Original Article

New Roller Pump Disposable Provides Safety and Simplifies Occlusion Setting

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ABSTRACT

A new disposable insert for the arterial roller pump, the Better-Header™, provides safety and functionality beyond what standard tubing provides. It automatically limits pump outlet pressure to a level determined by the user and provides a self-contained, simple means to set pump occlusion. The Better-Header™ consists of a Starling-like pressure relief valve connected across standard header tubing. As long as arterial line pressure at the pump outlet remains below a set limit, the valve is closed. If line pressure approaches the pressure limit, the valve opens, preventing overpressurization by shunting blood from pump outlet to inlet. The Better-Header™ can also be used to set occlusion by the "dynamic method" to obtain nonocclusive settings.

The Better-Header™ was evaluated in the lab for its pressure-flow characteristics. Even when the arterial line was completely clamped at a pump flow of 7 L/min, line pressure was limited to a safe level and all circuit connections were preserved.

The Better-Header™ has been used successfully at North Shore University Hospital in over 500 clinical cases covering a wide range of patients and procedures. In several instances, the user was alerted to high pressure situations by fluid flow through the valve and by an audible alarm, allowing rapid correction of the source of pressure. Compared to the standard setup, the Better-Header™ maintains outlet pressure within safe, user-settable limits, and permits consistent, nonocclusive settings with predictable retrograde flow.

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INTRODUCTION

Roller pumps are simple, reliable, and proven for extracorporeal pumping. However, they pump independently of the pressure conditions at their outlet, and therefore extreme overpressurization can occur if the arterial line is inadvertently kinked or clamped. Such overpressurization can cause damage to circuit components, burst connections, and disrupt flow to the patient. Line pressure at the pump outlet can be measured and monitored, but in many cases even the most vigilant perfusionist cannot respond quickly enough to prevent a dangerous situation. A switch coupled to the line pressure level may be used to interrupt power to the pump if pressure exceeds a certain level, but this method is cumbersome and the pump must usually be reset before flow can resume.

A new disposable device for the arterial roller pump is available, the Better-Header™[a], that automatically limits line pressure to a safe, user-determined level without stopping the pump. It also provides a means to set roller pump occlusion simply, quickly, and consistently. This paper presents the results of in-vitro evaluations of the Better-Header™, and relates our clinical experiences with it.

DESCRIPTION OF DEVICE

The Better-Header™ consists of standard polyvinyl chloride pump header tubing (1/4", 3/8", or 1/2" ID) connected by a specially designed pressure relief valve (PRV), shown in Figure 1. The bidirectional PRV is made from proprietary tubing with a thin wall section sealed in a rigid housing. The user pressurizes the housing space and connected compliance chamber with an air-filled syringe to the desired line pressure limit (Pset), which compresses the thin section of tubing and creates a normally closed valve. As long as line pressure at the pump outlet (P_L) remains below Pset, the valve is closed and pumping proceeds as with standard tubing. However, if a situation causes line pressure to approach Pset, the valve opens automatically, preventing overpressurization by shunting blood from pump outlet to inlet. High pressure conditions are indicated visually by fluid flow through the valve (Figure 2), and audibly if a pressure alarm is used. When line pressure returns below Pset, the valve closes automatically, directing all the pump flow to the patient.

MATERIALS AND METHODS

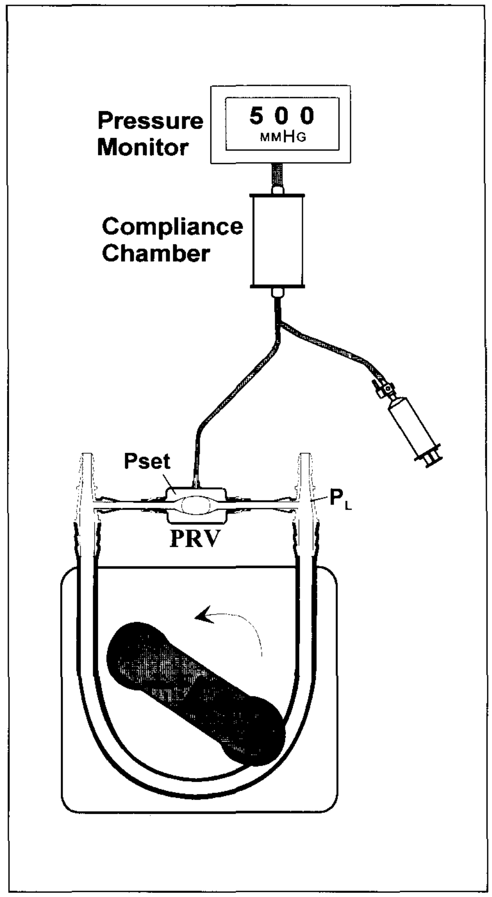
FUNCTIONAL TESTS

All functional tests were conducted with Better-Headers™ with 1/2" ID pump tubing (model BH12).

a Circulatory Technology Inc., Oyster Bay, New York
b Model HT109, Transonic Systems Inc., Ithaca, New York

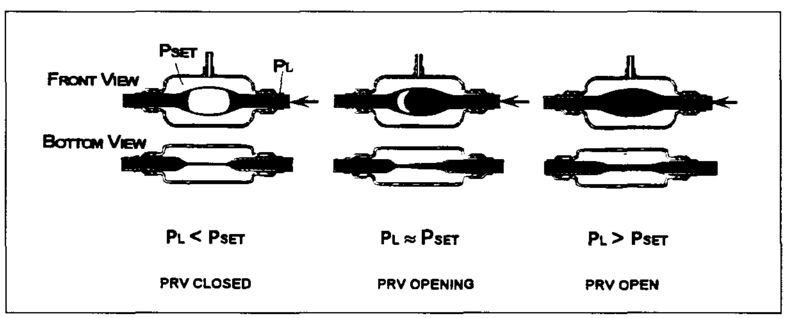
Pressure Limits. The maximum pressure at the pump outlet occurring with the Better-Header™ if the arterial line is completely clamped was determined in an in-vitro circuit with saline at 21±1°C. Flow was measured with a calibrated clamp-on ultrasonic flow probe and meter[b] and pressure was measured with a transducer at the pump outlet distal to the PRV. With

Figure 1: The Better-Header™ in a roller pump.



PRV, pressure relief valve; Pset, set pressure limit; P_L, arterial line pressure

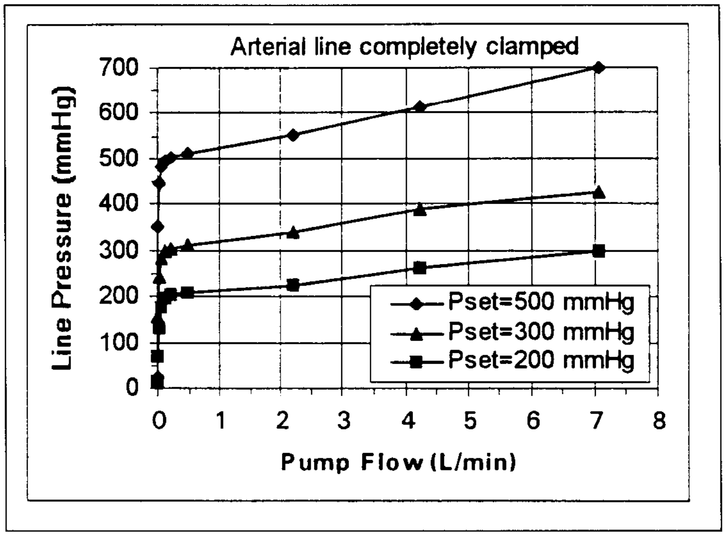
Figure 2: Flow indication through Better-Header valve.



the set pressure in the housing of the Better-Header™ PRV established at 200, 300, and 500 mmHg, the pump was run at various flows up to 7 L/min, the arterial line was clamped, and pressure was recorded. This procedure was repeated three times at each PRV set pressure.

Shunt Flow. The amount of pump flow shunting through the PRV in the Better-Header™ was determined at different arterial line pressures. The setup described above was utilized, except a screw-type clamp on the pump outlet tubing permitted adjustment of line pressure. The roller pump was set occlusively to allow calculation of pump flow as the product of pump speed and the tubing flow factor (ml/min/RPM) determined from calibration. Shunt flow was then calculated as the difference between pump flow and measured flow indicated by the flowmeter.

Figure 3: Maximum line pressure with Better-Header in pump.



Occlusion Setting. The Better-Header™ provides a simple way of achieving a nonocclusive roller setting using the "dynamic method," the scientific basis of which is described elsewhere (1). With the outlet tubing clamped and the rollers slowly rotating, occlusion is adjusted until a certain pressure is generated. When the Better-Header™ is used, the degree of occlusion is indicated by fluid flow through the valve.

Use of the Better-Header™ to set pump occlusion was assessed subjectively using an in-vitro circuit. The setting recommended in the device's instructions was used: nominal PRV set pressure was 500 mmHg, nominal pump speed was 5 RPM, the outlet tubing was clamped, and occlusion was adjusted until fluid began to flow through the valve for half the raceway distance that each roller compresses the tubing.

Retrograde flow with a nonocclusive setting obtained using the dynamic method is predicted by the pump speed used during the setting (2-3). For example, at the above setting, if line pressure is equal to the PRV set pressure (500 mmHg) the retrograde flow is equivalent to the flow produced by the pump at 5 RPM (approximately 225 ml/min for 1/2" ID pump tubing). During normal operation, line pressure is less than the PRV set pressure, so theoretically, actual retrograde flow should be less than predicted.

The retrograde flow occurring during clinical use of the Better-Header™ was assessed by recording the flow indicated by the roller pump display and the flow measured with a flowmeter at various times during several cases. The retrograde flow was then calculated as the difference between the two flows, converted into the pump speed that generates that flow, and compared to the pump speed used during the dynamic method to set occlusion.

CLINICAL USAGE

The Better-Header™ was used as the insert in the arterial roller pump during cardiopulmonary bypass procedures at North Shore University Hospital. The appropriate model Better-Header™ was used according to the required patient flow. Initially, a flowmeter was employed to measure pump outlet flow in order to assess the consistency of the nonocclusive settings achieved from case to case, as well as the validity of the dynamic method parameters in predicting retrograde flow (see above). A pressure monitor with high level alarm[c] was connected to the compliance chamber of the PRV to provide audible indication of an open valve, in addition to the inherent visual indication of fluid flow, as suggested in the device instructions. Conditions or situations in which the pressure relief valve opened were noted, as were any exceptional situations encountered during the use of the Better-Header™.

RESULTS

FUNCTIONAL TESTS

Pressure Limits. In no cases did circuit disruption occur during the in-vitro tests when the arterial line was completely clamped with the Better-Header™ in the roller pump. Figure 3 shows that the higher the pump flow, the greater the maximum line pressure. Also, at any flow, higher PRV set pressures result in maximum line pressures that exceed the set pressure by a slightly greater amount. In all cases, however, line pressure did not exceed 200 mmHg above the PRV set pressure, even at a pump flow of 7 L/min.

Shunt Flow. Figure 4 illustrates the relationship between line pressure at the pump outlet and flow shunting through the PRV. As can be seen, shunt flow is less than 30 ml/min if line

c Pressure Display 60000, DLP, Inc., Grand Rapids, Michigan pressure remains at least 50 mmHg below the PRV set pressure. If line pressure approaches within 50 mmHg of set pressure, shunt flow increases to approximately 50 ml/min. Beyond that point, the shunt flow becomes a large percentage of pump flow. In the extreme case of complete clamping of the arterial line, shunt flow equals pump flow.

Occlusion Setting. Table 1 provides a representative sampling of the flow values recorded at normothermia during a clinical case using the Better-Header™. Retrograde flow was calculated as the difference between the indicated pump flow, which assumes an occlusive setting, and the measured flow, which is the flow the patient receives. On average, a nonocclusive setting obtained using the dynamic method with the Better-Header™ results in retrograde flows of 285 ml/min under typical pumping conditions, or approximately 7% of the flow produced by an occlusive pump. The pump speed corresponding to the retrograde flow was calculated by dividing the flow by the calibrated flow factor for the 1/2" ID header tubing, 0.045 L/min/RPM. This value averaged 6.1 RPM, to be compared with the pump speed of 6 RPM used to set occlusion with the dynamic method.

In some cases, the flowmeter readings were slightly greater (up to 5%) than the flow indicated by the roller pump. Since the flow produced by a nonocclusive pump cannot be greater than that produced by an occlusive one, these readings were ascribed to drift in the flowmeter, a known characteristic of the meter as the measured flow temperature decreases.

Figure 4: Shunt flow through Better-Header valve as a function of line pressure.

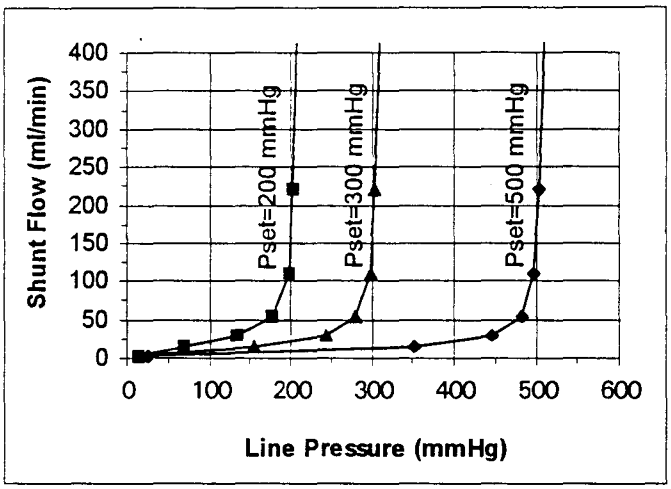


Table 1: Retrograde flow with Better Header.

Dynamic Method parameters: pump speed = 6 RPM, set pressure=468 mmHg

	Flow (ml/min)		Retrograde Flow		RPM equivalent
	pump	measured	ml/min	% of pump	to retrograde flow
	4060	3771	289	7	6.1
	3760	3490	270	7	5.7
	4450	4102	348	8	7.4
	4970	4782	188	4	4.0
	4420	4090	330	7	7.0
avg ± stdev	4332 ± 455	4047 ± 483	285 ± 63	7%	6.1 ± 1.3

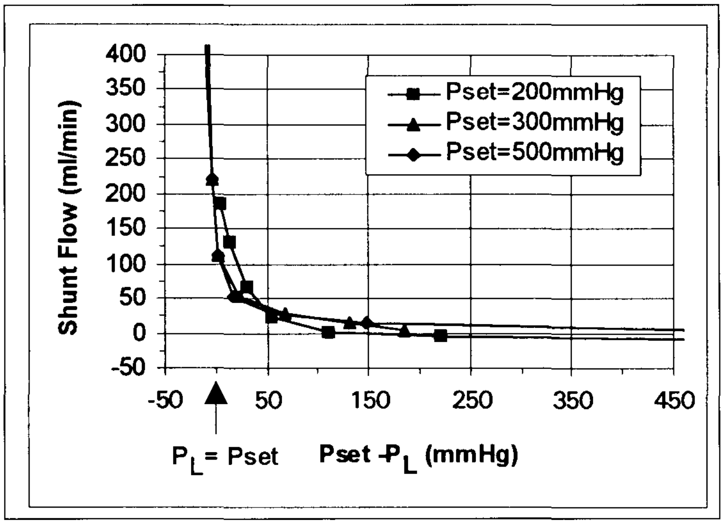
CLINICAL USAGE

The Better-Header™ has been used clinically at North Shore University Hospital for over 500 cases. Patient age ranged from newborn to 95 years (weight from 3.5 to 148 kg), procedures included aortic aneurysms with femoral cannulation, and pumping conditions included blood temperatures to 10°C. In several instances, the PRV on the Better-Header™ opened automatically and prevented overpressurization, but in no cases did circuit disruption occur. In one case, the arterial line was clamped instead of the venous line. The audible alarm on the pressure monitor connected to the PRV and the sight of full pump flow through the valve immediately alerted the team to the situation. The perfusionist stopped the pump, the cause of the high pressure was identified and corrected, and flow to the patient was resumed, all within a matter of seconds. Most instances of high pressure were signified by a momentary alarm and a pulse of blood across the valve, and were traced to a kink in or someone leaning on the arterial line. In one case the valve opened to relieve the pressure caused when the heart was manipulated in such a manner as to partially obstruct the aortic cannula.

DISCUSSION

If the arterial line is inadvertently clamped with the standard roller pump setup, pressure can exceed 2500 mmHg, with burst connections and flow stoppage to the patient a certainty. The Better-Header™ is a simple device that prevents overpressurization automatically, without requiring electrical connections to the pump. The user determines and sets the pressure limit desired, an advantageous feature since the maximum line pressure may vary depending on the aortic cannula used, the flow requirements of the patient, and the resistance of other components in the arterial circuit. Figure 5 is a normalized graph of the data shown in Figure 4, plotting shunt flow through

Figure 5: Better-Header™ shunt flow versus difference in line and set pressure (normalized for different set pressures)



the PRV as a function of the difference in set and line pressure (Pset - P_L). In the absence of high pressure conditions (line pressure at least 50 mmHg below Pset), the Better-Header™ valve remains closed with negligible shunt flow through it, and pumping proceeds normally.

At our institution, the perfusionists using the Better-Header™ to set pump occlusion with the dynamic method cite several reasons for preferring it over the standard drop rate technique., Increased flexibility was one; since the dynamic method is a procedure that is performed entirely within the Better-Header™ (it does not require a tubing open to atmosphere like the drop method), the user has the option of setting occlusion at any time between priming the circuit and going on bypass. The ability to achieve more reproducible, nonocclusive settings in a simple manner was another reason. The settings obtained, as indicated by flowmeter readings, seemed relatively consistent from case to case as well as among perfusionists. Discrepancies and fluctuations in flow readings were likely attributable to temperature and viscosity variations in the perfusate, which are known to affect the accuracy of the flowmeter. It should be noted that the flowmeter on the Bio-Medicus centrifugal pump has an accuracy of ±10%, compared with the 7% accuracy observed with the roller pump set nonocclusively using the dynamic method. Since occlusion is set while the rollers are rotating, variations in tubing wall thickness, roller extension, and raceway symmetry, which all affect the accuracy of the static drop rate technique, are averaged out with the dynamic method. Furthermore, differences in the amount of flow through the Better-Header™ valve between the two rollers or as a roller moves along the raceway indicate differences in occlusiveness, and can signal when the pump should be serviced.

Although roller pumps set almost occlusively (approximate drop rate of 1 inch/min as currently recommended by manufacturers) have been shown to be more hemolytic than centrifugal pumps (4-8), or no different than centrifugal pumps (9,10), or more or less hemolytic than centrifugal pumps depending on the pressure and flow conditions (11), roller pumps set nonocclusively have been shown to result in hemolysis levels lower than the Bio-Medicus centrifugal pump (2,3,12). This fact, in conjunction with the fact that retrograde flow with a nonocclusive setting achieved using the dynamic method is small, predictable, and easily corrected by increasing pump speed, makes a strong case for setting roller pumps less occlusively than the commonly regarded standard.

In our clinical experience, the Better-Header™ has performed as designed. It has averted the potentially disastrous consequences of an accidentally clamped arterial line, and prevented overpressurization on several occasions. In short, it permits simple roller pumping while bringing an added measure of safety to the patient and peace of mind to the perfusionist.

ACKNOWLEDGEMENT

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