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Evaluation of two low flow oxygen delivery devices in normal breathing subjects

Oxygen was discovered independently by the Swedish apothecary Karl W. Scheele, in 1772, and by the English amateur chemist Joseph Priestley (1733-1804), in August 1774. In 1783, the French physician Caillens was the first doctor reported to have used oxygen therapy as a remedy. In the 19th century oxygen was being used as a therapeutic drug. The current state of oxygen delivery systems is based on a dual prong cannula design that was introduced back in 1949, which was around the time hyperbaric oxygen therapy began with the work of Churchill-Davidson and Borema (1965).

Currently there are a wide variety of oxygen delivery systems available. The performance is dependent on the patient's ventilation conditions and the oxygen delivery systems. Patient ventilation characteristics and oxygen delivery systems can be evaluated by a number of methods and devices that reflect the different oxygenation process. These variable oxygen delivery systems include the dual prong and single prong nasal cannulas which have gained popularity due to their low cost, patient comfort and ease of use in current clinical conditions. Similarly, the use of Pulse Oximetry devices, as compared to inspired oxygen fraction measurements and calculations, have gained popularity. In 1998, Dr. T. Waldau compared the inspired oxygen fraction resulting from the use of five variable performance devices, including single prong and dual prong nasal cannula.[1] The data gathered in the Waldau study confirmed that the single nasal cannula system delivered a small statistically significant difference in inspired oxygen fraction in ten healthy patients as compared to the dual prong cannula.

The aims of this study is to describe and measure the Pulse Oximetry (POX) output throughout a defined respiratory cycles using two different delivery devices, to evaluate the effect of the oxygen delivery systems on POX output and to compare POX values for the two oxygen delivery systems within a patient population.

Methods

Ten subjects (five women and five men) were recruited to the study after giving their consent. The study was conducted under protocol # TP-001, titled: *Evaluation of two oxygen delivery devices in spontaneously breathing subjects.* All subjects were healthy and had no history of pulmonary history. Demographics data and mean value of heart rates and baseline POX are presented in Table1.

A calibrated SeQual Pulse Oximeter (model # 7588) was used to measure the Pulse Oximetry output (POX) and heart rate. The gas supply was 100% oxygen with continuous flow through an E-cylinder regulated by a Magus 50 PSI (2/00) oxygen regulator. A Precor treadmill model 9.2S was used to ambulate patients in the study. The two oxygen delivery systems were 1) the dual prong device, Westmed's, Comfort Soft Plus part # 0566, and 2) the single prong device, UPODS, Uni-Flo2 part #

[1] T. Waldau, V.H. Larsen and J. Bonde, "Evaluation of five oxygen delivery devices in spontaneously breathing subjects by oxygraphy", Anesthesia, 1998, 53, 2356-263.

PS007. Both devices were seven feet in length. The two devices were applied to the subjects per the manufactures Instruction for Use.

Table 1 Demographics, baseline heart rates and POX in the 10 subjects.

	AGE: YEARS	ROOM AIR: HEART RATE B/M	ROOM AIR POX
MEAN	50.7	72.7	97.5
RANGE	16-87	56-98	96-99

Each subject was measured while lying down in a supine position. A baseline heart rate was taken and recorded (Baseline HR). A baseline POX reading was taken at room air and recorded (Baseline POX). The clinical monitor then applied the dual prong device on the subject and started oxygen flow. A POX reading at 1.0 LPM was taken after a two minute oxygen flow period. The oxygen flow was reset to 2.0 LPM and a second POX reading was taken following a two minute oxygen flow period. The subject then rested for 10 minutes at room air. The subject then walked on the treadmill in the level position, at 2 miles per hour, for two minutes while receiving oxygen through the dual prong device at 2 LPM. Following the two minute walk a heart rate measurement was taken, which was followed by a POX reading at 2 LPM. The subject rested for a 20 minute period.

Following the twenty minute rest period the subject laid back down in a supine position. A baseline heart rate was taken and recorded (baseline HR2). A baseline POX reading was taken at room air and recorded (baseline POX2). The clinical monitor then applied the single prong device on the subject and started oxygen flow. A POX reading at 1.0 LPM was taken after a two minute oxygen flow period. The oxygen flow was reset to 2.0 LPM and a second POX reading was taken following a two minute oxygen flow period. The subject then rested for 10 minutes at room air. The subject then walked on the treadmill in the level position, at two mile per hour, for two minutes while receiving oxygen through the single prong device at 2 LPM. Following the two minute walk a heart rate measurement was taken, which was followed by a POX reading at 2 LPM.

Results

Table 2 The following table provides a comparison of room air baseline heart rates (beats per minute) B/M with standard error calculated (error bars) at all data points for the ten subjects.

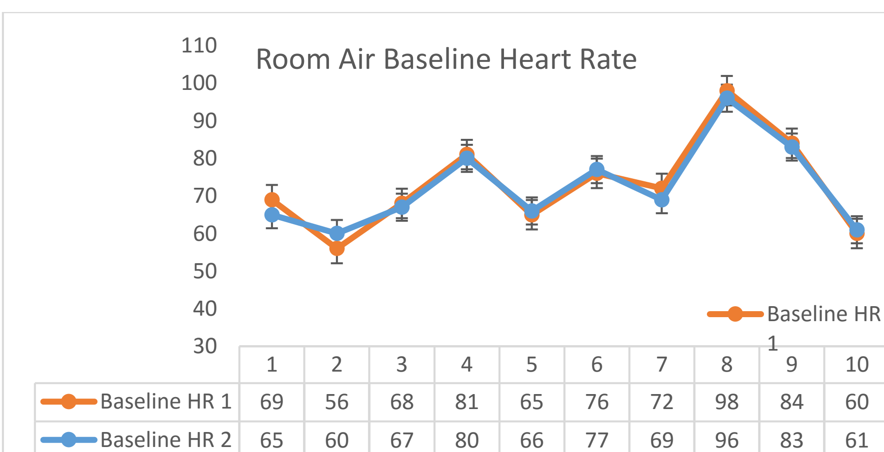
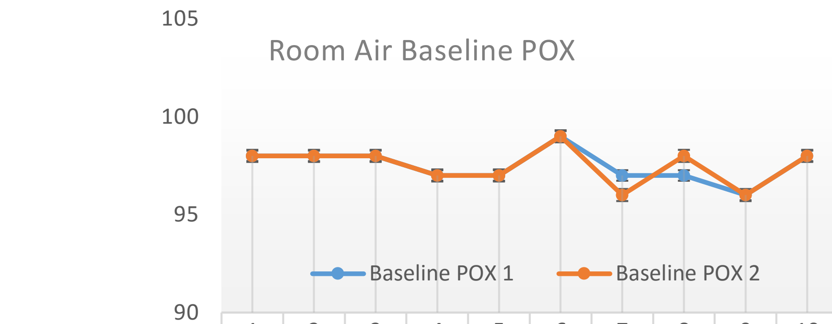
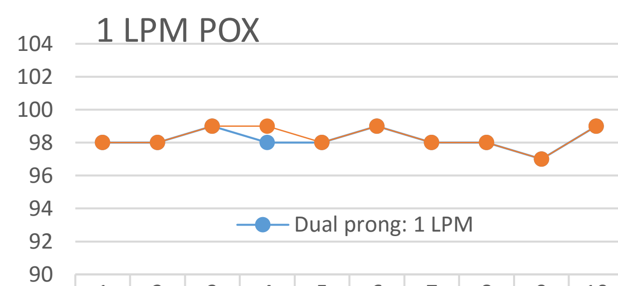


Table 3 The following table provides a comparison of room air baseline Pulse Oximetry (POX) readings with standard error calculated (error bars) at all data points for the ten subjects.



	1	2	3	4	5	6	7	8	9	10
Baseline POX 1	98	98	98	97	97	99	97	97	96	98
Baseline POX 2	98	98	98	97	97	99	96	98	96	98

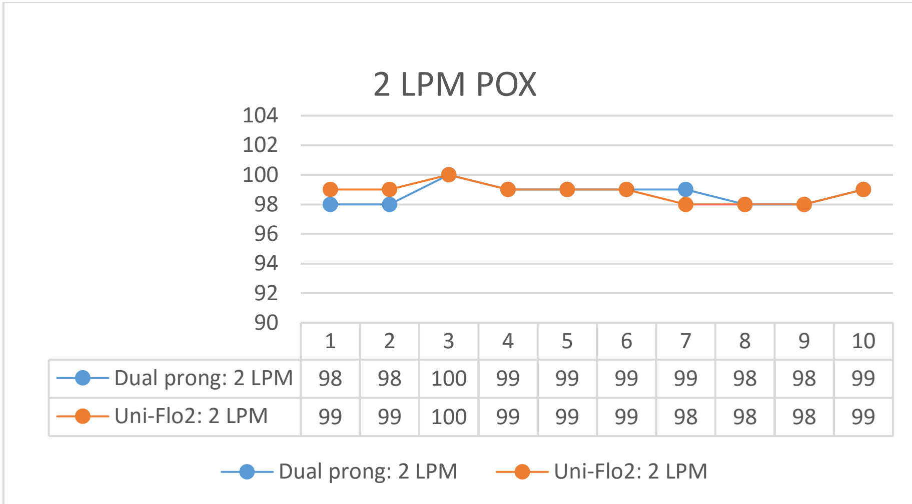
Table 4 The following table provides a comparison of the Uni-Flo2-single prong cannula to the Westmed-dual prong cannula, after 2 minutes of continuous oxygen flow, at 1 LPM for the ten subjects.



	1	2	3	4	5	6	7	8	9	10
Dual prong: 1 LPM	98	98	99	98	98	99	98	98	97	99
Uni-Flo2: 1 LPM	98	98	99	99	98	99	98	98	97	99

Note: There is a significant positive relationship between the Dual Prong and Single prong cannulas at the 1 LMP flow rates. The p-value is <0.05

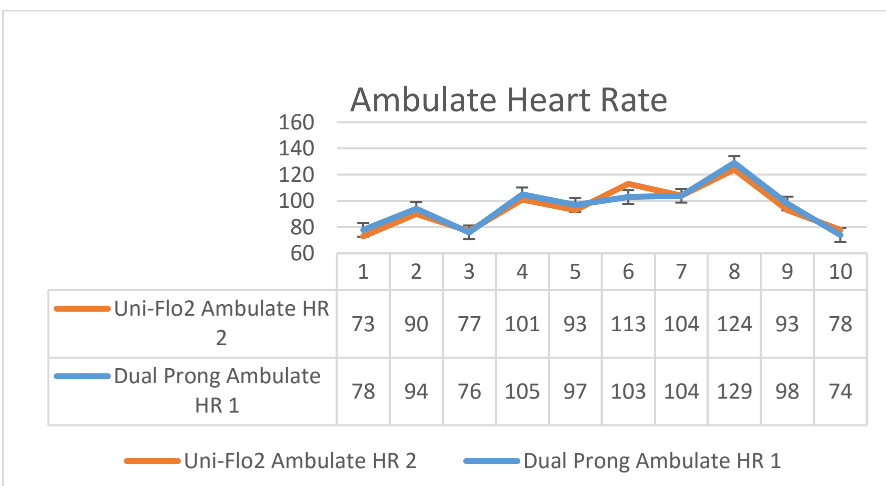
Table 5 The following table provides a comparison of the Uni-Flo2-single prong cannula to the Westmed-dual prong cannula, after 2 minutes of continuous oxygen flow, at 2 LPM for the ten subjects.



	1	2	3	4	5	6	7	8	9	10
Dual prong: 2 LPM	98	98	100	99	99	99	99	98	98	99
Uni-Flo2: 2 LPM	99	99	100	99	99	99	98	98	98	99

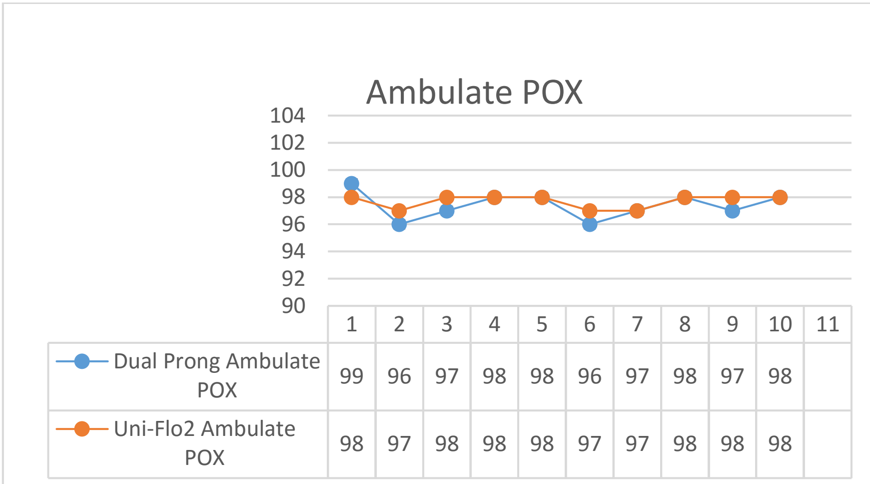
Note: There is a significant positive relationship between the Dual Prong and Single prong cannulas at the 2 LMP flow rates. The p-value is <0.05

Table 6 The following table provides a comparison of Uni-Flo2-single prong cannula to the Westmed dual prong cannula ambulated heart rates (beats per minute) B/M with standard error calculated (error bars), following a 2 minute treadmill walk, at 2 mile per hour, at all data points for the ten subjects.



	1	2	3	4	5	6	7	8	9	10
Uni-Flo2 Ambulate HR 2	73	90	77	101	93	113	104	124	93	78
Dual Prong Ambulate HR 1	78	94	76	105	97	103	104	129	98	74

Table 7 The following table provides a comparison of Uni-Flo2-single prong cannula to the Westmed dual prong cannula ambulated POX readings with standard error calculated, following a 2 minute treadmill walk, at 2 mile per hour, at all data points for the ten subjects.



Note: There is a small statistical difference in the POX relationship between the Single nasal cannula and the Dual prong cannula in the ambulated POX reading, which may suggest an improved condition in the POX results when using the Uni-Flo2 single nasal cannula. The p value is > 0.01

Conclusions:

Data was collected from 10 healthy volunteers during the use of a continuous low flow system, at different gas flow rates, in rested and ambulated conditions. The present study has confirmed the finding of Waldau, Larsen & Bonde (using a different methodology) that there is little or no statically difference between a single prong type cannula and a dual prong cannula in the effective delivery of low flow oxygen. The study showed the single prong cannula has equivalent POX performance as the dual prong cannula in low flow oxygen therapy. In addition the study showed the single prong cannula has a slightly improved POX performance in ambulated conditions over the dual prong cannula in low flow oxygen therapy.

Appendix A: Regression Analysis using Excel Data Analysis Tool Pack

1) Regression analysis and comparison of single prong vs dual prong at 1 LPM:

Regression Statistics								
Multiple R	0.884985							
R Square	0.783198							
Adjusted R Square	0.756098							
Standard Error	0.312348							
Observations	10							
ANOVA								
	df	*SS*	*MS*	*F*	*Significance F*			
Regression	1	2.8195122	2.8195122	28.9	0.000664913			
Residual	8	0.7804878	0.09756098					
Total	9	3.6						
	Coefficients	*Standard Erro*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	16.68293	15.163829	1.10017906	0.303254286	-18.2849249	51.65077856	-18.2849249	51.65077856
Uni-Flo2 1 LPM	0.829268	0.1542574	5.37587202	0.000664913	0.473549982	1.184986603	0.47354998	1.184986603
Note : There is a significant positive relationship between the Dual Prong and Single prong cannulas at the 1 LMP flow rates.								
The p value < 0.05								

2) Regression analysis and comparison of single prong vs dual prong at 2 LPM:

Regression Statistics								
Multiple R	0.624695							
R Square	0.390244							
Adjusted R Square	0.314024							
Standard Error	0.559017							
Observations	10							
ANOVA								
	df	*SS*	*MS*	*F*	*Significance F*			
Regression	1	1.6	1.6	5.12	0.053492987			
Residual	8	2.5	0.3125					
Total	9	4.1						
	Coefficients	*Standard Erro*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	32.83333	29.109766	1.12791471	0.292044526	-34.29390727	99.96057393	-34.2939073	99.96057393
Uni-Flo2 2 LPM	0.666667	0.2946278	2.2627417	0.053492987	-0.012746317	1.346079651	-0.01274632	1.346079651
Note : There is a significant positive relationship between the Dual Prong and Single prong cannulas at the 2 LMP flow rates.								
The p value < 0.05								

3) Regression analysis and comparison of single prong vs dual prong at 2 LPM in ambulant condition:

Regression Statistics	
Multiple R	0.761905
R Square	0.580499
Adjusted R Square	0.528061
Standard Error	0.663684
Observations	10

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	1	4.8761905	4.87619048	11.07027027	0.010427722
Residual	8	3.5238095	0.44047619		
Total	9	8.4			

	Coefficients	*tandard Erroi*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	-51.4762	44.745659	-1.1504175	0.283196231	-154.6598661	51.70748516	-154.659866	51.70748516
Uni-Flo2 Ambulate	1.52381	0.4579853	3.32720157	0.010427722	0.467693448	2.5799256	0.46769345	2.5799256

Note: There is a statistical difference between the Single nasal cannula and the Dual prong cannula in the ambulated POX reading, which may suggest a improved condition in the POX readings when using the single nasal cannula. The p-value is > 0.01