Clinical Evaluation of a Microporous Hollow-fiber Membrane Oxygenator with Large Gas Transfer Capability

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Abstract

A capillary tube membrane oxygenator composed of microporous hollow fibers has been evaluated in 400 cases of cardiac surgery. The available membrane area in this device is 5.4 M^2. The priming volume of the oxygenator and an integral heat exchanger is 700 ml. The perfusions were conducted with moderate hypothermia and hemodilution. Arterial pO_2 was controlled by appropriate adjustment of the FiO_2. The pCO_2 was controlled by changing the gas flow. The duration of perfusion was up to 476 minutes at blood flow rates of 2.0 to 6.7 L/min. Oxygen transfer was as high as 352 ml/min. The mean arterial pO_2 was 281 mm Hg and the pCO_2 38 mm Hg. Platelet count did not change significantly during perfusion.

This device has proven to provide good gas exchange for nearly eight hours in this series. Two units developed small leaks of blood into the gas phase of the device. These leaks did not affect gas exchange. This oxygenator-heat exchanger unit has proven to be simple to prime, easy to operate, provide adequate gas exchange for all adults and safe for cardiac surgery.

Introduction

Various patterns of membrane oxygenators have been developed for extracorporeal respiration. These devices have been limited in gas exchange by their design and by the nature of the membranes. With the advent of microporous membranes, the oxgenators could be built with smaller membrane surface areas and smaller blood priming volumes, which made them practical for routine use in open heart surgery.[1] These microporous membrane oxygenators have utilized a film of blood between two layers of membrane, with features to assure rapid change of the blood at the surface of the membrane to increase the efficiency of gas exchange[2].

Hollow fiber membrane oxygenators have been devised with the intention of increasing the membrane surface area while keeping the priming volume of the devices within practical limits. Previous oxygenators using silicone capillary tubes have had successful clinical application in heart surgery.[3] With the advent of microporous capillary tubes the area of capillary membrane and the priming volume of the device have been reduced substantially, making small compact oxygenators capable of sufficient gas exchange for all clinical requirements.[4,5,6]

This is a report of the clinical use of the largest Capiox II[a] capillary membrane oxygenator in 400 cardiac surgery cases.

Materials and Methods

This capillary membrane oxygenator is composed of a rigid cylindrical housing 42 cm long and 14 cm in diameter, with a blood inlet port at one end and blood outlet port at the other end (Fig. 1). There are 62,000 hollow fibers of microporous polypropylene, with a membrane area of 5.4 M^2, embedded into polyurethane end plates. Each fiber is 200 microns in diameter, with a wall thickness of 23 microns. The membrane pores average 700 Å in diameter, with a density of 50%. Blood flows through these capillaries in a parallel fashion and

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a. Terumo Corp., Piscataway, NJ 08854

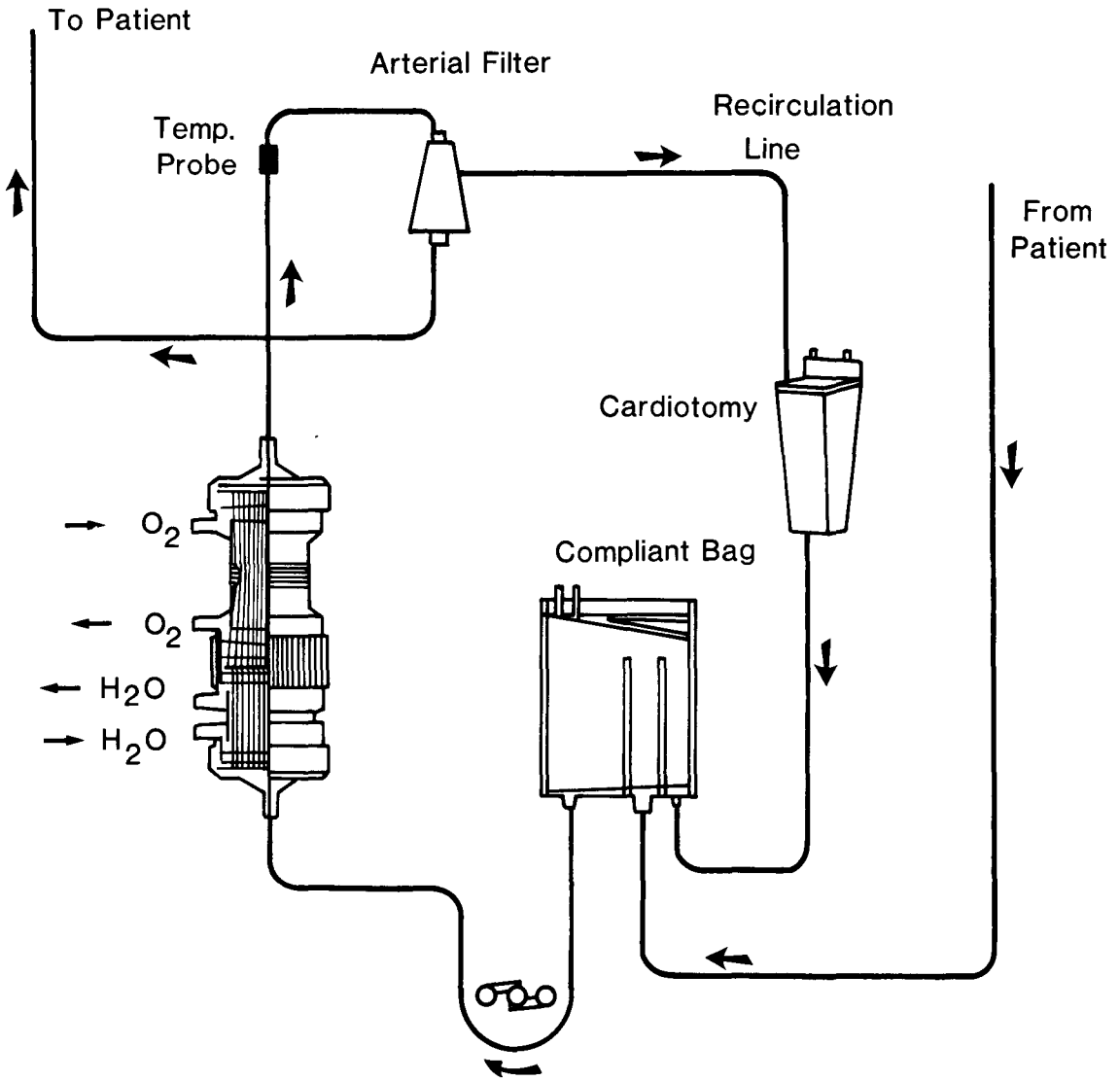

Figure 1.

FIGURE 1. Venous blood from the patient drains into a venous reservoir bag, from which it is pumped through the oxygenator to the patient.

the ventilating gas surrounds the capillaries, flowing countercurrent to the blood in the capillaries. There is an integral heat exchanger built into the venous end of the oxygenator housing. The priming volume of the oxygenator-heat exchanger unit is 700 ml.

The pump-oxygenator circuit in these perfusions consisted of a Terumo venous reservoir,[a] an Intersept filtered cardiotomy reservoir[b], a Stöckert arterial pump,[c] the oxygenator-heat exchanger unit, and an Intersept arterial filter [b] (Fig 1). The total priming volume of the whole system was approximately 2.5 L, including a 500 ml reserve in the cardiotomy reservoir. The prime consisted of 2,000 ml Plasmalytle-A, 500 ml 5% Albuminate, 10,000 u heparin, 50 meq sodium bicarbonate, and 20 ml 50% glucose.

Moderate hypothermia and hemodilution were employed in these 400 perfusions. Venous drainage was through cannulae in the superior and inferior vena cavae. Arterial return was into the ascending aorta. Total perfusion was achieved by occluding the superior and inferior vena cavae

b. Extracorporeal, Inc., King of Prussia, PA 19406
c. Cobe Laboratories, Lakewood, CO 80215

around the venous drainage cannulae. When the cardiac procedure was completed the vena cavae were released to allow free flow of blood into the right atrium and institution of partial perfusion, usually before the patient's temperature had returned to normal. The blood gas analyses reported were performed every 30 minutes during total perfusion. The blood gas determinations were not corrected for temperature (Table 1).

TABLE 1
Blood Gas Values in 400 Patients Who Underwent Perfusion for Cardiac Surgery

	Mean ± S.D.	Range	N
Arterial PO_2 (mm Hg)	281 ± 88	73-600	835
Arterial PCO_2 (mm Hg)	38 ± 5	17-57	835
Arterial Saturation (%)	99.7 ± 0.5	94-100	835
Venous Saturation (%)	74.2 ± 7.6	30-99	835
O_2 Transfer (ml/min)	103 ± 42	1-352	835
Arterial pH	7.41 ± 0.04	7.1-7.59	835

During these perfusions the ventilating gas was a mixture of air and oxygen. A Sechrist gas blender[d] was used to adjust the percent O_2 in the ventilating gas and thus to control the oxygen tension of the arterial blood. The rate of gas flow was adjusted to control the carbon dioxide tension of the arterial blood. Blood pressure at the inlet and at the outlet of the oxygenator-heat exchanger device were measured with strain gauges. Plasma hemoglobin was measured immediately after the start of the perfusion, when the prime and the patient's blood had been mixed, and again at the conclusion of total perfusion. Platelets were also counted at the beginning and at the end of total perfusion. Plasma hemoglobin and platelets were measured in only the first 20 patients due to cost limitations.

TABLE 2
Data on 400 Patients Who Underwent Perfusion for Cardiac Surgery

	Mean	Range
Age (yrs)	60	13-82
Weight (Kg)	76.7	36-120
Body Surface (m^2)	1.9	1.27-2.48

d. Sechrist Industries, Anaheim, CA 91802

The patients were between 13 and 82 years of age, and weighed between 36 and 120 kilograms. The largest had a body surface area of 2.48 M^2 (Table 2).

Results

The oxygenator performed satisfactorily for perfusions of up to 476 minutes in this series, with perfusion flow rates of 2.0 to 6.7 L/min (Table 3). The blood pressure at the inlet port of the oxygenator ranged between 125 and 375 mm Hg, with a mean of 256 mm Hg. The pressure at the outlet ranged between 65 and 235 mm Hg, with a mean of 157 mm Hg. Therefore, the mean drop in pressure across the oxygenator was 99 mm Hg.

TABLE 3
Perfusion Parameters in 400 Patients Who Underwent Perfusion for Cardiac Surgery

	Mean ± S.D.	Range	N
Perfusion Time (min)	99.3 ± 54	11-476	400
Perfusion Flow (L/min)	4.16 ± 0.7	2.0-6.7	835
HCT (%)	21.5 ± 4	10-39	835
Perfusate Temperature (^oC)	30.5 ± 4.2	15-39	835
Gas Flow (L/min)	2.39 ± 1.0	0.5-8.0	835
FIO_2	0.617 ± .1	0.4-1.0	835
Oxygenator Inlet Pressure (mm Hg)	256 ± 48		77
Oxygenator Outlet Pressure (mm Hg)	157 ± 37		77

The maximal oxygen transfer during this study was 352 ml/min (Table 1). The average arterial PO_2 was 283 mm Hg and the average arterial PCO_2 was 38 mm Hg.

The platelet count did not change significantly, being a mean of 110.2×10^3 at the end of perfusion. The plasma hemoglobin increased significantly, being 34 mgm percent at the end of perfusion ($p = 0.002$) (Table 4).

TABLE 4
Platelet Count and Plasma Hemoglobin in Perfusions for Cardiac Surgery

	Mean ± S.D.	Range	N
Platelet Count ($x10^3/mm^3$)			
Beginning of Perfusion	109 ± 30	59-102	20
End of Perfusion	110 ± 39	50-226	20
Plasma Hemoglobin (mgm %)			
Beginning of Perfusion	23 ± 10	1-46	27
End of Perfusion	34 ± 14	16-52	23

Discussion

The employment of hollow fibers has provided a large membrane surface area relative to the volume of blood prime. The semipermeable fiber has reduced the required membrane surface compared with silicone fibers and has increased the efficiency of the oxygenator.

Although the blood was pumped from the venous reservoir through the oxygenator, the pressure required to overcome resistance in the blood pathways was not excessive, the maximum pressure proximal to the oxygenator being 375 mm Hg at 5.7 L/min flow. Most of this pressure was required to sustain the patient's arterial pressure and to overcome resistance in the 7.8 mm Argyle aortic cannula.

Flushing the oxygenator and perfusion circuit with CO_2 prior to priming and filling the vertically mounted oxygenator from below, together with recirculation through an effective filter have made initiation of perfusion free of difficulty. Slow recirculation is continued until the start of perfusion and after the end of perfusion to prevent the possibility of stagnation of blood and fibrin formation in the capillary tubes. There is virtually no pressure exerted by the gas surrounding the capillary tubes due to the low gas flow and large exit port.

The 5.4 M^2 oxygenator used in these perfusions is the largest microporous hollow fiber unit available and has gas exchange capability for the largest patients at normothermia. Smaller similar oxygenators with 1.6 M^2, 3.3 M^2, and 4.3 M^2 of membrane have also been manufactured. No malfunction sufficient to change the device during a perfusion was noted in this series, though two units developed small blood leaks into the gas compartment. These leaks did not impair the function of the oxygenator. The oxygenator showed no detectable deterioration of gas exchange during perfusions of nearly eight hours' duration in this experience.

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