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STUDIES ON MULTILAYER MEMBRANE ARTIFICIAL LUNG

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ABSTRACT

Studies were carried out to devise a new multilayer membrane artifiilal lung. It was determined from the present studies on flow patterns and dye clearance that the basic design of the multilayer membrane artificial lung should have one-inlet and one-outlet and be elliptic in shape. Many little projections were made on both surfaces of a distributing mat in order to support membranes and to give turbulences to the flowing blood. Distance between two membranes or the thickness of the blood layer was determined to be 0.8-0.9 mm. Fifty Hs silicon rubber was used as material for the distributing mats in order to prevent blood leakage from between the membranes.

Silicon rubber membrane and Teflon membrane were investigated for gas permeability by using a model of the elliptic artificial lung and a model of the Peirce-Galletti's artificial lung. Nineteen mongrel dogs were subjected to the studies. Phycon membrane or silicon rubber membrane, made in Japan, showed an excellent gas exchange capability and proved to be the best membrane now available.

One unit of the artificial lung comprises two mats and two membranes, having an oxygenating surface area of 1540 cm^2. This elliptic membrane artificial lung with a stack of ten oxygenating units has approximately 60 ml/min of oxygen uptake when Phycon membrane is used, and can be applied to total cardio-pulmonary bypass for infants and small children.

INTRODUCTION

Recently cardiac surgery has remarkablly progressed and many patients are enjoying a better life, having successfully been operated on open heart surgery. At the First Department of Surgery, School of Medicine, Nagoya University many cardiac surgeries, including such difficult surgeries as the radical operation of Tetralogy of Fallot or valve replacement, have been carried out with the aid of either simple hypothermia[1)2)3)], or normothermic[4)5)6)7)] or hypothermic cardiopulmonary bypass[8)9)].

Although such oxygenators as of bubble, disc and screen types are popular and widely used, they have a disadvantage of having a raw blood-gas interface. Blood destruction, denaturation of plasma proteins[10)-15)], disturbance of coloidal

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fat[16], solid or gaseous embolization[16] and so on are the results of a raw blood-gas interface and cause various post-perfusion syndromes[13].

To minimize this disadvantage by protecting blood from direct contact with gaseous oxygen as is naturally done in the gill and lung, a search for a membrane artificial lung has been pursued, especially in U.S.A.

The membrane artificial lung has a characteristic that the membrane separates the gas and fluid phases into distinct compartments. Therefore, the lung has no blood-gas interface, no contamination with open air and maintains a constant volume of blood. It is with this characteristic that the membrane artificial lung is superior to other types of gas exchange devices in clinical use[17)-21)].

There are several types of membrane artificial lung heretofore devised. One of them is the Kolff's membrane oxygenator[22] invented in 1956, which flows blood through thin gas permeable polyethylene tubings which serve as membranes. An oxygenator proposed by Clowes[23] in 1956 is provided with multilayered oxygenating units, one of the units consisting of two plastic membrane layers between which blood flows in the state of a thin film while oxygen flows outside the membranes. Thomas (1958)[24,25] pioneered another method for blood oxgenation across membranes. Blood was spread on one side of a silicon-coated nylon mesh while on the other side a mist of oxygenated, buffered saline provided a thin layer of liquid saturated with oxygen. Lewis, *et al.* (1958)[26] proposed a stretched plastic bag as a membrane oxygenator. Blood flowed in the state of a thin film in a bag which is encased in an oxygen-filled box. Peirce (1960)[20] reported to have made a modification of the Clowes oxygenator, which was somewhat simpler, easier to assemble and much less expensive.

The most important parts in these oxygenators are the membrane and its supporting mechanism. As gas diffusion across a membrane depends upon the nature, thickness and surface of the membrane[25], the membrane with sufficient gas permeability should be used for clinical application. Moreover, the membrane should have the strength not to be broken or torn during assembling or while it is used.

It is desirable that the supporting mechanism meet the following conditions;

1) There should be no blood leakage.
2) The blood layer should be as thin as possible.
3) Even blood distribution should be obtained.
4) The hemodynamic resistance should be small.
5) The priming volume should be small.
6) The oxygenator should be portable and autoclavable.

Blood leakage, blood distribution, blood layer, hemodynamic resistance and priming volume could be controlled by means of the materials, shape and structure of the mechanism.

A new type of a multilayer membrane artificial lung for silicon rubber membrane has been developed in our department. In the determination of its design, the Peirce's modification of the Clowes membrane oxygenator was referred to regarding an excellent oxygenating capability, simple construction and low costs.

The newly devised multilayer membrane artificial lung is constructed by stacking the units, one of which consists of two distributing mats and two sheets of membrane inserted between them. Blood is made to flow between two sheets of membrane in a state of a thin layer set by the supporting mechanism, while oxygen is made to flow outside the membrane. The stacked units are compressed from the upper and lower frames by means of clamps so as to have no blood leakage from between the membranes.

The efficiency of the membrane artificial lung is determined by the membrane and its supporting mat. In order to develop a new membrane artificial lung, basic studies were carried out for designing the distributing mat. Flow patterns and dye clearance were investigated for the purpose of obtaining even blood distribution. For determining the material of the mats, a study was made on the relation between the hardness, compressibility of the material and blood leakage. A study was also carried out on gas permeability of silicon rubber and Teflon membranes.

This paper aims at reporting the studies made on the multilayer membrane artificial lung, especially on the basic design of its distributing mat and the gas permeability of the membrane.

MATERIALS AND METHODS

I) On Basic Design of Distributing Mat

Six cells made of transparent acryl plate in three different shapes, that is, two round, two square and two rectangular cells were used for this study. In one of the round cells is made an inlet on one end of its diameter and an outlet on the other end, and in the other one of the round cells are made an inlet in its center and an outlet on each end of the diameter. In one of the square cells is made an inlet near one of the corners and an outlet near the corner positioned diagonally to it, and in the other one of the square cells are made an inlet in the center and an outlet near each end of the diagonally positioned corners. Two rectangular cells are also provided with inlets and outlets in the same manner as the square cells. Each cell is 400 cm^2 in area and 0.1 cm in thickness.

Each cell was first filled with undyed water. Dyed water was then flowed into the cell through its inlet and was taken out of it through one outlet or two outlets, so that the flow pattern of the dyed water was made visible in an excellent contrast to the undyed water. The flow pattern of the dyed water in the cell was photographed and analyzed.

Dye clearance was investigated at the same cells. Each cell was filled with water to which was added a definite amount of dye. Then, water was put into this dyed water in the cell, so that the diluted dyed water came out of the cell. The ratio of the dye in the diluted dyed water to the total amount of the dye used was measured by a Beckman's Spectro-Colorimeter.

A cell was divided into two compartments by a distended membrane for making a study on blood layer and oxygenation. The blood was made to flow at a rate of 150 ml/sec into one of the compartments which was 400 cm^2 in area and 0.1 cm. in thickness. Oxygen was flowed in the other compartment. The oxygenated blood was taken for determining its oxygen saturation.

As silicon rubber was to be used as the material of the distributing mat, it was tested on its compressibility. Ten discs of doughnut shape, 68 mm in outer diameter, 30 mm in inner diameter and approximately 5 mm in thickness, were piled and two sheets of membrane of the same shape were inserted between the discs. A metal plate was placed on each end of the pile and was made to compress the pile by three screws, as illustrated in Fig. 1. Air was compressed into the space within the pile and the air pressure in the space was checked up with a mercury manometer.

While applying pressures of 30, 60, 90, . . . , 200 mmHg in succession, the round plates were pressed from both ends by means of screw clamping to the degree in which no leakage occurs at the particular pressures, and compressi-

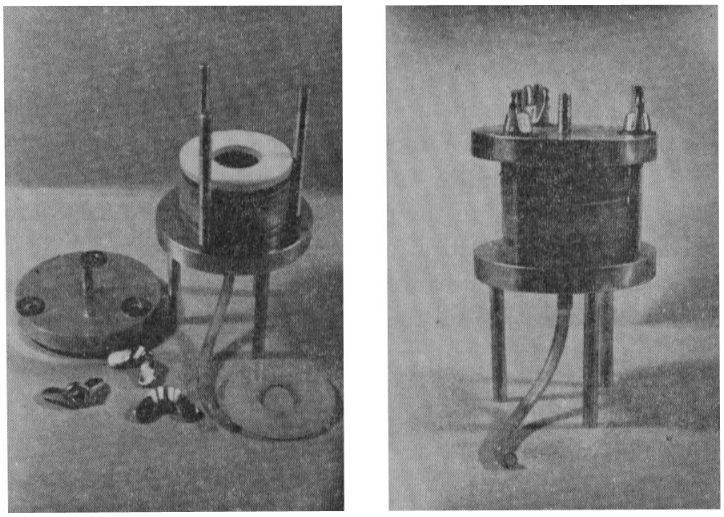

FIG. 1. Apparatus for leak test.

bility of the silicon rubber pile then was observed.

II) On Membranes and Gas Diffusion

A model of an elliptic artificial lung was constructed for the studies on memdrane and gas diffusion (Fig. 2). This lung consists of a pair of supporting plates and mats in which were placed two sheets of membrane with an oxygenating area of 350 cm^2. Blood was flowed between two sheets of membrane and was arterialized with oxygen which was flowed outside the membrane between a supporting mat and a membrane.

A model of the artificial lung eqnipped with a pair of the Peirce and Galletti's supporting mat twice as large as the elliptic lung on the membrane surface area was made for the same purpose (Fig. 3).

Nineteen mongrel dogs weighing between 10 and 15 kg of both sexes were used for the study (Table 1). The animals were anesthetized with a dose of

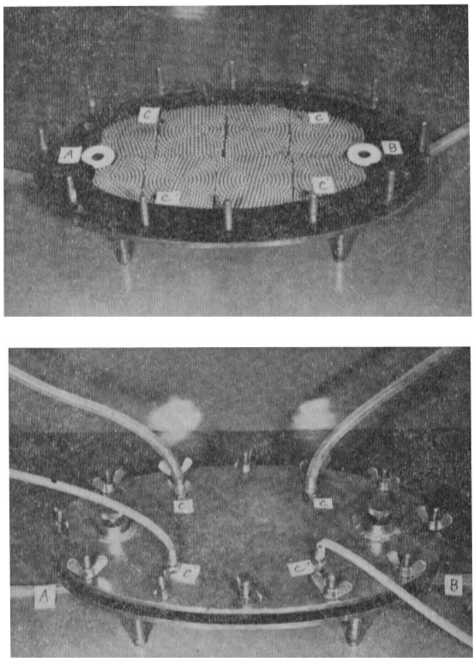

FIG. 2

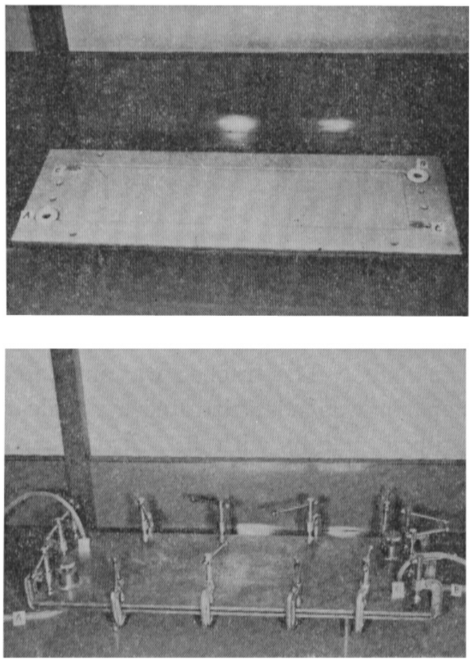

FIG 3

FIG. 2. Elliptic type of membrane artificial lung model (inside and outside).
A. Blood inlet B. Blood outlet
C. Gas inlet C'. Gas outlet

FIG. 3. Peirce-Galletti's type of membrane artificial lung model (inside and outside).
A. Blood inlet B. Blood outlet
C. Gas inlet C'. Gas ontlet

TABLE 1. Number of investigations on various membranes by using dogs and elliptic and Peirce Galletti's types of artificial lung models

	Elliptic type	Peirce-Galletti's type
Teflon membrane	2	2
Silastic membrane	2	
Phycon membrane No. 1	2	
Phrcon membrane No. 2	3	
Phycon membrane No. 3	3	5

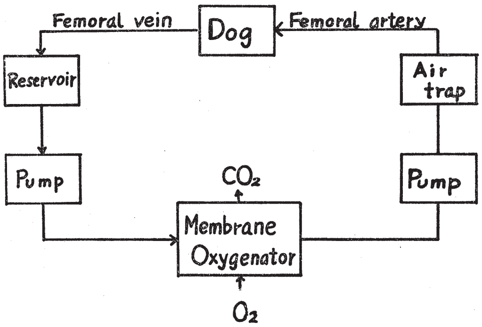

FIG. 4. Block diagram for experimental perfusion.

20 mg/kg of Isozol, sodium 5-allyl-5 (1-methyl-butyl)-2-thiobarbiturate, intravenously. The trachea was intubated or not intubated. A 2.0-3.0 mg/kg of heparin was administrated systemically. The apparatus and its circuit were primed mainly with 5% dextrose solution in water. Cannulations into the vena cava and the femoral artery were done. The blood was withdrawn through the vena cava into a blood reservoir by gravity and was sent by means of a roller pump to the artificial lung, where the blood was oxygenated through membranes. The arterialized blood was reserved in the other reservoir and air-trap, and was sent back to the animal through the femoral artery by means of a roller pump (Fig. 4). The venous blood was sampled just before the artificial lung and the oxygenated blood was sampled near the outlet of the artificial lung. Gas analysis was made by Van Slyke-Neill method[27]. PO_2 was measured by an Astrap micro-equipment. pH was measured by a Metrohm glass pole pH-meter and PCO_2 was read from the Singer-Hasting nomogram[23]. Hematocrit was also measured. Gas permeability of the membrane was calculated by the differences of the content of oxygen and carbon dioxide between the venous blood and the oxygenated blood.

The membranes used for this study are Teflon (tetrafluoroethylene) 1/3 mil in thickness made by Dilextrix Corp., U.S.A. and silicon rubber membrane, or Silastic membrane 3 mil in thickness made by Dow Corning Co., Ltd., U.S.A., and silicon rubber membrane made by Fuji Polymer Industries Co., Ltd., Japan. The silicon rubber membrane of Fuji Polymer Industries Co., Ltd. is named Phycon membrane. Phycon membrane is made of silicon rubber covered nylon mesh and is classified into three kinds by its thickness. Although the thickness is irregular from part to part, one approximately 85 in thickness is named Phycon membrane No. 1. Phycon membrane No. 2 is about 95 in thickness and Phycon No. 3 110.

RESULTS

I) On Basic Design of Distibuting Mat

Fig. 5. shows the flow patterns of the three different shapes with one inlet and one outlet at a flow rate of 150 ml/sec. These patterns indicate that water flows mostly in the middle of the cell and stagnates at the circumference. Various flow patterns at a flow rate of 100-200 ml/min showed almost the same results.

Dye clearance for these cells was the best with the rectangular cell, the second with the square cell and the worst with the round cell. The cells with one inlet and two outlets proved to have worse flow patterns and dye clearance than those with one inlet and one outlet.

With a larger cell, it was found that the dyed water flowed in the form of an ellipse 2:1 in diameters in it. Better flow and dy eclearance were obtained by the elliptic cell 2:1 in diameters (Fig. 6).

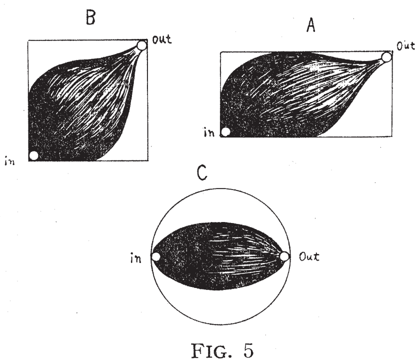

FIG. 5

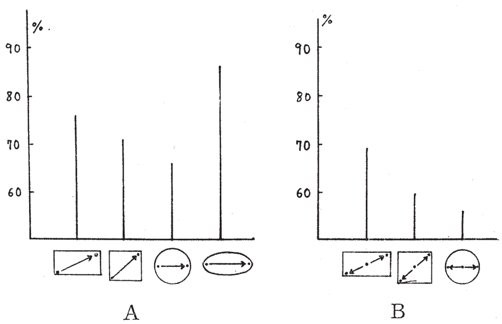

FIG. 6

FIG. 5. Flow patterns made when dyed water is flowed at 150 ml/sec into cells 400 cm² in area, 0.1 cm in thickness.

A. Rectangular B. Square C. Round

FIG. 6. Dye clearance for various cells, A for one inlet-one outlet type, and B for one inlet-2 outlet type.

TABLE 2. Relations between compressed thickness of stack 56 mm ino riginal thickness and pressures causing no leakage

Original thickness of "Stack"	56 mm				
Compressed thickness of "Stack"	52 mm	50	49	48	46
Pressure of no leakage	30 mmHg	60	90	150	200

When blood was actually made to flow at a flow rate of 150 ml into a compartment of 400 cm^2 in area, 1 mm in thickness and to contact with oxygen through a membrane, its oxygen saturation was over 90%.

Table 2 shows the relations between the compressibility of 50 Hs silicon rubber and the maximum pressure with no air leakage.

When a silicon rubber of 50 Hs was used and the utmost pressure of an ordinary man was applied, there was no leakage even if air was sent in under a pressure of 200 mmHg upward. Before compression the silicon rubber pile was 56 mm thick approximately, but when compressed it was 46 mm thick or its thickness was four fifths of the original. When a pressure of 30 to 60 mmHg was applied and the silicon rubber pile was compressed by one tenth approximately, no leakage was observed.

Test was also conducted in the same manner with a silicon rubber of 55 Hs and the result indicated that there is more leakage with it than with that of 50 Hs.

II) On Membranes and Gas Difiusion

Table 1 shows the number of experiments made on the membrane by means of the elliptic model of artificial lung and the Peirce-Galletti's model. The membrane once used was disposed of. Gas permeability of the membranes is shown in Table 3 and Table 4.

a) O_2 Diffusion

The rates of oxygen diffusion through the various membranes were compared by the following formula:

$$\text{ml. } O_2 \text{ diffusion/m}^2 \text{ surface area/min} = \frac{O_2 \text{ content (Vols\%)} \times \text{Volume blood} \times 100}{\text{Surface area membrane (cm}^2) \times \Delta T \text{ (min)}}$$

As shown in Fig. 7, the rate of oxygen diffusion in the elliptic model of artificial lung was 18 ml/m^2/min with the Teflon membrane, 28 ml/m^2/min with the Silastic membrane of Dow Corning Co., Ltd., 71 ml/m^2/min with

TABLE 3. Gas diffusion through various membranes in elliptic type of membrane artificial lung model

	Dog No.	PO_2 A-V	PCO_2 V-A	O_2 Vol% A-V	O_2 diffusion $ml/m^2/min$	CO_2 Vol% V-A	CO_2 diffusion $ml/m^2/min$
Teflon membrane	1	20		1.5	18	0.5	6
	2	10	3	1.5	18	0	0
Silastic membrane	3	40		1.4	17	1.0	12
	4	90		3.1	38	3.6	43
Phycon membrane No. 1	5	21	6	4.8	58	3.9	47
	6			6.8	83	3.2	38
Phycon membrane No. 2	7			1.9	34	5.7	99
	8	21	2	1.9	34	4.5	79
	9			2.3	53	1.0	23
Phycon memdrane No. 3	10	36	6	2.9	35	6.0	72
	11	58	1	2.8	34	0.5	6
	12	28	4	2.8	34	2.0	24

TABLE 4. Gas diffusion through various membranes in Peirce-Galletti's type of membrane artificial lung model

	Dog No.	PO_2 A-V	PCO_2 V-A	O_2 Vol% A-V	O_2 diffusion $ml/m^2/min$	CO_2 Vol% V-A	CO_2 diffusion $ml/m^2/min$
Teflon membrane	13	15	3	2.4	29	0	0
	14	9	3	1.7	20	0	0
Phycon membrane No. 3	15			1.0	12	0.5	6
	16	20	7	5.2	63	2.1	23
	17			3.4	41	1.5	18
	18	32	12	2.3	28	0.2	2
	19	12	4	5.3	65	5.2	61

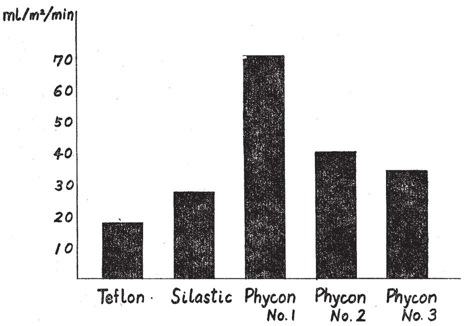

FIG. 7

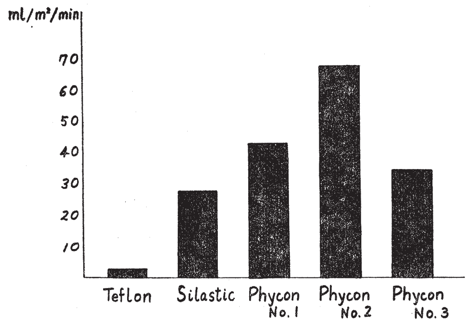

FIG. 8

FIG. 7. Average O_2 diffusion through various membranes in elliptic type of membrane artificial lung model.

FIG. 8. Average CO_2 diffusion through various membranes in an elliptic type of membrane artificial lung model.

Phycon membrane No. 1, 40 ml/m^2/min with Phycon membrane No. 2 and 34 ml/m^2/min with Phycon membrane No. 3. Phycon membrane No. 3 exhibited a better ability for diffusing oxygen (42 ml/m^2/min) than the Teflon membrane (24.5 ml/m^2/min), in the Peirce-Galletti's model.

b) CO_2 diffusion

The average rate of carbon dioxide diffusion through the membranes is shown in Fig. 8. In the elliptic artificial lung, carbon dioxide diffuses at the rate of 3 ml/m^2/min through the Teflon membrane, 27.5 ml/m^2/min through the Silastic membrane made by Dow Corning Co. Ltd., 42.5 ml/m^2/min through Phycon membrane No. 1, 64 ml/m^2/min through Phycon membrane No. 2 and 24 ml/m^2/min through Phycon membrane No. 3.

In the Peirce-Galletti's membrane lung, the diffusion rate of carbon dioxide was 22ml/m^2/min tnrough Phycon membrane No. 3, while carbon dioxide did not diffuse through the Teflon membrane.

c) P_{O_2}

The Silastic membrane of Dow Corning Co. Ltd. showed the largest P_{O_2} difference of 65 between the venous blood and the arteriallzed blood, while the Teflon membrane showed the smallest P_{O_2} difference of 13. Phycon membrane No. 3 revealed 31 of P_{CO_2} difference and the other two of Phycon membrane showed 21.

d) P_{CO_2}

P_{CO_2} difference between the venous blood and the oxygenated blood was 6 with Phycon membranes and 3 with the Teflon membrane.

DISCUSSION

With a membrane artificial lung, blood flows into it from an inlet or inlets, and comes ont of it from an outlet or outlets. But it was supposed as a matter of course that the more inlets and outlets were made, the more complex the design and the set-up would be and the more chance of blood leak would be made. Therefore, it was required for simplification of the set-up to reduce the inlets and outlets as much as possible.

Bramson and others made a round distributing mat[29] provided with an ilnet at its center and 4 outlets near its periphery. In our research, however, efforts were made for devising a one inlet-one or two outlet system owing to reasons stated above. As the results, our study indicated that one inlet-one outlet system was superior to one inlet-two outlet system with regard to dye clearance, the former system was adopted.

In the cases of round, square and rectangular cells on the one inlet-one outlet system, flow was comparatively more in the middle part, indicating a spindle elliptic pattern, but outside the pattern flow stagnated, making it impossible to obtain a satisfactory flow pattern. However, the elliptic cell of 2 to 1 in diameters on the one inlet-one outlet system gave a flow pattern which showed a fairly good dye clearance, and so an elliptic shape of 2:1 in diameters was adopted for the basic form of the new membrane artificial lung.

The Peirce-Galletti's membrane artificial lung[15] has a rectangular distributing mat provided with one inlet and one outlet. The mat has a groove on each of its sides. The blood flowed in from the inlet is first stored in one of the grooves, then flows across the surface area into the other groove, and finally goes out through the outlet. Thus, the blood flows at the right angles along the grooves, resulting in decreased dead areas. But with this system the blood flows only a small distance, and so it may be that the blood gets contact with O_2 for a rather too short time.

Peirce-Galletti's idea is excellent, and it seems their idea should be adopted and further improved for devising a distributing mat which makes blood contact with O_2 in a better manner.

Thus, basic design was determined for the new membrane artificial lung which is now being developed at the University of Nagoya.

An erythrocyte is fully oxygenated when it is exposed to oxrgen for 0.1-0.1 second at 100 mmHg of PO_2. In order to gain excellent oxygenation in the membrane lung, an erythrocyte should be exposed to the oxygenating area as much as possible. Although it is desirable that the blood layer be as thin as possible, resistance to flow increases according to thinning of the layer, making it impossible to obtain an adequate flow rate for perfusion. In order to resolve this problem, the blood layer of such a thickness as flows with low resistance should be determined for successful oxygenation. For this purpose, raising the oxygen pressure would be a useful method[30]. Mixing the blood by turbulences is another useful method. Turbulences of the blood can be caused by means of many little projections on the surface of the distributing mat.

The study indicates that when the blood layer is designed to be 0.1 cm thick the most favorable oxygenation will be obtained by means of the distributing mat with many little projections and high oxygen pressure.

It is an important matter to determine the material of the distributing mat. In view of silicon rubber having a comparatively large durability and showing less leakage due to its adaptability to the film, it was temporarily chosen for the material of the distributing mat, and leak test was made to see whether it could actually be used or not.

With silicon rubber of 50 Hs no leakage was indicated if ordinary pressure below 60 mmHg was applied to it. Especially, when the mat was compressed to 9/10-4/5, even a pressure of 200 mmHg did not cause any leaks. Thus, it was ascertained that silicon rubber could be used for the mat.

As a general rule, three factors are involved in the passage of gas across a membrane: the nature of gas, the degree of hydration of membrane, or wettability, which strongly influences the degree of solubility of gas[31] in the membrane, and the gas tension difference between the two sides of the membrane. In the case of a membrane artificial lung, since pure oxygen is used in the gas phase and since the partial pressure of CO_2 in blood should not exceed 50 mmHg, a ratio of at least 12:1 exists in favor of O_2 in terms of pressure gradient. To counteract the partial pressure ratio and insure an equal transmission of CO_2 and O_2 the membrane should be 12 times more permeable to CO_2 than to O_2. Only then a gas exchange ratio of one can be maintained. Most synthetic membranes are only four to five times more permeable to CO_2 than to O_2[31][32][33] and this is insufficient for the transfer of equal volumes of O_2 and CO_2.

To develop a membrane with a sufficient gas permeability was the most important matter for the study of the membrane artificial lung. To find out a membrane with an excellent gas permeability and of strength not to be pinholed or torn during assembling or while it is used, many kinds of membrane were investigated[23][31][32]. They were ethylcellulose, polyvinylchloride, polystyren, polyester, nylon, tetrafluoroethylene (Teflon) and so on. Many of them proved to be unsatisfactory to meet the conditions. But Teflon was once considered to be the best membrane available[31][34][35] for clinical use, because it provided a good oxygen permeability and the advantage of giving minimal traumatization and denaturation to blood, not absorbing fatty acids and other blood components as did polyethylene and cellophane. It was believed that silicon rubber would eventually supersede Teflon for gas exchange[36]. Peirce[37] reported that silicon membrane appeared about 40 times more permeable to oxygen and 81 times more permeable to carbon dioxide than Teflon membrane of the same thickness.

In our studies on membrane, silicon rubber membrane, especially Phycon membrane No. 1 and No. 2, showed an excellent oxygen and carbon dioxide permeability as written in the results and maintained transmission of equal volumes of O_2 and CO_2 on the whole, while Teflon showed less oxygen permeability and transmission of unequal volumes of O_2 and CO_2. Phycon membrane is moderate in P_{CO_2} reduction and so there is no problem with it. Even if its P_{CO_2} reduction is low, the matter should not be taken so seriously. With the use of buffer amine, tris (hydroxymethyl) amino-methane, which acts as hydrogen ion acceptor from carbonic acid, CO_2 and PH can easily be controlled even with total CO_2 retention[33]. So, Phycon membrane can be considered to be the best membrane now available. Phycon membrane is made of silicon rubber spread on a nylon mesh. Weaving a nylon mesh and spreading silicon rubber on it greatly affect the strength and gas permeability of the membrane. As present membranes used in the study are unevenly spread silicon rubber, thickness of the membranes is different from part to part. This will be the cause of the tiny perforations in the membrane and unsatisfactory gas exchange. It is for tiny perforations that Phycon membrane No. 1, the thinnest of three, cannot be used in spite of its excellent gas exchange. As to these matters, research should be continued in cooperation with the manufacturer.

When efficiency of the elliptic type is compared with that of the Peirce-Galletti's type, the former is superior to the latter on CO_2 diffusion while the latter to the former on O_2 diffusion. Consequently, it is impossible to determine which is superior. But the elliptic type diffuses CO_2 well and exchanges gas in an almost ideal 1 to 1 ratio. So, the elliptic type is superior or at least equal to the Peirce-Galletti's type, fully qualifying itself for the intended use.

The supporting mechanism is important for successfully manufacturing the membrane artificial lung, and especially the design of the blood distributing mat, which is one of the parts of the supporting mechanism, is the most important since this will determine the effectiveness of the membrane artificial lung.

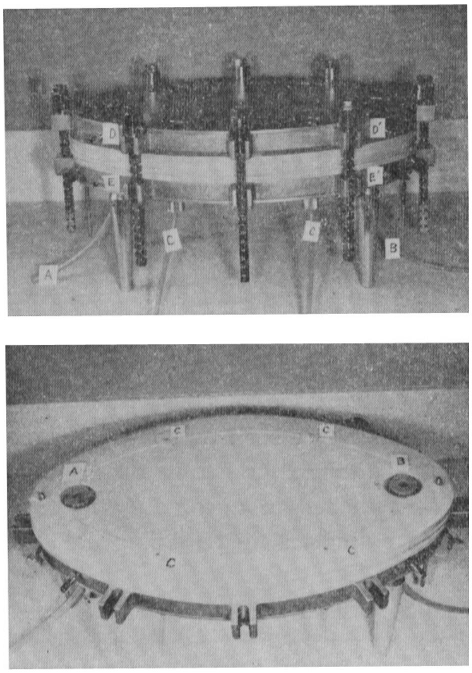

FIG. 9. The assembled apparatus and distributing mats of elliptic multilayer membrane artificial lung.

A. Blood inlet
B. Blood outlet
C. Gas inlet and outlet
E., D.) Inlet to water jacket
D'., E'.) Outlet from water jacket

In manufacturing the new type membrane artificial lung, studies were made on a variety of its designs. According to the results obtained thereby, it was determined that the design of the blood distributing mat should be of silicon rubber 50 Hs, elliptic in shape 2 to 1 in diameters, and on a one-inlet one-outlet system for simplifying its mechanism. Cares were also taken of the new artificial lung to be handy and capable of being sterilized by the gas sterilizer equipped in the present Surgery Department of the University of Nagoya. Consequently, the surface area of the elliptic blood distributing mat was made to be 45 cm in long diameter and 22.5 cm in short diameter (Fig. 9).

Many projections were made on both surfaces of the mat. These projections cause the membrane applied on them to wave, so that turbulences are made in the flowing blood. Consequently, the blood is thoroughly mixed and gets contact with oxygen more sufficiently. Furthermore, the projections prevent the film from being pressed and stuck to the mat by the pressure of the flowing blood, and thus also prevent the oxygenating area from decreasing[39)40)].

Each of these projections is a cone 1 mm of high and 1 mm in bottom diameter. The distance between the cone tops is 2 mm and the distance between the bottom surfaces of the cones is 1 mm. In order to protect a weak silicon rubber membrane put on it, the top of the cone is slightly rounded.

An arrangement is made so that blood of 1 mm thick will flow in the space between two membranes put on two mats. Actually, however, a blood layer of 0.8-0 9 mm thick flows due to the mats being compressed by the metal plates on both upper and lower ends for preventing blood leakage from between the membranes.

A round hole is made as a distributing port at each of the two ends of the mat, and a distributing disc is put in it. The mat is pressed on its peripheral part, and this part is made wide so that it will have enough packing effects-4 cm at each end of the long diameter, 3.7 cm at each end of the short diameter, and 6.0 cm at its widest. And this packing part is provided with two inlets and two outlets of oxygen.

One unit of the membrane lung comprises two mats and two membranes, the latter being inserted between the former. The oxygenating area of a membrane is 770 cm^2 and that of one unit 1540 cm^2. Consequently, 7 units or 14 membranes are sufficient for obtaining 1 m^2 of an oxygenating area.

Made of silicon rubber, the distributing disc is provided with a blood flowing hole at its center. From this hole are made 6 holes in a radial manner toward the circumference. The distributing discs are used for distributing the blood into the proper spaces between the membranes in the "stack" that constitutes an assembly. The discs are stacked in a column, and they interdigitate with the membranes, forming a cylindrical distribution manifold acceptable for blood.

The stacked mats and membranes are compressed from the upper and lower frames by means of frame clamps.

Made of a stainless casting, the upper frame contains disc clamps and thrust bearings for compressing the discs for preventing leakage from between the discs and the membrane, and a water jacket integral with the frame for accepting a warming fluid when necessary.

The lower frame is also a casting which contains supporting legs for the entire unit, tubing connectors which communicate with the distribution manifolds when they are assembled, guide pins, and a water jacket integral with the frame.

Fig. 9 shows the assembled apparatus.

The apparatus has 1.54 m^2 of an oxygenating area when 10 units are employed, so it will have approximately 60 ml/min of oxygen uptake when Phycon membrane with 40 ml/m^2/min of oxygen diffusion is used. When this membrane artificial lung proves to display fully its oxygenating ability, it can be applied to total cardiopulmonary bypass for infants and small children.

SUMMARY

An elliptic multilayer artificial lung was devised in our department. This apparatus consists of membrane, blood distributing mats and frames. In order to determine the design, the present studies were carried out. Experimental data obtained from the studies were analyzed, discussed and summarized as follows:

A) A blood distributing mat should:

1) Have one inlet and one outlet;
2) Be elliptic in shape of 2 to 1 in diameters;
3) Have many little projections on both surfaces;
4) Form a blood layer of 0.8-0.9 mm thiek; and
5) Be made of 50 Hs silicon rubber.

B) The membrane for clinical use is Phycon membrane (Silicon rubber membrane made in Japan).

C) One unit of the membrane artificial lung comprises two mats and two membranes, having an oxygenating surface area of 1540 cm^2.

D) This apparatus can be used for total cardiopulmonary bypass in infants and small children.

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