NuMRis

An automated computational tool to study MRI safety of implanted passive cardiovascular medical devices.

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Purpose

The absorption of radiofrequency (RF) energy during an MRI scan may cause tissue heating in the vicinity of an implanted device,such as a stent or a stented valve, potentially causing patient harm. Computational modeling and simulation (M&S) can be used by medical device manufacturers to assess the RF-induced heating of implanted devices during MRI scan.

NuMRis is an automated web-based application to set-up and solve RF-heating analysis in line with existing standards [1,2]. It is integrated within the web-based InSilicoTrials platform and was developed in collaboration with Ansys and as part of a Research Collaboration Agreement with US FDA.

InSilicoTrials

Methods

Through the NuMRis web-interface the user can:

i) upload or select the medical device 3D model or select a simplified geometry from the library;
ii) define its material properties; ii) set the desired input parameters specific to an MRI exposure scenario;
iii) insert optional extraction probes within the ASTM phantom;
iv) run simulations on the Microsoft Azure cloud;
v) view results, including the temperature rise over time;
vi) download the automatically generated report that follows FDA guidelines on M&S reporting [3]. Validation of the tool was performed against experimental measurements on stent-like structures composed by bare hollow rods. Heating tests following the ASTM 2182-11a Standard [1] were performed using the MITS 1.5 system (Zurich Med Tech, Zurich, Switzerland), while computational transient thermal simulations reproducing the same standard were run with NuMRis. Temperature values were extracted at both rod tips.

Set up & Launch Simulation | **Results** | **Report**

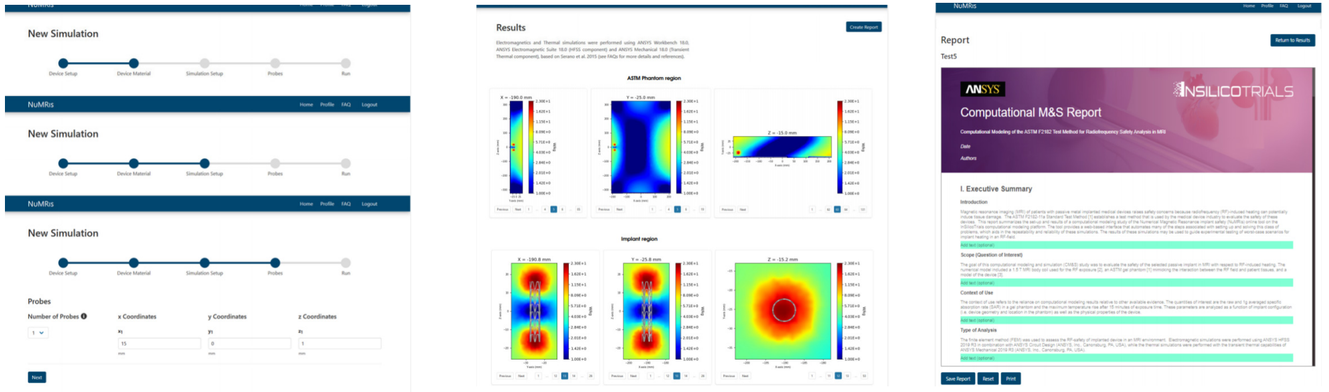

Figure 1: User workflow through NuMRis web interface. The example shows the RF safety assessment simulation on an implanted stent.

Results

The bare stent-like rod showed a peak value at 200 mm length for both tips (Fig. 2). The temperature difference between measurements and simulations was always below 5%.

Results were consistent with previously published results [4,5]. Additional analyses will be performed to assess the temperature increase at longer exposures.

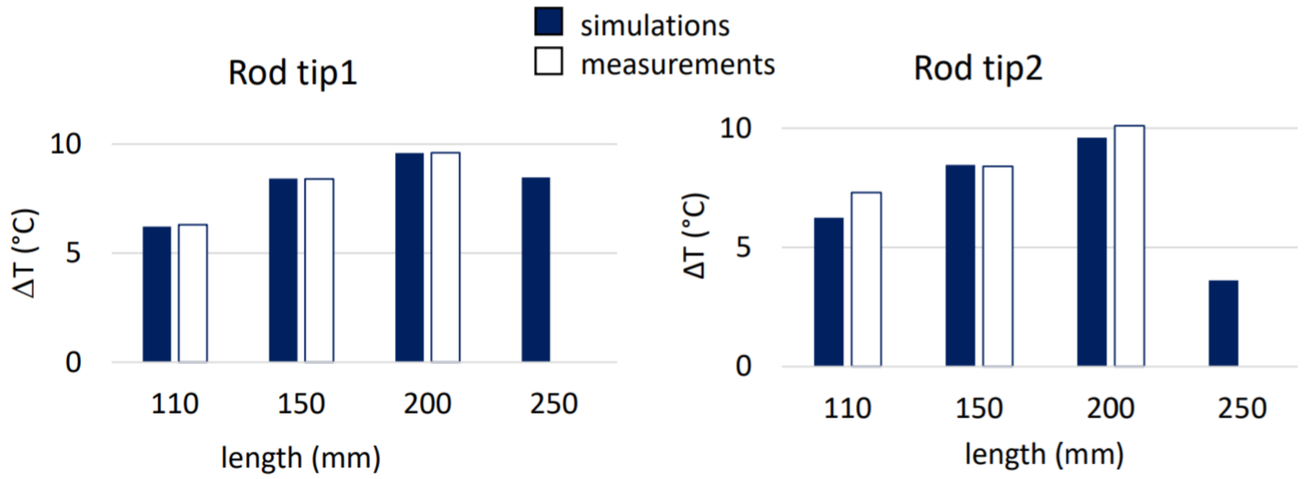

Figure 2: Temperature rise for the bare hollow stent-like rod at different lengths.

Conclusions

NuMRis is a web-based tool that allows users to perform thermal safety assessment of implantable medical devices during an MRI scan. Minimal training or background in computer modeling is required.

Potential applications include RF-heating assessment of cardiovascular devices (e.g., stents, stented valves, stent retrievers). NuMRis also supports the regulatory submission process and pre-market evaluation by promoting the broader adoption of digital evidence in RF safety analysis.

References

[1] ASTM F2182-11a, ASTM International (2011)
[2] Assessment of RF-Induced Heating in the MR Environment for Multi-Configuration Passive Medical Devices, US FDA CDRH (2016)
[3] Reporting of Computational Modeling Studies in Medical Device Submissions, US FDA CDRH (2016)
[4] Armenean et al., Magnetic Resonance in Medicine 52:1200 –1206 (2004)
[5] Bottomley et al., Medical Physics 37(7):3828-3843 (2010)

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