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A left heart ventricle simulator manufactured by 3D printing

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Abstract: Mechanical circulatory assistance devices have been researched and used to assist the pumping function of the failing heart. Examples of these devices are intra-aortic balloon pumps (IABP) and ventricular assist devices (VAD). In order to perform the *in vitro* tests of these devices, before the *in vivo* tests, cardiovascular simulators are required. One important part of a cardiovascular simulator is the simulation of the left ventricle which is a pulsatile blood pump. Most of the existing left ventricle simulators use pneumatic actuator. This type of actuator creates negative pressure inside the ventricle chamber which is not physiological. The objective of this work is to develop a pulsatile pump that simulates the left ventricle without creating negative pressure. The concept of the pulsatile pump was evaluated using 3D printing to manufacture the prototype. The developed pulsatile pump is composed of two reservoirs: a rigid one with 5.0 x 10^4 mm^3 of volume which corresponds to the residual systolic volume and a flexible one which ejects 8.0 x 10^4 mm^3 of fluid per beating cycle when compressed by a platform. Two caged-ball valves simulating the mitral and the aortic valve are responsible for the unidirectional flow. A constant pressure of 1,333 Pa inside an open reservoir maintains the fluid flowing into the pulsatile pump through the mitral valve. A DC motor is connected to a lever mechanism that transforms the rotational movement of the motor into vertical movement of the platform. The vertical movement of the platform is responsible for the pulsatile flow of the pump, generating a pressure of 10,640 to 15,960 Pa at the outlet of the pump. Since the platform is not attached to the flexible reservoir, there is no generation of the negative pressure inside the simulator.

Keywords: Medical systems, Computer aided manufacturing, Physiological models, Prototyping, Simulators, Blood pump, Heart failure.

1. INTRODUCTION

The heart is a pump which is responsible for maintaining blood circulation. It is composed of two atria responsible for pumping the blood to the ventricles and two ventricles which pump the blood to the systems. The right side of the heart is responsible for the pulmonary circulation while the left side is responsible for the systemic circulation. The heart beating cycle is divided in diastole, when the ventricle is filled with blood and systole, when the ventricle wall contracts and expels the fluid to the arteries

Several heart diseases, such as hypertension and ischemia, can cause heart failure. In severe cases of heart failure, mechanical circulatory support is required in order to maintain the blood flow. This circulatory support can be provided by a Ventricular Assist Device (VAD) or by an Intra-Aortic Balloon Pump (IABP).

Figure 1 shows a schematic of a VAD and an IABP implanted inside the body. As the left ventricle is responsible for the systemic circulation, it is more affected by heart failure and the circulatory support device is usually used to assist the left ventricle.

VAD is a blood pump that assists the pumping function of the failing heart ventricle. It receives blood from the left ventricle and pumps it to the aorta, as shown in Fig. 1a, and decreases the work of the left ventricle muscle (TIMMS et al, 2005).

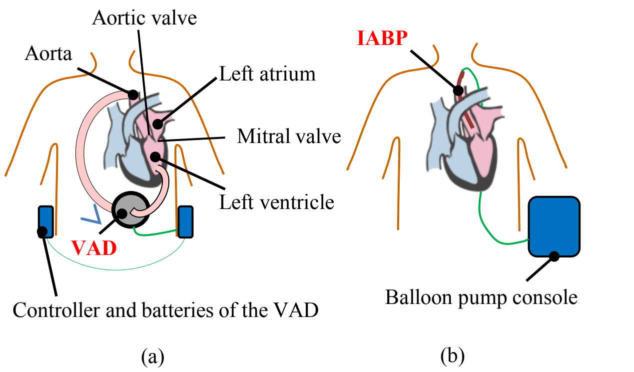

Fig. 1. Schematics of mechanical circulatory assistance devices: (a) the VAD and (b) the IABP.

IABP is used to increase the coronary blood flow and the cardiac output. It consists of a cylindrical balloon that is placed inside the aorta. The balloon deflates during systole and inflates during diastole. This way, there is a decrease of the aorta pressure which increases the blood flow during systole and there is an increase of aorta pressure during diastole which increases the blood flow to the coronary arteries via retrograde flow (KOLYVA et al, 2010).

During the development of VADs and IABPs, *in vitro* tests are important to evaluate the operation, the durability and the performance of the devices, and to accelerate their design process (TIMMS et al, 2010). The *in vitro* tests are made by using a circulatory simulator that mimics the physiology of the human circulatory system (PAI et al, 2010; PAI et al, 2009; HOSHI et al, 2006).

A left cardiovascular simulator usually comprises an aorta simulator, a left atrium simulator, a pulsatile pump to simulate the left ventricle and a flow clamp to simulate peripheral vascular resistance, as shown in Fig. 2.

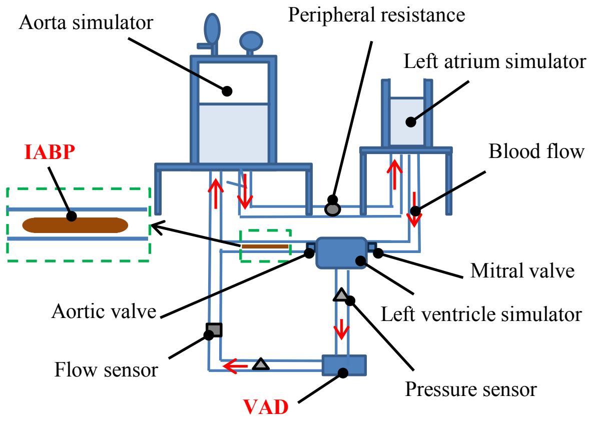

Fig. 2. Schematic of a mock circulatory loop for evaluation of VAD and IABP.

Most of the available pulsatile pumps are driven by a pneumatic actuator (LIU et al, 2005). This kind of mechanism creates a negative pressure inside the pulsatile pump which is not physiological (LIU et al, 2005) and compromises the evaluation of the mechanical circulatory support devices.

3D printing is a new Computer Aided Manufacturing (CAM) technology that builds a product from the creation of successive layers of material. A Computer Aided Design (CAD) program is used to design the product and to transfer the file directly to the 3D printer. The advantages of this new technique is that it allows a greater freedom to the designer when creating new products, is faster than the conventional manufacturing process, there are a variety of materials that can be used and, as the product is fabricated directly from the design, the error is minimized. Therefore the 3D printing process is useful for evaluation of the concept of a design.

The objective of this study is to model and to develop a pulsatile pump which simulates the left heart ventricle to be used in a left cardiovascular simulator.

2. MATERIALS AND METHODS

The cardiovascular system is described by the Windkessel model, consisting of arterial compliance, peripheral resistance, characteristic impedance of the aorta which accounts for the local inertia and local impedance of the proximal ascending aorta, fluid inertia and venous compliance (STERGIOPULOS et al, 1999; TOY et al, 1985).

Usually, for evaluation of the mechanical circulatory assistance devices, a left cardiovascular simulator that mimics the arterial compliance and peripheral resistance would suffice (LIU et al, 2005; TIMMS et al, 2010). Therefore, it simulates aorta compliance, the left atrium, the left ventricle and the peripheral vascular resistance. All elements are usually discretized in the simulators, resulting in lumped values for different segments of the cardiovascular system.

In order to model the left ventricle it is necessary to understand the variation of the blood pressures and the blood volume. These variations are shown in Fig. 3. The variations of pressure are shown at the top graph, while the variation of volume is shown at the bottom graph.

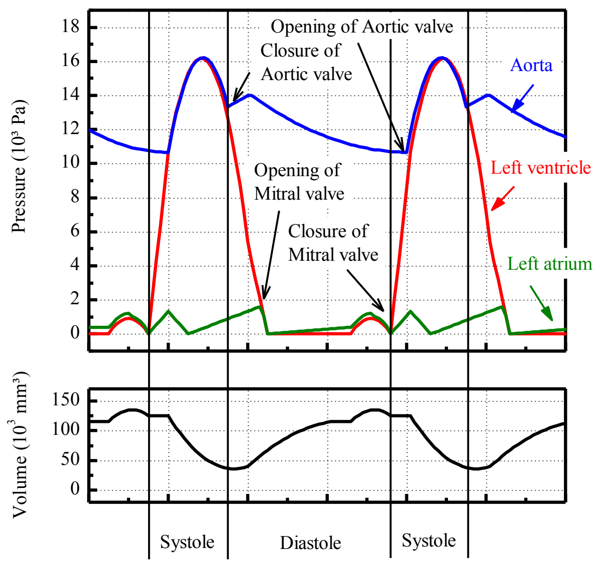

Fig. 3. Variations of pressure and volume in a cardiac cycle.

Analyzing the left side of the heart, the blood flows from the lungs to the left atrium, passing through the mitral valve, located between the left atrium and left ventricle and fills the left ventricle. The filling process of the ventricle is called diastole. After diastole, the left ventricle contracts, expelling the blood to the aorta through aortic valve. This process is called systole.

The inflow to the ventricle is mostly passive because about 80% of the blood flows directly from the atrium to the ventricle before the contraction of the atrium and the maximum pressure inside the atrium is small, about 1,333 Pa, as shown in Fig. 3, in green.

During systole the mitral valve closes and the ventricular pressure increases, leading to the opening of the aortic valve. The blood is then pumped into the aorta which has a variation of pressure of 10,640 to 15,960 Pa (GUYTON and HALL, 2011).

During diastole, the normal filling of the ventricle increases the blood volume to around 1.20 x 10^5 mm^3. This is called the end-diastolic volume. As the ventricles are emptied during contraction, the volume decreases by approximately 7.0 x10^4 mm^3 which is called the stroke volume. The remaining volume in the ventricle, 4.0 to 5.0 x10^4 mm^3, is called end-systolic volume.

In order to simulate the variation of blood volume, several authors use pneumatic actuators that supplies pressurized and vacuum air to compress and expand a flexible diaphragm alternatively (LIU et al, 2005; PANTALOS et al, 2002). In this design there is generation of negative pressure inside the ventricle simulator because of the vacuum air used to expand the diaphragm. This negative pressure is not present in a normal heart ventricle, as shown in Fig. 3.

In our study, a pulsatile pump with a rigid and a flexible reservoir was designed. The rigid reservoir is used to obtain the end-systolic volume and the flexible reservoir is used to provide the stroke volume.

An open tank is connected to the inlet of the left ventricle simulator, simulating the left atrium, as shown in Fig. 2 (HOSHI et al, 2006). A certain amount of working fluid inside the open tank provides a fixed pressure of 1,333 Pa in the pump inlet leading to a passive filling of the pulsatile pump. Therefore, the left ventricle simulator can be filled without the generation of the negative pressure, and the left atrium pressure is assumed to be constant because its variation is small.

A hermetically sealed tank is connected to the outlet of the pump. This tank simulates the aorta and maintains the outlet pressure between 10,640 to 15,960 Pa (80 to 120 mmHg) (LIU et al, 2005). This tank is simulating the arterial compliance, described in the Windkessel model.

The designed left ventricle simulator is shown in the Fig. 4. The pumping mechanism to generate a pulsatile flow is driven by a DC motor (DMX-K-DRV-11, Arcus Technology Inc., U.S.A.). A lever mechanism is used to convert the rotational motion of the motor to linear motion of a platform. The axis of the motor is attached to a motor disc which is also attached to the arm of the platform. So the platform moves vertically according to the rotation of the motor.

The vertical movement is restricted by a cylinder which is part of the support for the rigid reservoir. The support is also responsible for attaching the flexible reservoir in the rigid reservoir. When the platform goes up, it compresses the flexible reservoir and expels the fluid, simulating the systole and when the platform goes down, the rigid and the flexible reservoir can be filled, simulating the diastole.

Since the platform is not attached to the flexible reservoir, there is no generation of negative pressure during diastole, and the ventricle simulator filling process is passive, as the natural ventricle. Two caged-ball-like valves are responsible for unidirectional flow of the fluid. These valves are printed with the rigid reservoir as one piece which is impossible to be manufactured using conventional manufacturing process.

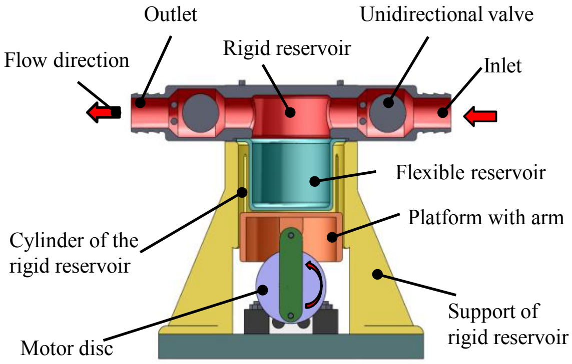

Fig. 4. Cross sectional frontal view of the designed left ventricle simulator.

A simple hydraulic circuit composed of a fluid reservoir, the designed left ventricle simulator, three pressure sensors, a flow sensor and a peripheral resistance, was constructed to evaluate the performance of the simulator. All this parts are connected with flexible tubes, as show in the Fig. 5.

One pressure sensor is located before the ventricle simulator to measure the left atrium pressure; one is located after the simulator to measure the aorta pressure; and the third one measures the pressure inside the ventricle through the connector of the rigid reservoir to connect the VAD.

Variations of pressure and flow rate during the systole and diastole was measured by using a data recorder.

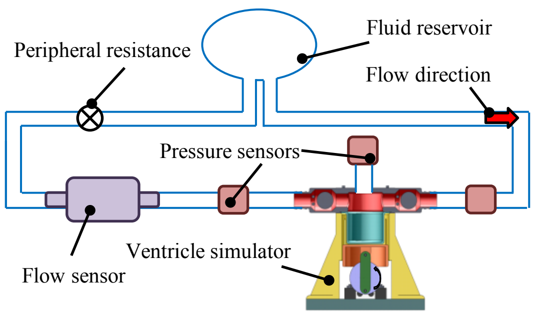

Fig.5. Hydraulic circuit to evaluate the left ventricle simulator.

3. RESULTS AND DISCUSSION

3.1. Previous left ventricle simulator

Since there are several materials available for 3D printing, a pre-experiment was performed in order to analyse the quality of the material.

Some pieces of the left ventricle simulator were fabricated by using the 3D printing technique and the material denominated Vera White Plus. The fabricated parts were rigid reservoir, molds for fabrication of silicone flexible reservoir, motor disc, support of the rigid reservoir and the lever mechanism.

It was observed that the porosity of this material allowed fluid to seep into the rigid reservoir which may cause swelling and warping over time. Besides, the porosity prevented the flexible reservoir to be fabricated by silicone molding process because the silicone penetrated into the pores and both molds were stuck together. Also, the Vera White Plus does not provide the required mechanical strength for the fixation of the motor disc to the axis of rotation of the motor.

To solve these problems, in this present study, a material with low porosity denominated digital ABS was used to fabricate the rigid reservoir and the flexible reservoir was printed using a rubber-like material. Additionally, Aluminium was used to fabricate the motor disc by the conventional manufacturing process.

Another problem observed in the previous prototype was related to the lever mechanism. The previous platform was too thin and the gap between the platform and the cylinder was too big which allowed large angular movements of the platform. This caused great friction between them and made the vertical movement difficult.

This problem was solved in this study by increasing the height and thickness of the border of the platform, allowing more surface contact between the platform and the cylinder of the support of the rigid reservoir, avoiding angular movements of the platform.

3.2. New left ventricle simulator

The final dimensions of the ventricle simulator are 170 mm in width, 150 mm in depth and 147.5 mm in height.

To simulate the systole and diastole, the rotational speeds of the DC motor are maintained between 60 to 120 rpm which represent 60 to 120 beats per minute of simulated heart rate.

The components of the pulsatile pump are shown in Fig. 6, while the assembled pulsatile pump is shown in Fig. 7. These components are: rigid reservoir with two unidirectional valves attached, flexible reservoir, support of the rigid reservoir, platform with arm, and motor disc. Detailed of each component are described as follow.

3.2.1. Rigid reservoir with two unidirectional valves attached

The reservoir has the external shape of a quadrangular box with 85 mm in side length and 32.5 mm in height. On two opposite sides of the reservoir there are attached two unidirectional valves with an inner diameter of 19 mm for fluid flow, as the average diameter of the mitral and aortic valve. In this study, a mechanical model known as a caged ball-valve was used, but it can be easily changed in the future by the biological valves and by the other type of mechanical valve, the bi-leaflet valves, due to the advantages of the 3D printing process.

Conventionally, the caged ball-valve should be manufactured in several parts and assembled by welding process. By using the 3D printer, the manufacturing process is simplified and the rigid reservoir, valves and connectors are manufactured as a single piece, eliminating the need of screws or glue to assemble the parts, resulting in a more durable component.

A connector having an internal diameter of 10 mm can be observed on one face of the reservoir. This connector is used for the attachment of the VAD, as during ventricular assistance, as shown in Fig. 2.

The reservoir has a cylindrical cavity inside, open at the bottom side for connection to the flexible reservoir. The cavity is 50 mm in diameter and 26.5 mm in height, equivalent to 5.0×10^4 mm^3 in volume which corresponds to the end-systolic volume of the heart ventricle.

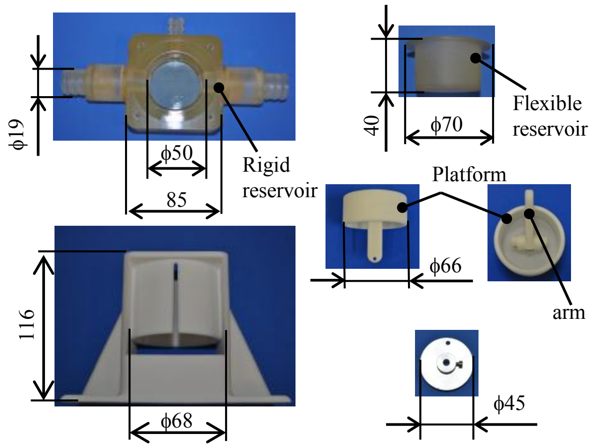

Fig. 6. Cross sectional frontal view of the designed left ventricle simulator.

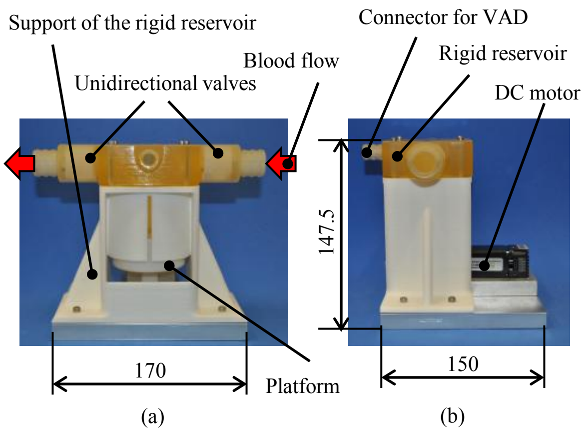

Fig. 7. (a) Front and (b) lateral views of the developed pulsatile pump to simulate the left ventricle

3.2.2. Flexible reservoir

The flexible reservoir has a cylindrical shape with an opening at the top. It is 50 mm in inner diameter, 70 mm in outer diameter and 40 mm in height. These dimensions correspond to an inner volume of approximately 8.0 x 10^4 mm^3 which is the stroke volume of the heart or the volume of blood pumped into the aorta for each heartbeat.

The flexible reservoir has a brim which is designed to be compressed between the rigid reservoir and the support of the rigid reservoir for fixation and to avoid leakage.

3.2.3. Rigid reservoir support

This part of the left ventricle simulator is designed to support the rigid reservoir, to attach the flexible reservoir to the rigid reservoir and to guide the vertical movement of the lever mechanism which is responsible for the compression of the flexible reservoir. The inner part of the support has the shape of a hollow cylinder with 68 mm in diameter. This cylinder guides the platform in its vertical movement to compress the flexible reservoir.

Two lateral plates in “L” format are responsible for the support of the entire structure. These “L” plates are also used for the fixation to the base of pulsatile pump. The material used in this component is nylon, due its mechanical resistance and lower price.

3.2.4. Platform with the arm

The platform has a cylinder shape and it is 66 mm in diameter and 30 mm in height. In its bottom there are two hooks with 9.5 mm of distance between them. The hooks have 3.6 mm diameter holes used for the connection with the arm.

The arm is a rectangular structure with rounded border. It is 58 mm in length, 15 mm in width and 7.5 mm in thickness. Two 3.6 mm diameter hole is placed on each side of the arm for the connection with the platform and with the motor disc. The material used in this component is also nylon.

3.2.5. Motor disc

The motor disc is 45 mm in diameter and 7.5 mm in thickness. A 3.6 mm diameter hole on the disc allows the connection with the arm. There is a cylinder in the central and posterior part of the disc. It is 16 mm in outer diameter, 5 mm in inner diameter and 15 mm in height for the connection to the shaft of the motor. It was conventionally manufactured using aluminium, due its high resistance for the fixation with the axis of the motor using a screw.

3.3. Left ventricle simulator evaluation

The initial idea was to evaluate the performance of the left ventricle simulator according to the methodology described, using the hydraulic circuit shown in Fig. 5. However, the acquired flow and pressure sensors are for industrial use and their response time is too slow for the pulsatile flow.

Normally the beating frequency of the heart is around 1 Hz which is the sampling frequency of the industrial flow and pressure sensors. This is because in industry the average value of flow rate and pressure is enough, and a high response sensor is not required.

In our case, a flow and a pressure sensor, specific for measurement of pulsatile flow, are required. This type of sensors can be found in medical field, and are being acquired.

3.4. Cardiovascular simulator

Although the performance of the left ventricle simulator could not be evaluated, others simulators for aorta and left atrium were developed and the entire cardiovascular simulator is constructed, as shown in Fig. 8.

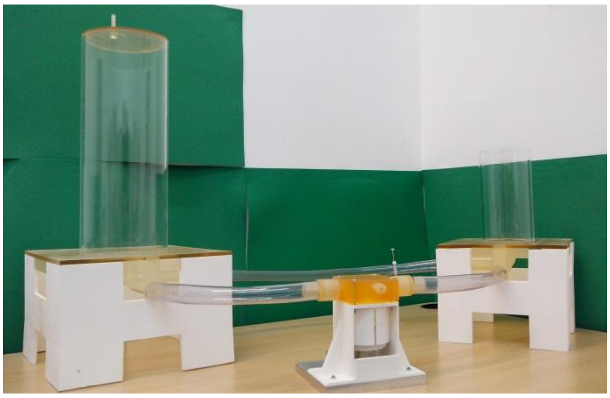

Fig. 8. Photograph of the left cardiovascular simulator

4. CONCLUSION

The pulsatile pump to simulate the left ventricle works properly. The left ventricle is simulated by a rigid reservoir with an internal volume of 5.0 x 10^4 mm^3 which represents the end-systolic volume of the heart; two unidirectional valves attached to the rigid reservoir; a flexible reservoir with an internal volume of 8.0 x 10^4 mm^3 which is equivalent to the cardiac output.

A lever mechanism is manufactured to transform the rotational movement of a DC motor to vertical movement of a platform which will compress the flexible reservoir to simulate pulsation of the heart, generating the pulsatile flow.

Several parts of this simulator, such as rigid reservoir with two attached unidirectional valve and lever platform can only be fabricated by using the 3D printing technique, but not by conventional manufacturing process.

As future work, it is planned to measure the pressure and the flow rate of the developed left cardiovascular simulator by using the flow and pressure sensors for medical use.

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