Evaluation of ASTM and Racetrack Phantom for Safety Test of Medical Implants in Respect to ASTM F2182–11a and ISO/TS 10974 (technical specification)

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Purpose

RF induced heating during MR imaging can be increased surrounding the medical implants in the human body. To estimate the risk, the implant could be evaluated in a similar artificial environment (in-vitro evaluation). The in-vitro evaluation has to be performed for the maximum possible induced heating of the implant (worst-case). When the worst-case is defined and the maximum RF E-field is calculated, the implant has to be tested in a homogenous E-field environment with the same magnitude and phase. According to ISO/TS 10974 (technical specification) [1], testing shall be performed using a known uniform electromagnetic field in magnitude and phase. The objective of the test system is to obtain the smallest uncertainty with respect to test results. Important test conditions are a constant E-field amplitude and phase of less than 1 dB deviation in magnitude of E_{tan}-field over the entire AIMD as well as less than 20 degree phase variation. These conditions can be obtained with various RF sources (coil systems) and different phantoms. The homogeneity of the E-field is only important wherever the field is tangential to the implant, i.e. for the complicated structure, finding the constant tangential E-field and therefore a homogenous field is nearly impossible. This document focuses therefore on a simple and general case of implant, a long wire.

Method

An example of a coil system that meets the requirements is a birdcage coil, which is mentioned in the ISO/TS 10974 and we use in the simulation setup with SEMCAD X (Speag, Zurich, Switzerland) without considering the shield room. Examples of phantoms are provided in Annex M of the ISO/TS, which we intend to simulate and compare here. These examples are so called 'ASTM' and 'Race-track' oval phantoms. The E_{tan} -field has been extracted from full 3D simulation of both phantoms along an arbitrary closed loop in terms of magnitude/phase and evaluated based on the defined limits. The ASTM phantom is defined in ASTM F2182-11a [2] standard as a rectangular slab of gel, the simulating tissue material. The material properties are mentioned in the standard's text.

Results

Results of simulations with a generic birdcage coil show a variation of more than 8 dB in magnitude at the ASTM phantom along the closed loop together with phase variation beyond the limits. In case of race track phantom, the change in magnitude of Etan-field is registered to be less than 1 dB and the phase variation is approximately 20 degree along the path. The measurement of E-field in an in-house built horizontal positioned racetrack phantom proves the numerically calculated E-field using SEMCAD X. Fig. 1 and Fig. 2 show the method of extracting E-field magnitude and phase along the same arbitrary path inside the racetrack and ASTM phantom respectively. Although the phase variation in ASTM is within the defined limit same as the racetrack phantom, but more than 3 dB variation of magnitude in ASTM phantom over the exact same path (same in shape and dimension) in compare with 0.88 dB variation of magnitude in racetrack phantom is considered as a drawback for using this phantom for safety test of active implants. However there could be a smaller path found in ASTM phantom with relatively high power deposition and homogeneous E-field fulfilling the requirement of ISO/TS 10974, but not long enough to host many of major active implants with high risk of generating hazard for patients. The results could slightly vary by adding additional shielding room to the simulation setup.

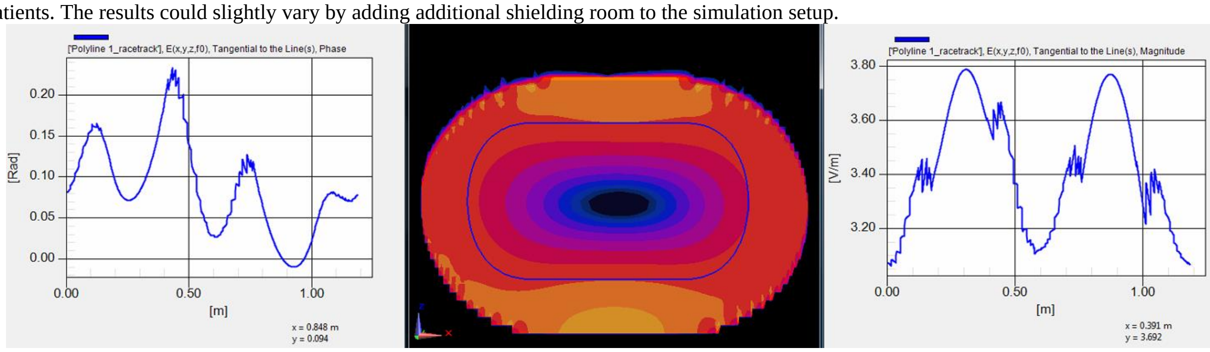

Fig.1 13° phase variation and 0.88 dB Magnitude variation of tangential E-field along the loop path in racetrack phantom

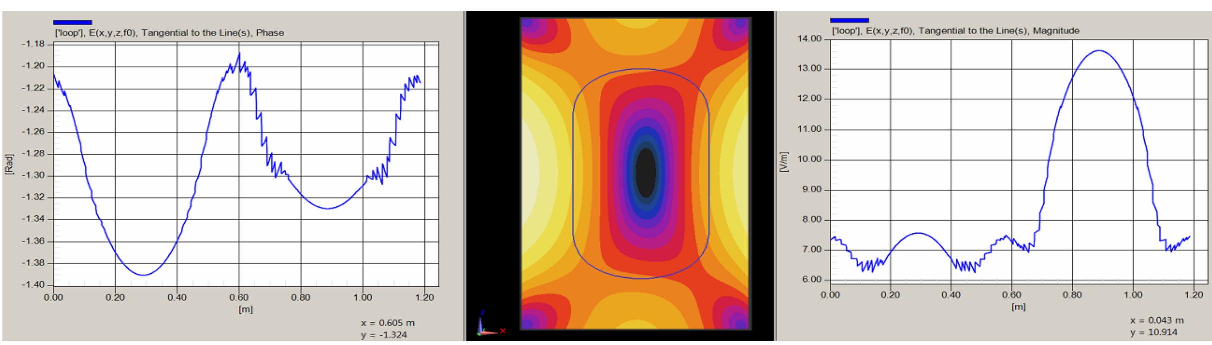

Fig.2 12° phase variation and more than 3 dB Magnitude variation of tangential E-field along the same loop path in ASTM phantom

Conclusions

Two body phantom designs with the same human body tissue simulating medium have been compared in terms of homogeneity of E-field in a loop path. The purpose of this study is to verify whether it's feasible to locate a long lead active implant in these phantoms by fulfilling the requirement of ISO/TS 10974. Based on the simulation and measurement results, the racetrack phantom is providing a long homogeneous area thus fulfilling the minimal requirements of ISO/TS 10974 considering amplitude and phase homogeneity. This area can be used to place a long thin lead implant for testing in respect to ISO/TS 10974 Clause 10 and 19. The ASTM phantom is found to be not suitable and doesn't meet the mentioned requirements. Nevertheless, the racetrack phantom electric field characteristic has difficulties hosting broad implants as the homogeneous zone is very narrow and therefore rather suitable only for thin implants. The extraction of the E_{tan}-field in the implementation area of a broader object with all dimensions is large (similar to a hip implant). Such device is better to be placed in the ASTM phantom since there is a larger space of relatively homogeneous E-field area fulfilling the requirement of ASTM and ISO/TS 10974.

References

[1] Technical specification ISO/TS 10974 "Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device"1st edition 2012. [2] F2182 – 11a "Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging".

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Introduction

The safety of Magnetic Resonance imaging systems becomes more critical since the use of MRI is becoming more popular and developed for various diagnostics including the patients wearing medical implants. To estimate the risk, the implant could be evaluated in a similar artificial environment (in-vitro evaluation). These phantoms are developed and introduced in ASTM F2182 – 11a [1] as ASTM phantom and ISO/TS 10974 (technical specification) [2] as 'Race-track' oval phantom. However for both passive and active implants, the E-field should be uniform along the implantation area in terms of magnitude and phase in order to eliminate the effect of variation of electric field in absence of implant from the final test. Nevertheless the evaluation has to be performed for the maximum possible induced heating of the implant. By fulfilling these requirements, minimum uncertainty could be obtained for the evaluation. Appropriateness of Racetrack phantom for implementing large passive medical implants is studied in this article by extracting the E-field along the implantation path. Currently the ASTM phantom is the most popular and appropriate phantom for such an implants. The homogeneity of the E-field is only important wherever the field is tangential to the implant.

Methodology

A tuned generic birdcage coil has been used for simulations with SEMCAD X (Speag, Zurich, Switzerland) without considering the shield room. The E_{tan}-field has been extracted from full 3D simulation of phantom and the containing gel simulating the human tissue along an arbitrary closed path shaped as a generic hip implant. The defined limits in ISO/TS 10974 for active implants specifies less than 1dB variation of magnitude and less than 20 degree variation in phase shift of E_{tan}-field along the implantation area. Although the desired path is more similar to passive implants, but this could be a reference to evaluate the E-field in this study.

Results

Fig. 1 (left) exhibits the results of simulations with a tuned generic birdcage coil with two source ports as in realistic clinical coils showing a variation of maximum 0.9 dB for magnitude of E-field (by ignoring two small dimensions of the path which are perpendicular to the local E-field). The phase of E-field is plotted in Fig. 1 (right) and shows maximum 14 degree phase variation which is fulfilling the requirement of ISO/TS 10974 for even larger medical implants like hip and not only thin and long implants which is demonstrated in Annex M of standard. The measurement of E-field in an in-house built horizontal positioned racetrack phantom proves the numerically calculated E-field using SEMCAD. However the path we have specified here is a 2 dimensional path which is not realistic as a real hip implant is large in the third dimension too, therefore Racetrack phantom could not host a 3D large implant, but only thin and long implant could be hosted for safety tests. Fig. 2 and Fig. 3 show the E-field magnitude and phase along the same arbitrary path inside the racetrack and ASTM phantom respectively. Although the phase variation in ASTM is within the defined limit same as the racetrack phantom, but more than 3 dB variation of magnitude in ASTM phantom over the exact same path (same in shape and dimension) in compare with 0.88 dB variation of magnitude in racetrack phantom is considered as a drawback for using ASTM phantom for safety test of active implants.

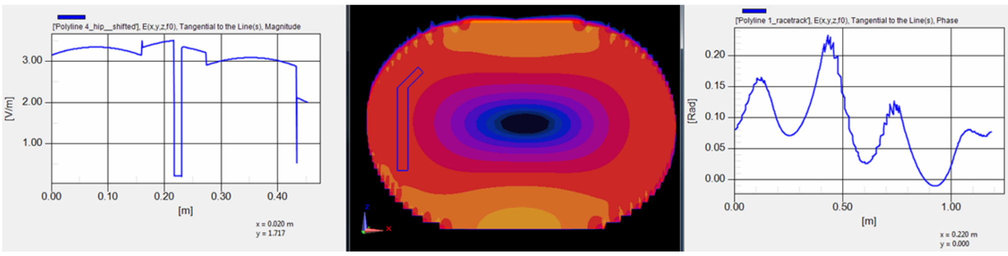

FIG. 1: 14° phase variation and 0.9 dB Magnitude variation of tangential E-field along the generic hip path in racetrack phantom.

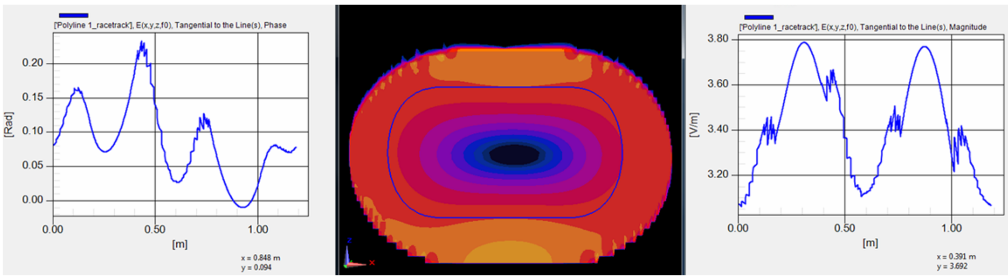

FIG. 2: 13° phase variation and 0.88 dB Magnitude variation of tangential E-field along the loop path in racetrack phantom.

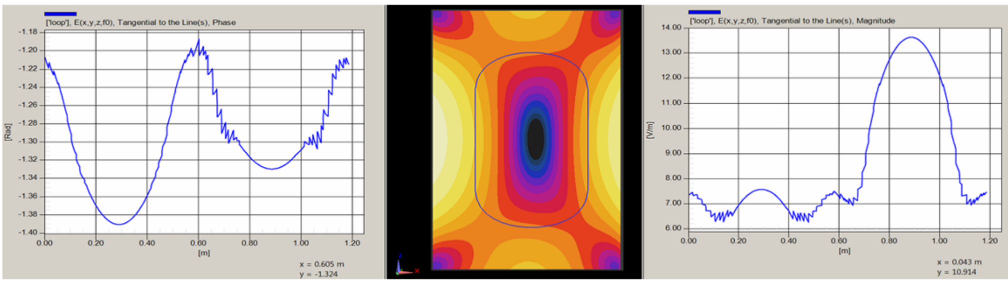

FIG. 3: 12° phase variation and more than 3 dB Magnitude variation of tangential E-field along the same loop path in ASTM phantom.

Discussion and Conclusion

Two body phantom designs with the same human body tissue simulating medium have been compared in terms of homogeneity of E-field over the same loop path as well as in a generic orthopedic implant path. The purpose of this study is to verify whether it's feasible to locate a long lead active implant or a large size implant in these phantoms by fulfilling the requirement of ISO/TS 10974. Based on the simulation and measurement results, the racetrack phantom is providing a long homogeneous area thus fulfilling the minimal requirements of ISO/TS 10974 considering amplitude and phase homogeneity. This area can be used to place a long thin lead implant for testing in respect to ISO/TS 10974 Clause 10 and 19. Although the amplitude of E-field in ASTM phantom over the same size of the loop exceeds the limits, as shown in the results of simulations, smaller loop path could be specified in this phantom to fulfil the limits. Nevertheless, the racetrack phantom electric field characteristic has difficulties hosting broad implants as the homogeneous zone is very narrow and therefore rather suitable only for thin implants. The extraction of the E_{tan}-field in the implementation area of a broader object (similar to a hip implant) has been studied. Such device is better to be placed in the ASTM phantom since there is a larger space of relatively homogeneous E-field area fulfilling the requirement of ASTM and ISO/TS 10974.

References

[1] F2182 – 11a "Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging".

[2] Technical specification ISO/TS 10974 "Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device"1st edition 2012.