
Evaluation of Three Types of Membrane Oxygenators and Their Suitability for Use with Pulsatile Flow

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Abstract

(*J. Extra-Corpor. Technol.* 19[3] p. 297–304 Fall 1987, 26 ref.) Three types of single-pumphead arterial line microporous polypropylene membrane oxygenators were evaluated: 1) flat plate; 2) hollow fiber with blood path inside the fibers; and 3) hollow fiber with blood path outside the fibers. These oxygenator types were evaluated to determine what hemodynamic effects they would have on the pulse waveform in the extracorporeal arterial line and the radial artery monitoring line of the patient during pulsatile cardiopulmonary bypass. Gaseous microemboli (GME) generated by these oxygenators during pulsatile cardiopulmonary bypass were also measured.

Hemodynamically, the flat plate type exhibited the greatest tendency to dampen the pulsatile waveform because it is the most compliant membrane of the three types evaluated. The hollow fiber with blood path inside the fibers type had the highest line pressures proximal to the membrane and low pressure distal to the membrane because it is the most resistant to flow (i.e., high resistance across the membrane). The hollow fiber with blood path outside the fibers type had the least effect on the transmission of the pulsatile waveform because it has very low resistance across the membrane and very little compliance.

With regard to gaseous microemboli, the flat plate type and the hollow fiber with blood path outside

the fibers type had negligible counts, during both continuous flow and pulsatile flow. The hollow fiber with blood path inside the fibers type had somewhat elevated gaseous microemboli counts, especially during initiation of pulsatile cardiopulmonary bypass; however, these diminished with time.

We conclude that the hollow fiber with blood path outside the fibers type is the type oxygenator of choice when employing pulsatile cardiopulmonary bypass with an arterial line membrane oxygenator.

Introduction

The superiority of membrane oxygenation¹⁻⁴ and pulsatile flow⁵⁻⁸ has been reported in previous studies. However, until recent technological developments in equipment design and manufacture, these two superior techniques have been mutually exclusive. The intent of this study was to quantitatively compare the kinetic energy transmission capability of different arterial line membrane oxygenators (ALMOs) to the pulsatile waveform generated by a modified roller pump.

When the heart generates a pulse, the aortic valve is the only obstruction to flow between the left ventricle and the aorta. In contrast, in the extracorporeal circuit the pump is distantly removed from the aorta, having the arterial line and its components interposed. These components have a tremendous impact on the pulse waveform generated by the roller pump. If we wish to generate a blood flow pattern which mimics the pulsatile flow generated by the heart, the pulsatile roller pump must generate a waveform which, when modified by the components of the extracorporeal circuit, appears the same in the aorta as the natural waveform. Riley, et al.⁹ investigated, in vitro,

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the effects of combining ALMOs and pulsatile flow. Based on their findings, they ranked various ALMOs according to their ability to preserve a pulsatile waveform. When we attempted to use their recommendations clinically, we found the resulting pulsatile waveforms to be less than satisfactory. We therefore embarked on our own in vivo quantitative comparison of the kinetic energy transmission capability of ALMOs to the pulsatile waveform generated by a modified roller pump.

ALMO pressures were recorded at the inlet and outlet of each oxygenator to evaluate how flow through each device modifies the pump-generated pulsatile waveform. Patient left radial artery pressures were recorded to determine the effects of these modifications on the resultant patient pressures. GME counts were recorded at the outlet of each ALMO at selected intervals to determine the affect of pulsatile blood flow on GME generation in comparison to continuous blood flow.

We selected three clinically-proven ALMOs representing the three basic design configurations currently available. From the flat plate (FP) group we chose the Shiley M-2000.^{a,10,11} From the hollow fiber with blood path inside the fibers (HF_i) group we chose the American Bentley CM-40.^{b,12,13} From the hollow fiber with blood path outside the fibers (HF_o) group we chose the Johnson & Johnson Cardiovascular Maxima.^{c,14,15} Five units of each type were used on consecutive adult patients undergoing coronary artery bypass grafting surgery.

Materials and Methods

Our standard cardiopulmonary bypass circuit is designed in such a way as to optimize pulsatile perfusion. This circuit was utilized unchanged throughout this study except for the substitution of the three different ALMOs being evaluated. The circuit consists of a 51Fr/36Fr two-stage right atrial/inferior vena caval venous drainage cannula^d, a hardshell combination venous/cardiectomy reservoir^e, a 22-inch segment of 3/8-inch polyvinylchloride tubing from the venous reservoir to the roller pumphead, a modified pulsatile roller pump^f with a 1/2-inch polyvinylchloride arterial pumphead boot, a 26-inch segment of 3/8-inch poly-

vinylchloride tubing from the roller pumphead to the arterial line membrane oxygenator, a 40-micron arterial line filter^g, a 110-inch segment of 3/8-inch polyvinylchloride tubing for the arterial line from the oxygenator to the arterial cannula, and a reversed-bevel aortic arch cannula^h. The size of the arterial cannula was determined by the patient's weight.¹⁶ Our cannula size selection criteria is shown in Table 1.

Table 1
Aortic cannula size selection

< 55 Kg.	22 Fr.
55–85 Kg.	24 Fr.
85–100 Kg.	26 Fr.
> 100 Kg.	28 Fr.

All circuit components, including the combination hardshell venous/cardiectomy reservoir, the arteriovenous loop, the ALMO, and the arterial line filter, were purged with carbon dioxide for at least ten minutes prior to priming.¹⁷ All of the ALMOs were primed according to their manufacturers' instructions. Each circuit was primed with 1,800 milliliters of Hartmann's (lactated Ringer's) solution. Normal serum albumin, 50 grams, was added to increase viscosity and colloid osmotic pressure. Homologous red blood cells were added as necessary to maintain the patient's hematocrit at or above 25 grams percent. Various medications were also added to the prime (heparin, mannitol, sodium bicarbonate, steroid, and antibiotics) in physiological dosages.

Cardiopulmonary bypass (CPB) was initiated at a flow rate of 2.6 +/- 0.2 L/min/m² with rapid core cooling to 30° C. Core temperatures were monitored with both a rectal temperature probe and a bladder temperature probe. Hypothermic perfusion flow rates were maintained at 2.0 +/- 0.2 L/min/m². Pulsatile flow was introduced immediately upon decompression of the left ventricle (via a left superior pulmonary vein vent catheter) and cessation of cardiac ejection. Pulsatile CPB was maintained throughout the surgical procedure except during construction of proximal anastomoses to the ascending aorta in patients undergoing coronary artery bypass grafting. The pulsatile pump was timed according to a modification of the indexed constant stroke volume technique developed

a Model M-2000, Shiley Inc., Irvine, CA 92714
 b Model CM-40, American Bentley, Inc., Irvine, CA 92714
 c Model 1380, Johnson & Johnson Cardiovascular, King of Prussia, PA 19406
 d Model 12340, Sarns Inc./3M, Ann Arbor, MI 48106
 e Model HSVRF, Shiley Inc., Irvine, CA 92714
 f Model 7400, Sarns Inc./3M, Ann Arbor, MI 48106

g Model 1362, Johnson & Johnson Cardiovascular, King of Prussia, PA 19406
 h Model 1869, Bard Cardiosurgery Division, C.R. Bard, Inc., Billerica, MA 01821

by Davis, et al.¹⁸ Our modifications (Gassmann, et al.: Clinical implications of roller pump timing for pulsatile perfusion. Manuscript in press.) involve using a 25% baseline flow as opposed to the 0% baseline flow utilized by Davis. Our technique also requires precise control of the accelerate and decelerate points in the raceway.

A Honeywell 1508B Visicorderⁱ was used to record patient and arterial line pressures. The amplifiers were utilized in their CATH position, yielding the highest possible frequency response (20 Hz to 1.0 kHz).¹⁹ Gould P-50 transducers^j were attached to the arterial line with three-way stopcocks and leur-lock connectors located 3 inches proximally and 3 inches distally to the ALMO. Patient pressures were recorded using American Edwards Trantec^k transducers attached to the left radial artery monitoring line of the patient.

GME counts were made using the Hatteland BD-100^l ultrasonic bubble detector.²⁰ A 3/8-inch sensor was connected adjacent to each ALMO's outlet port. Data acquisition was accomplished with an Otrona Desktop Computer^m utilizing software developed by Riley, et al.^{21,22}

Pressure tracings and GME counts were recorded at six intervals: 1) at initiation of CPB with continuous flow; 2) at initiation of pulsatile CPB; 3) at 5 minutes after initiation of pulsatile blood flow; 4) at 20 minutes after initiation of pulsatile blood flow; 5) after rewarming for 2 minutes with pulsatile blood flow; and 6) at reinstatement of continuous flow after fully rewarming the patient to a rectal temperature of not less than 34° C and removal of the left ventricular venting catheter.

Results

Superimposed inlet and outlet pressure recordings for each type of ALMO are shown in Figure 1. Two tracings are shown for each ALMO in this figure. The upper tracing represents the pulsatile wave pressure, in millimeters of mercury (mmHg), at the inlet of the ALMO. The lower tracing represents the outlet pressure. Patient left radial artery pressure waveforms, in millimeters of mercury, are depicted in Figure 2. Examination of these waveforms demonstrates that the Johnson & Johnson Cardiovascular Maxima has

the least apparent effect on the pump-generated pulse wave and the best resultant patient pressure waveform. The American Bentley CM-40 appears to have a higher pressure gradient as well as a reduced patient pressure upstroke slope. The Shiley M-2000 appears to exhibit considerable dampening of the total waveform. In an effort to quantitate these differences, we calculated several parameters. Tables 2 and 3, respectively, show the peak pressure drops, and patient pulse pressures and pulse upstroke changes, for these

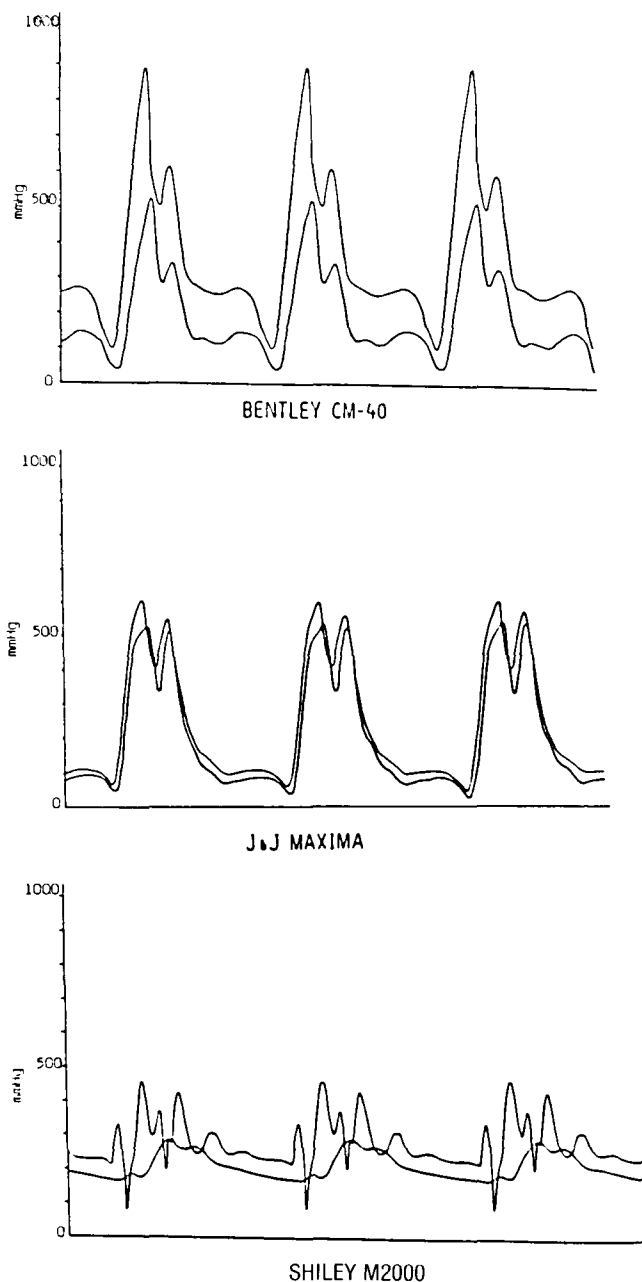


Figure 1: Superimposed, simultaneous inlet and outlet pressure waveforms. The higher peak pressures are at the ALMO inlet.

i Model 1508B, Honeywell Corporation, Philadelphia, PA 19104

j Model P-50, Gould Corporation, Philadelphia, PA 19104

k Model Trantec, American Edwards Laboratories, Inc., Irvine, CA 92714

l Model BD-100, Hatteland Instrumenteering, Oslo, Norway

m Model Desktop, Otrona Advanced Systems Corp., Boulder, CO 80306

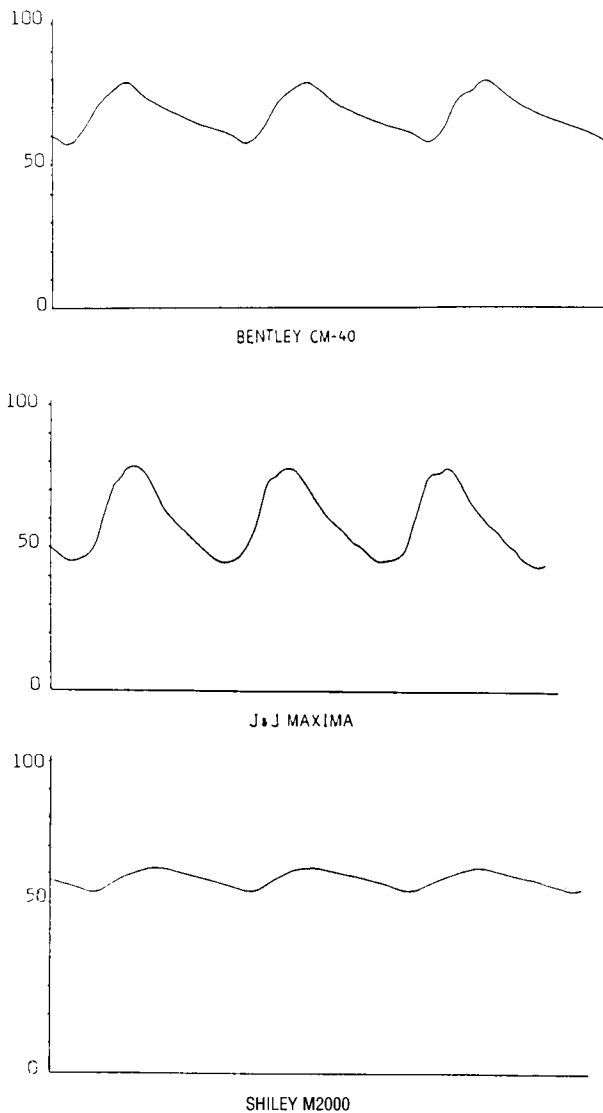


Figure 2: Patient left radial artery pressure.

	Oxygenator		
	J&J CV	Bentley	Shiley
Peak Inlet	590	890	460
Peak Outlet	535	525	280
I-O	55	365	180
Patient Pressure	76/42	78/56	72/62
Pulse Pressure	34	22	10

three ALMOs. These data demonstrate that the Johnson & Johnson Cardiovascular Maxima had a peak pressure difference of 55 mmHg as opposed to 365 mmHg for the American Bentley CM-40 and 190 mmHg for the Shiley M-2000. Additionally, the patient pulse pressures were higher for the Johnson & Johnson Cardiovascular Maxima than for the American Bentley CM-40 or the Shiley M-2000. In fact, we could not obtain a patient pulse pressures greater than 10 mmHg with the Shiley unit. The Johnson & Johnson Cardiovascular Maxima conserved 93% of the pump-generated upstroke slope as opposed to 69% for the American Bentley CM-40 and only 20% for the Shiley M-2000. The patient pressure upstrokes were greatest with the Johnson & Johnson Cardiovascular Maxima, followed by the American Bentley CM-40 and the Shiley M-2000, respectively.

Gaseous microemboli counts are presented in Figure 3. The Shiley M-2000 demonstrated the best performance in this part of the evaluation. In fact, we were able to measure only one 20- to 40-micron bubble at the outlet of one M-2000 (5 units were evaluated). The Johnson & Johnson Cardiovascular Maxima was second with very low bubble counts and the American Bentley CM-40 finished third with acceptably low levels of GME. No GME were recorded at the initiation of CPB with continuous flow from either the Johnson & Johnson Cardiovascular Maxima or the American Bentley CM-40. However, with the institution of pulsatile blood flow, the GME counts increased from both devices and remained elevated during the entire period of pulsatile blood flow. GME counts returned to baseline (zero) levels when continuous blood flow was reinstated with both devices. It should be noted that the greatest proportion of bubbles measured from all of these ALMOs was less than 40-microns in size.

	Oxygenator		
	J&J CV	Bentley	Shiley
$\Delta P/\Delta T^{(I)}$	7900	7350	7300
$\Delta P/\Delta T^{(O)}$	7350	5100	1450
$\frac{\Delta P/\Delta T^{(O)}}{\Delta P/\Delta T^{(I)}}$	93%	69%	20%
Patient $\Delta P/\Delta T$ (LRA)	266	138	49

LRA = Left Radial Artery

Discussion

When assessing an ALMO for its hemodynamic affect on the pulsatile waveform, there are two primary factors to consider: 1) resistance; and 2) compliance. Resistance is opposition to flow defined by the hemodynamic equivalent of Ohm's Law: $R = \Delta P / F \times 79.7$ (where ΔP equals pressure difference in torr and

F equals flow in liters/min).²³ The resistances of the ALMOs evaluated in this study are calculated from pressure drop data available from the manufacturers of the three units (personal communications: Mr. Scott Bell/American Bentley, Inc.; Mr. Kenneth Jones/Shiley, Inc.; and Mr. Anthony Badolato/Johnson & Johnson Cardiovascular). These calculated resistances are presented in Table 4. The American Bentley CM-40 has the greatest resistance, followed by the Shiley M-2000. The Johnson & Johnson Cardiovascular Maxima demonstrated the least resistance.

Compliance is the relationship of volume to pressure. Most manufacturers do not publish a specification for compliance. However, manufacturers do measure the dynamic priming volumes of their devices. Compliance correlates directly with dynamic priming volume; hence, dynamic priming volume can be used as a measure of compliance. The dynamic priming volume data from the 3 MO manufacturers involved in this investigation are presented in Table 5.

Flat plate ALMOs demonstrate more compliance than hollow fiber ALMOs. In fact, the volume storage capacity of the Shiley M-2000 exceeds the usual stroke volume used for pulsatile CPB. At four liters per minute of blood flow, the Shiley M-2000 has a peak inlet pressure of 460 torr. At this pressure, the Shiley M-2000 oxygenator could be expected to increase its

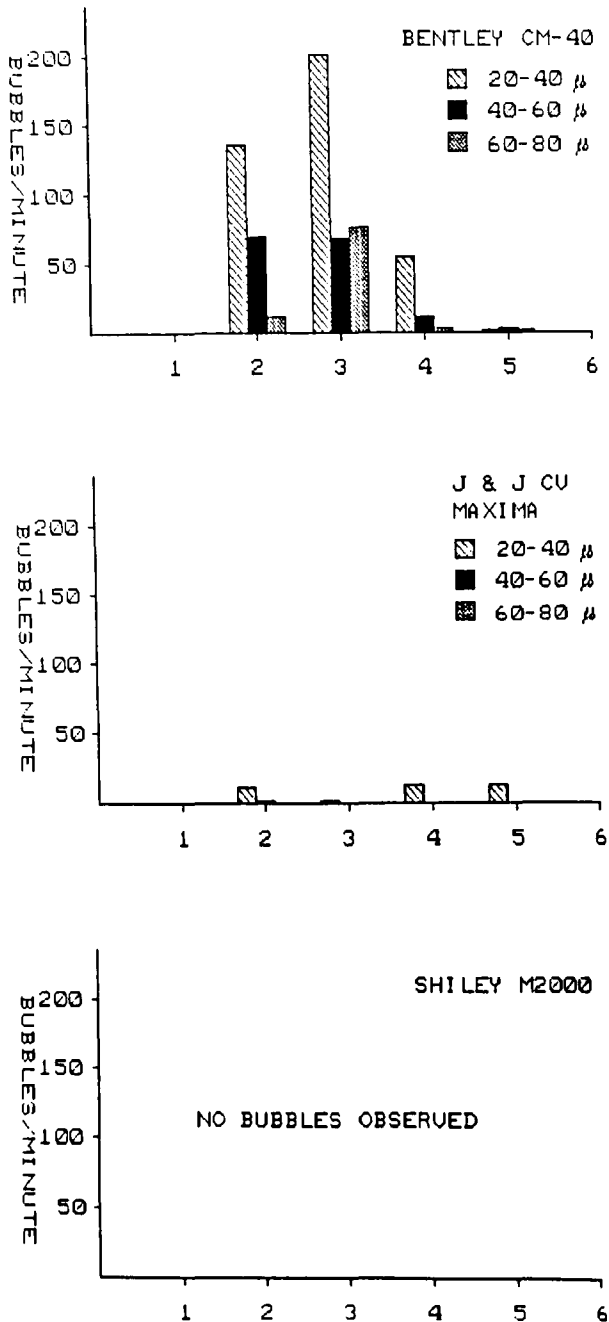


Figure 3: Gaseous microemboli (GME) counts at six intervals during cardiopulmonary bypass. See text for explanation of intervals.

Table 4
ALMO Resistance

Oxygenator	Resistance (dyne-sec/cm ⁵)
J&J CV	1237.5
Bentley	3088
Shiley	2329

Table 5
Dynamic Priming Volume (DPV) and Calculated Compliance Index (CI)

Pressure	J&J CV	Bentley	Shiley
0	Baseline	Baseline	Baseline
100	+1.5	+1	+25
200	+3	+3	+42
300	+4.5	+5	+58
400	+6	+13	+77
500	+8	+15	+92
CI	1.6	3	18.4

$$CI = \frac{\text{Avg } \Delta \text{DPV}}{100 \text{ mm Hg}}$$

priming volume 85 milliliters. This volume (85 milliliters) is almost double our group's standard pulsatile CPB stroke volume of 45.8 milliliters.

We have devised a formula which considers both resistance and compliance when evaluating an ALMO's pulse flow characteristics. This formula therefore defines an ALMO's pulse fidelity index (PFI). The PFI formula is:

$$CI \times R = PFI$$

where CI (compliance index) is the mean change in dynamic priming volume per 100 torr and R is the resistance in $\text{dyne} \times \text{sec} \times \text{cm}^{-5}$. We have calculated the PFI for each of the three ALMOs evaluated in this study; the results are presented in Table 6.

We have shown that all of these ALMOs can be safely used for pulsatile CPB. Each ALMO demonstrated sufficient durability on gross examination to withstand the extra stresses imposed on a device by the use of pulsatile blood flow. Furthermore, none of the ALMOs evaluated generated excessive levels of GME. All of the GME counts from these ALMOs were well below the GME levels of bubble oxygenators.²⁴

Riley, et al.⁹ conducted a similar study comparing ALMOs for their ability to preserve a pulsatile waveform. The two oxygenators that they ranked first and second for overall suitability and safety for use in clinical pulsatile flow were both flat plate designs. They next ranked two hollow fiber ALMOs with blood paths inside the fibers as suitable. Their last choice for suitability among the three types of oxygenators we evaluated was a hollow fiber ALMO with blood path outside the fibers. These conclusions are in direct contradiction to our results. There are many reasons for this dissimilarity. First, their study was in vitro whereas our study was in vivo. This is significant because the type of outflow resistance which the ALMO must overcome changes dramatically when used in vivo versus in vitro. Riley, et al. used a partial occluding clamp on the arterial line to simulate patient systemic vascular resistance. This may have added static resistance to their circuit but it could not have realistically duplicated the dynamic effect of the patient's vascular compliance on the ALMO (i.e., dynamic back pressure). More importantly, since there was no patient

in their circuit, they were not able to ascertain the quality of the resultant patient pressure waveform; therefore, this criterion was not used in their ranking of the ALMOs.

We believe that the resultant patient pressure waveform is the ultimate criterion of quality pulsatile CPB. Riley also uses 9 different categories to rank their ALMOs. These categories entailed parameters we feel are unrelated to the assessment of the pulsatile flow characteristics of an ALMO. For example, one category used by Riley was "Prime Volume." While we agree that prime volume is important in the overall selection of any oxygenator, it is not a critical factor in assessing an oxygenator's pulsatile flow characteristics. Instead, we believe that dynamic priming volume is the critical factor; this parameter was not mentioned in Riley's study. In fact, there appears to have been no quantification of ALMO compliance in their investigation.

Another category Riley et al. assesses is " ΔP ." It should be noted that this category is really mean pressure change (mean ΔP) between inlet and outlet. Several investigators have shown that mean pressure is an inaccurate parameter in assessing pulsatility.^{19,25,26} If one examines the mean ΔP of the Shiley M-2000 in Riley's study, one will see that mean pressure changed by 170 mmHg. However, peak pressure changed by 365 mmHg and pulse pressure decreased from 450 mmHg to 75 mmHg. The Cobe CMLⁿ, another FP design ALMO, had a mean pressure change of 45 mmHg but a peak pressure change of 145 mmHg; pulse pressure dropped from 270 mmHg to 55 mmHg. In his introduction, Riley states: "The ideal pulsatile flow waveform leaving an ALMO probably has a mean pressure of 130 mmHg, a pulse pressure greater than 80 mmHg, . . ." and yet the ALMO they rated as "best" (the Cobe CML) has a mean outlet pressure of 155 mmHg but a pulse pressure of only 55 mmHg. We agree with Riley's statement that excess pressure is needed to "allow for further drop across the arterial line filter, tubing, and aortic cannula." However, in the clinical setting, we found that a pulse pressure of at least 400 mmHg at the membrane outlet was necessary to allow for these arterial line component pressure drops. One must remember that peak flow rates during pulsatile flow can reach in excess of 10 liters per minute and that the pressure drops across the arterial line components are significantly higher at these higher flow rates than those usually quoted for nonpulsatile flow.

Editor's Note: A large portion of the data presented originated from the manufacturers. Obviously this data is biased and will lack consistency among manufacturers.

Table 6
Pulse Fidelity Index (PFI)

Oxygenator	R	CI	PFI
J&J CV	1237.5	1.6	1980
Bentley	3088	3	9264
Shiley	2329	18.4	42853

R = Resistance ($\text{dynes} \times \text{sec} \times \text{cm}^{-5}$)

CI = Compliance Index (ml./100 mmHg)

ⁿ Model CML, Cobe Laboratories, Inc., Englewood, CO 80215

References

1. Pearson, D.T., McArdle, B., Poslad, S.J., Murray, A.: A Clinical Evaluation of the Performance Characteristics of One Membrane and Five Bubble Oxygenators: Haemocompatibility Studies. *Perfusion* 1(2):81–86, 1986.
2. Van Oeveren, W., Kazatchkine, M.D., Deschamps-Latsche, B., et al.: Deleterious Effects of Cardiopulmonary Bypass: A Prospective Study of Bubble Versus Membrane Oxygenation. *J. Thorac. Cardiovasc. Surg.* 89(6):888–899, 1985.
3. Muraoka, R., Yokota, M., Aoshima, M., et al: Subclinical Changes in Brain Morphology following Cardiac Operations as Reflected by Computed Tomographic Scans of the Brain. *J. Thorac. Cardiovasc. Surg.* 81(3):364–369, 1981.
4. Ward, B.D., Berry, G.L.: Comparative Platelet Function during Prolonged Extracorporeal Bubble and Membrane Oxygenation. *Proc. AmSECT*, 1975.
5. Tornabene, S.P., Tyndal, C.M., Keller, C., et al: Differences in Cerebral Blood Flow with Pulsatile and Nonpulsatile Blood Flow in Normal and Ischemic Brain. *J. Extra-Corpor. Technol.* 18(2):68–71, 1986.
6. Taylor, K.M., Bain, W.H., Davidson, K.G., Turner, M.A.: Comparative Clinical Study of Pulsatile and Nonpulsatile Perfusion in 350 Consecutive Patients. *Thorax* 37(5):324–330, 1982.
7. Taylor, K.M: Pulsatile Perfusion. *Cardiopulmonary Bypass: Principles and Management*, Taylor, K.M. (ed). Baltimore: Williams & Wilkins Company, 1986, pp. 85–114.
8. Philbin, D.M., Levine, F.H., Kono, K., et al: Attenuation of the Stress Response to Cardiopulmonary Bypass by the Addition of Pulsatile Flow. *Circulation* 64(4):808–812, 1981.
9. Riley, J.B., Winn, B.A., Justison, G.A., Hurdle, M.B.: Observations on the Ability of Arterial Line Membrane Oxygenators to Preserve a Pulsatile Flow Waveform. *Proc. American Society of Extra-Corporeal Technology*, 1985.
10. Gourlay, T., Gibbons, M., Adams, S., et al: Evaluation of the Shiley M-2000 Membrane Oxygenator. *Perfusion* 1(2):125–134, 1986.
11. Servas, F.M., Dietrich, L.J., Jones, K., et al: High Efficiency Membrane Oxygenation. *Trans. Am. Soc. Artif. Int. Organs* 29:231–235, 1983.
12. Sinkewich, M., Ogella, D., Golding, L.R., et al: Early Clinical Experience with the New Bentley Oxygenator System—Capillary Membrane (BOS-CM). *Proc. Amer. Acad. Cardiovasc. Perf.* 5:125–129, 1984.
13. Chrostowski, A.M., Palanzo, D.A., O'Neill, M.J., Jr., Harrison, L.H.: Utilization of the Bentley CM-50 Capillary Fiber Membrane Oxygenator with a Bio-Medicus Pump for Long Term Right Ventricular Assist: A Case Report. *J. Extra-Corpor. Technol.* 18(2):159–164, 1986.
14. Iatrides, A., Chan, T., Thompson, R.: Experimental and Clinical Trials with the Extracorporeal Hollow Fiber Lung. *Proc. Amer. Acad. Cardiovasc. Perf.* 6:47–50, 1985.
15. Alpha, D., King, E., Bicknell, D.A., et al: Clinical Evaluation of the Extracorporeal Maxima Hollow Fiber Membrane. *Proc. Amer. Acad. Cardiovasc. Perf.* 7:32–34, 1986.
16. Brodman, R., Siegel, H., Lesser, M., Frater, R.: A Comparison of Flow Gradients Across Disposable Arterial Perfusion Cannulas. *Ann. Thorac. Surg.* 39(3):225–233, 1985.
17. Wellons, H.A., Nolan, S.P.: Prevention of Air Embolism due to Trapped Air in Filters Used in Extracorporeal Circuits. *J. Thorac. Cardiovasc. Surg.* 65(3):476–479, 1973.
18. Davis, J.P., Sheff, D., Sheffield, A., Cleveland, R.: Roller Pump Pulsatile Perfusion Utilizing a Constant Stroke Volume Technique. *J. Extra-Corpor. Technol.* 14(2):355–360, 1982.
19. Caro, C.G., Pedley, T.J., Schroter, R.C., Seed, W.A.: *The Mechanics Of The Circulation*. New York: Oxford University Press, 1978. pp. 266.
20. Pedersen, T.H., Hatteland, K., Karlsen, H., et al: An In-Vivo Investigation of the Creation and Transportation of Free Gas Bubbles in the Extracorporeal Circulation System by Use of Doppler Ultrasound Technique. *Proc. American Society of Extra-Corporeal Technology*, 1985.
21. Riley, J.B., Fitch, R.W.: A Technique for Computerized Monitoring and Analysis of Pulsed Doppler System to Count Extracorporeal Circulation Gaseous Microemboli. *J. Extra-Corpor. Technol.* 18(2):151–155, 1986.
22. Hill, A.G., Groom, R.C., Vinansky, R.P., et al: Gaseous Microemboli and the Extracorporeal Circuit. *Proc. Amer. Acad. Cardiovasc. Perf.* 7:131–137, 1986.
23. Ream, A.K., Fogdall, R.P.: *Acute Cardiovascular Management: Anesthesia and Intensive Care*. Philadelphia: J.B. Lippincott Company, 1982. pp 40, 126.
24. Loop, F.D., Szabo, J., Rowlinson, R.D., Urbanek, K.: Events Related to Microembolism during Extracorporeal Perfusion in Man: Effectiveness of In-Line Filtration Recorded by Ultrasound. *Ann. Thorac. Surg.* 21(5):412–420, 1976.
25. Sheppard, R.B., Simpson, D.C., Sharp, J.F.: Energy Equivalent Pressure. *Arch. Surg.* 93(5):730–740, 1966.
26. Milnor, W.R.: Pulsatile Blood Flow. *N. Engl. J. Med.* 287(1):27–34, 1972.

Questions from the Audience

Question: Aaron Hill, Falls Church, VA: In your priming of the circuits did you use CO₂ in any of the priming techniques for any of these oxygenators?

Response: We CO₂ purged each circuit for at least 10 minutes prior to priming.

Question: Now in our experience using the same micro emboli detector in pulsing we did not see those microemboli counts that you were seeing. Yours tapered off after five minutes, is that true?

Response: That is correct.

Comment—Hill: We did not see that initial phase. My feeling was that with proper CO₂ flushing and priming we did not see those microemboli counts because we measured it during priming and then during bypass as well. We were not able to duplicate your results with the Terumo. We did, however, have the same experience that you had with the Shiley, with no microemboli counts. I'm not sure that you could explain why you had them for five minutes then they tapered off to nothing.

Response: I have to give that some thought. Thank you.

Question: Joel Davis, South Bend, IN: You demonstrated relatively low bubble counts really with the Shiley in particular. What I'm referring to is in the microporous membranes. There have been some warnings

by manufacturers and individuals about pulsing through microporous membranes because of the potential for drawing gas across the microporous membrane itself. My question is: What technique should you use in terms of stop, start or small roll in between? Did you try both and did you see differences between the two techniques?

Response: Yes. Unfortunately, I was in the process of producing a movie demonstrating our pulsatile pump timing scheme. It didn't work out quite well. What we're doing is using a 20% baseline, we start and stop the roller pump, at the identical position in the raceway each time and with a slight forward movement, so that the occlusion of the roller is at the very distal part of the raceway. We make only one single 360° turn. When we stop the rollers completely or use the zero baseline we found that we generated tremendous pressures both at the bottom end significantly negative and up to 900 millimeters. And we found much more significant bubble activity using that technique versus the technique we've used in this study.

Question: Jeff Riley, San Diego, CA: I think one thing you need to emphasize is that when you do these types of studies and evaluate the pulse flow transmission characteristics, you have to make sure that you challenge the membranes with the same inlet pulse pressures and flow waveforms. Otherwise it's not a valid comparison. And to emphasize Joel's point, you have to make sure your timing scheme is correct. I know Craig Gassmann has done a lot of work on that, and you have as well. I hope that is emphasized in your method.