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step-stress testing, standard performance measurements, correlation of performance between different sizes/types and establishment of methods of measuring, reporting and interpreting in-vivo performance.

If the annual international heart valve market is taken as 60,000 units (mechanical and tissue) and this demand is spread over a group of 600 to 800 major centers, the largest customers purchase no more than a few hundred valves per year. Generally the purchase decision is made by the individual physician, based mainly upon reports of other physicians in medical journals. Typically, these papers do not analyze the findings with respect to fundamental laws and quantitative models. This situation has led to extensive confusion and misinformation. Since the world demand is met by four major US manufacturers, offering several models in six sizes with both aortic and mitral cuff configurations, it is clear that rational, quantitative decision making is needed to select an optimum prosthesis for a particular patient. Regrettably, neither users nor regulatory bodies have demanded consensus performance standards anchord upon fluid-mechanics fundamentals which could be used to measure and rank the engineering performance of commercial devices. A decision analysis procedure has been developed based upon the following "must" characteristics:

1. Pressure gradient
2. TE rate
3. Failure rate (structure or components)

and a series of ten additional "like-to-have" features such as:

1. Lowest TE rate
2. Lowest gradient
3. Longest follow-up history
4. Least anticoagulant reqd.
5. Lowest reported failures/recalls
6. Lowest hemolysis
7. Relative ease of implantation
8. Complete accessories available
9. Lowest cost
10. Highest ratio of orifice diameter to TAD

A COMPUTER TEST CHAMBER FOR PROSTHETIC VALVE DESIGN

Charles S. Peskin and David M. McQueen
Courant Institute of Mathematical Sciences
251 Mercer St., New York, N.Y. 10012

This talk will describe a computational technique which is now available as a research tool for the design of prosthetic mitral valves. In this method, the computer is used to solve the equations of motion of blood in the heart and to predict the hemodynamic performance of the valve. The valve is studied in a contractile computer test chamber, the walls of which have the mechanical properties of cardiac muscle. The computer generates a ciné film showing the predicted motions of the valve, heart walls, and blood. Streamline plots giving the details of the flow pattern at selected times are also generated.

On the following pages, streamline plots are given for three prosthetic mitral valves: caged ball, pivoting disc, and curved pivoting disc. For each valve, the first four flow patterns show the opening sequence, and the last two show the closure movement of the occluder. A somewhat unusual feature of these figures is that streamlines cross boundaries. This is a consequence of the motion of the boundaries. It does not mean that fluid particles are crossing the boundaries, and our ciné films confirm that they are not.

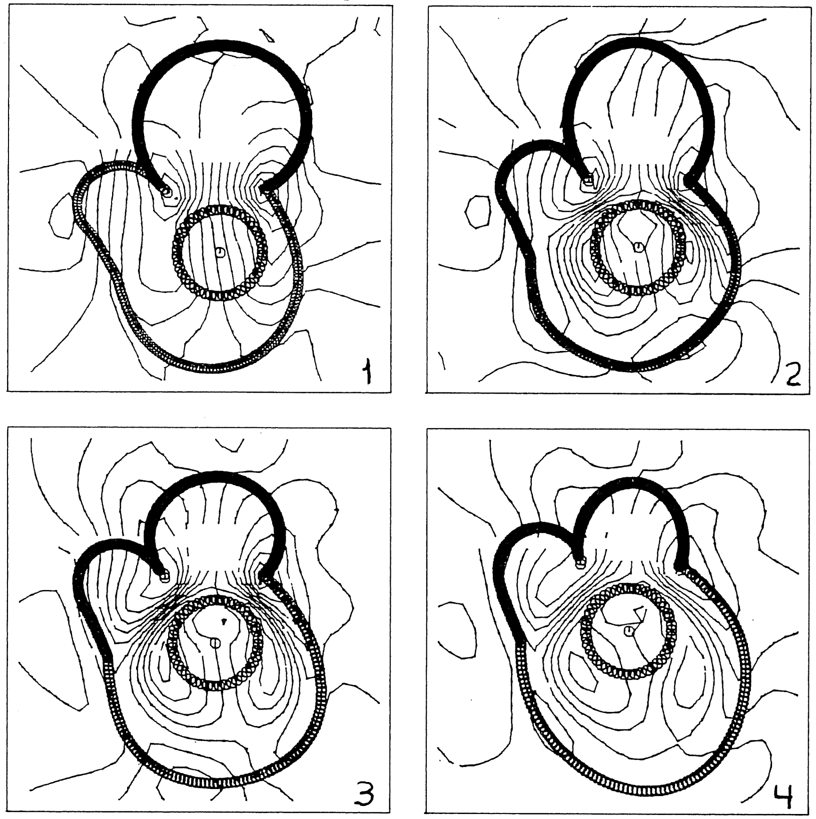
As these figures illustrate, the strengths of the method are as follows: First, we can test mitral valves of essentially any design. Next, we study the motions of each valve and the interaction of the valve with the flow pattern, not just flow past an occluder in a fixed configuration. Finally we study the valve in a contractile test chamber with geometric and physiological parameters that are under the control of the investigator. The principal limitations of the method are two-dimensionality, low Reynolds number, and high cost.

Acknowledgement: This work was supported by the National Institutes of Health under research grant HL 17859. Computation was also supported in part by the Department of Energy under contract EY-76-C-02-3077 at the Courant Mathematics and Computing Laboratory of New York University.

References:

1. Peskin, C.S.: "Numerical Analysis of Blood Flow in the Heart" J. Computational Physics 25, 220-252, 1977.
2. McQueen, D.M., Yellin, E.L., Frater, R.W.M., and Peskin, C.S.: "Studies of the Mitral Valve in a Computer Test Chamber," these Proceedings.

CAGED BALL
Opening (1-4):



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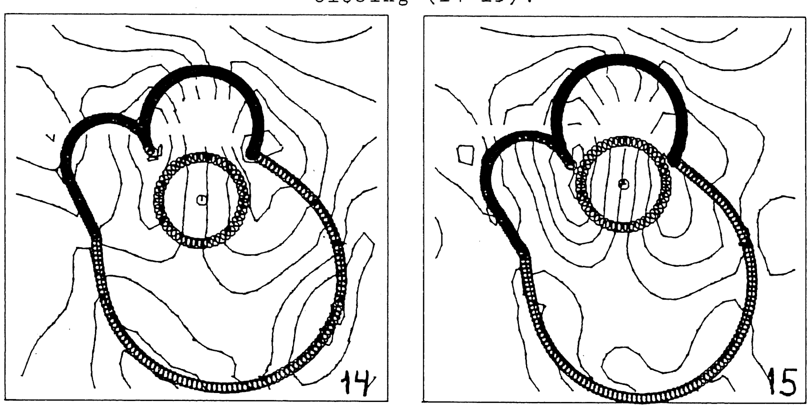
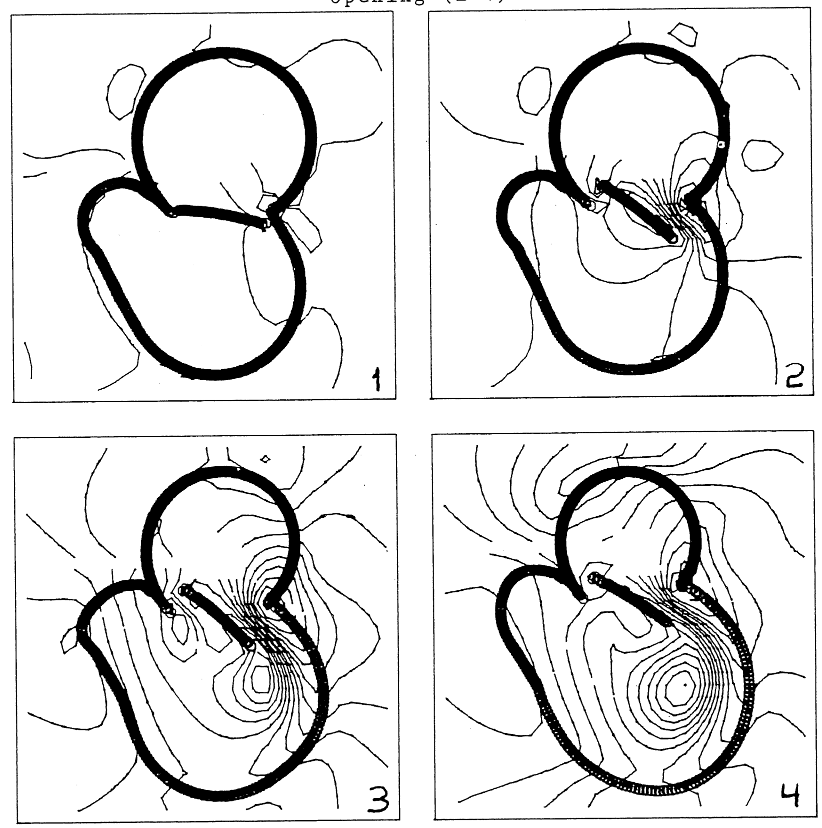


PIVOTING DISC
Opening (1-4):



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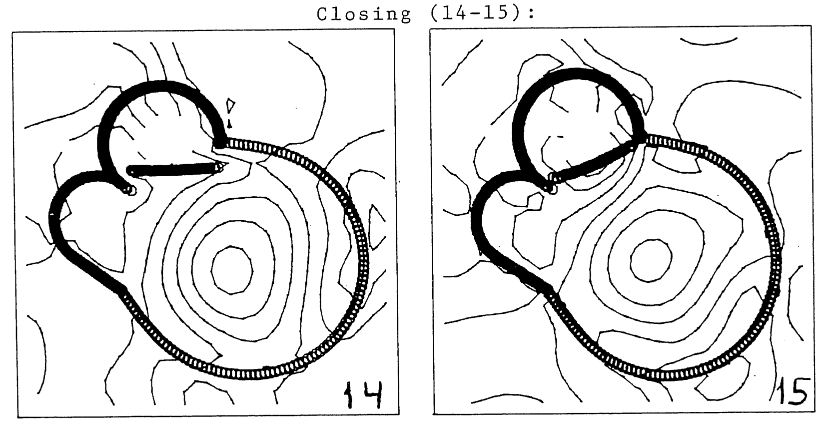
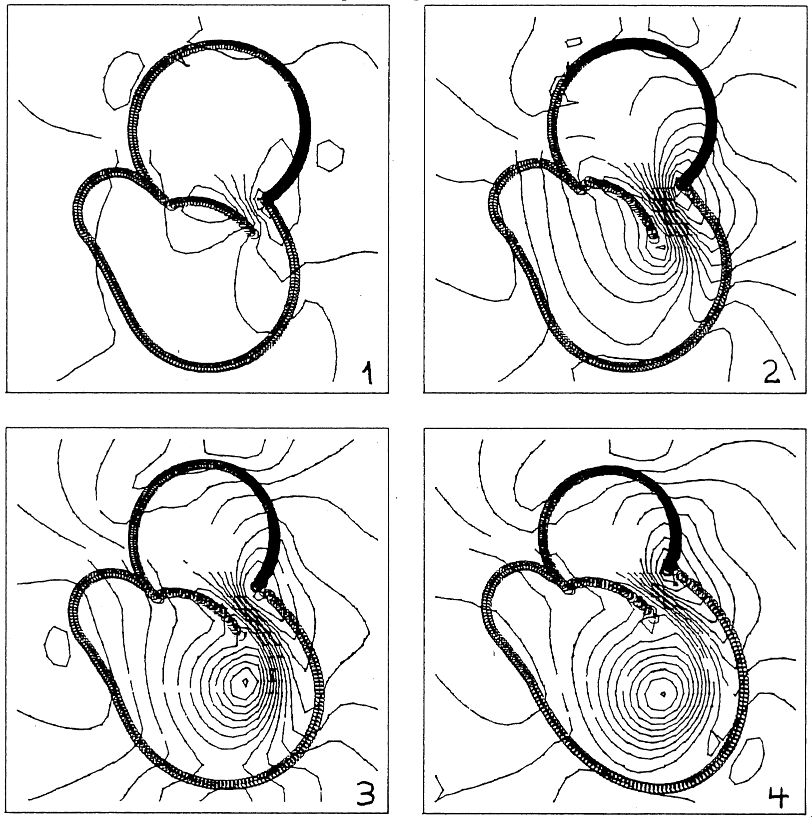


CURVED PIVOTING DISC
Opening (1-4):



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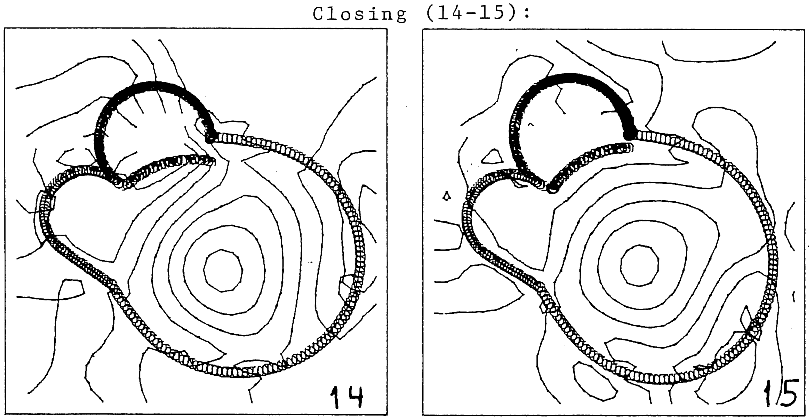


STUDIES OF THE MITRAL VALVE IN A COMPUTER TEST CHAMBER

D.M.McQueen,* E.L.Yellin,** R.W.M. Frater,** and C.S. Peskin*

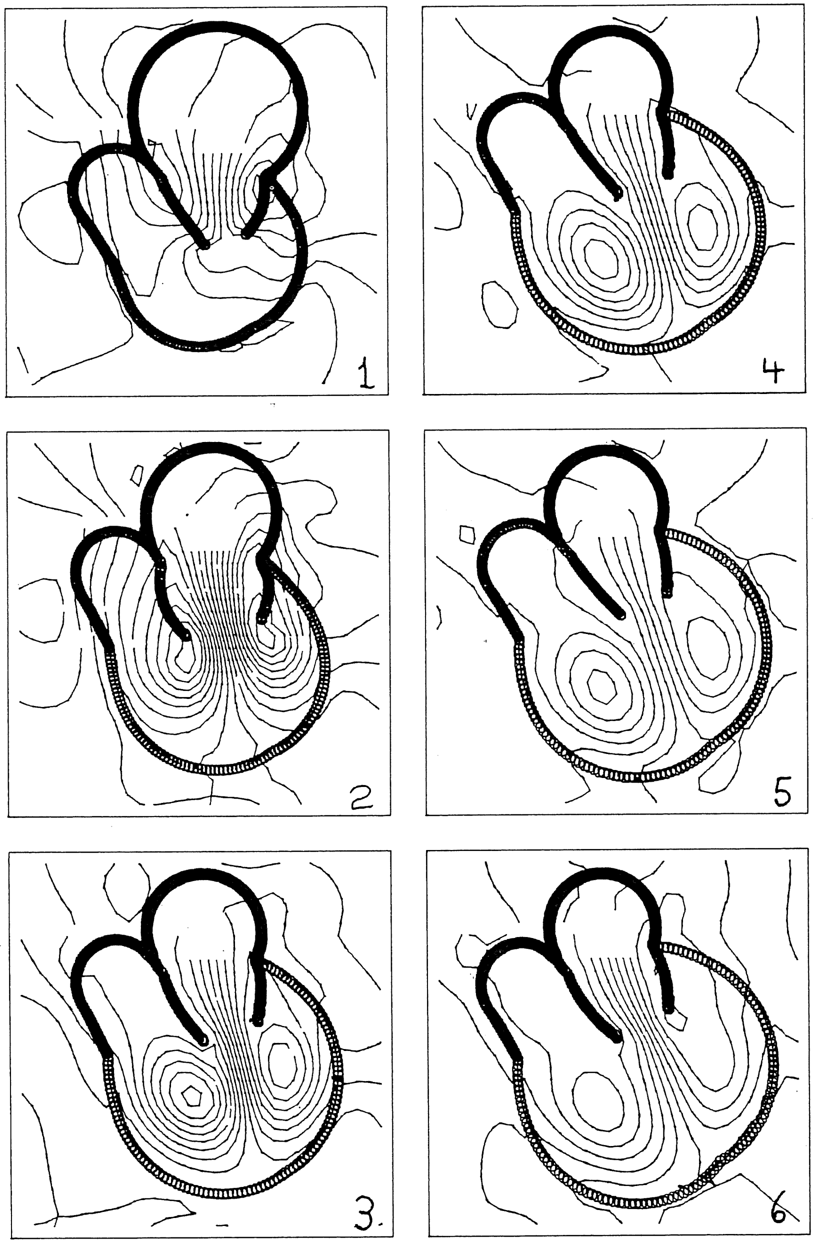
This talk will describe studies of mitral valve performance utilizing a computational technique discussed in (1). While the application of the technique to prosthetic valve design is stressed, the first study of interest is on the natural valve. This is so for two reasons: First, to demonstrate that a reasonable simulation of in-vivo conditions has been achieved, and second, to provide a reference against which simulated prosthetic valve performance can be judged.

Figures 1-9 consist of computed streamline plots for a natural valve at equally spaced times during ventricular diastolic filling. The graphs which follow these streamline plots compare records of transmitral flow and atrial and ventricular pressures in a dog (2) with the results of the simulation. Both show a period of relatively high flow in early diastole, followed by decay and a second flow maximum during atrial systole. Early diastolic flow achieves its first maximum somewhat sooner in the simulation than in the animal record. (Note the difference in time scales.) The two traces on the computed mitral flow correspond to flow meter measurements at the mitral ring and the tips of the leaflets. The latter flow starts later and shows no spurt of backflow during valve closure.

Figures 10-15 are the results of a study of prosthetic valve performance. The purpose of the study was to determine the influence of the position of the pivot point on the angle of opening of pivoting disc valves (in the absence of any mechanical constraint on the maximum angle of opening.) The occluder consists of thirty points which interact with their neighbors so as to resist extension and bending. Figures 10-15 show the streamlines at the time of maximum opening of the valve as the pivot point is moved sequentially from point 10 to point 15 on the occluder. Both the value of the maximum angle of opening and the time of maximum opening are functions of the location of the pivot points.

References: 1. Peskin, C.S. and D.M. McQueen: A Computer Test Chamber for Prosthetic Valve Design," these Proceedings.
2. Yellin, E.L. and R.W.M. Frater: Unpublished data.

*Courant Institute of Mathematical Sciences, N.Y.,N.Y.10012.
Supported by the N.I.H. under research grant HL 17859. Computation was also supported in part by the D.O.E. under contract EY-76-C-02-3077.
**Albert Einstein College of Medicine, Bronx, N.Y. 10461.
Supported by the N.I.H. under research grant HL 19391.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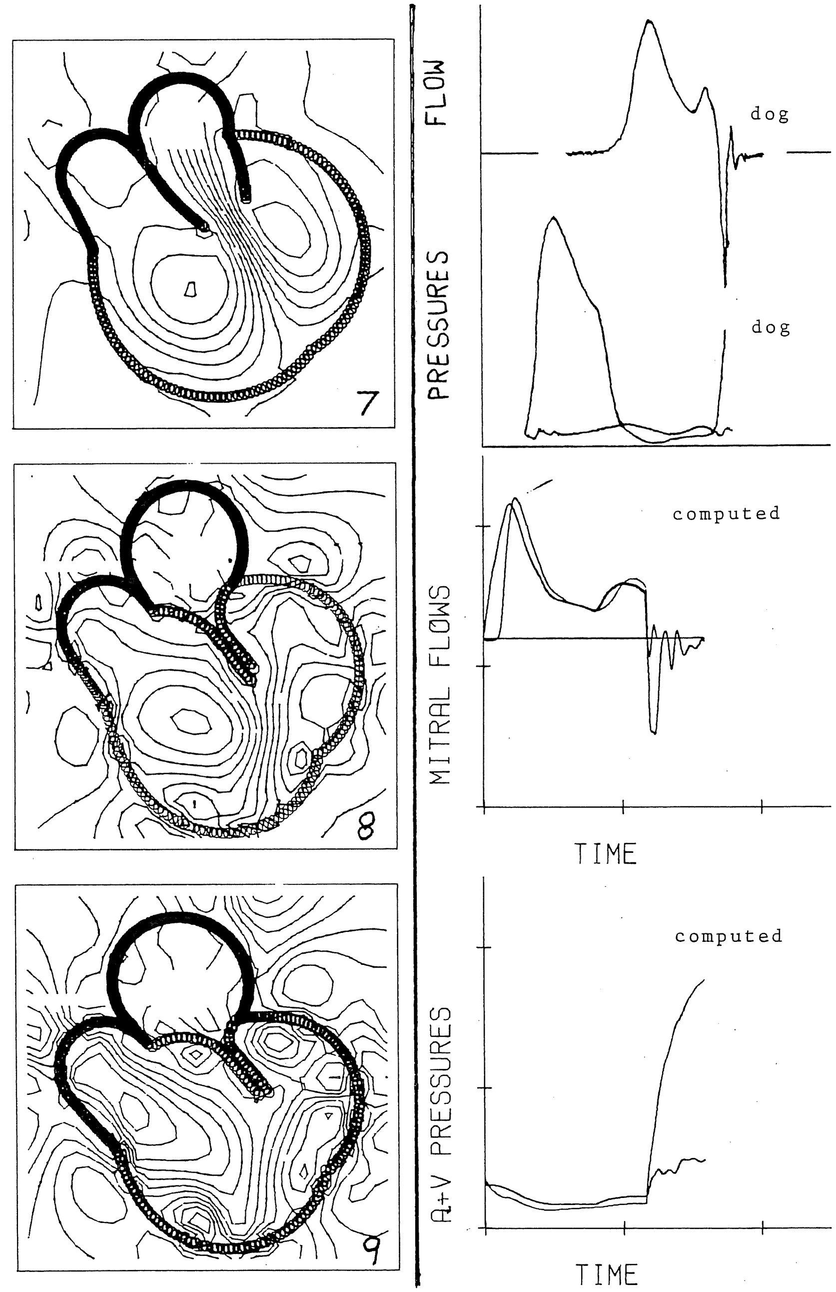
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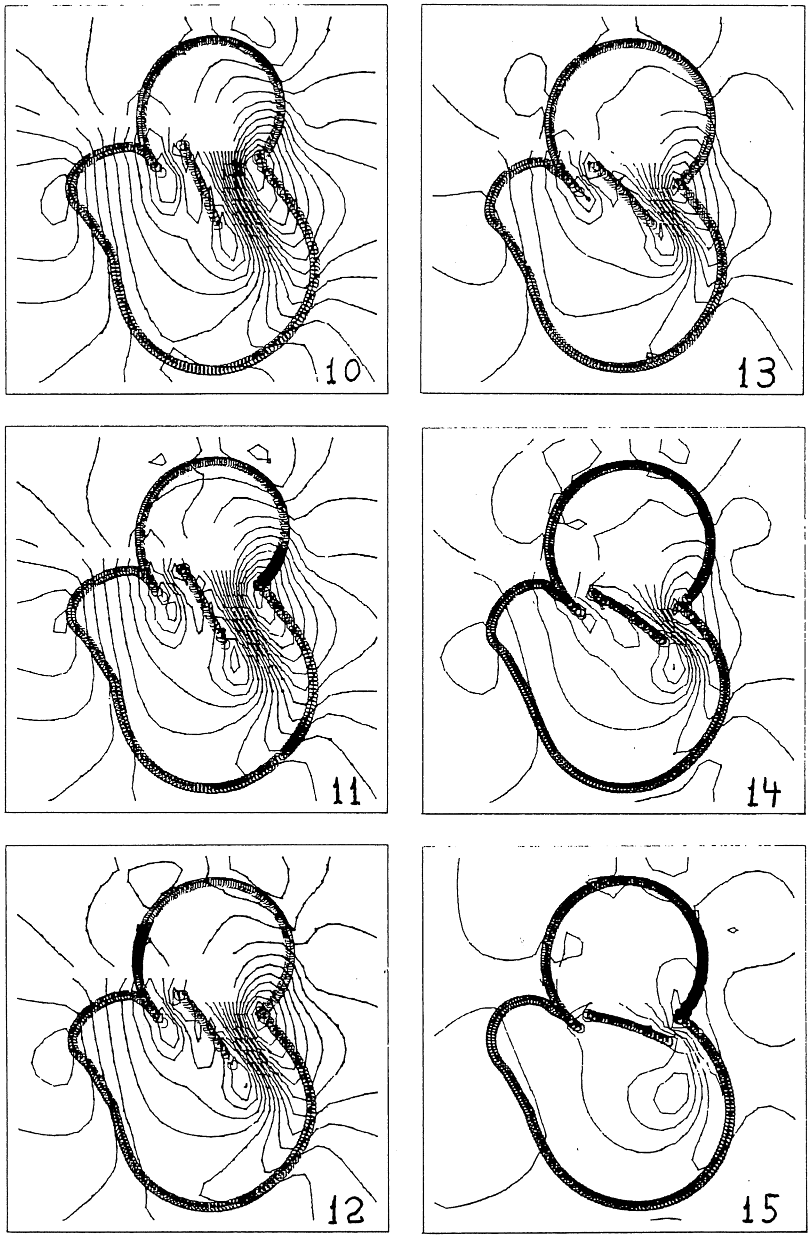

TURBULENT PROPERTIES OF AORTIC VALVE PROSTHESES

Ned H.C. Hwang, P.C. Lu, A. Sallam, and H. Reul*

Study of turbulence structures in the close vicinity of heart valves has been largely neglected in the past due to technical difficulties. Hot-film anemometer probes have been applied to measure turbulence in natural heart valves installed in a model flow chamber (Hwang, 1977; Hwang et al, 1977), and in prosthetic valves installed in a flow loop (Underwood and Mueller, 1977; Figliola and Mueller, 1978). The physical presence of the probe in the pulsating flow field presents a serious problem in measurement of valvular flow, particularly in regions immediately behind the occluder, and near the moving vessel walls. The relatively low frequency response (about 400 Hz)+ also severely limited the utility of hot-film in turbulence measurement.

Flow measurements in the close vicinity of heart valves by laser Doppler anemometer was made possible recently. Yoganathan and his colleagues reported their measurement of velocity profiles and shear stresses downstream from several conditions (Yoganathan, 1978; Yoganathan et al, 1978; Yoganathan et al, 1979a; and Yoganathan et al, 1979b). This paper presents the results of our recent laser Doppler anemometer measurements of turbulent characteristics downstream from three basic types of mechanical aortic valve prostheses in a distensible valve conduit under physiological pulsatile flow conditions. The three types of aortic prostheses studied are: (a) the Lillehei-Kaster (tilting-disc), (b) the Smeloff-Cutter (caged-ball), and (c) the Cooley-Cutter (caged-disc).

The pulsatile flow loop used in the experiments consists basically of three components: (a) the pulse generator, (b) the collapsible valve conduits, and (c) the afterload simulator.

The pulse generator includes a cassette tape recorder which plays back a pre-recorded waveform and feeds it into a KIM-1 ++ microprocessor. The waveform is then digitized and used to control the movement of the piston. A hydraulic pump, which circulates a high pressure hydraulic fluid, provides the power to activate the piston.

\+ Dynamic calibration performed in a vibrator-turntable system in our laboratory indicated a flat response to about 400 Hz, consistent with that of Clark (1974) and Pawel (1977).

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