31st Annual International Conference of the IEEE EMBS
Minneapolis, Minnesota, USA, September 2-6, 2009

Assessment of Synchronization Measures for Effective Ventricular Support by using the Shape Memory Alloy Fibred Artificial Myocardium in Goats

Y. Shiraishi, T. Yambe, Y. Saijo, F. Sato, A. Tanaka, M. Yoshizawa, T. K. Sugai, *Member, IEEE*
Y. Kaneko, Y. Sato, M. Uematsu, M. Umezu, T. Fujimoto, N. Masumoto, H. Liu, A. Baba, S. Konno, K. Tabayashi, H. Sasada and D. Homma

***Abstract*— Thromboembolic and haemorrhagic complications are the primary causes of mortality and morbidity in patients with artificial hearts, which are known to be induced by the interactions between blood flow and artificial material surfaces. The authors have been developing a new mechanical artificial myocardial assist device by using a sophisticated shape memory alloy fibre in order to achieve the mechanical cardiac support from outside of the heart without a direct blood contacting surface. The original material employed as the actuator of artificial myocardial assist devices was 100um fibred-shaped, which was composed of covalent and metallic bonding structure and designed to generate 4-7 % shortening by Joule heating induced by the electric current input. In this study, we focused on the synchronization of the actuator with native cardiac function, and the phase delay parameter was examined in animal experiments using Saanen goats. Total weight of the device including the actuator was around 150g, and the electric power was supplied transcutaneously. The device could be successfully installed into thoracic cavity, which was able to be girdling the left ventricle. The contraction of the device could be controlled by the originally designed microcomputer. The mechanical contraction signal input had been transmitted with the phase delay of 50-200 msec after the R-wave of ECG, and hemodynamic changes were investigated. Cardiac output and systolic left ventricular pressure were elevated with 20% delay of cardiac cycle by 27% and 7%, respectively, although there was smaller difference under the condition of the delay of over 30%. Therefore, it was suggested that the synchronization measures should be examined in order to achieve sophisticated ventricular passive/active support on physiological demand.**

Manuscript received June 20, 2009. This study was supported by Grant in Aid for Scientific Research of Ministry of Education, Culture, Sports, Science and Technology (17790938, 20659213).

Y. Shiraishi, T. Yambe, Y. Kaneko, H. Liu, S. Konno, S. Nitta are with the Institute of Development, Aging and Cancer, Tohoku University, Sendai 980-8575, Japan (corresponding author to provide phone: +81 22 717 8517; fax: +81 22 717 8518; e-mail: shiraishi@idac.tohoku.ac.jp).

T. K. Sugai, F. Sato, Y. Saijo are with the Graduate School of Biomedical Engineering, Tohoku University, Sendai, Japan. N. Masumoto is with the Department of Mechanical Engineering, Nippon Institute of Technology, Saitama, Japan. M. Uematsu is with the Division of Medical Devices, National Institute of Health Sciences, Tokyo, Japan. Y. Sato, T. Fujimoto, M. Umezu are with Waseda University, Tokyo, Japan. M. Yoshizawa is with the Cyber Science Center, Tohoku University, Sendai, Japan. A. Tanaka is with the Faculty of Symbiotic Systems Science, Fukushima University, Fukushima, Japan. A. Baba is with Shibaura Institute of Technology, Tokyo, Japan. K. Tabayashi is with the Department of Cardiovascular Surgery and the Graduate School of Medicine, Tohoku University, Sendai, Japan. H. Sasada is with the Graduate School of Agriculture, Tohoku University, Sendai, Japan. T. Fujimoto is with the Shibaura Institute of Technology, Tokyo, Japan. D. Homma is with the Toki Corporation, Tokyo, Japan..

I. Introduction

Chronic heart failure (CHF) is functionally and structurally characterized by pathophysiological remodeling of the ventricle. In general, ventricular assist devices (VADs), such as artificial hearts, are used for the surgical treatment of the patients with the final stage of severe heart failure [1]. However, thromboembolic and haemorrhagic complications are still the primary causes of mortality and morbidity in patients with VADs, which are known to be induced by the interactions between blood flow and artificial material surfaces. Several concepts of the mechanical assistance from outside of the ventricle have been presented so far, such as Anstadt's ventricular cup, providing a solution to these problems without direct contacting surfaces against blood [2]. And also some new devices, such as Myosprint, demonstrated improvements in eliminating mitral regurgitation in dysfunctional left ventricle as well as in preventing the ventricular enlargement which was to compensate for the reduction in cardiac function [3].

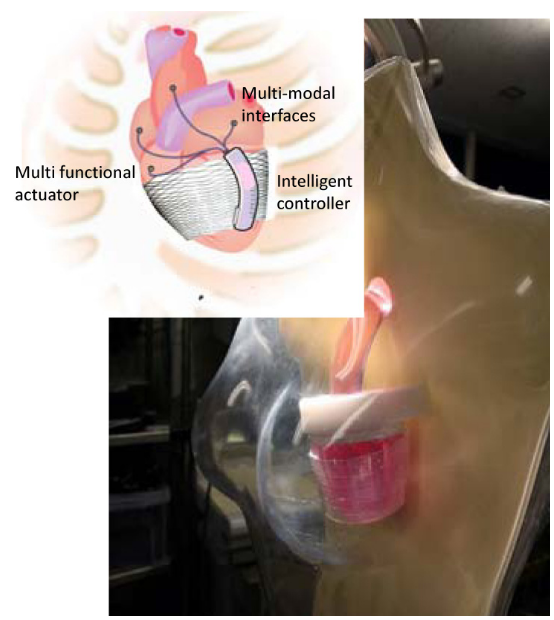

Fig. 1: Schematic illustration and an installation in the mock of an artificial myocardium attached on the ventricular wall; the synchronous contraction can be achieved according to the natural physiological demand.

Although the passive implantable devices, which are girdling the ventricle from the outside, have been already applied for clinical trials in patients with chronic congestive heart failure for the passive assistance as well as for the prevention of enlargement of the left ventricle to compensate for the reduction in cardiac function, there might be a limitation to passive assistance in the case of sudden changes of cardiac contractile function, such as angina of effort. We have been developing an artificial myocardial assist device by using a covalent type nano-tech shape memory alloy fibre, which is capable of assisting natural cardiac contraction from outside of the ventricular wall as shown in Figure 1. The purpose of this study was to examine the function of the artificial myocardium, which was designed to assist the heart synchronously with native contraction, and its feasibility in chronic animal experiments. In this study, we examined the hemodynamic changes under the different synchronous conditions of the artificial myocardial assist system with native heart beat.

II. Materials and Methods

A. Artificial Myocardium using Shape Memory Alloy Fibres

The artificial myocardium consists of ten shape memory alloy fibres which were covered by silicone rubber as shown in Figure 2 and 3. Special features of the shape memory alloy fibre material (Biometal®) which was to be employed as the actuator of the artificial myocardium were as follows: a) composition of covalent and metallic bonding structure, b) 4-7 % shortening by Joule heating induced by the electric current input, c) linear characteristics of electric resistance against shortening, d) strong maximum contractile force of 10N with 100um-fibre, e) high durability of over one billion cycles, f) contractile frequent response by 1-3 Hz, and g) elective diameter size smaller than 30um [4-7]. As the martensitic temperature is able to be selected by fabrication processing from 45 to 70 Celsius, the 70-Celsius fiber was employed in this study. The contraction can be regulated by an originally designed microcomputer system. The device is controlled percutaneously by electrical signal input. Each signal for the contraction is synchronized with native electrocardiogram (Figure 4). Originally designed ladder-shaped hinges were constructed on the parallel-linked shape memory alloy fibres belt, specifically on the surface attaching to the left ventricular free wall in order to simulate the wall-thickening effect as well as to promote the mechanical shortening perpendicularly to the left ventricular long axis.

B. Structural and Functional Design of the Device Based on the Anatomical Examination of Native Heart

Myocardial streamline was confirmed by the CT investigation in a healthy goat heart which was extracted and unfolded based on the Torrent-Guasp's myocardial band concept [8]. The orientation of the device contraction might

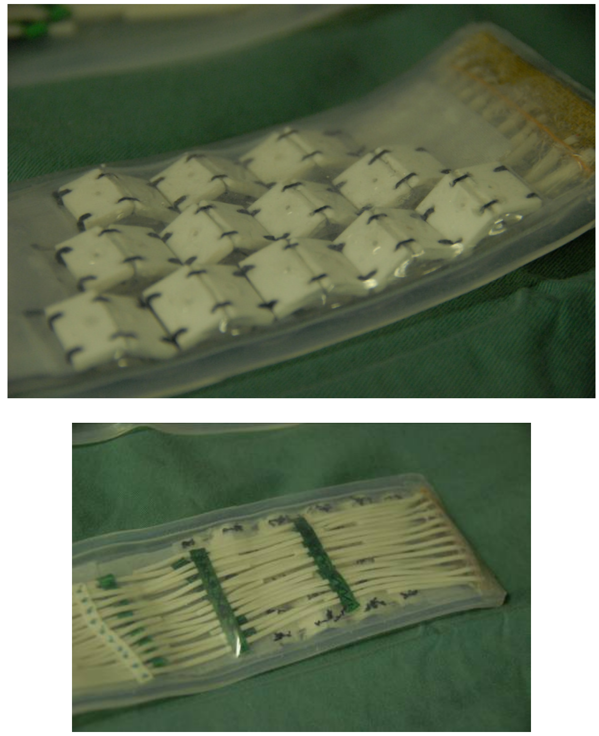

Fig. 2: The structure attached on the artificial myocardial actuator developed and employed in this study on animal experiments (top), and its connection of shape memory alloy fibres covered with silicone membrane (bottom).

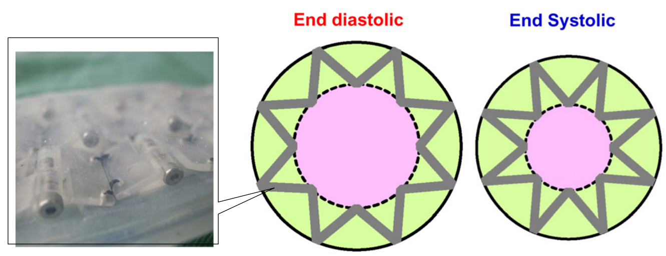

Fig. 3: Structural design of the sophisticated myocardial assist system implemented onto the surface of the myocardial band, which is simulating the native "wall-thickening effect".

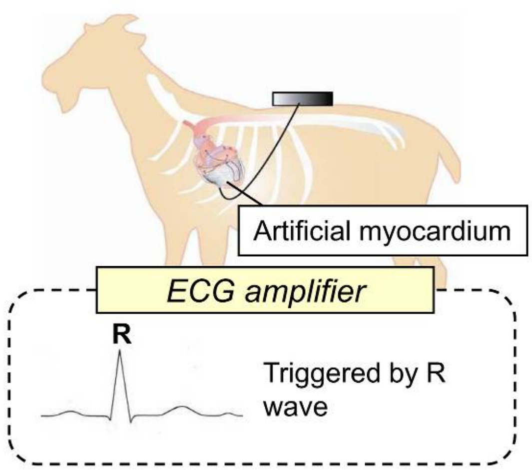

Fig. 4: Schematic illustration of the signal connection for the control of myocardial contraction

promote native systolic function while avoiding both the external and internal critical structures of the heart. The myocardial streamline was detected from the data with plastic markers plot by the multi-ditector-row CT, and the angular configuration to the left ventricular long axis was calculated. A systolic physiological delay, which is set from 10 to 30 % of mean cardiac cycle in each hemodynamic condition, is observed from the beginning of an electrophysiological constrictive trigger to the hemodynamic systole. Therefore it is necessary to maintain the time corresponding to that physiological delay in the device in order to achieve effective dynamic contraction from outside of ventricle. Each unit of the device can be constricted with Joule heating by an electric current input. The pulse input signal length for the mechanical contraction for each fibre was able to be changed from 50 to 200 msec.

C. Experimental Procedure

The acute animal experiments were performed in healthy female adult Japanese Saanen goats (n=5), which weighed around 45+/-2kg. Implantation of the device was performed as part of an open-chest cardiac procedure on a beating heart under the normal inhalation and anesthesia followed by endotracheal intubation using 2.5% halothane. The band-shaped myocardial assist device was installed into the thoracic cavity girdling from the apex to the base and one of the ends was parallel to the left ventricular long axis myocardial streamline on its free wall side. Coronary vasculature was visually identified and avoided on the exterior of the heart during the implantation. There was no direct suture on the tissue or muscles with the device.

The chronic animal experiments were performed in healthy female adult Japanese Saanen goats (n=2), which weighed 45 kg. Implantation of the device was performed as part of an open-chest cardiac procedure. We started the assistance in postoperative one week. These animal trials were electively terminated after postoperative one month.

All animals received humane care in accordance with "the Guideline for the Care and Use of Laboratory Animals" published by the National Institute of Health (NIH publication 85-23, revised 1985) as well as with "the Guidelines for Proper Conduct of Animal Experiments" formulated by Science Council of Japan (2006) and the guidelines determined by the Institutional Animal Care and Use Committee of Tohoku University.

III. RESULTS AND DISCUSSION

A. Hemodynamic Response against the Different Phase Delay or Pulse Length of the Artificial Myocardium

Figure 6 showed the relationships between the incremental ratio of hemodynamic data obtained with the different condition of phase delay or pulse length for mechanical assistance in the acute experimentation.

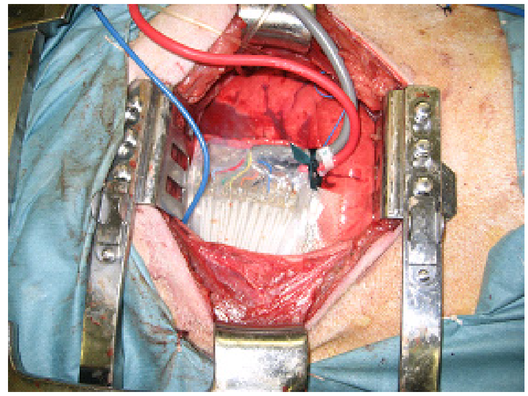

Fig. 5: Attachment of the artificial myocardium via left thoracotomy in the animal experiments.

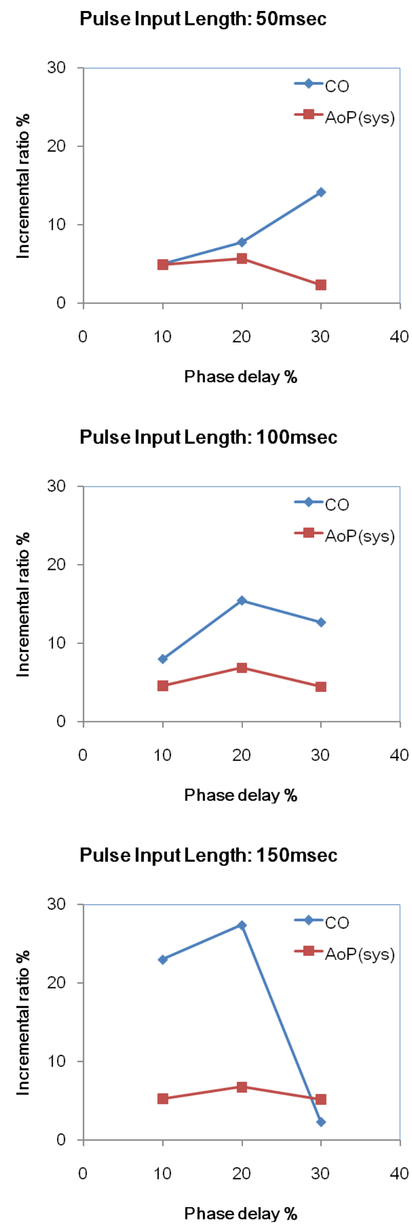

Fig. 6: An example of the changes in cardiac output (CO) and systolic aortic pressure (AoP(sys)) obtained in one goat during the acute experimentation under the different phase delay or pulse length conditions.

The aortic pressure data were increased in each driving condition of the actuator under the 20% phase delay condition. And the ventricular volume assistance effectiveness was higher with the conditions of the pulse input length of 100 and 150msec, which corresponded to 50-80% of the systolic phase in goats' cardiac cycle. As a result, it was indicated that the mechanical assistance from outside of the left ventricle could be effective with the phase delay from R-wave of ECG of around 20%. And it was also anticipated that the overextended delay of artificial myocardial support might cause the decrease of cardiac function. The relationships between hemodynamic data and pulse input duration were obtained in a goat as shown in Figure 7, and consequently, it was suggested that the afterload matching with native cardiovascular systems could be adjusted by the artificial myocardial control.

B. *Hemodynamic Effects in Chronic Study*

In the chronic test, there was no significant eventual misalignment of the devices in the thoracic cavity. Left ventricular and aortic pressures were increased by the assistance (Figure 8). Each waveform was calculated as the average of the data in the period of 90sec. There were no significant changes in the end diastolic pressure, so that it was suggested that there might not be any diastolic dysfunction during the assistance using the artificial myocardium. As a result, left ventricular systolic pressure was increased from 110 to 118 mmHg (7%), and assisted flow rate was elevated for 70msec, which was around 20% of the cardiac cycle and was equivalent of the mechanical contractile duration. Consequently, the assistive effect on cardiac output during the assistance was calculated to be 3% higher than the control condition without mechanical contraction in the chronic study, and it was suggested that the interaction between native cardiovascular systems and the artificial myocardium was affected by the reaction of the autonomic nervous activities under the awake condition.

IV. Conclusion

The improvement of an artificial myocardial control using the sophisticated covalent shape memory alloy fibres was achieved, and the optimum control for the matching of native cardiovascular impedance was examined in goat experiments.

Acknowledgment

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

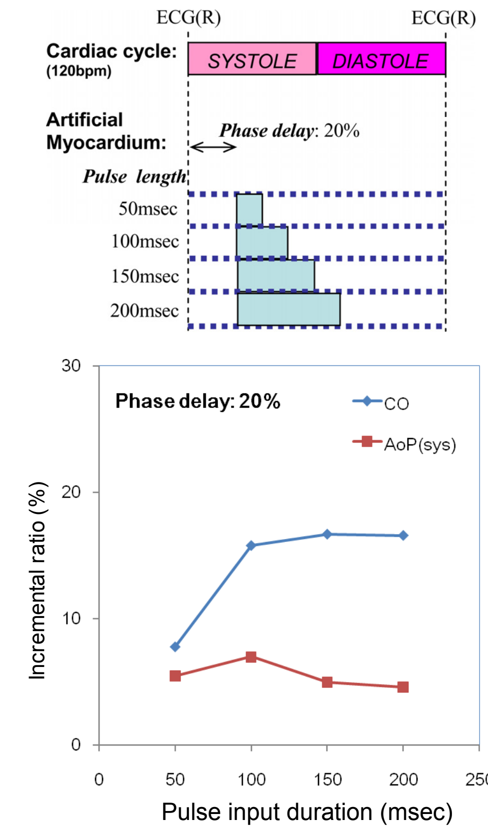

Fig. 7: Schematic illustration of the settings of the pulse input length (top), and changes in cardiac output and systolic aortic pressure obtained in a goat against the different pulse input length of the myocardial assistance by the device under the 20% phase delay condition (bottom).

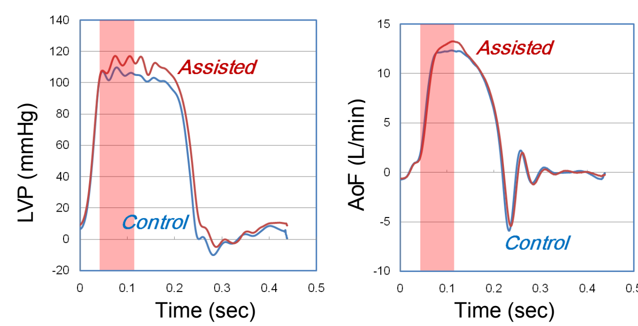

Fig. 8: An example of the changes in hemodynamic waveforms obtained at the goat with myocardial assist device in the chronic test. 'Control' indicates the waveforms taken without assistance, while 'Assisted' were with mechanical contraction; LVP: left ventricular pressure, AoP: aortic flow..

References

[1] Taylor TD, et al., "Registry of the International Society for Heart and Lung Transplantation: Twenty-fourth Official Adult Heart Transplant Report–1998," *J Heart Lung Transplant*, 26(8), pp.769-781, 2007.

[2] Anstadt GL, et al., "A new instrument for prolonged mechanical massage," *Circulation*, 31(Suppl. II), p.43, 1965.

[3] Fukamachi K, McCarthy PM, "Initial safety and feasibility clinical trial of the Myosprint device," *J Card Surg*, 20, pp.S43-S47, 2005.

[4] Buehler WJ, et al., "Effect of low-temperature phase changes on the mechanical properties of alloys near composition TiNi," *J Appl Phys*, 34, 1465, 1963.

[5] Homma D, et al., "Shape memory alloy effect in Ti-Ni alloy during rapid heating," *Proc 25th Japan Congress on Materials Res*, 1982.

[6] Sawyer PN, et al., "Further study of nitinol wire as contractile artificial muscle for an artificial heart," *Cardiovasc Diseases Bull Texas Heart Inst*, 3, 65, 1976.

[7] Homma D, et al., "Functional anisotropic shape memory alloy fiber and differential servo actuator," *Proc of Int Conf on Shape Memory and Super elastic Technologies*, pp.463-472, 2008.

[8] Buckberg G, et al., "Structure and function relationship of helical ventricular myocardial band," *J Thorac Cardiovasc Surg*, 163(3), pp.578-89, 2008.