

The OxyMask™ development and performance in healthy volunteers

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Background: The OxyMask™ is a unique, open-style, oxygen mask that was originally developed in 2005. The original mask was modified, using computational fluid dynamics numerical simulations, with the goal of allowing it to produce a wider range of FiO₂. This analysis was used to guide the modification of the mask shell and the location for the oxygen diffuser.

Methods: The new OxyMask was attached to 10 healthy subjects and used to deliver escalating levels of oxygen (1.5, 2, 2.5, 3, 5, 10, 15, 20, 25 and 30 LPM) for 90 seconds at each level and the resulting FiO₂ was recorded (at the lips) from 5 consecutive measurements at each oxygen flow rate.

Results: Mean FiO₂ was 25.4% at 1.5 LPM of oxygen, 30.1% at 2 LPM, 36.5% at 2.5 LPM, 41.8% at 3 LPM, 57.6% at 5 LPM, 74.4% at 10 LPM, and 80.1% at 15 LPM. Each FiO₂ achieved at these escalating oxygen levels was significantly greater than all the previous levels. The mean FiO₂ was 82.8 at 20 LPM, 84.2% at 25 LPM and 84.3% at 30 LPM. All of these values on average were not significantly greater than the FiO₂ achieved with 15 LPM. In a few subjects a maximum FiO₂ of 90% was reached.

Conclusion: The original OxyMask was successfully modified so that the second generation of the mask can provide a wide range of FiO₂, from 25% to 90%, while keeping its unique open design.

Keywords: oxygen, oxygen masks, oxygen therapy, OxyMask™, OxyArm™, clinical trial, computational fluid dynamics (CFD), equipment design, biomedical engineering

Introduction

Oxygen was discovered over two centuries ago and the first published account of its production occurred in 1775 by Joseph Priestly.¹ For the first time, compressed oxygen in copper bottles became available in 1868, prior to this it had to be manufactured by anyone wanting to administer it. In the late 1800s and early 1900s several devices were developed for the purpose of inhaling oxygen. These devices included mouthpieces, and facemasks constructed of silk, or cotton, or leather with some rubber parts.² Bacterial pneumonia was the first disease that was systematically treated with supplemental oxygen in the 1890s.³ John Haldane, who published “The therapeutic administration of oxygen” in 1917, ushered in the modern era of oxygen therapy by founding a rational scientific basis for this treatment.⁴ World War One (1914–1918) led to advancements in oxygen therapy because of its need in the treatment of phosgene gas poisoning. During this time the Haldane oxygen mask, nasal prongs, oxygen masks with a reservoir bag, and pressurized oxygen cylinders were developed.¹

Commercial versions of these oxygen masks and cannulae found their way into clinical practice, initially for intermittent oxygen therapy and later in the application of continuous oxygen therapy.⁵ These low flow devices were variable performance devices, in that they delivered a FiO₂ (fraction of inspired oxygen) that depended on patient factors and how the masks were used. Specifically, since the delivered oxygen flow rates were less than a patient’s peak inspiratory flow rate (PIFR) the delivered oxygen is diluted by room air entrained from around the masks. These types of masks

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can also lead to rebreathing of CO₂ because of retention of expired gases. With the addition of non-rebreathing reservoir bag a low-flow Hudson mask can deliver a FiO₂ as high as 97%.^{6,7}

By contrast, fixed performance venturi masks, developed in the 1960s, are high flow devices that deliver an oxygen flow rate equal to or in excess of the PIFR.^{8,9} Leigh made the original division between fixed and variable performance oxygen delivery systems in 1970.¹⁰ High flow, fixed performance venturi masks use an application of the Bernoulli principle whereby the gas flow of delivered oxygen is accelerated by passing it through a Venturi valve that has a short constriction followed by an expanded area with vents that entrain room air into the delivered stream because of the resulting low pressure gradient created by the abrupt increase in valve cross-sectional area. The advantage of these devices is their ability to deliver controlled amounts of oxygen such that the FiO₂ is less variable. Within the normal physiological range of PIFRs it was found that three types of venturi masks (high and low volume Venitmask and the low volume Inspiron) behaved as fixed performance devices.⁸ In a comparison of five fixed performance devices, involving varying conditions of PIFRs generated by a ventilator attached to an Anatomic Annie resuscitation trainer, it was found that only the Vickers Ventimask was able to provide true fixed oxygen concentrations in all conditions.¹¹ Table 1 summarizes the salient features of the oxygen delivery devices.^{7,12}

The distinction between fixed and variable performance becomes important when treating patients with an exacerbation of chronic obstructive pulmonary disease (COPD).

In these patients there is a risk of oxygen-induced respiratory acidosis if inappropriately high concentrations of oxygen are administered.^{13,14} Accordingly, the British Thoracic Society guidelines, published in 1997, recommends that patients with a moderate-severe exacerbation should initially receive 28% oxygen (via a venturi mask or 2 L/min via nasal cannulae), their blood gases should then be checked within 60 minutes (to assess for hypercapnea) and the goal of therapy should be to achieve a pO₂ of at least 50 mmHg without a fall in pH below 7.26.¹⁵ Despite this recommendation excessively high concentrations of oxygen (FiO₂ of 40%) have been achieved with nasal cannulae delivering just 1 L/min of oxygen and this is likely due to the considerable variability in the FiO₂ delivered via nasal cannulae.^{16,17} For the treatment of other conditions (eg, post-operative recovery, pneumonia, asthma, and myocardial infarction) requiring supplemental oxygen there is less concern over keeping the FiO₂ < 40% and it is often desirable to deliver considerably higher concentrations.⁵

Since the original development of clinical oxygen delivery devices modifications and incremental improvements have been made but their fundamental designs have not changed substantially. The OxyArm™ (Southmedic Inc., Barrie, ON, Canada), a novel minimal contact, open oxygen delivery system, modeled after the headsets used in hands-free telecommunications devices, was introduced in 2001.¹⁸ This device was designed to offer an alternative to traditional devices and was characterized by a headband, an adjustable boom (with oxygen and optional CO₂ sampling lines) and a diffuser that generated an oxygen and air plume that was directed at the mouth and nose. The design of the OxyArm was aided with the use of computational fluid dynamics (CFD) numerical simulations that were used to estimate the oxygen concentration fields that emanated from the gas plume.¹⁹ The OxyArm was subsequently shown to be equivalent to nasal cannulae in maintaining the saturation levels by pulse oximetry in COPD patients on chronic domiciliary oxygen therapy.^{20,21} In addition, the OxyArm was shown to provide good quality capnographic monitoring in healthy volunteers and adequate oxygenation for series of 60 consecutive surgical patients for the initial period following endotracheal extubation.^{22,23}

The diffuser technology developed for the OxyArm was applied to a new mask design called the OxyMask™ (Southmedic Inc., Barrie, ON, Canada) in 2005.²⁴ This mask, like the OxyArm, has an open design with the diffuser pointed directly at the mouth and nose by a mask skeleton consisting of a pentagon of five arms that project up from the mask base. The initial OxyMask prototype was investigated, using

Table 1 Types and characteristics of oxygen delivery devices

	Fixed performance	Variable performance
Other Names	High flow-jet mixing	Low flow
FiO ₂ Range	24 to 85	24 to 50
Characteristics	Provide a specified FiO ₂ throughout the respiratory cycle	Provides an FiO ₂ that depends on PIFR and how its used
Description	Flow rate ≥ PIFR ^a	Flow rate < PIFR
Rebreathing of CO ₂	Avoided because mask is flushed by the high flow rates	Rebreathing may occur (for masks)
Indication	Controlled oxygen therapy required	Higher concentrations of oxygen required and controlled oxygen not necessary
Examples	Venturi	Hudson, MC, Nasal Cannulae

^aPIFR, peak expiratory flow rate.

numerical simulation, by Dr Hangan, from the Boundary Layer Wind Tunnel Laboratory at the University of Western Ontario in London, Ontario, Canada, with the goal of achieving a mask design capable of a therapeutic FiO_2 range of 24% to 90%. The advantage of such a device would be that a single oxygen device (as opposed to multiple staged devices) could be used for a given patient for a wide range of oxygen requirements.^{7,12,25}

A clinical study of healthy volunteers was designed to investigate the performance of the second-generation OxyMask to see if it was able to generate the desired ranges of FiO_2 . This manuscript will describe the background design rationale that followed from the numerical simulations and the clinical trial that investigated the delivered FiO_2 .

Methods

OxyMask development

CFD simulations were employed in the design of the OxyMask. Simulations were performed for an initial open-concept oxygen-delivery mask and the velocity and oxygen concentration fields were investigated. Based on these preliminary configuration results the design of the mask was modified with a larger open area to reduce the accumulation of expiration CO_2 from being trapped in flow recirculation areas. The position and shape of the mask's diffuser was then optimized to provide the best performance possible over the entire range of flow rates targeted (between 1 and 40 LPM [liters per minute]). The final design was numerically tested and the results of these simulations were compared with the results of the clinical trial as well as with a simplified analytical model developed during the optimization phase.

Numerical methods

Steady state simulations were performed for the final OxyMask design for 5 oxygen-delivery flow rates of 1.5, 5, 10, 20 and 40 LPM. The continuity and Reynolds averaged Navier-Stokes (RANS) equations were solved to obtain the flow field, and the passive scalar (species) transport equation was solved for the oxygen concentration field. In addition the Reynolds-stress term in these equations was modelled by solving the classical turbulent kinetic energy and the rate of dissipation transport equations. The ensemble of these equations is detailed in Hangan and Bekele¹⁹ and therefore will not be presented herein. The OxyMask is a face-attached device with an oxygen inflow directed towards the center and it has several large openings (see Figures 1 and 2). Flow calculations were performed on

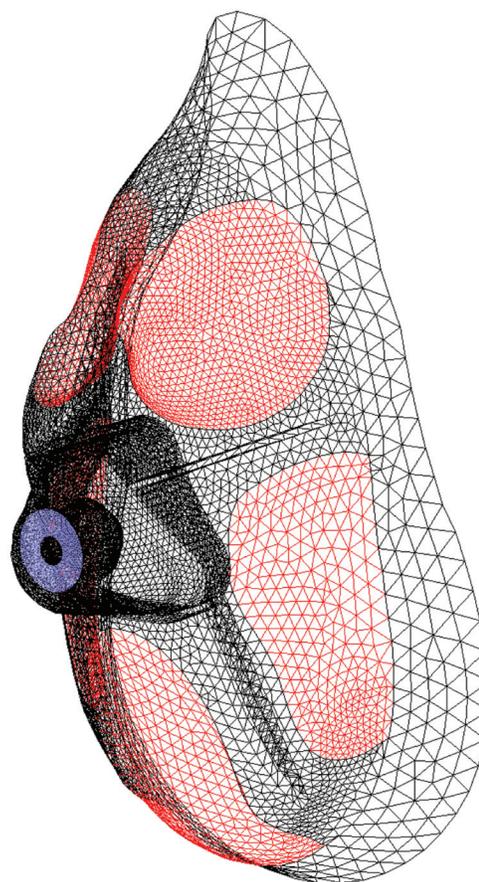


Figure 1 Geometry and numerical mesh for OxyMask™. The structure of the mask is depicted in black and the openings are in red.

an unstructured numerical grid (or mesh) which was then refined in regions of interest using the commercial software Gambit.²⁶ The mesh size was gradually increased until no noticeable differences in flow patterns were observed. All computations were performed based on a convergence

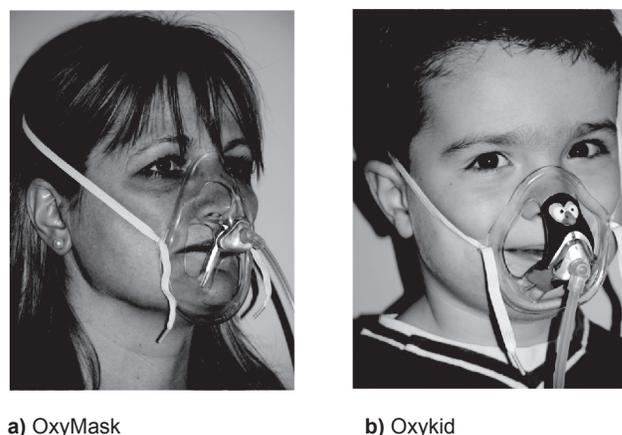


Figure 2 The oxyMasks: a) oxyMask – second generation, and b) oxyKid (Southmedic Inc, Barrie, Ontario, Canada).

criteria of 10^{-4} and steady-state numerical solutions were obtained using Fluent.²⁷ The computational domain was discretized using a second order scheme. A RNG k- ϵ turbulence model was adopted as a compromise between computational costs and simulation accuracy for all cases.

Diffuser design rationale

The oxygen supply for the Southmedic respiratory devices (OxyArm and OxyMask) is through a diffuser with a mushroom-like structure at its center (see Figure 1). Variable flow rate respiratory devices function at flow regimes that span over the transition from laminar to turbulent flow.¹⁹ For a typical 4.2 mm diameter medical tube (area = 1.4 cm²) the transition happens for a flow rate of approximately 8 LPM. If the flow is initially laminar, increasing the flow rate will produce transition from laminar to turbulent regimes, the mixing will increase and therefore concentrations will drop. If the flow is initially turbulent, no transition will occur and the FiO₂ concentration can be controlled by simply adjusting the flow rate (increasing the flow rate will increase the concentration).

As opposed to the simple medical tube, the OxyMask device uses the mushroom/diffuser that by mixing and convection produces turbulent flow at any flow rate. Therefore the oxygen concentration levels coming out of the OxyMask device can be conveniently adjusted by controlling the flow rate while the only way of controlling the oxygen concentrations coming out of a simple tube is by adjusting the position of the tube from the target (higher concentrations at shorter distances).

By modifying the size and/or shape of the oxygen diffuser one can obtain either a dominant flow of oxygen or, by using a larger diffuser, the flow of oxygen can be balanced by mixing providing improved sampling of expired gases at the position of the diffuser so breath to breath monitoring of CO₂ (capnographic measurement) is optimized.¹⁹

Establishment diffuser location and orientation

The delivery of oxygen in classical venturi masks is parallel to the face surface and directed towards the nasal cavities. Therefore, these masks are not particularly well suited for oral or mixed (oral-nasal) inhalation. At the mouth level this masks produces low oxygen concentration levels of the order of 22%.¹⁹ In designing the OxyMask these factors were taken into consideration and the diffuser was placed at a central position inside the mask and at an angle that allows the oxygen delivery being oriented towards a mid-point between the nasal and oral cavities.

Consequences of on open system

Beside the disadvantages related to the strict direction of delivery, classical masks, being quasi-closed systems, can trap expiratory CO₂ in regions of flow re-circulations such as the lower (chin) area of the mask.¹⁹ The OxyMask has the benefits of an open system being patient-friendly at the same time avoiding accumulations of CO₂ inside the mask. Based on CFD design all regions prone to CO₂ accumulations, eg, volumes where the flow would be trapped and re-circulated have been eliminated. As a result the preliminary OxyMask design was modified with larger and optimally placed open areas.

Clinical trial

Measurement of FiO₂ at various oxygen flow rates

After informed consent, 10 healthy adult subjects were recruited to the study. The study used an un-blinded crossover design. Specifically, the subjects were seated in the upright position, the OxyMask was secured with the head strap, and a sampling line was applied to the center of their lower lip and it was connected to a Datex-Ohmeda AS/5 multi-gas monitor. Each subject was then delivered escalating levels of oxygen (1.5, 2, 2.5, 3, 5, 10, 15, 20, 25 and 30 LPM) for 90 seconds at each level and the resulting FiO₂ was recorded from 5 consecutive measurements at each oxygen flow rate. For this pilot trial, the measurements were made throughout the respiratory cycle and no spirometry or gas flow measurements were taken.

Analysis

The FiO₂, at each oxygen flow rate, was plotted in a box plot with the median value displayed as a horizontal line, the upper and lower quartile ranges (50%) as a box, the extreme values as error bars representing the 95% confidence intervals and the extreme values beyond that plotted individually. The FiO₂ values, at each flow rate, were compared using a one-way analysis of variance (ANOVA) with the Tukey's honestly significant difference test as a post hoc analysis. For the ANOVA, significance was assumed with a p value less than 0.05.

Results

Numerical simulations

The numerical CFD simulations determined the oxygen velocity and concentrations. The concentration levels are presented as mass fraction of the initial oxygen concentrations and as a function of axial distance from the diffuser mushroom outer edge in Figure 3. Results are presented for

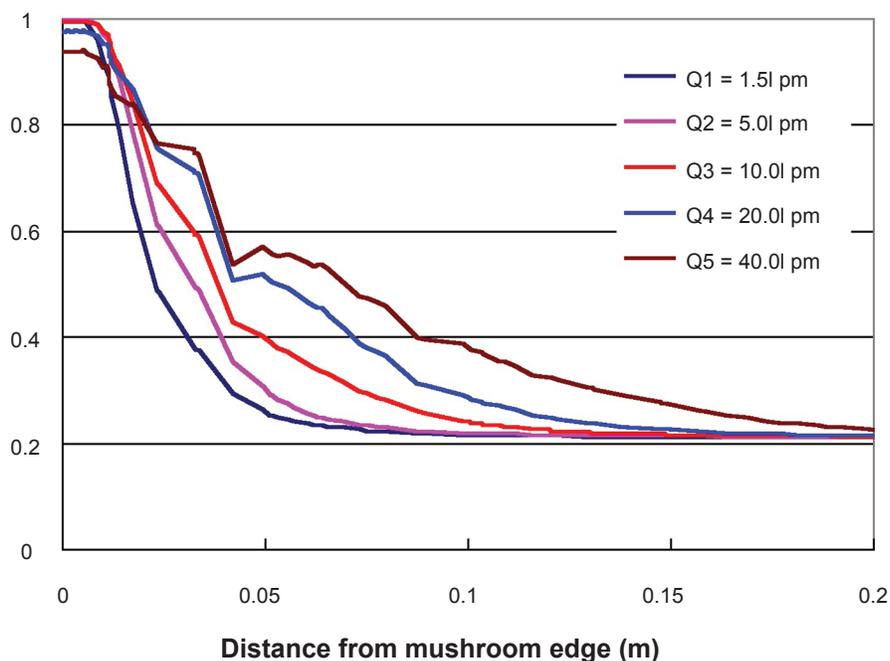


Figure 3 Computational fluid dynamics calculated mass fraction of oxygen as a function of axial distance from diffuser for 5 oxygen delivery flow rates.

the 5 (five) oxygen delivery flow rates. The decay of oxygen concentration levels with increasing axial distance shows a similar trend for all flow rates. As expected, the higher the delivery flow rate the larger the calculated oxygen concentrations are at every axial position. It is clear that the OxyMask oxygen levels are the greatest for distances up to approximately 15 mm from the diffuser. Based on these results the original OxyMask design was modified so that the diffuser was placed 13 mm from the face.

To better understand the overall oxygen delivery, Figure 4 presents the contours of oxygen mass fraction and the velocity vectors for an oxygen delivery flow rate of 20 LPM. This combined diagram shows that, as expected, maximum oxygen concentrations are quasi-symmetric about the axis of the diffuser-mushroom. This indicates that the diffuser-mushroom has to be directed towards the mid-point between the nasal and oral openings in order to provide the best performance. These results have been carefully incorporated in the final design of the mask, which was then submitted to a clinical trial.

Clinical trial

The box plots of FiO_2 values at each oxygen delivery rate are shown in Figure 5. The mean FiO_2 was 25.4% at 1.5 LPM of oxygen, 30.1% at 2 LPM, 36.5% at 2.5 LPM, 41.8% at 3 LPM, 57.6% at 5 LPM, 74.4% at 10 LPM, and 80.1% at 15 LPM. Each FiO_2 achieved at these escalating oxygen levels was significantly greater than all the previous levels.

The mean FiO_2 was 82.8 at 20 LPM, 84.2% at 25 LPM and 84.3% at 30 LPM. All of these values on average were not significantly greater than the FiO_2 achieved with 15 LPM. In a few subjects a maximum FiO_2 of 90% was reached.

Finally, the clinical trial results are compared with the CFD simulation results in Figure 6. The CFD calculated oxygen levels fit well between the extremes (maximum and minimum values) of oxygen concentrations measured during the clinical trials.

Discussion

CFD dynamics played an important role in the development of the OxyMask. The oxygen flow and concentration fields were numerically investigated. These analyses were essential in establishing optimal diffuser design and orientation, effective capnographic sampling (that did not interfere with oxygen delivery) and the correct diffuser distance from the face. It was found that the OxyMask operates in a critical range of Reynold's numbers (the ratio of inertial forces to viscous forces) between 500 and 1000.^{19,28} The OxyMask, like its predecessor the OxyArm, produces vortices, and the diffuser balances convective and diffusive transport mechanisms resulting in turbulent flow for which the FiO_2 concentrations are increased by simply increasing the flow rate. Using the results from steady state equations, for the concentration of mass, it was confirmed that 13 mm from the face was an optimum location for the oxygen diffuser.

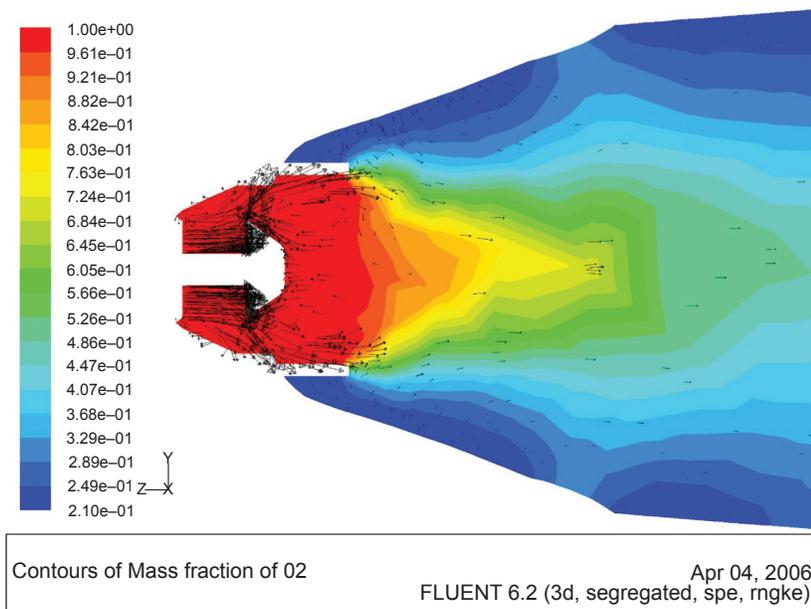


Figure 4 Contours of oxygen mass fraction and velocity vectors for an oxygen delivery flow rate of 20 LPM.

Lastly, the vector diagrams of oxygen flow confirmed that the best orientation of the diffuser was pointed directly between the mouth and nose.

The preliminary clinical trial on the performance of the OxyMask showed that the device was effective at supplying

a wide range of FiO_2 values, from 25% at 1.5 LPM up to a maximum of 80% at 15 LPM. Further increases in oxygen flow rates, above 15 LPM, did not significantly improve the delivered FiO_2 . Consequently, in the clinical setting the effective range of oxygen flow rate settings would be from

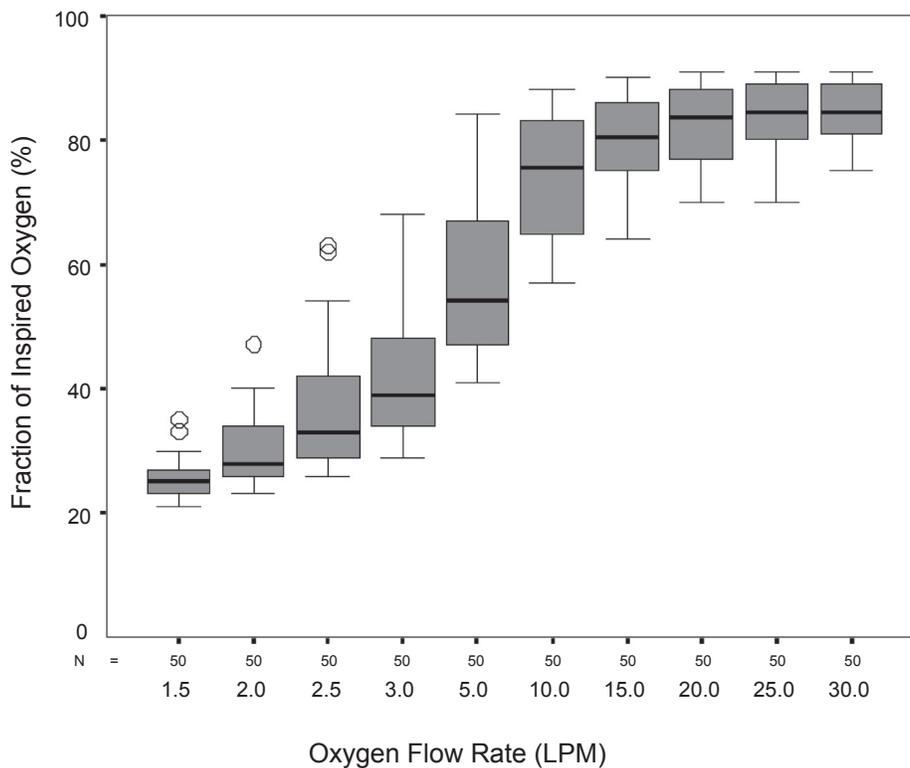


Figure 5 Box plots of FiO_2 values versus oxygen delivery flow rates (LPM).

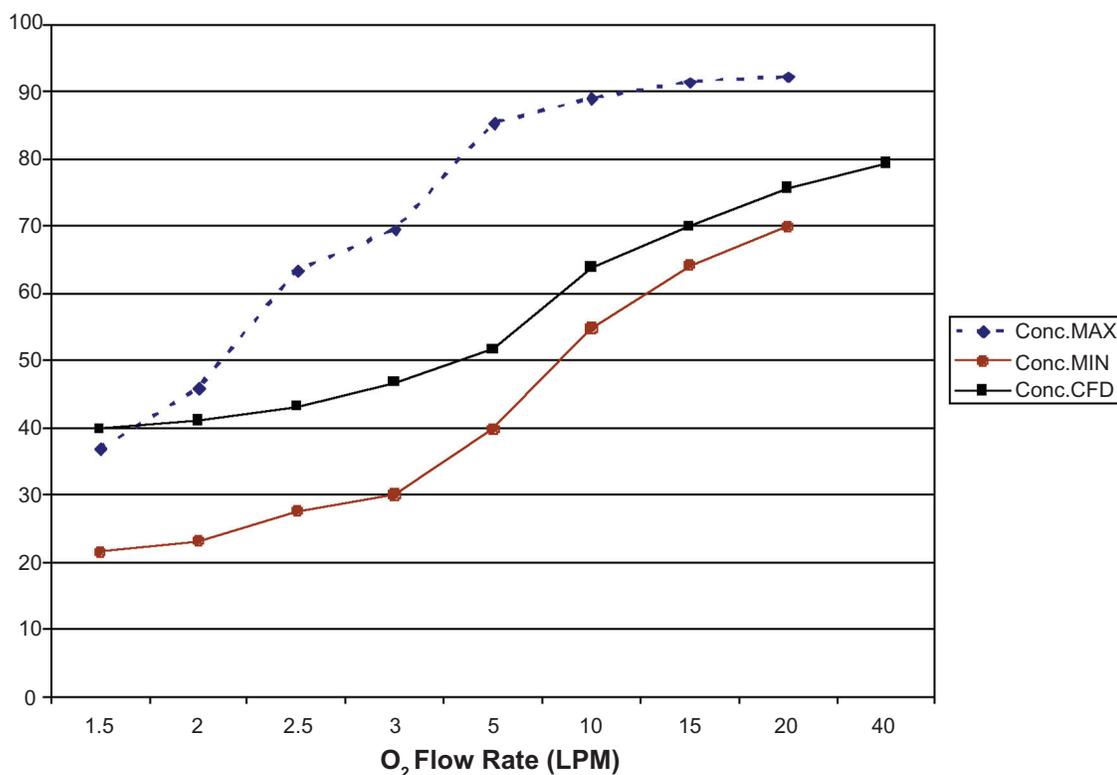


Figure 6 Oxygen concentrations at an axial distance of 3 cm from the diffuser. The plots show a comparison between the computational fluid dynamics result (black line) and the clinical trial (blue line = max, red line = min) results.

1 to 15 LPM. The delivered FiO_2 values delivered by the OxyMask tended to follow a normal distribution, with the distribution being symmetrical around the mean and 95% of the values being within 2 standard deviations from the mean. Overall, the second generation of the OxyMask was able to meet the design objectives of maintaining an open design while providing a high concentration of FiO_2 .

A previous study by Beecroft and Hanly, showed that the OxyMask was more efficient than the venturi mask in supplying oxygen to patients with chronic, stable respiratory disease.²⁴ In this crossover study, after establishing baseline oxygen saturation, patients were treated with oxygen with either the OxyMask or venturi mask (in random order) titrated to maintain their saturation at a low level (4%–5% above baseline) initially and then a high level (8%–9% above baseline). The results showed that the OxyMask was more efficient. Specifically, the oxygen flow rate required to maintain a high saturation was significantly lower (one sixth: 2.1 versus 12.2 LPM) and the resulting PiO_2 at the lip was significantly higher (323 mmHg versus 257 mmHg).

While this study showed that the OxyMask can deliver an wide range of FiO_2 values and previous work shows that it is more efficient than the venturi mask it is still unknown

if the OxyMask behaves like a fixed (high flow) or variable (low flow) device. When Leigh made the original distinction between fixed and variable performance oxygen systems in 1970 the only fixed performance systems available were the low flow anesthetic circuit (attached to an endotracheal tube) and the venturi mask.¹⁰ The OxyArm and OxyMask use a novel diffuser technology in an open system that allows for the entrainment of room air. To determine the performance characteristics of these devices will require further study, but given their design it is likely that they behave as low flow, variable performance devices. This could be tested using the methods of Waldau et al whereby a sampling catheter in the nasopharynx is used to measure end-tidal oxygen and this is used to calculate FiO_2 .⁹ Under these testing conditions, the variable performance systems exhibit characteristic M-shaped inspiratory waveforms, illustrating the effect of inspiration and the entrainment of room air on the delivered gas flow. Even among oxygen masks classified as fixed performance devices there is considerable variation in performance. In a comparison of five masks (Blease OEM Mixomask, Inspiron Accurox, Hudson Venturi, Sandoz Lifeline, and Vickers) only the Vickers was found to provide a consistent FiO_2 (within 4% of the set value) in varying

conditions of tidal volume and respiratory rate over a range of oxygen concentrations (24%–60%).¹¹ Among the masks tested the Vickers had the least peak difference between the nominal and observed values (being $\pm 4\%$ at 40% oxygen) whereas the other masks varied between $\pm 8\%$ and 20%. Another oxygen mask investigation showed that all venturi-type masks behaved as fixed performance devices at low inspiratory flow rates and their performance became variable at high PIFRs.⁸ Interestingly, there are no Canadian, British or American standards that stipulate oxygen delivery device performance for fixed performance devices.^{29–32}

There are several potential advantages to an open oxygen mask design. Patients may feel less closed in and claustrophobic, it enables the use of nasogastric tubes without interfering with the mask seating or seal, verbal communication is easier for patients, oral hygiene is possible without removing the mask and the patient is able to drink from a straw while maintaining the oxygen therapy. An open oxygen delivery system is particularly suited for the paediatric population where it is often difficult to get sick children to tolerate a closed facemask, head box, or nasal cannulae. Medical staff sometimes waft oxygen from the steam created from tubing directed towards the face as a last resort; the OxyMask may be useful in this setting.³³ The OxyMask has the advantage over nasal cannulae in that it would be equally effective for mouth or nasal breathing. The OxyMask is more adaptable to patients in the hospital setting than the OxyArm because the standard head strap keeps the device positioned correctly even while sleeping. The OxyArm's headband works well for ambulating and resting in a chair but can be come dislodged while sleeping.

There are also potential cost advantages to an oxygen delivery device that can deliver a wide range of FiO_2 values. For example, a patient could start out by requiring a modest amount oxygen therapy (say 24%) and then their condition could deteriorate over a period of days such that they require increasing amounts of oxygen supplementation, from 24% to 40% and ultimately to 80%. Using traditional oxygen devices this patient could go through four devices: nasal cannulae (from 24% to 40% oxygen), a simple mask (up to 50%) a partial rebreathing mask (up to 70%) and, finally, a non-rebreathing mask (up to 80%). By contrast, a single OxyMask could be used for a patient like this with escalating oxygen requirements with the savings being from the cost of three oxygen device (see Table 2).^{7,12,25}

Conclusion

CFD is playing an increasing role in biomedical engineering to aid with the development of medical devices.

Table 2 OxyMask versus traditional oxygen devices

Desired FiO_2	OxyMask	Traditional devices
24	1 LPM	Nasal Cannulae (1 LPM)
28	2 LPM	Nasal Cannulae (2 LPM)
40	3 LPM	Simple Mask (10 LPM)
60	5 LPM	Partial rebreathing mask (10 LPM)
80	15 LPM	Non-rebreathing mask (10 LPM)

The advantage of this technique is that designs can be modelled and tested using numerical simulations that allow for the final device design to be optimized for their clinical requirements. The original OxyMask was successfully modified using these techniques so that the second generation of this mask can provide a wide range of FiO_2 , from 25% to 90% at flow rates ranging from 1 to 15 LPM, while keeping its unique open design.

Abbreviations

PIFR, peak inspiratory flow rate; COPD, chronic obstructive pulmonary disease; ANOVA, analysis of variance.

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Disclosures

The authors have no conflicts of interest to disclose.

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