Can we use a stochastic approach to MR implant safety?

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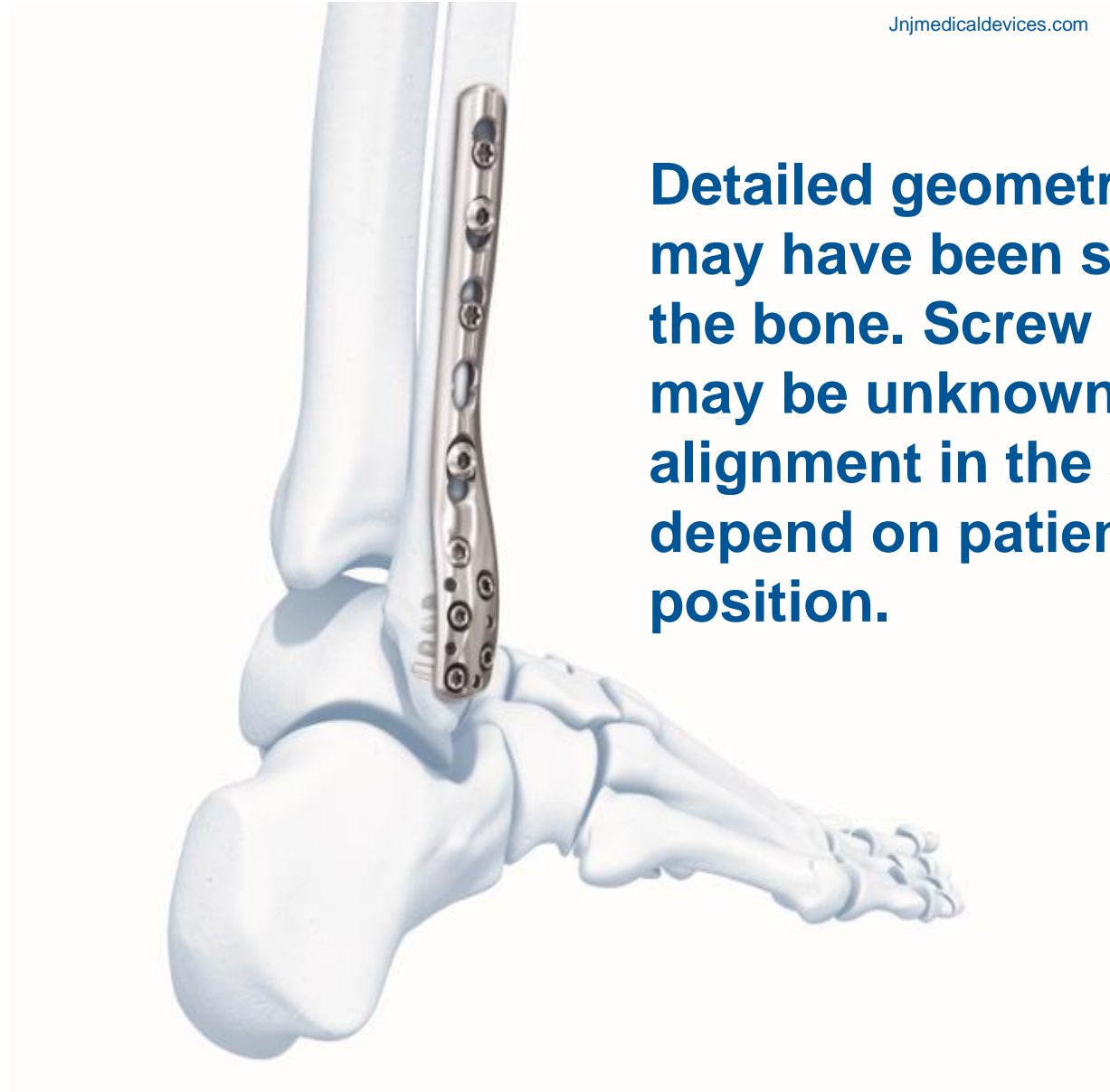
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- Why is a stochastic approach necessary?

- What does a stochastic approach need?

- Do we have what a stochastic approach needs?

Stochastic?

- "Having a random probability distribution or pattern that may be analysed statistically but may not be predicted precisely."

- Acknowledges variability and unknown or poorly known factors.

- For MRI safety, means considering what is the risk of harm occurring, given knowledge of:
  - implant structure and material properties,
  - implant location,
  - scanner type, sequence, and settings,
  - patient details.

- Definition of what constitutes an acceptable risk level is not discussed here.

Why stochastic?

NPL
National Physical Laboratory

Lots of the factors that affect the temperature rise in the patient during an MRI scan are either unknown or variable.

Detailed geometry: implant may have been shaped to fit the bone. Screw locations may be unknown. Implant alignment in the scanner will depend on patient's choice of position.

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Implant material properties: material properties may vary from batch to batch. Implants may be made of several materials.

Why stochastic?

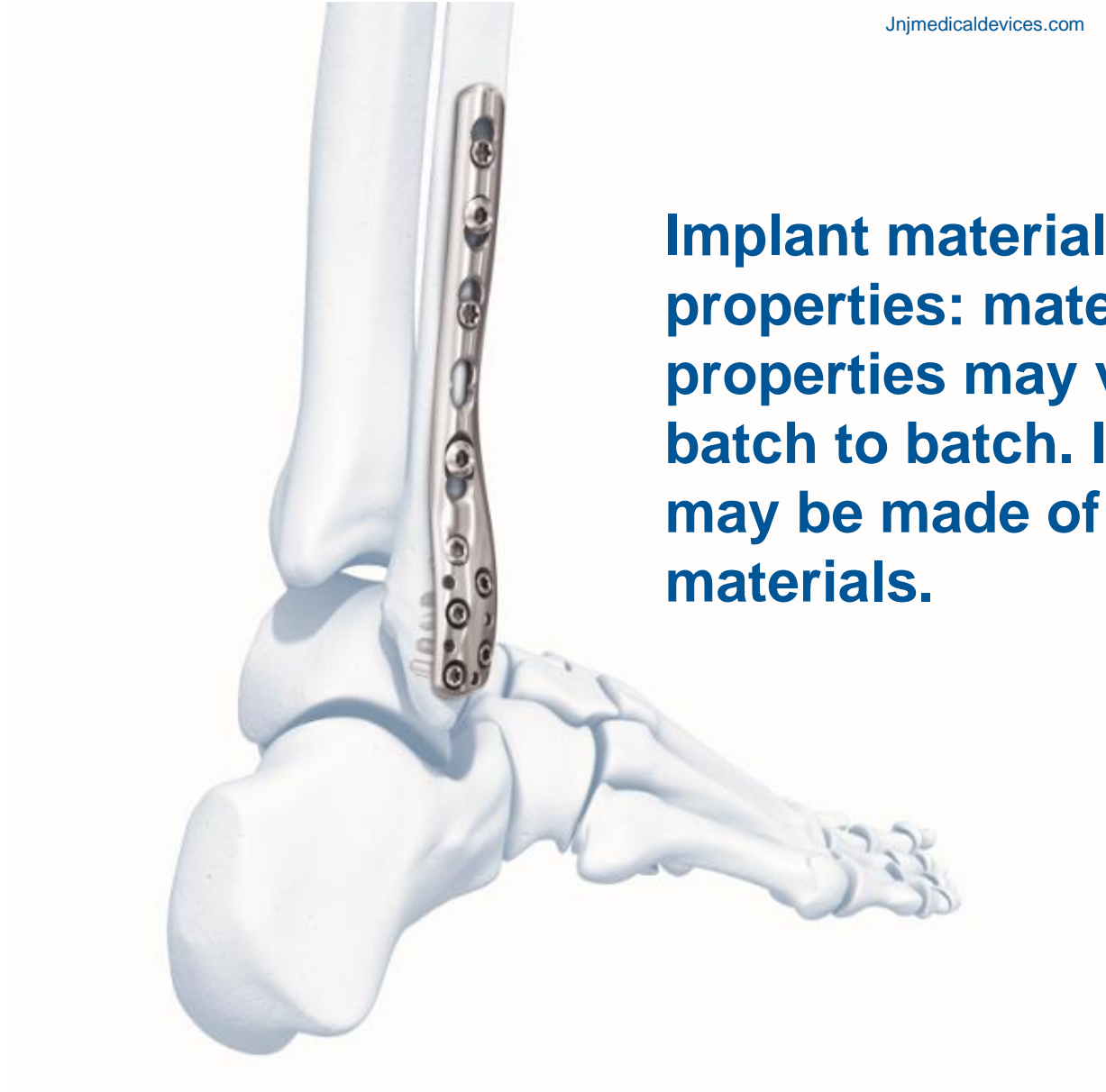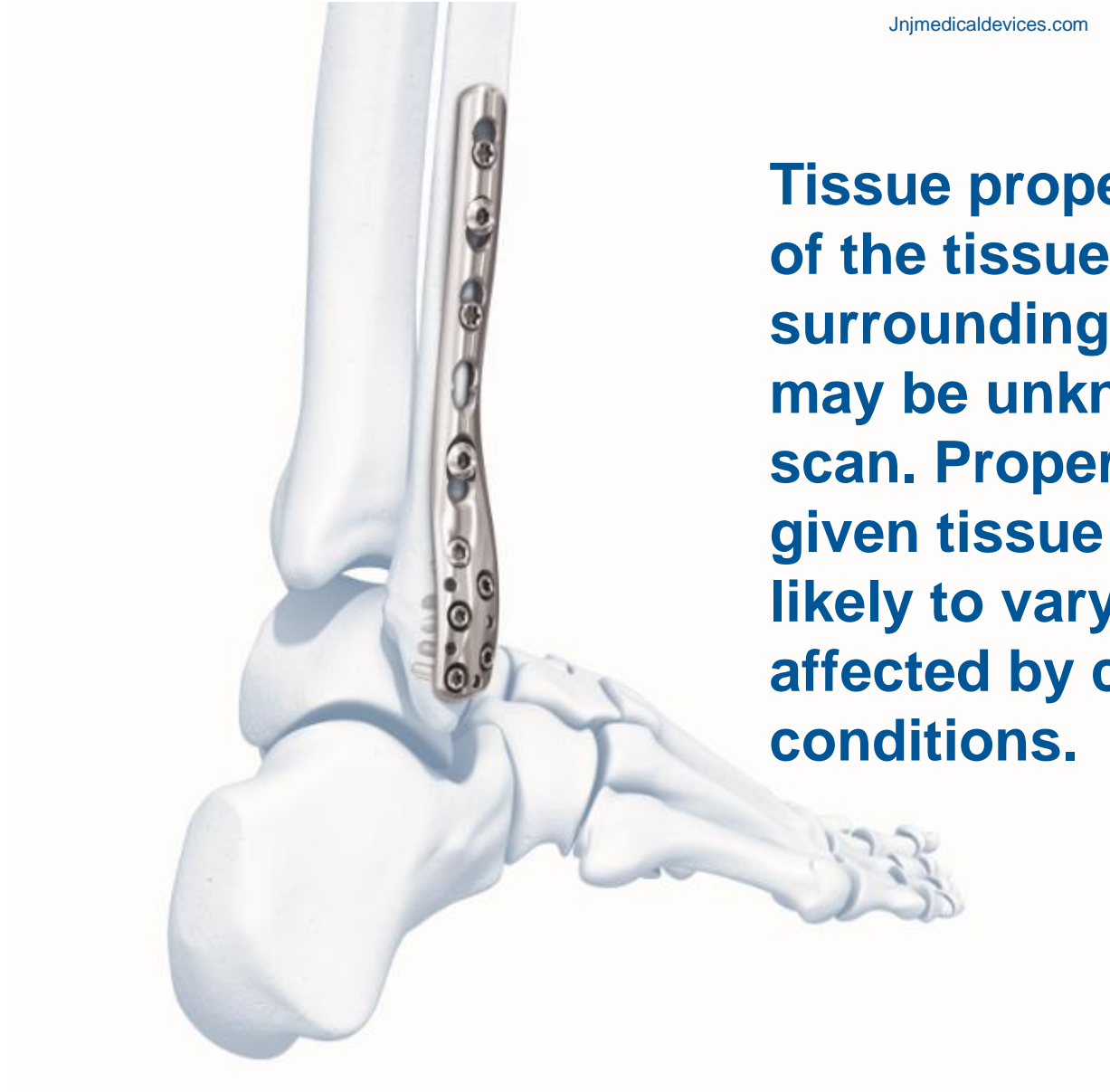Lots of the factors that affect the temperature rise in the patient during an MRI scan are either unknown or variable.
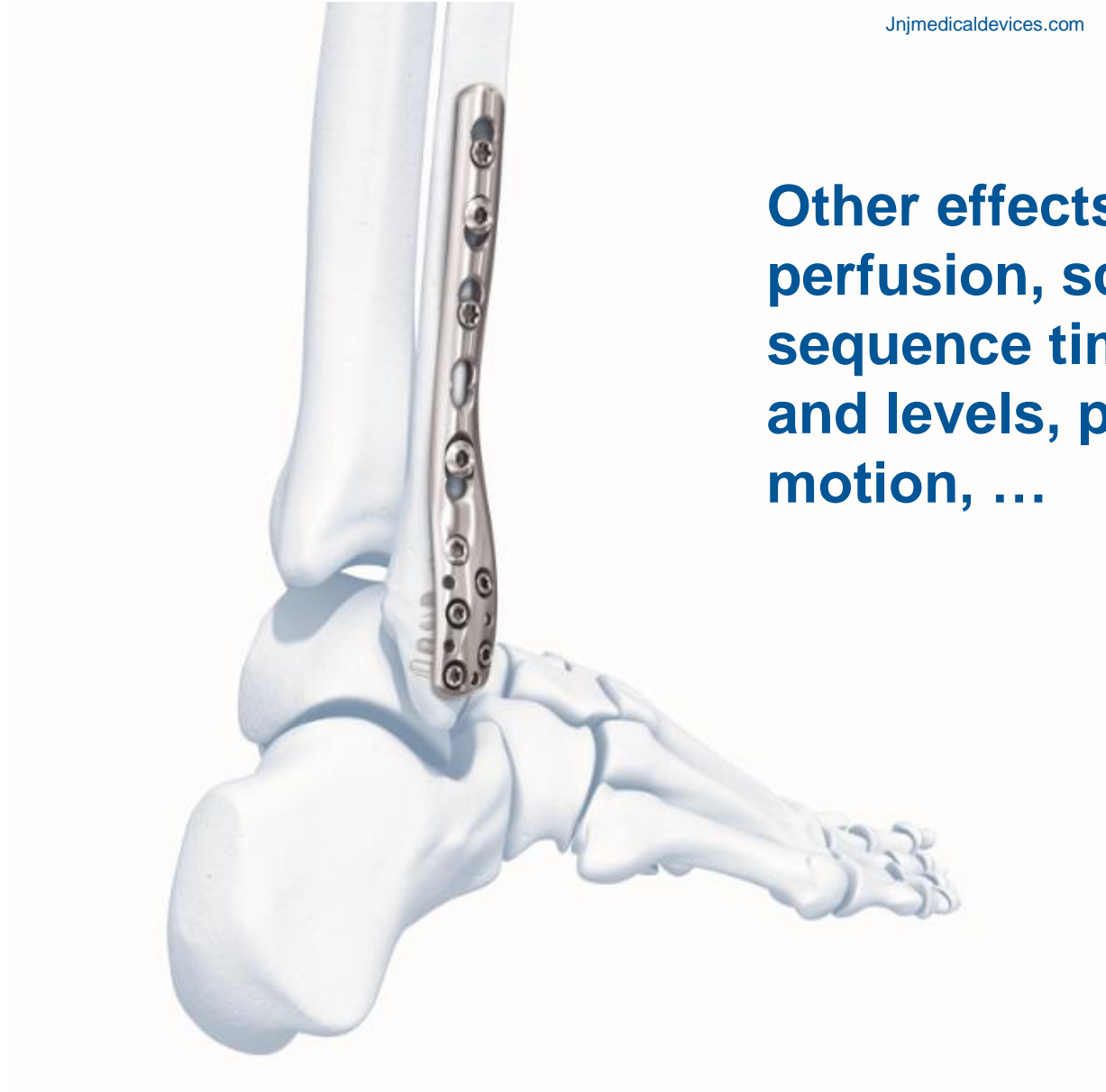
Tissue properties: Details of the tissue types surrounding the implant may be unknown pre-scan. Properties for a given tissue type are likely to vary and may be affected by clinical conditions.

Why stochastic?

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Lots of the factors that affect the temperature rise in the patient during an MRI scan are either unknown or variable.

Other effects: perfusion, scan sequence timings and levels, patient motion, …

What does a stochastic approach need?

- Statistical description of the influence factors.
  - Usually a mean value and an associated uncertainty, sometimes a probability distribution.
- Model that calculates the quantity of interest given a set of values of the influence factors.
  - Usually a deterministic model but could be stochastic itself (in theory).
- Method for propagating uncertainties through the model.
  - Probably Monte Carlo simulation or similar.
- May need a method for turning the distribution of the quantity of interest into a quantified risk to the patient.
  - Also useful to think about how the results and the risk will be communicated.

Existing work: ZMT work on active implants

- https://zmt.swiss/applications/mri-active-implant-safety/
- Toolbox & framework for risk assessment associated with ISO/TS 10974:
  - Generate a calibrated AIMD response model,
  - Validate against measurement,
  - Run a large set of models based on varied realistic human phantoms in multiple scanning positions with the implant model in place,
  - Statistical analysis of power deposition at the tip of the AIMD lead in all possible scenarios.
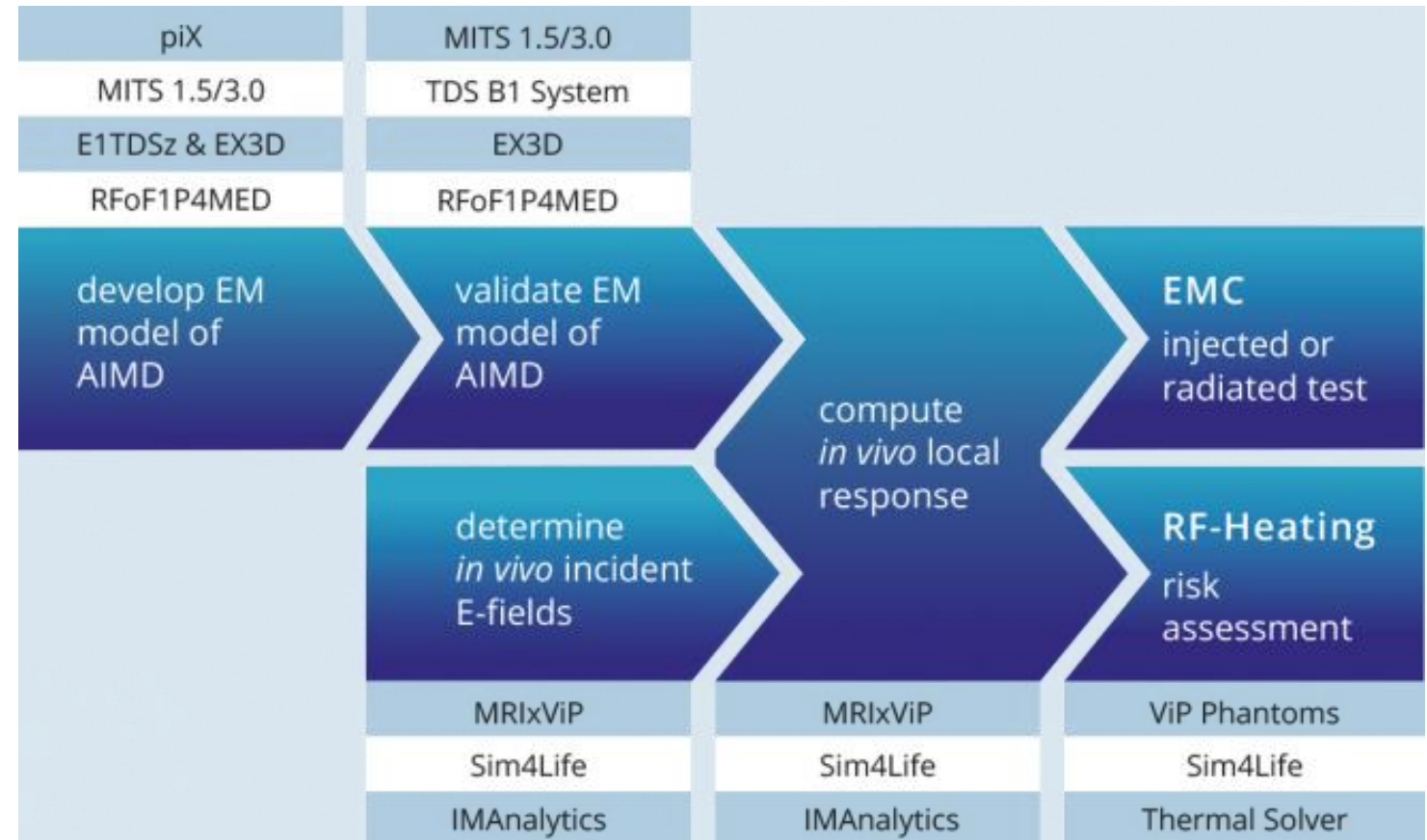
Method used in MIMAS work

- Focussed on small implants (<10 cm).
- Simulate same exposure approach as ASTM F2182-11 (2011)
- Approximation of screws and plate fixtures as cylinders and cuboids.
  - Test analysis showed that screw thread and point were second order effects.
  - Geometric parameters are easy to control.
- Uniform surrounding material.
- Also looked at ellipsoids in GC.
- Calculated temperature rise for a range of cylinder and cuboid sizes and aspect ratios.
- Fitted polynomial models to approximate temperature rise as a function of geometric parameters.

Do we have what we need? Influence factors

- Some quantities are likely to be well-controlled and/or well-characterised.
  - Scan sequences and settings, implant material properties, …
- Some quantities are less likely to be known but can have fairly tight limits placed on them.
  - Implant configuration, patient position, …
- Some quantities are more or less unknowable but can have wider limits placed upon them.
 - Tissue properties around the implant, effects of perfusion, …

We have a lot of what is needed, but more and better information would give a more accurate risk assessment.

Do we have what we need? Models

- Physics-based simulations of individual implants within realistic human models can be constructed.

    - Solution time limits the number of models that can be run: problematic for Monte Carlo simulation.

- Work carried out in MIMAS has run parametric sweeps for some influence factors for some implant types.

    - Quantitative results led to some qualitative observations.

    - Attempts to fit polynomial models not sufficiently successful.

    - Focus was largely on geometric parameters and simplified geometries.

    - Complexities of real tissue largely unaddressed.

We have made steps towards what is needed. Need simpler models that are quick to evaluate and cover all influence factors.
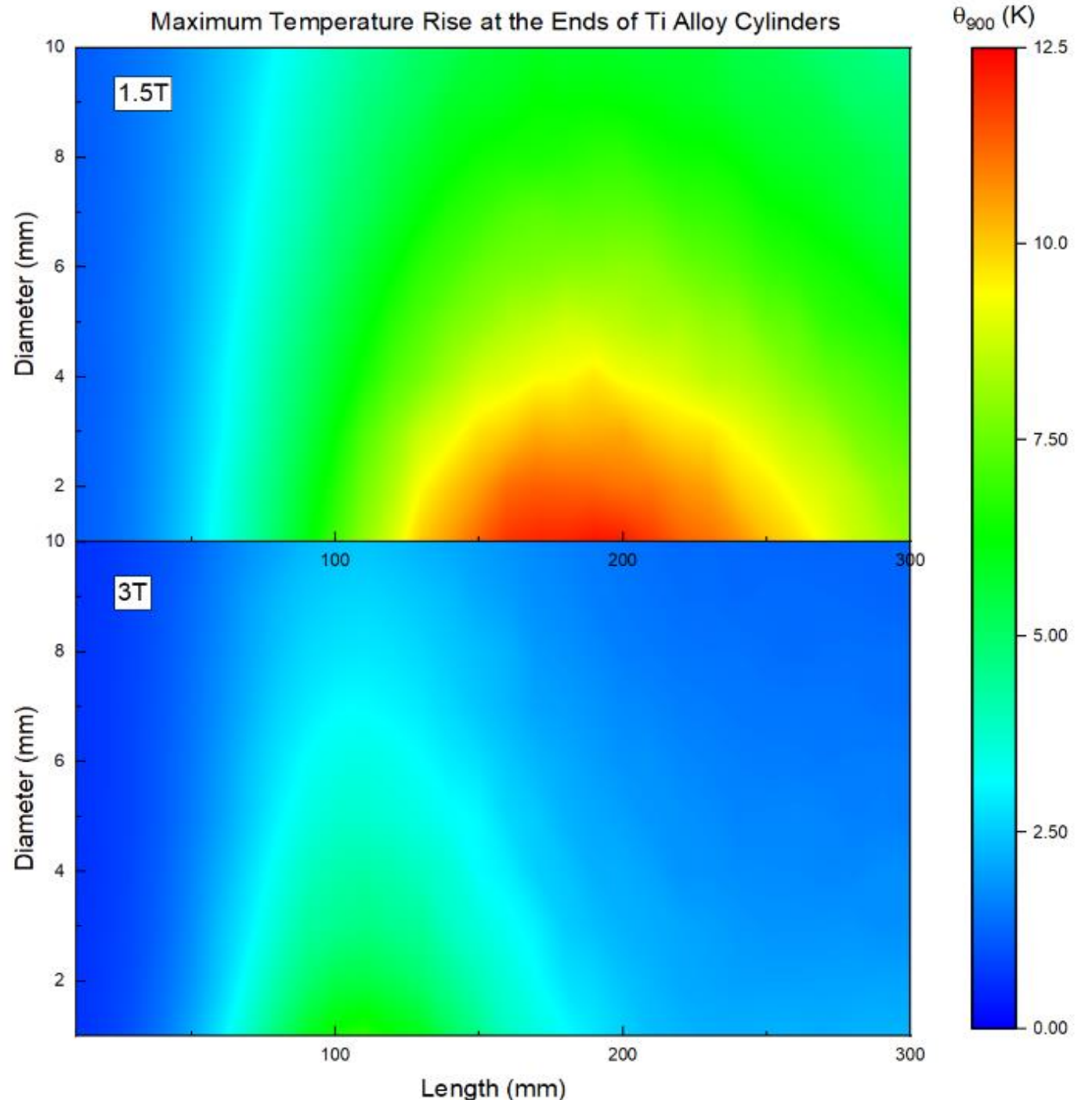
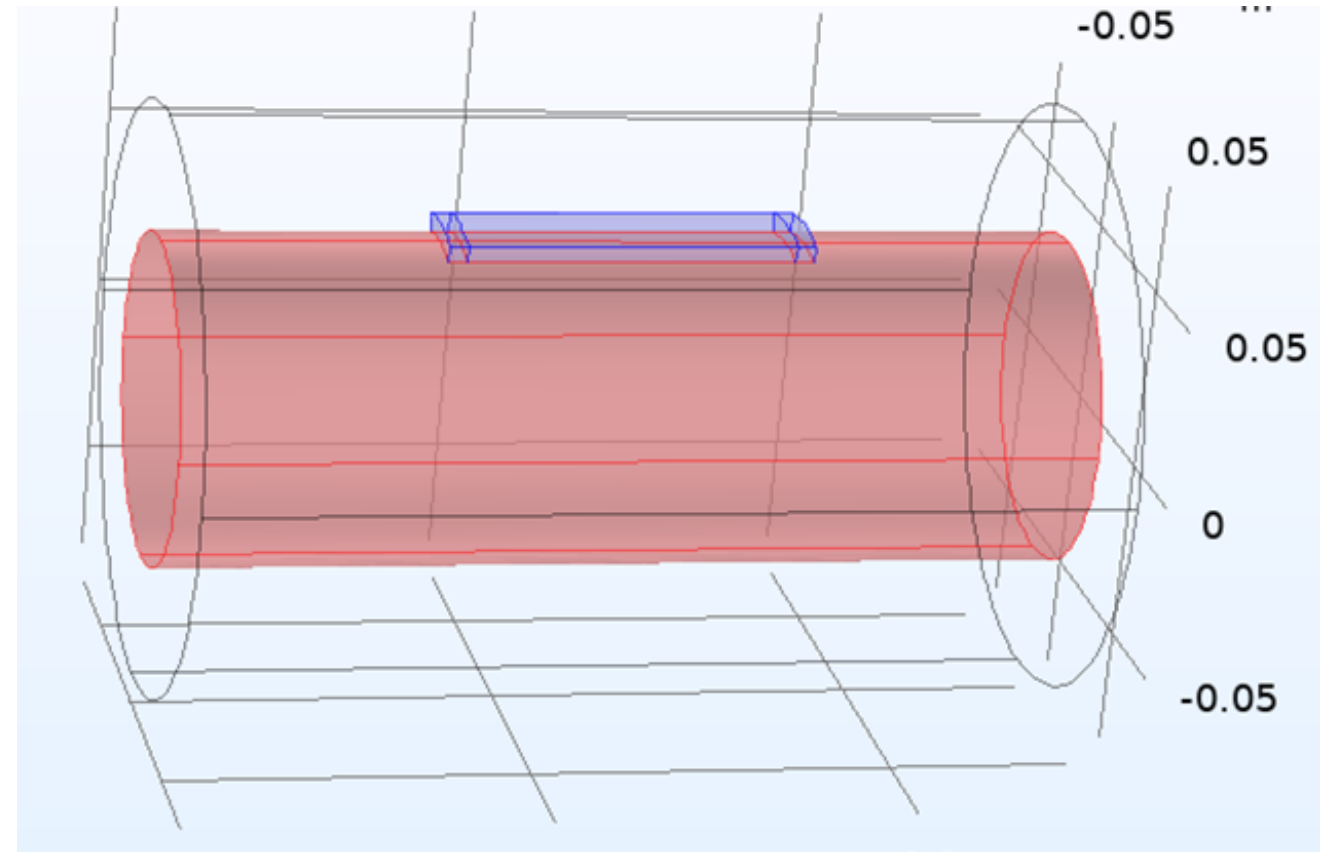# Parametric models for cylinders/screws
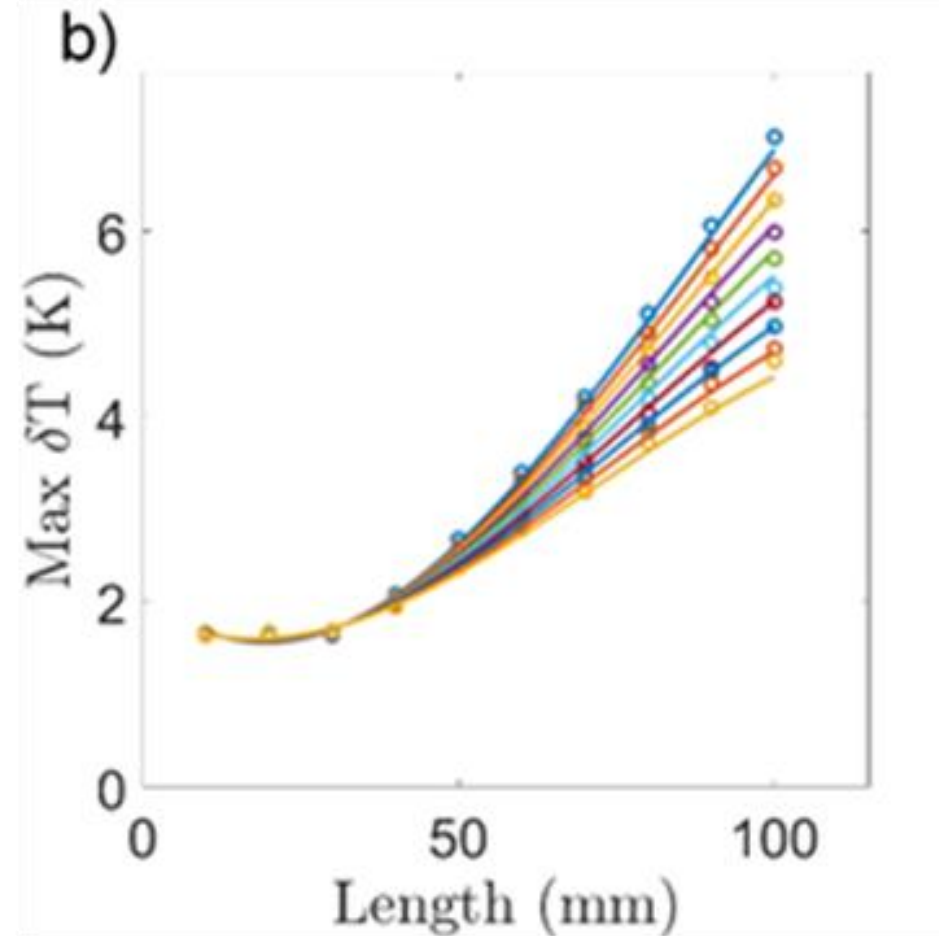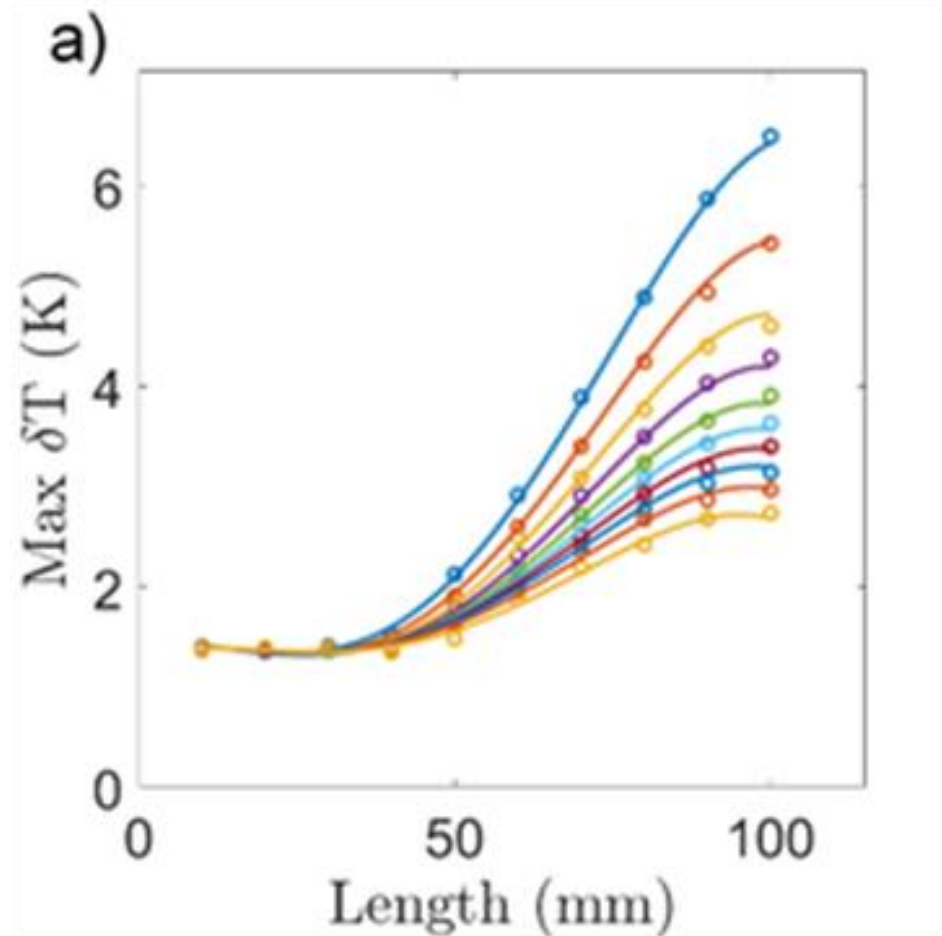
Cylinder temperature rise results

- Cylinder models for RF showed antenna-like behaviour.

- Resonant length exists.

- Attempts to fit with polynomials have not been successful.
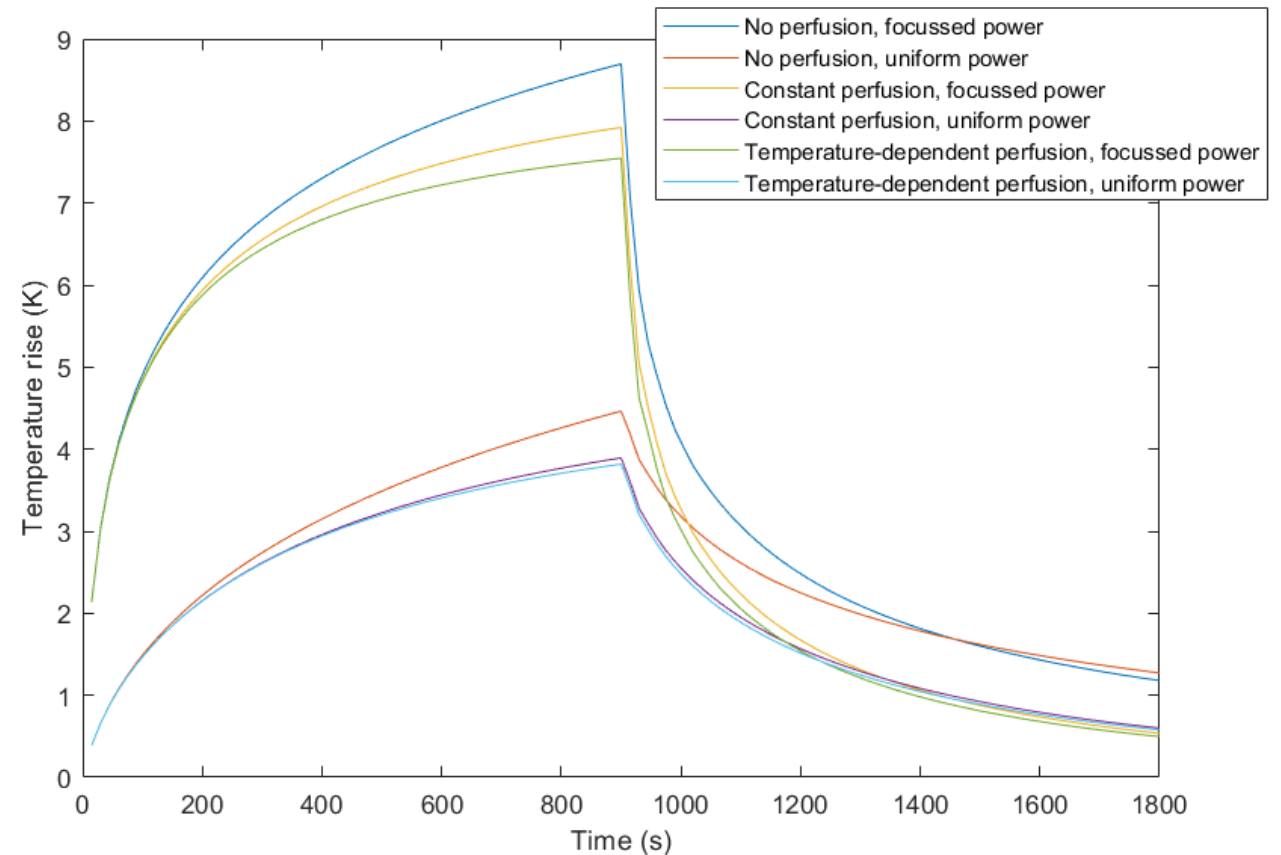
- Similar behaviour observed for plate-like objects.

Maximum Temperature Rise at the Ends of Ti Alloy Cylinders

Perfusion

- Looked at "plate" on "bone" surrounded by "tissue", thermal model only.

- Calculated maximum temperature rise.

- Varied how power was deposited in plate.

    Linear dependence on total deposited power.

- Perfusion: none, constant, temperature-dependent.

- Look at ratios to estimate correction factors.

- Results show that factor depends on detailed temperature history.

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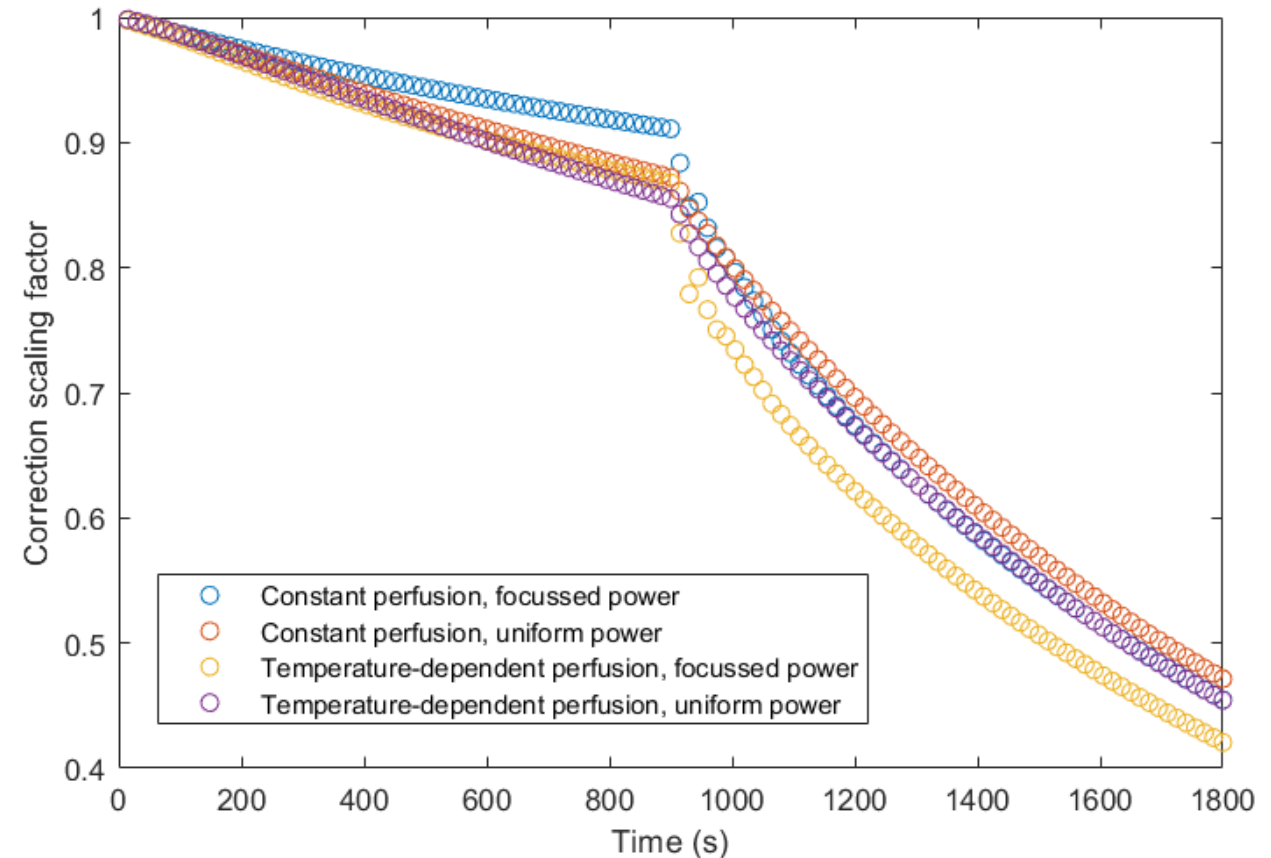- Look at ratios to estimate correction factors.

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Do we have what we need? Propagation approach.

- GUM approach: requires linearity or near-linearity of model and derivative information.
- Monte Carlo simulation: need a large number of model evaluations to obtain accurate results.

- Smart sampling: more structured methods for getting as good estimates as possible from a small number of samples.
- Surrogate models: replace computationally expensive model with something quicker to run that produces sufficiently similar results.

Approaches exist, but choice of methods may be limited and has knock-on effects.

Conclusions

- A stochastic approach requires
    - statistically characterised inputs,
    - a model linking inputs and outputs, and
    - a method to propagate the statistical characterisation through the model.
- We do not currently have the components required for a stochastic approach.
    - Some effects (e.g. perfusion, local variation in tissue properties) still need characterisation.
    - Accurate physics-based models exist but take a long time to run.
    - Attempts to build simpler models for plates and screws have not produced sufficiently reliable results.
    - Choice of propagation method will depend on outcome of other points.

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