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Controlling Methods of a Newly Developed Extra Aortic Counter-pulsation Device using Shape Memory Alloy Fibers.

Mohamed O. Hashem, A. Yamada, Y. Tsuboko, H. Muira, and D. Homma, Y. Shiraishi, T. Yambe, *Member, IEEE.*

***Abstract*— Diastolic counter-pulsation has been used to provide circulatory augmentation for short term cardiac support. The success of intra-aortic balloon pump (IABP) therapy has generated interest in long term counter-pulsation strategies to treat heart failure patients. The authors have been developing a totally implantable extra aortic pulsation device for the circulatory support of heart failure patients, using 150µm Ni-Ti anisotropic shape memory alloy (SMA) fibers. These fibers contract by Joule heating with an electric current supply. The special features of our design are as follow: non blood contacting, extra aortic pulsation function synchronizing with the native heart, a wrapping mechanical structure for the aorta in order to achieve its assistance as the aortomyoplsty and the extra aortic balloon pump. The device consisted of rubber silicone wall plates, serially connected for radial contraction. We examined the contractile function of the device, as well as it controlling methods; the phase delay parameter and the pulse width modulation, in a systemic mock circulatory system, with a pneumatically driven silicone left ventricle model, arterial rubber tubing, a peripheral resistance unit, and a venous reservoir. The device was secured around the aortic tubing with a counter-pulsation mode of 1:4 against the heartbeat. Pressure and flow waveforms were measured at the aortic outflow, as well as its driving condition of the contraction phase width and the phase delay. The device achieved its variable phase control for co-pulsation or counter-pulsation modes by changing the phase delay of the SMA fibers. Peak diastolic pressure significantly augmented, mean flow increased ($p<0.05$) according to the pulse width modulation. Therefore the newly developed extra aortic counter-pulsation device using SMA fibers, through it controlling methods indicated its promising alternative extra aortic approach for non-blood contacting cardiovascular circulatory support.**

M. O. Hashem is with the Department of Medical Engineering and Cardiology, Tohoku University, Graduate School of Medicine, Sendai 980-8575, Japan (corresponding author to provide phone:+81-22-717-8517; fax:+81-22-717-8518; e-mail: hashemohamed@idac.tohoku.ac.jp).
Y. Shiraishi, is with the Institute of Development Aging and Cancer, Tohoku University, 980-8575 Sendai, Japan (e-mail: shiraishi@idac.tohoku.ac.jp).
T. Yambe, H, Muira are with the Institute of Development Aging and Cancer, Tohoku University, Sendai, Japan.
A. Yamada, Y. Tsuboko are with the Graduate School of Biomedical Engineering, Sendai, Japan.
D. Homma is with the Toki Corporation, Tokyo, Japan.

I. INTRODUCTION

The use of diastolic counter pulsation devices to improve circulatory efficiency has been developing as a concept over the last 30 years [1,2]. Counter-pulsation may lead to an improvement in left ventricular function by a reduction in the central aortic end-diastolic pressure and the after-load, as well as an increase in diastolic coronary blood flow by augmenting the peak diastolic pressure. Intra-aortic balloon pump (IABP), remain the most widely available system for this application, particularly in the setting of cardiogenic shock after myocardial infarction or cardiac surgery [2,3]. Despite notable advantages, including wide availability, percutaneous insertion, acceptable cost, and proven efficacy, the long term use of the IABP to support patients with end stage heart failure is seriously limited by the vascular complication [4,5,6]. Even though, the success of IABP therapy for short term hemodynamic support has generated interest to develop long term counter pulsation methods, such as aortomyoplasty [7], which is a sophisticated surgical procedure involve raping of the lattissmus dorsi muscle (LDM) around the aorta, extra aortic balloon pump (EABP) (Sunshine Heart, C-pulse) a pneumatic driven device secured around the aorta [8], and para-aortic CPDs [9,10], all these are aiming to improve the peripheral circulation and promote myocardial recovery. Yet these approaches still in the developmental stages. We have been developing a totally implantable, non-blood contacting, extra aortic counter pulsation device using shape memory alloy (SMA) fibers as an actuator [11,12], for the circulatory support of moderate-severe heart failure patients. The fibers contract by Joule heating with an electric current supply, contraction and relaxation are timed by a special control unit [13].

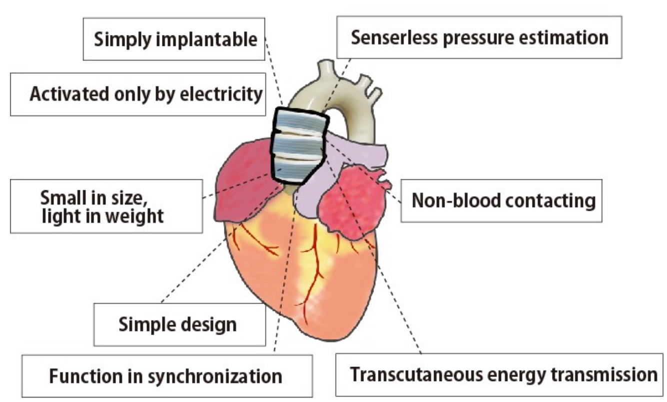


Fig 1. Schematic illustration of an extra aortic pulsation device using shape memory alloy fibers.

This device is activated by electricity only, and it has been designed to be simple to implant, to accommodate aortic anatomic variability as shown in (Fig. 1). And to provide improvement in the hemodynamic circulation and to avoid the hemorrhagic and the thromboembolic complication of the ventricular assist device (VADs), and the vascular complication of the IABP. Still it will not be applicable for arteriosclerotic patients. The purpose of this study in the mock circulatory model was to examine the contractile function of the device using 150 micrometer Ni-Ti anisotropic SMA fibers, and to investigate the effect of it is driving condition of the contraction phase width and the phase delay in relaxation, and it controlling methods pulse width modulation, as a power input control.

II. MATERIALS AND METHODS

A. Extra Aortic Counter-Pulsation device using Shape Memory Alloy Fibers

We employed 150 microns Ni-Ti anisotropic shape memory alloy fibers for the device. In general Ni-Ti alloy is well known as a material with the shape memory effect, these fibers contract when their temperature reach 70º Celsius with an electric current supply, the fibers are covered by (2mm in diameter) heat resistance silicone tubing. In order to achieve effective mechanical support from outside of the aorta, and with the intention of reducing the high temperature effect on the surrounding tissue, we designed a new controlling mechanism in this study for the use of SMA fibers. The device consisted of four rubber plates of silicone, each plate was fabricated in the size of 15 cm in length and 3.5 cm in width and 8mm in thickness as shown in (Fig. 2). Then we connected the rubber plates serially as the plates could cover an aortic tubing of 5cm in diameter by circumferential position, and providing a radial displacement of 8 to 10mm during contraction, the plates were connected together by the SMA fibers through tunnels made on the rubber plates, as shown in (Fig. 3 and 4).

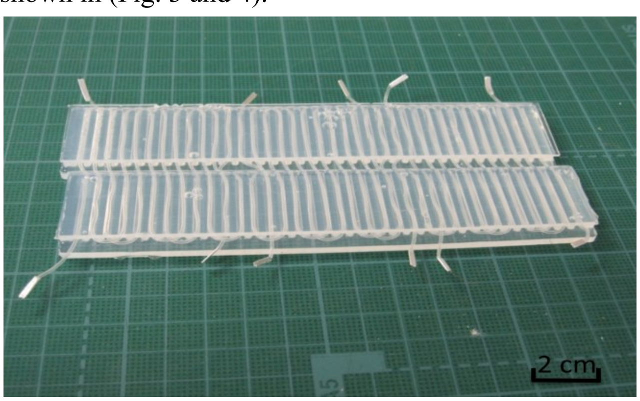


Fig. 2. Shape memory alloy fibers connect the plates with each other, so when they contract they will pull each other to generate an external pulsation mechanism.

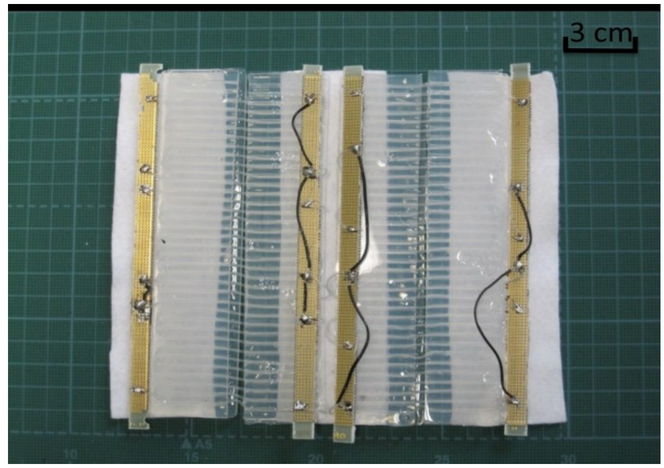


Fig. 3. Whole view of the extra aortic pulsation device

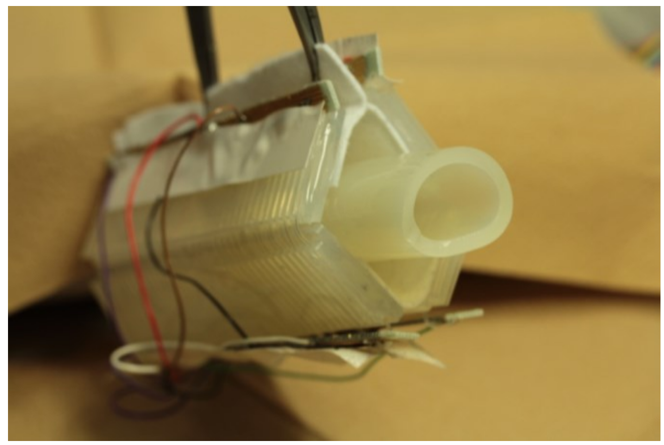


Fig. 4. Serially connected by circumferential position for radial displacement in order to achieve external displacement force.

B. Mock circulatory evaluation

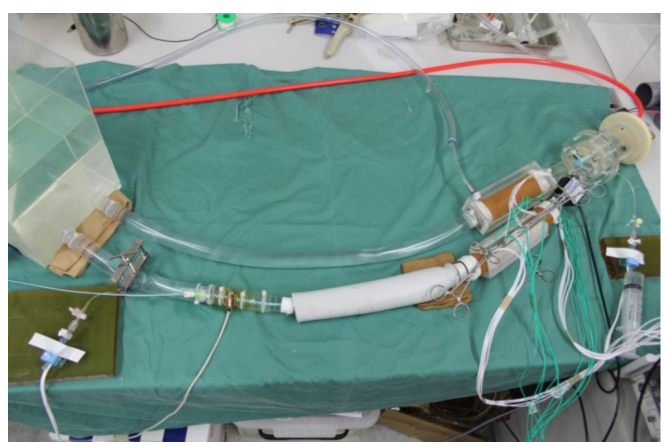


Fig. 5. Whole view of the mock circulatory system for the extra aortic counter-pulsation SMA fibers device evaluation.

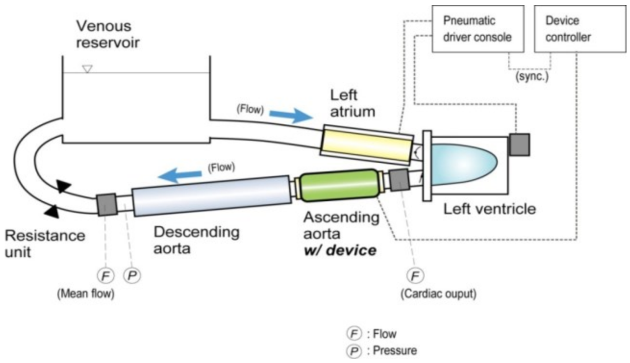


Fig. 6. Schematic illustration of the circuit with it controlling system of the mock circulatory system.

The contractile function of the device was examined in a mock circulatory system, which was capable of simulating natural hemodynamic (Fig. 5 and 6). And it consisted of a pneumatically driven silicone left ventricle model, and pneumatic driven rubber tube left atrium, an arterial rubber tubing represent ascending aorta. Descending aorta was represented with a sponge layer sandwiched by two silicone layers. The impedance of the arterial units was arranged by the resistance unit, and a venous reservoir, and the system was filed with water as a circulating fluid.

Pressure waveform and the main flow were recorded by a pressure transducer and trans-magnetic flow meter, both were fixed at the distal portion of the descending aortic tubing. The device was secured around the ascending aortic tubing and its contraction was driven with a counter pulsation mode of 1:4 against the heartbeat, we set the timing for the duration by the controller, and the power input pulse width modulation (PWM) was set on 50% and then increased up to 75% and 100%. We also examined its function under the different contraction and relaxation speeds by changing the parameters of width and phase delay, and its physiological effect under different phase delay parameters were measured at 0msec and up to 600msec.

III. RESULTS AND DISCUSSION

The hemodynamic effects of the new counter pulsation device using SMA fibers were compared between the assisted and the unassisted beat, by calculating the integrate, which is the area under curve.

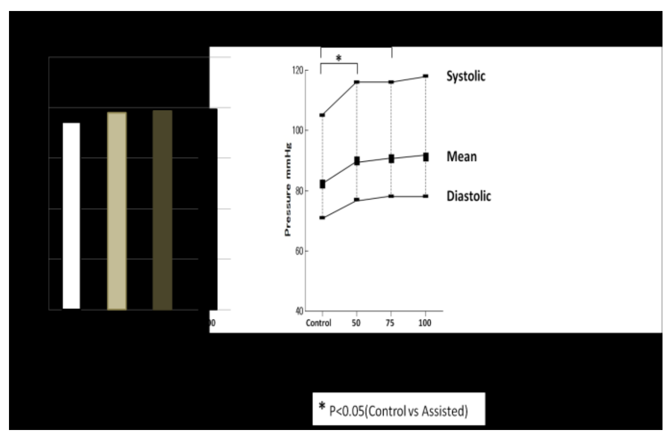
A. Hemodynamic effects of the extra aortic Counter-pulsation SMA fibers device

The device significantly increased the mean flow and the mean pressure in the assisted beat compared to unassisted beat (Fig. 7). The main flow increase from 3.71 L/min to 3.89 L/min co-pulsation (5%, $p<0.05$) and to 3.9 L/min counter-pulsation (5.1%, $p<0.05$) with device PWM of 50%, when we increased the PWM to 75%, the main flow increased to 3.91 L/min co-pulsation (5.6%, $p<0.05$) and to 3.93 counter-pulsation (6.5%, $p<0.05$), noticing slight increase in the main flow but without statistical significance difference between 50% and 75% PWM. Even though the difference between 50 and 75% PWM wasn't significant, although an increase in the contractile force can be achieved by increasing the PWM, which can be employed as a control methods for the power input.

B. Hemodynamic response against the different phase delay of the extra aortic Counter-pulsation SMA fibers device

Fig. 8. Shows the effect of the different condition of phase delay or pulse length for the mechanical assistance of both systolic and diastolic pressure by measuring the integrate of the aortic pressure wave form. The aortic pressure data were increased in each driving condition of the SMA fibers, systolic pressure assistance was higher with the condition of 150msec phase delay without any significant change above baseline regarding the diastolic pressure as shown in (Fig. 9.A). While the peak diastolic pressure augmentation was achieved with the condition of 500 and 600msec phase delay, without any effect on the systolic phase during the complete cardiac cycle. This can be clearly illustrated in (Fig. 9.B), with the condition of 400msec. As a result, it was indicated that the co-pulsation assistance from the outside of the aortic rubber tubing could be achieved with the condition of 100-200msec phase delay, while the counter-pulsation assistance could be achieved by the condition of 300-600msec phase delay.

Further hemodynamic studies, including acute and chronic animal experiment, is essential for evaluating the device durability, and the possibility of fibrotic growth, as well as the sympathetic and parasympathetic reaction against the controlling method of the SMA fibers device.



A. B.

Fig. 7. A) Mean flow (area under the curve), unassisted beat (control) as compared to assisted beat with different pulse width modulation as power input.

B) Shows the pressure changes under the assistance of the SMA fiber pulsation device with different pulse width modulation power input.

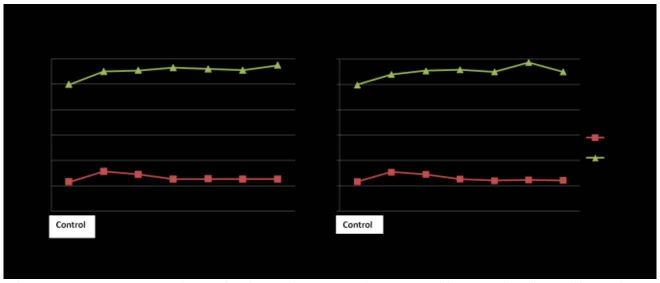
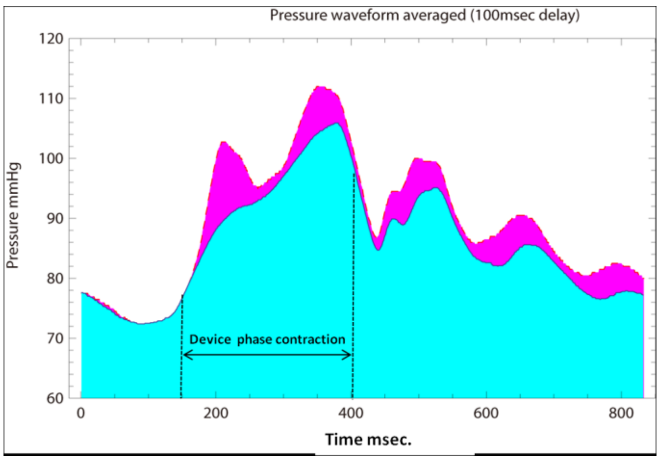
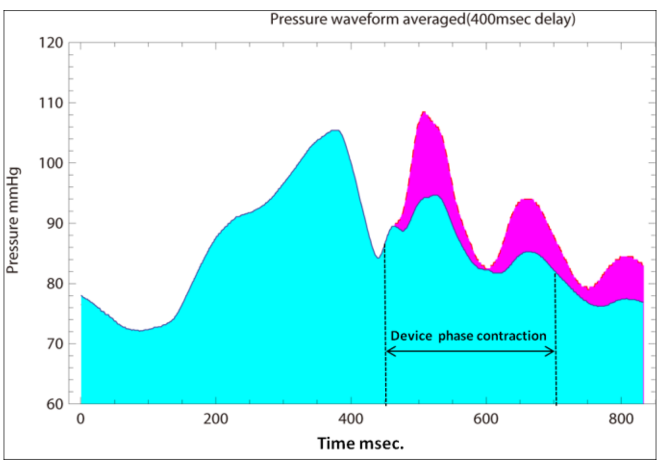


Fig. 8. An example of the changes in systolic and diastolic phase (integrate: $W = \int Pdt$ [mmHg.sec]) per full cardiac cycle, under the effect of different phase delay.



A.



B.

Fig. 9. An example of the hemodynamic waveform changes, (A) where the shadow represent the augmented pressure caused by the contraction of the SMA fibers device with 100msec delayed contraction from the initiation of the systolic phase (phase delay), (B) with 400msec phase delay. While the arrow shows the duration period of the contraction in both figures.

IV. CONCLUSION

We developed a new controlling method for extra aortic counter-pulsation device. The preliminary function of the newly developed extra aortic pulsation device using SMA fibers was examined. An increase in the contractile force of the actuator was achieved through the pulse width modulation. Moreover we achieved its variable phase control for co-pulsation or counter-pulsation modes by changing the phase delay of the SMA fibers. The results of the mock experiment indicated its promising alternative extra aortic approach for non-blood contacting cardiovascular circulatory support.

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