Project No. H-14-Nano-020

Implantable Artificial Myocardium using Nano Technology

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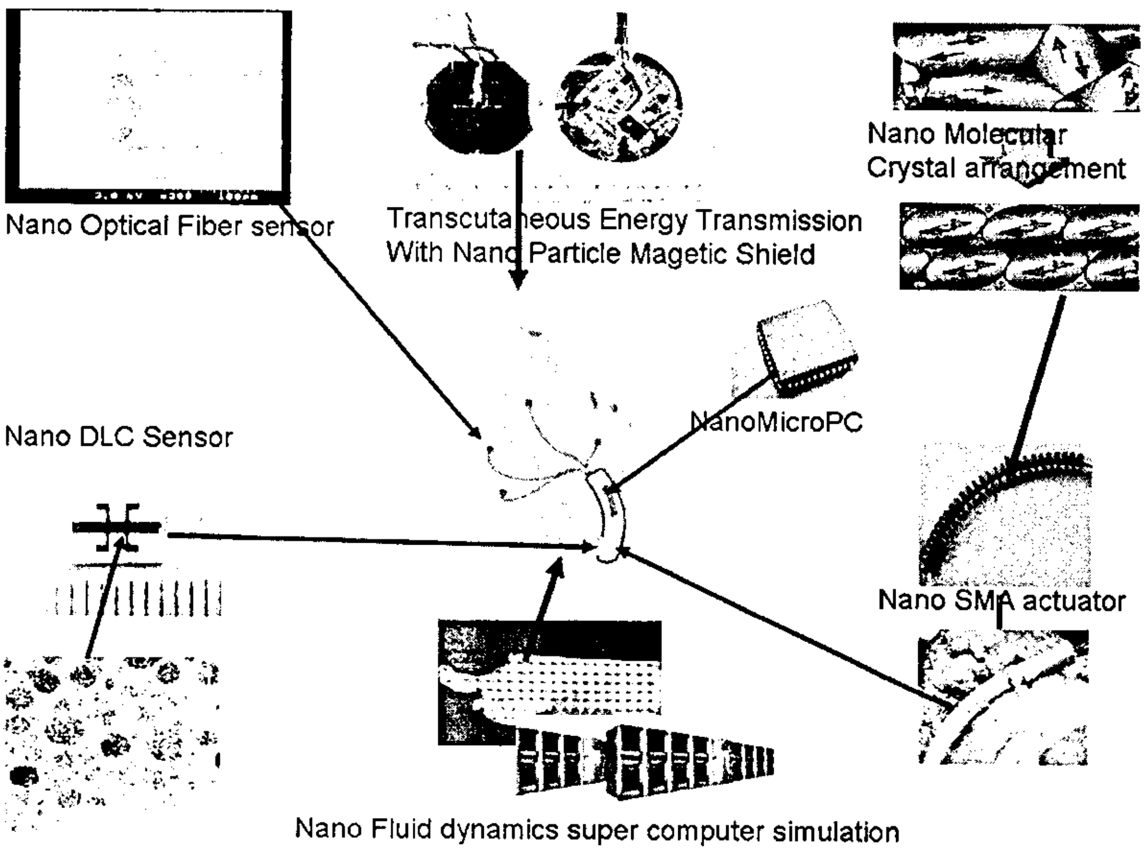

Tomoyuki YAMBE
Professor
Institute of Development Aging and Cancer
Tohoku University

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ナノテク集積型埋め込み式心室補助装置

平成14－16年度研究報告書

主任研究者
山家智之
東北大学加齢医学研究所

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Chief Investigator; Tomoyuki YAMBE, Tohoku University

Investigators:

Shin-ichi NITTA

Masayoshi ESASHI

You-ichi HAGA

Makoto YOSHIZAWA

Eiji OKAMOTO

Shigenao MARUYAMA

Toshiuyuki HAYASE

Toshiyuki TAKAGI

Yun LUO

Hidetoshi MATSHUKI

Fumihiro SATO

Hiroshi FUKUDA

Kouichi TABAYASHI

Yoshifumi SAIJO

Toshihiko IIJIMA

Motohisa OSAKA

Yutaka KUBO

Satoyuki KAWANO

Yoshio HORI

Yoshinori KONNO

Kiyoshi YAMAUCHI

Satoshi KONNO

Mitsuya MARUYAMA

Kenji YAMAGUCHI

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研究組織

研究代表者　山家智之　東北大学加齢医学研究所教授

研究分担者　仁田新一　東北大学加齢医学研究所教授
研究分担者　江刺正喜　東北大学未来科学技術共同研究センター教授
研究分担者　芳賀洋一　東北大学大学院工学研究科講師
研究分担者　吉澤誠　東北大学情報シナジーセンター教授
研究分担者　田中明　ベイラー医科大学研究員
研究分担者　岡本英治　北海道東海大学工学部助教授
研究分担者　圓山重直　東北大学流体科学研究所教授
研究分担者　早瀬敏幸　東北大学流体科学研究所教授
研究分担者　高木敏行　東北大学流体科学研究所教授
研究分担者　羅雲　東北大学流体科学研究所助手
研究分担者　松木英敏　東北大学大学院工学研究科教授
研究分担者　佐藤文博　東北大学大学院工学研究科助手
研究分担者　福田寛　東北大学加齢医学研究所教授
研究分担者　田林晄一　東北大学大学院医学系研究科教授
研究分担者　西條芳文　東北大学加齢医学研究所助手
研究分担者　飯島俊彦　秋田大学医学部長
研究分担者　大阪元久　日本医科大学老人病研究所講師
研究分担者　久保豊　東京女子医科大学第２病院助手
研究分担者　川野聡恭　東北大学学際科学国際高等研究センター助教授
研究分担者　梅津光生　早稲田大学理工学部教授
研究分担者　堀義生　東北大学先進医工学研究機構助教授
研究分担者　紺野能史　東北電子産業株式会社開発部員
研究分担者　山内清　東北大学先進医工学研究機構教授
研究分担者　金野敏　東北大学加齢医学研究所助手
研究分担者　丸山満也　東北大学加齢医学研究所助教授
研究分担者　山口健二　トキコーポレーション部長

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CONTENTS

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Implantable Artificial Myocardium using Nano Technology

Tomoyuki YAMBE
Institute of Development, Aging and Cancer, Tohoku University

Abstracts: We have developed a novel assisted-circulation apparatus through the integration of nanotechnology, including nano-optical sensor, nano-DLC sensor, nano-control integrated circuit, nano-particle percutaneous energy transfer and nano-actuator. This new device is completely different from the artificial hearts or the ventricular assist devices currently used. Researches have already established the elemental technology, and we are now entering into the integrated experiment phase. Animal experiments have confirmed the cardioassist effect of the new device. According to the timetable, a chronic experiment on the integrated system, with a view to determining the cardioassist effect of the apparatus, and a durability test will be conducted, before we proceed with a preclinical test.

Key words: Artificial myocardium, Nano technology, Nano sensor, Transcutaneous energy transmission system with Nano particle, Nano fluid dynamics

Introduction

Nowadays, the pension system is said to be failing, and with the aging of society, it is beyond question that the rehabilitation into society of aged patients with cardiac insufficiency will be increasingly necessary in the near future.

While in serious cardiac failure cases there are no other means of saving their lives than artificial heart or heart transplantation, the shortage of organs needed for transplants is already serious and there are mounting expectations for artificial hearts. However, it is widely accepted that the artificial-heart systems which are under development in Europe and the United States are too big to implant into the body of a Japanese patient.

Returning to the original intention, it is not always necessary to remove the heart totally or to implant a pump to assist the circulation. As is clear when we think of the theory of cardiac massage in an emergency, the heart can maintain its pumping motion relatively easily if it is pressurized from outside. An open chest massage, in which the heart is grasped by the hand and squeezed rhythmically, can bring about sufficient blood pressure and circulation.

The purpose of this study is to

develop, through the application of nanotechnology, a completely new type of ventricular assist device which maintains cardiac output by directly pressurizing the heart, that is, a versatile and easy-to-apply implanted microminiature ventricular assist device with a built-in intelligent control mechanism which detects myocardial function and hemodynamics, making the most of a nano-sensor under development in Tohoku University, and calculates the necessity of assisted circulation with a controlling microchip, assisting those patients who suffer from cardiac insufficiency

Since the ventricular assist device to be developed is a device which assists the patient on an as-needed basis, unlike pump systems such as the artificial heart, which brings the risk of thrombus formation unless it is constantly throbbing, it has excellent durability and offers promising prospects. The control mechanism to be developed therefore will be highly versatile; that is, it will be applicable to a wide range of artificial organs as well as to artificial hearts, including those currently under development in Japan and overseas.

B. Method of study

The artificial myocardium to be developed in this study will be a system which assists the myocardial beat with a microminiature actuator.

Since it will be sewn onto the external surface of the heart, there will be no danger of thrombus formation, unlike in the case of the conventional artificial heart, and there will be no durability problem, unlike in the case of the prosthetic cardiac valve. Its durability is expected to be excellent because the heart contracts on its own whenever aid from the device is unnecessary, and its miniaturization is possible due to its simple mechanism.

The definitive schematic drawing of the ventricular assist device, in which nanotechnology is integrated, is shown below. Its ultimate goal is the nano-myocardium, which is a combination of a nano-sensor, a nano-controller and a nano-actuator, exceeding even the performance of the human myocardium.

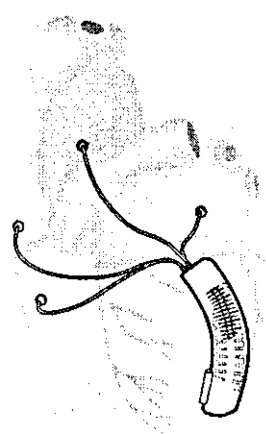

Fig. 1 Artificial myocardium with the nano technology

The Peltier device (patent pending; patent application number: 11292727), which can be manufactured as a nano micromachine using a shape-memory alloy / shape-memory resin, is currently considered to be a promising candidate for the actuator to be used in patients with relatively mild cardiac problems.

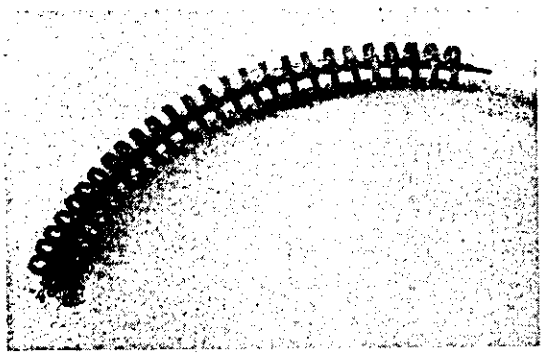

Fig. 2 The Peltier device

Also, nano-sized artificial muscles were created through the development of a nano-SMA actuator in which the crystalline orientation is controlled at the molecular level nanotechnologically.

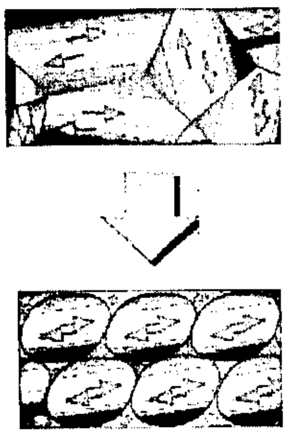

Fig. 3 SMA crystalline orientation control through nanotechnology

For more serious left-ventricular failure cases, the development of a motor-driven actuator is intended. Currently, a ball-screw actuator which is to be attached between the ribs is under development.

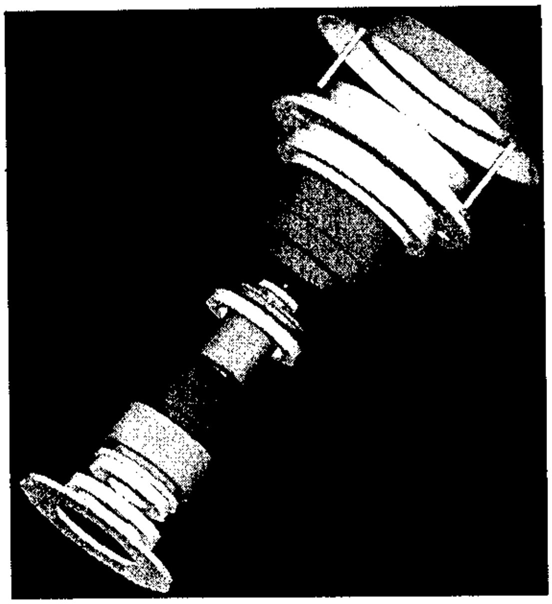

Fig. 4 A ball-screw actuator

The ball-screw actuator is remarkable as a small and highly efficient actuator, and computer-aided design (CAD) and computer-aided manufacturing (CAM) are used to implant it between the ribs.

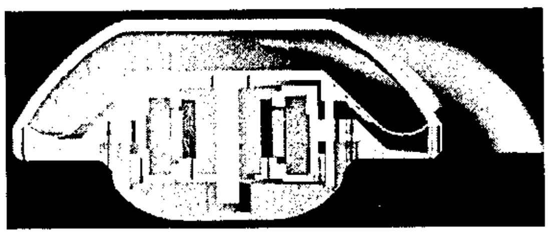

Fig. 5 Actuator which is to be attached between the ribs

The ultimate goal is a nano-machine which is a total ventricular assist system. Before the experiment was commenced, the study was subjected to strict examination by the Ethics Committee on Animal Experiments, the Institute of Development, Aging and Cancer, Tohoku University, and upon completion of the examination, we have conducted the experiment in accordance with the stipulated rules and regulations.

C. Results of the study

The purpose of the animal experiment was the development of a directly driven artificial myocardium. Since the smallest possible artificial myocardium was desirable therefor, an animal experiment with a Peltier device was set up.

Fig. 6 Animal experiment with a Peltier device

The animal experiment revealed that the driving velocity of the Peltier device was above 1 Hz. Thus, the Peltier device reached a remarkable driving velocity in comparison with that attained by an ordinary shape-memory alloy, which can only give about 0.1 Hz at most. This means that the Peltier device has an excellent potential of applicability to the artificial myocardium.

However, because the Peltier device, which comprises a rod-shaped shape-memory alloy, was directly sewn onto the myocardium, the device became twisted laterally along the longitudinal direction of the myocardium during myocardial contraction. It seemed, from the anatomical viewpoint, that it was essential to sew the device onto the myocardium along the direction of travel of the myocardium fibers.

It is known that the myocardium comprises three anatomical layers, and that each of these three layers contributes its own specific functionality to the contraction. There have been reports that myocardial-infarction patients suffer various disabilities according to the sites or regions affected. Such reports seem to suggest the possibility that sewing the device along an anatomically optimal direction may bring about an effective cardiac output from the pathophysiological viewpoint.

Next, an attempt at direct driving by the ball-screw motor shown in Fig. 4 was made, with the intention of making it available to a wide range of myocardial-infarction patients and dilated-cardiomyopathy patients.

For the development of an artificial myocardium, it is necessary to fix the actuator onto the heart in a sophisticated manner.

Emergencies commonly arise during cardiac surgery. During coronary-artery bypass surgery under cardiac pulsation, for instance, a procedure which has recently become standard, extracorporeal circulation is not performed despite the fact that the surgery itself is a considerable burden on the heart already subjected to ischemia. Under such circumstances, ventricular fibrillation can occur, accidentally causing cardiac arrest at any time during the difficult operation.

If there were an artificial-myocardium system, which is easily applied under such an emergency, its value would be quite significant from the clinical viewpoint as well.

With this in mind, the ventricular cup shown in the figure was designed.

Even in cases of accidental cardiac arrest, it is possible to attach it to the ventricle immediately.

An animal test, in which an adult goat with about the same weight as the mean weight of Japanese male adults was used, showed that a preliminary ventricular cup made of polycarbonate could be attached to the ventricle of the goat within about 3 seconds.

Numerous studies in Europe and the United States, where heart strokes are frequent, have reported that unless an individual recovers within 3 minutes after the cardiac arrest, a resumption of consciousness in the patient cannot be expected due to irreversible damage caused by cerebral ischemia. If there were a device which can be attached to the heart extremely quickly, its value would be highly significant even during operations.

It is a matter of course that, during an operation, various accidents, including anesthetic accidents and hemorrhagic shock, can occur at any time, and in the worst cases the patients suffer the utmost adversity.

It is evident that if there were any easy-to-use device which can prevent such accidents, its scope of application would be limitless.

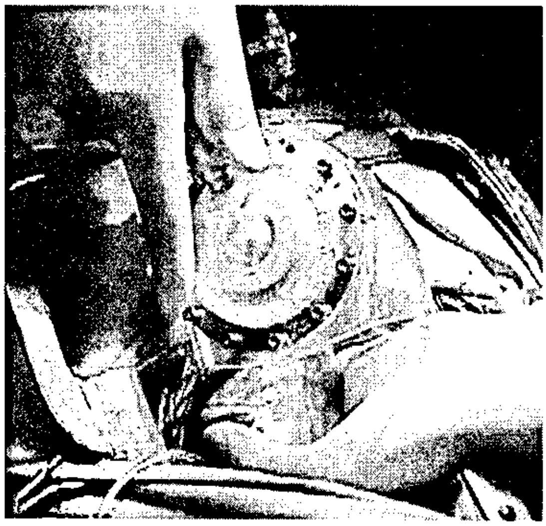

Fig. 7 A ventricular cup during an animal experiment

However, one problem of the ventricular cup is that it hinders the diastolic function of the ventricle; in some cases of enlarged heart, etc., the attachment of the ventricular cup brought about a tendency toward a decrease in arterial pressure due to a slight diastolic disorder.

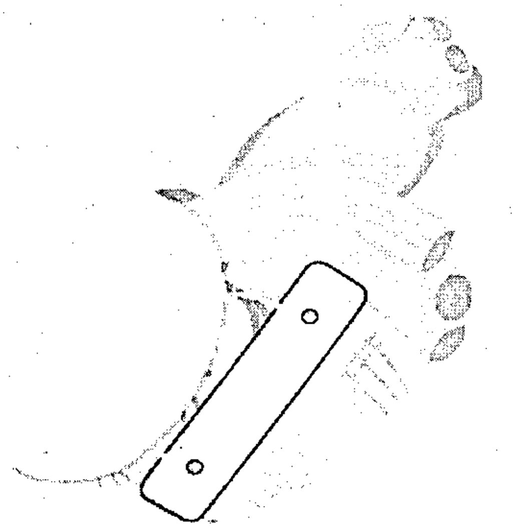

Fig. 8 The bandage-fixing method

As an alternative to the ventricular cup, the bandage method, in which the artificial myocardial device is fixed onto the heart without disturbing the diastolic function of the ventricle, was considered.

The results of animal experiments showed no tendency toward a decrease in arterial pressure due to the diastolic disorder observed with the ventricular cup, and confirmed a significant cardioassist effect of the artificial myocardial device.

However, the fact that the thoracic cavity of a small goat was not spacious enough to accommodate a directly driven ball-screw motor suggested the need for further miniaturization. This poses a difficult problem, because in a ball-screw motor one stroke-long axis juts out in the opposite direction as well.

With a view to resolving this problem, an electrohydraulic artificial myocardium was devised.

We have attempted to develop an electrohydraulic artificial myocardium, that is, a nano-tech-intensive ventricular assist device.

The concept of this system is to place the actuator outside the thoracic cavity in order to save thoracic space.

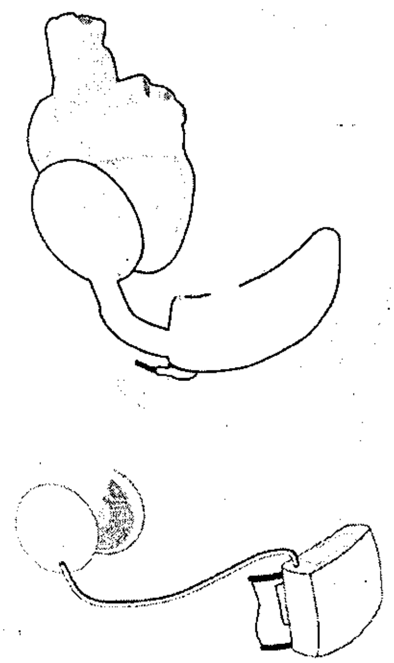

Fig. 9 A schematic drawing of the implanted electro hydraulic artificial myocardium system

The actuator is placed between the ribs, so that the thoracic space can be used efficiently. The actuator is driven as follows: the diaphragm is actuated by way of silicone oil, pressing the ventricle as in cardiac massage.

The driving energy is supplied from outside the body by a percutaneous energy-transfer system. The percutaneous energy-transfer system currently being developed at Tohoku University is characterized by a magnetically shielded outer surface with amorphous fiber.

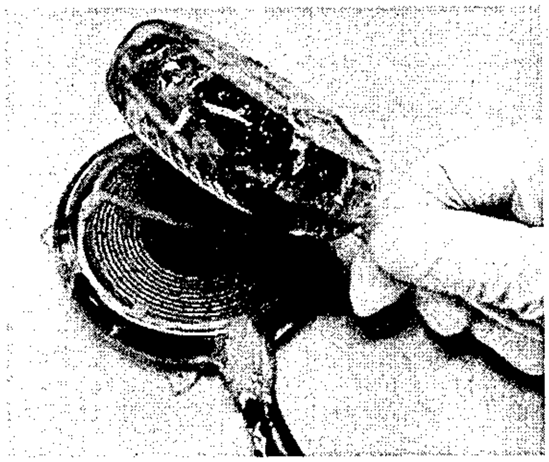

Fig. 10 Percutaneous energy transmission system

Magnetic shielding involves considerable technical difficulties, but Tohoku University has succeeded in solving them thanks to its original technology, and attained the world's top-level transfer efficiency by reducing the leakage of magnetic force to the outside. Furthermore, since the final aim of this system is to ensure a stable power supply without the constant involvement of the patient, a full-implant-type artificial myocardium will very likely be realized through the development and mounting of an electrical compensator and controller.

Accordingly, this study dealt with the development of a percutaneous power-transfer device which can automatically control the electrical impedance mismatch caused by the displacement between the coils or the change in coil space. This device automatically improves the electrical power factor by properly changing the power transfer frequency. Also, this study examined the miniaturization of the transfer coil. This system can process the functioning of the device solely according to the extracorporeal response, and also it seems to be a system compatible with the miniaturization of the power supply actuating the myocardium.

Fig. 11 A chronic experiment on percutaneous energy transfer

Currently, the device is in the chronic animal experiment phase, in which its biocompatibility and durability are being examined (1 month has passed as of March 20).

The artificial myocardium has an important advantage over the artificial heart and the ventricular assist device.

The advantage of the artificial myocardium is that there is no need for full-power operation on a constant basis. The artificial heart and the ventricular assist device are basically pumping systems, so unless the blood flow is constant, the inside of the pump becomes congested with blood, leading immediately to thrombus formation. Immediately after the formed thrombi are transported to the cerebral artery, they are likely to cause fatal strokes or cerebral infarctions. In fact, Jarvik-7, which was applied in a clinical setting as the world's first artificial heart for permanent use, left a trail of tragic cases; all five patients which had received it developed cerebral thrombosis or embolism.

However, if the artificial heart is always operated at full stroke in order to maintain a smooth blood flow in fear of thrombus formation, the artificial valve becomes overloaded and eventually damaged due to water hammer action.

That is, both slow operation and full-stroke operation cause problems.

By contrast, the artificial myocardium which has been devised in this study is, in essence, outside the ventricle and not directly exposed to the blood flow. Therefore, it is by far the best alternative in terms of avoiding thrombus formation.

Furthermore, it is sufficient to develop a system which assists the heart only when and insofar as assistance is needed. It is needless to refer to the NYHA classification: most heart failure patients develop symptoms of heart failure only during physical exertion. This means that systolic assistance is needed only when the patients engage in physical activity. For example, a pacemaker with a built-in vibration sensor can increase the heart rate when the patient is performing physical activity. Also, there are many patients who need the assistance of an artificial myocardium only when performing physical activity.

The question is how to confirm when assistance is needed. The development of an implant-type sensor is necessary from this viewpoint.

Researchers at Tohoku University have been engaged in research for the development of biometric sensors for a long time, by making the most of nano-micro-technology. We have successfully developed a catheter-tip manometer and applied it in a clinical setting. Also, we have succeeded in the chronic animal testing of an input unit for controlling the artificial heart.

Accordingly, by combining these systems, we can expect the realization of an input system for controlling the operation of the artificial myocardium based on stable biometry.

Regarding the implant-type sensor, it is obvious that the smaller, the better. We have also successfully developed a subminiature nano-sensing device with a thickness of 700 nm, thanks to the recent progress in nanotechnology.

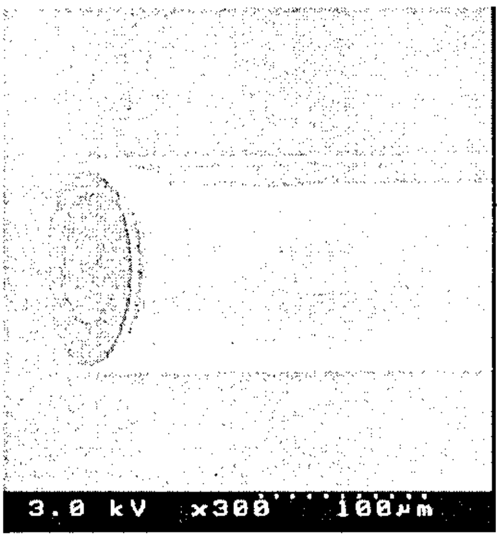

Fig. 12 An optical nano-sensor with a thickness of 700 nm

That is, we have developed an ultrafine optical-fiber pressure sensor with a diameter of merely 125 μm, to which a silicone-micro-machining diaphragm is attached at the end section of the optical fiber, as an input unit for controlling the nano-tech-intensive ventricular assist device. A combined mirror and diaphragm with a diameter of 120 μm was manufactured using micro-machining technology, and by joining it to the end section of the optical fiber with a diameter of 125 μm, to which a half mirror was connected, a Fabry-Pérot interferometer was formed at the tip of the optical fiber. Light coming into the optical fiber from a light source enters the detector upon modulation at the interferometer located at the tip of the fiber. Since the diaphragm yields in accordance with the pressure of the surroundings where the sensor is placed, the optical path difference between the mirror and the half mirror varies; thus, the pressure can be measured by the detector based on the modulation.

The sensor structure can be mass-produced using the silicone-nano-machining technology.

If a white light source or a light-emitting diode (LED) with a short coherence length is used as the light source, the optical path difference produced between the half mirror at the end section of the optical fiber and the diaphragm is compensated by the two half mirrors of the detector, and interference occurs. When the gap between the mirrors is the same, the strongest interference occurs, and with increasing gap difference, the strength of interference decreases.

Based on this theory, pressure sensing utilizing nano-microstructures has become possible.

The integration of this technology into the artificial myocardium is currently planned.

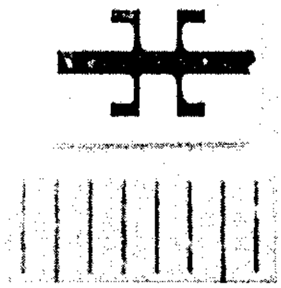

Fig. 13 DLC nano-sensor

Furthermore, we have recently developed a diamond-like carbon (DLC) nano-sensor and are actually developing a way to attach it to the inner surface of the artificial myocardium.

The DLC nano-sensor was originally developed as a temperature sensor, but since it proved to be effective as a pressure sensor as well, further R&D for it is underway (a multilayer resistance distortion gauge mainly consisting of carbon; patent application No. 2003-317956).

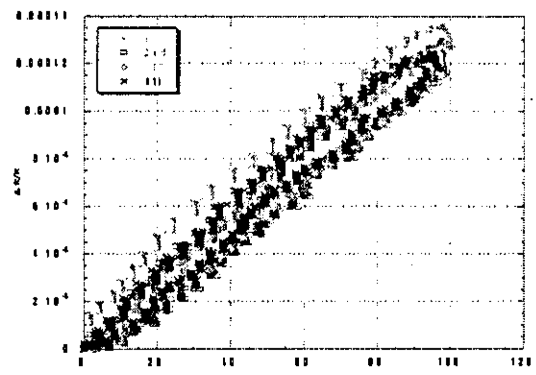

Fig. 14 Characteristics of the diamond-like carbon (DLC) nano-sensor used as a pressure nano-sensor

As shown in the figure, it is the best sensor for incorporating into the ventricular assist device which is under development in this study. If the artificial myocardium made of shape-memory alloy becomes a reality, this sensor can be used as an integrated intelligent element by coating the inner surface of the artificial myocardium with it (thickness: about 20 μm).

That is, it is very promising as an intelligent material with a potential of surpassing the living myocardium. We expect it to be the sign of a promising new field of study.

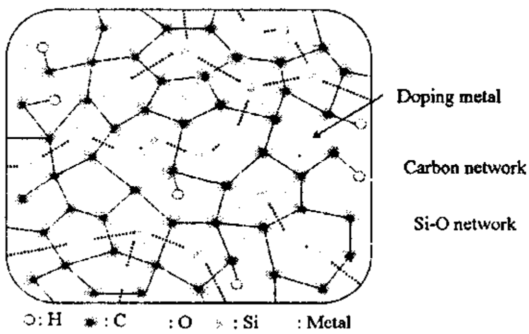

Fig. 15 A nano-sensor which can sense various elements can be realized by combining the molecular structure of diamond-like carbon with dopping metal.

As the control algorithm for the artificial myocardium, we are developing the "artificial blood-pressure reflection" control algorithm, which is the most versatile and universal. This automatic control system is applicable to the total artificial heart, the ventricular assist device and even the rotary pump, and it automatically controls the devices upon calculating in real time the peripheral vascular resistance based on the hemodynamic data.

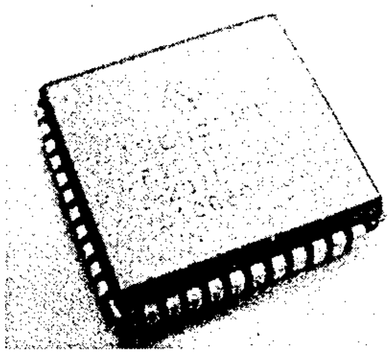

Fig. 16 A nano-micro control chip

If the blood pressure increases due to an external disturbance, the artificial heart can reduce the systolic output accordingly. That is, it is an automatic control system with the same effect as blood-pressure reflection, resulting in the maintenance of the blood pressure at a constant value, in order to ensure physiological homeostasis.

Thanks to the introduction of this system, the automatic control of the artificial myocardium is becoming a reality.

In developing the algorithm for controlling the artificial myocardium, it is necessary to estimate the particular pumping function of the patient's ventricle. In the past, the author, et al. had proposed the parameter optimization method (POM) as a way to estimate the maximum elastance (Emax), which is an indicator of the pumping function of the ventricle. However, this method requires the measurement of the aortic flow rate (AoF) and left ventricular pressure (LVP) in the systolic phase. In the past, the measurement of LVP and AoF had been very invasive, but as a result of subsequent research, a noninvasive technique of estimating LVP based on radial artery pressure was proposed. Regarding AoF, while direct measurement is still invasive, it is possible to obtain its value noninvasively by processing the ultrasonic Doppler echocardiographic image. Therefore, in this study, with a view to estimating the Emax by entirely noninvasive means, we formulated a system of automatically estimating AoF based on the video signal of an ultrasonic diagnostic equipment which is in widespread use, in order to examine the estimated accuracy of the Emax determined based on the estimated value of AoF.

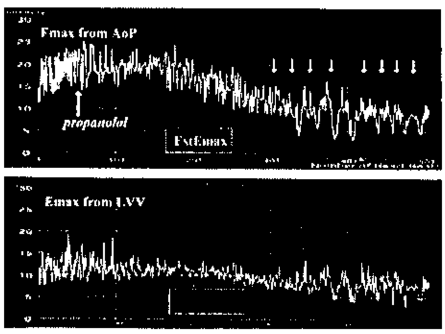

Fig. 17 Emax: estimated value and measured value

The study results have suggested the possibility that the Emax may be estimated automatically in an entirely noninvasive manner through a combination with the method of estimating the left-ventricular pressure based on radial arterial pressure. Hereafter, in order to check the validity of the estimated aortic flow rate, it is necessary to compare it with the measured value. But once this study is complete, it will greatly contribute to the development of an algorithm for controlling the artificial myocardium.

In order to attach a nano-tech subminiature artificial myocardium to the living heart, an accurate understanding of the systolic behavior and an accurate measurement and simulation clarifying the way in which the damaged part of the heart should be assisted are necessary. Consequently, we proceeded with the development of an entirely new flow simulation device for the cardiovascular system by bringing together the current expertise in such diverse fields as hydrodynamics, hydraulics, ultrasonic medicine, nuclear medicine and circulatory pathology.

The study on flow control is expected to evolve into a study on the control of the flow field itself, without being limited to the traditional study on fluid control with fluid as the pressure medium. Researches into a new analysis technique which combines experimental measurements and supercomputers for the purpose of obtaining in real time the enormous fluid data in the flow field, and into the technique of controlling the flow field, are actively being undertaken at the Institute of Fluid Science and producing remarkable results.

Traditionally, various test methods and devices for determining the blood flow, including the Doppler-method ultrasonic diagnostic apparatus, the cardiovascular catheter test and nuclear magnetic resonance computed tomography (NMR-CT), are known. The Doppler-method diagnostic apparatus, which has a broad range of clinical applications, displays the velocity vector in color.

However, since ultrasound probing is usually done perpendicularly to the body surface and the velocity component of the blood flow, which is parallel to the transmitted beam, is small in most blood vessels which are parallel to the cutis, it is difficult to display accurately the vector velocity of the blood flow. As just described, since the conventional Doppler-method ultrasonic diagnostic apparatus cannot measure the vertical velocity of the blood flow, the blood flow cannot be pinpointed. Also, as of now there is no technology for measuring the intravascular pressure distribution, which is important in foreseeing the rupture, etc., of blood vessels. It is evident that there is no method or technique for determining the intracardiac pressure distribution, which is important for understanding intracardiac vascular behavior.

Although it is presumed that numerical simulation is important for revealing the mechanism of the steady-state intravascular blood flow, as a matter of course its arithmetic precision will be insufficient due to the difficulty in choosing the boundary conditions.

Accordingly, we attempted to combine ultrasonic measurement, which is the typical measurement technique for the cardiovascular system, with computer simulation. The results of this combined measurement showed a remarkable precision, one not attained heretofore. This combined technique raises high expectations for the development of an entirely new diagnostic device with a wide range of applications in cardiovascular diseases as well as the design of an artificial myocardium.

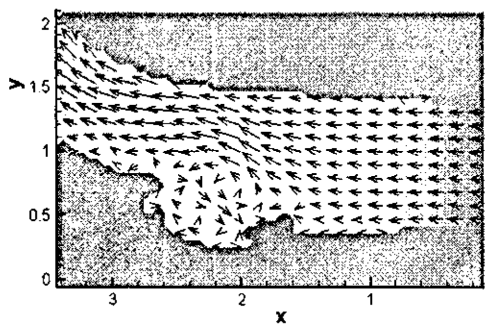

Fig. 18 Visualization of the intravascular flow, achieved through the integration of ultrasonic measurement and computer simulation

Also, the nano-tech artificial myocardium is expected to be driven in a manner friendly to the living body while itself participating in the control thereof.

However, the heart-rate variation (HRV), which is the fluctuation in antral tuning, displays a so-called "complex" behavior due to the autonomic nerves, controlling elements such as neurosecretion, and the interactions among them.

Therefore, by analyzing them, we can obtain a wide range of information regarding the cardiovascular control system. We have conducted research aiming at physiologically controlling the artificial myocardium, through analyses of the fluctuation, including HRV information, by making the most of nonlinear mathematical theory.

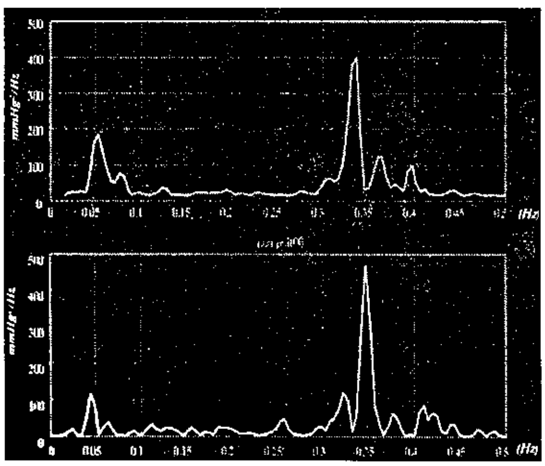

Fig. 19 The periodic fluctuation in heart-rate variation before and after the actuation of the artificial myocardium

HRV analysis was conducted based on the results of electrocardiography, and in the analysis, the relevance of the mean heart rate, SDNN, HF, LF/HF and Hurst index to the neurobehavioral function was examined. All of the resulting scores of the neurobehavioral function test showed a correlation with age. Also, the results of the cubic test showed a significant correlation with the palmic Hurst index, and between the neurobehavioral function and the complexity of the heart-rate variation some association was suggested. It is expected that such an approach will bring about the physiological control of the artificial myocardium in accordance with the behavioral characteristics of the elderly. With the aim of realizing a total nano-tech system, we have undertaken and are continuing to undertake chronic animal testing of the artificial myocardium. So far, 5 animals have survived over extended periods.

Fig. 20 A goat in the chronic testing of the nano-tech-integrated ventricular assist device

As of now, the fourth & fifth animal has survived for two months after the implantation.

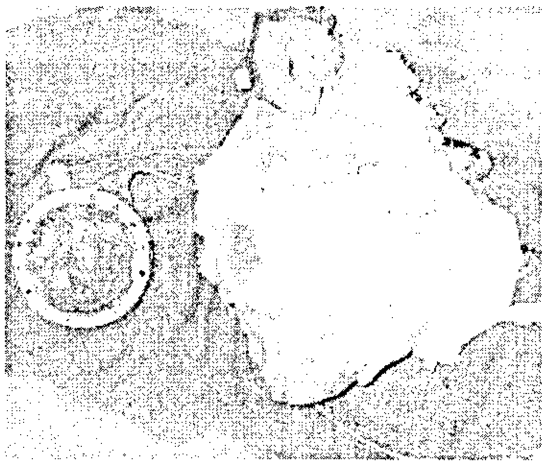

Fig. 21 The heart extracted after the ventricular assist device had functioned for three weeks

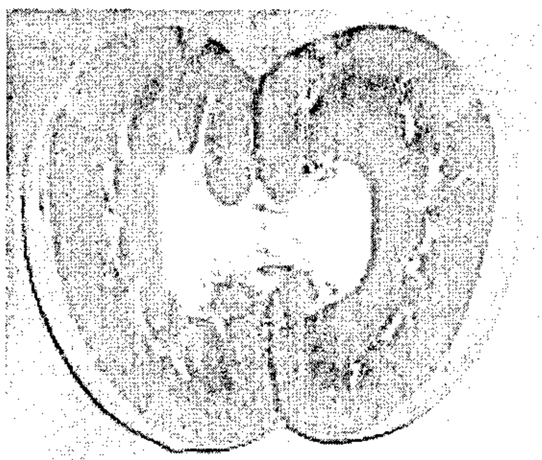

Fig. 22 The left kidney extracted after the ventricular assist device had functioned for three weeks

Fig. 23 The liver extracted after the ventricular assist device had functioned for three weeks

No necrosis caused by thrombosis in the liver or kidney has been found. That is, the hypothesis that the nano-tech ventricular assist device poses no risk of thrombus formation has been demonstrated.

Also, there have been no findings of congestion in the liver or kidney; that is, excellent maintenance of the right-heart circulation has been confirmed, with the exception of some congestion on the contact surface of the ventricle.

D. Discussions

The anatomical treatment and improvement of disease conditions via surgical operation of anatomical changes such as obstruction of the coronary artery, shape changes of valves, etc., is currently no longer very difficult. Among heart diseases, that which is finally most difficult to treat, and which remains until the end, is surely insufficient myocardial contraction due to pathological changes of the myocardium itself.

In other words, if one were to consider at what site cardiac insufficiency can finally be assisted, this would surely be at the heart contractions themselves. Considering the principle of heart (cardiac) massages, one can easily imagine that cardiac output can be preserved through pushing of the cardiac ventricles. Thus, if one were to “suture in” a system for pushing the cardiac ventricles as in a heart massage, then the beating of a heart could be assisted.

At Tohoku University, research and development of “artificial myocardium” has progressed since the past. Already success has been achieved in chronicity tests with an air-pressure driven type artificial myocardium, and its cardiac assistance effects have been confirmed in survival experiments surpassing three (3) months. Further, a development project has been launched toward the development of artificial myocardium which incorporates superior QOL (quality of life) characteristics, and research and development has begun with the aim of rapid progress via integrated tie-ups with the most advanced medical engineering sciences.

The key technologies for this development are artificial myocardium actuators, nanosensors, control nanochip