



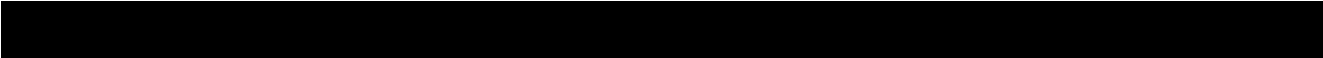
C02 CONCENTRATION ANALYSIS SELECTED MASKS VRS.OXYMASK

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Confidential

Summary



Various masks were tested for any pooling effect that may occur in an Oxygen mask by ETCO₂ gases, and measured for CO₂ gas concentrations using a O₂ Concentrator and High Pressure Cylinder. Also tested was confirmation that the OxyMask O₂ concentration was consistent with the published O₂-concentration table when using an Oxygen Concentrator at low flow rates (5 LPM)

The masks included:

- Capnoxygen Mask
- Medium Flow Adult Mask
- Re-breathe Mask
- OxyMask

The results reveal that the OxyMask performs as expected meeting the published O₂ concentration levels when using a O₂ concentrator.

The results also reveal that the OxyMask has approximately .5 to 1% less (depending on the flow rate) CO₂% retention than the tested masks when using High Pressure Cylinder, and about the same or .5% less (depending on the flow rate) when using a oxygen concentrator

Introduction

The OxyMask was designed initially due to published reports that CO₂ retention is high in a standard Oxygen Mask, and to resolve this problem flow rates had to set at higher levels to purge the excess CO₂.

This was initially addressed in a report entitled “ CO₂ Concentration Analysis on Oxygen Masks” written October 22, 2004. The mask was designed so that the evacuation of CO₂ trapped gas can escape at relatively low flow rates.

Since then, the mask has now been marketed to home care use, and used with a O₂ Concentrator.

The flow rates in a concentrator are limited to 1 to 5 LPM (some specialized concentrators higher), as opposed to a High Pressure Cylinder (similar to compressed system in acute care), which in Canada are 1-15 LPM and the United States to be as high as 40 LPM.

Design

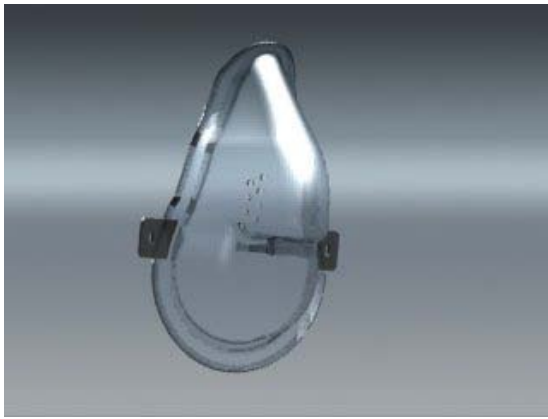


Figure 1

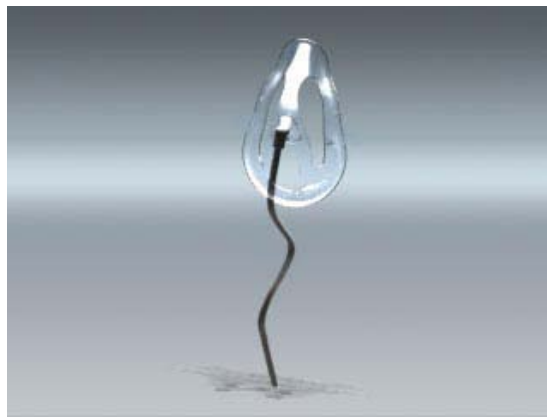


Figure 2

As can be seen in the pictures above a standard mask (Fig.1) does not have as many openings for evacuation of CO₂ Gases as the OxyMask has.

Methods

A sampling tube was attached to the participant's face with tape, located at the center of the lower lip, so that the sampling line was in line with the top of the lip.

A base reading was taken at atmosphere, to be 5.2% ETCO₂. The mask was placed on face as per directions, and a base reading was taken inside the mask prior to the Oxygen turned on.

The respiration was taken and maintained, and Five (5) readings were taken at oxygen flow rates of 1.5 to 15 LPM (for the CO₂ tests) and 1.5 to 5 LPM for the O₂ tests on the Oxygen Concentrator. An average of these readings were tabulated These were noted at one (1) minute apart with a 1 minute stabilization period.

The concentrator used in this test was NewLife Elite built by Airsep,

The ETCO₂/O₂ concentration levels were monitored and recorded using Datex-Ohmeda AS/5 recorder.

Results and Discussion

The effectiveness of the mask design has an impact on the entrapped CO₂ Gases

The less material in front of the face decreases the level of CO₂ gases. Higher air flow does not necessarily decrease the ETCO₂ concentrations in the mask, as this can be seen the Respan adult mask, even at 12 LPM, the concentration level averages over 4%. Yet the Percento Adult mask is extremely efficient, forcing the EtCO₂ levels lower at 4 LPM.

It can be seen that the base CO₂ levels inside the masks can be quite high from the onset, and that 3 masks have almost the identical amount of CO₂ % retention, on both the High Pressure Cylinder and the Oxygen Concentrator, yet the OxyMask performs effectively at reducing the CO₂ % when using a High Pressure Cylinder, and comparable, but more effective as the flow rates increase when using the oxygen concentrator.

The re-breathe masks could not be tested on the Oxygen Concentrator due to limitations in the flow, and for what it was designed.

The following graphs demonstrate the results of the tests. For the sake of completeness the tabulated numbers have been added in Appendix1.

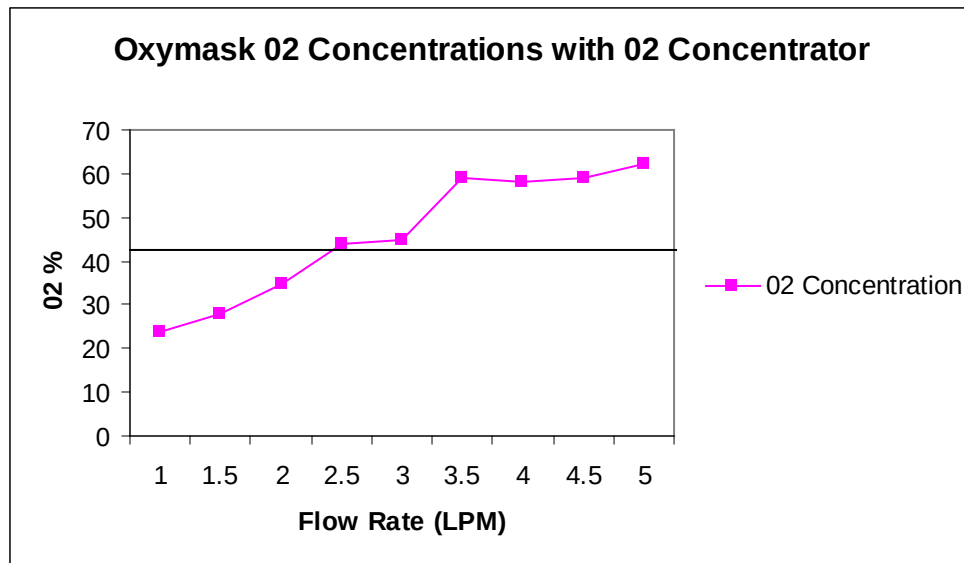


Figure 3

As can be seen by Figure 3, the OxyMask O2 concentration maintains the same levels as the published Concentration levels, when using an Oxygen concentrator.
For Reference:

Flow Rate (LPM)	O2 Concentration
1-3	24%-42%
3-5	42%- 58%
5-10	58%- 74%
>10	74%- 90%

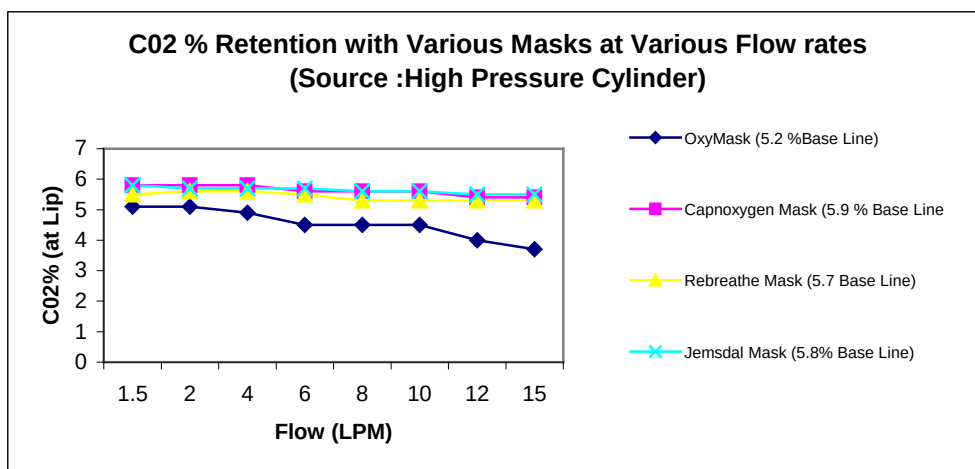


Figure 4

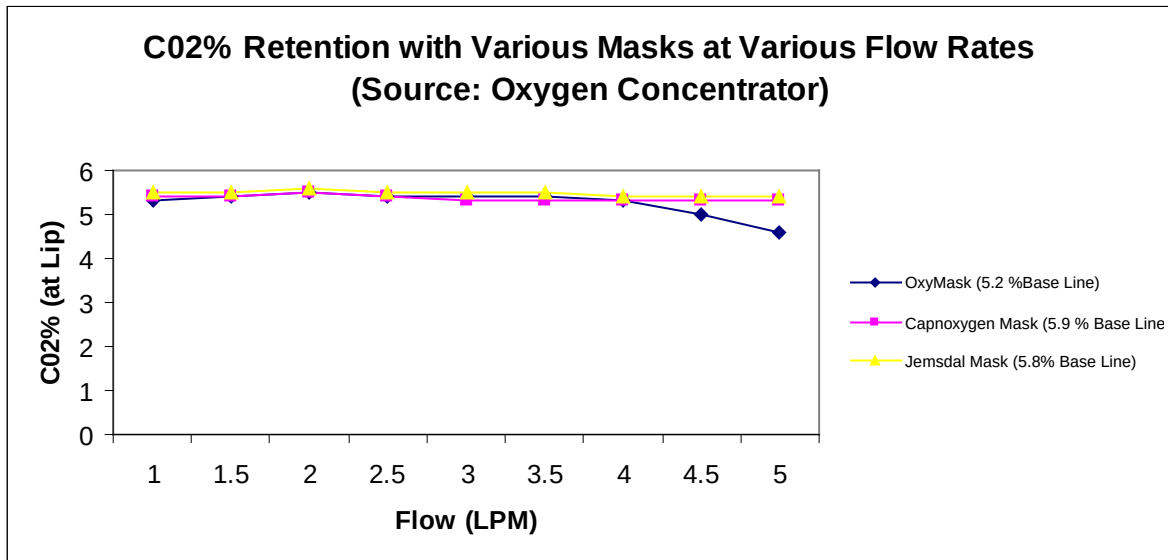


Figure 5

When the OxyMask is analyzed for ETC02 retention (Fig.4), it immediately becomes apparent that at baseline levels (mask, no oxygen flow) that the C02 levels inside the OxyMask is .5% lower than all the other masks. It can also be seen that in a concentrator, the OxyMask is similar at retention as the comparison masks, however as the flow increases, the C02 is cleared out more readily dropping by 1%. (Fig.5)

Conclusion

The results reveal that the OxyMask performs as expected meeting the published O2 concentration levels when using a O2 concentrator.

It also shows that by wearing the OxyMask, the ETC02 % (when measured at the lip) does not increase when the mask is placed over the face (baseline 5.2%) as opposed to increased levels of ETC02 when other masks are used. This demonstrates that build-up of C02 does not occur.

The results also reveal that the OxyMask has approximately .5 to 1% less (depending on the flow rate) C02% retention then the tested masks when using High Pressure Cylinder, and about the same or .5% less (depending on the flow rate) when using a concentrator. This can be attributed to the pressure differences (greater pressure from the cylinder as opposed to the minimal pressure from the concentrator).

The open concept mask continues to prove to be beneficial and safe both in providing high levels of O2% at the prescribed flow rate and lower levels of ETC02 retention in the mask.

APPENDIX 1

TABLE 1: O2 CONCENTRATION OF OXYMASK ON CONCENTRATOR

FLOW (LPM)	O2 CONCENTRATION (%)*
1	24
1.5	28
2.0	35
2.5	44
3.0	45
3.5	59
4.0	58
4.5	59
5.0	62

*Average of 5 readings

TABLE 2: CO2 MEASUREMENT COMPARISON OXYMASK VERSUS STANDARD OXYGEN MASK USING HIGH PRESSURE CYLINDER.

FLOW RATE (LPM)	OXYMASK (BASELINE 5.2%) ETC02%	CAPNOXYGEN MASK (BASELINE 5.9%) ETC02%	REBREATHE MASK (BASELINE 5.7%) ETC02%	JEMSDALE MASK (BASELINE 5.8%) ETC02%
1.5	5.1	5.8	5.5	5.9
2	5.1	5.8	5.6	5.7
4	4.9	5.8	5.6	5.7
6	4.5	5.6	5.5	5.7
8	4.5	5.6	5.3	5.7
10	4.5	5.6	5.3	5.6

12	4	5.4	5.3	5.6
15	3.7	5.4	5.3	5.5

*Average of 5 readings

TABLE 3: CO2 MEASUREMENT COMPARISON OXYMASK VERSUS STANDARD OXYGEN MASK USING CONCENTRATOR

FLOW RATE (LPM)	OXYMASK (BASELINE 5.2%) ETC02%	CAPNOXYGEN MASK (BASELINE 5.9%) ETC02%	JEMSDALE MASK (BASELINE 5.8%) ETC02%
1	5.3	5.4	5.5
1.5	5.4	5.4	5.5
2.0	5.5	5.5	5.6
2.5	5.4	5.4	5.5
3.0	5.4	5.3	5.5
3.5	5.4	5.3	5.5
4.0	5.3	5.3	5.4
4.5	5.0	5.3	5.4
5.0	4.6	5.3	5.4

*Average of 5 readings

CONCENTRATOR: NEW LIFE MADE BY AIRSEP

BASELINE: READING IN MASK WITH NO O2 FLOW

READING AT LIP: 5.3%