Southmedic

OxyMask vs Non-Rebreather Mask
A Pressure Comparison

Data provided by: Dr. Horia Hagan, Ph.D., P. Eng., Associate Professor and Director of The Boundary Layer Wind Tunnel Laboratory at the University of Western Ontario.

Summary Report written by: Julius Hajgato, Research and Development Project Manager, Southmedic Inc.

Summary:

A surface pressure test was conducted between the OxyMask, a generic Non-rebreather O2 mask and a Partial Non-rebreather O2 mask.

Surface pressure was measured inside all three devices, on flow rates of 15, 30 & 60 LPM. It was determined that positive pressure could be significantly increased within a closed mask system, like the Non-Rebreather, when flow rates exceed manufacturer's specifications.

The positive pressure realized during this test along with the clinical findings noted in "[1] *Tobin A, Groves N, High Flow nasal oxygen generates positive airway pressure in adult volunteers.* **Australian Critical Care (2007) 20, 126-131" gives technical evidence and clinical credence to the fact that Intrinsic PEEP can indeed be administered during high flow oxygen therapy.**

This simple test does provide enough evidence to state with certainty that OxyMask and it's open mask design, provides zero to low probability of inadvertently delivering positive pressure, on high flow O2 therapy. Past studies have also proven that OxyMask can deliver higher FiO2 than the traditional Non-Rebreather. It can therefore be stated with reasonable certainty that OxyMask can deliver the full range of O2 therapy and can do so safely without the risk of Intrinsic PEEP.

It is not the intent of this test and document to state unequivocally that Intrinsic PEEP can be delivered to all patients whose flow rates exceed 15 LPM. Nor is it to state that all patients, receiving such therapies are at risk of being exposed to excessive pressures. It is however, intended to communicate evidence of excessive surface pressures when using standard oxygen masks at flow rates exceeding manufacturer's specifications. It is for the clinical professional to draw his or her own clinical summations if the surface pressures measured can raise the probability of delivering inadvertent or Intrinsic PEEP.

Further clinical studies on live subjects, using sophisticated and possibly invasive positive pressure measuring devices, is required to prove with absolute certainty that Intrinsic PEEP is probable when using closed mask systems during high flow oxygen therapy.

Introduction:

Dr. Horia Hagan, Ph.D., P. Eng., Associate Professor and Director of The Boundary Layer Wind Tunnel Laboratory at the University of Western Ontario, conducted a flow vs. surface pressure test, using the following devices: a Non-Rebreather mask, Partial Non-Rebreather, OxyMask, Oxygen cylinder, a high flow 50 PSI regulator and flow meter.

The BLWTL (Boundary Layer Wind Tunnel Laboratory) identified the areas of suspected pressure found within the boundaries of each masks. The masks were independently mounted to mimic the centered position on a

facial structure. .

Methodology:

A grid system was developed for the surface area of the OxyMask, NRM & PRM. Highly sensitive pressure sensors (Taps) were positioned inside each mask (see figure 2) as well as on the surface of an anatomically shaped curved surface (see figure 1). The pressure sensors (Taps) enabled measurement of surface pressures at the face. Twenty (20) numbered pressure sensors (Taps) were used at a sampling frequency of 400Hz.

Each mask was positioned to mimic the placement and seal on a face. The pressure sensors (Taps) were plugged into two (2) pressure 'Scanivalve' transducers (16 Taps each). Although only the mean pressures have been recorded, the BLWTL pressure system provides minimum, maximum and RMS pressures from a recorded time series. The results from the recorded pressures were placed in a table format (see figure 3) and subsequently graphed.

Figure 1-Mask Mounted on Cylindrical Surface

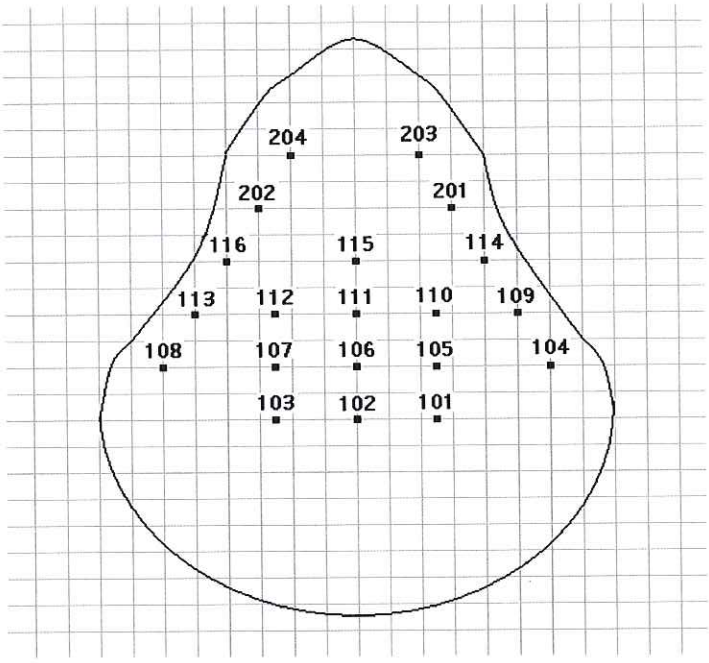


Figure 2. Pressure Tap Locations and Identifiers

Results (Figure 3):

Nasal Flow (L/min)	Expiratory Pharyngeal Pressure 0	10	20	40	60
Mouth Open (cmH_2O)					
Group	0.3 (0.3 - 0.5)	0.7 (0.6 - 0.9)	1.4 (1.3 - 1.8) [a]	2.2 (2.0 - 2.5) [a,b]	2.7 (2.4 - 3.1) [a]
Male	0.4 (0.2 - 0.6)	0.7 (0.6 - 0.9)	1.4 (1.0 - 1.8) [a]	2.0 (1.9 - 2.3) [a]	2.6 (2.3 - 2.7) [a]
Female	0.3 (0.3 - 0.4)	0.7 (0.6 - 1.0)	1.4 (1.3 - 1.8) [a]	2.3 (2.1 - 2.7) [a]	3.1 (2.6 - 3.9) [a]
Mouth Closed (cmH_2O)					
Group	0.8 (0.5 - 1.3)	1.7 (1.2 - 2.3)	2.9 (2.2 - 3.7) [a,b]	5.5 (4.1 - 7.2) [a,b]	7.4 (5.4 - 8.8) [a]
Male	0.7 (0.2 - 1.0)	1.2 (1.0 - 1.6)	2.2 (2.0 - 2.9) [a]	4.1 (3.2 - 5.2) [a]	5.4 (5.0 - 6.0) [a]
Female	1.2 (0.5 - 1.7)	2.3 (1.9 - 2.6)	3.7 (2.9 - 4.0) [a]	7.2 (5.9 - 7.7) [a]	8.7 (7.7 - 9.7) [a]

^a Significant adjusted p-value for comparison with zero flow.

^b Significant adjusted p-value for comparison with previous flow rate.

OxyMask Tap	Flow Rate (LPM) 15		30		60	
	PA	cmH20	PA	cmH20	PA	cmH20
101	1	0.01	1	0.01	9	0.09
102	-4	-0.04	-2	-0.02	7	0.07
103	-2	-0.02	-3	-0.03	1	0.01
104	0	0.00	3	0.03	23	0.24
105	0	0.00	2	0.02	-6	-0.06
106	-2	-0.02	0	0.00	-8	-0.08
107	-2	-0.02	-5	-0.05	-25	-0.26
108	3	0.03	5	0.05	-8	-0.08
109	-20	-0.20	-3	-0.03	12	0.12
110	1	0.01	4	0.04	-5	-0.05
111	1	0.01	4	0.04	16	0.16

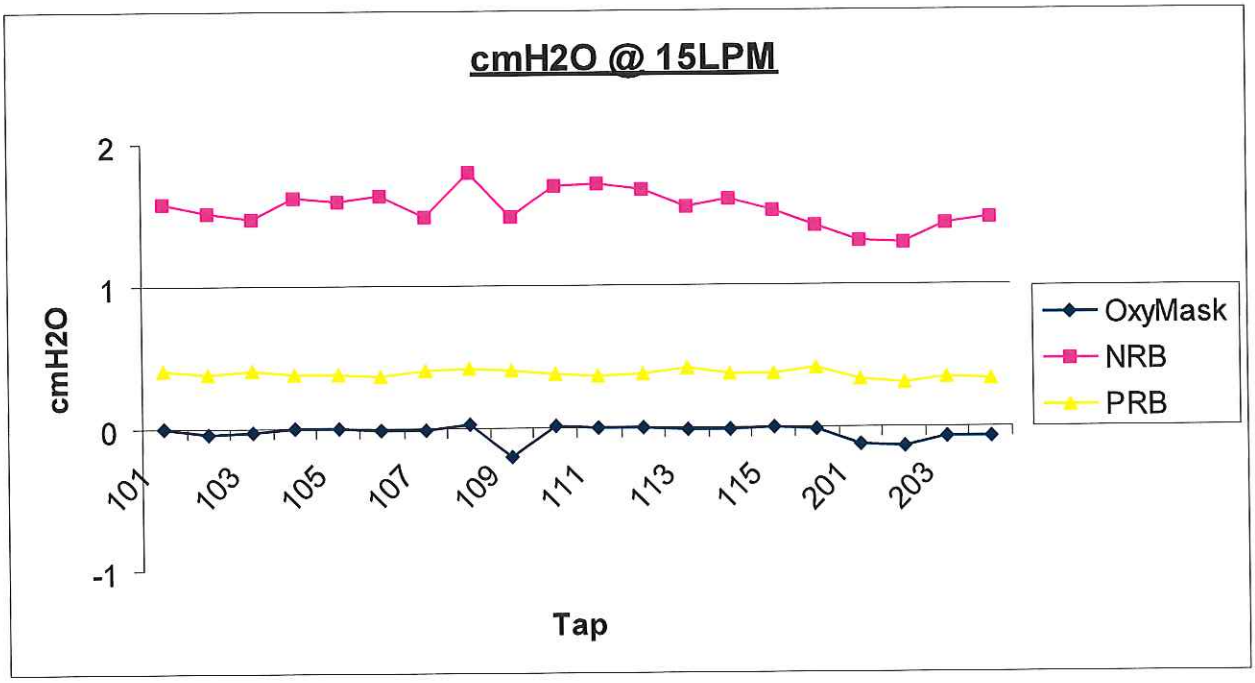
Southmedic

112	0	0.00	5	0.05	58	0.59
113	-1	-0.01	0	0.00	9	0.09
114	-2	-0.02	1	0.01	24	0.24
115	-1	-0.01	11	0.11	227	2.31
116	-1	-0.01	9	0.09	64	0.66
201	-12	-0.12	-9	-0.09	108	1.10
202	-14	-0.14	-15	-0.15	27	0.27
203	-7	-0.07	-4	-0.04	57	0.58
204	-7	-0.07	-7	-0.07	27	0.27

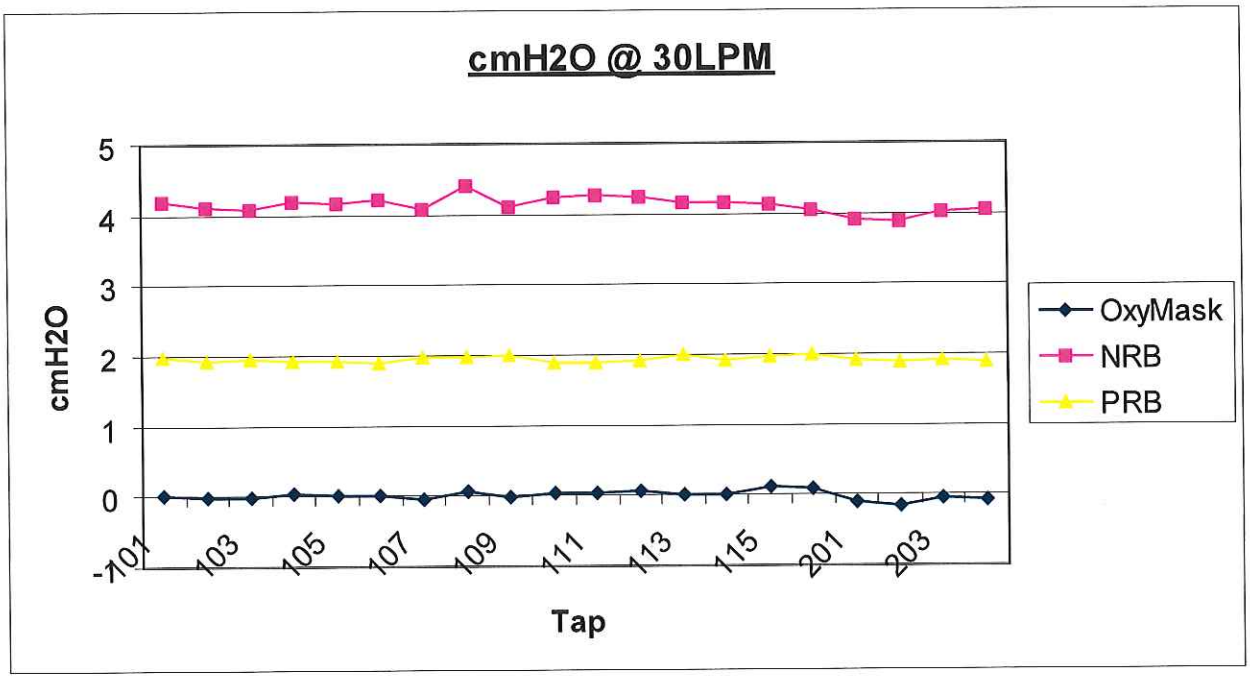
NRM Mask	Flow Rate (LPM)					
Tap	15		30		60	
	PA	cmH20	PA	cmH20	PA	cmH20
101	155	1.58	410	4.18	2128	21.70
102	149	1.52	401	4.09	2120	21.61
103	144	1.47	398	4.06	2119	21.60
104	159	1.62	410	4.18	2131	21.73
105	157	1.60	407	4.15	2127	21.69
106	161	1.64	412	4.20	2132	21.74
107	146	1.49	400	4.08	2121	21.62
108	176	1.79	431	4.39	2154	21.97
109	146	1.49	401	4.09	2135	21.78
110	167	1.70	417	4.25	2136	21.79
111	168	1.72	419	4.28	2137	21.79
112	164	1.67	417	4.25	2132	21.74
113	152	1.55	407	4.15	2129	21.71
114	158	1.61	407	4.15	2144	21.86
115	149	1.52	405	4.13	2136	21.78
116	139	1.42	397	4.04	2124	21.66
201	129	1.32	384	3.92	2130	21.72
202	127	1.30	381	3.89	2121	21.62
203	141	1.43	395	4.03	2119	21.60
204	145	1.48	396	4.04	2122	21.64

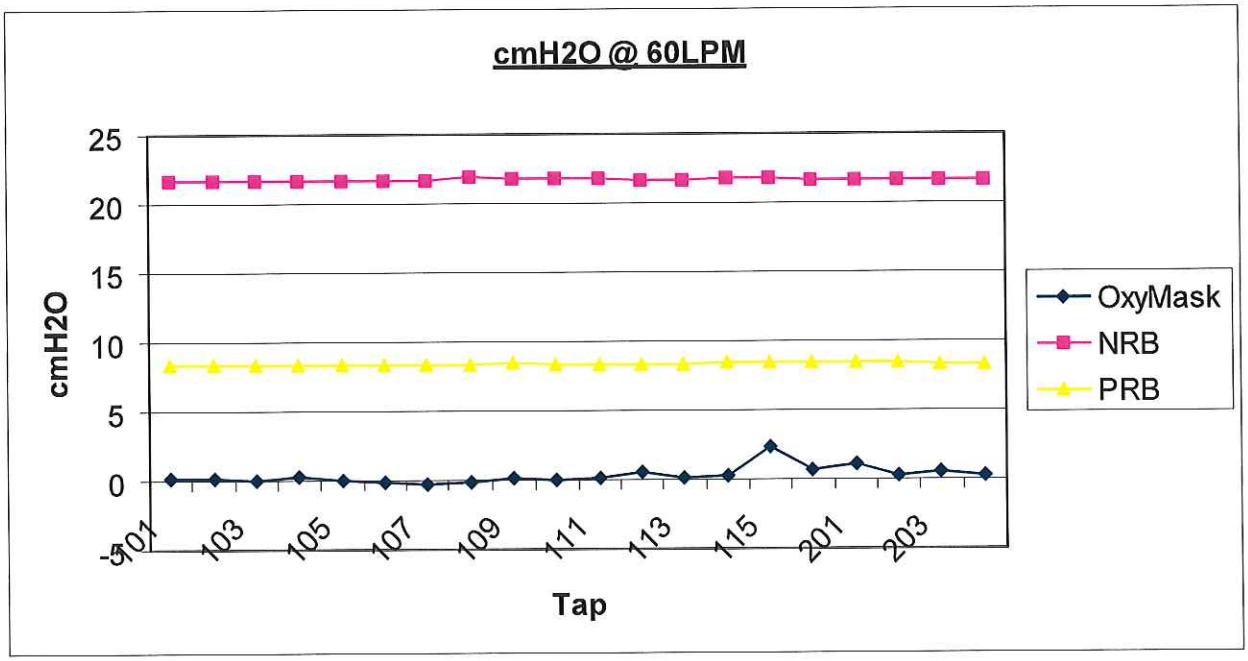
PRM Mask	Flow Rate (LPM)					
Tap	15		30		60	
	PA	cmH20	PA	cmH20	PA	cmH20
101	40	0.41	193	1.96	822	8.38
102	38	0.38	189	1.93	819	8.35
103	39	0.40	192	1.95	823	8.39
104	38	0.38	189	1.92	819	8.35
105	38	0.38	188	1.91	816	8.32
106	35	0.36	186	1.89	813	8.29
107	40	0.41	193	1.97	821	8.37
108	41	0.42	193	1.97	822	8.38
109	40	0.41	195	1.99	831	8.47

110	37	0.38	185	1.89	813	8.29
111	35	0.36	186	1.89	813	8.29
112	38	0.38	188	1.92	813	8.29
113	42	0.42	196	1.99	824	8.40
114	37	0.37	189	1.92	829	8.45
115	38	0.38	193	1.96	835	8.51
116	42	0.42	197	2.01	836	8.53
201	34	0.34	188	1.92	826	8.42
202	30	0.31	185	1.88	829	8.45
203	34	0.35	188	1.92	816	8.32
204	33	0.34	185	1.89	819	8.35



Graphical Comparison:





Typical airway pressure is 2.72 cmH_20. It becomes obvious in light of the testing (refer to the aforementioned tables) that the High flow nasal cannula exceeds this pressure at 20 LPM, the Non-rebreather mask (NRM) at 30 Lpm and the Partial non-rebreather (PRM) at 60 LPM.
The OxyMask reveals minimal or no pressure at any flow rate.

The highest average surface pressures recorded at 60 LPM for the devices is as follows:

Device	Pressure @60 LPM(cmH_20)
OxyMask	.31
NRM	21.72
PRM	8.38
HFN	7.4*

*Note: Averaged, Male Female, Mouth Closed.

Discussion:

The potential adverse effects of inadvertently delivering uncontrolled PEEP, especially to a patient that is already clinically compromised has the potential of increasing the intrathorasic pressure; increasing the patient's work of breathing (WOB), thus the "fatigue factor" is introduced; the probability of risk is obviously higher for Pneumothorax, Hemodynamic Changes; Aerophagia and thus Aspiration.

Studies have now provided enough evidence to state for a fact that the high flow nasal cannulas (HFN), can potentially deliver continuous positive airway pressure (CPAP)[1]. The results of this study is tabulated below:

(Endnotes)

[1] Tobin A, Groves N, High Flow nasal oxygen generates positive airway pressure in adult volunteers. *Australian Critical Care* (2007) 20, 126-131