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HOT TOPIC IN CARDIAC DEVICES

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Leadless cardiac dual-chamber pacing

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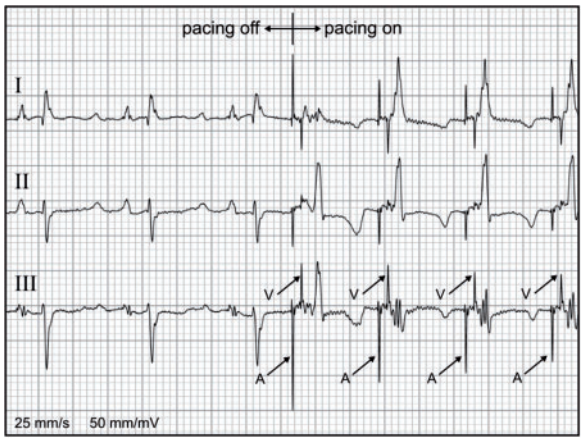
Background: Recently introduced leadless cardiac pacemakers effectively overcome all lead-related limitations of conventional pacemaker systems. However, these devices only feature single-chamber pacing capability although dual-chamber pacing is highly desirable due to physiologic reasons. Implanting a leadless pacemaker into the right atrium and a second one into the right ventricle would enable leadless dual-chamber pacing but requires wireless communication for device synchronization. Conventional radiofrequency telemetry is not suitable for this purpose due to its high energy consumption. Thus, an ultra-low power wireless communication method is crucial to preserve the pacemaker's longevity (modern pacemakers consume only 5-10 μW of power).
Purpose: Dual-chamber pacing capability for leadless pacemakers.
Methods: Two pacemakers were developed that feature bidirectional wireless communication. Intra-body communication was implemented as communication method. This method uses the electrical conductivity of blood and tissue: the data from one device is modulated and applied as a small alternating current signal to the myocardial tissue and blood via electrodes. The signal is registered almost simultaneously by the other device. The communication frequency is ≥100 kHz and therefore does not influence the heart's functioning. The pacemakers feature an electrode pair for bipolar stimulation, the communication is performed over the same electrodes. The pacemakers were tested in an acute in-vivo trial on a 60 kg domestic pig. One pacemaker paced the right atrium, the other one the right ventricle. The atrial pacemaker served as master device and dictated the actual pacing rate, the atrioventricular (AV) pacing delay and pacing activity to the ventricular pacemaker in a wireless manner.
Results: The pacemakers successfully performed dual-chamber pacing (D00) with wireless intra-body communication using the myocardium and blood as transmission path. No interference with the cardiac function was observed. The ECG sequence in Figure 1 shows the onset of leadless dual-chamber pacing recorded during the in-vivo trial: the atrial (A) and ventricular (V) pacing spikes are indicated by the arrows. The pacing rate was set to 120 bpm and the AV delay to 50 ms. Less than 1 μW average power was applied to the tissue for wireless communication.
Conclusion: To our knowledge, this is the first report on successful leadless dual-chamber pacing during an in-vivo trial. Intra-body communication was integrated into a pacemaker system and has proven to be a promising, power-efficient wireless communication method for leadless dual-chamber pacemakers.



Abstract 38 Figure.

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Sensing of atrial contraction by an accelerometer within a ventricular leadless pacemaker

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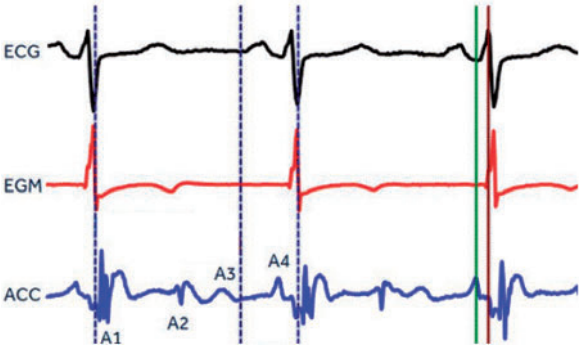
Background: Micra is a leadless single chamber VVIR pacemaker implanted in the right ventricle (RV) with a 3-axis accelerometer (ACC) capable of sensing heart motion. A method to detect the atrial contraction from the ACC may enable AV synchronous pacing in a single chamber ventricular leadless pacemaker.
Purpose: To measure intracardiac accelerations via the ACC signal in subjects implanted with a ventricular leadless pacemaker.
Methods: The Micra Accelerometer Sensor Studies (MASS and MASS2) were prospective non-randomized, multi-center clinical research studies designed to characterize the ACC signal in subjects with implanted Micra devices. Subjects in sinus rhythm (SR) were preferentially enrolled. Custom software was downloaded into the device to enable continuous telemetry of ACC and EGM waveforms to an ambulatory recorder. Surface ECG, RV EGM, and ACC recordings were collected during in-office recordings with posture and exercise tests.
Results: Seventy-five subjects were enrolled, of which 66 were in SR, 9 were in AF. Mean age was 74±12 years. Mean time since implant was 13.6 months (range: 0 to 35.5 months). For SR subjects without AVB or frequent ventricular pacing (n=39): four distinct segments of the ACC were identified (Figure) and characterized corresponding to: isovolumic contraction and mitral/tricuspid valve closings (A1), aortic/pulmonic valve closing (A2), early passive ventricular filling (A3), and atrial contraction generating active filling (A4). The mean peak-to-peak A4 amplitude for SR subjects was measured for each posture/axis combination (Table). The A4 amplitude in Axis 2 was significantly larger than Axis 1 and 3 ($p < 0.05$). Axis 2 is longitudinal to the device body, while Axis 1 and 3 are radial. The A4 amplitude was lowest while Standing, ($p<0.05$ vs. Left Side, Right Side, and Supine).
Conclusion: Intracardiac accelerations related to the atrial contraction can be measured via a 3-axis accelerometer within a ventricular leadless pacemaker. Sensing of atrial contraction from the ventricle may provide a method for AV synchronous pacing.

Abstract 39 Table. A4 Amplitudes by Axis and Posture

Posture	ACC Axis 1	ACC Axis 2	ACC Axis 3
Supine	0.29 ± .15g	0.35 ± .18g	0.33 ± .18g
Lying right side	0.31 ± .18g	0.43 ± .16g	0.35 ± .16g
Lying left side	0.34 ± .19g	0.33 ± .20g	0.32 ± .24g
Sitting	0.30 ± .15g	0.33 ± .19g	0.28 ± .13g
Standing	0.26 ± .14g	0.28 ± .17g	0.23 ± .10g

units = g's, 1g = 9.8 m/seĉ2



Abstract 39 Figure. Representative ECG, EGM and ACC signals