In Vitro MR Evaluation of Implantable Electrical Device Heating Trends at 1.5T.

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Introduction

The first implantable electrical devices introduced into the medical industry were pacemakers and since then the field has broadened to include treatment of chronic pain, nervous system disorders and movement disorders. There are many future applications for implantable electrical devices including treatment of epilepsy, depression and obsessive compulsive disorder. MRI is often used for pre-, intra-, and post-operative evaluations because of its ability to visualize both an implant and the anatomy of interest. With the increase in MR image clarity, the ability of MRI to scan patients with implantable electrical devices in complex anatomy can be utilized . Patients may also require MRI scans for medical conditions unrelated to their implant. It has been shown that heating in implantable electrical systems from MR exposure is concentrated at the exposed electrode tips (1). This report summarizes the heating trends measured *in vitro* at the tip electrode of implantable electrical devices in a 1.5T MR environment.

Methods

All testing was performed using a 1.5T superconducting magnet (Signa™, GE Medical Systems, Milwaukee WI USA) in accordance with the associated ASTM standard[2]. Sequence parameters produced an estimated SAR of 1.37W/kg with a peak estimated SAR of 2.74W/kg. The transmit gain was increased 2.5 dB above the pre-scan value to yield an extra 1.78X factor for SAR values of 2.44W/kg avg. and 4.88W/kg peak. The phantom morphology consisted of a head and torso with the following inside dimensions: torso width 16.25", torso height 23.25", head width 6", and head height 11.5". The phantom material consisted of 5.85g polyacrylic acid and 0.8g NaCl per liter of deionized distilled water. A plastic grid with insertable posts was used to hold the temperature probes, leads, extensions, and implantable pulse generators (IPGs) in place.

Temperatures were measured every 10seconds using a fiberoptic temperature system (Luxtron™, Luxtron Inc, Santa Clara CA USA) and every measurement represented an average of 8 readings. The fiberoptic probes were tied to the tip electrode of the lead using silk suture, which optimized the proximity of the probe to the electrode under investigation. The baseline temperature was recorded for a minimum of 2 minutes or until the temperature reading stabilized prior to initiation of the scan. The baseline temperature is reported as an average of the ten data points prior to initiation of the scan. During imaging, the temperature was recorded for 10 minutes or until the temperature reading stabilized, whichever was shorter. The peak temperature was reported as an average of the ten data points prior to ending the scan. Four temperature probes were used in the following locations: the tip electrode at both ends of the lead, a reference point in the phantom gel and a reference point outside the phantom.

All tests were landmarked at the center of the lead. Trend characterization was performed at maximum SAR levels to magnify the potential heating in the system. Experiments were performed to characterize heating patterns associated with lead position, lead length, insulation/wire ratio, loop location, and loop quantity. The effect of lead position was tested with a 30cm lead in three positions within the phantom: at the L/R center of the phantom (centerline), 3" from the center (midpoint) and 6" from the center (lateral). The effects of lead position with a 60cm lead and of lead length were tested at the centerline and the midpoint. The insulation/wire ratio was tested by comparing a 4-wire lead to an 8-wire lead with the same insulation thickness. The effect of loop location was tested by measuring the temperature increase at the tip of a 90 cm lead connected to an IPG for three scenarios: no loops; one loop at the top of the head and 1 loop at the IPG; one loop at the top of the head and 2 loops at the IPG. The effect of loop quantity oriented in both the clockwise and the counter-direction was examined by testing a 60cm lead at midpoint in the phantom and by adding 4 loops while maintaining the same effective length.

Results

The temperature change at the tip electrode increased 50.6°C when the 30cm lead was shifted from the centerline to the midpoint position and 51.1°C when shifted from the centerline to lateral position. The temperature change at the tip electrode increased 42.4°C when the 60cm lead was shifted from the centerline to the midpoint position. The temperature change at the tip electrode of a 60cm lead was 1.6°C lower than that for a 30cm lead when positioned at the centerline, and it was 9.8°C lower when positioned at the midpoint. The temperature change at the tip electrode was 2.9°C higher for an 8-wire 30cm lead than a 4-wire 30cm lead. Adding a loop at the top of the head and another at the IPG decreased the temperature change at the tip electrode of a 90cm lead attached to an IPG by 46.3°C. When an additional loop was added at the IPG the temperature change decreased to only 30.8°C from the no-loop configuration. Adding four clockwise loops to a 60cm straight lead at a midpoint lead position in the torso of the phantom decreased heating at the distal tip electrode by 17.6°C. The temperature measured at the tip electrodes fluctuated by less than or equal to 0.6°C when this test was repeated with counter-clockwise loops.

Conclusion

Lateral position of the lead is the most significant factor in the production of major temperature changes at the electrode tip. A 60cm lead experiences less heating than a 30cm lead, suggesting the 30cm lead was closer to the critical lambda/4 length for this phantom material. Decreasing the insulation/wire ratio by increasing the number of wires slightly increases heating. The significant reduction of heating with the addition of loops to the lead length seems to indicate that the loops act as RF chokes. However, the opposite effect is seen when a second loop is added at the IPG in the 90cm lead + IPG configuration. This testing supports many of the MR literature reports on the heating effects of conductive structures in tissue. This evaluation was not performed at clinical settings and is not intended to provide guidelines for clinical use.

References:

1. Rezai AR et al. "Neurostimulation Systems For Deep Brain Simulation: In Vitro Evaluation Of Magnetic Resonance Imaging-Related Heating At 1.5 Tesla". JMRI 15:241-250. (2002)
2. ASTM Standard F2182-02a "Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging".