A Fractal Coated, 1.3 mm² High Impedance Pacing Electrode: Results from a Multicenter Clinical Trial

G. PIOGER
Clinique Alleray, Paris, France

A. LAZARUS
Clinique du Val d'Or, Saint-Cloud, France

Summary

Clinical performance of tined bipolar ventricular leads with the silicone rubber insulation and the 1.3 mm² iridium fractal coated electrode (Synox, model SX 60 BP, Biotronik, Germany) was evaluated in a total of 331 patients in 11 clinical centers. Mean age of the patients was 78 ± 11 years. Unipolar pacing impedance, pacing threshold and bipolar R-wave amplitude were measured at implantation, patient discharge, and at 1-month, 3-month, 6-month, 12-month, and 18-month follow-up controls. Acute voltage thresholds were determined in 0.1 V steps at pulse durations of 0.1 ms steps (from 0.1 ms to 1.5 ms). The strength-duration curve was reconstructed from the mean threshold values. The acute threshold value at 0.5 ms was 0.35 ± 0.22 V and the voltage chronaxy 0.49 ms. During the follow-up, the pacing threshold was determined at a pulse width belonging to the 0.37 - 0.50 ms range. Peak threshold was 1.01 (1-month control) and chronic value about 0.8 V. The median value of polarization losses determined during implantation with the aid of an oscilloscope and ERA 300 pacing system analyzer (Biotronik) was 0.245 mV, ranging from 100 to 500 mV in the individual patient. The acute impedance of 1,097 ± 275 Ohms decreased slightly in the weeks to come and stabilized at > 1,000 Ohm mean value at controls later than the 3-month control. Mean acute R-wave amplitude was 12.33 ± 5.09 mV and chronic 13.01 ± 5.57 mV. The studied lead exhibited favorable electrophysiological values and reliable performance, and may conserve battery energy by means of high pacing impedance.

Key Words

Small electrode surface (1.3 mm²), high impedance, fractal coating, low energy pacing

Introduction

Pacemaker leads with small stimulation electrodes (1 - 3.5 mm² geometric surface area) were recently introduced into clinical practice in order to conserve pacemaker battery energy by means of elevated pacing impedance and reduced stimulation threshold [1-7]. Battery energy savings accomplished by low-energy pacing lead to an increase in pacemaker longevity, a reduction of the pulse generator size and the incorporation of additional features into future pacemakers [3-7].

Since the reduced electrode size requires a rough surface texture to maintain a large electrochemically active electrode surface area for adequate sensing performance and in order to minimize polarization losses, only two electrode-manufacturing technologies could offer geometric electrode surface areas below 1.5 mm²:

- the microporous platinized steroid-eluting electrode, with > 10x larger electrochemically active than geometric surface area and
- iridium fractal coated electrode, with the magnification factor of 1,000x [2,8-12].

While the clinical performance of the 1.2 mm² steroid-eluting electrode (CapSure Z, Medtronic, USA) has been extensively investigated and published, the available reports on the clinical behavior of the 1.3 mm² fractal coated electrodes (Synox, Biotronik, Germany) have to date been limited to smaller patient populations [1,3,5,6,13,14]. The aim of our multicenter study involving 11 centers in France was to evaluate and document clinical performance of the Synox leads in a large cohort of patients.

Material and Methods

A tined bipolar ventricular lead with the silicone rubber insulation and the 1.3 mm² iridium fractal coated electrode (Synox, model SX 60 BP) was subject to evaluation. A description of the fractal coating technology has been provided elsewhere [2,15-17]. The leads were implanted in a total of 331 patients and connected to a variety of pacemaker models. The mean age of the patients was 78 ± 11 years (184 males, 147 females). Unipolar pacing impedance, pacing threshold and bipolar R-wave amplitude were measured at implantation, patient discharge, and at 1-month, 3-month, 6-month, 12-month, and 18-month follow-up controls.

In the course of implantation, different centers used different pacing-system analyzers to make acute measurements. The impedance values were, however, always determined at the 5 V / 0.5 ms output setting and voltage thresholds assessed in 0.1 V steps at the pulse duration of 0.1 ms, 0.2 ms, 0.3 ms, etc., up to 1.5 ms (in 0.1 ms steps). The acute voltage strength-duration (Lapicque) curve was reconstructed from the mean threshold values.

In one center, additional measurements of polarization losses were undertaken. For this purpose, a Tektronik oscilloscope was connected in parallel with the output outlets of the ERA 300 pacing-system analyzer (Biotronik). The implanted lead was then connected to the ERA 300 and the constant-current pacing pulse of 2.5 mA in amplitude and 0.5 ms in duration was injected. Subsequently, the shape of the pacing pulse was studied on the oscilloscope screen (Figure 1) and the polarization losses were calculated as the difference between the leading-edge and the trailing-edge voltage during the pacing pulse (overpotential in mV).

During the follow-up, the pacing threshold was measured in either 0.2 V or 0.25 V steps, at a pulse duration within the 0.37- to 0.5 ms range, depending on the pacemaker model used. The study results are presented as mean values ± standard deviations, except for polarization losses that are shown as minimum-to-maximum range and a median value. The frequency distributions of acute impedances and pacing thresholds were also determined. The two-tailed t-test was used to evaluate the differences between the mean values, with $p < 0.05$ considered statistically significant.

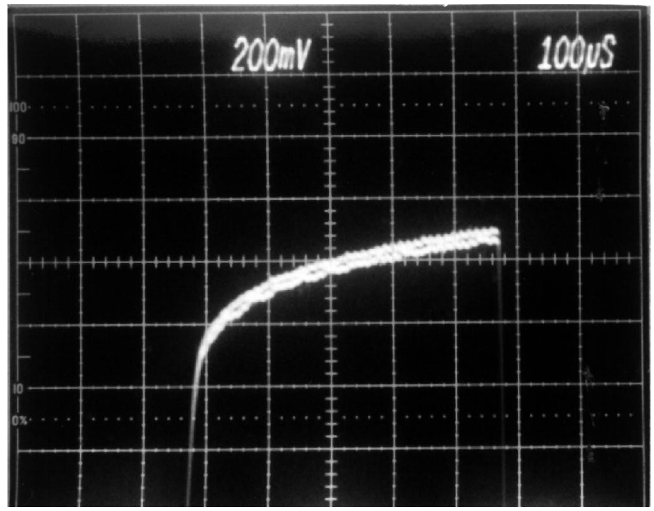

Figure 1. Polarization-losses measurement on the oscilloscope screen (equal to about 250 mV in this example). See text for further explanations.

Results

The mean acute threshold at the 0.5 ms pulse duration was 0.35 ± 0.22 V. The chronaxy value derived from the Lapicque strength-duration curve (Figure 2) was 0.49 ms. Figure 3 illustrates the frequency distribution of the acutely measured threshold values.

Median polarization losses were 0.245 mV, and ranged from 100 to 500 mV in the individual patients. The mean acute impedance was 1,097 ± 275 Ohms, and the mean acute R-wave amplitude 12.33 ± 5.09 mV. Figure 4 illustrates the frequency distribution of the acutely measured impedance values.

The trends of pacing thresholds and impedances following patient discharge are shown in Figures 5 and 6, respectively, and selected explicit values are given in

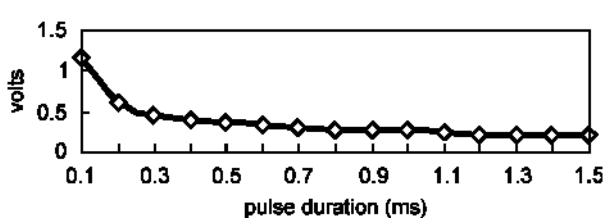

Figure 2. The strength-duration curve constructed from measurements during implantation.

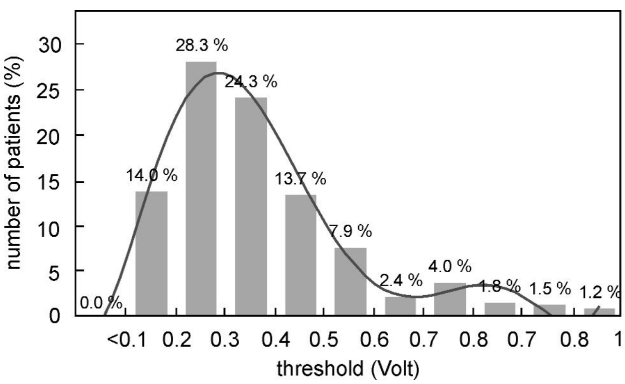

Figure 3. Frequency distribution of the acute threshold values at 0.5 ms pulse width.

Table 1. The threshold peak occurred at the 1-month control (mean value 1.01 V), which was followed by a significant threshold decrease in the subsequent months ($p < 0.0001$ for the controls later than the 3-month control versus 1-month control). Chronic threshold stabilized at about 0.8 V level after the 6-month control. The pacing impedance significantly increased ($p < 0.0001$) from the time of patient discharge (800 Ohms) to the 6-month control (1,054 Ohms). No significant change in impedance was observed thereafter ($p > 0.05$).

Discussion

When chronic impedance and threshold values are compared for Synox leads and CapSure Z leads (data in literature), a great similarity of the results is evident, implicating that both leads exert approximately the same, favorable effect on battery energy consumption. In particular, chronic pacing impedance with Synox leads appear to be slightly higher than that in CapSure Z leads (1,100 Ohms versus 950 Ohms in the unipolar configuration) while chronic thresholds are slightly less favorable (about 0.8 V in Synox versus 0.5 V in CapSure Z) [1,3,5,6]. Having in mind that the thresholds in our study were determined at a pulse duration slightly shorter than 0.5 ms (in the 0.37 ms to 0.5 ms range), the comparative difference between the thresholds for the two leads at a fixed pulse duration would be even smaller. Thus, Synox leads provide some extra battery savings compared to the CapSure Z lead on the account of the higher pacing impedance, but in case of output setting optimization, this advantage may be abolished by the need for slightly higher pacing output [4,6].

Both Synox and CapSure Z leads offer clear advantages compared to the conventional leads featuring pacing impedances around 500 Ohms and slightly higher pacing thresholds due to lower current density

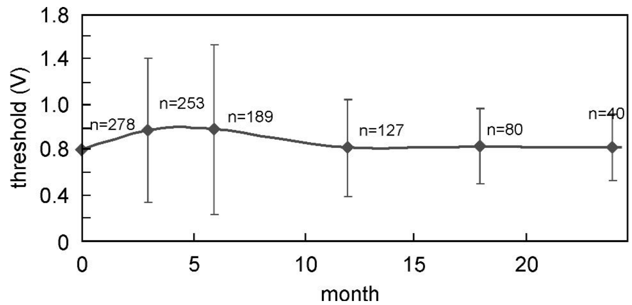

Figure 5. Pacing threshold trend following patient discharge (0-month control).

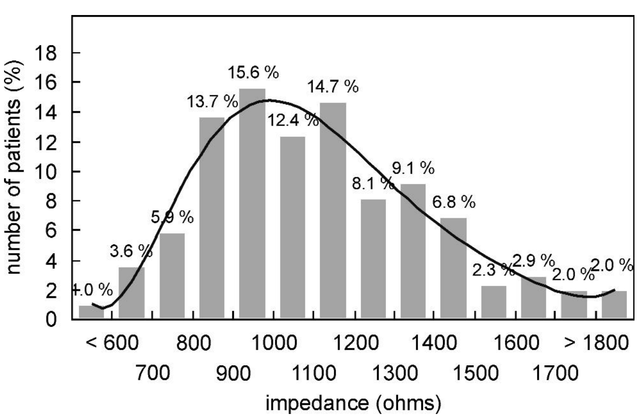

Figure 4. Frequency distribution of acute impedance values.

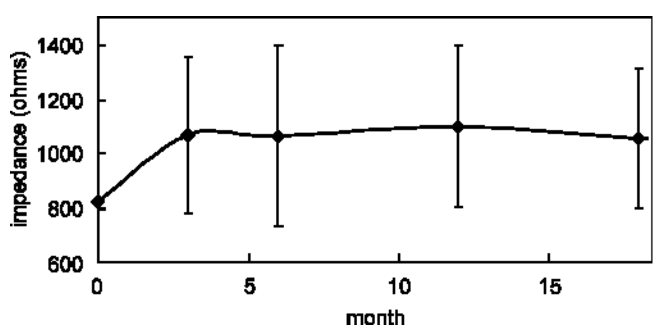

Figure 6. Pacing impedance trend following patient discharge (0-month control).

	Implant	Month 6	Month 12
N	331	184	121
Threshold (V)	0.35±0.22	0.96±0.77	0.80±0.43
R amplitude (mV)	12.33±5.09	11.78±4.59	13.01±5.57
Impedance (Ω)	1097±275	1054±334	1098±302

Table 1. Mean values of the observed parameters at the three major control points.

at the electrode-tissue interface [2-6]. The Synox lead may, however, be regarded as more safe in the chronic phase with respect to lead integrity (silicone insulation in Synox vs. silicone/polyrethane insulation in CapSure Z) and threshold stability. While the CapSure Z lead relies on steroid elution for threshold suppression and this mechanism may not be permanently efficient due to the limited amount of steroid incorporated into the lead tip [6,18,19], the inflammation-moderation effect of the fractal coated electrode surface is everlasting, decreasing the risk of exit block particularly when pacing outputs are optimized to low values.

The further analysis of the study results suggests that acute thresholds in Synox leads aggregated in the 0.2 - 0.3 V range (Figure 3), thereby being clearly better than with standard impedance leads and in line with published data on CapSure Z leads [1,3,5]. The explanation for the reduced acute thresholds in high impedance leads has been already provided in the literature [1,2,7,20]. During acute threshold peaking, the fractal coated lead exhibited slightly higher peak thresholds than the steroid-eluting lead (about 1 V versus 0.7 V). Both results represent fully satisfactory outcome and the difference may be of little clinical relevance. Chronaxy values in Synox and CapSure Z leads are similar (0.5 ms) [21]. Interestingly, clinical results on chronaxy values are not in line with the theoretical expectations based on extrapolation methodology, where chronaxy values in the 0.1 - 0.2 ms range would be expected for electrodes with » 1.3 mm^2 surface area [22].

While acute unipolar impedances in Synox and CapSure Z leads were similar (around 1,100 Ohms), the steroid-eluting design seems to exhibit a larger impedance drop in the chronic phase [1,5]. In contrast, fractal coated electrodes ensure chronic values similar to the acute ones. Acute and chronic R-wave amplitudes were fully satisfactory and comparable with the published data on CapSure Z leads as well as standard-impedance electrodes.

The limitation of our study is the lack of a systematical evaluation of the complication rate associated with the use of Synox leads. The most frequently encountered complications with high impedance leads are lead dislodgment, intermittent exit block and high threshold. In our preliminary publication conveying a single-center experience (Clinique Alleray), the complication rates were 6 % for Synox leads (3 out of 50) and 6 % for CapSure Z leads (2 out of 33). There was no control group implanted with standard-impedance leads. The controversy over whether the high-impedance leads result in a higher complication rate than standard-impedance leads has thus far not been settled, with different centers having different experiences and attitudes [1-7,13,14]. Although our multicenter study was initially not designed to gather systematic data on the complication rate with the Synox leads, the complaints on complications did not emerge as a striking problem during the study. Seemingly, a low complication rate can be obtained with handling experience and by taking care of the following:

- Avoid pushing the lead against the endocardium with the stylet completely inserted, to prevent intrusion and perforation of the lead tip, especially in patients with thin cardiac walls (in the atrium, or the ventricle due to dilated cardiomyopathy).
- Verify the electrode contact stability during normal and deep breathing and coughing by observing threshold stability. This should minimize the risk of later lead dislodgment and microdislodgment.

Members of the French Multicenter Study Group:

M. Boursier: Regional Hospital of Bon Secours, Metz

M. Brémondy: Clinique Axium, Aix en Provence

G. Chapus: Clinique Pasteur, Ris Orangis

J. Fabre: Clinique of Residence du Parc, Marseille

P. Gaudeul: Côte Basque Hospital, Bayonne

A. Lazarus: Clinique du Val d'Or, Saint-Cloud

Y. Pansard: Beaujon Hospital, Thionville

G. Pioger: Clinique Alleray, Paris,

P. Scan: University Hospital, Caen

J.-Y. Thisse: Bel Air Hospital, Thionville

O. Thomas: Lariboisiere Hospital, Paris

References

[1] Danilovic D, Breivik K, Hoff PI, et al. Clinical performance of steroid-eluting pacing leads with 1.2-mm^2 electrodes. PACE. 1997; 20: 2799-2809.

[2] Fröhlig G, Bolz A, Ströbel J, et al. A fractally coated, 1.3 mm^2 high impedance pacing electrode. PACE. 1998; 21: 1239-1246.

[3] Moracchini PV, Cornacchia D, Bernasconi M, et al. High impedance low energy pacing leads: long-term results with a very small surface area steroid-eluting lead compared to three conventional electrodes. PACE. 1999; 22: 326-334.

[4] Ohm O-J, Danilovic D. Improvements in pacemaker energy consumption and functional capability: four decades of progress. PACE. 1997; 20: 2-9.

[5] Ellenbogen KA, Wood MA, Gilligan DM, et al. Steroid eluting high impedance pacing leads decrease short and long term current drain: results from a multicenter clinical trial. PACE. 1999; 22: 39-48.

[6] Danilovic D, Ohm O-J, Breivik K. Clinical use of low output settings in 1.2-mm^2 steroid eluting electrodes: three years of experience. PACE. 1998; 21: 2606-2615.

[7] Pioger G. Low surface are electrodes: comparison between Synox 60 BP (1.3 mm^2), CapSure Z 5034 (1.2 mm^2) and Stela BT26 (2 mm^2): 158 cases. In Vardas P (ed.): Europace '97. Monduzzi Editore, Bologna, 1997: 607-612.

[8] Stokes K, Stephenson NL. The implantable cardiac pacing lead - just a simple wire? In Barold SS, Mugica J (eds.): The Third Decade of Cardiac Pacing: Advances in Technology and Clinical Applications. Futura Publishing Company, Inc., Mount Kisco, NY, 1982: 365-416.

[9] Schaldach M, Hubmann M, Weikl A, et al. Sputter-deposited TiN electrode coatings for superior sensing and pacing performance. PACE. 1990; 13: 1891-1895.

[10] Sinnaeve A, Willems R, Backers J, et al. Pacing and sensing: How can one electrode fulfill both requirements? PACE. 1987; 10: 546-554.

[11] Ripart A, Mugica J. Electrode-heart interface: Definition of the ideal electrode. PACE. 1983; 6: 410-421.

[12] Lazarus A, Mugica J. Advances in Lead Technology. In Barold SS, Mugica J (eds) : Recent Advances in Cardiac Pacing: Goals for the 21st century. Futura Publishing Company, Inc., Mount Kisco, NY, 1997: 337-356.

[13] Johnson WB, Voegtlin L, Greene C, et al. Clinical performance of the 5034 ventricular lead - a balance of consequences of a new high impedance lead? (abstract) PACE. 1997; 20: 1150.

[14] Joglar JA, Welch PJ, Wilkinson WE, et al. Initial experience with a high-impedance tined endocardial pacemaker lead: Evidence for increased lead failure. Am Heart J. 1997; 134: 161-164.

[15] Bolz A. Die Bedeutung der Phasengrenze zwischen alloplastischen Festkörpern und biologischen Geweben für die Elektrostimulation. Schiele & Schön, Berlin, Germany, 1995.

[16] Schaldach M. The stimulating electrode. In Schaldach M (ed.): Electrotherapy of the Heart. Springer-Verlag, Berlin, Germany, 1992: 145-168.

[17] Hubmann M, Hardt R, Bolz A, et al. Pacing and sensing performance of leads with fractally structured tips. In AE Aubert (ed.): Europace 93. Monduzzi Editore, Bologna. 1993: 419-423.

[18] Stojanov P, Djordjevic M, Velimirovic D, et al. Assessment of long-term stability of chronic ventricular pacing thresholds in steroid-eluting electrodes. PACE . 1992; 15: 1417-1420.

[19] Mond HG, Stokes KB. The electrode-tissue interface: The revolutionary role of steroid elution. PACE. 1992; 15: 95-107.

[20] Lindemans FW, Zimmerman ANE. Acute voltage, charge, and energy thresholds as functions of electrode size for electrical stimulation of the canine heart. Cardiovasc Res. 1979; 13: 383-391.

[21] 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.

[22] Irnich W. The chronaxie time and its practical importance. PACE. 1980; 3: 292-301.