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Low-cost physiological simulation system for endovascular treatment of aneurysms

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Abstract: Minimally invasive procedures are more and more becoming the standard treatment for many surgical procedures such as the treatment of cerebral aneurysms. In an endovascular procedure the aneurysm is filled with flexible platinum coils leading to embolization and blocking the blood flow in the aneurysm. This established treatment needs high skills and experience on the surgeon. In order to practice and plan a specific procedure or test a new device, a realistic simulation environment is needed. Modern 3D printing technology allows the fabrication of patient specific models incorporating the exact geometry of the pathological anatomy.

This article describes the development of a low-cost physiological simulation system for the training of the endovascular treatment of aneurysms. In order to practice the procedure in a realistic scenario, a 3D printed model of the aneurysm is embedded in a fluidic simulation system. In addition to the patient-specific anatomy of the aneurysm a pulsatile water flow is generated, which emulates the influence of blood flow on the behaviour of catheters and coils during deployment.

The system consist of a controllable pump circuit generating a pulsatile flow which can be regulated automatically and additionally controlled externally by the user. For a suitable representation, a display which graphically represents the sensor data and settings is employed.

The components were compactly integrated in a small case allowing for easy deployment in training workshops. The simulation setup was successfully tested in prospective patient specific treatment planning and workshops for students.

Keywords: simulation system for endovascular treatment, aneurysm treatment, 3D printed patient-specific models

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1 Introduction

Cerebral aneurysms usually develop at arterial bifurcations or a fragile spot of the vessel wall, usually without any symptoms. Due to their inherent risk of rupture, aneurysms pose one of the leading risks of subarachnoid haemorrhage [1]. Endovascular coiling has become an established method for the treatment of intracranial aneurysms as an alternative to surgery with clipping [3]. In this minimally invasive procedure the cranial aneurysm is filled with flexible platinum coils which leads to an embolization. The treatment requires a skilled and experienced surgeon, carefully planning the procedure.

A system which allows for a patient specific training and preparation of the procedure is thus of high value. Such a system may also be employed for teaching students and for scientific research aiming at improved treatments. Other research areas are concerned with the virtual 3D preparation and planning of minimally invasive procedures [8].

A key component of the system is a realistic model of the aneurysm and the connecting blood vessels based on patient specific measurements. In the last years a common fabrication method for patient specific models is the 3D printing technology [5], [6], [7]. The diagnosis of intracranial aneurysm is usually based on 3D digital subtraction angiography and time resolved two-dimensional angiography. The image data from angiography can be used for the fabrication with high anatomic details in stereolithography 3D printers.

The measurement of the blood flow is usually done with Doppler flowmetry. This information can be used in the model to offer realistic reproduction of the blood flow. The arteria carotis interna is an important vein for blood supply in the brain and therefore plays a decisive role in examining characteristics of the cerebral flow. Tests revealed that the blood flow in this arteria is about 250 ml/min [2], which needs to be maintained by the system. Another method is to compute the velocity field for pulsatile physiological flow in cerebral aneurysms with the computational fluid dynamics (CFD) method [9].

2 Material and methods

2.1 Concept and system setup

The setup is build up with 3D models of aneurysms and a water circuit representing veins and blood circuit. The 3D model is placed in a water tank to ensure permanent flow of the liquid. A control unit allows the user to simulate physiological conditions such as pulsatile flow with user-defined offset and amplitude. A simple user interfaces provides means to control all relevant values of the system. To ensure the safety of the users, the standard DIN VDE 0100-410 is implemented and no voltage above 12V is used throughout the system. Compliance with the requirements of the standard should make it possible to classify the entire body into protection class 3.

2.2 Manufacturing of 3D-Aneurysma

The 3D model of the aneurysma is fabricated with a 3D printer which uses the data of high resolution 3D rotational angiographic image of the brain arteries. Manufactured by formlabs SLA rapid prototyping system, the model has an resolution of 0.025 mm and shows high anatomic details because of laser induced photopolymer solidification [10]. Due to the transparent and flexible polymer, device deployment is visual and the model simulates vessel flexibility. The veins for the blood supply in the brain are represented by flexible hoses which have inner diameter of 5mm corresponding the arteria carotis interna [4].

2.3 Simulating imaging capabilities

The entire water circuit system is contained in a transparent tank placed on an illuminated surface. Due to the transparent 3D model of the aneurysm, the resulting view into the transparent tank offers a reasonable resemblance of a time resolved two-dimensional angiography during the training procedure without resorting to X-ray based fluoroscopy. The visualization of the entire process of the treatment is particularly helpful for inexperienced physicians, but also for endovascular interventionalists to detect complications prematurely.

2.4 Simulating physiological conditions

The most relevant physiological condition are the blood flow and the blood temperature which both have an impact on the endovascular procedure. The change in blood flow hinders the control of the catheter and affects the insertion of the coils.

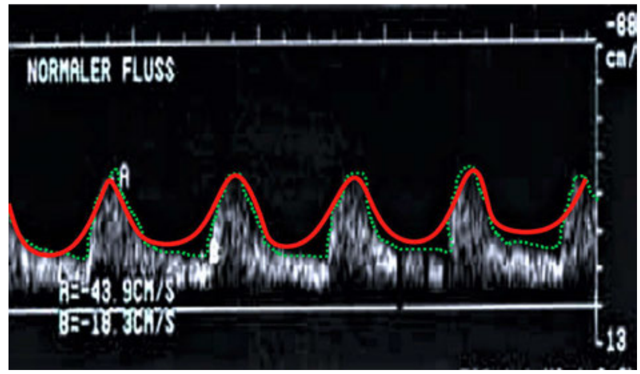

Fig. 1: The regulated flow (red) and the flow profile of the *artery carotis interna* (green) (with scaled and interpolated values)

Different temperatures also change the characteristics of the coil material. Temperature control can be achieved by controlling the water temperature of the tank, but was excluded for this prototype for the sake of simplicity.

Pulsatile flow may be generated by various different means of instrumentation. A proportional valve was excluded due to the high price point. Instead a controllable pump with a high dynamic range and quick reaction is capable of producing different flow rates. The Kavan gear pump is capable of delivering 1800 ml / min and thus covers the required dynamic range [12]. The flow can be regulated steplessly by a pulse width modulated signal (PWM) generated by the control unit. A power control is used to regulate the pump and thus the flow.

A regulator circuit for controlling the pulsatile flow is necessary because of different unknown disturbances e.g. catheters in the vessels. This requires a flow sensor which has the necessary range. The flow sensor "flow100" by manufacturer Aquacomputer used in this setup is based on a differential pressure measurement and has only a very low internal resistance [11]. The sensor transmits the data with the bus system I2C. The regulation is handled by a Atmel ATmega2560 low-power CMOS 8-bit microcontroller. The sensor data is processed and matched with the user input. A feedback controller steplessly adjusts the flow, allowing the generation of pulsatile flows. The set point can be variably adjusted by the user via a control dial.

2.5 User interface and software

The user must be able to adjust values in the system and visually track changes. The output and visualization of the data is handled by a graphical display and inputs are made via potentiometers and switches. The display used in this setup is a 2.8 inches colorful LCD screen. The decisive values are blood

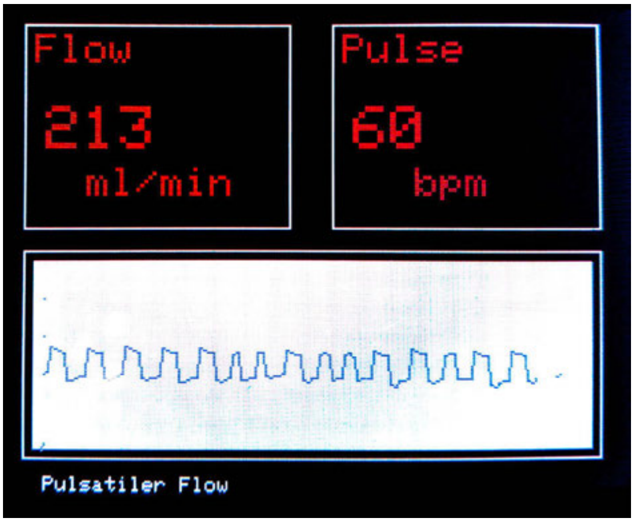

Fig. 2: Graphical representation of flow, pulse and curve on the integrated LCD display

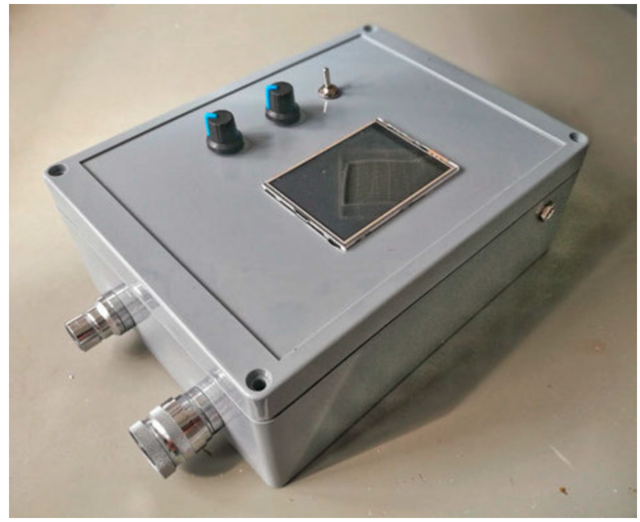

Fig. 3: The case of the simulation system with circuit points, input devices and display

flow and pulse rate. In addition, it should be possible to adjust the offset as well. By displaying the flow curve, all adjustments can be checked visually. The program code separately processes inputs and outputs and the regulation of the flow.

2.6 Complete setup

The case of the system should accommodate all components compactly and allow for easy maintenance. In order to separate the water-carrying parts from the electronic hardware, the pump and the sensor are mounted in the lower part of the box. The electronic circuit with microcontroller, display and input devices is integrated in the cover of the case, allowing for simple access. The plastic case used is made of acrylonitrile butadiene styrene (ABS), classified in protection class IP65 and distributed by RND components. Two circuit points combine the case with the water circuit and bring the pulsatile flow to the entire system.

3 Results

A realistic training and simulation system for the endovascular treatment of aneurysms is useful not only for training but also for preparing individual treatments and performing research. Due to the high resolution 3D aneurysm model paired with a physiological flow a realistic treatment simulation can be executed. The system can be tailored patient specifically by incorporating almost any aneurysm geometry and by adjusting a reproducible simulation of blood flow. The user is able to tune rate, frequency and offset of the flow. Furthermore it is possible to visually control the behavior and performance of the system. The accuracy of the flow control is about ± 5 ml/min and in application there were no perceptible difference to this specification. Different application scenarios have been tested, such as pre-vitro deployment, sizing tests and training. The system was used for several treatments and helped the physician during the preparation. Patients thus benefit from improved choices of size and device for their treatment and premature elimination of possible errors. Particularly for specific and complex aneurysms the system can increase the confidence of the treating physician. The second important area is teaching and continued practice for surgeons and medical students. The system may thus also serve as an alternative to lab animals which are typically used for practicing endovascular procedures.

4 Discussion

The user feedback after using the entire system for treatment planning and sizing tests revealed that there was a clear impact of the system on the correct choice of size and device. Furthermore the users state that working with the system increases confidence and experience. A main issue with the existing setup is the different elasticity of the hose and 3D printed aneurysm models compared to the much more elastic in vivo conditions. Future work will focus on extension of the physiological conditions and concepts for workflow and teaching purposes. Besides there are considerations of manufacturing more of these systems in order to gain more experience through more intensive workshops for students and scientific

Component	Estimated price [Euro]
Pump	25,00
Sensor	50,00
Microcontroller	30,00
Display	15,00
Waterhoses	5,00
Electronic	10,00
Case with connections	15,00
Total costs	150,00

Tab. 1: Overview of the costs of the entire system without manufacturing costs

Fig. 4: The simulation system in a pre-vitro deployment and sizing test

research. There are some continuation ideas for a complete workflow using image data and the system to simulate patient-specific blood flow. Moreover the setting can be used for coil and stent resistance and life cycle tests. Additional extensions for the system also include the temperature regulation of the liquid addressing the temperature-dependent characteristics of coils and stents. Another adaptation may concern the use of a processing liquid closer resembling the properties of blood. This however needs to be weighted against the easier handling of water.

The components of the system have a total purchase price of less than 150 Euro. Table 1 shows the approximate costs of the entire system. For use in workshops or research, the system can be replicated cost-effectively due to the simple set up.

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Author Statement

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