Unleaded: The Fluoroless 3D Lead Implant

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OBJECTIVE Intraoperative fluoroscopy during cardiac pacing lead implantation presents an occupational hazard to implanting physicians and their staff, both through cumulative radiation exposure and the orthopedic burden of wearing protective lead (Pb) garments. Pacemaker and defibrillator implantation is typically performed using fluoroscopy in a highly rationed manner due to the radiation hazard. We assessed preliminary feasibility of anatomic mapping and device lead implantation using an unrationed non-fluoroscopic 3D imaging system based on bioimpedance.

METHODS A 44 kg swine was premedicated with verapamil as antiarrhythmic prophylaxis and anesthetized with isoflurane. The animal was placed in dorsal recumbency. A jugular venous and carotid arterial cutdowns were made. An introducer was placed in the carotid to measure arterial pressure. A venotomy was made in the jugular vein for insertion of transvenous catheters and leads. The subject was instrumented with body surface electrodes as used with the Medtronic LocaLisa™ cardiac navigation system. A research system, **Implant sans Fluoro (IsF)**, was constructed using the LocaLisa position sensing unit, a notebook PC running Windows XP and customized software application.

Eight device implanting physicians (7 EP, 1 surgeon) from four countries presented to the operating suite in groups of 1, 2, 2 and 3. The eight self-reported **prior experience** with swine cardiac anatomy, deflectable sheath and catheter delivered lead. The deflectable sheath and balloon catheter were used to explore the vena cava and right ventricle, creating a 3D display of points from 12 position samples per second.

Specific landmarks identified and annotated with the IsF system were the junctions of the right atrium with the superior and inferior vena cava, the tricuspid valve, right ventricular apex, pulmonic valve, coronary sinus and right ventricular outflow tract (RVOT).

A brief (14,15,9 and 8 minutes) demonstration of IsF was provided by an experienced veterinarian implanter (PF) using a deflectable sheath (C304, Medtronic), Swan-Ganz pacing balloon catheter (Edwards Lifesciences), and pacing lead (3830, Medtronic). Following the demonstration, the physicians were asked 1)to perform the same mapping with identification of all landmarks except the coronary sinus, 2) implant the catheter delivered lead to the right ventricle, then 3)repeat the mapping. All work was performed without fluoroscopy or wearing of lead (Pb) garments.

RESULTS Eight physicians mapped the swine heart in 8.2 minutes†, implanted the catheter delivered lead in 2.4 minutes† and, following lead testing, performed a second mapping in 4.8 minutes†. Pacing threshold was 2.6 volts†, at 0.4 mS pulse duration; ventricular electrogram amplitude was 6.9 mV†; all values were measured with the programmer analyzer (2090, Medtronic). [† = mean]

DISCUSSION The physician users reported they were relatively unfamiliar with swine cardiac anatomy. This was consistent with their questions during the instruction/proctoring demonstration prior to their hands-on experience.

The swine right ventricle is oriented such that its largest profile appears in the right lateral view which corresponding to the human anterior-posterior view. Most of the eight physicians reported more experience with the deflectable sheath than familiarity with swine anatomy. Their manipulation of the deflectable sheath did not appear to be a barrier to use of IsF.

The swine right ventricle in this study was considerably smaller than hearts to which the physicians were accustomed to in their clinical practice. The smaller size necessitated smaller radius bends, especially to negotiate the turn from the tricuspid valve to the right ventricular outflow tract. The propensity of the balloon to follow blood flow when extended beyond the sheath was useful in directing it to the pulmonary artery.

While there was little emphasis to the physicians on the timing aspect of the exercise, there was clearly a rigid and busy schedule of activities for the day involving more than this IsF experiment. With multiple physicians present in the operating suite, there was an implied sense of pressure to complete the exercise so colleagues would have adequate opportunity to map and implant. Most physicians took between 5 and 10 minutes to perform their first map, and the time to perform their second map was generally less than the first. The first implanter mapped the RVOT late leaving too little time for a second map. Some physicians explored the pulmonary artery and the coronary sinus. In so doing, they took more time than might be required for implantation of a pacemaker lead.

The physicians were asked to implant the lead in the right ventricle (RV). Locations varied but all were within the RV. Stimulation thresholds varied considerably and some would likely be unacceptable for chronic use. Variation in thresholds might be attributed to unfamiliarity with the swine, with the deflectable sheath or the lumenless pacing lead.

LIMITATIONS The number of physicians varied between groups, some had the benefit of observing colleagues map and implant before it was their turn, some were more adventuresome and explored the heart more thoroughly than others who completed their task more quickly. There was an inequitable level of familiarity with swine anatomy and deflectable sheath experience between implanters.

CONCLUSIONS This was the first exposure for all physicians to the IsF system and all were able to implant following a brief introduction. Experience or lack thereof with the deflectable sheath, the catheter delivered lead or swine anatomy did not appear to affect the results. The Swan-Ganz pacing catheter with the deflectable sheath allowed safe exploration and creation of a right heart image. No complications were observed during the procedure although one lead implantation may have perforated the heart.

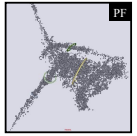
Time reduction from the first to second mapping suggests IsF may be practical for introduction to clinical practice which might lead to a reduction of radiation and orthopedic occupational hazards for the implantation of pacemakers and defibrillators.

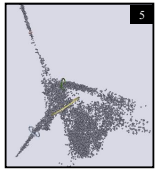
Clinical trials are needed to assess the feasibility in humans.

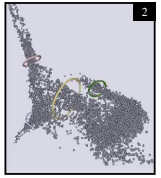
C304 Deflectable sheath with Swan-Ganz catheter

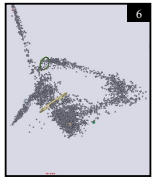
3830 4F Lead

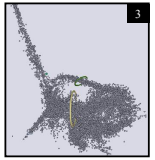
IMAGES Below is the map created by our experienced veterinarian (PF) while demonstrating the IsF system. To the right are those created by the physicians.

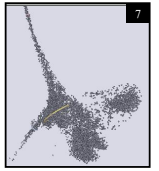


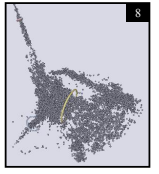












Prior Experience

Results

Physician #	Swine Anatomy	Deflectable Sheath/3830	IsF Demonstration minutes	1st Map minutes	Implant minutes	Threshold V@0.4 mS	Sensing mV	2nd Map minutes
Group 1 — 1	3	5	14	15	3.0	0.8	6.9	Insufficient time For 2nd map
Group 2 — 2	2	4	15	7.0	4.5	0.9	9.2	3.0
Group 2 — 3	2	2		10	3.0	3.2	10.1	5.5
Group 3 — 4	4	5	9	5.5	2.0	2.0	5.1	3.0
Group 3 — 5	2	5		6.5	2.5	3.5	3.0	4.8
Group 4 — 6	1	4		5.0	1.0	5.5	3.8	5.0
Group 4 — 7	4	5	8	8.8	1.8	3.0	8.9	7.5
Group 4 — 8	2	3		8.0	1.5	2.2	8.3	5.0
mean±SD	2.3±1.1	4.1±1.1	11±3	8.2±3.1	2.4±1.1	2.6±1.5	6.9±2.7	4.8 ±1.6