
Clinical Evaluation of the New Harvey H-1500 Oxygenator

Paul A. Page, B.S., CCP, PA., Ranney Thomas, CP., Irv Birenbaum, CP.

Over the past five years we have utilized the Harvey H-1000 oxygenator in over 2500 clinical cases at The Johns Hopkins Hospital.⁽¹⁾ During the past months we have evaluated a new Harvey oxygenator, the model H-1500.

Construction and Functional Characteristics_____

The new H-1500 unit utilizes the same hybrid method of oxygenation as in the other Harvey units.^(2,3) Oxygenation is accomplished partially by gas bubble action and partially by laminar blood filming. The H-1500 unit is the same physical size as the H-1000 unit, 17 inches high and 6 inches in diameter. Unlike the H-1000 unit which has 32 round tubes 14 inches long (35.56 cm.), the H-1500 utilizes 24 elliptically shaped epoxy coated aluminum tubes. The elliptical design provides three primary advantages over the previous round design. First, it provides a thinner cross-sectional dimension on the inside of the tube which decreases the distance the heat has to travel (versus a round tube) thus heating and cooling occur more quickly. Second, a larger surface area per unit volume increases heat exchange and gas transfer efficiency during oxygenation. Third, due to the increased efficiency of the elliptical tubes, fewer tubes are required thus reducing operating and priming volumes. A new polyurethane foam mixing ring has been inserted in the downcomer above the heat exchanger. This helps maintain the oxygen and carbon dioxide gas exchange by providing thorough mixing of the foaming blood then resizes the bubbles before they enter the

defoamer. The defoamer has been changed to provide a more direct blood flow path than in the H-1000 unit. This reduces the dynamic holdup of the H-1500 significantly. A small volume venous reservoir has been incorporated to further reduce prime and operating volumes. Several other design changes have been incorporated in the H-1500 unit to improve its performance and make the unit more convenient. These include stainless steel temperature probe sites in the arterial reservoir and in the venous inlet. Quick disconnect water couplings have also been incorporated.

Methods and Materials_____

Induction of anesthesia was with thiamylal and was maintained with morphine, pavulon or curare, N₂O, and/or halothane or ethrane. Priming solutions included lactated Ringer's solution with 5% dextrose, 25% serum albumin, and mannitol 12.5 grams. In the event the patient's hematocrit was low enough to require the addition of blood to the prime then whole CPD or packed cells were added. When blood was required in the prime, then calcium, heparin and sodium bicarbonate were added as necessary to adjust pH and offset calcium depletion.

Most medications given during bypass were added through the venous inlet port to insure rapid and thorough mixing with the blood. Hypothermia (20–28 degrees centigrade) was utilized on most cases; however, there were a few cases done at normothermia. All patients were given beef lung heparin 3 to 4 mg. per Kg. of body weight prior to cannulation. Superior and inferior vena cava or two stage single venous cannulae were used for venous return. Arterial blood was returned in most patients using an ascending aortic cannula. Blood gases, hematocrit, and hemoglobin

Address Reprint Request to: Paul A. Page, B.S., Department of Surgery, The Johns Hopkins Hospital, 601 North Broadway, Baltimore, Maryland 21205

TABLE I

Shows comparison of data collected on fifty patients done using the H-1500 model Harvey oxygenator and fifty patients done using the model H-1000.

ITEM	Mean	H-1500			Mean	H-1000		
		High	Low	S.D		High	Low	S.D
Patient Weights (kg)	72.3	146	40.7	20	76.9	116	43.1	14.5
Patients Ages (years)	50.8	76.0	15.0	14.0	52.2	78.0	25	11.3
Total Bypass Time (min)	112.9	300	35	45.1	114.8	305	40	51.9
Hematocrits During Bypass (%)	26.9	39	19	3.9	26.9	38	19	3.2
Oxygenator Blood Level (cc)	1515	2900	500	505	1261	2800	500	444
Blood Flow While Cold (deg)	4323	5800	2800	675	4457	5600	3100	670
Blood flow warm (cc)	4383	5500	2000	726	4716	6000	2800	585
Esop Temp at Rewarm (deg)	25.2	32.3	19.7	2.6	26.3	30.7	19.6	2.3
Rect Temp at Rewarm (deg)	26.7	32.9	21.4	2.9	27.8	36.3	22	2.6
Number Degrees Esop Warm	12.3	17.3	5.3	2.5	10.9	18.8	6.4	2.3
Number Degrees Rect Warm	6.7	11.6	1.8	2.6	5.4	11	0.2	2.3
Rewarm Time (rect=33) (min)	34.5	60	10	12.9	34.2	72	8	13.3
Esop Rewarm to 37 Deg	23.1	45	8.0	8.0				
Rectal Temp at 37 Esop	31.1	36.7	25.1	2.8				
95/5% Gas Flow Cold (1/min)	3.4	8	1	1.3	4.6	8	2	1.1
95/5% Gas Flow Warm (1/min)	2.9	6	1	1.01	4.4	8.5	2.0	1.3
Oxygen Flow Cold (1/min)	2.4	4	1	1.0	3.9	9.5	0.5	2.0
Oxygen Flow Warm (1/min)	2.0	7	0	1.4	3.8	12	0.5	2.2
Total Gas Flow Cold (1/min)	3.7	8	1	1.6	5.5	10	2	1.9
Total Gas Flow Warm (1/min)	4.6	8.5	1.5	1.5	7.4	12	3.9	1.7
Gas to Blood Flow Ratio Cold	0.83	1.7	0.29	0.33	1.2	2.1	0.4	0.37
Gas to Blood Flow Ratio Warm	1.02	1.9	0.3	0.34	1.6	2.7	0.85	0.36
PAO ₂ Values While Cold	239	413	105	72.8	220	389	68	65.2
PAO ₂ Values Warming & Warm	232	392	92	69.7	192	337	101	63.8
PV0 ₂ Values While Cold	51.3	189	25	32.5	40.9	103	18	16.2
PV0 ₂ Values Warming & Warm	48.0	74	27	9.8	43.9	69	25	10.3
PAC0 ₂ Values While Cold	30.4	43	20	4.7	27.5	39	16	5.4
PAC0 ₂ Values Warming & Warm	37	49	22	5.5	33	47	22	5.4
PVC0 ₂ Values While Cold	31.4	71	22	6.3	28.6	38	18	5.3
PVC0 ₂ Values Warming & Warm	43.6	64	27	7.2	36.4	54	26	6.1
Art Sat During Hypothermia	99.9	100	94	0.68	99.9	100	94.5	0.65
Art Sat While Warming & Warm	100	100	99.9	0.01	100	100	99.9	0.02
Ven Sat During Hypothermia	72.2	100	41	17.1	68.5	99	30	13.9
Ven Sat While Warming & Warm	74.5	93	44	10.1	70.4	94	40	12.8
Pul Art Pressure on Bypass	7.6	34	0	6.1	6.9	22	0	5.3

determinations were done preoperatively, during bypass, and at the end of bypass.

The pump circuit consisted of Sarns 5000 console pumps, Harvey H-500 cardiectomy reservoir, Johnson & Johnson cardiectomy filter and a Pall arterial filter. The oxygenators were usually positioned approximately 18 inches below the right atrium to provide adequate venous drainage. Oxygenating gas consisted of 100% oxygen and/or 95% oxygen-5% carbon dioxide.

Results

A total of 100 patients was done for this study. Fifty patients were perfused using the H-1500 unit and fifty were done using the H-1000 unit. A summary of the

mean values, highest value, lowest value and the standard deviation are shown in Table I. Their ages ranged from 15 to 78 years. Weights ranged from 40.7 to 146 kilograms. Blood flows ranged from 2800 to 5800 cc/per minute during hypothermia. While warming and warm the flow ranged from 2800 cc to 6000 cc/per minute. Bypass time ranged from 35 minutes to 5 hours and 5 minutes. Total gas flow during hypothermia averaged 3.7 liters/per minute with the H-1500 unit and 5.5 liters/per minute with the H-1000. Total gas flow during warming averaged 4.6 liters/per minute with the H-1500 and 7.4 with the H-1000. Gas to blood flow ratios during hypothermia averaged 0.83:1 for the H-1500 and 1.2:1 for the H-1000. While warming the ratio was 1.02:1 for the H-1500 and 1.6:1 for the H-

TABLE II
Heat exchange comparison of the H-1500 and the
H-1000 Harvey blood oxygenators using the
kilogram per degree per minute formula.

	REWARM DATA
H-1500	
Patient Weight	72.3
Rewarm Time	34.5
Esophageal Temperature Rise	12.3
Rectal Temperature Rise	6.7
H-1000	
Patient Weight	76.9
Rewarm Time	34.2
Esophageal Temperature Rise	10.9
Rectal Temperature Rise	5.4
FORMULA	
Pt. Weight $\times$ Avg. Degree Temp Change	
Rewarm Time in Minutes	
H-1500	
Esophageal —	
$72.3 \times 12.3 / 34.5$	= 25.77 Kg/per deg/per min.
Rectal —	
$72.3 \times 6.7 / 34.5$	= 14.04 Kg/per deg/per min.
H-1000	
Esophageal —	
$76.9 \times 10.9 / 34.2$	= 24.50 Kg/per deg/per min.
Rectal —	
$76.9 \times 5.4 / 34.2$	= 12.14 Kg/per deg/per min.
This equals about a 5% INCREASE over the H-1000 units in ESOPHOGEAL Warming.	
This equals about a 14% INCREASE over the H-1000 units in RECTAL Warming.	

1000. In spite of the lower gas/blood flow ratios the H-1500 unit produced higher pO₂ values both during hypothermia and while warm. Also the H-1500 unit maintained higher pCO₂ values than the H-1000 unit.

Warming took an average of 34 minutes in both groups; however, the H-1500 unit produced more total degrees of warming than the H-1000 unit. (Table II)

Discussion

Since first introduced there has been continued improvement in disposable oxygenators.^(4,5,6,7,8,9) Membrane oxygenators which possess the advantage of no direct blood-gas interface, have been utilized in recent years.^(10,11,12,13) It is difficult to manufacture and assemble a membranous material thin enough to allow high levels of oxygen and carbon dioxide transfer. This along with the additional reservoirs and tubing required makes the units more expensive. The membrane units usually require a more complex circuit

making them more difficult to set up and debubble than hard shell units. For the average 2–3 hour bypass case the membranes do not provide much advantage over the recently improved hard shell units. Manufactures of hard shell units such as the H-1000 or the H-1500 are making these units more efficient and less traumatic to the blood and also less expensive than the membrane units.^(14,15)

Over the past several years we have been lowering the average temperature for hypothermia during bypass. Several years ago when we reported on the H-200 oxygenator the average esophageal temperature at the start of rewarm was 29.1 degrees centigrade.⁽³⁾ Two years later in another paper on the H-1000 unit the average esophageal temperature was 27.5 degrees centigrade.⁽¹⁾ During this study the average esophageal temperature at the start of rewarm in the H-1500 group was 25.2 degrees centigrade. This shows that it continues to be critical to have an efficient heat exchanger in the oxygenator unit. A series of tests were conducted in-vitro using bovine blood to compare the performance of the H-1000 and the H-1500 heat exchangers. The

EXPLANATION OF REWARM FACTOR

The time taken to rewarm is proportional to the weight of the patient and also proportional to the number of degrees the patient must be rewarmed. Expressed mathematically:

$$\begin{aligned} \text{time} &\propto \text{wt.} \\ \text{and} \\ \text{Time} &\propto \# \text{ degrees} \\ \text{or} \\ \text{time} &\propto \text{wt.} \times \text{degrees} \end{aligned}$$

If we assume the relationship is linear between time and weight and similarly time and # degrees (see Fig. 1), then the relationship can be given a proportional constant K:

$$\text{time} = (\text{wt.} \times \text{degrees}) K$$

Solving for K:

$$\frac{1}{K} \times \frac{\text{wt.} \times \# \text{ degrees}}{\text{time}}$$

1/K can be presented as its reciprocal, k. Therefore:

$$1/K = k = \frac{\text{wt. (kg)} \times \# \text{ degrees (}^{\circ}\text{C)}}{\text{time (min.)}}$$

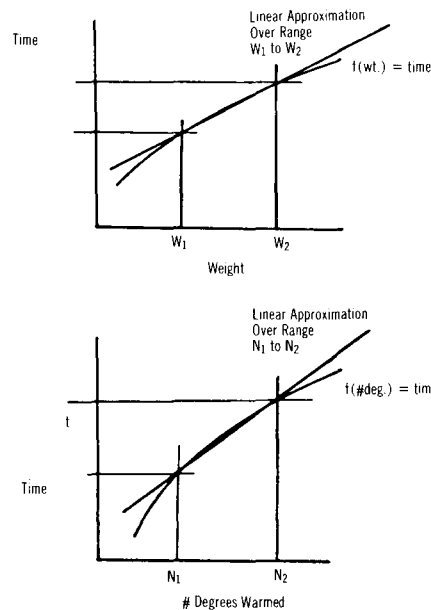
The units of this constant (rewarm factor) would be $\text{kg} \times ^{\circ}\text{C}$ per minute and it estimates "heating power"—i.e. how many kilograms can be raised a number of degrees in temperature in a specified time.

The rewarm factor can be calculated from the patient's weight, number of rewarmed degrees and rewarm time for each case, but is most useful and indicative as an average of many cases. When the rewarm factor for two oxygenators (used according to identical techniques) are compared, a judgment can be made concerning effectiveness in rewarming.

FIGURE 1. Explanation of the rewarm factor.

blood at 30 degrees centigrade with a hematocrit of 40% was passed through the oxygenators with an equal amount of gas (gas to blood flow ratio of 1 to 1). Water at 40 degrees centigrade was passed through the oxygenators at 15 liters/per minute. The resulting blood outflow temperature was measured and the performance factor was calculated using the formula temp of blood out, minus temp of blood in, divided by temp of water in, minus temp of blood in. Five oxygenators each were tested and the averaged results shown in Fig. 2. In these test the heat exchange of the H-1500 is shown to be 24% greater than the H-1000 at 2 liters blood flow, 26% at 4 liters blood flow, and 33% at 6 liters blood flow.⁽¹⁶⁾ Many parameters affect how quickly a patient can be rewarmed using an extracorporeal circuit. Some of these parameters are physiologic: patient size, degree of vascular constriction and the amount of body fat for instance. Other parameters

IF NOW LINEAR, A CURVE CAN BE GIVEN A LINEAR APPROXIMATION OVER A NARROW RANGE.



are related to the perfusion circuit and other equipment, for example, blood flow rate, the flow rate and heat exchange capacity of the heater cooler unit, and the blood to water temperature gradient. Comparing the average results of many procedures helps to isolate some of the physiologic and technique related parameters. In our clinical study we choose to use the Kilogram/per degree/per minute method to compare these units instead of esophageal or rectal temperature comparisons. Using this method provides a better estimate of the actual rate at which the heating work is being done and provides an excellent value for oxygenator comparison. An explanation of this method is shown in Fig. 1. Using this method of comparison the H-1500 units show a 14% increase in rectal warming over the H-1000 units. In the data both units took the same amount of time to rewarm the rectal temperature to 33 degrees; however, the H-1500 units were able to warm the patients an additional 1.4 degrees esophageal and 1.3 degrees rectal in that same amount of time. Another factor which helped the H-1000 group in warming was that the average blood flow was 333 cc/per minute higher while warming. The rewarm to 37 degrees esophageal (which averaged 12.3 degrees) took only 23 minutes for the H-1500 unit.

The static hold-up is 100 to 125cc less with the H-1500 than with the H-1000 model. This was measured

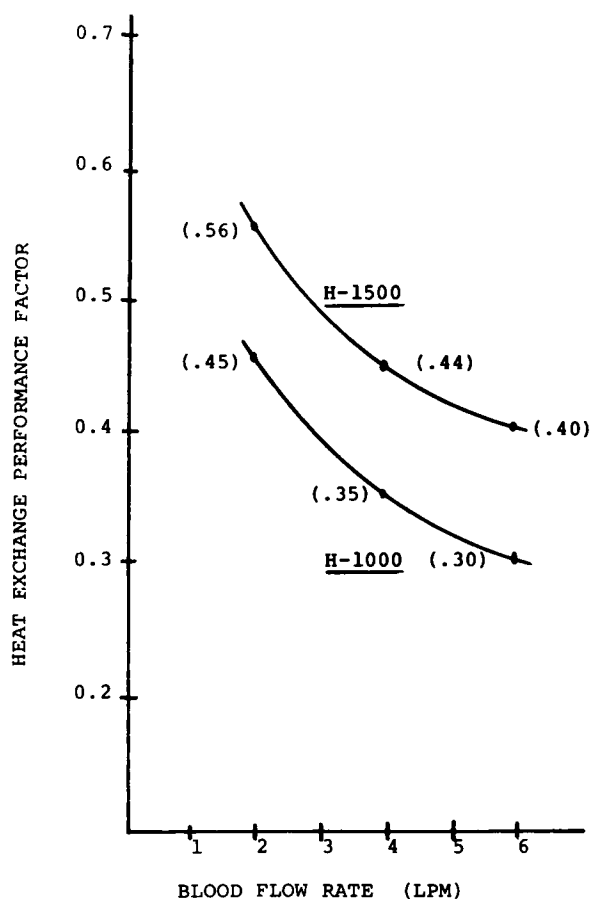


FIGURE 2. In-vitro Heat Exchange Performance Factor

by circulating non cellular prime in a closed recirculation loop at 5 liters/per minute and the gas flow at 5 liters/per minute. When the fluid flow was stopped, for one minute, the arterial reservoir level was recorded. The level was approximately 110–125 cc higher in the H-1500 units showing less hold-up in the oxygenator than in the H-1000 unit.

The units were also tested for dynamic hold-up during operation. This was tested by using a closed recirculation loop and measuring the difference in the reservoir level at a flow rate of 5 liters/per minute of fluid and 5 liters/per minute of gas flow. The average arterial reservoir level was then recorded. Comparison between the two units showed that the H-1500 held up 450–500 cc less volume than the H-1000 unit during operation. This could also be dramatically seen when both going on and when coming off bypass. Going on bypass there was only a 50–75 cc drop in the arterial reservoir level with the H-1500 units while there was a significant drop of 400 to 500 cc with the H-1000 units. When stopping the bypass quickly during the

case, (e.g.) during cross clamping, the arterial reservoir level changed only 50–75 cc on the H-1500 units while on the H-1000 units it would change several hundred cc in level.

No significant differences in platelet or plasma hemoglobin levels were noted when comparing the units during in-vitro and clinical runs.⁽¹⁶⁾

Blood gas values remained within normal limits with both units; however, the H-1500 units required a lower gas to blood flow ratio to maintain the same pO₂ levels. Also at the lower ratio the pCO₂ values with the H-1500 units averaged 3.5 mm/Hg. higher.

One of the interesting things that we noticed about the new H-1500 units was the consistency of its performance. We tabulated the data when the first 25 patients were done. Then after we completed all 50, we compared the data for the complete group. The data was amazingly similar. For example the rewarm times were 34.4 & 34.5 minutes. The number of degrees esophageal warmed was 12.3 both times. Rectal temperature warmed was 6.6 & 6.7, paO₂ warm was 234 & 232 mm/Hg., and paCO₂ warm was 37 mm/Hg. All our previous experience has shown the Harvey units to be consistent and the H-1500 is an improvement over these previous units.

We have found the Harvey oxygenators to be dependable units and we are glad to see the continued improvement in these units.

References

1. Page, P. A.: Clinical Experience in Four Models of the Harvey Oxygenator in over 1000 Patients. *AmSECT Proceedings* 3:61, 1975
2. Page, P. A., and Haller, J. A.: Clinical Evaluation of the New Harvey H-200 Disposable Blood Oxygenator. *J. Thorac. Cardiovas. Surg.* 67:213, 1974
3. Page, P. A., and Haller, J. A., and Benson, D. W.: Harvey H-200 Disposable Blood Oxygenator: Experience in 300 Patients. *Ann. Thorac Surg.* 18:364, 1974
4. Hirose, T., Everett, H., and Bailey, C. P.: A Single Pass Oxygenator for Cardiopulmonary Bypass. *Trans. Am. Soc. Artif. Intern. Organs* 11:321, 1965
5. DeWall, R. A., Najafi, H., and Roden, T.: A Hard Shell Temperature Controlling Disposable Blood Oxygenator: Use in Clinical Open-Heart Surgery. *J.A.M.A.* 197:1061, 1966
6. Hirose, T., Everett, H., Marshall, D. V., and Bailey, C. P.: The Single-pass Oxygenator. *Ann. Thorac. Surg.* 9:313, 1970
7. Keon, W. J. et al: Clinical Observation of Twelve Patients Using A New Concept in Bubble Oxygenator: BOS 10. *AmSECT Proceedings* 6:83, 1978
8. Gott, V. L., DeWall, R. A., Paneth, M., Zulidi, M. N., Weirick, W., Varco, R. L., and Lillehei, C. W.: A Self-Contained Disposable Oxygenator of Plastic Sheet for Intercardiac Surgery. *Thorax* 12:1, 1957
9. Williams, D. R. et al: Clinical Comparison of Harvey-Hybrid And Cobe Optiflo Bubble Oxygenators. *AmSECT Proceedings* 6:115, 1978

10. Page, P. A.: Clinical Evaluation of The Sci-Med Spiral Coil Membrane During Cardio-Pulmonary Bypass in the Pediatric Patient. *AmSECT Proceedings* 3:82, 1975
11. Page, P. A.: Clinical evaluation of a New Microporous Teflon Membrane Oxygenator. *J. Extracorporeal Technology*. VI:199, 1974
12. Subramanian, V. A., Wright, W. L., and Berger, R. L.: A New Efficient Disposable Rotating Disk Membrane Oxygenator vs. Bentley Bubble Oxygenator. *Surgical Forum* 25:132, 1974
13. Bramson, M. L., Osborn, J. J., Main, F. B., O'Brien, M. D., Wright, J. S. and Gerbode, F.: A New Disposable Membrane Oxygenator with Integral Heat Exchanger. *J. Thorac. Cardiovasc. Surg.* 50:391, 1965
14. Williams, D. R., et al: Comparison of Membrane and Hybrid Oxygenators. Presented at American Heart Assoc. Meeting Nov. 17, 1975
15. Miller, D. W., Hessel, E. A., Winterscheid, L. C., Merendino, A., Dillard, D. H.: Current Practice of Coronary Artery Bypass Surgery: *J. Thorac. Card. Surg.* 73:75, 1977
16. Harnsberger, F.: personal communication: January 17, 1980