The Fractally Coated Lead as Ideal Sensor and Actuator for the Electrotherapy of the Heart

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Summary

The recording of monophasic action potentials (MAPs) give access to the transmembrane potential and the electrophysiological state of the myocytes. This technique is already being used in temporary applications. However, from a clinical point of view it may be interesting to obtain MAPs for longer periods. Possible applications may be the control of antitachycardia devices or medication control. This goal requires a better long-term stability and biocompatibility as it is achieved with the present „gold standard", the Ag-AgCl electrode.

From a physical point of view the electrode has to have a low interface impedance and a low polarizability. From interface physics it is shown that both requirements are met by electrodes with a large Helmholtz capacity. Modern coating techniques allow the deposition of the noble metal iridium with a fractal surface structure providing an enlargement of the active surface and Helmholtz capacity respectively by a factor of more than 1000.

The low polarizability and long-term stability has been proven in vitro in electrochemical tests showing that the electrodes provide good physical and chemical stability. The in vivo stability is proven by monitoring the pacing and sensing properties, especially the sensing of evoked responses. First experiences with implantable leads show, that fractally coated electrodes promise that long-term (months) recording of MAPs becomes technically feasible. Whereas the interface seems to be stable, first experiments with implantable leads show that the electrode design and the geometry has still to be improved, at least for endocardial applications.

Key Words

Fractally coated electrode, low polarization, interface impedance, Helmholtz capacity, Ag-AgCl, drug monitoring.

Introduction

Monophasic action potentials (MAPs) are extracellularly recorded waveforms which can reproduce the time course of the transmembrane action potentials (TAPs). Since the measurement of TAPs requires the impalement of an individual cell, it is not usable in clinical practice. In contrast, the MAP can be recorded of the in situ beating heart and thus monitoring of electrophysical phenomena on a cellular level becomes possible, even in clinical settings [[9],[10]]. The analysis of the MAP has long been used as a diagnostic tool, e.g. for medication therapy monitoring [[20],[24]].

MAPs reflect the local de- and repolarization course of myocytes and allow to investigate the local effects of heart related drugs and arrhythmogenic mechanisms with a better spatial resolution than ECG recording [[9],[24]]. Thus, MAP recordings are more accurate than ECG tracings in defining and distinguishing ventricular fibrillation and ventricular tachycardia and will gain increasing importance for an electrical device therapy, for instance by implantable defibrillators [[10]].

The „gold standard" for MAP recording are catheters with Ag-AgCl electrodes [[8],[24]]. However, in histological studies toxic reactions of Ag-AgCl electrodes were observed [[25]]. Therefore, up to now electrodes of this type were not implanted chronically. The aim of this work was to develop a new electrode, which combines adequate electrical properties for recording the heart potentials in conjunction with high biocompatibility and long-term stability.

In the following section the physical requirements for such an electrode system are analyzed and possible solutions will be discussed. It will be shown that the electrochemically active surface area plays an important role and has to be maximized. After presenting a technical solution based on modern thin film technology the so called „fractally coated electrodes" are evaluated in vitro as well as in vivo.

Physical Requirements for Implantable Electrodes

From the user's point of view, electrodes should provide low and frequency independent damping, a low polarizability in order to pace and sense via the same electrode and a high long-term stability. In order to meet these requirements the interface between electrode and myocardium has to be analyzed in detail.

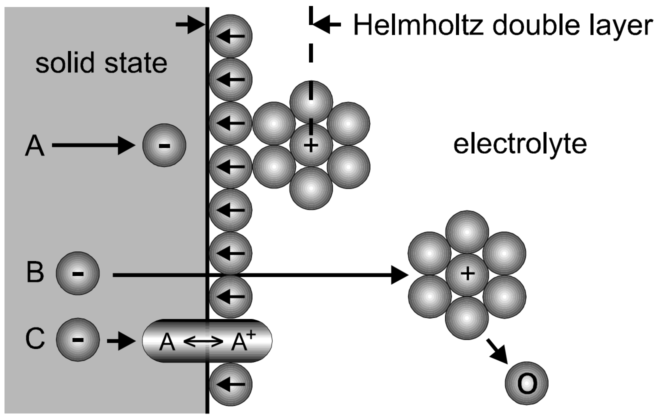

Figure 1: *Transport mechanisms for electrical charges at the metal-electrolyte interface: capacitive charge transfer via the Helmholtz double layer (A), redox reaction within the solution (Faraday current) (B), and redox reactions at the surface of the solid (C).*

Across the interface between a metal and an electrolyte various charge transport phenomena contribute to the electrical current [[4]]. The dominant process originates from the different transport mechanisms in the solid and the solution, respectively. If a voltage is applied between these two phases, electrons accumulate at the solid's surface and ions are driven to the interface to form a layer which is separated from the metal by a monolayer of adsorbed water molecules, resulting in the so called Helmholtz double layer. To a first order approximation, this structure is equivalent to a parallel plate capacitor with water as the dielectric (figure 1, A). The second contribution to the transport of electrical charge results from the Faraday current of electrons from the solid through the Helmholtz double layer leading to reduction of positive ions in the solution (figure 1, B). Third, particles of the solution may adsorb at the surface of the solid and react with its components (figure 1,C).

The relevant conduction mechanisms are summarized in the schematic of figure 2. The capacity of the Helmholtz double layer is given by the specific capacity C_P times the geometrical area A of the electrode. R_F symbolizes the specific Faraday resistance which is related to the Faraday conduction mechanism and has to be divided by A to obtain the value of the corresponding ohmic resistance. Finally, the lead resistance R_L has to be taken into account.

To optimize the pacing behaviour as well as the sensing properties of the electrode, the impedance of the electrode system (figure 2) has to be minimized for the following reasons: Lowering the impedance of the electrode results in a reduction of energy consumption when delivering a stimulus to the heart as well as higher intensities when detecting intracardiac signals. Since the parameters R_F and R_L cannot be significantly reduced, the strategy has to be maximizing the specific capacity C_P because the impedance is inversely proportional to C_p.

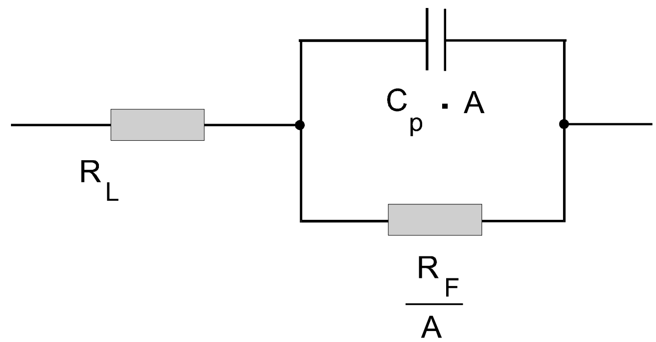

Figure 2: *Equivalent electrical circuit of the metal-electrolyte interface.*

The well-known polarization artifact voltage following a pacing stimulus results in another requirement with regard to C_P. The polarization artifact voltage U is given by

$$U = Q_{St} / A \cdot C_P \quad (1)$$

where

$A \cdot C_P$= the capacity of the Helmholtz double layer and

Q_{St}= the total charge delivered by the stimulus.

Thus, maximizing C_P leads not only to a higher intensity of signals passing through the electrode by lowering the impedance, but also reduces the polarization artifact voltage. Thus, an almost undistorted detection of intracardiac signals like MAP shortly after pacing becomes possible.

Finally, the influence of the geometrical area A of the electrode on the sensing behaviour must be considered. A smaller electrode provides better spatial resolution, smaller catheters and better electrical contact between electrode and myocardium. However, reducing the geometrical area A tends to limit the Helmholtz capacity ($C_P \cdot A$).

The requirements for the electrode parameters originating from the demand of low impedance, low polarization artifact voltage and good mechanical and electrical contact, can simultaneously be matched by using a small geometrical area A together with a highest possible specific Helmholtz capacity C_P. Thus, the technological goal must be to maximize the specific Helmholtz capacity.

The Technical Realization

In lead technology two basic approaches are known to enhance the Helmholtz capacity: By providing a suitable redox-pair on the surface of the electrode, an unhindered charge transfer between the metal and the electrolyte is possible. The most common example for such a system is the Ag-AgCl-electrode [[8]]. However, this system suffers from the disadvantage that ions diffuse to the surrounding tissue and induce chronic inflammatory and toxic reactions [[25]]. Thus, long-term stability of this type of electrode is not given. In conclusion, Ag-AgCl electrodes may be used for temporary applications. However, for chronically implanted leads they are not suitable.

The second approach to enhance the Helmholtz capacity is simply to enlarge the electrochemically active surface of the electrode tip, since the Helmholtz double layer can be regarded as a parallel plate capacitor and the capacity is proportional to the size of the plates. This is usually realized by increasing the surface roughness of the electrode. Approaches reported in the literature include sandblasting, using metal meshes [[16]], drilling small pores with a laser [[14]] or sintering small metal speres [[14]]. The electrochemical active surface area of these types of tips is approximately two to five times larger than their geometric surface area. Thus, the Helmholtz capacities achievable with these methods are too small for an undistorted detection of MAPs.

Recently, a new approach to the enlargement of the electrochemically surface area has been found: the fractal coating of electrodes [[4]]. The basic idea behind the fractal principle is depicted in figure 3, showing a schematic electrode tip with a fractal coating to the left. The tip is covered by small hemispheres. An enlargement of the latter reveals, that each of the hemispheres again is covered by - now even smaller - hemispheres. Each „doubling“ of this structure yields an enhancement of the active surface area by a factor of 2, giving rise to a total increase in active surface area by a factor of 2^n, where n is the number of doubling steps. Interestingly, nature seems to apply this fractal principle whenever transfer processes have to be optimized, e.g. in the ramified structure of the blood vessels in the liver or in the branchial-alveoli system of the lung [[18]].

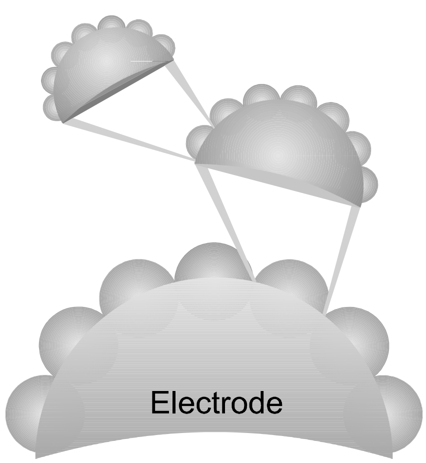

Figure 3: *Principle of the fractal surface structure of a coated electrode tip.*

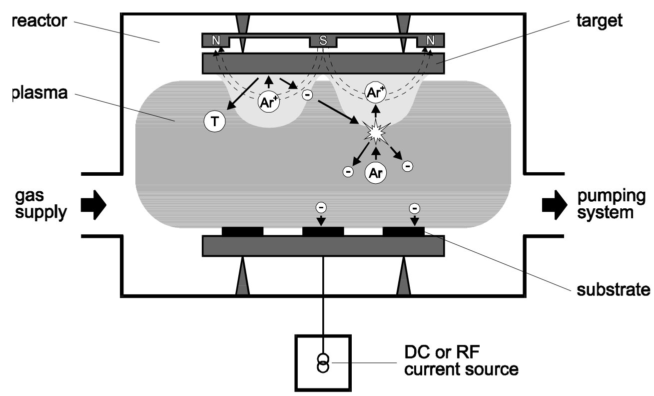

Figure 4: *Schematic view of the physical vapour deposition reactor for manufacturing of fractal iridium coatings.*

Technically, coatings with a fractal surface structure are achieved by physical vapour deposition [[3]]. Figure 4 shows a schematic view of the reactor, in which the deposition takes place. The material, which is to be deposited, is being used as a target. The Ar-ions present in the plasma are accelerated towards the target. Since the kinetic energy of these ions is sufficient to remove target atoms, some of them will diffuse through the reactor and are subsequently deposited on the substrate. Interestingly, the resulting surface structure of the substrate is determined mainly by the process parameters and not - or to a lesser degree - by the material itself. For our experiments the noble metal iridium was used as target material due to its high chemical stability.

Figure 5 shows the surface structure of a fractally coated electrode tip. The first image was taken with a scanning electron microscope and the second image with a scanning tunneling microscope, respectively. At these different magnifications (the black bars below the corresponding images represent 10 µm and 100 nm, respectively) it can be seen, that the microscopic surface structure of the tip is cauliflower-like, resulting in a scale-invariant morphology of the surface, which is called fractal.

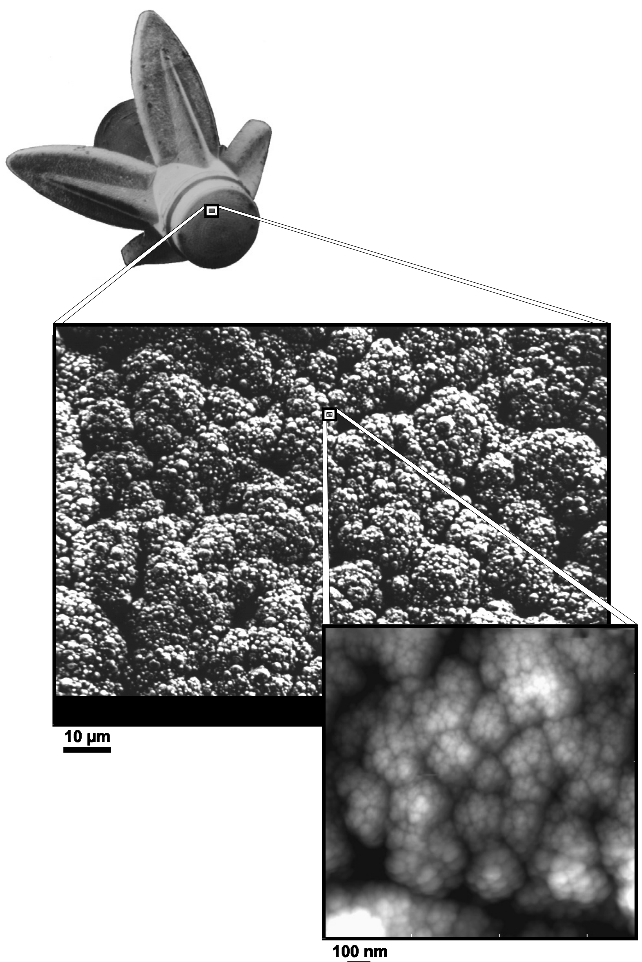

Figure 5: *Scanning electron micrograph (middle) and scanning tunneling micrograph (bottom) of the electrode's surface (top). (Note the difference in resolution of the micrographs by two orders of magnitude.)*

Electrical Properties of Electrodes with Fractal Coating - In Vitro Results

In order to evaluate the electrochemical characteristics of fractally coated electrodes and to compare these to the properties of polished electrodes, potentiostatic measurements were performed. Figure 6 shows the interface impedance versus frequency for electrodes with different surfaces. It can clearly be seen, that the baseline remains constant in all cases. However, the cut off frequency of the fractally coated electrode is approximately three orders of magnitude lower compared to the polished electrode. Based on this observation, the enhancement of the Helmholtz capacity can be estimated. Accordingly, an increase in the capacity of approximately a factor of 1000 is observed. Correspondingly, the electrochemical active surface area of the fractally coated electrode is also enlarged by a factor of 1000 with regard to its geometric surface area.

Compared to Ag-AgCl electrodes, the interface impedance of the fractally coated leads is considerably lower (see figure 6) [[11]]. This leads to an improved signal-to-noise ratio (SNR) since the SNR is determined by the ratio of interface impedance and input impedance of the amplifiers [[21]]. However, the most important advantage is, that the rise in impedance at lower frequencies, which is due to the capacitive properties of the interface, starts below 0.5 Hz in the case of fractally coated electrodes. Thus, a frequency independent damping is guaranteed in the frequency range above 0.5 Hz.

In a next step, the polarization properties of the fractally coated electrodes were compared to uncoated electrodes. In an experimental setup an external pacemaker was connected to the electrodes, while the tip was placed in saline. The top of figure 7 shows

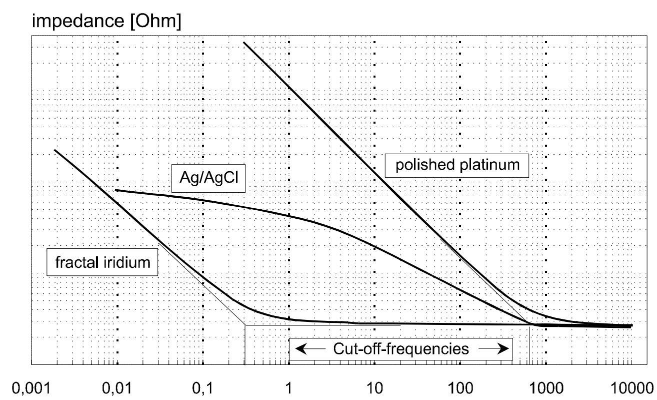

Figure 6: *Frequency spectra of fractally coated, polished platinum, and Ag-AgCl electrodes, respectively. In the frequency range below 1 kHz, the impedance of the electrode-electrolyte interface is much lower for fractally coated electrodes than for polished electrodes.*

the electrode potential of an uncoated Elgiloy electrode (DN 60-BP, BIOTRONIK) with varying stimulation amplitudes. It can be seen, that there is a considerable polarization artifact, which increases with increasing stimulation amplitude. In contrast to this behaviour, the fractally coated electrode shows no polarization artifact at stimulation amplitudes below 10V (see bottom of figure 7). As mentioned above, the stimulus charge Q_{st} leads to a negligible polarization artifact due to the high Helmholtz capacity (see equation 1).

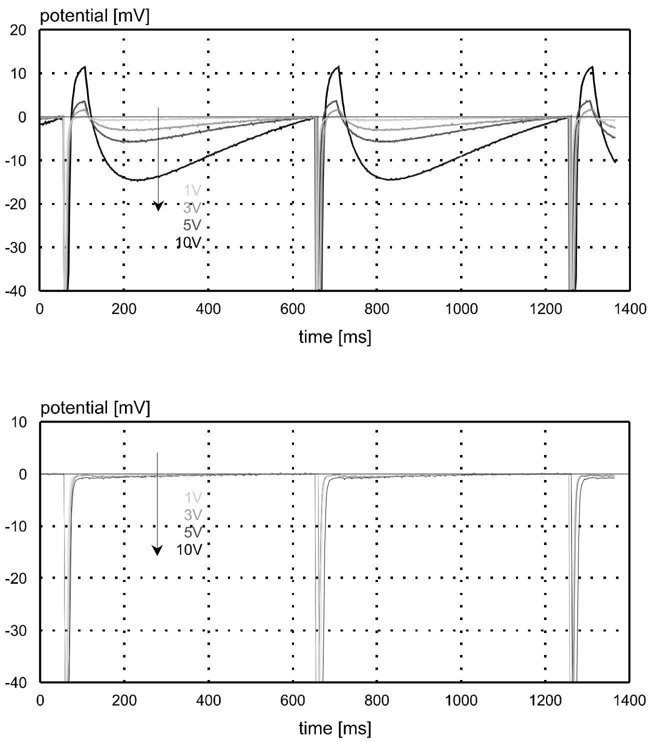

Figure 7: *Potential of an uncoated Elgiloy electrode (DN 60-BP, BIOTRONIK) (top of fig.7) and a fractally coated electrode (TIR 60-BP, BIOTRONIK) (bottom of fig.7) in saline when connected to a pacemaker.*

Based on these encouraging results, experiments addressing the long-term stability of fractally coated electrode tips were performed. The electrode tips were placed in saline and the change in Helmholtz capacity was monitored, the latter being a measure for the long-term stability. Figure 8 shows the capacity of a fractally coated tip as a function of storage time in saline at 37°C. After a small initial decrease the Helmholtz capacity remains constant for the rest of the measurement time, indicating that the electrical properties of the fractal coating of the electrodes are stable over an extended time period. It was shown, that the growth of an oxide layer on top of the fractal coating is responsible for the small initial decrease of the capacity [[4]].

Meanwhile this fractal coating is established in pacemaker and defibrillator technology as standard electrode for more than 5 years. Since the fractal coating is certified for medical products, the manufacturer had to continue the lifetime tests during these 5 years. During this time no degradation of the coating has been observed. However, with regard to our goal - the long-term recording of intracardiac signals - additional tests have to prove the suitability of these electrodes in vivo.

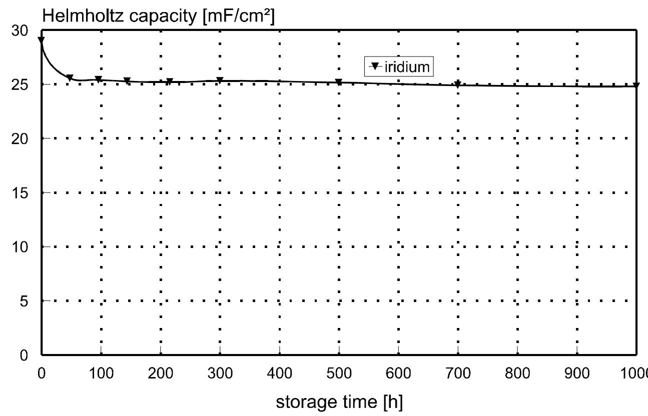

Figure 8: *Helmholtz capacity of fractal iridium tip as a function of storage time in saline at 37°C. After at least 200 h, a stable condition is established.*

In Vivo Evaluation of Fractally Coated Leads

In vitro evaluation proved low polarizability and long-term stability under artificial conditions. Saline served as an electrolyte that induces oxidation and diffusion processes at the interface. Thus, only physical and chemical influences have been included so far. The more important part is the effect of biological components, especially proteins and cells. On one hand, these may have an effect on the lead and its properties. On the other hand, the lead may also affect the tissue. Both directions have to been taken into consideration.

In addition to these experiments, an in vivo evaluation of leads has been performed. These tests require an implantable recording system, which will be described first.

Technical Requirements for Long-Term Recordings of Intracardiac Signals

For clinical long-term measurements with implantable leads an implantable telemetry system is required. Since enhanced diagnostic features are often needed in patients who suffer from pathological changes in the electrophysiological state, this recording capability should be implemented in a pacemaker. However, conventional pacemakers do not provide appropriate input channels and telemetry systems, since their input filters alter the morphology of intracardiac signals and the transmission of data to external devices does not take place with sufficient time and amplitude resolution. Thus, a new system had to be developed.

High resolution requires measurements free of amplifier offset voltages. Therefore, high pass filtering is needed in order to suppress DC- and low-frequency components. Conventional pacemakers are using a cut-off frequency of 3 Hz or higher and are not able to measure intracardiac signals without severe distortion. Thus, postoperative measurements of an MAP result in distorted morphologies due to the influence of the detection system, as it is demonstrated in figure 9.

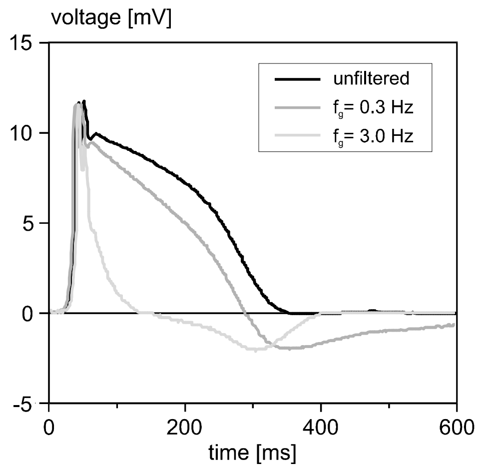

Figure 9: *Influence of the cut-off frequency of the input-filters on the distortion of an MAP signal. The value of 0.3 Hz is a compromise between distortion and settling time.*

On the other hand, the lower the cut-off frequency, the larger the size of the filter will be. In addition, lower cut-off frequencies lead to an increase in settling times (i.e. the time after which a measurement can be done when the electrode is connected). This settling time is of no importance under steady state conditions. However, if we want to switch between different leads the switching speed is limited by the settling time. In conclusion, distortion free measurements are contradictory to acceptable settling times and size of the device. As figure 9 shows, a compromise for the cut-off frequency is 0.3 Hz. However, it should be noted that the small distortions of the signal for the cut-off frequency of 0.3 Hz are not caused by the fractal electrode itself. These distortions rather come from the limiting requirements of an implantable detection system.

These features have been implemented in a standard dual chamber pacemaker (PHYSIOS CTM 01, BIOTRONIK). The new telemetry provides atrial and ventricular monitoring channels. Telemetry functions are programmable by an external device. Thus, the measurement can be switched between the atrial and the ventricular channel. Marker signals with an amplitude of +/- 10 mV allow easy calibration of the signals. The signals are band-pass filtered with a lower cut-off frequency of 0.33 Hz and an upper limit of 200 Hz. The data are transmitted by a pulse distance modulation system which provides an analogous telemetry. The analogous data are digitized externally with 1 kHz sampling rate and 12 bit resolution. If not otherwise specified, all the following data have been measured with such a modified pacemaker.

In Vivo Results

This part summarizes the clinical results with respect to low polarizability and long-term stability. Since the specific Helmholtz capacity of an implanted lead cannot be measured directly and the explantation may alter the properties of the interface, the electrical characteristics of the electrode had to be determined indirectly from accessible data.

Polarizability

Figure 10 shows the electrical signals recorded from an uncoated (PE 60/2K10, BIOTRONIK) and a fractally coated lead (TIR 60 BP, BIOTRONIK). These data have been measured during a pacemaker replacement surgery with a digital DC recorder using an external pacemaker and a counter electrode for pacing. The uncoated lead has been implanted for 8 years, the coated lead for 14 months. The autoshort interval was set to 50 ms. The cathodic pacing pulse is shown with negative amplitude. All measurements were performed in a unipolar setting with the pacemaker housing being the reference (tip against housing). To improve the resolution of the curves the y-axis was limited to $\pm$ 20 mV.

The results of a conventional uncoated elgiloy electrode with smooth surface structure are demonstrated in a) and b) of figure 10. The threshold voltage was 1.6 V at a pulse width of 0.5 ms. In figure 10a) an output voltage of 1.1 V was used, i.e. the pacing pulse was below threshold. It can be seen that each pacing pulse is followed by a short interval of zero voltage due to the autoshort followed by the slowly decreasing polarization artifact. Some QRS signals occur asynchronously to the pacing pulse indicating the autonomous activity of the heart. On the contrary figure 10b) shows the output signal for an pacing voltage of 2.0 V. The QRS is replaced by a ventricular evoked response. However, due to the high polarization artifact the evoked responses are superimposed on the after potential.

A totally different situation is encountered if coated electrodes with a fractal surface structure are used. The figures 10 c) and d) shows the output signal of a unipolar fractally coated lead. Again, figure 10c) represents the no capture situation, the bottom one (fig. 10d)) illustrates captured beats; the threshold voltage has been determined to be 0.8 V at 0.5 ms pulse width. Especially in figure 10 c) no polarization artifact can be observed. After the autoshort, the baseline is only disturbed by noise and asynchronous QRS signals. Consequently, above threshold stimulation results in undistorted ventricular evoked responses as they are recorded by conventional two electrode measurements (see bottom right inset of figure 10) [[5]]. Thus, it is proven that the Helmholtz capacity of this lead is high enough (i.e. the polarizability is low enough) for artifact free measurements even in the implanted state.

Long-term Stability

The data shown in figure 10 show results from leads that have been implanted for already several months. Although these data prove that low polarizability is maintained in the body for longer periods, it was found to be desirable to get more information about the long-term stability of the electrode-myocardium interface. For this purpose the pacing and sensing performance has been evaluated as a function of time.

Pacing threshold as well as lead impedance is a very sensitive measure for the stability of the lead both with regard to the physical properties as well as the induced changes in the surrounding tissue. Figure 11 shows the pacing threshold (top) and the lead impedance (bottom) of a fractally coated lead with a very small tip (SYNOX, BIOTRONIK, geometric tip size 1.3 mm^2) [[12]]. Whereas the impedance goes down during the first 4 weeks, the pacing threshold in terms of charge goes up during the same period. After that time both values are basically constant.

This behaviour can be explained by changes in the tissue. Mechanical stress induced by the lead as well as the influence of the electrode material itself induces inflammatory reactions in the tissue which leads to a swelling of the tissue [[21]]. This swelling increases the extracellular space, thus decreasing the lead impedance. A decreased impedance must be compensated by a higher charge in order to depolarize the heart. Thus, the threshold increases. This effect is stopped as soon as a thin layer of scar tissue has been formed, which coats the electrode and prevents further irritation. In conclusion: During the first weeks after implantation an equilibrium is established resulting in a protecting scar tissue layer. After this ingrowth period the lead has stable electrical properties. In comparison to conventional high polarization leads, the magnitude of this ingrowth effect is much smaller [[4],[12]].

The second source of information about the stability of the interface was obtained by measuring the sensing, especially the sensing after a pacing event. In 118

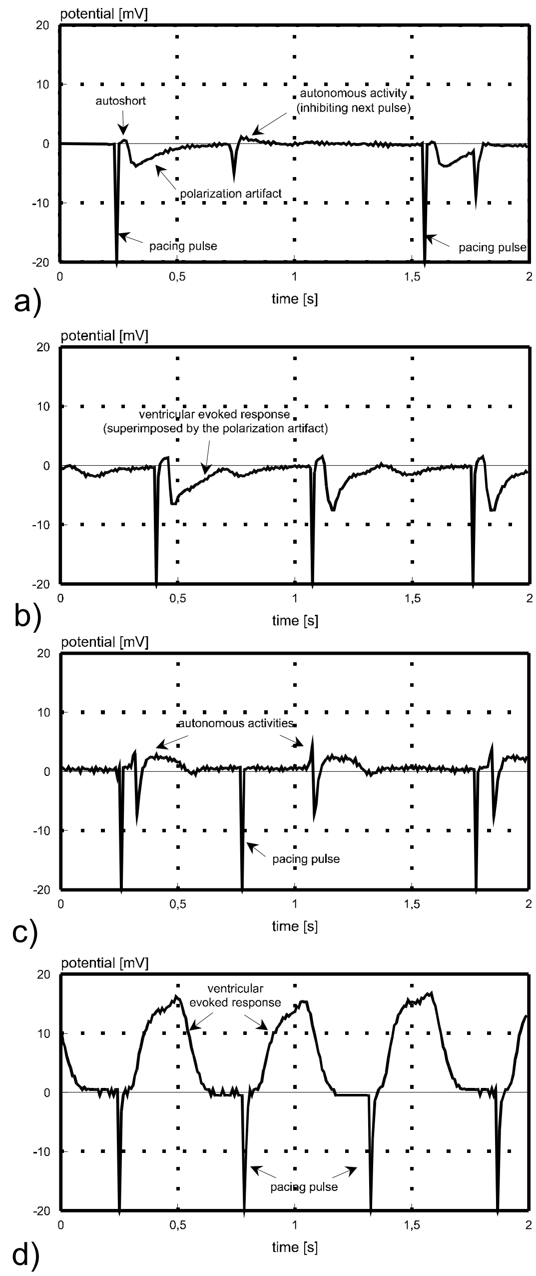

Figure 10a-d: *Ventricular evoked response signal of an uncoated Elgiloy electrode (PE 60/2K10, BIOTRONIK) and a fractally coated electrode (TIR 60-BP, BIOTRONIK): (a) Uncoated Elgiloy electrode. The pacing pulses (1.1 V/0.5 ms) were below the threshold (1.6 V/0.5 ms). (b) Uncoated Elgiloy electrode. The pacing pulses (2.0 V/0.5 ms) were above the threshold (1.6 V/0.5 ms). (c) Fractally coated electrode. The pacing pulses (0.3 V/0.5 ms) were below the threshold (0.8 V/0.5 ms). (d) Fractally coated electrode. The pacing pulses (1.0 V/0.5 ms) were above the threshold (0.8 V/0.5 ms).*

patients pacing below threshold was recorded and the

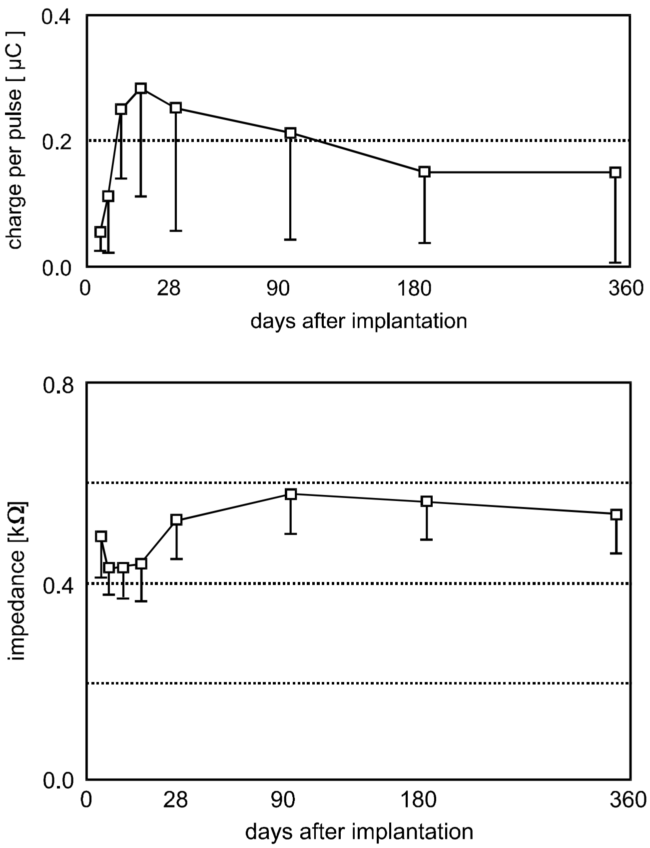

Figure 11: *Pacing threshold (top) and lead impedance (bottom) of a fractally coated lead with a very small tip (SYNOX, BIOTRONIK; geometrical tip size 1.3 mm^2). From [[12]].*

resulting after potential was monitored as a function of time. Experience gained over more than two years showed no after potential at all [0]. This could be confirmed by measuring the ventricular evoked response of an implanted TIR-60 BP lead (BIOTRONIK) at different times after implantation revealing no significant changes in amplitude and morphology.

Fractally Coated Leads as a Sensor for MAP Measurements

Evoked responses provide the global information as a sum potential. The only difference to an intracardiac ECG is the fact, that the cells are triggered by the pacing pulse and not the AV-node. The more important information is contained in the local signal, the monophasic action potential. However, for measuring the MAP the electrode interface is only one prerequisite. In addition, electrode size and geometry as well as the distance and location of the indifferent electrode plays an important role. In addition, a perpendicular positioning of the lead with regard to the wall is required [[9]]. In order to evaluate whether fractally coated leads are suitable for measuring MAPs, different experiments were performed: First of all, fractally coated leads were compared to the present „gold standard" in MAP recording, the Ag-AgCl electrode. In addition, MAP sensing with defibrillator leads has been performed as well as evaluation of active fixation leads with regard to their positioning behaviour.

In order to evaluate whether the signals recorded with fractally coated leads correlate with MAPs, these signals were compared to those of the mentioned Ag-AgCl electrode. However, the quality of this comparison was impaired by the following effects: In principle, it is not possible to provide the same electrode size, configuration and position at the same time for both types of electrodes. All of the following results have to be considered under these limitations.

Since the position of the electrode was found to be of highest importance for comparison, a quadrupolar catheter (similar to [[13]]) was designed that provides simultaneous recording capabilities with two fractally coated and two Ag-AgCl-electrodes [[11],[22]]. The catheter was temporarily used during conventional electrophysiological procedures in the right ventricle. The signals were recorded simultaneously with both pairs of electrodes with a DC coupled digitizing data logger.

MAP measurements with both types of electrodes result in nearly identical waveforms (figure 12). The somewhat higher MAP amplitude of the Ag-AgCl-electrode seems to be related to differences in the electrode size and configuration. Since the tip of the Ag-AgCl electrode is smaller, it provides a higher pressure between tip and myocardium, which results in a higher MAP amplitude.

In order to determine the correlation between the signals of both types of sensors quantitatively, the MAP durations at 25, 50 and 90%-repolarization (MAPd90) were calculated. A good correlation between both electrode systems is obtained (r=0.99). Similar results are obtained for MAPd25 (r>0.98) and MAPd50 (r>0.98). In addition, both signals showed the same heart rate dependence. Thus, the sensing properties of both electrode signals seem to be comparable [[22]].

As mentioned above, the advantage of fractally coated electrodes is a negligible polarization artifact. This should enable the measurement of MAPs immediately after pacing via the electrodes which were used for stimulation. According to figure 13, intrinsic and stimulated MAPs have nearly the same morphology. This is advantageous for implantable leads since a lower number of electrodes reduce the risk of lead fractures and improve the reliability.

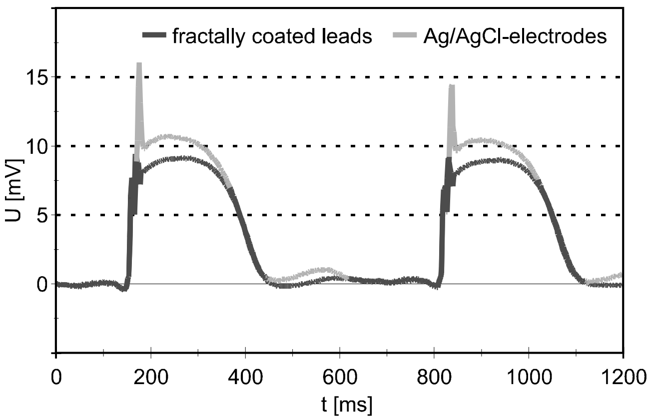

Figure 12: *Comparison of MAP wave forms measured with Ag-AgCl electrodes and fractally coated electrodes.*

A future challenge for developing new diagnostic implantable decives is the long-term recording of MAPs which requires a stable and nearly perpendicular position of the lead against the ventricular wall. Therefore, in the next step an active fixation lead was used (YP 60/10 BP, BIOTRONIK). First results (figure 14) of signals recorded after 3 months promise that that long-term recording of the MAP becomes possible. In addition, also other groups reported that MAP recording is technically feasible over several days in principle [[15],[19]]. However, the morphology of the signals still requires an optimization of the electrode design. An improvement could be achieved with the epicardial MAPOX lead (BIOTRONIK) which guarantees stable positioning due to its design as well as good correlation to epicardial MAP signals as reported in the literature [[1]]. Presently, this lead shows the best long-term stability at sensing MAP signals using the advantages of fractal coatings.

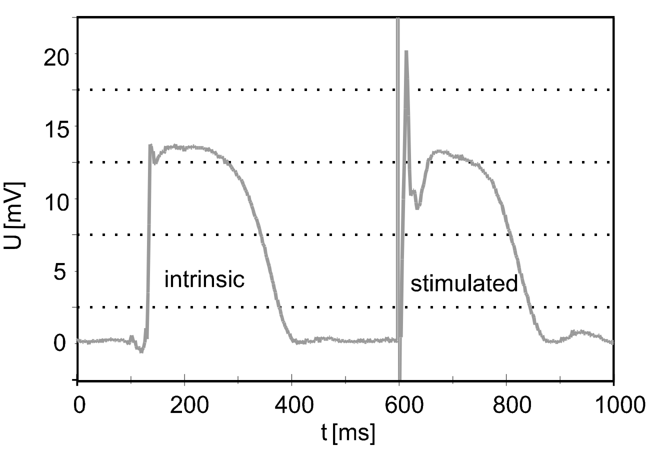

Figure 13: *Morphology of intrinsic and stimulated MAP signals.*

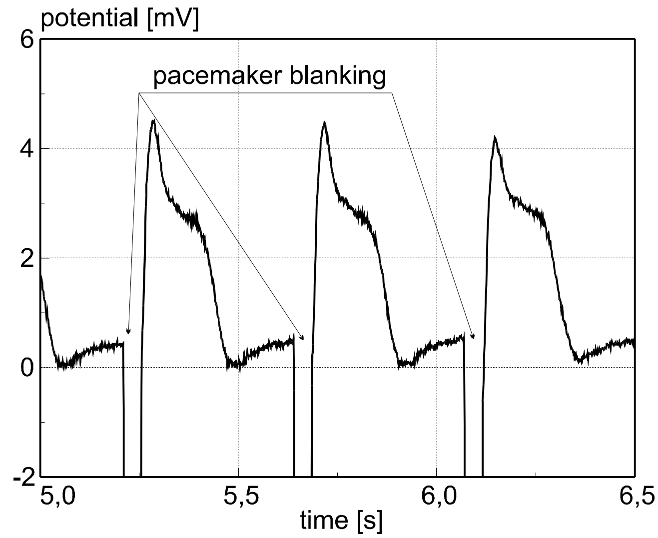

Figure 14: *MAP recorded from an active fixation fractally coated lead (YP 60/10-BP, BIOTRONIK) 3 months after implantation.*

As a further application, MAP sensing with fractally coated lead is expected to play an important role in implantable defibrillators. Figure 15 shows first recordings with implantable defibrillator leads (SPS 65, BIOTRONIK) that were taken during ICD implantation before inducing VF. The defibrillator lead was not pushed against the wall, only its own weight provided the electrode pressure. Similar results were obtained from pacing leads (SYNOX and TIR-60 BP with 5 mm distance between different and indifferent electrode, BIOTRONIK). This sensing behaviour will not only improve the diagnostic capabilities of implantable stimulators but also the reliability of detecting tachycardias (e.g. by reducing the risk of T-wave oversensing).

Conclusions

It has been shown that high resolution sensing of heart signals like MAP depends on the design of the electrode. Especially the properties of the interface between the heart and the detecting system is of critical importance. The requirements of a large Helmholtz capacity and a small tip size were matched by electrodes fractally coated with iridium achieving an electrochemical active area about 3 orders of magnitude larger than the geometrical surface.

The in vitro tests prove that fractally coated leads provide excellent stability with regard to their physical or chemical behaviour. Clinical results with pacing leads revealed that these leads cause only a low degree of tissue irritation during the first weeks after implantation. It has been proven, that the sensing as well as

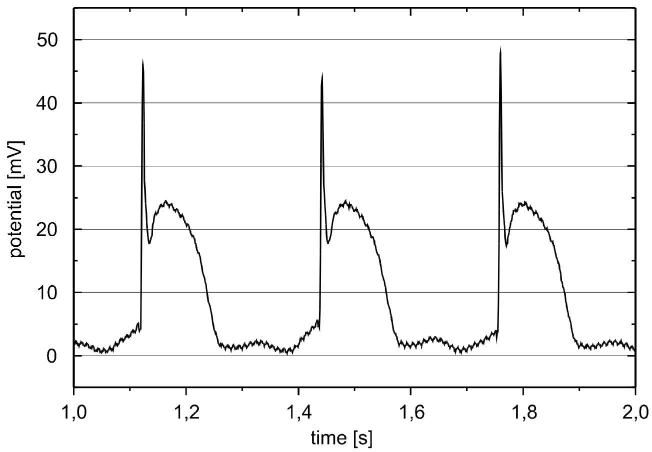

Figure 15: *MAP recording from an implantable defibrillator lead (SPS 65, BIOTRONIK) before inducing VF.*

the pacing properties of fractally coated leads are stable over a time period of more than 5 years. A comparison of the MAP signal obtained with Ag-AgCl electrodes and fractally coated electrodes at the same endocardial location has shown a near perfect correlation (r>0.98).

It is expected that these results will have strong impact on further development of the electrotherapy of the heart. The possibility of evaluating the MAP by an implantable pacemaker or defibrillator may trigger research especially in the fields of cardiac diagnostic as well as antitachycaria therapy based on fundamental information about the heart's condition on a cellular level. Drug monitoring or dosage control, rate adaptation for pacing and predetection of tachyarrhythmias may be possible applications for long-term recording of MAPs via implantable leads.

References

[1] Antzelevitch C, Sicouri S, Litovsky SH, *et al.*: Heterogeneity within the ventricular wall. Circ. Res. 1991; 69: 1427-1449.

[2] Auer T, Schreier G, Hutten H, *et al.*: Paced Epimyocardial Electrograms for Noninvasive Rejection Monitoring after Heart Transplantation. J. Heart Lung Transplant 1996; 15: 993-998.

[3] Bolz A: Applications of Thin-Film Technology in Biomedical Engineering, in: Encyclopedic Handbook of Biomaterials and Bioengineering, Wise DL, Trantolo DJ, Altobelli DE et al. (eds.) Marcel Dekker, New York 1995.

[4] Bolz A: Die Bedeutung der Phasengrenze zwischen alloplastischen Festkörpern und biologischen Geweben für die Elektrostimulation, Fachverlag Schiele&Schön, Berlin, 1995.

[5] Brouwer J, Nagerlkerke D, De Hongste MJL, *et al.*: Analysis of the Morphology of the Unipolar Endocardial Paced Evoked Response. PACE 1990; 13: 302-313.

[6] Eichstaedt HC, Bolz A, Schmid M, *et al.*: Morphologie des endokardialen, ventrikulär evozierten Potentials bei unterschiedlichen externen Stimulationsparametern. Herzschrittmacher 1995; 15: 184-188.

[7] Eichstaedt HC, De Vivie R, Fischer G. *et al.*: Monitoring the Adrenergic Stimulation of the Heart by Analysis of the Ventricular Evoked Response. PACE 1995; 18: 1102.

[8] Franz MR, Chin MC, Sharkey HR, *et al.*: A New Single Catheter Technique for Simultaneous Measurement of Action Potential Duration and Refractory Period In Vivo. JACC 1990; 4: 878-886.

[9] Franz MR: Method und Theory of MAP Recording. Prog. Cardiovasc. Dis. 1991; 6: 347-368.

[10] Franz MR: Bridging the Gap between Basic and Clinically Electrophysiology: What Can be Learned from Monophasic Action Potential Recordings. J. Cardiovasc. Electrophysiol. 1994; 5: 699-710.

[11] Fröhlich R, Wetzig T, Bolz A, *et al.*: Messung und Analyse monophasischer Aktionspotentiale mit Hilfe fraktal beschichteter Elektroden - Teil I. Biomed. Techn. 1995; 40: 154-159.

[12] Fröhlig G, Lawall P, Kindermann M, *et al.*: Stimulationsimpedanz - Grundlagen und Verwirklichung des Hochohmkonzeptes, Herzschrittmachertherapie und Elektrophysiologie. 1996; 7: 198-205.

[13] Hardman SMC, Young GE, Walker JM, *et al.*: A Multi-Electrode Catheter for Simultaneous Pacing and Registration of Endocardial Monophasic Action Potential. Europ. Jour. C. P. E. 1991; 2: 75-82.

[14] Hirshorn MS, Holley LK, Skalsky M, *et al.*: Characteristics of Advanced Porous and Textured Surface Pacmaker Electrodes. PACE 1983; 6: 525-536.

[15] Lang V, Pichlmaier AM, Harringer W, *et al.*: Long Term Recordings of the Monophasic Action Potential from Human Epicardium. EUR.J.C.P.E. 1996; 6: 110.

[16] MacCarter DJ, Lundberg KM, Corstjens JPM: Porous Electrodes, Concept, Technology and Results. PACE 1983; 6: 427-435.

[17] Moussy F, Harrison DJ: Prevention of the Rapid Degradation of Subcutaneously Implanted Ag-

AgCl Reference Electrodes Using Polymer Coatings. Anal. Chem. 1994; 66: 674-679.

[18] Nonnenmacher TF, Losa GA, Weibel ER: Fractals in Biology and Medicine. Birkhäuser, Basel 1994.

[19] Pichlmaier AM, Lang V, Harringer W, *et al.*: Long-Term Recordings of the Monophasic Action Potential using New Implantable Pacing Leads. Proceed. of the 7th European Symposium on Cardiac Pacing 1995: 3-7.

[20] Rosen MR, Jeck CD, Steinberg SF: Autonomic Modulation of Cellular Repolarization and of the Electrocardiographic QT Intervall. Journal of Cardiovasc. Electrophys. 1992; 5: 487-497.

[21] Webster JG: Design of Cardiac Pacemakers. IEEE Press 1995.

[22] Wetzig T, Fröhlich R, Bolz A, *et al.*: Messung und Analyse monophasicher Aktionspotentiale mittels fraktal beschichteter Elektroden - Teil II, Biomed. Techn. 1995: 40: 160-167.

[23] White RL, Gross TJ: An Evaluation of the Resistance to Electrolysis of Metals for Use in Biostimulation Microprobes. IEEE Transactions on Biomedical Engineering 1974; 21: 487-490.

[24] Yuan S, Blomström-Lundquist C, Olsson SB: Monophasic Action Potentials: Concepts to Practical Applications. J. Cardiovasc. Electrophys. 1994; 5: 287-308.

[25] Yuen TG, Agnew WA, Bullara LA: Tissue Response to Potential Neuroprosthetic Materials Implanted Subdurally. Biomaterials 1987; 8: 138-141.