Do Depleted SCS Systems Meet Required Conditions for MRI Scans?

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Introduction

Inadequate pain relief or loss of efficacy is the main reason for explant of spinal cord stimulation (SCS) systems. When SCS stops providing pain relief, patients likely abandon use of the therapy, causing the battery to deplete. While some patients have the system explanted, another patient population likely retains, but no longer uses the system. As patients continue to seek treatment for their pain or other health conditions, a depleted SCS system may impede their access to optimal healthcare.

Study	Therapy/ System Type	Sample Size	Explant Rate and Explants Due to Loss of Efficacy	Follow-Up
Al-Kaisy et al (2020)[7]	Tonic, 10 kHz, Multiple (burst/tonic)	1177	Overall: 182/1177 (15.5%) Kaplan-Meier survival analysis (explants due to loss of efficacy): 13.3% at 5 years, 17.5% at 10 years	Up to 11 years
Van Buyten et al (2017)[8]	PC, RC, 10 kHz RC	PC: 462 RC: 329 10 kHz RC: 155	Overall: 7.9% per year Explants due to inadequate relief: PC: 32/462 (6.9%), RC: 37/329 (11.2%), 10 kHz RC: 22/155 (14.2%)	Median: 2.24 years
Dupre et al (2018)[9]	Systems with surgical leads	595	Overall: 165/595 (27.7%) Explants due to inadequate relief: 121/165 (73%)	Median implant time: 665 days
Pope et al (2017)[10]	PC, RC	352 explanted	Explants due to inadequate relief: 152/346 (43.9%)	5 year data collection period
Slyer et al (2020)[11]	PC, RC, multiple systems	767	Overall: 75/767 (10%) Explants due to inadequate relief: 38/75 (50.1%)	Minimum of 1 year follow-up

Up to 84% of implanted SCS patients are expected to need an MRI scan within 5 years of implant, with the expectation reaching up to 98% by 10 years.1

There is a high probability that patients who stop using their system and have a depleted battery will need an MRI. For many MRI Conditional SCS systems, a depleted battery will not meet the required conditions and, therefore, be ineligible for an MRI scan.

Methods

SCS system labeling was reviewed to understand the MRI requirements for conditional systems. Research on features that enable scanning of depleted battery are described.

Results

Impedance requirement for most SCS systems. Once an SCS device is depleted, it can be impossible to perform an impedance check of the system. Nearly all SCS systems require an evaluation of impedances as a condition for MRI scanning. For example, excerpts from labeling warned against performing an MRI procedure on leads with "lead impedance measurements not within the lead impedance limits",[2] "when the impedances are not within the acceptable range",[3] and "if the impedance check on the Remote Control does not pass."[4]

"Nonfunctional leads. Do not perform an MRI scan on patients with broken or intermittent MR Conditional leads, or lead impedance measurements not within the lead impedance limits. MRI scans of patients with nonfunctional leads may result in higher than normal heating occurring at the location of the implanted lead electrodes."[2]

"Warning: An MRI scan is not recommended when the impedances are not within the acceptable range. Higher or lower than normal impedances could indicate compromised Stimulator-Lead integrity. Scanning under these conditions may increase the risk of potential adverse effects listed in the "Safety Information" section under "Potential Interactions with MRI Environment."[3]

If the IPG cannot enter MRI Mode using the HFX iQ App or if the impedance check on the Remote Control does not pass, DO NOT perform the MRI scan and contact Nevro Technical Services."[4]

Testing and features enabling scanning of depleted systems. Evaluation of impedance was not a requirement for some SCS devices.[5] These systems include protective radiofrequency shielding around the lead that dissipates heat. Monte Carlo temperature predictions for 100 million independent simulated scans demonstrated lead temperatures stayed below 43°C.[6] Additional analysis showed that broken lead wires for this lead design result in insignificant electrode temperature increase, and therefore the MR Conditional labeling does not require lead impedance to be verified.

Conclusion

Most SCS systems are MR Conditional. Most, but not all, MRI Conditional SCS systems require an impedance check prior to scanning. Depleted SCS systems not meeting the impedance check requirement would not be eligible for an MRI scan.

Workflow for a depleted MR Conditional SCS system without impedance check requirements

Some MR Conditional SCS systems with depleted batteries WOULD meet the required conditions for an MRI scan, since an impedance check is not required. Based on the labeling and MRI eligibility guidance, a workflow for confirming eligibility for a depleted battery is proposed.

1. Confirm the device is at end of service (i.e., "off") using the patient controller and/or clinician programmer to attempt communication with the device.
2. Research the medical records or conduct an X-ray to confirm the implanted system components meet MRI eligibility requirements.
3. Document the components and eligibility for scanning on the MRI eligibility sheet and in medical records for the radiology center.
4. If eligibility cannot be confirmed, then a scan should not be performed.

The ability to scan a depleted SCS system ensures a patient has timely and reliable access to MRI, even in cases where SCS therapy has been abandoned.

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Disclosures

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