THE TRICUSPID ARTIFICIAL HEART VALVE An Analysis of Opening Characteristics

by

WARREN VAN GENDEREN

Submitted in Partial Fulfillment

of the Requirements for the

Degree of Bachelor of Science

at the

MASSACHUSETTS INSTITUTE OF TECHNOLOGY

June, 1960

Signature of Author. Department of Mechanical Engineering, May 21, 1960 Gertified by Thesis Supervisor Accepted by. Chafrman, Departmental Committee on Theses

TABLE OF CONTENTS

PREFACE

This thesis is an attempt to look into the field **of** artificial heart valves. This is a very new and transitory area of research. In fact, the criteria for the design of an effective heart valve have not yet been definitely established. With this in mind, I have analyzed one type of valve, not that it supplies the answer to the heart valve problem, but rather gives a point to start in the search for better understanding of artificial valves.

Because of the scarcity of artificial heart valves, it was possible to obtain and test only two. The thesis, therefore, is based on the results of these two valves. Although it is not sound to base a theory for heart valves on only two, the suggestions and theories herein concentrate on characteristics that would apply to most tricuspid valves with the hope that they will be tested when a wide variety of valves become available.

I hope, therefore, that this thesis may serve as a reference to those who undertake a project in the many untouched aspects of heart valves. I have written the thesis with this in mind. I have listed the criteria considered essential at the present time, stated the results from the experiments carried out and analyzed the valves in light of these results. Throughout the thesis I have mentioned problem areas and concluded the thesis with a summary of unsolved problems.

I wish to thank Professor Kenneth Wadleigh for being

a helpful thesis adviser and Dr. Selwyn McCabe for the use of the tricuspid valve which he developed.

ABSTRACT

A series of tests were run on artificial heart valves to determine whether the present valves met a set of prescribed criteria and to learn more about the opening characteristics of artificial valves.

The device to carry out these tests was designed so that at different pressure levels across the valves, the flow rate through the valve could be measured and the open area of the cusp observed.

The results showed that:

- **1.** The valves displayed different opening characteristics.
- 2. The valves opened with pressures above 5 mm Hg.
- 3. The valve fluttered at high pressure differences (above 12 inches water)
- 4. The valves withstood a back pressure of 180 mm **Hg** without failing.
- 5. The valves displayed a hysteresis effect in opening and closing.

On the basis of these results, an analysis of the opening of the valve was carried out. It was proposed that an area of the cusp called the crest controlled the opening of the valve. The crest area is a result of the cusp geometry and can be altered by changing the cusp dimensions. A valve can be made to open with less pressure difference by decreasing the thickness of the cusp or increasing the effective radius of the crest. Hysteresis, flutter, and step opening were explained in terms of crest movement. The relation of particular cusp dimensions to cusp geometry of the valve were analyzed to determine the optimum cusp geometry.

THE TRICUSPID ARTIFICIAL HEART VALVE An Analysis of Cpening Characteristics

STATEMENT CF THE PROBLEM

The program of developing a heart valve is a relatively new and unexplored field. In fact, in an article in Scientific American, Dr. C. W. Lillehei states that "the most challenging task currently before cardiac surgeons is the development of complete artificial valves to take the place of valves so totally destroyed by disease that repair is likely to fail."¹ The first published data on the testing of artificial heart valves appeared in May of 1959.²

In order to obtain a better understanding of the operation and the characteristics of a heart valve, we decided to run a series of tests on an artificial tricuspid valve developed by Dr. Selwyn McCabe. It was hoped that from these tests it would be possible to determine the changes necessary for making the present valve satisfactory, if it proved unsatisfactory, and to determine the important factors in the designing of an entirely new valve.

Dr. McCabe developed his heart valve for two particular reasons. The first reason was for use in an artificial

 \mathbf{I}

¹ C. Walton Lillehei and Leonard Engel, "Open Heart Surgery," Scientific American, (February, 1960) B. Dreyer, T. Akutsu and W. Kolff, "Testing of Artificial Heart Valves," Journal of Applied Physiology, (May, 1959)

heart-lung machine. This particular heart-lung machine was designed to assimilate the human heart as closely as possible. There was, therefore, a need for a variety of valves in the heart-lung machine. This need resulted in the design of the tricuspid valves.

The second reason for the design of a heart valve was the acute need for a valve that could be inserted into the human vascular system to replace the human valve which had been diseased or destroyed. Since this artificial tricuspid valve is similar to the tricuspid valve found in the human heart, a perfected valve of this type could be used in both the heart-lune machine and the human heart. However, since the criteria for an artificial human heart valve are much more stringent than those for a valve in the heart-lung machine, a perfected valve for a heart lung machine would not necessarily be satisfactory for the human heart.

CRITERIA

The criteria listed here are those stated by Dr. McCabe and those listed in articles by Kolff³ and Lillehei. Many of the criteria are obvious. However, there are some points which one author includes while another does not. Probably more time and experiments are necessary to determine the exact criteria.

 $\frac{3}{4}$ Kolff, ibid. Lillehei, op. cit. $\overline{2}$

PRESSURE

The valve should open with a pressure difference of 5 mm of **He** on its afferent side. The maximum allowable pressure difference is 1C mm of Hg, although this is by no means desirable. The aortic valve in the human system opens with approximately 1 mm of **Hg.** of pressure difference. The valve should be able to withstand pressure on its efferent side of 18C mm of Hg. To insure this the valve should be tested at pressures well over 200 mm of Hg . EM0OLYSIS

Hemolysis is a dissolution of the red corpuscles thereby liberating the hemoglobin of the blood. This process occurs whenever the blood is exposed to abnormal forces which cause the blood to become bruised. If moving parts of the valve are not designed properly, they can exert forces which injure the blood.

STAGNATION POINTS

The geometry of the valve should cause no stagnation points in the fluid stream due to the valve.

PARALLEL FLCW

It is necessary that all blood leaving the valve, flow parallel to its axis since any flow that is not parallel to the axis has a dilating effect on the vessel containing the valve.

TURBULEN **CE**

The geometry of the valve should not cause the blood to become excessively turbulent as it flows through it. MATERIAL

A material must be found which is compatible with blood. It must not induce the deposition of fibrin. It must be inert and not rejected by the tissues. The blood must not react with the material in any way causing it to change in physical property. For an artificial heart valve to last ten years, the valve must undergo approximately 10^8 cycles in this period. This means it is necessary to find a material with unusual faticue characteristics. The material must be readily workable.

CFENING **TIAE**

The valve's action of opening and closing must be extremely rapid. When the heart is beating at a fast pulse rate, the time allowable for the mitral valve to transmit encugh blood to fill the ventricle is less than .2 seconds. This means that the valve muct open almost instantaneously. The moving parts of the valve must have small mass to move this rapidly and not cause excessive damage to the blood. SEW INTO AORTA

A valve must be designed that can be placed at the natural site of our present valves. For instance, an aortic valve must be able to fit in the one quarter inch length of aorta between the point where the aorta leaves

the heart and the opening of the coronary arteries. The casing should be designed so that it can be easily sewn to the aorta wall.

LEAKAGE

There should be negligible leakage when the efferent pressure of 180 mm of Hg is applied to the valve.

Some of the criteria listed above need not be so stringent when applied to the heart-lung machine. The reason for this is that a valve in the heart-lung can easily be replaced. A criterion like the fatique property of the material is virtually eliminated. The blood need not flow parallel to the axis of the valve because the tubing of the heart-lung machine will not stretch readily.

DESCRIPTION OF THE VALVE

Figure I shows the artificial heart valve used in this thesis. It consists of an outside casing surrounding cusps. The cusps themselves consist of a body, a nodulus, and the lunulae. The nodulus is the center tip of the cusp. Since the lunulae are the portion of the cusps that come in contact with each other, it is necessary that they be extremely thin to insure gentle closing and delicate treatment of the blood. The lunulae of the cusps are three thousandths of an inch thick. Sinuses are molded into the walls of the outside casing to insure a gentle

 \sim

 \sim \sim

SIDE

washing action and no stagnation points on the back stroke. The valves used in this exoeriment were made of silicone rubber.

TESTING **APPARATUS**

The apparatus, containing the valves to be tested, is best described by referring to figure2 . The tank, A, is a constant level reservoir, filled with tap water, which can be varied in height to give different pressure heads to the system. The water flows from this reservoir to a long tube, T, whose inside diameter is the same as the valve's outside diameter. This tube is made in two sections. Each section has a flange, F, and a Lucite end, E. The end is made of Lucite so that the valve may be observed during the entire test. The valve, V, is inserted into the tube at the location of the flanges to hold the valve in position. C-rings are placed in between the flanges and a seal is made by applying pressure with C ϵ clamps, C , to the periphery of the flanges.

The water flows through the valve and out into a measuring container, K, which is placed cn a scale to determine the rate of flow. The pressure drop across the valve is measured by the monometer, M, placed on each side of the valve.

 ~ 10

FIGURE 2

 \mathbf{r}^{\prime}

 ∞

TESTING PROCEDURE

Each test began with the reservoir at the level of the tube so that there was no flow. Then the reservoir was raised in small increments. At each increment the pressure drop across the valve, the flow rate of the water through the valve, and the open cross section of the valve were observed and recorded. When the reservoir was at its maximum height, it was lowered in increments and the same data recorded.

The valve was removed from the apparatus to measure the pressure drop due to the apparatus alone.

The valve was also inserted in the tube in the opposite direction so that the competence of the valve against back pressure could be measured. Here again the reservoir was initially placed at the level of the tube and slowly raised to increase the back pressure on the valve.

THE VALVES

The valve A was the original valve given us by Dr. McCabe. It had been tested before we received it and was tested by us on at least ten occasions. It was handled and flexed a great deal to determine its characteristics. Valve B on the other hand was from a later batch of valves made by the Neimer Industries of Washington, D.C. Its handling was kept to a minimum and was tested on only three occasions. In comparing the two after all the testing

was completed, valve B was much stiffer.

RESULT S

VALVE A

The different slopes in figure3 are marked to indicate the number of cusps that were open during that portion of the curve. The valve initially separates a small amount between the cusps and allows a small amount of water to flow. At a pressure difference of $2\frac{1}{2}$ inches of water, one cusp opens. Just one cusp remains open until a pressure difference of about $3\frac{1}{2}$ inches of water when the second cusp opens. At 8 inches the third cusp opens. This means that the valve does not open completely until there is a pressure difference of 15 mm of **Hg.** This opening of cusps on valve A is not a gradual prosess. At a certain pressure difference, the cusp becomes unstable and "pops" open. By varying the reservoir in very small increments, it is possible to establish the unstable pressure condition and see the cusp oscillate between opened and closed positions.

As the pressure across the valve is decreased, the cusps begin to close one by one. However. the cusps do not close at the same pressure at which they open. They close at a lower pressure difference as indicated by the dotted lines, thereby giving the hysteresis effect.

PRESSURE DROP-INCHES OF WATER

VALVE B

The striking difference between the valves A and B is that valve E does not open one cusp at a time. The three cusps open more or less simultaneously giving the smooth curve in figure **4** . The cusps open by slowly folding back as the pressure difference was gradually increased instead of a definite opened-closed position as exhibited in valve A. Valve *B* is completely open with a pressure difference of 24.4 mm of **Hg.** The valve, however, does have a lower flow rate for a given pressure difference in the increasing pressure direction than was present in the decreasing pressure direction, thereby giving a slight hysteresis effect. Violent flutter was predominate in the cusps of valve B at pressure differences above 12 inches of water.

BACK PRESSURE

Both valves withstood 96 inches of water (approximately 180 mm of Hg) back pressure with negligible leakage. This was the maximum pressure difference at which the valves were tested since this was the largest available pressure difference with the cresent set-uo. The valves showed no signs of failing at this pressure level.

*PRESSURE****AREA CHARTS**

Figures 5 and 6 give the area change in the valve as a function of pressure difference. The general shape of the

FIGURE 4

 $\overline{\omega}$

PRESSURE DROP **-** INCHES OF WATER

FIGURE 5

 $\overline{4}$

 $\mathcal{A}_\mathbf{a}$, and $\mathcal{A}_\mathbf{a}$, and $\mathcal{A}_\mathbf{a}$, and $\mathcal{A}_\mathbf{a}$, and $\mathcal{A}_\mathbf{a}$, and

 $\mathcal{L}^{\text{max}}_{\text{max}}$, where $\mathcal{L}^{\text{max}}_{\text{max}}$

 \mathcal{L}^{max}

curve is similar to the flow versus pressure drop charts.

PrESSURE DROP DUE TC **AFFARATUS**

The pressure drop of the apparatus without the valve present was less that **1/10** inch of water at maximum flow. This means pressure drops recorded in the data can be considered due to the valve alone.

MATERIAL

In performing simple fatique tests with whiskers of sllicone rubber, it was noticed that for approximately five cycles the material will take relatively large stress and strain. Then it would break with a very small amount of stress.

CONCLUSIONS

Our results show that the valves do not meet the criteria of opening under 5 mm **Hg.** Valve A does not open until it has a pressure difference of 15 mm Hg across it and valve E does not open until there is a pressure difference of 24.4 mm **Hg.**

the valve to meet the criteria, it is necessary to analyze the opening process of the valve. The critical portion of the valve,which will be called the crest of the cusp, controls the movement of the entire cusp. It is indicated in figure **⁷** In order to determine what should be changed for

 $\hat{\boldsymbol{\beta}}$

The crest is a result of the particular cusp geometry and is formed by the meeting of the sides and the front of the cusp. The sharpness, thickness and length of the nodulus have a very great effect on the formation of the crest area. The crest acts like a spherical plate that is held by the rest of the cusp. Because of the geometry of the cusp, a small displacement of the crest is transmitted through the whole cusp and causes large displacements of the nodulus (point A). This can be seen by displacing the crest with a pencil and noticing the movement of the nodulus. As a pressure difference is placed across the crest it will move a small amount and cause a displacement of the nodulus and the lunulae that is characteristic of the cusp shape when it is initially opening. This was observed in tests. As the pressure increases, the crest continues to be displaced until it reaches the point where it buckles. The buckling, which occurs in two locations, takes place whenever the cusp opens. The crust buckling is prevalent in every cusp.

The characteristics of the crest are related to the characteristics of the entire cusp. For instance, if C-B is relatively stiff, this portion of the cusp will act like a beam. The cusp will then bend at C giving a displacement to the crest and the entire cusp before the crest buckles. This form of opening causes smoother opening than when the buckling occurs with little deflection.

This is similar to what happens in valve B. Instead of the crest moving a small distance and then buckling, the whole crest moves as if it is on the end of a beam and then buckles when the beam has made its maximum deflection. Since the deflection of the beam is proportional to the pressure difference, there is a gradual opening of the cusps instead of a smapping open. As the valve becomes older, the beam becomes less stiff and buckles sooner. These different types of openings are shown in figure T **.**

When the crest is in the buckled position it has a tendency to stay there. It therefore takes more force in the opposite direction (ie.,lower pressure difference) to have the valve unbuckle and come back to its normal position. It is for this reason that the hysteresis appears in flow-pressure charts of the valves.

It is desirable to have the valve cusps identical. If the cusps are not identical the crests buckle at different pressure'differences and the valves open in steps'as is done by valve *A.*

When the cusp has buckled and is open, there appears to be an excess of material which flutters violently. This is due to poor design of the valve. By taking advantage of a unicue feature of the tricuspid valve it is possible to minimize flutter. This feature is best pointed out by asking this cuestion: Into how many cusps should a valve be divided in order for the material of the cusp to lie against the circumference of the valve

wall when the valve is open? Let us assume that the answer is four cusps. Figure **8** shows a cross section perpendicular to the axis of a valve with four cusps. The circumference is $2\pi r$, or approximately $6r$. If the cusp material were placed around the circumference as is the case when the valve is open, we see that we are trying to put 8r of material in a space capable of handling 6r.

If we take a similar cross section of a tricuspid valve we see that there is approximately 6r worth of inside material which fits very nicely in a circumference of approximately 6r. This means that if each cross section perpendicular to the axis were made in such a manner that the cusp material length ecualed the effective circamference, all excess material would be eliminated. This would mean that when the valve is open, the material would be against the wall and flutter would be greatly reduced. In figure 9 a cross section of a tricuspid valve, perpendicular to the axis, has been divided into six ecuilateral triangles. If we look at one of these triangles, we see that chord BB approximating the arc **EE** is equal to the equivalent radius BA for every cross sectional area. Cr, in other words, the cusp is formed by rotating cross section **BA** through 120⁰. This means that a cross sectional area taken through this chord EB will have the same shape as the cross sectional area taken along the radius BA. Therefore, the shape of the line

1 20 20

SEC. B-B **S EC.** B-A

FIGURE 9

FOUR CUSPID VALVE

formed at the Junction of the cusp and the valve wall will be very similar to the shape of the valve cut along EA as shown in figure **9** . This shows that if valves are to have a large diameter and short length, then the crest will have a large radius of curvature and be relatively flat.

If we approximate the crest by a section of thin sphere, we find that the pressure difference at which buckling occurs is directly proportional to the thickness, squared and inversely proportional to the radius squared.⁵ This means that the valves would open much more easily if we made them thinner. However, we do not want to do this because they are very thin already and this will only increase faticue. It would also open more easily if we made the radius of curvature of the crest smaller. This could be done by making the cusps flatter, ie., the length of valve shorter for a given diameter. as described in the paragraph above.

The geometry of the tricuspid valves in the artificial state are much more conducive to holding back a large pressure than opening with a minimum amount of pressure on its afferent side. Almost every tricuspid valve will close and seal because of the tremendous back pressure on a concave surface. It would therefore be desirable to make the concave surface less pronounced by reducing the

5Timoshenko, S., "Theory of Elastic Stability," Engineering Societies Monograph, McGraw-Hill Book Company, Inc., New York, 1936.

radius. This would cause the valve to open with less pressure. If the radius is made too large, the valve will invert under back pressure and be worthless. It is therefore necessary to determine the optimum radius of curvature for opening with a pressure of **5** mm Hg on the afferent side of the valve and yet capable of holding a back pressure of 180 mm **Hg.**

Our experiments were all made with water **while the** valve actually functions in blood. How would the test results be altered if blood were used instead of water? The density of blood is very nearly that of water, while its viscosity is approximately four to five times that of water. For a given pressure drop (ie., 5 mm of Hg) there will be the same pressure force across the valve. However we will have a greater shear stress because of the increased viscosity. The forces which cause the valve to open, by buckling the crest, are the forces across the cusp which are the normal to it. The shear stress is generally much smaller than the pressure by a few orders of magnitude. Bedause the shear stress is tangent to the cusp and of much smaller magnitude than the pressure, its effect on opening the valve can be considered negligible. As is shown in Appendix A, it is reasonable to assume that the blood would not cause the valve to open with a pressure difference of 5 mm Hg.

ADDITIONAL AREAS OF RESEARCH

The main consideration of the thesis has been the mechanical properties of the valve. We have not dealt in any manner with the valve's effect on blood. For instance, we have not checked hemolysis caused by the valve or stagnation points inherent in the valve. It is interesting to note that Kolff in his article makes no reference to either of these points when he lists his criteria. A reason for this could be that since his tests were run completely with water, he did not observe or become aware of these as problems. On the other hand, perhaps he does not consider these criteria essential. There are medical people who claim that the consideration of hemolysis is of minor importance in the design of an artificial heart valve. However, I feel it is better desian philosophy to incorporate the consideration of hemolysis as a criterion in the initial stages of a valve program and remove it later if it is unimportant that it is to take the opposite approach.

The tricuspid valve has some real advantages as an artificial heart valve. It has the ability to hold very large back pressures with negligible leakage. It closes tightly with very little surface contact. It has fast reaction time, and if properly designed it effectively provides a large cross section area when opened.

Since the tricuspid has such advantages, it would be

desirable to redesign the present valve.

Much of the effect of the crest could be reduced by redesigning the cusps in the manner described above. The smaller the effective crest area becomes, the less the cusp acts like a sphere and the more easily it opens. It would be desirable to minimize the effect of the crest area and have the valve open like a large flexible sheet with no buckling occurring at all.

The design of the ncdulus has a great effect on the crest area. When the pointed, thick, and relatively long nodulus in the present valve was removed by cutting it from the cusp, the effective crest area was virtually eliminated and buckling disappeared. The valve opened in a very flexible manner. Therefore, in a new valve it is essential that the nodulus blends in with the rest of the valve. This would mean giving the nodulus a small radius, eliminate the crease that extends from the nodulus, and make it the same thickness as the rest of the cusp.

It is noted that the buckling occurs at the same location on the cusp each time the valve is open. This extreme bending concentrated at a point will reduce the fatique life of the valve greatly.

It would also be advantagecus to put small fillets at the junction of the valve cusp and wall to relieve the stress concentration at this point. The most

effective step that could be taken from here is to design a set of valves with different definite prescribed geometries. **A** series of tests should be run on these valves to determine the effect of each geometric parameter on the fatique, opening characteristics, etc.

In addition, there is the problem of developing a. technique for manufacturing the valves with the desired geometries. **If** the valves are continued to be cast, it mefans the development of a process to turn out male and female dies within a tolerance of **1/10CC** of an inch. This has been one of the big problems in manufacturing the present set of valves.

Nature uses the tricuspid effectively for its mitral and aortic valves. The one difference between the natural valve and the artificial valve is that the human tissue has the ability to renew itself as it is worked, whereas a synthetic does not have this ability. This is probably the largest problem standine in the way of an artificial heart valve. It is necessary to find a synthetic which can withstand the large number of pulsations a heart valve must encounter within the lifetime of a person.

Most of the criteria for the chemical stability and biological compatibility of a synthetic have been met in synthetics like Dow Chemical's Silastic (silicone rubber) Or teflon.

It is seen that the artificial heart valve for the

heart-lung machine can be a reality in the very near future since no stringent recuirements as to the life of the valve have to be met.

MOMENTUM EQUATION GIVES: $P_1A_1 - P_2A_2 - \rho Q(V_2-V_1) = A COSO - (P_1-P_2)S/NO A$ FOR GIVEN PRESSURE DRUP; P_i , P_k , A_i , $A \nearrow A$ are the SAME FOR BLOOD & WATER Q WILL SMALLER DUE TO VISCOSITY T IS NEGLIGIBLE FOR UNIT DEPTH: $A_2 = A_1 - A \leq IN\Theta$ $P_iA_i-P_z(A_i-ASIN\Theta)-\rho Q(V_z-V_i) = - (P_i-P_z)SIN\theta A$ FROM CONTINUITY: $V_1 A_1 = V_2 A_2$

$$
P_{i}A_{i} - P_{z}(A_{i} - A \sin\theta) - \rho Q V_{z}[1 - (A_{i} - A \sin\theta)] = -(P_{i} - P_{i})S_{IN}\theta A
$$

\n
$$
S_{IN}\theta(P_{j}A - P_{j}A^{*}P_{j}P_{j}QV_{z}A) = P_{z}A_{i} - P_{i}A_{i}
$$

$$
SIN \Theta = \frac{P_{2}A_{1}-P_{1}A_{1}}{P_{1}A+POQV_{2}A}
$$

SINCE Q # V2 ARE SCARLIER FOR BLOOD, O WILL BE SMALLER FOR BLOOD

APPENDIX B

PRESSURE-FLOW CHARACTERISTICS--VALVE A

PART **I:** INCREASING HEAD

 $\ddot{}$

APPENDIX **C**

PRESSURE-FLOW CHARACTERISTICS--VALVE B

PART I: INCREASING **HEAD**

 ~ 10