Factors Affecting Distal Tip Stiffness of Pacemaker and Defibrillator Leads

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Statement of Purpose: Implantable cardioverter defibrillators (ICDs) and pacemakers are implanted into more than 350,000 patients in the United States every year [1] for the management of cardiac arrhythmias, ventricular dysrhythmias, and congestive heart failure [2]. One potential complication of transvenous ICD and pacemaker lead implantation is perforation of the myocardium during or following lead implantation. Perforation of the lead through the myocardium can result in lead dislodgement, cardiac tamponade, or death [2]. Therefore, it is important to understand the factors that affect lead performance and the interaction between the lead and heart tissue. Current test protocols measure peak load at the distal tip of the lead as the lead undergoes buckling, commonly known as a "tip stiffness" test. This measurement is typically conducted without any transverse constraint on the lead. However, in clinical use a lead is constrained in both the transverse and longitudinal directions maximized during right ventricular (RV) shortening during systolic contraction of the heart. In this study, we investigate the impact of several test parameters, including the presence of a transverse RV constraint, on the peak loads at the lead distal tip and how these parameters could affect lead performance.

Methods: For testing, leads were secured 75 mm above the distal tip of the lead, with the distal tip in contact with a metal plate attached to a load cell. The load cell measured the load applied to the distal tip of the lead. For tests using a transverse RV constraint, a cylindrical tube 16 mm in diameter was placed around the upper 2/3 (50 mm) of the gauge length of the lead (Figure 1). Thirteen lead models from 5 manufacturers were tested in four different test configurations: (A) *dynamic loading without stylet and with transverse constraint,* (B) *static loading without stylet and with transverse constraint*, (C) *static loading without stylet and without transverse constraint*, and (D) *static loading with stylet and without transverse constraint*. Static tests were conducted at a displacement rate of 50 mm/min and dynamic tests were run at 50 mm/sec (1 Hz) for 25 cycles. Overall displacement was 25 mm for all tests. Three runs were completed for each lead in each configuration. Peak load values were recorded for each run and averaged.

Results: A comparison of the peak load values for the 4 test groups shows differences with and without the transverse constraint (Figure 2). ANOVA showed significant differences between these groups ($p<0.001$), with the *no stylet and no constraint group* (C) showing significantly lower peak loads compared to all other test groups. In addition, the loading profile for this group was different from the other groups, with the load value plateauing before maximum displacement was reached (not shown). Average peak values for static (B) and dynamic (A) conditions (with constraint) showed no significant difference. For the unconstrained cases (C and D), the presence of the stylet resulted in a significant increase in load ($p<0.001$). Similar results were observed with the stylet in a constrained configuration (not shown here). In all test configurations, peak load values between individual lead models showed large variation.

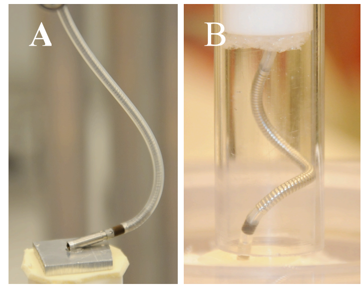

Figure 1: Image of lead buckling test without (A) and with (B) transverse RV constraint showing difference in lead response.

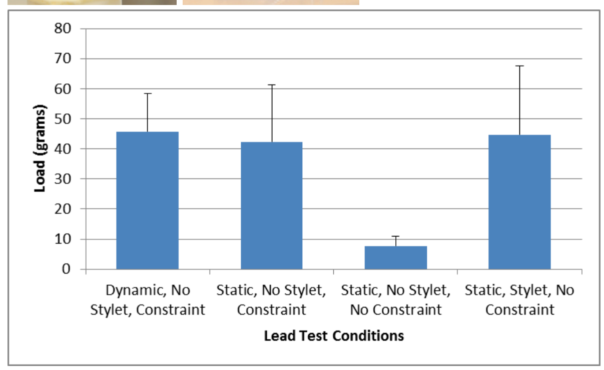

Figure 2: Comparison of peak load measured at distal tip of all lead models under multiple test conditions.

Conclusions: The absence of the transverse RV constraint results in significant underreporting of peak loads experienced at the lead tip. Therefore, it is important to account for this clinically relevant constraint in developing test protocols to assess distal lead tip performance. The presence of the stylet also significantly affects the load at the lead tip. It is important to recognize the contribution of the stylet (used during lead implantation) and the RV constraint to lead tip loads and consequently, their potential contribution to tissue damage during and after implantation. Much remains to be studied regarding the relationship between lead tip characteristics and patient variability and lead performance. Our long term goals are to identify test parameters relevant to distal lead tip performance and determine clinically relevant ranges for these parameters that will be useful in the development of standard test methods for new and existing leads. Ultimately, we hope this work will result in decreased perforation rates for implanted ICD and pacemaker leads.

References:

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