# THE DESIGN AND ANALYSIS OF A VENTRICULAR ACTUATING MECHANISM FOR A CARDIAC PROSTHESIS

by

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# CHAPTER I

## INTRODUCTION

Heart disease is the nation's number one killer, and is responsible for 54% of all deaths.[1] A mortality statistic such as this, however, provides only a partial picture. According to the results of a National Health Survey, compiled between 1960 and 1962, 13.2% of all American adults--14,000,000 in number--have definite heart disease. Of these, 2,000,000 are seriously handicapped by their disease.[1]

Many of the victims have been helped by current therapeutic treatment such as chemotherapy, surgery, and mechanical intervention.[1]

Chemotherapy involves the application of drugs to reverse certain pathological heart conditions. Although a powerful method of treatment, chemotherapy may be directed only at symptoms and not at a cure in a great percentage of cases.

Surgical techniques include repair of vessels, valves, and sections of the heart musculature, as well as complete replacement of the human heart with a donor heart (transplantation). These surgical techniques have only limited applications. The future of heart transplants, in particular, looks grim. Because of tissue rejection, 167 of the 194 people who have received transplants have died.[2]

Mechanical intervention includes 1) replacement of vessels, valves, and sections of the heart wall with artificial substitutes, 2) temporary paracorporeal (outside the body, but connected to the human cardiovascular system) pumping assistance such as tho heart lung machine and, most recently, 3) intracorporeal (inside the body and connected to the cardiovascular system with external control lines) implantation of pump-

ing assist devices such as the intra-aortic balloon pump.

Chemotherapeutic, surgical, and mechanical approaches are valuable techniques in certain of the more minor cases of heart disease. Because of the inadequacy of the approaches in the case of a severely failing heart, however, heart specialists have been recently directing their attention towards replacement with a prosthetic heart. It has been estimated that between 80,000 and 350,000 Americans per year could benefit from an artificial heart.[3]

The need for a cardiac prosthesis has been recognized for many years, and for the last twenty years, a concentrated effort devoted towards building such a device has been in effect. The hearts developed have been tested in a wide variety of animals, including sheep, dogs, and cows. The longest survival time that has been achieved to date for a total mechanical heart is 247 hours of successful implantation in a calf.[4] For an indication of the success of the prosthetic heart program, this figure should be compared to 87,700 hours, or 10 years--a reasonable goal for a cardiac prosthesis.

The problem is far more difficult than perceived by many of the early investigators. This misconception is further illustrated by Dr. Charles K. Kirby in his address to the American Society of Artificial Internal Organs in 1961, when he said:

> The successful construction and implantation of an artificial heart is going to be a reality much sooner than the most optimistic among us believed seven years ago. We have all the know-how that is required, from the surgical, physiological, and engineering standpoints. Many details must still be worked out, but these are merely a matter of time and money, in my opinion... With adequate funds, and the concentrated efforts of highly skilled surgeons, physiologists, and engineers, it seems almost certain that an

> artificial heart suitable for implantation in patients could be developed within two to five years.[5]

The remainder of the thesis concerns 1) a literature search which includes first, a presentation of the important requirements of an effective cardiac prosthesis and then, a description of the most significant ventricular actuating devices (the crucial element in a prosthetic heart system) which represent attempts to satisfy the requirements and, 2) a presentation of the design and analysis of a particular approach for a ventricular actuating mechanism. It will be shown that this design follows directly from the analysis of the previous attempts presented in the literature search.

## CHAPTER II

## LITERATURE SEARCH

### Requirements of a Cardiac Prosthesis

If the requirements for a cardiac prosthesis may be consolidated into a single criterion, the universally accepted criterion is that the prosthesis simulate the natural heart in every respect as closely as possible. This criterion may be subdivided into the following five requirements which are recognized as crucial for successful heart replacement: 1) long life, 2) tissue and blood compatibility, 3) feasibility of power delivery and utilization, 4) sufficient output performance and, 5) reasonable size and weight. Each of these requirements will be considered in greater detail.

The first requirement for a successful cardiac prosthesis is long life. Ideally, the prosthesis should perform for the remainder of the potential life of the recipient; alternatively, it should at least perform for several years. Careful attention should therefore be devoted to the mechanical elements such that they will be capable of surviving the number of cycles which would take place in 10 years--approximately 370,000,000.

The second requirement for a cardiac prosthesis is that both the performance and the materials of the entire system be compatible with the tissues of the thoracic cavity and the blood. The external surfaces of the prosthetic heart must not react with the tissues of the thoracic cavity and, similarly, the internal surfaces of the heart must not react with the blood. The two most important reactions between the internal heart surfaces and the blood which must be guarded against are 1) blood

clot formation (thrombosis), and, 2) red blood cell destruction (hemolysis), both of which are caused most often by improper pumping action and improper physical configuration of the valves and interior of the ventricle.

The third requirement for a cardiac prosthesis involves the power required to activate the system. First of all, the power supply must be safe and reliable. Secondly, the energy should be transported through the thoracic wall in a manner which will minimize problems in the wall tissues, since virtually all intra-thoracic cardiac prostheses developed to date depend on a source of power which is located outside of the body. Finally, the prosthesis and its power supply must have a high mechanical, electrical, and/or hydraulic efficiency in order to minimize heat dissipation and thus maintain the finely tuned metabolic balance of the surrounding tisues.

The fourth requirement for a cardiac prosthesis is adequate output performance. This performance may be subdivided into 1) aortic pressure/time waveform production and, 2) sufficient and regulated cardiac output. Both the waveform and the output should be comparable to that produced by a natural heart. The aortic pressure/time waveform should be characterized by a sudden increase from 80 to 120 mm Hg, as shown by Figure 1.[6] The cardiac output should vary from 5 to 15 liters per minute, depending on the tissue need for oxygen. The means by which the pump output of the natural heart varies with the need is called cardiac output regulation, and should be duplicated as closely as possible by the mechanical heart. Natural output regulation is comprised of three parallel functions: 1) Frank-Starling regulation, the system by which the heart automatically

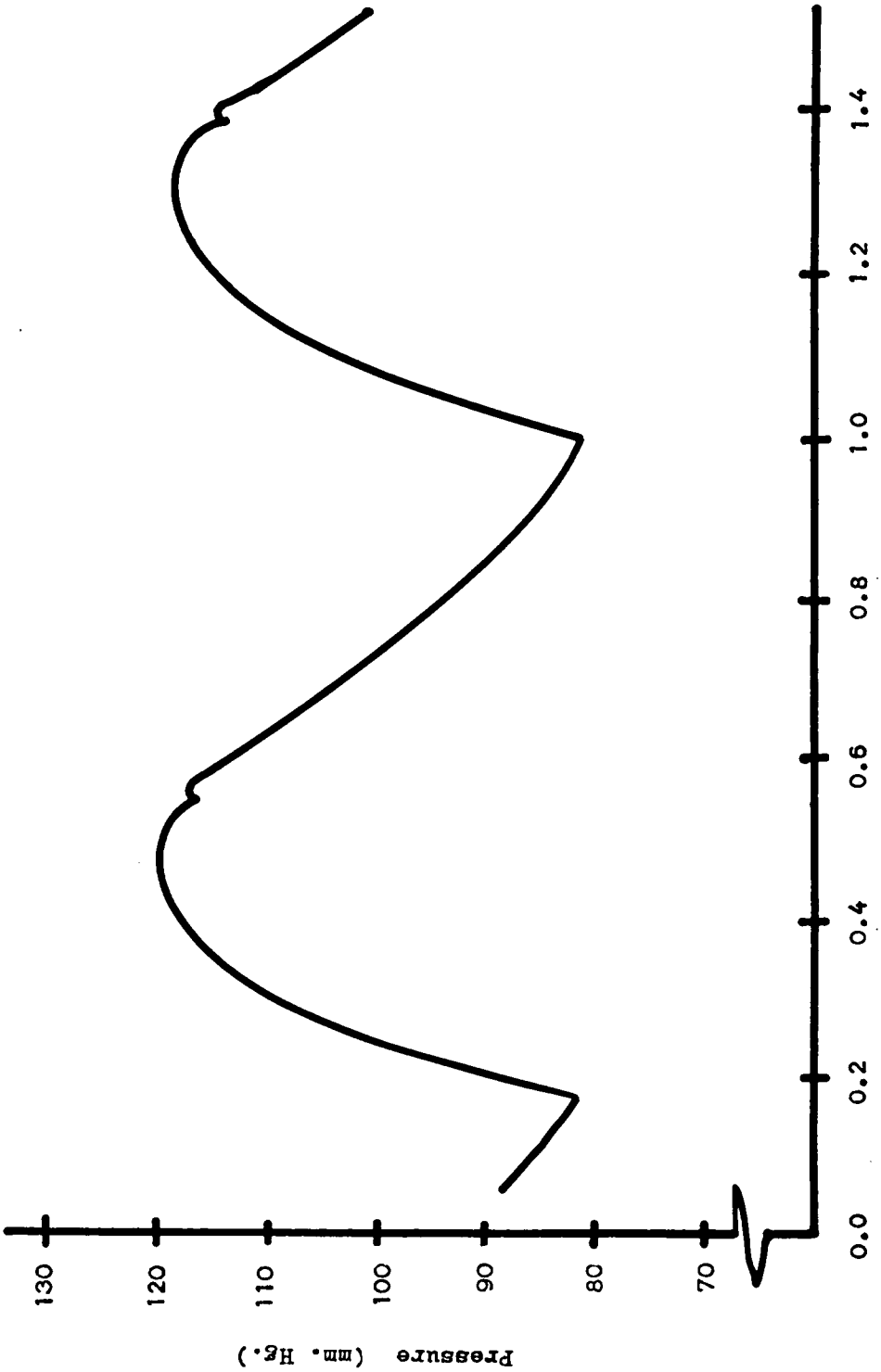



Figure 1. Physiological Aortic Pressure/Time Waveform

pumps exactly that amount of blood returned to it by the tissues, 2) sympathetic (nervous) control and, 3) humoral (chemical) control. The latter two functions, besides being most difficult to simulate, play a relatively minor role in the regulation of the cardiac output. Indeed, Frank-Starling control is believed to be responsible for 81% of cardiac output regulation and is therefore the sole form of regulation modeled by the more successful prosthetic hearts.[7]

The fifth and final requirement for a cardiac prosthesis is that it have reasonable size and weight. The average, human, male, adult heart weighs approximately 312 gm, and the female, 225 gm, both comprising about .4 to .5 per cent of the total body weight. The volume is approximately equal to that of a man's fist, with measurements of about 12.5 cm from base to apex and 8.7 cm in its greatest width.[8] The size and weight of the prosthesis should approximate these values.

History of Attempts

With few exceptions, investigators agree on the major requirements for a successful cardiac prosthesis. Such uniformity is not the rule, however, when it comes to the means of satisfying the requirements. The attempts to date may be described in one word: varied.

The year 1937 marks the date of the first major attempt. The Soviet investigator, Vladimir P. Demikov, Chief of Moscow's Transplantation Laboratory, kept an animal alive for two and a half hours on a mechanical pump.[9] Twenty years went by without another significant attempt. Then, in 1957 began a concentrated, multi-nation effort on the part of dozens of investigators representing a wide variety of scientific disciplines.

The result of the last 27 years of research is an extremely wide variety of designs, the more significant of which are shown diagrammatically in Figure 2. Each of these approaches will be briefly described and analyzed with respect to its principle cause of failure.

From the figure it may be seen that the first major division of devices distinguishes between pneumatically, electromechanically, and mechanically actuated pumping mechanism.

The first division of devices to be considered is the pneumatically actuated hearts--devices which rely on compressed gas as a source of power. The compressed gas for the pneumatic prostheses is derived from an external source, and is transported to within the thoracic cavity by means of a tube which extends through the chest wall. At the prosthesis, the compressed gas collapses some form of ventricle, resulting in the expulsion of blood.

The pneumatic hearts include both assist and total pumping devices, the latter achieved by placing two pneumatic ventricles in parallel. The most significant assist devices include the intra-aortic balloon pump (IABP),[10] the left ventricular series pump (LVSP),[11] and the left-ventricular by-pass pump (LVBP).[12] Significant total pneumatic prosthetic hearts include the diaphragm-driven,[13] the wave-pulsating,[14] and the well-known sac-type pneumatic heart. In the sac-type hearts, compressed air is used to alternately reduce and increase the volume of a flexible sac which represents the natural ventricle. On the upstream side of the sac is a one-way valve allowing flow only towards the sac, and on the downstream side, a one-way valve allowing flow only away from the sac. Thus the result of the alternate increase and decrease of the

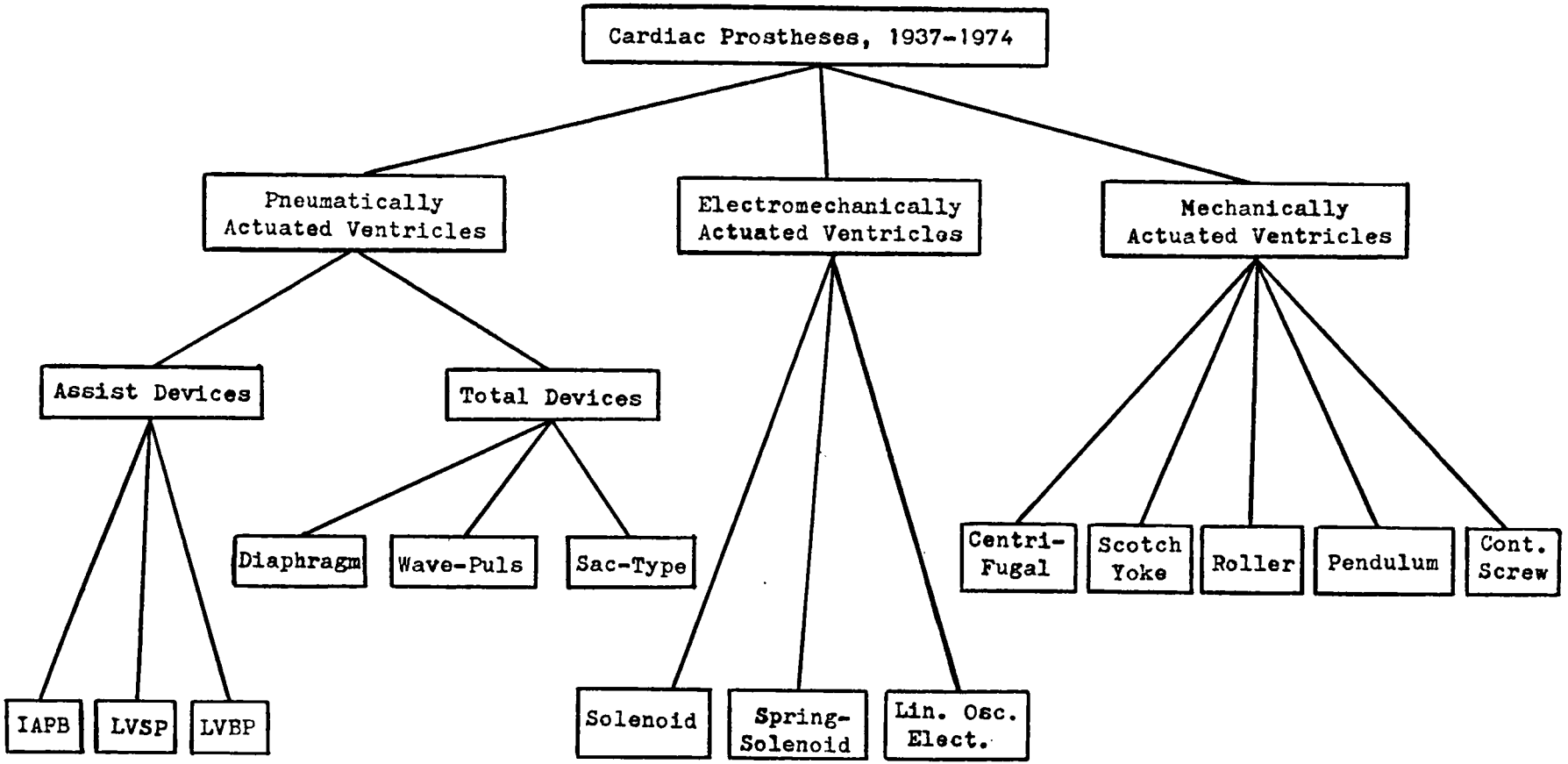



Figure 2. Twenty-Seven Years of Cardiac Prostheses

volume of the sac is the pumping of blood in a manner analogous to that of the natural heart.

It was a sac-type pneumatic device which made history in 1969. Dr. Denton Cooley and Dr. D. Liotta implanted such a heart in a 47 year old man with terminal heart disease as a means of supporting the circulation until a cardiac allograft (transplant) was available. After 64 hours of successful mechanical support, a human heart was transplanted. The patient died later from pneumonia and renal complications not directly attributed to the function of the cardiac prosthesis.[5]

The success of the pneumatic cardiac prostheses in temporary applications such as the one described above may be a result of the lack of restriction on the size and weight of the externally located control and waveform producing equipment.

The disadvantage inherent in pneumatically powered hearts involves the extension of the air hose through the chest wall: the interface between the hose and tissue will be a constant source of infection. The pneumatic devices are therefore restricted to temporary applications such as the example described.

The next major division of prosthetic hearts is the group of electromechanically-driven hearts, which also include both assist and total devices. The power for these devices is usually derived from an external source of alternating or direct current. Such electrical energy may be transmitted electromagnetically across the chest without disturbing the tissues, a technique called transcutaneous power transfer.

The simplest of the major electromechanical designs is the solenoid drive device, whereby the core of a solenoid is activated on command

to drive a plunger which reduces the volume of an artificial ventricle. The result is expulsion of blood in a fashion similar to that of the pneumatic sac-type hearts.[15]

The problems inherent in the solenoid configuration are 1) the inability of the solenoid to develop the steep rise in the aortic pressure waveform, 2) excessive weight, and, 3) electromechanical inefficiency.[15] The inefficiency of the solenoid results in excessive heat dissipation and, in addition, a rate of transcutaneous power transfer which could jeopardize the tissues of the thoracic wall. Although the solenoid device has been tested in-vivo, survival times have not been published.

The spring-solenoid configuration represents the second of the most significant electromechanical devices. In this design, the solenoid serves to compress the spring which, in turn, is released against the plunger. The release of a spring closely approximates the muscle action of the heart and is therefore potentially capable of generating an acceptable aortic pressure waveform. Thus, the spring solenoid configuration may solve the problem of the waveform. The problems of inefficiency and excessive weight remain. The spring-solenoid pump was tested in-vivo by means of a series of implantations in dogs, yielding a maximum survival time of 15 hours.[16]

The third and last of the more significant electromechanical devices is the linear oscillating electromotor. The operation principle is similar to that of the solenoid pump. The design consists of two coils in series which produce opposing magnetic fields. A magnet, which is placed within the coils, may be oscillated back and forth, pressing against two

plungers. The plungers, in turn, collapse a pair of ventricular sacs. Problems inherent in the design are similar to those of the solenoid device, namely inefficiency and excessive weight.[17] The linear oscillating electromotor has not been tested in-vivo at this time.

The third and last major division of ventricular actuators is the group of mechanically-driven devices. Again, these designs include both assist and total devices. In each case, the actuating mechanism is driven by a rotating shaft. Power for this rotating shaft is provided by either an electric motor, or a gas cycle engine such as a Rankine or Stirling engine.

There are five significant mechanically-driven devices, as shown in Figure 2: 1) the centrifugal heart, 2) the Scotch yoke pump, 3) the roller pump, 4) the pendulum heart and, 5) the continuous screw pump.

The first of these, the centrifugal heart, works on a principle similar to that of a turbine and, as does a turbine, produces continuous rather than natural pulsatile flow. Preliminary in-vivo testing produced unacceptably high hemolysis and a maximum survival time of three hours.[18] More recently, investigators generally have agreed that pulsatile flow is an essential requirement for an effective cardiac prosthesis.

The second of the major mechanically driven pumping mechanisms is the Scotch yoke configuration. The most prominent example of a heart employing this mechanism is the Atomic Energy Commission's design (the AEC Heart). A Stirling cycle engine, which derives power from an implanted radioactive heat source, drives a Scotch yoke. The Scotch yoke, in turn, drives two ventricular sacs, expelling the blood in a manner similar to the sac-type hearts. The device is characterized by pseudo-

self-regulation in that the plunger has a fixed travel. If the blood fills, for example, to one-half the capacity of the sac, the plunger travels free for one-half its stroke, at which time it strikes the sac.[19] In the case of true Frank-Starling regulation, the plunger (analogous to the cardiac musculature) must move in unison with the filling. Results of in-vivo testing of the Scotch yoke pump have not been published.

The third of the five significant mechanically-driven configurations is the group of pendulum hearts. A number of these devices have been designed but the most notable device was developed by Kolff in 1964. In this design, a motor, which is offset about its shaft, behaves as a pendulum, pressing against two ventricles and thus pumping the blood. The problems reported were that the device is too heavy, inefficient, weak, and generates too much heat.[9] Again, in-vivo test results have not been published.

The fourth mechanically-driven configuration is the roller pump. This device has been used extensively for short term paracorporeal applications such as the heart lung machine. The operating principle involves two rollers attached to opposite ends of a rod. An electric motor turns the rod and the rollers alternately collapse a tube through which the blood flows. The result is continuous pumping of blood through the tube. Unfortunately, the flow is non-pulsatile, produces excessive hemolysis, and, as a result of tubing wear from contact with the rollers, the pump has a short life. One in-vivo test of a roller assist pump implanted in a lamb yielded a one-week survival time.[20]

The fifth and final mechanically-driven device is the continuous screw pump. This design incorporates a large "screw" which rotates in

a sealed chamber, resulting in pulseless, valveless, unidirectional flow. Hemolysis is the major problem associated with the mechanism.[21] In-vivo test results have not been reported.

Conclusions from the Literature Search

It is at this point evident why each of the prosthetic heart designs have been unsuccessful in terms of long-term circulatory support. Each of the mechanisms fall short of satisfying one or more of the design requirements. After carefully studying these various configurations and their shortcomings, one may see that by combining certain operating principles of some of the previously described devices, he may envision a pump capable of the desired performance. The devices under consideration were 1) the spring-solenoid device and 2) the group of mechanically-driven (rotating shaft) devices. First, since one is forced to abandon the pneumatic designs as a wave-producing medium in order to avoid infection in the chest wall, the spring seemed to be a simple and reliable alternate approach. Next, it was believed that a mechanism could be designed which would serve to derive power from a rotating shaft. This rotation could be converted to linear motion which would serve to compress and release the spring. The mechanism must also provide true Frank-Starling control of cardiac output. The power to turn the shaft could be provided by an electric motor, powered in turn by transcutaneous power transfer to avoid the problem of chest wall infection.

# CHAPTER III

## DESIGN OF THE VENTRICULAR ACTUATING MECHANISM

### Operating Principles

Based on conclusions drawn from the literature search, the following were chosen as specific requirements of the ventricular actuating mechanism. First, the device must be capable of converting from the rotating motion of an electric motor shaft to the linear motion necessary to operate the spring. Next, during compression of the spring, the plunger, which rests against the ventricular sac, must be free while the ventricle fills, to satisfy the requirement of Frank-Starling regulation. Finally, during the release phase, the spring should release against the plunger and thus expel blood through the one-way valve located downstream of the ventricular sac.

Although attention was given to minimum size, blood handling ability, long life, ventricular configuration and material, and reliability, the major effort at this stage was directed towards design of a mechanism capable of self-regulation and production of a physiological aortic pressure/time waveform.

After examining a large number of possible mechanisms, a configuration was chosen which appeared capable of performing the desired functions. This configuration, shown in Figure 3, is illustrated in a fully extended, conceptual position to demonstrate the principles of operation. Not seen in the figure for the reason of clarity are the electric motor and gearbox, which are located behind, and attached to, the drive wheel. The motor would be geared down such that the speed of the drive wheel is

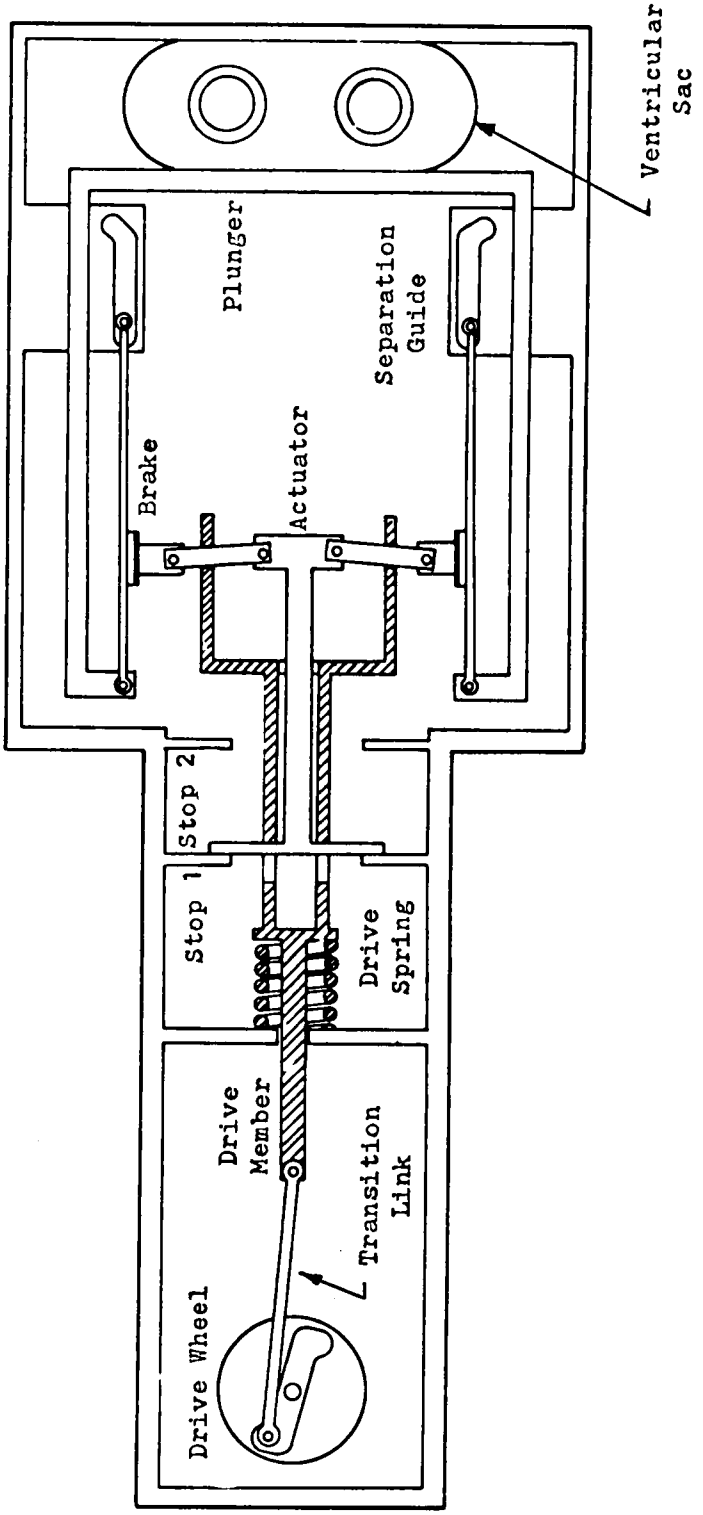



Figure 3. Conceptual Schematic of Ventricular Actuating Mechanism

30 rpm in the direction shown by the arrow in the figure.

One half of one revolution of the drive wheel results in one cycle of operation of the mechanism, corresponding to one heartbeat. Each cycle consists of 1) diastole (ventricular filling) and, 2) systole (ventricular emptying). The wheel is shown in a position exactly between diastole and systole.

Diastole will first be described. During rotation of the drive wheel from a position 180° before its present position to its present position, the roller attached to the left end of the transition link is forced to remain in the left hook of the slot in the wheel. The counterclockwise rotation of the electric motor shaft is thus converted to leftward linear motion of the drive member and, consequently, compression of the spring.

It is seen in Figure 3 that a few more degrees of rotation will free the roller to initiate systole. During this phase of the cycle, the spring is allowed to release, resulting in a sudden rightward movement of the drive member.

The remainder of the mechanism, which includes the plunger, brakes, brake actuator, brake plates, and separation guides, is devoted to fulfillment of the requirement of self-regulation. During most of the diastolic phase of the cycle, the brake shoes are disengaged from the brake plate, thus allowing the plunger freedom to move in accordance with whatever amount of blood which is returned to the pump from the veins. The engagement and disengagement are accomplished by means of the brake actuator, shown in the figure. Near the end of the diastolic phase, the extensions of the brake actuator come into contact with

"stop 1", shown in the figure. The brake actuator moves in the slot of the drive member, forcing the brakes to contact the brake plate. Immediately following engagement of the brakes, the cam on the end of the transition link rolls off the hook in the slot of the drive wheel, allowing the spring to propel not only the drive member, but, because of engagement of the brakes, the plunger as well. Near the end of the systolic phase, the extensions of the brake actuator come into contact with "stop 2". The springs push the drive member to the end of the stroke, but since the brake actuator is held fixed by "stop 2", the brake arms are pushed to the right, and the brake shoes are thus withdrawn from contact with the brake plate. The drive member may now be pulled back against the force of the spring by the drive wheel, leaving the plunger free to move with the entering blood.

The one remaining set of parts which has not been described and which is vital to proper functioning is the set of separation guides and associated rollers. The distance of travel of the drive member during distole is the length of the slot in the drive wheel. The plunger should travel this same distance only for the case of 100% filling of the ventricle. For the case of non-complete filling, the plunger should travel only a fraction of the maximum possible travel; otherwise, the plunger will hit the right case wall. The separation guides assure, therefore, that the travel of the plunger automatically terminates short of the case wall.

## Design Specifications

The next step in the project was to specify exact performance parameters which would dictate the actual design of the pump. The

parameters which were of importance at this stage of the study involve, 1) the pressure/time waveform, and, 2) the pump output.

Parameters involved with the pressure/time waveform are the systolic and diastolic pressures. As a first iteration of the design, the spring force was calculated to develop a systolic pressure of 120 mm Hg. In order to meet the diastolic pressure requirement of 80 mm Hg, it was believed that adjustments of the mock circulatory system could be made during the testing of the device to initiate systole at a point in the cycle when the pressure reached a value of 80 mm Hg.

In order to determine the spring force needed to develop 120 mm Hg, it was first necessary to determine the diameter of the ventricular sac, $D_S$. The ventricular sac volume, $V_S$, was specified as 100 ml, as will be discussed later. A stroke length, $L_S$, of 1.9cm was chosen on the basis of miniaturization considerations, as described in the following section. The sac diameter was calculated using the assumption that the shape of the sac approximates that of a cylinder:

$$D_S = \sqrt{\frac{4 \cdot V_S}{\pi \cdot L_S}}$$

$$= \sqrt{\frac{4\ (100\ cm^3)}{\pi\ (1.9\ cm)}}$$

$$= 8.9\ cm.$$

The plunger force, $F_p$, needed was next calculated by multiplying the desired systolic pressure, $P_S$, by the approximate contacting area of the ventricular sac:

$$F_p = P_s \cdot A_s$$

$$= P_s \cdot \frac{\pi D_s^2}{4}$$

$$= (120 \text{ mm Hg}) \left[ \frac{.00136 \text{ kg/cm}^2}{\text{mm Hg}} \right] (52.5 \text{ cm}^2)$$

$$= 8.57 \text{ kg.}$$

The plunger force, $F_p$, was increased by an approximated percentage, 60%, to account for frictional losses, to yield the required total spring force, $F_{ts}$:

$$F_{ts} = F_p + .60(F_p)$$

$$= 8.57 \text{ kg} + .60(8.57)$$

$$= 13.7 \text{ kg.}$$

Finally, the total spring force, $F_{ts}$, was divided between six parallel springs to increase the safety factor. The final design force per spring, $F_s$, was therefore:

$$F_s = F_{ts} / 6$$

$$= 13.7 \text{ kg} / 6$$

$$= 2.28 \text{ kg.}$$

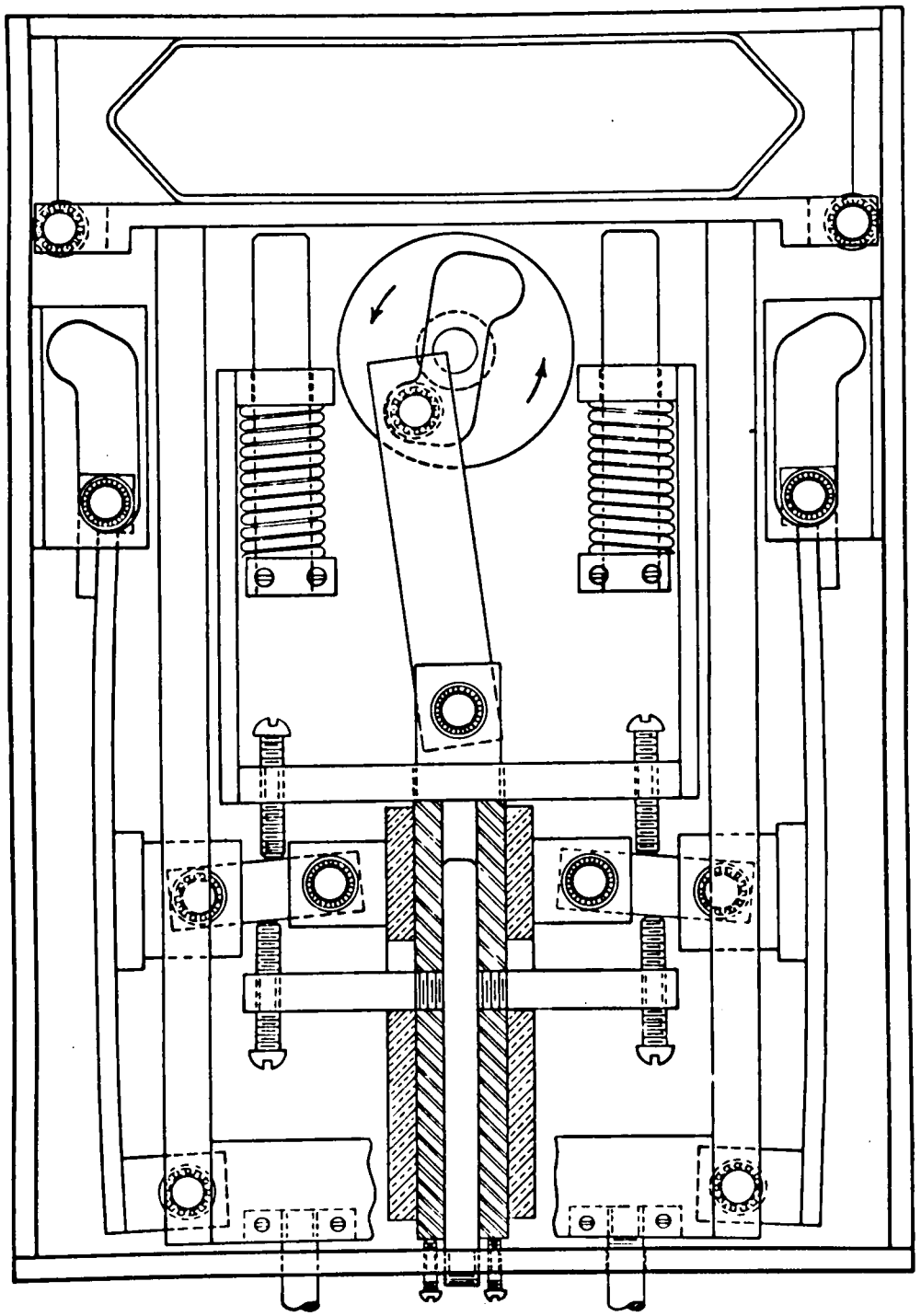
The design parameters involved with the pump output were also based on human physiological values. The normal human stroke volume, at rest, is approximately 70 ml. The normal resting cardiac output is approximately five liters per minute. Exercise increases both the stroke volume and the heart rate to give a cardiac output over fifteen liters per minute. The pump was therefore designed to pump a variable stroke volume of zero to 100 ml. In addition, variable frequency capability

was to be incorporated into the system at a later stage in the project.

Miniaturization and Final Design

Once the specifications for the pump were determined, attention was given to the problem of miniaturization. One of the important variables was stroke length. For a given maximum stroke volume, the less the cross-sectional area of the plunger, the longer the stroke length. The reverse, of course, is equally true. A suitable compromise was reached which conformed with another phase of the miniaturization, overlapping. The attempt at overlapping was necessary to reduce the length of the configuration shown in Figure 3. The overlapping and its relationship to stroke length are illustrated by the assembly drawing of the mechanism, shown in Figure 4.

A final structural consideration involved with miniaturization was the choice of bearings, necessary to reduce friction in each of the joints. Full complement precision instrument ball bearings were chosen on the basis of long life and high radial load capability.



Scale 1 : 1

Figure 4. Assembly Drawing of Ventricular Actuating Mechanism

# CHAPTER IV

# ANALYSIS OF THE MECHANISM

## Scope of the Analysis

Following the design, fabrication, and assembly of its components, the mechanism was run through a number of cycles as a brief preliminary check of its performance capability. It was discovered during this check that the locking and unlocking functions of the brakes were partially ineffective. The throw of the brake shoe between the locked and unlocked positions was not great enough to insure, respectively, positive locking and total freedom. The problem could be corrected by increasing the distance of the throw. The longer the throw, however, the greater the percentage of stroke length employed by the locking and unlocking action. The compromise which was reached turned out to be inadequate from the standpoint of positive action. The course chosen was to limit the scope of the analysis to those functions which the pump was capable of performing.

A function which was impossible to check was instantaneous flow rate capability. The functions which could and were tested were 1) self-regulatory ability and, 2) pressure/time waveform production capability.

## Method of the Analysis

Prior to the two tests, it was necessary to design, construct, and check the operation of 1) a ventricular sac and, 2) a set of valves.

The sac was constructed by first turning on the lathe a wax mold in the shape of a oblate ellipsoid with dimensions which yielded a volume of approximately 100 ml. Around the wax mold was formed several layers

of silicone rubber and nylon mesh. An inlet and an outlet line were made by a technique similar to that used for the sac, except that the material was formed around 1.27 cm dia Teflon rod. The lines were then attached to the sac, and the wax was melted from within the sac and inlet and outlet lines. The sac and lines were rinsed with xylene to dissolve the wax film which remained and, to complete the fabrication, the sac was rinsed with alcohol to remove the remaining xylene.

The valve configuration chosen was ball and cage. Each ball was 1.90 cm in diameter and seated on the bevel surface of its Plexiglas housing.

The purpose of the first major test performed, the test of self-regulatory ability, was to determine the capability of the plunger of the mechanism to move freely with the blood which entered the ventricular sac. For this test, the brakes were secured in their unlocked position to allow complete freedom from the brake plates.

The second test was designed to determine the capability of the mechanism to produce a physiologically shaped pressure/time waveform. The brake shoes were thus secured in their locked position to insure that they remained attached to the brake plates. It was also necessary to construct a mock circulatory system, shown in Figure 5, which was modified from Kolff.[9] The column of water shown in the figure is 108 cm. in height, corresponding to 80 mm Hg. This column simulates the physiological pressure head into which the natural heart must pump.

The pump was run through a number of cycles for each of three sets of springs. The first set of springs was designed to produce 5.0 kg force upon release; the second set was designed to produce 13.7 kg,

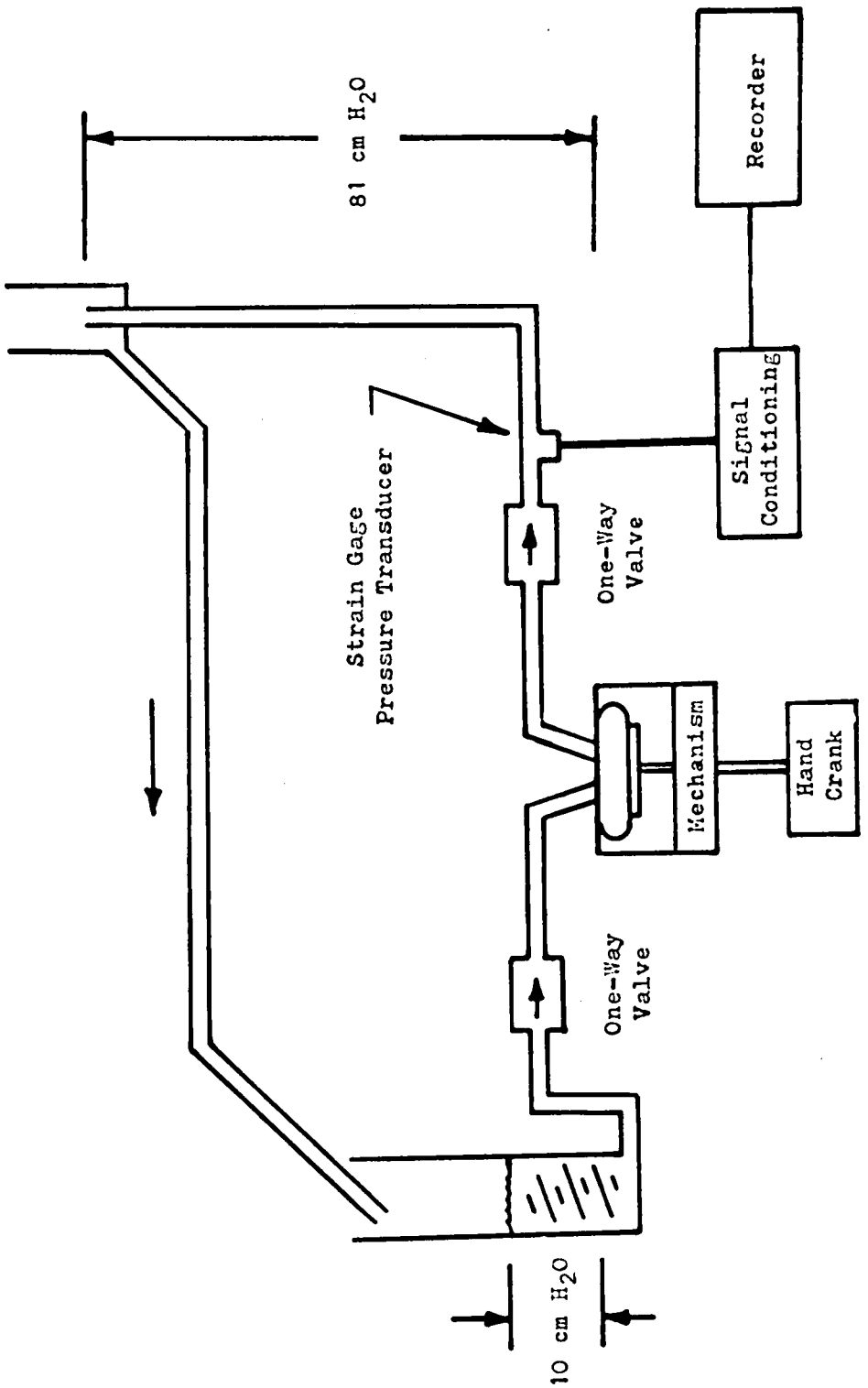



Figure 5. Mock Circulatory and Measurement System

corresponding to the previously described calculations involving pressure, area and force; the third set was designed to produce 23.1 kg. It was hoped that the two additional sets of springs would provide additional data on the relationship between spring force and wave shape.

# CHAPTER V

## DISCUSSION OF RESULTS

Results of the test of self-regulatory ability (performed with the brakes in the free position) demonstrate that the pump is capable of filling under the influence of any pressure from 4 to 6 mm. Hg., a pressure range which corresponds closely with physiological left atrial filling pressures. These results indicate that the chance of self-regulatory ability are favorable, assuming that the re-design of the lock/unlock mechanism is realized.

Results of the test of the capability of the pump to produce a physiological pressure/time waveform (performed with the brakes in a locked position) are illustrated in Figure 6. The waveforms are characterized by systolic pressures of approximately 130, 130, and 220 mm. Hg., which correspond to the spring sets designed to produce, respectively, 5.0, 13.7, and 23.1 kg. of force upon release. It is seen in the figure that the second experimental waveform is the closest in shape to the physiological waveform. Decreasing or increasing the spring force appears to result in decreased effectiveness of the waveform production. The remainder of the discussion of results will therefore concern only the second experimental waveform.

The most important characteristic of the second experimental waveform is the shape. By comparing Figure 6 with Figure 1, it may be seen that although the experimental waveform is characterized by a steep rise from diastolic to systolic pressure, its shape differs from that of the physiological waveform in principally four respects: 1) the peak of the

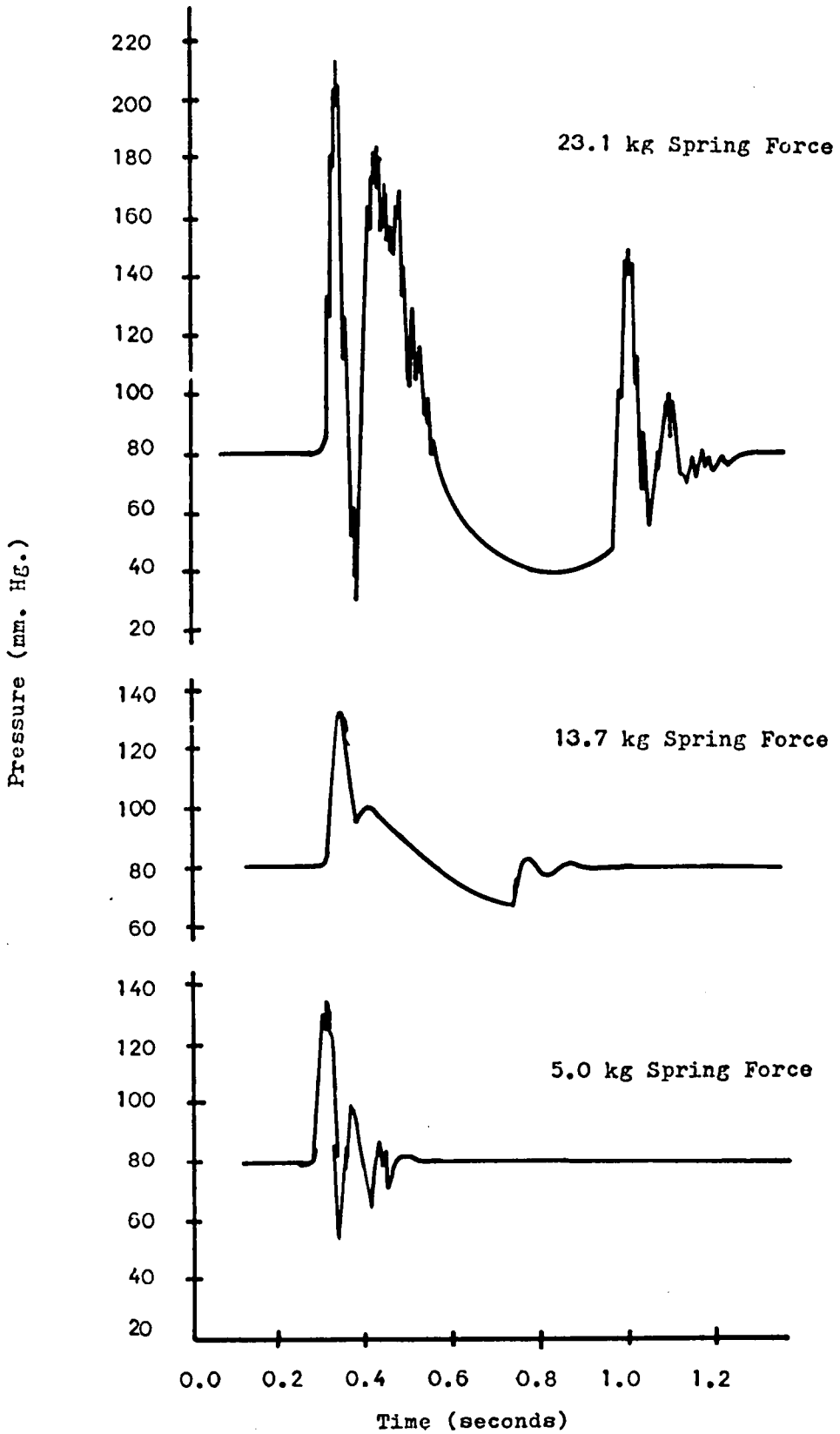



Figure 6. Experimental Pressure/Time Waveforms

systolic rise is considerably sharper in the experimental than the physioligical waveform, 2) the pressure dropped below the diastolic pressure on the experimental and not the physiological waveform, 3) high frequency pressure oscillations occurred in the last part of the experimental and not the physiological waveform and, 4) the area above the diastolic pressure level was considerably less in the experimental than in the physiological waveform.

The first difference between the physiological and the experimental waveform, that of the sharp peak of the experimental waveform, leads one to question the design of the valves. The plastic ball of each valve is 1.9 cm in diameter and therefore possesses considerable mass, particularly when compared to the relatively light construction of the moving parts of the natural heart valves. The sharp pressure peak is therefore believed to have been caused by inertial resistance of the ball. The notch on the downslope of the peak was likely a result of the ball's sudden deceleration as it reached the end of the cage.

The second difference between the physiological and the experimental waveform is the drop in pressure below the diastolic pressure of 80 mm Hg. As a result of the termination of the driving force of the springs, the pressure in the aorta was allowed to fall below 80 mm Hg. This reversed pressure gradient and resultant backflow was, of course, responsible for closure of the valve, an event shown on the curve at the point where the sub-diastolic pressure suddenly returned to 80 mm Hg.

The third difference between the physiological and experimental waveform is the pressure oscillation which occurred following the return of the pressure from sub-diastolic to the diastolic level. This oscil-

lation is believed to have resulted from ball chatter (slight "bouncing" of the plastic ball as it seated itself while closing). The ball chatter was responsible for two phenomena which caused oscillations in the pressure 1) momentary return of the backflow through the valve orifice until proper seating took place and, 2) vibrations in the tubing which resulted from the ball bouncing on its seat.

The fourth and final difference is the difference in area above diastolic pressure between the physiological and the experimental waveform. Flow is approximately proportional to pressure gradient. If the positive and negative (with respect to the steady state diastolic) areas of the curve were equal, a net flow of approximately zero would result. The physiological waveform is characterized by a large area above the diastolic pressure, while the experimental waveform has considerably less. This difference resulted in decreased flow and was most probably caused by 1) restriction of flow in the outlet lines and across the valve oriface and, 2) the inability of the springs to complete their full travel of 1.9 cm. as a result of stiffness of the ventricular sac.

# CHAPTER VI

## CONCLUSIONS AND RECOMMENDATIONS

Although the results of the analysis were disappointing, much valuable information was obtained from this attempt to solve an extremely complex and difficult problem. Nearly every phase of this study deserves further attention; the scope of the analysis, however, was limited to the test of self-regulatory and wave-production ability. Suggestions for future work will therefore lie primarily in these two areas.

The function of self-regulatory ability was proven to be ineffective by the analysis. The action of the brakes exploited too great a percentage of the stroke length. Furthermore, the locking and unlocking mechanism was not positive enough to be be considered safe and reliable for long periods of operation. These conclusions lead to the following suggestions for future work regarding the function of self-regulation: 1) the stroke length should be increased and/or, 2) the lock/unlock mechanism should be modified. Each of these approaches will be discussed in greater detail.

The first suggestion regarding self-regulation is to increase the stroke length of the plunger--an action which would correspondingly necessitate a decrease in diameter of the ventricle sac in order to maintain the same stroke volume. This action would serve to reduce the effect of the locking and unlocking motion in limiting the unrestricted travel of the plunger corresponding to various filling states.

The second suggestion regarding self-regulation is to modify the design of the lock/unlock mechanism. This modification could either

supplement or replace the first suggestion. The criteria of the modification should be positve action, long life, and efficiency with respect to distance required for full activation.

The second test described in the analysis is that of waveform production ability. It was determined that the original design spring force was the most capable of producing a physiological waveform. Even this waveform, however, fell short of satisfying the physiological requirement. The following suggestions for future work would serve to remedy this problem: 1) a valve modification incorporating a lighter ball, a shorter distance of ball travel, and the addition of some kind of energy absorbing valve seat to reduce chatter, 2) modification of the ventricular sac to lighten its construction and yet maintain adequate strength, 3) an increase in the diameter of the tubing to decrease flow resistance and, 4) the initiation of spring release at a point in the cycle before the pressure falls below diastolic pressure, action which would be possible only after the completion of the modification of the self-regulation system (allowing continuous, cyclic pumping).

In the event that such changes do not fully perfect the waveform, it is suggested that a study be undertaken of the original premise concerning the use of the spring as a choice for production of a pressure waveform.

The ultimate result of future work as recommended above could be the realization of a cardiac prosthesis which would not suffer from the problems which have plagued previous work. The prosthesis would then become the integral component of a total cardiac prosthesis system, shown in Figure 7.

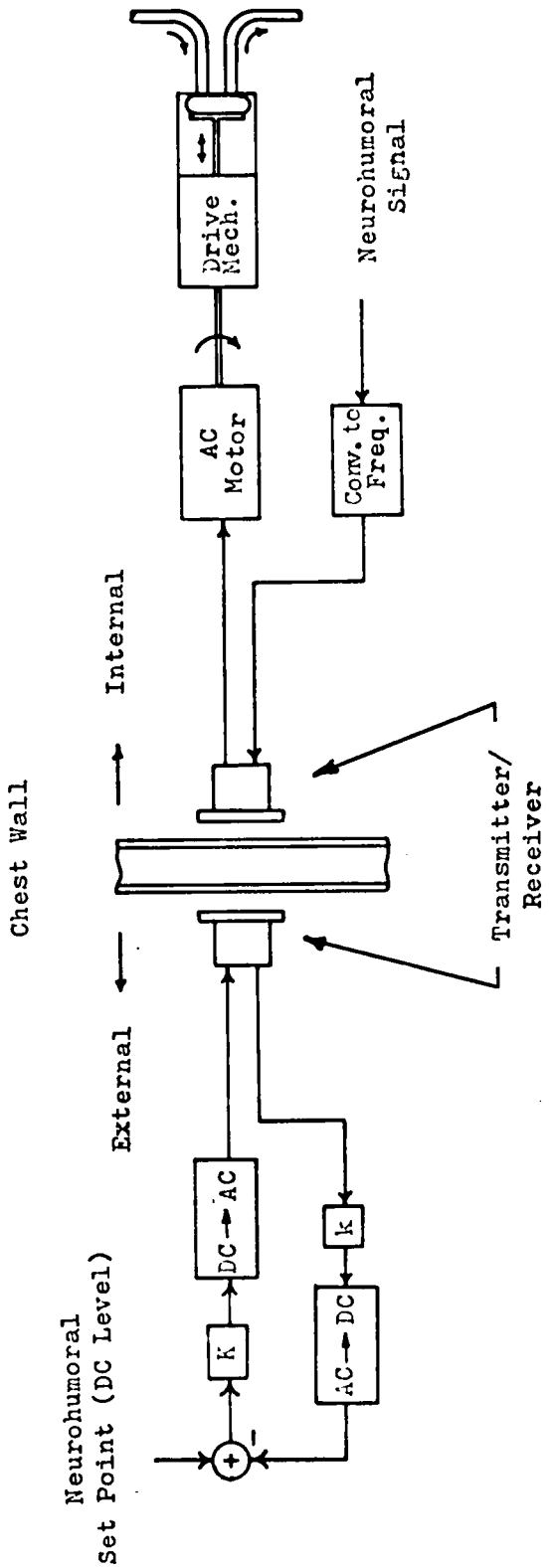



Figure 7. Cardiac Prosthesis System

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# THE DESIGN AND ANALYSIS OF A VENTRICULAR ACTUATING MECHANISM FOR A CARDIAC PROSTHESIS

by

Ronald Stewart Peterson

(ABSTRACT)

From a review of the many and varied attempts to date to design a successful cardiac prosthesis, it was shown that 1) every attempt to design a ventricular actuating mechanism (the crucial element in a cardiac prosthesis) has failed to satisfy one or more of the design requirements and has thus resulted in a maximum survival time for an animal on a cardiac prosthesis of 247 hours and, 2) by combining the operating principles of two previously developed actuating mechanisms (spring-driven and rotating shaft-driven), a successful design could be the possible result.

A description of the design and construction of a prototype of such a hybrid configuration was next presented.

The mechanism presented in the study was then briefly evaluated with respect to its ability to 1) self-regulate its pump output and, 2) produce a physiological aortic pressure/time waveform.

Results of the study demonstrated that the pump was capable of producing a quasi-physiological pressure/time waveform. Self regulatory ability was proven to be ineffective.