Additively manufactured anatomical heart model for performance evaluation of aortic valve implants

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Abstract: It is suspected that the minimal invasive implantation of aortic valves (TAVI procedure) causes damage to the implant that affects its performance. Medical simulators can be used to investigate this suspicion systematically, repeatedly and under constant conditions. This paper describes the development of a heart model that extends the existing HANNES simulator for aortic valve performance evaluation. The advantages of additive manufacturing (AM) are used to provide an anatomically realistic replication of the relevant anatomical sections of the heart and the aortic root.

I. Introduction

Medical simulators reproduce physically medical-anatomical details in a targeted manner, so that they can be used for various applications. In addition to the training of medical professionals, this includes, for example, the examination and testing of medical implants and instruments. Physicians and other medical staff can apply realistically the instruments and implants on the physical model and evaluate their performance. Thus, more meaningful results can be achieved by using the same conditions for every test run. In addition, evaluation and validation tests can be carried out with no ethical hurdles and at any desired frequency. Due to various advantages such as a large freedom of geometry or the efficient and flexible production of small quantities, additive manufacturing (AM) offers good possibilities for the reproduction of anatomical details within medical simulators [2, 3]. This is, for example, applied for the neurointerventional training model HANNES [1, 2], where blood vessel models are reproduced by using AM to simulate vascular diseases such as intracranial aneurysms (pathological dilatation of blood vessels), stenoses (pathological narrowing of blood vessels) or the vessel occlusions by clots [4]. Besides treatment training and other applications, HANNES is for instance used for testing innovative flow diverter designs for the treatment of intracranial aneurysms [5].

In addition to intracranial vascular disease, HANNES offers the potential to be used in the study of other vessel diseases caused by anatomical malformations. One of these is the aortic valve stenosis, in which pathological calcification prevents the valve wings from opening and closing completely [6]. Due to the narrowing, the heart musculature is strained and the body is supplied with (too) less oxygen-rich blood. The pressure inside the heart increases, since the blood cannot be completely transferred from the left ventricle to the aorta. Therefore, the increased pressure gradient before and after the aortic valve, which is almost negligible in a healthy human body, is an indicator of the severity of the stenosis [6]. For treating the stenosis, an artificial aortic valve is implanted. As an alternative to open heart surgery, the Transcatheter Aortic Valve Implantation (TAVI) can be used [7]. In this procedure, the implant is crimped, pushed through a catheter in the aorta till the beating heart and expanded over the native aortic valve by inflating a balloon [7]. However, it is suspected that the process of crimping and ballooning causes damage to the artificial aortic valve [7], which impairs performance and causes the pressure gradient on the aortic valve to rise again. This suspicion will be investigated with the help of HANNES. For this purpose, the existing blood vessel system must be supplemented by an anatomical replication of the aortic root. Additionally, sensors have to be integrated to measure the pressure gradient and thus allow an assessment of aortic valve performance. The development of this heart model as an additional module for HANNES is the subject of this paper and is described below.

II. Development of a heart model

The procedure for the development of the heart model is based on VDI 2221, and familiar processes of the development and production of blood vessel models for HANNES (see [3]) are used.

After a research and analysis of existing heart models, the first step is to record the requirements for the heart model for integration into HANNES. In this process, both

requirements regarding sensor integration and medical anatomical requirements are recorded in interdisciplinary exchange discussions. Subsequently, the requirements are transferred into a functional structure and concepts are generated with the help of different partial solutions. The selected concept describes a heart model consisting of the components *aortic root* and *ventricle*. In addition, interface components are added to enable integration into HANNES. By adding the anatomical replication of the left ventricle, realistic flow patterns can be generated at the aortic valve. Standardized interfaces between the components allow any combination of components. Also, an implanted aortic valve can be removed non-destructively through the interface between ventricle component and aortic root component. The aortic root component is also equipped with interfaces for the integration of pressure sensors. The components are designed in CATIA, where the freedom of free-form surface modelling is exploited.

After finishing the detailed design, the components are manufactured additively with the Form2 and Form3 printers of Formlabs, Somerville, USA. The printers use the stereolithography process, with which the models are produced layer by layer from a liquid synthetic resin that hardens under UV light. The rigid material *Clear* is selected for the aortic root component in order to simulate a hard, calcified aortic root. For the other components, the elastic material *Elastic* is chosen to realistically replicate the properties of a blood vessel. The AM post-processing is carried out according to the manufacturer's specifications.

After additive manufacturing, pressure sensors are integrated. The model includes eight ports for placing a set of pressure sensing boards to estimate the flow pattern through the valve. Four sensors are located before and four after the area dedicated for the TAVI-valve under test. Each sensing unit consists of a single pressure transducer with a signal conditioning unit and a low power microcontroller. The units are connected via wires to a read-out unit that synchronizes the pressure reading in such a way that all eight measurements are done at the same time and therefore the flow pattern through the artificial valve can be correctly mapped over time.

Figure 1 sums up schematically the development of the heart model.

III. Results and discussion

The interaction of the anatomical AM model with the pressure sensors is investigated in a spare circuit system consisting of a pump and a tank. Functionality and tightness are checked and the sensors are calibrated. After the integration of the heart model into HANNES, artificial aortic valves can be implanted using the TAVI procedure, since the entire relevant vascular tree from the inguinal artery via the aorta to the heart is reproduced. It is necessary to check whether further adjustments, such as an optimization of the pump, are necessary to optimize the blood circulation system for the application.
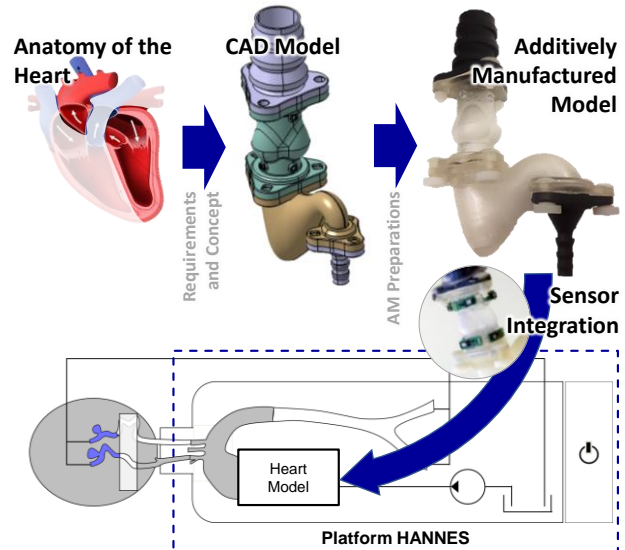

Figure 1: Development of a heart model for the medical simulator HANNES for evaluating the performance of aortic valve implants after TAVI procedure (partly based on [3],[8])

IV. Conclusions

Additive manufacturing offers great potential in the reproduction of anatomical-medical details. In this paper it is used to manufacture a heart model for the integration into the medical simulator HANNES. Different AM materials are used to reproduce realistic properties. The heart model with integrated sensors can help to evaluate minimally invasive aortic valve implants with respect to their performance. In this way, conclusions can be drawn about the risks and complication hazards of the minimally invasive treatment procedure TAVI.

AUTHOR'S STATEMENT

The authors state no conflict of interest.

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