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DEVELOPMENT OF THE NASA/BAYLOR VAD

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ABSTRACT

A cooperative effort between the NASA/Johnson Space Center (JSC) and the Baylor College of Medicine (BCM) has been underway since 1988 to develop a long-term implantable Ventricular Assist Device (VAD). The VAD is intended to boost the cardiac output of patients with deteriorated cardiac function. For many of these patients, the best alternative is heart transplantation. Heart transplantation is a complex and expensive procedure and usually requires a long waiting period for a donor heart. The condition of the patient often deteriorates during this waiting period which complicates the pre and post-operative care. Because of these factors, the need for a long-term implantable VAD for use as a bridge-to-transplant device or as a permanent assist device has become the focus of much research. The need for a VAD has been estimated at 50,000 to 60,000 patients per year in the United States alone[1]. A device which satisfies all the system performance and reliability requirements has yet to be achieved. However, the development of the NASA/Baylor VAD has progressed to state in which commercial viability can begin to be considered. The device is small, simple, efficient and reliable which meets all requirements for a totally implantable VAD.

HISTORY OF VAD'S

The first widely successful device used to pump blood was invented over fifty years ago by Dr. Michael DeBakey. This pump was called the roller pump and utilized flexible tubing squeezed by rollers to propel the blood. This type of pump is still used today during open heart surgery; however, advances with other types of pumps is rendering the roller pump obsolete. During the 1960 - 1980 time period, much work was focused on the development of a Total Artificial Heart (TAH). This work was culminated by the implantation of the Jarvik-7 TAH in six patients[2] during the 1980's, but with limited success. Attention has recently shifted toward the development of a VAD rather than a TAH for several reasons. A VAD operates in parallel with the natural heart by drawing blood from the ventricle (usually the left) and discharging into the descending aorta as shown in Figure 1. Typically, VAD's are utilized in patients unable to be weaned from heart bypass systems after open heart surgery. Weaning is necessary after cardiac surgery when the natural heart is unable to sustain life. This application of a VAD is generally short term (up to one week); however, some cardiac patients could benefit from a permanently implanted device. For those patients who cannot be weaned from the temporary artificial assist system, a permanent implantable VAD can be used negating the need for a total transplant, artificial or biological. For these reasons several types of VAD's have recently been developed to fulfill a variety of medical needs.

Many of these second generation pumps are centrifugal designs which have been modified to meet the needs for providing circulatory assist. They are much smaller and more efficient than the original roller pump, but are restricted to extracorporeal pulmonary and systemic circulatory assist. The need for an implantable device led the NASA/Baylor team to pursue an axial flow design which has resulted in a VAD which is small enough to fit inside small children. The two main obstacles which had to be overcome were hemolysis and thrombosis. Hemolysis is the mechanical and chemical destruction of red blood cells resulting in the release of hemoglobin into the blood plasma. This causes two problems, the first being a reduction in the oxygen carrying capability of the blood and the second is toxicity due to excess levels of hemoglobin in the plasma. The kidneys and liver can remove small amounts of hemoglobin from the bloodstream through filtration and metabolic absorption, respectively. If the destruction of red blood cells exceeds a threshold, then hemolytic anemia and hemoglobin toxicity begin to occur. Thrombosis is the formation of blood clots within the pump which can cause pump seizure, increased hemolysis, or blockage of the circulatory system itself. Blood tends to clot when contact is made with any foreign substance

within the bloodstream. Other causes of thrombosis are stagnant areas in which blood is allowed to collect and coagulate and platelet damage which causes the release of platelet factors. These factors initiate the coagulation cascade which results in an aggregate of fibrin, platelets, erythrocytes, etc. These blood components can adhere to pump surfaces and cause the pump to seize. Coatings can to some extent reduce thrombosis, but the basic design of the pump must be antithrombogenic if the device is expected to last long periods of time within the circulatory system. Both the roller pump and second generation centrifugal pumps are limited to a pump life of less than two days for these and other reasons. Pulsatile VAD's using flexible diaphragms have demonstrated much longer pump life, but have yet to be reduced to a size which would allow implantation in a wide range of patients. In addition, pulsatile VAD's have proven to be very expensive and complex to produce prohibiting their use on a wide basis.

DESIGN REQUIREMENTS

The design requirements for the NASA/Baylor VAD were based on years of practical medical experience as well as the demanding environment inside the circulatory system. The basic requirements of low hemolysis and antithrombogenicity were of primary concern. However, careful attention to minimizing size and maximizing efficiency have resulted in a device which has the potential to satisfy wide ranging circulatory assist needs. As with any device which will be put to use in an environment with limited access, the importance of system and component reliability could not be overemphasized. This drove the design towards simplicity with a minimum number of components, both electrical and mechanical. Output was required to be 5.0 liters/minute against a pressure head of 100 mm-Hg. This was based on the required assist flow during previous clinical usage of temporary VAD systems. A power input of less than 10 watts was highly desirable to minimize the size of the battery pack and the frequency of recharging. After evaluation of these requirements, it was decided that a small, efficient, axial flow pump was most likely to fulfill all the criteria while maintaining a relatively low production cost.

PUMP DESIGN

The NASA/Baylor VAD is shown in Figure 2. The envelope dimensions of the device are 2.5 inches (7.0 cm) in length and 1.0 inch (2.5 cm) in diameter. The unit consists of a spinning inducer/impeller with a fixed flow straightener and diffuser which reside inside of a flow tube. The inducer/impeller is 0.46 inches (1.2 cm) in diameter and is designed to rotate between 10,000 to 15,000 RPM depending upon the required pump output. The inducer serves two roles, one is to pre-rotate the blood before entering the impeller section and the other is to provide a two-stage pumping effect. The impeller also serves a dual purpose by housing rare earth magnets in the blades to act as a rotor of a brushless DC motor as well as providing pumping action. Magnets implanted in the impeller blades allows for a small air gap which results in a high motor efficiency. The inducer and impeller perform together to provide an efficient pumping mechanism to propel the blood while maintaining low shear levels and minimizing strong vortices. As a result, hemolysis is kept at an acceptable level for permanent human use. The blood flow is axially directed by the flow straightener before entering the inducer to boost performance. The flow straightener also provides a support for the front bearing. The diffuser axially redirects the highly tangential flow leaving the impeller to build pressure for increased pump performance and also minimizes turbulence to reduce hemolysis levels. The diffuser also serves as a support for the rear bearing. The front bearing consists of a ceramic ball riding in a matching sapphire cup. This simple bearing design accommodates both radial and axial forces encountered during pump operation. The rear bearing, equally simple, consists of a ceramic shaft riding inside a sapphire sleeve. The clearance between the shaft and the sleeve is kept very small to ensure precise alignment and minimize blood leakage into the bearing. The small amount of blood which does initially enter the bearing area is cross-linked by localized heat and effectively fills all the bearing voids. This prevents a constant infusion of fresh blood which could cause the bearing to seize. A brushless DC motor winding is located outside the flow tube and placed over the impeller to provide a magnetic drive for the inducer/impeller. The pump components (inducer/impeller, flow straightener, and diffuser) are currently machined from polycarbonate, but other materials are being investigated in terms of both biocompatibility and mass production issues.

CONTROLLER AND POWER SYSTEM DESIGN

Minimizing the size of the controller was a major design goal since it also is intended for implantation A brushless DC motor drive was chosen due to its simplicity, reliability and high efficiency. Commercially available controllers are relatively complex requiring multiple components and sensors, all of which are potential failure points. Among these are Hall effect sensors used to detect rotor position. These signals are used to commutate the motor. A control scheme was adopted for the NASA/Baylor VAD which is shown in Figure 3. This scheme eliminated Hall effect sensors and the related electronics by relying on the back-electromotive force (back EMF)

generated in the motor stator. The back-EMF signals can be used to detect the rotor position and enable optimum commutation of the motor. This control method not only reduced the number of electronic components to a minimum, but also was slightly more efficient than standard Hall effect sensor controllers. The power delivery system, borrowed from existing technology with little modification, is called the Transcutaneous Energy Transfer System (TETS). This system was developed for pulsatile VAD's and has proven to be safe, reliable, and efficient. It uses AC coupling to transfer power through the skin eliminating possible infection sites.

SYSTEM PERFORMANCE

Hydraulic and Electrical

Hydraulic performance of the device is shown in Figure 4. The RPM required for 5.0 liters/min against 100 mm-Hg is relatively low at 10,800 for a device of this size. These flow curves were obtained using a mixture of 37% glycerin and 63% water. This mixture produces a fluid viscosity and density similar to that of human blood. The pump is capable of producing much higher flows and pressures as can be seen in Figure 4. This capability allows the pump to supply sufficient flows for a wide variety of patients depending upon their cardiac output and mean arterial pressure. It also enables the pump to be used in applications which involve the use of an oxygenator for pulmonary assist such as Extracorporeal Membrane Oxygenation (ECMO). The hydraulic efficiency of the pump has been estimated at 33% using the glycerin/water mixture. This coupled with a high motor efficiency allows the pump to draw only 9 watts of power to produce the required flow and pressure. A new motor design which is currently under development is expected to reduce this power requirement to between 5 and 6 watts.

Hemolysis and Thrombosis

The hemolytic nature of a pump is characterized by the level of hemoglobin in the blood plasma. Evaluation of hemolysis *in vivo* is impractical due to the fact that the kidneys and liver remove or metabolically absorb hemoglobin to varying degrees depending upon organ function. If a pump is run with blood *in vitro*, the amount of liberated hemoglobin can be precisely determined by measuring plasma free hemoglobin levels at specific time intervals. In 1967, Koller [3] established an Index of Hemolysis (IH) to specify an acceptable level of hemolysis for human use and to facilitate comparison of different pumps under development. A normalized Index of Hemolysis (N.I.H.) [4,5] was established to compensate for different hematocrit levels found in different tests. It is defined as:

$$N.I.H = \Delta Hgb \times V \times (1 - Ht) \times 100 / (Q \times T) \quad (1)$$

where,
ΔHgb = change in plasma free hemoglobin in grams per liter
V = blood volume of fluid circuit in liters
Ht = hematocrit of blood in decimal percent
Q = blood flow rate in liters/minute
T = time in minutes at specified flow rate

The N.I.H. is measured as grams per 100 liters and is defined as the grams of hemoglobin liberated by a pump which passes 100 liters of blood against a standard pressure of 100 mm Hg. An acceptable value of IH for permanent human use has been established at less than 0.06 g/100L. This value is characteristic of the performance of the original roller pump. The IH of the NASA/Baylor pump has been determined to be 0.018 g/100L using bovine blood. An increase of roughly three times is typical when transitioning from bovine to human blood due to an increase in the fragility. This would place the IH of the NASA/Baylor pump at 0.042 g/100L with human blood. Testing with human blood in the near future will likely confirm this extrapolation. *In vivo* experiments with calf models have shown that the pump produced no hemolysis problems. Further reductions in hemolysis are expected as the surface finish of the pump components is improved by a combination of mechanical and chemical polishing. Mass production parts are likely to be injection molded which will produce a superior surface finish.

Thrombosis can be evaluated *in vivo*. Blood clotting involves a complex cascade of chemical reactions which has not yet been duplicated *in vitro*. For this reason, initial animal studies have been conducted to evaluate thrombus formation with the NASA/Baylor VAD. Two calf implants have been conducted to date in which the pump was implanted paracorporeally. The first experiment was terminated after 36 hours due to excessive hemolysis caused by improper sealing of the magnets in the impeller blades resulting in rapid magnet corrosion. The magnet sealing problem was solved for the second implant. The second experiment lasted 4.5 days before termination. No hemolysis problems were observed and the pump provided more than sufficient flow while drawing 11 watts of power. The increased power required was due to the added resistance of the tubing used to implant the pump paracorporeally. This resulted in an increased RPM requirement which in turn required slightly

more power than expected. This increased power would not be required when the pump is implanted close to the heart. The animal tolerated the pump well with no adverse effects. The pump stopped after 4.5 days due to thrombus formation around the rear bearing. A redesigned rear bearing has been developed which will likely solve this problem. In addition some thrombus formation was noted on the leading edges of the inducer blades. Upon examination under a microscope, it was determined that this area possessed a very poor surface finish. It is expected that improvements in surface finish will not only reduce hemolysis, but also reduce if not eliminate thrombus formation on the leading edges of the inducer blades.

CONCLUSION

A small, implantable, and efficient VAD has been developed by the NASA/Baylor team. This system has a great potential for satisfying the requirements for a long-term VAD for use as a bridge-to-transplant or permanent assist device. The technology has been developed sufficiently to begin to consider commercial application. The potential market for an implantable VAD has been estimated to be substantial and will grow at a rapid pace once a safe, reliable, and cost-effective system is available. The potential benefit to mankind is equally great given the global shortage of donor hearts and the reality that a commercially viable TAH will probably not be achieved in the immediate future.

REFERENCES

1. Hogness J, VanAntwerp M, ed. ***The Artificial Heart, Prototypes, Policies and Patients.*** Washington, D.C.:National Academy Press, 1991.

2. Cecchin, A, Total Artificial Hearts, ***Medical World News,*** 1993,34:15-22.

3.Koller T, Hawrylenko A. Contribution to the in vitro testing of pumps for extrocorporeal circulation. ***J Thorac Cardiovasc Surg*** 1967,54:22-9.

4. Damm G, Mizuguchi K, Orime Y, Bozeman R, Akkerman J, Aber G, Svejkovsky P, Takatani S, Nosé Y, Noon GP, DeBakey ME. In vitro performance of the Baylor/NASA axial flow pump. ***Artif Organs*** 1993,17:609-613.

5. Naito K, Mizuguchi K, Nosé Y. The need for Standardizing the index of hemolysis. ***Artif Organs.*** 1994,18:In press.

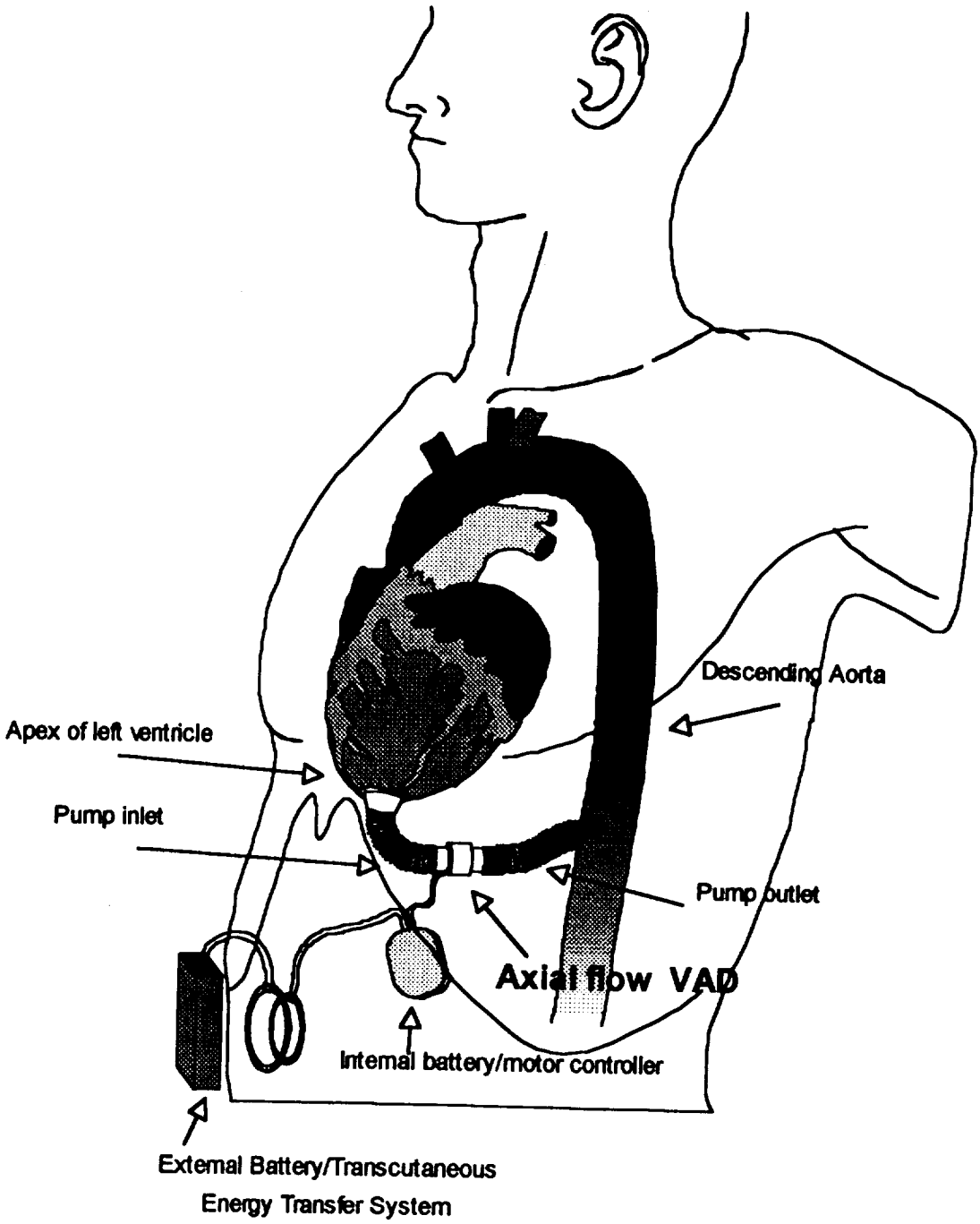

Figure 1. Placement and configuration of implanted NASA/Baylor axial flow VAD.

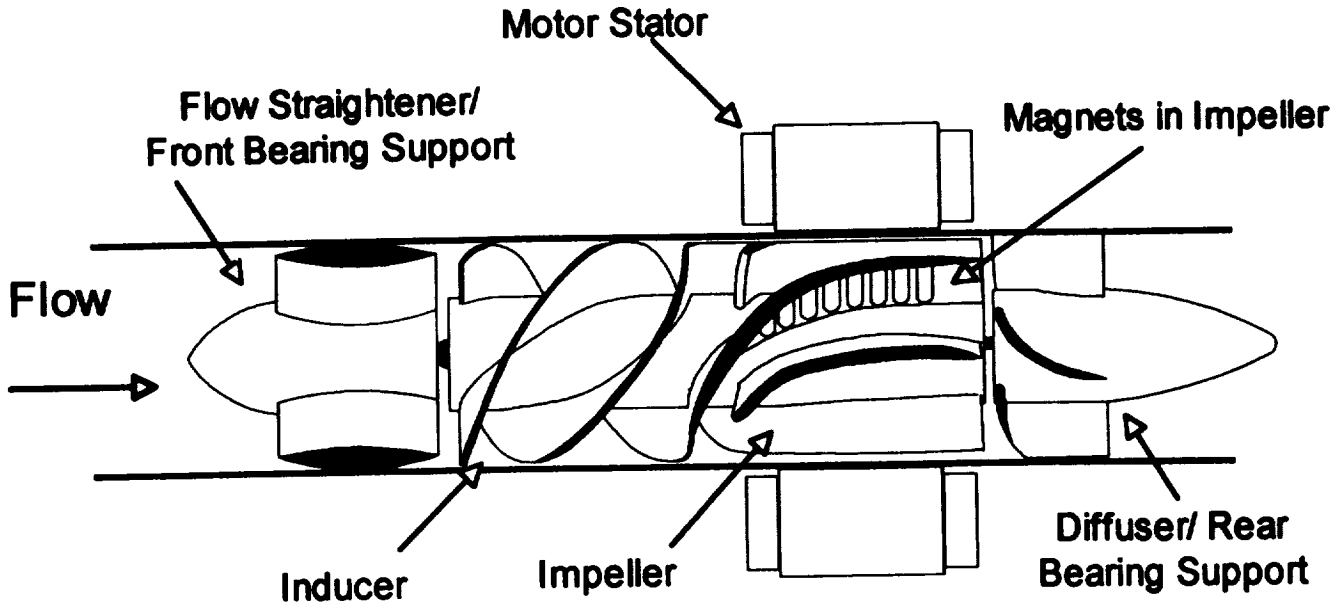

Figure 2. Schematic of NASA/Baylor axial flow VAD.

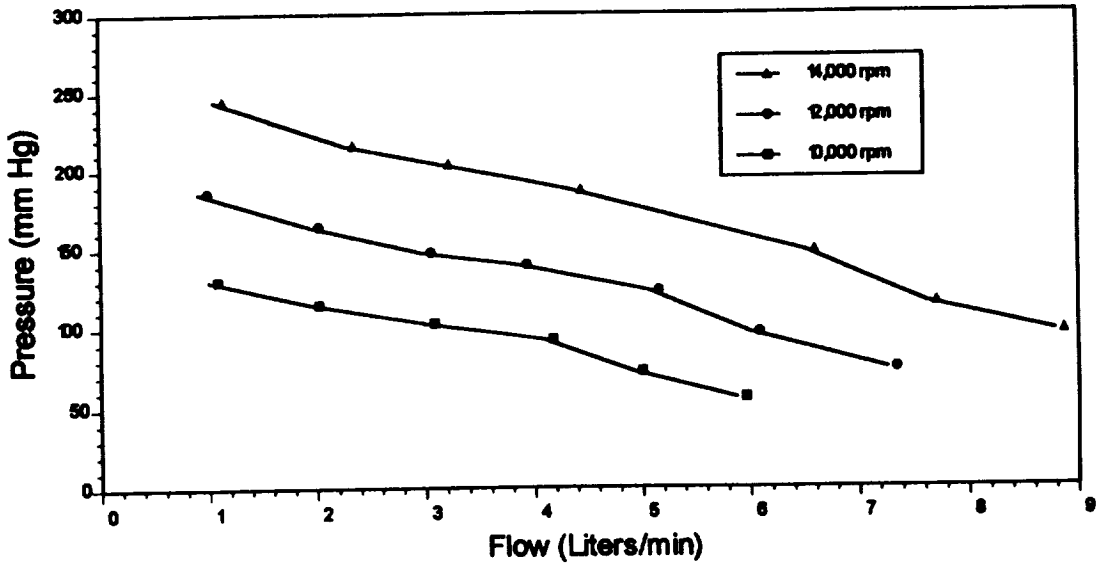

Figure 4. Flow-Pressure curves of the NASA/Baylor axial flow VAD.

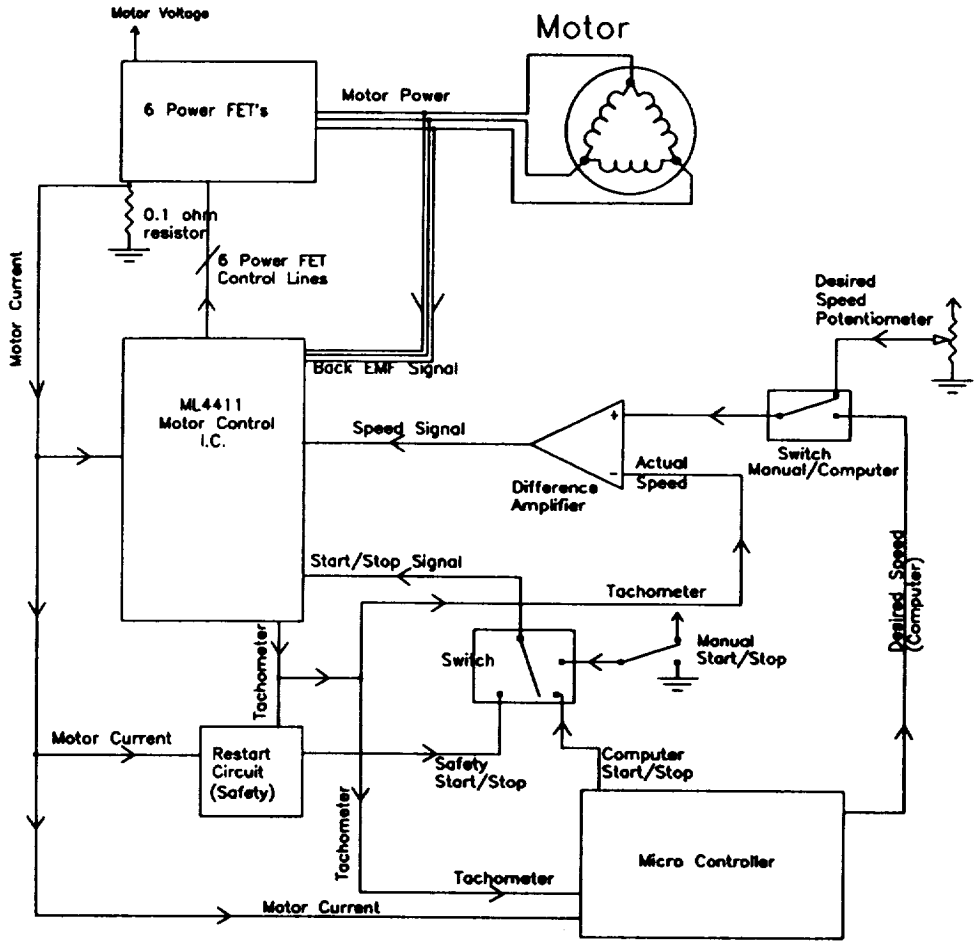

Figure 3. NASA/Baylor axial flow VAD controller.