6.1.3 心筋収縮補助装置の製作及び水力学的回路における基礎特性評価

（第 4 章）

第 2 章で解析を行った心筋構造を考慮にいれた，生体心との力学的整合性の高い新しい心室収縮補助装置の製作とその基礎特性評価を目的とした．そこで得られた結果を以下にまとめる．

1）2005 年度に開発した左室短軸方向から心臓中心部への収縮補助を行う装置（周囲固定法-Circumferential type）に対して，心筋走行を模擬することにより心筋構造再構築を目指した装置（斜方固定法-Oblique type-1，2）を新しく設計，製作した．（第 4.2.2 項）

2）2005 年度に開発した装置に対して，新しく製作した装置（Oblique type-1，2）の基礎特性評価として，左心系模擬循環回路において性能比較評価，基礎特性評価実験を行った．（第4.3 節）

3）性能比較評価の結果，直線状の装置により心筋走行を模擬した斜方固定を行った Oblique type-2 が周囲固定法（Circumferential type）に対して約 40%補助流量（8.2→11.9mL）増加した．（第 4.4.1 項）

4）基礎特性評価の結果，斜方固定法による装置（Oblique type-2）によって，駆動周波数 0.2Hz，左心系模擬循環回路における圧較差 50mmHg のとき，一拍あたりの最大補助量 25mL を得た．（第 4.4.1 項）

5）駆動装置により心筋構造を再構築することにより，流体拍出方向に収縮ベクトルを合成でき，また，補助面積を増加することができたことにより収縮効率増加が可能となった．（第 4.5.2 項）

6.1.4 心筋収縮補助装置の生体系における血行力学的評価

（第 5 章）

心筋構造を再構築した心筋収縮補助装置の生体系における血行力学的評価を行うことを目的とし，健常成山羊を用いた急性動物実験により装置の比較評価を行い，以下の結果が得られた．

1）急性動物実験において，心筋構造を再構築した心筋収縮補助装置を胸腔内に固定でき，また駆動を行うことができた．（第 5.3.1 項）

2）周囲固定法（Circumferential type）では，補助を行ったとき収縮期における大動脈流速，流量は 13.7L/min から 15.4L/min と 12%の増加，3.2L/min から 3.5L/min と 11%の増加が得られた．また，左心室内圧においては，53 mmHg から 56 mmHg と 5%の増加が得られた．（第 5.3.2 項）

3）斜方固定法（Oblique type-2）では，補助を行ったとき収縮期における大動脈流速，流量は 13.7L/min から 15.4L/min と 12%の増加，3.2L/min から 3.5L/min と 11%の増加が得られた．また，左心室内圧においては，53 mmHg から 59mmHg と 11%の増加が得られた．（第 5.3.2 項）

4）本動物実験の結果より，心筋構造を模擬することで，装置の流量に対する補助効率が増加することがわかり，圧容積仕事で比較した場合，周囲固定法装置の 11%の増加に対して，23%の増加という結果が得られた．（第 5.4.2 項）

よって，これらの結果より形状記憶合金を応用し，心筋構造を立体的に再現することで，心筋収縮補助装置の補助効率が増加し，また生体との力学的整合性の高いシステムとして構築することができたと考えられる．

6.2 今後の展望

6.2.1 本装置の適応範囲[1]

心不全の治療方針は，心不全を起こした病因，病態解剖及び病態生理を確実に判断する．これらを判断した上で，病状に対して試みようとする医療，個々の手段及びこれらの組み合わせが，患者の救命救急，さらに慢性期の QOL（Quality of Life）の改善，具体的には自覚症状の寛解や運動耐容能の向上を予測して決定される．

まず，軽度の急性心不全の場合は，β 遮断薬や利尿剤などといった薬物治療を行う．さらに現在

ではこれらに加えて，大動脈内バルーンパンピング法（Intra-aortic Balloon Pumping，以下 IABP）が一般的に有用化が認められている．また，内科医が使うことができる補助循環装置として，経皮的心肺補助装置（Percutaneous cardio-pulmonary support，以下 PCPS）が使われるようになってきている．IABP はカウンターパルセーション法の一種で，胸部大動脈内に留置したバルーンの拡張により大動脈拡張期圧を上昇させて diastolic augmentation 効果を，バルーンの収縮により収縮期圧を低下させて systolic unloading 効果を得る方法である．この 2 大効果が冠動脈血流量と心拍出量を増加させる．近年，経皮挿入法が開発され装着が容易になったため広く利用されている．しかし圧力補助がメインと考えられることから，心補助能力は心臓ポンプ機能の 10～15％程度が限界である．また，PCPS はカニューレを大腿静脈より右心房に挿入して静脈血を脱血し，膜型人工肺でガス交換して動脈側に送血することによって流量補助を行う．右心補助とともに左心の前負荷をも軽減可能である．現在では，IABP と人工心臓による治療の中間的手段として使用されており，心拍出量の 70％程度までの補助能力がある．しかし，現状では PCPS は人工肺，補助流量，抗凝血療法などに問題があり，長期使用では満足な成績が得られていない．また，重度の心不全においてはバイパス量が大きくなり，逆に左室後負荷が増大して左室が十分に拍出できず肺うっ血となるため，IABP との併用することが多くなる$^{2)}$．さらに重症度が進行すると，人工心臓による治療が行われる．しかし，人工心臓は開胸操作が必要でありかつ非常に高価である．

本装置は，PCPS で対応できなくなった患者に対して用いることを目的とする．本研究によって示されたとおり，本装置は心臓の外部から力を加えて心筋の補助を行うため流量，圧力を補助することが可能である．また構造がシンプルであるため将来的にはさらに小型化が見込め，比較的低侵襲な内視鏡を用いたロボット手術による治療を行う可能性を秘めている．また，本装置は血液と完全に非接触であるため，常に駆動する必要がない．よって，労働負荷時のみに心不全の症状が現れる比較的軽度の心不全の患者にも応用できると考えられる．

6.2.2 新しい循環系モデル構築の必要性と応用に関する基礎的検討

人工臓器の評価方法としては，動物実験による評価が一般的である．しかし動物実験では，第 4.3 節で示したように，

1) 生体系における血行動態の解明が未だに不完全であるために，動物実験から得られたデータを有効に分析できない．
2) 生体特有の個体差によって，実験結果の再現性が保障されない．
3) 動物自体も大変高価であるし，その飼育費や手術に伴う費用，さらに検査器具は使い捨てなどコストが非常に高い．

という問題点があげられる．そこで，梅津らは流体回路を用いて左心系を表現し，機械式血液循環シミュレータ（mock circulatory system，以下 MCS）として，以下の特徴を有する動物実験代替試験装置として位置付けている．

1) 倫理面や動物愛護の面から動物実験回数の削減に貢献
2) 人工臓器（主に人工弁，人工血管，補助人工心臓）の基礎特性評価に使用する定量的かつ再現性のある拍動流試験装置
3) 生体器官の形態が及ぼす血行動態変化の再現
4) 心臓機能として負荷依存性および収縮力の表現や神経系を模擬した循環調節機構の再現
5) 各パラメータの変更により，重症心不全や弁閉鎖不全症といった特殊な血行動態を任意に設定できる利便性
6) 各病態の血行動態について，視覚的な理解 を助け，心臓・血管分野の初学者に対する教育支援ツールとしての役割

そのなかでも，左心系の血液拍出源として左心室のポンプ機能が重視される．現在，MCS 左心室

ポンプの駆動装置には機械駆動式と空気圧駆動式の二つが用いられる．それぞれの駆動装置の特徴を以下に示す．

1）機械駆動式ポンプの特徴

駆動源はサーボモータまたはステッピングモータを使用したリニアアクチュエータであり，シリンダ内に収められたピストンの往復運動により，封入された流体を介して砲弾型シリコーン製サックを収縮・拡張させる構造を有する．制御方法には供給電流または電圧制御，パルス列制御があり，ピストンの位置および速度制御が容易であるため，任意の流量波形の生成やセンサによるフィードバック制御系の構築に適している．また，心室前後負荷に対するピストン運動の変化の影響はほとんどない．

2）空気圧駆動式ポンプの特徴

本来，拍動型補助人工心臓の駆動装置として開発されたもので，陽圧タンクと陰圧タンクを設定値に基づき，切換弁により交互に作用させ拍動を生成する方式である．したがって心室モデル内の設定圧力に対し，流入，流出負荷の条件により，発生する流量が決定される．すなわち作用した圧力に応じた圧力差が発生した結果，流量が生じるという因果律に沿う．

問題点としては，（1）機械駆動は，任意の流量波形を生成するために，十分な出力を有するアクチュエータを使用する．よって，ピストン運動は負荷にほとんど依存せず，心室モデルとしても心室の前後負荷に依存しないものとなる．（2）空気圧駆動においては，陽圧，陰圧の2つのパラメータのみ設定可能であり，詳細な流量波形の生成が困難である．また，両者ともに，流体や気体を介して砲弾型シリコーン製サックを収縮・拡張させる構造となっており，心室外部をアクリル等により密閉する必要があり，心室外壁の形態模擬は不可能である．

本研究で用いた繊維状のアクチュエータであるバイオメタルにより心室モデルを構築することにより，心筋の走行方向を模擬した心室モデルが可能である．このことは，

1）局所的な心室壁動態

2）解剖学的に心室外壁の外形

の模擬が可能であることを意味し，より高度な心室モデルの開発を可能とする．また，機械駆動式ポンプに対して動脈系などの負荷にも依存する極めて生体に近い評価モデルとして製作することができると考えられる．

このような特徴ある新しい循環系シミュレータにより具体的には，心不全モデルの製作により，補助循環などによる補助に対して心機能がどの程度回復するのかなどの評価が可能となる．

6.2.3 心筋収縮補助装置としての今後の展望

本研究で製作された心筋収縮補助装置は心筋収縮メカニズムに対応するために心筋構造を立体的に再現することを目的とした．その結果，構造の観点から生体心臓との力学的整合性の高いシステムとすることができた．

今後，さらに生体との整合性を高めるためには，生体心臓の収縮形態を解析することにより，本装置の生体心臓に対する制御方法を確立することが重要となってくると考えられる．これは，本装置が生体心に対してどうのような影響（圧，流量，心拍など）を及ぼすのかといったことを多角的に評価することによって可能となると考えられる．このことによって，生体心臓について構造だけでなく機能の観点からも解析を進めることができ，生体心臓の収縮にさらに適合した装置製作につながると考えられる．

別紙 4

研究成果の刊行に関する一覧表

書籍

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Support Mechanism of a Newly-Designed Mechanical Artificial Myocardium using Shape Memory Alloy Fibres

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Abstract— **As the heart failure is caused by the decrease in the myocardial contraction, 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 fibres based on nanotechnology. Some methodologies using novel devices other than the artificial hearts are proposed so far with severe heart disease. However, it was also anticipated that the decrease in cardiac functions owing to the diastolic disability might be caused by using those 'static' devices. Then, this study was focused on an artificial myocardium using shape memory alloy fibres with a diameter of 100 – 150 um, and the authors examined its mechanism in a mock circulatory system as well as in animal experiments using goats. Basic characteristics of the material were evaluated prior to the hydrodynamic or hemodynamic examination using a mock ventricular model. The results were as follows: a) The length of the structure was able to be adjusted so that the system could wrap the whole heart effectively. b) In the hydrodynamic study using the mock circulatory system, the myocardial system was able to pump a flow against the afterload of arterial pressure level. c) In the animal experiments, aortic pressure and flow rate were elevated by 7 and 15% respectively by the mechanical assistance of the artificial myocardium, which was driven synchronising with the electrocardiogram, and also, d) The anatomically-identical shape of the artificial myocardium might be more effective for the assistance. In conclusion, it was indicated that this controllable artificial myocardial support system was effective for the mechanical cardiac support for the chronic heart failure.**

Keywords— **Artificial myocardium, Shape memory alloy fibre, goat experiment, mock ventricular model, hemodynamic effect**

I. INTRODUCTION

In general, the artificial ventricular assist systems, such as artificial hearts, were employed for the treatment of the severe heart failure in order to increase the circulation volume. However the complications caused by the hemolysis or thrombosis on the surface of the artificial materials are still outstanding problems in the application of those devices to patients. 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]. The authors assumed that the essence of the pathophysiological development of severe heart failure was in the decrease in the cardiac contractility. Then an artificial myocardium has been developed using a covalent nano-tech shape memory alloy fibre, which is capable of assisting natural cardiac contraction from outside of the ventricular wall as shown in Fig. 1. The purpose of this study was to develop a sophisticated artificial myocardium unit, and also to have examined the hemodynamic effects of the myocardial assist system on cardiac function.

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, a design to surround the total heart has been established in order to refrain from the stress concentration by the mechanical assistance, and the hemodynamic performance of the artificial myocardial assist system were examined in a mock circulatory system as well as on animal experiments using goats.

II. MATERIALS AND METHODS

A. Basic constuctions of a newly-developed artificial myocardium using shape memory alloy fibres

The myocardial assist system, as shown in Figure 2, consists of a covalent type shape memory alloy fibre (Biometal®). The diameter of the fibre is 100 microns, and it is contracted by the Joule heating. In general, Ti-Ni alloy is well known as a material with the shape-memory effect[10]-[12]. The fibre material is able to be covered with a silicone –tubing (diameter: 150um). The configuration of the material was basically constructed by covalent bond, so that it indicated a big strain change by 5 to 10% in length. 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.

B. Mock circulatory examination and animal experiments

Contractile function of the device developed was examined onto the originally-designed silicone mock left ventricle (Figure 3). Hydrodynamic evaluation was conducted against the afterload of 80 to 100mmHg without mock ventricular contraction.

Hemodyamic data were also obtained from normal adult healthy goats, the mean weight of which was 50kg. Prior to the measurement, the artificial myocardial assist device with parallel-linked shape memory alloy fibres was covered with silicone rubber, and it was attached onto the ventricular wall. Left ventricular (LV) pressure was measured by a catheter tip transducer (Millar, SVPC-664A), The sensor was inserted at the left atrial portion through the mitral valve. These hemodynamic data were recorded by a digital recording unit (TEAC, LX-10) and the sampling frequency was 1.5kHz.

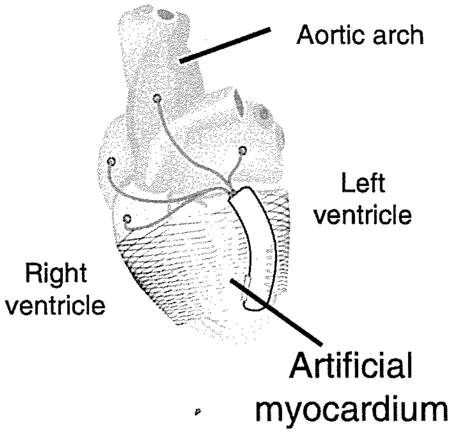

Fig. 1 Schematic illustration of an artificial myocardium attached on the ventricular wall; the synchronous contraction can be achieved according to the natural physiological demand.

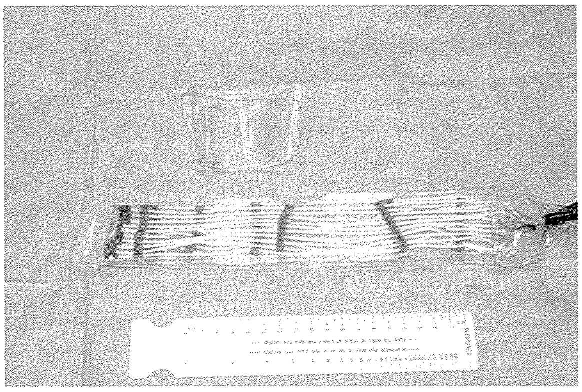

Fig. 2 Whole view of the mechanical artificial myocardium developed; the ventricle was covered by the band-shaped device and it was able to support the contractile function synchoronising with natural heart beat.

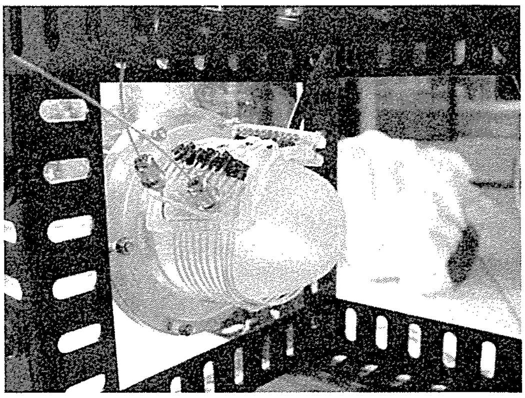

Fig. 3 Hydrodynamic examination of the artificial myocardium; the device was attached onto the silicone mock left ventricular model.

III. RESULTS AND DISCUSSION

A. Hydrodynamic function in the mock circulatory system

The several mechanisms were examined in the mock circulatory system, which was attached onto the silicone left ventricle. An example of the hydrodynamic test was shown in Figure 4. The length of the structure of the myocardial assist device was adjusted to fit the ventricular model so that the system could wrap the whole heart effectively. And as shown in Figure 4, the elevation of the pressure and flow rate measured at the outflow portion of the ventricular model were around 10mmHg and 1L/min, respectively. The it was indicated that the myocardial system was able to pump a flow against the afterload of arterial pressure level.

B. Hemodynamic effects on animal experiments

The myocardial device developed was successfully installed into the goats' thoracic cavity. Prior to the installation of the device, it was covered with silicone tubings and sheets as shown in Figure 2. 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.

Hemodynamic waveforms were changed by the mechanical assistance as shown in Figure 5. The aortic flow rate as mean cardiac output 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 as shown in Figure 6. Therefore it was indicated that the effective assistance might be achieved by using the Biometal shape-memory alloy fibre.

IV. CONCLUSIONS

A myocardial assistive device has been developed and it was suggested that the effective assistance could be achieved in goats. When it is attached onto the ventricular wall, it should be considered the forced refrigerant effect by blood circulation such as coronary perfusion. It consisted of shape memory alloy fibres, which was capable to be totally installed into the thoracic cavity. It was easy to attach the device onto the ventricular wall. The elevation of the cardiac functions followed the changes in vascular hemodynamics were investigated by the mechanical assist.

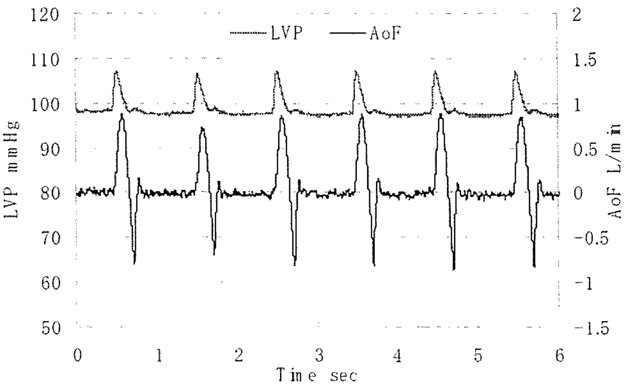

Fig. 4 Changes in pressure and flowrate derived at the outflow portion of the mock left ventricular model by the assistance of the artificial myocardium. These hydrodynamic data were obtained from the mock circulatory system with the afterload of 100mmHg.

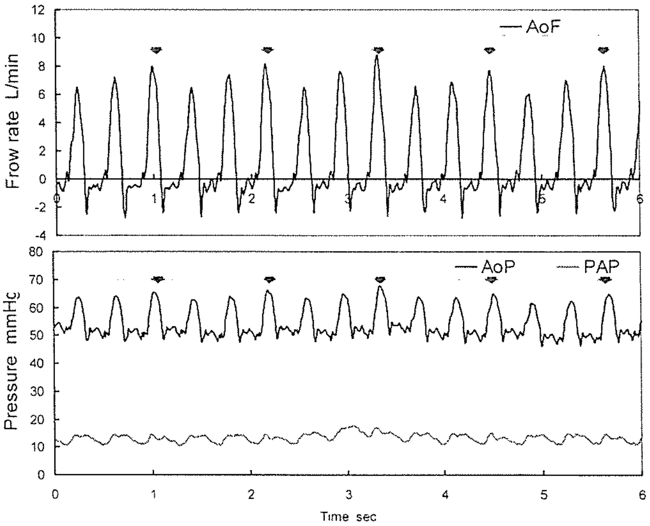

Fig. 5 Changes in the hemodynamics obtained from a goat (50kg); AoP: aortic pressure, AoF: aortic flow measured at the root, PAP: pulmonary arterial pressure. The arrows indicated the mechanical support aspects by the artificial myocardium, and each assistance was synchronising with natural electrocardiograms.

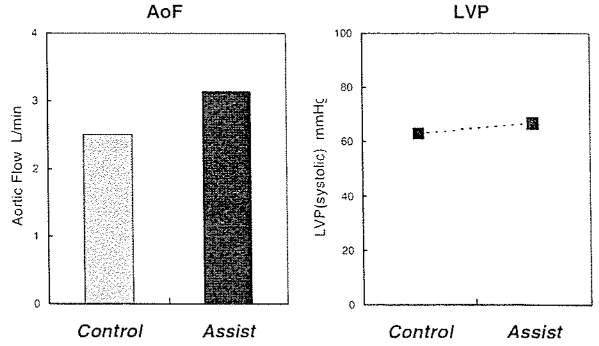

Fig. 6 Changes in the left ventricular pressure (LVP) and mean cardiac output calculated by aortic flow volume; 'control': without assistance, 'assist': mechanical assistance by the artificial myocardium.

As our system could assist natural ventricular functions with physiological demand, it might be applied in patients with angina of effort or for the artificial circulatory support for the patients with chronic heart failure, as well as the cardiac massage at lifesaving emergency for the recovery from ventricular fibrillation.

Therefore, it was indicated that this controllable artificial myocardial support system was effective for the mechanical cardiac support for the chronic heart failure.

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, 2004-2006.

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The authors would like to extend their appreciation to Mr. Kimio Kikuchi and Mr. Tomio Kumagai for their cooperation in the animal experiments. This study was supported by Grant in Aid for Scientific Research of Ministry of Health, Labour and Welfare (H17-nano-009), and Ministry of Education, Culture, Sports, Science and Technology (17790938). And this study was partly supported by Grant in Aid for Scientific Research of Pharmaceuticals and Medical Devices Agency (02-1).

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A Newly-designed Myocardial Assist Device Using a Sophisticated Shape Memory Alloy Fibre

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Recently, the ventricular assist devices are widely applied for a surgical treatment of the final stage of severe heart failure as the bridge to heart transplantation or the destination therapy. However, it was anticipated that the artificial components in the ventricular assist devices might cause the problems concerning thrombosis and infection. As heart failure involves the decrease in myocardial contractile function, the mechanical assistance by using an artificial myocardium might be effective. In this study, the authors developed a mechano-electric artificial myocardial assist system (artificial myocardium), which is capable of supporting natural contractile function from the outside of the ventricle.

Keywords: shape memory alloy fibre, heart failure, cardiac assist device, hemodynamics

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1. Introduction

In general, patients with severe heart failure, who present an increased ventricular filling pressure or insufficient amount of blood supply to the tissue, are given medical or surgical treatment. Recently, artificial circulatory assistance by using ventricular assist devices, such as artificial hearts, has been provide, which is followed by heart transplantation. However, the deficiency of donor hearts might be a serious problem in the world. And the transplantation waiting period in this country extends to several years. Therefore, necessity of clinical application of artificial hearts with long-term durability has arisen. As the size of the western ventricular assist devices, which are provided at present, is still big for the smaller body size Asian people, several artificial heart projects are being conducted in Japan, and one of these has started clinical trials.

There are also some devices or procedures suggested to be useful for the surgical treatment of severe heart failure, such as the ventricular CorCup, Myosprint or Dor's procedure. And recently, cell transplantation to repair or supplement the impaired heart tissue has been reported on as an alternative therapy for that [2]. There are many problems about the tissue reproduced *in vitro* or *in vivo* that are not yet solved. Moreover, any control of the implanted tissue might be impossible from the outside.

As the heart failure is caused by a decrease in the myocardial contractile function, the direct mechanical myocardial assistance in response to physiological deficit, i.e. a 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 would be 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 on 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 on 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 shown in Fig. 1, and its basic hemodynamic performance was examined in goat experiments.

2. Materials and Methods

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

In general, Ti-Ni alloy is well-known as a material with the shape-memory effect [10–16]. The fibre material (Biometal, Toki Corporation), which was used in this study for the development of artificial myocardium, has the configuration of

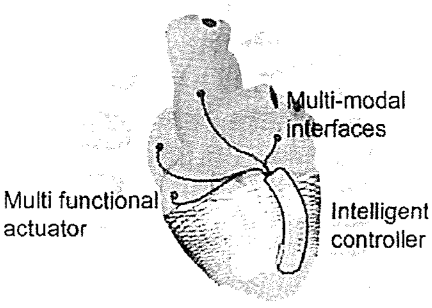

Fig. 1. Schematic illustration of a concept of the newly-designed artificial myocardium using a shape memory alloy fibre

a covalent bond, and demonstrates a marked strain change as shown in Fig. 2, which is similar to the changes in the surface strain in natural ventricle [17]. 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.

The basic stress-strain characteristics were examined in a test circuit as shown in Fig. 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.

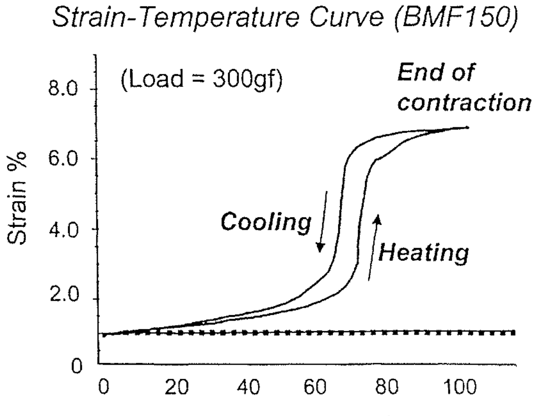

Fig. 2. Typical relationship between strain and temperature obtained from the Biometal fibre (diameter: 150 μm). Because of the linearity between the strain and the electric resistance, the displacement can be controlled by the simple circuit and also the sense of force can be estimated

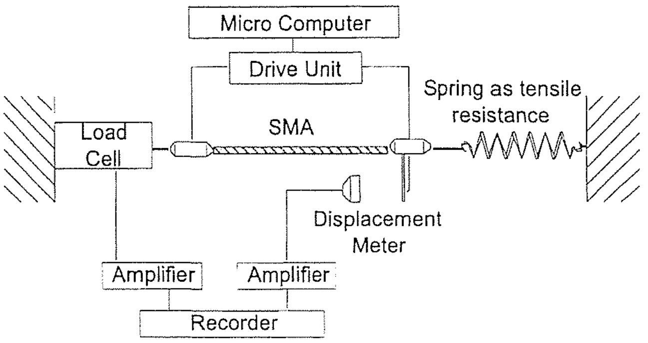

Fig. 3. Schematic drawing of the measurement system for the stress-strain characteristics of the shape memory alloy fibre. The spring constant as the tensile resistance was selected from 1.7 to 4.1 N/mm

The newly-developed electro-mechanical artificial myocardium consists 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 14 mg, and the length was set to be 280 mm. The total weight of the whole actuator was around 15 g. The myocardial actuator shown in Fig. 4 was attached onto the heart, 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.

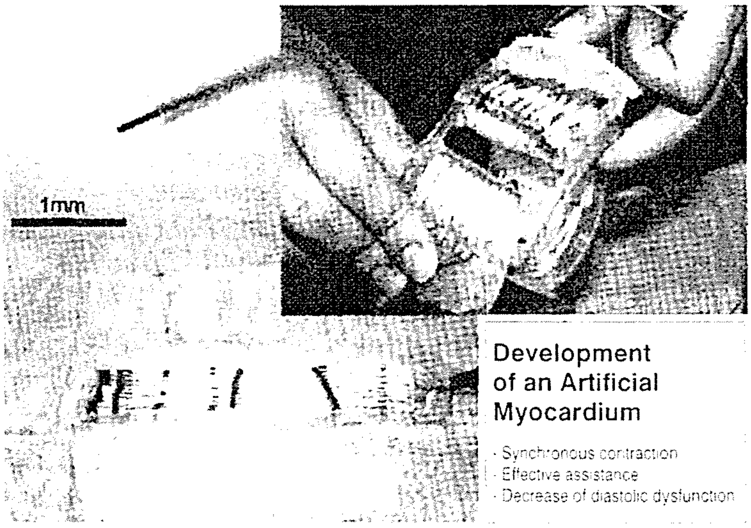

Fig. 4. A shape memory alloy fibre covered by a silicone tubing (upper left), and a prototype of artificial myocardium developed in this study (bottom left); the artificial myocardial fibres were covered with waterproof polymers

(2) Animal experiments

Prior to the measurement, the myocardial assist device was installed in the thoracic cavity and anchored onto the surface girdling the heart by under general anesthetising procedure. The hemodynamic waveforms were obtained from healthy goats, the mean weight of which was 53 kg. Pulmonary and aortic blood pressures were measured by transducers and amplified with a polygraph (Fukuda Denshi, MCS-5000). The aortic flow rate was also measured at the 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 1.5 kHz.

All the animal experiments related to this study were scrutinised and approved by the Ethical Committee on Animal Experiments of the Department of Medicine, Tohoku University, and also the Institute of Development, Aging and Cancer, Tohoku University, 2004–2006.

3. Results and Discussion

Figure 5 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 variation of the speed of the stress gain. As the actuation was conducted only by the cooling-and-heating process in the fibre, neither a sound nor an electric noise could be easily generated in each part.

The myocardial device developed was successfully installed into the goats' thoracic cavity. Prior to the installation of the device, it was covered with silicone rubber

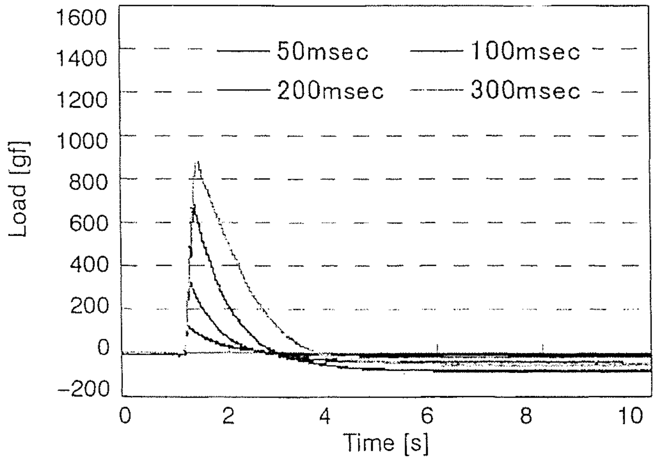

Fig. 5. Basic characteristics of the transient response obtained from a single fibred module under the different pulse wave modulation input conditions; the duty of the input was set to be 50, 100, 200, 300 msec respectively at the room temperature (25°C)

and PVC polymer. 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 fit it into the thoracic cavity. But in this study, by using shape memory fibres, the actuator itself was so small that it would require even a smaller volume 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 associated with the operation were not confirmed in goats yet.

Hemodynamic waveforms were changed by the mechanical assistance as shown in Fig. 6. 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 2.5 l/min by the mechanical assistance. Therefore, it was indicative of the point that the effective assistance might have been achieved by using those shape-memory alloy fibres.

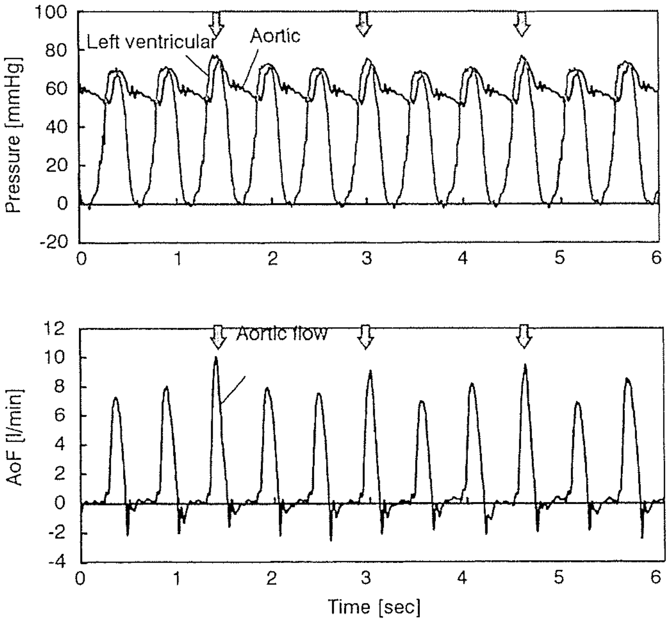

Fig. 6. Changes in hemodynamic waveforms obtained in a goat; the arrows indicated the mechanical contractile assistance by the artificial myocardial developed. The assistance was carried out one third of the natural heart beat

4. Conclusion

The newly-designed mechano-electric artificial myo-cardium 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 the preliminary examination of the performance of the device was conducted in goat experiments. The amelioration of the cardiac functions following the changes in the vascular hemodynamics were investigated by the mechanical assist. As our system could be a symbiotic autonomous system which is capable of assisting natural ventricular functions with physiological deficit, it might be useful for the application in patients with chronic heart failure, such as angina of effort, and also as the cardiac massage in life-saving emergency for the recovery from ventricular fibrillation, as an alternative circulatory support.

Acknowledgments

The authors would like to extend their appreciation to Mr. Kimio Kikuchi and Mr. Tomio Kumagai for their cooperation in the animal experiments. This study was supported by Grant in Aid for Scientific Research of Ministry of Health, Labour and Welfare (H17-nano-009), and Ministry of Education, Culture, Sports, Science and Technology (17790938). And this study was partly supported by Grant in Aid for Scientific Research of Pharmaceuticals and Medical Devices Agency (02-1).

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Preliminary Study on the functional reproduction of an Artificial Myocardium using Covalent Shape Memory Alloy Fibre Based on Control Engineering

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Abstract: The authors have been developing an artificial myocardium using a sophisticated covalent shape memory alloy fibre, which is capable of assisting natural cardiac contraction from the outside of the ventricular wall. We applied engineering method based on robotics control and constructed the artificial myocardial assist system which might be able to regulate derangement and regenerative tensile force on the surface of heart. In this study, a design to surround the total heart has been established in order to refrain from the stress concentration by the mechanical assistance, and the hemodynamic performance of the artificial myocardial assist system were examined in a mock circulatory system as well as on animal experiments using goats. Basic characteristics of the shape memory alloy fibre unit were examined and the displacement control could be achieved under the condition of the different external temperature by feedback using the PID control. And also the increase of the external work of the goats left ventricular pressure-volume relationship were obtained by the assistance using an artificial myocardium with parallel-linked configuration, and therefore it was indicated that the effective ventricular mechanical support could be performed by the device.

Keywords: Artificial myocardium, hemodynamic assistance, pressure-volume relation, shape memory alloy fibre

1. INTRODUCTION

In general, the artificial ventricular assist systems, such as artificial hearts, were employed for the treatment of the severe heart failure in order to increase the circulation volume[1-10]. However the complications caused by the hemolysis or thrombosis on the surface of the artificial materials are still outstanding problems in the application of those devices to patients. The authors assumed that the essence of the pathophysiological development of severe heart failure was in the decrease in the cardiac contractility. Then an artificial myocardium has been developed using a covalent nano-tech shape memory alloy fibre, which is capable of assisting natural cardiac contraction from outside of the ventricular wall without any blood contact surfaces of the device[11-16]. The purpose of this study was to develop a sophisticated artificial myocardium unit, and also to have examined the hemodynamic effects of the myocardial assist system on cardiac function.

2. MATERIALS AND METHODS

2.1 Basic characteristic of myocardial unit

The myocardial assist system consists of a covalent type shape memory alloy fibre, 'Biometal'. The material of the shape memory alloy fibre was structured as covalent shape, so that it had long durability of periodic contraction over 800 million cycles. The relationship between the temperature and the strain of the fibre was shown in Figure 1. The diameter of each fibre employed for the ventricular supporting girdle is 100-150 microns, and it is contracted by the Joule heating by 5 to 10% of the total length. The artificial myocardium has been constructed to be parallel link structure by using those fibres. Firstly, the electric resistance of a fibre in the length of 200mm, which was suitable unit length for the circumferential girdle of the ventricle, was obtained with different percent shortening.

And secondly, in order to achieve the accurate settlement of the displacement of the shape memory alloy fibre unit, the authors applied the PID control against the electric resistance of the fibre. Each electric resistance value of the fibre was obtained and converted to electric voltage through a bridge circuit, and those values were imported into the originally-designed microcomputer by using SH2-7044 for the control of PID. The control algorithm was configured to generate sequential pulse with pulse width modulation in order to change the wattage, which was input into each fibre.

The changes in displacement were obtained by the laser meter (Keyence, LB-01) as well as the mechanical load by the load cell (Kyowa, LVS-1KA) under the conditions as shown in Table 1: a) different ambient heat transmission in the room temperature air and water, and b) different bias tensile force.

2.2 Hemodynamic changes in goat

Hemodyamic data were obtained from normal adult healty goats, the mean weight of which was 50kg. Prior to the measurement, the artificial myocardial assist device with parallel-linked shape memory alloy fibres was covered with silicone rubber, and it was attached onto the ventricular wall as shown in Fig. 2 and 3. For the first stage evaluation of the myocardial assist girdle system, the actuation of the device was regulated by

Table 1 An example of the experimental condition for the comparison of the characteristics of the biometal fibre

Items	Values
Voltage applied	36VDC
Length of fibre	200mm
Frequency	0.5Hz
Duration energised	200msec
Ambient heat transmission	2.4×10^{-2},6.0×10^{-1} J/(m sec K)
Bias tensile force	5.0×10^{-2}, 1.7×10^{-1} N/mm

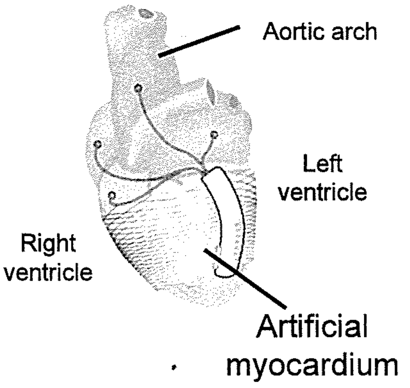

Fig. 3 Schematic illustration of an artificial myocardium attached on the ventricular wall; the synchronous contraction can be achieved according to the natural physiological demand.

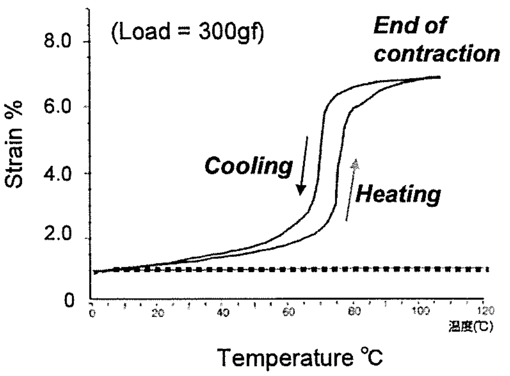

Fig. 1 Schematic illustration of the temperature-strain curve obtained from the Biometal Fiber.

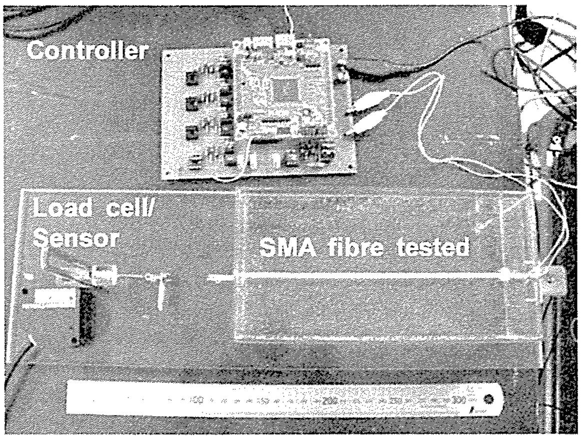

Fig. 2 Whole view of the tensile force and displacement test circuit for the examination with the PID control.

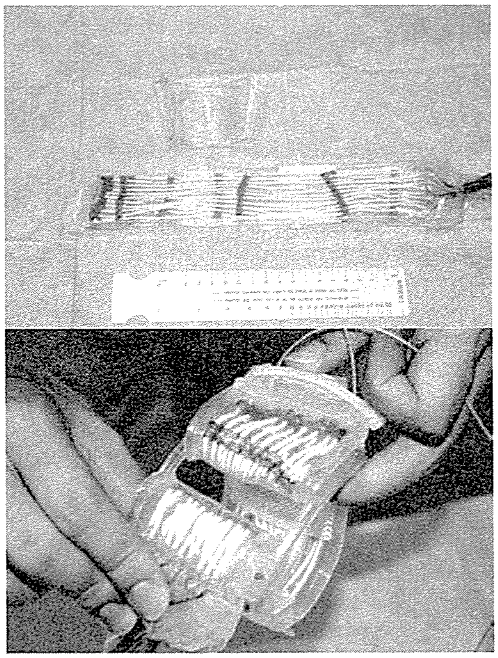

Fig. 4 Whole view of the newly-designed artificial myocardium which is able to girdle the ventricle.