Results from long-term In-vivo Tests of a Wireless, Intravascular Blood-Pressure Monitoring System for Hypertension Patients

Cleven N.J., Department of Cardiovascular Engineering, Institute of Applied Medical Engineering, Helmholtz Institute, RWTH Aachen University, Aachen, Germany cleven@hia.rwth-aachen.de

Woitok A., University Hospital Aachen; Institute for Laboratory Animal Science, Aachen, Germany, awoitok@ukaachen.de

Penzkofer, T., Department of Diagnostic and Interventional Radiology, University Hospital RWTH Aachen, 52074 Aachen, Germany. penzkofer@ukaachen.de

Isfort, P., Department of Diagnostic and Interventional Radiology, University Hospital RWTH Aachen, 52074 Aachen, Germany. isfort@ukaachen.de

Görtz M., Fraunhofer Institut für Mikroelektronische Schaltungen und Systeme, Duisburg, Germany, michael.goertz@ims.fraunhofer.de

Goettsche T., Osypka AG, Rheinfelden-Herten, Germany, t.goettsche@osypka.de

Steinseifer U., Department of Cardiovascular Engineering, Institute of Applied Medical Engineering, Helmholtz Institute, RWTH Aachen University, Aachen, Germany, steinseifer@hia.rwth-aachen.de

Schmitz-Rode T., Institute of Applied Medical Engineering, Helmholtz Institute, RWTH Aachen University, Aachen, Germany, smiro@hia.rwth-aachen.de

Introduction

Long-term monitoring of malign hypertension patients is important for physicians to prescribe appropriate medical treatment in order to reduce the incidence of secondary consequences such as stroke, kidney failure or heart insufficiency. However, current devices are not suited for long-term blood-pressure measurement. In order to address this need, we developed and conducted in-vivo tests on a novel, fully-implantable, wireless blood-pressure monitoring system.

Methods

The monitoring system was tested for six months in 12 chronic ovine models. The sensor was implanted with X-ray-control in the femoral artery by means of a dedicated sheath (PASIS). Reference measurements were recorded with industry standard pressure sensors post implantation. Position and proper functioning of the sensor were controlled via regular readout measurements and CTs. At the end of each trial, a histological examination was conducted.

Results

Chronic in-vivo studies revealed that blood pressure measurement over a period of six months was possible with the novel implantable sensor system. Stable pressure histories were recorded. However, the mechanical resilience of the sensor system requires improvement. The in-vivo tests in the femoral artery of sheep produced high stress on the sensor system. Several implanted systems became inoperative despite efforts to stiffen the sensor-cable. The histological analysis detected no thrombi, however mild ingrowth was observed in several cases.

Conclusion

The results of the chronic in-vivo tests on the novel implantable blood-pressure monitoring system were encouraging. Improvements need to be made regarding the mechanical resilience of the system and the coating needs to investigated to reduce ingrowth-behavior. Additional trials at a modified implantation spot will be conducted in order to reveal further insights regarding system performance.