The Implant and the Cardiovascular Feedback Loop

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Summary

The aim of biomedical development activities for therapeutic and diagnostic devices increasingly extends from lifesaving tasks to an improvement of the patients' quality of life, far-reaching device automaticity, and additional functionality supporting the physician during follow-up. For the achievement of these goals, the implant must be equipped with the capability to reliably register and interpret the status of the intrinsic cardiovascular control loop. Suitable sensor signals are required for that purpose, as e.g. contraction dynamics, ventricular evoked response (VER), and monophasic action potential (MAP). The presented paper discusses the role of implanted devices, incorporating such sensor signals, in the cardiovascular feedback loop and the clinical validation of the mentioned signals.

Key Words

Cardiovascular feedback, closed-loop regulation, electrical cellular activity, MAP, VER, mechanical contraction dynamics, rate adaptive pacing

Introduction

For therapeutic and diagnostic devices the aim of biomedical development has changed from merely lifesaving and symptom-limiting tasks to more sophisticated achievements, like increasing the quality of life of the patient, providing diagnostic support for the physician, and adding automaticity for the adjustment of the working parameters of the device.

These tasks require a strongly improved ability of the implant to perceive the actual status of important cardiac parameters. Effectively, the implanted device must become an integral part of the cardiovascular control loop.

The aim of this paper is to discuss the implications of the integration of a cardiovascular implant into the body.

Cardiovascular Feedback

The closed-loop regulation is a basic principle in the body that is used, whenever an intrinsic parameter of the organism (e.g. body temperature, blood pressure, blood-glucose level etc.) needs to be kept within certain limits, in spite of environmental disturbances^[1].

The concept of a closed-loop regulation is depicted in figure 1. A sensor detects deviations of the regulated

parameter from its current setpoint. The regulation center processes the sensor output and reacts by controlling the effector. The main characteristics of a closed-loop regulation is a *negative* feedback: if the sensor detects a parameter deviation in *one* direction, the regulation center causes a change in the *opposite* direction that compensates for the initial deviation.

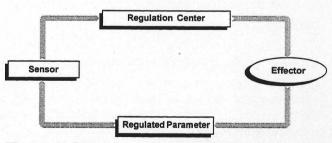


Figure 1. Structure of a closed-loop regulation with negative feedback.

One example for such a closed-loop regulation, the blood pressure regulation of the body^[2], is demonstrated in figure 2. The regulated parameter, the mean arterial blood pressure (MABP) is directly influenced by changes in cardiac output (CO) and total peripheral resistance. As changes in MABP occur, the baroreceptors form a negative feedback loop in conjunction with the circulatory centers. This feedback controls

both contraction dynamics and sinus node function via the sympathetic and parasympathetic control of the heart.

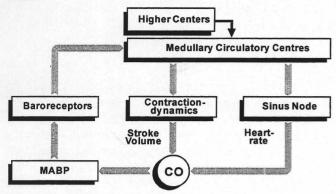


Figure 2. Cardiovascular control loop of a chronotropically competent patient.

In case of a disease that affects parts of a closed-loop regulation (e.g. chronotropic incompetence) an optimal therapy is only possible, if the therapeutic device is able to loop into the regulation system. By substituting or supporting the affected part of the control loop, the functionality can be restored in an optimal way.

For that purpose, monitoring and interpretation of information about the control signals that flow in the regulation loop is required. The availability of this information is a valuable tool for the diagnosis of diseases that impede the functionality of a closed-loop regulation.

In the following, the identification of suitable cardiovascular parameters and the realization of the corresponding implantable biosensors is discussed.

Signals representing Cardiovascular Status

From the different parameters that are involved in the cardiovascular regulation (figure 2) a suitable signal for detection of the cardiovascular regulation status must be selected.

One possibility is to measure the regulated parameter itself, the MABP, or a signal generated by the baroreceptors. But, besides technical difficulties, this method is not adequate, because the circulation center additionally takes into account a large set of intrinsic parameters (figure 3), that are relevant to the circulatory regulation. This may lead to, e.g., a change of the setpoint for the MABP. In that case, the implant will counteract the intentions of the circulation center. On the other hand, it is impossible to monitor all intrinsic parameters that are important for determination of cardiac demand and to combine them correctly.

The solution for this problem is to choose a sensor parameter, that already contains the information about the cardiac *demand*. The circulation center includes all relevant intrinsic sensor signals (figure 3, "input path") in its calculation of the cardiac demand and for the generation of the control signals for the required heart performance (figure 3, "output path"). These signals control the sinus rate, the contraction dynamics, and the atrioventricular delay. The contraction dynamics has the advantage to be available even for chronotropic incompetent patients and for patients with atrioventricular block.

Using this approach delegates the complicated, and technologically unresolved, task of combining the different input signals to form the correct rate, to the "natural computer", i.e. the circulation center.

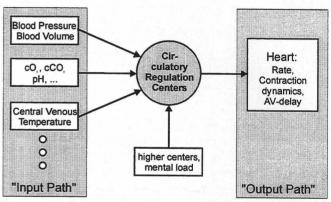


Figure 3. Parameters in the "input path" and "output path" of the circulation center.

Monitoring of Cardiovascular Feedback-Signals

For implantable devices, the sensor must fulfill further crucial requirements: it must be biocompatible and long-term stable. Using conventional pacing leads for sensing has the advantage to combine the monitoring abilities with the well-known reliability of these leads. Therefore, in the following, two such sensor signals are presented that fulfill their task by monitoring the electrical activity of myocardial cells (a, b) and one by assessing the mechanical ventricular contraction process (c).

a) Electrical Activity: Monophasic Action Potential

The circulation center controls the pumping performance of the heart by adrenergic stimulation of the