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26.10.2018

Project Title:	PulmoStent2 - Validation of innovation potential of a biohybrid stent for use in the respiratory tract
Project Partner:	Lehrstuhl für Angewandte Medizintechnik (AME) NRW-Schwerpunktprofessur Biohybrid & Medical Textiles (BioTex) LuF Kardiovaskuläre Technik (CVE) Universitätsklinikum RWTH Aachen University (UKA)
Duration:	10/2017 – 09/2020
Funding Agency:	Bundesministerium für Bildung und Forschung

Mission Statement

Stents are used to keep the airways open in the case of narrowing of the airways of patients who cannot be treated surgically. Currently available stents are considered the last choice due to possible complications. The accumulation of mucus in the dependent parts of the lung is of particular relevance here. In a healthy condition, so-called cilia on the surface of the respiratory tract clean the respiratory tract by transporting the mucus towards the pharyngeal cavity. If this transport system is interrupted by the foreign surface of the stent, the secretion accumulates behind the stent and can only come out of the lungs by coughing with considerable effort. The result is frequent lung endoscopies to remove the secretion and, as a complication, pneumonia. Since respiratory stents are often used in patients with cancer, the quality of life of severely ill patients is further worsened by these complications.

Solution. The PulmoStent concept

The PulmoStent concept aims at coating the inner side of a respiratory stent with respiratory epithelium, i.e. the cells that carry cilia. In this way, the continuity of the purification system of the respiratory tract is restored. Secretion in the dependent areas of the lungs can thus be prevented. The feasibility of this concept was demonstrated in the project "PulmoStent - Development & Evaluation of a Viable Stent Device for the Treatment of Broncho Tracheal Cancer" within the 7th EU Framework Research Programme.

Within the framework of the project, the validation of this concept will be carried out with the aim of a preclinical evaluation of the stent within the meaning of the Medical Devices Act. Initially, a further iterative optimization of the design and production of the stent is planned. In order to enable preclinical evaluation, the biological safety and performance of the stent must be evaluated. Biosafety testing is carried out in accordance with ISO 10993. The performance of the stent is first checked by in vitro tests. Subsequently, the stent is validated in animal experiments.

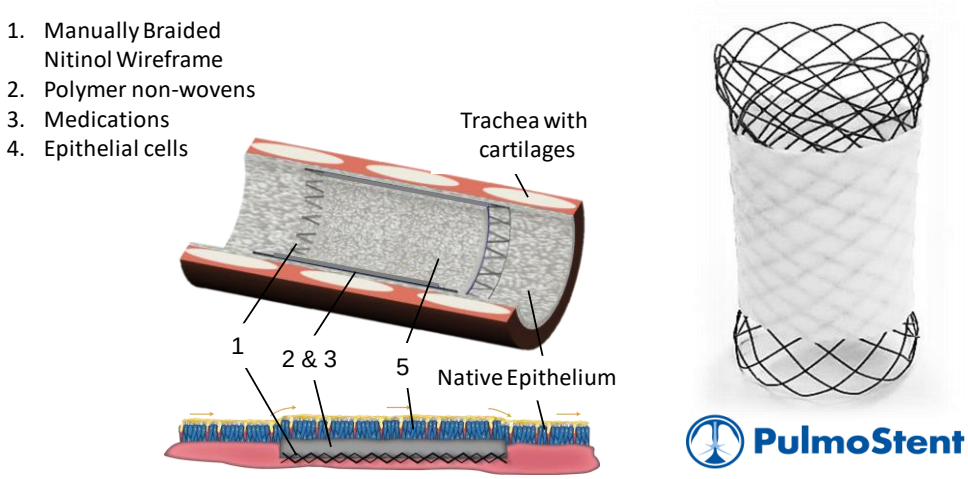

Fig. 1: Prototype and scheme of the PulmoStent

Based on a then possible preclinical evaluation, a clinical trial of the product will be carried out as a result of this project. The quality management required for the production of the stent within the framework of such a trial will also be established within the framework of the project applied for, in accordance with good manufacturing practice.

Acknowledgement

The project on which this report is based is funded by the Federal Ministry of Education. The author is responsible for the content of this publication.

GEFÖRDERT VOM
Bundesministerium für Bildung und Forschung

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