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Original Research Article

Improving Iatrogenic Complication Awareness in Neurointerventional Training: A Novel Vessel Rupture Model

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Abstract: Neurovascular conditions such as acute ischemic stroke and intracranial aneurysms necessitate complex neurointerventional procedures, posing significant risks including subarachnoid hemorrhage (SAH). Effective training is critical for minimizing these risks, yet current simulation models lack realistic, animal-free training options for managing complications like SAH. This paper aims to develop and integrate a vessel rupture model into the Hamburg Anatomical Neurointerventional Simulator (HANNES), enhancing training for intraoperative complication management. The rupture model was designed by incorporating requirements from both engineers and medical professionals. Key features include modular integration into HANNES, reusability, and adjustable bleeding rates controlled by the training supervisor. The model simulates the perivascular spread of contrast agent, with a point-specific origin and diffuse contour, ensuring realistic SAH visualization on digital subtraction angiography (DSA). The additively manufactured model includes a sponge-filled subarachnoid space and a valve for activating or deactivating the simulated hemorrhage. Evaluations by experienced neuroradiologists demonstrated effective control and realistic appearance of the simulated bleeding, giving the model an overall Likert scale rating of 3.7 out of 5. Identified optimization potentials included the distal bleeding position, while the realistic extravasation of contrast agent was positively noted. The rupture model successfully meets the defined requirements, offering a practical tool for training in the management of neurointerventional complications. Future improvements will address the distal position of the hemorrhage to further optimize the effectiveness of the training, ultimately enhancing the preparedness of neurointerventionalist in handling SAH.

I. Introduction

Various neurovascular conditions, such as acute ischemic stroke and intracranial aneurysms, can be treated by neurointerventional procedures [1, 2]. These require catheterization of the vascular system with devices such as wires and catheters, using fluoroscopy [3]. Every step of a neurointerventional procedure carries risks [4]. The risk of complications varies, among other factors, depending on the experience of the neurointerventionalist [4].

Neurovascular procedures can sometimes lead to subarachnoid hemorrhage (SAH) [4]. This involves a lesion of the vessel wall, leading to bleeding into the space between the arachnoid and pia mater, known as the subarachnoid space [5]. Potential consequences of SAHs include neurological impairments and, in the worst case, death. Intraoperatively, SAHs can be detected, among other methods, through digital subtraction angiography (DSA) [6, 7]. This method visualizes how in case of an active bleeding the injected contrast agent spreads extravascularly [8].

Due to their high complexity and often urgent setting of endovascular procedures, training and competency assessments are crucial to achieve the necessary level of skill to perform endovascular procedures safely and efficiently [9]. Animal-free training can be conducted using physical simulators such as the EndoVascular Evaluator (EVE) and virtual simulators such as the VIST LAB (Mentice AB, Gothenburg, Sweden) [10, 11]. The Hamburg ANatomical NEurointerventional Simulator

(HANNES) is a physical simulator that offers a modular vascular tree for practicing various neurointerventional procedures in a realistic and controlled environment [12, 13].

To our knowledge, there is currently no animal-free physical model designed for training the intraoperative management of complications such as SAH. This represents a significant gap in the available training resources for neurointerventionists, highlighting the need for a realistic and ethical training tool.

The aim of this paper is to develop and test a rupture model that can be modularly integrated into HANNES, increasing risk awareness, and enabling training of intraoperative complications management.

II. Design and manufacturing of the rupture model

The development of the rupture model was based on the VDI 2221. First, the requirements for the rupture model to be developed were analysed and documented in the form of a requirements table. Gathering these requirements necessitated close collaboration from an interdisciplinary team, which is comprised of engineers and medical professionals. The key requirements are listed in Table 1.

The rupture model is designed to expand the training portfolio on HANNES, enhancing trainees' ability to promptly identify and respond to acute complications such as SAH. This requires modular integration into the simulator. Additionally, the model should be reusable for multiple training sessions.

Table 1: List of vessel rupture model key requirement.

Description of requirement	Type of requirement
Geometric requirements	
Perivascular spread of hemorrhage along the subarachnoid space	demand
Diffuse hemorrhage contour	demand
Point-specific origin of rupture	demand
Functional requirements	
Modular integration in HANNES	demand
Reusability	demand
Adjustable bleeding rate	wish
Trainer-induced triggering of hemorrhage	demand

In order to continue specifying the training complexity and scenario, and to adapt them to the level of the trainees, the bleeding should be controlled by the training supervisor. This includes triggering, regulating, and stopping the bleeding. Other requirements relate specifically to the characteristics of the contrast agent extravascular flow on DSA. The extravascular flow should have a point-specific origin, spread perivascular in the subarachnoid space over time and exhibit a diffuse outer contour.

Based on the identified requirements, several solution concepts were developed and evaluated regarding their technical and economic feasibility.

Due to the partially turbulent flow of the contrast agent and the correspondingly difficult-to-predict behavior, evaluating the technical feasibility posed a particular challenge, necessitating the development and analysis of several prototypes. For further development, the concept with the best balance of economic and technical feasibility was selected.

The rupture model features a short, generic vessel section and a sponge-filled volume representing the subarachnoid space. Figure 1 shows the simplified hydraulic circuit diagram of the final rupture model and its integration into HANNES. The model can be modularly inserted between the vascular system and the existing return flow tubes of HANNES. A circular opening in the vessel wall simulates the vascular lesion, permanently connecting the vascular lumen to the subarachnoid space.

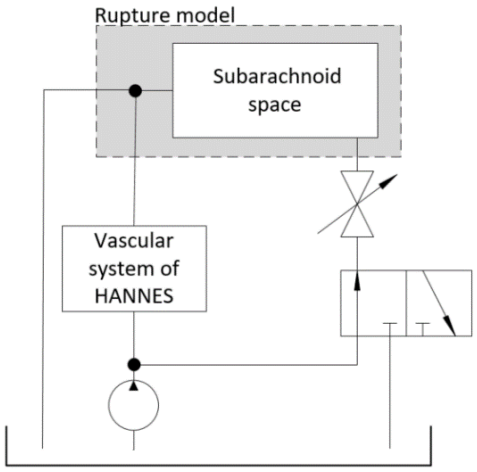

Figure 1: Simplified hydraulic circuit diagram of the final rupture model and its integration into HANNES.

Moreover, the rupture model features an additional connection, which, depending on the position of a 3/2-way valve, connects the subarachnoid space directly to the pump or to the simulator's tank. This activates or deactivates the visibility of the simulated SAH on DSA imaging. Figure 2 shows the simplified path of the contrast agent in red as a function of the position of the 3/2-way valve, superimposed on a half-section view of the constructed rupture model.

Depending on the position of the 3/2-way valve, a pressure gradient is established in the subarachnoid space. When the bleeding is activated, the 3/2-way valve allows the outflow

of the vascular system through the subarachnoid space into the tank (see Figure 1 and 2b). Consequently, contrast agent injected during an intervention flows through the subarachnoid space, making the rupture visible when DSA is performed.

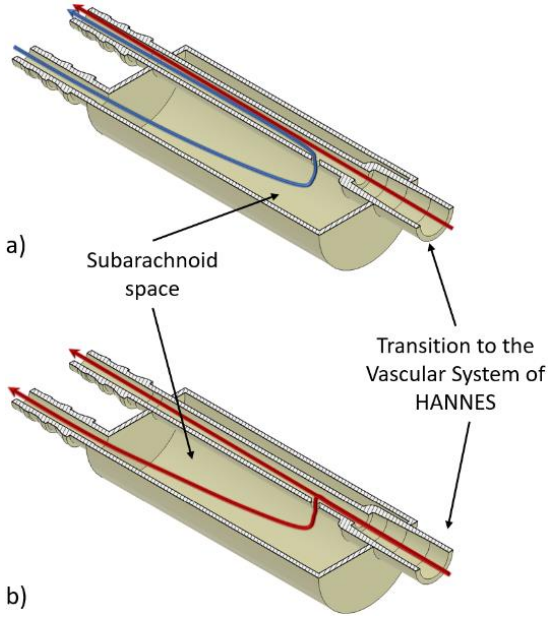

Figure 2: Simplified path of the contrast agent (red) in the case of (a) an inactive rupture and (b) an active rupture, superimposed on a half-section view of the rupture model.

When the rupture is deactivated, the 3/2-way valve ensures a direct connection between the pump and the subarachnoid space, shown as a blue flow in Figure 2a. Due to the flow resistance of the vascular system, the pressure on the side of the subarachnoid space facing the vascular system is lower than on the side facing the pump. This prevents the water flowing through the vascular system from entering the subarachnoid space. The same applies to the contrast agent, making the subarachnoid space not visible on DSA imaging. In the event of an activated rupture, the bleeding rate can be adjusted via a ball valve (see Figure 1).

The 3D CAD design of the rupture model was carried out in CATIA (Dassault Systèmes, Somerville, Vélizy Villacoublay, France). Special care was taken to ensure that the contrast flow in the subarachnoid space follows a perivascular path. Accordingly, the inflows and outflows of the subarachnoid space were positioned close to the vessel.

In addition, the distance to the outer wall of the housing was taken into account, which, in combination with the filling of the subarachnoid space with a sponge, is intended to achieve a diffuse outer contour of the bleeding. Furthermore, it was ensured that the opening between the vessel lumen and the subarachnoid space would not create noticeable edges during the catheterization.

The constructed enclosure was additively manufactured out of Clear V4 using a Form 3L (Formlabs Inc., Somerville, Massachusetts, USA). Subsequently, the housing was cleaned with isopropanol, cured in a Form Cure L (Formlabs Inc, Somerville, MA, USA), and the support structure was removed. Finally, the interior of the rupture model was filled with Glitzi PUR Active sponge (Vileda GmbH, Weinheim, Germany). The final rupture model is depicted in Figure 3. The sponge ensures a diffuse flow of the contrast agent, providing flow resistance and allowing for slight pooling of the contrast agent. This mimics the natural diffusion and pooling characteristics of hemorrhage in the subarachnoid space, contributing to a realistic simulation. Additive manufacturing enabled rapid and cost-effective prototyping, essential for iterative testing and incorporating feedback from physicians. It also allowed for the creation of complex three-dimensional structures with internal cavities, which are not feasible with conventional manufacturing methods.

Figure 3: Manufactured rupture model, consisting of an additively manufactured housing and a subarachnoid space filled with sponge.

III. Results and discussion

Evaluation of the model was done by experienced neuroradiologists. The model was integrated into HANNES according to the hydraulic circuit diagram shown in Figure 1, with the rupture model located inside the skull [14] of HANNES.

To test the activation and regulation of the rupture, multiple DSA series were performed, each with the addition of iodinated contrast agent. The results demonstrated that the simulated bleeding could be controlled and activated or deactivated as needed. If the bleeding is deactivated, no extravasation of the contrast medium is visible (see Figure 4a). When the bleeding is activated, the contrast agent flows into the subarachnoid space and follows a perivascular path (see Figure 4b).

Additionally, it was observed that the visible bleeding could be regulated by adjusting the ball valve. Excessive bleeding rates resulted in the entire subarachnoid space being filled with contrast agent, making the outlines of the housing visible as sharp edges. Reducing the bleeding rate prevented this, giving the rupture a diffuse contour (see Figure 4b). When the bleeding is deactivated, excessive flow through the subarachnoid space could cause undesirable retrograde flow within the vessel. However, properly adjusting the ball

valve position can prevent retrograde flow. During testing, the rupture model was catheterized to check for any potential edges, and no obstacles were detected.

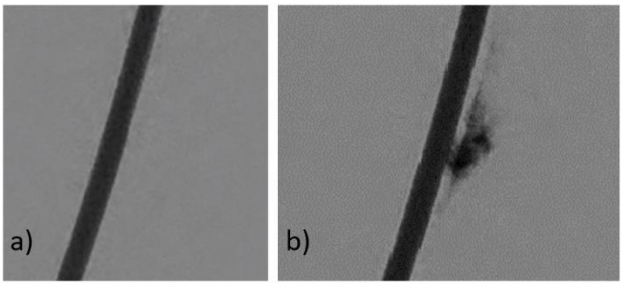

Figure 4: DSA of the rupture model with (a) the rupture deactivated and with (b) the rupture activated.

Attempts were made to treat the rupture endovascularly using a balloon catheter and a temporary coil. However, due to the lack of coagulation in the simulator, the treatment interventions did not result in a sufficient reduction of the bleeding. Therefore, to visualize treatment success during training, it is necessary for the instructor to regulate the rupture via the built-in ball valve or to completely stop it using the 3/2-way valve, indicating that the complication management algorithm has been carried out by the trainee correctly.

To further evaluate the model, an online survey was conducted with nine neuroradiologists. The participants, who had a median of 8 years and an average of 9.8 years of professional experience in neuroradiology, were asked to rate the realism of the bleeding depicted in the provided DSA images of the rupture model. They rated the model on a Likert scale, giving it an overall score of 3.7 out of 5 points, with 5 points indicating a perfectly realistic model. An analysis of the feedback revealed that the primary criticism was that the rupture was located too distally. On the other hand, it was positively noted that the contrast agent extravasation appeared realistic.

IV. Conclusions

The development and integration of the rupture model in HANNES fulfilled the previously defined requirements. The model simulates SAH realistically, with features such as adjustable bleeding rates and activation controls, thereby providing trainees with practical experience in handling such complications. Testing and evaluations by medical professionals indicated that the model effectively demonstrates the perivascular spread of contrast agent. While there were some concerns about the distal placement of the rupture, overall feedback was positive, recognizing the model's value in enhancing neurointerventional training.

The use of additive manufacturing allowed for rapid and cost-effective iterative development and optimization of the model. In the future, the rupture model can broaden HANNES training portfolio and increase awareness among trainees about the danger of SAHs.

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Author's statement

The authors state no conflict of interest. No animal experiments were carried out. Consent was obtained from all persons involved in this study. 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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