Stimulation Properties of Fractally Coated High Impedance Leads

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Summary

A clinical study was performed to compare the stimulation properties of fractally coated high impedance electrodes with an optimized tip geometry and a surface area of 1.3 mm^2 (SYNOX, BIOTRONIK), to those of conventional fractally coated pacemaker leads with a surface area of 6 mm^2 (TIR 60-BP, BIOTRONIK). The results prove that the optimized electrodes provide significantly higher pacing impedances (886 $\pm$ 227 Ω versus 502 $\pm$ 152 Ω) and lower threshold voltages (0.62 $\pm$ 0.19 V versus 0.94 $\pm$ 0.28 V) during 6-month investigation. The amount of charge required for effective stimulation of the heart is reduced by using these electrodes instead of conventional leads. Consequently, a prolonged lifetime of pacemaker systems can be achieved.

Key Words

high impedance electrodes, fractally coated electrodes, stimulation properties

Introduction

One of the main restrictions inherent in implantable pacemaker systems is a limited lifetime due to a finite battery capacity. Therefore, pacemaker- and electrode-developers strive to reduce the amount of charge required for effective stimulation to prolong the pacemaker operating lifetime.

To reach this goal, the reduction of the geometrical surface area of pacing electrodes has been proposed. This size reduction ensures that only a minimum of cells must be excited to provoke an effective cardiac stimulation. As previous studies show, if conventional electrodes are used the reduced interfacial area between electrode and tissue results in a limitation of the charge transfer and therefore in significantly increased stimulation thresholds [1].

The use of fractally coated electrodes avoids these undesirable effects. Because of their unique structure, these electrodes combine small, geometrical dimensions and large, electrochemically active surface areas, providing an unrestricted charge flow between electrode and tissue [2].

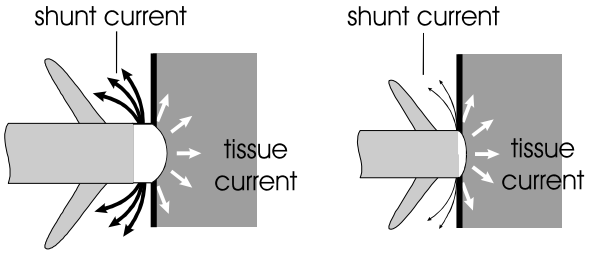

Figure 1. *Principle of high impedance pacing leads.*

Furthermore, as shown in Figure 1, a small surface area of pacing leads reduces the fraction of the induced charge that does not reach the excitable tissue, but flows directly through the surrounding blood to the counter electrode, creating a “shunt current.” This results in an increased pacing impedance of the new electrode and in lower charge consumption during pacing.

The aim of this comparative study is to investigate the stimulation properties of these newly developed high impedance leads.

Methods

The pacing properties of high impedance electrodes with a geometric surface area of 1.3 mm^2 and a fractally iridium coating (SYNOX, BIOTRONIK) were compared to those of fractally coated pacing leads with a surface area of 6 mm^2 (TIR 60-BP, BIOTRONIK). The leads were implanted into the apex of the right ventricle in 59 patients (SYNOX) and 46 patients (TIR 60-BP), respectively. Unipolar pacing threshold and unipolar pacing impedance of these electrodes were measured during a 6-month follow-up period.

Results

Both types of electrodes showed low initial threshold voltages with an increase in amplitude during the first week after implantation (Figure 2). Within the following months, the threshold voltage decreased to low chronic values. Throughout the entire investigation period, the high impedance electrodes provided significantly lower values compared to the results obtained with standard leads. The chronic thresholds were 0.62 ± 0.19 V (SYNOX) versus 0.94 ± 0.28 V (TIR) 6 months after implantation.

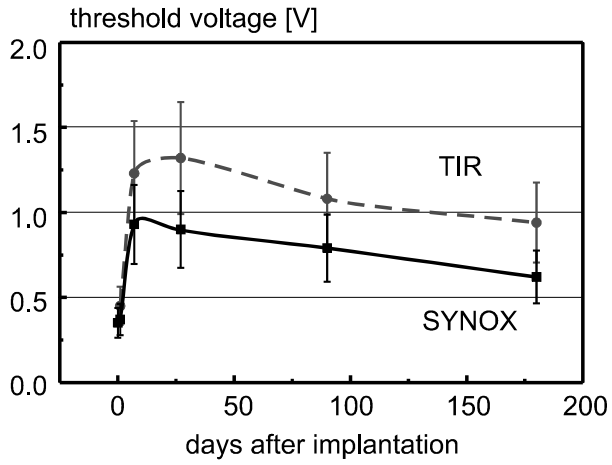

Figure 2. *Comparison of the threshold voltage of SYNOX and TIR at 0.5 ms pulse width.*

The comparison of pacing impedance between high impedance electrodes and standard leads shows a close correspondence in behavior (Figure 3). After the initial decrease in impedance during the first week after implantation, the pacing impedance increased to its chronic value for both types of electrodes. Due to the small surface area, the high impedance leads revealed significantly higher pacing impedances throughout the investigation period. The chronic values were 886 ± 227 Ω (SYNOX) and 502 ± 152 Ω (TIR), respectively.

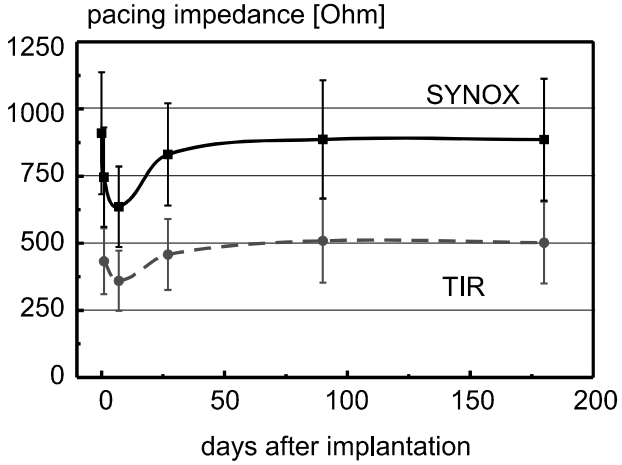

Figure 3. *Comparison of the pacing impedance of SYNOX and TIR at 4.8 V pacing voltage.*

Discussion

The comparison of the stimulation properties of fractally coated high impedance electrodes to those of standard leads shows significantly reduced threshold voltages and higher pacing impedances. Therefore, these electrodes reduce the amount of charge required for effective stimulation and even improve the well-documented, excellent pacing and sensing performance of fractal coated leads with larger surface areas.

These results prove that the altered tip geometry reduces energy losses during pacing. Thus, a prolonged lifetime of pacemakers is achievable by using these electrodes in lieu of conventional leads.

References

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