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Concept of an in-vitro model for endovascular stroke treatment using additive manufacturing

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Abstract: The success of treatment of acute ischemic stroke depends essentially on the time passed until the vessel is reopened. For this reason, training is necessary for the already complicated endovascular stroke treatment under high time pressure. Current in-vitro models do not offer the full range of different stroke cases and the use of various treatment options. This paper describes a conceptual design of a stroke in-vitro model using additive manufacturing to map a range of patient-based training cases. The model considers special aspects of vessels of elderly patients, such as curvatures and stenoses, which complicate the removal of clots.

I. Introduction

An ischemic stroke is one of the major reasons causing disability and death worldwide. The most common cause is permanent occlusion of a cerebral artery by a blood clot leading to hypoxia of a brain region and cerebral infarction. Catheter-based endovascular treatment, called mechanical thrombectomy, is established as the first-line therapy [1]. This procedure is always performed under significant time pressure aiming for immediate reopening of the affected vessel. Due to patient-specific anatomical features, such as vessel curves and stenosis, typical for elderly patients [2], it can become a real challenge for the neurointerventional doctor. Opportunities for physician training outside of the clinical emergencies are limited, although they would be very desirable, particularly for practicing challenging anatomical scenarios.

Training of stroke treatment and thrombectomy research are mainly performed on living animals, e.g. pigs, rats or rabbits [3]. These models have many disadvantages. Besides the ethical aspects, the training is not very realistic [3]. In order to avoid animal models, a few synthetic in-vitro thrombectomy models are described in literature [e.g. 4,5,6]. All models have in common that they represent a blood circulation and bring a clot of animal blood mixture into the system. The existing in-vitro models have already been used successfully for thrombectomy research. However, there are still limitations. They are not free of animal blood and therefore not free of animal experiments. Often only one specific clot is generated for each model, which does not reflect the range of human clots (variations in terms of hardness, brittleness) [4,5,6]. No model takes into account the curvature of the vessels and stenosis as well as the difficulties of the interventional entry route, in particular because cervical vessels and the peculiarities of the aortic arches are not depicted. With the models described, it has not yet been possible to reproduce a wide range of different stroke cases for treatment in one training session.

This results in the need for developing an in-vitro model that eliminates the aforementioned weaknesses. In this paper, clot and stenosis modules of an in-vitro model for endovascular stroke treatment are designed based on an existing model (see II), enabling thrombectomy and stenosis treatment to be performed. A first conceptual approach of an in-vitro model for endovascular stroke treatment is described and tested qualitatively.

II. Conceptual design of the model

The stroke model is built upon an existing model called **HANNES** (Hamburg ANatomical NEurointerventional Simulator [7]). The focus of HANNES is the training of endovascular aneurysm treatment. Due to the modular platform of HANNES (Fig.1c), single modules can be replaced easily to represent different anatomies in one training model. Additive manufacturing (AM) is used for the production of patient-original vessels, as it offers advantages for the small number of pieces to be produced and with regard to freedom of geometry [8].

In order to adapt the HANNES platform to simulate stroke treatments, special changes are required to the cerebral, cervical and the aortic vessel module. The adaptations will be implemented in **HANNES-Stroke**, the in-vitro model for endovascular stroke treatment. Fig.1a) presents the schematic structure of the conceptual design of HANNES-Stroke using a Module Interface Graph (MIG) (see [7,9]). Three main model details extend the HANNES platform (Fig.1c) for stroke simulation. In Fig.1 they surround the MIG, each depicted with a digital subtraction angiography (DSA) picture and the respective model (Fig.1b,d,e).

Stenosis models are inserted both cervical and cerebral. AM is used for the fabrication of the **cervical vessels** and allows a wide range of different types of geometric stenoses and curved vessels to be easily made available for training (Fig.1e). For the **cerebral vessel** models, alternatives for creating a functional stenosis (remain open after dilatation) are compared. Two concepts for a patient-original stenosis of the MCA M1 segment are chosen for

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the design. Concept 1 is an AM-model of a healthy vessel (TangoPlus, Objet500 Connex), which is narrowed mechanically from the outside by a breakable perforated mounting (Fig.1d). Concept 2 is a narrowed vessel model with a stenosis area (TangoPlus and VeroClear, Objet500 Connex) that can be mechanically destroyed so that the vessel remains open after dilatation. A study on materials to represent different types of **blood clots** is currently conducted. For the first reproduction, a child's play slime (Simba Toys) is initially used (Fig.1b). The functional stenosis models are applied in angioplasty with a balloon catheter (PTA), and evaluated concerning the quality of the passage with the catheter and the opening. The clot is extracted with a stent retriever. The procedures were performed using the stroke model details and qualitatively evaluated by experienced neuroradiologists.

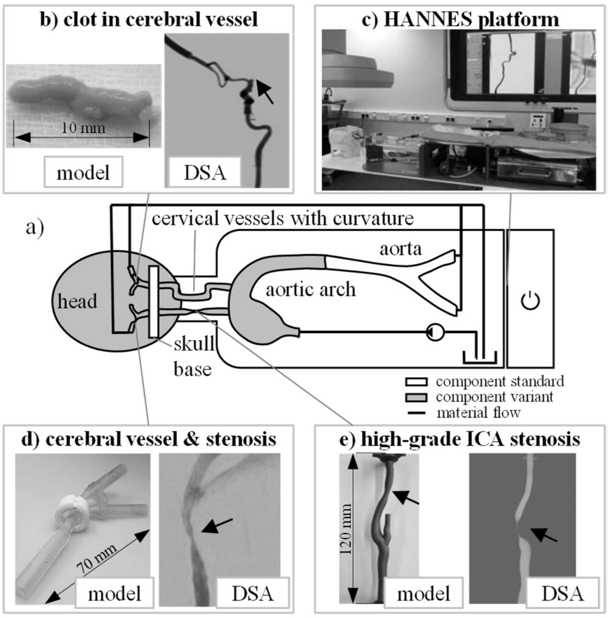

Figure 1: In-vitro HANNES-Stroke model, a) schematic structure of the conceptual design, c) HANNES platform in the OP environment, b),d),e) stroke model details

III. Results and discussion

By producing vascular models with AM, patient-original anatomies can be replicated realistically. Geometrical cervical stenosis models simulated the problems of catheterization according to the qualitative evaluation as in realistic condition. All functional models of cerebral stenosis show a constriction like a real stenosis. The opening behavior varies depending on the chosen design. Concept 1 enables DSA images (Fig.1d) similar to real patient treatment, but some cases are not indestructible. The vessel in concept 2 closes after dilatation so that they do not represent the desired functionality. The initial clot model disrupts the fluid circulation in the vessels, which is realistically represented in the DSA (Fig.1b).

HANNES-Stroke shows initial good results under qualitative evaluation in the application of thrombectomy procedures for radiographer training purposes and for the extension of functional stenoses. For the training of physicians and research purposes, the model requires some improvements. These include the change of the clot material, which currently under qualitative evaluation does not resemble the mechanical properties (e.g. fragmentation) of human clots adequately. Geometric stenoses can already create different levels of treatment difficulties in the model, further anatomies will be replicated in future. Concept 1 is very promising for functional stenoses but needs further improvements to make the balloon opening pressure more realistic.

IV. Conclusions and outlook

An in-vitro model called HANNES-Stroke is conceptually designed for the simulation of endovascular stroke treatment. The geometrical freedom of AM can be used to create complicated anatomies. Moreover, the flexibility in production allows patient-original vessel replicas in small quantities to be produced. Besides the removal of clots, the stenosis treatment is planned to be replicated. Hence first concepts of stenosis models were presented, which remain open after dilatation. Other improvements include the expansion of the intracranial vessels to an entire intracranial vascular tree, the design of different types of aortic arches and a better synthetic replication of a clot. The previous concepts for the model details were qualitatively rated as good. On this successful basis, quantitative evaluations can be carried out in future work.

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