CHRONIC ELECTRICAL PERFORMANCE OF A NEW ULTRA-THIN LEFT VENTRICULAR QUADRIPOLAR PACING LEAD

F. Anselme, MD, PhD[1]; F. Ziglio, MSc[2]; N. Shan, MSc[2]; L.I.B. Heckman[3], MD, M. Kuiper[3], F.W. Prinzen[3], PhD.

(1) Hôpital Charles-Nicolle, Rouen, France; (2) MicroPort CRM, Clamart, France; (3) Department of Physiology, Maastricht University, The Netherlands

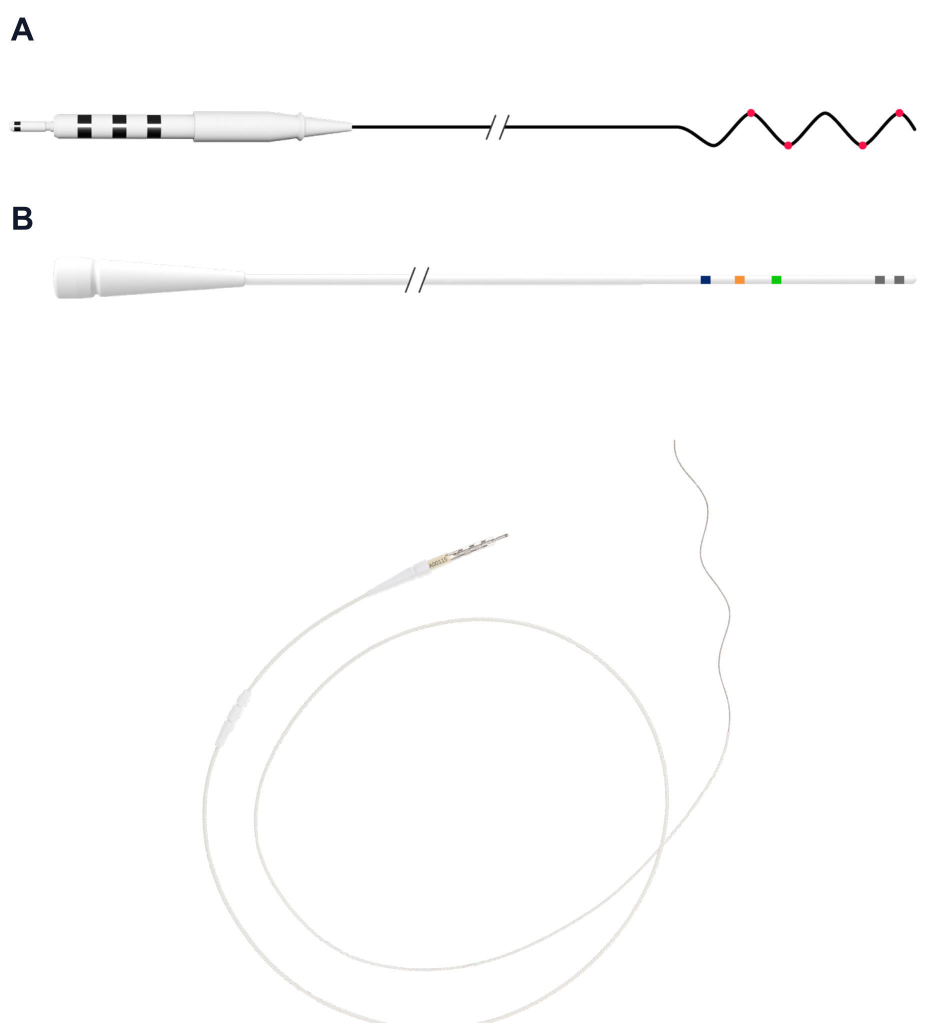
DEVICE DESCRIPTION

Axone 4LV (MicroPort CRM, France) is a 1.2 Fr composite microcable lumenless LV microlead, with four distant and selectively programmable electrodes (***Figure 1A***).

The LV microlead is implanted with the help of a specific microcatheter, Axone µ-Guide (***Figure 1B***). This microcatheter is an implant accessory for venous navigation and microlead delivery, and it remains implanted with the Axone 4LV microlead.

Thanks to its thin diameter and increasing flexibility towards its distal end, the Axone system is able to enter small collaterals of the LV coronary venous network, which allows pacing electrodes to pass from one LV vein into another.

Figure 1. *The Axone 4LV microlead (A) and the Axone µ-Guide microcatheter (B).*



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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

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

METHOD

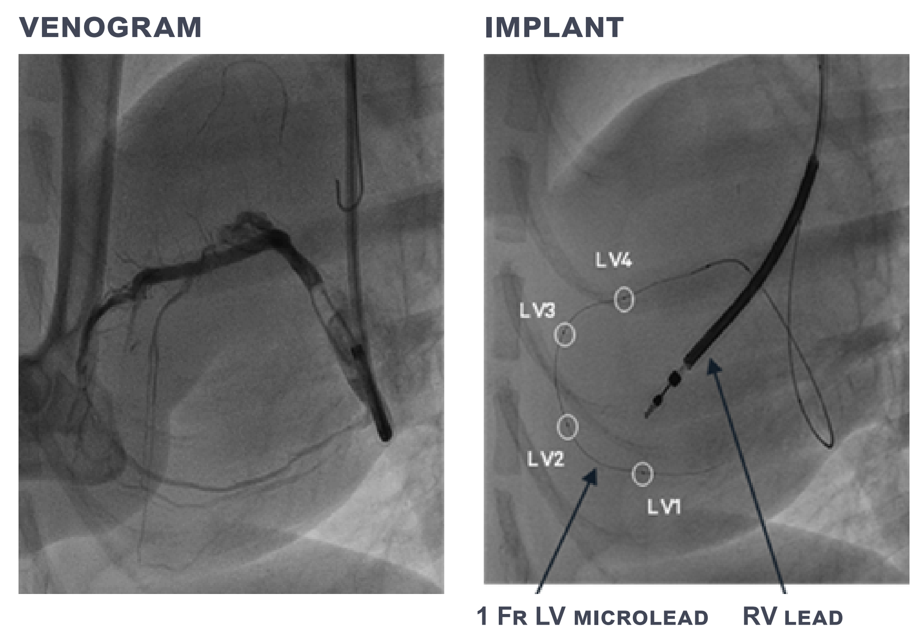
Seven healthy adult dogs underwent CRT defibrillator implantation including a right ventricular (RV) lead and the novel Axone 4LV microlead. They were followed up at 1, 15, 30 and up to 90 days post-implant for the evaluation of:

- ▶ Axone 4LV microlead **implant success:** The feasibility of passing 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 in extended-bipolar pacing configurations (RV lead coil as anode reference) at 0.5 ms pulse width via the CRT-D device over the 4 LV pacing electrodes. For each animal and at each follow-up, the lowest capture threshold was determined with the corresponding pacing impedance and derived pacing energy.
- ▶ 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.

RESULTS

Lead Implant

- 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 into the coronary sinus (CS) network using the Axone µ-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 7 cases (***Figure 2***).
- Distal electrodes (LV1-LV2) were positioned in the mid-apical zone of the postero-lateral vein in 5 cases, and the more proximal electrodes were always placed within the great cardiac 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.



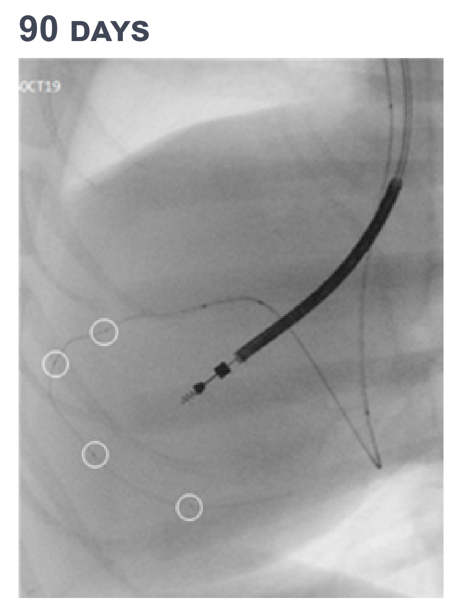


Figure 2. *Venogram and fluoroscopic views of the Axone 4LV microlead at implant and 90 days post implant. LV1 and LV2 electrodes are placed in the apical zone of the postero-lateral vein, and LV3 and LV4 in the great cardiac vein.*

RESULTS

Lead Stability

- The position of the Axone 4LV lead was analyzed via fluoroscopic images at each follow-up, and it was determined that the position of the LV microlead was stable in all cases.

Lead Electrical Performance

- Mean values of LV capture threshold, pacing impedance and pacing energy at 0.5 ms pulse width are reported in ***Figure 3***. Under chronic conditions at 90 days post-implant, the mean capture threshold was 1.7±0.5 V with a pacing impedance of 1323±245Ω. The mean pacing energy to obtain LV capture was 1.1±0.5µJ, and less than 2µJ in all cases (2µJ ≈ 1.4V @500Ω, 0.5ms, (***Figure 4***). No phrenic nerve stimulation was observed during LV microlead pacing.

Figure 3. *Mean pacing threshold, impedance and pacing energy at each follow-up visit (there are no significant differences in electrical performance for any parameter vs day 1).*

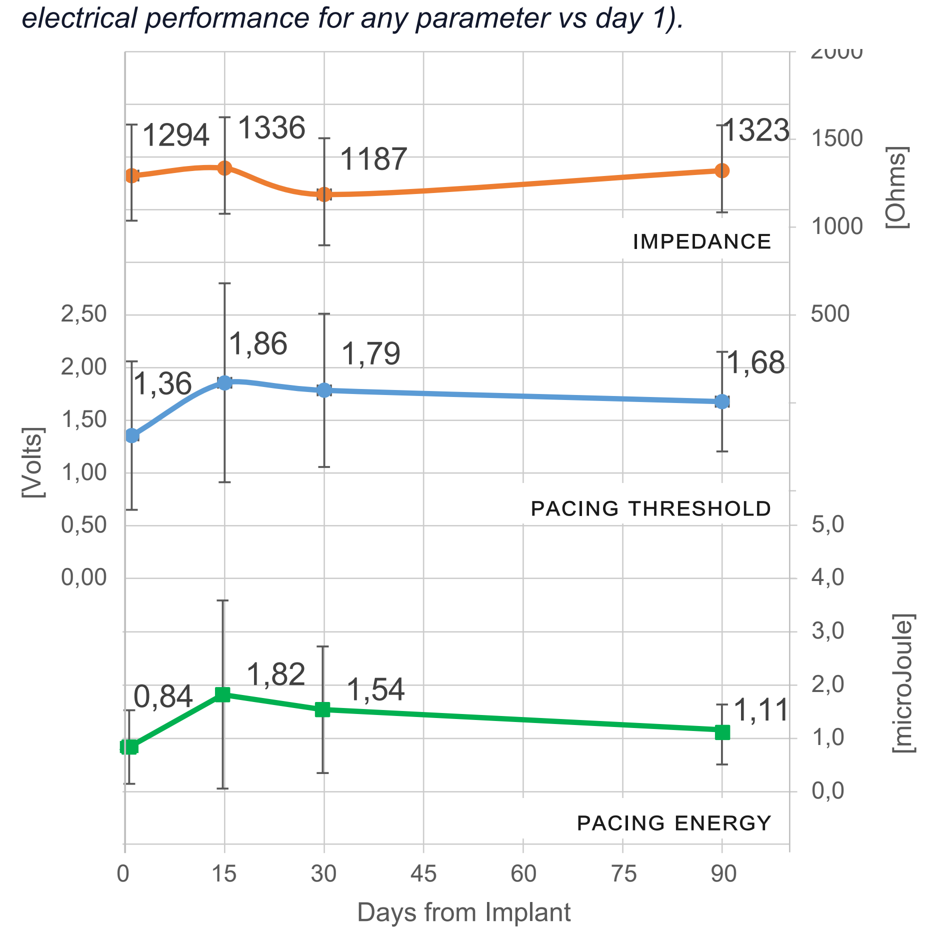
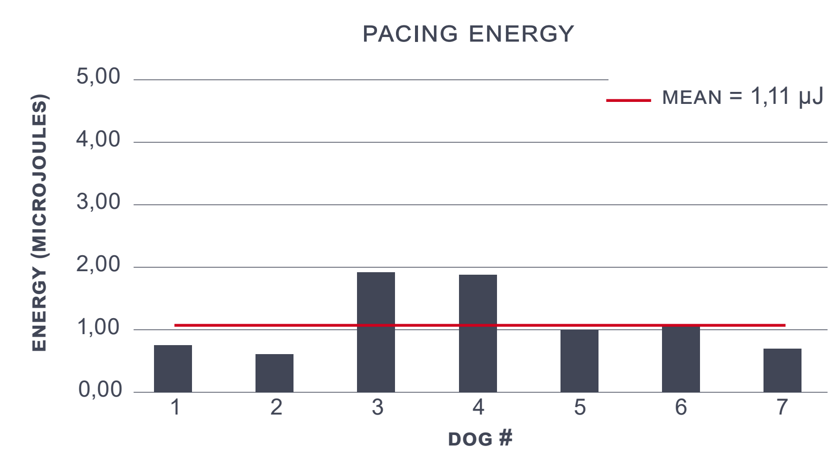


Figure 4. *Pacing energy associated with capture threshold at 3 month follow-up*

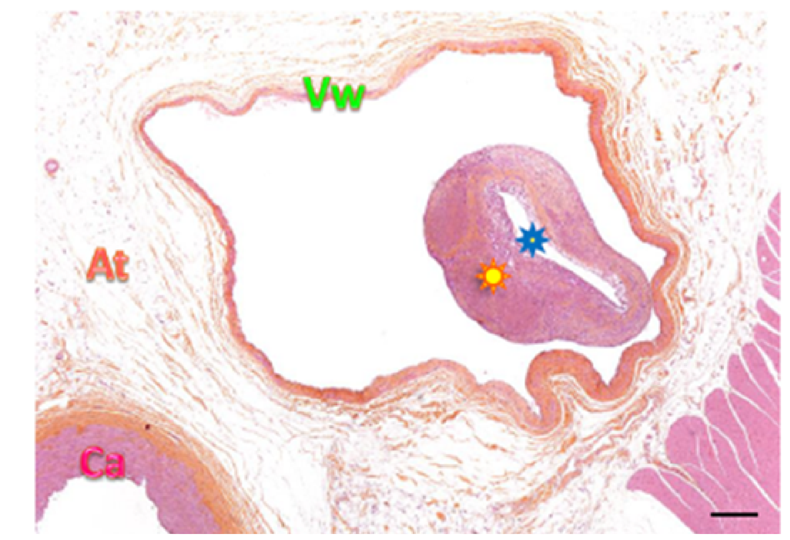


RESULTS

Histology

- After 3 months, an almost continuous tissue capsule had formed around the intravenous Axone lead. The formation of a fibrous sheath around the device was an expected finding three months after placement of a lead in the venous coronary system of this species. Thrombosis was very rarely noted and, when present, was minimal. Local tolerance of the device — as indicated by the minimal local inflammatory reaction — was excellent (***Figure 5***).

Figure 5. *Histological cross-section of a left ventricular vein through which an Axone 4LV microlead has passed (Vw: venous wall, Ca: coronary artery, At: Adipose tissue, blue star: passage of Axone lead, yellow star: fibrous tissue)*



CONCLUSIONS

▶ The novel 1.2 Fr quadripolar microlead demonstrated adequate stability and good electrical performance allied to low energy consumption. This quadripolar microlead may extend pacing options while increasing device longevity in CRT.

FINANCIAL DISCLOSURES

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