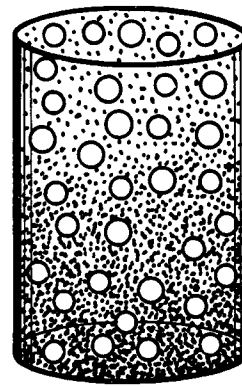


THE SINGLE-PASS DISPOSABLE OXYGENATOR

for
cardio-pulmonary
bypass



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Part of this work was supported from the grant by the
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INTRODUCTION

The ideal type of oxygenator is an apparatus which can oxygenate blood effectively without traumatizing the blood components. To achieve this, the oxygenator should not cause any turbulent flow or frothing. The conventional oxygenators, including the newest type of membrane oxygenator (1) all cause turbulent flow or frothing. The single-pass disposable oxygenator* offers a completely fresh approach to the oxygenation of extracorporeally circulated blood. There is no turbulent flow during its operation. In addition, it has minimum priming volume with maximum oxygenating capacity. This perfusion device was developed at the St. Barnabas Hospital in New York City in 1964 (2) and after major structural changes in 1968 (3) and in 1971 (4), it has finally become available in disposable form. This type of oxygenator has been tested in more than 500 clinical cases.

DESCRIPTION OF APPARATUS

The single-pass oxygenator oxygenates the blood through specially constructed tubular plastic strands. (Fig. 2) No recirculation of any part of the blood is required to oxygenate the blood. The filming mechanism is fully static and no moving parts are used either to establish or to maintain filming. There is no visible turbulence of the blood. Each full-length strand is made up of a series of alternately connected circular tubes. Exposure to oxygen occurs at the openings between the circles.

On initiation of bypass, the overall inner surface of each strand becomes lined with a film of blood. One strand measuring 5mm. in diameter and 50cm. in length fully oxygenates 20ml of blood per minute. Fifty such strands are mounted within a modular frame. (Fig 3) One frame provides an oxygenating capacity of 1000ml of blood per minute.

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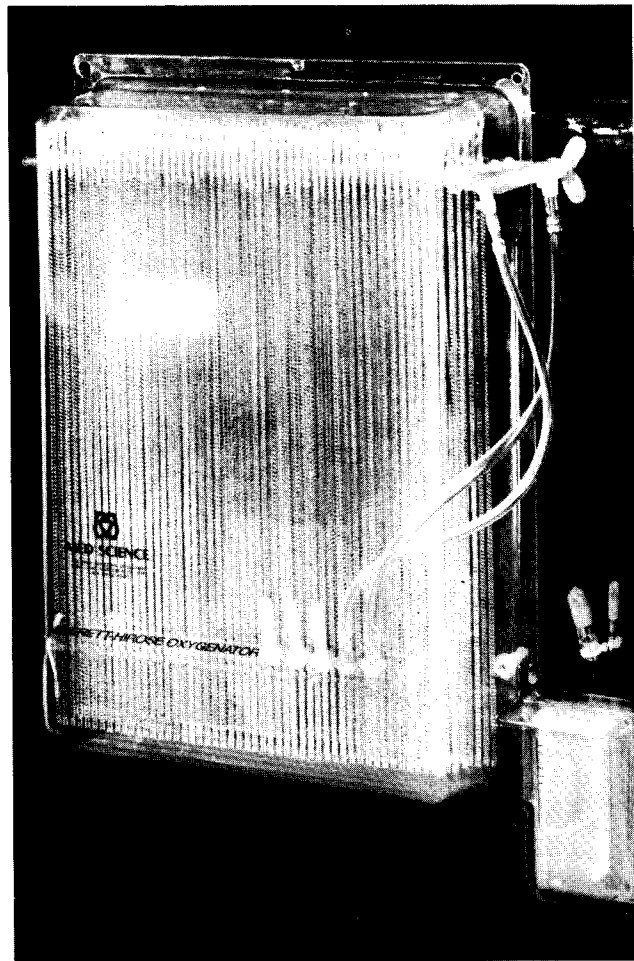


Fig. 1. Hirose-Everett single-pass disposable oxygenator, pediatric size.

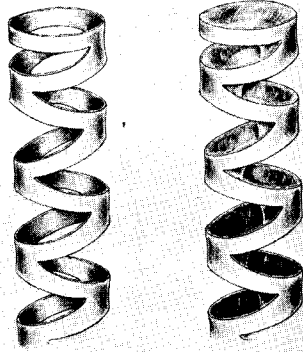


Fig. 2. The tubular strands which are formed into a series of alternately connected circles.

The oxygenating chamber holds up to 10 frames. There are three sizes, designed for the use of newborn, pediatric and adult patients. The frames are mounted in a plastic chamber and the entire unit is disposable. On initiation of bypass, frames are opened successively until full flow levels are reached. The option of switching one or more frames off or on remains available at all times. (Fig. 4)

There are two venous inlets situated high enough to permit return of blood by gravity siphonage from both venae cavae (or from the right ventricle or the pulmonary artery) to the oxygenator. The venous inflow is divided by a distributing manifold so as to supply each frame equally. The flow is then redistributed through ventricular feeder tubes, to provide for uniform, proportionate flow to the strands. Flow is through the strands to the lower part of the chamber and then into a separate arterial reservoir.

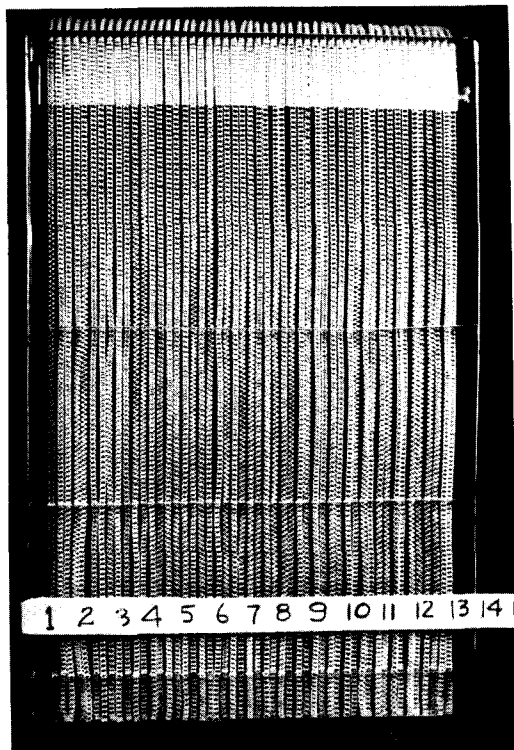


Fig. 3. Fifty open tubular strands (5mm in diameter by 47cm. in length) mounted in a frame will oxygenate 1,000ml. of human blood per minute.

A plastic filter screen is incorporated in the arterial reservoir to prevent the passage of any thrombus or fatty particles into the arterial pump. A direct contact level probe prevents dangerous loss of blood from the unit. The reservoir is also equipped with a temperature probe, transfusion fittings, and a stop-cock for samplings.

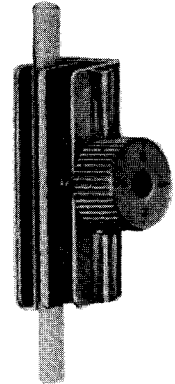
Three independently controlled low-pressure suction chambers (5) (improved Everett Auto-Flow) are integrally incorporated within the oxygenator mechanism. Each chamber has an independent control for regulation of negative pressure. Air admittance to the chambers is automatically controlled, and inflow becomes reduced to a minimum in the event that a suction tip is left openly exposed to the air. A Brown's heat exchanger (6) is usually installed in the arterial line to prevent hypothermic effect during the long bypass.

The minimum volume requirement for priming for the adult size is 400ml of fluid, which is usually buffered Ringer's lactate solution. Thus the blood requirement for priming is eliminated. To moisten a 50-strand frame 165 ml. of blood is needed. The three cardiotomy suction chambers each require 70ml. of added priming fluid; however, the suction volume, and the amount used to wet the frames, is simply obtained from the patient as bypass is commenced; it is not part of the priming volume. All of the priming fluid and wetting blood except for 50 ml. in the arterial reservoir can be returned to the patient after termination of the bypass.

EXPERIMENTAL RESULTS

Five dogs were put on extracorporeal circulation using the single-pass disposable oxygenator. The results are shown on the table. Priming of the pump was

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HARVARD APPARATUS

Circle No: 36

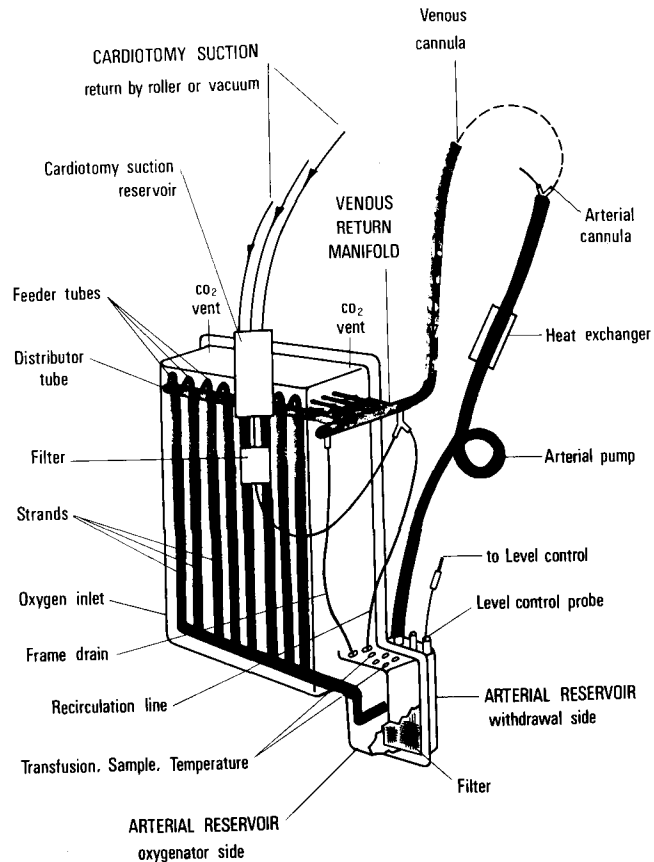
Single-Pass Oxygenator

accomplished with a volume of 280-400ml. of Ringer's lactate solution, depending on the size of the animal. Plasma hemoglobin levels did not rise more than 20mg.% after two hours of bypass time.

The oxygen saturation ranged from 90% to 100% for flows averaging 2000ml./min. The pH and pCO₂ levels were maintained without using CO₂ gas in the animal experiments. (In clinical cases 5% CO₂ with 95% O₂ was used). Blood flows ranged from 600ml./min. to 3000ml./min. (60-80 Kg. body weight) with oxygenation ranging up to 100%.

Serum sodium and potassium levels were maintained within normal limits during bypass. However, potassium levels became slightly lower due to hemodilution. S.G.O.T. and S.G.P.T. levels did not rise. The platelet and fibrinogen levels were slightly lowered but always remained at a safe level.

The body temperature was maintained at 38°C. throughout bypass in all experiments using Brown's heat exchanger. All animals survived the cardio-pulmonary pass without ill effects. Blood pressure and other vital signs remained stable throughout the procedure.



EVERETT - HIROSE OXYGENATOR

Fig. 4. Schematic drawing of a single-pass oxygenator assembly in use.

The total bypass time for the entire group of 500 cases varied from 26 minutes to 402 minutes. The bypass flow rates varied from 600 ml/minute to 7500 ml/minute. The patients ranged in age from two years to seventh-three years. Half of the 500 cases required reconstruction of the mitral or aortic valves using fascic lata.

There were no deaths attributable to the use of the oxygenator, and there were no renal complications. The authors believe that the single-pass oxygenator is superior to other types of machines for open heart surgery which requires a long bypass period.

A comparative study of blood trauma by various extracorporeal oxygenators, including the single-pass oxygenator (3), the disc oxygenator (8), and the bubble oxygenator (9) was performed in the hematology department of St. Barnabas Hospital in 1966. (7) Various tests mapped the changes which occurred in the blood components during the bypass time clearly showed that the single-pass oxygenator caused less trauma to all measurable parameters.

During the two hour period when the blood was pumped through the oxygenator, the mean drop in the platelet count was smallest in the single-pass oxygenator. In the single-pass oxygenator less than 35% of

EXPERIMENTAL RESULTS ON DISPOSABLE SINGLE-PASS OXYGENATOR

| | Pre-perfusion | One Hr. | Two Hr. | Post Perfusion |
|------------------|---------------|-----------|-----------|----------------|
| PH | 7.45 | 7.51 | 7.52 | 7.42 |
| pO ₂ | 58mmHg. | 62.0mmHg. | 63.0mmHg. | 58.0mmHg. |
| PCO ₂ | 25.3mmHg. | 27.3mmHg. | 30.5mmHg. | 31.0mmHg. |
| Hematocrit | 38.5% | 32.5% | 31.0% | 32.5% |
| Plasma Hgb. | 18mg.% | 25mg.% | 38mg.% | 46mg.% |
| Platelets | 125,000 | 70,000 | 60,000 | 50,000 |
| Fibrinogen | 380mg. | 340mg. | 310mg. | 210mg. |
| Serum K | 3.1mEq. | 2.5mEq. | 2.5mEq. | 2.8mEq. |
| Serum Na | 143mEq. | 143mEq. | 145mEq. | 148mEq. |
| SGOT | 63 units | 48 units | 54 units | 81 units |
| SGPT | 22 units | 24 units | 23 units | 24 units |

*Average values of five animal experiments with disposable single-pass oxygenator. All animals survived bypass.

DISCUSSION

More than 500 clinical cases were treated using this oxygenator. Several types of oxygenators were tried clinically prior to the invention of the single-pass oxygenator in our clinic. However, none of them produced consistently satisfactory results for a bypass time of more than two hours.

Furthermore, of the 500 cases, more than 70 cases belonged to the faith of the Jehovah's Witnesses. None of the latter received any blood transfusion before, during, or after the cardio-pulmonary bypass; among this group the mortality rate was less than 10 percent.

the platelets were destroyed in a one-hour run. The increase of the plasma hemoglobin level due to the traumatic destruction of the red cells by the oxygenators was even more impressive.

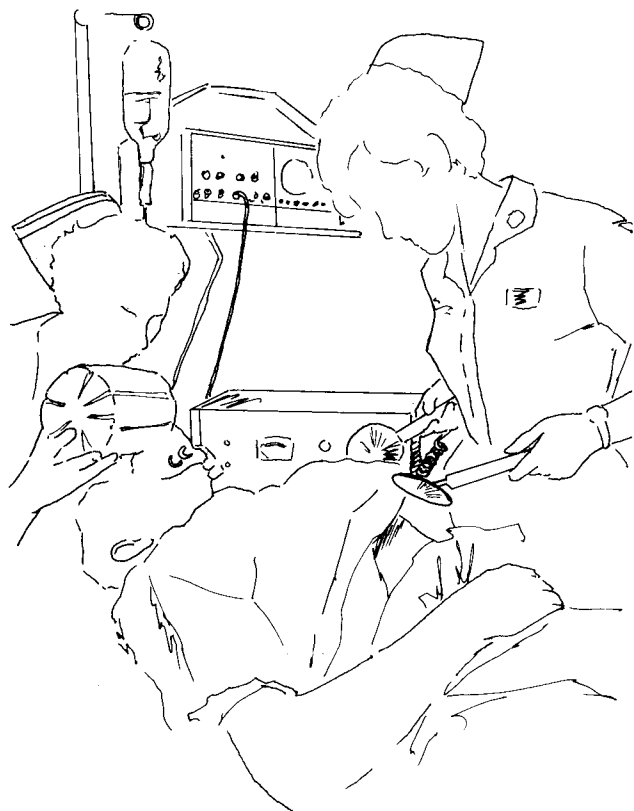
The bubble oxygenator caused an increase in the plasma hemoglobin from the 10mg% prebypass level to 100mg% after a two hour run. The use of the single-pass oxygenator resulted in only a minimal increase from the same pre-bypass level to 15 mg.% after a two hour run.

The fibrinogen level and white blood cell count showed only minimal changes when the single-pass oxygenator was used. The S.G.O.T. and the S.G.P.T. increased slightly, but remained within normal limits.

Each type of oxygenator presents certain practical disadvantages. In addition to the problem of blood trauma which occurs during its use, the disc oxygenator (8) required a high priming volume (a minimum of three liters), and its assembly is complicated and time consuming. Because it is not disposable, it must be cleaned and reassembled after each use.

The bubble oxygenator is disposable. (9) However, the bubbles of oxygen create turbulent frothing of the blood during bypass, and an antifoam agent is required to obviate the possibility of air embolism. Because of the possibility of a minute air embolism, and because of the high degree of blood trauma which occurs during the bypass, this oxygenator is safe only for short-term cardio-pulmonary bypass.

Sheet and screen oxygenators (10) are very expensive, complicated structures. Special provision must be made to establish filming in the initial period of the bypass, and the blood must be recirculated. Therefore, a large quantity of blood (5 liters) is required. In addition, the apparatus itself occupies a great deal of space.



The inventors claim that the membranous oxygenator (1) is superior to the other existing oxygenators. However, the assembly of this machine is complicated, and turbulent flow through the tight membrane sheets causes a significant amount of cellular destruction of the blood during the bypass. A large amount of blood (three liters) for priming is necessary, and there is always the danger of leakage of the blood or gas through a faulty membrane during the bypass.

The single-pass oxygenator is simply constructed. It is disposable and inexpensive. In addition, blood components show only slight denaturing during a long cardio-pulmonary bypass period.

SUMMARY AND CONCLUSION

The new Everett-Hirose disposable single-pass oxygenator films blood efficiently and with minimum turbulence. The required priming volume is small (400 ml.) No moving or manually operated parts are needed to establish or to maintain filming. No recirculation of blood is required to achieve proper pO_2 and CO_2 levels.

Filming can be started or stopped at will. Venous blood is returned to the oxygenator from the patient by gravity siphonage and is divided to flow equally through a variable number of open tubular strands. Fully oxygenated blood passes by gravity from the strands onto the surface of a collecting chamber which serves as an arterial reservoir.

This oxygenator will permit flows within any practical limit (300ml. to 8,000ml. per minute). The oxygenating capacity can be changed at will even during use. Practically all the extracorporeal blood can be recovered for return to the patient. This oxygenator has been used in 500 consecutive human cases with minimum destruction of blood components and with no overt clinical disadvantage.

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