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Noninvasive Blood-Flow Meter Using a Curved Cannula with Zero Compensation for an Axial Flow Blood Pump

Ryo Kosaka, Kyohei Fukuda, Masahiro Nishida, Osamu Maruyama, Takashi Yamane

Abstract— **In order to monitor the condition of a patient using a left ventricular assist system (LVAS), blood flow should be measured. However, the reliable determination of blood-flow rate has not been established. The purpose of the present study is to develop a noninvasive blood-flow meter using a curved cannula with zero compensation for an axial flow blood pump. The flow meter uses the centrifugal force generated by the flow rate in the curved cannula. Two strain gauges served as sensors. The first gauges were attached to the curved area to measure static pressure and centrifugal force, and the second gauges were attached to straight area to measure static pressure. The flow rate was determined by the differences in output from the two gauges. The zero compensation was constructed based on the consideration that the flow rate could be estimated during the initial driving condition and the ventricular suction condition without using the flow meter. A mock circulation loop was constructed in order to evaluate the measurement performance of the developed flow meter with zero compensation. As a result, the zero compensation worked effectively for the initial calibration and the zero-drift of the measured flow rate. We confirmed that the developed flow meter using a curved cannula with zero compensation was able to accurately measure the flow rate continuously and noninvasively.**

I. INTRODUCTION

The implantable blood pump for the left ventricular assist system (LVAS) has made significant progress as a bridge to heart transplantation or as permanent implantation [1]. Patients with serious heart failure using the LVAS have been discharged from the hospital. The inlet cannula of the LVAS is connected to the apex of the left ventricle, and the outlet cannula of the LVAS is connected to the aorta. By delivering blood flow from the left ventricle to the aorta, the LVAS assists the cardiac function of the left ventricle. For discharged patients implanted with the LVAS, in order to monitor the condition of patients and the driving condition of the blood pump, blood flow should be measured continuously and noninvasively. However, reliable determination of blood-flow rate has not yet been established for clinical usage. Commercially available flow meters that use ultrasound waves and electromagnetic force are so large that implantation in the body is difficult. Currently, a flow estimation method has been proposed [2]. This estimation method estimates the flow rate based on the power consumption and the rotational speed of the blood pump. However, many of the proposed flow estimation methods are directly affected by mechanical friction losses of the contact-bearing and by changes in fluid viscosity. Furthermore, although the power consumption of the centrifugal blood pump has a linear relationship with the pump flow rate, the relationship between the power consumption of the axial flow blood pump and the pump flow rate is inherently nonlinear. Therefore, it is difficult to estimate the flow rate in the axial flow blood pump.

We previously developed a noninvasive blood-flow meter using a curved cannula to measure the blood-flow rate [3]. The developed flow meter has a simple mechanism, a simple electric circuit, and is independent of mechanical friction losses and fluid viscosity. However, since a strain gauge was used as the sensor element, the initial calibration between the output of the strain gauge and the flow rate was complicated. Furthermore, the zero-drift of the strain gauge caused measurement error of the flow rate.

The purpose of the present study is to develop a noninvasive blood-flow meter using a curved cannula with zero compensation for an axial flow blood pump and to evaluate the measurement performance of the developed flow meter using a mock circulation loop that can reproduce ventricular suction.

II. MATERIALS AND METHODS

A. Principle of flow measurement

Some implantable artificial hearts connect the blood pump to the body using a curved cannula. Therefore, the curved cannula was used as the sensing probe of the blood-flow meter. First, the principle of the flow measurement using the curved cannula was analyzed. In the curved 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 ΔP is the static pressure increase due to centrifugal force, ρ is the mass density, ω is the angular velocity, and r_0 and r_1 are the inner and outer radius, respectively, of the curved cannula. Therefore, the angular velocity corresponding to the flow rate can be measured using the differential pressure caused by the centrifugal force.

Based on Eq. 1, in the absence of a flow, only static pressure affects the cannula wall. Whereas, if a flow is present, both static pressure and centrifugal force caused by the flow rate act on the wall of the curved area in the cannula. Therefore, the developed flow meter

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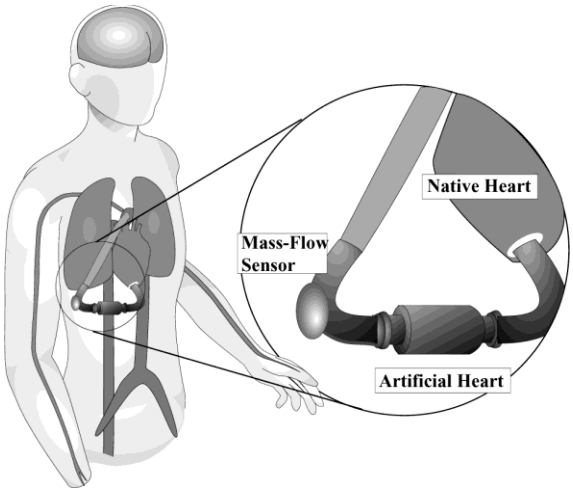

Figure 1 Developed noninvasive blood-flow meter

measured the flow rate as the increase in inner pressure in the curved area using two strain gauges. The first strain gauge was attached to the outside of the curved area to measure the centrifugal force and the static pressure. The second strain gauge attached to the side of the straight area to measure the static pressure for the static pressure compensation. The flow rate could be determined by the differences in output from the two gauges.

B. Zero compensation algorithm

The developed flow meter measures the inner static pressure from the surface strain of the tube using the strain gauge. The relationships between the outputs of the two strain gauges and the static pressure are obtained at a flow rate of 0 L/min, as follows:

$$p_0 = \alpha_0 \times \varepsilon_0 + \beta_0$$
$$p_1 = \alpha_1 \times \varepsilon_1 + \beta_1 \quad (2)$$

where p_0 and p_1 are the static pressures in the straight and the curved areas, respectively. ε_0 and ε_1 are outputs of the strain gauges in the straight and the curved areas, respectively. α_0, α_1, β_0, and β_1 are coefficients. From Eq. 1, the flow rate is determined using the following first-order approximate equation:

$$\mathrm{F} = \alpha_\mathrm{f} \times (\mathrm{p}_1 - \mathrm{p}_0) + \beta_\mathrm{f} \quad (3)$$

where F is the flow rate. α_f and β_f are coefficients. Therefore, from Eqs. 2 and 3, the calibration formula is expressed as follows:

$$F = \alpha_f \times \{(\alpha_1 \times \varepsilon_1 + \beta_1) - (\alpha_0 \times \varepsilon_0 + \beta_0)\} + \beta_f \quad (4)$$

In a previous study, the zero-drift of the strain gauge was found to be caused by changing the zero-points of the calibration formula indicated by β_0 and β_1 in Eq. 2. However, the gains of the calibration formula indicated by α_0 and α_1 in Eq.1 were constant [2]. Therefore, the coefficients related to the zero-drift in Eq. 4 are combined as follows:

$$\mathrm{F} = \alpha_\mathrm{f} \times \{(\alpha_1 \times \varepsilon_1) - (\alpha_0 \times \varepsilon_0)\} + \gamma \quad (5)$$

where γ is the coefficient related to the zero-drift. The gains, α_f, α_0, and α_1, were constant. The unknown parameter of the calibration formula was the zero point, γ.

In order to perform the zero compensation without using the flow meter, the zero point γ of the calibration formula was able to be compensated for as follows:

$$\gamma = F_{est} - \alpha_f \times \{(\alpha_1 \times \varepsilon_1) - (\alpha_0 \times \varepsilon_0)\} \quad (6)$$

where F_{est} is the estimated flow rate.

The flow rate was estimated using the two driving conditions. First, the initial driving condition was used for the initial calibration. In clinical use, before the pump is started, the pump is filled with saline. The inlet and outlet of the pump are closed. Therefore, the estimated flow rate under this condition was determined to be 0 L/min. Second, the suction condition for a very short time was used for the zero compensation of the measured flow rate. The suction condition occurs when the driving conditions changed suddenly, such as over pumping or physiological changes. Under this condition, the inlet cannula connected to the left ventricular apex pulls on walls of the natural heart at the end-systole period. Therefore, the estimated flow rate under this condition was determined to be 0 L/min. It is reported that the suction condition occurred in approximately 5 % of the pump flow data clinically collected from approximately 100 patients [4]. Therefore, the proposed zero compensation method is considered to be performed using the suction condition that happens to occur without purposely causing the suction condition.

In order to detect the suction condition automatically, the simple algorithm for the suction detection was constructed based on the past animal experiments. A 1.0-Hz low-pass filter was used to eliminate high-frequency noise. The average flow rate, F_{5sec_ave}, and the average minimum flow rate, F_{5sec_min}, for five seconds were calculated. The equation for the detection of the suction condition is obtained as follows:

$$F_{5\mathrm{sec}\_ave} - \left(F_{5\mathrm{sec}\_ave} - F_{5\mathrm{sec}\_min}\right) \times 1.25 > F_{min} \quad (7)$$

where F_{min} is the measured minimum flow rate. If the measured flow rate satisfies Eq. 7, the current condition is determined as the suction condition.

Under these two conditions, since the estimated flow rate is determined as 0 L/min, the calibration formula is able to be established by the proposed zero compensation method, based on Eq. 6.

C. Developed noninvasive blood-flow meter

The developed blood-flow meter using a curved cannula is shown in Fig. 2. The bending radius was 30 mm, and the bending angle was 120º. The inner and outer diameters were 12 and 14 mm respectively. A thin part of a wall was manufactured in the measurement area in order to adequately measure strain. The wall thickness in the smallest area was 150 μm. Micro-strain gauges of 0.2 mm in length (specially ordered from Nissho Electric Works Co. Ltd., Tokyo, Japan) were used as sensors. The first gauges were attached to the curved area to measure static pressure and centrifugal force, and the second gauges were attached to straight area to measure static pressure. Four strain gauges were used in each measurement area, and connected to the full Wheatstone bridge and the strain gauge amplifier (DSA-100A, Nissho Electric Works Co. Ltd.). The amplification factor was 10,000. The flow rate was then determined based on the differences in amplified output between the two sensors using Eq.5. The measured data were collected 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).

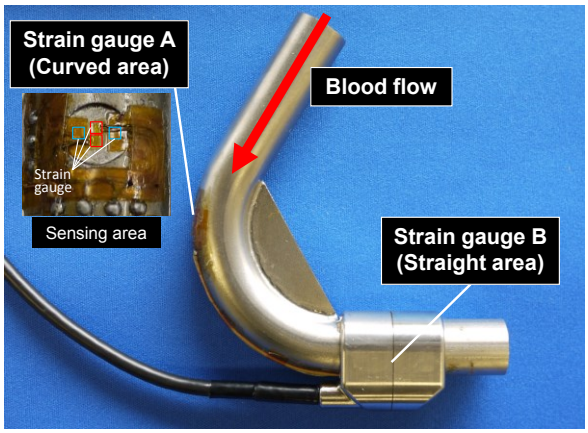

Figure 2 Developed blood-flow meter using a curved cannula.

D. *Evaluation test using a mock circulation loop*

In order to evaluate the measurement performance of the developed blood-flow meter with zero compensation, a mock circulation loop that could reproduce ventricular suction was constructed, as shown in Fig. 3 [5]. The mock circulation loop was composed of a specially constructed pulsatile pump with two plastic valves that modeled a natural heart, two compliance chambers that modeled aortic and venous compliance chamber, and a rotating clamp that modeled the total peripheral resistance. The developed rotary blood pump was attached as an LVAS, and a small bag having a volume of 25 ml was attached to the inlet port of the rotary blood pump in order to reproduce the ventricular suction. The developed blood-flow meter was attached to the outlet of the rotary blood pump. The mock circulation loop was filled with water. The pulsatile rate of the pulsatile pump was set at 62 bpm. In order to evaluate the measurement performances of the developed blood-flow meter, the pump flow rate was measured using a commercial flow meter (Transonic Systems Inc., Ithaca, NY, USA). The measured data were collected every 0.01 seconds using a measurement computer with an analog-to-digital card.

In order to evaluate the measurement performances of the developed blood-flow meter with zero compensation, four kinds of the experiments, including the evaluation of the mock circulation loop were performed:

1. Evaluation of the mock circulation loop. The mock circulation loop that reproduced the ventricular suction was evaluated by the waveform of the pump flow, when the rotational speed of the rotary blood pump was increased from 2,800 to 3,200 rpm.

2. Evaluation of zero compensation for the initial calibration. The measurement accuracy was evaluated, when zero compensation for the initial calibration was performed at the initial driving condition.

3. Evaluation of zero compensation for the zero-drift of the measured flow rate. The measurement accuracy was evaluated, when zero compensation for the zero-drift of the measured flow rate was performed at the suction condition.

4. Evaluation of the measurement accuracy for 24 h. The measurement accuracy of the developed blood-flow meter was evaluated for 24 h.

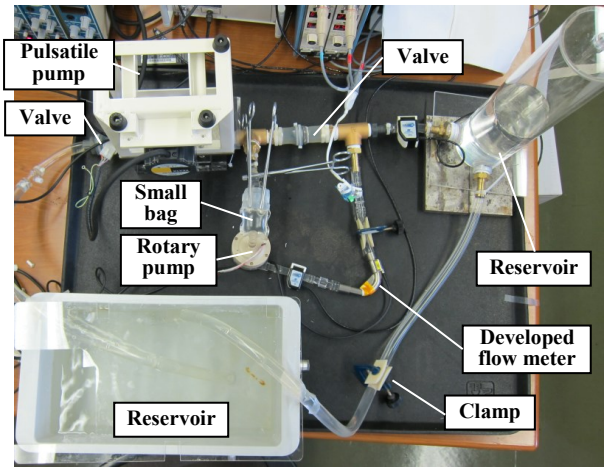

Figure 3 Mock circulation loop to evaluate the developed flow meter.

III. RESULTS AND DISCUSSION

Figures 4 and 5 show the evaluation results of the mock circulation loop that reproduces the ventricular suction. Figure 4 shows photographs of the small bag that modeled the left ventricular apex at the normal and suction conditions. At the normal condition, the rotational speed of the rotary blood pump was set to 2,800 rpm. The small bag was filled with water during diastole, as shown in Fig. 4(a). In contrast, under the suction condition, the rotational speed of the rotary blood pump increased to 3,200 rpm. The small bag shrank rapidly, and the inlet cannula of the rotary blood pump pulled on the wall of the small bag during diastole, as shown in Fig. 4(b). Figure 5 shows the waveforms of the pump flow at the normal condition and the suction condition. During diastole, the minimum flow rate was greater than 1.0 L/min at the normal condition, as shown in Fig. 5(a). In contrast, the minimum flow rate reached 0 L/min at the suction condition, as shown in Fig. 5(b). Therefore, the developed mock circulation loop was able to sufficiently reproduce the suction condition.

Figure 6 shows the evaluation result of the zero compensation for the initial calibration at the initial driving condition. At the beginning of the measurement test, the mock circulation loop was closed using a tube clamp, and the flow rate was kept at 0 L/min. The zero compensation for the initial calibration was performed in order to determine the calibration formula. In Fig. 6, after 4.2 s, the tube clamp was released from the circulation. The flow measurement was started using the commercial flow meter for the evaluation of the developed flow meter. As a result, the average measurement error between the commercial flow meter and the developed flow meter was less than 0.004 L/min, and the time delay was less than 0.1 s. Therefore, the measurement performance was enough to apply the clinical use, and the calibration formula was able to be determined accurately using the zero compensation.

Figure 7 shows the evaluation results of the zero compensation for the zero-drift of the measured flow rate at the suction condition. At the beginning of the measurement test, the pulsatile rate of the pulsatile pump was set to 62 bpm, and the rotational speed of the rotary blood pump was set to 2,800 rpm. The condition of the

mock circulation loop was normal. At this condition, the average measurement error between the commercial flow meter and the developed flow meter was approximately 0 L/min. In Fig. 7, after 3.8 s, the zero-drift of the flow rate occurred by purposely adjusting the offset in the strain gauge amplifier. The average flow rate measured by the developed flow meter was changed to 5.1 L/min. After 7.0 s, the rotational speed of the rotary blood pump was increased from 2,800 to 3,200 rpm. Ventricular suction occurred after 8.5 s. The suction condition was then automatically detected, and the zero compensation method was performed. After zero compensation, the average flow rate measured by the commercial flow meter was 2.6 L/min, and that measured by the developed flow meter without the compensation was 5.7 L/min. The measurement error increased to 3.1 L/min. In contrast, using the zero compensation, the average flow rate measured by the developed flow meter was 2.5 L/min. The measurement error was improved to 0.1 L/min. Therefore, the zero drift of the measured flow rate was able to be compensated for using zero compensation.

Figure 8 shows the evaluation results of measurement accuracy for 24 h. The average flow rate was maintained at approximately 2.0 L/min. As a result of applying the zero compensation to the developed flow meter, the measurement error decreased from 1.0 to 0.25 L/min.

Therefore, these evaluation tests demonstrated that the measurement performance of the developed blood-flow meter was sufficient to measure the blood flow for discharged patients with an LVAS.

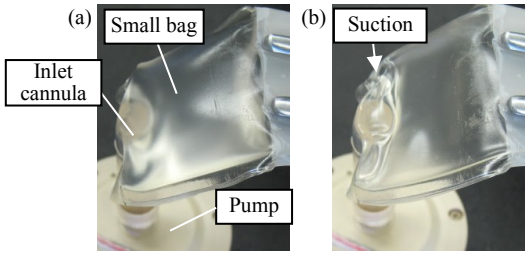

Figure 4 Photographs of the small bag that modeled a left ventricular apex at (a) the normal condition and (b) the suction condition.

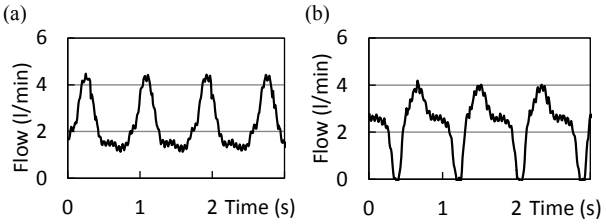

Figure 5 Flow waveforms at (a) normal and (b) suction condition

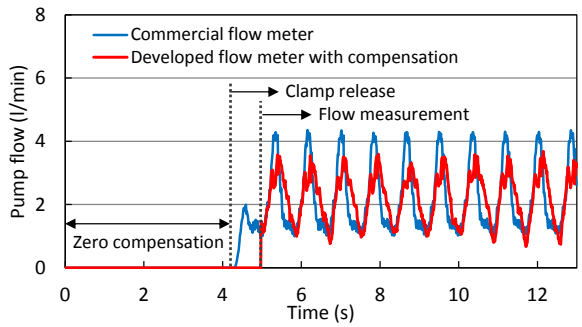

Figure 6 Effect of zero compensation on the initial calibration at the initial driving condition.

IV. Conclusion

In the present study, a noninvasive blood-flow meter using a curved cannula with zero compensation was developed for an axial flow blood pump, and the measurement performance was evaluated using a mock circulation loop. The proposed zero compensation worked effectively for the initial calibration and the zero-drift of the measured flow rate. We confirmed that the developed noninvasive blood-flow meter was able to accurately measure the flow rate continuously and noninvasively.

Acknowledgment

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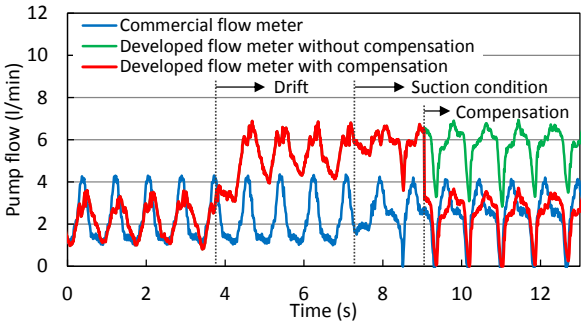

Figure 7 Effect of zero compensation on the zero-drift of the measured flow rate at the ventricular suction condition.

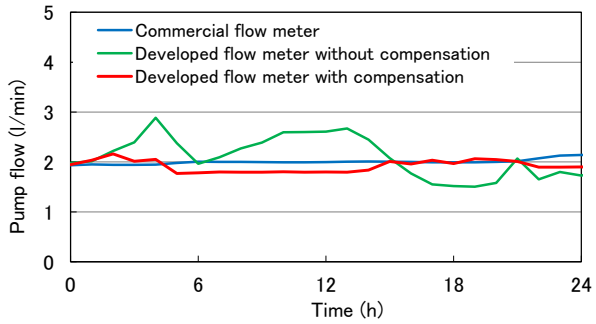

Figure 8 Results of measurement accuracy for 24 h.