Assessment of Artificial Heart Valve Using Dynamic Mock Circulatory System

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ABSTRACT

Valvular heart disease (VHD) is a disorder of heart valve such as heart valve stenosis and valve regurgitation. VHD is cured by heart valve replacement therapy, artificial heart valve is also an alternative treatment of heart valve replacement. However, the artificial heart valve should be evaluated its performance before the replacement operation, therefor, mock circulatory system (MCS), a system reproducing a heart condition, was applied to study the artificial heart valve performance. In this study, left ventricular (LV) and artificial heart valve (AHV) were designed and installed into the mock circulatory system. The process of construction has 3 stage; 1.) The MCS hardware which is consists of atrium, aortic chamber and ventricular sack. The ventricular sack was mold from a silicone rubber so that pulsatile rhythm of systolic and diastolic from myocardium could be reproduced. AHV was also made from a flexible silicone rubber because its properties are similar to human heart valve. 2.) The developing of MCS control system by MATLAB/Simulink. To generate a desires volume of LV which relates to physical conditions, the control system changed LV sack volume by driving a bellow pump, a linear motor with bellow rubber. 3.) The evaluated function of artificial heart valve. The MCS was applied to study a performance of an artificial heart valve. This performance was described by EOA parameter, a parameter indicating an ability of opening valve while fluid is flowing through. EOA parameter is calculated from gradient pressure and mean flow rate which was measured from the MCS. The gradient pressure was measured at left ventricle, aortic and atrium chamber by pressure sensor. The flow rate was measured by flow sensor. In conclusion, the results from MCS with passive filled pressure can be used to study an artificial heart valve performance by calculating EOA parameter. When the peripheral resistance was altered by adjusting a flow between left atrial and aortic chamber, the result showed that EOA index was decrease from a normal stage to a vascular constriction stage.

Keywords: Mock circulatory system, Effective orifice area, artificial heart valve

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1. INTRODUCTION

Heart disease is a significantly cause of death worldwide in this recent year. In Thailand 2014, approximately 40,000 patients died by heart failure and the number of dead have been still increasing [1]. Heart diseases are mostly caused by heart valve disorders which are known as Valvular heart disease (VHD). VHD is normally cured by repairing or replacement heart valve. VHD Patients and Cardiomegaly disease must be implanted from a heart donor but this implantation leads to many side effects to patients such as acute denial from donor, infection, etc. [2]. Nowadays, many researchers have developed an artificial heart valve as an alternative treatment. There are many types of the artificial heart valves; a mechanical valve, a biological valve and a polymeric heart valve. Before an implantation of the artificial heart valve, the assurance of the artificial heart valve must be evaluated by applying a mock circulatory system (MCS) to the study.

Mock circulatory system is an imitation system of a heart condition by simulating a circulatory of blood flow. MCS is normally used to tested device performances such as Ventricular assist device (VAD), vascular graft and prosthesis heart valve. MCS can also represent hemodynamic parameters; cardiac output (CO), blood pressure (BP), blood volume, etc. These hemodynamic parameters are applied to the calculation of the standard continuity equation, effective orifice area (EOA) which is a standard parameter presenting an open area of valve while it is opening. EOA is generally used to analysis an efficiency of artificial heart valve in commercial product such as The Trifecta Valve, CE PERIMOUNT Magna valve and Mitroflow valve, which are the products of ST. JUDE MEDICLETM^{TM} [3]. Human heart normally pump blood from left atrium to ventricle by passive filled pressure, in 1991, Takatani et al had brought the system of passive filled pressure to develop a total artificial heart (TAH) using 2 pusher-plate for a blood circulatory control. [4]. Following to the development of MCS, Bjork, Intonti, and Meissl had developed MCS to examine the performance of an artificial heart valve.

The system consisted of a pulse duplicator for an LV pressure adjustment during a systolic and diastolic conditions, a valve testing chambers, aortic analogue, peripheral resistance and left atrium analogue. The results demonstrated that this system can product overall static performance of mocked loop [5]. However, some elements of MCS have been eliminated and adapted in order to improve the accuracy of heart simulation. In 2001, L.A. Baloa had developed MCS with the control Starling response in native human heart [6]. This control system was based on Sugas elastance model to determine the relationship between the instantaneous pressures and intraventricular volume in form of the elasticity, the normally ejecting canine left ventricle [7].

The elasticity control loops were applied to calculate a desired ventricular pressure which could be adjusted by a bellow pump that connected to a close hydraulic system. The results described that elasticity and pressure control loops affected to a modification of ventricular contractility. These various contractility lead to variations of preload, afterload and stroke volume. Hence, the elasticity-based controller could be applied to MCS controlling for changing variations of human heart conditions.

There are 2 objectives in this study, 1) the development of MCS, a 3-D model was created to construct the MCS (hardware part). A passive filled principle was adapted to this MCS by controlling pressure and volume following the physiology conditions. Both pressure and volume were controlled by pulse duplicator, therefore, the pulse duplicator played an important role for The MCS. [8]. 2) the development of the control system (Software part), a driving motor was controlled to generate a heartbeat pulse signal. Furthermore, pressure sensors and flow meter would detected pressure and velocity which affected by a peripheral resistance. Finally, the pressure and velocity measured from sensors were an important parameters for EOA calculation which indicated the artificial heart valve performance.

2. MATERIAL AND METHOD

2.1 Mock circulatory system

MCS is an imitation of human heart functions. Fig.1 shows an overall structure of MCS. There are 7 significant components; a) Aortic chamber, b) Atrium chamber, c) Pressure sensor, d) Resistance, e) Flow meter, f) Heart valve, g) Bellow pump, h) Left ventricular and i) Ultrasonic displacement sensor. The MCS has 3 sensors which were installed at (c), (e) and (i) so that flow rate and pressure could be measured for EOA calculation. The bellow pump (g) was connected to a computer control to drive a DC motor (MY6812, China) by sending a pulse width modulation as an input.

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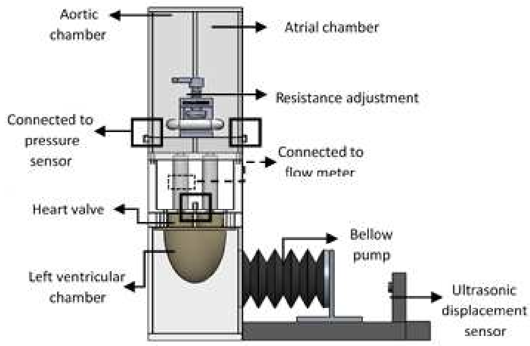

Fig.1:: The MCS components

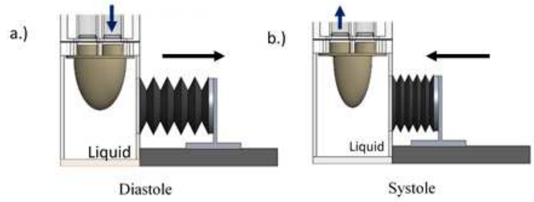

Fig.2:: The direction of bellow during diastolic (a) and systolic (b) using passive filled pressure model

2.2 Passive filled ventricular pressure

Passive filled ventricular consists of Left ventricle sack and Bellow pump. The left ventricle sack was mold from a silicon rubber with the maximum stretch volume 190 ml. The sack was installed in a chamber with sealing for preventing a water seeping. The rubber bellow, made from T913041, Triple Five®, was fixed to the sealed chamber to adjust the volume of ventricular sack by changing the bellow length. DC motor and linear guide with lead screws which connected at the end of the bellow were mounted to a flexible coupling connector to keep the stable motion. The change of bellow length resulted from a motor rotation was measured by an ultrasonic displacement sensor (SRF04). During the systolic, left ventricular pressure was higher than aorta pressure, in contrary, left ventricular pressure was lower than aorta pressure during the diastolic. This pattern was a characteristic of passive filled pressure so that the pressure would be force to flow in the same direction of human heart.

There are 2 artificial heart valves in this study; the valve between left atrium and left ventricle and the valve between left ventricle and aorta. The valves were made from a silicone molding and both artificial heart valves are tri-leaflets valve.

2.3 Ultrasonic sensor and volume calibration

Khienwad and Naiyanatr et al. [9] had done a method to predict a volume of left ventricular sack and an algorithm of control system. A relative function between ultrasonic sensor and ventricular volume had done by 1) The detection of bellow motion using ultrasonic sensor and 2) The weight measurement of

Table 1:: Resistance (%) for the assessment

Test	Resistant (%)
1	0
2	40%
3	60%
4	80%
5	95%

water losing during a contraction of left ventricular sack. These data were collected to STM32F4 so that the relative graph would be constructed.

2.4 Volume and motor speed calibration

A speed of motor controlled a length of bellow which resulted to left ventricular sack volume. Therefore, it is necessary to calibrate or find relationship between a motor speed (PWM) and a left ventricular sack volume [9]. There were 2 steps of calibration procedure; 1) Finding how much length of bellow change at each volume sack. 2) Transforming the bellow length to a duty cycle (PWM). The bellow length changing has 2 stages following the heart physical; systolic and diastolic stages. These collected data of the length was transformed to a PWM to control a motor.

2.5 Volume control system

The MCS was controlled using the ventricular volume as an input. The references volume was transformed into a duty cycle using a relative function from volume and duty cycle calibration. MATLAB/Simulink generated a duty cycle to control motor by sending a signal through driver board and microcontroller. A various form of duty cycle resulted in various left ventricular pressure and artificial heart valve flow rate. These pressure and flow rate were significant output of the MCS. The pressure and flowrate were also affected by a peripheral resistance. The peripheral resistance was adjusted by changing a diameter of tube which connected between atrium and aorta chamber.

2.6 Effective orifice area calculation

In vitro testing of artificial heart valve used Effective Orifice Area (EOA) index deriving from Gorlin equation [Gorlin] which is the European Standard UNI EN ISO 5840 [10-11]. This equation is shown in following:

$$EOA\left(cm^3\right) = \frac{Q_{rms} \times \rho}{51.6 \times \sqrt{\Delta P}} \tag{1}$$

Where ρ is a fluid density, ΔP is a pressure drop between an aortic (Pa) and ventricular (Pv) and Q_{rms} is the root mean square of ejection interval. There were 5 different percentage of resistance for EOA calculation.

Fig.3:: The completely installation of MCS

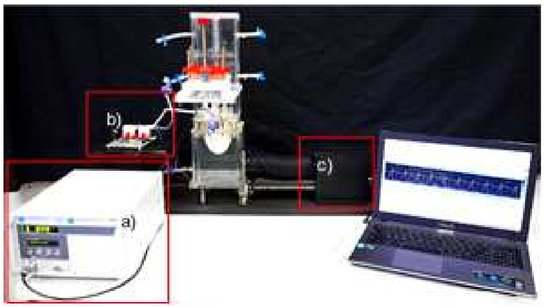

Fig.4:: The measurement sensors of MCS; Flow meter (a), Pressure sensors (b) and ultrasonic sensor(c)

3. RESULTS

3.1 The installation of mock circulatory system

All components were neatly installed, Fig. 3 shows a completely installation of the MCS. The components consist of left ventricular sack, artificial heart valve, adjustable resistance, pulse duplicator, atrium and aorta chamber. The chambers were well-sealed. Measurement sensors, pressure sensor (Fig.4a), flow sensor (Fig.4b) and ultrasonic sensor (Fig. 4c), were connected to the MCS and microcontroller/STM32F4. These sensors were calibrated with accuracy more than 95%.

3.2 Duty cycle waveform versus ventricular volume

The volume of the MCS wasnt constant because there were 2 stages, systolic and diastolic. The volume at each stages had transformed to a duty cycle (PWM) to drive a motor. Equations show a relationship between volume, which adjusted by changing a bellow length and duty cycle (PWM) are as follows;

$$\begin{aligned} y_{sys} &= \sqrt{(3.918x^2 - 1.27x^2 + 0.143x - 0.0054) \times 10^8} \\ y_{di} &= exp\left\{\left(2.6578x^2 - 1.0128x^2 + 0.1319x \right.\right. \\ &\quad \left.\left. - 0.0056\right) \times 10^4\right. \end{aligned} \tag{2}$$

Where y_{sys} is a systolic PWM, y_{di} is a diastolic PWM, X is a bellow length.

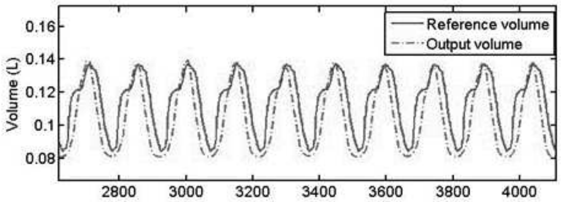

Fig.5:: The volume of left ventricular from bellow comparing with reference

During the systolic stage, the motor was controlled in a clockwise direction whereas during the diastolic stage, the motor was controlled in an anticlockwise direction.

3.3 Left ventricular volume

A left ventricular volume which related to a length of bellow was defined by sending a duty cycle of PWM to a motor driver. This duty cycle related to the left ventricular volume during both systolic and diastolic stages. Each stages were transformed to a PWM using a personal function. The PWM was sent to the motor driver to adjust a speed so that the length of bellow would be defined during the changing volume of left ventricular. Fig. 5 shows a volume curve from the bellow length comparing with a reference volume.

3.4 Pressure and flow characteristic

Left ventricular and aortic pressure curve which was resulted from volume controlling describe the performance of left ventricular sack and artificial heart valve. During systolic stage, artificial heart valve acted as an aortic valve (AAV) and opened, therefore, left ventricular pressure was rapidly increase (Fig.6a). By the way, at aortic pressure consideration, the aortic pressure was increase during systolic system but this increasing pressure wasnt as much as the ventricular pressure because an artificial heart valve, which placed between the left ventricle and aortic chamber, acted as a resistance against the fluid flow. Therefore, the aortic pressure during the systolic stage was decrease. During the diastolic stage, the ventricular pressure was unsteady decrease. Fig. 6b shows a slope of left ventricular pressure which was lower than aortic pressure because of a volume curve influence. The aortic pressure was gradually drop but still preserved a range of minimum point. This condition caused by a compliance of tube which acted as a vascular area nearby the artificial heart valve which placed between left atrium and left ventricle (AMV) (Fig.6d). Eventually, AMV closed and then this cycle was repeated.

Fig. 7 shows a diagram of AAV performance which refers an ability of opening area, it also described an ejection flow in the other term. Fig.7a shows that there was a swaying curve before fluid from a left ventricular was ejected to an aorta chamber, this shows that AAV wasnt open instantly. When AAV opened, fluid rapidly flew to an aorta chamber resulting to

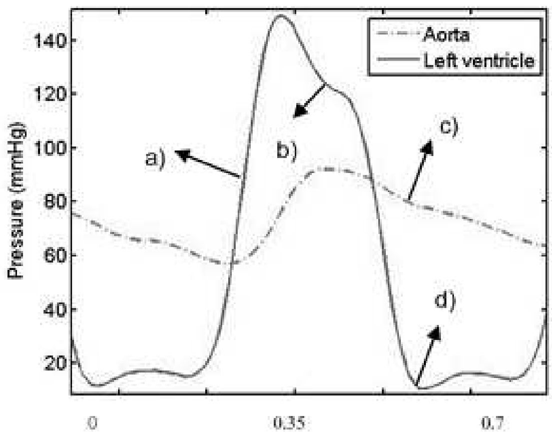

Fig.6:: Characteristic of left ventricular pressure and aortic pressure

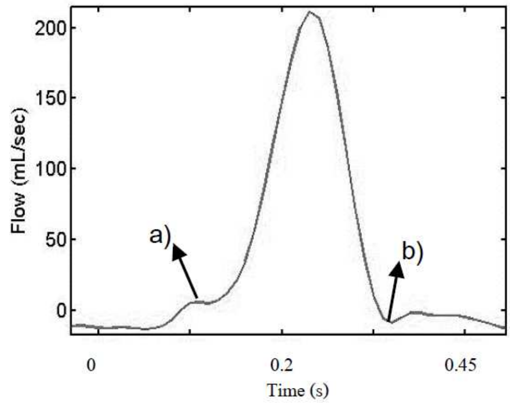

Fig.7:: Configuration of flow rate

an increasing of flow rate, AMV opened afterward caused a negative flow rate (Fig. 7b).

Fig. 8 shows ventricular pressure and aortic pressure at each peripheral resistance. There are the maximum pressure in aorta and left ventricle when the resistant was increase to the maximum (%). In the contrast, an ejection flow rate (Fig. 9) of the highest percentage is less than the other.

3.5 Valve analysis

Resistances with difference percentage show the sensitive value of ventricular pressure, aortic pressure and flow rate. These value were brought to calculate EOA index of artificial heart valve. The pressure drop and root mean square of ejection interval are shown in Table. 2 present that pressure drop at the highest resistance, furthermore, there is the lowest interval ejection at the highest resistance

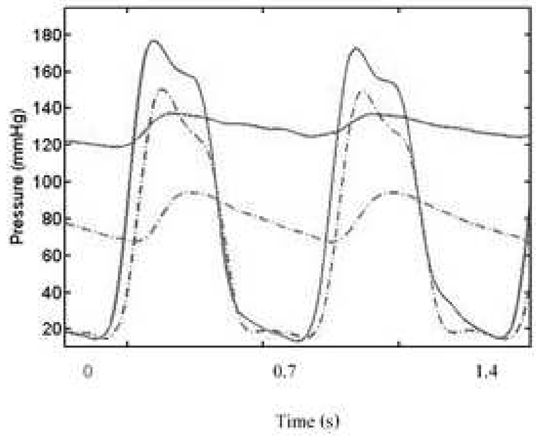

Fig.8:: Left ventricular and aortic pressure at 0% and 95%

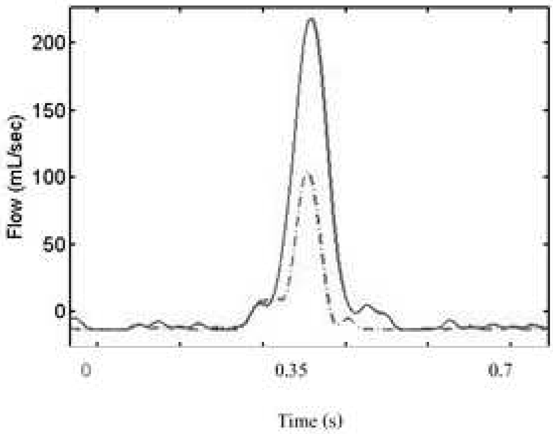

Fig.9:: Ejection flow at 0% and 95%

Fig.10:: Structure of AAV (a) while opening (b) and closing (c)

Table 2:: EOA value at each resistance.

Resistant %	**Pressure gradient (mmHg)**	**Flow root mean square (mL)**	**EOA (cm^2)**
0	9.7469	81.8195	0.1627
20	9.6870	80.1539	0.1596
40	9.7302	79.4707	0.1590
80	10.3352	79.9019	0.1498
95	7.9828	49.4621	0.1201

4. DISCUSSION

The artificial heart valve performance can be evaluated by applying the MCS as a human physiological system. The system was controlled by volume controlling by generating ventricular volume curve following a reference volume, however, there was still some errors. The coefficient of determination, R square, was equal to 0.79 which indicated to a satisfied range, therefor, the MCS was applied to measure important parameters for EOA evaluation. EOA is a significant factor used to define the artificial heart valve performance by determining pressure drop and flow rate. The result shows that when a load of peripheral resistance was increased resulted from an increasing of aortic pressure, a pressure drop across the artificial heart valve decrease. Likewise flow rate measurement, when a load of aorta was increased, flow rate across the artificial heart valve decreased.

The result of left ventricular pressure at resistance from low to high was almost similar because of the MCS control system. The control system was an opened loop control, so, there wasn't any feedback from output and therefore a contraction of left ventricular sack is the same for all resistance. However, this result didn't relate to a physiological of human heart. Therefore, control system of MCS will be developed into the new version for a better performance and more accuracy.

The value of EOA index from the MCS shows less value than normal because of a heart valve properties. The AAV is too thick to open distinctly. Fig. 11 shows AAV while it is opening. EOA index which was calculated at each resistance shows that this value decreases while the resistance percentage increases. This result described that an increasing of aortic pressure caused more load to press on the leaflet of AAV. This condition leads to a decreasing of ejection flow. In contrast, a pressure gradient at each resistance rarely differs, so, the ejection flow is an influential variable of EOA.

5. CONCLUSION

The development of the mock circulatory system including hardware and software parts can be applied to test the performance of an artificial heart valve using EOA as an indicating parameter of the performance.

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