Lead Anchoring and Mechanical Stability of a Substernal Extravascular ICD Lead

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**Introduction**: The extravascular defibrillator (EV ICD) system may offer patients critical sudden cardiac death protection while remaining outside the heart and preserving the native vasculature. The EV ICD system uses a novel design and implant procedure to keep lead electrodes in place under the sternum. To understand factors that affect lead stability in the substernal space, pre-clinical data were acquired using acute and chronic animal studies, human cadaver evaluation, and bench testing.

**Methods**: Multi-species chronic studies have been conducted in ovine (n=4), porcine (n=9), and canines (n=4) with two different veterinary implanters. Animals were implanted with an EV ICD lead, anchoring technique for each animal was recorded, and imaging data were collected over 12 weeks. Chronic lead slip was measured using CT scans by tracking electrode and anchor sleeve position over time. In addition, human cadavers were implanted with the EV ICD system to measure holding force of the anchor sleeve. The effects of suture technique, suture tie down force, and number of sutures on lead holding force at the anchor sleeve were assessed. Acute animal studies were performed to compare suture tie down forces between veterinarians using the same anchoring method, same suturing technique and same number of sutures.

**Result**: In the chronic animal studies, 9 different suture techniques were recorded, and lead motion was quantified as ranging from 0 mm-31 mm (Figure 1a). Large variation in lead motion was also observed within suturing techniques that were used more than 3 times through the animal studies. Bench test, cadaver studies, and acute animal test data showed an effect of type of knot, number of sutures, and tie down force, on the holding force of the anchor sleeve. (Figure 1b). Tie-down forces measured in the lab ranged from 1 pound (0.45 kg) to 3 pounds (1.36 kg) between veterinarians.

**Conclusion**: Before standardizing suture technique for the EV ICD lead, variable amount of lead motion was observed in the chronically implanted animals. Significant variability in suturing technique, including tie-down force and number of sutures used, was seen between veterinary implanters, suggesting that suturing techniques affect the lead holding force of the anchor sleeve. This was confirmed in the cadaver studies and the bench testing, where the suturing techniques, specifically tie down forces were controlled. Different suture technique resulted in different holding forces. Furthermore, standardizing the type and number of sutures and controlling the tie down force resulted in consistent holding forces (Figure 1b). These studies suggest that there is a need to use robust suturing technique to assure appropriate mechanical stability of the EV ICD system for its unique use conditions.