Original articles

Comparison of tissue oxygenation achieved breathing oxygen from a demand valve with four different mask configurations

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Key words
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Abstract
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Introduction: High concentration normobaric oxygen (O_2) is a priority in treating divers with suspected decompression illness. The effect of different O_2 mask configurations on tissue oxygenation when breathing with a demand valve was evaluated.
Methods: Sixteen divers had tissue oxygen partial pressure ($P_{tc}O_2$) measured at six limb sites. Participants breathed O_2 from a demand valve using: an intraoral mask (IOM®) with and without a nose clip (NC), a pocket face mask and an oronasal mask. In-line inspired O_2 (F_IO_2) and nasopharyngeal F_IO_2 were measured. Participants provided subjective ratings of mask comfort, ease of breathing and holding in position.
Results: $P_{tc}O_2$ values and nasopharyngeal F_IO_2 (median & range) were greatest using the IOM® with NC and similar with the IOM® without NC. O_2 measurements were lowest with the oronasal mask which also was rated as the most difficult to breathe from and to hold in position. The pocket face mask was reported as the most comfortable to wear. The NC was widely described as uncomfortable. The IOM® and pocket face mask were rated best for ease of breathing. The IOM® was rated as the easiest to hold in position.
Conclusion: Of the commonly available O_2 masks for use with a demand valve, the IOM® with NC achieved the highest $P_{tc}O_2$ values. $P_{tc}O_2$ and nasopharyngeal F_IO_2 values were similar between the IOM® with and without NC. Given the reported discomfort of the NC, the IOM® without NC may be the best option.

Introduction

Arterial gas embolism (AGE) and decompression sickness (DCS), collectively termed decompression illness (DCI), are risks for scuba divers. AGE results from pulmonary barotrauma introducing gas directly into the vascular system. DCS is caused by the formation of bubbles primarily from dissolved inert gas.[1] During a dive, an increase in the ambient pressure leads to a higher breathing gas pressure being delivered to the lungs, and more inert gas (nitrogen in air diving) dissolving in the blood and body tissues. This process is called on-gassing. At the end of a dive as the diver ascends, both the ambient pressure and the pressure of the inspired inert gas decrease. The on-gassing process is reversed as tissue inert gas diffuses into the blood for carriage back to the lungs. However, if the pressure of dissolved gas in a tissue significantly exceeds ambient pressure (a condition referred to as '*supersaturation*') the gas may form bubbles either in the extravascular space or within tissue capillaries. These bubbles are considered to be the primary cause of injury leading to the symptoms of DCS.

It follows from the above that arresting the growth of bubbles and encouraging their involution is a primary goal of treatment in DCS. Breathing a high concentration of oxygen (O_2) and therefore a lower partial pressure of inert

gas, creates a larger diffusion gradient between the blood and body tissues and blood and alveoli such that more inert gas moves from the tissue into the blood, and is then transported to the lungs to be exhaled.[2] Bubbles formed in decompressed divers without DCS have been demonstrated to resolve more quickly during O_2 breathing.[3] Therefore, it is recommended that O_2 be given early to a diver with signs and symptoms of DCI, DCS and AGE, enhancing inert gas elimination from the body and supplying O_2 to hypoxic tissues.[2,4–6]

The current pre-hospital care recommendation for divers with symptoms and signs of DCI is for O_2 delivery at the highest possible concentration (close to 100%).[7] Divers Alert Network (DAN) has designed a variety of portable O_2 delivery units to provide divers with pre-hospital O_2.[8,9] These units have two common components: (1) a constant flow capability for use with a non-rebreather mask (NRB) or other constant flow delivery device; and (2) a pressure-activated demand valve. Previous research comparing tissue oxygenation found that the NRB performed better than the demand valve with an oronasal mask.[10] This research has been questioned as experts believe that the demand valve should be able to provide near 100% O_2 and therefore better tissue oxygenation than the NRB.

The present study used transcutaneous oximetry measurement (TCOM) to determine tissue oxygenation at multiple standardised sites in participants breathing O_2 from a demand valve using four different mask configurations. TCOM is a non-invasive technique that uses heated electrodes on the skin to measure the partial pressure of tissue oxygen ($P_{tc}O_2$).[11] The null hypothesis was that there would be no difference in the $P_{tc}O_2$ achieved after 10 minutes (min) of breathing O_2 with any of four different mask configurations.

Methods

Ethics approval was granted from the Townsville Health Service District Human Research Ethics Committee (HREC16/QTHS/196). The volunteers for this study were healthy non-smoking certified scuba divers of both sexes. Participants were recruited from James Cook University and the diving community in Townsville, Queensland, Australia. All participants were older than 18 years of age and had performed at least one dive within the previous year. Exclusion criteria included facial hair or anatomical abnormality that might impair mask seal, any medical condition or medication that may affect tissue oxygenation, or an allergy to the topical anaesthetic. All participants received a study information sheet and gave their written informed consent.

Participants were asked to refrain from consuming food or caffeine or performing heavy exercise for six hours prior to participating in the study. Age and sex were reported; height, weight and waist and hip circumferences were measured upon arrival for the study day. The participants were then placed in a supine position on a hospital stretcher with their head slightly raised on one pillow and remained in this position for the duration of the study. The room temperature was maintained between 22.4 and 23.7°C; participants were covered with a blanket for comfort and to limit any vasoconstrictive effects of being cold.

Resting baseline measures included heart rate, respiratory rate, O_2 saturation and blood pressure. Topical lignocaine (5%) and phenylephrine (0.5%) (Co-Phenylcaine™ forte spray, ENT Technologies Pty Ltd., Hawthorne East, Australia) was sprayed into the right nares and an 8 French paediatric feeding tube (ConvaTec Ltd., Deeside, UK) was inserted. Position was verified visually with the tip of the tube placed just proximal to the soft palate and the tube then secured in place. The tube was attached to the E-sCO-OO module of a bedside monitor (GE Carescape Monitor B650, GE Healthcare Finland OY, Helsinki, Finland) allowing for both inspired O_2 (F_IO_2, paramagnetic) and end-tidal carbon dioxide ($ETCO_2$, infrared) measurements via a water trap (D-fend Pro+ Water Trap™, GE Healthcare Finland OY, Helsinki, Finland). The gas module was calibrated against room air before each mask configuration was used. The gas sampling rate was 120 $ml \cdot min^{-1}$.

Tissue oxygenation was measured using the TCM400 Transcutaneous (tc) PO_2 Monitoring System (Radiometer, Copenhagen, Denmark) with tc Sensor E5250. Zero current calibration of the $P_{tc}O_2$ electrode using CAL2 gas (10% CO_2 with N_2 as balance) was performed prior to commencement of the study and calibration with atmospheric air occurred prior to each monitoring period. A 'humidity correction factor' was entered into the machine prior to each monitoring period. All assessments were performed by the same technician (AB). The TCM400 displayed $P_{tc}O_2$ values in units of mmHg.

Six sensors were used: three on the left arm and three on the left leg.[10] One sensor was placed on the lateral aspect of the upper arm, mid-way between the acromial process and the olecranon process, one sensor 5 cm distal to the brachial crease on the lateral aspect of the lower arm and one sensor over the thenar eminence (palm hand). One leg sensor was placed 10 cm distal to the lateral femoral epicondyle (lateral leg); one 5 cm proximal to the lateral malleolus (lateral ankle) and one on the dorsum of the foot between the first and second metatarsal heads, attempting to avoid large superficial vessels. Participants rested quietly while the sensors were placed. They were requested to minimise talking during the study, but were not allowed to sleep. Initial normobaric, room air readings from all sensors were recorded after a minimum 20-min equilibration period that allowed all sensors to stabilize.

The participants were then asked to breathe O_2 for 10 min from a demand valve (L324-020, Life Support Products (LSP), Allied Healthcare Products, St. Louis, MO, USA)

Figure 1
Demand valve, spacer with side port, one-way valve configuration and intraoral mask

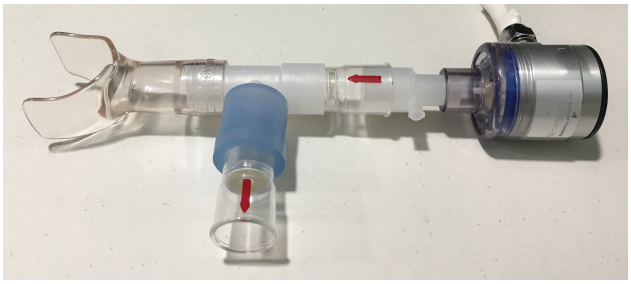

Figure 3
Study configuration with demand valve, spacer with side port, in-line and intra-mask gas sampling lines, nasopharyngeal catheter and pocket face mask (with subject's permission)

using each of four different mask configurations in randomized order:

- Intraoral mask (IOM®) with nose clip (NC) (NuMask®, Inc., Woodlands Hills, CA, USA) (Figure 1);
- IOM® without NC;
- Adult soft silicone oronasal mask (Tru-Fit mask, Allied Healthcare Products Inc., St. Louis, MO, USA) (Figure 2);
- Pocket face mask with air cushion (Sturdy Industrial CO., Ltd., Wugu Shiang, Taipei County, Taiwan) (Figure 3).

The oronasal, pocket face mask and demand inhalator valve which are provided in portable DAN O_2 units were used for this study. A flexible high-pressure O_2 hose was used to connect the demand valve to the hospital wall medical grade O_2 outlet (415 kPa). The demand valve was attached to a spacer with a side port allowing pressure and gas measurements. To measure the delivered O_2, a one-way valve was attached to the spacer and a T-piece with a one-way exhaust valve on the side (Figure 1). The side port was connected to the bedside monitor and a delivered O_2 percentage of 99% was obtained. The one-way valves and T-piece were removed and the single spacer with side port (in-line F_IO_2 measurement) was attached to each O_2 mask in turn during the study (Figure 2). A pressure line

Figure 2
Study configuration with demand valve, spacer with side port and oronasal mask

was attached to the side port and then to the bedside monitor via a BD DTXPlus™ pressure transducer (Argon Medical Devices Inc., Frisco, TX, USA). The monitor was configured to settings used for central venous pressure monitoring to give a high sensitivity in the lower range, and zeroed before each participant.

A single, new demand valve was used and the inspiratory opening pressure required to trigger the valve and the expiratory resistance pressure were verified prior to studying each new participant. The cracking pressure of the demand valve is 0 to -2 cm H_2O and exhalation pressure is 1.5 to 6.4 cm H_2O dependent on flow (LSP demand inhalator valve product insert). The pocket face mask has a nipple for the attachment of supplemental O_2, through which a gas sampling line (Microstream®, Oridion Medical Ltd., Jerusalem, Israel) was inserted and secured near the central opening of the mask to measure intra-mask F_IO_2 levels (Figure 3). Mask dead space was determined by measuring the amount of water required to fill each device. Fill levels were estimated by placing the masks on a mannequin's face and visual inspection of the intrusion of the facial features into the mask.

The order of the four O_2 mask configurations was randomised using the random number generator in Excel (Microsoft® Corporation, Redmond Washington, USA). The participants were asked to position and hold each mask for comfort and to ensure a tight seal to avoid leakage and to breathe deeply enough to trigger the demand valve as outlined in DAN educational material.[8,9] In-line F_IO_2, nasopharyngeal F_IO_2, $P_{tc}O_2$ and other respiratory measures were recorded at the end of the 10-min breathing period. Nasopharyngeal gas sampling was intermittent and frequent throughout the

Table 1
Demographic and baseline measurements for the 16 participants; IQR - inter-quartile range

Characteristic	Median (IQR)	Range
Age (years)	27 (23, 30)	20–57
Body mass index (BMI) ($kg \cdot m^{-2}$)	23 (22, 25)	17–29
Underweight (BMI < 18.5) (*n*)	1	
Normal (BMI 18.5–24.9) (*n*)	11	
Overweight (BMI 25.0–29.9) (*n*)	4	
Obese (BMI ≥ 30.0) (*n*)	0	
Waist-to-hip ratio		
Males (optimal < 0.82)	0.86 (0.84, 0.92)	0.84–0.92
Females (optimal < 0.71)	0.76 (0.74, 0.79)	0.69–0.88
Heart rate ($beats \cdot min^{-1}$)	66 (60, 72)	52–85
Systolic BP (mmHg)	109 (100, 116)	96–137
Diastolic BP (mmHg)	66 (58, 67)	52–87
Respiratory rate ($breaths \cdot min^{-1}$)	16 (12, 19)	12–22
Oxygen saturation (%)	97 (96, 98)	95–100
End-tidal CO_2 (mmHg)	36 (34, 39)	32–47

study to prevent clogging of the catheter and in an attempt to capture peak values. Consistent repeated values were seen during each oxygen breathing session. After each 10-min O_2 breathing period, participants breathed room air for 10 min, allowing all $P_{tc}O_2$ levels to return to baseline before the next mask was trialled.[12] At the end of the data collection period all participants used a five-point Likert scale to rate each mask configuration on comfort, ease of breathing, and ease of holding the device in place. A final open-ended question asked about any adverse effects while breathing O_2.

ANALYSIS

Collected data were de-identified and entered into a preformatted Excel worksheet, then exported into Statistical Package for the Social Sciences version 23.0.0 (SPSS®, IBM® Corporation, Armonk, New York, USA) for analysis.

Based on recent research, we expected mean $P_{tc}O_2$ values between 310 mmHg (forearm) and 421 mmHg (upper arm), with a sample standard deviation of 75 mmHg, when subjects breathed 100% oxygen.[13] Using the mid-point of that range (365 mmHg), assuming a difference of 75 mmHg (smallest increase in $P_{tc}O_2$ at one sensor site breathing 100% oxygen with a hood[13]) would be clinically significant, and allowing for substantial correlation (r = 0.90) between the repeated measures, we estimated that a sample size of 16 subjects would provide a power of 80% (with $\alpha = 0.05$) to detect significant changes in tissue oxygenation.

Using G*Power (version 3.1.9.2)[14] with medium effect size and the plan for a 2-way ANOVA, a sample size of 16 was calculated to give a power of 90% ($\alpha = 0.05$) to detect a significant change in inspired O_2 values (notionally defined as 5%). We estimated this by using a 4 x 2 (4 masks x 2 O_2 values, in-line and nasopharyngeal F_IO_2) within and between factor analysis plan as no set values from previous research were available.

The Shapiro-Wilk test was used to evaluate normality of data distribution. None of the data were normally distributed. Thus, differences between median $P_{tc}O_2$, $ETCO_2$, in-line, and nasopharyngeal F_IO_2 readings whilst breathing O_2 using the various masks and mask configuration ratings were analysed using non-parametric tests. Initial analysis was completed using the Friedman Test with *post hoc* paired analyses completed using the Wilcoxon Sign Rank test with Bonferroni correction. For the *post hoc* tests, a corrected *P*-value of 0.008 (0.05/6) was considered significant.

The primary outcome measure was a comparison of the median $P_{tc}O_2$ measurements recorded across the six

Table 2
Transcutaneous oxygen partial pressures (median and inter-quartile range shown in mmHg) while breathing oxygen using the demand valve with four different mask configurations; * *P*-values based on the Friedman test

Anatomical site	Baseline (room air)	Intraoral mask with nose clip	Intraoral mask without nose clip	Pocket face mask	Oronasal mask	*P*-value*
Upper arm	69 (59, 75)	454 (437, 488)	427 (396, 474)	376 (347, 415)	250 (160, 326)	< 0.001
Lower arm	65 (59, 82)	393 (332, 437)	357 (324, 427)	312 (256, 383)	187 (135, 263)	< 0.001
Palm hand	77 (67, 81)	283 (229, 323)	263 (208, 285)	248 (160, 277)	157 (104, 217)	< 0.001
Lateral leg	61 (50, 75)	358 (283, 398)	345 (248, 394)	278 (243, 333)	156 (95, 294)	< 0.001
Lateral ankle	59 (51, 63)	310 (255, 329)	281 (238, 329)	252 (205, 286)	137 (110, 184)	< 0.001
Dorsum foot	64 (55, 78)	199 (175, 237)	188 (124, 228)	156 (132, 219)	123 (67, 137)	< 0.001

Figure 4
Transcutaneous oxygen partial pressures (median in mmHg) while breathing oxygen using the demand valve with four different mask configurations

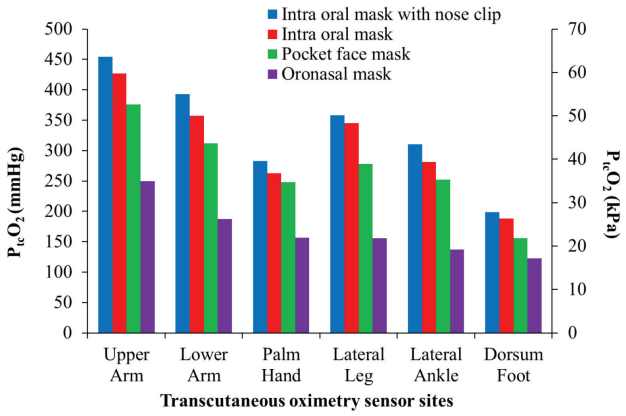

Table 3
Statistically significant differences in transcutaneous oxygen partial pressures *post hoc* comparisons using Wilcoxon Sign Rank test with Bonferroni correction; $P < 0.008$ (0.05/6) considered significant; IOM® – intraoral mask

Post hoc analysis:
IOM® with nose clip ≈ IOM without nose clip (all *P*-values > 0.01)
IOM with nose clip > Pocket face mask
IOM with nose clip > Oronasal mask
IOM without nose clip > Oronasal mask
Pocket face mask > Oronasal mask (for all sensor sites)
IOM without nose clip > Pocket face mask (for 3 of the 6 sensor sites)
Upper arm $P = 0.003$
Lower arm $P = 0.001$
Lateral leg $P = 0.005$

sensor sites after breathing O_2 for 10 min using each mask configuration. Secondary outcome measures included in-line and nasopharyngeal F_IO_2, $ETCO_2$, mask comfort, ease of breathing and holding of each device.

Results

Sixteen healthy volunteers, 13 female and three male, met all inclusion criteria and completed the study protocol. Their demographic and baseline measures are shown in Table 1.

Figure 4 displays the median $P_{tc}O_2$ readings across all sensor sites and mask configurations. $P_{tc}O_2$ values were statistically different across each mask configuration for each sensor site (Table 2). The IOM® with NC delivered statistically better tissue oxygenation than the pocket face mask and the oronasal mask at all sensor sites and was similar to the oxygenation achieved with the IOM® without NC. Table 3 summarizes the *post hoc* comparison results.

Nasopharyngeal F_IO_2 was highest using the IOM® and similar results achieved with and without the NC. Nasopharyngeal F_IO_2 was lowest when breathing with the oronasal mask (Table 4). One participant's nasopharyngeal F_IO_2 values were lost due to ongoing catheter clogging. $ETCO_2$ was statistically lower when participants breathed O_2 using the oronasal mask (Wilcoxon Signed Rank Test $P < 0.008$), but this almost certainly represents an artefactual reading due to an imperfect mask seal. In-line F_IO_2 did not exceed 97% with any of the mask configurations and was lowest using the oronasal mask (Table 4). Estimated mask assembly dead space is presented in Table 4. Actual individual pocket face and oronasal mask volumes would vary slightly depending on each participant's facial features.

The pocket face mask was rated as most comfortable (Table 5). Ease of breathing rating for each mask is listed in Table 6. Participant ratings for the holding of each mask configuration are presented in Table 7. On *post hoc* analysis no statistical

Table 4
Inspired oxygen and respiratory measurements while breathing oxygen using the demand valve with four different mask configurations and estimated mask assembly dead space (median and inter-quartile range); n/a – not applicable; $ETCO_2$ – end-tidal carbon dioxide; * *P*-values based on the Friedman test

Parameter	Intraoral mask with nose clip	Intraoral mask without nose clip	Pocket face mask	Oronasal mask	**P*-value
In-line O_2 (%)	95 (94, 96)	96 (94, 97)	94 (93, 95)	93 (89, 95)	< 0.001
Nasopharyngeal O_2 (%) (n = 15)	95 (95, 96)	96 (95, 96)	84 (75, 88)	56 (37, 70)	< 0.001
Intra-mask O_2 (%)	n/a	n/a	84 (72, 88)	n/a	
$ETCO_2$ (mmHg)	34 (30, 38)	32 (30, 36)	35 (28, 38)	29 (23, 36)	0.001
Respiratory rate (breaths·min^{-1})	9 (8, 12)	10 (9, 10)	10 (8, 11)	10 (8, 12)	0.945
Mask assembly dead space (ml)	14	14	119	195	n/a

Table 5
Mask comfort rating for each mask configuration (n (%)); * *P*-value = 0.000, Friedman test

Comfort assessment	Intraoral mask with nose clip	Intraoral mask without nose clip	Pocket face mask	Oronasal mask
Very uncomfortable	2 (12.5)	0	0	3 (18.8)
Uncomfortable	5 (31.3)	3 (18.8)	1 (6.3)	2 (12.5)
Neither	5 (31.3)	4 (25.0)	0	5 (31.3)
Comfortable	4 (25.0)	8 (50.0)	7 (43.8)	5 (31.3)
Very comfortable	0	1 (6.3)	8 (50.0)	1 (6.3)
Median (IQR)*	3.0 (2.0–3.8)	4.0 (3.0–4.0)	4.5 (4.0–5.0)	3.0 (2.0–4.0)

Table 6
Ease of breathing rating for each mask configuration (n (%)); * *P*-value = 0.020, Friedman test

Breathing assessment	Intraoral mask with nose clip	Intraoral mask without nose clip	Pocket face mask	Oronasal mask
Very difficult	0	0	0	2 (12.5)
Difficult	0	0	1 (6.3)	6 (37.5)
Neither	8 (50.0)	4 (25.0)	3 (18.8)	2 (12.5)
Easy	2 (12.5)	5 (31.3)	5 (31.3)	4 (25.0)
Very easy	6 (37.5)	7 (43.8)	7 (43.8)	2 (12.5)
Median (IQR)*	3.5 (3.0–5.0)	4.0 (3.3–5.0)	4 (3.3–5.0)	2.5 (2.0–4.0)

Table 7
Ease of holding rating for each mask configuration (*n* (%)); * *P*-value = 0.015, Friedman test

	Intraoral mask with nose clip	Intraoral mask without nose clip	Pocket face mask	Oronasal mask
Very difficult	0	0	0	1 (6.3)
Difficult	0	0	1 (6.3)	3 (18.8)
Neither	3 (18.8)	3 (18.8)	3 (18.8)	4 (25.0)
Easy	8 (50.0)	7 (43.8)	8 (50.0)	6 (37.5)
Very easy	5 (31.3)	6 (37.5)	4 (25.0)	2 (12.5)
Median (IQR)*	4.0 (4.0–5.0)	4.0 (4.0–5.0)	4 (3.25–4.75)	3.5 (2.25–4.00)

difference was found between each mask configuration for ease of breathing and holding of each mask configuration. The NC was frequently described as uncomfortable. The IOM® was described as easiest to use as it rested in the mouth whereas constant pressure was required to maintain a seal against the face with the two other masks.

Discussion

Oxygen is the primary first-aid treatment for divers suspected of having DCI.[1,2,7] Oxygen has been shown in retrospective reviews to improve symptoms and decrease the subsequent number of hyperbaric treatments required.[4] Of the commercially available O_2 masks for use with a demand valve delivery system designed for diver first aid, our study has shown that the IOM® with NC is the configuration that achieves the highest level of tissue oxygenation and nasopharyngeal F_IO_2.

DAN portable O_2 delivery units can provide a constant flow capability or operate as a pressure-triggered demand valve. The demand valve only delivers O_2 when the diver breathes in and, therefore, allows for conservation of O_2, dependent on the respiratory minute volume of the user. The ease of use, familiarity for divers, potential to deliver high inspired O_2 concentrations,[15] as well as the potential for O_2 supply conservation, has led to the recommendation of the demand valve as the O_2 delivery method of choice in the pre-hospital treatment of DCI.[2]

However, previous research unexpectedly showed that the demand valve with oronasal mask provided less tissue O_2 than a constant flow NRB.[10] $P_{tc}O_2$ readings whilst breathing O_2 via the demand valve with oronasal mask were anticipated to exceed those achieved with NRB at 15 $L{\cdot}min^{-1}$.[10] The previous contradictory findings[10] were almost certainly explained by poor fit of the oronasal mask and subsequent entrainment of air. This assumption is supported by the current findings. Not only are the $P_{tc}O_2$ values lowest whilst breathing O_2 using the oronasal mask, but the in-line and nasopharyngeal F_IO_2 values are also consistent with dilution of the O_2 with entrained air. The demand valve has been promoted to provide near 100% O_2;[2] however, this study highlights the need to assess the complete O_2 delivery system as different mask configurations provide different levels of O_2. It is important to remember that the one-way valve and filter provided for use with the pocket face mask and IOM® must be removed prior to use with the demand valve as leaving them in place leads to entrainment of air.

Oxygen therapy devices have traditionally been referred to as fixed or variable performance devices.[16] When used appropriately, fixed performance devices deliver a constant fraction of O_2 to the patient's airway whereas the fraction delivered by variable performance devices can be affected by factors such as O_2 supply flow rate and the patient's respiratory minute volume. Demand regulators have traditionally been regarded as fixed performance devices based on the assumption that the composition of gas delivered to the patient's airway matches that delivered to the demand valve itself.[16] However, our results show that even a demand regulator can, in fact, behave like a variable device depending on the interface between the valve and the patient. Use of an oronasal mask introduces variability to the behaviour of a demand valve depending on the adequacy of the seal on the patient's face, whereas when used with an IOM and NC the demand regulator likely behaves as a true fixed delivery device.

The IOM® with NC obtained the best $P_{tc}O_2$ results. Previous research comparing demand systems using both an oronasal mask and a mouthpiece with NC found no difference in inspired O_2 and nitrogen washout between the masks.[17] We verified F_IO_2 of the demand system using one-way valves (99%), but these valves were removed for the study. In-line F_IO_2 measured during the study did not reach 99% and was significantly lower when breathing with the oronasal mask (Table 4). These lower in-line F_IO_2 levels are reflective

of gas contamination with exhaled air and possible air entrainment from mask leakage. The differences between the in-line F_IO_2 using the different masks in our study are subtle (Table 4). It is only when examining the delivery of the O_2 to the participants ($P_{tc}O_2$ and nasopharyngeal F_IO_2) that the differences between the masks become obvious. The IOM® out-performs both oronasal masks.

Divers are accustomed to breathing from a demand valve with a mouthpiece. This is reflected in their rating of the different mask configurations. The IOM® was commonly rated as easy to breathe from and easy to hold (Tables 6 and 7). The NC was reported as uncomfortable. The oronasal mask was ranked as the most difficult in terms of breathing ease and holding the device. Two subjects were noted to have difficulty breathing using the oronasal mask. When questioned, they stated that they had to hold the mask tightly and use larger breaths to trigger the demand valve. It is likely that poor mask fit and the large mask dead space (Table 4) contributed to a larger breath being required to adequately trigger the demand valve.

$ETCO_2$ was significantly lower when breathing with the oronasal mask though there were no differences in the respiratory rates while breathing with the different masks (Table 4). Entrained air from a sub-optimally fitting mask diluting the $ETCO_2$ is the most likely explanation and is onsistent with the observed lower in-line F_IO_2 measured with this device.

There was a low number of male participants in this study due to a predominance of facial hair (an exclusion factor) as it was thought it could contribute to mask leak.[18] Previous research showed no significant difference in $P_{tc}O_2$ by sex,[13] but facial size may be a factor in mask fit.

Other investigators have explored closed-circuit O_2 delivery devices, other than demand valves, for the delivery of O_2 in DCI.[19,20] None of these closed-circuit devices, however, are commonly used by recreational divers, partly due to increased complexity and operational requirements.[2,21] Future research should compare continuous flow devices with demand valve and closed-circuit O_2 delivery systems.

LIMITATIONS

P_aO_2 was not measured but, rather, TCOM was used as a non-invasive method of measuring tissue oxygenation.[22] Some DCS symptoms are presumably caused by tissue inert gas bubbles; therefore, a measurement estimating tissue oxygenation seems relevant to a study of first aid O_2 delivery. It could be argued that a higher $P_{tc}O_2$ must inevitably indicate higher values at all levels of the pre-tissue O_2 cascade, and that this, in turn, likely indicates greater drive for tissue inert gas elimination, bubble resolution and oxygenation of hypoxic tissues.[2,5,6] However, although obvious, it is acknowledged that this is speculative as this study did not address the clinical efficacy of these devices in treating DCS.

The nasopharyngeal catheter provided valuable information on the oxygenation provided by each delivery system but may have compromised the seal of both the pocket face and oronasal masks. The catheter was secured to the nares and laid against the face, passing under the edge of the masks. The pocket face mask has an air-filled cushion which can easily mould around irregular facial features. The oronasal mask has a soft but more rigid edge and may have been more affected by the position of the catheter. However, participants who had difficulty sealing the oronasal mask felt air leaks at the apex of the mask at the bridge of the nose, not at the site of the catheter. Indeed, poor mask fit to facial contours and the large dead space likely contribute more to the poor performance of the oronasal mask than any small leak near the catheter.

Nasopharyngeal gas sampling was intermittent but frequent throughout the study with only the peak values recorded. Plotting any variable $F_IO_2/ETCO_2$ values obtained during the 10-minute oxygen breathing period was not possible.[16]

Conclusion

Of the commonly available O_2 delivery systems for use with the demand valve, the IOM® with NC is the device that achieved the highest $P_{tc}O_2$ values at the measured sites. We do not dispute previous findings that an oronasal mask could perform as well as a mouthpiece and noseclip,[17] but this would require that great care be taken to ensure a perfect seal. Our results suggest that this would be very unlikely in field use of oronasal masks by divers. The IOM® is likely the most effective option of those tested. $P_{tc}O_2$ and nasopharyngeal F_IO_2 values were similar between the IOM® with and without NC. Given the reported discomfort of this, the IOM® without NC may be the best option.

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Conflicts of interest

Professors Mitchell and Pollock are members of the Editorial Board of Diving and Hyperbaric Medicine but had no involvement in the peer review or publication decision-making process for this article.

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