

Title: Radiofrequency-induced heating in orthopedic implants: a cadaveric study

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Structured Abstract:

Introduction: Magnetic resonance imaging (MRI) is becoming exceedingly widespread, to the degree where it is predicted that everyone will undergo at least one MRI exam in their lifetime. Rising rates of joint replacements in Canada[1] makes it increasingly likely that a patient undergoing an MRI exam will have some sort of implanted medical device. Orthopedic devices often perform poorly/fail current MRI device safety tests, limiting the patient to low resolution scans (which have little clinical utility), or a lifetime ban on MRI studies (in more extreme cases). The current radiofrequency (RF) heating test is extremely conservative in its approximation of human tissues, leading to overestimation of device heating. The current standard fails to consider important factors such as blood flow, physical properties of different tissues, and realistic implant positioning. This project aims to address the weaknesses of current testing methods and utilize empirical data to establish more realistic heating thresholds for orthopedic devices. We will be using increasingly complex test platforms (gel phantoms, large animals, and cadaveric specimens) to quantify true device heating. We hypothesize a decrease in observed heating with increasing complexity of the specimen.

Methods: The ASTM F2182-11a standard (RF heating in passive implants) was used to test a 10cm titanium rod as an implant mimic. Heating tests were performed in the Medical Implant Test System (MITS - Zürich MedTech, Switzerland) – a platform used to recreate the RF fields of 1.5 and 3 Tesla scanners. Temperature rise (ΔT) data were analyzed in MATLAB (R2017B), and no stats were performed.

Results: Fresh-from-frozen cadaver leg (n=1) was used in our pilot study as a realistic test platform in terms of geometry and anatomy. Temperature rise was compared to the ASTM standard gel phantom. Cadaver ΔT (1.5T/3T) = 1.57 °C/9.87 °C. Whereas gel phantom ΔT (1.5T/3T) = 9.66 °C/13.48 °C. This represents an ~84% and ~27% decrease in ΔT at 1.5T and 3T, respectively.

Discussion: This successful proof of concept showed device heating to be lower in the cadaver compared to the 'gold standard' gel phantom. Although blood flow was not simulated (often considered the most important method of heat dissipation in-vivo[2]), our hypothesis was supported and device heating is expected to be even lower in simulated perfusion conditions. More cadaver work is planned to elucidate the relationship between accurate tissue mimicking and heating. Furthermore, we are planning a large animal study to evaluate in-vivo tissue behavior in response to device heating. Proof of reduced heating in-vivo could influence regulatory changes, meaning less devices fail the RF heating tests. This improves patient access to potentially life-saving MRI scans that were previously unattainable.

[1] Canadian Institute for Health Information – Joint replacements (2017)

[2] Adair et al., Bioelectromagnetics, 24.S6 (2003)