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# Closed Loop Stimulation during Cardio-Pulmonary Exercise Tests: First Experiences in Two Cases

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## **Summary**

One of the most vital tasks of the circulatory regulation in the body is to maintain an appropriate level of blood pressure during physical load. During this adaptation, heart rate and the consumption of oxygen increase in parallel. Closed Loop Stimulation represents a new approach to providing heart rates that support the momentary hemodynamic needs in cases of inadequate chronotropic function. This report describes the cases of two patients with rate-adaptive dual-chamber pacemakers (Inos² CLS, BIOTRONIK) who were examined during a cardio-pulmonary exercise test. Patient 1 (female, 73 years of age) was mostly chronotropically competent during exercise with heart rates of 70 bpm during warm-up and 125 bpm during maximum load. The courses of oxygen consumption and heart rate were parallel. Patient 2 (male, 63 years of age) was mostly chronotropically incompetent during exercise with heart rates of 88 bpm during warm-up and 105 bpm during maximum load. Again, the courses of oxygen consumption and heart rate were parallel. In summary, in these two patients, Closed Loop Stimulation provided rate-adaptive pacing with heart rates in the physiologic range and with good correlation to the oxygen uptake

## **Key Words**

Closed Loop Stimulation, circulatory regulation, cardio-pulmonary testing, ergospirometry, oxygen uptake

#### Introduction

Maintaining an adequate level of blood pressure (BP) during physical load is one of the most important tasks of circulatory regulation. During this adaptation, heart rate and consumption of oxygen (VO<sub>2</sub>) increase in parallel [1]. Myocardial contractility also rises during physical load. In sinus rhythm, a sufficient heart rate is usually provided, satisfying hemodynamic needs. In cases of chronotropic dysfunction, a pacemaker must also provide such an appropriate heart rate. Closed Loop Stimulation (CLS) represents a new approach to reaching this ambitious goal [2]. Unlike common sensor-driven pacemakers, the rate determined with CLS is controlled by the intrinsic regulation center, thus providing physiologic pacing rates [2].

This report describes the results of cardio-pulmonary exercise tests from two patients with Closed Loop Stimulation pacemakers. A well-proven method for monitoring hemodynamic parameters (e.g., BP and VO<sub>2</sub>), the cardio-pulmonary exercise test affords the opportunity to demonstrate the physiologic heart rates achieved with Closed Loop Stimulation.

### **Materials and Methods**

Two patients (female, 73 years of age; male, 63 years of age) were implanted with Closed Loop Stimulation pacemakers (Inos² CLS, BIOTRONIK)-implantable devices which are able to adapt the heart rate to hemodynamic needs through integration into the natural circulation system. The Inos² CLS measures a unipolar impedance signal between the electrode tip and the pacemaker housing. This signal represents the changes in myocardial contractility [3]. A stronger myocardial contraction means a greater cardiac output, which is

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the product of the stroke volume and the heart rate. When the body requires a greater cardiac output (e.g., during physical exercise), then the myocardial contractility is increased accordingly. These contractility dynamics are likewise reduced when the body requires a lesser cardiac output (e.g., during rest). The Inos<sup>2</sup> CLS measures the changes in myocardial contractility, regulating the heart rate with this information. Closed Loop Stimulation can take the hemodynamic needs into account through an individual and physiologically central parameter [4]. Thus, each patient is provided with a pacing rate that is determined by the body's own circulatory system, not a sensor system.

Patient 1, a 73-year-old female, was mostly chronotropically competent during exercise. She had undergone aortic valve surgery due to aortic valve stenosis, and her left ventricular function was not impaired. Her pacemaker indication was intermittent atrial fibrillation and persistent third-degree AV block. At the time of examination, she had been implanted with the pacemaker for 4 months and was clinically stable (corresponding to NYHA Class II).

Patient 2, a 63-year-old male, was chronotropically incompetent during exercise. His pacemaker indication was a binodal dysfunction. He had coronary artery disease with a posterior myocardial infarction; left ventricular ejection fraction was mildly reduced up to 50 %. At the time of examination, he had been implanted with the pacemaker for 12 months and was clinically stable (corresponding to NYHA Class II-III).

Both patients performed an exercise test which was

monitored with an ergospirometric device (Ganshorn, ErgoScope LF8.2Q). During the test, oxygen consumption measurements were obtained with continuous breath-by-breath sampling every 10 seconds. The native and stimulated heart rates were recorded by the pacemaker and stored on a PC. The maximum exercise test consisted of: a warm-up phase (3 min, at 0 W), a load phase (increased by 25 W, every 2 min) and a cool-down phase (2 min, at about 15 W) initiated when the patients' maximum load had been reached. Both pacemakers were programmed to the DDD-CLS rate-adaptive mode. Basic rates were 50 bpm and 60 bpm for patient 1 and patient 2, respectively. The maximum closed loop rate was 100 bpm and 120 bpm for patient 1 and patient 2, respectively.

## Results

Before the exercise test, the 24-h trend was interrogated from the pacemaker. Every point on the atrial trend represents an average value of 32 min. The 24-h trend of patient 1 shows a circadian heart rate variation with elevated diurnal ( $73 \pm 6$  bpm) and low nocturnal rates ( $63 \pm 4$  bpm) (Figure 1). Figure 2 depicts the ratio of the atrial paced to atrial sensed events during the 24-h trend. There are more paced events during the night than the day. The daytime percentage of atrial paces was 30% to 70%, nighttime, 60% to 90%.

The exercise test of patient 1 shows a continuous increase in oxygen consumption (up to 0.7 l/min) during the increasing load (Figure 3). This patient rea-

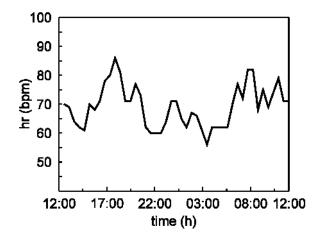


Figure 1. 24 h trend of patient 1.

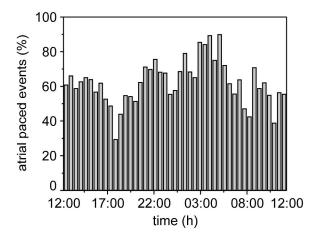


Figure 2. Ratio of atrial paced events in respect to atrial sensed events (24 h trend, patient 1).

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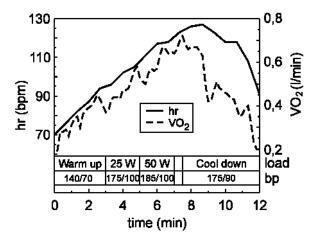


Figure 3. Heart rate (hr), oxygen consumption (VO<sub>2</sub>) and blood pressure (bp) during maximal exercise test (patient 1).

ched a maximum load of 75 W. After the load phase, oxygen consumption decreased up to 0.26 l/min. The heart rate shows a course identical to that of the oxygen consumption. At the beginning of the warm-up phase, heart rate was 70 bpm. During load, the heart rate reached 125 bpm and decreased during the cooldown phase up to 91 bpm. The oxygen consumption reached its maximum at 7.5 min (at the point of maximum load), and the heart rate reached its maximum at 8.5 min. At the beginning of exercise, blood pressure was 140/70 mmHg. During load, blood pressure rose to 185/100 mmHg, decreasing once the load condition had ceased. Figure 4 shows the ratio of atrial paced

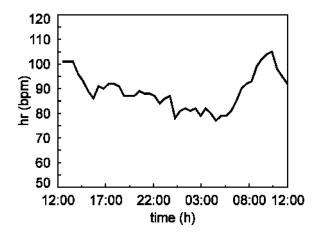


Figure 5. 24 h trend of patient 2.

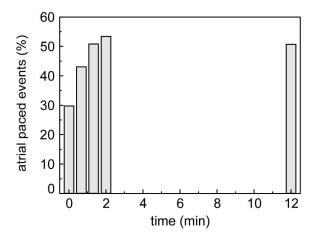


Figure 4. Ratio of atrial paced events in respect to atrial sensed events during maximal exercise test (patient 1).

events to atrial sensed events. During the warm-up and cool-down phases, pacemaker stimulation was partial (30% to 53%). As the load increased, sinus rhythm dominated, and no atrial pacemaker stimulation was necessary.

The 24-h trend of patient 2 shows a circadian heart rate variation with elevated diurnal (93  $\pm$  6 bpm, 105 bpm maximum) and low nocturnal rates (80  $\pm$  2 bpm) (Figure 5). Figure 6 depicts the ratio of the atrial paced to atrial sensed events during the 24-h trend, illustrating the patient's diagnosis of chronotropic incompetence. In this patient, stimulation during the 24 hours prior to the exercise test was 74% to 88%.

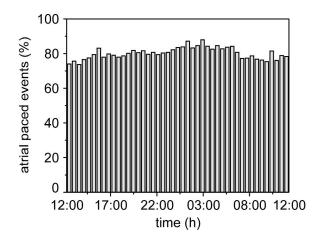


Figure 6. Ratio of atrial paced events in respect to atrial sensed events (24 h trend, patient 2).

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The exercise test of patient 2 shows a continuous increase in oxygen consumption (up to 0.75 1/min) during the increasing load (Figure 7). This patient reached a maximum load of 50 W. After the load phase, oxygen consumption decreased up to 0.56 l/min, and the heart rate shows a comparable course. At the beginning of the warm-up phase the heart rate was at 88 bpm. During load, the heart rate reached 102 bpm and decreased during the cool-down phase (90 bpm). The oxygen consumption reached its maximum at 8 min (30 sec after the point of maximum load), and the heart rate reached its maximum at 7 min. At the beginning of exercise, blood pressure was 130/80 mmHg. During load, blood pressure rose to 150/90 mmHg, decreasing once the load condition had ceased. Figure 8 shows the ratio of atrial paced events to atrial sensed events. In the beginning of the warm-up phase, pacemaker stimulation was 70%, when the load was increased, it was 98%.

#### Discussion

The 24-h trends of both patients show circadian heart rate variations with elevated diurnal and low nocturnal rates. Considering the ratio of atrial paced events to atrial sensed events, Closed Loop Stimulation worked very well for patients who are chronotropically competent or incompetent. Patient 1 primarily needed stimulation during the night. Closed Loop Stimulation regulated her heart rate to 63 bpm on average. Although a basic rate of 50 bpm was programmed,

CLS realized the need for a higher heart rate. During the day, the native heart rate was sufficient. Thus, less atrial stimulation occurred under load in this patient than at rest (during the night). The exercise test confirmed these results. CLS intervened at the beginning and end of the test only. The parallel course of VO2 and heart rate demonstrates the hemodynamic need of stimulation during the warm-up and the cool-down phases. Conversely, the parallel course of the curves shows the adequate native heart rate during load. Because of the adequate heart rates, the blood pressure remained within a physiologic range during the exercise test. Patient 1 demonstrates the capability of CLS to satisfy hemodynamic needs through an appropriate heart rate. The CLS discriminates between an adequate heart rate and the need for stimulation.

Patient 2 primarily needed CLS-regulated heart rates throughout the entire 24 h, an indication of the patient's chronotropic incompetence. At night, the average heart rate was 80 bpm. At first this value seems to be excessive, but the rate is a result of the reduced left ventricular function. Usually heart rates in chronotropically competent people with reduced left ventricular function are higher than those of healthy people with normal left ventricular function. CLS recognizes the hemodynamic need for a higher heart rate and increases the rate accordingly. By day, the heart rates reached a maximum of 105 bpm. On average, the heart rates were 13 bpm higher by day than by night. During the exercise test, pacemaker stimulation dominated. At the beginning of the test, the heart rate was 88 bpm. That

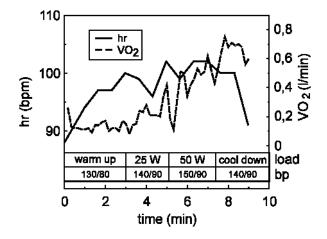


Figure 7. Heart rate (hr), oxygen consumption( $Vo_2$ ) and blood pressure (bp) during maximal exercise test (patient 2).

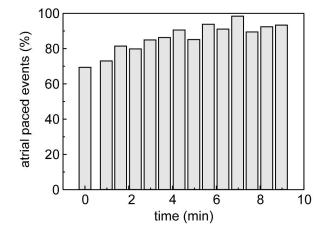


Figure 8. Ratio of atrial paced events in respect to atrial sensed events during maximal exercise test (patient 2).

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value can be explained by the reduced left ventricular function and the stress of putting on the mask for the ergospirometric device. The parallel course of VO2 and heart rate demonstrates the physiologic CLS pacing rate. The pacing rate moderately increased during load (up to 102 bpm). At first, this value seems to be too low with the 50-W load. But this patient has coronary artery disease with posterior myocardial infarction, so a heart rate of 102 bpm is adequate under load. CLS recognizes the pacing rate, which is adequate to the condition of that heart, although the maximal closed loop rate was programmed to 120 bpm. During the 2min cool-down phase, the heart rate decreased to 90 bpm. Because of the adequate heart rates, the blood pressure remained in a physiologic range during the exercise test. Blood pressure increased to only 150/90 mmHg during maximum load-an adequate value given the patient's state of health. This case shows that CLS is able to provide physiologic heart rates to chronotropically incompetent patients. By monitoring myocardial contractility, CLS takes into account the reduced left ventricular function and the coronary artery disease with the posterior myocardial infarction.

### Conclusion

The Inos<sup>2</sup> CLS represents a new physiologic pacemaker system for rate-adaptive pacing. The indication for rate-adaptive dual-chamber pacing (DDDR) was given in one patient with a binodal dysfunction. During exercise, this patient showed an increase in heart rate that correlated well with the oxygen uptake. The increased heart rate during rest is a result of the reduced left ventricular function. The maximum heart rate corresponds to load while the patient stops exercise because of peripheral exhaustion. The other patient, who was chronotropically competent, showed an excellent correlation between the increasing heart rate and oxygen uptake. This test demonstrated that the heart rate calculated by the pacemaker, deduced from myocardial contractility, was not higher than the rate during sinus rhythm in a chronotropically competent patient.

In summary, in these two patients examined, Closed Loop Stimulation provided rate-adaptive pacing with heart rates within a physiologic range and in good correlation to the oxygen uptake.

#### References

- Astrand PO, Rhyming I. A monogram for calculation of aerobic capacity (physical fitness) from pulse rate during submaximal work. J Appl Physiol. 1954; 7: 218-221.
- [2] Malinowski K, Czygan G, Bernhard J, et.al. Contractility-controlled rate adaptive pacing during general anaesthesia. Eur J Pacing Electrophysiol. 1998; 8 (1): 41-43.
- [3] Bernhard J, Lippert M, Ströbel JP, et. al. Physiological rateadaptive pacing using closed-loop contractility control. Biomed Techn (Berl). 1996; 41 (2): 13-17.
- [4] Schaldach M. What is Closed Loop Stimulation. Prog Biomed Res. 1998; 3: 49-555.