Clinical Evaluation of Epicardial Fractal Coated Pacing Leads

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Summary

The performance of sixteen ELC 54 epicardial fractal coated screw-in leads was (BIOTRONIK) studied over a period of 18 months. The ELC 54 leads exhibited markedly lower pacing thresholds than the standard non-fractal epicardial screw-in control group. The thresholds of the epicardial leads were significantly higher than those in endocardial fractal ones, as expected, maintaining their maximum even in the third month after implant. Therefore, we recommend reducing the pacemaker energy output of ELC 54 leads later (during the 3rd to the 6th month after implantation) than with endocardial leads (in the 6th week). A low impedance observed with the ELC 54 leads appears to be disadvantageous, since it additionally increases the pacemaker current drain.

Key Words

Fractal surface structure, epicardial leads, pacing threshold, pacing impedance

Introduction

An ideal pacing lead is supposed to meet the following requirements: low pacing thresholds, high and stable cardiac signals, and low-volt polarization artifacts. The fractal coated lead tip design strikes a good compromise between these controversial demands. The metallic fractal layer is based on thin-film technology and obtained by bias sputtering. The typically cauliflower-like, microscopic surface structure enlarges the electrochemically active area by a factor of more than 1.000, yet the geometric size of the tip remains small. Featuring a high current density and low pacing thresholds, such a tip strongly reduces the undesirable polarization artifact voltage and reliably senses intracardiac signals [1-8].

Comparative studies [1-3][7] of long-term performance have shown that the fractal structure in endocardial leads was capable of keeping both acute and chronic thresholds at a low level that was comparable to steroid-eluting leads [9-12].

Even though transvenous access has gained greater popularity than epicardial lead placement, there is a continuous need for epicardial lead insertion in infants, small children, and also in adults with cardiac or vascular abnormalities which preclude the transvenous approach to cardiac pacing. Limited indications for epicardial pacing exist, namely for: patients undergoing open-heart surgery or in whom an infected endocardial lead has been removed, thrombotic conditions, endocarditis, right-to-left shunts, or after tricuspid valve replacement. Therefore, a reliable epicardial electrode possessing low thresholds is still in great demand [13][14].

To our knowledge, no clinical, comparative epicardial threshold data have been reported for conventional versus fractal leads. The objective of our prospective study was to assess whether the iridium fractal structure improves the performance of an epicardial screw-in lead, as well as repeatedly proven in endocardial leads.

Materials and Methods

ELC 54 (BIOTRONIK) is a unipolar, epicardial screw-in lead, 54 cm long with silicone insulation (figure 1). The geometric electrically active area of the screw

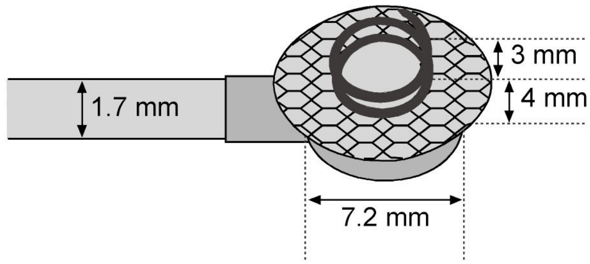

Figure 1. A tip of the ELC 54 lead.

amounts to 10 mm^2 and is coated with the fractal layer of iridium. The penetration depth of the screw is 3.5 mm (used in adults) or 2.0 mm (used in pediatrics). This lead was implanted by thoracotomy in 16 patients who underwent heart surgery and was placed on the right ventricle anterior wall after the spot of the lowest possible pacing threshold has been found. The group of patients was made of two subgroups: of 7 adults aged 50 - 77 (mean 63.0) years and of 9 children aged 0.2 - 18.7 (mean 5.3) years. The patients were implanted with the DDD/R or VVI/R pacemakers Physios TC, Dromos DR or Dromos SR (all BIOTRONIK). Intraoperative measurements were performed with the analyzer ERA 300 or ERA 20 (BIOTRONIK). Pacing thresholds at four different pulse widths (of 0.25, 0.5, 0.75 and 1.0 ms) were regularly taken 7 days, 1, 3, 6, 12 and 18 months after implant using the high resolution threshold test (steps by 0.1 V). The R-wave amplitude was evaluated by filtered intracardiac electrogram. The pacing impedance was measured at 4.8 V by pacemaker telemetry. The obtained values were compared with two control groups of unipolar ventricular leads:

1) Endocardial iridium coated fractal leads TIR 60-UP (BIOTRONIK) of geometric area of 6 mm^2, n = 14.
2) Epicardial non-fractal screw-in leads ML 150 or ML 160 Pt-Ir (BIOTRONIK) of geometric active area of 6 mm^2 or 6917A Pt-Ir (Medtronic) leads of geometric area of 10 mm^2, n = 16.

Both subgroups of the patients were pooled. This has been supported by the fact that
1) there is no difference in myocardial metabolic pathways between adults and children,
2) no significant difference has been found between the threshold results in both subgroups (p = 0.5224).

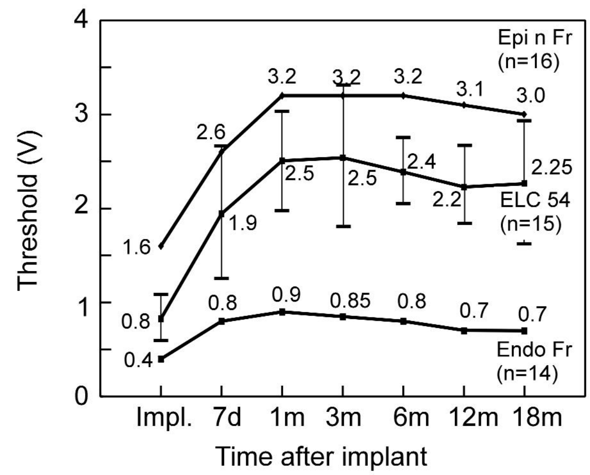

Figure 2. Mean pacing thresholds in the ELC 54 lead and in two control groups. (Epi n Fr = epicardial non-fractal leads, Endo Fr = endocardial fractal leads.)

Statistics

1. ANOVA with repeated measurements, Dunnet's test,
2. t-test.

Results

The 18-year-old boy was excluded from the threshold analysis in view of progressive increase of pacing threshold resulting in permanent exit block.

The iridium fractal coating suppressed the pacing threshold in the epicardial screw-in leads in comparison with conventional epicardial screw-in electrodes (figure 2). Both groups have differed significantly at the 12th month after implant (t-test, p = 0.0392), nevertheless, the statistical significance has not been found in the 1st (p = 0.4811), 6th (p = 0.1358) and 18th (p = 0.2416) months due to wide range of values. The ELC 54 threshold curve has significantly exceeded that of the endocardial fractal control group (p < 0.05 at least) and has reached its maximum in the 1st month after insertion maintaining it until the 3rd month, i.e. in the same way as the non-fractal epicardial group, but longer than the endocardial fractal group has done. The threshold values have gradually gone down in all types of the leads in chronic stage (figure 2).

After a sharp drop within 7 postimplant days, the R-wave amplitude has gradually risen over the follow-up period (figure 3). The pacing impedance has sharply fallen after the implant while a slight rise has been

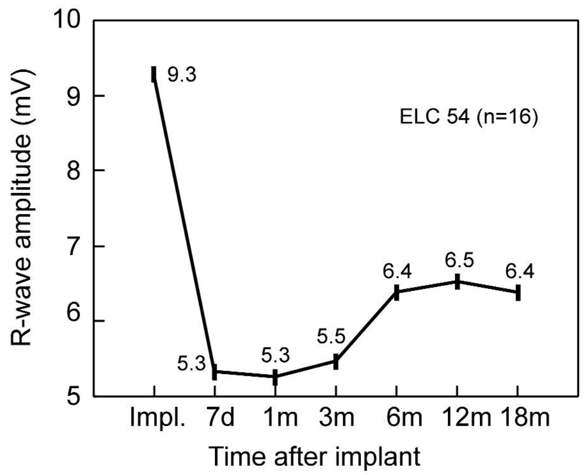

Figure 3. Mean R-wave amplitude in the ELC 54 lead.

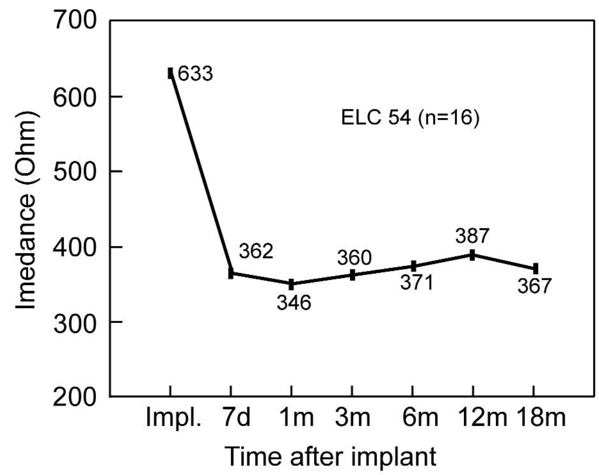

Figure 4. Mean pacing impedance in the ELC 54 lead.

observed in the chronic stage (figure 4). The impedance in ELC 54 has been significantly lower in the chronic stage (one year after implant) as compared to the epicardial non-fractal leads (t-test, $p = 0.0108$) and to the endocardial fractal leads (t-test, $p = 0.0253$) (figure 5).

Discussion

Our findings in the endocardial fractal leads have shown their excellent performance and have confirmed the other author's results [1][8][9][17][20][21].

It is generally known that epicardial leads show distinctly higher pacing thresholds than the endocardial ones, presumably because of more expressed cellular infiltration and fibrotic production [2][6][11].

Occassional comparative studies in epicardial electrodes have shown high pacing thresholds in stab-on Pt alloy leads [5][14], which have exceeded those in screw-in conventional leads in the Kugler's study [14] as well as those in our non-fractal screw-in epicardial group. Chronic values in non-fractal fish-hooked Osypka MP models [2][3], in non-fractal screw-in leads [7], as well as in non-fractal stab-on versions [7][12] were oscillating around 3 V at 0.5 ms reaching their maximum from the 3rd to the 6th months after implant. Our measurements in the epicardial non-fractal control group are entirely consistent with above mentioned findings (figure 2).

Karpawich [11], who compared conventional polished stab-on epicardial leads with those of the same design but with the platinized finish of the tip, which significantly enlarges the true microscopic surface area, found in puppies both acute and chronic thresholds distinctly lower in the platinized group. Moreover, his histological findings clearly demonstrated less cellular and fibrotic infiltration in the platinized electrode. Also Galloni [4] verified milder inflammatory response in sheep in fine-textured endocardial leads than in the uncoated ones. In this connection keeping electrochemical reactions and their products, which can induce chemical inflammation, down by a large surface should be taken into consideration [8] when explaining lower threshold values. Regrettably, such comparison

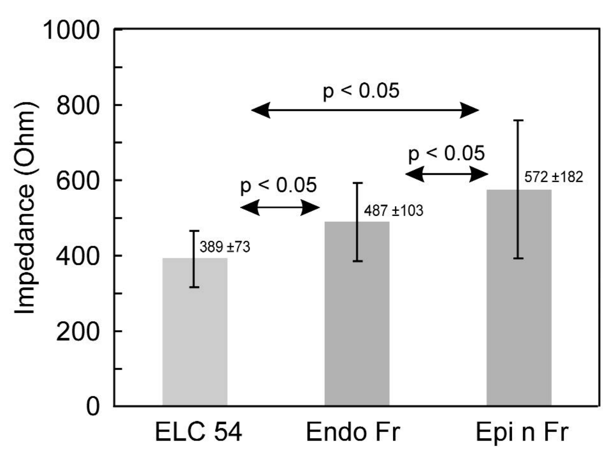

Figure 5. Pacing impedance in the ELC 54 lead as compared to both control groups 1 year after implant.

between standard and fine-textured large-surface epicardial leads is still lacking in humans. Thanks to the fractal structure first of all, and also to the screw-in mechanism, the ELC 54 has met expectations of lower pacing thresholds in comparison with the conventional epicardial leads in our study. Both the ELC 54 and the control epicardial non-fractal group have comparable geometric area and the same penetration depth of the screw. Thus it is possible to expect similar mechanical properties, similar damage of the myocardium and comparable current density in the vicinity of the screw. The main difference is just the fractal finish that has been proved to decrease adverse polarization voltage [1][17] and to exhibit low thresholds. This merit as well as the anticipated less tissue reaction around the tip [4][11] could be possibly the cause of striking improvement in thresholds in the ELC 54.

As for the low chronic impedance of the ELC 54, which has significantly differed from our non-fractal epicardial group, only Johns [10] and Esperer [2] reported on such low values in standard epicardial leads, whereas other authors found it mostly above 500 Ohms [3][5][11][12]. We find such a low impedance a flaw especially in the epicardial leads with respect to their pacing thresholds of a higher level. Low pacing impedance, together with a high pacing threshold, increases the current drain of the pacemaker reducing its longevity.

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