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Development of an Artificial Myocardium using a Covalent Shape-memory Alloy Fiber and its Cardiovascular Diagnostic Response

Y. Shiraishi, T. Yambe, K. Sekine, N. Masumoto, J. Nagatoshi, S. Itoh, Y. Saijo, Q. Wang, H. Liu, S. Nitta, S. Konno, D. Ogawa, P. Olegario, M. Yoshizawa, A. Tanaka, F. Sato, Y. Park, M. Uematsu, M. Higa, Y. Hori, T. Fujimoto, K. Tabayashi, H. Sasada, M. Umezu and D. Homma

Abstract— **The authors have been developing a newly-designed totally-implantable artificial myocardium using a covalent shape-memory alloy fibre (Biometal®, Toki Corporation), which is attached onto the ventricular wall and is also capable of supporting the natural ventricular contraction. This mechanical system consists of a contraction assistive device, which is made of Ti-Ni alloy. And the phenomenon of the martensitic transformation of the alloy was employed to achieve the physiologic motion of the device. The diameter of the alloy wire could be selected from 45 to 250μm. In this study, the basic characteristics of the fiber of 150μm was examined to design the sophisticated mechano-electric myocardium. The stress generated by the fiber was 400gf under the pulsatile driving condition (0.4W, 1Hz). Therefore it was indicated that the effective assistance might be achieved by using the Biometal shape-memory alloy fiber.**

I. Introduction

HEART transplantation has been widely performed as destination therapy for the severe heart failure. However, it is limited by donor organ shortages, selection criteria, as well as the cost [1]. And recently, cell transplantation to repair or supplement impaired heart tissue has been reported as an alternative therapy for that [2]. But, there are many problems that are not yet solved about the tissue reproduced in vitro or in vivo. Moreover, it is anticipated that any control for the implanted tissue is impossible from the outside.

The authors have been developing a totally-implantable artificial myocardial assist device [3]-[6]. The methodologies of the direct ventricular support systems were already reported as direct mechanical ventricular assistance (DVMA) by

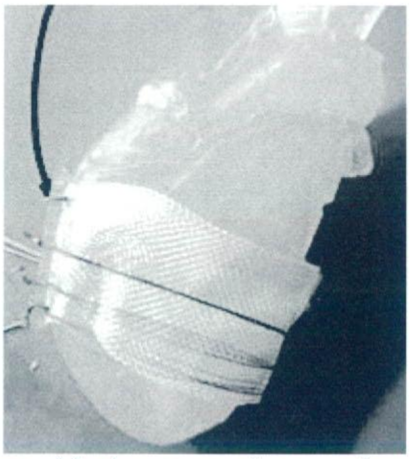

Fig. 1: An image of the shape-memory alloy myocardium; the fiber was attached onto the silicone moulded ventricle.

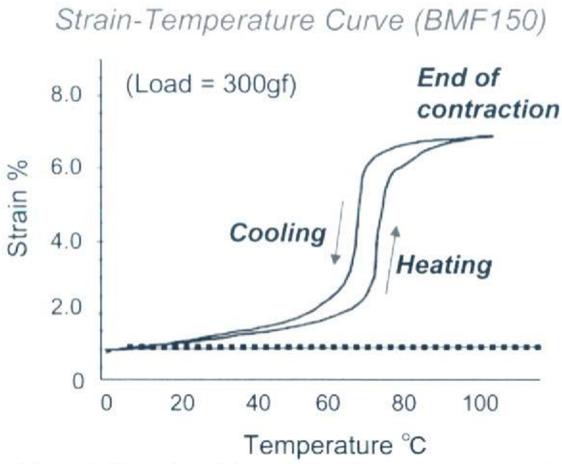

Fig. 2: Schematic illustration of the typical strain-temperature curve obtained from the Biometal fiber (diameter: 150μm). Because of the linearity between the thermal and the electric resistance, the displacement can be controlled by the simple circuit and also the sense of force can be estimated.

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Anstadt's or other groups, as well as the right ventricular assist device which was invented and reported at IDAC, Tohoku University [7]-[9]. In this study, the covalent shape-memory alloy fiber (Biometal®) was employed for the development of a sophisticated artificial myocardium, as shown in Figure 1.

II. Material and Methods

A. Ti-Ni alloy fiber (Biometal)

In general, Ti-Ni alloy is well known as a material with the shape-memory effect[10]-[12]. The fiber material (Biometal®), which was used in this study for the development of artificial myocardium, has the configuration of the covalent bond, and indicates a big strain change as shown in Figure 2. The linearity of the recovery strain and the changes in electric resistance could be adjusted through the fabrication process, so that the strain of the fiber could be easily controlled by using the digital-servo system without potentiometers. And the input power was controlled by the pulse wave modulation.

B. Dynamic characteristics of the fiber

To achieve the development of the myocardial systolic assistance by the shape-memory fiber, we examined the functional behavior of the material under the pulsatile condition using the fiber with the diameter of 150μm. The driving frequency and voltage was changed from 0.1 to 1Hz and 6.5 to 8V, respectively, by an amplifier (Yokogawa Electronics, Japan, FG300), and the mechanical load was measured by the load cell (Kyowa, LVS-1KA), as shown in Figure 3.

III. Results and Discussion

Figure 4 shows the transient response of the Biometal fibre under the different input conditions. The duty ratio was changed from 50 to 300msec, and there was no discernible difference of the speed of the stress gain. As the actuation was conducted only by cooling-and-heating process in the fiber, neither a sound nor an electric noise could be easily generated in each part.

The exergy change against the input power was also examined as shown in Figure 5. Saturation of heat radiation, which was caused by the increase of thermal resistance around the input power of 0.5W, could be investigated. And the heat transfer should be optimized around the myocardium by the design of the structure.

The cyclic test of the material had also been carried out over 700 million times so far and there had not been any changes of the composition. Therefore it was concluded that it might be suitable for the sophisticated artificial myocardium.

Contractile force and systolic displacement could be changed by the pre- or afterload that were determined by the pressure of atrium and arterial system, respectively. The artificial myocardium using Biometal might have moderate flexibility which is caused by the superelasticity and the vibration

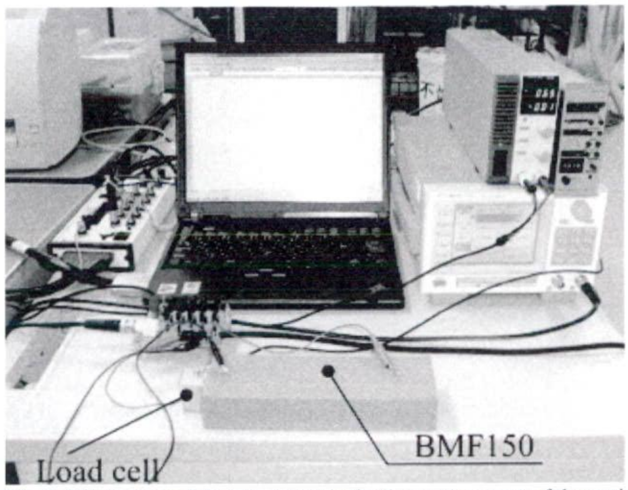

Fig. 3: Whole view of the test apparatus for the measurement of the strain and stress of the shape-memory alloy fiber.

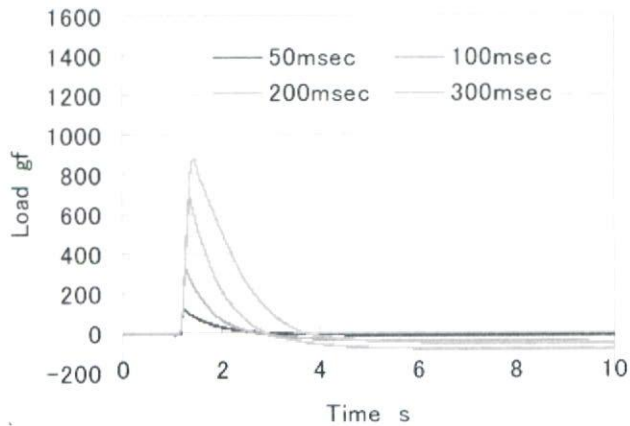

Fig. 4: Basic characteristics of the transient response obtained from the fibre under the different PWM conditions; the duty of the input was set to be 50, 100, 200, 300msec respectively, and 4.5kgf/sec could be achieved in each condition at the room temperature (25°C) by unit step input.

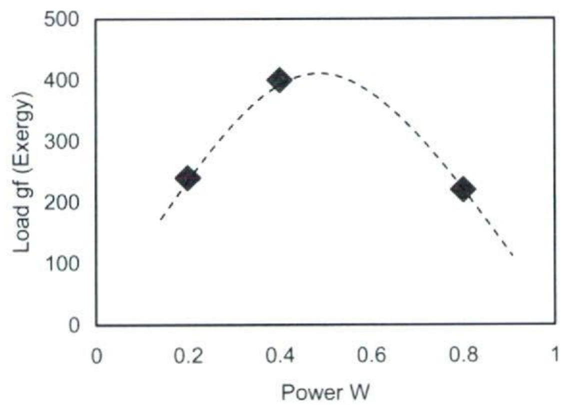

Fig. 5: Changes in the exergy obtained from the fiber (diameter: 150μm) under the pulsatile condition of 1Hz.

damping ability. And this function seemed to be useful for buffer preventing the sudden drift of loading conditions. Therefore, the newly-developed mechano-electric myocardium was easy to evade breakdown of natural tissue as well as the system itself.

From the physiologic point of view, it is said that the discrepancy between geometry and sustainability of mechanical function of the heart is attributed to the fact that mass reduction causes changes in diastolic compliance. Some of the device, such as Acorn® cardiac support device, succeeded to reduce the volume at the dyskinetic portion of the ischemic heart and to prevent the development of lesional remodelling followed by the increase the cardiac wall thickness [13]-[16]. Therefore, our system using an 'Active' fiber might become more effective device for the treatment of severe heart failure. And the moderate changes by the shape-memory fiber would be also the suitable containment device for ventricles.

IV. Conclusions

Preliminary function of the dynamic characteristics of the alloy fiber was examined, which was capable of being installed into the thoracic cavity as the epicardial actuator. In this myocardial system, the load, which was generated by the natural cardiac function, could be estimated by measuring the electrical resistance of the shape-memory alloy fiber.

As our system could assist natural ventricular functions with physiological demand, it might be applied in patients with exertional heart stroke, as well as the cardiac massage at lifesaving emergency for the recovery from ventricular fibrillation.

Acknowledgment

The authors would like to extend their appreciation to Mr. K. Kikuchi and Mr. Kumagai for their cooperation in the experiments.

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DEVELOPMENT OF AN ELECTROHYDRAULIC MYOCARDIAL ASSIST SYSTEM INSTALLED INTO THE INTERCOSTAL SPACE

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Abstract: The authors have been developing a newly-designed totally-implantable myocardial assist system, which is attached onto the ventricular wall and is also capable of supporting the natural ventricular contraction. This system consists of an electrohydraulic actuator and a contraction assistive device, which is made of polyurethane and covered by the acrylic casing. The weight of the actuator is 550g, and the shape of it (W: 70mm, H: 59mm, L: 110mm) was designed to be installed into the intercostal space in the thoracic cavity. Its functional requirements are not only to be totally implantable but also to be able to assist the diseased heart function effectively according to the physiological demand. In this study, the totally-implantable electrohydraulic myocardial assist device was installed into the intercostals space of goats, and the preliminary hemodynamic performance of the device was examined. And the effects of the synchronous mechanical contraction generated by the electrohydraulic actuator on the cardiovascular function was also evaluated.

Introduction

Artificial organs such as ventricular assist systems or blood pumps are generally and successively applied in the treatment of severe heart failure. However, the artificial materials might cause hemolysis or thrombus formation on the blood contacting surface.

The authors have been developing a miniature artificial myocardial assist device (so called '*artificial myocardium*'), which is capable of supporting the cardiac contractile function from outside the ventricular wall. The methodologies of the direct ventricular support systems were already reported as direct mechanical ventricular assistance (DVMA) by Anstadt's or other groups, as well as the right ventricular assist device which was invented and reported at IDAC, Tohoku University [1-8].

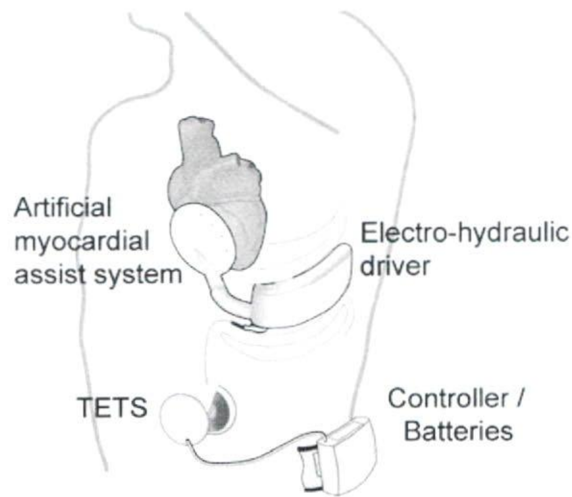


Figure 1: Schematic illustration of an image of the electrohydraulic myocardial assist system. The portion of the driver will be installed into the intercostal space.

The purpose of this study was to develop a totally-implantable electrohydraulic myocardial assist system, and the design image was shown in Figure 1[9]. The diaphragm assisting ventricular motion is driven by an electrohydraulic actuator, which is controlled by an embedded system. The transcutaneous electric transfer system, which has been developed at Tohoku University, can be applied for the system, and used to transmit the information of the system parameters not only of the mechanical system, but also of natural cardiovascular systems.

In this study, the development of a totally-implantable myocardial assist device could be achieved and we examined the hemodynamic performance of the device, and evaluated the effect of the motion of the system on cardiac functions in goats.

Materials and Methods

(1) Mechanical myocardial assist system

The newly-developed electrohydraulic myocardial assist system consisted of the following mechanical components: a) a fluid-filled chamber; a fluid-filled polyurethane diaphragm with disc shaped acrylic casing (D:52 mm x H:14 mm), in which the amount of change in the internal volume is 50 mL, and b) an originally-designed electrohydraulic cylindrical actuator, which was controlled by an originally-designed micro-computer. The fluid-filled chamber was fixed to the heart by a fiberglass belt as shown in Figure 3. And its mechanical contraction was synchronized with the ECG.

Several prototype models were developed in order to be installed into the intercostal space while the feasible performance could be demonstrated The actuator was covered by the acrylic casing, and the size was W: 70mm, H: 59mm, L: 110mm, which was designed to be fit the curvature of costae. The weight of it was 550g. In this study, the embedded controllers or TETS were set up outside of the body and connected to the actuator transcutaneously. The contractile duration was set at 120–150 msec so as not to disrupt the natural cardiac diastolic function, and the actual time delay from the input of 'R' pulse of the ECG signal to the effective contractile motion generated by the actuator was around 50 msec in that contraction. Figure 4 and 5 shows the schematic drawing of the mechanism and the illustration of the control diagram of the device.

(2) Chronic examination of hemodynamic performance in goat

Prior to the measurement, the myocardial assist device was installed in the thoracic cavity and anchored on the surface of the heart by a belt under general anesthetising procedure. The hemodynamic waveforms were obtained from healthy goats. Pulmonary and aortic blood pressures were measured by pressure sensors and amplified with a polygraph (Fukuda Denshi, CM-5001), and aortic pressure was also monitored by using the catheter-tip transducer (Millar, SPC-464D). Myocardial perfusion was obtained by the laser-doppler flowmeter (Omegaflow, FLO-C1BV), and cardiac output was also measured at the main trunk of the pulmonary artery by an ultrasonic flowmeter (Transonic Systems, TS420). Each data was digitally recorded with a data recorder (TEAC, LX-10) by the sampling frequency of 1.5kHz.

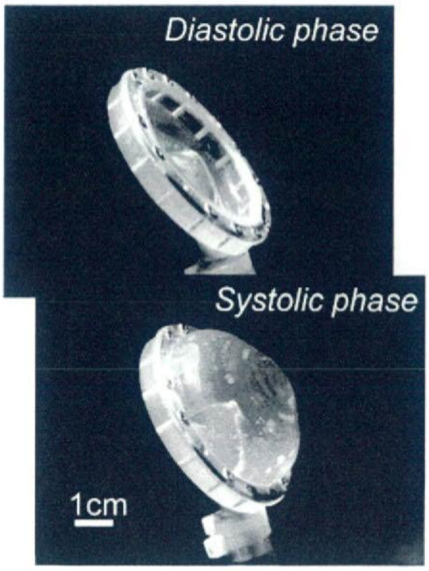
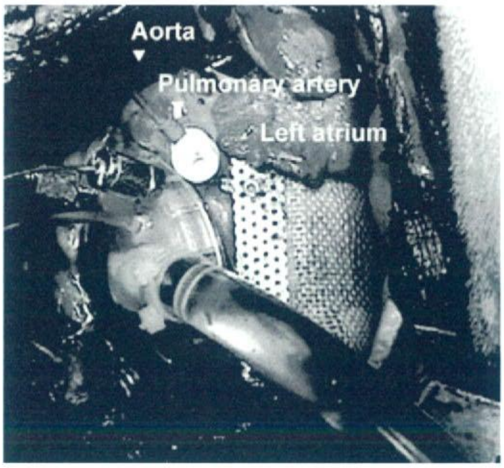


Figure 2: Discomposed illustration of the contractile motion of the device, which was to be attached onto the ventricular wall.



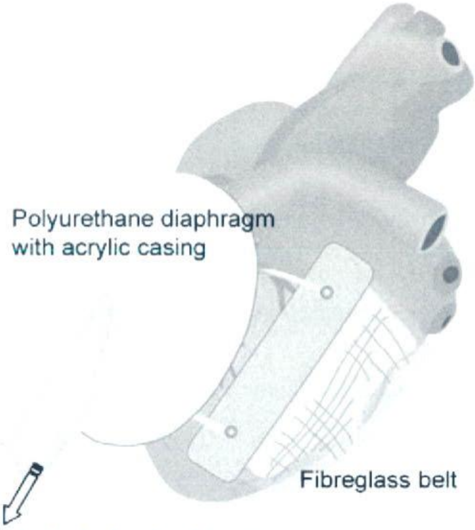


Figure 3: Device attached onto the ventricle (upper) and a schematic drawing of it joined with a fibreglass belt (below).

Results and Discussion

(1) Shape design of the electrohydraulic actuator

Figure 3 and 4 shows the prototype model of the electrohydraulic myocardial assist system, which was to be installed into intercostal space. For the installation of the former model (Figure 3, type No.2), it was necessary to remove the fourth and fifth and a part of sixth costae to make enough room to be fitted in the thoracic cavity, but any complications which might have been caused by the operation were not confirmed in goats.

The revised model, which was optimised for the thoracic cavity, was also developed as shown in Figure 4, and consequently the procedure of closing chest found to become much easier.

(2) Hemodynamic examination in chronic animal experiment

The actuator made the assistance synchronously with natural heart once against every two beats of systolic contraction. The period of the assistance duration was set to around two hours a day, and the hemodynamic effects were obtained as shown in Figure 7. Then it was indicated that the increase of aortic pressure as well as the cardiac output could be achieved by the mechanical assistance by using this system.

However, there seemed to be a difference in the effect according to the portion of the ventricle where the device attached. Also the trade-off between the damage on the myocardial tissue and the strength of mechanical assistance should be examined further. And as the heart rate might have been decreased during the assistance from the outside, further investigation should be carried out from the physiological point of view focusing on the influence on autonomic nervous systems.

It is also necessary to optimise the driving efficiency on the electrohydraulic systems, because the efficiency in the transcutaneous energy transmission system will become important, too, when it is employed.

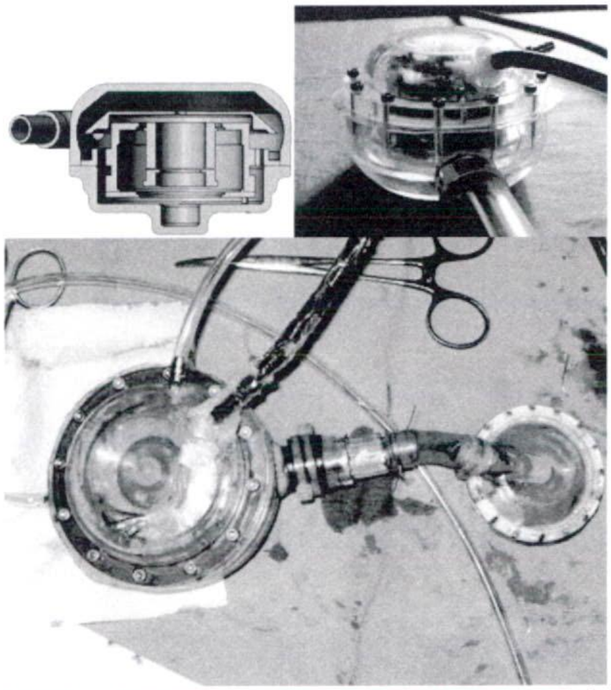


Figure 3: Schematic illustration of the prototype model (No.2) of the totally-implantable electromyocardial assist system (upper left). The originally-developed linear actuator was covered by the acrylic casing (upper right), and the hydraulic port was connected to the device which was attached onto the ventricle (below).

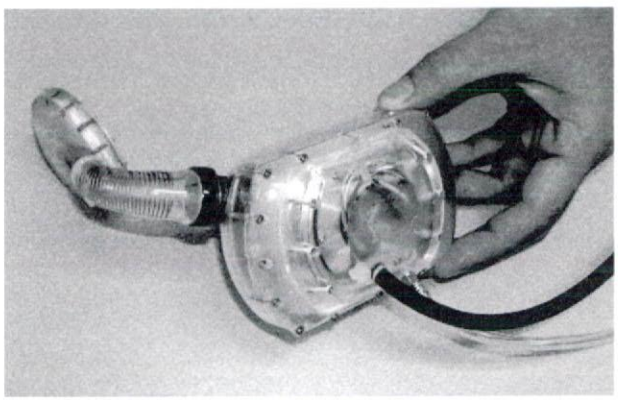


Figure 4: Revised model (No.3) which was to be easier to be installed into 4-5 intercostal space, and the size of which was W: 70mm, H: 59mm, L: 110mm.

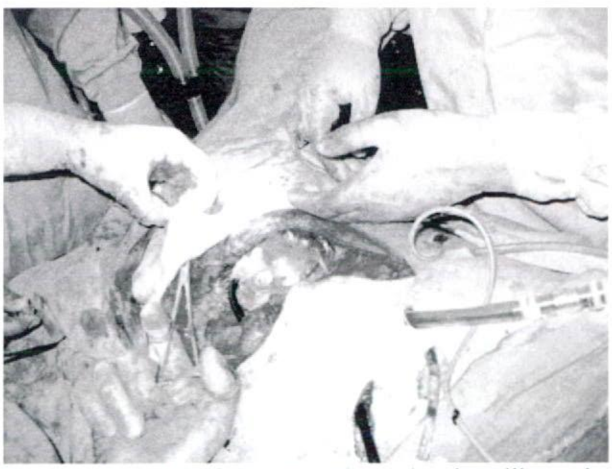


Figure 5: Surgical procedure in installing the electrohydraulic myocardial assist system into the goat's thoracic cavity.

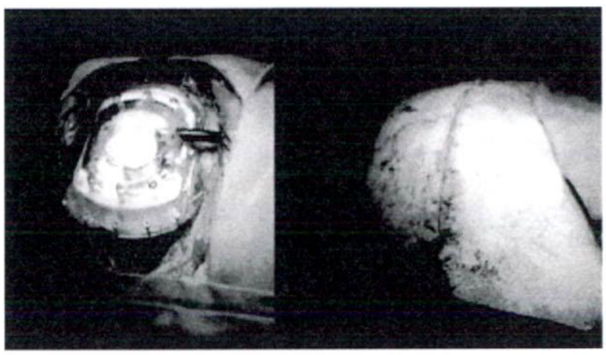


Figure 6: Installation of the system (left) and there was no remarkable strain on the skin by the suture (right).

Conclusions

Newly-designed electrohydraulic myocardial assist system was developed, which was capable to be installed into the intercostal space. It was easy to attach the device onto the ventricular wall and to fix the electrohydraulic actuator into the thoracic cavity. And also preliminary examination of the performance of the device was conducted in goat experiments. The elevation of the cardiac functions followed the changes in vascular hemodynamics were investigated by the mechanical assist. As our system could assist natural ventricular functions with physiological demand, it might be applied in patients with exertional heart stroke, as well as the cardiac massage at lifesaving emergency for the recovery from ventricular fibrillation.

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The authors would like to extend their appreciation to Mr. Kimio Kikuchi for his cooperation in the experiments. This study was supported by the Promotion of Fundamental Research on Advanced Medical Technology of the Ministry of Health, Labour and Welfare (H14-Nano-020), and Grant in Aid for Scientific Research (10480253). It is also partly supported by the Program for Promotion of Fundamental Studies in Health Science in Organising for Drug ADR Relief, R&D Promotion and Product Review of Japan.

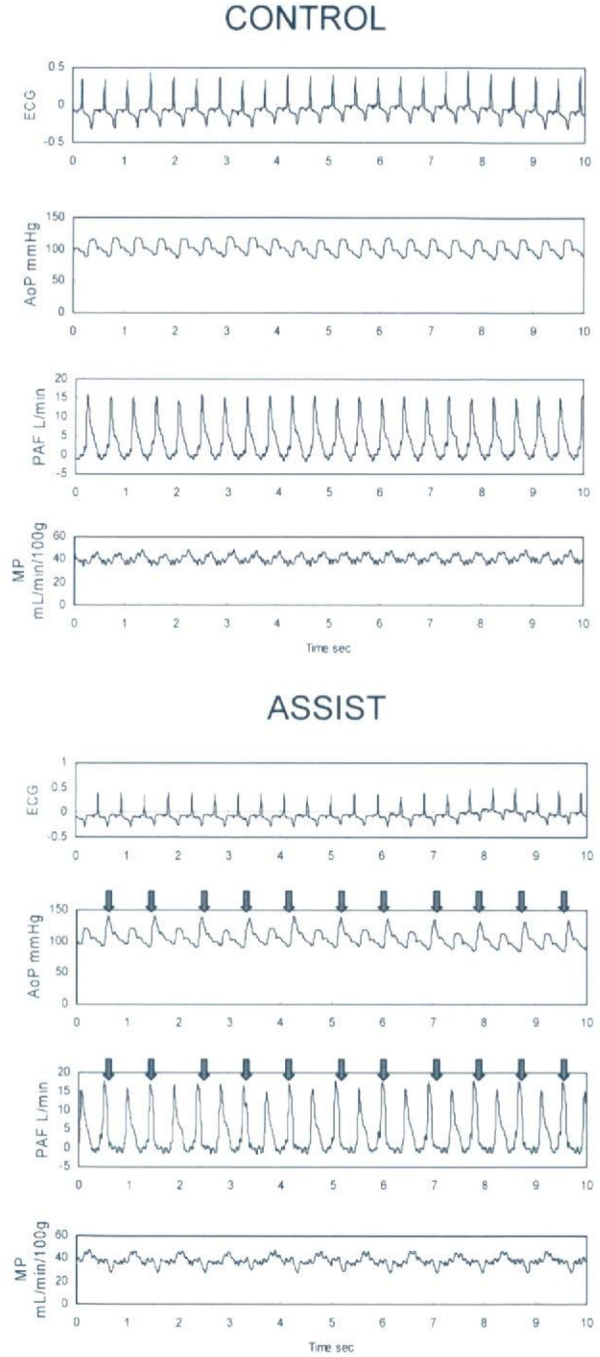

Figure 7: Changes in hemodynamic waveforms obtained from a goat under standing condition. 'control' indicated the insensitive condition of the actuator (upper). Red arrows pointed out the 'assistance' by the electrohydraulic device (below). 'AoP': aortic pressure, 'PAF': pulmonary arterial flow, and 'MF': myocardial perfusion obtained by the laser-doppler flowmeter which was attached on the left ventricular wall inside th fibreglass belt.

* All the animal experiments related to this study were scrutinised and approved by the ethical committee on the animal experiment of the Department of Medicine, Tohoku University, and also the Institute of Development, Aging and Cancer, Tohoku University, 2002, 2003, 2004.

EFFECT OF MECHANICAL ASSISTANCE ON CARDIAC FUNCTION BY USING A SHAPE MEMORY ALLOY FIBERED ARTIFICIAL MYOCARDIUM

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Abstract: A prototype system of the mechano-electric artificial myocardium was developed, which was to be installed totally into thoracic cavity and attached onto the ventricular wall from outside by using a parallel-linked covalent shape memory alloy fibres, and its basic hemodynamic performance was examined in goat experiments. Prior to the measurement, the artificial myocardium was installed into the goat's thoracic cavity and attached onto the ventricular wall without any blood-contacting surface. Then the changes in hemodynamic data was obtained with the synchronous assistance by the device, which was controlled with pulse wave modulation method. The results were as follows: a) maximum tensile force of a single fibre was around 10N, b) the system could be installed successfully without severe complications related to the heating, c) the aortic flow rate was increased by 23% and the systolic left ventricular pressure was elevated by 6% under the low cardiac output condition at 2.5L/min by the mechanical assistance. Therefore it was indicated that the effective assistance might be achieved by using the Biometal shape-memory alloy fibre.

Introduction

In general, a ventricular assist device is employed as definitive therapeutic approach of the patient with the end stage of heart failure. However, it is anticipated that the problem of its blood compatibility such as hemolysis and thrombogenesis might be induced at the blood-contacting surface. Heart transplantation has also been widely performed as destination therapy for the severe heart failure. But it is limited by donor organ shortages, selection criteria, as well as the cost [1]. And recently, cell transplantation to repair or supplement impaired heart tissue has been reported as an alternative therapy for that [2]. And there are many problems that are not yet solved about the tissue reproduced in vitro or in vivo. Moreover, any control for the implanted tissue might be impossible from the outside.

As the heart failure is caused by the decrease in the myocardial contractile function, the direct mechanical myocardial assistance in response to physiological demand, that is, the synchronous support of the contractile function from outside of the heart, might be effective. The purpose of this study was to develop an artificial myocardium which was capable of supporting the cardiac contraction directly by using the shape memory alloy fibre of a minute diameter based on nano-technology.

The authors have been developing a totally-implantable artificial myocardial assist device [3]-[6]. The methodologies of the direct ventricular support systems were already reported as direct mechanical ventricular assistance (DVMA) by Anstadt's or other groups, as well as the right ventricular assist device which was invented and reported at IDAC, Tohoku University [7]-[9]. In this study, the authors developed a prototype system of the mechano-electric artificial myocardium by using a parallel-linked covalent shape memory alloy fibres, which was showin in Figure 1, and its basic hemodynamic performance was examined in goat experiments.

Materials and Methods

(1) Basic characteristics of the fibre and design of an artificial myocardium

In general, Ti-Ni alloy is well known as a material with the shape-memory effect[10]-[12]. The fiber material (Biometal®), which was used in this study for the development of artificial myocardium, has the configuration of the covalent bond, and indicates a big strain change as shown in Figure 2. The linearity of the recovery strain and the changes in electric resistance could be adjusted through the fabrication process, so that the strain of the fibre could be easily controlled by using the digital-servo system without potentiometers.

Basic stress-strain characteristics were examined in a test circuit as shown in Figure 3. Tensile force which was generated by the fibre and its displacement were measured simultaneously by a force transducer (Kyowa, LUR-A-50SA1) and a laser position sensor (Keyence, LB-01), respectively.

The newly-developed electro-mechanical myocardial assist system (artificial myocardium) consisted of the following components: a) an actuator which was made of parallel-linked shape memory alloy fibres, b) an originally-designed signal controller. The weight of each fibre was 14mg, and the length was set to be 280mm. The myocardial actuator was attached onto the heart as shown in Figure 3, and it could support the natural contractile function from the outside of the ventricular wall. Its mechanical assistive motion was synchronized with the electrocardiogram so as not to obstruct the natural cardiac diastolic functions.

(2) Animal experiments

Prior to the measurement, the myocardial assist device was installed in the thoracic cavity and anchored on the surface of the heart by under general anesthetising procedure. The hemodynamic waveforms were obtained from healthy goats, the mean weight of which was 53kg. Pulmonary and aortic blood pressures were measured by transducers and amplified with a polygraph (Fukuda Denshi, MCS-5000). Aortic flow rate was also measured at aortic root by an ultrasonic flowmeter (Transonic Systems, TS420). Each data was digitally recorded with a data recorder (TEAC, LX-10) by the sampling frequency of 1.5kHz.

All the animal experiments related to this study were scrutinised and approved by the ethical committee on the animal experiment of the Department of Medicine, Tohoku University, and also the Institute of Development, Aging and Cancer, Tohoku University, 2004, 2005.

Results and Discussion

Figure 4 shows the transient response of the Biometal fibre under the different input conditions. The duty ratio was changed from 50 to 300msec, and there was no discernible difference of the speed of the stress gain. As the actuation was conducted only by cooling-and-heating process in the fibre, neither a sound nor an electric noise could be easily generated in each part.

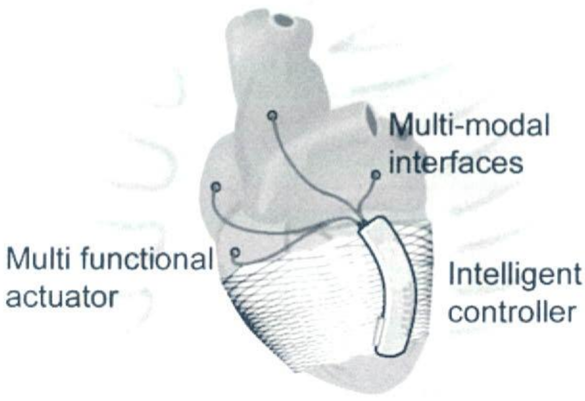


Figure 1: Schematic illustration of a concept of the newly-designed artificial myocardium using a shape memory alloy fibre.

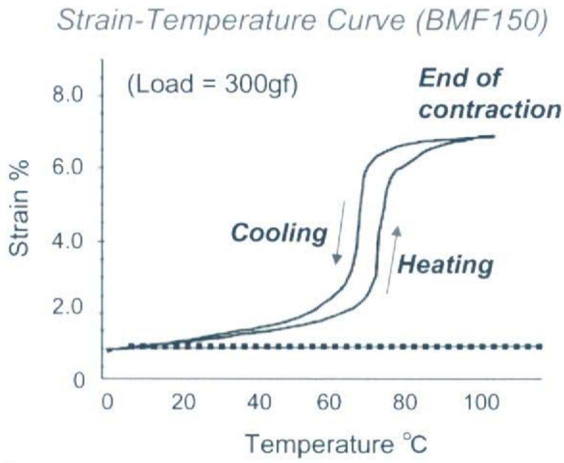


Figure 2: Typical relationship between strain and temperature obtained from the Biometal fibre (diameter: 150μm). Because of the linearity between the strain and the electric resistance, the displacement can be controlled by the simple circuit and also the sense of force can be estimated.

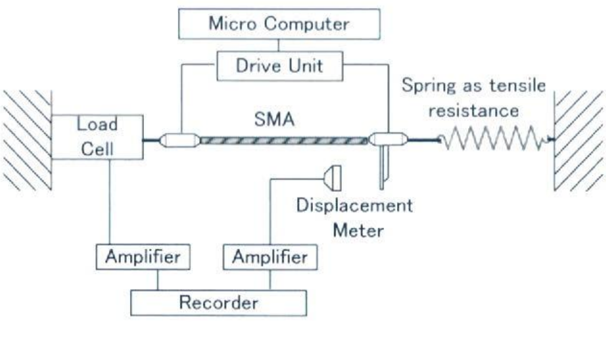


Figure 3: Schematic drawing of the measurement system for the stress-strain characteristics of the shape memory alloy fibre. The spring constant as the tensile resistance was selected from 1.7 to 4.1 N/mm.

The myocardial device developed was successfully installed into the goats' thoracic cavity as shown in Figure 6. Prior to the installation of the device, it was covered with latex rubber and PVC polymer (Figure 6a). For the installation of the former electrohydraulic myocardial assist device which was developed by the authors [6], it was necessary to remove at least the fifth costa to make enough room to be fitted in the thoracic cavity. But in this study by using shape memory fibres, the actuator itself was so small that it would be enough in less capacity for it in the thoracic cavity. Moreover, the procedure of the closed chest was found to be much simpler. However, any other complications which might have been caused by the operation were not confirmed in goats yet.

Hemodynamic waveforms were changed by the mechanical assistance as shown in Figure 7. the aortic flow rate was increased by 23% and the systolic left ventricular pressure was elevated by 6% under the low

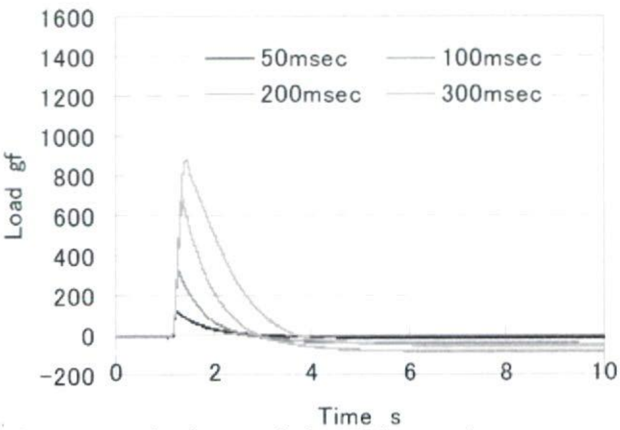


Figure 4: Basic characteristics of the transient response obtained from the fibre under the different pulse wave modulation input conditions; the duty of the input was set to be 50, 100, 200, 300msec respectively at the room temperature (25°C).

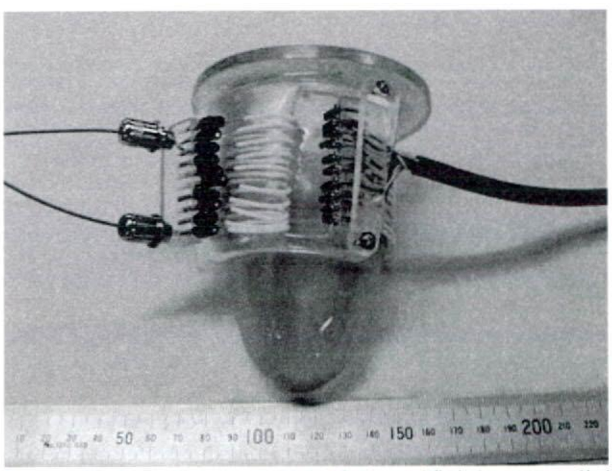
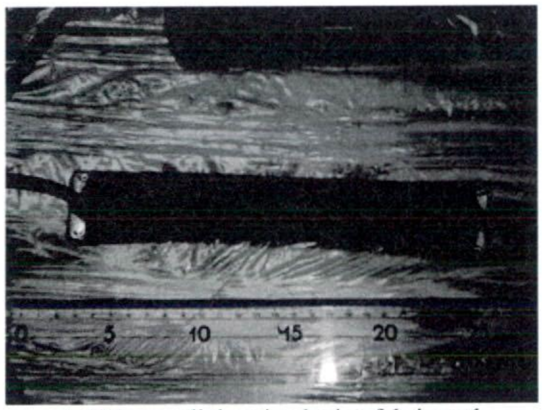
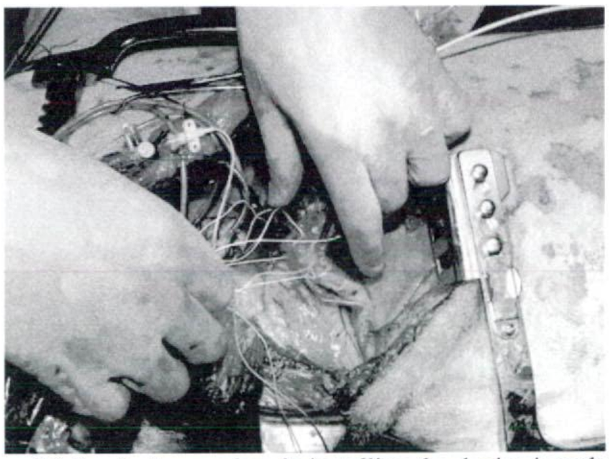


Figure 5: A prototype model of the artificial myocardial assist device; the parallel-linked shape memory alloy fibres were attached onto the silicone ventricular wall.



(a) Myocardial assist device fabricated



(b) Surgical procedure in installing the device into the goat's thoracic cavity

Figure 6: An prototype of artificial myocardium developed in this study (a), and the surgical procedure for the device (b); the artificial myocardial fibres were covered with waterproof polymer.

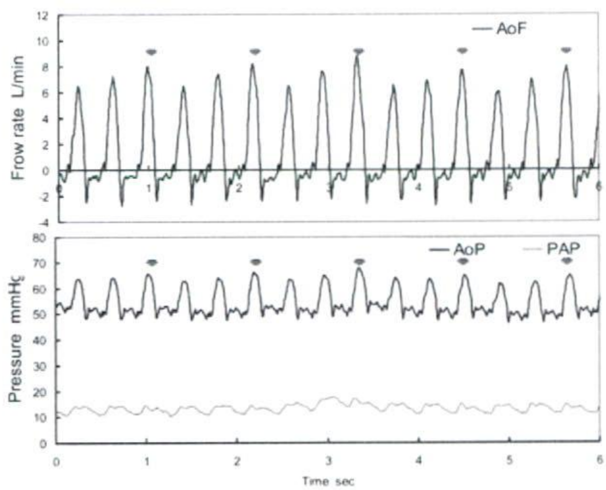


Figure 7: Changes in hemodynamic waveforms obtained in goat; the arrows indicated the mechanical contractile assistance by the artificial myocardial developed. The assistance was carried out once per three natural cardiac beat.

cardiac output condition at 2.5L/min by the mechanical assistance. Therefore it was indicated that the effective assistance might be achieved by using the Biometal shape-memory alloy fibre.

Conclusions

Newly-designed mechano-electric artificial myocardium was developed by using a shape memory alloy fibre, which was capable to be totally installed into the thoracic cavity. It was easy to attach the device onto the ventricular wall. And also preliminary examination of the performance of the device was conducted in goat experiments. The elevation of the cardiac functions followed the changes in vascular hemodynamics were investigated by the mechanical assist. As our system could assist natural ventricular functions with physiological demand, it might be applied in patients with exertional heart stroke, as well as the cardiac massage at lifesaving emergency for the recovery from ventricular fibrillation.

Acknowledgement

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Non-blood contacting electro-hydraulic artificial myocardium (EHAM) improves the myocardial tissue perfusion

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Abstract. Artificial heart (AH) and ventricular assist devices (VAD) are widely used in the clinical setting to assist severe heart failure patients. The concept of direct cardiac compression (DCC) has been in use for several decades and has advantages over intravascular VAD. The process involves compressing the dysfunctional heart from its epicardial surface to avoid the thromboembolic events and decrease the complications and mortality.

An Electro-hydraulic Artificial Myocardium (EHAM) system was designed and fabricated by Tohoku University. This system may assist cardiac contraction and create pulsatile blood flow. The aim of this study was to clearly define the hemodynamic efficiency of the EHAM system in myocardial tissue perfusion during its application in acute animal experiment. Eight healthy adult goats were used; left lateral thoracotomy was performed and the chest was opened by the resection of the 4th and 5th ribs. Hemodynamic parameters including ECG, blood pressure and cardiac output were continuously monitored.

Myocardial tissue perfusion was measured by using Omega flow laser fiber attached to the surface of the heart. During the EHAM compression, and increase in blood pressure and myocardial tissue perfusion was observed in all animals when compared with pre-assisted mode. To conclude, EHAM effectively improves myocardial tissue perfusion and increases the pressure on the initiation of direct cardiac compression immediately. Thus it can be a potentially valuable adjunct in the management of severe heart failure.

1. Introduction

Left ventricular assist devices (LVAD) have been widely and successfully used as a bridge to heart transplantation to assist severe heart failure patients in the clinical setting. Unfortunately, direct contact

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between the device and the patient's blood, thromboembolic events, the need for anticoagulation and infections contribute significantly to complication and mortality. Therefore, investigators are interested in developing techniques for supporting and maintaining physiological circulation by compressing the dysfunctional heart from its epicardial surface.A non-blood contacting method of direct mechanical ventricular actuator compression system could provide ventricular support and pulsatile blood flow and avoid the interactions between the blood and the surface of the artificial assistance system [1,2]. Use of non-blood contacting direct cardiac compression (DCC) systems would avoid cardiopulmonary bypass and bleeding complications and would be technically simpler for use in institutes, thereby allowing its widespread use. We have developed an Electro-hydraulic Artificial Myocardium (EHAM) that may assist heart muscle contraction. The belted-type EHAM is fabricated from plastic and polyurethane can be used for either the left or right ventricle. It consists of a plastic outer shell with an inner flexible diaphragm connected to a driveline that alternatively produces positive pressure (systole), which compress the ventricle and negative pressure (diastole), which augment ventricular filling. The purpose of this study was to determine the efficiency of the EHAM system in maintaining myocardial tissue perfusion and overall hemodynamic parameters during its compression when applied in acute animal experiment.

2. Material and methods

Eight healthy adult goats, weighing 53–68 kg (65 ± 6 kg) were used in this study. The animals were continuously anesthetized with 2% halothane using tracheal intubation and mechanically ventilated with 50% oxygen. Electrodes for electrocardiogram were attached to the legs to enable continuous electrocardiographic monitoring. A left lateral thoracotomy was performed by the resection of the 4th and 5th ribs resection. Arterial blood pressure was monitored by using polyvinyl catheters inserted into the descending aorta, and pulmonary artery pressure was measured by using catheter inserted into the pulmonary artery. A 6 French micromanometer tipped catheter Millar transducer (Millar, SPC-464D, INC, Houston, TX) was positioned into the left ventricular cavity through the left atrium. An electromagnetic flow probe (Nihon Koden MFV-3100, Japan) was placed on the pulmonary artery. A laser fiber was attached to the surface of the heart to measure myocardial tissue perfusion by using Omega laser fiber (OmegaFlow, FLO-C1, OMEGA WAVE).

Belted-type EHAM fabricated from plastic and polyurethane was used either for the left or right ventricle (Fig. 1). The device consists of a plastic outer shell with an inner flexible diaphragm connected to a driveline, 60 mm in diameter and with a thickness of 14 mm during systole and 34 mm during diastole. This device alternatively produces positive pressure (systole), which compress the ventricle and negative pressure (diastole) which augment ventricular filling. The drive console used a cylindrical hydraulic pump (PWA100-15, Oriental Motor Co, Ltd, Japan). Operating parameters such as augmentation pressure and frequency can be adjusted from the console. The device was placed on an area between the apex and the atrioventricular groove. The EHAM was activated in synchrony with the native heart using an electrocardiographic gating signal from the epicardial leads. The drive setting was adjusted within the following ranges: systolic pressure 260 mmHg, and diastolic pressure −60 mmHg. The EHAM was maintained at a cycle rate of approximately 40 Beat/min and every third beat (3:3 ratio).

Hemodynamic parameters and ECG were continuously recorded using a data recording unit (TEAC, LX-10, TEAC Instruments Corporation, Tokyo, Japan). All hemodynamic signals and ECG were analyzed using a data analysis program on an IBM personal computer. All data were digitally sampled at 100 Hz. Data were expressed as mean $\pm$ standard deviation. A paired Student t-test was performed in order to compare the data obtained by using EHAM drive and pre-assist data. A P value less than 0.05 was considered to be statistically significant.

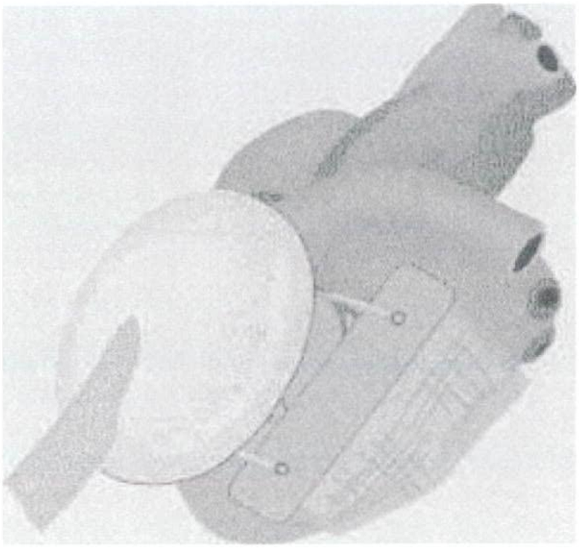

Fig. 1. A schematic of electrohydraulic artificial myocardium assistance system (EHAM).

3. Results

Eight adult healthy goats were used in our experiments on EHAM-assisted mode and unassisted mode. No sudden death or lethal arrhythmia occurred throughout the the animal experiments.

The effects of EHAM on the overall homodynamic parameters are shown in Fig. 2. Systolic left ventricular pressure, aortic pressure and pulmonary flow and myocardial tissue perfusion was found to be increased during EHAM drive when compared with that during non-drive mode, however it did not affect the heart rate.

Table 1 shows hemodynamic measurements based on the EHAM-assisted and unassisted mode. There was a significant increase in the systolic blood pressure by 14% (78.31 ± 16.9 vs. 89.59 ± 15.27 mmHg; $P < 0.0005$), diastolic blood pressure increased by 5% (63.36 ± 15.4 vs. 67.7 ± 16 mmHg; $P < 0.01$), mean blood pressure also increased by 7% (from 69.8 ± 16.6 to 75.39 ± 15.22 mmHg with $P < 0.005$). Pulmonary artery systolic pressure increased by 27% (17.73 ± 2.68 vs. 23 ± 2.61 mmHg; $P < 0.005$), pulmonary diastolic pressure increased by approximately 17% (10.22 ± 3.35 vs. 12.04 ± 3.62 mmHg; $P < 0.5$), there was a significant increase in the mean pulmonary artery pressure by 18% (13.36 ± 2.51 vs. 15.99 ± 2.89 mmHg; $P < 0.005$), left ventricular systolic pressure increased by 17% (73.58 ± 18.96 vs. 87.3 ± 21.01 mmHg; $P < 0.001$). In this experiment, myocardial tissue perfusion, which was the focus of the experiment, was found to be increased by approximately 40% when compared with pre-assisted condition (0.55 ± 0.13 vs. 0.80 ± 0.24 ml/min/g). Pulmonary artery flow which was considered as the total cardiac output further increased up to 18% (2.23 ± 0.42 vs. 2.63 ± 0.39 L/min; $P < 0.00001$). In our experiments, the EHAM was applied for about 3 hours and no evidence of edema, hemotomas or scars were found on the epicardial surface after the experiments.

4. Discussion

Results of this study show that the artificial myocardium assistance system, electrohydraulic ventricular actuator, augments myocardial contraction by external pressure. The increase in the hemodynamic

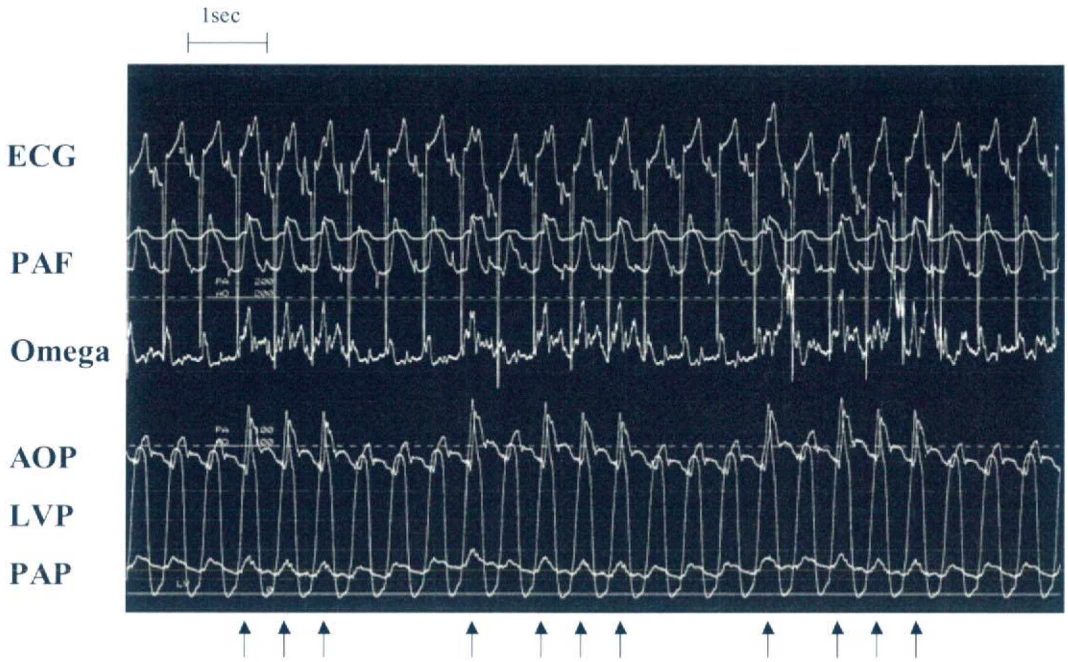

Fig. 2. Time series data of hemodynamic parameters in experiments. The arrow indicates EHAM direct compression mode. Comparison is made with pre-assisted mode at 3:3 stimulation ratio in this experiment ECG: electrocardiography; PAF: pulmonary artery flow; Omega: myocardial tissue perfusion; AOP: aortic pressure; LVP: left ventricular pressure; PAP: pulmonary pressure.

parameter indicates that director ventricular compression provides biomechanical assistance to the failing myocardium.

Mechanical ventricular assist devices are life-saving treatments for heart failure patients; however they require direct blood contact that could result in adverse effects such as thromboembolic events and infections. These difficulties have led to continued research and development of non-blood contacting circulatory support devices to assist the heart [2].

A squeezing action similar to epicardial massage using the EHAM system is useful for increasing the intramyocardial pressure and it increases the possibility of myocardial blood perfusion. This squeezing function of EHAM on left ventricular performance is complex and may affect both systolic function and diastolic filling because the squeezing movement may assist unloading the LV transformed muscle after the EHAM beating.

Most researchers concentrate on the use of mechanical force attempt to increase the pumping action of the ventricular wall. This study indicates that EHAM significantly augments cardiac pump function and increases myocardial tissue perfusion in healthy animals.

In this study, we measured myocardial perfusion to directly assess cardiac blood flow during direct ventricular compression using EHAM. A 3:3 stimulation ratio was used to analyze the effect of EHAM on myocardial perfusion in healthy goats although this may not be the best ratio for assisting the overall cardiac function. Research is being carried out to determine the optimum driving ratio.

The squeezing action of direct cardiac compression may limit coronary blood flow, which may even result in LV ischemia. Therefore, insertion of EHAM for surgical technology necessary does not involve not tightening the belt diaphragm to avoid limiting the coronary blood flow [3,4].

Table 1
Temodynamic parameter of assist and pre-assist electrohydraulic ventricular actuator

	Pre-assist mode		Assist mode		
	AVER	SD	AVER	SD	*P value*
SBP (mmHg)	78.31	16.98	89.59	15.27	*0.0005*
DBP (mmHg)	63.36	15.4	67.7	16	*0.0086*
MBP (mmHg)	69.8	16.6	75.39	15.22	*0.0047*
SPAP (mmHg)	17.73	2.68	23	2.61	*0.0011*
DPAP (mmHg)	10.22	3.35	12.04	3.62	*0.1025*
MPAP (mmHg)	13.36	2.51	15.99	2.89	*0.001*
LVPsystolic (mmHg)	73.58	18.96	87.3	21.01	*0.0007*
Omega flow (ml/min/g)	0.55	0.13	0.8	0.24	*0.0043*
PAF (L/min)	2.23	0.42	2.63	0.39	*7E-05*

Values are mean ± standard deviation for 8 adult healthy goat. Assist Mode means EHAM Driving assistance, and pre-assist mode means rest without EHAM driving.
SBP: systolic aortic blood pressure; DBP: diastolic aortic blood pressure; MBP: mean aortic blood pressure; SPAP: systolic pulmonary artery pressure; DPAP: diastolic pulmonary artery pressure; MPAP: mean pulmonary artery pressure; LVPsys: systolic left ventricular pressure; Omega flow: myocardium tissue perfusion; PAF: pulmonary artery flow.

A number of non-blood contacting circulatory mechanical support systems have been investigated for pre-clinical use. Artrip and associates have shown in laboratory studies that such director cardiac compression system devices are limited to short-term applications, however significant improvements in the cardiac output were observed when these devices were applied to an acutely failing heart [5].

Although direct cardiac compression system may also adversely affect the heart, investigations carried out by using such a method over a time period ranging from a few hours to several days have not indicated any such detrimental effects, even in a patient with failing heart who survived for more than 1 week, and no significant trauma was observed even after 3 months of the use of the support device [6,7]. Several non-blood contact devices, such as the CardioSupport system and the Heart Booster device, that assist the heart by directly compressing the external surface are currently under development [5,8]. Anstadt and associates first reported the application of clinical epicardial compression using the Anstadt cup in 12 patients with arrested heart [9,10]. A significant case report describes that successful circulation was maintained for 56 hours using the Anstadt cup as a successful bridge to transplantation, and at the 1-year follow-up, the patient was alive and well [6].

Alternative devices that have been recently proposed for the direct compression are system are limited to systolic augmentation and have undetermined effects on the myocardium. The present study estimated the efficacy of EHAM on myocardial perfusion. Myocardial perfusion pressure is directly affected by the wall stress and motion, which have been shown to change with the use of EHAM as a method of direct cardiac compression. Apart from the EHAM-assisted overall increase in the blood flow, an increase in the local myocardial perfusion was also observed in experiments. Improvements in systolic function are thereby complemented by accelerated diastolic filling. Our study shows that the EHAM can be placed within a few minutes after thoracotomy, enabling its application in a setting such as an intensive care unit or emergency room.

5. Conclusion

Direct ventricular compression using EHAM is not only capable of improving hemodynamics by direct cardiac contraction but also significantly enhances myocardial perfusion. Our initial results indicated that this device provides satisfactory circulatory enhancement in acute healthy animal experiment. Experiments on a heart failure model constructed by the occlusion the coronary artery are being performed in our lab and chronic experiments using the heart failure model will be performed in order to confirm the supporting efficiency and durability of EHAM in the near future. Further remodeled EHAM may have a candidate application for circulatory support.

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The authors thank Mr. Kimio Kikuchi for experimental preparation and kind cooperation, Miss Yoko Itoh, and Mrs. Hisako Iijima for their excellent technical assistance and kind cooperation.

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An Innovative Approach to Evaluate a Cardiac Function Based on Surface Measurement

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Y. Park, H. Ando, T. Matsumoto, S. Takeda, K. Iwasaki and M. Umezu

Abstract— **Major function of the heart is to pump blood flow up to all tissues or organs in the body, and it is generally recognized that cardiac function under various diseased conditions are mainly represented by a relationship between blood flow and pressure inside of the heart.**

In this report, an original proposal of evaluation method on cardiac function is introduced through a simultaneous measurement of various points of cardiac muscular surface. An optical three-dimensional location sensor was employed to measure a displacement change of anatomically specific points on heart surface. Then, changes in strain in each regional surface area were quantitatively obtained. This result indicated similar tendency obtained from echocardiogram. It was also indicated that there was a difference in displacements and phrases between control and arrhythmia.

Moreover, strain change in regional area was coincident with a contraction of natural heart. It was found that an attempt to superimpose the data of strain change onto the video images of natural heart was extremely helpful to understand a cardiac function visually.

Index Terms – **heart function, regional strain, surface movement, three-dimensional location sensor**

I. Introduction

RECENTLY, minimally invasive surgery has been widely accepted and surgical procedures become more complicated. Therefore, both technical proficiency and a high skill are required for surgeons to perform a well-planned effective surgery. For compensating and improving their abilities, many researchers have been developing a surgical simulation system [1]-[4]. However, further investigation is required to make virtual organ models more concrete to real organs. Especially, it is important to realize functional and anatomical changes of organs during operation, because these information is essential to develop a sophisticated simulation model, which might contribute to evaluate each surgeon's skill quantitatively as well as promote practical surgeon's skill.

An echocardiography is widely used in clinical diagnosis of cardiac function. The ultrasonic technologies have an advantage in terms of noninvasive, safety, and high temporal and spatial resolution. However, it is difficult to take an image of a whole heart at the same time and also difficult to track the same points sequentially. Moreover, as diagnosis depends largely on the expertise of sonologists, images obtained are with less objectivity.

To solve above problems, a new trial has carried out. This report dealt with a new proposal on functional analysis of living heart by using an information of superficial movement of the natural heart. For the first step, contractile measurement method was established, and changes in cardiac strain at specific surface sections of the heart were obtained.

II. Methodology

A. Animal Experiment

A schematic diagram of the experimental setup is shown in Fig.1. A thoracotomy was performed on 1 adult goat weighing 48.3kg under general anesthesia. Heart function was examined under a normal pulsating state and a disease state. Abnormal heart rhythm provoked by injecting vasopressor (epinephrine: 0.002mg/kg).

An optical three-dimensional (3D) location sensor (*Stereo Labeling Camera, CyVerse Inc.*) was employed to capture the motion of cardiac surface. Specifying a point in 3D space, a commercially available reflective ball marker with a diameter of 11mm was selected. As shown in Fig.1 (a), six reflective markers are stitched onto local points of the pericardium as follows: apex, septum, left atrium and anterior wall of left ventricle. The segment of the anterior wall is divided into two levels such as papillary muscle: A1 and tendinous chord: B1, B2. It was successfully identified that these levels move concentrically around the septum by images obtained from echocardiography. And also the physical data such as electrocardiogram, blood flow and pressure were simultaneously obtained and it was compared with this new approach.

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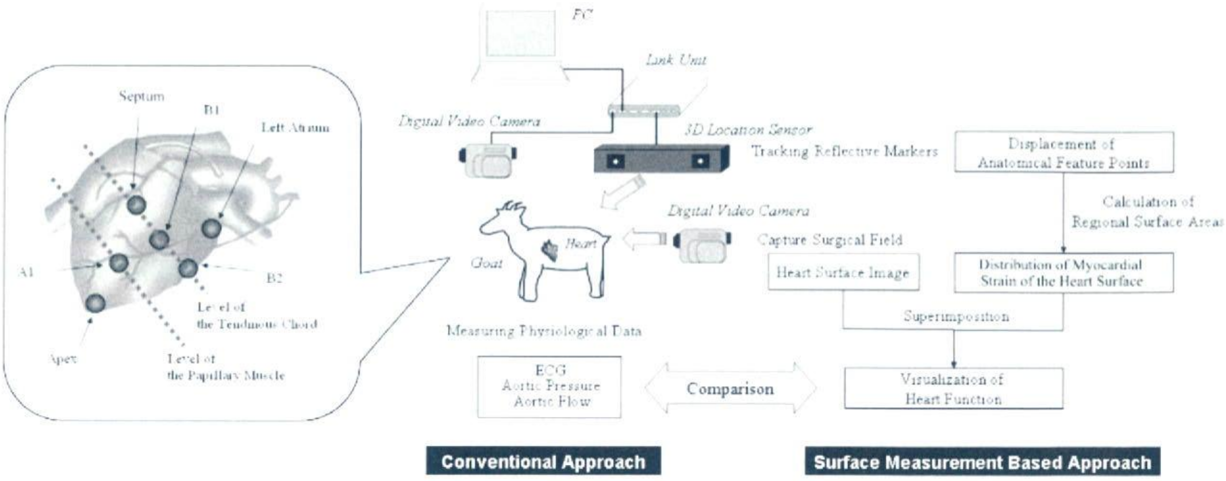

(a) Marker settings (b) Data processing

Fig. 1. Schematic diagram of the experimental setup.

In order to recognize the location of markers of the cardiac surface easily, video images were captured synchronously with the cardiac motion capture data. The camera parameters were obtained by a camera calibration algorithm [5] to correspond the marker position on the 3D space coordinates system with on the 2D video image coordinate system. Thus, derived data from 3D point measurement are allowed to be overlaid onto the video images.

B. Analysis of the heart function

1) Displacement of local points: Displacements of local points resulted not only from the contractile activity of the myocardium but also from the respiratory motion. To reduce the influence of movement of the whole heart, relative points were calculated from a reference point. Septum, which moves less than other points, was utilized as a reference point. In the 3D space, when the position of apex was given as (X_0, Y_0, Z_0), and the position of the others given as (X, Y, Z), the distance D between the apex and each point will be described as follows:

$$D = \sqrt{(X - X_0)^2 + (Y - Y_0)^2 + (Z - Z_0)^2} \quad \text{................(1)}$$

2) Regional myocardial contractile performance on surface: Deformation of an object that can be related to stresses is described by strain. Consider a string of initial length L_0, which is stretched to a length L. The strain measure e, a dimensionless ratio, is defined as the ratio of elongation with respect to the original length,

$$e = \Delta L / L_0 = (L - L_0) / L_0 \quad \text{..........(2)}$$

Consider the strain in a higher dimension. Connecting each anatomical point to its natural neighbors with a set of lines, Delaunay triangulation is applied and 3D heart surface is generated (Fig.2). The relationship between S and $\vec{a}$, $\vec{b}$ can be represented by the equation (3),

$$S = \frac{1}{2}\left|\vec{a} \times \vec{b}\right| \quad \text{..........(3)}$$

And the modulus of the regional area ΔS can be given by equation (4), where S_0 was defined as non-strain condition and $\bar{S}$ was defined as the average of S,

$$\Delta S = S - S_0 = S - \bar{S} \quad \text{..........(4)}$$

If the cardiac muscular surface doesn't change drastically, ΔS will be described as $\Delta S \ll \bar{S}$. Therefore, the strain of regional surface area ε is define as,

$$\varepsilon = \Delta S / \bar{S} \quad \text{..........(5)}$$

Figure 3 shows that the stain of each regional surface area varies corresponding to the shape of the heart surface in the 3D space.