

A PULSATILE PUMP FABRICATED BY 3D PRINTING TO SIMULATE LEFT HEART VENTRICLE IN A MOCK UP LOOP

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Abstract. Ventricular assist devices (VADs) have been used to solve the problem of lack of heart donors. In order to evaluate the performance of VADs, mock up loops with pulsatile pump that simulates the left ventricle are required. 3D printing is a new process of making a 3D solid object of virtually any shape from a digital model. The objective of this work is to evaluate the possibility to fabricate a pulsatile pump by 3D printing. The designed pulsatile pump is composed of a rigid reservoir of 50ml, connected to a flexible silicon bag of 70ml, and two unidirectional caged-ball valves simulating the mitral and the aortic valve. An open reservoir simulating the left atrium is connected to the inlet of the pulsatile pump. A constant pressure of 10 mmHg inside the open reservoir maintains the fluid flowing into the pulsatile pump through the mitral valve. A step motor connected to a lever mechanism is responsible for the pulsation of the pump. The lever pushes the flexible bag and expels the fluid out of the pulsatile pump through the aortic valve. As a result, the fabricated pump simulated the left ventricle as expected.

Keywords: Blood pump, Left ventricle Simulator, 3D printing, artificial heart

1. INTRODUCTION AND BACKGROUND

Ventricular Assist Devices (VADs) are blood pumps that have been developed to assist the pumping function of the failing heart ventricle. The VAD receives blood from the left ventricle and pumps it to the aorta, as shown in Fig. 1a. Therefore, it decreases the work of the left ventricle muscle.

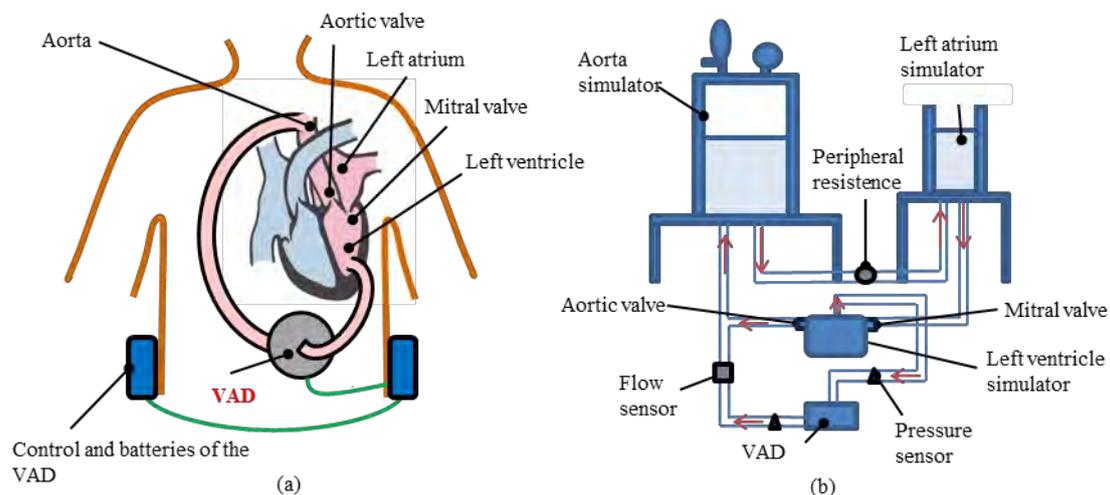


Figure 1. (a) Schematic of a VAD implanted inside the body and (b) schematic of a mock circulatory loop

During the development of VADs, they must undergo a series of *in vitro* tests, before the animal test and the clinical trial. During the *in vitro* test, the performance and the durability of the VADs are evaluated. However, in order to perform the *in vitro* tests, mock circulatory loops that mimic the physiology of the human circulatory system are required (PAI et al, 2010; PAI et al, 2009; HOSH et al, 2006). A complete mock circulatory loop 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. The most complex part of the mock up loop is the pulsatile pump, which can be driven by an electric motor or by a pneumatic mechanism.

3D printing is a new technique for additive manufacturing that builds a product from the creation of successive layers of material. The process begins with product design using a Computer Aided Design (CAD) program. After the

design process, the digital archive is exported to 3D printing machine, in which each layer is created and merged with the previous layer, successively, following the designed parameters.

Unlike the conventional manufacturing process, this new technique allows the manufacture of the product directly from the designs. Thus, it is possible to eliminate drawing interpretation errors, it is faster than conventional manufacturing process, and allows a greater freedom to the designer when creating new products.

However, like any new technology, 3D printing has its advantages and disadvantages. Since it is a new technology, especially in the field of Biomedical Engineering, these features are still poorly evaluated.

2. OBJECTIVE

The aim of this work is to evaluate the 3D printing manufacturing process used to fabricate a pulsatile pump that simulates the heart left ventricle, to be part of a mock circulatory loop.

3. PHYSIOLOGY OF THE HEART LEFT VENTRICLE

The blood flows from the lungs to the left atrium, passing 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.

In order to design a pulsatile pump to simulate heart left ventricle, it is necessary to understand the variation of its blood pressure and volume. These variations inside the left ventricle, during the cardiac cycle, are shown in Fig. 2.

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 variation of pressure inside the atrium is from 8 to 10 mmHg. Since the atrium is in communication with ventricle during this process, there is an increase of pressure inside the ventricle as well.

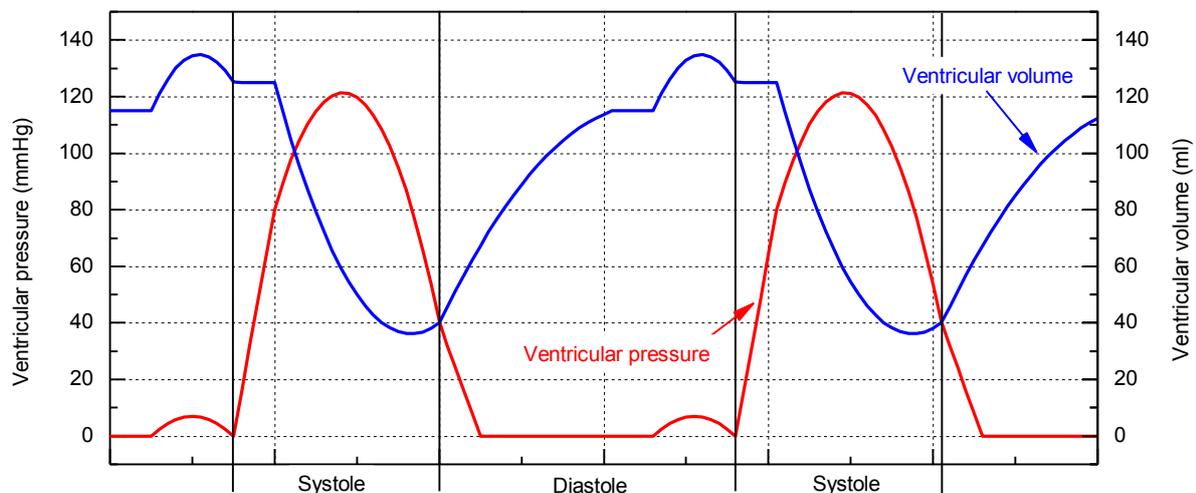


Figure 2. Variation of pressure (shown in red) and volume (shown in blue) in the left ventricle.

During systole, the mitral valve closes and the ventricular pressure increases until the opening of the aortic valve. The blood is then sent to the aorta, decreasing the pressure inside the ventricle (GUYTON and HALL, 2011).



Figure 3. Caged-ball valve.

During diastole, the normal filling of the ventricle increases the blood volume to 110 to 120 ml. This is called the end-diastolic volume. Then, as the ventricles are emptied during contraction, the volume decreases by approximately 70 milliliters, which is called stroke volume. The amount remaining in the ventricle, 40 to 50 ml, is called end-systolic volume.

The heart valves, mitral and aortic valve, are responsible for the unidirectional flow through the heart ventricle. In case of heart valve disease, they can be replaced by artificial valves. There are mechanical and biological artificial valves. The mechanical valves may be a caged-ball valve, as shown in Fig. 3, a valve with leaflets or a tilting-disc valve, while the biological valves usually are made by animal pericardium tissues.

4. MATERIALS AND METHODS

The pulsatile pump is filled by a fixed pressure of 10 mmHg in the pump inlet, which is applied by a certain amount of working fluid inside an open reservoir (HOSH et al, 2006). The pressure in the outlet of the pump changes from 80 to 120 mmHg, due to presence of a hermetically sealed reservoir in the outlet of the pump, which simulates the aorta (LIU et al, 2005).

The pumping mechanism is driven by a step motor (DMX-K-DRV-11, Arcus Technology Inc., U.S.A.), and a lever mechanism is used to convert the rotational motion of the motor to linear motion, and a platform is moved vertically according to the rotation of the motor. The vertical movement of the platform compresses a flexible reservoir and expels the fluid inside.

Two caged-ball valves are used to simulate mitral and aortic valve. This kind of valve was chosen due to their simple mechanism and absence of biological tissue, in order to increase the durability of the pulsatile pump.

All the components of the pulsatile pump, except the motor, are fabricated using 3D printing. In this project we used the 3D printing technology known as 3D printing polyjet. Polyjet 3D printing is a technique similar to printing documents with ink jet, but instead of jetting droplets of ink onto paper, Polyjet 3D gushes a photopolymer fluid on a construction tray and then cures the material using ultraviolet light. Layers are built to create a 3D model or prototype. The advantage is that prototypes can be fabricated and used almost immediately, and it can also produce prototypes with complex geometries, higher quality and speed with high accuracy. Also, a wide variety of materials can be used in the same print job. Among all the materials available, the one used in this project is the opaque material, denominated Vero White Plus. It is a rigid photopolymer with high durability. (FACTORY OF FACTORES, 2013; STRATASYS, 2013).

5. RESULTS AND DISCUSSION

5.1 Printed 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 stepper motor rotates 60 to 120 rpm, which represent 60 to 120 beats per minute.

The pulsatile pump is shown in Fig. 4a and the printed components of the pump are shown in Fig. 4b. These components are: mold (male and female), rigid reservoir with two unidirectional valves attached, flexible reservoir, rigid reservoir support, platform, arm and disc of the motor. The motor support, the motor fixing plate and the base were machined in aluminum. All these components are described as follow.

5.1.1 Mold

The molds were used for making the reservoir flexible. It is composed of two parts, a female mold that has a shape of a hollow cylinder of 42 mm in depth, and 54 mm in internal diameter, and a male mold with 40 mm in height and 50 mm in diameter. These two parts fit concentrically through salient structures in male and female molds. Between both there is an empty space, which is filled with liquid silicone, the material of flexible reservoir.

5.1.2 Rigid reservoir with two unidirectional valves attached

Externally, the reservoir has the 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.

Conventionally, these kinds of valves should be manufactured in several parts and assembled. 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 1/8 inch can be found on the third face of the reservoir. This connector is used for the attachment of the VAD, as during ventricular assistance, as shown in Fig. 2a.

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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 50 mL in volume, which corresponds to the end-systolic volume of the heart ventricle.

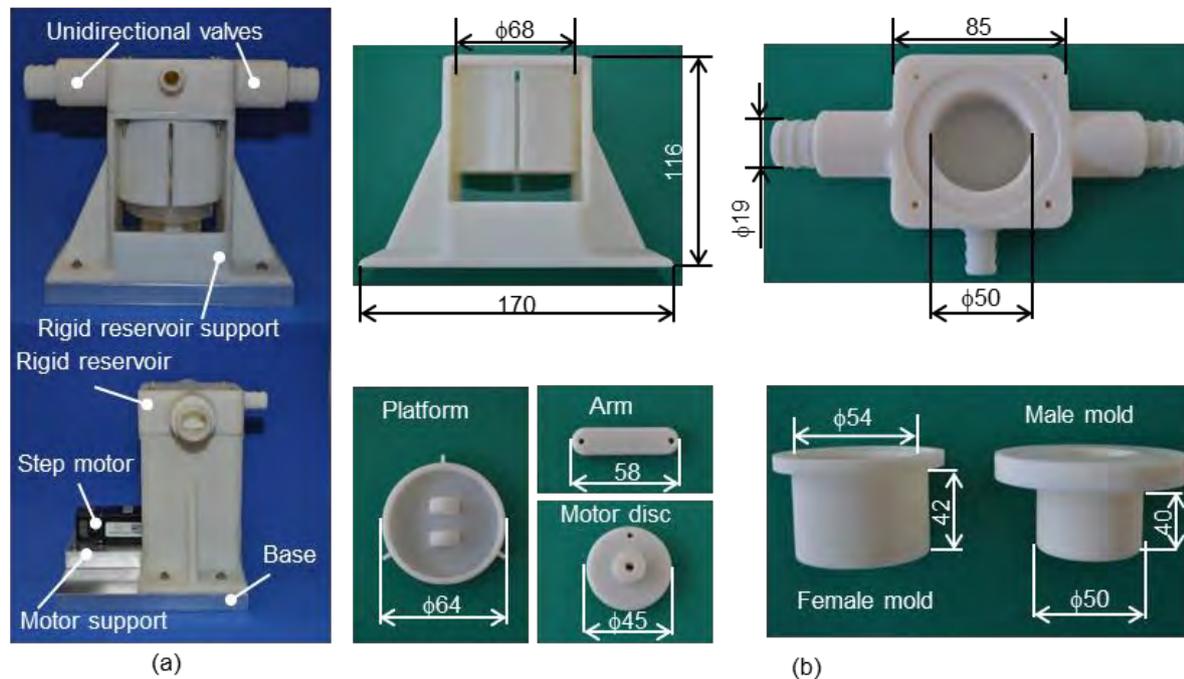


Figure 4. (a) Pulsatile pump to simulate the left ventricle and (b) printed components of the pump

5.1.3 Flexible reservoir

The flexible reservoir has a cylindrical shape with an opening at the top. It is 50 mm in internal diameter and 40 mm in height. These dimensions lead to a volume of approximately 80 ml inside, which is the ejection volume of the heart, or the volume of blood pumped into the aorta for each heartbeat.

The reservoir has a brim, which is designed to be compressed between the rigid reservoir and the rigid reservoir support, for fixation of the flexible reservoir and to avoid leakage. It is built by the silicone molding technique, using the molds described in subsection 5.1.1.

5.1.4 Rigid reservoir support

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

5.1.5 Platform

The platform has a disk shape and it is 64 mm in diameter and 10 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 edge of the disc has three rectangular protrusions which work as guide in the cylinder of the rigid reservoir support.

5.1.6 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. A 3.6 mm diameter hole is placed on each side for the connection with the platform and with the motor disc.

5.1.7 Motor disc

The 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 internal diameter and 15 mm in height for the connection to the shaft of the motor.

5.2 Evaluation of the prototype

After manufacturing the prototype of pulsatile pump, the following aspects were observed.

5.2.1. 3D printing material

The material used, Vero White Plus, presents high porosity, which makes the material permeable to fluid. The permeability to fluid impeded the manufacturing of the flexible reservoir, because during the silicone molding process, the silicone penetrated into the pores of the mold, sticking both molds.

In addition, the porous material detached easily and do not provide mechanical strength required for fixation of the motor disc.

To solve these problems, the 3D printing material will be changed in accordance to the functionality of the part. For instance, the motor disc will be conventionally manufactured using aluminum, and the mold used for the silicone molding process will be printed using another available material denominated digital ABS, which has low porosity, being suitable for use as the mold material.

Another solution for the manufacturing process of the flexible reservoir is printing the reservoir using a rubber-like material. This new material may be a replacement for the silicone, and in a future work we are going to compare the flexible reservoir fabricated by silicone molding process with the one printed using this rubber-like material. The possibility of using the rubber-like material may simplify the manufacturing process and decrease the production cost.

5.2.2. Lever mechanism

The proposed method of using the slots in the cylinder of the rigid reservoir support as guide for vertical movement of the platform has proved inefficient because the space between the two parts allowed large angular movements, which caused great friction between the rectangular protrusions of the platform and the vertical slots on the rigid reservoir support.

This problem can be solved by increasing the height of the border of the platform, restricting the angular movements of the entire platform. This solution was tested by removing the rectangular protrusions on the side of the platform and fixing a sheet of rigid plastic with 1 mm in thickness, 30 mm height and 200 mm in diameter with epoxy glue on the side of the platform, as shown in Fig. 6. This modification allowed more surface contact between the platform and the rigid reservoir support, avoiding angular movements of the platform.

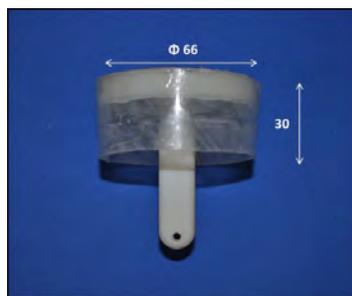


Figure 6. Modifications made on the platform to improve the lever mechanism.

However, due to the extension of the platform edge, the original idea of connecting the arm to the platform through a M3 screw will no longer be possible once there is no space for the placement of the screw. Thus, in the future, we are going to print the arm, the improved version of the platform, as well as the joint between the two parts as a single piece. This process is only possible by using the 3D printing process.

6. CONCLUSION

The 3D printing technique proved useful for prototyping, as seen in the analysis of the fabricated prototype of pulsatile pump to simulate the left heart ventricle. Certain deficiencies were detected both in the choice of material and in the design of some parts in a matter of days, decreasing the costs and the time of the production process. The left

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ventricle is simulated by a rigid reservoir with an internal volume of 50 mL, 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 70 mL, which represents the cardiac output. A lever mechanism is manufactured to convert the rotational movement of a stepper motor to vertical movement of a platform, which will compress the flexible reservoir to simulate pulsation of the heart.

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. The availability of new materials used in 3D printing increases the possibilities for the design of new products.

7. ACKNOWLEDGEMENTS

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