RF Heating Methods For Implants In Bone: An Ongoing Challenge In MRI Compatibility

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INTRODUCTION: The Food & Drug Administration (FDA) received over 1,500 adverse event reports for magnetic resonance (MR) systems between 2008 and 2017; the most common injuries were due to thermal events. FDA and international standards committees address MR-related risks by requiring medical device MR compatibility testing. RF-induced heating, or the thermal response of medical devices in the MR environment, is often assessed using ASTM F2182 and involves experimental evaluations using a tissue-mimicking phantom. However, the ASTM method has limited applicability to orthopedic implants because the tissue-mimicking medium matches the electrical/thermal properties of soft tissue, but not those of bone. An alternative method to ASTM F2182 is computational evaluation using virtual implantation and electromagnetic/heat transfer physics simulations in a human body model, per ISO/TS 10974:2018: Clause 8 Tier 4. While the virtual implantation method accounts for implantation in bone computationally, a reliable experimental approach to evaluate RF heating in bone does not currently exist. Therefore, our objective was to experimentally evaluate RF heating in bone, using a metallic reference implant in an ASTM F2182 phantom modified with bovine bone or bone-mimicking material.

METHODS: RF heating of a 0.32 x 10 cm titanium rod was evaluated in a gelled saline phantom per ASTM F2182 with the following modifications: 1) none (gelled saline only), 2) added bovine bone, 3) added porous (cellular foam, 12.5 PCF) or dense (solid foam, 40 PCF) sawbone material, and 4) added porous or dense sawbone material soaked in low-permittivity medium (LPM), per ISO/TS 10974 (Figure 1 A and B). The titanium rod was placed in the phantom 2 cm from the phantom edge, with its length aligned with the coil z-axis and midpoint aligned with z = 0. Temperature probes were placed at the superior end, 10 mm from the inferior end, and inferior end of the rod. For the bovine bone setup, the rod was placed inside the diaphysis (embedded in the bone marrow) of a bovine femur. For the sawbone runs, 18x4x4 cm sawbone blocks were machined and cored to allow rod placement in the center of the block and probe insertion. For the sawbone with LPM runs, the sawbone blocks were soaked in LPM for 24 ± 2 hours before the run to better mimic the electrical properties of bone. RF heating evaluations were performed in 1.5 T (64 MHz) and 3 T (128 MHz) birdcage coils. RF power representative of a whole-body specific absorption rate (SAR) of approximately 2 W/kg was deposited for 15 minutes. Temperature at the superior end of a 0.32 x 5.5 cm rod placed contralaterally in the phantom was monitored and used as a variability correction factor for all runs.

RESULTS SECTION: Maximum temperature increase of the 10 cm titanium rod exceeded 8°C in gelled saline at both 1.5 T and 3 T. In both sawbones and bovine bone, the 10 cm rod's maximum temperature increase was approximately 2°C or less in all cases (Figure 1C). Local SAR (LSAR, determined by control runs without the titanium rod present) was lower in the bovine/sawbone runs; thus, the temperature increase per background exposure was also calculated (Figure 1D). Heating per background exposure was still at least two times higher in the gelled saline compared to either the sawbones or bovine bone. In general, heating with or without (control runs) the titanium rod present was similar in bone or sawbones, whereas the presence of the titanium rod increased heating significantly in gelled saline (Figure 1C). Moreover, heating in bovine bone was similar to heating in the sawbone blocks.

DISCUSSION: In recent years, regulatory agencies have emphasized the importance of evaluating RF heating in bone for orthopedic implants, based on the differences in thermal and electrical properties between bone and gelled saline media. Our results demonstrated that different material properties between bone and gelled saline does result in substantially different heating. Moreover, when comparing the bone results to the bone surrogates, the same whole body RF exposure resulted in similar heating in the bovine femur and sawbones, regardless of sawbone density or presence of LPM. These results suggest that bone-like surrogates may capture the effect of bone on RF heating experimentally. Importantly, this study did not investigate differences in resonant length between tissue types, which is longer in bone (~20-35 cm) vs. connective tissue (~10-25 cm). Ongoing computational work has demonstrated agreement with this experimental approach, simulating a 10 cm titanium rod in gelled saline vs. bone/bone marrow (results not shown), but further work is needed to validate this modified ASTM F2182 test setup and assess the effect of implant length on the accuracy of this methodology.

SIGNIFICANCE/CLINICAL RELEVANCE: Evaluation of RF-induced heating is critical to ensure patients with orthopedic implants can safely receive the optimal diagnostic imaging that MRI can provide. Development of clinically relevant experimental techniques for heating evaluation directly decreases risk associated with MRI scanning.

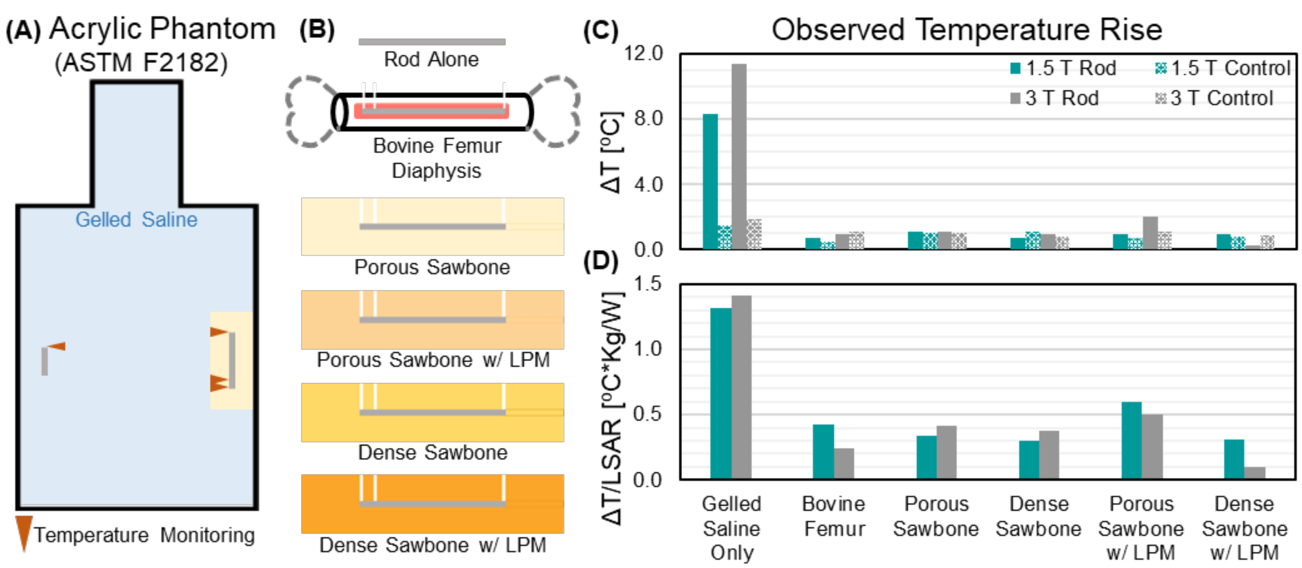

Figure 1. A) Experimental schematic, B) Test groups, C) Maximum temperature increases, (D) Temperature increases scaled to background exposure.