

In Vivo Temperature Threshold for Myocardial Thermal Damage

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Introduction: The current contraindication of pacemakers in clinical MR systems deprives a large patient population from an increasingly powerful diagnostic tool. With the rapid advancements in cardiac rhythm management technology, pacing systems are being challenged to contend with this harsh electromagnetic environment. One of the major patient safety hazards is the lead tip heating, where RF currents induced in conductive pacemaker and lead circuitry manifest as heat at the electrode/tissue interface. A proof of safety approach that is being considered by the International Organization for Standards (ISO) is the use of computational modeling to estimate the RF exposure *in vivo*, apply the latter to the pacing systems *in vitro* to measure the lead tip temperature, which is then compared against safety thresholds. However, this method has been limited by the unavailability of *in vivo* data characterizing the effect of elevated temperature doses on myocardial tissue. The objective of this study was thus to quantify the change in capture threshold (CT) following successive thermal exposures to 44°C, thereby providing insight to the physiological link required for demonstrating MR safety in the pacemaker patient population.

Methods: Sixteen adult canines were implanted with a pacemaker device and an active fixation endocardial pacing lead in the right ventricular apex. Each lead was modified to allow for thermal monitoring of the tissue 1 mm displaced from the helix where viable myocardium persists. Following a nine week maturation period, RF energy was delivered directly to the tissue of interest for one hour via the pacing lead to register 44°C. After two and four weeks, a second and third thermal dose was delivered. Therefore, three cumulative one-hour thermal doses at 44°C were applied to each canine beginning at week 9 and again at weeks 11 and 13. A change in pacing capture threshold (CT) has been shown as a sensitive and specific metric of thermally induced damage in mammalian cardiac tissue¹. Bipolar CT was measured weekly for the 14 week study duration as well as two hours following each thermal dose. CT measured two hours post-heating was compared to the Baseline CT calculated for each canine based on measurements taken during the chronic phase of implantation prior to any RF exposure. Macro and micro histological analysis was conducted to ensure a properly fixated lead with adequate scar formation, establishing a valid chronic implant condition.

Results: Of the sixteen implants, two leads dislodged by study conclusion and one canine showed evidence of focal hemorrhage at the helix tip. These three cases were then excluded from analysis. Appropriate helix fixation to the endocardial wall, as well as suitable fibrotic deposition, was verified in the remaining thirteen canines by gross dissection and light microscopy. In Figure 1, the two hour post-heating CT is shown relative to the Baseline CT for each canine. The average percent increase following the 1st, 2nd and 3rd thermal exposures was 68%, 81% and 83%, respectively. Furthermore, in 79% of cases the observed post-heating increase in CT subsided to within 0.5V of the Baseline CT one week following each thermal delivery.

Discussion: Among the most critical concerns for pacemaker patients in MRI is the RF induced heating at the tip of the lead and the potential loss of myocardial capture. The objective of this study was to determine the effects of consecutive thermal exposures simulating the heating that may result from multiple MRI scans leading to myocardial damage that can cause loss of capture. In the study, sustained damage is being defined as one persisting two hours post-heating. This is because thermally stimulated heat shock proteins (HSP) are known to be cardioprotective in the short term following heat exposure². Accordingly, the two hour waiting period has been selected to ensure that the acute effects of HSP are not emphasized. The results presented above indicate that three cumulative one hour thermal exposures to 44°C caused an average CT increase of 68%, 81% and 83% above the preheating baseline. These findings provide data that may serve as a foundation for proof of safety of pacemaker systems in MRI.

References:

1. Marshall MT. (2010) *Pacing Clin Electrophysiol*;33(7):826-33.
2. Gowda A. (1998) *Ann Thorac Sur*;65(5):1241-7.

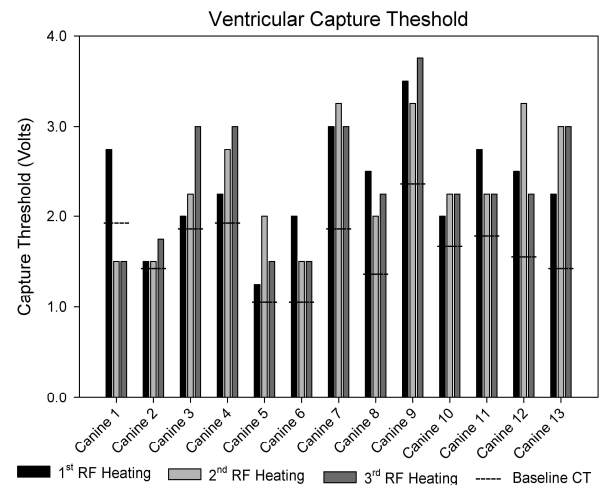


Figure 1. CT at three cumulative one hour thermal doses at 44°C