Retrospective Analysis of Data in RF Heating Tests of Small Passive Medical Implants

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Purpose

There has been an increasing use of MR Conditional medical implants. Consequently, hundreds of passive medical implants have been tested for their radio frequency (RF) induced heating of tissue during magnetic resonance (MR) scans using standardized methods [1-2] as part of the regulatory submission for MR labeling. It is well known that RF-induced heating is a complex function of several variables, including the physical dimensions of the device. The purpose of this study is to perform a retrospective analysis of data related to RF-induced heating tests of medical implants provided in U.S. FDA (Food and Drug Administration) submissions in order to understand trends and correlations.

Methods

We report interim data on 55 small passive medical implants for 1.5T and 3.0T. Devices include cardiac plugs, aortic valves, stents, inferior vena cava filters, fracture fixation screws, interbody spinal fusion devices, and dental bridges. The materials used in these implants include Co-Cr, nitinol, elgialoy, titanium, and tantalum. The data extracted from the reports of five test labs included tested device length (≤120 mm), changes in temperature measured using fiberoptic probes, calorimetry-based measurements of whole-body averaged specific absorption rate (WB-SAR, in W/kg), and baseline temperature-based measurements of background local exposure (local SAR) at the location of testing, in the absence of the implants (W/kg). The temperature change per unit of SAR (i.e. ºC/W/kg) was computed from the reports of 15 min exposure to RF. Because coil design, local exposure, device type, and testing lab affect the RF heating measurements, a subset of the data (stents only) from a single test lab was analyzed for dependence on local exposure.

Results

Figure 1 shows the RF-induced heating (i.e. the temperature change per WB-SAR, ºC/W/kg) versus medical device length (mm). Because the length of the tested device strongly affects RF-induced heating due to wavelength effects of the MR RF field, the comparison was performed for both 64MHz/1.5T (diamonds) and 128MHz/3.0T (squares). Figure 2 shows a subset of the data using local SAR, stents, and same testing lab. Correlation of data in each frequency was calculated. The R^2 of 64MHz was 0.72 and the R^2 of 128MHz was 0.22.

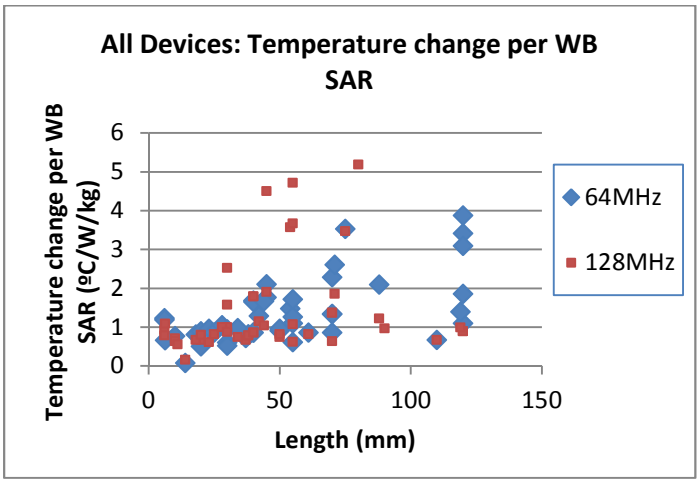

Figure 1. Temperature change for all devices, normalized to the same whole-body SAR

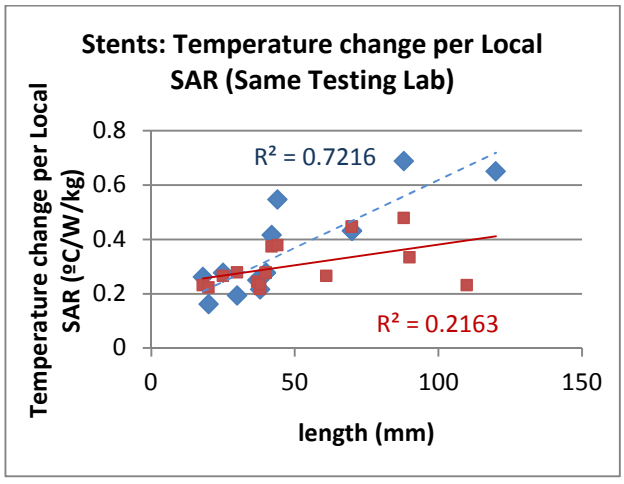

Figure 2. Temperature change for a stent, normalized to the same local exposure

Discussions and Conclusions

This is a preliminary retrospective data analysis on passive medical devices (≤120 mm) related to RF-induced heating. While considering only a limited number of reviewed submissions and devices, the data show that there is no clear length dependence for devices ≤120 mm even when the data are stratified by the magnetic field, device type, and test vendor. Most devices less than 50 mm in length showed less than 2.6 °C of temperature change per WB-SAR except for one device that showed 4.5 °C of temperature change per WB-SAR. Future analyses will include more types of passive medical implants with different materials, dimensions, and shapes.

References

1. American Society for Testing and Materials (ASTM) F2182 - 11a, "Standard test method for measurement of radio frequency induced heating on or near passive implants during magnetic resonance imaging."
2. FDA Guidance for Industry and FDA Staff, "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment, 2008."

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