FLOWMODDA

Flow Models for Device Tests in Aneurysms

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Background

Brain hemorrhage due to rupture of untreated aneurysms is often lethal and many survivors recover with permanent disability. Therefore, incidental cerebral aneurysms with significant rupture risk require treatment using endovascular devices for embolization. In complex aneurysms, prior careful planning of treatment is necessary as endovascular embolization and device options (e.g. coils with stent remodeling or flow diverters) are specific to the particular shape of aneurysm in each patient. The interventional physician will must therefore anticipate the behavior of devices, utterly relying on experience.

Treatment planning currently relies on prior diagnostic imaging (three-dimensional digital subtraction angiography and time resolved two-dimensional angiography) to select of the most appropriate type and size of devices based mostly on experience of the interventionalist. Suitable devices must be reliable and easy to use for a large range of different individual patient specific vasculature and shapes of aneurysms.

The Problem

Because every aneurysm is different in each patient, there remains uncertainty how devices will behave, however, at the same time margin of error is minimal, and expertise of the interventionalist is variable. This is particularly relevant for complex shaped large aneurysms with a wide neck wher complete embolization is difficult.

The Need

Patient specific aneurysm models with very high level of anatomical accuracy, that are transparent and exhibit lumen patency even for smaller arteries could allow simulation of patient treatment and device deployment. This would address the immediate need for

- Patient specific treatment planning: Embolization of complex aneurysms with stent remodeling or flow divertes can be simulated to increase confidence of interventionalist.
- Teaching and continuing practice: Repetitive procedure training of complex aneurysm models.
- In-vitro Device Tests: Device deployment in variable anatomic models based on a library of case specific aneurysms.

The Solution

Manufacture of 3D aneurysm models by rapid prototyping that offers

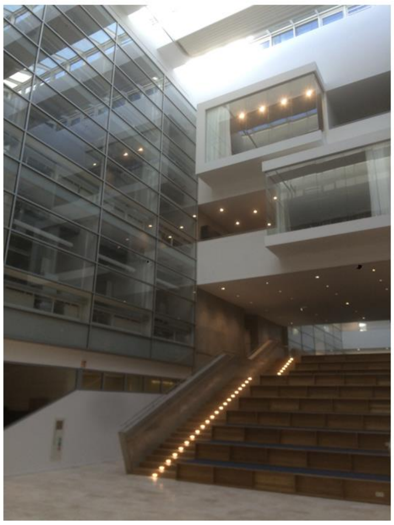
- low cost and short production time amenable to upscaling to a high numbers of cases
- high anatomic detail by laser induced photopolymer solidification to create patent vessel models < 0.5 mm in lumen diameter.
- transparent polymer resin so that 3D aneurysm models can be used for direct visualization of device deployment without the need of x-ray in DSA
- flexible polymer resin so that 3D aneurysm models can simulated vessel flexibility to a desired degree

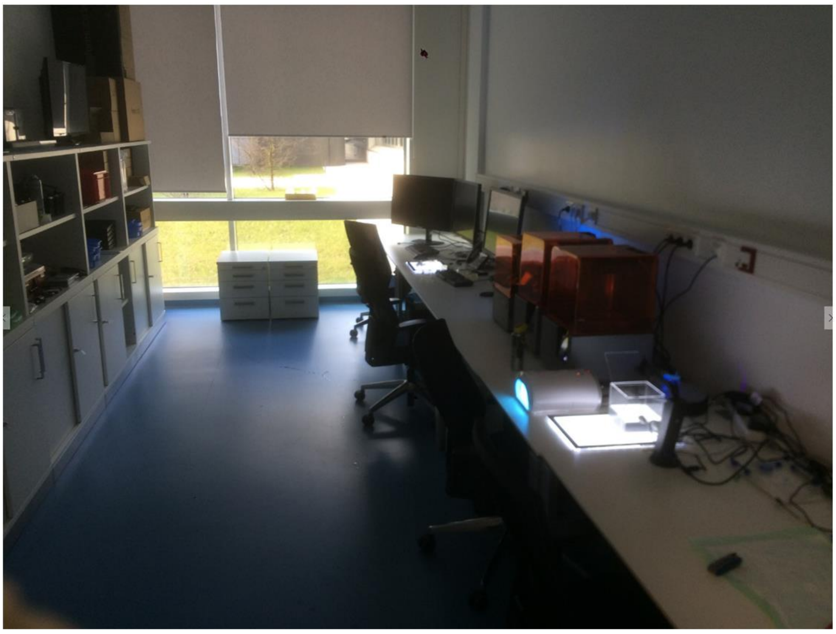
Current Research and Realization of the solution

A dedicated 3D printing lab was established at the Center of brain behavior and metabolism (CBBM) of the University of Lübeck. The printing lab is equipped with one Form1+ and two Form2 stereolithography 3D printers (Formlabs) that are regularly used on a daily basis to produce patient specific 3D models of brain aneurysms.

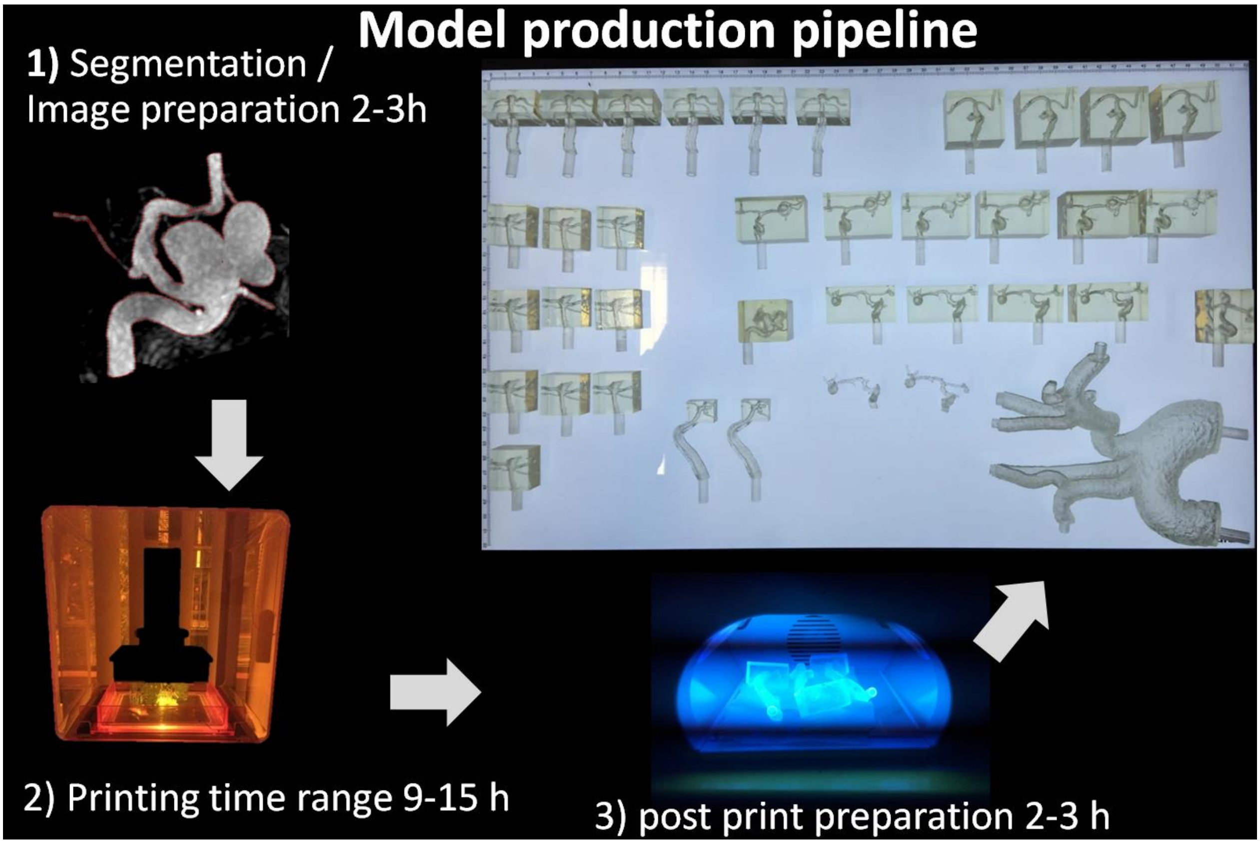
CBBM (center of brain behavior and metanbolism - University of Luebeck)

dedicated 3D Printing Lab



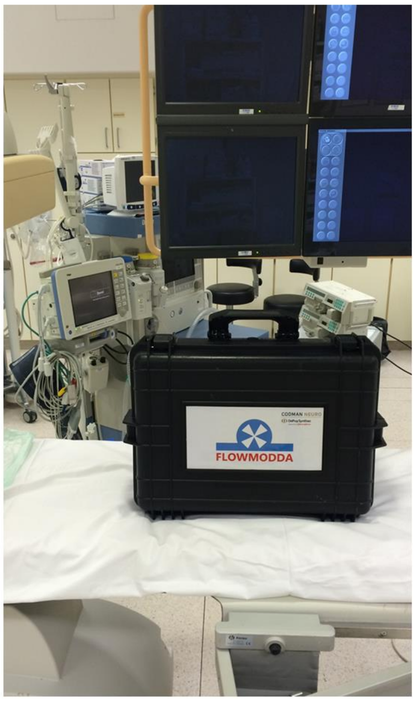


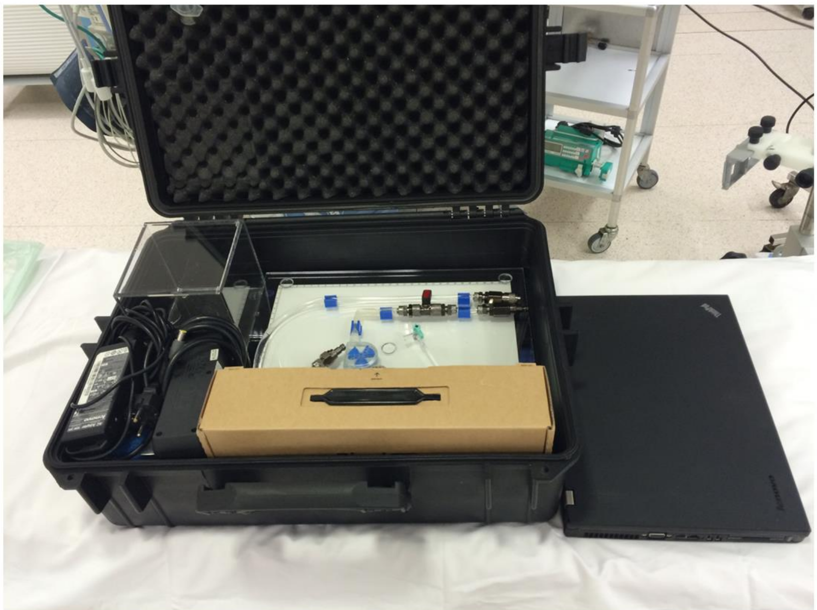
High resolution 3D rotational angiographic image data of brain arteries is processed to segment vessels and create a 3D surface file. The surface file in .stl format can then be directly processed by the Formlabs Peform software to create a print job which usually will take 10-15 hours at a print layer resolution of 0.025 mm.



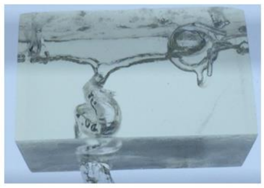
Dr. André Kemmling and Prof. Peter Schramm are interventional neuroradiologists at the Institute of Neuroradiology, University Hospital Lübeck who initiated the project "FLOWMODDA" (Flow Models for Device Deployment Tests in Aneurysms). This research project specifically addresses the need for 3D printed brain aneurysm models within an integrated pump assisted flow system that can be produced at low cost and high scale.

Pump assisted flow system with camera





training
intracranial procedure
(coiling, thrombectomy etc.)

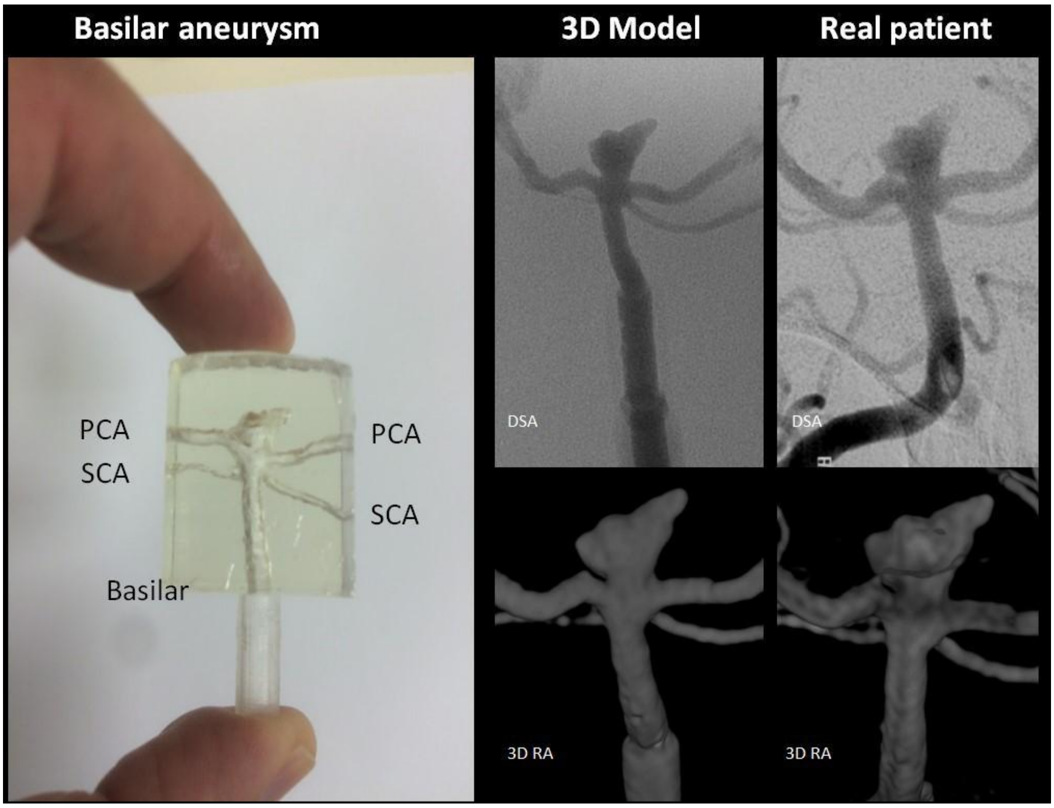


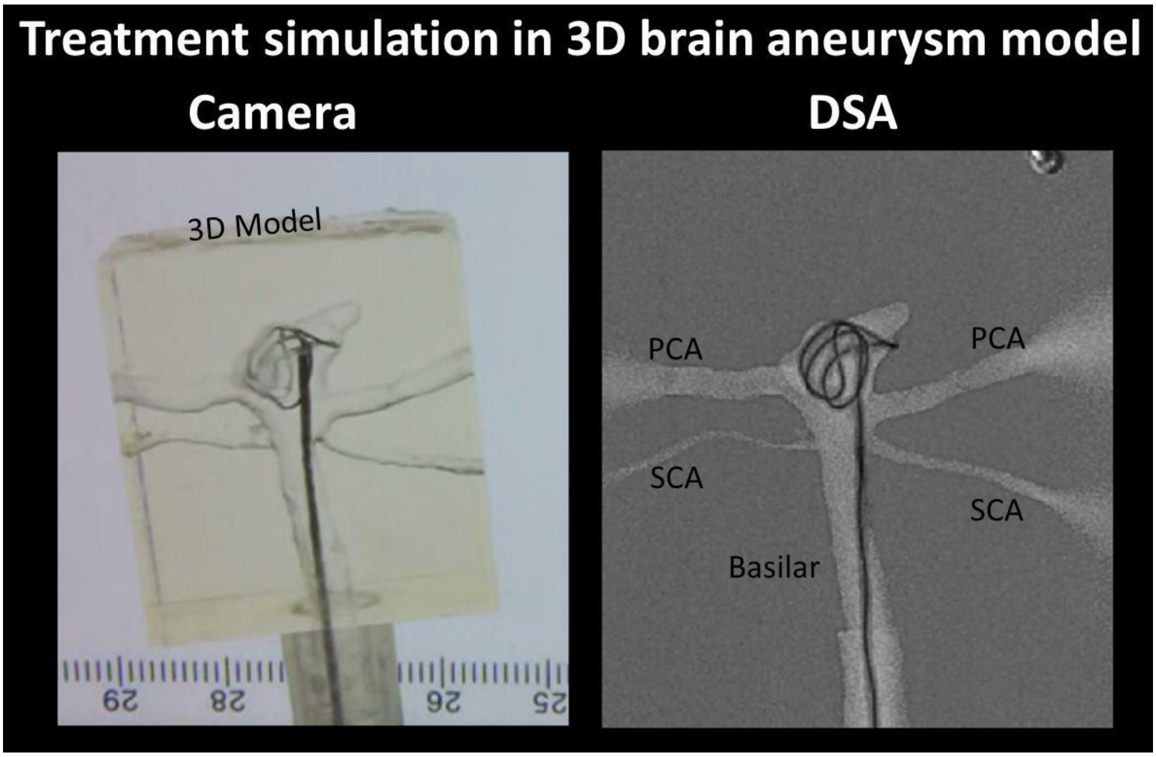
Patient specific 3D printed model of brain and neck arteries

training
extracranial access

Repetitive training in workshop setting

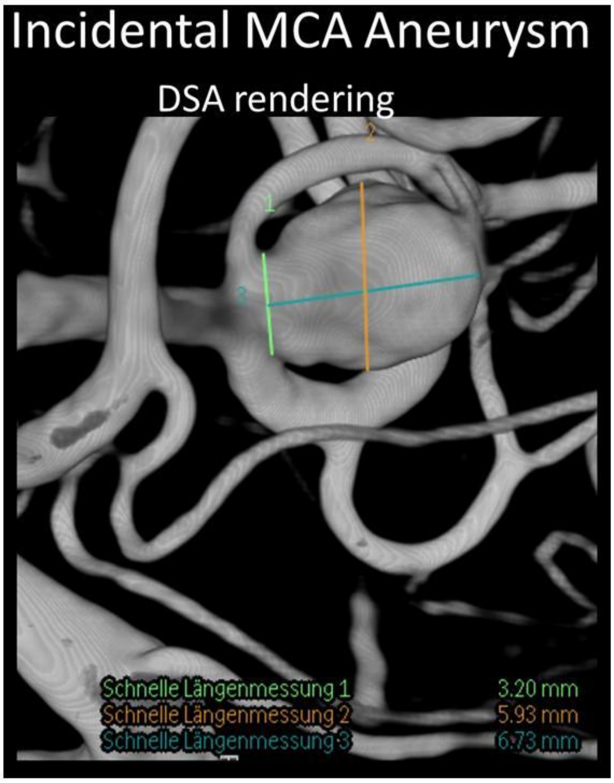
For teaching and continuing practice, the 3D printed models are now frequently used in workshops where participants can practice deployment of different available devices in different anatomic modes including their own case that may be planned in the future.

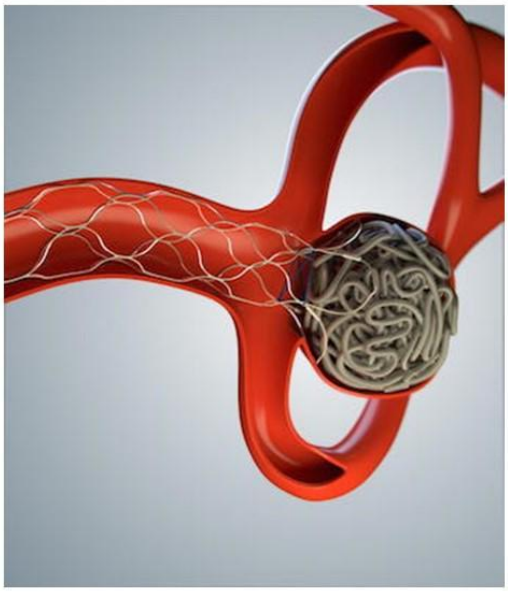


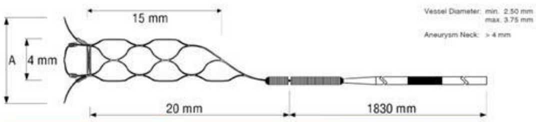


Prospective patient specific treatment planning on a clinical basis is performed in complex cases for sizing tests of devices and to increase the confidence of the interventionalist. In the example below, a wide neck aneurysm of the middle cerebral artery was planned to be treated by coil embolization with use of a pCONus remodeling device. Prior to treatment, device sizing tests were performed in a 3D printed aneurysm model of the patient.

Device Sizing Strategy ?

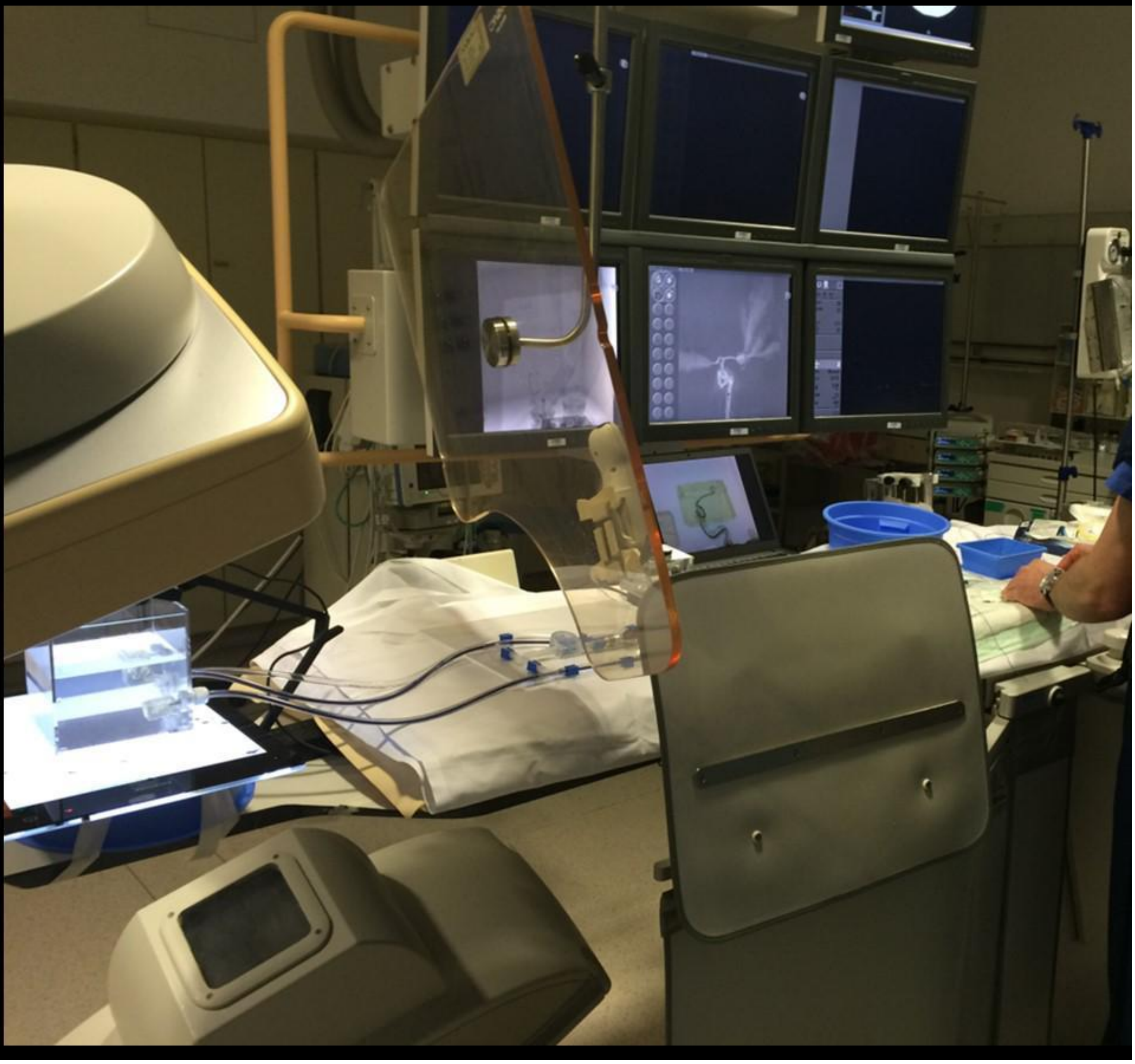


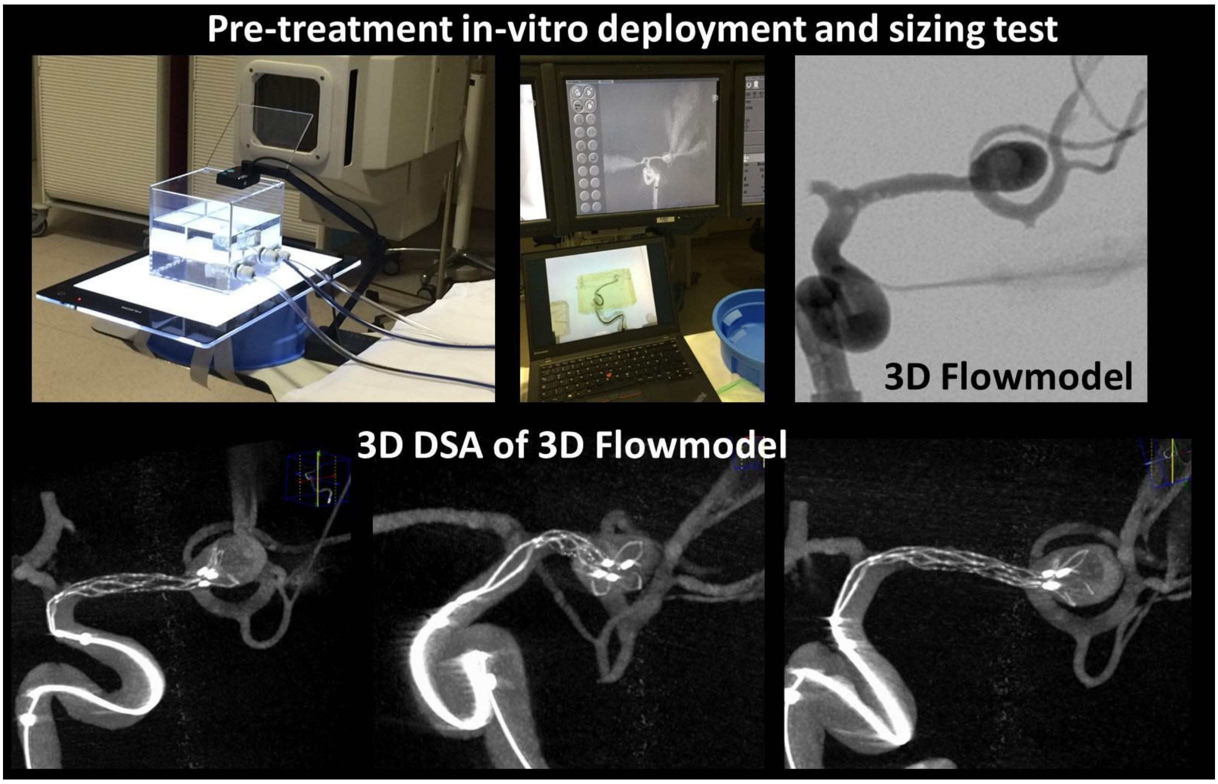


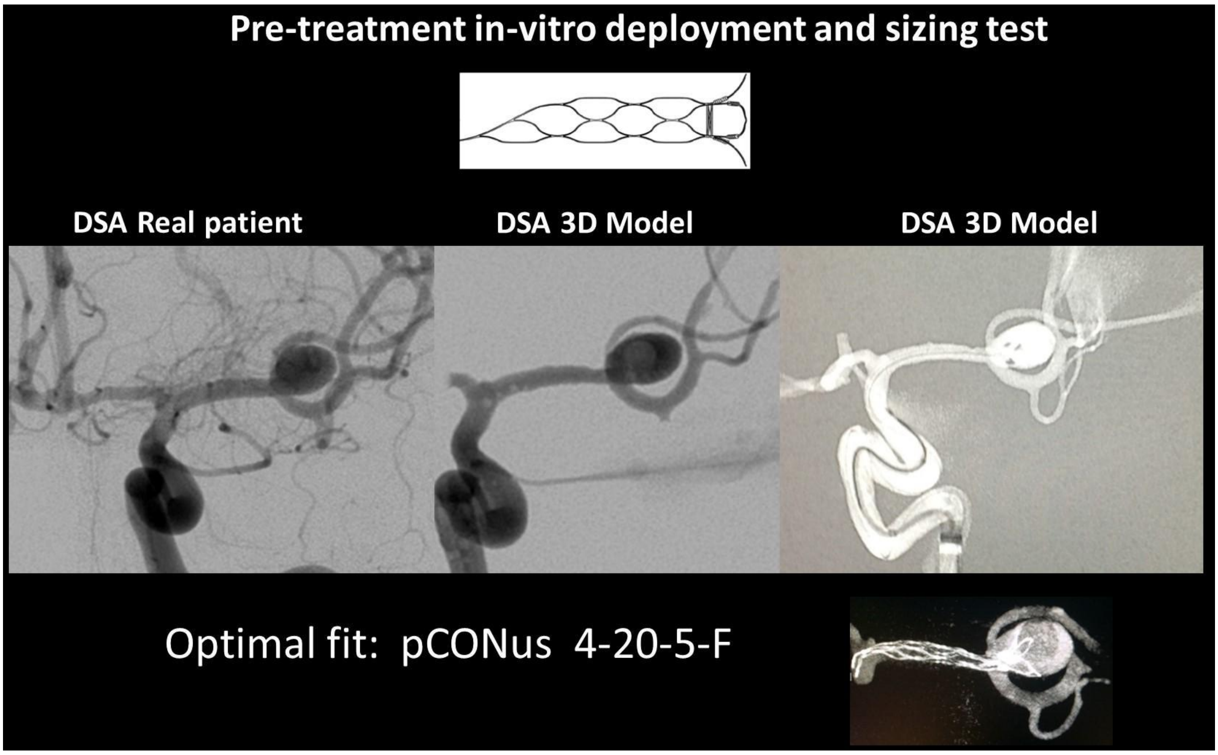


REF	Distal diameter (A) [mm]
PCON-4-20-5-F	5
PCON-4-20-6-F	6
PCON-4-20-8-F	8
PCON-4-20-10-F	10
PCON-4-20-12-F	12
PCON-4-20-15-F	15

Pre-treatment in-vitro deployment and sizing test

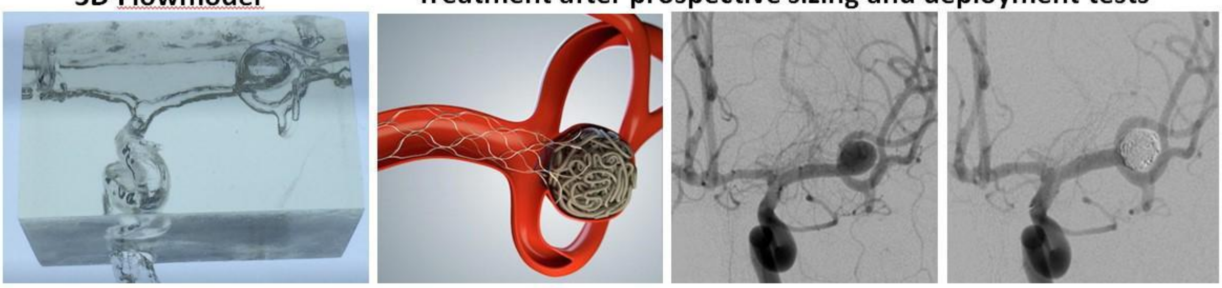






3D Flowmodel

Treatment after prospective sizing and deployment tests



Conclusions

Treatment of complex brain aneurysms requires expert experience of device behavior, but precise patient specific device behavior is often uncertain even with highest experience. All endovascular interventionalists have learning curves and the steep part of a learning curve is dangerous until expert level is reached. Gaining experience and confidence of the interventionalist should happen outside the patient as much as possible.

The FLOWMODDA system uses ultra-high resolution cerebral aneurysm models manufactured by SLA rapid prototyping to allow patient specific treatment simulation of brain aneurysms with remodeling devices and flow diverters in a realistic environment. The technique may allow precise planning of device deployment and significantly increased confidence of the endovascular interventionalist. The flow system is designed for ease of use, portability, extremely low cost, reliability and short term production workflow to meet the goal of high throughput and upscaling for widespread usage in a clinical setting.

Our Vision

- We strive to provide patient specific treatment simulation with 3D models for every patient with complex aneurysms on a global scale, the technology is there, but currently not offered to the patient.

- Patients should benefit from optimal choice of devices for their treatment of brain aneurysm, benefit from increased confidence of the treating physician and ultimately benefit from reduced risk of endovascular intervention.

- We strive to save lab animals that are used for practicing endovascular procedures.

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