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PRELIMINARY STUDIES WITH A VARIABLE TRANSFER COMPOSITE POLYMER MEMBRANE

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ABSTRACT

A preliminary study was done to determine the feasibility of using a compressed fibrous teflon (PTFE) silicone polymer membrane in extracorporeal oxygenation devices. A series of composite membranes were fabricated, using different concentrations of a dimethyl silicone polymer dissolved in petroleum ether, to give membranes having variable oxygen transfer properties. A gas-gas system was chosen to obtain the necessary transfer data. Data were obtained by transferring pure oxygen through the membranes into a mixture of 47 mole percent oxygen and 53 mole percent carbon dioxide. All analyses were obtained by chromatographic techniques. The results of these experiments show that membranes can be fabricated having a wide range of oxygen capabilities. The oxygen transfer coefficients, when translated to blood-oxygen data, indicate that these composite membranes may be feasible for use in oxygenator devices. This type of membrane has the desirable feature of using thin silicone membranes which are self supporting.

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PRELIMINARY STUDIES WITH A VARIABLE TRANSFER COMPOSITE POLYMER MEMBRANE

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I. INTRODUCTION

A voluminous amount of information, concerned with respiratory support through extracorporeal oxygenation, has been published in the past decade. It is generally acknowledged that dish, film and bubble oxygenators, or any device that brings blood into direct prolonged contact with a gaseous oxygen interface, can cause irreversible damage to the cells, platelets, enzymes and proteins of the blood.(1-7) Some of these problems can be eliminated at least partially through the use of membrane type oxygenators. For a given device the effectiveness of oxygen transfer into venal blood is a function of device design and operating parameters.(8-19) Encouraging but differing results have been obtained from both membrane and capillary type oxygenators employing largely silicone and Teflon polymer membranes, and silicone capillaries.(20-29)

Film resistance imposed by boundary layers is a major limitation in O_2 transfer and is now recognized by all investigators of recent publications. Lande, et al.(30) present a synopsis of current problems.

Various attempts have been made to produce more efficient membranes through combinations of materials. Pierce and Dibeliu(31) fabricated a copolymer membrane from a polycarbonate and a silicone. Blood distribution patterns were formed into the membrane using a solvent evaporation technique in conjunction with a molded design. Bromson, et al.(32) reported a circular membrane consisting of a silicone polymer impregnated into a glass fabric. Composite membranes of a silicone polymer impregnated, regenerated cellulose have been reported to exhibit good anticoagulant properties and satisfactory O_2 transfer. Esmond and Debelius(33) constructed an oxygenator which utilized thin silicone membranes in conjunction with nylon screen spacers with good results. Kylstra(34) pleated the edges of an unstretched polymer bag to produce a uniform pattern of transverse corrugations upon lateral traction which aided in O_2 transfer.

Membrane supports consisting of grooved polymer and elastomeric sheets, screens, nets and expanded corrosion resistant metals have also been used in attempts to alter blood flow paths.(35,36) Kolobow and Bowman(37) channeled O_2 through fiberglass strands between dacron-silicone membranes. Grode(38) attempted to obtain non-thrombogenic surfaces from coatings in order to make more stable membranes. Varying degrees of success were reported on the above based on in vivo and in vitro tests with animals and animal blood.

II. PROBLEM STATEMENT

The purpose of this work was to fabricate and test a series of composite membranes which exhibited variable transfer properties for the O_2-CO_2 system and to illustrate the ability of these membranes to withstand mechanical stresses. Since oxygen transfer requirements necessitate thin membranes, malfunctions have occurred because of the working membranes deforming to the shape of the backing materials which results in a decrease of blood flow through the oxygenator device.

The membranes investigated were composed of a compressed fibrous polytetrafluoroethylene (PTFE) impregnated with a dimethyl siloxane and some cases coated with a plasma-deposited film. These composite materials are potentially capable of a wide range of transfer capabilities and offer better mechanical stability than supported membranes.

III. EXPERIMENTAL

A series of experiments is described which was designed to determine if a self-supporting variable transfer membrane could withstand the range of pressures and mechanical stresses expected in an oxygenator system. Initial experiments were performed using a gas-gas system since this laboratory did not have a ready supply of blood.

Membrane Preparation

A Chemplast compressed fibrous PTFE membrane (bulk thickness = 0.018 inches) was twice extracted with methylene chloride to remove possible contaminants and loose fibers that resulted from the production of the substrate. After drying, the weight of each membrane was recorded.

The silicone polymer used to impregnate the membranes was Dow-Corning RTV-382. To obtain a range of working film thicknesses, the polymer was dissolved in petroleum ether prior to application. The solution was originally 40 weight percent polymer, with 0.125 weight percent stannous octoate (based on polymer) as a catalyst for crosslinking subsequent concentrations were obtained by diluting the 40% mixture.

The coating of the PTFE was accomplished by immersing the substrate into the polymer solution in an ultrasonic field. The membrane was taken from this solution, placed in the center of a flat glass plate, and the excess solution was removed by a draw down technique. The membrane was cured under ambient conditions for a minimum of 48 hours. Membranes were reweighed and stored in a desicator prior to testing.

Two separate series of membranes, one untreated PTFE and one which had been treated with silicone polymer, were coated with 5 microns of plasma-deposited polypropylene. (39)(40) Previous results obtained in this laboratory have shown that the silicone polymer has chromatographic qualities and that the physical properties of the silicone are altered by the adsorption of components from blood. A thin film of a plasma-deposited polymer has been shown to reduce the adsorption rate of blood components which we consider to be a desirable feature.(41)

IV. APPARATUS

The experimental apparatus is shown in Figures 1 and 2. The gas composition on one side of the permeability cell was an oxygen and carbon dioxide mixture in essentially the same mole ratio as in venous blood. ($46.5\%O_2/53.5\%CO_2$). UHP oxygen was used on the other side of the cell. The transfer was carried out with both sides of the cell vented to the atmosphere. Because of the dangers involved in using pure oxygen, all components and materials used in these experiments were thoroughly cleaned to remove traces of organic residues.

The oxygen flow rate was set at 100 ml per minute by adjusting a 1/8-inch metering valve (V-1) and measuring the volume of flow on a bubble meter (B-1) as a function of time. The oxygen flow rate was set with only the oxygen side of the permeability cell open to the atmosphere and set high enough to insure a measurable transfer coefficient to the venous side of the cell. Then the oxygen side of the cell was closed (V-3), (V-5) and the venous mixture side was opened (V-4), (V-6) to the

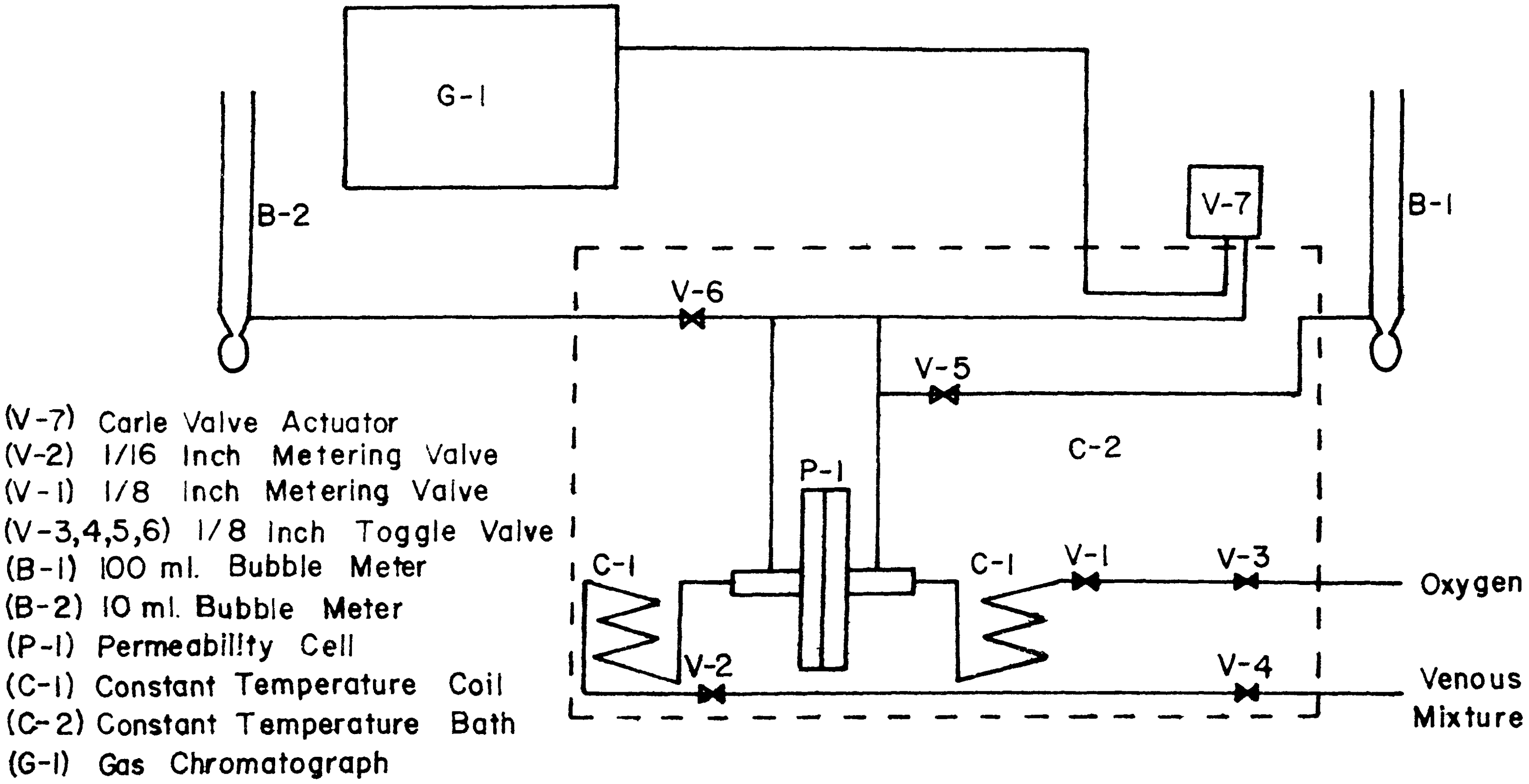

Figure 1. Flow Diagram of Experimental Apparatus

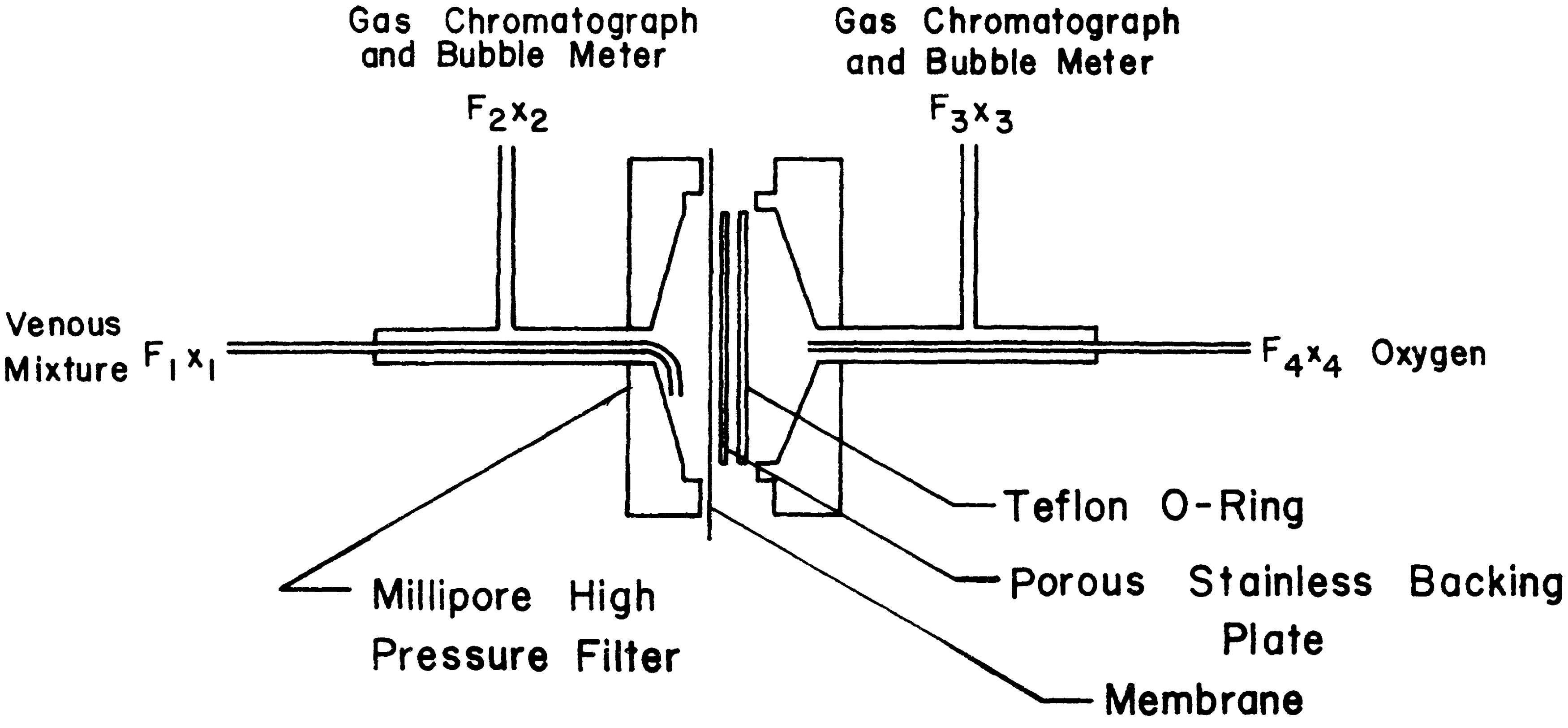

Figure 2. Details of Transfer Cell

atmosphere. The venous mixture flow rate was set in the same manner as the oxygen flow rate. A 1/16-inch metering valve (V-2) was used on the venous side of the cell. Venous mixture flow rates were set at 9 to 10 milliliters per minute, low enough to determine a transfer coefficient for the oxygen flow.

The permeability cell, the 1/16-inch metering valve (V-2), the 1/8-inch metering valve (V-1), the sample loop of the Carle Valve Actuator Model #4200 (V-7), and the 15 feet of stainless steel tubing were all immersed in a water bath maintained at 30.0 ± 0.5°C.

The composition of the venous mixture was checked every five minutes with an automatic sampling valve (V-7) until there was constant composition to within 2 percent according to the chromatographic results. When constant composition was attained, the oxygen side of the cell was again opened (V-3, V-5) to flow.

The permeability cell was then opened to flow on both sides of the membrane. Steady state was established in less than one minute after both sides of the membrane were opened to flow. Flow rates of the oxygen and venous mixture were checked again to determine any change. The composition was checked again according to the previous procedure.

Gas chromatography was used to separate intermittent samples of the oxygen and carbon dioxide gases and the results were recorded. A Varian Aerograph Series 1520 gas chromatograph with a thermal conductivity bridge detector was used for all analyses. Column packing was Poropak Type Z 100 mesh in a 5 feet x 1/8 inch diameter column, with helium carrier gas. A Beckman recorder with integrated was used to record the data.

A sample was taken every five minutes by the valve actuator. The sampling valve contained two one-ml stainless steel loops maintained at constant temperature, one of which remained in the test stream while the other was being vented to analyses. The carrier gas delivered the sample to the chromatograph. The retention time for the carbon dioxide was sufficiently greater than for the oxygen to insure complete separation.

The best column temperature was found to be 45-50°C and the detector temperature was 145°C. A calibration curve was established for mole ratios of CO_2 and O_2 from 1.00 to 0.00 as a function of thermal conductivity response The thermal conductivity response obtained from the chromatograph could then be converted directly to mole fractions. Carrier gas flow rate and chromatograph conditions were adjusted to insure complete resolution of the carbon dioxide and oxygen peak.

A JSM-2 scanning electron microscope was used to obtain micrographs of the surfaces and cross-sections of the membranes.

V. RESULTS AND DISCUSSION

The consistency of the PTFE substrate was somewhat random. Transfer properties of different lots varied by as much as 10-20%. These inconsistencies prevented a meaningful evaluation of 0.4 mil and thinner film thicknesses. However, with film thicknesses above 0.4 mil, reproducible results were obtained. Multidata points agreed within ±2%. The chromatographic methods used in this study are considered to be more accurate and precise for determining gas compositions than probe and absorption techniques. Chromatographic methods are also more rapid and give analyses of the gas streams at specified intervals. There was never any question as to when steady state conditions had been reached. For any particular run the analyses of composition at steady state agreed to within ±1%. The overall error limits of these experiments were established as ±3-4% based upon material balances across the membrane. Figure 2 is labelled to illustrate the streams used in the material balances. All material balances were based on the carbon dioxide of the venous composition. The CO_2 (IN) is the flow rate, F_1, times the mole fraction of CO_2, (X_1). The CO_2 (IN) must equal the CO_2 (OUT) of the cell which is represented by the following equation

$$F_1X_1 = F_2X_2 + F_3X_3$$

where:

F_1 is flow rate of venous mixture in, (ml/min)

F_2 is flow rate of venous mixture out, (ml/min)

F_3 is flow rate of oxygen out, (ml/min)

X_1 is mole fraction of venous CO_2

X_2 is mole fraction of enriched venous CO_2

X_3 is mole fraction of CO_2 in oxygen stream.

The mole fraction of CO_2 in the oxygen stream (X_3) was sometimes too small to detect, but since all other quantities were measured and known, the value of X_3 could be calculated and was in many cases less than 1% of the total stream.

The greatest sources of error (3-4%) were related to regulation of gas flow rates and the ability to accurately translate the chromatograph read out to mole fractions via the calibration curve.

The data obtained on the gas-gas system imply that the composite polymer membranes utilized in this study are capable of variably transferring oxygen over a wide range of polymer compositions and gas flow rates. Figure 3 shows the effects of apparent polymer film thickness on oxygen transfer to the venous side of the membranes. The upper curve (A) represents results for oxygen:venous mixture flow rates of approximately 10:1, and the lower curve (B) shows results for equal flow rates of 1:1. Apparent film thicknesses were obtained by dividing the

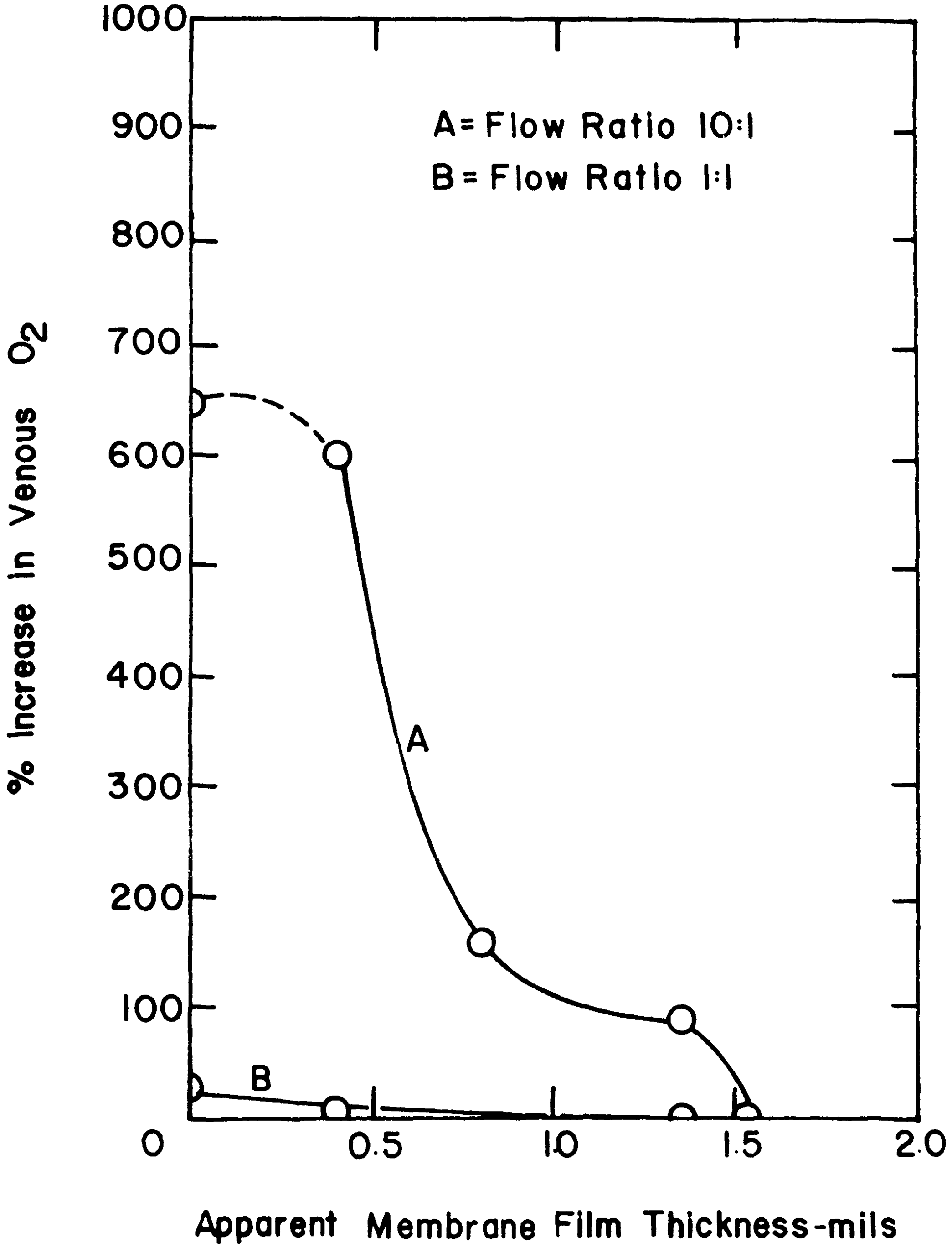

Figure 3. Oxygen Transfer as a Function of Silicone Polymer Film Thickness

weight of silicone polymer impregnated into the membrane by the density of silicone polymer and the face area of the membrane. These film thicknesses were not uniform throughout the membrane but serve as a reference for comparing different membranes. Table I relates the apparent film thickness to the concentration of polymer used to treat the membranes.

TABLE I

APPARENT FILM THICKNESS OBTAINED FROM SILICONE POLYMER SOLUTIONS

Silicone Polymer in Solution (wt%)	Apparent Film Thickness (mils)
10	0.4
20	0.8
40	1.35
50	1.5

Figure 3 for the 10:1 flow ratios shows that the 0.4 mil film (10%) had little effect on the oxygen transfer indicating that gross voids within the PTFE structure were not ffected. However, the oxygen transfer rate is significantly effected when the film thickness is increased to 0.8 mils (20%). Above 0.8 mil the oxygen transfer is greatly reduced, and for all practical purposes transfer is considered insignificant. At equal flow rates the oxygen transfer is a function of the oxygen concentration gradient across the membrane, as would be expected.

Figure 4 shows the carbon dioxide transfer to the oxygen side of the membranes which accompanied the results for the oxygen transfer. The curves A and B are consistent with curves A and B of Figure 3. It was possible to reproducibly vary the oxygen transfer from 600 to essentially zero percent by varying the flow rate on the oxygen side of the cell while keeping the venous flow rate at a constant value. Under these conditions the carbon dioxide transfer from the venous to the oxygen side of the cell varied from 16 to essentially zero percent for the higher oxygen flow rates and 31 to zero percent for equal flow rates. Table II lists the transfer coefficients calculated from these results.

The numbers reported here are not meant to bracket any particular transfer limits but are intended to show that it is feasible to construct a composite polymer membrane having variable oxygen and carbon dioxide transfer properties. It is of importance to recognize that this, or a similar, system allows a thin membrane thickness to be used which is strong enough to withstand pressures and mechanical stresses without external support. In a real situation the transfer of oxygen and carbon dioxide into

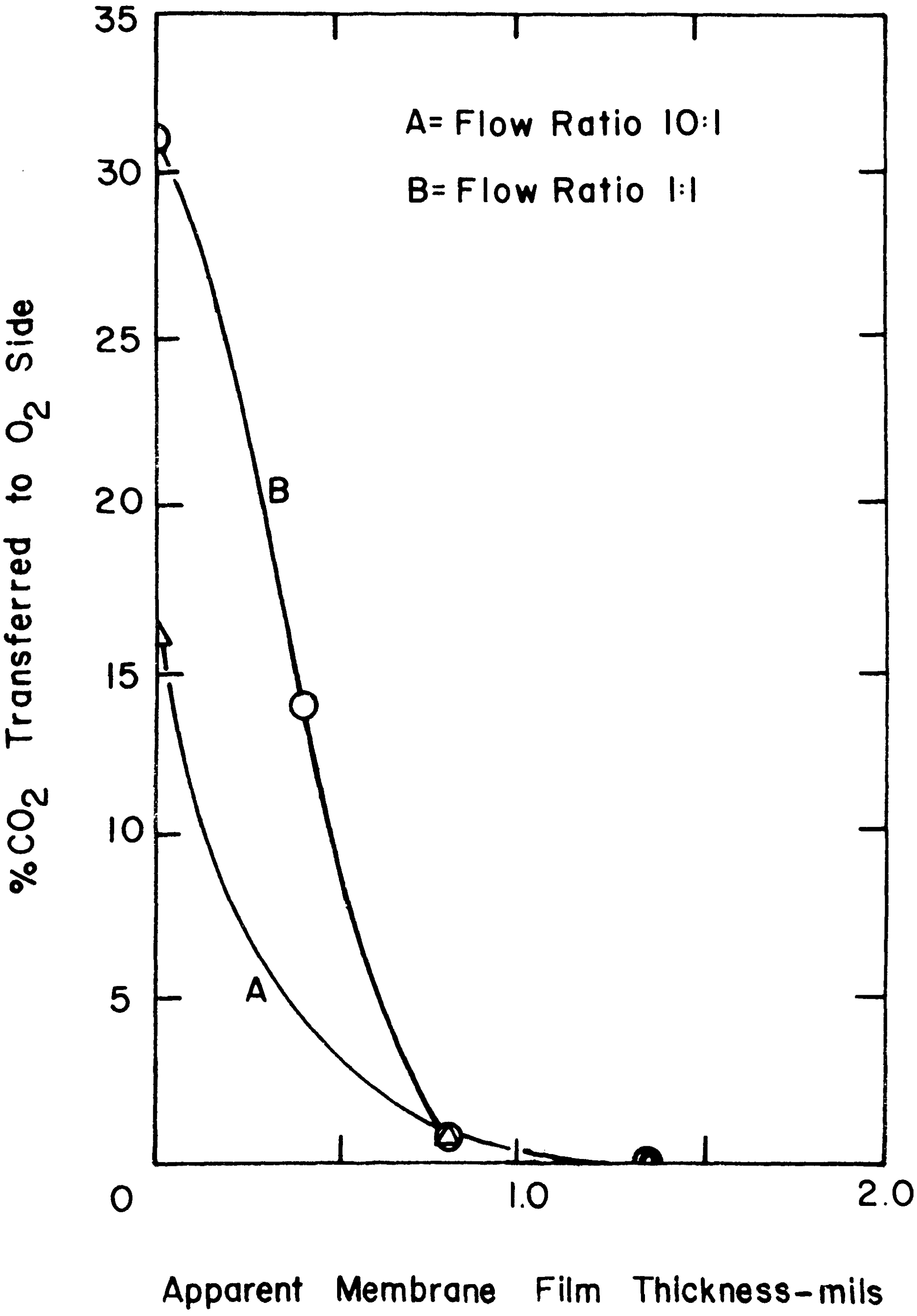

Figure 4. Carbon Dioxide Transfer as a Function of Silicone Polymer Film Thickness

TABLE II

OXYGEN TRANSFER AS A FUNCTION OF FILM THICKNESS

Apparent Film Thickness (mils)	F_2X_2 (ml/min)	F_1X_1 (ml/min)	$\Delta(FX)^*_{2-1}$ (ml/min)	$C_{Tr}\left(\frac{\text{mil}}{\text{min-cm}^2}\right)$	% Increase*
0	35.3	4.3	28.1	2.10	650
4	30.1	4.3	25.0	1.87	580
8	11.0	4.3	6.5	0.49	150
1.35	8.0	4.2	3.7	0.28	90
1.5	4.5	4.2	0.29	0.02	7

*Corrected to STP, average values for 10:1 flow rate.

and out of blood will take place through a boundary layer and will greatly reduce the gas transfer rate.

Pierce and Dibelius(31) and Bartlett, et al.(42) point out that a 1 mil silicone rubber membrane passes oxygen at the rate of 0.12 ml/cm^2-min when the pressure gradient is one atmosphere. When a 100 micron film of deoxygenated blood is introduced on one side of the membrane, the transfer rate falls 10 to 100 fold because of the lower diffusivity of oxygen in blood plasma. Other values are reported in the same range.

Pierce and Dibelius,(31) using a silicone co-polymer having conical depressions, achieved oxygen exchange rates varying from 0.0025-0.008 ml/cm^2-min at different blood flow rates with a membrane lung device. Bartlett, et al.(42) reported oxygen transfer rates on dogs of 0.005-0.020 ml/cm^2-min in an oscillating helix device using silicone membrane tubing. Dutton, et al.,(43) using a 10,000 to 20,000 tube bundle, reported oxygen transfer rates from 0.0022 to 0.000 ml/min-cm^2. Tubes were made of siloxane-polycarbonate copolymer. Palmer, Clark, and Mills(44) reported oxygen transfer rates of 0.00194 to 0.0045 cc/cm^2-min for 0.5 mil silicone rubber on a Dacron net. The data of Palmer, Clark, and Mills are for human blood. de Filippi, et al.,(29) employing a capillary membrane oxygenator, reported oxygen transfer rates of 0.00427 to 0.00064 ml/cm^2-min for a blood-gas system. The same oxygenator in use with dogs provided an oxygen transfer rate of 0.0027 to 0.0153 ml/cm^2-min. Dorson, Baker, and Hall(45) used a shell and tube oxygenator and reported an oxygen transfer rate of 0.0067 ml/cm^2-min. In some cases flow was in parallel tubes while in others it was in helical tubes. Kolobow, et al.(9) reported an oxygen transfer rate varying from 0.0018 to 0.0035 ml/cm^2-min for a spiral coil silicone oxygenator on partial bypass in newborn lambs.

The useful range of gas-gas transfer coefficients reported here are 0.5 to 1.9 ml/cm^2-min. If the presence of a blood film should show a 10 fold drop in the oxygen transfer rate as reported by Pierce and Dibelius the rates using the investigated membrane would be higher than any reported here by about an order of magnitude. If the presence of a blood film should reduce the transfer rate by two magnitudes of order (10^2), the transfer coefficients would be in the range 0.019 to 0.005 ml/cm^2-min, which is comparable to the numbers reported above. If this argument has any validity at all, it appears that the type of membrane proposed here has potential and warrants further study for use with blood in oxygenator devices.

Other work which accompanied this investigation includes the following.

A series of untreated and silicone-treated PTFE membranes was coated with a 5 micron film of plasma-deposited polypropylene. Previous work in this laboratory has shown that plasma-deposited polymers can reduce the solubility and permeability of oxygen and carbon dioxide when deposited on smooth polymer films. In addition, the chromatographic properties of the silicon polymers with respect to blood can be reduced with relatively thin films of plasma-deposited polymers. In vitro and some in vivo tests have indicated no abnormal response to blood and body tissue. The plasma films had no effect on the transfer properties of the untreated PTFE substrate. The oxygen transfer rates for the plasma-coated deposits showed only a 10-20 percent decrease in oxygen transfer rates for reasons demonstrated in Figures 5-9. The curve was the same as shown in Figure 3 except that it was displaced downward. Since the membranes in normal use must undergo mechanical stresses, these membranes were checked to see if the plasma coat would withstand repeated flexing. SEM micrographs of a flexed and unflexed composite membrane revealed that flexing has no effect on the adherence of the plasma-deposited film.

The composite membranes were also checked to determine the maximum pressure they could withstand. The cell shown in Figure 2 was adapted to test a free film membrane. A membrane was subjected to pressure from one side and the permeability measured. The pressure was increased in intervals to 8 psig where a marked increase in permeability was noted. When the membrane was removed from the cell, it was found to be slightly deformed but had not ruptured and showed no evidence of holes or tears. It was concluded that a fibrous or matted substrate could be a suitable base for an oxygenator composite membrane and that it would withstand mechanical stresses. The ability to withstand pressure is important from the standpoint that these membranes can be subjected to repeated vibrations and conformations which may be required to reduce boundary layers in a real situation.

Figure 5 is an SEM micrograph of the PTFE membrane and Figure 6 shows the PTFE with an apparent film thickness of 0.8 mils of silicone polymer. The uncoated membrane shows an uneven surface with numerous voids. This explains the high permeation properties of the uncoated membrane. A comparison of the uncoated to the coated substrate shows the disappearance of many of the discontinuities and a smoothing of the surface. A 0.4 mil coating of the silicone polymer fills in only some of the small voids. A 1.35 and 1.5 mil coat of the silicone polymer appears similar to the 0.8 mil membrane except that it is smoother.

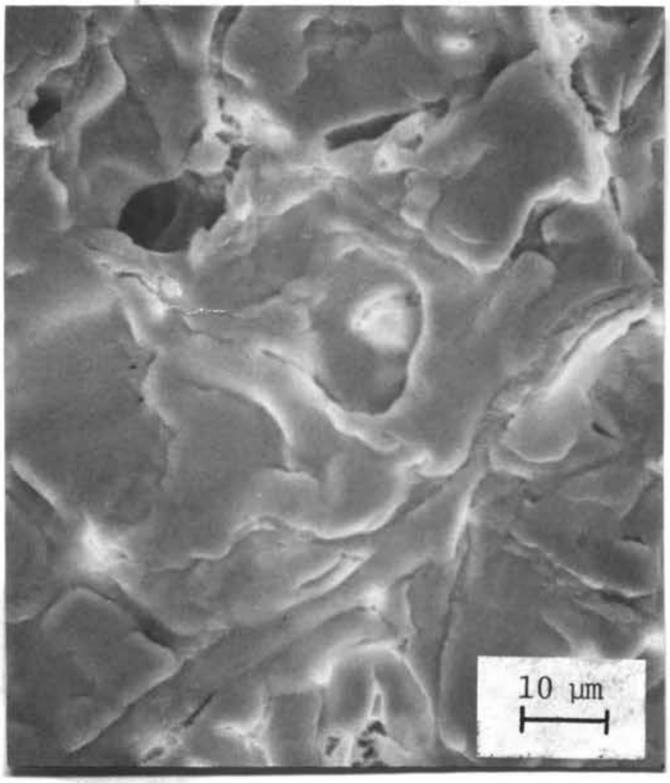

Figure 5. Normal view, untreated PTFE

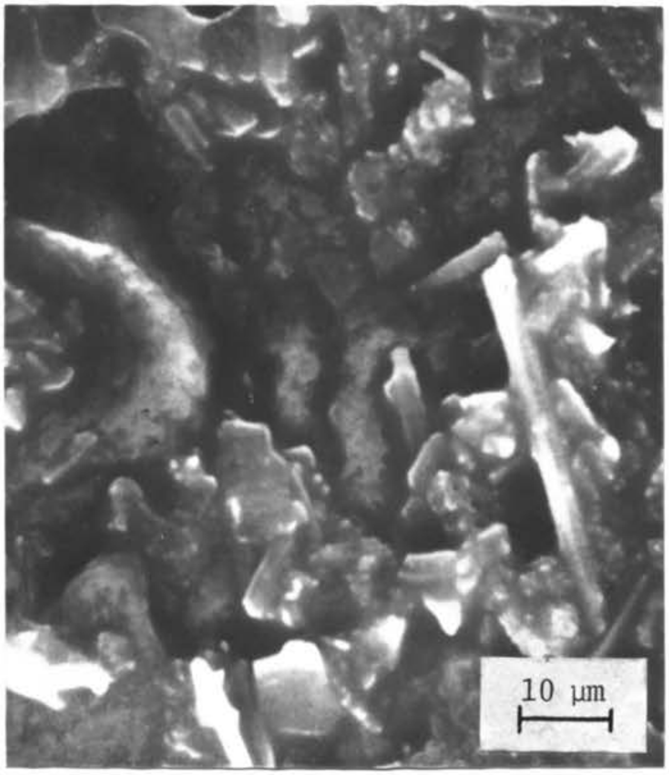

Figure 6. Normal view, 0.8 mil membrane

An attempt was made to examine the various membranes in cross-section. It was not possible to obtain brittle fractures, even at liquid nitrogen temperatures. The following series of micrographs were obtained by slicing the membranes with a sharp scalpel and examining the resulting cross-section.

Figure 7 shows the cross-section obtained for the PTFE substrate. Figures 8, 9 and 10 show surfaces from a membrane having an apparent film thickness of 1.35 mils. Figure 8 reveals both the normal surface (top portion of micrograph) and the cut surface (bottom portion). It is of interest to compare the normal surface of Figure 9 with Figure 5. It can be seen that the fillers normally present in the silicone polymer have been selectively filtered from the solution and deposited on the substrate surface. The roughness of the surface accounts for the unimpressive results obtained with the plasma-deposited polymer. Previous work has shown that a 2 micron coating of plasma polypropylene on 1 mil polyethylene sheets had a significant effect of retarding specific gas permeabilities and diffusions by greater than 50 percent. In the present case the surface appears too irregular to obtain a uniform plasma-deposited polymer.

Figure 10 shows that the silicon polymer which permeated the PTFE substrate exists as numerous thin membranes containing discontinuities. The stringing

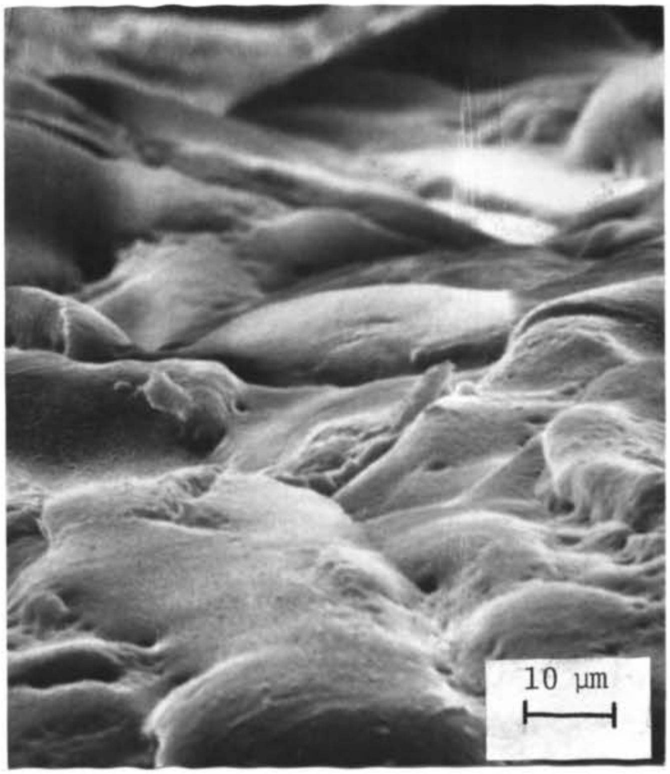

Figure 7. Cross-sectional view, untreated PTFE

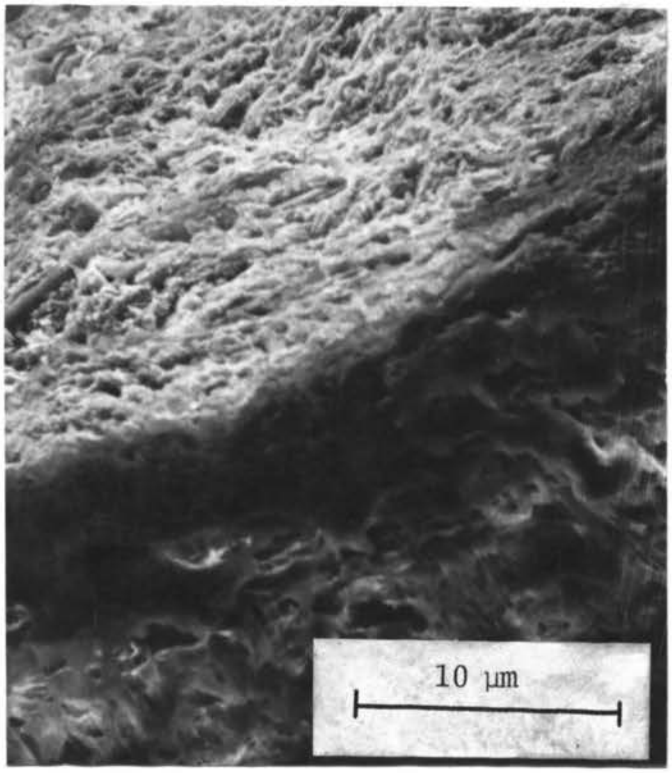

Figure 8. Isometric view of 1.35 mil membrane

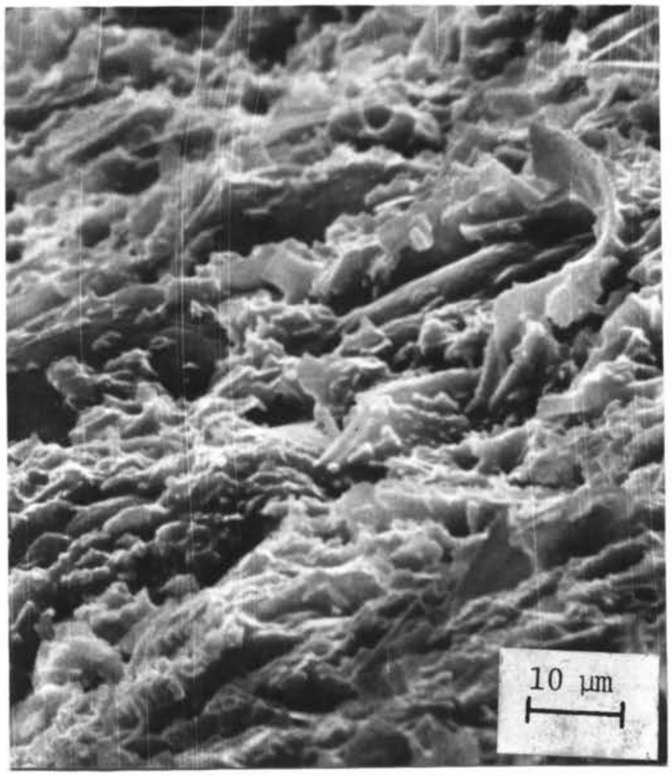

Figure 9. Inclined surface of 1.35 mil membrane

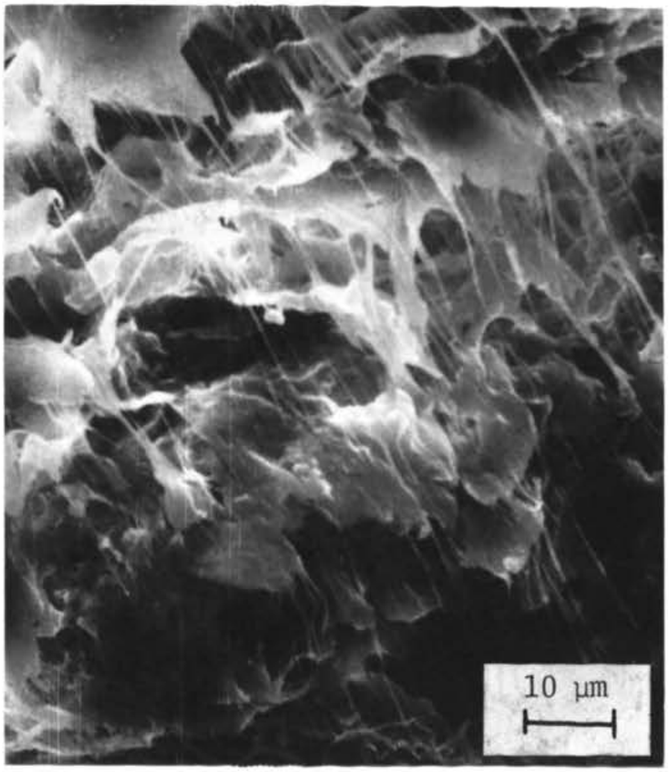

Figure 10. Cross-section of 1.35 mil membrane

effect seen in the mocrograph appears to be ultrathin sections of the silicone polymer which were ruptured and stretched during the cutting operation. The numerous discontinuities in the interstices of these particular composite membranes could present problems at a blood-oxygen interface. Should the blood permeate the membrane interior, coagulation of the blood would be possible. This potential problem can be eliminated through a change of structure in the PTFE substrate.

VI. SUMMARY

The composite membrane system investigated in this work represents a new approach to producing oxygenator membranes and has shown sufficient feasibility to warrant further study. The PTFE substrate selected was not as uniform as was desired and other PTFE substrates are being considered for these applications. Additional work is required with filler-free, silicone polymer systems. Subsequent evaluation of the present and other membranes will involve testing in synthetic fluid and heparinized blood media.

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VIII. VITA

Samuel Walter Dortch was born on October 18, 1948 in Bloomfield, Missouri. He received his primary and secondary education in Bernie, Missouri. He spent two years at Southeast Missouri State College in Cape Girardeau before transferring to the University of Missouri-Rolla where he received a Bachelor of Science degree in Chemical Engineering in 1971.

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IX. APPENDICIES

APPENDIX A

Calibration Curve for Gas Chromatograph

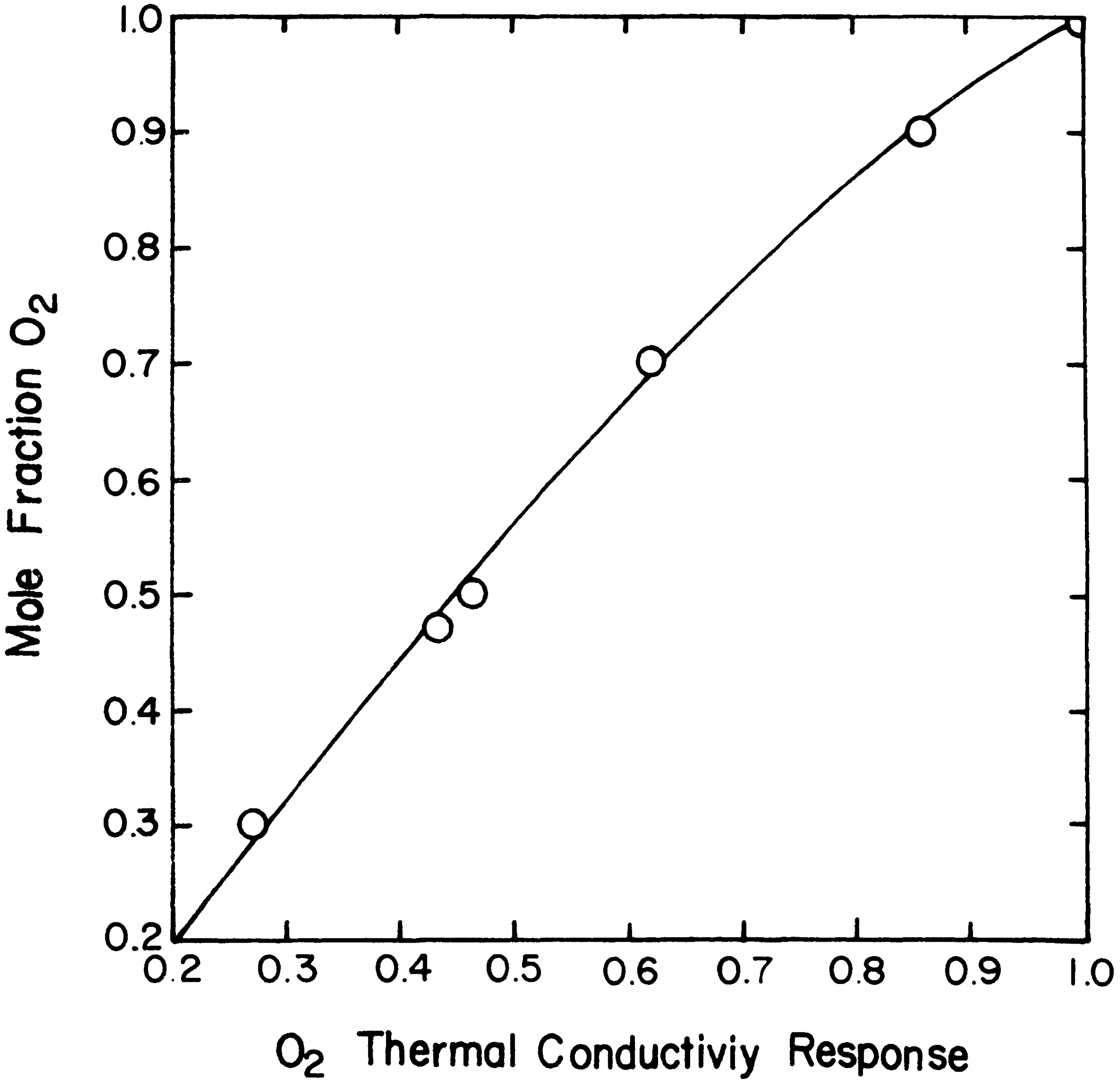

Figure 11. Calibration Curve for Gas Chromatograph

APPENDIX B

Data

TABLE III

LABORATORY DATA

Apparent Film Thickness-mils	Initial Conditions Mole Fr. O_2	Initial Conditions Mole Fr. CO_2	Initial Conditions Flow Rate Venous	Final Conditions Mole Fr. O_2	Final Conditions Mole Fr. CO_2	Final Conditions Flow Rate Venous
0	.486	.514	9.2	.920	.080	48.7
	.474	.526	9.7	.892	.108	32.1
	.476	.524	8.5	.892	.108	35.3
	.470	.530	8.9	.884	.116	41.1
4	.472	.528	9.1	.896	.104	33.6
	.474	.526	8.6	.920	.080	46.8
8	.462	.538	9.4	.672	.328	16.8
	.470	.530	9.4	.704	.296	16.4
1.35	.484	.516	8.7	.740	.260	12.8
	.466	.534	9.1	.624	.376	16.4
	.482	.518	9.3	.596	.404	12.1
	.472	.528	9.0	.556	.444	11.0
1.5	.476	.524	8.9	.482	.518	8.9
	.474	.528	8.9	.501	.449	8.9

TABLE III (Continued)

	Initial Conditions			Final Conditions		
Apparent Film Thickness-mils	Mole Fr. O_2	Mole Fr. CO_2	Flow Rate	Mole Fr. O_2	Mole Fr. CO_2	Flow Rate
		<u>With 5µ Plasma Polyproprylene</u>				
4	.473	.527	10.1	.868	.132	37.8
	.466	.533	9.6	.892	.108	44.6
8	.488	.512	8.8	.560	.440	10.2
	.472	.528	10.2	.540	.460	11.4
1.35	.480	.520	8.9	.588	.412	11.1
	.480	.520	8.9	.529	.471	9.7