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## Pulsatile Assist: Clinical Experience in 100 Cases

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In this day and age of cardiovascular surgery with cardiopulmonary bypass (CPB), the perfusionist strives to maintain or mimic normal physiologic parameters such as blood gases, electrolytes, blood flows and so on. The surgical team employs such myocardial protection techniques as topical cooling and cardioplegia. The anaesthesiologist endeavours to maintain hemodynamic and respiratory parameters within normal limits. However, during routine CPB, the phasic, pulsatile nature of arterial systemic pressure is completely omitted with current standard extracorporeal perfusion equipment. Lack of widespread acceptance of devices to create pulsatile flow during CPB may be a result of the unavailability of safe, simple equipment until recently. Lack of acceptance may also suggest the popular opinion is that steady "mean" arterial pressure is sufficient to support vital organs (eg. heart, brain, liver, spleen and kidneys). But previous investigators have recognized that pulsatile flow perfusion has significant clinical advantages.<sup>1-6,8,9</sup> Several investigators have even demonstrated the effectiveness of using an intra-aortic balloon to create pulsatile flow during CPB.<sup>10,11</sup>

Hence, a clinical evaluation of the AVCO Pulsatile Bypass Pump® (PBP) Device, was conducted.

The purpose of this paper is to detail our clinical experience with the PBP and outline the benefits we were able to appreciate.

### Materials and Methods

The AVCO\*PBP is a disposable device designed to be incorporated into the arterial line of the extracorporeal circuit prior to CPB. (Fig. 1) It is constructed of two separate single-lumen AVCOthane® balloons sealed within a rigid cylindrical polycarbonate shell. Attached to the PBP device are two lengths of  $\frac{3}{8}$ " I.D.,  $\frac{3}{32}$ " P.V.C. tubing, each with a  $\frac{3}{8}$ " I.D. "Y" connector joined in common with a length of  $\frac{3}{8}$ " I.D.,  $\frac{3}{32}$ " P.V.C. tubing. This configuration provides a shunt around the device should any problems be encountered. (Fig. 2) Also connected to the PBP is a 12 foot length of  $\frac{1}{4}$ " I.D. tubing, the lumen of which communicates with that of one of the AVCOthane balloons. This tubing is manually connected, prior to use, to a Model 7 AVCO Balloon Pump Console modified to "drive" the P.B.P. device. (Fig. 1)

The PBP connections to the arterial line were secured with locking plastic strap ties. Priming of the extracorporeal circuit was done in a normal manner with additional steps, to ensure complete purging of air from the PBP, performed just prior to cannulation.

Tubing clamps were placed on the  $\frac{3}{8}$ " I.D. tubing between the "Y" connector and the body of the PBP, thus diverting flow of the prime through the shunt. The

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\* AVCO Medical Products, Everett, Massachusetts.

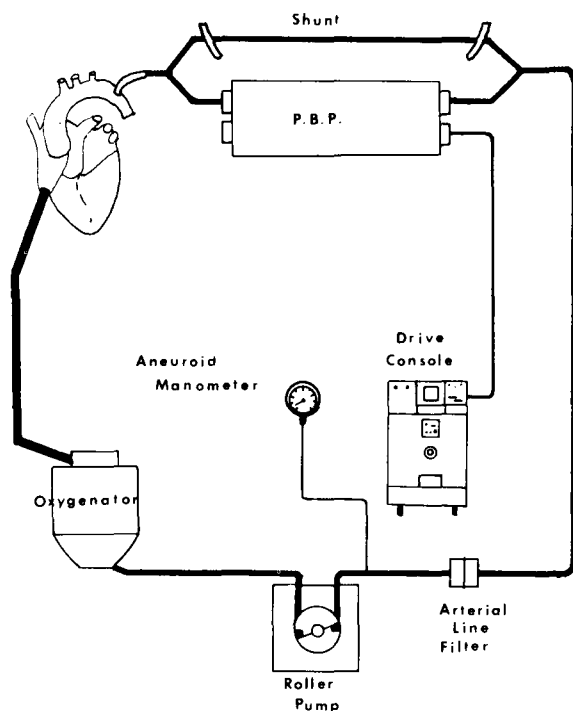


FIGURE 1. Diagram of extracorporeal circuit with PBP device (shunt clamped).

shunt was purged of air bubbles, and the roller pump stopped. The shunt line was then clamped proximal to each "Y" connector, and the clamps applied previously were removed to allow diversion of the flow through the PBP. Resuming recirculation with the roller pump, the PBP was then activated via the console and air was purged from the PBP. The PBP was then switched off, all clamps were removed and recirculation continued until all visible air bubbles had been purged. The arterial and venous lines were then clamped and the "sash" divided, ready for cannulation.

**Patient Selection**—From October 1977 to March 1979, 100 patients undergoing routine aorto-coronary bypass grafting (ACBG) were selected as candidates for pulsatile flow CPB. The PBP was inserted in the extra-corporeal circuit for any patients meeting at least one of the following criteria: grade III to IV (N.Y.H.S.) ventricle, poor preoperative endocardial viability ratio, poor renal function, carotid stenosis or left main stem coronary artery disease with a stenotic lesion greater than 70%.

A control group was selected for comparison. This groups consisted of all patients undergoing routine ACBG operations who did not meet the previous criteria and 3 patients who met the requirements but PBP devices were unavailable.

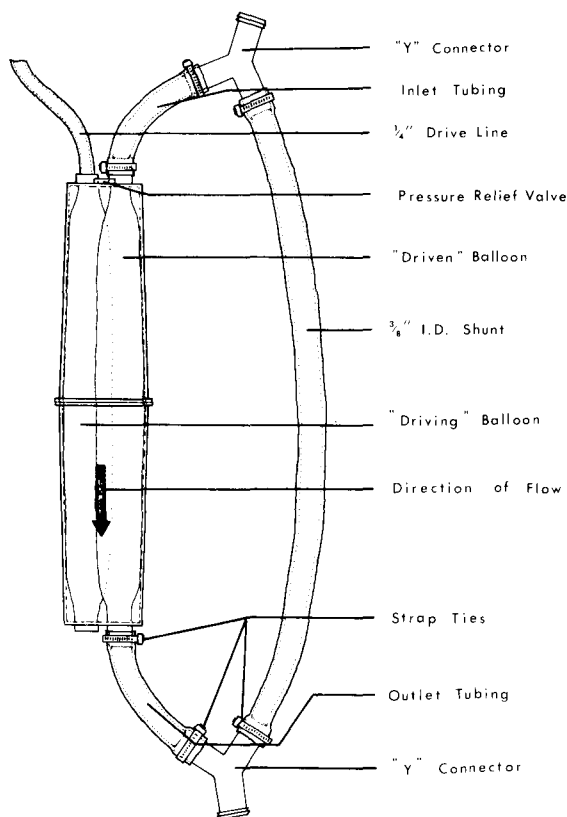


FIGURE 2. The AVCO Pulsate Bypass Pump Device.

All bypasses were performed using a Sarns\*\* Model 2000 pump console and E for M VR-6\*\*\* monitoring equipment (with Simultrace recorder). Arterial line resistance was routinely monitored with an aneuroid manometer gauge. (Fig. 1). Of the 100 cases, 24 utilized the Travenol T.M.O.\*\*\*\* oxygenator with the Bentley BOS-10 Spiraflo\*\*\*\*\* bubble oxygenator being used for the remainder. Priming of the extra-corporeal circuit was standardized to 2,000 ml. of heparinized lactated Ringer's solution with 5% Dextrose to which was added 20 mEq of potassium chloride and 2 grams of calcium chloride. Upon institution of CPB, 100 mEq of sodium bicarbonate was added to the circuit as a buffer. During CPB volume loss due to diuresis and blood loss was replaced with appropriate volumes of lactated Ringer's with 5% Dextrose.

Cannulation was via the femoral artery in 82 cases using U.S.C.I.\*\*\*\*\* cannulae, and aortic arch can-

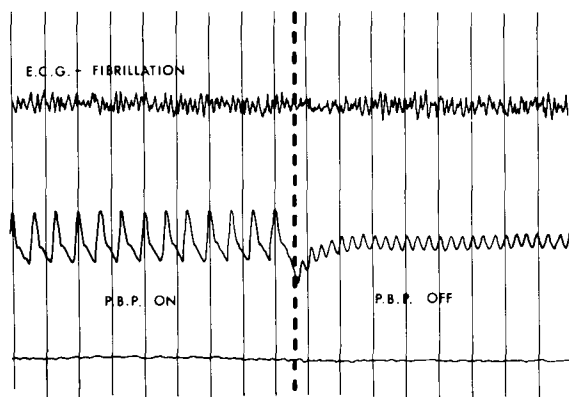
\*\* Sarns, Inc., Ann Arbor, Michigan.

\*\*\* Electronics for Medicine, White Plains, N.Y.

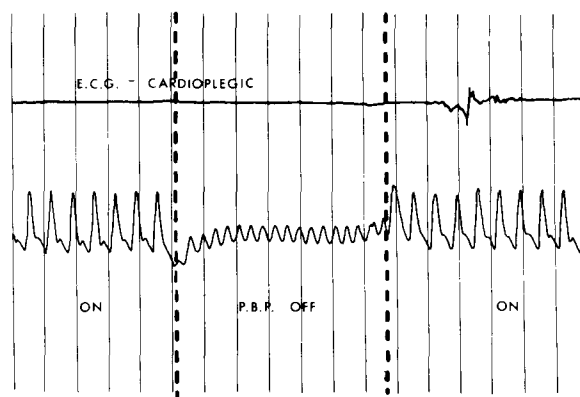
\*\*\*\* Travenol Laboratories Inc., Deerfield, Illinois.

\*\*\*\*\* Bentley Laboratories Inc., Oxnard, California.

\*\*\*\*\* C.R. Bard Inc., Billerica, Massachusetts.



**FIGURE 3.** Recording of Systemic Arterial Pressures on Total Cardiopulmonary Bypass (fibrillating heart) with and without Pulsatile Flow.



**FIGURE 4.** Recording of Systemic Arterial Pressures on Total Cardiopulmonary Bypass (cardioplegia induced asystole) with and without Pulsatile Flow.

nulation was carried out in 18 cases with rigid angled aortic cannulae (Argyle THI)\*\*\*\*\*. Moderate hypothermia (28°C) and left ventricular venting were routinely employed.

The technique of surgery varied due to surgical preference. With 45 patients, aortic anastomoses were accomplished with a partial aortic clamping prior to CPB coronary anastomoses being completed on total CPB with a fibrillating heart. Another 37 operations were performed employing the sequence of distal anastomoses first, on total CPB with a fibrillating heart and intermittent anoxic arrest, and proximal anastomoses secondly, on CPB with an empty beating heart. Eighteen cases were performed with cardioplegia for myocardial protection.

Pulsatile flow during CPB was instituted immediately following induced or spontaneous fibrillation of the heart. The balloon pump drive console was switched on and with internal triggering of the system set at a rate of 90 b.p.m. the PBP was activated, keeping a close watch on arterial line resistance. The volume setting of the device was increased if necessary to obtain optimal pulsatile flow, and after all parameters were deemed satisfactory, the bypass shunt was clamped.

Upon spontaneous or induced reversion to sinus rhythm, the PBP was deactivated by switching off the balloon console, and the shunt line was unclamped.

In 5 patients, diastolic augmentation during CPB was performed prior to and after weaning from CPB following unsuccessful attempts to wean the patient from bypass. Diastolic augmentation was achieved by input of the patient's E.C.G. into the drive console and

adjusting the inflation and deflation controls accordingly. In order to maximize the efficiency of the device as an augmentor, tubing clamps were applied to the shunt line during CPB and, additionally, proximal to the PBP device on the arterial line inlet side upon termination of CPB. Of the total 5 patients receiving counterpulsation of this sort, 1 had aortic cannulation while 4 had femoral artery cannulation.

Blood flows through the coronary artery bypass via saphenous vein grafts, were measured during CPB with and without pulsatile flow while the heart was fibrillating. Blood flows through vein grafts were also measured post-CPB with and without the PBP acting as a counterpulsation device. These measurements were not performed on all patients. Measurements were obtained with Statham Blood Flow Meter (SP2201) and Recorder (SP2007).\*\*\*\*\*

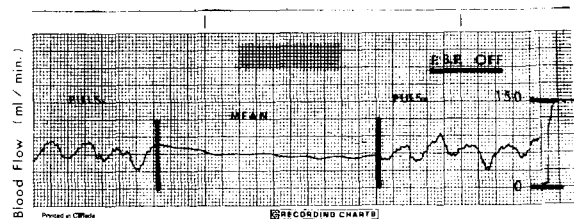
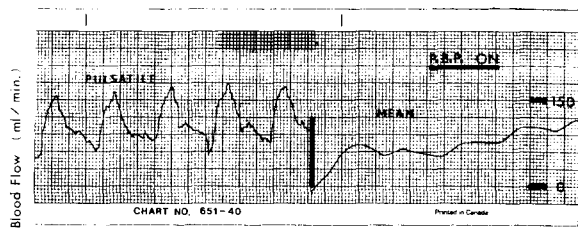
## Results

Pulse pressure created by the PBP during CPB ranged from 35 mm. Hg. to 60 mm. Hg with mean pressures ranging from 70 to 80 mm. Hg. The normal range of non-pulsatile bypass pressure was comparable as were average blood flows as shown in Figures 3 and 4.

There were no device-related complications. However, we found that smaller gauges of cannulae compromised the action of the PBP and generally resulted in lower pulse pressures with higher arterial line resistances. In one case, employing an 18 Fr.G. Cannula,

\*\*\*\*\* Sherwood Medical Industries, St. Louis, Missouri.

\*\*\*\*\* Statham Medical Division, Oxnard, California.



**FIGURE 5A.** Blood Flow Measurements in L. A. D. Saphenous Vein Bypass Graft With Pulsatile Flow During Cardiopulmonary Bypass With a Fibrillating Heart. Blood Flow Measurements in L. A. D. Saphenous Vein Bypass Graft Without Pulsatile Flow During Cardiopulmonary Bypass With a Fibrillating Heart.

use of the PBP was discontinued due to the creation of excessive arterial line resistance.

There were no intra- or post-operative deaths in this series. Approximately 2% of the patients sustained perioperative infarction as determined by post-operative serial E.K.G.'s and CPK studies.

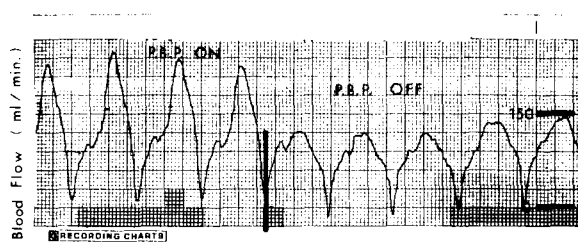
Prior to our experience with PBP as a counterpulsation device, only two patients had post-operative low cardiac output states and were successfully managed with insertion of an intra-aortic balloon for counterpulsation. Again, only three patients required management with inotropic agents (dopamine) post-operatively.

The control group experienced three post-operative deaths and two late post-operative deaths. Seven patients required post-operative intra-aortic balloon counterpulsation (this includes three of those who died post-operatively). Six patients (included in both previous groups) required management with inotropic agents.

During bypass, the urine output of patients undergoing pulsatile flow CPB was almost double that of patients without pulsatile flow.

Routine post-bypass hemolysis and platelet studies were comparable between the pulsatile and non-pulsatile flow groups.

Blood flow through the saphenous vein bypass grafts



**FIGURE 6.** Blood Flow in a Saphenous Vein Bypass Graft During Post-Bypass Synchronous Counterpulsation.

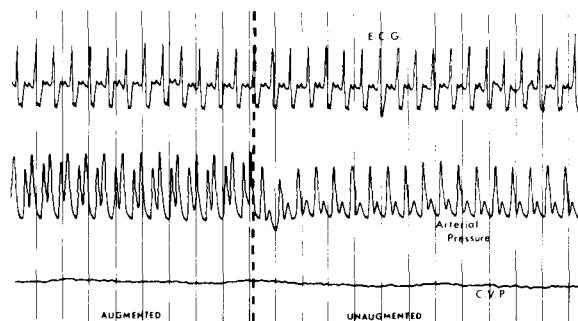
during CPB with a fibrillating heart showed marked improvement over non-pulsatile flow in both the pulsatile and mean values when the PBP device was in use. (Fig. 5 a & b).

Flow through the bypass grafts were also greatly improved when the PBP device was used as a counterpulsation device following CPB. (Fig. 6). Performance of the PBP as a counterpulsation device is visualized in Fig. 7 and 8. Counterpulsation has been performed in only 5 patients (one pre-bypass) and for periods of time not exceeding thirty minutes.

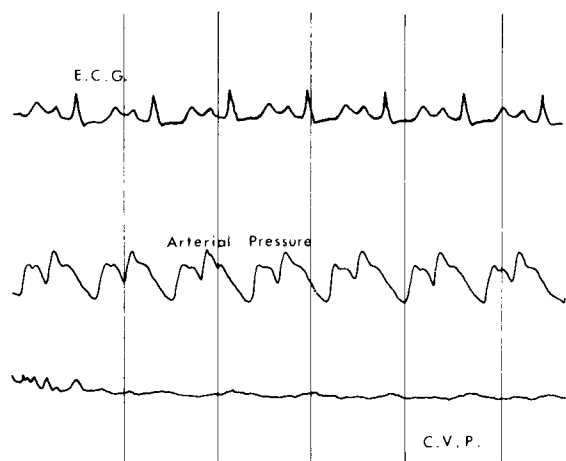
## Discussion

Pulsatile flow during cardiopulmonary bypass has been a topic of controversy for some time. Many investigators have, however, provided evidence in its favour,<sup>7</sup> and in total this evidence outweighs any arguments of refutation.

Our experience with the AVCO PBP lends support to the argument in favour of pulsatile flow. The increased urine output of the group with pulsatile flow suggests improved organ (kidney) perfusion. The result of blood flow measurements in a fibrillating heart with pulsatile flow (Figure 5 a & b) is an obvious indication of improved perfusion to the myocardium during bypass. The pressure tracings and blood flow measure-



**FIGURE 7.** Recording of Systemic Arterial Pressure Using the PBP as a Synchronous Counterpulsator (with femoral artery cannulation) post CPB.



**FIGURE 8.** Recording of Systemic Arterial Pressure Using the PBP as a Synchronous Counterpulsator (with aortic cannulation) post CPB.

ments shown in Figure 6, 7 and 8 demonstrate the excellent performance of the PBP as a counterpulsator.

The excellent mortality rate, lack of device-related complications, low incidence of perioperative infarction, infrequent requirement of inotropic pharmaceutical support and a sharp decline in the number of intra-aortic balloons used at our institution since the inception of the use of the PBP demonstrates the efficacy of the PBP and intimates the superiority of pulsatile flow.

The AVCO PBP has proven to be a reliable, atraumatic, safe device. Much of its safety is inherent in its design. A simplified explanation of the PBP's mode of operation will aid in clarifying this statement. As mentioned previously, the AVCO PBP is composed of two "balloons" within a cylindrical polycarbonate shell (Fig. 2)

The balloon connected to the pump console via the  $\frac{1}{4}$ " tubing (the "driving" balloon) is alternately inflated and deflated with compressed air. The other "balloon" (The "driven" balloon) is more appropriately an open-ended tube of AVCOthane®. When the device is connected into the arterial line, blood flows within this tube. The expansion and contraction of the driving balloon within the sealed polycarbonate shell, against the blood filled "balloon", results in a pulsatile flow in the arterial line. Should rupture of the driving balloon occur, the compressed air would simply be vented through a pressure relief valve in the polycarbonate shell (Fig. 2). Rupture of the blood-filled balloon would theoretically result in a displacement of air within the shell through the pressure relief valve with little chance

of ingestion of air. Rupture of both balloons simultaneously is highly unlikely. In any event, the PBP can be quickly omitted from the extracorporeal circuit by placing tubing clamps on the outlet and inlet sides of the device.

We entirely agree with the manufacturer in warning against use of the vacuum system incorporated in the original modification to the I.A.B.P. console, especially when using the device as a counter pulsator, as this may lead to cavitation and resultant microemboli. We also wish to recommend the use of the largest arterial cannula possible and advise against using cannulae smaller than 20 Fr.G..

Finally, we would like to point out a singular disadvantage with this system and that is cost. The expense of the AVCO PBP had led us to limit its use to only those patients meeting the criteria outlined in the materials and methods. If this device was less dear, or should a system of similar capability become readily available, we would not hesitate in utilizing pulsatile flow CPB on each and every open heart patient.

#### Acknowledgements

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#### References

1. Boucher, J. K.; Rudy, L. W. Jr.; Edmunds, L. H. Jr.: Organ Blood Flow During Pulsatile Cardiopulmonary Bypass. *J. Appl. Physiol.*, 36:86, 1974.
2. Wilkens, H.; Rogelson, W.; Hoffmeister, F. S.: The Physiologic Importance of Pulsatile Blood Flow. *N. Engl. J. Med.*, 267:443, 1962.
3. Habal, S. M.; Weiss, M. B.; Spontnitz, H. M., et. al.: Effects of Pulsatile and Nonpulsatile Coronary Perfusion on Performance of the Canine Left Ventricle. *J. Thorac. & Cardiovasc. Surg.*, 72:742, 1976.
4. Jacobs, L. A.; Klopp, E. H.; Seaman, W.; Topaz, S. R.; Gott, V. L.: Improved Organ Function During Cardiac Bypass With a Roller Pump Modified to Deliver Pulsatile Flow. *J. Thorac. & Cardiovasc. Surg.*, 58:703, 1969.
5. Dunn, J.; Kirsh, M. M.; Harness, J., et al.: Hemodynamic Metabolic and Hematologic Effects of Pulsatile Cardiopulmonary Bypass. *J. Thorac. & Cardiovasc. Surg.*, 68:138, 1974.
6. Mandelbaum, I.; Berry, J.; Silbert, M.; Burns, W. H., and Rothe, C.: Pulsatile and Nonpulsatile Blood Flow. *J. Am. Med. Ass.*, 191: 657, 1965.
7. Wright, G.; Dunn, W. E.: Pulsatile Pumps For Use in Open-Heart Surgery. *Am. Sect. Proceed.*, 6:74, 1978.
8. Bregman, D.; Bailin, M.; Bowman, F., et. al.: A Pulsatile Assist Device (PAD) For Use During Cardiopulmonary Bypass. *Ann. Thorac. Surg.*, 24:574, 1977.
9. Shepard, R. B.; Kirlin, J. W.: Relation of Pulsatile Flow To Oxygen Consumption and Other Variables During Cardiopulmonary Bypass. *J. Thorac. & Cardiovasc. Surg.*, 58:694, 1969.

10. Bregman, D.; Parodi, E. N.; Haubert, S. M., et. al.: Unidirectional Intra-aortic Balloon Pumping and Counterpulsation During Open Heart Surgery, *Mechanical Support of the Failing Heart and Lungs*, D. Bregman, Ed., Appleton-Century-Crofts, New York, 1977.
11. Philips, P. A.; Bregman, D.: Intraoperative Application of Intra-aortic Balloon Counterpulsation Determined by Clinical Monitoring of the Endocardial Viability Ratio. *Ann. Thorac. Surg.*, 23:45, 1977.