A FAST-TO-EVALUATE MODEL TO INFORM DEVICE DESIGN DECISIONS FOR PULMONARY ARTERY PRESSURE SENSORS

Adriano Schlief (1,2), Leonid Goubergrits (1,2), Jan Brüning (1,2)

1. Institute of Computer-assisted Cardiovascular Medicine, Charité – Universitätsmedizin Berlin, Berlin Germany; 2. Deutsches Herzzentrum der Charité, Berlin, Germany;

Introduction

The importance of in-silico models for the development and safety evaluation of medical devices has steadily increased over the last decades. Today, computer simulations can be used to replace expensive and complex in-vitro bench tests, allowing to save time and omit manufacturing of intermediate device designs. Furthermore, anatomical databases, atlases, as well as statistical shape models allow to properly quantify and assess the entirety of the shape variance observed in anatomical structures, which is relevant to inform device design aspects, such as the necessary sizes and configurations of the device to be applicable to a wide variety, if not the entire population.

Depending on the complexity of the numerical models, however, their application in large cohorts might be prohibitive with respect to computational time and resources, or even finances if commercial software solutions are used.

In this study we describe a combined approach using statistical shape modelling as well as a fast-to-evaluate model mimicking the device implantation procedure for a pulmonary artery pressure sensor. These devices are implanted within the pulmonary artery via a catheter-based procedure. The presented approach is intended to rapidly evaluate different device designs with respect to the availability of suitable landing sites and the risk of the device obstructing side branches of the pulmonary artery.

Methods

A large database of over 2,000 synthetic geometries mimicking the overall heterogeneity of the complex vascular anatomy of the pulmonary artery was generated using a centerline-based statistical shape model of the main-, left, and right pulmonary artery. Due to strong heterogeneity in the topology of side branches, these could not directly be incorporated into the statistical shape model but were generate based on the observed distributions of the azimuthal and inclination angle as well as the diameter of the side branches. Finally, a joint centerline-based representation of all synthetic pulmonary artery geometries including the side branches was generated.

The virtual implantation tool was strongly reduced in complexity to allow ad hoc assessment of valid positions that can occur during the implantation procedure. As the implantation procedure is only guided by mono- or bi-planar angiography, the landing site can only be chosen based on the vessel diameter and whether the device is to be implanted into the left or right pulmonary artery. To mimic this procedure, the fast-to-evaluate model is provided with a 3D geometry of the device and the intended landing site specifications. A random position along the centerline is selected from the entirety of all valid positions. Then, the azimuthal orientation of the device, which will be pressed against the vessel wall by its fixation, is chosen at random to mimic that no control of this rotation within the vessel is intended during implantation.

The model will inform the user whether a valid landing site could be identified within the current pulmonary artery geometry based on the specifications and whether the device is located close to a side branch or even covering one side branch entirely.

Results and Discussion

The fast-to-evaluate model requires only a couple of seconds for each implantation simulation allowing to rapidly evaluate hundreds of different implantation scenarios. While the model is relying on strongly simplified assumptions regarding the implantation procedure, it allows to compare different sensor designs with respect to the probabilities of available landing sites in the target population and the risk of non-optimal device positions. Based on these analyses, different device specifications with respect to the device dimensions and the fixation elements can be quickly compared. For potentially suitable configurations, best- and worst-case scenarios can be selected from the fast-to-evaluate analysis. For these cases, high-fidelity finite element simulations adequately mimicking the implantation procedure can then be performed to properly assess relevant mechanical properties, such as axial retention forces and the contact stresses exerted by the device fixation onto the vessel wall.

Acknowledgements

This work has been funded under the European Union's Horizon 2020 research and innovation programme under grant agreement N° 101017578 (SIMCor: In-Silico testing and validation of Cardiovascular IMplantable devices).