A SELF-CONTAINED, DISPOSABLE OXYGENATOR OF PLASTIC SHEET FOR INTRACARDIAC SURGERY

EXPERIMENTAL DEVELOPMENT AND CLINICAL APPLICATION

BY

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Since the first months of 1955 more than 200 patients at the University of Minnesota Hospitals have undergone direct-vision intracardiac surgery, utilizing a bubble oxygenator (DeWall, Warden, Read, Gott, Ziegler, Varco, and Lillehei, 1956; Lillehei, DeWall, Read, Warden, and Varco, 1956) in combination with a pump for supporting the systemic circulation during this interval when the heart and lungs are totally by-passed.

During this period of clinical experience this pump-oxygenator has passed through several stages of evolution, each design being more simple than its predecessor. All models have been constructed of expendable polyvinyl tubing and have employed the same principles of a vertical mixing tube, an antifoam-coated debubbling chamber, and a helix settling chamber for the final elimination of all bubbles.

Our clinical experience with these models has been most encouraging. In order to facilitate the widest application of these advantages of open heart surgery, experiments have continued with the object of providing an equally effective and inexpensive oxygenator which also would be expendable and adaptable to commercial manufacture in quantity.

THE SHEET OXYGENATOR

Using the same tested principles as mentioned above, an oxygenator (Figs. 1, 2, and 3) has been developed. It is constructed of two thin sheets of polyvinyl plastic, the desired channels and chambers being delineated by a heat seal of the plastic sheets. This oxygenator is a self-contained unit with an oxygen disperser, heat sealed in the lower end of the

mixing chamber, and a saran monofilament filter secured into the exit from the settling chamber. The oxygenator will be commercially available,§ and will come packed ready to use as a sterile unit containing antifoam in the debubbling chamber and a built-in thermostat pocket facilitating heat regulation. The complete oxygenator is suspended from a dynamometer scale|| (Fig. 3), which makes it possible to maintain the blood volume of the unit quite constant. Three heat lamps reflecting upon the oxygenator have served in our experimental work to control the tendency for a drop in temperature in the blood circulating extracorporeally. However, these lamps have a tendency to be uneven in their heat distribution, and therefore we have designed a reflecting pan with a self-contained heating element,¶ which in addition serves as a support for the oxygenator unit. This source of heat is automatically regulated by a thermostat§ (set at 40° C.) placed in the pocket designed for this element (Fig. 1).

THE BLOOD PUMPS

In all of our clinical experience to date the previously described (Lillehei, Cohen, Warden, and Varco, 1955) "sigmamotor" ** pump (multiple cam actuated metal fingers) has been used and has proved very dependable. For the developmental trials of the new oxygenator we have also relied upon the "sigmamotor" pump, but have tested a pump†† (Fig. 2) employing an adjustable rotating cam principle as well. This unit is compact, quiet, and has an output up to 4,000 ml./minute. This pump has an arterial and venous head, but differs from others of this general type in that the cams cycle at a constant rate (90 cycles per minute), and these cams are readily adjustable individually while in operation. Thus, since the compression

§ Travenol Division of Baxter Laboratories, Inc., Morton Grove, Illinois.

|| Chatillon Autopsy Scale No. 806, John Chatillon & Son Co., 65, Cliff Street, New York 38, New York.

¶ Volco Heating Company, Minneapolis, Minnesota.

** Sigmamotor, Inc., 3, North Main Street, Middleport, New York.

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FIG. 1.—Diagrammatic illustration of the plastic sheet oxygenator (Model IV). This is the unit used clinically.

exerted by the cams on the pump hose can be adjusted at any time during the perfusion run, the output of either the venous or arterial circuits can be varied independently. However, it is obviously more difficult to maintain a balanced calibration with this pump, because the cams are non-occlusive and their output therefore varies inversely with the resistance. As a result, it must be calibrated against a known resistance. There are both advantages as well as disadvantages in the use of such a principle. The disadvantage lies in the fact that a relatively minor increase in resistance (such as an undetected kink in the plastic tubing carrying blood to or from the patient, for example) can cause a significant reduction in pump output. The chief advantage is found in the ability to increase output automatically once it has been calibrated to give a certain flow against a normal blood pressure, e.g., 100 mm. Hg, if during the by-pass the blood pressure falls below this figure.

With the "sigmamotor" pump, because the pumping fingers are occlusive, the calibrated output does not vary appreciably over a rather wide range of resistance. (Varying the output resistance from 0 to 125 mm. Hg does not alter the measured output of the "sigmamotor" unit.)

METHODS OF STUDY

Total cardiopulmonary by-pass was carried out in 70 dogs during the development of this sheet-type oxygenator. In 37 of the dogs rather complete biochemical studies were made, and these are summarized in Table I. This report will deal more specifically with the last 15 dogs in which the latest model (IV) of the oxygenator has been tested (Figs. 1, 2). This oxygenator is capable of oxygenating completely blood flows up to 1,000 ml./minute. A larger unit similar in design can oxygenate blood flows up to 3,500 ml./minute. Test data derived with its use will be presented in a subsequent report.

METHOD OF PERFUSION

Before starting each perfusion the oxygenator unit is suspended from the spring scale and the filter chamber is filled in a retrograde manner with normal saline so as to eliminate air from the filter mesh. The residual filling of the oxygenator is then done with normal saline through the priming tube. This saline serves for calibration of the arterial head of the pump.

When the rotating cam pump was used, as in the metabolic studies (Tables I, II), the arterial head was calibrated to deliver 35 ml./kg./min. against a resistance of 100 mm. Hg. This delivery was achieved by placing a screw-type clamp at the distal end of the arterial limb and monitoring the pressure proximal to the clamp. Usually this arterial pump setting was not altered during the perfusion, but preferably the venous cam was adjusted so as to maintain a constant volume of blood within the oxygenator as determined readily by reference to the supporting scale. (It is worthy of emphasis that in perfusions carried out in desperately ill infants, weighing 2 to 4 kg., an imbalance of as little as 50 ml. of blood in either direction may be crucial in determining success or failure.)

For these perfusions dogs, 13 to 20 kg. in weight, were anaesthetized with 2½% pentothal and placed on a cam type respirator utilizing compressed air. Clean but not sterile technique was used. A right thoracotomy was performed and the arterial and venous cannulations were effected after heparinizing the animal with 1½ mg./kg. body weight.

Fresh canine arterial blood from an unanaesthetized donor (18 mg. of heparin dispersed in 30 ml. of normal saline in each 500 ml. of blood) was then introduced into the oxygenator so that the level was well up into the debubbling chamber. (Anectine is given intravenously to paralyse the dog, and procaine is used for local anaesthesia. Use of a general anaesthetic in the donor animal may result in the patient dog dying without awakening after an otherwise successful perfusion due to an overdose of anaesthetic.) One thousand millilitres of blood has been a convenient quantity to prime this oxygenator.

FIG. 2.—The plastic sheet oxygenator (Model IV). The oxygenator photographed during a perfusion with the adjustable rotating cam pump. The essential elements of this oxygenator, consisting of the mixing tube, debubbling chamber, and the inclined plane settling chamber may be noted. Below: The pump motor is on the right, and the arterial and venous pumping heads to the left. The blood is massaged unidirectionally by the non-occlusive rotating cams, which are adjustable while the pump is in motion by means of the knurled set screw located at the hub.

FIG. 3.—The method of suspension of the oxygenator unit from a spring scale. This scale is graduated in 10-g. increments, which allows positive and instantaneous determination of the contained blood volume.

To start the perfusion 100% oxygen was allowed to flow through the disperser at a rate such that an uninterrupted column of bubbles rose gently in the mixing chamber. A gas flow of 3 to 4 litres per minute through the disperser ordinarily was sufficient for complete oxygenation of venous inflow rates up to 1 litre per minute. The occurrence of "clear areas" in the mixing tube or production of foam are signs that too much oxygen is being delivered for that rate of venous inflow. The observer's eye has served as an excellent index of the efficiency of oxygenation. The most efficient debubbling action is achieved when blood fills the lower one-third of the debubbling chamber as pictured in Fig. 2. On completion of the perfusion, protamine sulphate was given intravenously at the rate of 3 mg. per kg. of the patient's body weight. The same dosage of heparin and protamine have been used regularly in the clinical cases. Heparin titration curves have not proved necessary or of value either experimentally or clinically.

All the dogs in the last group (Table II) had total cardiopulmonary by-pass for a one-hour interval during which time the oxygenation, carbon dioxide elimination, other metabolic changes, and haemolysis rates were studied. These perfusion studies have been directed towards two principal objectives. First, the development and testing of the biochemical efficiency

of this most recent oxygenator design; and secondly, the study of the flow characteristics and performance of this new type of adjustable rotating cam pump.

RESULTS

FLOW STUDIES ON THE ROTATING CAM PUMP.

Fig. 4 depicts the relationship of flow to output resistance when $\frac{1}{4}$ in. internal diameter latex pump hose was used in the adjustable rotating cam pump. Each curve represents a specific, constant hose compression by the pump cam. Graphs with a similar configuration were obtained for the other sizes of pump hose tested. It appeared that $\frac{3}{16}$ in. internal diameter latex gum rubber pump hose was superior for flows up to 400 ml./min., $\frac{1}{4}$ in. for flows from 400 ml. to 1,200 ml./min., $\frac{5}{16}$ in. for flows from 1,200 to 2,000 ml./min., and $\frac{1}{2}$ in. tubing was suitable for blood flows from 2,000 ml. up to 4,000 ml./min.

Reference to Fig. 4 reveals that, for example, with the arterial head of the cam pump calibrated to deliver 500 ml./min. at 100 mm. Hg, when the patient animal's systemic pressure fell to 70 mm. Hg, the output increased to about 675 ml./min. Using the "sigmamotor" pump with its principle of complete compression of the pump hose the output would not vary despite this pressure change.

Additional confirmation of this concept is demonstrated where the flow lines became more vertical at the right side of the graph. This fact, of course, indicates that the pump output is less affected by output resistance at these higher flows, since here nearly complete compression of the pump hose by the cam is required.

OXYGENATOR MODELS AND EFFICIENCY OF FUNCTION.

Fig. 1 depicts diagrammatically the version of the oxygenator to date (Model IV). It has now been adopted for clinical trial on the basis of these experimental studies.

Research carried out on the earlier models led to the present configuration of the oxygen disperser shown in Model IV. The design of the disperser and also its relationship to the venous inflow at the base of the mixing tube have proved important factors influencing the efficiency of oxygenation. These initial models differed also somewhat in regard to chamber size and configuration.

Data regarding the earlier models are presented briefly in Table I, and data from Model IV perfusions are presented in Table II. Table I shows the four types of dispersers diagrammatically. The oxygen disperser of Model I consisted of a plastic sack with many perforations and a venous blood-entry tube opened below this. The mixing chamber also had an effective diameter of only

TABLE I
RELATIONSHIP OF THE OXYGEN DISPERSER DESIGN TO EFFICIENCY OF FUNCTION

Model of Oxygenator Disperser	Number of Dogs	Length of Perfusion (min.)	Final Arterial Oxygen Saturation (%)	Final Arterial pH	HCO ₃ Deficit (mM.l.)	Rise in Platelet Hg (mg.-%)	Platelet Count Drop (%)	Mortality (%)
I	10	30	81.5	7.28	12.81	51	50	37.5*
II	7	60	97.6	—	—	87.2	50	0*
III	5	60	98	7.41	—	971	75	100
IV	15	60	96	7.48	8	77	60	13.3

* Excluding two acute studies.

Model IV is the presently preferred design

TABLE II
METABOLIC DATA ON 15 DOGS WITH TOTAL BODY PERFUSION AND CARDIOPULMONARY BY-PASS FOR 60 MINUTES USING ROTATING CAM PUMP AND MODEL IV SHEET OXYGENATOR

	Dog No.	Wt. (kg.)	Pump Flow (ml./min.)	Final Arterial Oxygen Saturation (%)	O ₂ Consumption (ml./kg./min.)	Final ¹ Arterial pH	HCO ₃ ² Deficit (mM./l.)	Lactic ³ Acid Rise (mg.%)	Plasma ⁴ Hg Rise (mg.%)	Platelet ⁵ Count Fall (%)	Mortality
1	544	15.4	830	97.3	9.23	7.42	9.67	41.0	8	85	0
2	611	13.4	860			7.38	11.56	36.2	118	59	0
3	590	13.0	620	100.0	4.40	7.51	7.32	9.2	125	46	0
4	80	12.5	700	98.7	6.60	7.62	8.77	22.7	90	64	+
5	642	15.0	720	95.7	5.46	7.49	11.76	16.3	65	58	0
6	1898	14.8	900	90.3	5.85	7.55	8.68	21.0	20	65	0
7	634	16.5	930	95.8	5.46	7.62	+3.92	16.5	38	68	0
8	405	13.6	950	88.0	10.65	7.40	13.32	51.7	117	59	0
9	691	15.2	720	94.9	5.65	7.48	3.07	25.5	45	52	0
10	717	14.1	750	91.1	4.51	7.43	11.89	22.7	74	51	0
11	728	14.8	850	99.9	9.33	7.37	4.84	18.1	63	49	0
12	445	13.8	900	99.1	11.04	7.47	11.47	11.5	147	60	0
13	774	16.4	530	99.2	5.82	7.49	12.25	5.9	43	62	+
14	783	16.3	900	100.0	9.82	7.51	2.57	13.7	185	69	0
15	742	12.6	800	91.8	7.74	7.49	9.97	16.55	18	66	0
Average values				96.0	7.25	7.48	8.20	21.9	77	60	13.3%

Average preperfusion values: ¹ Arterial pH, 7.54. ² Corrected HCO₃, 24.47 mM./l. ³ Lactic acid, 19.6 mg.%. ⁴ Plasma Hg, 11.3 mg.%. ⁵ Platelet count, 298,000.

$\frac{3}{4}$ in. Although oxygenation was rather poor in the 10 dogs perfused with this model, only one animal died during the immediate post-operative period among eight dogs operated upon for survival. Two additional animals succumbed from empyema one week post-operatively. In Model II, after widening the mixing chamber and bringing the venous blood in above the oxygen disperser, the oxygenation was substantially improved and haemolysis remained minimal. There were no deaths among the five dogs

operated upon for survival during testing with this design.

Despite the superior accomplishments with Model II, too much blood remained sequestered in the lower end of the mixing chamber and a better column of bubbles was sought for through use of a horizontally placed perforated membrane as the oxygen disperser. Model III tested this change. Initially, there were a relatively few, very fine perforations, which then emitted oxygen under high pressure. Although this design gave an excellent

FIG. 4

column of bubbles it brought about lethal changes in the blood through the degree of trauma caused by the oxygen jets entering the blood under such high pressures (Table I).

The dispenser was then altered so as to contain approximately 50 larger perforations. With subsequent tests with these changes haemolysis has been minimal, the oxygenation excellent, and the column of bubbles rises gently from a minimum pool of blood in the mixing chamber (Model IV).

BIOCHEMICAL OBSERVATIONS ON MODEL IV OXYGENATOR.—The data from the last 15 dogs perfused with the Model IV oxygenator (Figs. 1, 2) and using the rotating cam pump are presented in Table II. All studies were done with the animal's body temperature maintained in a normal range.

Oxygenation Data.—The pump flow rates listed were measured near the termination of the 60-minute perfusions when samples for the final blood chemistries were drawn. The average pump flow per unit time throughout the perfusion was, in most cases, about the same as this figure. One may note that the degree of oxygenation imparted to the venous blood was excellent, averaging 96%.

Acid Base Balance.—The final arterial pH after a total body perfusion for 60 minutes invariably approximated to normal values, and the average value for these 15 animals was 7.48. The fact that the arterial pH values remained in the normal range during these prolonged perfusions indicated that there had been an efficient maintenance by the pump-oxygenator of the animal's acid base balance. As a more precise measure of any acid base alteration in these dogs, the total plasma bicarbonate (alkaline reserve) was also determined and the average HCO_3 deficit for these animals was only 8.20 millimoles/litre. This seems to be a reasonable loss after one hour of total cardiopulmonary by-pass. This fall in the alkaline reserve was due in part to a slight to moderate rise in fixed acids as deduced from lactic acid determinations (Table II). It is worthy of emphasis that these values assessing acid base balance represented the animals' own responses to the perfusions, since no base was administered to any dog.

Haematological Changes.—The average plasma haemoglobin rise was 77 mg.%. This degree of haemolysis in 60 minutes is considered to be a very acceptable value, in view of the well-recognized fact that canine red blood cells are fragile in comparison with human red blood cells. It may be noted that in some perfusions there was virtually

no detectable haemolysis. Usually when the plasma haemoglobin was in the higher ranges the priming blood had been drawn some time before the perfusion. Moreover, typing and cross matching tests were not performed upon these dogs. The average drop in the number of platelets was 60% after one hour of perfusion. Scalabrino, Curtarelli, and Bianchi (1954) have shown that heparinization of blood alone may temporarily reduce the platelet count to 50% of the normal value.

Morbidity and Mortality.—Thirteen of 15 dogs were long-term survivals. One death occurred in an emaciated dog (No. 80) which had pneumonia at the time of surgery. This animal awoke immediately after perfusion and was walking within two hours, but died two days post-operatively with a severe pulmonary infection. The other fatality (No. 774), although the animal was alert and walking three hours post-operatively, died 12 hours later. This experiment was the only one in which post-operative bleeding was a problem. Five hundred millilitres of blood were aspirated from the animal's chest during the first eight hours after the perfusion. The final platelet count was 160,000. A study of this protocol indicates that very probably inadequate haemostasis was the cause of the abnormal blood loss, and death was due to hypovolaemic shock.

Most of the dogs were up and walking within four hours after operation. There were no neurological signs suggesting either embolism or cerebral anoxia in any animal.

DISCUSSION

Fundamentally, the sheet oxygenator described above differs in but one feature from the oxygenator which has been utilized effectively upon more than 200 patients. A shortened two-dimensional settling chamber has been substituted for the longer three-dimensional helix as the means of bringing about the ultimate removal of gaseous bubbles from arterialized blood.

The helix is, in effect, an inclined column of approximately 10 ft. in length which compels through physical forces the upward lamination of bubbles, directing them away from the arterial outflow at the lower level. Based upon the broad experimental and clinical experience, there is no question of the efficacy of this helical design. The helix has proved to be an absolute barrier to the outward progression of bubbles from the oxygenator. However, this three-dimensional form does not lend itself readily to a unified oxygenator design.

The oxygenator presented in this report has in effect a "two-dimensional helix" in the form of three relatively short inclined columns with a total length of less than 5 ft.

At the outset of these studies it was clear to us that the crucial question to be resolved experimentally was the safety and efficiency of this type of settling chamber. We now wish to report that in practice this shortened two-dimensional settling tube too has proved to be completely dependable. Certainly the reservoir of blood in the debubbling chamber serves as an excellent initial barrier to the passage of bubble-containing blood. Bubbles have never been seen in the middle or lower inclined planes of this oxygenator during perfusions. Only rarely have bubbles been noted in the proximal portion of the uppermost inclined plane and this only when the level of blood was extremely low in the debubbling chamber.

As a further and extreme test of the safety of this debubbling mechanism large amounts of air (300 to 400 ml.) were injected directly into the lowest inclined plane during some of the perfusions. This injected gas, each time, was observed to rise rapidly as a bolus into the debubbling chamber and was eliminated through the exhaust vent. One of the animals undergoing this test was sacrificed immediately after the perfusion and the dural vessels were examined carefully for evidence of gaseous embolization. No trace of this complication was seen.

In those animals undergoing cardiomy the blood sucked out of the open heart has been returned for use again to a reservoir inserted into the lower aspect of the oxygenator between the two sheets of polyvinyl plastic. This cardiomy sucker unit is similar to that used clinically in the helix reservoir oxygenator (Lillehei, Warden, DeWall, Adams, Ferguson, and Varco, 1957).

Sheet oxygenator units containing a built-in cardiomy reservoir chamber are soon to be available.

CLINICAL EXPERIENCE.—The Model IV sheet oxygenator has been used together with the "sigmamotor" pump for reparative intracardiac surgery in three patients (Table III). All of these patients had ventricular septal defects and pulmonary hypertension. The oxygenator functioned satisfactorily for each perfusion. The arterial saturation was 98–100%. Two of these patients are living and well. The third, an infant, succumbed 24 hours post-operatively with the clinical picture of severe respiratory distress. This baby had a pre-operative right ventricular pressure of 110/0 mm. Hg. At necropsy the ventricular septal defect had been completely and accurately closed and there was no reason to associate the use of this type of oxygenator with the fatal outcome. The more likely cause was found in the microscopic studies revealing widespread severe pulmonary arteriolar intimal proliferation. As we have indicated elsewhere (Adams, Lucas, Ferguson, and Lillehei, 1956), the successful curative management of this type of case with advanced occlusive pulmonary vascular disease remains a vexing and, to a large extent, unsolved problem.

CONCLUSIONS

A bubble oxygenator has been described which is constructed of two sheets of polyvinyl plastic, and the desired chambers and channels are delineated by a heat seal of the plastic material. This is a complete, self-contained, ready-to-use, sterile unit which will be commercially available in the U.S.A.

This latest model has resulted from research, evaluation, and development applied to several different designs. Perfusion data regarding these preliminary models have been presented briefly,

TABLE III
RESULTS IN FIRST THREE CASES OF VENTRICULAR SEPTAL DEFECT WITH PULMONARY HYPERTENSION RECEIVING DIRECT-VISION INTRACARDIAC SURGERY UTILIZING THE POLYVINYL PLASTIC SHEET OXYGENATOR*

Patient	Weight (kg.)	Direct Vision Intracardiac Procedure	Duration of Oxygenator Run (sec. min.)	Perfusion Rate (ml./min.)	Results
W. S. 2 yr.	9.8	Heart arrested with potassium citrate and polyvinyl† sponge sutured into defect for closure	26 37	600	Living and well
T. S. 1 yr.	6.4	Polyvinyl† sponge sutured into defect for closure	30 48	400	Awake and alert post-operatively but with respiratory retraction. This dyspnoea increased progressively and the patient died 24 hours post-operatively. Necropsy showed severe pulmonary arteriolar intimal proliferation. (Pre-operative right ventricular pressure was 110/0 mm. Hg, pulmonary artery not entered)
D. P. 1 yr.	7.2	Polyvinyl† sponge sutured into defect for closure	14 17	440	Living and well

* Together with the "sigmamotor" pump (Model T6S). † Ivalon, Clay Adams, Inc., New York 10, New York.

while data on the latest model have been included in greater detail.

Average values for 15 dogs undergoing total body perfusion for one hour with the latest design model of this oxygenator were as follows: Arterial oxygen saturation=96%, final arterial pH=7.48, bicarbonate deficit=8.20 mM./l., plasma haemoglobin elevation=77 mg.%, and platelet count drop=60%.

Thirteen of the 15 dogs were long-term survivals. These perfusion data compare very favourably with results gathered on our present clinical pump-oxygenator, which has been used on more than 200 patients and has served as the tested prototype for the principles of the oxygenator design presented herein. Most of these dogs were alert and walking within four hours after perfusion. None showed neurological signs of embolism or cerebral anoxia. Only one animal had any degree of excessive bleeding, and this appeared attributable to careless haemostasis.

A new pump (adjustable rotating cam principle) has also been tested and evaluated. This pump is compact, quiet, and has an output up to 4,000 ml./min.

This sheet oxygenator has been utilized in three patients for the repair of ventricular septal defects.

The perfusions in all were successful. One patient with severe pulmonary hypertension died 24 hours post-operatively. Necropsy revealed advanced intimal proliferation in the pulmonary arterioles as the cause of death.

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