ORIGINAL RESEARCH

# Evaluation of Two Oxygen Face Masks with Special Regard to Inspiratory Oxygen Fraction ($FiO_2$) for Emergency Use in Rescue Helicopters

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## Abstract

**Introduction:** Effective oxygenation during acute respiratory insufficiency depends on the inspiratory oxygen fraction ($FiO_2$) and the oxygen face mask used. Recent studies demonstrated significant advantages of the Hi-Ox80 mask as compared with a basic mask. The aim of this study was to measure $FiO_2$ in the laryngopharynx of patients and to apply these data to the setting in rescue helicopters.

**Methods:** In spontaneously breathing patients, $FiO_2$ was measured with an $O_2$-sensor (Draeger Medical, Luebeck, Germany) in the laryngopharynx, depending on the adjusted oxygen flow. Flow increments of 1 up to 12 L/min were analyzed using a basic oxygen mask (Intersurgical Ltd., Berkshire, UK) and a Hi-Ox80 mask (Viasys Healthcare GmbH, Hoechberg, Germany) in a randomized order on the same patient. Data were applied to the special helicopter environment and analyzed with respect to oxygen delivery per minute and resulting equipment benefits. Statistika (StatSoft GmbH, Hamburg, Germany) and *t*-test were used for statistical analysis. $P \leq .05$ was considered statistically significant.

**Results:** Twenty patients with a mean age of 69 ± 7 years were investigated. At a low oxygen flow up to1 L/min, the Hi-Ox80 mask was not superior to the basic mask ($FiO_2$ at 1 L/min 24% ± 3% vs. 27% ± 5% and partial pressure of arterial oxygen [$paO_2$] 164 ± 68 vs. 193 ± 53 mmHg; NS). Using a flow of 2 L/min or more, a significant difference for the $FiO_2$ and $paO_2$ in both masks was found ($P \leq .05$). Using the Hi-Ox80 face mask in a rescue helicopter with standard oxygen flows, it demonstrated 3.24 times longer oxygen availability because of a reduced required oxygen flow and therefore a potential calculated weight reduction.

**Conclusions:** The Hi-Ox80 mask allows more effective use of the administered oxygen flow. Efficiency of the new mask is greater; hence, similar flow adjustment produces a significantly higher $FiO_2$. Thus, oxygen, cost, and weight savings are feasible.



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## Introduction

Sufficient oxygenation is an indispensable precondition for life. Oxygen deprivation results in hypoxemia and thus in cellular hypoxia, which—depending on the level of severity—can lead to death within a very short time.

Critically ill patients threatened by an unexpected emergency often have a risk for acute hypoxia.[1] These patients often have to be transported with a rescue helicopter and an emergency medical services team to a center for further special therapy. Because of their critical condition, these patients often are dependent on optimal oxygenation and hence high oxygen flows with conventional (basic) masks.

Conversely, in emergency situations oxygen supply is often clearly limited, although patients are dependent on optimal oxygenation because of the nature of illness (for example myocardial infarction, stroke, or acute respiratory insufficiency).

One goal of all of therapeutic approaches is application of the maximum amount of oxygen per minute to produce the highest possible inspired oxygen fraction ($FiO_2$). The necessary amount of oxygen per minute (flow [L/min]) depends crucially on the designed condition efficiency and type of oxygen face mask used. Commercial and common oxygen masks without reservoir bags reach an $FiO_2$ of approximately 50% to 60% using a flow of 10 to 15 L/min maximum.[2-5]

Therefore, large amounts of oxygen are required for longer-term applications. The duration of oxygen application in the out-of-hospital setting is usually limited; hence, only limited oxygen resources are available (eg, 400 L oxygen in a 2-L pressure bottle at 2,900 psi weighing 5.90 kg), and high oxygen flows are often required. These facts result in an extremely short period for oxygen availability: At a flow of 15 L/min, oxygen flow is suspended after approximately 26 minutes. Financial aspects are added to this problem because refilling of such a pressure bottle usually costs $35 to $40.[6,7] Using a more effective oxygen mask, savings in oxygen flow per minute are conceivable, or vice versa, utilization of any given, limited resource may last longer. Because of these facts, additional weight savings may be feasible.

Apart from this problem, it would also be plausible from an economic point of view to save costs by using an improved oxygen mask for a similar treatment (same $FiO_2$).

A recently published study by Hinkelbein et al[8] evaluating two different oxygen face masks in the aviation field (hypobaric hypoxia) for flights up to 22,500 feet altitude showed clear disparities with respect to oxygen delivery. In this study, parachute jumpers were investigated with a potential risk for hypobaric hypoxia during climbing flight. In this environment, atmospheric pressure dropped to 356 hPa (ie, $pO_2$ 75 hPa when breathing no supplemental oxygen). When using the Hi-Ox80 mask, a significantly lower oxygen flow was required to produce the same oxygenation as compared with a basic mask. Measurement of the actual available $FiO_2$ (efficiency) was not analyzed in this study; it was not possible in the airplane environment.

The aim of the current study was to analyze the $FiO_2$ in a clinical setting for two intentionally different masks and to apply these results to the special requirements of helicopter emergency medical transportation of patients.

## Materials and Methods

### Inclusion and Exclusion Criteria

Twenty patients were investigated after approval of the local ethics committee of the Medical Faculty Mannheim (Heidelberg University, Germany) and after written informed consent. Spontaneously breathing patients who agreed to participate within the context of orthopedic surgery and with whom regional (or local) anesthesia was planned were exclusively investigated (spinal or combined spinal-epidural anesthesia). Only patients of at least 18 years of age with no history of pulmonary disease were included in this study. Patients did not receive any sedating medication shortly before intervention.

To identify pulmonary disease, lung function measurement (SpiroPro, VIASYS Healthcare GmbH, Hoechberg, Germany) was performed on the preoperative day. A functional vital capacity less than 3 L, forced expiratory volume after 1 second less than 3 L, and a peak expiratory flow less than 7 L/sec were considered exclusion criteria. Additionally, pregnant women, smokers (more than 10 cigarettes/day), and patients with an acute or chronic pulmonary disease (eg, chronic obstructive pulmonary disease, asthma) were refused participation in this study. Patients with a spinal anesthesia level above T5 and patients who received benzodiazepines or opiates for sedation during the surgery (possible interaction with the respiratory function inducing an acute respiratory impairment) also were excluded from the study.

**Figure 1.** Basic oxygen face mask (Intersurgical Ltd., Berkshire, UK).

**Figure 2.** Hi-Ox80 face mask (VIASYS Healthcare GmbH, Hoechberg, Germany).

### Analysis of Mask Efficiency (Measurement of $FiO_2$)

Measurements were performed during surgery in the operation theater. $FiO_2$ was measured depending on the administered oxygen flow as a measure for the efficiency of each oxygen mask. For oxygen application, two different oxygen masks (basic vs. Hi-Ox80 mask) were used in random order (crossover design) on each patient. The randomization took place by drawing lots directly before the beginning.

The basic oxygen mask (Intersurgical Ltd., Berkshire, UK; weight, 62 g) is a simple, single-use, common oxygen mask design with neither valves nor a reservoir. Oxygen rebreathing is not possible with this mask (Figure 1), because only a given amount of oxygen can be breathed in during inspiration; hence, the preset flow in the masks is limited.

The Hi-Ox80 mask (Viasys Healthcare GmbH, Hoechberg, Germany; weight, 146 g) is also a single-use oxygen mask equipped with three valves, one of which is directly attached to the reservoir to allow a sequential gas flow of the supplied oxygen (Figure 2).

**Figure 3.** Inspiratory oxygen fraction ($FiO_2$ [%]) depending on the adjusted oxygen flow (L/min) for both masks. Using a flow of 2 L/min or more, significance (*) was achieved (*N* = 20; *P*<.05). Black = Hi-Ox80 mask; gray = basic mask.

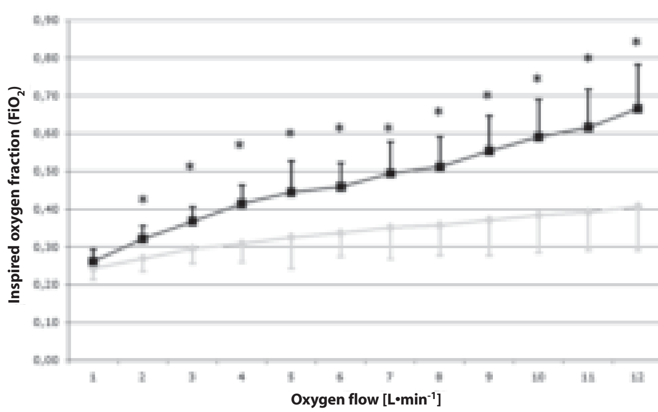
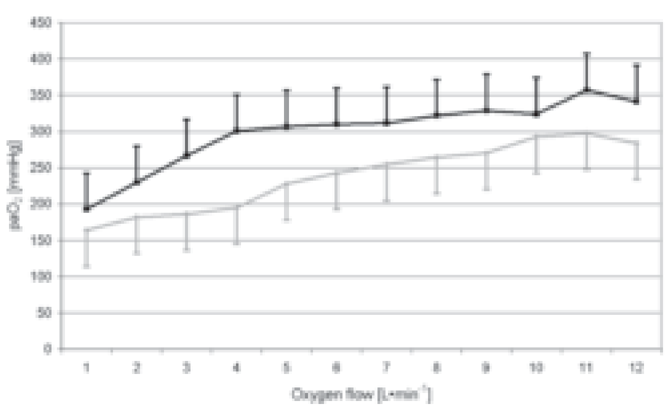



**Figure 4.** Relationship between $paO_2$ (mmHg) and oxygen flow (L/min) for both masks analyzed. Analysis of arterial blood gases also demonstrated the Hi-Ox80 mask to be superior to the basic mask. Black = Hi-Ox80 mask; gray = basic mask.




The expired air is exhaled directly through a valve during expiration. Additionally, oxygen flow influx is gathered in the reservoir during expiration. The reservoir valve opens first during inspiration, so that only pure oxygen from the reservoir will be breathed in at the first inspiration phase ($FiO_2$ nearly 100%). Another valve opens when the contents of the reservoir are depleted so that additional ambient air can be breathed in. The highest possible inspiratory oxygen concentration shall be reached by this sequential gas flow.[9]

A standardized 10 CH (B. Braun Melsungen AG, Melsungen, Germany) plastic catheter was positioned through a nostril[10] into the laryngopharynx to measure $FiO_2$ on every patient before the beginning and during the investigation. $FiO_2$ was continually measured with an oxygen cell (Draeger $O_2$-Sensor 6850645, Draeger Medical AG & Co. KG, Luebeck, Germany) during inspiration and expiration.

The two oxygen masks were always put on firmly by the same investigator in a random order to avoid measurement variances. The elastic straps were tightened as much as possible for a close fit to establish the same investigative conditions as well as to avoid any fluctuations resulting from a loose-fitting oxygen mask.

Patients were instructed to breathe normally after the mask was put on. The same measurement procedures for flow values of 1 through 12 L/min were conducted for both oxygen masks. A commercial continuous single-flow regulator was used to set the oxygen gas flow.

Starting at a flow of 1 L/min normal respiration and after 3 minutes' normal breathing, the inspiratory $FiO_2$ (recognizable by the graphic display) was registered by 10 consecutive breaths. Afterwards, flow was increased to 2 L/min, followed by a 3-minute waiting period, and so on up to a flow of 12 L/min. After the completion of the measurement, the masks were switched and the gas flow was measured again from low to high gas flow. For each patient, $FiO_2$ values from 10 consecutive inspirations (for each mask) were averaged. Mean data were used to subsequently compare both masks investigated.

Although an oxygen flow below 5 L/min may be used seldom during clinical practice with oxygen masks, oxygen flow in the range of 1 to 12 L/min was tested to gather data in the complete range.

In addition to the $FiO_2$ measurements, arterial blood samples from an arterial catheter were drawn in five randomly selected patients for both masks and at every flow increment (ie, 12 arterial blood samples per mask). The arterial blood samples were cooled on ice for a maximum of 15 minutes and partial pressure of arterial oxygen ($paO_2$) determined by arterial blood gas analysis (ABL 610, Radiometer, Brønshøj, DK).

## Analysis of General Conditions

A calculation for weight and possible duration of the oxygen flow depending on the total amount of oxygen carried in a rescue helicopter was performed. Additionally, costs and financial aspects (economic analysis) were highlighted. For these aspects, the following parameters were used: basic mask, \$0.60; Hi-Ox80 mask, \$13.00; 400 L oxygen refill, \$40 for a 2-L oxygen pressure bottle (pressure: 2,900 psi = 200 bar; weight: 5.90 kg).

## Statistical Analysis

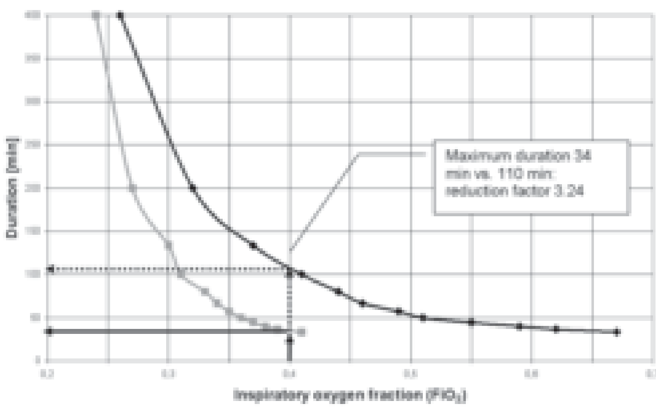
Data acquisition was carried out with Excel 2003 (Microsoft, Redmond, WA). For the statistical analysis, Statistika (StatSoft Europe GmbH, Hamburg, Germany), regression analysis, and the *t*-test were used. $P<.05$ was considered statistically significant.

# Results

## Patient Characteristics

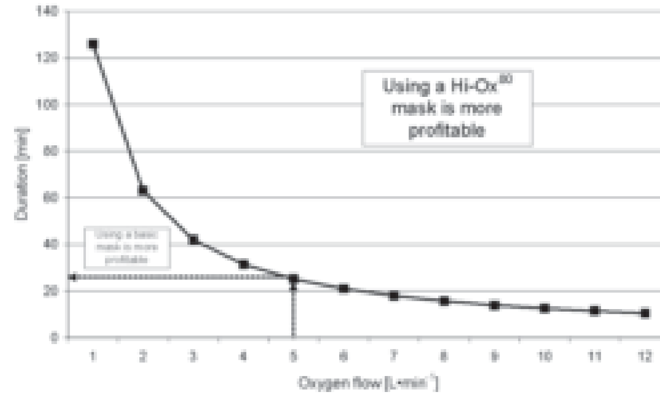
Twenty patients (9 male, 11 female) with a mean age of 69 ± 7 (58–82) years and body mass index of 26.7 ± 3.4 (20.7–33.8) $kg/m^2$ were investigated. No patients were excluded from the study at any time because of poor lung function.

**Figure 5.** Duration of possible oxygen usage for a 2-L oxygen pressure bottle (400 L of oxygen) depending on intended inspiratory oxygen fraction ($FiO_2$).*




*Based on data of Figure 3 (oxygen flow required for a given $FiO_2$), duration of oxygen flow was calculated for a 2-L oxygen pressure bottle. The graph shows how long oxygen flow is available with a 2-L pressure bottle, if a special $FiO_2$ is required. Example: Whereas the maximum duration is limited to 34 minutes when using a basic mask and an $FiO_2$ of 0.4 (black arrow), duration is extended to 110 minutes for the same $FiO_2$ when using a Hi-Ox80 mask (dotted arrow). This results in a duration extension of 3.24. Alternatively, absolute costs for oxygen also may be reduced by a calculated factor of 3.24. Black line 5 Hi-Ox80 mask; gray line 5 basic mask.

**Figure 6.** Relationship between oxygen flow (L/min) and duration of application (min).*




*Data are presented for increments of 1 L in oxygen flow. Black line indicates same costs when using a basic mask or a Hi-Ox80 mask. The area left or below the black line indicates the basic mask may be more profitable; area above the black line shows the Hi-Ox80 mask to be more profitable. Exemplary analysis of profitability for both masks in the out-of-hospital setting within an rescue helicopter and a 2-L oxygen pressure bottle (2,900 psi): Maximum duration (min) to amortize the Hi-Ox80 mask depending on the selected oxygen flow (L/min). The higher price for the Hi-Ox80 mask was amortized after a delivery of 126 L oxygen. At a flow of 5 L/min, both masks are redeemed (due to the high refill price) after 25 minutes. Exemplary costs: basic mask, $0.60; Hi-Ox80 mask, $13.00; 400-L oxygen refill, $40.

## Efficiency Analysis

At a flow of 1 L/min, the basic mask as well as the Hi-Ox80 mask reached comparable $FiO_2$ values (24% ± 3% vs. 27% ± 5%, NS). At a flow of 2 L/min and beyond, a statistically significant difference in the measured $FiO_2$ between the two groups was found ($P<.05$; Figure 3). At the highest flow of 12 L/min, the difference was the most pronounced ($FiO_2$: basic mask, 40% ± 12%; Hi-Ox80 mask, 67% ± 16%, $P<.05$). A significant difference between the two oxygen masks was also revealed using multiple regression analysis ($R = 0.7053$ vs. $R = 0.5296$; $P<.0001$).

Arterial blood gas analysis also demonstrated higher $paO_2$ values for each flow increment when using the Hi-Ox80 mask (Figure 4).

## Maximum Duration of Oxygen Application

Analyzing maximum duration of oxygen application showed significant differences for both masks (Figure 5). For example, whereas the maximum duration is limited to 34 minutes when using a basic mask, it is extended to 110 minutes for an $FiO_2$ of 0.40 when using a Hi-Ox80 mask. This calculates to 3.24 times longer oxygen availability when using a Hi-Ox80 mask or 3.24 times reduced oxygen delivery.

## Costs

With the costs for an out-of-hospital application in emergency medicine, the time leading to break-even costs was significantly lower because of the higher cost of oxygen (refill costs): The higher price of a Hi-Ox80 mask was amortized after 126 L oxygen was used. At a flow of 5 L/min, both masks were at the break-even point after a period of 25 minutes because of the high refill price (Figure 6).

# Discussion

Comparison of both oxygen masks demonstrated that the Hi-Ox80 mask has a higher achievable $FiO_2$ and $paO_2$. Furthermore, a higher $FiO_2$ (40% vs. 67%) can be achieved by the use of a high-performance oxygen mask in comparison with a basic one. This provides significant savings in oxygen because of the lower required flow and along with that a reduction in weight and costs.

The two rather different mask systems (basic vs. high-end) analyzed in this study were intentionally used to point out clear differences in efficiency. The basic mask has (in Germany) a broad acceptance, whereas the Hi-Ox80 mask is often believed to be too expensive with regard to its efficiency. The current study demonstrates a break-even point and furthermore that using the Hi-Ox80 mask may be cheaper under special circumstances.

## Studies on Oxygen Masks

Besides many anesthesiologic[4,11] and pulmologic[5,12,13] studies in volunteers or patients,[2,14,15] some other studies are addressed to other medical areas.[3,8,15,16] All of these studies evaluated efficiency of different oxygen masks under various conditions.

In most of the studies, different types of oxygen masks or nose cannulas were compared, mostly on healthy subjects. Only two previous studies have investigated the Hi-Ox80 mask.[15,17]

## Analysis of Efficiency

The current study illustrates that, in a direct randomized comparison, the Hi-Ox80 mask is clearly superior to the standard commercial mask with respect to efficiency. At a maximal investigated flow of 12 L/min, the Hi-Ox80 mask achieved a 1.67 times higher $FiO_2$ as compared with the basic mask.

Efficiency of the standard, commercially available (basic) oxygen mask is quite low because the volume inside of the mask often contains less than 40 mL (pure oxygen), and therefore a lot of ambient air is breathed in during every inspiration.[4] The effectiveness is greater in oxygen masks with a reservoir bag.[4]

Savings of 1.67 times the oxygen flow result in a significant cost reduction for emergency medicine within a very short time. At a flow of 5 L/min, the Hi-Ox80 mask is amortized after a period of 25 minutes because of the high cost of oxygen refilling.

Furthermore, more efficient utilization of oxygen flow leads to a clear extension in the possible application duration in emergency medicine and thus avoids bottle necks (empty bottles). If the flow is doubled, the maximum duration is reduced by 50%. An improvement in the typically limited storage conditions in rescue helicopters or emergency vehicles also exists (fewer bottles must be carried).

Whereas the total amount of oxygen of a 2-L pressure bottle (2,900 psi) is exhausted after approximately 34 minutes when using a flow of 12 L/min and a basic oxygen mask, the Hi-Ox80 mask only needs a flow of 4 L/min for a comparable $FiO_2$. On the basis of an $FiO_2$ of 0.40, the maximum duration is limited to 34 minutes when using a basic mask, but it is extended to 110 minutes for the same $FiO_2$ when using a Hi-Ox80 mask.

Besides these economical aspects, the possible weight and space reduction must not be omitted. Whereas the maximum duration is extended by the factor 3.24, weight may be reduced by the same factor with respect to a similar $FiO_2$. Especially in rescue helicopters with limited weight margins, reducing the absolute weight of oxygen bottles (5.90 kg each) may cut down the weight of medical equipment by 10 to 20 kg and therefore may enhance potential payload (eg, patient) or flight performance.

## Limitations

This study was conducted perioperatively in recumbent and spontaneously breathing patients who received regional anesthetics. Although it was indeed made certain that the patients exhibited normal lung function performance, the horizontal positioning of the patients could, in principle, influence the efficiency of the oxygen masks. These factors also apply to traumatized or critically ill patients, usually transported by helicopter. Of course, these patients may not be comparable to the patients of our study without any limitations. Unfortunately, it is not possible to make all the measurements performed (approximately 1 hour of $FiO_2$ and arterial blood gas measurements) in patients transported in a helicopter. Hence, we used the mentioned patient group as a substitute, although there are limitations.

Regarding the indicated costs for the oxygen masks and oxygen, different costs are used for different institutions. The calculation represented here is meant to be understood as exemplary and reflects the local conditions at the University Clinic, Mannheim, Germany.

## Conclusions

In comparison with basic oxygen masks, the Hi-Ox80 mask allows a more efficient use of oxygen flow and furthermore with the same flow settings a higher $FiO_2$. If the goal criterion is a determined inspiratory oxygen concentration, then the Hi-Ox80 mask requires a significantly lower oxygen flow. Beyond substantial oxygen savings, there exist also clear cost and potential weight savings when using a Hi-Ox80 mask.

Because we used an orthopedic patient group as a substitute for traumatized or critically ill patients transported by helicopter, some limitations to the data may apply. Further research, especially in traumatized patients, is required on this topic.

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