This shows that, within metal contents higher than 20 at.%, the amount of sp2 bonded carbon within the thin-film interior increases. Therefore, this increase in "N" is thought to be due to the generation of new localization states due to the sp2 bonds.

For the functional evaluation as a temperature sensor, temperature coefficients of resistance (TCR) and dimensionless temperature sensitivities (ST) were used. TCR shows the ratio of changes in resistance vis-à-vis changes in temperature, while ST shows sensitivities within the temperature ranges desired for measurements with the temperature sensor. Within the present research, by calculating ST, a functional evaluation was made [of the films] as temperature sensors.

ST is calculated according to the following formula.

As the results of calculations according to the above formula, within the temperature range where ST occurs between from 0.1 to 10, its use as a temperature sensor was favorable; all created thin films showed ST values of 0.1 to 10 within the 83-383 K temperature range.

A film's properties as a strain sensor can be modeled using an equivalent circuit whereby the resistors are the branch points of contained metal clusters. By application of a strain in the vertical direction and horizontal direction of the sensor, the potential barrier that can be shown with the equivalent resistor changes, and it is thought that this changes the resistance. For example, when a pull in a uniaxial direction is applied to a thin film, there is an expansion of the distance between metal particles. As a result of this, it is thought that the distance of the potential barrier through which electrons can pass through also expands, and therefore, the resistance value of the thin film overall increases.

E. Conclusions

Within the present research, DLN thin film including metals was made, and evaluations were performed with the aim of its application as an organism temperature sensor. From the Raman spectral analysis measurement results, it is thought that the internal structure of the thin film is dependant on the metal content. As for the temperature dependency of resistance, this was a classical conductor-insulator composite, since resistivity decreased as the temperature increased. It is thought that the electron conductance mechanism can be explained according to inelastic tunnel [tunneling] effects, and this had major impacts on the internal structure of the thin film. From the dimensionless temperature sensitivity, ST, evaluation results, it is thought that each of the created thin films can be used as

temperature sensors.

Also, from the measurement results of the three-point bending tests, the created diamond-like nanocomposite thin films also responded to strains. From this fact, not only do the created films have the functions of a strain sensor, it is thought that in the case where the substrate is removed, these also have the possibility of being used as pressure sensors. Thus, it is expected that such films can be used as sensors as demanded, according to as the amount of the thin film interior portion metal content and the shapes and sizes of the metals are controlled on a nanometric scale.

# Development of a transcutaneous energy transmission apparatus

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Summary; In the present project, created was a transcutaneous energy transmission apparatus using a flat-surface, within a nanotechnology-integrated, implantable-type cardiac ventricle assistance apparatus. The present system consists of a thin-type, circular-shaped unit that embodies a unified electrical power transmission system for transmitting electrical power to a cardiac ventricle assistance apparatus also having an included rectifier unit, and a signal transmission system for monitoring and controlling driving of the assistance apparatus. The system enables energy transmission of approximately 30 W, and signal transmission of 56 kbps. Also, while the coil configuration is an open magnetic circuit, through equipping this with a ferrite chip inductor magnetic body, high efficiency transmission has been enabled. As for the coil size, the diameter is 80 mm, and the thickness is 15 mm. In embedded transmission tests with adult mountain goats, it was confirmed that the desired energy transmission is performed, that the internal and external body units generate no heat, and favorable test results were obtained. Power transmission efficiency at DC-DC mean of 80% or above was regularly achieved; it was thus learned that this is a value sufficiently suitable for practical application. Further, in regards to the electromagnetic design methods regarding coil configuration, we performed our own investigation, and we also performed a detailed investigation regarding ideal circuit configuration for a fully-implantable model.

## A. Purpose of research

For the cardiac ventricle assistance apparatus which was investigated in the present project, as with artificial hearts, with an internal-body battery/batteries such as a pacemaker, continuous driving is not possible, and it is necessary to supply electrical power from outside of the body. However, when wiring that pierces through the skin is performed, not only does this interfere with the movements of a recipient, it also leads to infections. Thus transcutaneous energy transmission is used, such that, with a coil embedded within the body opposite an external body coil, via electromagnetic

induction, power can be supplied without having to pierce the skin.

As for methods of transcutaneous energy transmission, a number of methods are being investigated, including, among others, an external-body coupled type, and a flat-surface type coil as employed in the present investigations. The external-body coupled type has many merits, including the fact that high electromagnetic coupling is achieved between the coils, that there is extremely small magnetic flux leakage, that lagging [phase shifting] of the installed units due to physical movements, etc., has little impact on transmitted power and transmission efficiency, and that high transmission efficiency is achieved, etc. However, with this type, there exists a ring that is surrounded by skin, and it is possible that this can cause the recipient mental pain or stress. In terms of that point, the flat-surface type coil is superior; with this type, however, there is much magnetic flux leakage and changes in the coupling due to physical movements, etc., and control is thus necessary. In a transcutaneous electrical power transmission system, batteries placed at the body exterior generate, via an inverter, a high frequency, and the primary coil is driven. The high-frequency magnetic field generated by the primary coil "penetrates" the skin, and induces voltage in the secondary coil. This is converted to direct current with a rectifier circuit, and the cardiac ventricle assistance apparatus, etc., is driven.

For voltage stabilization, signals from within the body are fed back, and the inverter is controlled. Nevertheless, there is a possibility that signal transmission can become unstable due to external noise, etc., and it is thus desirous that control be enabled using only the information from the primary side. The coil that we used is a flat surface-type coil with an external diameter of 80 mm and an internal diameter of 40 mm.

When coils are set opposite to each other to make a transducer, the coupling coefficient changes from 0.8 to 0.2 within the range of the separating gap between the coils, from 0 mm to 20 mm. In other words, as it is supposed that the coil is to be actually imbedded within the upper portion of the left chest, when the gap between the transducers changes due to physical movements, etc., of the recipient, power can no longer be sent stably.

Therefore, the development of a transcutaneous energy transmission system can be stated as the development of an insulation-type DC-DC [DC/DC] using a transducer that can change when magnetic coupling is poor, and over a broad region.

From the perspectives described above, we performed investigation of a transcutaneous energy transmission system.

B. Research methods

B.1 Characteristics of a transcutaneous transducer comprised of connected power-factor improved capacitors in series

Compared with an ordinary transducer, with a transcutaneous transducer, sufficient voltage cannot be obtained when there is extremely large leakage inductance and the load is heavy. Thus, power-factor improved capacitors are introduced in series on the primary side to offset the leakage inductance; this equivalent circuit was evaluated.

Within this circuit, current flowing in mutual inductance is compared with primary current and secondary current, and when sufficiently small, is written into the LCR serial resonance circuit. This circuit has transmission characteristics of a secondary band pass filter. When the voltage and current phase from −90° to 90°, frequency increases and also changes; when the phase is 0—in other words, when the power factor is 1—a resonance frequency and maximum power is obtained.

B.2 Frequency power factor control

If this is used with a resonance frequency, in a rigorous circuit, although there is somewhat of a lag, mostly maximum power can be transmitted. However, if the gap between the coils increases as a result of physical movements, etc., of the recipient, the inductance L increases, and resonance frequency decreases.

To match resonance frequencies with movement frequencies, since it is difficult to replace frequency capacitors, the method of controlling the movement frequency is appropriate. Considering the case where, after the resonance frequency has first matched the movement frequency, the resonance frequency decreases, the movement frequency becomes higher than the resonance frequency, and it becomes a lead phase. If at this time, the phase is detected, and control is performed such that, if it is a lead phase, the movement frequency is lowered, and if it is a lag phase, the movement frequency is increased, than the power factor can be locked at 1, and maximum power can always be transmitted.

B.3 Configuration of the frequency power factor control circuit

In order to realize frequency power factor control, a phase locked loop (PLL) circuit is used. A phase comparator outputs as voltage the phase difference between primary current and primary voltage. Here, the primary current is detected by voltage Vc impressed at the resonance capacitor. In this way, loss can be reduced to less than that in the case where shunt resistance is used. Also, care

must be taken that this be a 90° lag phase vis-à-vis the primary current. An error amp is used to increase or decrease output voltage such that there is a match between the input voltage Vref corresponding to the target phase and phase comparator output. A voltage controlled oscillator (VCO) outputs a frequency according to the inputted voltage.

As a result of these steps, a feedback loop is created, which works to lock the power factor at 1. In the present paper, considered was the use of 1 as the power factor; however, by adjusting the input voltage Vref, locking can be performed at a desired power factor. Since transmitted power becomes smaller the farther the separation from the power factor of 1, a feedback circuit can also be incorporated for stabilization of the secondary voltage.

B4. Conditions that enable control

In the argument thus far, analysis has been performed with the hypothesis that the transmission characteristics of the transcutaneous transducer can approximate an LCR serial resonance circuit. However, in an actual system, somewhat different characteristics are shown. The most serious problem is the possibility that it will become impossible to lock the power factor. When frequency phase characteristics are computed with the equivalent circui, an extreme value is sometimes held under the following load conditions.

When an incorrect target phase is inputted, there are three frequencies that become the solution, and locking can no longer be performed.

Since, the power factor control circuit becomes positive feedback, locking cannot be performed. It is thus necessary to ascertain the range of the target phase at which stable control can be performed. By analyzing the circuit, the following characteristics are obtained.

1. Only one single resonance frequency gives the target phase of 0°, that is, gives a power factor of 1.
2. The frequency value for giving the extreme value is always larger than the resonance frequency.

In other words, when the target phase is in the range from –90° to 0°, the phase vis-à-vis the frequency is increased monotonically, and there is only one frequency that gives the target phase. Therefore, it is only necessary to select the target frequency as follows.

B5. Transmission characteristics when power factor control was performed

Transmission characteristics Vout/Vin when an LCR serial resonance circuit is approximated are always 1 if the power factor has been locked at 1. If it is considered that this becomes the equivalent circuit and that the resonance

frequency does not change very much, then this is inversely proportional to the coupling coefficient k. This means that the larger the gap between the coils, the larger the transmitted power becomes.

This model, however, is a model that ignores winding resistance, and in actual fact, the primary current becomes comparatively larger than the secondary current, and there is a decline in efficiency. Large voltage effects occur at the winding resistance of the primary coil, and when a certain gap value has been exceeded, transmitted power starts to decline.

C. Research results

C.1 Waveforms when located at a power factor of 1

The circuit was actually created, and setup confirmation was performed. The VCO is comprised of an oscillator circuit and a half-bridge MOSFET inverter. Here, this was loaded with pure resistance of 9.4 Ω. Waveforms for each portion are shown in Fig. 6. When the two coils are in contact—in other words, when the gap is 0 mm—the waveform is shown in the upper diagram. Vin is the inverter output, and Vc is the voltage impressed at the capacitor. Since there is a 90° lag phase with the primary current, it is known that the power factor has been successfully locked at 1. When the gap is increased by 10 mm in that state, the frequency declines from 135.9 kHz to 126.3 kHz, and the power factor continued to be successfully locked at 1.

C2. Gap-to-output characteristics

For gap size, outputted power, movement frequencies, and efficiency characteristics were measured. At this time, the inverter source voltage was set at 11.1 V. The load was, similarly, a pure resistance of 9.4 Ω. Output increases together with the gap, and it was learned that it starts to saturate in the vicinity of 20 mm. As described above, effects appear from the drop in voltage of the primary winding resistance. At the region from 5 mm to 10 mm hypothesized for actual use, high efficiency rates from 90% to 80% are obtained. The movement frequency declined as the gap increased. Here, at any gap size, power output of mostly 1 was maintained. When the gap exceeds 20 mm, the direct current power source becomes overloaded; thus, the power source was lowered to 3 V, and the same measurements were performed.

As the results, the maximum value of outputted power was taken when the gap was 20 mm. From the above description, it can be said that, for the present system, to the extent of 20 mm is the usable range.

C3. Target phase vis-à-vis output characteristics

Here, since comparison was made of

output voltage Vin and voltage Vc of the resonance capacitor that is equivalent to the primary current, a 90° offset occurs for the phases. The gap was set at 10 mm. When the Vref is 1.6 V, the power factor becomes 1, and maximum power is obtained. The lower limit and the upper limit are nonlinear; the causes are a narrow VCO frequency range and operational amplifier saturation. When the Vref is 1.6 V for any gap, the power factor becomes 1, and maximum power is obtained. By adjusting the Vref to within the range 0 V to 1.6 V, control from minimum output to maximum power is enabled.

D. Concluding summary

A frequency power factor control, transcutaneous energy transmission system was constructed, and locking was successfully performed for a desired target phase. When the power factor is locked at 1, maximum power is always obtained. It was made clear that the ranges of target phase where stable control is possible are 0° and below. When the target phase is set in the range of –90° to 0°, control of output voltage is possible. Into the future, studies will be made regarding the development of a synchronous rectifier circuit, stabilization of output voltage using feedback, and output power stabilization methods for the secondary side only, etc.

**Establishment of Electrohydraulic-Type Cardiac Ventricle Assistance Apparatus Element Creation Technologies, and Experimental Investigation concerning Optimal Design of an Embedded-Type Cardiac Ventricle Assistance Apparatus Using Engineering Modeling Methods**

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Summary; Currently, heart disease is the second most frequent cause of death of Japanese persons following malignant tumors, and cardiac failure, which accounts for around 30% of heart diseases, is a major problem. Causes inducing cardiac failure are many, and include hypertensive heart disease and valvular disease; the direct cause, however, is a decrease in blood flow. By using mechanical elements to which nanotechnology has been applied, to mechanically assist from outside the heart ventricular contraction, and thereby prevent reduced blood flow: such are the goals of the cardiac ventricle assistance apparatus for which development is to be performed. Also, as a special characteristic of a cardiac ventricle assistance apparatus, since there is no contact with blood, there is no need for constant driving; instead, driving that is "the needed amount at the needed time" is possible. The drive portion of the developed cardiac ventricle assistance apparatus is an actuator that uses a stepping motor. With an incompressible fluid such as water or oil as the medium, through causing pulsation of a polyurethane diaphragm, pressure is applied to the heart of the organism, and ventricular contraction is assisted. For the present research portion, within acute animal tests, on the basis of evaluation data from hemodynamics within living systems, a hydraulic circulation simulation circuit was established, and an evaluation was performed of basic characteristics of the cardiac ventricle assistance apparatus outside of an organism. The acute animal tests were performed for healthy mountain goats (61±6 kg, n=10); here, increases were obtained of 21% for end-systolic aortic pressure and 21% for end-systolic pulmonary arterial pressure. An increase of 29% for cardiac output was also obtained. Next, with the purpose of making quantitative analysis of load on the cardiac ventricle assistance apparatus on the ventricular wall, an engineering investigation was made of the dynamic consistency [compatibility] of the cardiac ventricle assistance apparatus and the cardiac ventricle. In the case where a left ventricle model with no active contraction was used, it was learned that flow assistance of 1.6 L/min could be obtained with a preload of 10 mmHg, an afterload of 100 mmHg, and heartbeats of 72 bpm.

A. Purpose of research

The purpose of the present research is to develop an apparatus for assisting contraction of cardiac ventricles, as a new therapeutic choice for patients with severe cardiac failure. A cardiac ventricle contraction assistance apparatus provides physical force to support ventricular contractions when the force for contracting ventricular myocardium has weakened, and thus for which sufficient blood flow cannot be obtained, thereby maintaining the required blood flow.

In the present research portion, three aspects are performed:

(a) Development and improvement of a cardiac ventricle contraction assistance apparatus;

(b) Basic characteristics evaluation of a cardiac ventricle contraction assistance apparatus; and

(c) Analysis of the dynamics of ventricular wall contraction assistance.

(1) Social contribution of the present research portion

It is said that more than 40,000 patients die from cardiac failure. Causes inducing cardiac failure are many, and include hypertensive heart disease and valvular disease; the direct cause, however, is a decrease in blood flow. If mechanical ventricular contraction assistance became possible, then it would become possible to prevent the decline in blood flow, and to prevent the symptoms induced as a result of insufficient blood flow. Especially for patients who have problems with their myocardium itself, such as cardiomyopathy or myocarditis, assistance of ventricular contraction could become an effective choice for therapy.

(2) Medical engineering contributions of the present research portion

With the development of a cardiac ventricle contraction assistance apparatus, at the same time as increasing the choices available for therapy, a shortening of surgery time is also imaginable. Different from the artificial heart operation, where the entire heart itself has to be replaced, with a ventricle assistance apparatus that is merely attached to the heart—so long as progress is made on miniaturization—it should become possible to perform attachment with endoscopic surgery. A shortening of surgery time would not only reduce the burden on the patient, but would also reduce the burden on the physician.

It is also thought that with an artificial heart that is a fully replaceable-type artificial heart, the performance by mechanisms of all functions of a single organ presents difficulties. If it becomes possible to perform the one act of "working" of a single organ as with a cardiac ventricle contraction assistance apparatus, since only a portion of an organ's function would be performed,

such could lead to development of new artificial organs using applied nanotechnology.

(3) Contributions to the medical-uses mechanical engineering field of the present research

Approaching from an engineering perspective, the heart, which functions as a pulsating pump, in terms of the dynamic characteristics of myocardium, which consists of contracting cells, contributes not only to medical applications, but also serves as an embodiment for the development of mechanisms that are based on new design principles using nanotechnology. The application of such fundamental technologies hints at even further possibilities of the development of novel medical machinery and diagnostic equipment.

B. Research methods

(1) Specifications design and structure of electrohydraulic-type cardiac ventricle assistance apparatus .

Even for a cardiac ventricle assistance apparatus which applies nanotechnology, in order to realize ventricular assistance on a microscale, there is a necessary to show, quantitatively, "at just which sites," and "at just what forces" such assistance is required. Especially in the optimization of the cardiac ventricle assistance apparatus that is our focus in the present fiscal year, we performed research concerning design methods as based on an analysis of the mutual dynamic relationship between living vascular wall and the cardiac ventricle assistance apparatus. The specifications of the present apparatus and an overview of the elements configuring the system are as shown hereafter.

a. Cardiac ventricle assistance apparatus

This is an apparatus for assisting the contraction of a heart, inasmuch as the artificial myocardium portion is mounted on the heart, and the polyurethane diaphragm is made to pulsate. With the present apparatus, in order to perform assisted ventricular contraction from each of the left ventricular wall and the right ventricular wall side, pressure is not given to the entire heart; rather, the specifications are such that assistance can be performed by applying pressure to one portion of the heart. Fig. 2 shows a diagram as viewed from the front side of a living organism's heart. In order to perform assistance from the left ventricular wall side and/or the right ventricular wall side, it is necessary to avoid the left coronary artery and the right coronary artery that comprise the main coronary artery. Thus, from the site shown with a broken [dotted] red line in Fig. 2, ventricular assistance is performed.

Also, means of fixing to the heart are shown in Fig. 3. Here, there are two types of methods [means]: means where it is fixed with an acrylic cup as shown in Fig. 3(a), and means where it is fixed using glass fiber as a belt, as shown in 3(b) of the same diagram.

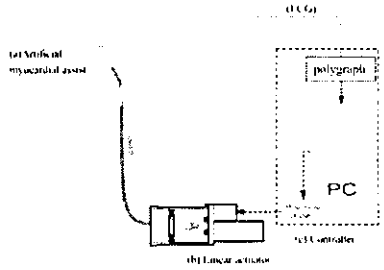


*Fig. 1 Overview of testing of the electrohydraulic-type cardiac ventricle assistance apparatus currently under development. The actuator was set at outside the body, and data was obtained concerning drive means and optimization of the diaphragm.*

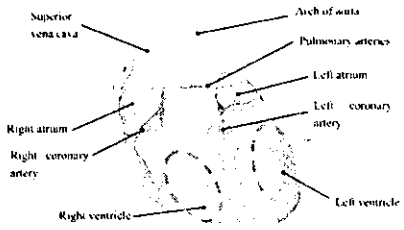


*Fig. 2 Morphology of living heart. The portion surrounded with a broken [dotted] red line shows the site for local contraction assistance (selective assistance of either the left or right heart) by the cardiac ventricle assistance apparatus.*

b. Configuration of cardiac ventricle assistance apparatus drive portion

For pulsating the diaphragm of the artificial myocardium portion, two methods are imaginable:

- an air pressure driving type, and
- a mechanical driving type.

Compared with the air pressure driving type, the mechanical driving type has the characteristic that it can output a fixed flow amount without dependency on the load. Within the present apparatus, we used a mechanical/fluid drive type with the incompressible fluids of water or oil as the medium.

*Fig. 3 Overview of cardiac ventricle assistance apparatus embedding method: In the left diagram (a), the apparatus is set at the outer circumference of the heart using a "ventricular cup," while in the right diagram (b), the apparatus is set such that a glass fiber ribbon is set at the reverse side of the apparatus, with a structure such that, by means of the cardiac ventricle assistance apparatus, it is set into the heart.*

c. Control system portion

Within the present apparatus, it is necessary to perform ventricular assistance by matching, in phase, pulsation of the diaphragm with self-contractions of the organism's heart.

Temporal variations of heart behavior are measured with an electrocardiogram. Fig. 7 shows an ordinary electrocardiogram, and the appearance of a living heart's contraction (systole) and expansion (diastole).

A heart contraction begins with the generation of an electrical current from the sino atrial node.

On an electrocardiogram, the first thing recorded is the contraction of the atrium, and the potential difference at this time is recorded as a P wave.

Next, the current flows through the atrioventricular node, and thereafter flows along the conduction pathway within the ventricle, and a contraction of the ventricle occurs.

This is the time when the most electricity is generated within the heart, and it is shown as the largest waveform, called a QRS wave, on the electrocardiogram.

Then, when the contraction has finished, a T wave is what is measured when the myocardium expands in preparation for the next contraction.

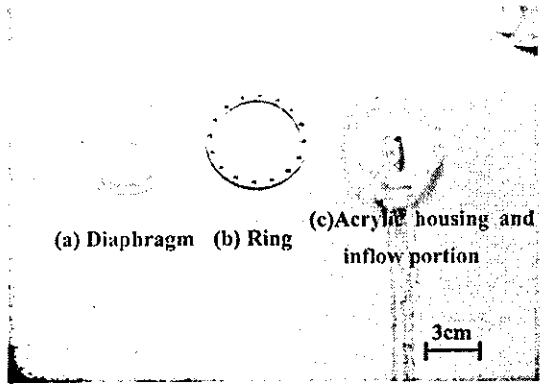


*Fig. 4 Electrohydraulic-type cardiac ventricle assistance apparatus portion for attaching to the ventricular wall surface. From the left, the polyurethane diaphragm, the duralumin flange, and the acrylic casing are shown. Within the present fiscal year, the creation method was established, and evaluation was made of desired duralumin thickness characteristics and contraction characteristics.*

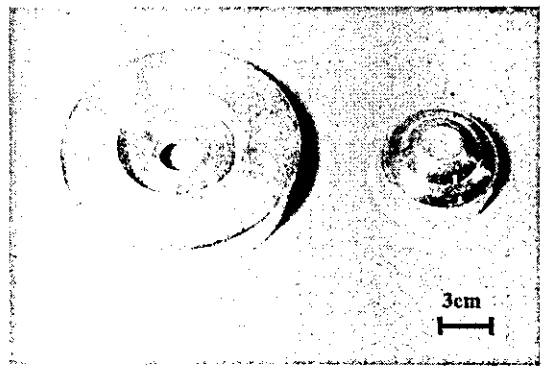


*Fig. 5 Model for creation of the polyurethane diaphragm. Here, polyurethane sheet worked at high temperatures using a vacuum molding method is worked into a convex shape.*

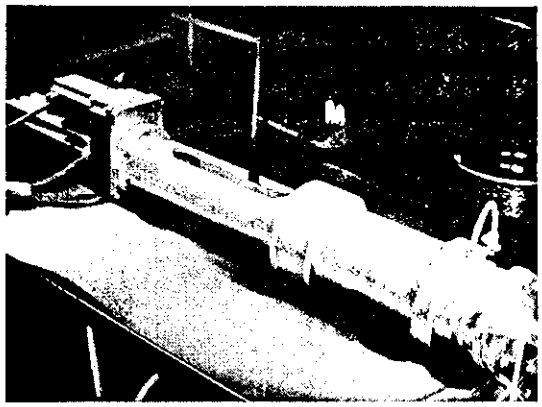

*Fig. 6 Independently developed, external body installation [placement]-type actuator. To optimize the drive method, detailed investigation of external body installation is thought to be necessary.*

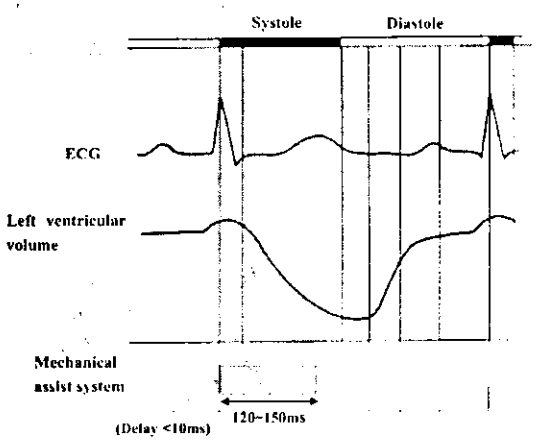


*Fig. 7 Behavior of a live organism's heart (electrocardiogram and intraventricular volume), and appearance at time of contraction of the cardiac ventricle assistance apparatus*

With the cardiac ventricle assistance apparatus to be developed within the present research, an electrocardiogram from the organism that will serve as the object for ventricular assistance is to be obtained, and using the R wave of the electrocardiogram as a standard, driving is to be performed in phase with heart contractions.

To do so, an electrocardiogram is incorporated within a polygraph, and an R wave start-up signal outputted from the polygraph serves as the trigger, and as the drive start signal of the cardiac ventricle assistance apparatus.

(2) Silicone-made left ventricle model and hydraulic simulated circulation apparatus

In the acute animal tests performed for healthy mountain goats (61±6 kg, n=10), through contract assistance by the cardiac ventricle assistance apparatus synchronized with contractions of the organic heart, a significant increase was obtained for aortic pressure, left ventricle intraventricular pressure, and pulmonary artery flow rate.

Nevertheless, at the time of hydraulic contraction assistance of the cardiac ventricle, the ventricular wall receives a concentrated load at its surface border with the diaphragm of the artificial myocardium. For this reason, during long-term cardiac ventricle contract assistance, the organic heart is thought to undergo histological effects due to stress generated by the cardiac ventricle assistance apparatus.

As for the use of animal tests as means of clarifying the dynamic consistency of the cardiac ventricle assistance apparatus and cardiac ventricles, and of performing redesign and improvements of the shape of the cardiac ventricle assistance apparatus, the following problem points can be listed:

a. Elucidation of hemodynamics within organic systems is still imperfect; therefore, data obtained from animal tests cannot be effectively analyzed.

b. Reproduction of test results is not guaranteed, due to the individual differences that are characteristic of living organisms.

c. The animals themselves are very expensive, and keeping fees, surgery-related expenses, and, further, disposable examination instruments and other costs are extremely high.

Therefore, it is necessary to perform evaluations of the cardiac ventricle assistance apparatus within a dynamics circuit that simulates a circulation system.

(a) Design specifications of a cardiac ventricle assistance apparatus evaluation circuit

To perform evaluations of a cardiac ventricle assistance apparatus, a novel dynamics circuit is to be designed. That is, an evaluation circuit that can apply pressure to a cardiac wall, and that also supports a model simulating an organic heart, is to be designed. As evaluation categories, with the emphasis on blood flow, the main elements for determining blood flood are as follows.

1) Left ventricular output
2) Systemic circulatory resistance
3) Right ventricular output
4) Pulmonary circulatory resistance

However, since left ventricular output and systemic circulatory resistance are much larger (approximately six (6)six times) than right ventricular output and pulmonary circulatory resistance, it is understood that blood flow is most determined by left ventricular output and systemic circulatory resistance. From the above reasons, we were to design an evaluation circuit that simulated the left heart system.

As for the left ventricle model, a model which does not actively pulsate was to be adopted. On the basis of the "Frank-Starling law of the heart" ("Starling's Law"), whereby cardiac output increases in tandem with an increase in end diastolic volume (EDV), when treating a cardiac disease, it is said that it is necessary to consider capabilities during the heart's diastolic phase. However, the purpose of the present evaluation circuit, on the basis of

pressure applied to the myocardial wall during the heart's systolic phase, is to perform a study of the dynamic consistency of the cardiac ventricle assistance apparatus and the cardiac ventricle, and it was thus thought possible to make evaluations with a left ventricle model which does not actively pulsate.

(b) Production of the left cardiac ventricle model

As described in the previous section, in order to clarify the dynamic consistency [compatibility] of the cardiac ventricle assistance apparatus and the cardiac ventricle, and to perform redesign and improvements of the shape of the cardiac ventricle assistance apparatus, there is a necessity of creating a novel left cardiac ventricle model.

The ventricular wall portion of the left ventricle model was produced with silicone, using the shell-shaped mold shown in Fig. 8. The volume is 150 mL, and thickness is 7 mm. The production procedures are described below.

(1) Silicone mixing

The main (major) agent, silicone KE-1310ST (Shin-Etsu Chemical Co., Ltd.) is mixed with hardener (curing agent) CAT-1310 (Shin-Etsu Chemical Co., Ltd.) and silicone oil KF96-50CS (Shin-Etsu Chemical Co., Ltd.). The weight ratio is 10:1:15.

(2) Silicone stirring [agitation] and degassing

When mixing the silicone, many gas bubbles are introduced. Since such bubbles lower the hardness of the silicone after hardening, degassing is necessary. Thus, a hybrid mixer (HM-500, Keyence Corp.) is used for stirring, and degassing is performed. The stirring and degassing times were set at two (2) minutes each.

(3) Mold setting

As shown in Fig. 5.2, the screw portion of the left ventricle model is mounted on the revolution axis of a uniaxial rotational molding machine, and the axis is rotated at 30 rpm. Also, using the heater of the rotational molder, the temperature within the rotational molder is maintained at 120°C.

(4) Silicone coating

Silicone is sufficiently applied to the rotating mold. Since a uniaxial rotational molding machine is used, membrane thickness in the revolving direction is nearly uniform, but it is difficult to make the applied film thickness even in the axial length direction. A method for enabling membrane-thickness application in the axial length direction as evenly as possible is as described below.

First, in a state where the mold axis is made to rotate at 30 rpm, silicone is applied from the upper portion of the mold. At this time, care is taken such that

membrane-thickness application in the axial length direction is made as evenly as possible; this, however, is not enough to ensure uniformity.

Thus, the rotation of the axis is stopped temporarily.

With the mixture ratio of silicone as used in the present section, since the viscosity is low, silicone over a large portion of the membrane thickness is removed by gravity.

Also, since the silicone as used in the present section is an addition-type silicone, hardness conditions are affected only by overheating.

Therefore, the temperature within the rotational molder is kept at a low temperature, and until uniformity is obtained in the axial length direction, the silicone is kept from hardening. Then, after the excess silicone has been removed, the axis is once again made to rotate at 30 rpm.

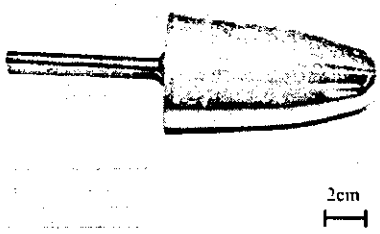


*Fig. 8 Left ventricle model mold for silicone rubber coating.*

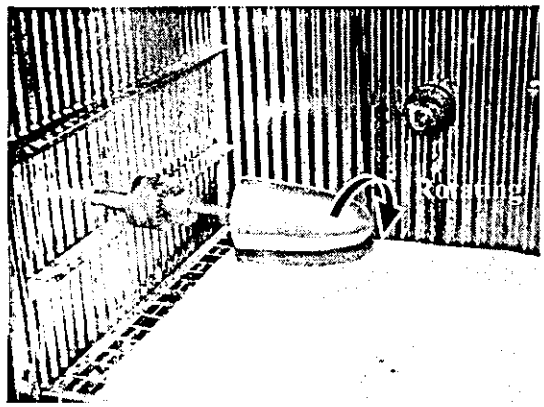

*Fig. 9 The left ventricle model mold is placed on the rotational molder, and under temperature control, the number of rotations is controlled, and the thickness of the silicone left ventricle wall is regulated.*

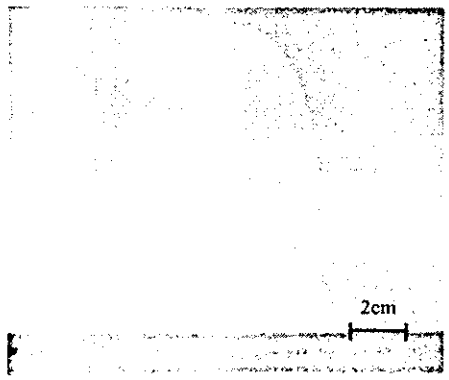


*Fig. 10 The produced silicone left ventricle. A silicone sheet is adhered, and a flange is formed. Model thickness is approximately 10 mm.*

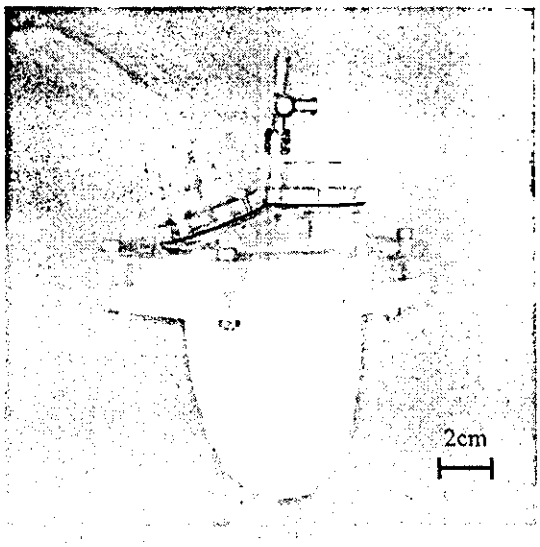


*Fig. 11 Left ventricle model with attached heart replacement valveat the inflow and outflow portions.*

(5) Silicone hardening

After silicone coating, while maintaining the temperature within the rotational molder at 120°C, silicone hardening is performed in a high temperature state. Hardening occurs at approximately 15 minutes.

(6) Silicone molding

Steps (4) and (5) are repeated until the thickness becomes 7 mm. Thereafter, the unit is sufficiently cooled, and the silicone is removed from the mold. When there are portions that are difficult to peel off, applying ethanol dropwise makes peeling easier. Since the mold volume is 200 mL, surplus portions are removed until the volume becomes 150 mL.

(7) Flange formation

The silicone molded in (6) is placed on an acrylic board with its front-most portion upwards. Silicone for the flange is applied to its circumference, and this is hardened at room temperature. After the hardening is complete, the silicone is removed from the acrylic board.

The completed sac is shown in Fig. 10. Here, valve attachment portions using duralumin and acrylic were made for the sac created as described above, and fixation with the artificial valves was performed. The overall diagram of the left cardiac ventricle model is shown in Fig. 11. As for the artificial values, used were a Bjork-Shiley valve (28 mm) for the mitral valve, and a Bjork-Shiley valve (23 mm) for the aortic valve.

(b) Overview of cardiac ventricle assistance apparatus evaluation circuit

With consideration of the specs design, an overview diagram of the created cardiac ventricle assistance apparatus evaluation circuit is shown in Fig. 12. Configuration elements are overflow tanks (inflow side and outflow side), a personal computer (PC) for creating flow-amount data for ventricle assistance apparatus driving, an actuator driver, a fluid machinery drive actuator, and an artificial myocardium portion. The present apparatus is an hydraulics circuit

simulating the left heart system, and, via a water head difference made using an acrylic tank, a preload (atrial and venous system hemodynamic load) 10 mmHg, and an afterload (arterial system hemodynamic load)100 mmHg, on the left cardiac ventricle were set.

(3) Tests of fundamental characteristics of cardiac ventricle assistance apparatus

With the purpose of performing redesign and improvements of the cardiac ventricle assistance apparatus, the key is clarifying the dynamic consistency of the cardiac ventricle assistance apparatus and cardiac ventricles. To do this, using the hydraulics circuit simulating the left heart system as created in the previous section, evaluations were made of six types of artificial myocardium fundamental characteristics at different diaphragm membrane thicknesses and internal volumes.

Specifications of the artificial myocardium portion of the cardiac ventricle assistance apparatus used in the tests are shown in Table 1. That used in the animal tests described in a previous portion of this paper had a maximum diaphragm volume—that is, a single-time output amount—of 40 mL. However, single-time output amount for the newly created type was 56 mL. When further designing anew this type, as shown in Fig. 13, while maintaining maximum placement of the midpoint of the diaphragm at a value of 20 mm, the value of the diaphragm diameter was redesigned to be 65 mm. Further, when making the diaphragms, polyurethane sheets of 0.3 mm, 0.5 mm, and 1.0 mm, respectively, were used, and for each artificial myocardium, diaphragms having [these] three types of membrane thickness were made.

Shown below are the categories measured in the present tests, and the instruments used for measurements.

(1) Aortic flow rate [pressure] (AoP, Nihon Kohden Corp., FF-160)

(2) Left ventricle intraventricular pressure (LVP, Edwards Lifesciences Corp., UK801(TW))

(3) Pressure given to the ventricular wall by the cardiac ventricle assistance apparatus (Load, Kyowa ([Electronic Instruments Co., Ltd.)], LM-5KA)

Here, as for pressure given to the ventricular wall by the cardiac ventricle assistance apparatus, measurements were performed by placing a load cell [又は loadcell] between the diaphragm of the ventricle assistance apparatus and the ventricular wall.

A summary of test methods is shown below.

(1) The artificial myocardium portion of the cardiac ventricle assistance apparatus is fixed to the left ventricle model.