

A Sealless Centrifugal Blood Pump with Passive Magnetic and Hydrodynamic Bearings

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Abstract: We are developing a permanently implantable ventricular assist system based on a sealless centrifugal blood pump. The impeller of the pump is supported by a passive radial magnetic bearing acting in synergy with hydrodynamic bearings. Torque is transmitted to the impeller by electromagnetic coupling via an integrated axial flux gap motor. Computer modeling has been used extensively to guide the hydraulic and electromagnetic design of the pump. As part of the development effort, a prototype system was built, which consisted of a radial magnetic bear-

ing, an axial air gap motor, and a pivot bearing to constrain the axial motion. The following testing has been completed to validate the design. First, hydraulic tests have demonstrated sufficient hydraulic performance. Second, preliminary in vitro evaluation of hemolysis was low compared to that of a BioPump control. Third, a 6 h in vivo experiment was successfully completed. **Key Words:** Magnetically suspended centrifugal pump—Ventricular assist device—Axial flux gap motor—Radial magnetic bearing—Hydrodynamic bearings.

Rotary pumps offer many potential advantages for use as ventricular assist devices compared to cyclic delivery systems. Unfortunately, in previous designs (1–4), sealing blood at the drive shaft has severely limited the durability of rotary blood pumps and precluded their evaluation as a ventricular assist device (VAD) for the treatment of chronic congestive heart failure (5–8). Clinical evaluation of a chronic implantable VAD based on rotary blood pump technology cannot be undertaken until a simple, durable alternative to the shaft seal is developed. Sealless designs which use magnetic or electromagnetic torque coupling may eliminate the need for a drive shaft and seal and make it possible to use a rotary pump as a chronic VAD. There are 2 basic approaches to sealless pumps, magnetic bearing suspension or blood lubricated bearings for support of the rotating assembly.

Complete suspension with active magnetic bearings can be truly mechanically frictionless; however,

the power requirements, 5–16 W, (9–13) for active magnetic suspension are much greater than any frictional losses observed in conventional bearings. The electromagnets used for active magnetic bearings add significant volume and weight, making these pumps large and heavy when compared to other rotary pump concepts. In addition, active suspension requires proximity sensors and servo circuits, which increase the complexity and number of conductors and may compromise reliability.

Blood immersed bearings may be surface lubricated with rubbing contact (14–16) or employ a thin film to produce true hydrodynamic support without rubbing contact (17). These approaches eliminate the seal by supporting the rotating assembly with blood lubricated bearings located inside the pump and by transmitting torque to the rotor via electromagnetic coupling. Although significant progress has been made, the durability of these devices in clinical trials is still unproven.

We are developing a pump that uses a combination of magnetic and blood immersed hydrodynamic bearings to suspend the impeller. The suspension of the impeller is achieved by passive permanent magnetic radial bearings acting in synergy with lightly loaded blood lubricated hydrodynamic bearings. The pump has the following advantages: no sensors are

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needed; the magnetic suspension employed is simple, passive, small, and light-weight; and the blood lubricated hydrodynamic bearings are lightly loaded and will not exhibit rubbing contact or excessive hemolysis. This pump has the potential to be a small, simple, efficient, and reliable VAD.

DESCRIPTION OF THE PROPOSED CENTRIFUGAL VAD

The anatomical placement of the proposed pump is shown in Fig. 1. The inlet of the pump also serves as the inflow cannula and is placed into the left ventricle via the apex. An arterial vascular graft is connected to the pump outlet and serves as a conduit to move blood from the pump to the aorta through an end to side anastomosis. The proposed pump is a centrifugal design with an axial inflow and a radial outflow; hence, the action of the pump results in a 90 degree turn of the blood flow without the need for an elbow fitting. A centrifugal pump provides a great deal of flexibility during implantation because the pump can be rotated on its axis to adjust the angulation of the pump outlet and minimize kinking and hydraulic losses in the outflow graft. Good anatomical compatibility is possible because the pump housing is disc shaped and displaces only 28 cc and should fit well within the pericardial space between the apex of the heart and the diaphragm.

DESIGN OF THE PROPOSED CENTRIFUGAL PUMP

The pump will displace about 43 cc and weigh approximately 195 g. The extracardiac volume will

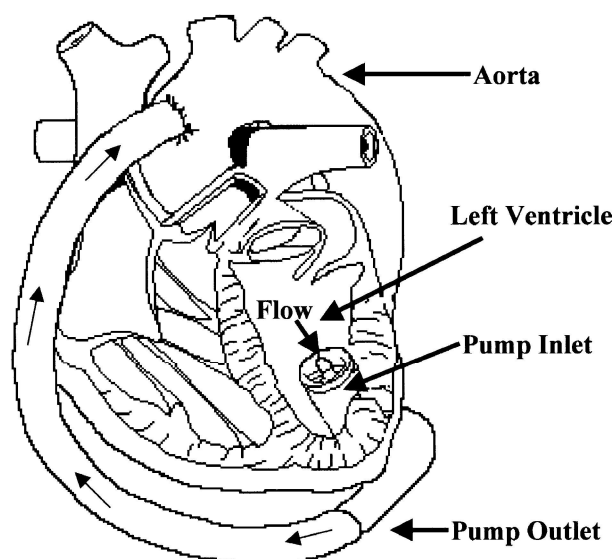


FIG. 1. The drawing shows the anatomical placement of the pump.

be only 28 cc. Figure 2 is a 3-D longitudinal cutaway view of the pump. Figure 3 is a cross sectional drawing of the prototype pump. The pump consists of a rotating assembly with an impeller and integral axial flux gap motor and a housing with a volute and an inlet tube. The spindle of the rotating assembly contains the inner magnets of the radial magnetic bearing, and the impeller contains the permanent magnets of the motor rotor. The housing consists of the outer magnets of the radial magnetic bearing and the stator of a flat axial flux gap motor.

Torque is transmitted to the impeller by means of the electromagnetic coupling between the motor stator and the rotor magnets embedded in the impeller. Blood then flows from the pump inlet to the impeller via the inflow annular area between the spindle of the rotating assembly and the bore of the housing inlet.

In the final design, thrust surfaces will be located on the front and rear surface of the impeller and serve to constrain the axial translation of the rotating assembly. The front and rear of the housing will have mating surfaces for the thrust bearings on the impeller.

Several unique features were implemented into the design to adapt the permanent magnetic bearings and electromagnetic coupling to the pump. These include the means of suspension, the means of power transmission, the means of axial constraint, and the thick bladed impeller.

Means of suspension

Radial support is provided by the action of permanent magnets configured as passive magnetic bearings located at the forward end of the impeller assembly. Because the flux gap of the magnetic bearings is also the flow path for the blood through the pump inlet, it is necessary to achieve high radial restoring forces over relatively large flux gap distances.

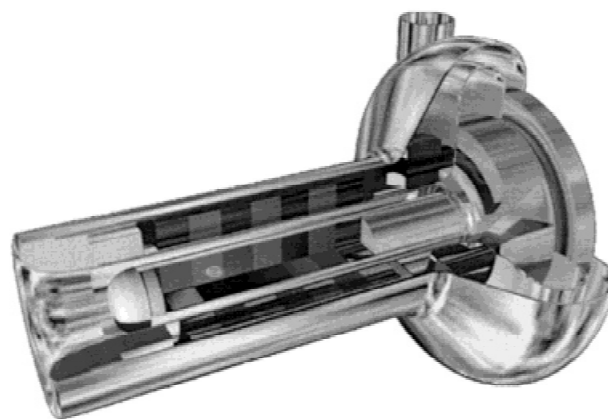


FIG. 2. Shown is a 3-D longitudinal cutaway view.

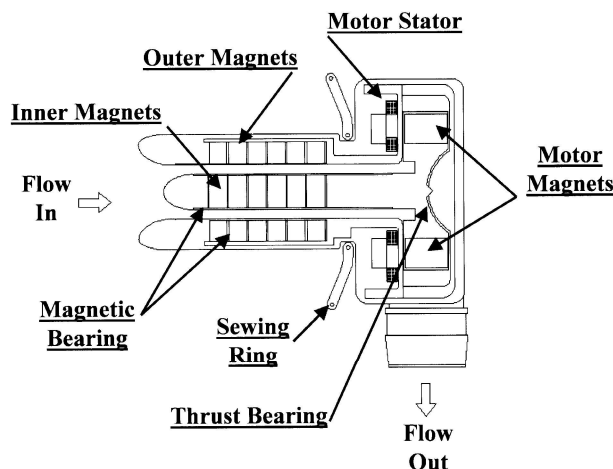


FIG. 3. Shown is a cross sectional drawing.

This is accomplished by stacking radial magnetic bearings in series as shown in Fig 3. Axially magnetized rings and discs are assembled like poles facing one another. This configuration produces strong fields that emanate radially from pole pieces stacked between adjacent magnets. When the stack of inner disc magnets is axially aligned with the stack of annular outer magnets, large restoring forces can be achieved as a result of the mutual repulsion between the 2 assemblies.

Power transmission

Torque is provided to the impeller by means of electromagnetic coupling with a brushless axial flux gap motor. Permanent magnets placed in the impeller are rotated by the electromagnetic fields produced by a flat motor stator commutated using back-emf sensing. Using a flat motor stator enhances anatomic compatibility and makes it possible to minimize the air gap between the stator and rotor magnets.

Axial constraint

Blood lubricated lightly loaded thrust bearings will be used to constrain translation of the rotating assembly in the axis of rotation. Small loading on the thrust bearings will be associated with minimal shear and low hemolysis. Several thousandths of an inch of axial play can be left between the contact points of the rotating assembly and the stationary thrust surfaces. Because the pump is working against the cycling delta pressure produced by the beating heart, it is possible to use this pressure to cause the rotating assembly to shuttle back and forth between the axial constraints with each cardiac cycle. This shuttling motion will produce a pumping action that will exchange blood in the touchdown or thrust area with fresh blood from the circulation. This will facilitate

removal of heat, decrease the residence time of blood in the thrust area, and minimize the risk of thrombus formulation.

Thick bladed impeller

Another important feature of the proposed pump relates to the novel geometry of the impeller. To provide volume for the placement of sufficient magnetic material and maintain an unshrouded impeller, it was necessary to depart from conventional pump design and make the blades very thick. The blood passes through the impeller in narrow deep passages rather than through the wide shallow passages as seen in conventional pumps. In addition to providing a place for the magnets, this unique geometry offers other advantages. This approach to impeller design makes it possible to increase blade solidity (ratio of working blade area to flow of blood through the impeller) without increasing the number of blades. This is a very important point because the hydraulic efficiency and hemolysis of these miniaturized pumps is very sensitive to the number of leading edges in the blood path. The thick blades also provide a much longer leak path than is possible with conventional blades, thus reducing the leakage flow and improving volumetric and overall efficiency.

METHOD

The hydraulic performance of the system was evaluated in a nonpulsatile mock loop using a blood analog. The flow was measured with a Transonic 16 mm in-line probe (Model #T106, Transonic Systems, Inc., Ithaca, NY, U.S.A.). The pressure differential was measured from the impeller inlet to a point 6 inches distal to the pump discharge using Digimano pressure meters (Model DPM 200IN, Netech, Hicksville, NY, U.S.A.). Pressure versus flow (Fig. 4) was measured as a function of speed in the range from 2,400 to 4,200 rpm.

A preliminary in vitro hemolysis test was performed with ovine blood, using the BioPump (Bio-medicus 520D, Medtronic BioMedicus Inc., Eden Prairie, MN, U.S.A.) as a control. Fifteen hundred cubic centimeters of heparinized blood with a hematocrit (Hct) of 24% was placed into each of 2 circulatory loops, 1 for the BioPump control and 1 for the prototype pump. The speed and pressure were adjusted to achieve a flow of 5.0 L/min at 100 mm Hg. Samples were drawn for a baseline and then repeated every 15 min for the duration of the 90 min test. The plasma free hemoglobin level was measured photometrically using a cyanomethemoglobin assay and a Jenway 6100 spectrophotometer (Jenway LTD, Felstend, Dunmow, Essex, U.K.). Hemo-

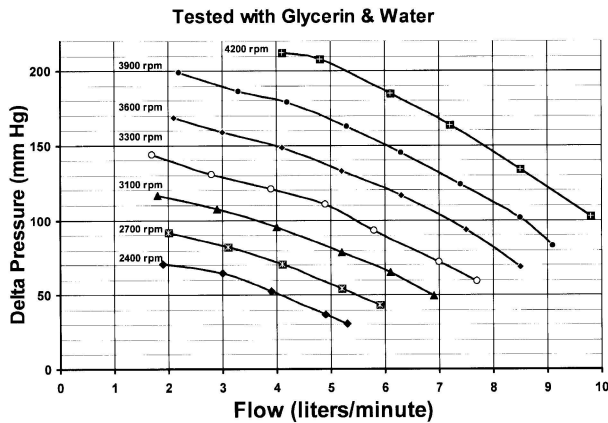


FIG. 4. The graph shows impeller hydraulic performance.

lysis was measured as a calculated free hemoglobin burden (CFHB) in g/day using the following formula where $DPFHgb$ is the change of plasma free hemoglobin in the test period (g/dl), Hct is the hematocrit, Vol is the total blood volume (ml), and $Time$ is the test time in days:

$$CFHB = DPFHgb \times (1 - Hct) \times Vol \times (1/Time) \quad (1)$$

Additionally, an acute 6 h in vivo test was performed on a 95 kg sheep to develop the implant geometry for the animal trials and to get a preliminary evaluation of in vivo hemolysis, platelet injury, and thromboresistance. All procedures conformed to the humane treatment of laboratory animals as described in *The Guide for the Care and Use of Laboratory Animals* by the Institute of Laboratory Animal Resources. The pump was implanted through a left lateral thoracotomy incision. One end of a 16 mm Hemashield graft (Hemashield Gold, Meadox Medicals, Inc., Oakland, NJ, U.S.A.) was anastomosed to the descending thoracic aorta and the graft clamped distally. The proximal end was secured to the pump discharge, and the pump flushed with heparinized saline. A 16 mm Transonic extra-vascular flow probe was placed around the graft. Intravenous heparin was given at a dose of 2 mg/kg, and the activated clotting time (ACT) maintained at 2 times that of the control. An 8 mm hole was made in the ventricular apex using a coring tool, and the inlet of the pump placed into the left ventricle. The pump was secured to the apex with horizontal mattress sutures placed through an integral sewing ring. The system was de-aired through a needle placed in the outflow graft while turning the impeller at a very low speed. The distal clamp was removed, and pumping was initiated. Arterial pressure was monitored through the carotid artery. Blood samples were taken as follows: a complete blood count (CBC), differential, and platelets were taken at 0, 1,

3, 5, and 6 h. The plasma free hemoglobin was measured every hour.

RESULTS

The hydraulic performance is shown in Fig. 4. The flow was from 2.0 to 10 L/min. At a flow rate of 5.0 L/min against a delta pressure head of 100 mm Hg, the total power required was 5.6 W.

In vitro hemolysis testing of ovine blood showed that the prototype pump produced 1.34 g/day of plasma free hemoglobin compared to 2.99 g/day for the BioPump.

The system ran normally for the duration of the in vivo experiment. The pump flow rate ranged from 2 to 6 L/min. The plasma free hemoglobin level was stable at 6 mg% above baseline, and there was no significant decrease in platelet count compared to the baseline measurement. No injury to the valvular mechanisms was seen. The hydraulic surfaces of the pump showed no evidence of thrombus deposition.

DISCUSSION

Ideally, a chronic ambulatory VAD should be simple, have a small displaced volume, and be light in weight. It should also have a life of 3–5 years and a power consumption low enough to permit 6–8 h of untethered operation from an implantable battery. These factors, which relate to patient comfort and lifestyle, are as important to the utility and commercial success of the VAD as are the physiological and clinical factors related to efficacy and safety. No device to date has been shown to meet all of these conditions.

Based on theoretical considerations and the design concepts validated by the prototype, we believe that this pump may have many advantages over other concepts. Its small extracardiac volume will permit placement within a single body cavity (the pericardium), thus avoiding diaphragmatic penetrations and the displacement of lung tissue. Magnetic and hydrodynamic bearings should provide a life of many years. Finally, the potential for a high efficiency system may result in a VAD that is capable of many hours of untethered operation.

Another prototype, suitable for implantation in animals for 2–4 weeks, is being fabricated to complete validation of the design.

CONCLUSION

The pump can produce flows up to 10 L/min at physiologic differential pressures. The observed performance of the pump correlated very well with the

predictions of the computer models. Hemolysis was low compared to that of the BioPump. The pump performed normally during the in vivo experiment. The plasma free hemoglobin was 6 mg% above baseline, and the platelet count was normal and stable for the duration of the experiment. The wetted surfaces of the pump were free of thrombus formation.

These results validate the concepts of the radial magnetic bearings, and the centrifugal pump and motor design, demonstrate that the pump has sufficient hydraulic power to function as an effective ventricular assist system, and show that minimal hemolysis is caused by the pump, suggesting resistance to thrombosis.

The design has the potential to be a useful VAD for the treatment of chronic congestive heart failure. This conclusion is based on the experimental validation of the magnetic bearing, axial flux gap motor, and the impeller design and the preliminary evidence that hemolysis and thrombus deposition appear to be acceptable.

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