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Original Research Article

Development and evaluation of a modular EVAR training model for the simulator HANNES

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Abstract: Endovascular treatment of abdominal aortic aneurysms, specifically through Endovascular Aneurysm Repair (EVAR), presents a complex and challenging procedure requiring precise technical skills and accurate interpretation of imaging. Realistic training models are essential for preparing new clinicians. This study presents the development and evaluation of a modular EVAR training model intended for future integration into the Hamburg Anatomical Neurointerventional Simulator (HANNES). Aimed at providing realistic and effective training using original treatment instruments, the model's design and manufacturing process included the development and evaluation of several concepts, ensuring modularity and reusability with potential for future expansion to accommodate additional aneurysm geometries. An interdisciplinary team of engineers and medical professionals conducted the requirement definition and documentation. The resulting EVAR model features a three-dimensional vascular tree designed to accommodate treatment instruments and provide a realistic simulation environment. Additive manufacturing were used to manufacture the complex geometries of the model, with materials chosen for their flexibility and X-ray compatibility. Experimental validation by an experienced vascular surgeon using an angiography system demonstrated the model's capability to replicate real procedural conditions. Despite some issues with vascular wall friction and component durability, the overall feedback was positive. The model realistically depicted necessary vascular sections and facilitated successful placement and removal of the stent graft. However, the high friction of the vascular wall material indicated a need for further material optimization to prevent intraoperative tears. Future iterations will focus on reducing friction and integrating the EVAR model into HANNES. By achieving these improvements, we aim to create a versatile simulator that enhances medical education across multiple disciplines, ultimately contributing to improved clinical outcomes.

I. Introduction

The endovascular treatment of abdominal aortic aneurysms is considered extremely challenging. Endovascular Aneurysm Repair (EVAR) is a minimally invasive method used in vascular interventions to treat aortic aneurysms. By using specialized catheters, stent grafts and imaging techniques, vascular interventionalist can examine and repair the inside of the aorta. Performing an EVAR procedure successfully requires selecting the appropriate device, accurately interpreting complex imaging, and possessing advanced technical skills [1].

Realistic training on simulators can help ensure optimal preparation of new clinicians [2]. Currently, there are many physical and virtual EVAR training models available on the market [2-5]. However, only the virtual models, using non-original treatment instruments, are suitable for endovascular training across multiple disciplines, such as radiology and endovascular vascular surgery. While training on virtual models provides excellent flexibility, training with original treatment instruments remains necessary to replicate the exact behavior and haptic feedback of the devices.

The Hamburg Anatomical Neurointerventional Simulator (HANNES) [6] is a physical simulator featuring a modular vascular tree where various neurointerventional procedures can be practiced using clinically established instruments [7, 8]. This paper addresses the development of an EVAR model for training infrarenal EVAR procedures, which can be integrated into the simulator HANNES in the future. By expanding the capabilities of HANNES, it could become a

versatile tool for training across multiple disciplines, enhancing the overall quality of medical education.

II. Design and manufacturing of the EVAR model

The development of the EVAR model was based on the VDI 2221. Initially, requirements were defined and documented in a requirements list. This process necessitated close interdisciplinary collaboration between engineers and medical professionals. The EVAR model is intended to enable realistic training for the treatment of infrarenal aortic aneurysms using original treatment instruments. To achieve this, the three-dimensional vascular tree must include all the vascular sections necessary for the procedure and allow for the insertion of treatment instruments into the common femoral artery. Additionally, the model should feature a heated and pulsatile circulatory flow provided by the technical fluid system of the HANNES simulator.

To enable future training for various aneurysm geometries, the vascular tree should be modular with standardized interfaces. Cost-effective training for EVAR treatments can only be ensured if the model is reusable and allows non-destructive removal of the used stent grafts. Furthermore, the development of the EVAR model must consider an X-ray compatible design and the use of suitable materials.

Based on the identified requirements, several solution concepts were developed and evaluated. The final selected concept is shown in Figure 1. This concept includes the EVAR model, which is externally connected to the HANNES simulation model and consists of four vascular components with a total of two inguinal accesses and a vessel support block.

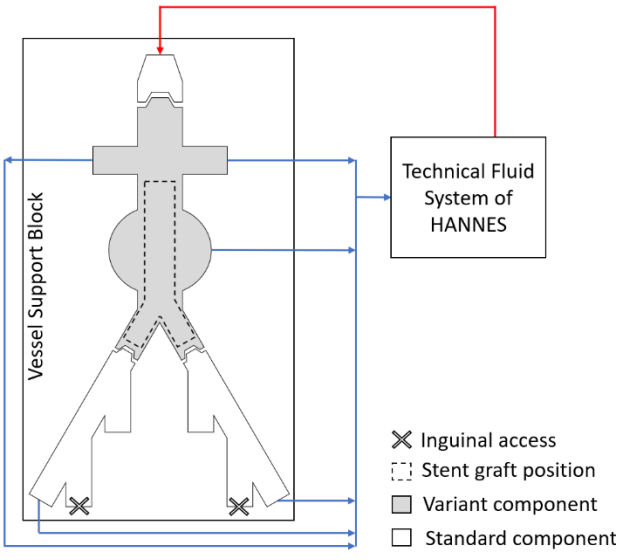

Figure 1: Schematic representation of the EVAR model and its connection to HANNES.

Although long-term plans include full integration into HANNES, the concept initially avoids direct integration of the EVAR model into HANNES due to the extensive modifications required. The individual vessel components are connected to each other using the standardized clamp connectors of HANNES. The division into a variant aneurysm component and three standardized vascular components allows for the future integration of different infrarenal aneurysm components into a largely standardized EVAR model. The femoral components located below the aneurysm component in Figure 1 each have an inguinal access for performing the EVAR procedure. At the end of the training, the stent graft can be removed in the cranial direction. To access the stent graft, only the funnel-shaped inlet located above the aneurysm component in Figure 1 needs to be disassembled.

During operation, the inlet is supplied with a solution containing approximately 0.4% shampoo (PENATEN Shampoo by Johnson & Johnson GmbH) mixed with water from the HANNES technical fluid system. This solution then flows through the vascular system of the EVAR model before being returned to HANNES. In the aneurysm component, the fluid is returned to HANNES via two renal branches. An additional outlet in the aneurysm (similar to the inferior mesenterial artery) supports the complete venting of the model. Each of the two femoral components features its own return outlet.

Following the concept development, the selected concept was further refined and a CAD model was developed. Initially, an abdominal CT scan featuring an infrarenal aortic aneurysm was selected, and the targeted vessels were segmented using the software 3D Slicer [9]. Subsequently, the EVAR model was constructed in CATIA (Dassault Systèmes, Somerville, Vélizy Villacoublay, France) based on the previously segmented vessel models. The vascular components were designed with a wall thickness of 2 mm, applied as an external offset. This wall thickness was adopted from the existing HANNES model to ensure an overall realistic behavior of the vessel walls, despite the simplified nature of the model. Although a 2 mm wall thickness results in a stiffer vessel wall compared to the human aortic wall, this design choice compensates for the absence of other tissue structures that would normally provide additional stiffness from the outside. The vessel support block, also designed in this process, aligns with the three-dimensional vascular course and supports the vessels from below. Additionally, the vessel support block secures the inguinal accesses integrated into the femoral components.

Upon completion of the design phase, the vessel support block was manufactured using fused deposition modeling (FDM) technology with PLA material on an UltiMaker S5 (UltiMaker, Utrecht, Netherlands). The print preparation was done using the slicer Cura from UltiMaker. Due to the limited print volume, the vessel support block had to be

manufactured in two separate parts, which were subsequently joined together.

Given the positive experiences with the stereolithography (SLA) material *Flexible 80A* form Formlabs (Formlabs Inc., Somerville, Massachusetts, USA) on the HANNES simulator, it was decided to use this material for the vascular components of the EVAR model as well. Consequently, the vascular components were fabricated on a Form 3L from Formlabs. The necessary print preparation was carried out using the slicer PreForm from Formlabs. It was found that internal support structures were necessary for fabricating the aneurysm component. Since these supports would have been difficult to remove, the aneurysm component was split into two separate parts along the midline of the aneurysm, which were then glued back after manufacturing.

With the additive manufacturing process complete, the femoral components were equipped with introducing sheaths. Since different sized treatment instruments need to be inserted into the vessels during the EVAR procedure, the components were fitted with two differently sized sheaths. A shortened *24 F Check-Flo* introducing sheath (Cookmedical, Limerick, Ireland) was inserted into the opening of the right component, and a shortened *26 F Sentrant* introducing sheath (Medtronic, Dublin, Irland) was inserted into the femoral opening of the left component. To achieve a proper seal, a press-fit connection was employed between the sheath and the vessel. The completed EVAR model is shown in Figure 2.

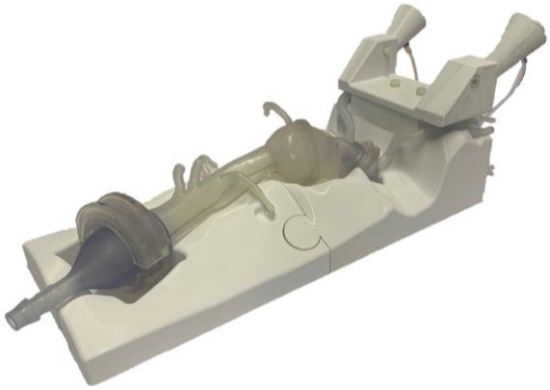

Figure 2: Manufactured EVAR model, consisting of four vascular components, a vessel support block, and two inguinal introducing sheaths.

III. Results and discussion

The EVAR model was tested by an experienced vascular surgeon using an Allura Clarity FD 20 angiography system from Philips Healthcare (Philips Healthcare, Amsterdam, Netherlands). The experimental setup is shown in Figure 3. The EVAR model was placed on the angiography table and connected to the technical fluid system of HANNES via tubing. This setup enabled a pulsatile flow with 37 °C warm water. To reduce vascular wall friction, 25 ml of baby shampoo (PENATEN Shampoo by Johnson & Johnson GmbH) was added to the 6.5-liter water tank of HANNES.

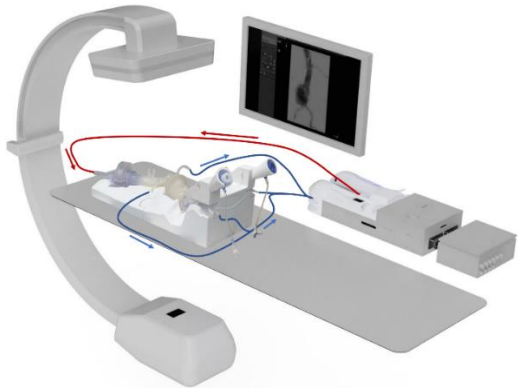

Figure 3: Experimental setup for testing the developed EVAR model.

The EVAR model was tested by performing an EVAR procedure to treat the infrarenal aortic aneurysm. The vascular system was initially examined using native X-ray imaging. During this process, the vascular surgeon noted that the infill and geometry of the vessel support block were partially visible in the native X-ray images, which was considered as a negative aspect. A selective angiography with Iomeron was performed, to inspect the Aneurysm (see Figure 4a). Subsequently, the aneurysm was treated using TREO Abdominal Stent-Grafts (Terumo, Tokyo, Japan). Specifically, a 28-B2-33-100S main bifurcated body, along with a 28-L2-20-100S leg extension and a 28-L2-17-100S leg extension, were implanted. During the procedure, a tear occurred in the right femoral component, leading to a leakage and a pressure drop in the model. Despite the leakage, the procedure was continued, and the success of the treatment was verified using another digital subtraction angiography with contrast medium (see Figure 4b). This showed a complete exclusion of the aneurysm volume and still patent vessel branches of the aorta.

Finally, the vascular components were disassembled, and the stent graft was removed from the aneurysm component using forceps. It was demonstrated that the stent graft could be removed without damage, allowing for reuse.

Following the testing, an evaluation was conducted using a questionnaire. The vascular surgeon was overall very satisfied with the EVAR model. It was positively noted that all necessary vascular sections were realistically depicted and that the vascular model had no internal edges. The main point of criticism was the material used. The realism of the vascular wall friction was rated 1 out of 5 points on a Likert scale. The material, in combination with the SLA manufacturing process, appears to result in significantly high wall friction. This may have led to the surgeon needing to exert considerable force during the procedure, which subsequently caused the vascular wall to tear. Another potential cause for the tearing of the vascular wall could be

the significant intraoperative deformation of the femoral vascular components due to the straightening by the treatment instruments. Another Limitation is, that the Experiment was done by only one trained surgeon. In future experiment we will analyse the experiment with several experienced surgeons.

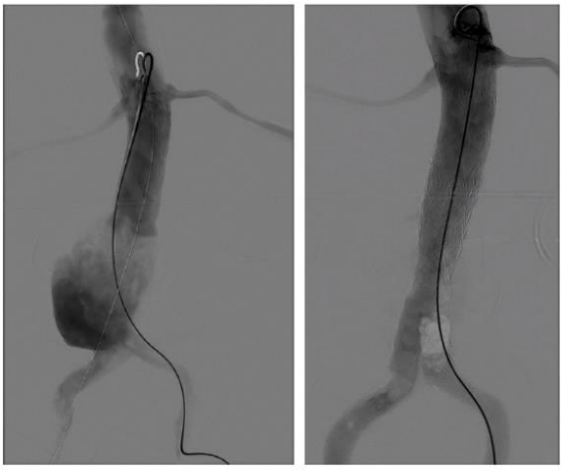

Figure 4: Digital subtraction angiography of the EVAR model (a) before and (b) after inserting the stent graft.

IV. Conclusions

In this study, we developed and evaluated a new EVAR model that is intended to be integrated into the Hamburg Anatomical Neurointerventional Simulator (HANNES) in the future. The EVAR model aims to provide realistic and effective training for the treatment of infrarenal aortic aneurysms using original treatment instruments. Our approach involved a detailed design and manufacturing process, ensuring that the model is modular, reusable and can be expanded to include additional aneurysm geometries in the future.

The experimental validation conducted by an experienced vascular surgeon demonstrated the potential of the EVAR model to replicate real procedural conditions. Despite some issues with vascular wall friction and component durability, the overall feedback was positive. The model realistically depicted the necessary vascular sections and allowed the successful placement and removal of the stent graft.

Future versions of the model will focus on reducing friction, preventing intraoperative tears, and integrating the model into HANNES. By achieving these improvements, we aim to create a versatile simulator that enhances medical education and surgical preparation across multiple disciplines.

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Author's statement

Conflict of interest: Authors state no conflict of interest. Animal models: No animal experiments were carried out. Informed consent: Informed consent has been obtained from all individuals included in this study.

Ethical approval: The research related to human use complies with all the relevant national regulations, institutional policies and was performed in accordance with the tenets of the Helsinki Declaration, and has been approved by the authors' institutional review board or equivalent committee.

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