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ABSTRACT

In Vitro Testing and Evaluation of Intraaortic and Extraaortic Balloon Counterpulsation Devices

by Joseph V. Izzo

The primary purpose of this project was to develop an in vitro environment in which the intraaortic and extra-aortic balloon pumps could be tested and evaluated. This was done by modifying a mechanical heart simulator -- the pulse duplicator system -- to accomodate both devices, and developing a software system that could collect and process the data relevant to the operation of the two balloons.

Both counterpulsation techniques were tested in the pulse duplicator where the aortic pressure and flow data were collected. The software system then processes the data to calculate all of the parameters affected by counterpulsation.

While the results produced were not overly conclusive, there were some trends which were noted. While neither device demonstrated a more dominant effect on the mean systolic pressure, the extraaortic balloon appeared to have a more beneficial effect on the end diastolic pressure, stroke volume, and cardiac output.

Since the pulse duplicator is a mechanical simulation of the human cardiac cycle, it does have its limitations.

Future tests should be conducted with proper modifications made to the pulse duplicator. More extensive testing could reveal the extraaortic balloon pump to be a much more effective device for counterpulsation than the intraaortic balloon pump.

IN VITRO TESTING AND EVALUATION OF INTRAAORTIC AND EXTRAAORTIC BALLOON COUNTERPULSATION DEVICES

by
Joseph V. Izzo

A Thesis
Submitted to the Faculty of
New Jersey Institute of Technology
in Partial Fulfillment of the Requirements for the Degree of
Master of Science in Biomedical Engineering

Biomedical Engineering Committee

January 1994

APPROVAL PAGE

IN VITRO TESTING AND EVALUATION OF INTRAAORTIC AND EXTRAAORTIC BALLOON COUNTERPULSATION DEVICES

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ACKNOWLEDGMENT

I would like to thank Dr. Gabbay of the University of Medicine and Dentistry of New Jersey for his unending guidance and motivation throughout this project. I also wish to thank him for allowing me to use his facilities and equipment in the Cardiothoracic Research Laboratory at UMDNJ.

I would also like to express my gratitude to Dr. Mayott of the New Jersey Institute of Technology for his continued support and assistance in preparing this document.

My special thanks go out to Dr. Kristol of the New Jersey Institute of Technology for serving as a committee member for my thesis evaluation. I would also like to thank him for his overall support during my graduate education.

And finally, a very special thanks to all of my friends and family who encouraged me, and motivated me all of my life.

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CHAPTER 1

INTRODUCTION

Counterpulsation has been used for several years as a means of aiding the failing heart in many patients. While extensive research had been conducted in the 60's and early 70's to find the best device for counterpulsation, very little research has been done in this area since that time. Since research has been minimal, it is not surprising that one method of counterpulsation has been used in clinical situations more often than any other.

The most predominant form of counterpulsation device in use today is the intraaortic balloon pump (IABP). While the intraaortic balloon pump has been used for many years, little has been done to increase its clinical effectiveness. As such, the medical research community may soon begin to reevaluate other methods of counterpulsation relative to the intraaortic balloon. One of the purposes of this thesis project has been to provide an in vitro environment where devices of this type can be tested and evaluated. By conducting in vitro testing of these devices, the researcher can determine if in vivo testing is warranted before the monetary investment in animal subjects, operating room time and staff have been made.

Although one purpose of this project was to develop the in vitro testing environment for various counterpulsation devices, the main focus of this project was the evaluation of the overall effectiveness of the intraaortic balloon pump versus the extraaortic balloon pump (EABP). Both devices were tested in a mechanical heart simulator -- the pulse duplicator system -- while pressure and flow data were collected and processed by a computer. The software system isolates a single wave cycle and determines several important pieces of information, including peak and mean pressures, stroke volume, and cardiac output among others. The software also generates a report containing all vital information related to the test. This data can then be compiled and analyzed accordingly.

CHAPTER 2

BACKGROUND AND HISTORY

2.1 The Goal of Counterpulsation

The basic purpose of counterpulsation is to assist the failing heart. When the heart is in failure, that simply means that the cardiac muscle must perform too much work for the amount of oxygen it is receiving via the coronary blood supply. There are several situations where these conditions exist, and they will be discussed in a later section.

The description of heart failure stated above implies that any method of assistance must perform two primary functions. First, it must reduce the overall work done by the heart. Secondly, it must increase coronary perfusion, thereby increasing the flow of oxygen to the cardiac muscle.

The work performed by the myocardium can be defined by the following equation:

$$W = PV + mv^2/2 \qquad (2.1)$$

In this equation, W is the myocardial work, V is the volume of blood discharged during systole, P is the mean pressure that the heart works against (i.e. mean arterial systolic pressure), m is the mass of the ejected blood, and v is the average velocity of the ejected blood (1). It is obvious from this equation that when the mean pressure is reduced, so is the total work done by the heart.

In order to meet the second requirement to assist the

failing heart, the amount of blood circulating through the coronary arteries must be increased. This could be done by reducing the amount of blood flowing to the body, but that would result in systemic ischemia and, perhaps, gangrene or other serious complications. Instead, the coronary perfusion must be increased by increasing the cardiac output. In other words, the total volume of blood ejected with each beat, or stroke volume (SV), must be increased. How this is done will be discussed in the next section.

2.2 Physical Basis for Counterpulsation

Counterpulsation can be defined as a balloon generated pressure pulse that occurs in a cycle counter to the normal cardiac pulse (2). From this definition it can be inferred that the peak pressure of the balloon generated wave will occur during the diastole phase of the cardiac cycle. Likewise, the minimum of the balloon pressure cycle will occur at the high pressure phase of the cardiac cycle (systole).

The counterpulsation wave is generated by a balloon of a particular volume that is placed in some vicinity to the aorta. In the case of the intraaortic balloon pump, the device is placed inside the aorta in the descending arch (Figure 1). The extraaortic balloon is connected to the ascending arch via a cannula and is located outside of the patient's aorta (Figure 2). The wave is then generated by

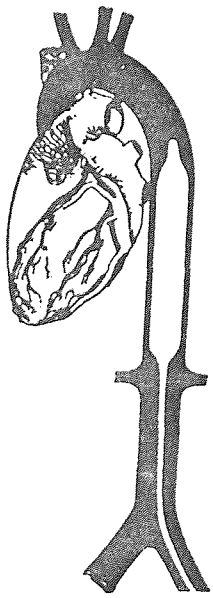

Figure 1 Diagram Showing Proper Positioning of the IABP. (10)

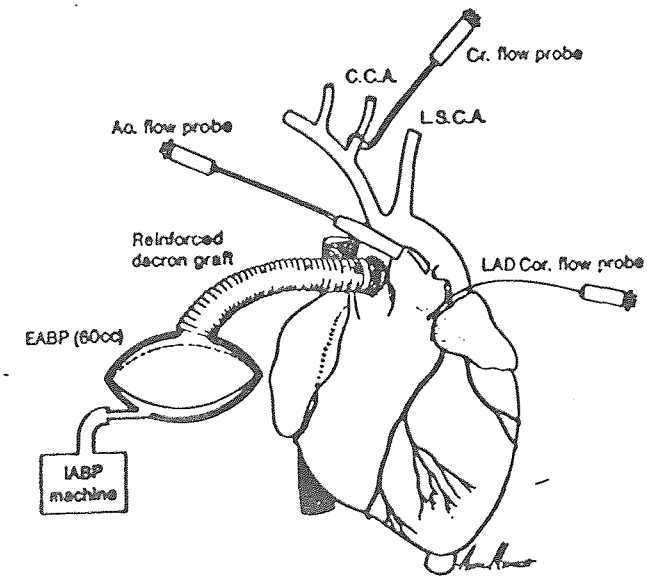

Figure 2 Diagram Showing Proper Positioning of the EABP. (9)

inflating and deflating the balloon devices at specific times in the cardiac cycle.

By inflating the aortic balloon at the end of diastole, just as the aortic valve closes, a volume of blood

equivalent to the volume of the aortic balloon is displaced. By pushing blood out of the volume occupied by the balloon and into the aorta, the diastolic pressure within the aorta is increased. As such, the blood is pushed into the systemic and coronary circulations during the relaxation phase of the heart (2).

At the beginning of the pumping phase of the heart, the balloon should be deflated. When the volume previously occupied by the balloon becomes vacant, it creates a small vacuum in that area. This causes a sharp reduction in the aortic pressure during the systolic phase. The net result at this point is that the amount of muscular force needed to pump blood out of the heart is reduced (2). This correlates directly with a reduction in myocardial work.

2.3 Timing of the Aortic Balloon Pump

Obviously, the timing of the balloon inflation and deflation points is extremely critical. There are four instances of improper timing of the aortic balloon. These, of course, are late inflation, early inflation, late deflation, and early deflation (2,3). The drawbacks to each of these scenarios will be discussed in this section.

The first situation to be discussed is late inflation. If the balloon were inflated too late, much of the diastolic pressure augmentation would be lost. This reduces the pressure available to push blood into the coronary arteries.

As such, the oxygen supply to the heart muscle is not appreciably increased.

On the other hand, if the balloon were to be inflated too early, this would cause a substantial increase in aortic pressure before the aortic valve closes. This scenario would result in a decreased stroke volume since the aortic valve would be forced to close before the ventricle could eject its maximum volume.

While errors associated with inflation timing can diminish the effectiveness of the aortic balloon pump, so can errors in the deflation timing. For example, if the balloon were to be deflated late (i.e. balloon is still inflated during systole), the heart muscle would have to apply more pressure to push its volume past balloon. This would greatly increase the aortic systolic pressure which is contrary to what counterpulsation is trying to accomplish. Likewise, if the balloon is deflated too early, the vacuum caused by the balloon deflation would occur while the ventricle is still filling. This means that the aortic valve will open later than if optimum timing were used. As such, there will be little adjustment in the stroke volume of the heart, and thus the oxygen supply to the heart will not increase substantially.

Obviously, the proper timing of the aortic balloon device is essential to its success in the clinical situation. Any deviation from the proper timing of the balloon can cause the assistance to the failing heart to be

diminished, if not hindered. In either case, the benefits to the patient are not what they should be. Therefore, careful consideration must be used when adjusting the timing of the aortic balloon pump.

2.4 Clinical Uses of Counterpulsation

As stated earlier, the primary purpose of counterpulsation is to assist the failing heart. Failure is determined by the imbalance of oxygen supplied to the heart and the oxygen required by the heart in order to function. Therefore, conditions where this imbalance is demonstrated are likely to indicate the need for some sort of counterpulsative assistance.

While the general need for counterpulsation is the same in each case, the underlying cause of the problem can differ from one condition to another. The increased oxygen demand or diminished oxygen supply to the heart can be caused by a number of different factors. Some may be medical in origin, while others may result from mechanical defects (2). A few of these situations will be mentioned in this section so as to give an introduction into some areas where counterpulsation would be used.

2.4.1 Medical Indications

Some of the medical problems which may require counterpulsative assistance are cardiogenic shock after a myocardial infarction, septic shock, and unstable angina.

In each case, it is a medical, not mechanical, defect that is responsible for heart failure.

In the case of a myocardial infarction, a portion of the cardiac muscle dies from oxygen starvation. The initial destruction of the myocardium usual comes from a narrowing or blockage of the cardiac circulation. Once a section of the heart muscle dies, it can no longer contract. As a result, the rest of the heart must increase its activity to compensate for the part lost to the infarction. In essence, the contractility of the heart is reduced.

Cardiogenic shock can result after a myocardial infarction if the compensatory mechanisms of the body are unable to make up for the loss of myocardial tissue. Essentially, an avalanche effect occurs where more of the heart muscle is damaged until patient death ultimately occurs. If counterpulsation is employed at an early enough stage, the avalanche effect can be avoided with the hope that the bodies natural healing and compensatory mechanisms would become effective.

Septic shock is similar to cardiogenic shock in that the heart muscle does not get the oxygen supply that it demands. However, septic shock is the result of an extreme reduction in systemic pressure. This type of shock is usually brought on by the presence of a toxin in the body which attacks the smooth muscle surrounding the blood vessels. The smooth muscle is paralyzed so that the blood vessels are dilated to an extreme amount. The net result is

to increase the volume in the body that the blood has to occupy. By keeping the volume of the fluid the same, and increasing the volume of the container, the systemic pressure drops dramatically.

When the pressure of the system is reduced by a substantial amount, that in turn causes a lack of coronary circulation. When counterpulsation is used in this scenario, the pressure in the aorta is increased to the point where coronary perfusion, and thus coronary oxygen supply, is increased. Again, this technique is used so that the normal healing process of the body may deal with the underlying medical problem accordingly.

The last medical indication for the use of counterpulsation that will be discussed is unstable angina. In a large number of cases, angina will be a predecessor to a myocardial infarction. In this case, the oxygen supply is reduced to the point where the patient will feel discomfort or pain, but the myocardium is not destroyed.

For most people, prescription drugs (such as nitroglycerine) can help control angina, but in severe and unstable cases more drastic techniques must be used. Counterpulsation can be very effective in relieving the discomfort in some patients after only a few minutes of pumping. The main advantage here is that it allows more time for the physician to further analyze the patient's condition.

It should be reiterated here that these are only a few of the medical indications for counterpulsation use. There are several other conditions where oxygen supply to the heart is reduced, or oxygen demand is increased to a point where damage to the myocardium is the result. Again, this section was meant only to illustrate how a variety of different conditions can have a similar result that can be countermanded by the use of counterpulsation.

2.4.2 Mechanical Insufficiencies

As mentioned above, not only medical problems can lead to the insufficient oxygen delivery to the heart muscle. This same condition can result from mechanical defects of the heart as well. Two such conditions are valvular stenosis (narrowing of the valve opening) and valvular insufficiency.

Valvular stenosis is described as the narrowing of the valve opening. By reducing the valve orifice, the pressure required to push blood through that opening is increased. When the aortic valve is stenotic, the left ventricle must contract harder and longer in order to eject the same volume as a normal valve. Similarly, when the mitral valve is stenotic, the volume entering the left ventricle is reduced, and there is a pressure build up in the right ventricle and pulmonary circuit. Both of these situations serve to decrease the efficiency of the heart.

Counterpulsation is beneficial when valvular stenosis exists because it reduces the pressure in the aorta that the

ventricle is pumping against. As a result, the heart must do less work to move a comparable volume of blood than without the use of a balloon pump.

The other type of mechanical defect is mitral valvular insufficiency. This situation results when a valve is unable to completely seal off the atrium from the ventricle when closed. Since the valve is not completely sealed, it allows some volume of blood to be ejected in the opposite direction of desired blood flow. Obviously, this decreases the stroke volume of the heart.

By using counterpulsation in this instance, the pressure of the aorta is greatly reduced, thereby increasing the tendency for blood to flow towards it. This effect serves to increase the amount of blood flowing forward, despite the presence of mitral valvular insufficiency.

2.5 History of Aortic Balloon Pumps

The concept of counterpulsation is not a new idea. It was initially introduced in an article by Clauss and Birtwell in 1961 (1). The device that they used consisted of an artificial ventricle attached to an actuator that simulated the volume changes of an actual ventricle. The artificial ventricle was located exterior to the body and was attached to the circulatory system via the femoral artery.

The first design for an aortic balloon device came in 1962. The first aortic balloon was an intraaortic type made by Moulopoulos and Kolff (6). The balloon used in these

cases was driven by a carbon dioxide pump and had only a 20 cc displacement volume. Most of the initial tests performed by this group were in a mock circulatory system, on dogs (deceased and living), and human cadavers. The initial tests showed that cardiac output could be increased, and that the end diastolic pressure (and thus, the cardiac work) could be reduced with the use of the aortic balloon. However, the later clinical tests were not as successful. The intraaortic balloon pump still had several more years of research and improvements to undergo.

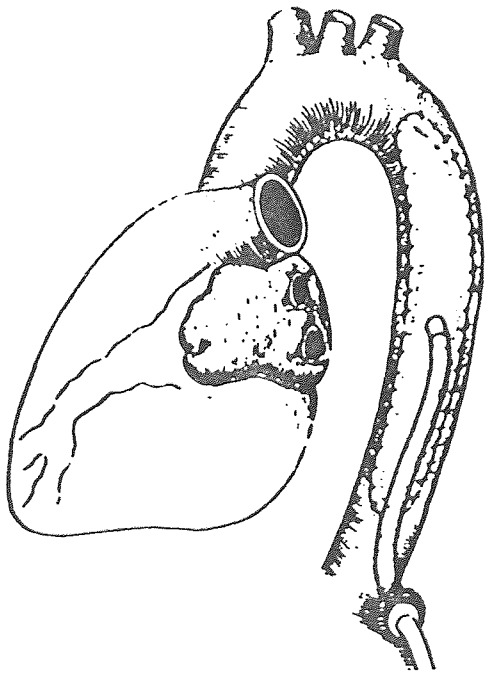

Figure 3 The Dynamic Aortic Patch. (5)

In 1972, Kantrowitz proposed a device which was similar to the intraaortic balloon pump in function, but was meant to serve as a permanent assisting device (5). This device was known as the dynamic aortic patch (Figure 3). It was

basically constructed as an ellipsoidal balloon which gets sewn into the wall of the descending aorta. As such, when it is inflated, its volume expands from one side of the aorta across to the other, rather than from the center of the aorta outwards in all directions.

The first clinical test of the aortic patch on a human showed that the device could be effective. Prior to this test, many patients had died from emboli formation. In the case reported by Kantrowitz in 1972, the dynamic aortic patch resisted the formation of thromboemboli. Unfortunately, his patient died from a massive infection 96 days after implantation of the aortic patch.

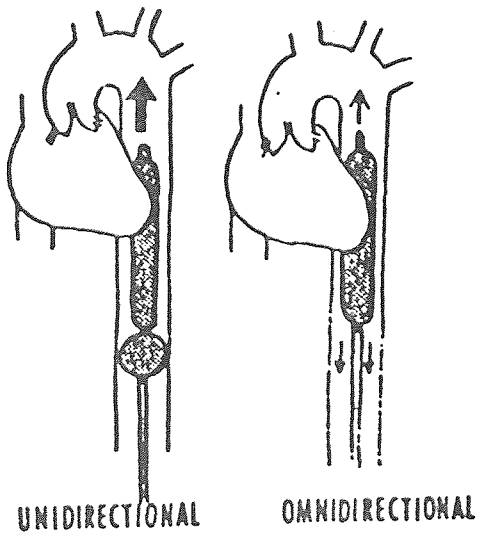

Figure 4 Diagram of the Single and Dual Chambered IABP's. (7)

Also in 1972, the idea of a dual chambered balloon was introduced (Figure 4). Bregman and Goetz designed a balloon

that had two sections (7). It had the long, cylindrical segment which looked and functioned exactly like the standard intraaortic balloon. However, attached to the distal portion of the balloon was smaller balloon. The smaller balloon had a larger diameter than the larger balloon. The purpose was to inflate the smaller balloon before the larger balloon. The smaller balloon would then obstruct the flow of blood to the systemic circulation. As such, most of the ejected blood volume from the heart would be forced into the coronary circulation.

While the double chambered intraaortic balloon did not become very popular, its design introduced the use of an external safety chamber for the pumping mechanism. (Figure 5) The safety chamber is used to regulate the volume of gas used to inflate the balloon with each cycle. It consists of a rigid, plastic cylinder placed outside of the body. Inside the rigid cylinder is a balloon which has the same volume as the aortic balloon. The system is primed so that

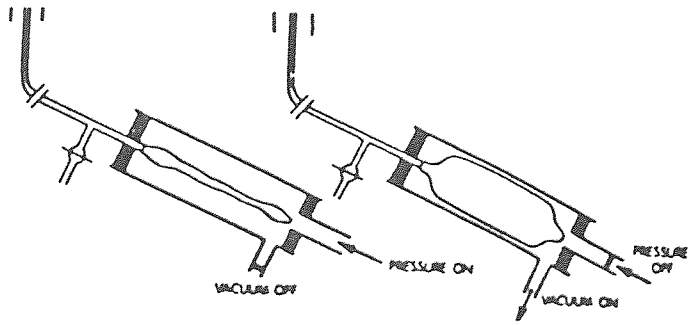

Figure 5 Schematic Diagram of A Rigid Safety Chamber. (7)

when the aortic balloon is deflated, the safety balloon is completely inflated.

By increasing the pressure in the safety chamber, the balloon contained in the safety chamber is deflated. As a result, the full volume of the safety balloon is pushed into the aortic balloon. Conversely, by reducing the pressure in the safety chamber, the safety balloon can draw gas out of the aortic balloon, causing it to deflate.

The safety chamber has several beneficial properties. First, it can regulate the amount of gas used to inflate the aortic balloon. As such, the likelihood of over or under inflation of the balloon is reduced. Similarly, if the aortic balloon should rupture for some reason, only a limited volume of gas would be introduced into the patients blood stream. Due to its beneficial design, the external safety chamber is still used on many modern intraaortic balloon control units.

In the early 1960's, several groups experimented with devices that would deliver counterpulsation from a position that was external to the aorta. The first of these devices was described in 1963 by Nose and Kantrowitz (8). This device served as an auxiliary left ventricle that was pumped by an external controlling unit (Figure 6). The auxiliary ventricle was connected to the ascending aorta on one side, and the descending aorta on the other. In some cases, the aorta was actually severed and sealed at the arch, just proximal to the coronary arteries.

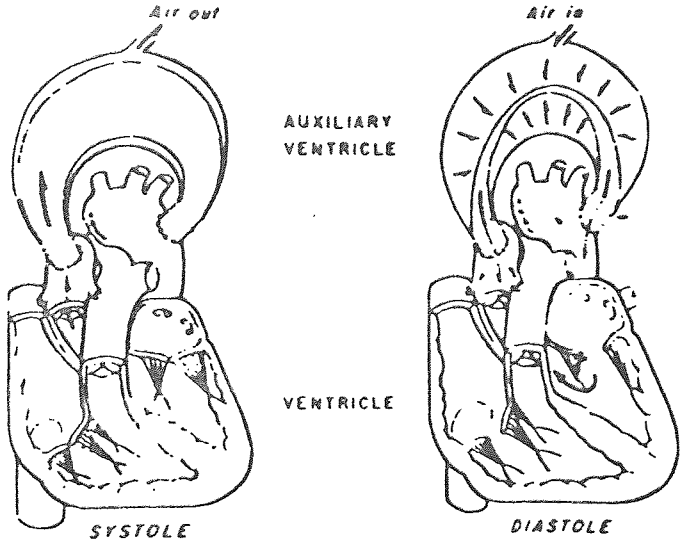

Figure 6 The Auxiliary Ventricle. (8)

Over the next ten years, Kantrowitz and Nose continued to research and develop the auxiliary ventricle. Many of the clinical studies did not have promising results. Most of the dogs that had the device implanted died within two weeks. In the last clinical case, the patient only survived for 12 days. The autopsy of this subject showed that there had been extensive damage due to emboli formation.

It was not until several years later that anyone produced positive results with an extraaortic counter-pulsation device. In 1981, Gabbay proposed the device which is currently called the extraaortic balloon pump (9). It consisted of a rigid external housing with a balloon inside. The balloon was inflated and deflated by applying

an alternating positive/negative pressure to the balloon inside the housing. When a negative pressure was applied the balloon would inflate, thereby drawing blood out of the aorta. The opposite would occur when a positive pressure was applied.

This device differed from the auxiliary ventricle in that it was open to the circulatory system at one end only. As such, it was hoped that any emboli formation would be limited to the inside of the device only. Should extensive emboli formation take place, the device could be removed (emboli and all) and replaced with a new one.

The early animal test results looked promising. In most cases, it outperformed the intraaortic balloon in systolic reduction, diastolic augmentation, and cardiac output increase. Despite its efficiency, the extraaortic balloon pump did not become overly popular because of the methods and difficulties of inserting it via a very invasive surgical procedure.

In 1983, Gabbay published another article dealing with a redesigned extraaortic balloon that is commonly called the EABP II (10). In this case, the balloon inside the rigid shell was replaced with a diaphragm that was stretched across the shell. In this position, the balloon (diaphragm) was inflated from one side only. Through this construction, the overall size of the extraaortic balloon pump was decreased while its efficiency was increased. It was a

balloon of this type that was tested, along with the intraaortic balloon, for this project.

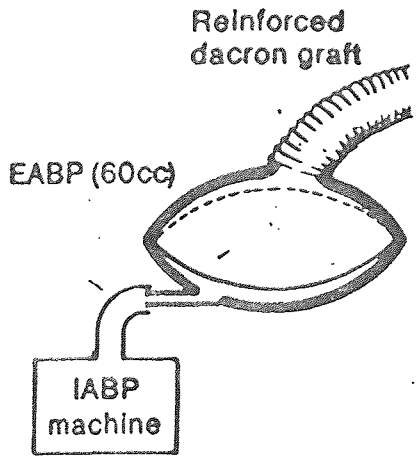

Figure 7 Diagram of the EABP II. (10)

As can be seen from this section, the overall idea of counterpulsation to assist the failing heart has been around for many years. Due to the initial success and easy use of the intraaortic balloon pump, it gained favor in the medical community. As such, most efforts to improve counterpulsation went into improving the intraaortic balloon rather than developing the extraaortic balloon. One of the primary purposes of this thesis is to help rejuvenate an interest in the research and development of the extraaortic balloon pump.

CHAPTER 3

METHODS AND MATERIALS

3.1 The Pulse Duplicator System

The pulse duplicator system (PDS) is a device used as a mechanical simulator for the cardiac cycle. It was developed over several years at the Cardiothoracic Research Laboratory at the University of Medicine and Dentistry of New Jersey (UMDNJ). Over the years, many individuals have contributed to the pulse duplicator project.

The primary function of the pulse duplicator system to date has been the hemodynamic testing of prosthetic heart valves. As such, it was designed so that pressure and flow data could be measured at the mitral and aortic positions. Since the balloon pumps are located in or near the aorta, it was this position that was used in their testing.

The overall idea behind the construction and architecture of the pulse duplicator is relatively simple. It consists of several plexiglass chambers and tubes which are meant to represent the left atrium, left ventricle, and aorta. Another chamber is used to represent the compliance of the aorta and the systemic circulation. The peripheral resistance of the system is generated by the serial combination of a filter and a column of water. Holes were drilled in the plexiglass where pressure taps were desired. For this project, one pressure tap was used and it was located

slightly beyond the aortic valve. A schematic diagram showing the general positions of each piece can be seen in Figure 8.

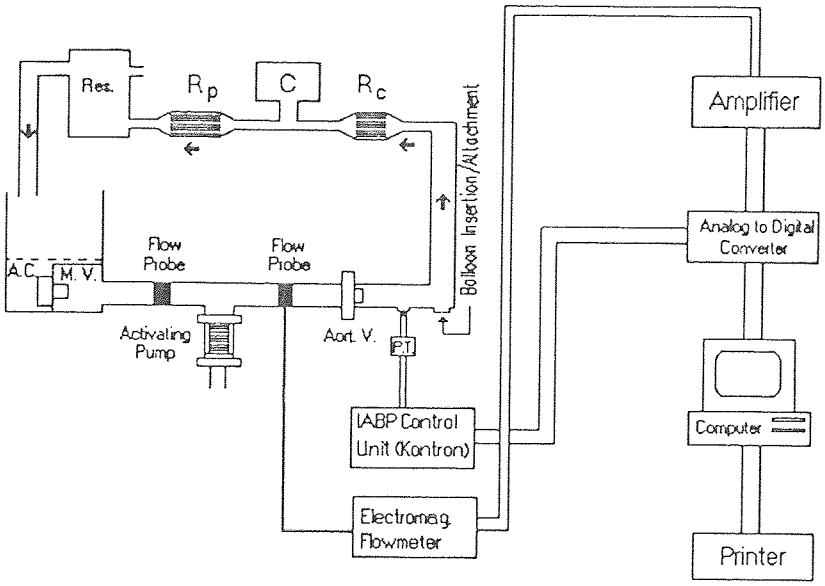

Figure 8 Schematic of Pulse Duplicator System.

The pulse duplicator is also equipped with a piston pump which is used to generate the pumping action of the simulated heart. The stroke volume can be adjusted by changing the length of the piston displacement. The pump rate can be adjusted by changing the speed of the motor. By doing so, the simulated heart rate can be set to the desired level. Both of these factors were adjusted during the testing procedures.

The pulse duplicator system is set up to collect pressure and flow data via a computer. As such, the pulse duplicator is equipped with two electromagnetic flow probes that are permanently mounted on the device. One probe is

used to measure the flow through the mitral valve, while the other is arranged to measure flow through the aortic valve. For the purpose of this project, the aortic flow probe was used.

The pressure data for the aortic balloon testing is collected from a pressure transducer located just beyond the aortic valve. The pressure measured at this point is read into the Kontron aortic balloon control unit (to be discussed later) where it is used for the timing trigger of the balloon. This information then gets passed to the computer where it is stored on disk.

3.2 The Computer and Data Acquisition Hardware

The data collection system for this project consists of two major components -- the computer, and the analog to digital data acquisition card. The pulse duplicator system was coupled with a computer many years ago to fascilitate data collection and processing speed. Over the years, the system has been upgraded to its present condition. Both of the components that were used for this project will be discussed in this section.

The computer used for the aortic balloon pump project, as well as other projects in the Cardiothoracic Research Laboratory, is based on an 80386 IBM compatible computer. The computer is also equipped with a floating point math coprocessor to speed up the data processing portion of the software system. The computer is attached to a Super VGA

color monitor for a high resolution graphic representation of wave forms, and a Hewlett Packard Laser Jet III printer for hardcopy print outs of test results.

The computer is also equipped with a Keithley/MetraByte DAS8/PGA data acquisition card (13). The analog to digital converter on the card is a 12 bit, successive approximation converter with an average conversion time of 15 milliseconds. While only two of the channels were used for this project, the presence of 8 channels allows for the easy expansion of this project in the future.

The card also incorporates into its design three programmable counters and a one megahertz crystal oscillator. When these two components are coupled together, they can generate a suitable square wave to trigger interrupt driven data acquisition. As such, an equal time interval between data points can be assured at all times.

Another convenient characteristic of the Keithley/MetraByte data acquisition board is that it comes with several software library files which make initialization and data collection with the board very easy. This eliminated the need for tedious, and difficult software coding.

Overall, many of the components of the computer hardware system were chosen because of their speed, reliability, and ability to be upgraded. The system can easily be repaired or upgraded by replacing only one portion of the system. This eliminated the need to purchase a new system whenever one component is to be changed.

3.3 The Computer Software System

The computer software system for the aortic balloon testing project was developed in the Cardiothoracic Research Laboratory at UMDNJ specifically for use during this project (18). Under the supervision of Dr. Gabbay (UMDNJ) and Dr. Mayott (NJIT), the system was designed to interface with the existing pulse duplicator system, collect the relevant pressure and flow data, and to process that information accordingly. The program was also written in a modular type of format so it could easily be debugged and modified.

While most of the program was written for this project, some of the subroutines were written by Mr. John Andrews of NJIT who wrote the software for the testing of heart valve prosthesis in the pulse duplicator system. The routines which were borrowed from Mr. Andrews' program were mainly for cosmetic purposes. Since both systems now have the same look and feel, a user who is familiar with one system may use the other without much difficulty.

The software system was coded using Microsoft QuickBASIC and the QuickBASIC library files that accompanied the Keithley/MetraByte data acquisition card. The library files made programming the data acquisition board very simple. It allowed certain functions to be called by setting the values of a few variables and executing a CALL statement.

The workings of the program are very straight forward. It firsts collects relevant data about the test to be

performed, including the date, balloon size, and test number. This information is stored so it can be recalled at a later date.

The computer also prompts the user through a calibration sequence. A water manometer is used in calibrating the pressure transducer, while two reference voltages are used to calibrate the electromagnetic flow meter. In each case, a linear interpolation technique is employed to determine the appropriate calibration factor for each instrument. The data collected in this segment is stored in a special calibration file to be referenced for use in other portions of the program.

Much of the remainder of the program is dedicated to the collection, storage, and processing of the test data. Once the program is instructed to start collecting data, it automatically collects 2.75 complete cycles of the pressure and flow wave forms. It then isolates a single wave of each, aligns them properly, and continues to process them. The data for each wave form is also stored in its own data file so it may be recalled at a later time.

There are several pieces of information which are calculated by the software system. All of the parameters which are either measured or calculated by the computer program are:

- Peak Systolic Pressure (PSP)
- Peak Diastolic Pressure (PDP)
- End Diastolic Pressure (EDP)
- Mean Arterial Systolic Pressure (MASP)
- Mean Arterial Diastolic Pressure (MADP)
- Mean Arterial Pressure (MAP)
- Heart Rate (HR)
- Stroke Volume (SV)
- Cardiac Output (CO)

These are the predominant parameters that can be measured to document the effectiveness of the aortic balloon pump.

Each of these parameters is found by either direct measurement or by calculation. The peak systolic and diastolic pressures are the values where the pressure curve has zero slope. The end diastolic pressure is simply the minimum value of the pressure curve. On the other hand, the mean arterial pressures are calculated by integrating under the appropriate portions of the pressure curve. These are not arithmetic means, but area means (i.e. the total area bounded by the mean pressure and the pressure wave form is zero). In a similar fashion, the stroke volume is found by integrating under the flow curve. The cardiac output is simply the stroke volume multiplied by the heart rate. Once all of these steps and calculations have been performed, the computer moves on the next stage.

The final section of the program generates a report which is printed out on the laser printer. The report presents all of the data mentioned above, including the test date, balloon type and size. The report also contains a visual representation of the actual flow and pressure wave forms. Since all the data for each test is stored at one

point or another, a duplicate report can be generated at any time by supplying only the test number that is to be reviewed.

In general, the system was designed to be easy to use, and also to allow for the recalling of the various data. As such, the data is stored in two places (a print out, and on the computer) and makes the data storage easier.

3.4 The IABP/EABP Control Unit

As mentioned in an earlier section, the timing of the aortic balloon is extremely important. As such, it must be coupled with a driving unit which can control the inflation and deflation of the device. There are many different types of machines that are available to perform this function. For this project, a Kontron Air Ambulance Transport Intraaortic Balloon Pump System was used (2).

The Kontron control unit is a very versatile device for controlling the intraaortic balloon pump. It is equipped with a safety chamber as described earlier to inflate and deflate the aortic balloon. The balloon itself is filled with helium gas because it is easier to move through small tubes, and is less likely to form emboli that can block capillaries. It contains a small helium tank for this purpose.

The control unit is also equipped with a CRT screen to show the user several different pieces of information. The CRT constantly displays three wave forms -- the patient's

ECG wave, either the arterial pressure wave or an auxiliary pressure wave, and the balloon pressure wave. The control unit also displays several other parameters, including the peak diastolic pressure, the peak systolic pressure, the end diastolic pressure, the mean arterial pressure and the heart rate.

Surrounding the CRT screen are a set of "soft keys" which are used to pull up menus and perform various functions. The menus which can be selected are The Operations Menu, the Calibration Menu, the Alarms Menu, and the Recorder Menu. The Operational Menu allows the user to set the balloon inflation volume, the pump ratio, and the trigger pattern. From the Calibration Menu, the pressure transducer is calibrated, and the display ranges can be set. The Alarms Menu allows the user to disable any alarms that may cause the system to shut down automatically. Finally, the Recorder Menu is where the parameters for the optional strip chart recorder are set, including which waves (up to two) will be displayed, and how fast the recorder paper will move. All of these functions are explained in more detail in the operations manual for this particular device.

On the front panel of the control unit, there are also a set of analog inputs and analog outputs. The inputs allow signals to be entered from other devices, such as an external ECG monitor, or external pressure signals. The analog outputs allow the signals which are obtained by the control unit to be output to another device. For this

project, the arterial pressure wave was read by the control unit's pressure transducer and is then sent to the computer via these output plugs.

One of the reasons that this particular unit is so versatile is because it can trigger the balloon inflation/deflation from several different inputs including electrocardiogram (ECG), arterial pressure wave, or an internal trigger source. The availability of several trigger sources is very beneficial in a clinical situation. However, since this project dealt with an in vitro testing environment, only the arterial pressure wave could be used for triggering the balloon operation.

While the control unit controls the timing of the balloon inflation/deflation, it does not perform the timing in an optimal fashion. Therefore, the control unit is equipped with two controls knobs which allow the user to adjust the balloon inflation and deflation timing. As such, the operator can fine tune the balloon inflation and deflation points.

Overall, the intraaortic balloon pump control unit, manufactured by Kontron Instruments, is a typical example of the various balloon pump control units that are commercially available. Many of the features described above are also present on devices manufactured by other medical device companies.

3.5 The Intraaortic and Extraaortic Balloons

The design of the intraaortic and extraaortic balloons are relatively simple. This section will briefly describe the each of these devices.

The first device that will be described is the intra-aortic balloon. The actual balloon is a long, slender cylinder of thin polyurethane. The balloon is placed so it covers the last several inches of a semiflexible catheter. The catheter is used to carry the inflating gas (helium) from the control pump unit to the balloon. The covered portion of the catheter contains several holes so the inflation/deflation of the balloon is uniform, rather than from one end to the other.

The intraaortic balloons can come in a number of different volumes. For this project, a 40 cc balloon was used. The dimensions of the balloon all depend on the maximum volume of the balloon. The diameter is limited since the balloon should not completely occlude the artery when it is inflated. The balloon that was used for this project had a length of approximately 26 centimeters and a diameter of a little less than 1.5 centimeters.

The construction of the extraaortic balloon is quite different than the intraaortic balloon. The extraaortic balloon which was tested for this project was the EABP II design which was in the previous chapter. It has a rigid, outer shell made of polyurethane with the flexible diaphragm stretched across the center of the shell. This balloon had

a shell volume of 60 cc, but the diaphragm was shaped so it could only displace 40 cc.

The extraaortic balloon has an advantage over the intraaortic balloon when it comes to size limitations. While the diameter of the intraaortic balloon should not be equal to or greater than the diameter of the aorta, the size and shape of the extraaortic device do not have such limitations. Since the extraaortic balloon is placed outside of the circulatory system, the only limitations would be placed on the size of the catheter that was used.

As is described in this section, the design and construction of both devices, while very different, are relatively simple. For the most part, each device is just a set of various plastic components that are assembled in the required fashion.

3.6 Method of Testing

The testing procedure both of these devices was relatively straight forward. The goal was to evaluate the intraaortic balloon and the extraaortic balloon versus a no balloon (control) situation. A protocol was devised to test both devices at several pump rates and a variety of stroke volumes. The object was to simulate failure in the system, where failure is defined as a cardiac output below four liters per minute. A summary of the testing procedure is as follows:

1) Test system with: No Balloon (Control Group)
   Intraaortic Balloon Pump
   Extraaortic Balloon Pump

2) Heart Rates: 75, 85, 95, 105, and 115
   (each device) beats per minute

3) Stroke Volumes: 35, 40, and 50 ml per beat
   (each device)

This testing procedure resulted in a total of 45 individual tests being performed. The software system generated a report containing values for several parameters after each test run. The parameters which are the main focus of this study are the mean arterial systolic pressure (MASP), the mean arterial diastolic pressure (MADP), the cardiac output (CO), and the end diastolic pressure (EDP). A discussion of the data that was obtained comes in the next chapter.

CHAPTER 4

SUMMARY OF RESULTS

There were four complete sets of data that were collected during the course of this project. Each data set consisted of test runs at three different stroke volumes, and 5 different heart rates. One set of data was collected with the intraaortic balloon pump and another set with the extraaortic balloon pump. There were two complete sets of data for the control (no balloon) situation -- one set for each balloon pump.

The initial objective of this project was to evaluate how the aortic balloon pumps would affect the failing heart. For this project, "failure" was defined as having an unassisted cardiac output below four liters per minute. Due to limitations of the pulse duplicator system, the number of points that actually met this criterion was less than the total number of points collected.

The data that was collected will be analyzed and presented in a number of different ways in order to find any trends that may exists. First, the average data for all points will be described. This data will be compared to the average data for points that correspond to failure only, where failure is defined as a condition where the unassisted cardiac output is below four liters per minute. Then, the

major parameters will be shown versus other parameters such as heart rate and unassisted cardiac output.

It was also mentioned in the previous chapter that there were five parameters which were the primary focus of this project. They are the mean arterial systolic pressure, the mean arterial diastolic pressure, the end diastolic pressure, the stroke volume, and the cardiac output. The effect of the balloon pumps on these parameters as described above will be discussed throughout the remainder of this chapter.

4.1 Mean Data

First, the effects of counterpulsation on the three pressure parameters will be discussed. It is expect that there will be a reduction in both the mean arterial systolic pressure and the end diastolic pressure. It is also expected that there will be an increase in the mean arterial diastolic pressure. In fact, all of these occurred during the in vitro testing that was performed.

Figure 9 contains a graph showing the mean effects of the counterpulsation devices on the three pressure parameters. The information for this graph comes from the arithmetic average of all data points that were collected. Figure 10 shows the same parameters, but using only those points that occurred during failure (unassisted cardiac output less than 4 L/min) were used in its construction.

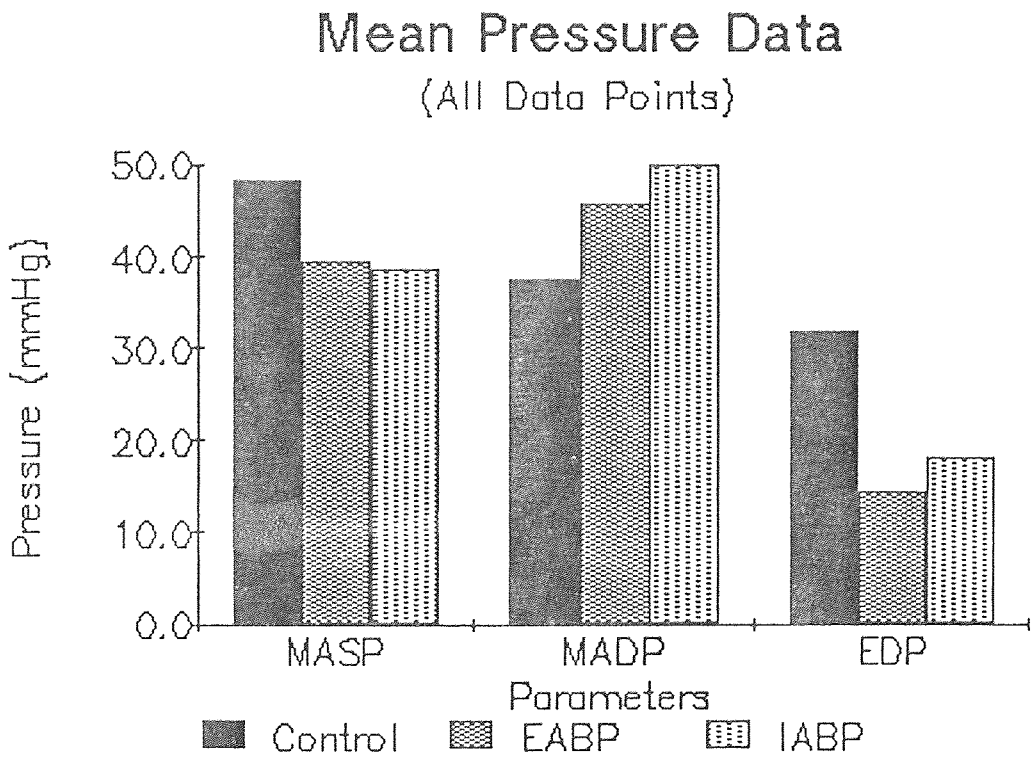

Figure 9 Mean Pressure Data (All Data)

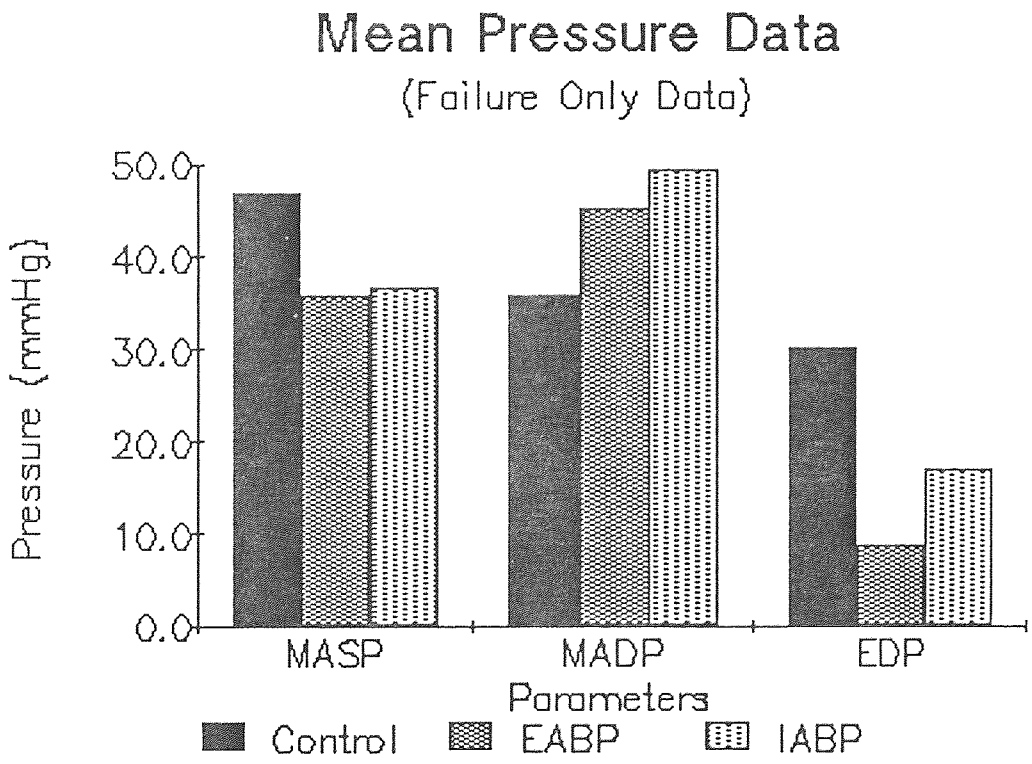

Figure 10 Mean Pressure Data (Failure Only)

In both cases, the mean arterial systolic pressures and the mean arterial diastolic pressures are relatively consistent. The mean values of the systolic pressure remain very close to each other (around 47 mmHg) while the balloons are operating. Similarly, the mean pressure of the control group changes by less than 3%. Overall, the intraaortic balloon and extraaortic balloon appear to have a similar effect on the mean arterial systolic pressure.

On the other hand, the diastolic pressure is noticeably higher for the intraaortic balloon than the extraaortic balloon. While the diastolic pressure of the control group was centered around 36.5 mmHg, the intraaortic and extraaortic balloon groups showed mean diastolic pressures of 50 mmHg and 45 mmHg respectively. Note that the diastolic pressure of the intraaortic balloon group is roughly 10% higher than the pressure from the extraaortic balloon group.

However, when looking at the end diastolic pressure, the average value related to the extraaortic balloon pump, while always lower than the intraaortic balloon pressure, drops from 14 mmHg to around 8.5 mmHg (Figure 11 and Figure 12). This indicates that the effect of the extraaortic balloon pump on the end diastolic pressure was diluted when the points that were not considered failure were included in the average pressure value.

From these graphs, it can be inferred that the level of "failure" did not have a substantial effect on either the

mean arterial systolic or diastolic pressures. On the other hand, it seems that the extraaortic balloon had an increased effect on the end diastolic pressure when the heart was in simulated failure.

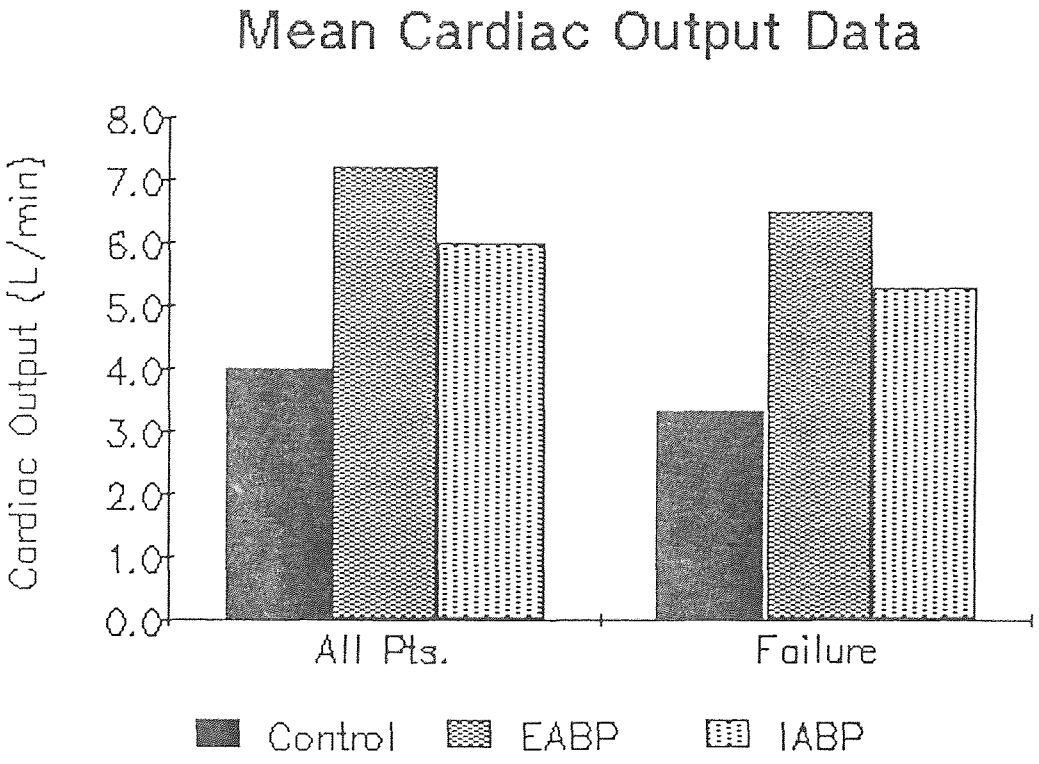

Figure 11 Mean Cardiac Output Data

The effects of the counterpulsative devices on the cardiac output will now be examined. Figure 11 shows the effect on cardiac output for all data points and the data points which correspond to failure only. Like before, these points are the arithmetic average of the points that are specified. From this figure, it is obvious to see that the extraaortic balloon pump consistently provides a cardiac output that is 1.2 L/min more than the intraaortic balloon,

and 3.2 L/min higher than the control situation. It should also be noted that the mean data from the failure points is consistently 0.7 L/min less than the data obtained from all of the data points.

The information presented in Figure 11 illustrates two noticeable trends. First, cardiac output of the extraaortic balloon pump shows a marked increase over the intraaortic balloon pump. Secondly, it can be seen that the value of the cardiac output is related to the level of failure that is encountered. This second trend is not unexpected since the definition of failure is based on a low value for the cardiac output. By eliminating points that were outside of the failure limits, several of the points of higher cardiac output were eliminated as well.

Lastly, the mean values of the stroke volume will be discussed. Figure 12 contains this information in failure only, and from all points obtained. As with the cardiac output data, it should be noted that the extraaortic balloon produces as larger increase in stroke volume (about 34 ml above control) than the intraaortic balloon pump (around 22 ml above control). The net effect is a 12 milliliter per beat advantage for the extraaortic balloon over the intra-aortic balloon.

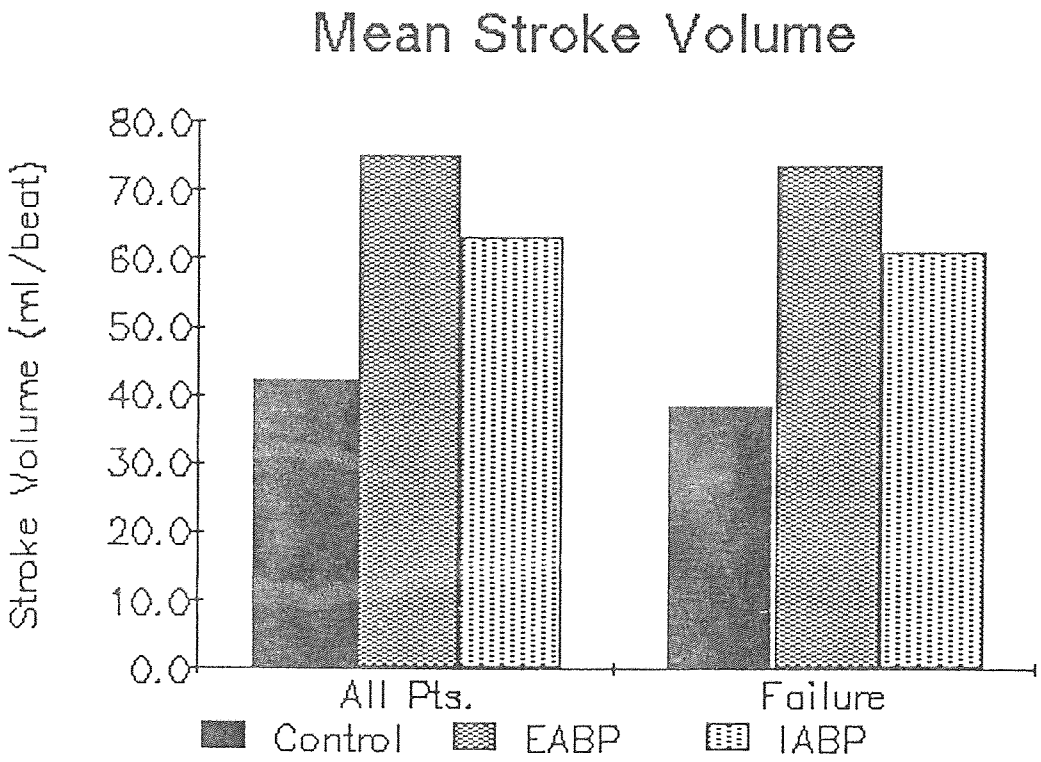

Figure 12 Mean Stroke Volume Data

4.2 Parameters Versus Heart Rate

This section will present the same five parameters listed above, but as a function of heart rate rather than the overall mean data. By presenting the data in this format, additional trends may become visible.

Table 1 contains the values of the mean systolic pressure as related to heart rate. The information for the mean arterial diastolic and end diastolic pressures can be seen in Tables 2 and 3 respectively. A series of corresponding graphs related to these tables can be seen in Appendix B.

Table 1
Mean Arterial Systolic Pressure vs. Heart Rate

HR	Control (mmHg)	EABP (mmHg)	IABP (mmHg)
75	45.4	35.2	37.9
85	48.8	37.5	34.6
95	50.0	40.4	38.1
105	47.6	40.6	39.7
115	48.8	43.2	42.0

Table 2
Mean Arterial Diastolic Pressure vs. Heart Rate

HR	Control (mmHg)	EABP (mmHg)	IABP (mmHg)
75	33.2	46.6	48.9
85	36.8	49.2	49.3
95	38.4	45.8	50.1
105	38.9	42.9	50.9
115	39.7	42.8	50.6

Table 3
End Diastolic Pressure vs. Heart Rate

HR	Control (mmHg)	EABP (mmHg)	IABP (mmHg)
75	27.7	5.8	10.3
85	30.6	13.8	16.4
95	32.1	14.9	18.2
105	33.2	16.8	22.1
115	34.8	20.5	24.2

The data in these tables demonstrates that there is not a substantial difference between the effect of the intra-aortic balloon and the extraaortic balloon pump on the systolic pressure. Both seem to reduce the systolic pressure by a similar amount. However, there does seem to be a trend where the mean arterial systolic pressure increases as the heart rate increases.

As for the effect of each device on the mean arterial diastolic pressure, it appears that again, the intraaortic balloon produces a higher mean diastolic pressure than the extraaortic balloon pump, especially at higher heart rates. The numbers show that the intraaortic balloon maintains an average advantage of four millimeters of mercury over the extraaortic balloon. Also, it seems that the mean diastolic pressure drops down as heart rate increases for the extraaortic balloon while the pressure remains relatively constant for the intraaortic balloon.

It can also be seen from Table 3 that the extraaortic balloon pump still shows a larger end diastolic pressure reduction than the intraaortic balloon pump. There also seems to be a trend where the end diastolic pressure increases with an increase in heart rate. This information is not remarkably different from the mean data that was presented in the previous section.

Table 4 contains the stroke volume data related to heart rate, while Table 5 shows the cardiac output data. The results here are very similar to those indicated by the mean data that was discussed above. It is easy to see from these tables that the extraaortic balloon pump increases the stroke volume by an average of 12 milliliters above that of the intraaortic balloon. Similarly, the extraaortic balloon increases the cardiac output by one liter per minute above the intraaortic balloon. In both cases, this is a

substantial advantage of the extraaortic balloon over the intraaortic balloon pump.

Table 4
Stoke Volume vs. Heart Rate

HR	Control (ml)	EABP (ml)	IABP (ml)
75	41.1	83.1	61.8
85	43.0	73.9	63.2
95	44.2	75.6	68.2
105	40.4	75.9	59.0
115	43.0	67.8	64.7

Table 5
Cardiac Output vs. Heart Rate

HR	Control (L/min)	EABP (L/min)	IABP (L/min)
75	3.1	6.5	4.6
85	3.7	6.4	5.4
95	4.2	7.2	6.5
105	4.3	8.0	6.2
115	4.9	7.8	7.4

4.3 Parameters Versus Unassisted Cardiac Output

As was seen in Section 4.1, some parameters seemed to be more profoundly effected if only those points that were considered failure were used in their evaluation. Since the ultimate goal of this project was to see how the counterpulsation devices performed under simulated failure conditions, only these points will be presented in this section.

Figures 13, 14, and 15 all show plots of the three measured pressures versus the unassisted cardiac output of the heart. Since the definition of failure used for this

project was based only on the unassisted cardiac output, these graphs show how the system pressures were effected by the level of failure that was experienced by the system.

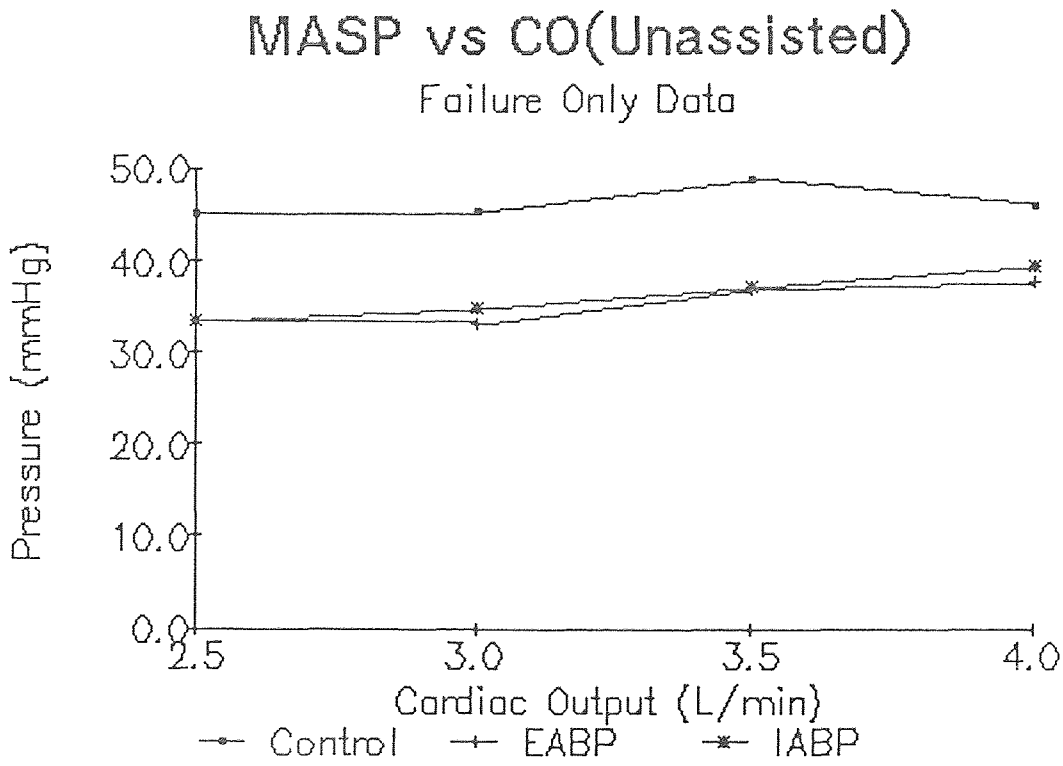

Figure 13 Mean Arterial Systolic Pressure Versus Unassisted Cardiac Output

This information indicates that neither device produces a more beneficial effect on the mean arterial systolic pressure. In fact, these graphs shown them to be almost identical for each cardiac output.

However, the graph showing the mean arterial diastolic pressure shows an interesting trend. While the intraaortic balloon shows a relatively constant pressure, the extraaortic balloon seems to cause an increase in diastolic pressure

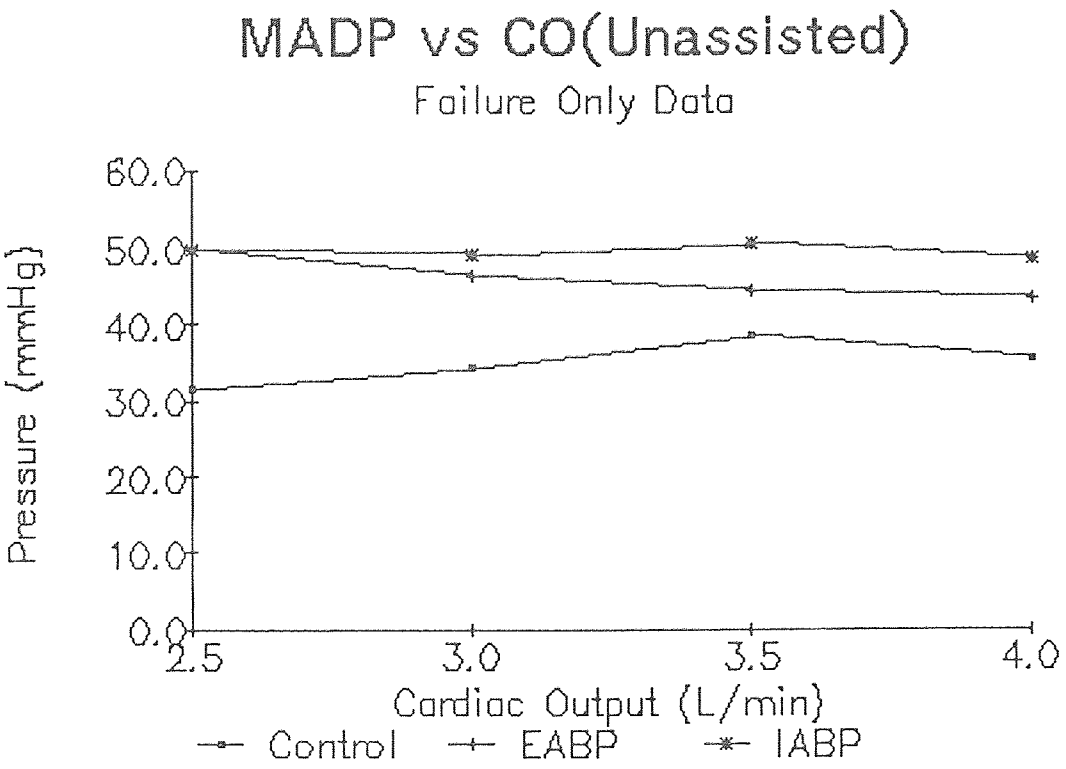

Figure 14 Mean Arterial Diastolic Pressure Versus Unassisted Cardiac Output

as the cardiac output decreases. This leads to the notion that the extraaortic balloon may produce a higher mean diastolic pressure, and thus coronary perfusion pressure, as the level of failure increases.

A look at the plot for end diastolic pressure does not seem to indicate any new trends. The end diastolic pressure produced by the extraaortic balloon is substantially lower than the pressure produced by the intraaortic balloon. The plot also shows that the extraaortic balloon seems to have a more prominent effect on this parameter when the level of failure increases.

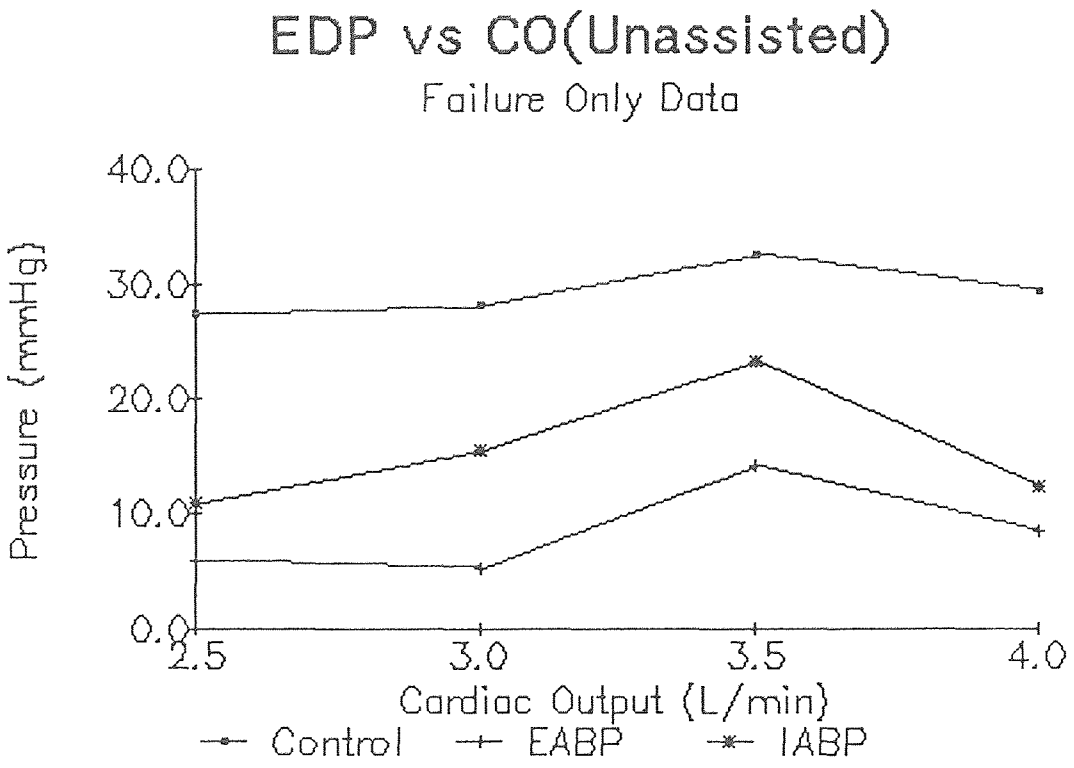

Figure 15 End Diastolic Pressure Versus Unassisted Cardiac Output

The final parameter that will be examined in this section is the measured cardiac output with respect to the unassisted cardiac output. This information can be seen in Figure 16. It should be noted that the extraaortic balloon produces a cardiac output that is either the same as, or higher than the cardiac output generated when the intraaortic balloon pump is used. However, the points from the extraaortic balloon are quite scattered on the graph. Because of this scattering of data points, it is very difficult to interpret any trends that may exist on this graph. As a result, further testing would have to be done

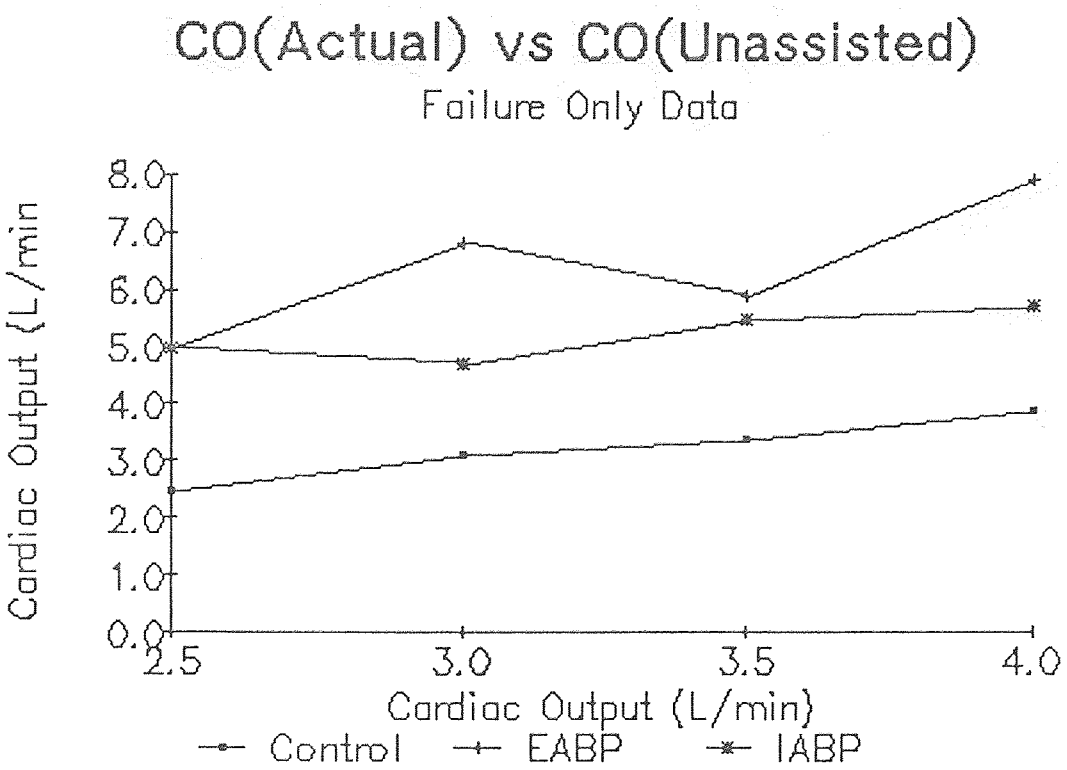

Figure 16 Actual Cardiac Output Versus Unassisted Cardiac Output

in order to gain any other conclusive evidence from this relationship.

CHAPTER 5

CONCLUSIONS

At this point, it should be reiterated that one of the primary purposes behind this project was to demonstrate that research behind alternative counterpulsation devices -- namely the extraaortic balloon pump -- is an avenue that should not be abandoned. While the intraaortic balloon pump has become the standard for counterpulsation, it has been shown that the intraaortic and extraaortic balloons effect certain physiological parameters to different degrees.

One of the goals of counterpulsation is to cause a reduction in the arterial systolic pressure. The test results from this project consistently showed that there is very little difference between the intraaortic balloon and extraaortic balloon when it comes to the reduction of the systolic pressure. Both devices appeared to have generated comparable systolic reduction in all levels of failure.

It was noted in the previous chapter that the intraaortic balloon tended to produce a higher mean arterial diastolic pressure than the extraaortic balloon pump. However, since this is an in vitro study, these numbers may be misleading. The function and position of the intraaortic balloon is such that it will cause blood to flow both forward, through the systemic circulation, and backwards, through the coronary circulation. The pulse duplicator

system is not equipped with a coronary circulation circuit upstream from the balloon placement. This means that the blood flow in the reverse direction has no path to follow. As such, there would be a slight build up in pressure behind the intraaortic balloon in the in vitro system that probably would not be seen in a physiological system.

Another parameter that is effected by the balloons is the end diastolic pressure. The data that was collected indicated that the extraaortic balloon caused a larger reduction in end diastolic pressure than the intraaortic balloon. Physiologically, this means that the heart would experience a shorter isovolumetric contraction phase. In the testing environment, it would indicate that the piston pump had to do less work. The pulse duplicator pump operates at a constant velocity and constant stroke volume. By lowering the end diastolic pressure in the aorta, the piston pump experiences a lower resistance pressure through its displacement. Therefore, it would seem likely that the larger pressure reduction seen in the in vitro system might be observed in an in vivo system as well.

Finally, it should be noted that the extraaortic balloon pump of the same displacement volume produced a much higher cardiac output and stroke volume than the intraaortic balloon. This indicates that the extraaortic balloon has a certain advantage over the intraaortic balloon in this area. By increasing the fluid ejected from the heart, the oxygenated blood supply to the myocardium is being increased

as well. This is a highly advantageous and desirable situation in the case of a failing heart.

From the data obtained in this study, it cannot be decided conclusively which device is best for supplying counterpulsation. Neither has the advantage in mean systolic reduction. However, the intraaortic balloon appears to have the advantage in diastolic pressure augmentation, while the extraaortic balloon seems to be superior when comparing the end diastolic pressure and the fluid output of the heart.

Although this study has shown neither device to be exceptionally superior over the other, it would seem to indicate that further study is required. Future studies may include a model of the coronary circulation to see how the pressure and flow data will be affected. Also, the piston pump could be modified to accommodate even lower stroke volumes so that tests could be conducted in more severe levels of failure. Another way of improving the testing procedure would be to use a flexible piece of tubing for the aorta. Since the aorta for this project was made of rigid plexiglass, any localized effects of its compliance was lost. Of course, in vivo studies should be conducted in the near future as well.

While there are still many areas of study that should be addressed in the future, this work indicates that further studies are warranted. Scientists and engineers involved in

the medical field should always look to improve the quality and efficiency of existing techniques. The intraaortic balloon pump has shown very little increase in efficiency and effectiveness over the past several years. The extraaortic balloon may very well be the next level in counterpulsative technology.

APPENDIX A

Tables of Collected Data

Table 6 Stroke Volume = 35 ml

Data Group	HR (bt/min)	MASP (mmHg)	MADP (mmHg)	EDP (mmHg)	SV (ml/bt)	CO (L/min)
Control (EABP)	73.9	46.8	29.3	26.1	35.7	2.6
	84.5	46.7	33.8	26.0	38.6	3.3
	96.2	52.4	35.3	27.9	37.2	3.6
	107.1	41.9	35.4	28.9	31.9	3.4
	117.2	48.1	40.5	35.0	38.4	4.5
Control (IABP)	78.1	43.7	33.8	28.8	32.2	2.5
	87.0	44.8	35.6	30.1	34.2	3.0
	94.6	49.7	41.0	35.8	30.7	2.8
	104.9	49.7	40.8	36.7	32.2	3.4
	117.2	50.3	40.9	37.8	32.9	3.9
EABP	75.4	33.5	49.5	5.8	66.2	5.0
	86.7	31.6	49.0	4.5	79.7	6.9
	96.8	35.3	43.0	9.1	70.7	6.8
	107.5	37.6	39.2	12.0	55.2	5.9
	114.9	42.9	42.7	17.0	57.6	6.6
IABP	73.9	33.5	49.5	10.8	66.2	5.0
	85.0	31.6	49.2	19.1	68.7	5.8
	96.8	37.6	50.9	24.9	60.4	5.8
	104.5	39.5	49.9	26.8	49.0	5.1
	114.1	44.4	49.4	28.4	65.9	7.5

Table 7 Stroke Volume = 40 ml

Data Group	HR (bt/min)	MASP (mmHg)	MADP (mmHg)	EDP (mmHg)	SV (ml/bt)	CO (L/min)
Control 1 (EABP)	75.6	42.3	31.9	26.1	39.4	3.0
	85.5	51.3	40.0	34.7	42.5	3.6
	95.8	45.5	38.7	31.2	45.4	4.4
	105.6	43.2	35.6	28.9	35.6	3.8
	112.8	44.0	35.2	29.3	40.0	4.5
Control 2 (IABP)	76.3	47.8	35.9	30.5	39.6	3.0
	85.7	48.0	37.3	31.3	39.3	3.4
	94.9	49.8	37.7	31.8	43.0	4.1
	105.6	47.9	37.2	32.9	39.2	4.1
	115.4	47.3	36.6	33.1	47.9	5.5
EABP	77.5	34.6	45.1	5.9	86.7	6.7
	88.2	37.9	50.1	20.6	57.7	5.1
	94.6	40.2	45.0	12.1	65.0	6.2
	104.5	38.0	41.2	10.9	77.1	8.1
	112.8	40.1	39.0	15.1	64.3	7.3
IABP	75.6	38.0	48.9	11.7	48.0	3.6
	85.7	33.9	50.1	17.2	65.9	5.6
	97.1	37.6	50.8	14.8	61.7	6.0
	106.0	36.7	48.6	15.9	57.9	6.1
	114.1	36.2	48.8	18.3	64.2	7.3

Table 8 Stroke Volume = 50 ml

Data Group	HR (bt/min)	MASP (mmHg)	MADP (mmHg)	EDP (mmHg)	SV (ml/bt)	CO (L/min)
Control 1 (EABP)	78.1	44.6	32.9	26.1	49.3	3.9
	87.2	53.1	38.7	33.3	52.2	4.6
	95.5	51.7	41.9	35.6	56.5	5.4
	106.0	51.0	42.8	36.0	49.6	5.3
	115.4	50.6	42.4	36.5	51.7	6.0
Control 2 (IABP)	75.2	47.4	35.3	28.7	50.2	3.8
	86.5	48.7	35.4	28.4	51.7	4.5
	95.5	51.2	35.7	30.2	51.6	4.9
	106.8	52.2	42.0	36.1	54.1	5.8
	114.5	52.6	42.7	37.6	47.0	5.4
EABP	80.4	37.6	45.2	5.6	96.5	7.8
	86.5	43.1	50.6	16.3	84.3	7.3
	95.5	45.8	49.3	23.4	91.0	8.7
	105.3	46.2	48.4	27.6	95.3	10.0
	115.8	46.5	46.7	29.6	81.5	9.4
IABP	74.8	42.1	48.3	8.4	71.1	5.3
	87.5	38.2	48.7	13.0	54.9	4.8
	94.9	39.0	48.6	14.8	82.6	7.8
	105.6	42.9	54.3	23.5	70.1	7.4
	114.9	45.4	53.6	25.9	64.0	7.4

APPENDIX B

Plots of Data vs. Heart Rate

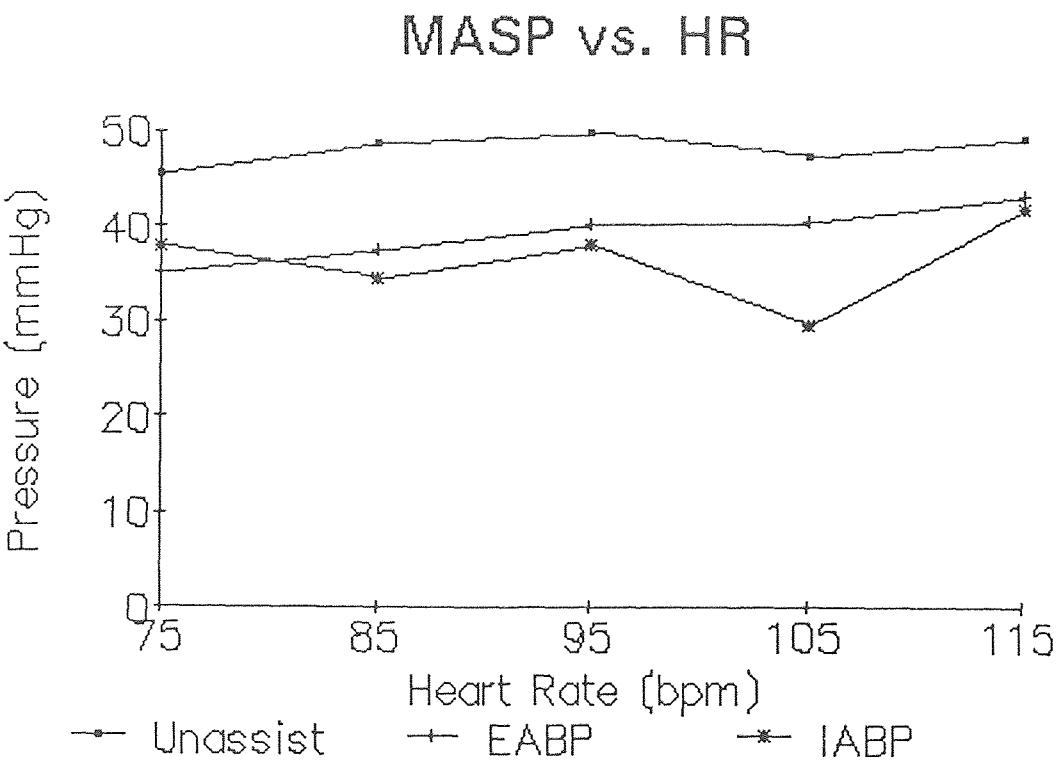

Figure 17 Mean Arterial Systolic Pressure vs. Heart Rate

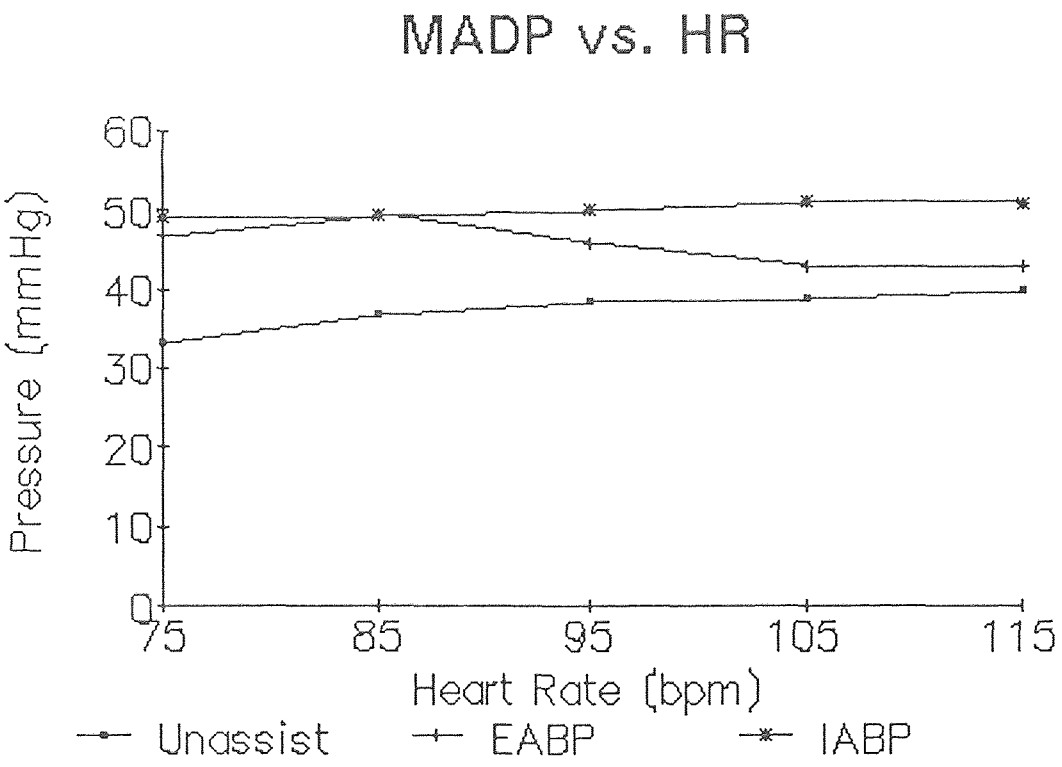

Figure 18 Mean Arterial Diastolic Pressure vs. Heart Rate

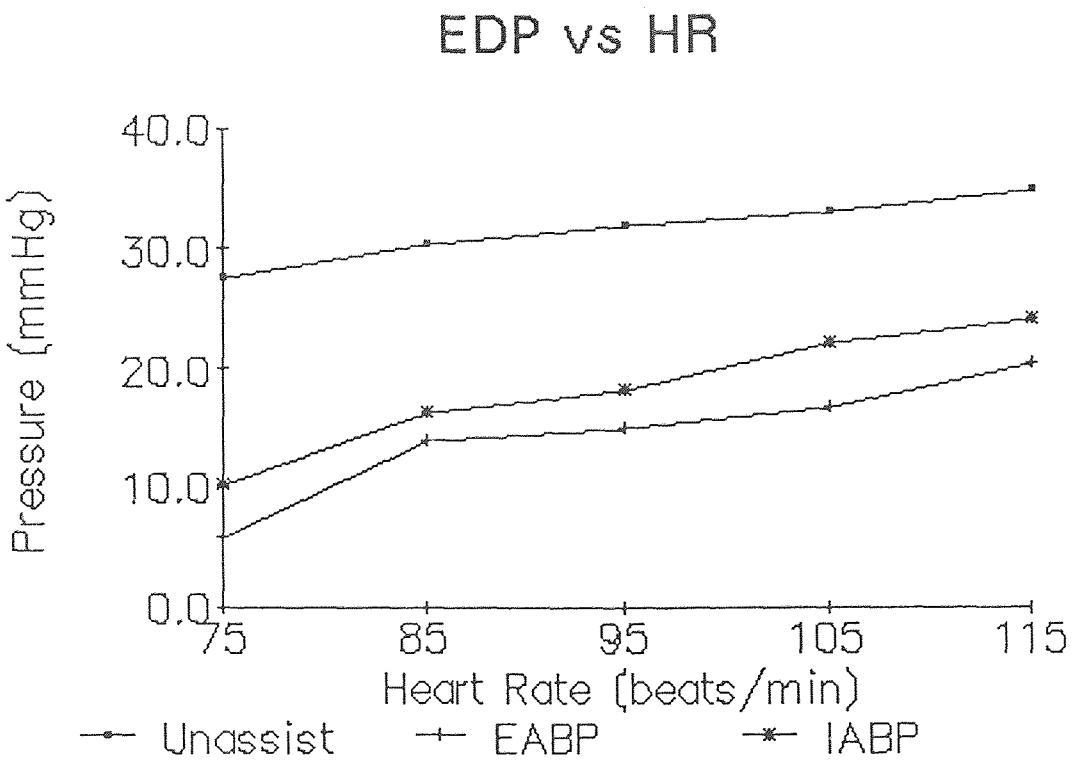

Figure 19 End Diastolic Pressure vs. Heart Rate

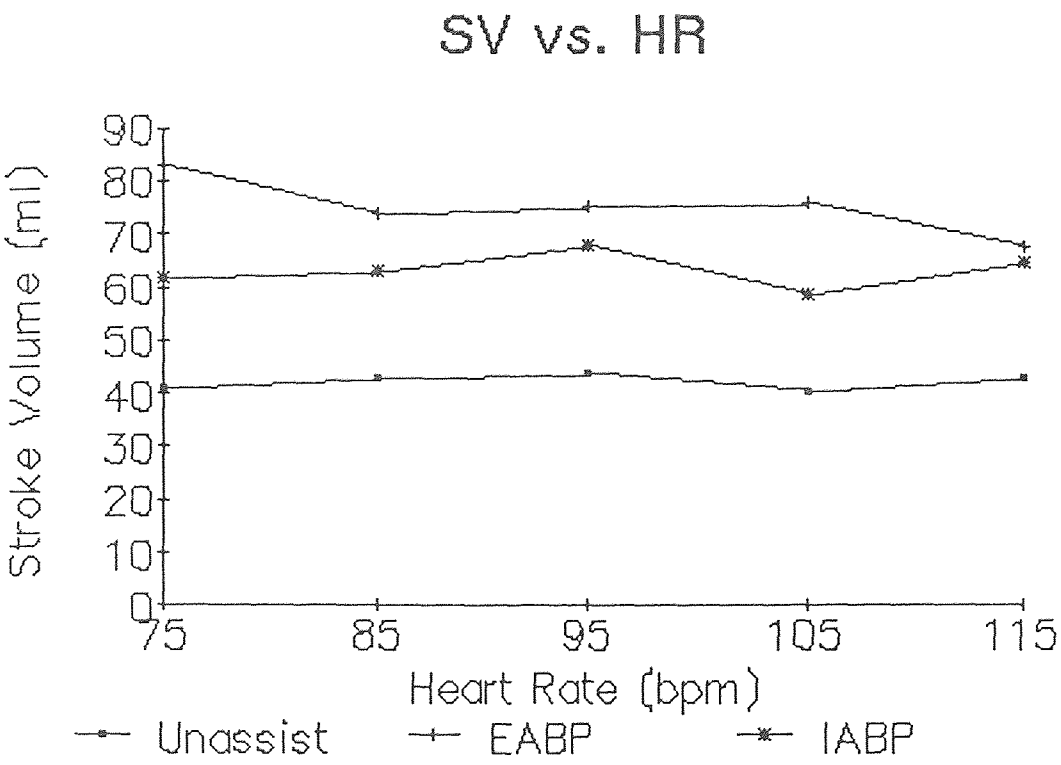

Figure 20 Stroke Volume vs. Heart Rate

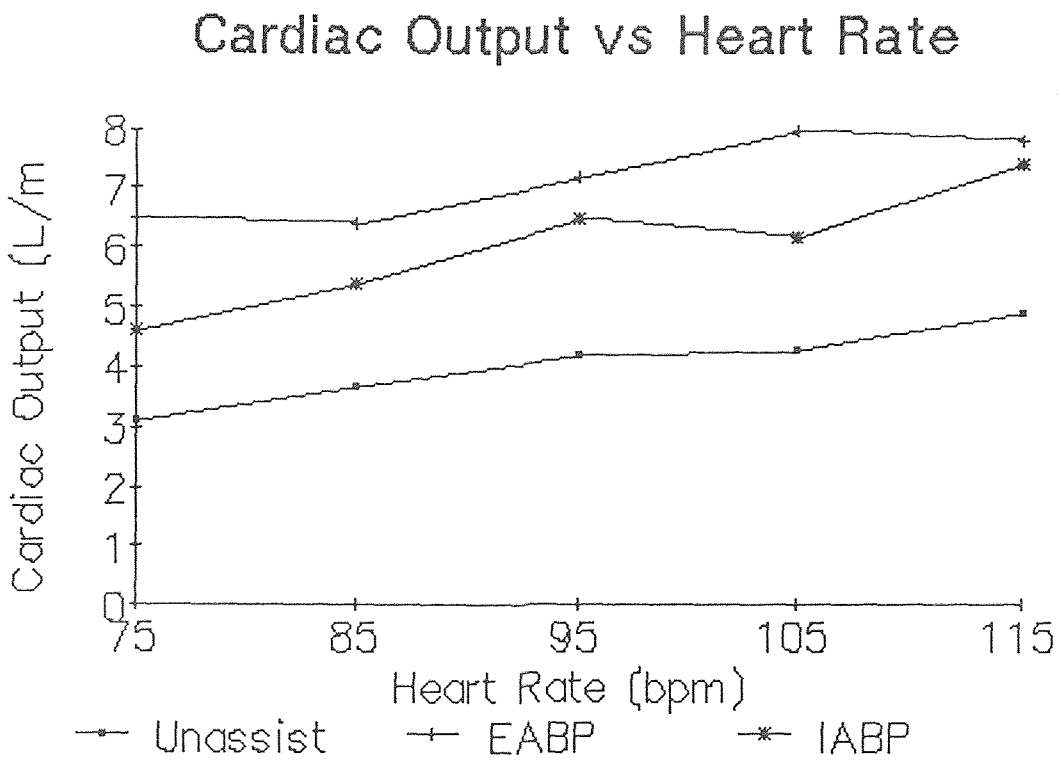

Figure 21 Cardiac Output vs. Heart Rate

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