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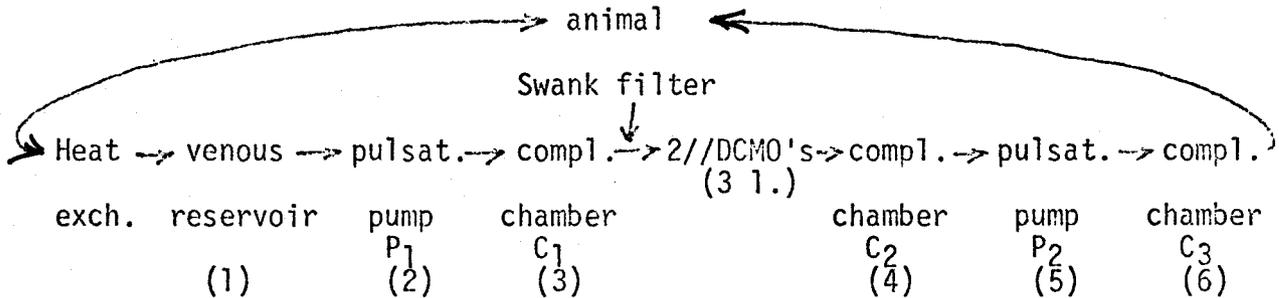
Review of VAB System

- Based on: -- Operator's Manual for TECO-Harmison H.L. machine model #104 - Thermo Electron Corporation.
-- Screening report VAB system TR 102-1-T0.001. 1 September 1972. Utah BTL.
-- Conversations with Frank Altieri.

Comments on design

The VAB pump system seems to have been designed essentially for use in conjunction with the Dow Capillary Membrane oxygenator (D.C.M.O.). According to Frank and Roger, at the time this project was initiated under Dr. Hastings, several developmental and testing procedures were intentionally by-passed in order to assemble as rapidly as possible a system which the T & E facilities could test.

The pump design corresponds to the following schema:



It contains no less than six chambers through which the blood must circulate (not counting the heat exchanger and the DCMO's). These chambers are shaped in the form of cylindrical segments and are connected by means of much narrower circular conduits (Re - Operator's Manual figure IV-3). When circulated through the pump, the blood is therefore subjected to successive accelerations (in the conduits) and decelerations (in the chambers) with possible formation of jets and trauma to the constituents of the blood. The statement (UBTL p. 4-1), unsubstantiated by either data or references, that piston pumps may be gentler than rollers is difficult to understand in the light of this design.

The high input resistance (up to 125 mmHg) of the DCMO requires the use of a feeder pump. In the absence of comparative data related to the performance of the DCMO under pulsatile and linear flow both modalities were kept in pump P₁ rendering the system complicated. As will be seen later, continuous flow seems to be more suitable. Because the DCMO is a rigid non-compliant device, the pulsatile pump P₂ cannot accept a continuous flow from pump P₁, which renders the presence of compliance chamber C₂ mandatory.

The complexity of the pump is further underlined by 1) the presence of six air gauges plus an array of control knobs on the back panel of the unit (Operator's Manual figure II-4) and this in addition to the controls on

the front panel; 2) by the fact that 13 test procedures are required before the unit can be deemed to be in functioning order; 3) by the necessity of prolonged rinsing of the system prior to priming in order to eliminate the formaldehyde from the DCMO's.

The location of the heat exchanger on the venous input side of the pump, where blood flows in continuous fashion, can presumably be explained by the fact that a pulsatile flow through this device is contraindicated. A better place could have been found between the DCMO's and compliance chamber C₂. As it is, the unacceptably high priming volume (2700 ml) and alimentionation of the DCMO with room temperature gas mixtures (O₂ - CO₂) must cause a change in blood temperature. Therefore, the maintenance of temperature in the arterial line would require a larger H₂O to blood temperature gradient and this may in turn contribute to hemolysis.

Comments on Testing and Evaluation

The UBTL report is relatively succinct but can be criticized on the following grounds:

- 1) The data are presented in a diffuse and incomplete manner.
- 2) The methodology used is not always well chosen for gathering of the desired data.
- 3) The testing and evaluation procedure is incomplete.

Referring to table 5-V comparing the physiological data during total bypass with roller pump (group A) and with VAB (group B) for 2-4 hours, only 2 animals were used in group A while 9 or 11 (it is not clear how many, since no indication is given whether only smooth flow VAB experiments or both smooth flow and pulsatile VAB experiments were used for comparison; see table 5-1) were used in group B. This does not permit a valid comparison. Neither is there any explanation as to why Swank filters were interposed both proximal and distal to the DCMO's in the roller pump system and only proximal to the DCMO's in the VAB system.

From table 5-V I extracted the following additional data:

<u>Roller pump group</u>	<u>VAB group</u>
Pre bypass Hb = 13.6 gm%	= 12.8 gm%
Bypass Hb = 8.5 gm%	= 8.8 gm%
37% hemodilution	31% hemodilution
O ₂ capacity: 8.5x1.34=11.4 Vol %	8.8x1.34=11.8 Vol %
Bypass flow: 3.6 l/min	3.9 l/min
S _a O ₂ : 92%	91.1%
S _v O ₂ : 35.6%	56.0%
A-V diff. SO ₂ 56.4%	35.1%
* O ₂ Uptake $\frac{11.4 \times 56.4 \times 3.6 \times 10}{100}$	$\frac{11.8 \times 35.1 \times 3.9 \times 10}{100}$
= 231.5 ml O ₂ /min	= 161.5 ml O ₂ /min

* Excluding dissolved O₂ fraction: pO₂'s and O₂ disolution coefficient (α) in bovine blood not given.

This difference in the O_2 animals was not detected. In view of almost equal perfusion flows and normal pH_a 's and p_aCO_2 's was it due to differences in the weights of the animals or in their body temperature during bypass??

Perfusion flow in the VAB group seems to have been just adequate (normal pH_a and p_aCO_2 , normal A-V difference in O_2 saturation, mean art P 72 mmHg) but insufficient in the roller pump group (normal pH_a and p_aCO_2 ; A-V difference in O_2 saturation 56.4% instead of normal 33-36%). The insufficient flow and greater hemodilution in this group may also explain the low mean arter. press. of only 60 mmHg which is at the lower limit of that required to insure adequate coronary perfusion especially with hemodilution.

The SO_2 A-V difference values also indicate that performance of the DCMO's was better with the roller pump than with the VAB. For similar arterial SO_2 's and with almost equal perfusion flows, the O_2 extraction was larger when the DCMO was used in conjunction with the roller pump. However, especially in the case of the VAB system, the inability of the 2//DCMO (operating at 60% of flow capacity) to raise SO_2 from 56% to above 91% when the blood has been subjected to over 30% hemodilution indicates a marginal level of performance.

Although hemolysis values with the VAB and with the roller pump were not comparable because different priming volumes were used during in vitro hemolysis testing, the VAB system is a hemolysis machine.

Blood parameters given in table 5-IX are not very useful since changes from pre-bypass to post bypass levels were not determined.

Conclusions

- 1) The VAB is inferior to currently used equipment.
- 2) Its complexity precludes practical function in the O.R.
- 3) Despite survival of a number of animals put on total bypass, the design is not compatible with prolonged perfusion.
- 4) Clinical testing is contraindicated.
- 5) Cost of continued development and testing is not justified.

Summary of Personal Opinions

This review indicates:

- 1) The need to characterize the functional capabilities of such systems according to more complete and more rigorous criteria.
- 2) The need to obtain comparative data under more standardized in vitro experimental conditions before proceeding to expensive T & E on the live animal.