A NEW PULSATILE ROLLER PUMP: CHARACTERIZATION AND PRELIMINARY CLINICAL APPLICATION.

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A new pulsatile roller pump based on the concept of intermittent flow produced by one roller instead of two in conjunction with a compliant pump head tube and a pinch valve on the outlet side of the pump head has been developed. The pressure and flow characteristics mimick those of the natural heart, having even the equivalent to the isometric phase and the fast initial ejection of the natural heart. The pump delivers one stroke per each revolution. The stroke volume is a function of the tube size, but for a given size there is an optimal rpm rate at which the stroke volume is largest. Smaller tubes (6 and 9 mmID) for use in infants or children have a high optimal rate (100-130/min), while tubes larger than 12.5 mmID have an optimal rate of 60-90/min and are suited for use in adults. In vitro mean flows of 10 l/min with peak flow velocities reaching 25-27 l/min are consistently obtained. The in-vitro hemolysis is similar to that induced by conventional roller pump or the pneumatically driven valved ventricular assist device (Nihon Zeon LVAD) but significantly less (p<0.01) than that induced by the arterial line pulsator (Kontron PBP). Preliminary clinical application in 60 patients has proven its efficacy as a pulsatile pump (pulse pressure of 45 to 65 mmHg being consistently obtained), as well as its simplicity and low operational cost.

Key words: Pulsatile monoroller pump, solenoid driven pinch valve, cam driven pinch valve, pressure-flow characteristics, hematologic effects, pulsatile pump hemolysis, clinical perfusion pulse pressure, pulsatile efficacy, pump head tube compliance.

The wide clinical application of the conventional biroller pump delivering continuous flow for cardiopulmonary bypass is testimony of its reliability, at least for relatively brief procedures. Although controversial, numerous reports have appeared endorsing the superiority of pulsatile perfusion systems, especially for long perfusions. A number of pulsatile systems have been reported: air driven piston pumps(1), mechanically driven bellows type pumps (2,3), mechanically driven diaphragm devices incorporating cardiac ball valves (4), and roller pumps modified to deliver pulsatile flow by alternating the speed of rotation which is perhaps the simplest and most commonly used method (5,6,7). The development of intraaortic balloon pumps (IABP) led to its application as pulsators within the aorta (8) or in the arterial perfusion line (9) (Kontron pulsatile bypass pump=PB, or the Datascope pulsatile assist device=PAD) of roller or centrifugal pump systems. Desjardins et al (10) achieved pulsatile perfusion by combining two conventional roller pumps in parallel, from one of which (arterial line pulsator pump) one roller had been removed, and fitting a distally blinded silicone rubber tube whose proximal end was connected via a "Y" connector to the arterial line from the perfusing second conventional roller pump. Although all systems deliver "pulsatile" flow, the pressure and flow characteristics are all dissimilar, the complexity and reliability are variable, and finally the additional cost might be considerable, a fact that can not be overlooked in these days of cost containment. The present investigation was aimed at solving these major drawbacks by further developing the concept of the roller pump.

MATERIAL AND METHODS

Fundamental principles of the new pulsatile monoroller pump (MRP). The pump is designed based on the interaction of the milking effect of the ONE ROTATING ROLLER on the tube fitted within the horse shoe shaped RACEWAY, and the ELASTICITY or COMPLIANCE of the PUMP HEAD TUBE itself (MERA-MS tube). Since there is only one roller and the raceway is less than 360°, a PINCH VALVE on the outlet of the pump head tube must be provided to prevent back flow. By proper timing of the opening and closure of the pinch valve, not only the back flow is prevented but adequate PRESSURIZATION of the elastic pump head tube can be achieved (Fig 1). The pinch valve can be driven with either a solenoid or a cam mechanism. Since each revolution of the pump delivers one pulse or stroke, it does not require complex and costly control systems. For a given pump head diameter, the
internal diameter (ID) of the used tubing determines the stroke volume, and the speed of rotation of the pump (rpm or strokes per minute) the minute-flow or pump output.

Pressure and flow characterization. These physical parameters of the flow produced by the MRP when using different tube sizes, and different raceway arc lengths were analyzed. Figures 1 and 2 depict the circuit used and the sites from which pressures (Nihon Kohden transducer) and flows (Nihon Kohden electromagnetic flow probe) were obtained. The reservoir of the circuit was held at 136 cm above the pump head level.

In vitro hemolysis. The traumatic effect of this pump to the blood elements, specifically the red cells, was evaluated by determination of free hemoglobin in plasma. The hemolysis induced by this pulsatile MRP was compared to that induced by the golden standard, the conventional roller pump, as well as the pneumatically driven left ventricular assist device (Nihon Zeon LVAD). Single donor beef fresh blood, citrated and heparinized immediately after bleeding, strained, filtered (Pall filter) and adjusted to hematocrit of 26-27 with isosmotic dextrose and saline solution was used to prime each of the circuits with 4,000 ml. The change or Δ of free hemoglobin concentration was determined hourly for 4 hours of pumping at 3,700 ml/min which was the maximal flow obtainable by the Zeon-LVAD pump of 45 ml capacity driven at +250 and ±10 mmHg. In a separate but similar study the hemolysis induced by arterial line pulsators at 60 beats/min (Kontron PBP driven at +650 and ±20 mmHg, and the compliant chamber as described by Desjardin et al) were compared against the conventional roller pump at 4,000 ml/min flow rate for 4 hours.

RESULTS
Pressure and flow characterization of the MRP. Figure 3 illustrates the recording obtained with two different length raceways (150° and 180° arc) and the two driving mechanisms of the pinch valve (solenoid and cam). The pressure within the pump head tube upstream the pinch valve (P1) is the equivalent to the LV pressure of the heart, and the pressure in the outlet tube downstream the pinch valve (P2) is the equivalent to the aortic pressure. Although the tracings obtained with the cam driven pinch valve MRP are somewhat more complex than those obtained with the solenoid driven pinch valve MRP, the overall sequence of events is similar for both pumps. One full cycle can be divided in three phases: a) pressurization phase, produced by the roller milking the compliant tube against the closed pinch valve; b) ejection phase, during which the pinch valve is opened, has an initial fast component contributed by the pressurized compliant tube followed by a period of constant velocity flow produced by the milking roller, and c) filling phase, during which the pinch valve is closed, the extent of the filling being determined by the elasticity of the tube and the existing preload in the inlet tube.

The stroke volume is a function of the pump head tube ID and the length of the tube being milked by the roller against the raceway, in turn a function of the pump head diameter and the arc of the raceway (Figs 4, 5). Also, like with the natural heart, the preload and frequency determine the degree of filling of the elastic tube; shortening of the filling time below a limit results in a decrease of the pump output, just like excessive tachycardia impairing the cardiac output of the natural heart. This determines the interesting fact that for a given ID tube and a given arc raceway there is an optimal speed of rotation (rpm) at which the stroke volume is maximal. Increasing or decreasing the rpm beyond that optimal rate results in a decrease of the stroke volume. However even at its worst setting the stroke volume is close to the predicted one, at least in this less than perfect mock system.

In vitro hemolysis. The hemolysis produced by the MRP is similar to that of the conventional roller pump and of the pneumatically driven valved Zeon LVAD, at least up to 4 hours of pumping (Fig 6), well within the ranges reported in the literature for the conventional bi-roller pump (4).

The hemolysis produced by both arterial line pulsators is significantly (p<0.01; "t" Student test) greater than that induced by the conventional roller pump (Fig 7). Although the hemolysis produced by the conventional roller pump alone in this study was somewhat less than that in the previous series, the conventional roller pump served as the standard against which other systems were compared, and it is obvious that arterial line pulsators are more hemolytic than the MRP or the pneumatically driven Zeon LVAD.

PRELIMINARY CLINICAL APPLICATION

The pulsatile MRP has been used in 60 patients older than 65 when perfusion times were anticipated to be longer than 3 hours, or regardless of the age when preoperative renal function, liver function or brain perfusion impairment was documented. A detailed report on this experience will be reported in a separate study comparing the MRP to the pneumatically driven arterial pulsator (Kontron-PBP) or the pulsatile roller pump based on rotational speed alternation. It suffices to state that proper selection of the pump head tube size in relation to the size of the patient is of paramount importance to obtain adequate pulse pressure waves as shown in Figure 8, which illustrates two extremes: one adult 80 Kg patient and one child of 5.3 Kg in body weight. Pulse pressures of 40 to 65 mmHg are consistently obtained when the proper size tube had been selected, as opposed to 25 to 35 mmHg only when too small tube size was chosen (Fig 9).
The controversy over pulsatile and non-pulsatile perfusion during cardiopulmonary bypass continues, and perhaps this conflict stems from the fact that the various forms of pulsatile perfusion are all dissimilar, some more or less effective than others. It is not the purpose of this paper to discuss the physiological aspects or advantages of pulsatile perfusion, nor to determine the superiority of one system over the other. In order to duplicate a normal aortic pulse wave, the pump should be designed so that the ejection phase is less than 30% of the cycle, the arterial pump tubing should be short and rigid, and the arterial cannula should be equal in diameter to the aortic annulus. This is obviously impossible to achieve short of using the artificial heart in the orthotopic position. Therefore, regardless of the system used, the arterial pulse wave produced by any pulsatile pump system for routine cardiopulmonary bypass will be far from being an exact duplication of the pulse wave produced by the normal contracting heart.

The complexity, reliability and running cost of the systems currently in use are also variable. For pulsatile perfusion to be used in every day practice of cardiac surgery routinely, the following conditions must be fulfilled: a) the system must be capable to produce an effective pulse pressure consistently, i.e., as close to that produced by the natural heart as possible, b) it must be simple engineering wise as well as in term of its operation, c) it must be as safe as the golden standard, i.e., the conventional roller pump, and lastly d) it must be inexpensive to run to be cost-effective in this era of having to curtail medical care budget.

The simplicity and reliability of the conventional biroller pump has stood the test of time, and any new device must measure up to it. The new pulsatile MRP takes advantage of this aspect of the roller pump and has modified it to produce an intermittent flow with pressure and flow characteristics resembling those of the natural heart. To achieve this the concept of a pinch valve has been introduced to the present perfusion technology. This pinch valve adds a new dimension to the roller pump when combined to tubes with proper compliance characteristics. It allows building up and storing pressure before the actual flow starts (pressurizing phase), just as the natural heart has an isometric phase during which there is building up of pressure but no flow. When the pinch valve opens and the flow starts (ejection phase), it does so at a high velocity initially followed later by a period of constant speed flow according to the rotational speed of the pump (rpm), a pattern of flow similar to that of the natural heart ejection. It is interesting to note that for a given ID tube, there is an optimal rotational speed at which the stroke volume is the largest, just as the natural heart has an optimal efficiency rate. The remarkable similarity is that smaller tubes have a higher optimal rpm rate than larger tubes, just like smaller size hearts (infants or small animals) have a higher basal rate than larger hearts (adults or larger animals). What is most interesting is that tube sizes with stroke volumes adequate for a given body weight have an optimal rpm rate closer to the natural heart rate for such size body. Commercially available (MERA–MS tube) sizes of 6, 9, 12.5, 15 and 18 mm ID will cover effectively flow requirements from 900 ml/min at a rate of 100 rpm, up to 6,000 ml/min or more at a rate of 80 to 90 rpm. For smaller infants or newborns, tubes with less than 6 mm ID, or a pump head with smaller diameter should provide the required smaller flow rates at higher rpm than 100/min. Delivering the proper stroke volume in the time period closest to the normal cardiac systole at intervals as close to the normal heart are the determinants for a normal pulse pressure and flow wave forms, and the selection of the proper size tube as well as pump head diameters are crucial when using any pulsatile pump systems.

The MRP delivers one stroke or pulse for each revolution, thus the speed or rpm to maintain a given pulsatile flow are significantly lower than the rpm required by roller pumps producing pulsatile flow by alternating speed of rotation. Increased hemolysis by high revolution roller pumps have been reported (11), and it seems logical to anticipate less hemolysis with the MRP than alternating speed pulsatile roller pumps.

The engineering simplicity of the MRP, particularly the cam-driven pinch valve MRP, makes this pulsatile pump as safe and as simple to operate as the conventional roller pump. The traumatic effect of this pump on the blood elements is no worse than the conventional roller pump, and at all similar to that induced by pneumatically driven LVADs. This has important implications in environments like Japan, where the use of mechanical assist devices as a bridge to transplantation is still far from the horizon. Under these circumstances, the MRP might fulfill all that is needed to support mechanically patients in profound shock long enough for their recovery, at a fraction of the cost of the pneumatically driven valved assist devices being tested clinically at the present time.

Thorough understanding of the flow characteristics of this pulsatile MRP is essential to use it clinically, especially in patients requiring large flows. The MRP demands inlet and outlet tube diameters capable to handle instantaneous flow rates of up to 30 l/min. Although in the clinical setting mean flows in excess of 6 l/min are seldom needed, even to satisfy this limited flow, inlet tubing of at least 12.5 mm ID, and outlet tubing and cannula of 9 mm are mandatory. Commercially available oxygenators were designed to be used with continuous flow pumps and the arterial line connector is of only 9 mm, obviously inadequate to be coupled with the inlet tube of the MRP. To overcome this physical limitation a 200 ml bag type reservoir with an outlet tubing of at least 12.5 mm ID to fit the inlet tube of the pump head is placed upstream the MRP. To fill this reservoir gravity is adequate for bubble or externally perfused hollow fiber oxygenators;
otherwise it could be filled with a separate roller pump assigned to the membrane type or internally perfused hollow fiber oxygenators. The instantaneous flow velocities reached by the MRP also precludes the use of the currently available blood filters downstream the pump; such filters must be placed upstream the reservoir. Taking these precautions, however, allows clinical pulsatile perfusion with the MRP for prolonged periods (longer than 8 hours, unpublished data) without evidence of undue excessive blood trauma.

Lastly but not least is the cost-effectiveness aspect. This pulsatile MRP needs no expensive additional gadgets like the arterial line pulsators, the IABP nor valved mechanisms inside the blood stream. It uses pump head tubes that are currently being used routinely for extracorporeal circulation with the conventional biroller pump. Whatever the beneficial effects of truly pulsatile perfusion, they can be achieved at no additional cost, thus questioning the pedestal position of the conventional biroller pump producing non-pulsatile flow as the standards of perfusion during cardiopulmonary bypass for cardiac surgery.

REFERENCES


Fig 1. Schematics of the pulsatile monoroller pump. The pinch valve remains closed during the initial phase of the roller's race on the raceway; the ejection phase starts when the pinch valve opens. The valve closes again just before the roller leaves the raceway.

Fig 2. Schematic representation of the used circuit.
Fig 3. Pressure and flow characteristics of the pulsatile mono-roller pump. \( P_1 \) = Pressure upstream the pinch valve. \( P_2 \) = Pressure downstream the pinch valve. BPM = beats per minute or rpm.

Fig 4. Relationship of stroke volume to the rpm of various size tubes. Solenoid driven pinch valve monoroller pump; raceway arc = 150°. Free flow against a load of 100 mmHg pressure measured for 10 strokes and averaged.

Fig 5. Relationship of stroke volume to the length of raceway (arc) and to the rpm. Constant tube size (15 mm ID). Flow measurements with electromagnetic probe.
Fig 6. In vitro hemolysis induced by the monoroller pump, the Nihon Zeon LVAD and the conventional roller pump.

Fig 7. In vitro hemolysis induced by the arterial line pulsators (Kontron PBP and Desjardin's compliant chamber) and the conventional roller pump.
Fig 8. Representative recording of patients perfused with the pulsatile monoroller pump and adequate size tubes. Adequate pulse pressures (45 to 60 mmHg) are noted in either case: child of 5.3 Kg or adult of 80 Kg body weight.

Fig 9. Representative recording of patients perfused with the pulsatile monoroller pump with too small size tubes for their body weights.