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Assessment of the Pulmanex® Hi-Ox® for aeromedical evacuation at 8000 feet

F. Bouak
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Defence R&D Canada
Technical Memorandum
DRDC Toronto TM 2006-200
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Canada

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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

DRDC Toronto was tasked by the Canadian Forces Health Services Group Headquarters (CF H Svc Gp HQ) to verify that the Pulmanex® Hi-Ox® mask system (HiOx) is suitable, safe and efficient for use in aircraft at cabin altitudes up to 8000 feet (ft). The objective is to use the HiOx mask to provide oxygen (O_2) to patients during aeromedical evacuation. Performance and safety were compared at ground level and 8000 ft and at four different O_2 flow rates (0, 2, 4 and 6 litres per minute (L/min)). An experiment was conducted by eight male volunteers inside the hypobaric chamber of DRDC Toronto. Subjects were at rest in a seated position. The data showed that it is possible to use the HiOx safely for aeromedical evacuation at 8000 ft with relatively low O_2 flows. The HiOx at altitude, like at ground level, significantly increased the blood O_2 saturation at as little as 2 L/min. The oxygen partial pressure of the inhaled mixture showed that the HiOx would require an increase to the O_2 supply flow rate at altitude to provide equivalent oxygen treatment as that at ground level. However, as demonstrated in previous studies, the O_2 requirement at any altitude would be substantially less than with traditional oxygen masks, thereby extending the duration of supplemental oxygen and enabling the use of miniature O_2 concentrators.

Résumé

RDDC Toronto a été chargé par le Quartier général du Groupe des Services de santé des Forces canadiennes (QG Gp Svc S FC) de vérifier si le masque Pulmanex^{MD} Hi-Ox^{MD} (HiOx) était adapté, sûr et efficace dans les aéronefs à des altitudes cabine pouvant atteindre 8000 pieds (pi). L'objectif est d'utiliser le masque HiOx pour administrer de l'oxygène (O_2) à des patients durant une évacuation aéromédicale. Nous avons comparé la performance et la sécurité du masque au niveau du sol et à 8000 pieds d'altitude et pour quatre débits d'O_2 (0, 2, 4 et 6 litres par minute (L/min)). L'expérience a été menée chez huit volontaires de sexe masculin à l'intérieur d'un caisson hypobare de RDDC Toronto. Les sujets étaient au repos en position assise. Les données ont montré qu'il est possible d'utiliser en toute sécurité le HiOx pour une évacuation aéromédicale à 8000 pieds avec des débits d'O_2 relativement faibles. En altitude, comme au niveau du sol, le HiOx a nettement augmenté la saturation du sang en O_2 et ce, à un débit aussi faible que 2 L/min. D'après la pression partielle d'oxygène du mélange inhalé, il faudrait augmenter le débit d'alimentation en O_2 du HiOx en altitude pour offrir une oxygénothérapie équivalente à celle dispensée au niveau du sol. Toutefois, comme l'ont démontré des études antérieures, les besoins en O_2 à n'importe quelle altitude devraient être inférieurs avec le HiOx qu'avec les masques à oxygène classiques, ce qui devrait prolonger la durée de l'oxygénation d'appoint et permettre d'utiliser des concentrateurs d'O_2 miniatures.

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Executive summary

Assessment of the Pulmanex® Hi-Ox® for aeromedical evacuation at 8000 feet

F. Bouak; B. Michas; D.J. Eaton; DRDC Toronto TM 2006-200; Defence R&D Canada – Toronto; March 2007.

Introduction: Defence R&D Canada – Toronto (DRDC Toronto) was tasked by the Canadian Forces Health Services Group Headquarters (CF H Svc Gp HQ) to verify that the Pulmanex® Hi-Ox® mask system (HiOx) is suitable and safe for use in aircraft at cabin altitudes up to 8000 feet (ft). The objective is to use the HiOx to provide oxygen (O_2) efficiently to patients during aeromedical evacuation. The HiOx mask is an open-circuit, continuous-flow mask designed to improve gas usage efficiency, that is, low O_2 flow rates to achieve the oxygen concentration levels required for oxygen therapy. In previous studies, this mask significantly exceeded the commonly-used simple facemask in terms of O_2 content at ground level (approximately 600 ft above sea level) and for O_2 supply flow rates from 9 litres per minute (L/min) down to 0.5 L/min. Mask function is not affected by altitude, while performance was expected to be safe at 8000 ft but not equivalent to performance at ground level. This report compares the performance and safety of the HiOx at ground level and 8000 ft in terms of O_2 content for selected flows of supplemental O_2.

Methods: Eight male volunteers between the ages of 30 and 55 years participated in the study. The test procedure consisted of 14 breathing periods of 4 to 5 minutes each to reach system and physiologic stability. Subjects sat comfortably inside DRDC Toronto's hypobaric chamber and breathed O_2 at their own resting respiratory rate. The HiOx was evaluated at two altitudes (ground level and 8000 ft), at four different O_2 supply flows (0, 2, 4 and 6 L/min), and with and without induced mask leakage. Measurements included inhaled and end-tidal O_2 and carbon dioxide (CO_2) fractions, arterial blood O_2 saturation, mask pressures, exhaled gas and inhaled air volumes and inhaled gas temperature.

Results: The data showed that it is possible to safely use the HiOx for aeromedical evacuation at 8000 ft, and with relatively low O_2 flows. Induced mask leakage was too low to demonstrate any significant effects. The HiOx at altitude significantly increased the blood O_2 saturation from 90% without a mask to over 98% at as little as 2 L/min. The mean peak inhaled O_2 fraction varied from 0.51±0.13 at 2 L/min to 0.80±0.12 at 6 L/min at ground level and from 0.60±0.18 at 2 L/min to 0.86±0.12 at 6 L/min at altitude. But, according to the inhaled O_2 partial pressure data, the HiOx would require an increase to the O_2 supply flow rate at altitude to provide equivalent oxygen treatment as that at ground level. However, as demonstrated in previous studies, the O_2 requirement at any altitude would be less than with traditional oxygen masks.

Significance: The use of the HiOx to evacuate a patient on oxygen treatment in an aircraft is safe at cabin altitudes up to 8000 ft. Since the HiOx compared to simple facemasks provides high O_2 concentration which results in high arterial blood O_2 saturation with a relatively low O_2 supply flow rate, the duration of oxygen supply would be extended. Moreover, the lower flow rate makes the use of miniature O_2 concentrators to provide an indefinite supply of O_2 to the HiOx feasible. The replacement of currently used O_2 systems (i.e., a high flow rate mask and O_2 cylinders or

chemical generators) by the system HiOx-O_2 concentrator would greatly increase the efficiency while minimizing risks of O_2 delivery (no compressed O_2 and less oxygen entering the cabin space of the aircraft). Given the effectiveness and the safety of the HiOx at altitudes and low O_2 flows, this mask should be further investigated in the field.

Sommaire

Assessment of the Pulmanex® Hi-Ox® for aeromedical evacuation at 8000 feet

F. Bouak; B. Michas; D.J. Eaton; DRDC Toronto TM 2006-200; R & D pour la défense Canada – Toronto; Mars 2007.

Introduction : R & D pour la défense Canada – Toronto (RDDC Toronto) a été chargé par le Quartier général du Groupe des Services de santé des Forces canadiennes (QG Gp Svc S FC) de vérifier si le masque Pulmanex^{MD} Hi-Ox^{MD} (HiOx) était adapté, sûr et efficace dans les aéronefs à des altitudes cabine pouvant atteindre 8000 pieds (pi). L'objectif est d'utiliser le masque HiOx pour administrer efficacement de l'oxygène (O_2) à des patients durant une évacuation aéromédicale. Le masque HiOx est un respirateur à débit constant et à circuit ouvert visant à assurer une utilisation plus efficiente des gaz, c'est-à-dire de faibles débits d'oxygène combinés à une forte concentration d'oxygène. Dans des études antérieures, ce masque a nettement surpassé le simple masque facial couramment utilisé en ce qui a trait à la concentration en O_2 au niveau du sol (environ 600 pieds d'altitude), et les débits d'alimentation en O_2 sont passés de 9 litres par minute (L/min) à 0,5 L/min. On s'attendait à ce qu'en altitude, son fonctionnement soit sûr et équivalent à celui observé au niveau du sol. Le présent rapport compare la performance et la sécurité du masque HiOx au niveau du sol et à 8000 pieds pour ce qui est de la concentration en O_2 à certains débits d'O_2 d'appoint.

Méthodologie : Huit volontaires de sexe masculin âgés de 30 à 55 ans ont participé à l'étude. Le test comportait 14 périodes d'inhalation de 4 à 5 minutes chacune jusqu'à l'atteinte d'une stabilité du système et d'une stabilité physiologique. Les sujets étaient confortablement assis à l'intérieur du caisson hypobare de RDDC Toronto et ont inhalé de l'O_2 à leur propre rythme respiratoire au repos. Le masque HiOx a été évalué à deux altitudes (niveau du sol et 8000 pieds), à quatre débits différents d'alimentation en O_2 (0, 2, 4 et 6 L/min), ainsi qu'avec ou sans fuite provoquée. Au nombre des paramètres mesurés figuraient les fractions d'O_2 et de dioxyde de carbone (CO_2) dans l'air inspiré et en fin d'expiration, la saturation en O_2 du sang artériel, les pressions au masque, les volumes de gaz exhalés et d'air inhalé et la température des gaz inhalés.

Résultats : Les données ont montré qu'il est possible d'utiliser en toute sécurité le HiOx pour une évacuation aéromédicale à 8000 pieds avec des débits d'O_2 relativement faibles. L'effet de la fuite d'oxygène était trop faible pour être significatif. Le HiOx en altitude a nettement augmenté la saturation en O_2 du sang, qui est passé de 90 % sans masque à plus de 98 % à un débit d'à peine 2 L/min. La fraction moyenne maximale d'O_2 inhalé variait entre 0,51±0,13 à 2 L/min et 0,80±0,12 à 6 L/min au niveau du sol et entre 0,60±0,18 à 2 L/min et 0,86±0,12 à 6 L/min en altitude. Mais d'après la pression partielle de l'oxygène inhalé, il faudrait augmenter le débit d'alimentation en O_2 du HiOx en altitude pour fournir une oxygénothérapie équivalente à celle dispensée au niveau du sol. Toutefois, comme l'ont démontré des études antérieures, les besoins en O_2 à n'importe quelle altitude devraient être inférieurs avec le HiOx qu'avec des masques à oxygène classiques.

Importance : L'utilisation du HiOx lors de l'évacuation médicale d'un patient sous oxygénothérapie dans un aéronef est sûre à des altitudes cabine allant jusqu'à 8000 pieds. Comme

le HiOx assure de fortes concentrations en O_2 résultant en une saturation élevée en O_2 du sang artériel à des débits d'O_2 relativement faibles, la durée de l'alimentation en oxygène peut être prolongée. En outre, à cause du faible débit d'O_2, il est possible d'utiliser des concentrateurs d'O_2 miniatures pour l'alimentation du HiOx en O_2. Le remplacement des systèmes d'O_2 traditionnels (i.e., combinaison d'un masque à haut débit d'O_2 avec une bouteille d'oxygène ou une générateur chimique) par le système HiOx-concentrateur d'O_2 pourrait grandement accroitre le rendement en minimisant les risques de l'administration d'O_2 (l'oxygène ne serait plus transporté sous pression dans des bouteilles et il y aurait moins d'O_2 dans la cabine de l'avion). Compte tenu de l'efficacité du HiOx en altitude et à de faibles débits d'O_2, ce masque devrait être étudié sur le terrain.

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1 Introduction

1.1 Background

The Canadian Forces Health Services Group Headquarters (CF H Svc Gp HQ) needs an efficient oxygen (O_2) breathing system to provide less O_2 to patients during aeromedical evacuation [1]. The objective is to transport a reduced amount of O_2 during this type of operation, thereby reducing cost, weight, volume and risk associated with pressurized O_2 cylinders. Constant-flow supplemental oxygen systems comprising an oxygen source, usually a compressed-gas tank, and a breathing mask are commonly used to deliver an O_2-enriched air mixture to patients to maintain an acceptable level of oxygen content in their blood. Typically the mass flow rate of oxygen can be manually adjusted at several discrete values, but these systems are often inefficient with as little as 2% of oxygen delivered used by the patient and the rest exhaled or vented directly to ambient from the system [2]. This may be acceptable for treating patients in an urban area; but, transporting O_2 to a remote area is a logistic challenge. Previous studies [2-3] have demonstrated the effectiveness of the Pulmanex® Hi-Ox® mask system (HiOx) in providing significantly higher O_2 concentrations at lower flow rates than provided by commonly used constant-flow O_2 masks such as the simple facemask. In a recent investigation, Bouak and Eaton [4] showed that the HiOx is efficient and can deliver O_2 in therapeutic ranges with flow rates low enough to be compatible with miniature O_2 concentrators. The use of a mask like the HiOx will not only reduce the amount of O_2 to be transported but also allow an eventual replacement of traditional compressed O_2 cylinders or chemical generators by O_2 concentrators. The results of these two studies ([2, 4]) and the need for an efficient O_2 breathing system led the Canadian Forces Health Services Group Headquarters to task DRDC Toronto to assess the HiOx for use in aircraft at cabin altitudes up to 8000 feet (ft).

The basic functionality of breathing masks including the HiOx is not affected by altitude. For a given mass flow, actual volume flow increases with altitude according to Boyle's Law. The increased volume raises the oxygen fraction in the breathing gas mixture. This partially offsets effects on oxygen therapy of lower barometric pressure and correspondingly lower oxygen partial pressure at altitude. Both of these factors, higher oxygen volume flow and lower pressures, relate to system performance, and their effects are somewhat predictable. Faceseal leakage, relating to the oronasal mask/patient interface, can also reduce the oxygen content breathed by the patient.

1.2 Equipment under Test

The test item for this evaluation is the HiOx (Figure 1), a commercial product by VIASYS™. Its main components are a flexible oronasal mask, two light elastic straps, the reservoir bag, a flexible oxygen supply hose and a manifold. The mask is supported on the face by wrapping the straps around the head. A metal strip incorporated in the nose area of the mask enables shape adjustment for fit and seal. Two 1/16-inch holes were punched on each side of the mask (Figure 2), and tape was used to enable inducing and removing a simulated faceseal leak in a consistent manner.

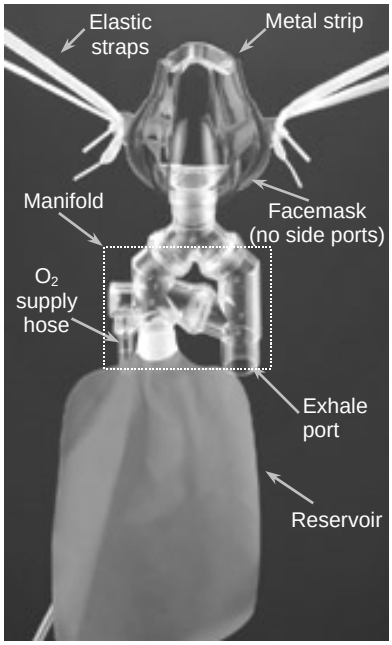

Figure 1: The Pulmanex® Hi-Ox® mask.

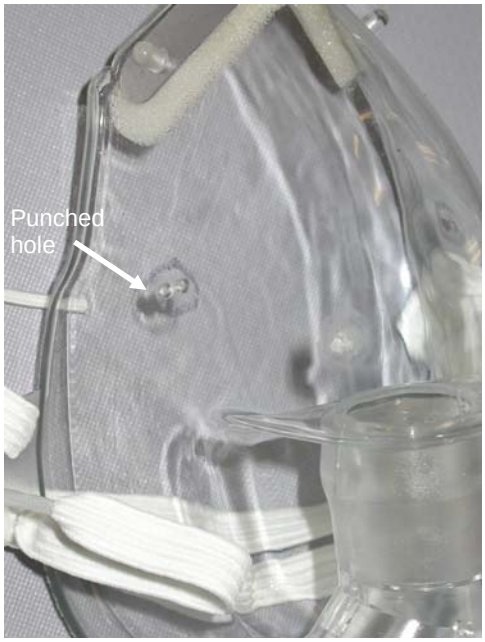

Figure 2: Holes in HiOx Mask for simulated leakage.

As illustrated in Figure 1, the manifold interfaces with the oxygen supply hose. It incorporates four one-way valves to direct gas flow paths to and from the mask. One of the valves acts as an anti-suffocation valve, providing a second path for ambient air to the mask in the event of excessive inspiratory flow resistance. During inspiration, the sequence of gas flow to the mask is from highest to lowest oxygen concentration – that is, first 100% oxygen from the supply line and the reservoir, then the small volume of expired gas remaining in the manifold, and finally ambient air drawn in through the open exhale port from the surrounding atmosphere. During non-inspiratory periods, flow of 100% oxygen from the supply line collects in the reservoir bag.

2 Methodology

2.1 Subjects

A total of eight military and civilian subjects volunteered to participate in this study. Ages were between 30 and 55 years. All subject candidates were recruited from DRDC Toronto staff and, prior to conducting the experiments, underwent a medical screening by a physician to determine respiratory symptoms and eligibility. The DRDC Human Research Ethics Committee (HREC) approved the experimental protocol [5]. 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. None of the subjects withdrew from the study. Table 1 summarizes their physical characteristics. Annex A lists individual subject characteristics.

Table 1: Subjects Characteristics.

	Mean ± SD[1]	Range
Age *(yr)*	43.4±6.6	33 – 53
Weight *(kg)*	79.6±8.5	70.3 – 91.6
Height *(m)*	1.75±0.05	1.70 – 1.83

([1]) SD: Standard deviation

2.2 Test description

A single HiOx test run was conducted individually by each subject. The subject sat comfortably inside DRDC Toronto's hypobaric chamber throughout the test period, donned a HiOx mask as directed by an attendant and breathed calmly at their individual respiratory rate. As shown in Table 2, independent test variables were altitude (ground level (GL), 8000 ft), supplement O_2 flow rate (0, 2, 4, 6 L/min STPD[1]) (Q_{O2}), and induced leakage (no, yes). The duration at each condition was sufficient to reach system and physiologic stability, typically 4 minutes. The test could be terminated at any time based on physiological criteria (listed in Annex B), a technical problem or subject request.

Test condition sequence was fixed but two conditions at ground level (period 2 and period 7 in Table 2) were repeated at the end of the run (after period 14) to test an assumption of no order effects (reliability test).

[1] All flow rates are referenced to 0^{o}C and 101.3 kPa, dry gas, i.e. standard temperature and pressure, dry (STPD) unless indicated. No mask was worn for zero flow condition (0 L/min).

Table 2: Test conditions.

Period	Altitude	Simulated Mask Leak	Supplemental O_2 Flow (L/min)
1	Ground Level (~600 ft)	N/A	0
2		Yes	4
3			6
4			2
5		No	2
6			6
7			4
8	8000 ft	No	4
9			6
10			2
11		Yes	2
12			6
13			4
14		N/A	0

2.3 Experimental set-up

Aviator's breathing oxygen [6] 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/min). A chain-compensated gasometer (Warren E. Collins, 120 L) was used to calibrate the flow controller.

Data measurements are listed in Table 3. The overall instrumentation set-up is illustrated in Figure 3, and mask instrumentation details are shown in Figure 4. Data were continuously measured at a sampling frequency of 50 Hz using a data acquisition (DAQ) card (National Instruments, PCI-6052E). The DAQ card was installed into a computer running Microsoft Windows 2000. Custom-written data acquisition and analysis software in LabVIEW™ (National Instruments) was used to control the DAQ card and computer, and to determine the following parameters (dependant variables):

- For each breath:
    1) Maximum (or peak) inspiratory O_2 fraction (f_IO_2)
    2) End-tidal O_2 fraction ($f_{ET}O_2$)
    3) End-inspiratory carbon dioxide fraction (f_ICO_2)
    4) End-tidal carbon dioxide fraction ($f_{ET}CO_2$)
    5) Mask cavity temperature

6) Peak inspiratory mask cavity pressure (p_{insp})
7) Peak expiratory mask cavity pressure (p_{exsp})
8) Volume of expiratory gas mixture (V_{Exp})
9) Volume of inspiratory air through the exhale port

- For the final minute:
  1) Mean arterial O_2 blood saturation (SaO_2)
  2) Minute ventilation ($\dot{V}_E$)
  3) Mean gas fractions (f_IO_2, $f_{ET}O_2$, f_ICO_2, $f_{ET}CO_2$), and corresponding partial pressures (pp_IO_2, $pp_{ET}O_2$, pp_ICO_2 and $pp_{ET}CO_2$)
  4) Mean p_{insp} and p_{exp}

Table 3: Data Measurements.

Parameter	Location	Instrument	Calibration / Specification
Oxygen fraction Carbon dioxide fraction	mask cavity mask cavity	Hiden HPR20 mass spectrometer, gas sample rate 30 ml/second (gas sample not returned to breathing circuit)	Calibrated before each test using two calibration gases (certification tolerance: ±0.02 mole %), Gas 1: 100% O_2 and Gas 2: 5% CO_2, 75% O_2 and 20% nitrogen.
Pressure	mask cavity	Validyne DP-15 transducer, ±0.5 psig diaphragm	Calibrated with MP6KD MICROMANOMETER ±0.5% best straight line (±0.0025 psig or ±0.175 cmH_2O)
Temperature	mask cavity	Yellow Spring Instrument thermister, Model 44004	
Arterial oxygen saturation	middle or index finger	Radiometer Copenhagen OXI pulse oximeter	
Inspiratory air volume Expiratory gas mixture volume	manifold exhale port	Interface Associates turbine ventilation module	Calibrated with one litre syringe 2000 pulses = 1 L; Resolution 0.5 ml or one pulse; Output characteristic of transducer linear with guaranteed accuracy 1.5% at 0.02-3 L/sec.
Ambient pressure (altitude)	hypobaric chamber	Druck PDCR 910 transducer, 0-20 psia	Combined non-linearity, hysteresis and repeatability ±0.1 % best straight line (±1.034 mmHg)

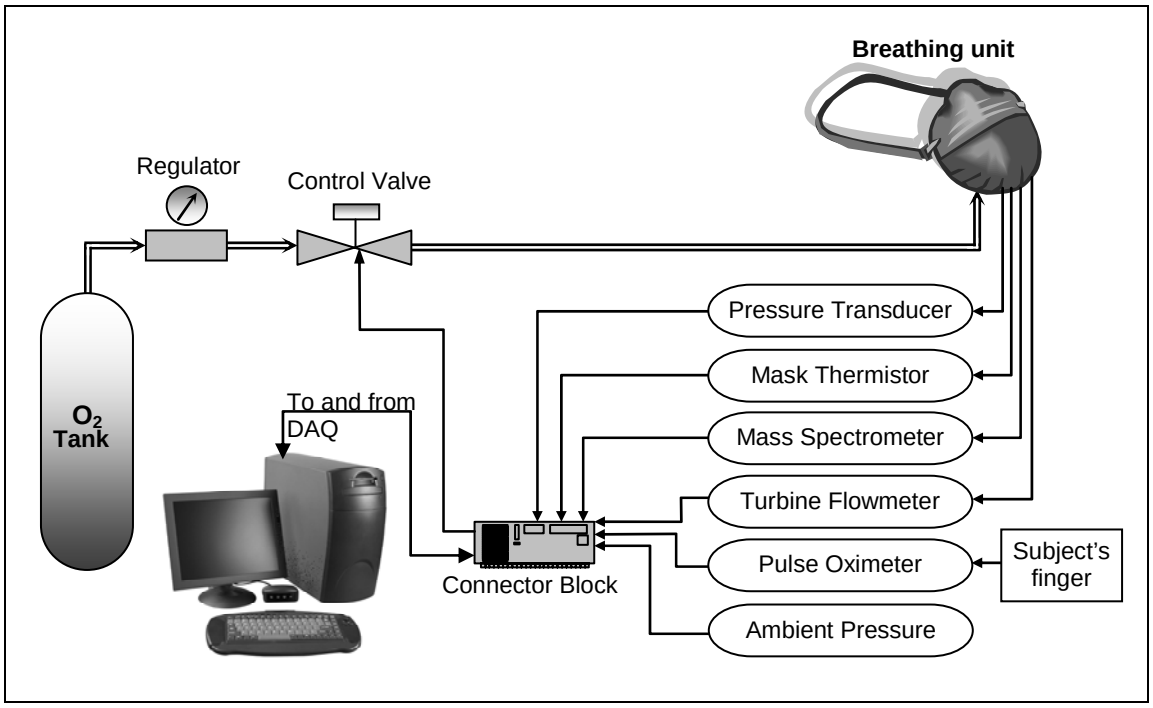

Figure 3: Instrumentation Layout.

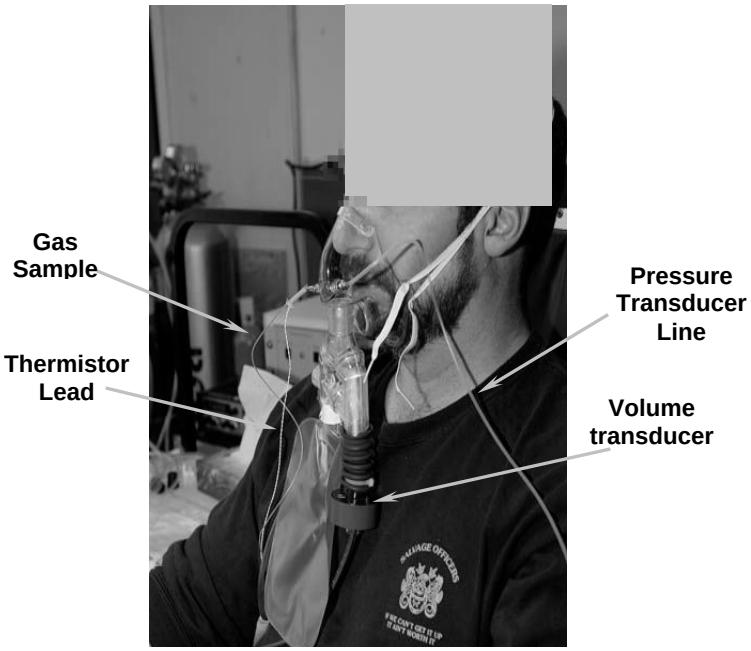

Figure 4: Instrumented mask detail.

Arterial blood oxygen, SaO_2, was the only measured dependant variable during the no-mask (ambient air) breathing (i.e., periods 1 and 14 in Table 2).

Minute ventilation, $\dot{V}_E$, was computed by summing V_{Exp} over the final minute for each test condition.

Instantaneous CO_2 and O_2 fractions (f_mCO_2 and f_mO_2), measured from the mass spectrometer, were used to determine inhaled and end-tidal gas fractions for each breath. The f_ICO_2 was taken at the time of the lowest f_mCO_2, while $f_{ET}CO_2$ and $f_{ET}O_2$ were taken at the time of the highest f_mCO_2. Peak inhaled oxygen fraction (f_IO_2) was the maximum value of f_mO_2 during the inhale phase of each breath. Minute-averaged values were then calculated for each computed breath-by-breath fraction.

Mean O_2 and CO_2 partial pressure (pp) values were computed using the following equation:

$$\mathrm{pp}_{I\ or\ ET}\ gas = \mathrm{f}_{I\ or\ ET}\ gas \times P_a \tag{1}$$

where the term $f_{I\ or\ ET}\ gas$ is either the mean f_IO_2, $f_{ET}O_2$, f_ICO_2 or $f_{ET}CO_2$, and P_a is the hypobaric chamber pressure.

2.4 Statistical analysis

The effects of altitude, simulated leakage and supplemental oxygen flow rate on levels of O_2 and CO_2 content in the HiOx mask, arterial oxygen saturation in the subject and mask cavity pressure were evaluated using a multi-factor, repeated measures analysis of variance (ANOVA) for any significant differences in the dependant variables. Arterial O_2 blood saturation at ground level and altitude were analyzed using ANOVA to determine if there were any significant differences between subjects supplemented with O_2 and subjects not supplemented with O_2 (subjects without mask). When statistical significance was present, Tukey's HSD *post hoc* test was used to assess main effects and interactions. Significance was accepted at $p<0.05$ for all statistical tests.

3 Results

All subjects completed the protocol without complications. Mean values of SaO_2, f_IO_2, $f_{ET}O_2$, f_ICO_2, $f_{ET}CO_2$, O_2 partial pressures, minute ventilation and mask cavity pressure, averaged across all subjects, are shown in Figures 5 to 11 respectively. In all figures, error bars are standard deviations.

3.1 Data reliability

All results of the repeated conditions (periods 2 and 7 in Table 2) were not significantly different to the initial ones.

3.2 Arterial blood oxygen saturation, SaO_2

Figures 5 and 6 show that, compared to breathing ambient air, using the HiOx significantly increased mean SaO_2 from 95.6% to over 98% at ground level ($p<0.001$) and from 90.4% to over 98% at altitude ($p<0.001$). Moreover, at altitude, the HiOx, regardless of O_2 flow, not only restored the No-Mask, ground-level SaO_2 value but significantly exceeded it (e.g., 98% at 2 L/min versus 95.6% with no supplemental O_2). In the Mask-On condition, supplemental O_2 flow rate, simulated leakage and altitude had no significant effect on SaO_2.

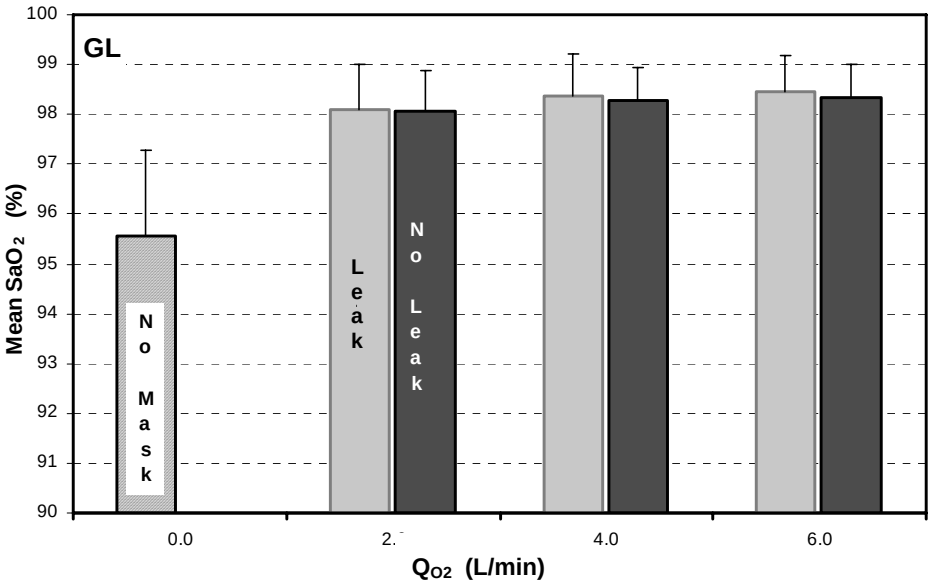

Figure 5: Mean arterial oxygen saturation at ground level. No-Mask: subjects breathing ambient air; GL: ground level (600 ft).

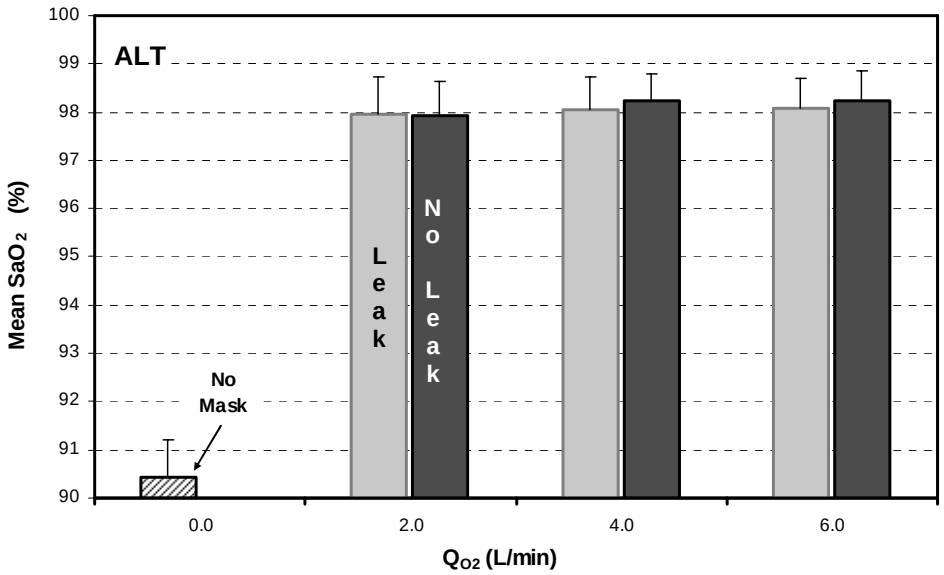

Figure 6: Mean arterial oxygen saturation at altitude. No-Mask: subjects breathing air; ALT: altitude (8000 ft).

3.3 Inhaled and end-tidal oxygen content

Figure 7 presents mean f_IO_2 and $f_{ET}O_2$ at each test altitude and Q_{O2} for the non-leakage condition only. As expected, both variables significantly increased with Q_{O2} and altitude. For example, peak f_IO_2 varied from 0.51±0.13 at 2 L/min to 0.80±0.12 at 6 L/min at ground level and from 0.60±0.18 at 2 L/min to 0.86±0.12 at 6 L/min at altitude. Only the differences between 2 and 4 L/min and between 2 and 6 L/min were significant. At 4 L/min and ground level, the HiOx delivered a peak O_2 fraction of 0.72±0.12, which is comparable to the value obtained in previous studies [2, 4] with the same conditions.

The effect of simulated leakage on f_IO_2 was not significant ($p<0.1$), regardless of Q_{O2} or altitude (see Figure 8 a). However, f_IO_2 obtained with simulated leakage was slightly higher than without leakage.

In terms of partial pressure, all above observations on f_IO_2 and $f_{ET}O_2$ apply, except that while the O_2 fractions of the breathing gas mixture were, as expected, significantly higher at 8000 ft ($p<0.001$) than at ground level as shown in Figures 7 and 8a, pp_IO_2 at altitude was significantly lower ($p<0.001$) as shown in Figure 8b.

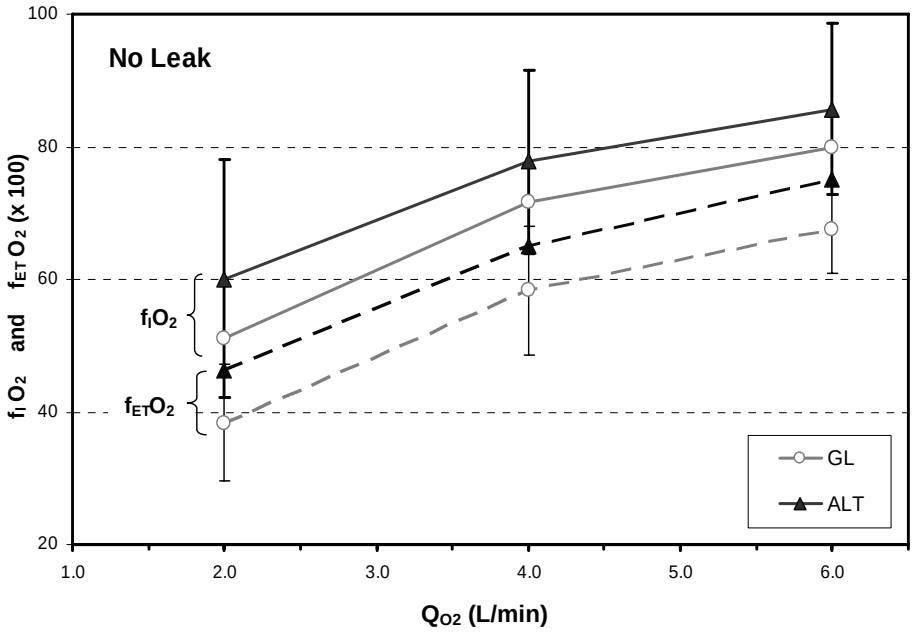

Figure 7: Effects of O_2 flow (Q_{O2}) and altitude on mean inhaled and end-tidal oxygen fractions for the non-leakage condition. GL: ground level (600 ft); ALT: Altitude (8000 ft).

Predictably, O_2 content of the gas mixture provided by the HiOx at any O_2 flow, altitude level or simulated leakage significantly exceeded the O_2 content of air. For example, for the non-leakage condition, Table 4 and Figure 8 data show that of f_IO_2, $f_{ET}O_2$, pp_IO_2 and $pp_{ET}O_2$ at 2 L/min (which were the lowest mean values when compared to 4 and 6 L/min) were greater than the No-Mask (zero supplemental O_2 flow) ground-level values (0.21 and 156 mm Hg respectively).

Table 4: Mean values of f_IO_2, $f_{ET}O_2$, pp_IO_2 and $pp_{ET}O_2$ at ground level (600 ft) and altitude (8000 ft); Q_{O2} = 2 L/min; Mask-on without simulated leakage.

		Ground level	Altitude (8000 ft)
Fraction	f_IO_2	0.51±0.14	0.60±0.18
	$f_{ET}O_2$	0.38±0.06	0.46±0.09
Partial pressure (mm Hg)	pp_IO_2	381±104	338±101
	$pp_{ET}O_2$	283±45	259±51

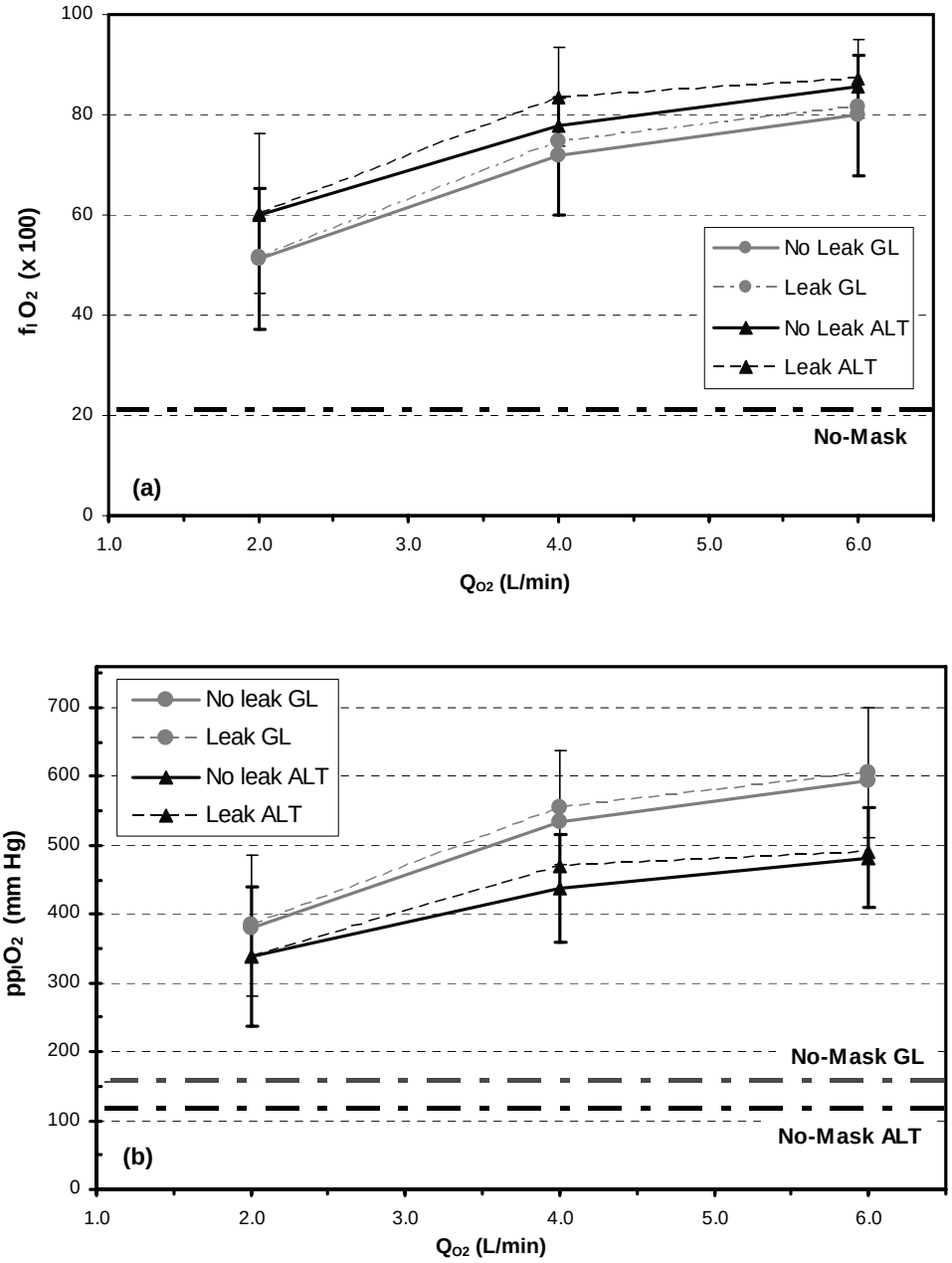

Figure 8: Effect of simulated leakage. (a) f_IO_2; (b) pp_IO_2; GL: ground level (600 ft); ALT: altitude (8000 ft).

3.4 Inhaled and end-tidal CO_2 content

Figure 9 shows that mean f_ICO_2 and $f_{ET}CO_2$ were not affected by Q_{O2}, regardless of both altitude and leakage conditions. On average, f_ICO_2 and $f_{ET}CO_2$ were both significantly higher at altitude than at ground level ($p<0.005$), regardless of the leakage condition. The influence of altitude is less evident on pp_ICO_2 ($p<0.07$) than on f_ICO_2 (see Figure 10). Simulated leakage had no significant effect on all four variables, f_ICO_2, $f_{ET}CO_2$, pp_ICO_2 and $pp_{ET}CO_2$, regardless of Q_{O2} and altitude conditions.

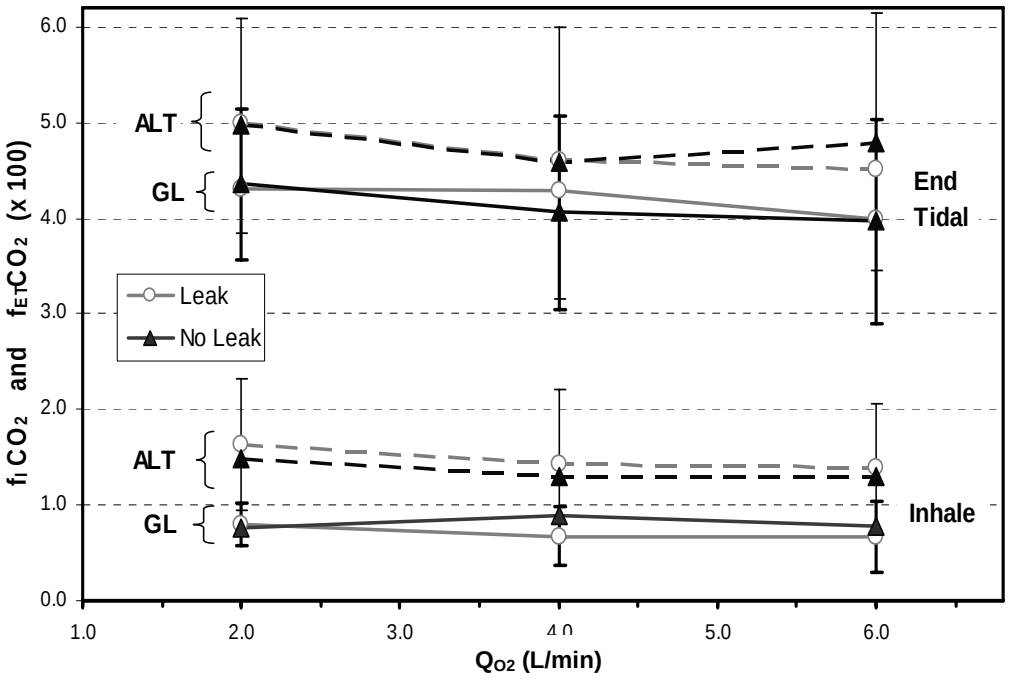

Figure 9: Mean inhaled and end-tidal CO_2 fractions. GL: ground level (600 ft); ALT: Altitude (8000 ft).

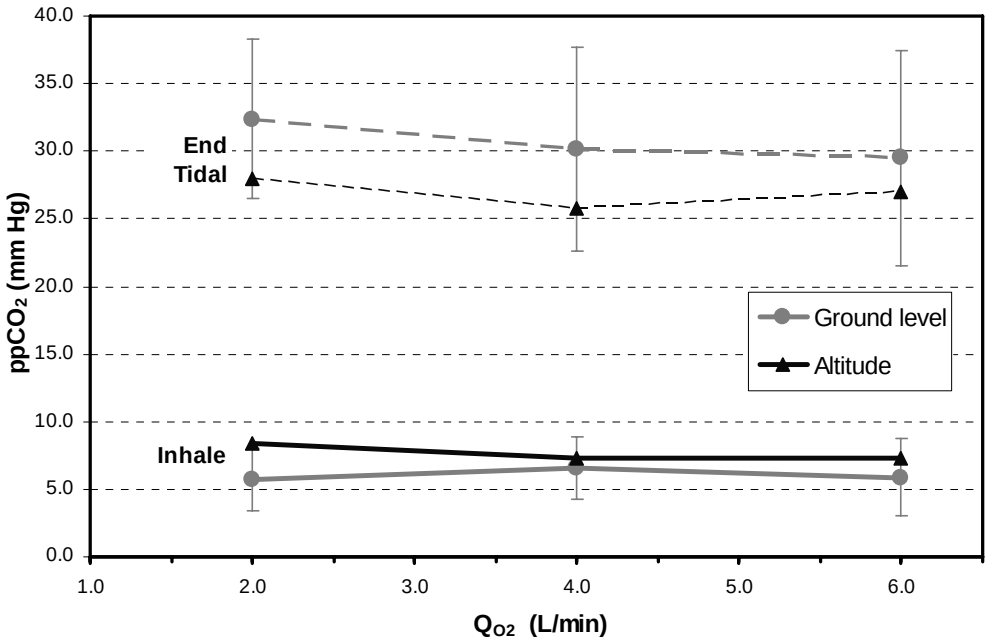

Figure 10: Mean inhaled and end-tidal CO_2 partial pressures. Mask with no simulated leakage. Ground level = 600 ft; Altitude = 8000 ft.

3.5 Peak inspiratory and expiratory pressures, p_{insp} and p_{exp}

As illustrated by Figure 11, p_{insp} and p_{exp} for the non-leakage condition was higher than that for the simulated leakage condition, the difference being significant at 8000 ft. While the effect of altitude on p_{exp} was not significant, p_{insp} at altitude was significantly lower than that at ground level ($p<0.003$), regardless of Q_{O2}. This is likely attributable to higher actual volume of O_2 supply (due to gas expansion from reduced pressure at altitude). In terms of breathing resistance, maximum p_{insp} at 8000 ft (Figure 11b) did not exceed 2 cm H_2O while maximum p_{exp} was lower than 1 cm H_2O. Both maximum p_{insp} and p_{exp} at ground level (Figure 11a) were comparable to previously obtained values in references [2 and 4].

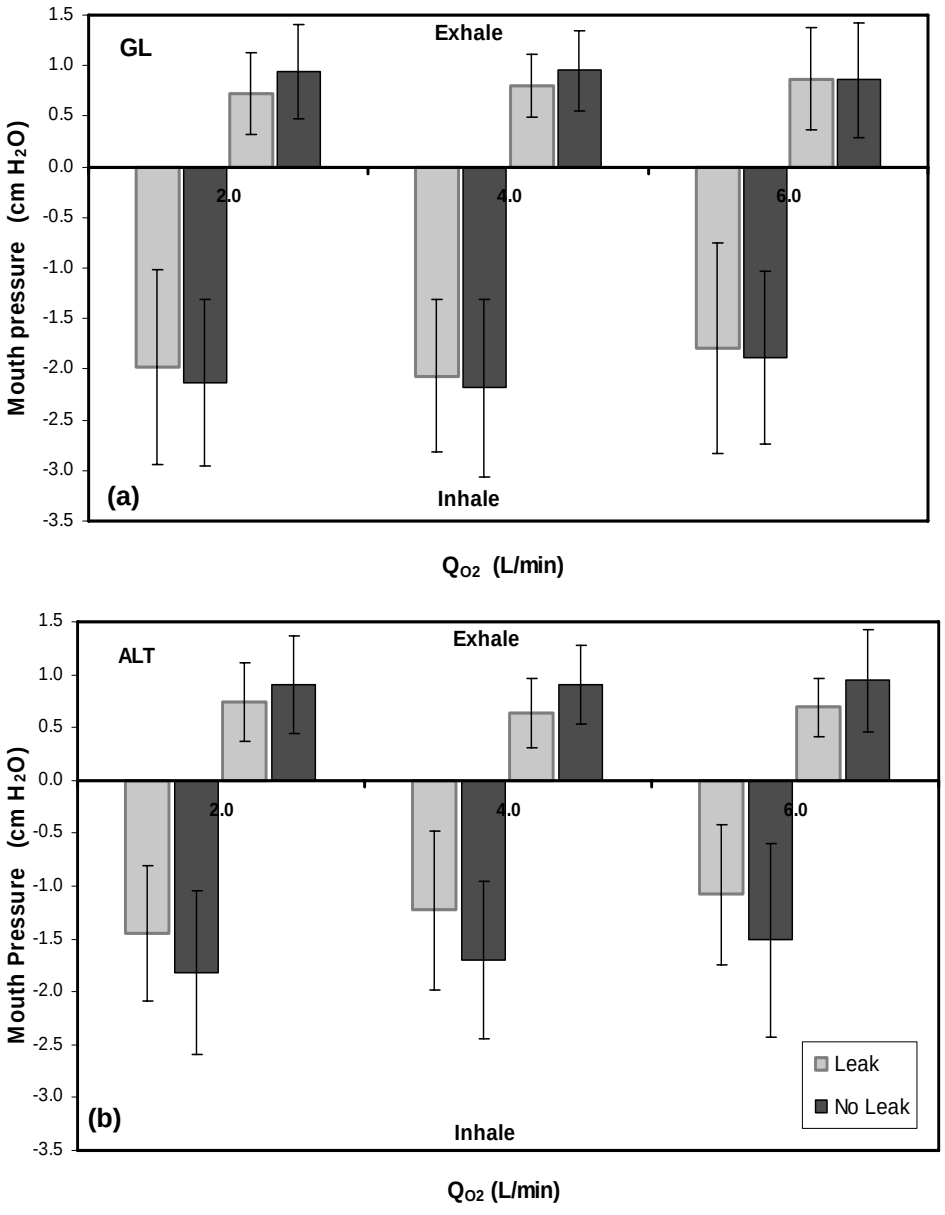

Figure 11: Mean peak inhale and exhale pressures versus supplemental oxygen flow rate (Q_{O2}). (a) GL: ground level (600 ft); (b) ALT: altitude (8000 ft).

4 Discussion

The data showed that it is possible to use the HiOx safely for aeromedical evacuation at an altitude of 8000 ft, and with relatively low O_2 flows. The increase of SaO_2 by the HiOx from the no-mask condition was lower magnitude at ground level (600 ft) than at 8000 ft (2.5% at ground level versus 8% at altitude) as the test subjects were all healthy and hence their SaO_2 while breathing ambient air (no-mask condition) saturated near the normal values of 94-96% at 600 ft (i.e., in the flatter portion of the oxygen-heamoglobin dissociation curve). At 8000 ft, SaO_2 levelled and saturated at 98% independently of the O_2 supply flow rate considered in this study (2, 4 and 6 L/min). Therefore, one can expect that healthy persons (such as pilots or passengers during long-duration flights) who might suffer from in-flight minor hypoxia at altitude would need a lower O_2 flow rate (in the range of 0.5 to 1 L/min) to increase their SaO_2 to their normal ground-level values (94-96%). Hinkelbein et al. [16] reported that healthy test subjects on the HiOx mask required 1.3 L/min to increase and maintain their SaO_2 in the range of 95% to 97% at an altitude of 13000 ft. Nevertheless, in cases where SaO_2 is well below normal values (e.g., a patient with compromised cardio-pulmonary system in need of oxygen-enriched breathing mixture or anyone at sufficiently high altitude), the minimum supplemental O_2 flow rate required to increase SaO_2 to normal values is expected to be higher than 2 L/min. Indeed, Hinkelbein et al. [16] reported that the HiOx required an O_2 flow rate of 3.4 L/min (higher than 2 L/min) to increase SaO_2 to 95-97% at 22500 ft. The simple facemask required a higher O_2 flow rate (5.5 L/min) with the same conditions. They showed a significant difference between the two masks at altitudes higher than 13000 ft.

Inhaling a gas with a CO_2 partial pressure higher than 7.6 mm Hg ($\cong$ 1% near sea level) will usually induce a spontaneous increase in pulmonary ventilation [17], which is unnoticed by the subject. For the no leak condition, mean pp_ICO_2 at 8000 ft was higher, on average, than that at ground level and varied between 7.3±3.6 and 8.4±3.3 mm Hg, slightly increasing $\dot{V}_E$ greater than the normal level found in subjects under resting conditions. Moreover, this increase of $\dot{V}_E$ may have induced the decrease of $pp_{ET}CO_2$ at altitude.

In the literature, f_IO_2 is determined using various techniques [2-4, 7-15]. Each of them has limitations in representing f_IO_2. Generally, they can be classified into the following groups:

i. Determination of peak values only ($f_IO_{2\text{-peak}}$) from measured instantaneous O_2 fraction in the mask (f_mO_2) [2, 4, 7-9]. Peak values alone do not reflect the true f_IO_2, since instantaneous f_IO_2 varies throughout inspiration and might be affected by mask leakage. However, it is a good indication of the maximum level of O_2 that a patient may receive using a given mask.

ii. Use of the alveolar gas equation (see equation 2) [3, 10-13] using the *exhaled* O_2 and CO_2 concentrations. In this equation, RQ is the respiratory quotient, and f_AO_2 and f_ACO_2 are the alveolar O_2 and CO_2 fractions. Most investigators assume that RQ equals 0.8 while f_AO_2 and f_ACO_2 are replaced by end-tidal O_2 and CO_2 fractions respectively.

$$f_A O_2 = f_I O_2 - (f_A CO_2 / RQ) \times (1 - f_I O_2 (1 - RQ)) \quad (2)$$

iii. Use of equation 3 [14-15] as follows:

$$f_I O_2 = \frac{\%O_{2\text{-}air} \dot{V}_{air} + \dot{V}_{O2}}{\dot{V}_I} = \frac{0.2095\left(\dot{V}_I - \dot{V}_{O2}\right) + \dot{V}_{O2}}{\dot{V}_I} \quad (3)$$

where $\dot{V}_I$ is the inspiratory gas flow rate and $\dot{V}_{O_2}$ is the actual volume flow of supplemental oxygen. This model requires simultaneous measurements of instantaneous $\dot{V}_I$ and supplemental O_2 flow rate, and assumes negligible leakage. When $\dot{V}_I$ is difficult to measure, the minute ventilation $\dot{V}_E$ is usually used as an estimate [17].

To compare the three techniques, the variation of mean f_IO_2, taken from the present data for the non-leakage and ground level conditions, is shown in Figure 12. Mean $f_{ET}O_2$ is also included for comparison. "True" f_IO_2 cannot be higher than the one obtained from peak values. Similarly, it cannot be lower than $f_{ET}O_2$. Figure 12 shows that f_IO_2 calculated from Equation 3 are very similar to $f_{ET}O_2$, regardless of the O_2 supply flow rate. While this may be surprising in that f_IO_2 should be higher than $f_{ET}O_2$, it can be attributed to the fact that $\dot{V}_E$ observed in this experiment for non-leakage and ground level conditions is higher, on average, than normal "resting" values observed in earlier studies (10.3 L/min BTPS at Q_{O2}=2 L/min and 12.4 L/min BTPS at 6 L/min in this study versus a constant 8 L/min BTPS independently of Q_{O2} in [2]). It remains unclear why $\dot{V}_E$ in this experiment was slightly higher. While a high pp_ICO_2 could be a factor (as seen above) [17], it could also be attributed to measurements errors (which include errors due to malfunction and poor calibration and even incorrect altitude compensation calculation. Another cause could be the fact that the experiment did not include air break between breathing periods to allow subject's data (e.g., $f_{ET}O_2$ and $\dot{V}_E$) to return to baseline before each measurement.

While f_IO_2 computed from Equation 2 is a good estimate ($f_{ET}O_2 < f_IO_{2\text{-Eq. }2} < f_IO_{2\text{-Peak}}$) of f_IO_2, as suggested by Slessarev et al. [3] and shown in Figure 12, the presentation of the pair $f_IO_{2\text{-Peak}}$ and $f_{ET}O_2$ might be a better illustration of the true f_IO_2 delivered by a mask, since no calculation or estimate is involved in their determination.

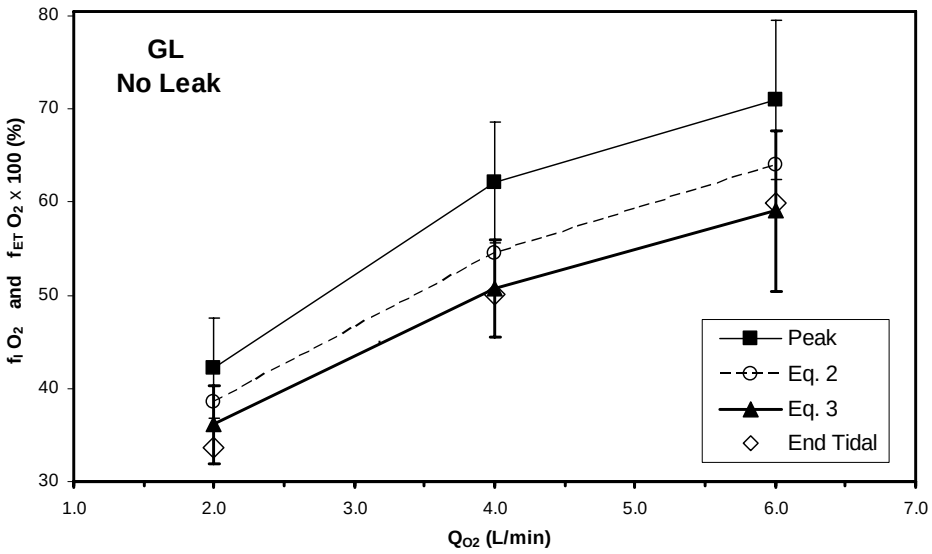

Figure 12: Comparison of three techniques used to obtain f_IO_2. GL: ground level (600 ft).

5 Conclusions

The HiOx mask at an altitude of 8000 ft, like at ground level, significantly increases the blood O_2 saturation at as little as 2 L/min. Moreover, SaO_2 obtained at both altitudes are similar. No significant difference was found between the two conditions for the healthy individuals only. With respect to the oxygen partial pressure of the inhaled mixture, the data show a small altitude effect, indicating a slight increase to the supplemental oxygen flow rate at altitude would give oxygen treatment equivalent to ground level. Given the high SaO_2, high O_2 concentrations, safe and constant levels of inhaled and exhaled CO_2, and low breathing resistance, the HiOx can be used safely in aeromedical evacuation at 8000 ft. The effective and efficient use of oxygen with this mask, as would be expected and has demonstrated in previous studies, indicates that the O_2 requirement at any altitude would be less than with traditional simple oxygen masks; thereby, extending the duration of supplemental oxygen.

References

[1] Canadian Forces Health Services Group Headquarters (2006). Science and Technology – Direct Support to the CF by DRDC Toronto – Business Line 2 Request form.

[2] Bouak, F. and Eaton, D. J. (2005). Possibilities for mass casualty oxygen systems in search and rescue missions. Part 1: The VIASYS Hi-Ox$^{80™}$ mask. (DRDC Toronto TR 2005-207). Defence R&D Canada – Toronto.

[3] Slessarev, M., Somogyi, R., Preiss, D., Vesely, A., Sasano, H., Fisher, J. A. (2006). Efficiency of oxygen administration: Sequential gas delivery versus "flow into a cone" methods. *Crit. Care Med.*, 34, 829-834.

[4] Bouak, F. and Eaton, D. J. (2006). New advanced mass casualty breathing system for therapy; Phase 1. (DRDC Toronto TR 2006-201). Defence R&D Canada – Toronto.

[5] Michas, B. and Bouak, F. (2006) Performance of oxygen breathing systems for search missions. DRDC Human Research Ethics Committee Protocol #L-472, Amendment #3. Defence R&D Canada – Toronto. 15 May 2006.

[6] Canadian Forces. (1987). *Oxygen Aviator's Breathing, Liquid and Gaseous*. CF standard D-22-03-003/SF-000 1987-10-27 Table 1, Department of National Defence, Canada.

[7] Pollock, N. W., Natoli, M. J., Hobbs, G. W., Smith, R. T., Winkler, P. M., Hendricks, D. M., Mutzbauer, T. S., Müller, P. H. J. and Vann, R. D. (1999). Testing and Evaluation of the Divers Alert Network Closed Circuit Oxygen Breathing Apparatus ($REMO_2$). Duke University Medical Center, Durham, NC.

[8] Hunter, J., Olson, L. G. (1988). Performance of the Hudson Multi-vent oxygen mask. *The Medical Journal of Australia*, 148, 444-447.

[9] Milross, J., Young, I. H., Dennelly, P. (1989). The oxygen delivery characteristics of the Hudson Oxy-one face mask. *Anaesth Intens Care*, 17, 180-184.

[10] Boumphrey, S. M., Morris, E. A. J., Kinsella, S. M. (2003). 100% Inspired oxygen from a Hudson mask - a realistic goal? *Resuscitation*, 57, 69-72.

[11] Jeffrey, A. A., Warren, P. M. (1992). Should we judge a mask by its cover? *Thorax*, 47, 543-546.

[12] Waldau, T., Larsen, V. H., Bonde, J. (1998). Evaluation of five oxygen delivery devices in spontaneously breathing subjects by oxygraphy. *Anaesthesia*, 53, 256-263.

[13] Siggaard-Andersen, O., Wimberly, P. D., Fogh-Andersen, N. and Gothgen, I. H. (1988). Measured and derived quantities with modern pH and blood gas equipment: calculation algorithms with 54 equations. *The Scandinavian J of Clinical & Laboratory Investigation*, 48, Suppl. 189, 7-15.

[14] Jones, H. A., Turner, S. L., Hughes, J. M. B. (1984). Performance of the Large-reservoir oxygen mask (ventimask). *The Lancet* 1427-1431.

[15] Wexler, H. R., Levy, H., Cooper, J. D., Aberman, A. (1975). Mathematical model to predict inspired oxygen concentration: description and validation. *Canad . Anaesth . Soc. J.*, 22, 410-416.

[16] Hinkelbein, J. G. E., Doerrstein, J., Genzwuerker, H. V. (2006). Oxygen delivery comparison of two constant-flow masks during flight to 6863 m. *Aviat Space Environ Med.* 77, 540-544.

[17] Brobeck, J. R. (1979). Best and Taylor's physiological basis of medical practice. 10th ed. The Williams and Wilkins Company, p 6-10.

Annex A Subject Physical Characteristics

ID	Sex	Age	Weight	Height
		year	*kg*	*cm*
S01	Male	52	70.3	170
S02	Male	53	70.3	174
S03	Male	44	72.6	174
S04	Male	33	88.5	183
S05	Male	42	70.3	170
S06	Male	41	91.6	183
S07	Male	43	75.5	175
S08	Male	39	81.6	173
Mean		43.4	79.6	175
SD		6.6	8.5	5

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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.
- Arterial O_2 blood saturation goes below 85%.
- Total pure O_2 breathing duration reaches 2.5 hours.
- Loss of O_2 supply.
- Loss of room ventilation.
- Inhaled O_2 fraction goes below 21% or inhaled O_2 partial pressure goes below 156 mm Hg.
- Excessive breathing resistance (peak inhale or exhale pressures no greater than ± 15 cm H_2O).
- Signs of subject hyperventilation.
- Any other event at the discretion of the Run Director, e.g., loss of data acquisition.

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List of symbols/abbreviations/acronyms/initialisms

ALT	Altitude
ANOVA	Analysis of Variance
BL	Business Line
BTPS	Body temperature and pressure, saturated
CF	Canadian Forces
CO_2	Carbon dioxide
DAQ	Data acquisition
D H Svcs Ops	Directorate of Health Services Operations
DRDC	Defence R&D Canada
f_AX	Alveolar fraction of gas X (O_2 or CO_2)
$f_{ET}X$	End-tidal fraction of gas X (O_2 or CO_2)
f_IX	Inhaled fraction of gas X (O_2 or CO_2)
f_mX	Instantaneous fraction of gas X (O_2 or CO_2)
Ft	Foot
GL	Ground level
HiOx	Pulmanex® Hi-Ox® mask
HREC	Human Research Ethics Committee
Hz	Hertz
kPa	Kilo Pascal
L/min	Litres per minute
mmHg	Millimetre of mercury
O_2	Oxygen
P_a	Barometric pressure
pp_IA	Inhaled partial pressure of gas A (O_2 or CO_2)
$pp_{ET}A$	End-tidal partial pressure of gas A (O_2 or CO_2)
Q_{O2}	Supply (or supplemental) oxygen flow rate
R&D	Research & Development
RQ	Respiratory quotient
SaO_2	Arterial blood oxygen saturation
SD	Standard deviation

STPD	Standard temperature and pressure, dry
$\dot{V}_E$	Minute ventilation (expiratory gas flow)
$\dot{V}_I$	Inspiratory gas flow
$\dot{V}_{O_2}$	Actual volume flow of supplemental oxygen (depends on *Pa*)
$\%O_{2\text{-air}}$	Oxygen fraction in air (= 0.2095)

Other subscripts

Eq.2	Calculated from Equation 2
ET	End-tidal
I	Inhaled
peak	Maximum or peak value

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DRDC Toronto was tasked by the Canadian Forces Health Services Group Headquarters (CF H Svc Gp HQ) to verify that the Pulmanex® Hi-Ox® mask system (HiOx) is suitable, safe and efficient for use in aircraft at cabin altitudes up to 8000 feet (ft). The objective is to use the HiOx mask to provide oxygen (O_2) to patients during aeromedical evacuation. Performance and safety were compared at ground level and 8000 ft and at four different O_2 flow rates (0, 2, 4 and 6 litres per minute (L/min)). An experiment was conducted by eight male volunteers inside the hypobaric chamber of DRDC Toronto. Subjects were at rest in a seated position. The data showed that it is possible to use the HiOx safely for aeromedical evacuation at 8000 ft with relatively low O_2 flows. The HiOx at altitude, like at ground level, significantly increased the blood O_2 saturation at as little as 2 L/min. The oxygen partial pressure of the inhaled mixture showed that the HiOx would require an increase to the O_2 supply flow rate at altitude to provide equivalent oxygen treatment as that at ground level. However, as demonstrated in previous studies, the O_2 requirement at any altitude would be substantially less than with traditional oxygen masks, thereby extending the duration of supplemental oxygen and enabling the use of miniature O_2 concentrators.

RDDC Toronto a été chargé par le Quartier général du Groupe des Services de santé des Forces canadiennes (QG Gp Svc S FC) de vérifier si le masque Pulmanex^{MD} Hi-Ox^{MD} (HiOx) était adapté, sûr et efficace dans les aéronefs à des altitudes cabine pouvant atteindre 8000 pieds (pi). L'objectif est d'utiliser le masque HiOx pour administrer de l'oxygène (O_2) à des patients durant une évacuation aéromédicale. Nous avons comparé la performance et la sécurité du masque au niveau du sol et à 8000 pieds d'altitude et pour quatre débits d'O_2 (0, 2, 4 et 6 litres par minute (L/min)). L'expérience a été menée chez huit volontaires de sexe masculin à l'intérieur d'un caisson hypobare de RDDC Toronto. Les sujets étaient au repos en position assise. Les données ont montré qu'il est possible d'utiliser en toute sécurité le HiOx pour une évacuation aéromédicale à 8000 pieds avec des débits d'O_2 relativement faibles. En altitude, comme au niveau du sol, le HiOx a nettement augmenté la saturation du sang en O_2 et ce, à un débit aussi faible que 2 L/min. D'après la pression partielle d'oxygène du mélange inhalé, il faudrait augmenter le débit d'alimentation en O_2 du HiOx en altitude pour offrir une oxygénothérapie équivalente à celle dispensée au niveau du sol. Toutefois, comme l'ont démontré des études antérieures, les besoins en O_2 à n'importe quelle altitude devraient être inférieurs avec le HiOx qu'avec les masques à oxygène classiques, ce qui devrait prolonger la durée de l'oxygénation d'appoint et permettre d'utiliser des concentrateurs d'O_2 miniatures.

14. KEYWORDS, DESCRIPTORS or IDENTIFIERS (Technically meaningful terms or short phrases that characterize a document and could be helpful in cataloguing the document. They should be selected so that no security classification is required. Identifiers, such as equipment model designation, trade name, military project code name, geographic location may also be included. If possible keywords should be selected from a published thesaurus, e.g. Thesaurus of Engineering and Scientific Terms (TEST) and that thesaurus identified. If it is not possible to select indexing terms which are Unclassified, the classification of each should be indicated as with the title.)

Pulmanex Hi-Ox; Aeromedical evacuation; Oxygen therapy

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