

Safety Aspects for a Pre-clinical Magnetic Particle Imaging Scanner

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Abstract – Magnetic Particle Imaging is a promising new imaging technique using magnetic fields to image magnetic tracer material in the body. As with MRI systems, time varying magnetic fields raise some safety issues. The stimulation of peripheral nerves and tissues is one of them. In the paper, the stimulation thresholds are explained and an evaluation of the stimulation generated by a pre-clinical scanner is calculated. It appears clearly that, even if driving fields of high amplitude are used, cardiac arrhythmias are unlikely to be induced. However, it is yet unclear whether some peripheral nerve stimulation may be induced.

Introduction

Imaging devices using non-ionizing energy offer safer imaging acquisition procedures for patients and medical staff. Although Magnetic Particle Imaging (MPI) belongs to this category, some safety criteria are still to be evaluated to ensure a safe routine use of such technologies, similar to what has been done for MRI [1].

A conventional 3D MPI device is based on two different magnetic fields [2]: one static gradient field, which aims to saturate the tracer magnetization everywhere in the imaging volume, except for one point, the field free point (FFP); and three different time varying fields, which are applied in order to move the FFP through the space. By varying in time, those three magnetic fields will induce currents in the object, i.e. the patient, which may be sufficiently high to trigger tissue stimulation. Two different levels of stimulation are commonly defined [3, 4], based on the tissues which are stimulated. The first level is the stimulation of the peripheral nerves (called the Peripheral Nerve Stimulation - PNS - threshold), going from the onset of sensation to intolerable or painful stimulation [1] for the patient, and the second level comes from the stimulation of myocardial muscles, which leads to cardiac stimulation. As in MRI, it may be possible to operate the scanner beyond the painful PNS threshold, but this has only to be done in very rare cases and requires a specific ethical approval. For normal daily use, the scanner has to be operated below the painful PNS threshold, and thus, below the cardiac stimulation threshold.

Unfortunately, those thresholds are not well defined, and may considerably vary from one patient to another [1, 3, 4]. Moreover, the relation between the field output of a scanner in the imaging volume and the PNS threshold greatly vary according to patient size and coil design. The Maxwell-Faraday law defines the relationship between the patient geometry and the magnetic and electrical field properties through the equation:

$$\oint_{\partial S} \mathbf{E} d\mathbf{l} = \int_S \frac{\partial}{\partial t} \mathbf{B} d\mathbf{A}. \quad (1)$$

With \mathbf{B} being the magnetic field over the surface S bounded by the closed contour ∂S and \mathbf{E} being the electrical field on the contour of that area. The Biot-Savart law can be used to calculate the magnetic field according to the coil geometry with the following equation:

$$\mathbf{B} = \frac{\mu_0}{4\pi} \int \frac{I d\mathbf{l} \times \mathbf{r}}{r^3}.$$

With μ_0 being the permeability of free space, I the current in the coil, $d\mathbf{l}$ a vector element with a length equal to that of the wire carrying the current and \mathbf{r} is the displacement vector between the wire and the point at which the field is calculated. From those two equations, we can say that the induced current in the tissue will depend on the surface perpendicular to the vector of the absolute magnetic field, and that the magnitude of the magnetic field decreases according to the distance to the current-carrying wire.

Thus, we can conclude that for two scanners with the same driving field amplitude, if the PNS threshold is exceeded for a human sized system with a human patient, it may not be exceeded for a small animal sized system with a small animal inside. In other words, the safety aspect regarding PNS is not solely related to the driving field amplitude, but it depends also of the scanner geometry.

Material and Methods

The scanner we want to evaluate is an open scanner for interventional Magnetic Particle Imaging. Driving fields in the x, y and z direction are designed to have a center value of around 40, 17 and 23 mT, respectively. The maximum magnetic field values are reported on table 1 for each coil and field direction.

Table 1. Maximum field values of the driving coils in the mid plane of the scanner.

	B_x / mT	B_y / mT	B_z / mT	B_{abs} / mT
x driving coil	40	0	0	
y driving coil	0	17	7	
z driving coil	0	10	23	
Sum of fields	40	27	30	57

Each coil is fed with sinusoidal current at a slightly different frequency: 24.51 kHz, 25.25 kHz and 26.04 kHz [5]. The maximum value, the time and the perpendicular surface of the peak $d\mathbf{B}/dt$ value will thus depend on the frequency applied to the different coils. In order to simplify the calculation, the animal will be approximated as a sphere with a radius r of 10 cm. The maximum

dB/dt value is then numerically calculated assuming a uniform magnetic field distribution, and the induced electrical field E_i (in V/m) is calculated according to equation (1) as

$$E_i = \frac{r}{2} \max\left(\frac{d|B|}{dt}\right).$$

As threshold for PNS, two standards will be considered. The first one is the ICNIRP guideline [6], which considers the safety of general exposure to electro-magnetic fields from 1 Hz to 100 kHz, the second one is the PNS and cardiac stimulation thresholds from J.P. Reilly [4], which are also used as reference for MRI safety criteria [1].

The ICNIRP takes, for field frequencies between 3 kHz and 10 MHz, a limit of 170 V/m whereas Reilly proposes the following equation for our frequency range:

$$E_t = E_0 \left(\frac{f}{f_e}\right)^{0.9}.$$

Where E_t is the electric field threshold (in V/m), E_0 is the minimum threshold at the optimum frequency (in V/m), which is equal to 7.2 V/m in our case [4], f is the considered frequency (in Hz) and f_e is an empirically determined frequency. There are two values for the f_e frequency regarding PNS, namely 500 Hz and 5400 Hz. The first one has been determined based on a literature review done by Reilly [4], and the other one stems from simulations carried out by Reilly [4]. For cardiac stimulation, a third value, $f_e = 120$ Hz, has been determined by Reilly [4], based on a literature review. For our calculations, we will consider the heart of the animal as a sphere of 4 cm in radius.

Results

The maximum value for E_i has been calculated for different frequency configurations. When the x, y and z drive fields are used with frequencies of 24.51 kHz, 26.04 kHz and 25.25 kHz respectively, we induce a maximum electrical field of 447 V/m for

the whole body, and 179 V/m for the heart. When we use other configurations, we may induce a field up to 2% higher. Those induced fields are above the two Reilly PNS and the ICNIRP thresholds, but still below the Reilly threshold for cardiac stimulation. Those data are summarized in table 2.

Table 2. E values calculated for the different thresholds and for the configuration which produces the smaller E_i value

	Reilly 5400 Hz (body)	ICNIRP (body)	Reilly 500 Hz (body)	This scanner (body)	This scanner (heart)	Reilly 120 Hz (heart)
E / V/m	29	170	247	447	179	2230



Discussion

To consider the magnetic field to be constant over the whole volume with an amplitude equal to the maximum value of the magnetic field in the mid plane seems to be conservative, but we have to keep in mind that the higher field value will be generated near the coils, i.e. near the animal skin, and thus, a higher electrical field may be induced. However, considering the electrical field induction as a sinusoidal signal with a constant amplitude equivalent to the peak value of the field induction is conservative [7]. Moreover, PNS thresholds seem to be higher for inductive excitation than for direct electrical excitation [8]. As Reilly's thresholds are based on direct electrical excitations, the use of those thresholds for inductive excitation is also a conservative assumption. Moreover, ICNIRP thresholds are calculated using high a factor to compensate for dosimetric uncertainties [9]. Nevertheless, those preliminary numbers show that the induced electrical field with our scanner is below the threshold of cardiac stimulation, thus allowing us to perform animal experiments in good condition. We still have to perform calculations with more precise models, in terms of magnetic field representation and animal model geometries. Finally, heating of the animal tissue still has to be examined according to Specific Absorption Rate (SAR) standards and actual work on MPI related application [10].

Conclusion

Through this paper, we showed that our animal scanner should not cause any cardiac arrhythmias on the animal, even if we use high driving field amplitudes. But the threshold for PNS is still too vague to conclude on peripheral nerve stimulation, and further experiments have to be carried on.

Acknowledgments

The authors gratefully acknowledge the financial support of the German Federal Ministry of Education and Research (BMBF) under grant number 13N11090, of the European Union and the State Schleswig-Holstein (Programme for the Future – Economy) under grant number 122-10-004 and of Germany's Excellence Initiative [DFG GSC 235/1].

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