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Full Paper

Measuring RF-induced currents inside implants: Impact of device configuration on MRI safety of cardiac pacemaker leads

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KEYWORDS

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ABSTRACT

Radiofrequency (RF)-related heating of cardiac pacemaker leads is a serious concern in magnetic resonance imaging (MRI). Recent investigations suggest such heating to be strongly dependent on an implant's position within the surrounding medium, but this issue is currently poorly understood. In this study, phantom measurements of the RF-induced electric currents inside a pacemaker lead were performed to investigate the impact of the device position and lead configuration on the amount of MRI-related heating at the lead tip. Seven hundred twenty device position/lead path configurations were investigated. The results show that certain configurations are associated with a highly increased risk to develop MRI-induced heating, whereas various configurations do not show any significant heating. It was possible to precisely infer implant heating on the basis of current intensity values measured inside a pacemaker lead. Device position and lead configuration relative to the surrounding medium are crucial to the amount of RF-induced heating in MRI. This indicates that a considerable number of implanted devices may incidentally not develop severe heating in MRI because of their specific configuration in the body. Small variations in configuration can, however, strongly increase the risk for such heating effects, meaning that hazardous situations might appear during MRI. Magn Reson Med, 2009. © 2009 Wiley-Liss, Inc.

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ARTICLE TEXT

With the rapidly growing availability of magnetic resonance imaging (MRI) in clinical routine, this imaging technique is becoming increasingly important in a large number of clinical applications. This is justified by the excellent imaging abilities, the noninvasiveness, and the rare side effects compared to other diagnostic procedures. However, along with the still growing usage of MRI, safety aspects are becoming increasingly relevant. This is especially the case if MRI investigations include the use of additional technical/electric equipment inside the scanner, as in interventional MRI, or if patients with medical implants are scanned. Elongated objects like (ECG) cables, guide wires, or pacemaker leads have specifically been shown to add to the potential patient risk in MRI, as such electrically conducting structures may interact with the electromagnetic fields inherent to this imaging technique. In particular, these devices can concentrate radiofrequency (RF) power emitted by the MR system's RF transmit coils, potentially causing high power depositions in the vicinity of these objects. Severe MRI-related RF heating of electrically conducting structures and associated risks have been shown for interventional guide wires ([1-3]), ECG cables ([4]), as well as implanted electrodes for deep brain stimulators ([5][6]) and cardiac pacemaker leads ([7]). As a result, ongoing discussions focus on the question of how to avoid such incidents in the future.

Recent studies have suggested a strong impact of the implant position inside the surrounding medium on the amount of implant heating generated. Various phantom studies have been performed with straight lead or wire paths in an effort to allow for strong heating effects combined with good reproducibility ([8][9]), whereas in others a small number of selected configurations mimicking anatomical pathways were used ([10][11]). It has been shown that, in general, the highest RF pickup, and therefore implant heating, appears if both the phantom/body is centered inside the scanner bore along the z-axis, implying an overall high energy transfer ([7][12]), and if the implant roughly follows the course of the most intense RF-related E-fields induced inside the surrounding medium ([13]).

Meanwhile, it is as yet an open question to what extent phantom measurements with specifically configured lead paths - for example, straight wires - might be extended to other geometric lead paths or even the situation in the human body. It might even been argued that phantom measurements with straight lead paths highly overestimate the risk of MRI-related burns near leads or wires compared to anatomically feasible device geometries. This point of view is supported by the growing number of studies reporting on successful MRI of pacemaker patients without the occurrence of adverse events ([14][15]). On the other hand, studies reporting significant changes in pacing threshold after MRI can be seen as evidence for RF-related burns ([16]). There are also documented deaths of pacemaker patients who underwent MRI ([17][18]), and although the exact circumstances are not described in the literature, cardiac arrhythmia caused by RF-related heating cannot be excluded as cause of death ([19]). A recent study reporting on significant serum troponin increase in some pacemaker patients who underwent an MRI suggests that the described heating effects seem to appear in some cases, even if state-of-the-art MRI of pacemaker patients is performed with great care ([20]).

Over the last years, measurements in gelled saline phantoms with fluoroptic temperature measurement systems have become the gold standard in basic research of RF-related implant heating in MRI ([21]). Nevertheless, this measurement approach is associated with a couple of disadvantages, mainly that precise measurements are very time consuming and particularly hard to achieve. It has been shown that even for in vitro measurements with fluoroptic temperature probes the error can be as high as 45% ([22]). On the other hand, there is not yet an in all respects adequate alternative for these temperature measurements. In particular, precise in vivo measurements of MRI-related heating effects are hard to achieve with any technique currently available. A different approach to measure an implant's potential for RF-related heating would be to measure the electrical currents that are induced inside the implant by the absorbed RF energy, as these induced currents are held to be directly responsible for heating at high resistance locations within the circuit, as at small device-to-tissue surfaces ([23]).

In this study, our focus was an estimation of how much the heating of a pacemaker lead might vary in dependence on its anatomically predetermined pathway inside the human body. These situations were also compared to straight lead paths frequently used in phantom measurements. Furthermore, we aim for a deeper insight into RF heating mechanisms of elongated conductive implants in MRI through direct measurements of the induced electrical currents within the implant. By development of an appropriate measurement technique, we sought to enable precise and at the same time fast measurements of the RF heating potential, allowing us to run through a large number of possible pacemaker configurations. This work should enable further specification of patient risk in the future in terms of high-risk and low-risk situations.

METHODS

Rationale for Current Intensity Measuring Technique

A custom pacemaker lead based on a commercially available lead design was built to allow for the measurement of RF-induced currents inside the implant, in order to enable precise and reasonably fast investigations of MRI-related heating effects in various implant configurations. The electrode (unipolar pacemaker lead with coiled metal conductor and passive anchor fixation; total length 53 cm including IS-I connector) was equipped with a sensor directly behind the lead tip based on the design of a probe for electric field measurements in MRI, which has been recently established by our group ([13]). It basically consists of a light-emitting diode (LED) supplied by a rectifier bridge, which transforms the electrical quantity to be measured into a light signal. The light signal from the LED is forwarded by an attached fluoroptic cable to a phototransistor outside the scanner room, where the light signal is converted into an electrical signal, linearly amplified, and then measured with a true root mean square (RMS) multimeter (model 87V, Fluke, Everett, USA) (Figs. 1,2).

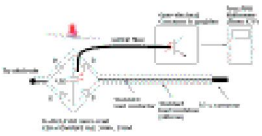


Figure 1. Circuit diagram of the sensor for measurements of RF-induced currents in MRI.
[Normal View 24K | Magnified View 52K]

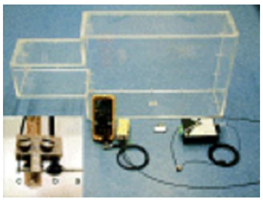


Figure 2. Experimental setup for measurements of the RF-induced current intensity inside the pacemaker lead and heating at the implant tip during MRI. The pacemaker device was positioned inside the gel-filled acrylic phantom in the MR scanner and the lead tip - and therefore lead pathway - was then varied according to the measurement matrices. The close-up view shows the pacemaker lead (a) equipped with both the current sensor (b) and a fluoroptic temperature probe (c) at the lead tip, all fixed to the wooden frame used to vary the lead tip position inside the phantom.
[Normal View 55K | Magnified View 237K]

As learned from preliminary measurements ([13]), this sensor can be assumed to provide a nearly linear characteristic within the intended working range. Therefore, the output of the measurement amplifier is expected to be proportional to the electric current intensity (I) through the LED. Because the probe is placed very close to the tip, the current measured by the probe is assumed to be equal to the current flowing at the tip into the tissue. Consistent with electric theory, the squared RMS value of this current is proportional to the electric power transformed into heat, which itself linearly contributes to the temperature increase. Taking these assumptions into account, a quadratic relationship between the temperature increase at the lead tip and the output of the measurement amplifier is expected.

This approach allows for subsequent calculations of the temperature increase (■*T*) adjacent to the lead tip, which depends, however, on the tip geometry and the medium properties (conductivity, thermal coefficient) in the area surrounding the lead tip (■*T* proportional to the electric power converted into heat, the square of the induced voltage, as well as the square of the electric current intensity) ([23]). Once the coefficients of the quadratic equation are assessed by a calibration procedure for this specific lead and a given medium using standardized temperature measurement equipment, ■*T* can be easily computed from the amplifier output voltage. The light signal actually encodes the envelope of the RF pulses, but the relationship between the RMS value of the current and the RMS value of the amplifier's output voltage is still linear.

Because the gel used (described below) effectively avoids heat convection, and the RF power is constant over time, the power is the only determinant for the temperature increase. Therefore, ■*T* even after several minutes of scanning is proportional to I^2, which can be measured quickly by the described electric probe. Consequently, this method allows for computing the temperature increase within only a few seconds, which otherwise would require several minutes of scanning for each temperature data sample. Hence, the method is uniquely suited for the acquisition of a large number of data points for high resolution temperature maps in a reasonably short time.

Current Intensity Measurements in Anatomically Matched Configurations

All MRI experiments were performed on a 1.5T whole-body MR scanner (Magnetom Avanto, Siemens Healthcare, Erlangen, Germany). An acrylic plastic phantom according to ASTM F2182-02a ([21]) was used to provide a surrounding approximating the size and shape of the human head and torso ([5]). This phantom was filled with 45 kg of a viscous hydroxyethylcellulose gel ([13]), providing conductivity similar to that of body tissue (0.47 S/m) ([21]). The phantom was registered supine, head first, and the geometric center of the torso section was positioned in the isocenter of the scanner bore.

The custom pacemaker lead was connected to the RV-port of a commercial cardiac pacemaker (Stratos LV, Biotronik GmbH, Berlin, Germany), and inserted into the phantom gel. A fluoroptic temperature probe (STF-10 connected to Labkit m3300, Luxtron, Santa Clara, CA) was attached with its temperature-sensitive tip perpendicular to the lead tip for calibration of the current measurements. A small plastic clamp was used to avoid movement of the probe in relation to the lead between the different measurements (Fig. 2, close up). The RF-induced current intensity within the pacemaker lead and temperature evolution at the lead tip were then measured simultaneously while running a conventional steady state free precession (SSFP)-based TrueFISP sequence, with the sequence parameters set as follows: repetition time = 3.29 ms; echo time = 1.65 ms; matrix = 64 × 64; field of view = 500 mm; slice thickness = 10 mm; slices = 1; averages = 32; number of measurements = 45; acquisition time = 5:06 min. Provided reasonable scanner transmit power, this pulse sequence can serve as a correlate for commonly used imaging sequences in thoracic MRI. A series of measurements was performed with a constant pacemaker device/lead configuration while the flip angle was varied between 10 and 63°, resulting in variation of the system provided scanner's transmit power between 3.3 and 132.4 W and a corresponding indicated specific absorption rate (SAR) between <0.1 and 2.8 W/kg. On the basis of the results, the current intensity sensor output was correlated to the temperature elevation values as described.

To mimic the situation in the human body regarding device position and lead pathway, an overlay of chest X-rays of 20 patients with cardiac pacemakers implanted in the left or right pectoral region was scaled to the phantom size. The geometrical coordinates of the implanted pulse generator (IPG) and lead were extracted for each patient, so that both an averaged geometric implant configuration and the outer limits of device implantation site and lead pathways in the body could be determined. The pacemaker device and lead were positioned in the phantom in different configurations on the basis of these overlays: three IPG positions on each side of the body (left/right pectoral region) were chosen covering the medial, lateral, and superior IPG position maxima that were found; the device and the first centimeters of the lead were attached to a plastic grid inside the gel according to the anatomic images.

Although the position of the IPG was held constant, the tip of the pacemaker lead with the incorporated sensor was fixed to a movable wooden frame attached to the phantom. The lead tip position was varied inside the predetermined approximate cardiac volume (as three-dimensionally acquired by evaluation of frontal and lateral X-rays) for each IPG position. The current intensity at the lead tip was then acquired running one TrueFISP experiment in each configuration with the flip angle set to 63° and the acquisition time set to 4.9 s (number of averages = 16, number of measurements = 1). Resulting temperature elevation values (■*T*) were calculated on the basis of the described calibration process. To get an estimate for the measurement error, the temperature rise was additionally determined with the fluoroptic temperature measurement system in an arbitrarily chosen assortment of these experiments (*n* = 30) using a total acquisition time of 5 min as for the calibration measurements. Finally, a set of experiments with straight lead configurations close to the phantom wall along the *z*-direction of the scanner bore was performed to compare configurations found in the human body with configurations that are commonly used in RF heating investigations in terms of heat developed.

RESULTS

Calibration of Current Intensity Measurements

First the calibration procedure was performed with variable transmit power as described. The ■*T* values indicated by the temperature measurement system after 5 min of heating are plotted over the amplifier output (RMS value) of the current sensor (Fig. 3a). To prevent dislocations of the temperature probe, the IPG and lead were not moved during the entire calibration process. Each experiment of temperature measurements was followed by a cooling period, typically in the range of 5 to 15 min, to allow the gel to return to baseline temperature, preventing subsequent measurement errors. The quadratic function assumed by electric theory was fitted to the data calculating the equation coefficients by the least mean square method

$$y = 2E\text{-}05^2 - 0.0086x + 0.9993(R^2 = 0.9997).$$

The linear term and the offset in this equation indicate a shift of the parabola ($y = a_* x^2$), which is based on the fact that the linear part of the LED characteristic does not go through the origin.

Figure 3. Measurements of current intensity induced inside the

pacemaker lead and corresponding lead tip heating in various configurations. a: Measurements with varying MRI transmit power in one device configuration. The extracted calibration was thereafter used to calculate ■*T* values from the current measurements. Note that a minimum current intensity is required to start lighting the LED in the sensor, which is apparent in the offset of the equation. b: Correlation of measurement results acquired with both measurement techniques in various implant configurations (*n* = 30) using the specified imaging sequence. ■$T_{measured}$: temperature elevation measured with the fluoroptic temperature measurement system. ■$T_{calculated}$: current intensity values measured with the custom sensor and converted to ■*T* values by means of the calibration procedure (a).
[Normal View 32K | Magnified View 72K]

Considering these terms, the temperature increase at the lead tip was calculated for all following current intensity measurements. The correlation of the calculated and actually measured ■*T* values in the later experiments (arbitrary assortment within the measurement matrices) is shown in Figure 3b (y = 0.9587x + 0.8395).

It should be noted that the correlation between calculated and measured temperature was modestly disturbed by changes in pacemaker device position performed in between the measurements and especially by movement of the lead tip (R^2 = 0.9768 vs. R^2 = 0.9974). Consecutive current measurements in the same configuration (*n* = 10) revealed a standard deviation of less than 1% of the measurement value.

Measurements in Anatomically Matched Configurations

The induced current intensity inside the pacemaker lead was measured in a total of 720 IPG position/lead path combinations on the basis of the X-ray photograph-matched feasible anatomic geometries. A representative overlay of a chest X-ray with the lead pathways of 20 pacemaker patients is shown in Figure 4. The region of interest for the IPG and lead tip position, as extracted from the different lead paths depending on patient anatomy and surgery technique, is also shown.

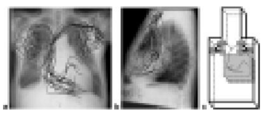


Figure 4. Pacemaker position and lead pathway in the human body. 20 thoracic X-ray photographs in pacemaker patients were evaluated and scaled to equal size. The coronal (a) and sagittal (b) overlays show ventricular leads in black and atrial leads in white. The extracted IPG positions were subsumed to three representative positions for both the left and right pectoral regions. As the lead pathways in the large veins showed only minor differences, one presumable course was determined for each side. The pathway of the distal part of the lead and the position of the lead tip showed remarkable variability, particularly for LV leads, virtually covering the entire heart. Therefore, a three-dimensional approximate heart volume was assessed, which was fully probed with the lead tip in the subsequent investigations, varying the lead tip to 120 positions within this volume per IPG position. c: In vitro experimental setup extracted from the X-ray photographs. Tested IPG positions are marked as crossed circles; the approximate three-dimensional cardiac volume, which was mapped for each IPG position, is represented by the gray rectangular area.
[Normal View 54K | Magnified View 174K]

The highest current intensity induced inside the lead corresponding to an anatomically matched configuration correlated to 45.9°C ■*T* (IPG close to the right thoracic wall, lead tip position atrium/vena cava inferior). The lowest current intensity was found with the tip in the same region, but the IPG on the left phantom wall. A mean temperature elevation of 10.4°C was found for all tested configurations with the IPG in the right pectoral region (highest overall value: 45.9°C ■*T*, lowest overall value: 0.8°C ■*T*). With the IPG on the left, the mean temperature elevation was 2.9°C (highest overall value: 35.5°C ■*T*, lowest overall value: <0.1°C ■*T*). An overview on the current measurement results dependent on IPG position and lead path is given in Figure 5.

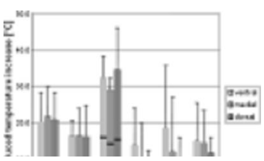
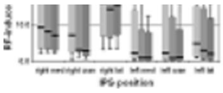


Figure 5. Pacemaker lead tip heating dependent on IPG position and lead pathway, as converted from the current measurements inside the lead as described. For each IPG position (medial, superior, and lateral in both right and left pectoral regions) the lead tip position, and



therefore lead pathway, was varied over three surface areas orientated in a coronal plane (ventral, medial, and dorsal), thereby covering the entire cardiac volume. The graph shows the absolute range of heating values (in °C) in each of these measurement matrices (each containing various relating lead paths), reaching from the maximum to the minimum value measured in each IPG position (black outer bars), the median (black middle bars), and the 10% and 90% percentile (gray bars).
[Normal View 31K | Magnified View 61K]

In summary, shifting the lead paths to an either more ventral or dorsal region only slightly modified the induced currents. In contrast, a shift of the IPG position significantly altered the current intensity in the implant for particular lead paths in the coronal plane. Moving the IPG from the right to the left pectoral region had an especially high impact on the current intensity values. Figure 6 summarizes the configuration-dependent measurement results focusing on the lead pathway in the coronal plane for all right pectoral IPG positions, Figure 7 for all left pectoral IPG positions.

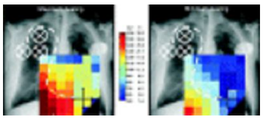


Figure 6. Pacemaker lead heating of a single chamber system with the IPG in the right pectoral region dependent on the lead tip position. Three IPG positions were investigated, with the associated lead paths covering the entire predetermined approximate cardiac volume. The induced current intensity inside the implant was determined in each configuration and then converted to lead tip heating values as described. Maximum (left) and minimum (right) implant heating is shown dependent on the lead tip position/lead pathway in the coronal plane, summarizing the measurement results in different IPG positions (medial/lateral/superior) and lead tip positions (measurement surface areas ventral/medial/dorsal).
[Normal View 62K | Magnified View 198K]

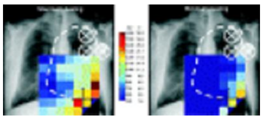


Figure 7. Pacemaker lead heating of a single chamber system with the IPG in the left pectoral region dependent on the lead tip position. Three IPG positions were investigated, with the associated lead paths covering the entire predetermined approximate cardiac volume. The induced current intensity inside the implant was determined in each configuration and then converted to lead tip heating values as described. Maximum (left) and minimum (right) implant heating is shown dependent on the lead tip position/lead pathway in the coronal plane, summarizing the measurement results in different IPG positions (medial/lateral/superior) and lead tip positions (measurement surface areas ventral/medial/dorsal).
[Normal View 61K | Magnified View 194K]

In comparison to the anatomically matched device configurations, implant heating was even more pronounced in straight lead configurations close to the phantom wall along the *z*-direction. Here, the highest RF pickup was found in the left ventral corner, correlating to 68.5°C ■*T*. Moving the whole device dorsally inside the gel while maintaining its configuration, ■*T* decreased to 35.48°C.

DISCUSSION

The insights gained in the present study extend the options in future investigations focusing on the problem of implant safety in MRI. The sensor technique which was developed is suitable for measuring the RF-induced current intensity inside the pacemaker lead with expedient precision to conclude the resulting heating values at the lead tip surface under the particular circumstances. RF heating at the lead tip was found to be a quadratic function of the current intensity induced inside the lead, which is in line with theoretic assumptions.

In our measurements, we found higher scatter between the calculated and measured temperature elevation depending on whether the lead tip was moved (standard deviation 0.88°C) or left in place between the different measurements (SD <0.34°C). The most likely explanation for this observation is that, despite very robust fixation, microdisplacements of the fluoroptic probe relative to the lead tip seem to transpire when moving the tip in the viscous gel. Fluoroptic temperature measurement systems, despite currently being the gold standard in MRI-related implant heating investigations, in general suffer from the problem that RF heating is very localized to distinct hot spots. Thus, exact positioning of the probe is critical, leading to potentially high errors and low reproducibility even in ex vivo phantom measurements under standardized conditions and with the probe directly fixated to the heating source ([22]). In the current study, this difficulty in performing precise fluoroptic RF heating measurements had only a small impact as only one lead type was employed and the sensitive part of the fluoroptic probe was permanently fixed perpendicular to the lead tip inside the gel, restricting the error of the temperature measurements. Thus, the fluoroptic temperature measurements were in good agreement with the current intensity measurements, even when the lead tip was moved inside the phantom. Even though small alterations of the lead are required for our measurements, these changes rarely affected the induced currents in the lead. Recently, a measurement method has been introduced using inductive coupling for measurement of RF-induced currents; therefore, under certain circumstances being suitable for current measurements without implant alterations at the expense of a potentially higher measurement error ([24]).

Precise measurements of heating effects typically require minutes or even hours if confounding effects like heat dispensation need to be accounted for, while in contrast, the induced current intensity can be determined precisely in only a few seconds. Therefore, this measurement method offers distinct advantages if a large set of experiments is required and measurement precision is critical, as in large mapping studies. Current intensity measurements could also be used to calculate worst case induced heating under a condition of interest. Preliminary investigations proved the induced currents inside the implant to be mainly dependent on the conductivity of the surrounding medium. Fluoroptic probes or thermocouple wires ([7]) presently both suffer from the problem of frequent underestimation of the heating that might occur within the tissue adjacent to the implant, mainly because probe positioning problems will often lead to an underestimation of the heating effects that occur ([22]), but also the lead-to-tissue contact is critical for the actual amount of heating. Measurements of the RF-induced current intensity in implants in contrast offer the benefit of being suitable to calculate worst case implant heating (direct tissue contact, no blood flow, etc.), preventing possible nonobservance of potential hazards. The introduced sensor can easily be implemented into commercially available pacemaker leads or catheters.

Our measurements point out the strong impact that device case position and lead path have on RF-related implant heating of cardiac pacemaker systems in MRI. The specific high-risk and low-risk lead paths differed in some cases strongly for different IPG positions. We found no IPG position that was associated with only noncritical lead tip heating values if all reasonable lead configurations are taken into account (Fig. 5). The results do not suggest large differences in the general potential for implant heating dependent on IPG implantation in either the left or right pectoral regions, even though in the present measurement matrix particularly strong heating effects were found more frequently and the mean temperature elevation for all lead tip configurations was significantly higher with the IPG on the right. There are probably two main reasons for the difference in heating patterns with the IPG in either pectoral region: first, analogous to the situation in the human body the implant configurations are not exactly symmetric for left and right pectoral IPG situations, as the first centimeters of the lead follow the run of the vena cava superior located in the right thoracic region and the heart is on the left side (Fig. 4). Second, as recently shown, the circularly polarized electric fields of the MR scanner have been shown to generate asymmetric E-fields even inside the homogeneous, left-right symmetric phantom used in the current study, therefore accounting for different heating patterns on either side even without an asymmetric conductive implant ([13]). This asymmetric response is an important aspect that should be taken into account if investigations in the field of MR safety draw conclusions from a limited amount of experiments without comparing configurations on the left and right side of the phantom/body.

Looking at specific lead paths, the highest implant heating for lead paths found for typical right ventricular pacemaker leads appeared if the device case was placed in the left pectoral region, whereas implant heating for lead paths found for typical atrial leads was negligible with the IPG on the left (Fig. 7). With the IPG on the right, an opposite relationship could be found, with the highest heating values for atrial lead configurations and only slight heating for leads in ventricular configurations (Fig. 6). In general, the highest RF pickup, and therefore implant heating, was observed in configurations with the lead in a straight configuration or roughly forming a large (half-) circle, provided that the course of the eddy currents in the surrounding medium ([13]) was approximately met. In this context, it is important to note that in this study only single-lead configurations were investigated; in multiple-lead configurations interferences might lead to a shift in E-field, and therefore heating patterns. Moreover, we did not include configurations with the lead forming loops around the pacemaker, which have also been found in the X-rays. This could be a factor leading to even more variation in the heating extend, especially if leads longer than 53 cm are taken into account.

In comparison to the highest heating effects found in straight lead path configurations along the phantom side walls in the *z*-direction (which is a commonly used geometric configuration to maximize heating effects) the highest RF pickup in anatomically matched geometries proved to be only slightly lower. Hence, such straight lead paths along the most intense E-fields in the phantom can be used in implant heating investigations to allow for good reproducibility while still giving reasonable implant heating values regarding worst case conditions for the human anatomy. In the present study, only in vitro measurements in a simplified head and torso model were performed, and it is clear that the results can not be converted 1:1 to in vivo investigations. On the other hand, the phantom approach presented in this study allowed for extensive and highly reproducible investigations on the problem of device positioning, which would have been impossible in any living organism.

In the human body perfusion or blood flow might be significant factors in limiting the amount of tissue heating. Thus, in most cases the actual amount of heating developed when performing MRI in pacemaker patients will probably be significantly smaller than the maximum ■*T* of 45.9°C (68.5°C in straight lead configuration), which was found in our study. However, these effects are hard to predict. Furthermore, the present study points out that the energy transfer accounting for MRI-related heating follows the same laws as energy transfer in radiofrequency ablation procedures, with the exception of the RF being in the MHz range in MRI. The heat-reducing influence of blood flow or perfusion should, therefore, not be uncritically overestimated ([6]).

In a recent study of 115 pacemaker patients who underwent MRI, in most patients no adverse effects could be detected, while 4 of them revealed a significant increase in serum troponin after undergoing an MRI ([20]), which might be seen as evidence for RF-related myocardial injury through tissue heating. The reasons for these discordant findings in different patients could not be clearly defined. Looking at the measurements of our study, only relatively minor implant heating of considerably below 10°C was found for the majority of pacemaker system configurations (504 of 720 configurations). This mild heating was despite the fact that in comparison to the situation in patient MRI there were several factors in our study provoking high heating such as the low-convection gel and the relatively high SAR values. Nevertheless, there is potential for significant heating effects in several configurations matching the situation in the body, which is exceptionally apparent in the cases which developed a ■*T* of more than 40°C. Overall, 64 configurations were accompanied with heating above 20°C (>30°C: 12).

Even minimal alterations in configuration such as 2-cm movement of the tip might in some cases double or halve the implant heating. This extreme variability in implant heating dependent on exact configuration could, therefore, be an important reason amongst several others why significant tissue heating near implanted leads apparently does not appear in a relatively large percentage of pacemaker patients in MRI, while it does appear in others, even when the exam is performed under relatively hazardous objective circumstances such as with comparatively high SAR values. Therefore, general statements on MRI safety regarding electronic devices such as cardiac pacemakers or deep brain stimulators should be very carefully considered, particularly with the potential for RF-related implant heating to be dependent on the specific device and MRI scanner in use ([25]). This issue is not yet sufficiently resolved, and can be summarized with the statement ■Failing to identify an adverse event is not equivalent to demonstrating safety■ ([26]), which has also just recently been pointed out in an AHA scientific statement on the safety of MRI in patients with cardiovascular devices ([27]).

On the other hand, as we found only minor heating in a relatively large number of device configurations (mean temperature elevation of only 2.9°C for all configurations with the IPG in the left pectoral region), the current results also support recent studies suggesting acceptable risk-benefit ratios for MRI of certain pacemaker patients ([15][20]). Nevertheless, in the long term implantable devices will be needed, which are safe by design - and not by chance - to sincerely preclude patient risks dependent on MRI examination, investigator, and individual patient.

CONCLUSION

The potential for RF-related heating of elongated conductive implants in MRI was determined by measuring the intensity of the electric currents induced inside a cardiac pacemaker system. This method was revealed to be a robust measurement technique for MR safety investigations that yields some major benefits compared to fluoroptic temperature measurements.

The MRI-induced current intensity in a pacemaker lead is strongly dependent on the device position and lead pathway inside the body. Although this current intensity and resulting heating effects are small in many configurations, in some anatomical arrangements implant heating can be almost as high as in worst-case configurations with the lead pathway along the phantom wall in the z-direction. The mean temperature elevation, and therefore averaged patient risk taking into account all related lead paths, was significantly lower if the IPG was placed in the left pectoral region compared to IPG placement in the right pectoral region. However, cardiac pacemaker systems implanted in either the left or right pectoral region can develop high RF-related implant heating in at least some anatomically reasonable configurations. For ventricular lead configurations an IPG position in the right pectoral region in most cases led to less implant heating than with the IPG on the left, whereas for atrial lead configurations an IPG position in the left pectoral region performed superiorly.

The new insights highlight the complex characteristics of the interrelations between the circularly polarized electric fields inherent to MRI technology, the actual E-field distribution in the body (which can potentially be asymmetric even in a symmetric homogeneous phantom), the properties of highly conductive medical implants in the human body, and resultant implant heating.

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