Importance of Pacemaker Lead Preconditioning for MR Safety In-Vitro Studies

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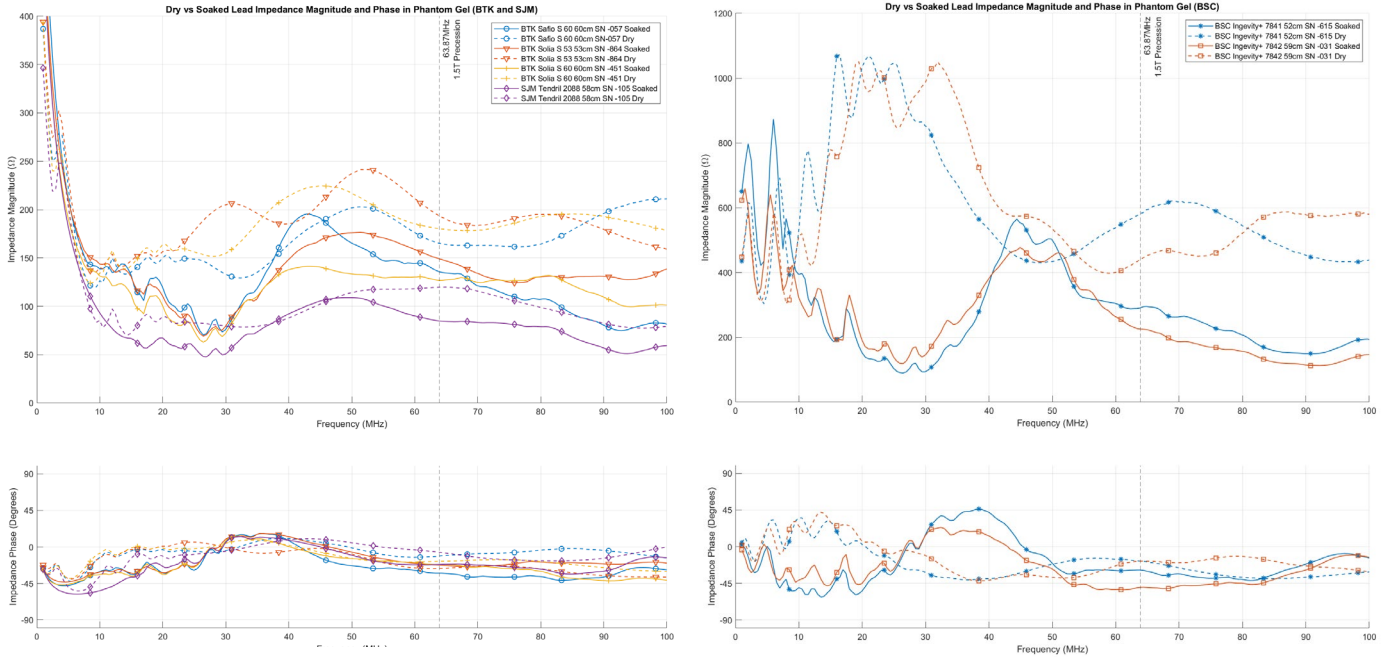
This study investigates the change in the RF filtering characteristics of the leads of active implantable medical devices (AIMDs) as body fluids seep into the leads during the initial post implant period. Our findings indicate that the RF characteristics change dramatically with fluid absorption, making it necessary to precondition the leads by soaking in isotonic saline solution to simulate the in-vivo scenario when conducting in-vitro MR safety testing. Furthermore, leads designed with RF-attenuating lumped inductances must consider the effect of fluid absorption on changing the peak RF attenuation frequency.

METHODS: We measured the open- and short-terminated impedances of a number of current MR-conditional leads samples before and after soaking them for 10 days in isotonic saline solution (0.9% NaCl) at 37°C using an Anritsu MS46522A, 8.5GHz bandwidth vector network analyzer (VNA). The characteristic impedance $Z_0 = \sqrt{Z_{open} \cdot Z_{short}}$ was calculated from measurements of the open (unterminated) lead impedance Z_{open} and the short-circuit-terminated impedance Z_{short}.

RESULTS:

LEADS	DRY 63.87 MHz Z_0 [Ω]	SOAKED >10 DAYS 63.87 MHz Z_0 [Ω]	ΔZ_0 [%]
Biotronik Solia S 53 cm	160.80	120.57	**25.02**
Biotronik Solia S 60 cm	174.70	97.29	**44.31**
Biotronik Safio S 60 cm	168.80	121.61	**27.96**
Abbott Tendril 2088 58 cm	96.80	88.63	**8.44**
Boston Sci Ingevity+ 7842 59 cm	620.30	266.19	**57.09**
Boston Sci Ingevity+ 7841 52 cm	551.80	258.07	**53.23**
MEAN	**266.50**	**147.27**	**32.99**

The impedance changes approximately along a constant X circle (in Z=R+*j*X), suggesting a change in the resistive properties of the lead as it is soaked.



It is interesting to note that the outer coils of the Boston Scientific Ingevity+ leads are made of ETFE-insulated filars, thus increasing the outer coil's inductance. As the leads soak, their impedance decreases together with an increase in the frequency at which the impedance peaks. Presumably, the lead is designed to stabilize such that the peak would occur in the proximity of the 63.87 MHz 1.5 T MRI frequency. However, the conditions necessary for this seem prone to be sensitive on lead aging.

DISCUSSION and CONCLUSION: It is critical to precondition leads by soaking in an isotonic saline solution to simulate the in-vivo scenario prior to conducting MR safety testing in-vitro. This step is necessary to avoid misleading safety results as the diffusing body fluids change the peak impedance of the lead. Furthermore, the design of MR Conditional leads with RF-filtering lumped inductances must consider the effect of post implantation fluid diffusion in shifting the peak RF attenuation frequency of the lead.