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Yao, Aiping Murbach, Manuel; Goren, Tolga; Zastrow, Earl; Kainz, Wolfgang; Kuster, Niels

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Induced radiofrequency fields in patients undergoing MR examinations: insights for risk assessment

Aiping Yao^{1,2,4}, Manuel Murbach¹, Tolga Goren¹ , Earl Zastrow¹, Wolfgang Kainz³ and Niels Kuster^{1,2,*}¹ IT²IS Foundation, 8004 Zurich, Switzerland² Swiss Federal Institute of Technology (ETH) Zurich, 8092 Zurich, Switzerland³ US Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), Silver Spring, MD 20993, United States of America⁴ Present address: School of Information Science and Engineering, Lanzhou University, No. 222 Tianshui South Road, Lanzhou, People's Republic of China.

* Author to whom any correspondence should be addressed.

E-mail: aiping.yau@gmail.com, manuel@murbach.eu, goren@itis.swiss, earl.zastrow@gmail.com, wolfgang.kainz@fda.hhs.gov and kuster@itis.swiss**Keywords:** magnetic resonance imaging (MRI), radiofrequency (RF) exposure, AIMD, PIMD, ASTM phantom, incident RF fields, induced RF fieldsSupplementary material for this article is available [online](#)

Abstract

Purpose. To characterize and quantify the induced radiofrequency (RF) electric (E)-fields and B_{1+rms} fields in patients undergoing magnetic resonance (MR) examinations; to provide guidance on aspects of RF heating risks for patients with and without implants; and to discuss some strengths and limitations of safety assessments in current ISO, IEC, and ASTM standards to determine the RF heating risks for patients with and without implants.

Methods. Induced E -fields and B_{1+rms} fields during 1.5 T and 3 T MR examinations were numerically estimated for high-resolution patient models of the Virtual Population exposed to ten two-port birdcage RF coils from head to feet imaging landmarks over the full polarization space, as well as in surrogate ASTM phantoms.

Results. Worst-case B_{1+rms} exposure greater than $3.5 \mu T$ (1.5 T) and $2 \mu T$ (3 T) must be considered for all MR examinations at the Normal Operating Mode limit. Representative induced E -field and specific absorption rate distributions under different clinical scenarios allow quick estimation of clinical factors of high and reduced exposure. B_1 shimming can cause +6 dB enhancements to E -fields along implant trajectories. The distribution and magnitude of induced E -fields in the ASTM phantom differ from clinical exposures and are not always conservative for typical implant locations.

Conclusions. Field distributions in patient models are condensed, visualized for quick estimation of risks, and compared to those induced in the ASTM phantom. Induced E -fields in patient models can significantly exceed those in the surrogate ASTM phantom in some cases. In the recent 19⁹² revision of the ASTM F2182 standard, the major shortcomings of previous versions have been addressed by requiring that the relationship between ASTM test conditions and *in vivo* tangential E -fields be established, e.g. numerically. With this requirement, the principal methods defined in the ASTM standard for passive implants are reconciled with those of the ISO 10974 standard for active implantable medical devices.

Introduction

The potential hazards of magnetic resonance (MR) examinations have been acknowledged since the 1970s (Bottomley and Andrew 1978, Bottomley and Edelstein 1981, Bottomley *et al* 1985), and their extensive study has led to procedures and safety guidelines to mitigate potential adverse effects (ICNIRP 2004, IEC 2015, U.S. Food and Drug Administration 2014). Still, accidents involving MR systems have occurred that resulted in

patient injury or death (Dujovny *et al* 1985, Kelly *et al* 1986, Brown *et al* 1993, Klucznik *et al* 1993, Spiegel *et al* 2003, Zrinzo *et al* 2011). Patients with conductive active or passive implantable medical devices (AIMD and PIMD) bear additional risks during MR examinations, as the implant may interact with the electromagnetic field, leading to potential hazards (U.S. Food and Drug Administration 2019a) including mechanical movement or dislodgment due to magnetic field induced forces and torques, damage to the circuitry of the AIMD, and heating of the device and adjacent tissue due to pick-up and concentration of radiofrequency (RF) energy. The MR image can also be distorted around implants, compromising accurate diagnostics and subsequent medical decisions. Ensuring a safe scanning environment for patients with implants is a continuous challenge in medical care, as the benefits of the MR examination for the patient must be weighed against the risk assessments provided by MR scanner and PIMD/AIMD manufacturers, radiologists, and MR technologists.

The RF hazards of MR examinations are directly correlated with the patient's RF exposure level to the MR system's B_1 field, and depend on a variety of factors, such as the MR system (particularly the RF transmit coil), patient anatomy, imaging position, and type and duration of the scan. The relevant safety standard limiting patient specific absorption rate (SAR) exposure during MR examinations is IEC 60601-2-33 (IEC 2015), which establishes SAR and temperature limits for the patient population, and defines a set of MR system operating modes. The SAR limitation scheme in IEC 60601-2-33 is based on separate limits of head averaged SAR (hdSAR), whole-body averaged SAR (wbSAR), and partial-body averaged SAR (pbSAR). At Normal Operating Mode, the operation mode in which none of the outputs should reach a value that may cause physiological stress to patients, these limits are 3.2 W kg^{-1} , 2 W kg^{-1} , and $2\text{--}10 \text{ W kg}^{-1}$, respectively; the maximum allowed B_1 field is the one where any of these limits is estimated to have been reached. The assessment of PIMD/AIMD compatibility with MR examinations is performed according to ASTM F2182 (ASTM 2019), which defines the RF-heating assessment of PIMDs by means of exposure in a homogeneous phantom; and ISO 10974 (ISO/TS 2018), which describes a set of hybrid experimental/numerical approaches for AIMDs. The results may result in MR labeling indicating that implants are safe during scans at Normal Operating Mode, or requiring limitations on the SAR or B_1 levels that the scanner may attain. For 3 T scanners, the polarizations used by the MR system may also be restricted; the upcoming revision of ISO 10974 extends the application range to 3 T and requires that the potential shim space be considered in the risk assessment process.

Previous studies have compared the spatial distribution of the RF-induced electric (E -) field inside the ASTM phantom in two different MR systems (Nordbeck *et al* 2008), and the use of the ASTM phantom as a patient surrogate has been evaluated under specific exposure conditions (Kozlov *et al* 2015, Guo *et al* 2016). The peak spatial SAR and whole-body averaged SAR inside different patient models have been compared (Murbach *et al* 2013), and the influence of different RF coil feed configurations on different anatomies has been investigated (Murbach *et al* 2013, Lucano *et al* 2018). However, none of these studies considered a wide range of clinical factors (patient models, imaging positions, RF transmit coil geometries, implant exposure conditions) which determine the *in vivo* induced RF fields. Modern simulation tools can quickly assess the induced fields across the patient population for a lead routing or region of interest by taking advantage of pre-computed field libraries, allowing these shortcomings to be addressed. The latest edition of ASTM F2182 (ASTM 2019) includes the new section 'Significance and Use', recommending that implant evaluation in the ASTM phantom be supported with simulations using high-resolution patient models in realistic clinical settings—an approach that is considered essential to the methodologies described in ISO 10974.

In this work, we describe the strength and distribution of RF-induced fields in patients undergoing MR examinations and compare them to those induced *in vitro* in homogeneous phantoms. We further summarize the approaches to estimate those fields, as required by the ASTM standard historically and in its latest revision, and by the newer ISO 10974 Technical Specification (ISO/TS 2018). Finally, we provide useful guidelines to estimate the risks of MR-induced RF fields for patients with and without medical implants.

Methods

In brief, the induced E -fields and $B_{1+\text{rms}}$ fields in two high-resolution patient models of the Virtual Population exposed to ten two-port birdcage RF body coils from head to feet imaging landmarks over the full polarization space at the Normal Operating Mode limits were estimated via finite-difference time-domain (FDTD) simulation. The local SAR, the maximum averaged E -field over any 1 cm^3 cube of tissue ($E_{1\text{cm}^3}$), and the tangential E -field (E_{tan}) for relevant implant trajectories are characterized, and the latter compared to the induced E -fields in surrogate ASTM phantoms.

Table 1. Physiological parameters of the two selected patient models, obtained from discretized models with a uniform grid size of $0.5 \times 0.5 \times 0.5 \text{ mm}^3$.

	Age (years)	Height (m)	Mass (kg)	BMI (kg m^{-2})	DOI (prefix 10.13099)
Fats	37	1.82	119.5	36	ViP-Fats-V3.0
Thelonious	6	1.16	18.5	13.8	ViP-Thelonious-V3.0

Table 2. Geometry and topology of the birdcage RF body coils considered in the study. All birdcage coils are assumed to have high-pass topology with 16 rungs, a constant shield length of 150 cm, and rung-shield spacing of 2.5 cm. The 65 cm diameter coils were too small to accommodate the obese model Fats and were therefore excluded from the evaluations performed with him.

Name	Coil diameter (cm)	Coil length (cm)	Shield diameter (cm)	Frequency (MHz)
B65_L50	65	50	70	64/128
B65_L60	65	60	70	64/128
B65_L70	65	70	70	64/128
B75_L40	75	40	80	64/128
B75_L50	75	50	80	64/128
B75_L60	75	60	80	64/128
B75_L70	75	70	80	64/128
B80_L50	80	50	85	64/128
B80_L60	80	60	85	64/128
B80_L70	80	70	85	64/128

Simulation of the MR environment

Patient models

Two advanced high-resolution numerical patient models with distinct anatomical features were used in this work, namely the Virtual Population (ViP) models (Gosselin *et al* 2014), Fats (obese male model), and Thelonious (child model). The model properties are described in table 1.

RF Coils and feeding

Experimental *in situ* evaluations of commercial MR systems were conducted to define the geometric envelope of RF body coils. Based on the results, ten birdcage RF body coil models were defined, operating in quadrature mode (channel I and channel Q) tuned to resonate at 64 MHz or 128 MHz, corresponding to 1.5 T and 3 T MR scanners, respectively. The simulation approach described in (Murbach *et al* 2013) was used. Briefly, the birdcages were tuned to the resonance frequency using a broadband quadrature excitation with two ports in one endring. The applied Huygens' box approach ensured identical birdcage current distributions, and incident fields correspond to an ideal CP current distribution, for all models and positions. Altered current distributions due to loadings were not evaluated in this study as they depend on the specific RF coil design and implementation. Due to the size of the patient model Fats, seven of the ten birdcage RF body coils were selected to represent typical clinical RF body coils. The geometry features of the birdcage RF body coils are listed in table 2. To cover the potential RF shimming space, 361 different exposure polarizations were considered in this study: B_1 polarizations distributed from left- and right-handed circular polarizations to both linear polarizations were attained at the isocenter of the unloaded coil by varying the I and Q channel magnitude and phase such that the polarization ellipse major axis angle $\epsilon = [-45^\circ: 5^\circ: 45^\circ]$ and the minor axis angle $\tau = [0^\circ: 10^\circ: 180^\circ]$ (Kraus and Carver 1973). The polarization ellipse and definition of the major and minor axis angles are shown in figure S1 (available online at stacks.iop.org/PMB/66/185014/mmedia).

Computational electromagnetic platform

The RF exposures were assessed with FDTD simulations, performed with the multi-physics simulation platform Sim4Life V5.2 (ZMT Zurich MedTech AG, Zurich, Switzerland). For both patient models, landmarks from head to foot at imaging positioning steps of 10 cm were applied for each birdcage RF body coil. The models were discretized with a maximum resolution of $2.0 \times 2.0 \times 2.0 \text{ mm}^3$, and dielectric properties at 64 and 128 MHz were assigned to the tissues according to the IT'IS Tissue Database (Hasgall *et al* 2018). Simulation convergence was checked for each FDTD run. The generated dataset, as well as the tools used for extracting and post-processing the data, are part of the FDA-qualified computational modeling medical device development tool, Q181884 IMAnalytics with MRIxViP and BCLib (U.S. Food and Drug Administration 2019b).

Figure 1. Field enhancements: seven typical locations of E -field hotspots during MR examinations, distinguished by the anatomical feature primarily responsible. Lateral enhancement: (a) shown for the thighs, also present at the lateral torso and arm. Dielectric contrast: (b) pronounced effect around the inner organs. Anatomical body-constrictions: (c) around the neck towards the shoulders, (d) axilla, and (e) groin. Tissue constriction around bones: (f) shown for the wrist and knee, also present at the other extremity joints of the elbow and ankle, and (g) around the pelvis.

ASTM field analysis

The ASTM F2182 standard provides guidelines to assess tissue heating near PIMDs during exposure to the MR RF field. It is based primarily on the experimental assessment of the implant heating within a test phantom (ASTM phantom), originally defined with the motivation of approximating the induced E -fields in a patient and is the most widely accepted safety assessment method for PIMDs today. The permittivity and conductivity of the phantom material substantially differs from the actual tissue, especially for implants inside bone or fat (the surrounding tissue defines the effective electric lengths of the implant), and the absence of anatomical features leads to induced E -field in the ASTM phantom not reflecting the actual induced E -fields in the patient. For most of its history, the ASTM F2182 standard indirectly assumed that the response of the implants in the ASTM phantom represents a conservative estimate with respect to patient exposure. The latest revision ASTM F2182-19^{e2} standard (ASTM 2019) added the section ‘Significance and Use’, which allows to account for the differences of exposures of the PIMD in the ASTM phantom and the exposures in the patient population in realistic clinical s.

To quantify the differences in induced E -field strength and distribution between the ASTM phantom and high-resolution patient models, we performed a direct comparison of the induced E -fields inside the ASTM phantom and the ViP models Fats and Thelonious. The local SAR, the maximum averaged E -field over any 1 cm³ cube of tissue ($E_{1\text{cm}^3}$), and the tangential E -field (E_{tan}) along three representative orthopedic implant trajectories were compared.

Induced field analysis

Numerical FDTD simulations of the RF exposure under different clinical MR examination scenarios were performed, comprising two distinct patient models (Fats and Thelonious), RF coils (seven birdcage RF body

Figure 2. Total minimum-maximum spread of hdSAR, wbSAR, and pbSAR reached in the Normal Operating Mode for Fats (obese model) and Thelonious (child model), at 1.5 T and 3 T, for the birdcage RF body coils in table 2 driven in CP mode covering all major MR bore sizes. The hdSAR limit is always reached first in head imaging; while the wbSAR limit is always reached first from sternum to knee imaging. In the neck imaging position, the limit for either hdSAR or wbSAR can be reached first, depending on the patient and the birdcage RF body coil geometry; the same applies to imaging below the knees for wbSAR and pbSAR. The pbSAR limit ranges from 2 to 10 W kg⁻¹, depending on the exposed partial body mass.

coils at each frequency), imaging positions (more than 10 imaging positions from head to feet), and the selected shimming space with 361 different B_{1+} polarizations. For each exposure scenario, the obtained field distributions, i.e. the SAR and the magnetic field $|B_{1+rms}|$, were scaled to the exposure limits of the Normal Operating Mode as specified by the MR safety standard IEC 60601-2-33. $|B_{1+rms}|$ was derived by spatially averaging $|B_{1+rms}|$ over the central axial slab of the patient, as suggested by IEC 60601-2-33 (IEC 2015). The root-mean-square (rms) refers to the temporal average over the pulsed RF sequence of the scanner. For each patient model, birdcage, landmark, and polarization the power was scaled to the corresponding SAR limits of the Normal Operating Mode.

Next, three typical clinical routing groups of an AIMD were defined: (i) the deep brain stimulator (DBS) routing group runs underneath the skin from the proximal ends of the left pectoral muscles, along the side of the neck behind the left ear, up to the crown of the head, through the skull, and terminating in the distal end of the thalamus; (ii) the pacemaker (PM) routing group runs underneath the skin from the proximal end of the left pectoral and along the veins, and terminating in the distal end of the left heart ventricle; (iii) the spinal cord stimulator (SCS) routing group runs underneath the skin from the left buttocks below the waistline, along the epidural space from the T10 vertebra, and terminating at the C1 vertebra. Each routing group is comprised of 100 random routings following the basic trajectory.

The distributions of the induced E -field averaged over a 1 cm³ tissue cube ($|E_{1cm3,rms}|$), for the birdcage RF body coil B70_L60 (coil diameter of 70 cm, coil length of 60 cm) driven at circular polarization (CP), were extracted for Fats and Thelonious. Finally, the averaged induced E -fields ($|E_{tan,rms}|$) tangential to the three defined AIMD clinical routings (DBS, PM, and SCS) were extracted for each exposure scenario. Note that no simulations with generic or commercial implants were performed or any assumption made about the implant response; only the E -fields inside the patient, which would be incident to an AIMD along these representative clinical routing groups, were characterized.

Results

MR examination-induced RF fields at the exposure limits

Induced RF field magnitude and distribution depend on many factors, such as patient anatomy, imaging position, and the RF coil's design and setting. Substantial field enhancements (see figure 1) are caused by anatomical features, which can be classified into (i) lateral enhancement due to higher lateral eddy currents,

(ii) dielectric contrast, (iii) anatomical body-constrictions, and (iv) tissue-constrictions around bones. As illustrated in figure 2, the hdSAR is typically reached first in head and neck imaging, wbSAR from neck to knee imaging, and pbSAR for imaging positions below the knee. pbSAR is less relevant for the Normal Operating Mode than for the first level controlled operating mode, where pbSAR is often reached already from below the pelvis (Murbach *et al* 2016).

Figure 3 shows the allowed $|B_{1+,rms}|$ values for the Normal Operating Mode. In leg imaging, especially below the knees, very large $|B_{1+,rms}|$ values of up to 25 μ T (1.5 T) and 10 μ T (3 T), respectively, would be allowed by the standard. However, most manufacturers are not exploiting this region due to RF amplifier limitations and safety considerations. Implant manufacturers typically label their AIMDs to the maximum allowed SAR, but $|B_{1+,rms}|$ labeling is becoming more frequent as well.

In summary, the induced fields depend on the anatomy, imaging positions and bore length of the RF coils. In general, patient models with larger BMI and imaging position near the thorax tend to have higher induced fields, corresponding to lower B_1 field limits to maintain compliance with the limitations of the operating mode. MR systems with higher frequency and longer RF coil length will also generate high induced fields, corresponding to lower B_1 field limits; while the bore diameter of the RF coils does not strongly affect the induced fields.

The effect of B_1 shimming on patient models to maximize the $|B_{1+}|$ amplitude, or alternatively maximize the $|B_{1+}|$ homogeneity (minimum covariance), over the central axial slab, are shown for 3 T examinations in figure 4. Shimming efforts towards either goal exceed the CP value by 30%, i.e. achieving higher exposure at the SAR limit, especially for the smaller patient models and imaging positions near the lower limbs and feet.

Induced E -fields as incident field for medical implants

The behavior of AIMDs/PIMDs during MR examinations predominantly depends on the induced E -field tangential to the length of the implant ($|E_{tan,rms}|$, i.e. the incident E -field for the implant), as well as their characteristic response to that incident field. An electrically conductive implant picks up E_{tan} and focuses it into the surrounding tissue near conductive surfaces of the implant, or into electronic terminals as induced voltage.

Figure 4. Root-mean-square of $|B_{1+,rms}|$ averaged over the isocenter plane, obtained under three different RF-shimming constraints; black: minimum $|B_{1+,rms}|$ variation (i.e. min. covariance), blue: maximum $|B_{1+,rms}|$, and red: circular polarization (CP) mode. Shaded area indicates imaging positions with $|B_{1+,rms}|$ difference bigger than 20%. Top: Fats at 1.5 T (left) and 3.0 T (right) normalized to Normal Operating Mode SAR limits, i.e. hdSAR, wbSAR, or pbSAR. Bottom: Thelonious at 1.5 T (left) and 3.0 T (right) normalized to Normal Operating Mode SAR limits.

Direct exposure simulations of the patient with the implant present are computationally too expensive to address the many permutations of implant placement and configuration, and exposure conditions. Instead, the patient exposure can be approximated by decomposing the assessment into two steps: (1) computationally estimating the incident E -field to the implant, i.e. $|E_{tan,rms}|$, without the implant present, and (2) computationally or experimentally estimating the local E_{tan} enhancement due to the presence of the implant.

The induced E -fields for the patient models Fats and Thelonious are illustrated in figure 5. The visualization shows the maximum E -field averaged over any 1 cm^3 cube of tissue ($|E_{1\text{cm}^3,rms}|$) (Murbach *et al* 2016). A maximum intensity projection has been chosen to visualize all ‘hotspots’ in a single plane, and to combine various imaging positions. For example, the ‘upper torso’ in figure 5 shows the maximum E -fields for the imaging positions from the upper sternum to the upper abdomen, vertically projected through the patient model.

From figure 5, we can visually estimate that AIMD routings for pacemakers (PM) and SCS are only marginally exposed for head/neck and leg imaging. Whereas, typical DBS routings reveal low E -fields in lower torso and leg imaging. This visual estimation is confirmed by the actual E_{tan} evaluations of the three implant-categories in figure 6.

When diverging from circular polarization to elliptical or linear polarizations (as typically applied in 2-port RF shimming at 3 T), the maximally induced $E_{1\text{cm}^3}$ magnitude and the local SAR can change by up to about ± 3 dB (approximately a factor of 1.4 for the E -field or 2 for the SAR) (Graaf *et al* 2014). As the E_{tan} along the trajectories of AIMDs/PIMDs includes more localized and directional E -field components, the use of RF-shimming instead of CP mode can cause field enhancement of up to +6 dB (factor 2 in E -field, as shown in figure 6), or—in the case of favorable RF shimming—mitigation by −30 dB (a factor of 33 for the E -field or 1000 for the induced power). To avoid the potential +6 dB enhancement, most implant manufacturers restrict the RF exposure to circular polarization in their AIMD/PIMD MR Conditional labeling.

ASTM phantom analysis

Figure 7 illustrates the differences between a realistic patient model and the homogenous ASTM phantom. The normalization to 2 W kg^{-1} phantom-averaged SAR results in roughly one fifth the delivered power as for the patient model Fats. The local 1g-averaged SAR can be seven times higher in the patient model, and the square of the induced

Figure 5. Maximum intensity projection of the induced E -field averaged over 1 cm^3 ($|E_{1\text{cm}^3,\text{rms}}|$) for Fats (top) and Thelonious (bottom) for the birdcage RF body coil B70_L60 (coil diameter of 70 cm, coil length of 60 cm) driven in circular polarization (CP) mode. The maximum is projected orthogonal to the depicted plane, as well as for typical imaging positions (highlighted in white). Typical routings of AIMD (DBS, PM, SCS) are shown on the rightmost images. Note the differing dB-scale references for Fats and Thelonious.

E -field more than 50 times higher. For typical AIMD lead routings inside the torso (such as pacemakers, evaluated later in this paper), the average induced E -field remains below 150 V m^{-1} , which is similar to the field level in the ASTM phantom. However, for PIMDs (trajectories for orthopedic implants on the femur, ulna, and clavicle were evaluated), the induced E -field can exceed 200 V m^{-1} . In other words, the local induced E -fields inside the ASTM phantom only have a weak correlation to realistic induced E -fields and, importantly, are not always conservative. Substantial field enhancements (see figure 1) are caused by anatomical features, which can be classified into (i) lateral enhancement due to higher lateral eddy currents, (ii) dielectric contrast, (iii) anatomical body-constrictions, and (iv) tissue-constrictions around bones. The other critical factor is the large difference in electrical conductivity: ASTM F2182 recommends for the phantom material an electrical conductivity of $0.47\text{ S m}^{-1} \pm 10\%$, which is based on a weighted average of the tissue conductivities for an average adult. However, the actual electrical conductivity of tissue ranges from 0.02 to 0.05 S m^{-1} for bone, fat, and teeth at 64 MHz to 1 – 2 S m^{-1} for blood, eye, small intestine, and cerebrospinal fluid at 128 MHz. It is obvious that the induced E -fields in a homogeneous phantom with a single conductivity cannot cover conservatively the induced E -fields for the entire patient population with tissue conductivities varying up to a factor of 100.

Discussion and conclusions

This paper provides a comprehensive analysis of the induced $B_{1+\text{rms}}$ fields, E -fields and SAR, and the associated risks in high-resolution patient models with and without medical implants undergoing MR examinations, as

well as the definition and use of induced fields in current standards. The induced field limits based on different clinical scenarios (RF coils, imaging positions, anatomy, and exposure conditions) are presented, allowing safe imaging positions to be quickly identified based on implant locations and configurations. For example, in all leg imaging positions (figure 5, rightmost panel), the pacemaker and DBS devices are essentially not exposed, while the SCS routing still encompasses some high field regions. This is confirmed by the over 1 cm^3 averaged E -field data shown in figure 5. The actual magnitude for a specific routing may still be considerably lower than seen in figure 5, because E_{tan} only considers one spatial component and the routing does not necessarily encompass the highest values shown in the maximum-intensity projection.

In general, large patients with a high body mass index, and imaging positions around the abdomen, tend to have higher induced E -fields inside the body. The RF coil length has a greater influence on the induced E -fields than the coil diameter. The influence of patient anatomy on the induced fields is clearly visible in figures 3–6; indeed, the scanner operating limits are based on SAR which depends on patient anatomy as well as scan conditions. Therefore, it is essential that a wide range of models covering the patient population are considered in any safety evaluation. This is consistent with previous work that showed that local quantities can vary over more than 10 dB as a function of anatomy and scan landmark. (Yao *et al*, 2019).

The influence of RF shimming on the induced E -fields is also demonstrated. Restriction to CP mode prevents a potential +6 dB E_{tan} enhancement originating from RF shimming, which is therefore often imposed by the implant label. On the other side, restriction to CP mode also prevents potential exposure mitigation from favorable RF shimming configurations. The effect of B_1 shimming to achieve maximum B_{1+} uniformity (minimum covariance) can exceed 30% E_{tan} enhancement in 3 T MR systems at Normal Operating Mode limits. More research on developing RF shimming parameters able to concurrently increase image quality and implant safety, and the ability to adjust the RF shimming parameters on the MR scanner console for implant patients is needed before AIMD/PIMD favorable shimming becomes a reality. The identified hotspot locations may support an initial assessment of implant safety. However, if the implant is close to such a region, refined safety considerations may be necessary. Note that these hotspots may be compounded by the presence of an implant.

The comparison of the induced fields inside the ASTM phantom to those inside the ViP models demonstrated that PIMD exposure is overestimated in many cases but, more importantly, can be greatly underestimated in some cases. In other words, the heating response of the PIMD in the ASTM phantom is not always conservative, as was implicitly assumed by the ASTM F2182 standard. However, with the release of the new 19^{ε2} revision of ASTM F2182, the methods developed for ISO 10974 to determine the induced E -fields tangential to the surface of an implant can be directly applied to PIMDs by relating the measured heating in the ASTM phantom to the actual implant exposure conditions in patient models for each device. This approach eliminates the shortcomings of the former ASTM standard and makes the methods and results of ASTM F2182 and ISO 10974 compatible. Transition to the new version of the ASTM standard ensures that the additional analyses described in the section ‘Significance and Use’ of ASTM F2182-19^{ε2} are performed for PIMDs going

Figure 7. Heating relevant induced E -field comparison ($|E_{1cm3,rms}|$) between the Virtual Population (ViP, IT'IS Foundation) patient model Fats (shown with maximum intensity projection over all imaging positions) and the ASTM phantom (slice view at the vertical center, where the implant is placed). When both are normalized to a wbSAR of 2 W kg^{-1} , the local 1g-averaged SAR and the maximum $|E_{1cm3,rms}|$ in Fats is $\sim 7\times$ higher, i.e. a factor $\sim 50\times$ in power. The large difference in the E -field is at least partially due to high E -fields in fat tissues, where the local 1g-averaged SAR is only $\sim 7\times$ (instead of also $\sim 50\times$) due to the lower electrical conductivity of the fat tissue. The tangential E -field ($|E_{tan,rms}|$) along three typical orthopedic implant trajectories (at the maximum imaging position for each) are considerably higher in Fats than in the ASTM phantom (factor $> 3\times$ in power). Note the factor 3.3 (10 dB) difference in the scale normalization between Fats (850 V m^{-1}) and the ASTM phantom (260 V m^{-1}). The inset magnifies the thigh/knee region, where the SAR is typically highest in muscle tissue, while the E -field is highest in fat tissue (*). These results show the importance of relating temperature measurements in the ASTM phantom to predicted incident field conditions in patient models, as described by ISO 10974, and recently also by the 19^{e2} revision of ASTM F2182.

forward. While relating to realistic incident field conditions is a step in the right direction, it still requires applying conservative safety margins to derive the maximum allowable RF exposure, which can lead in some cases to a sub-optimal MR Conditional labeling, i.e. a labeling which is not able to give the patient access to the full imaging capabilities of the scanner. An optimal MR Conditional labeling minimizes the RF exposure safety margin while still ensuring patient safety. To achieve such optimal MR Conditional labeling for PIMDs, the RF-induced *in vivo* heating needs to be assessed using computational modeling. Such modeling allows to embed ('to implant') realistic 3D CAD models of the PIMD in patient models and assess the RF-induced heating under clinically realistic worst-case exposure conditions. While this type of modeling, i.e. the Tier 4 RF-induced heating method according to ISO 10974, is currently not possible for AIMDs (due to limited computational power), many PIMD manufacturers have applied this modeling strategy successfully to develop optimal MR Conditional labeling for their patients, and we hope in the interest of the patient that soon all PIMD manufacturers follow this strategy.

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ORCID iDs

Tolga Goren <https://orcid.org/0000-0002-4377-0676>

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