The OxyArm™ – a new minimal contact oxygen delivery system for mouth or nose breathing

[Le nouveau système de distribution d'oxygène à contact minimal OxyArm™ pour la respiration buccale ou nasale]

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Purpose: To describe the development and performance of a new minimal contact oxygen (O_2) delivery system for both nasal and oral breathing, with capnographic capabilities.

Methods: The development and design challenges of the OxyArm™ (OA) prototype are described. The innovative design utilizes a headset with a semi-rigid boom and an O_2 diffuser. The OA was compared to the Venturi mask in eight healthy adults after informed consent. Inspired O_2 fractions were measured in the hypopharynx using continuous gas sampling at low to high O_2 flow rates. Mean data were compared using two-tailed paired t tests with significance set at 0.05.

Results: The measured inspired O_2 concentration was higher in the OA at 2 (26.3 ± 2.5 *vs* 23.3 ± 0.5, $P < 0.01$) and 6 $L \cdot min^{-1}$ (33.5 ± 3.3 *vs* 28.8 ± 1.2, $P < 0.01$) flow rates. At 12 $L \cdot min^{-1}$, the O_2 concentration was less in the OA (39.2 ± 6.3 *vs* 46.0 ± 2.7, $P < 0.02$). All subjects found both systems comfortable for the short duration of the study.

Conclusions: The OA delivered predictable concentrations of O_2 over low to medium flow rates. This system is comfortable, easy to use, non-obtrusive, odorless, and latex-free. The ability to monitor capnography makes this device ideal for monitored anesthesia care or in other settings (intensive care) where monitoring of respiration is warranted. This device does not contact the face and thus may be ideal for pediatric patients and those on long-term home O_2 therapy. Further clinical trials in these areas are warranted.

Objectif : *Décrire la mise au point et la performance d'un nouveau système de distribution d'oxygène à contact minimal pour la respiration buccale et nasale, doté de capacités capnographiques.*

Méthode : *Les défis du développement et de la conception du prototype de l'OxyArm™ (OA) sont présentés. De conception innovatrice, il utilise un casque de monture semi-rigide et un diffuseur d'O_2. L'OA a été comparé au masque Venturi chez huit adultes en bonne santé ayant consenti au test. Les fractions d'O_2 inspiré ont été mesurées dans l'hypopharynx grâce à un échantillonnage gazeux continu d'O_2 de bas débit à haut débit. Les données moyennes ont été comparées selon des tests t bilatéraux appariés comportant des niveaux significatifs à 0,05.*

Résultats: *La concentration d'O_2 inspiré a été plus élevée avec l'OA pour des débits de 2 (26,3± 2,5 vs 23,3 ± 0,5,$P < 0,01$) et de 6 $L \cdot min^{-1}$ (33,5± 3,3 vs 28,8 ± 1,2, $P < 0,01$). Pour un débit de 12 $L \cdot min^{-1}$, la concentration d'O_2 a été plus faible avec l'OA (39,2 ± 6,3vs 46,0 ± 2,7, $P < 0,02$). Tous les sujets ont jugé les appareils confortables pendant l'étude de courte durée.*

Conclusion : *L'OA a distribué des concentrations prévisibles d'O_2 de débits bas à moyens. Ce système est confortable, facile à utiliser, non obstructif, inodore et sans latex. Les possibilités capnographiques de cet appareil font qu'il est idéal pour l'anesthésie avec monitorage ou d'autres installations (soins intensifs) où le monitorage de la respiration est justifié. L'appareil n'entre pas en contact avec le visage, le rendant idéal pour la pédiatrie et l'oxygénothérapie de longue durée à domicile. Il faut d'ailleurs poursuivre les essais cliniques dans ce sens.*

TREATMENT of respiratory insufficiency and postoperative hypoxemia most often necessitates supplemental oxygen (O_2).[1,2] O_2 is most commonly administered to patients using a variety of different face masks and

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Developmental work was carried out at Southmedic Inc., and clinical work at Dr. S. McDonald's office in Barrie, Ontario. Supported by a grant from Southmedic, Inc. of Barrie, Ontario, Canada.

Accepted for publication September 5, 2001.

Revision accepted November 16, 2001.

nasal cannulae. The performance of such devices is somewhat variable, particularly in terms of the inspired O_2 concentration delivered to the patient. The standard O_2 mask ensures supplementation of inspired air with O_2 for mouth and nose breathing. However, some patients find these masks uncomfortable, claustrophobic and their speech is hindered. In those with borderline hypoventilation, dead space is increased.[3] Routine mouth care, postoperative nausea and vomiting, and restlessness all lead to mask removal or displacement, resulting in no O_2 delivery at all.[4]

Nasal cannula delivery systems lie in close proximity with mucous membranes. With dry O_2 flow, this may lead to local irritation, infection and bleeding.[3,5] Air embolism is a rare but described complication.[6] Mouth breathing presents another underestimated problem with these devices, since O_2 is not inhaled.[7,8] This occurs when talking and while snoring during sleep.[9] Nasal cannulae are less likely to be removed than face masks, although they are frequently dislodged.[10]

The OxyArm™ (OA) (Southmedic Inc., Barrie, Ontario, Canada), a new minimal contact open O_2 delivery system, has been designed to overcome the problems of face masks and nasal cannulae. Capnography monitoring has also been incorporated into this novel device. We describe the development of this system and results of preliminary clinical studies.

Materials and methods

The concept of an open O_2 delivery system came from anecdotal evidence of open tubes fixed in proximity to the face.[11] The headset design originated from adapting the headsets used in hands-free telecommunications device. Subsequent modification of the commercial headset allowed delivery of O_2 through an open-ended tube. The first prototype of the OA included a tension band that traversed the top of the head (headset), O_2 supply and carbon dioxide (CO_2) sampling lines attached to an adjustable boom, and a diffuser consisting of both a "cup" and "pin" to deliver a premixed O_2 plume and sample end-tidal CO_2. The patented cup and pin consists of a plastic molded 'pin' centrally located in the diffuser cup (Figure 1).

Several design challenges led to the further development of the prototype. The headset went through various transformations after studying available headsets in the marketplace. Modifications were incorporated so the headset could rest either behind or on top of the head to allow for various patient positions. The final headset prototype fits around the back or the top of the patient's head, with arms resting on top of the ears (Figure 2). Positional stability of the headset and boom became an issue due to the weight of the O_2 supply tubing. The design of the boom had to be flexible enough to allow for adjustments, but sufficiently rigid to stay in place. This was achieved by inserting a length of stainless steel wire through the lumen of the boom. This semi-rigid boom was designed to be either left-or-right-sided and also made adjustable so it could be shortened or lengthened to fit. The shape of the boom follows the contour of the cheek and rests out of the line of sight.

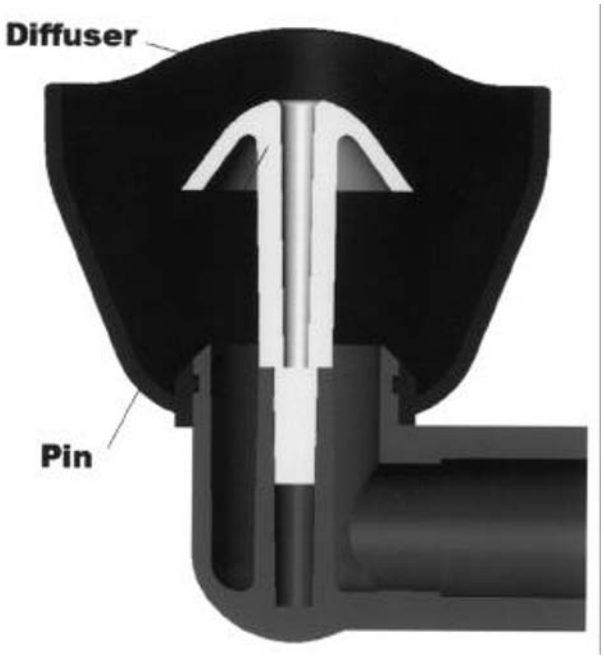

FIGURE 1 Cross-sectional drawing illustrating shape of the cup that houses the pin diffuser unique to the OxyArm™.

The requirements that impacted the design of the diffuser were the need to incorporate O_2 delivery and CO_2 sampling, without the patient feeling the O_2 supply stream. Initial testing revealed that an open O_2 hose continually blowing in the face was not well tolerated and also not effective at delivering O_2. O_2 needed to be focused and directed at the mouth and nose area. Various shapes of diffuser prototypes were initially constructed using dental molds, and their subsequent airflow properties studied. A variety of cup and pin configurations were tested for both O_2 delivery efficacy and reproducibility of end-tidal CO_2 waveforms. Utilizing computer simulated wind tunnel modeling, it was possible to understand and illustrate the open O_2 flow dynamics from the diffuser. Thus computerized fluid dynamics were studied on the O_2 plume at the Boundary Layer Wind Tunnel Laboratory at the

FIGURE 2 Final prototype of the OxyArm™ *in situ.*

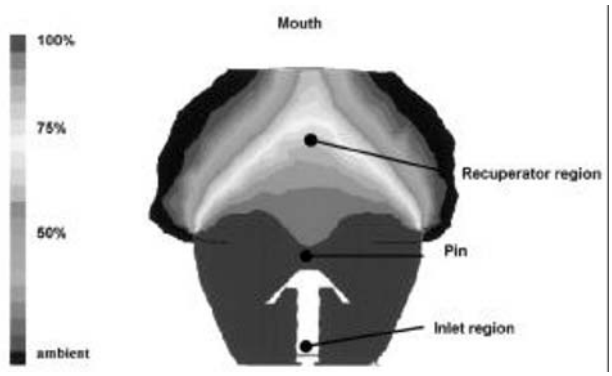

FIGURE 4 Oxygen (O_2) mass fraction gradient of the OxyArm™ at 4 L·min^{-1} with inspiration from computer simulated wind tunnel testing. The shape of the diffuser (recuperator region) causes velocity vortexes to develop which concentrate the flow of O_2 from the pin into a flame-like shape towards the face.

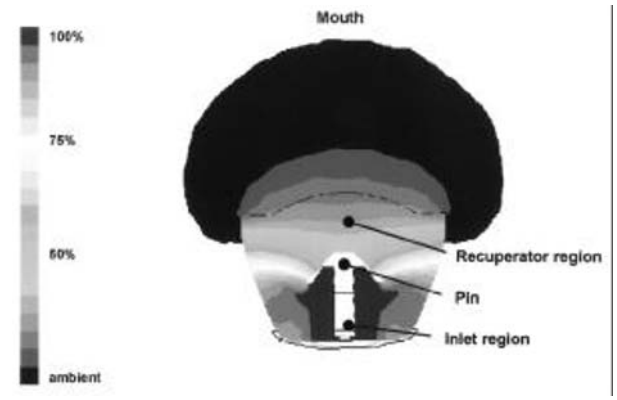

FIGURE 3 Oxygen (O_2) mass fraction gradient of the OxyArm™ at 4 L·min^{-1} from computer simulated wind tunnel testing. O_2 diffuses from the inlet region out from the pin like a mushroom cloud towards the face in passive conditions (no inspiration). The recuperator region is the concave area of the diffuser cup.

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The three-dimensional geometry of the OA was reproduced in a computer simulation, based on an AutoCAD (computer-aided design) generated drawing. The geometry was meshed with a finite volume grid consisting of many independent cells. The momentum (Navier-Stokes), continuity and a passive scalar equation were solved for every cell in the domain. The result of this process was the calculation of velocities, pressures and O_2 concentrations at every point in space inside and around the device. A standard -epsilon turbulence model was employed in the context of steady state simulations. Figure 3 shows the O_2 concentration profile at passive conditions, as calculated through the computer simulation. O_2 diffuses out from the inlet and pin in the shape of a mushroom. During inspiration, the shape of the diffuser causes complex velocity vortexes to form, which forces O_2 into a flame-like shape towards the face (Figure 4). This dynamic property of the diffuser is unique to the OA, concentrating O_2 delivery during inspiration, and allowing sampling of CO_2 during expiration.

Initial clinical testing compared inspired O_2 concentrations in the hypopharynx with varying O_2 flows between the OA prototype and the Venturi mask (Airlife™, Percento$_2$ Mask, Allegiance) in healthy adults.

Oxygen concentrations in the hypopharynx

Eight healthy adults (ages 26–59 yr, ASA I) were studied after giving informed consent. Subjects were seated at rest under normal respiratory conditions. No instructions were given on breathing pattern. Subjects were shown how to use the OA once and no further feedback was provided. A sampling catheter was attached to a pediatric suction catheter (Baxter T64C, Chicago, Illinois, USA) and inserted nasally by an anesthesiologist to lie between 8–10 cm in the hypopharynx. The sampling catheter was connected to a multigas analyzer and recorder (Datex-Ohmeda AS/3) calibrated according to manufacturer's guidelines. Medical grade pure O_2 was supplied to each sub-

TABLE Oxygen concentrations measured in the hypopharynx using the OxyArm™ and the Venturi mask at incremental flow rates

O_2 (L·min^{-1})	Device	Mean [O_2] %	SD	95% CI	P*
2	OA	26.3	2.5	24.3, 28.3	
	Mask (24%)	23.3	0.5	22.9, 23.7	0.01
4	OA	29.4	3.2	26.8, 32.0	
	Mask (28%)	26.8	0.3	26.6, 27.0	0.06
6	OA	33.5	3.3	30.9, 36.1	
	Mask (31%)	28.8	1.2	27.8, 29.8	0.01
8	OA	34.0	4.2	30.6, 37.4	
	Mask (35%)	32.8	1.4	31.7, 33.9	0.47
10	OA	35.9	2.7	33.7, 38.1	
	Mask (40%)	37.0	1.2	36.0, 38.0	0.39
12	OA	39.2	6.3	34.2, 44.2	
	Mask (50%)	46.0	2.7	43.8, 48.2	0.02

OA=OxyArm; O_2=oxygen; Mask=Venturi mask; SD=standard deviation; CI=confidence interval. *two-tailed paired t test.

ject at flow rates of 2, 4, 6, 8, 10, and 12 L·min^{-1} using the OA and the Venturi mask, in no predetermined order. In addition, the corresponding diluter jets were attached to the Venturi mask at the appropriate flow rate to provide O_2 concentrations of 24, 28, 31, 35, 40, and 50%. Flow rates were determined by an O_2 regulator needle valve (Western Medica XA-2831). At each stage, the concentration of inspired O_2 was measured in the hypopharynx at least ten times over 90-sec intervals, after steady state inspired O_2 and end-tidal CO_2 concentrations had been reached.

Mean data and standard deviations were compared for the two delivery systems using two-tailed paired t tests with significance set at 0.05.

Results

Oxygen concentration in the hypopharynx

The mean O_2 concentrations and 95% confidence interval measured in the hypopharynx for each flow rate are presented in the Table. Both the OA and Venturi mask delivered acceptable O_2 concentrations for clinical administration at low to medium flow rates. The measured O_2 concentration in the hypopharynx using the OA was higher than with the Venturi mask at flow rates of two (26.3 ± 2.5 *vs* 23.3 ± 0.5, P=0.01) and 6 L·min^{-1} (33.5 ± 3.3 *vs* 28.8 ± 1.2, P=0.01). At a flow rate of 12 L·min^{-1}, the OA delivered lower O_2 concentrations as compared to the Venturi mask (39.2 ± 6.3 *vs* 46 ± 2.7, P=0.02). At all other flow rates, there was no difference between the two O_2 delivery systems. All subjects found both systems comfortable for the short duration of the study period. Noise levels from the OA were perceived to be low and consistent at all flow rates.

Discussion

Postanesthetic care units handle large volumes of patients each year, the majority requiring higher concentrations of inspired O_2 to prevent postoperative hypoxemia. Evaluation of O_2 delivery systems should be based on adequacy of O_2 delivery, simplicity and ease of use, patient acceptability and compliance, and cost effectiveness. Traditional O_2 masks and nasal cannulae are most commonly used, but both have disadvantages.[3–10] The OA was designed primarily as a means of offering some advantages over the O_2 mask and nasal cannula, while also incorporating end- tidal CO_2 monitoring capabilities.

Compared to the Venturi mask, the OA delivered the same or a greater fraction of inspired O_2 concentrations at flow rates from 2–10 L·min^{-1}. At the highest flow rate of 12 L·min^{-1}, the fraction of measured inspired O_2 in the hypopharynx was less using the OA. However, delivery of O_2 at this flow rate lies outside that of the conventional mask and one would likely consider using a rebreathing mask. It should be stated that this study was of a very preliminary nature with a small number of subjects. Nevertheless, the OA was well tolerated without any side effects, easy to adjust and simple to use.

The OA is a novel, minimal contact, open O_2 delivery system and is well suited for either oral or nasal O_2 delivery. The unique headset design with the baffled cup diffuser offers controlled delivery of variable concentrations of O_2 in an unencumbered and comfortable way. It is simple to modulate the O_2 concentration with the OA by adjusting the supply flow rate. To achieve this with the Venturi mask, matching combinations of diluter jets and flow rates must be changed.

The minimal contact design allows patients to talk comfortably, and routine nursing tasks may be accomplished without disturbing O_2 delivery. Patient anxiety and claustrophobia may be reduced due to the lack of facial contact and unhindered line of sight. The entire system is odorless and latex-free. The OA received

Food and Drug Administration approval in Canada in May 2000 and is currently pending a worldwide patent. It is currently available in 57 countries.

In further studies, use of the OA for long-term O_2 therapy may prove beneficial. Compliance in these patients may be improved due to improved comfort, minimal contact, and the global acceptability of headsets giving it a non-medical appearance. Talking, eating and drinking may be permitted with uninterrupted O_2 delivery. It may also prove to be an important alternative in the postoperative pediatric population, as some are intolerant of traditional O_2 delivery systems. The ability of the OA to incorporate capnography may prove useful in the operating room during monitored anesthesia care. Future clinical trials are ongoing and will further define the clinical utility of the OA in these various settings.

Acknowledgements
The authors wish to thank Dr. James Paul for statistical assistance and Dr. Sandy McDonald for his support in this project.

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