QUARTERLY PROGRESS REPORT

BIOMEDICAL ENGINEERING SUPPORT

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SUMMARY

During the quarter covered by this progress report (November 15 - February 14, 1974), four implantation experiments were conducted to develop surgical procedures, as well as to assess the overall performance and adequacy of the AEC blood pump and ventricles. All experiments were primarily directed at determining and improving pump and ventricular efficiency and evaluating the reliability of the blood pump components, which include the flexible drive shaft, the blood pump mechanism, and the blood handling ventricles.

Experiment No. AEC-6 was a short term experiment designed to determine the proper experimental animal size to be used for succeeding experiments. Earlier implantation experiments had used calves of 110 to 123 kg in weight with no significant problems. However, under present pumping capacity, a smaller calf would be much more desirable for long term evaluation of the blood pump and ventricles. For this experiment a calf with a preoperative weight of 95 kg was chosen.

Experiment No. AEC-7 was conducted using what was determined from AEC No. 6 an ideal sized calf of 107 kg. An externally placed electric motor with a 36 inch drive shaft was used to drive the blood pump. This experiment was scheduled as a long term experiment. The animal survived surgery and was stabilized physiologically by 20 hours postoperative. However, at 25 hours the flexible drive shaft broke, terminating the experiment. From this and other experiments it was determined that complete implantation of the drive shaft and electric motor would be a much more successful implantation scheme, since an external electric motor with the drive shaft exiting the animal's chest provides

an excellent pathway for infection and imposes concentrated mechanical stress on the drive shaft at the point of entry into the chest.

Experiment No. AEC-8 was a short-term experiment designed to confirm and evaluate the surgical protocol for a complete implantation of the electric motor and flexible drive shaft. From this experiment, it was also determined that more rigid support of the stainless steel quick-connects to the ventricles should be made. The connection of the quick-connect assemblies to the AEC blood pump ventricles is heavily stressed during surgery due to handling and positioning, and subject to damage which occurred during the experiment. This condition was corrected in subsequent experiments.

Experiment No. AEC-9 capitalized on experience gained in previous experiments and was scheduled as a long term study to evaluate the pumping performance of the blood pump and ventricle with a totally implanted electric motor and flexible drive shaft. Reinforced quick-connect junctions were used with good success. The animal was stabilized and standing at 25 hours postoperative and extubated at 30 hours. Excellent in vivo pumping performances were recorded during this experiment. At 36 hours the drive shaft failed, terminating the experiment. During the course of this experiment the animal fell in the cage, possibly damaging the internally placed drive shaft. In future experiments greater care will be taken to more adequately protect the drive shaft.

In conclusion, all experiments conducted so far this quarter have been designed to evaluate some specific aspect of the AEC blood pump fit and performance. A conclusion to this series of experiments resulted in a successful implantation of the overall system using an implantable

electric motor and internally placed drive shaft in an appropriately sized animal.

Experimental observations and findings submitted to the ASAI0 annual conference in the form of a manuscript were accepted and presented at the April meeting in Chicago. The paper will be included in the next quarterly report.

Results of fit trial experiments to determine minimum and maximum bend radii with an internally placed drive shaft are presented and dissipation measurements conducted on the electric motor that will be implanted are included.

Dr. Kent Backman devoted approximately 80 percent of his time to this project until he left the Institute to take another job in January. Mr. Lee Smith then assumed Dr. Backman's role in this program, devoting 80 percent of his time. There have been no problems encountered with this change-over in personnel. Dr. Gary Sandquist has devoted 33 percent of his time to this project during this quarter and will devote approximately 33 percent of his time next quarter.

Dr. Jay Volder has devoted 25 percent of his time to this project and has begun training his replacement. Dr. Volder will be leaving the Institute in mid-April 1974, and we wish to have adequately trained surgical help when he leaves. Dr. Don Olsen has been assisting in the past five experiments and is well qualified to replace Dr. Volder. Contract requirements are thus being fulfilled.

SUMMARY OF AEC EXPERIMENT # 6 TH73-C43 B40 AEC6

Experiment No. 6 was a sterile, short-term evaluation with the purpose of determining the smallest experimental calf whose chest cavity would accommodate the AEC blood pump with an external electric motor.

Previous animal experiments were carried out using 110 to 123 kg calves. It was the purpose of this experiment, in addition to gaining surgical experience in implanting the AEC blood pump, to determine the minimum weight of calves that could be successfully implanted with the AEC blood pump.

The surgery was performed by Dr. Jay Volder, Dr. Hartmut Oster, and Mr. Neil Eastwood. A 93 kg male Holstein calf was used, with no preoperative antibiotics administered. Björk-Shiley 29 AXP inflow valves and 27 AXP outflow valves were sealed into the fibrilized Silastic ventricles and the entire blood pump was autoclaved prior to surgery. An external electric motor was used to drive the blood pump at 120 beats per minute. A sternal split surgical procedure was followed with the animal on bypass for 136 minutes. The animal was induced with Brevane followed by GOF as anesthesia.

Results of AEC No. 6. After atrial and great vessel grafts were sutured in place and the blood pump inserted and connected, the chest cavity was closed. Aortic outflow and venous inflow pressures indicated that there was severe kinking of pulmonary artery. Opening of the chest revealed severe kinking of the pulmonary artery against the chest wall. Several attempts were made to manipulate the blood pump and grafts to reduce kinking. However, in all attempts to close the chest, the outflow pressures were reduced, due to kinking of inflow lines (venous and pulmonary). These results have demonstrated that the use of the AEC blood

pump should be restricted to calves with weight greater than 100 kg.

From this and other past experiments it has been found that an ideal calf weight is 105 to 110 kg.

SUMMARY OF AEC EXPERIMENT # 7 - TH73 C46 B43 AEC7

Experiment No. 7 was designed as a sterile long term evaluation of the pumping performance of the AEC blood pump using an external electric motor. From previous experiments it was determined that an ideal experimental calf size would be 105 to 110 kg.

Surgical Procedure. A sternal split surgical procedure was performed by Drs. Jay Volder and Don Olsen, and Mr. Neil Eastwood using a 107.5 kg male Holstein calf. Anesthesia was Brevane followed by G.O.F. Silastic ventricles with fibrilized surfaces were used with Bjork-Shiley (29 AXP) inflow valves and (27 AXP) outflow valves. Ventricles and blood pump were autoclaved prior to surgery and the flexible drive shaft and casing were gas sterilized. Surgery lasted 3½ hours with the calf on heart lung bypass for 130 minutes. Preoperative pulmonary function tests indicated adequate functional residual capacity of the calf's lungs. Recording equipment was adjusted to record venous and aortic pressures as well as pump rpm and motor torque.

Postoperative Results. The calf was off bypass and the circulation totally pumped with the AEC blood pump at 3½ hours after surgery started. Tidal volume was excellent with mechanical ventilation support using 100% oxygen. Nine hours postoperative the animal's temperature was normal and was supported by 40% oxygen with a mechanical respirator. Cardiac pressures were excellent, venous filling pressure was 10 mm Hg and aortic outflow pressure of 125/75 mm Hg. Chest drainage had decreased, and tidal volume stabilized at 2000 cc. Blood gases were normal and the calf attempted to stand every 10 to 20 minutes. Motor speed was steady at 900 rpm with an average motor torque of 0.6 in-pounds and pump vacuum maintained constant at 5 in Hg. At 25 hours

postoperative, the flexible drive shaft broke. There was no increase in torque noted at failure. The animal was quiet with little body movement. The shaft broke approximately 2 inches from the blood pump end. This coincided with the point where the shaft exited the chest wall.

Autopsy Results. Autopsy revealed kinking of the aorta and pulmonary artery graphs and moderate compression of left atria. No kinking of the superior and inferior vena cava was observed. The thorax contained approximately 100 ml of unclotted blood and 400 ml of clotted blood. The lungs were excellent with no atelectasis or consolidation apparent. A large amount of ascites (6 liters) was present, but yellow in color with no blood present. Severe edema of the anterior mesentery was observed and the liver was congested and blood filled. The general appearance of the kidneys was good with only a few old infarcts.

The pusher cup of the AEC blood pump was free with no apparent sign of pump malfunction. The break in the drive shaft occurred quickly with a clean break. Worn portions of the flexible shaft were noticed on both ends of the shaft at approximately 2 inches from either end. There was a general lack of lubrication on the surface of the drive shaft. The lubricant had most likely worked its way into the core of the shaft. There was no evidence of shaft corrosion during the autopsy inspection. Torque and speed measurements were recorded and the initial values were obtained from the tracings just prior to the shaft breaking. As was deduced from the recorded tracing, there was no increase in torque or decrease in motor speed that might be indicative of pump malfunctions. Death was due to failure of the drive shaft. The physiological condition of the calf prior to termination was such that the animal could have survived at least 100 hours.

SUMMARY OF AEC EXPERIMENT # 8 - TH74 C2 B2 AEC8

Experiment No. 8 was designed as a sterile, short term experiment to evaluate and confirm the surgical protocol for internally implanting a small electric motor and flexible drive shaft to power the AEC blood pump. See Fig. 1.

Surgical Procedure. The surgical procedure was similar to that used in AEC Experiments No. 6 and 7. Due to the short-term nature of this experiment a slightly heavier than normal calf that was available was used (120 kg male Holstein). Silastic ventricles with fibrilized surfaces and Bjork-Shiley valves were implanted. Preoperative pulmonary function tests indicated that the calf's lungs were within normal limits. Recording equipment was set up to measure both venous and aortic pressures together with motor speed and torque.

Results of Experiment. The electric motor was implanted to the right of the mid-line, subperitoneally near the costal arch anteriorly (see Fig. 2). A short 8 inch flexible drive shaft was tunneled under the diaphragm from the chest cavity to the abdomen. The drive shaft was connected first to the blood pump and then to the electric motor. Difficulty in connecting the quick-connect atrial graft and great vessel connectors to the blood pump ventricle arose. Great force was needed to facilitate closing the quick-connects. This caused the ventricle quick-connect junction to rupture. Several attempts to repair the ventricles proved useless. However, the experiment was continued to evaluate the anatomical fit of the implanted electric motor. See Figs. 4-5.

The electric motor and short 8 inch flexible drive shaft system was well accommodated in the calf's abdomen. The electric connections were tunneled under the calf's skin and exited from the animal's right

FIG. 1. Implantable electric motor, flexible drive shaft and blood pump assembly as it would appear in the experimental animal.

FIG. 2. Electric motor and flexible drive shaft implanted in abdomen prior to suturing overlying tissue.

FIG. 3. Implantation site for electrical motor after closure.

FIG. 4. Blood pump ventricle illustrating the tearing of the Silastic ventricle in the region of the quick-connect ventricle juncture.

FIG. 5. Close-up of torn quick-connect ventricle juncture.

side. The electric motor was started and the blood pump was allowed to pump blood. There was very little vibration or motion observed in the flexible drive shaft. Upon closing the muscle tissue and skin over the electric motor, it was noted that a 6 inch flexible drive shaft would be better suited to this internal electric motor implantation procedure.

Analysis of the bonding of the flexible drive shaft confirmed our cadaver fit trial experiments. We found that an 8 to 10 inch bend radius would be the minimum bending expected during the course of the experiment. Photographic evidence of the electric motor and flexible drive shaft positions were made and the animal was terminated.

Summary of findings indicate that a small electric motor can be easily installed in the calf abdomen and that a short 6 to 8 inch flexible drive shaft can be tunneled from the chest cavity into the abdomen with very little bending produced in the drive shaft. Problems encountered with the ventricle quick-connects indicated that more rigid support is necessary to adequately secure the quick-connect rings (female portions) to the AEC blood pump ventricles. See Fig. 6.

FIG. 6. Flexible drive shaft installed in the calf coupling the electric motor (left side of the photograph) to the AEC blood pump (extreme right hand side of the photograph). Bend radius of the flexible drive shaft is approximately 9 to 10 inches.

SUMMARY OF AEC EXPERIMENT # 9 TH 74 C9 B9 AEC9

Experiment No. 9 was designed as a sterile long-term evaluation of the internally placed electric motor and drive shaft to power the AEC blood pump.

Surgical Procedure. A sternal split surgical procedure was performed by Drs. Jay Volder, Don Olsen, Hartmut Oster, and Mr. Lee Smith. The experimental animal was a male Hereford calf weighing 105 kg. Anesthesia was Brevane followed by G.O.F. Preoperative lung functions were within normal limits. Blood pump ventricles were constructed of Silastic rubber and all blood contacting surfaces were coated with fibrils. Ventricles and blood pump were autoclaved prior to surgery. Bjork-Shiley heart valves were glow discharged prior to insertion into the ventricles. The flexible drive shaft and electric motor were gas sterilized 72 hours prior to surgery using ethylene oxide. Surgery lasted 3½ hours with the calf on heart-lung bypass for 120 minutes. Recording equipment was set up to record central venous and aortic pressure as well as electric motor r.p.m.

Postoperative Results. As the calf was going off heart-lung bypass and onto total support with the AEC blood pump, the electric motor controller stopped. Due to temporary pulmonary hypertension, very high aortic pressures on the order of 210/90 mm Hg were noticed. By reducing the blood volume added to the calf, the pressures were brought back down to normal physiological limits (150/90 mm Hg). Shutdown of the electric motor lasted approximately 1½ minutes, during which time circulation was aided by the heart-lung machine. One hour into the experiment the calf was on mechanical breathing support with 40% oxygen, with a tidal volume of 2,200 cc. Atrial pressures were 145/90 mm Hg with 3 mm Hg central venous pressure. Chest drainage was minimal.

At ten hours postoperative the calf was still on 40% oxygen with mechanical ventilation. Atrial pressures were excellent (135/75 mm Hg), with mean CVP of 8 mm Hg. Motor temperature had increased to 44° C. Fluctuations in motor temperature from 43° C to 48° C were noticed and were most likely due to movement of the temperature probe near the internal electric motor. At 19 hours the animal stood for approximately 2 minutes. Just after 20 hours postoperative the motor controller overheated and once again stopped. Torque (average) measurements made during this incident were 7 to 11 oz.-in. Since the motor is rated at 10 oz.-in. we most likely were operating too near its peak capacity. The controller is built to trip if a current of 2 amps or more is drawn for a short period of time. This current corresponds to an average torque of 13 oz.-in. The controller was off for approximately 2 minutes, after which the thermal relay device cooled sufficiently to allow the controller to operate again. A backup controller system was placed on standby at this time.

At 25 hours the animal again stood up for a few minutes, chest drainage had stopped and the animal's reflexes were good. Motor temperature was 45° C.

At 30 hours the animal was extubated and placed on 70% oxygen with a face mask. The animal once again stood. Atrial pressures were 125/80 with CVP of 8 mm Hg mean. Respiratory rate was normal at 30 breaths/min. At 35 hours postoperative the animal was doing very well on the face mask with 70% oxygen. Respiratory rate was 33 with atrial pressures of 125/80 and CVP mean pressure of 8 mm Hg. At 35 hours and 20 minutes the calf attempted to stand and fell forward out of the cage. Two minutes later we had the animal back into the cage with no apparent damage other than one chest tube pulled out. At approximately 36 hours the motor

controller again turned off, the backup controller was connected up and it too turned off. Switching back and forth from one control unit to another for several minutes failed to maintain the blood pump operating. Vacuum readings indicated that we were regulating the blood pump vacuum at 5 in. Hg. Torque readings were off scale (greater than 15 oz.-in) while r.p.m. was low (approximately 200 to 300 r.p.m.). After five minutes of attempting to operate the blood pump and electric motor, the r.p.m. suddenly returned to normal (900 r.p.m.) and the torque lowered to 3 oz.-in. The shaft had broken terminating the experiment. See Figs. 7-9.

Autopsy Results. Upon autopsy no kinking of the aorta or compression of the left and right atria was seen. There was approximately 30% kinking of the pulmonary artery. General appearance of the thorax showed only small amounts of free and clotted blood. Ventral atelectasis was present in both the right and left lungs. No ascites was present in the abdomen. The external appearance of the liver indicated a small degree of swelling, but the liver appeared smooth. Both kidneys showed no signs of infarcts. The spleen, intestines, bladder and brain all appeared in excellent condition.

Tissue in the vicinity of the electric motor metal end plates showed signs of severe thermal damage. A large hematoma was present around the electric motor, probably resulting from suturing in the electric motor before anticoagulants had taken effect. Autopsy revealed that the electric motor temperature probe was approximately 2 cm from the rear motor end plate. The thermal heat flux dissipated from the electric motor to the calf's body was approximately 10 watts. Most of this 10 watts was discharged through the end plates attached to the electric motor. Because of the small surface area of the end plates and therefore, high flux per unit area, some tissue damage resulted.

FIG. 7. Detailed view of the point of failure of the flexible drive shaft.

FIG. 8. View showing point of failure of drive shaft relative to position in shaft housing.

FIG. 9. View of flexible shaft opposite to failure end.
Note unwinding at this end of the flexible shaft.

Results of Experiment No. 9 have demonstrated that with a calf of suitable size and with proper reinforcement of the blood quick-connect rings, an electric motor can be used to simulate the thermal converter in driving the blood pump. Complete implantation of the electric motor seemed well tolerated by the calf and if proper attention is given to reducing high heat flux areas, there should be minimal trauma due to implanting and maintaining the electric motor within the abdomen.

FIT TRIAL EXPERIMENTS TO DETERMINE FLEXIBLE SHAFT LENGTH FOR IMPLANTED POWER SUPPLY

In conjunction with development of an implantation protocol for a totally implanted electric motor, we have carried out several fit trial experiments to determine the proper length for flexible shaft. The choice of flexible shaft length should not be dependent upon the use of an electric motor or the thermal converter power source, since the initial protocol utilizes first an electric motor, followed by replacement of the electric motor with the thermal converter. The fit trial experiments were conducted using a mock-up of the thermal converter since the surgical implantation of the electric motor offered more latitude in positioning. Any satisfactory flexible drive shaft length suitable for use with the thermal converter could be readily adapted to electric motor.

In order to accurately determine the proper length of flexible shafting and the typical bend radii after implantation, we used short lengths of $\frac{1}{2}$ inch diameter lead wire to simulate the flexible shaft. The lead wire was easily deformed by hand, but retained its shape throughout the fit trial experiment.

After implanting the AEC blood pump and thermal converter, the lead wire was cut to several lengths, 8, 6, and 4 inches. These were then positioned in the calf for both photographic and X-ray analysis.

From these experiments, the following drawings were made to show the positioning of the blood pump in relation to the thermal converter with both the 6 and 8 inch shaft lengths. Refer to the figures' dimensions for proper bend radii and lengths. See Figs. 10 - 12.

These experiments indicated that a 6 inch flexible shaft would allow a much better anatomical fit of the thermal converter than would an 8 inch

Dimensions for 8-Inch Shaft

- R_1 8 in. ± 1
- R_2 12 in. ± 1
- A_1 +45 dg. ± 15
- A_2 -30 dg. ± 15
- A_3 +15 dg. ± 5
- A_4 -15 (position of ventricles)
- D_1 2 in. $\pm .5$
- D_2 2 in. $\pm .5$
- L_1 11 in. ± 1

Dimensions for 6-Inch Shaft

- R_1 8 in. ± 1
- R_2 12 in. ± 1
- A_1 +55 dg. ± 15
- A_2 -30 dg. ± 5
- A_3 +15 dg. ± 5
- A_4 -15 dg. (position of ventricles)
- D_1 2 in. $\pm .5$
- D_2 2 in. $\pm .5$
- L_1 9 in. ± 1

Side view

FIG. 10. SIDE VIEW OF FIT TRIAL EXPERIMENT

FIG. 11. TOP VIEW OF FIT TRIAL EXPERIMENT

Dimensions for 8-Inch Shaft

- R_1 8 in. ± 1
- R_2 12 in. ± 1
- A_1 +45 dg. ± 15
- A_2 -30 dg. ± 15
- A_3 +18 dg. ± 5
- A_4 -15 (position of ventricles)
- D_1 2 in. $\pm .5$
- D_2 2 in. $\pm .5$
- L_1 11 in. ± 1

Dimensions for 6-Inch Shaft

- R_1 6 in. ± 1
- R_2 12 in. ± 1
- A_1 +55 dg. ± 15
- A_2 -30 dg. ± 5
- A_3 +15 dg. ± 5
- A_4 -15 dg. (position of ventricle)
- D_1 2 in. $\pm .5$
- D_2 2 in. $\pm .5$
- L_1 9 in. ± 1

FIG. 12. END VIEW OF FIT TRIAL EXPERIMENT

RESULTS OF INERT MODEL IMPLANT OF AEC THERMAL CONVERTER

In September 25, 1972, Dr. Jun Kawai was the first surgeon to implant a mock AEC thermal converter into the abdominal cavity of a Hereford calf. This AEC model was unique in that it was highly polished, milled aluminum, coated with reinforced Silastic and had a suture cuff along the edge. Noteworthy was the fact that this engine was implanted just subperitoneal to the left of the umbilicus and near the coastal arch anteriorly. All muscle layers were then sutured and the skin closed. This calf was housed at the Institute's research farm in Granite, Utah. The calf's recovery was uneventful and some personnel questioned if, in fact, this particular calf did receive the AEC model implant. Once, Mr. Monroe threw this animal down and palpated its stomach to verify the presence of the model since it was not obvious from external appearance.

On December 11, 1973, this Hereford Heifer was terminated to evaluate the effects of the long term implantation of the AEC model. At autopsy the model was very well encapsulated by a white fibrosis connective tissue capsule which completely surrounded the Silastic coated aluminum model. There were no discolorations, no signs of infection at any time during the course of this experiment. The interior of the rumen and reticulin which came in constant contact with the AEC model through the peritoneum was remarkable and on external appearance the rumen and reticulin showed no sign of inflammation of peritonitis. On opening the Silastic encasement, the highly polished aluminum model retained its polished surface and it was apparent that no body fluids had gained access to the aluminum surface. It is a well known fact that any body fluids in apposition to aluminum causes immediate oxidation of the aluminum with severe black precipitates. On microscopic anatomy, the tissue

capsule formed around the Silastic was dense fibrosis connective tissue, very healthy, with no indication of foreign body reaction or infection.

This experiment demonstrated that a healthy calf can tolerate and carry the AEC thermal converter configuration for periods of up to and excess of 15 months with no untoward reactions. Items which made this particular experiment unique in the series of model power supplies implanted are:

1. The model was implanted within the abdominal cavity immediately beneath the peritoneum. All other models were implanted either subcutaneously or within the muscle sheets.
2. This model was made of highly polished, milled, aluminum, drilling and weighted to the correct weight distribution, whereas other implants were of room temperature vulcanizing rubber (RTV).
The question thus arises, is there some material in the RTV rubber that diffuses through the Silastic, creating the untoward tissue reaction observed in that group of experiments?
3. The fact that several of the RTV model implantations were carried out while the RTV rubber was still hot due to autoclaving.

THERMAL LOSSES FROM THE IMPLANTABLE ELECTRIC MOTOR

To determine the amount of heat radiated from the implantable electric motor, we have conducted two experiments to measure the heat loss from the motor under normal operating conditions.

We used an Electrocraft Series 550 motor and controller, connected to the AEC blood pump on a Donovan mock circulation system, with a 12 inch flexible drive shaft.

Indirect Approach. The Donovan mock circulation system was adjusted such that the blood pump was maintaining 100 mm Hg outflow pressure with 10 mm Hg inflow pressure. When cardiac outflow was approximately 11 liters/minute, current and voltage measurements were taken of the power into the electric motor after it had run sufficiently to warm up (15 minutes). Voltage and current measurements gave the power input to the electric motor. Torque (in.-lbs.) and r.p.m. measurements yielded the power out of the electric motor. The difference between the power in and power out can be attributed to the heat losses from the electric motor. Small losses, as a result of noise and vibration, can be ignored.

From electrical measurements:

1. Power in = $(p=IV)$ = 18.90 watts:

I = current

V = voltage

2. Power out = {torque (in.-lbs.) x r.p.m. x 10.65} = 8.52 watts

3. Difference approximately equal to heat loss:

$$18.90 \text{ watts} - 8.52 \text{ watts} = 10.38 \text{ watts}$$

$$(\text{power in} - \text{power out} = \text{heat loss})$$

To confirm the above measurements we repeated the above test conditions but placed the implantable electric motor in a Dewar flask with

3,500 gm (7.709 lbs.) of water. The Dewar flask insulated the water bath from the surrounding room temperature environment. The water bath and electric motor were equilibrated with the room temperature overnight. The motor was allowed to operate initially 15 minutes to equilibrate with the water bath. Measurements were then made of the temperature rise in the water bath as a function of time while the electric motor was operating under the test condition specified earlier. By calculating the temperature rise for a given time period with a specified mass of water, one can easily calculate the thermal energy imparted to the water bath environment from the electric motor.

Since:

$$1 \text{ watt} = 0.05688 \text{ BTU/minute}$$

and,

$$1 \text{ BTU} = \text{amount of energy to raise 1 lb. of water } 1^{\circ} \text{ F}$$

then from Figure 13 we see that after the motor has equilibrated thermally (warmed up) the curve of temperature rise (ΔT) versus change in time (Δt) is fairly linear. From this data we calculated that the heat loss = 9.04 watts. This compares favorably with the indirect measurement of 10.38 watts. The direct approach is most likely a more accurate technique. Our least accurate readings are from the measurement of torque and r.p.m. which are made electrically and probably are only accurate to within 10 percent.

We nevertheless can plan to design the cooling system for the electric motor to dissipate at least 9 to 10 watts of power.

THERMAL LOSS FROM AN IMPLANTABLE ELECTRIC MOTOR

FIG. 13. Thermal loss from implanted electric motor.

EVALUATION OF TECO QUICK CONNECT SYSTEM

At our request Dr. William Mott of the U.S.A.E.C. and Mr. Frank Altieri of NALI invited Dr. Fred N. Huffman of Thermo Electron Corporation to send us one of their quick connects (see Figs. 14 - 17).

Upon our evaluation the TECO quick connects proved too large for our use. The weight of one quick connect device was approximately 116 grams, with a volume displacement of 48 cc. With four such devices there would be very little space available for placement of the blood pump mechanism. Whereas the weight of our present quick-connect (without the valve) is less than 11 grams and a volumetric displacement of 8.6 cc, this represents an order of magnitude decrease in weight. The positive twist locking action of the TECO quick-connect device is impressive but this feature must be reduced in size for our application. In addition, blood is not exposed to any metal parts except the valve ring in our quick-connect device, with all parts covered with a Silastic sheath. The thermoelectron device has a large surface area that must be suitably protected.

FIG. 14

FIG. 15. Valve Disk View of TEC Quick Connect

FIG. 16. View of Mating Parts of TECO Quick Connect

FIG. 17. TECO Quick Connect System Mating

HEMODYNAMIC CONSIDERATIONS OF BLOOD FLOW IN THE AEC BLOOD PUMP VENTRICLES

Because blood contains a suspension of formed elements (erythrocytes, leukocytes and platelets) as well as fluid (plasma or serum), blood is not a true Newtonian fluid and is more correctly classified as a rheological fluid. However, the mathematical modeling for rheological fluids is difficult and poorly developed and is therefore an impractical model for examining the hydrodynamic characteristics of blood flow in an artificial blood pumping ventricle.

As a preliminary model we will assume that whole blood (formed elements and plasma) can be treated as an incompressible, Newtonian fluid. If blood is incompressible, which is valid over a broad range of pressures, then from the continuity equation

$$\frac{\partial \rho}{\partial \tau} + \nabla \cdot \bar{u} = 0$$

and since $\frac{\partial \rho}{\partial \tau} = 0$, we have that

$$\nabla \cdot \bar{u} = 0$$

Furthermore, assuming that blood is a Newtonian fluid, then the viscous forces $\bar{f}_v$ can be mathematically related to the fluid velocity by the Newtonian viscosity relationship

$$\bar{f}_v = \mu \nabla^2 \bar{u}$$

where μ is defined as the coefficient of viscosity.

The general equation of motion for an incompressible, Newtonian fluid which is a consequence of Newton's Second Law is given by

$$\rho \left\{ \frac{\partial \bar{u}}{\partial \tau} + (\bar{u} \cdot \nabla) \bar{u} \right\} = - \nabla p - \rho \nabla \phi + \mu \nabla^2 \bar{u}$$

which is generally referred to as the Navier-Stokes equation. The left side of the equation is the rate of change of fluid momentum which

results from the presence of the external forces upon the fluid which are given by the right side of the equation. The three force terms on the right side of the equation are the pressure, gravitational (or other conservative forces), and viscous forces respectively.

It is apparent that the Navier-Stokes equation together with appropriate boundary and initial conditions poses a formidable burden to analytically solve to determine blood flow behavior in a ventricle. However, it is possible to gain some basic information about the characteristics of blood flow in the ventricle. For example, it can be shown that for a given system, geometry and configuration, then the flow behavior of a Newtonian, incompressible fluid is uniquely determined by a single dimensionless parameter called the Reynolds number. Thus, if the flow behavior for water through the ventricle is known for the same Reynolds numbers as those which occur for blood flowing through the ventricle, then the blood flow behavior is also known. This observation is of great importance since the in vivo behavior of blood flow through this ventricle can be inferred from bench model tests using water flow in the ventricle.

To show that the Reynolds number is adequate to uniquely characterize flow through a given system, we will introduce a new dependent variable called the vorticity function and defined by the curl of the fluid velocity, i.e.

$$\bar{\Omega} = \nabla \times \bar{U}$$

and if we take the curl of each term in the Navier-Stokes equation and introduce the vorticity function we have

$$\frac{\partial \bar{\Omega}}{\partial \tau} + \nabla \times (\bar{\Omega} \times \bar{U}) = \frac{\mu}{\rho} \nabla^2 \bar{\Omega}$$

We observe that both the pressure and gravitation forces have been eliminated since the curl of any gradient term vanishes.

Now let us consider a flow system such as a ventricle in which we can define a characteristic dimension, such as a mean ventricle diameter D and furthermore, let us define also an instantaneous speed of flow through the ventricle V . Then if we define new dimensionless variables as follows

$$\bar{u} = D \bar{u}'$$

$$\bar{v} = V \bar{v}'$$

$$\bar{\tau} = \frac{D}{V} \tau'$$

$$\bar{\Omega} = \frac{V}{D} \Omega'$$

then our equation for flow through the ventricle becomes

$$\frac{\partial \bar{\Omega}}{\partial \bar{\tau}} + \nabla \times (\bar{\Omega} \times \bar{u}) = \frac{\mu}{\rho V D} \nabla^2 \bar{\Omega}$$

Observe that all the parameters which are associated with the fluid properties can be grouped into a single factor which is dimensionless and is called the Reynolds number where

$$Re = \frac{\rho V D}{\mu}$$

To determine the range of values assumed for the Reynolds number by blood flowing through the AEC Blood Pump ventricle we recall that pumping action is sinusoidal and the blood displacement rate D_r in the ventricle as a function of time is given by

$$D_r = D_0 \sin w\tau \text{ (cc/sec)}$$

where w is the angular velocity ($w = 12.6$ radians/sec for a pumping rate of 120 rpm).

The stroke volume, S_v , i.e. the volume of blood displaced by each stroke of the pump is given by

$$S_u = \int_0^{\pi/w} D_r(\tau) d\tau = \frac{2D_o}{w} \left(\frac{\text{cc}}{\text{stroke}} \right)$$

where integration of the displacement rate is carried out over the time for one stroke, π/w . The displacement rate at any instant in time is also equal to the flow area cross section A and the mean flow velocity V through that flow area

$$D_r = AV$$

So we have for the mean velocity

$$V = \frac{D_r}{A} = \frac{S_u w}{2A} \sin w\tau$$

Now the Reynolds number for blood flow through the ventricle under these conditions becomes

$$\begin{aligned} Re &= \frac{\rho V D}{\mu} = \frac{\rho S_u w}{2\mu A} \sin w\tau \\ &= \frac{2w S_u}{\pi v D_h} \sin w\tau \end{aligned}$$

where $v = \mu/\rho$ is the kinematic viscosity and D_h is the hydraulic diameter given by $D_h = 4 \times \text{flow area/wetted perimeter}$ ($4A/\pi D$). Now if we consider maximum flow through the outlet valve of the ventricle which has a diameter of 2.7 cm and assume the following value for the kinematic viscosity of blood, the stroke volume and angular velocity

$$w = 12.6 \text{ rad/sec}$$

$$S_r = 100 \text{ cc/stroke}$$

$$D_h = 2.70 \text{ cm}$$

$$v = \frac{\mu}{\rho} = 0.0196$$

then the maximum value of the Reynolds number is

$$Re_m = \frac{2(12.6)(100)}{\pi(0.0196)(2.7)} = 15,150$$

and over the pumping cycle the Reynolds number becomes

$$Re = 15,150 \sin 12.6\tau$$

Laminar flow which occurs for $R_e \leq 2000$ is characterized by smooth potential flow with orderly streamlines and typical parabolic type velocity distributions. When R_e exceeds 2000 to 4000, flow becomes turbulent and very irregular with eddy domains produced wherever the flow stream is perturbed. A significant portion of the flow energy of the is converted to vortices, i.e. rotational flow regimes which diffuse through the flow system. The relationship of turbulent flow to thrombosis and hemolysis in the blood is not completely understood, but evidence seems to indicate some correlation. It is interesting to observe that over 83 percent of the stroke volume $R_e \leq 4000$ and flow is turbulent. Because of the time required for vorticity to diffuse and dissipate through frictional losses in the fluid, it is probable that fluid in the ventricle is always in a turbulent condition.

Fig. 18. Pulmonary function equipment for pre and postoperative measurements. W.E. Collins Spirometer.

DEVELOPMENT OF NEW PULMONARY FUNCTION TESTING TECHNIQUE

As indicated in our surgical protocol we now have developed a method of measuring the lung functions and residual capacity of the experimental animals. This technique serves a twofold task:

1. To serve as a screening device for preoperative lung evaluations of calves.
2. To monitor on a routine basis the respirator capabilities of the calves after surgery while they are maintained with the AEC blood pump.

The equipment (see Fig. 18) is a Warren E. Collins residual volume and diffusion study spirometer console. Along with this equipment we have developed a protocol for properly using the equipment on a pre and post-operative basis, along with a work sheet to facilitate calculating lung function studies (see accompanying work sheet as Fig. 19).

We have performed this testing procedure on sufficient calves to develop some normal values based on a calf with an average weight of 95 kg.

Normal values for a 95 kg Holstein calf:

1. Minute volume: 28 ± 4 Liters/minute
2. Respiratory rate: 44 ± 10 Breaths/minute
3. Tidal volume: 700 ± 100 Liters/breath
4. Oxygen uptake: 545 ± 50 cc/minute
5. Functional residual capacity: $4,800 \pm 500$ cc.

Department of Artificial Organs

PULMONARY FUNCTION TESTS

Work Sheet for Spirometry

Calf No. _____ Date _____ Weight _____ Kg.
 Pre-Op. _____ Post-Op. _____ / _____ Hrs. Standing _____ Sitting _____
 Person conducting test _____ Temp. _____ C° Press. _____ mmHg.

I. Minute Volume

A. Ventilograph displacement _____ mm/3 min.

B. Minute volume = (A) x (0.1884)* = (BTPS) _____ L/min

* Correction factor (0.1884) = $\frac{(20.73 \text{ cc/mm} \times \text{Vent. Fact. (25)} \times 1.093)}{(3.0 \text{ min.} \times 1000 \text{ cc/L})}$

II. Respiratory Rate

A. Respirations recorded for three minutes/ 3.0 = Resp/m

III. Tidal Volume

A. Minute Volume (I-B) / Resp. Rate (II-A) = (BTPS) _____ L/Brea

IV. Oxygen Uptake

A. Base line change for 3. minutes = _____ mm.

B. $\frac{(\text{IV-A mm/3 min.}) \times (2.475) \times (\text{Press.} - 47 \text{ mmHg.})}{(273 + \text{Spior. Temp. C}^\circ \text{K}^\circ)}$ = _____ cc/min
 (STPD)

V. Functional Residual Capacity (FRC)

A. Trial # 1 $C_1 =$ _____ %; $C_2 =$ _____ %; $C_3 =$ _____ %

Volume of Air added = Vol. A. = _____ L.

Switch Error = Sw. Er. = _____ cc. (+)

B. Trial # 2 $C_1 =$ _____ %; $C_2 =$ _____ %; $C_3 =$ _____ %

Vol. A. = _____ L. ; Sw. Er. = _____ cc. (+)

C.
$$\text{FRC (BTPS)} = \left(\frac{C_1}{C_3} \right) \times \frac{(C_2 - C_3)}{(C_1 - C_2)} \times (\text{Vol. A.}) \times 1.093 - 300 \text{ cc.} + (\text{Sw. Er.})$$

FRC (trial #1) (BTPS) _____ cc.