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DESIGN AND DEVELOPMENT OF A MAGNETICALLY-DRIVEN VENTRICULAR ASSIST DEVICE (MVAD): IN VITRO IMPLEMENTATION IN THE FONTAN CIRCULATION

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Abstract. A rapidly testable novel Magnetically-Driven Ventricular Assist Device (MVAD) with no moving parts that can be used to provide assistance to the cardiovascular circulation while reducing caval pressure in patients who have undergone the Fontan procedure to palliate the Hypoplastic Left Heart Syndrome (HLHS) is proposed and studied. A benchtop Mock Flow Loop (MFL) of the cardiovascular circulation with a Fontan total cavopulmonary connection (TCPC) is configured to validate this hypothesis. The MFL is based on a Lumped-Parameter Model (LPM) comprised of upper and lower systemic circulation as well as left and right pulmonary circulation compartments. Needle valves are used to accurately replicate vascular resistance (R) while compliance chambers are used to mimic vascular compliance (C). The MFL centerpiece is the truncated aortic arch with an implanted MVAD. A ferro-fluid solution is mixed in water to simulate magnetically-charged blood. The pulsating flow is induced by drawing the ferro-fluid from a main reservoir with a Harvard Apparatus Medical pump while the MVAD provides assistive momentum to the TCPC. Flow and pressure sensor data at specific points in the MFL are acquired via a National Instruments multichannel data acquisition board and processed using LabView. Different prototypes of the MVAD are tested to validate the hypothesis.

1 INTRODUCTION

Around 8% of all newborns with a Congenital Heart Defect (CHD) have a single functioning ventricle. This condition is known as the Hypoplastic Left Heart Syndrome (HLHS) where the malformation of the left ventricle renders it minimally or non-functional and therefore the right ventricle is overloaded as it pumps both oxygenated and deoxygenated blood to parallel pulmonary and systemic circulations. As a result, research has been conducted towards the reduction of the load from the single ventricle. This can be achieved by establishing a connection between the systemic and pulmonary circulation resulting in a single univentricular pump powering the entire circuit, [1].

1.1 Palliative Procedure

A surgery is performed in three sequential stages to mitigate the flow pattern of HLHS:

Stage 1: Norwood
Stage 2: Glenn/Hemi-Fontan
Stage 3: Fontan

The Fontan operation has served as the 3rd stage palliation for this anomaly for decades but the surgery entails multiple complications and survival rate is less than 50% by adulthood. In this procedure, the Inferior Vena Cava (IVC) is disconnected from the right atrium and connected directly to the pulmonary arteries for a Total Cavopulmonary Connection (TCPC), [1]. This results in total passive drainage of the caval blood flow to the pulmonary circulation and therefore relieving the single ventricle from pumping blood to the pulmonary circulation.

1.2 Post-Fontan Paradox

The Fontan procedure often leads to multiple complications and survival rate of patients is of less than 50% by adulthood. The circulatory pattern of the patient can fail, even in patients with relatively good ventricular function. Pharmacological therapies have variable success and the probability of successful outcome with heart transplantation is low, [2,3].

1.3 Hypothesis

A novel alternative is proposed by creating a Magnetically-driven Ventricular Assist Device (MVAD) with no moving parts that can be used to provide assistance to the cardiovascular circulation while reducing the caval pressure. A bench top Mock Flow Loop (MFL) of the cardiovascular circulation with a Fontan TCPC coupled with the MVAD is configured to validate this hypothesis.

2 GOVERNING EQUATIONS

A ferro-hydrodynamic (FHD) model, based on the Navier-Stokes equation, to estimate the average ferro-flow velocity is developed. This model considers effective viscosity, magnetic flux density and volumetric concentration of the ferrous particles in the fluid. In this section, the governing equations to model the coupled problem provided by the fluid and the magnetic domain are discussed.

2.1 Fluid Flow Equations

The velocity field u of the fluid domain is governed by the Navier-Stokes equations such that,

$$\rho\left(\frac{\partial u}{\partial t}+u.\nabla u\right) = -\nabla p+\boldsymbol{F}+\mu(\nabla^2 u) \tag{1}$$

Where $\boldsymbol{F}$ is the Volumetric Body Force exerted on the fluid. In the case of this experiment, the MVAD produces this body force as a result of the magnetic field acting on the ferrous nanoparticles.

2.2 Magnetic Force Equations

The magnetic force can be calculated such that,

$$\boldsymbol{F} = (m\cdot\nabla)\boldsymbol{B} \tag{2}$$

Where **m** is the magnetic dipole moment and **B** is the magnetic flux density provided by the inductance of the electromagnetic coil. The magnetic flux density is directly proportional to magnetic intensity with permeability constant, μ, for a particular medium, where,

$$\boldsymbol{B} = \mu H \tag{3}$$

In this case, the working domain for the electromagnet is air, which has a permeability constant of 1.00000037. The following Maxwell field equations are used to quantify the magnetization effect of the developed electromagnet prototype:

$$\nabla\cdot\boldsymbol{B} = 0 \tag{4}$$

$$\nabla\times\boldsymbol{B} = \mu J+\mu\varepsilon\frac{\partial E}{\partial t} \tag{5}$$

$$\nabla\cdot\boldsymbol{E} = \rho/\varepsilon \tag{6}$$

$$\nabla\times\boldsymbol{B} = -\frac{\partial B}{\partial t} \tag{7}$$

Equations (4) and (5) are known as magnetostatics equations and equations (6) and (7) are known as electrostatics equations. By using the Helmoltz theorem, it is known that **B** is an irrotational vector which can be expressed as,

$$\boldsymbol{B} = -\mu\nabla\varphi \tag{8}$$

Where φ is known as the magnetic scalar potential. The material property of the developed electromagnet depends on the magnetic moment, **m**. The magnetic susceptibility of a material within a magnetic field determines the tendency of the material to form a magnetic dipole. The magnetic susceptibility of iron is $3\text{x}10^4$. Hence, the magnetic flux density can be rewritten as,

$$\boldsymbol{B} = \mu(1 + X)\mathrm{H} \tag{9}$$

The magnetization vector **M** which determines the net magnetic dipole of the material can be calculated as,

$$J = \nabla \times \boldsymbol{M} \tag{10}$$

Hence, the magnetization vector can be defined as,

$$M = X\boldsymbol{H} \tag{11}$$

Therefore, by using the above equations, one may obtain the magnetic flux density provided by the electromagnet as,

$$\boldsymbol{B} = \mu\boldsymbol{H} + \boldsymbol{B_{rem}} \tag{12}$$

Where B_{rem} is the remnant flux density.

3 COMPUTATONAL FLUID DYNAMICS

An axisymmetric model of the magnetic inductor used to propel the ferro-fluid within the flow field is developed using COMSOL Multiphysics® Modeling Software. The geometry consists of four different domains with distinctly selected material properties. To represent the accurate mixture of the working fluid which constitutes the water as the main carrier fluid and ferro-fluid as the dispersed phase fluid in the water medium the “Mixture mode” is selected in the software. Through this mode, the volume fraction and velocity of the two fluids of different phases can be controlled by tuning the velocity components *u* and *v,* the pressure *p*, and volume fraction, Φ. This model relies on the following equation to solve for the output.

$$\rho\left(\frac{\partial \boldsymbol{u}}{\partial t}\right) + \rho(\boldsymbol{u}\cdot\nabla)\boldsymbol{u} = -\nabla p - \nabla\cdot\left(\frac{p\Phi_d\rho_d}{\rho\left(1-\frac{\Phi_d\rho_d}{\rho}\right)}\right)\boldsymbol{u}_{slip}\boldsymbol{u}_{slip} + \nabla\cdot(\eta[\nabla\boldsymbol{u}+\nabla\boldsymbol{u}^{\boldsymbol{T}}]) + \rho g + \boldsymbol{F} \tag{13}$$

Where ρ is the mixture density, η is the dynamic viscosity, and *p* is the mixture pressure. In this experiment, the force **F** is coupled with the magnetic force provided by the electromagnets. Hence, this volumetric body force is the resultant of two components that are calculated in the “Magnetostatics” module of the software using the following equations:

$$F_{tx} = \Phi_d\left[\left(M_x\frac{\partial^2 A_z}{\partial x^2} + M_y\frac{\partial^2 A_z}{\partial x\partial y}\right) + \frac{X}{\mu_o}\left(\frac{\partial A_z}{\partial x}\frac{\partial^2 A_z}{\partial x^2} + \frac{\partial A_z}{\partial y}\frac{\partial^2 A_z}{\partial x\partial y}\right)\right] \tag{14}$$

$$F_{ty} = \Phi_d\left[\left(M_x\frac{\partial^2 A_z}{\partial x\partial y} + M_y\frac{\partial^2 A_z}{\partial y^2}\right) + \frac{X}{\mu_o}\left(\frac{\partial A_z}{\partial x}\frac{\partial^2 A_z}{\partial x\partial y} + \frac{\partial A_z}{\partial y}\frac{\partial^2 A_z}{\partial y^2}\right)\right] \tag{15}$$

Where A_z is the magnetic potential.

4 EXPERIMENTAL SETUP

4.1 Benchtop Model

A benchtop Mock Flow Loop (MFL) is designed to resemble the cardiovascular system of the target population for the palliative procedure, using a Lumped-Parameter Model (LPM) of the Fontan circulation anatomy with four branches, or lumps. These lumps represent the upper and lower systemic circulations as well as the left and right pulmonary circulations. Each lump is comprised of an area-reducing needle valve and a flow accumulator to model vascular resistivity and vascular compliance respectively. The MFL is driven by a Harvard Apparatus pulsatile pump.

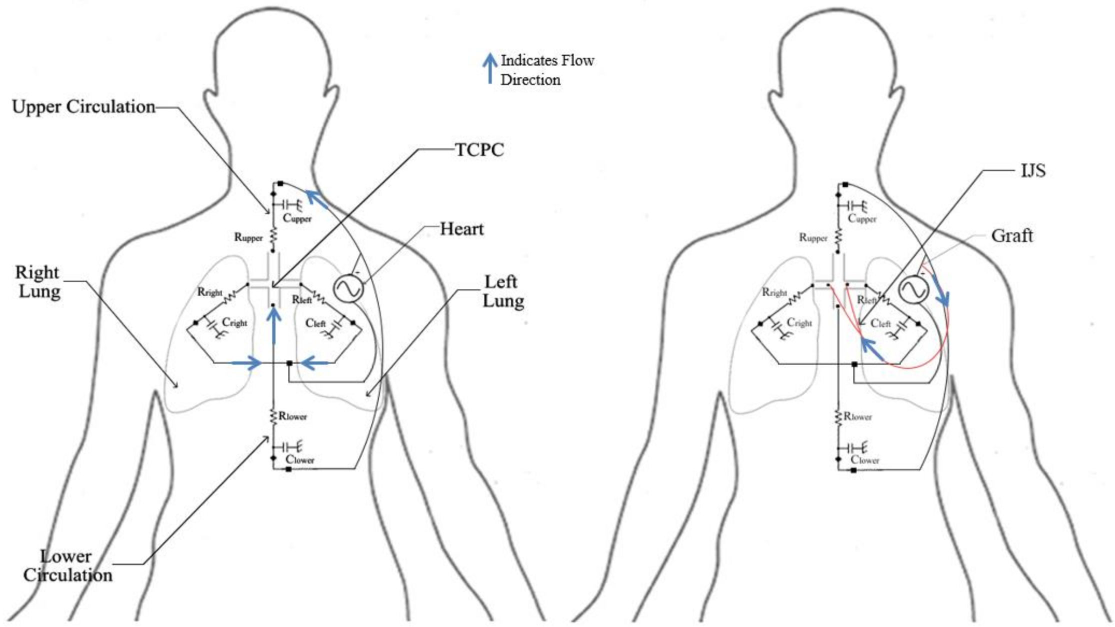

Figure 1: Lumped Parameter Model of the Body

It is important to note that the MFL is not an artificial equivalent of patient anatomy but rather represents an observable analogy of the anatomy, producing flow behavior that is physiologically relevant and accurate.

4.2 Dimensional Analysis

As the MFL will be operated using water instead of blood, it is important to match non-dimensional parameters to ensure physiologically relevant behavior. These non-dimensional parameters include the Womersley number, denoted α, and the Reynolds number, denoted Re. These non-dimensional parameters are matched by adjusting the Harvard Pump settings based on the MFL geometry. This process is described in [3].

4.3 Ferro-fluid

A Ferro-fluid is produced using an appropriate ratio of Ferrous Chloride ($FeCl_2^-$) and Ferric Chloride ($FeCl_3$) solutions mixed together in a base solution of ammonia (NH_3). The solution is kept at a steady temperature of around 50 degrees Celsius by resting on a hot plate under constant homogenization. Oleic Acid is used as a surfactant to inhibit clumping. The solution is centrifuged to eliminate ammonium hydroxide and to segregate the magnetite particles. The excess liquid is then replaced with Polyethylene Glycol (PEG). The diameter of the ferro-fluid particles is determined by placing a sample of the solution onto a silicon wafer for an examination in a Scanning Electron Microscope (SEM). The ferro-fluid sample is sputter coated with gold particles. For further investigation, the sample was put under a localized Energy-dispersive X-ray spectroscopy (EDX).

4.4 Magnetically-driven Ventricular Assist Device (MVAD)

According to equations (1) and (2), it can be seen that in order to maximize the acceleration of the fluid, one must maximize the magnetic flux density, or gauss (G) affecting the ferro-fluid. Additionally, it is imperative to minimize any obstruction of the flow due to the structure of the MVAD. To do so, the MVAD is essentially constructed by winding magnet wire around a hollow cylinder, which will be seated around the flow field, similar in fashion to an arterial stent. In the experimental development of the MVAD, several designs were considered with respect to core materials and winding configuration and then tested using a Gaussmeter. In all cases, 28 AWG copper wire was used.

5 RESULTS

The results of the prescribed experimentation are summarized as follows.

5.1 Ferro-fluid

The average diameter of the particles is 147 nm (see Fig. 3).

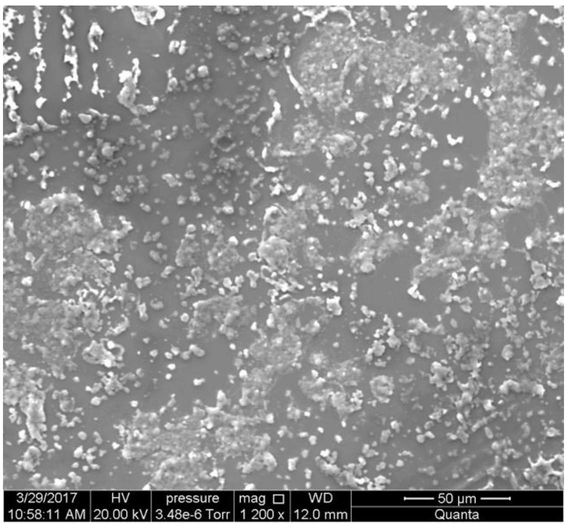

Figure 2: Sample under SEM with Quanta of 50 μm and magnification factor of 1200

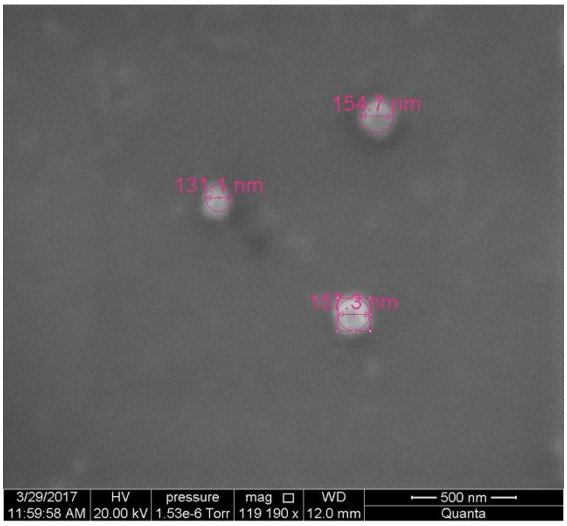

Figure 3: Nanoparticles under SEM with magnification factor of 119190

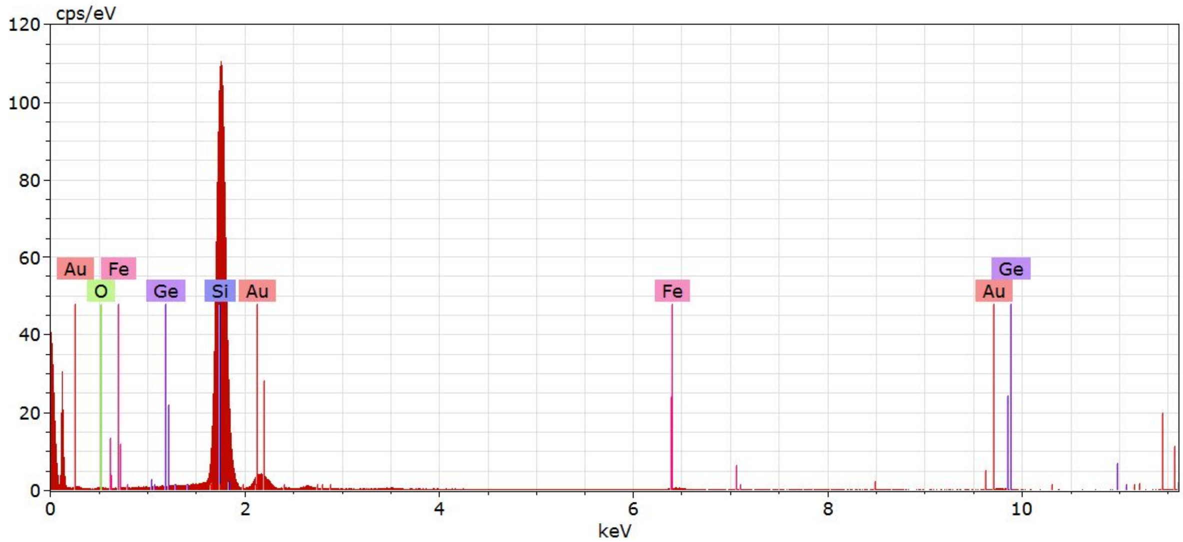

Figure 4: Distribution of elements present in EDX sample along with their energy levels

Table 1: Elements present in EDX sample and respective normalized weights

Element	Atomic Number	Normalized Weight (%)
Silicon	14	82.4
Gold	79	9.6
Oxygen	8	3.3
Germanium	32	2.8
Iron	26	2.0

It can be seen in Fig. 4 that the sample contains iron (Fe) particles at two different energy levels, (K_{α} and L_{α}) along with germanium (Ge) and other chemicals in small amounts. The gold (Au) detected in the EDX sample is a result of the sputter coating of the particles. Also, the silicon (Si) results from the silicon wafer on which the specimen is placed.

5.2 Magnetically-driven Ventricular Assist Device (MVAD)

Important observations were made on the subject of electromagnet core materials and winding configuration. Two materials were tested for suitability as the annular base material around which the electromagnet will be wrapped. The first, a steel pipe representative of ferrous based cores. The second, a PVC pipe used to observe non-ferrous core behavior.

Rather counter-intuitively, ferrous based cores proved ill-suited to this application. The ferrous core behaved as a sort of Faraday cage, absorbing the magnetic field generated by the inductive coil. This produced a large magnetic flux density within the bounds of ferrous material itself, but reduced the measureable Gauss present at the center of the annulus, the domain through which the fluid would flow. Due to this, a non-ferrous material is used in the construction of the MVAD core.

It was observed that a singular winding does generate sufficient magnetic flux density to appreciably accelerate the ferro-fluid. Therefore, several variations in wire wrapping, utilizing multiple strands of wire were tested. It was determined that by wrapping several layers of coils, each layer wrapped around the previous layer with wires in parallel circuits to another, one could achieve higher Gauss ratings within the fluid domain at lower power requirements.

Finally, to prevent suspension of the ferrous particles within the magnetic field, several sets of coils are placed along the length of the test section and are sequentially activated to propel the flow.

6 CONCLUSIONS

A Magnetically-Driven Ventricular Assist Device (MVAD) to provide assistance to the cardiovascular circulation while reducing the caval pressure is implemented in computational and benchtop experiments. A benchtop Mock Flow Loop (MFL) of the cardiovascular circulation with a Fontan total cavopulmonary connection (TCPC) is configured. A ferro-fluid solution is mixed in water to simulate magnetically-charged blood. The average ferro-fluid particle diameter produced is approximately 150 nm rendering it suitable for this application as it allows the particles to separate under the presence of an external magnetic field. The pulsating flow is induced by drawing the ferro-fluid from a main reservoir with a Harvard Apparatus Medical pump while the MVAD provides assistive momentum to the TCPC. A functioning MVAD prototype is implemented resulting in observable acceleration of the ferro-fluid. While the MVAD is operable and the non-ferrous core is advantageous to this application, further development must ensue due to the inability of thermoplastics to operate in close proximity to the heat dissipated by the current carrying wire.

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