



A smarter way to design MRI-safe implants

Eliminating repeated prototyping and
accelerating development timelines with
efficient modelling of transfer functions

Full-body MRI compatibility is rapidly becoming a baseline expectation for active implantable medical devices.

Clinicians and patients increasingly expect MRI access as standard, and most implant recipients will need at least one scan over the lifetime of their device. Meanwhile, major manufacturers have raised the bar with substantial investment in MRI safety, increasing competitive pressure across the market.

For implants with long leads, RF-induced heating is the critical bottleneck. Tissue heating driven by RF currents induced in long leads is one of the hardest risks to control and demonstrate effective risk reduction. In practice, it often determines whether a system can achieve MRI-conditional labelling, especially for full-body claims. Yet effective and scalable approaches for MRI labelling are limited, and repeated prototype build-test cycles quickly become unaffordable for mid-sized and emerging companies.

In this paper, we outline an efficient way to design leads that meet MRI-induced heating limits. It supports rapid, scalable evaluation across lead designs, enabling earlier down-selection and reducing the burden of repeated build-test iterations. This provides a clearer regulatory narrative and can shorten development timelines on the route to full-body MRI-safe devices. The approach leverages ISO 10974:2018(E), which explicitly recognises transfer function (TF) modelling for evaluating RF heating.



Examples of MR labelling of different AIMD systems from leading manufacturers

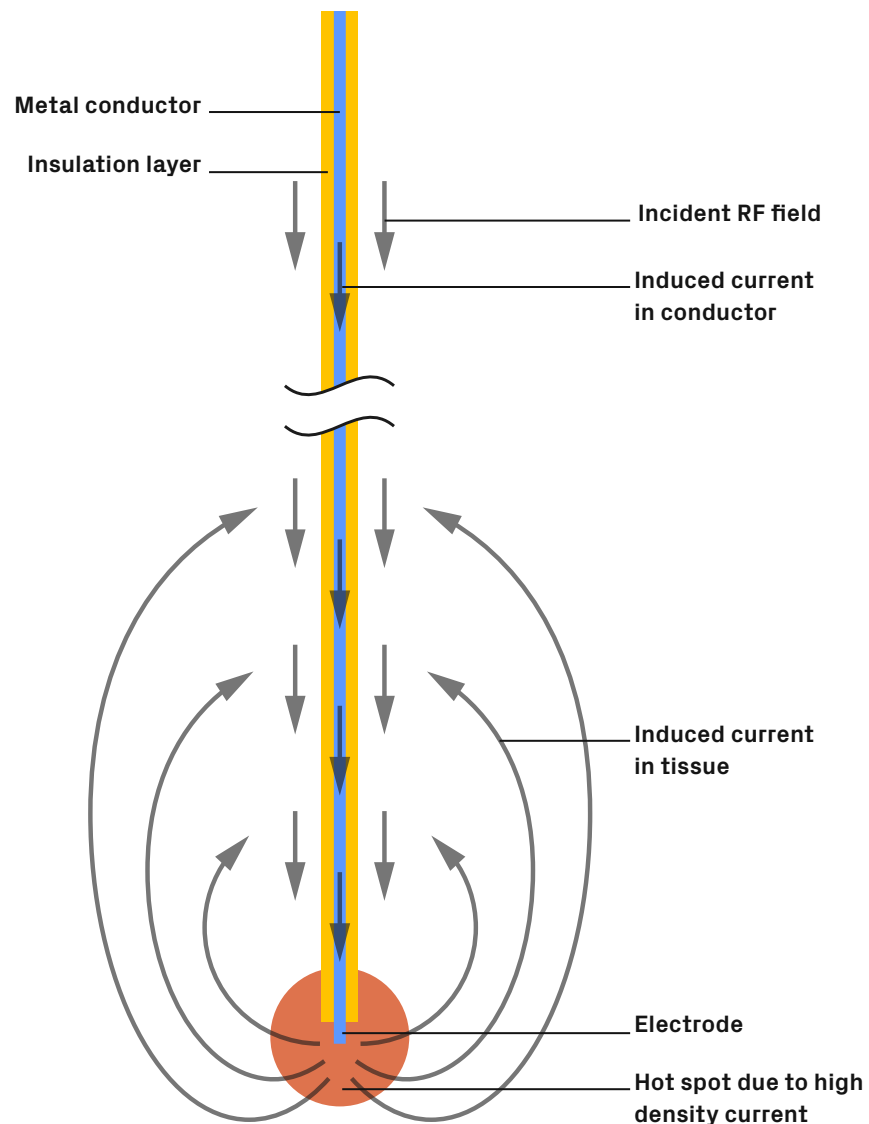
Company	Therapy	Device	MRI labelling
Medtronic	SCS	Inceptiv™ SCS	Full-body MR conditional, 1.5T & 3T
	DBS	Percept™ PC/RC	
	SNS	Interstim™ Micro/X	
	Pacemaker (CRM)	Advista™ MRI SureScan™	
Boston Scientific	SCS	WaveWriter Alpha™	Full body MR conditional, 1.5 T
	DBS	Vercise Genus/Gevia	MR conditional, 1.5 T
	SNS	Axonics© r-SNM/SNM	Full body MR conditional, 1.5 T & 3 T
Abbott	SCS	Proclaim™ XR, Eterna™	Full body MR conditional, 1.5 T
	DBS	Infinity™ DBS	MR conditional, 1.5 T
	Pacemaker (CRM)	Assurity MRI™	MR conditional, 1.5 T & 3 T
Biotronik	SCS	Prospera™ SCS	Full body MR conditional, 1.5 T & 3 T
	Pacemaker (CRM)	Edora/Evity/Enitra ProMRI©	MR conditional, 1.5 T & 3 T
LivaNova	VNS	SenTiva™ / AspireSR™	MR conditional, 1.5 T & 3 T
Cochlear	Cochlear implant	Cochlear™ Nucleus© Profile Plus	MR conditional (magnet in place), 1.5 T & 3 T

MRI compatibility labelling of AIMDs

MRI compatibility labelling for AIMDs addresses several patient safety and device integrity aspects. Evaluations consider magnetic forces and torques that could displace or rotate the implant, image artifacts that may obscure diagnosis, damage of implant electronics by electromagnetic interference, and RF-induced heating that could harm tissues or impair device function.

The labelling follows ASTM F2503 guidelines (Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment), while ISO 10974:2018(E) provides the evaluation framework for assessing AIMD safety in the MR environment. AIMDs typically consist of an implantable pulse generator (IPG) that houses the electronics in a hermetic enclosure, and one or more leads that connect the IPG to electrodes interfacing with the tissue.



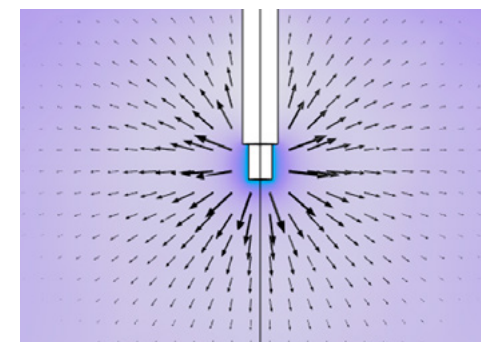


Risks from magnetic forces and torques are mitigated by avoiding high-permeability materials, such as ferrites, in the IPG.

Image artifacts are largely unavoidable with metallic housings, but their extent can be contained through careful device design and labelling of imaging conditions. Electronics can be protected against electromagnetic interference through passive filtering at IPG inputs and proactive switching of the device into an MRI operating mode.

RF heating is a specific challenge in AIMDS with long leads. While relatively little MRI RF energy couples into IPGs due to their small size, long conductive leads can act as unintended antennas, picking up significant RF energy from the MRI field.

Since the main lead body is insulated, coupled currents are discharged into the tissue at metallic electrode contacts that must remain exposed for therapeutic stimulation. As these contacts are relatively small, the resulting current densities lead to localised tissue heating at the electrode-tissue interface. This mechanism is illustrated in the diagram to the left.



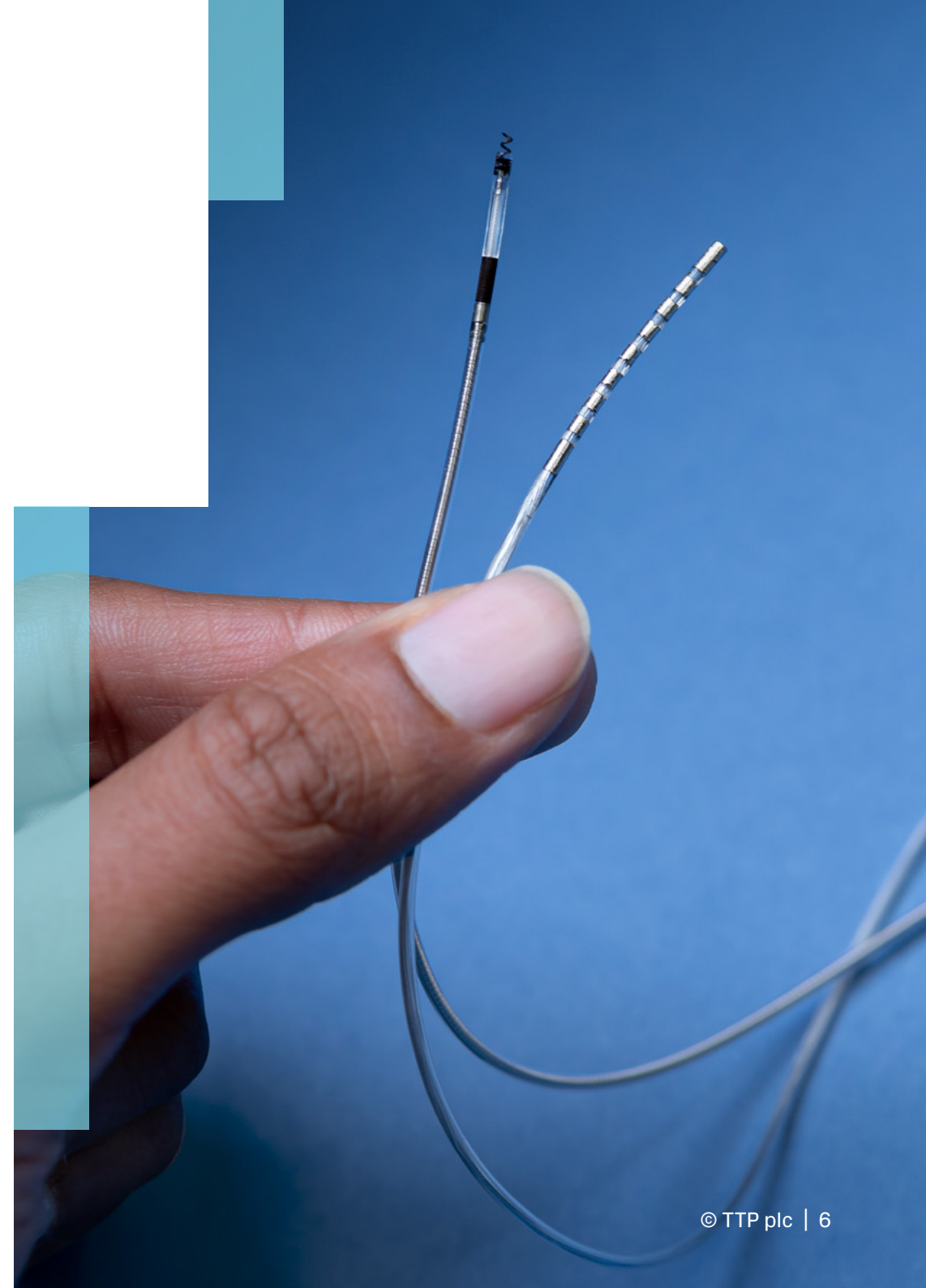
Finite element simulation showing the spatial distribution of electrical current in tissue surrounding a metallic electrode contact

Active methods for suppressing RF-induced heating in AIMDs focus on modifying lead design and adjusting the high-frequency circuit properties at the lead-IPG connection, for example RF filtering or shunting at the input.

Simple lead modifications include increasing lead's ohmic resistance or increasing its inductive resistance by coiling the wire. More advanced approaches use high-impedance RF traps, where coil inductance is tuned with discrete capacitors or conductive shielding, or deploy “billabong” leads with reversed coiled sections. Additional approaches include RF shielding and optimisation of insulation thickness.

Each lead design must be evaluated not only for its expected reduction in Specific Absorption Rate (SAR), but also for its impact on lead functionality, surgical handling, anchoring, manufacturability, cost, physical size, and time to market.

While these broader considerations are critical for successful product development, this paper focuses specifically on the efficient evaluation of design choices with respect to SAR suppression performance, leveraging the ISO 10974:2018(E) guidelines.

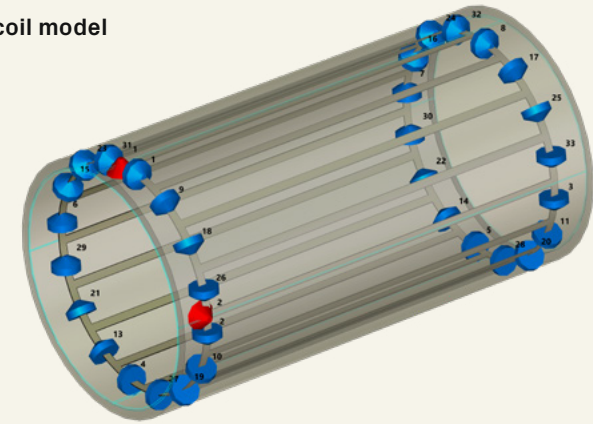


Regulatory framework for RF safety modelling

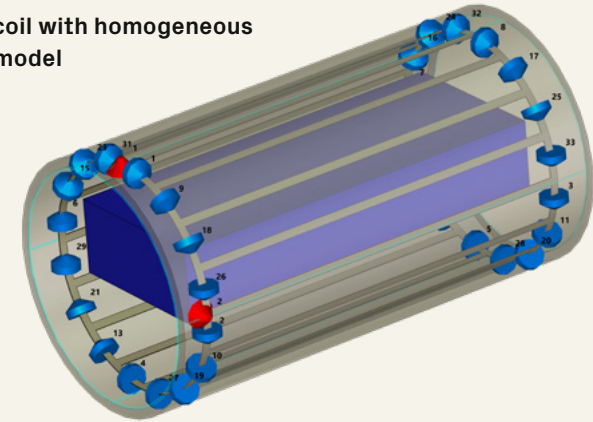
The ISO/TS 10974 standard (2012/2018) establishes a tiered modelling framework for assessing RF safety of long conductive AIMDs:

- **Tier 4** is the “holy grail” of MRI safety modelling. It involves full-system electromagnetic simulation of the RF coil, the patient body model, and the implant. In principle, Tier 4 offers the most accurate and reliable assessment, capturing all interactions directly. However, it is computationally unfeasible since the problem spans multiple scales, requiring fine resolution of microscopic features such as lead wire coatings while also solving macroscopic RF fields generated by the MRI birdcage coil. Even with modern HPC resources, Tier 4 is impractical for routine use.
- **Tier 3** Is the practical compromise adopted by industry and regulators. Here, the implant is characterised separately using the transfer function (TF) which captures how local tangential electric fields couple into the lead. The TFs are then combined with MRI exposure simulations in anatomical models to estimate worst-case heating. By separating the scales, Tier 3 avoids the impossible computational burden of Tier 4, while still providing repeatable, efficient, and scalable evaluation across implant routings, patient anatomies, and scanner configurations.

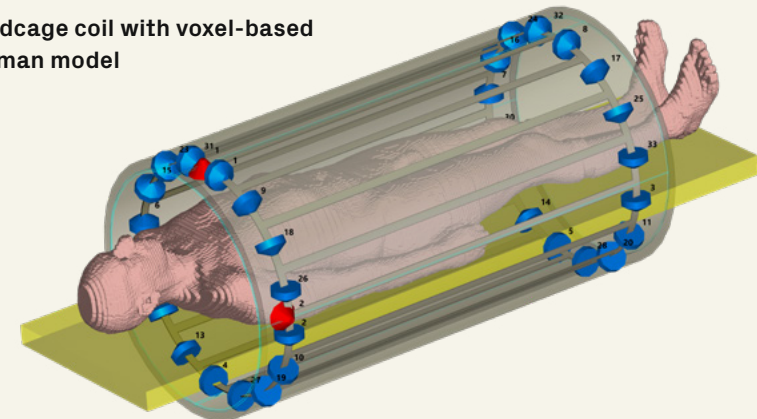
Birdcage coil model



Birdcage coil with homogeneous phantom model



Birdcage coil with voxel-based human model



ISO 10974 specifies several techniques for deriving the TF, including reciprocity, modal decomposition, and current-based methods. Among these, the piecewise excitation (PWE) method is explicitly endorsed and has become the industry and regulatory standard.

In practice, however, TFs are often still determined experimentally in phantoms and then integrated with precomputed RF exposure fields. This workflow requires physical prototyping of leads, and if a design fails to meet requirements, iterative and costly prototyping and retesting are necessary.

To address this limitation, TTP's Neurotechnology team developed a finite element (FEM)-based approach to compute transfer functions directly and efficiently. This method short-circuits repeated prototyping and testing cycles, enabling faster design iteration and allowing engineers to make informed, simulation-driven decisions early in development.

Crucially, this shifts Tier 3 from a prototype-bound workflow (where TFs must be measured) toward a model-informed one, where TFs can be estimated early to guide design and reserve experiments for targeted, confirmatory validation.

Implementing Tier 3: the Transfer Function workflow

Tier 3 is implemented by separating the MRI RF exposure problem into two coupled parts: a background RF field solution that captures the patient/phantom and transmit coil environment, and a lead characterisation that captures how that field couples into the implant.

Using linearity of Maxwell's equations, the induced response at the point of interest can be expressed as a weighted superposition of the tangential field along the lead:

$$\mathbf{E}_s(\mathbf{r}) = \int TF(\mathbf{r}, z) E_{\text{tan}}(z) dz$$

where $E_{\text{tan}}(z)$ is the local tangential field along the lead and $TF(\mathbf{r}, z)$ is the transfer function.

Step 1 – Background field

Simulate the RF coil with a body model (or phantom) without the lead and extract the tangential electric field $E_{\text{tan}}(z)$ along possible lead trajectories.

Step 2 – Lead characterisation

Obtain the transfer function $TF(\mathbf{r}, z)$ to describe how tangential RF fields couple into the lead.

Step 3 – Combine

Convolve $TF(\mathbf{r}, z)$ with $E_{\text{tan}}(z)$ to estimate the induced response for each routing and RF exposure condition.

By computing transfer functions using a robust modelling workflow, our approach reduces reliance on repeated prototyping and testing, accelerating design iteration and reserving measurement for pivotal verification and validation steps.



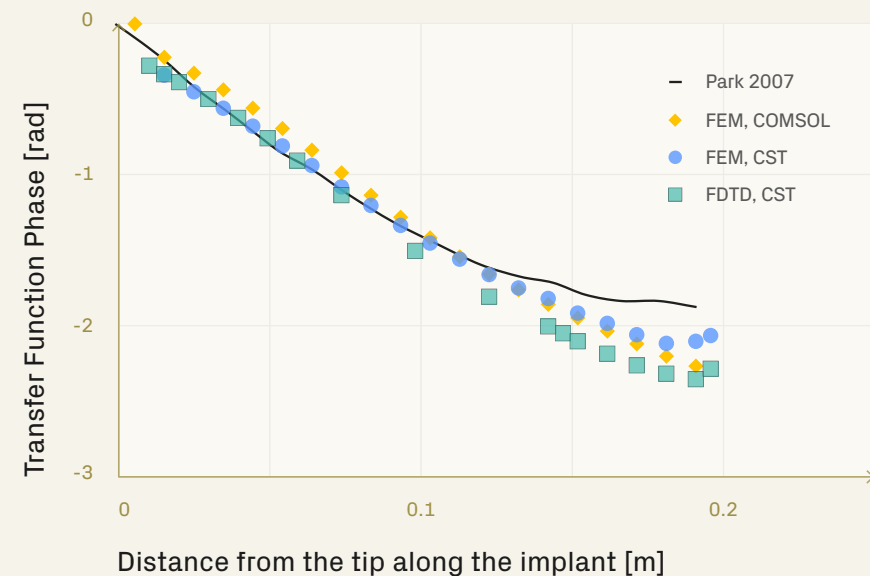
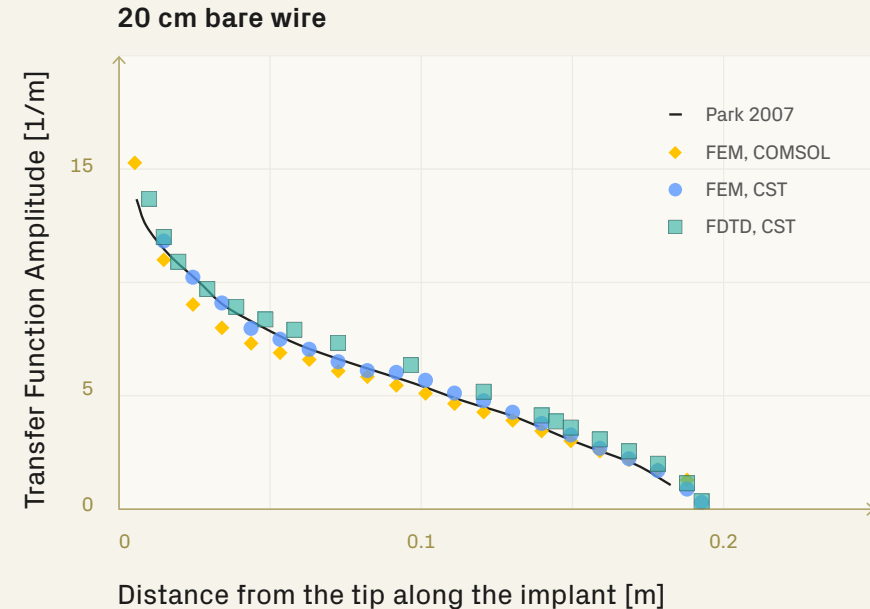
A practical, simulation-driven derivation of TF

Our project involved developing a modelling toolchain for the efficient modelling of TF and implementing it in two commercial RF simulation platforms: COMSOL and CST.

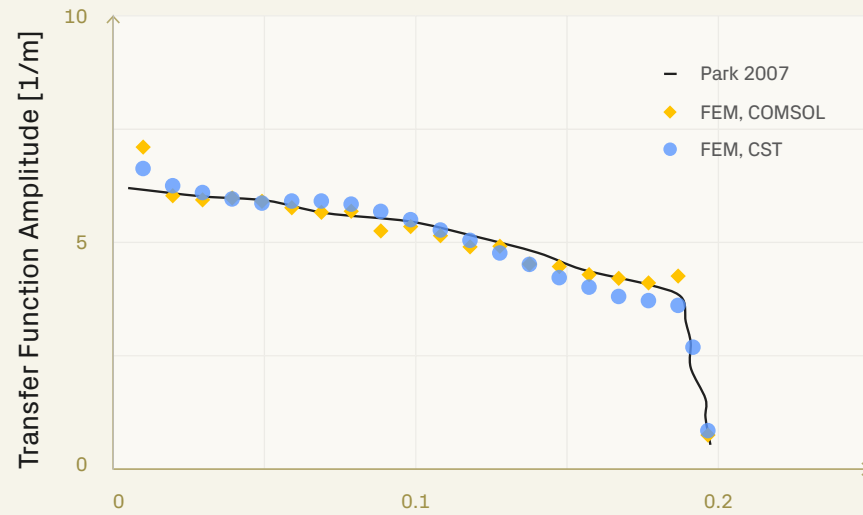
We established that FEM (Finite Element Method)-based frequency-domain solvers are more efficient than FDTD (Finite-Difference Time-Domain), which are computationally expensive due to structured meshing constraints.

COMSOL and CST frequency domain solvers were in excellent agreement, but COMSOL provided a much more flexible post-processing environment and integrated thermal modelling, while CST may integrate better with full-body MRI models with anatomically representative phantoms.

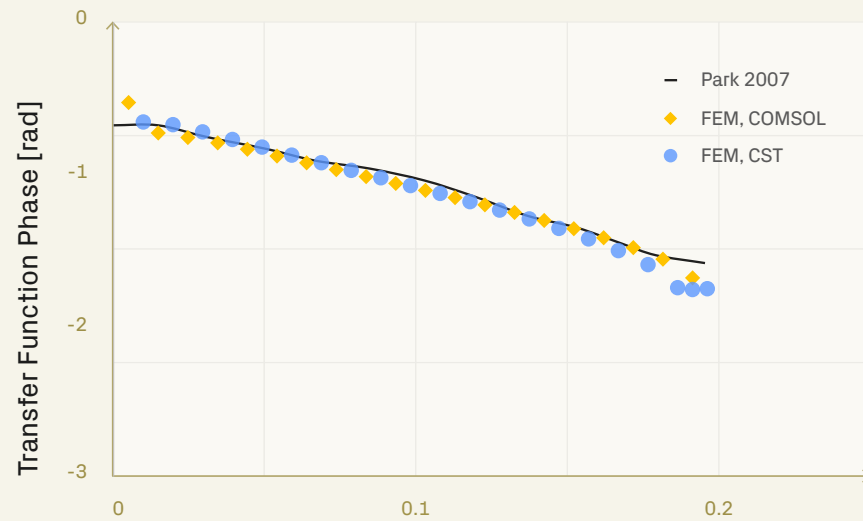
We benchmarked our TF simulations against published benchmark data (Park, 2007) using three representative cases: a 20 cm bare wire, a 20 cm insulated wire, and a 40 cm insulated wire. All models demonstrated excellent agreement with the reference, matching both the phase and amplitude of the transfer function shown in the following charts.



20 cm insulated wire

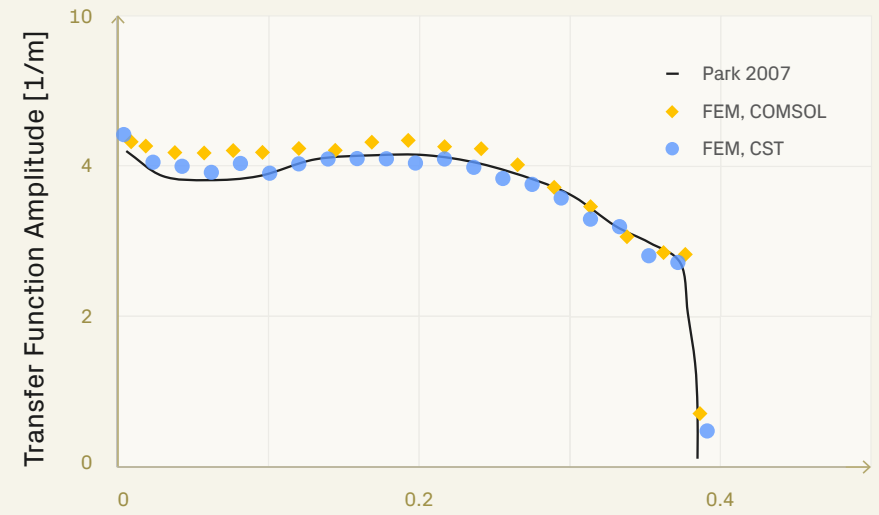


Distance from the tip along the implant [m]

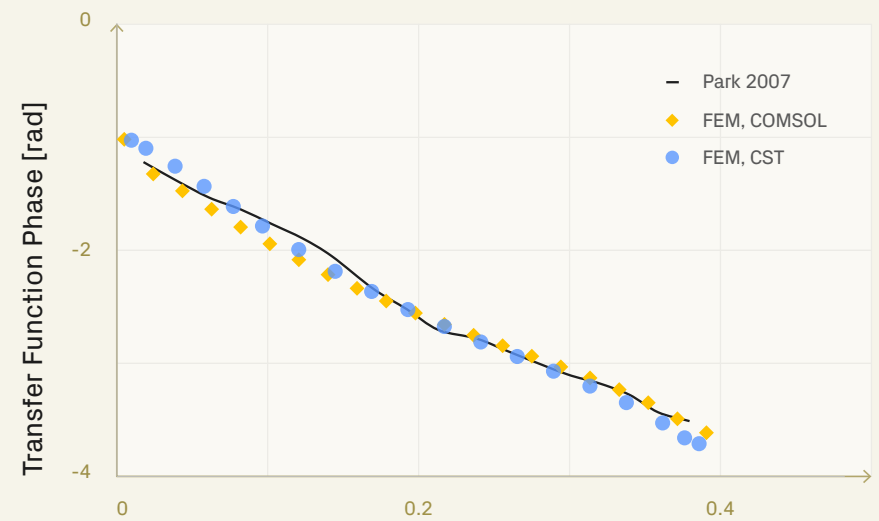


Distance from the tip along the implant [m]

40 cm insulated wire

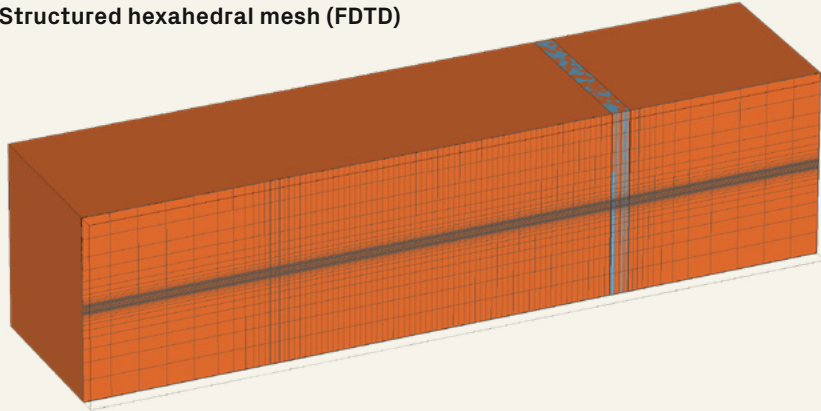


Distance from the tip along the implant [m]

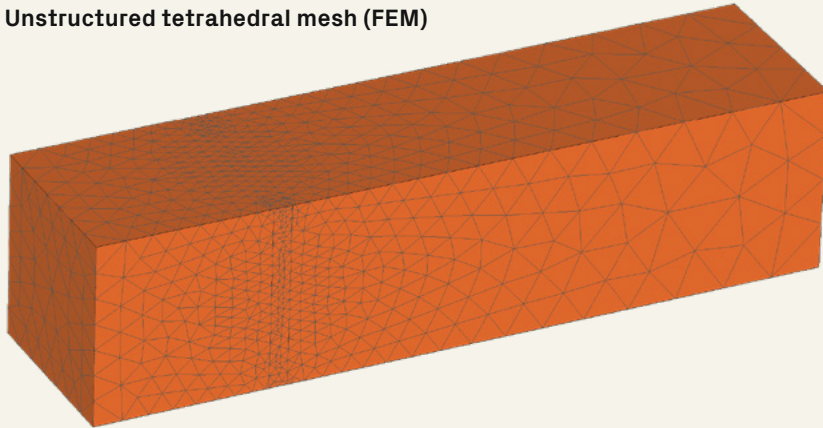


Distance from the tip along the implant [m]

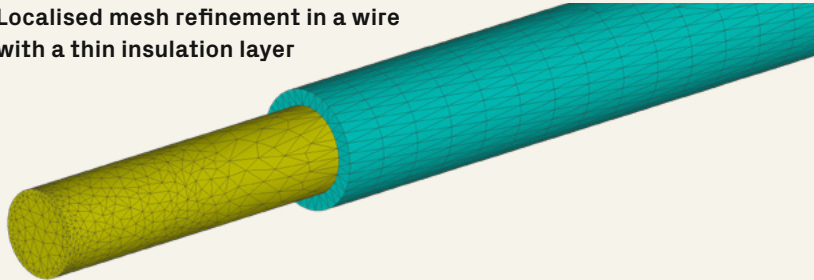
Structured hexahedral mesh (FDTD)



Unstructured tetrahedral mesh (FEM)



Localised mesh refinement in a wire with a thin insulation layer

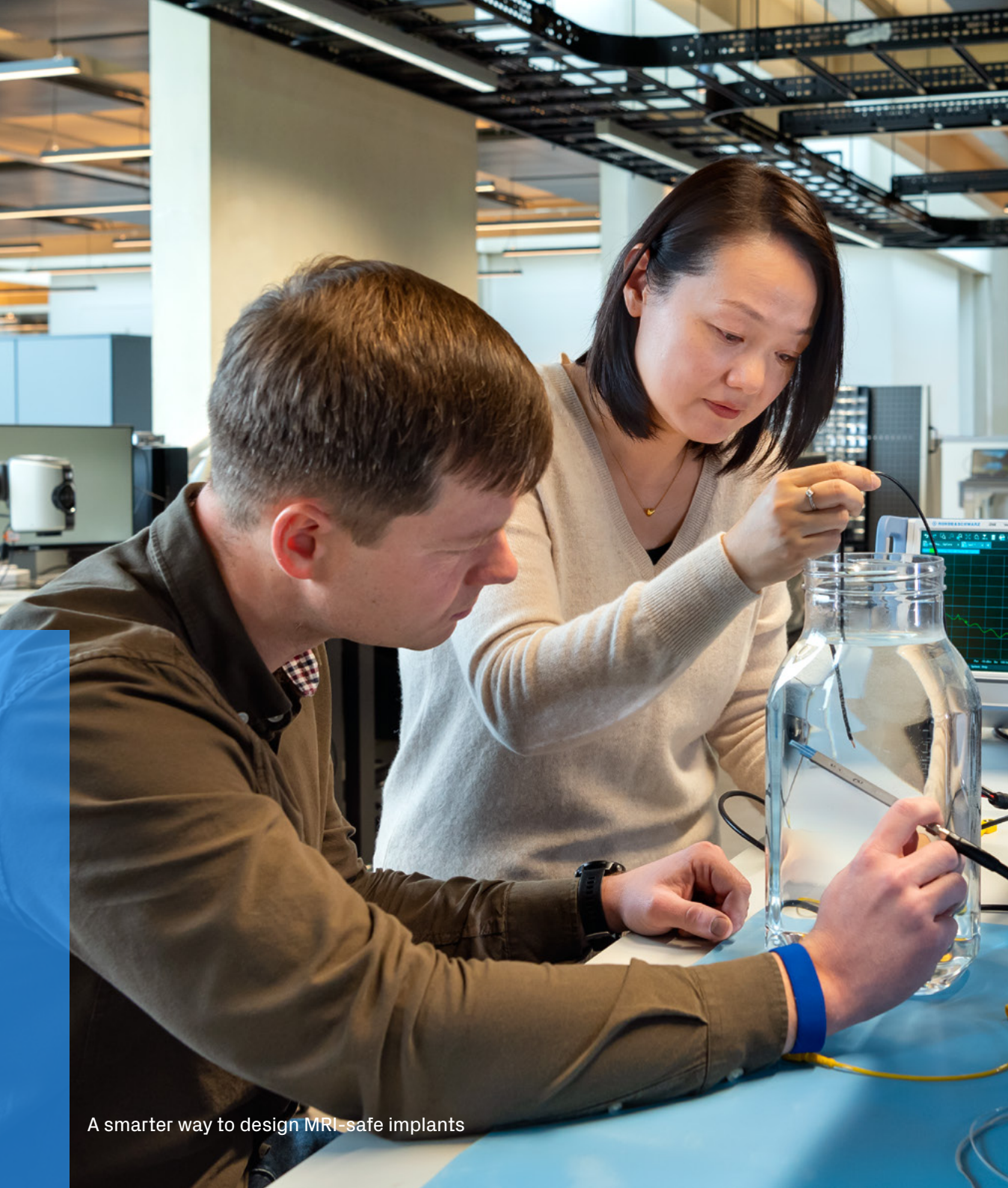


We also found that FEM frequency domain solvers offer significant computational efficiencies for TF calculation. The FEM frequency-domain approach supports unstructured meshing which allows local refinement around fine features such as insulation and coatings without forcing global refinement across the entire model.

Local mesh refinement with unstructured meshes keeps the model sizes manageable and significantly reduces computation time. In contrast, FDTD requires structured meshes that cannot be refined locally, resulting in much higher computational costs.

Therefore, although FDTD offers strong parallelisation benefits, FEM provides a more efficient approach for TF modelling, particularly when long-distance wave propagation or interactions with large metallic boundaries are not the dominant factors determining the computational requirements. Additionally, FEM's use of tetrahedral meshes provides greater geometric flexibility and higher accuracy for complex, curved structures.

In our models, we replaced the copper conductor with a surface impedance boundary condition to avoid resolving skin layers and selectively applied local mesh refinement to resolve thin insulation layers.



In summary, frequency-domain FEM solvers provide the optimal balance between modelling fidelity and computational efficiency, achieving typical runtimes on the order of minutes per case.

This approach is both practical and scalable and can be used to support iterative design evaluation of leads. Importantly, it aligns with ISO 10974 guidance, supporting efficient transfer function modelling as a reliable pathway for MRI safety assessment of AIMDs.

What this means for device developers

Our Tier 3 simulation framework for TF computation tackles one of the most critical technical barriers to MRI labelling of AIMDs: accurately assessing RF heating in long leads. Our modelling toolchain enables accurate RF heating risk assessment and scalable evaluation across diverse implant geometries, delivering results within minutes and supporting faster, evidence-based design decisions.

These efficiencies in Tier-3 modelling go beyond academic value and have direct commercial significance. Faster, more reliable simulations reduce dependence on repeated prototyping and testing, shorten development timelines, and help navigate the regulatory pathway with greater confidence. This can mean achieving MRI-conditional labelling earlier and with fewer resources, and the ability to support portfolio expansion into full-body MRI-safe devices that are increasingly demanded by clinicians and patients.

About TTP's MedTech team

At TTP, we combine deep technical expertise in modelling and simulation with practical experience in active implantable medical device development. By partnering with our clients, we help accelerate the design, evaluation, and certification of complex implantable systems, including MRI-compatible devices, by identifying and addressing safety and performance risks early. This ensures robust, clinically viable solutions supported by the insight and evidence needed to bring safe, competitive products to market faster.

A smarter way to design MRI-safe implants



About the authors



Qing Liu PhD

RF and Antenna Engineer for Medical Devices at TTP. Expert in electromagnetic simulation and implantable wireless systems.



Ilya Tarotin PhD

Physicist at TTP. Expert in early-stage design and development of neuromodulation devices.



Alon Greenenko PhD

Commercial lead for Neurotechnology at TTP. Expert in applied physics.

Get in touch at ttp.com/neuro



TTP plc

TTP Campus, Cambridge Road,

SG8 6HQ

+44 1763 262626

ttp.com