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Noninvasive Miniaturized Mass-flow Meter using a Curved Cannula for Implantable Axial Flow Blood Pump

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***Abstract*— Blood flow should be measured to monitor conditions of patients with implantable artificial hearts continuously and noninvasively. We have developed a noninvasive miniaturized mass-flow meter using a curved cannula for an axial flow blood pump. The mass-flow meter utilized centrifugal force generated by the mass-flow rate in the curved cannula. Two strain gauges served as sensors. Based on the numerical analysis, the first gauge, attached to the curved area, measured static pressure and centrifugal force, and the second, attached to the straight area, measured static pressure for static pressure compensation. The mass-flow rate was determined by the differences in output from the two gauges. To compensate for the inertia force under the pulsatile flow, a 0.75-Hz low-pass filter was added to the electrical circuit. In the evaluation tests, numerical analysis and an actual measurement test using bovine blood were performed to evaluate the measurement performances. As a result, in the numerical analysis, the relationship between the differential pressure caused by centrifugal force and the flow rate was verified. In the actual measurement test, measurement error was less than ± 0.5 L/min, and the time delay was 0.12 s. We confirmed that the developed mass-flow meter was able to measure mass-flow rate continuously and noninvasively.**

I. Introduction

A left ventricular assist system (LVAS) has been developed as a bridge to heart transplantation or as a permanent implantation. The inlet cannula of the LVAS is connected to an apex of a left ventricle, and the outlet cannula of the LVAS is connected to an aorta. By delivering blood flow from the left ventricle to the aorta, the LVAS assists diseased cardiac function of the left ventricle. Currently, implantable blood pumps for the LVAS have made significant progress, and patients have been discharged from a hospital [1]. For the discharged patients with the LVAS, it is important not only to develop the implantable blood pump but also to develop physiological sensors for management of patients.

Reliable determination of blood flow is important for monitoring the condition of patients and the condition of the blood pump. To determine pump flow rate, flow estimation method has been proposed. This method estimates flow rate based on power consumption of the blood pump [2]. However, flow estimation method is directly affected by the mechanical friction losses and by the change in fluid viscosity. Furthermore, although the power consumption of the centrifugal blood pump has linearity with respect to pump flow rate, the power consumption of the axial flow blood pump has inherently nonlinearity with respect to pump flow rate [3].

In the present study, a noninvasive miniaturized mass-flow meter using a curved cannula for discharged patients with an implantable axial flow blood pump has been developed, and the measurement performance was evaluated in numerical analysis and in *in-vitro* tests using bovine blood.

II. Materials and Methods

A. Principle of flow measurement

Since many implantable artificial hearts connect the blood pump with the body via a curved cannula, we used a curved cannula as the sensing probe of the mass-flow meter, as shown in Fig. 1. Initially, a principle of the flow measurement using the curved cannula was analyzed based on equilibration of forces in the cannula. Assuming that angular velocity is independent of the radius of the cannula, the static pressure differentiated by the radius is related to the angular velocity as follows:

$$\Delta P = \frac{\rho\omega^2}{2}(r_1^2 - r_0^2) \quad (1)$$

where ρ is mass density, ω is angular velocity, ΔP is static pressure increased by the centrifugal force, r_0 is the inner radius and r_1 is the outer radius of the curved cannula. The

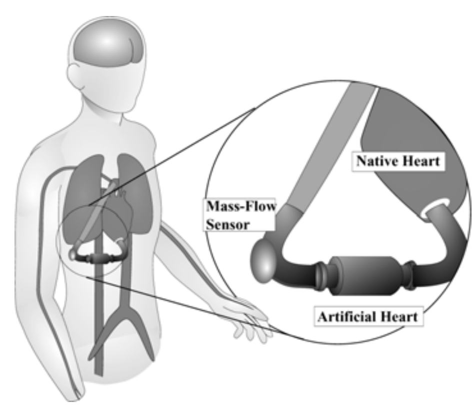

Fig. 1 Illustration of miniaturized mass-flow meter in an LVAS

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angular velocity corresponding to mass-flow rate is able to be measured by the differential pressure caused by the centrifugal force.

Under the pulsatile flow, the differential pressure is changed not only by the flow rate but also by the inertia force based on the variance of the flow rate, as follows:

$$\Delta P = \frac{m}{A} \times \frac{d}{dt} V \tag{2}$$

where A is cross sectional area of the flow passage, m is weight of the blood, t is time, and V is fluid velocity. By the inertia force, the phase of the static pressure shifts earlier, and the static pressure changes. Therefore, a simple low-pass filter that is able to compensate the inertia force was incorporated to the electrical circuit.

B. CFD analysis

In order to determine the measurement positions of the mass-flow meter, and to evaluate the measurement performances under continuous flow and pulsatile flow, the computational fluid dynamics (CFD) analyses were performed using commercial CFD analysis software (Ansys CFX ver.5, ANSYS Inc., Canonsburg, PA, USA). First of all, a 3-dimensional analytical model was constructed based on the curved cannula that has already been used in the actual animal experiment. The inner and outer diameter was 12 and 14 mm respectively. The bending radius was 30 mm, and the bending angle was 120°. The working fluid was assumed to be blood with a specific gravity of 1.05, viscosity of 3.0 cP. An unstructured tetrahedral domain mesh was generated using ANSYS CFX-Mesh (ANSYS Inc.). The mesh size was 0.5 mm, and the number of cell was 177,510.

In order to determine the measurement positions of the mass-flow meter, the CFD analysis was performed under constant flow. The boundary condition of the inlet was set as the flow rate of 7.0 L/min, and the boundary condition of the outlet was set as the reference static pressure of 13.3 kPa. In this condition, the pressure distribution in the curved cannula was analyzed.

In order to evaluate the measurement performance of the mass-flow meter, the CFD analysis was performed under continuous flow and under pulsatile flow. In the CFD analysis under the continuous flow, the flow rate was changed by 1.0 L/min from 0.0 to 7.0 L/min. In the CFD analysis under the pulsatile flow, the prepared flow rate was a 1-Hz sine-wave flow from 0.0 to 6.0 L/min.. In these conditions, the relationship between the flow rate and the simulated differential pressure was analyzed.

C. Developed non-invasive mass-flow meter

The mass-flow meter was developed based on the principle of flow measurement and CFD analysis as shown in Fig. 2. The inner and outer diameter was 12 and 14 mm respectively. A thin part of the wall was manufactured to adequately measure strain. When blood flow was absent, only static pressure affects the cannula wall. Whereas, when blood flow was present, static pressure and centrifugal force caused by the mass-flow rate affect the wall of the curved area of the cannula. Therefore, two micro strain gauges (Specially ordered products, Nissho Electric Works Co. Ltd., Tokyo, Japan) with a 0.2-mm length were adopted as sensors. Strain gauge A attached to the curved area measured static pressure and the mass-flow rate, and strain gauge B attached to the straight area measured only the static pressure. The mass-flow rate was then determined by the differences in output between the two sensors.

D. In vitro measurement test

In the evaluation tests, the actual measurement test using bovine blood was performed. The mock-up circulation loop comprised a non-pulsatile blood pump, an adjustable resistor, and a 500-ml volumetric blood reservoir (Senko Medical Instrument Mfg. Co., Ltd., Tokyo, Japan) as shown in Fig. 3. These components were connected by a polyvinyl chloride tube (Senko medical instrument mfg. Co., Ltd, Tokyo, Japan). The bovine blood (Funakoshi Co., Ltd., Tokyo, Japan) was employed as a working fluid. The hematocrit of the blood was 30 %, and the viscosity was 3.15 mPa·s. The temperature of the blood was maintained at 37ºC using a constant temperature reservoir. The pump flow rate was measured using a commercial flow meter (Transonic Systems Inc., Ithaca, NY, USA), and the pressure was measured using a commercial pressure transducer (DX-100; Nihon Kohden Corp., Tokyo Japan) and an amplifier (AP641G; Nihon

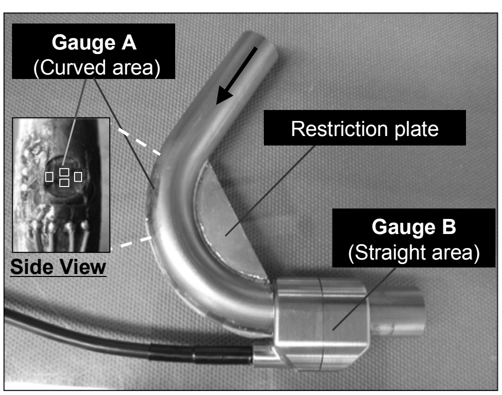

Fig. 2 Developed mass-flow meter using curved cannula.

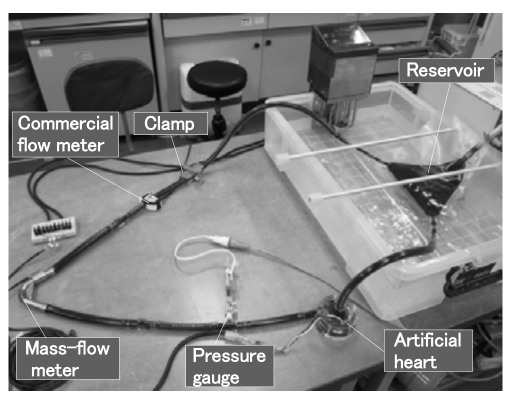

Fig. 3 Mock-up circulation loop for measurement evaluation

Kohden Corp). The measured data were collected every 0.01 seconds using a measurement computer (Let's Note W2, Panasonic Co., Ltd., Tokyo, Japan) with an analog-to-digital card (ADA16-8/2, Contec Co., Ltd., Osaka, Japan).

In order to evaluate measurement performance, measurement accuracy test and tracking performance test were performed. The measurement accuracy was determined by varying the flow rate in increments of 1.0 L/min by increasing the rotational speed of the blood pump. In this condition, the measurement error between the commercial flow meter and the mass-flow meter was evaluated. The tracking performance was determined by varying the flow rate at the square wave by controlling the rotational speed of the blood pump. In this condition, the time delay between the commercial flow meter and the mass-flow meter was evaluated.

III. RESULTS

Figure 4 shows the pressure distribution in the curved cannula at the flow rate of 7 L/min. The pressure distribution in the outside of the curved area was increased, and the pressure distribution in the outlet of the straight area was almost constant, in comparison with the pressure distribution at flow rate of 0.0 L/min. Therefore, it is found that the measurement sensor A, placed on the curved area, is able to measure both the flow rate and the static pressure, and the measurement sensor B, placed on the straight area, is able to compensate the static pressure.

Figures 5 and 6 show the results of CFD analysis for the evaluation of the measurement performance of the mass-flow meter. Figure 5 shows the relationship between the flow rate and the simulated differential pressure under the continuous flow. The calibration formula between the flow rate and the simulated differential pressure was determined by fitting the experimental data, as follows;

$$\Delta P = 5.70 \times Flow^2 + 2.19 \times Flow + 0.37 \qquad (3)$$

where ΔP (Pa) is differential pressure and *Flow* (L/min) is flow rate. And the order of the calibration formula was determined based on Eq. 1. Figure 6 shows the relationship between the flow rate and the simulated differential pressure under the pulsatile flow. The gray line in the graph shows the relationship between flow rate and the differential pressure that did not compensate the inertia force. The differential pressure changed not only by the flow rate but also by the inertia force caused by the variance of the flow rate, as shown in Eq. 2. Therefore, the relationship between the flow rate and differential pressure became the hysteresis loop. Whereas, the black line in the graph shows the relationship between flow rate and the differential pressure with inertia compensation. A 0.75-Hz low-pass filter was applied to compensate inertia force. The cutoff-frequency was determined manually to fit the phase between flow rate and the differential pressure. As a result, it was found that the inertia force could be compensated under the pulsatile flow. The calibration formula was obtained as follows;

$$\Delta P = 5.55 \times Flow^2 + 2.33 \times Flow + 2.16 \qquad (4)$$

The calibration formula under the pulsatile flow was almost equivalent to that obtained under the continuous flow, when the inertia compensation was applied.

Figures 7 and 8 show the results of the in-vitro tests using bovine blood. In the measurement accuracy test, measurement error between the commercial flow meter and the mass-flow meter was large under the flow rate of 1.0 L/min, because the sensitivity of the strain gauge is too low to accurately measure strain under low static pressure. Whereas, measurement error decreased at flow rates greater than 1.0 L/min, and the error became below ± 0.5 L/min. In the tracking performance test, the time delay was caused by a low-pass filter incorporated to the electrical circuit in order to compensate the inertia force.

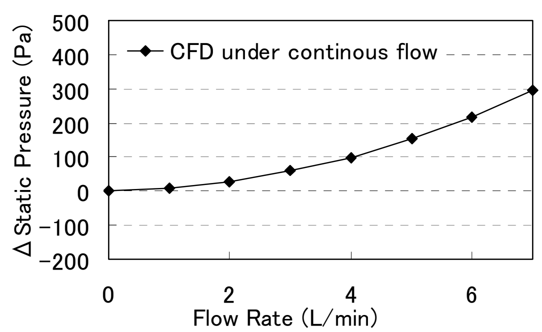

Fig. 5 Relationship between flow rate and differential pressure under continuous flow

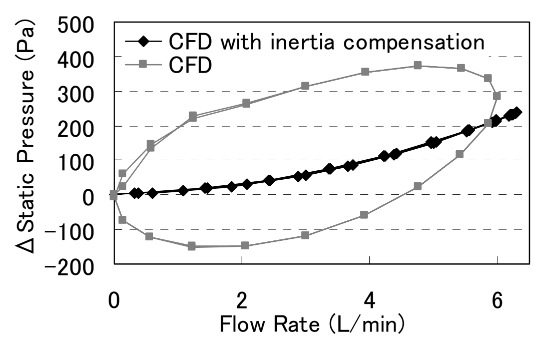

Fig. 6 Relationship between flow rate and the differential pressure under pulsatile flow

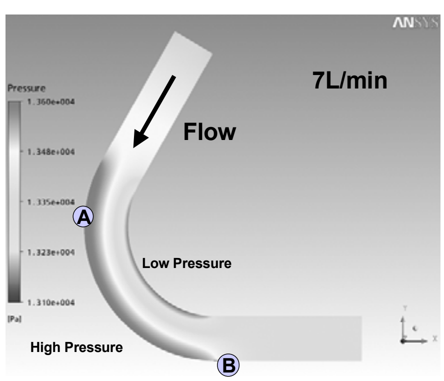

Fig. 4 Static pressure distribution to determine measurement position.

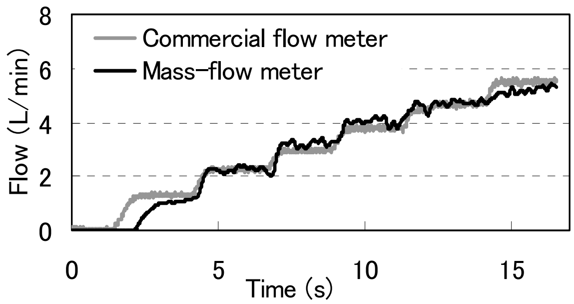

Fig. 7 Comparison of the measurement accuracy between commercial and mass-flow meter

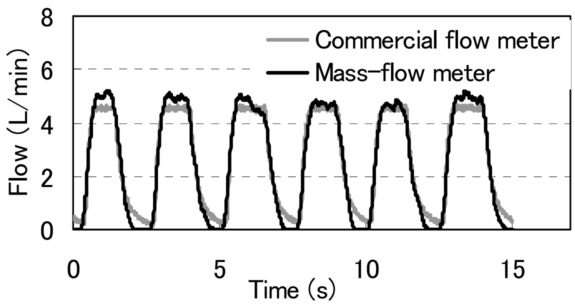

Fig. 8 Comparison of the tracking performance test between commercial and mass-flow meter

However, the time delay between the commercial flow meter and the mass-flow meter was 0.12 s. Therefore, it was found that the measurement performance of the mass-flow meter is sufficient to measure the blood flow in patients with an artificial heart.

IV. Discussion

In order to measure the blood flow rate, there are several conventional flow measurement methods, such as an ultrasonic flowmeter or an electromagnetic flowmeter. Compared to these conventional flow measurement methods, the developed mass-flow meter has some advantages. Since the mass-flow meter uses existing curved cannula, the size of the flow probe is small, and since the mass-flow meter adopts the strain gauge as the sensor, the electrical circuit is simple and is able to make miniaturization easier.

In order to apply the developed mass-flow meter, it is necessary to determine the calibration formula for the mass-flow meter in advance. The calibration formula changes depending on the specific weight of the working fluid as shown in Eq. 1. Therefore, the compensation method for the specific weight was investigated. In the in-vitro test using bovine blood, the specific weight of the bovine blood, whose hematocrit was adjusted to 30% with saline, was 1.039. In the past experiment using the glycerol water solution [4], the specific weight of 38 wt% glycerol water solution was 1.099. The measurement result using the calibration formula obtained by the 38wt% glycerol water solution was shown in Fig. 9 ("Glycerol solution"). The error was caused by the

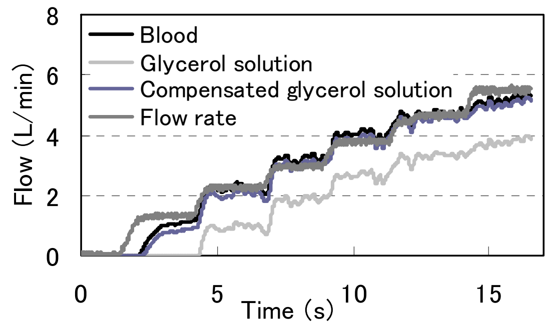

Fig. 9 Comparison between mass-flow rate determined by the calibration formula using the bovine blood and the mass-flow rate determined by the calibration formula using the glycerol solution.

differences in the specific weight. Therefore, the measurement results were compensated as follows;

$$\Delta P_{blood}=\Delta P_{Glycerol}\times\rho_{blood}/\rho_{Glycerol} \quad (5)$$

where ΔP_{blood} is differential pressure using the bovine blood, $\Delta P_{Glycerol}$ is differential pressure using the 38wt% glycerol water solution, ρ_{blood} is specific weight of the bovine blood and $\rho_{glycerol}$ is specific weight of the 38 wt% glycerol water solution. As a result of the specific weight compensation, the measurement results were obtained in Fig. 9 ("Compensated glycerol solution"). The flow rate determined by the calibration formula using the glycerol water solution was almost equivalent to that determined by the calibration formula using the bovine blood, when the specific weight was compensated. It was found that the calibration formula was able to determine in advance.

V. Conclusion

We developed a miniaturized mass-flow meter using a curved cannula. Based on the CFD analysis, the optimal design of the mass-flow meter was determined. In *in-vitro* evaluation tests, we confirmed that the noninvasive miniaturized mass-flow meter is able to accurately measure the mass-flow rate continuously and noninvasively for an artificial heart.

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