An Experimental Evaluation of the Capiox 1.6 and 5.4M² Membrane Oxygenators for Air Removal Efficiency in the Conventional and Inverted Positions

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Abstract

Membrane oxygenators do not create bubbles but most will transmit the bubbles which are common in venous reservoir bags. We previously reported the elimination of arterial micro-air in the $0.8m^2$ Capiox when operated in the inverted position with an open purge line. This same lung failed to eliminate micro-air when operated in the conventional orientation.

The purpose of this study was to test the effectiveness of the Capiox as a bubble trap in lungs with a larger surface area (subgroup a-$1.6m^2$) (subgroup b-$5.4m^2$) and at higher flows.

Two test circuits were constructed for each size lung (Group 1—conventional orientation) (Group II—inverted). The circuits were primed with dilute, outdated human blood (Hct. 20 ± 2%). Ten injections of air (5ml) were done for each lung in both test positions. A bubble counter on the outlet side of the lung was used to count bubbles passed through the membrane oxygenator following the air challenge.

Thirty second counts were significantly higher ($p<.001$) in Group I than in Group II for both size lungs. The counts for both groups were:

Group I (a/b)	*Group II-inverted (a/b)*	*Size*
39.4±20.2/30.7±7.8	0.6±0.96/2.0±1.3	(21-30μ),
23.6±11.6/19.6±7.93	0.22±0.6/0.2±0.6	(31-40μ),
18.8±9.13/13.4±4.03	0/0.1±0.3	(41-50μ),
14.5±7.53/21.1±2.99	0/0	(51-60μ),
10.7±6.38/10.1±3.18	0/0	(61-70μ),
8.6±3.47/7.5±3.5	0/0	(71-80μ),
7.9±3.51/5.7±2.91	0/0	(81-90μ)
17.7±14.67/50.0±4.52	0/0	(>90μ).

The inverted orientation of both the Capiox 1.6 and 5.4 m² lungs with an open purge line was superior to the conventional orientation for micro-air removal. As a bubble trap, both lungs compare favorably to an arterial filter in air handling characteristics.

(All data reported as mean ± S.D.).

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Introduction

We have previously[1] presented data which supports our view[2] that an infant (0.8 M²) Terumo Hollow Fiber Membrane Oxygenator (HFMO) can function as effectively as an arterial filter in removing micro bubbles if it is inverted and used with a purge line. Using the HFMO in this way eliminates the need for an arterial filter (and the added volume) in the infant circuit without compromising safety.

In the previous study[1] we only looked at the infant oxygenator and flows of 800 ml per minute. It was our feeling that the safety advantages of inverting the lung were partly a function of the low flows and would perhaps be lost if the flows were increased even in a larger lung. We do use HFMOs in larger children and adults and wanted to test the bubble handling characteristics of the larger lungs at higher flows.

The purpose of this study was to test the larger lungs in the inverted position and at higher flow rates to see if there was a decrease in microbubble counts at the outlet of the lung and to see if we could dem-

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onstrate the safety advantages found in our previous study.

Materials and Methods

Test circuits were constructed using commonly available components (Figures 1 and 2). The tubing was medical grade polyvinyl chloride (PVC) with a 3/8 inch inside diameter and 3/32 inch wall thickness. A standard roller pump was used[a]. A 400 ml venous reservoir bag[b] and Capiox[b] 1.6 (subgroup a) or 5.4 M^2 lung (subgroup b) were connected together with the lung positioned with the fiber bundle below the bottom of the bag.

In one series of tests (Groups Ia and Ib), the lungs were positioned in the conventional way with blood flow in the bottom and out the top (IBOT). In the second series (Groups IIa and IIb) the lungs were inverted after priming and debubbling. Blood flow through the lungs in Group II was in the top and out the bottom (ITOB). Group II oxygenators had a one-way valved purge line attached to a luer port on the inlet (upper) end of the lung, which line was open and emptied into a cardiotomy reservoir. (There were ten experiments done in each subgroup.)

Six inches distal to the outlet of the lung there was a probe from the Hatteland BD-100 microbubble detector[c]. Three feet distal to the arterial outlet of the lung there was a purged arterial filter[d] which was part of the "air evacuation system" we used to decrease the possibility of recirculation and recounting of bubbles. Distal to the arterial filter was a filtered cardiotomy reservoir,[e] the same one into which the filter and lung purge lines (in Group II) were drained. Blood drained from the cardiotomy reservoir into the venous reservoir bag.

The priming solution was Plasmalyte A[f] and outdated human blood. The hematocrit was maintained at 20 ± 2%. The circuit volume was kept at room temperature and no attempts were made to regulate the temperature.

The blood flow was 1600 ml per minute for the 1.6 M^2 lungs (group a) and 5000 ml per minute for the 5.4 M^2 lungs (group b). Line resistance was measured and kept constant at about 175 mmHg using a tubing clamp partially occluding the arterial line distal to the arterial filter.

a Cobe Laboratories, Lakewood, CO 80215
b Terumo Corp., Piscataway, NJ 08854
c Hatteland Instrumentering, Oslo, Norway
d Pall EC3840, Pall Biomedical Products Corp., Glen Cove, NY 11542
e BCR 3500, Bentley Labs, Irvine, CA 92714
f Travenol Labs, Deerfield, IL 60015

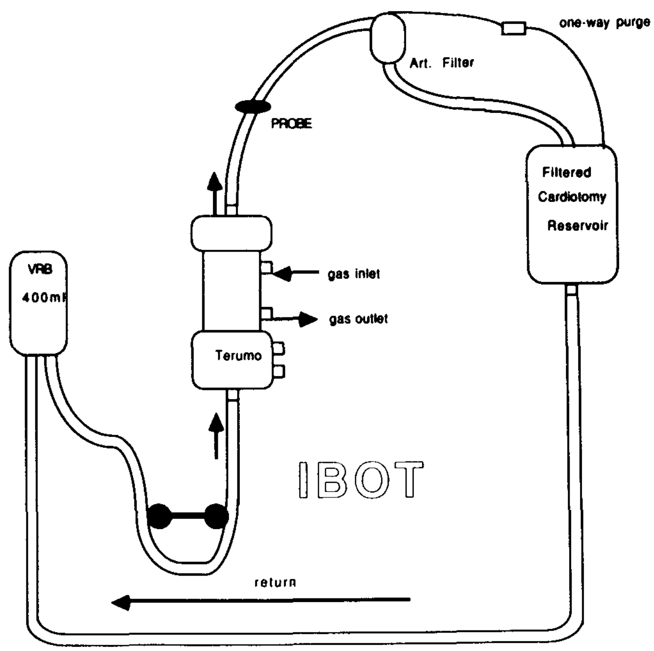

Figure 1: Circuit for Group I lungs-conventional orientation. Blood flow "In the Bottom/Out the Top" (IBOT).

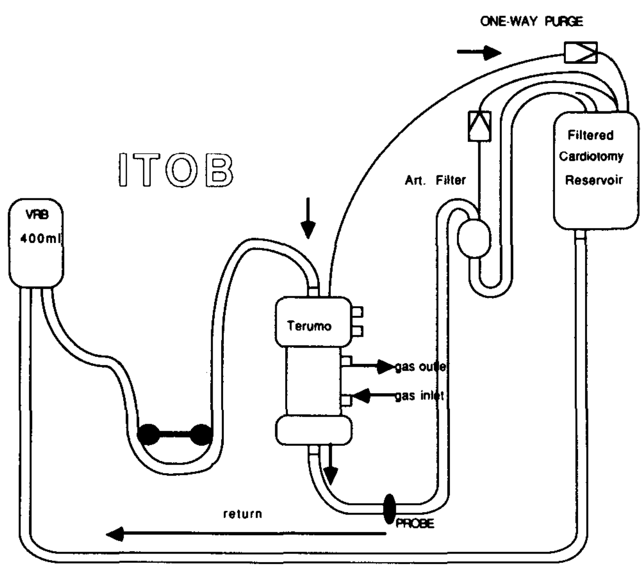

Figure 2: Circuit for Group II lungs-inverted with open purge. Blood flow "In the Top/Out the Bottom" (ITOB).

The Hatteland bubble counter has a sample time of thirty seconds. Due to the short sample time, the large volume in the circuit (approximately 2000 ml), and the "air evacuation system," we are certain, and the bubble count profiles (decay in counts with time) confirmed, that we were not recounting bubbles.

Air was introduced into the circuit from a 6 ml syringe and a 25 gauge needle stuck through the wall and into the lumen of the PVC tubing on the negative side of the roller pump. Five mls of air were injected into the circuit over a period of 2 seconds. After each 30 second counting period, the lung was subjected to recirculation with vacuum applied to the gas phase until bubble counts were zero for at least one minute before a new test was begun.[1,3]

Statistical analysis was performed on a Macintosh™ Computer[g] using the Statworks™ statistical package[h]. The test of significance was the T test.

Results

Bubble counts (per 30 second period) were separated into size ranges and the groups were compared (Tables 1 and 2). All values are reported as mean ± standard deviation. There was a statistically significant difference between groups in all bubble sizes (p values <.001).

Discussion

There has been an insufficient amount of concern about micro-air in cardiopulmonary bypass circuits. The fact that many people still use bubble oxygenators is proof of this problem. Part of the dilemma relates to the amount of information about the clinical significance of micro-air. There is, however, an adequate amount of information, if one looks hard enough, to stimulate an increased effort to investigate the problem.[4,5,6] There is also an unacceptable rate of transient neurologic deficit or brain injury following cardiopulmonary bypass (CPB).[7]

We know that micro-air entering a venous reservoir bag also leaves the bag.[8] We also know that air can be harmful even in normally undetectable amounts.[4,5,6] When you put that information together with the 50–70% incidence of post CBP transient neurologic deficit or evidence of brain injury,[7] you must be concerned about eliminating all micro-air from even a membrane oxygenator circuit.

This study shows that both the Capiox 1.6 and 5.4 M^2 lungs run in the ITOB orientation act as very efficient bubble traps and are therefore much safer than when run in the traditional orientation-IBOT. It is not our purpose to argue against the use of arterial filters, except in the micro-prime ($0.8M^2$) and $1.6M^2$ circuits due to volume limitations. It is possible that an adult circuit with an inverted/purged Terumo and no filter is as safe, with regard to gross and micro-air, as a circuit with an arterial filter—but neither this nor any study we are aware of has addressed this question.

Our contention, however, is that a circuit with an inverted/purged Terumo *and* an arterial filter is probably safer than a similar circuit with the Terumo run in the conventional orientation because some micro air does pass through arterial filters.[9]

In an effort to conserve on priming volume and decrease the use of bank blood in pediatric cardiac surgery, we have now elected to use the $1.6M^2$ lung in a circuit with no arterial filter and keep the priming

Table 1.
Bubble count comparison in the Capiox™ $1.6m^2$ lung.
Note the difference in bubble counts between subgroups a and b. Subgroup a-conventional orientation (IBOT) and subgroup b-inverted (ITOB).

TERUMO 1.6
BUBBLE COUNTS/30 SECONDS
Grouped According to Size

n = 10 for both groups

	11-20μ	21-30μ	31-40μ	41-50μ	51-60μ	61-70μ	71-80μ	81-90μ	>91μ
Ia	39.4 ±20.9	39.4 ±20.0	23.6 ±11.7	18.8 ±9.1	14.5 ±7.5	10.7 ±6.4	8.6 ±3.5	7.9 ±3.5	17.7 ±14.7
IIa	5.0 ±2.9	0.6 ±0.96	0.222 ±0.6	0 ±0	0 ±0	0 ±0	0 ±0	0 ±0	0 ±0

The difference between groups is significant (p<0.001) in all bubble sizes. All values reported as mean ± S.D.

Table 2.
Bubble count comparison in the Capiox™ $5.4m^2$ lung.
Note the difference in bubble counts between subgroups a and b. Subgroup a-conventional orientation (IBOT) and subgroup b-inverted (ITOB).

TERUMO 5.4
BUBBLE COUNTS/30 SECONDS
Grouped According to Size

n = 10 for both groups

	11-20μ	21-30μ	31-40μ	41-50μ	51-60μ	61-70μ	71-80μ	81-90μ	>91μ
Ib	45.4 ±6.5	30.7 ±7.8	19.6 ±7.9	13.4 ±4.0	12.1 ±3.0	10.1 ±3.2	7.5 ±3.5	5.7 ±2.9	50.0 ±4.5
IIb	17.9 ±4.5	2.0 ±1.3	0.2 ±0.6	0.1 ±0.3	0 ±0	0 ±0	0 ±0	0 ±0	0 ±0

The difference between groups is significant (p<0.001) in all bubble sizes. All values reported as mean ± S.D.

g Mac Plus, Apple Computer Co., Cupertino, CA
h ver. 1.2, Cricket Software, Philadelphia, PA

volume down to about 450 ml in patients from 4.5 to 6 kg and 650 ml up to 10 kg. We suggest the manufacturer recommend this technique and further suggest this system for evaluation by other perfusionists.

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Questions from the Audience

Sandra Pfefferkorn, Atlanta, GA: Question: Would you please tell me how you held that thing upside down?
Answer: It was very easy Sandy, you simply turn it over in the standard Terumo holder and lock it into place.
Question: The locking mechanism works upside down?
Answer: Yes. In my experience there is no change in the gas exchange characteristics of this method and I think this has been borne out by studies at Terumo. I must tell you that just turning it upside down does not in and of itself prevent air, unless you open a purge line, you will trap large bubbles, but those large bubbles will be subjected to oncoming volume and will shatter many of them and the small bubbles will be carried out. Small bubbles of 100 microns or less have virtually no buoyancy.
Tom Gibson, Mobile, AL: Question: I have had the same questions you have posed here for the last several years and I have run the CM50, Terumo, and SciMed oxygenators upside down during that time. One observation I had was why the manufacturer, when they went for soft reserviors, had you pumping in the bottom and out the top, and then when they went over to hardshell they had you pumping in the top and out the bottom. There are no studies to support any differences with the change in the hard shell. Have you ever addressed this to the manufacturers?
Answer: No, not specifically. But I think it might be that the reservior bags in that generation of the membrane were early on and perhaps people like yourself, question manufacturers so that in subsequent generations, the development of hard shell types, there was an increased awareness of microair handling or maybe the engineers were more astute at that point. You have to wonder why they couldn't figure that out, as Dr. Harken pointed out in his film last night, that water runs down hill and air rises.
Question: You just made my point. For years I have said that the reason we get poorly designed equipment is that they let the engineers do it with very little input from the people that use them and I think if they turned this thing around a little, that they would end up with a lot better quality.
Answer: That is true in any service manufacturing industry. You need to ask for input from the customer and in my experience, I would be asked for input after the thing had been designed—they would bring a group in and say, what do you want, and they would say, this is what we have, what do you think of it and market it anyway. That's pretty typical, but I'm afraid, that sort of customer relations doesn't work in today's market.