

An endovascular simulator based on exchangeable 3D-printed real vascular pathologies as alternative to the use of animals

M. Kaschwich¹, F. Matysiak¹, J. Bouchagiar¹, A. Dell¹, A. Bayer¹, M. Horn¹, M. Kleemann¹

¹ Department of Surgery, Division of Vascular and Endovascular Surgery, University Medical Center Schleswig-Holstein, Campus Lübeck, Ratzeburger Allee 160, 23538, Lübeck, Germany

* Corresponding author, email: Mark Kaschwich, mark.kaschwich@uksh.de

Abstract: The increasing importance of endovascular surgery requires the development of authentic simulation environments to test new endovascular devices and navigation systems. Objectives: Purpose of this project was the development of a simulator that mimics endovascular procedures as realistic as possible to minimize the use of animal models. Methods and Results: Using the technique of rapid prototyping we developed an endovascular simulator with exchangeable 3D-printed realistic vascular pathologies. The technique of 3D-printing opened the door to produce endovascular simulators with authentic vascular pathologies. This can reduce the use of animals for research purposes.

I. Introduction

Since their establishment, endovascular procedures have become a standard repertoire of modern vascular surgeons and replace more and more conventional open surgery. Nowadays, they are recommended for the most peripheral interventions [1]. By 2026, one can predict that 75 % to 95 % of all vascular lesions requiring treatment will undergo an endovascular procedure [2].

Therefore, the continuous further development of new endovascular devices, techniques and navigation systems requires simulators that adequately reflect the complex vascular pathologies.

To prevent humans from harm, up to now animal models are generally part of the translational process into clinical practice. But on the other hand the directive of the European parliament and the council of the European Union says that “wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used instead of a procedure” [3].

3D-prototyping has led to a new era of producing complex three-dimensional objects accurately and economically. Over time this technology has also arrived in medicine and has opened the door for producing patient specific anatomical models based on computerized scanning data [4].

Within the context of the NavEVAR project, that aims to implement a new radiation-free endovascular navigation system, one subgoal was the development of an authentic simulation environment to mimic endovascular procedures and to avoid the use of animals.

II. Material and methods

Considering the variability of vascular pathologies, we planned the simulator as a modular system with exchangeable segments for thoracic and abdominal 3D-

printed aortic pathologies. Fig. 1 shows the CAD-reconstruction of the planned simulator.

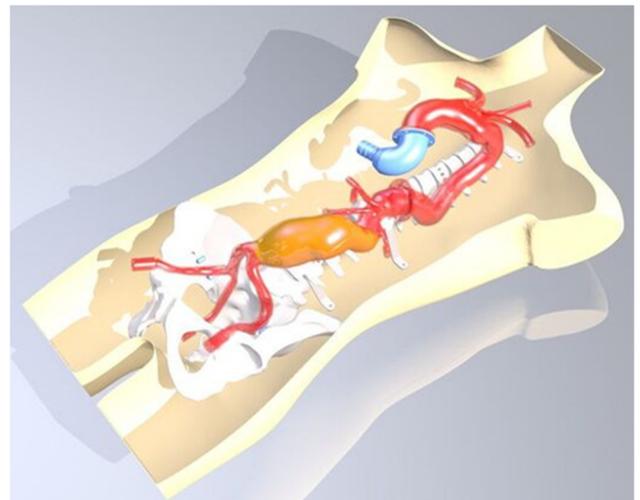


Figure 1: CAD model of the planned endovascular simulator with exchangeable 3D-printed vascular pathologies

Digital Imaging and Communications in Medicine (DICOM) data served as basis for the segmentation of patient specific aortic pathologies. The images were all taken with a 128-line scanner (Somatom Definition®, Siemens Healthcare, Erlangen, Germany). As standard, a layer thickness of 1mm at 120 kilovolts (kV), pitch of 1.2 and field of view of 391x-8 millimeters (mm) was used.

The 3D vascular models were manufactured (1) by hybrid additive manufacturing using fused deposition modelling (Felix 3, FELIXprinters, Utrecht, Netherlands), whereby a water soluble material was used to print the inner contours of the vessels, (2) by covering the printed model with silicone (Shore A 37), (3) by flushing out the soluble material. The 3D-vascular models were printed in collaboration with the company HumanX, Wildau, Germany.

To make the simulation as realistic as possible we connected the “vascular system” to a diaphragm dosing pump (Sigma, ProMinent® Deutschland GmbH, Heidelberg, Germany). To validate the feasibility and authenticity of the simulator, we implanted an endovascular stent-graft (Endurant II, Medtronic, Dublin, Ireland) following all the procedural steps that take place in a real case.

III. Results and discussion

Figure 2 shows the final simulator with two exchangeable 3D-printed vascular pathologies (thoracic and abdominal) integrated. As planned, the whole “vascular system” is perfuseable. Figure 3 shows an intraprocedural screenshot of the implantation of the endovascular graft (Endurant II, Medtronic) into the simulator under fluoroscopy.

The intraprocedural view of the simulator is very realistic, especially the bony structure, which is important for the orientation during the endovascular intervention. All procedural steps could be done step by step as in a real case. Because of the perfusion, even angiographies were possible. Due to the use of 3D-printed real vascular models the feeling while guiding the endovascular devices was authentic.

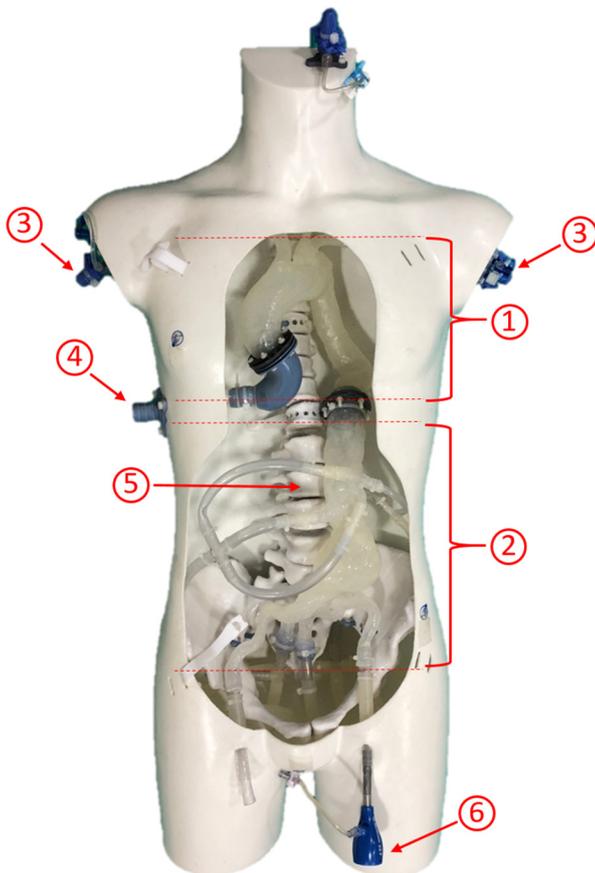


Figure 2: Final endovascular simulator; 1. thoracic part; 2. abdominal part; 3. brachial access; 4. connection for pump; 5. 3D-printed backbone and pelvis; 6. sheath for inguinal vascular access

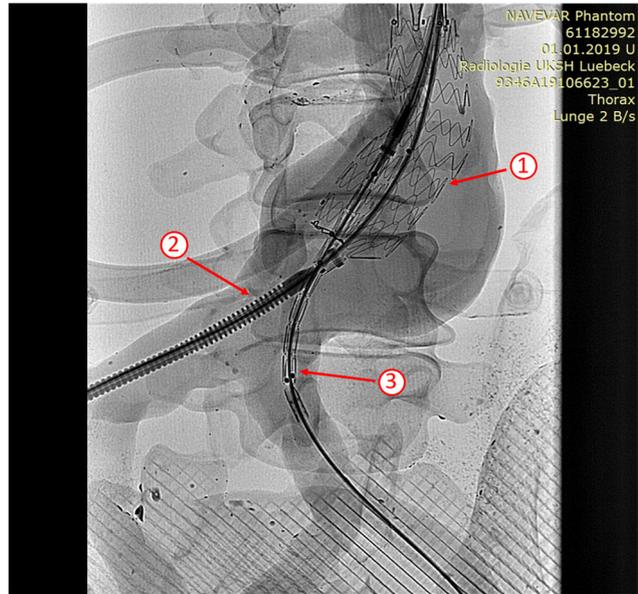


Figure 3: Implantation of an endovascular stent graft (Endurant II, Medtronic) under fluoroscopy using the developed simulator; 1. partly unfolded endograft; 2. application device for stent-graft; 3. application device for contralateral stent-graft

IV. Conclusions

Nowadays the technique of 3D-printing offers the production of patient specific 3D vascular pathologies and therefore the opportunity to develop authentic endovascular simulators. Not at least this can minimize the use of animal models for research purposes.

AUTHOR'S STATEMENT

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REFERENCES

1. Lawall H, Huppert G, Rümenapf G (2015) S3-Leitlinie zur Diagnostik, Therapie und Nachsorge der Peripheren Arteriellen Verschlusskrankheit. Dtsch. Gesellschaft für Angiol. Gesellschaft für Gefäßmedizin
2. Veith FJ (2016) A look at the future of vascular surgery. J Vasc Surg 64:885–890. doi: 10.1016/j.jvs.2016.07.096
3. (2010) DIRECTIVE 2010/63/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2010 on the protection of animals used for scientific purposes.
4. McGurk M, Amis A, Potamianos P, Goodger NM (1997) Rapid prototyping techniques for anatomical modelling in medicine. Ann R Coll Surg Engl 79:169–174. doi: 10.1103/PhysRevD.72.023508