The Fractally Coated Lead as Implantable Sensor for Monophasic Action Potentials

R. FRÖHLICH, T. WETZIG, A. BOLZ, M. SCHALDACH
Department of Biomedical Engineering, University of Erlangen-Nürnberg, Erlangen, Germany

Summary

Experience gained with fractally coated leads for cardiac pacemakers has already demonstrated the excellent long-term stability and biocompatibility of these leads. In this paper the properties of fractally coated leads in terms of extended signal detection performance are discussed. In-vitro investigations prove that due to their large active surface area, fractally coated leads have lower impedance than Ag/AgCl-electrodes over a wide frequency range. The results of clinical investigations comparing the detection performance of fractally coated and Ag/AgCl-electrodes show the very high correlation between MAPs measured with both types of electrodes. However, biocompatibility and long-term stability of fractally coated leads render them suitable for implantation. A recently designed implantable pacing lead allows the monitoring of MAPs with implantable devices for the first time.

Key Words

fractally coated lead, silver-silverchloride electrode, monophasic action potential

Introduction

Pacemaker electrodes as the interface between synthetic implants and living tissue determine decisively both the quality of detected signals as well as efficiency and power-consumption of stimulation. So far, the development of new pacemaker electrodes was focused on the reduction of energy losses in order to increase lifetime of battery-powered pacemaker systems. Some years ago the design of electrode tips was still dominated by smooth metal surfaces. A decisive reduction of energy consumption was obtained by the use of sintered or etched structures obtained by modern surface technologies and the preparation of electrodes with steroides in order to suppress irritative reactions of tissue.

Furthermore, recent developments in pacemaker therapy aim at a detailed analysis of intracardiac signals and their application for the physiological electrotherapy of the heart. Firstly, the growing complexity of modern pacemaker systems requires the possibility of automatic adaptation of therapeutic parameters to support diagnosis and therapy effectively. Secondly, physiological restoration of lost natural cardiac functions requires exact information about the state of the myocardium. For this purpose in particular the monophasic action potential (MAP) and the ventricular evoked response (VER) contain extensive information about the physiological status of the heart. However, monitoring these signals makes high demands on the pacemaker electrode as sensor.

The MAP represents a summed signal of action potentials from myocardial cells close to the tip of the electrode. Therefore, the analysis of the MAP provides detailed information about numerous physiological and pathophysiological effects on the myocardium. Clinically, the MAP has long been used as a diagnostic tool, e.g. for medication therapy monitoring [7]. All known recordings of the MAP were obtained with Ag/AgCl-electrodes up to now [7][2]. But owing to their toxicity and limited long-term stability Ag/AgCl-electrodes cannot be implanted chronically [3][8]. A sensor system is required, which therefore combines outstanding electrical properties for the measurement of heart potentials with high biocompatibility and long-term stability. Fractally coated leads, widely approved in pacemaker therapy as stimulating electrodes as well as in measuring the ventricular evoked potentials, show decisive advantages: Due to their surface structure they exhibit excellent transmission behavior for the potentials of the heart and negligible polarization artefacts. The inert noble material iridium which is used for the fractal coating provides an unrestricted long-term stability. Therefore, in this study the measurement performance of fractally coated leads is compared to Ag/AgCl-electrodes regarding the monitoring of the MAP. For this purpose different fractally coated leads have been designed and were implanted with respect to the measurement performance of Ag/AgCl- and fractally coated electrodes. To investigate the requirements on the mechanical design of fractally coated pacing leads for reliable chronic MAP measurement the influences of electrode pressure and orientation on MAP recordings were evaluated analyzing MAP measurements on isolated rabbit hearts [9].

Electrode principles

From the clinical point of view high demands are made on the implantable electrode as stimulator and sensor:

- The amount of charge for effective stimulation has to be minimized.
- For measurement of intracardiac signals high amplitudes and a good signal-to-noise-ratio are undispensable requirements.
- For measurement and analysis of heart potentials immediately after stimulus a negligible polarization artefact is necessary.
- Furthermore, electrodes used as permanent implants must comply with high requirements concerning biocompatibility and longterm stability.

From the physical point of view the interface between intracardiac electrode and the myocardium, the so called phase-boundary, is of elementary importance for a profound understanding of the stimulation and detection behaviour.

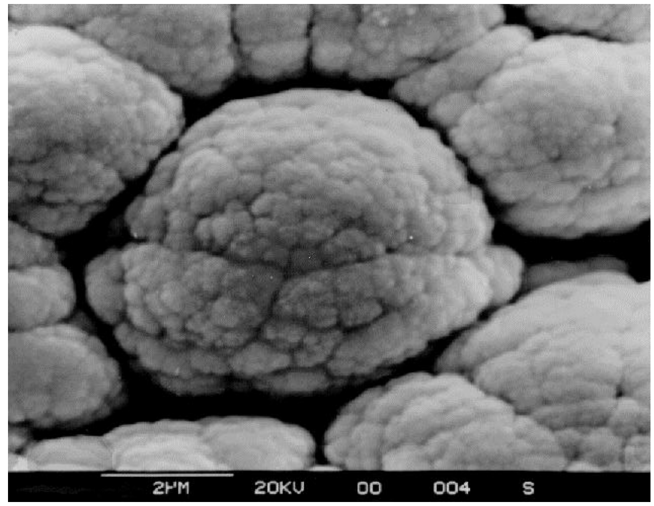

Figure 1. *Scanning electron microscopic picture of the surface structure of fractally coated electrodes*.

At this phase-boundary two different conduction mechanisms meet, electronic conduction in the metal and ionic conduction in the electrolyte. Adsorbation of water molecules at the electrode and hydratation of ions in the solution prevent the electrolyte-ions from direct contact to the electrode surface. According to this, the phase-boundary between solid-state and electrolyte can be modeled as a capacitor. Electrode and electrolyte represent capacitor plates which are separated by a double layer of adsorbated water molecules, the so-called Helmholtz-layer.

The principle of the Ag/AgCl-electrode is well established: According to the applied potential, chloride ions of the electrolyte react reversibly with a silver-chloride layer positioned on the surface of a silver electrode. The resulting current flow across the interface leads to a low interface impedance compared to a smooth metallic surface.

The principle of fractal coatings is based on a geometrical effect: Due to the fractal surface structure (figure 1) the electrode has a very large active surface area which is increased by more than three orders of magnitude. This results in a high electrical capacitance of the interface between electrode and electrolyte being several 1000 times higher than the electrical capacitance of smooth metallic electrodes and to a very low interface impedance.

Figure 2 shows the impedance spectrum of an Ag/AgCl-electrode and a fractally coated electrode

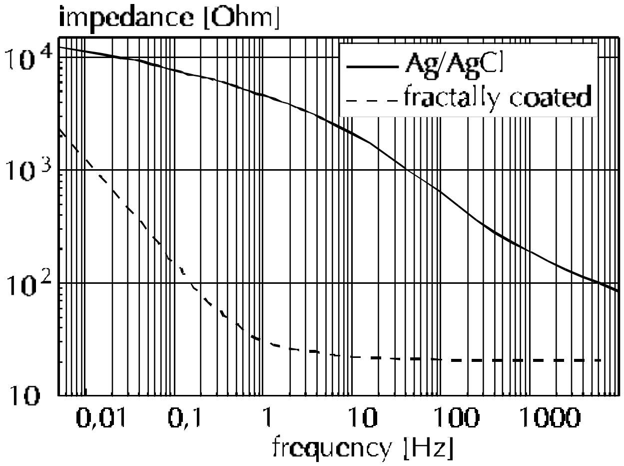

Figure 2. *Frequency spectrum of Ag/AgCl- and fractally coated electrodes measured in physiological saline. In the frequency range below 1 kHz the impedance of the electrode-electrolyte interface is much lower for fractally coated electrodes than for Ag/AgCl-electrodes.*

which demonstrates the high pass characteristics of the interface between electrode and electrolyte. From an electrical point of view the impedance of the interface has to be as low as possible to get an undistorted transmission of heart potentials and a high signal-to-noise ratio. Both electrodes provide low impedances compared to smooth platinum electrodes. The even lower impedance of the electrode-electrolyte interface in case of fractal surface is the prerequisite for a better detection performance than the Ag/AgCl-electrode. Moreover, the low interface impedance of fractally coated leads especially at frequencies of 50 Hz or 60 Hz respectively ensures a higher signal-to-noise ratio.

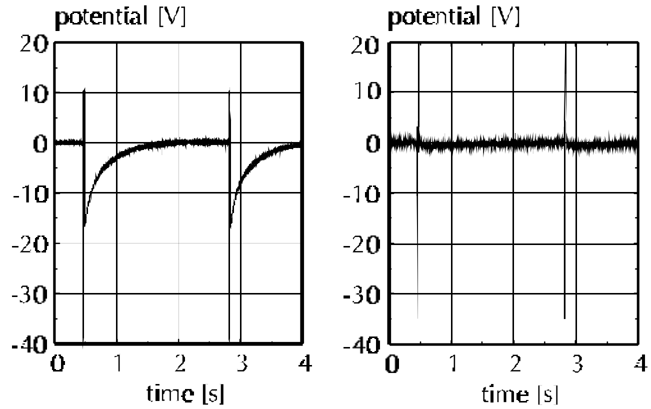

Figure 3. *Polarization artefact of Ag/AgCl- (left) and fractally coated electrodes (right) after stimulation with 4.8 V and 0.5 ms.*

The fractal surface structure provides an additional advantage for the monitoring of the heart's signals immediately after stimulus. During stimulation pulse the phase boundary is charged because of its capacitive characteristics. The remaining charge at the interface leads to a deterioration during sensing, the polarization artefact, which only slowly decays. This potential is superposed to measured signals. Because of this the exact evaluation of heart potentials is impossible using conventional electrodes. Attempts to reduce the polarization artefact by charge-controlled counterpulses appeared not to be useful because of the additional demand of charge. The implantation of additional electrodes for measurement of these signals is not justifiable clinically, too, because of higher risk and effort for the patient. Equal stimulation current transfers equal amount of charge to the capacitor plates. However, the voltage drop between the capacitor plates gets the higher, the smaller the capacitor is.

Thus, the requirement of a high capacity of the phase-boundary represents the only way to reduce the polarization artefact to negligible values (figure 3) [1].

Methods

For in-vivo validation of MAP measurements with fractally coated electrodes a quadrupolar catheter enabling simultaneous MAP recordings with two fractally coated and to Ag/AgCl-electrodes was designed (figure 4). For fractal coating the noble metal iridium is used, because it provides an excellent long-term stability and biocompatibility [6]. This catheter was positioned temporarily into the right ventricle during electrophysiological examinations and the MAP was recorded simultaneously with both pairs of electrodes at the same position in the heart.

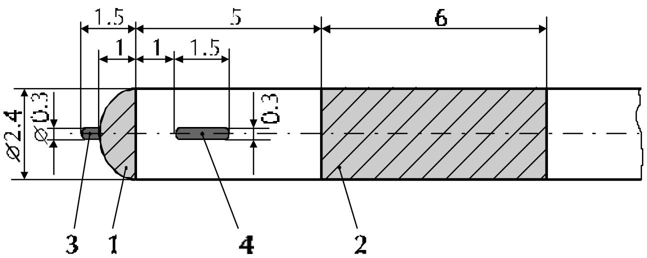

Figure 4. *Catheter with two fractally coated (1,2) as well as two Ag/AgCl-electrodes (3,4).*

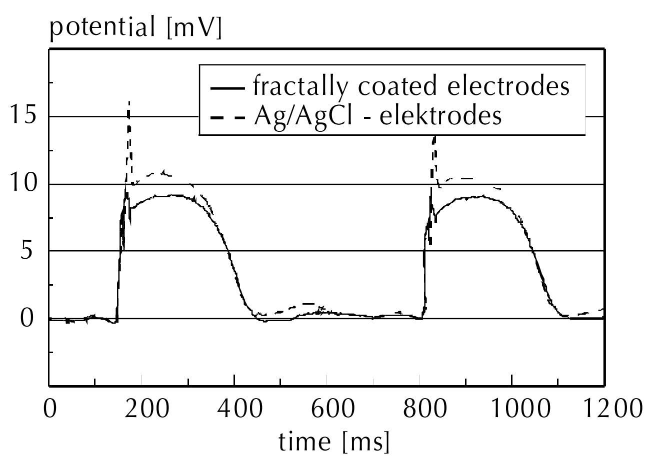

Figure 5. *MAP´s simultaneously measured by fractally coated as well as Ag/AgCl-electrodes*.

To develop an implantable fractally coated electrode the influence of electrode design on the morphology of intracardiac signals has to be investigated. Therefore, the effects of angle between the lead axis in the frontal section of the lead as well as pressure between the different electrode and the myocardium were investigated. Epicardial MAP was recorded in perfused Langendorff preparations of 6 isolated rabbit hearts as described in detail elsewhere [9]. The MAPs were recorded with different levels of electrode pressure (10 to 100 kPa) on the myocardium and for varying angles (10° to 90°) between lead and myocardium. Plateau amplitude as well as MAP-duration at different levels (25, 50, 90%) of repolarization (figure 6) were analyzed for varying electrode pressure. The ratio between R-amplitude and plateau amplitude was evaluated for varying electrode angle.

Results

Using the quadrupolar catheter described above, the fractally coated electrodes were compared to Ag/AgCl-electrodes as a reference. The waveform of the MAP measured with both types of electrodes is nearly identical as it is demonstrated in figure 5. The slightly higher MAP amplitude of the Ag/AgCl-electrode is due to the shape of the catheter. The distal Ag/AgCl-pole is smaller than the distal fractally coated pole and therefore gives rise to a higher pressure between myocardium and electrode resulting in an increased signal amplitude as it is demonstrated later in this article.

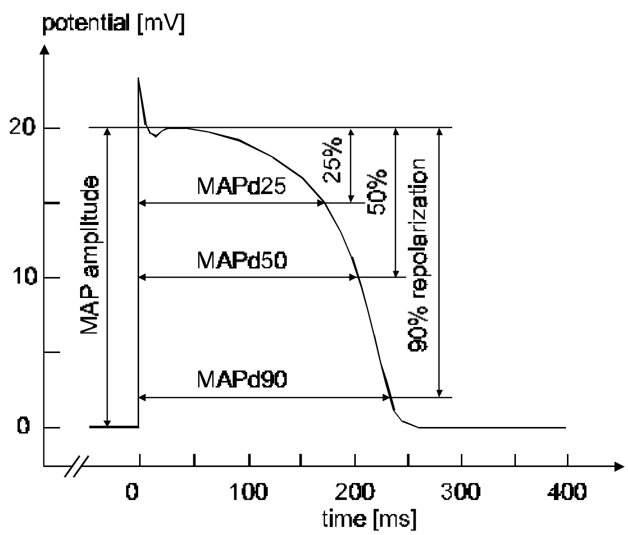

Figure 6. *Definition of MAP-duration by parameters MAPd25, MAPd50, MAPd90.*

In order to get a quantitative criterion for the correlation between the measurement with both sensor types, the MAP durations at 25, 50 and 90%-repolarization (MAPd90) were determined (figure 6). In figure 7 the MAPd90 of Ag/AgCl-electrodes is plotted against the MAPd90 of the corresponding MAP measured with fractally coated electrodes at different MAP durations. A high correlation coefficient between both measurement systems of more than 0.99 is obtained. Similar results are observed for MAPd25 and MAPd50. Therefore the sensing behavior of both sensors is equivalent. The advantage of fractally coated electrodes is a negligible polarization artefact providing the possibility of measuring the MAP after pacing pulses with the same electrodes used for stimulation. As figure 8 shows, intrinsic and stimulated MAPs have nearly the same morphology. This demonstrates, that the MAP is a local signal which does not reflect the propagation of the excitation in the heart, which is different for autonomous and stimulated events.

The investigations mentioned above show that fractal coating provides excellent performance of the electrode-electrolyte interface for the measurement of the MAP. To investigate the requirements for the mechanical design of a chronically implantable MAP-sensor, the influences of angle and pressure between electrode and tissue were observed. The typical MAP morphology is obtained in the range of 60° to 90°. With increasing angles up to the optimal angle of 90° the R-amplitude decreases, whereas an increase of the plateau amplitude is observed [9].

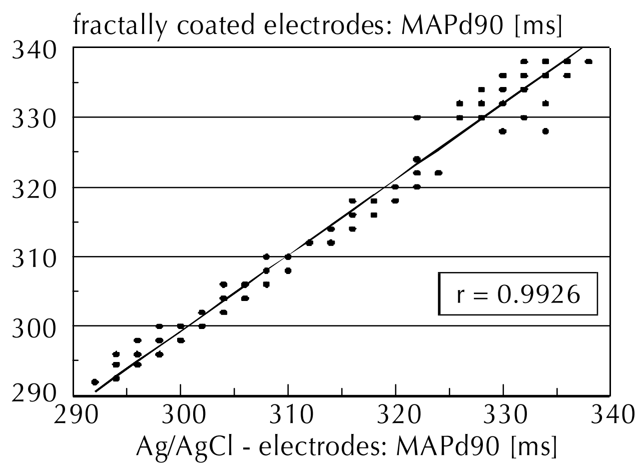

Figure 7. *Correlation of MAPd90 of simultaneously measured MAP´s (Ag/AgCl-electrodes versus fractally coated electrodes).*

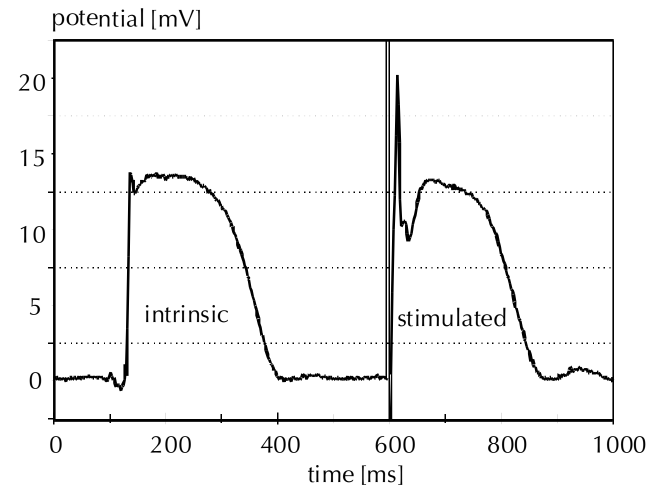

Figure 8. *Comparison of intrinsic and stimulated MAPs using the same pair of electrodes for stimulation and sensing.*

For varying pressure between electrode and myocardium MAP-duration, representing the most common parameter for the MAP analysis remains almost unchanged. Figure 9 shows the MAPd25, MAPd50 and MAPd90 dependent on electrode pressure. In contrast to MAP-duration, the plateau amplitude of the MAP changes significantly for varying electrode pressure. The pressure dependent increase of the plateau amplitude of the MAP can be explained by a growing number of myocytes contributing to the MAP signal. However, since the waveform of the MAP is shown to be independent from the electrode pressure, the pressure between electrode and myocardium is allowed to differ in a wide range. The lower limit of electrode pressure is determined by the lowest plateau amplitude providing a sufficient signal-to-noise ratio. Due to the low impedance of fractally coated electrodes the noise level is usually between two and three times smaller as compared to Ag/AgCl electrodes, so that fractally coated electrodes enable a sufficient signal-to-noise ratio for lower electrode pressure and therefore reduced plateau amplitudes of the MAP.

To fulfill these requirements fractally coated leads with active fixation and a shortened distance between the different and the indifferent electrode were developed (YP 53/10-BP, BIOTRONIK). The active fixation ensures the required minimum pressure between different electrode and myocardium. First clinical MAP measurements were performed with this type of electrodes and a dual chamber pacemaker (Physios CTM 01, BIOTRONIK) with modified atrial and ventricular monitoring channels (bandwidth: 0.33 ... 200 Hz) adapted to the frequency spectrum of the MAP.

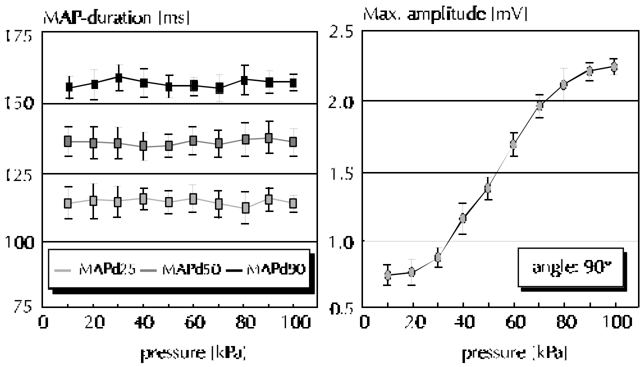

Figure 9. *Influence of electrode-pressure on MAP-duration at angle 90°.*

Conclusions

Fractally coated pacemaker electrodes represent a decisive step forward on the field of electrode development. Fractally coated electrodes have excellent performance regarding conventional parameters as pacing threshold and sensing amplitudes. Low thresholds are required for energy-saving stimulation and longevity of the pacemaker system. Detection of autonomous events with high signal-amplitudes of P- and R-waves allows reliable synchronization of intrinsic activity and electrical stimulation. Based on these advantages fractally coated leads have achieved wide clinical application for implantable pacemakers and cardioverter/defibrillators. Moreover fractal electrodes provide fundamentally new and advanced properties for the use as biosensor for intracardiac signals.

The sensing behavior for heart potentials is comparable with Ag/AgCl-electrodes widely used for MAP recordings. The decisive advantages of fractally coated leads are high biocompatibility and long-term stability, high signal-to-noise ratio as well as negligible polarization artefacts which allow the measurement of stimulated MAPs with the stimulating electrodes. To fulfill the mechanical and electrical requirements for chronic MAP recordings fractally coated endocardial pacing leads with active fixation have been developed.

The fractally coated electrodes represent multifunctional sensory systems, which with regard to therapeutic and diagnostic applications allow reliable monitoring of myocardial state. Evaluation of various external influences, which are in particular reflected by the signal course of MAP and VER, has already been integrated into clinical practice and are expected to provide progress on the field of diagnosis of heart diseases and their electrotherapeutic treatment.

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