

PERFORMANCE CRITERIA CONSIDERATIONS FOR TRANSPORT AIRCRAFT PASSENGER OXYGEN TECHNOLOGIES

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INTRODUCTION: Passenger oxygen will remain an integral component of transport aviation for the foreseeable future. The implementations of recent technical approaches to improve passenger oxygen delivery efficiency during and after a decompression are often not directly interpretable within the context of regulations. Specifically, the historic approach of developing flow profiles to achieve tracheal oxygen pressures do not necessarily correlate with other approaches that clearly provide sufficient oxygenation at altitude. The applicability of new approaches needs to be better understood by many in terms of the physiological demands and how they are met in terms of the anticipated environment and associated constraints. **METHODS:** Testing of a number of high efficiency passenger oxygen systems for both new and existing transport airframes have been conducted in recent years. Available results and associated model and simulation data are presented in context of extensive discussions on how the results should be assessed. This has been a topic of active debate in both the standards development community and among regulatory agencies. A comparison of the generic aspects of basic continuous flow, reduced flow, and dose dependent delivery schemes is presented within the context of physiological demands anticipated during decompression and subsequent descent. The ramifications of associated assumptions of each are discussed in terms of meeting physiological requirements and regulatory mandates. **DISCUSSION:** The history of aviation is effectively one of continually doing things better. Supplemental oxygen delivery for passengers started in earnest during the early 1950s and attempts to refine and improve associated technologies has continued ever since. The developments of both electronic and pneumatic capabilities in recent years have made possible the optimization not functionally possible 20 or 25 years ago. The technology is potentially applicable to all operational environments where supplemental oxygen might be needed. Therefore, implementation is discussed in consideration of two basic issues. First, the protective goal or requirement that must be specifically identified; second, the quantification of both the capabilities needed and limitation inherent to a given technology in terms of those expectations.

INTRODUCTION

After the turn of the most recent century development of the Boeing 787 transport aircraft was characterized as advanced and visionary. As part of the many development programs designated for this aircraft, the passenger oxygen system was to leverage a high efficiency approach long known to be successful in clinical applications requiring oxygen supplementation ⁽¹⁾. Whereas the historical approach to the passenger system utilized a continuous flow of oxygen either from cylinders or generators, the new system was going to provide an altitude specific volume of oxygen triggered by inspiration. A relatively extensive research and development program defined the performance of a pulse based system for aircraft. Complicating the regulatory performance assessment is the fact that the applicable mandate ⁽²⁾ is written in context of a design standard written for continuous flow systems. After extensive discussions with the FAA, the use of blood oxygen saturation as determined by pulse oximetry (SpO_2) was deemed acceptable as the performance criteria for testing. The successful performance of the 787 system clearly demonstrated that pulse systems were functional as aviation applications. It also brought into question the flow levels previously required. For both operational and marketing reasons, a number of independent development efforts were made to identify and develop “high efficiency” aircraft oxygen systems.

Though numerous aviation equipment manufacturers have reviewed and/or investigated the dose concepts, the simplicity of reducing flow below the arguable excess of existing regulations has received considerable attention. It has been repeatedly demonstrated that for a representatively normally healthy person that a reduction in oxygen flow delivered through the standard passenger mask with reservoir bag can maintain SpO_2 consistent with the higher flows used in the past. Such performance improvements are difficult for some to conceptualize and even when achieved has led to questions and concerns regarding undocumented hypothetical scenarios that might have been considered or driven the original requirements. Such views on the regulatory side has led to manufacturers being requested to develop some construct of equivalence to the higher flow levels different from the historical testing paradigms ^(3,4) for systems submitted for certification. Some of the paradigms suggested are conceptually addressed using modeling techniques originally used in the design and development of the newer high efficiency systems. The intent is to present data and associated results in a contextual framework of performance issues without direct commentary or evaluation regarding current or previous discussions related to specific oxygen systems or technologies.

METHODS

The author has been involved in oxygen system evaluation and development for over two decades. In the course of those experiences both with the Federal Aviation Administration and private industry, modeling tools were developed and customized specific to a variety of applications. A detailed control system model of the respiratory system specific to hypoxic exposures is primary^(5, 6). The other resource used herein is a model specific to the functioning of the passenger oxygen mask and reservoir bag design that is effectively ubiquitous to transport category aircraft. Every attempt has been made to make these tools representative of the normal population and results should be considered accordingly. Limited populations (e.g., younger children, pathologic states, smoking and similar activities known to result in respiratory impairments) would have to be considered separately with the appropriate physiological characteristics set accordingly. The limited human subject response data that is presented was gathered from reports of passenger oxygen system testing at altitude. All testing was conducted with appropriate internal review board approval and granting of informed consent by participants.

Many regulations mandate a tracheal partial pressure of oxygen (P_{trO_2}) as a performance reference for providing supplemental oxygen. Alternatively, options do exist for the use of SpO_2 . The latter approach has been used predominantly in recent decades and it is the variable presented for comparison in the figures.

The information presented is in context of development or qualification efforts related to passenger oxygen system design concepts and associated performance that are characteristically different from the those used in the past in terms of the effectiveness of oxygen delivery. It is reflective of conceptual approaches that have received consideration by various manufacturers in discussions with either the Federal Aviation Administration (FAA) or European Aviation Safety Agency (EASA). Fundamental questions have arisen related to equivalent performance of systems in context of existing regulations and standards from the age in which the original passenger oxygen systems were originally being optimized for modern transport aviation and technologies for more precise control and delivery were not available or anticipated. The purpose is to provide an unbiased quantitative framework that provides insights into the physiological responses along with the potential strengths and weaknesses of each approach.

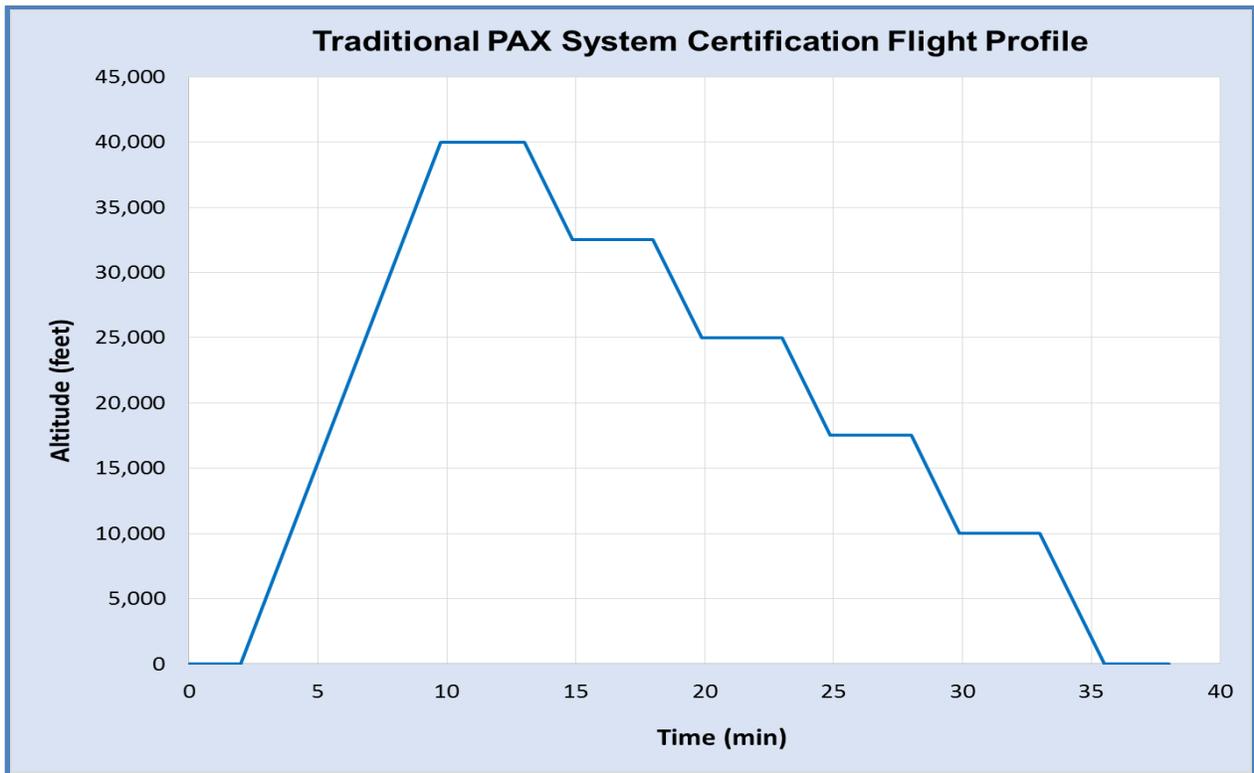


Figure 1A: Traditional PAX System testing profile

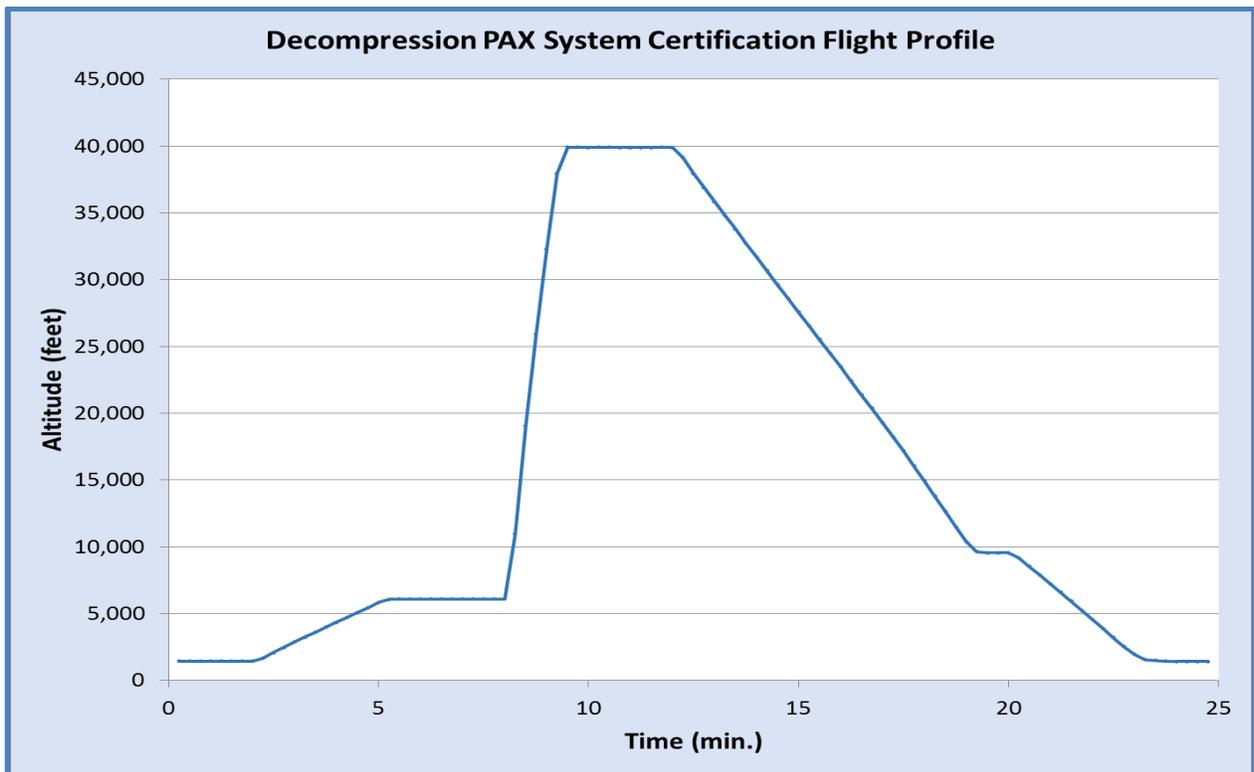


Figure 1B: Proposed PAX System testing profile

Historically, a flight profile similar to that in Figure 1A has been used to evaluate a systems ability to attenuate altitude hypoxia. Considerations of the operational / emergency environment have led to a profile presented in Figure 1B being suggested.

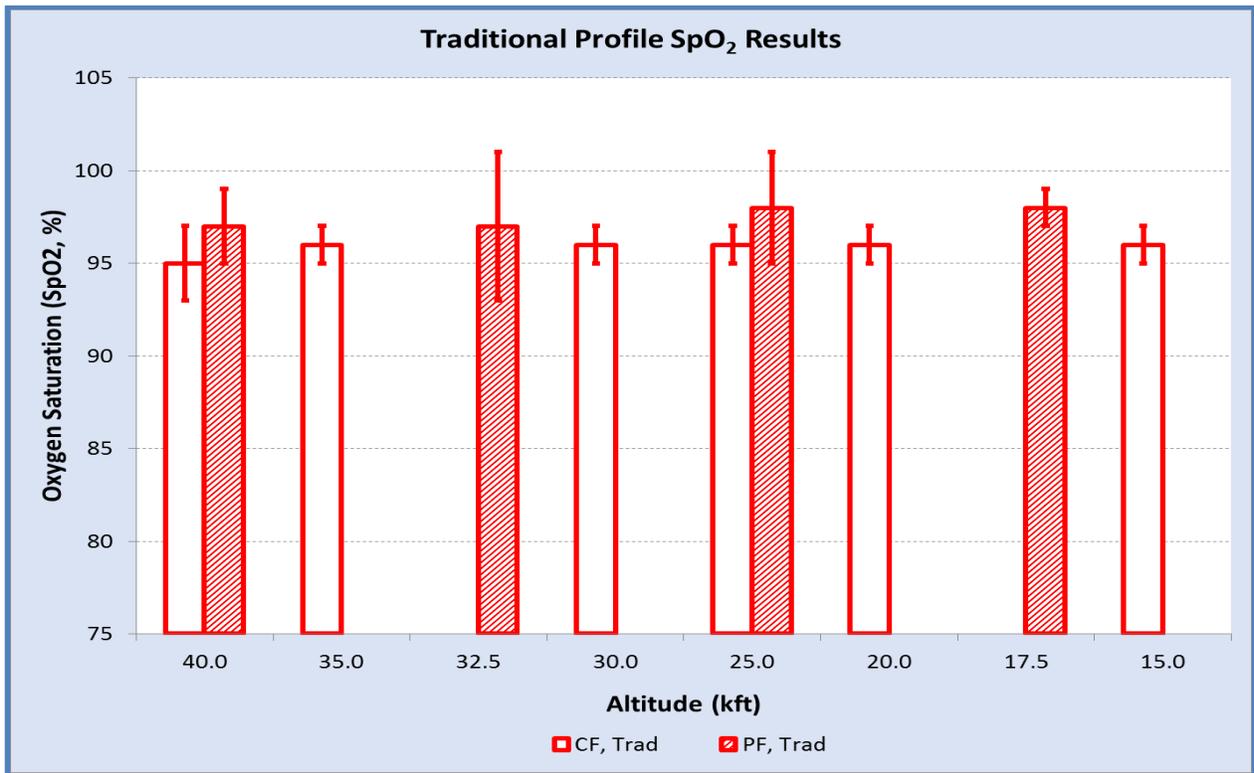


Figure 2A: Results from testing using a traditional step down profile (n=4)⁷.

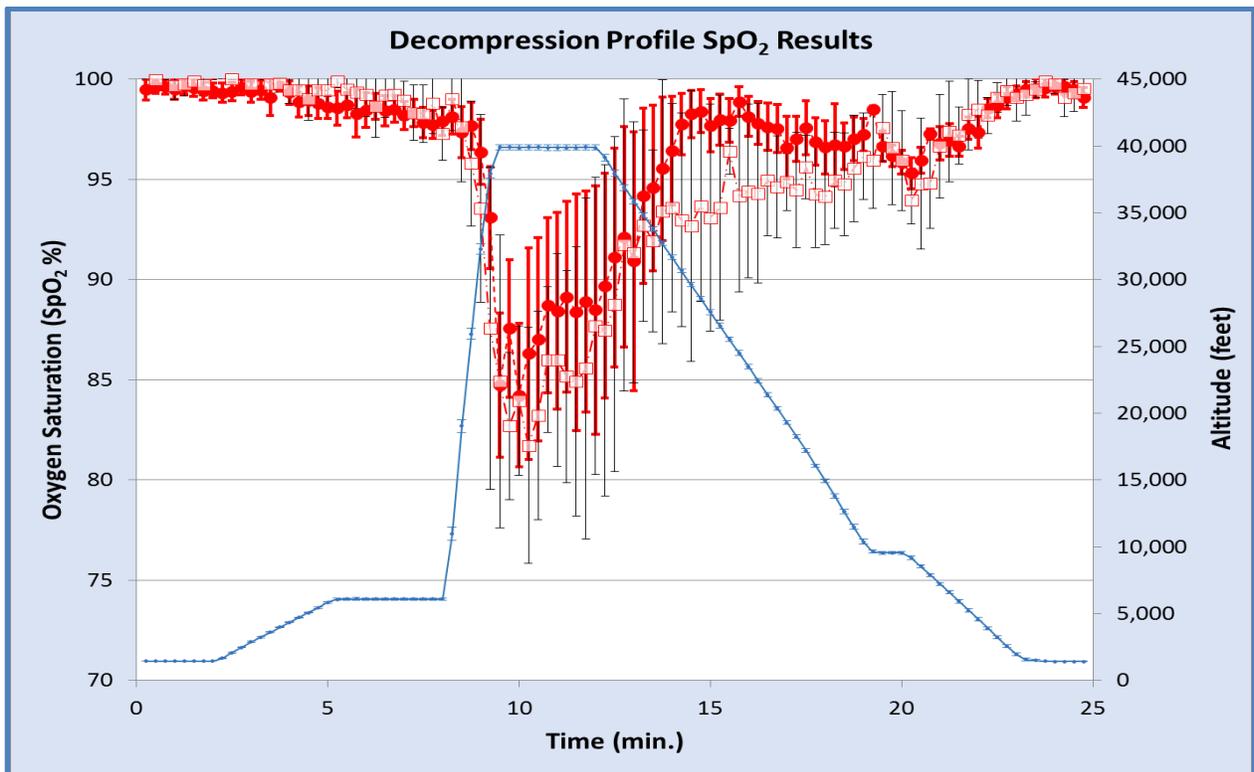


Figure 2B: Results from testing using a decompression profile.

Regardless of profile the results comparing continuous flow and dose delivery systems are very similar. The issue that has become a topic of debate is how to demonstrate such similarities for various “high efficiency” systems currently being proposed while minimizing high altitude exposures.

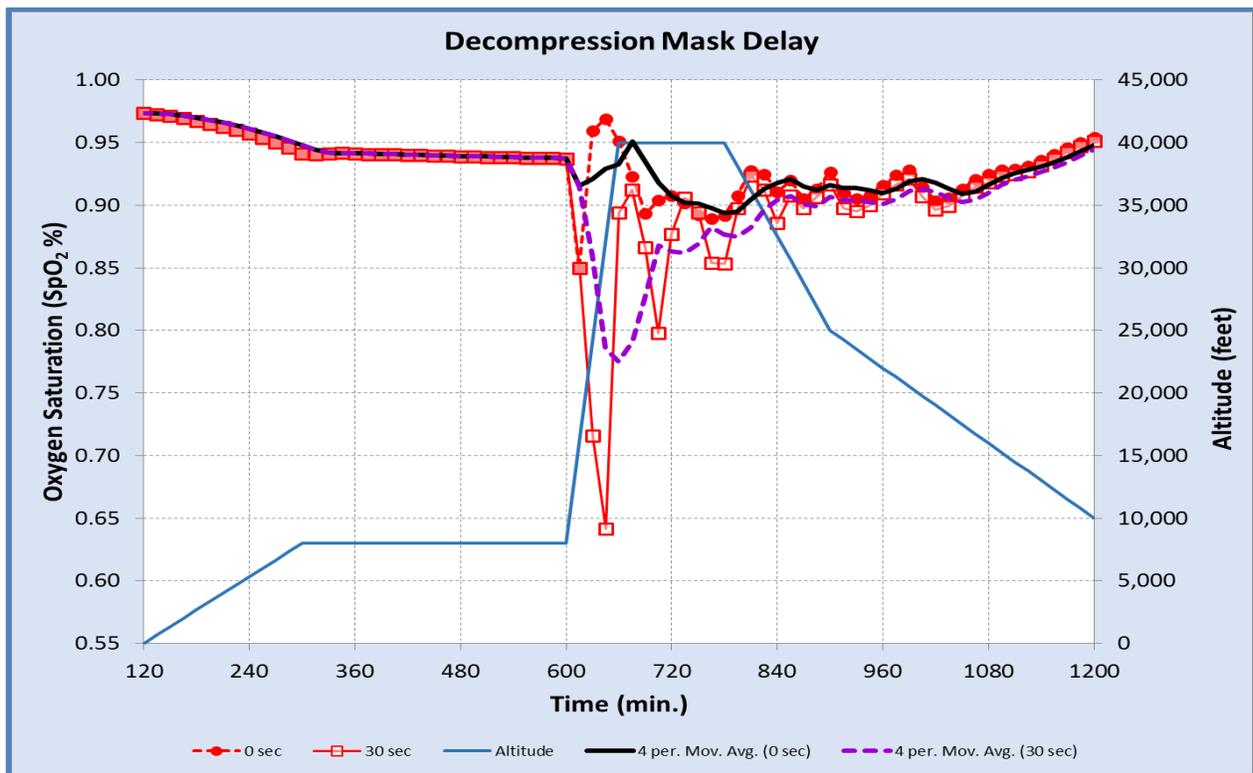


Figure 3: Effect of mask donning delay during decompression to 40kft.

A concern that has been expressed regarding recent “high efficiency” systems relates to the reduction in oxygen flow that is often included in the design. Though the fundamental ability to maintain acceptable levels of oxygenation are clear some in the regulatory communities have hypothesized that any difference in flow may have represented preventative hedge against some undocumented concern in development of the original performance requirements. Before considering potential approaches to this issue, the impact of a delay in providing oxygen during a decompression is present in Figure 3 above. Immediate donning of the mask when it is presented (~14-15kft) does not prevent a drop in SpO₂ during decompression but certainly attenuates the magnitude. The simulation results are relatively consistent with observed responses (Figure 2A). Delaying oxygen administration by 30 seconds results in a precipitous drop in SpO₂ to below 65%. A longer delay might result in incapacitation of the individual. Providing oxygen early is critical to minimizing the impact of aviation altitude exposure. This fact is reflected in regulations requiring the preemptive use of oxygen by flight crewmembers in certain operational scenarios. The exacerbating characteristic is the general pressure loss occurring during the decompression. Is there a means to characterize this dynamic without actually performing a decompression? If not, what would be the most acceptable criteria for demonstrating the equivalence of various technologies in providing supplemental oxygen?

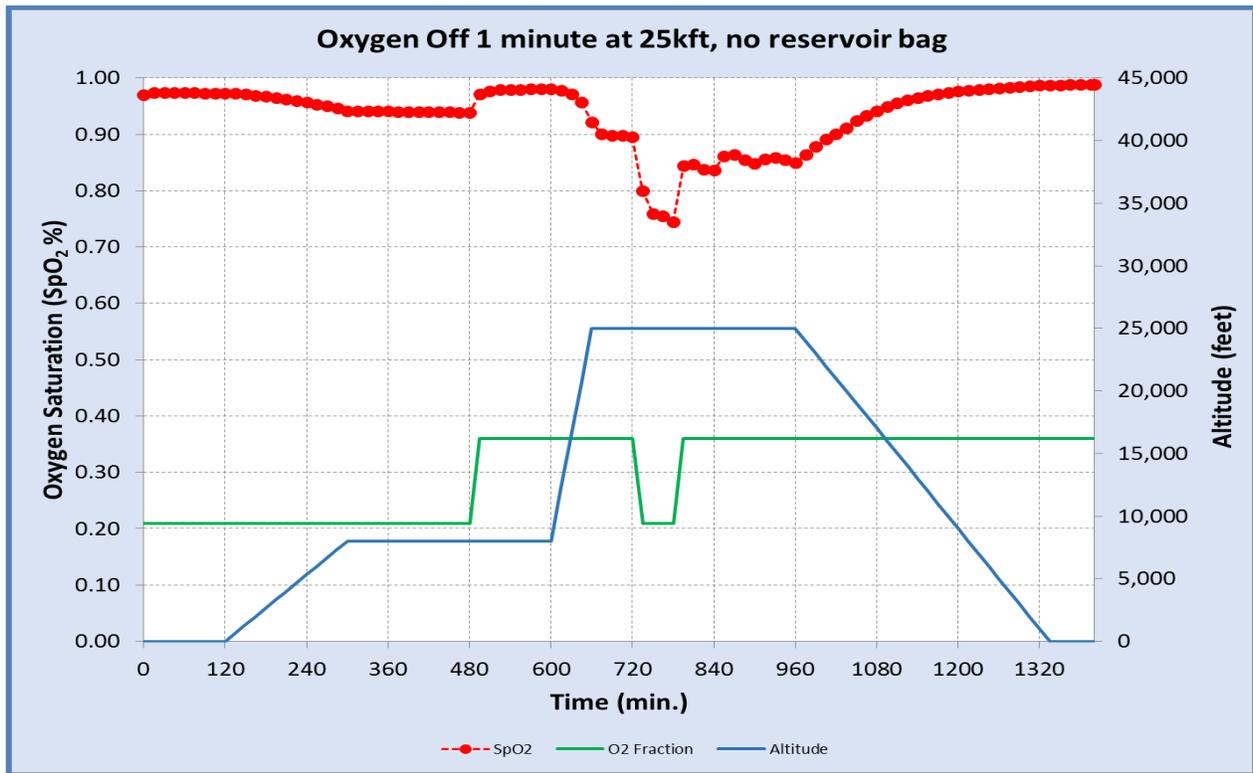


Figure 4: Recovery from an oxygen deficit using a hyperoxic gas mixture.

Currently, the most predominant hypothesis is that the use of excessive flows to prevent basic altitude hypoxia was intended to assist an individual from recovering from any oxygen deficit that may be present as a result of donning delays or other factors. Again, how does one demonstrate equivalence among different systems? Theoretically, the reference P_{rO_2} could be calculated for an altitude of interest and the response from an imposed oxygen deficit considered. As depicted in Figure 4 above one might go to a given altitude providing sufficient oxygen then simply cut the oxygen off for a period of time imposing a drop in SpO₂. A comparison would be made between the recovery characteristics of the two systems under evaluation. A limitation to this approach is that breathing of an oxygen enriched gas mixture is characteristically different (as demonstrated in Figure 5) than breathing 100% oxygen at some flow through a system utilizing a reservoir bag. The little yellow “dixie cup” masks and reservoir bags ubiquitous to transport aviation perform exceptionally for basic delivery of supplemental oxygen. It seems rational that coupling that effective design with material and mechanical changes currently available would result in improvements creating systems that may be more effective in delivering oxygen.

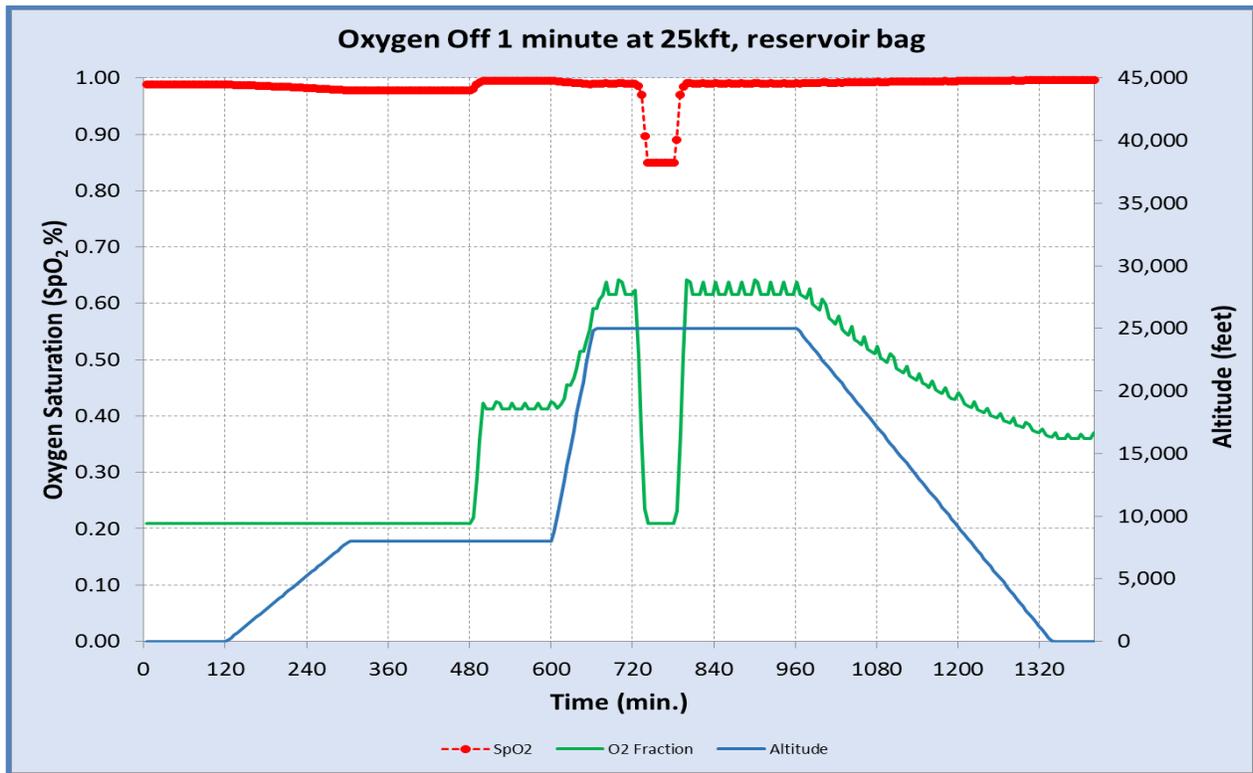


Figure 5: Fractional oxygen delivery using a reservoir bag.

A different approach that may better directly consider performance aspects would be to directly compare the oxygen deliveries under evaluation. An example is presented in Figure 5 above. First, as previously referenced, the use of a reservoir bag results in an elevated inhaled oxygen fraction even though the flows, tidal, and minute volumes were held consistent in the simulations. The reduction in SpO₂ when the oxygen flow is removed remains higher. Increased lung and body stores of oxygen may have contributed but the most significant difference may have been an extra breath or two of oxygen enhanced gas as a function of the reservoir bag. The impact of this as a factor would vary as a function of the tidal volume of the person being tested potentially complicating interpretation of the results. Other issues deserving consideration are the test altitudes. Herein, 25kft has been used since it is the predominant altitude used in basic physiological training readily eliciting hypoxic symptoms while maintaining a relatively high margin of safety. However, there is nothing magically about the altitude and it seems that agreement on one or more altitudes as sufficiently representative to investigate the stated concerns need to be identified.

DISCUSSION

The first pressurized transport aircraft made its initial flight on December 31, 1938 and entered into commercial service in July 1940⁸. Due to the advantages it offered pressurization quickly became the primary protection against hypoxia. Even so it is recognized that pressurization systems can overcome or fail and oxygen systems continue to be developed for provision of supplemental oxygen during decompression for both crew and passengers.

In terms of aviation supplemental oxygen, new technologies are an inherent part of the systems. The approaches offer potential cost and operational benefits. Obviously, these must be realized without sacrificing performance in terms of relative flight safety. This challenge is exacerbated by the fact that many of the design characteristics are inconsistent with existing regulations. In recent years, defining safety equivalence for many new systems has represented a significant challenge for manufacturers and regulators alike. Not that the ultimate goals are characteristically different but that perspectives on any given issue can be open to interpretation based on diverse backgrounds and organizational priorities of those involved.

Information herein represents an attempt to conceptually present a previous approach and others that are currently proposed or being discussed. Manufacturers are effectively forced to characterize offerings as unique in terms of patent or marketing considerations. For these reasons, it would seem reasonable for regulatory entities to establish baseline criteria consistent with quantitative system performance characteristics that extend beyond the basic protections against altitude hypoxia if that is truly needed. More importantly, such an approach should represent unbiased, responsibly established criteria truly reflective of the associated challenges the basis of the requirement(s) easily demonstrated and/or explained.

The information presented only represents some of the most recent considerations in the debate regarding evaluation of aviation oxygen systems. There are many other issues that also need to be addressed as pointed out at AsMA meetings decades ago⁹ as well as research papers dating back to the early years of the Civil Aerospace Medical Institute (CAMI)^{10, 11}. Failure to give greater prioritization to updating oxygen regulations is most likely a function of allotting time to where there is the greatest perceived need. As systematic improvements continue to accrue towards real physiological limits it may be the optimum time to establish prudent requirements to reference for the foreseeable future.

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