HYDRODYNAMIC PERFORMANCE
OF
MECHANICAL PROSTHETIC HEART VALVE

BY
TOSHINOSUKE AKUTSU
M.A.Sc. University of British Columbia
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TOSHINOSUKE AKUTSU

Department of Mechanical Engineering

The University of British Columbia,

Vancouver V6T 1W5, Canada

Date Nov. 27, 1985
ABSTRACT

Each year, more than 10,000 operations aimed at replacement of diseased heart valves by prosthetic devices are carried out in North America alone. Physiological compatibility, structural integrity and favorable hemodynamics represent three important criteria governing the design of a prosthetic heart valve. The thesis studies fundamental fluid characteristics of three widely used mechanical heart valve configurations, namely, the Starr-Edwards, Bjork-Shiley and St. Jude.

In the beginning, the pertinent available literature is reviewed which clearly points out limitations concerning the available information and their presentation.

This is followed by a detailed description of design, construction, calibration and instrumentation of a steady flow glycerol-water solution tunnel and a pulsatile flow cardiac simulator. The former test facility is ideally suited for testing heart valves under fully open condition during which the maximum flow and pressure (energy) losses occur. The latter simulates the transient condition over a typical cardiac cycle rather precisely. Highly sensitive Barocel pressure transducing system, magnetic flowmeters, laser-doppler anemometer, and a microprocessor controlled waveform generator together with sophisticated data acquisition and processing system makes the facility ideal and unique for the purpose.

Finally, the results of three distinct series of experiments with prosthetic valves using:

(i) the steady flow glycerol-water solution tunnel;
(ii) the steady flow in the cardiac pulse duplicator; and
(iii) the pulsatile flow cardiac simulator;

are presented and discussed.

The significant contribution of the project lies in the fundamental
data on pressure drop and its partial recovery; velocity profile, turbulence intensity, shear stress and their decay downstream; both in steady and pulsatile flow conditions. The results provide a comprehensive picture, fundamental insight and physical appreciation as to the hydrodynamic performance of prosthetic heart valves which would serve as reference for future development.

Emphasis throughout is on the use of proper nondimensional parameters to make the information independent of test facilities, flow velocities, size of the models, etc., which should represent a welcome step forward. It would make comparison of results obtained by different investigators using different test-facilities possible.

Based on the results following general conclusions can be made:

(a) Nondimensional pressure drop and discharge coefficient results suggest the Starr-Edwards configuration to be fluid dynamically superior.

(b) There is a significant and rapid recovery of pressure in the wake which depends on the Reynolds number and size of the downstream section. In the present study it was found to be as large as 24%! Hence, considering pressure drop immediately across a heart valve as a measure of its performance, as widely reported in literature, can be misleading.

(c) The Starr-Edwards prosthesis has a relatively lower value for the maximum velocity and turbulence intensity and their rapid decay in the wake compared to the Bjork-Shiley and St. Jude valves.

(d) Adjustment of parameters characterizing the cardiac network affect details of the cardiac cycle.

(e) At the onset of systole all the valves show negative flow until the valve-closure is complete. The Starr-Edwards valve has the largest negative flow rate as well as the longest duration until
its closure while the St. Jude valve shows the smallest amount of reversed flow over the shortest time. Negative flow is a significant parameter since the loss in volume must be compensated either by increasing the heart rate or the stroke volume.

(f) All the valves show a decrease in $C_p$ with an increase in the Reynolds number. Thus the valve performance improves at higher Reynolds numbers. The degree of improvement depends on the valve configuration and is relatively smaller for the ball and cage geometry.

(g) During the pulsatile flow study, the maximum velocity recorded for the Starr-Edwards valve, at a given downstream location, is essentially the same as that observed during steady flow case. On the other hand, the turbulence intensity is distinctly lower. Similar trends were observed for the other two configurations. In general, the peak velocity and turbulence intensity for the St. Jude valve are smaller than those for the Bjork-Shiley case.

(h) For the Starr-Edwards prosthesis, the sticking character of the ball may substantially alter the pressure-flow rate relation.

The thesis ends with several recommendations for future work which are likely to be rewarding.
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LIST OF SYMBOLS

Cd  discharge coefficient, \( Q / \frac{\pi d^2}{4} E \left[ \frac{2(P_u - P_d)}{\rho} \right]^{1/2} \), \( E = \left[ 1 - \left( \frac{d}{D} \right)^4 \right]^{1/2} \)

Cp  pressure coefficient, \( \Delta P / (1/2 \rho V_0^2) \)

D  upstream inside tube diameter

D_d  downstream test-section diameter

D_{0.5}  ventricle diameter at L/D = 0.5

d  annulus diameter

L  distance downstream as measured from valve location

P  static pressure

\( \bar{P} \)  mean flow rate during the forward flow phase

P_d  pressure immediately downstream of valve location

P_s  pressure in settling chamber

P_u  pressure immediately upstream of valve location

Q  flow rate

\( \bar{Q} \)  mean flow rate during the forward flow phase

Q_p  peak flow rate

Q_{rms}  rms flow rate during the forward flow phase

R_f  pressure recovery

R_n  Reynolds number,

T  time measured from the onset of mitral flow

U  local velocity

\( \bar{U} \)  average velocity based on upstream tube diameter

U^-  nondimensional velocity, \( U / \bar{U} \)

U_{V0}  nondimensional velocity, \( U / V_0 \)

u'  fluctuation about the local velocity U

V_0  average velocity based on annulus area

X  transverse location as measured from tube wall

X_d  probe displacement of the displacement transducer
\( \nu \)  kinematic viscosity
\( \rho \)  density
\( \sigma_{\overline{u}} \)  turbulence intensity based on \( \overline{U} \), \( \sqrt{\overline{u}^2/\overline{U}} \)
\( \sigma_{\nu} \)  turbulence intensity based on \( \nu_0 \), \( \sqrt{\overline{v}^2/\nu_0} \)
\( \tau \)  viscous shear stress, \( \mu (dU/dX) \)
\( \mu \)  dynamic viscosity
1. INTRODUCTION

1.1 Preliminary Remarks

One of the most exciting developments in cardiology and cardiovascular surgery during the past two decades has been an increasing interaction between medical and engineering professions. As a result, a large number of heart valve prostheses, pacemakers, fabric patches or vascular grafts, catheters, etc., have been developed which have exhibited a varying degree of success. The present investigation, which reflects such an interaction, belongs to the general field of bioengineering with an emphasis on prosthetic heart valves.

Importance of the subject becomes apparent when one recognizes that more than half the deaths in Canada last year, around 80,000, were attributed to cardiovascular diseases. More than 2.5 million Canadians, about 10% of the total population, suffer from some forms of cardiovascular diseases. Around 100,000 operations per year for heart valve replacements are conducted in North America alone.

The heart beats around 60-70 times a minute, which amounts to around $40 \times 10^6$ times a year or about 2.5 billion times in an average lifespan of 70 years. No man made material can maintain structural integrity over such a prolonged cyclic loading. A remarkable feat by any engineering standard.

The main objective of this study is to acquire a better appreciation as to the fluid dynamical characteristics of mechanical prosthetic heart valves using steady and pulsatile flow simulation facilities. However, before proceeding with the subject matter proper it would be useful to review historical evolution of prosthetic heart valves, methodology employed in studying their hemodynamical performance and the current state of our knowledge to appreciate the scope of the present investigation.
1.2 Heart and Heart Valves

The heart, an intricately woven muscular organ, almost the size of our fist, is the central unit in our cardiovascular system (Figure 1-1). It is a double acting pump. Its main function is to:

(i) receive pure, oxygenated blood from the lungs and pump it to the different parts of the body (systemic circulation);

(ii) receive impure blood and pump it to the lungs for purification (pulmonary circulation).

Sir William Harvey discovered the circulatory system in 1628.

This tiny pumping system delivers about 75 ml every beat or 5 liters per minute. This amounts to 70 barrels in a day and around 2 million barrels in a lifetime. The average power produced by a heart is only 1.3 watts. This may appear small, however, over a lifetime the heart does enough work to raise approximately 30 tons of load to the height of the Mount Everest (8846 m).

In simple terms, the heart can be looked upon as having two sides, the left and the right with each side further partitioned into two chambers, the top and the bottom, referred to as atrium and ventricle, respectively. Separating these chambers are valves which regulate the flow of blood. Between the left atrium and the left ventricle there is a valve with two flaps or leaflets called the mitral valve (Figure 1-2). The aortic valve with three leaflets or cusps is located at the junction of the left ventricle and the aorta. Similarly on the right side we have tricuspid and pulmonary valves.

The smooth function of the heart is, at times, impeded due to diseased condition of the valves. There are a number of leaflet abnormalities which cause the valves to malfunction. However, the most common ones pertain to
Figure 1-1 A schematic diagram of the blood circulation system
Figure 1-2 Natural mitral valve
pathologies due to rheumatic fever, bacterial endocarditis, and congenital anomalies. The leaflets may stick together as a result of lesions at their base or along their commissures, or they may become calcified and rigid. Consequently, if the leaflets fail to close properly, massive regurgitation of blood may occur, for example, into the ventricle during diastole for aortic valve. To compensate for this lost volume the heart must work harder. This is referred to as valve incompetency. If, on the other hand, the leaflets fail to open fully, i.e., stenotic condition would lead to a higher resistance across the valve and hence a larger energy loss. Although this higher demand of energy may be tolerated to an extent, it often proves excessive leading to further complication necessitating replacement of the diseased valve by a prosthetic device.

1.3 A Brief History of Heart Valve Replacement

The history of valvular replacements is one of constant evolution. Between 1944 and 1952 the first extensive experimental studies concerning permanent replacement of diseased valves were taken [1-3]. The repair of damaged valves in situ had, of course, been carried out for many years, but in some cases the complete valve replacement was the only way to restore its proper function. The first successful heart valve replacement by Hufnagel [4] in 1951 established a possibility in the therapy of valvular failures. This first clinical correction of aortic insufficiency was performed, employing a ball type valve prosthesis. The plastic valve, evolved following the success of the permanent intubation of the aorta, is essentially a modification of the tube. Primarily it consisted of an inlet, a chamber containing a ball, and an outlet. The entire valve, made of polyethylene, was molded into a single piece to provide an extremely smooth and seamless inner surface. The hollow ball with no outside seam was made of methacrylate
with the specific gravity slightly less than one. At each end of the valve, there was a groove on the outer surface to hold the aorta by means of a fixation ring of solid semiflexible nylon. The outside surface of the fixation ring was grooved so as to maintain in position the heavy braided silk ligature. The arrangement is schematically shown in Figure 1-3.

Although it was inserted far from the original aortic position because of technical difficulties involved in reaching the aortic root, the valve function was observed to be satisfactory and the improvement in the patient condition dramatic. On the other hand, the first surgical attempts at open-heart correction were made in late fifties by simply debriding the calcific and stenosed aortic valves [5,6]. The operation was safe, but the encouraging results proved to be short-lived, with reoperation often necessary within 3 to 5 years. As the frequency of aortic incompetence and nondebrideable valve increased, the efforts were directed towards the replacement of the diseased portion of the valve if possible [7-10], or else insertion of an entire substitute valve. The successful demonstration by Hufnagel that such a prosthesis could function satisfactorily for prolonged periods of time stimulated efforts at development of prostheses which could be placed in the normal valvular position and be useful in
correction of both aortic stenosis and insufficiency. Appropriately enough, the prosthetic valves were modeled after the natural valves and were made of the best material available at the time: tough and relatively friction-free polyester films such as Teflon, Nylon, Decron, etc. Although the plastic films were not thrombogenic, other serious limitation became evident, notably the fatigue characteristics.

In general, the performance was found to be far from desirable until 1960, when Harken [12] and Starr [13], utilizing the cage-ball principle, simulated function rather than form for both the aortic and mitral valves. Subsequent rapid advance in prosthetic valve design has been phenomenal with dramatic decrease in complications and improvement in hemodynamics. Kalmanson [14], Harken [12], Ionescu [15] and several other investigators have presented excellent up-to-date reviews on the state of the art in this important area of bioengineering. Yet certain disadvantages of these types of prostheses are difficult to overcome. In general, just about every cardiac surgeon has his own ideas about configuration and performance of prosthetic heart valves. Consequently, various types of heart valve prostheses are available commercially which differ markedly in design. The variation in configuration includes such as ball-cage, disc-cage and tilting disc type of mechanical devices together with homograft, heterograft, and valves made from biological tissues. Figures 1-4 and 1-5 show the early and recent examples of several valve configurations. Chronological development of more important valve designs for clinical use is summarized below (Table 1-1).

Broadly speaking all available designs can be divided into two categories: occluder type and leaflet valves. Indeed all the valves have one thing in common: they are far from ideal. Yet numerous open-heart operations are performed annually to correct for valvular diseases.
Several earlier models of mechanical and tissue valves: (a) silastic trileaflet aortic valve; (b) Bahnson trileaflet valve; (c) Starr-Edwards ball valve; (d) disc valve; (e) Hufnagel butterfly hinged leaflet valve
Figure 1-5 Representations of several recent prosthetic heart valves: (a) Bjork-Shiley Tilting disc valve; (b) Omniscience floating disc valve; (c) Saint Jude valve; (d) Hall-Kaster valve
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<tr>
<td>1965</td>
<td>Bine-Carpentier</td>
<td>Central disc occluding prosthesis</td>
</tr>
<tr>
<td>1966</td>
<td>Lillehei</td>
<td>First valve replacement using specially prepared aortic valve xenograft</td>
</tr>
<tr>
<td>1967</td>
<td>Wada-Cutter</td>
<td>Cageless free floating pivoting disc valve</td>
</tr>
<tr>
<td>1968</td>
<td>Pierce et al.</td>
<td>Teflon tilting monocusp valve</td>
</tr>
<tr>
<td></td>
<td>Bjork-Shiley</td>
<td>Disc prosthesis</td>
</tr>
<tr>
<td></td>
<td>Kalke-Lillehei</td>
<td>Hingeless, rigid double leaflet prosthesis (precursor to St. Jude valve)</td>
</tr>
<tr>
<td>1968</td>
<td>Hancock</td>
<td>Earliest tilting disk valve</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Glutaraldehyde preserved grafts</td>
</tr>
<tr>
<td>Year</td>
<td>Name</td>
<td>Description</td>
</tr>
<tr>
<td>------</td>
<td>---------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>1970</td>
<td>Lillehei-Kaster</td>
<td>pivoting (pyrolite) disc valve</td>
</tr>
<tr>
<td></td>
<td>Euryclides, Zerbini</td>
<td>Dura mater homografts</td>
</tr>
<tr>
<td>1972</td>
<td>Starr-Edwards</td>
<td>track valve</td>
</tr>
<tr>
<td>1975</td>
<td>Carpentier-Edwards</td>
<td>tissue valve</td>
</tr>
<tr>
<td>1976</td>
<td>Ionescu-Shiley</td>
<td>pericardial bioprosthesis</td>
</tr>
<tr>
<td></td>
<td>Edwards</td>
<td>pericardial valve</td>
</tr>
<tr>
<td>1977</td>
<td>Hall-Kaster</td>
<td>rod guide pivotal disc prosthesis</td>
</tr>
<tr>
<td></td>
<td>St. Jude Medical</td>
<td>rigid, double leaflet all pyrolytic carbon</td>
</tr>
<tr>
<td></td>
<td></td>
<td>prosthesis</td>
</tr>
<tr>
<td>1982</td>
<td>Mitroflow</td>
<td>pericardial valve</td>
</tr>
</tbody>
</table>
As can be expected, each manufacturer of prosthetic heart valves claims superior performance for his own design, based on data obtained using his own test facility. Unfortunately, as test facilities, instrumentation and experimental procedures differ rather markedly, it is difficult to verify individual claims and establish their relative merits. Hence, for a surgeon it is difficult to make decisions concerning the selection of a valve suitable for a specific situation based on reliable and comprehensive information. Performance of a valve is governed by the biological compatibility, durability, and hydrodynamical efficiency. While the biological compatibility as well as the durability of the valve can be proved only through long term in vivo tests, the hydrodynamical efficiency of the valves can be evaluated by in vitro experiments. Moreover, in the U.S., Medical Device Amendments of 1976 to the original act (P.L. 94-295) have placed extra emphasis on in vitro experiments to evaluate the valve performance before its clinical application. Thus development of artificial heart valves depends upon reliable knowledge of the hemodynamic performance and physiology of the cardiovascular system in addition to a fair understanding of the associated fluid mechanics. Unfortunately, it is evident from the literature that critical fluid dynamic information bearing on valve performance is indeed quite scarce. Even today, the average useful life of the most widely employed heart valve prostheses is quite limited. The fluid mechanical aspects of the problem suggest a possibility of an engineering contribution to this medical problem. In an evolutionary process of design, performance evaluation and modification are essential interactive stages. In vitro testing plays an important role in this approach to the design of a prosthetic valve [16-19].
1.4 A Summary of In Vivo Results for Prosthetic Valves

In vivo performance results for a large number of prosthetic heart valves have been reported rather extensively. However, most information pertains to actuarial survival rate, failure statistics, probable cause of failure, etc., and seldom provide results on fluid dynamical parameters such as energy loss, velocity profiles, pressure drop and its partial recovery, turbulence intensity and shear stress. Mostly our knowledge in this area is based on observation of effects, rather than fundamental understanding of the cause, because of challenging problems involved in obtaining reliable in vivo information. Results of an extensive clinical test program involving 350 patients with the Ionescu-Shiley pericardial xenograft valves are reported by Tanden and Ionescu [20]. Actuarial representations of survival rates and complications are given for both mitral and aortic valves. Similar information for other more widely used tissue and mechanical valves is given by Ionescu [15], Kalmanson [14] and many others [21-33]. Corresponding data for valve replacement in children age 1-19 years are also reported [34-38]. In most cases complications included thromboembolism, hemolysis, hemodynamic problems (obstruction, regurgitation) and material failure. Of these complications, there are suggestions that thromboembolism is by far the most common, the most serious and most difficult to prevent [23].

Considerable amount of information pertains to specific valve geometry. Edminston et al. [24] have discussed clinical experience with the Kay-Shiley mitral valve prosthesis. An eleven year follow-up study involving 63 patients found late death occurrence in 33% with the 10-year actuarial survival of 65%. Around 49% of the patients had at least one thromboembolic event. Such information should prove useful in assessing comparative performance of different valve geometries. Similar information is also
reported for Bjork-Shiley, St. Jude, porcine xenograft and other valves [15,14].

1.5 A Brief Review of the In Vitro Experimental Studies

In the last two decades, a flurry of experimental investigations have resulted in a sizable body of information concerning the flow characteristics associated with the heart valve in general, and prosthetic heart valves in particular. Scope of the investigations has covered a wide spectrum of problems associated with the use of prosthetic heart valves such as stenosis, hemolysis, incompetence, regurgitation, clotting and others. Researchers have employed a variety of approaches to gain insight into the problem particularly with reference to parameters governing the valve performance and its failure. These may be classified as follows:

(a) flow visualization;
(b) comparative study of valve performance essentially based on pressure drop;
(c) shear stress;
(d) velocity measurement using hot wire or laser doppler anemometer (LDA);
(e) fatigue test;
(f) fundamental fluid dynamic aspects governing the cardiac history.

Often, an investigation may cover several of the above mentioned areas.

The first successful attempts at visual observation of heart valve movements were those by Smith, and Kantrowitz and their associates [39,40], but it was McMillan [41,42] who developed post mortem cinematography as a practical technique for studying the valve action. Leyse and his colleagues [43] have investigated the flow pattern associated with heart valves using flat two dimensional models in birefringent solution of bentonite clay in
aqueous-glycerol. Meisner and Rushmer [44] extended the method of Leyse et al. to two dimensional rigid models of diseased heart valves using both pulsatile and steady flow. Although the information obtained through these experiments was rather limited, the flow visualization results did help establish qualitative character of the flow. Davila et al. [45-47] employed the bentonite clay visualization technique to observe turbulence generated by artificial heart valves, and to evaluate its role in the production of thrombosis.

Temple et al. [48] applied the principle of dynamic similarity to design a pulse duplicator and conducted a significant in vitro study of the flow properties of healthy and diseased human heart valves. India ink was injected automatically during each diastole through a hypodermic needle placed in one of the coronary arteries at the base of the aorta. This bolus of ink was then observed in both pulsatile and steady flow as it proceeded downstream through a glass tube aorta. Existence of turbulence was identified for the stenotic valve.

Wieting et al. [49,50] utilized slit lighting technique with aluminum particles to study the hydrodynamic characteristics of five early types of mechanical aortic prostheses and a homograft. Movement of the particles recorded by still and cinephotography was then analyzed to provide visual flow pattern across the valves and velocity profiles at selected locations. He reported that presence of prosthetic heart valves introduced significant disturbance in the flow field.

Davey [51,52], Smeloff and their colleagues [53] employed a flow visualization technique similar to that reported by Wieting. A high speed camera was used to photograph the fluid motion and valve action. By careful study of the movies, Davey was able to draw the flow patterns which apparently existed across the aortic valves. Existence of bouncing motion
of ball and initiation of separation was identified. Smeloff et al. [53] extended the study to the five different prosthetic heart valves.

Saklad and his associates [54] have described a flow visualization technique which utilizes slit lighting in conjunction with electrolytically generating hydrogen bubbles within the aqueous-glycerol solution.

A unique technique based on tracer particles of Mearlmaid pearl essence AQ. is of some interest [55]. Fluid shear tends to align the elongated wafers of tracer particles in the direction of the shear force resulting in patterns of varying light density.

Bjork [56] and Olin [57] have used a technique similar to that reported by Wietng [50]. Using a suspension of gold particles they attempted to evaluate performance of the then newly developed Bjork-Shiley tilting disc valve with reference to four commonly used aortic valve prostheses: Starr-Edwards, Kay-Shiley, Wada-Cutter, and Smeloff-Cutter. It was reported that the major portion of the flow field remained laminar during passage through the Bjork-Shiley valve.

Injection of multicolor dye-stream as well as suspension of polystyrene beads in conjunction with slit lighting were used by Wright and Temple [58] in their study of prosthetic mitral heart valves. It was observed that in the mitral region each tilting disc valve produced a large vortex which dominated the ventricular cavity. In contrast, disc and ball valves produced an annular vortex, and the bioprosthesis generated a central flow. In the aortic region the flow patterns produced by a tilting disc valve depended on the orientation of the valve. The aortic ball valve was found to produce less disturbance than either tilting disc valve or the porcine bioprosthesis.

An alternate approach to the problem, and probably a more realistic one, would be to explore hydrodynamic character of a prosthetic device using flow visualization as well as measurement of pressure drop across the valve. Depending on the required information one can utilize either a steady state
tunnel (for fully open condition of valve) or a pulsatile simulator, if the entire cardiac cycle is of interest (opening and closing delay, transient response, etc). There are other considerations as well in selecting an appropriate experimental facility. In general, due to relative simplicity of a steady flow tunnel one is likely to obtain more reliable data. On the other hand, pulsatile facilities usually require a complex drive system such as a positive displacement pump [59], a cam drive mechanism [60], a rotary valve [61], a reciprocating piston pump between constant head tanks [62], etc. Resistance and compliance circuits used by different investigators also vary considerably. Moreover, there is a general lack of standardization in presentation of data. Hence relative performance can be assessed with a measure of confidence only for those valves which are tested using the same facility. Most of the earlier studies using this procedure are confined to the pressure measurement across the valve for different flow rates and/or different orifice designs [63,64]. Smeloff and associates [53] compared flow characteristics for five different prostheses (Roe molded leaflet valve, Gott leaflet valve, Kay-Suzuki discoid valve, Starr-Edwards ball valve, and Smeloff-Cutter ball valve) and concluded the Smeloff-Cutter ball valve to have several favorable features which are helpful in reducing the incidence of thromboembolism. On the other hand, using the results of their investigation with six valves (Gott leaflet, Teardrop discoid, Pin teardrop, Starr-Edwards, Trileaflet, Heavy Teflon, and Hammersmith) Kelvin et al. [65] found (based on orifice size, time of actuation and regurgitation) Starr-Edwards ball valve and Gott hinged leaflet valve to be most suitable for the aortic and mitral position, respectively.

Kaster et al. [66,67] conducted comparative tests on eleven prostheses (Menisus disc; Smeloff-Cutter ball valve #2,3,4,5; Starr-Edwards ball; pivoting disc; Kay-Shiley disc #4,5; Toroidal Disc; Gott-Dagget leaflet). In general ball, pivoting disc, and butterfly leaflet valves showed good
flow volumes with minimal pressure gradients. The leaflet valve was found to require less mechanical energy for activation than the disc or ball valve and allowed minimal regurgitation during diastole. Finally, it was concluded that the Smeloff-Cutter full flow orifice ball valves have good flow characteristics together with a modest pressure gradient. Wieting and his associates [68] investigated flow characteristics of five different aortic valves (Starr-Edwards 12A, Kay-Shiley disc #5, Benson Roe flexible cusp 27 mm, Gott hinged leaflet 29 mm, and Barnard Poppet LICT A06). All of them were found to have similar aortic, left ventricular, and mean left arterial pressure contours, but none could match that of the human aortic valve. Furthermore, it was observed that the flexible cusp, hinged leaflet and caged disc valves have less regurgitation compared to the ball valve. This, to some extent, contradicts the conclusion of Kelvin et al. [65] mentioned earlier.

Duff [55] studied six early models of aortic valve prostheses using a pulsatile flow facility and obtained information concerning pressure and reflux flow loses, valve closing time, and local disturbances in the flow past the valves using flow visualization. Unfortunately, no attempt was made to formulate a performance index to rank the valves. Bjork [56] and Olin [57] did hydrodynamic evaluation of five mitral and five aortic valves with reference to the Bjork-Shiley tilting disk valve: aortic heterograft (pig) with 30 mm external diameter, Starr-Edwards (M2), Smeloff-Cutter (M5), Kay-Shiley (5) and Bjork-Shiley for aortic and Starr-Edwards (9A), Kay-Shiley (3), Smeloff-Cutter (4A), Wada-Cutter (23) and Bjork-Shiley for mitral location. Based on the mean pressure difference and visual observation Bjork-Shiley tilting disk valve was found to have excellent flow characteristics in mitral location. It was noticed that a subaortic obstruction was avoided with this low profile tilting disk valve prosthesis. Also in the aortic location, the Bjork-Shiley valve, for a given tissue
diameter, had the lowest pressure difference (2.5 mmHg) at the flow rate of 220 ml/sec.

Mohnhaupt et al. [69], using a pulsatile flow test facility, presented a comparative performance analysis of eight aortic prostheses based on systolic and diastolic transvalvular energy loss. The group consisted of both leaflet (Affeld Silastic, Reul Polyurethane, Nakiri Dura Mater, and Edwards pig aortic) and occluder type (Bjork-Shiley, Lillehei-Kaster, Wada-Cutter, and Starr-Edwards) of prostheses. On the basis of the sum of systolic and diastolic loss of energy, Lillehei-Kaster valve performed the best among the occluder type and the Silastic leaflet among the leaflet type.

Several important parameters such as mean diastolic pressure, incompetence, mechanical movements, and flow disturbances were studied by Wright [70]. He found:

(a) many of the prostheses to produce mild to moderate stenosis;
(b) only valves with large orifice diameter (22 mm or larger) to be free of significant stenosis;
(c) disc valves to have velocity gradient near the ventricle wall;
(d) the Starr-Edwards 6120/3M to cause more high frequency turbulence than the other valves.

Gabbay and his associates [71] compared the hydrodynamic characteristics of seven different types of mitral valve prostheses at high pulsatile and steady volume flow rates. Valves tested in this study were Hancock, Ionescu-Shiley, Beall, Bjork-Shiley, Starr-Edwards, Lillehei-Kaster, and Cutter-Cooley. The Gorlin formula was found to be inappropriate for computing the valve area. Furthermore, it was observed that the root mean square and peak flows combined with the appropriate transvalvular pressure difference yield accurate characterization of valvular hydrodynamic performance. On the other hand, the mean flow predicted an effective
orifice area 10% smaller than that given by the root mean square and peak flows. Based on these parameters Bjork-Shiley valve was judged to have the best hemodynamic performance among the valves tested in the series.

Wright [72] has reported the hydrodynamic characteristics of approximately forty tissue valves of five different types operating in pulsatile and steady flow. He found the results of the steady flow tests unsuitable for predicting in vivo pressure drop. The valves were assigned an order of merit based on calculated orifice area. The lowest gradients were generally associated with the valves fabricated from non-valvular tissues. In each size the Ionescu-Shiley pericardial xenograft produced lower gradient and gave a larger calculated area. Yoganathan and Corcoran [18] measured transvalvular pressure loss across ten prosthetic aortic valves in pulsatile and steady flows (two Bjork-Shiley, two Smeloff-Cutter, two Cooley-Cutter, and four Starr-Edwards valves). The results showed that over the range of flow rates of interest, the test fluid viscosity had negligible effect on the transvalvular pressure loss. Their analysis predicted, and subsequent tests confirmed, that it is possible to determine mean systolic transvalvular pressure loss during pulsatile flow using steady flow measurements.

Walker et al. [73] compared the performance of five prosthetic mitral valves (Ionescu-Shiley, Hancock, Carpentier-Edwards, Starr-Edwards, and Bjork-Shiley) all having the same nominal size (29 mm) in a hydromechanical simulation of left heart at three pulse rates. The mean and maximum transvalvular pressure difference, the observed and/or calculated area, and the energy loss for each valve were compared. It was found that each measure of performance rates the value in the same order of merit with the Ionescu-Shiley valve giving the best and Hancock the worst performance. They emphasized the total transvalvular energy loss per cycle as a useful measure of overall valve performance.
Gabbay and his associates [74] compared in vitro hemodynamic performance of three new tilting disc prostheses (St. Jude, Hall-Kaster and Bjork-Shiley concave-convex) with the previous model of the Bjork-Shiley valve. The results showed this new generation of valves to offer less resistance to flow compared to the previous designs. The St. Jude valve proved to be an improvement in valve design with low levels of stenosis and regurgitant fraction. Scotten et al. [75] have studied hydrodynamic performance of four new prosthetic mitral valves (Omniscience, Hall-Kaster, Bjork-Shiley c-c and St. Jude Medical) all having a tissue annulus diameter (TAD) of 29 mm. The hydrodynamic performance of the valves in different orientations was observed to be nearly equal. The overall performance as measured by the total transmitral energy loss suggested posterior orientation of the Omniscience valve to be favorable. Kohler and his colleagues [76] also evaluated performance of the newer valve designs (Bjork-Shiley c-c, Omniscience, and St. Jude Medical). All of them led to a substantial reduction in pressure loss with reference to the plane disc Bjork-Shiley valve.

These comparative studies have been useful in assessing valve performance according to the figure of merit, especially its stenotic condition. However, there are often equally important parameters such as thromboembolism and hemolysis. Unfortunately, information on the velocity and shear stress profiles in the near vicinity of a heart valve prosthesis is indeed sparse. Wieting [50] attempted to measure velocity profiles under pulsatile flow condition using a photographic technique but had limited success. Swope and Falsetti [77] measured velocity under steady-flow conditions for a few representative conditions. Stein and Sabbah [78] mapped the velocity field in the ascending aorta with a hot-wire anemometer probe. The results indicate that turbulent flow can occur in the ascending aorta
even for subjects with normal cardiac function; and it is invariably present there in case of individuals with abnormal aortic valves.

Figliola and Mueller [79] conducted experiments using a steady flow apparatus with axisymmetric aortic shaped test chamber. They used hot-wire anemometry to obtain local momentum transfer and turbulence data in the vicinity of a disk model, Kay-Shiley disk, Starr-Edwards ball and Bjork-Shiley tilting disk valve. Wall shear stress was measured by Tillman [80] using hot-films at the valve ring location. He found that the available test results were for the subcritical range and they were two orders of magnitude lower than the critical value. The role of subcritically sheared red blood cells and platelets and their possible interactions in the thrombus formation process is not clear yet. Yoganathan and his associates [81,82] utilized a Laser-Doppler Anemometer (LDA) for in vitro measurements of velocity profiles in the vicinity of aortic prostheses at steady flow rates of 167 cm$^3$/sec to 417 cm$^3$/sec. Results showed that at these high flow rates the wall shear stresses were in the range around 1000 dynes/cm$^2$. It was concluded that this level of shear stress can damage the endothelial lining of the ascending aorta, red-blood cells and platelets, and lead to thrombus formation. The lining is particularly susceptible to damage when the blood elements adhere to the wall of the aorta. Figliola and Mueller [19] have also extended their study using LDA and hot-film anemometry to measure momentum transfer and turbulence around and distal to the valve occluders. Tests were performed on a Kay-Shiley disk, a Bjork-Shiley tilting disk and Starr-Edwards Models 1260 and 2320 ball prostheses at Reynolds numbers between 2000 and 6200. The results showed that the region directly surrounding the valve occluders was subjected to relatively higher stresses. Aortic wall shear measurements revealed magnitudes potentially damaging to the vessel lining. Slowly moving regions of separated flow correlated with clinical findings of thrombus formation. Fukushima and his associates
[83] investigated turbulence associated with the flow past Bjork-Shiley, Kay-Suzuki and SAM-MT valves. Turbulent flow downstream of the valves was held primarily responsible for the energy loss. Velocity measurement using LDA revealed existence of peak flow far downstream of the Bjork-Shiley valve however its correlation with turbulence intensity could not be established due to difficulties. Yoganathan and his associates [84] compared, using LDA, flow characteristics of the new convexo-concave model of Bjork-Shiley tilting disk valve against the conventional configuration. In vitro velocity measurements in the immediate downstream vicinity of the convexo-concave Bjork-Shiley aortic valve showed the design changes to have decreased the size of the stagnation zone together with an increase in flow and shear in the minor outflow region. It was concluded that the new configuration may reduce the problems of thrombus formation and tissue overgrowth.

The literature shows that numerous attempts to explain the fluid mechanics of cardiac valve function have a thread of similarity. The attention has been primarily on the closure mechanism of the valves. This interest in the associated fluid mechanics has grown with evolution of the valve designs. Obviously, understanding of the complex fluid mechanics of the natural valves would accelerate development of an efficient prosthetic valve. However, by and large, it has remained elusive.

It has been widely held for a long time that to avoid or at least minimize regurgitation, the cardiac valves should partially close prior to the onset of adverse pressure gradients, i.e., in the case of the mitral valve, before ventricular contraction. However this view is by no means accepted universally. Bellhouse et al. [85-87] through their studies of model aortic and mitral valves have discussed the role of vortices during closing phase of the valve. Their study had shown that without a strong vortex the valve would stay open at the time the ventricle starts contracting leading to a significant amount of regurgitation. On the other hand Talukder
et al. [88], and later Reul et al. [89], have shown that the valve closed during deceleration of the flow under an adverse pressure gradient which also provides forces moving the valve towards closure. They suggested that the ventricular vortices appear to play no significant role in the actual valve closure, though they might be contributing to the mid-diastolic partial valve closure for the mitral valve. It was further shown that no regurgitation is necessary for such a valve closure.

1.6 Purpose and Scope of the Investigation

Development of prosthetic heart valves depends upon the synthesis of several diverse disciplines. Besides reliable knowledge of the human physiology, cardiovascular system and hemodynamics it depends on material science, structural mechanics and fluid dynamics. It is evident from the literature survey that in spite of vast body of test data (in vitro as well as in vivo) critical information bearing on fluid dynamical criteria for evaluating valve performance is indeed quite scarce. Efforts to date, though significant, have been mostly too specific and hence lacked broader perspective. Often the models and test procedures have failed to simulate real life situations. Moreover, presentation of data in dimensional form has masked important trends and made comparison of results by different investigators using different test facilities virtually impossible. In a sense, the whole field is in the infant state and needs to be put on a sound engineering foundation for well-directed evolution. The investigation reported here represents only a small step in that direction.

It should be emphasized that the project has taken innovative steps at just about every stage—from design of steady and pulsatile flow facility to instrumentation, test procedures and data reduction methodology. Although some of the concepts are well known in engineering, their application to
this class of bioengineering problems is novel. Mostly the information is of pioneering character and often there is no base information even to compare trends. Emphasis throughout is on reliable and reproducible data which can serve as a standard for future reference. The main objectives of the project may be summarized as follows:

(a) Design, construction, calibration, instrumentation of a reliable test facility to study this class of problems;

(b) Identification and measurement of fundamental fluid dynamical parameters governing performance of mechanical prosthetic heart valves. This base information would be helpful in:

(i) evolution of fluid dynamically superior valve configurations;

(ii) in establishment of performance criteria for the Federal Department of Health and Welfare to regulate marketing of commercial prosthetic heart valves.

In the beginning, design, construction and calibration of a steady flow glycerol-water solution tunnel and a pulse duplicator system are described. The facilities form the heart of the whole investigation. This is followed by a description of the LDA system, traverse mechanism, pressure and displacement transducers, and the test procedures adopted. Data acquisition and reduction methodologies are briefly touched upon before analysis and discussion of results. The thesis ends with concluding remarks and recommendations for future work. The plan of study is shown schematically in Figure 1-6.
HYDRODYNAMIC PERFORMANCE
OF
MECHANICAL PROSTHETIC HEART VALVES

Design, Construction and Calibration of Test Facility

Steady Flow Glycerol-Water Solution Tunnel
  Instrumentation
  - Laser Doppler Anemometer
  - Traverse Mechanism
  - Pressure Transducer
  - Displacement Transducer
  - Electro Magnetic Flow Meter
  - Orifice Flow Meter

Pulsatile Flow Cardiac Simulator

Steady State Tests using Glycerol-Water Solution Tunnel
  Pressure Measurements
  - Pressure distribution upstream and downstream of prosthetic heart valves
    - Reynolds number
    - Size
    - Downstream geometry

Steady State Tests using Pulsatile Flow Cardiac Simulator
  Velocity Measurements
  - Velocity Profiles downstream of prosthetic heart valves
    - Reynolds number
    - Size
    - Downstream geometry
    - Frequency spectrum analysis
    - Velocity and turbulence decay

Pulsatile Flow Tests
  Pressure and Velocity Measurements
    - Beat rate (Reynolds number)
    - Downstream location
    - System parameters (peripheral and characteristic and compliance)
    - Input waveform

Seven mechanical prosthetic valves and 3 sharp edged orifices

Three mechanical heart valves

Figure 1-6 Scope and purpose of the investigation
2. MODELS AND TEST FACILITY

This chapter attempts to introduce the test facility used in the experimental program. Some of the instrumentation constitute the standard equipment in any well equipped fluid mechanics laboratory and hence needs no elaboration. On the other hand, design and constructional details involved in the development of a specific equipment are often numerous and hence, though important and relevant, cannot be covered in their entirety. One is, therefore, forced to confine attention to more salient features. To start with, test models are described briefly. Undoubtedly, two of the most demanding equipments in terms of time and effort were the design and modifications of a glycerol tunnel and a pulsatile flow simulation facility, which are described next. This is followed by a description of the LDA system, traverse mechanism, pressure measuring system, flow and displacement transducers, etc. Wherever appropriate, calibration procedures are explained and corresponding charts included.

2.1 Test Models

Although numerous different configurations of prosthetic heart valves have been introduced during the past two decades and tried clinically, only few of them have survived years of rigorous testing to reach the production stage. Starr-Edwards ball prosthesis is one of them. It has been used quite successfully from the onset of the clinical application of prosthetic heart valves. The standard Bjork-Shiley tilting disk prosthesis is one of the most widely used valve configuration today. Widely differing in geometry, these two types of valves form a basis of comparison. Two other configurations are the Bjork-Shiley c-c (convexo-concave) disc valve and the St.Jude Medical valve. The models tested thus represent about 95% of
all the mechanical heart valve replacements used in the Western World, and newer trends in designing of prosthetic heart valves. Sharp edged orifices are also included to provide some appreciation as to the change in fluid dynamical characteristics introduced by the valve geometry. Details of valves and orifices tested are presented in Table 2-1 and Figure 2-1.

2.2 Test Facilities

2.2.1 Steady flow glycerol-water solution tunnel

The fundamental facility for the steady test program is the glycerol tunnel designed and fabricated entirely in the department. The facility was originally designed by Aminzadeh [91] for his experimental work to study hydraulic performance of the aortic prosthesis using an enlarged valve model and later modified extensively to suit requirements of the present study. The main criterion governing the design was the Reynolds number, which for the anticipated model sizes, was around 10-50000 based on the orifice diameter and velocity at the orifice. The choice of concentration of the working fluid provided a degree of flexibility, but only to a certain extent as governed by the characteristics of the power unit. The tunnel is shown schematically in Figure 2-2.

Primarily it consists of two separate test circuits and three subassemblies: the test chambers; the fluid return system; and the power unit consisting of a pump and a drive motor. The large test section is built of four plexiglas walls 2.44 m long, 1.905 cm thick and wide enough to produce an inside cross-section of 20.32 cm x 20.32 cm. The long length was purposely chosen to ensure sufficient room for installation of flow distributing and straightening devices, and to permit positioning of the model with ease. A vent, 10.16 cm in diameter and 30.5 cm high, located on the downstream end of the test section provided for fluid expansion as well
Figure 2-1 Schematic diagram of the Starr-Edwards, Bjork-Shiley and St. Jude prostheses used in the program
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<th>ORIFICE DIAMETER, mm</th>
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<td>21.5</td>
</tr>
<tr>
<td>ORIFICE C</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>24</td>
</tr>
</tbody>
</table>

* RECOVERED DURING POSTMORTEM
Figure 2-2  A schematic diagram of the glycerol-water solution tunnel used in the steady flow investigation.
as an escape route for the air bubbles. It also serves as an effective check against the over pressurization of the test section, particularly, near the model location, irrespective of the pump's operating condition. There are five ports permitting access to the inside of the section: through each end, via two hatches and a porthole at the top of the "box". The hatches and porthole are strategically located to admit an arm to reach, position and adjust models almost anywhere in the tunnel. During a typical operation all hatches and porthole are sealed watertight employing "0"-rings. In addition, several smaller portholes which could take 5/8 in. N-C plugs were drilled and tapped on the top of the plastic "box". Furthermore, 2.54 cm portholes are also provided on the side face of the "box". These openings were used to mount models, and convey pressure conducting lines. When not in use they were sealed off employing the plugs with "0"-rings. Two glass plates, 63.5 cm x 13.97 cm x 1.27 cm, recess-mounted in the sides of the test section provided optically flat, homogeneous and thermally stable walls for inspection and photography. A drain positioned at the bottom of the "box" facilitated complete emptying and flush cleaning of the tunnel.

The tunnel is provided with an alternate channel of flow consisting of a PVC settling chamber, a plexiglas test-section and support blocks. Settling chamber is made from 25.4 cm diameter PVC tube with length of 104 cm. It is connected to the plexiglass tube test section carrying a valve mount plate. The system is purposely designed in a modular fashion to permit changes in diameter of the upstream and downstream sections thus providing a wide variety of test configurations.

In the present study three sets of upstream and downstream tubes ranging from 3.175 cm to 6.985 cm were used. The arrangement of test-section (plexiglas tubes), support plate and blocks is shown in Figure 2-3. In order to facilitate proper connection between different sizes of tubes adaptor inserts were employed. The whole test section (excluding the settling
Figure 2-3 Details showing modular construction to facilitate changes in the upstream and downstream sections.
chamber) can be installed inside the large test-section, described earlier, for velocity measurements using a LDA where curved surface of the test-section is not desirable. Of critical importance, from velocity profile consideration, was the transition of the flow from the pump outlet to the test-section. For the larger test-section where flow from the pump has to expand from 7.62 cm diameter tube to 20.32 cm x 20.32 cm box, the jet like flow has to be diffused and spread evenly across the test cross-section. This was achieved using the following arrangement:

(a) deflection annular vanes were positioned in the incoming stream to force some of the fluid away from the center of the stream;
(b) several sections of honeycombs followed the annular vanes to straighten the flow through turbulent exchange and laminar damping;
(c) brass screens of different pore size with or without fiberglass wool in between.

For the smaller test-section, the fluid is first introduced into the settling chamber containing several honeycombs and brass screens. The essentially stagnant flow is then introduced into the upstream test-section tube through a bell-mouth shaped entrance.

Located between the end of the test-section and the power drive unit is the return section essentially comprising a heat exchanger, PVC pipes and elbows with connecting flanges, flow control valves and a radiator hose. A copper pipe, 3.05 m x 7.62 cm dia. in conjunction with 2.44 m x 15.24 cm dia PVC plastic sewer pipe formed an annular single pass heat exchanger. With the coolant supplied by a water main it was possible to maintain temperature of the working fluid within 0.2°C. PVC elbows and sections of the radiator hose provided relatively easy, anti-corrosion and vibration free connections between the test-section and the heat exchanger.

The power unit consists of a centrifugal pump (Auora type GAPB, 200 gal/min, 7.6m head, 1750 rpm) driven by a three horsepower, variable speed,
D.C. motor. The pump impeller and housing are of cast brass to guard against possible corrosion. The motor is energized by a three phase grid, the voltage being adjusted through an autotransformer (Variac model 4T11) and rectified by selenium diodes. No further smoothing of the D.C. output was required.

Flow rate in the tunnel was monitored using a sharp edge orifice plate mounted two feet (61 cm) upstream of the pump inlet. The plate location was selected so as to make its reading relatively independent of upstream and downstream disturbances in the form of elbows, change in section at the pump inlet, pump suction, etc. Before final assembly the orifice plate and associated plumbing were calibrated, under simulated test conditions, by pumping water from a large sump into a weighing tank. The calibration plot thus obtained is presented in Figure 2-4.

It was important to minimize dirt contamination of fluid. This was achieved by incorporating a filter (10 micron) in a bypass circuit across the pump. The system filters the entire volume at least once in twenty four hours of operation.

2.2.2 Pulsatile flow cardiac simulator

In vitro pulsatile experimental study of the heart valves requires a complex duplicator which must closely simulate the physiological function as well as the anatomical shape of the natural heart and its circulation system. As pointed out in Appendix A, a wide variety of test facilities have been used in practice in an attempt to satisfy these criteria. Construction of a pulse duplicator requires careful consideration of its constituent subsystems: test chamber, drive unit and circulation system.

The approach adopted attempts to improve upon the existing designs and provides it a degree of versatility in undertaking experiments simulating a range of physiological conditions. Throughout, the design approach has
Figure 2-4 Calibration plot for the orifice plate
tried to simulate natural physiological conditions as closely as possible. Emphasis has been on the ease of construction and control of test variables.

The test chamber consists of a valve support block, which contains atrium and aorta, a flexible transparent ventricle and a surrounding plexiglas box as shown in Figures 2-5 and 2-6. The basic design follows the example developed by Cardiac Lab. group in Victoria, Canada [92]. The housing containing the mitral and aortic valves is made from solid plexiglas in accordance with the anatomical information. Attached to the block is a conically shaped thin transparent polyurethene film ventricle simulating the shape and the flexible character of the natural ventricle [93]. Transparent character of material was essential for the LDA based velocity measurements and flow visualization. The flexible ventricle itself is supported inside the plexiglas box which, in turn, is connected to the positive displacement piston (Bellofram rolling diaphragm) pump. Motion of the piston is transferred to the flexible ventricle through essentially incompressible surrounding medium (water) between the ventricle and the plexiglas box.

Circulation system is an adaptation of the lumped circuit proposed by Westerhof [94]. Immediately following the straight plexiglas aorta section is the adjustable Windkessel which provides a desired characteristic resistance through a filter element and a compliance by the air chamber above it. Peripheral resistance is provided either by another Windkessel or a water valve. Connecting this is the adjustable constant head tank to maintain desired back pressure. Overflow blood analogue fluid returns to the left atrium.

The drive unit is the heart of the pulse duplicator system. It should be able to provide a physiological waveform corresponding to the natural heart function. After careful consideration of the available options, it
Figure 2-5  Details of the pulsatile flow facility showing the left atrium, aorta and a section of the left ventricle with mitral and aortic valves in position.
Details of the cardiac pulse duplicator showing the pressurizing chamber (plexiglas box) and Bellofram rolling diaphragm positive displacement pump

Figure 2-6
was decided to use a mechanical drive system mainly due to its ability to impart precise displacement time history to the positive displacement piston. However, the conventional mechanical drive mechanism such as cam and lever or skotch yoke arrangement lacks a degree of flexibility in terms of selection of different waveforms particularly during actual progress of the experiment. In order to overcome this limitation, a microprocessor controlled stepping-motor was selected as a drive source. It consists of a 16 bit microprocessor board (Texas Instrument 9900/100M), a translator module (SLO-SYN Type STM 103), a stepping-motor (SLO-SYN M112-FJ12), and a power supply. Further details are recorded in Appendix B. The operational principle is quite simple. The required digitized waveform is stored in the memory of the processor board. This information is then read sequentially from beginning of the waveform to the end. For each digitized value of the waveform, the processor calculates necessary time intervals and number of pulses required to move the stepping-motor corresponding to its stored value. A potential advantage of this arrangement is to improve flexibility of the movement of the piston while maintaining accuracy of the mechanical drive (compared to a pneumatic system). By programming different waveforms, one can create any desired movement of the piston. The cardiac simulation system is also equipped with a bypass circuit with its own pump and a small orifice plate for steady flow rate measurements in the left ventricle cavity. Figures 2-7 and 2-8 show schematically the microprocessor controlled drive system and main features of the pulsatile flow cardiac simulator, respectively.
Figure 2-7 Details of the drive system showing stepping-motor, reduction gear and mechanism for imparting translational motion to the piston.
Figure 2-8 Main features of the pulsatile flow cardiac simulator
2.3 Instrumentation

2.3.1 Measurement of velocity

Fundamental parameters governing performance of a heart valve are velocity and pressure. Peak velocity, velocity profile, local velocity gradient and turbulence intensity are all known to have some correlation with the occurrence frequency of thromboembolism and hemolysis. Thus, understanding of the flow field around a heart valve is essential to evaluate its performance.

Charting of the velocity field around a valve, however, is a challenging task. At the outset it must be recognized that the limited size of the heart makes introduction of conventional probes generally unacceptable. We are dealing with a pulsatile flow with the heart rate ranging over 50-180 beats per minute (bpm). Recognizing that the heart and its valves lead to complex passages, the turbulent flow field has regions of acceleration, deceleration, regurgitation and stagnation. Thus the flow measuring system should:

(a) have moderately high frequency response in order to detect rapid changes in velocity for accelerating and/or turbulent flow;
(b) be able to monitor stagnant and negative flow; and
(c) not perturb the local flow, i.e., it should be preferably noninvasive.

Currently only two systems are available for velocity measurement under the conditions mentioned above: hot film and laser doppler anemometers. While a hot film anemometer can generally satisfy condition (a), it is hopelessly inadequate with reference to (b) and (c), not to mention the problems of electrolysis, bubble formation [95] and susceptibility to dirt contamination [96].

Laser doppler anemometers are non-contact optical instruments for the investigation of fluid flow structures in gases and liquids. Laser
Anemometry is a technique which utilizes scattered light from particles in a fluid element to measure the velocity of that element. This relatively new technique is based on the invention of gas laser in the early sixties with its unique property of spatial and temporal coherence. Currently most laser anemometers measure either the rate of change of frequency of the scattered lightwaves or the time of flight between spatial regions of high intensity in the measuring volume. The former is called Laser Doppler Anemometer (LDA) while the latter is called the Laser Transit Time Anemometer (LTA). LDA, being better suited for the real time measurements, was preferred.

A split laser beam from a single laser source is made to cross in the flow field to form a measuring volume, the region of interference fringe pattern. This is accomplished using a beam splitter and a focusing lens. Fluid particles in the measuring volume at a given instant scatter light in all directions with frequency modulation. As a cross-section through the measuring volume consists of alternate light and dark regions, a particle passing through the fringe system emits light pulses at a frequency dependent upon its velocity. This is referred to as the beat or doppler frequency. Note, the standard laser anemometer system has a 180 degree direction ambiguity as in the case of a hot film anemometer. In other words, it cannot distinguish between forward or backward flow. In the present study this would be a serious limitation. In a refined system the problem is overcome by a frequency shift between the split beams using the Bragg cell thus causing asymmetry in the interference fringe pattern.

The use of a laser doppler anemometer for velocity measurement involves careful consideration of the system elements such as:

(a) Optics and optical arrangement;
(b) seeding of the flow;
(c) size and type of laser;
(d) type of signal processor;
(e) data acquisition and reduction system.

These were considered in conjunction with anticipated characteristics of the flow field:

(a) near zero and/or negative velocity;
(b) turbulence;
(c) complex anatomical shape;
(d) Continuous data.

After considerable deliberation following components were selected for the LDA system:

(i) Spectra Physics Helium-Neon Laser Model 124B 35mW output;
(ii) OEI LDA Transmitter Optic Module consisting of
     - LD-0-0102 Optics adapter;
     - LD-0-210 Polarization rotator module;
     - LD-0-310 Beam splitter module;
     - LD-0-420 Double Bragg cell module;
     - LD-0-610 Lens Module f=310mm;
(iii) DISA 55X34 PM Receiving optics;
(iv) TSI Photomultiplier Model 962 with Model 965 power supply;
(v) DISA 55L20 Signal processor consisting of
     - 55L30 Preamplifier;
     - 55L37 Frequency tracker;
     - 55L40 Meter unit.

2.3.2 Traversing mechanism

To facilitate wake traverse during velocity measurements, the LDA system was supported on a platform with three degrees of freedom permitting, within limits, any desired spatial positioning of the measuring volume.
The traversing gear consists of two subassemblies: base traverse mechanism for rough positioning and a micrometer controlled X-Y translation stage for finer movement in a horizontal plane.

The base traverse mechanism was designed and fabricated entirely in the department of mechanical engineering. It consists of three platforms of which two ride on a pair of hardened steel rods with liner bearings permitting movement in a horizontal plane while the third rides on a modified mechanical jack permitting vertical movement. Maximum travel distance available is 86.6 cm x 23.7 cm along horizontal plane and 22.8 cm in the vertical direction. All platform components are made from heavy aluminum plates with 13mm thickness to minimize static deflection and vibration problems.

The fine adjustment horizontal translation stage, supported by the base, was made by A. W. Becker GmbH of West Germany. It is free to move 10 cm in each direction with an accuracy of 0.001 mm. Figure 2-9 shows the LDA system with its traverse mechanism.

2.3.3 Pressure transducer

Two types of pressure transducing systems are employed in this experimental study.

During the steady state study, mean pressure components at certain locations being extremely small demanded a highly sensitive instrumentation for their measurement. This was accomplished using a "Barocel Modular Pressure Transducing System" developed by Datametrics Inc. of Waltham, Massachusetts. The type 550-5 Barocel sensor is designed to operate with fluids over the pressure range of 0-10 psia. The unit is a high precision, stable capacitive voltage divider with a variable element in the form of a thin prestressed steel diaphragm which deflects proportionally to the
He-Ne Laser

Transmitter Optics

Photo Multiplier

Receiving Optic

Support Beam

X-Y Translation Stage (fine pitch)

X-Y-Z Translation Stage

Figure 2-9  LDA system with a traversing gear providing three translational degrees of freedom
magnitude of the applied pressure. To isolate the external pressure medium from the sensor diaphragm-capacitance system, the unit uses highly sensitive metallic bellows. The volume between the bellows, isolator and sensor diaphragm is filled with degassed silicone oil which serves both as a pressure transmitting fluid and as a dielectric. The pressure signal from the external liquid medium is transmitted by the bellows to the silicone oil which in turn deflects the diaphragm to produce the required change in capacitance. An A.C. carrier voltage at 10 KHz is applied to the stationary capacitor plates, and a bridge circuit determines an output voltage dependent on the ratio of the capacitance of the diaphragm to each of the stationary plates. The carrier voltage is therefore modulated according to the input pressure. The unit sensitivity is 0.007N/m² provided the pressure sensor is fully isolated from external sources of vibration and noise. It was imperative to ensure removal of all traces of air pockets from the pressure ducting for satisfactory operation. Barocel is accurately calibrated for steady pressure.

Although the system served well during the steady flow tests, it proved to be unsuitable for the pulsatile flow experiments. Due to the relatively large internal volume of the Barocel transducer, frequency response was found to be rather limited for the physiological condition. Because of this limitation, Statham model P-23 series physiological pressure transducers were employed during this phase of the study. This unbonded strain gage type transducer consists of a stainless steel diaphragm and a plastic dome. The liquid conducting pressure information is introduced in the plastic dome and is directly in contact with the stainless diaphragm. Because of this direct contact with the conducting liquid and small internal volume of the dome, it has excellent dynamic characteristics with high stability over the physiological pressure range. The Statham pressure transducer was used in conjunction with the Cambridge type 1-176 pressure/DC amplifier
and resulting signals were recorded using an IBM PC (personal computer) based data acquisition system.

2.3.4 Flowmeter

Two types of flow metering devices are used in this experimental study: a sharp edged orifice plate flowmeter and electromagnetic flowmeters. For steady state experiments, a built-in sharp edged orifice flowmeter of the glycerol-water tunnel monitored the average flowrate. The orifice plate was calibrated according to the standard ASME procedure. Pressure difference across the orifice plate was recorded using a Barocel pressure transducer in conjunction with a Data Metrics Electric Manometer model 1018. Calibration plot for the orifice plate was shown earlier (Figure 2-4).

During the pulsatile flow study, a pair of electromagnetic flowmeters were used to monitor time history of the flow rate. Magnetic flowmeters utilize the fact that the conducting fluid through a magnetic field produces a voltage potential difference proportional to the velocity of the conducting fluid. A magnetic flowmeter is free of moving parts, does not obstruct the flow field, and has a higher frequency response which is necessary in the pulsatile flow situation. The type used in the test program was In Vivo Metric Systems blood flow transducer model K26 and K50 in conjunction with a pair of matching Statham blood flowmeters model SP2202. Model K blood flow transducer is designed for the through-flow applications and have cannulating lumens which normally accepts blood vessels or flexible tubings. In the present study, both transducers were directly incorporated in the design of the mock circulation system: model K26 (26mm dia.) was placed at the aortic location and K50 (50mm dia.) is at the atrium to monitor aortic and mitral flow rate, respectively.
Due to reaction between the electrode and the conducting fluid, the magnetic flowmeter exhibits a gradual drift of calibration constant over a long run (around a couple of months) and zero drift over short intervals (30 min) thus requiring frequent recalibration. For this reason, a pulsatile flow simulator was also provided with a bypass steady flow circulating system, with a built-in small orifice plate flowmeter to facilitate recalibration. Calibration plot for the small orifice plate is shown in Figure 2-10.

![Calibration plot for the orifice plate used in the bypass circuit of the pulsatile flow facility](image)

Figure 2-10 Calibration plot for the orifice plate used in the bypass circuit of the pulsatile flow facility
2.3.5 Magnetic flowmeter calibration

It would be useful to briefly describe the procedure used to calibrate magnetic flowmeters.

The advantage of having obstruction free, fast responding transducers with linear output is indeed attractive, however, there are times when its limitations are difficult to deal with. Calibration of a magnetic flowmeter at times becomes a challenging task to unsuspected users. The standard procedure using a constant head tank usually provides quite an accurate calibration result if the transducer size is within the normal physiological range. However, for a larger transducer such as the model K50 used in the experiment, this seemingly simple calibration procedure presents some problems. As mentioned elsewhere, the signal strength from the magnetic flow transducer is directly proportional to the magnetic field intensity and velocity of the conducting fluid passing through that field. As the size of the transducer becomes larger, average velocity corresponding to the same amount of flow rate diminishes in an inverse square fashion. The same is true for the magnetic strength at a point for a specified magnetic strength at the coil. Hence the signal from a larger transducer is considerably weaker and susceptible to minor variations in the external condition. To account for this possible source of error the larger size magnetic flow transducer was calibrated using three different procedures as described below.

(a) Continuous Calibration Procedure.

Instead of using a standard calibration procedure which requires a separate facility, the present approach utilizes a pulse duplicator itself for steady state calibration. Output signals from the two magnetic flowmeters are compared with orifice reading. Results are monitored with
a systematic variation of flow rate from zero to about 400 ml/sec and then reduced back to zero. Typical results are shown in Figure 2-11. The smaller transducer was found to be quite stable while the larger one exhibited considerable drift (not shown), perhaps due to an interaction (chemical reaction) between the voltage sensing catheters and the conducting fluid. Commercially available magnetic flowmeters normally utilize alternate current for excitation and platinum or gold plated catheters to minimize the contamination problem. Unfortunately this precaution did not prove to be adequate for the larger transducer where signal strength is weak as explained before. This behavior was confirmed through observation of signal drift even at zero flow. It was therefore decided to search for an alternate procedure.

(b) Intermittent Calibration Procedure

It was recognized that flow at a uniform speed promotes drift. It was, therefore, decided to vary the magnitude of flow velocity between zero and a desired value almost as a step function in time. Thus the flow is activated and stopped intermittently over short intervals of time repeatedly and the transducer output recorded. With this procedure the smaller transducer's response remained almost identical to the continuous calibration data obtained before (Figure 2-11) and the large transducer showed a substantial improvement in stability. However, although the drift was reduced, it was considered unacceptable and yet another alternative was sought.

(c) Calibration using piston displacement information

As the piston displacement is accurately monitored during the experiment, the rate of volume change can be calculated quite readily and used to calibrate flow transducers in real time. The rate of volume change,
however, may not necessarily be the same as actual flow rate through the transducer since during certain phase of the cardiac cycle flow can occur through both the valves at the same time. One can overcome this problem by selecting a suitable time interval for calibration. When the maximum flow occurs through one of the valves, the other is usually closed completely. By

Figure 2-11 Calibration plots for magnetic flowmeters using progressively increasing and decreasing flow rates
Comparing the flow rate information from one of the magnetic flowmeters and the rate of volume change (of positive displacement piston) during the maximum flow condition, accurate calibration of the transducers can be accomplished. Figure 2-12 compares the time history of volume swept by the piston with the flow rate measured by the transducer using the calibration constant obtained using one of the previously mentioned calibration procedures. Note, that the maximum values in both the cases are almost identical, indicating that real time calibration is possible. This enables one to calibrate the transducers every time the experiment is conducted. The problem of drift between the experiments is thus eliminated. Any possible discrepancy in results due to inaccuracy in the constant is thus minimized.

Figure 2-12 A comparison between the histories of the rate change of stroke volume and flow rate as measured by the magnetic flowmeter (K50)
2.3.6 Linear displacement transducer

The time history of the piston displacement was monitored by a linear displacement transducer. The transducer employs the principle of the differential transformer and consists of three main components:

(a) a soft iron core;
(b) a non-conducting spool supporting primary and secondary windings;
(c) a brass tubular casing.

A 30 KHz, 10 volts rms carrier from a function generator to the primary is modulated by the core displacement. The corresponding modulated signal from the secondary is rectified in linear proportion to the core displacements. Figure 2-13 shows the calibration plot for the displacement transducer.

2.4 Test procedures

With this as background let us turn to the procedures adapted during the experimental program. The success of any experiment depends, to an extent, on recognition of the capability and limitation of the equipment used. Performance specifications for instruments normally provide this information, however, they must be checked through actual operation. Furthermore, at times, it was necessary to push the equipment to its utmost capability to collect vital data. Hence extensive preliminary tests were carried out before embarking upon an experiment to ensure accuracy (implies reliability through repeatability) of results.
Figure 2-13 Calibration plot for the displacement transducer

2.4.1 Steady state experiments.

Figure 2-14 shows schematically the arrangement of the instrumentation used for the steady state measurement of pressure and velocity.

The pressure distribution along the test section was measured using a Barocel pressure transducer (Datametrics Type 550-5) in conjunction with an electric manometer (Datametrics Type 1028). Barocel being a differential
Figure 2-14 Details of LDA, pressure measuring, data acquisition and processing system used in conjunction with the steady flow tunnel.
pressure transducer, one side is connected to the locations of interest through its system of distributing valves, while the other side is exposed to upstream location. Actual pressure tap locations used are shown in Figure 2-15. All air bubbles from pressure conducting lines were carefully removed as they affect the results. This was achieved by opening all the distributing valves to allow the conducting fluid to flow through the pressure conducting line with the tunnel running for about 30 minutes. This also ensured uniform concentration of the glycerol-water solution throughout the test system. Pressure levels being often very low, especially at a low Reynolds number, any change in viscosity and density of the simulation fluid resulted in a zero shift. To account for this all measurements were preceded by the monitoring of pressure at no flow condition. After removing all traces of air bubbles, distributing valves were closed and the tunnel stopped. One of the distribution valves was, now, opened for the measurement of zero flow pressure at that tap location. Depending on the viscosity of the solution used, normally a few minutes of settling time was necessary for the pressure to be stabilized. The pressure was recorded and the valve closed. The procedure was repeated at all the pressure tap locations. Now the tunnel was activated to establish a desired steady flow rate as given by the orifice meter and new pressure signals measured.

Velocity measurements were accomplished using the LDA system described previously. The circular tube test-section having a bell-mouth entrance was placed inside the large square section of the glycerol-water solution tunnel with the same simulation fluid surrounding it to minimize the effect of changes in refraction index between the tunnel material (plexiglas) and the solution. To further minimize the refraction effect due to the circular cross section of the flow test-section, velocity measurements were conducted in the horizontal plane through the center of the test-section. Only the
Figure 2-15  Details of the pressure tap locations
velocity component along the test-section was measured in this experiment. To start with the tunnel was set for an appropriate flow rate. Now the laser beam was focussed inside the test tube wall, which gave a constant frequency unaffected by the flow field thus confirming the setting of the LDA system. Next the measuring volume was moved to the interface between the wall and the flow field using the transverse mechanism. It was possible to identify the interface accurately by monitoring a sudden change in the LDA signal. Having established the wall boundary, the measuring volume progressively scanned the flow field. Signal from the LDA system was filtered prior to data analysis to eliminate high frequency noise. Mean velocity value was noted using a digital voltmeter with appropriate time constant (DISA Type 55D31) and rms value of fluctuations around the mean measured using a rms voltmeter (TSI Model 1060). Average flow rate as given by the orifice meter was also recorded.

2.4.2 Pulsatile flow measurements

During the pulsatile flow simulating a cardiac cycle, pressure measurement at left atrium, left ventricle, and aorta were carried out using Statham model P-23 transducers. Actual position of the transducers and magnetic flow meters are shown in Figure 2-16. Although the pressure transducers have good frequency response and accuracy in the physiological range, their absolute character demanded careful calibration of the zero pressure point. External calibration of the transducers (i.e., away from their intended locations at left atrium, etc.) proved to be inadequate as even a minute variation in relocation affected repeatability of results. Hence calibration and zero pressure checks were carried out with transducers in actual operating positions in the fluid field. After the initial warm up period the pulse duplicator was stopped, the fluid allowed to settle to a
Figure 2-16 A schematic diagram of the pulsatile flow facility and associated instrumentation
uniform level and the pressure signal recorded as a zero flow point. Although the procedure gives the pressure with respect to the initial fluid level rather than its absolute value, it left the system undisturbed resulting in assured accuracy and repeatability. After carefully establishing the zero flow reference, the pulse duplicator was activated and simulation parameters adjusted to give the normal physiological condition. Three pressure signals - flow rate through mitral and aortic valves (In Vivo Metric Systems blood flow transducers model K50 and K26), piston displacement (linear displacement transducer), and velocity inside the ventricle (LDA) - were recorded.

It is important to point out here that wide variations in the mean flow with a highly turbulent character superposed on it stretched the LDA's capability to its limits. The Bragg cell was adjusted to give a shift frequency of 399.92 KHz which proved to be quite stable for the present LDA system. A low pass filter (Krohn-Hite model 3202R) was used between the TSI photomultiplier and DISA signal processor (model 55L20) in order to eliminate unwanted high frequency noise. Due to the highly fluctuating nature of the flow the processor occasionally mistracked the signal. This usually appeared as a spike. In order to minimize the problem, output from the tracker was processed using a low pass filter (Krohn-Hite model 335) with a frequency setting at 150 Hz. The choice of the frequency setting was based on the spectrum analysis during the steady flow.

Velocity signals were mostly monitored at a station 25.4 mm downstream from the mitral valve position. Figure 2-17 shows location of the data stations and orientation of the measuring plane.

Signals from the flowmeters, displacement transducer, and LDA were directly processed by an IBM PC personal computer through a DATA Translation analog to digital convertor board with a rate of 500 sample per second per channel.
Figure 2-17 Top and side views showing details of inlet and exit geometries together with locations of velocity measurements
3. RESULTS AND DISCUSSION: STEADY FLOW CONDITION WITH SIMULATED TUBE GEOMETRY

With some appreciation as to the background of the problem, instrumentation used and the experimental procedures adopted, let us turn to the test results and their interpretation. The amount of experimental data obtained is rather enormous, thus dictating a compromise in presentation between conciseness and comprehensibility. The guiding principle has been to include only those results which have immediate relevance to the study in hand, and help in establishing definite trends. In general, the sequence in which the results are presented also denotes the chronological order of the test. Test data for steady state experiments are presented in this chapter. This is followed by the results of pulsatile experiments in chapter 4.

The approach to data reduction is discussed first. This is followed by the presentation of pressure results, in nondimensional form, as affected by variables such as Reynolds number, size of the valve, beat rate, etc. Velocity profiles are analyzed next in both dimensional and nondimensional forms. Finally, correlation between steady and pulsatile results are discussed. Information from the literature is included for comparison when available to assist in arriving at reliable conclusions.

3.1 Comment on Data Reduction and Presentation

Before proceeding with the presentation and discussion of results, a comment concerning the manner in which data in this general area of bioengineering have been presented, particularly in medical journals, would be appropriate. The knowledge of complex fluid dynamics associated with
prosthetic heart valves of complicated geometries is indeed important to evaluate their performance. However, the governing parameters are many: fluid flow rate; density and viscosity; valve configuration and size; geometry and dimensions of the test-section; etc. Combination of these variables is endless. Unfortunately, a considerable amount of information recorded in the literature, being in dimensional form, is valid only for specific situations and fails to evolve general conclusions.

The widely accepted procedure for assessing performance of a heart valve has been based on pressure vs flow rate or rate of heart beat data. Pressure is often expressed in mmHg and flow rate in terms of cm³ per minute. This dimensional form of results gives a better appreciation of the magnitudes involved and has proved useful in clinical practice. Unfortunately, such dimensional approach is indeed inadequate in establishing relative hemodynamic performance of prosthetic heart valves. This is because pressure depends on velocity which, in turn, is governed by cross-sectional area of the passage. Hence comparison of results by investigators using different test facilities, operating conditions and size of models is virtually impossible.

The widely used Gorlin-Gorlin formula [97] to assess stenotic condition of a valve through an estimate of its open area is thus quite inadequate because of its dimensional character. Furthermore, it involves use of the discharge coefficient which depends on the Reynolds number. Hence computation of the unknown area assuming a value for the discharge coefficient becomes a pointless exercise when the valve orifice area is known and the discharge coefficient is unknown as for in vitro experiments.

Gabbay and his associates [71] have suggested the use of effective orifice area to characterize the overall hydrodynamic performance of a prosthetic valve. However, concepts such as performance index [71], effective area index [98], and the efficiency index [99], as a measure of how
well the valve uses its primary flow area, are not based on the fundamental fluid dynamical principles.

Viggers [100] has emphasized the importance of pressure drop and associated work load on the heart in any prosthetic valve design. Based on the measured pressure drop, an empirical hydraulic efficiency parameter is suggested to assess effectiveness of an artificial device in relation to that of the natural valve. Gentle et al. [101] have proposed a rather simple relation to evaluate fluid dynamical performance of a valve based on pressure drop across an ideal orifice. It was found that most mitral valves proved to be only 30-40% efficient thus presenting an enormous scope for improvement. Scotten et al. [102] compared performance of six existing valves (Carpentier-Edwards, Hancock, Ionescu-Shiley, Bjork-Shiley, Lillehei-Kaster, Starr-Edwards) with their own bicuspid mitral configuration on the basis of mean and peak gradients, open area and energy loss and stressed that energy loss is the only criterion which can measure performance of prosthetic valves throughout the cardiac cycle. However, it is increasingly becoming clear that nondimensional presentation of information is the only way that can provide a sound basis for comparing hemodynamic performance of prosthetic heart valves.

3.2 Pressure Drop and Recovery

One of the major concerns in using a prosthetic heart valve to correct valve abnormality is the stenotic condition created by its presence. Normally a medical professional judges stenotic condition by examining the pressure drop for a given blood flow rate. This information is then used to calculate the effective open area of an implanted valve by applying the Gorlin formula [97] or employed directly. Hence, in the beginning, pressure drop data are purposely presented in dimensional form.
Two series of valves were tested to assess the effect of size. The first series had a mean suture ring diameter of 29-30 mm and hence contained larger valves. In the second series the valves were relatively smaller with the mean suture ring diameter of 27-28 mm. The results are presented in Figures 3-1 and 3-2. Orifice data are also presented when useful for comparison.

As expected, the orifice performance improves (smaller pressure drop) with an increase in the annulus area. However, the Starr-Edwards valve shows a considerably larger pressure drop in both the diagrams although it has a slightly larger nominal diameter. The St. Jude valve shows a slightly better performance compared to the Bjork-Shiley valve in both the cases. Based on such dimensional information, one might erroneously conclude apparently inferior performance for the Starr-Edwards prosthesis due to its poor geometry. As shown next, the more rational nondimensional presentation of information proves that the ball-cage configuration is indeed fluid dynamically sound.

Dimensional presentation of pressure makes it highly sensitive to the valve size. Thus valves even with identical configuration but different size will have to be tested independently in this system of data presentation. This is not only time consuming but also leads to misleading conclusions.

A more reliable way of judging hemodynamic performance of a valve would be to present information in a nondimensional form based on flow parameters at the orifice. This is shown in Figures 3-3 and 3-4. Here pressure drop is divided by the dynamic head based on velocity at the orifice and the flow rate is nondimensionalized as the Reynolds number using diameter and velocity at the orifice. As the circular shape is common to all orifices, ideally the corresponding data should collapse on a single curve.
Figure 3-1 Variation of pressure drop with flow rate for the Starr-Edwards, Bjork-Shiley and St. Jude valves with nominal diameters of 29-30 mm
Figure 3-2 Variation of pressure drop with flow rate for the Starr-Edwards, Bjork-Shiley and St. Jude valves with nominal diameters of 27-28 mm
Figure 3-3 Nondimensional representation of pressure drop results given in Figure 3-1
Figure 3-4 Nondimensional representation of pressure drop results given in Figure 3-2
The small variations are due to differences in valve size. More interesting are the heart valve data. Although relative rating between the SJ and B-S valves remains the same, performance of the S-E valve is relatively quite different: It is better than that of the B-S as well as the SJ valves, in spite of its smaller orifice diameter, thus indicating its superior fluid dynamical configuration. This is indeed logical because of the marked difference in the boundary layer separation condition. Figures also show a dependency on the Reynolds number as indicated by the slope of the pressure plots. It is of interest to note, in the case of the St. Jude valve, a presence of hump in the pressure plots suggesting a critical Reynolds number region associated with transition from laminar to turbulent separation. Though not quite distinct similar transition regimes can also be discerned for the Starr-Edwards and Bjork-Shiley valves.

Effectiveness of the nondimensional presentation lies in the fact that it makes results independent of size as long as the geometric similarity is maintained. A comparison of results presented in Figure 3-5 and 3-6 illustrates this point rather vividly. Figure 3-5 shows, in conventional format, variation of pressure drop with flow rate for three different sizes of the Starr-Edwards ball valve. The effect of valve size is apparent and as expected: The pressure drop increases as the annulus diameter decreases. However, nondimensional presentation of the same results collapses (Figure 3-6) the data essentially on a single curve suggesting dynamic similarity. Small differences are due to the contraction and expansion effects upstream and downstream, respectively. The Bjork-Shiley and St. Jude valves also showed the same trend (Figure 3-7 to 3-10).

Effect of the Reynolds number on pressure drop and its downstream recovery for the entire family of valves mentioned in Table 2-1 as well as the 19 mm diameter orifice is shown in Figure 3-11 through 3-18. The orifice data serve as a reference (Figure 3-11) to help assess influence
Figure 3-5  Influence of flow rate on pressure drop for different sizes of the Starr-Edwards ball prostheses
Figure 3-6  Nondimensional representation of pressure drop for three sizes of the Starr-Edwards prostheses showing near collapse of the data.
Figure 3-7  Effect of valve size on variation of pressure with flow rate for the Bjork-Shiley disc prosthesis
Figure 3-8 Nondimensional representation of the pressure drop and flow rate in terms of the pressure coefficient $(C_p)$ and Reynolds number $(R_n)$ showing near collapse of the data.
Figure 3-9  Dependence of pressure drop on valve size for the St. Jude prosthesis
Figure 3-10 Plots showing near independence of the variation of the dimensionless pressure drop with the Reynolds number for two sizes of the St. Jude prosthesis. Note the hump in the pressure profile continues to be present at around Rn=4500 due to transition.
of the valve geometries. Since the reference pressure corresponds to a location upstream of the bell-mouth entrance, pressure upstream of the orifice is slightly negative. At the orifice location, flow acceleration due to contraction of the passage results in a large negative pressure. Due to inertia affects the flow continues to converge beyond the orifice reaching a minimum cross-section referred to in fluid mechanics as vena contracta. Thus the lowest pressure occurs around $L=0.5-1 \, D$ downstream of the orifice where $D$ represents diameter of the upstream tube. Beyond the vena contracta the pressure recovery begins due to deceleration of the fluid reaching a near constant value $3-4 \, D$ downstream from orifice location. This is quite similar to the results of axi-symmetric nozzles studied by Clark [103]. Due to energy dissipation pressure can not be fully recovered. It is apparent from the plots that even the sharp edged orifice shows a Reynolds number dependency. Note, pressure at a fixed location increases with the Reynolds number. Figures 3-12 to 3-14 show the same trend for Starr-Edwards ball valves. The negative pressure attained immediately after the valves is between $-1.5$ and $-2.0$ which is less than that of the orifice (around $-2.5$). Note, there is a sudden increase in the pressure at around $0.5 \, D$. This is attributed to peripheral diversion of the flow causing a jet impinging on the wall in the vicinity of a pressure tap which now measures a contribution for the dynamic head depending on the flow direction. The pressure recovery is now completed within $1.5-3 \, D$ which is a considerably shorter distance than that in the orifice case. However, the extent of pressure recovery seems to be less. As to the Reynolds number effects, the valves exhibit essentially similar trends: an increase in Reynolds number leads to a decrease in pressure coefficient. It seems, however, that the degree of recovery after the minimum pressure point is essentially independent of the Reynolds number. Thus the pressure recovery process (recovered pressure / pressure drop across a valve) improves as a result
Figure 3-11 Effect of the Reynolds number on pressure variation across the sharp edged orifice (annulus diameter = 19 mm)
Figure 3-12 Effect of the Reynolds number on pressure variation across the Starr-Edwards prosthesis (2M6120)
Figure 3-13 Effect of the Reynolds number on pressure variation across the Starr-Edwards prosthesis (3M6120)
Figure 3-14 Effect of the Reynolds number on pressure variation across the Starr-Edwards prosthesis (annulus diameter = 21.5 mm)
of an increase in the Reynolds number.

The tilting disk of the Bjork-Shiley valve creates a rather complex flow field downstream. The fluid is directed to one side of the valve and a large separation region is created behind the disk. Preliminary tests showed that the pressure profile remains substantially unaffected by the pressure tap location unless the flow directly impinges on it. The pressure drop and recovery plots presented in Figures 3-15 and 3-16 correspond to tap locations at 90 degree to the open orientation. The negative pressure at the valve location is spread around $C_p=-2.5$, which is similar to that observed in the case of an orifice, and a minimum pressure is attained around 0.5 D downstream. The recovery process is relatively slow and takes around 4D, however, as seen before, the extent of pressure recovery does improve with an increase in the Reynolds number. This is particularly true for the Bjork-Shiley prostheses where shape of the pressure profile remains essentially the same over a wide range of the Reynolds number extending from 500 - 50,000. As expected, at a given downstream station, pressure tends to increase with the Reynolds number. Corresponding plots for two St. Jude prostheses are presented in Figures 3-17 and 3-18. Trends are essentially the same as before. The negative pressure immediately downstream of the valve is a little more negative than that of the orifice but slightly less than that for the Bjork-Shiley valve. As before, the minimum pressure is attained at around 0.5 D downstream and the pressure recovery is completed at around 3 D, nearly the same as in the orifice case. Of interest is a reversal in the Reynolds number effect downstream. The pressure recovery results are in good agreement with those obtained by other investigators for the Bjork-Shiley [104,83] and St. Jude [83] valves.

Figure 3-19 summarized streamwise variation of the pressure coefficient for three different valve configurations and three orifices at a Reynolds number around 14000. As seen before, there is a significant and rapid
Figure 3-15 Effect of the Reynolds number on pressure variation across the Bjork-Shiley prosthesis (29MBRP)
Figure 3-16 Effect of the Reynolds number on pressure variation across the Bjork-Shiley prosthesis (27MBRC)
Figure 3-17 Effect of the Reynolds number on pressure variation across the St. Jude prosthesis (29M)
Figure 3-18 Effect of the Reynolds number on pressure variation across the ST. Jude prosthesis (27M)
Figure 3-19 A comparison of streamwise variation of $C_p$ characteristics for three different valve configurations and sharp edged orifices at a fixed Reynolds number of around 14,000
recovery of pressure in the wake which is dependent upon the valve configuration. Figures 3-20 to 3-22 show variation of pressure recovery with the Reynolds number and size for the three valve configurations. Since the degree of pressure recovery is dependent on the dissipation of energy, it is reasonable to expect that the smaller the open area the larger the expansion and hence the higher dissipation. Plots confirm this observation for all the valve configurations studied. Thus lower pressure recovery is associated with smaller opening valves. In the present study a pressure recovery of as large as 24% was reached. This would suggest that considering pressure drop immediately across a heart valve as a measure of its performance, as is often reported in literature, could be misleading because considerable amount of energy is recovered downstream.

Figure 3-23 summarizes percentage recovery of pressure for three different valve configurations and two orifices. As discussed previously, orifice data clearly show the effect of size on pressure recovery. Larger orifice shows a markedly better pressure recovery than the smaller one due to a smaller contraction and expansion of the flow resulting in lower energy dissipation. It also shows less dependency on the Reynolds number, as indicated by the nearly flat profiles over a wide range due to the well-defined sharp edge separation of the boundary layer. On the other hand, all the valves show a degree of dependency on the Reynolds number. The Starr-Edwards prosthesis because of its rounded configuration is affected most due to the Reynolds number dependent boundary layer type separation. For both the Bjork-Shiley and St. Jude valves having relatively sharp edges, dependency on the Reynolds number is less noticeable. As can be expected, larger opening of the St. Jude valve resulted in a better pressure recovery compared to the Starr-Edwards valve. Note, the orifice, St. Jude and Starr-Edwards data show similar trend. Both the valves exhibit a lower recovery at higher end of the Reynolds number. The Bjork-Shiley
Figure 3-20 Variation of pressure recovery with Reynolds number and size for three different sizes of the Starr-Edwards prostheses.
Figure 3-21 Variation of pressure recovery with Reynolds number and size for two different sizes of the Bjork-Shiley prostheses.
Figure 3-22 Variation of pressure recovery with Reynolds number and size for two different sizes of the St. Jude protheses
Figure 3-23 A percentage recovery of pressure for three different valve configurations and two orifices.
configuration, however, does not recover well even compared to the Starr-Edwards valve and is noticeably worse than the St. Jude prosthesis. Thus boundary layer type separation of the Starr-Edwards prosthesis and multiple passages of the St. Jude (minimizing the effect of an occluder) tend to promote the pressure recovery downstream.

3.3 Discharge Coefficient

As pointed out in the earlier section (section 3.1), a desirable way to compare valve performance is through nondimensional presentation of the measured data. To that end, the discharge coefficient is widely used by engineers in fluid dynamics studies. It is defined as the ratio of the measured flow rate to the flow rate calculated from the measured pressure difference across the device. It is a measure of how well the device utilizes its area open to the flow. Of course, ideally the discharge coefficient should be unity. Figures 3-24 to 3-26 show variation of Cd with the Reynolds number for the three different valve configurations under study. Figure 3-24 shows variation of Cd for three sizes of the Starr-Edwards valve. Although the collapse is not quite complete because of the reasons mentioned earlier, the general trend is quite apparent. Note, the plots are ordered according to the orifice diameter, indicating differences due to contraction and expansion effects. It also shows a substantial dependence on the Reynolds number. An increase in the Reynolds number tends to improve the Cd value. The Bjork-Shiley (Figure 3-25) and St. Jude (Figure 3-26) valves show the same trend. Figure 3-27 compares the results with the orifice data. A striking difference between the two sets of data is apparent. The configuration effect being absent for the orifices, the discharge coefficient is essentially the same, at a given Reynolds number except for minor differences caused by upstream and downstream flow conditions. On the other
Figure 3-24 Variation of discharge coefficient (Cd) with the Reynolds number for three different sizes of the Starr-Edwards prostheses.

\[ Cd = \frac{Q}{\frac{\pi}{4} d^2 E \sqrt{\frac{2(Pu-Pd)}{\rho}}} \]

where \( E = \frac{1}{\sqrt{1 - \left(\frac{d}{D}\right)^4}} \)}
Pu Pd

\[ Cd = \frac{Q}{\frac{\pi}{4} d^2 E \sqrt{2 \frac{(Pu-Pd)}{\rho}}} \]

where \( E = \frac{1}{\sqrt{1-\left(\frac{d}{D}\right)^4}} \)

**Bjork-Shiley Valve**

- **Model** \( d, \text{ mm} \)
  - 27MBRC 22
  - 29MBRP 24

Figure 3-25 Variation of discharge coefficient (Cd) with the Reynolds number for two different sizes of the Bjork-Shiley prostheses
Figure 3-26 Variation of discharge coefficient (Cd) with the Reynolds number for two different sizes of the St. Jude prostheses.
Pu Pd
d
cd = \frac{Q}{\frac{\pi}{4} d^2 E \sqrt{\frac{2(Pu - Pd)}{\rho}}} \text{ where } E = \frac{1}{\sqrt{1 - \left(\frac{d}{D}\right)^4}}

Figure 3-27 Variation of discharge coefficient (Cd) with the Reynolds number for three different valve configurations and orifices
hand, configuration effects and the Reynolds number dependency are quite evident for the valves. The results suggest that formulae often used to predict open area of stenotic valves which fail to account for the effect of Reynolds number and valve configuration, could lead to somewhat misleading conclusions. Note, surprising as it may seem, the Starr-Edwards configuration performs much better than the other two valves for the same orifice area.

3.4 Characterization of the Downstream Flow

3.4.1 Nondimensional velocity profile based on upstream velocity

To have a better appreciation as to the hemodynamics associated with prosthetic heart valves one must turn attention to parameters characterizing the downstream flow. The amount of information obtained through a systematic variation of valve configurations, Reynolds number and downstream station is rather extensive. For conciseness, only a typical set of results suggesting trends are recorded here.

Figures 3-28 to 3-31 show the nondimensional velocity profile, turbulence intensity (in the direction of the flow) and local shear stress distribution at a station 0.5 diameter downstream (L=0.5D) for: Sharp edged orifice (opening diameter, d=19 mm); Starr-Edwards (2M6120) prosthesis; Bjork-Shiley tilting disk (27MBRC) prosthesis; and St. Jude Medical (M27) prostheses.

For the orifice, classical character of the jet flow with a peak velocity at the center and associated essentially potential core are apparent (Figure 3-28). Moving radially outwards, this is followed by a turbulent mixing region. Reversed flow near the wall suggests recirculation. Note the expected two sharp peaks for turbulence intensity in the mixing region, while the surrounding reversed flow shows a drastic reduction in turbulence.
Figure 3-28 Typical plots showing the variation of velocity, turbulence intensity (in the direction of the flow) and local shear stress at a station 0.5 diameter downstream for the sharp edged orifice (d=19 mm)
This basic information would serve as a model assessing changes in the flow pattern brought by different valve geometries.

Corresponding results for the Starr-Edwards prosthesis, whose characteristic feature is the presence of a spherical occluder, are presented in Figure 3-29. Being directed around the occluder, the peak flow occurs between the poppet and the channel wall. It is important to point out that the maximum velocity recorded here was relatively smaller than that measured for other valve configurations, in spite of a smaller annulus opening. This may be attributed to the fact that the presence of the occluder helps divert the flow towards the wider channel area. A complex interaction between the mixing layer of the jet and separation from the occluder result in high turbulence intensity in the peak flow region.

The two sharp peaks in the velocity profile observed for the Bjork-Shiley valve are associated with the disc position nominally at 60° to the flow when fully open (Figure 3-30). The lower velocity peak is due to the deflected jet type flow, caused by the disc, while upper peak is governed by the separating shear layer. Note a steep rise in turbulence intensity (250%) and local shear stress (6N/m²) near the lower peak. Such a high level of turbulence intensity and shear stress are suspected to promote thromboembolism together with possible deformation and damage to the red cells.

As a central flow device, the Saint Jude valve has a unique characteristic velocity profile as shown in Figure 3-31. Presence of two half-discs leading to three flow regions at the annulus create corresponding three peaks downstream. Interactions between jets and separation from the discs lead to a rather complex variation in the turbulence intensity. Relatively larger opening angle of the disc (compared to the Bjork-Shiley valve) produces a slightly lower turbulence level, for the same annulus area.
Figure 3-29 Typical plots showing the variation of nondimensional velocity, turbulence intensity (in the direction of the flow) and local shear stress at a station 0.5 diameter downstream for the Starr-Edwards prosthesis (2M6120) using the velocity based on the upstream area.
Figure 3-30: Typical plots showing the variation of nondimensional velocity, turbulence intensity (in the direction of the flow) and local shear stress at a station 0.5 diameter downstream for the Björk-Shiley prosthesis (Baroclinic) using the velocity based on the upstream area.

\[ U_\theta = \frac{U}{U_0} \]
Figure 3-31 Typical plots showing the variation of nondimensional velocity, turbulence intensity (in the direction of the flow) and local shear stress at a station 0.5 diameter downstream for the St. Jude prosthesis (27M) using the velocity based on the upstream area.
However, this trend was reversed at a further downstream station (L/D=1) due to mixing of the three flow regions.

3.4.2 Nondimensional velocity profile based on annulus velocity

The previous section compared wake characteristics of a class of prosthetic heart valves having essentially the same suture ring dimensions with clinical application in mind. However, this does not assess effectiveness in terms of hydrodynamic performance of the various valve configurations. Obviously, the annulus diameter, and the associated velocity, should represent one of the major parameters as against the constant upstream velocity U used in nondimensionalizing results in the earlier figures.

Figures 3-32 to 3-35 show velocity, turbulence intensity and shear stress distribution at L/D=0.5 for the orifice, Starr-Edwards, Bjork-Shiley and St. Jude valves using the velocity based on the annulus area. Note the striking differences in magnitude of the peak velocity and turbulence intensity which were not so apparent earlier. Thus, although for the same suture ring diameter, the two valves showed essentially comparable performance, for the same annulus dimension the Starr-Edwards prosthesis exhibits lower turbulence intensity attesting to its favorable fluid dynamic geometry.

The inclined sharp edged disc of the Bjork-Shiley valve leads to the formation of strong vortices resulting in high turbulence intensity. Half-discs of the Saint Jude valve being more aligned with the flow gave turbulence intensity slightly lower than that for the Bjork-Shiley valve but above the Starr-Edwards' configuration.
Figure 3-32 Typical plots showing the variation of nondimensional velocity, turbulence intensity (in the direction of the flow) and local shear stress at a station 0.5 diameter downstream for the sharp edged orifice (d=19 mm) using the velocity based on the annulus area
Figure 3-33 Typical plots showing the variation of nondimensional velocity, turbulence intensity (in the direction of the flow) and local shear stress at a station 0.5 diameter downstream for the Starr-Edwards prosthesis (2M6120) using the velocity based on the annulus area.
Figure 3-34 Typical plots showing the variation of nondimensional velocity, turbulence intensity (in the direction of the flow) and local shear stress at a station 0.5 diameter downstream for the Bjork-Shiley prosthesis (27MBRC) using the velocity based on the annulus area.
Figure 3-35 Typical plots showing the variation of nondimensional velocity, turbulence intensity (in the direction of the flow) and local shear stress at a station 0.5 diameter downstream for the St. Jude prosthesis (27M) using the velocity based on the annulus area.
3.4.3 Variation of the characteristic parameters downstream

Figure 3-36 to 3-39 summarize the effect of downstream location on the above mentioned parameters at three stations (L/D=0.5, 1.0, 1.5) for the Starr-Edwards (3M6120), Bjork-Shiley (27MBRC) and St. Jude (M27) prostheses. Based on the results following general remarks can be made:

(i) The Starr-Edwards prosthesis with its recirculation region near the center shows a relatively rapid decay in the maximum velocity and turbulence intensity compared to the Bjork-Shiley valve which has a recirculation region near the wall (Figure 3-36 and Figure 3-37).

(ii) Disc affected character of the flow in case of the Bjork-Shiley valve was found to persist for L/D=3 to 4 (Figure 3-37).

(iii) The Bjork-Shiley valve not only exhibits higher turbulence intensity even though it has a larger opening, but it persists for a longer distance downstream (Figure 3-37). Figliola and Mueller [19] as well as Fukushima and his associates [83] have also arrived at similar conclusions.

3.4.4 Effect of Reynolds number

Figures 3-39 to 3-41 show effect of the Reynolds number on the wake velocity profiles for the Starr-Edwards ball (2M6120), Bjork-Shiley tilting disk (29MBRP), and St. Jude medical (27M) valves. It is apparent that over a range of the Reynolds numbers tested, general shape of the profile remains essentially unaffected for the Starr-Edwards configuration (Figure 3-39) except for minor local deviations in the details. With an increase in the Reynolds number, flow is further diverted outwards as indicated by the proximity of the peak velocity closer to the wall (0.5D). Furthermore, size
Figure 3-36 Downstream variation of velocity profile and turbulence intensity associated with the Starr-Edwards prosthesis (3M6120)
Figure 3-37 Downstream variation of velocity profile and turbulence intensity associated with the Bjork-Shiley prosthesis (27MBRC)
Figure 3-38 Downstream variation of velocity profile and turbulence intensity associated with the St. Jude prosthesis (27M)
Figure 3-39 Effect of the Reynolds number on the wake velocity profile for the Starr-Edwards ball prosthesis (2M6120)
of the separation region is reduced as indicated by a smaller reversed flow region (1D). It seems, however, strength of circulation immediately downstream of the ball location is increased as indicated by larger regurgitant velocities. Note, the velocity profile at 2D for \( Re=4345 \) suggests that an increase in the Reynolds number promotes mixing the wake region.

The Bjork-Shiley tilting disk valve (Figure 3-40) shows similar insensitivity to the Reynolds number as indicated by almost identical peak velocity at 0.5D location and similarity in general character of the velocity profiles. The St. Jude Medical valve, on the other hand, shows definite effect of an increase in the Reynolds number (Figure 3-41). At \( Re=509 \) three openings of the valve produce uneven flow at the orifice. The peak velocity in the central region is noticeably lower than that in the outer openings (0.5D). The unevenness grows as the fluid proceeds downstream and eventually forms two distinct peaks without any noticeable velocity loss even at 2D. As the Reynolds number increases, the flow becomes more coherent in the central region resulting in a small reduction in velocity in the outer openings, and smaller peak values than the previous case. With further increase in the Reynolds number (\( Re=2658 \)), flow through three openings tends to be more evenly distributed and results in a relatively flatter velocity profile at 1D downstream. As the fluid moves further, the flow field becomes more mixed and quick dissipation follows.

Figures 3-42 and 3-43 show the effect of Reynolds number at two locations: 1D, 2D downstream for the St. Jude prostheses. From the diagrams (particularly Figure 3-43) it can be concluded that an increase in the Reynolds number tends to smooth the velocity peaks as the Reynolds number approaches 2000. Above \( Re=2000 \), velocity profiles were found to be identical.
Figure 3-40 Effect of the Reynolds number on the wake velocity profile for the Bjork-Shiely tilting disc prosthesis (29MBRP)
Figure 3-41 Effect of the Reynolds number on the wake velocity profile for the St. Jude prosthesis (27M)
Figure 3-42 Velocity profiles at L/D=1 for the St. Jude prosthesis (27M)
Figure 3-43 Velocity profiles for the St. Jude valves showing the peak velocity to be associated with the lower Reynolds Number (L/D=2)
3.4.5 Effect of valve size

Ideally one would like to predict the hydrodynamic performance of different sizes of a given valve configuration (say the Starr-Edwards) from tests conducted on an available model. To this end the effects of model size on wake parameters would be useful. Figure 3-44 shows the velocity profile at L/D=0.5 for two identical Starr-Edwards models differing only in size. Their annulus diameter of 17.8 mm and 21.5 mm correspond to area ratio of 1:1.5. When the local velocity is nondimensionalized using U, the velocity profiles are quite different, as expected, because U does not account for the difference in annulus diameters. However, nondimensionalizing the data using annulus velocity $V_0$ should, theoretically, collapse the plots to a single curve. Figure 3-45 shows this trend towards a single curve, but the collapse is not quite complete because of several factors: The expansion ratio (i.e., annulus diameter/tube diameter) and hence the expanding flow patterns with associated losses are different for the two cases. Slight misalignment at the valves and minor poppet oscillations upon impacting the cage would also contribute to the same end.

3.4.6 Frequency analysis of the wake

High level of shear stress is known to have adverse effect on blood flow as it promotes deformation, functional impairment and even destruction of cell constituents. The total shear stress is composed of viscous and turbulence based components. Contribution of the viscous shear stress at the wall was presented earlier. In order to determine the level of turbulent stress (Reynolds stress), velocity fluctuations in two orthogonal directions must be known.
Figure 3-44 Effect of size on nondimensional velocity profile for the Starr-Edwards prostheses (2M6120 and 21.5 mm unidentified, see Table 2-1) based on velocity at the upstream area.
Figure 3-45 Effect of size on nondimensional velocity profile for the Starr-Edwards prostheses (2M6120 and 21.5 mm unidentified, see Table 2-1) based on velocity at the annulus area.

<table>
<thead>
<tr>
<th>d(mm)</th>
<th>Rn</th>
</tr>
</thead>
<tbody>
<tr>
<td>21.5</td>
<td>3846</td>
</tr>
<tr>
<td>17.8</td>
<td>4246</td>
</tr>
</tbody>
</table>
A relatively recent development of two-beam LDA accomplishes this. Unfortunately, the present experimental set-up allows for measurement of only one velocity component at a time. Thus the direct measurement of the Reynolds stress was not possible. Even measurement of turbulence intensity in a direction transverse to the flow would involve extensive modification in the test-arrangement. Although it could provide some qualitative information concerning regions of high shear stress, it is unlikely to add to the information already presented. On the other hand, a frequency analysis of velocity would provide better physical appreciation as to the mechanism governing the flow field.

Figure 3-46 to 3-48 show the spectrum densities at selected locations for the Starr-Edwards, Bjork-Shiley and St. Jude valves.

The Starr-Edwards prosthesis (Figure 3-46), being a peripheral flow device, creates two velocity peaks which correspond to high turbulence intensity regions. Immediately behind the occluder, the separated shear layers form a wake with a relatively slowly moving flow. The velocity spectrum in this region is primarily composed of low frequency turbulence. Moving outwards, the flow becomes more turbulent as it interacts with the fast moving jet flow. This mixing region is characterized by a higher frequency component. Moving further outwards, approaching the peaks, an increasing contribution at all frequency components is observed. This is the area where the effect of vortex shedding from the ball occluder is felt resulting in a substantial increase in contribution of low frequencies. In the peak flow region, turbulence intensity remains high but the low frequency contributions slightly decline together with a small increase around 100 Hz. Beyond this the frequency spectrum remains virtually unchanged. Thus the spectrum is governed by the disturbance generating mechanism. As mentioned before, the region slightly inside the peak is affected by the
Figure 3-46 Variation of the spectrum densities at selected locations for the Starr-Edwards prosthesis (ZM6120)
vortex shedding from the ball while the flow in the outside regime is
governed by the ring vortex from the valve seat.

Although the Bjork-Shiley valve (Figure 3-47) with its two-peak velocity
profile produces equally high turbulence intensities in that region, an
examination of the frequency spectrum shows distinctive features. The major
flow region is characterized by a high speed jet injected into a relatively
slowly moving flow field, resulting in high frequency turbulent mixing. The
peak in the secondary flow regime is more likely affected by the separating
shear layer from the disk occluder, and hence is dominated by the low
frequency spectrum. Note the spectrum at the peak in the primary flow is
rather different than that in the stagnation region where the turbulence
intensity is quite small. While the stagnation region shows predominantly
a low frequency spectrum the peak flow region is essentially free of the low
frequency components. A small peak around 70 Hz is probably due to the
orifice ring at annulus of the Bjork-Shiley valve.

Two half-discs of the St. Jude valve (Figure 3-48) produce a rather
complex frequency spectrum in the wake. The low frequency content in the
recirculation region suggest slowly moving disturbances. Progressing
inwards, a jet type of flow creates turbulent mixing thus introducing a
high frequency component. A small peak around 100 Hz is due to the orifice
ring as in the two previous cases. Further inwards, the turbulence mixing
becomes more vigorous thus increasing the overall frequency component.
At the peak flow, however, the spectrum showed a more steady character,
as in the case of the Bjork-Shiley valve, suggesting the so called potential
core. This is followed by a separating flow from the half-disc which
creates, another turbulent area. As expected, low frequencies dominate the
spectrum. Finally, at the center, the flow becomes less turbulent suggesting
a potential core type flow. This region, however, is affected by the two
Figure 3-47: Variation of the spectrum densities at selected locations for the Bjork-Shiley prosthesis (27MBRC)
Figure 3-48 Variation of the spectrum densities at selected locations for the St. Jude prosthesis (27M)
neighboring half-discs and the orifice ring thus producing a rather unique frequency spectrum.

3.5 Effect of the Size of the Downstream Section

For mitral and aortic valves, the downstream section corresponds to the left ventricle and aorta, respectively. In practice nominal size of the human aorta and left ventricle vary depending upon age, sex, geographical location, racial character and many other factors. Even for a given heart, size of the left ventricle changes significantly over a cardiac cycle. To get some appreciation as to the influence of the downstream section on the fluid dynamical parameters mentioned earlier, its size was varied systematically. Three downstream sections were used to assess the effect of unchanged (straight or nominal), contraction (smaller than nominal) and expansion (larger than nominal) conditions.

Figures 3-49 to 3-51 show the wake pressure distribution and recovery as affected by the downstream tube size and the Reynolds number. Although the Reynolds number effect is essentially the same for the three tube sizes tested, the rate and amount of pressure recovery is considerably different. Note, the smaller downstream tube (Figure 3-49) results in a substantially rapid and larger pressure recovery compared to the bigger tube (Figure 3-51). In both the cases the same size of a Starr-Edwards valve is used (2M6120, 17.8 mm orifice dia.). Figure 3-52 summarize this effect of size for a Reynolds number around 7500. While smaller tube completes the pressure recovery process within 1-1.5D, for the large tube the recovery is delayed to 2.5-3D. For the nominal downstream section it was in between, 1.5-2D. Note, both larger as well as smaller sections result in higher negative peak pressure compared to that for the nominal size tube. This is true within
Figure 3-49 Effect of the Reynolds number on pressure variation across the Starr-Edwards prosthesis (2M6120) with smaller downstream test-section.
Figure 3-50 Effect of the Reynolds number on pressure variation across the Starr-Edwards prosthesis (2M6120) with nominal downstream test-section
Figure 3-51 Effect of the Reynolds number on pressure variation across the Starr-Edwards prosthesis (2M6120) with larger downstream test-section
Figure 3-52 Effect of downstream test-section sizes on pressure variation across the Starr-Edwards prosthesis (2M6120) at around Rn=7400
Although both the larger and the smaller tubes show an increase in the negative pressure immediately across the valve, fluid dynamical mechanism associated with the two cases is quite different. For the smaller downstream section, as in the case of a sudden contraction, average flow velocity downstream of the valve location will be much higher than the in the nominal tube case. This leads to a higher negative pressure as the fluid enters the smaller test-section. Higher velocity and more vigorous mixing would normally result in a lower level of pressure recovery than that in the nominal condition if there were no additional changes in the flow passage. For the Starr-Edwards valve, however, the situation is slightly different as the occluder poses additional constraint on the flow. A rapid and significant recovery of pressure suggests that the ball occluder, together with the surrounding wall, actually create a favorable condition for pressure recovery. A larger blockage ratio results in an accelerating flow due to contraction so that the mixing is restricted leading to a quick and relatively large pressure recovery. For the larger downstream tube, however, the situation is quit different. As in the case of a sudden expansion, the energy loss because of vigorous mixing of flow resulted in a higher negative pressure compared to that in the nominal case. Since the blockage ratio for the occluder in this condition is low, dissipation of energy due to mixing continues to play its role further downstream resulting in a lower pressure recovery than that for the nominal tube.

In Figure 3-55 variation of pressure coefficient is plotted as a function of the Reynolds number for three different test-sections. Up to the Reynolds number of $10^4$, both smaller and larger test-sections, which represent the condition of sudden contraction and sudden expansion respectively, show a slightly higher pressure difference than that for
Figure 3-53 Effect of downstream test-section sizes on pressure variation across the Starr-Edwards prosthesis (2M6120) at around Rn=5000
Figure 3-54 Effect of downstream test-section sizes on pressure variation across the Starr-Edwards prosthesis (2M6120) at around Rn=12000.
Figure 3-55 Variation of pressure coefficient \( (C_p) \) as a function of Reynolds number for three different downstream test-sections.
the nominal section, due to additional energy losses contributed by the sudden contraction and expansion. For a Reynolds number above $10^4$, however, the behavior was observed to be quite different. While the nominal test section result shows continual change in pressure coefficient with an increase in the Reynolds number, the smaller test section results shows the reverse effect in the higher Reynolds number range. On the other hand, the larger section results seem to follow the trend similar to that of the nominal tube, however, no clear conclusion can be established as the data does not extend sufficiently in the higher Reynolds number range.

Figure 3-56 shows the variation of discharge coefficient ($C_d$) as a function of the Reynolds number and test-section size. As in the previous case, both the smaller and the larger downstream sections gave consistently lower $C_d$ up to the Reynolds number of $10^4$ due to the additional energy loss. Note the trends similar to those observed in Figure 3-55 for unchanged and reduced sections. The larger tube results, although limited, seem to indicate that it too follows the trend set by the nominal unchanged section.

Figure 3-57 presents the data on percent recovery as affected by the size of the downstream sections. Results for the nominal test-section shows only a slight dependency on the Reynolds number up to $R_n = 10^4$ and are essentially independent in the higher Reynolds number range. The large section also shows a similar trend. On the other hand, the contraction effects seem to be highly dependent on the Reynolds number over the entire test-range ($10^3$-$4\times10^4$). Note, the pressure recovery improves as the Reynolds number increases. This means that there should be a reversal in trend immediately across the valve as the Reynolds number is increased. Detailed observation of pressure distribution (Figure 3-49) reveals that this is indeed so.

Figure 3-58 shows velocity profiles at three different downstream sections. Peripheral character of the flow peculiar to the Starr-Edward
Figure 3-56 Variation of discharge coefficient (Cd) as a function of Reynolds number for three different downstream test-sections.
Figure 3-57 Variation of percent recovery of pressure as affected by the size of the downstream test-section.
Figure 3-58: Downstream variation of velocity profile and turbulence intensity associated with the three different downstream test-sections.
ball valve is evident in all the three cases as indicated by the distinctive two peaks at around 0.5D location. While the larger and the unchanged section experienced similar peak velocity the smaller tube, as expected, showed a large value due to the narrowing of the flow passage. Of particular interest is an increase in the turbulence intensity due to both sudden contraction and sudden expansion. With the progress of the flow downstream to 1D, a decay in peak velocity for the contraction case is clear. Note at around 1.5D the velocity profile in the smaller tube tends to be uniform and turbulence intensity is lower than that for the other two cases. This indeed confirms the earlier observation concerning better recovery in the smaller test-section.
4. DISCUSSION OF RESULTS OBTAINED USING THE PULSATILE FLOW FACILITY

With the knowledge of the valve performance under several steady flow conditions in hand, the next logical step would be to extend the study to the unsteady case represented by a typical cardiac cycle. The results of steady state experiments such as pressure difference across a valve, pressure recovery in the wake, discharge coefficient, velocity profile, turbulence intensity, etc., as affected by the Reynolds number, valve configuration, size of the valve and downstream test-section size help us to understand fluid dynamical characteristics of prosthetic heart valves under fully open condition. The results and their correlation with the incidence of stenosis, hemolysis and thromboembolism assist in establishing the role of fluid dynamical parameters in valve failures. This is an essential prerequisite in improvement of the present configurations and development of newer ones.

The steady state experiments, though useful, lack one of the fundamental parameters of pulsatile character. It is time independent and simulates only the fully open condition of the valve. Obviously, a heart valve in practice undergoes time dependent movements. Any realistic test of a prosthetic heart valve must simulate this physiological condition. Obviously, radically different nature of valve designs, with the associated distinct movements of the occluder, would result in fluid dynamical characteristics peculiar to the individual configuration. Opening and closing phases of the valve action during a cardiac cycle, which is valve configuration dependent, would obviously influence the transient fluid dynamics. One is thus forced to respond to two fundamental questions: How does the pulsatile flow affect the fluid dynamical parameters assessing valve performance under the steady state condition? Is it possible to establish a correlation between the two? The questions are challenging and the response to them in general has been, so far, elusive. The magnitude of the challenge
can be appreciated by a large number of variables involved and the need for their precise simulation for dependable information. As in the case of the steady state experiments, pressure and velocity are affected by valve configuration, size, shape of the test section, Reynolds number as well as the cardiac time history, beats per minute, compliance, peripheral resistance, characteristic resistance, etc. Limitations imposed by the instrumentation add to the problem. Obviously, it is impossible to cover every combination of these parameters within a reasonable time frame and hence one is forced to identify more important parameters affecting the valve performance for study.

4.1 Comments on Pulsatile Flow Experiments

Before proceeding with the presentation and discussion of results, a few comments concerning the pulsatile flow experiments would be appropriate. As previously described (section 2.4.2) the cardiac pulse duplicator is equipped with three physiological pressure transducers, two electromagnetic flowmeters, a positive displacement transducer, and the LDA system to monitor fluid dynamical characteristics of prosthetic heart valves. Since the shape of the physiological pressure, flow rate, piston movement and local velocity involve steep gradients, instrument response plays an important part in data interpretation. When one is looking for a difference between two parameters during a period of time when they are following very nearly a step input, an adequate frequency response is essential to avoid an undesirable phase shift. Sutterer and Wood [105] have illustrated how improper and unmatched responses can introduce drastic errors in interpretation of the true event. Normally pressure is measured using a pressure conducting tube. When the response of a pressure transducer is analyzed diameter, length and other physical properties of the conducting
tube and fluid must be taken into account. As pointed out by Duff [55], the fluid dynamical response of the pressure transmitting line and the transducer diaphragm are frequently overlooked. Normal practice, therefore, is to use similar transducers with identical pressure conducting lines during calibration and experiment. To minimize the problem, the three pressure transducers were directly connected to the tap location to avoid any unwanted phase delay due to pressure conducting lines. Signals from magnetic flow meters or local velocity from the LDA system do not rely on mechanical conduction of signals and hence have far superior frequency response characteristics.

Ideally, signals from a transducing system should give the desirable information free of any distortion in terms of magnitude and phase shift. Unfortunately, this is seldom the case. Signals usually carry unwanted information in terms of background noise introduced by electrical interference and mechanical vibrations. Filtering of signals can reduce the problem only at a cost of phase shift and magnitude change. Signal processing, therefore, is a compromise between frequency response and noise reduction. After considerable experimentation, signals from transducers (except from LDA) were processed by an identical set of low pass filters with a cutoff frequency of 30 Hz. This resulted in satisfactory pressure signals with minimum amount of frequency shift. Determination of the zero pressure point was a source of concern as mentioned earlier in Chapter 2. Insufficient torque of the stepping-motor limited the flow rate to a lower value resulting in small pressures. This tended to magnify percentage errors due to a zero pressure shift. In spite of considerable care, the error due to a drift in zero pressure could not be eliminated entirely. Fortunately, the errors were sufficiently small not to affect the trends.
4.2 **System Parameters**

Any new experimental system requires calibration to identify the effects of major parameters on measured data.

In the earlier history of in vitro experiments with prosthetic heart valves, importance of system parameters on pressure and flow rate profiles were either neglected or overlooked. The main objective of a pulsatile simulation facility is to test prosthetic valves under a condition closely representing the physiological one. The proper arrangement of system parameters is therefore important to simulate characteristics of the circulation system. As discussed in Appendix A, simulation of the circulation system can be achieved in several different ways. The procedure adapted in this experimental study is similar to the one proposed by Westerhof [94]. It includes characteristic resistance offered by a filter element after the straight aortic section, the compliance provided by an air-volume after the filter element, and the peripheral resistance due to a valve downstream of the windkessel (which houses the filter element and the air-chamber). These help simulate physiological pressure and flow condition at the heart valve locations. Hence a systematic test program was undertaken to identify their effects on pressure and flow rate profiles.

4.2.1 **Effect of compliance**

The effect of compliance was assessed by systematically changing air-chamber volume of the mock circulation system at a constant pulse rate nominally set at 71 beats per minute. Prosthetic valves used in this series of experiments were the St. Jude (27M) at the mitral location and the Starr-Edwards (21.5 mm annulus diameter) at the aortic location. When the peripheral resistance was set to give the peak ventricle pressure of around
160 mmHg, the compliance had virtually no effect on flow rate either at the mitral or the aortic location as indicated in Figure 4-1. This is understandable since the flow between the heart chamber is governed by the pressure difference across the valve separating the chambers. Thus for the same geometry of valves the flow rate characteristics are expected to be near identical. On the other hand, effect of compliance was more noticeable in the pressure wave-forms especially during the systole portion of the cardiac cycle. As clearly shown in the Figure 4-1, a decrease in the air-chamber volume is associated with a decrease in the first peak and an increase in the second peak pressure value resulting in an overall pressure increase. Since the air-chamber is acting as an energy absorbing device, a reduction in the chamber volume implies a lower capacity for energy storage during the cardiac cycle. A decrease in the chamber volume resulted in an increase in pressure which is higher if the initial volume is small. Thus an increase in pressure during the systole phase of the ventricle movement and a rapid decay of aortic pressure during the diastole phase is understandable. In other words, the aortic pressure tries to follow the changes in ventricle pressure because of the reduced energy storage capability of the compliance module due to a smaller air-volume. At the end of systole and the beginning of diastole, the ventricle and aortic pressures begin to fall simultaneously until the aortic valve closes. This occurs at almost the same instant of time despite different values of compliance. The time required to close the aortic valve, from the instant of phase change from systole to diastole, is essentially unaffected by the air-volume. However, the resulting aortic pressure at the time of valve closure is higher for the small compliance case. Subsequent decay of the aortic pressure, as mentioned before, depends on the air-volume. For small air-volume with its smaller energy storing capacity, decay of the aortic pressure is rapid. Thus the compliance affects the peak pressure, the pressure at the instant of aortic valve closure and decay of
Figure 4-1 Pressure-flow rate records as affected by the change in compliance. Air volume: (a) 2964 ml; (b) 2153 ml; (c) 1342 ml; (d) 1099 ml
Figure 4-1 Pressure-flow rate records as affected by the change in compliance. Air volume: (e) 694 ml; (f) 369 ml
4.2.2 Effect of characteristic resistance

Effect of characteristic resistance was studied for two different values of peripheral resistance at 71 beats per minute. The stroke volume used in this set of experiments was approximately 53 ml. The results showed that an increase in the characteristic resistance leads to a corresponding increase in peak ventricle and aortic pressures while the minimum ventricle and atrium pressures remained essentially unaffected. This is understandable since the characteristic resistance is a measure of the obstruction offered by the cardiovascular system downstream of the aortic valve. Hence the resisting element has a substantial effect on the aortic flow while the mitral condition remains unchanged. As Figure 4-2 clearly shows, only portion of the cardiac cycle affected corresponds to the forward aortic flow phase. It is of interest to note that the aortic pressure drop is quite sensitive to the characteristic resistance but not so for the mitral case. This seems to confirm the observation made earlier concerning the nature of the flow through the valves. As emphasized before, flow is regulated by the pressure difference across a valve and its physical characteristics, i.e., anatomical features. These factors being fixed during the test, resulting flow should have similar pressure difference and flow rate profiles. However, the similarity was confined to only small changes in characteristic resistance. A large change in the characteristic resistance, as indicated by Figures 4-2 a and Figure 4-2 h, the effect becomes more apparent. When the resistance is small (Figure 4-2 a), the flow progresses almost uninterrupted, the peak pressure build-up is low, and the major volume of the flow is delivered quickly. Note, the flow rate data in this series of experiments were filtered heavily to minimize the aortic pressure.
Figure 4-2  Pressure-flow rate records as affected by the change in the characteristic resistance. Filter insertion: (a) 0 %; (b) 8.3 %; (c) 16.6 %; (d) 25 %
Figure 4-2 Pressure-flow rate records as affected by the change in the characteristic resistance. Filter insertion: (e) 33.3%; (f) 50%; (g) 66.6%; (h) 100%
fluctuations, hence there is a time delay in the profile (as indicated by the early large peak). A significant increase in the characteristic resistance resulted in higher ventricular and aortic pressures as well as a higher peak pressure difference. The increased resistance also gave a longer duration of positive pressure difference to maintain the flow. It is of interest to recognize that the opening and closing pressures for the aortic valve seem to be unaffected by the characteristic resistance change, only the time history of pressure change between these two values is affected. To summarize, the effect of characteristic resistance is confined to the phase of the cardiac cycle when forward aortic flow takes place. It increases the peak ventricle and aortic pressures. However, it does not affect either the pressure difference or the flow rate at the mitral valve position.

4.2.3 The Effect of Peripheral Resistance

Influence of the peripheral resistance was assessed by adjusting opening of its downstream valve. Effect on the pressure difference and flow profile at both the locations (i.e., mitral and aortic) was quite small suggesting that these parameters are affected only by the anatomical or geometric nature of prosthetic valves used in the experiment. On the other hand, a change in the value of the peripheral resistance should affect the discharge rate or the rate at which the energy is stored. Hence the peripheral resistance should have a noticeable effect on the aortic pressure profile. As shown in Figure 4-3 (a-g), an increase in the peripheral resistance leads to a higher pressure of the onset of the closing of the aortic valve suggesting that the stored energy is greater than the leakage. A more gradual decay of aortic pressure during diastole, would suggest leakage energy rate to be small. Furthermore, the overall aortic and ventricle pressures increased
Figure 4-3  Pressure-flow rate records as affected by the change in peripheral resistance. Control valve percentage opening:  (a) 100 %; (b) 76.7 %; (c) 53.4 %; (d) 30.2 %
Figure 4-3 Pressure-flow rate records as affected by the change in peripheral resistance. Control valve percentage opening: (e) 18.6%; (f) 6.9%; (g) 2.3%
with the peripheral resistance while the pressure profiles remained almost identical during systole except during incipient closing of the aortic valve.

As observed in the previous few sections, parameters of the circulating system affect the pressure profile. With this as background one can generate a desired pressure profile by appropriately adjusting the three parameters. Pressure difference across the valve, whether in aortic or mitral position, is not significantly affected by these three circulation system parameters. Hence, if the pressure difference across a valve is the item of major concern then minor variations in the circulation system parameters will have little effect on the outcome. The system parameters were carefully adjusted to provide near physiological condition in the following experimental program: the pressure was set at around 130/80 and the pressure time history over a cardiac cycle adjusted to the nominal shape. As pointed out before, torque limitation of the stepping-motor imposed some restriction on choice of the heart rate, stroke volume and waveform. After some experimentation, a standard parameter set was established; stroke volume of 53 ml, heart rate from 60 to 90 BPM and a sinusoidal piston movement.

4.3 Explanation of the Cardiac Cycle

Typical pressure-flow records for the pulsatile test facility are shown in Figure 4-4. Here pressures from left atrium, left ventricle and aorta as well as flow rate through mitral and aortic valves together with history of ventricle volume change are presented. The sole function of the heart is to pump blood through the extensive network of blood vessels. The pressure generated by cardiac contraction accomplishes this task, the heart valves serving only to direct the flow. Time history of the flow and pressure changes induced by heart contractions are clearly shown in this figure. Since an understanding of the cardiac cycle is essential for the proper
Figure 4-4 Typical time history of pressure-flow records for the pulsatile test facility during a simulated cardiac cycle
appreciation of the valve action, analysis of the pressure-flow relation obtained from pulsatile flow tests would be useful to correlate the event to its natural counterpart. We will start our analysis with the event of systole at the left heart which is simulated by the test facility.

**Systole**

Systole, the period of ventricular contraction, is initiated in natural case by a wave of depolarization passing through the ventricle and triggering its contraction. As the ventricle contracts, it squeezes the blood contained in it and the ventricular pressure rises steeply. Almost immediately, the pressure exceeds the atrial pressure and closes the mitral valve, thus preventing backflow into the atrium. Since for a brief period the aortic pressure still exceeds the ventricular, the aortic valve remains closed and ventricle does not empty despite contraction. This early phase of systole is called isovolumetric contraction because the ventricular volume remains constant. In the present simulation facility, ventricular volume continues to change during this stage despite an absence of any flow through the aortic valve. This is because all the mitral valves tested with the cardiac simulator showed a large backflow during this phase suggesting an absence of isovolumetric condition. This brief phase ends when ventricular pressure exceeds the aortic, the aortic valve opens, and ventricular ejection begins. The ventricle does not empty its content completely; the amount remaining after ejection is called the end-systolic volume. As blood flows into the aorta, the aortic pressure rises with the ventricular pressure. The atrial pressure is supposed to rise slowly throughout the entire period the of ventricular ejection because of the flow of blood from the veins. This aspect is not simulated by the test facility since a large size of the atrium prevents any noticeable pressure rise despite the continuing return flow from the circulation system. Note, the peak aortic pressure is reached long
before the end of ventricular ejection as in the natural condition, i.e., the pressure actually is beginning to fall during the later part of systole despite the continued ventricular ejection. This is explained by the fact that the rate of blood ejection during the terminal phase of systole is quite small, less than the rate at which blood is leaving the aorta via the arterioles, leading to the pressure within the aorta to decrease.

**Diastole**

When systole ends, the ventricular muscle relaxes rapidly owing to a release of tension created during the contraction. The ventricular pressure therefore falls almost immediately below that in aorta, and the aortic valve closes. However, the ventricular pressure still exceeds the atrial value hence the mitral valve remains closed. This phase of early diastole, the mirror image of early systole, is called isovolumetric ventricular relaxation. It ends as ventricular pressure falls below the atrial, the mitral valve opens, and the ventricular filling begins. The flow is rapid at first and then slows as the atrial pressure decreases. The left atrium and ventricle are both relaxed at this stage. The left atrial pressure is nearly equal or slightly higher than that in the left ventricle and hence the mitral valve is still open. Note, the aortic valve is closed because the aortic pressure is higher than the ventricular pressure. The aortic pressure is slowly falling, because the blood is moving out, as in the natural case. In contrast, the ventricular pressure is rising slowly as the blood begins to enter from the atrium. In the natural condition, towards the end of diastole, the SA node discharges, the atrium depolarizes, the atrium contracts, and a small volume of blood is added to the ventricle. Obviously, these details are not reproduced by the cardiac simulator as there is no provision for the atrium contraction.

As seen before, despite the differences in heart movement, which is
sinusoidal in this case, the pressure-flow record follows the behavior of the heart and heart valve actions in vivo closely thus confirming the sound duplicator design.

4.4 Steady Flow Tests using the Cardiac Pulse Duplicator

In the following section pressure and flow rate results are examined for three different valve configurations. Since the effect of valve size under steady state condition was found to be almost negligible when the data is presented in nondimensional form, it is reasonable to assume that the same should be valid for the pulsatile flow case. Hence the pulsatile flow tests were conducted with the valves of a nominal diameter of 27-28 mm. The cardiac duplicator was first used in a steady state mode to provide reference information for comparison with the glycerol-water solution tunnel data as well as the pulsatile flow results.

Figure 4-5 shows variation of pressure drop across the valves (at mitral location) with steady flow rate through the simulated left ventricle of the pulsatile facility. The flow was intercepted between the compliance and a peripheral resistance units and redirected to the left atrium tank through its own orifice meter and a centrifugal pump. The arrangement gave steady flow with a minor change in the cardiac simulator thus ensuring a direct comparison of steady and pulsatile flow data. As observed in the previous chapter, the pressure drop-flow rate relation is nonlinear (parabolic) in character. This would suggest separated flow, as in the classical hydrodynamic analysis of flow through orifices, as against a linear dependence during predominance of viscous dissipation. This is understandable since all the valves under test have rounded orifices and their flow controlling components are the form of poppets, tilting disks or bileaflet half-disks. The order of performance in terms of pressure
Figure 4-5  Variation of the pressure drop with steady flow rate through the simulated left ventricle of the pulsatile flow facility for the Starr-Edwards, Bjork-Shiley and St. Jude valves
drop is the same as before: the Starr-Edwards valve has the worst performance while the St. Jude medical valve has the lowest pressure drop. To facilitate comparison between two steady flow tests, previous result are included (Figure 4-6). While the Starr-Edwards result shows almost identical trends despite physical differences in the test section shape, the same is not true for the Bjork-Shiley and St. Jude valves. Thus, as expected, test-section shape and size have definite effect on pressure drop. Hence any comparison of results in dimensional form must account for the test-section geometry. Note, the pressure is quite uniform around the circumference at a given radius (Figure 4-7) in spite of obvious flow modulations within the ventricle. Variation of pressure along the ventricle axis, however, shows a rather rapid and significant recovery (Figure 4-8). From comparison with the results of the previous chapter (corresponding to the effect of the downstream section size), it is apparent that the pressure recovery characteristic is quite similar to that of the smaller tube. Figures 4-9 to 4-11 show variation of the pressure coefficient, discharge coefficient and percent recovery of pressure with the Reynolds number for the Starr-Edwards prosthesis (2M6120). Note, the same valve was used during the downstream section size study. It is of interest to recognize that there is much more than similarity in trends - the numerical values themselves are almost identical, thus substantiating the earlier test data and the conclusions based on them. The ventricular geometry imposes a confined condition downstream creating a favorable pressure gradient thus helping the recovery process. This again emphasizes careful choice of location for pressure drop measurement to avoid misleading conclusions.
Figure 4-6 Variation of the pressure drop with flow rate for the Starr-Edwards, Bjork-Shiley and St. Jude valves during the glycerol-water solution tunnel tests.
Figure 4-7  Variation of pressure inside the simulated left ventricle during the steady flow at $\text{Rn}=8160$
Figure 4-8  A comparison of streamwise variation of $C_p$ as affected by upstream and downstream geometry of the test-section during the steady flow
Figure 4-9 Effect of Reynolds number on pressure coefficient during steady flow through the simulated left ventricle for the Starr-Edwards prosthesis
Figure 4-10 Variation of discharge coefficient (Cd) with Reynolds number for the Starr-Edwards prosthesis during steady flow through the simulated left ventricle.

$Cd = \frac{\pi}{4} \frac{Q}{d^2E\sqrt{\frac{2(Pu-Pd)}}}{\rho}$

where $E = \frac{1}{\sqrt{1 - \left(\frac{d}{D}\right)^4}}$
Figure 4-11  Pressure recovery for the Starr-Edwards prosthesis during steady flow through the simulated left ventricle
4.5 **Pulsatile Flow Results**

4.5.1 **Pressures and flow rate histories**

Figures 4-12 to 4-17 present the typical pressure-flow rate variations for Starr-Edwards (2M6120), Bjork-Shiley (27MBRC) and St. Jude (27M) valves over a range of heart rate. Several samples of enlarged scale representations are purposely included to recognize minute differences in characteristics between the valves. It is apparent that general character of the flow with pressure variations remain essentially unaffected by the valve geometry. In all the cases, mitral flow initiates as soon as the transmitral pressure becomes negative. There is no significant delay in the start of the flow and the pressure gradient responsible for it. The end of the forward flow also correlates rather well for all the three configurations. However, a careful study of details do reveal minor differences between the valves. Although the Starr-Edwards valve opens as soon as the pressure gradient becomes negative, peak pressure and corresponding peak flow rate occur a little later compared to other configurations. Note also a slightly flatter pressure and flow rate profiles for the Bjork-Shiley valve compared to the St. Jude valve, which shows the peak pressure and flow rate to occur at an early stage of the forward mitral flow phase. At the onset of systole all the valves show regurgitation until they are completely closed. The Starr-Edwards valve was found to have the highest negative flow rate as well as the longest time to closure while the St. Jude valve showed the lowest reversed flow rate and the shortest time duration to closure. These observations suggest that a relatively large mass of the ball occluder contributes to a sluggish opening and closing characteristics while a small inertia of the bileaflets (St. Jude) results in a prompt response. This was found to be valid over the entire heart rate range studied in this set of experiments. Figure 4-18 summarizes dependence of the reversed flow
Figure 4-12 Typical pressure-flow rate variation for the Starr-Edwards prosthesis (2M6120) as affected by heart rate: (a) 60 bpm; (b) 65 bpm; (c) 68 bpm; (d) 71 bpm
Figure 4-12 Typical pressure-flow rate variation for the Starr-Edwards prosthesis (2M6120) as affected by heart rate: (e) 74 bpm; (f) 77 bpm; (g) 81 bpm; (h) 85 bpm
Figure 4-13 Enlarged representation of pressure-flow rate variation for the Starr-Edwards prosthesis (2M6120) at two specific heart rates: (a) 71 bpm
Figure 4-13 Enlarged representation of pressure-flow rate variation for the Starr-Edwards prosthesis (2M6120) at two specific heart rates: (b) 81 bmp
Figure 4-14 Typical pressure-flow rate variation for the Bjork-Shiley prosthesis (27MBRC) as affected by heart rate: (a) 60 bpm; (b) 65 bpm; (c) 71 bpm; (d) 77 bpm
Figure 4-14 Typical pressure-flow rate variation for the Bjork-Shiley prosthesis (27MBRC) as affected by heart rate: (e) 81 bpm; (f) 85 bpm; (g) 90 bpm
Figure 4-15 Enlarged representation of pressure-flow rate variation for the Bjork-Shiley prosthesis (27MBRC) at two specific heart rates: (a) 71 bpm
Figure 4-15 Enlarged representation of pressure-flow rate variation for the Bjork-Shiley prosthesis (27MBRC) at two specific heart rates: (b) 81 bpm
Figure 4-16 Typical pressure-flow rate variation for the St. Jude prosthesis (27M) as affected by heart rate: (a) 60 bpm; (b) 71 bpm; (c) 81 bpm; (d) 90 bpm
Figure 4-17 Enlarged representation of pressure-flow rate variation for the St. Jude prosthesis (27M) at two specific heart rates: (a) 71 bpm
Figure 4-17 Enlarged representation of pressure-flow rate variation for the St. Jude prosthesis (27M) at two specific heart rates: (b) 81 bpm
Figure 4-18 Effect of heart rate on reversed flow as a fraction of the forward flow for the Starr-Edwards, Bjork-Shiley and St. Jude valves
data, expressed as fraction of the forward flow, on heart rate. It is apparent that the Starr-Edwards configuration has the largest back-flow while the St. Jude valve is the best in terms of regurgitation. Note also a weak dependency of the back-flow on beat rate: in general the back-flow increases with bpm. The presence of reversed flow is significant since the loss must be compensated either by an increase in the heart rate or the stroke volume. Either situation imposes more load on the heart which may prove to be critical in certain situations, such as patient with an enlarged heart.

4.5.2 Average flow rate and mean pressure

As observed in the previous section, pressure and flow rate are time dependent functions during a pulsatile flow. However, in a clinical situation, it is a normal practice to use their average values because of the complexity involved in the measurement of instantaneous real time pressure and flow rate histories. Measured mean pressure and average flow rate are then used to assess stenosed condition of a valve by estimating effective open area of the annulus using the classical Gorlin formula [97]. As pointed out during the discussion of steady flow results (section 3.1, page 72) the procedure is open to errors and can result in misleading conclusions. One aspect of concern is the use of constant discharge coefficient in the Gorlin formula which, of course, would be incorrect. As seen before it is highly dependent on the Reynolds number. Gabbay and his associates have shown [71] that the use of mean values of the pulsatile flow parameters, as normally done in clinical situations, may yield effective orifice area 10 percent smaller than that obtained using steady, root mean square or peak flow results. As observed during the steady flow tests pressure drop across a valve is related to square of the velocity, hence
it seems reasonable to use rms and not the mean flow rate value.

In this section pressure and flow rate data are examined for the three valve configurations with the mean pressures plotted against the mean, rms and peak flow rates. It may be pointed out that in calculation of the mean and rms flow rates relatively small reversed flow contribution was neglected.

Figure 4-19 shows the variation of mean pressure calculated from the pressure history during the forward mitral flow period plotted against the rms flow rate for the same period. In spite of the scattered character of the data, a similarity in trend with the steady flow results is evident. Furthermore, the results are almost numerically identical. When plotted against the mean flow rate (Figure 4-20), the trend remains similar except for a small shift to the left (slightly smaller flow rate for the same mean pressure). In general, the mean pressure drop for a given mean flow was found to be 14.3% greater on the average than that for the rms flow. This is generally in good agreement with the results presented by Gabbay and his associates [71] although the difference between rms and mean flow pressure drop was found to be slightly smaller in this experiment (within the range of experimental scatter). The peak flow (Figure 4-21), on the other hand, showed a slightly lower flow rate than the steady case which is in contrast to their results. This may be attributed to differences in test facilities and test chambers. Presence of vibrations and air bubbles in pressure conducting lines can affect results significantly. To minimize the possibility of vibration, rotational movement of the stepping-motor was converted into a translational movement through the use of a slightly flexible cable system (instead of rigid gear arrangement) to reduce the vibration level. Furthermore, a small rubber insulator was placed between the cable and piston rod. The arrangement reduced the vibration level to a minimum. The presence of any residual vibration would not affect the mean pressure over a sufficiently long period of time. However, the peak pressure
\[ \Delta P = |P_u - P_d| \]

- S-E Valve (2M6120)
- B-S Valve (27MBRC)
- SJ Valve (27M)

Figure 4-19 Variation of mean pressure during the forward flow phase with rms flow rate for the Starr-Edwards, Bjork-Shiley and St. Jude valves
Figure 4-20 Mean pressure during the forwards flow phase as affected by mean flow rate for the Starr-Edwards, Bjork-Shiley and St. Jude valves.
Figure 4-21 Pressure during peak flow rate for the Starr-Edwards, Bjork-Shiley and St. Jude valves
cannot be corrected in this manner.

4.5.3 Pressure Coefficient (\(C_p\)) and Discharge Coefficient (\(C_d\))

Although the plots of pressure drop as a function of flow rate are useful in determining valve performance, the true measure of hydrodynamic merit should be in terms of nondimensional parameters such as pressure and discharge coefficients as used in the steady flow investigation. In this study, pressure and discharge coefficients were calculated based on steady, rms, mean and peak flow conditions for the valve configurations. To facilitate comparison effective orifice area (EOA) and performance index (PI) results are also presented in the same form as suggested by Gabbay and his associates [71].

There was some discrepancy between the results corresponding to the two distinct series of experiments (one carried out early in the test program while the other at a later date) with the Starr–Edwards prosthesis. This is discussed in Appendix C.

The procedure used to calculate the pressure coefficient was described earlier in chapter 3. Variation of the pressure coefficient with Reynolds number for the valves in the pulsatile facility under steady flow condition is presented in Figure 4-22. All the valves show a decrease in \(C_p\) as the Reynolds number increases. This suggests that the valve efficiency improves at a higher Reynolds number. The amount of improvement, however, is governed by the valve design as indicated by the slope of the plots. In fact, there is a crossover point around \(Re=10^4\) beyond which the order of efficiency is changed. The Starr–Edwards valve still performs better than the Bjork–Shiley but is less efficient than the St. Jude. Comparing with the similar results of chapter 3, it seems that the difference in size and shape of the test-section affects performance of the Starr–Edwards valve much more than
Figure 4-22 Variation of pressure coefficient (Cp) with Reynolds number for the Starr-Edwards, Bjork-Shiley and St. Jude valves in pulsatile flow facility under steady flow condition.
the other two valve configurations. This is understandable due to predominantly peripheral (as against central) character of the flow with the Starr-Edwards prosthesis. Here the confined nature of the test section together with the presence of a ball occluder create a flow field which is readily affected by changes in the test-section geometry. On the other hand, the Bjork-Shiley and St. Jude valves with their central jet type flow are relatively insensitive to the character of the surroundings.

Figure 4-23 shows dependency of the discharge coefficient on the Reynolds number for the same set of valves under steady flow conditions. Note the crossover point at Re=10^4 as before. This confirms that presentation of Cd without any reference to the Reynolds number, as normally done in practice, does not represent the true fluid dynamical picture. For example, a comparison of results obtained using two different concentrations of the glycerol-water working solution with the kinematic viscosity differing by a factor of four can result in a change in Cd by 8-10%.

Figures 4-24 to 4-26 show variation of the pressure coefficient with the Reynolds number calculated using the pulsatile data based on rms and mean flow rates, mean pressure difference for the duration of forward mitral flow, and the pressure coefficient based on the peak flow rate and the corresponding pressure difference. Although a scatter in the data is evident, pressure coefficient based on the rms flow rate (Figure 4-24) shows good agreement with the steady flow results, especially for the Starr-Edwards valve. Both the Bjork-Shiley and St. Jude valves show slightly lower Cp values than the steady case. The pressure coefficient based on the mean flow rate (Figure 4-25) tends to over estimate the value although the difference is rather small. However, the pressure coefficient corresponding to the peak flow rate (Figure 4-26), is considerably larger than that given by the other two reduction procedures. This may be due to minor vibrations of the pulse
Figure 4-23 Variation of discharge coefficient (Cd) with Reynolds number for the Starr-Edwards, Bjork-Shiley and St. Jude valves in pulsatile flow facility under steady flow condition
Figure 4-24 Variation of pressure coefficient (Cp) with Reynolds number for the Starr-Edwards, Bjork-Shiley and St. Jude valves based on mean pressure during the forward flow phase and rms flow rate.
Figure 4-25 Variation of pressure coefficient (Cp) with Reynolds number for the Starr-Edwards, Bjork-Shiley and St. Jude valves based on mean pressure during the forward flow phase and mean flow rate
Figure 4-26 Variation of pressure coefficient ($C_p$) with Reynolds number for the Starr-Edwards, Bjork-Shiley and St. Jude valves at peak flow rate.
duplicator as mentioned before. The discharge coefficient (Figure 4-27 to 4-29) shows a similar trend. Note neither Cp nor Cd establish clear order in terms of relative performance. Perhaps this is due to the Reynolds number range close to the boundary layer transition. Average pulsatile flow values and the corresponding steady flow results together with the EOA and PI data are summarized in Table 4-1.

The results suggest that the different types of occluders affect Cd and Cp results essentially in the same manner irrespective of the reduction procedure adapted (rms, mean or steady flow). Compared to the steady flow data, the rms reference gave 2.3 % higher Cd on the average while the mean results predicted around 4.6 % lower values. The table also presents information on the Effective Orifice Areas (EOA) computed using four different references: rms, peak, mean or steady flow. It is apparent that the EOA results based on rms, mean or steady flow are very similar. However, the mean flow tends to under estimate the open area by 6.4 % compared to the rms reference, which is generally in good agreement with the results by Gabbay et al. [71].

4.6 Velocity Measurements
4.6.1 Procedure for analysis of the measured data

Figure 4-30 shows three typical traces of signals obtained during the experiment: velocity signal from the LDA system (top); flow rate through the mitral magnetic flow meter (center); and signal from the positive displacement piston (bottom).

The traces clearly reveal the dominant periodic nature of the phenomenon with intermittent turbulence superposed on it. The LDA trace shows that velocity at the measuring location increases rapidly with the initiation of the mitral flow and becomes highly disturbed as the maximum velocity
Figure 4-27 Variation of discharge coefficient (Cd) with Reynolds number (Re) for the Starr-Edwards, Bjork-Shiley, and St. Jude valves based on mean pressure during the forward flow phase and rms flow rate.

\[
Cd = \frac{\pi d^2}{4} E \sqrt{\frac{2(\rho u - \rho_f)}{\rho}}
\]

where \( E = \sqrt{\frac{4}{D^4}} \)
Figure 4-28 Variation of discharge coefficient ($Cd$) with Reynolds number for the Starr-Edwards, Bjork-Shiley and St. Jude valves based on mean pressure during the forward flow phase and mean flow rate.

$Cd = \frac{Q}{\frac{d^2}{4} \sqrt{2(E_{Pu-Pd})}}$ where $E = \frac{1}{\sqrt{1-(\frac{d}{D})^4}}$
\[ Cd = \frac{Q}{\frac{\pi}{4} d^2 E \sqrt{\frac{2(P_{u} - P_{d})}{\rho}}} \]

where

\[ E = \frac{1}{\sqrt{1 - \left(\frac{d}{D}\right)^4}} \]

Figure 4-29 Variation of discharge coefficient (Cd) with Reynolds number for the Starr-Edwards, Bjork-Shiley and St. Jude valves at a peak flow rate.
Table 4-1 Summary of discharge coefficient (Cd), pressure coefficient (Cp), effective orifice area (EOA) and performance index (PI) for the Starr-Edwards (2M6120), Bjork-Shiley (27MBRC) and St. Jude (27M) valves obtained using rms, mean, and peak flow data. Note, corresponding steady data are also included to facilitate comparison.

<table>
<thead>
<tr>
<th>Type</th>
<th>Cd</th>
<th>Cp</th>
<th>EOA</th>
<th>PI</th>
<th>Rn</th>
<th>Cd</th>
<th>Cp</th>
<th>EOA</th>
<th>PI</th>
<th>Rn</th>
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<tr>
<td>rms</td>
<td>S-E</td>
<td>0.727</td>
<td>1.847</td>
<td>1.808</td>
<td>0.294</td>
<td>11651</td>
<td>0.733</td>
<td>1.812</td>
<td>1.824</td>
<td>0.296</td>
</tr>
<tr>
<td></td>
<td>B-S</td>
<td>0.730</td>
<td>1.795</td>
<td>2.776</td>
<td>0.485</td>
<td>9203</td>
<td>0.698</td>
<td>1.957</td>
<td>2.653</td>
<td>0.463</td>
</tr>
<tr>
<td></td>
<td>SJ</td>
<td>0.733</td>
<td>1.774</td>
<td>2.864</td>
<td>0.500</td>
<td>9329</td>
<td>0.710</td>
<td>1.889</td>
<td>2.773</td>
<td>0.484</td>
</tr>
<tr>
<td>mean</td>
<td>S-E</td>
<td>0.684</td>
<td>2.083</td>
<td>1.702</td>
<td>0.276</td>
<td>10970</td>
<td>0.732</td>
<td>1.816</td>
<td>1.822</td>
<td>0.296</td>
</tr>
<tr>
<td></td>
<td>B-S</td>
<td>0.680</td>
<td>2.067</td>
<td>2.584</td>
<td>0.451</td>
<td>8460</td>
<td>0.695</td>
<td>1.976</td>
<td>2.640</td>
<td>0.461</td>
</tr>
<tr>
<td></td>
<td>SJ</td>
<td>0.667</td>
<td>2.036</td>
<td>2.675</td>
<td>0.467</td>
<td>8613</td>
<td>0.702</td>
<td>1.930</td>
<td>2.743</td>
<td>0.479</td>
</tr>
<tr>
<td>peak</td>
<td>S-E</td>
<td>0.646</td>
<td>2.336</td>
<td>1.608</td>
<td>0.261</td>
<td>15569</td>
<td>0.744</td>
<td>1.758</td>
<td>1.852</td>
<td>0.301</td>
</tr>
<tr>
<td></td>
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<td>0.735</td>
<td>1.762</td>
<td>2.872</td>
<td>0.502</td>
</tr>
</tbody>
</table>

Cd = \( \frac{Q}{\pi d^2 E \sqrt{2(Pu-Pd)}} \)

where \( E = \frac{1}{\sqrt{1-(\frac{d}{D})^4}} \)

Cp = \( \frac{Pu-Pd}{\frac{1}{2} \rho Vo^2} \)

EOA (effective orifice area) = Cd x measured internal orifice area

PI (performance index) = EOA / measured external mounting area
Figure 4-30 Typical traces of signals from LDA, magnetic flowmeter and displacement transducer showing periodic nature of signals.
is reached. With the beginning of the systole, the LDA output decreases suggesting a reduction in the transient turbulence. Clearly, the nature of the flow is periodic and, indeed, well correlated with the periodic nature of the cardiac cycle.

Periodic nature of the flow together with turbulence makes its characterization rather difficult for analysis with available techniques. In a conventional steady flow test, such as the one described in Chapter 3, stochastic transient parameters such as mean and rms velocities are measured using the time averaging technique. The mean velocity is normally measured using a voltmeter equipped with an integrating circuit which in essence averages the incoming signal over a specified duration. The fluctuating velocity component is monitored using a rms voltmeter. However, in a pulsatile flow condition, like the one under investigation in this chapter, the conventional time averaging technique does not represent any meaningful fluid dynamical parameter of the flow: deviation of the signal from a time-average is not the random velocity fluctuation. Hence an alternate approach involving elaborate measurements and analysis such as the concept of phase average [106], use of a high-pass filter and smoothing of instantaneous velocity signals [107] was adopted. A high-pass filter provided turbulence component rather simply and directly. However, it cannot smooth or average a periodic signal over a number of cycles which is necessary to chart the instantaneous velocity distribution within the test-section (model left ventricle). The phase average technique represents an appropriate approach if the periodic velocity is quite consistent. The technique identifies the deterministic part of the periodic signal so that deviation from this average gives a true measure of the velocity fluctuations. However this demands a high degree of consistency between the successive cycles in the details of shape as well as magnitude.

The flow field downstream of a valve is indeed complex. It is affected
not only by the presence of the valve but also by the movement of its components. It is, therefore, reasonable to expect small variations in periodic velocity signals which may introduce error if the conventional phase averaging technique is used. Figure 4-31 emphasizes this point. The top curve represents a velocity signal over 20 cycles while the lower curve shows instantaneous velocity during the same period. It is apparent that although the periodic nature of the velocity is well presented in both the cases, the details are substantially different. Thus application of the conventional phase averaging technique would predict a higher fluctuating velocity component, since the difference between the two records includes turbulence component as well as deviation from the mean.

The approach taken involves measurement of the instantaneous fluctuation velocity following the clock signal, generated at the onset of systole by the stepping-motor controlling computer, thus identifying the measuring window. The instantaneous velocity signal is then smoothed using a forward averaging technique involving five neighboring points (including the epoch point). The process is repeated until a smooth curve is obtained. A repeat cycle of 5 was used in this study. The fluctuating velocity component (turbulence) was now obtained by subtracting the instantaneous velocity signal from the forward averaged data. A total of 20 measuring periods were averaged to obtain the final result. Figure 4-32 shows typical signals obtained using this procedure. The instantaneous signal is also included for comparison. Note the fluctuations are susceptible to noise as indicated by the presence of spikes.

4.6.2 Time history of velocity profile for the Starr-Edwards prosthesis

With some appreciation as to the data acquisition methodology, let us turn our attention to velocity profiles under pulsatile conditions.
Figure 4-31 A comparison between average velocity and instantaneous velocity together with flow rate and ventricular volume data showing slight difference in velocities.
Figure 4-32 Typical traces of average velocity and fluctuating velocity components calculated using procedure described in the text together with instantaneous velocities, flow rate and ventricular volume.
Unlike the steady flow experiments, here the flow field is affected by time and space as well as the valve configuration under study. Hence the acquisition of even sample information involved enormous time and effort. With the available apparatus and associated scanning technique which is not yet automated, it was not possible to chart the entire ventricular flow field within a reasonable time. Hence it was necessary to identify, rather carefully, appropriate regions for exploration that would yield useful information regarding the flow characteristic of the valve configuration. Figure 4-33 shows the measuring section selected for this set of experiments. Since the mitral valve axis is inclined at 20° to the axis of the ventricle and is at 65° to the LDA traversing plane, the measuring plane is not precisely parallel to the seat.

Figures 4-34 and 4-35 present velocity and turbulence intensity profiles, as affected by time and location, together with the corresponding pressure-flow relations. Time is measured from the onset of the flow. Time advances to the right while the three rows represent downstream locations as shown in Figure 4-33. The time separation between each sequence is about 40 milliseconds and the initial figure corresponds approximately to the onset of mitral flow. It is apparent (Figure 4-34) that the mitral flow initiates a little after the beginning of the diastole cycle. Initially, the flow within a ventricle is mostly due to its expansion hence the velocity everywhere is fairly uniform as indicated by a small positive flow at each downstream location. Although the downstream region close to the valve location is likely to be affected by the flow, this is not detected at any of the three measuring locations at this early stage of diastole, perhaps because of the time required by the fluid to reach the measuring locations. As the region close to the apex of the ventricle sweeps a smaller volume for a given linear displacement of the ventricle wall (compared to the upper region), and the fact that the apex is artificially fixed by a support rod during the
Figure 4-33  Top and side views showing details of inlet and exit geometries together with locations of velocity measurements.
Figure 4-34  Pressure-flow rate variation for the Starr-Edwards prosthesis (2M6120) at 71 bpm
Figure 4-35 Time history of velocity profile for the Starr-Edwards prosthesis (2M6120) as affected by locations:
(a) $T = -14$ msec to $T = 66$ msec
Figure 4-35 Time history of velocity profile for the Starr-Edward prosthesis (2M6120) as affected by locations:
(b) $T = 106$ msec to $T = 186$ msec
Figure 4-35 Time history of velocity profile for the Starr-Edwards prosthesis (2M6120) as affected by locations:
(c) T = 226 msec to T = 306 msec
Figure 4-35 Time history of velocity profile for the Starr-Edward prosthesis (2M6120) as affected by locations:
(d) $T = 346$ msec to $T = 426$ msec
Figure 4-35 Time history of velocity profile for the Starr-Edwards prosthesis (2M6120) as affected by locations: (e) T = 466 msec to T = 546 msec
Figure 4-35 Time history of velocity profile for the Starr-Edwards prosthesis (2M6120) as affected by locations:
(f) $T = 586$ msec to $T = 666$ msec
experiment thus further restricting the movement of the ventricle, the velocity generated due to expansion of the ventricle has a lower magnitude at the lowest section (section 3). This trend continues until the flow reaches the first measuring location after a lapse of around 110-130 milliseconds. At this instant the flow field assumes the classical nature of the peripheral flow profile with recirculation regions immediately behind the valve due to the presence of a ball occluder. Note the peak velocity on the left side is much larger than that on the right due to a slight difference in distance from the valve location. Negative flow at the center draws fluid from the downstream thus causing almost zero velocity at the second measuring location. As the diastole cycle progresses, peak flow at the location closest to the valve grows. Peak velocity occurs around 170 milliseconds after the initiation of the flow. Now the recirculation region becomes less noticeable as indicated by the flatter velocity profile. A possible reason might be vibration of the ball. Significant vibratory motion of the ball during the forward flow phase was observed both in mitral and aortic positions. Such vibrations of the ball prosthesis have been reported in literature for aortic valves [108,109]. Considering the fact that the pressure information suggests the flow inside the ventricle to be similar to that with a small tube in steady flow, i.e., the condition of the aortic valve, the presence of vibration is understandable. Vibration of the ball resulted in more random separation of the boundary layer than that in the steady case. A distinct separation region is, therefore, less noticeable. By this time, most of the filling through the mitral flow is completed, however, velocity within the ventricle continues to have large positive value due to inertia of the fluid. The peak flow continues to propagate as indicated by its delayed occurrence at the downstream locations.

In Figure 4-36, the peak flow condition at three measuring locations is reconstructed to determine the decay of peak velocity and turbulence
Figure 4-36 A comparison of downstream variation of velocity and turbulence intensity during pulsatile and steady flow conditions for the Starr-Edwards valve (2M6120)
Intensity. Corresponding steady flow results are also included for comparison. It is apparent that offset and inclined valve position in the pulsatile experiment generates a distinctly different flow field compared to the axi-symmetric steady flow configuration. Although the shape of the velocity profiles shows the effect of valve orientation, the peak velocity at 0.5 D for steady and pulsatile flow conditions is almost identical. Turbulence intensity, on the other hand, is significantly lower in the peak region and of comparable value in the central wake. At 0.75 diameter downstream, decay in the peak velocity and turbulence intensity are fairly comparable although the peak turbulence intensity continues to be lower. The decay of forward velocity as the fluid moves downstream to 1.0 D is rapid since the flow field is constrained by the ventricle as well as redirection of the flow as it approaches the apex region of the ventricle. The lower turbulence intensity with the pulsatile flow may be attributed to the shape of the test-section. Conical contraction of the ventricle progressively restricts random movement of the disturbed flow. Late diastole is a continuation of this process. The forward fluid motion persists although flow through the mitral valve has almost ceased. At the onset of systole, fluid motion generated by the contraction first appears near the apex region and propagates upward as suggested by a delay in negative flow at the location closest to the valve. As the systole phase progresses, all the stations register a negative flow indicating ejection of fluid from the ventricle. It is of interest to recognize the difference in timing for the peak velocity and the peak turbulence intensity. For the Starr-Edwards prosthesis peak turbulence intensity occurs slightly before onset of the peak velocity and the turbulence level during the interval continues to remain high.
4.6.3 **Time history of velocity profile for the Bjork-Shiley tilting disk valve**

As observed in Chapter 3, the Bjork-Shiley tilting disk valve create two distinct flow regimes: the major and the minor orifice flow areas. A distinctive character of these flow regions was the jet type flow with twin peaks. To help identify these features two sections were selected for measurement, one in each region. Since the major interest in this series of experiments is the identification of maximum velocity and turbulence intensity, only the location closest to the valve was used. Figures 4-37 and 4-39 show the time history of velocity and turbulence intensity at the two measuring sections mentioned as well as the pressure and flow rate variations. The convention used to present the results is the same as the Starr-Edwards case.

As in the case of the Starr-Edwards valve, initial phase of diastole is characterized by a small positive flow. This, however, lasts for a very short period and a relatively large positive flow is detected, in the major flow area, relatively earlier (30 milliseconds after initiation of the flow) than in the Starr-Edwards case. The minor flow area, however, shows very little change during this period. Although detection of the flow through the mitral valve is almost immediate, the peak flow occurs a little later (100 milliseconds after), as in the Starr-Edwards case. However, a rather rapid decay of the peak flow with time is in contrast to what was observed with the ball prosthesis. This may be due to a change in the direction of the major flow as the velocity increases. The peak velocity in the minor flow region occurs slightly later than that in the major flow, around 150-180 milliseconds after the onset of the flow. Since velocity in the minor flow region is likely be lower than that in the major flow as explained in Chapter 3, the time required to reach the measuring location is longer. The peak
Figure 4-37  Pressure-flow rate variation for the Bjork-Shiley prosthesis (27MBRC) at 71 bpm
Figure 4-38 Time history of velocity profile for the Bjork-Shiley prosthesis (27MBRC) at the major flow region: (a) $T = -8$ msec to $T = 312$ msec
Figure 4-38  Time history of velocity profile for the Bjork-Shiley prosthesis (27MBRC) at the major flow region: (b) $T = 352$ msec to $T = 672$ msec
Figure 4-39 Time history of velocity profile for the Bjork-Shiley prosthesis (27MBRC) at the minor flow region: (a) $T = -12$ msec to $T = 308$ msec
Figure 4-39  Time history of velocity profile for the Bjork-Shiley prosthesis (27MBRC) at the minor flow region: (b) $T = 348$ msec to $T = 668$ msec
values in the two flow regimes are essentially the same although the major flow intersects the measuring plane at a higher angle, i.e., the actual maximum velocity is likely to be higher. Furthermore, because of the orientation of the measuring planes, the location is slightly more downstream for the major flow region leading to a lower peak velocity. Negative flow in the minor region following the peak may be due to redirection of the major flow by the ventricle. This is indicated by the fact that, even before the systole cycle begins, a negative flow region grows in magnitude as diastole progresses. This suggests a large circulatory flow within the ventricle. As the systole phase advances, the flow in both the major and minor regions gradually become negative. Magnitude of the back flow, however, is quite different in two planes. As the large scale circulatory flow is already in progress, inertia of the fluid together with a back-flow due to contraction of the ventricle tends to reduce the negative flow in the major area while the minor flow regime tends to maintain or strengthen the negative flow. This negative flow in the minor region in turn affects the mitral flow when diastole cycle begins, which tends to delay further occurrence of the peak velocity at the minor region.

4.6.4 Time history of velocity profile for the St. Jude Medical valve

Figure 4-40 shows a typical pressure and flow rate relation over a cardiac cycle. The St. Jude valve being a central flow device, no peculiarity as exhibited by the Bjork-Shiley valve was observed during the velocity profile and turbulence intensity study (Figure 4-41). A peak flow begins slightly later than that for the Starr-Edwards valve, around 180-210 milliseconds after initiation of the flow. Once the peak flow is attained, the profile becomes fully developed in a short period of time. The velocity profile is flatter than that observed for the other two valve configurations
Figure 4-40 Pressure-flow rate variation for the St. Jude prosthesis (27M) at 71 bpm
Figure 4-41 Time history of velocity profile for the St. Jude prosthesis (27M): (a) $T = -14$ msec to $T = 306$ msec
Figure 4-41 Time history of velocity profile for the St. Jude prosthesis (27M): (b) $T = 346$ msec to $T = 666$ msec
indicating its superior flow characteristics. Major difference is the turbulence intensity which is significantly lower at the peak flow. Because of the flatter velocity profile, the major portion of the volume flow is delivered rather quickly. Hence a decay in forward velocity with the passage of time is slightly accelerated. Because of an offset between the mitral valve location and the ventricle axis, there is a small recirculation region towards the aortic valve side. Figure 4-42 shows this trend. The measuring plane offset is 3.5 mm towards the aortic valve. Note a region of negative flow (T=186-506 msec). Velocity profiles during the systole phase showed characteristics similar to those obtained with the Starr-Edwards prosthesis.

4.6.5 Effect of heart rate on velocity

In the previous section, flow characteristics based on the velocity profile was described for three valve configurations revealing their distinctive features and design differences. As mentioned before, the velocity information was obtained at a heart rate of 71 beats/min. This leads to an obvious question as to the effect of heart rate on velocity data. Results presented in this section attempt to answer this question. Measurements were carried out in the main flow region which is likely to be less affected by a change in the heart beat rate. Figures 4-43 and 4-44 show some sample results for the Starr-Edwards valve. Here, instantaneous velocity is normalized using the maximum annulus velocity based on the magnetic flowmeter record. The flow rate measured by the magnetic flowmeter was also normalized by the peak flow rate so that the profiles can be compared directly. It is apparent that both instantaneous velocity and flow rate are periodic. The instantaneous velocity shows not only the consistent periodic nature of the phenomenon but also the timing of events and the numerical values. Profiles of the flow rate also show the same
Figure 4-42 Time history of velocity profile for the St. Jude prosthesis (27M) at a station slightly towards the aortic valve:
(a) T = -14 msec to T = 306 msec
Figure 4-42 Time history of velocity profile for the St. Jude prosthesis (27M) at a station slightly towards the aortic valve:
(b) $T = 346$ msec to $T = 666$ msec
Figure 4-43 Nondimensional representations of velocity and mitral flow rate for the Starr-Edwards prosthesis. Note, the plots are essentially independent of pulse rate: (a) 60 bpm; (b) 71 bpm; (c) 81 bpm; (d) 90 bpm
Figure 4-44 Nondimensional representations of velocity and mitral flow rate for the Starr-Edwards prosthesis: (a) 60 bpm; (b) 71 bpm; (c) 81 bpm; (d) 85 bpm
trend. It is apparent that the nature of the flow is unaffected by the heart rate over the range tested. The St. Jude valve showed the same trend confirming the above observation (Figure 4-45). It is worth mentioning that turbulence intensity based on annulus velocity showed an almost identical result at a different heart rate.

4.6.7 Effect of valve configuration on peak velocity and turbulence intensity

Nondimensional Velocity Profile based on Upstream Velocity

The amount of information obtained over a cardiac cycle is rather extensive as velocity and turbulence intensity constantly change with time and spatial location. Only a typical set of results suggesting characteristics of the three valve configurations are presented here. The main parameters of interest are the peak velocity and the maximum turbulence intensity which are suspected to promote thromboembolism and hemolysis.

Figure 4-46 shows the nondimensional velocity profile and turbulence intensity (in the direction of the ventricle axis) at a station around 0.5 diameter downstream (L=0.5D) for the Starr-Edwards (2M6120); Bjork-Shiley tilting disk (27MBRC); and St. Jude Medical (M27) prostheses.

The spherical poppet is a distinctive element of the Starr-Edwards prosthesis. The incoming fluid is directed around the occluder causing the peak flow to occur between the poppet and the ventricle wall. Inclination between the valve and the ventricle axes together with an offset would obviously result in asymmetric profiles (Figure 4-46 a). Note, the maximum velocity recorded here is almost identical to that observed during the steady case while the turbulence intensity shows a smaller value in spite of a much smaller annulus opening. Complex interactions between the
Figure 4-45 Nondimensional representations of velocity and mitral flow rate for the St. Jude valve: (a) 60 bpm; (b) 71 bpm; (c) 81 bpm; (d) 90 bpm
Figure 4-46 Typical plots showing variation of nondimensional velocity and turbulence intensity (in the direction of the ventricle axis) at a station 0.5 diameter downstream for the Starr-Edwards, Bjork-Shiley and St. Jude valves using the velocity based on the upstream area: (a) Starr-Edwards (2M6120); (b) Bjork-Shiley (27MBRC) at the major flow region; (c) St. Jude (27M)
mixing layer of the jet type flow and separated shear layer from the occluder result in a high level of turbulence intensity in the peak flow region.

The Bjork-Shiley tilting disk valve, due to the nature of the occluder (disk) and its opening, produces two distinct regions identified before as major and minor flow regimes. The main velocity peak is due to the deflected jet type flow (Figure 4-46 b) caused by the disk nominally inclined at 60° to the flow when fully open. The peak flow in the minor region (Figure 4-46 c) is governed by the separating shear layer. Note a steep rise in turbulence intensity (220%) in the major flow region. Such a high level of turbulence is suspected to promote thromboembolism together with possible deformation and damage to the red cells. The peak velocity seems to have a lower value compared to the steady case data. This, of course, does not mean necessarily that the actual value is lower than the steady flow results because of the difference in orientation caused by the axes inclination and the offset.

As seen during the steady test, the St. Jude valve with its twin half-discs has a unique characteristic velocity profile. However, that unique feature was not apparent in the pulsatile flow results (Figure 4-46 c). This may be attributed to a difference in the test Reynolds numbers. For the pulsatile flow case with its higher Reynolds number, the disk boundary layer effect becomes relatively less, the flow remains essentially unaffected by their presence and three distinct peaks merge to form a flat velocity profile. However, rather complex variation in the turbulence intensity persist. As in the case of the steady flow test, in general, lower turbulence levels are associated with the St. Jude valve compared to the Bjork-Shiley, for almost the same annulus area, except for a sharp turbulence peak (maximum 200 %, Figure 4-46 c). The peak velocity also showed a significantly lower value compared to the Bjork-Shiley case which is in contrast to the steady flow data. Additional sample plots for the
Figure 4-46 Typical plots showing variation of nondimensional velocity and turbulence intensity (in the direction of the ventricle axis) at a station 0.5 diameter downstream for the Starr-Edwards, Bjork-Shiley and St. Jude valves using the velocity based on the upstream area: (d) Starr-Edwards (2M6120); (e) Bjork-Shiley (27MBRC) at the minor flow region; (f) St. Jude (27M)
same valves showed similar trends (Figure 4-46 d-f).

Nondimensional Velocity Profile based on Annulus Velocity

Figure 4-47 shows velocity profile and turbulence intensity variations for the same set of three valves with annulus velocity as the nondimensionalizing parameter. Note striking differences in magnitude of peak velocity and turbulence intensity which were not so apparent in the earlier plots using the upstream velocity as reference. The remarks made during the analysis of steady flow data are also applicable here. The inclined sharp edged disc of the Bjork-Shiley valve leads to the formation of strong vortices leading to higher levels of turbulence intensity. On the other hand, half-discs of the St. Jude valve (Figures 4-47 c and f), being aligned with the flow, resulted in a slightly lower level of turbulence compared to the Bjork-Shiley valve (Figure 4-47 b and e). As before, in general, the Starr-Edwards ball prosthesis outperforms the other two configurations (Figure 4-47 a and d).

4.7 Effect of Ball Sticking on the Valve Performance

During the course of the experimental program, some irregularity in the pressure-flow relation for the Starr-Edwards ball prosthesis was observed. Considerable attention and efforts (in terms of careful observation, checking and rechecking of calibration and repetition of tests) were directed to identify the source of discrepancy. Initially, the cause of irregularity remained a puzzle because although results during a series of experiments were consistent they differed from series to series. A detailed examination of pressure and flow rate histories, however, suggested a possibility of the ball occluder sticking to the cage under certain condition. Figure 4-48 presents typical results of pressure and flow rate
Figure 4-47 Typical plots showing variation of nondimensional velocity and turbulence intensity (in the direction of the ventricle axis) at a station 0.5 diameter downstream for the Starr-Edwards, Bjork-Shiley and St. Jude valves using the velocity based on the annulus area: (a) Starr-Edwards (2M6120); (b) Bjork-Shiley (27MBRC) at major flow region; (c) St. Jude (27M)
Figure 4-47 Typical plots showing variation of nondimensional velocity and turbulence intensity (in the direction of the ventricle axis) at a station 0.5 diameter downstream for the Starr-Edwards, Bjork-Shiley and St. Jude valves using the velocity based on the annulus area: (d) Starr-Edwards (2M6120); (e) Bjork-Shiley (27MBRC) at minor flow region; (f) St. Jude (27M)
Figure 4-48 Typical pressure-flow rate variation for the Starr-Edwards prosthesis (2M6120) as affected by ball sticking: (a) no sticking; (b) moderate sticking; (c) severe sticking
time histories as affected by a varying degree of the poppet sticking problem. All the tests were conducted with almost identical values of circulation parameters. The timing of negative transmitral pressure, which is normally the initiation of the mitral valve opening, was maintained the same in all the cases. The instant the mitral flow initiates is, however, clearly different. Under normal conditions, mitral flow starts as soon as the transmitral pressure becomes negative as shown in Figure 4-48 a. Any sticking of the ball is reflected in a delay of the flow initiation caused by friction. Figures 4-48 b and c show this trend. Since a delay in opening of the mitral valve creates the condition similar to isovolumetric expansion, there is a resulting pressure build-up during this stage. Naturally, the pressure level attained depends on the degree of delay. Because of the pressure build-up, the mitral valve opens rather suddenly causing an early and higher peak flow. Any further delay in the opening was found to result in a higher peak mitral flow rate. Thus a sticking poppet distorts the pressure-flow rate relation. Figure 4-49 shows variation of mean pressure and rms flow rate as used in studies discussed in the previous sections. It is of interest to recognize that a log-log presentation of the results shows a shift in the plots with little effect on the slope. Thus the general character of the flow remains unaffected by a sticky poppet.

Figure 4-50 shows time histories of velocity and turbulence intensity for conditions corresponding to different levels of ball sticking condition. In absence of this problem (freely moving ball), initiation of the mitral flow and attainment of the peak flow rate are relatively gradual. However, with a sticky poppet, timings of the above mentioned events are significantly altered. The interval between onset of the mitral flow and attainment of the peak flow is governed by the magnitude of the maximum velocity: it is shortest in the severe sticking condition. Corresponding velocity profile and turbulence intensity distribution reflect this difference in the maximum
Figure 4-49 Log-log representation of mean pressure drop during the forward flow phase as affected by rms flow rate and ball sticking for the Starr-Edwards prosthesis (2M6120)
Figure 4-50  Time history of velocity profile for the Starr-Edwards prosthesis (2M6120) as affected by ball sticking:
(a) no sticking
Figure 4-50 Time history of velocity profile for the Starr-Edwards prosthesis (2M6120) as affected by ball sticking:
(b) moderate sticking
Figure 4-50 Time history of velocity profile for the Starr-Edwards prosthesis (2M6120) as affected by ball sticking: (c) severe sticking
velocity (Figure 4-51). However, when the same data are nondimensionalized with respect to the maximum velocity at the annulus (Figure 4-52), the results are remarkably similar (virtually unaffected by the different conditions of the ball). Although the shape of the velocity profiles and turbulence intensity plots show some differences, probably due to the Reynolds number effect, the magnitude is almost identical indicating the fluid dynamical process to be dynamically similar.

4.8 Effect of Waveform

Present series of experiments were confined to the sinusoidal waveform, because of its simplicity, to facilitate comparison with results by other investigators when available and the limitation imposed by present stepping-motor. A question still remains as to the dependence of the results on different waveforms. In order to resolve this issue a short experimental investigation was undertaken. It attempts to assess the effect of waveform on pressure-flow rate relation. Though necessarily incomplete, it does establish useful trends. A modified waveform as shown in Figure 4-53 was used in this series of experiments.

Figures 4-54 to 4-56 show typical results obtained with the new waveform together with corresponding sinusoidal waveform results. It is apparent from the pressure-flow rate variations that even a small change in the waveform could dramatically affect their character. However, consider the log-log presentation of mean pressure against rms flow rate together with the selected original waveform data as presented in Figure 4-57. Although there is a slight shift in results for the two waveforms, the slopes are almost identical suggesting dynamical similarity. The results seem to indicate that any effect of waveform is likely to be negligible.
Figure 4-51 A comparison of peak velocities at a station 0.5 diameter downstream for the Starr-Edwards prosthesis (2M6120) as affected by ball sticking: (a) no sticking; (b) moderate sticking; (c) severe sticking
Figure 4-52 Nondimensional representation of velocity and turbulence intensity at a station 0.5 diameter downstream for the Starr-Edwards prosthesis (2M6120) as affected by ball sticking: (a) no sticking; (b) moderate sticking; (c) severe sticking.
Figure 4-53 A diagram showing shape of modified waveform in comparison with sinusoidal waveform
Figure 4-54 Typical pressure-flow rate variation for the Starr-Edwards prosthesis (2M6120) as affected by heart rate using a modified waveform: (a) 54 bpm; (b) 64 bpm; (c) 70 bpm; (d) 77 bpm
Figure 4-55 Enlarged representation of pressure-flow rate variation for the Starr-Edwards prosthesis (2M6120) using a modified waveform at 64 bpm
Figure 4-56 Corresponding presentation of pressure-flow rate variation for the Starr-Edwards prosthesis (2M6120) using a sinusoidal waveform at 71 bpm
Figure 4-57 Log-log representation of mean pressure drop during the forward flow phase as affected by rms flow rate and waveform for the Starr-Edwards prosthesis (2M6120)
5. CONCLUDING REMARKS

5.1 Summary of Results and Their Importance

The primary objectives of the research program have been fourfold:

(a) to design, construct, calibrate and instrument a steady glycerol-water solution tunnel and a pulsatile flow cardiac simulator;
(b) utilize the steady flow glycerol-water solution tunnel to study hydrodynamic performance of prosthetic mitral valves under fully open condition;
(c) study hydrodynamic performance of prosthetic mitral valves under physiological flow condition using the pulsatile flow cardiac simulator;
(d) using the results attempt to establish fluid dynamical criteria to evaluate hemodynamic performance of mechanical prosthetic heart valves.

Considering the fact that the field is rather young and evolving, the objectives presented formidable challenges at every step. Design of test facilities, instrumentation, calibration and data reduction demanded careful planning and innovation. Repeatability and accuracy of results was held to be of utmost importance leading to a considerable increase in the length of the experimental program. Looking back at the project, one can say with a measure of satisfaction and confidence that all the objectives have been realized, in some cases beyond expectation. However, it must be emphasized that this thesis represents only a small beginning in exploration of a challenging and complex problem. I have barely touched upon the fringes.

The steady glycerol-water solution tunnel and the pulsatile flow cardiac
simulator with their precise controllability and flexibility served as ideal tools for studying fundamental fluid dynamical problems associated with prosthetic heart valves.

Perhaps the most valuable contribution of the project is the fundamental results on pressure, velocity, turbulence intensity and shear stress, during both steady and pulsatile flow conditions, obtained through a carefully planned experimental program. They provide a comprehensive picture of hydrodynamic performance of widely used prosthetic heart valves and would serve as reference for future developments.

Successful identification of proper nondimensional parameters for presentation of information so that the results are essentially independent of test facilities, flow velocities, size of the models, etc., is a welcome step forward and would make comparison of data obtained by investigators using different experimental set-ups possible.

Coming to the results proper, some of the more significant conclusions may be summarized as follows:

(a) Dimensional presentation of results can lead to misleading conclusions. Presenting valve performance in terms of pressure and discharge coefficients as functions of the Reynolds number suggest the Starr-Edwards configuration to be fluid dynamically superior.

(b) There is a significant and rapid recovery of pressure in the wake which is dependent upon the valve configuration, size of downstream section and the Reynolds number. In general, the pressure recovery improves with an increase in the Reynolds number and a reduction in the size of the downstream section. In the present study it was found to be as large as 24%. Thus considering pressure drop immediately across a heart valve as a measure of its performance, as is often reported in literature, can be misleading.
(c) Configuration effect being absent for the orifices, the discharge coefficient is essentially the same for the orifices except for minor differences caused by upstream and downstream flow conditions. Furthermore, the Reynolds number dependency is virtually absent because of the fixed separation position of the boundary layer. On the other hand, Reynolds number effects are quite evident for the valves, particularly the Starr-Edwards with its spherical occluder. Furthermore, the discharge coefficient is substantially affected by the size of the downstream section due to expansion or contraction losses. The results suggest that the formulae often used to predict the open area of stenotic valves (which fail to account for the effect of Reynolds number and valve configuration,) could lead to erroneous conclusions. Results obtained using the pulsatile flow facility also substantiated this observation.

(d) The Starr-Edwards prosthesis with its recirculation region near the center shows a relatively lower value for the maximum velocity and turbulence intensity and their rapid decay in the wake compared to the Bjork-Shiley and St. Jude valves.

(e) Frequency analysis of the wake region for the three different valve configuration tested showed markedly different spectrum at the same downstream station. This would suggest the valve performance to be governed by interactions between a variety of fluid dynamical phenomena such as transition, laminar or turbulent separation, vortex shedding, etc.

(f) Adjustment of parameters characterizing the arterial and venous networks affect details of the cardiac cycle. A reduction in
compliance is associated with a decrease in the first peak pressure and an increase in the second peak value leading to an overall pressure increase. The timings of the peaks are delayed and there is a rapid decay of aortic pressure during the diastole portion of the cardiac cycle. As the time required to close the aortic valve is fairly constant, (from the time at which the cycle changes from systole to diastole), apparent aortic pressure at the time of valve closure is higher for a smaller compliance case. With a small air volume the energy storage capacity is reduced and decay in the aortic pressure is rather steep. An increase in the characteristic resistance results in a corresponding increase in the peak ventricular and aortic pressures while the minimum ventricular and atrium pressures remain essentially unchanged. Similarly, pressure drop and flow rate at the mitral location also remained substantially the same. The peripheral resistance affects pressure at the onset of the aortic valve closure as well as decay of the aortic pressure during diastole. Overall aortic and ventricle pressures increase when the peripheral resistance is raised although the pressure profile during systole remains almost unchanged (except for the pressure at the incipient aortic valve closure).

During simulation, it is not essential to reproduce the heart movement precisely. Even with a sinusoidal piston movement it was possible to mimic the pressure-flow record thus attesting to the effectiveness of the pulse duplicator as an in vitro test facility.

Steady flow tests using the Cardiac Simulator showed pressure recovery characteristics similar to those obtained using the glycerol-water solution steady flow tunnel with a smaller downstream
A confined condition within the ventricle creates a favorable pressure gradient and helps the pressure recovery process.

Although the Starr-Edwards valve opens as soon as the pressure gradient become negative, the peak pressure drop and the corresponding peak flow rate occur some time later compared to other configurations. In this context, it may be pointed out that the Bjork-Shiley valve showed slightly flatter pressure and flow rate profiles compared to those for the St. Jude valve, which displayed peak pressure and flow rate at an early stage of the forward mitral flow.

At the onset of systole all the valves showed negative flow until the valve-closure was completed. The Starr-Edwards valve had the largest negative flow rate as well as the longest duration until its closure while the St. Jude valve showed the smallest reversed flow over the shortest time. This would suggest that a relatively large mass of ball occluder adversely affects its opening and closing characteristics. Negative flow is a significant parameter since the loss of volume should be compensated either by increasing the heart rate or the stroke volume.

During the pulsatile flow study, mean pressure plotted against the RMS flow rate, not only showed a similar trend to the steady flow results but even numerical values were almost identical. However, when plotted against the mean flow rate, although the trend remained similar, the mean pressure drop for a given mean flow was about 14.3 percent greater. Note, peak flow rate was observed to be slightly lower than that in the steady case which is in contrast
to the observation by Gabbay and his associates [71].

(1) All the valves showed a decrease in \( Cp \) with an increase in the Reynolds number. Thus the valve performance improves at higher Reynolds numbers. The degree of improvement depends on the valve configuration and is relatively smaller for the ball and cage geometry. There is a cross over point around \( Re=10^4 \), beyond which the order of efficiency changes. Although the Starr-Edwards valve still performs better than the Bjork-Shiley, it is less efficient than the St. Jude.

(m) Pressure coefficient based on the RMS flow rate showed good agreement with the steady flow data especially for the Starr-Edwards valve. On the other hand, Both the Bjork-Shiley and the St. Jude valves gave slightly lower \( Cp \) values. The pressure coefficient based on mean flow rate tends to over estimate the value although the difference is very small. The pressure coefficient based on peak flow rate, however, gave considerably larger \( Cp \).

(n) Average values of \( Cp \), \( Cd \) during the pulsatile flow study, the corresponding steady results together with EOA and PI showed that, the effect of occluder geometry is unaffected by the rms, mean or steady flow data used.

(o) Instantaneous velocities showed highly consistent periodic nature of the phenomenon with timings of various events during a cardiac cycle remaining almost identical. Thus over the BPM range used, the cardiac pulse duplicator is reproducing individual cycles quite faithfully. It is of interest to point out that turbulence
intensity, when expressed in terms of annulus velocity remained essentially unchanged with the heart rate.

During the pulsatile flow study, the maximum velocity recorded for the Starr-Edwards valve, at a given downstream location, was essentially the same as that observed during the steady flow case while the turbulence intensity was distinctly lower. Accounting for the difference in relative orientation of the valve-mount and the measuring plane, the peak velocity is likely to be comparable to that for the steady flow also for the tilting disc configuration. The peak velocity and turbulence intensity for the St. Jude valve were found to be smaller than those for the Bjork-Shiley case (except for a sharp turbulence intensity peak of around 200%).

For nondimensional velocity profiles based on the annulus area, conclusions based on the steady tests remain valid. Inclined sharp edged disc of the Bjork-Shiley valve leads to strong vortices resulting in high turbulence intensity. Half-discs of the St. Jude valve, being aligned with the flow, resulted in a slightly lower turbulence level than that of the Bjork-Shiley valve but a little above the Starr-Edwards valve.

For the Starr-Edwards prosthesis, sticking character of the ball substantially affects the pressure-flow rate relation.

Velocity and turbulence intensity profiles are essentially independent of the valve size, for a given configuration, when results are nondimensionalized with reference to velocity at the annulus.
5.2 Recommendation for Future Work

The investigation reported here, although complete in itself, represents merely one phase of the enormously challenging and complex problem.

It provides some appreciation as to the fundamental fluid dynamical aspects associated with several popular mechanical heart valves, but it is still a first step. There is a vast vacuum in terms of information and understanding and much needs to be learned through a well organized experimental program. With sophisticated experimental facilities for both steady and pulsatile conditions operational, and procedure for analyzing data established, the stage for further exploration is indeed set. However, the number of system variables involved are rather enormous, hence, any attempts at achieving precise dynamic similarity is likely to demand considerable time and patience. Only a few of the more significant avenues of future efforts, which are likely to be rewarding, are briefly indicated here.

(a) The obvious and logical immediate extension of the present work would be to aim at expanding its scope to cover the following:

(i) more precise assessment as to the effect of stroke volume, waveform, valve size and working solution;
(ii) test over an extended range of heart rate;
(iii) more comprehensive scanning of the fluid field for velocity profile and turbulence intensity;
(iv) additional mechanical valve configurations.

These can be accomplished quite readily with the addition of a more powerful stepping-motor without any further change in the facility.
(b) Conduct tests with tissue valves. This will involve the use of saline solution to preserve the valves and hence minor modifications in the material used for construction of the test facility to make it compatible with the corrosive environment.

(c) Serious consideration should be given to modify the present arrangement into a two component LDA system. This will make it possible to measure the Reynolds stress component of the shear stress. The viscous component having been already measured, the total stress will help predict the possibility of thromboembolism better.

(d) Attempts should be made to develop a model to predict pulsatile flow data from steady flow measurements.

(e) It would be useful to set-up an effective flow visualization facility with the steady flow glycerol-water solution tunnel as well as the cardiac pulse duplicator. This will help towards qualitative assessment of:

(i) vortex shedding;
(ii) regurgitant flow;
(iii) opening and closing characteristics of valves and their correlation with the flow field.

(f) Fluid dynamical parameters represent only one of a set of criteria to evaluate performance of a prosthetic heart valve. Equally important would be the structural integrity. To that end it would be useful to design and construct a facility to test fatigue strength of mechanical as well as tissue valves under the measured fluid
At a more fundamental level, it would be of far reaching importance to develop similarity relations for accelerated fatigue testing. Although fatigue testing of valves carried out at present is always at higher than nominal heart rate, reduction of these results to real life situation becomes questionable in the absence of such dynamic similarity parameters.

Effect of fixation procedures on mechanical properties of biological tissues represents an area of fundamental importance. Unfortunately, there is hardly any reliable information available.

Effort should be made towards compilation of a large data bank which would serve as a reference for:

(i) establishing performance criteria which commercially available prosthetic heart valves must satisfy. The aim would be to protect patients as well as provide better engineering information that would assist cardiac surgeons in selection of an appropriate prosthesis.

(ii) evolution of newer and hopefully better designs.
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APPENDIX A: A REVIEW OF PULSATILE FLOW FACILITIES FOR IN VITRO PROSTHETIC HEART VALVE STUDIES

The use of a pulse duplicator to simulate the human heart action for evaluation of the prosthetic heart valve performance is relatively recent. Several groups around the world have attempted to develop cardiac simulator facilities with varying degree of sophistication and success. In general, a pulse duplicator tries to model, fluid dynamical consideration, left heart and its associated circulation system. A variety of system configurations have evolved over the past 15 years using different combinations of ventricle arrangement, drive mechanism and circulation system. However, it must be emphasized that it demands a careful planning to assure not only the geometrical (anatomical) similarity but also the physiological and fluid dynamical modelling. A typical cardiac simulation facility consists of three subassemblies: (a) test chamber usually representing the left ventricle; (b) circulation system; and (c) drive unit. It would be useful to touch upon each of them briefly.

(a) Test Chamber

Obviously one of the most important component of the pulse duplicator is the heart pump. Its main objective is to provide physical environment for testing valves. A valve or valves under test are located in the chamber to simulate relative geometry and positions. Thus, the test chamber should mimic anatomical nature of the appropriate heart component. Pulse duplicators developed so far for in vitro testing of prosthetic heart valves have one or more, rigid or flexible test chambers. Some with a single chamber strive to simulate the left ventricle for aortic and mitral valves, while the others have separate test chambers for these valves. Obviously selection of the test chamber configuration depends on the scope of a particular study. There are obvious good reasons to adopt the two separate chamber approach.
It can isolate each valve so that the parameters affecting their performance can be easily identified. However, the approach is not quite suitable in the situation where the performance of one valve is affected by the presence of other as in the natural condition. For instance, use of the Starr-Edwards type ball prosthesis at mitral location is known to create an obstruction to the flow towards the aortic valve during the systolic phase. Thus, there are two basic approaches to the design of a heart pump: One tries to simulate anatomical condition as closely as possible while the other attempts to model its functional condition and the shape is of little consequence.

Some of the major simulation facilities in use today are classified below:

(i) Simulated Left Ventricle Type

**Flexible ventricle**

- Oxford University, U.K. [87,88];
- Cardiac Development Laboratory, Victoria, B.C., Canada [110,111,73,75];
- Henry Ford Hospital, Detroit, Mich., U.S.A. [112];
- RWTH Aachen, Aachen, W. Germany. [113,114,115,116].

**Piston type ventricle**

- Washington University, St. Louis, Missouri, U.S.A. [108,117,118,119,120];
- Providence Hospital, Seattle, Wa., U.S.A. [100,121,122];
- University of Liverpool, Liverpool, U.K. [123,58,124,72];
- Keio University, Yokohama, Japan. [125,126,127];

(ii) Two Separate Test Chambers

- Karolinska Sjukhuset, Stockholm, Sweden. [56,128,57];
- Albert Einstein College of Medicine, Bronx, N.Y., U.S.A. [17,129];
- Henry Ford Hospital, Detroit, Mich., U.S.A. [130];
- Baylor College of Medicine, Houston, Texas, U.S.A.
[50,49];

Tulane University Schools of Medicine and Engineering, New Orleans, U.S.A. [131];

University of Iowa, Iowa City, Iowa, U.S.A [132];

(iii) Straight Tube Type

RWTH Aachen, Aachen, W.Germany. [76];

Sutter Memorial Hospital, Sacramento, Calif., U.S.A. [51,52,53];

Waseda University, Tokyo, Japan. [133,134,135,136];

Tokyo Women's Medical College, Tokyo, Japan. [137,138];

National Cardiovascular Center, Osaka, Japan. [139,140,141,142]

(b) Circulation System

Human circulation system is a complex network of arteries, capillaries, veins and attached organs with a varying degree of size and flexibility. One is left with the first impression that it is virtually impossible to correctly represent or simulate such a complex system. Its functional importance was not appreciated in early stages of in vitro experimental studies. In fact in some of the pioneering experiments modelling of the circulation system was not considered essential and completely neglected. Perhaps this can be justified in a qualitative study of the flow in immediate vicinity of a valve. This is a kind of rational often used in flow visualization studies. On the other hand, quantitative study usually involves an elaborate simulation of the circulation system particularly in terms of its impedance and compliance. This is indeed essential to evaluate fluid dynamical performance of a valve through in vitro tests.

With the passage of time attempts were made to correct this limitation in simulator. Some designs have tried to model the major organs in the circulation system through a series of resistance and compliance elements
thus mimicking, in a closed loop fashion, the natural circulation system complete with the left and right side of the heart. Of course, the correct artificial load to the model left ventricle must have the input impedance corresponding to the systemic circulation system to assess the valve performance under a quasi-physiological condition. This was first appreciated by Westerhof in his studies with the isolated beating heart [94]. One can simulate the circulation system by setting each of its segment with a measure of resistance and compliance.

An alternate approach is more simple. Westerhof [94], Reul et al., Martin and Black [144], and Swanson and Clark [119] have developed lumped parameter representations for the systemic circulation system. The whole circulation system is treated as one functional block and is represent by a set of resistances and compliances. Since the main concern of any in-vitro study is mostly confined to the heart itself, the circulation system appears only as an input impedance. To this end, Westerhof's approach is widely used because of its simplicity and adaptability to different pulse duplicator systems. The simulation results obtained using the approach compare well with the physiological and in vivo data.

Lumped parameter system:

Oxford group (Cornhill), Oxford, U.K. [141];
Cardiac Development Lab., Victoria, Canada [110,111,73,75];
Karolinska Sjukhuset, Stockholm, Sweden [56,128,57];
Sutter Memorial Hospital, Sacramento, Calif., U.S.A. [51,52,53];
Washington University, St. Louis, Missouri, U.S.A. [108,117,118,119,120];
University of Liverpool, Liverpool, U.K. [123,124,72];
Henry Ford Hospital, Detroit, Mich., U.S.A. [130,112];
Albert Einstein College of Medicine, Bronx, N.Y., U.S.A. [17,129];
Baylor College of Medicine, Houston, Texas, U.S.A. [50,49];
Drive unit is the source of movement for the test chamber simulating the heart. Under normal condition, the heart pulsates at around 72 beats per minute pumping out about 130 ml per each beat. These numbers change considerably depending on the condition of the body function.

Pulse duplicators developed so far for the in vitro testing of prosthetic heart valves utilized either mechanical or pneumatic drive units. Mechanical drive unit usually consists of a dc motor and a transfer unit, which may be a cam and a lever, a mechanical shaker, a crank or a sketch-yoke, to translate rotational motion into linear movement. The transfer unit, in turn, is connected directly or indirectly to a positive displacement piston to generate desired movement of the simulated heart. The mechanical drive unit thus generates a known and variable flow (generally sinusoidal) through the test-valve. Change of wave form during the test used to be impossible. The natural wave form being non-sinusoidal, a better simulation facility should try to mimic it. In fact Fourier analysis suggests that the human blood flow pulse has significant components up to tenth harmonic. Thus, a simple sinusoidal flow as used by a number of investigators cannot represent a true ventricular ejection curve. On the other hand, use of a simple known waveform is often desirable when only a relative performance comparison is in question.

Pneumatic drive unit producing quasi-physiological waveform often depends on the adjustment of input impedance of the systemic circulation.
system in order to obtain an acceptable aortic pressure wave. This is because the pneumatic drive using either a solenoid, electromagnetic or electrohydraulic valve for control of air or fluid as a working medium, is inherently less precise than the mechanical counterpart. Although often relied upon during in vitro experiments, adjustment of the drive unit and input impedance of the systemic circulation system make it almost impossible to determine whether the changes in the measured parameters result from the valve under test or due to the adjustments made to the circulation system. On the other hand, this may not be a serious limitation, since the natural human system also compensates for small changes in order to maintain systemic pressure fairly constant.

For a realistic simulation, consideration of the heart muscle mechanics is also important as suggested by Martin and Black [144]. The contractile element is often simulated by a cam driven by a variable speed motor, the series elastic element by a linear compression spring and the parallel elastic element by a tension spring. This system is able to model, to an extent, the interaction between the left ventricle and after-load during systole.

In selecting a proper drive unit one must note effectiveness of the above mentioned arrangements in simulating physiological condition of the human heart and at the same time minimize the number of unknown parameters in order to facilitate analysis of the test data. The drive units used by research facilities around the world are summarized below.

(1) Mechanical Drive Unit

Cam and lever

Cardiac Development Laboratory, Victoria, B.C., Canada [110,111,73,75];

Sutter Memorial Hospital, Sacramento, Calif., U.S.A. [51,52,53].
Mechanical shaker

Oxford University, U.K. [87,88].

Crank

Karolinska Sjukhuset, Stockholm, Sweden [56,128,57];
Washington University, St. Louis, Missouri, U.S.A. [108,117,118,119,120];
Providence Hospital, Seattle, Wa., U.S.A. [100,121,122];
Albert Einstein College of Medicine, Bronx, N.Y., U.S.A. [17,129];
Henry Ford Hospital, Detroit, Mich., U.S.A. [130].

Skotch yoke

University of Liverpool, Liverpool, U.K. [123,58,124,72].

(ii) Pneumatic Drive Unit

Solenoid valve controller

Oxford University, U.K. (Cornhill) [143];
Baylor College of Medicine, Houston, Texas, U.S.A.;
RWTH Aachen, Aachen, W. Germany [113,114,115,116];
Waseda University, Tokyo, Japan [133,134,135,136];
Tokyo Women's Medical College, Tokyo, Japan [137,138];
National Cardiovascular Center, Osaka, Japan [139,140,141,142].

Electro-magnetic valve control

Keio University, Yokohama, Japan [125,126,127].

Electro-hydraulic drive

RWTH Aachen, Aachen, W. Germany [76].
Stepping-Motor Drive System and Control

Initially a precisely contoured metallic cam, driven by a variable speed d.c. motor, was used to generate a simulated cardiac pulse wave-forms. This required appropriately machined individual cams for simulation of different waveforms. In addition to this inconvenience, the lever and cam arrangement was susceptible to and induced undesirable oscillations. Thus it was felt that there is a need for a better design which would allow simulation of a large set of waveforms quite readily and retaining the desirable features of the earlier systems. To achieve this flexibility, computer control is a logical choice. A well-programmed computer could simulate different waveforms by a mere change of the input data.

The simulated fluid flow through a valve is achieved through a positive displacement piston driven by a stepping-motor. Hence the computer has to control the movement of the motor.

The following criteria should be met by the drive unit:

a. good stability (no undesirable oscillations);
b. fast acceleration and deceleration;
c. quick change of direction of movement with little backlash;
d. easy to interface with a computer;
e. cost effectiveness;
f. reliability and long life.

Three types of drive systems were considered:

1. d.c. servo motor;
2. hydraulic servo valve;
3. stepping-motor drive.

The d.c. servo drive was rejected because of the lack of stability,
difficulty in interfacing with a microprocessor, and slow response. The hydraulic servo valve is rather expensive, has a long response time, and is unstable. There is also a possibility of oil leakage in this case. The stepping-motor closely met the criteria set and therefore was chosen as the drive for the system.

Design of the subsystems as well as the test conditions suggested that the motor should be able to sustain a minimum load of 20 lbs and should be able to impart a minimum velocity of 6 inches/sec (260 steps/sec). A Slo-Syn M093PD14 motor was chosen which meets and surpasses the above specifications. The motor is interfaced with a microprocessor through a translator. The later receives pulses from the microprocessor and steps the motor accordingly.

Obviously, the translator must confirm to certain standards to assure desired performance:

a. it should be able to drive the motor at speed higher than 1000 steps/sec;

b. amenable to direct interface with a microprocessor without the use of buffers;

c. able to drive the motor with MANUAL/AUTO options.

The Slo-Syn TMS103 translator module, which meets the above specifications, was selected.

Since the motor drives a heavy load, it may miss some steps. This can be prevented by employing a feedback system, which senses the location of the motor. After a careful consideration of several options, the potentiometer feedback was chosen due to its relatively good accuracy (0.1% linearity) and the simplicity of interfacing.

It should be noted that at present, the program does not support feedback system. However, it is written in a way to accommodate the feedback mode by changing one functional block of the flow chart.
The heart of the system is the microprocessor. Due to a large amount of data processing and real time constraints, a powerful microprocessor with the following capabilities was needed:

(i) ability to multiply and divide instructions;
(ii) the word-length should be at least as large as the length of the waveform data in order to manipulate information accurately and quickly;
(iii) memory reference instructions should be provided in order to process the data (in memory) efficiently.

The following three microprocessors were considered: Intel 8086; Motorola 6809; and Texas Instrument 9900. The Motorola 6809 does not meet the second criterion and barely meets the third one, and hence was rejected. The Intel 8086 microprocessor was rejected due to its high price (at the time of development). The TI 9900 microprocessor was selected as it meets all of the specifications, however, it does have some undesirable features: a long instruction cycle time, poor documentation and difficulty in obtaining hardware and software supports. Besides the microprocessor requires three levels of voltage to operate it.

To interface the feedback potentiometer with the microprocessor, an ADC (analog to digital converter) was needed to digitize the analog output of the potentiometer. During the later stages of the design, a new constraint was imposed on the system: it should have a provision to read a large set of analog data from a set of pressure transducers and flow meters, and the digitized data had to be stored in memory for processing later. It was decided that a proven A/D board would better serve the purpose than using an A/D chip for each input. Analog Devices RT1-1240S board was selected for this. With 32 A/D ports, 4 D/A channels and a conversion time of 8 microseconds was chosen for the purpose. It is completely compatible (hardware and software) with the TMS990/100M CPU board.
System Hardware Configuration

The computer terminal was connected to the microprocessor through a build-in TMS 9902 serial I/O chip. The Slo-Syn STM-103 translator was connected to the microprocessor through a build-in TMS9901 parallel I/O chip as shown in Figure B-1. Figure B-2 indicates how the translator is interfaced with the TMS9901 parallel I/O chip. The translator can be directly connected to chip since the inputs of the STM103 are TTL compatible.

A single pulse to P0 drives the motor one step clockwise and a pulse to P1 drives it a step counterclockwise. The high setting on P2 moves the motor at full-step and the "high" on P3 moves it at half-step. The "high" setting on P4 energized two windings of the motor at the same time thus increasing its torque by almost 30 percent.

The "high" setting on P5 switches on the internal oscillator of the translator and drives the motor in the direction specified. The oscillator starts ramping the motor until it reaches the speed set by the operator. During deceleration, the internal oscillator will again ramp the motor down to zero speed.

The "high" on P6 drives the motor at the base speed according to the direction specified. The translator is connected to the motor as shown in Figure B-2.

Necessary electrical setting of the pins are generated by a program written in machine language for maximum speed. A simplified flow chart for the control of stepping-motor is shown in Figure B-3.

A high-precision Bourne's 5 Kohms linear potentiometer has been interfaced with the Analog Devices RT1-1240S board.

The waveshape is monitored through the D/A output port of the Analog Devices board, which is displayed on a scope. The scope is triggered at the start of a new cycle by a short-duration negative travelling pulse from
Figure B-1 A block diagram showing major components of the microprocessor controlled drive system
Figure B-2 A diagram showing a connection between parallel I/O and translator module
Figure B-3  A simplified flow chart for the stepping-motor control
port #8 of the TMS9901 parallel I/O chip.
APPENDIX C: ACCURACY OF RESULTS

In the investigation of this nature with very little available information it was almost a responsibility to obtain data, which would serve as reference in future, with utmost care and assured repeatability. Hence, almost invariably, a set of experiments in a given series was repeated at least twice. Normally, a repeated test was conducted a few days apart to ensure validity of data under independently adjusted experimental conditions. In most cases, the repeated experiments help establish precise trends in spite of the highly unsteady and turbulent flow-field. The Starr-Edwards valves, however, showed consistent discrepancy, even when the data were plotted nondimensionally both in the form of pressure and discharge coefficients, particularly at the higher end of the Reynolds number range as shown in Figures C-1 and C-2. Initially, the problem was attributed to minor deviations in the model and instrumentation set-up. This was soon ruled out as more careful experiments yielded the same trends. A careful study of each plot revealed that the variations were not random but rather associated with the boundary layer transition leading to change in separation mechanism (laminar to turbulent separation):

(a) Since the Reynolds number is based on the average velocity at the annulus region, the actual peak velocity at the poppet of the Starr-Edwards valve and hence the effective Reynolds number is likely to be much higher, perhaps in the transition range.

(b) The poppet of the Starr-Edwards valve was observed to be vibrating even under steady flow condition. This would suggest as well as promote transition from laminar to turbulent separation.

(c) The incoming flow is not uniform with little disturbance, but rather a type of jet flow of essentially a turbulence-free core surrounded by a highly turbulent outer region which may propagate disturbances
at the poppet location.

(d) Presence of the left ventricle wall imposes a confined condition affecting the flow pattern around the poppet.

Similar discrepancy was also observed during the steady glycerol-water solution tunnel tests.
Figure C-1  Variation of pressure coefficient (Cp) with Reynolds number for the Starr-Edwards prosthesis showing instability at higher Reynolds numbers.
Figure C-2 Variation of discharge coefficient (Cd) with Reynolds number for the Starr-Edwards prosthesis showing instability at higher Reynolds numbers.

\[ Cd = \frac{Q}{\frac{\pi}{4} d^2 E} \sqrt{\frac{2(P_u - P_d)}{\rho}} \]

where \( E = \frac{1}{\sqrt{1 - (\frac{d}{D})^4}} \)