Acute and Chronic Performance Evaluation of a New Ultra-Thin LV Quadripolar Pacing Lead in a Canine Model

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BACKGROUND

Left ventricular (LV) lead positioning is one of the main contributors to cardiac resynchronization therapy (CRT) response. Additional and multiple LV sites could be stimulated by passing a new ultra-thin LV quadripolar lead from one LV vein into another via venous collaterals.

OBJECTIVE

To study the acute and chronic stability and electrical pacing performance of a novel 1.2 Fr LV microlead in a canine model.

DEVICE DESCRIPTION

Axone 4LV (MicroPort CRM, France) is a 1.2 Fr LV quadripolar microlead, designed without any internal lumen and with incremental flexibility towards the distal end (diameter varies from 4 Fr in the proximal part to 1.2 Fr in the distal part) ***(Figure 1)***. The thin diameter of the lead allows it to enter small collaterals of the LV coronary venous network and for the pacing electrodes to pass from one LV vein into another.

Figure 1. The Axone 4LV microlead

METHODS

Six healthy adult dogs underwent CRT defibrillator implantation, including a right ventricular (RV) lead and the novel Axone 4LV microlead. They were followed at 1, 15, 30 and up to 90 days post-implant for evaluation of:

- Axone 4LV microlead implant success: the feasibility of passing the pacing electrodes from one LV vein into another through available collaterals was assessed.
- Axone 4LV microlead electrical pacing performance: pacing threshold and impedance were measured via the CRT-D device at each follow-up. Mean ventricular capture threshold was determined at 0.5 ms pulse width in extended-bipolar pacing configurations (RV lead coil as anode reference) over the 4 LV pacing electrodes, with the corresponding pacing impedance.
- Axone 4LV microlead stability: the position of the lead was analyzed via fluoroscopic imaging at each follow-up.
- Axone 4LV microlead bio-tolerance: at necropsy, the lead was removed and the heart was collected for microscopic evaluation.

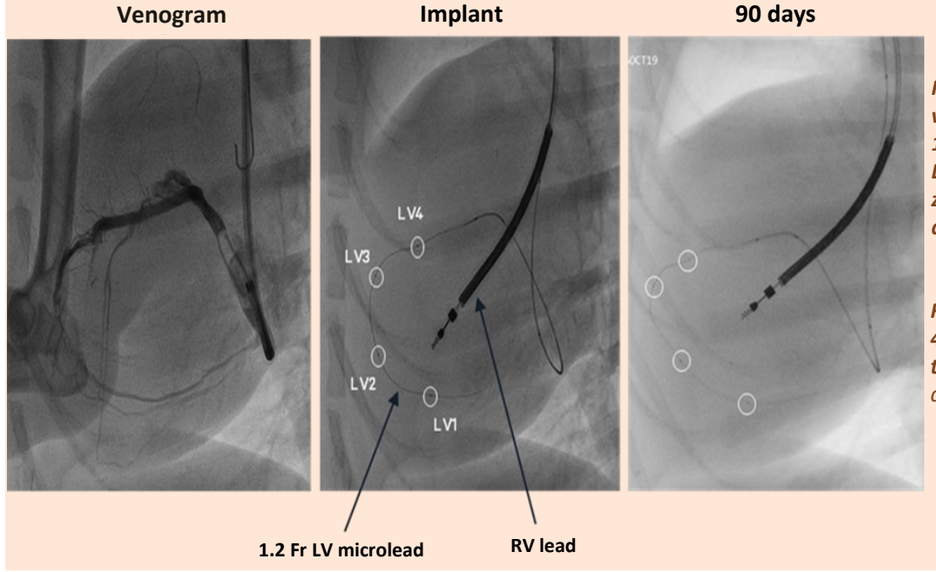


Figure 2 (left). Example of fluoroscopic views at implant and at 90 days of the 1.2 Fr Axone 4LV microlead. LV1 and LV2 electrodes are placed in the apical zone of the posterior vein, while LV3 and LV4 are in the anterior vein.

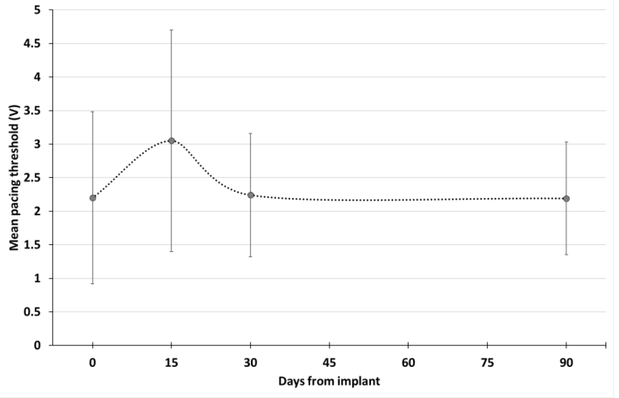
Figure 3 (below). Change in the Axone 4LV microlead pacing threshold over time. *Mean ± SD (4 LV electrodes tested at each follow-up).*

RESULTS

Lead implantation success Before lead implantation, a retrograde coronary venogram was performed in each dog. Successful uncomplicated implantation was achieved in all cases. The LV microlead was advanced in the coronary sinus (CS) network using a microcatheter guide and, despite the thin veins of the animal model, it was feasible to pass the pacing electrodes from one LV vein into another through available collaterals in 5 out of 6 cases ***(Figure 2)***. Distal electrodes (LV1-LV2) were positioned in mid-apical zone of the posterior vein in 5 cases; all the other electrodes were always placed in the interior interventricular vein. A defibrillation lead was also implanted at the apex of the RV chamber and both leads connected to a CRT-D device placed subcutaneously in the upper neck position.

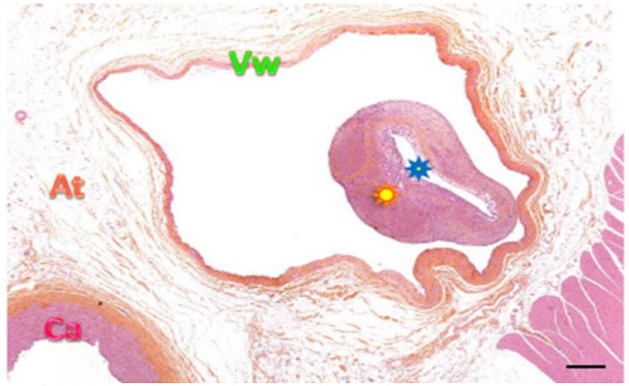
Post-implant follow-up	Pacing threshold	Pacing impedance
1 day	2.2±1.3 V	1180±179 Ω
15 days	3.1±1.7 V*	1295±227 Ω*
30 days	2.2±0.9 V	1242±300 Ω
90 days	2.2±0.8 V	1334±279 Ω*

*Table 1. Mean pacing threshold and impedance of the Axone 4LV micro lead (*P <0.05 compared to day 1)*



Lead electrical performance Mean extended-bipolar ventricular capture threshold at 0.5 ms pulse width over the 4 LV pacing electrodes was 2.2±1.3 V with 1180±179 Ω of pacing impedance at 1 day post-implant, and 2.2±0.8 V with 1334±279 Ω at 90 days (*P*=0.965 and *P*=0.039 compared to day 1, respectively) ***(Table 1)***. No phrenic nerve stimulation was observed during Axone 4LV microlead pacing. An elevation of pacing thresholds during the first 15 days post-implant was generally observed followed by a consequent decrease and stabilization of values at 1-month post-implant ***(Figure 3)***.

Lead stability The position of the Axone 4LV microlead was analyzed via fluoroscopic imaging at each follow-up and stable position of the LV microlead was achieved in all cases.



HE&S, Original magnification x 4, scale bar: 250

Figure 4. Bio-tolerance of the Axone 4LV microlead - example of a histological cross-section of vein involved in the passage of the microlead. **Abbreviations and symbols:** *Vw: venous wall, Ca: coronary artery, At: Adipose tissue, blue star: passage of Axone lead, yellow star: fibrous tissue*

Lead bio-tolerance The local bio-tolerance of the device, indicated by local inflammatory reaction, was excellent ***(Figure 4)***. After 3 months, an almost continuous tissue capsule had formed around the intravenous Axone 4LV lead. The formation of a fibrous sheath around the device was within the range of expected findings three months after placement of a lead in the venous coronary system in this species. Thrombosis was very rarely noted and, when present, was minimal.

CONCLUSIONS

In this canine model, implanting a novel 1.2 Fr LV microlead was possible in all cases, with the placement of pacing electrodes in different veins via a collateral pathway in 5 out of 6 dogs. Moreover, with good positional stability, electrical performance and bio-tolerance, the microlead has the potential to extend pacing options in CRT.

Disclosure information: F. Anselme is a consultant for MicroPort CRM, Medtronic and Boston Scientific.