Transactions on Additive Manufacturing Meets Medicine
Trans. AMMM, 2025, Vol. 7, No 1, Article ID 2056, 4 Pages

Infinite Science Publishing

Original Research Article

3D printed embolization module for treatment training of chronic subdural hematomas in interventional neuroradiology

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Abstract: Minimally invasive techniques have revolutionized the treatment of cerebrovascular disease, including middle meningeal artery embolization (MMAE) as a promising alternative to open surgical treatment of chronic subdural hematoma (cSDH). However, training in MMAE still requires the use of animal models, which raise ethical concerns and are not anatomically realistic. This study presents the development of a 3D printed, interchangeable including middle meningeal artery (MMA) embolization module for integration into the HANNES neurointerventional simulator with the previously developed MMA model to allow realistic simulation of cSDH treatment with the liquid embolic agent Onyx. The module was designed in a patient-like geometry and manufactured using stereolithography (SLA) printing with two different materials. A detailed evaluation of the manufacturing parameters showed that the choice of material and printing orientation had a significant impact on post-processing efficiency. The final module was tested in a realistic angiography suite with original treatment instruments. The module was rated by two physicians using a Likert scale questionnaire (1 very poor to 5 very good). Anatomy was rated as realistic with a score of 4, and flow characteristics and embolic agent distribution were rated as realistic with a score of 5. The results highlight the potential of the module as an effective tool for neurointerventional training, reducing the need for animal models while providing a standardized, reproducible training platform.

I. Introduction

Modern medicine has made major advances in recent decades, particularly in the diagnosis and treatment of complex diseases. In the field of neuroradiology, the introduction of minimally invasive techniques has redefined the treatment of cerebrovascular disease. Instead of traditional open surgery, pathological blood vessels can now be treated using catheters that are navigated through the vascular system under X-ray guidance [1-3]. Recent developments in catheter technology and smaller, more flexible instruments have made it possible to target even tiny vessels less than 2 mm in diameter, such as chronic subdural hematomas (cSDH) [4,5]. A cSDH is an accumulation of blood, fluid and its breakdown products caused by bleeding in the subdural space between the hard and soft meninges [6]. This bleeding is often treated surgically by burr hole trepanation or craniotomy, procedures that aim to evacuate the hematoma by opening the head [5,7-9]. However, these methods have a high recurrence rate of up to 37%, as the continued blood supply from the middle meningeal artery (MMA) can perpetuate the condition [8]. To address this, MMA embolization (MMAE) has emerged as a minimally invasive technique to stop the bleeding by occluding the artery, significantly reducing recurrence rates [5,8]. Embolization can be performed using a variety of methods, including liquid embolization, particle embolization and coil embolization [10]. Liquid embolic agents solidify by phase change within the vessel and conform to its geometry, while particulate embolic agents act through microparticles or microspheres that accumulate or expand in the vessel to

disrupt blood flow [10]. Coils are specifically positioned, flexibly conform to the vessel structure and, thanks to their metal surface, promote the formation of blood clots for permanent vessel occlusion [10]. The rapidly advancing field of MMAE requires physicians to master both clinical knowledge and the effective use of numerous neurointerventional instruments. There is a great need for systematic training of interventional physicians and further practice of the technique. The training of MMAE is mainly based on animal models, despite disadvantages like the ethical aspects and their unrealistic anatomical replication of the human brain [11,12]. There are no published in vitro models that simulate the treatment of cSDH with liquid embolic agents. The study by Sadasivan et al. does not focus on treatment training, but on investigating the different distributions of liquid and particle embolic agents in their in vitro model [13]. In a previous work, MMA models were developed for integration into the existing neurointerventional simulator HANNES (Hamburg ANatomical NEurointerventional Simulator) [14]. However, these models have been used either only for MMA probing [15] or only for particle embolization [16]. This highlights the need to develop an embolization module for treatment simulation using liquid embolic agents. The aim of this work is to develop an interchangeable 3D printed MMA embolization module for integration into the existing simulator HANNES to simulate MMAE with liquid embolic agents. The training and further education of physicians in the field of MMAE can thus be carried out in several simulators without the use of animals. The HANNES simulator provides a realistic simulation of blood pressure using a fluid system with adjustable temperature, pulse rate and volume flow [14]. The integrated patient-based vascular models are modular, interchangeable and offer edge-free connection using standardised connectors [14].

II. Design and manufacturing of the cSDH embolization module

The development of the embolization module was based on VDI 2221 (Development of technical products and systems - Model of product development) with the steps planning, conception, design and development [17]. This process requires close collaboration between engineers and physicians to integrate both technical and clinical requirements. The first step was to define the requirements and documented these in a structured requirements list. Requirements for the embolization module include patient-like geometric mapping of the peripheral vessels to ensure realistic simulation. In addition, continuous flow through the module must be ensured. The vessel diameters should be smaller than 2 mm. An edge-free connection is required to allow smooth navigation of the instruments. In general, the module should be modularly integrated into HANNES and easily replaceable after successful treatment simulation.

In an iterative process, a number of design concepts were developed and evaluated from both economic and technical perspectives. The favoured design concept is shown in Fig. 1. The module was designed in a CAD software (Autodesk Inventor, San Rafael, USA) and modified with connectors for integration into the MMA model in the HANNES simulator.

When modelling the peripheral vessels, 90° connections between individual vessel segments were avoided to reduce edges for catheter navigation and to improve resin drainage after printing. In addition, the influence of 90° component orientation with a predominantly normal vessel course to the building platform and 0° orientation with a parallel vessel course to the building platform during printing on the free cavities of the module was investigated based on the previous results [18].

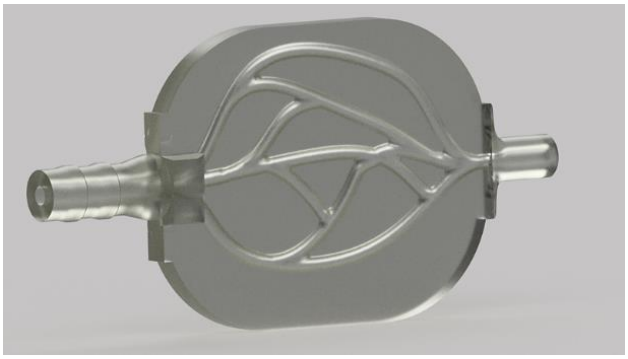

Figure 1: Final designed embolization module with 1.6 mm vessel diameter

The designed embolization module was then saved as an STL file and prepared for manufacturing using Preform printing software (Formlabs Inc., Somerville, Massachusetts, USA) with regard to component orientation and support structures. The module was printed through stereolithography (SLA) on the Form 3L printer (Formlabs Inc., Somerville, Massachusetts, USA) using Flexible 80A and Clear V4 material. To complete the fabrication process, the model was post-processed and the support structures were removed. For post-processing, the model was washed in isopropanol (IPA) according to the manufacturer's instructions followed by curing under UV light.

III. Results and discussion

All models could be successfully printed regardless of orientation, material used and vessel diameter. However, when washing out the hollow channels of the embolization modules, which were made visible using red food colouring, a clear influence of both the part orientation and the material used was observed. The hollow channels of the Flexible 80A modules could not be completely washed out regardless of part orientation. Resin residues remained in the hollow channels even after manual post-processing in addition to the manufacturer's instructions. Manual post-processing consisted of rinsing the components several times with IPA through a syringe and then blowing them out with compressed air. With the Clear V4 material, almost all of the channels with a 90° orientation could be rinsed out largely without residue, in contrast to the models with a 0° orientation. However, the manual post-processing was still required to achieve an optimum result. In total, a 90° orientation of the components leads to better drainage of the uncured resin from the adapters, thus facilitating washout. The influence of material properties, particularly

viscosity, appears to be an important factor in the cleaning process. For the following physician evaluation of the cSDH embolization modules, only the Clear V4 models with the different vessel diameters of 1.2 mm and 1.6 mm were used.

To evaluate the embolization modules integrated into the existing MMA model (PJ5, Vulcan Soft [16], tests were performed with two experienced physicians. The models were integrated into the HANNES simulator using edge-free connectors to connect to the MMA. To ensure consistent alignment of the MMA model with the embolization modules, a holder was fabricated using 3D printing (Form 3L (ClearV4), Formlabs Inc., Somerville, Massachusetts, USA). Fig. 2 shows the setup of the cSDH treatment simulation in the HANNES simulator with the MMA model and the integrated embolization modules.

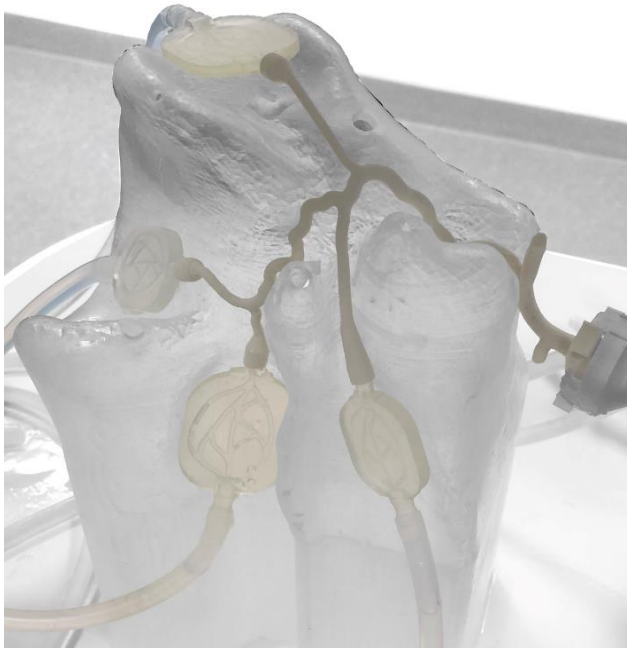

Figure 2: Setup of the cSDH treatment simulation in the HANNES simulator with the MMA model and the integrated embolization modules

The modules were tested with original treatment devices in a realistic angiography suite to simulate real-life procedural conditions. Two interventional neuroradiologists with 8 and 11 years of experience, respecttively, performed a simulation of cSDH treatment with Onyx liquid embolic agent to test the functionality of the embolization module in the HANNES simulator. A standard microcatheter (Headway™ 17, Terumo Neuro, Shibuya, Tokyo Prefecture, Japan) was used for the study and inserted transfemoral into the vascular tree of the simulator. Under X-ray guidance, the catheter was navigated through the existing vascular tree to reach the MMA with embolization modules. Flow through the vessel models was analysed using digital subtraction angiography (DSA). For this, contrast agent was injected into the arterial system via a catheter (Fig. 3).

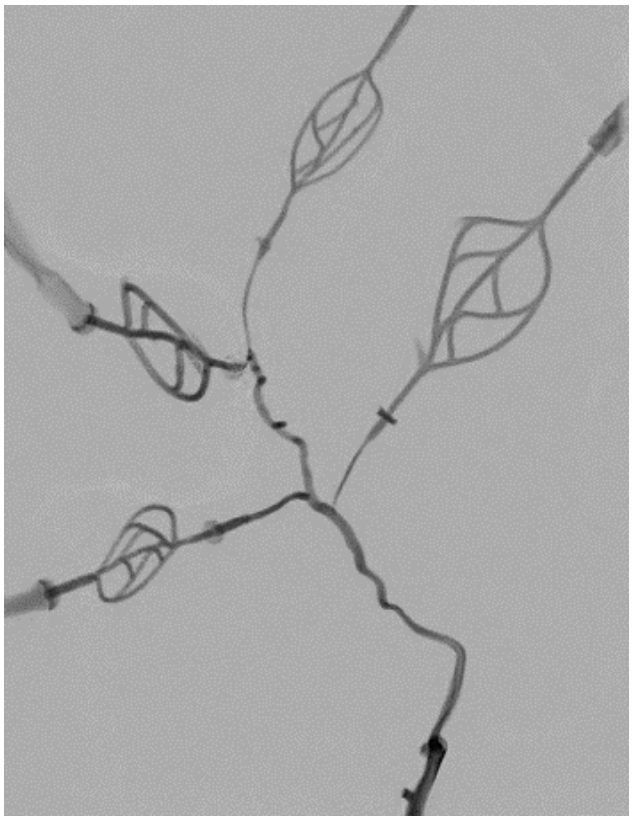

Figure 3: DSA image of the MMA with embolization modules

Onyx embolization was then performed and the physicians were questioned about the geometric mapping, flow and distribution of the embolization using a questionnaire. A Likert scale was used for this evaluation. The scores ranged from 1 ('very poor') to 5 ('very good'). Table 1 lists the six questions. The questions are categorised according to the aspects of geometric mapping, physiological mapping and medical-therapeutic mapping.

Table 1: Questions from the questionnaire for the evaluation of the embolization module, 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 embolization module compared to a real human artery?	4
Physiological mapping	
How would you rate the physiological mapping of the human anatomy in terms of flow and pressure of the model?	4
Medical–therapy mapping	
How realistic would you rate the distribution of the embolic agent?	5
How would you rate the amount of injected embolic agent compares to a real dose?	5
How would you rate the flow stop through embolization?	4
How realistic would you rate the angiographic visualization of the embolization?	5

The embolization module was rated as having good geometric mapping and flow. To improve the flow rate, the venting of the modules must be optimized. The true-to-life distribution and amount of embolic agent injected as well as the visualisation in the angiography were considered to be very good. The flow stop through embolization in the module was rated as good. Fig. 4 shows an embolization module with a vessel diameter of 1.6 mm, which is closed after the simulation of the treatment with Onyx (black). The model cannot be reused due to the embolization and must be replaced after training. The application test should be repeated in a large study with several physicians for a more detailed evaluation of the module.

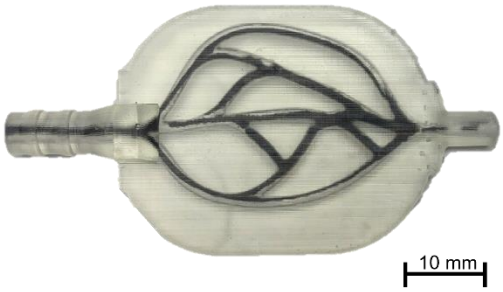

Figure 4: Embolization module 1.6 mm vessel diameter after the treatment simulation with Onyx (black)

IV. Conclusions

The development of an interchangeable 3D printed MMA embolization module for integration into the HANNES simulator successfully enables the simulation of cSDH treatment with the liquid embolic agent Onyx. The study showed that the module allows realistic geometric and physiological mapping, with good flow characteristics and embolic agent distribution, as confirmed by experienced neuroradiologists. A key finding was the influence of material selection and part orientation on the manufacturing process and post-processing efficiency. Clear V4 material was found to be more suitable than Flexible 80A. In addition, a 90° orientation of the printed parts facilitated better removal of uncured resin, whereas a 0° orientation resulted in more persistent blockages. The embolization module was tested under realistic conditions in an angiography suite using original treatment devices. Physician evaluation confirmed the module's high degree of realistic geometric mapping, flow dynamics and embolic agent distribution. These results highlight the potential of the module as a valuable tool for neurointerventional training, reducing reliance on animal models and providing a standardised platform for skills development. Future work could focus on integrating the module into structured training courses to improve physician training in MMAE. Due to its transparency, the model has the potential to be adapted for radiation-free training in the future to provide a safer learning environment for trainees. In addition, the integration of objective assessment metrics into the simulator would allow systematic evaluation of procedural performance and skill acquisition, further enhancing the training process. Analysis of the embolization distribution and return flow could be used to differentiate between a well-performed embolization and one that requires further training.

Acknowledgments

The authors would like to thank the Federal Ministry of Education and Research – BMBF for funding the project MONTYPIE (FKZ: 16LW0301K). a

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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