

# Preclinical Assessment of the Safety, Lesion Durability, and Feasibility of a Novel Linear Pulsed Field Ablation to Create Durable Lesions at the Outflow Tract

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**Background:** Ventricular arrhythmia commonly arises from the right and left ventricular outflow tracts (RVOT and LVOT). It is unknown if pulsed field ablation (PFA) can create durable lesions safely on the outflow tract.

**Objective:** To demonstrate the safety, acute efficacy, and chronic durability of a novel PFA catheter to deliver focal ablations to the RVOT and LVOT.

**Methods:** A total of 12 Yorkshire swine (40-50 kg) were divided into three groups: (1) acute (24-hour); (2) 14-day; and (3) 30-day. A 7F PFA catheter (PFLine, EnChannel Medical) was used to deliver a biphasic-bipolar 750V waveform using fluoroscopy, navigation (Ensite, Abbott), and intracardiac echocardiography (Figure 1A). Ablation sites were located in the RVOT at the free wall (Free), Septum (Septal), left, right, and anterior cusp (LC, RC, and AC) and in the LVOT at the left, right, and non-coronary cusp (LCC, RCC, and NCC). Pre- and post-ablation mapping and electrophysiology studies were performed to measure the changes in voltage amplitude, pacing thresholds (PT), A-H, and H-V intervals. Coronary angiography and ST-segment elevation from ECG were used to assess coronary artery lesions. Histologic examination was performed for all three groups when sacrificed.

**Results:** All subjects survived with no adverse events reported. Significant changes ( $p < 0.01$ ) between pre- and post-ablation voltage amplitude and PTs were noted at all locations (Figure 1B). There were no significant changes observed in A-H and H-V intervals, ST-segment elevation, or rate acceleration following RVOT and LVOT ablations. Histologic examination (Figure 1C) showed well-demarcated lesions at the ablation sites without damage to surrounding structures.

**Conclusions:** In this swine study, PFA is shown to be safe and effective in creating durable lesions to the RVOT and LVOT. Damage to the adjacent coronary artery or His-bundle was not observed.

