

Publication update

A retrospective review of elevated lead impedances in impedance-dependent magnetic resonance-conditional spinal cord stimulation devices.

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Some MR Conditional SCS systems become ineligible for MRI due to impedance conditions.

To maintain MR conditionality, some SCS systems require all contacts to be within an acceptable impedance range. This publication discusses the occurrence of out-of-range impedance for MR Conditional SCS systems that require an impedance check prior to an MRI.

Methods overview

- Single-center, retrospective, chart-based review from the United Kingdom.
- 363 patients implanted with impedance-dependent MR Conditional systems (Nevro, Abbott, Boston Scientific) with a documented impedance check at least six months after implantation.
- Medtronic MR Conditional systems were specifically excluded since their MR conditionality is not dependent on lead impedance.
- Average follow-up time at last recorded impedance check was 2.25 years (SD: 1.49).

Key points

Objective

Retrospectively analyze the rate of elevated lead impedances in impedance-dependent magnetic resonance conditional (MR Conditional) SCS devices to determine the rate of failure of MR Conditional modes.

Results

- 18.5% of Nevro, Boston Scientific, and Abbott patients (67/363) had leads with at least one contact impedance $> 10,000 \Omega$ at an average of 2.25 years follow-up.
- 43% of Nevro, Boston Scientific, and Abbott MR Conditional SCS devices had at least one out-of-range impedance at five years postimplant.

Significance

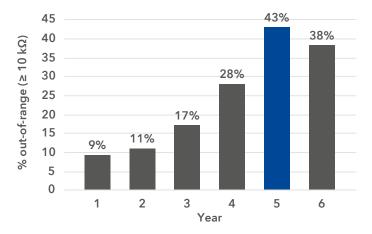
Elevated impedance in certain MR Conditional SCS devices results in loss of MR conditionality, consequently making them ineligible for MRI. The authors conclude, "If future MRI is likely, patients and clinicians should consider implanting impedance-independent [Medtronic SureScan™] MR conditional systems and possible failure of MR conditionality should be routinely incorporated into patient consent prior to implant."

Key results

Table 1. A substantial number of patients **(18.5%)** had at least one elevated impedance, resulting in loss of MR conditionality.

Patients included, n (%)	363 (100%)
Total contacts, n (%)	4815 (100%)
One lead implanted, n (%)	124 (34.2%)
Two leads implanted, n (%)	239 (65.8%)
Average follow-up, years (SD)	2.25 (1.49)
Patients with impedances $> 10k\Omega$, n (%)	67 (18.5%)
Contacts with impedances $> 10k\Omega$, n (%)	186 (3.9%)
Time to first impedance $> 10k\Omega$, years (SD)	2.75 (1.57)
Predicted lead survival, years (95% CI)	4.77 (4.40-5.13)

Figure 1. The annual rate of lead impedance failure increased each successive year to a peak of **42.9%** at year five.



Key conclusions

- 18.5% of patients (67/363) had leads with at least one contact impedance $> 10,000\Omega$ at an average of 2.25 years follow-up.
- The risk of lead impedance failure increased by 35.4% with each successive year, peaking at 43% of patients with impedance failure by year five.
- A Kaplan-Meier survival analysis suggested the mean duration a lead will last is approximately 4.8 years before it will fail an impedance check.
- Most patients with a high-impedance had just one or two contacts out-of-range. While a single contact may not impact delivery of therapy, the out-of-range impedance makes the SCS system ineligible for MRI.



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Limitations

- The single-center study was limited by being retrospective. While routine clinical practice may include impedance checks, those who come in for device interrogations could be more likely to need an impedance issue for troubleshooting. This could cause over-representation of elevated lead impedances.
- Disparities in sample size and follow-up time make it difficult to draw conclusions between manufacturers.
- The Kaplan-Meier survival analysis should be interpreted with caution.
- The types/brands of leads included in the analysis were not reported.
- Impedance requirements for MR Conditional systems vary between manufacturers. The actual incidence of high or out-of-range impedance may be underestimated using a $10,000\Omega$ threshold, since some systems may have lower impedance thresholds.

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.eu.

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