

Magnetic Resonance Safety Evaluation of a Novel AMC Ceramic Knee and Image Artifact Comparison to a Metal Knee Implant of Analogous Design

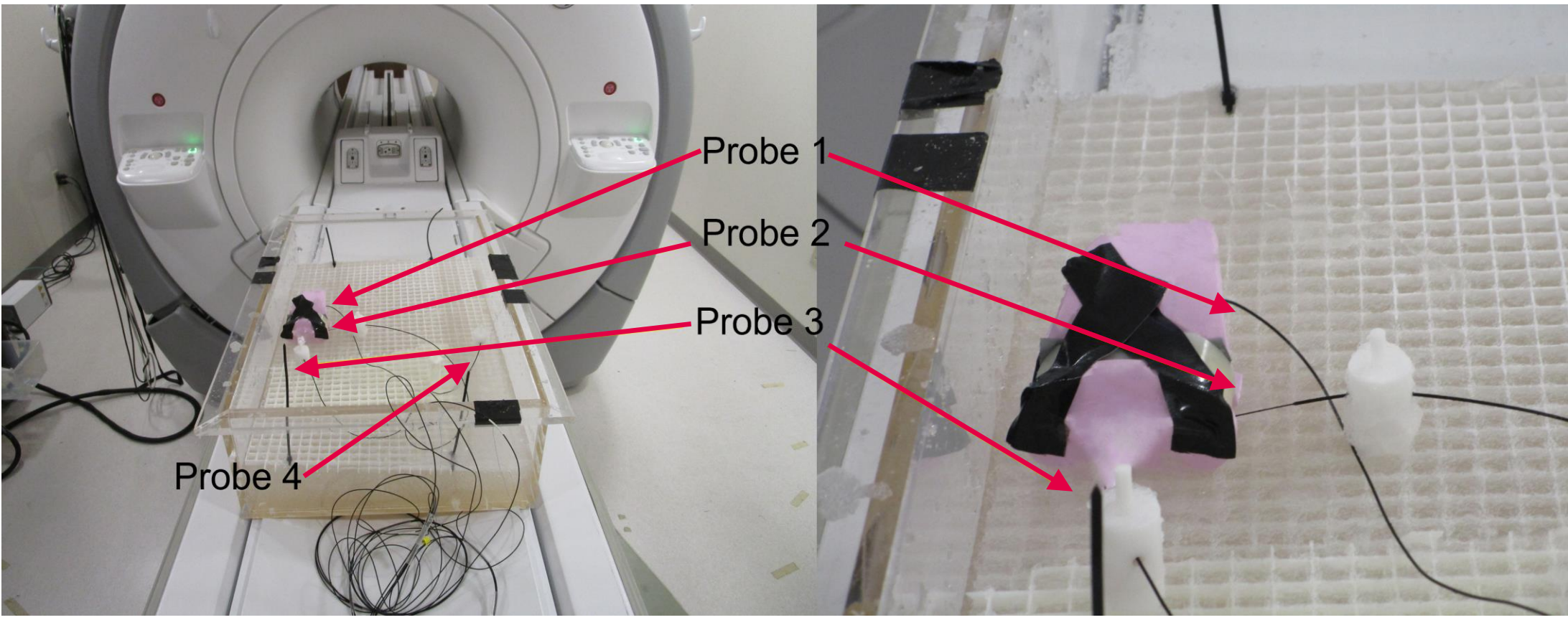
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Background

Image artifacts caused by the presence of metal knee implants in 1.5T and, to a greater extent, in 3T magnetic resonance imaging (MRI) systems complicate imaging-based diagnosis of the peri-implant region after total knee arthroplasty (TKA). Alternatively, metal-free knee prostheses could effectively minimize MRI safety hazards and offer the potential for higher quality diagnostic images.



Test Setup: Measurement of RF-induced heating of the AMC ceramic knee in a 3T MRI Scanner. Note: the image (right side) has been modified to blur implant contours.

Results

Minimal RF-induced Heating of the AMC Ceramic Knee

Minimal heating of the AMC Ceramic Knee (below 1°C) after 15 minutes of scan time, as assessed in a heat-insulating gel phantom.

No Magnetically Induced Displacement Force or Magnetically Induced Torque

No movement or dislocation of the AMC Ceramic Knee due to the applied magnetic field (displacement force $F_m = 0$ N).

Minimal Image Artifacts of the AMC Ceramic Knee compared to the CoCr Knee

Minimal image artifact distance of the AMC Ceramic Knee (7 mm) in comparison to the CoCr knee (88 mm).

Extremely Low Magnetic Susceptibility of the AMC Ceramic

Extremely low magnetic susceptibility values were measured for the AMC ceramic (2 ppm), compared to CoCr (820 - 2885 ppm) and Ti (157 - 190 ppm) alloys.

Study Design & Methods

A novel knee arthroplasty device without metallic components composed of BIOLOX[®]delta, a zirconia-toughened alumina matrix composite (AMC) ceramic, was tested in an MR environment (3T). American Society for Testing and Materials (ASTM) standard test methods were used for evaluating the magnetically induced displacement force, magnetically induced torque, radiofrequency (RF)-induced heating, and MR image artifacts. In addition, volumetric magnetic susceptibility of AMC, cobalt-chromium (CoCr) and titanium (Ti) test cylinders was determined.

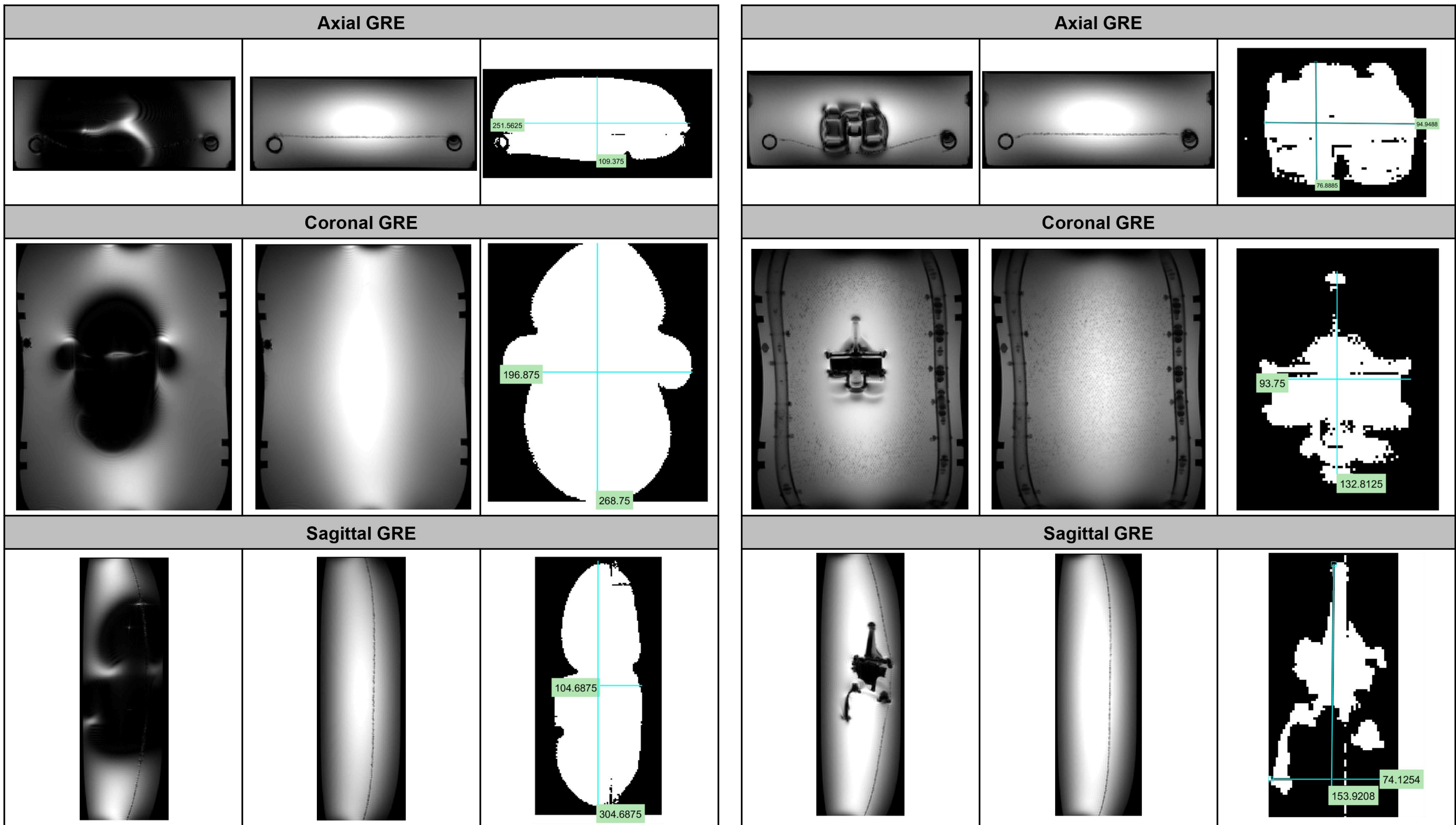
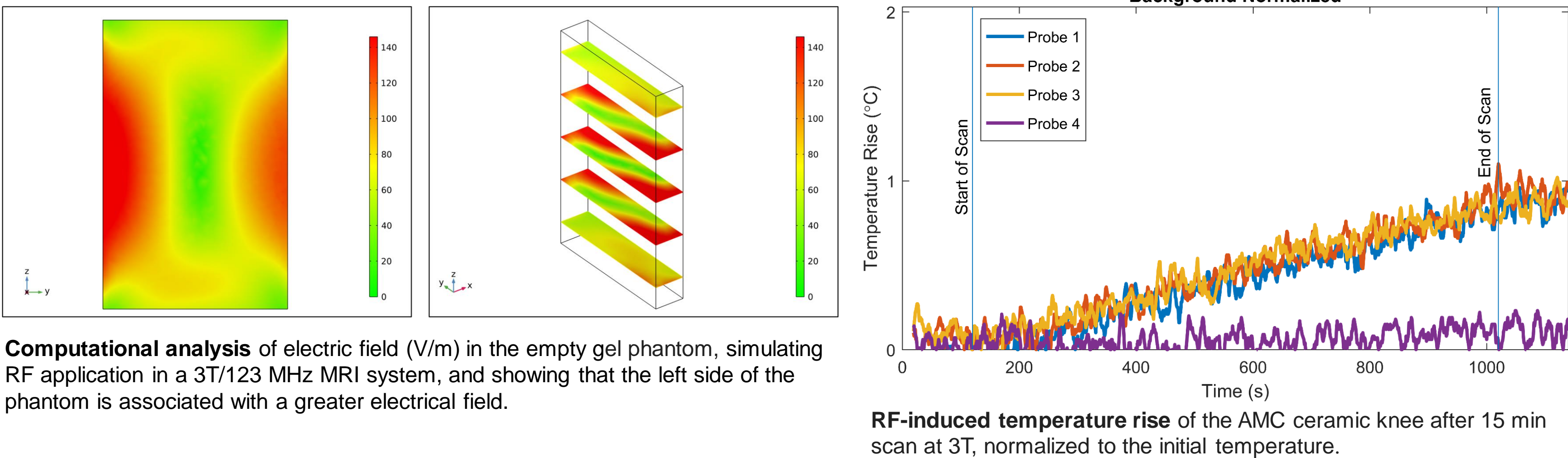


Image artifacts of the CoCr Knee (left) and the AMC Ceramic Knee (right) scanned at 3T with GRE pulse sequence. GRE: Gradient Spin Echo.

Image artifact distance of the test devices scanned at 3T with GRE pulse sequence. Values in mm.

Test Device	Orientation	Artifact Dimension	Test Device Dimension	Image Artifact Distance
AMC ceramic knee	Axial	95	81	7
	Coronal	94	81	6
	Sagittal	154	140	7
CoCr knee	Axial	252	75	88
	Coronal	269	75	64
	Sagittal	305	140	82

BIOLOX[®]delta is a material well suited for the manufacturing of MR Safe orthopedic implants.

There are no known hazards from exposure of the AMC Ceramic Knee to an MR environment, suggesting that the implant can be regarded as MR Safe.



BIOLOX[®] and BIOLOX[®]delta are registered trademarks of the CeramTec Group. This material is intended for health care professionals. Please check the regulatory status at www.bioloxx.com. The AMC Ceramic Knee is under development and is not cleared or approved by the FDA for distribution in the United States. The study was conducted in accordance with ASTM standards and the FDA Guidance document: Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment (May 2021).