
Is Your Oxygenator Failing? Diagnosis and Suggested Treatment

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Abstract

(*J. Extra-Corpor. Technol.* 19[3] p. 330–337 Fall 1987, 3 ref.) Oxygenator failure during open heart surgery can be a serious complication but one with which perfusionists should be prepared to deal. We hypothesize that oxygenators are often replaced unnecessarily and when they are performing within the manufacturers' specifications. This suspicion was confirmed by surveying several oxygenator manufacturers. Discriminating between oxygenator and nonoxygenator problems is critical. In the face of the correct diagnosis of oxygenator failure a simple, safe, expedient, and familiar method of replacement is needed.

By using the gas transfer equations one can determine if the oxygenator is transferring adequate gas, after other associated problems are considered and ruled out.

After oxygenator failure has been diagnosed, a plan for replacement which has previously been established and practiced should be implemented. We studied 2 techniques for hollow fiber membrane oxygenation (HFMO) replacement and found the risk of micro-air, as a result of the changeout procedure, decreased when the new oxygenator was vacuumed.

The purpose of this paper is to help identify when/if an oxygenator is failing and suggest a planned replacement drill to help minimize confusion, delay,

and possible complications. We will also present a technique for decreasing the risk of micro-air which may result from a quick oxygenator changeout.

Introduction

The diagnosis and response to oxygenator failure should be planned and well defined. Before changing an oxygenator one must be certain that the unit is at fault and there is not another mechanical or patient-related problem. This may be accomplished by the use of a checklist and oxygenator replacement drills carried out by the entire perfusion team at regular intervals. The result will be a team of perfusionists who can change an oxygenator rapidly and safely.

After surveying 5 major membrane oxygenator manufacturers, we agree that oxygenators are often changed for low PaO₂s unnecessarily.¹ When manufacturers evaluate returned "failed" oxygenators they often find the problems are not oxygenation but improper anticoagulation, improper Fraction of Inspired Oxygen (FiO₂), or small blood to gas leaks.

There are many mechanical (equipment) considerations that need to be evaluated prior to the membrane evaluation. Some of these are:

- 1) Is oxygen being delivered to the membrane?
- 2) Is the gas path obstructed?
- 3) Is the gas connected to the correct gas port?
- 4) Are FiO₂ and gas flow appropriate?

All of these equipment-related problems can cause inadequate oxygenation. Certain patient considerations should also be evaluated. Some of these are:

- 1) Is the hematocrit adequate?
- 2) What is the temperature?
- 3) Is blood flow adequate?

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4) Are anesthesia and muscle relaxant levels adequate?

Once these external factors have been evaluated, the gas transfer of the oxygenator should be calculated with use of the O₂ Transfer Equation.²

$$(\text{Arterial O}_2 \text{ content} - \text{Venous O}_2 \text{ content}) \times (10) \times (\text{Flow-LPM})$$

$$\text{Art. Content} = [(\text{Art. Sat. \%}) \times (1.34 \text{ ml O}_2) \times (\text{Hgb gm\%})] + [(\text{PaO}_2) \times (.003)]$$

$$\text{Ven. Content} = [(\text{Ven. Sat. \%}) (1.34 \text{ ml O}_2) (\text{Hgb gm\%})] + [(\text{PvO}_2) (.003)]$$

Maximum Value = 350 cc @ 6 LPM gas flow
 12 gm% hemoglobin
 normothermia
 sea level

Once inadequate gas transfer is diagnosed, the perfusionist should have a replacement strategy that is quick and safe. Our suggestion is to have a rehearsed oxygenator changeout drill. This drill will help identify the safest and most expedient method to deal with oxygenator changeout. If used regularly, this drill will develop and maintain the perfusionist's proficiency with oxygenator changeout.

Our group tested 2 techniques (unprimed and pre-primed) for HFMO changeout. Additionally, we measured the effect vacuum had on microbubble activity.

The results of this observation suggest that oxygenators are often unnecessarily replaced. We propose a method of streamlining the diagnosis of oxygenator failure and describe a method of changing an HFMO which is quick and has minimal microbubble generation.

Materials and Methods

The Cobe-Stöckert Heart Lung Machine^a, J & J Maxima Membrane Oxygenator^b, Terumo 1000cc Reservoir Bag^c, and Bentley 3/8-inch tubing^d with connectors were used for all experiments. The circuit was primed with 2000cc Plasmalyte A^e.

Method 1

The following method provides a fully primed oxygenator for changeout.

a Cobe Laboratories, Lakewood, CO 80215
 b Johnson & Johnson Cardiovascular, King of Prussia, PA 19406
 c Terumo Corporation, Piscataway, NJ 08854
 d American Bentley, Irvine, CA 92714
 e American Travenol, Deerfield, IL 60015

Additional Equipment

- 500cc Plasmalyte A with pressure bag
- One Blood Component Infusion Set (Plt. Infusion Set) (Figure 1)
- One 3/8" connector
- Two 3/8" Luer connectors
- Two 3-way stopcocks
- Two 2" pieces 3/8" tubing
- One 2" piece 1/4" tubing
- One 1/4" connector
- Sterile Scissors
- Tubing Clamps

Set-Up

Connect to oxygenator blood inlet port two 2-inch pieces of 3/8-inch tubing with 3/8-inch luer connector and stopcock in middle for priming (Figure 1). Connect to the oxygenator blood outlet port one 2-inch piece of 3/8-inch tubing with a 3/8-inch luer connector and stopcock for debubbling. Connect the 2-inch piece of 1/4-inch tubing with 1/4-inch connector to the recirculation port (Figure 1).

Priming

Place priming solution in pressure bag, clamp infusion line, apply 300 mmHg, and connect infu-

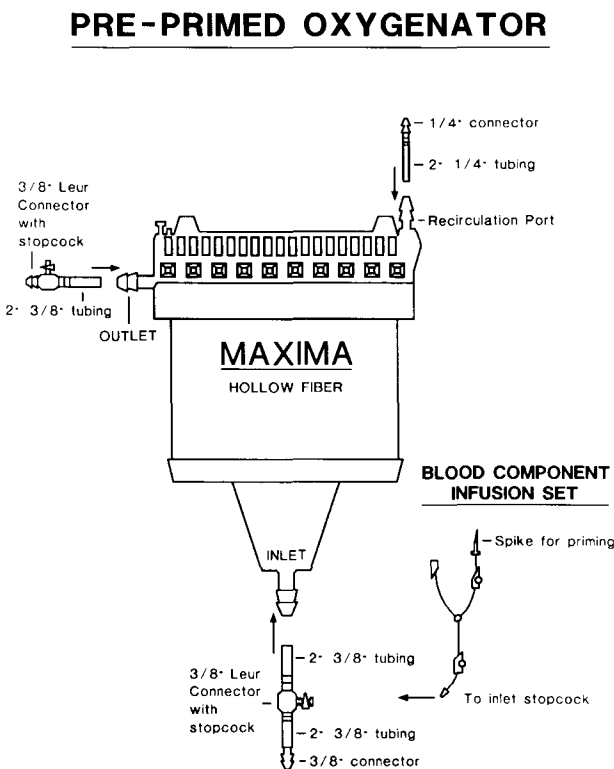


Figure 1: Set-up of membrane to be placed in circuit

sion set to meet inlet port stopcock (Figure 1). Position oxygenator vertically and clamp between inlet 3/8-inch leuc connector and 3/8-inch straight connector and between 1/4-inch connector and recirculation port. Prime through threeway stopcock using the blood component set. Tilt oxygenator to debubble outlet port and clamp line. Turn threeway stopcock off and disconnect infusion set.

Replacement

1. Before stopping perfusion double clamp recirculation line; one clamp close to port and the other 2 inches away allowing enough space for reconnecting line to 1/4-inch connector on new oxygenator.
2. Stop perfusion, turn oxygen off, clamp patient venous and arterial line.
3. Clamp oxygenator inlet blood line close to inlet port and again 2 inches away allowing for reconnection.
4. Clamp oxygenator outlet blood line close to outlet port and again 2 inches away.
5. Sterilize prep tubing and use sterile scissors to cut lines between clamps.
6. Place newly primed oxygenator in holder and connect all lines.
7. Recirculate through recirculation line at 2 LPM.
8. Apply unrestricted vacuum to the gas phase of the oxygenator (*all other gas vents occluded*).
9. While vacuuming, remove clamp between arterial line connectors and remove air using 60 cc syringe through blood inlet line stopcock. Reclamp arterial line to check for air.
10. Stop pump, clamp recirculation line, remove vacuum, *open gas vents*, and slowly resume perfusion inspecting for air.
11. Re-establish gas flow.

Method 2

The following method may be used for an unprimed oxygenator, to be primed in line.

1. Add 500 ml extra prime to circuit.
2. Clamp recirculation line at 1/4-inch recirculation port and again 2 inches away allowing for connection.
3. Stop perfusion, clamp patient arterial and venous lines, double clamp oxygenator blood inlet and outlet lines allowing for reconnection.
4. Sterilize prep tubing and cut with sterile scissors between clamps allowing for reconnection.

5. Place new oxygenator in holder and connect all lines.
6. Remove oxygenator blood inlet and recirculation line double clamps and recirculate at 2L/min.
7. Vacuum oxygenator gas path (*all gas vents occluded*) 30 sec. while tilting and debubbling. Check oxygenator outlet for air under clamps.
8. Inspect entire system.
9. Stop pump, clamp recirculation line, remove vacuum, *open gas vents*, and resume bypass slowly inspecting for air.
10. Re-establish gas flow.

We compared 4 methods of priming and changing an HFMO in the cardiopulmonary bypass circuit. We compared an unprimed oxygenator to a preprimed oxygenator, and compared both with and without vacuum (to decrease micro air).³ Then we compared the time required for changeout and microbubble removal in all 4 groups.

Results

A 2-Way ANOVA (analysis of variance) was used to evaluate the results using Statworks™ statistical package for the Macintosh computer. This allowed the simultaneous evaluation of two variables. The changeout times are listed in Figure 2. It took significantly longer to changeout the vacuumed lungs than those not vacuumed ($p < .03$). This is probably a result of the learning effect due to the order of the groups tested and not of clinical significance. The vacuumed groups were tested first and the nonvacuumed last. Randomizing the order of the tests may have eliminated this difference.

CHANGEOUT TIMES

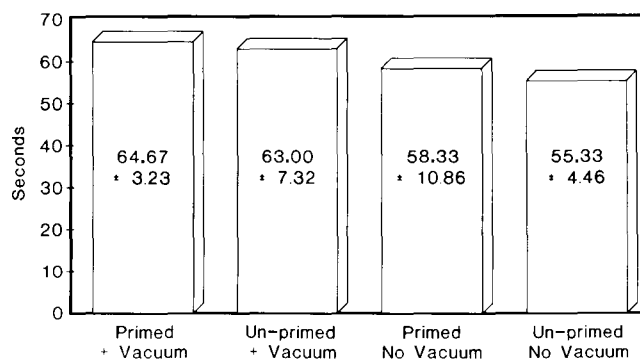


Figure 2. Membrane changeout times

The 10 micron bubble counts are listed in Figure 3. Use of vacuum had a profound effect on the 10 micron bubble counts ($p < .001$). Mean bubble counts in the pre-primed group without vacuum were $315.83 \pm 90.35^*$ versus $1.0 \pm .89$ in the same group with vacuum. The unprimed group also showed substantial decrease in bubble counts. The mean bubble counts for the unprimed lungs without vacuum were 527.33 ± 124.13 , versus 14.83 ± 4.45 in the vacuumed lungs. Prepriming of these lungs is significantly, but secondarily, better ($p < .005$).

The 50 micron bubble counts are listed in Figure 4. As with the 10 micron bubbles it is better to vacuum ($p < .003$). Prepriming the oxygenator did not offer any advantage to debubbling ($p < .261$). Mean bubble counts in the preprimed without vacuum were 3.83 ± 1.94 versus 0.67 ± 1.03 in the same group with vacuum. The mean bubble counts for the unprimed without vac-

uum were 8.67 ± 6.31 versus 2.33 ± 1.75 in the same group with vacuum.

There is little ischemic time difference between the preprimed or unprimed methods. The preprimed method offers the convenience of connecting and debubbling rather than connecting, priming, and debubbling in the arterial circuit. For the unpracticed perfusionist this method may also offer less ischemic time.

The technique of vacuuming the HFMO for 30 seconds during 2 LPM of recirculation before reinitiating bypass offers the tremendous advantage of a bubble-free membrane. This is especially well demonstrated in the 10 micron range (Figure 3), but is also significant in the 50 micron range (Figure 4). This technique is applicable for all HFMOs, especially those which do not require gas path anatomy modification.

If vacuum is not used, there is some advantage to prepriming the HFMO. Although microbubble counts were not significantly different in the 50 micron range ($p < .261$) in the non-vacuumed groups the 10 micron range exhibited significant reduction in microbubble counts when preprimed ($p < .007$).

10 MICRON BUBBLE COUNTS

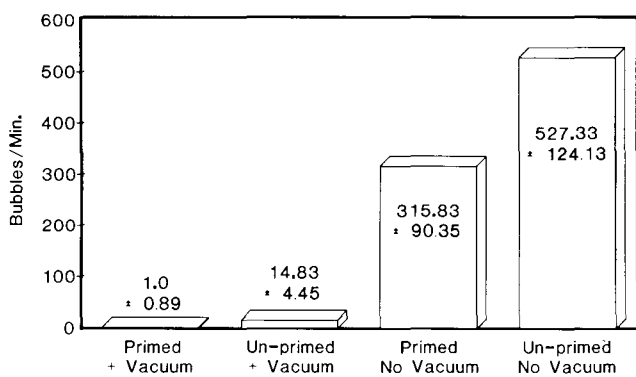


Figure 3: Ten micron bubbles

50 MICRON BUBBLE COUNTS

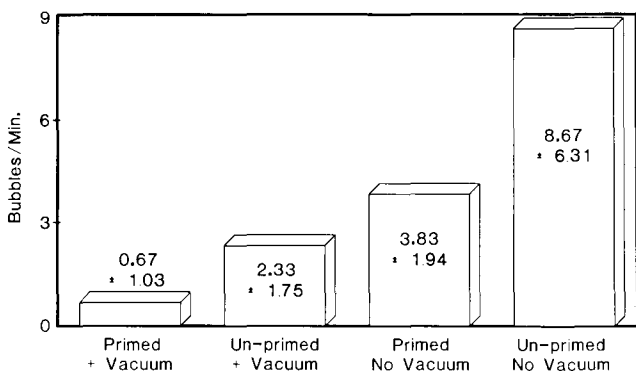


Figure 4: Fifty micron bubbles

Discussion

When a HFMO is returned for reported failure to oxygenate, the manufacturer attempts to recreate conditions similar to those that existed at the time of reported failure. If a complete perfusion record is returned with the oxygenator the manufacturer can more efficiently evaluate the complaint. If no records are returned the manufacturer has little to go on, and must impose standard AAMI conditions on the unit. The 1986 Manufacturer Quality Control Inadequate Oxygenation Evaluations for 5 major manufacturers' returned units is summarized in Figure 5.

It is important to properly prepare the oxygenator for return to the factory. An improperly prepared oxy-

	1986 Membrane Failure Statistics		
	Returned	Failed	%*
Manufacturer #1	7	1	.003
Manufacturer #2	19	1	.0001
Manufacturer #3	4	0	.0005
Manufacturer #4	not given	not given	.004
Manufacturer #5	4	0	.000

Figure 5

* All means reported as mean \pm standard deviation of the mean (sd)

*% of total oxygenators manufactured which failed
The numbers are estimates, each manufacturer uses different methods for classifying complaints.

generator limits the manufacturer's ability to accurately test it. One manufacturer suggested a method for lung preparation. The lung should first be rinsed with saline until the effluent is clear. Then it should be flushed and recirculated with a 3% solution of H₂O₂. Finally, it should be filled with 3% H₂O₂, capped, and promptly returned.

Testing of oxygenators which may have failed is quite expensive. It often requires an entire day of laboratory time, blood for the circuit, and most importantly, personnel to determine if the lung has in fact failed. Given the exceptionally low failure rate, one should be relatively certain that the lung has failed before returning it for testing.

An oxygen analyzer connected to the gas circuit, distal to the vaporizer, may help assure that the proper concentration of oxygen is being delivered from the blender. This blender should be routinely checked for accuracy before each procedure use. **No oxygen/air blender should be used without the concomitant use of an oxygen analyzer.**

A backup oxygen tank with regulator and proper connecting tubing should always be available in the event of loss of wall oxygen supply. Check to be sure that there is a hospital alarm that sounds if the oxygen supply is interrupted.

The diagnosis and response to oxygenator failure should be planned and practiced. This may be accomplished through the use of a checklist or algorithm (Figure 6), and oxygenator replacement drills carried out by the perfusion team at regular intervals.

The procedure in Figure 6 is provided with the intent of being a convenient flow chart for diagnosing oxygenator failure. It is a helpful tool and is not intended to be all inclusive. Anyone who suspects that an oxygenator is failing may use the algorithm, but should

not limit their investigation to it. Any suggestions for revision are welcomed. This algorithm may be enclosed in a plastic cover and placed in a convenient location for referencing. The O₂ Transfer formula may be printed on the back of the algorithm for easy reference.

We have recommended an algorithm that we think will help in making the diagnosis of oxygenator failure. We have also recommended a technique for replacing the failed oxygenator with one which is pre-primed. The replacement technique offers minimal microbubble counts when the lung gas path is vacuumed. On the basis of this study, we strongly recommend that whenever a HFMO is changed, that vacuum be applied to the gas phase to reduce the microbubbles generated by the changeout process. The potential for catastrophic accident during oxygenator changeout may be reduced if the perfusion team will choose an appropriate method for replacing the HFMO, and participate in regular practice drills before a failure occurs.

Acknowledgment

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References

1. Personal Communication.
2. Reed, C.C. and Clark, D.K. *Cardiopulmonary Perfusion*, Houston: Texas Medical Press Inc., 1975.
3. Berryessa, R., Tyndal, D.M., and Tornabene, S.: A Technique for the Effective Removal of Air from a Hollow Fiber Membrane Oxygenator Circuit. *J. Extra-Corpor. Technol.*, 18:156-158, 1986.

Questions from the Audience

Question: Aaron Hill, Falls Church, VA: Very nice presentation. An observation and a question. In the second step with FiO₂, is FiO₂ maximum? There should be some reference to measuring oxygen content. According to the survey of Kurusz, referring back to accidents and problems, blender failures have been much more on the increase since the advent of the widespread use of oxygenators. So I think it's essential that you establish what's coming out of your blender. Now I think an oxygenator analyzer is essential to be able to do that. And I believe one of the blender manufacturers has that label right on the blender. The other question: during your priming changeout do you have CO₂ in that or not? Is it just vacuum? Is it just fluid?

Response: No CO₂.

Question: In our experience, we use a different bubble counter, the Hadelon as opposed to the TM8. We were able to establish lower values by CO₂'ing the oxygenator as well—and decreasing subsequent bubble counts. Would you comment about the FiO₂ thing? Do you believe it's necessary to measure oxygen?

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DIFFERENTIAL DIAGNOSIS OF OXYGENATOR FAILURE

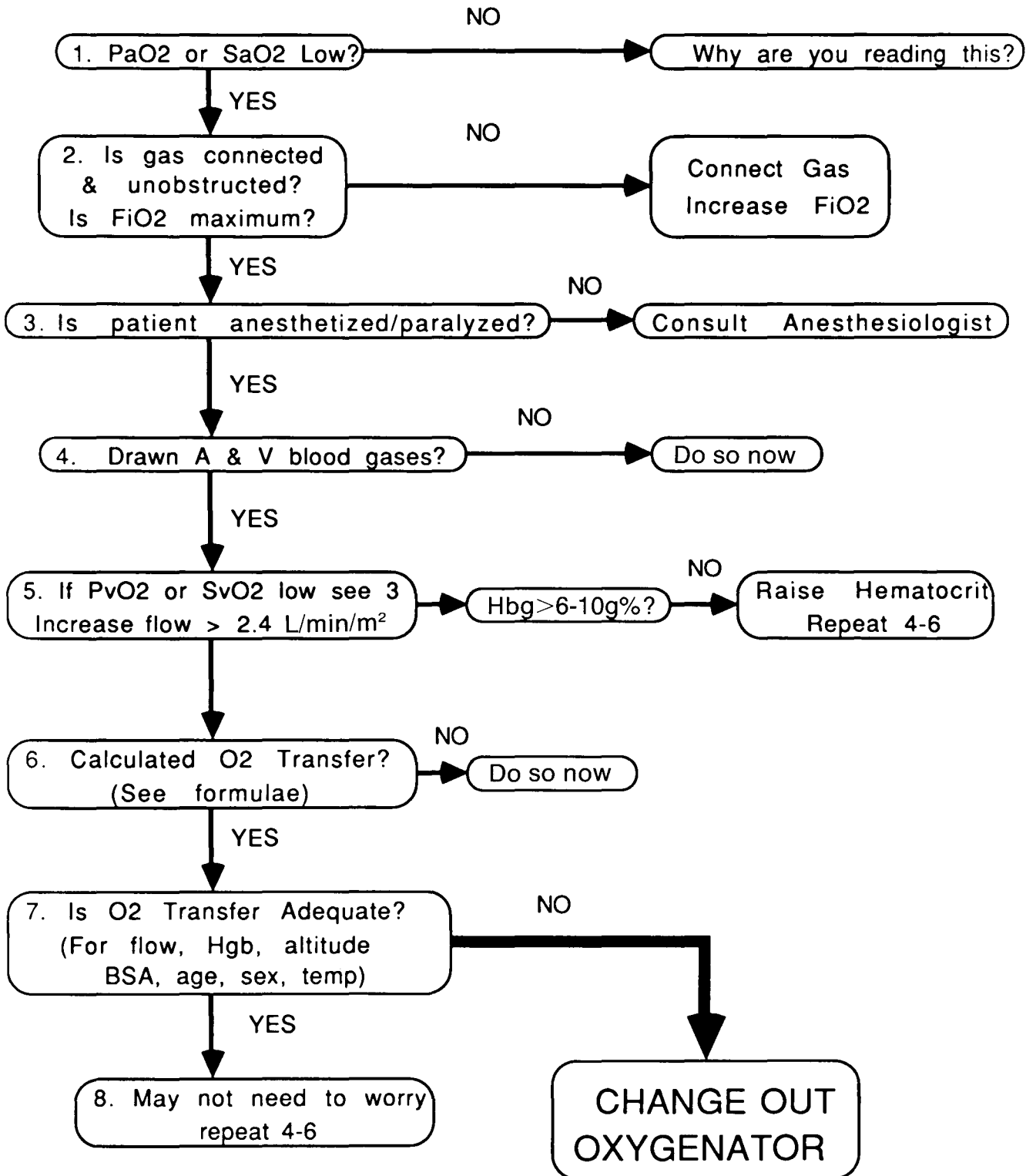


Figure 6: Differential diagnosis algorithm

OXYGEN TRANSFER

(ARTERIAL O₂ CONTENT- VENOUS O₂ CONTENT)(10)(FLOW-LPM)

ART. CONTENT=[(SaO₂%)(1.34 mL O₂)(Hgb gm%)] + [(PaO₂)(.003)]

VEN. CONTENT=[(SvO₂%)(1.34 mL O₂)(Hgb gm%)] + [(PvO₂)(.003)]

NORMAL VALUE = 350cc @ 6LPM BLOOD FLOW
12 g% HEMOGLOBIN
37°C
SEA LEVEL

Figure 6: continued

Questions, continued

Response: Yes. This is a very good point. In the box number 2 there, [onscreen in the figure] it would also be helpful if you had your oxygen analyzer in line. There are also other factors to be considered in there. Is the O₂ line obstructed? Is there a hospital alarm system that would go off if there were an oxygen failure in the operating room? So that's a very good point.

Question: Dave Hoff, Flint, MI: Very nice presentation. In setting up the Maxima for the switchout, do you modify it or alter it in any way to be able to use an unrestricted vacuum source? And if so, do you recommend, after the oxygenator is in line, making any further alterations?

Response: Are you referring to the preprimed or the unprimed?

Question: To the oxygenator that is switched out. Because of the various safety vents that are devised in the production of the Maxima, how do you alter them?

Response: With the Maxima we bone wax the large vent that goes around the side here. We found no problems. It has created no problem for us. There is also a vent port on the bottom side which we occlude with a small piece of tape. Then once our vacuuming process is completed, we remove the tape. And I found that this offers no deleterious effects for the membrane itself and the bubble-free environment has many advantageous effects. That's how we do it.

Comment: Richard Berryessa, Denver, CO: It should be noted that we use the Maxima in this case, because it happened to be one of the few unsterile units that we have. You do not have to modify any of the other oxygenators on the market that I can think of. Most of them have but one gas exit source. If you were to use Maxima, for instance, and wanted to vacuum, it's probably not a good idea to alter the thing, such that you change it differently from the way the manufacturer made it. J&J made this to be foolproof and unfortunately they overlooked the potential for being able to vacuum an oxygenator. And you don't have to worry about that with anybody else. We have talked to them about our desire to be able to vacuum a lung, because there are occasions when you do get air in the circuit for one reason or another and they may or may not address it in the next version of their oxygenator. However, I wouldn't recommend it, and we do not clinically modify the oxygenator to be able to vacuum it. If you were able to do it in a temporary way, that would be reasonable. But you also have to be very careful that you did not leave it modified in the course of the case. You still have one open gas port which is the same as any other oxygenator. But the fact that you modify an oxygenator from the way the manufacturer made it does leave you open for some liability if someone could prove that that caused some problem with the patient. In answer to Aaron's question also, there are a number of things in the text of the paper that Michael did not have time to present in this presentation, including recommendations that blenders be routinely monitored with an oxygen analyzer and that the flow meters in the blenders be routinely calibrated, as well other recommendations.

Comment: Frank Hurley, Chicago, IL: Just two comments. One on the blenders: in discussion with our biomedical department, we found that the Bird blenders seem to be especially susceptible to higher failure rates after two years of use. And Aaron's point about checking the output of those units is well taken. The second issue: it might be well for you in the future to look into the comparison of vacuum priming, which is your technique, versus the CO₂ flush, which a number of us use. I'd be curious to see which is more effective, and the time it takes to be able to remove the bubbles in the system.

Response: I guess I'll do a follow-up study on that when I do the effects of vacuuming.

Comment: Richard Berryessa: If I may answer that: in some instances it is difficult and/or time-consuming to CO₂ flush. One example is if you decide that you need to changeout an oxygenator, which happens very infrequently, that you really need to. If you take the time to CO₂ flush, for instance, you'd probably recirculate, anyway, before you go on. If, however, you do not CO₂ flush, and take the oxygenator out of the bag, and stick it in the circuit and recirculate for 30 seconds, with vacuum on the gas phase, we've shown that 30 seconds recirculation time, which you're going to do anyway, is enough to decrease the bubble counts significantly—to the range of a mean of 1. So we *do* CO₂ flush all our clinical units. There are, however, other circumstances, which we reported last year.