Clinical Experience with the Shiley S-100 Disposable Blood Oxygenator

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ABSTRACT

The Shiley S-100 oxygenator with an integral heat exchanger is described and data from 180 perfusions in adult patients analyzed. The oxygenator produces satisfactory pO_2 and pCO_2 values with a mean gas flow/blood flow ratio of 0.87. The platelet counts following perfusion were reduced by only 40% of the pre-perfusion levels. The mean value of plasma free hemoglobin was 26.2 mg/100 ml/60 minutes of bypass. The performance of the heat exchanger was investigated in 44 patients. The mean cooling and rewarming times (from 36.5 to 29.6°C and from 29.6 to 37°C) were 0.9 and 2.2 minutes for each degree of temperature per m^2 surface area respectively. There have been neither mechanical-hydraulic problems with this unit during perfusion nor oxygenator related morbidity or mortality in the entire series of patients.

INTRODUCTION

During the last few years a considerable amount of research has been carried out towards the development of new types of oxygenators which would produce optimal oxygen (O_2) and carbon dioxide (CO_2) concentrations with minimal trauma to blood constituents.

Laboratory and clinical data seem to indicate that membrane types of oxygenators have theoretical advantages.[1-4] However, at present, several factors such as bulk and difficulty of assembly, cost, and lack of real proven advantages for routine operations, limit their practical use and widespread clinical application. Therefore attempts at further improvement of the present generation of bubble oxygenators seem fully justified.

DESCRIPTION OF THE OXYGENATOR

The model S-100 Shiley oxygenator* has a compact body composed of 2 cylinders (Figure 1). The gas inlet (1) is connected to the base of the smaller cylinder; the gas is dispersed through the blood by a gas sparger (2) made from epoxy bonded glass beads (Tegraglas).† The blood and gas mixture then passes through an open-cell porous sponge (3) whose pore size (10 pore/in.) and thickness have been chosen to optimize the exchange of oxygen and carbon dioxide. The sponge induces laminar mixing. Defoaming takes place in a reticulated polyurethane sponge (4) with Dow Corning** antifoam A compound.

* Shiley Laboratories, Inc., Irvine, California.
† 3M Corp., Minneapolis, Minnesota.
** Dow Corning, Midland, Michigan.

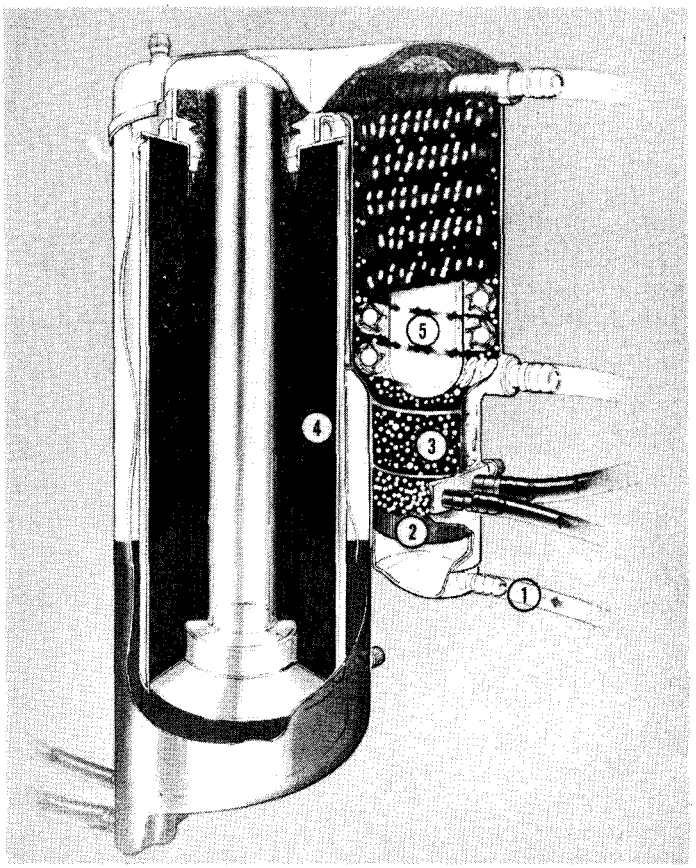

Figure 1. The Shiley S-100 Disposable Blood Oxygenator.

A nylon tricot cloth surrounding the defoaming sponge provides a final filtration of the blood entering the arterial reservoir. The heat exchanger (5) is an integral part of the oxygenator. It is comprised of a helically coiled and axially twisted aluminum tube, coated with polyurethane and placed above the open cell porous sponge in the venous reservoir. The grooves between the helical fins designed to provide an increased surface area for thermal transfer during the cooling and rewarming of blood required for hypothermic perfusions. Moreover, they continue the laminar mixing process. As the coil is molded in one piece there are no seals or welds in locations which could lead to a water to blood leak.

PATIENTS AND METHODS

The oxygenator has been used in 180 consecutive open heart operations performed at our institution during the past 12 months. The surgical procedures involved (Table 1) are representative of the common pathological conditions encountered in adults in our series.

TABLE 1

Open heart operations performed with the use of the S100 Shiley disposable oxygenator

Surgical procedure		Number of patients
Aortic valve replacement		39
with MVR	5	
replacement ascending aorta	2	
SVBG	6	
Mitral valve replacement		59
with tricuspid annuloplasty	6	
SVBG	5	
repair of coronary fistula	1	
repair ASD	1	
Mitral and aortic valve replacement		30
with SVBG	2	
tricuspid annuloplasty	6	
Mitral and tricuspid valve replacement		4
Mitral, aortic and tricuspid valve replacement		3
LV aneurysmectomy		11
with SVBG	4	
SVBG		27
Resection of HOCM		1
Repair ASD		4
with anomalous pulmonary venous drainage	2	
pulmonary infundibulectomy	1	
Repair Fallot's tetralogy		2
TOTAL		180

MVR = mitral valve replacement, SVBG = saphenous vein bypass graft, ASD = atrial septal defect, HOCM = hypertrophic obstructive cariomyopathy

TABLE 2

Priming solution for the heart-lung machine used in 180 open heart operations

Components	Millimoles per litre	
Sodium	101.2	
Potassium	5.0	
Chloride	105.8	
Calcium	2.5	
Magnesium	0.8	
Gluconate	2.5	
Phosphate	1.2	
Dextrose	25.0	g
Freshly distilled water	1.0	l

Anesthesia was induced in all patients with thiopentone and maintained with 50% nitrous oxide-oxygen, 0.5% (maximum) Halothane and Pancuronium bromide. Some patients also received up to 100 mg of pethidine (in divided doses). The priming solution consisted of an isotonic dextrose/saline solution containing potassium, chloride, calcium, magnesium, gluconate and phosphate (Table 2). Variable volumes of bicarbonate and mannitol were added as required by the clinical situation. The total priming volume of the entire heart-lung machine was 1600 to 1800 ml. This comprised 800 ml for the oxygenator, 100 ml for the filter and cardiotomy reservoir and 900 ml for the pump tubing. Both euthermia and moderate hypothermia (28–32°C) were used according to the type and length of the surgical procedure. Anticoagulation was achieved with 3 mg of Heparin per kg body weight prior to cannulation and half the loading dose was repeated every 90 minutes for longer procedures. Both venae cavae and the ascending aorta were cannulated on each occasion. A Pemco pump console unit, Shiley cardiotomy reservoir, Cimid polyethylene tubing and Pall Ultipor blood filter (40 μ) placed in the cardiotomy circuit were used in all patients.

The gas mixture used for all patients was 97% O_2 and 3% CO_2, available pre-mixed in a cylinder. This was maintained constant irrespective of temperature. Gas flow was adjusted to maintain optimum pO_2 and pCO_2, and gas flow/blood flow ratio recorded. The heat exchanger efficiency was assessed by measuring the cooling and rewarming times with an esophageal thermistor (Yellow Springs monitor, Model 5340-5).*

The following parameters were monitored before, during and after heart-lung bypass: pO_2, pCO_2, pH and non-respiratory pH^{5-7} using a Corning model 165 pH blood gas analyzer.** The pO_2 and pCO_2 were corrected for temperature. The hemoglobin (Hb), hematocrit and platelet count values were obtained with a Coulter counter.† The measurements were made every 10 minutes for the first 40 patients operated upon and every 15 minutes in the remaining 140 patients. In addition, the free plasma hemoglobin was measured during the operation at 60 minutes of bypass using the Cyan-Methemoglobin method and a SP 500 ultraviolet spectrophotometer.‡ Esophageal, rectal and heat exchanger water temperatures were continuously monitored. The temperature of the water in the heat exchanger never exceeded 42°C.

RESULTS

The results obtained in these 180 patients perfused with the Shiley S-100 oxygenator are summarized in Tables 3 and 4.

There were no oxygenator-related accidents or deaths and no mechanical or hydraulic faults occurred during perfusion. Satisfactory pO_2, pCO_2, and pH were achieved in all patients (Tables 3 and 4). The gas flow/blood flow ratio ranged from 0.6 to 1.71 with an average of 0.87.

The degree of hemolysis as estimated by mean plasma free Hb per 60 minutes of perfusion was 26.2 mg/100 ml. The mean value of the platelet count fell from 216 ± 47 pre-operatively to 129 ± 28 following the operation. The significance of this reduction

* Yellow Springs Instrument Co., Yellow Springs, Ohio 45387.
** Corning Scientific Instruments, Medfield, Mass. 02052.
† Coulter Electronics Ltd., Cold Harbour Lane, Harpenden, Herts, England.
‡ UNICAM Ltd., York Street, Cambridge, England.

TABLE 3

Laboratory data from 180 patients perfused with the Shiley S100 disposable oxygenator

Laboratory data	Before bypass mean	Before bypass standard error	During bypass mean	During bypass standard error	After bypass mean	After bypass standard error
pO_2 (mm Hg)	150	3.4	198	5.2	150	2.9
pCO_2 (mm Hg)	38	0.5	45	0.4	35	0.2
pH	7.36	0.006	7.35	0.003	7.36	0.003
Non-respiratory pH[5-7]	7.38	0.004	7.44	0.003	7.40	0.003
Haematocrit (%)	39.4	0.38	23.1	0.28	37.3	0.22
Haemoglobin (g/dl)	13.8	0.14	7.4	0.09	12.7	0.06
Platelats (x 10^9/1)	216	4.7	100	3.1	129	2.3
Free plasma haemoglobin (mg/100 ml per 60 minutes of bypass)			26.2	1.7		

TABLE 4

Summary of clinical and laboratory data from 180 patients perfused with the Shiley S100 disposable oxygenator

Clinical data	Mean	Range
Patient BSA	1.67	1.29 - 2.3
Patient age	48	15 - 69
Blood flow rate (1/min)	3.9	2.8 - 5.5
Gas flow rate (1/min)		
97% O_2	3.5	2.0 - 6.75
3% CO_2		
Gas flow / blood flow ratio	0.87	0.6 - 1.71
Bypass time (minutes)	94.5	27- 285
pO_2 (mm Hg)	198	73 - 360
pCO_2 (mm Hg)	44	30 - 58
Pump priming volume (ml)	1700	
Post-operative blood loss (ml/m^2)		
at 6 hours	128	
at 24 hours	296	

BSA = body surface area

TABLE 5

Performance of the heat exchanger incorporated in the Shiley S100 disposable oxygenator
(Data from 44 patients)

Number of patients	Body surface area (m^2)	Cooling time (minutes) to 29.6°C Mean	Range	Minutes per 1°C	Rewarming time (minutes) to 37°C Mean	Range	Minutes per 1°C
11	1.3 to 1.6	6.8	3-16	1.0	25.0	11.46	3.4
15	1.6 to 1.8	10.2	4-30	1.6	26.6	20.43	3.5
18	greater than 1.8	15.0	4-45	2.0	33.5	15.52	4.4

in platelet count during perfusion is difficult to assess because of the influence of hemodilution and sequestration of platelets in the liver.[8] This fall is comparable with figures encountered with other disposable oxygenators.[9,10] The postoperative blood loss in this series was very low and only one patient required reoperation for bleeding.

Renal function, as estimated by the hourly urinary output and blood/urine urea ratio, remained satisfactory in all patients.

The heat exchanger performance in a random group of 44 patients is shown in Table 5. The mean cooling and rewarming times (from 36.5 to 29.6°C and from 29.6 to 37°C) were 0.9 and 2.2 minutes for each degree of temperature per m^2 surface area respectively.

The cardiotomy reservoir performed very satisfactorily and there was no visible fibrin deposition on its wall even after the longest perfusions.

DISCUSSION

Experience with the Shiley S-100 oxygenator was recently published by Bjork, et al.[9] They reported no complications directly related to the oxygenator in 100 patients. The main attraction of this new unit appears to be the very low gas flow/blood flow ratio which was confirmed to be less than 1.0 in our series. Several studies have pointed out that excessive gas flow and uncontrolled entering of O_2 into a column of blood creates turbulence, hemolysis and air microemboli.[11,12] These may be responsible for a sequence of detrimental metabolic events.[13]

The design of the S-100 oxygenator incorporates the following advantages:

1. The gas passes through a diffuser which delivers bubbles of small diameter to the blood. In a bubble oxygenator the oxygen transfer efficiency is related to the size of the bubble,[14] which is a possible factor explaining the improved transfer of O_2 in this oxygenator.
2. After the blood and gas have passed through the porous sponge where most of the gas exchange occurs, they enter the rest of the oxygenating chamber where prolonged contact of blood with gas bubble is probably enhanced by the helicoidal shape and the fins of the heat exchanger. The duration of the gas-bubble to blood contact seems, once again, to be an important factor in producing an efficient O_2 transfer.
3. Thermal transfer occurs at the same time and in the same area as the blood to gas-bubble contact. If gas transfer occurs at the same time as the change in temperature, it is unlikely that O_2 will be released from the blood, as happens when a heat exchanger acts on already arterialized blood.
4. The oxygenator requires a low priming volume.
5. The performance of the polyurethane coated heat exchanger incorporated into the oxygenator was found to be satisfactory and related to the patients body surface area. Its capability for thermal transfer is comparable with that of other oxygenators of similar design.[10] However, the latest clinical model of the Shiley oxygenator incorporates a heat exchanger coil made of anodized aluminum with greatly superior efficiency in heat transfer. Results with this oxygenator are being assessed and will be reported separately.

We noted that CO_2 transfer during the rewarming period was not always adequately

achieved. Gas flow to the oxygenator was increased so that occasionally excessive pO_2 with slightly raised pCO_2 were encountered during this time. However, this could have been due to our method of maintaining a fixed mixture of O_2 (97%) and CO_2 (3%) throughout the heart-lung bypass, including the rewarming period. A circuit with separate O_2 and CO_2 inlets with finely calibrated gas flow meters might overcome this problem.

CONCLUSION

In conclusion the S-100 Shiley oxygenator has, in our experience, proved to be practical, easy to assemble, and reliable, with satisfactory performance in administering O_2 and removing CO_2. The incorporated polyurethane coated coil proved to be an adequate and safe heat exchanger. The priming volume of this unit is minimal at the safe level of operation during clinical perfusions.

Initial experience with the new anodized version of the heat exchanger coil suggests even greater heating and cooling capacities than those reported here.

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