Design and Modeling of a Soft Artificial Heart by Using the SolidWorks and ANSYS

Saad Mahmood Ali1,2, Zahraa Jasim Ali2, and Mays Mahde Abd3
1 Biomedical Engineering Department, University of Technology, Iraq
2 Corresponding author’s e-mail: 30249@uotechnology.edu.iq
3 Control and Systems Engineering Department, University of Technology, Iraq

Abstract. Investigating the biomechanical behaviour of a soft artificial heart is a hard task as such things are very complicated in terms of both material properties and geometry. This work focused on developing, designing, modeling and analysing a new generation, low cost, easily operable, full-size, low power consumption, and durable soft artificial heart intended to replace an original heart on a permanent basis. Numerical simulation and investigation of the artificial heart were implemented using SolidWorks 17 and ANSYS 15.7, with a Multiphysics static structural model, fluent fluid flow (CFX), and fluent fluid poly-flow (CFD) analysis systems used in order to determine the dynamic response and effects of pressurised blood on heart performance during blood flow cycles. The biomechanical modeling and analysis of the soft artificial heart were implemented using the finite element modelling in ANSYS R18.0. To improve and verify the biomechanical performance, Design Expert 11.0 software and a response surface methodology (RSM) technique were used. The simulation results showed that as maximum levels of absolute pressure were applied on the ventricles and air pressurised chambers, the performance of the heart remained secure. The results also showed that strain energy, total deformation, maximum principal elastic strain, stress and fatigue safety factors, and fatigue life all reached thier optimum values when using the SIBSTAR 103T with polyetherimide/silicone (PSN4) Nano-composite elastomers.

Key words: Total artificial heart, Soft artificial heart, SOLIDWORKS modeling, ANSYS fluent fluid flow (CFX) simulation, Computational fluid dynamics (CFD), silicone-based nanocomposites, silicone rubber (elastomer), zinc dimethacrylate, PEI, poly (dimethylsiloxane), hydroxyapatite

1. Introduction

The human heart beats about 100,000 times each day, around 30 million times annually, and 2.5 billion times in an average lifetime [1]. It is thus capable of pumping 7,000 litres of blood per day, that is, 2.5 million per year, and 200 million throughout an individual’s life. The total blood volumes in the average human body are about 5 to 6.5 litres [2]. The cardiovascular system is thus a complex structure, as required to manage this constant blood circulation within the human body [3], and cardiovascular disease, which includes heart failure, is the number one cause of death worldwide. The need for replacement hearts is thus continually growing, while the number of donor hearts available for transplant remains flat. To save adults from dying of end-stage biventricular heart failure, medical teams around the world have thus developed 13 different types of artificial hearts since 1969 that have been implanted into patients.
According to the American Heart Association (AHA), about 60 million Americans currently suffer from some form of cardiovascular condition [5-6], and each year, about one million deaths are attributed to cardiovascular disease [7-8]. These include cardiogenic shock, congenital heart disease, infection, and myocardial infarct. According to the American National Heart, Lung and Blood Institute, about 4.8 million Americans also suffer from Congestive Heart Failure (CHF), in which the heart cannot pump enough blood [9].

The human heart is a muscle that pumps blood around the body. It has four chambers: the left and right atria (receiving chambers), and the left and right ventricles (the pumping chambers). Blood in the left ventricle (left heart) is pumped into the aorta and thus through the body, while the blood in the right ventricle (right heart) is pumped into the pulmonary artery, which leads to the lungs [1].

An artificial heart is a mechanical device implanted in the chest or connected to the heart to replace or help a failing heart. It has several valves that propel blood and one or more chambers [8, 10], being powered by either compressed air or electricity, with a thin cable connecting a control console to the pumping chamber to regulate the pump. The first artificial heart was transplanted into a dog in 1937 [11], and in 1952, the Dodrill-GMR heart machine was first successfully used [5]. The John Heysham Gibbon heart-lung machine was then used in 1953 during a successful open-heart surgery [12].

The first use of a total artificial heart (TAH) designed for permanent implantation rather than acting as a bridge during transplant occurred in 1982. These have since demonstrated great efficacy in supporting patients with massive acute myocardial infarction and associated acute irreversible heart failure [13]. There have now been 1,413 implants of various artificial heart designs over a period from 1969 to 2014 [10, 14], and the overall survival to transplantation and survival after transplantation rates indicate success [15].

The human heart is a soft muscle with pulsatile flow, while state-of-the-art artificial hearts are generally built from rigid materials. Silicone elastomers are already important materials in artificial blood pump drivelines, however, and such silicone elastomer drivelines could offer a new approach to improving tissue integration and preventing infections in heart replacements [16]. In 2017, Cohrs presented a new concept, a soft total artificial heart, and a version that looks like a real heart was developed in the Functional Materials Laboratory at ETH Zurich [17]. A further novel artificial soft heart was developed using three-dimensional printing technology that permitted complex chamber geometrics [18].

The current work’s main objectives are designing and modelling a soft human artificial heart that is of low cost, easily operable, full-size, and low power consumption, to fulfil the growing demand for heart replacements. Numerical simulation and investigation of the soft artificial heart thus developed and designed were done using finite element modelling, SolidWorks 17.0, and ANSYS 15.0, with fluent fluid flow (CFX) and fluent fluid poly-flow (CFD) [19] analysis systems used to determine the dynamic effects of pressurised air on performance during daily activity as simulated in the soft artificial heart’s flow cycle.

2. Design and Modelling of a Soft Artificial Heart

The researchers of the largest artificial heart programme in Europe, the Zurich Heart Project (a collaboration of 20 research groups from various disciplines and institutions) developed a silicone heart imitating the human heart as closely as possible in July 2017, which beats almost like a human heart [17]. The currently used blood pumps have several disadvantages, however, with the mechanical parts being susceptible to complications and patients lacking a physiological pulse. They currently last for around a half to three-quarters of an hour before the material can no longer withstand the strain. The performance and tensile strength of the materials used must thus be enhanced significantly. The latest version of the heart lasts for about 1 million heartbeats, an exponential increase from the original 3,000 beats; however, this still only represents about 10 days’ worth of life.

In the current work, modelling and analysis of a new generation soft artificial heart designed to replace a living heart permanently were implemented using SolidWorks 17 and finite element modelling in ANSYS 15.0. Investigating the biomechanical behaviours of the soft artificial heart is a hard task, as it is very complicated in terms of both material properties and geometry, changing all the time. Of all possible methods, finite element analysis (FEA) is the most reliable way of examining such a fluid system. By using
fluent finite element analysis with different simulations, any weak points of the design can be identified and better biomaterial selections made to assist with the design.

Before a viable total artificial heart (TAH) suitable for implantation can be successfully achieved, several design criteria must be satisfied, including anatomical fit, material biocompatibility, compatible cardiac output, sensitivity to venous return, antithrombogenicity, and the elimination of "locus minoris" in terms of material fatigue [26]. To address some of these issues, silicone material used in fabricating the artificial soft heart enables the heart to have a soft, flexible shell that can be compressed by the contraction of the muscle wall [7-8].

In an ellipsoidal shaped heart, the two pumps contact each other only at a single point, resulting in a very inefficient volumetric use of the limited space available. The diaphragm is thus required to flex through a larger angle during cycling, resulting in a lower diaphragm cycle life due to the high-stress concentrations that predominate at this location. The blood chamber is designed to be small for easy implantation in the pericardial space of the human body, to simulate the natural heart. The width of the whole heart body is thus 76 mm, while the height from the left atrial portends to the top of the heart body is 95mm [8].

The main material used for fabrication of the soft artificial heart blood chamber shell is industrial grade silicone; the pump is titanium alloy (Ti-6Al 7ND) [27]. The best diameter for the inside chamber to maximise stroke volume without exceeding anatomical limits was estimated to be 40 mm with a wall thickness of 5 mm, causing the outside diameter to be 50 mm [8]. The area of the chamber is thus 4,161.04 mm² and the delivery suction pipe diameter is 20 mm. The human heart provides the body with 5 to 7 l/min of blood circulation; the optimum design for required pump delivery (Q) is thus 12 l/min = 2 *10⁻⁴ m³/s. The blood pressure measurement range is 100 to 400 mmHg. Motor hydraulic power can thus be calculated, using the design factor of safety (1.3), as

\[
\text{Motor Power} = g \times Q \times H = P \times Q \times \text{design factor}
\]

\[= 2 \times 10^4 \times 53228.96 \times 1.3 = 13.866 \text{ Watt}\]

The hydraulic motor’s number of revolutions per minute = 95, which provides maximum cardiac output as estimated from the human heart’s beats per minute. The allowable crank pin bearing pressure is usually in the range of 7 to 12.5 MPa, and thus can be assumed at 10 MPa; the motor shaft torque (T) can thus be calculated (where the angular velocity ω = 9.94 rad/sec) as

\[P = T \times \omega\]

\[T = 13.866 / 9.94 = 1.394 \text{ N.m.}\]

The motor shaft force (F) is

\[T = F \times R\]

The radius equals half the stoke (R), thus being equal to 6.6 mm; the desired load (FD) is thus

\[F_D = 211.212 \text{ N} \]

For the piston pin bearing, the allowable bearing pressure is usually in the range of 10.5 to 15 MPa; for safety, this is taken to be 10.5 MPa. Assuming that the bearing will be working 24 hours a day for 5 years and the k = 3 for the ball bearing with a rating life (Ln) = 43,800 hours, then the catalogue loading rating (Cr) is [28]

\[Cr = F_D \times L^{1/k}\]

and the bearing life (L), where (N) is the rating speed, is

\[L = 60N \times Ln / 1000000 = 249.66 \text{ million of revolution}\]

Thus, \(Cr = 1329.94 \text{ N}\) and the chosen bearing must be the No. MR63ZZ, with an outside diameter of 3 mm and a thickness of 2.5 mm.
2.1 Modeling the Artificial Heart

Human heart anatomy and the constitutive behaviour of heart tissue are both very complex. The first step in planning a complex FEA simulation project is thus to identify the potential challenges in both the physical problem formulation and the numerical implementation of the simulation. The geometric representation must retain sufficient detail to maintain structural response while being simplified sufficiently to create general applicability rather than a single specific heart model.

A computer-aided design (CAD) model of the soft artificial heart geometry was created using 3D SolidWorks 2017. The modelling dimensions of the heart were taken from a plastic copy of an adult heart, and the presented model was assumed to be characterised by isotropic and homogeneous properties. The suggested 3D model was represented by two sections, front and top.

The created SolidWorks model sections of the soft artificial heart are shown in figure 1, with the front model section of the soft artificial heart shown in figure 1 (a). The height of the heart model was divided into 14 model sections to accomplish the jobs required for its operation, as shown in figure 1 (b). Figure 1 (c) shows the blood vents required for the artificial heart’s operation, while figure 1 (d) illustrates the compressed air vents required for the operation.

![Figure 1. The SolidWorks model sections of the designed soft artificial heart: (a) The front model section; (b) The created top model sections; (c) The blood vents required for the operation of the artificial heart; (d) The compressed air vents required for the operation of the artificial heart](image)

Figures 2 and 3 show the 3D and projection curvature and ordinary models of the soft artificial heart, respectively, while figure 4 shows the inner section 3D model projections created to build the diaphragm necessary for the functioning of the soft artificial heart, including the right and left ventricles. Figure 5
shows the 3D sections of the designed heart, with the right and left ventricles and the drag and air pressure zones required to perform the necessary heart mechanisms.

2.1.1 Simulation of Soft Artificial Heart
Simulation of the modelled soft artificial heart was done after importing the 3D model into ANSYS 15.7. In the first step, the mechanical and physical properties data for the silicone materials used for fabricating the heart body were entered into the engineering data cell along with the human blood and air properties required for the heart moving mechanisms. In this study, the fluent fluid flow (CFX) analysis system derived from ANSYS Multiphysics static structural analysis was used to determine the dynamic response of the pressurised blood to the performance of the designed soft artificial heart during the flow cycle [29].

To calculate the volume of liquid blood that the heart model could pump, finite element analysis (FEA) was used to identify deformation under different pressures. The 3D FEA model of the designed soft artificial heart, which consists of 519 faces, was discretised using the static structural and fluent fluid poly-flow (CFD) analysis systems, using a high-quality Mesher curvature-based solid volumetric meshing type as shown in figure 6. To avoid unrealistic stress concentration points, a mesh refinement was performed in the desired segments by using higher gradients to magnify the accuracy and to ensure the quality of results. The number of created nodes was 189,706 and 997,438 elements were used.
Figure 4. The inner section and 3D model projections for the functioning of the soft artificial heart.

Figure 5. The 3D sections of the designed heart, with the drag and air pressure zones required to perform the heart mechanisms.
Each section boundary is labelled in the geometry by the creation of named selections for the soft artificial human blood inlets and the outlet valves, (outer wall boundaries are automatically detected by ANSYS FLUENT). In the selection name dialog box, the right and left tricuspid and pulmonary valves were entered, as shown in figure 7. The same operation was then performed for the small inlets for air pressurisation and the outlets, the air drag valves, as shown in figure 8.

2.2. Model Geometry
The model material used for the modelling of a soft artificial heart model was silicone rubber monoblock with a complex inner structure that offers hyperelastic deformation. The model geometry shows that the maximum length, height and width are 142.62, 167.38, and 70 mm, respectively. The total volume is 2.6663x105 mm³ and the net weight is 293 gm, while the total weight when filled with blood and pressurised air is 577 gm. It is thus a silicone monoblock with a complex inner structure. Tables 1 to 3 illustrate the mechanical and physical properties for the silicone rubber and human blood and the thermo-physical properties for the air.

This silicone soft heart can be custom fitted for individual patients. Just like a real human heart, this soft artificial heart has both a right and a left ventricle, which pump blood and are separated by an additional chamber. This chamber is filled and deflated by means of pressurised air in order to pump the blood fluid from the blood chambers to mimic and replace the muscle contraction of the human heart.

Figure 6. The 3D FEA model of artificial heart discretised (a) using static structural analysis; (b) using fluent fluid flow (CFX) analysis system.

Figure 7. Named selections for the right and left tricuspid and pulmonary

The right tricuspid valve
The right pulmonary valve
The left tricuspid valve
The left Pulmonary valve
The inlets air pressurized valves

Figure 8. Named selections for the inlets air pressurized and the outlet air drag valves

Table 1. The mechanical properties for silicone rubber [30-31]

| Property                  | Unit  | Value          |
|---------------------------|-------|----------------|
| Chemical Definition:      | -     | Polysiloxane   |
| Colour                    | -     | grey           |
| Young modulus (E)         | MPa   | 3.05           |
| Elongation (ε)            | %     | 280 (max. 700) |
| Hardness                  | N/mm² | 50             |
| Tensile strength          | psi   | 1400 (8.54 MPa)|
| Tear strength             | ppi   | 250            |
| Elongation at break       | %     | 894            |
| Specific gravity          | gm/cm³| 1.15           |
| Low-Temperature Usage     | °C    | 50 to -100     |
| High-Temperature Usage    | °C    | Up to 250      |

Table 2. The mechanical and physical properties for human blood [28]

| Property                  | Unit  | Value                                      |
|---------------------------|-------|--------------------------------------------|
| Colour                    | -     | Red, due to haemoglobin                    |
| Amount                    | ml/kg | 79 (7-9% of total body weight)             |
| Blood volume              | litres| 5-6                                        |
| Viscosity                 | mPa   | 3.5-5.5                                    |
| Specific Gravity          | gm/cm³| 1.065                                      |
| PH                        | -     | 7.4 (slightly alkaline), Venous blood has a lower pH than the arterial blood as venous blood has more CO |
| Temperature               | °C    | 38 (100.4F)                                |
| Osmotic pressure          | mm Hg | – 25                                       |

Table 3. The thermo-physical properties for the air [28]

| Property                                | Unit            | Value                                    |
|-----------------------------------------|-----------------|------------------------------------------|
| Bulk modulus                            | Pa or N/m²      | 1.01325 x 10³                            |
| Density (at 0°C and 1bar)               | kg/m³           | 1.276                                    |
| Enthalpy (heat) of air at 0°C and 1 bar | kJ/mol          | 11.57 = 399.4 kJ/kg                      |
| Entropy of air at 0°C and 1 bar         | kJ/mol K        | 0.1100 = 3.796 kJ/kg K                   |
| Molar mass                              | g/mol           | 28.9647                                  |
| Specific heat capacity (Cp) air at 0°C and 1 bar | kJ/kgK          | 1.006= 0.24028 Btu (IT)/ (lbm °F) or kcal/ (kg K) |
| Specific heat capacity (Cv) air at 0°C and 1 bar | kJ/kgK          | 0.7171= 0.17128 Btu (IT)/ (lbm °F) or kcal/ (kg K) |
| Thermal conductivity at 0°C and 1 bar   | mW/ (m K)       | 24.35= 0.02094 kcal (IT)/ (h m K)        |
| Thermal expansion coefficient at 0°C and 1 bar | 1/K             | 0.00369                                  |
| Viscosity, dynamic, at 0°C and 1 bar    | µPa s           | 17.22= 0.01722 cP                        |
| Viscosity, kinematic, at 0°C and 1 bar  | m²/s            | 0.0001349                                |
In the aorta, the pressure waveform resembles the pressure waveform from the human heart, and as with existing ventricular assist devices and total artificial hearts currently on the market, the designed soft artificial heart would be powered by a portable pneumatic driver worn externally. To produce the heart is expected to cost around $400 USD, though implanting it into a human body is much more expensive.

The designed soft artificial heart is not intended to be a bridge to a new heart; it is designed for use as a true heart replacement, being generally without side effects, unlike hard material total artificial hearts implants, which have multiple side effects as the immune system grows hostile towards the foreign object, which can cause blood clots. Metal and plastic mechanisms can also be difficult to integrate with tissue and may damage the blood because of their unnatural movements.

2.3. Soft Artificial Heart Blood Flow Simulation
The ANSYS Fluent analysis system was used to set up and solve the computational fluid dynamics (CFD) for the soft artificial heart’s blood flow simulation as shown in figure 9.

Some general settings were set for the CFD analysis in the navigation pane to perform mesh-related activities and to choose the solver, including changing the units for length to mm; setting up the models for the CFD simulation’s viscosity by activating a multiphase and viscous model; enabling the volume and viscosity of fluid as laminar; and enabling the Energy Equation option, the K-equation turbulence model, and the k-epsilon from the Model list to expand the Viscous Model.

Setup of the materials for the CFD simulation was then performed by creating new materials called “air”, “human blood” and “silicone” using the Create/Edit Materials dialogue box, setting up the cell zone conditions for the CFD simulation, and determining the boundary conditions for CFD analysis at the inlet air pressurised valve (operating pressure =250 kPa), at the outlet air drag valves (operating pressure = -50 kPa).
kPa), and at the right and left tricuspid valves (operating pressure = 50 kPa). The solution parameters for the CFD simulation were then set by changing the convergence criteria for the continuity equation residual. Finally, the solution was calculated using 250 iterations, as shown in figure 10.

The results displayed in ANSYS FLUENT and ANSYS CFD-Post were shown as filled contours representing the pressure magnitude on each symmetry plane. Figures 11 and 12 show the simulation of the

Figure 11. Simulation of absolute pressure at the AH ventricles during ingress of pressurised air equal to 100 kPa

Figure 12. Simulation of absolute pressure at the pressurised AH air chamber equal to 100 kPa

Figure 13. Simulation of absolute pressure over the whole soft artificial heart
absolute pressure at the artificial heart (AH) ventricles and the air pressurised chamber during the ingress of the pressurised air, equal to 100 kPa, and in the whole the soft artificial heart model, as shown in figure 13, showing that the performance of the heart is adequate under all conditions.

Figure 14 shows the velocity of air mass at the flow inlet for the pressurised air chamber; the performance of the heart is adequate here, too. The blood and air path lines in the ventricles and air pressurised chambers are shown in figure 15, while figure 16 shows an animation of blood movement through the ventricle chambers during the air drag process.

![Figure 14. The velocity of the air mass flow inlet at the pressurised air chamber](image1)

![Figure 15. The blood and the air paths in the ventricle chambers and in the air pressurised chamber](image2)

![Figure 16. Animation of blood movement through the ventricle chambers during air drag process](image3)

3. Stress Analysis and Fatigue life
Six advanced silicon-based composite elastomers materials were chosen for testing alongside Polysiloxane silicone rubber to identify the best choice for fabrication of the soft artificial heart. The selections were based on obtained material properties, including material strength, the stresses generated, the percentage elongation, fatigue life, the minimum amount of strain energy required for heart performance, and the safety factor.
The first selected material was a 20% hydroxyapatite (HAp) powder mixed with the poly(dimethylsiloxane) (PDMS). The composite was fabricated by pressing between two metal plates to obtain samples about 3 mm thick, which were then cured at 185 °C for 35 min. The commercial poly(dimethylsiloxane) (PDMS) type NE-140 matrix was fabricated by Wenda Co. PDMS has been extensively applied in implants and artificial organs for more than 50 years due to its excellent bio-inertness, biostability, and softness. It has an equivalent mechanical performance to medical silicone [20].

The second selected composite material was polysiloxane Methyl vinyl silicone rubber matrix/zinc dimethacrylate (VMQ/ZDMA; 100/30) The nanocomposite elastomer contained 0.15% vinyl substituent obtained from Chenguang Chemical Research Institute, Sichuan, China, while Zinc dimethacrylate (ZDMA) (grade Saret 634) was purchased from Sartomer Co., USA. The peroxide used was 2,5-bis(tert-butylperoxy)-2,5- dimethyl hexane (DBPMH), purchased from Akzo Nobel Cross-Linking Peroxide Co., Ltd., Ningbo, China [21].

The third selected composite material was reinforced with 30% Nano-SiO₂ particles (modified by hexamethyldisilazane (HMDS), supplied by Evonik Degussa GmbH), on a vulcanized silicone rubber (RTV-1 SiR) matrix, prepared by using polydimethylsiloxane (PDMS, Wacker Chemie), anilino-methylthioxysilane (ND42, Liyang Mingtian Chemical Co.), titanium complexes (D-60, Hubei Lantian Chemical Co.), and HMDS-modified SiO₂ particles [22].

The fourth selected composite material was magnetic rubbery silicone (superparamagnetic elastomers), containing silicone rubber matrix and 12% chemically coprecipitated nanocrystalline magnetite particles. Any air bubbles that appeared during mixing were removed by performing degassing under a primary vacuum bell at ambient temperatures so that silicone polymerization took place. The colloidal suspension was stabilised using ultracentrifugation during mixing to prevent magnetic agglomeration. This elastic composite material has been useful in making artificial muscles [23].

The fifth composite material was linear triblock poly(styrene-b-isobutylene-b-styrene) (SIBS) (SIBSTAR103T), a self-assembling thermoplastic nanostructured rubber. In clinical practice, such polymers are used as drug-eluting stent coatings and offer a promising biomaterial alternative to silicone rubber. The as-received pellets of SIBSTAR 103T by Kaneka Corp. were compression-moulded using a hot press with liquid nitrogen to detach the moulded materials, and contained 34.2 (wt%) polystyrene content, 107.0 (g/mol) Mn, and 1.34 Mw/Mn [24].

The sixth material was polyetherimide/silicone rubber nanocomposite reinforced with nanosilica particles (PSN4) containing 85% polyetherimide (PEI, Ultem 1000), supplied by Sabic Innovative Plastic (USA), 15% silicone rubber (VMQ (Silastic NPC-40), supplied by Dow Corning, USA), and reinforced with 4% modified Nanosilica Particles (organo-modified CAB-O-SIL® TS-720, supplied by Cabot, USA) using a melt mixing process with the help of a co-rotating twin screw extruder [25].

The main mechanical properties of the selected materials to be used for fabrication of a soft artificial heart are given in table 4.

Table 4. Main mechanical properties of the selected materials used for fabricating the soft artificial heart

| Des. No. | Sample                                      | Elastic Modulus (MPa) | Tensile strength (MPa) | Elongation at break (%) |
|----------|--------------------------------------------|-----------------------|------------------------|-------------------------|
| 1-       | VMQ/ZDMA; 100/30                           | 1.73                  | 4.50                   | 373.00                  |
| 2-       | 30% SiO2/ RTV-1 SiR                        | 1.53                  | 4.5                    | 450.00                  |
| 3-       | Silicone rubber + 12% magnetite            | 2.88                  | 6.80                   | 260.00                  |
| 4-       | Silicone Rubber (Polysiloxane)             | 3.05                  | 8.54                   | 280                     |
| 5-       | PDMS/20% HAp composites                    | 3.37                  | 9.64                   | 139.62                  |
| 6-       | SIBSTAR 103T                               | 5.92                  | 18.10                  | 506                     |
| 7-       | PSN4                                       | 13.35                 | 39.13                  | 108.5                   |
To create the simulations and analyse models for stress and strain distribution and fatigue life, finite element ANSYS R18.0 was used in conjunction with the response surface methodology (RSM) technique; Design Expert 11.0 software was also used. The mechanical properties of the nanocomposites are given in table 5.

**Table 5. Mechanical properties resulting from nanocomposite performances for the soft artificial heart**

| Sample | Strain Energy (mJ) | Total Deformation (mm) | Equivalent Elastic Strain (mm/mm) | Stress Safety Factor | Fatigue Life (Cycle) | Fatigue Safety Factor | Fatigue Life (Years) |
|--------|--------------------|------------------------|----------------------------------|---------------------|----------------------|----------------------|----------------------|
| 1- VMQ/ZDMA; 100/30 | 0.03199 | 0.30235 | 0.15873 | 5.14 | 1.36x10^7 | 5.14 | 0.34 |
| 2- 30% SiO2/ RTV-1 SiR | 0.03617 | 0.34187 | 0.19093 | 5.14 | 1.70x10^7 | 5.14 | 0.42 |
| 3- Silicone rubber + 12% magnetite | 0.01922 | 0.18162 | 0.09535 | 7.87 | 4.05x10^6 | 5.1 | 10.09 |
| 4- Silicone Rubber (Polysiloxane) | 0.01815 | 0.17150 | 0.09003 | 9.59 | 2.31x10^9 | 5.68 | 57.52 |
| 5- PDMS/20% HAp composites | 0.01642 | 0.15521 | 0.08149 | 10.95 | 5.61x10^9 | 6.28 | 139.7 |
| 6- SIBSTAR 103T | 0.00935 | 0.08836 | 0.04639 | 15.00 | 3.99x10^11 | 10.54 | ~ |
| 7- PSN4 | 0.00415 | 0.03918 | 0.02057 | 15.00 | 3.65x10^13 | 15.00 | ~ |

Figure 17 (a) shows the boundary conditions for the fixed support locations and the applied air pressure required to run the soft artificial heart, using transient repeated and continuous pressure values of 200 Pa for durations of 0.5 seconds followed by an absorption pressure of -50 Pa for 0.3 seconds; to simulate the diastolic and systolic process that occur in a natural heart, taking about 0.8 second per pulse.

Figure 17 (b) shows that the resulting maximum equivalent (von-Mises) stress distribution for the soft artificial heart was equal to 0.292 MPa, which represents five times the required stress (offering a safety factor = 5), and thus ensuring the high performance of the artificial heart in different circumstances.

Figure 18 shows the internal strain energy of the soft artificial heart during external mechanical stresses from daily human activities. The ANOVA analysis of the strain energy for all nanocomposites are given in table 6, using the 2FI power transform model, where an F-value of 42.57 confirms that the model is significant.

![Figure 17](image_url)

**Figure 17. (a) Boundary conditions; (b) Equivalent (von-Mises) stress of the designed soft artificial heart**
Table 6. ANOVA for 2FI power transform model of strain energy

| Source          | Sum of Squares | df | Mean Square | F-value | p-value |
|-----------------|----------------|----|-------------|---------|---------|
| Model           | 0.0008         | 3  | 0.0003      | 42.57   | 0.0059  |
| A-Tensile strength | 0.0006     | 1  | 0.0006      | 98.72   | 0.0022  |
| B-Elongation at break | 0.0000    | 1  | 0.0000      | 5.73    | 0.0965  |
| AB              | 0.0002         | 1  | 0.0002      | 41.59   | 0.0076  |
| Residual        | 0.0000         | 3  | 5.996E-06   |         |         |
| Cor Total       | 0.0008         | 6  |             |         |         |

Figure 18. Internal strain energy of the designed soft artificial heart for all nanocomposites

Figure 19 (a) shows the 3D graph of the strain energy values, which decreased with increases in the tensile strength and with decreases in the percentage elongation, reaching a minimum strain energy value of 0.00415 mJ in polyetherimide/silicone (PSN4) advanced nanocomposite elastomer.

Figure 19 (c) shows the 3D graph of the maximum principal elastic strain values, which also decrease with increases in the tensile strength and with decreases in the percentage elongation, reaching a minimum value at 0.02057 mm/mm with polyetherimide/silicone (PSN4) nanocomposite elastomer.

Figure 20 shows the total deformation for the proposed soft artificial heart under the application of external pressurised air equivalent to daily artificial heart mechanical work activities. The ANOVA analysis results are given in table 7; these confirm that the 2FI power transform model F-value, 42.46, implies that the model is significant. Figure 19 (b) shows the 3D graph of the total deformation values, which decrease with increases in the tensile strength and decreases in the percentage elongation, reaching a minimum value as 0.03918 mm with polyetherimide/silicone (PSN4) nanocomposite elastomer.

Table 7. ANOVA for 2FI power transform model of total deformation

| Source          | Sum of Squares | df | Mean Square | F-value | p-value |
|-----------------|----------------|----|-------------|---------|---------|
| Model           | 0.0684         | 3  | 0.0228      | 42.46   | 0.0059  |
| A-Tensile strength | 0.0529     | 1  | 0.0529      | 98.48   | 0.0022  |
| B-Elongation at break | 0.0031    | 1  | 0.0031      | 5.71    | 0.0968  |
| AB              | 0.0223         | 1  | 0.0223      | 41.47   | 0.0076  |
| Residual        | 0.0016         | 3  | 0.0005      |         |         |
| Cor Total       | 0.0700         | 6  |             |         |         |
Figure 19. ANOVA analysis 3D graphs for the soft artificial heart for all proposed nanocomposites

VMQ/ZDMA; 100/30
30% SiO$_2$/RTV-1 SiR
Silicone rubber + 12% magnetite
Silicone Rubber (Polysiloxane)

PDMS20% HAp composites
SIBSTAR 103T
PSN4

Figure 20. Total deformation of the ANSYS soft artificial heart for all investigated nanocomposites
Figure 21 shows the ANSYS model for the maximum principal elastic strain of the proposed soft artificial heart. The ANOVA analysis results are given in table 8; the 2FI power transform model F-value of 37.39 implies that the model is significant.

![ANSYS model images]

**Table 8.** ANOVA for 2FI power transform model of maximum principal elastic strain

| Source          | Sum of Squares | df | Mean Square | F-value | p-value | Significance |
|-----------------|----------------|----|-------------|---------|---------|--------------|
| Model           | 0.0208         | 3  | 0.0069      | 37.39   | 0.0071  | significant  |
| A-Tensile strength | 0.0005        | 1  | 0.0005      | 2.56    | 0.2079  |              |
| B-Elongation at break | 0.0068     | 1  | 0.0068      | 36.52   | 0.0091  |              |
| AB              | 0.0072         | 1  | 0.0072      | 38.85   | 0.0083  |              |
| Residual        | 0.0006         | 3  | 0.0002      |         |         |              |
| Cor Total       | 0.0213         | 6  |             |         |         |              |

**Table 9.** The ANOVA for quadratic power transform model of the stress safety factor

| Source          | Sum of Squares | df | Mean Square | F-value | p-value | Significance |
|-----------------|----------------|----|-------------|---------|---------|--------------|
| Model           | 102.60         | 5  | 20.52       | 13554.06| 0.0065  | significant  |
| A-Tensile strength | 0.7777        | 1  | 0.7777      | 513.70  | 0.0281  |              |
| B-Elongation at break | 0.1549   | 1  | 0.1549      | 102.30  | 0.0627  |              |
| AB              | 0.0433         | 1  | 0.0433      | 28.63   | 0.1176  |              |
| A²              | 1.31           | 1  | 1.31        | 862.53  | 0.0217  |              |
| B²              | 0.0000         | 1  | 0.0000      | 0.0324  | 0.8866  |              |
| Residual        | 0.0015         | 1  | 0.0015      |         |         |              |
| Cor Total       | 102.60         | 6  |             |         |         |              |

Figure 22 shows the ANSYS R18.0 model of the stress safety factor for the proposed soft artificial heart. The ANOVA analysis results are given in table 9, and the 2FI power transform model F-value of 13554.06 implies that the model is significant. Figure 19 (d) shows the 3D graph of the stress safety factor values, which increase with increases in the tensile strength and the percentage elongation, reaching a maximum...
value of 10 to 15 with Silicone Rubber (Polysiloxane), PDMS20% HAp composites, the SIBSTAR 103T, and the polyetherimide/silicone (PSN4) nanocomposite elastomers.

\[
\text{VMQ/ZDMA; 100/30} \quad 30\% \text{ SiO}_2 \text{ RTV-1 SiR} \quad \text{Silicone rubber + 12\% magnetite} \quad \text{Silicone Rubber (Polysiloxane)}
\]

\[
\text{PDMS20\% HAp composites} \quad \text{SIBSTAR 103T} \quad \text{PSN4}
\]

**Figure 2.** Stress safety factor of the ANSYS designed soft artificial heart for all Nanocomposites

The fatigue life endurance limits (\(S_{e}^*)\) in cycle values for the proposed soft artificial heart for all the investigated nanocomposites were calculated as \(= 0.5 \times \) the ultimate tensile stress (\(S_{u}\)) values [28], where

\[
\text{Modified Endurance Limit (S_e) = S_e^* k_a k_b k_c k_d k_e k_f}
\]  

The Surface Condition Factor \((k_a)\) for the grinding surface is equal to

\[
(k_a) = a S_{u}^{b} = 1.58 \times 150 -0.085
\]  

For the bending and torsion size factor \((k_b)\), assuming that the mean diameter of the soft artificial heart is 50 mm,

\[
(k_b) = 1.23 d^{-0.107} = 0.81
\]

and for the same conditions, the loading factor \((k_c)\) for bending and torsion = 1.0 (for bending load) + 0.85 (for axial load)/2. The temperature factor for human life \((k_d) = 1\), while, corresponding to 8% standard deviation of the endurance limit, and 99% reliability, the reliability factor \((k_e) = 0.82\), with a miscellaneous-effects factor \((k_f) = 1\). Thus, fatigue life, measured as the number of cycles to failure \((N)\) at the given fatigue stress \((\sigma)\) is found by

\[
N = \left(1 /a\right)^{1/b}
\]  

For \(S_u < 490\) MPa; \(f = 0.9\), then

\[
a = \left(f S_{u}\right)^{2} /S_{e}
\]  

\[
B = -1/3 \log \left(f S_{u} /S_{e}\right)
\]  

Figure 23 shows the AANSYS model of fatigue life stress for the proposed soft artificial heart under a Goodman ratio loading, using transient repeated and continuous applied air pressure values of a 200 Pa for
durations of 0.5 seconds followed by an absorption air pressure of -50 Pa for 0.3 seconds to simulate the diastolic and systolic processes in the natural heart at each pulse. The ANOVA analysis results are given in table 10; the 2FI power transform model F-value of 401.00 implies that the model is significant. Figure 19 (e) shows the 3D graph of the fatigue life values, which are increased with increases in the tensile strength and decreases in the percentage elongation, reaching a maximum value of $2.31 \times 10^9$ to $3.65 \times 10^{13}$ cycles, when using Silicone Rubber (Polysiloxane), PDMS 20% HAp composites, SIBSTAR 103T, and polyetherimide/silicone (PSN4) nanocomposite elastomers. The fatigue life for the proposed soft artificial heart in years, with one year being equal to 366 Days x 24 Hours x 3600 Seconds x 1.27 Pulses/Second = $40.16 \times 10^6$ pulses; the four main nanocomposite elastomers thus offer many years of action.

Table 10. The ANOVA for 2FI model fatigue life

| Source                   | Sum of Squares | df  | Mean Square | F-value | p-value | p-value |
|--------------------------|----------------|-----|-------------|---------|---------|---------|
| Model                    | 1.135E+27      | 3   | 3.783E+26   | 401.00  | 0.0002  | significant |
| A-Tensile strength       | 1.160E+26      | 1   | 1.160E+26   | 122.99  | 0.0016  |          |
| B-Elongation at break    | 1.132E+26      | 1   | 1.132E+26   | 119.93  | 0.0016  |          |
| AB                       | 1.156E+26      | 1   | 1.156E+26   | 122.54  | 0.0016  |          |
| Residual                 | 2.830E+24      | 3   | 9.435E+23   |         |         |          |
| Cor Total                | 1.138E+27      | 6   |             |         |         |          |

Finally, figure 24 shows the ANSYS models of the fatigue safety factor for the artificial heart in each material. The ANOVA analysis results are given in table 11, and the 2FI power transform model F-value of 226.56 implies that the model is significant. Figure 19 (f) shows the 3D graph of the fatigue safety factor values, which increase with increases in the tensile strength and the percentage elongation, reaching a maximum value of 10 or 15, when using SIBSTAR 103T and polyetherimide/silicone (PSN4) nanocomposite elastomers, respectively.
In the current work, the main conclusions are

1. The modelling and analysis of a new generation soft artificial heart to replace the living heart permanently can be supported by establishing 3D projections for curvature, ordinary formation, inner diaphragms, the right and left ventricles, and the drag and air pressure zone sections necessary for the soft artificial heart mechanisms.

2. The model geometry implemented showed that the maximum total volume of the soft artificial heart = 2.6663x10^5 mm³ and the net weight was 293gm, while the total weight filled with blood and air was 577 gm, close to the measurements of a living heart, making this artificial heart a candidate for being a true permanent replacement.

3. To simulate the modelled soft artificial heart, different mechanical (ANSYS) analysis systems were used to determine the dynamic response during the activity of the blood flow cycles.

4. The ANSYS Fluent analysis system can be used to solve the computational fluid dynamics (CFD) of the blood flow simulation, with a maximum level of absolute pressure applied on the ventricles and air pressurised chamber and the whole artificial heart; the displayed and animated graphs both showed that the performance of the heart is adequate at all stages.

5. The results show that the strain energy, the total deformation, and the maximum principal elastic strain values were decreased with increases in the tensile strength and decreases the percentage elongation,

Table 11. ANOVA for 2FI model fatigue safety factor

| Source          | Sum of Squares | df  | Mean Square | F-value | p-value |
|-----------------|----------------|-----|-------------|---------|---------|
| Model           | 86.59          | 3   | 28.86       | 226.56  | 0.0005  |
| A-Tensile strength | 45.71          | 1   | 45.71       | 358.80  | 0.0003  |
| B-Elongation at break | 2.49          | 1   | 2.49        | 19.56   | 0.0215  |
| AB              | 0.3686         | 1   | 0.3686      | 2.89    | 0.1875  |
| Residual        | 0.3822         | 3   | 0.1274      |         |         |
| Cor Total       | 86.98          | 6   |             |         |         |

Figure 24. Fatigue safety factor (in cycles) of the soft artificial heart for all nanocomposites
reaching minimum values as 0.00415 mJ, 0.03918 mm, and 0.02057 mm/mm, respectively, when using polyetherimide/silicone (PSN4) nanocomposite elastomer.

6. The fatigue safety factors values were increased with increases in the tensile strength and the percentage elongation, reaching maximum values of 10 and 15, when using SIBSTAR 103T and polyetherimide/silicone (PSN4) nanocomposite elastomers, respectively.

7. The fatigue life values also increased with increases in the tensile strength and decreases in the percentage elongation, reaching maximum values of $2.31 \times 10^9$ to $3.65 \times 10^{13}$ cycles, when using Silicone Rubber (Polysiloxane), PDMS20% HAp composites, SIBSTAR 103T, and the polyetherimide/silicone (PSN4) nanocomposite elastomers.

8. Further work is required to fabricate the proposed soft heart with the appropriate geometrical dimensions to meet the needs of different patients, and a testing system necessary to evaluate the performance of such a prototype in accordance with the relevant international standards organisations such as the FDA and ISO must also be developed.

References

[1] Brian B, Nuno R, David D, Robert L T and Ellen K, 2014 The Living Heart Project: A robust and integrative simulator for human heart function, European Journal of Mechanics A/Solids, 48, 38-47.
[2] Davy K P and Seals D R, 1994 Total blood volume in healthy young and older men, J. Appl. Physiol., 76(5), 2059-62.
[3] Sophie Collin, 2018 Preoperative planning and simulation for artificial heart implantation surgery. Signal and Image processing. Ph.D. thesis, University of Rennes.
[4] Robert E and Michler M D, 2013 Stem Cell Therapy for Heart Failure, Methodist DeBakey Cardiovasc J., 9 (4), 1-8.
[5] American Heart Association, 2002 The Mechanical Heart celebrates 50 lifesaving years.
[6] Martha S Lundberg, Timothy B J, and Denis B B, 2017 Building a bioartificial heart: Obstacles and opportunities, The Journal of Thoracic and Cardiovascular Surgery c, 748-750.
[7] Akshay P, Lianjun W, and Yonas T, 2014 Artificial heart for a humanoid robot, Electroactive Polymer Actuators And Devices, I, 1-16.
[8] Mohammed E S, Ali M A, 2016 Study of an Artificial Heart: Design and Simulation, Research Gate publication, No.297013927, 1-9.
[9] Stenberg M, 2006 Concept design and In Vitro evaluation of a novel dynamic displacement Ventricular Assist Device, A thesis in Technology and Health, University of Florida, USA.
[10] Slepian M J, Marvin J S, Yared A, Silva S, Richard G S, Shmuel E, Danny B, 2013 The Syncardia™ total artificial heart: in vivo, in vitro, and computational modeling studies, Journal of Biomechanics, 46, No.2, 266-275.
[11] Italian Man Surpasses, 1,000 Days of Support with SynCardia’s Total Artificial Heart, https://www.businesswire.com/news/home/20101012005771/en/Italian-Man-Surpasses-1000-Days-Support-SynCardia%E2%80%99s.
[12] Langer R M, Vladimir P and Demikhov, 2011 A pioneer of organ transplantation, Transplant Proc., 43 (4), 1221-1222.
[13] Gino Gerosa, Silvia Scuri, Laura Iop, Gianluca Torregrossa, 2014 Present and future perspectives on total artificial hearts, Ann Cardiothorac Surg, 3 (6), 595-602.
[14] Silvay G and Castillo J G, 2013 Heysham Gibbon and the 60th anniversary of the first successful heart-lung machine: brief notes about the development of cardiac surgery in Europe and Slovakia, Bratisl Lek Listy., 114 (5), 247-50.
[15] Marvin J and Slepian M D, 2011 The Syncardia Temporary Total Artificial Heart- Evolving Clinical Role and Future Status, Heart Failure, 39- 46.
[16] Cohrs N H, 2018 Silicone Elastomers for Artificial Hearts: 3D-Printing, Bioactive Glass and Potential, Ph.D. thesis, ETH Zurich.
[17] Cohrs N C, Petrou A, Loepfe M, Yliruka M, Schumacher C M, Kohl A X, Starck C T, Schmid Daners M, Meboldt M, Falk V, and Stark W J, 2017 A soft Total Artificial Heart - First Concept Evaluation on a Hybrid Mock Circulation, *Artificial Organs*. doi: 10.1111/aor.12956.

[18] Mitra M, Editorial on Advances in Artificial Heart, *Ann Heart*, 3 (1), 51-52.

[19] Jafari M, Toloei A, Ghasemlu S, and Parhizkar H, 2014 Simulation of Store Separation Using Low-Cost CFD with Dynamic Meshing, *IJE TRANSACTIONS B: Applications*, 27, No. 5, 775-784.

[20] Bareiro O Santos L, 2012 A Poly (Dimethyl Siloxane)/ Tetraethyl Orthosilicate Modified Hydroxyapatite Composites: Surface Energy, Roughness and Mechanical Performance, 56th Brazilian Congress of Ceramic 1st Latin-American Congress of Ceramic IX Brazilian Symposium on Glass and Related Materials, 1787-1798.

[21] Meng Y, Wei1 Z, Lu Y L and Zhang L Q, 2012 Structure, morphology, and mechanical properties of polysiloxane elastomer composites prepared by in situ polymerization of zinc dimethacrylate, *Polymer Letters*, 6, No.11, 882–894.

[22] Lianfeng W, Xianming W, Liang N, Jianjun H, Zhong W, Min L, 2016 Improvement of silicone rubber properties by addition of nano-SiO2 particles, *J Appl Biomater Funct Mater*, 14 (1), 11-14.

[23] Dragoş V B, 2014 Magnetic Elastomers Based on Nanocrystalline Magnetite Particles, The Scientific Bulletin of Valahia University, *Materials and Mechanics*, 9, 53-56.

[24] Goy T L, Stephanie A V, Cherie R, Mary M E, Judit E P, Walter I H, Steven P S, 2013 New biomaterial as a promising alternative to silicone breast implants, *Journal of the mechanical behavior of biomedical materials*, 21, 47 – 56.

[25] Mishra R M and Rai J S P, 2016 Polyetherimide (PEI)/Silicone Rubber Composite Reinforced with Nanosilica Particles, *International Journal of Scientific and Technology Research*, 5, (3), 176-180.

[26] Cheng K, James W, Miguel A S, and Tetsuzo A, 1977 The design and fabrication of a new total artificial heart. *Cardiovascular diseases*, 4, No. 1, 7-17.

[27] Abbaspour S, and Sadrnezaad S K, 2018 Loading Drug on Nanostructured Ti6Al4V-HA for Implant Applications, *IJE TRANSACTIONS B: Applications*, 31, No. 8, 1159-1165.

[28] Shigley J E, Mischke C R, 2006 Mechanical Engineering Design, *McGraw-Hill Inc.*, 8th ed.

[29] Soleimani S, Pennati G and Dubini G, 2014 A Study on Ratio of Loss to Storage Modulus for the Blood Clot, *IJE TRANSACTIONS B: Applications*, 27, No. 8, 1167-1172.

[30] https://www.timcorubber.com/rubber-materials/silicone-rubber/properties/

[31] http://www.onlinebiologynotes.com/blood-compositionproper-ties-functions/