Published in final edited form as:

JACC Clin Electrophysiol. 2015 August ; 1(4): 273–283. doi:10.1016/j.jacep.2015.04.012.

Percutaneous Epicardial Pacing using a Novel Insulated Multi-electrode Lead

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Abstract

Introduction—Epicardial cardiac resynchronization therapy (CRT) permits unrestricted electrode positioning. However, this requires surgical placement of device leads and the risk of unwanted phrenic nerve stimulation. We hypothesized that shielded electrodes can capture myocardium without extracardiac stimulation.

Methods—In 6 dog and 5 swine experiments, we used a percutaneous approach to access the epicardial surface of the heart, and deploy novel leads housing multiple electrodes with selective insulation. Bipolar pacing thresholds at prespecified sites were tested compare electrode threshold data both facing towards and away from the epicardial surface.

Results—In 151 paired electrode recordings (70 in 6 dogs; 81 in 5 swine), thresholds facing myocardium were lower than facing away (median [IQR] mA: dogs 0.9 [0.4–1.6] vs 4.6 [2.1 to >10], $p < 0.0001$; swine 0.5 [0.2–1] vs 2.5 [0.5–6.8], $p < 0.0001$). Myocardial capture was feasible without extracardiac stimulation at all tested sites, with mean $\pm$ SE threshold margin 3.6 ± 0.7 mA at sites of high output extracardiac stimulation ($p = 0.004$).

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Disclosures

None of the authors have a relationship with industry that might pose a conflict of interest in connection with the submitted manuscript.

Conclusion—Selective electrode insulation confers directional pacing to a multielectrode epicardial pacing lead. This device has the potential for a novel percutaneous epicardial resynchronization therapy that permits placement at an optimal pacing site, irrespective of the anatomy of the coronary veins or phrenic nerves.

Keywords

Biventricular pacing; bioelectrical therapy; cardiac resynchronization therapy; epicardial pacing; epicardial mapping; minimally invasive; multisite pacing; pericardial intervention; phrenic nerve stimulation; steerable pericardial sheath

INTRODUCTION

Cardiac resynchronization therapy (CRT) results in a significant reduction in mortality and symptoms in selected patients with heart failure (1). However, challenges remain with current approaches to resynchronization, including a high rate of non-responders, due in part to anatomical limitations in negotiating the coronary venous system resulting in suboptimal lead placement; phrenic stimulation precluding therapy delivery; and the risks and challenges associated with endovascular lead placement in specific patients such as those with congenital heart disease and patent foramen ovale (2,3). The alternative is the use of epicardial leads placed directly onto the left ventricle. However, this currently requires a surgical approach and there may need to be multiple revisions over time as these leads have an increased failure rate on long-term followup (4). With 2% of the adult population in the developed world currently suffering from heart failure, a rising prevalence as longevity increases, and with an estimated 5% to 10% of heart failure patients having an indication for CRT (5), there is an increasing role for more versatile pacing approaches to help overcome some of these limitations.

The technique for percutaneous subxiphoid access to the pericardial space, initially described by Sosa for the purpose of epicardial mapping of ventricular tachycardia (6), lends itself well to epicardial pacing, as much of the cardiac surface is reachable through the anterior approach (7,8). However, the phrenic nerves are also intimately related and pacing in the pericardial space risks inadvertent phrenic capture.

We developed percutaneously delivered leads with multiple electrodes arranged in a forked configuration (Figure 1), allowing for multiple pacing vectors over a wide area of myocardium. We hypothesized that use of selective insulation on the pericardial-facing aspect of the lead would direct the electric field towards cardiac tissue, permitting pacing without extracardiac stimulation and defibrillation without pain. The purpose of this initial study was to confirm that these self-expanding novel leads could be placed percutaneously in the pericardial space, and that they could selectively pace myocardium while avoiding extracardiac stimulation irrespective of their position.

METHODS

Lead Design and Prototyping

The novel partially-insulated multi-electrode lead was designed to be introduced percutaneously into the pericardial cavity and permit multiple pacing vectors to be applied over a variably wide epicardial surface area. This was accomplished through use of an expanding design, which could be introduced into a sheath in a low profile state, and then expanded once deployed in the pericardium to permit pacing and sensing from desired regions (Figures 1–3). Electrodes were selectively insulated to direct the electric field toward the myocardium and shaped to a convexity closely representing that of the epicardial surface to maximize contact.

The prototype lead has a 50-cm long, 16-French central body containing a central 8 French channel (Supplemental Figure 1), and wired in nylon insulation. The distal end of the device has a forked design, with two arms 5.4 cm long and 1.5 mm in diameter, curved to a convexity similar to the epicardial surface. Each arm hosts 3 to 4 stainless steel circumferential electrodes placed 7 mm apart and covered circumferentially by Pebax® (polyether block amides) insulation on all sides except at the exposed surface (3.2×1.5 mm) intended to be placed onto the epicardium.

The lead is deployable in the pericardial space through a percutaneously introduced steerable sheath (Figure 2). The sheath has a round caliber measuring 24 French in external diameter, with a 20-French central channel sealed with a one-way valve. In certain prototype iterations, it is designed with distal mapping electrodes and a detachable proximal handle to enable it to function as a platform that directs therapies towards the myocardium and enable instrument exchanges. A proximal steering mechanism allows for flexion/extension of the distal end (Supplemental Movies 1 and 2), with an additional central port for aspiration or injection of fluid.

Prototypes were refined in the first three canine experiments. A nitinol loop was introduced between the distal tips of the lead arms. This prevented spontaneous drift of the pacing lead arms within the pericardial space and electrical crosstalk between the electrodes on each arm, as well as allowing the arms to be deployed in a controlled fashion at variable separations (maximum separation at tips 31 mm) through a pulley at the proximal (operator's) end (Figure 1, and Supplemental Movie 3). An additional nitinol loop leveraged the pericardium for further support to resist migration of the lead itself within the pericardial space. A radio-opaque marker was added to help identify the attitude of the electrodes with respect to the myocardium (Figure 3).

Electrophysiology Laboratory Setup

All experiments were carried out in purpose built large animal translational cardiac catheterization laboratories (Siemens, Erlangen, Germany) at the Cardiovascular Innovation Laboratory at Mayo Clinic, Rochester, MN, USA (canine studies) and the Cardiovascular Animal Research Center in the Laboratory for Advanced Cardiovascular and CNS Interventions at the School of Veterinary Medicine, University of Veterinary and Pharmaceutical Sciences, Brno, Czech Republic (porcine studies). Electrophysiological

studies were performed using the Cardiolab System (6.8.1 release 2, GE Healthcare, Wauwatosa, Wisconsin) using standard cardiac stimulators. Regular bipolar configurations between electrodes arranged in parallel between lead arms (1–2, 3–4, 5–6 and 7–8) or serially along each arm (1–3, 2–4, 1–5) were used (Figure 3). Sensed signals were gained 500 times and processed with 30 – 500 Hz band pass and 60 Hz notch filters.

Animal Preparation

The study was approved by the Mayo Clinic Animal Care and Use Committee and the Ethics Committee of the University of Veterinary and Pharmaceutical Sciences, Brno. Six male mongrel dogs (mean $\pm$ SD mass 30.2 ± 3.6 kg) and 5 female swine (47.6 ± 4.8 kg), all in sinus rhythm on study initiation, were maintained under general anesthesia using ketamine (10 mg/kg), diazepam (0.5 mg/kg) and mechanical ventilation with 1% to 3% isoflurane. Paralytic agents were not used. Continuous surface electrocardiography (ECG) was monitored with placement of standard limb leads and a V1 chest lead. Continuous intra-arterial blood pressure was monitored using a 9 French left femoral artery sheath. An intracardiac echocardiography (ICE) catheter was introduced via a 12-French sheath placed in the right external jugular vein. A 9-French sheath was placed in the right and left femoral veins for additional endovascular access. Sheaths were placed using Seldinger technique.

Percutaneous Pericardial Access

Percutaneous pericardial access of the anterior surface of the heart was obtained using the technique described by Sosa (6) and, upon progressive dilatation of the access site with serially larger diameter dilators, 1 to 2 of the prototype steerable sheaths were deployed in the pericardial space. Pneumopericardium and pericardial effusions were monitored for using ICE and fluoroscopy, and controlled using pericardial aspiration from the sheath. The novel leads were introduced into the sheath, which was steered under fluoroscopic guidance to guide the lead to standardized locations over the right ventricular outflow tract (RVOT), anterolateral left ventricular free wall (LV), and the left atrial appendage (LAA). The radiopaque marker was used to ascertain which direction the exposed electrode surfaces faced (Figure 3).

Epicardial Pacing and Extracardiac Stimulation

Bipolar pacing was tested in regions with adequate sensed signals and no significant mechanical or electrical interference. Pulsed square waves of 2-msec duration were delivered at a regular frequency of 15% above basal heart rate, starting at 10 mA output and reducing gradually until capture threshold was reached. Capture was confirmed by a concordant change in surface ECG and arterial pressure waveform rates. Paced QRS complex and epicardial electrograms were compared to those sensed in intrinsic rhythm to differentiate atrial and/or ventricular capture (Supplemental Figure 2).

Sensed signals were analyzed offline for slew, ensuring that signals <0.5 mV from uninsulated electrode surfaces facing the myocardial surface were excluded from analysis. Slew was measured at the highest frequency near-field electrogram deflection.

Extracardiac stimulation (both phrenic and chest wall musculature) was noted using inspection, palpation, and fluoroscopy whilst pacing. If stable extracardiac stimulation was noted, the capture threshold was determined as the pacing output at which no further extracardiac stimulation occurred. If no extracardiac stimulation was noted during standard pacing maneuvers, then phrenic location and integrity was confirmed by high output pacing with electrodes facing away or using a pacing probe through the lead's central channel.

Using side by side fluoroscopic images to ensure comparable catheter location, leads were rotated such that the electrodes were turned from facing the heart to facing the serosal surface of the parietal pericardium, and the above protocol repeated to generate paired sensing and pacing data. At the end of the procedure, a standard endovascular electrophysiology catheter was introduced into the ventricle and the animal was sacrificed by inducing ventricular fibrillation through either rapid ventricular pacing or application of direct current. Necropsy was performed immediately upon death to assess pericardial access and document injury to cardiac and extracardiac structures.

Statistical Analysis

Statistical analysis was performed using JMP 10.0.0 (SAS Institute Inc., San Francisco, California). Non-normally distributed data was expressed as median and interquartile range (IQR). Paired readings of slew and pacing thresholds were assessed using the Wilcoxon signed rank test. Correlation between slew and threshold was compared using Spearman rho. Differences in lead parameters between sites and electrodes were compared using the Wilcoxon rank sum test. The null hypothesis was rejected at a 2-tailed p-value of less than 0.05.

RESULTS

Epicardial Lead Placement

Successful epicardial access and placement of one to two epicardial sheaths was achieved for all animals. The steerable sheaths allowed for easy maneuverability of the pacing leads within the pericardial space and for placement over the RVOT, anterolateral LV, and LAA, whilst the nitinol loops leveraged the pericardium to provide lead stability.

Insulated Sensing and Pacing

Data from a total of 151 paired electrode recordings were analyzed (70 in dogs and 81 in swine) to compare pacing thresholds when the exposed electrode surfaces were directed toward the myocardial surface versus facing away. In both animal models, the pacing threshold was significantly lower when facing the myocardium versus facing away (dogs: median [IQR] 0.9 [0.4 – 1.6] vs. 4.6 [2.1 to >10] mA, $p < 0.0001$; swine: 0.5 [0.2 – 1] vs 2.5 [0.5 – 6.8] mA, $p < 0.0001$, Figure 4).

With electrodes directed towards myocardium, capture was feasible without extracardiac (either phrenic or chest wall musculature) stimulation at the pacing sites in all experiments, including sites in juxtaposition with the phrenic nerve. With high output, extracardiac capture with electrodes facing myocardium was noted at 4/70 (5.7%) sites in canine and

5/81 (6.2%) sites in porcine experiments. Thresholds were significantly lower for myocardial as compared with extracardiac capture thresholds (0.3 [0.1 – 1.5] vs 5 [1.7 – 7] mA, mean $\pm$ SE] threshold margin 3.6 ± 0.7 mA, $p=0.004$).

Analysis of sensed epicardial signals in canine experiments demonstrated a clear, high frequency signal after an initial low frequency signal, which presumably represented near-field epicardial activation following initial far-field endocardial activation, permitting analysis of slew on the near field component (Figure 5). There was a significant difference between sensed signals obtained from electrodes directed onto the myocardium versus away (median [IQR] 3.4 [1.4 to 6.5] Volts/sec towards versus 1.7 [1.0 to 2.7] Volts/sec away ($p<0.0001$) and inverse correlation between slew and myocardial pacing threshold (Spearman's $\rho -0.401$, $p=0.0002$). In contrast, the sensed signals obtained in porcine experiments were multicomponent with multiple discrete, high frequency components, which rendered slew analysis unreliable, despite a visible reduction in signal frequency when electrodes were directed away (Figure 6).

Effect of Lead Position and Inter-electrode Distance on Lead Function

Depending on electrode position, pacing captured the atrium (when electrodes over appendage or atrial tissue) or the ventricle. The lower pacing thresholds with electrodes facing the myocardium were consistently present, irrespective of pacing site or electrode vector. In dogs, there was more variability in thresholds when pacing thresholds were obtained at the LAA as compared to the RVOT and LV, whereas in swine, there was less variability at the LAA as compared to RVOT and LV (Figure 7). We noted a difference in anatomical approach in navigation to the pre-specified pacing sites between the two species. To reach the LAA in dogs, the lead had to be maneuvered to a left posterolateral position, whilst in swine a more anterior approach was often sufficient and required less distortion of the lead, particularly the distal-most electrode bipole, which had the least accuracy, particularly in canine experiments (Figure 7). To confirm that the increased thresholds that were noted on the distal-most electrodes were not due to increased inter-electrode distance, we repeated threshold testing for electrodes with arms apart vs. together over the RVOT in a single canine experiment. There was no significant difference between thresholds of parallel bipoles (apart: 0.55 [0.35 – 1.4] vs. together: 0.95 [0.3 – 3.2], $p=0.31$).

Complications and Necropsy Findings

Successful entry into the anterior pericardial space through the connective tissue superficial to the diaphragm was confirmed in all animals (Figure 8). There were no significant arrhythmias caused by lead placement and pacing. Sheath and access related were seen in 3 experiments. In one, inadvertent laceration of the distal left anterior descending artery during serial sheath dilatation was tolerated hemodynamically once pericardial blood was aspirated, allowing for successful completion of the study. In another the study was performed with a wire entrapped in the left ventricle after inadvertent entry and knotting therein after ensuring that it was not causing ventricular ectopy, mitral regurgitation or ventricular dysfunction. In a third, there was inadvertent puncture and exit of the sheath through the pericardium overlying the left atrial appendage, which resulted in an inability to manipulate the lead over the appendage for sensing and pacing due to exit from the pericardium each time. Isolated

minor abrasions on the inferior surface of the heart were noted in 4 experiments and were of uncertain significance, possibly created during sheath placement, with no bleeding or evidence of myocardial injury during the procedure. There were no pacing-related complications in any experiment.

DISCUSSION

The main findings of our study are that 1) epicardial pacing via subxiphoid percutaneous access is feasible using novel self-expanding leads that collapse for sheath placement and expand in the pericardium, and 2) insulated electrodes confer directionality and preference to pacing the myocardial surface, and permitting epicardial pacing without extracardiac stimulation, even when the electrodes are positioned directly opposite the phrenic nerve. A standardized experimental protocol and prototypes yielded comparable results at two separate experimental sites located on separate continents, with multiple operators involved, with different large animal models used, suggesting a robustness to this approach and a shallow learning curve. To the best of our knowledge, this is the first reported use of percutaneously placed, insulated epicardial electrodes to confer directional pacing for these purposes.

Previous studies have reported on the use of subxiphoid and subcostal surgical approaches for epicardial pacing(9–11) and, together with our report on a completely percutaneous approach, support the utility of the pericardial space as a vantage point for bioelectrical therapies for heart failure. Specifically for pacing for CRT, these include access to left-sided chambers without the limitations set by coronary sinus anatomy, bloodstream infections due to endovascular foreign material, or lead thromboembolism.(3) This may be particularly relevant to those with an especially high risk of adverse events from endocardial leads, such as those with cyanotic congenital heart disease, intracardiac shunts, or blood stream infections (2). Furthermore, coronary sinus leads have a significant failure rate due to both dislodgement and from revisions necessitated by symptomatic extracardiac stimulation, although similar long-term experience using percutaneous epicardial leads is lacking in comparison.

We designed our leads to harness the pericardium for mechanical support, introduced supportive nitinol loops to provide additional lead and lead arm stability, and contoured the lead to the natural curvature of the cardiac surface. These together resulted in good lead stability and function at the areas of interest. A combination of fluoroscopic and electrical navigation was sufficient for accurate placement and ICE was used to monitor for complications to chambers, valves, and pericardium. The use of steerable sheaths greatly facilitated maneuverability of leads and the successful use of this strategy for epicardial ablation has been previously reported (12). We investigated whether our data was influenced by the difference in inter-electrode distance between the parallel bipolar configuration, with the more distal electrode pair being further apart than the proximal (Figures 1 and 3), and were not able to demonstrate this. We did, however, find that owing to the size and shape of the forked design, the distal-most pair had a higher threshold, most likely due to interaction with the valvular annuli, great vessels, and over corners that needed to be negotiated, a

finding which is being incorporated into designing the next prototypes for chronic, indwelling use.

On account of the course of the phrenic nerves in intimate proximity to the pericardium (13), and other electrically active thoracic structures in close vicinity (nerves and skeletal muscle), preventing phrenic and extracardiac stimulation are important considerations as epicardial pacing strategies are developed. With coronary sinus lead placement, phrenic stimulation affects approximately 15% to 30% of patients (14,15), requiring either repositioning the lead or electrically reprogramming another vector, both of which may result in lead dysfunction (16,17). Detecting phrenic stimulation at implantation has poor sensitivity due to positional dependency (18) calling for alternative strategies for preventing stimulation. We demonstrate that our insulated lead has differential sensing and pacing function depending on the side insulated, resulting in a significant threshold margin between myocardial and extracardiac stimulation. In clinical studies, a threshold difference less than 3 V has been associated with clinically significant phrenic stimulation (19). Other strategies that have been reported in the literature include using leads with multiple electrodes allowing for reprogramming between electrodes (20), using closely spaced bipoles (21), and having longer pulse duration (22), although we did not attempt to replicate these findings for epicardial pacing or investigate whether they have incremental effect.

In clinical practice 25% to 40% of patients fail to benefit from resynchronization therapy (23–25). An important mechanism for failure to response may be absence of pacing at a late electrically activated site (26–28). The ability to freely position electrodes anywhere over the left ventricular free wall, irrespective of coronary venous anatomy, holds promise for increasing response rates by overcoming that limitation. The ability to do so without regard to the position of the phrenic nerve due to selective insulation may be an important advance.

Another factor contributing the lack of response may be impaired hemodynamics due to poor atrioventricular coordination. All current CRT systems sense or pace the *right* atrium, so that *left* atrial to *left* ventricular timing depends on the propagation of a wavefront from the right to the left atrium, often through diseased and variably conducting tissue. We found that the expandable leads were able to pace *both left atrium and the lateral wall of the left ventricle*. By independently energizing distal then proximal electrodes on an intrapericardial, left atrial to left ventricular timing may be optimized, thus affording another level of resynchronization and potential mechanism for response. Lastly, it has been proposed that some patients fail to respond to CRT despite improved left ventricular contraction due to the development of tricuspid regurgitation, caused by a lead in the right ventricle, that mechanically disrupt tricuspid valve function. The development of new tricuspid regurgitation leads to adverse hemodynamic effects that counteract the benefit of resynchronization when present (29,30). A totally percutaneous epicardial system would also eliminate the deleterious effects of a right ventricular lead, affording another benefit of such a strategy.

These preliminary findings demonstrate proof of concept, but require additional studies prior to human implementation. Based on comparably similar performance in both large animal species in this study, we predict that the currently prototyped platform would require

minimal modification for clinical use. The complications seen were all related to pericardial access and sheath deployment, which suggest that an alteration to sheath profile may be required. In addition, future studies are ongoing and/or planned to establish the medium to long-term effectiveness, stability, safety, and tolerability of a chronic lead design. Prototyping and testing of a screw-in mechanism and imaging guidance to identify and thereby avoid coronary vasculature are currently underway.

We did not investigate the effects of pacing on cardiac activation and recovery(31) or the various forms of dyssynchrony (atrioventricular, interventricular, and intraventricular), nor have we fully explored the utility of this approach for ablation, defibrillation, or autonomic modulation (32,33). Given the growing understanding of autonomic modulation of arrhythmogenesis, selectively insulated electrodes facing away from the myocardium may be useful for adjunctive autonomic stimulation as part of an implanted system. The long-term human application will also have to consider the relative risks and benefits of such an approach once prototype refinement is finalized, as well as the challenges in pericardial access imparted by cardiac surgery, thoracic irradiation, and prior pericarditis.

CONCLUSION

A novel, percutaneously placed multi-electrode epicardial pacing lead confers directional pacing to the myocardial surface. Combined with the use of a steerable sheath, effective myocardial pacing at multiple sites was possible with good lead stability and without extracardiac stimulation. This strategy may prove promising for a percutaneous epicardial atrial and ventricular pacing device.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Mayo Clinic owns intellectual property related to the investigated technology reported in this manuscript, under issued US Patent Number 7620458B2 and filed US Patent Application Number 61/968977. Neither Mayo Clinic nor the inventors (issued Patent 7620458B2: SJA, PAF and CJB; filed Patent 61/968977: FFS, CJB, CVD, PAF, SJA, TK, PL, MN, ZS, JW) will receive any compensation for the use of this product with Mayo Clinic patients. This work was supported by the European Union Regional Development Fund Project FNUSA-ICRC (No. CZ. 1.05/1.1.00/02.0123).

Funding: Dr. DeSimone is supported by an NIH Training Grant #T32 HL007111

LIST OF ABBREVIATIONS

CRT	Cardiac resynchronization therapy
ECG	electrocardiography
ICE	intracardiac echocardiography
IQR	interquartile range
LAA	left atrial appendage

LV	left ventricle
mA	milliamps
RVOT	right ventricular outflow tract
SD	standard deviation
SE	standard error

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CLINICAL IMPLICATIONS

This novel multi-electrode lead with insulated electrodes demonstrates effective myocardial pacing in preclinical large animal studies without extracardiac stimulation. This device has the potential for a novel percutaneous epicardial resynchronization therapy that permits placement at an optimal pacing site, irrespective of the anatomy of the coronary veins or phrenic nerves.

PERSPECTIVES

Competency in Medical Knowledge

A novel self-expandable lead designed for percutaneous epicardial pacing with multiple electrodes, shaped and directed to maximize myocardial contact and selectively insulated to minimize extracardiac pacing, allowed for directionality and preference to pacing the myocardial surface. This permitted epicardial pacing without extracardiac stimulation, even when the electrodes are positioned directly opposite the phrenic nerve.

Translational Outlook

This innovation provides a therapeutic approach for epicardial pacing which overcomes current limitations of cardiac resynchronization therapy, including a high rate of non-responders due in part to suboptimal lead placement afforded by coronary venous anatomy; phrenic stimulation; and vascular lead complications.

Figure 1.

Prototype of novel multi-electrode lead. Top left: Diagram depicting contoured shape and forked multi-electrode lead design incorporating insulated electrodes designed to pace myocardium without extracardiac stimulation such as that of phrenic nerve (in yellow). Top right: Demonstration of insulated electrodes and low profile Pebax insulation. Middle left: A prototype iteration that has a single nitinol loop for lead arm stability. Middle right: A prototype iteration that incorporates a second nitinol loop to harness the pericardium for additional support which, in this iteration, also houses 3 additional insulated electrodes. Bottom: The bottom *en face* profile demonstrates dimensions in inches (with millimeters in parentheses).

Figure 2. Prototype of novel steerable sheath. Left and middle panels demonstrate the general design of the sheath, the proximal operator end of the sheath, central channel and flush port. Length is in inches (with millimeters in parentheses). Right panel demonstrates the utility of the sheath in navigating within the pericardial space (see also Supplemental Movies 1 and 2).

Figure 3.

Multielectrode lead with electrodes facing down (left) and up (right), with corresponding fluoroscopic images of the lead deployed in the pericardium during a canine experiment. The radiopaque marker (red circle) aided in orientating the electrodes. Numbers depict the standardization used for lead numbering (correspond to the pacing bipole nomenclature when used in the text and other figures). The left two panels (photograph above, x-ray image below) show the electrodes in the desired configuration for cardiac pacing, with exposed electrodes facing the myocardium. In contrast, the right two panels show the lead with electrodes facing externally, favoring phrenic stimulation over cardiac stimulation.

Figure 4.

Paired pacing thresholds in 6 canine (left) and 5 swine (right) experiments, demonstrating differences in myocardial capture threshold with exposed electrodes facing towards and away from the myocardial surface. Median and interquartile range. mA – milliamps.

Figure 5.

Paired sensed signals in a canine experiment adjacent to representative fluoroscopic images of the lead with electrodes directed towards myocardium, demonstrating typical far field (single arrow) and near field (double arrow) signals. Numbers represent standard electrode leads and epicardial electrode configuration as depicted in Figure 3. RVOT – right ventricular outflow tract. LV – left ventricle. LAA – left atrial appendage.

Figure 6.

Left: Comparison of sensed epicardial signals in dogs versus swine obtained from comparable sites over the left ventricle (LV). Note the multicomponent near field signals in swine. Right: Paired sensed signals in a swine experiment demonstrating the qualitative difference in sensed signals when electrodes are directed towards the myocardium (top part of right panel) as opposed to facing away (in this instance over the right ventricular outflow tract [RVOT], bottom part of right panel). Numbers represent standard electrode leads and epicardial electrode configuration as depicted in Figure 3.

Figure 7.

Variability in pacing thresholds from electrodes directed towards myocardium at different anatomical sites (top) and between electrode configurations (bottom). The box and whisker plots summarize individual pacing thresholds from all experiments (6 dogs with 70 data points, 5 pigs with 81 data points), with median, first and third quartiles marked by the middle band and the top and bottom of the box respectively, range marked by the whiskers, and potential outliers by disconnected points. Note that the LAA was the site with greatest variability in pacing threshold in dogs and least variability in swine, and that the distal-most electrode pair (1–2) had greatest variability. See text for details. Numbers represent epicardial electrode configuration as depicted in Figure 3. RVOT – right ventricular outflow tract. LV – left ventricle. LAA – left atrial appendage, mA – milliamps.

Figure 8.
Necropsy findings in a canine study demonstrating deployed sheath and pacing lead (pericardium removed on the right).