Implant Safety: Novel Mechanistic Approach at WPT Frequencies

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Current safety guidelines regulating the exposure of the general public to electromagnetic fields (EMF) do not cover wearers of medical implants. The scientific basis on implant-related power deposition and resulting tissue heating is sparse, preventing committees from being able to draw conclusions on safety limits that are applicable also to wearer of implants. Current implant safety standards (ISO/TS 1974) focus on patients undergoing magnetic resonance imaging (MRI) and the potential for irreversible injury induced by MRI-generated radiofrequency (RF) fields in the presence of elongated implants. However, wireless power transfer (WPT) technologies at frequencies <10 MHz present additional concerns regarding implant safety, as very high power levels could be emitted close to exposed subjects. At those frequencies, exposure of an implant lead embedded in tissue would be enhanced locally, posing a risk at the standardized field level thresholds considered safe for the general public. The concepts developed so far in MRI safety standards cannot be applied in uncontrolled environments. Furthermore, it has been demonstrated with simulations that the mechanistic view applicable in MRI safety assessment based on energy pick-up by the lead and deposition at critical implant locations, is not valid at the lower frequencies of WPT, where observed dependence on tissue conductivity and tip insulation are inconsistent with the mechanism. A safety assessment concept and mechanistic understanding valid for any implant and WPT system needs to be developed. In this study, we propose a mechanism based on the hypothesis that voltage-driven current through an implant short-circuit is constrained by tissue resistance at the tip, which we model as serial resistances with known dependence on tip shape and local tissue conductivity. This mechanism has been confirmed by numerical simulations of insulated and bare wires of varying length in globally or locally homogeneous tissues with varying dielectric properties exposed to uniform tangential electric (E-) fields at 3 kHz – 10 MHz. The peak spatial specific absorption rate (pSAR), temperature increase, and induced E-field have been predicted and compared to the model predictions. The induced E-field and pSAR vary <5% when normalized according to the predictions of the mechanistic model. Tip shape affects very localized induced fields and pSAR, but the temperature increase typically varies <3%. For magneto-quasistatic exposure, the voltage difference is replaced by the integrated tangential field (electromotoric force) with <2% deviation. The results were validated in a human anatomical model with a generic implant: the difference after normalization was 5% for exposure to magnetic fields, 15% for electric fields. The proposed generalized electromagnetic safety concept represents a rigorous approach that can be applied to extend the current safety standards to cover implant wearers.