Comparison of Chronic Clinical Performance of Fractal Coated and Polished Screw-In Electrodes

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Summary

The fractal coating technology consists of iridium deposition on the pacemaker electrode surface, resulting in a 1000 times larger electrochemically active area than the geometric surface area of the electrode. Increased electrochemically active area is expected to enhance sensing performance of the pacemaker lead. This study compared clinical performance of the chronically implanted ventricular screw-in leads with and without fractal coating. Thirty patients with fractal coated 10 mm^2 iridium electrodes and 27 patients with 10 mm^2 polished platinum-iridium electrodes were evaluated for lead electrophysiologic parameters at the time of pacemaker replacement. Fractal electrodes exhibited significantly higher R-wave amplitudes than the polished electrodes (12.45 versus 9.03 mV, $P < 0.05$), while pacing threshold and pacing impedance did not differ significantly. Our study showed that fractal coating technology is able to improve sensing of intracardial signals compared to conventional leads, which may be of primary importance in the field of electrophysiological investigations and in the future development of sophisticated diagnostic and therapeutic pacemaker features.

Key Words

Fractal coated leads, lead performance, pacemaker sensing

Introduction

Clinical diagnosis of heart disease during electrophysiological studies requires catheters with excellent sensing performance, in order to maximize intracardiac signal amplitudes and allow for unmistakable discrimination of very small signal peaks. The sensing and pacing behavior of a pacemaker lead is largely determined by the interface between the electrode and the tissue. From the physical point of view, the electrode must exhibit low interface impedance and low polarization, which may be fulfilled by enlarging active surface area of the electrode using fractal coating technology [1,2].

The fractal electrode represents a beacon in the lead technology progress. Using a physical vapor deposition reactor, titanium electrodes are coated with an iridium layer forming a microscopic "cauliflower-like" surface (Figure 1). In accordance with the fractal principle from chaos theory, an integrative pattern is observed when substructures are magnified, resulting in a very large active surface area - more than three orders of magnitude greater than the surface area in conventional polished electrodes. This yields a high electrical capacitance at the electrode surface, several thousand times higher than in polished electrodes, producing a very low electrode-tissue interface impedance [2,3].

The goal of this study was to compare clinical performance of fractal coated and polished screw-in electrodes chronically implanted in the ventricle.

Materials and Methods

Clinical characteristics of 57 patients enrolled in the study are shown in Table 1. Thirty patients had a ventricular screw-in fractal lead with a 10 mm^2 iridium

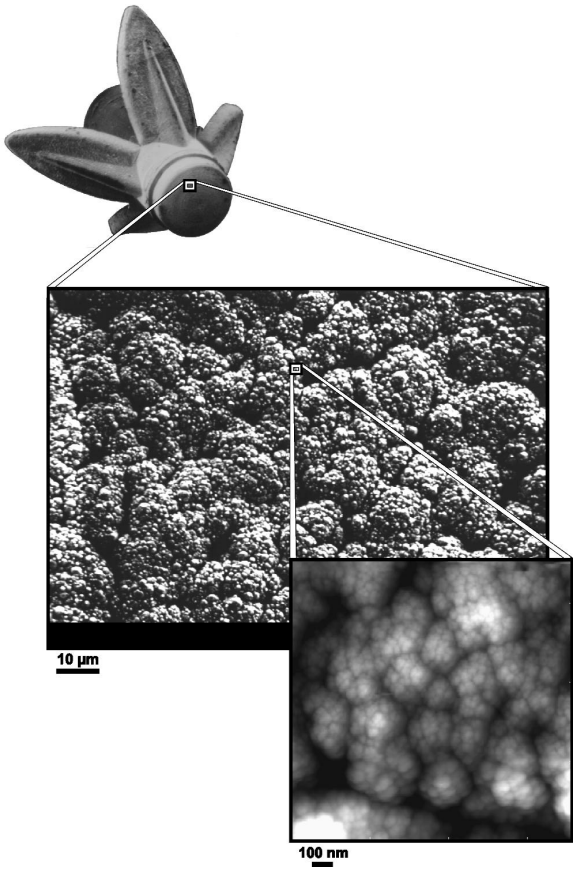

Figure 1. Macroscopic and microscopic view of the fractal electrode surface.

electrode (Y 60-BP, Biotronik, Germany) and 27 had polished screw-in lead with a 10 mm^2 platinum-iridium electrode (FH 60-BP, Biotronik, Germany). The two leads had a very similar geometric form, with the major difference represented by the presence or absence of fractal coating. The evaluation of chronic electrophysiologic parameters of the leads was performed uniformly in all the patients, using a two-step procedure:

- During pacemaker replacement due to battery depletion or system upgrade, the stimulation impedance, pacing threshold at 0.5 ms, and the R-wave amplitude were determined.
- Eight months after the pacemaker replacement, the same measurements were repeated using pacemaker telemetry.

Results for fractal coated and polished electrodes were compared using Student's t-test. P value < 0.05 was considered statistically significant.

	Fractal lead	Polished lead	P
n	30	27	
Age	59 ± 10 years	62 ± 9 years	ns
Sex (male)	57 %	65 %	ns
Chagas´ disease	89 %	91 %	ns
Amiodarone	67 %	71 %	ns
Systemic hypertension	15 %	17 %	ns
Time between 2 evalations	7.9 ± 0.5 months	7.5 ± 0.8 months	ns
Time after implantation	30.2 ± 17.1 months	67.8 ± 15.1 months	P < 0.05

Table 1. Baseline characteristics of study patients.

Results

There were no statistically significant intraindividual differences in the measured parameters between the two control points. This was due to the achieved long-term stability at the electrode tissue contact, as no lead was replaced during pacemaker exchange and all the leads have completed their growing-in and encapsulation processes. From Figures 2 and 3, pacing impedance and pacing thresholds did not differ significantly between the two leads (P > 0.05). Pacing thresholds for fractal electrodes were not significantly lower, as it might have been expected, probably due to a relatively large electrode surface area of 10 mm^2. Difference in pacing thresholds between the two surface technologies should be more pronounced in smaller size electrodes [4]. Additional reason for the absence of significant differences in pacing parameters in the studied leads could be the use of active fixation, resulting in a thick fibrotic encapsulation "dominating" the pacing performance. On the other hand, R-wave amplitudes were significantly larger in fractal coated (12.45 mV) than in polished leads (9.03 mV, P < 0.05) (Figure 4).

Discussion and Conclusions

Fractal coated leads exhibited better sensitivity than polished electrodes at pacemaker replacement and at the follow-up control 8 months later, with the results being consistent in time. This is due to the unique "porous" surface structure of fractal coating, resulting

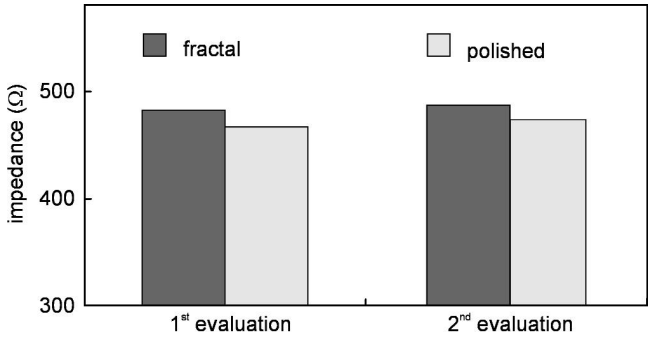

Figure 2. Mean pacing impedance in fractal coated versus polished screw-in electrodes (ventricular position). The first evaluation was conducted at pacemaker replacement, the second 8 months later.

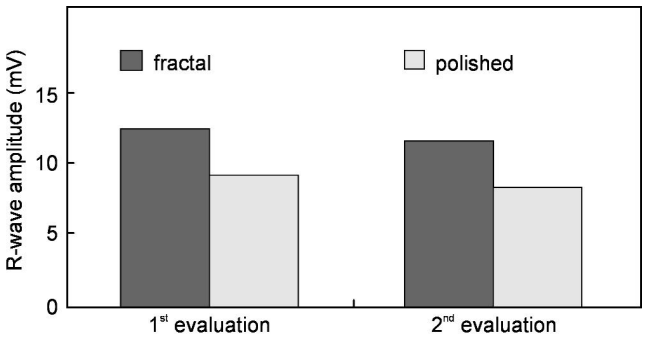

Figure 4. Mean R-wave amplitudes in fractal coated versus polished screw-in electrodes during pacemaker replacement and 8 months later (ventricular position).

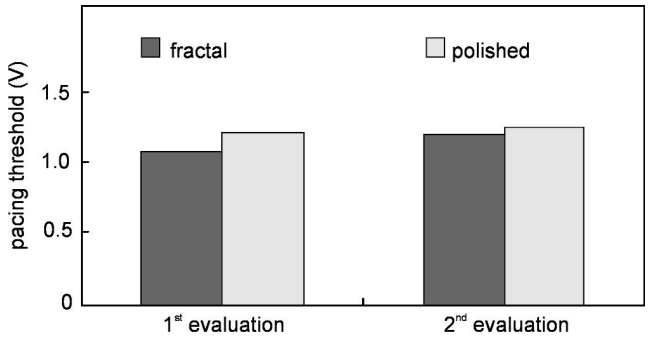

Figure 3. Mean pacing thresholds in fractal coated versus polished screw-in electrodes during pacemaker replacement and 8 months later (ventricular position).

in a 1000 times greater electrochemically active area than that in conventional polished electrodes with the similar geometry. The difference in pacing impedance and pacing thresholds between two surface technologies was insignificant, probably due to the relatively large geometric electrode surface area and the use of active fixation.

Our study indicates that the main advantage of the new fractal coating technology is enhanced sensing of intracardiac signals, bearing the potential for an improved evaluation of the actual status of the heart. This may be of a major importance in modern cardiac pacing systems, where effective sensing of intracardiac signals increasingly permit introduction of new diagnostic and therapeutic pacemaker functions. Based on the proven high biocompatibility of the iridium and the high-quality sensing demonstrated by fractal surface in our study, fractal coated leads may be considered a "key" technology for future development of sophisticated cardiac pacemakers.

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