Clinical Experience with Low Threshold Pacing Leads

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Summary

Fractally coated pacing leads were implanted as atrial (TIJ 60-UP) or ventricular (SD 60-UP, TIR 60-UP/BP) pacing leads. These leads have geometrical surface areas of 6mm² (TIR 60-UP, TIR 60-BP, TIJ 60-UP) and 5mm² (SD 60-UP). During the implantation, the acute threshold voltage as well as the P- and R-wave amplitudes were measured. The long-term behavior of these leads was investigated for up to one year using pacemaker telemetry. The results show very low acute threshold voltages of 0.76±0.42V in the atrium and 0.46±0.21V (SD 60-UP) and 0.73±0.23V (TIR 60-UP) in the ventricle. No significant difference was observed in the long-term behaviour between unipolar and bipolar pacing. The reduction of the tip size from 6 mm² to 5 mm² results in lower threshold voltages and is maintained over the long-term duration. The fractal surface structure also ensured large R-wave and P-wave amplitudes.

Introduction

The pacing and sensing performance of the pacing lead largely determines the behavior of the whole pacemaker system. The most important requirement for low threshold stimulation and adequate sensing of cardiac signals is a low electrode-tissue interface impedance which can be maintained over the long-term and with a high degree of biocompatibility.

A large electrochemical active surface area facilitates the charge transfer across the phase boundary between the metallic electrode and the biological tissue and therefore results in a low interface impedance. In contrast to this, investigations show that the geometrical surface area of the pacing lead should not be larger than few mm² (Stokes, 1992) in order to achieve lower threshold voltages. This is due to the fact, that a smaller region of the myocardium has to be excited directly by the electrode, which in turn requires less energy.

In order to solve the apparent contradiction between the need for a large active area but a small geometrical surface area, the surface of a modern pacing lead has to be structured. Numerous methods have been used for structuring the lead surface, e.g., sintering or surface etching, but these do not result in an active surface area which is large enough for stimulation with minimal energy. Fractal surface structuring, however, provides an optimal ratio between the active and the geometrical surface area of more than 1000:1, which results in a very low interface impedance and subsequent reduction in the loss of energy at the electrode-tissue interface. In addition, the large active surface area provided by fractal coating of the pacing lead, ensures a reduction of the polarization artifact which significantly improves the ability to detect cardiac signals such as the ventricular evoked response (Eichstaedt et al., 1995) or the monophasic action potential (Wetzig et al., 1995) after a pacing pulse.

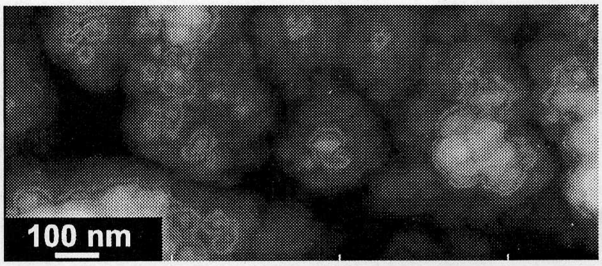

Figure 1: *Scanning tunneling microscopy picture showing the self-replicating or fractal geometry of the surface structure.*

In particular, the low impedance in the frequency range above 0.1 Hz allows the recording of these signals without any disturbances. Figure 1 shows the fractal structure of this coating.

Methods

Pacing leads made of titanium were fractally coated by a sputtering technique. In this process, argon ions existing in an argon plasma are accelerated by a high electrical field to an Iridium (Ir) target (Bolz, 1994). Due to the bombardment of Argon ions, Ir atoms are released from the target and deposited on the substrates. By careful handling of the process parameters a fractal structure can be produced. The sputtered material Iridium is well known for its high biocompatibility.

Different unipolar fractally coated leads having surface areas of 5 mm² (SD 60-UP, Biotronik GmbH, Berlin) and 6 mm² (TIR 60-UP, TIJ 53-UP, Biotronik GmbH, Berlin) and fractal bipolar leads (TIR 60-BP, Biotronik GmbH, Berlin) were implanted in the right ventricle or the right atrium respectively. The acute threshold voltage as well as the R- and the P-wave amplitudes were measured. The long-term behaviour was observed for up to one year after the implantation.

Results

The results of the stimulation threshold measurement with the ventricular implanted unipolar pacing leads are shown in Figure 2. The threshold voltage measured with a pulse width of 0.5 ms is very low for both kinds of pacing leads and the mean threshold voltage is below 0.9V in all cases. The reduction of the tip size from 6mm² (TIR 60-UP) to 5mm² (SD 60-UP) results in a significant diminution of the chronic threshold voltage by more than 45% from 0.73±0.23V to the excellent value of the SD 60-UP lead of 0.4±0.2V.

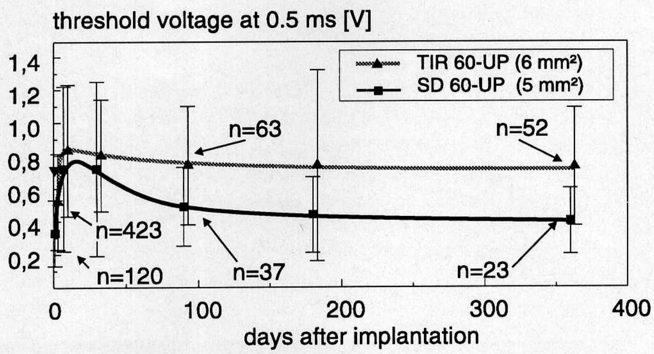

Figure 2: Long-term behaviour of the stimulation threshold of ventricular unipolar pacing leads TIR 60-UP (surface area 6 mm²) and SD 60-UP (surface area 5 mm²).

In Figure 3, the long-term behaviour of the threshold voltage of unipolar (TIR 60-UP) and bipolar pacing leads (TIR 60-BP) is seen. The initial increase of the threshold voltage is more pronounced in case of the bipolar stimulation. However, due to the fractal coating of the tip as well as the ring electrode, the chronic threshold voltage shows no significant difference between the unipolar (0.73±0.23 V, TIR 60-UP) and the bipolar lead (0.79±0.39 V, TIR 60-BP).

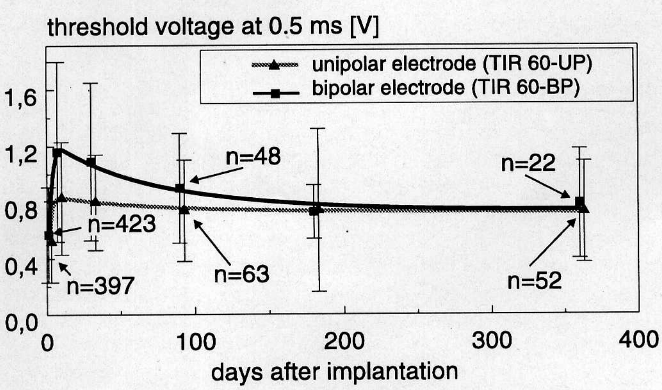

Figure 3: Long-term behaviour of the stimulation threshold voltage of ventricular implanted unipolar (TIR 60-UP) and bipolar (TIR 60-BP) leads.

Similarly, fractal coating results in very low atrial threshold voltages as seen in Figure 4. The mean chronic value of the atrial leads (TIJ 53-UP) being 0.79±0.23 V.

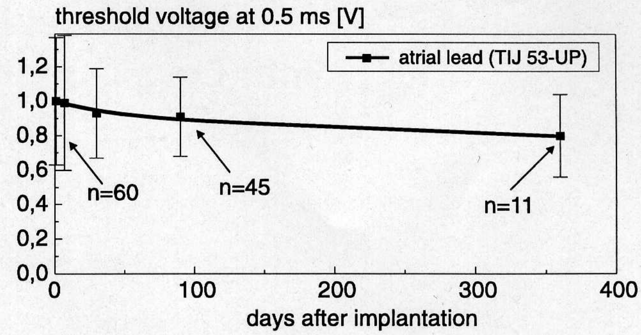

Figure 4: Threshold voltage of fractal atrial pacing leads (TIJ 53-UP).

Lead	SD 60-UP unipolar	TIR 60-BP unipolar	TIR 60-BP bipolar	TIJ 53-UP unipolar
P-wave [mV]				2.8 ± 1.2
R-wave [mV]	12.4 ± 4.4	13.4 ± 4.6	12.9 ± 3.9	
n	109	384	407	67

Table 1: Acute P- and R-wave amplitudes of different fractally coated pacing leads.

Table 1 shows the excellent sensing performance. All leads show high values for the acute P- and R-wave amplitudes. There is no significant difference between leads having different surface areas and between unipolar and bipolar sensing. In addition, due to the fractal surface structure polarization artifacts are reduced by more than 90% compared to conventional pacing leads.

Conclusion

Fractal surface structure provides significantly lower stimulation threshold voltages and excellent sensing performance. A decisive benefit of these leads is their outstanding long-term behaviour due to the stable surface structures and high biocompatibility of the materials used. Unlike steroid-eluting electrodes, no finite drug reservoir is necessary. The low polarization behaviour and the low interface impedance above 0.1 Hz offers the opportunity to use these leads for monitoring of cardiac signals such as the ventricular evoked response (Eichstaedt et al., 1995) and the monophasic action potential (Wetzig et al., 1995) without the problems associated with polarization artifacts and disturbances.

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