# Single Lead OLBI<sup>™</sup> Stimulation in Antibradycardia and Antitachycardia Therapy

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# Summary

The study presented investigates the reliability of atrial stimulation with the OLBI<sup>TM</sup> (OverLapping BIphasic) principle by means of floating electrodes in a single lead pacing system. The mean atrial threshold of 37 patients with severe AV block was  $1.8 \pm 0.7$  V upon implantation,  $2.1 \pm 0.9$  V after 1 month, and  $2.2 \pm 0.8$  V after 3 months (pulse width = 0.5 ms). Effective atrial pacing without phrenic nerve stimulation was possible for 89 % of the patients during the 1-month follow-up, and for 97 % after 3 months. The OLBI<sup>TM</sup> configuration was also successfully used for antitachycardia pacing.

## **Key Words**

Atrial pacing threshold, phrenic nerve stimulation, OLBI<sup>™</sup> technique, floating electrodes

# Introduction

Single-lead VDD pacemakers combine an AVsynchronous mode of operation with a reduced number of electrodes. This feature simplifies the implantation procedure and minimizes the risk of complication as compared to dual-lead systems. Furthermore, as opposed to VVI stimulation, operating in VDD mode leads to a crucial improvement of hemodynamic characteristics. To date, single-lead pacemakers have offered outstanding atrial sensing but were not able to provide pacing via floating electrodes in the atrium. As a result of this restriction, such pacemakers required strict observance of their contraindication for patients with AV block. One difficulty in pacing the atrium via floating electrodes resulted from parasitic stimulation of the phrenic nerve. This investigation of a new single-lead system demonstrates that the innovative OLBI<sup>TM</sup> (overlapping biphasic) principle enables effective pacing of the atrium via floating electrodes, without adverse stimulation of the diaphragm.

# **Materials and Methods**

The present study involved examination of 37 patients (19 female, 18 male) with a mean age of  $67 \pm 12$  years. The main indication was symptomatic 2nd (15 patients) and 3rd (20 patients) degree AV block without sinus node dysfunction.

Dromos SL M7 was implanted in 25 patients, and Eikos SLD in the remaining 12 (both pacemakers by BIOTRONIK, Germany). The leads implanted included 1 SL 60/11-UP, 19 SL 60/13-UP, and 17 SL 60/14-UP (BIOTRONIK), all with fractal coating. Atrial stimulation was done by means of two floating ring electrodes and the OLBI<sup>TM</sup> technique. The OLBI<sup>TM</sup> operational principle features the application of two unipolar pulses with the same amplitude and pulse width but with opposite polarity. The two pulses are simultaneously emitted with the pacemaker case acting as the counter electrode.

In conjunction with implantation, the atrial and phrenic pacing thresholds were measured and compared for various stimulation configurations with a pulse width of 0.5 ms. During patient follow-up, atrial pacing thresholds (including thresholds in different postural positions) were determined under OLBI<sup>TM</sup> configuration conditions. In addition, implementing atrial OLBI<sup>TM</sup> stimulation in clinical practice was investigated in patients temporarily demonstrating low atrial rates. Also, OLBI burst stimulation was applied in one patient for purposes of antitachycardia pacing.



Figure 1. Atrial and diaphragmatic pacing thresholds for various stimulation configurations.

#### Results

Intraoperative comparison of atrial pacing thresholds and diaphragmatic stimulation thresholds disclosed the most favorable ratio of these thresholds. This ratio occurred with an OLBI<sup>TM</sup> configuration in which the distal ring electrode emits positive pulses and the proximal one, negative pulses (Figure 1). In this case, the difference between atrial and diaphragmatic pacing thresholds was 6 V, while it was only 2.4 V for bipolar and 2.1 V for unipolar stimulation via floating electrodes. The safety margins between the atrial and phrenic pacing thresholds were 333 %, 104 %, and 58 % for the aforementioned electrode configurations, respectively.

Plotted with respect to time, the behavior of the atrial pacing thresholds remained stable for OLBI<sup>TM</sup> stimulation (Figure 2). The mean values for 37 patients were as follows:  $1.8 \pm 0.7$  V upon implantation,  $2.1 \pm 0.9$  V upon the follow-up examination one month later, and  $2.2 \pm 0.8$  V after 3 months (pulse width = 0.5 ms). Over a medium-term period, the atrial pacing thresholds



Figure 2. Atrial  $OLBI^{TM}$  pacing threshold plotted with respect to time.

were  $1.9 \pm 0.3$  V after 6 months, and  $1.6 \pm 0.3$  V after 8 months (as measured in 5 patients on each occasion). The OLBI<sup>TM</sup> technique proved to be likewise insensitive to postural changes (Figure 3). At the one-month follow-up, the mean pacing threshold was  $2.1 \pm 0.9$  V in the supine and  $2.4 \pm 0.8$  V in the sitting position. Effective atrial pacing via floating ring electrodes without phrenic nerve stimulation was possible for 89 % of the patients. The mean values for the atrial threshold after 3 months were  $2.2 \pm 0.4$  V for supine and  $2.4 \pm 0.8$  V for sitting positions. Stable atrial capture without diaphragmatic stimulation was achievable in 36 out of 37 patients (97 %).

Patients with AV block, who require atrial pacing only temporarily, are considered the ideal user group for this single-lead pacemaker which offers dual-chamber therapy. Tests revealed continuous AV-synchronous pacing for patients whose spontaneous rate falls significantly during the night (Figure 4).



Figure 3. IEGM recording of atrial OLBI<sup>TM</sup> pacing threshold test in the sitting position.

# **Progress in Biomedical Research**



Figure 4. Recording of rate trends for a patient with low spontaneous rates at night.

Even for patients with reduced intrinsic cardiac activity due to cardiodepressive medication (beta-blockers), the use of this pacemaker enabled the maintenance of the hemodynamically preferred course of excitation, from the atrium to the ventricle.

In the case of one patient whose sinus node function worsened during the course of therapy, the atrial pacing feature replaced the, otherwise necessary, VVI stimulation. During bradycardia episodes in the sinus node, this patient was successfully paced in the DDD mode (Figure 5). Earlier studies [5][6] revealed that the OLBI<sup>TM</sup> principle enables simultaneous stimulation of a great number of myocardial cells. As a result, this new stimulation configuration makes it possible to realize an effective non-invasive burst stimulation via floating electrodes. For one patient with atrial tachycardia, burst stimulation was performed with OLBI<sup>TM</sup> pacing at 400 ppm. The atrial tachycardia episode was successfully terminated (Figure 6).



Figure 5. Recording of rate trends for a patient with worsening sinus node function during the course of therapy.

## **Progress in Biomedical Research**



Figure 6. Patient with atrial tachycardia (left side); same patient after successful termination of tachycardia (right side) with  $OLBI^{TM}$  burst stimulation (top).

### Conclusions

In contrast to unipolar or bipolar stimulation, the OLBI<sup>TM</sup> configuration with floating electrodes significantly reduces atrial pacing thresholds. In addition, stimulation with OLBI<sup>TM</sup> significantly increases the distance between the pacing thresholds of the atrium and the diaphragm, compared to unipolar and bipolar stimulation configurations. Consequently, this technique enabled effective and reliable pacing of the atrium via floating electrodes for 89 % of the patients in the presented study. Therefore, single-lead pacemakers with OLBI<sup>TM</sup> stimulation are now being used for treating patients with AV block who require temporary atrial pacing. By optimizing the implantation technic and the parameter settings of the pacemaker, single-lead therapy will become available for new areas of application in clinical practice.

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