Evaluation of Various Materials for Tip Penetration of Pacemaker and Defibrillator Leads

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Statement of Purpose: Perforation of the myocardium by a pacemaker or implantable cardioverter defibrillator (ICD) lead, though relatively uncommon, remains a serious and sometimes fatal complication of transvenous lead implantation [1]. During product development, a buckling test is commonly used to evaluate characteristics that may contribute to perforation, such as stiffness of the distal tip of the lead. However, the buckling test does not assess other lead characteristics that may contribute to perforation such as lead diameter, tip geometry, and lead type. Assessment of these key factors for perforation potential requires the selection of a material suitable for contacting the lead tip during testing. In this study, we investigated several materials that could be used for this purpose, as we continue our research to examine lead tip characteristics that may contribute to perforation.

Methods: Coupons of porcine tissue cut from the right ventricle (RV) were pinned to a circular holder with a 0.5" diameter hole underneath the tissue. To maintain tissue viability, the holder was placed within a small chamber containing Krebs-Henseleit solution, a widely used perfusion buffer [2]; the buffer was infused with 95% O_2, 5% CO_2 and maintained at 37 ˚C. The lead's distal helix was screwed into the tissue with a stylet in place, simulating the clinical implantation technique. The stylet was removed prior to dynamic testing that simulated lead motion during the cardiac cycle. Testing was conducted with the tissue holder moving toward the distal lead tip under sinusoidal displacement between 0 and 25 mm, 7° rotation, 1 Hz, for a maximum of 4 hours. Details of the test apparatus are described elsewhere [3]. Quasi-static compression testing of porcine RV tissue was conducted with the lead secured 5 mm from the distal tip, at a constant displacement rate of 5 mm/min up to a load of 9.5 N. The tissue holder in this case was a solid plastic dish. Agarose gel (6% and 2%), synthetic cardiac tissue (SynDaver Labs), and deli meat (bologna) were also tested, as tissue substitutes. Penetration was defined as migration of the distal tip into the tissue/substitute.

Results: Preliminary dynamic testing in porcine tissue produced visible penetration in some cases. Figure 1 shows migration of the distal tip of one pacing lead before and after 7200 cycles (120 min). In subsequent runs however, penetration of the same lead did not consistently occur (Table 1). The inconsistency was likely influenced by morphological variations present in the bulk material, manifested as small "hills" and "valleys" on the surface and variations in thickness.

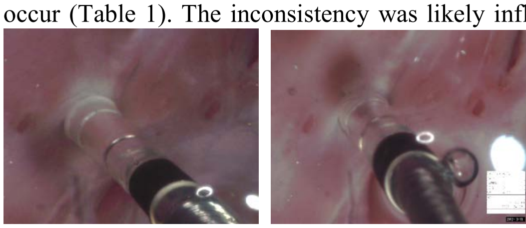

***Figure 1**: Lead with helix engaged in RV porcine tissue, before dynamic testing (left) and after 7200 cycles (right).*

***Table 1.** Preliminary penetration results with porcine RV.*

Lead	# Penetrations per Total # Runs
Pacing 1	3/8
ICD 1	1/4
ICD 2	0/1

Distinct responses of the lead tip to quasi-static compressive loading were observed for each material tested. Figure 2 shows force vs. displacement curves for a representative ICD lead. Similar results were observed for a pacing lead. The agarose gel and synthetic tissue showed steep, almost linear, increases in force during the initial displacement, in contrast to a much slower rise in load for the natural heart tissue. The response of the bologna was closer to the porcine tissue than were the other materials. However, the porosity of the bologna varied with slice and with production lot.

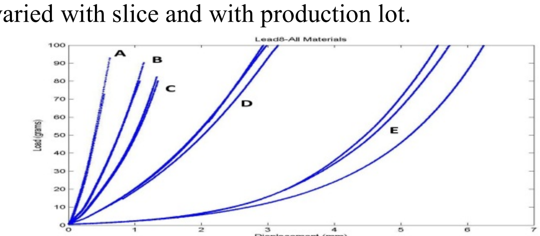

***Figure 2**: Quasi-static compressive loading of an ICD lead in 6% agarose (A), 2% agarose (B), synthetic cardiac tissue (C), bologna (D), and porcine RV (E).*

Conclusions: Intrinsic variations present in natural heart tissue resulted in inconsistent penetration of the porcine RV by cardiac leads under dynamic loading. These preliminary penetration results, along with the increased complexity of the test procedure required to maintain tissue viability, underscored the need to search for a more consistent material for evaluating perforation potential. Quasi-static loading of the distal lead tip in different tissue substitutes showed that agarose gel and synthetic tissue, though possessing some desirable characteristics, are less compliant than porcine tissue. Bologna responded more similarly to tissue than other materials, however, pore size and distribution in food products is variable. Additionally, while this test evaluated penetration, the precursor of perforation, of the lead tip into the bulk material, it did not account for other characteristics such as interactions between the lead helix and material. We will continue to search for a suitable material that may be used to refine our dynamic test for evaluating perforation potential.

References: [1] Hirschl et al. PACE 2007; 30: 28-32.
[2] Bessems et al. Laboratory Animals 2006; 40: 236-246.
[3] Walsh et al. ASME-SBC 2013, submitted (abstract).