MR Safety – Hybrid Environment: Intervventional and Intraoperative MR

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MRI Safety

<table>
<thead>
<tr>
<th>Source</th>
<th>Primary Safety Concern(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Static Magnetic Field (B₀ ~ Tesla)</td>
<td>Projected 'Projectile' hazards, Medical device displacement, damage or disruption, Transient bioeffects at high fields</td>
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<tr>
<td>Radiofrequency Field (B₁ ~ mT for ms at &gt; 32 MHz)</td>
<td>Tissue heating, Medical device heating, Medical device disruption, Interference with auxiliary equipment (i.e., patient monitoring)</td>
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<tr>
<td>Pulsed Gradient Magnetic Field (G ~ 50 mT/m with 250 ms rise times)</td>
<td>Peripheral nerve stimulation, Acoustic noise, Interference with auxiliary equipment, Bodily harm, Asphyxiation (oxygen displacement)</td>
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<tr>
<td>Cryogens (Liquid Helium @ 4K)</td>
<td>Nephrogenic systemic fibrosis (NSF)</td>
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What is different about the ioMRI & iMRI environments?

Why MRI for Image-Guided Intervention?

- US
- CT/Fluoroscopy
- MRI

Example MRI procedures:
- Intraoperative & endoscopic placement
- Biopsy & aspiration
- Implant/implantable device placement
- Local drug & stem cell delivery
- Vascular
- Arthroscopy (radiation, chemical, thermal)
**Why MRI for Image-Guided Intervention?**

- **Imaging for**
  - planning
  - targeting
  - monitoring/control
  - verification

- **Synergy with biological and physical modeling & simulation**

- **Endgame**
  - ‘close the loop’
  - increase procedure safety + efficacy
  - facilitate minimally invasive approaches previously not considered possible or safe

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**Example images from an MR-guided cryo-ablation procedure for renal cell carcinoma illustrating the ability to visualize and target the region for treatment as well as monitor progress of therapy and verify region of damage using changes in tissue perfusion.**

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**Planning:** T2-W FLAIR

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  - targeting
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**Verification:** T1+CE

**Model:** Arrhenius Damage

**Monitoring:** MR Temperature

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**Example:** MR-guided laser ablation of metastatic melanoma in brain.

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**Animal Model**

**Damage:**

**Temperature:**

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**Intraoperative vs Interventional paradigms**

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**Interventional:** Fast imaging for percutaneous procedure guidance. Access to patient is magnetic is helpful.

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**Intraop (BrainSUITE™):**

Extended anatomic imaging for stereotactic approaches. Geometric accuracy is critical.

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**Interventional (Angio-MR MIYABI):**

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**MR-guided biopsy of mixoid sarcoma:**

bSSFP + FS provides real-time imaging with T2-like contrast.

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**Core Biopsy:**

Fine needle aspiration

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**Intraoperative vs Interventional paradigms**

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**Interventional (Angio-MR MIYABI):**

Fast imaging for percutaneous procedure guidance. Access to patient is magnetic is helpful.
Intraoperative vs Interventional paradigms

Intraoperative: Extended anatomic imaging for stereotactic approaches. Geometric accuracy is critical.

1.5T MRI stereotaxy
Microscope
Pivoting O.R. table

Pre-Operative
Peri-Operative #2 => Post-Operative

Procedures:
- Craniotomy
- Laser Ablation
- Biopsy

MR-guided biopsy of mixoid sarcoma: bSSFP + FS provides real-time imaging with T2-like contrast.

Intraoperative vs Interventional paradigms

Interventional: Fast imaging for percutaneous procedure guidance. Access to patient in magnet is helpful.

Biopsies: renal, liver, MSK, prostate and breast
Cryoablation: renal, liver, bone

MRI Safety considerations begin during siting of the suite

- Suite often embedded in department outside diagnostic radiology (OR, IR, Cath lab, etc)
- Zoning & access considerations for patients and employees critical
  - Multi-room design? Where will procedures be performed?
- In-room workflow + instrumentation + storage
- Anesthesia + patient management
- Ancillary equipment in Zone 4
  - Procedure mix? Multi-modal? Integrated therapy devices?
- Emergent procedures

Expert Panel on MR Safety: Emanuel Kanal, MD,1,2 A. James Barkovich, MD,2
Charlene Bell, MD,1 James P. Borgsteede, MD,1 William G. Bradley Jr, MD, Ph.D,1
Larry W. Fruehan, MD,1,3 J. Fred Griesel, MD,1 John K. Gubitz, MD,1
Elliss Kohn-Kaminski, RT,1,4 Paul A. Larson, MD,3 James W. Looser Jr, MD,1,4
John Nyirjesy, PhD,1 Corinna Ose, RN, BSN,1 Elizabeth A. Sobek, RH, BSN,1
Jeffrey Weissert, MD,1,4 Bruce L. Wilmot, MD,1,4 Tony G. Woods, PhD,1,4
Leonard Lucey, JD,1,5 and Dan Heineman, BSEE

The principles listed above are not meant to imply that harsh guidelines are specifically intended to apply in every situation. Rather, they are intended to provide a management framework within which individual decisions can be guided by the various considerations, including those discussed in the guidance documents, institutional, and regulatory. Use MR equipment.

MR Site Safety Issues: Access Control & the 'Zone Defense'

- **Zone I**
  - Open access

- **Zone II**
  - Preparation and holding
  - May be partially within 5 G exclusion zone
  - Must be Level 1 or 2 to work in area unsupervised

- **Zone III**
  - May be partially within 5 G exclusion zone
  - Must be Level 1 or 2 to work in area unsupervised

- **Zone IV**
  - MR scan room
  - No admittance without documented training and screening
  - Level 2 supervision of non-MRI personnel
  - Access to any space contained in the 5 G (0.5 mT) fringe field (Zones I-III) have controlled access and appropriate signs posted
  - There can be no exceptions

Interventional MRI Suite

![Interventional MRI Suite Diagram]
Integrated MR Suites: Intraoperative

Single Room vs Multi-room

Integrated MR Suites: Interventional

Single Room vs Multi-room

Intraoperative MRI Suite

Technical Corridor

Main Entrance

Operator Console

Operator Access

No Dead Bolt

Zone III

Zone IV

Ax Real-Time bSSFP + FS (PA)

Ax Real-Time bSSFP + FS (Core)

MYXOID SARCOMA

Integrated MR Suites: Interventional

Single Room

vs

Multi-room

http://www.imris.com

BrainSUITE

IMRIS

Single Room vs Multi-room

http://xmr.ucsfmedicalcenter.org

Siemens MR-Fluoro Miyabi Suite

Philips XMR Suite

Interventional MRI: Magnet Designs

Examples of several lower field, "open" systems useful for interventions:

- 0.2T Siemens Magma
- 0.5T GE Signa SP
- 1.0T Philips Panorama
- 1.5T Siemens Espree

The trend toward high field systems for SNR advantage:
- Primary benefit is image quality & functional imaging
- Decreased access to patient in cylindrical bore

Compact length
Wide bore

=> Compact length
=> Wide bore
=> Stereotaxy and/or robotic assistance

Ancillary equipment and room integration considerations:

- Siemens Espree 1.5T Magnet
- VectorVision Sky and VectorVision Software Cranial
- Ziehs NC4 MultiVision with advanced integration
- OR Table with integrated headlamp and coil
- Automatic Image Registration
- BrainSUITE Data Billboard
- Digital Data Management and OR Device and Room Control System
- BrainSUITE RF Shielded OR Cabin
- Telemedicine

Note: 5G or higher accessible in Zone III

Access to any space contained in the 5 G (0.5 mT) fringe field
MUST have controlled access and appropriate signs posted
Ancillary equipment and room integration considerations

Need to address securing equipment in room, demarking regions of use and procedures for when-used, power management issues and assessing MR conditional status.

Instruments, needles, etc

Special procedure equipment

SeedNet™ mobile unit

Penetration panel & junction box

Junction box (to mobile unit)

SeedNet™ control unit (5 independent channels)

Cryoablation: Integrated Galil MRI SeedNet™

Communications: Optoacoustics IMROC™

Optical headset & switching unit

MRRC mixing console
Patient transfer from surgical arena into MRI arena

- Remove surgical instruments/sharps/sponges from table & count
- Remove ground patches, leads and/or electrodes from patient/arena
- Remove MR unsafe navigation instruments
- Prepare patient drapes
  - Nonmetallic ties, clothing, Ion clips
  - removed & sterile for transfer/transfer
- Prepare and drape patient field and area for transfer/transfer
- Anesthesia team
  - Remove laryngoscope handles, blades, stylet, nerve stimulator & count
  - Secure air & air, and monitoring lines
  - Position patient tubing, monitors, ventilators, etc, sterile
  - Position patient head, shoulders & neck, etc.
  - Patient positioning standards before (MRI is a time delay)
- Patient Hearing Protection
  - Position patient and RF suits for imaging
  - Management removal of conducting wires and skin-to-skin contacts
- Personnel MRI safety check
  - Nonmetallic or ear/ear, or MRI access during procedure
  - Patient check of personal items
- Ferromagnetic screening (if available)
- MRI time-out, visual check and audible + assess room readiness
  (if checklists strongly encouraged)

RF heating considerations

- From vendor safety manual:

  **WARNING**
  Exposure to RF electromagnetic fields in the Field Level Controlled Environment Risk

  Patient Burns
  - Do not examine patients with restricted thermoregulatory capability (e.g., small children, elderly, etc., or invasively patients).
  - Do not examine patients unable to communicate potential overheating effects (e.g., small children, unconscious, etc., patients, or patients, etc.
  - Carefully monitor the patient during the MRI examination.
  - Ensure that patients wear light clothing (e.g., light pajamas or nightgown).
  - Remove all additional insulation, e.g., blankets or coverings.

Geometric distortion is a safety issue in IoMRI and IMRI

- Acq. Matrix = 256 x 256, FOV = 450 mm, Slice Thickness = 1.75 mm, Pixel Bandwidth = 1300 Hz/pixel (i.e., minimized B0 effects)
- 24 cm + 24 cm corrected
- 2D & 3D T1 sag slice
- Corresponding 3D sag slice
- High BW Ax T2 = truth
- Lateral distance off isocenter on a 1.5T magnet
Geometric distortion is a safety issue in ioMRI and iMRI

Distortions primarily from:
- Non-linear gradients
- Field inhomogeneity ($B_0$)
- Higher resolution
- 3D vs 2D
- Higher rBW

For high resolution and high performance, an image-driven hardware and software solution is available.

Deep brain stimulation lead placement

MR-guided LITT: Intracerebral lesions

MR-guided LITT System

MRgLITT: Spine

- MRI guided placement of laser in epidural space
- Ablation of epidural tumor volume in region of compression
- Significant and rapid reduction in pain symptoms
- Mobile C-Arm brought into room for invasive fiducial placement


MRgLITT and the Medical Physicist

Magnetic Resonance-guided Laser Interstitial Thermal Therapy (MRgLITT) Devices: Letter to Healthcare Providers - Risk of Tissue Overheating Due to Inaccurate Magnetic Resonance Thermometry

FDA (Posted 06/15/2014)

Monteris Medical NeuroBlate System Recalled Due to Unexpected Heating of Laser Delivery Probes

FDA (08/04/2017)

The ioMRI/IbMRI physicist can provide expertise in both protocol and device safety to minimize risks of these procedures.

Personnel training and screening in IoMRI and ImRI suites

- MR Screening for employees
  - RN circulators, scrub personnel, housekeeping, surgeons, anesthesia
- MR Safety training (annually)
  - Level 1 versus Level 2 training
- Suite Orientations
  - Emergency procedure and patient transfer
  - Equipment operation and safety interlocks
- Procedure Orientations
  - Standard operating procedures/checklists
  - Special equipment, monitoring, etc.
  - Dry runs for new procedures
  - Observations/supervision of new staff
- Access control and core MR procedure group supervision
Additional policy and procedural considerations

• Policy considerations
  – dress codes (scrubs only, no pockets, etc)
  – no metal (pens, jewelry, watches, change, phones, etc)
  – personal item storage

• Inventory & Stocking
  – MR conditional equipment for in-bore procedures
  – Storage locations

• Emergent procedure outlined, practiced & table weight limits established

• Pre-procedural room preparation procedure

• Periprocedural instrument management

• Post-procedural room cleaning procedure

Summary

• MRI use in intraoperative and interventional environments is expanding

• Systems often in a non-diagnostic area with many traditionally non-MRI personnel involved

• Procedures can be complex and involve both MR conditional and MR unsafe devices and instrumentation in the suite

• Risk to staff and patient from missile effects and acoustic noise as well as heightened concern over patient SAR management

• A small, highly trained team with clearly written and periodically reviewed policies and procedures is essential to both safety and long term success
References


Thank you for your time!

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