

# Long-term electrical performance of the Micra™ leadless cardiac pacemaker

## Background

Leadless Cardiac Pacemakers (LCPs) have become An established treatment option for patients with an indication for Single Chamber Pacing since 2013, when the first in men implantation of a Micra™ LCP was performed. AV-synchronous pacing has become a new therapeutic option with the micra™ AV LCP. Whereas short- and mid-term stability of electrical device parameters and battery voltage of the Micra™ system have already been confirmed, long-term data are still limited.

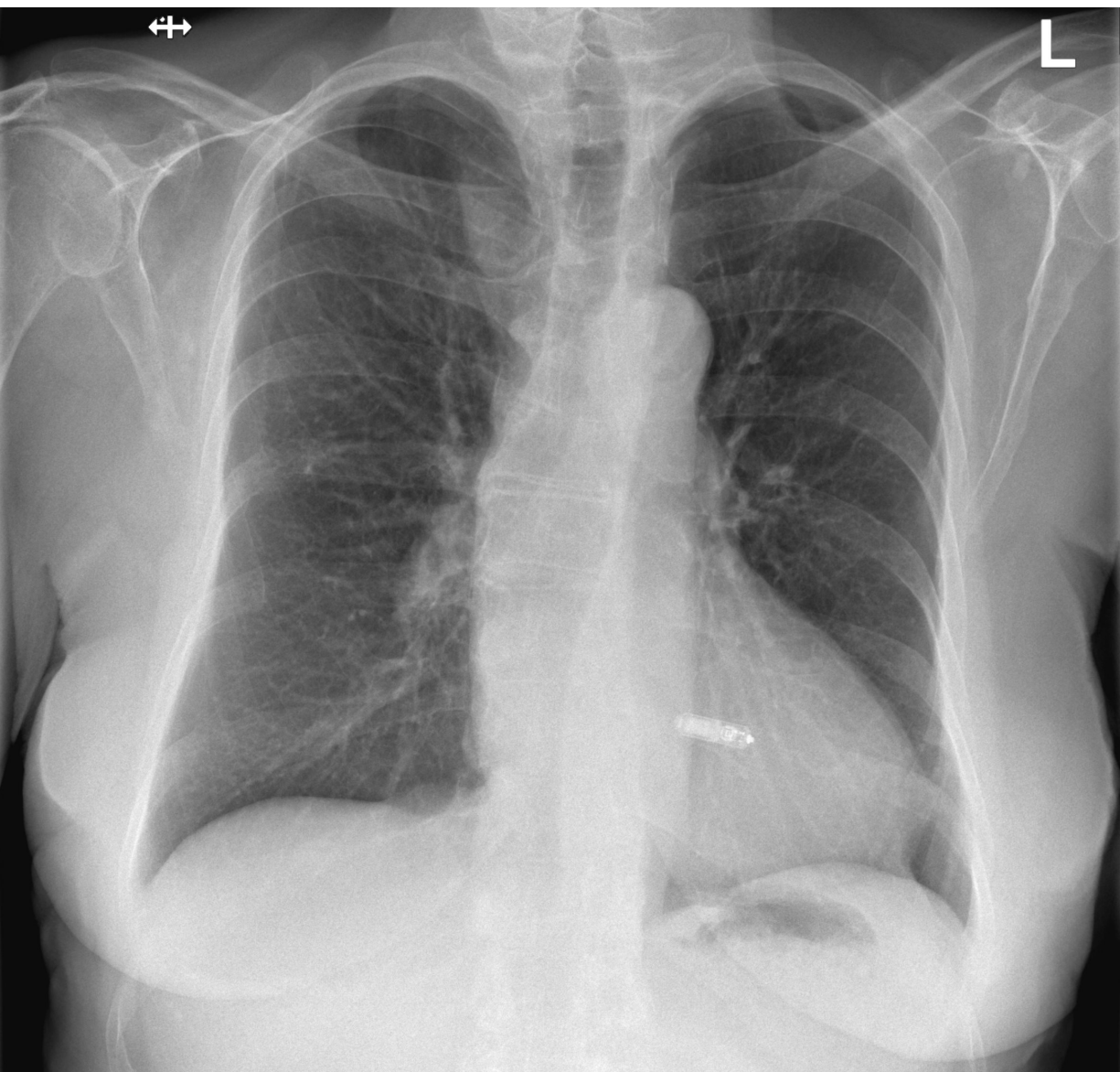
## Objectives

To describe the development of electrical parameters of the Micra™ LCP during a long-term follow-up.

## Methods

In this retrospective analysis we included all patients with a Micra™ LCP implanted at our center since december 2013. We analyzed electrical device parameters over time that were assessed during routine follow-up visits at our outpatient clinic (pacing threshold, sensing, impedance, battery voltage and proportion of ventricular pacing after 3, 12, 24, 36, 48, and 60 months, respectively). A descriptive statistical analysis and a regression analysis were performed.

Picture 1



Chest X-ray of a Micra™ LCP patient\*

## Results

Since 2013 a Micra™ LCP was implanted in 283 patients (age [Mean ± SD]: 79.2 ± 9.6 years, female: 36.4%, Cha<sub>2</sub>ds<sub>2</sub>-vasc [Median, IQR] (4; 3-5) at our center. The most frequent indications for pacing were atrial fibrillation with slow AV conduction (41.3%), third degree AV-block (30.4%) and Sick-Sinus-Syndrome (14.5%), respectively. Overall implantation success rate was 99.3% and 73.1 % of pacemakers were implanted In a septal position.

During a median follow-up of 25 months (IQR 14-47) battery voltage and impedance decreased significantly (p<0.001), while sensing and the proportion of pacing showed a significant increase (p<0.001). pacing threshold remained stable over the follow-up period (p=0.095) (See Table A, B and Graph 1).

The median proportion of ventricular pacing varied between 42.3% And 95.9%. The complication rate at implantation procedure was 4.2% and pacemaker dysfunction was detected in 1.4% of patients (increase in pacing threshold n=2, pacemaker induced cardiomyopathy n=1, sensing defect n=1) during follow-up. The mortality of the Micra™ LCP population was 21.2% during the follow-up period.

## Summary/Conclusion

Electrical parameters were stable in Micra™ LCPs over a median follow-up of 25 months, except for the expected small decline in battery voltage. However, prospective studies have to prove its performance in the long-term.

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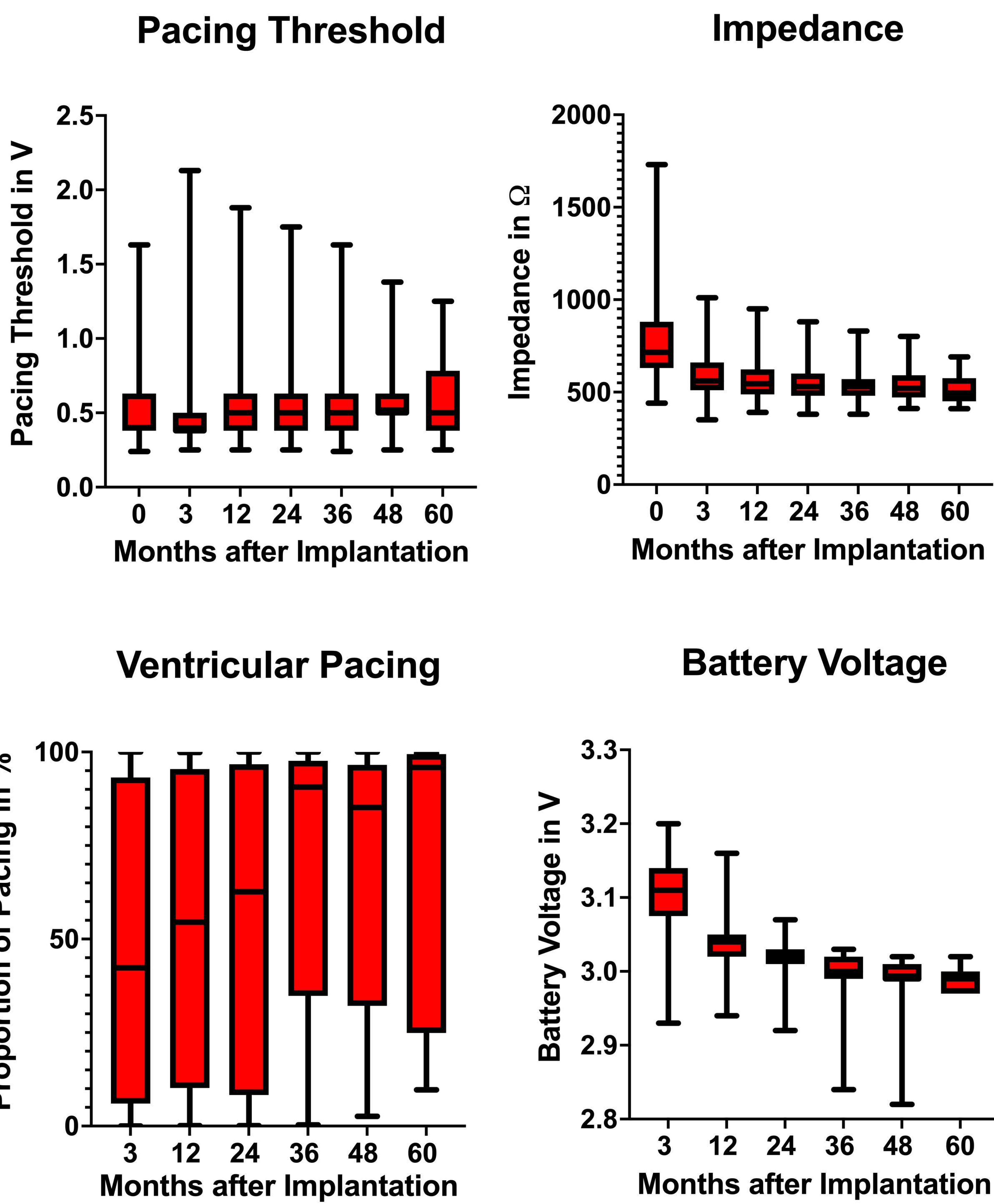
Table A

Time point	Baseline	3 Months	12 Months	24 Months	36 Months	48 Months	60 Months
n	273	218	158	118	76	48	14
Battery Voltage (V) Mean ± SD	not measured	3.11 ± 0.04	3.02 ± 0.25	3.01 ± 0.02	3.00 ± 0.03	3.0 ± 0.02	2.99 ± 0.01
Proportion of Pacing (%) Median IQR	not measured	42.3 (6.0-93.2)	54.5 (11.1-95.3)	62.7 (8.5-96.5)	90.7 (35.4-97.4)	85.2 (33.0-99.4)	95.9 (30.2-99.4)
Sensing (mV) Mean ± SD	10.67 ± 4.74	13.76 ± 4.90	13.95 ± 5.15	14.27 ± 5.20	14.60 ± 4.58	14.27 ± 4.91	14.01 ± 5.23
Impedance (Ω) Mean ± SD	773.72 ± 234.27	588.67 ± 125.71	563.05 ± 108.34	543.9 ± 93.91	535.6 ± 87.13	538.33 ± 89.89	521.4 ± 82.0
Pacing Threshold (V) Mean ± SD	0.53 ± 0.31	0.54 ± 0.38	0.59 ± 0.31	0.58 ± 0.27	0.57 ± 0.22	0.57 ± 0.20	0.59 ± 0.27

Table B

Parameter	Regression Coefficient	95% Confidence Interval	p-value
Battery Voltage (V)	-0.003 V/month	-0.003 to -0.003	p<0.001
Proportion of Pacing (%)	+0.17 %/month	+0.07 to +0.26	p<0.001
Sensing (mV)	+0.05 mV/month	+0.03 to +0.07	p<0.001
Impedance (Ω)	-4.55 Ω/month	-5.24 to -3.87	p<0.001
Pacing Threshold (V)	+0.001 V/month	+0.03 to +0.07	p=0.095

Graph 1\*\*



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\*\* Whiskers: Min/Max, Box: 25./75. percentile, Middle solid line: Median, Outliers not displayed

