# Utilizing 3D Additive Manufacturing to Develop a Biocompatible, Customizable, and Durable Mechanical Aortic Valve

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**Abstract**

*The trileaflet valve was made with an Elegoo Mars 3 and Resione elastic resin. It was designed in TinkerCAD and sliced with Voxeldance Tango. A mock circulatory loop was used for Insufficiency or Stenosis Equivalent (ISE) evaluation and data was further analyzed with CircAdapt. The blood utilized in the mock circulatory loop contained mock RBCs, which were microscopically evaluated for damage in biocompatibility evaluation. Trileaflet valve had an ISE of insufficiency = 8% stenosis = 0%. It showed normal trends in blood pressure and cardiac output when evaluated by CircAdapt at different heart rates and displayed a normal dip in blood pressure after 95 BPM. However, diastolic pressure was slightly low. Through blood evaluation, hemolysis rate = 3.5% using a hemocytometer, which was within target value. The valve had almost optimal performance in terms of hemodynamics and stenosis but could be improved in terms of ISE. Trileaflet design is TAVR-implantable. A print time of 12 minutes allows for rapid and dynamic production. Reported hemodynamics are superior to current valve designs and valves are easily customizable. Results are promising but more research is required.*

## 1. Introduction

Over 182,000 American patients receive Surgical Aortic Valve Replacement (SAVR) annually, with this number projected to reach 240,000 by 2026[1]. SAVR patients must choose between two undesirable options: mechanical or tissue valves. Mechanical valves require regular anticoagulation to prevent fatal thrombosis, whereas tissue valves are relatively short-lived. [2,3] Additive manufacturing promises a solution, with the ability to create complex structures rapidly and accurately with a variety of materials. [4] The purpose of this study is to evaluate the feasibility of utilizing additive manufacturing in developing an aortic valve prosthesis.

### 1.1. Methodology

The following materials were used in prototype construction:

- Elegoo Mars 3 Pro (3D printer)
- Resione F80 (Elastomer resin)
- Computer with CAD software installed (TinkerCAD and OnShape were used)
- Tango slicing software (Encodes 3D models into file type read by 3D printer)
- USB Drive (File transfer between computer and 3D printer)

Digital Light Processing (DLP) 3D-printing technology was used due to its high accuracy, speed, and variety of print materials with different physical characteristics. [5]

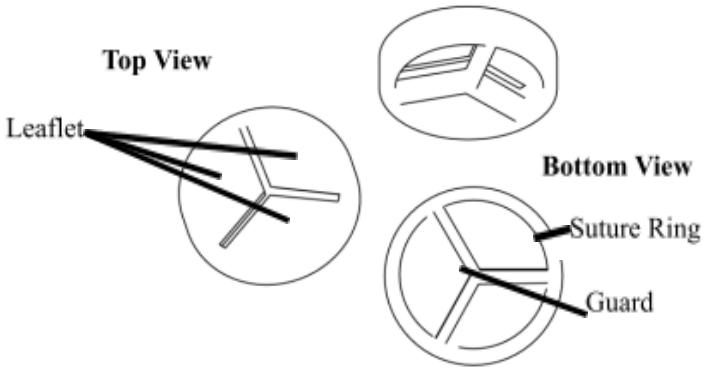
### 1.2. Principle of Operation

The prototype was designed to resemble the natural human aortic valve. It consists of three leaflets, each with a thickness of 100 microns.

Behind the leaflets, a three-armed structure with each arm at a 120-degree angle acts as a “guard”, preventing the leaflets from collapsing inward and allowing significant backflow.

Surrounding the valve was a 2.5-mm thick suture ring with a height of 5 mm. This suture ring provided an anchor point for the leaflets and the guards, and in practice would also be the valve’s anchoring point to the aortic base.

Figure 1. The prototype valve is displayed at multiple different angles.




The gap between the leaflets does allow a small amount of backflow; however, it is a "necessary evil", as it allows the leaflets to separate after printing, decreasing the amount of post-processing needed.

Due to the nature of the vinyl tube which represented the aorta in the MCL, it was necessary to print the valve in an elliptical manner, rather than the perfectly circular profile detailed in the image. It is reasonable to assume that this led to a slight decrease in performance, but it also simulated the creation of custom-sized and custom-shaped valves for patients.

## 1.3. Testing Protocols

A multifaceted testing approach was taken. This testing approach primarily consists of three aspects:

1. **Mock Circulatory Loop (MCL) Evaluation:** A mock circulatory loop (MCL) which consisted of a diaphragm pump system to simulate the pulsatile flow characteristics of the human heart, a vinyl tube roughly the same size of the aorta (at the base of which the valve was located), a reservoir, and a return tube representing the vena cavae. The aorta was graduated with volume measurements, and a camera was used to capture volume measurements for every heartbeat. From these volume measurements, insufficiency (regurgitation) and stenosis were calculated.

2. **Computer Simulation:** Insufficiency and stenosis values from MCL evaluation were inserted as parameters in the CircAdapt model (CircAdapt Research Team, Department of Biomedical Engineering, CARIM School for Cardiovascular Diseases, Maastricht University Medical Center, Netherlands). Outputs such as cardiac output, systolic blood pressure, and diastolic blood pressure allowed an accurate insight into the cardiovascular function of a patient who received the prototype valve as a valvular prosthesis.

3. **Hemodynamic Evaluation:** The fluid inside the MCL during MCL evaluation is Carolina Simulated Kidney Blood (Carolina Medical Supply, United States), which contains simulated erythrocytes roughly the same size and shape as human erythrocytes. After MCL evaluation, a sample of simulated blood was taken from the MCL reservoir and was seated in a hemocytometer slide and microscopically evaluated for signs of damage and/or lysis. The percentage of erythrocytes that were lysed was calculated.

This testing approach allowed multiple aspects of valve performance to be evaluated in a timely manner. The protocol tested insufficiency, stenosis, systemic cardiovascular function, mechanical biocompatibility, and hemodynamics effectively.

## 1.4. Results

The prototype underwent MCL evaluation, which yielded an insufficiency of roughly 8% and a stenosis of 0%, suggesting that while the valve did allow a somewhat elevated amount of backflow, it did not resist systolic flow whatsoever.

Through hemodynamic evaluation of 282 simulated erythrocytes over 6 samples, only 10 erythrocytes showed signs of damage or lysis, representing just 3.5% of cells.

Table 1. Blood pressures obtained from CircAdapt simulation across multiple heart rates.

| Heart Rate (BPM) | Systolic Pressure (mmHg) | Diastolic Pressure (mmHg) |
|---|---|---|
| 70 | 123.75 | 36.75 |
| 80 | 129.34 | 43.42 |
| 90 | 132 | 49.1 |
| 100 | 133.5 | 53.46 |
| 110 | 133.49 | 56.78 |
| 120 | 133.3 | 59.76 |
| 130 | 133.2 | 62.45 |
| 140 | 133.03 | 64.9 |

Table 2. Cardiac output obtained from CircAdapt simulation across multiple heart rates

| Heart Rate (BPM) | Cardiac |
|---|---|

| | Output (l/min) |
|---|---|
| 70 | 5.1 |
| 80 | 7.22 |
| 90 | 8.83 |
| 100 | 10.19 |
| 110 | 11.49 |
| 120 | 12.36 |
| 130 | 13.18 |
| 140 | 12.9 |

### 1.5. Analysis

As can be seen in Table 1, the CircAdapt simulation suggests that a patient with the prototype valve implanted would experience normal systolic pressure, experiencing normal trends such as a slight decrease as the heart rate increases beyond 90-100 BPM (demonstrated by CircAdapt model with normal parameters).

However, the patient would have an extremely low diastolic pressure, which can cause dizziness, fatigue, and/or unconsciousness. This is likely caused by the slightly elevated insufficiency rate. However, it is conceivable that with further design changes as outlined in section 1.7, the insufficiency can be decreased, and diastolic pressure returned to normal.

To the contrary, the simulated patient has a completely ideal cardiac output, increasing until 130 BPM[6] This certainly comes as a surprise, as low systolic or diastolic pressure is generally correlated with a lower cardiac output. [7]

## 2. Discussion

The purpose of this study is to develop a 3D-printed aortic valve. The developed trileaflet prototype mimicked the natural valve anatomy as closely as possible.

Through MCL evaluation, CircAdapt simulation, and hemodynamic evaluation, it was determined that the insufficiency was 8%, stenosis was 0%, and hemolysis was 3.5%.

When these values were loaded into the CircAdapt model as parameters for a simulated patient, it was found that the patient has ideal systolic pressure and cardiac output. However, the patient's diastolic pressure is low, likely due to an elevated insufficiency.

With further development aimed at decreasing backflow, the developed valve would be useful for many patients. The elastic properties of the valve mean that, with some adjustment, the valve is likely TAVR-implantable. This property allows the valve to be used in high-risk, elderly patients who do not want to take anticoagulants for long periods of time.

In the near future, design changes will be made to decrease valvular backflow and hemodynamic performance. Adding contours to the intersection of leaflets will likely lead to a better seal, decreasing backflow and omitting the guard. This would conceivably decrease flow turbulence and fluid shear stresses, further decreasing the hemolysis rate.

However, the valve is not the only component that requires modification. The MCL was somewhat crude, with very little diagnostic equipment (with the exception of volume measurements). In the future, a more refined MCL will be created. The aim is to develop a MCL which is automated and able to run for hundreds of testing hours at a time, allowing for durability assessment.

In addition to CircAdapt, CFD software may be utilized for more accurate assessment of hemodynamics.

This study created an aortic valve through additive manufacturing and developed a multifaceted valve testing protocol. While the future of additive manufacturing in treatment of aortic valve diseases certainly appears to be promising, further research will be needed.

## 3. Acknowledgements

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