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# Model of the Venous System for Training Endovascular Treatment in Interventional Neuroradiology

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**Abstract:** Background: Endovascular treatment of venous disease is introducing new therapeutic options in neuroradiology. These procedures are technically challenging and require extensive physician training. Currently, training is mainly conducted on animal models, which presents drawbacks such as ethical concerns and anatomical differences from human vascular architecture. There is no training model that simulates treating intracranial venous disease using original instruments in a real angiography suite. Methods: This work presents the development of a venous system model for endovascular training simulations for integration into the existing Hamburg ANatomical NEurointerventional Simulator (HANNES) for arterial interventions. Results: The manufacturing process established at HANNES and the material used for the arterial vascular models were successfully transferred to the larger 3D-printed vein models. The application test was conducted in a real angiography suite with original instruments by an experienced neurointerventional physician to evaluate the system in terms of geometric mapping, flow, haptics and probing. Conclusion: This newly developed model provides a first approach to simulate an endovascular intervention in the venous system within the HANNES environment. Future expansions might include specific treatment simulations for conditions such as arteriovenous malformations, dural arteriovenous fistulas, sinus vein thrombosis and hydrocephalus.

**Keywords:** endovascular therapy; venous vascular system; simulation model; HANNES; 3D printing; vein model

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## 1. Introduction

The introduction of endovascular treatments for venous disease represents a significant advance in modern vascular medicine, particularly in neuroradiology. While the treatment of arterial disease using endovascular procedures is already widespread and established [1,2], venous interventions are a relatively recent development [3–8]. These innovations open new treatment options that were previously limited to surgery or conservative approaches. However, these procedures are not yet widely available and require specialised expertise, which limits their use in clinical practice. Venous interventions are not only technically more challenging, but they also require an in-depth understanding of the complex anatomy and physiology of the venous system, particularly in the brain. In the field of interventional neuroradiology, the following procedures may be relevant to the venous vasculature:

- Arteriovenous malformations (AVMs), abnormal connections between arteries and veins;

- Dural arteriovenous fistulas (dAVFs), pathological connections between dural arteries and veins;
- Sinus vein thrombosis, thrombotic narrowing or blockage of the venous sinuses of the brain;
- Hydrocephalus, in which there is an excessive accumulation of cerebrospinal fluid in the brain, often caused by a disruption in venous outflow.

AVMs and dAVFs can be treated using either the arterial or venous systems or both in combination [5,7,9], whereas the other conditions are treated using only the venous system. Simultaneous navigation of multiple catheters in anatomically diverse vascular systems, combined with the variability and complexity of vascular malformations, is a challenging interventional procedure. This requires not only sound medical understanding, but also in-depth knowledge of the instruments used and the underlying technology to ensure that the procedures are carried out to a high standard. The introduction of these new treatment options has led to a growing interest in specialised training. In their review of current trends in the treatment of sinus vein thrombosis, Kharbat et al. [10] highlight the lack of preclinical models and call for the further development of models for treatment. The lack of adequate simulation models makes it difficult to test and practice new techniques before they are used in clinical practice. This not only delays progress, but also increases the risk of complications and misdiagnosis during real interventions. At present, the training is mainly limited to animal models [6,11–13]. A major disadvantage of animal models is the anatomical differences from the vascular architecture of the human body, which makes it difficult to transfer the techniques learned to everyday clinical practice [14,15]. Ethical concerns and the time and cost involved in preparation and follow-up are also limiting factors [14,15]. This highlights the need to use in vitro simulation models for training purposes. These should reflect reality as closely as possible in terms of anatomy, disease-specific preparation, use of materials, management of complications and duration of the procedure (‘true-to-life’ approach) [14]. Other benefits of using a simulation model include more frequent and reproducible training, which increase the safety and the quality of the procedure. No models of the venous vascular system were found in the literature or in manufacturers’ brochures. This lack of suitable models is a significant bottleneck in the training and development of new treatment techniques. Only the AV-AFSN-001+ flexible vein and heart model (Elastrat Sàrl, Geneva, Switzerland) [16] and the Angiogram Sam Venous Heart Path Training Model (Lake Forest Anatomicals, Lake Forest, IL, USA) [17] provide a venous system. These only represent circulation from the legs to the heart and have no arterial system [17] or connection to the arterial system, providing two separate circuits [16]. As a result, there are currently no training models available to simulate the treatment of venous vascular diseases in the head. This gap not only makes it difficult to train specialists, but it also limits the ability to develop specific treatments for head venous disease. The integration of venous pathologies into a holistic system of arterial and venous vessels has not yet been achieved. The availability of vein therapies for affected patients would be greatly improved by the development of a model-based training option.

This study is concerned with the extension of the existing Hamburg ANatomical NEurointerventional Simulator (HANNES), which is currently used to simulate arterial interventions in neuroradiology, such as aneurysm, stroke and stenosis treatment [18]. HANNES contains a detailed 3D-printed arterial vascular tree from the groin to the head vessels and is already used for training applications under real conditions with original instruments in a real angiography suite for aneurysm, stroke and stenosis treatment [18]. The simulator is modular, so it can be adapted to different clinical scenarios and requirements, allowing it to be used flexibly for a variety of training purposes. The vascular models are produced using stereolithography (SLA) and a flexible material that has been assessed as suitable [19]. The simulator has a fluid system with an adjustable temperature, pulse and volume flow to mimic realistic blood pressure. The aim of this work is to extend this model to include a venous system in order to be able to represent the above venous interventions and treatments in the future. The venous system was developed and tested in close collaboration with an interdisciplinary team of physicians and engineers to ensure that the anatomical and functional representation of the model meets clinical needs. The differences in veins, which have a different structure to arterial vessels and a larger lumen due to their thinner wall thickness, make it challenging to verify the transferability of the manufacturing process.

## 2. Materials and Methods

The model was designed by combining medical expertise and technical knowledge to replicate an anatomical structure as realistically as possible. It aims to capture in detail the complexity and the specific requirements of neurointerventional procedures. The development was based on the VDI 2221 (Development of technical products and systems—Model of product development) [20]. It included the steps of planning, conception, design and development. In addition, the development of the vessel model from image acquisition to design, manufacturing and application was based on the standardised process flow of Spallek et al. [21]. The arterial system has already been developed on this basis. This is now being tested for its transferability to vein models. After development, application tests were performed on the HANNES simulator with original treatment instruments in a realistic angiography suite by an experienced neurointerventionalist.

### 2.1. Requirements of the Venous System Model

Firstly, the requirements for the venous system model to be developed were analysed by interviewing physicians and documenting a list of requirements. The requirements were divided into geometric, physiological and medical–therapy aspects according to Wegner et al. [22]. Overall, the HANNES simulator should not be modified significantly during the integration of the venous system.

Geometric mapping: The venous system should represent the vessels from the *inguinal vein* to the cerebral vein (*superior sagittal sinus*) and be represented as a single, simplified strand without outlets for other veins. The geometry of the venous system should be anatomically similar with corresponding diameters of the veins. In the HANNES simulator, the diameter of the *vena cava* should be equivalent to that of the existing aorta model, given the comparable dimensions of the vessels in humans. The vein models should be positioned using external holders.

Physiological mapping: Similar to the existing vascular models integrated in HANNES, the vein models should have a hollow internal structure, a smooth inner surface and no inner edges. A throttle should be used to facilitate pressure regulation between the arterial and venous systems. In addition, the manufacturing process and the material already established for the arterial models should be used, since it was found to be suitable in previous research as it resulted in no image artefacts [18,19].

Medical therapy mapping: To allow for the subsequent insertion of a balloon catheter into the *transverse sinus* during the sinus thrombosis simulation, the vein should be at least 7 mm in diameter. It should be possible to probe through the venous system using original treatment instruments.

### 2.2. Design of the Venous System Model

After defining the requirements, the design phase began as described in VDI 2221 [20]. This involved the development of a functional structure representing the main and subfunctions of the vein system. Different operating principles for each subfunction were identified and systematically developed. The morphological box was used to work out solutions for the subfunctions in order to find a variety of possible solutions. Several alternative solutions were then developed and evaluated using a weighted scoring system based on technical criteria. These criteria included an anatomically correct representation of the vein system and economic criteria, such as manufacturing costs. The best solution was then selected for further development. The extension of the existing arterial system of the HANNES simulator, as illustrated in Figure 1, comprises the addition of a venous system comprising seven individual vein models. The arterial system is represented in red and the venous system is depicted in blue.

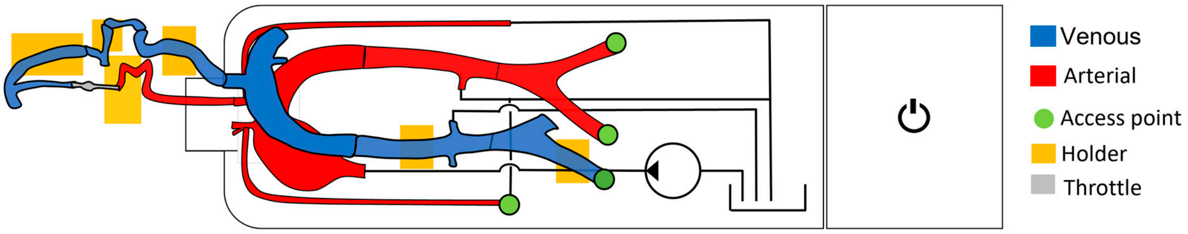


**Figure 1.** Schematic representation of the extension of the existing arterial system of the HANNES simulator (red) by a venous system consisting of seven individual vein models (blue). Adapted from Schmiech et al. [18].

In the best rated solution alternative, a pressure drop is achieved via an unregulated throttle (see Figure 1 (grey)). A cross-sectional constriction in a vessel model between the arterial and venous systems creates a pressure drop due to a vasoconstriction analogue in the human body, for example, in capillary vessels. Due to manufacturing limitations, the vessel sections are not divided according to the anatomical boundaries of the vessels. The individual vessel sections are simply connected by the adapters already used in the HANNES for the arterial system, which are placed on straight vessel sections. To avoid major modifications to the HANNES simulator, removable holders for the individual vein models are integrated (see Figure 1 (yellow)). The existing head module of the simulator cannot be used to add a venous system due to the limited installation space. The venous access point for the sheath is located close to the existing arterial access point and is based on the current design (see Figure 1 (green)). The venous valves and the anatomically correct circulation, which, unlike in humans, runs away from the heart from below the *vena cava*, remain unnoticed in the initial design of a venous system.

The venous system was designed and developed according to the standardised procedure of Spallek et al. [21]. Patient data were not available for the entire venous system. The 3D anatomical atlas of Zygote Body online (Zygote Media Group, American Fork, UT, USA) [23] and the diameter requirements were used as the basis for the vein models. The following veins were designed for the development of a venous system: the *inguinal vein*, the *vena cava*, the *brachiocephalic vein*, the *internal jugular vein*, the *sigmoid sinus*, the *transverse sinus* and the *superior sagittal sinus* (see Figure 1 (blue)). The holders were subsequently designed to hold the *internal jugular vein*, the *sigmoid sinus*, the *transverse sinus*, the *superior sagittal sinus*, as well as the connection between the arterial and venous systems on the angiography table (see Figure 1). Removable holders were also designed for the *vena cava* and the *inguinal vein* on the HANNES simulator (see Figure 1).

The *inguinal vein* and the *vena cava* were taken from the existing arterial system and customised to fit the position in the HANNES simulator. The vein models from the *brachiocephalic vein* to the *superior sagittal sinus* were completely redesigned. The CAD programme CATIA V5 (Version R20, Dassault Systèmes, Vélizy Villacoublay, France) was used to design the vein models. The models were then given an external wall thickness of 1.7 mm to 2 mm in order to find a compromise between mechanical stability and a material-saving design. Standardised interfaces were then added. The existing edgeless connectors were used to integrate the models into the vessel tree of the HANNES simulator [18]. The final CAD-designed vein models (blue) and the throttle (red) connecting to the arterial system are shown in Figure 2. At the end of the design phase, the models were prepared for manufacturing by creating a Standard Triangulation Language file (STL).

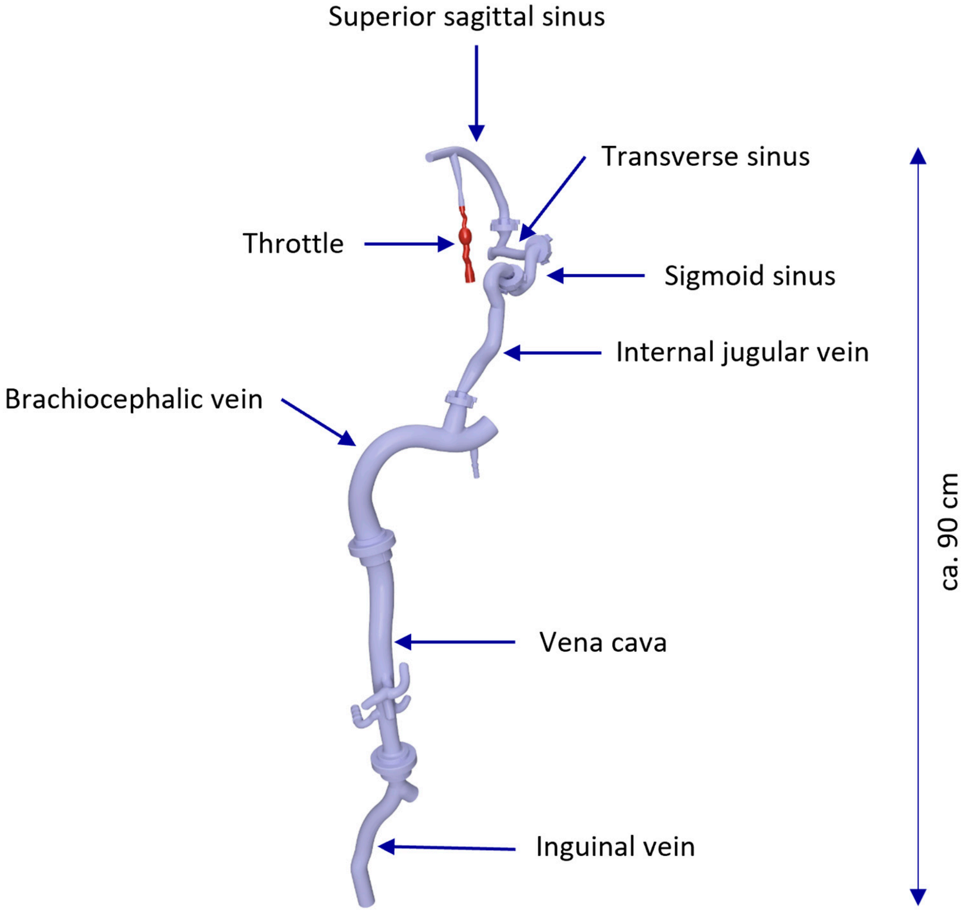


**Figure 2.** CAD design of the final vein models (blue) and throttle (red) connecting to the arterial system. The individual components of the vein system are connected to each other via the connectors.

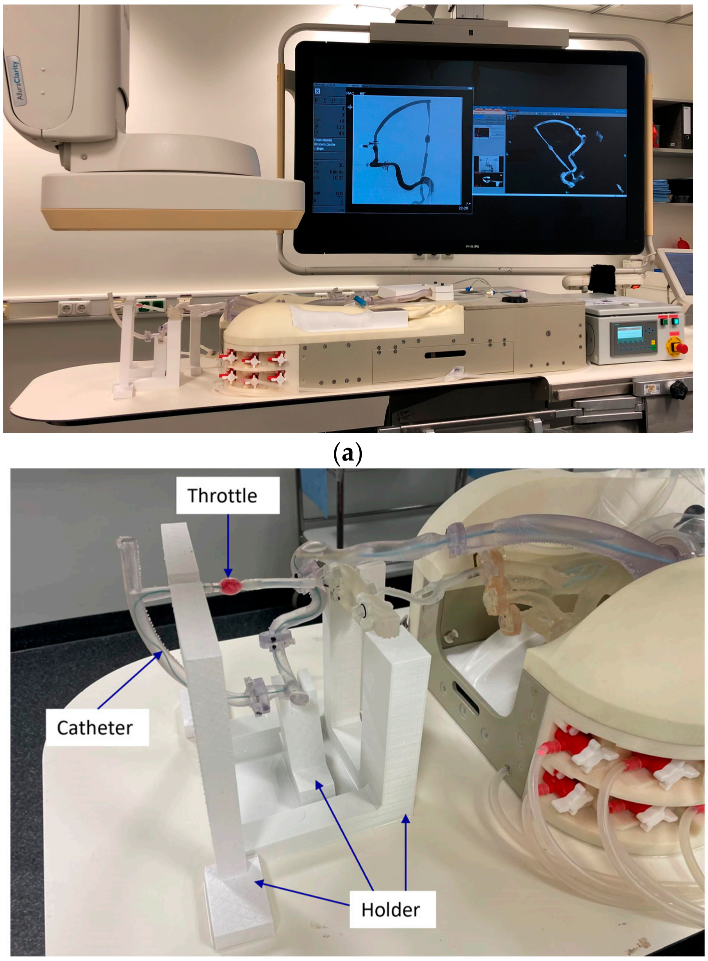
### *2.3. Manufacturing of the Venous System Model*

As mentioned above, the venous models are manufactured using the SLA process that has been established for HANNES arterial vessel models. This process is known for its high precision. It is used to ensure that the complex structures of the vein models are reproduced in detail. The Formlabs Form 3L printer (Formlabs Inc., Somerville, MA, USA) and the Flexible 80A material (Formlabs Inc., Somerville, MA, USA) were used. The models were prepared for printing using the Preform software (Version 3.43.1, Formlabs Inc., Somerville, MA, USA), provided with support structures and adjusted to a layer thickness of 0.1 mm. After printing, the models were manually washed out with isopropanol (IPA) and then cured in the Form Cure L machine (Formlabs Inc., Somerville, MA, USA) according to the manufacturer's instructions. Afterwards, the support structures were removed. An FDM printer (Ultimaker S5, Ultimaker, Utrecht, The Netherlands) and the material polylactide (PLA) (Das Filament, Emskirchen, Germany) were used to manufacture the holders. The print preparation software Cura (Version 5.2.2, Ultimaker, Utrecht, The Netherlands) was used to set the printing parameters, such as support structures and printing speed. Finally, the support material was manually removed.

## 3. Results

The venous system was tested and evaluated by three physicians that had four, eight and ten years of experience in interventional neuroradiology. In order to test the functionality and suitability of the model in detail, the physicians carried out several tests, including simulated probing of the venous vasculature. The model was tested with original treatment instruments in a realistic angiography suite to simulate real procedural conditions. The tests were carried out with regard to the following aspects: geometric mapping, flow, haptics and probing ability. In particular, it was investigated how accurately the model simulates the conditions of a real intervention and whether it can be used as an effective training model for interventional neuroradiology.

The individual vein models were connected to each other using the edge-free connections and connected to the arterial circuit of the HANNES simulator via the throttle valve. The holders were positioned for better and more stable alignment of the vein models. Figure 3a shows the complete HANNES simulator test setup in the angiography for this study. The redesigned vein models integrated into HANNES, from the *brachiocephalic vein* to the throttle and its holders, are shown in Figure 3b. In addition, probing with a catheter, highlighted with a blue arrow, can be seen through the transparent vessel models.



(**a**)

(**b**)

**Figure 3.** Test setup (**a**) of the complete HANNES simulator in the angiography and (**b**) of the redesigned vein models integrated into HANNES, from the *brachiocephalic vein* to the throttle and its holders. Probing with a catheter can be seen through the transparent vessel models.

To test the vein model with original instruments, access was made through a sheath in the *inguinal vein*, as in a real treatment (see Figure 1 (green)). A 7F ENVOY guiding catheter (Cerenovus Inc., Johnson & Johnson Miami, FL, USA) was inserted into the venous system. To reach the small vessels in the brain, a Headway$^{\text{TM}}$ 17 (Terumo Neuro, Shibuya, Tokyo Prefecture, Japan) microcatheter was used. The flow through the venous system was analysed using digital subtraction angiography (DSA). This was done by injecting a contrast agent via a catheter into the arterial system to ensure it would spread throughout the venous system.

Figure 4 shows the distribution of the contrast agent, starting from the arterial system and the throttle (a), through the *superior sagittal sinus* and the *transverse sinus* (b), the *transverse sinus* and the *sigmoid sinus* (c), and the *sigmoid sinus* and the *internal jugular vein* (d). The flow of the contrast agent in the venous system was followed in detail to visualise the flow dynamics and the distribution of the contrast agent. It is also possible to identify areas of non-flow (e.g., air bubbles) or constriction.

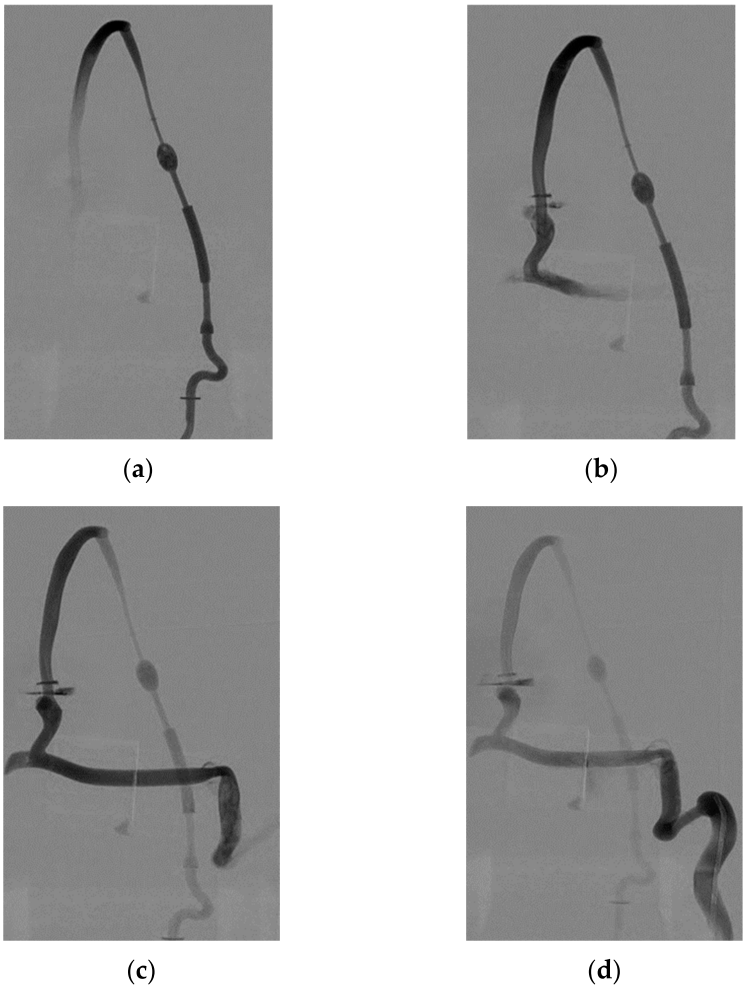

(**a**) (**b**) (**c**) (**d**)

**Figure 4.** DSA image of the venous system (**a**) starting from the arterial system and the throttle, (**b**) via the *superior sagittal sinus* and the *transverse sinus*, (**c**) the *transverse sinus* and the *sigmoid sinus* and (**d**) the *sigmoid sinus* and the *internal jugular vein*.

The DSA images show a well-perfused venous system that can be used as a roadmap for catheter navigation. The venous system was then probed under X-ray guidance. Figure 5 shows catheterisation of the *superior sagittal sinus*, the *transverse sinus*, the *sigmoid sinus* and the *internal jugular vein*. The microcatheter could be successfully navigated by the physician to the throttle.

**Figure 5.** Catheterisation of the venous system highlighted by a white arrow.

Finally, a 3D DSA image of the venous system was taken, as shown in Figure 6. The image was used to measure the diameter of the vein models. This shows that the vein system behind the throttle had the smallest diameter of 1.7 mm. The *superior sagittal sinus* had a diameter of 7.0 mm, while the *sigmoid sinus* had a diameter of 9.0 mm.

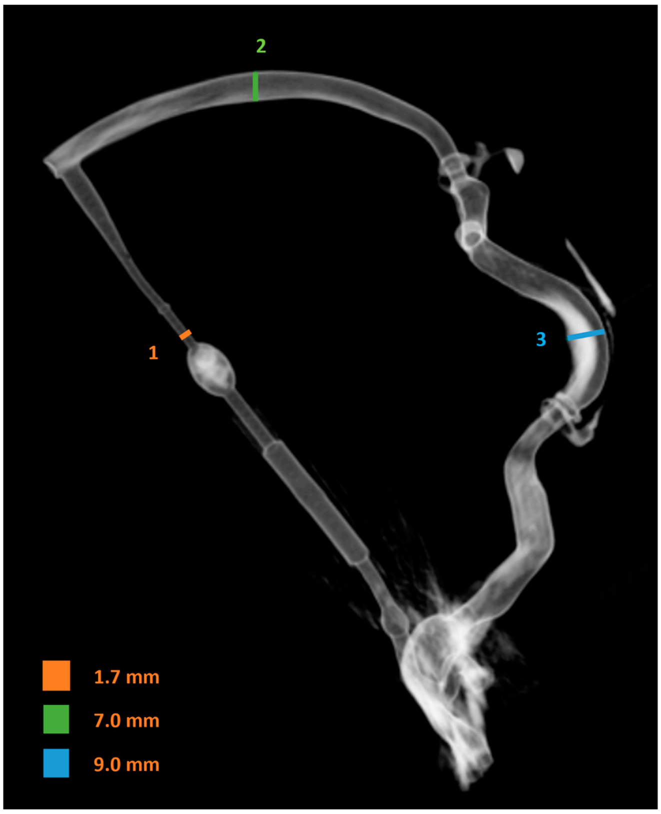


**Figure 6.** 3D DSA image of the venous system for diameter measurement behind the throttle (1), in the *superior sagittal sinus* (2) and in the *sigmoid sinus* (3).

At the end of the test, the physicians were questioned about the geometric mapping, flow, haptics and probing ability of the venous system using a questionnaire. A Likert scale was used for this evaluation, with scores ranging from 1 ('very poor') to 5 ('very good'). The six questions relevant to this study are listed in Table 1. The questions were categorised according to the aspects of geometric mapping, physiological mapping and medical–therapeutic mapping. The geometric mapping of the venous system and the simplified representation of a venous strand were awarded as 'good'. Additionally, the diameters of the individual venous models were evaluated as 'very good' and were suitable for the insertion of a balloon catheter. The flow through the venous system was visualised by the contrast agent and was present in all vein models. The flow was rated as 'good' by the physicians. Visualising the flow provides an important insight into how the model performs and helps assess its realism. However, it was not possible to clearly determine in this study whether realistic pressure regulation in the venous system can be achieved using the throttle integrated in the model. According to the physicians' clinical experiences, such a pressure difference is not directly perceptible in humans during interventional procedures. This represents a limitation, and therefore, cannot be assessed in a technical system. The internal surface roughness of the vein models compared to real vessels was rated as 'good' in terms of friction. The ability to probe the vessels using original instruments was rated as 'good'. Overall, the physicians rated the model as 'good' for simulation purposes in terms of geometric, physiological and medical–therapeutic mapping.

**Table 1.** Questions relevant to this study from the questionnaire for the evaluation of the venous system, divided into the aspects of geometric mapping, physiological mapping and medical–therapeutic mapping.

| Question | Score |
|---|---|
| **Geometric mapping** | |
| How realistic would you rate the geometric mapping of the venous system compared to a real human system? | 4 |
| How realistic would you rate the diameter of the vein models compared to a real human system? | 5 |
| **Physiological mapping** | |
| How would you rate the flow of the model? | 4 |
| How realistic would you rate the pressure regulation between the arterial and venous systems? | N/A |
| How would you rate the internal surface smoothness of the vein models compared to real vessels in terms of friction? | 4 |
| **Medical–therapy mapping** | |
| How would you rate the probing of the venous system using a catheter? | 4 |

## 4. Discussion

As part of this study, the existing HANNES simulator was successfully extended to include a simplified venous system from the *inguinal vein* up to the *superior sagittal sinus*. Unlike the other models mentioned above, this training model represents the venous system from the *inguinal vein* to the head and does not end at the heart. In addition, the extension of the HANNES provides a holistic system of arterial and venous vessels with a connection between the two circuits via a throttle.

The venous system was evaluated in a real angiography suite with regard to the aspects of geometric mapping, physiological mapping and medical–therapeutic mapping. A questionnaire was used to assess the suitability of the venous system in terms of geometry and diameter of the vein models, as well as flow, haptics and probing ability with instruments. The evaluation resulted in a rating of 'good' to 'very good' for all aspects. The simulation of an endovascular procedure in the venous system resulted in 'good' realistic geometric mapping and 'good' probing ability using original treatment instruments. The determined diameters of the individual vein models corresponded to the previously agreed upon requirements, thereby enabling the use of a balloon catheter in the *transverse sinus*. The vein models were produced using the established SLA manufacturing process and a material called Flexible 80A. Despite the different structure and the resulting different properties of veins and arteries, transferability to the simplified venous system was demonstrated. The physicians rated the hollow and smooth inner structure of the vein models and the friction properties during catheterisation as 'good' and realistic. The application test should be repeated in a large study with several physicians for a more detailed evaluation of the simplified venous model. For this purpose, the venous system model will be integrated into the existing HANNES training courses [18]. In addition, the suitability of the model compared to conventional methods such as animal testing should be investigated and the outcome of training on the simulator compared to conventional methods should be analysed in a further study.

A comparison of existing training methods with the newly developed venous system model for the HANNES simulator reveals advantages of the new model, but also limitations. A summary of these advantages and limitations is in Table 2. Compared to existing in vitro models, the HANNES venous system model offers the additional advantage of a direct connection between the arterial and venous circulations, which improves realism and extends applicability. However, all simulation models have the common weaknesses of not representing functions such as venous valves or pressure regulation and are dependent on blood substitutes. Animal models provide realistic physiology, but they are limited by ethical issues and are different from human vascular architecture. In addition, their long-term availability is restricted and vascular diseases have to be artificially induced, which increases the complexity. The newly developed HANNES venous system model provides a realistic link between the arterial and venous circulations but has room for improvement in terms of venous valve integration and pressure regulation.

**Table 2.** Comparison of the advantages and limitations of the newly developed HANNES venous system model with existing models.

| | |
|---|---|
| **HANNES venous system model** | + True-to-patient anatomy<br>+ Long-term availability<br>+ Connection from arterial to venous circulation<br>- Missing venous valves or pressure regulation<br>- Blood replacement material |
| **Other in vitro simulation models** | + True-to-patient anatomy<br>+ Long-term availability<br>- Two separate circuits<br>- Missing venous valves or pressure regulation<br>- Blood replacement material |
| **Animal models** | + Realistic physiology<br>- Ethical aspects<br>- Different from human vessel architecture<br>- Long-term availability<br>- Artificially generated vascular diseases |

Currently, the training model can only be used for probing the venous system with original instruments from the *inguinal vein* to the *superior sagittal sinus.* Expanding the system-specific treatment simulations, like the clinical pictures initially described, must be integrated. This encompasses, for instance, the design and fabrication of an AVM model. The next step is to extend the venous simulation model to include outlets such as cortical veins, thus creating a comprehensive training platform that enables interventionalists to safely learn and practice complex venous procedures. Moreover, an adaptation of the

HANNES simulator would be required to facilitate the simultaneous simulation of an arterial and venous system, as well as the utilisation of the head module. Furthermore, additional research is required to extend the vein models to include the venous valves and to conduct material studies to achieve a more realistic representation of the different types of veins (elastic and solid).

## 5. Conclusions

The venous system was developed and tested in close collaboration with an interdisciplinary team of physicians and engineers. The developed model enables a first approach to simulate an endovascular procedure in the venous system of the HANNES simulation model, with the aim of training physicians in the use of relevant treatment instruments and materials in a realistic angiography suite, thus improving patient safety. The simulation model offers new non-animal research and training opportunities for new endovascular treatment techniques that are currently being introduced into clinical practice, and therefore, have a high demand in training courses or animal experiments. A realistic simulation model, tailored to the human body, could be a valuable addition to create practical training environments and promote expertise in the performance of complex venous interventions. In the long term, the venous simulation model will be expanded to include medical conditions such as AVM, dAVF, sinus vein thrombosis and hydrocephalus to create a comprehensive training platform that allows interventionalists to safely learn and practice complex venous procedures.

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