MR SCANNING OF COMPLEX ACTIVE IMPLANTS: UNREIMBURSED WORK AND A BARRIER TO ACCESS
What is a “complex” active implant?

• Active implant: implant with its own power source
  • Example: pacemakers and bladder stimulators

• “Complex” active implant: non-standard term we use to denote active implants with on-label scanning criteria more restrictive than *Normal Mode and unlimited duration
  • Example: many deep brain stimulators

• Loop Recorder (Not a Complex Active Implant)
  • The Whole Body Specific Absorption Rate (WB-SAR) as reported by the MRI equipment must be ≤4.0 W/kg; the head SAR as reported by the MRI equipment must be ≤3.2 W/kg.

• Neuromodulation System (Complex Active Implant)
  • Whole Body Average SAR ≤ 0.24 W/kg
  • Head Average SAR ≤ 0.40 W/kg
  • Scan time:
    - 1.5T scanner: Total active scan time allowed is 30 minutes per study.
    - 3T scanner: Total active scan time allowed is 30 minutes per study.

*See next slide
Why are complex active implants of interest?

- Routine protocols used in MRI are Normal Mode indicating that heating and gradients are safe/suitable for any patient without implants.
- Routine protocols seldom limit scan duration for reasons of safety.
- Most passive and many active implants can be safely scanned without altering scan protocols.
- Complex active implants will often require protocol modifications to be safely scanned.

Lumbar spine of patient with Neuromodulation Implant. Pre-scan assessment was 45min of combined time and Protocol Modification and Scanning supervision was 85min of combined time.
What are the dangers of active implant scanning?

- Heating from the radiofrequency (RF) pulse
  - Implant may concentrate RF energy making scanning more dangerous
- Torque & pulling from static magnetic field and its gradient
- Implant malfunction from magnetic fields, gradients, or RF
  - Typically, a danger for active implants only
What are MRMD, MRSO, and MRSE?

- American Board of Magnetic Resonance Safety (ABMRS)
  - Certifies individuals charged with ensuring safety in MR suites
- MR Safety Expert (MRSE)
  - Typically, a physicist who advises MRMD/MRSO on questions of MR safety
- MR Safety Officer (MRSO)
  - Typically, a technologist overseeing and carrying out day-to-day MR safety tasks
- MRMD
  - Typically, a radiologist legally liable for MRI safety
What does a complex implant scanning workflow look like?

START

Scan Request for Patient with Implant

MRSO Review

Active?

MRSO Active Implant Data Collection

Complex?

MRSE Scan Feasibility Assessment

MRSE Scan

Off-Label Assessment

Off-Label Scan Approved?

No MR Scan - Possible Modality Change

No

Conditional On-label?

Yes

No

Scan Protocol Alterations

Device Configuration (if needed) & Patient Scan

Yes
What happens when assessing scanning feasibility for complex implants?

- MRSO collects information
  - 63 pieces of data
  - Implant-related (e.g., make & model)
  - Patient-related (e.g., other passive implants)
  - Procedure-related (e.g., sedation)
  - Retrieve most recent vendor manual
- May call for information missing from the EMR as needed from vendor, referring service, and patient

- MRSE assesses MRSO data in relation to on-label scanning criteria
  - 13 individual items assessed
  - Example: anatomical location of implanted device and leads

- MRSE extracts criteria for on-label scanning as related to the current patient
  - 16 criteria and data items
  - Example: patient position restrictions

- MRSE advises approval for scheduling on-label scan or requests off-label assessment
  - MRSE cannot choose not to scan
What happens when protocoling and supervising the scans?

- Complex implants typically require protocol alterations to meet on-label criteria or reduce off-label risk
- Typical alterations address heating, scan time, and/or transmit coil use
  - Keep only needed series
  - Reduce scan range
  - Alter series scan parameters
  - Create transmit coil protocols
  - Schedule multiple scanning sessions with cool-down period inbetween
- Heating metrics and scan time are reported for each series as the patient is scanned
- Protocols may need alteration at point of scanning under the direction of the MRSE
  - Physics Assistant acts as a second pair of eyes and recorder of information
- MRSE works through scanning checklist with Physics Assistant to ensure correct data is recorded and on-label criteria are met during the scan
What happens if on-label scanning is not possible?

• Send for off-label assessment (scheduling delayed)

• MRSO, MRSE, Physics Assistant, Radiologist, and MRMD (as needed) collect further data and discuss risk/benefit of scanning off-label

• Further discussions with vendor and referring physician may occur

• Only radiologist or MRMD can choose not to scan
  • Ensures all efforts are made to scan the patient

Sleep Apnea Device. Off-label for body imaging. Off-label review: 150 min MRSE, 30min MRSO, 30min Radiologist.
How much effort does data gathering & assessment take?

- Surveys during all complex implant cases between May of 2020 and December of 2021
- 355 patient scans were assessed
- Median MRSO time per case collecting data was 30 min (Interquartile range (IQR) 15 min)
- Median MRSE time per case assessing scan feasibility was 15 min (IQR 10 min)
How much effort does protocol alteration & scan supervision take?

- 185 patients were ultimately scanned by the time of analysis
  - Median MRSE time per scan altering protocols and supervising scans was 60 min (IQR 20 min)
  - Median Physics Assistant time per scan was 45 min (IQR 37.5 min)
- 36 scans included radiologist consultation during off-label review
  - Median radiologists time per off-label case was 10 min (IQR 5 min)

NB: Percentages % of total time spent not % of instances
What is the barrier to access for patients?

• Patients with complex implants often represent a cohort receiving long term therapy who will need additional imaging as their condition progresses.

• Substantial expertise and effort are needed to assess and scan.

• Serious injury can occur if incorrectly assessed and scanned creating potential legal liability for the institution.

• Extra effort is not reimbursed and so only a limited number of institutions are willing to accept the risk and resource commitment without commensurate reimbursement.
What are the shortcomings and future directions of the current study?

- Radiologist time spent in protocol modification was not captured
- Protocol alterations conducted at the point of scanning were included, but MRSE time working on protocols between assessment and scanning was not consistently recorded
- Time spent by referring services configuring implants for scanning was not recorded
- Future surveys will fill these gaps to better capture total effort
Can you summarize for me?

- Patients with implants often require MR scans
- Complex implants require a substantial investment in expertise and time by the institution
- The effort for patient scanning is not reimbursed disincentivizing scanning of these patients
- There is a potential for incorrect diagnosis and harm if a patient with a complex implant cannot access an institution to safely assess and scan them
- Effort for MRSE and radiologist/MRMD reported here are an underestimate of true effort