Development of a Leadless Conduction System Pacemaker - Electronic Aspects

Andreas Kummer

Supervisors: PD Dr. med. Dr. phil. Andreas Haeberlin, Prof. Dr. Thomas Niederhauser
Institutions: Department of Cardiology, Inselspital
Bern University Hospital and University of Bern
Examiners: PD Dr. med. Dr. phil. Andreas Haeberlin, Prof. Dr. Thomas Niederhauser

Introduction

Pacemakers are the most common electronic implant. Conventional pacemakers are implanted subcutaneously below the collarbone, with transvenous leads reaching the heart for endocardial stimulation. These transvenous leads can cause various complications. Leadless pacemakers (LLPMs) have been developed as a solution and are now an established implant. They are implanted fully inside of the heart.

The location of pacing within the heart is of great importance because conventional pacing of the left ventricle at the apex of the heart can cause cardiac dysynchrony and heart failure over time. Conduction system (CS) pacing, utilizing the natural conduction pathway, was developed very recently as a solution to this problem. Today, CS pacing is only possible with conventional lead-based pacemakers.

The overall goal of the work was to develop an LLCSPM including the delivery catheters, focusing on the electronic aspects.

Materials and Methods

For the development of the LLCSPM, a conceptual design phase was conducted in which various concepts were investigated. These concepts were then evaluated using the weighted-sum-model method to select the most appropriate concept.

The electronic circuit design and development was an iterative process of design, simulation, and evaluation. The final design was implemented in a prototype PCB for further testing and measurements. The final electronic circuit was implemented on a 4-layer PCB with a size of 4x15mm.

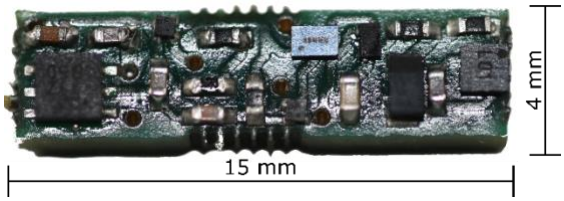

Fig. 1 Image of the Implant PCB for the Leadless Conduction System Pacemaker.

For the power supply of the pacemaker, several batteries were evaluated against various specified requirements. The selected batteries are coin cell batteries with a diameter of 4.8 mm and a height of 2.15 mm. For the pacemaker, 3 such batteries were connected in series. The electrode design was strongly influenced by the mechanical requirements.

Figure 2 shows the developed LLCSPM. On the right side is the pacemaker body with the electronics, on the left side the electrode for stimulation of the cardiac conduction system.

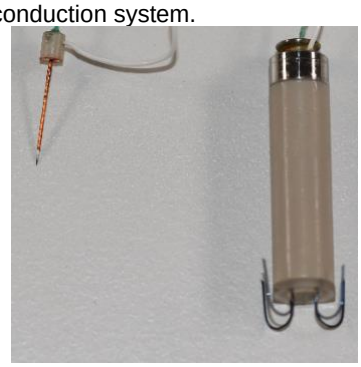

Fig. 2 Image of the developed LLCSPM. The pacemaker body has a diameter of 6.5 mm and a length of 28 mm. The needle electrode has a diameter of 0.3 mm and a length of 12 mm with a non-insulated tip of 2 mm.

The pacemaker and the deployment system were tested in an in vivo experiment in a pig.

Results

The figure 3 shows capture of the myocardium of our developed pacemaker during the In-Vivo trial.

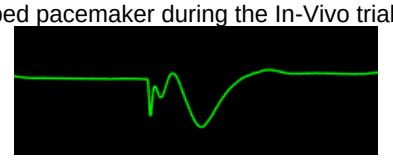

Fig. 3 The Image shows a section of the Lead II of a 12-Electrode ECG, recorded during the In-Vivo trial.

Discussion

The pacemaker developed was capable to capture the myocardium. The electronics contained the minimum necessary functionality to achieve this. The location of stimulation during the in vivo experiment could not be accurately determined.

References

Kenneth A. Ellenbogen et al. Clinical Cardiac Pacing, Defibrillation and Resynchronization Therapy, 5th Edition. ISBN: 978-0-323-37804-8

Acknowledgements

Many thanks to my supervisors and the team at the Cardiovascular Innovation & Test Center for giving me the opportunity and support to develop a cardiac pacemaker.