Magnetic Levitation Design for the PediaFlow™ Ventricular Assist Device

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Abstract—Over the past few decades, we have seen a tremendous progress in the development of implantable ventricular assist devices (VAD). The central part of the device is a magnetically levitated rotating pump which creates a pressure rise (~100mmHg) at a required flow rate (~0.5L/min) suitable for infants and small children. We have considered several different pump topologies, of which an axial mixed-flow pump configuration was chosen for further development. The pump impeller is supported by two radial permanent-magnet passive bearings. The rotor-dynamics analysis of the pump shows that the critical speeds of the pump are affected by the radial and yaw stiffnesses of the PM bearings. Hence, analytical expressions for the stiffnesses are derived and verified through FEA. In contrast to the radial suspension, the axial motion of the impeller is actively controlled using a voice-coil actuator. A toroidally-wound motor drives the pump with high efficiency and little additional negative radial stiffness. The design process relies heavily on optimization at the component-level and system-level. The preliminary results of the design optimization are presented in this paper.

I. INTRODUCTION

According to recent statistics, approximately 30,000 new cases of congenital heart disease (CHD) occur each year. The annual mortality is 5,000 to 6,000, and at least 20% of these patients die due to perioperative ventricular failure, progressive cardiomyopathy, or complications following cardiac transplant. There are also pediatric patients with a potentially “recoverable” heart, who either die without the opportunity for mechanical support or must rely on extracorporeal membrane oxygenation (ECMO), the current method of short-term support, which results in ongoing complications such as cytokine activation, altered hemostasis, risk of infection, among others.

These groups of patients would benefit from the availability of ventricular assist device (VAD) specifically designed for infants and young children. Patients that can be successfully supported via a pediatric VAD will become candidates for heart transplantation, and our experience suggests that these candidates will undergo transplantation well within 6 months. The use of a pediatric VAD for bridge-to-recovery applications represents a new therapeutic option, currently not available to pediatric cardiologists and pediatric cardiac surgeons.

Over the past few decades, we have seen a tremendous progress in the development of ventricular assist devices (VAD) for adult patients. As a result of this progress, there are several positive-displacement VADs on the market: HeartMate LVAS from Thoratec, “Thoratec VAD” also from Thoratec, and Novacor from WorldHeart, to name a few. More recently, number of turbodynamic blood pumps have been developed, and are currently being evaluated clinically (namely, the MicroMed DeBakey VAD, the HeartMate II LVAS, the Jarvik 2000, and the Ventracor by Ventassist). Over the past three decades, thousands of the adult heart failure patients have been supported by one of these VADs.

The number of pediatric patients treated over the same period are almost two orders of magnitude smaller (for example [1], [2]). The vast majority of these patients were teenagers (median weight, approximately 55 kg). With the exceptions of the MEDOS HIA VAD (MEDOS Medizinotechnik AG, Stolberg, Germany) and the Berlin Heart VAD (Berlin Heart AG, Berlin, Germany), most of devices that have been clinically used or are under development are not suitable for infants.

The lack of the VADs specifically designed for infants and the potential benefit of such devices prompted us to develop a pediatric ventricular assist device that satisfies the following design requirements.

- Chronic support (up to 6 months) of patients from birth to 2 years of age (3 kg to 15 kg body weight)
- fully implantable (versus paracorporeal) device with only a small caliber percutaneous lead crossing the skin for energy transmission
- minimal blood damage

An artistic rendering of such a device is illustrated in Fig. 1.
The central part of the device is a magnetically levitated rotating pump which creates a necessary pressure rise (∼100mmHg) at a target flow rate (∼0.5L/min). In this paper we describe the selection process of pump topologies, and the optimization of the suspension system.

II. SELECTION OF THE DESIGN TOPOLOGY

In addition to the fundamental hemodynamic performance cited above (pressure rise and flow rate), a successful pediatric heart pump must satisfy a number of requirements specific to the application in the body. Chief amongst these are avoidance of damage, and overall form factor suitable for the anatomy of these small patients. We have considered three pump topologies to meet these requirements: a symmetric dual–impeller centrifugal configuration, an asymmetric single–impeller centrifugal configuration, and a mixed–flow impeller configuration. These three pump topologies are illustrated in Fig. 2.

Preliminary analyses of the turbodynamics, magnetic suspension, thermal dissipation, and rotordynamics were conducted. Based on the preliminary designs, a weighted objective analysis was formulated and implemented. The analysis facilitates objective comparison of system configuration by identifying, ranking, and quantifying highly interdependent characteristics such as:

- anatomic compatibility – maximum size, inlet/outlet direction, shape/form factor
- biocompatibility – areas of local circulation, blood wetted surface area, number of blind crevices, number of wetted seams
- suspension robustness – critical speed margin, estimated shock tolerances, estimated performance of touchdown bearings, required sensor accuracy
- manufacturability – number of components, number of seams/welds, machining complexity, tolerance stack–up, estimated cost
- fluid dynamics performance – H-Q characteristics, efficiency characteristics, blade numbers, etc.

A composite index was generated and used to objectively/quantitatively compare pump topology options. As a result of this analysis, the axial mixed–flow impeller (AMF) pump configuration was selected for detailed design and fabrication of the first prototype.

III. PM BEARING MODELS AND ROTOR DYNAMICS

A. Permanent–Magnet Radial Bearings

The central part of the pump is the magnetically suspended impeller. We used both passive and active suspension. The six degrees–of–freedom of the rotor motion are controlled as follows: two radial DOFs and pitch and yaw are controlled by passive PM bearings, the axial motion, unstable due to the radial bearings is actively controlled with a voice coil actuator and the roll motion is driven by a DC brushless motor. The approach of combining passive and active suspension has been used in the team’s earlier work on adult-size heart pumps (Streamliner™ [3] and HeartQuest™ [4]).
There are two possible configuration for the passive radial bearings: axially polarized arrays and Halbach arrays. These two types are illustrated in Fig. 3. In order to discriminate between these two options, the load capacity and the stiffness of each configuration were estimated. For an axially polarized bearing, Yonnet et. al. [5] approximated the radial stiffness of the array from the stiffness of the single-layer passive bearing. Paden et. al. [6] extended the results of Backers [7], and provided an analytical expression for the load capacity and the stiffness of the axially polarized array.

Although they are very useful for design purposes, the analytical expressions in [5] and [6] are approximate and not suitable for Halbach configuration. Chen et. al. [4] used a more accurate (albeit more complex) approach by replacing the permanent magnets with the equivalent “current sheets” and summing the forces between the current sheets. This approach works well for both types of radial bearings and is adopted in this paper for the calculation of load capacity and radial stiffness.

To fully describe the dynamics of the suspension system, we need to consider the angular motion (yaw motion) as well as the translational motion. A slight yaw of the rotor array with respect to its geometric center creates both radial and axial motion (see Fig. 4). If we assume that the array is axially thin ($L_b \ll R$), the axial contribution to the yaw stiffness can be obtained by integrating the torque on a circumferentially infinitesimal segment $R d \theta$ of the rotor array due to the axial motion. For a small yaw angle, this torque can be approximated as

$$\tau_{yaw,axial} = \frac{K_z}{2} R^2 \phi$$  \hspace{1cm} (1)

where $K_z$ is the axial stiffness of the bearing. The radial motion due to the small yaw rotation $\phi$ can be approximated by $z \phi$ where $z$ is the distance from the bearing center. The radial force on the axially infinitesimal section of $dx$ would then be $K_r z \phi dz/L_b$. Integrating this force multiplied by the moment arm along the length of the bearing, we can obtain the torque as

$$\tau_{yaw,radial} = \frac{K_r}{12} L_b^2 \phi$$  \hspace{1cm} (2)

According to Earnshaw’s theorem [8], the axial stiffness $K_z$ is related to the radial stiffness $K_r$ as

$$K_z = -2K_r$$  \hspace{1cm} (3)

Therefore the total yaw stiffness of the radial passive bearing can be approximated as

$$K_{\phi} = \frac{1}{12} \left( L_b^2 - 3D_b^2 \right) K_r$$  \hspace{1cm} (4)

where $D_b$ is the diameter of the bearing. Note that (4) implies the length of the bearing must be $\sqrt{3}$ longer than the diameter to ensure the stability in yaw mode.

Fig. 5 shows the radial stiffnesses of the axially polarized array and Halbach array. When the widths of the magnet arrays ($w_{rm}$ and $w_{sm}$ in Fig. 3) are increased for the axially polarized array, the increase in the radial stiffness is minimal after $w_{rm} = 1$mm. As a matter of fact, this is in agreement with the analytic predictions in [5] and [6], where $w_{rm}$ reaches a point of diminishing return at the half of the pitch length of the array $\lambda$. The radial stiffness of the Halbach array continues to increase with the increasing $w_{rm}$. For the same magnet size, the stiffness of the Halbach array is at least 80% larger than that of the axial array if $w_{rm} > 1$mm. This result agrees with the observations in [5].

The validity of the analytic results were checked against the finite-element analysis using FEMM (Finite Element Methods for Magnetics), a public-domain finite element solver by Meeker [9]. For several different sets of arrays with varying configurations and geometries, it was found that the the worst mismatch between the analytic results and FEA was 3.5% for the axial arrays. The mismatches for Halbach arrays were less than 2%. These mismatches were utilized as correction factors in calculations of stiffnesses.

It is well known that the critical speed of the rotor is dependent upon the stiffness of the suspension. Therefore suspension stiffness is fundamentally related to the design objective of assuring the operating speed below the first critical speed. According to the above analysis, the only practical option for achieving this within a reasonable size envelope is through the use of a Halbach array.
In (5)–(8), \( x \) and \( y \) describe the translational motion of the impeller, and \( \delta_x \) and \( \delta_y \) are the rotational angles of the impeller around the center of mass, in \( x \) and \( y \) axis respectively. The rotor is assumed to be axisymmetric, and \( I_p \) denotes the mass moment of inertia about the axial direction, whereas \( I_r \) is the mass moment of inertia in any radial directions.

If we define

\[
K_{re} = \sum_i K_{ri}
\]

\[
K_{rz} = \sum_i K_{ri}z_i
\]

\[
K_{me} = \sum_i (K_{mi} + K_{ri}z_i^2)
\]

then (5)–(8) can be rearranged in a state–space form as

\[
\dot{x} = -\left(\frac{K_{re}}{m}\right)x - \left(\frac{K_{rz}}{m}\right)\delta_y \tag{9}
\]

\[
\dot{y} = -\left(\frac{K_{re}}{m}\right)y + \left(\frac{K_{rz}}{m}\right)\delta_x \tag{10}
\]

\[
\ddot{\delta}_x = \left(\frac{K_{rz}}{I_r}\right)y - \left(\frac{K_{me}}{I_r}\right)\delta_y - \Omega \left(\frac{I_p}{I_r}\right)\delta_y \tag{11}
\]

\[
\ddot{\delta}_y = \left(\frac{K_{rz}}{I_r}\right)x - \left(\frac{K_{me}}{I_r}\right)\delta_x + \Omega \left(\frac{I_p}{I_r}\right)\delta_x \tag{12}
\]

If we consider a case where two identical permanent magnet radial bearings are located symmetrically around the mass center. Then the radial motions are decoupled from the angular motions, because \( K_{rz} = 0 \). From (9) and (10), the radial mode critical speed is simply

\[
\omega_{radial} = \sqrt{\frac{K_{re}}{m}} \tag{13}
\]

The critical speeds for the angular motion (yaw mode critical speed) can be obtained by solving the characteristic equation

\[
\left(s^2 + \frac{K_{me}}{I_r}\right)^2 + \alpha^2 s^2 = 0 \tag{14}
\]

where \( \alpha \) is defined as

\[
\alpha = \Omega \left(\frac{I_p}{I_r}\right) \tag{15}
\]

The solutions of (14) is

\[
s = \pm \frac{j\alpha}{\sqrt{2}} \sqrt{1 + \frac{2K_{me}}{\alpha^2 I_r}} \pm \frac{1}{\sqrt{1 + \frac{4K_{me}}{\alpha^2 I_r}}} \tag{16}
\]

Since we are concerned with the smaller of two, we define the yaw mode critical speed as

\[
\omega_{yaw} = \frac{\alpha}{\sqrt{2}} \sqrt{1 + \frac{2K_{me}}{\alpha^2 I_r}} - \sqrt{1 + \frac{4K_{me}}{\alpha^2 I_r}} \tag{17}
\]

Based on the preliminary design, (13) and (16) were calculated with respect to the radial stiffness of the bearing. For the typical geometry of AMF pump, we found that the radial mode critical speed was always lower than the yaw mode critical speed. This means that the radial bearing must be optimized to provide the maximum stiffness to mass ratio.
A consequence of permanent-magnet radial bearings is that the rotor becomes axially unstable. We chose a voice coil actuator to actively control this instability. The voice coil actuator was selected because of linearity, bidirectionality and its ability to operate over relatively large gaps. The force due to the voice coil actuator was calculated by replacing the permanent magnets with equivalent current sheets and integrating the Lorentz force over the coil. The geometry of the magnets and coils were optimized to obtain the maximum force while minimizing the power consumptions. The actuator was designed also to satisfy the thermal requirement that the temperature rise due to the actuator must be maintained below 1 °C.

The initial conceptual controller for the axial bearing was designed using standard LQ regulator and Kalman filter design techniques. In order to create a controller that exhibited VZP (virtual zero power) behavior, the system model needed to be augmented with an additional state. The additional state represents the offset between the measured zero position and the actual magnetic equilibrium (zero power) position. This offset is due to DC forces (e.g. gravity) and manufacturing tolerances to guarantee that the exact zero power balance point will not be at the measured zero position, and that the equilibrium position may even change with time and environmental conditions. Fig. 7 illustrates this augmented model for the axial dynamics.

Adding this extra state to the system model allows the Kalman filter to estimate the equilibrium offset position, which can then be used by the feedback controller to drive the system to the estimated equilibrium point. In effect, when the additional state is incorporated into the system model in the Kalman filter, it becomes the “VZP integrator” [3] that allows the controller to seek the minimum power equilibrium point. In designing the Kalman filter, estimates of the sensor noise covariance and the covariance of the axial disturbance forces on the rotor were used to select the LQ optimal gains in the filter.

The added state is not a controllable state, so when the LQ regulator is designed, the original un-augmented two-state bearing model is used to design a two-state state feedback controller. Since the ( uncontrollable) augmented state $x_3 = x_{off}$ (refer Fig. 7) is simply subtracted from state $x_1 = x$ in the augmented model, it is a simple matter to introduce the estimate of $x_3$ from the Kalman filter into the full state controller by subtracting the estimates of $x_3$ from the estimates of $x_1$ and then using $x_1 - x_3$ in the state feedback where $x_1$ would have been used for the un-augmented system. The block diagram of the controller is shown in Fig. 8.

Fig. 9 shows the simulation of the controller that demonstrates the appropriate responses for a step force applied in the axial direction. The rotor is initially pushed off the equilibrium point and the bearing negative spring pushes it away, until the controller responds and pushes the rotor back past the old equilibrium point to settle at the new equilibrium point which is opposite of the direction of the applied force from the old equilibrium point. The actuator force settles to zero as the new equilibrium point is reached.

D. Motor

We have selected a radial–gap toroidally–wound motor [12], [13] for the rotational motion because of compactness, high efficiency, and ability to work across large air gaps. In order to reduce the mass of the rotor, we opted the design with no rotor back–iron. The increase in mass due to the thicker rotor magnet was much smaller than the combined mass of the magnet and the rotor back–iron. The geometry of the motor was again optimized to produce the maximum torque constant with minimum power consumption, while
satisfying the thermal constraints. The current design of the motor is estimated to dissipate 1.2 watts of power with the efficiency of 77%.

E. System–Level Optimization

Not only do we need to optimize each pump component for maximum performance, we must also optimize the geometries of the components as a whole that provide adequate pump operations. We defined the critical speed margin as the ratio of the critical speed to the operating speed, and used it as the cost function of the system–level optimization. For a pump size (outside diameter of 25 mm) which is anatomically acceptable for pediatric patients, several rotor sizes were considered. Fig. 10 shows the results of the system–level optimization. The combined axial length of the suspension elements (two PM bearings, a voice coil actuator, and a motor) has little effect on the critical speed margin. This is because that the stiffness increase in PM bearings results in bigger magnets for the voice coil actuator, which in turn increases the mass of the rotor. For subcritical pump operation, the rotor radius must be greater than 6.5 mm. According to our past experience, the critical speed margin must be higher than 1.15 for safe operation. We chose the rotor size of 7.6 mm in radius and 27 mm in axial length to meet this requirement.

Fig. 11 illustrates the current design of the axial mixed–flow pump, which depicts the components described so far. This design must be further refined after the completion of the fluid path design, detailed thermal analysis, and manufacturability considerations.

IV. CONCLUSIONS

The lack of the blood–pumps specifically designed for infants and the potential benefit of such devices prompted us to develop a pediatric ventricular assist device. In order to satisfy the stringent design requirements, we have selected an axial mixed–flow pump topology for our first generation prototype. The pump impeller is supported by two passive PM bearings and actively stabilized in the axial direction by a voice coil actuator. By selecting Halbach–type radial bearings and optimizing the magnet sizes, we were able to achieve the critical speed margin of at least 15%. We are currently in the process of finalizing the design for the first prototype, including the fluid path design, thermal analysis, and manufacturability.

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REFERENCES