**GEORGIA INSTITUTE OF TECHNOLOGY**
OFFICE OF CONTRACT ADMINISTRATION
# SPONSORED PROJECT INITIATION

Date: 11/5/80

Project Title: In Vitro Flow Studies of One AVCO-EVERETT Tri-Leaflet Valve

Project No: E-19-622

Project Director: Dr. A.P. Yoganathan

Sponsor: AVCO-EVERETT Research Laboratory, Inc. Everett, MA 02149

Agreement Period: From 8/25/80 Until 12/24/80

Type Agreement: Purchase Order No. RL 209570-S

Amount: $7,500 (fixed price - includes $500 for Patent & Data Rights)

Reports Required: None specified

Sponsor Contact Person (s):

Technical Matters

Dr. David M. Lederman
AVCO-Everett Laboratory, Inc.
2385 Revere Beach Parkway
Everett, MA 02149

Contractual Matters
(thru OCA)

Mr. John C. Maney
Subcontract Administrator
AVCO-EVERETT Research Laboratory, I
2385 Revere Beach Parkway
Everett, MA 02149
(617) 389-3000 ext. 247/248

Defense Priority Rating: None

Assigned to: Chemical Engineering (School/~~XXXXXXXX~~)

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GEORGIA INSTITUTE OF TECHNOLOGY — OFFICE OF CONTRACT ADMINISTRATION

# SPONSORED PROJECT TERMINATION SHEET

Date 12/3/81

**Project Title:** In Vitro Flow Studies of One AVCO-EVERETT Tri-Leaflet Valve

**Project No:** E-19-622

**Project Director:** Dr. A. P. Yoganathan

**Sponsor:** AVCO-EVERETT Research Laboratory, Inc. Everett, MA

**Effective Termination Date:** 12/1/81

**Clearance of Accounting Charges:** 12/1/81 (Fixed Price)

**Grant/Contract Closeout Actions Remaining:**

- [x] Final Invoice ~~and Closing Documents~~
- [ ] Final Fiscal Report
- [ ] Final Report of Inventions
- [ ] Govt. Property Inventory & Related Certificate
- [ ] Classified Material Certificate
- [ ] Other ____________

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FORM OCA 10:781

F19-622

FINAL REPORT TO AVCO-EVERETT LABORATORY INC.
(12/81)

## 1. Introduction

This report outlines the in vitro fluid dynamic performances of the size #18.5 and #25 Avco-Everett tri-leaflet heart valves prostheses. The size #18.5 valves studied were made out of two different materials. One material was opaque and the other was transparent. The valves made from the opaque material were manufactured as on unit with a conduit sleeve. The transparent valves were made as single heart valve prostheses. The #25 valves studied were manufactured from the transparent material.

Both sizes were studied in the aortic position in a symmetric aortic valve chamber under steady and pulsatile flow conditions. The aortic flow channel used is shown schematically in Figure 1. All pulsatile flow experiments were conducted under appropriate physiologic conditions. The following experiments were conducted: (i) pressure drop, (ii) regurgitation, (iii) photography of leaflet motion under pulsatile flow, (iv) flow visualization and (v) velocity and shear stress measurements.

The results of these experiments are given below and are compared to some of the size #25 heart valve prostheses in current clinical use.

## 2. Pressure Drop and Regurgitation Studies

Steady flow pressure drop mdasurements were conducted over a flow rate range of 10 to 30 l/min. $\Delta p_1$ and $\Delta p_2$ refer to pressure drop measurements made across taps I and II and taps I and III,respectively. The pulsatile flow experiments were conducted at a heart rate of 70 beats/min, systolic time of 300 ms, mean aortic pressure of 100 mmHg and cardiac outputs in the range of about 2.5 to 7.0 l/min. All pulsatile flow experiments were conducted under physiologic conditions.

The pressure drop studies of the two types of size #18.5 Avco-Everett valves show quite clearly that at a given flow rate the opaque valves create a larger pressure drop compared to the transparent valve prostheses. This finding is true under both steady and pulsatile flow conditions. For example, at a flow rate of 25 l/min the opaque valves had a pressure drop which was 4 to 6 mmHg larger compared to the transparent valves. All the pressure drop results for the size #18.5 and 25 are summarized in Figures 2-7. In Figures 4,5 and 7 the mean systolic pressure drop is plotted against root mean square of the flow rate during systole.

The steady and pulsatile flow pressure drops across the size #25 valves are fairly similar to those measured across a size #25 Ionescu-Shiley pericardial and Bjork-Shiley tilting disc prostheses. In addition, the pressure drop characteristics of the size #25 are definitely superior to those of a size #25 Carpentier-Edwards or Hancock (regular) porcine tissue valve. However, the Avco-Everett #25 valve is quite a bit more stenotic compared to a #25 St. Jude bi-leaflet valve. Steady flow pressure drops for the #25 Ionescu-Shiley, Bjork-Shiley, Carpentier-Edwards and St. Jude valves are shown in Figure 8. As can be seen from Figures 6 and 7 the slopes of the lines are in the range of 1.3 to 1.5. The Bjork-Shiley and St. Jude valves have slopes of 1.8 to 2.0, and the Ionescu-Shiley and Carpentier-Edwards tissue valves have slopes 1.6 to 1.7. Therefore, the pressure drops across the size #25 Avco-Everett valve do not increase as rapidly with flow rate compared to the other valves mentioned above. This could be significant factor under excercise conditions where the cardiac output increases to about 12 l/min and the root mean square of the systolic flow rate is about 60 l/min.

Comparing the size #18.5 Avco-Everett valve to size #21 Carpentier-Edwards and Ionescu-Shiley tissue valves shows that the A-E valves (opaque and transparent) have lower pressure drops. The size #18.5 A-E valve has pressure drop characteristics similar to those of a #21 Bjork-Shiley tilting disc valve. Both the #18.5 and #25 A-E valves had regurgitant volumes of 0.5 to 2.0 $cm^3$/stroke at a heart rate of 70 beats/min. The regurgitant volumes are very similar to those obtained with Carpentier-Edwards and Hancock porcine valves. The Bjork-Shiley and St. Jude mechanical valves have regurgitant volumes of about 5 to 10 $cm^3$/stroke at a heart rate of 70 beats/min.

3. Leaflet Photography Studies

Photographs of the opening and closing motion of the valve leaflets were taken under pulsatile flow conditions. Experiments were conducted at a heart rate of 70 beats/min, aortic pressure of about 120/80 mmHg and cardiac outputs of about 2.5 to 5.5 l/min. The photographs were taken at different times in the systolic phase, using Ektachrome 160 Tungsten slide film. The slides were projected on a screen and the valve opening areas were measured. The opening areas were then correlated to the times and instantaneous flow rates at which the photographs were taken.

The size #18.5 opaque valves had maximum opening areas of about 115 $mm^2$ and 85 $mm^2$ at cardiac outputs of about 4.5 and 2.5 l/min, respectively. At the corresponding cardiac outputs the #18.5 transparent valves had maximum opening areas of about 145 $mm^2$ and 135 $mm^2$, respectively. These results indicate very clearly that leaflets of the transparent valves open wider, especially at low cardiac outputs, and are less dependent upon the cardiac output through the valve prosthesis.

In addition, the photographys revealed that the leaflets of the transparent valves open quicker during systole compared to the leaflets of the opaque valves. It was, however, observed that the leaflets of the opaque valves opened more symmetrically.

The #25 Avco-Everett transparent valves had average maximum opening areas of about 225 $mm^2$ and 215 $mm^2$ at cardiac outputs of about 5.2 and 3.0 l/min, respectively. The results indicate that the cardiac output through the valve does not seem to significantly affect the maximum opening of the valve leaflets, nor the opening and closing characteristics of the valve. In addition, it was observed that the three leaflets did not open symmetrically, especially with one of the valves. The maximum opening areas, and the opening and closing characteristics are fairly similar to the size #25 Ionescu-Shiley pericardial valves (Maximum opening areas of about 250 $mm^2$), and superior to those of the #25 Carpentier-Edwards porcine valves. The opening and closing characteristics of the leaflets of the Ionescu-Shiley and Carpentier Edwards valves are however, a stronger function of the cardiac output through the valve leaflets.

4. Steady and Pulsatile Flow Visualization

The flow visuslization studies indicate that the flow fields downstream of both valve sizes are not symmetric because of the asymmetric opening characteristics of the valves. For the #18.5 valve, on the upper side of the flow section, a stagnation region is formed immediately downstream of the valve between the leaflet surface and the tube wall; on the lower side, reverse flow due to a region of flow separation are observed. For the #25 valve, both the regions of stagnation and flow separation are reduced due to the larger opening area compared to that of the #18.5 valve. Increasing the steady flow rate from 10 l/min to 25 l/min does not change the general features of the flow field, except in increasing the size of the stagnation and/or flow separation regions to a certain degree. At both flow rates, the flow field immediately downstream of both valve sizes is jet-like, and the jet diverges as it travels further downstream.

The flow fields under pulsatile flow conditions look essentially the same (qualitatively) as under steady flow conditions. The jet that emerges from the valves is more profound at peak flow, than during the acceleration or deceleration phases of systole, because of the high instantaneous flow rate. The vortices in the flow separation region can be seen more clearly; in addition, the levels flow disturbance and turbulence are higher than those observed during steady flow conditions.

An example of the flow visualization work is depicted by the enclosed photograph.

:eady Flow Velocity Measurements

Velocity measurements were made immediately downstream of the size #18.5 opaque) and #25 valves at a flow rate of 25 l/min. This flow rate corresponds .o the peak systolic flow rate at a cardiac output of about 4 to 5 l/min. The ıxial velocity profiles (Figs. 10 and 11) indicate a jet type flow emerging from the valve leaflets. This is very similar to the flow fields observed immediately downstream of porcine and pericardial bioprostheses. The velocity profiles are in addition not symmetric, and the effects of this phenomena will be discussed later. The maximum flow velocities at 25 l/min are about 3.7 m/s and 2.2 m/s for the size #18.5 and #25 valves, respectively. The velocity profiles for the #25 valve are much flatter in the center than for the #18.5 valve because of larger orifice area. The negative axial velocities immediately downstream of the valves (see Figs. 10 and 11) revealed a region of flow separation. Flow separation occurred at the valve sewing or mounting ring. The area of flow separation for both valve sizes is bounded within a region of about 4 to 6 mm from the vessel wall and extends about 40 mm downstream from the sewing ring.

The presence of the valves in the aortic flow chamber produced elevated levels of turbulence. The RMS values of the fluctuating component of the axial velocities were as high as 69 and 50 cm/s for the #18.5 and #25 valves, respectively. Turbulence intensity levels as high as about 50% were also measured. Figures 12 and 13 show squared RMS axial velocity profiles for the two valve sizes.

The results of the velocity measurements indicate that the flow field immediately downstream of the Avco-Everett valves can be treated as a type of jet flow. For an unbounded self-preserving jet, where $\bar{u}_{CL}$ is the mean center line velocity, the maximum turbulent shear stress can be estimated by

$$\tau = 0.025 \rho \bar{u}_{CL}^{2}$$

In this study, the maximum turbulent shear stresses should then be on the order of 3300 and 1100 dynes/cm$^2$ for the #18.5 and #25 valves, respectively.

The experimentally measured turbulent shear stress profiels are shown in Figure 14 and 15. The maximum turbulent shear stresses were found to be about 3600 dynes/cm$^2$ at a distance of 4 cm downstream of the sewing ring for the #18.5 valve and 1100 dynes/cm$^2$ for #25 valve. As can be seen from Figures 14 and 15 the shear stresses were lower at a distance of 3 cm from the valve for the both sizes. This is probably due to the fact that the jet was not fully developed closer to the valve. Measurements further downstream (> 4 cm) indicated a decrease in turbulence levels and turbulent shear stresses. Maximum wall shear stresses on the order of 500 and 200 dynes/cm$^2$ were measured downstream of the point of jet reattachment (i.e., reattachment of the region of flow separation) of the size #25 and #18.5 valves, respectively.

The asymmetricness of the measured profiles indicates that the mechanical properties of the three leaflets are not identical. Experimental results are strongly dependent on the orientation of the valve in the symmetric aortic flow chamber. For example depending on the orientation, flow separation may occur either on one or both sides of the axial velocity profiles. The peak velocity and maximum shear stress also tend to vary with with valve orientation but to a much lesser extent. The results for the size #25 valve at a downstream distance of 3 cm are presented half-way across the tube to highlight the performance of the valve in one specific orientation.

In general the velocity and shear fields observed with the Avco-Everett valves are similar to those observed with the Carpentier-Edwards and Ionescu-Shiley tissue valves. The magnitude of the turbulent shear stresses downstream of the size #25 A-E valve are somewhat less than those measured with the corresponding size Carpentier-Edwards and Ionescu-Shiley prostheses.

. Pulsatile Flow Velocity Measurements

Pulsatile flow measurements were made 4 cm downstream of the sewing ring, since this was the location at which the highest turbulent shear stresses under steady flow conditions occurred. The peak systolic flow rate was about 28 l/min and the cardiac output about 5 l/min. Data collection time was 30 ms for each cycle. The phase-averaged values were calculated based on 1000 to 2000 data points, to ensure that they were statistically valid.

The velocity and turbulent shear stress profiles at peak systolic flow are shown in Figures 16, 17 and 18 for both valve sizes. To observe and analyze the flow field at different instances during systole, measurements were taken at different time delays at both the center of the tube, and at or near the location of highest shear stress, 4 cm downstream from the valve. Results are shown graphically in Figures 19 to 24. Figures 19, 20, and 21 represent data taken at the center of the flow section, while Figure 22, 23 and 24 represented data taken at or near the location of maximum turbulent shear stress in the horizontal plane through the center of the aortic flow section.

The results for the size #18.5 valve are qualitatively similar to the steady flow results. The RMS axial velocities and shear stresses are, however, larger than those measured under steady flow conditions. These results indicate quite clearly that the flow field immediately downstream of the valve is more turbulent and disturbed under pulsatile flow conditions. The maximum turbulent shear stress measured was about 4500 dynes/cm$^2$ (see Figure 18). At the location of highest shear stress the magnitude of the shear is strongly dependent on the time during systole, and has its peak value at peak flow (see Fig. 24). The largest amount of turbulence also occurs at that time (Fig. 23).

The results for the size #25 are, however, qualitatively quite different from the steady flow results. The velocity and shear stress profiles at peak flow rate (Figs. 16 and 18) are asymmetric. The experiments were repeated to check the results. Photographs of the opening and closing motions of the valve leaflets showed that the leaflets of the size #25 valve opened more asymmetrically compared to the leaflets of the #18.5 valve. In addition, the #18.5 valve had a sleeve about 2 cm long which tended to centralize the downstream flow field. Therefore, the asymmetric opening characteristics of the #25 valve lead to an asymmetric flow field immediately downstream of the valve. As observed with the #18.5 valve, the RMS axial velocities and turbulent shear stresses are elevated under pulsatile flow conditions. The peak shear and turbulence occur at or around peak systole. The maximum turbulent shear stress measured was about 2200 dynes/$cm^2$ (see Fig. 18), while the maximum axial rms velocity was about 55 cm/s.

The complexity of the velocity and shear profiles in pulsatile flow indicate very clearly that the testing of leaflet type values must be conducted under pulsatile flow conditions.

7. Discussion Velocity Measurement Results

The turbulent shear stresses created by both A-E valve sizes are capable of causing sub-leathal and/or leathal damage to blood components such as red-cells and platelets. The wall shear stresses may cause sub-lethal damage to the endothelial lining of the aortic wall immediately downstream of the valve. If such cellular damage does occur *in vivo*, it could lead to hemolysis and thromboembolic complications. The regions of flow separation immediately downstream of the sewing ring could lead to excess tissue growth along the sewing ring, and deposition of thrombotic, fibrotic and calcific material on the outflow sufaces of the valve leaflts.

8. Conclusions

In an overall *in vitro* fluid dynamic analysis, the size #18.5 and 25 Avco-Everett trileaflet valves are superior to the tissue bioprostheses in current clinical use. The size #18.5 A-E values compare very favorably with the size

#21 low profile mechanical valves. The valves made from the Angio flex have better leaflet motion and cause less pressure drops compared to those manufactured from Avco there - 51. It is our opinion that further improvements can be made on the valve and stent design which would enhance the fluid dynamic characteristics of the A-E valve. A more symmetric and wider opening of the valve leaflets would reduce the pressure gradients across the valves as well as the levels of turbulence immediately downstream of the valves. It may also lead to a reduction in the size of flow separation region.

## 9. Figure Captions

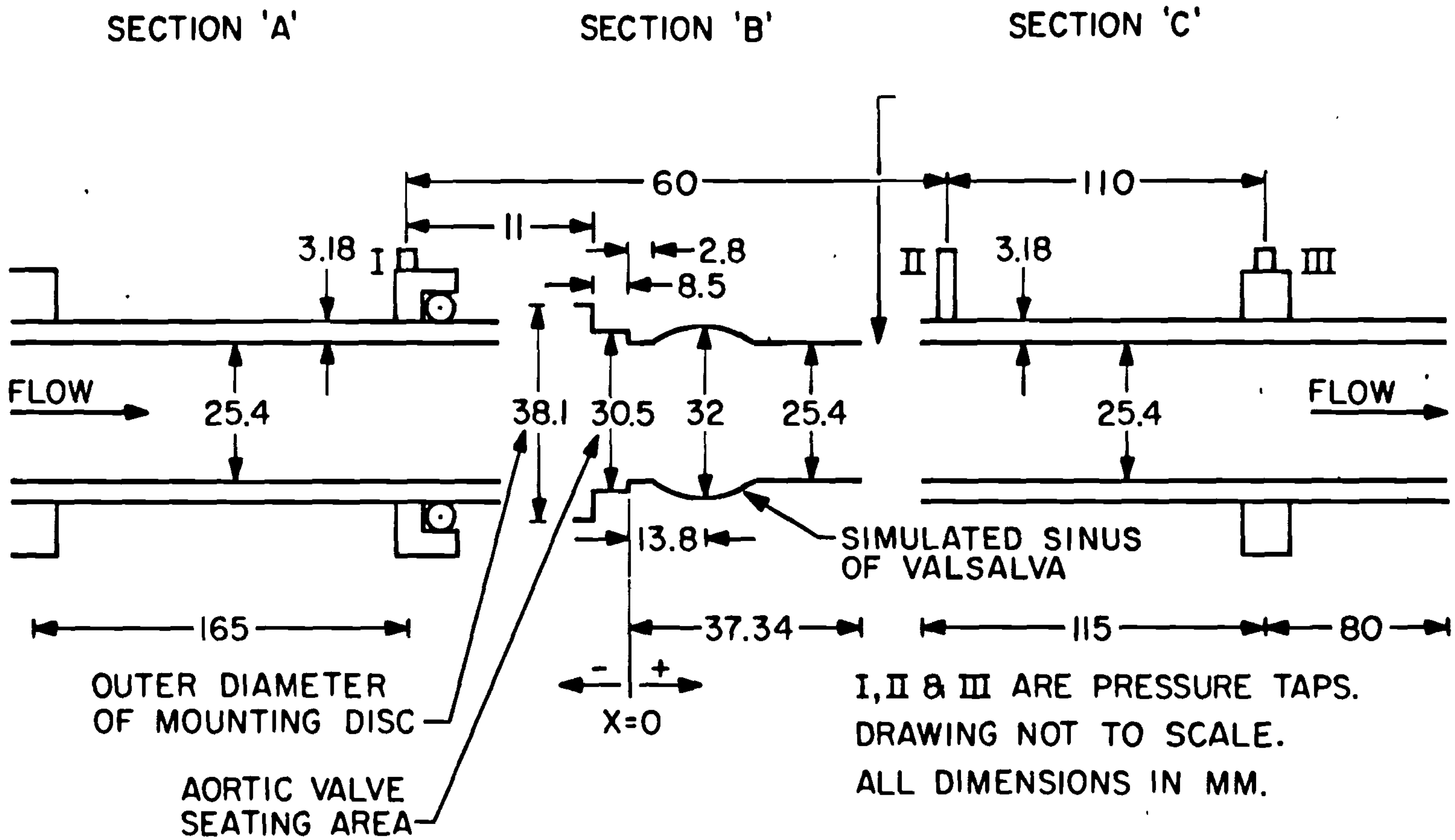
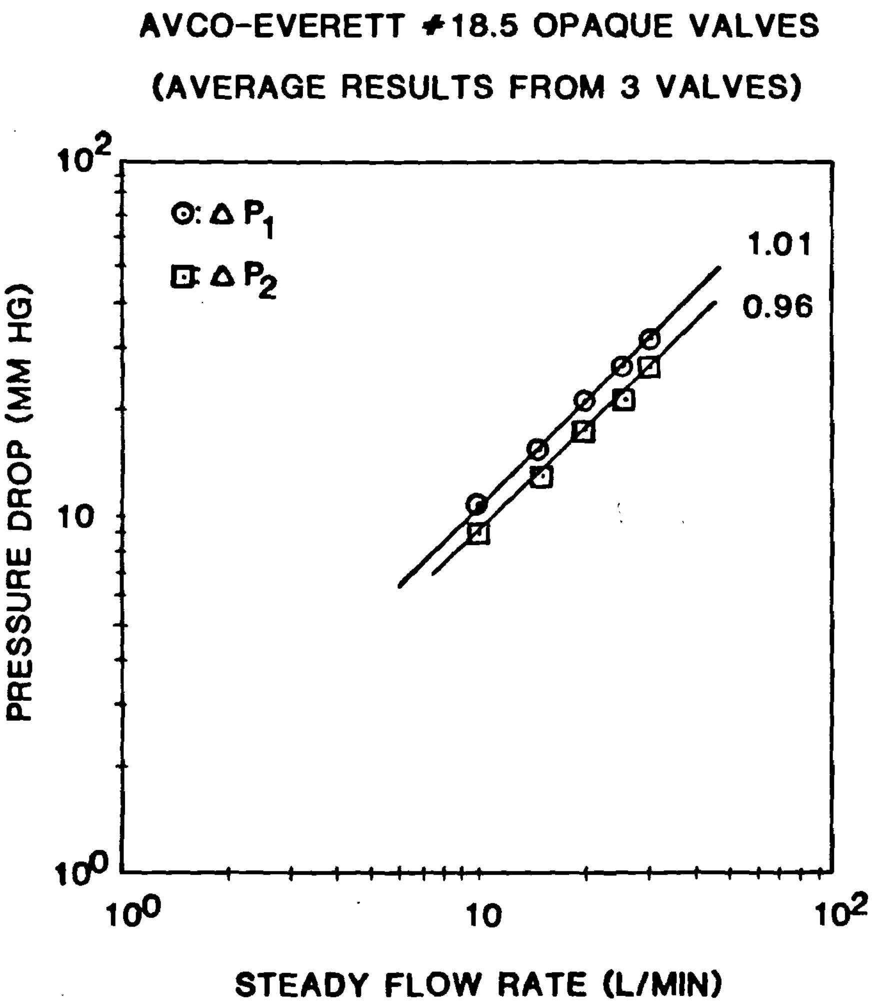

SECTION 'A'
SECTION 'B'
SECTION 'C'
60
110
11
2.8
8.5
3.18
I
II
III
3.18
FLOW
25.4
38.1
30.5
32
25.4
25.4
FLOW
13.8
SIMULATED SINUS
OF VALSALVA
165
37.34
115
80
OUTER DIAMETER
OF MOUNTING DISC
-
+
X=0
AORTIC VALVE
SEATING AREA
I, II & III ARE PRESSURE TAPS.
DRAWING NOT TO SCALE.
ALL DIMENSIONS IN MM.

Figure 1

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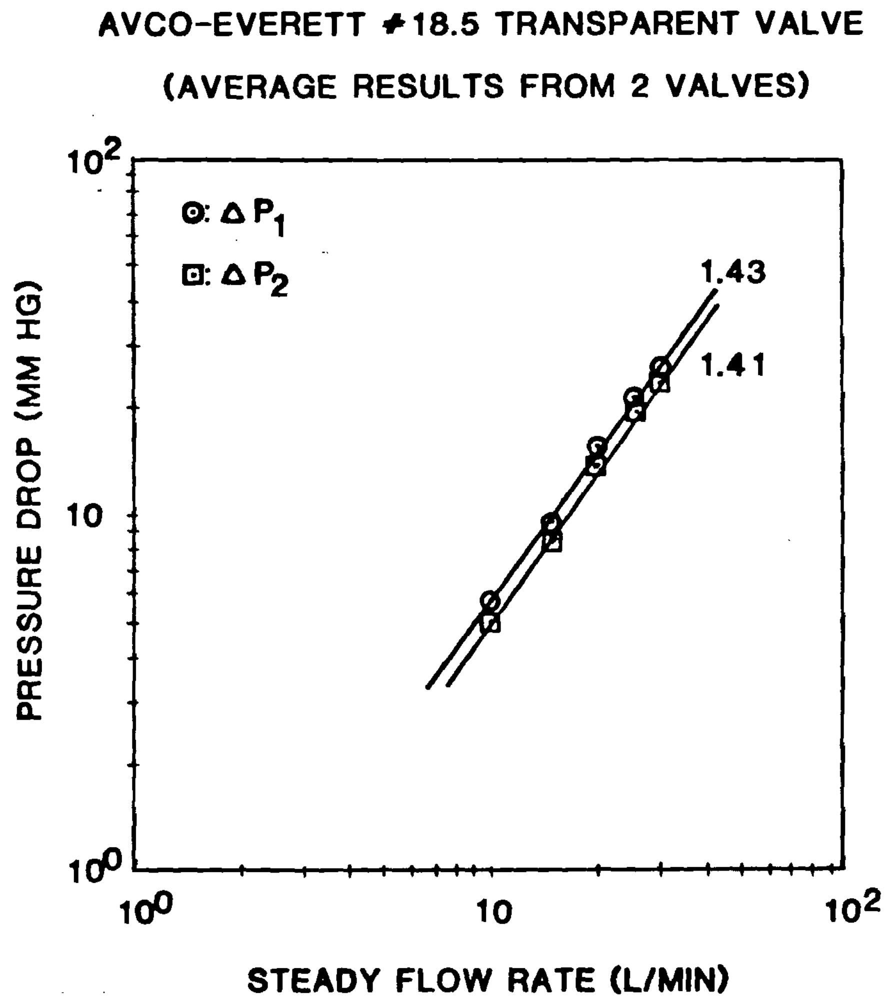


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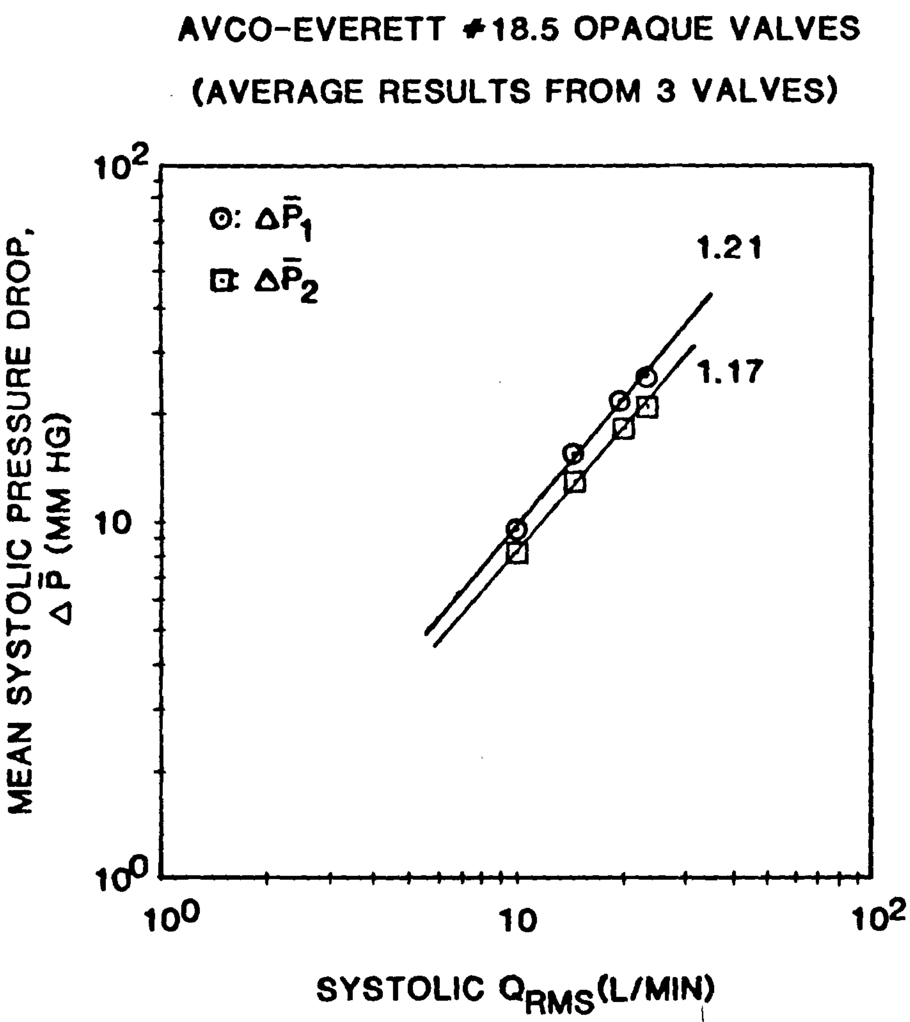


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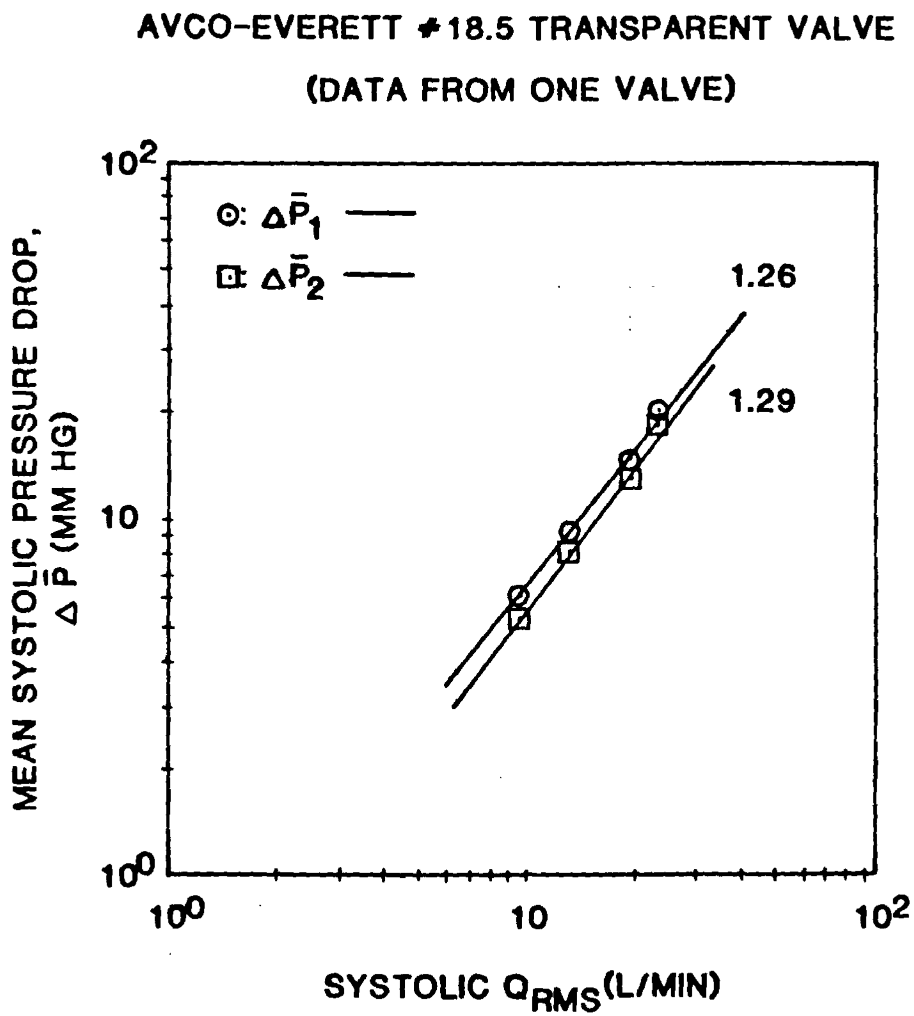


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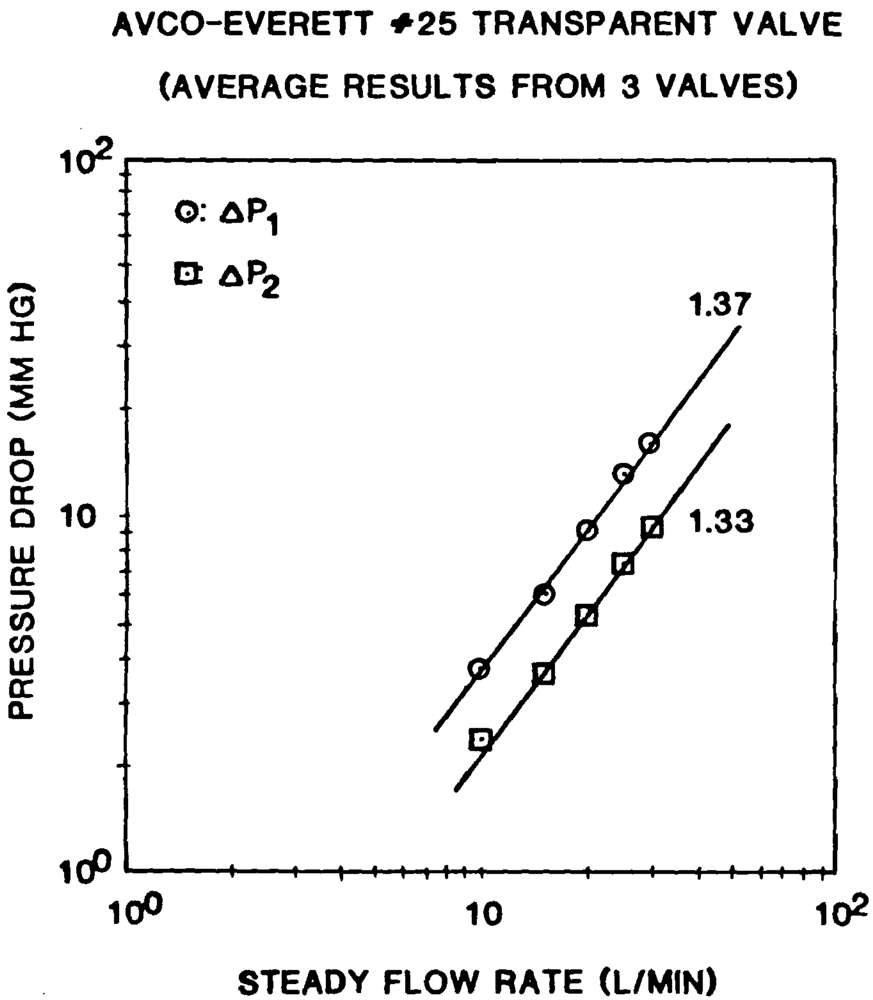


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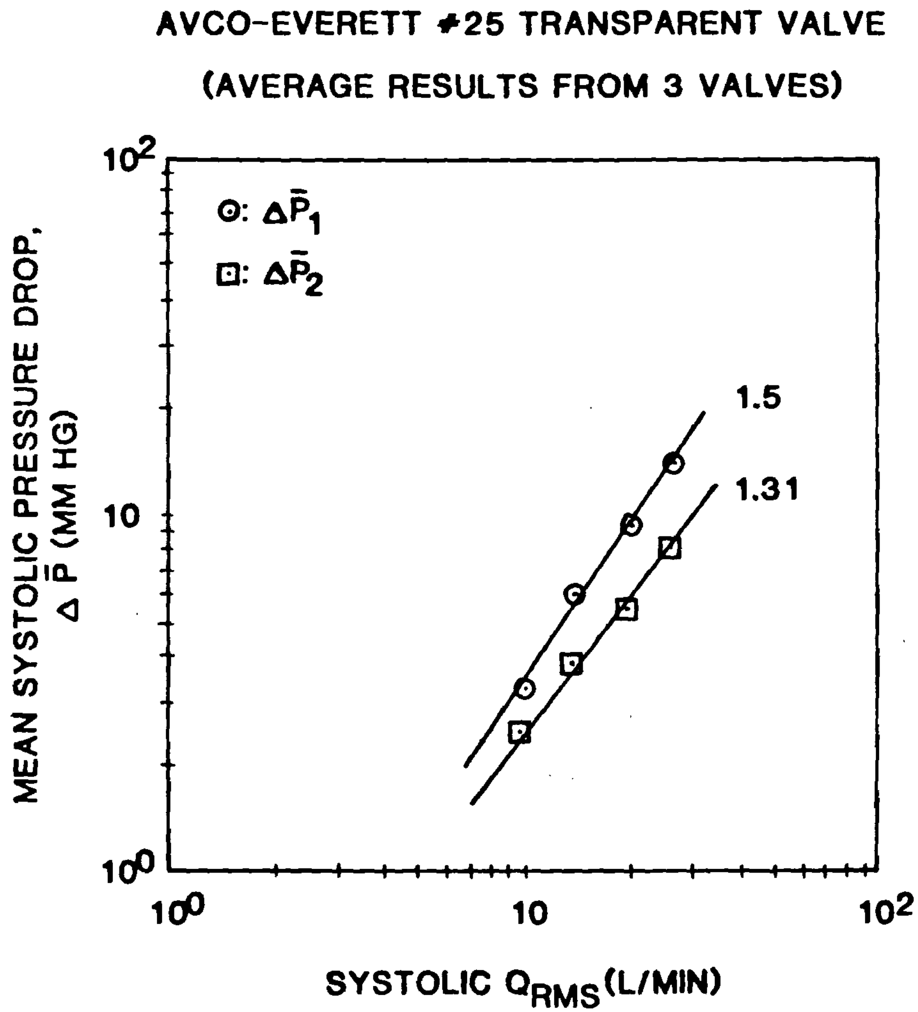


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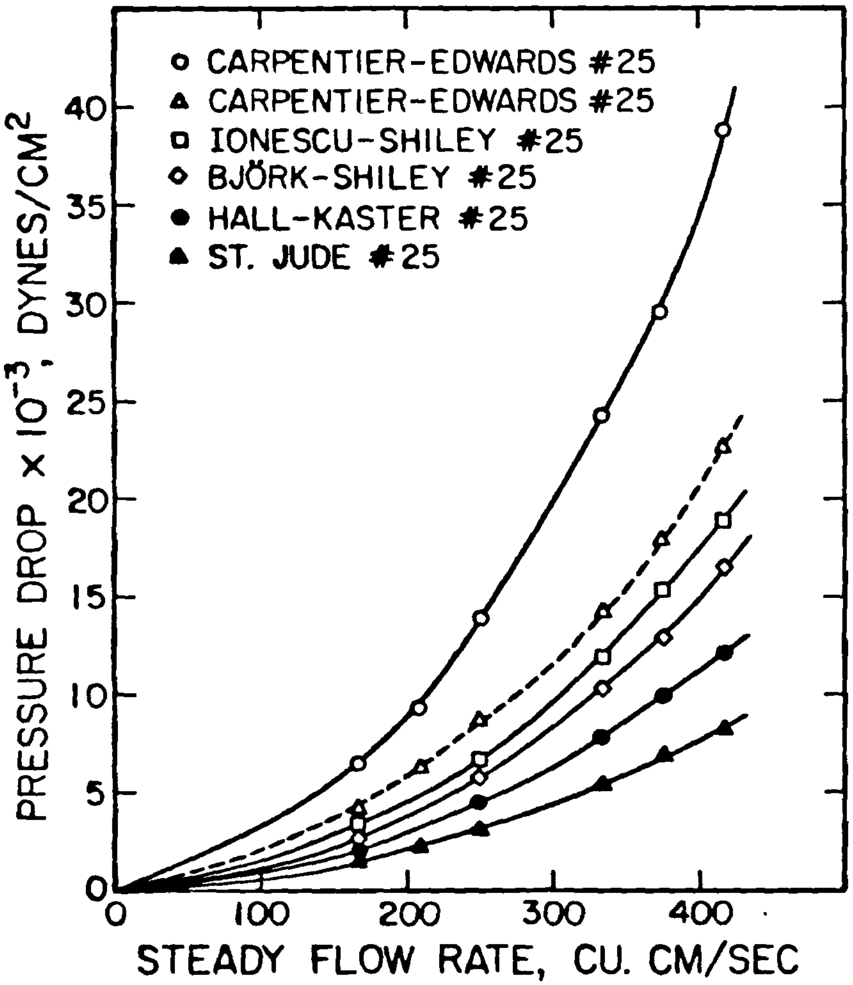



Figure 8

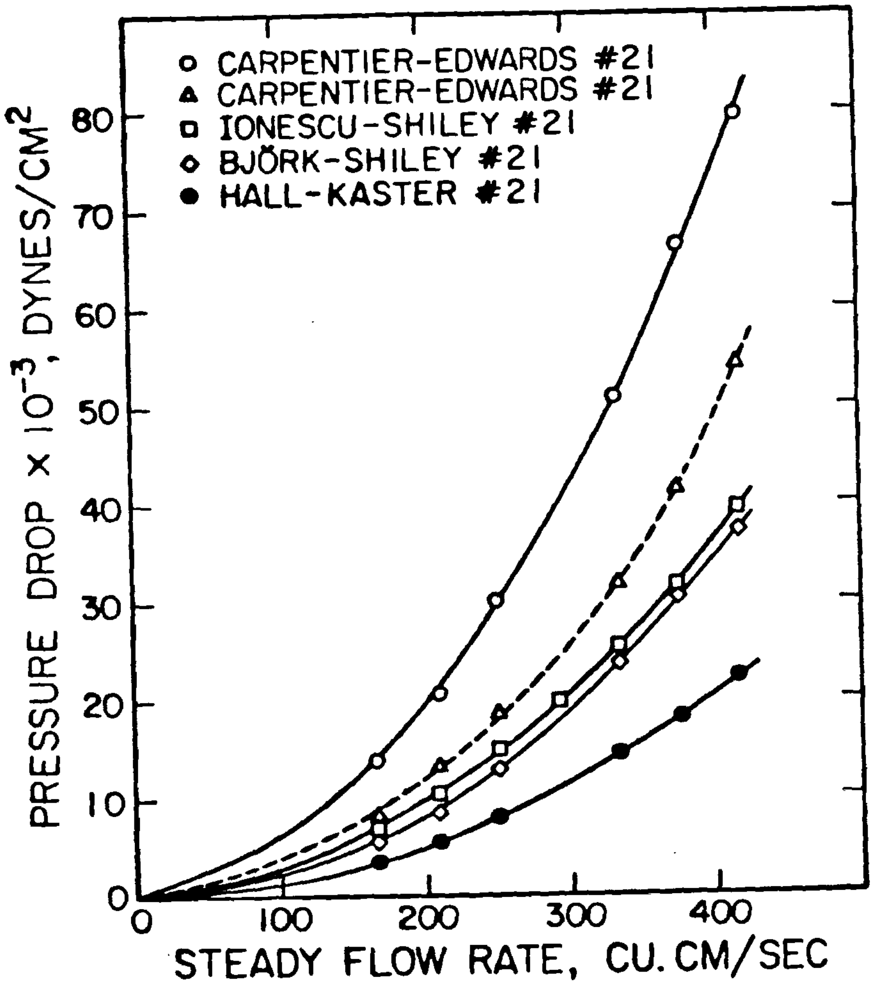



Figure 9

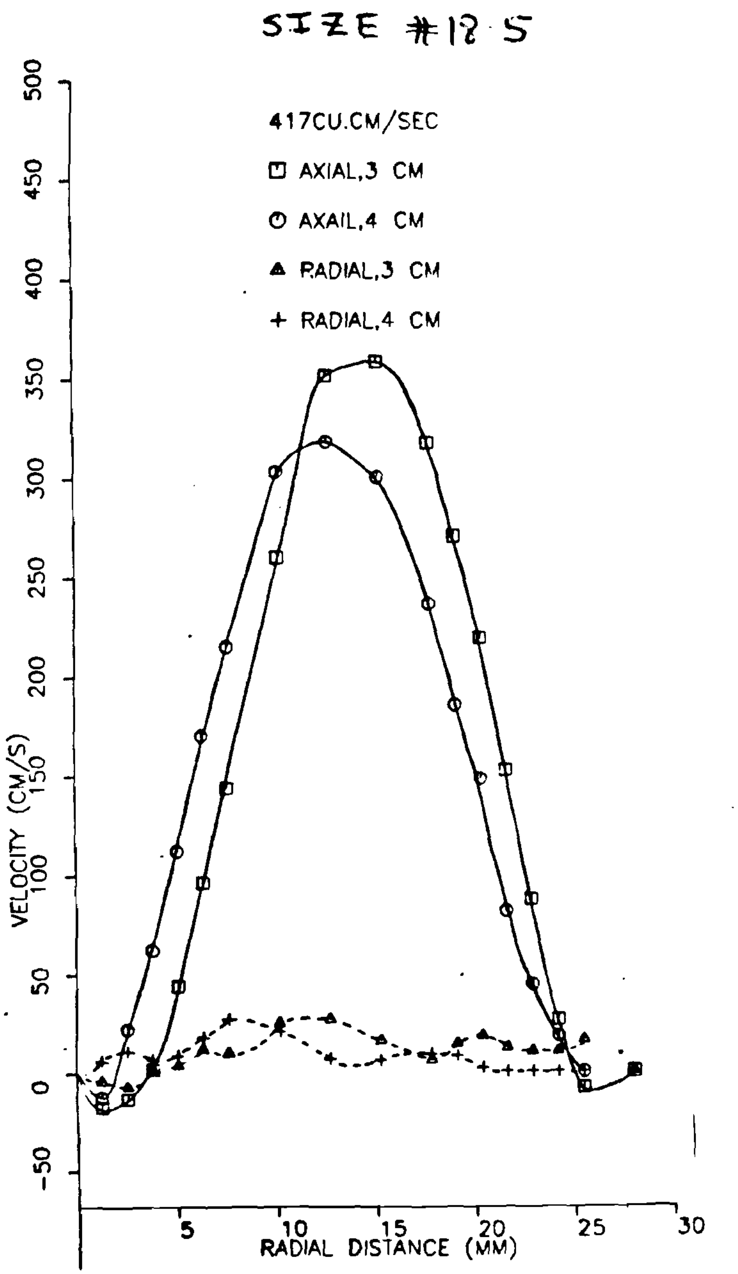
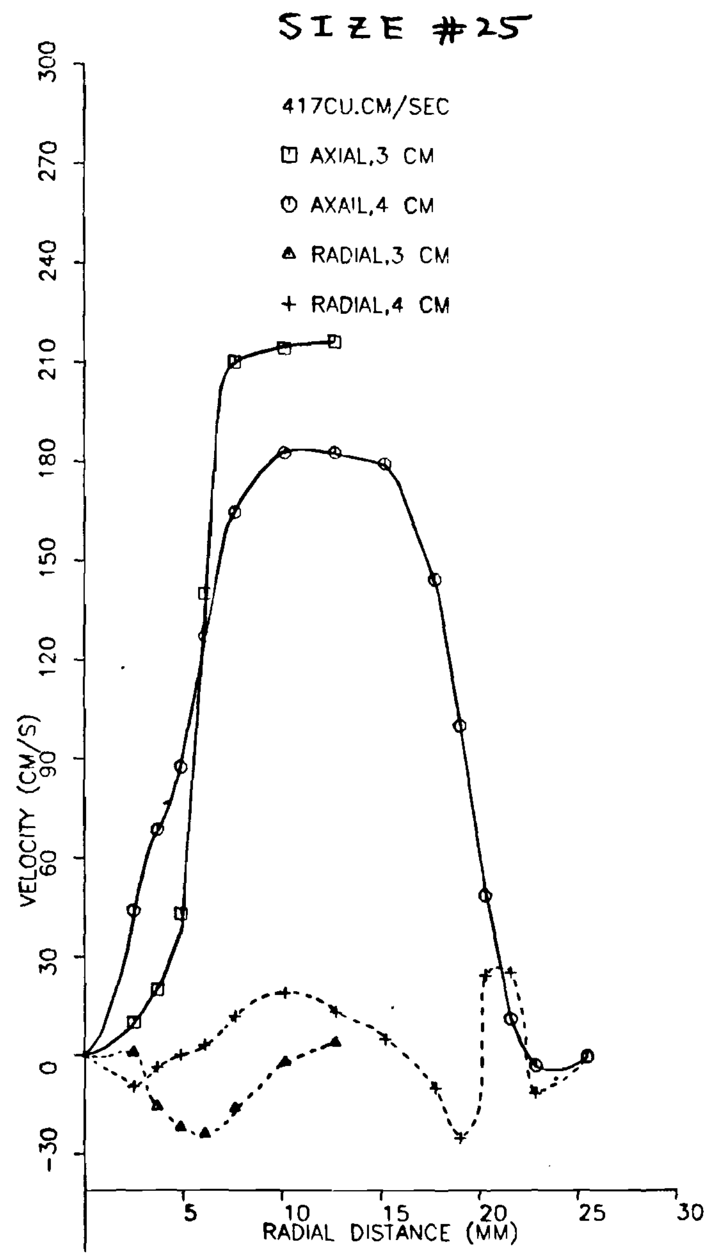



Figure 10

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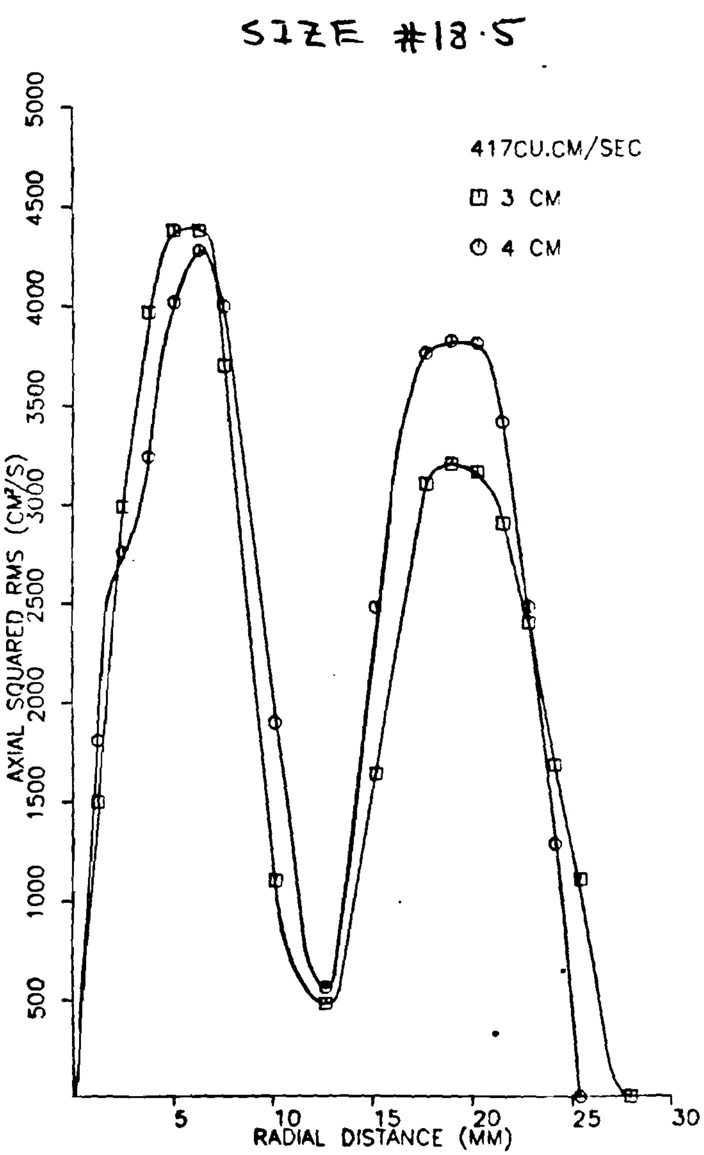


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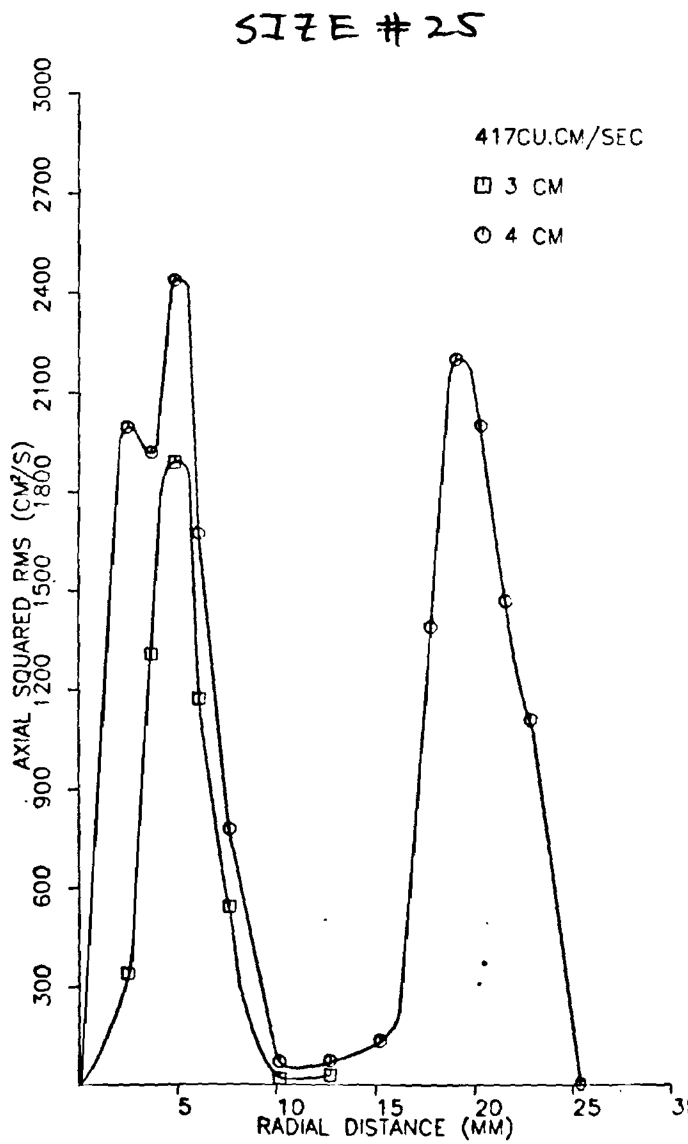



Figure 13

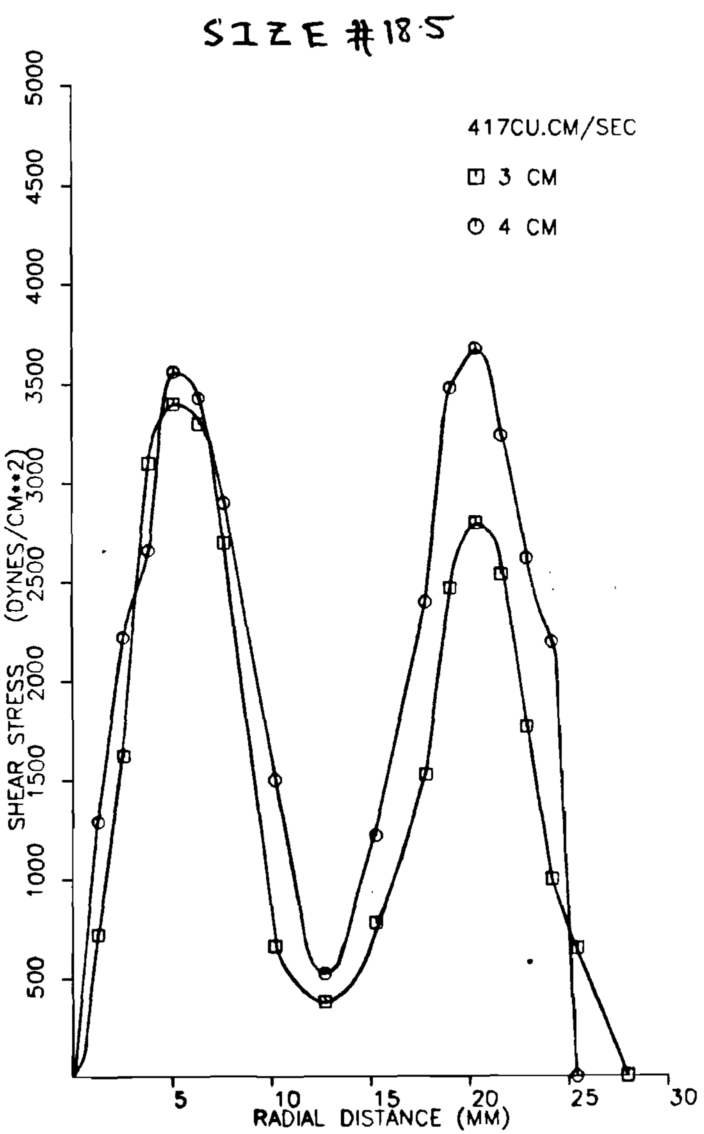



Figure 14

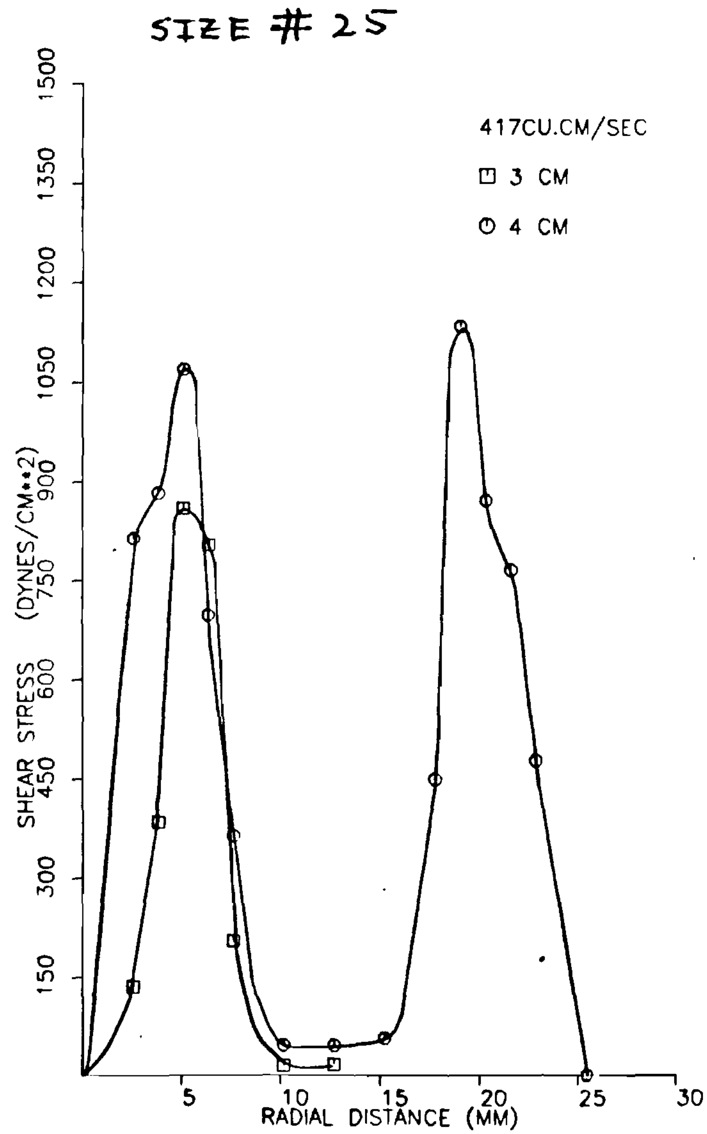
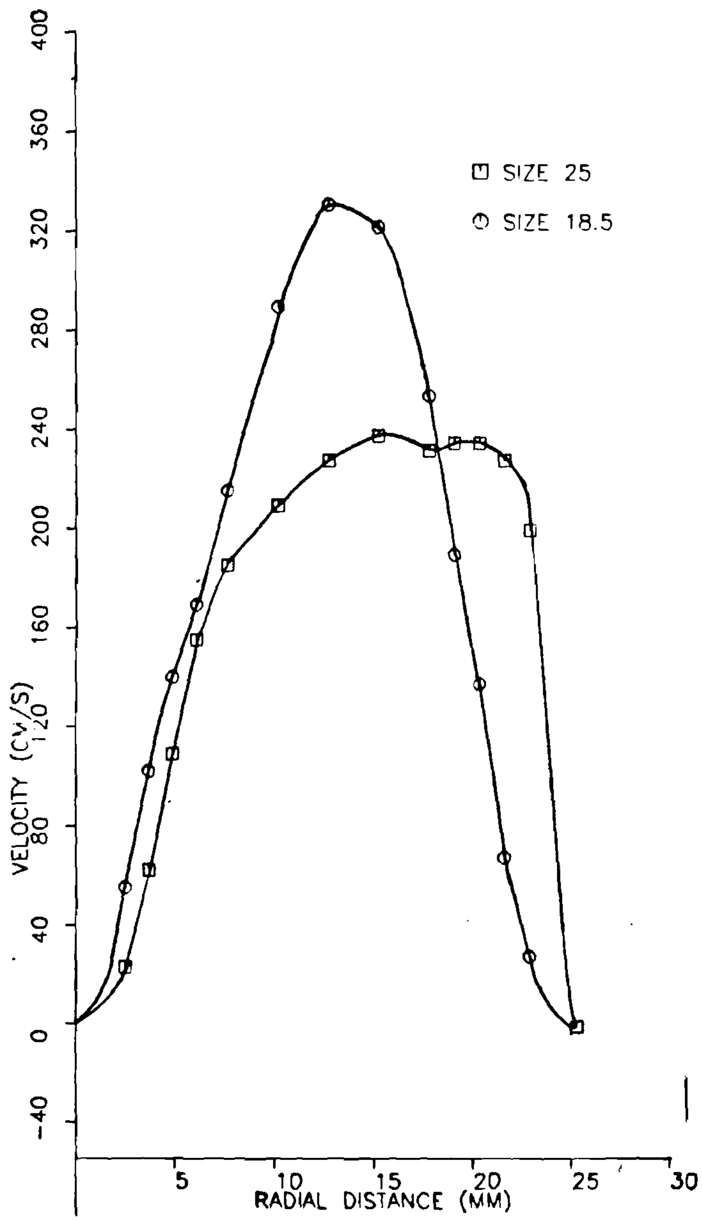



Figure 15

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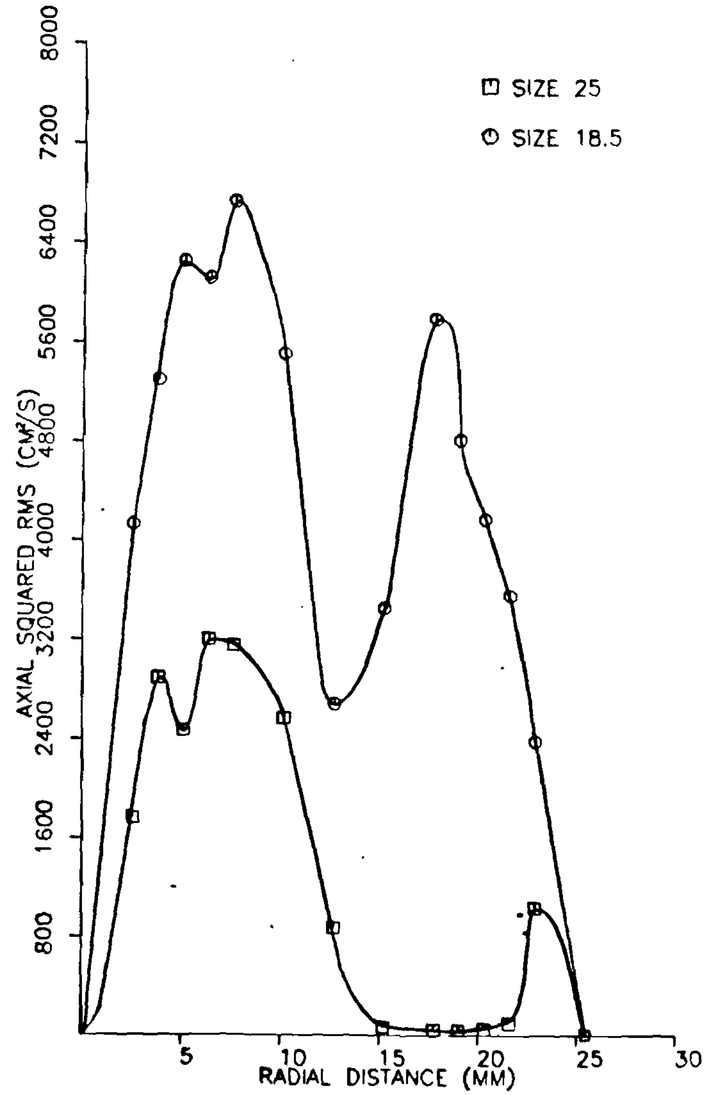


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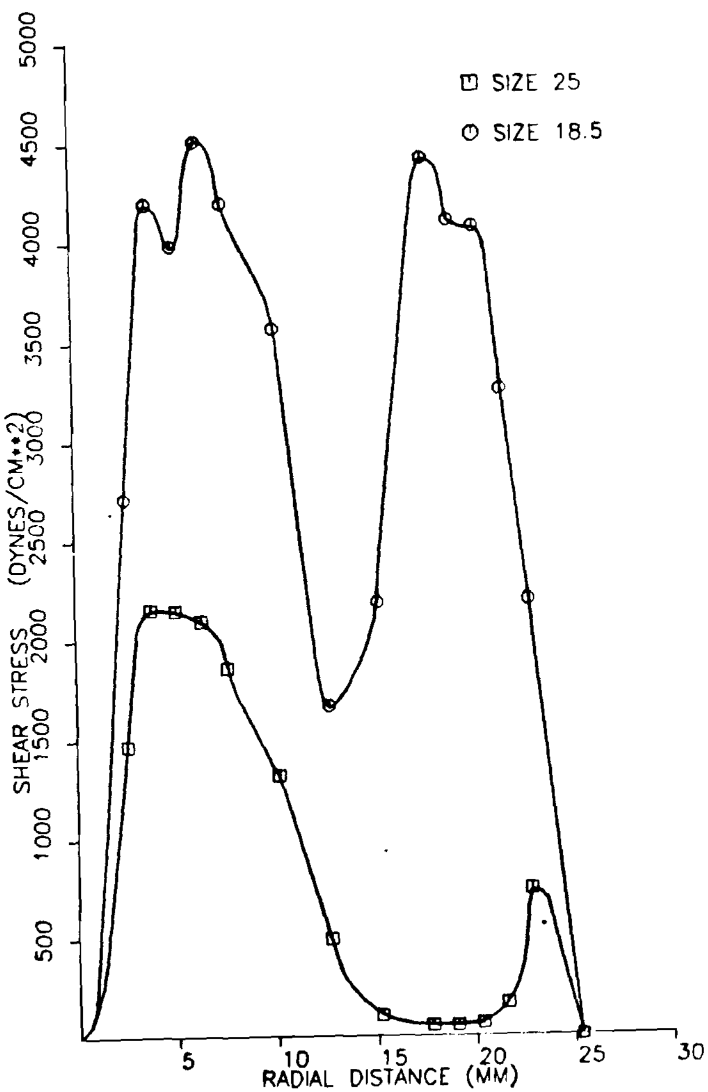



Figure 18

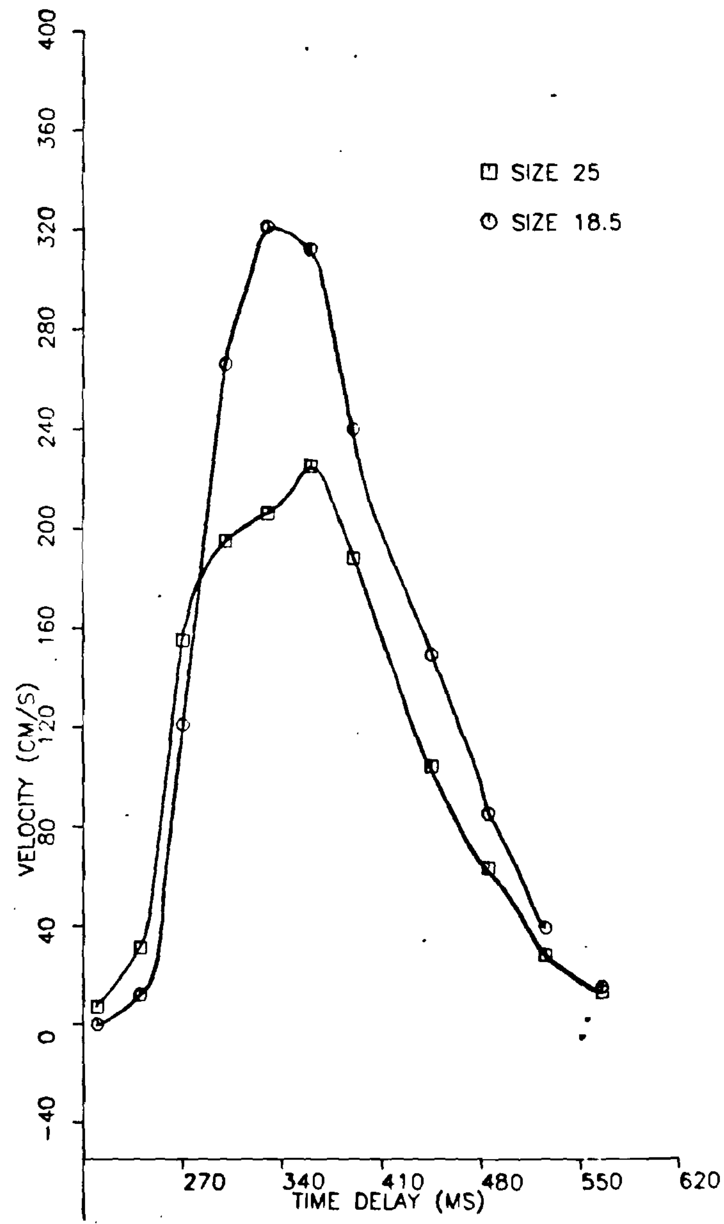



Figure 19

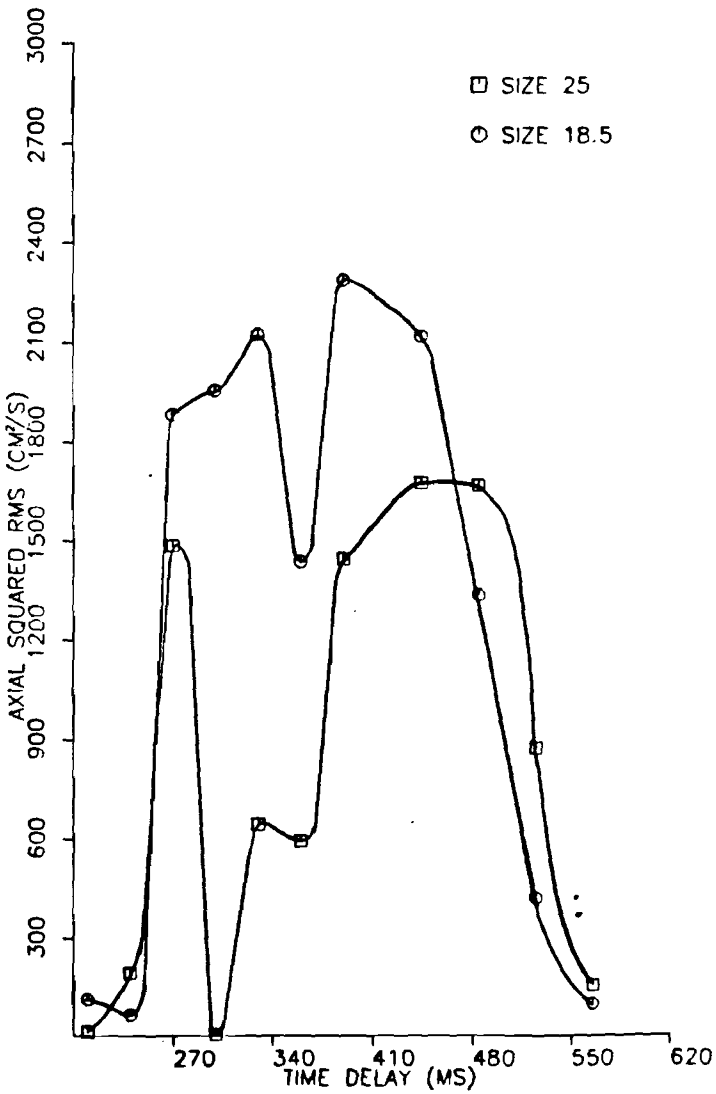
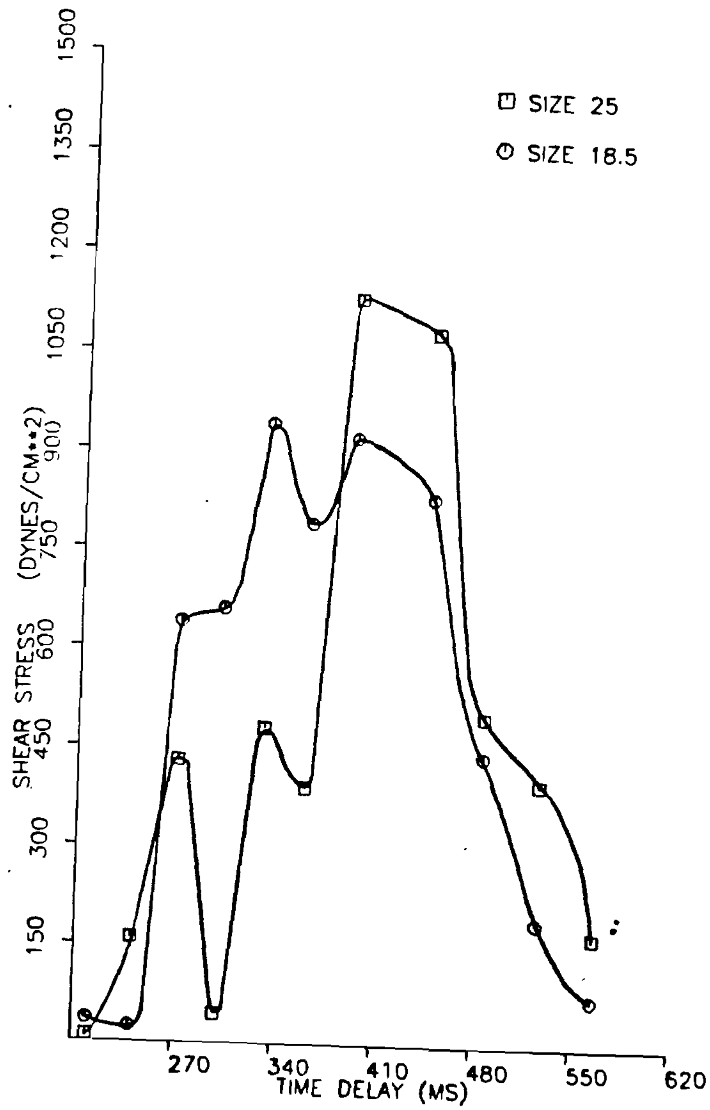



Figure 20

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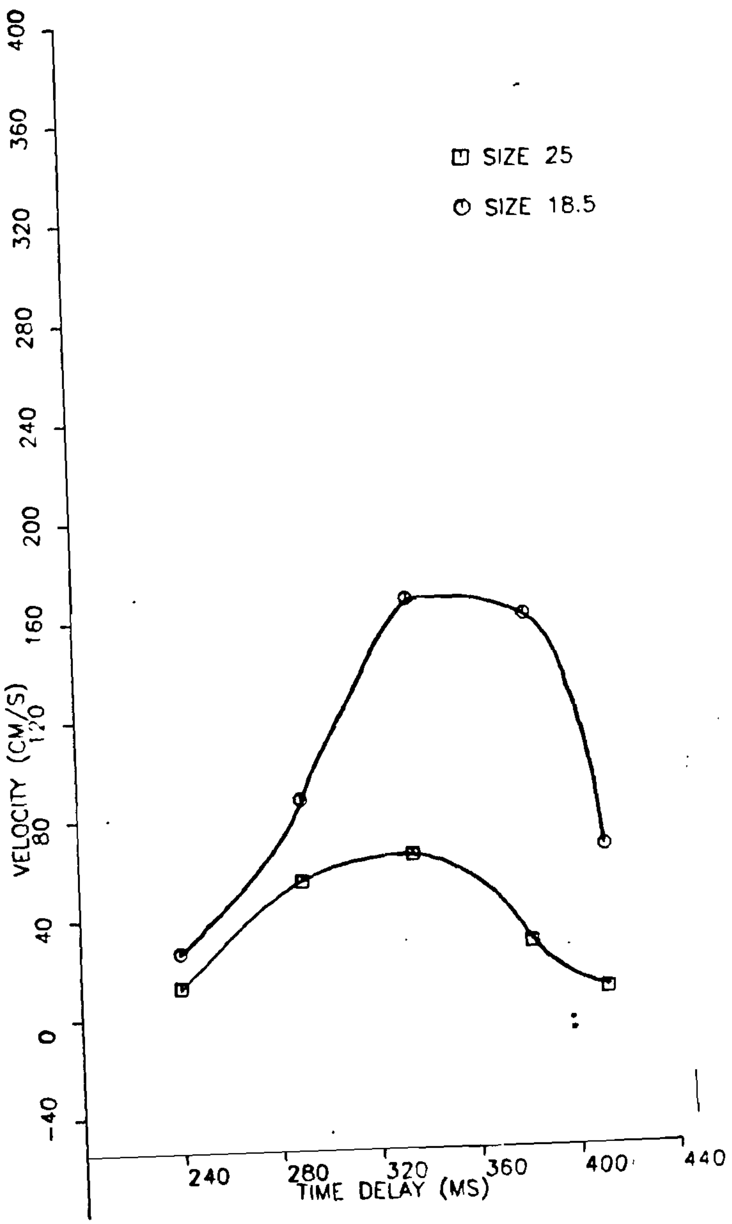


Figure 22

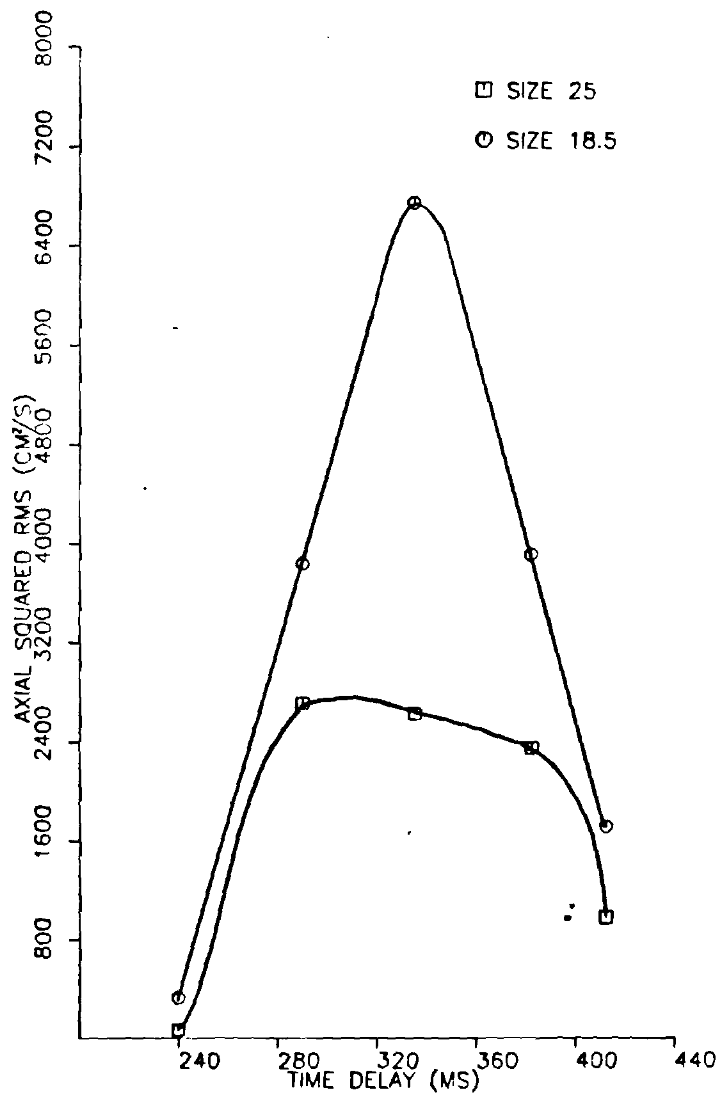


Figure 23

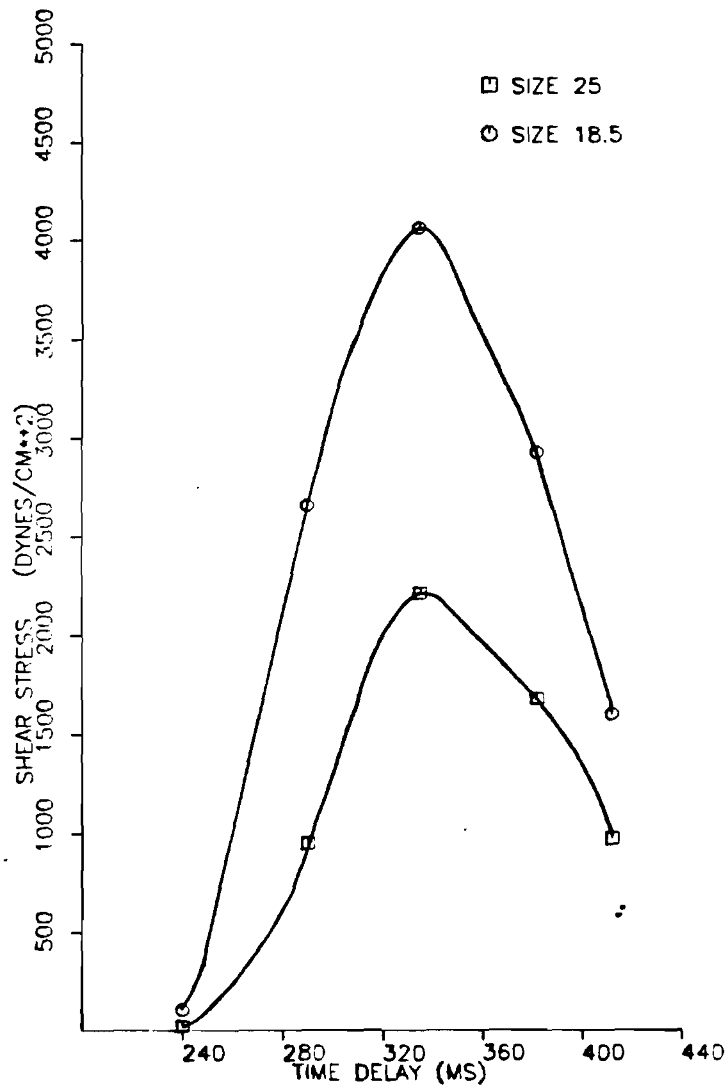
SIZE 25
SIZE 18.5
SHEAR STRESS (DYNES/CM**2)
5000
4500
4000
3500
3000
2500
2000
1500
1000
500
240
280
320
360
400
440
TIME DELAY (MS)

Figure 24