MDDT SUMMARY OF EVIDENCE AND BASIS OF QUALIFICATION DECISION FOR
Virtual MRI Safety Evaluations of Medical Devices

BACKGROUND

MDDT NAME: Virtual MRI Safety Evaluations of Medical Devices

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TOOL DESCRIPTION AND PRINCIPLE OF OPERATION

This medical device development tool (MDDT) is categorized as a non-clinical assessment model (NAM). This MDDT is a computational modeling and simulation (CM&S) tool that can predict the interactions of medical devices (i.e., medical implants) with the electromagnetic fields in the magnetic resonance (MR) environment. This MDDT uses a multiphysics model to simulate the full-field electromagnetics model of a known MRI RF coil, ASTM gel phantom, and medical device (placed inside the ASTM gel) to compute the extent of heating generated in the gel around the device due to the RF power deposition from the coil. Specifically, this MDDT is the in-silico analog of the ASTM F2182-19e2 bench test standard (*Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging*).

Electrically conductive medical devices can alter the electromagnetic fields generated in the body during MRI scans and cause local heating of tissue near the device. This heating effect can be partially evaluated using the ASTM F2182 test that utilizes a large gel phantom. The stationary full-field electromagnetic response of a radiofrequency (RF) coil can be computed by solving Maxwell's equations. Thus, a commercially available multiphysics finite element software is utilized to solve the sequentially coupled electromagnetics and transient conduction heat transfer equation to estimate the RF-induced heating of the gel around medical devices, during a 15-minute exposure of RF energy from the RF coil. This approach has been routinely used to determine worst case configuration or construct in premarket submissions of device sets that have multiple components or configurations.

QUALIFIED CONTEXT OF USE

"This MDDT is a non-clinical assessment model used to predict the RF power deposition induced temperature rise (i.e., less than 20°C temperature rise) using CM&S methods, near electrically passive, fully implanted, medical devices (e.g., orthopedic and cardiovascular implants) in lieu of physical testing according to ASTM F2182-19e2. It can be used when the measured and simulated induced peak RF heating near the Ti rod are comparable for an analogous electromagnetic field/RF power deposition at frequencies of 1.5 T/64 MHz and 3 T/128 MHz in cylindrical bore MRI systems. This tool can also help identify the appropriate worst-case device size, configuration (i.e., multi-component devices), and orientation by performing multiple simulations to determine the RF-induced heating. This tool does not include the estimates of SAR (Specific Absorption Rate) values in the regions around the modeled medical implant. This tool does not predict the induced SAR or temperature rise around the medical device in an anatomical model."

SUMMARY OF EVIDENCE TO SUPPORT QUALIFICATION

A number of actual medical device implants (n=34) were tested to validate this CM&S MDDT. The results of actual physical testing using the ASTM F2182 standard test method were compared with the output of the tool. A Bland-Altman analysis was used to evaluate the agreement of the simulation with the experimental measurements across all medical devices tested and simulated. The specific measurement parameter that was compared was the maximum temperature rise after 15 minutes of RF-induced heating. The mean difference between the simulation and experiment was plotted along with the limits of agreement. A paired t-test statistic was used to analyze the data with a significance level of 0.05 to demonstrate that there is no statistically significant difference between the paired simulation and experimental measurements. The passive device included various cardiovascular and orthopedic implants (filter, occluders, coil, stent, valve, screw, pin, staple, prosthetic joints) of various shapes, sizes (1 to 28 cm in length), and materials of construction. The range of heating for the devices extended from 1°C to 17°C, to keep within the well-defined properties of the gel. The Bland-Altman analysis shows the mean difference between the simulation and experiment is 0.04°C and the limits of agreement are 0.04°C ± 1.96σ, where σ is the standard deviation (σ = 1.2917°C). The upper and lower limits of agreement are 2.47°C and -2.59°C, respectively, and represent a confidence interval of 95%.

DISCUSSION OF THE EVIDENCE STRENGTH TO SUPPORT QUALIFICATION

The Strength of evidence of the validity of the tool is based on the well accepted underlying principle of operation, as well as the direct comparison of the scaled output (using the heating from a titanium rod standard) of the tool with the corresponding physical measurement.

ASSESSMENT OF ADVANTAGES/DISADVANTAGES OF QUALIFICATION

This MDDT addresses the parallel growth of installed MRI systems, number of patient scans, and prevalence of patients with implanted medical devices. Newly developed medical devices, as well as legacy medical devices without MRI safety information, need to be evaluated for safety in the MR environment. Many patients with implants will require an MRI scan within their lifetime. Additionally, there are numerous devices on the market (e.g., orthopedic implants) that have not been evaluated for MRI safety.

This MDDT tool may help estimate the induced heating near electrically passive, fully implanted, medical devices (e.g., orthopedic and cardiovascular implants) in lieu of physical testing according to ASTM F2182-19e2. It can be used when the measured and simulated induced peak RF heating near the Ti rod are comparable for an analogous electromagnetic field/RF power deposition at frequencies of 1.5 T/64 MHz and 3 T/128 MHz. This tool can also help identify the appropriate worst-case device size, configuration (i.e., multi-component devices), and orientation by performing multiple simulations to determine the RF-induced heating.

This MDDT has demonstrated that it accurately predicts absolute temperature rise for RF-induced heating with acknowledgement of the following limitations:

- This MDDT was validated using a scaling approach of the temperature rise using a titanium rod.
- This MDDT currently does not have validated data to support a predicted temperature rise greater than 20°C.
- There are many types and field strengths/frequencies of MRI systems. The focus of this MDDT is currently 1.5 T/64 MHz and 3 T/128 MHz closed bore or cylindrical bore MRI systems using circularly polarized RF body coils.
- This MDDT does not include electrically active medical devices or partially implanted or external medical devices.
- This tool does not include or provide the estimates of SAR values in the regions near the medical implant. This tool does not predict the induced SAR or temperature rise around the medical device in an anatomical model.

Assessments of Advantages of Using the MDDT:

The main advantage of using a computational tool instead of bench tests lies in the possible savings incurred in time and resources (e.g., RF coils, MRI systems, ASTM gel phantoms, etc.) to produce experimental results with physical test samples using the ASTM F2182 standard.

Assessments of Disadvantages of Using the MDDT: This should take into account the following factors:

The main disadvantages with the tool are that this tool is limited at this time to only 1.5 and 3T cylindrical bore MRI systems inherent in the ASTM F2182 Standard. As stated previously, the tool currently does not have validated data to support a predicted temperature rise greater than 20°C.

CONCLUSIONS

Based on the evidence provided, this non-clinical assessment model MDDT: "Virtual MRI Safety Evaluations of Medical Devices" was found to reliably predict the temperature rise caused by RF power deposition (i.e., less than 20°C temperature rise) near electrically passive, fully implanted, medical devices (e.g., orthopedic and cardiovascular implants). It can be used when the measured and simulated induced peak RF heating near the Ti rod are comparable for an analogous electromagnetic field/RF power deposition at frequencies of 1.5 T/64 MHz and 3 T/128 MHz. This tool can also help identify the appropriate worst-case device size, configuration (i.e., multi-component devices), and orientation by performing multiple simulations to determine the RF-induced heating.

CONTACT INFORMATION FOR ACCESS TO TOOL

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