The safety of MRI in patients with implanted sacral neuromodulation systems: RF-induced heating

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Background
Sacral neuromodulation (SNM), an important therapy in a variety of lower urinary tract and bowel dysfunctions, requires the surgical implantation of at least one pulse generator and one electrode lead. To date, despite an encouraging preliminary clinical safety study [1], the presence of these implants is widely considered to be a contraindication for MRI. Advice from the device manufacturer specifically supports this view [2]. While appearing superficially similar to deep brain stimulation (DBS) instrumentation, for which MRI safety has been more extensively explored [e.g. 3, 4], these implants may have different internal design, lead lengths, and orientation due to their location in the sacral region. These factors may critically alter electromagnetic interactions during MRI. To investigate this we measured, in an anatomically appropriate test object, temperature rises produced during MRI with a SNM system, as the scanner bed was moved through a number of positions.

Methods
An implantable pulse generator (IPG, InterStim® Model 3023, Medtronic Inc, Minneapolis, MN, USA) and quadripolar SNM lead (tined lead Model 3093, Medtronic Inc, Minneapolis, MN, USA) were positioned on an artificial pelvis (figure 1) immersed in an aqueous gel (polyacrylic acid 8g/litre and NaCl 0.70 g/litre) with electrical and thermal characteristics similar to those of human tissue [5]. MRI was performed using a Siemens 3Tesla Tim Trio VB15 system in body-coil transmit mode for all measurements. Temperature was measured continuously at 4 positions (the most distal electrode contact [electrode 0], a medial electrode contact [electrode 1], the IPG case and a reference position), using an optical-florescence thermometer (Luxtron). A 6min 33s duration turbo-spin echo sequence was used and measurements performed first with the scanner landmarked on the phantom and the phantom and the thermometer (Luxtron). A

Results

The scanner-reported SAR for the same 4-slice protocol varied widely with bed position, as did the concomitant maximum temperature rises (ΔTs) during each acquisition. For the acquisition centred on the head position, ΔTs were less than 0.1°C. At other positions, ΔT time-courses were qualitatively similar to those reported previously for DBS implants [3, 4]. ΔT was greatest at the most distal electrode contact, while ΔTs at the IPG were relatively small. ΔT at the reference position was always ≤ 0.2°C. The maximum ΔT at any position for SARs = 2W/kg was 1.7°C. On repeating the prescans in the same phantom with the implant removed the scanner-reported SARs changed by 1% or less.

Discussion
The ΔTs obtained at bed position 0mm suggest that SAR-restricted MRI examinations centred on the brain are likely to be safe with regard to RF heating in SNM patients. However, for MRI examinations centred upon the cervical, thoracic, lumbar and sacral regions, both the scanner-reported SAR and ΔTs may vary widely with bed position. Removing the implant had little effect on scanner-reported SAR hence we conclude that this variability was caused predominantly by position-dependent differences in loading of the body-coil by the simulated patient. These results further emphasize the difficulties of using scanner-reported SAR as a safety measure in patients with this type of implant [6]. However, since ΔTs in all bed positions remained modest in physiological terms, it is possible that MRI may be safely performed in SNM patients if a reliable, possibly scanner-specific, metric for controlling RF heating can be determined.