

Early Clinical Experiences with Terumo's New Hollow Fiber Membrane Oxygenator: Capiox II

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Abstract

Terumo's Capiox II is a hollow fiber membrane oxygenator with an integrated heat exchanger. This device is available in 1.6 m², 3.3 m², 4.3 m², and 5.4 m² sizes. Our clinical experiences have been with the 3.3 m², 4.3 m², and 5.4 m² sizes, in over 150 open-heart patients. The 3.3 m² was sized to patients up to 60 kg. The 5.4 m² was used in all patients >60 kg. Both normothermic and hypothermic (24°–30° bladder) perfusions were performed. The heat exchanger was efficient and demonstrated structural integrity. On bypass, patient vital signs, gas and blood flows, arterial and venous blood gases and blood chemistries were monitored. Arterial saturations were 100%. Venous saturations were at least 65%. No acid-base problems were encountered. Initially, 100% oxygen was used. Later a gas blender using O₂ and compressed air was utilized. Our experience concludes that the Capiox II is a safe, efficient one-pump membrane oxygenator with integral heat exchanger. It is easy to set up and recirculate, delivering satisfactory oxygen transfer rates with a blended gas to blood flow ratio (≤1:1).

Introduction

The Capiox II^a is a second generation capillary oxygenator and is the result of continued devel-

opments in hollow fiber technology by the Terumo Corporation of Japan. Initially, this hollow fiber oxygenator had no heat exchanger but was successfully used in Japan.^{1,2,3} After successful animal experimentation following the A.A.M.I. protocol,^{4,5,6} a clinical trial was performed.⁷ To make the oxygenating device more functional, a heat exchanger was incorporated. This second generation became the Capiox II.

Methods and Materials

The Capiox II is a cylindrically shaped membrane oxygenator utilizing a bundle of microporous polypropylene hollow fibers oriented vertically as the oxygenating medium. Incorporated at one end of the device is a heat exchanger.

The hollow fibers have an inside diameter of 200 micrometers with a 700 angstrom pore size and an effective length of 130 to 140 mm. These fibers are secured at either end in a polyurethane potting material and constricted in the middle. This design evenly distributes and diffuses the oxygenating gas in and around the fibers without channeling or shunting. It is through the micropores of the fiber that blood oxygenation and carbon dioxide removal take place. Also, the micropores facilitate the removal of water vapor which will adhere to the inside surface of the casing and not affect the oxygenation of the device.

The integral heat exchanger is made of vertically oriented stainless steel tubes 70 mm long with an internal diameter of 1.45 mm. The effective area is 800 cm² and 1,630 cm², in the Capiox

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Presented at AmSECT's 21st International conference, New Orleans, LA, April 10–13, 1983.

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1.6 m² and 5.4 m², respectively. The heat exchanger is pressure tested to 42 PSI.

The external housing of the Capiox II is a clear acrylonitrile and styrene co-polymer. One half-inch inlet and outlet blood ports are located at the ends of the device with one half-inch gas ports on the lateral surface of the plastic housing for oxygenation. One half-inch ports are located on the same lateral surface side for the water source for the heat exchanger. It is ethylene oxide sterilized and disposable. Currently, the Capiox II comes in four sizes: 1.6 m², 3.3 m², 4.3 m², 5.4 m² (Figure 1), with effective membrane surface area being a result of the number of fibers. The 1.6 m² has 20,000 hollow fibers, the 3.3 m² has 38,000 hollow fibers, the 4.3 m² has 53,000 hollow fibers, and the 5.4 m² has 62,000 hollow fibers. The patient size, flow rates, and other Capiox II specifications are shown in Table I.

Perfusion Circuit

The perfusion circuit (Figure 2) consists of a 950-ml collapsible Capiox venous reservoir, a Harvey H-700 cardiotomy with integral microaggregate filter,^b a Sarns roller pump,^c Capiox II, and an extracorporeal 20-micron arterial line filter^d. Currently, the custom tubing pack is manufactured by Texas Medical Products^e using Tygon^f tubing and Cobe^g connectors. Prior to priming, the entire system is CO₂ flushed, ensuring rapid, easy debubbling and recirculation.^{8,9} The total priming volume of the extracorporeal circuit is 1,700 cc for the 3.3 m² Capiox to 2,200 cc for the 5.4 m² Capiox. The prime is Plasma-Lyte A[®] electrolyte solution^h heparinized with 2,500 units/liter of porcine mucosal heparin. The water source for the heat exchanger was initially the Sarns heater/cooler which evolved to the in-house water system.¹⁰

The blood-flow rates are established based on the patient's body surface area calculated by the

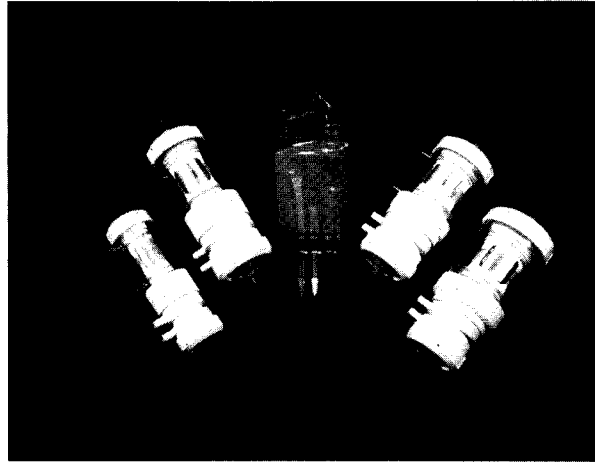


FIGURE 1. Shown left to right: 1.6 m², 3.3 m², Capiox reservoir bag, 4.3 m² and 5.4 m² Capiox II units.

Dubois nomogram. Blood flow is maintained at a minimum of 2 L/m²/min., and the oxygenating gas flow varies depending upon arterial and venous blood gases.

Initially, high gas flows of 100% oxygen, at 5–10 liters per minute, were used and then adjusted accordingly to blood gas samples. This usually resulted in a ratio of 1:1 gas-to-blood flow or less. Because of the high efficiency, arterial PO₂'s were greater than 300 mmHg. To gain better PO₂ control, room air or compressed gas was titrated with the 100% oxygen. This technique was further refined by using a Bird blender.ⁱ This resulted in physiologic PO₂'s while maintaining proper PCO₂ levels.

Patient Cannulation and Selection

In our early clinical experience, consenting elective revascularization patients with good ventricular function were selected. Reoperation, valve replacement, congenital anomalies or aneurysmectomies were not included. The patients were adequately heparinized represented by an Activated Clotting Time (A.C.T.) of 480 seconds. Preop blood samples were drawn for platelets, CBC's, plasma hemoglobin, serum electrolytes, and blood gases.

The patients routinely had a 26 Fr. aortic cannula inserted in the ascending aorta. Venous cannulation consisted of either a single two-stage 46–34 Fr. atrial cannula or bicaval cannulation with a

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^c Sarns, Inc., Ann Arbor, MI 48103

^d Extracorporeal Medical Specialties, Inc., King of Prussia, PA 19408

^e Texas Medical Products, Inc., Houston, TX 77099

^f Tygon, Norton Health Care Products, P.O. Box 350, Akron, OH 44309

^g Cobe Laboratories, Lakewood, CO 80215

^h Travenol Laboratories, Deerfield, IL 60015

ⁱ Bird Corporation, Palm Springs, CA 92263

TABLE 1

SUMMARY OF CAPIOX II SPECIFICATIONS

Description/Size		1.6m ²	3.3m ²	4.3m ²	5.4m ²
Oxygenator	Effective Membrane Area (m ²)	1.6m ²	3.3m ²	4.3m ²	5.4m ²
	Number of Fibers (pcs)	20,000	38,000	53,000	62,000
	Effective Length of Fibers (mm)	130	140	140	140
Heat Exchanger	Number of Pipes in Heat Ex. (pcs)	253	511	511	511
	Effective Length of Pipes (mm)	70	70	70	70
	Effective Area (cm ²)	800	1,630	1,630	1,630
Patient Weight (kg)		< 20	< 60	< 95	> 95
Max. Rated Blood Flow (l/min)		2.0	4.0	5.2	6.5
Priming Volume (ml)		200	420	550	700
Weight (grams)		800	1,350	1,500	1,750
Blood In/Out Port Dia. (in.)		3/8	1/2	1/2	1/2
Gas In/Out Port Dia. (in.)		1/2	1/2	1/2	1/2
Sterilization Method (gas)		E.O.	E.O.	E.O.	E.O.
Suggested, Appx. Cost (\$)		329	339	359	379

32 Fr. and 36 Fr. cannula inserted into the superior and inferior vena cava, respectively. Left ventricular decompression was accomplished with either an atrial vent, left atrial ventricular vent or a large needle vent in the aorta. Pericardial suction was used in all procedures. Cold potassium cardioplegia solution was infused through the aorta, and a cold topical solution was also administered. Perfusions were performed using either systemic hypothermia (24–30°C bladder) or normothermia.

While on bypass, perfusion pressures were maintained between 40 to 80 mmHg at a minimum of 2 L/m²/min blood-flow rate. The following parameters were monitored: mean arterial pressure (MAP); central venous pressure (CVP); gas-to-blood flow ratio; arterial filter gradient; transmembrane pressure; patient temperature at nasopha-

ryngeal, rectal or bladder; arterial and venous blood gases; hematocrit; serum electrolytes; and ACTs. Upon termination of bypass protamine was administered and the patient decannulated. The remaining perfusate was then collected in CPD blood bags and made available for reinfusion. Postoperatively, the following data was obtained: total blood loss; free serum hemoglobin; platelet count; and on the 7th day, hemoglobin, hematocrit, and platelet count.

Discussion

The Capiox II has proven itself to be a reliable and efficient oxygenator with integral heat exchanger. Because of its proven performance, the device is standard equipment in one of our seven operating rooms. It is apparent that the Capiox II is very efficient in its ability to oxygenate and remove CO₂. This was especially noticed when small patients (60–70 kg) were perfused using the 5.4 m² Capiox II. It was not uncommon to see arterial PO₂'s greater than 350 mmHg. This ability to over-oxygenate is the impetus to pursue a more physiologic technique in PO₂ control. This was accomplished using a blended gas source such as a Bird blender. Our recent experiences have been with the Bird blender and there is no problem in acid-base balance. Arterial saturations are 100% and venous saturations greater than 65%, with FIO₂ ranging between 70% and 100% at a 1:1 gas-to-blood flow ratio or less.

The Capiox II comes in four sizes. At the time of this writing we had just begun to study the 1.6 m² Capiox in the animal facility for its feasibility in our pediatric service. Our clinical experience is therefore with the 3.3 m², 4.3 m², and 5.4 m² (Figure 1). The devices are patient-sized. Our clinical experience demonstrates that the 3.3 Capiox is at its optimal effectiveness at approximately 60 kg., although we have found it performed satisfactorily in 70-kg patients. The authors caution that this device be operated within the recommended patient sizes. At the other extreme the Capiox 5.4 m² unit, rated for patients >95 kg, is a very dependable device. The largest patient supported was 143 kg, with a 1:1 gas-to-blood flow and an FIO₂ of 90% to 100%; the pH was maintained at 7.4, PO₂'s ranged from 106 to 142 mmHg, the PCO₂ was 39 to 41, the hematocrit was 31%.

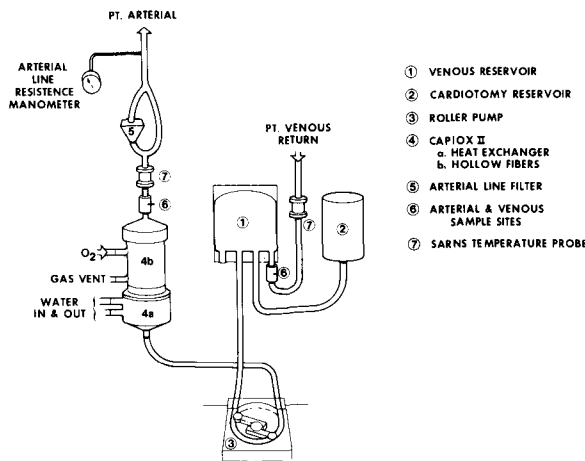


FIGURE 2. Extracorporeal circuit for Capiox II Oxygenator.

The newest member of the Capiox family is the 4.3 m² unit. The primary purpose of this device is to oxygenate patients in the range of 60 to 95 kg.

The Capiox II is designed to transfer 185 to 300 ml/min of oxygen and 190 to 310 ml/min of carbon dioxide at maximum blood flow rates with inlet saturations of 65% and hemoglobins of 12 gm/dl, in the 3.3 m² unit and the 5.4 m² unit, respectively.

In reviewing 13 patients using the 3.3 m², blood flow was 4 L/min. The O₂ transfer rate was 104.81 ± 23.7 ml/min with a 8.07 ± 1.0 gm/dl hemoglobin and venous O₂ sats of 83.3 ± 5.4%. In the 5.4 m² series, 24 patients were reviewed,⁷ and O₂ transfer rates were 105.0 ± 34.7 ml/min at an 8.0 ± 0.9 gm/dl hemoglobin and venous oxygen saturation of 87.5% ± 5.6%. Arterial saturations were 100%. The arterial PO₂'s were greater than 150 mmHg. Venous saturations were greater than 80%.

In early evaluations, transmembrane gradients were monitored. Our experience demonstrated the gradient across the Capiox II 3.3 m² to 5.4 m² to be 80 mmHg to 140 mmHg when at the patient's calculated flow of 2 L/m²/min. The hollow fibers and their noncompliant laminar blood flow exhibit a smooth blood flow. In early blood studies with the 3.3 m² device, platelet counts decreased from a preoperative value of 241 mm³ ± 97 mm³ to 153 mm³ ± 40.4 mm³ immediately postop. No post-operative hemostasis problems resulted.

The heat exchanger has an effective surface area of 1,630 cm². There were many variables involved with heat exchanger evaluation, such as: patient uniformity, patient anesthetic levels, metabolic activity, accuracy of temperature sites, and consistent water source temperatures. No accurate heat exchanger study has been initiated. However, in our clinical experience using both the Sarns heater/cooler and the Cleveland Clinic in-house blood conditioning unit,¹⁰ the heating and cooling rates seemed very efficient with an immediate patient response. Generally speaking, we were able to cool the patients to 28°C bladder in approximately 8 to 10 minutes and rewarm the patient from 28°C bladder in 12 to 20 minutes. The heat exchanger had no detectable leaks.

Although the hollow fibers exhibit uniform blood flow, they also possess the ability to allow oxygen to pass across them and become micro-

bubbles in the blood side. This situation develops if the gas side pressure becomes greater than the blood side pressure. To avoid this potentially dangerous situation, several guidelines must be established. First, the Capiox II must always be lower than the liquid level in the reservoir. There must always be this positive hydrostatic pressure on the blood side of the fibers. Failure to maintain this will allow the gas side to become the positive pressure side, allowing air to cross through the micropores of the fibers and enter the blood side as microbubbles. Secondly, the gas outlet port must always remain open. If the gas outlet port is inadvertently closed, gas pressure will immediately increase. This situation will also create microbubbles in the blood. Thirdly, the Capiox II must be positioned between the pump and the patient, as illustrated in Figure 2. With patient safety being of paramount importance, it is recommended that an arterial line filter be used, especially during the initial exposure to the Capiox II.

The Capiox II is a new approach to an old problem, that is, a more physiologic extracorporeal oxygenating device. The microporous hollow fibers provide the blood with a uniform, noncompliant, nonaugmented laminar flow. Its heat exchanger demonstrates efficiency and structural integrity. By virtue of design, it is capable of performing on the smallest to the very largest surgical candidate. The Capiox II affords a compact, straightforward one-pump extracorporeal membrane.

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