InSilicoMRI: An Automated Computational Tool to Study MRI RF Safety of Medical Devices

Elena Lucano[1], Peter Serano[2], Marc-Antonio Bisotti[1], Marc Horner[2], Luca Emili[1], Leonardo M. Angelone[3]

[1]InSilicoTrials Technologies, [2]ANSYS, Inc., [3] U.S. Food and Drug Administration, Center for Devices and Radiological Health, Office of Science and Engineering Laboratories

INTRODUCTION

The absorption of radiofrequency (RF) energy during a magnetic resonance imaging (MRI) procedure may cause tissue heating in the vicinity of an implanted device, potentially causing patient harm. Computational modeling and simulation (M&S) tools are frequently used by medical device manufacturers to assess the safety of implanted devices in an MR environment. The NuMRis (Numerical Magnetic Resonance Implant Safety) tool is proposed as a web-based application that automates the set-up and solution of RF heating analysis, in line with guidelines and existing standards for in-vitro testing.

MATERIALS AND METHODS

The NuMRis tool is part of the InSilicoMRI library within the InSilicoTrials platform. NuMRis was developed as part of a collaboration between:
- InSilicoTrials Technologies,
- US FDA Center for Devices and Radiological Health, and
- ANSYS, Inc.

The NuMRis tool consists of a web interface where the user defines the input parameters specific to an MRI exposure scenario. Each simulation is submitted to the IST cluster running on the Microsoft Azure infrastructure.
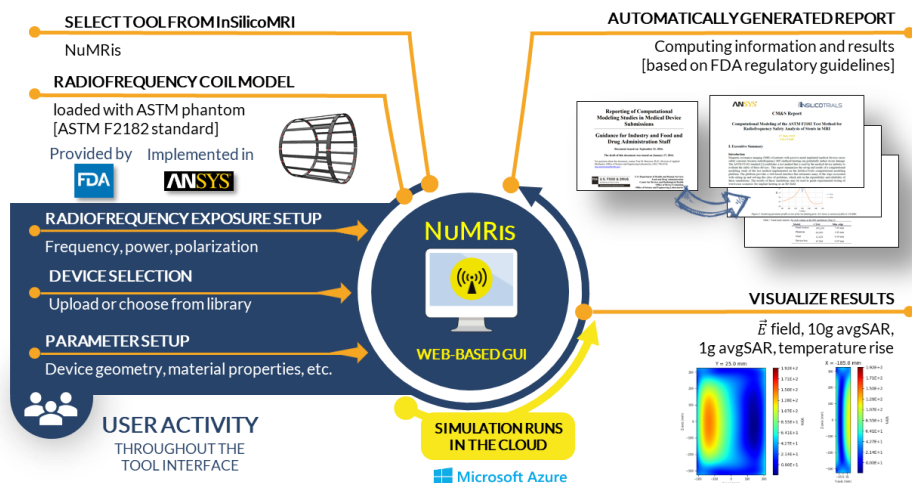

Figure 1. Overview of the NuMRis tool simulation workflow. The free (limited functionality) version of the tool allows users to simulate a simplified single or dual stent device. The geometrical dimensions (diameter and length) and material of each stent are defined by the user before initiating a simulation.

The tool uses ANSYS HFSS (v. 19.2, ANSYS, Inc.) and ANSYS Mechanical (v. 19.2, ANSYS, Inc.) to compute RF energy absorption and thermal heating for 1.5 T and 3 T MRI systems, replicating the directives of the ASTM F2182 standard.
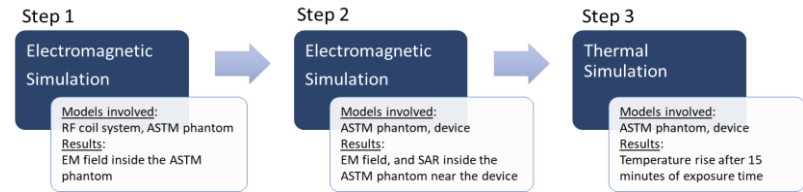

Figure 2. Simulation workflow performed using ANSYS Workbench 19.2. Results of the M&S study are obtained through a three-step simulation using the NuMRis tool, which automates the numerical calculations between the individual electromagnetic and thermal solvers.

RESULTS AND DISCUSSION

The NuMRis tool enables users to access the benefits of M&S for the thermal safety assessment of implantable medical devices during an MRI procedure following established good simulation practices. The platform simulation results are summarized in an automatically generated report that follows current FDA guidance on M&S reporting [1].

Minimal training/background in computer modeling is required to use the tool. A pay-per-use version of the tool was developed by IST as an extension of the free tool.

TRANSLATIONAL IMPACT

The proposed platform promotes the broader adoption of digital evidence in preclinical trials for RF safety analysis, supporting the device submission process and pre-market regulatory evaluation. Specific potential applications of the NuMRis platform include RF-heating assessment of orthopedic devices (e.g., rods and screws), and cardiovascular devices (e.g., stents) (see also V&V40 [2]).

Disclosure Statement: The mention of commercial products, their sources, or their use in connection with material reported herein is not to be construed as either an actual or implied endorsement of such products by the Department of Health and Human Services.

References

[1] Reporting of Computational Modeling Studies in Medical Device Submissions, FDA guidance (2016).
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