Long-Term Results with 3.5 mm² Fractal Coated Tined Electrodes

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Summary

Pacemaker electrodes with a smaller geometric surface area may reduce current drain during pacing but pose special challenges to the operator in view of the increased handling complexity and decreased electrode positional stability. We studied the acute and chronic clinical performance of 3.5 mm² fractal coated iridium leads (Polyrox). Ten patients with conventional pacing indications received different single- and dual-chamber pacemakers and a tined bipolar Polyrox lead in the ventricle. The complexity of different segments of the lead implantation was evaluated by the operator on a 3-point Likert scale, with "0" indicating maximum effort, "1" = standard effort, and "2" = minimum effort. Mean scores were: 1.1 for passing the tricuspid valve, electrode positioning in the right ventricular apex, and X-ray visibility of the inserted lead; 1.2 for the lead insertion into the vein; 1.4 for the lead advancement through the venous system into the right heart; and 1.9 for the stability of the electrode position and lead fixation. Electrophysiologic values were measured in the bipolar lead configuration immediately following implantation, after 1 and 7 days, and 3, 6, 12, 18 and 24 months following the procedure. After the initial threshold peaking subsided, only insignificant variation of all electrophysiologic values was observed. Pacing threshold at 0.5 ms was 0.34 ± 0.07 V acutely and 0.73 ± 0.29 at 24 months. No lead exhibited threshold instability during the study. Pacing impedance was 770 ± 218 W at implant and 576 ± 67 W at 24 months. Mean R-wave ranged from 12 to 20 mV. The lead exhibited very satisfactory clinical performance and favorable acute and chronic electrophysiologic parameters.

Key Words

Pacemaker lead handling, fractal coated electrode, pacing threshold stability

Introduction

Minimizing the geometric surface area of pacing electrodes increases impedance and reduces the current drain during pacing [1-5]. Although small electrodes (1 – 2 mm²) offer a lower pacing threshold than conventional leads in the acute phase as well as during the first postoperative months [4-7], a steady threshold increase occurring several years after implantation was observed in some designs [6,8]. Small-surface electrodes must also be handled more delicately during implantation than standard electrodes (5 – 8 mm²); they may also be associated with an increased complication rate caused by electrode positional instability and early or late lead dislodgment [7-13]. This has resulted in a limited acceptance of high-impedance leads in clinical practice, despite the favorable findings of several large clinical trials [3-5,14,15].

The use of leads with moderately reduced electrode surfaces (3 – 5 mm²) may represent a compromise, by reducing implantation delicacy and complications encountered with the very small electrodes, while still maintaining higher pacing impedance and a lower battery current drain than for standard-surface electrodes [16-20]. The goal of our study was to investigate acute and long-term clinical performance of 3.5 mm² fractal coated iridium leads (Polyrox, Biotronik, Germany) [13].

Materials and Methods

Patients and Implanted Devices

Ten patients (five men and five women) with a mean age of 77.5 ± 6.9 years received different single- and dual-chamber pacemakers for conventional pacing

Figure 1. Different Polyrox leads; Biotronik, Germany.

indications. Pikos LP01, Dromos SR, Physios 01, and Actros SR pacemakers were used (all from Biotronik), as well as the 2402L, 2308L, and Regency SCX from St. Jude Medical (Sylmar, USA). The bipolar Polyrox lead (PX 60-BP) was implanted in the ventricle in all patients. The lead is equipped with four tines for passive fixation in the trabecular network of the right ventricle (Figure 1). The lead design is co-axial, with an inner and outer silicone insulation.

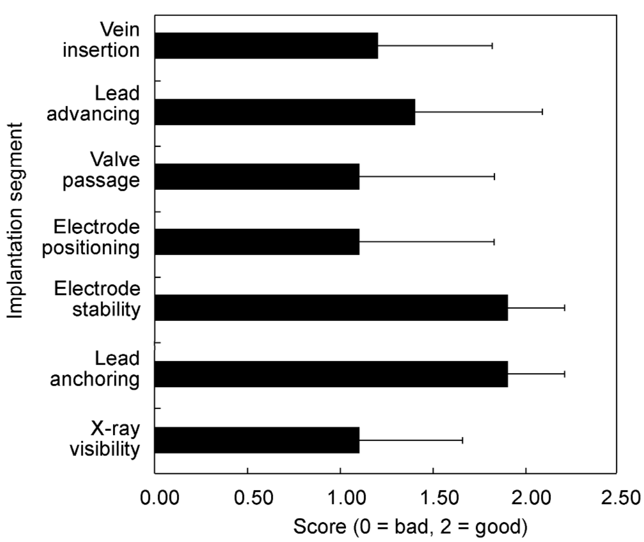

Figure 2. Complexity of lead implantation graded by the operator on a 3-point Likert scale: 0 = maximum effort, 1 = standard effort, and 2 = minimum effort.

Implantation Procedure

Two of the leads were inserted via the subclavian vein approach and others through the cephalic or brachiocephalic veins. The pulse generators were positioned subcutaneously in the right thoracic region. The complexity of different segments of lead implantation was evaluated by the operator on a 3-point Likert scale, where "0" indicated maximum effort, "1" = standard effort, and "2" = minimum effort. The following implantation steps were evaluated: insertion of the lead into the vein, advancement of the lead through the venous system into the right heart, negotiation of the tricuspid valve, electrode positioning in the right ventricular apex, stability of the electrode position, lead fixation, and X-ray visibility of the inserted lead.

Acute electrophysiologic values were assessed in the bipolar lead configuration, using a pacing system analyzer. This included the pacing threshold at 0.5 ms pulse duration and R-wave and pacing impedance measurement.

Follow-up Examinations

Following pacemaker implantation, patients returned to the hospital for follow-up examinations at 1 and 7 days, and 3, 6, 12, 18 and 24 months. At each visit, the above-mentioned values were assessed via pacemaker telemetry.

Data Analysis

Data are presented as mean values ± standard deviations. Differences between the mean values were evaluated using the unpaired two-tailed t-test; p-values < 0.05 were considered significant.

Results

Study results are shown in Figures 2 – 5. Two patients died between 18 and 24 months after implantation for reasons unrelated to pacemaker therapy. One patient was lost to follow-up after 6 months. No lead exhibited positional (threshold) instability following implantation. There were no significant differences in any electrophysiologic parameter for the controls between 6 and 24 months.

Implant threshold was 0.34 ± 0.07 V, which was significantly lower than at any other point. The peak threshold at 3 months (0.98 ± 0.24 V) was significantly higher than that during implantation and at day 1 and months 12 and 18. The 24-month threshold was 0.73 ± 0.29 V.

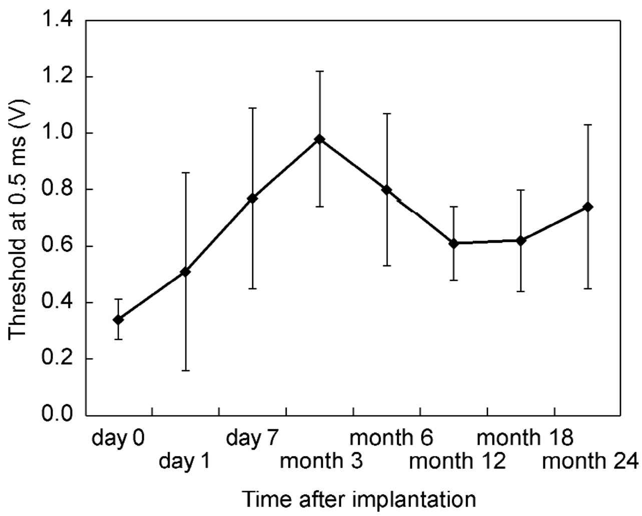

Figure 3. Trend of bipolar pacing thresholds at 0.5 ms. Day 0 = acute examination.

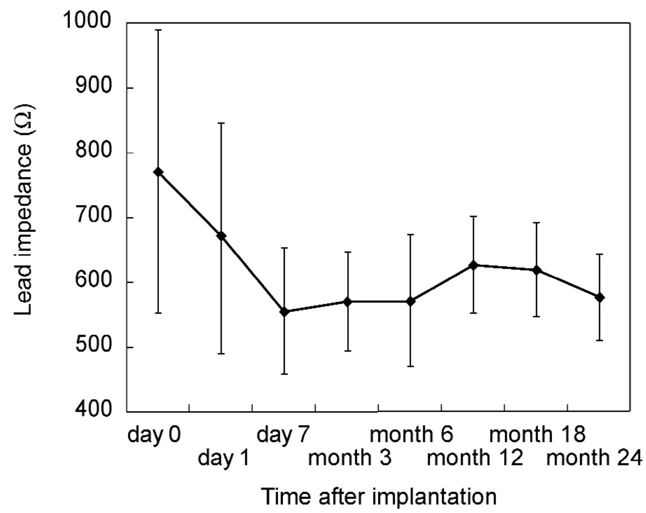

Figure 5. Trend of bipolar pacing impedance. Day 0 = acute examination.

Acute impedance (770 ± 218 Ω) was significantly higher than the measured values at day 7, and months 3 and 24 (576 ± 67 Ω). No significant difference was found in R-wave amplitudes between any two follow-up examinations. Mean R-wave ranged from 12 to 20 mV.

Discussion

Fractal coating represents an advanced surface technology that optimizes both charge transfer during stimulation and filtering characteristics of the sensed cardiac signals [13]. The fractal coating is obtained by depositing a thin layer of iridium on a titanium hemisphere. In contrast to the temporary effect found in steroid elution, fractal coated electrodes stabilize the electrode-tissue interface and improve the long-term stability of the lead's electrophysiologic parameters [7,13,15,17]. This may be of particular importance in small-surface electrodes that may be associated with increased positional and threshold instability.

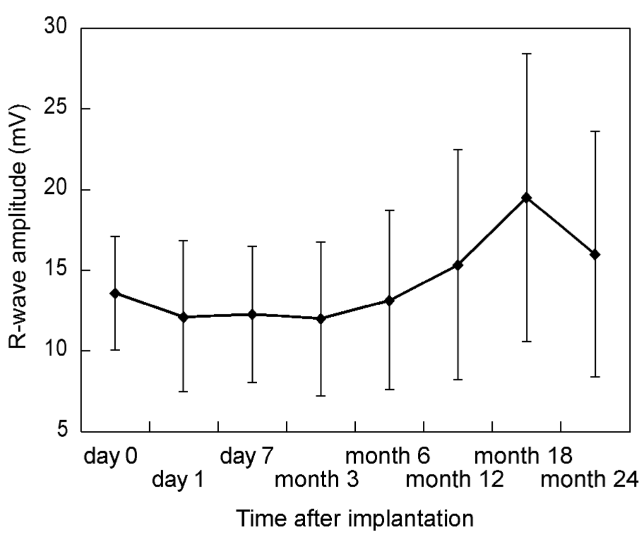

Figure 4. Evolution of R-wave amplitudes. Day 0 = acute examination.

Our findings are similar to those of Novak et al. [15] and Israel et al. [17], confirming that threshold peaking in 3.5 mm^2 fractal electrodes does not exceed 1.2 V at 0.5 ms (on average), whereas chronic values are in the range of 0.6 V (Figure 3). Additionally, the thresholds do not appear to increase during the chronic phase for either the 3.5 mm^2 or 1.3 mm^2 fractal electrode models [7,15,17]. The benefit of high pacing impedance is much more pronounced for the 1.3 mm^2 (typically > 1000 Ω) than 3.5 mm^2 surface area electrodes (around 600 Ω, Figure 3), when the standard 500-Ω electrode is taken as a reference [7,15,17]. However, it may be easier to implant the 3.5-mm^2 electrodes; in our study these were implanted with a minimum to standard amount of effort (Figure 2). By comparison, a list of precautionary measures for the handling of 1.3-mm^2 electrodes has been previously published based on the experience of researchers in a large multicenter trial [7]. Over the long-term, the use of recommended, safe, low and stable pacing thresholds in fractal leads results in the programming of low pacing outputs, which may significantly extend pacemaker longevity [21-23]. The expected prolongation of battery service life based solely on the increased pacing impedance in conditions when pacing output is not optimized is not remarkable for the 3.5 mm^2 electrodes, as they offer only about 20 % higher impedance than standard-surface electrodes.

Conclusion

The Polyrox lead with the 3.5 mm fractal coated electrode exhibits excellent handling characteristics, especially with respect to electrode positional stability and lead fixation. In the long term, favorable electrophysiologic parameters are stable and thus facilitate pacing output optimization for battery energy conservation.

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