Clinical Evaluation of Bentley 10 Plus Bubble Oxygenator

J.W. Basha, Jr., J.J. Sternlieb, V.O. Bjork, T.W. Gabrielson, and V. Hodges
Heart Institute of the Desert
Rancho Mirage, CA

Abstract

This is the first clinical report evaluating the accuracy, safety and operative simplicity of the new BENTLEY 10 PLUS (B10+) bubble oxygenator to control pO_2 and pCO_2 independently. Eleven patients undergoing cardiopulmonary bypass (CPB) were randomly selected. The Bentley Gas Stat (BGS) was used to obtain blood gas values during CPB at five-minute intervals, (N = 270). BGS calibration values were recorded. Confirming blood gas samples were sent to the hospital laboratory at approximately 15-minute intervals to ensure accuracy of the BGS. Adjustments to the gas flow controller (GFC) and total gas flow (TGF) were made to maintain the pO_2 and pCO_2 with predetermined ranges, 100–150 torr and 38–42 torr, respectively. The number of adjustments required to maintain values within ranges, GFC settings, TGF settings, Hemoglobin, and visual signs of hemolysis (hemoglobin-urea) were charted.

The B10+ unique gas flow control mechanism and central filming chamber enables the user to independently control pO_2 and pCO_2 during CPB: thus, A) maintain blood gases within physiologic ranges, B) reduces microgaseous emboli emission, C) reduces blood trauma and D) allows blood gas control similar to a membrane at significantly less cost. Use of a continuous on-line blood gas analyzer is recommended with this oxygenator.

Introduction

Historically, control of the oxygen (O_2) and carbon dioxide (CO_2) content of blood was accomplished by manipulating a single parameter, the total gas flow (TGF).[8] Therefore, independent control of PaO_2 and $PaCO_2$ with a bubble oxygenator was not possible.

A new concept in the gas flow dynamics of bubble oxygenators, gas flow splitting (GFS) has been developed and is available on the Bentley Bent 10 Plus[a] (B10+) bubble oxygenator. GFS is accomplished by creating two pathways for the TGF, one to the oxygen sparger plate and one to the central filming chamber. A gas flow control mechanism (GFC) acts as a valve and regulates the amount of TGF traveling down each path. O_2 transfer occurs predominately at the level of the O_2 sparger and CO_2 exchange is most prevalent in the central filming chamber; thus, GFS allows for independent control of PaO_2 and $PaCO_2$ with a bubble oxygenator.

This study was conducted in the clinical setting to evaluate the efficacy of GFS. The following criteria were also evaluated for the GEC: A) operative simplicity, B) reproducibility and C) safety.

Materials and Methods

Patients undergoing CPB for myocardial revascularization were randomly selected. Patient population (n = 11) consisted of eight males and three females with an average age of 71 and weight 77.6 kilograms (Table 1). The same CPB circuit, perfusionist and surgeon were used on each case. The Bentley Gas Stat[b] (BGS) continuous on-line blood gas analyzer (CLBGA) was used to accrue data points during CPB. Prior to each procedure a sample of perfusate was sent to the hospital laboratory for measurement on the Corning 178[c] and the BGS values stored. If necessary, a one-point calibration was performed on the BGS. Following initiation of CPB, data points were recorded from the BGS at five-minute intervals (N = 295) and confirming blood gas samples sent to the hospital laboratory every 15 minutes but not less than three per case. All blood gas results were reported at 37.0 degrees C. If the confirming blood gas values differed from the BGS five percent for pCO_2 or fifteen percent for pO_2,[4,5] the previously charted data points were discarded and a one-point calibration performed on the BGS. The GFC and the total gas flow (TGF) were

Direct communications to: Joseph W. Basha, Jr., C.C.P., Heart Institute of the Desert, 39600 Bob Hope Drive, Rancho Mirage, CA 92270.

a Bentley Labs, Irvine, CA 92714.
b Bentley Labs, Irvine, CA 92714.
c Corning Instruments, Palo Alto, CA 94306.

Table 1.
Patient Population

	Weight (Kg)	Age (years)
Number	11	11 (8 male, 3 female)
Maximum	103	81
Minimum	63	62
Mean	77	70

adjusted throughout the procedure to maintain the PaO_2 and $PaCO_2$ within a target range of 100–150 torr and 38–42 torr, respectively. GFC and TGF settings, and the number of adjustments made to each necessary to maintain the measured parameters within target ranges, were noted. Visual signs of gross hemolysis (hemoglobinuria) were also charted.

Results

The course of the PaO_2 and $PaCO_2$ for the eleven study case are graphically illustrated in Figures 1 and 2. The PaO_2 in the initial CPB period is frequently elevated out of target range, then decreases and remains nearly linear within target range for the remainder of the procedure. This initial elevation can be explained by our technique of initiating CPB with the GFC set on the MAX position (100% TGF through sparger), and the BGS sensors exposure to high pO_2 in the CPB circuit prime. A similar pattern is seen in Figure 2 for the $PaCO_2$ data. Forty-four data points did not correlate with the confirming laboratory values and were discarded. The mean PaO_2 was 143 torr (range 83–450 torr) with an in-target range percentage of 80 and the mean $PaCO_2$ was 39.8 torr (range 34–48 torr) with 92 percent of its values within target range seen in (Table 2). Further review of Figure 1 reveals that subtraction

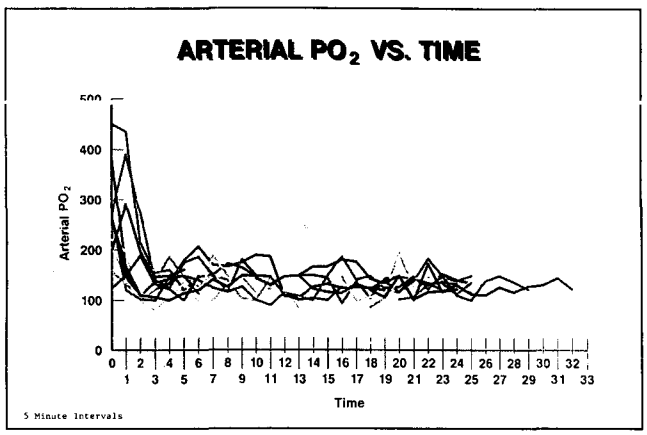


Figure 1. Graphic Illustration of PaO_2 Over Time for 11 Cases

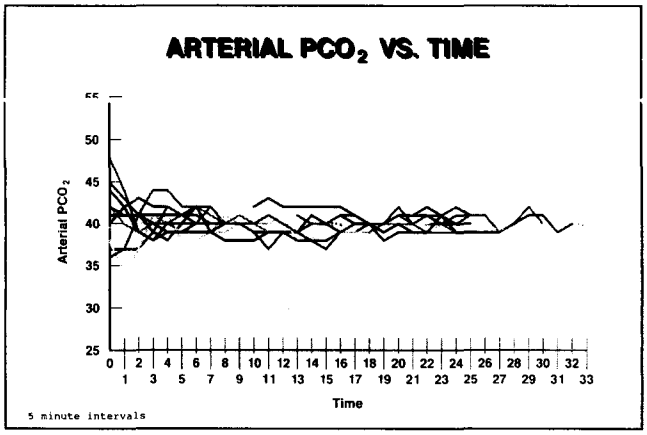


Figure 2. Graphic Illustration of $PaCO_2$ Over Time for 11 Cases

of the initial readings increases to greater than 84 percent the number of PaO_2 data points inside the target window. During periods of hypothermia and without GFS (Figure 3), the PaO_2 is significantly elevated to control $PaCO_2$ values at physiologic levels. With GFS at hypothermia (Figures 4 and 5), manipulating the GFC and TGF resulted in the PaO_2 and $PaCO_2$ comprising in-target window proportions of 97 and 100 percent, respectively. At the critical moment of aortic cross clamp removal (Table 3) 86 percent of the recorded PaO_2 values were within the target range. Shown in Table 4 are the adjusted and nonadjusted gas flow (Qg):blood flow (Qb) ratios and GFC settings. Adjusted Qg is defined as the TGF minus the proportional change of Qg to the sparger at the selected GFC setting. Thus, the adjusted Qg:Qb ratio is 0.50:1 with a mean GFC setting of 0.45. The average number of per procedure adjustments required to maintain the measured parameters within the prescribed ranges were 12 and 8, respectively. There were no visual signs of hemolysis in a twenty-four hour followup.

Table 2.
PO_2 and $PaCO_2$ Means, Target Range and Percent Within

	PO_2	PCO_2
Number	251	251
Maximum	450	48
Minimum	83	34
Mean	143	40
Target Range	100-150	38-42
Percent Within	80%	92%

Table 3.

Blood Gas Values During Reperfusion

	PO_2	PCO_2
Maximum	187	41
Minimum	125	38
Mean	147	39.5
Target Range	100-150	38-42
Percent Within	86%	100%

Table 4.

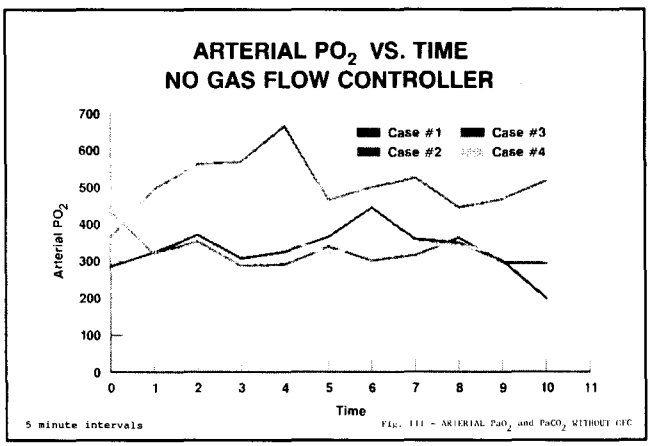
Gas Flow Controller Qg:Qb Ratios

	Blood Flow (LPM)	Gas Flow (LPM)	Gas Flow Controller	Qg:Qb	Qg:Qb (Adj.)
Maximum	5	10	1.0	2.50:1	.83:1
Minimum	3	.3	0.1	.08:1	.06:1
Mean	4.2	4.7	0.45	1.10:1	.50:1

Discussion

In review, GFS technology is the controlled separation of the TGF. The GFC allows for the separation to be regulated down two paths of a bubble oxygenator, either, undivided to the O_2 sparger plate where maximal O_2 transfer takes place, or fractionally to the central filming chamber where the preponderance of CO_2 exchange and only minimal O_2 transfer occurs. Therefore, a change in the TGF will affect both the PaO_2 and $PaCO_2$, while a change in GFC alone will only have an effect on PaO_2.

Maintaining PaO_2 at physiologic levels has several beneficial effects, including: A) reducing gaseous microemboli delivery to the patient[6,7] and B) by reducing production, limiting the deleterious effects of oxygen-free radicals on the myocardium during reperfu-



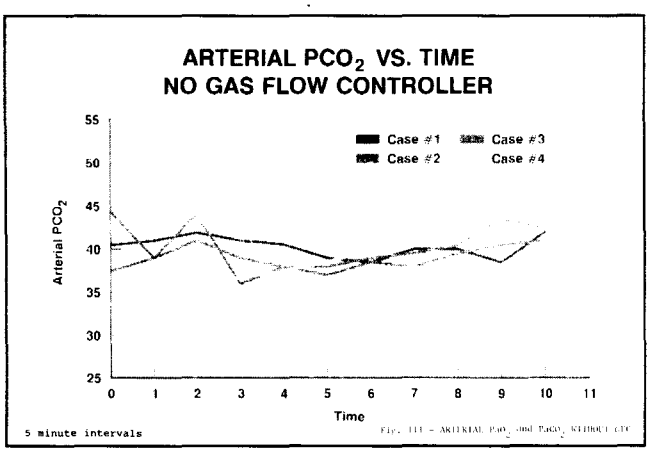


Figure 3. Arterial PaO_2 and $PaCO_2$ Without GFC

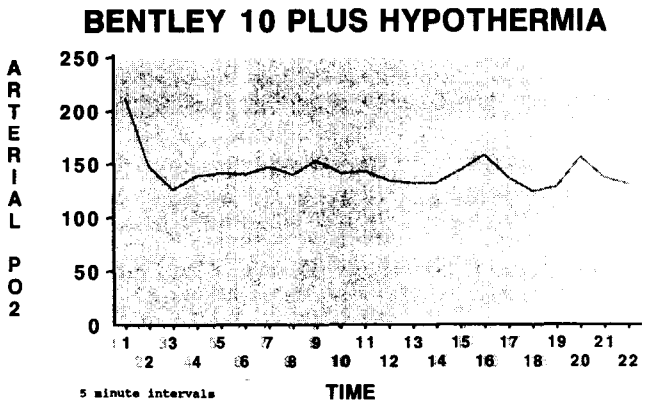


Figure 4. PaO_2 During Hypothermia

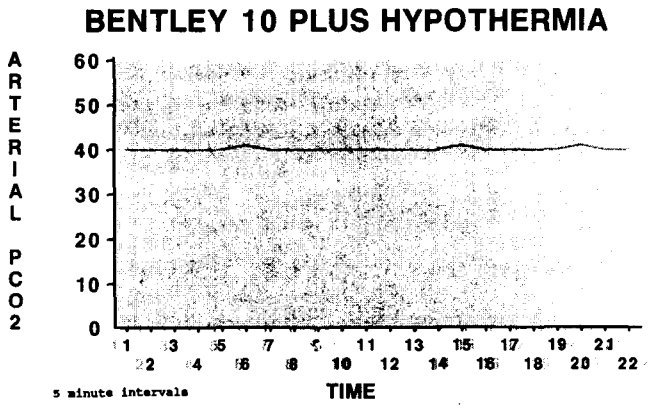


Figure 5. $PaCO_2$ During Hypothermia

sion.[1,2,3] Previously, the only way to derive the above-mentioned benefits of physiologic blood gases during CPB was with membrane oxygenators. The data presented in this evaluation demonstrates that the B10+ bubble oxygenator is, and to the best of this author's knowledge, the only bubble oxygenator capable of controlling PaO_2 and $PaCO_2$ independently in a 100% O_2 environment. Also shown is that GFS and the GFC of the B10+ is simplistic, reproducible and with the use of CLBGA, safe.

Acknowledgement

The authors wish to acknowledge the support of Matthew Jenusaitis towards accomplishing this evaluation.

References

1. Stammers, AH et al.: Age related differences in oxygen free radical injury during myocardial ischemia. *J. Extra-Corpor. Technol. Proc.* 19:245, 1987.
2. Hearse, DJ, Humphrey, SM and Bullock, GR: The oxygen paradox: two facets of the same problem. *J. Mol Cell Card.* 12:797, 1980.
3. Hess, ML and Manson NH: Molecular oxygen: friend and foe. *J. Mol Cell Card.* 16:969, 1984.
4. Bashein, G, et al.: Evaluation of continuous florometric arterial blood gas monitoring during cardiopulmonary bypass. *Anesthesiology.* 63:3A, 1985.
5. Metzger, LF, et al.: Detecting errors in blood gas measurement by analysis with two instruments. *Clinical Chem.* 33:512, 1987.
6. Pearson, DT, et al.: A clinical evaluation of the performance characteristics of one membrane and five bubble oxygenators: gas transfer and gaseous microemboli production. *Perfusion* 1:15, 1986.
7. Hill, A, et al.: On-line off-line blood gas analysis: cost vs. time vs. accuracy. *Am Acad Proc.* 6:148, 1985.
8. Reed, CC and Stafford, TB: *Cardiopulmonary Bypass*, 1st Ed., Texas Medical Press, Inc., Houston, TX. 1985, pp. 281–318.