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New advanced mass casualty breathing system for oxygen therapy:

Phase I

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Defence R&D Canada
Technical Memorandum
DRDC Toronto TM 2006-201
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Phase 1

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In conducting the research described in this report, the investigators adhered to the policies and procedures set out in the Tri-Council Policy Statement: Ethical conduct for research involving humans, National Council on Ethics in Human Research, Ottawa, 1998 as issued jointly by the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada and the Social Sciences and Humanities Research Council of Canada.

Abstract

This report describes the first phase of a project to develop an efficient mass casualty oxygen (O_2) breathing system for O_2 therapy in remote areas. In this first phase, DRDC Toronto was tasked to investigate the performance of the Pulmanex® Hi-Ox® mask (Hi-Ox) at O_2 flow rates from 4 litres per minute ($L \cdot min^{-1}$) down to 0.5 $L \cdot min^{-1}$. Performance was evaluated with eighteen male and female volunteers between the ages of 21 and 56 years. Subjects were at rest in a seated position. The data showed that it is possible to use the Hi-Ox for O_2 treatment with low flow rates. The peak concentration of inhaled oxygen was 31.7±5.6% at 0.5 $L \cdot min^{-1}$ and 80.3±7.8% at 4 $L \cdot min^{-1}$. To achieve a given level of O_2 concentration, the Hi-Ox required significantly less O_2 than the commonly used simple facemask. This will allow the use of portable O_2 concentrators to supply oxygen to the Hi-Ox, increasing the efficiency and minimizing risks.

Résumé

Le présent rapport décrit la première phase d'un projet de développement d'un système efficace d'oxygénothérapie pouvant servir auprès d'un grand nombre de blessés dans les régions éloignées. Au cours de cette première phase, RDDC Toronto a été chargé d'examiner la performance du masque Pulmanex^{MD} Hi-Ox^{MD} (Hi-Ox) à des débits d'oxygène (O_2) de 4 litres par minute ($L \cdot min^{-1}$) en diminuant jusqu'à 0,5 $L \cdot min^{-1}$. La performance a été évaluée chez dix-huit volontaires de sexe masculin et féminin âgés de 21 à 56 ans. Les sujets étaient au repos en position assise. Les données ont montré qu'il est possible d'utiliser le Hi-Ox pour l'oxygénothérapie à de faibles débits. La concentration maximale de l'oxygène inspiré était de 31,7±5,6 % à un débit de 0,5 $L \cdot min^{-1}$ et de 80,3±7,8 % à un débit de 4 $L \cdot min^{-1}$. Pour obtenir une concentration donnée d'O_2, le Hi-Ox requérait beaucoup moins d'O_2 que le masque facial simple couramment utilisé. On pourra ainsi utiliser des concentrateurs d'O_2 portatifs pour alimenter le Hi-Ox en oxygène, ce qui augmentera l'efficacité et réduira au minimum les risques.

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Executive summary

New Advanced Mass Casualty Breathing System for Oxygen Therapy: Phase 1

Bouak, F., Eaton, D. J.; DRDC Toronto TM 2006-201;
Defence R&D Canada – Toronto; October 2006.

Introduction

This report describes the first phase of a project to develop an efficient mass casualty oxygen (O_2) breathing system for O_2 therapy in remote areas. In this first phase, DRDC Toronto was tasked to investigate the inhaled O_2 concentration provided by the Pulmanex® Hi-Ox® mask (Hi-Ox) at O_2 flow rates lower than 4 litres per minute ($L \cdot min^{-1}$). The Hi-Ox mask is an open circuit continuous flow mask designed to improve gas usage efficiency, that is, low oxygen flow rates combined with high oxygen concentration. The Hi-Ox significantly exceeded the commonly used simple facemask in terms of performance and efficiency for O_2 flow rates higher than 4 litres per minute ($L \cdot min^{-1}$) and it was expected to outperform currently used O_2 masks at even low flow rates.

Methods

Eighteen volunteers (13 male and 5 female) between the ages of 21 and 56 years evaluated the Hi-Ox. The test procedure consisted of five breathing periods of 5 minutes each separated by 10-minute air-breaks. The oxygen flow rate was either 0.5, 1, 2, 3 or 4 $L \cdot min^{-1}$ during each breathing period. Subjects were at rest breathing calmly at their own resting respiratory rate in a seated position. Measurements included inhaled and end-tidal O_2 and carbon dioxide (CO_2) fractions, arterial blood oxygen saturation, mask pressures, exhaled gas and inhaled air volumes and inhaled gas temperature. Subjects rated their perceived breathing effort and mask discomfort.

Results

Data showed oxygen delivery in therapeutic ranges at low flow rates. The mean peak concentration of inhaled oxygen was 31.7±5.6% at 0.5 $L \cdot min^{-1}$ and 80.3±7.8% at 4 $L \cdot min^{-1}$. To achieve a given level of O_2 concentration, the Hi-Ox required significantly less O_2 than the commonly used O_2 masks such as the simple facemask. For example, to achieve a peak inhaled O_2 concentration of 60%, the Hi-Ox required just 2 $L \cdot min^{-1}$ while the simple facemask required an O_2 flow rate of at least 8 $L \cdot min^{-1}$. In addition, the Hi-Ox showed low levels of inhaled CO_2 and breathing resistance with low O_2 flows.

Significance

It is possible to use the Hi-Ox at flow rates in the range of 0.5 to 4 $L \cdot min^{-1}$. This will allow the use of portable O_2 concentrators to supply O_2 to the Hi-Ox, increasing the efficiency and minimizing risks. Given the effectiveness of the Hi-Ox at low oxygen flows, this mask should be further investigated in the field.

Sommaire

Nouveau système d'oxygénothérapie avancé pouvant servir auprès d'un grand nombre de blessés : Phase 1

Bouak, F., Eaton, D. J.; DRDC Toronto TM 2006-201;
R & D pour la défense Canada – Toronto; Octobre 2006.

Introduction

Le présent rapport décrit la première phase d'un projet de mise au point d'un appareil efficace d'oxygénothérapie pouvant servir auprès d'un grand nombre de blessés dans les régions éloignées. Au cours de cette première phase, RDDC Toronto a été chargé d'examiner la performance du masque Pulmanex^{MD} Hi-Ox^{MD} (Hi-Ox) à des débits d'oxygène (O_2) de 4 litres par minute ($L \cdot min^{-1}$). Le masque Hi-Ox est un appareil respiratoire à débit constant et à circuit ouvert conçu pour utiliser les gaz plus efficacement en combinant de faibles débits d'O_2 et une forte concentration d'oxygène. À des débits d'O_2 supérieurs à 4 litres par minute ($L \cdot min^{-1}$), la performance et l'efficacité du Hi-Ox surpassaient grandement celles du masque facial simple couramment utilisé, et on s'attendait à ce qu'il soit plus performant que les masques à O_2 couramment utilisés même à de faibles débits.

Méthodologie

Dix-huit volontaires (13 hommes et 5 femmes) âgés entre 21 et 56 ans ont évalué le Hi-Ox. La procédure d'essai consistait en cinq périodes de respiration de 5 minutes, chacune séparée par des pauses de 10 minutes. Le débit d'oxygène était soit de 0,5, 1, 2, 3 ou 4 $L \cdot min^{-1}$ durant chaque période de respiration. Les sujets étaient au repos en position assise et respiraient calmement à leur propre rythme respiratoire au repos. Les paramètres suivants ont été mesurés : fractions d'O_2 et de gaz carbonique (CO_2) dans l'air inspiré et en fin d'expiration, le taux de saturation du sang artériel en oxygène, la pression dans le masque, le volume de gaz expiré et le volume d'air inspiré ainsi que la température du gaz inspiré. Les sujets ont évalué, d'après leur perception, l'effort de respiration ainsi que l'inconfort lié au masque.

Résultats

Les données ont montré que l'appareil permettait d'administrer de l'oxygène à des niveaux thérapeutiques même à de faibles débits. Les concentrations maximales moyennes de l'oxygène inspiré étaient de 31,7±5,6 % à 0,5 $L \cdot min^{-1}$ et de 80,3±7,8 % à 4 L/min. Pour obtenir une concentration donnée d'O_2, le Hi-Ox requérait beaucoup moins d'O_2 que les masques à O_2 couramment utilisés tels que le masque facial simple. Par exemple, pour obtenir une concentration maximale d'O_2 inspiré de 60 %, le Hi-Ox n'avait besoin que d'un débit de 2 $L \cdot min^{-1}$ alors que le masque facial simple nécessitait un débit d'O_2 d'au moins 8 $L \cdot min^{-1}$. En outre, avec le Hi-Ox à de faibles débits d'O_2, on a observé de faibles niveaux de concentrations de CO_2 inspiré et de résistance respiratoire.

Importance

Il est possible d'utiliser le Hi-Ox à des débits faibles allant de 0,5 à 4 $L \cdot min^{-1}$. On pourra ainsi utiliser des concentrateurs d'O_2 portatifs pour alimenter le Hi-Ox en O_2, ce qui accroîtra l'efficacité et réduira au minimum les risques. Compte tenu de l'efficacité du masque Hi-Ox à de faibles débits d'oxygène, ce masque devrait être évalué plus à fond sur le terrain.

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Acknowledgements

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1. Introduction

The Pulmanex® Hi-Ox® Mask (Hi-Ox) (Figure 1), formerly the Hi-Ox^{80}, is a commercial product manufactured by VIASYS MedSystems. It is an open circuit continuous flow mask designed to improve gas usage efficiency, that is, low supply oxygen flow rates (Q_{O2}) combined with high oxygen (O_2) concentration. The Hi-Ox is also designed to prevent excess carbon dioxide (CO_2) elimination so that respiratory centre excitation produced by CO_2 chemoreceptors remains stable.

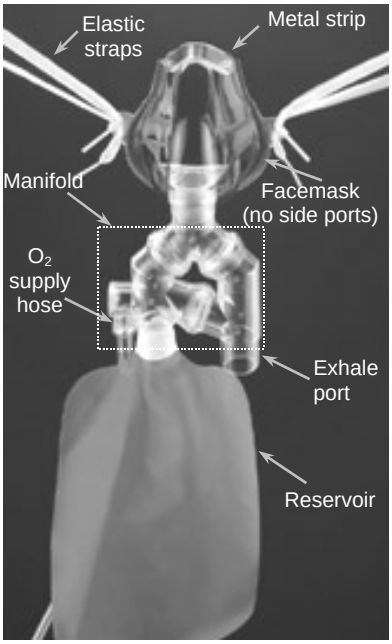

Figure 1: The Pulmanex® Hi-Ox® mask.

Bouak and Eaton [1] reported that the Hi-Ox significantly exceeded the commonly used simple facemask in terms of performance and efficiency for O_2 flow rates between 4 and 9 litres per minute ($L \cdot min^{-1}$) [1]. Basically, the Hi-Ox delivered more O_2 at lower flow rates. For example, the peak inhaled O_2 fraction (f_IO_2) was above 91% for flow rates greater than 7 $L \cdot min^{-1}$ and was 80% at 4 $L \cdot min^{-1}$ while the highest f_IO_2 delivered by the simple facemask was 60% at 9 $L \cdot min^{-1}$.

Given that the O_2 concentrations provided by currently available open-circuit masks such as the simple facemask [2] and the Venturi mask [2] are adequate in many situations, that is, low to moderate O_2 concentrations, it might be possible to use the Hi-Ox for achieving these O_2 levels with lower Q_{O2}. Taking into account that weight, volume and risk restrictions dictate the amount of O_2 available to the patient in the field, the use of a low flow rate mask such as the Hi-Ox

[1] All flow rates are referenced to 0^oC and 101.3 kPa, dry gas i.e. standard temperature and pressure, dry (STPD) unless indicated.

should decrease O_2 requirement for treatment in remote areas. DRDC Toronto proposed that the Hi-Ox could form the basis of an oxygen therapy system that would be supplied by miniature oxygen concentrators now being developed. This combination would eliminate the risk of transporting and using compressed oxygen in the field. Since the current literature does not address the delivery of O_2 by the Hi-Ox at low flows, this study examines the flexibility of using the Hi-Ox at flow rates in the range of 0.5 to 4 $L \cdot min^{-1}$.

2. Methods and Materials

2.1 Subjects

A total of eighteen military and civilian subjects, thirteen male and five female, between the ages of 21 and 56, volunteered to participate in this study. They were recruited from DRDC Toronto staff. Prior to conducting the experiments, all subject candidates underwent a medical screening by a physician to determine respiratory symptoms and eligibility. The DRDC Human Research Ethics Committee (HREC) approved the experimental protocol [3]. All subjects gave their written consent after being informed of the details, discomforts and risks associated with the experimental protocol. Remuneration for participation complied with guidelines established by DRDC Toronto. No subject withdrew from the study. Table 1 summarizes their physical characteristics. Table A1 in Annex A lists individual subject characteristics.

Table 1. Subjects Characteristics.

	Mean ± SD	Range
Age *(yr)*	38.17±9.31	21 – 56
Weight *(kg)*	79.53±17.01	52 – 102.9
Height *(m)*	1.73±0.09	1.57 – 1.83

2.2 Experimental set-up and data acquisition

Aviator's breathing oxygen [4] was provided from a K-cylinder (244 ft^3 STPD) using a high purity oxygen regulator (Matheson Gas Products, Model 3104C). The supply oxygen flow rates were adjusted using a computer-controlled mass flow controller (Brooks 5850 series, 0-10 $L \cdot min^{-1}$). A chain-compensated gasometer (Warren E. Collins, 120 L) was used to calibrate the flow controller.

The oronasal mask was instrumented to measure O_2 and CO_2 fractions, temperature and pressure (Figure 2).

A gas sample line (Intramedic polyethylene tubing by Clay Adams, Model PE-60, 0.76 mm I.D. x 1.22 mm O.D. x 1 m long) and the mask thermistor (Yellow Spring Instrument, Model 44004) were inserted into the facemask about two centimetres from the subject's mouth and nose. Mask gas was constantly sampled at a flow rate of 30 millilitres per minute ($mL \cdot min^{-1}$). The sample line was connected to the mass spectrometer (Hiden HPR20) via a heated capillary line of about 1.9 m long. For the flow rate and the sample line length used in this experiment, the sample line delay was about 6 sec.

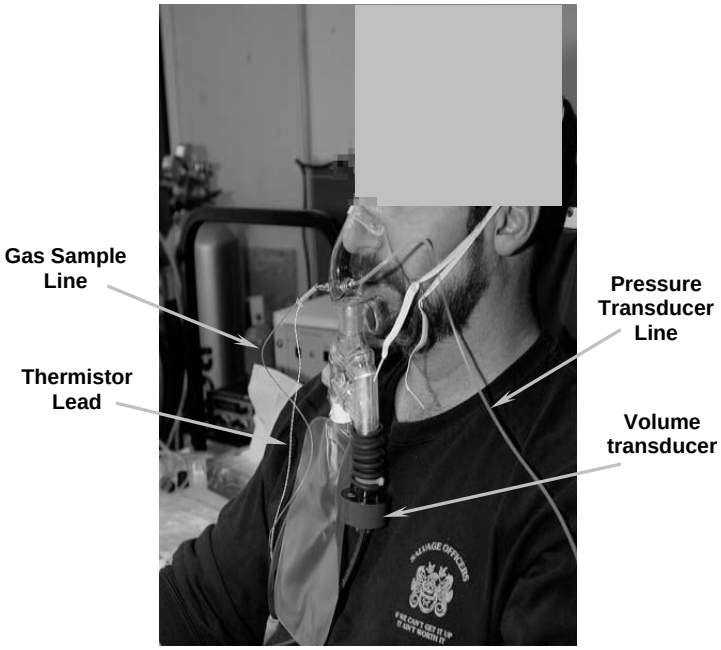

Figure 2: Instrumented mask detail.

Before each trial, the mass spectrometer was calibrated using two calibration gases (certification tolerance: ±0.02 mole %), one with 100% O_2 and the other being a mixture of 5% CO_2, 75% O_2 and 20% nitrogen (N_2).

A second sample line penetrated the left side of the mask (Figure 2) and was dead-ended to a pressure transducer (Validyne DP-15, ±0.5 psi diaphragm) for measuring instantaneous mask pressure.

Exhaled gas passed through a turbine volume transducer (Ventilation Measurement Modules by Interface Associates), incorporated in the exhale side of the Hi-Ox (Figure 2), to compute respiratory minute volume, $\dot{V}_E$, and inhaled atmospheric air through the exhale port of the mask.

Arterial blood oxygen saturation (SaO_2) was measured with a pulse oximeter (OXI by Radiometers Copenhagen) connected to the index or the middle finger of the subject's right hand. The measurements were taken before and during oxygen breathing for each O_2 flow rate.

Data from the instruments were continuously measured at a sampling frequency of 50 Hz. All lines from the instruments were connected to a data acquisition (DAQ) card (National Instruments, PCI-6052E) via a terminal block (National Instruments, TBX-68). The DAQ card was installed into a desktop computer running MS Windows 2000. All experimental data were stored on the hard drive of the computer for further computation and statistical analysis. The DAQ card and computer were controlled using custom-written software in LabVIEW™ (National Instruments).

Custom-written analysis software (written using LabVIEW™) was used to derive variables from the measured values. Instantaneous O_2 and CO_2 fractions (f_mO_2, f_mCO_2) were used to compute inhaled and end-tidal gas fractions for each breath. Inhaled CO_2 fraction (f_ICO_2) was taken at the time of the lowest f_mCO_2 in each breath while end tidal values of both O_2 and CO_2 ($f_{ET}CO_2$ and $f_{ET}O_2$) were taken at the time of the highest f_mCO_2 in each breath. Peak f_IO_2 were determined from the maximum values of f_mO_2. For comparison purposes only, inhaled O_2 fraction (f_IO_2) was also determined from $f_{ET}CO_2$ and $f_{ET}O_2$ through the alveolar gas equation [5]:

$$f_AO_2 = f_IO_2 - (f_ACO_2 / RQ) \times (1 - f_IO_2(1 - RQ))$$

The alveolar fraction of CO_2 (f_ACO_2) was assumed equal to $f_{ET}CO_2$ and the respiratory quotient (RQ) was assumed to be 0.8.

Minute-averaged values were then calculated for each computed fraction. Finally, a mean value was calculated for the last three minutes of each breathing period for analysis.

Mask thermistor and pressure data were used for determining end-inhalation and end-tidal temperatures and peak inhale and exhale pressures (P_{Ins} and P_{Exp}), respectively.

Subjects rated their perceived level for breathing effort (*BE*) and mask discomfort (*MD*). Rating tests were based on a 0 – 10 subjective scale [6].

2.3 Procedure

Baseline anthropometric measurements (weight and height) were collected for each subject (see Table A1, Annex A).

All tests were carried out at DRDC Toronto and subjects went through the following procedures:

- Subjects were first briefed on the test procedures, the use of the breathing unit to be tested and the psychophysical scales used to assess the breathing effort and mask discomfort.
- An attendant instructed the subject in the proper use and fit of the Hi-Ox. The subject's arterial blood oxygen saturation was measured before going on O_2. Then, the subject donned the Hi-Ox and was asked to breathe calmly at their own resting respiratory rate from the mask.
- The experiment was broken into five periods of 5 min each separated by 10 min air-breaks. Subjects rated breathing effort and mask discomfort at the end of each 5-min period. During these air-breaks, subjects took off their masks and breathed air. The O_2 flow rate, either 0.5, 1, 2, 3, 4 $L \cdot min^{-1}$, was selected in random order.

Any 5-minute period was halted when one of the criteria listed in Annex B were met.

2.4 Statistical analysis

Subject's Oxygen blood saturation, O_2 and CO_2 levels, mask pressures, and subjective rating for breathing effort and mask discomfort were analyzed using multi-factor, repeated measures analysis of variance to determine any significant differences in the dependent variables between the O_2 flow rates (breathing periods).

3. Results

Eighteen subjects completed the evaluation of the Hi-Ox at low Q_{O2}. Mean values of SaO_2, f_IO_2, f_ICO_2, $f_{ET}CO_2$ and peak inhale and exhale pressures, averaged across all 18 subjects, are shown in Figures 3 to 6 respectively. In all figures, error bars are standard deviations.

3.1 Arterial blood oxygen saturation, SaO_2

Figure 3 shows that the Hi-Ox significantly increased SaO_2 at each O_2 flow rate. For example, at 2 L·min^{-1}, SaO_2 increased from 95.1% without a mask to 98.3% with the Hi-Ox. Overall, the mean SaO_2 increased gradually with the increase of Q_{O2}. Only the differences between 0.5 and 3 L·min^{-1} and 0.5 and 4 L·min^{-1} were significant ($p<0.05$).

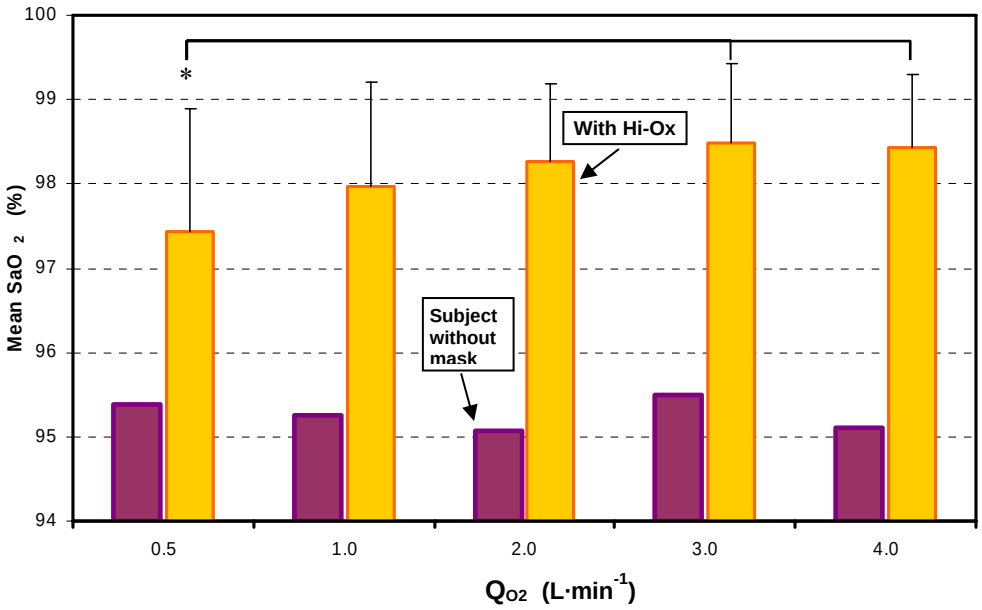

Figure 3: Mean arterial oxygen saturation. (*) $p<0.05$, 0.5 L·min^{-1} compared to 3 and 4 L·min^{-1}.

3.2 Inhaled oxygen fraction, f_IO_2

Inhaled O_2 fraction significantly increased ($p<0.0001$) with the increase of Q_{O2} (Figure 4). Peak f_IO_2 varied from 31.7±5.3% at a Q_{O2} of 0.5 L·min^{-1} to 80.1±7.7% at 4 L·min^{-1}, while mean f_IO_2 from the alveolar fraction ranged from 27.5±1.8% at 0.5 L·min^{-1} to 60.1±7.9% at 4 L·min^{-1}.

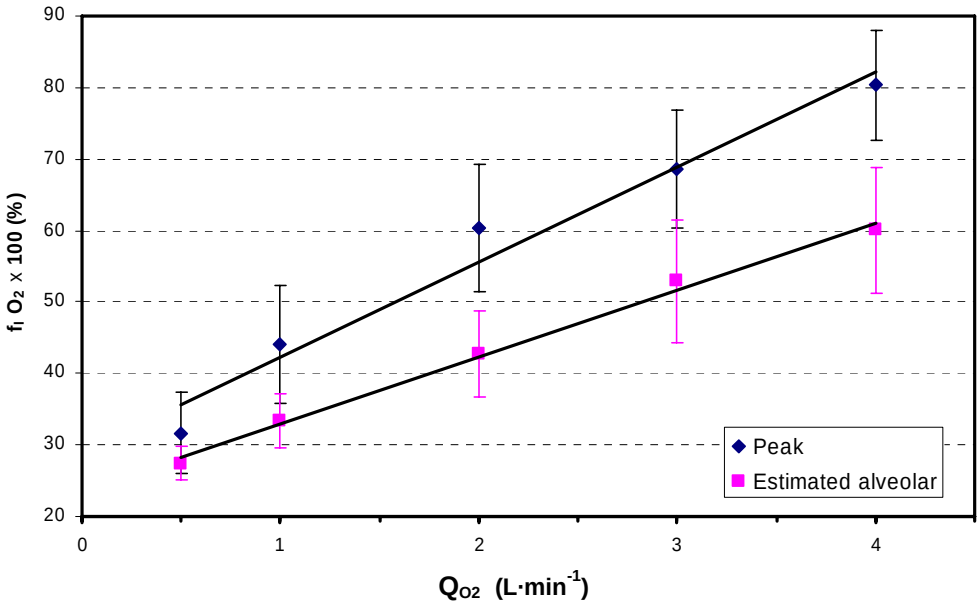

Figure 4: Mean inhaled oxygen fractions (peak values and values from alveolar equation)

3.3 Inhaled and end-tidal carbon dioxide fractions, f_ICO_2 and $f_{ET}CO_2$

Figure 5 shows mean f_ICO_2 and $f_{ET}CO_2$ at each Q_{O2}. On average, the Hi-Ox was able to maintain low f_ICO_2 levels (< 0.5%) and $f_{ET}CO_2$ nearly constant (around 5%). Oxygen flow rate had no significant effect on both f_ICO_2 and $f_{ET}CO_2$.

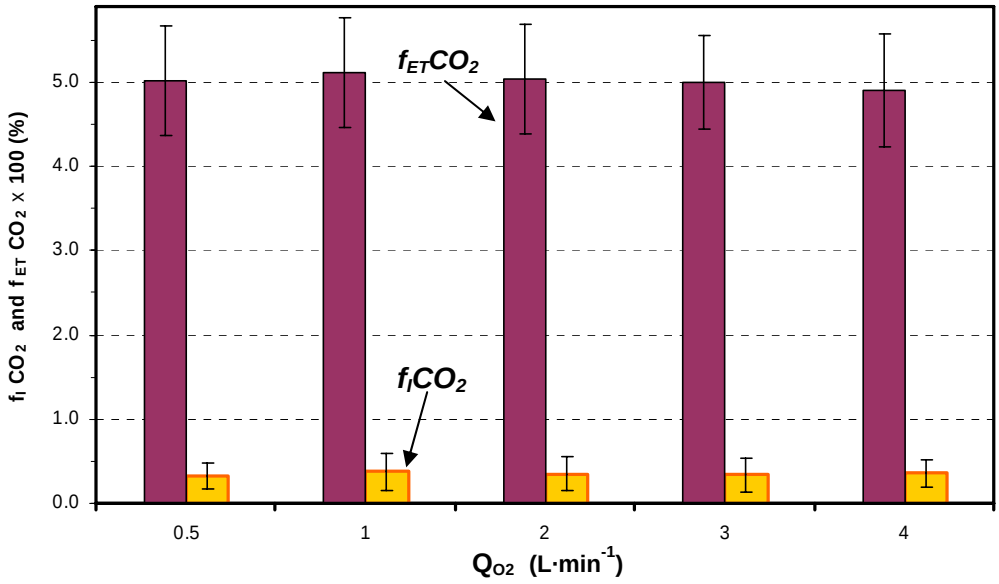

Figure 5: Mean inhaled and end-tidal carbon dioxide fractions

3.4 Peak inhale and exhale pressures, P_{inh} and P_{exh}

Whereas, Q_{O2} had no significant effect on either the peak inhale or exhale pressures, these two pressures were slightly higher at 0.5 and 1 $L \cdot min^{-1}$ (Figure 6). On average, the highest peak inhale pressure was less than 2 cm H_2O.

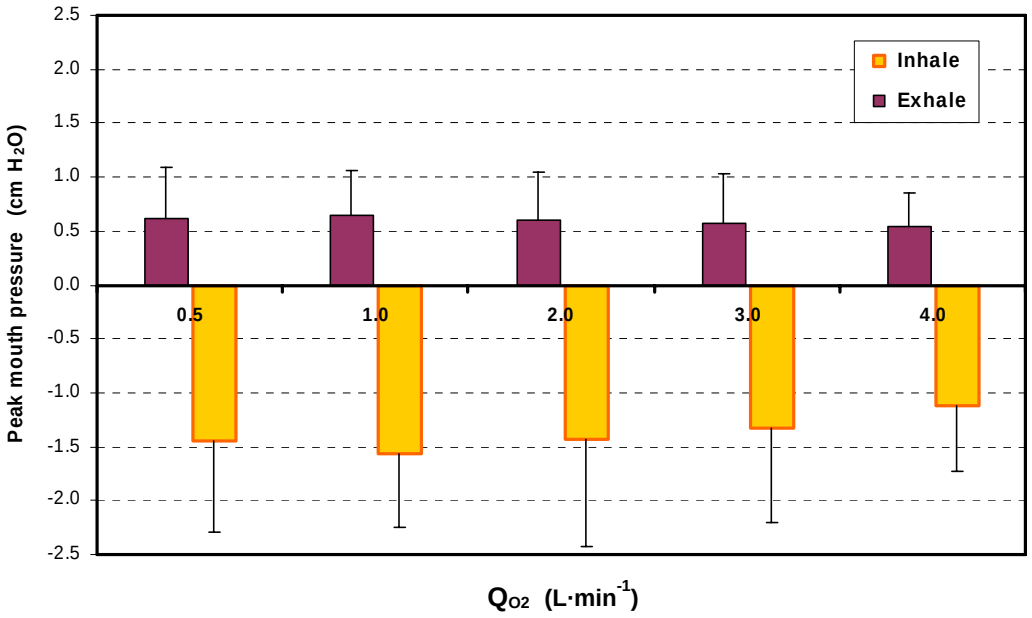

Figure 6: Mean peak inhale and exhale pressures

3.5 Subjective rating

Overall, the Hi-Ox rated, as shown in Figure 7, below "light" (<2 on a 10-point scale) for both mask discomfort, MD, and breathing effort, BE. Whereas, there was no significant difference between O_2 flows, both MD and BE were slightly lower at 3 and 4 $L \cdot min^{-1}$.

Subjects were also asked to give overall comments on the breathing unit or any other perceived discomforts (e.g., dryness, headache). The majority of the subjects complained about the lack of robustness of the two elastic straps. Several subjects indicated that O_2 leaked around the nose. Other subjects mentioned that the oronasal mask was slightly small.

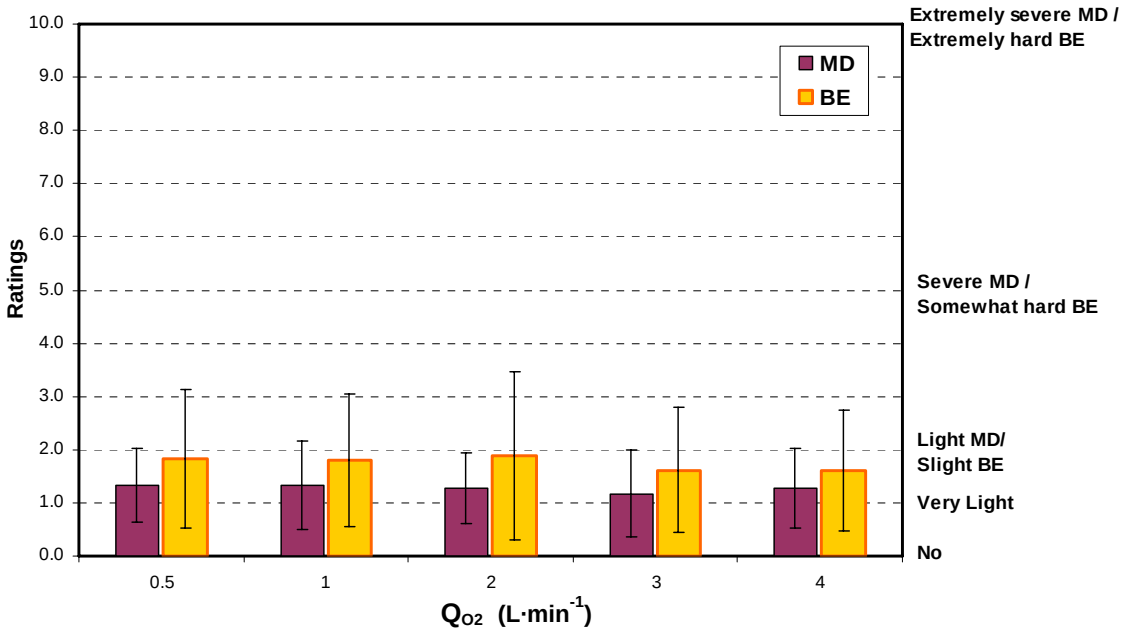

Figure 7: Mask discomfort (MD) and breathing effort (BE) ratings obtained from a 10-point scale.

4. Discussion and Conclusions

A total of 18 subjects used a Hi-Ox to evaluate its performance in terms of inhaled O_2 and CO_2 fractions and breathing resistance at low oxygen flows (i.e., 0.5, 1, 2, 3 and 4 L·min^{-1}). At an O_2 flow rate of 4 L·min^{-1}, the Hi-Ox delivered a peak O_2 concentration of 80.3%, which is in agreement with the value obtained in a previous study [1] with the same conditions (t=0.368, p=0.72) (see Table 2).

The oxygen level prescribed by a physician depends on the clinical condition of the patient. The present data showed that the Hi-Ox can cover clinical conditions that require, for example, an O_2 level of 60% given a supply O_2 flow rates of only 2 L·min^{-1}. For a patient at rest, this is significantly less O_2 than the commonly used O_2 breathing units such as the simple facemask which would require 8 L·min^{-1} to achieve the same O_2 level [1]. Even at 0.5 and 1 L·min^{-1} the Hi-Ox delivers clinically useful O_2 concentrations (Table 2).

Table 2. Literature comparison of inhaled O_2 fractions (x 100).

O_2 flow L·min^{-1}	**Peak f_IO_2**			**f_IO_2 from the alveolar equation** [5]	
	Current	**Hi-Ox** [1]	**Simple facemask** [1]	**Current**	**Hi-Ox** [7]
0.5	31.7±5.6			27.5±1.8	
1	44.1±8.2			33.4±3.4	
2	60.2±8.9			42.8±5.6	50.0±7.0
3	68.6±8.2			52.9±8.2	
4	80.3±7.8	79.60±6.2	50.13±6.7	60.0±7.9	73.0±6.0

Note: Mean±SD

With subjects breathing at their resting respiratory rate, Slessarev et al. [7] showed that the Hi-Ox, at 4 L·min^{-1}, achieved higher O_2 concentration than the non-rebreathing mask (NRM) at 8 L·min^{-1}. Table 2 compares f_IO_2 obtained in this study to Slessarev's data[2]. It appears that the latter are about 17 to 20% greater than the present data. This is mainly due to mask leaks encountered in the present study. While adhesive tape was used to ensure mask seal in Slessarev's investigation, the only attempt taken to seal mask leaks in this study was to fit the mask tight on the subject's face by using the mask's two elastic straps and the metal strip (see Figure 1). In addition, because the Hi-Ox was available in only one size[3] (adult size), mask leaks were worse when subjects had a small face, further diluting inhaled gas.

[2] Only f_IO_2 computed from the alveolar equation were compared.
[3] A paediatric Hi-Ox is now available.

The present study showed that the Hi-Ox significantly increased the blood O_2 saturation at each O_2 flow. With a low level of inhaled carbon dioxide and breathing resistance, it is possible to use the Hi-Ox at flow rates in the range of 0.5 to 4 $L \cdot min^{-1}$, decreasing O_2 requirement for treatment in remote areas and allowing the use of portable O_2 concentrators. This would increase efficiency and safety by replacing the need for bulky, dangerous compressed oxygen cylinders or chemical generators.

Fisher [8] reported that the Hi-Ox can be modified to deliver high O_2 concentrations with lower supply O_2 flow rates than the currently available Hi-Ox. It was claimed that O_2 concentration of the inhaled gas would increase from 80% to 100% at 4 $L \cdot min^{-1}$. For this, a special rebreathing bag would be connected to the exhale port of the Hi-Ox's manifold (see Figure 1) while the second end would be open to the atmosphere. If Fisher's claims are valid then the modified version of the Hi-Ox would increase the duration of O_2 supply, however, it is possible that this added bag may have some effects on the CO_2 level of inhaled gas. Future experiments should investigate the effectiveness of the Hi-Ox with the exhale side rebreathing bag.

5. Recommendations

Given the effectiveness of the Hi-Ox at low oxygen flows (≤ 4 L·min^{-1}), it is recommended to:

a. field test the Hi-Ox to assess its ruggedness;

b. evaluate the Hi-Ox using an O_2 concentrator;

c. assess the effectiveness of the Hi-Ox with the exhale side rebreathing bag; and

d. investigate the effect of cold temperatures on the one-way valves of the Hi-Ox.

References

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Annex A Experimental Data

Table A1. Physical Description of the Subjects

ID	Sex	Age *year*	Weight *kg*	Height *cm*
S01	Female	41	70.5	166
S02	Male	42	70.3	170
S03	Male	53	70.3	174
S04	Female	22	59.0	174
S05	Male	41	91.6	183
S06	Male	33	88.5	183
S07	Female	41	55.8	157
S08	Male	41	108.9	183
S09	Male	28	101.0	183
S10	Male	44	72.6	174
S11	Female	28	63.5	157
S12	Male	39	81.6	173
S13	Male	56	99	183
S14	Male	44	81.6	168
S15	Male	42	90.7	171
S16	Male	35	72.6	173
S17	Male	36	102.1	183
S18	Female	21	52.0	161
Mean		38.17	79.5	173
SD		9.31	17.0	9

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Annex B Termination Criteria

Experiments were stopped when any of the following criteria were reached:

- Subject request associated with fatigue, discomfort or any other reason.
- Total pure O_2 breathing duration reaches 30 minutes.
- Loss of O_2 supply.
- Arterial O_2 blood saturation goes below 92%.
- Inhaled O_2 fraction goes below 21%
- Inhaled CO_2 fraction exceeds 0.5% by volume.
- Loss of room ventilation.
- Excessive breathing resistance (peak inhale or exhale pressures no greater than ±10 cm H_2O over 5 min).

List of symbols/abbreviations/acronyms/initialisms

BE	Breathing effort
CF H Svc Gp HQ	Canadian Forces Health Services Group Headquarters
DND	Department of National Defence
DRDC	Defence R&D Canada
f_ACO_2	Alveolar carbon dioxide fraction
$f_{ET}CO_2$	End tidal carbon dioxide fraction
$f_{ET}O_2$	End tidal oxygen fraction
f_ICO_2	Inhaled carbon dioxide fraction
f_IO_2	Inhaled oxygen fraction
ft^3	Cubic foot
Hi-Ox	Pulmanex® Hi-Ox® mask
$L \cdot min^{-1}$	Litres per minute
MD	Mask discomfort
NRM	Non-rebreathing mask
O_2	Oxygen
OPI	Office of Primary Interest
P_{exh}	Peak exhale mask pressure (cm H_2O)
P_{inh}	Peak inhale mask pressure (cm H_2O)
psi or psig	Pound square inch or pound square inch gage
Q_{O2}	Supply oxygen flow rate
RQ	Respiratory quotient
R&D	Research & Development
SaO_2	Arterial blood oxygen saturation
SD	Standard deviation

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This report describes the first phase of a project to develop an efficient mass casualty oxygen (O_2) breathing system for O_2 therapy in remote areas. In this first phase, DRDC Toronto was tasked to investigate the performance of the Pulmanex® Hi-Ox® mask (Hi-Ox) at O_2 flow rates from 4 litres per minute ($L \cdot min^{-1}$) down to 0.5 $L \cdot min^{-1}$. Performance was evaluated with eighteen male and female volunteers between the ages of 21 and 56 years. Subjects were at rest in a seated position. The data showed that it is possible to use the Hi-Ox for O_2 treatment with low flow rates. The peak concentration of inhaled oxygen was 31.7±5.6% at 0.5 $L \cdot min^{-1}$ and 80.3±7.8% at 4 $L \cdot min^{-1}$. To achieve a given level of O_2 concentration, the Hi-Ox required significantly less O_2 than the commonly used simple facemask. This will allow the use of portable O_2 concentrators to supply oxygen to the Hi-Ox, increasing the efficiency and minimizing risks.

Le présent rapport décrit la première phase d'un projet de développement d'un système efficace d'oxygénothérapie pouvant servir auprès d'un grand nombre de blessés dans les régions éloignées. Au cours de cette première phase, RDDC Toronto a été chargé d'examiner la performance du masque Pulmanex^{MD} Hi-Ox^{MD} (Hi-Ox) à des débits d'oxygène (O_2) de 4 litres par minute ($L \cdot min^{-1}$) en diminuant jusqu'à 0,5 $L \cdot min^{-1}$. La performance a été évaluée chez dix-huit volontaires de sexe masculin et féminin âgés de 21 à 56 ans. Les sujets étaient au repos en position assise. Les données ont montré qu'il est possible d'utiliser le Hi-Ox pour l'oxygénothérapie à de faibles débits. La concentration maximale de l'oxygène inspiré était de 31,7±5,6 % à un débit de 0,5 $L \cdot min^{-1}$ et de 80,3±7,8 % à un débit de 4 $L \cdot min^{-1}$. Pour obtenir une concentration donnée d'O_2, le Hi-Ox requérait beaucoup moins d'O_2 que le masque facial simple couramment utilisé. On pourra ainsi utiliser des concentrateurs d'O_2 portatifs pour alimenter le Hi-Ox en oxygène, ce qui augmentera l'efficacité et réduira au minimum les risques.

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Pulmanex® Hi-Ox® mask, VIASYS Hi-Ox80; First-aid oxygen, O2 concentrator

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