Performance of Epicardial Fractal Coated Leads: A Three-year Follow-Up

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Summary

Sixteen epicardial leads (model ELC 54, Biotronik, Germany) attached onto the right anterior ventricular wall during a thoracotomy surgery were studied during a three-year follow-up period. The leads are fractal coated, unipolar, with a screw-in fixation mechanism. The stimulating electrode has a 10 mm² geometric surface area and is made of iridium. Lead polarization artifact was found negligible (< 1.73 mV). Good R-wave amplitudes were attained - mean values were 9.3 mV acutely and 6.5 mV chronically. Mean acute pacing threshold was 0.8 V at 0.5 ms, with a peak value of 2.5 V during the period 1-6 months after lead implantation. Mean chronic pacing threshold of 1.97 V was markedly lower than in a control group of unipolar epicardial screw-in leads without fractal coating (2.9 V) and considerably higher than in the second control group that comprised unipolar endocardial fractal coated leads (0.7 V). A comparatively lower pacing impedance was observed in the ELC 54 leads (mean 350-390 Ohms in the chronic phase) than in the epicardial screw-in leads without fractal coating (572 Ohms, 6-10 mm² Pt-Ir electrodes) and in the endocardial fractal coated leads (487 Ohms, 6 mm² Ir electrodes). This may result in a slightly increased pacemaker battery current drain and a shorter pacemaker longevity in the ELC 54 leads.

Key words

Epicardial leads, fractal coated lead, screw-in fixation

Introduction

Fractal structure of the pacing lead tip enlarges the electrochemically active surface area by more than 1,000 times, while actual size and geometric surface area of the lead tip remain small. This lead tip design yields a high current density, low pacing threshold, diminished undesirable polarization artifact voltage, and a reliable sensing of the intracardiac signals [1, 2]. Previous clinical studies have demonstrated that fractal coated leads are capable of maintaining low pacing thresholds in the long term for endocardial lead positions (3). Our prospective study aimed at evaluation of clinical performance of the epicardial fractal coated screw-in leads.

Material, patients, and methods

The ELC 54 leads (Biotronik, Germany) are unipolar, epicardial screw-in leads. The 10 mm² stimulating electrode is coated with a fractal layer of iridium. Two different models with a penetration depth of the screw of 3.5 mm or 2.0 mm, respectively, have been available. The leads were attached onto the right anterior ventricular wall in 16 patients udergoing heart surgery that required thoracotomy. The patients could be divided into two subgroups: seven were adults, aged 50-77 years (mean 63 years), and nine were children, aged 0.2-18 years (mean 5.3 years).

Pacing threshold at 0.5 ms, R-wave amplitude, and pacing impedance (at 4.8 V output amplitude) were assessed in the course of lead implantation and at 7 days, 1, 3, 6, 12, 24 and 36 months after the implantation. The attained lead electrophysiological values were compared to the results obtained with two control patient groups implanted with other types of unipolar ventricular leads: (1) epicardial screw-in leads without fractal coating, n = 16 (ML 150/160, Biotronik, with a

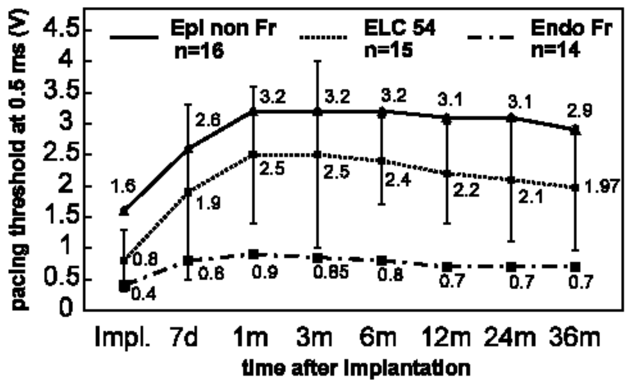

Figure 1. Pacing threshold trends (mean ± standard deviation) in fractal coated epicardial leads (ELC-54) versus epicardial leads without fractal coating (Epi non Fr), and fractal coated endocardial leads (Endo Fr).

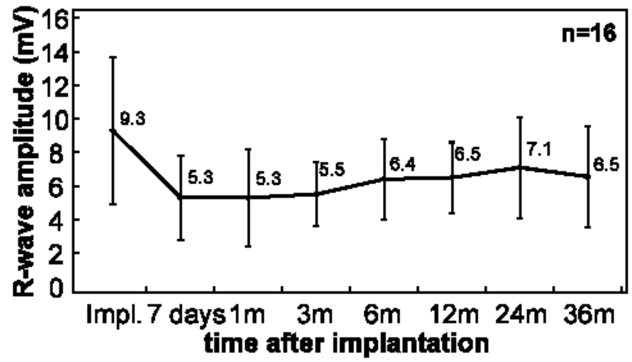

Figure 2. Trend of R-wave amplitudes in the ELC 54 epicardial fractal coated leads (mean ± standard deviation).

6 mm2 Pt-Ir electrode; and 6917A, Medtronic, USA, with a 10 mm^2 Pt-Ir electrode); and (2) endocardial fractal coated leads, n = 14 (TIR-60 UP, Biotronik, with a 6 mm^2 iridium electrode).

Statistical analysis of the gathered data was performed using ANOVA test with repeated measurements (Dunnet's test) and two-tailed Student's t-test. P-values < 0.05 were considered significant.

Results

One patient was excluded from pacing threshold analysis due to a progressive threshold increase, ending up in permanent exit block. Otherwise, pacing thresholds in the ELC 54 leads were considerably lower than in the control group of epicardial leads without fractal coating (Figure 1). Endocardial fractal coated leads offered significantly lower thresholds than either type of epicardial leads (Figure 1). Peak thresholds in the epicardial leads occurred during the period of 1-6 months after implantation. R-wave amplitudes exhibited a usual decrease within the first 7 days of implantation, followed by a gradual increase toward the chronic plateau (Figure 2). Nonetheless, the sensed amplitudes were at all the times within the acceptable limits. Pacing impedance also exhibited a marked decrease within a few days after implantation but, in contrast to the R-wave amplitudes, low impedance values were maintained during the chronic phase (Figure 3). Figure 4 provides a comparison of impedance values between the ELC 54 leads and the two control groups, with the corresponding statistical P-values indicated. Polarization artifact in the individual ELC 54 leads ranged from 1.41 to 1.73 mV during the first month after implantation and no clear trend against implant time was observable. The values compared favourably with the results in the endocardial leads (range 0.98 - 2.27 mV, mean 1.25 mV). Lead polarization measurements in the epicardial leads without fractal coating were not available for comparison.

Discussion and conclusions

The ELC 54 epicardial fractal coated leads exhibited distinctly lower pacing thresholds than epicardial leads without fractal coating and using similar electrode material. Pacing thresholds reached maximum during the first 1-6 months after lead implantation. Due

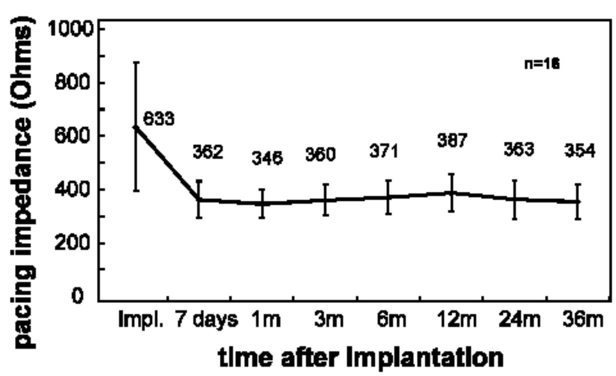

Figure 3. Trend of pacing impedance (at 4.8 V) in the ELC 54 fractal coated epicardial leads (mean ± standard deviation).

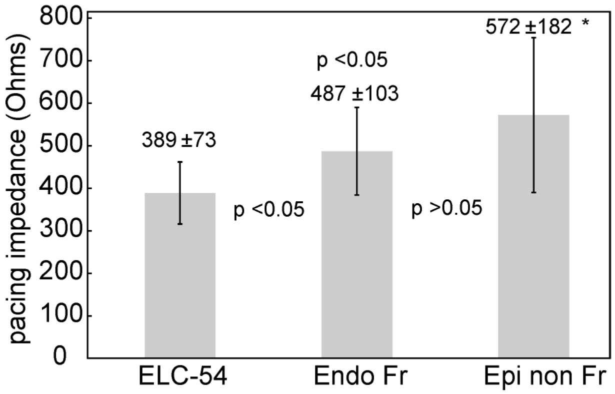

Figure 4. Mean pacing impedances and standard deviations determined at one year after implantation in fractal coated epicardial leads (ELC-54), fractal coated endocardial leads (Endo Fr), and epicardial leads without fractal coating (Epi non Fr).

to the prolonged tissue reaction, pacemaker outputs should be reduced to chronic settings later than it is usually done with endocardial leads. The lead polarization was low and the automatic capture verification function (active in one patient) appeared to work properly. A low pacing impedance observed in the chronic stage (< 400 Ohms) represents a slight drawback, as this in conjunction with relatively high pacing thresholds typical for epicardial pacing may result in an increased current drain from the pacemaker battery and a reduced pacemaker longevity. From this point of view, changes in the ELC 54 lead design aimed at increasing pacing impedance (for instance, by reducing electrode surface area from the present 10 mm2 value) may be clinically beneficial.

References

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