Advances in Pacemakers and ICDs: MRI Compatible Devices

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Disclosures

• Biosense Webster: Consulting, Speaker’s Honorarium

• Biotronik: Consulting, Speaker’s Honorarium
CAUTION
PACEMAKER PATIENTS - MICROWAVE OVEN IN USE
Background

- MRI is the reference standard and imaging modality of choice for imaging in many fields of medicine.

- Strong static, gradient and radiofrequency fields used to generate MR images may be detrimental to devices and potentially cause harm to patients.

- Recently, pacemakers specifically designed and tested for the MRI environment have been shown to be safe under certain conditions.
Need for MRI Technology

• MRI is the preferred imaging option for brain injuries, stroke, cancer, orthopedic issues, and many others.
• MRI usage is highest in the 55 - 80 age group, which includes patients more likely to receive a cardiac device.

¹
CT vs MRI

**CT**
- Better for bony tissue
- Uses ionizing radiation (x-ray dose is cumulative)
- Contrast (if used)
- Equipment costs less

**MRI**
- Superior for **soft tissue**
- Uses magnetic energy and RF
- Contrast (if used) has low risk
- Can be confining, noisy, scary
- High capital costs
MRI Terminology

• Tesla
  – Measure of magnetic field strength
  – 70% of all MRI scanners are 1.5T

• Specific Absorption Rate (SAR)
  – Rate of RF energy absorption by a pt’s body
  – Measured in watts/kg
MRI Scan Area

- The isocenter is used to position the patient in the MRI scanner (eye level or hips)
- The Field of View around the isocenter includes the tissue which can be scanned
- The Field of View varies per MRI manufacturer and model

88% of MRI scans are within field of view
MRI Scan Area

Example of MRI scan with isocenter on eye level

Real patient case with isocenter on eye level and Siemens MRI scanner. Patient length 5 feet 8 inches and scan taken within the ProMRI conditions.
Example of MRI scan with isocenter on hip level

Lower lumbar spine can be examined

Real patient case with isocenter on hip level and Siemens MRI scanner.
Patient length 5 feet 8 inches and scan taken according the ProMRI conditions.
What could go wrong?
Real Device Problems with MRI

A 2-second pause was noted...

...diminished battery voltage was noted immediately after MRI...

Significant changes were reported in 9.4% of leads... 1.9% required a change in programmed output.

...increased capture threshold was noted post MRI.
Forces Applied by MRI Could Affect Device Systems

Static magnetic field
Possible movement of device or lead

Combined field effects
- Mechanical vibration forces
- Electronic device reset

Radio frequency field
Possible damage of cardiac tissue due to heating at electrode tip

Gradient magnetic field
Possible pro-arrhythmic behavior as a result of induced voltages through leads creating over- and undersensing

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Forces Applied by MRI Could Affect Device Systems

MRI: Three Powerful Fields

Powerful electromagnetic fields

Static Field
- 30,000x Earth’s magnetic field

Gradient Field
- Creates loud scanner noise

Radio Frequency (RF) Field
- 1000’s of watts peak power
<table>
<thead>
<tr>
<th></th>
<th>Static</th>
<th>Gradient</th>
<th>RF</th>
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</thead>
<tbody>
<tr>
<td>Case Heating</td>
<td></td>
<td></td>
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<tr>
<td>Force &amp; Torque</td>
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<tr>
<td>Vibration</td>
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<td></td>
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<tr>
<td>Device Interactions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stimulation</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Lead Heating</td>
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Forces Applied by MRI Could Affect Device Systems
Mitigate MRI Risk

STEP BACK PLEASE
we're trying to fix this
Mitigate MRI Risk

• ProMRI® and SureScan® solution
  – Designed without ferromagnetic components
  – Lead design
  – MRI programming mode
  – MRI scan exclusion zone
Mitigate MRI Risk

- MRI testing challenge
  - Filter out 64 MHz energy emitted by 1.5 T scanners
  - Heating at lead tip is the most challenging hazard
    - Leads act as an antenna, converting energy into heat
    - Lead tip is highest risk because it has the smallest area and direct tissue contact
  - Many inter-related factors influence the potential risk of lead tip heating
Pacemaker Design Solutions

- Minimize ferromagnetic content
- Isolated circuit board
- Hall sensor
- Optimize input circuitry
- Circuit component change

Unintended cardiac stimulation
Mitigate MRI Risk

Lead Heating - Design Solution

- Lead inner conductor coil design mitigates lead heating
- 4 filars to 2 filars increases inductance and reduces heating
Mitigate MRI Risk

5086 MRI Lead Performance & Reliability

- 5076 Lead Survivability, 99% @ 8 years*
- Materials identical to 5076**
- 5086 MRI lead flex testing
  - Connector / body
  - Lead body
  - Tip / body - 10 year equivalent
- 5086 MRI clinical implant experience starting Feb 2007 (928 leads implanted)

*Medtronic Product Performance Report - 2009 Issue 2
**Exception of MRI Marker band and electrode coating
Mitigate MRI Risk

BIOTRONIK leads designed for MRI:

- Maximized inductance of conductor coil
  - Diameter and coil pitch are optimized
  - Capacitive coupling of cable
    - Correct proximity to conductor
- Thousands of measurements are performed to make sure multiple lead device combinations are covered
  - Various lead lengths and positions
  - Lead wrapping around device
  - Different implant sites
Data

“I don’t trust those newfangled, battery-powered pacemakers.”
Medtronic Advisa
Medtronic Data

Advisa MRI Clinical Trial confirms safety in MRI environment

Objectives:
- Prospective, randomized controlled, multi-center/263 patients
- Designed to confirm safety and effectiveness of the Advisa MRI SureScan Pacing System

Results:
- Similar pacing capture thresholds changes between MRI and control groups
- No MRI related complications

1 Medtronic, Inc. Advisa MRI SureScan Pacing System clinical report, in support of FDA premarket approval.
SureScan is supported by extensive evidence and experience

- Industry proprietary computer model evaluated more than 400,000 scenarios\(^1\)
- Over 2,600 patients studied in three prospective clinical studies\(^2-4\)
- Available internationally for more than four years with over 100,000 SureScan devices sold\(^5\)
- 10% SureScan patients scanned at 18 months post-implant in the United States\(^6\)

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\(^3\) Medtronic, Inc. Advisa MRI SureScan Pacing System clinical report, in support of FDA premarket approval.

\(^4\) Clinicaltrials.gov NCT01299675.


Biotronik Entovis
Pro-MRI Phase A

Atrial Threshold

Ventricular Threshold

Atrial Sensing

Ventricular Sensing

% Amplitude Change (1 Month/Pre-MRI)

1-Month Sensing Amplitude (mV)
Phase B Results

Five primary endpoints were evaluated to establish safety and efficacy of the ProMRI system:

**Primary Endpoint 1: SADE Free Rate**

- A rejection of the null hypothesis would demonstrate that there is evidence that the SADE-free rate at 1 month post-MRI is greater than 90%
  - One SADEs was adjudicated as related or possibly related to both the implanted pacing system and the MRI procedure resulting in an SADE-free rate of 99.5% (202/203), \( p < 0.001 \), 95% CI: (97.3%, 100.0%)
Phase B Results

Primary Endpoint 2: Atrial Pacing Threshold

The null hypothesis is rejected and Primary Endpoint 2 is met.

Results

N=178

Difference in atrial pacing threshold (V)

Mean $±$ SD

Range

0.00 $±$ 0.12

-0.7, 0.4

Proportion of subjects with atrial pacing threshold success

178 (100.0%)

P < 0.001, (97.9%, 100.0%)

Primary Endpoint 3: Ventricular Pacing Threshold

The null hypothesis is rejected and Primary Endpoint 3 is met.

Results

N=189

Difference in ventricular pacing threshold (V)

Mean $±$ SD

Range

0.01 $±$ 0.10

-0.2, 0.3

Proportion of subjects with ventricular pacing threshold success

189 (100%)

P < 0.001, (98.1%, 100.0%)

Primary Endpoint 4: P-wave Sensing Attenuation

The null hypothesis is rejected and Primary Endpoint 4 is met.

Results

N=157

Difference in P-wave sensing amplitude between 1-Month post-MRI and pre-MRI (mV)

Mean $±$ SD

Range

-0.21 $±$ 0.89

-2.7, 2.8

Proportion of subjects with attenuation-free P-wave sensing

154 (98.1%)

P < 0.001, (94.5%, 99.6%)

Primary Endpoint 5: R-wave Sensing Attenuation

The null hypothesis is rejected and Primary Endpoint 5 is met.

Results

N=173

Difference in R-wave sensing amplitude between 1-Month post-MRI and pre-MRI (mV)

Mean $±$ SD

Range

-0.26 $±$ 1.37

-6.1, 4.5

Proportion of subjects with attenuation-free R-wave sensing

173 (100.0%)

P < 0.001, (97.9%, 100.0%)

Atrial Threshold

Atrial Sensing

Ventricular Threshold

Ventricular Sensing
Conditions for MRI

"Don't worry, I gotcha..."
MRI Conditions for Advisa

System Requirements for MRI

• A complete SureScan pacing system including a Revo MRI SureScan pacemaker and two SureScan leads is required for use in the MRI environment.
  – Any other combination may result in a hazard to the patient during an MRI scan.

• The SureScan feature must be programmed to On prior to scanning a patient according to the specified conditions of use.

Conditions for Use: Radiology Requirements

• Horizontal cylindrical bore magnet, clinical MRI systems with a static magnetic field of 1.5 Tesla (T) must be used.
• Gradient systems with maximum gradient slew rate performance per axis of ≤ 200 Tesla per meter per second (T/m/s) must be used.
• The scanner must be operated in Normal Operating Mode:
  - The whole body averaged SAR must be ≤ 2.0 watts per kilogram (W/kg).
  - The head SAR must be < 3.2 W/kg.
MR Conditions for Entovis ProMRI®

- Entovis device and Setrox S 53 cm or 60 cm lead for 6 weeks
- There are no other implants in the patient’s body
- The lead-tissue interface is stable
- The system is operating normally
- The specific device programming for the MRI scan has been performed
- The MRI is performed in a standard 1.5 Tesla, closed bore scanner in the normal operating mode
- Mean slew rate is less than or equal to 200 T/m/s
MRI and ICD’s
## Pro-MRI Trial

<table>
<thead>
<tr>
<th></th>
<th>Phase A Pacemaker (Scan Exclusion Zone)</th>
<th>Phase B Pacemaker (No Scan Exclusion Zone)</th>
<th>Phase C ICD (No Scan Exclusion Zone)</th>
</tr>
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<tbody>
<tr>
<td>First Enrollment</td>
<td>March 2013</td>
<td>December 2013</td>
<td>May 2014</td>
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<tr>
<td>Enrollment/Follow-up Status</td>
<td>Closed to Enrollment and Follow-up</td>
<td>Closed to enrollment an follow-up. Submitted to FDA</td>
<td>Closed to enrollment. Follow-up ongoing</td>
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<td>Estimated Completion</td>
<td>FDA Approval May 4, 2014</td>
<td>FDA Approval March 15, 2015</td>
<td>Q1 2015</td>
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</table>
Investigational Sites

25 centers

12 centers
Phase C Study Design

- Baseline Evaluation
  - 1. Pre-MRI procedure
  - 2. MRI scanning procedure*
  - 3. Post-MRI procedure
  - Performed on the same day
  - Observation via Home Monitoring

- 1-Month follow-up

- 3-Month Follow-up

*Not earlier than 7 days after enrollment and not later than 2 months after enrollment/baseline evaluation
Device implanted for at least 6 weeks
Risks associated with failing to program a subject to MRI mode:

- Device may sense EMI by MRI and trigger an inappropriate shock
- Noise from MRI may cause battery drain, resulting in the EOS voltage of 1.75 V
- Wires inside the device may heat and cause damage to internal components, causing the device to become uninterrogatable
What does the future hold?

3T MRI with exclusion zones for PM and ICD

1.5T MRI without exclusion zones for PM and ICD

1.5T MRI with exclusion zone for BiV ICD and PM