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Abstract

During the left ventricular bypass, it is important to keep the arterial and atrial pressures at a physiological level to maintain the circulation and at the same time to rest the failing heart (recovery of the failing heart). We have developed a microcomputer based control system for the left ventricular assist pump (LVAP). The control system regulates the arterial and atrial pressures at a physiological level by adjusting the cardiac output of the LVAP. The superior feature of the control system is that it has an indirect measuring system. The arterial and atrial pressures are observed from the careful analysis of pressure in the LVAP air chamber. The assist air pressure shows that the air pressure at the specific momentary points when a diaphragm begins to move reflects the pressure in proportion to the arterial or atrial pressure. The specific momentary points are monitored by an optical diaphragm position sensor when a diaphragm begins to move at a systolic or diastolic period of LVAP, and the pressures at those points are measured by means of a drive air pressure transducer. A microcomputer obtains the indirectly measured arterial and atrial pressures through the A/D converters. The control system regulates the cardiac output of LVAP by adjusting the driving conditions (driving pressure, vacuum pressure, ejection duration, and driving rate) according to the indirectly monitored parameters. The control system consists of an optical diaphragm position sensor, pulse motor driven pressure regulators, a drive air pressure transducer, and a microcomputer. As a result of in vitro experiments, the control system regulated the arterial and atrial pressures smoothly at a desired level.

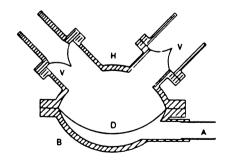
INTRODUCTION

The need for a mechanical circulatory assist device to support the failing heart has been well recognized. In the United States alone, more than million deaths are due to cardiovascular renal disease, accounting for about 55 percents of all the deaths. A large proportion of these deaths is

from coronary arterial disease, and it has been estimated that half of patients who died could have been helped by mechanical circulatory assistance. Many of these patients are men in the most productive years, during which their family responsibilities are greatest. In cardiogenic shock conditions, inadequate cardiac output induces decrease in blood pressure and increase in peripheral resistance. Resultant impaired coronary circulation and venous return would decrease cardiac output moreover (1).

A LVAP is used as a circulatory assist system to maintain the circulation and to assist the recovery of the failing heart in a cardiogenic shock. The artificial pumps are mainly divided into two groups, i.e., the air driven type and the mechanical driven type. The air driven type artificial pump is mostly used at many institutes in the world. The pump has several different designs such as the sack type, diaphragm type, tube type, and pusher plate type. All kinds of these pumps are the pulsatile pump, namely, the pump expels pulsatile blood flow to the aorta, which is realized by a back-and-forth motion of the diaphragm or the pusher plate. There are some kinds of blood access methods for an assist pump, i.e., the left ventricular apex to aorta, left atrium to aorta, left atrium to the femoral artery, biventricular bypass, and so on.

The diaphragm type assist pumps was used from the standpoint of that the diaphragm type pump has the best volume efficiency compared with the other air driven type assist pump. $Fig.\ 1$ shows the structure of the developed assist pump (2). The assist pump is an air driven diaphragm type pump. It takes the blood from the left ventricle through the apex and sends the blood to the aorta $(Fig.\ 2)$. The assists pump consists of a cannula for the suction of blood, pump body, and a cannula for expelling the blood.



B:Backplate D:Diaphragm H:Housing V:Valve A:Air inlet

Fig. 1 Structure of the developed assist pump

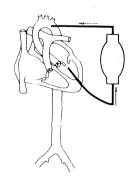


Fig. 2 Transapical-aor tic left ventricu -lar assist pump

The LVAP has been applied to more than a hundred patients clinically in the world. However, the results of the clinical applications were not always satisfactory. One of the reasons is thought that the control system for LVAP to satisfy the request of the human circulation has not been developed. The various driving mode has been developed, i.e., an asynchronous driving mode, synchronous driving mode, volume triggered driving mode, and so on. In the asynchronous driving mode, the LVAP is driven with fixed rate independently of the natural heart. It is the most simple driving mode. In the synchronous driving mode, the LVAP is driven by the driving system synchronizing with R-wave or T-wave of the electrocardiogram. The synchronous driving mode is able to realize a counterpulsation. The counterpulsation is advantageous from the standpoints of increasing the coronary blood flow and at the same time decreasing the afterload. The volume triggered driving mode is advantageous from the standpoint of antithrombogenisity. However, these driving modes do not respond adaptively to the hemodynamics during the left ventricular bypass.

We have developed the microcomputer based control system for the LVAP using the only indirectly monitored parameters, which controls the LVAP responding to the hemodynamics, i.e., arterial and atrial pressures. During the left ventricular bypass, it is important to keep the arterial and atrial pressures at a physiological level to maintain the circulation and at the same time to rest the failing heart (recovery of the failing heart). Realizing such a control system, it is essential to measure the arterial and atrial pressures. However, the chronic measurements of these parameters are difficult by conventional methods. Careful analysis of an assist pump air chamber revealed the air pressure at the specific momentary point when the diaphragm begins to move reflecting pressures proportional to the arterial and atrial pressures. The control system regulates the arterial and atrial pressures at a physiological level by adjusting the cardiac output of the LVAP based on an indirectly measured pressures. The cardiac output of LVAP is changed by the driving conditions, i.e., the driving pressure, vacuum pressure, ejection duration, and the driving rate.

OPTICAL DIAPHRAGM POSITION SENSOR (3)

Sensing of the instantaneous position of the flexing diaphgragm by the optical sensor is based on the attenuation of light intensity by its distance from a light source. The design objective of this sensor was to detect the distance of the diaphragm up to 3 cm (the maximum stroke displacement of the diaphram in the present pump). The optical sensor consists of a phototransistor (sharp, TP-550, angular response, 5 degrees) interposed between 2 infrared emitters (sharp, GL-513f, beam angle, 50 degrees). The sensor is attached to the backplate of a pneumatic pump facing the di-

aphragm. A white round fabric of 15mm in diameter is attached to the center of the diaphragm as an optical reflector. The infrared ray reflected by the diaphragm, gives the phototransistor the inverse function of the power of the diaphragm displacement. The two infrared emitters are used to emit intense infrared rays, and thereby give a sufficient signal level to the phototransistor. Also the alignment of the phototransistor in the middle of the two infrared emitters minimized the effect of an inclination of the diaphragm at the same distance on the output of the phototransistor. The block diagram of an optical sensor circuit is shown in Fig. 3. The infrared emitters are flashed in a series of pulses of 2 KHz to increase the light intensity. The phototransistor circuit is designed to amplify the light intensity. The phototransistor output is filtered by a band-pass filter. Only the 2 KHz signal is fed into the detector. Since the change in room light is usually slow, such a change does not affect the phototransistor output. The detector then extracts the diaphragm displacement signal from the high frequency signal. The signal is linearized by a logarithmic amplifier.

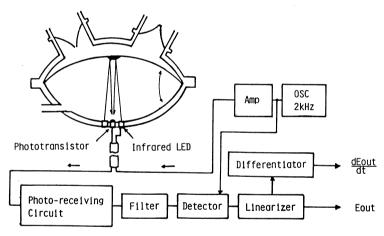


Fig. 3 Block diagram of optical sensor circuit

MEASUREMENT OF ARTERIAL AND ATRIAL PRESSURES

Careful analysis of the artificial pump air pressure shows that the air pressure at the specific momentary point when the diaphragm begins to move reflects the pressure proportional to the arterial pressure. When the drive air pressure is increased gradually during the systole, this pressure is transmitted to the blood in the pump through a flexible membrane and therefore the blood pressure in the pump is also increased slowly. In the beginning of the systole the pump pressure is higher than the atrial pressure but lower than the arterial pressure. Therefore the di-

aphragm can not move during this period. Once the pump pressure exceeds the arterial pressure, the diaphragm begins to move. The air pressure at this moment reflects the pressure proportional to the arterial pressure value. The diaphragm movement can be monitored by the optical senser (see *Fig. 4*).

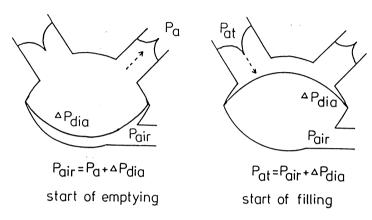


Fig. 4 Principle of arterial and atrial pressure measurements

The atrial pressure may also be determined from the information derived from the artificial pump air pressure. The principle of determining the atrial pressure from the drive air pressure is the same as in measuring the arterial pressure. During a diastole in the atrial pressure measuring mode, the air pressure decreases to an atmospheric pressure slowly. In the beginning of the diastole, the air pressure, that is the blood pressure, remains below the arterial pressure but above the atrial pressure. In this period the diaphragm can not move. Once the air pressure becomes below the atrial pressure, inflow to the pump starts and the optical sensor output exhibits an abrupt change. The air pressure at this moment is closely correlated with the atrial pressure (see *Fig. 4*) (3).

In the normal driving mode the three-way solenoid valve (FSIT-03-3, Chukyo Denki) EM1 switches the driving line back and forth between the pressure and the vacuum accumulator, then the other solenoid valve EM2 is magnetized to connect the reservior. Before the arterial pressure measuring mode, the air in the reservior is discarded to the atmosphere to decrease the reservior pressure to 0 mmHg. After the completion of decreasing the reservior pressure, EM2 is also magnetized (see Fig. 5).

In the arterial pressure measuring mode, microcomputer (Z 80 based on processor) sends the control pulses to the pulse mother attached to the pressure regulator (Filldex 11-018, Norgren

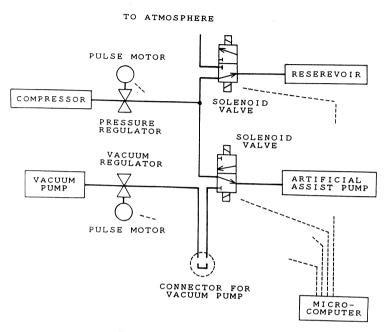


Fig. 5 Block diagram of air circuit

Tokyo Automatic Control Company) to increase the driving pressure slowly, and the microcomputer receives the derivative of the diaphragm movement signal (diaphragm velocity signal) and the drive air pressure through the A/D converters (4). When the diaphragm velocity signal changes abruply, i.e., the assist heart begins to pump blood into the systemic circulation against the arterial pressure, the drive air pressure at that moment is fed into the microcomputer. After the arterial pressure measuring mode, the microcomputer makes the pressure regulator return to the previous position by means of the pulse motor, and the normal driving mode is continued.

The feasibility of the method of obtaining the arterial pressure by means of the optical sensor and the drive air pressure transducer was intensively tested by *in vitro* on a mock circulation. The mock system consists of an aortic compliance (air cushion chamber), a peripheral resistance (backpressure regulator), and an atrial reservior. The pump filling pressure was maintained constantly by returning the output to the atrial reservior. *Fig.* 6 shows the arterial pressure measuring mode. *Fig.* 7 shows the relation between the arterial pressure measured directly by a pressure transducer (PAO) and the estimated pressure by the optical sensor and the drive air pressure transducer (PDs) with good relation. The relationship between them is described through a linear regression by the equation PDs = $0.92 \cdot PAO + 8.92$ (r = 0.996, n = 9).

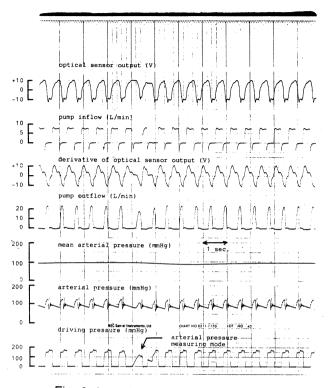


Fig. 6 Arterial pressure measuring mode

The atrial pressure measuring mode, EM2 is demagnetized to decrease the reservior pressure to the zero mmHg. The driving pressure is decreased slowly until A/D converter receives the derivative of the diaphragm movement signal. That is realized by the microcomputer which sends the control pulses to the pulse motor attached to the pressure regulator. The air in an assist pump is discarded slowly through the pressure regulator leakage. When the diaphragm velocity signal changes abruptly during an

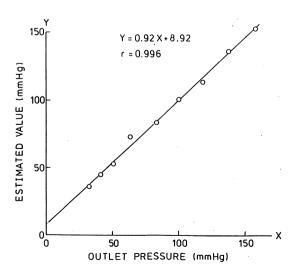


Fig. 7 Relationship between estimated arterial pressure and directly measured arteriaL pressure

assist pump diastolic period, the blood in the atrium begins to enter the assist heart. Ethe driving pressure at that moment is fed into the microcomputer through the A/D converter. After the completion of the atrial pressure measurement, the microcomputer makes the pressure regulator return to the previous position. Fig. 8 shows the relation between the atrial pressure measured directly by a pressure transducer (Pat) and the estimated pressure (PDs). The relationship between them is described through the linear regression by the equation PDs $=1.03 \cdot \text{Pat-}1.19 \ (r=0.996, n=8)$.

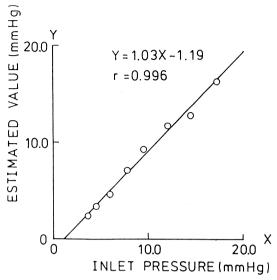


Fig. 8 Relationship between estimated atrial pressure and directly measured atrial pressure

THE CONTROL SYSTEM

The block diagram of the control system is shown in Fig. 9. The control system consists of a pressure regulator, a vacuum regulator (20UT-0-30, Hammel Dahl), two pulse motors (one is the attached to the pressure regulator and the other one is attached to the vacuum regulator), optical diaphragm position sensor, drive air pressure transducer, and the microcomputer. The pulse motor and the pressure regulator and/or the vacuum pressure are connected by a flexible coupler. The optical diaphragm position sensor and the drive air pressure transduc-

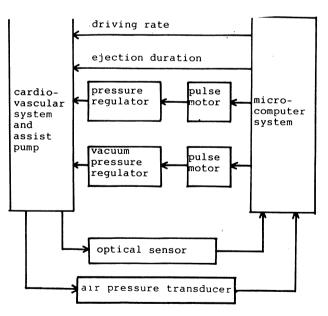


Fig. 9 Block diagram of developed control system

er are used to measure the arterial and atrial pressures indirectly.

The manipulated parameters of the air driven diaphragm type assist pump are 1) driving pressure, 2) vacuum pressure, 3) driving rate, and 4) ejection duration. In the developed control system all of these parameters can be manipulated. The driving pressure or the vacuum pressure is regulated by adjusting the pulse motor attached to the driving pressure regulator or the vacuum pressure regulator. The pulse motor is controlled by the microcomputer. The microcomputer sends the control pulses to the pulse motor through the 8255 programable peripheral interface. The ejection duration or the driving rate is also controlled by the microcomputer, namely, the microcomputer sends the control pulse to the electromagnetic valves in the control system.

We have performed the arterial and atrial pressures control at a physiological level by adjusting the driving pressure using the developed control system. The number of control pulses were supplied to the pulse motor, which changes the driving pressure, was in proportion to the difference between the desired arterial or atrial pressure and the indirectly measured pressures.

Pnub = G • (Pdesire-Pmeasure)

where: Pnub

; number of control pulses

Pdesire

; desired arterial pressure

Pmeasure; indirectly measured arterial pressure

; proportional gain

The pulse motor rotates 1.8 degrees per 1 control pulse and the pressure regulator makes the driving pressure increase about 1.8 mmHg by one control pulse.

The arterial and atrial pressures control was tested using a mock circulation. Fig. 10 shows the control of an arterial pressure by adjusting the driving pressure. In the beginning of the control, the driving pressure is about 30 mmHg and the mean arterial pressure was about 25 mmHg. However, a few minutes later the mean arterial pressure was regulated at about 100 mmHg since the control system makes the driving pressure increase to about 230 mmHg. The optical control gain G was determined experimentally. If G is larger than 1.5, an overshoot or an oscillation is observed in the response of arterial pressure control. If the proportional gain G is less than 1.5, it requires much time of control the arterial pressure at a desired level. Hence, 1.5 was chosen as the optimal proportional gain.

The atrial pressure control by the developed control system was also tested on a mock circulation. The constant flow was supplied to the atrial reservior and the pump outflow was discarded though the peripheral resistance. The peripheral resistance was adjustable by the backpressure regulator. The atrial pressure was also regulated by adjusting the driving pressure in proportion to the difference between the desired atrial pressure and the indirectly measured atrial pressure.

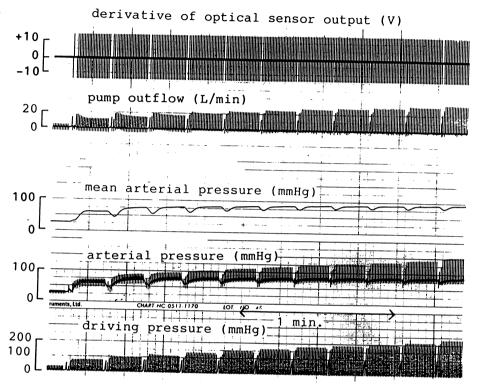


Fig. 10 Arterial pressure control by developed control system

Fig. 11 shows the atrial pressure control. Before the control, the atrial pressure is about 15 mmHg and the driving pressure was about 90 mmHg. However, a few minute later, the atrial pressure was regulated at about 6 mmHg of the desired level.

DISCUSSIONS

The objective of the LVAP is to maintain the circulation and at the same time to rest the failing heart (recovery of the failing heart). The LVAP has been applied to more than a hundred patients clinically in the world. However, the results of the clinical application were not always satisfactory. One of the reason is thought that the control system for LVAP did not satisfy the request of the human circulation.

Umezu et al. (5) have developed a microcomputer based automatic control system for the LVAP, which regulates an arterial pressure, atrial pressure, and total flow at a physiological level by adjusting the percent systole of an assist pump. They tried a chronic experiments by using seven

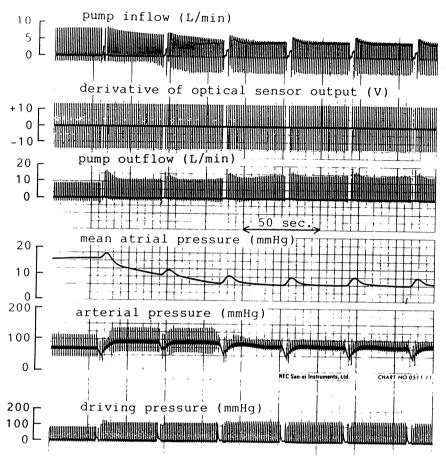


Fig. 11 Atrial pressure control by developed control system

adult goats in which the LVAP is implanted between the left atrium and the ascending aorta. They tried two kinds of a control mode, one is the left atrial and arterial pressures level control (group I), and the other one is the left atrial pressure and the total flow level control (group I). As the results of two kinds of experiments, the hemodynamics of the group I goats is more stable than that of the group I.

Kitamura et al. (6) fabricated an adaptive control system for the LVAP, which controls the trapezoidal piston motion. In their system, a blood pump is driven pneumatically by a hydraulic stepping cylinder, and a minicomputer is employed for a real time controller. The control algorithm is 1) state estimation of the hemodynamics, 2) identification of the parameters in a left ventricular and systemic circulation, and 3) optimization of the stepping of the pump driver. They tried the automatic control of the arterial pressure by using a mock circulation. *In vitro* experi-

ment, referential value is 100 mmHg and the control error is within 5 %.

McInnis et al. (7) proposed adaptive control system of LVAP, which realized the automatic control of the arterial and atrial pressures by adjusting the pneumatic driving pressure and vacuum pressure. The system design includes a two-input-two-output adaptive control algorithm which determines the value of the control variables. The control system determines the optimal PID control gain adaptively to hemodynamics every heart beat based on the ARMA model of the cardiovascular and the left ventricular systems. *In vitro* experiment was performed by using the mock system. The control system regulated the arterial and atrial pressures at a desired level by adjusting the driving pressure and the vacuum pressure adaptively to hemodynamics every heart beat. However, it was difficult to the direct application of the modern control theory to the LVAP system, because the system includes many nonlinear elements.

The superior points in our developed control system are indirect measurements of output parameters (arterial and atrial pressures). While the knowledge of the arterial and atrial pressures are essential for controlling LVAP, chronic measurements of these parameters have traditionally been very difficult to obtain in the LVAP implanted animal. The difficulties of obtaining the accurate measurements are a results of drift, vascular erosion, thromboemboli and infection associate with implanted or percutaneous transducers. Our indirect measuring system is free of these problems.

In the arterial pressure measuring mode, driving pressure was increased gradually during about 500 msec. During this period about 10 mmHg end-diastolic arterial pressure decreases from end-diastolic arterial pressure in the normal driving mode due to the reduction of the assist pump stroke volume. While these measuring modes requires a little bit slower change in drive air pressure than the normal driving mode, these do not seem to impair the pump function and hemodynamic in the assist pump implanted animal.

In the current measuring mode, slow increase of driving pressure is necessary for measuring arterial pressure or atrial pressure. Because the derivative of optical sensor signal is about 70 msec behind the assist pump flow. Therefore, when the movement of the diaphragm is detected, driving pressure has already reached plateau which has no relation to arterial pressure. One of the reason is that diaphragm begins to move from the peripheral part which is not monitored by the optical diaphragm position sensor. Therefore, if the start of pump flow is detected using several optical diaphragm position sensor in the assist pump, the arterial or atrial pressure can be estimated in the normal driving conditions.

Since the arterial pressure decreases gradually according to the peripheral vascular parameters during diastole, the indirect pressure measuring system measures the diastolic pressure which reflects more general hemodynamic condition than the systolic pressure during left ventricular bypass. In our control system, arterial and atrial pressures are controlled and measured intermittently. However, from the standpoint of clinical application, time interval of the control system has no problem, because hemodynamics of human circulation is slightly affected during that time interval.

CONCLUSIONS

A microcomputer based control system for LVAP has been developed. It has the indirectly measuring system. The control system regulated an arterial and atrial pressures smoothly at a desired level by adjusting the cardiac output of the LVAP. It can be concluded that the developed control system for LVAP is effective for the automatic control of the arterial and atrial pressures.

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