Adult Perfusions using Rygg-Kyvsgaard Oxygenators
(HL-254DF Paediatric and HL-252DF Low Price)
and the Harvey H-200 Oxygenator. A Clinical Comparison.

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INTRODUCTION

Rygg-Kyvsgaard oxygenators have been in constant clinical use for the past 15 years.[1,2,3,4,5,6,7,8,9,10] The Harvey oxygenator is a new generation of disposable lung, based on an established principle, which incorporates an integral heat exchanger.[11,12] It was felt that a clinical comparison of a well established device with a new generation device would prove both scientifically interesting and informative.

MATERIALS

Sarns Modular Roller Pumps[1]
Rygg-Kyvsgaard Oxygenators[2]
Harvey Oxygenator[3]
Heart-Lung Tubing Packs[4]
Swank CA-100 Extracorporeal Filter[5]
Bentley PF-427 Extracorporeal Filter[6]
Morris Aortic Arch Cannula[1]
Wire Reinforced Caval Catheters[7]
Mennen-Greatbatch Monitoring System with SP-37 Statham Transducer[8]
Continuous Intraflow Flush System[9]
Pall Ultipor Oxygen Gas Line Filter[10]

METHODS

Radial artery and venous pressures were monitored by cut down and percutaneous puncture, respectively, on all cases after induction. Each patient was continuously monitored during the operation and the first three post-op days with the SP-37 Statham Transducers connected to a continuous intraflow flush system, which kept the lines from clotting post-operatively.

Each patient was heparinized with 3 mg/Kg of body weight.

The great majority of patients were arterially perfused through the ascending aorta. For all coronary artery bypass cases a single right atrial venous catheter with a left atrial vent system was used for decompressing the left heart.

The priming techniques and the perfusion management were identical for all types of oxygenator used.

Total haemodilution at 20-25 ml/Kg of patient body weight was achieved using 5% Dextrose with Lactated Ringers Solution. Sodium bicarbonate (44.6 M. Eq/1000 ml)

[1] Sarns Incorporated, Ann Arbor, Michigan, U.S.A.
[2] Polystan A/S Generatorvej 41, DK-2730 Herlev, Denmark
[3] William Harvey Research Corporation, Santa Ana, California 92705, U.S.A.
[4] COBE Laboratories, Denver, Colorado, U.S.A.
[5] Pioneer Filters, Incorporated, P.O. Box 456, Hillsboro, Oregon, U.S.A.
[6] Bentley Laboratories, Incorporated, 17502 Armstrong Avenue, Irvine, California 92705, U.S.A.
[7] U.S.C.I., Incorporated, Billerica, Massachusetts, U.S.A.
[8] Mennen-Greatbatch Electronics, Incorporated, Clarence, New York 14031, U.S.A.
[9] Sorenson Research Company, Salt Lake City, Utah, U.S.A.
[10] Pall Corporation, Glen Cove, Long Island, New York, 11542, U.S.A.

was added to the diluent to give a resultant pH of 7.38-7.48. Heparin (2000 I.U./1000 ml) and Mannitol (25 g) were also added to the prime.

Fluid additions to the extracorporeal circuit during the perfusion as a result of volume depletion (i.e. urine loss) were with 5% Dextrose with Lactated Ringers Solution buffered with sodium bicarbonate.

At no time in any of the perfusions was whole blood used in the extracorporeal circuit. If during the perfusion, the haemoglobin concentration dropped below 5 g/100 ml, microfiltered whole blood was given intravenously.

Systemic hypothermia to 30°C was used on all the cases together with localized myocardial cooling during ischemic arrest, which was instituted by cross clamping the ascending aorta.

Perfusion flow rates were never below the minimum of 2.4 L./m^2 of patient surface area.

Arterial blood gases, sodium and potassiums, haemoglobins and plasma haemoglobins were done approximately every 20 minutes. An average of 40 M. Eq of potassium was added to the extracorporeal circuit during each perfusion to maintain levels within normal limits.

100% oxygen and 100% carbon dioxide were delivered to the oxygenators through a bacterial gas filter in volumes and mixtures maintaining arterial PO_2 between 100 and 300 mm Hg and arterial PCO_2 between 36 and 44 mm Hg. A special gas flow meter, which was constructed to accurately control the correct total oxygen flow and the percentage of carbon dioxide, also delivers a percentage of Halothane gas anaesthetic as required during bypass.

All coronary suction return passed through a microemboli extracorporeal filter before entering the oxygenator. All whole bank blood administered during and after surgery was similarly passed through a microemboli transfusion filter.

Anaesthetic premedication was with Valium (10 mg per os) two hours pre-op and Morphine Sulfate (8-10 mg). Hyocine or Atropine were given in some cases. Induction began with pre-oxygenation. Thiropentone (125-200 mg) or Ketamanine, and either Morphine or Innovar were used with Anectine (60-100 mg).

During surgery intermittent Halothane, Morphine or Innovar, nitrous oxide and oxygen with Curare or Pancuronium relaxant were administered with a semiclosed circle absorber and a bird or air shields respirator. Lungs were inflated during bypass with 50% O_2-50% N_2O or 100% O_2 at a pressure of 5 to 10 cm H_2O.

Coronary Artery Bypass	70
Aortic Valve Replacement	13
Mitral Valve Replacement	6
Multiple Valve Replacement	2
Atrial Septal Defects	3
Left Ventricular Aneurysm Resection	2
Open Mitral Commissurotomy	4
Total	100

TABLE I. Number of cases for each surgical procedure

RESULTS

A total of 100 perfusions were studied. Table I indicates the various surgical procedures that were performed on these cases.

The oxygenator types used are indicated in Table II.

Patient Weights

The patient weight distribution is shown in Table III.

Figure 1 illustrates the patient weight distribution and furthermore shows the percentage of patients of a particular weight for each oxygenator type used. The patients' weights determined the choice of oxygenator.

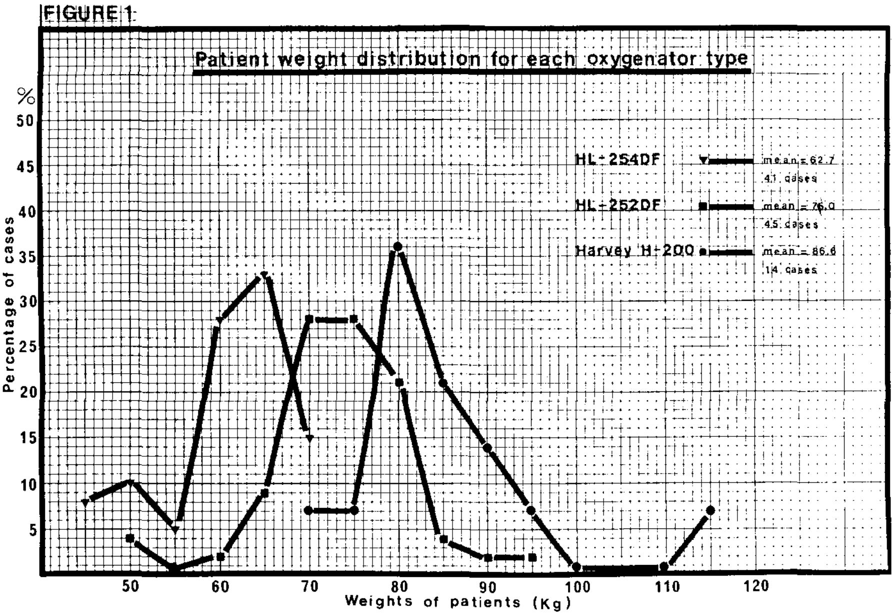
OXYGENATOR	NUMBER OF CASES
RK HL-254DF	41
RK HL-252DF	45
H-200	14
Total	100

TABLE II. Number of perfusions with each oxygenator type

OXYGENATOR	AVERAGE WEIGHT (Kgs)	RANGE (Kgs)
RK HL-254DF	62.7	45 to 70
RK HL-252DF	75.0	50 to 95
H-200	86.6	70 to 117

TABLE III. Patient weight distribution for each oxygenator type

FIGURE 1:



Haemoglobin Concentrations During Perfusion

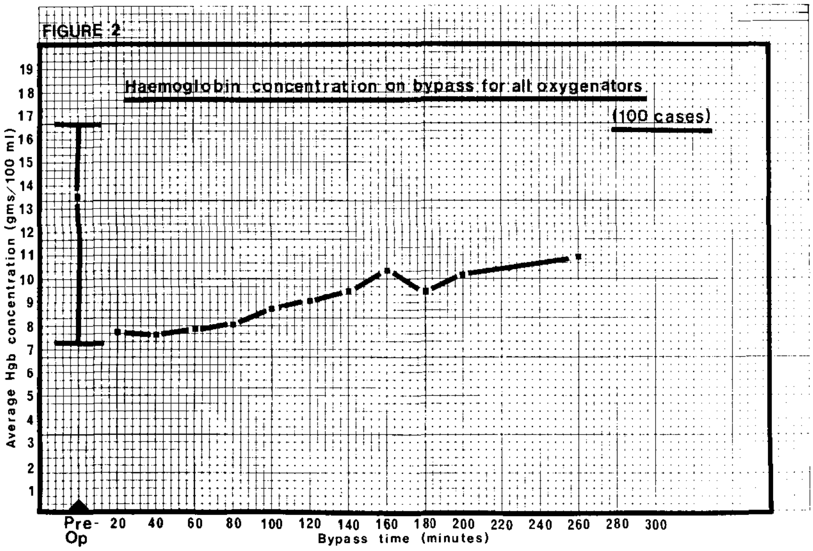
As previously stated, total haemodilution was used to effect the priming of the extracorporeal circuit. Figure 2 illustrates the preoperative haemoglobin concentration and the average haemoglobin concentrations for perfusions of different durations. These concentrations represent the average figure for each perfusion of a specific length. Preoperative haemoglobin concentrations ranged from 7.2 g/100 ml to 16.8 g/100 ml with an average of 13.5 g/100 ml.

Post Perfusion Plasma Haemoglobin

Plasma haemoglobin was measured frequently during each perfusion and Figure 3 illustrates the post operative measurement for each oxygenator type as a function of perfusion duration. The graphical line representing the H-200 oxygenator is somewhat misleading, as the last three plots were for one perfusion only, where the patient was maintained on a partial assist bypass for a total of 280 minutes, resulting in a post perfusion plasma haemoglobin determination of 206 mg/100 ml.

Blood Flow Rates

Figure 4 illustrates the average perfusion blood flow rates for each oxygenator type, expressed in terms of a percentage of the total number of perfusions for each oxygenator.



Gas to Blood Flow Ratios During Perfusion

Figures 5A, 5B and 5C illustrate the average gas to blood flow ratios during perfusions with the three oxygenator types. The solid heavy line indicates a 1 to 1 gas to blood flow ratio. The percentage of carbon dioxide contained in the total gas flows ranged from 1 to 2 percent. The amount of carbon dioxide supplied was calculated on the basis of the frequent blood gas analyses and was given in amounts that maintained an arterial PCO_2 of between 36 and 44 mm Hg.

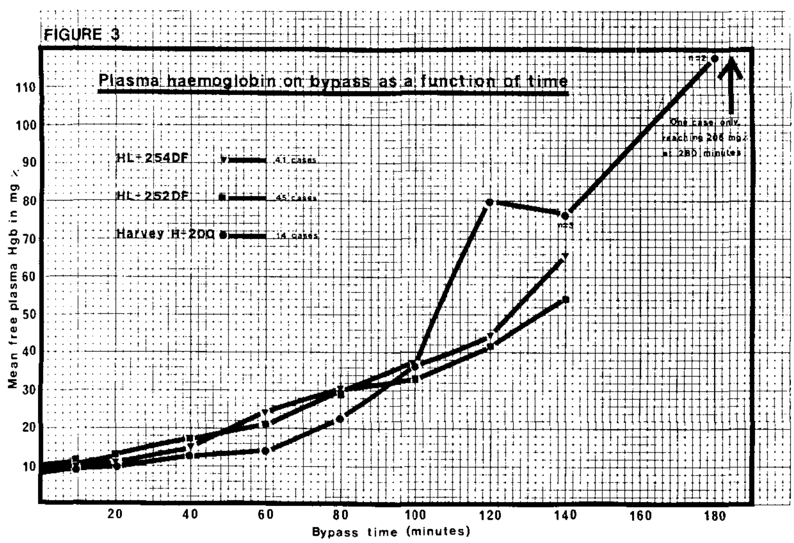
Figure 5A represents all perfusions with the RK HL-254DF. The average gas to blood flow ratio was 0.78 to 1.

Figure 5B represents all perfusions with the RK HL-252DF. The average gas to blood flow ratio was 0.74 to 1.

Figure 5C represents all perfusions with the H-200. The average gas to blood flow ratio was 0.78 to 1.

Figure 5D summarizes the data illustrated in Figures 5A, 5B and 5C, but in a manner that charts the average gas flow per litre of blood flow against the percentage of the total number of perfusions performed by each oxygenator type.

The following table indicates the average patient weights, average total blood flow rates, average blood flow per Kg of patient body weight and average blood flow rate per square meter of patient surface area.



	Average Blood Flow Rate (ml/min)	Average Patient Weight (Kgs)	Average Patient Surface Area (m^2)	Average Blood Flow in ml/Kg	Average Blood Flow in ml/m^2
HL-254DF (41 cases)	5389	62.7	1.70	85.9	3170
HL-252DF (45 cases)	5505	75.0	1.90	73.4	2894
H-200 (14 cases)	5453	86.6	2.02	64.4	2699
Total (100 cases)	5452	71.9	1.82	74.5	2995

TABLE IV. Average blood flow rates compared to patient weight and surface area for perfusions with each of three oxygenators and for the total 100 perfusions

COMMENTS

Methods

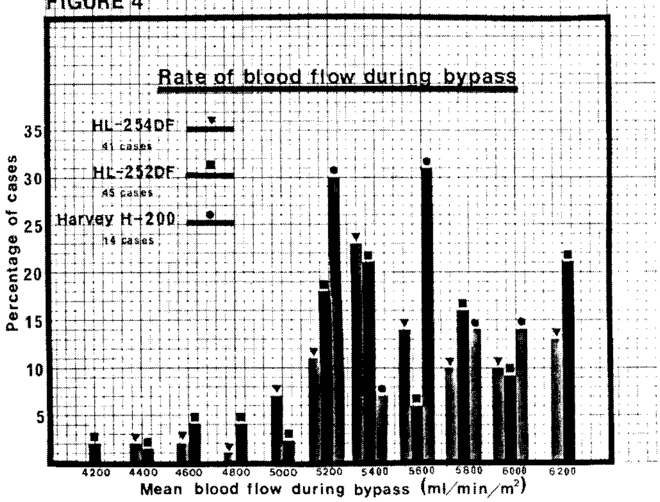
We found it of great importance to have a well functioning pressure monitoring system on all cases. This system has worked exceptionally well during surgery and throughout the first three post-op days. Blood was withdrawn from the arterial cut-down line and submitted for blood gas determination.

The established careful perfusion techniques used in this evaluation resulted in a high quality of post-perfusion patient status. 98 of the 100 patients perfused by the three oxygenator types in this study were discharged home from hospital. No patients displayed any clinical signs of post-operative neurological problems that could be attributed to the perfusion.

It is worth stating several of the important details that contributed to this excellent post-perfusion status. Serum potassium was frequently monitored during each perfusion and corrected to normal limits by the slow and diluted infusion of potassium chloride. Due to the high blood flow principles used in our hospital, urine loss during bypass is high. Serum potassium levels will change dramatically as potassium is excreted from the kidneys. We had to infuse an average of 40 M. Eq of potassium chloride to maintain normal potassium levels. This constant attention to potassium levels is very important in the coronary artery bypass graft patient who, in the immediate post-operative period, needs to have a good myocardial quality to avoid unnecessary arrythmias.

The microfiltration of coronary suction blood and old donor blood is, we feel, a necessary procedure. The importance of this type of filtration has been well documented elsewhere.[13,14,15] We feel that this filtration has contributed to our very acceptable levels of post-perfusion plasma haemoglobin. We do not use a micro filter in the arterial line.

FIGURE 4



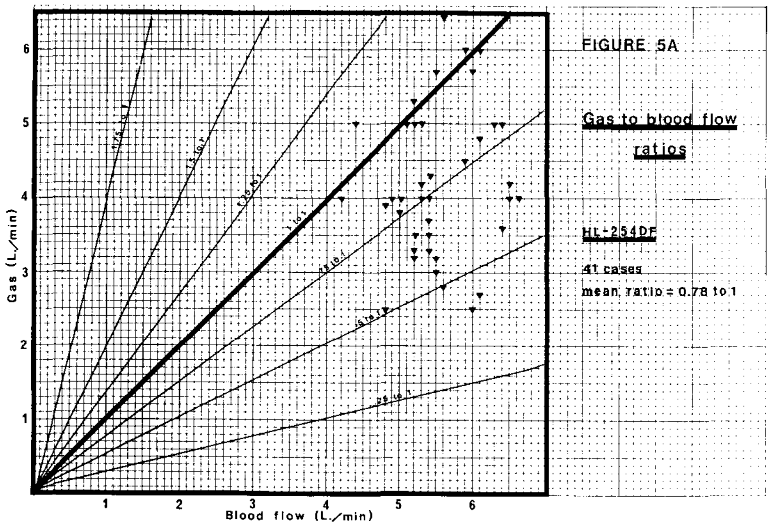


FIGURE 5A
Gas to blood flow ratios
HL-254DF
41 cases
mean ratio = 0.78 to 1
Gas (L./min)
Blood flow (L./min)

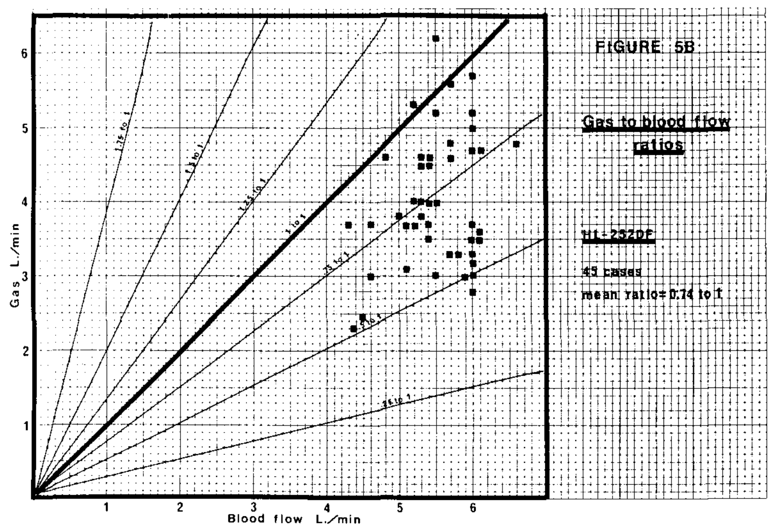


FIGURE 5B
Gas to blood flow ratios
HL-252DF
45 cases
mean ratio = 0.74 to 1
Gas L./min
Blood flow L./min

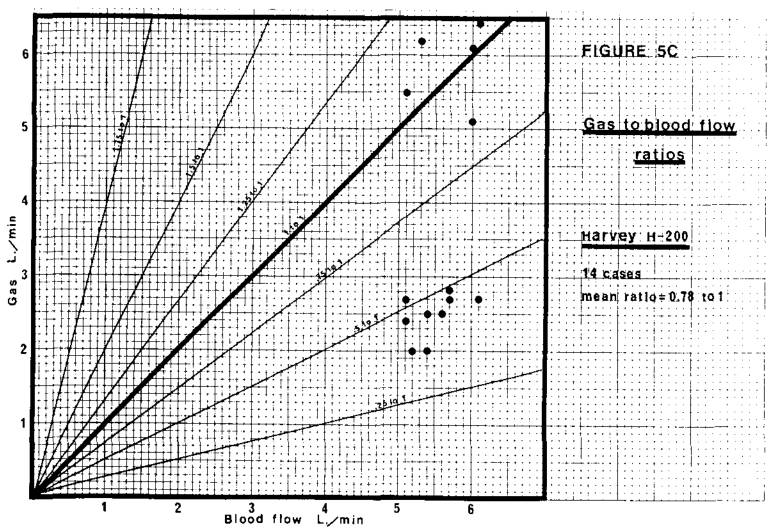
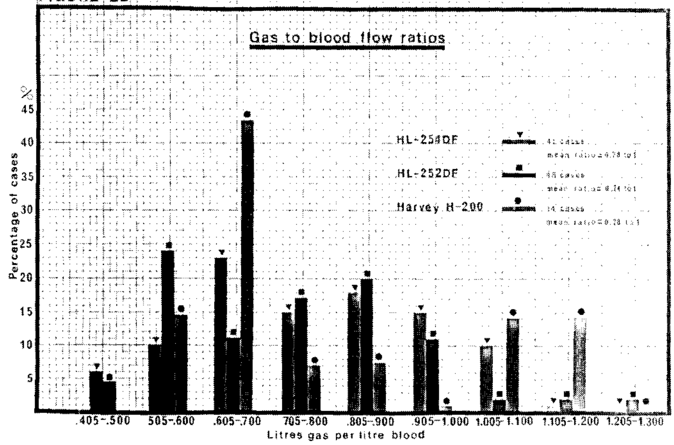


FIGURE 5C
Gas to blood flow ratios
Harvey H-200
14 cases
mean ratio = 0.78 to 1
Gas L./min
Blood flow L./min

FIGURE 5D



Patient Weights

The distribution of patient weight in this study ranges from 45 to 117 Kg and was used as a criterion for oxygenator selection. It was felt that the RK-254DF oxygenator should be used for the lower weight patients, while the H-200 should be used for the larger patients. As a result of this study, different criteria are being formulated as, firstly, the higher weight patients did not receive the highest perfusion blood flow rates and, secondly, the RK HL-254DF (Paediatric) oxygenator performed to entire satisfaction at the highest blood flow rates.

Haemoglobin Concentration

As stated previously, total haemodilution was used to prime and maintain the extracorporeal circuit volume, providing the haemoglobin remained above 5 g/100 ml. There is no doubt that the use of total haemodilution[16, 17] and the lowering of haemoglobin levels plays a significant part in reducing red cell damage due to the traumatic action of the extracorporeal circuitry. Perfusion and post-perfusion management of patients operated upon with low haemoglobin levels has not run into any problems whatsoever.

Post-Perfusion Plasma Haemoglobin

The increase in plasma haemoglobin during perfusion is generally inversely proportional to the duration of bypass and the blood flow rates. Our investigation has shown that there is very little difference between the post-perfusion plasma haemoglobin levels for each oxygenator type. We feel that the degree of destruction of red cells during the perfusion is highly correlated to the perfusion management. The more attentive the perfusionist is to gas flow rates, blood flow rates, occlusion settings, suction pump control, etc., the less trauma will be inflicted, irrespective of the type of oxygenator he uses. A cooperative surgeon can also contribute significantly to lower trauma figures.

Blood Flow Rates

As can be seen from Figure 4 and Table III, blood flow rates in this study tended to be high. The principle in this hospital is to perfuse the vasodilated patient with a volume equivalent to that which can be drained into the oxygenator. As Table III shows, although the average patient size for perfusions conducted with the H-200 was 86.6 Kg and 2.2 m^2 (as compared to 62.7 Kg and 1.7 m^2 for the RK HL-254DF and 75.0 Kg and 1.9 m^2 for the RK HL-252DF), the blood flow rates per Kg. and per m^2 were considerably lower.

Gas to Blood Flow Ratio

As is indicated in Figures 5A, 5B and 5C, all the perfusions were conducted with average gas to blood flow ratios of below 1 to 1, with more than satisfactory gas exchange characteristics. Interestingly, the RK HL-254DF and RK HL-252DF were able to function at very similar gas to blood flow ratios. We feel that our method of very accurately controlling the PCO_2 content of the supplied gas mixture has assisted us in utilizing these low ratios. All RK oxygenators had a varying percentage of carbon dioxide added to the gas supply. This is in agreement with the suggested gas supply rates which indicate the need to supply carbon dioxide to compensate for temperature changes. The H-200 was also supplied with varying percentages of carbon dioxide at the higher blood flow rates. However, at the lower blood flow rates, with the gas to blood flow ratios we were able to achieve, it was noticeable that an increase in the arterial PCO_2 was observed even though pure oxygen only was being used. This elevation of arterial PCO_2 at lower blood flow rates and low gas to blood flow ratios were not observed in the RK oxygenators.

CONCLUSIONS

100 perfusions were investigated in which three oxygenator types were used, the Rygg-Kyvsgaard HL-254DF, 41 perfusions, the Rygg-Kyvsgaard HL-252DF, 45 perfusions, and the Harvey H-200, 14 perfusions. The performance of all three oxygenator types was within normal limits, although certain individual variations were observed; 98 of the 100 patients were discharged home from hospital.

Correlation between body weight, anticipated flow rates and obtained flow rates/m^2 was low, because all obtained flow rates were above resting normal values.

Both types of Rygg-Kyvsgaard oxygenator performed well. The HL-254DF (Paediatric) displayed capabilities well beyond anticipated or specified levels and more than adequately handled blood flow rates of up to 6.2 litres per minute with gas to blood flow ratios of about 0.78 to 1. This finding may be of interest to those for whom the cost factor is important.

The Harvey H-200 performed well in the majority of cases, although a slight elevation of the arterial PCO_2 was noticed at the lower blood flow rates. The integral heat exchanger did not function to our satisfaction, as rewarming times tended to be rather long.

Post perfusion plasma haemoglobin levels were very acceptable for all types of oxygenator, and these levels reflect the careful and attentive perfusion management.

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