

# **Simulation on Mechanical Heart valve: Generative Design and Blood Flow Analysis of a Mechanical Heart Valve**

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## **Abstract**

Technologically advanced systems need simulation to build and apply strategic and experimental models. To reduce risk and costs while implementing Industry4.0. Biomedical challenges typically require finite element analysis. In reality, adopting new procedures with new methods and systems poses various challenges and hazards in biomedical fields. Generic design is the next frontier in CAD design for engineers working in practically every industrial industry. In addition to titanium, cobalt, and pyrolytic carbon, mechanical heart valves are constructed of polymers such as PTFE, polyacetal, and silicone. Most Mechanical Heart valves have a hinge, stent, leaflet, and sewing ring. Polymeric bio-inspired heart valves can imitate the natural valve's structure and fluid dynamics. To decrease risk and introduce new material Simulating is safer. Ansys software can monitor blood flow for a mechanical heart valve. Using generative design approaches, this study aims to main purpose is to improve blood flow via various mechanical valve types. Simulation can help determine the optimal material for the mechanical heart valve. This research suggests that simulations are more cost-effective and risk-free for biomedical engineering firms. FE simulations can reproduce the valve-fluid interaction and define the optimal material for a mechanical heart valve to replace the actual heart valve.

## **Keywords**

Industry 4.0, Generative Design, Finite Element Simulation, Biomedical Engineering, Biocompatible Material

## 1. Introduction

AM (also known as 3D Printing) technologies have been hailed as having the potential to play a significant role in the design and construction of the built environment due to their numerous advantages over traditional methods, such as rapid production, custom products, and cost savings. (Al Rashid et al. 2020). Additive manufacturing is the process of creating complex geometries and structures from 3D model data. The process of creating complex geometries and structures from 3D model data is referred to as additive manufacturing. 3D printing is also referred to as additive manufacturing, rapid prototyping, on-demand manufacturing, digital fabrication, desktop manufacturing, solid freeform manufacturing, layer manufacturing, direct manufacturing technique, and additive manufacturing. (Kumar, Kumar, and Chohan 2021).

Simulations are also used as part of the most recent industrial revolution, called Industry 4.0. Our research shows that simulation is at the heart of most of the technologies that Industry 4.0 uses or gives. Simulators play a big role in Industry 4.0 when it comes to the development and use of its technologies. (Gunal and Karatas 2019). Before, if manufacturers wanted to see if a process worked efficiently and effectively, they had to try and try again. Digital twins are made by using virtualization to make them. They are used for simulation modeling and testing, and they will play a bigger role in the optimization of production and the quality of the products that are made, as well. (United Nations Industrial Development Organization 2016)

Finite element simulation is presently used in industry and offers a valuable virtual manufacturing environment where components and the material-making process may be investigated without expensive testing. Finite element analysis has been frequently used to analyze biomedical issues. In real life, there are some issues and risks in biomedical sectors for implementing the new operations with some new techniques and systems. Where Finite element analysis can mitigate this risk and also easily implement new systems and techniques.

Engineers working in practically all industrial sectors may benefit from reverse engineering procedures such as Generative Design, which is the next frontier in computer-aided design (CAD). Generative design is an iterative design exploration technique that utilizes an artificial intelligence software program to generate new high-performance design iterations that aid in solving complicated problems, reducing component weight and manufacturing costs, scaling customization, and optimizing performance. A number of design choices for biomedical equipment may be developed quickly using this method. The mechanical Heart valve is a critical component of our human beings' health. It is common to develop mechanical heart valve thrombosis, which might result in thromboembolic events. In the case of mechanical heart valves, synthetic biomaterials such as titanium, cobalt, and pyrolytic carbon, as well as polymers such as polytetrafluorethylene (PTFE), polyacetal, polyethylene terephthalate (PET), and silicone, are used. Most mechanical heart valves are constructed of the following basic components: a hinge, a stent, a leaflet, and a sewing ring. Mechanical heart valves are often equipped with a ball or disc to enable their valve mechanisms to function as effective one-way valves in certain situations. In order to imitate the structural and fluid dynamic characteristics of the native valve, bio-inspired polymeric heart valves are great candidates for development. the new material must be implemented in order to lessen the danger Simulation is less difficult and more secure. In order to assess the performance of a mechanical heart valve, blood flow measurements may be made with the use of Ansys software. Unsteady flow through a bileaflet valve prosthesis in the mitral position is investigated in three dimensions, and a fluid-structure interaction technique for leaflet motion during the valve-closing phase is also presented. The goal of this study is to assess the accuracy of blood flow measurement using various mechanical valve designs using Generative Design methodologies. The most appropriate material for making the mechanical heart valve may be determined via simulation. In this study, we discovered that simulations are more appropriate for the biomedical engineering industry, and that they are also more cost-effective and risk-free. Mechanical heart valve simulations can be used to recreate the valve-fluid interaction while also providing realistic fluid dynamic findings. They can also be used to determine the optimal material for a mechanical heart valve that can be used to replace the genuine heart valve in an artificial heart.

### 1.1 Objectives

The objectives of this research are

- To Improve Mechanical Heart Valve Design Using Generative Design with CAD features
- To Find out the probable best biocompatible material that can be better for human body by analyzing with the finite element analysis tool
- To Improve the heart valve blood flow using the Ansys fluid flow tools

## 2. Literature Review

### 2.1.1 Additive Manufacturing

Additive Manufacturing (AM) refers to a group of manufacturing technologies that add units of standard materials one at a time to make unique physical products. (Leary 2020) Transitioning from drawing and making prototypes to replacing real parts opens up even more design options. (Al Rashid et al. 2020)

Additive Manufacturing has grown a lot over the last few decades, and it's a synonym for smart and efficient technology that can be used in a wide range of ways in developed countries around the world. These applications are used in a wide range of scientific fields, including biomedical, aerospace, and engineering. (Sepasgozar et al. 2020) AM technologies have been around for a long time, for example, in the form of common brick materials used to make complex buildings structures. A commercially relevant definition of AM must also say that the process must be digitally driven. This means that AM is enabled by digital definitions of the intended geometry and the associated process parameters. This caveat allows for a wide range of high-quality design results from modern AM technologies, such as inexpensive functional parts, high-complexity customized 3D structures, high-value structural systems, and inexpensive patient-specific surgical guides. (Leary 2020)

### 2.1.2 Additive Manufacturing Applications in Aerospace Industry:

From the very start, AM has been used in aerospace applications. A company called 3D Systems made the first commercial rapid prototyping machine in the late 1980s. The American company Pratt & Whitney was one of the first five customers. In the aerospace industry, it can be used to make rapid tooling, make direct parts, and repair things. It can also be used to save money and time during the product development process. (Liu et al. 2017)

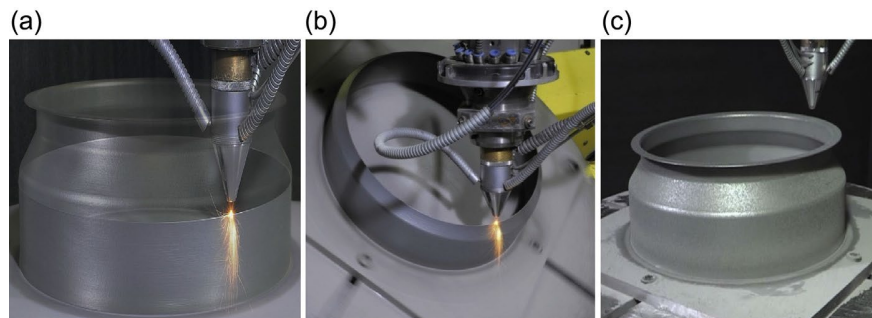


Figure: IN718 helicopter engine combustion chamber fabricated by a five-axis LMD process: (a) deposition showing the 2.5-dimensional tool path; (b) multiaxis deposition; and (c) the finished part (Liu et al. 2017)

### 2.1.3 Additive Manufacturing Applications in Automotive Industry:

Additive Manufacturing comes up with a new way to deal with the problems that the automobile industry is facing today. Design freedom is given while complex but lightweight parts can be added. (La Rocca, Capello, and Pera 2020)

3D printing makes it easy for automobile designers to quickly make a physical object or assembly prototype. This can be anything from a simple interior element to a dashboard or even a scale model of an entire car. Companies may use rapid prototyping to turn ideas into appealing proofs of concept. The time saved during the prototyping phase of the manufacturing process has a big impact on the time it takes to make the rest of the product. (Mohanavel et al. 2021)

### 2.1.4 Additive Manufacturing Applications in Biomedical sector:

During the last four decades, additive manufacturing (AM) has become a cost-effective, on-demand way to make very complicated things. There are a lot of new things that have been done in the field of tissue engineering and regeneration, therapeutic delivery, medical devices, and operative management planning that make it more and more important for the future of healthcare. (Ahanger et al. 2019). A wide range of biocompatible feedstock materials and processing systems are being developed by AM researchers. These materials and systems could be used to make hip, knee, or articular cartilage joints. (Singh and Ramakrishna 2017)

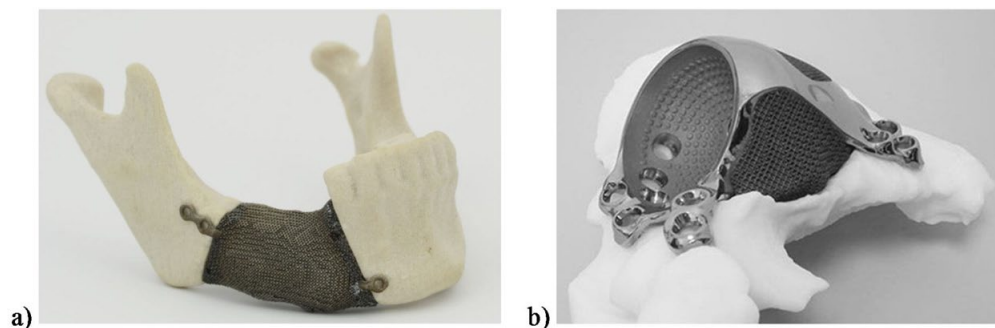
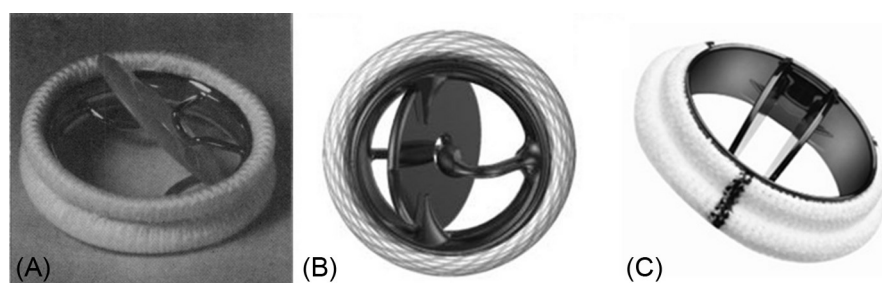


Figure: Example of a) customized jaw implant for oncological treatment [31], b) patient-specific acetabular hip implants (Szymczyk-Ziółkowska et al. 2020)

### 2.2 Mechanical valves

People who have mechanical heart valves (MHV) or ventricular assist devices that use MHV must take anticoagulants for the rest of their lives to prevent secondary strokes. (Alemu et al. 2010). Ones who make MHVs use either the tilting disk or bileaflet idea. As MHV design has changed, the materials used to make MHVs have been a bit more involved. There have been different types of prosthetic material. Pyrolytic carbon has been used a lot in MHVs. It has a lot of advantages, like being very hard, very durable, and very biocompatible. These are just some of the things that make MHVs unique. They also have to be made in a way that allows for the best flow conditions (Johansen 2004).



**Figure:** Mechanical heart valves: (A) Björk-Shiley tilting disc valve with Delrin disk tilted open to a 60 degrees angle in a Stellite cage (B) Medtronic Hall tilting disc valve, and (C) Medtronic ATS Open Pivot bi-leaflet valve. (Gourlay and Rozeik 2018)

With a single tilting disc, you can get better flow characteristics. When the disc is open, it is at about 60° to the flow direction. Struts are used to keep the disc in place. They can be made of plastic or metal and hold the disc in place. The most recent mechanical valve is a bileaflet valve that has two hemispherical plates that pivot on hinges that are built into a metal ring that the leaflets can flatten on when the valve is closed. (Lever 2005)

## 2.4 APPLICATION OF BIOMATERIALS IN HEART VALVES

TABLE: Commonly used natural and synthetic biomaterials in heart valve replacement and repair.(Taghizadeh et al. 2020)

Mechanical Heart valves	Biomaterials (Natural and Synthetic)
	Polypropylene
	Polyurethane urea
	Polyurethane (PU)
	Polyvinyl alcohol (PVA)
	Silicone
	Titanium
	Pyrolytic carbon
	Polyether urethane (PEU)
	Polycarbonate urethane (PCU)
	Polyethylene glycol (PEG)
Biological Heart valves	Gelatin
	Fibrin
	Collagen

### 2.4.2 Polymeric heart valves

Polymeric cardiac valves, comprised of PE or PMMA balls in a PMMA tube, were invented in 1952. PMMA (3 GPa) and PE (1 GPa) are stiff polymers with Young's moduli 102–103 times larger than native heart valve elements (2–15 kPa) (Balguid et al., 2007; Stradins et al., 2004). Later, trileaflet polymeric valves with natural shapes were created as heart valve replacements that would be more hemodynamically successful. When choosing materials for polymeric heart valves, consider mechanical qualities such as low creep, high toughness, and self-recovery, as well as modulus close to native valve and conduit tissues. Polymeric valves are less prone to calcification and failure than bioprosthetic valves and can be custom-designed for each patient. These materials, as well as their mechanical properties, are examined in detail in the following sections.

### 2.4.3 Polyurethanes

To make polyurethanes (PU), isocyanates ( $-N=C=O$ ) react with hydrogen atoms (e.g. alcohols or amines). Urethane bonds are formed by isocyanate and alcohol groups combining, while urea bonds are formed by isocyanate and amine groups. Areocyanates are used to make polyurethanes. Toxicities of aromatic isocyanates are higher than aliphatic isocyanates. Among the polyols used to make polyurethanes are polyesters, polyols (PEG or PPG), polycarbonates, polydisiloxane, and polybutadiene. A number of polyurethane family members have been used in the manufacture of heart valves, including polyester urethane, polyether urethane, polycarbonate, and polyether urethane urea (Gillian M. Bernacca et al., 2002; Wheatley et al., 2000).

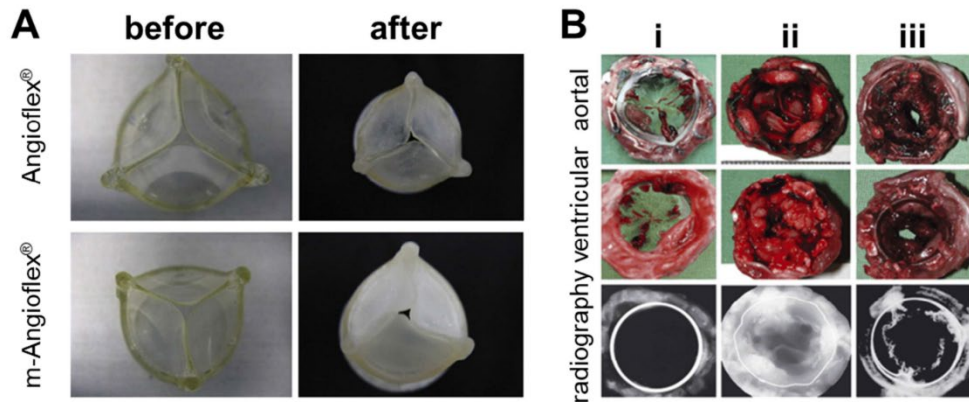


Figure: Angioflex® and bisphosphonate-modified Angioflex® (polyether-based polyurethane) valves before and after calcification (A) (Boloori Zadeh, Corbett, and Nayeb-Hashemi 2014). The type of calcification differs between the two materials, according to further investigation. (B) Polycarbonate urethane heart valves after 20 weeks I against Mosaic® after 10 days (ii) and Perimount® after 30 days (iii) In comparison to Moasic® and Perimount® samples, no apparent calcification was identified in radiography for polycarbonate urethane (Daebritz et al. 2004).

### 2.4.5 PTFE

Polytetrafluoroethylene (Teflon®) is a highly stable fluorinated polymer with a low surface energy (Scheme 2). PTFE is a crystalline polymer (40–70%) with temperature and rate dependent nonlinear mechanical properties including modulus and yield stress. At room temperature, PTFE has a Young's modulus of 1 GPa, a yield stress of 10 MPa, and an ultimate stress of 160 MPa (Nunes et al., 2011; Rae & Brown, 2005). In medical applications, such as cardiovascular engineering, PTFE's low surface energy and low friction coefficient make it an attractive candidate.

### 2.5.1 Finite Element Analysis

Recently there have been lots of changes in the systems and techniques in the designing sector which were used to designing, modeling, manufacturing products and implementation of some manufacturing methods. The widespread use of Finite Element Analysis has undergone enormous transformations since the 1950s (FEA). FEA becomes a regular usable tool to design products and systems. (Bi 2018). FEA tools significantly solve structural, fluid, and Multiphysics problems numerically. FEA tools are used roughly because engineers can quickly & comprehensively solve mathematical and numerical problems. There are three types of Finite element programs which are making major impacts and those are ASKA, NASTRAN, and SAP. NASTRAN and ASKA programs are important analyzing tools for both the automotive and aerospace industries. For Civil and mechanical engineering industries SAP programs are being used. FEA method nowadays is generally utilized in collaboration with commercial finite element systems. (Dhatt et al. 2013).

### 2.5.2 FEA in Aerospace Engineering (Bhat 2021)

FEA is used in the aeronautical engineering domains of:

- Composites
- FEA calculations for shock and vibration
- FEA calculations for durability and fatigue life
- FEA calculations for modal analysis and frequency response
- FEA calculations for weight reduction and shape optimization
- Stiffness and strain calculations for Composite Panels
- Life Calculations of safety systems
- Fluid Flow calculations for valves, pumps, pressure-regulating devices

### 2.5.3 FEA in Mechanical Engineering (Bhat 2021)

Finite Element Analysis (FEA) has been regularly used by automobile organizations and also FEA is used by engineers as an important tool for product development.

FEA becomes an absolutely important productivity tool for engineers which helps design engineers to reduce the product development time and cost so easily.

Misuse of FEA may lead to costly design errors later in the design process.

To better understand how various collision situations, affect automobiles and to improve automotive design engineers use finite element analysis (FEA).

### 2.5.4 Finite Element in Fusion Welding Processes

The element birth and death method were used in the welding simulation. It was a sequential coupled thermomechanical analysis. Good agreement was found between what the software did and what was done in real life. FEM analysis can be used to simulate PWHT, so it can be used to figure out which temperatures can be used to reduce residual stress and distortion with this treatment. (Marques, Silva, and Pereira 2020)

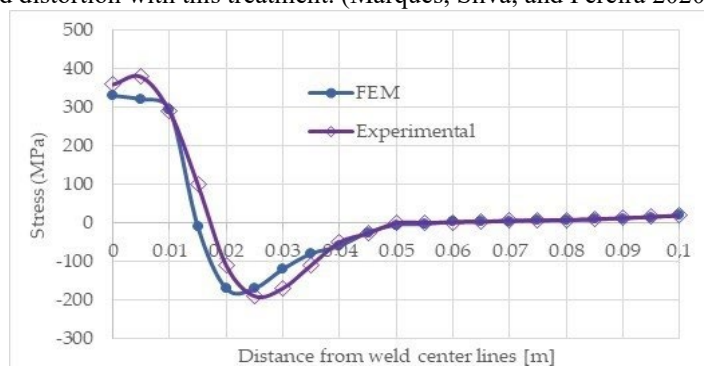


Figure: Comparison Between experimental welding with FEM (Marques et al. 2020)

### 2.5.5 FEA in Biomedical Sector:

Finite element (FE) simulation is a good way to study the behavior of any physiological unit, no matter how complicated it is. Today, it is a powerful tool in the field of Orthopedic Surgery and Traumatology. It helps surgeons better understand how the body moves in both healthy and unhealthy situations. (Gracia et al. 2012)

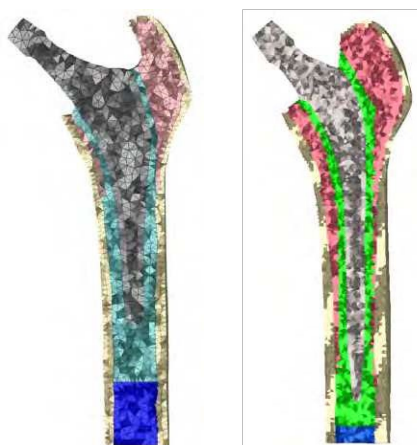
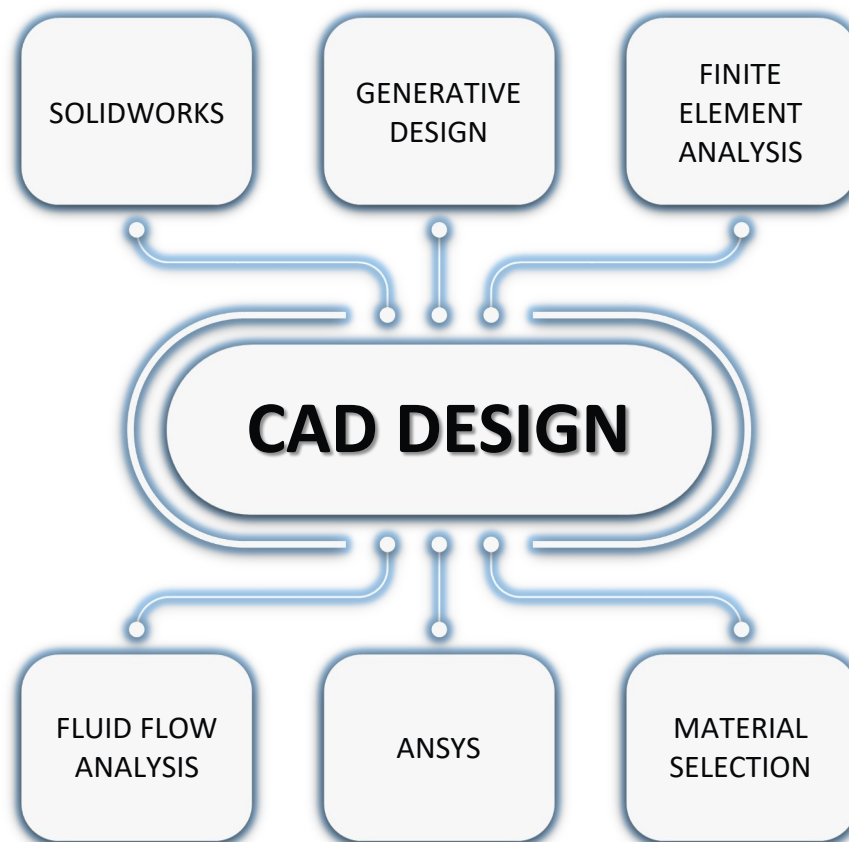


Figure: Longitudinal section of the FE models with cemented femoral prostheses: (a) cemented and (b) Versys. (Gracia et al. 2012)



### 3. Methods

With the use of Generative design methodologies, it is possible to measure the accurate blood flow using various mechanical valve designs. The most appropriate material for making the mechanical heart valve can be determined



through simulation. In this study, we showed that simulations are more appropriate for the biomedical engineering industry, and that they are also more cost-effective and risk-free. Mechanical heart valve simulations can be used to recreate the valve-fluid interaction while also providing realistic fluid dynamic findings. They can also be used to determine the optimal material for a mechanical heart valve that can be used to replace the genuine heart valve in an artificial heart.

### 4. Data Collection

Following the use of the tools and the analysis of the study, the following are some of the findings.

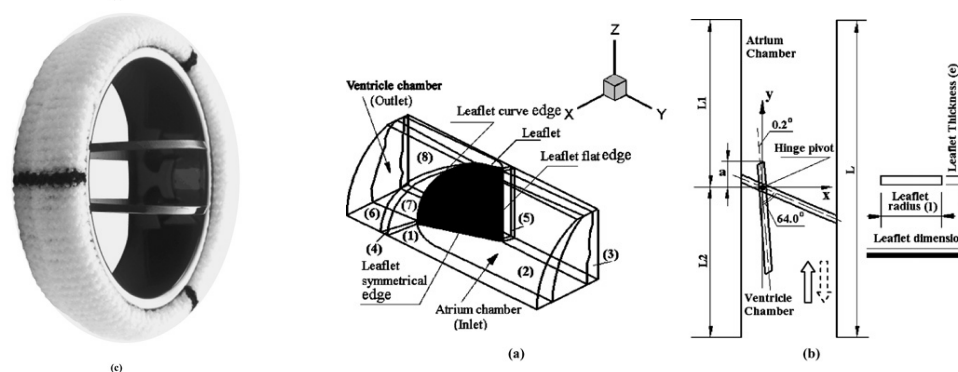


Figure 1 depicts a three-dimensional (3D) simulation model of a mechanical heart valve for fluid-structure interaction simulation. The fully closed leaflet is located on the  $x-z$  plane, with the  $y$ -coordinate indicating the distance from the leaflet surface on the atrial (inflow) side of the valve. (a) The three-dimensional geometry of one half of a leaflet in the flow chamber, with the ventricular and atrial sides indicated.



The numbers represent the various blocks in the mesh reconstruction for the flow dynamic simulation; (b) A top view of the simulation geometry showing the fully open and closed positions of the leaflet as well as the leaflet dimensions; and (c) A photograph of the Medtronic advantage bileaflet valve from which the nominal dimensions for the simulation were obtained.  
(Cheng, Lai, and Chandran 2004)

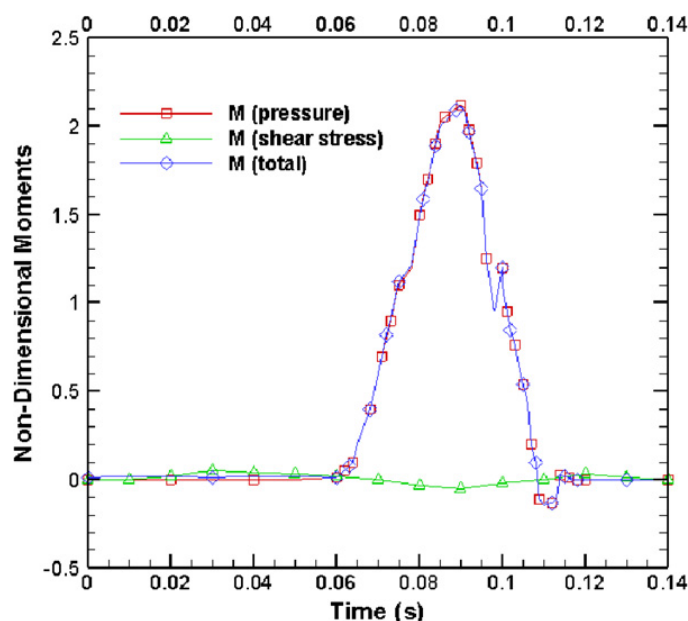


Figure: Variation of moments acting on valve leaflets for the opening phase (Xia, Zhao, and Yeo 2009)

## 5. Results and Discussion

Compared to biomimetic leaflet valves, straight-hinged leaflet valves have lower opening pressures. Stress on the leaflets of the hinged 6 leaflet valve was the least, whereas stress on biomimetic bowed leaflets was the most. Among the valve designs tested, the hinged 6 leaflet valve had the largest effective orifice area and the second lowest regurgitant fraction (14 percent), while the biomimetic bowed leaflets had the smallest effective orifice






Valve Type	Modification	Design	Opening Pressure (kPA)	Maximum Stress (kPA)	Effective orifice area	Pressure drop (mmHg)	Regurgitant fraction
Biomimetic	Straight leaflets		10	826	83%	18	16%
	Bowed leaflets		20	1765	41%	37	2%
Straight Hinge	Three leaflets		2	874	64%	23	96%
	Six leaflets		1	727	90%	8	14%
Fluid Diode	Seven leaflets		--	--	72%	21	93%

Table: After Using Generative Design tool and analyzing the Simulation Result

area and the lowest regurgitant fraction (13 percent) (2 percent). Despite the fact that the fluid diode had a wide effective orifice area, the design was not effective at preventing regurgitation of fluid (93 percent).

## 6. Conclusion

As a result of the advancement of computer-aided design (CAD) applications, the development of cardiac valves can be completed in less time with better data quality. When the styling of components in biomedical applications changes, or when the appearance of human errors occurs, this is the case. The Generative Engineering Design technique described in this paper presents a comprehensive process that includes linkages and tools to facilitate collaboration on styling development and engineering-related design tasks. In addition to enhancing data quality, it has the capability of shortening the development process. 3D printing technologies, finite element simulation, and generative design can all be used to create functional heart valves. Designing mechanically rather than biologically was found to have unanticipated advantages over designing biologically. When developing implantable 3D printed heart valves, the integration of unique designs with new materials will be critical.

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## Biographies

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