An Assessment of Radio Frequency Induced Heating of a Vascular Stent during Magnetic Resonance Imaging of a Pig

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Introduction: Radio Frequency (RF) induced heating of medical devices is an important safety concern as the number of patients implanted with medical devices increases along with the number of MRI procedures performed. Medical device manufacturers use a standard *in vitro* test method, ASTM F2182-11a, in order to measure the RF induced heating of medical devices during MRI. The RF induced heating results are used to evaluate MR safety and incorporated into the labeling of the medical device according to ASTM F2503-13. The *in vitro* phantom does not account for cooling mechanisms such as blood flow and perfusion. Therefore, we hypothesize that the standard *in vitro* test does not accurately reflect the *in vivo* conditions and over-estimates temperatures near a medical device[1]. In order to test our hypothesis we performed *in vivo* experiments using anesthetized pigs implanted with a vascular stent and fiber optic temperature probes. The purpose of this work is to compare the *in vitro and the in vivo* temperature rise of a vascular stent during RF induced heating.

Materials and Methods: Non-survival surgery was performed on four anesthetized pigs according to an approved IACUC protocol. First, two fiber optic temperature probes were advanced endovascularly via the contralateral femoral artery to the right carotid artery. Then a vascular stent (80 mm long, 7 mm diameter) was deployed in the right carotid artery fixing the fiber optic probes at the distal and proximal ends of the stent, between the arterial wall and the stent. Additionally, loosened snares were positioned on the proximal and distal ends of the carotid artery to allow carotid occlusion during part of the experiment. Experiments were performed using a gradient echo sequence on a Siemens Tim Trio 3T MRI system (TR = 34.73ms, TE = 2ms, flip angle = 23°**,** voxel size = 2.5 x 2.5 x 5.0 mm) with a Whole Body average Specific Absorption Ratio (WBSAR) of approximately 5.5W/kg, which was achieved by overriding the SAR limitations. The pig was positioned supine head first within the bore of the MR system, and off-center to the left so the vascular stent would be located where the electric field is known to be high. The fiber optic temperature probes measured the temperature at the ends of the stent inside the lumen of the carotid artery during MR-powered RF induced heating for approximately 10 minutes. The initial baseline case included blood flow and perfusion, which act as cooling mechanisms. Then the snares were tightened and the blood flow was occluded in the carotid artery, which allowed for RF induced heating measurements without blood flow but with perfusion. Cessation of blood flow was confirmed using phase-contrast MRI before and after occlusion. Finally, the pig was sacrificed and the RF induced heating experiment was repeated post-mortem, i.e., without blood flow or perfusion. The same size vascular stent was tested according to ASTM F2182-11a in a gel phantom with an MR console reported WBSAR of 2 W/kg.

Results: Table 1 shows the relative change in temperature of the luminal probe near the distal end of the vascular stent during RF induced heating for the three scenarios (i.e., blood flow and perfusion, perfusion without blood flow, and post-mortem) during four pig experiments at a WBSAR of 5.5 W/kg. Several of the experiments were repeated and the averaged results for each scenario and each pig are reported in Table 1. Figure 1 shows a temperature rise of over 10 °C near the vascular stent in the *in vitro* experiment with a WBSAR of 2 W/kg.

Table 1. Comparison of temperature results of four different pig experiments.

	RF Induced Heating of Vascular Stent during MRI ΔT after 10min at WBSAR of 5.5 W/kg		
Distal Luminal Probe	**Blood Flow and Perfusion**	**Perfusion without Blood Flow**	**Post-Mortem**
Pig 1	0.7 °C	1.2 °C	3.0 °C
Pig 2	N/A[†]	2.1 °C	2.8 °C
Pig 3	1.3 °C	3.5 °C	3.1 °C
Pig 4	0.8 °C	2.8 °C	1.9 °C

WBSAR = Whole Body Specific Absorption Ratio (MR console reported)
[†]Carotid artery was occluded prior to RF induced heating, which was confirmed using phase-contrast MRI.

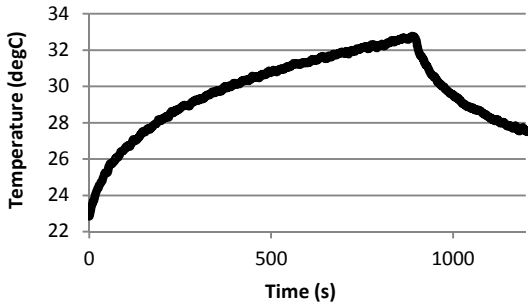

Figure 1. Temperature vs time plot of the vascular stent in the ASTM F2182-11a phantom, for 15 minutes at a WBSAR of 2 W/kg.

Discussion: The *in vivo* temperature results from Table 1 show that blood flow reduces the temperature rise near the vascular stent by more than 50% when compared to the post-mortem temperature results. The temperature effects of perfusion are difficult to determine since the overall post-mortem temperature rise near the vascular stent is relatively low. A comparison of the post-mortem temperature results from Table 1 and the *in vitro* temperature results from Figure 1 show the *in vitro* overestimation of RF induced heating of the vascular stent. The highest temperature achieved *in vivo* (3.5 °C) is approximately one-third the *in vitro* maximum temperature (10 °C), despite the *in vivo* WBSAR (5.5 W/kg) being more than double the *in vitro* WBSAR (2 W/kg). The large difference in the post-mortem and *in vitro* temperature results demonstrates the overall complexity of RF induced heating, arising from differences in anatomical geometry and complicated physiology, which affect the electromagnetic and thermodynamic results. The conservatism of the ASTM F2182-11a *in vitro* RF induced heating test results needs to be considered since the data are used in medical device labeling and ultimately determine the accessibility to MRI for patients with implanted devices.

Conclusion: *In vivo* cooling mechanisms such as blood flow and perfusion impact the overall temperature rise during MR-powered RF induced heating of a vascular stent. The results of this assessment indicate that there are parameters outside the scope of the *in vitro* test (ASTM F2182-11a) that need to be considered when evaluating RF induced heating of a medical device. This will lead to more accurate MR safety evaluations of medical devices, with the goal of ensuring that patients with "MR Unsafe" devices are precluded from MRI scans, and those with "MR Conditional" devices have access to clinically indicated MRI scans that may have otherwise been inappropriately withheld.

References:

[1] Leewood A, Gross D, Crompton J, et al. "Vascular Flow Effects on RF Heating of Passive Implants: The use of a Flow Modified ASTM F2182 Phantom in a Siemens Tim Trio 3T Scanner." Proc Intl Soc Mag Reson Med 2013;21:2836.