Electrophysiologic Performance of a New Iridium-Coated Electrode with Reduced Surface Area: A One-Year Study

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Summary

Pacing leads substantially determine the efficacy and - with increasingly smaller battery capacities, in particular - the lifetime of a pacemaker. Additionally, the sensing abilities of low-polarization leads amplify the diagnostic functions of the system beyond the mere measurement of P- and R-wave amplitudes, allowing, e.g., the detection of evoked potentials. This study evaluates the electrophysiologic parameters of a unipolar, fractal iridium-coated electrode with a geometric surface area of 3.5 mm^2 and passive fixation at the ventricular position. The electrode was implanted in 20 patients subjected to a one-year follow-up period. During implantation, a mean pacing threshold of 0.34 V at 0.50 ms was measured. After a temporary rise from 8 to 30 days following implantation, effective pacing was still possible with a mean chronic pacing threshold of 0.63 V at 0.50 ms at the one-year follow-up. The mean R-wave amplitude remained stable and high (16.56 mV at the time of implantation, 15.96 mV after one year). The mean pacing impedance of the electrode was 627 W during implantation, decreasing after 8 days. A mean chronic pacing impedance of 553 W was measured after one year. Thus, pacing impedance during implantation and after one year was about 100 W higher than in an electrode of the same design but with a stimulation surface area of 6 mm^2. Complications, such as dislocation, exit block, or loss of sensing, did not occur. The electrode described allows an energetically advantageous programming of the pacemaker system due to low threshold values, which extends battery longevity. The higher pacing impedance further reduces the charge needed for effective stimulation, but not as much as high-impedance leads with even smaller surface areas. Stable sensing throughout the follow-up period and stimulation values indicating a low electrode polarization further demonstrate the favorable electrophysiologic behavior of the electrode studied.

Key Words

Pacing leads, fractal coated electrodes, sensing and pacing thresholds, impedance, polarization

Introduction

Electrode performance largely determines the efficacy of a pacemaker system. Requirements include good handling during implantation (i.e., small diameter, smooth surface, good maneuverability, good radiological visibility, easy-to-operate fixation mechanism) and optimal mechanical properties (reliable insulation and long-term stability of the coil(s), in particular).

Research is increasingly focused on bioelectrical and electrochemical properties of the electrode tip. Through advances in the materials used, unique surface treatments, and special mechanisms, such as a local steroid release, biocompatibility has been improved, and the rejection reaction at the electrode/myocardium interface has been reduced in the last few years. Within this context, there are different aspects of lead optimization:

- Reducing the energy necessary for effective pacing. This task is of particular importance due to constantly decreasing battery capacities [1].
- Improving electrode sensing properties. This aspect addresses the desire to eliminate sensing problems found in unipolar electrodes. Information about the efficacy of intrinsic pacing or the analysis of evoked and monophasic potentials also expands the range of possibilities for pacemaker therapy [2][3].

The fractal electrode serves as a beacon of technical

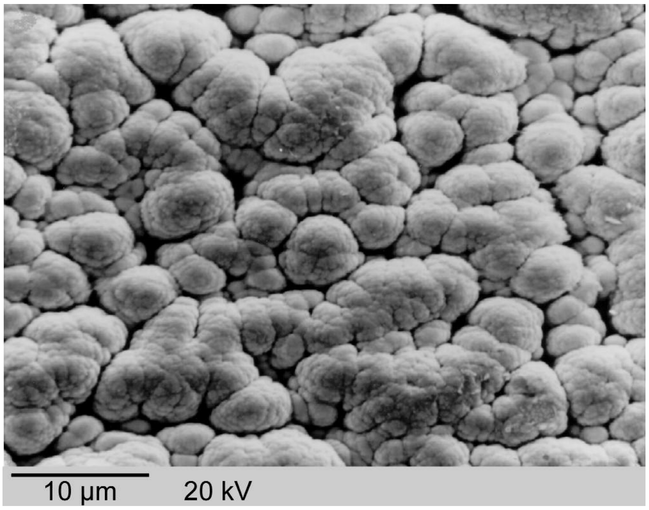

Figure 1. Fractal structure of iridium-coated electrodes [4].

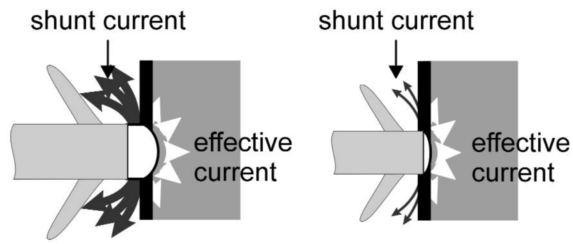

Figure 2. Wasteful shunt current flowing into the more conductive blood rather than the myocardium.

progress in lead technology. By physical vapor deposition (PVD), titanium electrodes are coated with an iridium layer, which exhibits a "cauliflower-like" surface under the electron microscope. Upon increased magnification, nearly identical substructures are seen within this structure. Following the fractal principle known from chaos theory, when these substructures are further magnified, an iterative pattern is observed. Thus, electrode surfaces treated in this manner are labeled fractal electrodes (figure 1).

The fractal treated electrodes possess an electrochemically active surface that is larger than the geometric surface by a factor of more than 1000 [4][5], affording a distinct advantage in sensing intrinsic myocardial actions. Such an enlargement reduces polarization, a phenomenon that inhibits the sensing of intrinsic actions and the sensing of pacing efficacy, as an afterpotential is formed. High polarization adversely affects the pacing threshold as well.

With the electrochemically active surface gained, it is possible to reduce the geometric surface area of the electrode tip. A smaller tip decreases the shunt current between the electrode tip and the blood (figure 2). This current flows through the blood because it is more conductive than the myocardium. As a result, limited resources for myocardial stimulation are wasted, and the pacing threshold increases. Conversely, the critical value for surface area in conventional electrodes is between 5 and 6 mm^2; if the area is any less, pacing and sensing properties worsen due to polarization [6][7].

Furthermore, an energy-saving in pacing can be expected with an improved contact between the electrode tip and the myocardium. A higher pacing impedance is a direct result of better insulation from the blood. In addition, the field density is increased because of the smaller geometric surface, which again favorably influences the pacing threshold.

Last but not least, the use of a highly inert and biocompatible material at the electrode/myocardium interface reduces the rejection reaction, thus keeping small the diameter of the scarred capsule of fibrotic tissue surrounding the electrode. Again, ability to sense intrinsic actions is heightened, and less energy is needed to pace the myocardium. These considerations form the basis for designing an electrode with a fractal iridium-coated surface.

The presented study explores whether the assertions outlined above indeed result in a clinical improvement of pacemaker leads. In particular, the following questions were pursued:

- Does this lead afford both an acute and chronic favorable pacing threshold?
- Do more dislocations occur due to the smaller area of contact between the electrode tip and myocardium?
- Does lead impedance increase as an indication of a decreased contact with the surrounding blood?
- Does the electrode sense intrinsic actions sufficiently?

Methods

Twenty consecutive patients (9 female, 11 male; mean age 74.9 ± 8.9) with indications for VVI pacemaker implantation were admitted to the study. Sixteen of the patients had chronic atrial fibrillation and intermittently impaired AV conduction or interruptions longer than

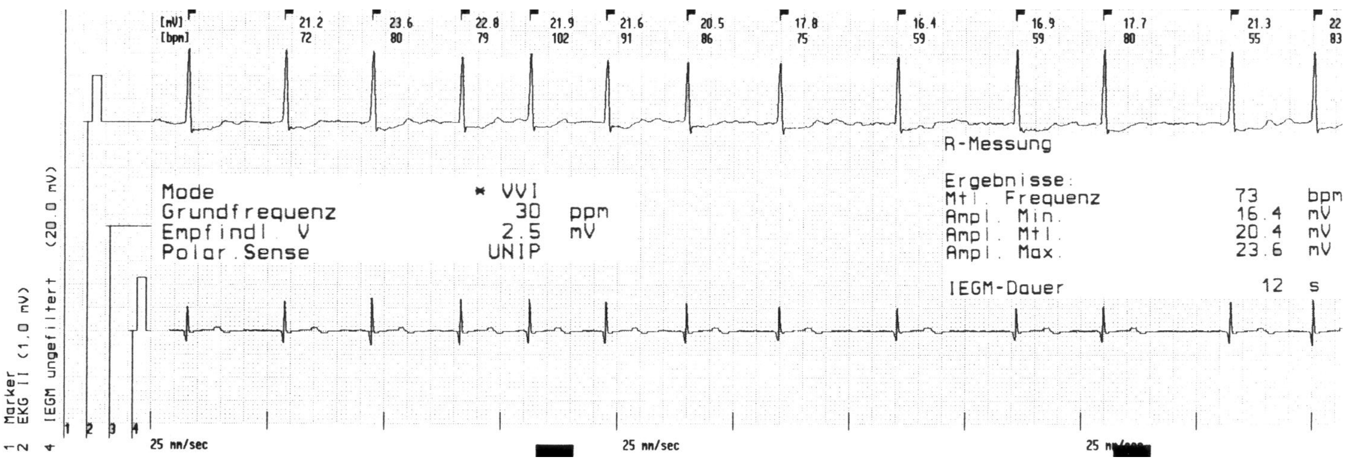

Figure 3. A breakdown of the automatic sensing test print-out. 1) marker 2) sensed R-wave amplitude in mV 3) heart rate in bpm 4) surface ECG 5) ventricular IEGM (here unfiltered).

4s, 2 patients had chronic atrial fibrillation and permanently impaired AV conduction, and 2 patients showed rare SA blocks and interruptions longer than 4 s.

A TIR 60-UP/V 131 lead (current commercial name: Polyrox or PX 60-UP, BIOTRONIK) was implanted at the ventricular position in each of the patients. This unipolar, passive-fixation (with tines) lead possesses a titanium electrode tip that is fractally coated with iridium and has a lens-shaped geometric surface with an area of 3.5 mm^2. The lead body is made of MP35N®, a nickel, chrome, cobalt, and molybdenum alloy, and is sheathed with silicone for insulation. The diameter is 1.7 mm. Lead resistance is 1.2 Ω/cm.

The leads were connected to the Pikos 01 VVI pacemaker (BIOTRONIK). This pacemaker offers telemetric functions in measuring pacing thresholds for impulse lengths of 0.25 ms, 0.50 ms, 0.75 ms, and 1.0 ms in 0.1 V increments within the range of 0.1 V to 4.8 V.

In addition to the telemetric interrogation of the filtered and unfiltered intracardiac signals, there is an automatic sensing test. During this test, the surface ECG and the ventricular intracardiac electrogram (IEGM) spanning 12 s are printed out; the heart rate and the signal amplitude sensed by the pacemaker are analyzed from beat to beat. Finally, the minimum, medium, and maximum signal amplitudes during the test period, as well as the heart rate, are printed (figure 3). The telemetric functions can interrogate: lead impedance; the voltage, current, energy, and charge of the pulse; and the voltage, current, and impedance of the battery.

The lead was implanted in the right ventricular apex. Intraoperative measurements were taken by a PSA 5311 (Medtronic) device. Intraoperatively, a minimum of 3 R-wave amplitudes (in mV) and the signal slew rate (in V/s) were determined. Furthermore, the pacing threshold (in V) at 0.50 ms, the pacing threshold current flow (in mA), and the lead impedance (in Ω at 5.0 V) were measured. For the 2 patients with intact sinus rhythm, retrograde conduction was ruled out. Diaphragmatic stimulation due to the unipolar configuration did not occur in any patient with 10 V pacing at 0.50 ms. The R-wave amplitude and the pacing threshold measurements were repeated after fixating the electrode at the point of lead insertion. This measure assisted in ruling out dislocations caused by lead manipulation during suturing. It also helped in checking whether values were still stable 5 min after the initial measurement. Finally, an X-ray was taken to document lead position.

Lead position had to fulfill the following conditions:

- R-wave amplitudes larger than 6 mV with a deviation smaller 20%
- Pacing threshold smaller than 1.0 V at 0.50 ms
- Impedance larger than 500 Ω at 5.0 V.

Postoperatively, the following parameters were telemetrically determined with the PMS 1000 (BIOTRONIK) 4 to 24 hours after implantation and also after 8, 30, 90, 180 and 360 days:

- Pacing threshold at 0.50 ms, with a 0.1-V resolution
- R-wave amplitude per automatic sensing test (figure 3). The patient was in the supine position, breathing normally. The pacemaker was temporarily pro-

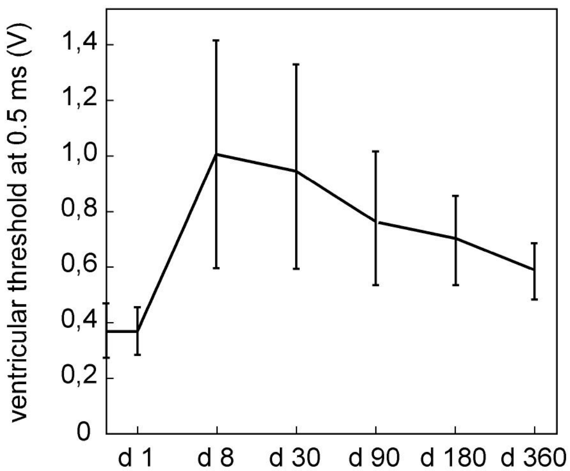

Figure 4. Averages and standard deviations for pacing thresholds at 0.50 ms pulse length.

grammed to VVI at 30 ppm.

- Lead impedance was measured telemetrically while pacing at 4.8 V for 0.50 ms (resolution: 1 Ω).

Results

Since the same implantation criteria as for conventional electrodes were applied, pacing thresholds smaller than 1.0 V at 0.50 ms were accepted. The leads were not repositioned to achieve better values. The average acute pacing threshold attained during implantation was 0.34 V at 0.50 ms. Intraoperatively, 5 patients had pacing thresholds of 0.2 V, 8 had 0.3 V, and 4 had 0.4 V. One patient each had values of 0.5 V, 0.6 V, and 0.7 V. Within 24 hours postoperatively, telemetric values largely corresponded to the intraoperative measurements.

Subsequently, the mean pacing threshold increased with maxima from 8 to 30 days after implantation. Individually, pacing thresholds changed at different rates: in 9 patients, there was a typical increase above 1 V on day 8; in 8 patients, on day 30 as well. Likewise, 11 patients showed continual pacing thresholds smaller than 1.0 V throughout the entire follow-up period. All patients showed pacing thresholds less than 1.0 V one year after implantation, the same applied for 14 patients who already underwent the 18-month follow-up examination. A continual decrease was notable in the average pacing thresholds from day 8 (1.05 V) to day 360 (0.63 V).

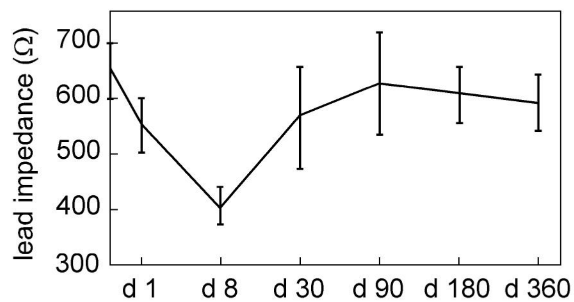

Figure 5. Averages and standard deviations for lead impedance at 4.8 V.

In 5 patients, the typical post-operative increase in the pacing threshold was completely absent, measuring not more than 0.3 V. Especially the patient with an intraoperative pacing threshold of 0.7 V showed a decrease to 0.6 V from day 1 to day 180, and then to 0.5 V (12 and 18 months after implantation).

On average, the pacing impedance was larger than 600 Ω at 5.0 V during implantation. Chronically, impedance was relatively high throughout days 90 to 360 with values ranging from 550 to 600 Ω at 4.8 V.

Two observations were made: The pacing threshold increased at the postoperative stage, and pacing impedance decreased, especially on day 8. These actions reflect the typical course of a reaction to a foreign body, thus the formation of an inflammatory edema possessing "good" conduction properties, which lowers pacing impedance and raises the pacing threshold. Fibrotic tissue eventually forms, leading to an increase in impedance.

Pacing at different voltage amplitudes caused only slight impedance changes. Eight patients were paced at 2.4 V and 4.8 V at 0.50 ms; the average change in impedance was 42 Ω. This effect can be interpreted as an indication of the low lead polarization due to a higher phase capacity.

The average R-wave amplitude remained above 15 mV for the entire patient group. Only on day 8 did the average R-wave amplitude fall (14.6 mV), coinciding with the minimum pacing impedance. Intrinsic event sensing chronically remained stable throughout the entire patient population. While intra-individual values hardly changed, notable differences existed from patient to patient. Among individual patients, sensing ranged from 6.0 mV to 24.7 mV after one year.

Lead dislocation, which would lead to an exit block, sensing loss, or floating, did not occur. If one defines micro-dislocation as a clear increase in the pacing threshold with a clear reduction of sensed R-wave amplitudes, then the issue can be debated whether electrode position changed slightly in a patient (58 yr). The pacing threshold of this patient increased on day 30 and the R-wave amplitude fell from 28.0 mV on day 1 to 12.9 mV on day 30. Since the sensed R-wave amplitude was nevertheless high, this fluctuation was more likely a pronounced rejection reaction.

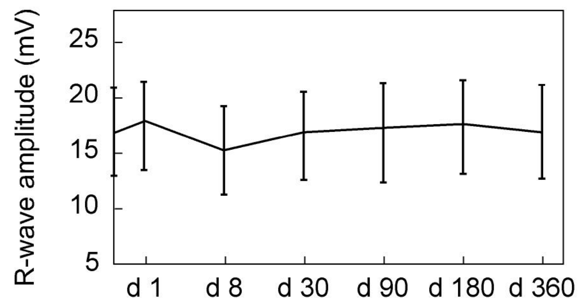

Figure 6. Averages and standard deviations for R-wave amplitudes.

Discussion

Different concepts have been developed for optimizing electrode pacing and sensing properties in cardiac pacemaker therapy: deposition of sintered platinum-iridium fibers [8], metallic powder sputtering (platinum-iridium [9], titanium nitride [10], or iridium oxide [11]), activated carbon coating [12], or releasing steroids (from a reservoir [13] or a membrane-coating [14]). The fractal iridium coating of the titanium electrodes presented in this study is one option to enlarge the electrochemically active surface significantly as compared to its geometric surface. With this method, the polarization effect at the electrode/myocardium phase boundary is reduced, and sensing functions and pacing properties benefit optimally.

The geometric surface of the lead investigated was reduced from the conventional 6 to 10 mm^2 surface area to 3.5 mm^2. Observations of excellent acute and chronic pacing thresholds altered earlier observations and technical considerations in which pacing thresholds were believed to increase when the surface areas of the electrode tip fell below 6 or 10 mm^2 [6][7]. These investigations were based on electrodes with smooth surfaces (mostly highly polished platinum), which showed high energy losses from polarization. Such results cannot be applied to modern electrodes with treated surfaces [15].

Low polarization leads allow reduction to a 3.5 mm^2 geometric surface without energy-losses incurred by polarization. The observed lack of correlation between pacing impedance and pacing amplitude can be evaluated as an indication that the phase boundary capacity of a 3.5 mm^2 surface area pacing at 4.8 V at 0.50 ms has not yet been exhausted.

Many factors can be attributed as causes for the permanently favorable pacing thresholds of the electrode examined:

- Good biocompatibility, reducing fibrotic encapsulation of the electrode tip.
- Increased field density.
- Reduced shunt current.
- Reduced polarization-related energy losses.

In spite of good pacing and sensing results, a reaction to a foreign body was apparent in the electrodes studied. The pacing threshold increase accompanied by an impedance decrease and a slight R-wave amplitude reduction between day 8 and day 30 showed the development of an inflammatory edema. This reaction is common in conventional electrode implantation. The continual decrease in pacing thresholds, which persists even after a year, supports good overall biocompatibility.

As to how much the reduction in shunt current accounts for good acute and chronic pacing thresholds cannot be judged by this study. The favorable average pacing impedance discovered, ranging from 500 to 600 Ω, is approximately 100 Ω higher than than for 6 mm^2 fractal electrodes [16], yet approximately 200 to 300 Ω lower than for 1.3 mm^2 fractal electrodes [16-18].

At implantation, the same methods for lead handling and data measurement as in conventional electrodes were used in this study: a pacing impedance of approximately more than 500 Ω at 5.0 V was accepted, and the impedance variability was not verified by multiple measurements intraoperatively. In contrast, when implanting comparable high-impedance leads, some authors only accept electrode positions if the pacing impedance is higher than 900 Ω and the variability less than 100 Ω during implantation [22].

No cases of (micro-)dislocation nor myocardial perfor-

	Geometric surface	n	Implantation	Day 1	Day 8	Day 30	> Day 180
Fröhlig [17]	10.0	20	0.52 - 441				
Fröhlich [20]	10.0	38	0.52 13.8 -	0.48 13.4 -	0.96 13.7 -	0.91 13.9 -	0.88 13.2 -
Veneziani [19]	6.0	156	0.38 13.1 882		0.63 10.4 695		0.39 12.7 777
Kamaryt [16]	6.0	46		0.45 - 433	1.23 - 360	1.32 - 458	0.94 - 502
BIOTRONIK Database	5.0	123	0.48 12.5 769	0.33 7.8 526	0.72 6.9 508	0.74 7.2 570	0.44 7.7 593
Israel	3.5	20	0.34 16.6 627	0.36 17.5 548	1.05 14.6 424	1.02 16.1 575	0.63 16 553
Kamaryt [16]	1.3	59	0.35 - 910	0.37 - 746	0.93 - 636	0.9 - 831	0.62 - 886
Fonteyne [21]	1.3	58	0.4 13.6 1089		0.5 13 895	0.7 13.6 994	0.5 15 1041
Pioger [18]	1.3	195	0.34 12.4 1067			1.01 12.8 1106	0.74 - 1183

Table 1. Comparison of electrophysiologic characteristics of fractal electrodes with differing geometric surfaces. Geometric surface in mm^2, n: number of patients. Data concerning the mean pacing threshold (at 0.50 ms in V, upper line) , R-wave amplitude (in mV, middle line) and pacing impedance (at 4.8 to 5 V in W, lower line) are provided under the columns Implantation, Day 1, Day 8, Day 30, ³ Day 180.

ation occurred. Electrode handling appeared similar to conventional unipolar ventricular electrodes with surface areas of 6 mm^2 to 10 mm^2. The same cannot be said of electrodes with a 1.3 mm^2 geometric surface area. For example, the SX 60-UP electrode incurred cases of micro-dislocation and pacing threshold increases (> 4 V), therefore, a modified implantation technique is suggested [18].

The favorable long-term pacing thresholds attained with the researched leads are especially important in light of reduced battery capacities of modern pacemakers: While the 1978 to 1982 models had an average capacity of 1.7 Ah (average service lifetime: 9.7 years), the 1988 to 1992 models had a 1.0 Ah capacity (average service lifetime: 6.2 years) [1]. This tendency has ensued. Meanwhile, models are sold that possess 0.37 Ah capacities. But the smaller batteries contribute also to smaller pacemakers, which entail an improved cosmetic effect. Only leads that enable low acute and chronic pacing thresholds and stimulation pulses with less than 2.5 V at 0.50 ms can support an adequate service lifetime in these miniaturized devices.

In the presented study, sensing properties were very good. Properties at the myocardium/electrode interface, such as low polarization and good biocompatibility, are more significant for optimal sensing than the mere area of geometric surfaces [6][23]. Furthermore, the bandpass response of electrode and battery input filter must be matched [24].

The electrophysiologic properties of the studied fractal iridium coated lead and electrodes of another design are represented in table 1. However, methods for determining pacing thresholds, sensing, and impedance varied. Often the resolution during pacing thresholds capture at 0.50 ms is not stated, and also the voltage used to measure pacing impedance. Patients numbers (the table reflects the initial number of study participants) decreased in many studies. In one case, only the data of 23 of the initial 195 patients were recorded after 12 months [18]. In this study, all 20 patients were examined at the one-year follow-up.

Conclusion

The lead studied showed favorable pacing and sensing properties, both acutely and chronically over the course of a year. In spite of the small electrode tip, neither (micro-)dislocation nor myocardial perforation occurred. Intraoperative handling was comparable to that of electrodes with larger stimulation surfaces.

In spite of high biocompatibility, shown by low chronic pacing thresholds and high R-wave amplitudes after one year, there was an acutely visible reaction to the foreign body in a large majority of the patients. Indications for such included a pacing threshold increase, a discrete decrease in R-wave amplitudes, and a clear decrease of the pacing impedance 8 to 30 days after implantation. The lack of correlation between pacing impedance and the programmed pacing amplitude and duration indicates a high phase boundary capacity with low electrode polarization.

Unlike electrodes with geometric surfaces smaller than 2 mm^2, there was no high impedance response in the leads studied, thus a lesser reduction of the shunt current must be assumed. However, the advantage of 3.5 mm^2 leads is that the same intraoperative procedures and intraoperatively accepted threshold values for conventional leads can be applied.

Reports by the Danish Pacemaker Register [25], for example, show higher long-term failure rates for bipolar than for unipolar leads, making the latter the lead system of choice for some authors [26]. Optimal sensing of intracardiac signals is of great importance when using unipolar leads. By sensing intrinsic activities well, the system can be programmed less sensitive, thus eliminating any oversensing problems.

Improved electrode sensing opens new fields of application for low polarization pacemakers: efficacy control of intrinsic pacing with artifact-free (afterpotentials) IEGMs; evoked potentials analysis, which could serve as an indication for implant rejection after a heart transplant [2]; and monophasic action potential analysis, e.g., searching for morphological signal changes shortly before atrial or ventricular fibrillation [3].

Excellent performance in both pacing and sensing, as found in the studied lead, will become a prerequisite in this age of pacemakers with reduced dimensions and lower battery capacities, yet an expanded array of functions.

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