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Development of a New Aortoscope System for the Use of Endovascular Intervention

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***Abstract*— "Balloon aortoscopy" is a technique for viewing inner wall of aorta and used in clinics [1, 2]. By this method, endoluminal aortic surface could be clearly monitored, however, during this period, the aortic blood flow is blocked off by the inflated balloon. To solve this clinical problem, we have been developing a prototype aortoscope system without blocking off aortic flow aiming for the use of an assistive technique for endovascular interventions such as stent-graft placement for aortic aneurysm and have been evaluating through *in vitro* and *in vivo* tests. The technique introduced for this purpose was the use of intermittent and instantaneous saline jet controlled by a high-speed electromagnetic valve synchronized to heart beat (diastolic phase). In the previous study, we designed an endoscope with two channels (one for saline discharge and the other for forceps insertion), and confirmed the validity of this method by *in vitro* and *in vivo* tests [3, 4]. Based on these findings, in this study, we have newly designed a conventional and low price endoscope system aiming for wide clinical use. From the results of *in vitro* tests using a mock circulation system, it was confirmed that the newly designed system was capable of visualizing a target installed on an inner surface of the mock system suggesting an availability of the system for an aortoscope without blocking off aortic flow.**

I. Introduction

Aortoscopy is the technique for visualizing aortic endoluminal anatomy mainly used as an assistive technology for endovascular interventions such as stent-graft insertion for aortic aneurysm [5,6]. Recently, due to the remarkable progress in 3D image processing technology, virtual aortoscopies using MRI, CT and IVUS are becoming more popular in clinics for its non-invasiveness [7,8]. However, there still exist strong clinical requirements for visually inspecting intraluminal pathologic changes. For this purpose, so called "Balloon aortoscopy" was developed and clinically used [1,2]. By this method, endoluminal aortic surface could be clearly monitored, however, during this period, the aortic blood flow is blocked off by the inflated balloon. This is the main and big problem of the balloon aortoscopy. To overcome this problem, we have been developing a prototype aortoscope system without blocking off the blood flow, and preliminary results of *in vitro* and *in vivo* tests were reported [3, 4]. In this study, we have newly designed a conventional and low price aortoscope system aiming for wide clinical use and some results of *in vitro* performance tests are presented.

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II. System description

Fig. 1 shows a basic concept for endoluminal aortic inspection without blocking off aortic blood flow. An endoscope with a saline discharge channel is retrogradely inserted into the aorta and intermittent saline jet is discharged from the tip of the endoscope. Timing of the jet discharge is synchronized to diastolic phase (minimal blood flow phase) so as to obtain more clear view of the wall. Synchronizing to the discharge, endoscopic view (movie) is captured and displayed on a monitor. During the other phase (systolic phase without saline jet flow), the latest picture of the captured view (still picture) is displayed so as to obtain "pseudo-movie" of the wall during whole cardiac beat.

In Fig. 2, photographs of the previously developed endoscope for this purpose are shown. In this fiber scope with outer diameter (o.d.) of 6.2mm, two channels are installed as shown in Fig. 2b; one is for saline discharge (inner diameter: i.d.= 1.8mm) and the other for forceps (i.d.=2.0mm). At the top of the tip, a special hood called "Hemo-visor" was installed (see Fig. 2d) for improving the ability of blood stream blockage. As we reported in the previous paper [4], visualization ability of the system using this endoscope was confirmed by *in vitro* and *in vivo* tests, however, there still

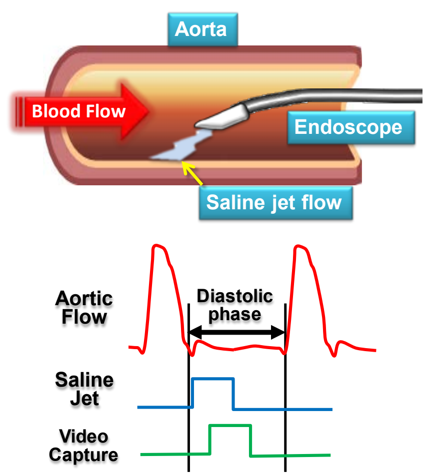

Fig. 1 Schematic explanation of basic concept

remained several points for improvement for wide clinical use, *e.g.*, reduction of the outer diameter for minimally invasive approach, and reduction of the cost for manufacturing.

To overcome these problems, we have newly designed a "conventional" and "low cost" endoscope system as shown in Fig. 3 aiming for the use of aortoscope. This system consists of two main parts; one is a commercially available conventional endoscope (Fig. 3a) with bending tip (FP-7RBS, PENTAX, o.d.=2.4mm), and the other is a specially designed plastic sheath (i.d.=3.4mm, o.d.= 4.7mm) with flexible flared top (Fig. 3c). The material used was a medical grade poly-amide elastomer. The endoscope is inserted from one of the two ports of Y-shape connector (Fig. 3d) and the other port is used for saline irrigation. And thus, the pressurized saline (see Fig. 4) is discharged from the flared top through the space between the endoscope and the sheath. By this improvement, total cost of the present system was remarkably reduced to about 1/20 compared with the previous system.

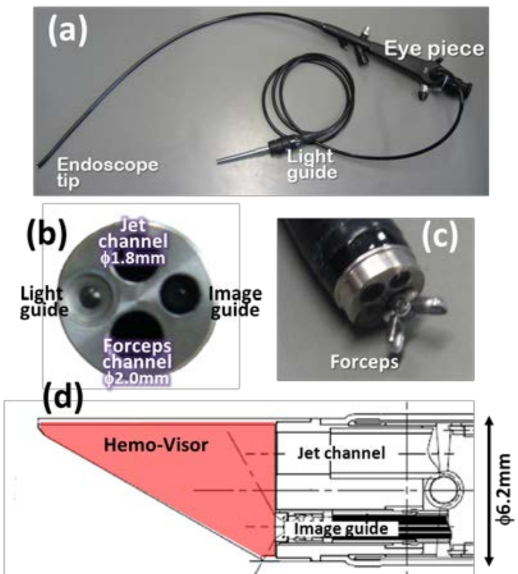

Fig. 2 Photographs and structural outline of the previously developed endoscope

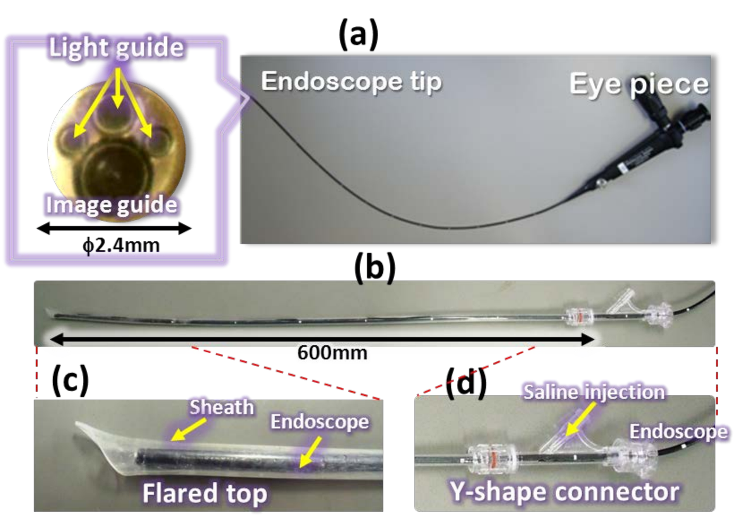

Fig. 3 Photographs of the newly designed endoscope system aiming for the use of aortoscopy

Fig. 4 shows an outline of the saline discharge control system. A saline tank (capacity: 5 litters, max. pressure: 0.6 MPa) was pressurized by a conventional air cylinder. At the outlet port of the tank, a high-speed solenoid valve (A2013, Precision Dynamics Co. Ltd.) was connected so as to control timing and amount of saline injection. The valve was operated by pulse signal generated by a function generator *via* a solid state relay (SSR).

III. Materials and Methods

A. Hydraulic tests

Using the system shown in Fig. 4, two kind of hydraulic characteristic test were conducted. One was "static" and the other was "dynamic". The former is the tests to investigate "pressure vs. flow" relationships of the discharge channel. And the latter is to evaluate the relationship between pressure and discharged volume during one pulse.

For the static test, the air chamber was not used. Out flow was measured using a conventional measuring cylinder. For the dynamic test, on the other hand, to evaluate the effect of outlet pressure (arterial pressure) on the discharge volume, the air chamber was connected to the endoscope and the chamber pressure was varied to 0, 100, and 200 mmHg. And the discharge volume was calculated from the water head change in the chamber and total number of the pulse.

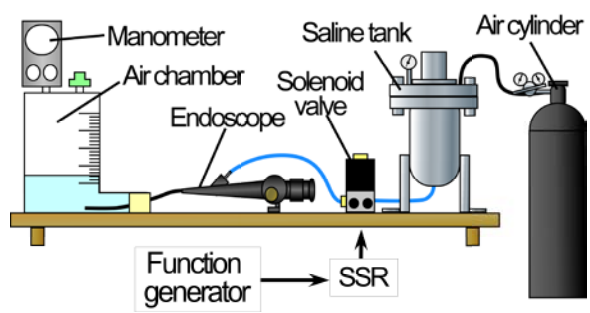

Fig. 4 Outline of the saline discharge system and experimental set up for hydraulic tests

Table 1 Endoscopic Specifications	
Field of view	95°
Depth of field	3 to 50 mm
Insertion Tube Outer Diameter	2.4 mm
Working Length	600 mm
Angulation range	Up 130° Down 130°
Total Length	870 mm

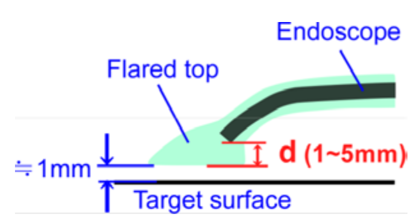

Fig. 5 Schematic drawing of the flared top of the sheath and the target surface

B. Visualization test

For evaluating visualization performance of the new endoscope system, we used the previously reported experimental set up and the visualization index[3]. Followings are brief description of the method. A mock-circulation system using a compressed-air-driven pulsatile pump was filled with "milky white" bath salts solution (10g/l; mainly sodium bicarbonate). A target (black concentric circles printed on a white film) was affixed on an inner surface of an acrylic tube connected to the outlet port of the pulsatile pump. The tip of the endoscope was retrogradely inserted into the tube using a specially made lantern-shaped stent. The intermittent saline jet flow made by the injection system was discharged from the saline channel during the diastolic phase of the pulsatile pump. For synchronization, the driving signal of the pump was used. The driving condition of the pulsatile pump and the values of circulation parameters were adjusted as follows considering the physiological values of the experimental animal (swine with body weight of about 30 kg);

- ✓ pumping rate : 100 bpm
- ✓ duty ratio: 30%
- ✓ mean pump flow: 3 l/min
- ✓ mean pressure: 100 mmHg
- ✓ pulse pressure: 50 mmHg (systolic: 130 mmHg, diastolic: 80 mmHg)

For quantitative evaluation of the "clearness" of the obtained picture (movie) of the target, we used the "visualization scale" [4] which was defined as a difference of the value of brightness between the black line and the white part of the target. The value of the visualization scale of the most "clear" picture will be "255", and the worst will be "0", which means "all white". According to the opinion of an expert in endoscope operation (a cardio-vascular surgeon), the value of the scale lower than "30" was judged as "unclear" level.

In order to investigate the proper position of the endoscope tip in the flared top of the sheath, the distance between the endoscope tip and the edge of the sheath: d (see Fig. 5) was changed from 1mm to 5mm. As shown in Fig. 5, about 1 mm gap was made between the surface of the target and the edge of the sheath. The reason of this gap is as follow; considering the clinical use, the endoscope tip will be circumferentially rotated for inspecting endoluminal surface. In such occasion, contact of the edge to the arterial wall should be avoided in order to eliminate intimal damage.

IV. Results and Discussion

A. Hydraulic tests

Fig.6 is the results of the "static" test. Plots are mean value of five trials. Standard deviation of each plot was less than 4ml/min. As shown in this figure, (1) slightly non-linear characteristics were observed both for the previous and the present system, (2) flow rate of the present system is slightly higher than the previous system, (3) flow rate of about 1 litter/min was attained at the applied pressure of 0.3 MPa in the present system. The reason of the higher flow rate of the present system would be explained by the difference of the cross-sectional area of the saline channel.

Fig. 7 shows the results of the "dynamic" tests. From these results, it was clearly shown in the present system that (1) under the applied pressure of about 0.2 MPa, discharged volume of about 1 ml was obtained during the pulse duration of 100 ms, (2) by the increase of the pulse duration (100 ms to 200 ms), discharged volume increased almost linearly, and (3) effect of the outlet pressure on the discharged volume was small. These results indicate that we could easily and freely control the discharge volume during one pulse by changing applied pressure and/or pulse duration.

Contrary to the results of the "static" test, deterioration of the "dynamic" characteristics was observed in the present system compared to the previous system. This may be caused from the big difference of the elasticity (compliance) of the material used for the saline channel. In the previous system, the jet channel is embedded in the endoscope (see Fig. 1), and therefore, compliance of the channel would be almost zero. In the present system, on the other hand, as the elastic polymer is used for the sheath material, its diameter will increase with high inner pressure. This compliant property of the sheath may decrease the "dynamic" characteristics.

Reinforcement of the sheath by thin stainless wire mesh will be effective for decreasing compliance and improving the "dynamic" characteristics.

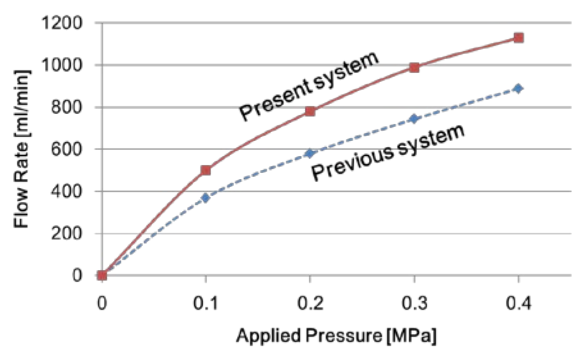

Fig. 6 Results of the "static" test showing the relationships between applied pressure and flow rate.

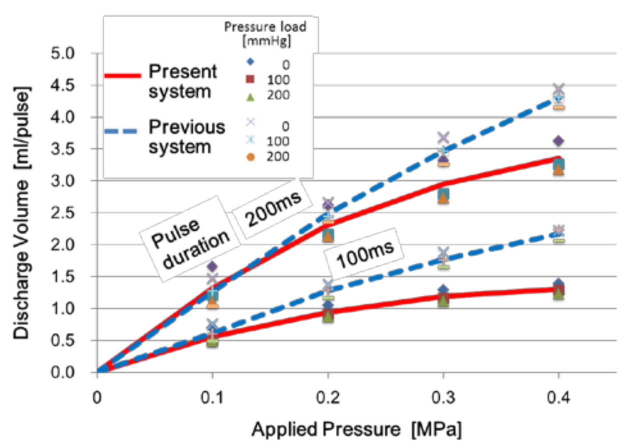

Fig. 7 Results of the "dynamic" test showing the relationships between outlet pressure and discharge volume during one pulse

B. B. Visualization tests

Fig. 8 is the results of visualization tests showing the values of visualization scale versus time under the various "d" values (see Fig. 5). The discharge parameters, *i.e.,* pulse duration (ΔT) and applied pressure (Ps), are also shown in the graph. At the "d" values of 4 mm and 5 mm, visualization scale was less than 30 (unclear region) during the whole period of the pumping cycle. At the "d" values from 1 mm to 3 mm, on the other hand, the values of visualization scale exceed 30 during diastolic phase and reached at the maximum values of about 100 or more.

This big difference in visualization characteristics could be explained by the condition of the discharged transparent fluid between the tip and the target surface (cavity). When the tip is far from the surface (d=4-5mm), the volume of the cavity is too large to remove the milky white solution during the limited period of discharge. On the other hand, when the tip is too close to the surface (d=1 mm), the field of view became narrow (see the still picture "d=1" in Fig. 8). From these reasons, we chose the "d" value of 2 mm for the following experiments.

Fig. 9 shows the results of various discharge conditions changing ΔT and Ps. As shown in this figure, accompanying the increase in ΔT and Ps, not only the maximum value of the scale, but also the duration of high scale value (higher than 30) increased (see the upper part of this figure). It should also be noted that the discharge condition of ΔT = 100 ms and Ps = 0.1 MPa is enough for obtaining "visible" picture of the target. This means that only 0.5 ml of discharge per pulse (see Fig. 7) is enough for visualizing the target. This also could be a great advantage of the present system for clinical use for reducing the total irrigation volume of saline.

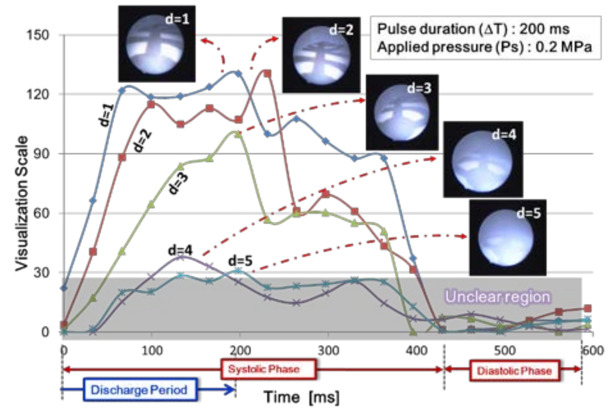

Fig. 8 Results of *in vitro* test using mock circulation system showing the effect of the distance "d" (see Fig. 5) on visualization characteristics

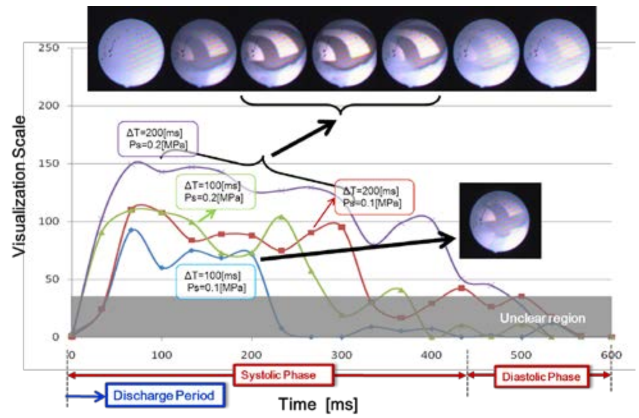

Fig. 9 Visualization characteristics under various discharge condition with the value of d=2mm.

V. CONCLUSION

Based on the findings of the previously reported studies [3,4], we have newly designed a "conventional" and "low-price" aortoscope system without blocking off blood flow and evaluated its performance through *in vitro* tests. From the results obtained, it was confirmed that using this system the target attached on the inner surface of the tube of the mock circulatory system could be observed without blocking off the fluid stream, and the flared shape of the sheath top was highly effective in obtaining high quality picture presumably due to high ability in keeping the transparent solution between the tip and the target.

From these results, it is suggested that the present system could be a useful technology for assisting endovascular interventions. To confirm the capability of the clinical use, we are now preparing *in vivo* experiments using swine.

Points for improvement would be; reduction of the sheath size for minimizing the invasiveness, multimodal approach for inspecting inside the vessel wall using IVUS (intravascular ultrasound) or OCT (optical coherence tomography), and application to an ablation device for atrial fibrillation, in which a balloon is usually used [9, 10].

REFERENCE

[1] B.B. Hill, G. L. Hyde, Chien-Suu Kuo, *et al.*"Aortoscopy: A guidance system for endoluminal aortic surgery", *Journal of Vascular Surgery*, vol. 24, no. 3, pp.439-448, 1996

[2] B. B. Hill, R. Neville, G. L. Hyde, *et al.*" Angioscopic Evaluation of an Endoluminal Aortic Graft: The First Clinical Experience", *Journal of Endovascular Surgery*, August 1995, vol. 2, no. 3, pp. 248-254, 1995

[3] S. Tanaka, K. Tokugi, M. Ogawa, *et al.*, "Development of a Vascular Endoscopic System for Observing Inner Wall of Large Arteries for the Use of Endovascular Intervention," *Proceedings of ITAB2010 (CD-ROM),* IEEE Catalog Number: CFP10ITA-ART, paper No.123, 2010

[4] S. Tanaka, T. Suzuki, M. Ogawa, *et al.* "Evaluation of a Newly Designed Endoscope for Observing Inner Wall of Large Arteries for the Use of Endovascular Intervention", *Proceedings of 33rd Annual International Conference of the IEEE EMBS*, pp.345-348, 2011

[5] G. Souto, L. A. Tinoco, C. S. Caetano, *et al.* "Aortoscopy in the treatment of acute dissecting aneurysms of the aorta", *Rev Bras Cir Cardiovasc*, vol. 14, no. 3, pp. 215-220, 1999

[6] G. C. Fernández, F. M. Tardáguila, D. Durán,*et al.*" Dynamic 3-dimensional contrast-enhanced magnetic resonance angiography in acute aortic dissection", *Current Problems in Diagnostic Radiology,* vol. 31, no. 4, pp. 134-145, 2002

[7] F. Hornero, V. Cervera, J. Estornell, *et al.* "Virtual Vascular Endoscopy for Acute Aortic Dissection", *Annals of Thoracic Surgery*, vol. 80, no. 2, pp. 708-710, 2005

[8] A. Miller, W. E. Lipson, J. L. Isaacsohn, *et al.*" Intraoperative angioscopy: Principles of irrigation and description of a new dedicated irrigation pump", *American Heart Journal*, vol. 118, no. 2, pp. 391-399, 1989

[9] C. S. Kuo and C. A. Koch, "In vivo angioscopic visualization of right heart structure in dogs by means of a balloon-tipped fiberoptic endoscope: Potential role in percutaneous ablative procedures", *American Heart Journal*, vol. 127, pp. 187-197, 1994

[10] W.B. Chik, M. A. Barry, Z. Malchano, *et al*, "In Vivo Evaluation of Virtual Electrode Mapping and AblationUtilizing a Direct Endocardial Visualization Ablation Catheter", *J. Cardiovasc. Electrophysiol.*, vol. 23, pp. 88-95, 2012