

Paper:

An In Vitro Patient-Specific Biological Model of the Cerebral Artery Reproduced with a Membranous Configuration for Simulating Endovascular Intervention

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We propose an in vitro patient-specific anatomical model of the human cerebral artery and its simulation of endovascular intervention, a potent treatment modality for cerebrovascular diseases. Our proposed model reproduces the 3-dimensional vasculature lumen, using computed tomography (CT) and magnetic resonance (MR) fluoroscopic information, within a thin artery-like membranous configuration having material properties close to arterial tissue. This cerebral arterial model reproduces an exceedingly realistic surgical feel, dynamic vascular deformation and, other important aspects involving endovascular intervention, realizing a highly realistic surgical simulation. We also propose another vasculature model that reproduces the subarachnoid space around the cerebral arteries. This version simulates endovascular intervention realistically. The model is compatible with current major imaging modalities such as CT, MR, and transcranial Doppler (TDC), and should provide effective platforms for applications, such as diagnosis, surgical planning, medical training, hemodynamic analysis and medical system development and evaluation, especially surgical robots.

Keywords: medical system, endovascular intervention, vascular model, rapid prototype, medical imaging

1. Introduction

Minimal invasive surgery has attracted much attention because it decreases pre- and postoperative distress in surgery [1–5].

Endovascular intervention involves surgery on cerebral arteries that drastically reduces surgical invasiveness through thin 1mm-diameter, 1m-long devices called catheters. Catheters vary in size and shape with their function and now are used to treat a with variety of diseases, instead of the craniotomy for which they were developed.

Cerebral artery is complex, varying greatly with the individual, so physicians must be highly skilled in catheter

use to avoid injury to the arterial wall. Despite this need for skill and experience, endovascular intervention is difficult to master due to the difference between practice and actual conditions.

Physicians conventionally depend on images on displays or paper for information obtained by CT scanning and other medical imaging modalities. Advances in image processing technology now enable 3-dimensional images to be reconstructed based on 2-dimensional slice images, but even this does not make it easy to image the 3-dimensional arterial structure and affected parts intuitively or precisely, or to correctly grasp the relationship between parts, even for skillful physicians. This is because the 3-dimensional image is projected on 2-dimensional planes, leading to potential misunderstanding of information. Even more difficult to grasp are actual size and physical properties.

Providing an in vitro anatomical model of individual arterial structures based on individual fluoroscopic information provided by medical imaging, physicians could practice on such models to master techniques required for endovascular intervention by inserting an actual catheter and other medical devices into the arterial lumens reproduced by the vasculature model. Physicians can thus intuitively and correctly grasp the morphology, configuration, and the precise dimension of arterial structure 3-dimensionally. Physical properties of arteries are also shown on this arterial model by applying the relevant material. Such a realistic organs model would also provide an effective platform for medical system and device R&D [6, 7].

We proposed a solid anatomical model of individual human cerebral arteries in previous report, demonstrating its feasibility and usefulness in medical use, such as surgical simulation, preclinical testing, and hemodynamics study [8]. The rigid structure, however, restricted arterial deformation during the insertion of medical devices, rendering surgical simulation impractical because it eliminated the technical difficulty and subtle touch required to deal practically with the deformation of the arterial structure.



In this report, we propose an individual cerebral arterial model reproduced using a flexible membranous vascular configuration with physical properties close to those of arterial tissue and demonstrate its feasibility for simulating endovascular intervention.

Research targeting anatomical models replicating organ structures, such as blood vessels, organs, and bones, has been done in the medical field [9–16], but techniques depended on organs from dead bodies used as molds for modeling. This made it difficult to produce individual organic structures.

2. Conditions Required for Cerebral Arterial Models as Surgical Simulators

2.1. Reproduction of Individual Arterial Structures

Human cerebral arteries have a basic structure common to all individuals. For which catheters and guide wires are designed for insertion through the basilar or carotid artery, depending on the location of the part of interest and arterial morphology. Arterial configurations differ widely among individuals, however, requiring physicians to judge whether the intravascular approach is applicable and when, for adequate medical device use.

These differences are also affected by the disease course. Cerebrovascular diseases such as aneurysms, embolisms, thrombosis, and stenosis have their own unique characteristics and locations, resulting in drastically different configuration. For aneurysms, for example, physicians must judge whether an intravascular or craniotomy approach is appropriate. With the intravascular approach, coils must be selected taking into account the type, shape, length, and number.

Thus, although conventional surgical simulators imitating generalized configurations or simplified arterial structures are helpful in teaching surgical technique, they are inadequate for communicating comprehensive surgical skills because generalized models do not reflect specialized morphologies involved in even the most ordinary cases [17–19]. This makes reproducing individual arterial structures using surgical simulators. Such individual models also can be used for diagnosis, explanation, and preclinical testing.

2.2. Reproduction of Membranous Vascular Configurations

The soft membranous configuration of arteries and the surrounding pliant tissue are deformed dynamically together with blood flow and pulse when catheters and other medical devices are inserted (**Fig.1**). Endovascular intervention commonly takes advantage of such deformation in treating with cerebrovascular diseases. Devices for such treatment include balloons for expanding arteries, stents for keeping arteries expanded, and clips for pinching off aneurysms. This deformation is, however, also a sourced of technical difficulties in endovascular intervention.



Fig. 1. Configuration of actual cerebral artery and its locating condition inside the subarachnoid space.

This makes the reproduction of structural deformation important in simulating different medical treatments and expressing technical difficulties due to deformation.

2.3. Reproduction of Arterial Characteristics

Information on endovascular intervention is largely limited to 2-dimensional monochromatic fluoroscopic imaging and the “feel” from medical tools. Physicians must manipulate catheters and other tools precisely when treating cerebrovascular diseases without inflicting injury such as vessel occlusion or perforation. Fluoroscopic imaging is not always continued use throughout surgery due to the side effects of contrast media – visualizing arterial structures may be continued only for seconds, limiting fluoroscopy to only a few times during surgery, thus increasing the importance of feel from medical tools in supplementing visual information.

Reproduction of feel and the reproduction of arterial characteristics is vital in surgical simulators that are to provide accurate information on force and on how force must be limited. Proposed models must also be compatible with major imaging modalities, especially X-rays, for use in practical interventional radiology (IVR).

2.4. Other Requirements

As indicated above, surgical simulators must provide individual arterial structures with an artery-like feel and pliant membranous configuration in endovascular intervention. Other important considerations include broadening applicability, and upgrading availability. This involves reproducing:

- 1) Precise arterial configurations
- 2) Individual arterial structures
- 3) Membranous artery configuration
- 4) Arterial elasticity
- 5) Arterial friction

- 6) Applicability to medical imaging modalities
- 7) Good visibility (transparency for visible light).

3. In Vitro Anatomical Cerebral Artery Model Reproduced with Membranous Configuration

In a previous report, we proposed a patient-specific anatomical model of cerebral artery that reproduces 3-dimensional configurations of the arterial lumen within a cube structure, demonstrating its effectiveness in simulating endovascular intervention [8]. Its rigidity, however, restricted arterial deformation by medical devices consequently restricting applicability.

Here we propose an individualized cerebral arterial model with a flexible membranous vascular configuration simulating different surgical treatment modalities and surgical difficulties seen in endovascular intervention.

3.1. Technical Conditions

As stated previously, the cerebral arterial model targets realistic neurosurgical simulation meeting the following technical conditions:

- 1) Construction is based on individual information obtained by medical imaging modalities.
- 2) Complex, thin, high-aspect arterial structures are reproduced precisely.
- 3) The thin membranous arterial configuration is reproduced highly accurately.
- 4) The membranous configuration is constructed using a material with elasticity resembling that of arterial tissue.
- 5) The membranous configuration is constructed with a material providing friction resembling that of arterial tissue.
- 6) The membranous configuration is constructed with a material having excellent transparency.
- 7) The membranous configuration is constructed with a material adaptable to medical imaging and sensing modalities.

In the next subsection, we propose detailed production methodology for the proposed model meeting all of the above conditions.

3.2. Production Methodology for Proposed Cerebral Arterial Model Reproduced with Membranous Configuration

We constructed the membranous cerebral arterial structure with silicone elastomer, which expresses arterial tissue characteristics particularly elasticity and friction. Silicone elastomer is moderately penetrated by X-ray and

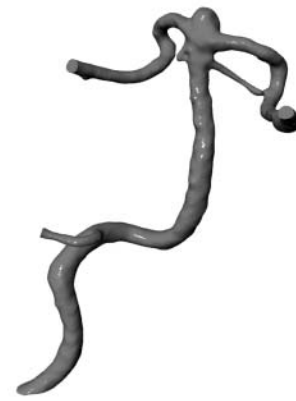


Fig. 2. 3-dimensional structure of the individual cerebral artery reconstructed from CT slice images.

ultrasound and is compatible with magnetic resonance, making an anatomical model of this material applicable to current major medical imaging and sensing modalities. Its excellent transparency also provides excellent visibility.

Our production methodology consists of 4 basic techniques: (1) 3-dimensional reconstruction for medical imaging, (2) rapid prototyping, (3) dip-coating for constructing thin silicone membranes, and (4) the “lost wax” technique.

We reconstructed the 3-dimensional cerebral artery using 100 digital slice images obtained by helical CT scanning at regular 0.5mm intervals and 0.3mm/pixel resolution. We virtually recreated each CT image 3-dimensionally on a PC as a 2-dimensional scalar CT field, based on the interval 0.5mm, building up a 3-dimensional scalar field. Adding a specific scalar value conforming to the CT value on the boundary between the artery and its surroundings, we extracted 3-dimensional outlines of the arterial structure. Interpolating this 3-dimensionally, we created 3-dimensional iso-surfaces composed of identical CT values. This iso-surface is then simplified by removing scattered irrelevancies part and ablating small branches, leaving only the basilar artery and aneurysm. This yielded the 3-dimensional structure of the individual cerebral artery from CT slice images. **Fig.2** shows the reconstructed arterial image.

We rapid-prototyped a tree-like solid wax model of the targeted cerebral artery using data from the above reconstructed 3-dimensional geometry (**Fig.3**). Each fabricated layer was 13 μ m thick. We used the fused deposition modality of rapid prototyping to fabricate of this wax model, which easily melts at relatively low temperature into a very low-viscosity liquid in the lost wax process. We used a chemical sulfonamide compound to construct it. This material has a melting point of about 100°C and easily dissolves in solvent, especially acetone.

This rapidly prototyped solid wax model was then coated with liquid silicone polymerizing into an elastomer by polymerization, providing elasticity and friction close

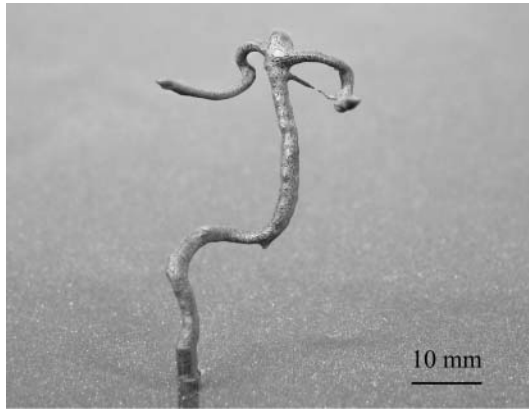


Fig. 3. Wax model of the targeted cerebral artery (basilar artery) rapid-prototyped with fused deposition modality.

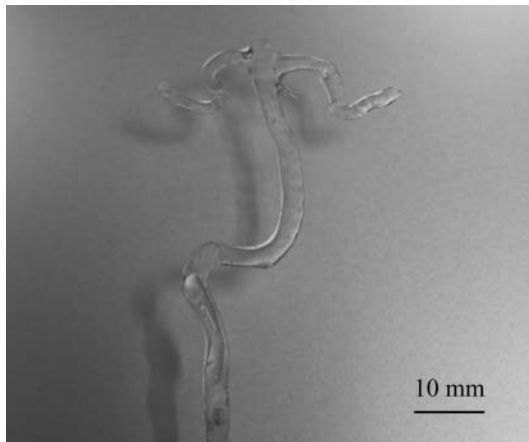


Fig. 4. In vitro patient-specific anatomical model of the cerebral artery reproduced with a membranous configuration for simulating endovascular intervention.

to that of arterial tissue, together with good transparency discussed later. We constructed a uniform thin membranous structure about $100\mu\text{m}$ thick by dipping the wax model in silicone liquid, drawing it up, and wiping off excess material. Dipping was followed by additional polymerization repeated until it reaches the desired wall thickness. This yield a thin membranous with uniform wall thickness of about $600\mu\text{m}$ around the wax artery model.

After the membranous silicone structure is obtained, the totally covered wax model is eliminated by the lost wax technique, which involves heating and dissolving. Most wax is eliminated from the silicone structure by melting at 120°C , slightly higher than the melting point of sulfonamide and lower than the heat-proof temperature of silicone (above 150°C), then completely removing residue by dissolving it in acetone.

This yielded an in vitro patient-specific anatomical model of the human cerebral artery with a biologically accurate membranous configuration (**Fig.4**). Narrow and high-aspect portion are thus entirely constructed.

New rapid prototyping reproduces complex, solid, ar-

bitrarily shaped 3-dimensional structures based on CAD data. With rapid prototyping and 3-dimensional reconstruction from CT images, anatomical models can replicate individual organ structures. This model is useful in anatomical study and clinical testing.

Material applicable to this methodology is limited to metals, resins, and waxes presenting favorable properties for fabrication, making it difficult to express physical organ tissue properties. Resulting models usually have rough surfaces of tired layers, disturbing the smooth insertion of medical tools and deteriorating visibility. Such models thus subvert the reproduction of vital subtle surgical feel.

3.3. Subarachnoid Reproduction

The cerebral arterial model reproduced with a pliant membranous configuration enables a variety of medical treatment modalities to be simulated, including balloon percutaneous transluminal angioplasty (PTA) and aneurismal clipping. Its structure did not, however, reflect the existence of circumferential pliant tissue that actually support most external force exerted on the arterial structure, making it difficult to maintain an anatomically correct configuration in actual use, since its low rigidity simultaneously causes deformation against gravity.

Much of the human cerebral artery is surrounded by a vacant subarachnoid space, formed by the wrinkle of brain. This space contains cerebrospinal fluid and other pliant tissues that support the cerebral arterial structure inside tissues from external loads exerted by blood flow and medical treatment.

Considering this, we propose another cerebral arterial model that partially reproduces this subarachnoid space within a cube shaped structure proposed previously [8]. This configuration enables physicians to simulate the deformation of cerebrovascular disease and area of interest precisely against blood flow and surgical treatment, excluding the effects of distortion caused in nonapplicable areas.

We fabricated this model with the subarachnoid space as follows: We reconstructed the 3-dimensional subarachnoid space using digital slice image obtained using MR and computer-aided design (CAD). Reconstructed geometrical data wax represented with fused-deposition modality-based rapid prototyping. We placed this wax structure around the silicone-coated wax arterial structure, fabricated through dip-coating, embedding the structure in liquid-state silicone elastomer and curing it in a cube structure. We removed the wax from the subarachnoidal and arterial structures through selective dissolution proposed, leaving the polymerized silicone structure.

Figure 5 shows an example of this model containing the partially reproduced subarachnoid space with membranous vascular configuration with the cube-shaped silicone structure. The subarachnoid space is around a basilar tip (BT) aneurysm showing the deformation in surgical treatment and blood flow. Although the proposed model cause unfavorable reflection at its subarachnoidal surface making

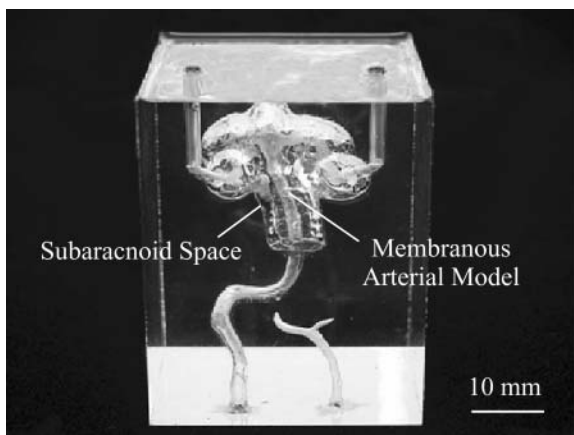


Fig. 5. In vitro cerebral arterial model with a membranous vascular configuration reproduced with circumferential sub-arachnoid space.

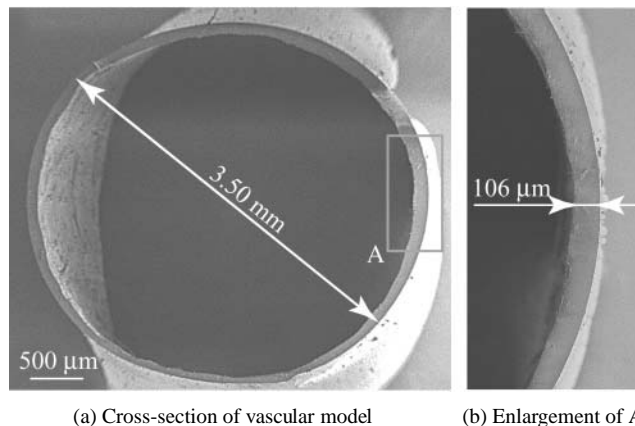


Fig. 7. SEM cross-section of vascular membrane fabricated through single dipping.



(a) State before filling the space



(b) State after the space is filled with silicone oil

Fig. 6. Elimination of reflection on subarachnoid space by filling the space with a liquid (silicone oil) having the same reflection indices as the model provides.

it difficult to observe the inside (**Fig.5**). This is eliminated by filling the subarachnoid space with a liquid having the same reflection indices as silicone provides the elastomer (n_D^{25} : 1.410). Silicone oil serves aptly for such a fluid (**Fig.6**).

This methodology also effectively express the distribution of circumferential tissue, such as brain tissue, adjoining artery or venous tissue, and tissues in the subarachnoid space by filling it with suitable material.

4. Results and Discussion

Production methodology in this paper enabled us to construct a very thin membranous silicone structure with uniform wall thickness – confirmed to be a minimum $100\mu\text{m}$, and sufficient in replicating the cerebral arterial wall treated in this surgery usually exceeds $200\mu\text{m}$ (**Fig.7**). We verified its feasibility in arterial pulsation reproduction (**Fig.8**), and the feasibility in practical surgery using arterial deformation in coil embolism treating cerebral aneurysm (**Fig.9**), with the hardware setup (comprised of arterial model, pulsatile pump, and a catheter) shown in **Fig.10**. The proposed membranous structure deforms dynamically with moderate elasticity from the accurate reproduction of elasticity and wall thickness, and this realistic deformation allows surgical treatments to be simulated with a realistic surgical feel.

Here, the cerebral artery is, practically, supported by pliant tissues such as brain tissue, therefore the structure should also be reproduced with human-like material and constitution. Meanwhile, the thickness of vascular membrane constructed with proposed method becomes little different where the vessel diverges at sharp angles. We deal with these subjects as future works.

The proposed structure consist of transparent elastic silicone elastomer realize elasticity and friction close to arterial tissue. Although it is difficult to completely reproduce elasticity, because arterial tissue is anisotropic and its elastic modulus varies with strain and takes different values depending on its condition, its approximate elastic modulus of normal tissue is said to be around 2MPa and the elastic modulus of silicone elastomer is fairly close at 19MPa [20]. This value is adjustable, for example, by mixing silicone oil into silicone elastomer before polymerization. The elasticity of the sclerotic artery and other condition are also reproducible.

The friction coefficient between the surface of the model (silicone) and LDPE (low density polyethylene) catheter was 0.041, which is fairly close to 0.039 between the arterial wall (pig aorta) and LDPE catheter (surfactant

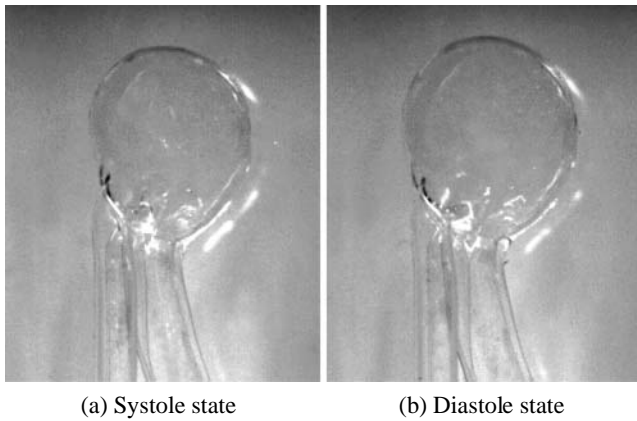


Fig. 8. Deformation of aneurysmal membranous model (15mm in diameter) against pulsatile blood flow (flow rate: 250ml/min, heart rates: 60).

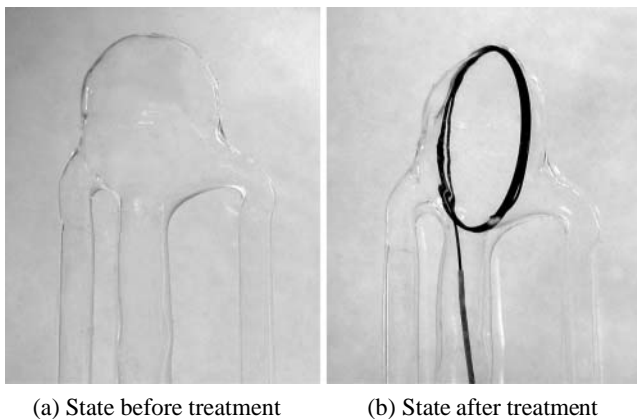


Fig. 9. Deformation of aneurysmal membranous model (15mm in diameter) against coil embolism simulation.

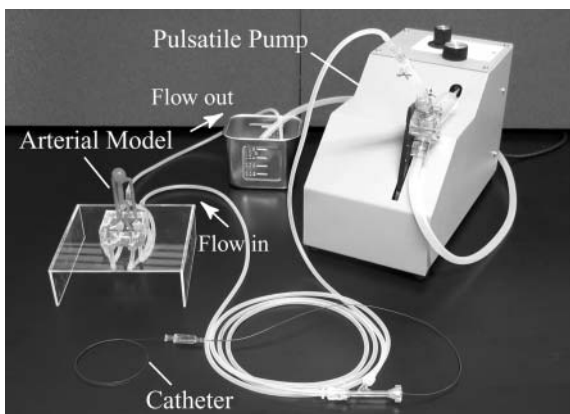


Fig. 10. Hardware setup for simulating endovascular intervention with proposed vascular model in the existence of pulsatile blood flow.

and blood serum used as a lubricant) [21]. These physical properties of silicone elastomer favorably reproduce arterial characteristics, confirmed by neurologists as pre-

Table 1. Physical properties of proposed cerebral arterial model.

| | Young's Modulus [MPa] | Poisson's ratio | Friction Coefficient |
|-----------------|-----------------------|-----------------|----------------------|
| Arterial Model | 1.9 | 0.46 | 0.041 |
| Arterial Tissue | 1-3 (Carotid) | 0.45 | 0.039 |

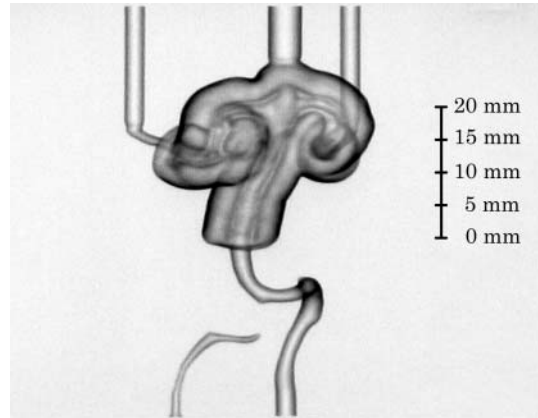


Fig. 11. 3-dimensionally reconstructed CT image of proposed subarachnoid space model.

senting membranous arterial structure with realistic feeling during the insertion of medical devices. We summarized the physical properties of proposed cerebral arterial model in **Table 1**.

The silicone elastomer used for the proposed model is transparent to visible light (transmission exceeding 10mm is over 88%), enabling us to clearly recognize the inner arterial structure and inserted medical tools. Since silicone is also X-rays (transmissivity: about 400HU) and ultrasound penetrable and compatible with MR, our model are applicable in major medical imaging methodology such as CT, MRA, and DSA. **Fig.11** shows a 3-dimensionally reconstructed CT image of proposed subarachnoid space model.

Since the proposed production methodology is adaptable to any hollow configuration, organic models and 3-dimensional medical and industrial structures of all types are reproducible.

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