Initial Experience with Fractal Coated Atrial and Ventricular Leads

J. VAN DEN BROEK
Ballarat Health Services, Ballarat, Australia

Summary

We entered patients with usual indications to cardiac pacing in a prospective non randomized clinical investigation with an aim to follow up for twelve months. The Polyrox PX 60 BP and PX 53 JBP pacing lead with an iridium fractal surface were implanted. This was conducted over a study of 17 patients (12 atrial leads and 17 ventricular leads) who required either a dual or single chamber pacing, to 12 months follow-up. The results showed an average atrial threshold of 0.6 V and an average ventricular threshold of 0.6 V at implant and 0.6 V and 0.6 V respectively at 12 months. An averaged sensed amplitude P-wave of 3.6 mV and R-wave of 12.0 mV where recorded at implant and 3.1 mV and 11.2 mV respectively at 12 months. Our results showed that the leads exhibited low acute and chronic pacing and sensing thresholds due to the fractal coating available on these pacing leads.

Key Words

Fractal coated lead, atrial and ventricular pacing threshold

Introduction

Recent pacemaker lead development has aimed to reduce energy consumption and ensure good detection of cardiac signal [4]. The main priorities in low energy pacing are to reduce the inflammatory reaction at the lead tip and to maximize the Electrochemically Active Surface area (EAS) [1].
Inflammatory reaction has been reduced by using biocompatible materials (platinum alloys and titanium) and the use of steroid eluting leads [7]. Further reduction in stimulation thresholds has been achieved with reduction with Geometrical Surface Areas (GSA), however, this is limited with conventional leads in a view of increasing resistance to charge transfer with reduction in EAS.
Iridium fractal surface treatment increased EAS, with smaller GSA [3,8].

Materials and Methods

Seventeen patients were implanted with either a dual chamber rate responsive pacemakers or with a single chamber rate responsive pacemakers. The fractal coated lead Polyrox PX 60-BP was implanted in the right apex of seventeen patients and the fractal coated lead (PX 53 JBP) (all Biotronik) was implanted in the right atrium on twelve patients.
The atrial and ventricular thresholds at a pulse width of 0.5 ms were measured, the sensed P-wave and R-wave amplitude were recorded and the ventricular and atrial electrode impedance were measured. These tests were performed at time of implant, one month, three month, six months and twelve months after implant.
At implant these measurements were made with the ERA 300 analyser. All subsequent follow-up were recorded with the PMS 1000C programmer (Biotronik).

Results

Table 1 and 2 summaries the values recorded over the 12 month follow-up period. At implant the average thresholds of 0.6 ± 0.3 V and 0.6 ± 0.1 V where recorded in the atrium and ventricle respectively. Within the first month there was a slight rise in thresholds only to return to the implant values by six months. At twelve months the average thresholds for the atrial lead of

Ventricular Lead	Implant	1 Month	3 Month	6 Month	12 Month
Threshold in V at 0.5 ms	0.6 ± 0.1	0.9 ± 0.3	0.7 ± 0.2	0.6 ± 0.2	0.6 ± 0.2
R-wave in mV	12.0 ± 1.0	10.1 ± 4.0	11.2 ± 4.0	11.3 ± 4.8	11.2 ± 3.8
Impedance in Ohms	726 ± 173	654 ± 112	700 ± 89	702 ± 83	655 ± 101

Table 1. Summary of the measured values of the ventricular leads during the investigational plan.

Atrial Lead	Implant	1 Month	3 Month	6 Month	12 Month
Threshold in V at 0.5 ms	0.6 ± 0.3	0.9 ± 0.2	0.8 ± 0.3	0.6 ± 0.1	0.6 ± 0.3
P-wave in mV	3.6 ± 2.0	2.8 ± 1.5	2.8 ± 1.5	2.6 ± 1.1	3.1 ± 1.2
Impedance in Ohms	474 ± 110	465 ± 61	511 ± 85	517 ± 95	528 ± 104

Table 2. Summary of the measured values of the atrial leads during the investigational plan.

0.6 ± 0.3 V and for the ventricular lead of 0.6 ± 0.2 V continued to exhibit low chronic thresholds.

At implant the average P-wave and R-wave amplitude sensed was 3.6 ± 2.0 mV and 12.0 ± 1.0 mV respectively. The sensed amplitudes from both leads in the first month where also effected by a decrease in the measured values compared to implant. However, by twelve months the average sensed amplitudes where up to 3.1 ± 1.2 mV in the atrium and 11.2 ± 3.8 mV in the ventricle.

The average electrode impedance for the atrial and ventricular leads at implant where 474 ± 110 ohms and 726 ± 173 ohms respectively.

The electrode impedance in the first month also decreased as seen in both the pacing and sensing thresholds. Thereafter the impedance values continued to rise back to the implant values.

The atrial lead exhibited a lower overall impedance measurement than the ventricular lead over the 12 months.

Both leads exhibited excellent pacing and sensing parameters and electrode impedance at implant.

The small changes at one month can be contributed to the inflammatory process a the lead tip.

Thereafter all three measured parameters exhibited low chronic values.

Conclusions

The thresholds recorded were comparable to thresholds achieved with current steroid leads at twelve months [9], an initial rise was apparent due to early inflammation which was improving by one month.

I experienced no complications in implanting the fractal iridium leads and found implantation equivalent to other pacemaker leads.

Advantages of using a fractal coated lead would be low energy pacing, equivalent threshold in unipolar and bipolar stimulation, superior sensing with application to rate adaptive pacing algorithms and applications such as detection of cardiac transplant rejection [5,6,10].

References

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