Electrical Performances of a Fractal Coated Lead: Polyrox Monocentric Study

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Summary

Leads are very important in pacing with respect to efficiency and pacemaker longevity. Fractal surfaces have been designed to improve leads performances. This study investigates the performances of a passive lead with a fractal surface. Pacing thresholds and impedances have been recorded to assess the lead safety and stability. Results showed low thresholds and stable impedances. The design of the passive fixation proved to be efficient as only a few lead displacements were found in the atrium or in the ventricle. Regarding their advantages in terms of handling, passive leads are thought to be a good alternative to active fixation in the atrium.

Key Words

Leads, electrodes, fractal surface, passive fixation

Introduction

Leads are together with the pacemaker part of a pacing system. Because they deliver the energy to the heart, they are the interface between the pacemaker and the heart. Therefore, they have a major influence regarding the stimulation efficiency and the energy consumption. In order to achieve a safe and efficient stimulation, and to keep the output energy low, the leads must be stable and have a high impedance [2].
A monocentric study has been carried out to evaluate the performances of a fractal coated electrode with a geometric surface of the tip of 3.5 mm^2 and with passive fixation (Polyrox, BIOTRONIK). Its iridium coated surface allows to maximize the active surface without increasing the geometric surface [1]. The fixation consists of four silicone tines (Figure 1).

Methods

200 patients with a mean age of 83 ± 7 years were implanted with a Polyrox lead in the atrium (175) and/or in the ventricle (185). The atrial lead is J-shaped. Hence, with our experience, there is no need for an active fixation in the atrium so that this lead is suited for atrial stimulation.
Impedances and thresholds were measured as well as the R-wave amplitude or the slew rate for the atrium. Different pacemakers have been used for the study in order to assess the compatibility of the lead with different manufacturers. Patients were then followed-up before discharge, at 1 month, 6 months, 1 year, 2 years, and 3 years. Each follow-up has been made normally as a routine task. Measures and settings were made according to each patient individual needs.

Results

Low thresholds were obtained at implantation: 0.51 ± 0.14 V in the atrium, 0.38 ± 0.10 V in the ventricle, with a pulse width of 0.5 ms. Moreover, due to good locations of the electrodes, no thresholds were higher than 1 V (atrium) and 0.7 V (ventricle). The impedances were 506 ± 96 Ω in the atrium and 593 ± 113 Ω in the ventricle, with the minimum values being respectively 336 Ω and 350 Ω. A good detection was obtained with a slew rate in the atrium of 1.43 ± 1.07 V/s, and a R-wave of 11.7 ± 4.5 mV.
Thresholds were measured after 2 months which is usually considered to correspond to the maximum threshold. The atrial threshold was 1.17 ± 0.67 V, and the ventricular threshold 0.93 ± 0.43 V. The actual val-

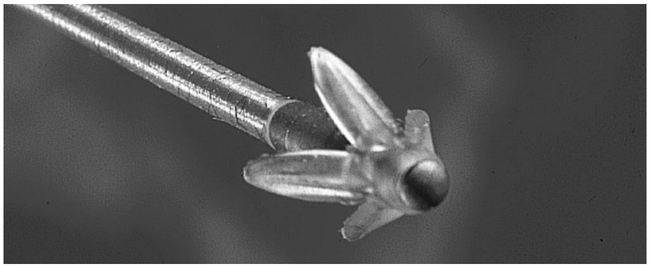

Figure 1. Polyrox lead tip.

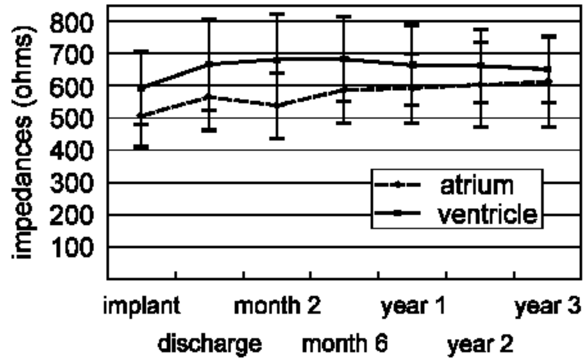

Figure 2. Impedance evolution over three years.

ues may even be lower as some pacemakers measure the threshold by steps of 0.5 V, which tends to give greater thresholds than a measure with a step of 0.1 V. Follow-ups showed remarkably stable impedances over three years (Figure 2 and Table 1).
Only 5 atrial and 4 ventricular leads (2.9 % and 2.2 % respectively) had to be repositioned due to displacement, which indicates a good stability in the atrium as well as in the ventricle.

Discussion

The study shows that the Polyrox lead can achieve low thresholds and high and stable impedances even in the long term. The fractal surface that reduces the effect of polarization allows good electrical performances of the lead. It is estimated that in five years, the thresholds have been reduced by 30 %. With such a reduction, the pacemaker longevity has been increased although in the same time new functions have been added and the size has been reduced [3]. These performances are especially satisfying with regards to the patients age and pathology.
The other relevant aspect of the study is that a passive fixation in the atrium is safe and allows a good stimulation although it is often admitted that an active fixation like a screw should be used in the atrium. The shortcoming of a passive fixation in the atrium is the higher rate of lead displacement than with a screw but, never the less, we showed that this rate can be kept low with a good technique. Moreover, this shortcoming is also an advantage as it is easier to move the lead tip during the implantation in order to find the best spot for stimulation. In our experience, we noticed that when the threshold is acceptable but not optimal, the physician will look for the best spot more often with a passive fixation than with a screw because it can be moved easily. As a result, the stimulation site is very often the same.
The main advantage of passive leads is their simple handling which makes the implantation more simple and allows to reduce its duration and, hence, the risk of infection. For this reason, physicians should consider more often using passive leads for atrial stimulation.

References

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	Implant	Discharge	Month 2	Month 6	Year 1	Year 2	Year 3
Atrial (Ω)	506 ± 96	566 ± 105	538 ± 102	586 ± 102	592 ± 106	603 ± 131	613 ± 140
Ventricular (Ω)	593 ± 113	665 ± 140	680 ± 130	682 ± 141	664 ± 125	661 ± 113	650 ± 101

Table 1. Impedance evolution over three years.