Controllability of 1/R control in non-pulsatile total artificial heart

Yusuke Abe, Takashi Isoyama, Itsuro Saito, Hidekazu Miura, Hidemoto Nakagawa, Wei Shi, Yusuke Inoue, Sachiko Yamaguchi, Ayumi Kishi, Minoru Ono, Akimasa Kouno, Toshiya Ono, Tsuneo Chinzei, Kou Imachi

[1]Department of Biomedical Engineering, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan.
[2]Research Center for Advanced Science and Technology, The University of Tokyo, Tokyo, Japan.
[3]Department of Cardiovascular Surgery, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan.
[4]Graduate School of Medical Science, Kitasato University, Sagamihara, Japan
[5]Graduate School of Biomedical Engineering, Tohoku University, Sendai, Japan

***Abstract*—The role of pulsatility in a total artificial heart (TAH) has been a subject of great debate. Additionally, it is unclear whether, in nonpulsatile TAH, a physiological control method such as 1/R control can keep the animal in physiological condition or not. To examine a controllability of 1/R control in non-pulsatile TAH, non-pulsatile flow mode was introduced to the undulation pump TAH (UPTAH) and the hemodynamic parameters in pulsatile and non-pulsatile flow modes with 1/R control was analyzed. The artificial valve was removed from UPTAH and the goat's natural heart was replaced with it. The UPTAH was first driven with a pulsatile flow mode and 1/R control was applied within one week after surgery. The pulsatile flow mode was switched to a non-pulsatile flow mode on the day 2 weeks after surgery. General condition did not change before and after the flow mode switching. Cardiac output and arterial pressure changed with the physiological condition of the goat in also non-pulsatile flow mode, which seemed not different from that in pulsatile flow mode. However, the sucking effect of atria was very significant in nonpulsatile mode. Although 1/R control could keep the animal in physiological condition in a non-pulsatile flow mode, nonpulsatile TAH was considered to be inadequate for 1/R control to stabilize atrial pressures in the present circumstances or some pulsatility would be necessary to avoid fatal sucking effect and to ensure sufficient inflow condition.**

Keywords—**Control, Undulation pump, Total artificial heart, Non-pulsatile, 1/R control**

I. INTRODUCTION

The continuous-flow blood pumps are promising for size reduction of total artificial hearts (TAHs). However, there was the subject of pulsatility. Concerning to the continuous-flow ventricular assist devices, a pulsatile flow can be produced to some extent according to the preload change when the heart keeps some contractility. However, the production of a physiological pulsatile flow is difficult to accomplish in TAHs with axial flow pumps or centrifugal pumps. While a pulsatile flow was reported to be more physiological than a nonpulsatile flow in TAHs, animal could survive with nonpulsatile TAHs. After all, the role of pulsatility in TAHs has been a subject of great debate still at the present time. Additionally, it is unclear whether the physiological control such as 1/R control [1], can be available or not, and can keep the animal in physiological condition or not, with nonpulsatile TAHs.

To examine a controllability of 1/R control in non-pulsatile TAH, non-pulsatile flow mode was introduced to the undulation pump TAH (UPTAH) and the hemodynamic parameters in pulsatile and non-pulsatile flow modes with 1/R control was analyzed.

II. MATERIALS AND METHODS

The fourth model of UPTAH [2] was used. Not a single artificial valve was installed. Animal experiments were conducted under the Guidelines of the animal experiment committee at the Graduate School of Medicine, the University of Tokyo.

Adult female goats weighing 45 to 55kg were used. The natural heart was replaced with UPTAH under extracorporal circulation. The valveless UPTAH was first driven with a pulsatile mode. 1/R control was applied when the mean right atrial pressure (RAP) was recovered. A nonpulsatile mode was applied 2 weeks after surgery.

In the pulsatile mode, the diastolic drive parameter of the left pump was determined to obtain near zero output and to prevent regurgitation at the diastolic phase. As a result, almost complete pulsatile flow, in which the diastolic output was almost zero, was obtained in the left pump. In the nonpulsatile mode, complete nonpulsatile flow was generated by providing equivalent drive conditions for both systolic and diastolic phases.

The automatic left-right balance control was performed to keep the mean right atrial pressure (LAP) and the mean RAP basically at the same value. Through the control period, sucking control to detect and release atrial sucking was performed.

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III. Results

The valveless UPTAH was implanted in 20 goats and 5 goats survived for more than one month. In one goat, 3 weeks of a long-term nonpulsatile mode with 1/R control was successfully performed.

In this goat, 1/R control started on POD 4. The pulsatile mode was changed to the nonpulsatile mode on POD 14 while 1/R control had been kept applied. The general condition was not changed by the switching from the palsatile mode to the nonpulsatile mode. The hemodynamic parameters did not change significantly. No significant changes were observed both in the liver function as well as the kidney function between the pulsatile mode and the nonpulsatile mode. Cardiac output and arterial pressure changed with the condition of the goat also in the nonpulsatile mode, which seemed not different from that in the pulsatile mode.

On POD 18, the cardiac output decreased due to the sucking of the atria. Then, the setting point of RAP was obliged to increase to prevent the atrial sucking. RAP and LAP levels increased by it. On POD 34, the inevitable atrial sucking occurred in spite that the RAP and LAP levels were relative high. Additionally, hemolysis occurred. Nonpulsatile mode was changed back to pulsatile mode on POD 35, and then hemolysis disappeared.

On POD 72, the experiment was terminated by the break down of the left pump caused by the wear of the shaft.

During nonpulsatile mode, regular fluctuation was sometimes observed in aortic pressure (AoP), which was corresponding to the fluctuation of LAP. The regular fluctuation in AoP tended to disappear when LAP was relatively high. When LAP was relatively low and atrial sucking was remarkable, the regular fluctuation disappeared.

IV. Discussion

The general condition and organ function were not changed by the change from pulsatile TAH to nonpulsatile TAH, which means that there was no drastic change in peripheral circulation. Concerning to the cardiac output, Nose et al. reported that the nonpulsatile TAH required 20% higher cardiac output to obtain the same physiological condition as that in the pulsatile TAH [3]. In 1/R control, it is difficult to find how much higher output would be necessary because the cardiac output changes automatically according to the animal condition. However, the present data suggested that there was no change in hemodynamics. In 1/R control, there is the possibility that peripheral circulation would not change so much with the change of flow pattern, which indicates that the active flow control responding to the animal condition is more important than the pulsatility in TAHs.

However, the sucking effect of atria was very significant in nonpulsatile TAHs. To prevent sucking effect in a nonpulsatile mode, we must have increased the setting point of RAP (RAP.set) in 1/R control and LAP level which was controlled through left-right balance control. In spite of that, the sucking effect had sometimes fallen into an uncontrollable state, which finally caused hemolysis. It was considered that a continuous respiration of a venous blood would occasionally cause a deflation of a vein or an atria in the TAH that defects a beating ventricle, and that a pulsatile flow might inflate the deflation during a diastolic phase and thus avoid the fatal sucking effect. Therefore, nonpulsatile TAHs with 1/R control were considered to be inadequate, unless some pulsatility would be introduced to avoid fatal sucking effect for ensuring sufficient inflow condition. Otherwise the atrial pressures should be maintained to be extraordinary high, however, which is not physiological.

Concerning to the regular fluctuation in AoP observed during the nonpulsatile mode, the cycle rate was similar to respiratory cycle. From the results, it was clear that the regular fluctuation found in the nonpulsatile TAH was caused by the periodic sucking effect in left atrium. Though further investigations are necessary, the regular fluctuation in AoP was possibly influenced by the respiratory change in inflow condition.

In conclusion, the sucking effect affected the controllability of 1/R control in non-pulsatile TAH.

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Author: Yusuke Abe
Institute: Graduate School of Medicine, The University of Tokyo
Street: 7-3-1 Hongo, Bunkyo-ku
City: Tokyo, 113-0033
Country: Japan
Email: abe@bme.gr.jp