PERFORMANCE CHARACTERISTICS OF A PNEUMATICALLY DRIVEN TOTAL REPLACEMENT ARTIFICIAL HEART

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This paper describes the design, fabrication, and in vitro performance of a pneumatically driven sac-type total replacement artificial heart which interacts with the inlet (left and right atrial) and outlet (aortic and pulmonary arterial) pressures and flow rates. The plastic and rubber pump is designed to replace the resected natural heart planted orthotopically within the chest and to be connected to the external power source and control system.

The pump is designed to obey Starling's Law permitting a simple electronically timed pneumatic driving mechanism.

The in vitro testing was performed by connecting the pump to a columnar chambered, water filled mock circulation which provides impedances similar to those of the natural circulations.

The pump is capable of producing blood flow rates satisfying human requirements up to and including moderate work at normal pressures demanded by the body. It is similar to the natural heart in weight and size and its cyclic action is at normal heart rates providing output pressure wave forms with contours comparable with those produced by the natural heart.

PHYSIOLOGICAL AND PHYSICAL REQUIREMENTS OF AN ARTIFICIAL HEART.

If the total replacement artificial heart is to mimic the function of the natural human heart, it should fulfill the following minimum requirements:

1. two separate pumps duplicating the left and right ventricles,
2. pump output range of 5 to 10 litres per min.,
3. aortic arterial pressure range of 120 to 180 mm. Hg, pulmonary arterial pressure range of 20 to 80 mm. Hg,
4. physical dimensions permitting easy surgical insertion within the pericardial sac,
5. a specific gravity near unity,
6. a minimum of noise and vibration,
7. a heat output of less than 25 watts,[1]
8. a low degree of hemolysis of blood cells,
9. compatibility with body chemicals.

CONTROL OF OUTPUT

If the outputs of the two ventricles were not balanced either the blood vessels in the lungs or those in the rest of the body would be congested with an excess accumulation of blood. In the natural heart, ventricle output is regulated by the principle known as Starling's Law.[2] The principle is that the output of each side of the heart is governed by the degree of filling of the ventricles, assuring identical flow rates. This type of intrinsic control of output balance is mandatory for an artificial heart. It is generally accepted that most, if not all control, is done outside the heart.[3] The heart's ability to pump seems to be affected by many variables including the output pressure load, sympathetic and parasympathetic nervous regulation, heart rate, intrathoracic pressure, and myocardial damage. The amount of blood actually pumped is determined by the demand for blood throughout the body and is reflected as a change in atrial pressure. Venous return is normally the dominant factor regulating the normal heart. For example, during moderate exercise 81% of the increased cardiac output can be attributed to the effect of venous return.[4] It appears then that a prosthetic device controlled by venous pressure alone would satisfactorily accommodate the host with an adequate range of cardiac output.

DESIGN AND FABRICATION DETAILS

a) <u>Pump</u> - The heart design is that of a ventricle sac type[5] driven by compressed air injected between a semi-rigid casing and the ventricle sac (Fig. 1). It is four-chambered and contains four one-way check valves. The shape of the pump resembles that of the natural heart and consists of two independent sides to provide ease of atrial anastomosis. Each side has identical ventricles but different atria. The right side has a completely artificial jumbo atrium providing for direct cannulation to the inferior and superior vena cavae. The left side has a partial jumbo atrium which would require anastomosis to the left atrial remnant of the resected heart. These atria form large elastic reservoirs providing for rapid ventricular filling, eliminating the necessity of applying vacuum to the ventricles during diastole. This greatly simplifies the driving mechanism and obviates possible damaging effects to the venous system produced by negative pressure gradients. The pulmonary and aortic arterial connections are rubber necks providing for simple cannulation. The sacs, atria and arteries are designed to be made of natural rubber by dipping male wax molds into liquid latex. Natural rubber is easy to use, exhibits excellent strength, flex life and durability, and may be readily made antithrombogenic by the incorporation of bonded heparin.[6] Commercially available heart valves are incorporated and the ventricles are encased in a brushed on coating of clear polyurethane. The pumps are fitted with vents into all chambers for pressure monitoring, and tubes into the spaces between the ventricles and casings to provide ports for the driving air.

b) <u>Timing and Driving Device</u> - The timing and driving system is capable of delivering compressed air of variable pressure to and from each side of the pump independently, with variable systole and diastole. The system consists of pressure regulators, pressure gauges, three-way air piloted solenoid valves, and a simple vibrator electronic circuit (Fig. 2).

c) <u>Mock Circulations</u> - All performance tests were conducted in vitro. The mock circulations are multi-chambered devices built of plexiglass. The pumping fluid (water) flows from one chamber to another to produce an analog of the systemic and pulmonary circulations. The capacitance and resistance of the two systems is variable by pumping air in or out of specific chambers. The chambers and pumps are connected in series so that the effect of a change in output of one side may be examined on the other.

PERFORMANCE CHARACTERISTICS OF PUMP AND DRIVING MECHANISM

With a constant frequency application the durations of systole and diastole are fixed. The stroke volume of the pump is then governed by the degree of filling of the ventricles. The greater the inflow of blood, the more complete is the filling of the ventricle and therefore the greater is the output. In this manner, the pump and driving mechanism exhibit an obeyance to Starling's Law, ensuring a balance of the output of both ventricles. This feature is illustrated in Fig. 3. For an example of this mechanism, an increase in atrial pressure in the left side of the mock circulation increases the output of the left ventricle which in turn provides the right ventricle with an increased filling pressure causing its output to come to equilibrium with that of the left ventricle. The response is rapid and should effect equilibration of ventricular outputs in vivo.

The optimum pump rate is one providing both high sensitivity of output to filling pressure and acceptable maximum output. Too slow a rate results in a reduction in output due to idle periods following complete diastole and systole. Too fast a rate allows only partial filling and expulsion of ventricle contents; again reducing efficiency. For these pumps the optimum rate is 80 beats per minute with a diastole of 0.47 seconds and a systole of 0.28 seconds (37% of cycle).

The shape of the output curve is unaffected by an increase in diastolic pressure if driving pressure is increased accordingly. At present this function is controlled manually but could be rendered automatic if autoregulation is to be complete. The pumps were tested to diastolic pressure of up to 200 mm. Hg.

The pumps weigh 200 grams, occupy 735 ml. during diastole, and have a specific gravity of 1. The light weight and small volume permit its surgical insertion within the pericardial sac requiring no restraints other than venous and arterial connections. Each ventricle has an internal volume of 160 ml. permitting a maximum stroke volume of 120 ml. maintaining a 25% residual volume.

Output pressure wave forms measured from the artificial aortic and pulmonary arteries in the mock circulations display features similar to those found in pressure recordings from normal animals (Fig. 4).[7]

The pumps produce negligible noise, vibration, and heat, and should produce a tolerable level of hemolysis. Materials used in their construction have exhibited a reasonable compatibility with the body.[6,8]

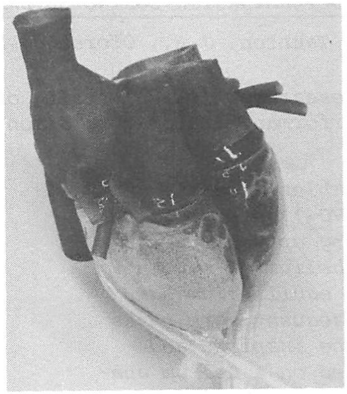

FIG. 1: PUMP COMPLETE - RIGHT AND LEFT SIDES

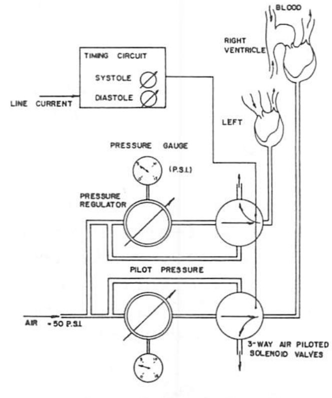

FIG. 2: SCHEMATIC OF TIMING & DRIVING MECHANISM

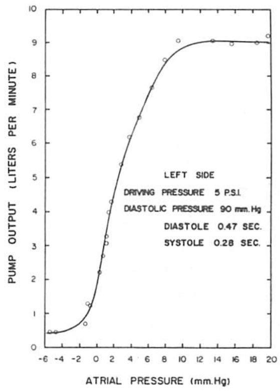

FIG. 3: PUMP OUTPUT & STARLING'S LAW

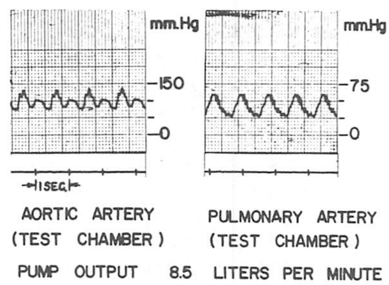

FIG. 4: OUTPUT PRESSURE WAVE FORMS

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