CARDIO ANKLE VASCULAR INDEX (CAVI) AS THE NEW DIAGNOSIS TOOL FOR ATHEROSCLEROSIS

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Abstracts. Brachio Ankle Pulse wave velocity (baPWV) measurement is a useful methodology for the quantitative evaluation of the atherosclerosis. In the conventional method, the pulse wave of a brachial artery and an ankle was measured by applying air pressure with the help of a volume plethysmograph. However, since this method measures pulse wave in an arm and foot, it may be said that aortic PWV is not reflected though a large amount of past PWV data indicate aortic PWV. Furthermore, baPWV is influenced by blood pressure. In the baPWV machine, blood-pressure compensation is not carried out. Furthermore, the pulse pressure is measured by air pressure therefore any stimulus that exerts pressure on an artery may influence these results. Due to these reasons, a Cardio Ankle Vascular Index (CAVI) was proposed. The pressure wave form indicating the closing of the aortic valve appears in arterial pressure wave after the relatively fixed delay time. This delay is the time difference between the actual closing of an aortic valve and the measuring point. CAVI is calculated from ECG, PCG, brachial and ankle artery waveform using a special algorithm based on the thesis of stiffness parameter independent form blood pressure. The feasibility of CAVI was confirmed from the data after heart transplantation. Even after the exchange of the heart, CAVI showed stable value, though baPWV was significantly altered. Our data suggested that CAVI represents breakthrough in the diagnosis of atherosclerosis.

Introduction

Unfortunately, there is a rise in the cholesterol levels among the youth. Preventive medicine have becomes more and more important enen in Japan. However, till date, there is a few simple method for accurately measuring arteriosclerosis. In order to diagnose arteriosclerosis, pulse-wave-velocity (PWV) measurement is a useful methodology. However, a special technology is required. Especially, a veteran medical technologist has to measure the pulse-wave of a carotid artery. It is also not possible to ensure reproducibility of results unless the medical technology is excellent.

Recently, using the volume plethysmographic method, the pulse wave velocity of a brachial artery and an ankle is measured by applying air pressure. Since it was a relatively simple and useful method, it soon gained popularity. However, regarding the baPWV measured by this methodology, it was found that the PWV was highly influenced by several factors such as blood pressure, arteriosclerosis, autonomic nerves, etc. ...and so on. Subsequently, a new method was developed and the new parameter which takes into account the aortic pulse wave velocity has attracted considerable attention.

In this paper, a new diagnosis methodology referred to as Cardio Ankle Vascular Index (CAVI) was measured, tested, and compared with baPWV, and the results were discussed. Furthermore, data of the patients before and after the heart transplantation was evaluated in this study.

Cardio Ankle Vascular Index (CAVI)

Recently, baPWV has enabled simple measurement of atherosclerosis however, the following problems have been noted

1. Since baPWV measures the pulse wave velocity in on an arm and foot, it may be said that aortic PWV is not reflected, though the large amount of past PWV data indicate aortic PWV.
2. BaPWV is significantly influenced by blood pressure, therefore, the baPWV data does not reflect arteriosclerosis in some cases. In the old baPWV machine, blood-pressure compensation is not carried out.
3. Pulse pressure is measured by air pressure in the baPWV machine; hence, the result may be influenced by the pressure exerted on the artery by any stimulus.

These drawbacks limit the result in the clinical utility because in such cases the relevance of baPWV data is questionable.

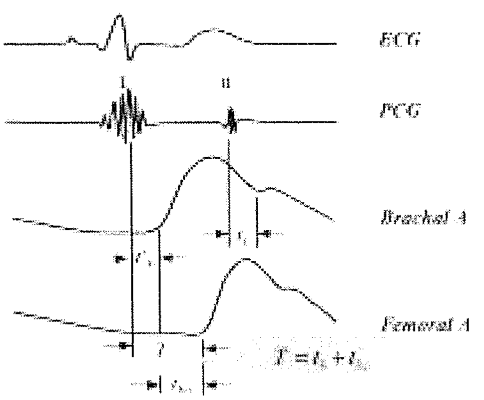

Fig.1 Time series data of the hemodynamic waveform. Starting with the uppermost tracing, an electrocardiogram, phonocardiogram, brachial arterial waveform, and ankle artery waveform are shown.

We aim to rectify the anomalies in PWV data that result from the influence of blood pressure using a simple technique that involves measuring PWV in the upper arm and the ankle.

The development of this new methodology is underway.

Time series data of the waveform are shown in the figure 1. Starting with the uppermost tracing, an electrocardiogram, phonocardiogram, brachial arterial waveform, and ankle artery waveform are shown. Simultaneously with the generation of the first sound, Mitral valve is closed. At the same time, an aortic valve opens. Subsequently, blood begins to flow into the aorta. The pressure on the arteries begins to increase after an interval that is equal to the time taken to transmit a wave. Simultaneously with the generation of the second sound, an aortic valve is closed. The closing of the aortic valve generates a notch in the arterial pressure. This notch, indicating the closing of the valve, appears in the arterial pressure wave after a fixed delay time. This delay time reflects the time difference in the generation of the second sound and that of the notch. This time difference is equal to the time delay in the actual closing of an aortic valve aid the measuring point. That is, t'b and tb are equal. This is because the time difference in transmitting the wave for the opening of the aortic valve is equal to that for closing. This concurrence is important because based on this phenomenon we can obtain measurement values similar to those of traditional PWV.

Prior to the invention of baPWV, PWV was measured on the carotid artery and the foot. The length of a carotid artery is almost equivalent to that of an aortic arch. Therefore, traditional PWV showed the transfer time of the pulse wave of a descending aorta. In order to imitate traditional PWV, baPWV uses the delay time between brachial artery and ankle artery. However, the carotid artery differs from the brachial artery, and the measured values differ if the arteriosclerosis is in the carotid artery or brachial artery. Moreover, the distance to the measuring point of a carotid artery differs from the distance to the measuring point of a brachial artery.

Thus, classic PWV and baPWV yielded different values, though negligible.

Due to this reason, results from past research studies will not be helpful in further examining baPWV.

In Cardio Ankle Vascular Index (CAVI), this problem was solved with a special algorithm. CAVI is measured from ECG, PCG, brachial artery waveform, and ankle artery waveform using a special algorithm for calculation. This data is mainly dependent upon the stiffness and compliance of the descending aorta, which enables the CAVI to use a vast amount of the past conventional PWV data.

This new method represents a breakthrough in rectifying pressure. In other words, this method is universally independent of a specific measurement area. Moreover, an important feature is that this method is compatible with conventional aortic PWV.

We want to engage in detailed research that aims at the standardization of the quantitative measurement of atherosclerosis.

CAVI and heart transplantation

Heart transplantation is the important medical methodology. However, a lot of papers reported that atherosclerosis tends to progress rapidly in a heart transplant patient. Various factors are reported as a cause of this problem. Therefore, the arteriosclerosis diagnostic method after heart transplantation is important. Various methods are used for diagnosis of arteriosclerosis. Since it is necessary to diagnose repeatedly, the un-destroying-method is desirable. However, it is difficult to diagnose the arteriosclerosis of the whole body correctly in non-invasively.

Pulse wave velocity (PWV) is an important diagnostic method. However, classic PWV is technically difficult and its reproducibility is low. Moreover, the gap of the data between hospitals is also large because of the technical differences. baPWV developed recently is simple methodology. It is not dependent on an inspection person and the reproducibility of this method is also high. However, this method is influenced by blood pressure and autonomic nerves.

Stiffness parameter β is reported to be not dependent on blood pressure. Recently, new stiffness parameter diagnosis machine called Cardio Ankle Vascular Index (CAVI) was developed in Japan. Then, the clinical evaluation is performed as a new index to diagnose the atherosclerosis.

In this research, we studied about the arteriosclerosis monitoring after the heart transplantation of newly developed CAVI.

Advance of the atherosclerosis after a heart transplant is an important problem. We examined this problem using CAVI. Seven patients after heart transplantation were used in this study.

Furthermore, measurement of baPWV and CAVI was performed before and after the heart transplant operation in a patient.

As the results, significant changing PWV before and after the operation of a heart transplant was observed in a patient. CAVI is measured before and after a heart transplant operation in the same patient, and a different result was obtained. CAVI did not show significant change before and after the operation of a heart transplant.

PWV and CAVI in seven patients of a heart transplant were measured. The average of seven examples was a very large value as compared with the normal value of the people-of-the-same-age group.

Before and after the heart transplantation, a blood vessel is the same blood vessel. In a short time, the atherosclerosis may not advance greatly. However, baPWV recorded the big increase. BaPWV is greatly influenced by a patient's blood pressure, amount of circulation blood, etc,...and so on. Therefore, baPWV is hard to be called stable parameter.

On the other hand, CAVI did not change before and after transplantation. This is a finding suggesting that CAVI is the stable parameter. Examination of the arteriosclerosis after heart transplantation is expected the stable parameter.

Therefore, CAVI is effective in the atherosclerosis diagnosis after heart transplantation.

As compared with the data of the people-of-the-same-age group, as for seven patients after transplantation, baPWV and CAVI showed a large value, suggesting the progress of the atherosclerosis..

From the data of this research, it can be concluded that CAVI is useful to the atherosclerosis diagnosis after heart transportation

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Evaluation of Flow Rate Estimation Method for Rotary Blood Pump with Chronic Animal Experiment

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***Abstract*— Rotary blood pumps are expected to be used as an implantable ventricular assist device (VAD). In the VAD system, flow rate is important for monitoring of the state of a recipient and for automatic control to maintain appropriate blood perfusion.**

To obtain flow rate of the pump without any sensors, we proposed a method of estimating flow rate with supplied power and rotational speed using a time series model. To evaluate the accuracy of the proposed estimation method from the aspect of long-term use, we implanted NEDO PI Gyro pumps in a calf and performed a chronic animal experiment.

Flow rate, supplied power and rotational speed were measured until post operation day (POD) 63, and the estimated flow rate was compared with the measured one. We confirmed that waveforms of the measured flow rate was sufficiently similar to the measured one, and correlation between them was higher than 0.9 in all the datasets. On the other hand, the root mean square error increased after 15 days. This error was probably due to the change in physiological condition, the operating point of the pump, or mild intima formation.

I. INTRODUCTION

Rotary blood pumps are widely used as a ventricular assist device (VAD), and developed by many research groups to realize implantation in the patient's body. When the VAD is implanted, then monitoring for the pump parameters, such as flow rate and pressure difference, is one of the important components in the VAD system.

In addition, such an assist device is usually implanted in the patient suffering from heart failure so severely that blood perfusion cannot be kept only by the intrinsic heart and pump flow must be assisted by the device. This means that the outflow of the VAD should be decided by an automatic control system to adapt physiological demand of the recipient. Many control methods for the blood pump have been proposed, and usually, they need flow rate or pressure as indices for the control.

On the other hand, sensors for measuring flow rate and pressure have problems such as thrombus formation, insufficient durability, and need for calibration. To obtain flow rate and pressure without such sensors, many research groups have tried to estimate flow rate and pressure difference using rotational speed of the impeller and supplied electric power to the actuator[1][2][3].

However, most of advanced researches have evaluated the accuracy of their estimation methods only in mock circulations or acute animal experiments. Tsukiya[1] and Ayre[4] reported cases of chronic experiment and achieved estimation in good accuracy. However, Ayre mentioned this success depends on the pump characteristic.

To evaluate the accuracy of flow rate estimation in the case of the PI Gyro pump, which was developed at Baylor College of Medicine, we have performed a chronic animal experiment. In this paper, the accuracy will be verified by comparing the estimated flow rate with the measured one.

II. MATERIAL AND METHOD

A. Estimation Method

Our flow rate estimation method is based on the method proposed by Yoshizawa et al.[5][6]. To correlate flow rate with rotational speed, supplied power, and other indices, we used an ARX model given by (1).

$$y(k)+\sum_{i=1}^{L}a_i y(k-i)=\sum_{j=1}^{3}\sum_{i=0}^{M_j}b_{ij}u_j(k-i)+w(k) \qquad (1)$$

Inputs $u_j(k)$ and output $y(k)$ are written as $[u_1, u_2, u_3] = [VI/N, N, K]$, and $Q(k)$, where $Q(k)$ is flow rate, I is electric current, and N is rotational speed, respectively. V is a constant voltage of 15 V.

K is given by (2), and represents a steady gain from supplied power to rotational speed. This steady gain K is introduced to compensate changes in physiological environment such as viscosity of blood.

$$K(k)=\frac{\sum_{i=1}^{n}N(k-i+1)}{\sum_{i=1}^{n}VI(k-i+1)} \qquad (2)$$

In this paper, the orders of the model L, M_j, and the data length n were 0, [5, 5, 1] and 1000, respectively.

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Fig. 1 shows the idea of flow rate estimation. In practical use, we can calculate $y(k)$ with measured $u_j(k)$ and parameters a_i and b_{ij} that should be identified before implantation of the VAD.

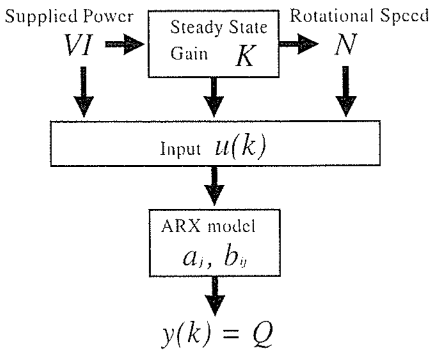

Fig. 1. Idea of flow rate estimation based on supplied power and rotational speed

B. Animal Experiment

Schematic illustration of measurement system for the animal experiment is shown in Fig. 2.

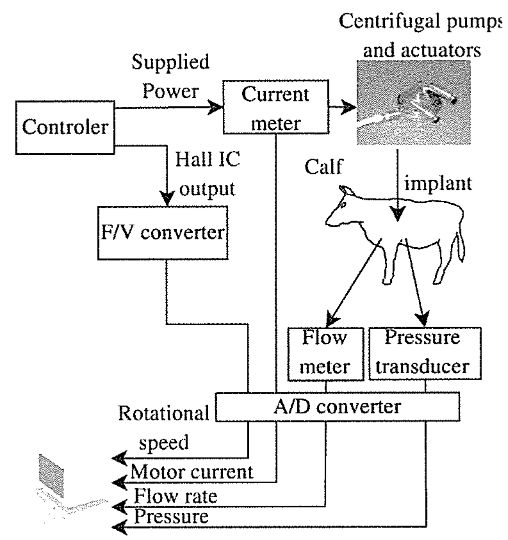

Fig. 2. Schematic illustration of measurement system

Two NEDO PI Gyro pumps (Miwatec Co., LTD.) were implanted in a calf, as a biventricular assist device (BVAD), which consists of left and right VADs. In the LVAD, blood was drained from the left ventricle apex with a titanium tip and a silicon cannula, and the outlet of that was grafted to the descending aorta.

Ultrasonic flow probe (Transonic Co., LTD. PAX-Series, ϕ = 12mm) was placed on the graft. Rotational speed and supplied power were measured with a F/V converter and a current meter in the controller of the VAD, respectively. Left ventricular pressure (LVP) was also measured.

Analog outputs of these measurement devices were stored with Ponemah Physiology Platform (Gould Instrument Systems, Inc.), at 500 Hz of sampling frequency. Measurement was performed every 2 days until post operation day (POD) 63, except POD 3 and 61, while the calf was on sitting position, except POD 19.

C. Evaluation of estimation method

Parameters of an ARX model were identified with data acquired on POD 11 and 13. Measurement was performed twice on POD 11 and 13, and we set rotational speed different in each measurement. Flow rate was estimated with every datasets, and estimated flow rate of 20 seconds were obtained.

Accuracy of the estimation was evaluated with the root mean square error (*r.m.s.e*) and the correlation (r), given by (3) and (4), respectively.

$$r.m.s.e. = \sqrt{\frac{1}{K_D}\sum_{k=1}^{K_D}\{y(k)-\hat{y}(k)\}^2} \tag{3}$$

$$r = \frac{\sum_{k=1}^{K_D}\{y(k)-\bar{y}\}\{\hat{y}(k)-\bar{\hat{y}}\}}{\sqrt{\sum_{k=1}^{K_D}\{y(k)-\bar{y}\}^2\cdot\sum_{k=1}^{K_D}\{\hat{y}(k)-\bar{\hat{y}}\}^2}} \tag{4}$$

where, $\hat{y}$ is estimated flow rate, and K_D is the number of data, respectively.

III. RESULTS

A. Evaluation of Waveform Estimation

Fig. 3 shows waveforms of measured electric current, LVP, and flow rate, and estimated flow rate of the left pump. In this case, *r.m.s.e.* and r were 0.80 L/min and 0.964, respectively. The error *r.m.s.e* was not so large but the figure indicates that most of error is due to small vibration and the rising edge of the estimated waveform. It means that there is no bias error between the measured and the estimated waveforms.

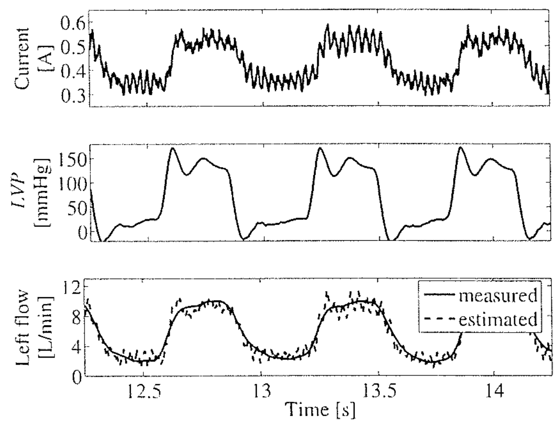

Fig. 3. Waveforms of measured data and estimated flow rate (POD 11).

Fig. 4 shows the measured and the estimated waveforms in the case of reverse flow was found. In this case, *r.m.s.e.* and *r* were 1.52 L/min and 0.958, respectively. Reverse flow is one of the unfavorable events, so this should be detected by the measurement system for the VAD. This phenomenon was not included in the datasets used for identification of the parameters. However, it was estimated successfully.

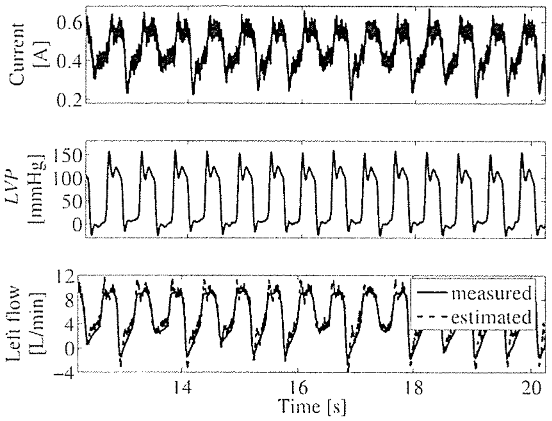

Fig. 4. Flow pattern estimation in case of reverse flow (POD 19).

B. Evaluation of Long-term Use

Fig. 5 shows the trend of *r.m.s.e.* and *r* during the experiment. From POD 11 to 21, *r.m.s.e* was not so large, but after that, *r.m.s.e.* tended to increase as day goes by. On the other hand, *r* was higher than 0.90 in all the datasets.

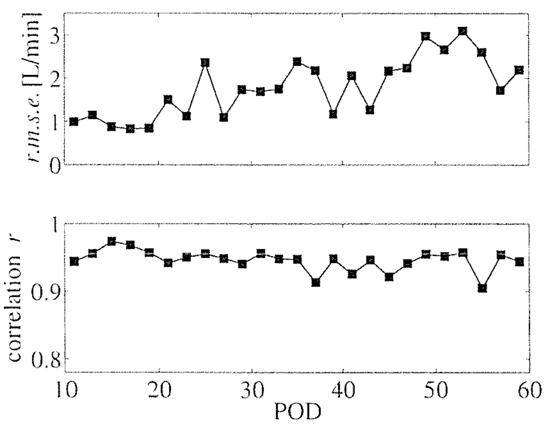

Fig. 5. Trend graph of *r.m.s.e.* and *r* during experiment.

k

IV. DISCUSSION

A. Evaluation of Waveform Estimation

Fig. 3 and Fig. 4 show that estimated flow rate could simulate the profile of measured one and that our method could estimate flow rate with good accuracy. The value of *r.s.m.e.* was not so small. However, most of error was due to the small vibration and the overshoot in the estimated waveform. A low pass filter (LPF) seems appropriate to neglect such a small vibration but it will also remove the steep change in the rising edge. Thus, *r.m.s.e.* will not be improved.

The previous studies [7][8] mentioned that electric current is affected by changes in preload particularly in the case of the pump with a small impeller. Our method can cope with dynamic response of flow rate to the change in preload because the ARX model has capability of such change in input information. However, our method cannot compensate for drastic shift of the operating point that would change in the parameters of the model. If we have a technique that can automatically interpolate the change in parameters depending on the shift of the operating point, the accuracy of the estimation will be improved. Fuzzy logic or artificial neural networks would have such capability.

B. Evaluation of Long-term Use

Increase in estimation error after POD 25 suggests that the increase was due to several reasons.

The first one is the variation of physiological condition. Errors from POD 11 to 19 were almost the same, but after POD 25, a bias error was found between the measured and the estimated waveforms. It can be guessed that the implantation of the blood pump was so invasive that physiological condition was different among a few days after the surgery, the recovery period and the stable period. If the change in physiological condition strongly influences the estimation capability, it will be difficult for our method to cope with such effects.

Second possible reason is the change in the operating point of the pump. In this experiment, flow rate decreased slightly as day goes by, so rotational speed was also increased to keep a certain level of flow rate. If this reason is dominant, interpolation technique mentioned above will be useful.

Third reason is mild intima formation at the outflow graft, which was found during an operation on POD 63. Judging from the decrease in amplitude of flow rate and the change in the waveform, we can guess that an occlusion at the outlet of the pump occurred.

Our method includes the term K to compensate such a physiological change. However, it is difficult to fully represent nonlinearity in circulation in a wide range as long as a linear model is used. To deal with this problem, we have to gather more datasets including various conditions to identify the model, and then we will be able to obtain more suitable parameters or use several sets of parameter according to the operation points to cope with such nonlinearity.

C. Limitation

In this experiment, the data to identify the parameters of the estimator was obtained on POD 11 and 13. In clinical use, however, it is impossible to measure flow rate after the implantation. The data for identification should be obtained during surgery. In our experiment, however, it could not be done because of a ventricular fibrillation.

It is desirable that generalized parameters for the estimator can be approximated before the implantation. In addition, if we can build a mock circulatory system simulating physiological condition shown in these results, the system also helps to identify parameters more shortly and easily. However, it is difficult to realize such a system until more detailed fluid dynamics of the actual cardiovascular can be clarified and there is a new technique simulating the clarified dynamics regardless of whether the system is composed of mechanical tanks or computer simulated one.

V. CONCLUSION

Our estimation method was evaluated with the data acquired from a long-term animal experiment. Estimation with good accuracy was confirmed until 15 days after the identification of the parameters. However, *r.s.m.e.* started to increase after POD 25 and a bias error was found. This problem has to be solved to use the estimation method for clinical use.

On the other hand, correlation r was higher than 0.9 in all the acquired data, and estimated flow rate could simulate the profile of measured one. Electric current waveform was affected by the preload, which was LVP in this experiment, so it is the main reason of increase in *r.m.s.e.*. To cope with this defect, we have to introduce other new paradigm or model to accurately simulate the actual circulatory system assisted by the VAD.

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Detection and Avoiding Ventricular Suction of Ventricular Assist Devices

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Abstract— **Continuous flow blood pumps, such as axial flow and centrifugal pumps, have been gaining interest as circulatory devices for total artificial hearts (TAHs) and a biventricular assist device (BVAD) because of their smaller size and simpler structure compared to pulsatile pumps. However, continuous flow pumps are more prone to suction of the left ventricle than pulsatile pumps are. Sudden increases in flow rate to meet changes in physiological demand, especially in the left pump, often cause ventricle suction. In this study, a control algorithm to prevent suction from occurring in the left ventricle by controlling the rotational speed of the right pump, instead of reducing the cardiac output of the left pump, was developed and investigated. The method was tested in acute animal experiments with calves. The results indicate that this proposed method is capable of preventing suction and could simultaneously maintain circulatory control. A key advantage of this control system is that flow rates can be maximized while avoiding ventricle suction conditions particularly when the circulatory system is unstable such as in a the first few days after operation.**

I. Introduction

Centrifugal blood pumps offer advantages for long-term total implantation because of their small size and high efficiency compared with pulsatile pumps. Presently, several groups are developing continuous-flow blood pumps for use as a total artificial heart (TAH)[1], and a biventricular assist device (BVAD) systems[2][3].

With centrifugal pumps, blood inflow and outflow rates are simultaneous, continuous and equal. That is why, in continuous flow artificial hearts, a sudden large change in venous return to the heart and, therefore, pump inflow rate may produce negative pressures at the tip of the inflow cannula and result in the heart wall being sucked into the inflow cannula which blocks blood flow and interrupts normal circulatory control.

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Inflow suction is most likely to occur when the circulatory condition is unstable such as during the early post-operative period. Therefore, it is important to control the pump flow rate and prevent inflow suction during periods of unstable circulatory conditions.

Yuhki et al. [4] and Fu et al. [5] proposed control algorithms to reduce atrial suction by decreasing pump flow rate after detecting the occurrence of atrial suction through analysis of motor current waveforms. For a BVAD or TAH, since the pumps support all or almost all of the circulation, temporarily stopping or reducing left pump flow rate to alleviate atrial wall suction could have deleterious effects including interruption of blood circulation to vital organs and the potential for thrombus formation inside the pump and cannula.

Our group has developed an automatic control system, where right pump flow rate is varied to maintain a constant left atrial pressure, that is responsive to changing physiologic demands and prevents atrial wall suction, which often occurs in continuous flow blood pumps [6].

For this method, the inflow cannulas were inserted into the atriums, therefore atrial pressures can be measured to detect inflow cannula suction. However, when inflow cannulas are implanted into the ventricles, inflow suction may occur without a simultaneous change in atrial pressure due to sudden ventricular collapse.

The purpose of this study is to evaluate a new control method to alleviate inflow suction of the left ventricle by increase right pump flow in biventricular bypass configuration in which centrifugal blood pumps are implanted between the ventricles and arteries.

II. Methods

A. Detection and Alleviation of Suction

In this study, blood pumps were installed in a BVAD fashion with the inflow cannulas implanted in the right and left ventricles. Although ventricular inflow cannula suction can be detected by monitoring ventricular pressure, this is impractical over the long term because of inadequate durability and reliability of indwelling pressure sensors. In addition, it is difficult to detect inflow suction by measuring the mean pump outflow rate because flow reductions are caused by not only inflow suction but also by increased afterload to the pump.

The pump outflow waveform during suction condition generally has negative spikes unlike that when flow reductions are caused by an increase in arterial pressure. Therefore, in this study, the index of suction (I_s) was determined using the following formula:

$$I_s = \mathrm{LPF}\{(Q_{mean} - Q_{min})/(Q_{max} - Q_{min})\} \quad (1)$$

where, LPF{ } denotes the low-pass filtering operation, Q_{mean}, Q_{max} and Q_{min} are the mean , maximum and minimum values of flow measured for 2 seconds, respectively. I_s is 0.5 when the mean value is the center of oscillation like sine wave. I_s is increased in a touch of a suction condition.

B. Animal Study

Animal experiments were conducted in order to acquire data during inflow suction conditions and to investigate the proposed suction alleviation method. Two Gyro PI710 pumps (Baylor College of Medicine) and actuators were implanted in a BVAD fashion. The experimental animals were healthy half-Dexter calves. All animals received human care in compliance with the Guide for the Care and Use of Laboratory Animals, prepared by the Institute of Laboratory Animal Resources, Commission on Life Sciences, National Research Council, and published by the National Academy Press, revised 1996.

The left pump was implanted in a left heart bypass fashion between the left ventricular apex and the descending thoracic aorta. The right pump was implanted in a right heart bypass fashion between the right ventricular outflow tract and the main pulmonary artery. In one study, ventricular fibrillation was induced after surgery. In this case, the alleviation of left ventricular suction was investigated by increasing the right pump flow rate.

Measurements taken were rotational speeds of the right and left pumps (*NR* [rpm], *NL* [rpm]), aortic pressure, and pulmonary artery pressures (*AoP* [mm Hg], *PAP* [mm Hg]), left atrial pressure (*LAP* [mm Hg]), central venous pressure (*CVP* [mm Hg]), the right and left pump flow rates (*QR* [L/min], *QL* [L/min]) and pulmonary artery flow (*PAF* [L/min]). The flow rates were measured using an ultrasonic flowmeter (Transonic System, Inc., NY). All data were sampled at 50ms intervals and stored on a computer hard disk by Ponemah system (GOULD Instrument Systems, Inc., OH).

III. Result

Fig. 1 shows the changes in *QR*, *CVP*, *NR*, and I_s when the pump speed was increased. In this experiment, the imprint of suction was recognized at the ventricular wall after the experiment though a definite suction condition in which the pump flow was zero was not occurred. With increasing pump speed, the mean flow rate increases despite the occurrence of inflow suction without a change in venous pressure. This phenomenon is different from that when the inflow cannula is located in the atrium, and indicates that it is difficult to detect suction by monitoring the mean value of pump flow. On the other hand, I_s increases with the deterioration of suction.

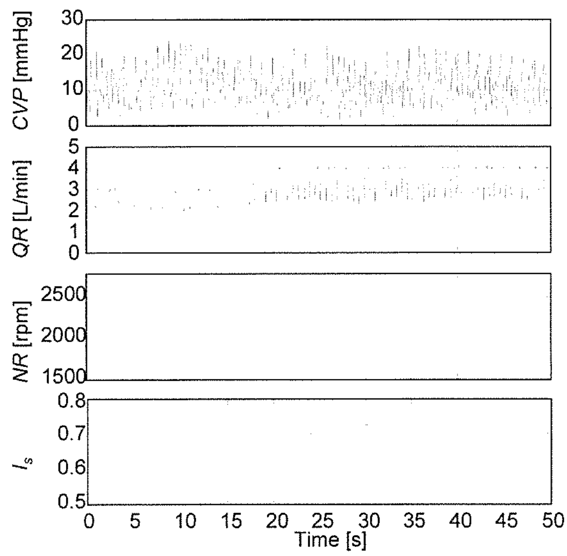

Fig. 1. Changes in CVP, QR, NR, and Is when suction is produced by increasing the pump speed.

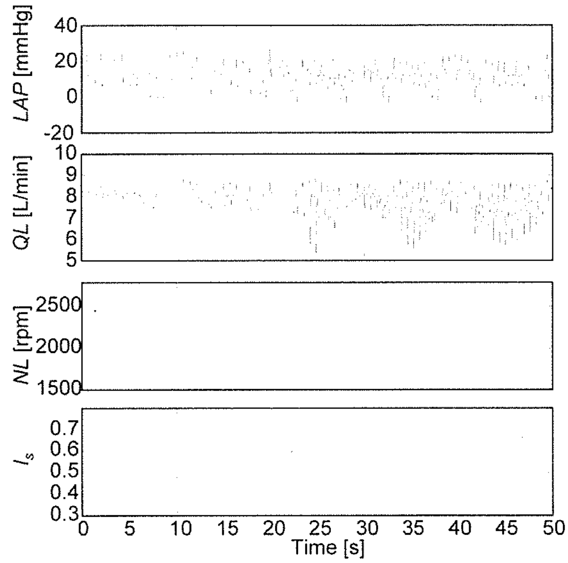

Fig. 2. Homodynamic trace illustrating that inflow suction may occur (QL around 30, 40 and 50 seconds) while pump speed remains constant.

Fig. 2 illustrates that inflow suction may occur (*QL* at 30, 40 and 50 seconds) while pump speed remains constant. In this case, the cause of suction was most likely due to a decrease of inflow (pulmonary venous return) to the left ventricle caused by respiration.

Fig. 3 shows the result of left ventricular inflow suction alleviation by increasing the right pump speed and flow. When the flow rate of right pump is increased, cancellation of left pump suction is instantaneous.

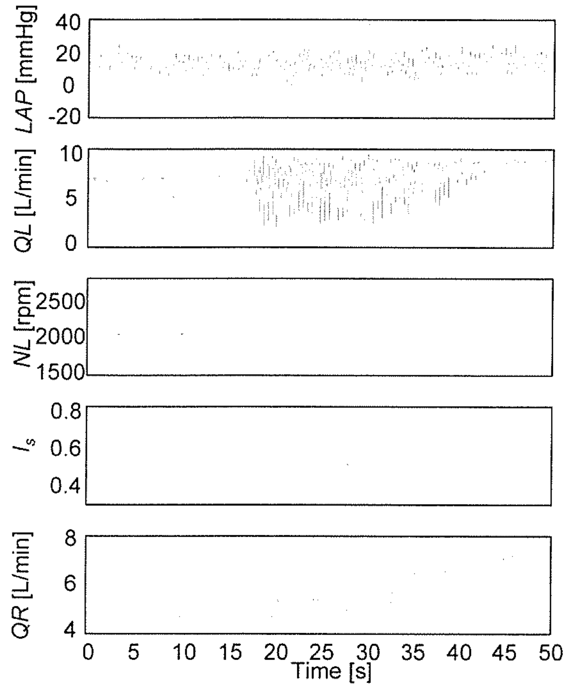

Fig. 3. Changes in *CVP*, *QR*, *NR*, and I_s when suction is produced by increasing the pump speed.

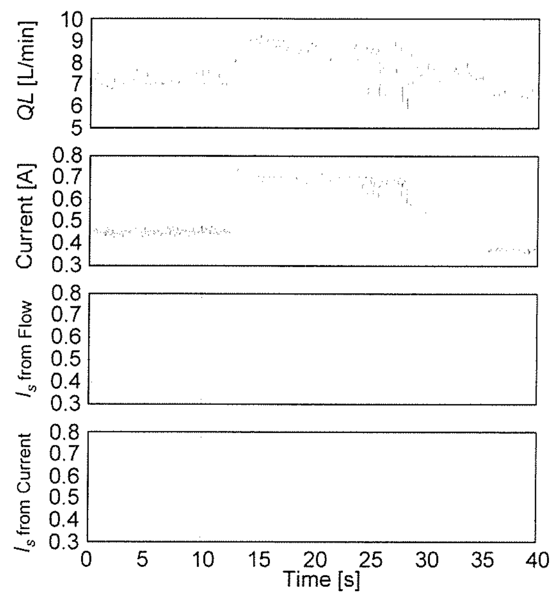

Fig.4. Comparison between the suction index determined from pump flow and that from motor current.

IV. Discussion

A. Suction Detection

These studies demonstrated that the mean pump flow rate may increase during suction conditions when the inflow cannula is located in the ventricle as shown in Fig. 1. Therefore, measurement of mean flow rate alone is not able to detect the beginning of suction. Most suction detection methods object the suction caused by an increase of pump flow and use the rotational speed information in order to distinguish from a flow decrease caused by regurgitation. However suctions may also occur by the change in balance of circulation even when the rotational speed remains constant as shown in Fig. 2. The Is increases when the foregoing suction condition occurs.

In general, the relation between motor current I, speed N and flow Q is expressed as:

$$KI = JdN/dt + a_1N + a_2NQ + T \qquad (2)$$

where K is torque constant, J expresses the inertia, a_1 and a_2 are constant coefficients, and T is the kinetic friction coefficient of the rotor axis. Since N is almost a constant value, the right-hand side of Equation 2 can be regarded as a first-order equation on Q. Therefore, I_s can be calculated from motor current alone. Fig. 4 compares the suction index determined from pump flow and that from motor current. This result indicates that Is may be calculated from motor current. Furthermore, when rotational speed is not regarded as a constant, I_s can be also calculated without flow by using a flow estimation method such as the authors have previously proposed [7].

B. Suction alleviation

As shown in Fig. 3, the result indicates that the regulation of right pump flow rate alleviates left pump suction. This result supports our previously reported method which is the balance control to prevent left atrial wall suction. However, there is an important difference, to pay attention to, when the inflow cannulas are implanted in the ventricles. In the case where the inflow cannulas are located in the atriums, the atrial pressure will decrease during a suction condition. On the other hand, when inflow cannulas are located in the ventricles, the atrial pressure rises because suction prevents blood flow into ventricle due to ventricular collapse.

In this situation, the flow balance controller that uses atrial pressure feedback will worsen the suction condition because the controller may reduce right pump flow when the left ventricle is collapsed by suction and increase right pump flow when the right ventricle is collapsed in order to regulate the atrial pressures equal.

The advantage of this control method is that prevention of suction and left circulatory control can be implemented almost entirely independent of each other. In other words, it is possible to suppress suction or prevent it from occurring, without interrupting normal circulatory control. This method is particularly effective when the bypass ratio is high or a total artificial heart is implanted.

V. Conclusion

In this study, a novel method to alleviate suction of the left ventricle by increasing right pump flow in a biventricular bypass situation in which pumps are implanted between the ventricles and arteries was evaluated. For this method, a suction index I_s was used for suction detection instead of left atrial pressure. The results indicate that this proposed method is capable of preventing suction and could simultaneously maintain circulatory control. A key advantage of this control system is that flow rates can be maximized while avoiding suction conditions particularly when the circulatory system is unstable such as in a the first few days after operation.

During future chronic animal studies, we will evaluate a control system that incorporates the dynamics of the pulmonary circulation, and investigate the physiological effects of this control method.

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体内へのエネルギー供給と治療

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Energy Transmission and Medical Treatment to the Inside of the Body.

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1．はじめに

人工心臓，機能的電気刺激装置等の埋込医療機器，更には介護福祉等の分野では非接触の電力・信号伝送システムに多大な要求が寄せられている．一般的にいわゆる遠方界と呼ばれる電磁波領域の適用を考えると周囲に対するエネルギー放射源となり配慮が必要となるが，近傍界に属する電磁界領域を使用するとエネルギー密度の高い領域を空間的に局在化できるため，電力を必要とする機器に対しては有効となる．磁気的結合を用いた電力伝送用平面渦巻型コイル対の代表的構成例としてはアモルファス強磁性繊維とリッツ線を組み合わせた可撓性に富む薄型コイルが挙げられる[1]．また信号伝送においては，動作の確実性，安全性の点から，常時，機器の動作状態の監視及び制御を必要とし，電力伝送系とは独立した系統を備えることが必要となるが，コイル形状の工夫により電力伝送コイルとの一体化を可能としたシステムが開発されている．

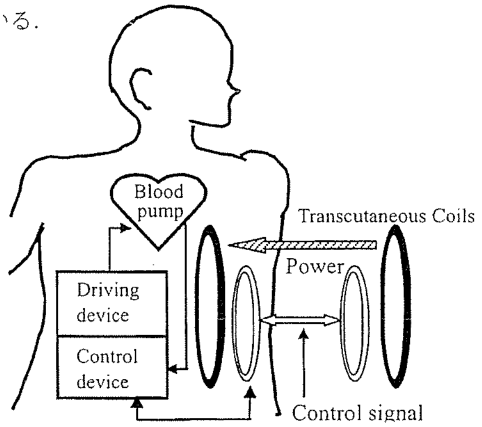

Fig. 1 Image of transcutaneous energy and signal transmission system.

2．体内電力伝送

現在開発が進められている埋込形電磁駆動人工心臓ではいずれも 20W を越える電力の供給が要求されている．平面渦巻型コイルにおいて，コイル厚みは 5mm 程度であり，背面に磁性体としてフェライトチップを配した構成において，温度上昇値３度以内で 20W の連続電力伝送が可能である．このようなコイルを用いて既に成山羊による埋込人工心臓システムの動物実験が行われており，伝送周波数 100kHz の場合，体内側での受電電力 45W，コイル間伝送効率は約 90%以上という結果が得られている．

3．小型埋込素子を用いたハイパーサーミア

ハイパーサーミアには様々な加温法があるが，加温部位の制御や温度モニタリングが困難であり，発熱体を体内に埋め込むインプラント加温法が見直されている．そのインプラント加温方式として，我々はソフトヒーティング方式を提案してきた．ソフトヒーティング法とは，感温磁性体を発熱体とし，これを体内に埋め込み，体外部から高周波磁界で励磁して発生するヒステリシス損などを発熱源とする加温方式である．ソフトヒーティング法では，小型の素子を用いるために体内の深部を局所的に加温することが可能であり，また感温磁性体のキュリー温度を参照温度とした加温方式であるために温度測定が不要といった利点を持つ．我々はこのソフトヒーティング法を応用し，感温磁性体に金属短絡環を巻きつけた複合型発熱体を提案してより高発熱な素子の開発を行っている．複合型発熱体では，金属短絡環によるジュール熱を発熱源として用いており，感温磁性体は主に鎖交磁束制御，即ち温度制御素子として用いている．現在では，良好な発熱特性が得られており，臨床応用にむけて検討を続けている．

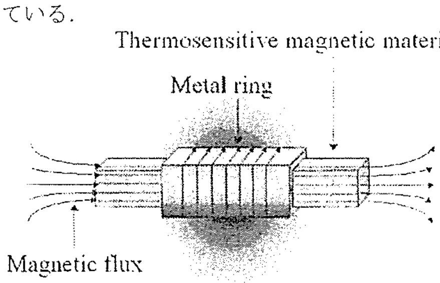

Fig. 2 Structure of soft-heating implanted device.

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VADにおける遠心ポンプの差圧・流量推定

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Pressure Head and Flow Estimation of a Centrifugal Pump for VAD

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1　はじめに

人工心臓の制御や監視をする際には，血圧・血流量の計測が必要となるが，生体適合性などの面から，センサの使用はなるべく避けることが望ましい．補助人工心臓(VAD)の場合では，差圧・ポンプ流量は自然心の拍動の影響を受けるので，TAHの場合と比べて推定が困難な可能性がある．本研究では，Yoshizawa, Tanakaらによるポンプ差圧および流量の推定手法(時系列法)を用いて，補助人工心臓において推定が可能かどうか，*in vitro*ならびに，*in vivo*において検討を行った．

2　方法

y(差圧Pまたは流量Q)と回転数N，電流Iとの関係を(1)式のようなARXモデルにより推定する．

$$y(k) = -\sum_{i=1}^{L} a_i y(k-i) + \sum_{j=1}^{7}\sum_{i=1}^{M_j} b_{ij} u_j(k-i+1) + w(k) \quad (1)$$

$$u_j(k) = \{N^2 I(k), NI(k), I(k), N^2(k), N(k), 1, K(k)\} \quad (2)$$

$$K(k) = \frac{N(k)+N(k-1)+\cdots+N(k-n+1)}{I(k)+I(k-1)+\cdots I(k-n+1)} \quad (3)$$

(3)式の$K(k)$は粘性変化を補償する定常ゲインである．同定実験で得られた入出力の系列y, u_jに基づき，未知のパラメータa_i, b_{ij}を最小2乗法で決定する．

3　実験・結果

遠心ポンプにはKyocera製Gyro C1E3を用いた．模擬循環系においては，クランプにより前負荷を変えることにより自然心の拍動を模擬した．動物実験では51.4kgの成山羊を用い，左心は心尖部より脱血している．模擬循環系，動物実験における推定精度をTable 1に，*in virto*における左心ポンプ差圧・流量の推定値の波形をFig.1にそれぞれ示す．以前用いていた体外循環用遠心ポンプ(テルモ製CAPIOX)と比較して，より高い精度で，自然心の拍動による変動に追従した推定が可能であることがわかった．この理由は，モータ電流に負荷依存性があることに関連すると思われる．

Table 1.　推定精度

	In vitro		*In vivo*	
	差圧	流量	差圧	流量
推定誤差	4.0[mmHg]	0.30[L/min]	4.8[mmHg]	0.17[L/min]
相関係数	0.85	0.96	0.73	0.98

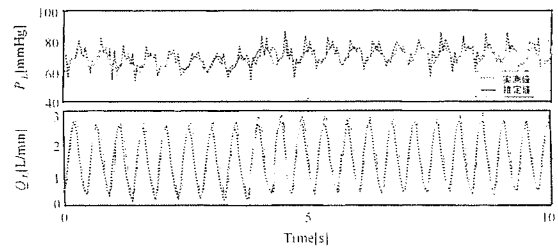

Fig.1.　*In vivo*における差圧・流量推定

4　おわりに

本研究において，時系列法によりVADにおいても*in vitro*, *in vivo*で推定手法が有効であることが示された．今後は生体の心拍数や末梢血管抵抗などの変化に対応できるかどうか検討していく必要がある．

人工心臓用経皮的電力伝送システムの開発

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Development of transcutaneous energy transmission system for the artificial heart

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1.緒言

完全埋込型の人工臓器を駆動するためには体外から電力を供給する必要があるが有線による電力供給法は皮膚を貫通するケーブルの存在により患者の行動を制限し，また感染症の危険をもたらす．皮膚を介したトランスを用いた経皮的電力伝送システムならばその問題は無いが，電力損失による発熱，コイルの位置ずれや出力電圧変動などの欠点がある．そのため，我々は高効率安定動作可能な回路パラメータおよび，同期整流を用いた整流回路における損失の低減について検討を行った．また実機を製作し成山羊に対する埋め込み試験を行った．

2.原理

我々の伝送システムの構成を Fig1 に示す．コイルのサイズを一定と仮定した場合，伝送効率ηは1次コイルの巻き数N_1には依存せず，2次コイルの巻き数N_2にのみ依存する．これにより最適なN_2が決定され，目標とする電圧比からN_1が決定される．負荷変動に対する出力電圧の安定化を図るため，電源側の内部インピーダンスZ_0を最小にする条件からC_1が決定される．またダイオードにおける電圧降下により電力損失が発生ため同期整流回路を開発し，この損失を低減した．

3.方法

製作した経皮的電力伝送システムの概観を Fig.2 に示す．同期整流回路は2次コイルの Mn-Zn 系フェライトコアの背後に設置され、小型化を実現した．これを成山羊に埋め込み、左心補助人工心臓（UPVAD）を駆動した．

4.結果とまとめ

本システムは成功裏に UPVAD を駆動できた。しかしコイルの横方向の位置ずれにより電圧低下がしばしば起こった。また発熱の大きい素子の付近に熱傷が見られた。今後は電圧の安定化をコイル形状の面から最適化する検討を行う．また，臨床応用を見据えたコイル等デバイスのフィッティング，耐久試験を含め，動物実験を通してより実践的なデータの取得，解析を行う．

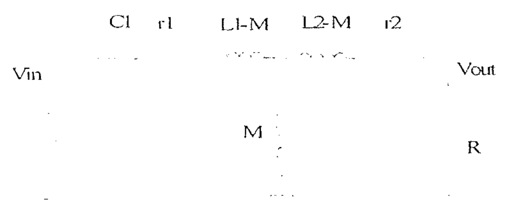

Fig.1 The equivalent circuit of transmission system

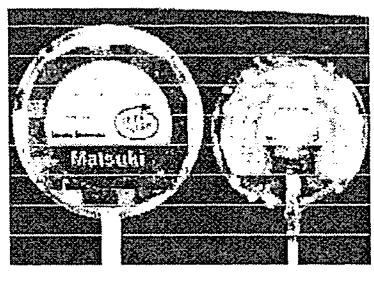

Fig.2 the primary coil (left) and the secondary coil with the synchronous rectifier (right).

磁気特性を利用した経皮的な出力制御及び温度計測

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Transcutaneous output power control and temperature measuring utilizing magnetic property

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1. はじめに

人工心臓をはじめとした人工臓器・体内埋め込み機器において，皮膚を貫通する電源ラインが不要となる，電磁誘導の原理を利用した経皮的電力伝送（Transcutaneous Energy Transmission System：TETS）が臨床段階に向けて活発に検討・実験されている．熱を発するような埋め込み機器，例えば形状記憶合金をヒーターで熱した場合の形状変化を利用して駆動する人工肛門括約筋[1]などではこのとき適切な出力電力の制御を行わないと生体内で熱傷を生じることになる．本検討では感温磁性体を磁心に用いたインダクタンスを利用することで，このような生体内における温度の制御をTETSと組み合わせて経皮的に実現し，また生体外部のパラメータからその時の内部の駆動状態を把握する方法を提案する．

2. 感温インダクタによる出力制御

感温磁性体はキュリー温度付近において急激にその磁気特性を変化させ，それを磁心としたインダクタはそれに応じて値が減少する．今回用いた感温インダクタ L_{TH} はキュリー温度 60℃の前後において 56～10 μH 程度の変化をする．経皮伝送コイルの2次側に L_{TH}，コンデンサ C，負荷 R を直列に配置し共振系を形成する．経皮コイル1次側の印加電圧を一定にし，然るべき周波数で励磁すると感温磁性体の温度に応じてFig. 1のように出力が自動的に制御される．また1次側力率の値を測定したところ，Fig. 2(a)が得られた．経皮コイルの1次側2次側の相対的位置関係によって異なる結果となるが，初期値で規格化をするとFig. 2(b)の通り，変化の割合は一定であり，体外から内部の温度が把握できることが示唆される．

Reference

[1] T. Takagi, Y. Luo: "Heat and mechanical characteristic of artificial sphincter utilizing shape memory alloy", JSME annual meeting, 1, pp55-56 (2000)

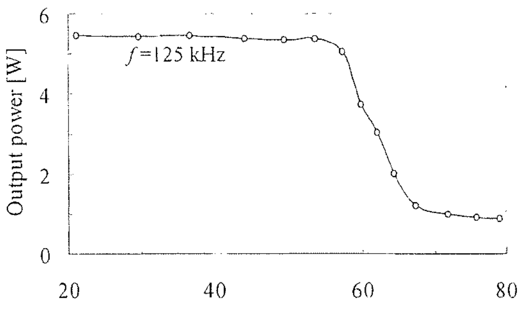

Fig. 1 Controlled output power depending on temperature.

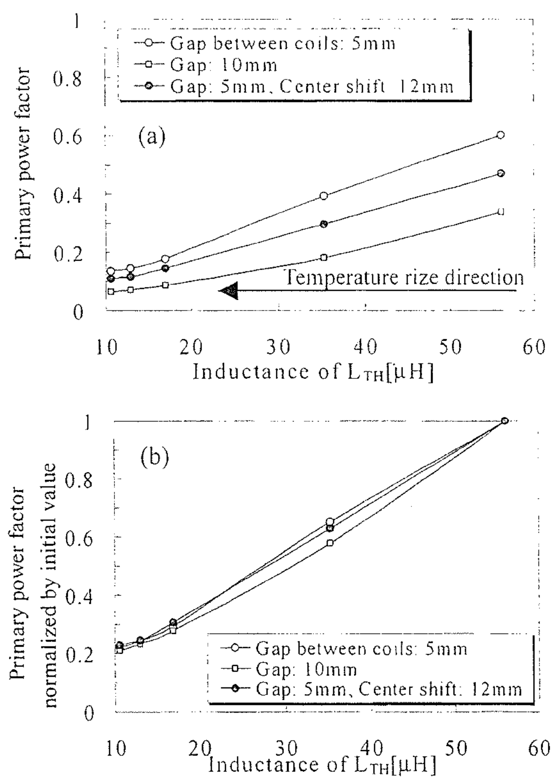

Fig. 2 Change of primary power factor (actual value: upper figure(a)/ normalized value: lower figure(b)).