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Printing study and design guideline for small hollow structures in medical technology

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Abstract

In recent years, interest in additive manufacturing has increased. To overcome challenges such as the correct use of the technology, guidelines are needed to help the user in the fabrication process. However, such guidance is not currently available for all applications. This paper dives into design methods in AM and their transfer to an application example in the field of medical technology. The aim of this paper is to analyse the transferability of a design method for vessel models to small vessel models. To this end, an initial printing study is carried out on simplified hollow structures.

Keywords: additive manufacturing, design methods, design guidelines, medical technology

1. Introduction

In recent years, additive manufacturing (AM) has become an important part of the modern manufacturing industry (Thompson *et al.*, 2016). With this versatile technology, complex geometric shapes and structures can be produced in just a few process steps. This considerably simplifies and accelerates the production of prototypes and end products. AM has become increasingly established across all industries. As a result of the increasing use of AM, the number of people employed in the field of AM machines, services, materials and development tools are growing. Despite all the advantages, AM also presents challenges in the design and manufacturing of components, models and products (Durakovic, 2018). These challenges include the correct use of the technology and the choice of material, as well as the design of the component (Gao *et al.*, 2015; Oropallo and Piegl, 2016; Durakovic, 2018; Djokikj and Kandikjan, 2022). In order to improve the use of AM, these challenges need to be overcome, which have a major impact on the quality, applicability and reproducibility of additive manufacturing technologies. To support the users during the process of designing and manufacturing of additive manufactured components, design methods and guidelines can be used. However, such assistance is currently not available for all areas of application.

An important area of application for AM is medical technology, where allows to replicate the natural complex geometries of the human body (Li *et al.*, 2020; Salmi, 2021; Wake, 2022). In this field, the combination of knowledge and principles from the fields of engineering and medicine poses a significant additional challenge. Among other things, surgical instruments and patient-specific implants can be manufactured (Salmi, 2021). AM is also suitable for the production of patient-specific anatomical models for surgical planning or the training of physicians (Li *et al.*, 2020; Salmi, 2021; Wake, 2022). The development towards ever smaller and better print resolutions and layer thicknesses, by now down to the nanometer range, is particularly interesting with regard to the production of small models for the medical field. Overall, ever smaller structures in medicine offer many advantages that improve patient care and advance medical research. One specific possible area of application within medical technology

is neuroradiology with its neurointerventional procedures. During these treatments, narrowed or occluded blood vessels in the brain are localized and treated using a catheter inserted into the inguinal artery under X-ray control (Hacke, 2016; Liu, 2006). With technological advances in the development of treatment instruments, it is now possible to use neurointerventional procedures to treat diseases in small peripheral vessels with a diameter of < 2 mm (Saver et al., 2020). As this treatment method is a relatively new treatment concept, there is a great need for systematic training of interventional physicians (Kashani et al., 2021). For training purposes, patient-specific vascular models can be additively manufactured and reused. Here, AM offers the possibility of producing complex geometries, such as patient-specific replicas, which would be difficult or impossible to realize using conventional manufacturing methods. Additionally, this technology enables rapid manufacturing of the parts and can be used by non- professionals, requiring no complex tooling or mold making (Thompson et al., 2016). Hence, AM is a great way for non-product developers to fabricate vascular models. For this, the users, who are often also physicians, need understandable procedures for producing these models, where many parameters can have an influence on the manufacturing (Sobirey et al., 2023). This paper investigates the transferability of an already developed design method for larger vascular models and identifies possible limitations in the manufacture of small vascular models. First, an overview of the challenges of AM is given and selected design methods as well as guidelines are presented. This is followed by a description of the design method for manufacturing larger vessel models using an exemplary simulation model. Finally, a printing study on the transferability of the applied design method to small hollow structures is being carried out. For this purpose, various influencing parameters such as diameter, length and component orientation are investigated in the production of initially simplified hollow structures in the form of tubes. Initial results of this printing study are presented in this paper. By combining engineering design and medical technology this article provides a first overview for users such as product developers as well as physicians about influencing factors to be considered in the manufacturing of hollow small vessel models.

2. Research background: Challenges in additive manufacturing and design methods

This Chapter first presents the aforementioned challenges of AM in more detail. This is followed by a brief overview of already developed design methods and guidelines.

2.1. Challenges in additive manufacturing

The alternative manufacturing process to conventional technologies requires a new design approach, which has resulted in Design for AM (DfAM) (Thompson et al., 2016). The development of DfAM represents a major challenge. Due to the rapid proliferation of AM technologies and advancements in lower cost machines and a variety of materials, there is a lack of comprehensive design principles, manufacturing guidelines and standardization of best practices. The use of AM is limited by the insufficient knowledge and utilization of AM designs. Design rules or guidelines can help to understand the AM process and the necessary design so that users can fully benefit from the potential of AM. However, these aids are often specific and do not always adequately cover the conditions of application areas, especially medical applications - if they are available at all. The challenges affect the end-to-end AM manufacturing process, from component design to fabrication and post-processing (Gao et al., 2015; Oropallo and Piegl, 2016; Durakovic, 2018; Djokikj and Kandikjan, 2022). The following is a brief summary of some of the challenges which AM faces:

- Printer selection
- Material selection
- Design process
    - CAD software selection
    - Geometric restriction
- Pre-processing components
    - Orientation
    - Support structures

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- o Slicing method
        - o Printing parameters
        - o Speed
    - Post-processing
        - o Removing the support structure
        - o Improving the surface quality

The many challenges involved in the application of AM highlight the need for user support. Users, who are also increasingly non-product developers, require design rules, design methods and guidelines for the design and fabrication of components. A selection of design methods is briefly presented below.

2.2. Design methods and guidelines for additive manufacturing

By using design methods and guidelines, users can be supported in the process of designing and manufacturing of additive manufactured components to overcome challenges. The relevance of the topic for the improvement and further development in working with AM is clearly identified by the many contributions in the literature. The differences between various design methods and guidelines are explained below using selected examples. There are many general AM design methods or guidelines which have design rules as a topic and already cover the challenges described above well (Adam and Zimmer, 2015; DIN EN ISO/ASTM 52910, 2020; Lachmayer et al., 2022; Materialise, 2023; Junk and Bär, 2023). Lachmayer et al. (2022) have developed a design catalogue for AM as a supporting tool for the design of standard components such as hollow cylinders. The catalogue provides information on orientation, size, walls and drill holes, among other things. However, no information is specified regarding the material and process. The DIN EN ISO/ASTM 52910 (2020) provides the designer with general information for the design of components such as overhangs and support structures or enclosed volumes. In addition, properties are listed to assist in the selection of materials and additive manufacturing technologies. The contributions from Adam and Zimmer (2015) and the company Materialise (Materialise NV, Leuven, Belgium) are more specific in their application for certain materials or additive manufacturing processes. Materialise (2023) has created basic rules and tips for the design of components using specific materials with regard to wall thickness, support structures and orientation. The company also refers to the typical use of the individual materials. As part of their work, Adam and Zimmer (2015) developed design rules for standard components for the laser sintering (LS), laser melting (LM) and fused deposition modeling (FDM) processes. The design rules are function-independent and easily transferable to individual component designs. Another field that design methods or guidelines focus on is print process optimization (Jiang and Ma, 2020; Shakeri et al., 2021; Junk and Bär, 2023). In their Review, Jiang and Ma (2020) developed a table as a guide for designers to select a suitable path planning strategy for specific applications. Path planning, which can be defined as a route description for material deposition, is a critical element in additive manufacturing as it has a major impact on the surface roughness, dimensional accuracy and (mechanical) properties of the printed parts. The path planning strategies were categorized into the groups of improved print quality, material and time reduction and achievement of desired properties. Shakeri et al. (2021) present experimentally determined process parameters for the FDM process using the Taguchi method. They report the optimization of FDM process parameters to reduce the cylindricity error of additively manufactured components. The effects of thickness, infill pattern, number of walls, and layer height were analysed. The article by Junk and Bär, 2023 focuses on the development of design guidelines that identify the possibilities and limitations of masked stereolithography (mSLA). Parameters such as wall thickness, diameter of holes, overhangs and tolerances for fits were studied to develop the guidelines. As a result of the series of tests, Junk and Bär (2023) were able to specify guide parameters for standard elements for the mSLA process. In their conclusion, the authors come to the conclusion that separate investigations and guidelines are necessary for each additive manufacturing process, as these have different strengths and weaknesses and process-specific effects.

As already described by Junk and Bär (2023), the AM design methods or guidelines are specific to each manufacturing process and the individual application. This does not always sufficiently cover the conditions of application areas, especially in medicine, for example. Particularly in the application area with a combination of engineers and physicians, users receive poor support in design and fabrication. In

the field of neuroradiology and vascular model manufacturing, the focus of the articles is on the final product and not on the manufacturing process and especially its influencing factors (Kuhl *et al.*, 2022; Spallek *et al.*, 2019; Cogswell *et al.*, 2020; McGuire *et al.*, 2021). Thus, there is a need for users to have an understandable guideline for the fabrication of these models. The challenge can be found in the transfer of existing AM design methods or guidelines to the field of medicine. Using a selected design method for the manufacturing of larger vessel models, the application to the fabrication of small vessel models will be investigated. A printing study with the analysis of various influencing parameters is being carried out and possible limitations identified.

3. Standardized individualization process of vessel models for HANNES

In the next Sections, the selected design method for larger vessel models to analyse the transferability to small vessel models using a printing study is described. First, the simulation model HANNES (Hamburg ANatomical NEurointerventional Simulator) is presented, in which the manufactured vascular models are applied. The training model is used for learning, practicing and researching neurointerventional procedures for physicians. Section 3.2 describes the design method for the manufacturing of large vascular models in more detail and presents the manufacturing process and materials used.

3.1. Hamburg ANatomical NEurointerventional Simulator

The simulation model HANNES, which was developed in several research projects by the Institute for Product Development and Mechanical Engineering Design at the Technical University of Hamburg (Spallek *et al.*, 2019; Spallek *et al.*, 2020) is used as inspiration for the manufacturing of small vessel models due to the known materials and the described edge-free connection of vessel modules. A modular product architecture was developed for HANNES, in which different training scenarios for aneurysm and stroke treatment can be simulated by combining standardized with variant modules (Wortmann *et al.*, 2019; Spallek *et al.*, 2020). Various materials for the additively manufactured vascular models were compared by (Kuhl *et al.*, 2022) in terms of their friction properties with animal models. The Flexible 80A material (Flexible 80A by Formlabs Inc., USA) is the most recommended. Through the use of defined interfaces and edge-free adapters, an easy change of the models in the vessel tree is possible. To realistically mimic blood flow, the simulation model has a fluid system with adjustable temperature, pulse and volume flow.

3.2. Standardized individualization process of vessel models

The design and fabrication of the patient-based vascular models for the simulation model HANNES are performed in a standardized individualization process introduced by Spallek *et al.* (2016) and Spallek and Krause (2016) and adapted in Spallek *et al.* (2019). It described the process from the acquisition of the medical data over the designing of specifications and the additive manufacturing of the model to its application. The process flow is based on the example of an aneurysm model. The individual process steps are listed below and will be explained in more detail in the subsequent part:

1. Data acquisition
2. Segmentation
3. Design of specification
4. Additive manufacturing
5. Postprocessing
6. Application

In the first step, the medical data is acquired by a three-dimensional angiographic scan. Thereafter, the data is segmented and relevant vessels are retained. In the third step, model specifications like the definition of wall thicknesses for the vessel models or adapters as the interface for the integration into HANNES take place. Afterwards, the vessel model is additively manufactured using stereolithography (SLA) (Spallek *et al.*, 2019; Nawka *et al.*, 2020; Kuhl *et al.*, 2022). In this process, a liquid photopolymer

is cured layer by layer with a UV laser to generate the three-dimensional part. In the final steps, the vascular model is post-processed and applied by the physicians in the simulation model.

In the following, measures and influencing factors for the manufacturing of small vessel models are defined and a first printing study with simplified geometries is started.

4. Towards a printing study: Analysing materials and methods

In this Chapter, the research method for the printing study to transfer the previously described process to the fabrication of small vessel models is presented. In order for small vessel models to be manufactured additively, specific challenges must be identified and possible influences described. For this purpose, a printing study on the influence of various factors is carried out as an aid for users in the production of such small hollow structures. First results of this study are presented in Section 5.
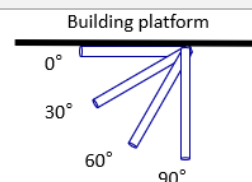
To study the transfer of the previously described standardized individualization process of vascular models for HANNES, the first two process steps (data acquisition and segmentation) are skipped, because no patient data is used. For a first printing study, simplified models as tubes were investigated, in order to test many possible influencing parameters. By using simplified samples, challenges for small hollow structures can be identified before they are studied on more complex models. The results will later be transferred to the complex structures of the small vessel models. The investigation started in the third process step "Design of specifications". Different tubes were designed in a CAD program (Catia by Dassault Systèmes, France) and specifications such as length, inner diameter and wall thickness varied. Subsequently, the models were prepared for printing. An STL file (Standard Triangulation Language) is created by tessellation, which divides the part into smaller geometries. In this study, however, the tessellation parameter of 0.01 was not changed, because the influencing parameters during printing were analysed first. For the fourth process step of additive manufacturing, the Form 3 printer (Form 3 by Formlabs Inc., USA) and the material Flexible 80A (Flexible 80A by Formlabs Inc., USA) was used, which was already applied for the study by (Kuhl *et al.*, 2022). First, the prints were prepared using the printer Software Preform (Preform by Formlabs Inc., USA). Here, the models were positioned in different orientations on the build platform. In addition, the support structures could be manually adjusted and a layer thickness based on the vertical resolution (z-direction) could be selected for the components. As described above, the vessel models are to be used for training catheter-based treatment within the vessels, so the parts are manufactured without internal support structures in order to achieve a smooth inner surface. The thinner layer thickness of 0.050 mm was applied for all models. Material characteristics of the material out of the datasheet of the resin manufacturer are added (Formlabs, 2020). The printer data is summarized below (Formlabs, 2019, 2023):

- Technology: Low Force Stereolithography (LFS)
- Build Volume: 145 x 145 x 185 mm
- Laser:
  - 250 mW laser
  - 405 nm violet laser
  - Spot Size 85 µm
- Layer Thickness (Axis Resolution): 25-300 µm
- XY Resolution: 25 µm

During the printing process, many different parameters can influence on the manufacturing of small vessel models (Sobirey *et al.*, 2023). The chosen printer does not allow any settings that could influence the curing of the material such as hatch spacing, the hatch overcure and the associated exposure time and the temperature. Thereby, the study during manufacturing is limited to the parameters of layer thickness and orientation of the models on the building platform. In the subsequent "postprocessing" process step, the models were washed out and cured. For all models the Form Wash (Form Wash by Formlabs Inc., USA) with isopropanol solution was used for washing and the Form Cure L (Form Cure L by Formlabs Inc., USA) was utilized for curing. The final process step, "application", does not take place. The first printing study is used to analyse the possible design and influencing parameters in the fabrication of small, simplified hollow structures. The simplified tubes are analysed regarding hollowness, uniform diameter and possible shrinkage. The table below summarizes the set and tested parameters.

Table 1. **Set and tested parameters for the printing study**

Parameter	Value
Printer	Form 3
Material	Flexible 80A
Layer thickness	0.05 mm
Inner diameter	2.0 mm; 1.75 mm; 1.5 mm; 1.25 mm; 1.0 mm; 0.75 mm; 0.5 mm
Wall thickness	0.25 mm; 0.5 mm; 0.75 mm; 1,0 mm; 10 mm
Orientation	0°; 30°; 45°; 60°; 90°
Length	20 mm; 50 mm; 100 mm; 150 mm

The first results of the printing study are shown in the following Section. First, each orientation was analysed for each inner diameter to determine the best orientation for the tubes. With this knowledge, the influences of the length of the tubes and the wall thickness were studied for only one orientation. In a further series of tests, the curvature and curves of the simplified hollow structures as well as the branching and the distance between two tubes are to be analysed based on the initial findings from this study.

5. Results of the printing study

The first results of the printing study for the transfer of the selected design method to the fabrication of small hollow structures are presented below. For this purpose, different influencing factors were analysed, such as inner diameter, wall thickness, length and orientation of the tubes (see table 1). The simplified tubes were studied with regard to hollowness, uniform diameter and possible shrinkage of the component. The results of this printing study identify possibilities and limitations in the transfer of the design method to small hollow structures and are significant for the successful application to small vessel models.

Table 2. **Results of the printed tubes (50 mm length, 1 mm wall thickness) with the investigated parameters inner diameter and orientation with regard to hollowness and uniform diameter: (+) good hollowness and uniform diameter; (o) good hollowness but non-uniform diameter; (-) no continuous hollowness**

Inner diameter / Orientation	2.0 mm	1.75 mm	1.5 mm	1.25 mm	1.0 mm		0.75 mm	0.5 mm
0°	o	o	o	o	o	-	-	-
30°	o	o	o	o	o		-	-
45°	o	o	o	o	o		o | -	-
60°	o	o	o	o	o		o	-
90°	+	+	+	+	+		+	-

Table 2 presents the results of the investigation of the inner diameter (2.0 mm - 0.5 mm) and orientation (0° - 90°) with constant wall thickness (1 mm) and length of the tubes (50 mm). The printed samples with an inner diameter of 0.5 mm have a non-continuous hollowness at every orientation. The orientation of 0° and 30° resulted in a sealed hollow structure at an inner diameter of 0.75 mm. The best findings in terms of hollowness and uniform diameter were achieved at the 90° orientation of the tubes to the building platform. The results of the other diameters and orientations show good hollowness but an irregular diameter. The classification of the categories (+) good hollowness and uniform diameter, (o)

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good hollowness but non-uniform diameter, (-) no continuous hollowness can be seen in Figure 1. Red food coloring was used and injected into the tubes to visualize and evaluate the hollowness. The orientation of 90° was used for the following experiments due to the good results.
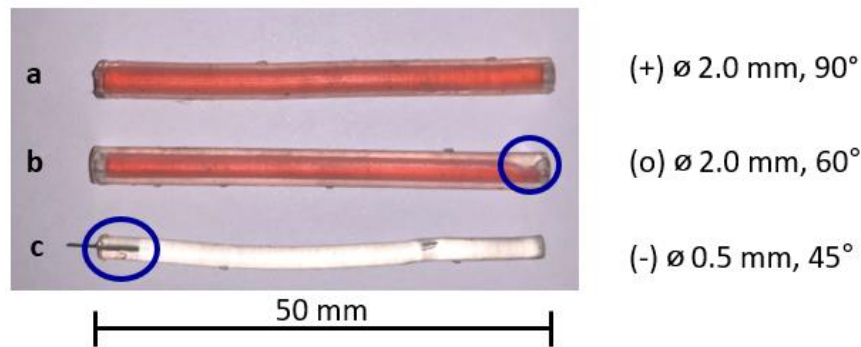

Figure 1. Printed tubes (50 mm length, 1 mm wall thickness) colored with food coloring to visualize the hollowness with (a) inner diameter 2.0 mm and orientation 90˚, (b) inner diameter 2.0 mm and orientation 60˚, (c) inner diameter 0.5 mm and orientation 45˚

In order to determine the influence of different inner diameters with varying wall thicknesses on the hollowness, the two parameters were examined at a constant length (50 mm) and the same orientation (90°). The results are summarized in Table 3a. The printed samples with an inner diameter of 0.5 mm still show a non-continuous hollowness even with different wall thicknesses. Printing the tubes in a block with a wall thickness of 10.0 mm also shows closed structures. The components with an inner diameter of 1.0 mm and 2.0 mm showed good hollowness and uniform diameter at different wall thicknesses. Only the samples with an inner diameter of 1.0 mm and a wall thickness of 0.25 mm have a non-uniform diameter in some cases.

Table 3. Results of the a) printed tubes (50 mm length, 90˚ orientation) with the investigated parameters inner diameter and wall thickness and b) the printed tubes (1 mm wall thickness, 90˚ orientation) with the investigated parameters inner diameter and tube length with regard to hollowness and uniform diameter: (+) good hollowness and uniform diameter; (o) good hollowness but non-uniform diameter; (-) no continuous hollowness

a)

Inner diameter / Wall thickness	2.0 mm	1.0 mm	0.5 mm
0.25 mm	+	o	-
0.5 mm	+	+	-
0.75 mm	+	+	-
1.0 mm	+	+	-
10.0 mm	-	-	

b)

Inner diameter / Tube Length	2.0 mm	1.0 mm	0.75 mm
50 mm	+	+	+
100 mm	+	o	-
150 mm	o		

The findings of the last investigation for the correlation between different tube lengths and inner diameters with the same wall thickness (1 mm) and orientation (90°) are shown in Table 3b. The tubes of length 50 mm exhibit a good hollowness and uniform diameter over all inner diameters. For a length of 100 mm, a good hollowness but non-uniform diameter can be observed for an inner diameter of 1.0 mm and even a no continuous hollowness for an inner diameter of 0.75 mm. A good hollowness but non-uniform diameter can already be identified at an inner diameter of 2.0 mm for the longer samples of 150 mm. Table 4 presents the results of the dimensions of the printed tubes (1 mm wall thickness, 90° orientation) using the microscope VHX-950F (VHX-950F by Keyence, Japan) and their difference from the designed part. For this purpose, two points were manually set on the outer contour of the inside diameter and a circle was created from which the diameter was automatically calculated by the device.

The dimensions of the inner diameters are all smaller than those of the designed part. Taking into account the printer-specific xy-resolution of 0.025 mm and the z-resolution of 0.05 mm, the differences of the inner diameters show very good results with a small deviation (+). The tubes with diameters of 0.75 mm have a medium deviation (o). The remaining results show a larger deviation, larger than 0.15 mm (-).

Table 4. **Results of the dimensions of the printed tubes (1 mm wall thickness, 90° orientation) using a microscope and their difference to the designed component**

Measurement / Inner diameter	Inner diameter [mm]	Difference [mm]	Evaluation
2.0 mm	1.96	-0.04	+
1.75 mm	1.70	-0.05	+
1.5 mm	1.35	-0.15	-
1.25 mm	1.09	-0.16	-
1.0 mm	0.84	-0.16	-
0.75 mm	0.67	-0.08	o
0.5 mm	0.24	-0.26	-

6. Discussion and conclusion

Overall, it can be summarized that many parameters can have an influence in transferring the design method from large the patient-based vascular models for the simulation model HANNES to small vascular models. In this article, an initial printing study was carried out with simplified structures such as tubes to analyse the possible design and influencing parameters in the manufacturing of small, hollow parts. For this purpose, parameters such as inner diameter, wall thickness, length and orientation of the tubes were investigated. The simplified tubes were examined with regard to hollowness, uniform diameter and possible shrinkage of the component. The investigations have shown that limitations arise for the transfer of the method and require special design guidelines for the manufacturing of small hollow structures. Figure 2 presents the results of the first printing study.
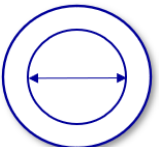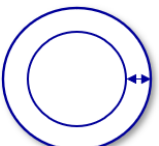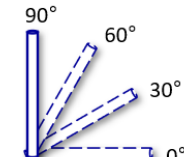

	Inner diameter ≥ 0.75 mm		Length ≤ 100 mm
	Wall thickness ≥ 0.5 mm ≤ 1.0 mm		Orientation 90°

Figure 2. **Graphical summary of the developed design guidelines for the transfer of the selected design method to the fabrication of small hollow structures**

The graphical summary developed from the transfer of the selected design method to the manufacturing of small hollow structures represents the first step towards a design guideline for small SLA-manufactured vessel models. The limitations regarding the inner diameter, the length of the tubes and the wall thickness were defined. The use of a different SLA printer with a better resolution such as a smaller layer thickness (z-direction) or the laser with the size of the laser spot (x-y-direction) could have a positive influence on the analysed parameters and their limits. Furthermore, another SLA printer with the possible adjustment of parameters like exposure time and temperature and their influence on the hollow structures should be investigated. The best orientation for samples with good hollowness and

uniform diameter at 90° was determined. A deviation of the samples in relation to the measured and designed inner diameter can be observed. In order to make a more precise statement about the difference further investigations must be carried out. The type and duration of post-processing can have a major influence on the deviation of the samples. The influence of the post-processing process should be studied in subsequent investigations, especially for the results that have minor defects. The non-uniform diameter could possibly be caused by cured resin residuals only after the printing process. Thus, a washing and curing process adapted for small hollow structures could change the limitations of this printing study. All in all, the study on the transferability of the design method shows that many factors can have an influence and that a simple application of the method is not possible. In a further printing study, the parameters of branching based on simplified structure, as well as the curvature and the distance between two tubes were to be analysed. In their article, Cogswell *et al.* (2020) describe that the appropriate printing technology and material should be selected specifically for each application when producing vessel models in order to achieve the best possible result. In this study, the SLA procedure was used due to the investigation of the transferability of the existing process. For a precise analysis of determining which AM procedure is best suited for small hollow structures, all available procedures should be evaluated. Various printing processes and materials for the fabrication of small vascular models are currently being investigated in an ongoing printing study.

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