Original Article

An Improved Bladder for Pump Control During ECMO Procedures

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ABSTRACT

A new inline reservoir called the Better-Bladder™, now FDA-cleared for long term use, overcomes some disadvantages of the silicone bladder and bladder box used in extracorporeal membrane oxygenation circuits. The Better-Bladder™ provides compliance in the venous line and allows for noninvasive pressure measurements. Both features are useful for controlling pump speed as a function of venous line pressure.

Bench tests showed that the Better-Bladder™ measures pressure noninvasively within ±4% of invasive (*i.e.*, liquid contacting) pressure measurements in a range from −200 to +500 mmHg and at temperatures from 10°C to 37°C. After 60 days, the error in noninvasive pressure measurement with the Better-Bladder™ was less than ±3%. The Better-Bladder™ withstood pressurization to 1700 mmHg for ten days without leaking or failing in other ways. The advantages of the Better Bladder™, along with its accuracy and durability, suggest its use for short and long term pumping applications.

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INTRODUCTION

For many years, a silicone bladder in a "bladder box" has prevented excess negative pressure at the pump inlet during extracorporeal membrane oxygenation (ECMO) procedures (1,2). Typically, blood drains passively from the patient into the bladder, and is actively pumped by a roller pump through an oxygenator and back to the patient. With this system, and at a given cannula size, the maximum pump flow depends on gravity drainage of blood into the bladder; a function of the height difference between the patient and the bladder and the patient's volume status. One way to increase flow is to increase the vertical distance between the patient and the bladder. For this reason the bladder box is placed as low as possible to maximize flow. However, this makes it difficult to monitor the bladder and it increases the tubing requirement. The additional length of tubing, in turn, requires greater prime volume, increases the opportunity for pathophysiological blood-surface interactions through a larger foreign surface area, and increases heat loss through a longer residence time for the blood in the extracorporeal circuit.

The silicone bladder used now is designed poorly for flow dynamics: blood cells tend to settle at its bottom, particularly at low flow, which may increase the likelihood of thrombus formation (Figure 1). Furthermore, the bladder is volume-sensitive rather than pressure-sensitive; i.e., most of its volume change occurs over a very small change in internal pressure. Therefore, as far as pump control is concerned, the bladder does not respond well to pump inlet pressure changes, and when combined with the bladder-box provides only ON-OFF control. In fact, the pump must be slowed manually to prevent jerky operation due to reduced venous drainage.

The objective of this study was to develop an improved bladder: one that overcomes the shortcomings of present bladders; specifically, one that provides controlled gravity drainage; provides flow conditions less conducive to the settling of cells; and on-off as well as continuous flow control.

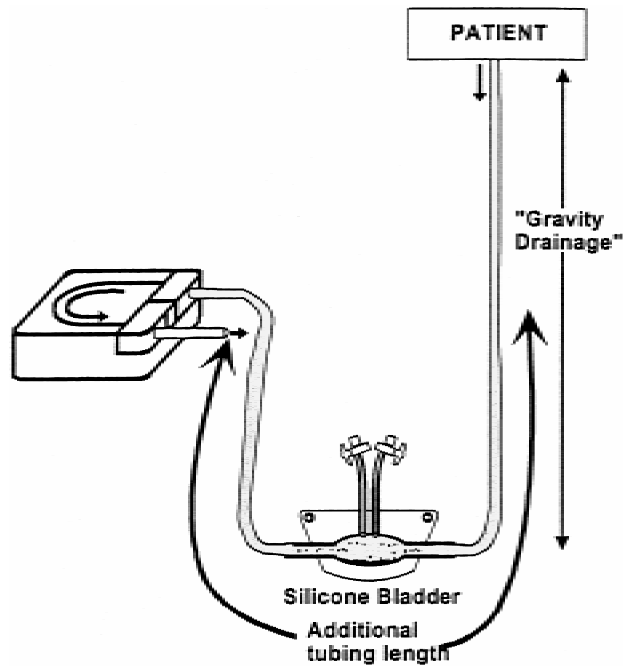

Figure 1: A typical ECMO circuit showing bladder placement.

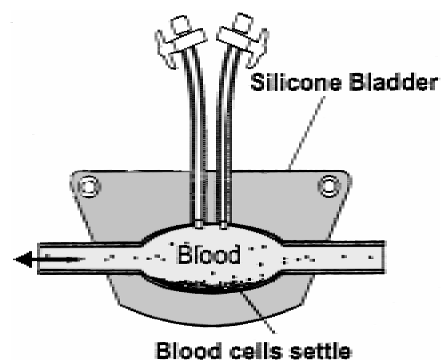

Figure 2: The silicone bladder has poor flow dynamics: blood cells settle at its bottom, which may increase the likelihood of thrombus formation, particularly at low flow conditions.

METHODS

DEVICE DESCRIPTION

The Better-Bladder™[a] has FDA clearance for short term and long term use. It is a simple device, manufactured from standard tubing that is processed to create a thin walled, enlarged and elongated bladder section that is sealed inside a rigid housing (Figure 2). The enlarged section of the Better-Bladder™ serves as an inline reservoir that provides adjustable compliance at the pump inlet or outlet. For maximum compliance, the housing space surrounding the bladder should be filled with air. Adding saline to the housing space will decrease the compliance but will increase the fidelity of the pressure signal transmitted.

Because the bladder has a thin wall, the blood pressure inside it is transmitted to the space in the housing, permitting noninvasive pressure measurements to be obtained by connecting a pressure transducer to the port in the housing. To maximize the range of pressure measurements with the Better-Bladder, the initial shape of the bladder portion is important. When measuring negative pressure, the bladder should be fully expanded (Figure 3) to allow collapse of the thin wall as the blood pressure becomes more negative. The pressure signals acquired from the Better-Bladder™ can then be sent to an On-Off pump controller such as the Minntech Pressure Moni-

a Circulatory Technology Inc., Oyster Bay, NY

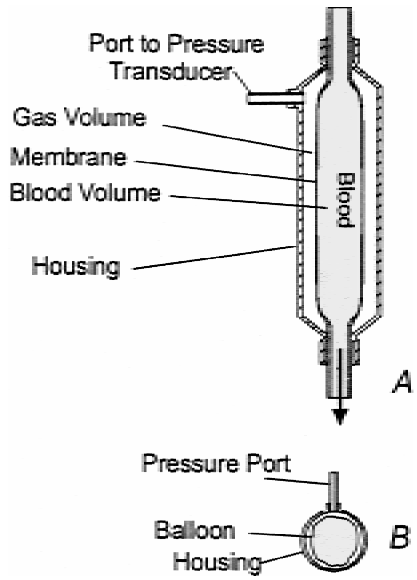

Figure 3: (A) The Better-Bladder™ is manufactured from standard tubing that is specially processed to create a thin walled, enlarged and elongated bladder section that is then sealed inside a rigid housing. (B) The initial shape of the Better-Bladder™ when measuring negative pressure should be fully expanded. This allows collapse of the thin wall as the blood pressure becomes more negative.

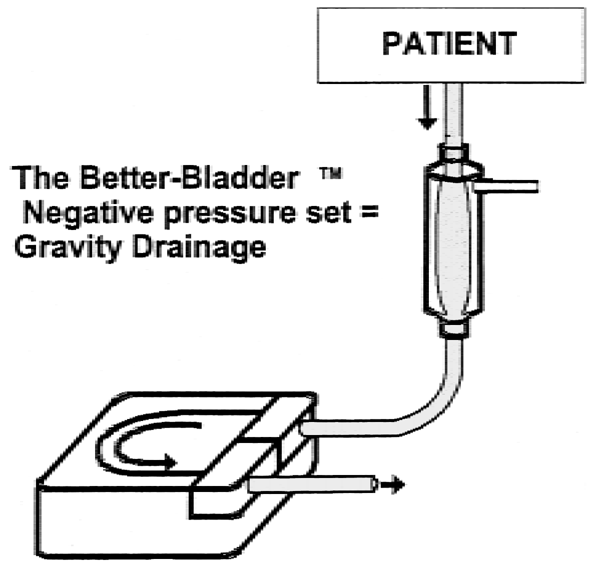

Figure 4: Placement of the Better-Bladder™ at the pump inlet. When placed vertically in the circuit, the Better-Bladder™ provides better flow dynamics than the silicone bladder. Its flow is in the same direction as gravity and therefore blood cells wash through the bladder instead of settling inside it.

tor and Pump Control Module,[b] or preferably, a continuous pump controller such as the Computer Assisted Perfusion System.[c] The controller slows or stops the pump at a pressure set by the user.

Figure 4 depicts placement of the Better-Bladder™ at the pump inlet. When placed vertically in the circuit, the Better-Bladder provides better flow dynamics than the silicone bladder. Since flow is in the same direction as gravity, blood cells wash through the bladder instead of settling inside it.

The Better-Bladder™ was evaluated with the circuit shown in Figure 5. A bladder was placed at the pump inlet and water was circulated from a reservoir, through the bladder, and then back to the reservoir. An adjustable clamp was used to establish desired pressures at the pump inlet r. Pressures were measured both invasively, *viz*, with a fluid filled pressure transducer connected via a luer fitting at the inlet of the pump and measured non-invasively via the bladder. A computerized data acquisition system sampled and recorded the pressures at a rate of 500 Hz. Ten bladders were tested. In a similar test the Better-Bladder™ was evaluated for measuring pump outlet pressure. The bladder was placed at the pump outlet.

FIDELITY

The noninvasive pressure measurements obtained via the Better-Bladder™ were compared to direct pressure measurements obtained invasively, at an average inlet pressure of −100 mmHg. Direct pressure measurements were made using a disposable pressure transducer[d] calibrated with a mercury manometer. A computerized data acquisition system was used for all pressure displays and data collection.[e]

COMPLIANCE

The effect of varying the amount of air in the Better-Bladder™ housing on the noninvasive pressure signal measured was investigated. The housing was filled with saline and the pressure signal was recorded. Five ml of air was then injected into the housing, replacing an equivalent volume of saline, and the pressure signal was recorded again. This procedure was repeated with 10 ml of air in the housing.

STABILITY

Tests were conducted to determine the stability of the noninvasive pressure measurements provided by the Better-Bladder over 60 days. The Better-Bladder™ was placed at the pump outlet at an average outlet pressure of 500 mmHg. The error was calculated as the difference between the direct and the noninvasive pressure measured.

TEMPERATURE

Pressure measurements were taken invasively and noninvasively at the pump inlet and outlet with water temperature at 10°C, 24°C, and 37°C. The error in the pressure measurements

b Minntech Corporation, Minneapolis, MN
c Sorin Biomedical, Irvine, CA
d Baxter Kit Model 33-1X2, Baxter Healthcare Corporation, Irvine, CA
e Strawberry Tree, Sunnyvale, CA

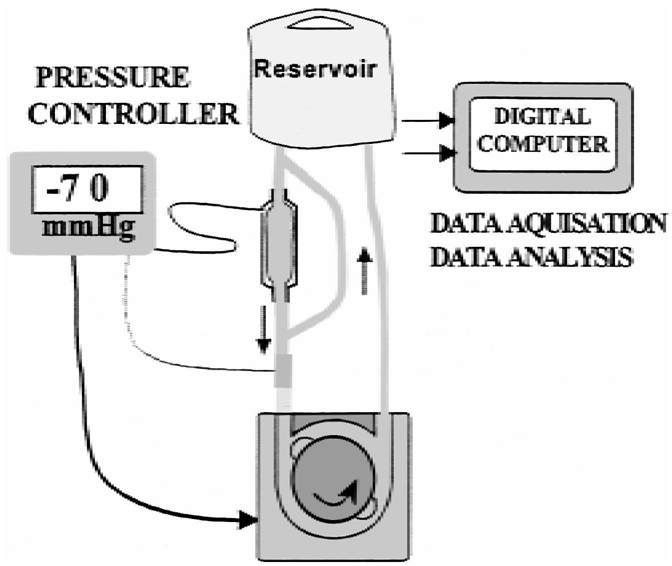

Figure 5: The bench top circuit used to evaluate the Better-Bladder.

(the difference between invasive and noninvasive measurements) was determined.

STRENGTH

A concern with using a thin walled bladder is its integrity under duress. Tests were thus conducted to expose the Better-Bladder to the worst case scenario: the housing was open to atmosphere, one end of the bladder was clamped off, and the other end was pressurized to over 1700 mmHg. The enlarged portion of the Better-Bladder™ was visually inspected for leaks or loss of integrity, and the pressure decay was monitored continuously over 3 days. The bladder was then repressurized to over 1600 mmHg and pressure was monitored for an additional 10 days.

CONTROL

To evaluate the use of the pressure signal provided by the Better-Bladder™ for pump speed control, a pressure transducer was placed at the Better-Bladder™ housing port to measure pump inlet pressure noninvasively, and the pressure signal was input into an analog to digital converter in a computer. A simple pressure control program was written using Workbench[e] software that established a range of pump inlet pressures between which the pump speed adjusts proportionally to zero. The program allows two pressure setpoints to be defined, resulting in three modes of pump operation depending on the pump inlet pressure: above Setpoint-1, the pump operates at the speed initially set by the user. If inlet pressure falls between Setpoint-1 and Setpoint-2, pump speed slows accordingly. If Setpoint-2 is reached, the pump stops completely, and starts automatically as inlet pressure increases and reaches Setpoint-2 again.

Various setpoints were defined between 0 and 150 mmHg with the pump operating at clinically relevant speeds. Inlet pressure was manipulated by adjusting a clamp on the inlet tubing, and inlet pressure and pump speed was recorded.

RESULTS

THE FIDELITY OF THE PRESSURE SIGNAL OBTAINED NONINVASIVELY

Figure 6 illustrates typical tracings of the direct and noninvasive pressures taken at the pump inlet over a period of approximately 1-sec. There is no significant difference between the two types of measurements, as shown by superimposed tracings.

THE DEGREE OF COMPLIANCE THE BETTER-BLADDER™ CAN PROVIDE

The inlet pressure curves obtained with different amounts of air in the Better-Bladder™ housing are shown in Figure 7. Note that varying degrees of compliance are provided depending on the amount of air. With only saline in the housing, the inlet pressure pulse was approximately 80 mmHg. With 5 cc of air in the housing, the pulse was reduced to approximately 30 mmHg. With 10 cc of air, the pulse decreased to approximately 20 mmHg. It is this drastic smoothing of the pressure measured with the Better-Bladder™ that allows pump speed to be controlled according to inlet pressure.

THE EFFECT OF FLUID TEMPERATURE ON THE FIDELITY OF THE PRESSURE SIGNAL

The temperature of the pumped fluid had minima affect on the pressure signal provided by the Better-Bladder™, see Fig-

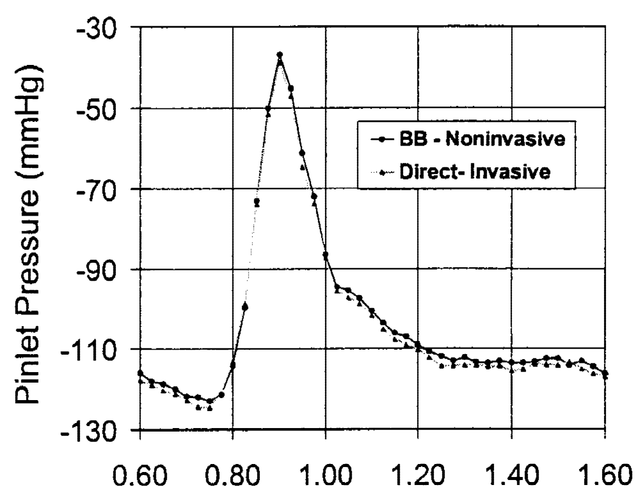

Figure 6. Typical tracings of the direct and noninvasive pressures taken at the pump inlet over a period of approximately 1-sec. There are no significant differences between the two types of measurements.

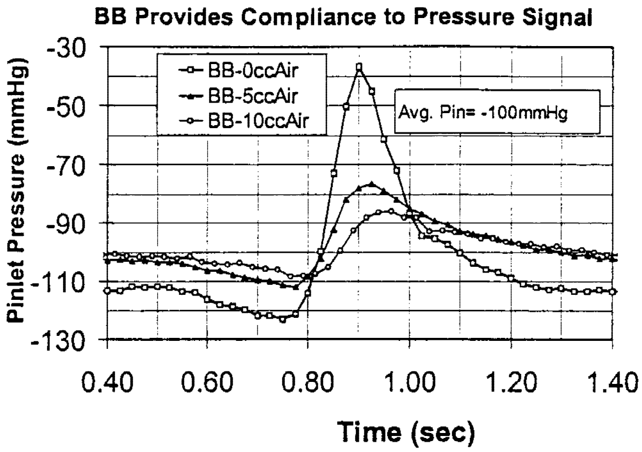

Figure 7: The degree of compliance the Better-Bladder™ provides can be reduced by adding saline to its housing. Here, inlet pressure curves obtained with different amounts of air in the Better-Bladder™ housing are shown.

ure 8a. At 37°C, 24°C, and 10°C, the error in the pressure signal was within ±6 mmHg, in the pressure range of −200 and +500 mmHg. Figure 8b shows the same data except the error is given as a percentage: the accuracy of the pressure measured noninvasively is within ±4% of the direct measurements.

THE STABILITY OF THE PRESSURE SIGNAL OVER TIME

The average error in the pressure signal provided by ten Better-Bladders™ over 60 days when pump outlet pressure was 500 mmHg is summarized in Figure 9. The maximum error was within ±15 mmHg, or ±3% of the direct pressure.

THE STRENGTH OF THE BETTER-BLADDER™ IF THE PUMP OUTLET IS ACCIDENTALLY CLAMPED

Under the worst case test conditions, the Better-Bladder™ balloon expanded until its wall reached the housing, whereupon the housing supported it. Figure 10 summarizes the pressures measured during the test. Initial pressurization to over 1700 mmHg was followed by a decay in pressure to 1200 mmHg due to a slight balloon expansion. The pressure signal then drifted downward to approximately 1000 mmHg over three days. When the balloon was repressurized to over 1600 mmHg, a slow decay to 800 mmHg over 10 days was observed due to further expansion of the balloon walls. In no case did any leaks or ruptures of the balloon occur.

THE ABILITY OF THE BETTER-BLADDER™ PRESSURE SIGNAL TO BE USED FOR PUMP SPEED CONTROL

Figure 11 shows a tracing of pump speed vs. pump inlet pressure when the Better-Bladder™ pressure signal was fed to the control system. Pump speed was initially set at 50 RPM, and Setpoint-1 and 2 were set to −50 and −100 mmHg respectively. Inlet pressure was initially positive (right side of graph) and pump speed began slowing when Setpoint-1 was reached, then decreased linearly with inlet pressure between −50 mmHg and −100 mmHg. The pump stopped altogether when inlet pressure reached −100 mmHg. The same response was found at other pump speeds and at various setpoint pressures.

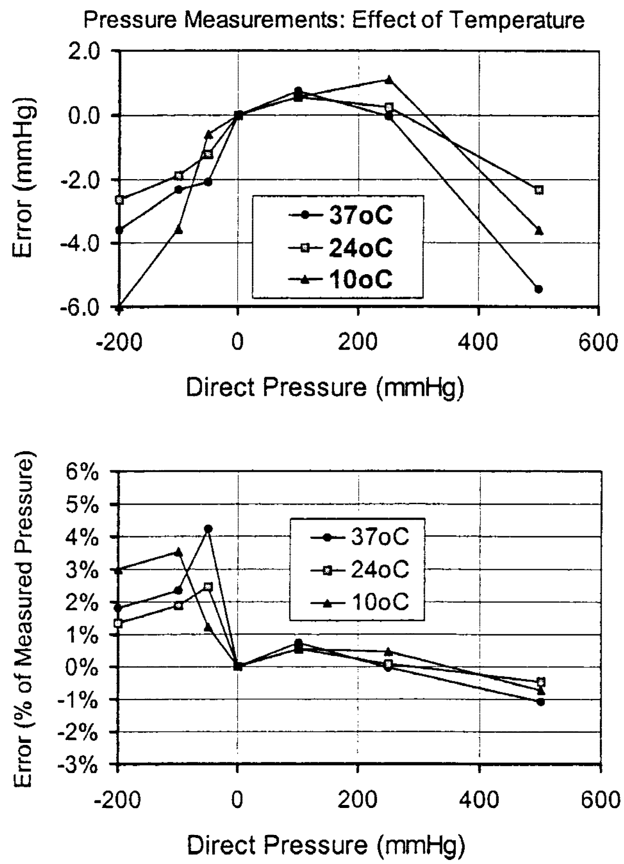

Figure 8: The temperature of the pumped fluid has minimal effects on the pressure signal provided by the Better-Bladder™. The data is presented as the error in mmHg (top) and as a percent of the actual reading (bottom).

DISCUSSION

Pump flow achieved during cardiac or respiratory support procedures is mostly limited by the resistance of the drainage cannula. During ECMO, a common maneuver aimed at overcoming the high cannula resistance is increasing the height difference between the patient and the silicone bladder. There is a practical limit to how high the patient can be above the floor, however. When inlet flow drops below pump flow, unless the pump is slowed down, excess negative pressure will occur, along with the associated damage to blood components and the cannulated vessel's intima (3). With the present bladder-box combination, the pump control is limited to ON-OFF, at best a "jerky" control. These limitations prompted the development of the Better-Bladder™.

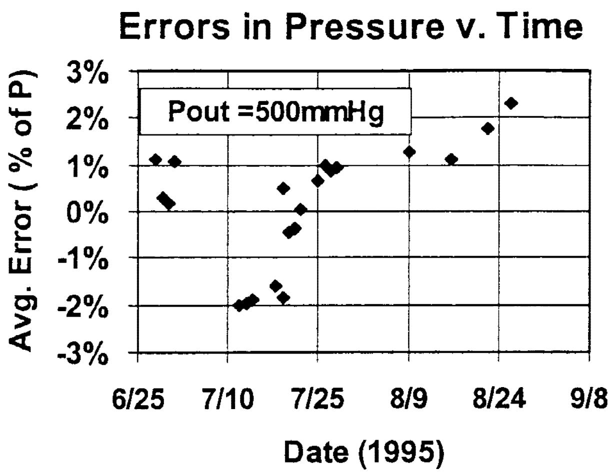

Figure 9: The average error in the pressure signal provided by ten Better-Bladders™ over 60 days when pump outlet pressure was 500 mmHg. The maximum error was within ±15 mmHg, or ±3% of the direct pressure.

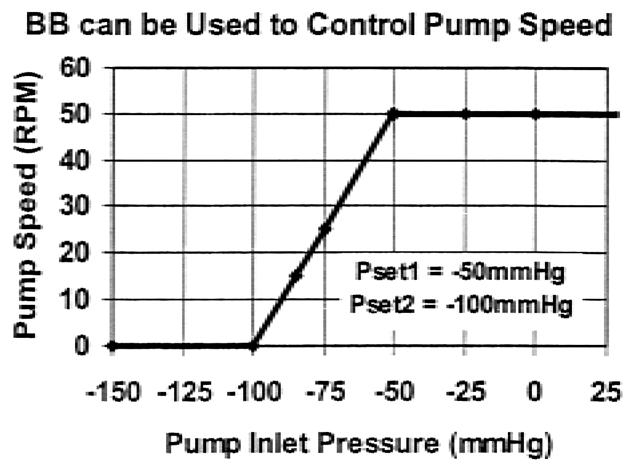

Figure 11: A typical curve of pump speed vs. pump inlet pressure when the Better-Bladder™ pressure signal was fed to the control system. Excellent control was obtained.

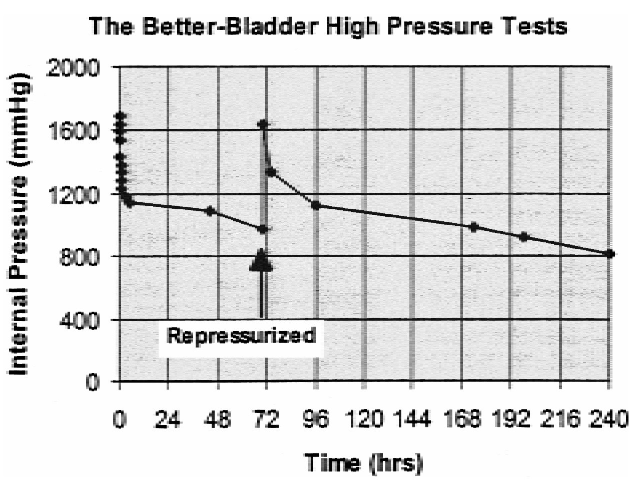

Figure 10. The Better-Bladder™ balloon can withstand pressures in excess of 1500 mmHg over a period of days. The downward drift in the pressure was due to a slight expansion of the balloon over time. None of the balloons failed.

The unique design of the Better-Bladder™ allows for two functions: 1) the bladder acts as an inline reservoir, providing adjustable compliance and a blood reserve at the pump inlet, and 2) the pressure of blood flowing through the bladder is transmitted across its thin wall to the housing space to permit noninvasive pressure measurements. Gravity drainage can be controlled by setting the negative pressure in the Better-Bladder housing (Figure 4), eliminating the need to place the bladder on the floor. This feature brings the advantages of shorter tubing length mentioned earlier. The vertical orientation of the Better-Bladder™ in the circuit facilitates continuous gravitational washout, reducing stasis conditions that promote thrombus formation. It should be pointed out that blood velocity within the bladder is lower than in the tube (e.g., at the same flow, blood velocity is nine times slower in a 3/4″ ID bladder than in a 1/4″ ID tubing). Whether using the silicone bladder or the Better-Bladder™, lower blood velocity is more conducive to thrombus formation.

A major feature of the Better-Bladder™ is the compliance it contributes between the patient and the pump inlet. Tests showed that with the Better-Bladder™ the large pressure pulse at the pump inlet is significantly diminished (see Figure 7) . The greater the amount of air in the housing, the greater the pulse dampening. Therefore, the compliance of the Better-Bladder™ can be maximized by not adding any saline to the housing.

Pressure signal fidelity is not compromised by the noninvasive nature of the Better-Bladder™ pressure measurements. The Better-Bladder™ provided stable pressure measurements, showing an error of only ±3% of the direct measurements over 60 days. Some of this small error may have been due to drift in the disposable pressure transducer and/or monitor over the measurement period.

The excellent fidelity (see Figure 6) and stability of the noninvasive pressure measurements provided by the Better-Bladder, in concert with the compliance provided, allow for smooth pump control as verified by tests with a pump controller. The pressures at which the pump slows down and stops completely are easily adjusted and controlled, a feature not possible with the silicone bladder-box combination. Pressure testing of the Better-Bladder™, despite its thin wall, showed that it can withstand extreme pressures up to 1700 mmHg. This value exceeds the maximum operating pressure for many other devices placed in the same circuit. For example, Baxter tubing packs are rated for 750 mmHg.

The advantages of the Better-Bladder™ and its excellent accuracy and durability suggest its use in both short and long term clinical applications requiring pump control as a function of inlet pressure.

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