MRI RF Heating of SCS Leads: Ensuring Patient Safety Through Lead Design, Simulation and Analysis

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Introduction

Magnetic Resonance Imaging (MRI) is an important diagnostic imaging technique and is the recommended diagnostic modality for many clinical indications. Up to 98% of spinal cord stimulation (SCS) patients may need an MRI scan within 10 years of implant.[1] However, creating MR Conditional labeling for SCS devices that ensures patient safety and maximizes clinical diagnostic utility is challenging because of the complexity of the MRI environment. Radiofrequency (RF) lead heating can potentially result in serious patient harm but is particularly difficult to evaluate because it is a function of the lead design, patient attributes, and scan conditions.

This poster describes the RF heating modeling and test methods used to support full-body Normal Operating Mode MR Conditional labeling for a novel RF shielded SCS lead designed to reduce RF electrode heating. The methods are compliant with Clause 8, Tier 3, of ISO/TS 10974:2018[2] that contains industry consensus test methods for evaluating implanted device safety in the MRI environment.

Methods

The risk of patient injury due to MRI related RF heating is evaluated using a transfer function (TF) lead model method (Clause 8, Tier 3, of ISO/TS 10974:2018). The TF is a measured property of the lead that determines its propensity to heat when exposed to RF energy. Once calibrated and validated, the TF lead model can be used to predict lead electrode temperatures for any simulated MRI scan scenario. The approach is illustrated in Figure 1 and summarized to the right.

References

[1]Desai MJ, Hargens LM, Breitenfeldt MD, Doth AH, Ryan MP, Gunnarsson C, Safriel Y. The rate of magnetic resonance imaging in patients with spinal cord stimulation. Spine (Phila Pa 1976). 2015 May 1;40(9):E531-7. D

[2]ISO/TS. 2018. ISO/TS 10974: assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device.

[3]https://www.itis.ethz.ch/virtual-population/virtual-population/overview/ (Accessed Aug. 8,2023)

Methods

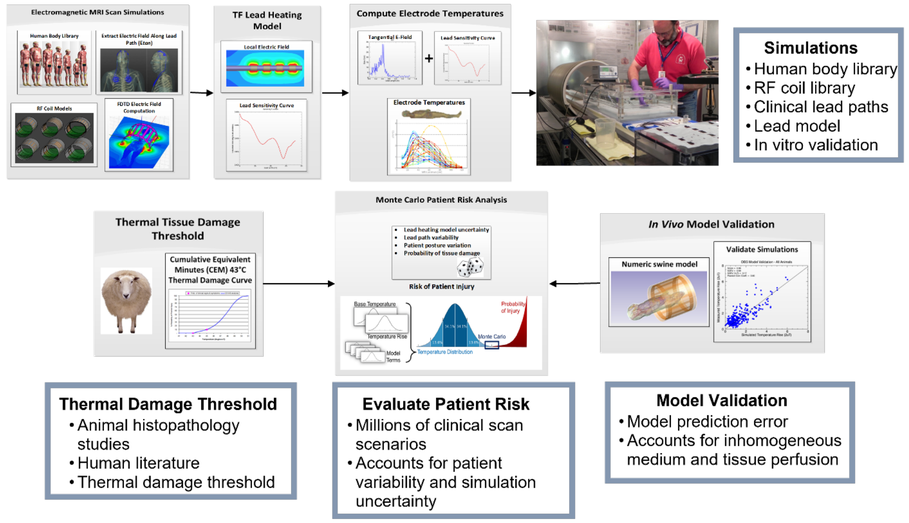


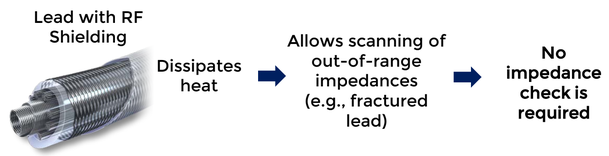
Figure 1. Schematic overview of the RF heating modeling and testing methods used to support full-body Normal Operating Mode MR Conditional labeling for an RF shielded SCS lead designed to reduce RF electrode heating. The lead heating transfer function models were verified in vitro and in vivo and used to predict electrode temperatures in 180,857 human simulated scan scenarios. A Monte Carlo analysis was used to account for lead heating model prediction error and to demonstrate that the probability of inducing detectable tissue thermal damage in human patients conservatively exposed to 30-minutes of continuous scanning at the Normal Operating Mode limits is less than 1 per million. Additional analysis showed that broken lead wires in the tantalum shielded leads result in insignificant electrode temperature increase and supports MR Conditional labeling without a lead impedance requirement.

- ❑ TF lead electrode heating models are measured with a specially designed apparatus and calibrated in vitro by measuring the lead model response to known RF exposures. The calibration error and part-to-part lead model variability due to manufacturing tolerance is determined.
- ❑ TF lead electrode heating models are verified in vivo by implanting swine with leads instrumented with fiber optic temperature probes. The electrode temperatures are measured during 1.5T MRI scans of the animals at a specified RF exposure level.
- ❑ Computational electromagnetic models of the experimental animals are constructed by segmenting 3-D CT and MRI image data.
- ❑ Electromagnetic simulations and electrode temperature predictions are made using the TF lead models and electromagnetic simulation results that replicate each in vivo measurement. An analysis of the simulated and measured temperatures determines the in vivo prediction error. This error term accounts for tissue perfusion and differences in thermal and electrical properties between tissue and saline.
- ❑ Clinically relevant SCS lead paths are created for a subset of models in the IT IS Virtual Family.[3]
- ❑ MRI scans are simulated for each body model at the governing Normal Operating Mode SAR limits at landmark locations from the head to the ankles and in the prone and supine positions using a library of whole-body MRI RF coil models that span the length, diameter, and basic design currently in use in commercial 1.5T MRI scanners. The TF lead heating model is used to predict the lead electrode temperature for each lead path in every simulation resulting in 180,857 simulated temperatures.
- ❑ Patient risk is evaluated using the results of 20 million iterations of a Monte Carlo analysis that randomly adjusts the 180,857 computed temperatures to account for the previously evaluated uncertainly terms. For each Monte Carlo electrode temperature, the probability of producing detectable thermal tissue damage is computed from a thermal dose and tissue damage function derived from the results of animal histopathology studies.
- ❑ The acceptance criterion is a probability of histologically detectable thermal tissue damage for 30-minutes of continuous scanning at the Normal Operation Mode SAR limits of less than 1 in 1 million.

Results and Conclusion

ISO/TS 10974:2018 compliant methods were used to assess safety scanning RF shielded SCS at the Normal Operating Mode SAR limits. The lead heating transfer function models are verified in vitro and in vivo and used to predict electrode temperatures in 180,857 human simulated scan scenarios. The simulated scans are conservative with respect to clinical scan protocols because they consist of 30-minutes of continuous scanning at the Normal Operating Mode limits as opposed to typical clinical MRI protocols that consist of multiple short scans at varying RF power levels with delays in-between.

A Monte Carlo analysis is used to account for lead heating model prediction error and to demonstrate that the probability of inducing detectable tissue thermal damage in human patients conservatively exposed to 30-minutes of continuous scanning at the Normal Operating Mode limits is less than 1 per million. Moreover, additional analysis shows that broken lead wires in the tantalum shielded leads result in insignificant electrode temperature increase and supports MR Conditional labeling without a lead impedance requirement.



Disclosures

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