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Advantages of Integrating Pressure-Regulating Devices into Mechanical Circulatory Support Pumps

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Abstract

Control of mechanical circulatory support pump output typically requires that pressure-regulating functions be accomplished by active control of the speed and/or geometry of the device, with feedback from pressure and/or flow sensors. This article presents a different design approach, with a pressure-regulating device as the core design feature, allowing the essential control function of regulating pressure to be directly programmed into the hydromechanical design. We show the step-by-step transformation of a pressure-regulating device into a continuous-flow total artificial heart that passively balances left and right circulations without the need for pressure and flow sensors. In addition, we discuss a ventricular assist device that prevents backflow in the event of power interruption and also dynamically interacts with residual ventricle function to preserve pulsatility.

Keywords

continuous flow total artificial heart; ventricular assist device; automatic control; sensorless; passive regulation

Purpose

Reduced complexity offers advantages for mechanical circulatory support. This study's purpose was to demonstrate devices that simplify control of continuous-flow (CF) pump output and to improve controlled response to changes in the hemodynamic environment.

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Disclosure

David Horvath and Barry Kuban are inventors of the CFTAH. The technology was licensed to Cleveland Heart, Inc., a Cleveland Clinic spin-off company. David Horvath, Kiyotaka Fukamachi, and Barry Kuban are inventors of the Advanced VAD. No other authors have a conflict of interest.

This article describes how to incorporate pump design features to implement a passive pressure-regulating function.

Technique

Cardiac support devices must take into account the variable effects of different pressures and flows from the ventricles. The inclusion of a differential pressure-regulating device allows the essential task of balancing output to be programmed directly into the pump's hydromechanical design, so that it occurs with automatic vigilance. Examples of this feature are Cleveland Clinic's CF total artificial heart (CFTAH)¹⁻⁷ (Figure 1), pediatric CFTAH (P-CFTAH), and advanced ventricular assist device (Advanced VAD)⁸ (Figure 2). These devices have an aperture at the outer diameter of the right (CFTAH and P-CFTAH) or primary (Advanced VAD) impeller, effectively changing pump capacity in response to changes in pressure forces and passive magnetic forces within the pump. The passive magnetic forces come from the interaction between the steel motor laminations and the motor magnet in the pump's rotor as it moves axially as pressures within the pump change. For the CFTAH, the essential control objective is to modulate right-pump output to correct an imbalance in atrial pressures. For the Advanced VAD, the objectives are to synchronize the aperture opening with the residual action of the left ventricle to enhance pulsatility and to close the aperture to prevent regurgitation in the event of pump stoppage due to power interruption.

Integrating a Passive Pressure-Regulating Device into a Continuous-Flow Total Artificial Heart

For the CFTAH, the essential control task is to self-regulate relative pulmonary and systemic output by virtue of hydraulic design to balance atrial pressures, allowing passive sensorless control. The only control parameter is pump speed. Pressure and magnetic forces balance against each other to open and close the right pump flow-control aperture to correct any atrial pressure imbalances or to respond immediately to an incipient suction condition of tissue being pulled in around the left or right inlet, restricting inlet flow. Figure 3a-f illustrates the simplicity of the concept and progression of features for integrating a pressure-regulating device with a CFTAH.

If either the right or left pump is dominant, the corresponding change in pressures within the pump push the rotor in the direction to correct the imbalance. For example, if the left pump is dominant, the left inlet pressure will decrease and the right inlet pressure increase, pushing the rotor axially away from the right inlet, increasing the aperture area and right pump output, thereby restoring the system to approximate atrial pressure balance. Similarly, if the right pump is dominant, the condition is corrected automatically by decreasing the aperture opening, with a corresponding decrease in the right pump outlet.

In the case of incipient suction of tissue being pulled in around the left pump inlet, the rotor will be pulled left, opening the right aperture, sending more flow through the circulation to fill the left atrium to help restore balance. If suction is at the right inlet, the rotor will be

pushed to the right, reducing aperture area and corresponding right pump output, helping to restore balance.

Integrating a Passive Pressure-Regulating Device into a VAD

The essential control task is to prevent regurgitation in the event of power interruption and to automatically synchronize with the left ventricle to augment flow pulsatility. Weak magnetic forces between the rotor magnet and steel laminations in the motor stator, push the flow-control aperture closed in the event of power interruption. At startup, the pressure generated by the impeller pushes the aperture open. During operation, the rotating assembly moves axially in response to cardiac cycle pressures to open and close the flow-control aperture with the systolic and diastolic phases of the cardiac cycle to synchronously modulate pump output and augment pulsatility. At low speed, the smaller aperture opening can alternatively allow operation of the device as a right VAD. Figure 4a–c illustrates how the pressure-regulation concept has been introduced with the Advanced VAD.

Comment

Pressure-regulating devices have been integrated successfully and validated by demonstration in adult CFTAH, P-CFTAH, and Advanced VAD pumps. Making these control features a part of the mechanical design by using passive forces for control reduces complexity of the system, improves vigilant automated response, and enhances device reliability.

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Figure 1.
The Cleveland Clinic CFTAH.

Figure 2.
The Cleveland Clinic Advanced VAD.

Figure 3.

Creating the CFTAH. (a) A pressure-regulating valve opens and closes an aperture in response to pressure forces. P1 and P2 are pressures acting on the ends of the cylinder. (b) When $P1 > P2$, the aperture opens. **Increased flow from P1.** (c) When $P2 > P1$, the aperture closes. **Decreased flow from P1.** (d) Add a motor to spin it. (e) Add left and right impeller blades to pump both left and right sides. **Aperture controls output of right impeller.** (f) Add left and right housings. RAP = right atrial pressure (P1); LAP = left atrial pressure (P2).

Figure 4.

Features of the advanced VAD. (a) **Backflow prevention:** During pump off/power interruption, the magnet assembly and the steel stator windings line up, closing the aperture to prevent backflow. Aortic pressure also contributes to aperture closure. $P_1 = P_2$ = intraventricular pressure. $P_3 = P_4$ = aortic pressure. (b) **Augmented peak flow during systole:** During operation at systole, the aperture opens by fluid forces. Systolic flow is reinforced by peak output. P_1 = systolic intraventricular pressure; $P_2 > P_3$, $P_4 < P_3$. P_4 = pressure at internal diameter of secondary impeller. (c) **Attenuated flow during diastole:** The aperture partially opens by fluid forces during diastole. Diastolic flow is diminished. P_1 = diastolic intraventricular pressure; $P_2 > P_3$, $P_4 < P_3$. P_4 = pressure at internal diameter of the secondary impeller.