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Evaluation of a Newly Designed Endoscope for Observing Inner Wall of Large Arteries for the Use of Endovascular Intervention

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***Abstract*— A prototype endoscope for observing inner wall of large arteries was specially designed and evaluated through *in vitro* and *in vivo* tests. The purpose of this endoscope is to visualize the inner wall of large arteries, *e.g.*, an aorta, without blocking off the blood stream aiming for the use of an assistive technique for endovascular interventions such as stent-graft placement for aortic aneurysm. The technique newly introduced for this purpose was the use of intermittent high-pressure saline jet synchronized to heart beat (diastolic phase). In the previous studies using commercially available bronchoscopes, we confirmed the validity of the system utilizing this technique [1, 2]. Based on these findings, in this study, we have specially designed a new endoscope with two channels, one for saline discharge and the other for forceps, and evaluated its performance through *in vitro* and *in vivo* tests. From the results of *in vitro* tests using a mock circulation system, it was confirmed that the newly designed endoscope was capable of visualizing a target installed on an inner surface of the mock system. Also confirmed through *in vivo* tests using swine was that we could observe bifurcation in descending aorta, *e.g.*, left renal artery, without stopping off the blood stream.**

I. Introduction

FOR minimally invasive endovascular therapy, vascular endoscopes with balloon have been commercially available [3] and widely used for visually inspecting inner wall of blood vessels. However, application of this method is limited to only small arteries because it requires blockage of blood flow by the balloon [4, 5]. On the other hand, there have been strong requirement for visually inspecting inner wall of large arteries such as aorta in case of stent-graft treatments for aortic aneurysms and so on [6]. Based on this requirement, we have been developing a prototype endoscope system applicable for large arteries without blocking off the blood flow, and preliminary results of *in vitro* and *in vivo* tests were reported [1, 2]. In this study, a new endoscope was specially designed for this purpose and some results of performance tests *in vitro* and *in vivo* are presented.

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II. System Description

Fig. 1 shows a basic concept for visualizing inner wall of large arteries (*e.g.,* aorta) without stopping 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 newly developed endoscope for this purpose are shown. In this fiber scope, two channels are installed as shown in the lower left part of Fig. 2; one is for saline discharge and the other for forceps. In the previous study, we use a conventional bronchoscope. In this endoscope, only one channel (for forceps) was available, and therefore, we use this channel for saline discharge. On the other hand, considering the future clinical use of endovascular interventions, strong requirements for simultaneous use of forceps during the visualization are expected. From this

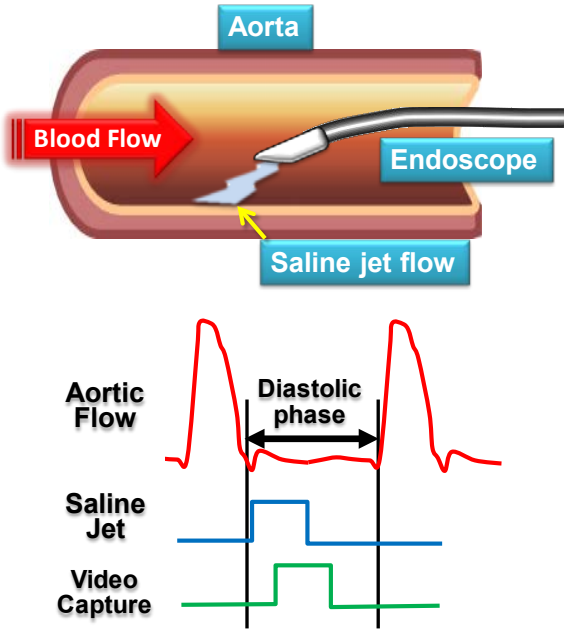

Fig. 1 Schematic explanation of basic concept

reason, we specially designed the two-channel endoscope with outer diameter of 6.2 mm. Other main specifications are as follows;

- Channel diameter: saline:1.8mm, forceps: 2.0mm
- Effective length: 550mm
- Flexion angle: up: 90deg, down: 90deg

At the top of the tip (see Fig. 3), a special hood called "Hemo-visor" was installed for improving the ability of blood stream blockage [2]. To reduce the wall thickness of Hemo-visor, the previously used material, *i.e.,* a conventional PVC tube, was changed to black plated stainless steel.

Outline of the saline discharge control system is briefly as follows; 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 the jet stream. For *in vitro* tests, the valve was operated by pulse signal generated by a function generator or operating signal of a pulsatile pump (see Fig.4) *via* a solid state relay. For *in vivo* tests, on the other hand, the pulse signal was triggered by ECG R-wave.

III. Materials and Methods

A. In vitro test

Fig. 4 shows an experimental set up of *in vitro* test for evaluating visualization performance of the new endoscope system. A part surrounded by a red solid line shows a mock circulation system which composed of (i) a compressed air driven pulsatile pump, (ii) an air chamber mimicking aortic compliance, (iii) a valve mimicking total peripheral resistance, (iv) a reservoir mimicking atrium, and (v) an acrylic tube for the endoscope insertion on the inner surface of which an observation target is installed (see the right upper part of Fig. 4). The fluid used was bath salts solution (10g/l; mainly sodium bicarbonate) color of which was milky white (impossible to observe the target through this solution). The driving condition of the pulsatile pump and circulation parameters were adjusted as follows considering the physiological values of male adults at rest;

- ✓ pumping rate : 60 bpm
- ✓ duty ratio: 30%
- ✓ mean pump flow: 6 l/min
- ✓ mean pressure: 100 mmHg
- ✓ pulse pressure: 50 mmHg

(systolic: 130 mmHg, diastolic: 80 mmHg)

Fig. 2 Photographs of the newly designed endoscope

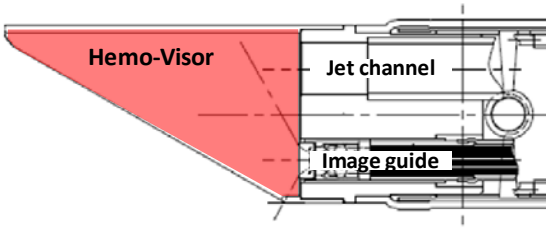

Fig. 3 Detail of the endoscope tip

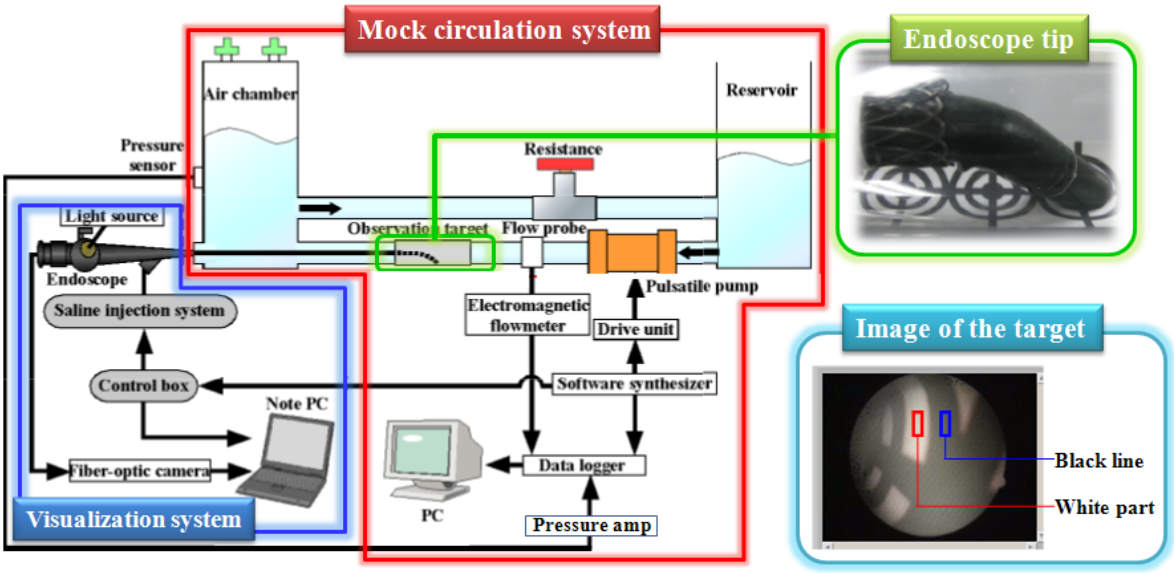

Fig. 4 Outline of the experimental set up for *in vitro* test

The tip of the endoscope was inserted retrogradely into the tube and fixed using a specially made lantern-shaped stent. The intermittent saline jet flow made by the injection system (a part surrounded by a blue line in Fig. 4) was discharged from the saline channel during the diastolic phase of the pulsatile pump. For synchronization, the driving signal of the pump was used.

For quantitative evaluation of the "clearness" of the obtained picture (movie) of the target, we used an index of "visualization scale" [2] which was a difference of the value of brightness between the black line and the white part of the target (see the right lower part of Fig. 4). Before the experiments, the mock system was once filled with water and the picture of the target obtained by the endoscope was recorded and the value of brightness of the each two part were calibrated to "0" for the black line and "255" for the white part, respectively. And thus, 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.

During the experiments, a parameter: Td, which was the delay time of the solenoid valve operation (opening) from the trigger signal (pump driving signal), was changed from 50 to 550 msec and the quality of the picture was quantitatively assessed by the scale. Also changed was the tip configuration, *i.e.,* with or without "Hemo-visor". As mentioned before, the "Hemo-visor" is our original naming of a small hood attached on the top of the endoscope tip expecting an effective role in keeping the saline solution between the endoscope tip and the target against the fluid (blood) stream to more clearly obtain the picture.

B. in vivo test

Fig. 6 shows an outline of the *in vivo* tests. Altogether 5 swine weighing about 30 kg were used. They were anesthetized with halothane + nitrous oxide and ventilated by a respirator with room air and oxygen. The endoscope was introduced from the abdominal aorta and inserted proximally about 30 cm. At this point, saline discharge was started using ECG-R wave as a triggering signal. In case of difficulty in obtaining stable ECG, pulse signal generated by the PC was used. To confirm the location of the endoscope tip, angiographs were simultaneously taken (ARCADIS Avantic, Siemens AG).

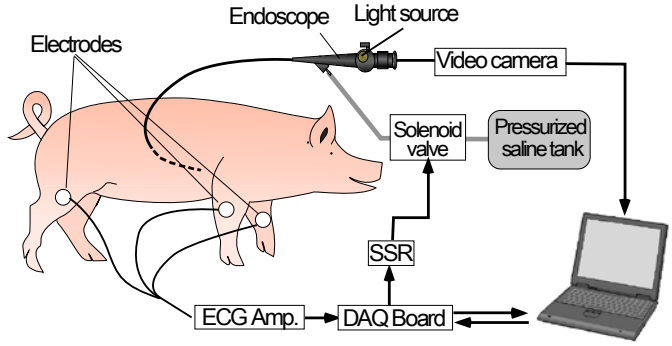

Fig. 5 Experimental set up for *in vivo* experiment

IV. RESULTS AND DISCUSSION

Fig.6 is the results of *in vitro* tests showing the values of visualization scale versus time under the various delay time (Td) without (upper) and with (lower) Hemo-visor (H-V). Regarding the results of "without H-V", almost all of the plots were within the "Unclear" region (under 30), especially with the short delay time. The plots over "30" were observed only when the timing of the discharge was synchronized to diastolic phase (Td: 350-550msec), but the scale values were less than 50.

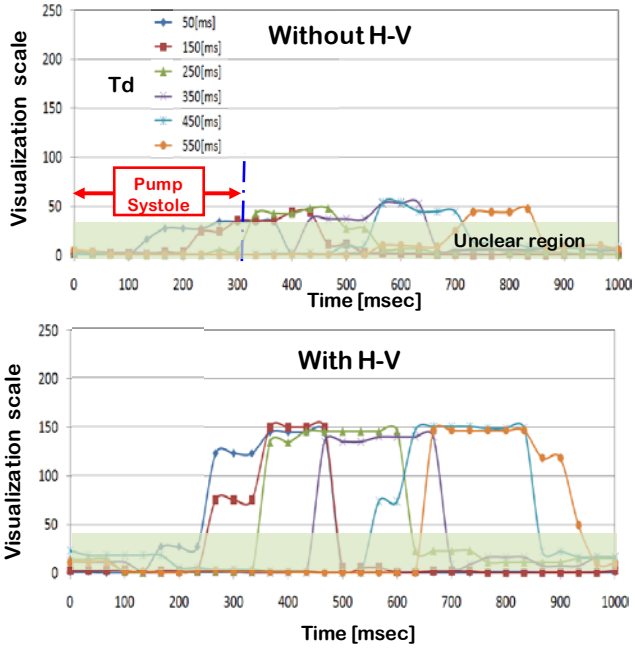

Fig. 6 Results of *in vitro* performance test

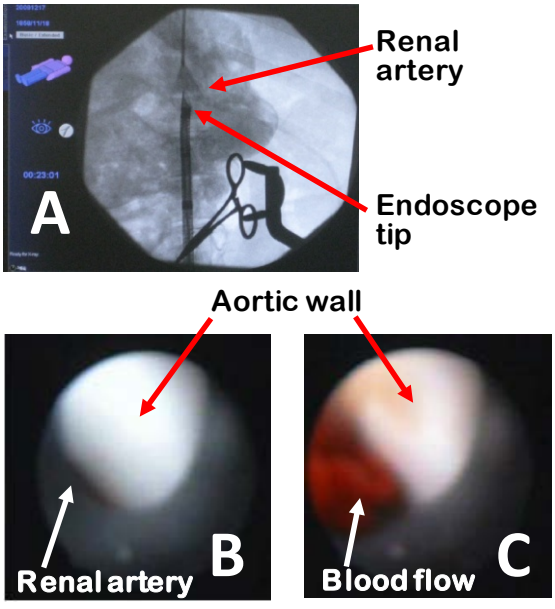

Fig. 7 Examples of the picture obtained by the *in vivo* experiments

On the other hand, with H-V, very high scale values (over 100) were observed with longer period of time even in the very short delay time (50 msec). With this delay time, the pump was still under the systolic phase when the saline jet started to discharge, indicating the effectiveness of the Hemo-visor for improving the quality of the picture.

Fig. 7 shows examples of the pictures obtained by the *in vivo* experiments. The upper one (A) is an example of the angiographs. It should be noted that the the endoscope was inserted into the descending aorta and the tip (opening of H-V) was face to the bifurcation of left renal artery. At this position, the endoscope system was operated using ECG-R wave as a trigger signal. The condition of the saline jet at this time was pulse period: 300 msec, delay time: 300 msec, driving pressure: 0.2 MPa, respectively.

The lower two pictures (B and C) in Fig.7 are the examples of the captured picture during the operation. In picture B, a part of the opening of the renal artery was observed (left lower part). From this opening, as shown in the picture C, blood was spurted out intermittently presumably due to the "back pressure" from the peripheral arteries during systolic phase.

V. CONCLUSION

Based on the findings of the previously reported studies [1,2], we have newly designed an endoscope for visualizing inner wall of large arteries without blocking off blood flow and evaluated its performance through *in vitro* and *in vivo* tests. From the results obtained, it was confirmed that using this endoscope 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 Hemo-visor was highly effective in improving the quality of picture presumably due to high ability in keeping the saline solution between the tip and the target. Also confirmed by the *in vivo* tests using swine was that this endoscope was capable of visually inspecting inner wall of aorta and bifurcations without stopping aortic blood flow.

From these results, it is suggested that the present system including the newly developed endoscope could be a useful assistive technology for the endovascular interventions in aorta. This method is highly invasive and has several points for improvement in practical use, *e.g.,* reduction of the tip size for enabling insertion from femoral artery in adult, although, it requires no large, bulky and extremely expensive instrument as an angiography and has no risk for the exposure to radiation. These two points are quite big practical advantages of our method.

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