Active Implanted Devices in the MRI Clinical Environment

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Clinicians currently face a complex decision when determining whether to perform MRI examination of a patient with an active implantable medical device (AIMD). There are known interactions between the MRI scanner and AIMD, and little data to support a clinical risk vs. benefit decision. Recent advances in AIMD technology and modeling are directed toward reducing the probability of harmful interactions occurring and toward assessing this probability.

Examples of AIMDs include cardiac rhythm management devices such as pacemakers, defibrillators, and cardiac resynchronization devices, other cardiac monitoring devices such as pressure sensors, neurostimulators, implantable drug pumps, and hearing assist systems. Many of these patients will develop a clinical need for an MRI scan; recent estimates indicate that up to 75% of pacemaker and defibrillator patients will develop a clinical indication for MRI examination [1] .

There have been numerous reports of complications of scanning AIMDs, including brain trauma from MRI scans of implanted direct brain stimulation systems, and arrhythmia induction or heart rate acceleration in patients with cardiac rhythm management systems [2, 3]. Systematic studies of patients with cardiac devices with specific programming prior to the scan have shown a low incidence of clinical problems other than elevated heart rate which resolved when the scan sequence was terminated [4]. Such studies are limited in size, and can only shed limited light on the probability of occurrence of hazards including tissue heating, unintended stimulation, and device failure which have low probability but potentially serious consequences.

The following potential interactions have been identified in the literature [5, 6]: Heating of the device by gradient fields; heating of the device or tissue near the device by RF fields; unintended electrical stimulation of tissue due to currents induced by gradients or by RF pulse rectification; translational or torque forces due to static field; vibration due to gradient induced eddy currents and the static field; system failure resulting in loss of therapy, incorrect therapy, and/or surgical replacement; and image distortion or artifacts.

An IEC/ISO Joint Working Group (ISO TC150/SC 6/JWG2) is identifying and documenting systematic methods to evaluate these hazards; publication of a Technical Specification TS 10974 is pending with guidance for evaluation of AIMDs for MR Conditional status [6]. Key to this effort are advancements in modeling of scanner fields [7], the resulting electromagnetic fields in the body [8], and modeling of the electromagnetic properties of the implanted system. Implanted system modeling is particularly important for any elongated structures such as pacemaker or neurostimulator leads, as these can act as antennas for the time varying fields in the MRI, and direct electrical current flow either into tissue or into electronic assemblies such as a pacemaker can [5, 9].

There is on-going collaboration between researchers, AIMD and MRI scanner manufacturers, and regulatory bodies to advance management of MRI/AIMD system interactions. Further efforts toward vertical standards to set specific test limits and labeling requirements for various AIMD categories are anticipated. Similar efforts are on-going to define an “implant mode” for MRI scanners with the goal of placing bounds on RF and gradient field intensity to provide a defined environment for future AIMD scanning. The presentation will describe the mechanisms of interaction between the MRI and AIMD, and will explore the opportunities for future work in this field.

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