

## HEATING OF THE INTERSTIM SACRAL NEUROMODULATION DEVICE IN A SIMULATED PHANTOM MODEL DURING LUMBAR AND PELVIC MAGNETIC RESONANCE IMAGING (MRI).

### Hypothesis / aims of study

All MRI studies other than a 1.5-Tesla MRI of the head are currently contraindicated in patients implanted with InterStim sacral neuromodulation devices. This contraindication exists primarily due to concerns over possible heating of the device during scanning. The aim of the study was to perform simulations to assess whether heating of the device would occur during lumbar and pelvic MR scanning under various scenarios.

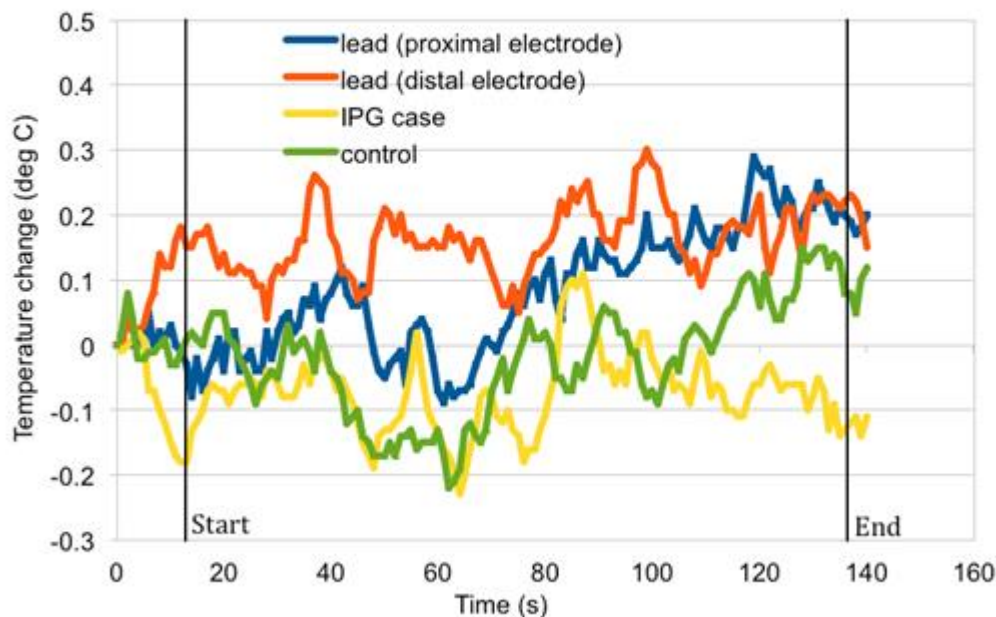
### Study design, materials and methods

Testing was conducted using a phantom model consisting of a polyacrylic gel-filled container that approximates a patient's head and torso. A tined lead connected to an InterStim II implantable pulse generator (IPG) was set up in the phantom positioned as it would be in a human. Four fluoroptic sensors were used to record temperature changes, one each on the IPG case, the "proximal" lead contact, the "distal lead contact", and one as a control in the gel away from the device. The phantom was then placed in a 1.5-Tesla MRI scanner. A standard lumbar and pelvic MRI protocol was performed which included six lumbar and eleven pelvic MRI sequences. The sequence that had the highest specific absorption rate (SAR) was then repeated, first with variations in the position of the phantom relative to the coil and then after disconnection and removal of the IPG.

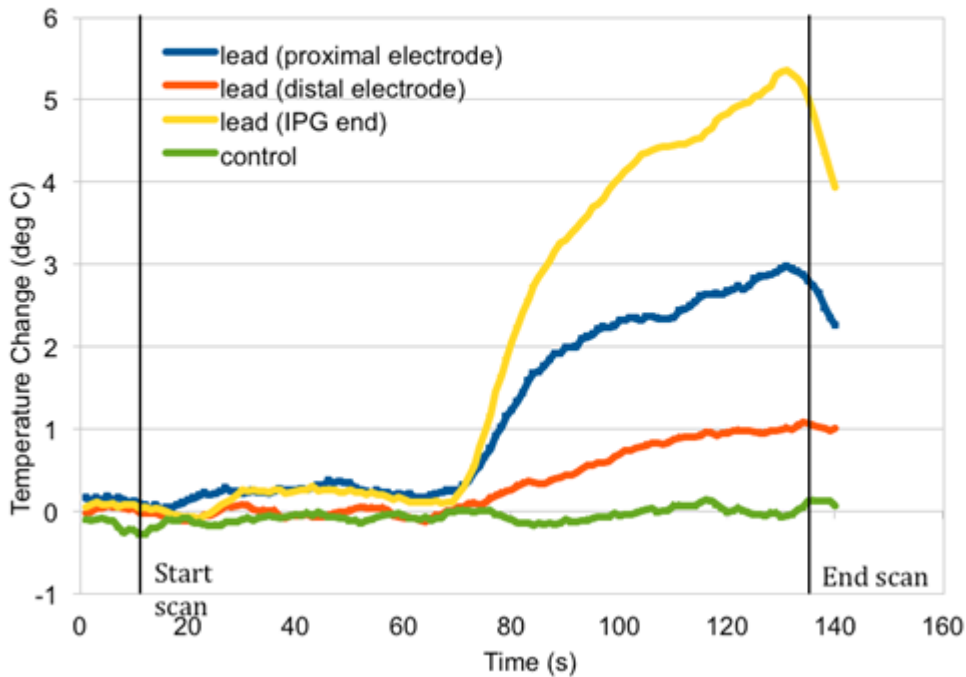
### Results

When the lead was connected to the IPG no significant temperature increases (greater than 1 degree Celcius) were detected for any of the lumbar or pelvic sequences. Figure 1 shows the temperature changes for the sequence with the greatest SAR. Similarly, none of the variations in the position resulted in significant heating. In contrast, figure 2 shows that when the IPG was disconnected and removed, heating of up to 5 degree Celcius was observed.

**Figure 1. Heating during Coronal HASTE sequence  
Intact system (lead connected to IPG)**



**Figure 2. Heating during coronal HASTE sequence  
Partial system (lead disconnected from IPG)**



Interpretation of results

These simulations provide preliminary evidence that the risk of heating is low for lumbar and pelvic MRI in the setting of an intact InterStim system (lead connected to an IPG). However, when the lead is disconnected from the IPG there appears to be potential for heating.

Concluding message

Further studies should evaluate the safety of MRI in patients with intact InterStim devices.

Disclosures

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