# Long-Term Performance of a High-Impedance Fractal-Coated Bipolar Ventricular Lead with 1.3-mm² Electrode

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**Summary**

*The aim of our study was to assess the long-term electrophysiological properties and complication rate in a tined bipolar ventricular lead with a very small (1.3 mm²) fractal coated electrode. The lead was implanted in 74 patients and followed for up to 4 years. At all follow-up controls (1 and 7 days, and 1, 3, 6, 12, 24, 36, and 48 months after implantation), pacing impedance at 4.8 V and 0.5 ms output setting, pacing threshold at 0.5 ms, and R-wave amplitudes were measured in both unipolar and bipolar lead configurations. At 4 years after implantation, the measured unipolar (bipolar) values were 732 (833) ± 119 (132) W (impedance), 0.6 (0.7) ± 0.3 (0.4) V (threshold), and 15.5 (15.7) ± 5.4 (6.3) mV (R-wave). During the entire follow-up period only two out of 74 leads (2.7 %) required invasive intervention, which was necessitated by microdislocation and insulation defect, respectively. In conclusion, the studied high-impedance fractal-coated leads offer stable and reliable clinical performance in the long-term and excellent electrophysiological values.*

**Key Words**

Fractal coated lead, high pacing impedance, pacing threshold, R-wave sensing

## Introduction

The goals in the development of permanent pacemaker leads have been to achieve minimum stimulation threshold and maximum amplitude of intracardiac potentials, to increase lead resistance to external interference, to diminish incidence of lead dislocations, and to prolong the overall lead and pulse generator service time. It has been proven that decreasing the pacing electrode surface results in higher pacing impedance and, according to Ohm´s law, in reduced lead current drain [1-5]. The aim of this study was to evaluate long-term electrophysiological and mechanical properties of a lead with a very small electrode surface area.

## Materials and Methods

Synox 60-BP tined ventricular bipolar lead (Biotronik, Germany) was implanted in 74 patients with a mean age of 69 ± 9 years, in the period from September 1996 to March 1997. The lead is insulated with the silicon rubber and has lead body diameter of 1.4 mm. When the three tines intended for passive fixation are closed, maximum lead diameter is 2.1 mm. The electrode tip has a geometric surface area of 1.3 mm² and is coated with fractal iridium. The fractal electrode structure increases the electrochemically active surface area by more than 1000 times [6]. The leads were implanted together with dual-chamber Physios TC 01, single-chamber Pikos 01, and single-chamber rate adaptive Dromos SR pacemakers (all from Biotronik, Germany). Intraoperative measurement were performed using a threshold analyzer (ERA 300, Biotronik) in both unipolar and bipolar lead configurations. The position of the electrode was accepted if X-rays showed that the lead tip was placed in the right ventricular apex, if pacing threshold did not exceed 1.0 V at 0.5 ms, the R-wave amplitude was at least 5 mV (exceptionally

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|---|---|
| Total implants | 74 |
| RV perforation | 0 |
| Microdislocation | 1* |
| Insulation defect | 1* |
| Conductor fracture | 0 |
| Conductor short circuiting | 0 |

*Table 1. Review of lead-related complications during the 4-year follow-up of the Synox 60-BP lead. RV = right ventricular, * = surgical revision was necessary.*

4 mV), the ST segment elevation was greater than 1.0 mV, and if the diaphragmal stimulation test at 6.0 V/1.0 ms was negative. We did not undertake any lead repositioning to improve acute parameters beyond the above mentioned minimum acceptable values. The lead was introduced via the cephalic vein in 56 patients and by subclavian vein puncture in 18 patients.

The follow-up controls took place at 1 and 7 days and 1, 3, 6, 12, 24, 36, and 48 months after pacemaker implantation. Pacing thresholds were measured via pacemaker telemetry in 0.1 V steps (from 0.1 V to 4.8 V) at a pacing rate of 90 – 110 pulses/min and at the 0.5 ms pulse duration. Stimulation impedance was assessed at the 4.8 V/0.5 ms output setting, and R-wave amplitudes were determined by a standard evaluation of the recorded intracardiac electrograms. All the measurements during the follow-up were performed in both unipolar and bipolar lead configurations. The pacemakers were permanently programmed to the unipolar pacing configuration and bipolar sensing configuration.

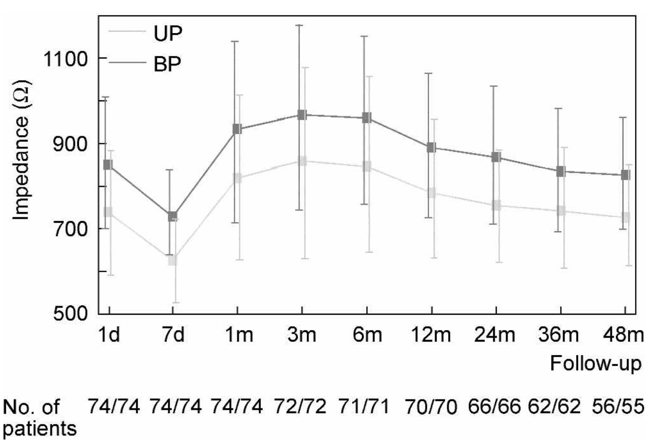


*Figure 1. Trends of unipolar (UP) and bipolar (BP) pacing impedance over time (mean value ± standard deviation). d: days, m: months. Number of participating patients is indicated for UP/BP configuration.*

## Results

Lead complications are given in Table 1. Sixteen patients died during the 4-year observation period. None of the deaths was thought to be related to the pacemaker therapy.

One day after implantation, unipolar pacing impedance was 745 ± 147 Ω. The minimum value was recorded on day 7 (630 ± 99 Ω) and the maximum at 3 months after lead implantation (867 ± 226 Ω). Thereafter, the impedance gradually decreased to 732 ± 119 Ω (4-year value). Bipolar impedance was about 100 Ω higher than the unipolar impedance at all instances, otherwise it followed the same time course. The 4-year bipolar impedance value was 833 ± 132 Ω (Figure 1).

During the first day after pacemaker implantation, unipolar pacing threshold was 0.4 ± 0.2 V. The maximum value was recorded within the first month of implantation (0.9 ± 0.6 V), with a gradual threshold decrease thereafter down to a chronic value of 0.6 ± 0.3 V after 4 years. Bipolar pacing thresholds followed the same pattern in the time and were always slightly above the unipolar values. The 4-year bipolar threshold value was 0.7 ± 0.4 V (Figure 2).

Mean R-wave amplitudes tended to be slightly higher in the bipolar lead configuration. The minimum value was recorded at 7 days after implantation: 11.9 ± 5.5 mV (unipolar) and 12.8 ± 5.8 mV (bipolar). Thereafter the sensing amplitudes increased and remained stable throughout the follow-up. The 4-year values were: 15.5 ± 5.4 mV (unipolar) and 15.7 ± 6.3 mV (bipolar) (Figure 3).

## Discussion

The studied fractal coated Synox leads with the small cathode surface area of 1.3 mm² offer significantly higher lead impedance in either unipolar or bipolar pacing configuration as compared to conventional leads. The attained chronic pacing thresholds were in line with the best values reported in the literature. Our follow-up schedule did not allow us to find out exactly when the threshold maximum occurred. On the basis

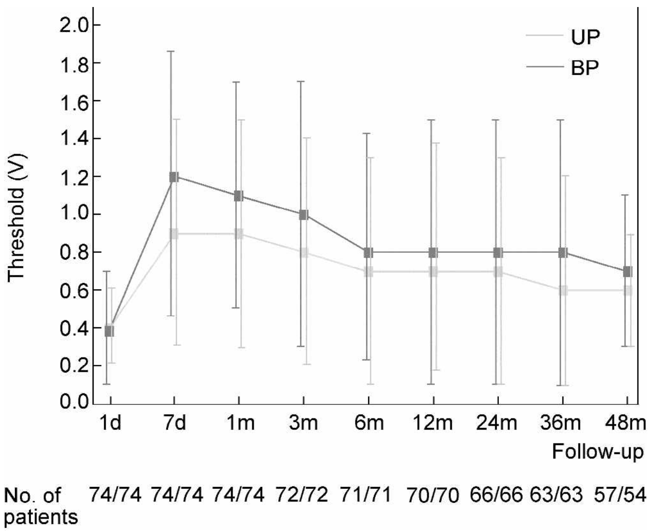


*Figure 2. Evolution of unipolar (UP) and bipolar (BP) pacing thresholds at 0.5 ms (mean value ± standard deviation). d: days, m: months. Number of patients is indicated for UP/BP configuration.*

of extrapolation, we expect that the maximum was reached between 7 days and 3 months after pacemaker implantation. However, it has been suggested that threshold peaking in small surface electrodes typically takes place earlier than with standard surface electrodes, and is most likely to occur within the first week

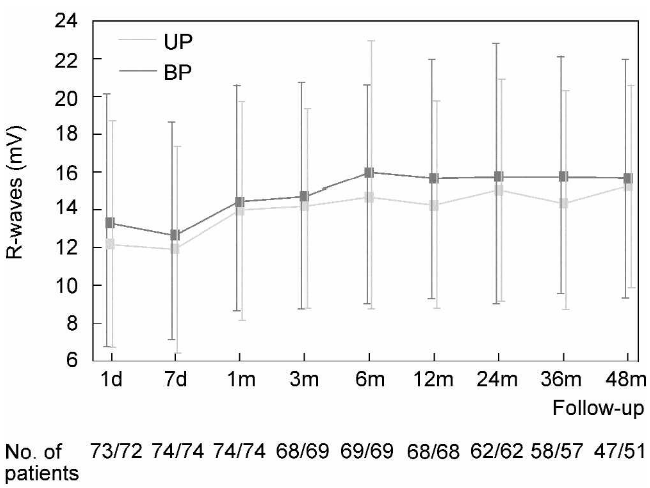


*Figure 3. Trends of R-wave amplitudes in unipolar (UP) and bipolar (BP) lead configuration (mean value ± standard deviation). d: days, m: months. Number of patients is indicated for UP/BP configuration.*

of pacemaker implantation [7]. For a comparison, we previously studied TIR-60 BP lead (Biotronik), with an electrode surface area of 6 $mm^2$ and otherwise very similar design to the studied lead [2], and found out that the threshold reached its peak value between postoperative days 13 and 27.

The achieved low chronic threshold in Synox leads (0.6 ± 0.3 V) allows to program the ventricular pulse amplitude to ≤ 2.0 V at the 0.5 ms pulse duration in 90 % of patients. The high pacing impedance will additionally decrease energy consumption and further prolong service life of the implanted pulse generators.

Mean chronic R-wave amplitudes of ≥ 15 mV represent a very favorable finding, in line with the best results seen in the literature. Other author groups has demonstrated that there is no difference in R-wave amplitudes between small- and standard-surface pacing electrodes [8].

We deem that the best solution generally is to program pacemaker to bipolar polarity with respect to sensing and to unipolar polarity with respect to pacing functions of the pacemaker. There are several reasons for such approach. First, the unipolar pacing configuration allows for larger (easy-to-read) pacemaker spikes to be recorded in the short-term or 24-hour ECG recordings. Second, the unipolar pacing configuration increases patient safety in case of inner insulation defect (i.e., short-circuiting of the two lead conductors), which can lead to pacemaker malfunction only in the bipolar pacing configuration. However, in pacemakers with an automatic switch to the unipolar pacing configuration should the problems in bipolar configuration occur, the latter argument is of less importance. Third, bipolar configuration is generally preferred for sensing functions as it greatly reduces chances for pacemaker inhibition by myopotentials. Our own experience shows that in some instances it is not possible to hinder pacemaker inhibition by myopotentials in the unipolar configuration even after the lowest possible sensing values have been programmed [2,3].

The results of the current study corroborate earlier observations that fractal coated electrodes exhibit very low acute and chronic thresholds, and that their threshold performance is thus comparable to that of steroid-eluting electrodes [2-5,9]. The only difference seems to be a slightly greater threshold peaking in fractal coated electrodes during the early postoperative phase [6,7,10]. In spite of theoretically increased risk of clinical complications with the small surface electrodes, the complication rate in our relatively large study with the Synox lead was impressively low. The incidence of surgical revision due to lead microdislocation of 1.35 % and due to lead insulation defect of 1.35 %, is in line with the results obtained with quality state-of-the-art pacemaker leads [11,12].

## Conclusion

The studied tined bipolar ventricular Synox lead with the 1.3 $mm^2$ fractal coated electrode surface showed impressively low complication rate during the 4-year follow-up. In addition, high pacing impedance and low pacing thresholds are achieved in both unipolar and bipolar pacing configurations. The favorable thresholds permit to program output pulse amplitudes to values lower than 2.0 V in 90 % of the patients. The low output and high pacing impedance will reduce the amount of charge required for effective pacing and prolong pacemaker life time in comparison to standard pacemaker leads.

## References


[1] Furman S, Hazes DL, Holmes DR. A Practice of Cardiac Pacing. Armonk, NY: Futura Publishing. 1986: 480.

[2] Kamaryt P, Novak M, Mach P, et al. Bipolar fractally iridium coated electrodes for permanent ventricular pacing. A comparative study of unipolar vs bipolar configuration. Cor Vasa. 1997: 39: 23-27.

[3] Kamaryt P, Novak M, Dvorak I Jr, et al. A comparative study of ventricular pacing electrodes of small surface and high impedance with electrodes of conventional surface. In: VI Asian-Pacific symposium on cardiac pacing and electrophysiology. Bologna: Monduzzi Editore SpA. 1997: 81-84.

[4] Kamaryt P, Novak M, Dvorak I Jr, et al. Stimulation properties of fractally coated high impedance leads. Progr Biomed Res. 1997: 2: 80-82.

[5] Anelli-Monti M, Mächler H, Oberwalder P, et al. Clinical performance of the Synox high impedance pacemaker lead. Prog Biomed Res. 1999: 4: 312-313.

[6] Schaldach M. Fractal coated leads: advanced surface technology for genuine sensing and pacing. Prog Biomed Res 2000; 5: 259-272.

[7] Danilovic D, Ohm O-J. Pacing threshold trends and variability in modern tined leads assessed using high resolution automatic measurements: Conversion of pulse width into voltage thresholds. PACE. 1999; 22: 567-587.

[8] Bernasconi M, Maestri R, Marzegalli M, et al. Time trends in the intracardiac potential recorded by pacemaker telemetry: comparison between steroid-eluting small area electrodes. PACE. 1999: 22: 164-172.

[9] Wiegand UK, Zhdanov A, Stammwith E, et al. Electrophysiological performance of a bipolar membrane-coated titanium nitride electrode: a randomized comparison of steroid and nonsteroid lead designs. PACE. 1999; 22: 935-941.

[10] Schwaab B, Fröhig G, Berg M, et al. Five-year follow-up of a bipolar steroid-eluting ventricular pacing lead. PACE. 1999; 22: 1226-1228.

[11] Glikson M, Hyberger LK, Hitzke MK, et al. Clinical surveillance of a tined, bipolar, steroid-eluting, silicone-insulated ventricular pacing lead. PACE. 1999; 22: 765-768.

[12] Deshmukh P, Casavant D, Anderson K, et al. Stable electrical performance of high efficiency pacing leads having small surface, steroid-eluting pacing electrodes. PACE. 1999; 22: 1599-1603.



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