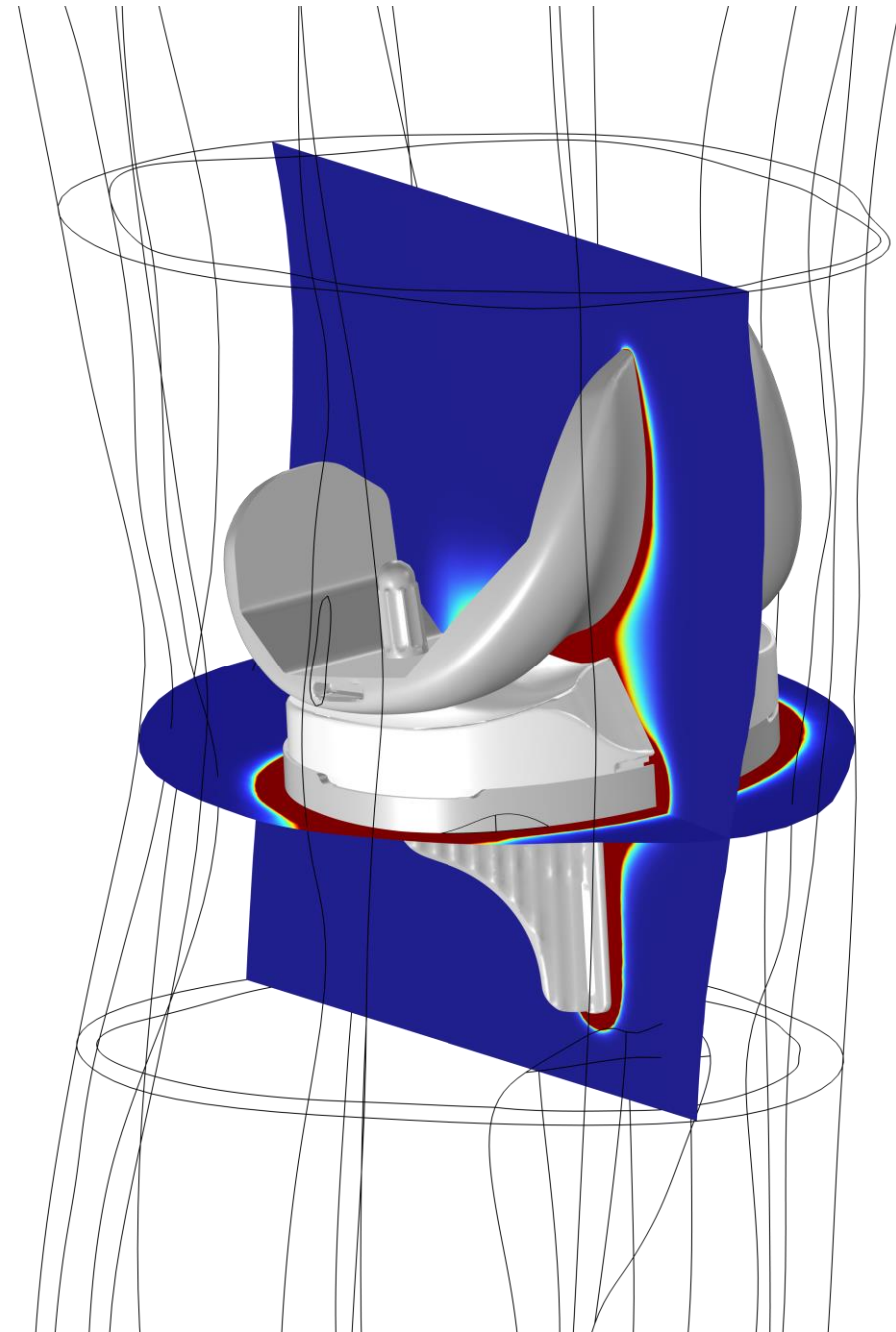


Electromagnetic Heating Simulation of Medical Treatment for Infections After Knee Replacement Surgery

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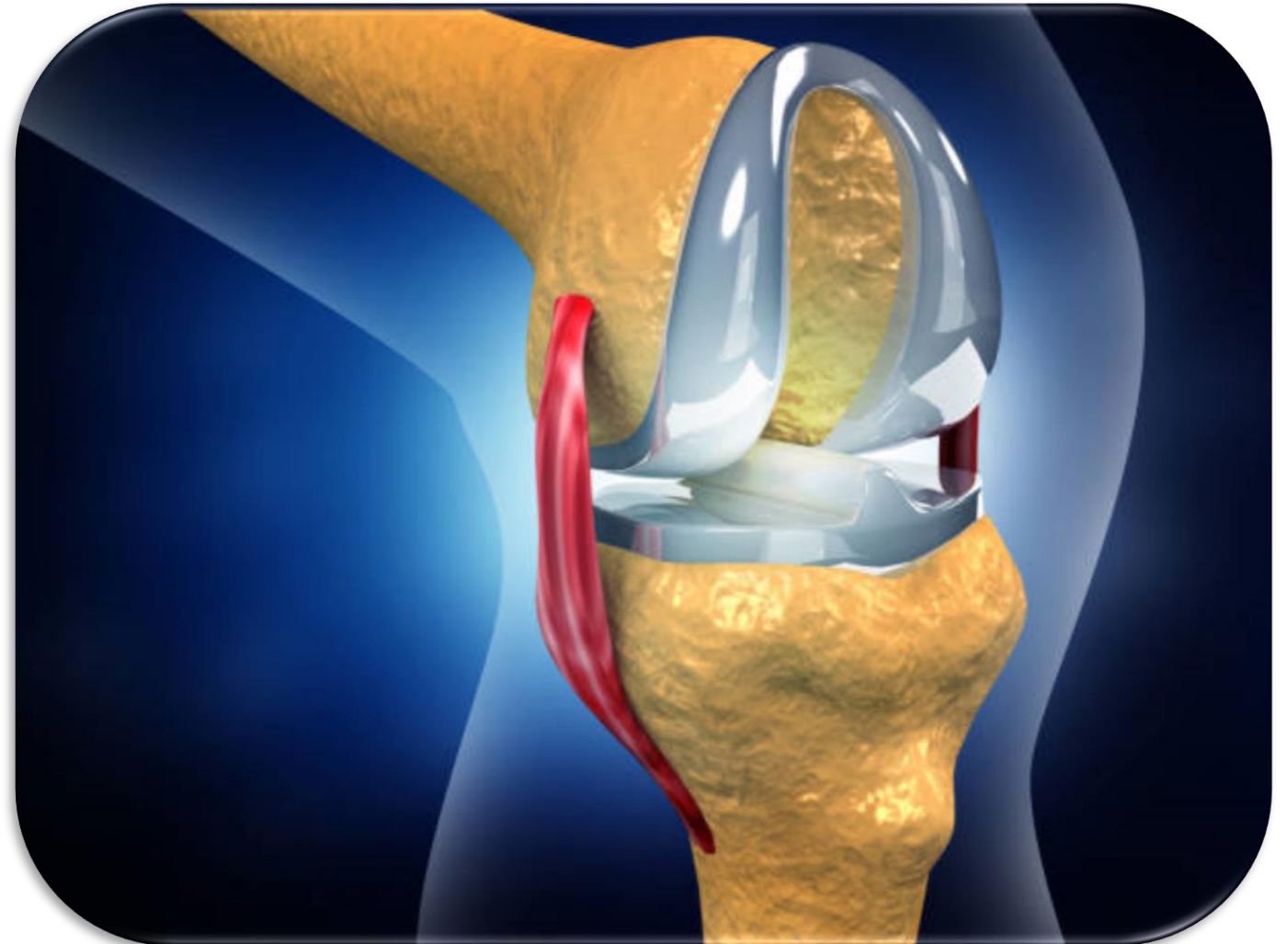




Introduction

Project Challenge

*Develop a device to
therapeutically treat
knee replacements*



Project Situation



- Start-up medical device company
- Identified significant medical issue
- Needed
 - Successful first physical prototyping
 - FDA approval of design
- Customer lacked internal simulation capabilities

PROJECT GOALS:

1. Rapidly show proof of concept
2. Model to support FDA approval of the device



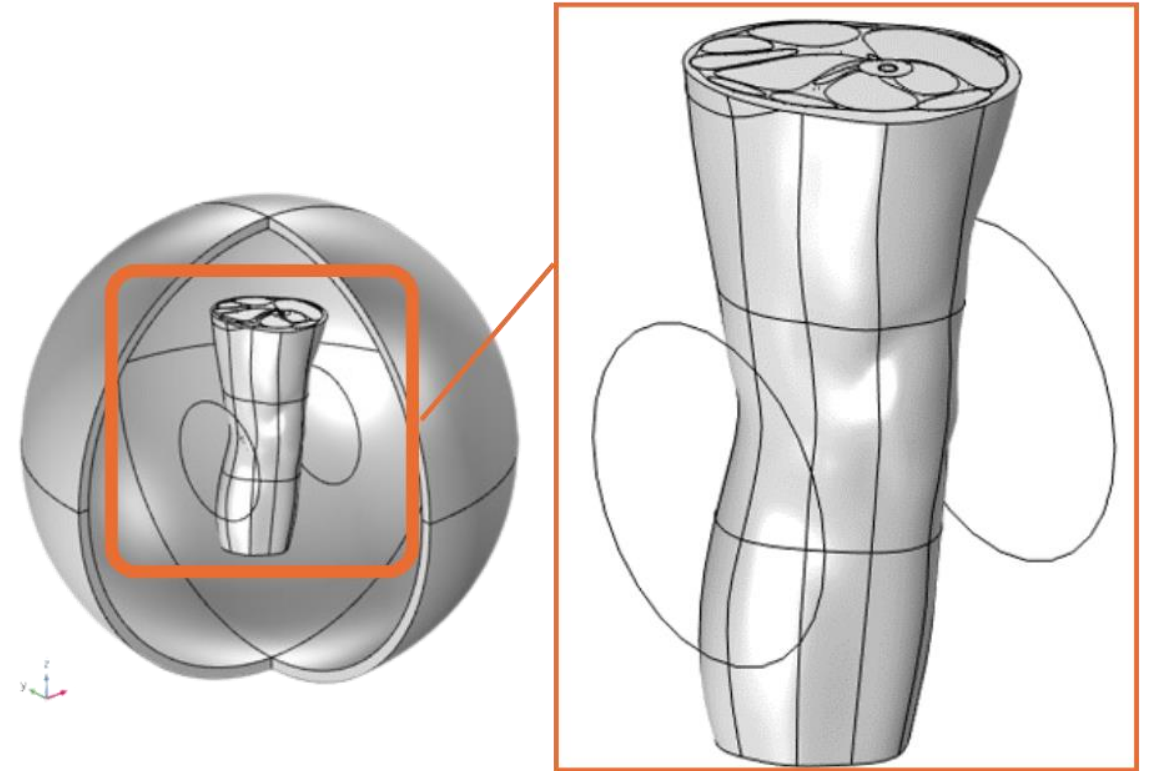
Methods and use of COMSOL Multiphysics®

Model Summary

- Current in a Helmholtz coil excites heating of implant metal
- Temperatures near metal implants provide therapeutic benefit
- Quantification of damage in tissue is critical for FDA

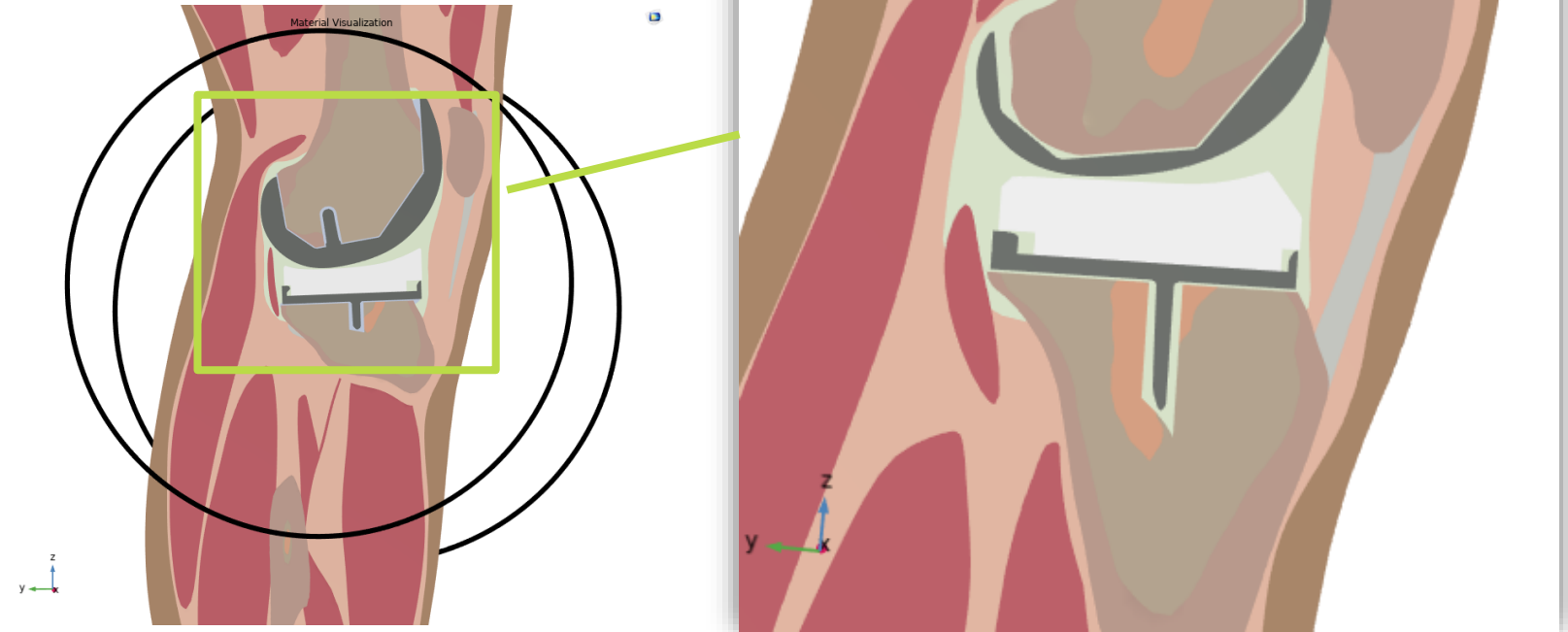
Geometry

- Magnetic fields physics included in all regions including spherical air space around knee
- Helmholtz coils on either side of knee
- Surgically replaced knee joint and surrounding tissue from mid-calf to mid-thigh



Detailed Anatomical Model

- Individual tissues included
- Femoral, tibial metal implant
- Plastic insert



Bioheat Physics Included

- Blood perfusion rate and Metabolic heat source specific to tissue type

$$Q_{\text{bio}} = \rho_b C_{p,b} \omega_b (T_b - T) + Q_{\text{met}}$$

▼ Bioheat

Arterial blood temperature:
 T_b K

Specific heat, blood:
 $C_{p,b}$ J/(kg·K)

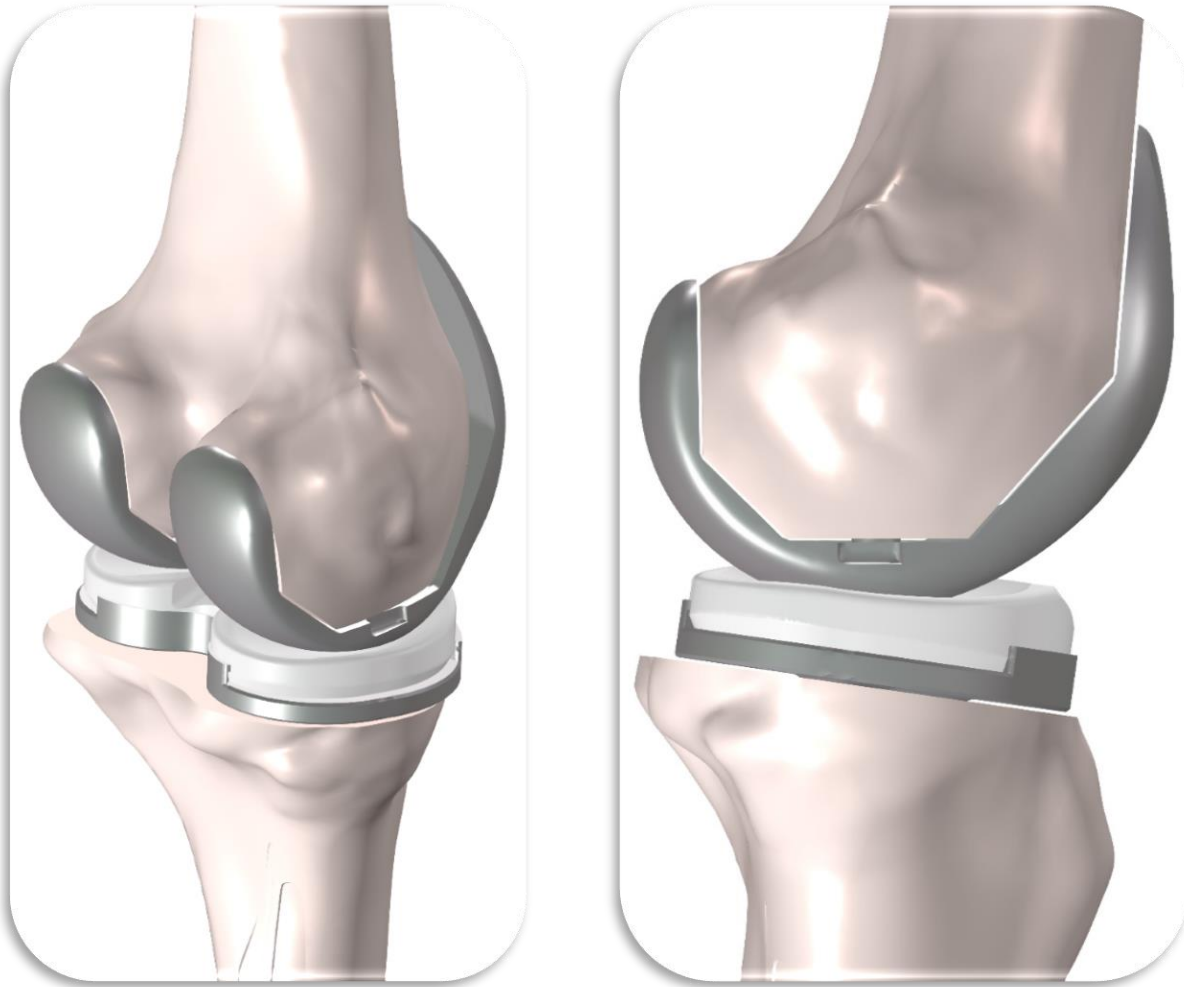
Blood perfusion rate:
 ω_b 1/s

Density, blood:
 ρ_b kg/m³

Metabolic heat source:
 Q_{met} W/m³

} Specific to tissue type from the literature

Cement Geometry



- No CAD for cement regions that provide a permanent surgical connection between metal and bone
- Custom PDE implementation to calculate the extent of cement gap fill between metal and bone

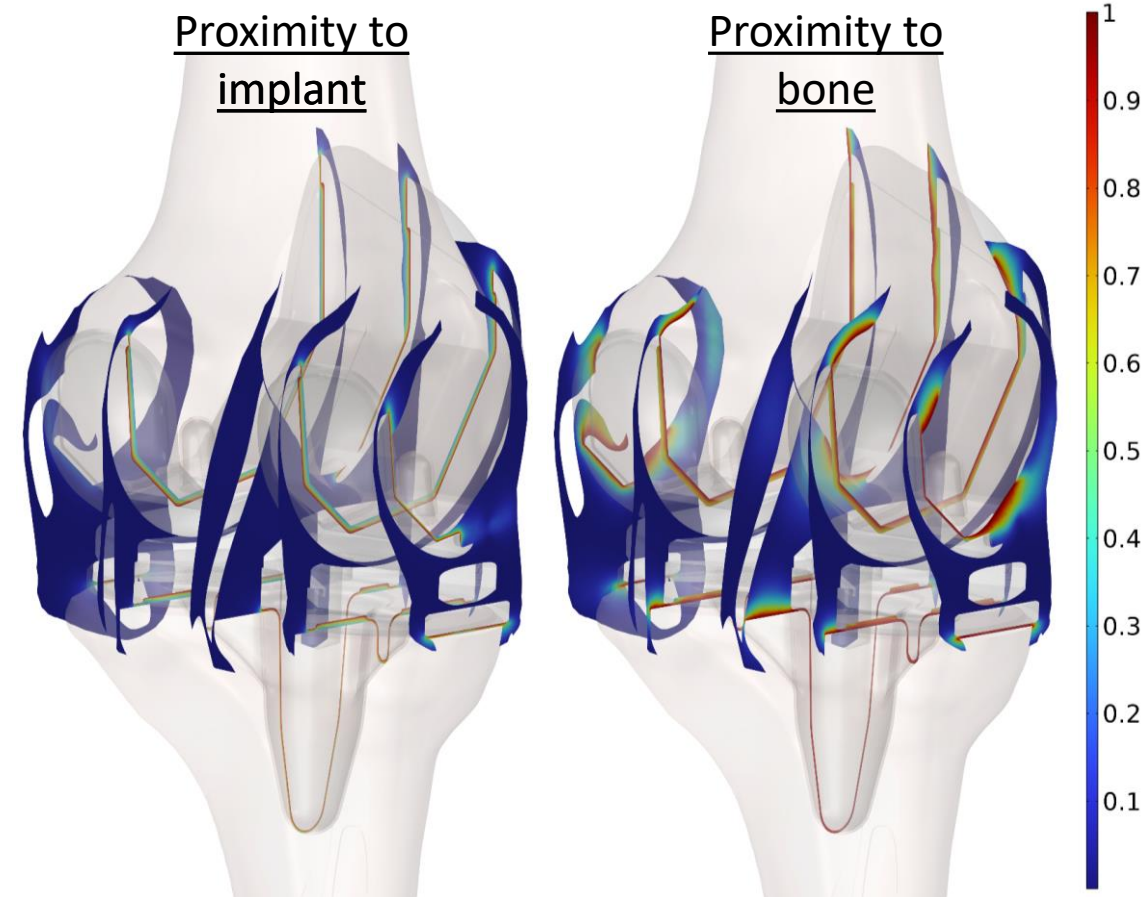
Used two reaction-diffusion equations to calculate proximity

- PDEs for proximity variables p_1 and p_2 :

$$\nabla \cdot [-(C_1 \cdot h)^2 p_1] = -p_1$$

$$\nabla \cdot [-(C_2 \cdot h)^2 p_2] = -p_2$$

- C_1 and C_2 are smoothing factors on order of 1; h is local element size
- Proximity variables are set to 1 on boundaries that contact cement

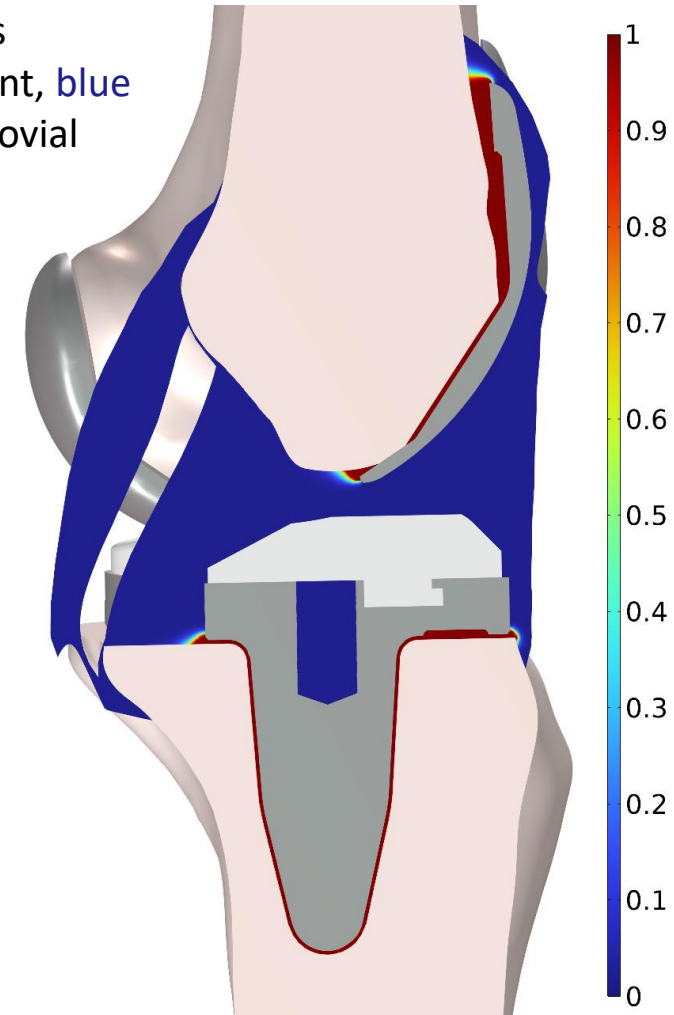


Calculated material properties from proximity variables

- Boolean variable is function of product of proximity variables:
 - Variable definition: $\varphi = \text{flc1hs}(10^{p_1 p_2} - 1.16, 0.15)$
 - Smooth transition from cement ($\varphi = 1$) to synovial fluid ($\varphi = 0$)
 - Expression is arbitrary and visually tuned
- Material properties smoothly transition between cement and synovial fluid:

$$k = k_{fluid} + (k_{cement} - k_{fluid})\varphi$$

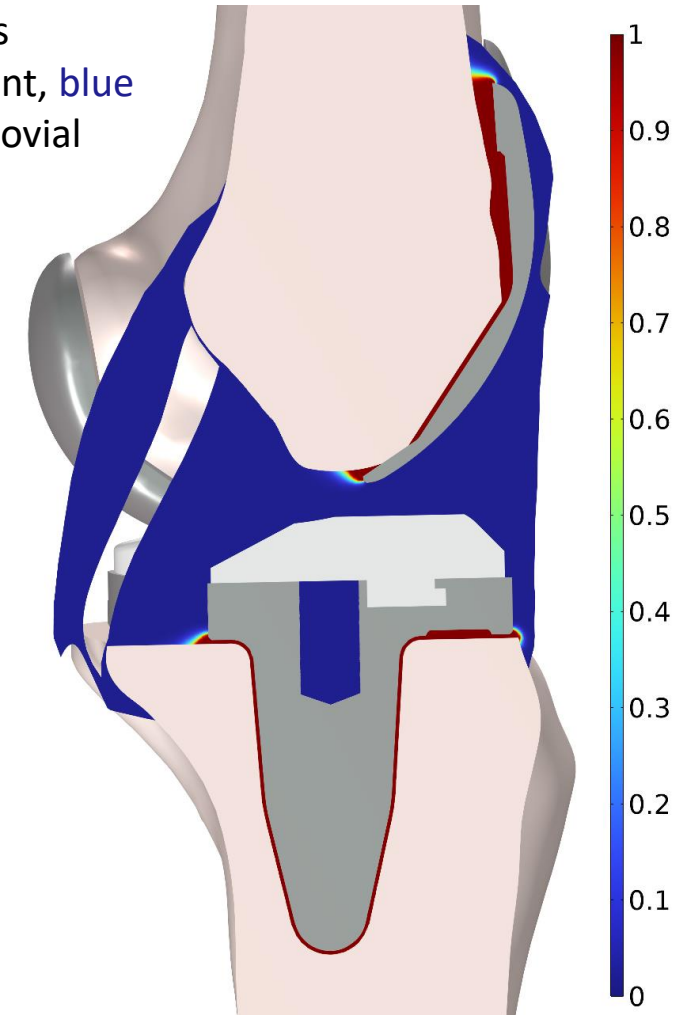
Red is cement, blue is synovial fluid



Calculated material properties from proximity variables

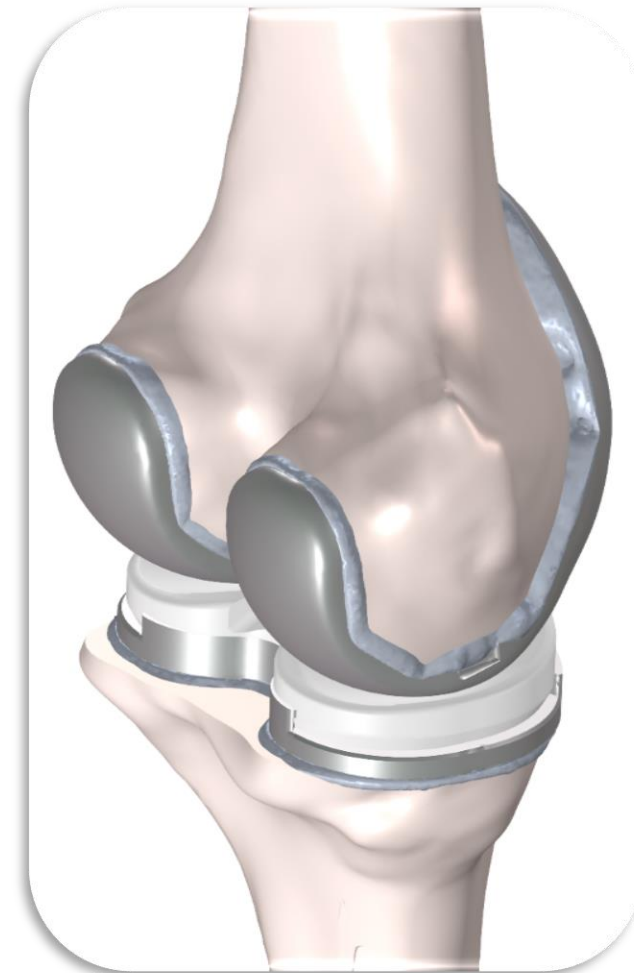
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Red is cement, blue is synovial fluid



Approach Produces Cement Distribution

- Cement fills all gaps between bone and implant
- Overfill at edges is relatively small
- Gives good approximation to expected cement distribution from “spread, press, wipe” process used by surgeons



Multiphysics Analysis

Magnetic Fields

$$\begin{aligned} \nabla \times \mathbf{H} &= \mathbf{J} \\ \mathbf{B} &= \nabla \times \mathbf{A} \\ \mathbf{J} &= \sigma \mathbf{E} + \mathbf{J}_e \end{aligned}$$



Heat Transfer

$$\begin{aligned} \rho C_p \mathbf{u} \cdot \nabla T + \nabla \cdot \mathbf{q} &= Q + Q_{ted} \\ \mathbf{q} &= -k \nabla T \\ Q_{bio} &= \rho_b C_{p,b} \omega_b (T_b - T) + Q_{met} \end{aligned}$$

- Magnetic fields interact with metal implants causing heating
- Frequency domain solution simulates heat source
- Transient temperature rise simulated via energy equation with metabolic heating and perfusion cooling effect

Thermal Boundary Conditions

Convective heat flux
on outside of skin

$$-\mathbf{n} \cdot \mathbf{q} = q_0$$

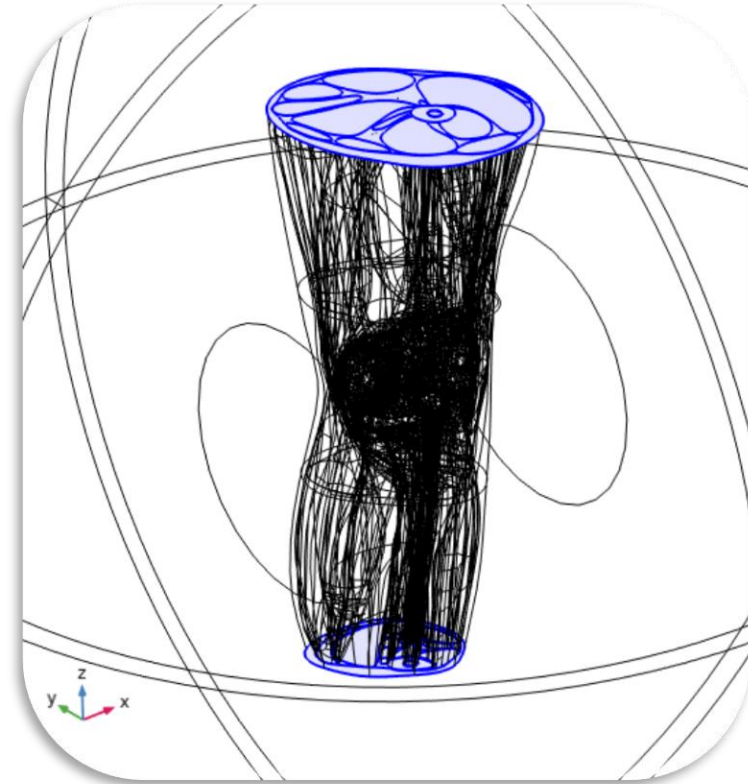
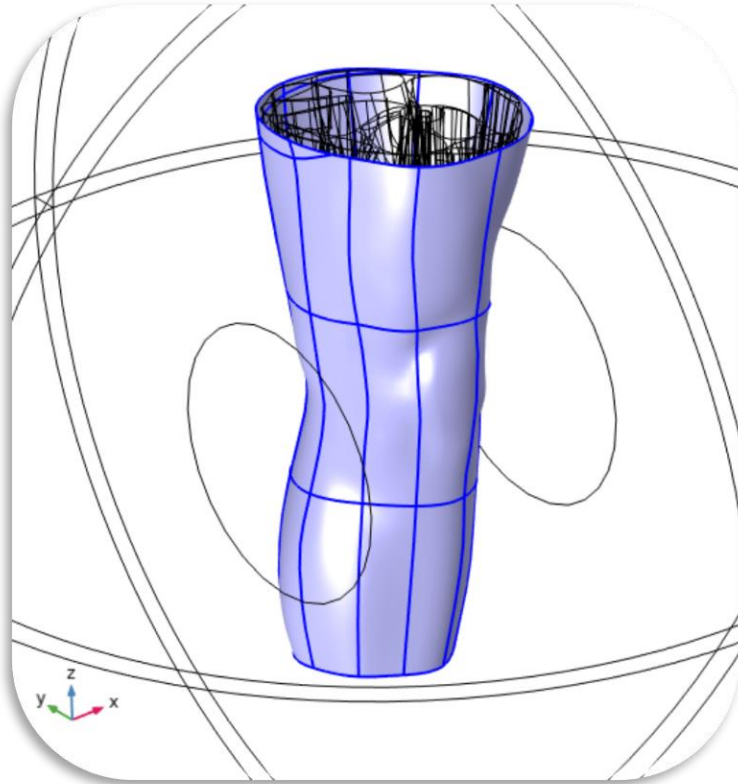
$$q_0 = h(T_{\text{ext}} - T)$$

$$h = 5 \text{ W/m}^2/\text{K}$$

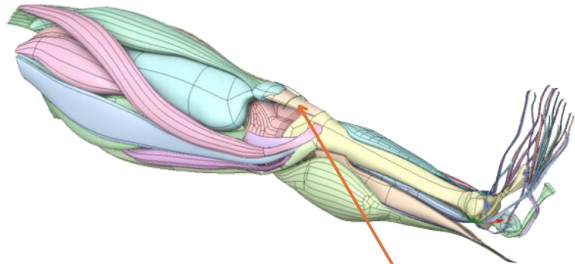
$$T_{\text{ext}} = 30^\circ\text{C}$$

Body temperature assumed
at ends where the model is
truncated

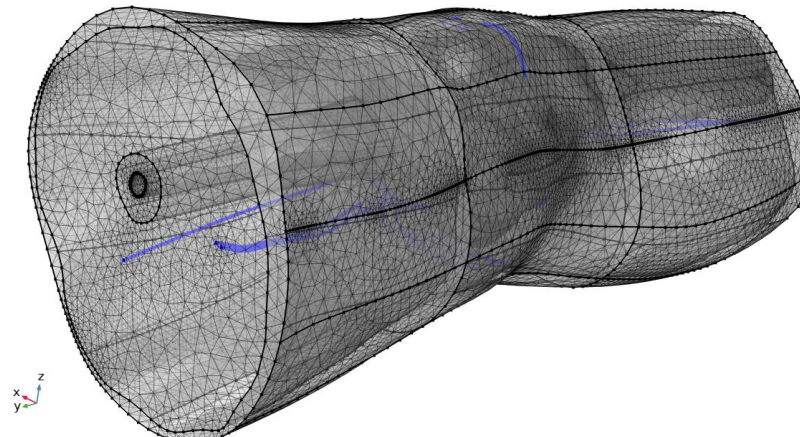
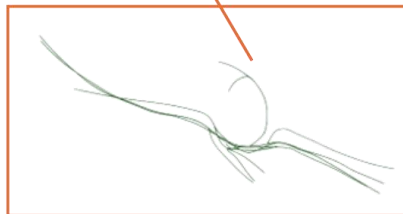
$$T_{\text{body}} = 37^\circ\text{C}$$



Arteries, Nerves, and Veins Added as 1D Edges



Veins, Arteries, and Nerves as Edges



$$\int_{S(R)} Q ds = A_1 Q_1 - \nabla_{\mathbf{t}} \cdot A_1 \mathbf{q}_1$$

$$\mathbf{q}_1 = -k_1 \nabla_{\mathbf{t}} T$$

$$A_1 = \pi r_1^2$$

$$\lim_{\partial s \rightarrow 0} \int_{\partial s} Q ds = A_1 Q_1 - \nabla_{\mathbf{t}} \cdot A_1 \mathbf{q}_1$$

▼ Line Heat Source

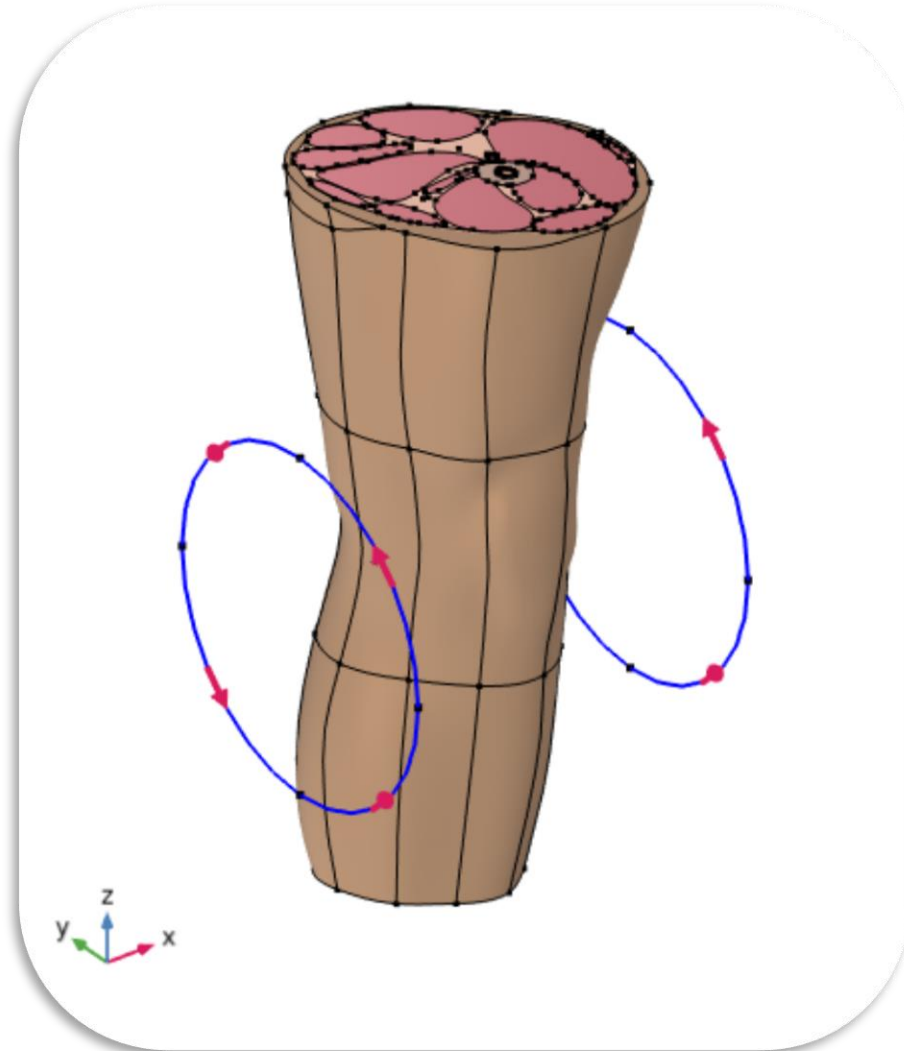
Heat source:

General source

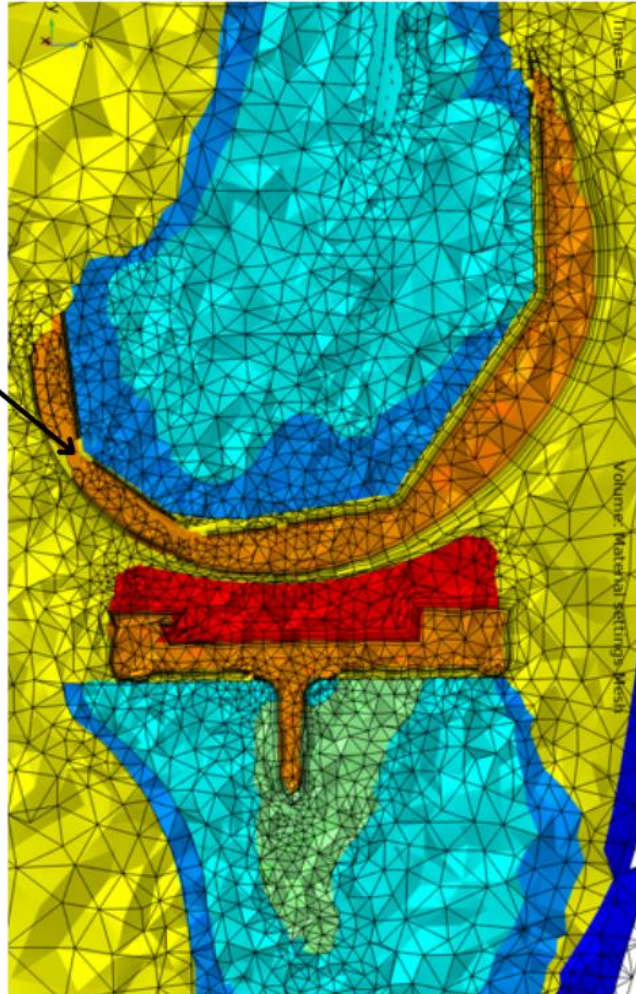
Q1 W/m³

Physical Loading on System

- Helmholtz coil
- Applied current at a specified frequency



Meshing



Colors Represent
Different
Material Regions

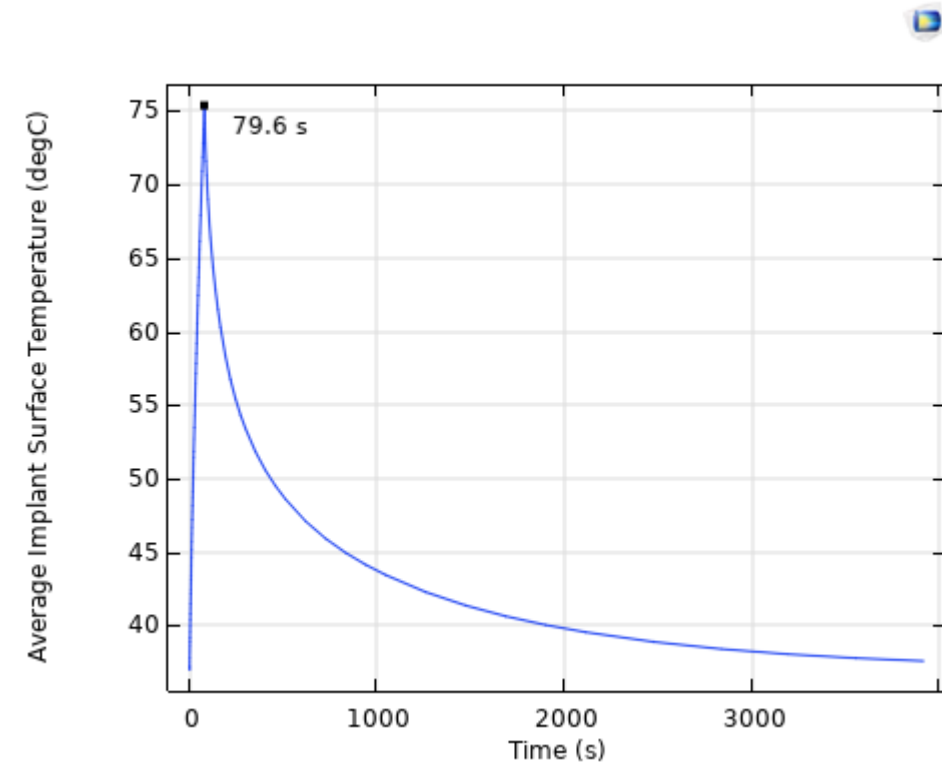
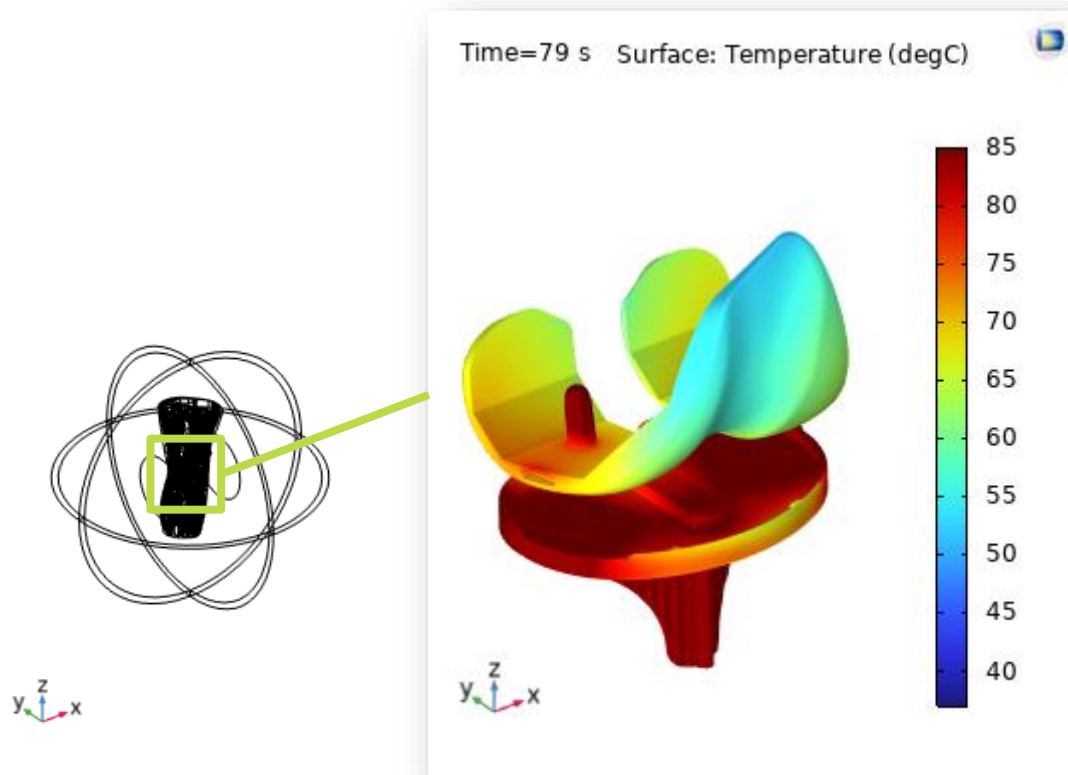
- Free tetrahedral baseline mesh
- Boundary layer mesh added to efficiently discretize field gradients near the implant



Results

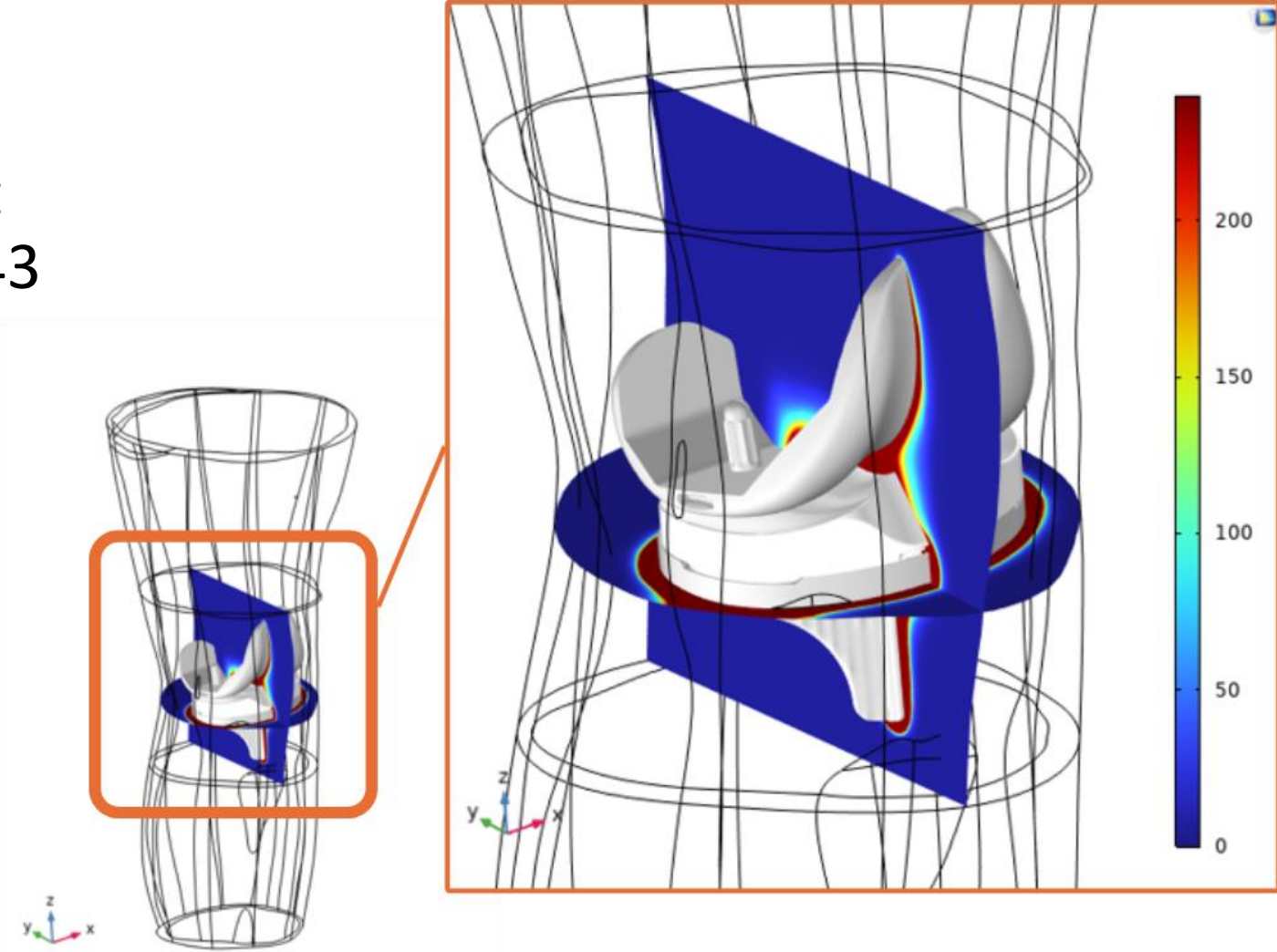
Thermal Results

- Heating occurs for 79.6 seconds then cool down for the remainder of the hour



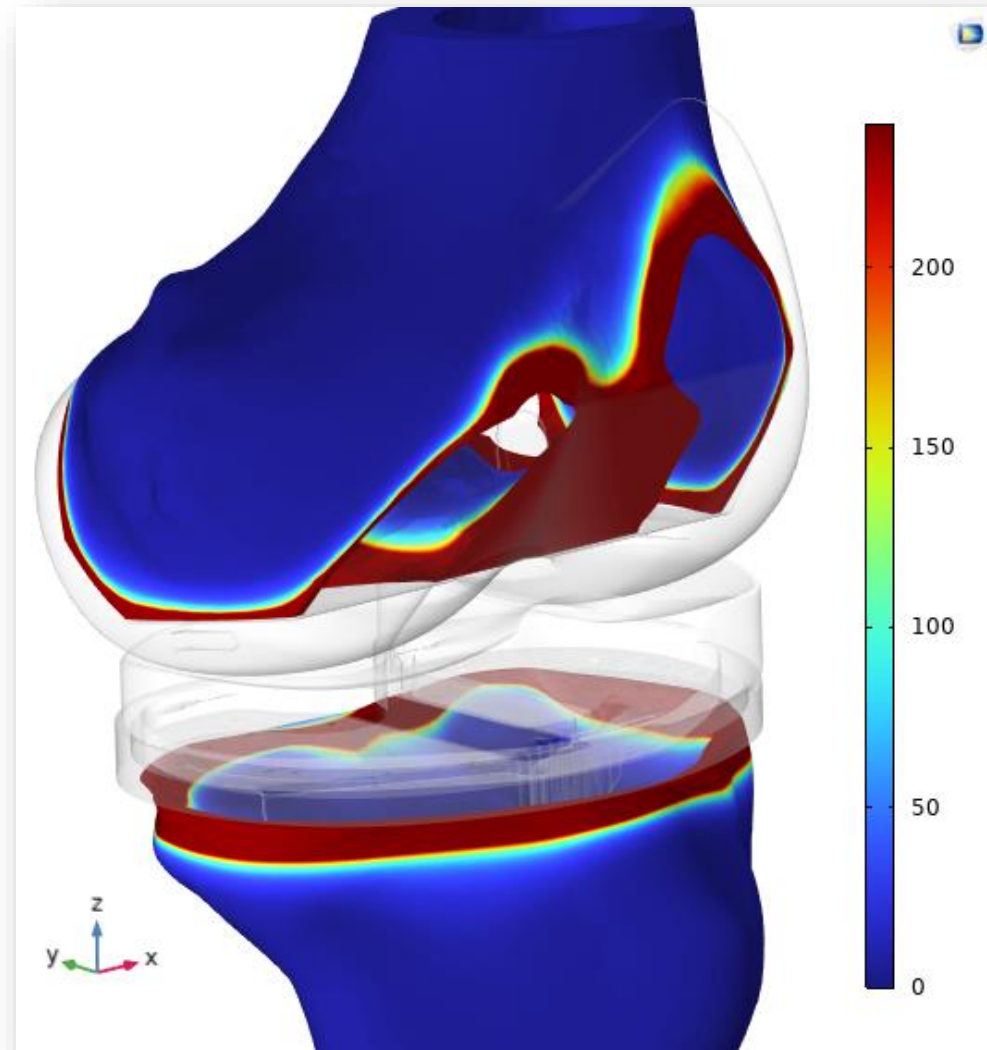
Damage Results

- Cumulative Equivalent Minutes at 43°C, CEM43
- Tissue damage after treatment



Cortical Bone Damage

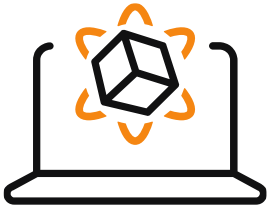
- Damage to the femur and tibia cortical bone





Conclusions

AltaSim Technologies' Solution



-
- Became simulation team for customer
 - Developed simulations that produced workable design
 - Provided simulations to customer and trained internal engineers to develop additional simulations

Customer – Private equity / device under FDA review





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