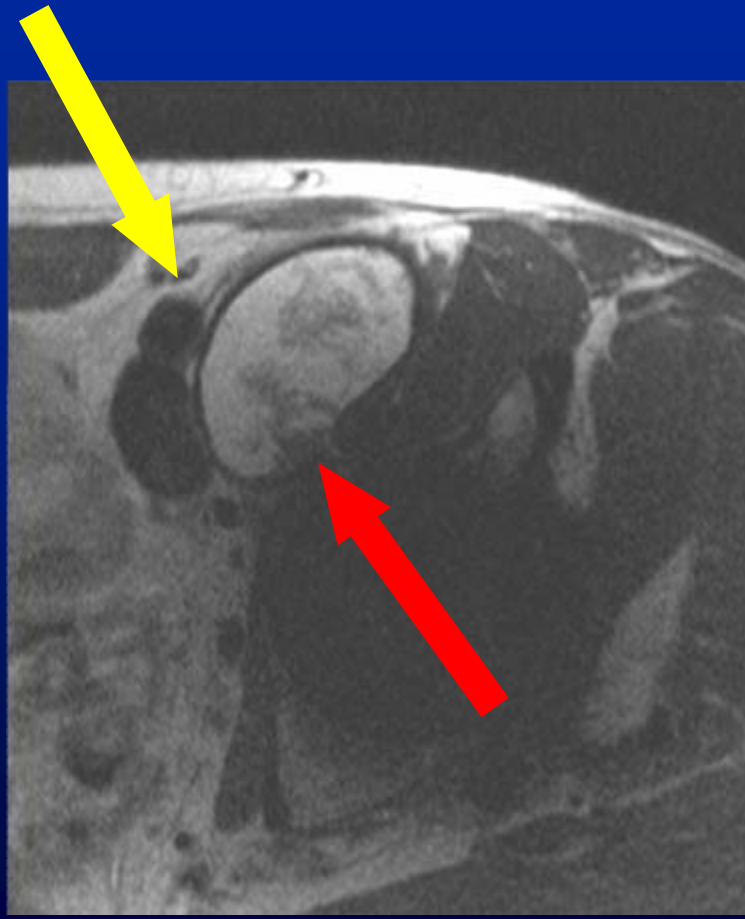
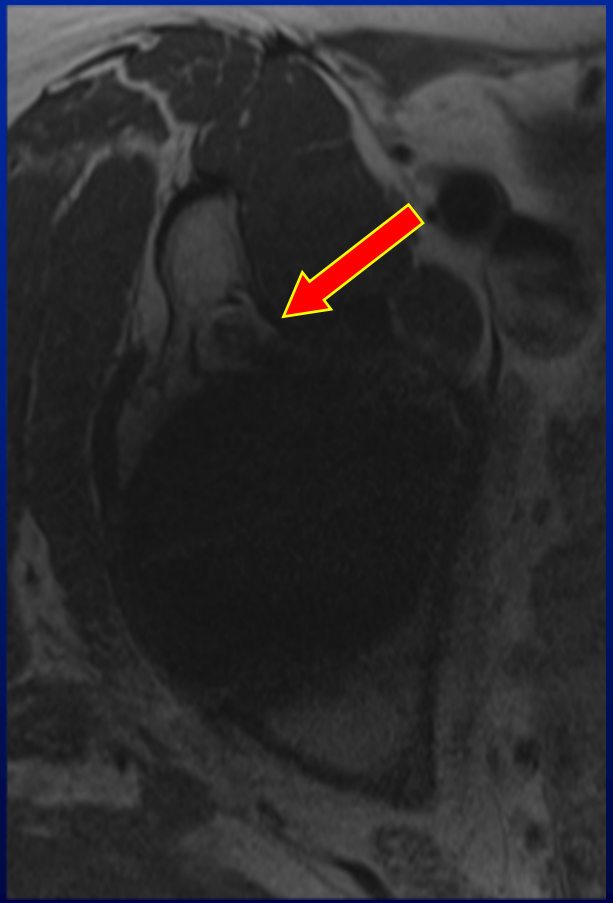




# MRI Neurovascular Structures

# MARS MRI: Utility

- Osteolysis
  - MRI accurate in detecting wear induced adverse synovial response predating osteolysis on radiographs (Potter *et al.* JBJS A 2004)
- Screening Asymptomatic (Wynn-Jones *et al.* Acta Orthop 2012)
  - N=77 Asymptomatic ASR
  - ‘Screened’ using MRI
  - Prevalence 31%



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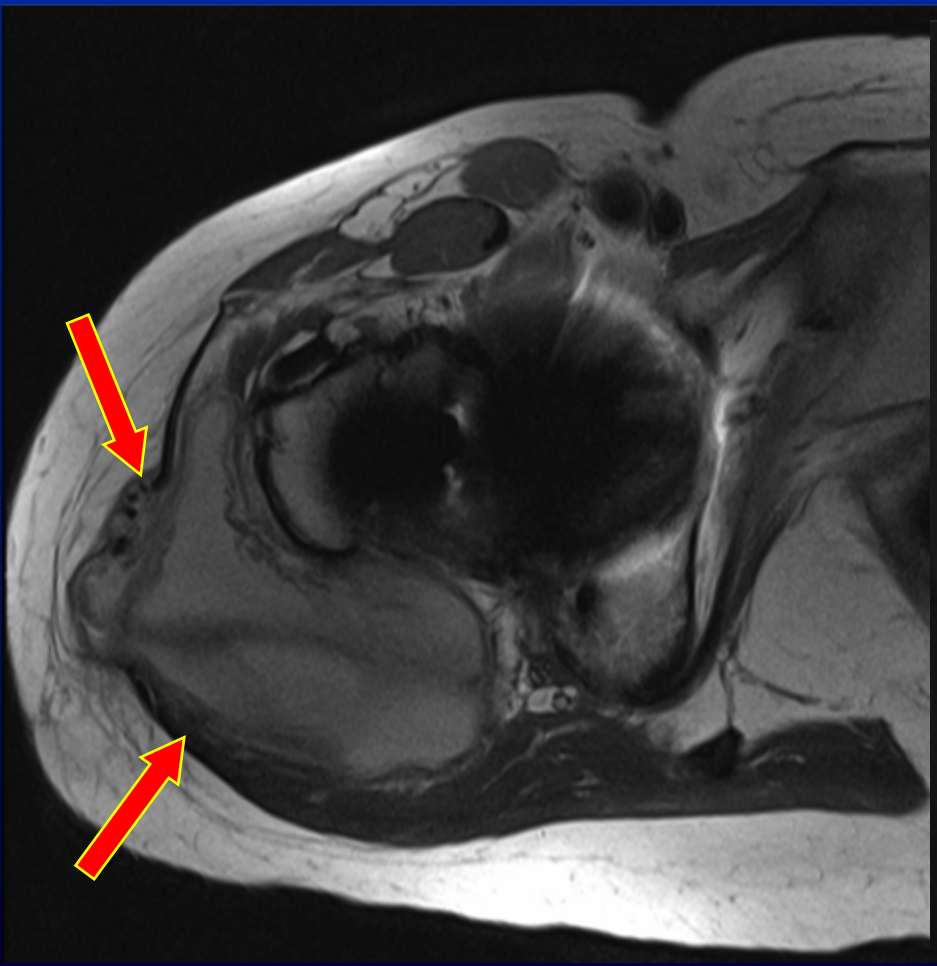

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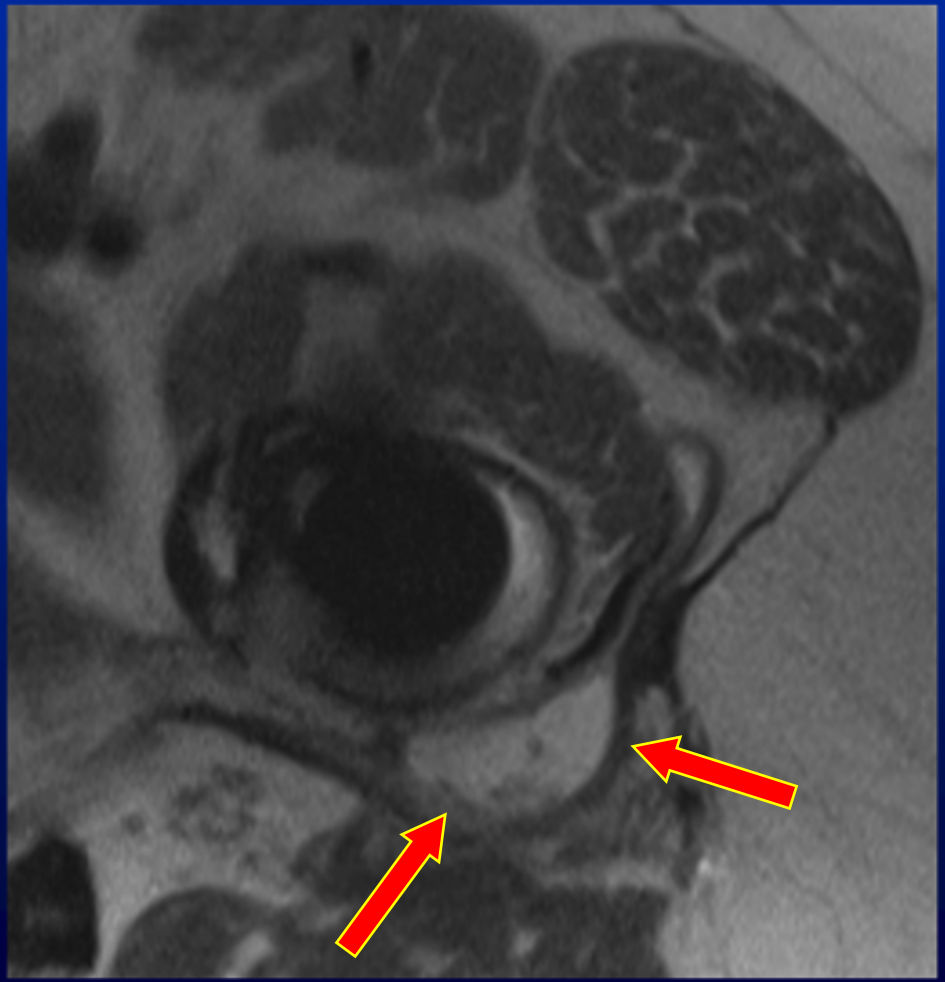

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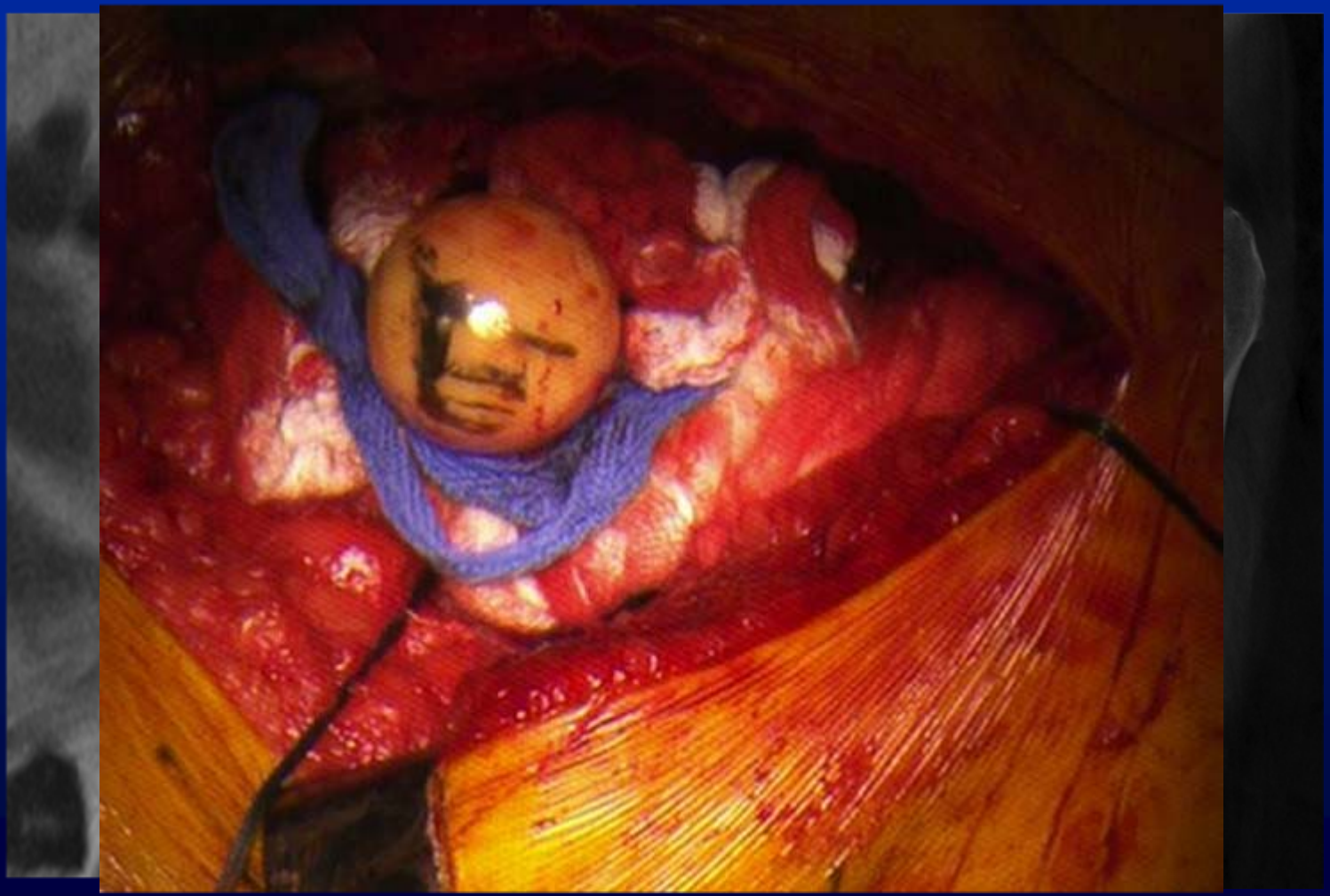

# MRI Classification

- Three Published
  - Anderson *et al.* Skeletal Radiol 2011 *(N=73)*
  - Hauptfleisch *et al.* Skeletal Radiol 2012 *(N=33)*
  - Hart *et al.* JBJS A 2012 *(N=58)*
- Classification based on
  - Lesion
    - Size (5cm), Consistency (solid vs. cyst), Position, Thickness of cyst wall (2-3mm)
  - Surrounding bone and muscle involvement

# MRI Classification

- High prevalence of abnormal findings
  - 65% graded as ‘soft tissue MoM disease’
  - 57% in symptomatic *vs.* 61% in asymptomatic
    - Cystic lesions
    - Equally prevalent in MoM patients with and without pain
- Characteristic signal intensity
  - Solid or Cyst wall low signal on fluid-sensitive sequences (T2 or STIR) relative to muscle

    (? metallic content)

# MRI Classification

- MRI ***not*** correlated to hip function
  - No correlation between the lesions and clinical symptoms
  - Consistency (solid) increases likelihood of revision surgery

# What We Already Know

- MARS MRI
  - Important cross-sectional imaging modality in detection of adverse local tissue reactions
  - Large Solid or thick cysts increases likelihood of revision
  - Involvement of surrounding muscle and bone poor prognosis

# What We Already Know

- Early and accurate diagnosis important as ‘late’ revision surgeries have poor outcome
- MoMHRA Revisions
  - 50% complications (dislocation, neurovascular injury)
  - 38% Re-revisions due to recurrence
- Pseudotumour revisions have poor outcome
- Recommend revision prior to significant tissue necrosis

Grammatopoulos, Kwon *et al.* JBJS Br 2009

# II. What We Do Not Know: Challenges

# What We Do Not Know

- Sensitivity and specificity
  - Ultrasound
  - MARS MRI
- ? Correlation between MRI classification features with
- Surgical operative findings, histological severity or clinical score
- ? Morphology *vs.* Necrosis

# What We Do Not Know

- Prognostic significance of identified lesions
  - ? Identify lesions leading to compromise of periprosthetic tissues
  - ? Small cysts without muscle and bone damage
- Symptomatic
  - ? MRI features predictive of progression
- Asymptomatic
  - ? Natural history

# III. What We Need to Know

Current Research

Future Focus

# What We Need to Know

- Maximise Clinical Utility of MRI
  - Optimisation of Imaging
    - New pulse sequence
    - Prototype Multiple Variable Resonance Image Combination (Hayter *et al.* AJR Am J Roen 2011)
  - Standardisation of Protocols
  - Standarisation of Reporting (Classification)
- Sensitivity and Specificity

# What We Need to Know

- Validation of MRI findings
  - Surgical operative findings
  - Histological severity
  - Clinical score
  - Retrieval analysis
  - Ongoing study (Potter *et al.* AAHKS Symposium 2011)
- Identify MRI ‘predictors’ of progression of lesion and/or symptoms
  - ? Volume ?Consistency ? Location

# What We Need to Know

- Prospective Longitudinal study to determine natural history
  - Asymptomatic
  - Mild Symptomatic
- Prevalence of adverse soft tissue reactions in other bearings (MoP and CoC)
- Multi-disciplinary approach to evaluate cost-effective imaging pathway

# Summary

- MoM Multiple modes of failure
  - Importance of comprehensive systematic evaluation
  - History, physical exam, ESR/CRP, XR
- Cross-sectional imaging an integral role
  - CT, US, MARS MRI
  - Each modality utility and limitations
- Avoid over-reliance on single diagnostic tool

# Summary

- Early and accurate diagnosis important
  - Late revision surgery poor outcome
- MARS MRI
  - Optimisation, standardisation and validation
  - Potential for early and accurate detection of adverse soft tissue reactions
  - Increasing role in clinical decision-making process
- Further longitudinal imaging study required to determine natural history


Thank You
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