P5

~~LIST OF PROCEDURES DONE~~

✓ PROJECT REPORT

TITLE OF THE PROJECT:

IN VITRO EVALUATION OF CHITRA HARD OXYGENATOR.

NAME..... Dr. M. Unni Krishnan

PROGRAMME: Mch - C.V.T.S.....

MONTH & YEAR OF SUBMISSION: February 1985.....

Note:— (i) In the case compilation of procedures done, the contents and the subsequent pages should be made into different sections (a) Procedures done (b) Procedures assisted (c) Procedures participated (d) Procedures attended/participated etc in Other Centres. Each section should be preceded by a leaf carrying the name of the section that is succeeding.

(ii) The Contents page will carry into. as per model given under

PROCEDURES DONE

Closed Mitral valvotomy.....124 (say)
Patent ductus arteriosus-ligation.....10
Atrial septal defects.....20
.....
.....

PROCEDURES ASSISTED

Closed Mitral valvotomy.....100 (say)
.....

(iii) In the subsequent pages details of each procedure done/assisted should be given in the format given below:—

Heading: **Closed mitral valvotomy**

Date	Name of the patient	Age	Sex	Patient No.

(iv) In the case of Project Report in the page immediately following the Certificate page the under-mentioned details should be given:—

(a) Title
(b) Duration
(c) Aim and scope
(d) 50 word summary of work done

CERTIFICATE

I, Dr. M. Unni Krishnan hereby declare that I have actually performed all the procedures listed/carried out the project under report.

Signature: Unni Krishnan

Place: Trivandrum.

Name in capital letters: D.R. M. UNNI KRISHNAN

Date: 15-1-1985

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ABSTRACT

This project was designed to assess the in Vitro performance of the indegenously fabricated CHITRA HARD SHELL OXYGENATOR. The test oxygenator was part of a closed loop technique of continous oxygenation and deoxygenation system. The gas transfer property and trauma to the formed elements of blood were studied for over 6 hours at various blood flow rates. The blood gases were excellent at all flow rates and acceptable gas to blood flow rates. The trauma to the formed elements was also within acceptable limits.

Bubble oxygenators have been found to be safe as an integral part of extra corporeal circuit for the heart lung bypass during the last 3 decades. In India, today, oxygenators are imported for clinical use. we have developed a hard shell oxygenator with an integral heat exchanger as a viable alternative to the imported models of disposable oxygenators. The objective of this project was to evaluate the in-Vitro performance of the indigenously designed and fabricated oxygenator at the biomedical technology wing of our institute.

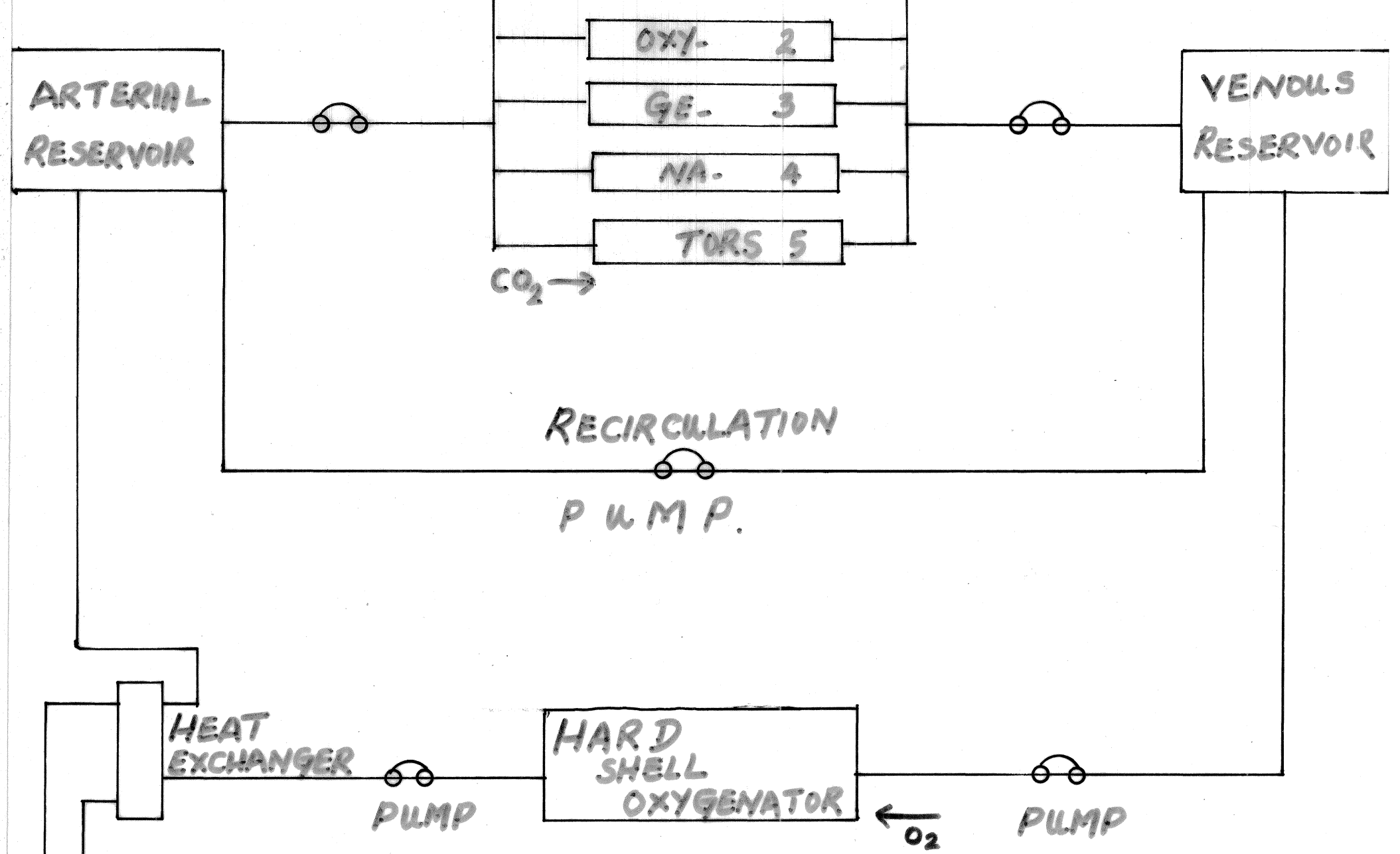
DESCRIPTION OF THE DEVICE

The oxygenator consists of, essentially two rigid concentrically placed shells made of polycarbonate. The venous and arterial ports connect the device to the external circuit. Venous blood enters the oxygenator through one of the venous ports. The other venous port is designed for return of cardiotomy suction during bypass procedure. Oxygen is administered through a

Sintered oxygen manifold. The blood oxygen interphase is very large and results in quick gas transfer. The blood gas mixture next enters the defoaming section made of polyurethane filter and sponge impregnated with silicon anti-foam A compound. Defoamed blood leaves the device through the arterial port. The gas from the oxygenator escapes through air vents provided.

MATERIAL & METHODS

In all 5 in-Vitro experiments were carried out. Bovine blood was collected in concentrated Acid citrate solution on the previous day of each experiment. Blood was collected from jugular veins of donor animals. This was done to ensure minimum damage to formed elements of blood and alviate the excessive damage when blood was collected directly from slaughterhouse. we utilised a closed loop technique of continous oxygenation - deoxygenation for our experiments in order to provide venous blood constantly as long as the experiment lasted. (Figure No: 1.). 5 soft shell oxygenators functioned as deoxygenators and nitrogen and carbon dioxide were



IN VITRO EVALUATION

CLOSED LOOP TECHNIQUE

bubbled through blood. The ensuing blood had the characteristics of venous blood. This was in turn passed through the test oxygenator and the return was arterial blood. Thus venous input conditions were continously maintained as long as the test oxygenator was being studied.

When blood flow is low, only two oxygenators functioned to provide venous blood. However, at blood flows over 3 L/mt, all 5 soft shell oxygenators functioned in unison to return venous blood.

Following were the parameters monitored.

1. blood flow, gas flow and temperature.
2. blood gases - both venous and arterial as well as oxygen saturation.
3. haematological tests which included haemoglobin in gm%, packed cell volume, RBC count, Total leucocyte count, platelet count and free plasma haemoglobin in plasma. These parameters were assessed in keeping up with the standards proposed by American Society of Artificial Internal organs (ASAIO) and American Association of Medical instrumentation (AAMI). A description of the device regarding fibrin deposition and clot formation was also included at the conclusion of procedure.

EXPERIMENT NO 1

TIME	BLOOD FLOW	OXYGEN FLOW	OXYGENATOR – TEST VENOUS BLOOD pH	pCO_2	pO_2	O_2 Satn	ARTERIAL BLOOD pH	pCO_2	pO_2	O_2 Satn	DEOXYGENATOR NITROGEN	CO_2
11 hr	1.0 L/mt	2.5 L/mt	7.518	20.7	43	65.5	7.526	14.8	355	100	8.0 L/mt	1.0 L/mt
6 more samples.												
1240 Hrs	2.0	3.5	7.286	46	55	64	7.404	30.6	220	~~97~~ 70	8.0	1.0
3 more samples at 15 mts interval												
1410 HRS	3.0	3.5	7.234	53.7	56	63.5	7.26	42.5	135	95.5	11.5	1.5
2 more samples.												
1515 HRS.	4.0	4.0	7.328	42.3	55	63.5	7.392	33.1	366	96.5	13.2	1.4
2 more samples.												
1620 HRS.	5.0	5.1	7.316	42.3	55	63.5	7.375	33.6	309	–	15.0	1.4
1720 Hrs.	6.0	6.0	7.358	39.1	57	68.5	7.40	31.6	301	96.5	15.0	1.4
						EXPT CLOSED at				1730 HRS		
						DURATION	7	HRS.				

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Blood gases and oxygen saturation of both arterial and venous blood were estimated every 15 minutes. At least 4 readings were obtained at each blood and gas flow rates to show consistent performance. Haematological tests were performed at the end of each hour of oxygenator performance. The pH of blood was measured along with blood gases and necessary correction was done from time to time to keep it in the normal range.

RESULTS

Blood gas estimations were done every 15 minutes for over an hour at each blood flow rate. Both arterial and venous parameters were studied. The results of Experiment No 1 is depicted in Table No: 1. In all 21 blood gas estimations were done during the 7 hours of experiment. The mean average pO_2 at every blood flow rate studied was above 300 mm Hg. The mean average pCO_2 was also brought down to 32 mm Hg from 43 mm Hg. Even at 1.0 L/mt blood flow, pO_2 improved to 355 from 43 mm Hg and pCO_2 was brought down to 14.8 from 30.7. As the blood flow rate was increased, this result was consistently obtained. Fig 2. shows the mean average increase in pO_2 and drop in pCO_2 of all the experiments put together at various blood and gas flow rates.

OXYGENATION AT A GIVEN FLOW

No	TIME	BLOOD FLOW	O_2 FLOW	VENOUS			ARTERIAL.		
				pH	pCO_2	pO_2	pH	pCO_2	pO_2
1	1015 Hrs	3.0	3.5	7.256	42.8	48	7.372	29	192
2	1030 Hrs	3.6	3.5	7.250	43.3	40	7.337	31.7	317
3	1040 Hrs	3.6	3.5	7.255	44.1	38	7.36	28.9	355
4	1055 Hrs	3.6	3.5	7.250	45	40	7.34	32.4	310

EXPERIMENT NO: 2.

BLOOD FLOW 3.6 L/mt

OXYGEN FLOW 3.5 L/mt.

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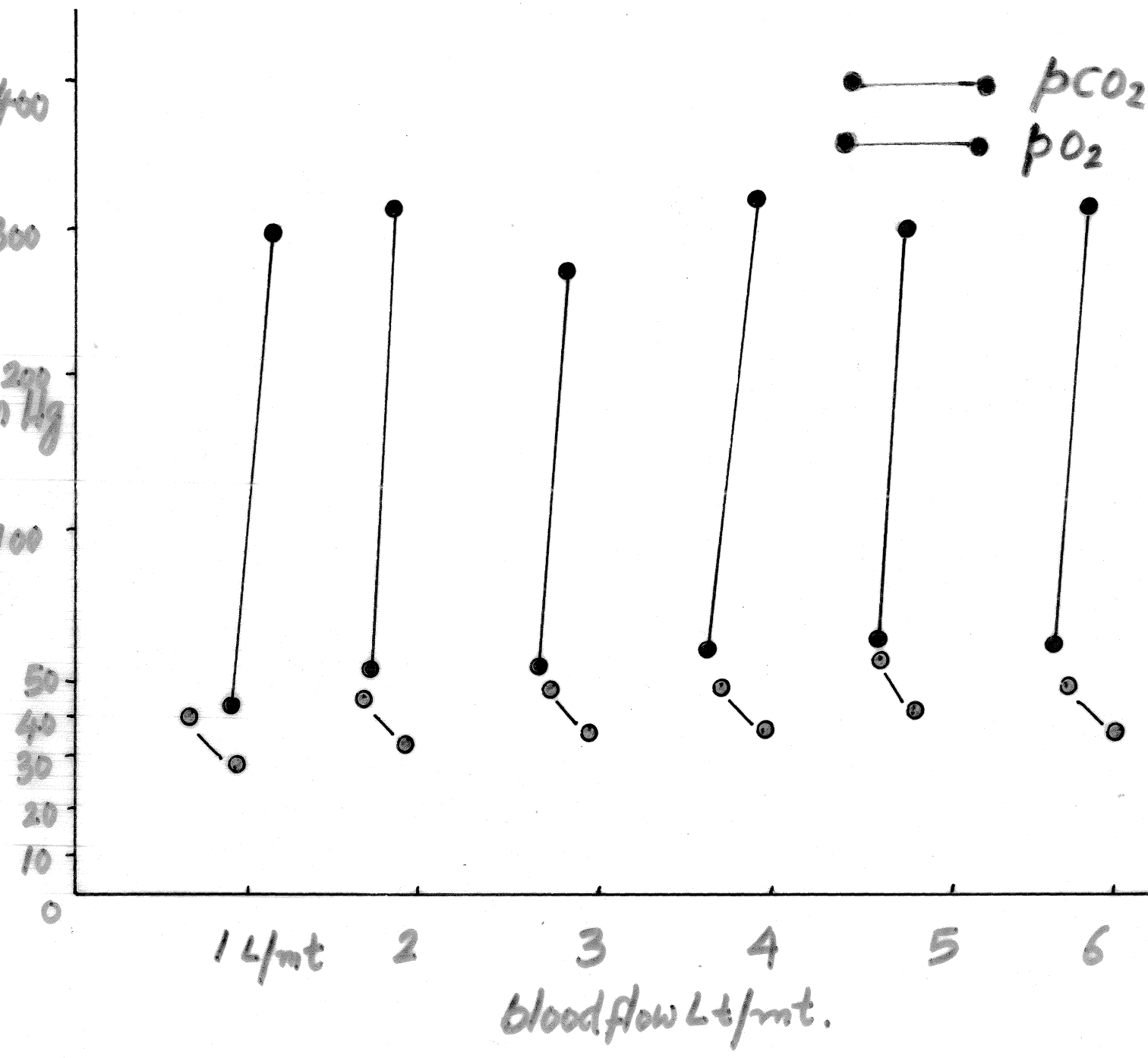

MEAN AVERAGE BLOOD GASES AT DIFFERENT BLOOD FLOWS

FIGURE NO: 2

BLOOD FLOW L/mt.	GAS : BLOOD RATIO
1.0	2:1
2.0	1.6:1
3.0	1.2:1
4.0	1:1
5.0	0.88:1

MEAN AVERAGE GAS to BLOOD RATIO.

TABLE-3

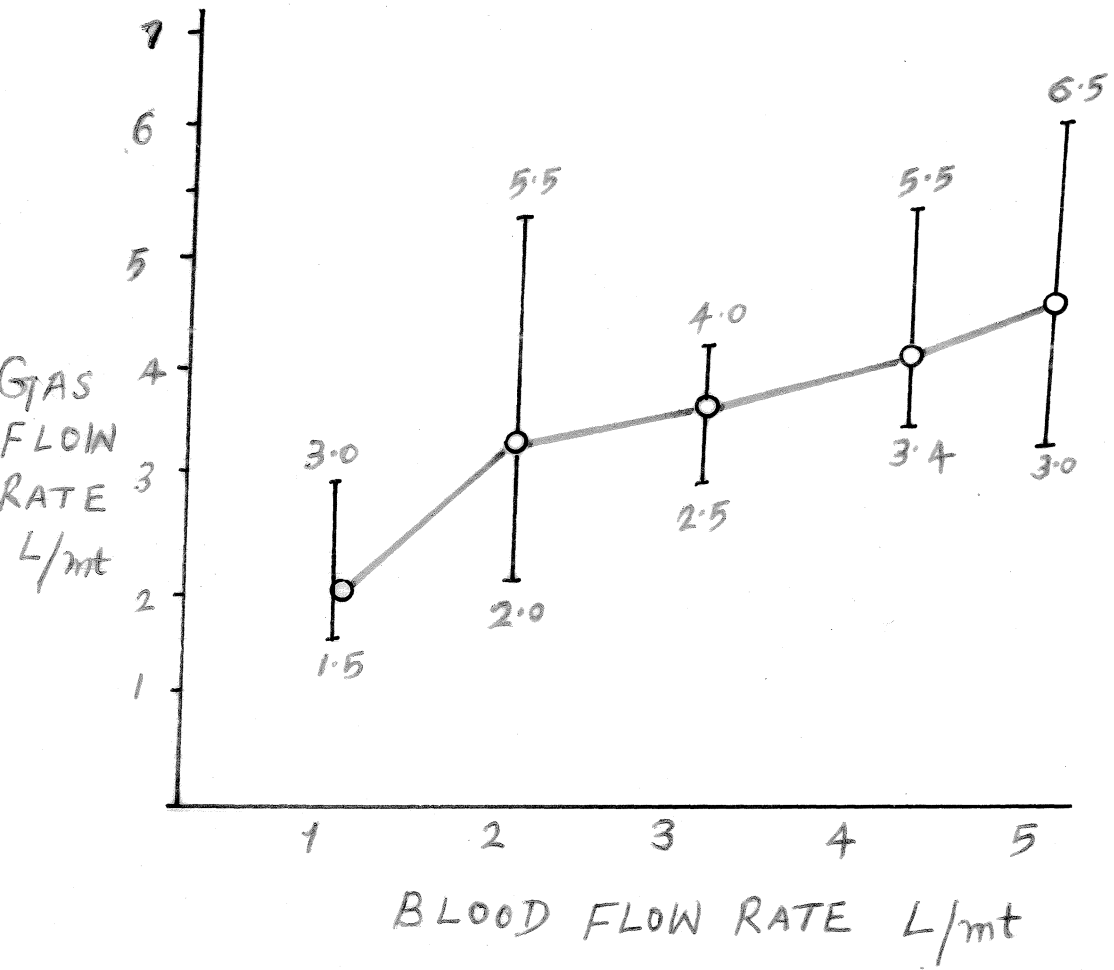

Fig.No:3 BLOOD & GAS FLOW RATE

HAEMATOLOGICAL TESTS

SERIAL No	TIME	Hb Gms%	PCV	PLASMA Hb% mg.	RBC COUNT	WBC COUNT	PLATELET COUNT
1	0900 Hrs	9·5	30	34·62	2·21 mill.	8150	5·56. Lakhs.
2	1030 "	10	30	31·74	4·86 "	9375	4·48.
3	1100 "	10·7	27	46·39	5·15	10450	2·94
4	1130 "	11·07	29	46·16	5·04	9100	2·55
5	1230 "	11·40	28	51·93	6·35	9900	2·06.
6	1430 "	10·1	28	86·55	4·52	6600	2·63

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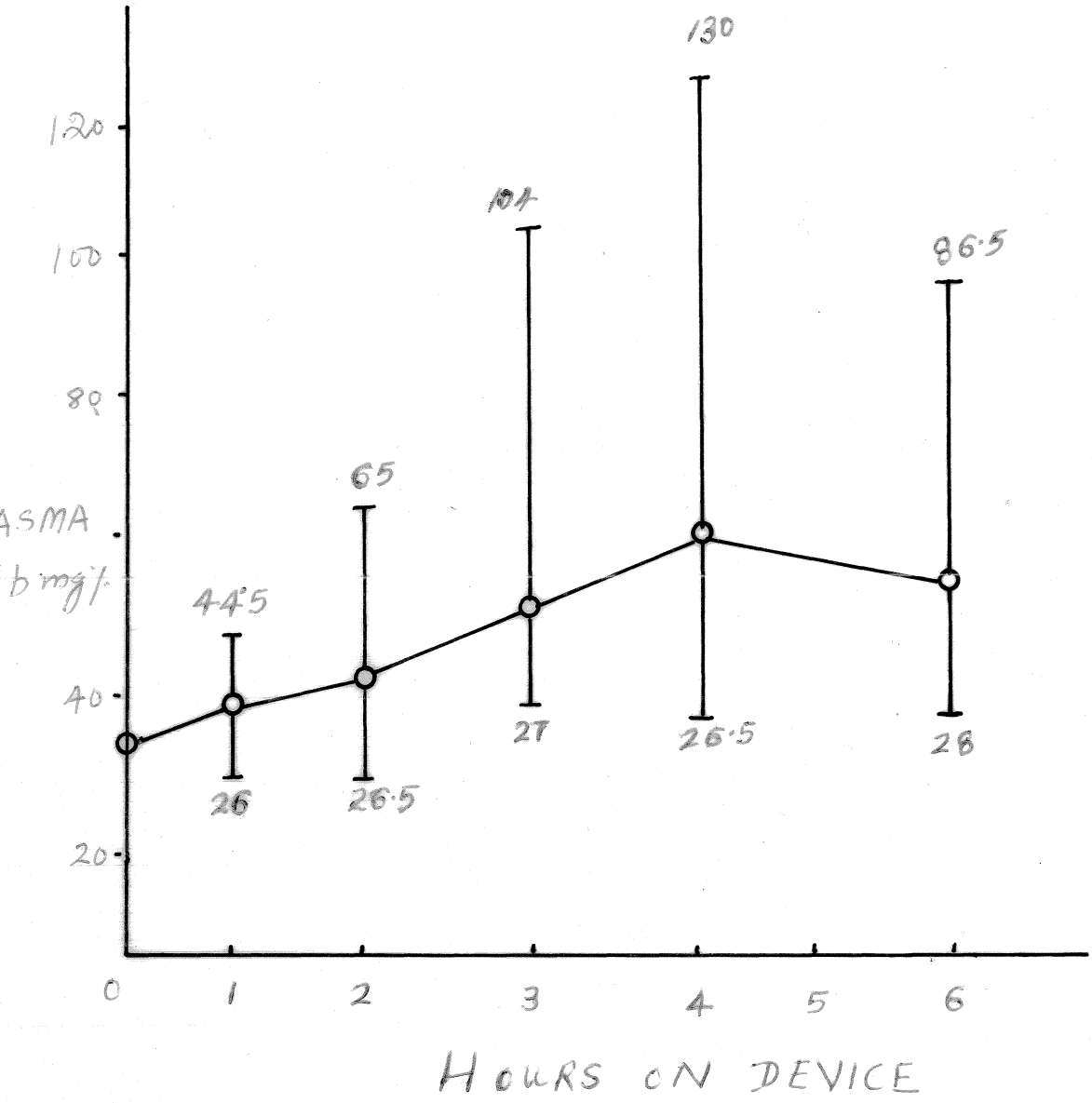

g.No.4 PLASMA HAEMOGLOBIN LEVELS DURING IN VITRO EXPERIMENTS

The oxygen flow rates in relation to various blood flows is depicted in Table. 3 . When blood flow rate is low, gas to blood flow rate was maintained at 2:1. However as the blood flow rate was increased, gas to blood ratio was 1:1. At the highest blood flow rates, it could be reduced to 0.8:1.

The platelet count showed a reduction to 50% of its pre experimental values at the conclusion of each experiment. ~~Fig~~ . Fig. 4 shows the increase in plasma haemoglobin which showed a linear increase according to the duration of the experiment.

At the conclusion of each experiment, the device was thoroughly examined. The amount of fibrin deposition and clot formation over the defoaming section were found to be within acceptable limits at the end of 6 hours run of ~~the~~ device.

DISCUSSION

The American Society for Artificial internal organs (ASAIO) sub committee has proposed standards for blood gas exchanger testing and data

reporting for blood gas exchangers during the past 10 years. They conform to minimum evaluation procedures for blood gas exchanger with special reference to clinical use and marketting.

Blood gas exchanger is any device which is designed to regulate the content of oxygen and carbon dioxide in blood by exchange of one or both of these gases. The committee recommended mammalian blood with a haemoglobin of 12 ± 2 gm% at 37°c for in-vitro tests. The following parameters were to be monitored.

1. blood flow rate, gas flow rate and temperature once / hr.
2. clotting time twice the normal.
3. haematocrit every 2nd hourly.
4. blood gases every 2 hrs corrected to temperature of the test.
5. Base excess measured every 2nd hr and adjusted to ± 1 meq/L by administering Sodium bicarbonate.

On completion of an experiment, the device should be closely observed for any malfunction such as foaming, leakage, and examined for fibrin or clot deposition.

Bovine blood was used in our experiments based on the experience of Nose et al. Their published work indicated that oxygen dissociation curve of bovine blood was similar to that of human. The function of an oxygenator is to oxygenate venous blood and remove carbon dioxide from it during cardio-pulmonary bypass. In the human body, tissues extract oxygen and blood returning to heart provides the venous blood constantly. However in an experimental set up, it is very hard to provide venous blood in an uninterrupted fashion over 5-6 hours. we have utilised a closed loop technique of continuous oxygenation-deoxygenation for our experiments.

The efficacy of gas transfer at virtually every blood flow rate studied had been excellent, throughout the duration of each experiment. Partial pressure of oxygen measured was more than 200 mm Hg for a number of readings at a given gas to blood flow rate. As the blood flow was increased, gas to blood flow rate could be brought down to less than 1:1 with good oxygenation. Carbon dioxide elimination was also consistently satisfactory during the experiments. These results confirmed excellent gas transfer properties using the test oxygenator.

At the end of 6 hours experiment, a 50% reduction in platelet count was noted. This is comparable to results obtained using bubble oxygenator in clinical perfusion. Our earlier in vitro and ex vivo evaluation using soft shell oxygenator also substantiated a similar drop in platelet count.

Plasma Haemoglobin level was found to increase proportional to the duration of the experiment, still up to an acceptable level. However during the in-Vitro experiments, 6 oxygenators including the test oxygenator were used. Nearly 25-to 30 litres of gas including oxygen, nitrogen and carbon dioxide were bubbled through blood. So much so this much elevation in free plasma haemoglobin is never bound to occur in a clinical perfusion set up.

The device was examined thoroughly at the end each experiment for fibrin and other clot formation and was found to be minimal.

The heat exchanger function was not checked during the in Vitro experiments.

SUMMARY

This project was designed to assess the in Vitro performance of the indigenously developed chitra hard shell oxygenator. Using bovine blood at standard test conditions, 5 such experiments were performed in a closed loop technique of continous oxygenation - deoxygenation ~~technique~~ system. The gas transfer efficiency of the oxygenator was found to be excellent at reasonable gas to blood flow ratio. The trauma to the formed elements of blood was acceptable at the conclusion of experiments lasting 6 hours. Thus the oxygenator has passed through the in-Vitro experiments successfully and is ready for ex-Vivo evaluation which is underway.