

(P9)

LIST OF PROCEDURES DONE
PROJECT REPORT

TITLE OF THE PROJECT:

- Ex-vivo evaluation of Prototype Chitra
Variflo hard shell oxygenator.

NAME..... DR Chandr Prakash Sheivastava

PROGRAMME..... M.Ch. (CVTS).....

MONTH & YEAR
OF SUBMISSION..... November 85

Forwarded & Recommended.

Prakash
HOD 16/11/85

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- 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.
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- (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... Chandra Prakashhereby declare that
Shrivastava
I have actually performed all the procedures listed/carried out the
project under report.

Signature..... 

Place: TVM.

Name in... DR. CHANDRA PRAKASH
capital letters SHRIVASTAVA.

Date: 15-11-85

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- 1/ Project Report " Ex vivo evaluation of Prototype Chitra variflo Hard Shell Oxygenator.
- 2/ Involvement in the ongoing project at BMT wing to improve surgical skill.
 - A) Interposition grafting in the descending (thoracic) aorta using SITRA vascular graft.
 - B). Mitral valve replacement in sheep using chitra tilting disc valve prosthesis.

EX-VIVO EVALUATION OF PROTOTYPE CHITRA VARIFLOW HARD SHELL OXYGENATOR.

Introduction:- Hardshell oxygenator is preferred in clinical use because of low priming volume, good blood gas exchanging capacity and better cooling and rewarming capacity on account of its in-built heat exchanger.

The Chitra Hard shell Oxygenator was developed in the Biomedical wing of Sree Chitra Tirunal Institute for medical sciences and Technology. A brief description follows:-

1) It has a special circuit, which can be changed from paediatric to adult CPB circuits as desired.

2) It has an in-built heat exchanger fixed in the oxygenating chamber of oxygenator.

3) It incorporates a cardiomy reservoir at top of the oxygenator unit.

Aims of Study:-

1) To evaluate the function of the oxygenator

in ex-vivo setup. i.e a) Oxygenation b) CO₂ elimination.

- 2) To evaluate temperature regulation efficacy.
- 3) To evaluate effect of CPB on blood elements.
- 4) To assess the embolic episodes, because of
 - a) poor defoaming b) Silicon particles.
- 5) To study effect of CPB using this device on vital organs like kidney and liver.

Animal model:- Sheep was chosen for following reasons:

- 1) Previous experience with soft shell oxygenator.
- 2) Stable animal as far as anaesthesia is concerned.
- 3) Easy availability.

weight of animals ranged from 29 to 40 kg, the mean being 33.9 kg.

Preoperatively animals were subjected to the following investigations and same investigations were repeated every day postoperatively for 7 days.

- 1) Haematological, Hb%, PCV, TLC, DLC.
- 2) Coagulation parameters, clotting time Prothrombin time, Partial Thromboplastin time

Platelet count.

3) Liver function tests: Serum bilirubin, SGOT.

SGPT.

4) Renal function tests: BUN, Serum creatinine

5) Serum electrolytes: K^+ , Na^+ , Cl^- .

Preoperative preparation consisted of:

a) 24 hours fasting.

b) No fluids 12 hours

c) Cap Neomycin 3×350 mgs 12 hours before surgery.

Pre medication:

- Ijv Diazepam 0.5 mg/kg body weight and

- Ijv Atropine sulphate 0.04 mg/kg body wt.
intramuscular, 30 minutes before surgery.

Induction and maintenance of Anaesthesia

General anaesthesia was induced by i.v. Thiopental sodium 10 mgs/kg body wt.

The animals were then intubated and anaesthesia maintained with $N_2O + O_2$

supplemented by subcutaneous Pethidine and Paralon when ever required.

Surgical Technique Animals were placed in the right lateral position. Central venous pressure line was introduced in the external jugular vein. Arterial line was placed in the left Common carotid artery. Lateral thoracotomy was done and chest entered through the IVth intercostal space. Pericardium was opened and marsupulised. Animal was heparinized using heparin 3 mgs/kg body wt. Descending thoracic aorta was cannulated for arterial return. Main pulmonary artery was cannulated to place the tip of venous cannula in the right ventricular outflow tract, for venous return. Cardiopulmonary bypass was established and left atrial vent introduced. The bypass was maintained for a minimum of one hour. Systemic temperature was allowed to drift to 31°C. Rewarming was done actively. Cardiopulmonary bypass was terminated when systemic temperature of animal was around 37°C, serum electrolytes and arterial blood gas analysis were within normal limits. Heparin was neutralized with protamine 6 mg/kg body wt. Animals were decannulated and chest closed in layers after putting

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one intercostal tube drain.

Post operative management: Animals were kept on ventilator and waking time was noted. When vital signs were stable effect of muscle relaxant was reversed. Spontaneous trial of respiration was given sufficiently (around 30 minutes) before extubation.

Surviving animals were subjected to the same investigations which had been done pre-operatively.

Observations A total of 7 experiments were done.

1) Priming Volume: Nonhaemic or haemodiluted prime was used, depending upon the pre-operative haemoglobin level to give a circulating packed cell volume between 20-25%. The average priming volume was 2,200 cc.

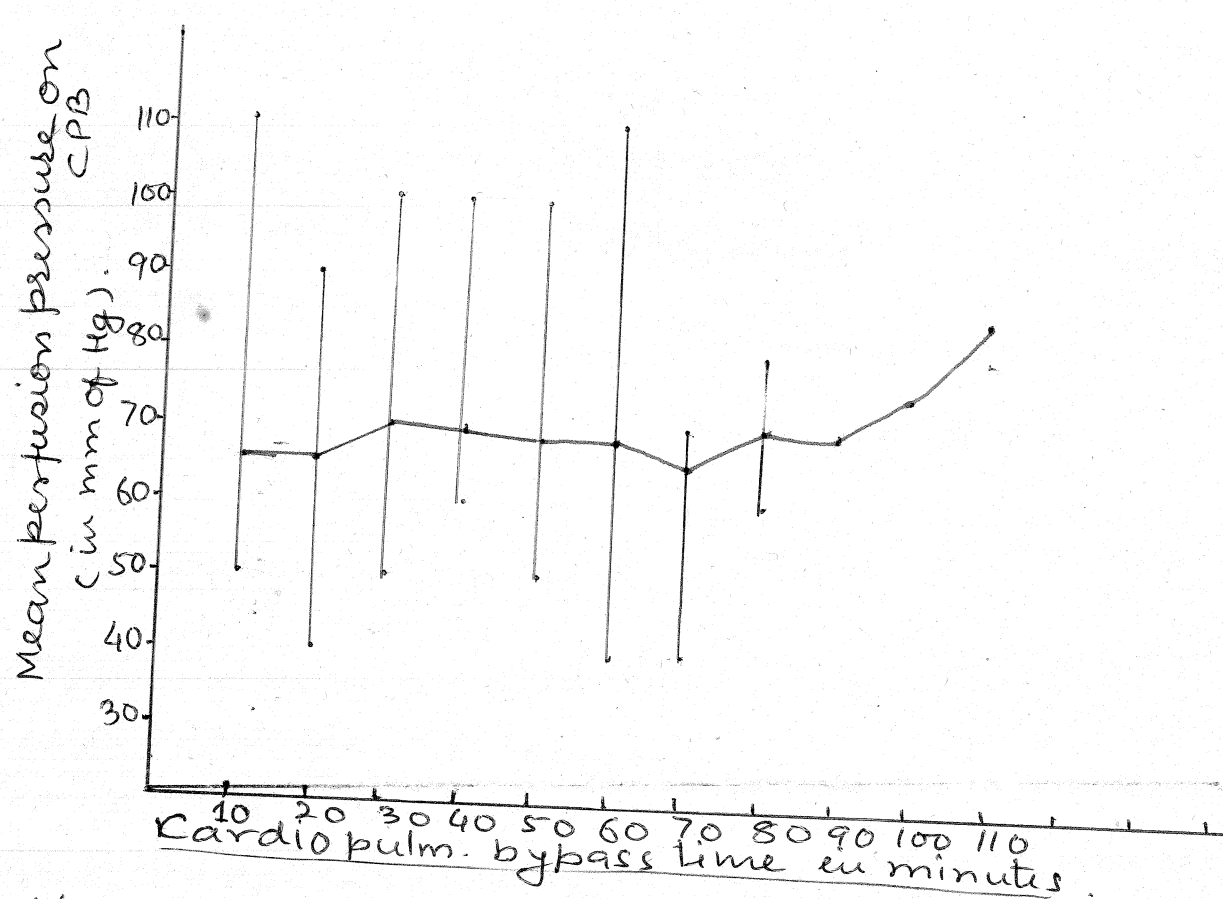
Paediatric circuit was used in all these experiments.

2) Cardiopulmonary bypass time: It ranged from 60 minutes to 107 minutes, average being 75.6 minutes.

3) Perfusion pressure on bypass: As shown in table, the average mean perfusion

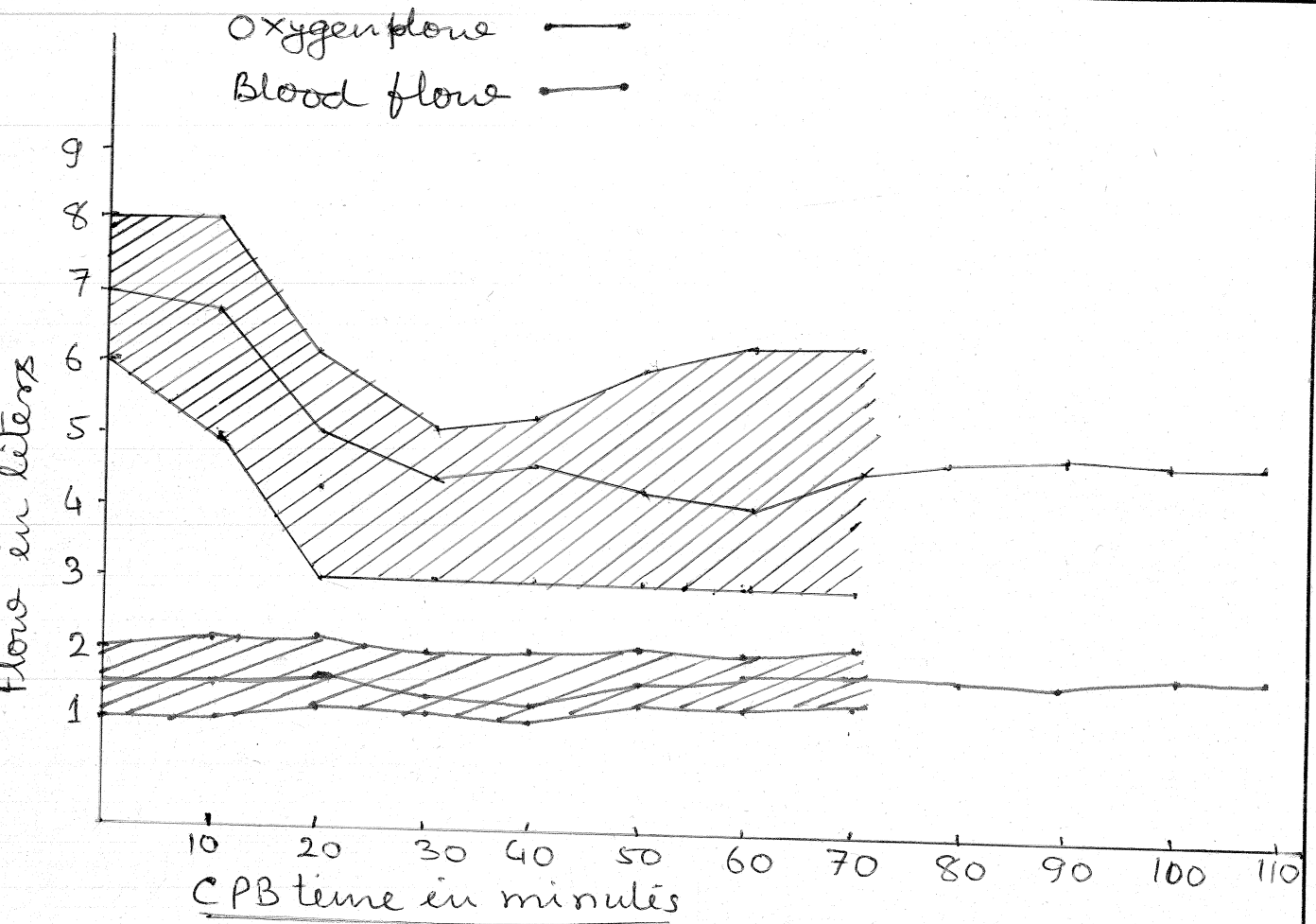
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pressures through out the bypass remained between 60-84 mm of Hg. However the lowest and highest mean perfusion pressures noted were 35 mm and 111 mm of Hg respectively.



4) Ratio of blood and gas flow. On CPB blood flow was maintained to 60 ml/kg body wt. of animal. Mean blood flow ranged between 1.4 liters to 1.6 liters/minute. Maximum blood flow was 2.3 liters/minute and minimum 0.8 lit/minute.

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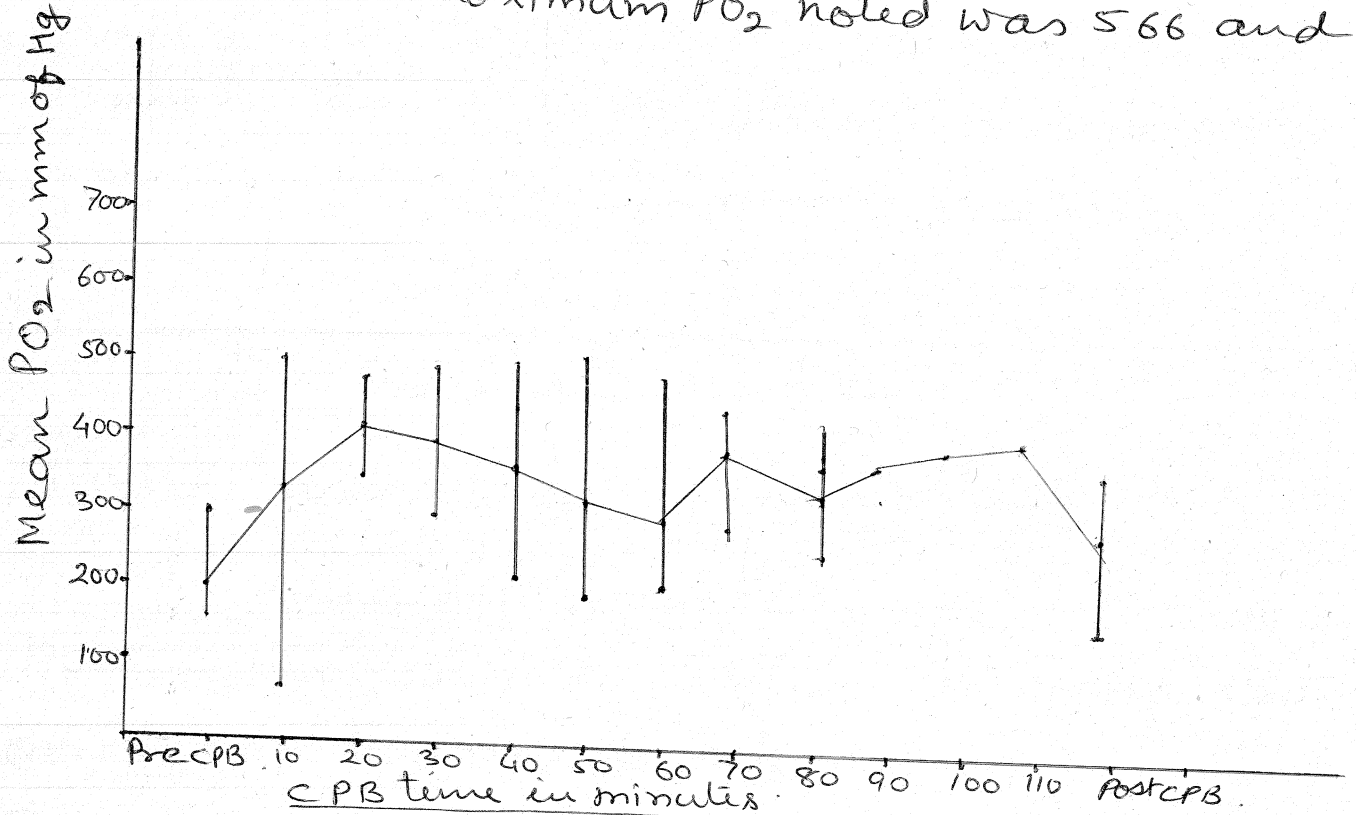


Oxygen flow ranged between 3.5 to 6.5 liters /minute. At the commencement of CPB O_2 flow ratio to blood flow ratio was 3:1 for initial 10-15 minutes. As priming of CPB circuit was non-haemic, we aimed to keep sufficient amount of dissolved O_2 till priming volume was thoroughly mixed with animal blood, when the first blood gas report after 10 minutes of CPB was satisfactory then gas: blood flow ratio was reduced to 2:1 and even 1.5:1.

This gas: blood flow ratio was maintained to keep arterial PO_2 between 200 to 300 mm of Hg. As PO_2 of more than 400 mm of Hg is also unphysiological.

5/ Partial O_2 pressure of oxygenated Blood.

The mean PO_2 remained between 230 to 422 Torr. The maximum PO_2 noted was 566 and

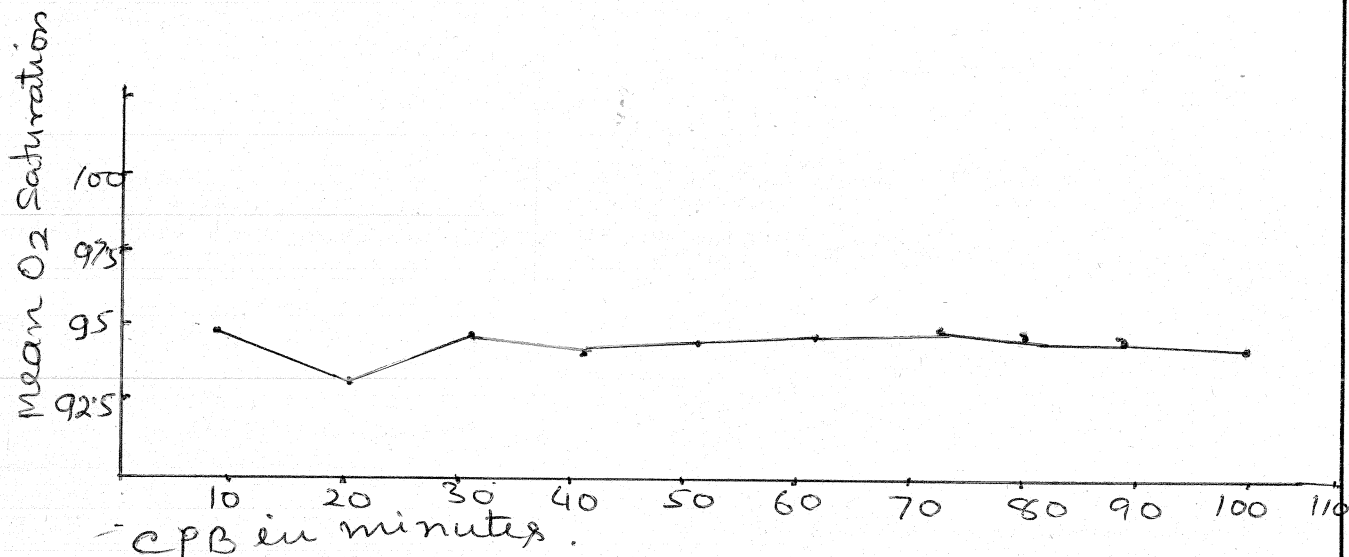


minimum 65 Torr. Among the PO_2 values recorded all but one were within the acceptable limits. Only one PO_2 value was seen below 100 mm of Hg i.e. 65 Torr. This was because of technical error in O_2 flowmeter. The oxygen flow was

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less than what it was showing.

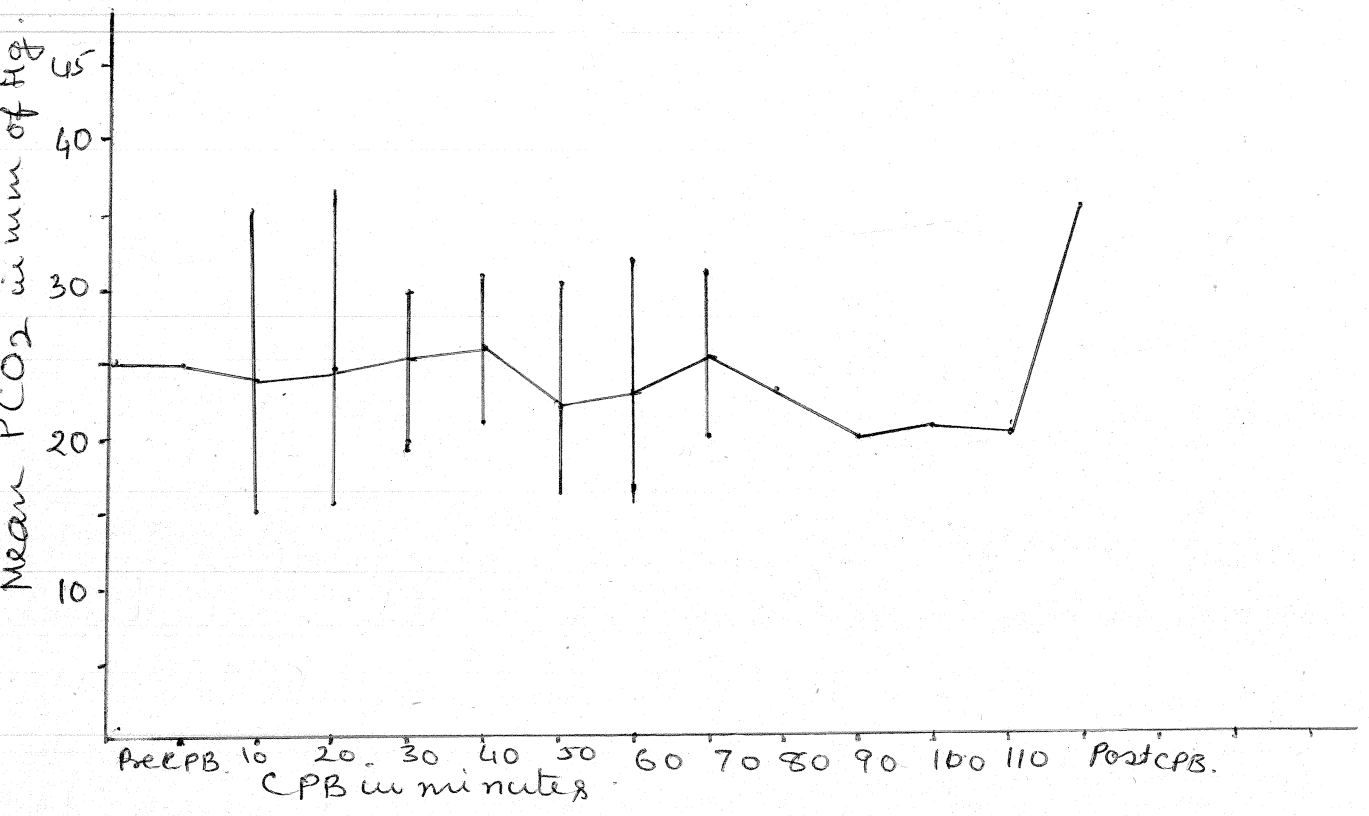
6) Oxygen Saturation O_2 saturation of arterial blood on CPB ranged from 92.5% to 96%, except one value (72.5%), due to technical error.



7) Partial pressure of CO_2 in arterial blood.

The mean prebypass PCO_2 was 24 torr and post bypass was 35.4 Torr. The mean PCO_2 on pump remained between 20.1 to 28 Torr. Minimum PCO_2 seen on pump was 16.6 and maximum 35 Torr.

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8) Temperature Regulation

As already mentioned, no active cooling was done. Active rewarming was started at 32.0°C and after a mean rewarming period of 33 minutes the mean temperature rose to 36.68°C. The rate of rewarming was 6.8 minutes for every 1°C rise.

9) Awakening time

Animal Nos. 1, 2, 3, 6 & 7 awoke after 55 min, 65 min, 2 Hr 10 min, 1 Hr 30 min and 1 Hr 35 min respectively. They were able to

breath spontaneously. All animals were extubated after a mean period of 1 Hr and 45 minutes except No. 2.

Results

All the animals could be weaned off from CPB. However only 4 of 7 animals could be extubated.

Animal No. 2 - maintained well till just before extubation on trial of spontaneous respiration. At this time sudden profuse bleeding was noticed from the chest tube. On exploration of thoracic cavity bleeding was found to be from the aortic pursestring site. By the time it could be controlled, heart fibrillated and could not be resuscitated.

Animal No. 4 - As soon as CPB was started heart arrested in diastole. The cause of arrest was high potassium content of priming volume, (ie > 20 meq). However with use of diuretics and insulin, serum K could be brought down to 3.6 meq/l and CPB could be weaned off, following which there was no urine output and serum K started rising and at value 7 meq/lit K heart

arrested again.

Animal No 5:- After coming off bypass, there was power failure and none of the parameters could be monitored. At the end of 2 hours there was QRS widening in ECG followed by ventricular fibrillation and could not be resuscitated.

Remaining 4 animals were long term survivors (>7 days). Their laboratory investigations (mean values of all 4 surviving animals) are shown in chart.

Following tables show pre and post-operative investigations.

1) Haematological profile.

Investigation.	Pre operative	Post operative.		
		Ist day	IIIrd day	VIIth day.
Plasma Hb%	10 mgs%	12.2 mg%	15.7 mg%	17.5 mgs%.
Platelets	4.5 lacs / ³ mm.	2.1 lacs.	1.6 lacs.	5.2 lacs.
Proth. time	16.6 sec.	21.2 sec.	33 sec.	32 sec.
P.T.T.	31 sec.	32 sec.	40 sec.	47 sec.
Hb% gm	9.63 gm	9.8 gm	9.5 gm	8.6 gm.
TLC	8.120 ³ mm	5.800	7.900	7.200

2. Liver function tests.

Investigation.	Pre operative	Post operative		
		1st day	3rd day	7th day.
Serum Bilirubin (mgs %)	0.68	1.0	0.92	0.8
SGOT (units)	132	151	98	60.7
SGPT. I.U.	8	10	10	7

3. Renal function tests

Inv.	Pre operative	Postoperative		
		1st day	3rd day	7th day.
BUN mgs %	24.4	26.5	17.7	20
Serum creatinine mgs %	0.97	1	1.5	0.6

4. Plasma Proteins and Electrolytes

Inv	Pre op.	Post operative		
		1st day	3rd day	7th day.
Total Pl. Proteins gm %	15.85	13.1	14.7	18.2
Albumen mgs %	7.3	7.39	8.4	7.2
Serum K ⁺	5.16	4.15	4.45	5.2.

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Conclusions. The chitra variflo oxygenator

has :-

- 1) Excellent capacity for transfer of oxygen and Carbon dioxide.
- 2) Good heat exchanging capacity.
- 3) Negligible ill effects on blood components, liver function tests, Renal function test and plasma proteins.
- 4) No evidence of embolism, which could be either due to faulty defoaming and/or Silicon particle dislodgement.
- 5) Imminent potential for clinical use.

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Acknowledgment:- I am thank full to Mr. Vekalesan and DR. Arthur & DR. Bhaskar Rao for their kind Co-operation.

A. Interposition grafting in the thoracic aorta using SITRA vascular graft.

Preoperative management:

Premedication:- The animals, (Pig & dog) were kept off feed about 20 hours prior to surgery, without restricting water intake. Each animal was premedicated as follows.

- 2ij Atropine (0.04mg/kg wt)
- +
- 2ij Promethazine hydrochloride (1mg/kg)
- +
- 2ij Pentazocine lactate (1mg/kg)
- +
- 2ij Diazepam (1 to 1.5 mg/kg)

Combination of above drug ^{was given} I.M, 45 minutes before shifting the animal to O.T.

Anaesthesia:- Anaesthesia was induced with halothane (4-5%) and N₂O (4:4) administered by a face mask attached to Boyles anaesthetic apparatus with a halothane vaporiser. Animal was intubated, and anaesthesia was maintained with a mixture of N₂O: O₂ (2:1) with IPPV using a ventilator.

Analgesics and muscle relaxant were supplemented as and when needed. Esophageal temperature was monitored. In some animals arterial pressure was also monitored with an indwelling arterial cannula, in left carotid artery and connected to a transducer and pressure monitor (dogs).

Operative procedure:- The animal was placed in the right lateral decubitus position and the left hemithorax was prepared and draped. left ^{full} lateral thoracotomy was done and chest entered through left 4th intercostal space. The chest retractor was placed. left lung was retracted anteriorly and downwards exposing the thoracic aorta. The mediastinal pleura over the aorta was incised and stay stitches were applied. The descending thoracic aorta was mobilised from the level of left brachial artery to the point of origin of 1st pair of intercostal arteries. A 4 to 5 cms of aorta was excised after applying the cross clamp above and below. As far as possible not more than one pair of intercostal vessels were sacrificed.

The gap was bridged by using suitable length of SITRA vascular graft. Both proximal and distal anastomosis were carried out using 3-0 Tevdek continuous suture. After release of cross clamp careful haemostasis was secured. Fluid was administered during release of aortic cross clamp, to maintain the pressure. Sodium bicarbonati was given intravenously to correct acidosis. Mediastinal pleura was approximated. The thoracic wound was closed in layers after leaving one I.C. tube drain.

The effect of muscle relaxant was reversed with atropine and neostigmine. When animal regained full consciousness, extubation was carried out. After few hours chest tube was taken out.

Analgesic and antibiotics were given for 5 days postoperatively.

Three such procedures were performed.

Two in dogs one in pig. 1st dog died because of uncontrollable haemorrhage from anastomotic site. 2nd dog was sacrificed because of Paraplegia, which did not recover. 3rd - Pig is still a long term survivor.

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Mitral valve replacement with Chitra tilting disc prosthesis in Sheep.

- Total experiments done one.
- Total experiments assisted Two.

Procedures: Preoperative preparation was same as in oxygenator evaluation technique.

Operative Procedure: After ~~anesthesia~~^{G.A.} was induced and endotracheal tube was put, animal was positioned in right lateral decubitus position. Left thoracotomy was done through the 4th intercostal space. Pericardium was opened and marsupialised. Cardiopulmonary bypass was established with arterial return to the descending thoracic aorta and venous drainage from RV outflow through the pulmonary artery in to the oxygenator. Core cooling was done up to 30°C. In view of the non accessibility of root the aorta, myocardial protection using cardioplegia was not possible. Hence ischemic arrest of heart with topical cooling was used. Mitral valve was approached through the LA appendage. Mitral valve

leaflets with chordae and papillary muscles were excised, leaving a 3 mm rim of cuspal tissue. Chitra tilting disc valve was seated at the mitral annulus using 12-14 interrupted horizontal mattress sutures with 2/0 ethibond. Sutures. Disc was tested for its mobility. LA incision was repaired. Separately LA vent was put. Aortic cross clamp was released ^{after} Deairing was done. heart was defibrillated with D.C. shock. Cardiopulmonary bypass was weaned off at 34°C. Venous cannula was taken out immediately as it obstructed the blood flow in MPA. Protamine was give and aortic decannulation was performed. Chest was closed in layers. after leaving one intercostal tube drain.

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