InSilicoMRI: Automated Computational Tool to Study MRI RF Safety of Medical Devices
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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 MR environment. For example, M&S has been used to study the variables that affect RF-induced heating and identify worst-case configurations within a given line of implants [1]. The InSilicoMRI simulation platform 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. The platform simulation results are summarized in an automatically generated report that follows FDA guidance on M&S reporting [2]. Specific potential applications of the InSilicoMRI platform include RF-heating assessment of orthopedic devices (e.g., rods and screws), pain management devices (e.g., leads), and cardiovascular devices (e.g., stents) (see also V&V40 [3]).

Materials and Methods: The InSilicoMRI environment was implemented in collaboration between InSilicoTrials Technologies (IST), the US FDA Center for Devices and Radiological Health, and ANSYS, Inc. 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 (Fig. 1). The 1.5 T RF coil follows the implementation procedures defined within the “interlab study” performed by Lucano et al. [4], whereas the 3 T RF coil is based on the implementation by Bonmassar et al. [5].

The InSilicoMRI 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 Microsoft Azure infrastructure for solution. A free (limited functionality) version of the tool is now available as a result of this collaboration, and a pay-per-use version of the tool was developed by IST as an extension.

Results and Discussion: The InSilicoMRI simulation platform 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. Minimal training/background in computer modeling is required to use the platform. InSilicoMRI also allows users to view and download the results for each simulation, including: electromagnetic fields, local specific absorption rate (SAR), and the temperature rise over time.

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.

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