DESIGN AND CONSTRUCTION OF A LEFT VENTRICULAR

CARDIOVASCULAR ASSIST DEVICE

A Thesis

by

MANMEET SINGH VEDI

Submitted to the Office of Graduate Studies of
Texas A&M University
in partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE

August 2004

Major Subject: Mechanical Engineering

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August 2004

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ABSTRACT

Design and Construction of a Left Ventricular Cardiovascular Assist Device.

(August 2004)

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Congestive heart failure (CHF) is a debilitating condition that afflicts 4.8 million Americans with an increasing incidence. Each year, there are an estimated 400,000 new cases. The incidence is on the rise as the age of the population is increasing and because most people are surviving their first heart attack. Pharmacological therapies are improving, yet many patients still reach end-stage heart failure and there are too few donor hearts available.

This thesis is presented as a first small step in a long process in the design and development of a novel cardiac assist device that would ultimately heal a diseased heart by the process of ventricular recovery. The device acts to restore the kinematics of a diseased heart by modulating the extra ventricular displacements.

The first surgery / trial were conducted on a bovine at the Veterinary School at Texas A&M University. Main objectives of the surgery were to test the method of attachment of the device and power requirements of the device. Details regarding the design and construction of the device have been presented in the thesis.

DEDICATION

I dedicate this thesis to my grandfather, Harbhajan Singh, who was always there for me and others in his family. At this time there is nothing more I could wish for than to spend one more moment with him just to say goodbye.

ACKNOWLEDGEMENTS

I would like to express my heartfelt gratitude to my advisors, Dr. K.R. Rajagopal and Dr J.C Criscione, for their excellent guidance and motivation. Not only have they always guided me but they have always shown a monumental amount of patience while teaching me how to go about things. This shall always be a source of inspiration for me.

 I would in particular give complete credit for the design and ultimately the construction of this device to Dr J.C Criscione. Without his foresight and vision this device could never have made that important leap from paper and theory to a working model. Although this device presents itself only as a small step in the development of the final device, many important lessons have been learnt that will be of major use in the future.

I am thankful to Chin Sook for his guidance, suggestions and most importantly, for his company during my long stays at the laboratory. His kind words and humor have many a times helped me get through a long day.

Finally I would like to thank my family and friends for their support that I have always enjoyed.

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INTRODUCTION AND LITERATURE SURVEY

Introduction

Congestive heart failure (CHF) is a debilitating condition that afflicts 4.8 million Americans with an increasing incidence. Each year, there are an estimated 400,000 new cases. The annual number of deaths directly from CHF increased from 10,000 in 1968 to 42,000 in 1993 with another 219,000 related to the condition. The incidence is on the rise as the age of the population is increasing and because most people are surviving their first heart attack. Pharmacological therapies are improving, yet many patients still reach end-stage heart failure and there are too few donor hearts available.

CHF is characterized by aberrant growth and remodeling of the heart. In particular, cardiac function declines as the left ventricular chamber enlarges and the muscle wall thins. Medical treatment of this condition has been primarily pharmacological, while a limited number of patients have been treated by transplantation. Even with pharmacological treatment, CHF can progress from moderate cardiac insufficiency to severe, class IV heart failure wherein patients lack sufficient cardiac output to stand or walk.

With the development of cyclosporine in the 1980's, heart transplantation was widely accepted as the most effective therapy for end stage heart disease. Statistics suggest that 10 year survival rates had risen as high as 50 percent. However the

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The journal model is Annals of Thoracic Surgery.

important role to be played by mechanical assist devices in therapy for end stage heart disease was assessed [1].

The condition of an increasing number of patients deteriorates, however, to the point that they require continuous intravenous inotropic support until a suitable donour heart becomes available – and up to 30 percent die before that occurs. In 1996, 10.4 percent of patients awaiting heart transplantation died before receiving a heart. Efforts aimed at increasing the supply of donor organs – currently about 2500 hearts annually – have failed to ameliorate the shortage, underscoring the crucial need for alternatives to cardiac allotransplantation. Mechanical support by means of ventricular assist devices is at present the most promising alternative.

A recent publication, [2], of the randomized evaluation of Mechanical Assistance for the treatment of CHF (REMATCH) trial states that

Patients with mild to moderate heart failure [SOLVD, 1991] and recently, some with more severe disease, [PACKER et al., 2001] have shown to benefit form drug therapy. Nevertheless, the survival and the quality of life of patients with severe heart failure remain limited. Cardiac transplantation is the only treatment that provides substantial individual benefit, but with fewer than 3,000 donour hearts available worldwide per year, its impact is epidemiologically trivial [Hosenpud et al., 2000].

The REMATCH trial was a major trial involving 20 centers and 129 patients. The trial was designed to compare long term cardiac assist to pharmacological treatment in:

- Survival
- Adverse Events
- Hospitalizations
- Quality of Life

A major finding of the study was that patients with assist devices despite having a higher number of occurrences of hospitalizations and adverse effects had a significantly higher survival rate and most importantly a better quality of life. Despite having an increased number of adverse events and hospitalizations, the group with mechanical assist had a higher survival rate and quality of life. The success of the REMATCH trial likely contributed to the recent action of the FDA to approve cardiac assist devices for use in end stage heart failure patients who are not waiting for a transplant. Prior to this, cardiac assist devices were only approved for so called "*bridge to transplantation*".

At the 2002 annual meeting of the European Society of Cardiology, Magdi H. Yacoub suggested that a combination of drug treatment and mechanical assist would be the most promising treatment for patients with End Stage Heart Failure. Recent Studies show that appropriate growth and remodeling of the heart can reverse and ultimately cure CHF in some patients. Such a cure for CHF is called *ventricular recovery*.

The response of the heart to altered hemodynamic loading is growth or remodelling of myocytes and the extracellular matrix. Most evidence both in tissue and at the cellular level, points to a mechanical factor as a stimulus, and most likely a deformation

signal is transduced to initiate protein synthesis [3]. Studies also conclude that mechanical stress directly induces gene expression in the cardiomyocytes and that the response of cardiomyocytes to mechanical stress is similar to that of other cells to growth factors [4].

A physiological strain pattern of the heart is one in which [5]:

- Hoop strain more contractile than apex-base strain

- Greater wall thickening on the inner wall

A failing heart has a much different (i.e., patho-physiological) strain pattern: [6]

- Hoop strain and apex-base strain are more equal

- Wall thickening is globally less but more uniform across the wall

Keeping in mind the above an important question may be asked

If a heart with CHF is stimulated with a healthy Mechanical Environment (Strain pattern) would the heart grow and remodel in a positve way that will lead to ventricular recovery?

It is this question that is at the core of the research ongoing in this field. There are at least 3 reasons that suggest that ventricular recovery could be achieved

- The heart is functionally a mechanical pump. Its performance is
  optimized based on mechanical performance.

- Myocytes are highly sensitive to pertubations in strain and respond with altered gene expression. This aspect of Myocytes has been reported [6, 7].

- End stage heart failure whether caused by Atrio entricular shunt, hypoxemia, myocarditis, myocardial infarction or over pacing, the end stage heart has essentially the same morphological shape and mechanical dysfunction.

The method of assist as proposed by Dr J.C Criscione falls into the catgory of direct cardiac compression devices (D.C.C.D), devices that compress the weakened heart by compressing the weakened heart from the epicardial surface. As discussed in length by LeGrice [6] and Costa [5], a weakened heart displays a more equitable variation of radial strain across the transmural depth whereas a healthy heart displays a higher radial strain on the epicardial surface. This mechanical environment of the heart would be restored by using a deformable membrane to modulate the extra-ventricular displacements and an outer rigid shell that would support the internal pressure thereby allowing the heart to adapt and remodel in a favorable way that would promote ventricular recovery.

Thromboembolic events, coagulation, hemolysis and immuno reactions which are ever present problems in other assist devices, are not present in D.C.C.D's as the device does not come in direct contact with the blood stream. Insights into the affects of D.C.C.D on ventricular pump function have been gained from early experience with biomechanical compression therapies such as *dynamic Cardiomyoplasty*. These surgical

procedures physically wrap the patient's skeletal muscles around the failing heart and electronically stimulate the muscle wrap to contract with the native heartbeat. *Cardiomyoplasty* however has certain inherent problems that prevent it from being a treatment from which many patients could benefit.

- *High Preoperative mortality rate*

- *Lenghty preconditioning period*

  A 2 week recovery period that allows adhesions to form between the heart and the skeletal muscle wrap, followed by a 6 week preconditioning period before the skeletal muscle is capable of ventricular support.

- *Arrhythmias*

  Use of myostimulator prevents the use of pacemakers and internal cardiac defibrilators in a patient prone to conduction disturbances and ventricular arrhythmias.

It is for these reasons that there has been a renewed interest in mechanical compression devices. The device proposed by Dr J.C. Criscione also acts to simulate the same effect on the failing heart. This, as explained in the latter sections of this proposal, involves the use of a deformable membrane to modulate the extra-ventricular displacements and an outer rigid shell that would support the internal pressure. The device would contract synchronously with the native heartbeat.

It may be noted that issues of biocompatibility will not be addressed during the course of the thesis. The primary reason for doing so is that study is an acute study, thus

immunogenic reactions would not be significant to alter the physiologic condition of the animal. Additionally building an entirely biocompatible device would prove to be very expensive and be entirely unnecessary as further improvements and modifications of the device are expected as the device is a prototype.

Present Cardiac Devices

Ventricular assist devices are mechanical pumps that assist or completely take over the function of the damaged ventricle. Ventricular damage may be caused due to many different reasons, such as myocardial infarction, myocarditis, ischemia, pericarditis and other coronary ailments. Table 1 provides a list of the historical developments regarding the development of ventricular assist devices. Application of these devices are normally warranted in two categories of patients

Partial Damage to the Ventricle

These categories of patients have either one or both of their ventricles partially incapacitated by a heart disease to a point where they are incapable of maintaining the normal cardiac output. The primary role of such assist devices is to unload the heart so as to allow it sufficient time to recover naturally.

Acute Ventricular Damage

These categories of patients are those whose hearts have deteriorated to a stage where cardiac recovery is not a possibility. Such a condition may arise due to myocardial

infarction, acute myocarditis and end stage heart disease. In such cases a heart transplant

or the use of an artificial heart are the only options for the patient's survival.

Table 1. Landmark events in the development of ventricular assist devices
(Source: [1])

Year	Event
1954	Development of the cardiopulmonary-bypass machine
1964	Chartering of the Artificial Heart program by the National Heart, Lung and blood institute.
1966	First use of a pneumatic device as a bridge to recovery
1967	First human heart transplantation
1969	First successful use of a pneumatic as a bridge recovery
1970	Development of a variety of extracorporeal and implantable pneumatic ventricular assist devices.
1974	Redirection of the efforts of the Artificial Heart program toward the development of implantable devices.
1984	First implantation of a total artificial heart as a permanent device.
1985	Multicenter evaluation of left ventricular assist devices as a bridge to transplantation.
1991	Moratorium on the use of a total artificial heart.
1993	FDA approval of a New Investigational Device exemption for a total artificial heart.
1994	FDA approval of a left ventricular assist device as a bridge to transplantation.
1994	First use of a wearable left ventricular assist device
1996-Present	Recruitment of patients for a randomized trial comparing wearable left ventricular assist device with medical therapy.

This section draws light on the current cardiac assist devices, their classification and

their drawbacks. Details regarding the structure and functioning of these devices may be

found in references 1, 8, 9 and 10. The cardiac assist devices may be broadly classified

into the following categories:

Implantable Assist Devices

These devices are implanted in the body of the patient. The device is normally placed in the abdomen of the patient. Advantages of such devices mainly are the potential for long term support and fact that the patient does not require to be hospitalized. Major disadvantages of such devices are the risk of infection and mechanical failure of the device in an enclosed environment could mean that any defect in the device may not be rectified in time. In addition, in case the device comes in direct contact with the blood stream thromboembolisms are possible. The following are different categories of implantable assist devices:

- Intravascular Assist Devices (IVAD)

  These devices assist in a bypass manner wherein some of the blood is diverted from the heart, and then pumped to a higher pressure and then returned to the aorta. As a result the overall pressure in the arteries rises. However as the device by its inherent nature comes in contact with the blood stream, issues such as thromboembolic events, coagulation, hemolysis and immuno reactions arise.

- Counter Pulsation Assist Devices (CPADS)

  A balloon, working fluid Helium, is inserted into the thoracic aorta via the femoral artery. The balloon is deflated at the end of isometric contraction prior to ejection, which in produces an appreciable reduction in pressure in the aorta due to the sudden decrease in volume. The low pressure in the aorta acts to increase the cardiac output by 15 to 50 percent. The balloon is inflated early in

diastole causing an increase in diastolic pressure in the aorta. Though the device

is currently popular, the device acts to reverse the pressure cycle, with the peak

being in diastole and the low being in systole. Such a pattern being abnormal to

the heart.

- Direct Cardiac Compression Devices (DCCS)

  These devices involve compressing the weakened heart from the epicardial

  surface. Within these devices further distinctions can be made.

  - RVADS   Right Ventricular assist devices

  - LVADS   Left Ventricular assist devices

  - BVADS   Bi-Ventricular assist devices

Extracorporeal Devices

   These types of devices are meant to support the heart for only a short period of time.

Major advantages of these devices are the minimum amount of time required to start

assisting the patient. In cases of non pulsatile flow a simple cannulation may be used to

assist the patient. During the therapy extensive anticoagulant therapy is needed and the

patient is often bedridden. Patients are at risk from Bleeding and thromboembolisms. In

addition continuous availability of trained bedside personnel is other major drawbacks.

   One of the earliest and most succesful devices, the *Anstadt cup (BVAD) was first

developed in 1966.* The method of actuation was direct mechanical ventricular actuation

(DMVA) which uses a pressure regulated heart cup, fabricated from silicone rubber for

mechanical massage of the heart.

The housing and diaphragms were constructed from either Silicone rubber dispersions or Pellathane sheeting. Solution casting techniques were used to fabricate the Silicone Rubber components. Polyurethane components were vacuum formed over dental castings of identical glass molds. Choices of measurements have been outlined as follows [10]:

> The thickness, durometer, and shore of the PU components were chosen to best match the physical characteristics of their SR counterparts. PU cups were assembled such that the diaphragm during systolic actuation approximated that of SR cups under similar driving pressures.

Attachment for this device was provided by vacuum delivered via the housing's apical port (See Figure 1). Mechanical actuation was provided by a pnuematic drive. However, the device acts to invert the curvature of the heart, thereby inhibiting chances of the heart growing and remodeling in a natural way. Achieving ventricular recovery by the *Anstadt cup* could always be considered improbable, as the heart is never stimulated to a physiologically favorable strain pattern.

In 1995 an extra cardiac ventricular device known as the *Abiobooster* was patented [11]. As described:
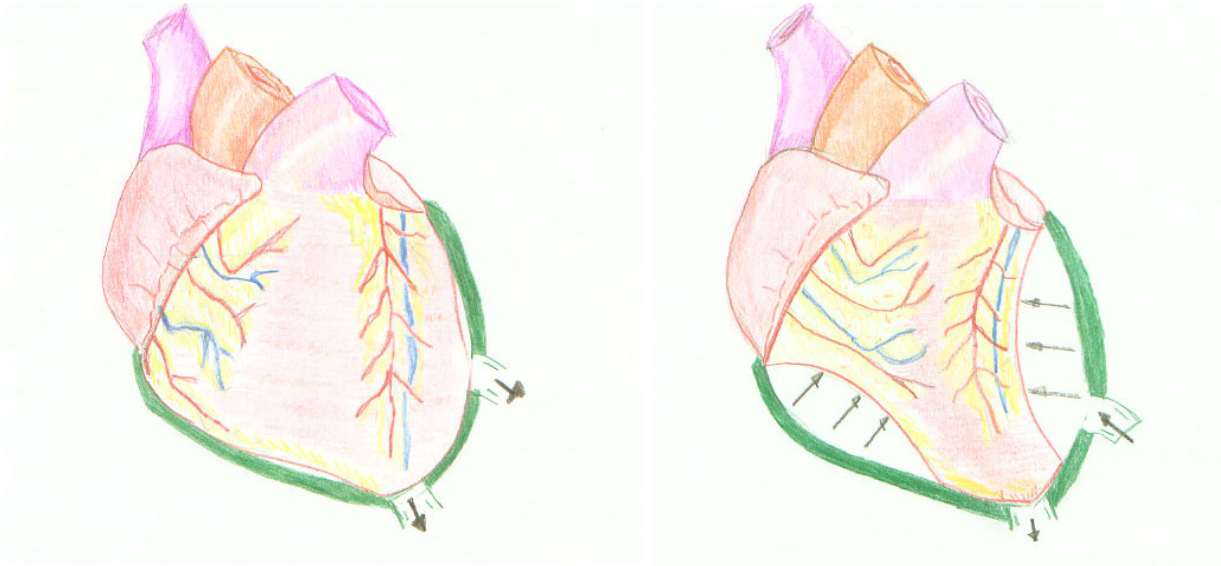
(a) Diastole　　　　　　　　　　　*(b) Systole*
Fig 1. Illustration of Anstadt cup

The contractile element of the Heart booster is based on a change in the shape of a thin wall (0.01 to 0.015 inch thick) tube from a circular cross section to a highly elliptical or flat cross section or vice versa. The shape change results in a change in the width of the tube. The device is contructed from a string of adjacently attached tubes, each pair joined along a line on the outer surfaces, forming a closed circular region shown in cross section in Figure 1. Inflation of the tubes (towards circular shape) results in a smaller enclosed volume (see systole in Fig 1), while deflation of the tubes (towards highly elliptical shape) results in a larger enclosed volume (see diastole in Fig 1).

The *Abiobooster* works to regulate extra ventricular displacements by means of cylindrical inflatable tubes that approximate on a whole the geometry of the heart. However due to the nature of inflation, cylindrical grooves corresponding to the deformations from the tubes would be caused on the heart, thus altering the hearts normal mechanical environment. Figure 2 illustrates the Abiobooster fitted to a patients heart.
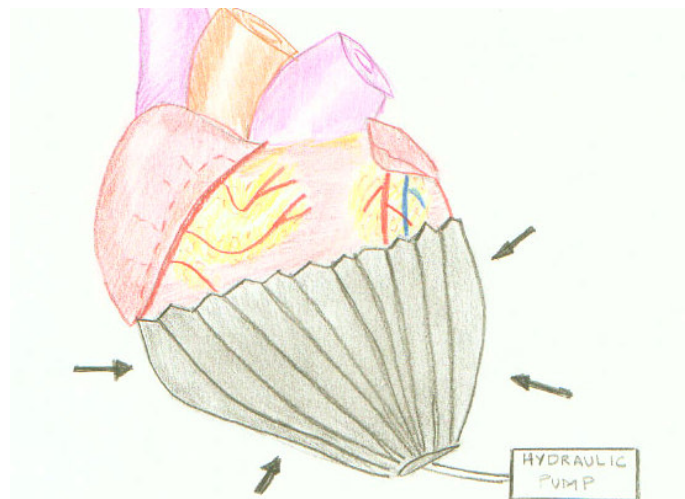
Fig 2. Illustration of the ABIOMED wrapped around a heart.
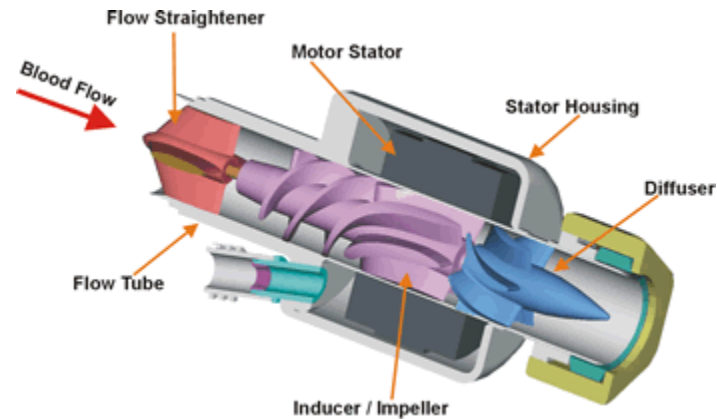
Fig 3. Debakey LVAD as copied from Micromed Technologies website
(With Permission)

Recently the *Debakey* LVAD, produced by Micromed Technologies was tested by Dr Theresa Fossum at Texas A&M University. Figure 3 shows a schematic of the device. The device being an IVAD acts to increase the aortic pressure by the use of a rotor and diffusor built into the device.

The functioning and method of attachment of the Debakey LVAD is best described by Micromed Technologies on their website www.micromedtech.com.

> The inducer/impeller is the only moving part of the pump. It has six blades with eight magnets hermetically sealed in each blade. The inducer/impeller spins at 7,500-12,500 RPM and is capable of generating flow in excess of 10 liters per minute.

The components are fully enclosed in a titanium flow tube that has been hermetically sealed. The pump is driven by a brushless, direct current (DC) motor stator that is contained in the stator housing.

The pump is attached to a titanium inlet cannula that is placed into the left ventricle. A graft is connected to the pump outlet and anastomosed to the aorta.

Advantages of the device include small size suitable for children and women, reduced complications and silent operation. The small size of the device and flexible percutaneous cable also provide lower infection rates.

After outlining the technique employed by some of the available devices, we propose a novel device that promotes ventricular recovery by modulating the kinematics of ventricles. Keeping in this in mind, the scope of this thesis is to make a small step in the creation of such a device by developing a prototype device along with its driver to test the whether the driver can sustain the loads experienced from the heart, to test the method of attachment of the device to the heart and estimate the loads exerted from the heart on the device.

PRELIMINARY MEASUREMENTS AND CALCULATIONS

Geometry of the Device

To build the proposed cardiac assist device it is important to establish a method of construction that would set a path in the further design and devlopment of the assist device. However, to construct the device it is important to take into consideration all neccesary parameters that influence the performance of the device. The parameters are outlined in the following paragraphs.

Cardiac Measurements

The geometry of the device is based on a set of 6 measurements, all of which can be made via a cardiac ultrasound. Defining a reasonably accurate device of the heart is important, as a device too small would never be able to fit the heart. Conversely, a device too large would risk the heart coming out of the device during operation. In addition a device too big would take up more than required space in the thoracic cavity thus cramping the lungs.

The cardiac ultrasound works on the principle of echolocation similar to that used by dolphins and submarines. The ultrasound machine transmits high-frequency (1 to 5 megahertz) sound pulses using a hand held probe positioned manually by the operating personnel. Sound waves are then reflected whenever they hit a boundary between tissues. Also, the sound waves get reflected differentially corresponding to changes in the speed of sound which in turn depend on density and bulk modulus of the material.

The reflected waves are then sensed by the probe and used to calculate the distance of the probe from the tissue or organ using the speed of sound in the tissue. Finally the intensities and the distance of the echoes of the machine are displayed on the screen.

Mainly two views are obtained from the ultrasound the long axis and short axis view. From the short axis view one may obtain the major diameter (D_{maj}) and minor diameter (D_{min}). From a long axis view one can obtain Distance from Apex to base (AB), Distance from equator to base (EB), radius of curvature of the base (R1) and the equater diameter (D_{eq}). Figure 4 illustrates how the above measurements are used to determine the Left Ventricular free wall profile (LVFWP).
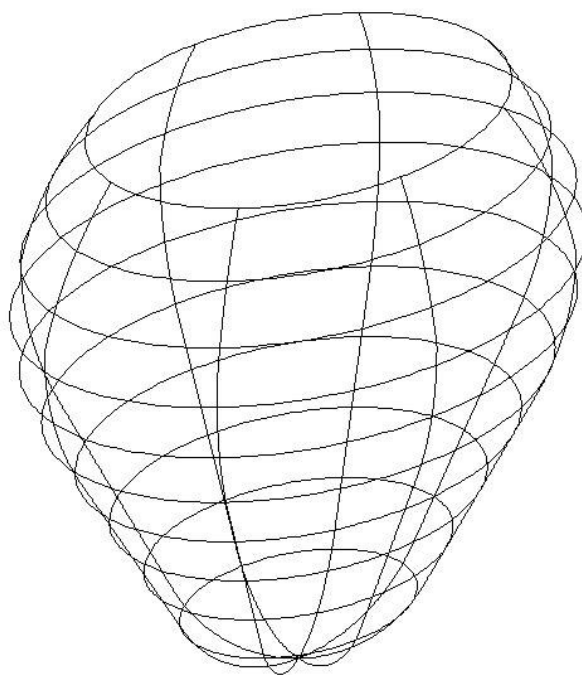
To generate the 3-D shell as illustrated in Figure 5, the LVFWP be the curve givn by $R_p(Z)$ where R_p is the distance from the longitudinal axis and Z is the height along the axis ($Z = 0$ at the apex).
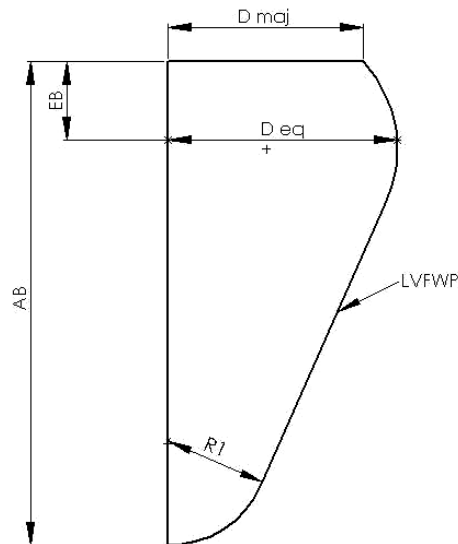
Fig 4. Illustrations of cardiac measurements

Mathematically the shell surface is defined by:

$$R(\theta, Z) = \left(\cos\theta + \frac{D_{\min}}{D_{\mathrm{maj}}} \sin\theta \right) R_p(Z)$$

Fig 5. Cage as generated from the cardiac measurements

It may be noted that the results of the cardiac ultrasound do not have a sharp contrast and the results appear very blurry. The main reasons for this are that the heart is a highly pulsating organ thus images tend to get distorted. Another reason for not having a sharp contrast in the ultrasound output is that the heart is composed of mainly two substances blood and myocardium both of which have a major percentage of water as its makeup, thus the difference in the speed of sound in two is not large enough to allow stark contrasts between the blood and the muscle wall.   Additional difficulties arise due to the state of the heart, as measurements are made from stills from the ultrasound, it is a very tedious process to decide which stage (systole or diastole) the heart is in. One way of reducing the difficulty is by making measurements during the ultra sound measurements itself. By doing do so it would be possible to isolate the major diameters of the heart by careful maneuvering of the ultrasound device.

Pump Driver Calculations

Calculation of Design Parameters

The prototype of the device was tested on a bovine heart. Prior to construction of the device, important parameters such as Heart rate, pressure amplitudes, stroke volume, etc were calculated in accordance with a healthy bovine heart. The casing of the device was built custom made to ensure a proper fit to the specimen's heart. Calculations regarding the geometry of the heart have been presented in the previous section. Choice of the working fluid for the pump was chosen as air after careful consideration of the available possibilities (mainly water). Methodology of selection of the working fluid has been presented in the succeeding sections. Figure 6 represents a typical pressure pulse.

Requirements of the Cardiac Compression Device

1. Pressure pulse of 50 mm of Mercury. Expected sinusoidal variation of pressure during a complete cardiac cycle.

2. Swept volume(expected volume change in the heart) for two Heart rates

   a. 60 beats per minute. Minimum expected heart rate of a bovine.

   b. 100 beats per minute. Maximum expected heart rate of a bovine.

Essential Components

The pressures encountered in the experiment are marginally above atmospheric pressure. To generate these low pulsatile pressures after careful consideration the Superpump Model SPS3891 available by Vivitro systems was chosen. Alternates to

the Vivitro system considered were low pressure tanks connected via a solenoid valve to the assist device. However construction of such a device would be laborious and the setup for the experiment would have been bulky.
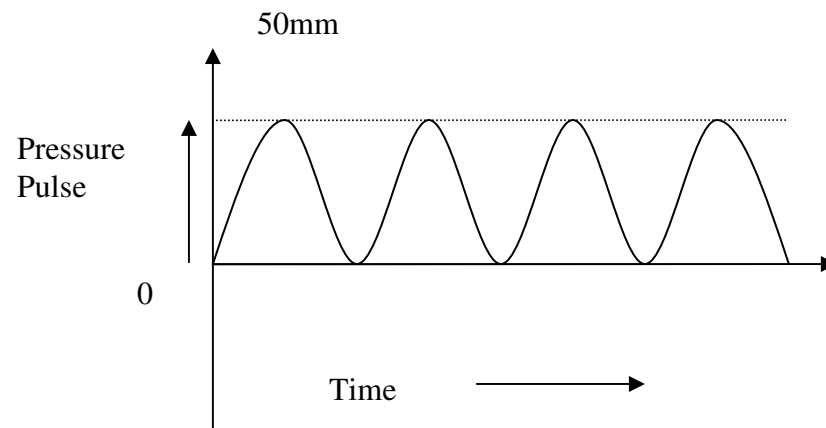
Fig 6. Illustration of pressure pulse required

1. Super pump System (Model SPS3891:As provided by Vivitro systems)

2. High Volume Super pump Head/Standard Pump head

3. Waveform Generator: Required to generate desired pressure pulses.

4. Casing with inflatable membrane that will finally enclose the Heart

5. 3 meter long pipe/hose connecting Super pump to the casing as mentioned above. This is required for easy maneuverability during attachment of the device.

6. Oscilloscope to view the output from the waveform generator.

7. Amplifier to amplify the output signal from the waveform generator.

8. Pacing leads to pace the atrium synchronously with the ventricles.

The calculations detailed in the following sections are done considering water and air as the working fluids. It may be noted that the standard pump head cannot use working fluid as air. The calculations for water have been shown as they may provide as an aid for the further design and development of such devices.

Calculation involving water as the working fluid.

(Calculation Shown for 60 beats per minute/Large Pump head)

$$\text{Fluid per heart beat} = \frac{Cardiac\ Output}{Heart\ Rate} = 0.1\ Litres/beat$$

To assist the heart in its pumping action either we may provide a pressure of 50 mm Hg or we may compress the heart by 100 ml externally thus doing the hearts work.

This may be readily seen as

Work = Pressure x Change in Volume

Thus keeping volume constant if the pressure were to be reduced by half the work done by the heart would also be reduced by 50%. Calculating the Stroke Length that would be required with the High volume pump head.(Calculations are per beat)

$$A\ x\ S = V$$

Where A is the effective Piston area 167.442 cm^2, S is the stroke and V is the Volume

$$\text{Thus S} = \frac{100}{167.442} = 0.5972\ cm$$

Similar calculations were carried out for the standard pump head with an effective area of 38.32 cm^2 and for a heart rate of 100 beats per second. Table 2 tabulates the results.

Table 2. Calculations using water as the working fluid

Heart Rate	Stroke Length	
	Large pump head	Standard head
60 Beats per minute	0.597cm	2.608cm
100 Beats per minute	0.358cm	1.56cm

Calculation of Pressure Losses

Losses in pressure head occur in the line due to obstructions, openings, line losses, etc. These losses act as a load on the motor. Losses in the experimental setup due to the following reasons

     a. Opening from the Pump to the pressure line.

     b. Line losses in the Pump.

     c. Bends and turns in the pipe.

     d. Resistance in the inflatable membrane/Stiffness of the membrane.

Of the above mentioned losses "c" and "d" can only be quantified experimentally as they depend on the exact setup. For this purpose, as a rough estimation of the total losses from "a" and "b" are multiplied by 2.

The connecting pipes may be chosen as 1/3" or 1/2 "diameter pipes as they available as standards in the market. Calculations for the losses have been presented in the following sections.

Losses may be calculated as:

$$Loss = \left(\frac{f\,L}{d} + \xi_{open}\right)\frac{v^2}{2g}$$

Where, f is the friction loss coefficient(0.016 Plastics), L is the length of thee pipe(3m), d is the diameter of the pipe, ξ_{open} are the losses due to opening, 0.5 (Sharp edge), v is the velocity of Flow through pipe and g is the acceleration due to gravity, 9.8 ms^{-2}

To obtain the losses in watts the following relation may be applied

$$P_o = P \; x \; Q$$

Where, P_o is the power (watts), P is the pressure loss (kgm^{-2}) and Q is the flow Rate, (m^3s^{-1}). The total losses in meters of water and watts have been tabulated in Table 3 for 1/3" and 1/2" hoses below.

Table 3. Losses caused in both types of pipes

Diameter of Pipes	Flow Rates	Losses (m)	Losses in watt
1/3"	50 ml s^{-1}	0.135m	0.487
1/2 "	50 ml s^{-1}	0.497m	0.013

Since the motor has a rated power out of 167 watts it is clear that in either case the motor will be capable of taking the load.

Calculation Involving Air as Working Fluid

Since air is a compressible fluid a pressure of 50 mm Hg is required to surround the heart and thus aid it in its pumping action. The frequency of this pumping action would be decided by the heart rate of the animal. These have been estimated in the range of:

    a. 60 bpm

    b. 100bpm

The experimental setup would consist of a 3m hose/pipe connected in series with the pump head. The hose pipe would in turn be connected to the cardiac assist device. Two diameter pipes have been considered for this purpose because of their easy availability in the market.

    a. 1/2 " Diameter

    b. 1/3 " Diameter

Heat exchange in the pipes is considered negligible and the compression process is reversible. Thus the process is modeled as an isentropic process. The following relationship is for air in an isentropic process.

$$PV^{1.4} = Constant$$

Where, *P* is the pressure and *V* is the Volume.

Thus to find the stroke length of the pump head we may find the change in volume required to produce the required pressure, while taking into account volume of air in pipes and the compressed volume of the heart (approx 100ml : Changes with different heart rate).

$$\frac{P_1}{P_2} = \left(\frac{V_2}{V_1}\right)^{1.4}$$

Where, P_1 is the initial pressure (10^5 Pascal), P_2 *is the required pressure (*106653.7 Pascal), V_1 is th volume of Pipe plus volume in pump head and V_2 Volume of Pipe plus 100ml.

The calculations have been tabulated in Table 4 below for both the diameter pipes.

Table 4. Stroke as calculated for working fluid as air

| Diameter Pipe	Volume of Pipe	Stroke
½ "	3.79 E-4 m³	7.3mm
1/3"	1.68 E-4 m³	6.7mm

Note: the stroke may be increased by including a residual volume in the Pump Head

Keeping the above results in mind a final choice of air was made fir the working fluid. This choice was based on two reasons:

1. In the case of water, the stroke for the standard pump head is 2.6 cm which is greater than the maximum stroke limit of the pump. In case the

pump reaches its maximum stroke limit the pump has an inbuilt safety mechanism whereby its shuts down when this limit is reached.

2. If the working fluid is water and the large pump head is used then the stroke of the pump (0.2cm-0.3cm) are prohibitively small. Thus sensitivity of the device and its accurate operation would present itself as a problem. Figure 7 is photograph of both, the standard pump head and large volume pump head illustrating their relative capacity.

3. In the case of air the stroke required are of the order of 7-8mm which is in midrange of the pump push limit.

4. In case the pressure needs to be increased further that also may be accommodated with the remaining stroke available using the Large Volume pump head.
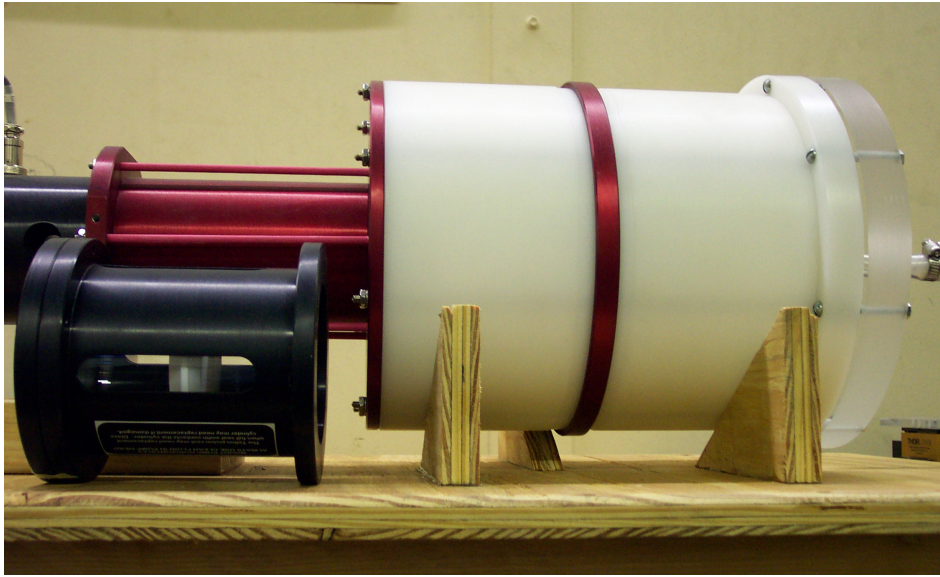
Fig 7. Comparison of standard and high volume pump head
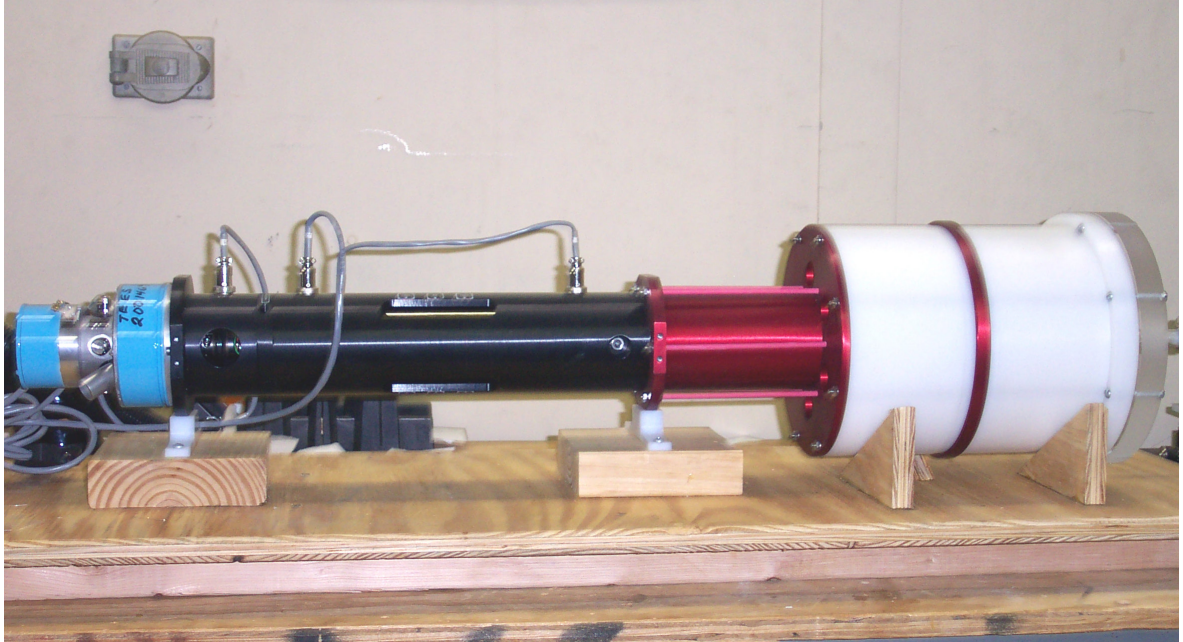
Fig 8. Illustration of complete setup with high volume head

CONSTRUCTION/ SETUP OF THE EXPERIMENT

Construction

The aim of the project is to build and test a novel cardiac assist device. Since the project is a pilot project many components of the experiment have been built from scratch in order to conduct the experiment. These components are:

Base of the Motor / Pump Stand

A base was constructed to ensure the pump and motor does not come in contact with any water or debris present on the working table. The base of the Motor / Pump has been constructed from wood and plywood.

Main considerations while designing the stand were that the plywood (*44 ¾" x 15" x ½"*) must not buckle under the weight of the pump and motor. For this purpose the plywood base has been strengthened by providing *2* wood planks (*44 ¾ "x 4" x 2"*) on the underside of the plywood base running along its length. This can be made clear to the reader by viewing Figure 8 illustrating the construction of the base. On the top side of the plywood two blocks (*5 ½" x 5 ½" x ½"*) of wood have been provided to raise the pump stand in order to align the pump and pump head axis. The pump is attached to the stand by means of wood screws that run through the stand and the pump. In addition three wedges, in the shape of 90 triangles have been provided to support the Circular pump head.

Base Plate for the Pump Head

The pump head is provided without the base plate from which the output from the pump-head can be obtained. For the experiment its calculations showed that a ½ "diameter output would be sufficient to obtain the desired results and that air would be the best choice for the working fluid. Keeping the above in mind a Plexiglas base plate was machined. The diameter of the Base plate is 8" and has been provided with a groove for an O-ring that acts as an air lock. In addition 8 taps have been provided in a radial pattern on the base plate that will fasten the base plate to the pump head. Corresponding holes are present on the outer flange of the pump head. A central port (½") for the pump output has been provided on the base plate. This port has been tapped with .25 "threads and will be connected to a pipe flange. Figure 9 shows a photograph of the pump base plate.


Fig 9. Photograph of the pump head

Assist Device

The prototype assist device was constructed over a period of 2 months staring from measurements from the cardiac ultrasound too the final construction of the device. A detailed account of the method of construction has been provided in the following paragraphs.

The cross section of the heart was generated from a MATLAB program that utilized the 6 cardiac measurements obtained from the 6 cardiac measurements. The outer surface of the heart was constructed by gluing together sheets of Plywood such that the LVFWP is defined by the outer edge of the plug mould which appears as a honeycomb structure. The sheets of plywood were aligned by two axes set 1cm offset from the central axis about the major diameter. Individually these sheets of plywood were cut such that the outer edge of the mould represents the profile of the heart at intervals of 0.25 inches along the longitudinal axis. Figures 10 and 11 show an individual plank of wood used to generate the mould and a cross section demonstrating the honey comb structure.
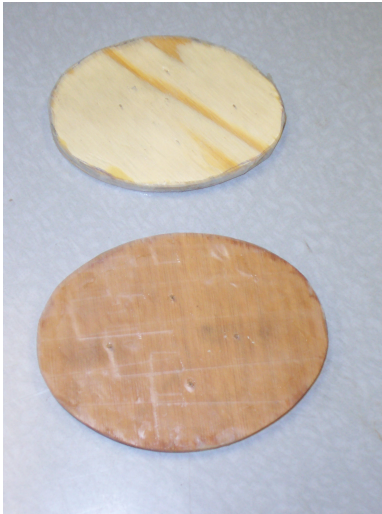
Fig 10. Sheets of plywood to generate the outer profile
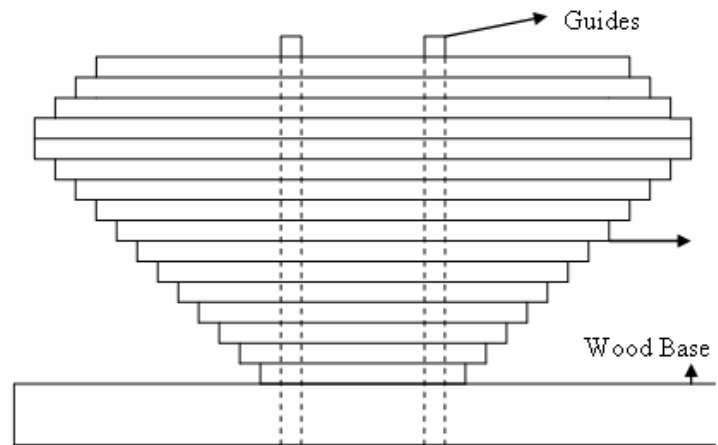
*Fig 11. Illustration of method of construction of hive structure*

To form a continuous outer surface on the mould Plaster of Paris was applied. The outer surface thus obtained was sanded using coarse and medium sandpaper to get a smooth outer surface. Multiple layers of epoxy reinforced with fiberglass were applied to the plug mould. A vacuum bag method was used to cure the mould, the fiber/ matrix ratio was increased within the mould by pushing the excess resins into pockets within the polyethene sheet. Once the mould cured (6-7 hours) the mould is sanded extensively to smooth the outer surface that contains many ridges caused due to the ridges in the vacuum bag. Figure 12 is a picture of the final mould after being smoothened. After surface of the mould is sufficiently smooth it is sawed in half, Figure 13 shows both halves of the plug mould. Each half was fixed to a separable butt joint and multiple coats of hard wax were applied. This was done to form a weak link between the two moulds, thus allowing easy separation between the two. Figure 13 is a picture of the

matching moulds obtained. Next multiple layers of Fiberglass-Epoxy are applied to the mould in addition to a plywood cut out to form matching moulds. The outer shell of the device was made from epoxy reinforced with fiberglass, using a vacuum bag method to remove excess resin and to increase the fiber/matrix ratio. Approximate curing time for the Fiberglass epoxy composite is estimated as 6-7 hours. Figure 14 shows the final shell obtained.

Fig 12. Photograph of the final plug mould
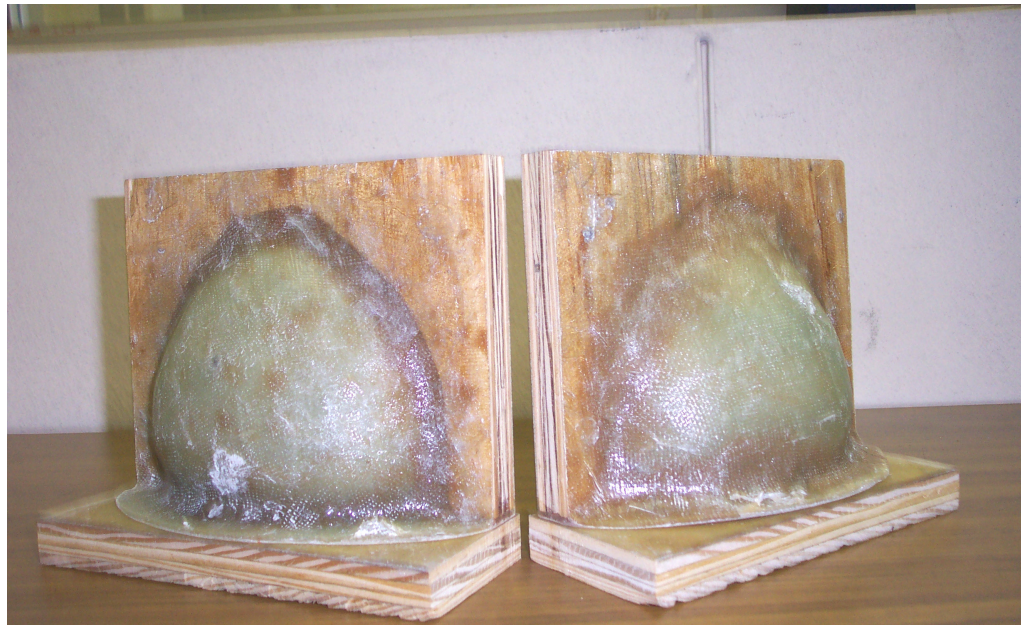
Fig 13. Photograph of the matching moulds

Fig 14. Photograph of the final cup made from the mould

For the purpose of a suction port, a brass, right angle, hose barb was attached to the apex after making a hole at the apex using a *Drummel.* It was fixed and sealed in place via an Epoxy-Alumina composite. A Latex membrane was used as a deformable membrane. The membrane was draped over the edges and held in place with circumferential suture and cyanoacrylate glue. Suture loops were fastened out of Nylon cord and affixed to the device using Epoxy. It may be may noted that even though Latex is a highly Immunogenic material was used as the experiment is short term (2-3 hours), immune reactions would not be significant to alter the state of the animal. Figure 15 shows the suture loops and Latex membrane attached to the device.

Since the outer casing is composed of fiberglass and epoxy it is opaque. To visibly inspect the compression and expansion of the membrane a Plexiglas's window was provided on the device, by cutting away material on the casing using a *Drummel*. Also provided was a mount to attach a camera, with the purpose of monitoring the deformation of the Latex membrane. The Latex membrane was marked with numerous black streaks to calculate the deformation of the membrane.

A clamp to fix a stent in place was provided on the outer surface of the mould. The purpose of the stent is to maintain a downward force on the heart into the device, so as to keep the heart from ejecting out of the device. A screw is placed on the clamp to fasten the stent by moving the two-parallel plates of the clamp together. The clamp was attached using an Epoxy-Alumina composite. Figure15 provides a view of the completed assist device.

Fig 15. Completed assist device

Finally a stent was provided that would push down on the heart while the device assisted the heart. The stent was designed so as to push down a point termed as the *"push point"* in between the pulmonary artery and the aorta. The choice of this point was based mainly on two criteria.

1. *Stiffness of the point*

The point lies on the valve plane that is composed of mainly cartilaginous tissue. Thus pushing down on this point would hamper the functioning of the heart muscle in any way.

2. Motion of the point

The motion of the valve plane is less compared to other regions on the heart. As the atria pump above and the ventricles pump below the heart.

However the design of the stents are based on the cardiac ultrasound which may at times be inconclusive, thus 3 stents were constructed with dimensions slightly above, below and at the design specifications. The material for the stent was chosen as a 1/8 "diameter brass rod. Main motivation for choice of this material was that it could be shaped as required by the surgeon while being attached to the device thus adding allowing a great deal of flexibility to the surgeon.

Setup of the Experiment

With all the essential components for the experiment acquired or constructed, the final remaining step was to construct the test bed. In short the essentials of the experiment can be broken down into the following steps, as illustrated in Figure 16.

i. Generation of the required input wave using the Vivigen software.

ii. Generation of Input signal on the wave form generator

iii. Amplification of the output signal from Waveform Generator is used to operate the super pump. The amplification is done on the Vivigen amplifier.

iv. Amplification of the clock pulse from the waveform generator is used to pace the atria. The amplifier is a standard commercial amplifier available in electronic stores.

v.   Speakers are connected to the above amplifier so that the pulse provides an auditory aid to the medical staff.

vi.   Finally attachment of the cardiac assist device to the bovine heart.
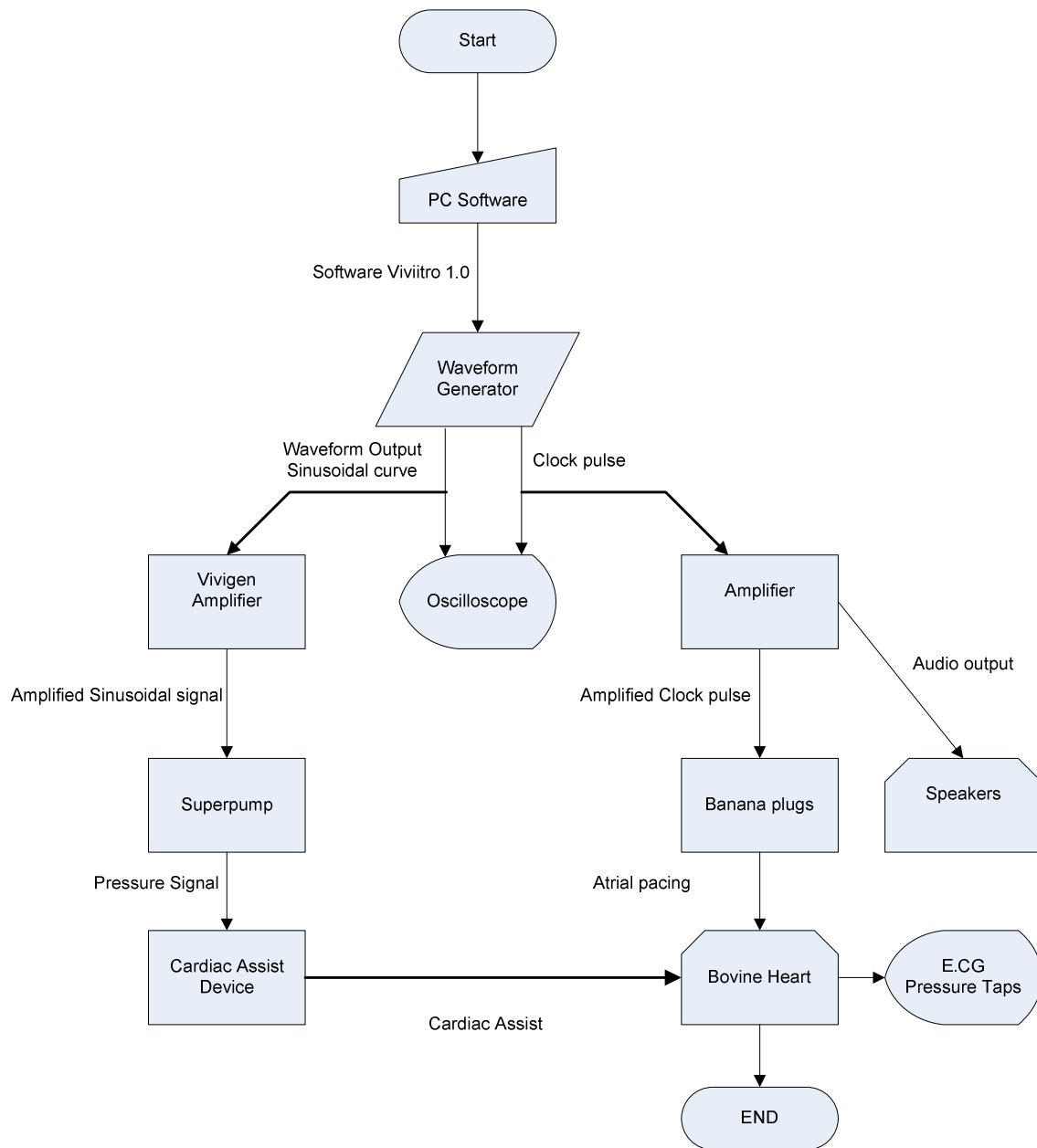
Fig 16. Flowchart of the experimental process

SURGERY

With the outline of the experimental setup outlined in the previous section. A detailed account of the surgical procedure employed to install the cardiovascular assist device has been provided below.

For the purpose of the experiment a young bovine was used. Cardiac measurements were made as detailed in the previous sections. Since the rate of growth of the young bovine is high cardiac measurements were made as late as 40 days prior to the surgery. To compensate for the increase of the size of the heart due to its natural growth the cardiac measurements were increased by 10 percent.

The heart was exposed via a left thoracotomy. To allow easy accessibility to the heart 3 ribs were removed from the left side of the chest. Heart failure was induced pharmacologically by administering Esmolol tetrachloride intravenously. Prior to induction of heart failure 4 catheters converted to pressure transducers were placed in the right Atrium, left Atrium, Left Ventricle and Aorta.

During the course of the surgery there was a requirement to pace the heart so that it beats in concert with the device. Atrial pacing was induced by pacing leads. The method of pacing was attaching two hooks to the atria with a gap in between to allow set up of an alternating electrical field in the tissue of the atria. Once the hooks are attached the amplitude of the signal is increased via the amplifier till pacing is achieved. It may

be noted that as the gap distance between the leads increases the voltage required to induce pacing also increases. Figure 17 illustrated the process.

Tissue

Pacing Leads
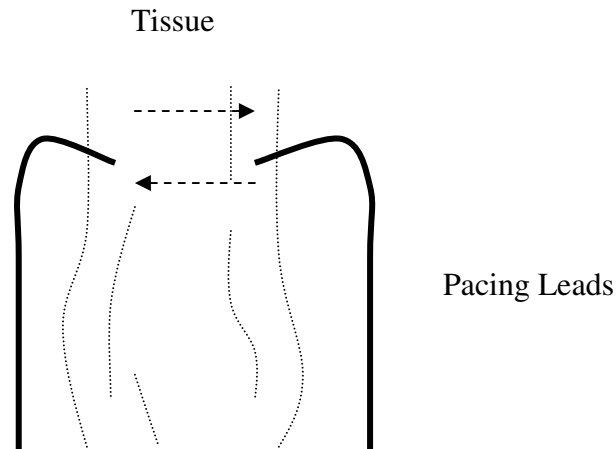
Fig 17. Illustration of atrial pacing

The heart was placed in the device by the surgeon and fixed firmly by means of a brass stent. The stent was positioned so as to push down in between the pulmonary artery and the aorta, termed as the push point. Details regarding the choice of the position of the stent have been presented in previous chapters. The stent once positioned by the surgeon was clamped firmly by means of a clamp provided on the device.

Once the device was firmly placed a camera was attached to the device the record the deformation of the membrane via the window provided on the device. Deformations of the membrane were monitored by tracking the marks provided on the membrane.

Initial partial heart failure was induced by administering 50 cc esmolol intravenously to the bovine. At this stage the device was paced at 90 bts/minute. An earlier attempt

was made to pace the device at 70 bts/minute however the vital signs of the bovine suggested that the animal was under stress.

Finally total heart failure was induced by administering and additional esmolol. At this stage the device assisted the heart completely for a period of 30 minutes. Figure 18 is a photograph of the device as placed in the bovine. The heart was arrested with potassium chloride and fixed in the device with coronary perfusion of formaldehyde.
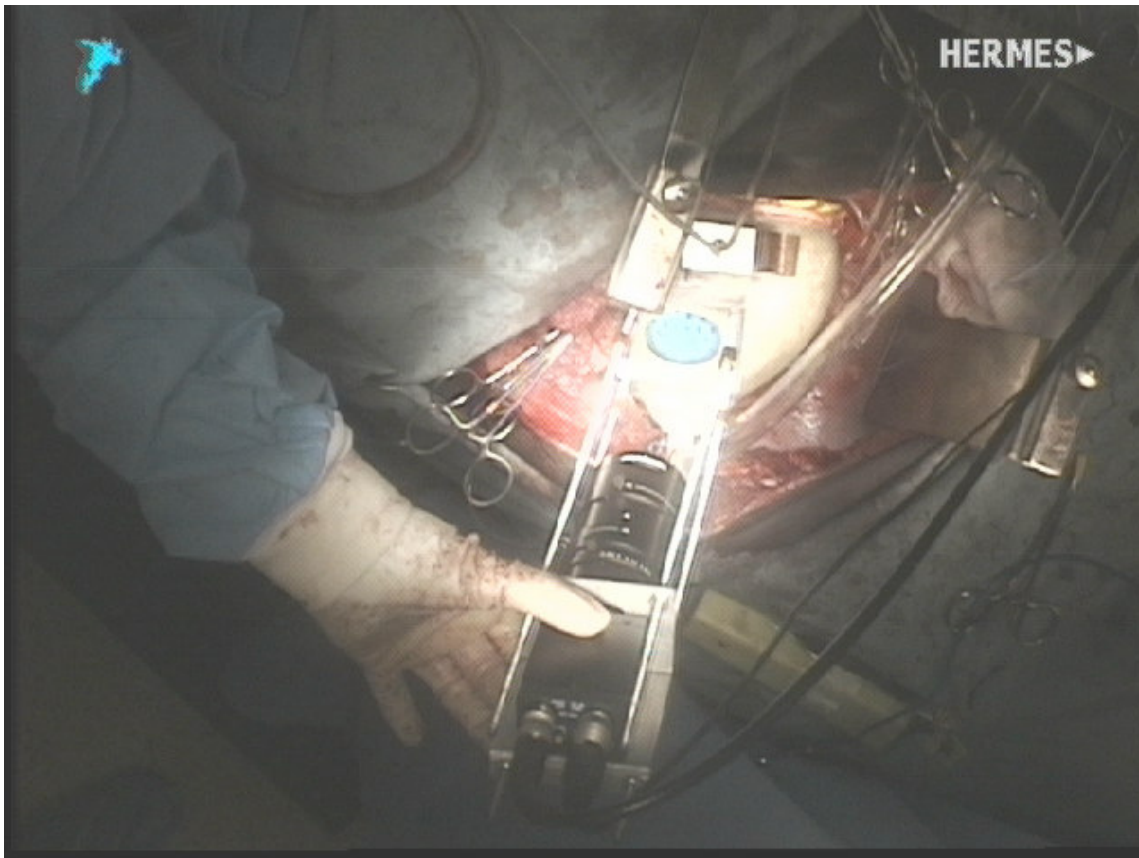
Fig 18. Photograph showing the final placement of the device

POST EXPERIMENT ANALYSIS

Having conducted the experiment the next step was to analyze the deformation of the stent to estimate the vertical force experienced by the stent exerted by the heart. Such an estimate would aid in the future design and development of such devices. The method of load estimation was that of a twin analysis that of the deformation as measured from the video of the surgery and the deformation as calculated from finite element modeling of the stent. Both the methods are discussed in greater detail in the following chapters.

Deformation Analysis from the Video

During the course of the surgery video clips were made that showed the stent deforming due to beating action of the heart. The video was then converted to individual frames at a rate of 25 frames per second by means of Matlab program as appended to the thesis (AVI file to Frames conversion). Once converted the vertical deformation of the upper curve of the stent was calculated with reference to the lip of the device which is rigid any motion of the lip would thus correspond to a translation of the entire device. With the available video it was possible to calculate the deformation over 6 cycles. As a scale to measure the deformations in real length, dimensions of the clamping mechanism (rectangular plate) were used which were visible in the frames. After analysis a deformation of 0.1865 cm was calculated.

Figure 19 is an example of the frames used to analyze the stent.

Fig 19. Example of frames used to calculate deformation of the stent

Stent modeling on Solid Works 2003

The stent was geometrically modeled on Solid Works 2003. The stent was deformed by the surgeon during the surgery to aid it's fitting thus complicating the shape of the stent. The resulting shape of the stent was geometrically modeled considering the stent as a circular profile sweeped about a curve, then the resulting curve could be broken down into two curves exiting in two different planes at an angle to each other. This angle was estimated by taking a thick sheet of paper and folding it along the stent to get a measure of the angle of the stent. After repeated trials an average of 135 degrees was calculated. Having both the planes of the stent the final step of constructing the stent

was relatively simple as this was done by measuring location at several points along the profile of the heart. Figure 20 illustrates the models obtained from Solid Works.
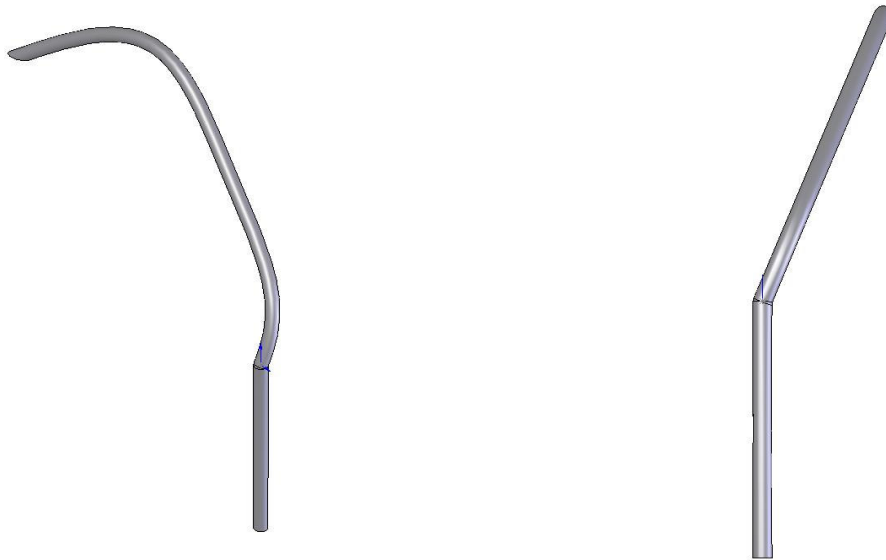
Fig 20. Geometric modeling of the stent (Isometric and Front view)

For analysis of the displacement of the stent, *Cosmos* was used. This was done by fixing the lower portion of the stent where it was clamped and placing a vertical force on the tip of the stent in the vertical direction. The magnitude of the force was increased till the deformation as obtained from the video matched that generated from the Model generated on solid works. A vertical force of 5 N was resulted in a similar deformation.

For the Solid works model of the stent file stent3.sldprt may be viewed in Solid Works.

CONCLUSIONS/FURTHER IMPROVEMENTS

The main aim of the study was to test the method of attachment of the device and the power requirement of the associated Vivigen Superpump. Also of concern was the method of construction of the device as to ascertain whether the 6 cardiac measurements were enough to generate the outer profiles of the ventricles.

From the experiment it was ascertained that the Vivitro superpump was capable of generating the required amount of power to stimulate the heart. The device was run at multiple rates of 70-90 bts per minute in each case with a sinusoidal wave profile.

Regarding the fit of the device, the heart was easily placed within the device after applying a negative pressure to the device. Finally the heart was to be secured firmly in the device using a brass stent, details of which have been discussed in previous sections. During the attachment of the device it was visible that the stent caused the aortic valve to deform. This problem was remedied by attachment of a cotton surgical gauge at the end of the brass stent that mitigated the problem considerably. The prime reason for this deformation was that the vertical load exerted by the device on the heart was supported only by a single stent causing a large stress at a single point of action. One solution to the problem could be a different design for the stent where the stent instead of having a single point of action has a line contact where a stent with a circular profile fits around the aorta of the specimen at the valve plane. This type of attachment would be favorable as the region around the aorta consists of a large of collagen tissue which is highly stiff.

Other designs may also utilize a mesh type structure that would support the heart based on the area of contact.

Another important observation made after the surgery was that the ventricles of the heart had deformed to a more spherical profile, this was as the deformable membrane was not compliant enough to allow the heart to retain its original shape. A more compliant membrane would be required to preserve the geometry of the heart in further tests.

REFERENCES

1. Goldstein, D.J., Oz, M.C., Rose, E.A. Medical progress: implantable left ventricular assist devices. N Engl J Med 1998; 339(21): 1522-1533.

2. Rose, E.A., Gelijns, A.C., Moskowitz, A.J., Heitjan, D.F., Stevenson, L.W., Dembitsky, W., Long, J.W., Ascheim, D.D., Tierney, A.R., Levitan, R.G., Watson, J.T., Ronan, N.S., Meier, P. Long-term use of left ventricular assist device for end-stage heart failure. N Engl J Med 2001;345(20): 1435-1443.

2. Rose, E.A. and Frazier, O.H. Resurrection after mechanical circulatory support. Circulation 1997;96(2): 393-395.

3. Omens, J.H. Stress and strain as regulators of myocardial growth. Prog. Biophys. Molec. Biol 1998; 69: 559-572.

4. Komuro, I., and Yazaki, Y. Control of cardiac gene expression by mechanical stress. Ann. Rev. Physiol 1993; 55: 55-75.

5. Costa, K.D., Takayama, Y., McCulloch, A.D., and Covell, J.W. Laminar fiber architecture and three-dimensional systolic mechanics in canine ventricular myocardium. Am. J. Physiol 1999; 276: H595-H607.

6. LeGrice, I.J., Takayama, Y., Holmes, W., and Covell, J.W. Impaired subendocardial function in tachycardia-induced cardiac failure. Am. J. Physiol 1995; 268: H1788-H1794.

7. Sadoshima, J., and Izumo, S. The cellular and molecular response of cardiac myocytes to mechanical stress. Ann. Rev. Physiol.1997; 59: 551-571.

8. Cooley, D.A., and Frazier, O.H. The past 50 years of cardiovascular surgery. Circulation 2000;102: IV88-93.

9. Helman, D.N., Rose, E.A. History of mechanical circulatory support. Progress in Cardiovascular Diseases 2000;43(1): 1-4.

10. Anstadt, M.P., Schulte-Eistrup, S.A., Motomura, T., Soltero, E.R., Takano, T., Mikati, I.A., Nonaka, K., Joglar, F., Nose, Y. Non-blood contacting biventricular support for severe heart failure. Ann Thorac Surg 2002; 73: 556-62.

11. Kung R.T.V, Phd, Rosenburg M. and M.M.E. Heart booster: A pericardial support device. Ann Thorac Surg 1999;68:764-7.

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