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Patient-Specific Neurovascular Simulator for Evaluating the Performance of Medical Robots and Instrumens*

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***Abstract* – An in vitro patient-specific vascular model, for simulating endovascular intervention is presented. Proposed vascular model reproduces the 3-dimensional vessel lumen structure using CT/MRI information with 13 μm resolution, and it also reproduce the physical characteristics of arterial tissue (elastic modulus and friction coefficient). Furthermore, in this paper, we propose a novel method to evaluate the stress on vasculatrue which is applied by surgical operations. This method allows quantitatively evaluating 3-dimensional stress condtion in real-time during surgical simulation. Finally we constructed a comprehensive surgical simulation sisytem, which reproduces whole human aorta stucture (with more than 1mm inside diameter), reproduce patient-specific pulsatile blood streaming, allowint to evaluate the stress applied to the aorta structure by surgical operations with almost same manner and environment as the practical endovasuclar intervention. Consequently proposed model, evaluation method and resultant system provides a very valuable platform for evaluating the performance of surgical robots and instruments developed by developers and researchers, and surgical procedures.**

Index Terms - Medical System; Endovascular Intervention; Vascular model; Rapid prototype; Medical imaging.

I. Introduction

Endovascular Intervention is recently established surgery for cerebrovascular diseases, which drastically reduces invasion for patients using thin and long (about 1 mm in diameter, 1 m in length) medical tool called catheter. However, as the cerebral artery is very thin, complicated and takes quite different configuration for respective patients, it is not easy to lead the tip of catheter skillfully to the diseased portion. Therefore, various kinds of catheters and other medical tools are developed to treat with diseases without making any injury [1-5]. Here, since subtle configurational difference of vessel result in thoroughly different behavior of medical tools, evaluation of developed medical robos and instruments must take this aspect into consideration. However, the current platform for evaluating medical robots and systems are generally far different from the true artery as to its configuration, especially physical property. For example, a lot of developers and researchers use very simple cylindrical straight plastic tube for evaluating its operational performance and its effectiveness [6][7]. Consequently, medical instruments developed with such a platform dose not give the expected performance in clinical stage in many cases. Thus the current situation makes it difficult for researchers and developers to materialize truly effective medical instruments [8-18].

To resolve this problem, we had proposed patient-specific anatomical models of human cerebral artery since 2001, firstly as a cubic-shaped construction hollowly reproducing vascular lumen inside it [20], secondly as a membranous configuration which reproduce the behavior of true vasculature [21], and thirdly as a configuration comprise of vascular membrane and circumferencial brain-like structure which reproduce visco-elastic behavior of cerebral artery [22]. These models were constructed from CT and MRI information with 13 μm modeling resolution.

In this paper, as a next step, we propose a novel method to evaluate the stress on vasculature wall applyed by surgical operations and blood stearming during endovascular intervention. Propose method allows quantitatively evaluate the performance of surgical robots / tools and surgical procedures in real-time.

Since, currently the evaluation of performance of these sophysticated instruments is very difficult, especially for researchers (becasue they are generally difficult applying developed materials to animals, especially to human for evaluation purpose, while there is almost no good artificial evaluation platform), proposed vascular simulator should provide very helpful environtment for various stage as a platform which satisfies their requirements at high standard.

II. Arterial Model

As a platform for simulating endovascular intervention in purpose of diagnosis and surgical planning, proposed vascular simulator must provide vasirous characteristic. We summarize the required important features as follows:

(1) Patient-specific vascular reproduction: Cerebral artery and cerebrovascular diseases take quite different morphology for each patient (Fig. 1, Fig.2). This difference requires thoroughly different shape and functionality of medical instruments, and technical difficuly also comes from this difference. Therefore it is ideal to reproduce patient-specific artery with more than 1 mm in diamter.

(2) Physical reproduction of vascular characteristics: Reproduction of physical characteristics: As a platform evaluating robots and surgical procedures, vascular model must reproduce the feeling and the behavior of vasculature. Therefore, it is ideal to reproduce the physical characteristic of artery on the vasculature model.

(3) Evaluation of stress: Interventionalist must pay great attention to the stress on vascular wall applied by surgical operations since excessive stress may cause significant . Meanwhile the growth of aneurysm (viz hazard of rupture)

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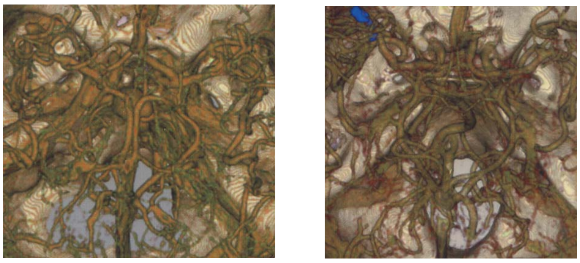
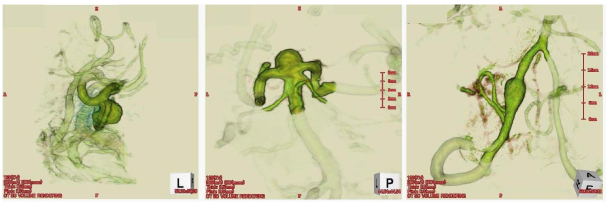


(a) Examinee A (b) Examinee B

Fig. 1. Difference of configuration seen in cerebral arterial



(a) MCA Aneurysm (b) BT Aneurysm (c) BA Aneurysm

Fig. 2. Some Morphologies of Cerebral Aneurysm

also depends on the stress applied by blood streaming. Consequently, model-based stress evaluation is worthwhile.

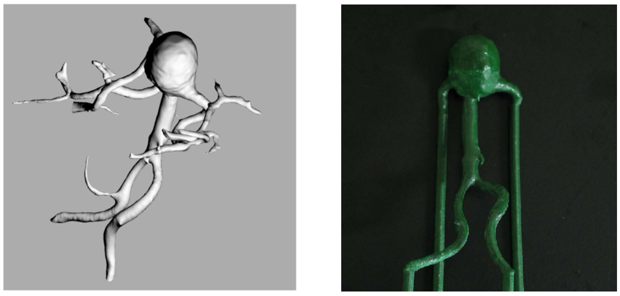
III. Modeling Method

We materialize the requirements described in previous section with the following production methodology. This procedures comprise of 4 fundamental techniques; (1) reconstruction of 3-D vasculature figure based on medical imaging, (2) rapid-production of vascular mold, (3) fabrication of vascular-like membrane through dip-coating, and (4) elimination of lost wax mold.

Firstly, we reconstructed 3-dimensional structure of individual cerebral artery, through the process presented in previous report [22], using 300 sheets of digital slice images obtained by multi-slice helical CT scanner with regular 0.3 mm intervals and 0.35 mm/pixel resolution. Figure 3 (a) shows the 3-dimensionally reconstructed basilar artery (size: 40 x 40 x 80 mm).

Then we rapid prototyped tree-like wax model of reconstructed vascular image using by fused-deposition rapid prototyping modality (Fig. 3 (b)). Layering interval in this modeling was set to 13 µm. And we applied thermoplastic resin (chemical compound of sulfonamide) for the modeling. This material easily melts at relatively low temperature (100 °C) into very low viscosity liquid, and easily dissolves in acetone(this features is very important in following lost wax process).

Then we dip-coated this wax model firstly with PVA (poly vinyl alcohol) at constant withdrawing velocity of 1.0 mm, and constructed 200 µm thick thin layer around this structure. Then we selectively dissolved only the inner wax model comprise thermoplastic (here, PVA persists acetone, while the sulfonamide easily dissolves in it. The resultant PVA membrane serves like a sacrificial layer in silicon etching in our process). After that, we secondly dip-coated this vascular-shaped PVA membrane with urethane elastomer, (provides remarkably high photoelastic coefficient (3.5×10^{-9} Pa^{-1}) among elastomers, allows to detect subtle miligram-order contact force between catheters and vessel wall. its methodology is in the next section) at



(a) 3-D structure of basilar tip artery with giant aneurysm reconstructed with CT angiogra- phy

(b) Wax model of reconstructed artery materialized with fused deposition modality-based rapid prototyping

Fig. 3. Materialization of vasculature structure based on patien's CT angiography by means of 3-dimensitonal image processing and following fused deposition modality-based rapid prototyping.

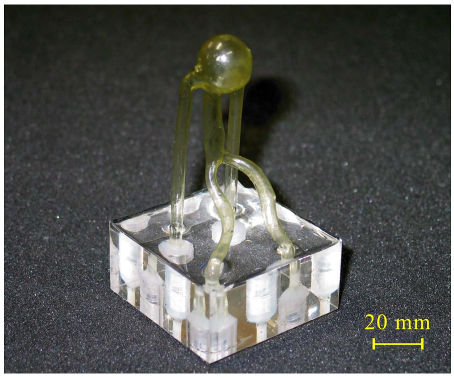


Fig.4 An in vitro patient-tailored biological model of human cerebral artery for photoelastic streress analysis

constant withdrawing velocity of 0.5 mm, and constructed 300 µm thick thin layer around this structue by twice repeating this dip-coating process.

Then we dissolved the PVA layer remaining inside polyurethane membrane using water (PVA easily dissolves in water, while polyurethane persist it; Here the polyurehtane elastomer can not resist under acetone, thus the PVA serves as a sacrifice layer). Consequently, we could construct a patient-specific vasculature model of basilar artery made of transparent uniform membrane made of urethane elastomer shown in figure 4.

IV. Photoelastic Stress Analysis

A. Photoelastic Stress Analysis with Circular Polariscope

Transparent isotropic material, including selected polyurethane elastomer, cause temporal birefringent effect (photoelastic effect) when external load is applied. And this effect allows presented vascular model to measure the stress applied by surgical operations, blood streaming and other factors. This photoelastic effect can be materialized as visual information with polariscope, and we applied circular polariscope (Fig. 5), which makes resultant optical phenomenon rather simple, to the stress visualization.

With this circular polariscope, stress applied on proposed vascular model wall can be visualized as iridescent gradation as shown in figure 6.

With this circular polariscope, correlation between retardation Re, a phase shift (unit: m) caused on transmitted light by bifringent effect, which is proportional to the applied strain, and principal shearing stress τ, which directly relates to the rupture and the growth of cerebrovascular disease is expressed as follows:

$$Re = \alpha(\sigma_1 - \sigma_2) D = \alpha \tau D \qquad (1)$$

Here, a and D indicate photoelastic coefficient and the length of light passage (approximated by the thickness of model membrane) respectively. And σ_1, σ_2 and τ indicates max./min. principal stress and principal shearing stress respectively. Consequently, the magnitude of applied shearing stress can be calculated by measuring the retardation *Re*. This retardation *Re* is quantitatively measurable measuring the intensity of transmitted light.

To obtain this correlation between *Re* and the light intensity, we extended a geometrically accurate (100 x 15 x 0.3 mm) membranous specimen constructed using proposed method and measured the transition of the light intensity transmitted through polariscope for three wave-lengths, red (609 nm), green (538 nm) and blue (453 nm) respectively. Figure 7 shows the measured correlation through this experiment, consequently, we formulated this correlation as follows:

$$R(Re) = 95\,Re \sin^2\frac{\pi}{609} + 20$$
$$G(Re) = 119\,Re \sin^2\frac{\pi}{538} + 28 \qquad (2)$$
$$B(Re) = 157\,Re \sin^2\frac{\pi}{453} + 31$$

Here, *R*, *G* and *B* means the intensity of red, green and blue light (maximum: 255). With this equation, it becomes possible to measure the retardation *Re* for each point on observed image, and we utilized the following function to match RGB ratio measured with Eq. (2). Here, the retardation *Re* is calculated as a value which minimizes Eq. (3)

$$E(Re) = (R_m - R(Re))^2 + (G_m - G(Re))^2 + (B_m - B(Re))^2 \qquad (3)$$

Here, *Rm*, *Gm* and *Bm* indicates the measured intensity of red, green and blue light respectively.
Finally, with above methods and equations, stress condition on figure 6 can be quantitatively analyzed as shown in figure 8.

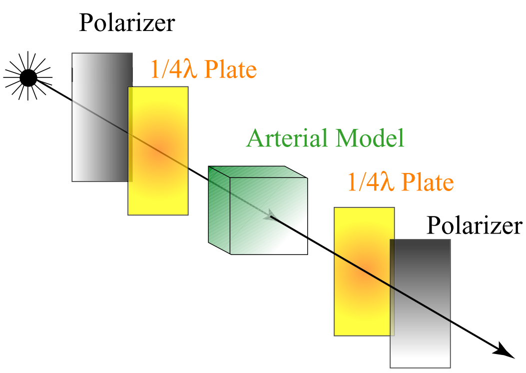


Fig. 5 Constitution of circular polariscope with crossed arrangement applied for proposed 3-dimensional stress analysis method

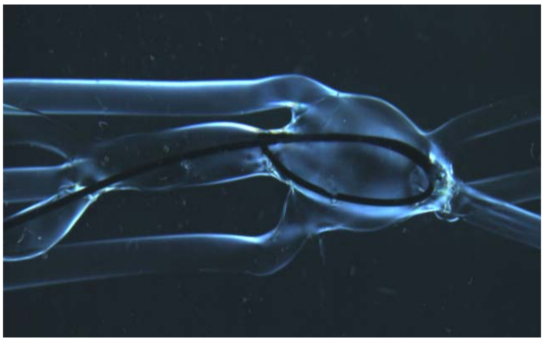


Fig.6 Stress condition on proposed vasculature model visualized by photoelastic effect using circular polariscope

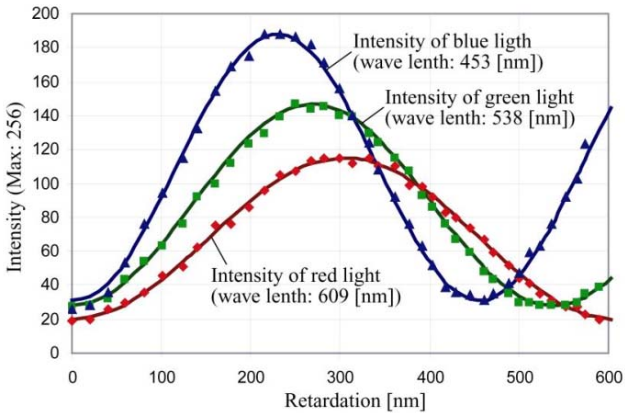


Fig. 7 Correlation between retardation Re and the intensity of transmitted light, for red (609 nm), green (538 nm) and blue (453 nm)wave lenght respectively.

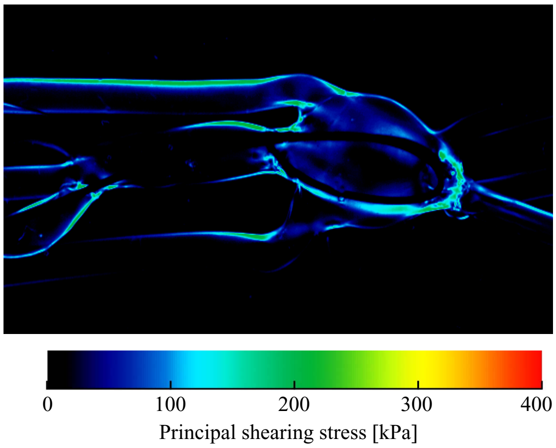


Fig. 8 Stress distribution on proposed cerebral arterial model calcurated from figure 6

B. Photoelastic Stress Analysis with A Polariscope Specially Designed for Endovascular Simulation

The method proposed in previous section allows quantitative stress analysis for neurovascular simulation and it is very helpful for evaluating the performance of instruments. However it had one big problem; inserted medical instrument is less visible, because the circular polariscope penetrate no light where no stress is applied.

To resolve this problem, we propose an another polariscope construction shown in figure 9 (added 1 extra wave plate between second set of 1/4λ wave plate and polarizer at slight inclination), specially designed for our purpose. With this construction, applied stress on proposed vascular model is visualized as figure 10 (same stress condition as figure 6).

Proposed construction realizes three very valuable features especially important for neurovascular simulation.

(1) transit background color from black to violet, remarkably improve the visibility of inserted surgical instruments
(2) improve the sensitivity to color transition (color changes from violet to red and blue at slight stress
(3) allowed real-time stress / stress direction analysis

For proposed polariscope, correlation between retardation Re and the light intensity transmitted I is expressed as follows (omit deduction) :

$$\begin{aligned} I =& 4 c_1^2 c_2^2 \sin^2(Re_{ex}/2)\cos^2(Re/2) \\ &+\{c_1^4 + c_2^4 + 2 c_1^2 c_2^2 \cos(Re_{ex}/2)\}\sin^2(Re/2) \\ &+ c_1 c_2 \sin Re\{(c_1^2 - c_2^2)\sin 2\theta - c_1^2 \sin(2\theta - Re_{ex}/2) \\ &+ c_2^2 \sin(2\theta + Re_{ex}/2)\} \end{aligned} \quad (4)$$

$$c_1 = \sin\varphi,\ \ c_2 = \cos\varphi \quad (5)$$

Here, Re_{ex}, φ and θ indicate phase shift of extra wave plate, inclination of the extra wave plate, and direction of principal shearing stress.

Figure 11 shows a color-map calculated from above equation (condition: Re_{ex}=1060 nm, ρ=22.5deg; experimentally obtained; disproportionally dispersing RGB ratio (color) on the map). This map indicates the correlation among observed color (combination of red, g reen, blue light intensity), magnitude of retardation *Re* and direction of the stress θ.

With this color-map and the matching function Eq. (3), RGB information measured on observed image (Fig. 11) is translated into the information (*Re*, θ). And the wanted stress condition (τ, θ) can finally be calculated by appling Eq. (1) to the (*Re*, θ).

This method is easily extensible to real-time stress analysis, and it should provide very helpful environment for evaluating the performance of medical instruments, validating hemodynamic FEM analyses, evaluating surgical procedures and other various purposes.

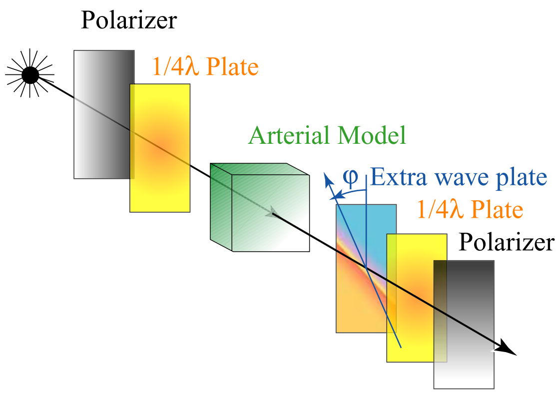


Fig. 9 Constitution of circular polariscope with a polariscope specially designed for proposed stress analysis method

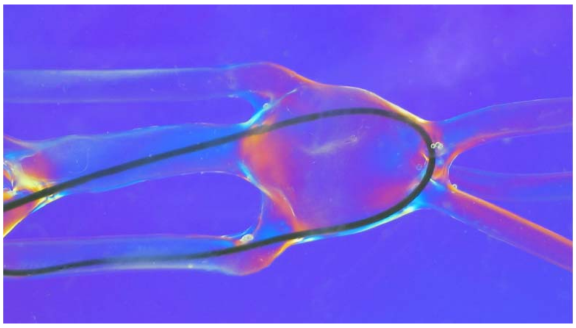


Fig.10 Stress condition on proposed vasculature model visualized by photoelastic effect using specially designed polariscope whon in Fig.9

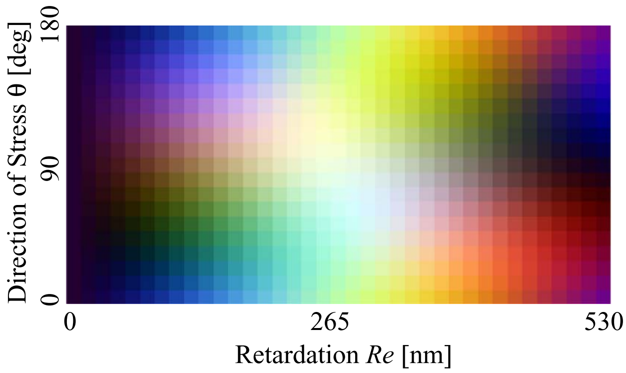


Fig.11 colormap calculated from Eq. (4) (condition: Re_{ex}=1060 nm, ρ=22.5deg; experimentally obtained; disproportionally disp ersing RGB ratio (color) on the map).

C. Thickness Measurement

In previous 2 sections we approximated the light path parameter *D* in Eq. (1) to be the thickness of vascular membrane. This approximation is reasonable where objective vascular wall is perpendicular to the direction of observation. However, in strict sense, the light path *D* depends on the inclination of objective wall, therefore the parameter *D* must be measured for strict analysis.

We realized this measurement, using brightness distribution observed on vascular model without using polariscope (substitutable by eliminating the final polarizer from polariscope) (Fig. 12). Figure 13, brightness distribution on line A indicated in figure15, shows an experimental result of this *D* measurement. As shown in this figure, the length of light path, namely, thickness of vascular membrane in

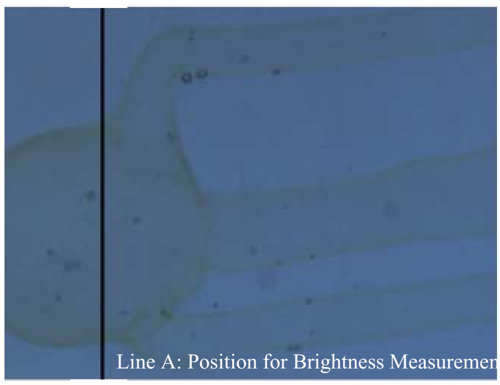


Fig.12 Image of vascular model observed without using polariscope (substitutable by eliminating the final polarizer from polariscope)

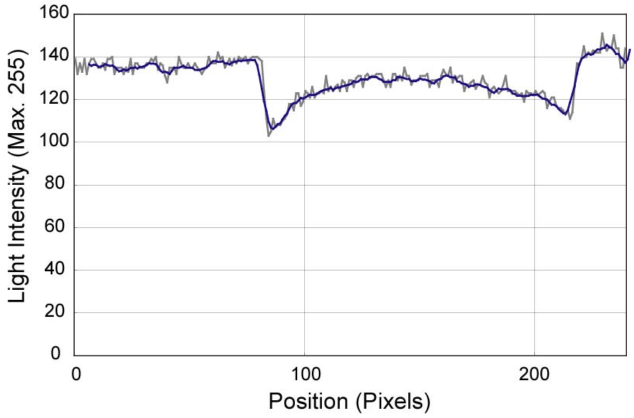


Fig.13 brightness distribution on line A indicated in figure15

direction of observation, can be measured from the bright ness. Figure 15 shows a modification of figure 8, taking the *D* parameter acquired by this method into consideration.

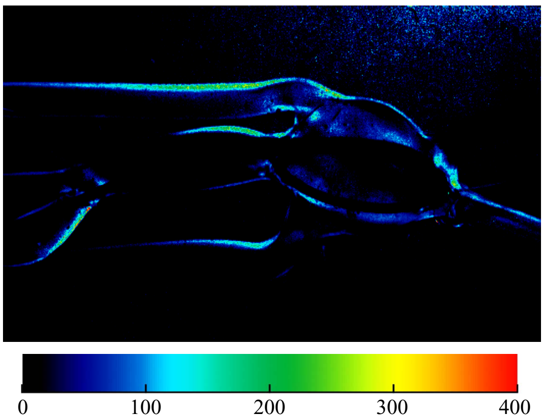


Fig. 14 Stress distribution on proposed cerebral arterial model analyzed taking thetlength of light path D distribution into consideration

V. Systematization

In endovascular intervention, catheters and other instruments are operated from thigh, where those get inserted into aorta. Therefore, reproduction of whole aorta structure is required to correctly reproduce the behavior of these instruments.

From this view point, we reconstructed the whole (from femoral to cerebral) aorta which has more than 1 mm inside diameter, using patient-specific information and the modeling method presented in previous report [22] (Fig. 16). Here, we applied, for this reconstruction, 2930 pieces of CT cross-sectional image (1134 pieces for cerebral part (resolution: 0.468 mm, interval: 0.3 mm), 1796 pieces for body part (resolution: 0.625 mm, interval: 0.8 mm)). And for the cerebral part, where stress evaluation become important, we applied a vasculature model for proposed photoelastic analysis presented in this paper, and connected these two structures at basis cranii interna. And we put a fluorescent white light panel (300 x 200 mm) attached with first set of 1/4λ plate and polarizer under the cerebral part, and placed a CCD camera attached with second set of 1/4λ plate and polarizer above the cerebral part using arm (display the CCD video image on a monitor put aside the simulator) (Fig. 17).

Meanwhile, we constructed a pulsatile pump which can reproduce patient-specific pulsative blood streaming obrtained by ultrasonic measurement or other modalities, , connected it to the aorta model and reproduced human-like pulsatile blood streaming inside the simulator (vascular model can reproduce vascular pulsation with the streaming [22]).

Consequently, constructed simulation system allow to simulate endovascular intervention in practical manner and environment, watching the monitor presenting actual DSA (digital subtraction angiograhy)-like penetrated image supplemented with stress information.

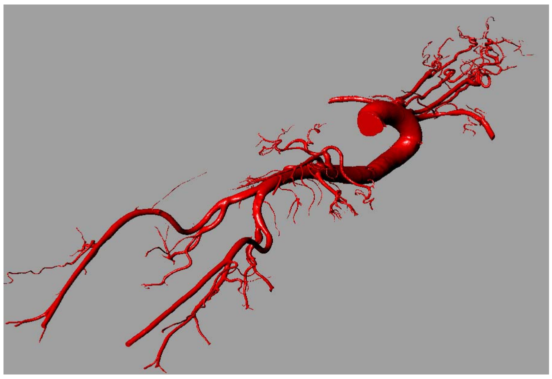


Fig.15 3 dimensional configuration of total human aorta system reconstructed with about 3000 pieces of CT slice images

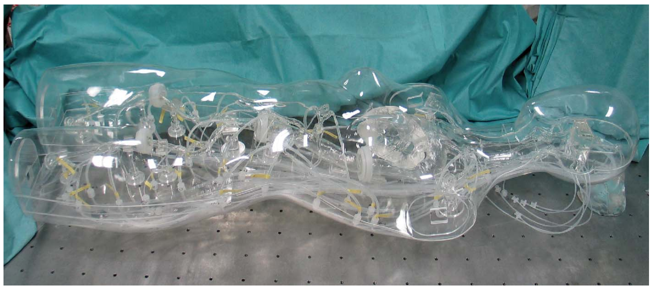


Fig. 16 Surgical Simulator for endovascular intervention, comprised of patient-specific vasculature model of whole human aorta structure

VI. Results and Discussion

Polyurethane elastomer that constitute proposed vasculature model also reproduces the physical property of arterial tissue in addition to 3-D geometry. Its elsatic modulus: 1.8 MPa is almost similar to artery: it normally ranges from 1 to 3 MPa [19]. Meanwhile, presented modeling technique allow constructing minimally 300 μm inside diameter, that is enough to reproduce endovascular intervention. Consequently interventionalists verified that the simulator can realize realistic surgical simulation reproduced with the feeling and and the behavior of vasculature, and effectiveness for evaluating surgical robots and instruments.

We evaluated the performance and applicability of a robotic tele-telesurgery system developed for endovascular intervention (developed by authors) [6][7] by simulating surgical procedures with the surgical simulator presented in section V. Though this experiment, we found that the feeding speed and acceleration of catheter were not sufficient to replicate some surgical procedures that

Fig.17 Surgical simulator for endovascular neurosugery, which allow evaluating stress condition on arterial structure applied with surgical operation and blood streaming, using photoelastic modality

affirmatively utilize the dynamic elastic behavior of catheters, and to evade applying excessive stress to vessel walls. Consequently, we could make some advancement on our tele-surgical system.

With this experiment and other several experiments made by authors and interventionalists, we confirmed that the proposed simulator reproduce the behavior of medical instruments operated inside vasculature, deformation of vasculature during endovascular intervention and feeling of operating catheters, consequently, very helpful for evaluating both surgical instruments and surgical procedures.

Since the presented modeling procedure is also applicable to other organic structures, such as organs and thin tracts, proposed method should provide good evaluation platform for various surgeries. And the model based stress analysis proposed in this paper should be helpful because it realizes real-time 3-dimensional stress analysis with practical surgical instruments, which was very difficult with conventional platform. Finally, presented vasculature model takes less than 24 hours for fabrication (for 50 x 50 x 50 mm size), it allows swift evaluation of patients and will safer treatments.

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