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# A Technique for the *In Vivo* Evaluation of Three Hybrid Blood Oxygenators with Integral Heat Exchangers

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## Background

Most previous attempts at clinical evaluation of blood oxygenators and heat exchangers have rarely quantitated the device performance but rather reported subjective experiences and gross measures of function such as the limits of excursion of the arterial pO<sub>2</sub> or the time required to warm the patients.<sup>1-3</sup> Quite often the myriad of variables at work in the open heart surgical arena prohibit strict control of an experimental method, hence clinical comparisons of extracorporeal devices rarely yield results backed with adequate statistical power to demonstrate significant differences either because the number of subjects is too small or the resulting data dispersion is too large. This method attempts to minimize individual variability from the outset by selecting accurately matched patient groups and rigorously controlling patient management during bypass.

This method presents a reproducible technique and ensuing results for oxygenator/heat exchanger clinical comparison in three categories; 1) device blood handling ability, 2) device respiratory function curves and 3) device-patient heat transfer ability. Lastly, pa-

tient-circuit physiological interaction is assessed to disclose any patient phenomenon that would cause interference with resulting device performance measurements.

## Method

**PATIENTS:** Three groups of 10 male coronary artery disease patients approximately two M<sup>2</sup> body surface area, 55-65 years old and 70-80 Kg. body weight were subjected to identical extracorporeal circuits except for the oxygenator with integral heat exchanger. All patients were scheduled for elective triple or quadruple coronary artery bypass surgery and patients with diffuse peripheral atherosclerosis were not selected. The three oxygenator-heat exchangers studied were the Bentley Laboratories Inc. BOS 10\*, the William Harvey Research Corp. H 1000\*\* and the Cobe Laboratories Inc. 42-221, Optiflo II\*\*\*. The groups will be referred to as BOS 10, H 1000 and OPTI II, respectively, in this presentation. Table I relates the oxygenator group patient parameters.

**CIRCUIT:** Heart lung bypass was established with separate cannulation of the superior and inferior vena

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TABLE I  
The mean  $\pm$  one standard deviation and statistical analysis of the oxygenator group patient parameters using a one-way analysis of variance

Oxygenator Group	Body Weight Kg.	Body Surface Area M <sup>2</sup>	Age Years	Length of Pump Run Minutes
BOS 10	78.1 +/- 4.7	1.96 +/- 0.7	59. +/- 5.1	102.7 +/- 26.5
H 1000	80.2 +/- 6.5	1.96 +/- .08	56.5 +/- 5.7	84.3 +/- 19.7
OPTI II	80.2 +/- 5.6	1.96 +/- .08	53.3 +/- 6.3	96.5 +/- 26.7
Significant Difference Tail Probability p Value	N.S. .63	N.S. .99	N.S. .10	N.S. .25

cavae for gravity venous return to the test device. Arterialized blood was returned to the ascending aorta from the circuit. Two hand held Kay suckers and an 18 Fr. Ferguson catheter sumping the left ventricle via the right superior pulmonary vein returned via occlusive twin roller pumps to a Swank filter integral to a Cobe Laboratories Inc, 42-300 cardiotomy reservoir draining directly to the test oxygenator. Oxygenated blood was returned to the patient by a barely nonocclusive, calibrated Cardiovascular Instruments Corp. (CINCO)\*\*\*\* twin roller pump through a Pall Corporation\*\*\*\*\* Ultrapor filter with a bleed line back to the oxygenator arterial reservoir. The occlusion of the arterial pump head with a 3/8" I.D., 1/16" wall PVC tubing ventricle was checked to be barely nonocclusive prior to each case. All PVC tubing was Tygon\*\*\*\*\* S-50-HL 3/32" wall thickness in the remainder of the circuit. The wall water supply entered the test heat exchanger at 30 P.S.I. regulated internally by the CINCO module console.

**ANESTHESIA AND PHARMACOLOGICAL MAINTENANCE:** Subjects were anesthetized with morphine sulfate (.5-1 mg/kg), diazepam (.25-.5 mg/kg) and scopolamine (.2-.4 mg/kg). Intratracheal intubation was carried out after muscle relaxation with Pancuronium (.1 mg/kg). Anesthesia and relaxation were maintained with nitrous oxide (no greater than 50%) and during bypass with Pancuronium, diazepam and Enflurane.

\*\*\*\* 134 Water Street, Box 188, Wakefield, Massachusetts, 01880.

\*\*\*\*\* Biomedical Products Division, Glen Cove, New York, 11542.

\*\*\*\*\* Norton Plastics and Synthetics Division, P.O. Box 350, Akron, Ohio, 44309.

Mean arterial blood pressure during bypass was maintained between 60 and 100 mmHg with the use of phenylephrine hydrochloride, nitroglycerine drip, and in extreme circumstances, phentolamine mesylate, chlorpromazine, methoxamine hydrochloride and nitroprusside drip.

**PATIENT MANAGEMENT DURING BY-PASS:** Bypass was established at a Cardiac Index of 2.1 to 2.4 L/min/M<sup>2</sup> and hypothermia immediately instituted by stopping the circulation of 38°C water in the patient warming blanket and dropping the heat exchanger water-in temperature to 12-18°C. The gas to blood flow ratio (G:BQR) was decreased and the percent CO<sub>2</sub> in the ventilating gas (VG<sub>CO<sub>2</sub></sub>) increased as the patient esophageal temperature approached and was maintained at 28°C. Patient warming began when the surgeon completed the next to last distal anastomosis of the vein graft with the proximal anastomoses yet to be completed. A 10°C gradient between water in and esophageal temperature was employed to warm the patients. A 42°C water-in temperature was never exceeded. As the patient was warmed to 37.8°C, the G:BQR was increased and the VG<sub>CO<sub>2</sub></sub> set at 0% or very low. Arterial and venous blood gases were drawn every 15 to 20 minutes during bypass and alterations made in the Cardiac Output, and the mixture of 100% O<sub>2</sub> and 100% CO<sub>2</sub> gas flows to maintain the PaO<sub>2</sub> at 100-250 mmHg, the PaCO<sub>2</sub> at 38-45 mmHg, the PvO<sub>2</sub> at 30-40 mmHg and the Base Excess at +/-2.5 mEq/L. Sodium bicarbonate was employed only in two patients, at the end of warming, to keep the PaH above 7.30 with a normal PaCO<sub>2</sub>. During warming the Cardiac Index was increased to 2.5 L/min/M<sup>2</sup>. The circulating blood volume was expanded with a balanced pH and electrolyte fluid. Bank blood was employed in two patients

where the hematocrit fell to 19%. The circuit was primed with 1000 ml of a balanced pH electrolyte solution, 150 ml of 15% mannitol solution, 500 ml of 10% dextran 40 in .9% sodium chloride, 1 Gm of Cephazolin sodium and 5000 u. heparin for all three circuits. The H 1000 circuit required 1250 ml of the balanced pH electrolyte solution.

Patients were heparinized with an initial dose of 350 u./Kg. body weight. Activated clotting times (ACT) were maintained greater than 450 seconds as measured by the Hemochron\* device. 5000-10,000 u. boli of heparin were given to maintain the ACT or after two hours a quarter of the initial dose was administered to elevate the ACT.

**MEASURED PARAMETERS:** YellowSpring Instruments Inc. (YSI)\* series 601 luer-loc in-line thermistors were employed to measure venous line blood temperature (T<sub>Bi</sub>), arterial line blood temperature (T<sub>Bo</sub>), water in (T<sub>Wi</sub>) and out (T<sub>Wo</sub>) of the heat exchanger. The probes were placed in immediate proximity to the oxygenator. YSI series 400 thermistors were placed in the esophagus (TE) and the rectum

$$\dot{V}O_2 = C.O. \times \left[ \frac{[[PaO_2 - PvO_2] \times aO_2] + \left[ \frac{[SaO_2 - SvO_2]}{100} \times 1.34 \times [Hb] \right]}{100} \right] \quad 3.$$

(TR) for monitoring. Radial artery and venous line

Where aO<sub>2</sub> is the solubility of O<sub>2</sub> in blood plasma.<sup>5</sup>

$$mlO_2/min = ml \text{ blood}/min \times \frac{\left[ mmHg \times \frac{mlO_2/ml \text{ blood}}{760 \text{ mmHg}} \right] + \left[ \frac{\%}{100} \times \frac{1.34 \text{ mlO}_2}{gmHb} \times \frac{gmHb}{100 \text{ mlBld}} \right]}{100}$$

blood samples were simultaneously drawn during total bypass and analyzed for arterial and venous pO<sub>2</sub>, pCO<sub>2</sub> and pH on the Radiometer BMS3ME2 blood micro gas analyzer.\*\* The values were temperature corrected to the TE and T<sub>Bi</sub> for the arterial and venous samples respectively according to Riley and Snyder.<sup>4</sup> Arterial and venous % O<sub>2</sub> saturation of hemoglobin (SO<sub>2</sub>) and the hemoglobin concentration were measured on the Radiometer OSM2 Hemoximeter\*\*.

**RECORDED PARAMETERS:** Arterial blood (C.O.), heat exchanger water (H<sub>2</sub>OQ) 100% O<sub>2</sub> (O<sub>2</sub>Q)

and 100% CO<sub>2</sub> (CO<sub>2</sub>Q) flows were recorded. Mean arterial (mABP) and mean central venous pressure (mCVP) were retrieved from calibrated strain gauge transducers.

**CALCULATED PARAMETERS:** Oxygenator related calculations were made for G:BQR (eq. 1), % VG<sub>CO<sub>2</sub></sub> (eq. 2), oxygen consumption (V̇O<sub>2</sub>, eq. 3), CO<sub>2</sub> production (V̇CO<sub>2</sub>, eq. 4) and the respiratory quotient (R.Q., eq. 5). Peripheral vascular resistance (PVR, eq. 7) was calculated in addition. The units of measure follow each equation.

$$G:BQR = \frac{O_2Q + CO_2Q}{C.O.} \quad 1.$$

$$\text{unitless} = \frac{L/min + L/min}{L/min}$$

$$\% VG_{CO_2} = \frac{CO_2Q}{O_2Q + CO_2Q} \times 100 \quad 2.$$

$$\% = \frac{L/min}{L/min + L/min} \times 100$$

$$\dot{V}CO_2 = C.O. \times \frac{[Arterial CO_2 \text{ VOL}\% - \text{venous CO}_2 \text{ VOL}\%]}{100} \quad 4.$$

$$mlCO_2/min = ml \text{ blood}/min \times \frac{[vol\%CO_2]}{100}$$

Where arterial and venous CO<sub>2</sub> vol% are derived from the nomogram according to Singer and Hastings.<sup>6</sup> The resulting total mM/L of CO<sub>2</sub> from the nomogram is multiplied by 2.226 vol%/mM/L according to Davenport.<sup>7</sup>

$$R.Q. = \frac{\dot{V}CO_2}{\dot{V}O_2} \quad 5.$$

$$\text{unitless} = \frac{mlCO_2/min}{mlO_2/min}$$

\* International Technidyne Corp., 138 Forrest Street, Metuchen, New Jersey, 08840.

\* Scientific Division, Yellow Springs, Ohio, 45387.

\*\* Radiometer, A/S, Endrupvej 72, DK-2400, Copenhagen, NV, Denmark.

**TABLE II**  
The mean  $\pm$  one standard deviation of the oxygenator group plasma free hemoglobin values (mg%) measured during bypass analyzed by one-way ANOVA and the occurrence of hemoglobinuria

Oxygenator Group	Prebypass Control	Minutes into Bypass Plasma Free Hemoglobin (mg%)				Occurrence of Hemoglobinuria
		20	40	60	80	
BOS 10	6 $\pm$ 4.3	22.3 $\pm$ 7.6	24.7 $\pm$ 9.4	31.6 $\pm$ 5.4	48.3 $\pm$ 18.7	0
OPTI II	5.8 $\pm$ 5.4	21.6 $\pm$ 7	25.5 $\pm$ 10.7	39.7 $\pm$ 14.3	61.6 $\pm$ 30.	3
H1000	5.5 $\pm$ 3.1	17 $\pm$ 6.7	24.9 $\pm$ 13.8	32.3 $\pm$ 19.1	53.6 $\pm$ 26.4	1
Significant Difference	N.S.	N.S.	N.S.	N.S.	N.S.	
Tail probability p value	.98	.91	.97	.91	.79	

The parameter that reflects the heat exchangers' ability to transfer heat to the patient is blood heat flow (QBld; equation 6).<sup>8</sup>

$$QBld = C.O. \times D \times SH \times (TB_o - TB_i) \quad 6.$$

where: D = density of 25% hematocrit blood = 1.08 gm/ml

SH = specific heat of 25% hematocrit blood = .98 cal/gm/°C  
calories = ml/min  $\times$  gm/ml  $\times$  cal/gm/°C  $\times$  °C

The patient's vasomotor status was assessed by calculating:

$$PVR = (mABP - mCVP) / C.O. / 60 \quad 7.$$

$$\text{mmHg/ml/sec} = \text{mmHg/ml/min} \times \frac{60 \text{ sec}}{\text{min}}$$

In addition, urine output, bank blood addition, non-blood fluid addition, throw away suction and drug administration were recorded.

**OXYGENATOR BLOOD HANDLING:** Control samples were drawn for baseline plasma free hemoglobin values and platelet counts prior to bypass. During bypass, plasma free hemoglobin samples were drawn every 20 minutes for analysis. Post bypass and two to three hour post surgery platelet counts were collected. The .1% benzedine method and Coulter Counter were employed for the plasma free hemoglobin (HbPl) and platelet count (PtCt) analysis, respectively.

**DATA COLLECTION:** Blood gas samples were drawn and data recorded every 10 to 20 minutes after initiation of bypass until warming began. Data was

recorded at baseline, every four minutes, and after TE = 37.5°C and TR = 35°C (post) during the warming process. Blood gases were drawn approximately every 10 to 20 minutes during warming.

**PARAMETER ANALYSIS AND REPRESENTATION:** Most measured and calculated parameters are either plotted against minutes of bypass or warming of TE during the warming period. A one way analysis of variance (ANOVA) for the three oxygenator groups was then performed on the data at one elapsed time or at one value of TE. Some oxygenator function curves were subdivided to hypothermia (28–30°C) and normothermia (36–38°C) and then analyzed in a similar manner at a certain value of the independent variable.

## Results and Discussion

**BLOOD HANDLING:** Table II lists the PIHb for each oxygenator group during bypass. One-way analysis of variance of the hemolysis rates at all times shows no significant difference between oxygenator groups. There is a significant increasing trend effect ( $p < .01$ ) with time. Time plotting yields three phases in the hemoglobin lysis; initiating bypass and hypothermia yield values of 15–20 mg%, warming with a TWi-TE gradient of 10°C causes a rapid increase in PIHb at a rate of approximately .6 mg%/minute where the values plateau during the third phase (maintaining normothermia) at 50–60 mg%. This measured hemolysis with rapid warming probably warrants judical use of a TWi-TE gradient greater than 8°C with the greater capacity heat exchange devices integral to the test de-

TABLE III

The mean  $\pm$  one standard deviation of the prebypass platelet counts and the % of the prebypass platelet count post bypass and in the early recovery period analyzed by one-way ANOVA

Oxygenator Group	Prebypass Platelet Count	Post bypass % of Prebypass	Early recovery % of Prebypass
BOS 10	225.1 $\pm$ 37.6	40.2 $\pm$ 17.4	46.6 $\pm$ 15.7
OPTI II	272.8 $\pm$ 39.9	43.2 $\pm$ 11.1	58.1 $\pm$ 17.5
H-1000	226.4 $\pm$ 47.9	53.1 $\pm$ 9.9	56.6 $\pm$ 10.8
Significant Difference	OPTI II > BOS 10, H1000	N.S.	N.S.
Tail Probability p value	.04	.165	.151

vices in this method. The OPTI II group experienced the greatest degree of hemolysis and hemoglobinuria (Table II) although it was not significantly greater. ( $p = .79$ )

Table III lists the PtCt for each oxygenator group before and after bypass and in the early recovery period. There was a significant loss of platelets in all groups post bypass to approximately 46% of the initial PtCt ( $p < .001$ ). The H1000 appeared to preserve a greater % of platelets (53.1%) post bypass. OPTI II group had the greatest % recovery of the PtCt (15.1%) however this measurement is also a function of the two patients in the OPTI II AND H 1000 groups and the

one BOS 10 patient that received platelet supplement during the early recovery period.

**RESPIRATORY FUNCTION:** Figure one depicts the device respiratory performance curves under the operating conditions described in Table IV and the method. One device's performance in the group of patients described in this method must be related to the oxygenator inlet blood conditions ( $PvCO_2$ ,  $SvO_2$  and Hct) to compare groups.

Each oxygenator was capable of performing at average G:BQR's less than 1.0 during all phases of bypass. The G:BQR was increased and the %  $VG_{CO_2}$  was decreased as the patients were warmed. Table IV shows

TABLE IV

The hypothermia and normothermia mean  $\pm$  one standard deviation of oxygenator blood inlet parameters;  $PvCO_2$ , %  $O_2$  saturation of hemoglobin and the hematocrit and the Cardiac Index in L/min/M<sup>2</sup> are listed to aid in interpreting the operator and physiological responses to rapid warming in Figure 1.

OXYGENATOR GROUP	HYPOTHERMIA (27-29°C)				NORMOTHERMIA (36-38°C)			
	$PvCO_2$	$SvO_2$	Hct	C.I.	$PvCO_2$	$SvO_2$	Hct	C.I.
BOS 10	45.5 $\pm$ 6.6	95.4 $\pm$ 2.6	24.6 $\pm$ 3.5	2.72 $\pm$ .11	46.3 $\pm$ 6.7	82. $\pm$ 5.4	23.5 $\pm$ 2.9	2.75 $\pm$ .11
OPTI II	44.2 $\pm$ 5.2	91.9 $\pm$ 3.6	23.6 $\pm$ 1.9	2.66 $\pm$ .09	47.0 $\pm$ 5.2	73.3 $\pm$ 5.	23.5 $\pm$ 1.4	2.75 $\pm$ .12
H-1000	42.5 $\pm$ 3.6	89.7 $\pm$ 4.8	25.4 $\pm$ 2.	2.49 $\pm$ .15	44.7 $\pm$ 3.9	75.8 $\pm$ 3.9	24.9 $\pm$ 2.2	2.60 $\pm$ .09

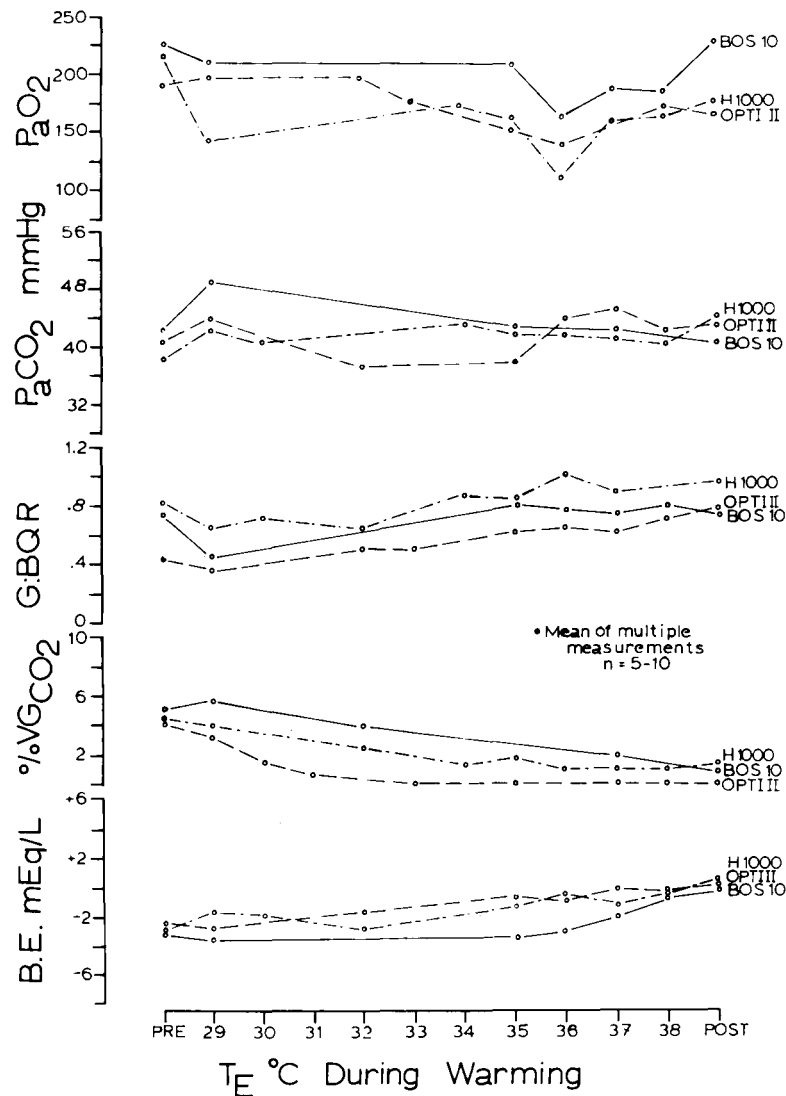


FIGURE 1. Oxygenator Ventilation Function Curve; the means of multiple measurements of the PaO<sub>2</sub>, PaCO<sub>2</sub>, ventilating gas % CO<sub>2</sub>, gas to blood flow ratio and the base excess at various esophageal temperatures during rapid warming.

that the C.I. was slightly increased during warming. The BOS 10 was operated at a G:BQR from .5 to .75 employing a VG<sub>CO<sub>2</sub></sub> as great as 5% and as low as .9% on the average. Figure 1 is also an operator reaction curve as well as device performance curve. The PaCO<sub>2</sub> reached an average of 50. mmHg at 29–39°C when the VG<sub>CO<sub>2</sub></sub> was maintained at 5%. In retrospect and examination of these curves, the BOS 10 could probably have been operated at a slightly lower G:BQR and very little CO<sub>2</sub> gas flow at this point. The ease with which CO<sub>2</sub> may be retained on warming, the response time of laboratory blood gas analysis and the rapidity of warming practically necessitate the continuous, in-line

monitoring of blood gases if the heat exchanger's maximum capacity is employed. The lower the operating G:BQR built into the device, the more complicated the blood gas control becomes with small gas flow changes and rapid warming.

The H 1000 probably required the greater G:BQR and % VG<sub>CO<sub>2</sub></sub> of the 3 devices, however in Figure 1 the H 1000 group had the lower average SvO<sub>2</sub> and greater Hct during bypass resulting in greater average G:BQR requirements yielding a lower average PaO<sub>2</sub> during the warming phase.

There were no substantial differences in device respiratory performance in this protocol when the par-

TABLE V

The mean esophageal and rectal times (minutes) ± one standard deviation analyzed by a one-way ANOVA. The times reported are to reach TE = 37.5°C and TR = 35°C

OXYGENATOR GROUP	ESOPHAGEAL WARM TIME	RECTAL WARM TIME
BOS 10	14.8 ± 6.1	23.1 ± 10.6
OPTI II	22.3 ± 6.9	27.6 ± 6.0
H 1000	25.9 ± 6.4	32.2 ± 8.5
Significant Difference	BOS 10 > OPTI II, H 1000	N.S.
Tail Probability p value	.05	.078

ameters in Table IV are compared. The BOS 10 and to a lesser degree, the OPTI II and H 1000 enhance the possibility of retaining CO<sub>2</sub> because of the rapid warming capability and operator mismanagement in a rapidly changing patient situation.

HEAT TRANSFER ABILITY: Figure 2 relates the average esophageal and rectal warm times for each test device group. Table V lists the analysis of the warming times. The BOS 10 integral heat exchanger has a significantly greater capacity to transfer heat (Table VI) using the warming technique described in the method. On the average, each patient in each device group received a similar total number of kilocalories to reach a rectal temperature of 35°C. The rise in esophageal temperature followed a similar pattern of

significant difference as blood heat flow (Table VI).

PATIENT-CIRCUIT PHYSIOLOGICAL INTERACTION: Figure 3 plots the systemic vascular resistance (SVR) versus temperature during warming. The pre-warming resistance values demonstrated no significant difference (p = .727) and the percent change in the resistance compared to prewarm values showed no significant difference through the warming period (p = .22-.79) and post warming (p = .87). Each device patient group vasodilated in a uniform manner during the warming period. Figure 2 warming curves were not affected by an unequal vasomotor status between patient groups. Figure 3 depicts a sharp drop in SVR at the beginning of warming (28-30°C), a plateauing or small increase at 32-34°C and a drop in

TABLE VI

The mean ± one standard deviation of the blood heat flow in Kcal/min during warming and the average total number of Kcal required to raise a patient's TR to 35°C.

Minutes of Warming	OXYGENATOR GROUP KILOCALORIES/MINUTE DELIVERED			Significant Difference	Tail Probability p value
	BOS 10	OPTI II	H 1000		
0	20.6 ± 1.6	15.9 ± 5.5	16.1 ± 2.8	N.S.	.168
4	16.3 ± 3.7	12.1 ± 3.5	11.4 ± 2.1	BOS 10 >	.006
6	13.7 ± 2.2	10.6 ± 2.9	9.7 ± 2.1	BOS 10 >	.006
8	10.9 ± 4.	11.2 ± 2.9	9.9 ± 3.2	N.S.	.71

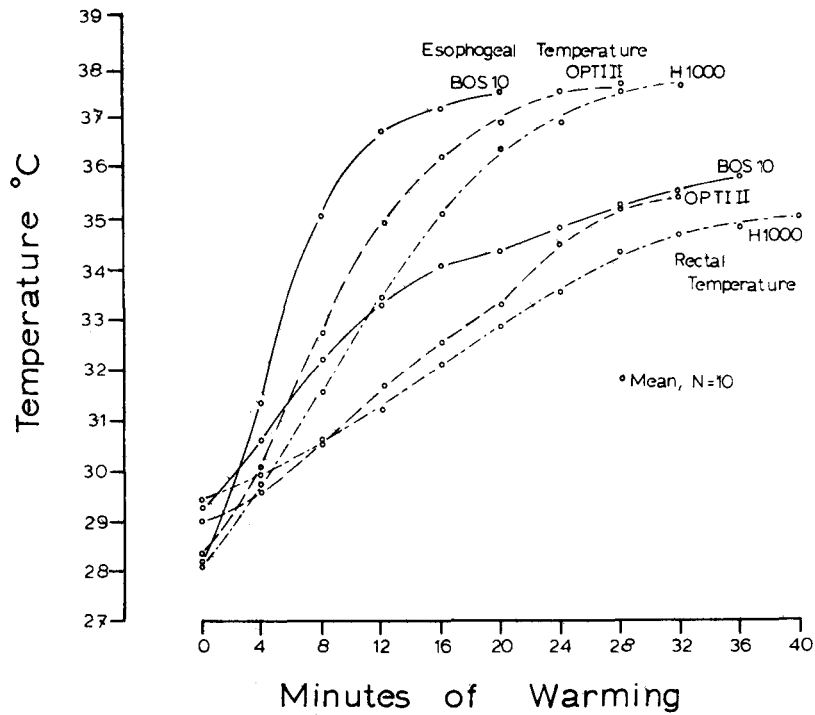


FIGURE 2. The mean esophageal and rectal temperatures versus duration of warming for the three test integral heat exchanger groups.

SVR on reaching 38°C. The final decrease in SVR is especially pronounced in the BOS 10 and OPTI II groups. The peripheral vasodilation is beneficial at

bypass termination to maximize the decrease in afterload. Venodilation with increased temperature before separation of bypass decreases the chance of

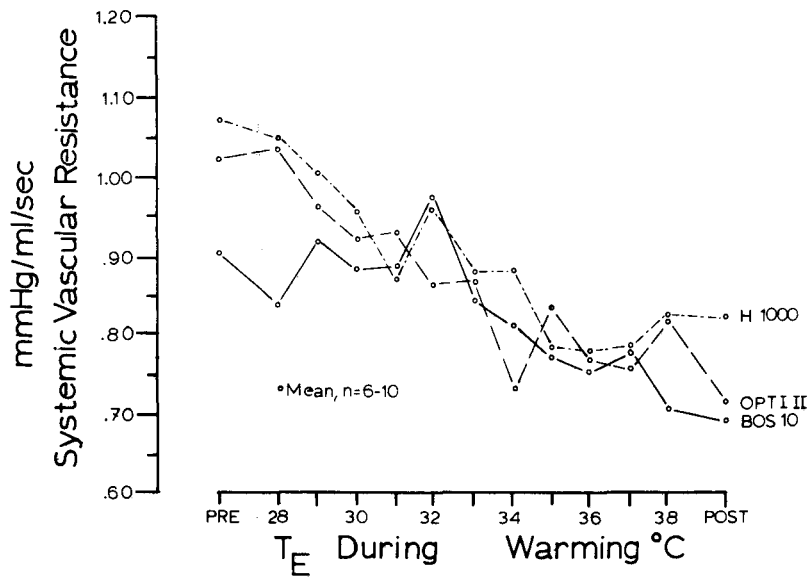
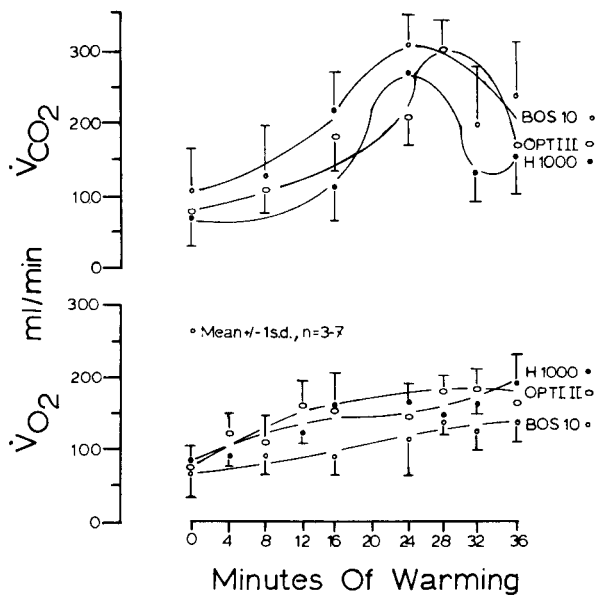


FIGURE 3. The mean systemic vascular resistance (mmHg/ml/sec) for each patient group versus the esophageal temperatures during rapid warming. To convert mg/ml/sec to dynes-sec-cm<sup>-5</sup> multiply by 1333 dynes/cm<sup>2</sup>/mmHg.





**FIGURE 4.** Mean  $\pm$  one standard deviation of oxygen consumption and carbon dioxide removal in ml/min versus minutes of rapid warming.

shifting volume to the vascular tree (causing a hypovolumic crisis) in the early recovery period when a patient finally warms.

It should be noted that the BOS 10 group was at a slightly greater C.I. than the OPTI II and H 1000 perhaps enhancing the difference in heat flow, TE warming time and the drop in SVR observed (Table IV).

Figure 4 plots  $\dot{V}_{O_2}$  and  $\dot{V}_{CO_2}$  for the patient groups. Initial  $\dot{V}_{O_2}$  showed no significant difference ( $p = .127$ ) in the device groups, however, the H 1000 and OPTI II groups showed substantially greater  $\dot{V}_{O_2}$  during the same time and TE of warming. The greater  $\dot{V}_{O_2}$  and greater kilocalories of heat delivered to reach TR = 35°C in the OPTI II and H 1000 groups suggests that less of the BOS 10 patients' tissue were at the same temperature as the esophagus. On the average, the H 1000 patients received 4685 mlO<sub>2</sub> during warming to TR = 35°C. The OPTI II and BOS 10 received an average of 3640. and 2030. mlO<sub>2</sub>, respectively. The lower total ml of O<sub>2</sub> delivered to the BOS 10 patients further suggests that rapid core warming deprives other body tissue of equal heat and oxygen. Figure 4 depicts a sudden rise in  $\dot{V}_{CO_2}$  after TE has reached 36–37°C in the patient groups. On warming to 36°C, other body tissues are increasing metabolism and the % VG<sub>CO<sub>2</sub></sub> is being decreased, and a rapid flux of CO<sub>2</sub> is noted. The BOS 10 group had the greatest flux of CO<sub>2</sub> after

warming. The rapid core warming, the failure of the operator to adequately ventilate the oxygenator between 29–34°C retaining CO<sub>2</sub> and the sudden addition of body tissues' CO<sub>2</sub> on warming create a large rise in  $\dot{V}_{CO_2}$  and  $\dot{V}_{O_2}$  after TE has reached 37°C. These changes would present clinically as a rapid drop in SvO<sub>2</sub>, PvO<sub>2</sub> and rise in PvCO<sub>2</sub>. If the operator fails to recognize the inlet blood alterations and adjust the device ventilation, the PaO<sub>2</sub> will drop and the PaCO<sub>2</sub> will rise, possibly leading to acid base imbalances if allowed to persist.

**FLUID BALANCE:** There was no significant difference in positive fluid balance at the termination of bypass ( $p = .946$ ). The mean positive fluid balance and one standard deviation for each group was BOS 10, 2160.  $\pm$  497.ml; OPTI II, 2292.  $\pm$  1124.ml; and H 1000, 2188.  $\pm$  847.ml.

**QUALITY CONTROL:** sixteen BOS 10's were opened to find ten units that were defect free. BOS 10 problems ranged from label absence, ports breaking off in hand, to inability to make the water connections. Three H 1000's had water port or path leaks to air that could not be stopped, however, they did not necessitate replacement. The OPTI II devices were free of quality control problems.

## Conclusions

1. Three well matched groups of 10 male coronary artery diseased patients were exposed to identical extracorporeal circuits except for the oxygenator with integral heat exchanger. The BOS 10, Optiflo II and H 1000 were studied for blood handling, respiratory function, heat exchange capability and lastly the device—patient physiological interactions employing a hypothermia, rapid warming total heart lung bypass model described in the method.
2. There were no significant differences in platelet consumption post-bypass and in the rate of hemolysis between oxygenator groups. Platelet loss was 43–53% of the prebypass count and plasma free hemoglobin rose from control values of 5–6 mg% to 50–63 mg% at 80 minutes of bypass.
3. Fixing patient characteristics and given equal oxygenator inlet blood PvCO<sub>2</sub>, SvO<sub>2</sub> and hematocrit, there are no substantial differences in the test device's ability to oxygenate and remove CO<sub>2</sub> in this method.
4. The BOS 10 delivered a significantly greater heat flow to the patients the first 12 minutes of warming and warmed the patients to TE = 37°C at a signif-

- icantly greater rate. The H 1000 lagged the Optiflo II group in warming, but not significantly.
5. There were several physiological consequences that were consistent within the three groups employing this method:
    - a. The vascular resistance fell rapidly as the patient was warmed (to 60% of the prewarm value).
    - b. Oxygen consumption appeared to be an inverse function of the rapidity of warming. The H 1000 and Optiflo II group consumed more oxygen per minute at the same esophageal temperature during warming than the BOS 10 group.
    - c. Carbon dioxide blow off maximizes when the patient reaches 36–37°C esophageally.
  6. There are several operator mediated sequela to rapid esophageal warming with greater heat transfer capacity devices (e.g. BOS 10).
    - a. The rapid flux of carbon dioxide and repaying of an oxygen debt on reaching normothermia that follows rapid core warming enhances the possible hypoventilation of a low rated gas to blood flow oxygenating device.
    - b. The % CO<sub>2</sub> in the ventilating gas and the gas to blood flow ratio must be altered in small graded changes during the first 12–16 minutes of rapid warming in order to avoid carbon dioxide retention and arterial % oxygen saturations of hemoglobin less than 95%.
    - c. The large increase in hemolysis observed during the warming period in this protocol suggests that use of a TWi-TE less than 10°C could be less traumatic.
    - d. Control of arterial blood gases would be facili-

tated by employing lower TWi-TE's and in line, continuous blood gas and pH monitors.

- e. The lower  $\dot{V}O_2$ , fewer total kilocalories delivered and the spike in  $\dot{V}CO_2$  at 36°C during warming observed in the BOS 10 group suggests that many other body tissues are at lower temperatures than the esophagus during rapid warming. Therefore, the use of a TWi-TE less than 10°C is indicated in the BOS 10 and Optiflo II.

The authors wish to thank Joseph Craver, M.D. and Ellis Jones, M.D. for their cooperation in the study. The authors also wish to thank Edward Lewis, John Findley and Alfred Yin for their technical assistance, Carolyn Holmes for secretarial services and Steven Moffitt, Ph.D. for his aid in statistical analysis of data.

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