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**.

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.

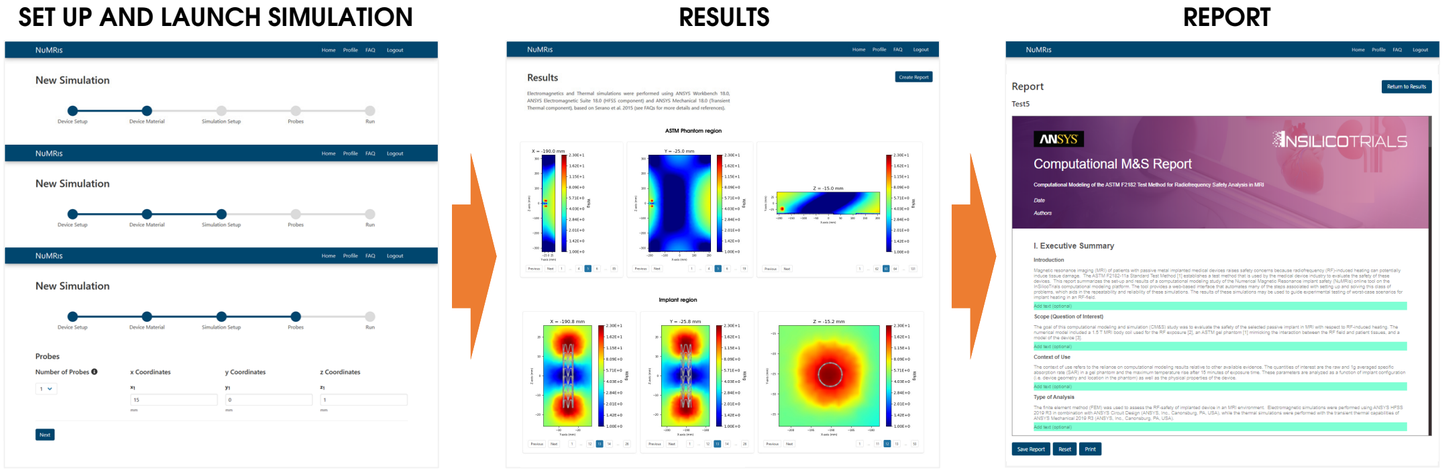

Figure 1: User workflow through NuMRis web interface. *The example shows the RF safety assessment simulation on an implanted stent.*

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.

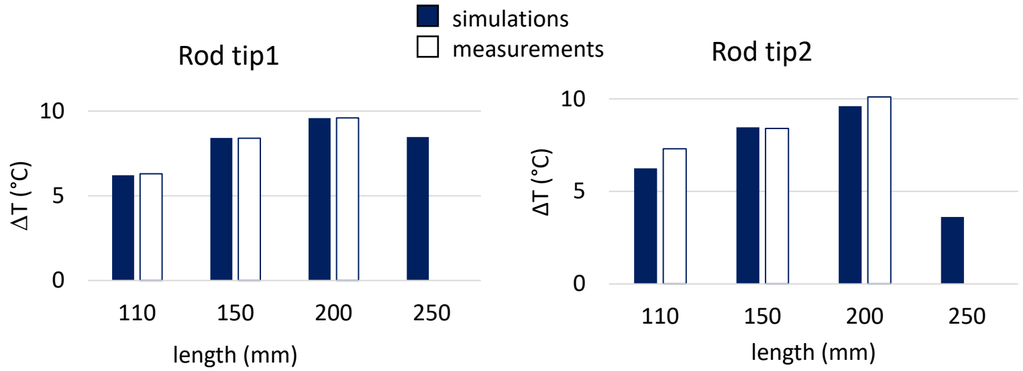

Figure 2: Temperature rise for the bare hollow stent-like rod at different lengths.

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)