Post-mortem in-situ vs in vitro and in vivo RF Safety Evaluation of a Two-Channel Intravascular Active Guidewire for Cardiovascular Interventional MRI

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INTRODUCTION

Radiofrequency (RF) induced heating is a potential concern for devices used during interventional MRI procedures. To ensure the safety of devices such as guidewires and catheters and to bring them to clinical use, thorough device testing is necessary (1). Various standards specify *in vitro* phantom testing to evaluate MR device safety but it is difficult to extend this data to expected performance during actual interventional procedures. Moreover, phantoms may not accurately model conductive and convective heat transfer expected to occur *in vivo*. In this work, we performed standard RF phantom heating tests in addition to *in vitro* and *in vivo* testing that more closely represent the intended use of the two-channel active guidewire under evaluation. Specialized phantom designs with realistic vessel geometries were used for *in vitro* testing followed by *in vivo* and postmortem *in situ* heating tests in swine to further examine heating *in vivo* with and without perfusion and innate temperature regulation mechanisms.

METHODS

Animal protocols were approved by the institutional Animal Care and Use Committee. All testing was performed on a short, wide bore Siemens Espree 1.5T MRI scanner (Siemens Medical Solutions, Erlangen, Germany) with spine and body matrix coils as receivers in addition to the independent active device channels. A real-time balanced steady-state free precession (SSFP) imaging (TR/TE 3.23/1.62ms, ST 6mm, Flip Angle 45°, FOV 340x340mm, Matrix 192x144) sequence typically used for MRI-guided cardiovascular procedures was employed during phantom testing and *in vivo* experiments.

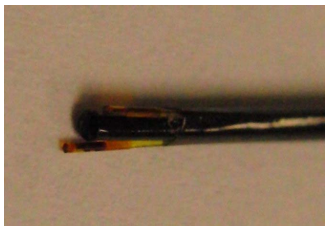

Figure 1: Temperature probe placement

Miniature fiber-optic temperatures sensors (Opsens, Quebec, Quebec CN) were attached to the guidewire at main transition points on the guidewire based on preliminary heating data and maintained at the same position for all testing. Guidewire mechanical performance was minimally affected and measurements of guidewire electrical characteristics (impedance, tune/match) as well as heating tests performed before and after placement of the temperature sensors were consistent.

An 28"Lx16.5"Wx8"D acrylic phantom was constructed (Acrylic Custom Works, Rockville, MD) and filled with 10 g/L polyacrylic acid and 1.32 g/L NaCl (Sigma Aldrich, St. Louis, MO) in 30 L of distilled water. A realistic anatomic model of the iliofemoral arteries and distal aorta (Lake Forest Anatomics, Lake Forest, IL) was used to mimic the intended locations of use and potential geometric configurations of the two-channel guidewire (2).

A range of realistic guidewire insertion lengths and trajectories into the iliac vessels up the distal aorta were tested. More complex curvatures including retrograde access from iliac access on one side across the iliac bifurcation to the contralateral iliac vessel were also evaluated (illustrated in graphic in Figure 3). Similar configurations were examined *in vivo* during terminal experiments with Yorkshire and Yucatan pigs ranging in size from 25-75 kg. The guidewire was placed via right or left femoral artery access sheaths and advanced to increasing insertion lengths from the vessel access up to the aortic arch. Scanning and temperature recordings were performed *in vivo* and repeated at each position once the animal was euthanized with the guidewire plugged in and unplugged to its tune, match and decoupling circuitry.

RESULTS

For the varying insertion lengths and configurations, minimal heating was observed in phantom, *in vivo* and *in situ* testing with the guidewire properly attached to its circuit boxes. Heating with the device disconnected demonstrated the effectiveness of our decoupling circuitry as well as our ability to measure an increase in temperature due to guidewire placement.

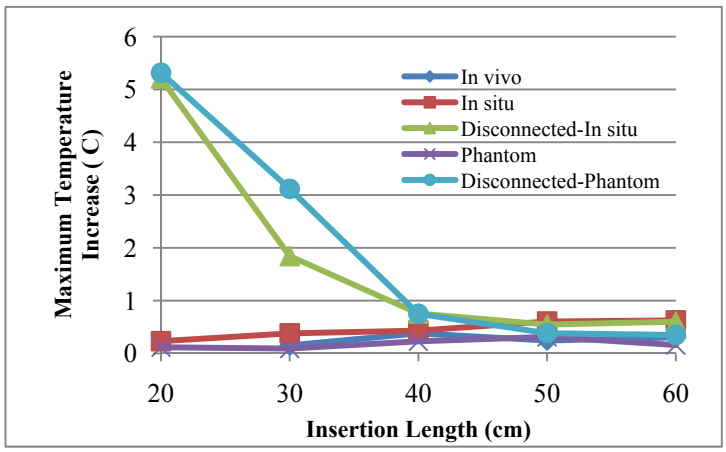

Figure 2: Maximum tip heating for varying insertion lengths during in vivo and in situ animal testing. Same line colors for both graphs.

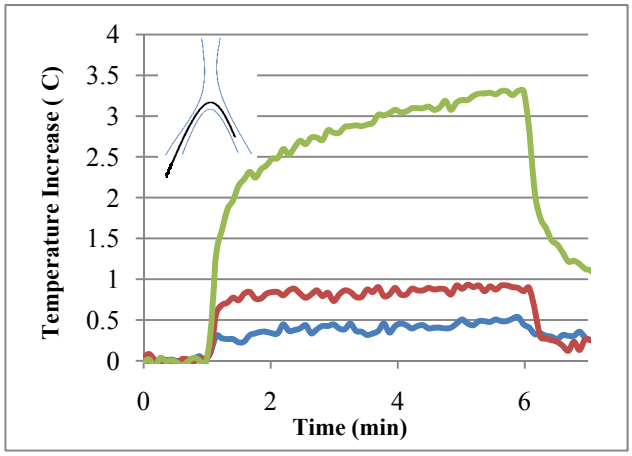

Figure 3: Tip heating with guidewire placed across iliac bifurcation in a half-loop configuration. Guidewire was not moved between acquisitions.

DISCUSSION

Inclusion of the miniature temperature sensors in the device allowed valuable measurement of potential device heating *in vivo* to serve as a complement to traditional phantom testing. This combined approach can help further our understanding of the factors that influence device heating and of potential situations that may be seen during actual *in vivo* use. Stop-flow testing, either post-mortem *in situ* as shown here, or *in vivo* during inflow balloon occlusion of target blood vessels may also provide additional valuable information on the impact of obstructions that can influence perfusion pressures and flow.

REFERENCES

1. Martin AJ, Baek B, Acevedo-Bolton G, Higashida RT, Comstock J, Saloner DA. *MR imaging during endovascular procedures: an evaluation of the potential for catheter heating*. Magn Reson Med 2009;61:45-53.
2. Kocaturk et al., *An Active Two-Channel 0.035" Guidewire for Interventional Cardiovascular MRI.* J Magn Reson Imaging 2009, 30 (2): 461-465.