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Original Research Article

Design and experimental validation of a novel additively manufactured stenosis model for neurointerventional training

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Abstract: Stenoses, or pathological narrowings of blood vessels, are significant risk factors for cardiovascular events. While various stenosis models exist for training purposes, they often present limitations for intracranial applications due to their size and inability to maintain vessel dilation after treatment. This paper presents the development and evaluation of a novel stenosis model specifically designed for compact, intracranial applications within the neurointerventional simulator HANNES. The model utilizes a C-shaped clip mechanism that selectively constricts an elastic vessel, incorporating a designed breaking point that ensures permanent vessel dilation upon reaching a critical pressure during balloon angioplasty. The model was stereolithographically 3D printed and underwent experimental evaluation using a standard PTA balloon catheter. Results demonstrated reproducible burst pressures of 12±1 bar, aligning with typical clinical parameters. X-ray imaging confirmed successful integration into the HANNES simulator, enabling realistic simulation of stenosis treatment procedures. Experiments showed that the developed stenosis model should be used with elastic silicone tubes connected to additively manufactured vessel models, as direct application to printed vessels either resulted in vessel wall damage during compression or insufficient constriction depending on the C-clip geometry. Based on these findings and the successful validation results, the model represents a reliable and reproducible platform for neurointerventional training, with its parametric design allowing adaptation to various clinical scenarios.

I. Introduction

Stenoses - pathological narrowings of blood vessels - are a major risk factor for cardiovascular events such as strokes and heart attacks [1]. In endovascular therapy, stenoses are frequently treated using percutaneous transluminal angioplasty (PTA) in order to restore blood flow by expanding the vessel lumen [2]. For training and the continuous improvement of interventional skills, the use of animal-free training models is essential, especially given ethical and economic considerations.

Although various stenosis models exist [3, 4, 5, 6], they are often designed for extracranial applications and, due to the space requirements, cannot be applied intracranially. Furthermore, many models revert to their stenotic state after PTA, meaning that no lasting therapeutic success can be achieved. This limits their use in neurointerventional training. To close this gap, a novel stenosis model specifically designed for compact, intracranial applications was developed within the scope of the present work. To provide realistic evaluation conditions, the new stenosis model was integrated and tested in the established Hamburg ANatomical NEurointerventional Simulator (HANNES) [7].

II. Design and manufacturing of the stenosis model

The development of the stenosis model was based on the VDI 2221 (Development of technical products and systems - Model of product development) [8]. In the first step, requirements were systematically analysed and documented in the form of a structured requirements list. Table 1 presents a selection of particularly relevant requirements.

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Table 1: List of stenosis model key requirement.

Description of requirement	Type of requirement
Geometric requirements	
Compact design for intracranial applications	demand
Functional requirements	
Reusable vessels	demand
Flexible placement of the stenosis	wish
Modular integration into the Simulator HANNES	demand
Elastic behaviour at the beginning of dilation	demand
Complete release of the stenosis upon reaching the final pressure	demand
Imaging Requirements	
Suitable for angiography-based applications	demand

In an iterative process, several design concepts were developed, each evaluated from both economic and technical perspectives. The favoured design concept, as illustrated in Fig. 1, is based on a C-shaped clip that selectively constricts an internal elastic vessel. Without the application of the clip, the vessel retains its physiological lumen.

When the clip is applied, its inner contour influences the remaining residual volume. During balloon dilation, the elastic deformation initially leads to a temporary and partial expansion of the lumen.

When the pressure of the balloon catheter reaches the critical value, a notch introduced on the back of the C-clip causes a local increase in stress. This leads to crack formation in the C-clip, causing the clip to break and the vessel lumen to be fully released.

The design was parametrically modeled using Autodesk Inventor, allowing flexible adaptation to various vessel and stenosis diameters (see Fig. 2). In this study, the C-shaped clamps were configured with a 2 mm wall thickness, an overall clip thickness of 4.5 mm, an outer diameter of 8 mm, and a 2 mm gap between the inner parallel faces. Parts were fabricated using stereolithographic additive manufacturing with Clear V4 resin on a Form 3L printer (Formlabs Inc., Somerville, Massachusetts, USA). Printing was carried out with an in-plane resolution of 25 µm and a layer height of 100 µm.

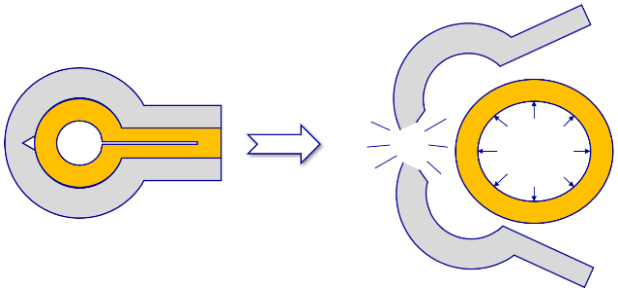

Figure 1: Schematic illustration of the concept of stenosis mechanisms.

After fabrication, the model underwent post-processing, including the manual removal of all support structures. The part was then washed in isopropanol (IPA) in accordance with the manufacturer's instructions, followed by UV curing.

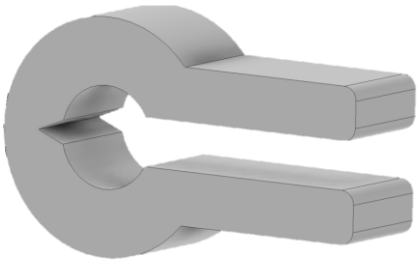

Figure 2: CAD model of the developed stenosis mechanism.

III. Results and discussion

Two integration configurations were evaluated to assess the performance of the developed stenosis model. Before attaching the clip, the circulation pump of the simulator was switched off so that the vessel segment remained non-pressurized; this ensured that any mechanical load on the predetermined breaking point remained minimal, thereby preventing partial fracture during placement.

In the first configuration, the stenosis element was incorporated into the HANNES simulator by connecting a 6 × 4 mm silicone tube - serving as the vessel model - directly to the ACI outlet of the aortic arch. In the second configuration, additively manufactured vessel models (Formlabs Flexible 80a) were used instead of the silicone tube.

For evaluation, a 5.5 mm × 20 mm 135 cm Sterling™ Monorail™ PTA Balloon Dilatation Catheter (Boston Scientific Limited, Ballybrit Business Park, Galway, Ireland) was employed. In a series of ten trials using the silicone tube configuration, the burst pressure - defined as the pressure at which the C-clip fails during balloon dilation - was measured. The obtained data showed an

average burst pressure of 12±1 bar, which corresponds well with the clinical pressures typically applied during balloon dilation.

These results demonstrate that the model enables a reproducible and controlled simulation of the transition from elastic to plastic material behavior. The initial elastic deformation of the C-clip results in a partial constriction of the vessel lumen; upon reaching the burst pressure, the clip fractures and the lumen is fully restored.

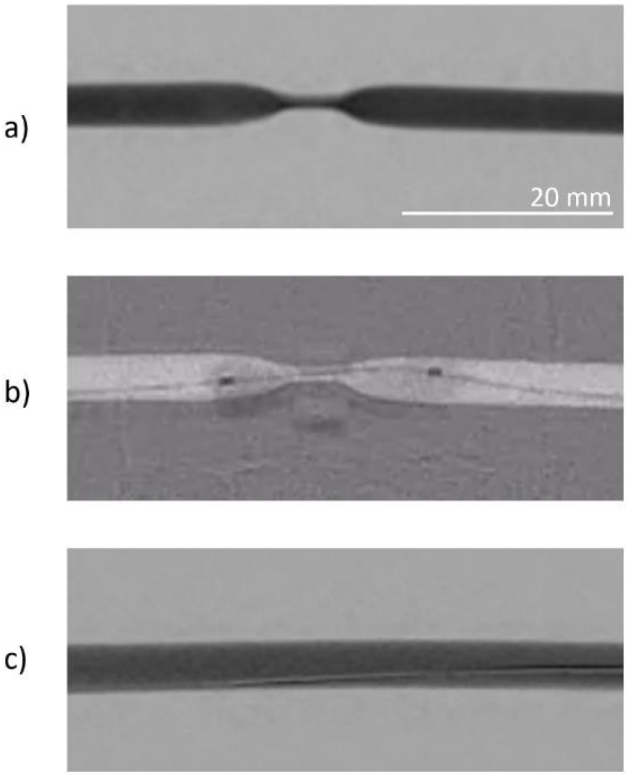

Figure 3: X-ray sequence of a simulated stenosis treatment procedure in the HANNES simulator.(a) Constricted vessel segment visualized under contrast medium;(b) balloon catheter positioned using the roadmap function. The two radiopaque markers of the balloon catheter are visible as bright spots, indicating the proximal and distal ends of the balloon;(c) post-dilation image showing no residual stenosis.Scale bar: 20 mm.

In contrast, experiments using the additively manufactured vessel models revealed significant limitations. Depending on the chosen C-clip geometry, the printed vessel walls either cracked under compression or the clip was too soft to provide sufficient constriction, with the overall vessel stiffness also limiting realistic deformation.

The successful integration of the stenosis model within the HANNES simulator was further confirmed by X-ray imaging. Fig. 3 illustrates an exemplary simulated treatment procedure: the constricted vessel segment is first visible under contrast medium (a), followed by the positioning of the balloon catheter using the roadmap function (b), and finally, the restoration of the physiological vessel lumen after the clip fracture (c).

IV. Conclusions

In summary, the developed stenosis model provides a reliable and reproducible training platform that opens up new possibilities in the neurointerventional field. The experimentally determined burst pressure values confirm reproducibility, and the parametric design allows adaptation to different scenarios.

Although only one clip geometry was tested, the parametric design allows rapid adaptation to different stenosis severities; validating these variants is planned. Moreover, the comparison with additively manufactured vessel models highlights potential areas for improvement, which should be addressed in future studies. Furthermore, the behavior of different balloon types (non-compliant, semi-compliant, and compliant) should be investigated, and corresponding training scenarios developed.

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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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