Development of a Balloon Volume Sensor for Pulsating Balloon Catheters

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Helium pulsed balloons are integral components of several cardiovascular devices, including intraaortic balloon pumps (IABP) and a novel intravenous respiratory support catheter. Effective use of these devices clinically requires full inflation and deflation of the balloon, and improper operating conditions that lead to balloon under-inflation can potentially reduce respiratory or cardiac support provided to the patient. The goal of the present study was to extend basic spirographic techniques to develop a system to dynamically measure balloon volumes suitable for use in rapidly pulsating balloon catheters. The dynamic balloon volume sensor system (DBVSS) developed here used hot wire anemometry to measure helium flow in the drive line from console to catheter and integrated the flow to determine the volume delivered in each balloon pulsation. An important component of the DBVSS was an algorithm to automatically detect and adjust flow signals and measured balloon volumes in the presence of gas composition changes that arise from helium leaks occurring in these systems. The DBVSS was capable of measuring balloon volumes within 5–10% of actual balloon volumes over a broad range of operating conditions relevant to IABP and the respiratory support catheter. This includes variations in helium concentration from 70–100%, pulsation frequencies from 120–480 beats per minute, and simulated clinical conditions of reduced balloon filling caused by constricted vessels, increased driveline, or catheter resistance. *ASAIO Journal* 2004; 50:225–233.

Several clinically used medical devices use rapidly pulsating, helium filled balloons within the cardiovascular system. A prime example is the balloon catheter used in intraaortic balloon pumping (IABP) for cardiac assist.[1] The IABP catheter consists of a balloon inserted into the aorta, which is pulsed in countersynchrony to the heart. Balloon inflation during diastole encourages coronary and peripheral perfusion, whereas balloon deflation during systole reduces the mechanical pumping load on the heart. The balloon volume is matched to the stroke volume of each patient because the greatest benefit occurs when these volumes match.[2] Variations in the aortic pressure can result in under-filled balloons, even during an operation designed to maintain full inflation.[3] Pulsating balloons have also been incorporated into a novel respiratory support catheter that is under development by the present group. The respiratory catheter is a microporous hollow fiber membrane oxygenator designed for temporary use within the vena cava of patients with acute respiratory failure.[4] Balloon pulsation in this catheter mixes blood as it flows past the hollow fiber membranes and enhances the transfer of oxygen and carbon dioxide. Increasing the frequency of balloon pulsation increases gas exchange in the respiratory catheter, provided that the balloon fully inflates and deflates.[4–6] A certain critical frequency of pulsation exists, which is dependent upon balloon size and operating conditions, above which the balloon does not fully inflate and deflate and gas exchange diminishes.[6]

Monitoring balloon volume during pulsation in both intraaortic balloon pumping and in our respiratory support catheter would be useful to ensure proper balloon inflation and deflation under conditions of *in vivo* use. An under-inflated IABP catheter causes a weakened heart to work more than necessary, decreases peripheral perfusion, and leads to reduced patient recovery.[2] An under-inflated respiratory support catheter reduces the intensity of mixing in blood and limits both the oxygen delivered to the patient and CO_2 removed from the patient.[6] Accordingly, a balloon volume sensor for these catheters would detect improper balloon inflation/deflation, could be used to control balloon inflation/deflation, and could potentially improve the function of these cardiovascular catheters.

The most logical method for monitoring balloon volume during *in vivo* use of pulsating balloon catheters is to measure the flow of gas into and out of the balloon and integrate the flow to determine the balloon volume. Typical pulsating balloon catheters use helium as the drive gas because of the low inertial load and low internal friction of the gas. Helium concentrations in both IABP and the respiratory support catheter drive systems can change over time because of small leaks in the driveline and helium diffusion through the plastic components of the system. The leak rate of helium can be up to 1 cc/hour in IABP balloons,[1] and similar leak rates have also been observed for the respiratory support catheter. Flow meters that could be used to monitor balloon volume would be affected by any changes in gas concentration. For example, flow meters based upon temperature losses caused by fluid flow will be affected by varying viscosity or thermal conductivity of the gas. As helium leaks and gas concentration changes in the driveline, the potential exists for errors in flow measurement, which would affect the monitoring of balloon volume during pulsation. A compensation algorithm for helium leakage and drive gas composition changes is a necessary

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component of any balloon volume sensor based upon flow measurement.

Another necessary component of a balloon volume monitor is a flow sensor with a sufficiently fast time response because pulsation rates in the balloon catheters of interest can reach several hundred beats per minute. A hot wire anemometer (HWA) has a sufficiently fast response time and is an ideal candidate for measuring flow to monitor balloon volume. Hot wire anemometry is well established for measuring oscillatory volumes in the spirography of respiration,[7,8] where it can be calibrated to known exhalation pressures and gas concentrations. Whereas the HWA will be affected by changes in gas concentrations, as with other flow meters, this change can be compensated for because of the predictable response of the HWA sensor.[9,10] Plakk *et al.*[8] presented a method for compensating for concentration changes in inspired and expired air during spirometry. Although a compensation method was developed, the errors caused by the difference between inspired and expired air were minor (approximately 1%) because the reduced oxygen and increased carbon dioxide in the expired air did not significantly change the gas density and thermal properties. The compensation method was not really needed nor was it validated under conditions of more substantive differences in gas composition. In the application of helium pulsed balloon catheters of interest to the present authors, the thermal conductivity of helium is 16 times that of air, and so even small changes in gas composition could significantly affect gas thermal properties and require compensating for gas composition in the flow measurement used to monitor balloon volume.

This article describes the development, validation, and testing of a dynamic balloon volume sensor system (DBVSS) for application in pulsating balloon catheters. The authors' DBVSS combines techniques of HWA spirography with an algorithm to compensate for changes in the driveline gas composition caused by helium leaks. The authors describe the development of the basic flow relations from theory, the development of the compensation algorithm for changing helium concentrations, and the combination of these elements into a functional DBVSS. Ultimately, the authors show that the DBVSS can determine pulsating balloon volumes within 5–10% of actual balloon volumes for conditions relevant to the clinical application of pulsating balloon catheters of interest.

Methods

Development of the Dynamic Balloon Volume Sensor System

The DBVSS consists of a HWA flow meter to measure the helium flow into the balloon, a data acquisition system, and a computer program that converts and integrates the flow signal and calculates the volumes delivered to the balloon. The flow meter is a TSI 840101 submersible thermal mass flow transducer (TSI inc., St. Paul, MN). The transducer suspends a thin, high aspect ratio wire in a flow stream and maintains the wire at a constant temperature by passing electrical current through the resistive wire. The sensor measures mass flow by measuring the heat lost by the wire to the fluid stream, which increases as the flow increases. The sensor provides a voltage output equivalent to the voltage required to maintain the sensor temperature in different flows, and a calibration is used to relate the voltage signal to flow.

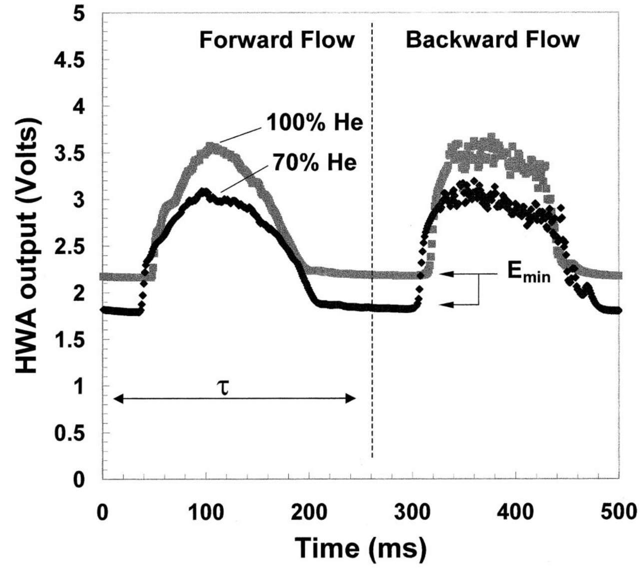

Figure 1. Example of the voltage output from hot wire anemometry in oscillatory flow at 100% and 70% helium, showing the positive flow pulse with the integration interval τ, as well as the minimum voltage between pulses, E_{min}.

The flow signal is integrated to determine the volume delivered to the balloon using the following formula:

$$V_b = \int_t^{t+\tau} Q(t)\,dt \qquad (1)$$

where V_b is balloon volume, Q is the flow, and τ is the time interval for inflation. Computation of this integral is done numerically and is performed on the discrete data points that come from sampling the voltage signal. **Figure 1** is an example voltage signal during the filling and emptying phases of balloon pulsation. The HWA flow sensor has a preferred direction of measurement (forward flow), and the DBVSS uses the forward flow direction for filling. **Figure 1** does indicate some voltage response during backward flow or emptying, but this portion is not processed into flow or balloon volumes by the DBVSS. Also shown is the zero flow region between pulsations, E_{min}, which defines the length of τ, and plays a pivotal role in our gas compensation algorithm.

The data is recorded and analyzed by a LabVIEW (National Instruments, Austin, TX) program, which runs a Matlab (The MathWorks Inc., Natick, MA) subroutine for the flow conversion and numerical integration. The program uses an algorithm to detect the flow pulses by the zero flow regions and E_{min} and then integrates the flow into the balloon to find the volume in each pulsation.

Flow Response of the Hot Wire Anemometer

The volume measurement requires determining flow rate from the HWA voltage response. The theoretical relationship for voltage *versus* flow in hot wire anemometry is known as King's Law:[11–13]

$$E_t^2 = E_{min}^2 + bQ^n \quad (2)$$

where E_t is the HWA output voltage caused by convective and conductive heat transfer from the wire, and E_{min} is the zero flow voltage output caused by conduction of heat from the hot wire in the absence of fluid motion. The coefficients b and n are constants specific to the HWA used, and b and E_{min} are dependent upon the gas composition, as discussed in the following sections.

The authors' DBVSS needs to account for the changes in the King's Law relationship (b, E_{min}) caused by changes in gas composition. **Figure 1** shows the voltage output for one HWA sensor in two concentrations of helium during full balloon pulsation. The flow starts at zero, rises as the balloon is filled, and then returns to zero flow before reversing direction. The change in helium concentration affects both E_{min}, the voltage offset, and b, which is related to the amplitude of the flow signal (the theory states and the authors' experiments confirm that n is independent of gas composition).[11–13] The authors' DBVSS algorithm assumes a unique relationship between the value of E_{min} and b, which provides a King's Law relationship for any given gas concentration by monitoring changes in E_{min} as the gas composition changes. The relationships were explored further in steady flow experiments described in the following sections.

Hot Wire Anemometer Response In Steady Flow

Steady flow tests were performed to determine the King's Law coefficients and their dependence upon gas composition. The authors connected the HWA on one end to a vacuum pump and on the other end to a gas source, either a helium tank, room air, or a gas mixer blending helium with room air. Either a 0–10 LPM or 5–25 LPM digital bubble flow meter (Series 5200, Accura Flow Products, Warminster, PA) was placed upstream of the HWA as the flow standards. The authors varied the flow with a downstream needle valve and measured the steady state voltage *versus* flow relationship over a range of 0–20 LPM. **Figure 2** shows results for the King's Law relationship for pure helium, pure air, and a 70% helium/air mixture. The dotted lines and equations represent the nonlinear regressions of King's Law coefficients to the data, performed in MATLAB, and confirm that the Q exponent in King's Law (n = 0.63) is independent of the gas composition.

Figure 2 confirms the direct relationship between E_{min} and gas composition. To determine a more specific relationship, we measured the zero flow response of the HWA under different helium concentrations. The sensor was sealed at both ends (zero flow) and filled with 100, 90, 70, and 50% helium mixtures created by known ratios of helium and air. **Figure 3** shows the linear relationship between helium concentration, [He], and E_{min}. The E_{min} at 100% helium agreed with the intercept of the 100% helium steady flow test, and the 0% helium (room air) agreed with the 0% helium steady flow tests. All helium percentages reported in the remainder of this article were determined by the inverse of the relationship shown in **Figure 3**, given by the following formula:

$$[He] = \frac{E_{min} - 0.5009}{1.7866} \quad (3)$$

Although the steady flow tests did confirm King's Law and the dependence or independence of its coefficients upon gas composition, the authors questioned the direct use of the steady flow calibrations in our oscillatory flow application. Although Bruun[11] found similar dynamic and steady flow responses in HWA, the authors wanted to optimize the volume determination of pulsating balloons. Accordingly, the authors performed experiments to refine the King's Law calibrations determined from steady flow using oscillatory flow representative of the authors' applications of interest.

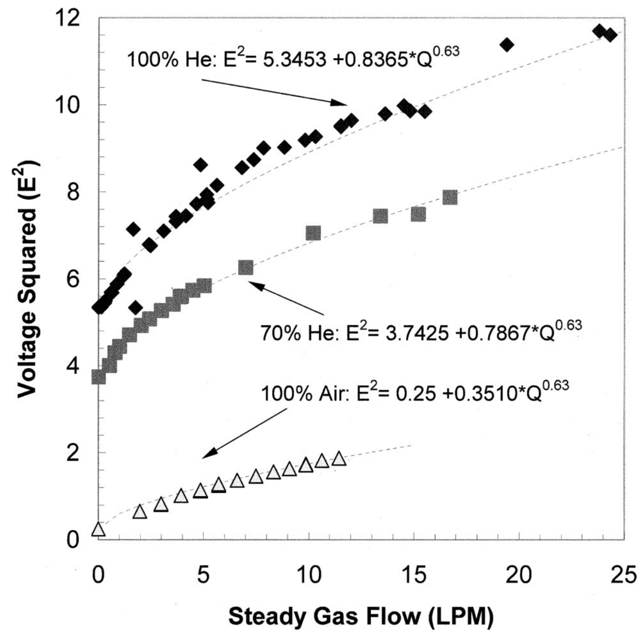

Figure 2. The voltage response of the hot wire anemometer during steady flow at different gas concentrations. Also shown are the regressed King's Law relationships at each concentration.

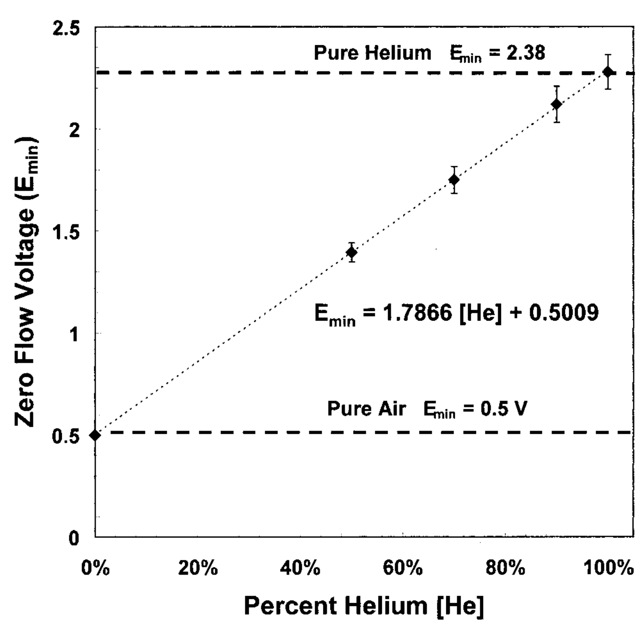

Figure 3. The change in zero flow voltage, E_{min}, with helium concentration.

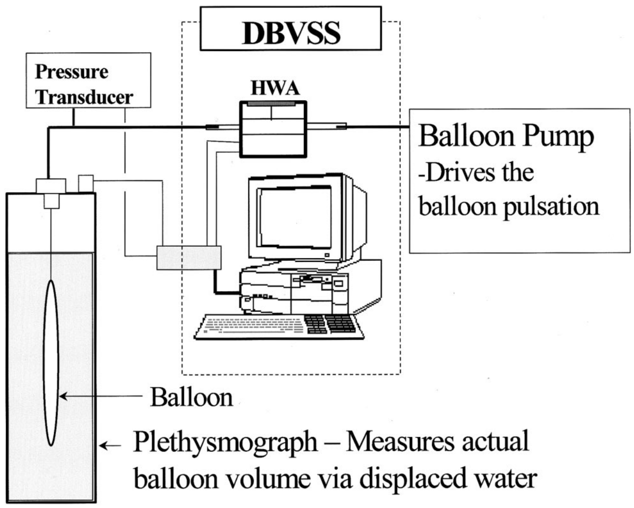

Figure 4. Schematic of the test setup for the DBVSS in balloon pulsation experiments. DBVSS, dynamic balloon volume sensor system.

Refinement of King's Law in Pulsation Tests

Figure 4 shows the setup used to determine the King's Law relationship for oscillatory flow. The HWA sensor of the DBVSS was connected in line between a helium drive console and a 40 cc intraaortic balloon catheter (Datascope, Fairfield, NJ), which was inserted into a sealed, partially water-filled chamber, which acted as a plethysmograph to provide a measure of actual displaced balloon volume, as described in the following sections. Pressure transducers (Sensym 921 A, ± 780 mm Hg, Milpitas, CA) were connected to the plethysmograph and the driveline. Plethysmograph pressure, driveline pressure, and the HWA voltage signal were sampled at 1,000 Hz using the National Instruments AT-MIO-16E-10 data acquisition board and a custom LabVIEW (National Instruments, Austin, TX) data acquisition program. Signal conditioning consisted of a 10 Hz Butterworth low pass filter on the plethysmograph pressure transducer box (PTB 1), and a control voltage that grounded the unused channels on the DAQ card. The DBVSS converts the voltage signal to a flow signal using the King's Law relationship matched to the data set in question and uses trapezoidal integration of the flow pulse to calculate DBVSS volume.

Actual displaced balloon volume, V_b^{act}, was determined from the pressure signal of the plethysmograph by assuming adiabatic compression of air and using the following relationship:

$$V_b^{act} = \frac{1 P \cdot V_0}{\gamma \;\; P_0} \tag{4}$$

where γ is the adiabatic constant for air, P is the absolute plethysmograph pressure at full balloon inflation, P_0 is the plethysmograph pressure at balloon deflation, and V_0 is the volume of air in the plethysmograph at balloon deflation.

The HWA was a mass flow meter, so to calculate volumetric flows, the authors compensated for gas compression with the ideal gas law. This attention to gas compression is necessary because the sensor measures the mass flow rate, and hence mass within the balloon is computed. The volume of the mass of gas within the balloon depends upon the ambient pressure within the balloon when filled. The measured volume of gas that passed through the flow meter, V_b^{DBVSS}, was converted to the compressed volume by multiplying V_b^{DBVSS} by the ratio of the ambient pressure, P_{amb} to the absolute calibration pressure of the flow meter (730 mm Hg). P_{amb} was measured at the entrance port to the balloon with the balloon in a filled state.

A dynamic volume standard enables us to find the proper flow equation so that the DBVSS volume, V_b^{DBVSS}, matches the actual volume from the plethysmograph standard, V_b^{act}. The authors had a starting value of n from the steady flow tests, but there was no guarantee it exactly matched the dynamic flow equation. The first set of tests was designed to find the best value of n because the theoretical *b versus* E_{min} relationship is very dependent upon the coefficients for King's Law (**Equation 2**), especially to the exponential coefficient n.[11,12] The theory also states that n can be treated as a constant, once measured for a specific anemometer.

The drive system pulsed the balloon underwater at 120 beats per minute (BPM), with drive gas as close to 100% helium as possible. The authors then diluted the drive gas by mixing a 5 cc bolus of air into the system and measured the pulsation again. Eight of these mixtures gave the authors a good profile of dilutions down to approximately 70% helium. Calculating the DBVSS volumes using the 100% helium steady flow equation showed a steady divergence from the actual volume, so the authors knew that it was necessary to change the equation with concentration.

The authors needed to find a relation between E_{min} and b that would best match V_b^{DBVSS} to V_b^{act} across the helium dilution tests. The authors analyzed the data using values of n from 0.45 to 0.7, with the value of n fixed for each set of tests. E_{min} was directly measured as the flow went to zero between pulsations, and the authors would regress the b value at each dilution until the King's Law equation gave a DBVSS volume, V_b^{DBVSS}, that matched V_b^{act} for that data set. The final b values from across all the concentrations were plotted against the measured E_{min} to generate an E_{min} *versus* b relationship for each separate value of n.

The authors then applied each of these separate flow models (one for each value of n) to a new set of data to test which n value produced the most accurate regression. The new set of data was similar to the previous test. The authors purged the system with helium, measured three different balloon volumes at this concentration, diluted across a number of tests, and again tested the 70% mixture at three different volumes. The authors used the *b versus* E_{min} equation to compensate for the helium loss in each experiment.

The authors measured the statistical coefficient of determination, R^2, to find which value of n resulted in the best correlation of V_b^{act} to V_b^{DBVSS}. **Figure 5** shows that the best correlation value of n is approximately 0.65, which is close to the 0.63 calculated in the steady flow nonlinear fit, and that the R^2 values drop for n values higher and lower than 0.65. **Figure 5** also shows that n = 0.63 had a high degree of correspondence, and was a valid starting point. The value of n = 0.65 corresponded to a b value of 1.0588 for 100% helium, which provided the linear *b versus Emin* relationship plotted in **Figure 6** and given by the following formula:

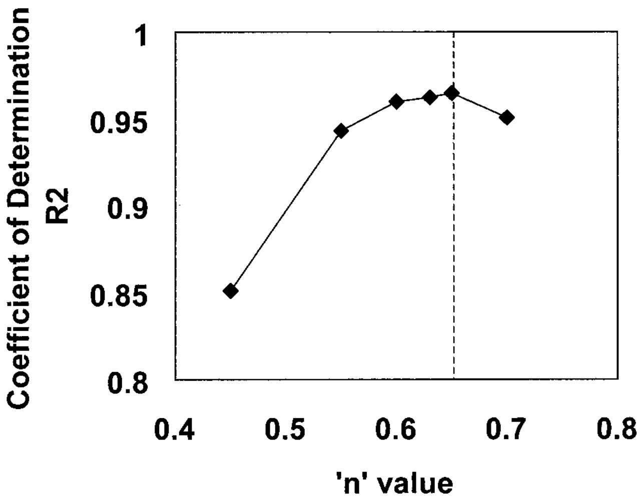

Figure 5. Correlation of actual balloon volumes and those calculated using King's Law with different values of n. The maximum correlation was for n = 0.65.

$$b = 0.1963 + 0.3655 \cdot E_{\min} \quad (5)$$

Equation 5 allows us to rewrite King's Law in terms of E_{min} and the flow, Q, resulting in:

$$E_t^2 = E_{\min}^2 + (0.1963 + 0.3655 \cdot E_{\min}) \cdot Q^{0.65} \quad (6)$$

Equation 6 can be rearranged to allow the flow to be calculated from the voltage, E_t, provided that E_{min} is also measured at any concentration:

$$Q = [(E_t^2 - E_{\min}^2)/(0.1963 + 0.3655 \cdot E_{\min})]^{1/0.65} \quad (7)$$

Testing of the Dynamic Balloon Volume Sensor System for Typical Intraaortic Balloon Pump Conditions

The basic transduction relationship underlying the DBVSS, **Equation 7**, needed to be evaluated in an independent series of tests to show that the DBVSS could be used in conditions beyond those in which it was directly calibrated. The best system to test this was an actual IABP console running in auto fill mode. This system would lose helium over the course of 2 hours until it paused to automatically refill the driveline and balloon using 100% helium before continuing pulsation. The DBVSS measured the balloon volume at 15-minute intervals throughout the refill cycle, with the same plethysmograph and DBVSS setup as used in the calibration tests.

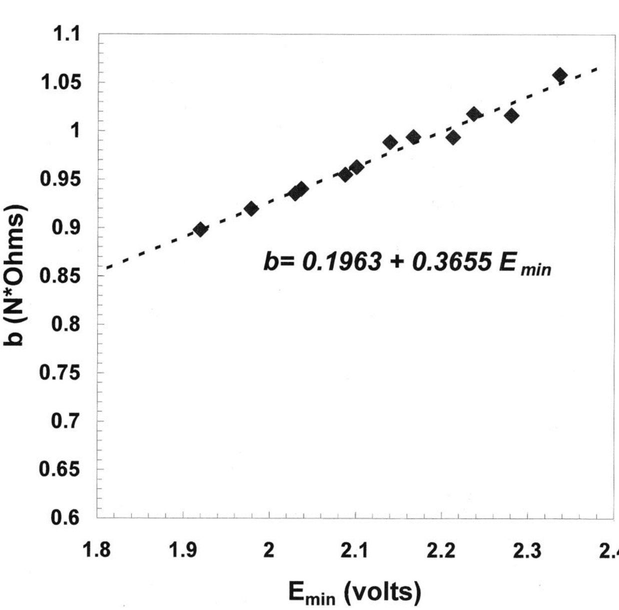

Figure 6. The linear relationship between *b* and *Emin* calculated at n = 0.65

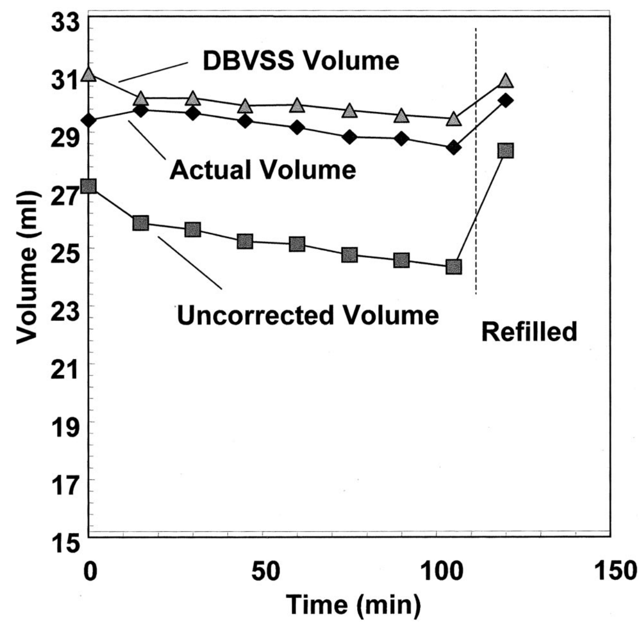

Figure 7. Balloon volume measurement using the DBVSS during the two hour refill cycle of an intra-aortic balloon pump console. Uncorrected volume is the DBVSS volume assuming 100% helium without the compensation algorithm for changing gas concentration. DBVSS, dynamic balloon volume sensor system.

The results of the volume measurement during IABP pulsation are shown in **Figure 7**. The helium loss and change in volume was much smaller in this test than in the earlier tests, with the helium ranging from 90% down to 80%. The uncorrected balloon volumes, which do not use the helium compensation algorithm of the DBVSS, are approximately 4 ml lower than the actual values, an error of 15%. Conversely, the correlation of V_b^{DBVSS} to V_b^{act} was within 6% across the tests and was within 2% for seven of the tests. This agreement between V_b^{DBVSS} and actual balloon volumes was within the design goal set for this DBVSS system.

The authors also tested the helium compensation algorithm of the DBVSS in forced dilution of helium over a greater range than that seen in standard running of the IABP console. The system was purged with helium and pulsated at 120 BPM using the drive system for the authors' respiratory catheter.[4–6] Subsequent tests each mixed a 5 ml bolus of room air into the driveline and removed a 5 ml bolus of the resultant mixture. This mixing provided a range of helium dilutions from 90% to 66% helium, enabling the authors to test concentrations lower than the 80% helium low seen in normal IABP operation. **Figure 8** shows that V_b^{DBVSS} was within 5% of V_b^{act} over the entire range of dilutions, whereas the uncorrected volumes, V_b^{UC}, deviated by up to 30% of the actual volume.

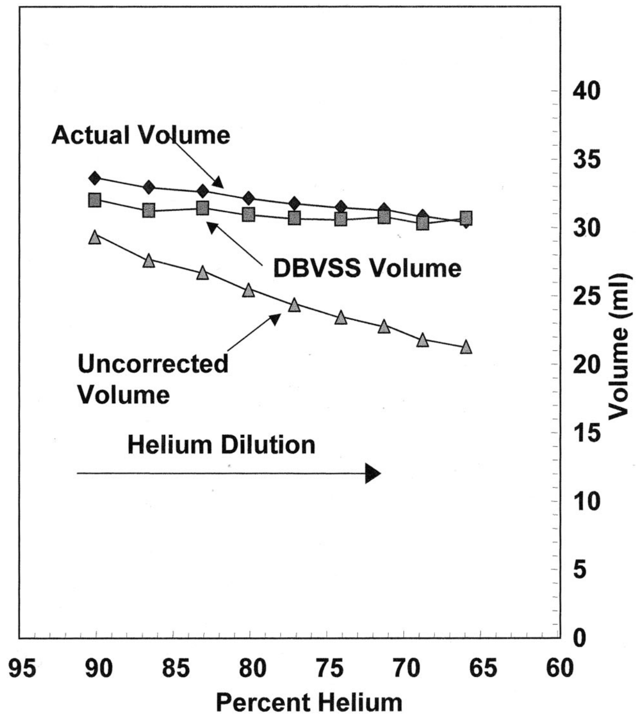

Figure 8. Balloon volume measurement using the DBVSS during forced dilution of the helium driveline gas with air. Uncorrected volume is the DBVSS volume assuming 100% helium without the compensation algorithm for changing gas concentration. DBVSS, dynamic balloon volume sensor system.

Testing Over a Range of Pulsation Frequencies

The authors extended the test of the DBVSS over a broad range of frequencies to cover expected pulsation rates in IABP and in the respiratory catheter.[2–5] IABP use does not typically exceed 120–180 BPM, but the current respiratory support catheter has been pulsated up to 300 BPM in animal tests and up to 480 BPM in recent bench tests. Accordingly, the authors varied frequency from 120–480 BPM in intervals of 60 BPM and recorded 15 seconds of data at each pulsation rate. Two sets of data were recorded, one in ascending and one in descending order of frequency. A second experiment tested the effect of frequency on the DBVSS in a lowered helium concentration. The authors tested the system again from 120–480 BPM but in a system diluted with 20 cc of room air to approximately 65% helium. The authors again recorded two sets of data, ascending and descending in frequency.

Figures 9 and 10 compare the DBVSS-calculated balloon volumes, V_b^{DBVSS}, with the actual balloon volumes, V_b^{act}, determined from the plethysmograph measurements across the frequency range from 120–480 BPM for 90% helium and 65% helium, respectively. Also shown are the uncorrected DBVSS volumes, V_b^{UC}, determined without the compensation algorithm for diluted helium concentration. The actual volume delivered to the balloon decreased with increased frequency because the balloon has less time to fill. In 90% helium (**Figure 9**), V_b^{UC} was consistently approximately 13% below actual volumes, whereas V_b^{DBVSS} remained within 10% of the actual balloon volume and showed approximately half of the deviation of the uncorrected volumes. In 65% helium (**Figure 10**),

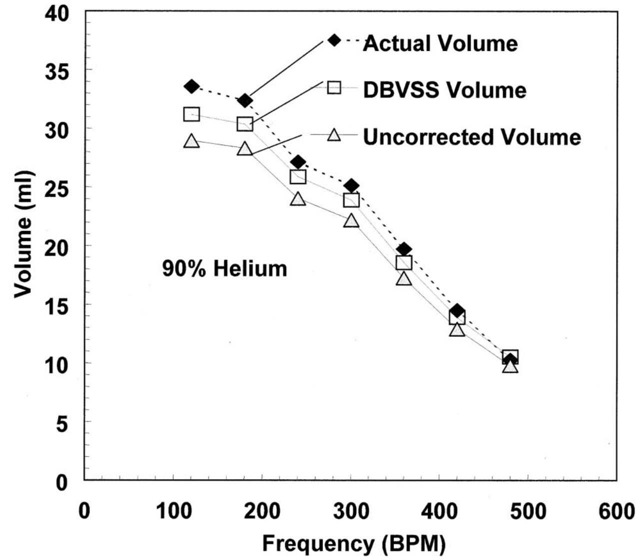

Figure 9. Balloon volume measurement using the DBVSS across a broad range of pulsation frequencies for 90% helium driveline gas. Uncorrected volume is the DBVSS volume assuming 100% helium without the compensation algorithm for changing gas concentration. DBVSS, dynamic balloon volume sensor system.

V_b^{DBVSS} did substantially better than V_b^{UC} and was within 5% of V_b^{act} up to 420 BPM, but diverged significantly above 420 BPM, indicating an upper frequency limit for the current DBVSS.

Balloon Constriction Tests

Pulsating balloon catheters may be affected clinically by insertion into a tortuous or constrictive anatomic region that could limit balloon inflation. Balloon constriction could also be caused clinically by improper insertion or deployment of the balloon catheter.[2] The DBVSS must be able to detect

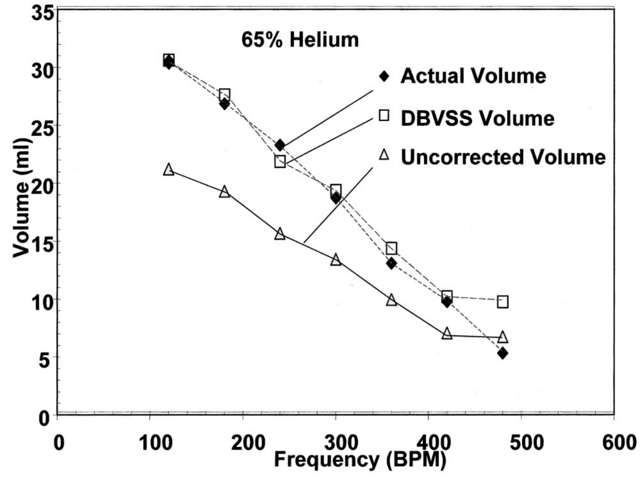

Figure 10. Balloon volume measurement using the DBVSS across a broad range of pulsation frequencies for 65% helium driveline gas. Uncorrected volume is the DBVSS volume assuming 100% helium without the compensation algorithm for changing gas concentration. DBVSS, dynamic balloon volume sensor system.

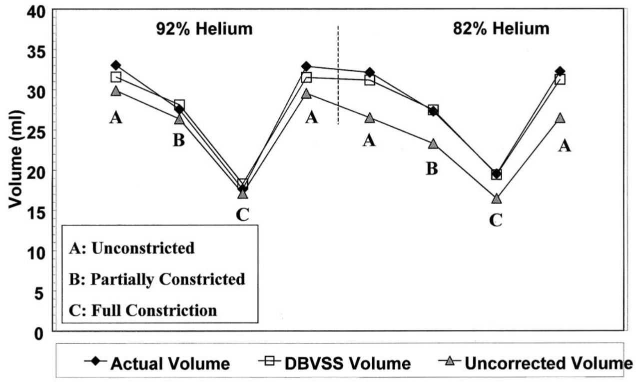

Figure 11. Balloon volume measurement using the DBVSS with different imposed constrictions of the catheter balloon. Uncorrected volume is the DBVSS volume assuming 100% helium without the compensation algorithm for changing gas concentration. DBVSS, dynamic balloon volume sensor system.

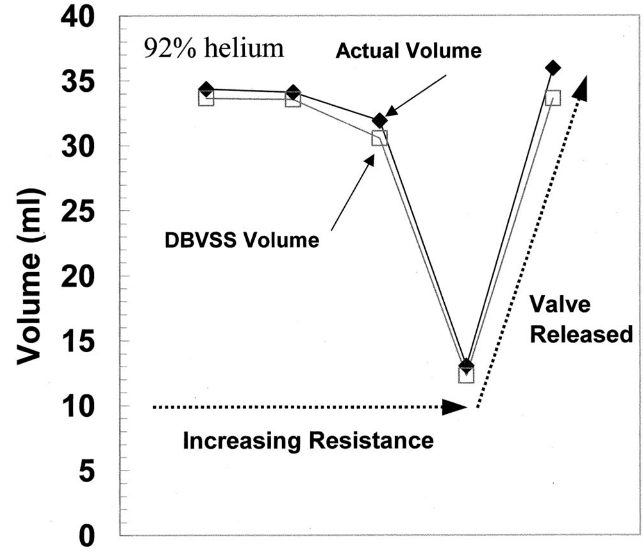

Figure 12. Balloon volume measurement using the DBVSS with changes in the driveline resistance using an in-line needle valve to simulate driveline crimping. DBVSS, dynamic balloon volume sensor system.

improper balloon inflation associated with any cause. Accordingly, the authors needed to test whether the DBVSS would measure correct balloon volumes when balloon pulsation occurs within a constricted environment, balloon filling is reduced, and a backpressure develops in the balloon. In these tests, the authors inserted an intraaortic balloon into a constricting half-inch rubber tube to limit balloon filling. The balloon was tested at three levels of constriction: outside the tube, then inserted to half its length, and finally completely inserted into the tube, followed by a repeated test outside the tube. All tests were performed with the balloon catheter and rubber tube ensemble within the plethysmograph so that actual balloon volumes could be measured. The balloon constriction tests were performed at pulsation rates of 120 BPM and at 2 helium dilutions, 92% helium and 82% helium. Balloon pulsation in each specific constriction test was for 15 seconds, but otherwise data acquisition and analysis was the same as for all other tests.

Figure 11 shows the results of the balloon constriction tests. From left to right, the first set of volumes were for the unconstricted balloon, the next two sets of reduced volumes were for the balloon partly and fully inserted into the rubber tubing, and the fourth set of volumes were for the balloon removed from the constricting tube, all at 92% helium. The next four sets of volumes were the analogous tests for 82% helium. These results indicate that V_b^{DBVSS} detected well the partial balloon filling associated with pulsation in the constricting tube and was within 5% of V_b^{act} at 92% helium and within 3% at 82% helium. The uncorrected balloon volumes, V_b^{UC} also tracked the reduction in actual balloon volumes, but as expected the deviation from V_b^{act} was greater than for the DBVSS balloon volume, being 15% below the actual balloon volumes at 92% helium and more than 25% below at 82% helium.

Increased Driveline Resistance Tests

Driveline crimping/constriction and increased driveline resistance could also limit the filling ability of pulsating balloon catheters by reducing the flow of gas delivered to the balloon. The final experimental tests assessed the performance of the DBVSS under conditions simulating a driveline constriction, in which increased driveline resistance reduces balloon filling. In these tests, the authors used the same measurement and drive system setup as in previous tests, but a needle valve was inserted between the DBVSS and the balloon to increase the driveline resistance, thus simulating driveline crimping. The needle valve was tightened, and the line resistance was increased across four tests, reducing the delivered volume with each increase in resistance. The final test repeated the first, with the valve completely open. All of these tests were performed at maximum helium concentration (approximately 95% helium).

Figure 12 shows the reduced volumes obtained with increasing driveline resistance as the needle valve was tightened, then the recovery of balloon volume after the needle valve was reopened. The DBVSS reliably determined the balloon volumes delivered with changes in the driveline resistance. Across all data points in **Figure 12**, the agreement of V_b^{DBVSS} to V_b^{act} was within 7% and within 5% for many of the data points. These results demonstrate that the DBVSS can detect specific reductions in pulsating balloon volumes that might result from driveline crimping/constriction and increased driveline resistance.

Discussion

The goal of the present study was to develop a sensor system for helium pulsed balloon catheters that could reliably determine the delivered volumes to the balloon from measurements done on the shuttle gas flowing through the driveline to the patient. It is important that the sensor system needed to reliably measure the delivered balloon volume as the helium concentration in the driveline changed because of natural or other helium leaks in the system. The results presented here demonstrate that this DBVSS can reliably measure balloon volume for operating conditions relevant to the clinical use of intraaortic balloon catheters and the authors' pulsating respiratory support catheter. The DBVSS developed in this study met the goal of measuring balloon volume during rapid pulsation to within 10% of the actual pulsation volume of the balloon. The DBVSS design allows it to be readily used with existing balloon drive consoles, with the HWA flow sensor placed in line between the catheter and the drive system console, as in the experimental setup. Ultimately, the DBVSS could be directly integrated into future designs of balloon drive consoles to directly monitor and control balloon inflation.

This development of the DBVSS built upon the basic science of HWA [11–13] and upon previous related work in spirography.[7–10,14] HWA used in spirography was previously limited to applications where compensation for changing gas concentration was not required or, if required, was measured by a second sensor. The present work has expanded the application of HWA in volume measurement by providing and validating an algorithm that enables compensation for changes in gas concentration directly from the output of the HWA during flow and volume measurement. The authors' approach does not involve assumptions about gas composition and related changes in gas properties. Previous work in respiratory spirography by Plakk *et al.*[8] did address the issue of compensation for changes in gas composition, but the approach described involved the measurement of both gas density and viscosity and was ultimately not used in their study. The present method simplifies the Plakk *et al.* approach by using a single measurable variable, the HWA voltage during no flow (E_{min}), which can be taken from the HWA sensor voltage already gathered in the flow signal integrated to get volume. This DBVSS simplifies the compensation algorithm for gas composition and extends the functionality of HWA to determine delivered volumes in pulsating systems in the presence of changes in drive gas composition.

The authors tested the DBVSS over a range of balloon volumes and frequencies pertinent to pulsating balloon catheters, including pulsation frequencies up to 480 BPM. A concern as frequency increases is the measurement of the minimum voltage, E_{min}, because the zero flow time between pulsations decreases with increasing pulsation frequency. The reliable determination of E_{min} may underlie the discrepancy between DBVSS and actual balloon volumes seen at the high frequency limit in **Figure 10**. The DBVSS algorithm could be modified in future applications to address this potential issue. For example, the rate of helium loss and change in gas composition is relatively slow, and E_{min} does not need to be measured continuously or even frequently. If necessary, the DBVSS could be integrated into the overall drive console and instruct the console to briefly suspend pulsations (for less than 1 second) at regular intervals. The consoles driving the balloon catheters discussed here pause for refilling, and hence the short and infrequent zero flow pauses for E_{min} determination should not adversely affect patient treatment.

The balloon drive systems studied here used helium as the fill gas, and hence the gas composition algorithm of the DBVSS addressed helium-air mixture effects. Nevertheless, the DBVSS could be used in other applications like respiratory spirography or even balloon drive systems using other gases, if the gas composition algorithm is recast appropriate to the gas mixture relevant to the application. The theory underlying this DBVSS and HWA indicates that for other gas mixtures a new *b versus* E_{min} relationship would be required, but this relationship could be readily determined from calibrations, as performed here for helium-air mixtures. The compensation for changing gas concentration may not even be required if the gases composing the mixture have similar thermal and inertial properties. This DBVSS specifically addressed the effects of a change in the helium-air composition in the driveline upon the HWA flow sensor, but other environmental changes might also need to be considered. Significant changes in ambient humidity could affect the HWA flow sensor if the ambient humidity altered the composition of the driveline gas. The change in gas composition in the driveline, however, is mainly caused by helium loss from the system, not ambient gases diffusing into the system, which occurs more slowly. Ambient humidity should not significantly affect the performance of the DBVSS. Significant changes in the temperature of the driveline gas would also affect the HWA flow sensor by changing the temperature difference between the constant temperature wire of the HWA and the flowing gas past it. The present authors have not seen significant temperature variations in the shuttle gas caused by changing ambient temperature or cyclic compression and expansion. Nevertheless, if significant temperature variations become an issue in future applications, the HWA sensor has an integrated thermistor that could be used to compensate for changes in gas temperature.

Conclusion

The development of the DBVSS extends previous work in spirography to the measurement of delivered volumes in a rapidly pulsating/oscillating system. Our method of compensating for changes in gas composition from only measurements of the HWA voltage response to flow expands the capabilities of hot wire anemometry and its application to spirography. Volume measurement can now be performed with reduced instrumentation, and under wider variations of gas properties. This volume measurement ability will enable clinicians to better treat patients through better stroke volume matching in IABP, and through greater gas exchange to the patient treated with the respiratory support catheter. Accordingly, these results may find future application beyond the measurement of balloon volumes in pulsating medical catheters, including applications to the anemometry systems currently being developed in the areas of MEMS and nanotechnology, as well as enhancing the current use of hot wire anemometry.

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