

Original Article

A Multi-Center Trial with a Modified Design of the Sarns Membrane Oxygenator

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Keywords: Sarns modified membrane oxygenator, membrane oxygenator performance, gas transfer, oxygenation efficiency

Abstract

A redesigned hollow fiber bundle was incorporated into an existing oxygenator that underwent clinical trials at seven cardiovascular surgery centers. Clinical investigators were asked to assess gas transfer performance under clinical conditions that could be considered challenging to any microporous membrane oxygenator, i.e., with large body weight patients, long bypass times, or normothermic bypass and surgery. Sixty-six patients,

ranging in weight from 54.5 kg to 143 kg, constituted the initial evaluation population. Enhanced oxygen transfer was noted by all of the investigators. FiO_2 requirements for patients weighing 100 kg or more never exceeded .85, despite oxygen consumption levels reaching as high as 396 mL/min. Two centers documented a 15% to 18% reduction in FiO_2 requirements compared to their standard oxygenator.

Introduction

The conditions under which oxygenators are expected to perform vary widely. Differences in perfusion protocols and anesthesia techniques, as well as the advent of normothermic perfusion and more technically demanding procedures can have a significant impact on the typical indicators used to assess performance of a membrane oxygenator, and ultimately on clinical results. (1-3)

Increased gas transfer efficiency with microporous membrane oxygenators has been achieved through design innovations that provide improved blood-side convective mixing. (4) Better mixing is the critical feature that enables reduced membrane surface area, facilitating lower priming volumes without compromising gas transfer.

Numerous techniques are currently employed to induce effective but gentle mixing of blood over a microporous gas exchange surface. Flat plate or sheet membranes use a specially designed screen that attenuates laminar flow at the membrane surface. (5) Hollow fiber oxygenators with blood flow outside the fibers rely on bundle geometry or fiber

winding patterns to create mixing. Hollow fiber devices with blood flow inside the fibers cannot induce mixing and, therefore, rely solely on membrane surface area to achieve adequate gas transfer. Hence, such oxygenators require larger priming volumes. The goal of newer devices is to obtain a high level of gentle blood-membrane interaction while simultaneously limiting contact between blood and the synthetic material.

Gas transfer performance of the original Sarns membrane oxygenator^a was based upon a carefully defined winding pattern and fiber bundle geometry that can be expressed mathematically. (6) The correlation between clinical outcomes and the theoretical design was contingent upon consistency and uniformity in the fiber placement.

In the modified oxygenator, changes in fiber dimension and layout have been employed. The fiber is assembled in a mat configuration that looks somewhat like a bamboo curtain (Figure 1). Certain specifications are made for fiber dimensions, fiber angle, and the number of fibers per inch (Figure 2). These specifications are then incorporated into the design and manufacturing equations for each fiber bundle. Because dimensional tolerances vary in both the fiber strand and the fiber mat, fiber bundles are not wound to meet a surface area specification but rather to meet performance and dimension specifications. Winding to performance specifications is

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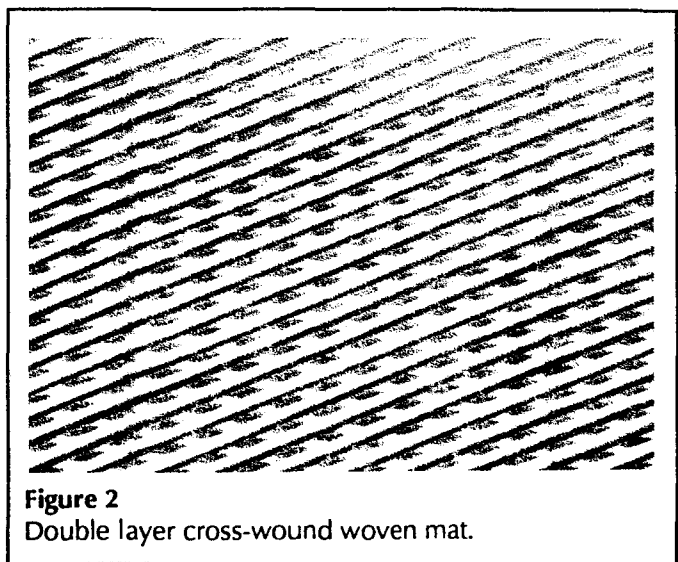
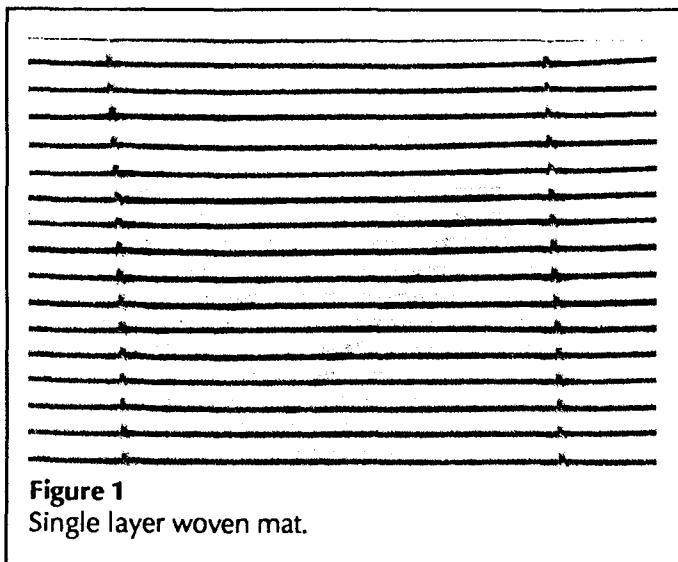


Figure 1
Single layer woven mat.

Figure 2
Double layer cross-wound woven mat.

Fiber Material	Microporous polypropylene
Fiber Outside Diameter	380 microns
Fiber Inside Diameter	280 microns
Porosity	35%
Pore Size	0.3 microns
Fiber Count	0,500 (approximate)
Surface Area	1.9 m ²
Blood Flow Range	1 to 7 L/min
Total Prime Volume	270 mL
In-vitro Performance Specifications	In accordance with AAMI and ISO draft standards

	Center Averages							Overall Average	Range	S.D.
	A	B	C	D	E	F	G			
# Cases	9	9	5	15	9	9	10			
Weight (kg)	74.7	79.0	87.3	84.0	91.9	79.1	84.5	82.8	56.5-143	18.1
Height (cm)	165	172	176	168	174	173	173	171	152-188	9.5
BMA (m ²)	1.84	1.96	1.96	1.97	2.07	1.94	1.97	1.96	1.52-2.66	0.23
Pump Flow (L/min)	153	110	92	121	118	102	121	119	40-263	48.2
Q Blood (L/min)	4.35	4.50	3.73	4.33	4.68	4.08	5.28	4.41	2.1-6.5	0.81
Cardiac Index L/min/m ²	2.37	2.27	1.83	2.10	2.26	2.09	2.72	2.29	1.04-3.05	0.39
Q Gas (L/min)	3.1	4.6	3.5	3.5	2.9	3.2	3.2	3.4	1.5-7.5	1.15
Qr/Qb Ratio	.71	1.0	.97	.85	.61	.81	.60	.77	0.3-1.8	0.26
FiO ₂ (%)	53	75	61	50	50	42	64	55	21-100	24.8
Hgb (gm/dL)	8.2	7.9	8.4	8.2	8.2	7.4	7.9	8.0	4.2-11.8	1.41

	248	405	359	246	201	227	248	274	60-509	99.6
PvO ₂ (mmHg)	7.42	7.42	7.42	7.46	7.42	7.41	7.42	7.43	7.30-7.57	0.53
PvCO ₂ (mmHg)	34	35	38	35	40	37	39	37	16-51	4.4
PvO ₂ (mmHg)	41	52	37	45	37	46	44	43	15-84	18.9
pH	7.38	7.37	7.38	7.41	7.38	7.38	7.38	7.39	7.23-7.50	0.050
PvCO ₂ (mmHg)	41	43	44	39	44	41	44	42	10-57	8.2
pH	7.4	81	71	76	71	77	74	75	46-95	10.1
VO ₂ (mL/min)	156.3	138.2	156.5	136.1	183.7	133.3	104.2	152.2	50.8-392.7	67.1

possible because the gas transfer performance of any given fiber bundle can be expressed as a design equation. (6) This method of manufacture insures that oxygenator performance is consistent despite discrete variations in fiber outer diameter between different fiber lots. To prevent shunting, the dimension of the bundle is matched to that of the housing. Consequently, the membrane surface area purposefully varies. The blood contact surface area of the new membrane bundle is approximately 1.9 m². The priming volume of the oxygenator and heat exchanger has been reduced to approximately 270 ml.

Materials and Methods

Product Description

The modified oxygenator has the same physical appearance and heat exchanger as the original oxygenator. (7-9) The new fiber bundle conforms to the characteristics listed in Table 1. In-vitro testing of the modified oxygenator in accordance with the Association for the Advancement of Medical Instrumentation (AAMI) and International Standards Organization (ISO) draft standards (10) yielded the results shown in Figure 3 for oxygen transfer, Figure 4 for carbon dioxide transfer, and Figure 5 for heat exchanger efficiency.

Clinical Evaluation

Adult cardiopulmonary bypass cases were conducted at seven participating centers (Centers A-G, Table 2). Perfusionists at each center were asked to evaluate the ability of the modified oxygenator to accommodate difficult or challenging bypass conditions. At the end of the trials, 10 patients weighing more than 100 kg were retrospectively assigned to Group I (Table 3) for additional analysis. Three patients whose time on bypass exceeded four hours were assigned to Group II.

The arterial and venous blood gases of 24 patients from centers D and E were continuously monitored using in-line

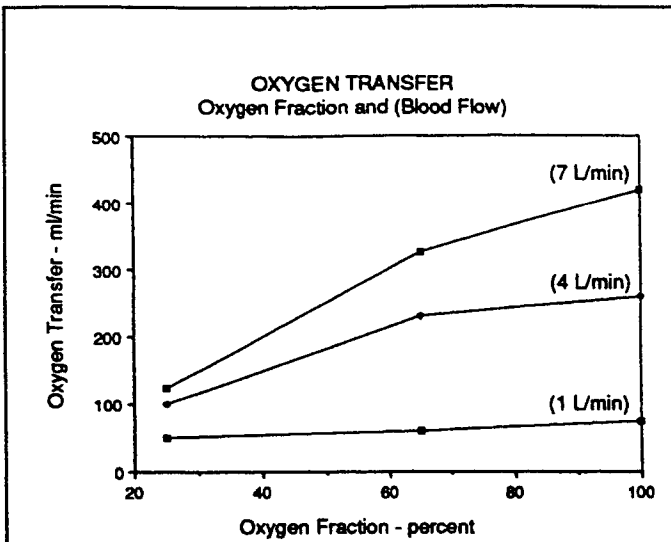


Figure 3
In-vitro oxygen transfer determined using AAMI conditions as specified. Results do not necessarily reflect rates to be achieved under clinical conditions. 12 gm/dL Hgb; 37°C; 65% Inlet Oxygen Saturation; 47 mmHg PvCO₂; 7.4 vpV

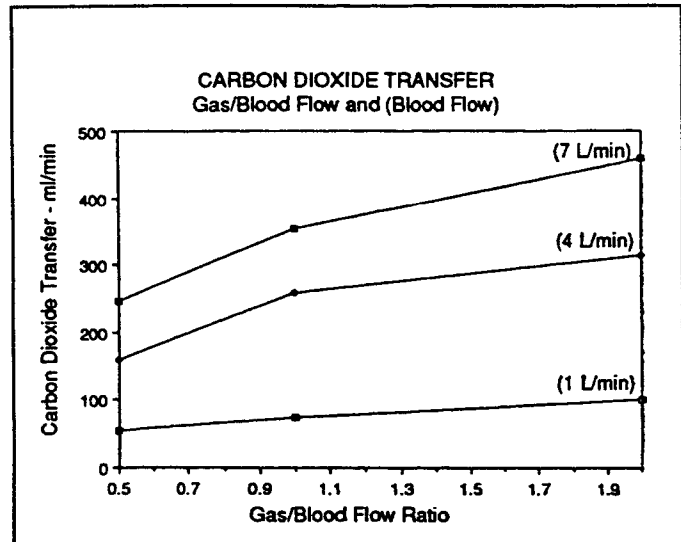


Figure 4
Carbon dioxide transfer determined using AAMI conditions as specified. Results do not necessarily reflect rates to be achieved under clinical conditions. 12 gm/dL Hgb; 37°C; 65% Inlet Oxygen Saturation; 47 mmHg PvCO₂; 7.4 vpV

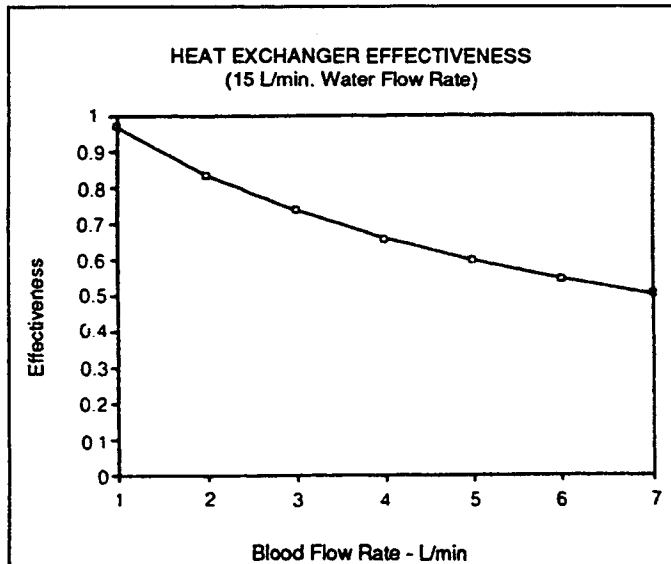


Figure 5
Heat exchanger effectiveness determined using AAMI conditions as specified. Results do not necessarily reflect rates to be achieved under clinical conditions. 12 gm/dL Hgb; 37°C; 65% Inlet Oxygen Saturation; 47 mmHg PvCO₂; 7.4 vpV; Temp Blood_{in} = 30°C; Temp Water_{in} = 40°C

Table 3
Patients and Perfusion Settings for
10 Large Body Weight Patients (Group I)

	Average	Range	S.D.
Patient Weight (kg)	116.3	101-143	11.5
Patient Weight (kg)	178	160-188	10.4
HbA _{1c} (%)	2.35	2.20-2.66	0.13
Bypass Time (min)	99	62-150	28.3
Q Blood (L/min)	5.23	3.4-6.5	0.78
Cardiac Output (L/min/m ²)	2.24	1.5-2.64	0.30
Q Gas (L/min)	4.0	3.3-7.5	1.37
Gr/FH Ratio	.76	.38-1.2	0.26
PiO ₂ (%)	61	29-85	14.1
Pump Hgb (gm/dL)	6.0	6.1-11.6	1.37
PaO ₂ (mmHg)	260	134-555	95.5
apH	7.41	7.32-7.57	0.047
PaCO ₂ (mmHg)	39	32-66.7	8.52
PvO ₂ (mmHg)	40	32-54	6.6
vpH	7.37	7.20-7.46	0.047
PvCO ₂ (mmHg)	44	36-53	4.04
SvO ₂ (%)	72.0	61-87.4	6.8
VO ₂ (ml/min)	196.0	66.2-395.7	77.0

The data from these 24 patients, retrospectively assigned to Group III, were examined for the oxygenator settings at the end of bypass (Tables 4 and 5). Their results were then compared with those of randomly designated patients at the same centers who had undergone bypass using the original Sarns oxygenator in the recent past.

Additionally, centers B, E, and G obtained pre- and post-bypass plasma hemoglobin and platelet data to assess blood handling characteristics of the modified oxygenator (Table 6).

Perfusion circuits were set up in the fashion routinely used

monitoring equipment. Perfusion protocols at these centers are followed to maintain PaO₂ levels within prescribed limits.

Table 4
Comparison of Standard Oxygenator to Modified Oxygenator, Center D

Oxygenator	All Samples		End of Bypass	
	Standard	Modified	Standard	Modified
Cases	14	15	14	15
Patient Weight (kg)	74.3	84.0	--	--
Patient Height (cm)	163	168	--	--
BMA (m ²)	1.81	1.97	--	--
Bypass Time (min)	106	121	--	--
Q Blood (L/min)	3.90	4.13	4.40	4.56
Cardiac Index (L/min/m ²)	2.19	2.10	2.44	2.31
Q Gas (L/min)	3.4	3.5	3.3	3.6
O ₂ /Q ₂ Ratio	0.90	0.85	0.76	0.79
FiO ₂ (%)	68	50	84	61
Pump Hgb (gm/dL)	8.0	8.2	7.0	8.3
Patient Temperature (°C)	31.2	30.7	35.6	35.0
PaO ₂ (mmHg)	235	246	226	223
apH	7.47	7.46	7.45	7.45
Paco ₂ (mmHg)	33	35	33	35
Pvo ₂ (mmHg)	47	45	44	34
vpH	7.43	7.41	7.46	7.41
PvCO ₂ (mmHg)	37	39	34	39
SpO ₂ (%)	77	76	73	68
VO ₂ (ml/min)	124.3	136.1	147.1	184.9

Table 5
Comparison of Standard Oxygenator to Modified Oxygenator, Center E

Oxygenator	All Samples		End of Bypass	
	Standard	Modified	Standard	Modified
Cases	10	9	10	9
Patient Weight (kg)	83.7	91.9	--	--
Patient Height (cm)	173	174	--	--
BMA (m ²)	1.98	2.07	--	--
Bypass Time (min)	101	118	--	--
Q Blood (L/min)	4.56	4.68	5.0	5.44
Cardiac Index (L/min/m ²)	2.32	2.26	2.53	2.64
Q Gas (L/min)	2.7	2.9	2.9	3.1
O ₂ /Q ₂ Ratio	0.60	0.61	0.57	0.56
FiO ₂ (%)	65	50	72	59
Pump Hgb (gm/dL)	8.3	8.2	8.5	7.5
Patient Temperature (°C)	34.5	33.5	37.0	36.2
PaO ₂ (mmHg)	198	201	201	198
apH	7.41	7.42	7.44	7.42
Paco ₂ (mmHg)	40	40	39	39
Pvo ₂ (mmHg)	NA	37	NA	35
vpH	NA	7.38	NA	7.39
PvCO ₂ (mmHg)	NA	44	NA	44
SpO ₂ (%)	69.5	71	69	70
VO ₂ (ml/min)	154.7	182.7	177.5	211.2

at each center. No special provisions were made for incorporating the modified oxygenator into the circuit. Two set-up recommendations were made: 1) Use a CO₂ flush before priming, and 2) Maintain continuous gas flow of 1 to 3 L/min after priming and debubbling and until going on bypass. Each center was asked not to change the customary perfusion protocol. A computer simulation of oxygenator-patient interaction was undertaken before the clinical trials began to demonstrate the expected FiO₂-oxygen transfer relationship for the modified oxygenator. (11) Results of the simulated bypass were provided to clinical evaluators.

Each center continued to use the anticoagulation protocol that was already in place. Each center measured activated clotting times at regular intervals to assure adequate anticoagulation. Arterial and venous blood gas data, along with hemoglobin and hematocrit values, were measured at intervals following the established sampling protocol at each center. All blood gas samples were analyzed at 37°C. Heat exchange efficiency was not calculated during this clinical investigation, because the modified oxygenator employs the same heat exchanger as the original membrane oxygenator.

Results

Sixty-six cardiopulmonary bypass procedures were performed with the redesigned Sarns membrane oxygenator on adults ranging in weight from 54.5 kg to 143 kg. The patients presented oxygen transfer requirements of up to 395.7 ml/min. Patient data averages for all seven centers are listed in Table 2.

FiO₂ requirements for patients weighing more than 100 kg (Table 3) never exceeded .85, despite oxygen consumption levels reaching as high as 396 ml/min. Units that ran for bypass

times exceeding 4 hours did not demonstrate blood gas change indications of compromised or deteriorating performance. Two centers were able to document a 15% to 18% reduction in FiO₂ requirements to achieve blood oxygenation levels comparable to those of their standard oxygenator (Tables 4 and 5).

Three patients at one center were on bypass longer than 4 hours. PaO₂ values averaged 209 mmHg (range 135-385 mmHg) with an average FiO₂ setting of only .41 (range .21-.68). Patient temperatures averaged 33.1°C. Post-bypass plasma hemoglobin levels, measured and averaged at three centers, were 67.1 mg/dl, 48.0 mg/dl, and 40.4 mg/dl (Table 6). Average post-bypass platelet counts from the same centers were 134,000, 91,000, and 191,000.

Discussion

The clinical data for the modified oxygenator was consistent with data collected from in-vitro testing completed before the evaluation began. When comparing the performance of the modified oxygenator to the current Sarns oxygenator or other devices used at the trial centers, investigators observed either higher PaO₂ values or lower FiO₂ requirements with the Sarns modified oxygenator.

One purpose of the evaluation was to examine oxygenator performance under conditions that might "stress" the gas transfer ability of a microporous membrane oxygenator. Membrane oxygenators with small surface areas are often perceived to be "underpowered" in support of the large body weight patient or of the patient whose bypass time will be extended. The use of normothermic perfusion can compound these difficulties.

	Pump Time (min)	Plasma Hemoglobin (mg/dL)		Index (gm/dL/100 L pumped)	Platelet Count (x 1000)	
		Pre-Bypass	Post-Bypass		Pre-Bypass	Post-Bypass
Center B Averages	110	9.4	67.1	11.7	239	134
Center E Averages	118	10.4	48.0	7.3	187	91
Center O Averages	121	4.2	40.4	6.0	274	191

Table 1 Perfusion Parameters for a Large Body Weight Patient with High Oxygen Demands	
Patient Weight (kg)	143
Q Blood (L/min)	6.3
Cardiac Index (L/min/m ²)	2.37
Q Gas (L/min)	7.5
O ₂ :Q _b Ratio	1.2:1.0
FiO ₂ (%)	85
Patient Temperature (°C)	36.5
Pump Time (min)	92
PaO ₂ (mmHg)	235
apH	7.38
Paco ₂ (mmHg)	41
PvO ₂ (mmHg)	32
ypH	7.33
PvCO ₂ (mmHg)	49
VSAT (%)	61

Large Body Weight Patients

Upon evaluation of bypass data for 10 large body weight patients (Group I), all of the indices used to assess gas transfer performance were within acceptable limits (Table 3). FiO₂ settings for Group I patients never exceeded .85, even when the oxygen requirement was as high as 396 ml/min (one patient). Data for that patient are summarized in Appendix A.

The observed FiO₂ reserve was due, in part, to a mixed venous oxygen saturation that never dropped below .61. Such reserve is indicative of diligence on the part of the anesthesiologist, and the ability of the perfusionist to optimize O₂ delivery by keeping the cardiac index high and hemodilution to a minimum.

Extended Bypass

For three cases at one center (Group II) the time on bypass exceeded 4 hours. A primary concern when a microporous membrane is used during long procedures is that moisture accumulation in the gas path will cause "wetting out," (12,13) which results from water vapor transfer across the membrane and is a function of time and temperature. Because oxygen diffuses less efficiently through water than does carbon dioxide, slight water accumulation will result in decreased oxygen transfer. Progressive accumulation of moisture in the gas path (inside the fibers) could also lead to a gradual maldistribution of gas flow through the fibers, or eventually to "bridging" of the membrane pores that allows penetration of plasma through the pores. "Wetting" reduces the functional membrane surface area and reduces CO₂ transfer as well. Normothermia can exacerbate this phenomenon. Because the micropores of the

Table 1 Perfusion Record Data from an Extended Normothermic Case					
Elapsed Time (min)	13	53	110	186	237
Patient Temperature (°C)	37.0	37.0	37.0	37.0	37.0
Q Blood (L/min)	4.0	4.3	4.5	4.5	5.0
Q Gas (L/min)	3.0	2.3	1.8	3.2	2.5
FiO ₂ (%)	47.0	47.0	45.0	44.0	43.0
Hemoglobin (gm/dL)	7.2	7.4	7.3	7.4	7.3
SeO ₂ (%)	99	99	99	99	99
PaO ₂ (mmHg)	385	256	195	173	140
apH	7.39	7.34	7.37	7.41	7.40
Paco ₂ (mmHg)	36	42	43	38	41
PvO ₂ (mmHg)	58	38	43	36	38
ypH	7.34	7.33	7.32	7.39	7.37
PvCO ₂ (mmHg)	42	47	51	43	46
PvO ₂ (%)	68	68	74	70	70

Table 2 Predicted vs. Actual Oxygen Transfer for an Extended Normothermic Case					
Elapsed Time (min)	13	53	110	186	237
Actual PaO ₂ (mmHg)	385	256	195	173	140
Predicted PaO ₂ (mmHg)	244	166	154	149	135
Actual SeO ₂ (%)	99	99	99	99	99
Predicted SeO ₂ (%)	99.7	99.2	99.1	99.1	98.8
Clinical VO ₂ (ml/min)	83	168	136	160	159
Calculated VO ₂ (ml/min)	72	154	120	154	158

Table 3 Predicted vs. Actual Carbon Dioxide Transfer for an Extended Normothermic Case					
Elapsed Time (min)	13	53	110	186	237
Actual Paco ₂ (mmHg)	36	42	43	38	41
Predicted Paco ₂ (%)	35.5	41.6	46.2	36.7	40.9
Clinical VCO ₂ (ml/min)	137	145	198	156	164
Calculated VCO ₂ (ml/min)	148	153	132	186	167

new membrane are more uniform and the new membrane is thicker (50 microns as opposed to 25 in the material formerly used), the modified oxygenator is thought to be less susceptible to "wetting."

Evaluation of the data for long pump cases (Group II) revealed a marked FiO₂ reserve, while blood gas values were maintained within desirable ranges. The average PaO₂ was 209 mmHg, and the average FiO₂ was .41.

One normothermic case was evaluated further to assess performance over time (Appendix B). The analysis used equations developed by Mockros and Leonard (6) that correlate the membrane design criteria to performance outcomes. The conditions of bypass recorded in the perfusion record (Appendix B, Table 1) were inserted into the equation to determine predicted oxygenator performance with regard to the transfer of oxygen (Appendix B, Table 2) and carbon dioxide (Appendix B, Table 3). The correlation between actual and predicted gas transfer, even after 237 minutes, suggests that significant

deterioration of oxygenator performance over time was not observed.

FiO₂ Reserve

If FiO₂ must be run at 1.0 to keep the PaO₂ within acceptable limits, there is no reserve in the event that oxygen delivery mechanisms are compromised or oxygen demands increase. We examined perfusion and blood gas data from two centers D and E (Group III) to compare the average FiO₂ at termination of bypass with the average FiO₂ setting for each case. To maintain an average termination PaO₂ of 200 mmHg, perfusionists at both centers had an average FiO₂ requirement of .60.

Original vs. Modified Oxygenator Performance

At two centers (D and E), average end-of-bypass FiO₂ values for the original and modified oxygenators were compared (Tables 4 and 5). At center D the average off-bypass FiO₂ was .23 lower for the modified oxygenator; at center E it was .13 lower. There was essentially no difference between the standard oxygenator and the modified oxygenator with respect to gas flow requirements.

Blood Handling

During the course of the evaluation, investigators experienced no problems in maintaining hemodynamics while supporting the metabolic needs of their patients. There were no unusual findings in the parameters used to assess blood handling.

We attempted to index the rise in plasma hemoglobin for each case by factoring in the total volume of blood pumped during bypass (elapsed time x average blood flow). The resulting value reflects the gm/dl increase in plasma hemoglobin per 100 L of blood pumped. Platelet count (as measured at centers B, E, G) decreased by an average 42%.

The great variability noted in plasma hemoglobin measurements could be attributed to a number of differences in equipment and technique at the three centers. In center B a roller pump and a flexible venous reservoir are standard equipment. A centrifugal pump and a flexible venous reservoir are used at center E. Perfusionists at center G use a roller pump and a stand-alone hard shell venous reservoir with an integral cardiotomy filter. Arterial filters are used routinely in all three centers. Differences in volume management, cardiotomy suction, red cell transfusion, and surgical procedures can affect plasma hemoglobin levels. The protocols used for sampling and analyzing plasma hemoglobin may also have contributed to the reported differences.

Conclusions

The modified Sarns membrane oxygenator offered consistent and reliable gas exchange. Enhanced oxygen transfer,

as demonstrated by higher PaO₂ values or lower FiO₂ requirements, was observed by all of the investigators who evaluated the modified oxygenator. FiO₂ settings for large body weight patients never exceeded .85, even in the case of one patient with an oxygen requirement of 396 mL/min. From the data accumulated from long pump cases, there was a marked FiO₂ reserve, while blood gas values remained within desirable ranges. There was no clinically observable deterioration of oxygenator performance over time, as demonstrated by one case in which bypass lasted for 237 minutes. The average end-of-bypass FiO₂ was .13 - .23 lower for the modified oxygenator as compared to its predecessor.

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