3D printing of elastic stenosis phantoms

T. Friedrich[1*], F. Wegner[2], and T. M. Buzug[1]

[1] Institute of Medical Engineering, University of Lübeck, Germany

[2] Department of Radiology and Nuclear Medicine, University Hospital Schleswig-Holstein, Lübeck, Germany

[*] Corresponding author, email: friedrich@imt.uni-luebeck.de

Abstract: Minimally invasive endovascular interventions play an important role in clinical practice. The procedures are a versatile tool to physicians and are therefore also important for the development of devices and imaging systems, which leads to a high demand for preclinical evaluation. This work focuses on the feasibility of 3D-printing for vessel phantoms with user defined stenoses made of elastic materials. This opens up new ways of preclinical in-vitro studies, which can be used to minimize the need for in-vivo experiments.

I. Introduction

Image guided endovascular interventions play an important role in clinical practice. One of the most frequently performed interventions is the implantation of endovascular stents in constricted or occluded arterial vessel segments – so called stenoses. The minimally invasive procedures are a versatile tool to physicians and the patients benefit from less complications and a faster recovery [1]. For the development of therapeutic procedures and imaging systems as well as interventional devices, there is a high demand for preclinical evaluation [2-7]. To evaluate specific parameters of newly developed instruments, imaging systems and protocols, the availability of suitable vascular phantoms is required. In order to achieve reliable test results, these phantoms have to be reproducible and geometrically accurate.

Additive manufacturing technologies have rapidly developed during the last decades and have become part of an increasing number of different disciplines not just in research and industry, but also in healthcare. With the emerging of more soft and elastic materials, it became possible to print elastic parts directly, instead of 3D-printing a casting mold, which could be used to produce the actual part from elastic materials like silicone. This direct approach increases the design freedom and reduces the technical effort and time consumption for the production of soft parts.

In this work, we bring together both, the interventional procedures and the 3D-printing of soft materials to investigate the feasibility of producing tailored preclinical phantoms for the treatment of stenosis.

II. Material and methods

For simplicity, synthetic stenosis phantoms of different geometry have been modeled with CAD software, but the reproduction of anatomic structures extracted from radiological datasets would also be possible in a similar manner. Two exemplary stenosis geometries have been 3D-printed with a commercially available stereolithography printer (Form2, Formlabs, Massachusetts, USA). In order to achieve elastically deformable parts to mimic the physiology of blood vessels, the commonly used solid photopolymers cannot be used. But the proprietary “elastic resin” which is provided by the manufacturer of the printer has a shore hardness of 50A [8] and a silicone like appearance, and thus seems to be a good candidate for elastic vessel phantoms. Figure 1a shows a printed stenosis phantom with a length of 5 cm, an inner diameter of 6 mm and a wall thickness of 0.4 mm. It has an asymmetric stenosis on one side with a spherical shape that occludes 50% of the vessels cross section. In Figure 1c, another stenosis phantom is shown, which has the same length, inner diameter and wall thickness as the asymmetric one, but features a rotationally symmetric hourglass shaped stenosis which occludes 75% of the vessels cross section.

The described phantoms were printed in an upright orientation directly on the build platform of the printer, and could be printed without any supports, which results in a very nice clean surface of the parts. However, more complicated geometries can also be printed in the same way but there, usually the use of support structures will be necessary. Those supports would have to be removed manually during postprocessing after the print is completed and can leave little marks on the surface of the parts, which however should not significantly influence the mechanical properties of the parts. The resulting parts are soft and elastic and resemble the appearance of silicone. For thin structures they feature a high level of transparency, which comes in handy when performing tasks inside the printed parts.

In both stenosis phantoms, balloon-expandable stents from cobalt-chrome (diameter: 6 mm, length: 16 mm) have been implanted. Fig. 1b shows the stented asymmetric stenosis phantom, and the symmetric stenosis with the implanted stent is show in Fig. 1d.

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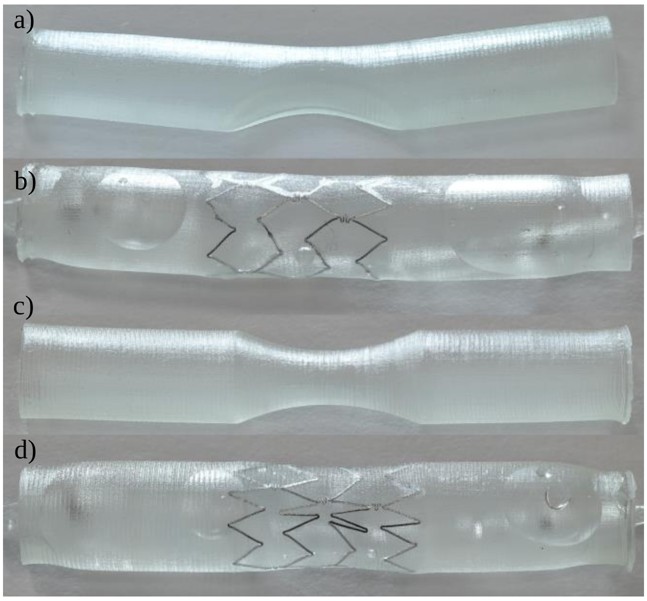

Figure 1: Stenosis phantoms with a length of 5 cm, inner diameter of 6 mm and a wall thickness of 0.4 mm; a) asymmetric stenosis phantom, b) asymmetric stenosis phantom with stent dilated by balloon catheter, c) symmetric stenosis phantom, d) symmetric stenosis phantom with stent dilated by balloon catheter

III. Results and discussion

Stenosis phantoms of two different configurations have been 3D-printed exemplarily. The phantoms were dilated easily with a balloon catheter and metallic stents have been successfully implanted into the stenoses. The elastic properties of the printing material are suitable for the performed procedure, and none of the stenosis phantoms was ruptured by the forces transmitted by the balloon-catheter. The transparent appearance of the printing material allows for visual feedback during the simulated procedure, which is an advantage for the testing of an intervention, as it is possible to perform and monitor the procedure without an additional imaging system. However, as the polymer-material is nonconductive and nonmagnetic, it is also well suited to be used within various clinical and preclinical imaging systems.

The printed stenosis phantoms can be easily adapted to the requirements of the study. Size, wall thickness and geometry are barely limited by the additive manufacturing process, and the reproducibility of the commercially available printing process is very high. The elastic properties of the material allow for an elongation of the material for about 160% until failure [8], which makes it possible to dilate the printed stenosis with a balloon catheter without breaking the material.

In order to perform more complex interventional simulations, parts like the described ones can be easily adopted for an integration into interventional simulators like [4] [6] [7]. In addition to the vascular system, a number of other anatomical stenosis localizations are plausible, e.g. the trachea [5], biliary tract or the esophagus. To mimic more realistic pathologies, actual anatomic geometries can be extracted from medical image data to simulate a pathology- or patient-specific treatment [3]. Due to the versatility of 3D-printed phantoms in general, the use of specifically designed parts can help to reduce the amount of animal experiments in preclinical research and development.

IV. Conclusions

3D-printed stenosis phantoms can provide an efficient and feasible way to test interventional devices and procedures. The design freedom gained by additive manufacturing allows to make reproducible tests with precisely specified geometries, while more application or patient specific geometries will be implemented in upcoming studies. The elastic printing material is suitable for the simulation of interventions with balloon-catheters and stents, and opens up new ways of preclinical in-vitro studies, which can be used to minimize the need for in-vivo experiments.

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AUTHOR'S STATEMENT

Conflict of interest: Authors state no conflict of interest.

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