



Safety, Efficacy and Validation of AMF Heating on a Primary Prosthetic Knee Implant and Surrounding Tissues Using Human Cadaver and Digital Knee Models

Bibin Prasad¹, Varun Sadaphal¹, Luke Gritter², Joshua Thomas², Jose Guzman¹, John Tepper¹, Haley Alegria¹, Jared Smothermon³, David Greenberg⁴, and Rajiv Chopra¹

¹Solenic Medical, Inc., Addison, TX, USA, 75001, ²AltaSim Technologies, Columbus, OH, USA, 43085, ³Aava Technology, Plano, TX, USA, 75074, ⁴Department of Internal Medicine, UT Southwestern Medical Center, Dallas, TX, 75009

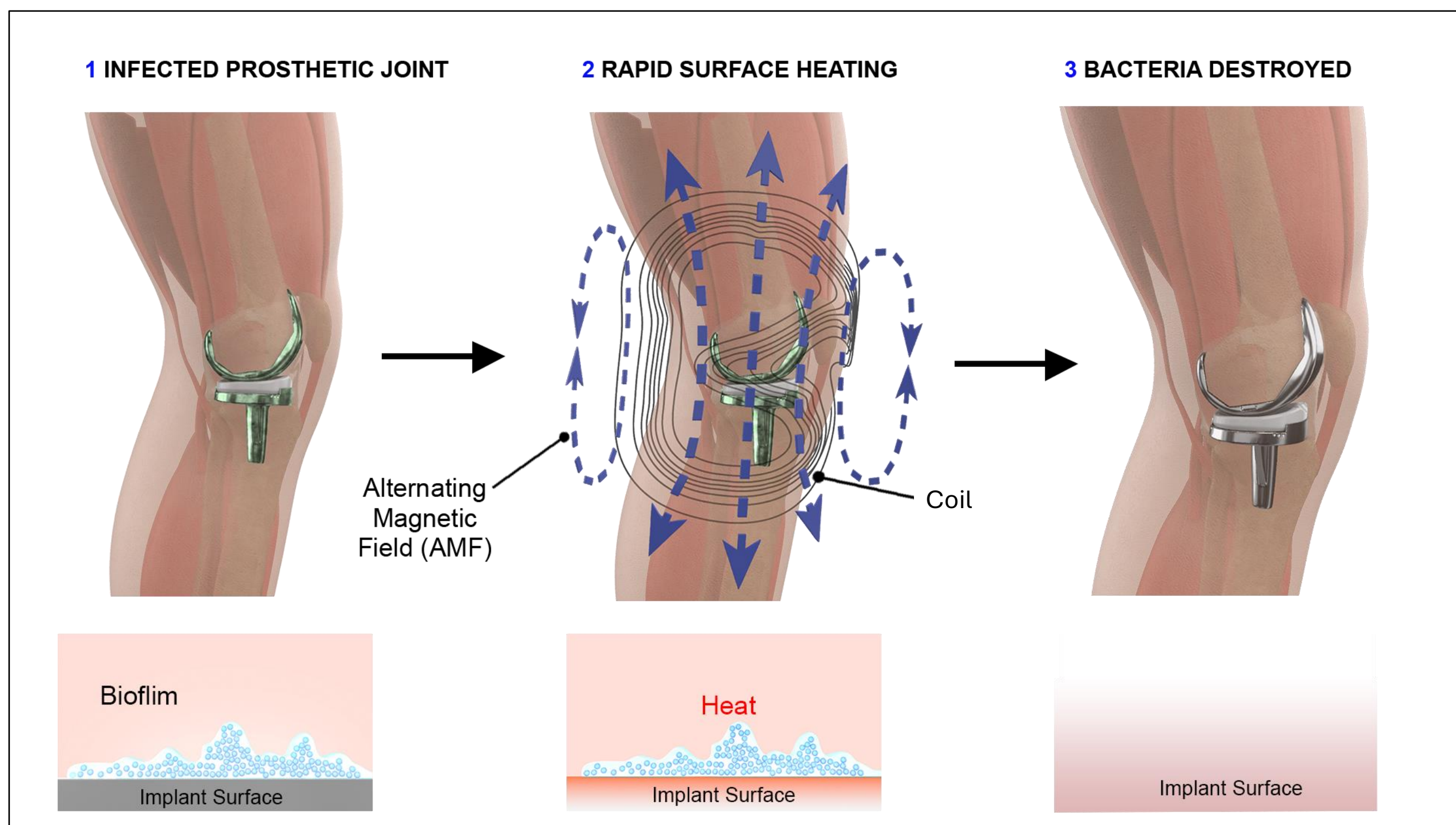
Corresponding author: bibin.prasad@solenic.com



Introduction

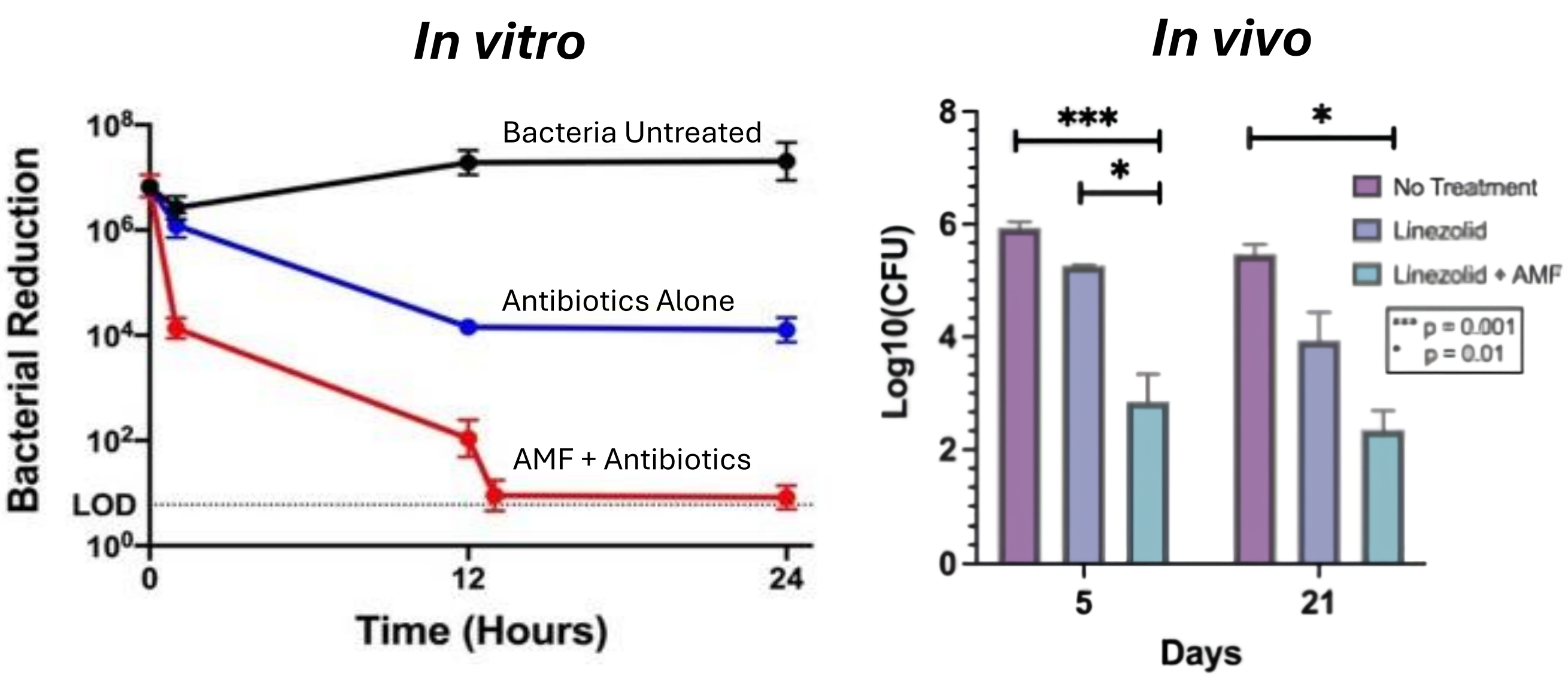
- The formation of biofilm on medical implants restricts the effectiveness of antibiotics, and often the most effective treatment is to remove and replace the implant surgically with a new device.
- Treatment of prosthetic joint infections (PJI) can require multiple surgeries + prolonged antibiotic administration. The annual cost to treat PJI in the U.S. is > \$1B/year
- When exposed to high frequency AMF, skin-depth heating (<1 mm) can be generated on metal implants via eddy currents. This surface heating coincides with the location of biofilm and can be used to reduce bacteria and/or sensitize them to antibiotics.

Concept



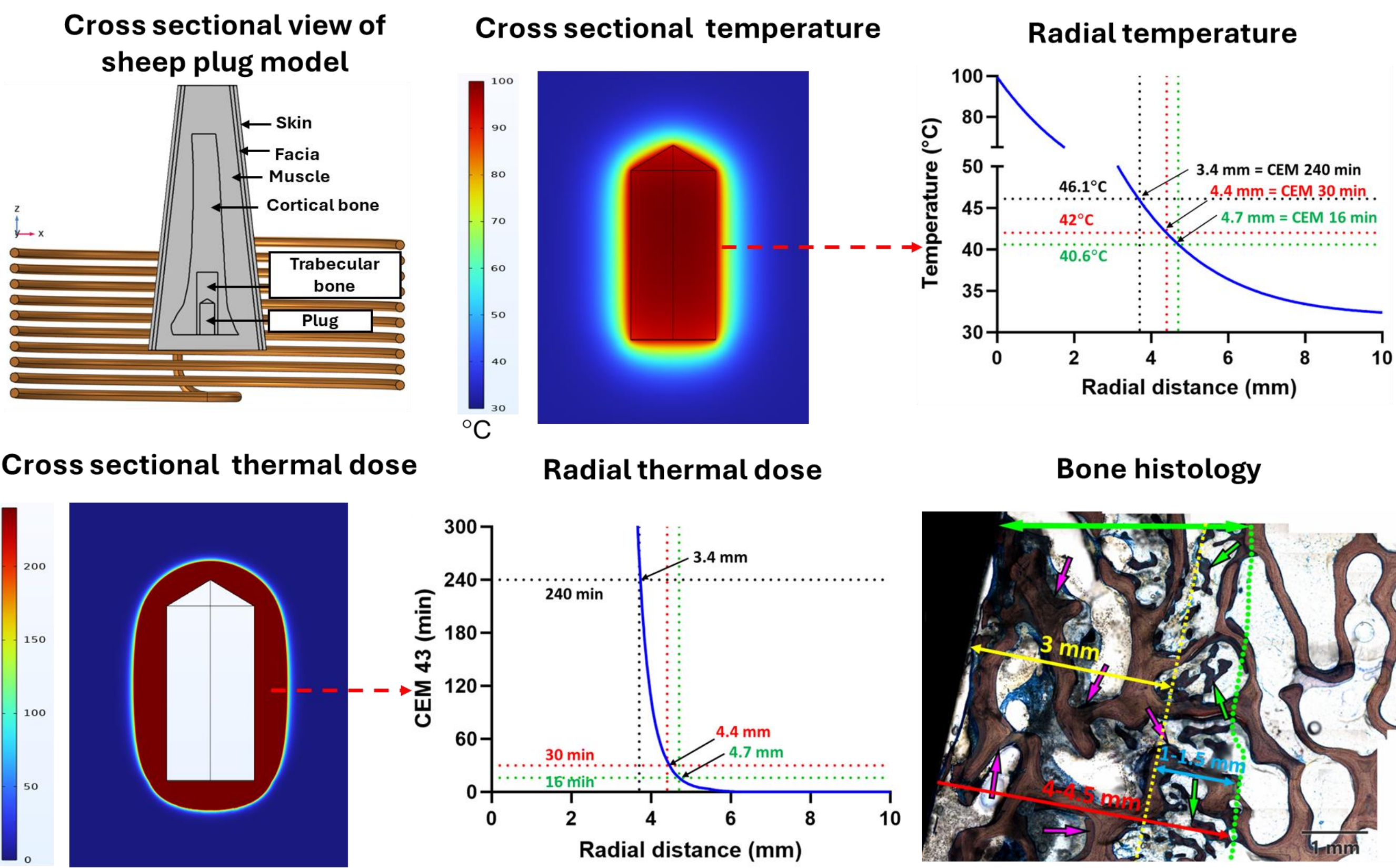
- Targeting biofilms located on the surface of prosthetic knee implant with high-frequency AMF

AMF is Synergistic with Antibiotic SOC



- Across pathogens (gram + and gram -) and multiple antibiotics
- In a sheep implant model, AMF + linezolid results in 90% further reduction of biofilm over linezolid alone at Day 5

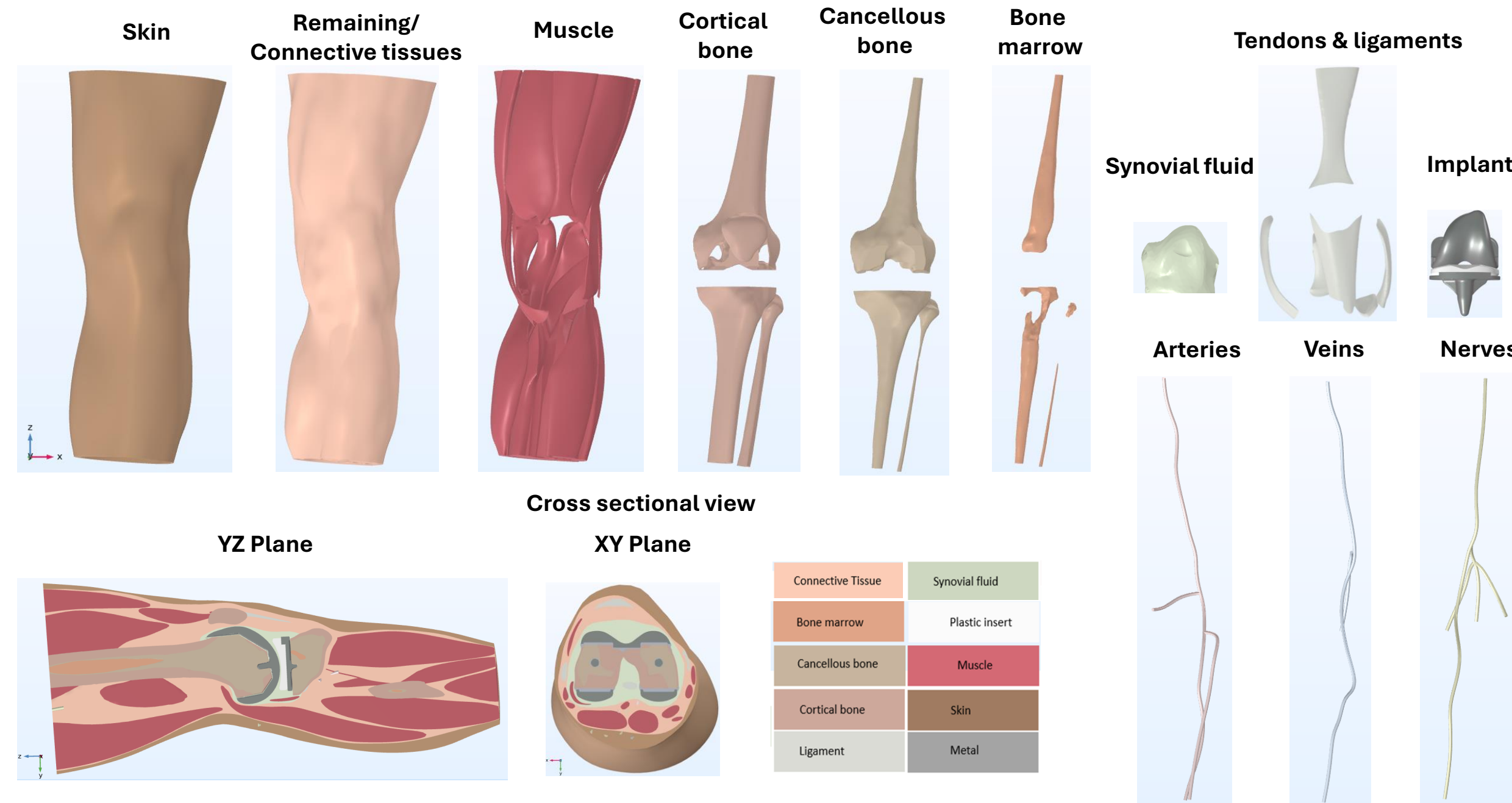
GLP Sheep Safety Study



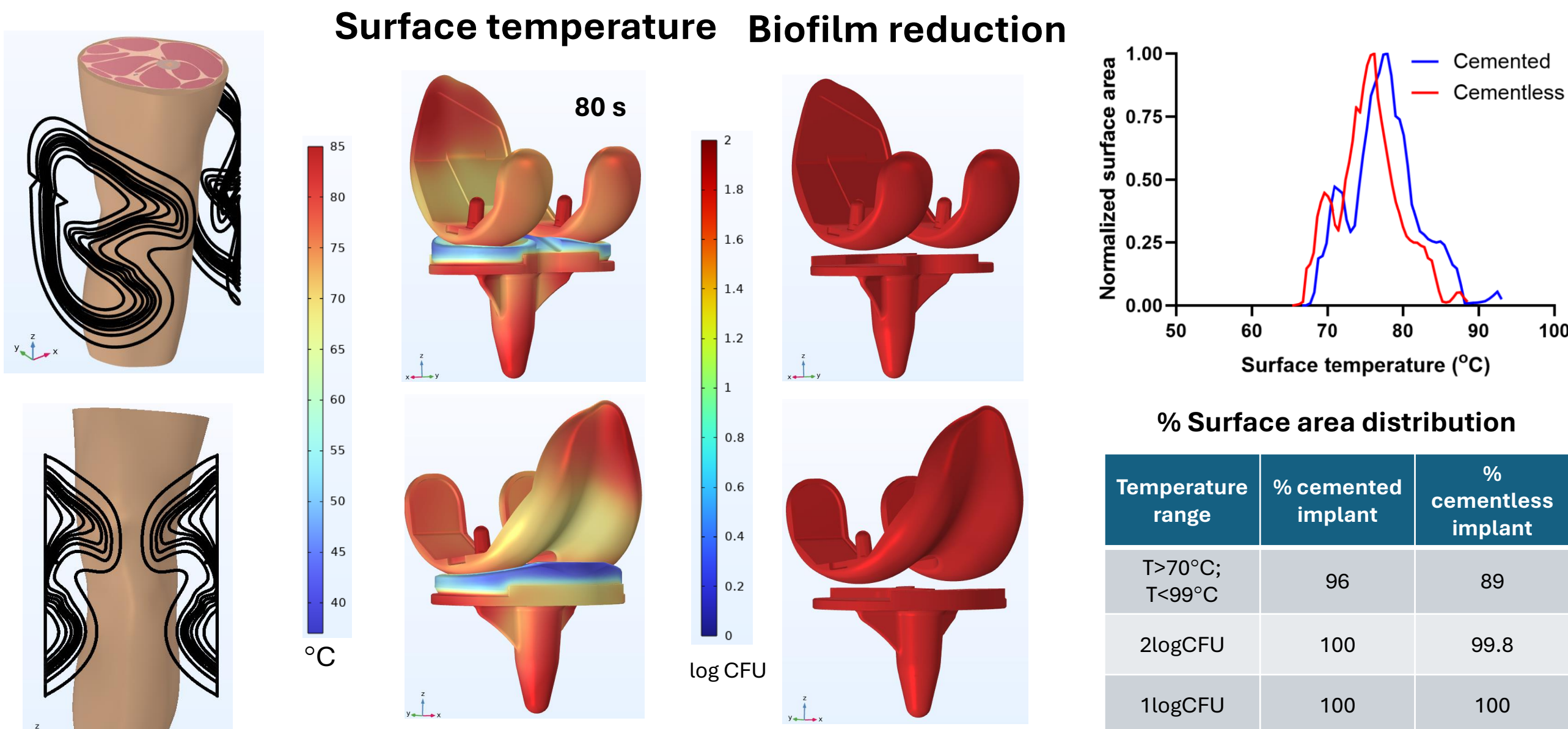
- Simulations showing minimal thermal injury of 5mm in bones after heating to maximum 99°C with 120s AMF.
- Histology shows signs of osseointegration and bone deposition after 6 and 12 weeks of AMF treatment.

Digital Knee Model

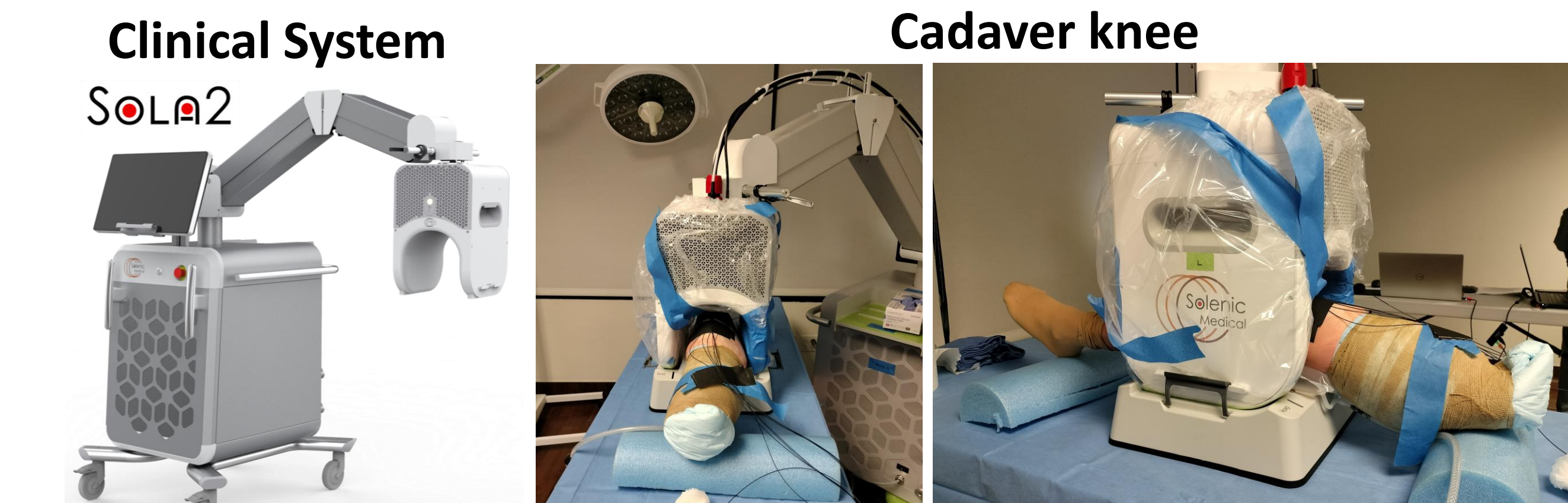
Human leg model with Attune Sz 9 implant



Uniform heating and biofilm reduction of Attune CR Sz 9 implant



Cadaver study using clinical system SOLA 2

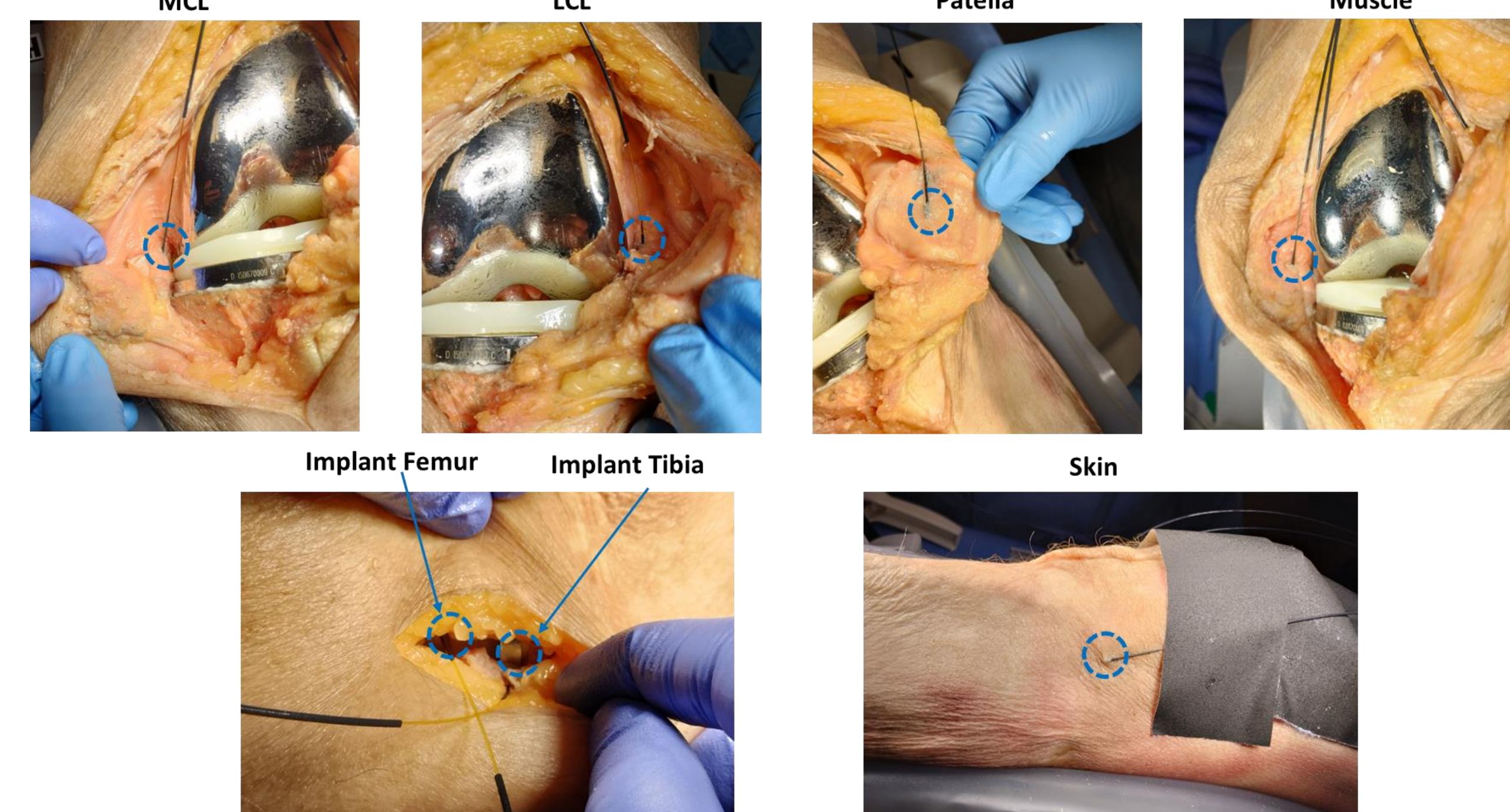


C - Arm positioning of implant w.r.t to coil

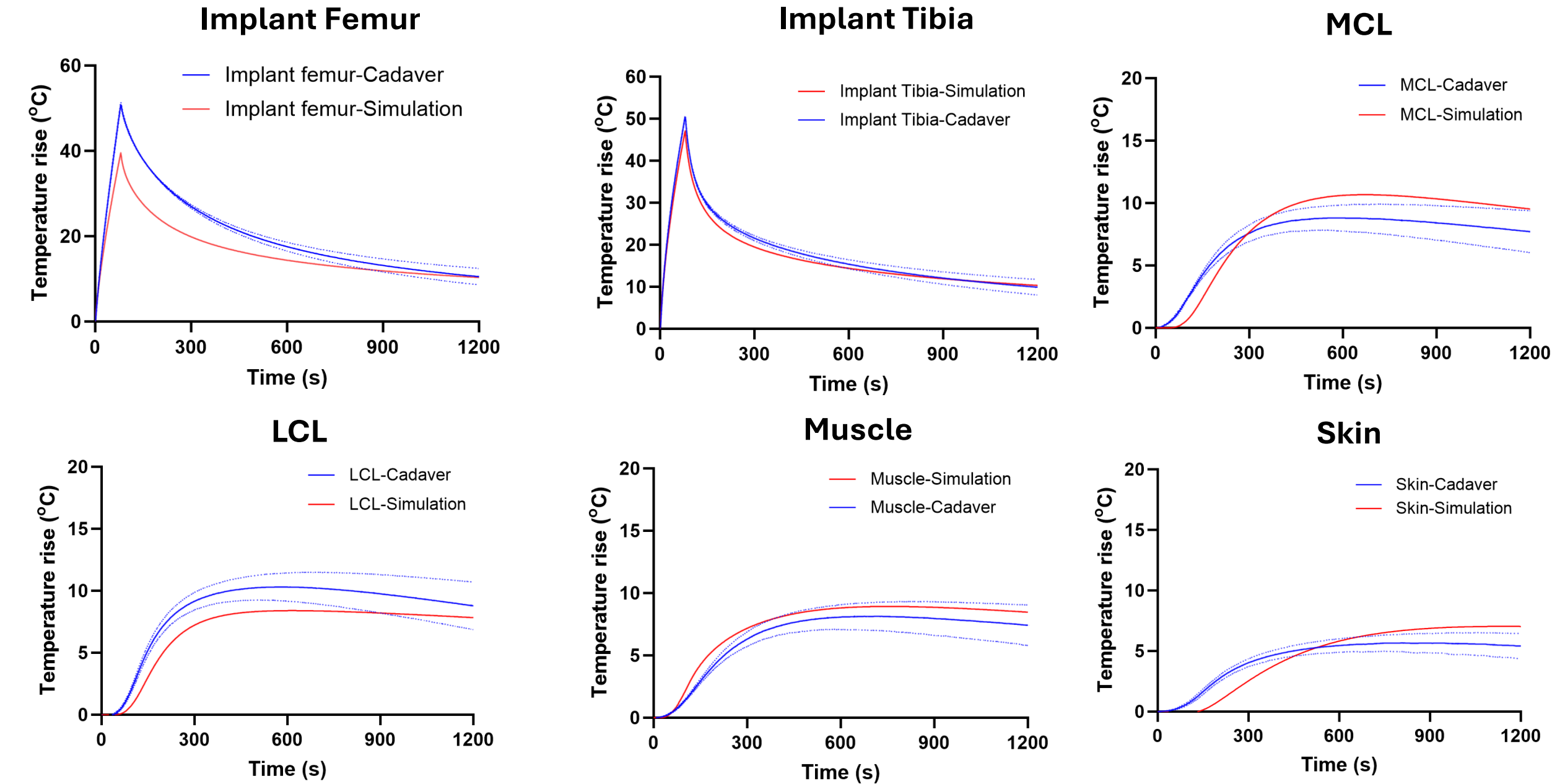


Temperature Validation

Sensor positions in cadaver

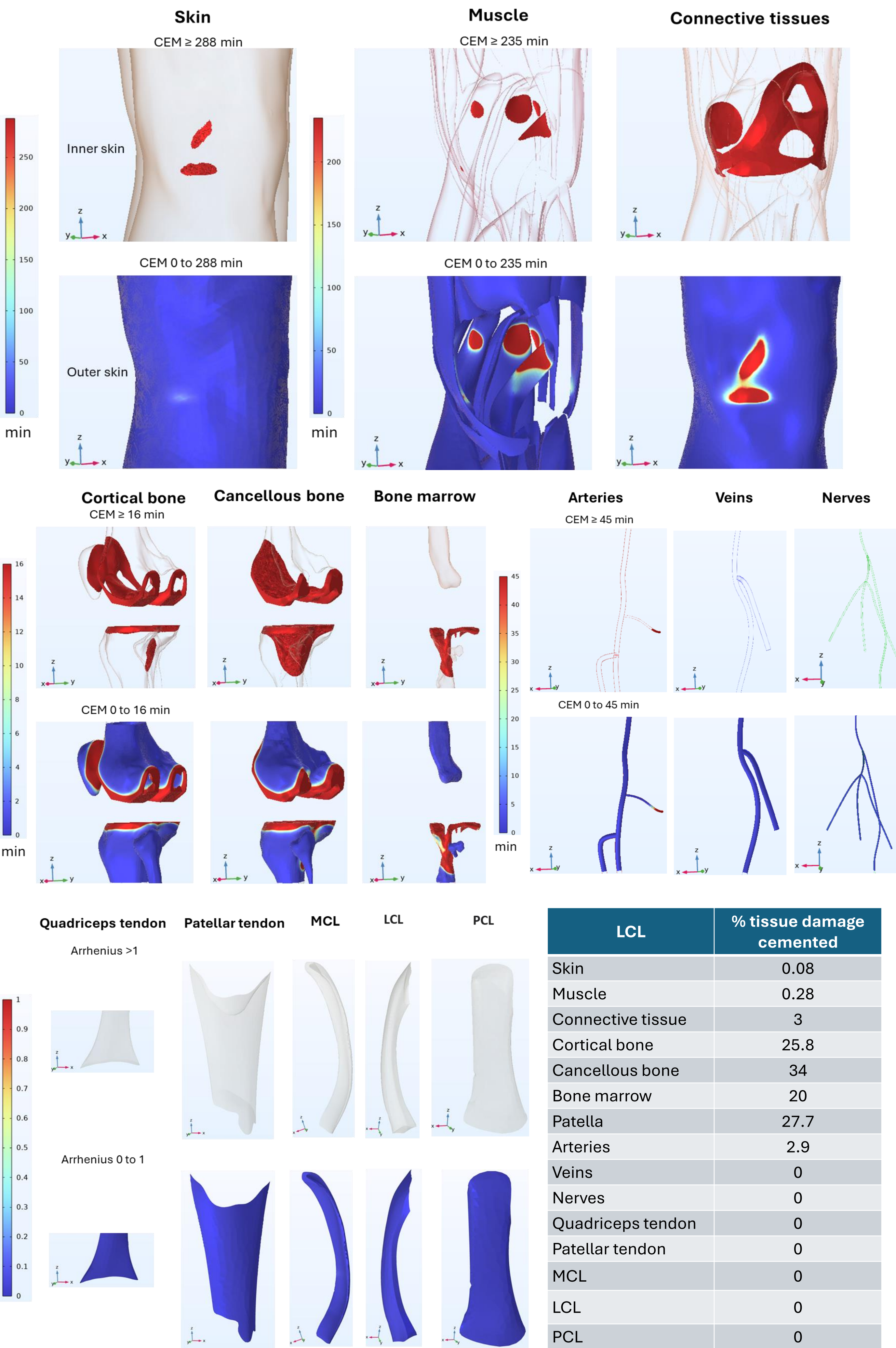


Comparison of temperature between cadaver and simulations



- Comparison of temperature rise in implant and surrounding tissues shows only a variation of <10% between simulations and experiment.

Thermal injury analysis



- Simulation results shows only minimal thermal injury (≤5 mm) in all critical tissues surrounding a knee implant.

Summary

- In a treatment strategy of achieving an average surface temperature of 75°C in single 80s exposure, <5 mm of thermal injury was observed to surrounding tissues.
- This study indicates accurate heating, safe and effective implementation of AMF treatment in clinics for PJI.

