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3D-printing of the aortic root for *in vitro* hydrodynamic assessment of transcatheter aortic valve prostheses

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Abstract: Transcatheter aortic valve implantation has become the treatment of choice for inoperable or high-risk patients with symptomatic aortic stenosis. In vitro investigation of the hydrodynamic performance of transcatheter aortic valve prostheses (TAVP) is necessary to predict the expected clinical performance during prostheses development. Opening and closing behavior of TAVP are influenced by complex vortices inside the aortic root distal the implanted valve. Therefore, technical and physiological models of the aortic root must be used to obtain reliable data in an in vitro testing environment. The current study presents the 3D-reconstruction and -printing of a technical model of the aortic root based on a human aortic root for the hydrodynamic in vitro testing of TAVP.

I. Introduction

Additive manufacturing is approaching mainstream adoption as a highly innovative and flexible processing technique, which can be applied to a variety of materials due to its advantage when complex structures are required [1]. In medicine, this technique opens the field for patient-specific 3D-models for *in vitro* testing in physiological anatomies, preoperative planning or guidance for surgical interventions [1]. In the current work, 3D printing was used as rapid tooling technique for generating a technical model of the aortic root as a vessel model for the *in vitro* hydrodynamic testing of transcatheter aortic valves prostheses (TAVP). Transcatheter aortic valve implantation (TAVI) has become the treatment of choice for inoperable or high-risk patients with symptomatic aortic stenosis [2]. Clinical performance of established TAVP increases constantly, leading to an extension of the therapy from high-risk to intermediate-risk patients [2]. The *in vitro* investigation of the hydrodynamic performance of TAVP is a useful opportunity to predict the desired clinical performance of these devices. In general, hydraulic models of the left human heart and the left circulatory system, so-called pulse duplicators, are used to obtain comprehensive information about the complex hydrodynamic properties of TAVP [3]. However, opening and closing behavior of TAVP is influenced by complex vortices inside the aortic root distal the implanted valve. Therefore, it is necessary to design technical and physiological models of the aortic root to obtain reliable data for the *in vitro* testing of TAVP.

II. Materials and methods

For the development of a technical, physiologically based model of the aortic root, an aortic root of a female human body donor was dissected. After dissection, the aortic root was stabilized in formalin until further investigation.

II.I. Aortic root scanning and reconstruction

To obtain a litigable dataset, the human aortic root was scanned and reconstructed via micro-computed tomography (Micro CT Skyscan 1172, SkyScan, Kontich, Belgium). The STL-dataset of the aortic root was processed by means of MeshLab [4]. Holes and non-manifold surfaces were removed, see Fig. 1.

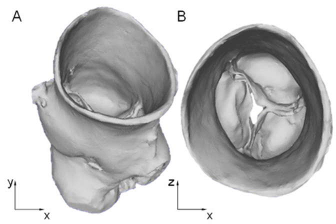

Figure 1: Reconstructed STL-dataset of a human aortic root.

II.II. Development of a technical model of the aortic root

For the development of a technical model of the human aortic root, the STL-dataset was analyzed by means of 3D-CAD software (Creo Parametric 3.0, Needham, MA, USA) and characteristic dimensions were derived to generate a technical model of the human aortic root based on the physiological dataset, see Fig. 2.

II.III. 3D-printing of the aortic root model

The technical model of the aortic root was printed using a commercially available stereolithography printer with a methacrylate based photo reactive polymer (form 2, gray resin, Formlabs Inc., Somerville, MA, USA) and a layer thickness of 50 µm, see Fig. 3.

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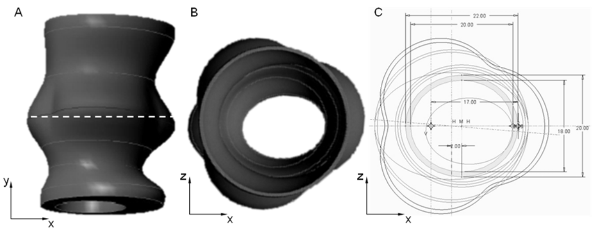

Figure 2: Technical model derived from a human aortic root (A), STL-dataset of the human aortic root (see Fig. 1) was analyzed in different planes representing characteristic dimensions of the aortic root (B) and exemplary dimensions of the technical aortic root model (C).

II.III. Implementation of the aortic root model in a pulse duplicator system for *in vitro* hydrodynamic testing of heart valve prostheses

In order to investigate the influence of the new developed aortic root model on hydrodynamic performance of a TAVP prototype, measurements of effective orifice area (EOA) and regurgitation were performed according to ISO standard 5840-3:2013. A commercial pulse duplicator system (ViVitrolabs, Victoria, BC, Canada) was used for the characterization of hydrodynamic performance of a pericardial, nitinol-stented heart valve prosthesis prototype.

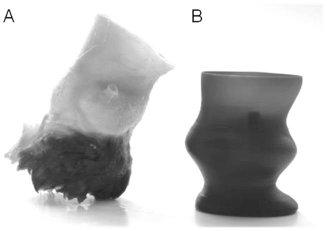

Figure 3: dissected human aortic root (A) and 3D-printed technical model derived from the human aortic root (B).

The following testing parameters were applied: heart rate: 70 BPM ± 5 BPM, mean aortic pressure: 100 mmHg ± 2 mmHg, systolic duration: 35% ± 5%, cardiac output: 5.0 l/min ± 0.2 l/min, test solution: 0.9% NaCl, temperature: 37°C ± 2°C. A total number of n = 10 cycles was recorded for the measurement.

III. Results and discussion

The developed aortic root model was successfully adapted to the pulse duplicator system and a TAVP prototype could be implanted into the vessel model. A characteristic diagram of pressure and flow across the TAVP during a cardiac cycle is shown in Fig. 4. Measurements according to ISO 5840-3:2013 were performed. The determined EOA was 2.8 cm², the closing volume was 3.5 ± 0.1 ml and the leakage volume 20.61 ± 0.53 ml resulting in a percentage regurgitant fraction of 25.57% (n = 10).

In earlier studies, another TAVP prototype was investigated in silicone mock vessels with different grades of aortic stenosis. Here a regurgitant fraction of 5.2% ± 1.0% and an EOA of 1.5 cm² were measured [3]. Rhamani et al. characterized a CoreValve (Medtronic) and a Sapien XT (Edwards Lifescience) in a generic aortic root model, EOAs of 2.1 cm² and 1.7 cm² as well as regurgitant fractions of 33.0% and 23.9% were quantified for the commercial TAVP [5]. Differences especially regarding the regurgitant fractions may mainly result from different valve types as well as different aortic root models used in the experiments.

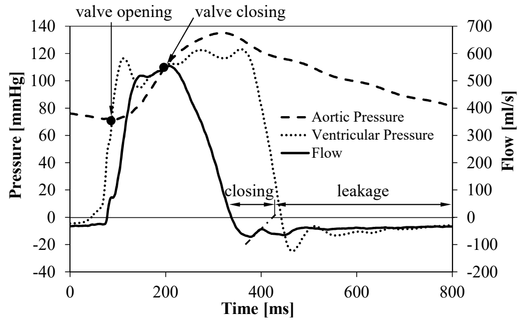

Figure 4: Mean aortic pressure, mean ventricular pressure and mean flow of n=10 cycles captured during hydrodynamic testing of a TAVP in the aortic root model in a pulse duplicator system.

Future investigations have to evaluate if the model can be printed in transparent and elastic material for flow field measurements distal to the valve, e.g. with particle image velocimetry.

IV. Conclusions

For the improvement of *in vitro* hydrodynamic test methods for TAVP it is necessary to develop technical but physiological models of the aortic root, because hydrodynamic performance and valve opening and closing is strongly influenced by the aortic root geometry. Therefore, within the presented work, manufacturing of a technical model of the aortic root based on a dissected human aortic root is described. First *in vitro* hydrodynamic tests according to ISO standards were performed to characterize TAVP in physiologically relevant anatomies. In further research, compliance of the model and its influence on measurements of hydrodynamic properties of TAVP have to be investigated. In addition, more human aortic roots need to be investigated to develop a generalized technical model of the aortic root representing relevant geometries.

AUTHOR'S STATEMENT

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REFERENCES

[1] B. Ripley, T. Kelil, M.K. Cheezum, et al. 3D printing based on cardiac CT assists anatomic visualization prior to transca-theter aortic valve replacement. Journal of Cardiovascular Computed Tomography, 20016, 10:28-36.

[2] D.A. Jones D. Tchetche J. Forrest, et al.. The SURTAVI study: TAVI for patients with intermediate risk. EuroInter-vention, 2017, 13: e617-e620.

[3] S. Kaule, S. Pfensig, R. Ott, et al. Impact of aortic root geometry on hydrodynamic performance of transcatheter aortic valve prostheses. Current Directions in Biomedical Engineering 2017; 3.

[4] P. Cignoni, M. Callieri, M. Corsini, et al. MeshLab: an Open-Source Mesh Processing Tool Sixth Eurographics Italian Chapter Conference, page 129-136, 2008

[5] B. Rahmani, S. Tzamtzis, R. Sheridan R, et al. In Vitro Hydrodynamic Assessment of a New Transcatheter Heart Valve Concept (the TRISKELE). Journal of cardiovascular translational research 2017; 10: 104–115.