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Treatment Planning for Image-Guided Neuro-Vascular Interventions Using Patient-Specific 3D Printed Phantoms

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Abstract

Minimally invasive endovascular image-guided interventions (EIGIs) are the preferred procedures for treatment of a wide range of vascular disorders. Despite benefits including reduced trauma and recovery time, EIGIs have their own challenges. Remote catheter actuation and challenging anatomical morphology may lead to erroneous endovascular device selections, delays or even complications such as vessel injury. EIGI planning using 3D phantoms would allow interventionists to become familiarized with the patient vessel anatomy by first performing the planned treatment on a phantom under standard operating protocols. In this study the optimal workflow to obtain such phantoms from 3D data for interventionist to practice on prior to an actual procedure was investigated. Patient-specific phantoms and phantoms presenting a wide range of challenging geometries were created. Computed Tomographic Angiography (CTA) data was uploaded into a Vitrea 3D station which allows segmentation and resulting stereo-lithographic files to be exported. The files were uploaded using processing software where preloaded vessel structures were included to create a closed-flow vasculature having structural support. The final file was printed, cleaned, connected to a flow loop and placed in an angiographic room for EIGI practice. Various Circle of Willis and cardiac arterial geometries were used. The phantoms were tested for ischemic stroke treatment, distal catheter navigation, aneurysm stenting and cardiac imaging under angiographic guidance. This method should allow for adjustments to treatment plans to be made before the patient is actually in the procedure room and enabling reduced risk of peri-operative complications or delays.

Keywords

Vascular Phantoms; 3D Printing; Patient-Specific Phantoms; Additive Manufacturing; Treatment Planning; Image Guided Interventions; Neuro-vascular; DSA

1. INTRODUCTION

Cardiac and cerebral-**E**ndovascular **I**mage **G**uided **I**nterventions (EIGI)[1] are challenging in patients with complicated vascular anatomy potentially resulting in adverse effects.[2–9] Cardiovascular disease, including stroke, accounts for the leading cause of death (30% of total deaths) in the world. In the US the associated costs represent 15% of the total health

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expenditures in 2009, more than any major diagnostic group.[10] Many therapies are based on EIGIs due to reduced invasiveness and lower mortality.

During an EIGI, the interventionist navigates catheters and devices using x-ray image guidance. For each particular patient geometry and intervention type, there are a plethora of devices to choose from: catheters with different tip shapes, sizes and stiffness, guide-wires, stents, balloons, coils etc. The costs of interventional catheter based procedures are still expensive due to the high costs of device research, development, and testing. Patient anatomies vary with the individual, and patients with tortuous vasculatures present a limitation in the current technology. Difficult anatomy impedes catheter traversal through vessels and may lead to erroneous device selection, surgical delays or complications, and vessel injury or puncture.

Endovascular devices themselves represent a challenge in that these devices are still fairly crude and rely on distal actuation. This fact can lead to inaccurate or total device misplacement,[11, 12] inability to perform the procedure,[13] prolonged surgical time and increased radiation dose to the patient[14–17], vessel injury and thrombolytic events.

Patient specific vascular phantoms present a new solution to the issue of challenging anatomy by providing a means of physician testing and training pre-operatively on phantoms made from patients with known challenging anatomies, allowing familiarization with the geometry. In addition to physician training, these phantoms can be used to determine the optimal course of treatment for a given patient geometry. A treatment plan can be established based on mock-surgical trials performed by the interventionist on the phantom to determine the treatment that is most effective and best suits the patient anatomy. By acquiring patient data from those individuals whose anatomy is deemed particularly difficult and practicing various procedures, dose, procedure time, and probability of complications can be reduced in future treatments.

Overall, the purpose of this study is to determine the feasibility of using additive manufacturing to support endovascular surgical procedure planning and endovascular device research and development. Endovascular treatment planning (ETP) using patient specific phantoms can be regarded as a novel and affordable point-of-care procedure. The pipeline to develop patient specific phantoms in clinical settings is presented with the goal to guide diagnostic and therapeutic efforts for the heart, brain, and vascular disorders in other organs.

Acquired data from mock interventional procedures show that ETP could offer a robust engineering solution to clinical challenges encountered by endovascular interventionists in every day practice. In addition, this study could offer evidence to speed the adoption of additive manufacturing based ETP in clinics as a viable safety tool.

2. MATERIALS AND METHODS

2.1 Phantom design

The process of making patient specific phantoms has become well characterized with increasing efficiency. The current method for acquiring the patient data for the phantoms

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employ CT, MRI, or CBCT scans of the patient anatomy relevant to their respective treatment. The manufacturing process[28] leading to the creation of phantoms is shown in Figure 1. Patient data is acquired via the aforementioned imaging modalities, and 3D reconstructed volumes of the patient anatomy are loaded into a Vitrea 3D Station (Vital Images, Inc., Minnetonka, MN) to be rendered and processed. The anatomy relevant to the treatment and essential peripheral vasculature is manually selected, and segmented from unnecessary surrounding anatomical features. The segmented vasculature geometry can be further simplified by trimming superfluous smaller branches. The geometry is then exported as a stereolithographic file to a mesh manipulation software (www.MeshMixer.com) for any alterations to the number of inlets and outlets. Having too many outlets can negatively affect the reliability of a flow loop for contrast-based imaging, flow evaluation, or device testing, so the number of outlets must be reduced by merging small vessels to create closed loops until an acceptable number of outlets has been achieved. By doing this, the geometry maintains the integrity of the patient shape but is adapted for practical use in a flow loop. After this process is completed, the vessel wall thickness and vessel diameter can be altered to meet design requirements, and if necessary support structure (as seen in Figure 1) can be created and included. Once the geometry has been completed, the phantom is printed using an Objet Eden 260V Polyjet 3D printer (Objet-Stratasys, Inc., Eden Prairie, MN).

2.2 Phantom Printing

The Objet Eden 260V is capable of printing 17 different materials, both rigid and flexible, in ultrafine 16 μm layers, excelling at printing fine detail, complex geometries and thin walls. The maximum printing volume is 255 × 252 × 200 mm, which is of ample size to print most vasculatures. Printing accuracy varies with the material chosen for printing: for rigid materials, the accuracy in all planes is between 20–85 μm for features smaller than 50mm, and up to 200 μm for full model size. For flexible materials, nominal resolution in the z-axis is 32 μm, and up to 200 μm for in plane accuracy. The patient specific vascular phantoms are commonly printed in one of two materials, one of which is a rigid and transparent material called VeroClear, most similar to acrylic. The other material is a semitransparent elastic material called Tango+ that behaves similar to polyurethane.

2.3 Experimental Setup and Testing

The process described above will be implemented for treatment planning, device testing and young interventionist training. The process has five steps: (1) patient or controlled vasculature geometry model selection, (2) manufacturing of patient specific phantoms, (3) pre-treatment angiography, (4) treatment and (5) post-treatment angiography.

The entire study was performed at the Gates Vascular Institute in Buffalo NY. The institution has 14 angiographic rooms where all the proposed interventions will be done. The planning was performed in the Toshiba Stroke and Vascular Research Center where two dedicated research angiographic rooms and an additive manufacturing facility are available. The patients signed a consent which was approved by the IRB committee.

For step 1 (Patient Selection) only non-emergency scheduled patients were included, all of whom had already had volumetric data of the diseased vascular region acquired (no

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additional 3D data acquisition was required). For the neurosurgery cases, only patients with unusual carotid geometry and aneurysms were selected. Neurovascular interventions, such as those for strokes are, in general, emergencies and ETP was not feasible. Other scheduled interventions such arteriovenous malformations or moyamoya disease have very fine and intricate structures beyond the scope of current additive manufacturing capabilities and were not included in this study. For the cardiovascular interventions, three patients were selected with mild cardiac stenoses or no complications. Idealized geometries of intracranial pathologies were also created, as well as phantoms with various geometry structures which were used for device testing and training.

The phantoms were connected to a pump to simulate realistic circulatory conditions. For aneurysm phantoms various procedures were performed which represent the current techniques employed in clinical situations, including treating aneurysms with flow diverters, coils, and stent-supported coils. Intracranial ischemic stroke, simulated using artificially created clots, were treated using various standard clot retrieving techniques.

3. RESULTS

3.1 Phantom manufacturing results

A patient specific Circle of Willis and a coronary phantom are shown in Figure 2. They were printed using Tango+ material, and successfully used in practice interventions. The Circle of Willis phantom was used for clot retrieval training and for comparison of efficacy of various clot retrieving techniques. The coronary phantom was mainly used for acquiring angiographic images to verify vessel patency and accuracy for future use in the suite of phantoms.

A new Circle of Willis phantom II (Figure 3) has been designed and printed from the same material, to be used as a learning tool for interventionists. The new phantom has five aneurysms in different locations throughout the Circle of Willis, each with a different geometry to present challenges based on aneurysm pathology as well as placement. These variations diversify the possible uses for the phantom as a learning tool.

In order to make the mock interventional procedures more realistic, separate segments of vasculatures were designed and printed to mimic the path of the catheter from the femoral artery to the treatment site. To achieve this, five 3D printed segments of human vasculatures were printed and connected, as seen in Figure 4. These segments include the left and right external iliacs, the lower region abdominal aorta, the superior region of the aorta, the aortic arch, the coronaries, the left and right brachiocephalic plus subclavian plus section of the brachial arteries, and the cerebral vasculature which includes the carotids and the vertebral arteries. These vasculatures were connected via specially made connectors designed to allow smooth passage of the catheter between each phantom.

3.2 Procedural Results

3.2.1 Comparative Clot Retrieval Results—Interventional procedures and studies have been performed using patient specific phantoms, including studies that required multiple trials. Two comparative studies[18, 19] used a Circle of Willis phantom to evaluate

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the performance of a clot retrieval method compared to the same retrieval method combined with thrombus aspiration. The clots used for the procedures were created in house and introduced into arterial segments of the phantom, their location verified with digital subtraction angiography (DSA) as shown in Figure 5.

The phantom setup allowed a flow loop which simulated the flow through the circle of Willis, the collateral flow allowed the clot to be delivered with high precision. In general, a simple phantom with one inlet and a reduced number of outlets will cause a pressure buildup which would eventually push the clot through the phantom. The general push and pull experienced by the neurosurgeons were similar with that experienced in patients. One snapshot of a general procedure is shown in Figure 5. A clot placed was into the left side of the Middle Cerebral Artery (white arrow) and blocked the circulation in the left side. Either a Solitaire FR device (Covidien, Irvine, California) or a Trevo ProVue Stentriever (Stryker, Kalamazoo, MI) was advanced using the 0.021-inch microcatheter, deployed at the occlusion site, left in place for 5 minutes, and then retrieved. Visualization of the device was much better than for human cases due to lack of attenuation material and scatter. In most cases, only the platinum markers at the end and start of the device are visible in clinical situations.

Twenty two trials (eleven of each method) were performed on the same phantom. The interventionist performing the procedures reported a close anatomical resemblance between the circulation of a human vascular system and that exhibited by the phantom. This is due in part to the strong similarity of the tensile strength of the phantom to that of a human arterial wall. The interventionist was able to successfully demonstrate the effectiveness of the clot retrieval methods as well as assess the possible negative outcomes of the procedure, including potential clot disengagement or fragmentation. Using a realistic phantom eliminates confounding factors that would arise from having multiple human subjects. The phantom allowed for many trials to be carried out in a standardized geometry such that the results of thrombectomy device testing can be compared with confidence and reported in clinical journals.[18, 19]

3.2.2 Aneurysm Phantom Procedure Results—A novel asymmetric flow diverter deployment study was performed using the new aneurysm phantom (shown previously in Figure 3). A guide wire was first advanced into the anterior communicating artery (ACA) as seen in Figure 6, and over the wire a catheter with a preloaded stent was advanced. Navigation of the catheter over the carotid siphon on the left and right side and into the MCA was straightforward, and stent placement was verified within the artery via angiography.

The treatment was evaluated by examining bolus arrival time in the aneurysm and adjacent vessel branches as compared to the pre-treatment arrival times. The object of this treatment was to reduce blood flow in the aneurysm, but not in the main blood vessel, the ACA. Figure 6 shows DSA acquisitions of the treatment region before and after stent deployment, exemplifying the post-treatment change in flow through the affected region. This first stent location resulted in satisfactory deflection of the initial jet of contrast, but the bolus arrival time was delayed in the ACA. The stent was re-sheathed and deployed again at a more distal

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location, resulting in less diversion of flow to the aneurysm dome, but patency of the ACA was achieved. This exemplifies how valuable a learning tool the aneurysm phantom can be: the interventionist was able to see the potential safety issues that can arise from stent misplacement without endangering a human patient.

Standard aneurysm treatments were performed using the aneurysm phantom shown in Figure 3. The phantom was connected to the full body vascular phantom (Figure 4). The first treatment performed was on an Anterior Communicating Artery aneurysm. Using fluoroscopy, a micro-catheter was advanced into the aneurysm dome and four detachable coils were deployed as seen in Figure 7. The procedure followed all protocols as would be performed in a real patient. The neurosurgeon performing the procedure indicated that the perception and the mechanical feedback felt slightly rougher than that of real situations, however, the feeling of coil deployment and micro-catheter motion were still very realistic. After coil deployment a DSA run was performed, revealing reduced flow of contrast in the aneurysm dome.

A third kind of procedure is shown in Figure 8. In this case, an aneurysm was treated using a stent supported coiling approach. This approach is very common for aneurysms with a large neck or for aneurysms treated with flow diverters such as Pipeline. Similar with the previous case a micro-catheter was advanced in the Middle Cerebral artery, and a Wingspan 3 stent (Boston Scientific, Boston MA) was placed across the neck, as seen in Figure 8b to the right of the markers. Through the struts of the stent, a 0.021 inch micro-catheter was advanced, which was used to place embolization coils. DSA was performed to assess the aneurysm occlusion after each coil deployment. Figure 8 shows the results after the deployment of one coil. As expected, there was still significant flow of the contrast in the aneurysm, indicating a need to increase the occlusion through the deployment of additional coils.

3.2.3 Cardiac Phantom Procedure Results—Following the same approach as the neurovascular phantoms, a cardiac phantom was designed and manufactured as seen in Figure 5. It was connected to a flow loop and a pump which provided physiologically relevant flow conditions. A catheter was advanced through the aortic arch, which in this case was simulated by a length of tubing. Using digital angiography, vessel patency was successfully evidenced, as shown in Figure 9. A 6 Fr catheter was advanced into the aorta and a high speed angiogram was acquired using iodine contrast. A DSA sequence was averaged to reduce the noise and identify the smaller vessels, as seen in Figure 9(a). Even the smaller structures with diameter 0.5 mm were patent (as shown in Figure 9(b)) despite the tortuous geometry and challenge in removing the support material from inside such a small vessel.

With the cardiac phantom included in the suite of phantoms, treatment planning can be done for a wide range of cardiovascular interventions including trans-catheter aortic valve replacement (TAVR), increasing the diversity of the program. These are complex procedures that require a multidisciplinary approach involving collaboration between experienced interventional cardiologists and cardiac imaging specialists, all of whom can benefit from treatment planning.

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4. DISCUSSION

This study provides a set of the complete logistics to develop patient-specific phantoms which are accurate from a geometrical, mechanical and imaging point of view. We demonstrated how these features could help the treatment planning, interventionist training, improve the relevance of bench-top model testing for device manufacturing companies, and ultimately result in less device failures during animal and clinical trials.

Previously reported phantoms[20–25] are very simple and often difficult to produce. The presented approach eliminates and simplifies certain aspects of the phantom manufacturing process. Prior investigations, including our own, used complex approaches to create relatively simple patient specific geometries to evaluate new devices[26] or well established ones.[22, 27] While such approaches are needed in order to report device behavior in a reproducible setup, they lack a true clinical situations test, such as delivery through a realistic arterial geometry. Additive manufacturing (3D printing) offers new possibilities for device testing in extreme simulated clinical conditions. We show improved patient specific and precise geometrical models which are more realistic from both a mechanical and imaging point of view.

ETP before an endovascular procedure is feasible and could improve the treatment outcome in patients with challenging vascular geometry undergoing EIGI. Until now manufacturing vascular phantoms for each patient with such anatomy has not been feasible, due to high costs and extended turnaround times needed for the manufacturing. Additive manufacturing offers a unique opportunity to build accurate patent specific vascular phantoms, which can be used for ETP. Now, 3D printers are becoming available and medical imaging vendors are starting to offer options to convert patient specific geometries from a CT or MRI into stereo-lithographic files (STL) used by the additive manufacturing machines. Thus patient specific phantoms can be created within hours after the 3D diagnostic scan. By performing the ETP, interventionists could reduce the number of failed attempts to treat a patient, reduce the number of devices wasted trying to approach the disease location, help them chose among multiple approaches or devices, reduce the procedure duration, and reduce the radiation dose. All these factors could result in better care and ultimately better patient treatment outcomes.

5. CONCLUSIONS

There is a need for safer and more reliable vascular procedures than the results that conventional open surgeries currently provide. Endovascular image guided interventions (EIGI) provide great benefits compared to their conventional counterpart, but are very expensive due to the high costs of research for device testing. Complications may also arise for those patients treated with EIGIs who have complex vascular anatomies. Three dimensional printed vasculature phantoms provide a standardized experimental platform for device testing trials, and patient specific printed phantoms can be used for familiarizing physicians with anatomies before operating. By first performing planned treatments on a model of the patient’s anatomy, any necessary changes in selected devices or therapies can be anticipated and the treatment plan can be adapted accordingly. This may shorten the

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duration of the procedure, which could reduce dose to the patient, as well as reduce the risk of thrombolytic events, pre-procedural complications, and the number of devices wasted on failed attempts. Patient specific phantoms were successfully used in mock EIGIs with positive reports and results from interventionists. Patient specific phantoms represent a versatile and powerful tool, and a unique learning opportunity for physicians and the endovascular field.

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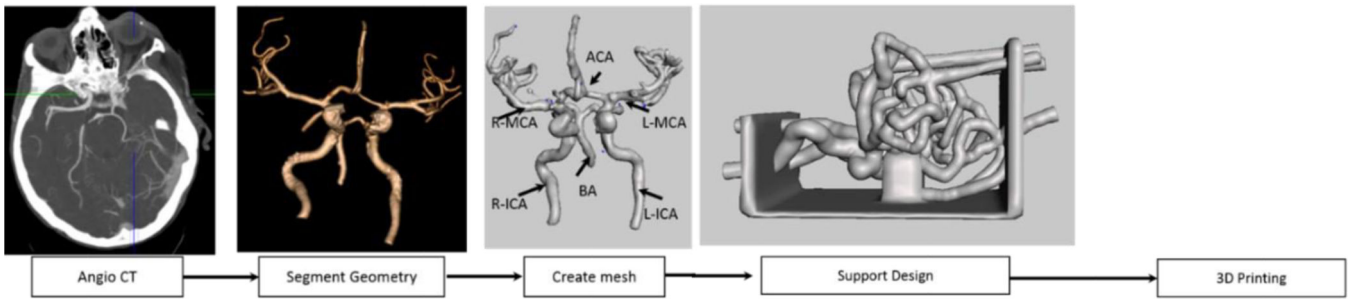

Figure 1.

Flow chart of images describing the manufacturing process for a patient specific phantom of a Circle of Willis. The phantom shown is designated as Phantom I for the purpose of this study.

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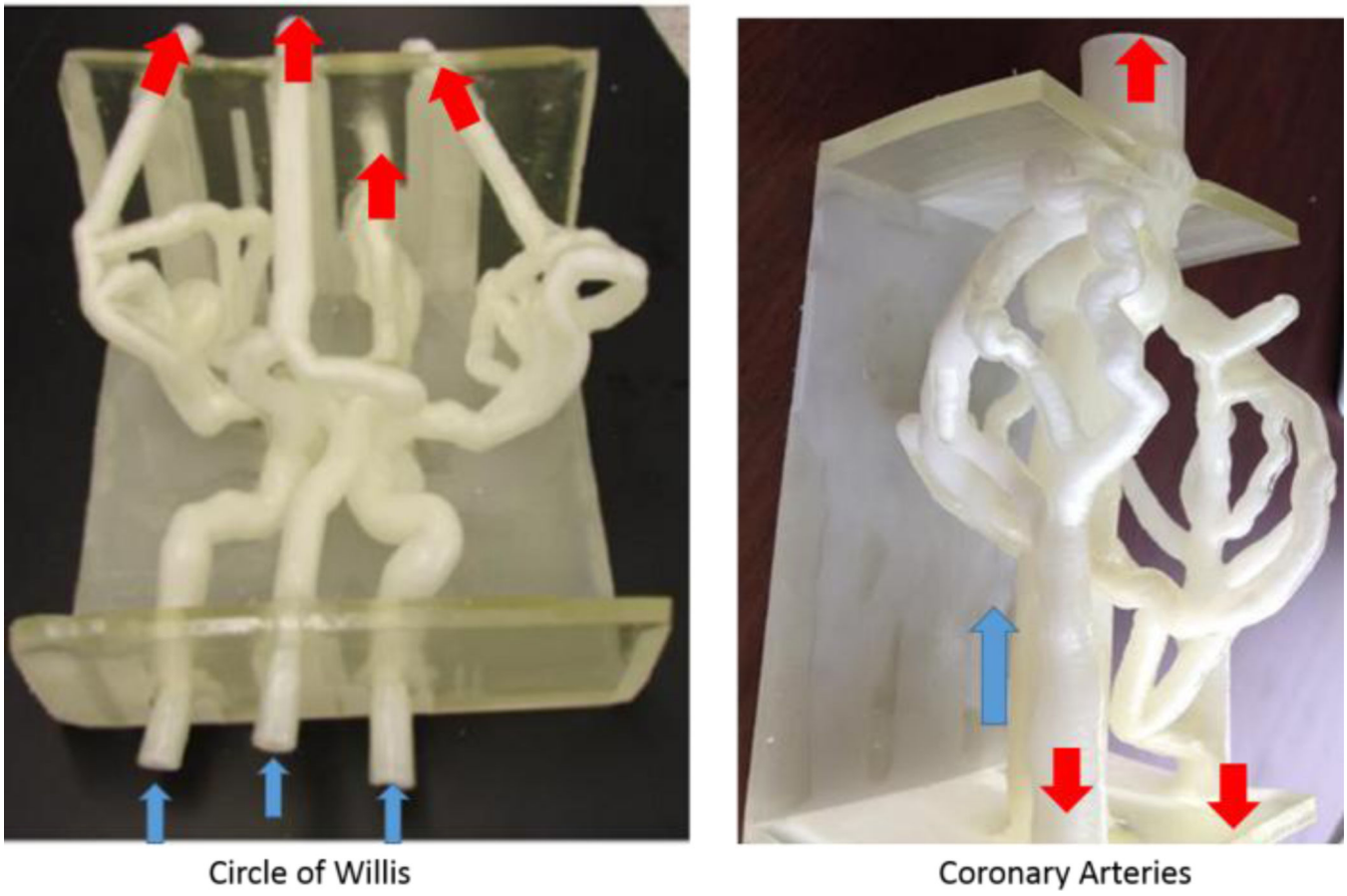

Figure 2.

New 3D printed cardiac phantom. Left picture shows a phantom of a nearly completed Circle of Willis. Right picture shows a cardiac phantom. Blue and red arrows indicate the inflow and the outflow, respectively.

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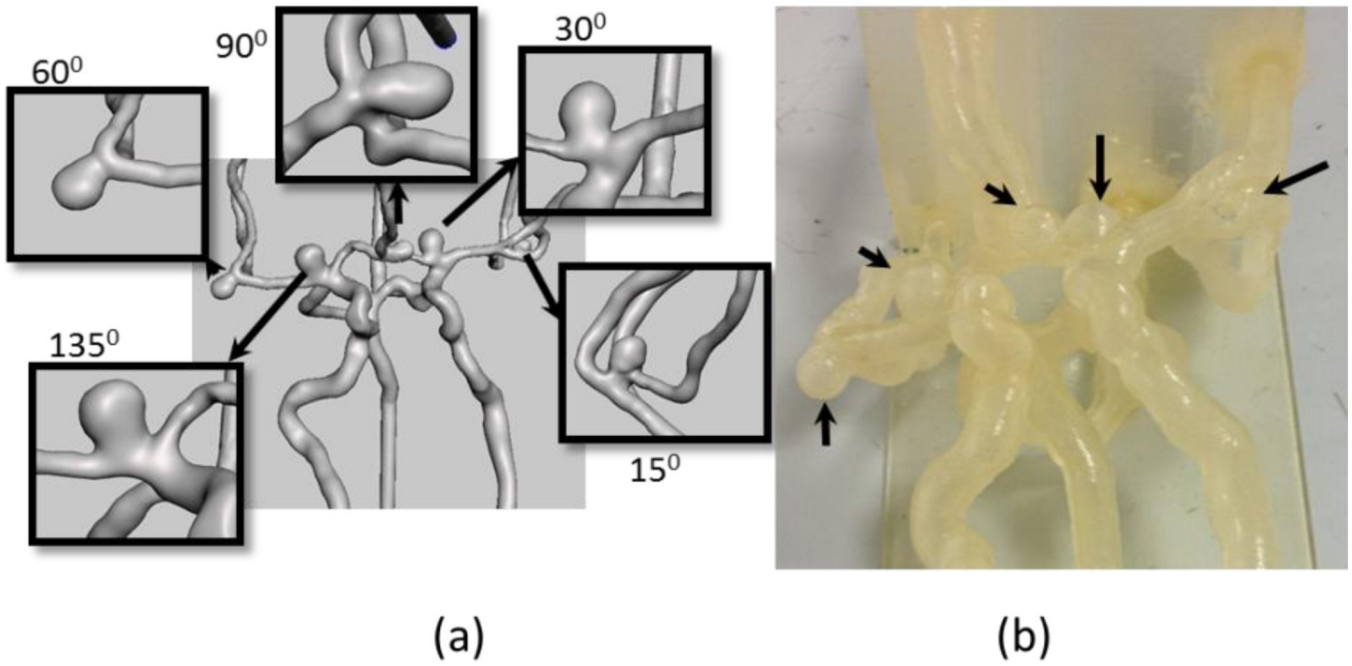

Figure 3.
(a) A segmented image showing location and configuration of all five aneurysms (b) New aneurysm phantom, phantom II, to be used as a learning tool for physicians and interventionists.

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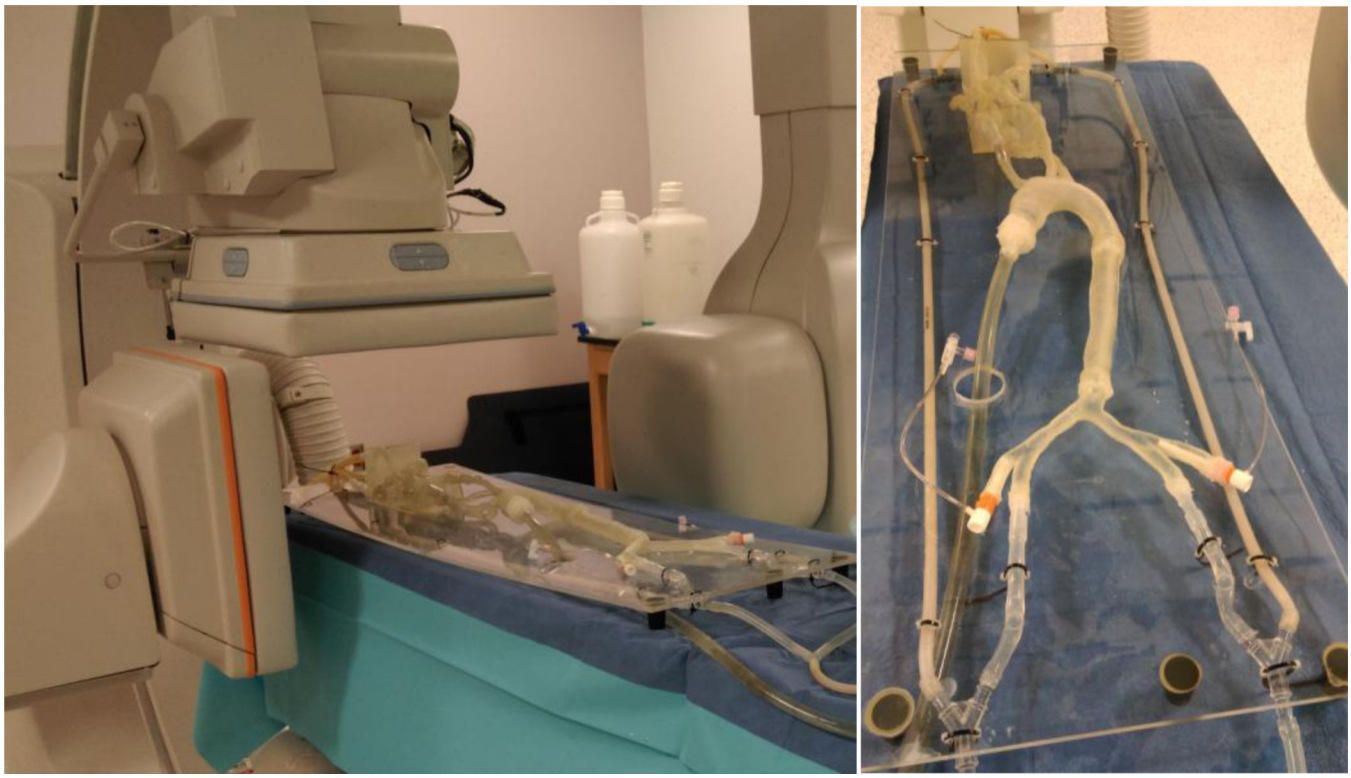

Figure 4.
Several printed phantoms put together to better simulate the traversal of the catheter from the entry point in the femoral artery to the treatment site.

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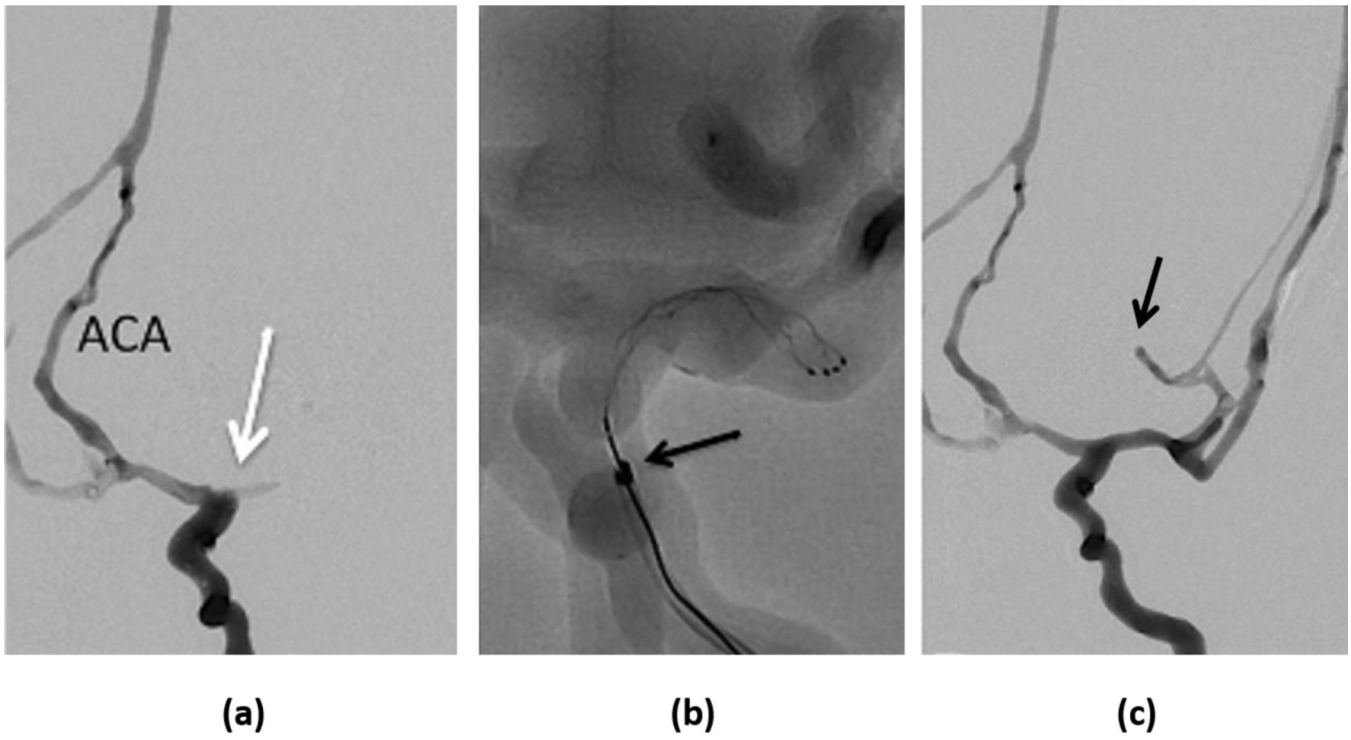

Figure 5.

Example of a clot retrieving procedure. (a) DSA after clot was placed in the Middle Cerebral arteries, white arrow indicates the location of the clot. (b) Fluoroscopic snapshot of the stent retriever (Solitaire FR) deployment over the clot using a micro-catheter, (black arrow). (c) DSA after clot retrieval showing opened Middle Cerebral Artery. However, fragments of the clot traveled distally (black arrow) occluding smaller vessels.

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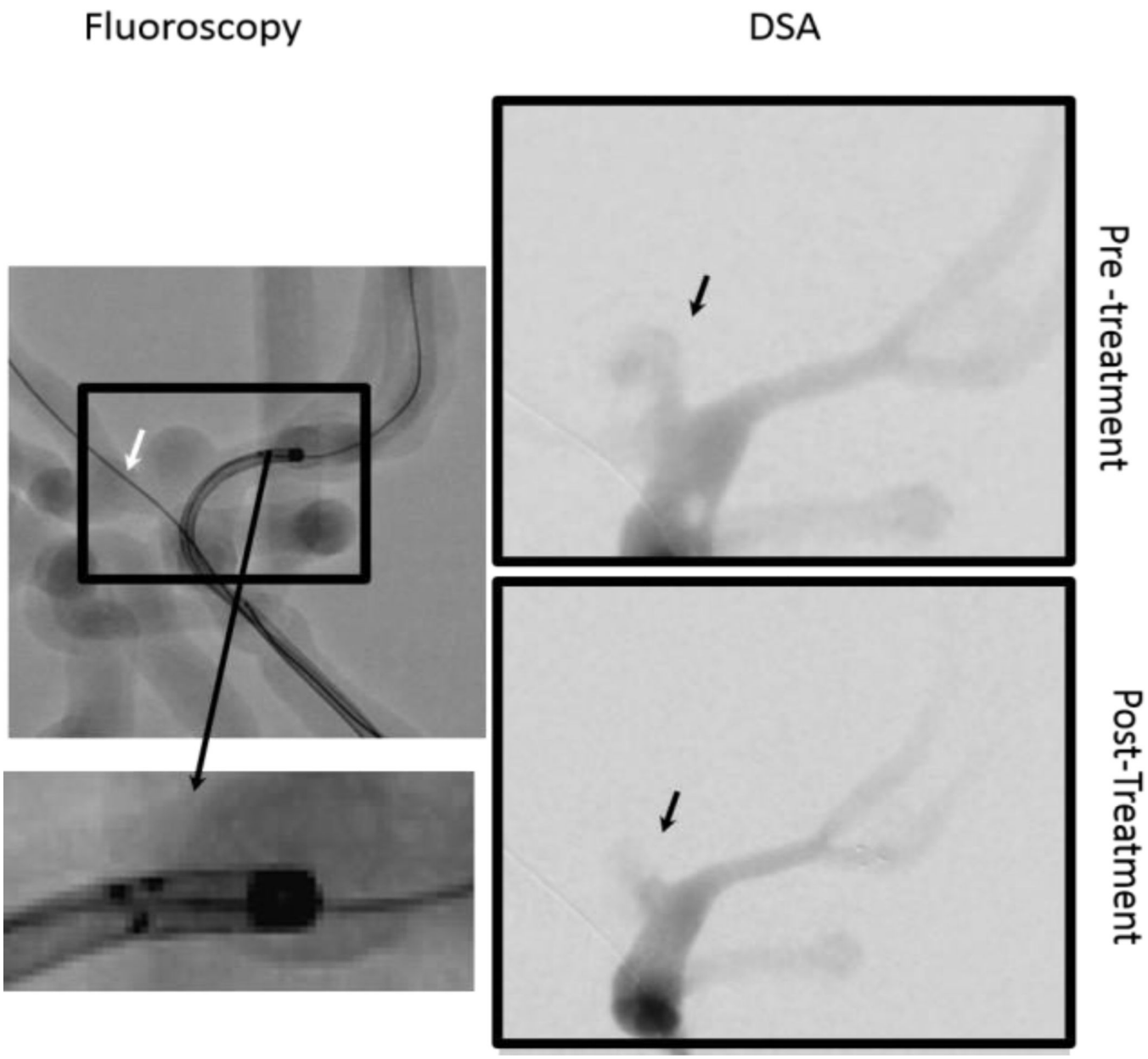

Figure 6.

Pre- and post-treatment fluoroscopic and DSA acquisitions of flow. The black arrow in the DSA images indicates the ACA where flow was reduced post-treatment.

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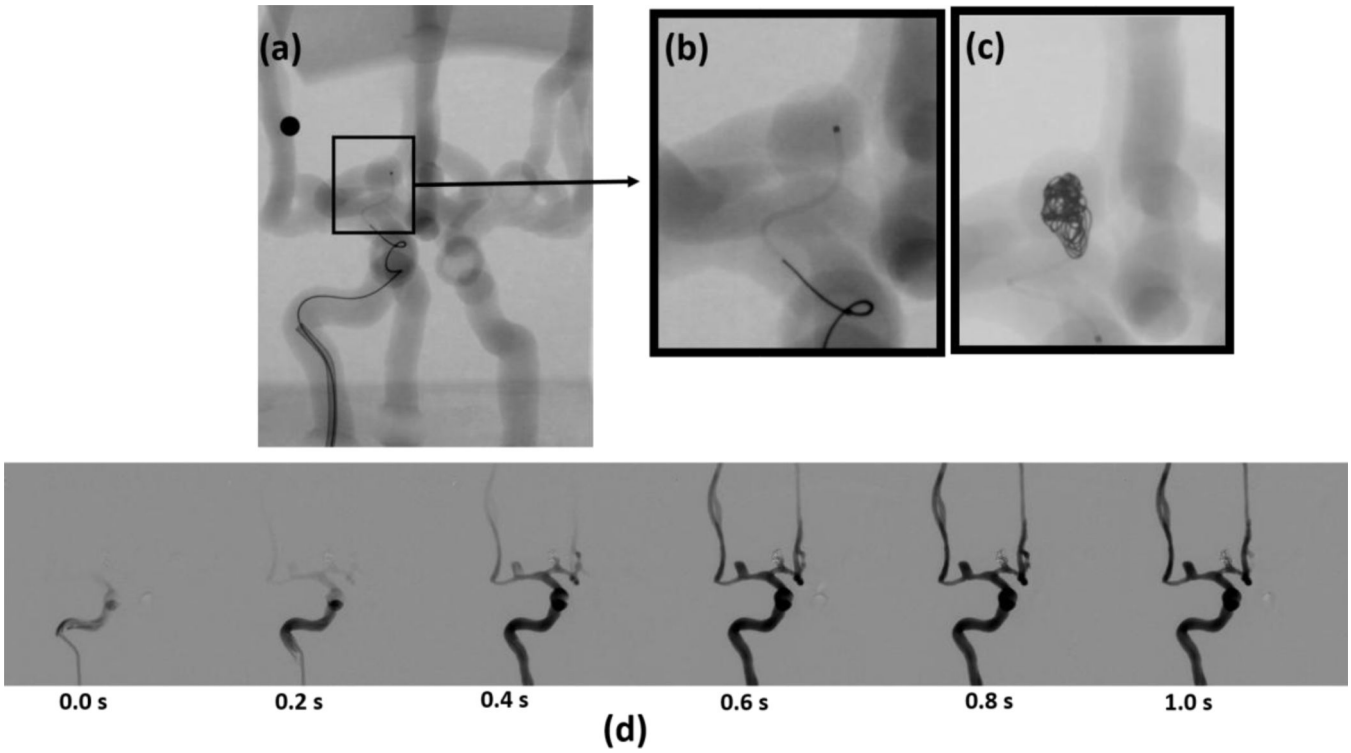

Figure 7.

Aneurysm coiling example. (a) Fluoroscopic snapshot of the initial part of the procedure. (b) Detail of the micro-catheter placed in the aneurysm. (c) Final fluoroscopic snapshot of a coil mass placed in the aneurysm dome. (d) DSA showing initial arrival of the bolus contrast.

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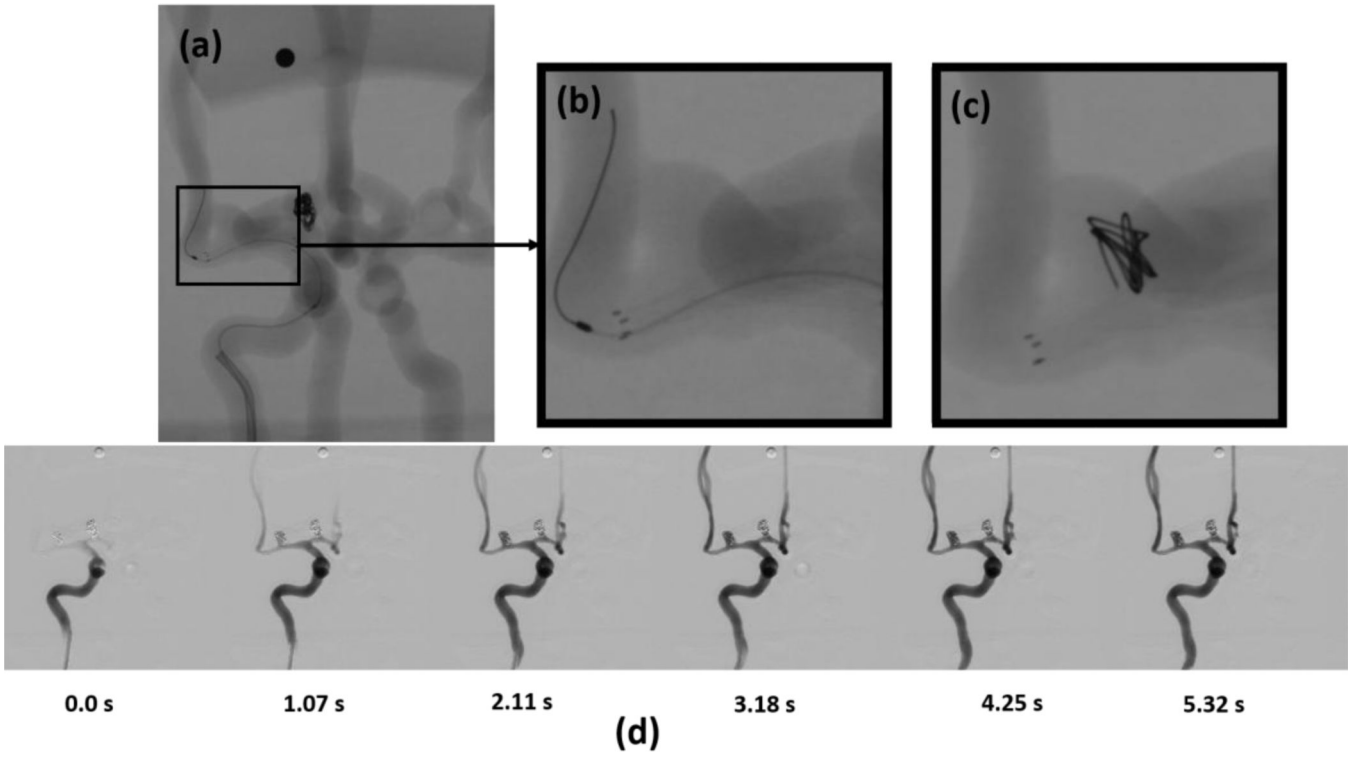

Figure 8.

Aneurysm stent supported coiling example. (a) Fluoroscopic snapshot of the initial part of the procedure with a neurovascular stent deployed across the aneurysm neck (b) Detail of the stent deployed across the aneurysm neck. (c) Final fluoroscopic snapshot of a coil mass placed in the aneurysm dome. (d) DSA showing initial arrival of the bolus contrast. Contrast flow was not significantly reduced, indicating a need for greater occlusion through deployment of additional coils.

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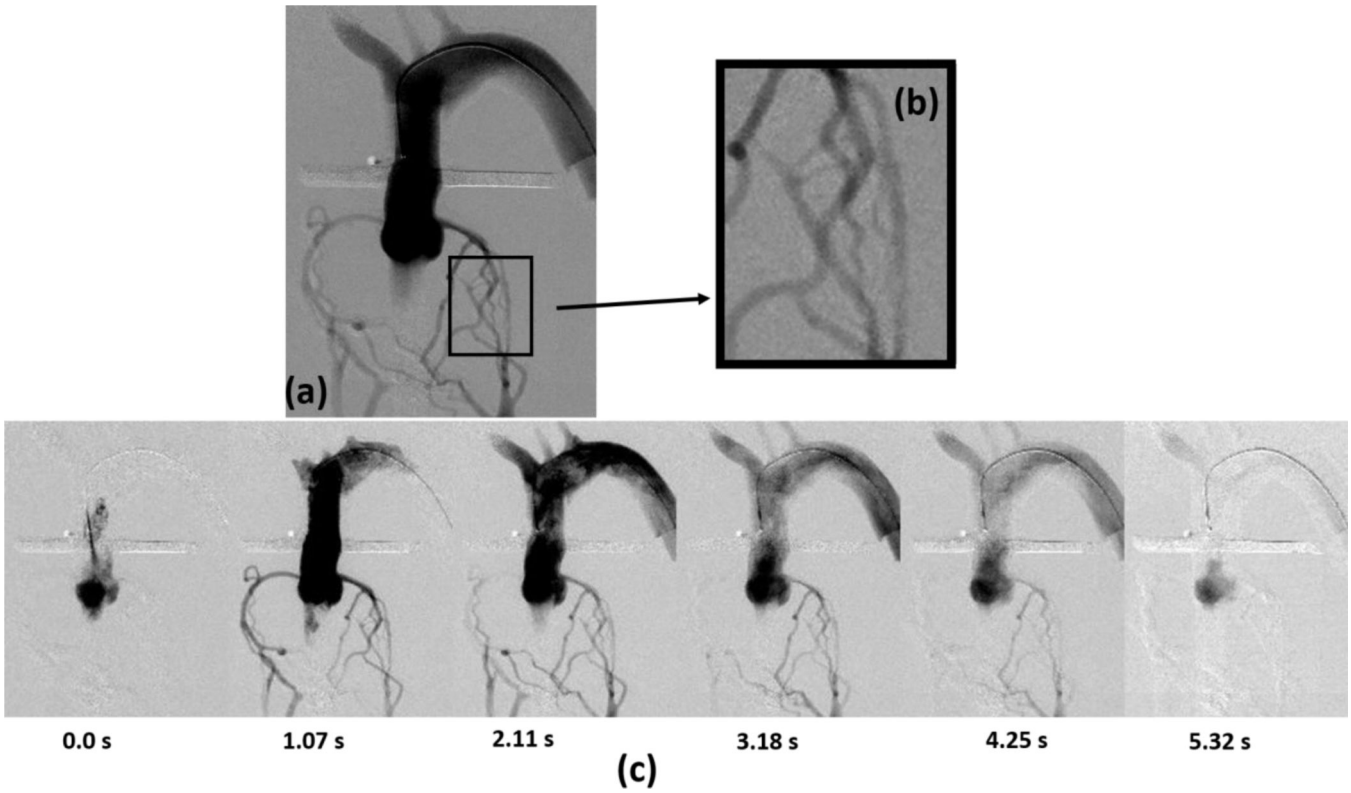

Figure 9.

Coronary phantom exemplification. (a) Result of an averaged DSA sequence (b) Detail of the coronary arteries, the smallest vessels are around 0.5 mm (c) Final DSA showing initial arrival of the bolus contrast and flow through the coronary arteries