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Performance of a Portable Oxygen Breathing System at 25,000 Feet Altitude

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16. Abstract

A portable oxygen system utilizing open port dilution rebreathing mask technology was tested for its ability to deliver an adequate supply of oxygen at an altitude of 25,000 feet above sea level. Twenty-two subjects, 11 females and 11 males, participated in the study. Blood oxygen saturation (SaO_2) baseline levels for hypoxic exposure were established for each subject. Altitude testing consisted of the subject being placed in a hypobaric chamber and it being decompressed to an altitude of 25,000 feet. Immediately after the start of the decompression, the subject was instructed to don the oxygen mask and start the flow of oxygen from the portable cylinder. Oxygen flow to the mask was continuous at 4 liters per minute. Once at altitude, the subjects pedaled a cycle ergometer at a resistance of 15 watts for five minutes. SaO_2 and other physiological variables were monitored throughout the altitude exposure. SaO_2 levels were maintained at ground level values for all subjects throughout the altitude exposures. At no point during the testing did oxygenation levels approach baseline levels for hypoxic exposure. The portable oxygen system tested provided protection from hypobaric hypoxia at an altitude of 25,000 feet.

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PERFORMANCE OF A PORTABLE OXYGEN BREATHING SYSTEM AT 25000 FEET ALTITUDE

INTRODUCTION

The amount of oxygen relative to the total amount of atmospheric gases remains constant at approximately 21.0% to altitudes of approximately 300,000 feet. Ascent to altitude results in a drop of the atmospheric pressure. Therefore, the partial pressure of oxygen available to the body decreases. Both cognitive and physical performance deficits are known to occur as a result of altitude exposures above 14,000 feet (1, 2). To prevent the effects of hypoxia, the Federal Aviation Regulations require supplemental oxygen aboard aircraft. Portable systems have been designed to provide the flight crew with the ability to move throughout the cabin during conditions in which oxygen availability has been decreased. These systems are also used to provide supplemental oxygen to passengers suffering cardiovascular or respiratory distress in flight.

Numerous manufacturers build or assemble small, lightweight, self-contained oxygen breathing systems for use in the aviation environment. These systems normally consist of a small cylinder of oxygen mounted in a carrying strap for portability. The oxygen is delivered to the user through a continuous flow regulator attached to appropriate delivery tubing and mask assembly. When equipped with an open port dilution rebreathing type of mask, the systems are required to maintain tracheal oxygen partial pressures of 100 mmHg when breathing 15 liters/minute standardized to body temperature, ambient barometric pressure, and saturated with water vapor (BTPS) under nonpressurized conditions (3, 4). This type of portable system is versatile, in that it can be altered to fit specific operational requirements by varying the volume of oxygen available, the number of regulator outlets, connectors, and type of constant flow mask utilized.

Performance requirements for this type of oxygen system aboard transport category aircraft are covered under Federal Aviation Regulation (FAR) Part 25.1443, Section a (3). Prior to use aboard an aircraft, equipment performance must be certified, consistent with federal regulations. Testing procedures for continuous flow oxygen systems used in aviation have been standardized. They are described in Technical Standard Order (TSO) C103 – Continuous Flow Oxygen Mask Assembly (For Non-Transport Category Aircraft) (5) that references Society of Automotive Engineers Aerospace Standard (AS) 1224A – Continuous Flow Aviation Oxygen Masks (For Non-Transport Category Aircraft) (4). If the manufacture or assembly of a piece of equipment or system has the potential to alter performance, additional certification tests may be required before the equipment is approved for use aboard aircraft. Alterations in one manufacturer's (O_2 Corporation, Wichita, KS) production of delivery tubing and rebreathing apparatus utilized in a portable oxygen system resulted in the FAA Wichita Aircraft Certification Office (ACO) requesting additional certification test support from the hypobaric facilities within the Protection and Survival Laboratory at the FAA Civil Aeromedical Institute (CAMI). The purpose of the tests was to identify performance capabilities of the modified portable oxygen system in the context of existing standards. The project was conducted as a component of the FAA Aeromedical Research program.

METHODS

Test Subjects: Test subjects were drawn from recruits that had previously participated, or expressed interest, in altitude research studies at CAMI. Subjects were recruited and paid through a contract agreement with Aero Tech Service Associates (Oklahoma City, OK). Prior to participation, each subject completed a familial medical history and cardiovascular risk assessment questionnaire. The subjects were required to pass the functional equivalent of a Class III physical exam at the CAMI clinic. A total of 22 subjects participated in the testing. The group consisted of 11 males and 11 females between the ages of 18 and 30. No specific ethnic background or prior specialized training was required. Pregnancy

was a disqualifying characteristic for the female participants. Recruits were fully informed of the details of the study, including risks inherent to altitude exposure, before giving informed consent for participation in the testing. Subjects were free to withdraw from participation in the testing at any time without penalty. All test protocols and consent forms were reviewed and approved by the CAMI Institutional Review Board (IRB) for human subject use.

Oxygen Equipment: The portable oxygen equipment tested consisted of the delivery tubing, rebreathing apparatus, and open port dilution mask assembly distributed by O_2 Corporation attached to oxygen cylinders sold by Scott Aviation (Buffalo, NY) and Puritan Bennett Aero Systems (Lenexa, KS). Each cylinder contained approximately 22 ft^3 of oxygen when fully charged.

Monitoring Equipment: The primary monitoring equipment used in this study was a pulse oximeter (Nellcor, model N-200). This provided continuous measurement of blood oxygen saturation (SaO_2) and heart rate (HR) during all testing. During tests utilizing hypoxic gas mixtures, end tidal oxygen ($PetO_2$) and carbon dioxide ($PetCO_2$) values were collected using fast responding gas analyzers (Applied Electrochemistry, S-3A/II and CD-3A, respectively). Transcutaneous pressures of oxygen ($PetO_2$) and carbon dioxide ($PetCO_2$) were monitored using a Sensormedics Transend II. $PetO_2$ and $PetCO_2$ values were recorded from a mass spectrometer (Marquette, MGA-1100) during altitude tests. A Novametrix System 800 was used to record transcutaneous gas pressures at altitude. Each subject's electrocardiogram (Marquette, MAC 6) was also monitored during altitude exposures. Electronic signals from the measurement instruments were collected using a digital computer (Intel architecture) and data acquisition boards (National Instruments, AT-MIO-16F and AT-MIO-64F). The data collection programs were written using the LabVIEW graphical programming environment (National Instruments).

Test Protocol: At least 24 hours prior to altitude testing, subjects had their SaO_2 response to a hypoxic stimulus measured. The SaO_2 values obtained were used as a baseline reference of each individual's response to hypoxia. All baseline data were collected with the subject in a seated position at rest. For the baseline tests, the subject breathed compressed gas mixtures through diluter demand regulators (Type CRU 68/A) set to the 100% oxygen position. Regulator flows were directed through a multidirectional flow valve to allow immediate manual switching among gas mixtures. The subject breathed different gas mixtures through the regulator-based breathing system using a unidirectional breathing valve (Hans Rudolf, Kansas City). Ground level exposure (Oklahoma City, approximately 1300 feet above sea level) initiated the baseline tests. At 4 minutes, the inspired gas was switched to a mixture consisting of 14.4% oxygen. Physiological variables were monitored for 4 minutes and until steady state levels were observed. The breathing gas was then switched to a 13.1% oxygen/nitrogen mixture for 4 minutes. The subject was then switched back to breathing ambient air. The values obtained were taken to represent the altitude exposures of 10,000 and 12,500 feet, respectively.

The reference guidelines for this testing require that SaO_2 and tracheal PO_2 estimates be maintained at required levels. Failure of the breathing system to maintain these physiological parameters at any point during the altitude tests required immediate termination and an analysis of failure given for that particular test trial of the system being evaluated. The performance tests for the portable oxygen breathing equipment required the subject be taken to a simulated altitude of 25,000 feet in the hypobaric chamber. The first step in this process was a check to verify that the subject could clear ear and sinus passages. This consisted of decompressing the hypobaric chamber to an altitude of 5,000 feet. Upon successful completion of the ear and sinus check, the subject was instrumented with transducers required to make the necessary test measurements. Testing consisted of the hypobaric chamber initially being decompressed to an altitude of 7,000 feet above sea level. This pressurization level was maintained for five minutes. The chamber was then decompressed at a rate of 12,500 feet per minute to an altitude of 25,000 feet above sea level. At a simulated altitude of 10,000 feet, the subject was instructed to don the portable oxygen system's mask and start the flow of oxygen from the cylinder. An oxygen flow rate of 4 liters per minute was used for all tests. Upon reaching the 25,000 feet altitude, the subject was instructed to begin self-paced pedaling of a cycle ergometer at a work rate of 15 watts to mimic movement in an aircraft cabin.

The subject was monitored for 5 minutes at altitude. At the end of 5 minutes, descent commenced at a rate of 2,500 feet per minute until ground level was reached.

RESULTS

None of the 25K altitude exposures had to be terminated prematurely due to a decrease in SaO_2, which would indicate the presence of hypoxia in a subject. All monitored variables remained within the expected range during altitude exposures. The data are summarized in Figures 1-7. Each figure contains two panels. Panel A contains the female subject data collected from the tests; panel B represents the male subject data. Data from both altitude exposure and ground level hypoxia are presented on each panel.

Summary graphs of SaO_2 levels, grouped by female and male responses, are presented in Figure 1. The data points in this, and other figures, represent minute averages ± 1 standard deviation. Due to adaptive responses resulting from physiological control systems and delays associated with equipment response times, the most representative comparisons can be made between minutes 2 and 5 of the 25K altitude exposure using the portable oxygen system and the last 2 minutes of the hypoxic conditions created using mixed gases. As expected, exposure to the mixed gases resulted in a decrease in SaO_2. The 14.4% oxygen mixture resulted in an average SaO_2 of 93.5% in both females and males between minutes 2 and 4 of exposure. The 13.1% oxygen gas mixture resulted in an average SaO_2 of 90.0% for females and 89.7% for males between minutes 2 and 4. Exposure to a simulated altitude of 25,000 feet while using the portable oxygen system resulted in SaO_2 levels of 98.5% and 97.7% for females and males, respectively, between minutes 2 and 5 at altitude. These SaO_2 levels are consistent with values expected in healthy humans at or near sea level. The male subjects SaO_2 responses appeared more variable than the females for all conditions tested.

Heart rate responses were consistent with what one would expect, given the experimental protocol used in the tests (Figure 2). At rest, the average female heart rate was slightly higher than the males. Both groups' heart rate increased with the hypoxic stimuli. The increased heart rate observed during altitude exposure is indicative of the low-level exercise task the subjects were required to perform. This response may have been somewhat attenuated by the high oxygen levels while breathing from the portable system.

Ventilatory frequencies during the tests are presented in Figure 3. During the baseline hypoxia exposures, the trend was for the females to have a slightly higher ventilatory rate than the males. This pattern was not as clear during altitude exposure. Both females and males demonstrated a slight increase

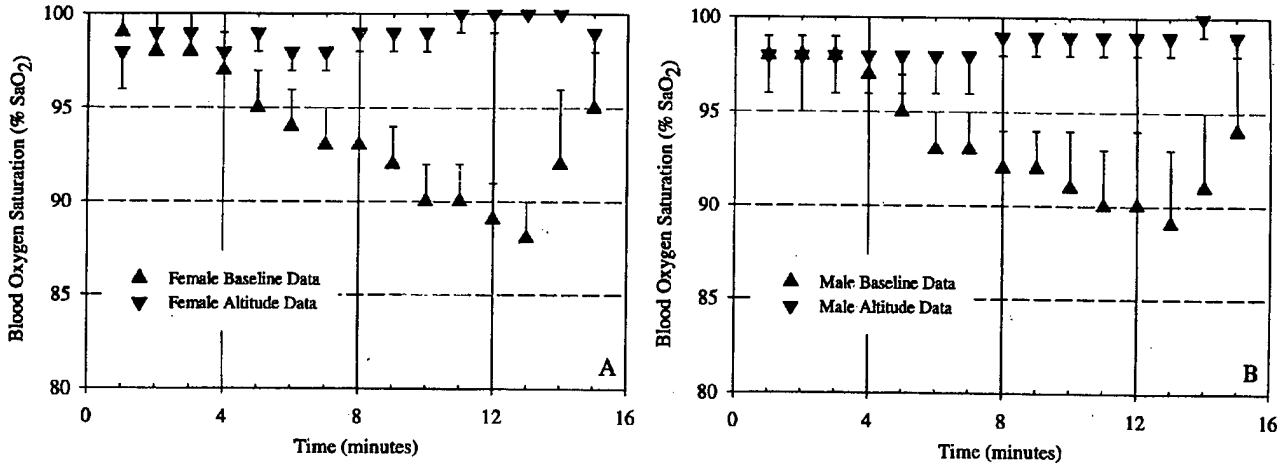

Figure 1. Subject SaO_2 responses during the different test scenarios. The data clearly indicate that Sa O2 levels were maintained during altitude exposure using the portable oxygen system. Panel A – Females. Panel B – Males. The points and bars represent the average, ± 1 standard deviation.

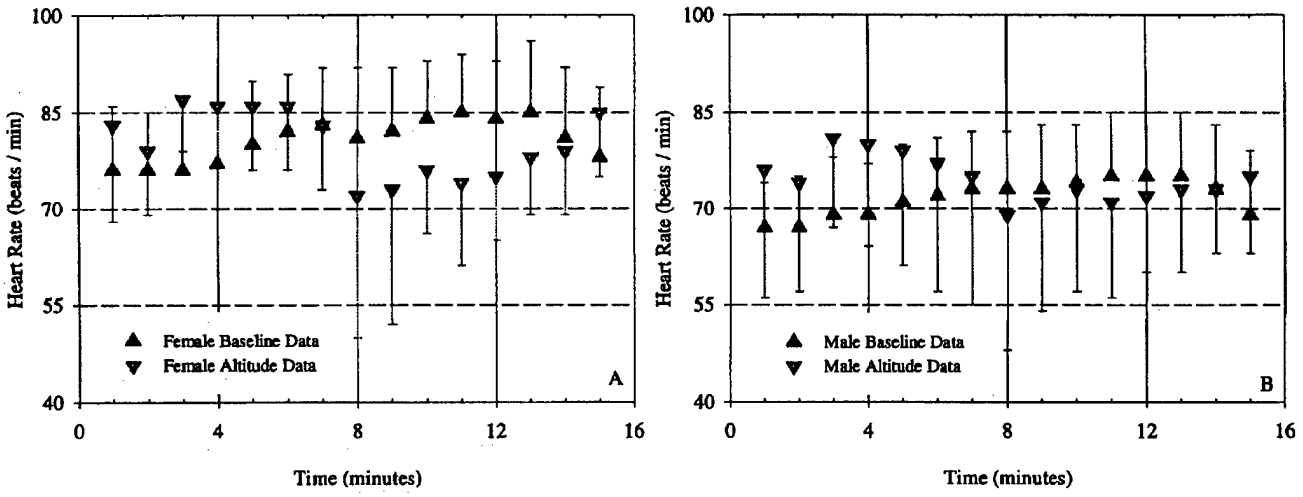

Figure 2. Heart responses during the experimental treatments. Panel A – Females. Panel B – Males. The points and bars represent the average, ± 1 standard deviation.

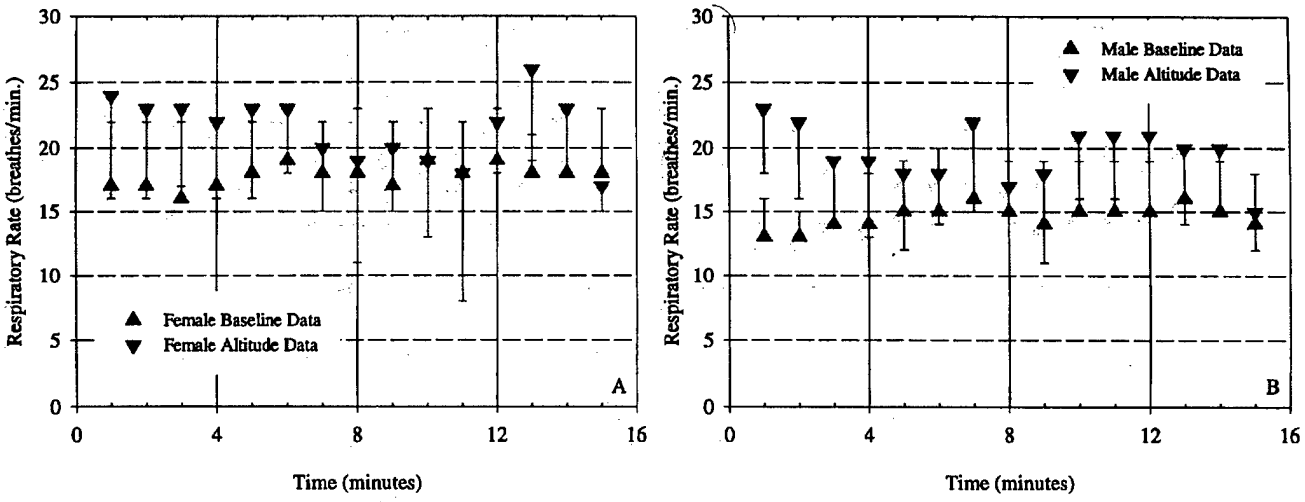

Figure 3. Breathing frequency during the different test periods. The points and bars represent the average, ± 1 standard deviation.

in ventilatory rate while breathing the hypoxic gas mixtures. Subjects' ventilatory frequency tended to be increased in the first minute of altitude exposure. The contrast with rest while breathing air with atmospheric oxygen concentration was particularly pronounced in the male subjects. The first minute of data collection represents the time after the subjects have donned the mask and the hypobaric chamber was still being decompressed towards the final altitude of 25,000 feet.

Ventilatory rates were tallied from end-tidal readings of oxygen ($PetO_2$) and carbon dioxide ($PetCO_2$). These data are expressed as percentages of O_2 and CO_2 in Figures 4 and 5, respectively. The oxygen data are very consistent for both groups during the baseline tests and predict the SaO_2 data exceptionally well. $PetO_2$ values were at 8.9% during the last minute exposure to the 14.4% oxygen/nitrogen mixture and 7.8% during the last minute of exposure to the 13.1% oxygen/nitrogen mixture. This is indicative of lung oxygen partial pressures of approximately 65 and 58

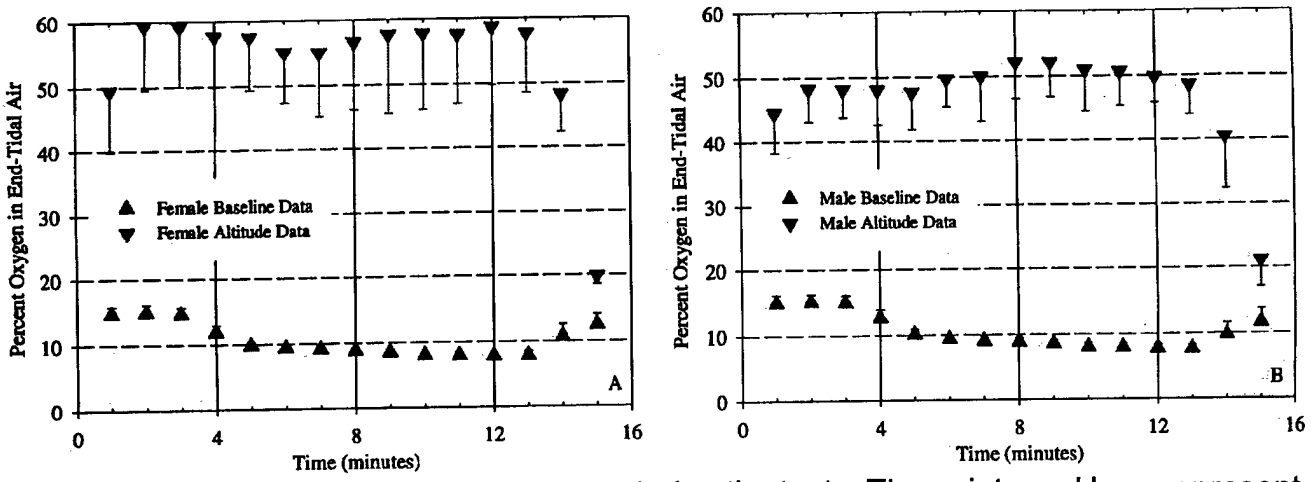

Figure 4. End-tidal oxygen data collected during the tests. The points and bars represent the average, ± 1 standard deviation.

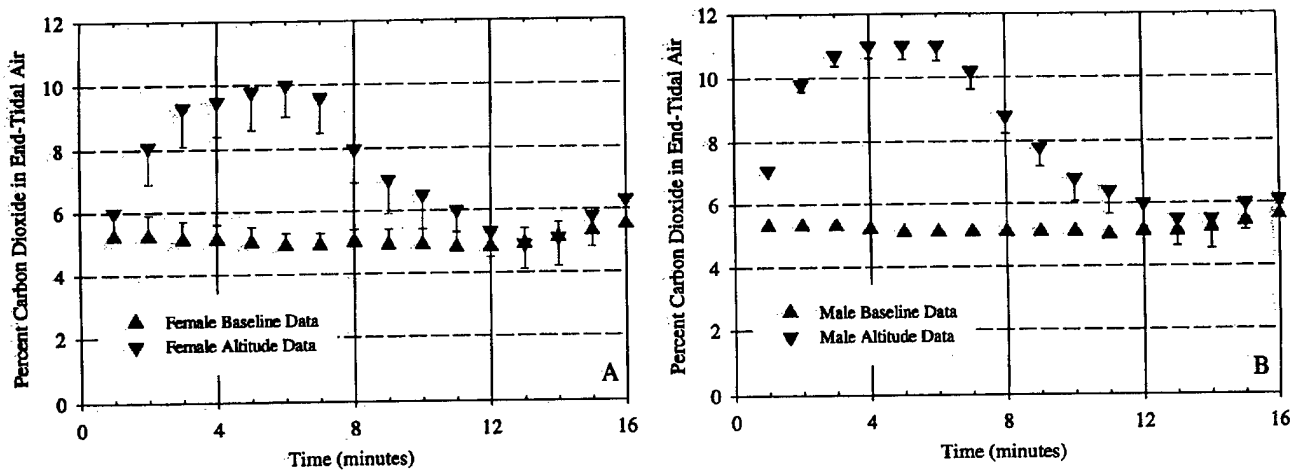

Figure 5. PetCO2 data collected during the test periods. The points and bars represent the average, ± 1 standard deviation. Where the bars are not present, the standard deviation was below a level demonstrable on the scale of the graph.

mmHg, respectively. The oxyhemoglobin dissociation curve predicts that PO_2 values of 65 and 58 would result in SaO_2 values of 93 and 90. These values are consistent with the test data. As anticipated, there were large fluctuations in $PetO_2$ at altitude using a continuous flow oxygen system and open port dilution mask. The average value was between 50 and 60% O_2 for females and consistently near 50% O_2 for males. At an altitude of 25,000 feet, this represents an alveolar PO_2 of approximately 140 mmHg and is consistent with SaO_2 values being maintained at ground level values.

$PetCO_2$ data were consistent with physiological responses anticipated under the test conditions. It increased during the mild exercise at altitude and demonstrated a slight decrease during the mixed gas exposures. This probably reflects a mild hyperventilation resulting from the hypoxic stimulus. In addition to end-tidal values, transcutaneous partial pressures of O_2 and CO_2 were also tracked.

$PtcO_2$ and $PtcCO_2$ measures are qualitative at best. The values are best used to track changes or trends. Therefore, to allow meaningful grouping of individual responses, the average value from the first

minute was divided into all subsequent time averages to normalize the transcutaneous data. The results are presented in Figures 6 and 7. The $PtcO_2$ data did track $PetO_2$ in form during the hypoxia baseline tests. $PtcO_2$ increased during the simulated altitude exposure in the hypobaric chamber. This response was particularly pronounced during the descent from altitude period of the test and is consistent with the high $PetO_2$ observed coupled with an ever-increasing atmospheric pressure associated with descent from altitude. Even though the pattern is consistent with the $PetO_2$ data, the high individual to individual variability in this measurement is clearly demonstrated by the size of the error bars in figure 6.

$PtcCO_2$ demonstrated the same pattern as the $PtcO_2$ data, in that the $PtcCO_2$ response generally followed $PetCO_2$ data during the baseline tests and was highly variable during altitude testing. $PtcCO_2$ did tend to be decreased during the time spent at 25,000 feet. This is consistent with the increased $PetCO_2$ observed (Figure 5).

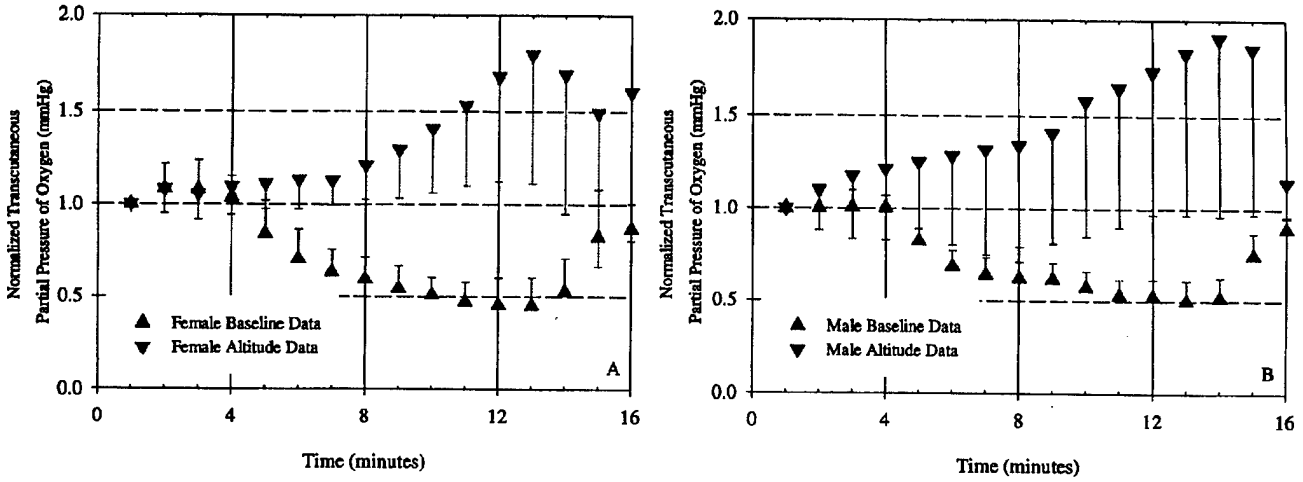

Figure 6. $PtcO_2$ data collected during the test periods. The points and bars represent the average, ± 1 standard deviation.

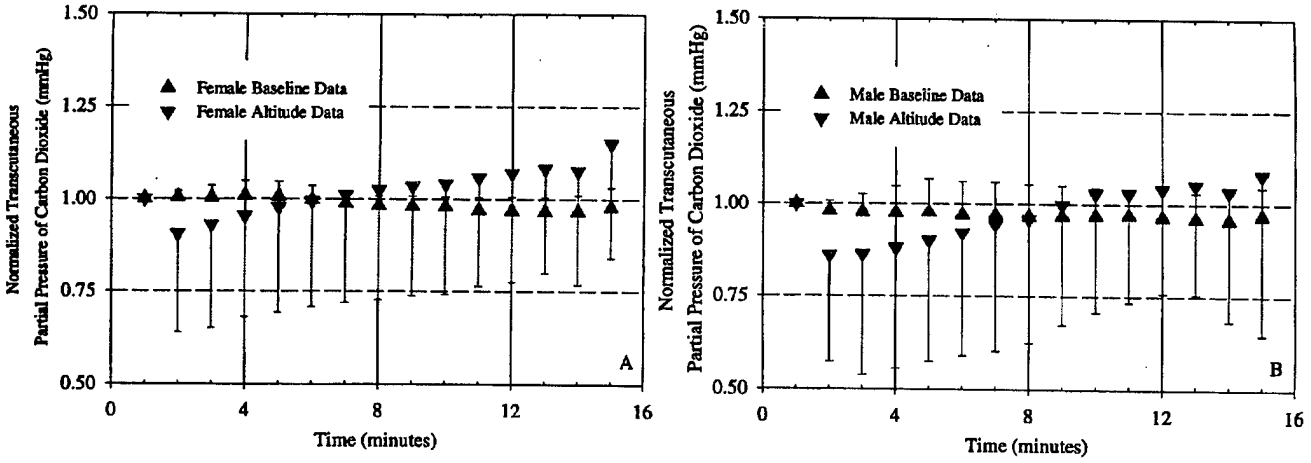

Figure 7. $PtcCO_2$ data collected during the test periods. The points and bars represent the average, ± 1 standard deviation.

DISCUSSION

The aviation industry is expected to see continued growth in the coming decades. Many current aviation safety equipment designs will remain on aircraft. Undoubtedly, new and/or improved components will continue to be incorporated into these systems, since the ability of innovators to develop and modify systems to be more efficient or cost-effective in accomplishing a given task has limitless potential. The difficulty for the FAA, or other aviation regulatory organizations, is making the determination as to whether or not a given change has the potential to result in a substantive alteration in the performance of the equipment. Any modification to an aviation safety system must be evaluated on its own merits. If there appears to be a question as to the ability of a safety device to function properly, the equipment should be thoroughly tested in a manner consistent with its intended use and existing regulatory standards. Alterations in the production and assembly of an open port dilution system led to this series of tests to determine if performance capabilities were maintained at an altitude of 25,000 feet.

Open port dilution masks are described in AS 1224A (4). This type of mask is fed by a rebreather bag that works to catch oxygen rich air previously contained in dead space volumes associated with the previous breath. The air in the rebreather bag can then be inhaled into the gas exchanging regions of the lung during the next breath. The inhaled air is diluted with ambient air that flows in through holes designed into the body of the mask. These orifices do not have any type of valve associated with them, thereby allowing the free flow of gas into and out of the mask cavity as a function of the pressure differential between the mask cavity and the ambient environment. This arrangement is the reason that open port dilution masks are not a highly effective means of supplying supplemental oxygen at altitudes beyond 25,000 to 30,000 feet.

The physiological data collected during the baseline tests were consistent with the responses that would have been anticipated, given the mild hypoxic stimulus presented the subjects (6, 7). The altitude data were consistent with there being a supply of supplemental oxygen sufficient to maintain blood oxygen saturation levels equivalent to ground level conditions. In fact, the data suggest that hypoxia protection would be provided at even higher altitudes while using this equipment at a flow of 4 liters per minute. Previous work, recently performed at CAMI, that evaluated a continuous-flow passenger oxygen mask system supports this contention (8). Additional, more detailed experiments would have to be performed to truly determine the rational safety limits of this type of portable oxygen system.

Equipment testing at altitude must represent a balance between subject safety and determining acceptable performance in an inherently dangerous environment. The dangers of altitude exposure to 35,000 to 45,000 feet often prevent the use of a test protocol consistent with the emergency altitude exposure conditions that the safety equipment is designed to protect individuals against. In contrast, this set of altitude tests was conducted in the context of how the system might be used aboard an aircraft. In theory, a user would don a portable system during the decompression and continue using it until safe cabin/flight altitudes are again achieved. For flight altitudes of 25,000 feet and below, the tested equipment worked very well. The maintenance of oxygenation levels at altitude while using the portable oxygen system indicates that the manufacturer's production changes did not negatively influence the system's ability to provide sufficient supplemental oxygen at an altitude of 25,000 feet.

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