A Disposable Unitized Plastic Sheet Oxygenator for Open Heart Surgery*

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Since 1955, more than 350 patients have undergone direct vision intracardiac surgery at the University of Minnesota Hospitals utilizing a pump oxygenator of the bubble type.1, 2, 3

Because of the simplicity, reasonable cost, and eminently satisfactory performance of this oxygenator, we have sought to adapt its principle features in an equally effective oxygenator which could be commercially manufactured in quantity. Attainment of this objective promises not only to facilitate the performance of open cardiac surgery in those centers where it is already in progress, but also to widen the applicability of the benefits of open cardiotomy in many other areas. Moreover, there are innumerable potential applications for a readily available pump oxygenator system in the treatment by partial cardiopulmonary bypass of medical emergencies coincident with a failing myocardium (coronary thrombosis) or reversible pulmonary disease (edema, infection) as well as for the resection of certain aneurysms and unusual tumors.

The Oxygenator

This unitized oxygenator is constructed of two sheets of polyvinyl plastic. The desired channels and chambers are delineated by a heat seal of the plastic material (Figure 1). It incorporates the same chambers as its three dimensional prototype. There is a vertical mixing tube, a siliconized debubbling chamber, and a series of three short inclined columns (settling chamber) for the final removal of any remaining free gas. This two dimensional modification of the helical settling chamber has proved completely dependable as a barrier to the downward progression of bubbles. The oxygenator is a self-contained unit with an oxygen disperser heat-sealed into the lower end of the mixing chamber, a saran filter fabricated into the exit of the settling chamber, and a thermostat pocket built into the arterial (settling) chamber to facilitate heat regulation. Two venous inflow tubes enter the lower mixing chamber. One tube is the main inlet to the oxygenator for venous blood from the cavae and the other tube permits the entrance of blood aspirated by the cardiotomy sucker into the mixing chamber. The arterial outflow tube returns the arterialized blood from the oxygenator to the patient.

The complete oxygenator is suspended from a dynometer spring scale.†

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†Chatillon Scale $806, John Chatillon & Son, Co., New York, N. Y.
making it readily possible to maintain the blood volume of the unit quite constant.

The heat source may be obtained either from a set of three heat lamps** (Figure 2) or a heating element contained in a reflecting pan.† Either is automatically controlled by a simple thermostat and relay switch‡ contained in the thermostat pocket (Figure 1). A thermometer may be inserted

**G. E. reflector infrared heat bulbs (clear glass), 250 watts each.
†Volco Heating Company, Minneapolis, Minnesota.
‡Travenol Division of Baxter Laboratories, Inc., Morton Grove, Illinois.

FIGURE 1: Diagrammatic illustration of the plastic sheet oxygenator suspended from the spring scale.
into this same pocket for manual regulation of the heat source. The oxy-
genator is commercially available, and comes packaged as a ready to use ster
e unit containing antifoam in the debubbling chamber.

The oxygenator described herein evolved through a continuing modifica-
tion of several designs tested in more than 74 dogs. It has been utilized in eleven clinical cases to date and the results of these perfusions are pre-
sented herein.

Methods

The clinical trials of this oxygenator have been in conjunction with the Sigmamotor pump (multiple cam activated metal fingers). The pump

FIGURE 2: Photograph of the sheet oxygenator in combination with the Sigmamotor pump. Note: the suspending spring scale which allows instantaneous assessment of the blood volume. Heat loss is being controlled by the three heat lamps directed on the settling chamber. These lights are automatically turned on and off as necessary by the simple thermostatic relay switch inserted in the special pocket.
oxygenator connections are diagrammed in Figure 3. This diagram also depicts the gravity venous drainage system and the cardiotomy blood return system. This cardiotomy return unit permits aspiration of the coronary sinus blood, returning it promptly to the oxygenator circuit. The collection of systemic venous blood by gravity drainage rather than pump suction offers several advantages. It prevents a periodic rise in the venous pressure due to caval flutter (occasioned by the pliable caval walls being sucked against the venous catheters), and provides a more stable flow, minimizing the adjustments of the venous pump during the perfusion. If desired, the venous pump can be eliminated by dropping the oxygenator inlet to a level 10-12 inches below that of the right auricle. The arterial head of the pump is set to deliver 50-75 cc./kilogram/minute and may be increased during the perfusion if the monitoring electroencephalogram

Stainless steel connectors specially designed to obviate blood trauma available from Phelan Mfg. Co., Minneapolis, Minnesota.

Autoclavable plastic catheters designed and internally polished specifically for this use are obtained from C. R. Bard, Inc., Summit, New Jersey.

Polyvinyl plastic, Mayon Co., Hopkins, Minnesota.
and systemic blood pressure (obtained through a polyethylene tube in the internal mammary artery) show any significant changes. This range of flows, which depends upon the patient's age and the type of cardiac lesion, permits adequate tissue oxygenation and also prevents any marked depletion of the bicarbonate level (alkaline reserve). 6, 7

In eight clinical operations 100 per cent oxygen was used in the mixing tube of the oxygenator. A gas mixture of 95 per cent oxygen and 5 per cent carbon dioxide was employed in the three cases. The mixture appears to maintain the pCO2 at a more stable level than does the pure oxygen.

After suspending the oxygenator from the scale, the filter chamber should be filled with normal saline in a retrograde manner to eliminate air bubbles from this area, but the arterial pH was depressed. Thus, we currently favor the use of 100 per cent oxygen.

The oxygenator described herein is designed for flows to 1500 cc./minute and two pints of blood* are recommended for priming. After directing the heat lamps onto the oxygenator for two to three minutes the priming blood is introduced into the oxygenator through the mixing tube. This blood flows down the settling chamber and mixes with the few cubic centimeters of saline remaining in the filter chamber. The priming blood should be at or slightly warmer than body temperature for if the blood is substantially colder, the plasma may take up dissolved oxygen which can be released as gaseous emboli upon being warmed within the patient's body. It is emphasized that this precaution applies to oxygenators of all types and designs and constitutes the important reason for not allowing the blood temperature in the oxygenator to drop below the patient's temperature during perfusion.

After giving the patient 1 1/2 mg./kilogram of heparin** the great vessels are cannulated and the connections to the pump oxygenator are made (Figure 3). Henceforth until perfusion has ceased and the protamine is given all blood transfused into the patient or into the extracorporeal circuit is heparinized. Before and after this interval the standard citrated bank blood is used for whatever replacement may be necessary.

As the perfusion starts venous blood enters the mixing chamber and the gas flow is adjusted so that a gentle uninterrupted column of bubbles rises in the mixing tube. Usually a gas flow of 2.5 to 5 liters/minute is sufficient but this consideration is dependent upon the blood flow rate. The presence of a churning motion or of clear areas in the mixing tube indicates that the oxygenating gas is entering too slowly or too fast, respectively, for that particular blood flow rate. The blood level in the oxygenator unit is maintained such that the lower 1/3 of the debubbling chamber remains filled with blood (Figure 1).

On completion of the perfusion, protamine sulfate is given to the patient in a dosage of twice the amount of heparin given. We have not found the performance of heparin-protamine titrations to be necessary.

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*This blood is drawn into siliconized bottles (600 cc.) with 20 mg. heparin contained in 30 cc. of saline as the anticoagulant. These bottles are commercially available from Travenol Division of Baxter Laboratories, Inc., Morton Grove, Illinois.

**Patients weighing more than 35 kilograms should receive 2 to 2.5 mg. heparin/kilogram of body weight.
Results

The observations recorded in these first eleven patients having open cardiotomy utilizing this oxygenator are presented as follows.

Biochemical Observations During Perfusions

Five arterial blood samples have uniformly been drawn during these operations as indicated in Table I.

Sample 2 (Table I) was drawn about three minutes after perfusion began. This allowed time for entrance of the patient's blood into the oxygenator. The average time for sample 3, drawn after repair of the defect, was 20 minutes and the average time for sample 4, drawn from the oxygenator on completion of the perfusion, was 27 minutes 20 seconds.

1. Acid Base Changes

The pH values of the arterial blood samples have been averaged for the eleven patients and are listed in Table I. The range of variation is indicated in the parentheses. Prior to the bypass the pH was usually elevated and as the perfusion proceeded it dropped gradually, attaining a normal value at the conclusion of the bypass. A more precise measurement of the acid-base alteration, however, was the plasma bicarbonate level (alkaline reserve). The patient's average pre-perfusion level of bicarbonate was 19.10 mM/Liter. The bicarbonate level was 15.79 mM/liter (mean) in sample 2 drawn from the arterial limb of the pump three minutes after starting the perfusion. This drop in bicarbonate represents the mixing of the patient's blood with the slightly acidotic priming blood in the oxygenator. The bicarbonate level dropped an additional 3.74 mM/Liter (mean) during the remainder of the perfusion. These values are considered to be very reasonable considering the length of the bypass and the fact that no alkali was administered to these patients to restore the bicarbonate content of the blood. Part of this fall in plasma bicarbonate can be attributed

<table>
<thead>
<tr>
<th>Sample Number</th>
<th>Average Time After Bypass</th>
<th>Arterial pH</th>
<th>Arterial Plasma Bicarbonate (mM/L)</th>
<th>Venous Lactic Acid (mg. Per Cent)</th>
<th>Arterial Oxygen Saturation Per Cent</th>
<th>Plasma Hb (mg. Per Cent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>15 minute Pre-perfusion</td>
<td>7.50</td>
<td>12.16</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Perfusion started 3'</td>
<td>7.45</td>
<td>15.79</td>
<td>37.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(7.28-7.58)</td>
<td>(10.28-18.73)</td>
<td>(31.5-50.5)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Defect corrected 20' 30'</td>
<td>7.41</td>
<td>13.50</td>
<td>96</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(7.18-7.52)</td>
<td>(11.64-14.99)</td>
<td></td>
<td>(94-100)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Perfusion concluded 27' 20'</td>
<td>7.37</td>
<td>12.06</td>
<td>45.8</td>
<td>98</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td>(7.15-7.50)</td>
<td>(8.28-13.81)</td>
<td>(33.0-61.4)</td>
<td>(94-100)</td>
<td>(28-79.6)</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>15 minute Post-perfusion</td>
<td>7.40</td>
<td>12.15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(7.32-7.48)</td>
<td>(9.96-14.30)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
to a rise in fixed acids as evidenced by the slight rise in the venous blood lactic acid level during the perfusion (Table I).

2. Oxygenation of Venous Blood

Satisfactory oxygenation of the venous blood was achieved. The oxygen saturation reached 96 per cent at the time the defect was closed and was measured at 98 per cent upon termination of the bypass. This efficiency of gas exchange is a fundamental characteristic of bubble diffusion oxygenators.

3. Hemolysis

The average of the plasma hemoglobin values drawn at the end of the bypass in these eleven patients was 50 mg. per cent. From previous studies we know that some if not most of this low level of hemolysis can be attributed to the cardiotomy sucker unit rather than to the pump oxygenator. Usually 15 mm. of Hg. suction is applied to the cardiotomy reservoir, however when the intracardiac return is excessive it may be necessary to increase this amount of suction and the resulting hemolysis is usually correspondingly higher.

Operative Results

The performance of this sheet oxygenator was very satisfactory in all 11 perfusions. All patients were responsive and alert post-perfusion. Neither immediate nor remote neurologic sequelae were detected in any of the 11 patients. There were nine patients with isolated ventricular septal defects undergoing closure and two patients with pulmonary stenosis and other defects as indicated in Table II. Of the nine patients with ventricular septal defects, six are living and well (Table II).

Of the three patients not surviving, one child (J. M.) sustained a complete heart block during the closure of a ventricular septal defect. Two hours post-operatively while receiving Isuprel* treatment she came out of block and developed sinus tachycardia with a rate of 240-260 beats/minute. Because the blood pressure was adversely affected by this severe tachycardia, digitoxin was administered despite the risk of precipitating a recurrence of the heart block. The rate dropped to 140 beats/minute and the blood pressure returned to normal levels, however she died of cardiac arrest eight hours post-operatively. Autopsy revealed complete closure of the ventricular septal defect and no other anatomic abnormality. Death was due to the sudden recurrence of complete heart block. Since the introduction of the myocardial electrode together with the artificial pacemaker for treatment of this complication, we have managed 18 patients with complete atrioventricular dissociation with only one death.

Two other infants (T. S. and M. D.) each 12 months of age had severe pulmonary hypertension accompanying their ventricular septal defects. Both had uneventful operative procedures. Post-operatively they both had progressively increasing respiratory distress with death ensuing 18 and 24 hours after surgery respectively. In each of these infants, autopsy confirmed the complete and correct closure of the septal defects. In both

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age</th>
<th>Weight</th>
<th>Defect</th>
<th>Pul. Pressures</th>
<th>Sys. Pressures</th>
<th>Duration of Perfusion</th>
<th>Perfusion Rate cc./min.</th>
<th>Operative Procedure</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>W. S.</td>
<td>7</td>
<td>9.8 Kg.</td>
<td>IVSD</td>
<td>42/13 110/70</td>
<td></td>
<td>26' 37&quot;</td>
<td>600</td>
<td>Heart arrested with K citrate and polyvinyl sponge* sutured into defect for closure</td>
<td>Living and well</td>
</tr>
<tr>
<td>T. S.</td>
<td>1</td>
<td>6.4 Kg.</td>
<td>IVSD</td>
<td>110/0 115/60</td>
<td></td>
<td>30' 48&quot;</td>
<td>400</td>
<td>Polyvinyl sponge sutured into defect for closure</td>
<td>Awake and alert P.O. Resp. distress progressing until death 18 hrs. later. Severe pul. arteriolar intimal proliferation at autopsy</td>
</tr>
<tr>
<td>D. P.</td>
<td>5</td>
<td>7.2 Kg.</td>
<td>IVSD</td>
<td>48/20 110/70</td>
<td></td>
<td>17' 17&quot;</td>
<td>470</td>
<td>Polyvinyl sponge sutured into defect for closure</td>
<td>Living and well</td>
</tr>
<tr>
<td>M. B.</td>
<td>Pul. &amp; 8.0 Kg</td>
<td>IVSD</td>
<td>20/10 90/56</td>
<td>15' 25&quot;</td>
<td>500</td>
<td>Stenotic pulmonary valve repaired through pul. arteriotomy exploratory rt. ventriculotomy</td>
<td>Awake and alert P.O. Died suddenly 8 hrs. P.O.12 mm. IVSD at autopsy visible only from left side of septum</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S. T.</td>
<td>30</td>
<td>11.2 Kg.</td>
<td>IVSD</td>
<td>60/30 120/70</td>
<td>35' 600</td>
<td>Heart arrested with K citrate &amp; polyvinyl sponge sutured into defect for closure</td>
<td>Living and well</td>
<td></td>
<td></td>
</tr>
<tr>
<td>J. M.</td>
<td>36</td>
<td>15.9 Kg.</td>
<td>IVSD</td>
<td>65/18 120/70</td>
<td>41' 3&quot;</td>
<td>850</td>
<td>Heart arrested with K citrate and polyvinyl sponge sutured into defect for closure</td>
<td>Patient sustained complete A-V block at surgery. Died 8 hrs. P.O.</td>
<td></td>
</tr>
<tr>
<td>M. D.</td>
<td>12</td>
<td>6.1 Kg.</td>
<td>IVSD</td>
<td>62/16 70/40</td>
<td>31' 8&quot;</td>
<td>360</td>
<td>Polyvinyl sponge sutured into defect for closure</td>
<td>Awake and alert P.O. Severe resp. distress progressing until death 24 hrs. P.O. Severe pul. art. intimal proliferation at autopsy</td>
<td></td>
</tr>
<tr>
<td>J. M.</td>
<td>5</td>
<td>8.2 Kg.</td>
<td>IVSD</td>
<td>36/10 104/70</td>
<td>22' 5&quot;</td>
<td>500</td>
<td>Polyvinyl sponge sutured into defect for closure</td>
<td>Living and well</td>
<td></td>
</tr>
<tr>
<td>C. B.</td>
<td>15</td>
<td>16.6 Kg.</td>
<td>IVSD</td>
<td>42/19 95/75</td>
<td>24' 31&quot;</td>
<td>750</td>
<td>Heart arrested with K citrate and polyvinyl sponge sutured into defect for closure</td>
<td>Living and well</td>
<td></td>
</tr>
<tr>
<td>R. B.</td>
<td>15</td>
<td>20.2 Kg.</td>
<td>IVSD</td>
<td>78/37 96/70</td>
<td>38' 33&quot;</td>
<td>900</td>
<td>Heart arrested with K citrate and polyvinyl sponge sutured into defect for closure</td>
<td>Living and well</td>
<td></td>
</tr>
<tr>
<td>P. T.</td>
<td>Pul. &amp; I.A.S.D. (scundum)</td>
<td>4yr &amp; 14.4 Kg</td>
<td>110/70</td>
<td>17' 6&quot;</td>
<td>650</td>
<td>Stenotic pulmonary valve repaired via pulmonary artery. Atrial septal defect closed with interrupted sutures by atriotomy</td>
<td>Living and well</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

patients microscopic study of the lungs disclosed advanced intimal proliferation of the pulmonary arterioles. Death of these infants was due to circulatory failure resulting from the high resistance in the pulmonary circuit. We have previously emphasized the factors responsible for an increased operative risk for infants requiring open heart surgery at an early age.\textsuperscript{10}

The two other patients operated upon had pulmonary stenosis associated with an atrial septal defect in one instance (P. T.) and a ventricular septal defect in the other (M. B.). The former survived and the latter did not. This last patient (M. B.) was particularly instructive. She had a preoperative diagnosis of isolated valvular pulmonary stenosis. The preoperative studies had included both cardiac catheterization and angiography. At surgery, this defect was present and was repaired under direct vision through a pulmonary arteriotomy. However, the surgeon suspected the possibility of additional defects in this infant because the clinical disability had been much more severe than one could have expected from the degree of valvular pulmonary stenosis found. Therefore, a short ventriculotomy incision was made to allow direct vision inspection of the ventricular septum and insertion of a finger through the tricuspid valve to palpate the atrial septum. No defects were detected by these maneuvers. The patient died suddenly eight hours after surgery. Post-mortem examination demonstrated a sizeable ventricular septal defect in this infant (12 mm. in diameter), visible only from the left side of the septum, for it was obscured completely by hypertrophied trabeculations of the right ventricle. (The pathologist also missed detecting this defect until later when the left ventricle was opened.) Since this chastening lesson, these concealed ventricular septal defects have been correctly diagnosed by injecting through a needle, Evans blue dye (T-1824) into the left ventricle (and momentarily compressing the aorta between the fingers) after performing the right ventriculotomy. If there is a ventricular septal defect obscured by hypertrophied trabeculations or located in an unusual site, the dye will make the defect apparent.

Discussion

The oxygenator described in this report appears to be equally as effective as its three dimensional prototype. Values for oxygenation, acid-base shift and hemolysis are comparable to those measured during 250 clinical perfusions with the previously described bubble oxygenator.\textsuperscript{9,7}

The technique of suspending the oxygenator from a spring scale provides an accurate and practical method for maintaining a constant blood volume in the patient. It is important to note that in perfusions carried out in seriously ill infants weighing a few kilograms, there is at best a narrow margin between success and failure, and an imbalance of as little as several ounces of blood in either direction may be crucial in determining success or failure.

The oxygenator described herein effectively accommodates flows up to 1500 cc./minute. At the present time we are completing the experimental evaluation of a larger model of the same design which is capable of han-
dling effectively blood flows up to four liters/minute. There have been no obstacles encountered in the experimental perfusions evaluating this larger unit.

CONCLUSIONS
1. A unitized, disposable, inexpensive bubble diffusion oxygenator constructed of two sheets of polyvinyl plastic has been used successfully in 11 clinical cases.
2. This oxygenator is commercially available as a sterile packaged unit ready to hang up, prime, and use.
3. Seven of 11 patients had intracardiac defects completely corrected and are living and well at this time. The remaining four patients (three were seriously ill infants) succumbed from complications including pulmonary hypertension and complete atrio-ventricular heart block. In none of these four patients did it appear that the performance of the pump or oxygenator could be incriminated in the unsuccessful outcome.
4. Biochemical perfusion data on these 11 patients compares favorably with determinations made on 250 patients perfused with the three dimensional prototype of this unit.

RESUMEN
1. En once casos clínicos se ha usado satisfactoriamente un oxígenador construido con dos hojas de polivinil. Es unificado, puede descartarse una vez usado, no es costoso y funciona por difusión de burbujas.
2. Este oxígenador se puede obtener comercialmente para usarse en un paquete esterilizado, para colgarse, prepararse y ponerse a funcionar.
3. De once enfermos con defectos intracardíacos siete se corrigieron completamente, están vivos y bien al presente. Los cuatro restantes (tres niños gravemente enfermos) sucumbieron debido a complicaciones incluyendo hipertensión pulmonar y bloqueo cardíaco completo, atrioventricular.
   En ninguno de estos cuatro enfermos pareció que el trabajo del oxígenador o de la bomba pudiese ser causante del mal resultado.
4. Los datos bioquímicos de la perfusión de estos once enfermos se comparan favorablemente con las determinaciones hechas en 250 enfermos perfundidos con el aparato prototipo, tridimensional de esta unidad.

RESUME
1. Un oxygénateur à barboteur, bon marché, maniable, composé de deux feuilles de polyvinyle, a été utilisé avec succès dans onze cas cliniques.
2. Cet oxygénateur est présenté dans le commerce en paquet stérile, prêt à l'emploi.
3. Sept des onze malades avaient des malformations intracardiaques complètement corrigées, et sont maintenant en vie et en bonne santé. Les quatre autres malades (dont trois étaient des bébés gravement atteintes) succombèrent de complications comprenant l'hypertension pulmonaire et un syndrome d'Adam-Stokes atrio-ventriculaire. Chez aucun de ces quatre malades, il n'apparait que l'on puisse mettre en cause le fonctionnement de la pompe ou de l'oxygénateur dans l'issue fatale.
4. Les données biochimiques de la perfusion chez ces onze malades peuvent être comparées favorablement à celles qui ont été déterminées chez
250 malades, qui reçurent des perfusions avec le prototype à trois dimensions de ce service.

ZUSAMMENFASSUNG

1. Es wurde ein vereinheitlichtes leicht verfügbares, wohleines Sauerstoffgerät mit Sprudel-Diffusion hergestellt aus 2 Plastikscheiben und Polyvinyl, und in 11 klinisch behandelten Fällen erfolgreich eingesetzt.

2. Dieser Oxygenator ist im Handel erhältlich in vollständig sterilier Verpackung, fertig zur Befestigung, Aufladung und Benutzung.


REFERENCES


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