Initial Experience with Fractal Coated Atrial and Ventricular Leads

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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 were 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
Threshold in V at 0.5 ms: 0.6 ± 0.1 V at implant, 0.9 ± 0.3 V at 1 month, 0.7 ± 0.2 V at 3 months, 0.6 ± 0.2 V at 6 months, and 0.6 ± 0.2 V at 12 months.

R-wave in mV: 12.0 ± 1.0 mV at implant, 10.1 ± 4.0 mV at 1 month, 11.2 ± 4.0 mV at 3 months, 11.3 ± 4.8 mV at 6 months, and 11.2 ± 3.8 mV at 12 months.

Impedance in Ohms: 726 ± 173 ohms at implant, 654 ± 112 ohms at 1 month, 700 ± 89 ohms at 3 months, 702 ± 83 ohms at 6 months, and 655 ± 101 ohms at 12 months.

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

Threshold in V at 0.5 ms: 0.6 ± 0.3 V at implant, 0.9 ± 0.2 V at 1 month, 0.8 ± 0.3 V at 3 months, 0.6 ± 0.1 V at 6 months, and 0.6 ± 0.3 V at 12 months.

P-wave in mV: 3.6 ± 2.0 mV at implant, 2.8 ± 1.5 mV at 1 month, 2.8 ± 1.5 mV at 3 months, 2.6 ± 1.1 mV at 6 months, and 3.1 ± 1.2 mV at 12 months.

Impedance in Ohms: 474 ± 110 ohms at implant, 465 ± 61 ohms at 1 month, 511 ± 85 ohms at 3 months, 517 ± 95 ohms at 6 months, and 528 ± 104 ohms at 12 months.

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

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.

References

