

Towards a new patient-specific, modular aortic vascular phantom with clinically relevant mechanical properties

A. Gallarello¹, A. Palombi², E. De Momi¹, G. Burriesci², S. Homer-Vanniasinkam^{2,3}, H. Wurdemann²

1) Department of Electronics, Information and Bioengineering (DEIB), Politecnico di Milano, Italy

2) Department of Mechanical Engineering, University College London, United Kingdom

3) Leeds Vascular Institute, Leeds General Infirmary, United Kingdom.

1. Introduction

According to [1], the cardiovascular devices market was valued at over US\$33 billion worldwide in 2015 with a projected growth of a CAGR (Compound Annual Growth Rate) of 6.6% until 2024.

For early-stage validation of emerging tools, *in vitro* tests are usually preferred to *in vivo* tests as animal experiments and clinical trials are costly, time-consuming and can pose ethical issues [2].

Simulators able to mimic physiological pulsatile flow and pressure are commercially available (e.g., Endovascular simulator by Vivitro Labs). Researchers have further created both rigid and flexible phantoms based on simplified geometries [3] or patient-specific 3D reconstructions [4]. However, the challenge remains to develop hard-wearing vascular testbeds with clinically relevant mechanical properties reproducing the physiological environment.

This paper presents a step-by-step development process of a vascular phantom which will be able to mimic human-like distensibility and thus allow haemodynamic analysis and device testing.

2. Methods

The presented phantom environment should

- comprise the aortic arch, the descending and abdominal aorta as well as the common iliac arteries including the branches
- be modular, using patient-specific data
- be able to mimic human-like distensibility
- be cost-effective
- be MR-compatible

3. Results

A threshold-based image segmentation has been carried out on selected regions of interest of a CT angiogram, using the open-source (OS) software 3D Slicer (Fig.1a). The 3D reconstruction has been manually refined and edited with OS CAD software (Fig.1b). A number of soft materials suitable for moulding (silicone material) and 3D printing (TangoPlus Full Cure 930[®]) have been characterised by uniaxial tensile testing. The results of the tensile tests followed by a finite element analysis permitted the fabrication of a modular phantom environment made of Eco-Flex 00-30 silicone with a thickness of

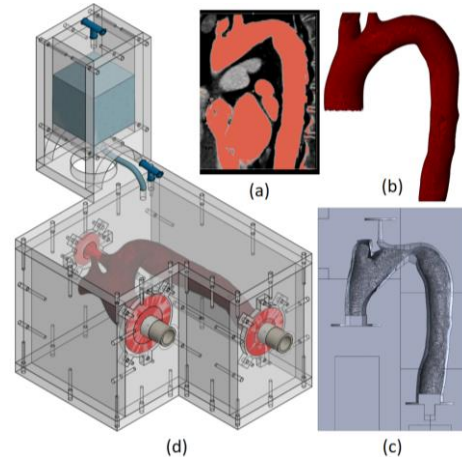


Figure 1. Example of the manufacturing process for a cardiovascular module (here: the aortic arch): (a) Segmentation of CT images; (b) refining and 3D reconstruction of the vessels; (c) post-processing for mould design; (d) final module design with Windkessel chamber.

2.2mm. The external mould is designed as shown in Fig.1c. Furthermore, a Windkessel chamber connected to the water-filled bucket containing the phantom allows variation in the distensibility (Fig.1d).

4. Discussion & Future work

To the best of our knowledge, this is the first description of the development of a patient-specific, modular aortic vascular phantom with clinically relevant mechanical properties. We envisage this phantom environment to be of paramount importance for early-stage validation procedures of medical devices for cardiovascular applications include diagnostic and monitoring devices as well as surgical tools. Ongoing efforts will be dedicated to the fabrication of each module as well as the assembly of the entire phantom environment. Validation results will be carried out and presented at the conference.

References

- [1] Cardiovascular Devices Market Size, Global Industry Report, 2024, Grand View Research, 2016.
- [2] A. Knight, "Weighing the Costs and Benefits of Animal Experiments," *Eighth World Congr. Altern. Anim. Use life Sci.*, pp. 289–294, 2011.
- [3] T. L. Poepping, H. N. Nikolov, M. L. Thorne, and D. W. Holdsworth, "A thin-walled carotid vessel phantom for Doppler ultrasound flow studies," *Ultrasound Med. Biol.*, vol. 30, no. 8, pp. 1067–1078, 2004.
- [4] E. Vander Poorten *et al.*, "Cognitive Autonomous Catheters operating in Dynamic Environments," *J. Med. Robot. Res.*, 2016.