ONGOING DEVELOPMENT AND FIRST LONG-TERM TRIALS OF A CARDIAC OUTPUT MONITORING SYSTEM IN THE PULMONARY ARTERY (COMPASS)

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Abstract: Current research in heart failure treatment is focused on therapy optimization by early diagnosis leading to cardiac decompensation. An innovative approach is the measurement of the pulmonary artery pressure by remote monitoring (COMPASS). First in-vivo trials, with acute and long-term settings were performed, evaluating minimally invasive implantation procedure, pressure sensor functionality, fixation, ingrowth and explantability. Histological examinations were done. Results are promising.

Keywords: heart insufficiency, cardiac decompensation, implantable blood pressure sensor, in-vivo trials

Introduction

One of the most frequent reasons for hospital admissions of heart failure patients is decompensation. Since hospitalization accounts for the largest parts of treatment costs, heart failure is one of the most cost intensive chronic diseases [1]. Precise and regular monitoring of first signs of decompensation may therefore help to prevent prolonged hospitalization, reduce treatment costs and increase patient outcome.

One of the most prominent early signs of cardiac decompensation is an increased pulmonary artery pressure (PAP). We are therefore developing the implantable sensor system COMPASS for remote monitoring of PAP, allowing physicians to timely adjust heart failure therapy and thereby prevent hospitalization [2-4]. The key element of the COMPASS system is a pressure sensor which is implanted in the pulmonary artery (Fig. 1). It is connected to a subcutaneous radio frequency (RF) capsule, which contains the RF telemetry and a battery. The recorded data is sent to an external CardioMessenger which is utilized by the BIOTRONIK Home Monitoring System for further data processing.

Design changes in sensor fixation were made and tested with dummy systems in long-term animal trials. First working sensor prototypes were tested in acute and long-term settings.

Figure 1: COMPASS pressure monitoring system, consisting of a pressure sensor (1) implanted in the pulmonary artery, which is connected to a subcutaneous implant (2) with a sensor cable, and an external patient device (3).

Methods

An ovine animal model (Rhoen sheep) was chosen as test setup. The probe was implanted in the PA using a specially developed minimally invasive implantation technique [4].

Fixation Trials

Two in-vivo trials with dummy systems (three and six months) were conducted to evaluate a new fixation mechanism. In comparison to the previously meander structure a straight sensor tail was designed for fixation in the wedge position of the pulmonary artery (PA). Explantability was tested at the end of the six month trial. Additionally, histological examinations were performed.

Sensor Functionality Trials

Acute animal trials with working sensor prototypes were conducted in preparation for following long-term trials. A Millar-Catheter was used as pressure reference. The sensor performance was tested by simulation of different heart rate and cardiac output scenarios. Therefore, a stimulation catheter was positioned in the right atrium for external stimulation. Dobutamine was given to increase cardiac output [2,3].

After these first trials, fully working sensor prototypes were implanted for a period of six months. During im-
plantation the same Millar-Catheter reference setup was used as in the previous acute trials. A CardioMessenger was utilized for data reception and onward transmission to the Biotronik Home Monitoring Network. An integrated barometric pressure sensor was used for environmental pressure compensation. Regular X-ray computed tomography (CT) scans were carried out to control the sensor position. Histological examinations were performed after completion of the trial.

Results
The new fixation design proofed reliable in terms of stability and could easily be explanted after an implantation period of six month. Histological examinations revealed less ingrowth behaviour than before. The prototype of the COMPASS pressure sensor showed good performance in comparison with the Millar-Catheter during acute animal trials. Response sensitivity to physiological heart rate changes was satisfactory. During long-term animal trials the data transmission from implant to CardioMessenger was stable and pressure data was transmitted on a regular basis. Figure 2 shows an exemplary pressure waveform recorded for 30 seconds.

![Figure 2: Pressure waveform over 30 seconds.](image)

The barometric pressure compensation sensor integrated in the external CardioMessenger was in good agreement with the local weather station. Control CT scans confirmed a stable fixation of the sensor in the PA, no dislocation was detected (Fig. 3).

![Figure 3: 3D reconstructed image of CT data after 24 weeks.](image)

Conclusion
The redesigned sensor fixation showed less ingrowth behaviour and feasible explantation. Pressure data from the sensor was successfully transmitted wirelessly. Further testing will be required to analyze the long term stability of the pressure signal during long-term animal trials.

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Bibliography