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In vitro assessment of tissue heating near metallic medical implants by exposure to pulsed radio frequency diathermy

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Abstract

A patient with bilateral implanted neurostimulators suffered significant brain tissue damage, and subsequently died, following diathermy treatment to hasten recovery from teeth extraction. Subsequent MRI examinations showed acute deterioration of the tissue near the deep brain stimulator (DBS) lead's electrodes which was attributed to excessive tissue heating induced by the diathermy treatment. Though not published in the open literature, a second incident was reported for a patient with implanted neurostimulators for the treatment of Parkinson's disease. During a diathermy treatment for severe kyphosis, the patient had a sudden change in mental status and neurological deficits. The diathermy was implicated in causing damage to the patient's brain tissue. To investigate if diathermy induced excessive heating was possible with other types of implantable lead systems, or metallic implants in general, we conducted a series of *in vitro* laboratory tests. We obtained a diathermy unit and also assembled a controllable laboratory exposure system. Specific absorption rate (SAR) measurements were performed using fibre optic thermometry in proximity to the implants to determine the rate of temperature rise using typical diathermy treatment power levels. Comparisons were made of the SAR measurements for a spinal cord stimulator (SCS) lead, a pacemaker lead and three types of bone prosthesis (screws, rods and a plate). Findings indicate that temperature changes of 2.54 and 4.88 $^{\circ}$C s^{-1} with corresponding SAR values of 9129 and 17 563 W kg^{-1} near the SCS and pacemaker electrodes are significantly higher than those found in the proximity of the other metallic implants which ranged from 0.04 to 0.69 $^{\circ}$C s^{-1} (129 to 2471 W kg^{-1}). Since the DBS leads that were implanted in the reported human incidents have one-half the electrode surface area of the tested SCS lead, these results imply that tissue heating at rates at least equal to or up to twice as much as those reported here for the SCS lead could occur for the DBS leads.

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1. Introduction

Short wave diathermy has been used for many years to provide tissue heating for the treatment of several muscular conditions (Bruner and Leonard 1989, Dommerholt and Issa 2001). This type of diathermy is applied with short wave radio frequency radiation at 27 MHz and is known to induce voltages and currents that can result in tissue heating near implanted conductive medical implants (Geddes and Baker 1989). This is why the application of short wave diathermy over metallic implants is usually contraindicated. However, the recent report by Nutt *et al* (Nutt *et al* 2001, Nutt 2001, FDA MAUDE Database 2001a) demonstrates that these precautions are not always heeded. Nutt and associates report that a 70 year old patient with bilateral neurostimulators implanted with deep brain stimulator (DBS) leads for tremor reduction from Parkinson's disease (two Medtronic (Minneapolis, MN) Itrel model 7424 implantable generators each with a quadrapolar model 3387 electrode) was treated with pulsed short wave diathermy and suffered severe brain injury at the site of the implanted brain electrodes. The diathermy treatments were applied in the patient's jaw area to 'hasten recovery from the (oral) surgery', which likely exposed the implanted leads and pulse signal generator (leads implanted under the skin in the neck and generator in the upper chest area) to high levels of radio frequency (short wave) energy. Nutt and associates reported that the patient showed signs of significant brain tissue damage around the locations of the subthalamic electrode implant locations and the patient later died. They concluded that the patient suffered tissue damage around the DBS brain implanted electrodes induced by the application of diathermy. A second non-published incident was reported following diathermy treatment for a patient with implanted neurostimulators had diathermy for the treatment of kyphosis (FDA MAUDE Database 2001b).

Concern for the safety of patients with such implants as well as for patients with other types of metallic implants led the authors to perform a series of *in vitro* measurements. Using non-perturbing temperature probes, tissue heating was investigated near the conductive electrodes of a spinal cord stimulator (SCS) (Medtronic model 3487A quadrapolar lead with 7495 extension) lead exposed to pulsed short wave diathermy. Tissue heating was also investigated for a cardiac pacemaker electrode (Medtronic model 4523) and passive metallic implants (orthopaedic screws, a fracture plate and rods). Since this was a comparison of passive system components, and the possibility of destroying the electronics of the neurostimulator and pacemaker generators existed, it was decided not to attach the pulse generators to the lead systems during these tests. Measurements of the specific absorption rate (SAR) were performed because this parameter is a well-defined measure of the RF energy deposition in human tissue that can be applied to static phantom simulations and performed quickly before the effects of heat conduction and tissue cooling mechanisms begin to dominate. No attempt was made to average these point SAR measurements over a tissue mass. Significant tissue heating was generally confined to fairly small volumes around the implant, usually within a few cubic millimetres. The measurement of SAR is cited in the IEEE C95.1 RF human exposure standard (IEEE Standard for Safety Levels 1992) and is defined as the time derivative of the incremental energy ($\mathrm{d}W$) absorbed by an incremental mass ($\mathrm{d}m$) contained in a volume element ($\mathrm{d}V$) of given density (ρ)

$$\mathrm{SAR} = \frac{\mathrm{d}}{\mathrm{d}t}\left(\frac{\mathrm{d}W}{\mathrm{d}m}\right) = \frac{\mathrm{d}}{\mathrm{d}t}\left(\frac{\mathrm{d}W}{\rho \mathrm{d}V}\right).$$

SAR can also be shown related to the induced tissue temperature rise over unit time multiplied by the tissue specific heat capacity

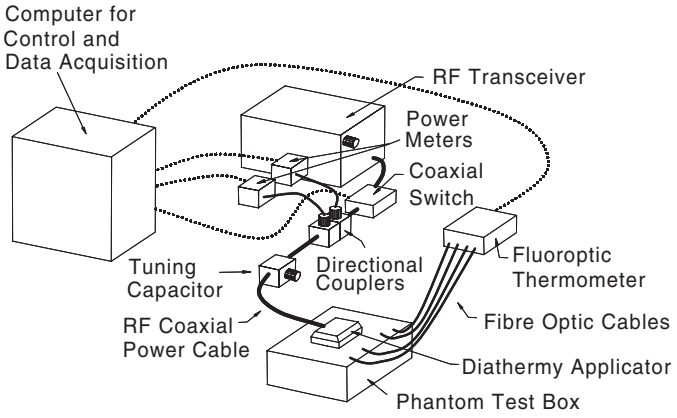

Figure 1. *In vitro* SAR measurement set-up.

$$\mathrm{SAR} = \left(\frac{\Delta T}{\Delta t}\right) c$$

where T is the temperature, t is time and c is the specific heat capacity.

2. Material and methods

Figure 1 shows the experimental set-up for the SAR measurements taken with the SCS and pacemaker leads and implantable bone fixation devices. The SCS lead was immersed in a human torso simulator phantom filled with gelled tissue phantom material that simulates the electrical properties of human tissue. SAR measurements were performed during exposure by the inductively coupled diathermy applicator, which was supplied radio frequency (RF) power via a coaxial cable through a tuning capacitor that was controlled and monitored using directional couplers. RF power was supplied by a 100 W RF transceiver with a controllable key switch that was monitored and controlled with a personal computer and custom software to control the exposure RF power and record temperature data. The SAR measurements were performed using a fluoroptic thermometer (Luxtron model 3100 fluoroptic Thermometer with the model SMM probe) to accurately measure tissue temperature rise while minimizing perturbations of the RF exposure fields. The SCS lead with tissue stimulation electrodes at the distal end was arranged in the phantom material 0.5 cm below the tissue phantom top surface simulating the implanted lead in the human body. The other devices were placed at the same 0.5 cm depth to facilitate SAR comparisons between the devices.

2.1. Human torso simulator phantom test box

The CDRH torso simulator that was used as the phantom text box consists of a plastic Rubbermaid 'Keepers' Clear Box (28 quart, 58.4 × 42.5 × 15 cm) filled with a gelled saline based phantom. For our tests the diathermy applicator rests on the top grid of the simulator to simulate the applicator located over the patient. The grid consists of a rigid plastic grid material (fluorescent light fixture cover, constructed of 0.16 cm wide × 0.87 cm thick beams spaced 1.35 cm apart in two directions) 0.873 cm thick that was cut to fit the torso simulator box's opening and align with the box's top rim. The grid forms an array of square holes approximately 1.27 cm (0.5 in) on a side over the entire top surface of the torso simulator to

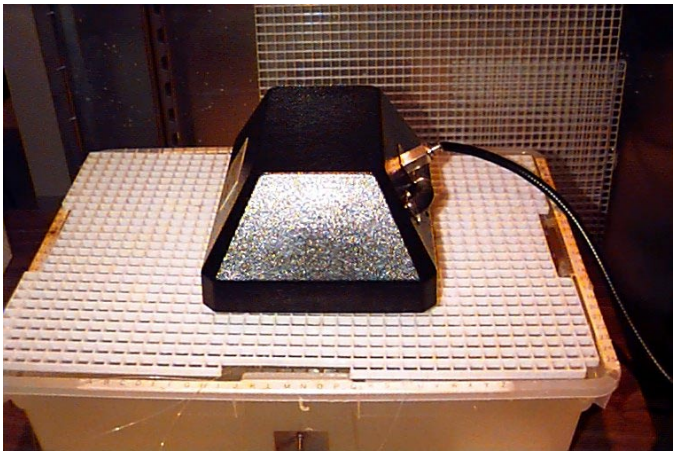

Figure 2. Diathermy applicator on support grid of the exposure phantom box.

support the applicator while minimizing the material between the diathermy applicator and the gelled phantom surface. Figure 2 shows the torso simulator (phantom) and the top support grid where the diathermy applicator is located during exposure and SAR measurements.

A second 23 × 36 cm grid is submerged in the phantom gel to support the implant being tested and maintain consistent separation distances between the implant, phantom material surface and applicator. The second grid can be adjusted so that the top of the implant being studied is located 0.5 cm below phantom surface and the applicator is 3 cm above the phantom surface.

The phantom material gel was composed of the following materials in percentages by weight:

1.46 hydroxy ethyl cellulose (HEC)
0.20 Dowicil 75 preservative
0.34 sodium chloride
98.0 water.

This produced a gelled material with a conductivity of 0.74 siemens m^{-1} at 27 MHz and a specific heat capacity (c) of 3600 J (kg °C)$^{-1}$. The simple *in vitro* test method used here is not intended to simulate the dynamics of blood and body fluid, but rather simulates the nearly instantaneous energy deposition and resultant tissue heating.

The Luxtron 3100 fluoroptic thermometer was used for performing accurate temperature measurements and minimizing perturbations to the RF fields applied by the diathermy applicator. The Luxtron system contains four fibre optic temperature sensors accurate to 0.1 °C at the point of calibration (17 °C in our case) that were placed at various distances from the implanted electrodes or metallic implant being tested. This temperature measurement system does not contain conductive material in the temperature sensors that could perturb the exposure fields, and it can be placed into the gelled phantom material. The Luxtron system was interfaced into the computer system for data acquisition.

2.2. Magnatherm diathermy machine

Nutt *et al* report that the DBS patient was treated with a Magnatherm diathermy machine that can have two active applicators operating at one time. Thus, we obtained a Magnatherm 1000

diathermy machine and an applicator to perform this study. The Magnatherm 1000 emits pulsed RF radiation with a pulse duration of 100 microseconds (μs) and variable pulse rate set by the operator. The pulse rate settings can be varied from 1 (with a 1433 μs period) to 12 (with a 153 μs period) that correspond to pulse rates between 0.7 and 6.5 kHz. RF power to the Magnatherm applicator is controlled by dial settings also ranging from 1 to 12. The reported patient injury occurred with a pulse setting of 8 corresponding to a pulse period of 242 μs or 4.1 kHz, and RF power setting of 10.

The Magnatherm diathermy machine does not have a RF power metre to monitor the power applied to the applicators, but there is a small waveform (oscilloscope-like) display that shows increased amplitude of the waveform as the dial setting is increased. In addition, because the Magnatherm RF power feed into the applicator is tuned to the coaxial feed power cables and is not the usual 50 Ω impedance, the introduction of direct RF power measurement components into the power feed line will create impedance mismatches that result in unknown uncertainties and potentially false readings. By analysing the RF power circuit a good estimate of the maximum RF power available to each of the two applicators can be obtained. Five pentode tubes (maximum plate dissipation of 40 W) wired in parallel make up the primary components of the RF power circuitry. Thus, assuming 100% efficiency, the maximum RF output for each applicator that is expected is 100 W (40 W $\times$ 5 tubes $=$ 200 W total/2 applicators $=$ 100 W). For our measurements a reference technique was utilized to determine the actual power that was delivered by the Magnatherm for the control settings described by Nutt *et al*.

2.3. Applicator power measurement and control

As noted above, the Magnatherm machine does not incorporate a direct way to measure the RF power being fed into the applicators, yet the RF output power, pulse duration and rate are critical parameters to characterize the diathermy exposures. An approach was conceived to measure the Magnatherm RF power to the applicator for the settings reported by Nutt and then substitute standard RF power equipment that could be directly measured and controlled to drive the applicator during the SAR measurements. First, the RF power was fed into one of the applicators by the Magnatherm machine using the dial settings reported by Nutt (pulse rate 8, amplitude 10) and measurements were recorded of the power induced onto a 1 cm diameter single-turn loop antenna probe placed on the back corner of the diathermy applicator (see figure 3). For the Magnatherm pulse rate setting of 8 and amplitude setting of 10 0.518 W was measured from the loop probe on the applicator. Measurements were made at other Magnatherm settings, with 1.83 W measured from the loop probe for the maximum pulse rate setting of 12 and maximum amplitude setting of 12. From these measurements it would be expected that the actual RF power used during the treatment was approximately 28% of the maximum power available for each applicator. Recall from the basic circuit analysis above that the maximum power expected to be available to each applicator was 100 W. Therefore, the power during treatment where the problems are reported should have been no higher than 28 W.

For a direct power measurement, the diathermy applicator was then connected to the substitute RF power and monitoring equipment (transceiver, directional couplers, power meters, switch and tuner seen in figure 1). The tuner was adjusted for maximum forward and minimum reflected RF power. The RF power to the applicator was increased until measurements from the loop probe matched the 0.518 W measurements seen with the Magnatherm machine in place. The net power being delivered to the applicator was then measured via the power meters to be 25 W, which agrees well with the maximum expected

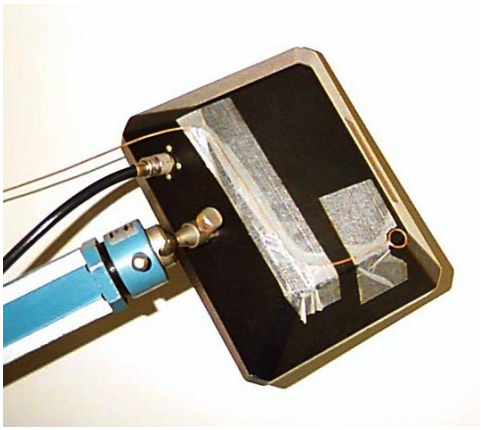

Figure 3. Single-turn 1 cm diameter coaxial loop taped to back corner of the diathermy head.

28 W calculated earlier based on probe measurements and circuit analysis. Given that 100% efficiency would not be expected from the diathermy machine, it seems reasonable to assume that the RF power delivered to the applicator during the DBS patient treatment reported by Nutt would most likely be closer to the actual direct measured value of 25 W. Thus, 25 W of RF power into the applicator was used for the experiments and SAR measurements to examine the *in vitro* tissue heating near the electrode leads and other implants.

2.4. SAR measurement procedure

Using the measurement set-up depicted in figure 1, each of the implants was placed in-turn under the phantom material surface and exposed to the RF fields from the diathermy applicator. The diathermy applicator was positioned on a 38 cm $\times$ 75 cm support grid 3 cm above the gelled phantom surface (figure 2). The implant was positioned at a depth of 0.5 cm below the phantom surface directly beneath the applicator. The effects of applicator alignment over the implant on the SAR were also examined, as well as the orientation of the applicator with respect to the long axis of the torso simulator. Figure 4 shows the relative position of the implanted leads, temperature sensors, torso simulator box and applicator. The four temperature sensors were placed near the four conducting electrode surfaces of the SCS lead, and at the two conducting surfaces and nearby for the pacemaker lead. The temperature sensors were placed near the smallest part of the conducting surface for the other implants because these locations are where we expect the electrical currents induced onto the implants to be concentrated and the tissue temperature to be most affected.

In vitro SAR measurements were performed with the following implanted device components:

- SCS lead
- pacemaker lead
- fracture plate and screws
- stainless steel (SS) rod
- titanium rod
- bone screw (3 mm diameter $\times$ 10 cm long).

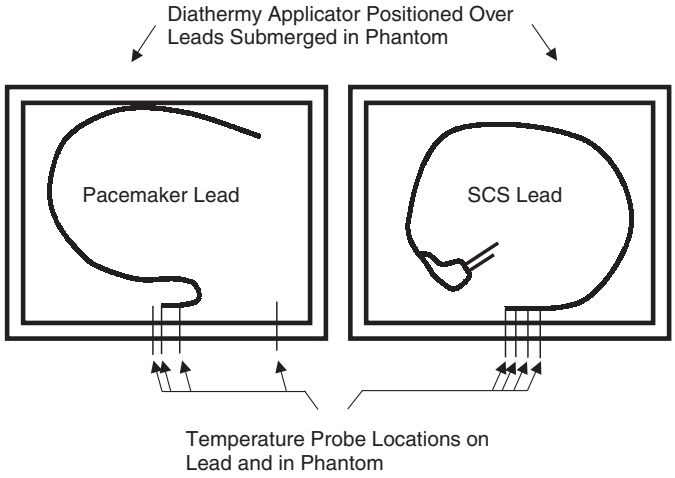

Figure 4. Diathermy applicator and temperature probe positions for measurements with the pacemaker and SCS leads.

Table 1. Measurement results and SAR findings for the *in vitro* implant diathermy exposures.

	Pacer leads	SCS leads	Fracture plate		SS rod	Titanium rod	3 mm diameter 10 cm screw
			Screw	End			
Time period (s)	0.99	1.49	5.21	5.49	4.28	4.01	1.32
Temp change (°C)	2.7	2.8	0.2	0.3	0.4	0.4	0.9
Average watts/time	14	18.5	26.64	25.16	24.71	26.31	24.83
dT/dt using 25 W (°C s^{-1})	4.88	2.54	0.04	0.05	0.09	0.09	0.69
SAR using 25 W (W kg^{-1})	17 563	9129	129	195	340	341	2471

Each of these devices was exposed to the radiation emissions from the diathermy applicator and temperature measurements recorded via the Luxtron. The temperature increase from room temperature during the first few seconds of heating (from 1 s for the pacemaker lead to 5.5 s for the fracture plate) was measured at various locations near the implants. Longer time periods were needed for the larger implants in order to assure that the appropriate temperature change was measured. SAR was calculated from the change in temperature measurement over time for each of the implants. In the case of the fracture plate, temperature measurements were taken near the small end of the plate and near the tip of one of the screws that are used to hold the plate in place over bones.

3. Test results

Table 1 shows the data recorded from the probe near each implant that had the maximum temperature rise during diathermy exposure. The table reports the time period used to determine the temperature rise, the change in temperature measured in degree Celsius (°C), the average power into the applicator divided by the time period, the change in temperature divided by the time period using 25 W of diathermy power, and the SAR using 25 W of diathermy power. The power of 25 W was used in the calculation of the last two set of values

because that was the power believed to have been used during one of the treatments as has been previously discussed. The highest SAR values were found near the electrodes of the implanted leads, and the lowest values were seen near the fracture plate.

As an example of the temperature distributions recorded during this testing, refer to the probe locations of figure 4. From left to right, for the pacemaker lead, the recorded dT/dt using 25 W ($^{\circ}C\ s^{-1}$) were 1.19, 4.88, 3.96 and 0.16. These corresponded to the locations 2 mm from the distal tip electrode, distal tip electrode, ring electrode, and 10 cm away from the lead in the phantom. Similarly, for the SCS lead, 1.54, 1.45, 2.54, 2.45 were recorded. These were at the four electrode locations. The maximum values of 4.88 for the pacemaker lead and 2.54 for the SCS lead were selected for inclusion in table 1 for comparison to other implants.

4. Discussion

Tissue heating by RF diathermy near conductive implants has been noted for many years, which is why there are precautions about use of diathermy over implanted medical devices. The conductive implant acts like an antenna coupling into the RF diathermy energy and concentrating the coupled currents at points on the implant that are physically small creating high current density that in-turn lead to tissue heating. Similar tissue heating near implanted metallic medical devices has been noted for exposure to the large magnetic and RF fields from magnetic resonance imaging (MRI) systems (Ho 2001, Nyenhuis *et al* 1999, Sommer *et al* 2000). From our measurements, we observed that the efficiency of the energy transfer to the implant and consequential tissue heating appears to be highly dependent on several factors, including:

- the distance from, and location and orientation of, the diathermy applicator relative to the implant;
- the length and size of the implant;
- the shape of the implant, especially the existence of sharp points or edges on the implant at the ends of the implant and,
- if there is insulation covering portions of the outer surface of the implants.

The hypothesis is that the electromagnetic energy from the diathermy applicator is 'collected' by the conductive (metallic) implant, and redistributed in the form of radio frequency electrical current that is conducted into tissue surrounding the conductive surfaces of the implant. The concentration of these currents at the implant sites with small cross-sectional areas creates high current density that results in heating of the adjacent tissues. The rate of temperature rise and the final temperature of the tissues are related to the total size and shape of the implanted metal–tissue interface, the level of RF exposure at the implant and the specific heat capacity of the implant and surrounding tissue. The presence of insulation along portions of the implant (in the case of the implanted leads) reduces the area of direct boundary between the metallic implant and the tissue, which appears to lead to higher tissue heating and resultant SAR values at the electrode/tissue interfaces. This would also account for the larger SAR value seen from the pacemaker lead compared to the SCS lead. The pacemaker lead has only two small conductive surfaces near its tip, while the SCS lead has four conductive surfaces near the tip.

The SCS lead has similar construction (4 in-line electrodes) as the patient's DBS leads described by Nutt *et al* (2001). The electrode diameters are the same (1.27 mm), but each of the SCS electrodes is twice as long. The result is that the SCS lead has twice the electrode surface area in contact with tissue; and therefore, it can be expected that it would heat tissue at one-half the rate of a DBS lead under identical RF exposures.

In general, the SAR measurements around the six metallic implanted devices showed that the maximum heating was observed at the ends of the implant, with the highest values occurring near the implants with the smallest end area. The implanted lead tips and sharp tip of the bone screw were the locations seen with the highest SAR. Significant tissue heating was generally confined to fairly small volumes around the implant, usually within a few cubic millimetres. The highest SAR values were seen near the conductive tips of the two implanted leads, with the maximum SAR observed for the pacemaker lead.

5. Summary and conclusions

The reports of significant consequences for patients with implanted deep brain neurostimulators following exposure to pulsed RF diathermy led the authors to investigate the potential for tissue heating near various conductive implanted medical devices. Obtaining the same type of diathermy machine mentioned in the Nutt *et al* report, an *in vitro* exposure system was developed to model the situation experienced by that patient. Because the Magnatherm diathermy machine does not contain a direct way to measure the RF output into the applicator, the authors developed a means to quantify the RF power to the applicator and replaced the diathermy machine with a more reproducible and controllable RF system. SAR measurements were performed near six different implanted medical devices and components: two active implant electrode leads (SCS, pacemaker), a bone fracture plate, two bone rods and a bone screw.

The results of the SAR measurements reveal the highest SAR values near the smallest area of contact between the conductive implant surface or electrode surface and the tissue. The largest SAR values were seen at the conductive electrode tips of the SCS lead and the pacemaker leads. Since the DBS lead has one-half the surface area of the tested SCS lead, these results imply that tissue heating at rates equal to or up to twice as much as those reported here for the SCS lead could occur for the DBS leads. These results clearly suggest the brain tissue damage seen by Nutt *et al* was the result of tissue heating caused by the RF diathermy. Since the DBS electrodes are implanted in critical areas of brain tissue heating of these sensitive tissues is likely to have profound effects on the patient. As a result of the report by Nutt *et al* and other information, the DBS manufacturers (Medtronic (2001), Cyberonics (2001) and Advanced Neuromodulation Systems (2001)) issued warnings to avoid RF, microwave and ultrasound diathermy exposure. Additionally, manufacturers of many types of active implants with leads, and the leads themselves have placed warnings in their labelling, i.e., pacemakers, spinal cord stimulators. Diathermy equipment itself is contraindicated for use on patients with implanted leads as well. In addition, the MDA issued a safety alert (2001) and the FDA issued a Public Health Notification (2002) warning against the use of short wave (RF) or microwave diathermy in patients with implanted leads.

In the case of the implanted leads there is significantly more tissue heating as evidenced by the much larger SAR values of 9129 and 17 563 W kg^{-1} near the electrode conducting surfaces of the SCS and pacemaker leads. The corresponding temperature changes associated with these SARs are 2.54 and 4.88 $^{\circ}C\ s^{-1}$. We surmise that this is due to 'collection' of the RF energy from the diathermy along the length of the lead and then concentration of the energy at the low impedance areas of direct tissue/electrode contact. The energy collection by the larger surface area of the fracture plate and rods appear to be quickly dissipated over the entire contact area with the tissue, with some concentration at the ends of these implants. SARs ranged from 129 to 341 W kg^{-1} for these implants which correspond to temperature changes from 0.04 to 0.09 $^{\circ}C\ s^{-1}$. The diathermy energy appears to be more concentrated at the screw tip implant with an SAR of 2471 W kg^{-1} and temperature change of 0.69 $^{\circ}C\ s^{-1}$ than for the

other passive-type implants, but the energy likely bleeds off over the entire conductive surface of the screw. SAR values were seen to be higher for the pacemaker lead electrodes than the SCS electrode conducting surfaces. This would suggest that implanted pacemaker leads may be more vulnerable to tissue heating from exposure to RF diathermy. A search of incident reports related to pacemaker devices did not find evidence of patients with these devices having experienced problems from diathermy. Nevertheless, it appears clear that significant tissue heating will result from the application of RF diathermy over conductive metallic implants. Because of the potential for tissue damage from this unintended tissue heating near medical implants, especially active implants, RF diathermy treatment should be avoided over patient implants.

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