Southmedic

OxyMask™

Advancing Oxygen Therapy for Better Patient Care

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Table of Contents

Note: The OxyMask™ technology was originally launched as an OxyArm™ product. OxyMask™ was also previously known as High Flow Mask.

1. Abstract

OxyMask™ is one of the latest breakthroughs in advanced oxygen delivery technology. It features an open design that is ideal for patients whose oxygen requirements vary throughout their hospital stay. Clinicians can respond to a patient's changing oxygen needs simply by increasing or decreasing oxygen meter flow from 1 litre per minute (lpm) up to flush (>15 lpm) to deliver 24%-90% FiO_2 and maintain the desired $Sp0_2$. OxyMask™ is designed to deliver a broad range of oxygen in a safe and effective manner.

OxyMask™ delivers supplemental oxygen via a 'virtual reservoir' formed by a vortex of oxygen flow directed at the patient's mouth and nose through a patented pin and diffuser assembly.

The large openings in the OxyMask™ design provide multiple patient benefits allowing the wearer to communicate effectively with caregivers and drink fluids. Higher humidity room air is drawn in through the mask openings as the patient inhales. This usually negates the need to use additional devices to humidify the delivered oxygen.

Mask openings also allow the patient to feel less claustrophobic, significantly improving patient comfort and compliance with their oxygen therapy.

Most importantly, the open mask design improves patient safety allowing carbon dioxide (CO_2) to escape the mask on exhalation, reducing the risk of CO_2 rebreathing and potential sentinel events.

2. The history of oxygen therapy

Oxygen is essential to life on our planet. Following hydrogen and helium it is the third most abundant element in the universe and comprises 65% of the mass of the human body.[1] Oxygen is vital to aerobic respiration, generating energy to support our daily lives, but it may also be harmful as reactive oxygen molecules can degrade biological tissue.

The acknowledgement of oxygen as a potentially valuable resource for patients with respiratory conditions was recognized by pharmacist Karl Scheele in 1771 and in 1777 by the theologian-chemist Joseph Priestly, after both performed experiments with mercuric oxide and potassium nitrate.[2] Thomas Beddoes, considered the father of respiratory therapy, worked with the inventor James Watt to generate oxygen and other gases. Watt opened a Pneumatic Institute in Bristol, England in 1798, using oxygen and nitrous oxide to treat asthma, congestive heart failure and other ailments. By 1885, George Holtzapple used oxygen to manage a young patient with pneumonia and established its role in acute care.[3]

In 1907, Arbuthnot Lane devised rubber tubing that served as a nasal catheter for oxygen administration and J.S. Haldane, who first described hypoxemia after a trek up Pike's Peak, developed designs for modern-day oxygen masks. The oxygen tent was invented in the 1920s by Leonard Hill constructed out of canvas with slots cut for patient access. Initially there were no means of ventilation, until ice chunks and soda lime were added to cool and absorb carbon dioxide.[4, 5] Alvan Barach developed his own oxygen delivery systems and became the first to report the use of oxygen in support of hospitalized patients with pneumonia.[6] Barach and Haldane developed the first "venturi masks" called "meter masks" with valves that diluted oxygen with room air, allowing the adjustment of delivered oxygen concentrations. Barach also developed hoods to provide patients with continuous positive airway pressure.[7]

In the 1980's, pulse oximetry became the standard for measuring blood oxygen levels, replacing frequent arterial blood gas sampling. This advancement has allowed for rapid assessment and subsequent titration of supplemental oxygen.

3. Oxygen therapy today

The primary goal of oxygen therapy administration is to maintain adequate tissue oxygenation while minimizing cardiopulmonary work in patients who are hypoxemic, have shortness of breath, or are hemodynamically unstable. The clinical indications of inadequate oxygenation include tachypnea, accessory muscle use, dyspnea, cyanosis, tachycardia and hypertension. [8] Supplemental oxygen is also used for chronic cardiac and pulmonary illnesses.

Currently, there are a wide array of oxygen delivery devices available to the health care professional. The choice of oxygen delivery device depends on the patient's oxygen requirement, efficacy of the device, reliability, ease of use and patient comfort. Design plays an important role in device selection and thorough clinical assessment will determine how and which device should be selected.[8] Choices of oxygen delivery include cannulas and masks, with features such as heated humidity, high flow or low flow, reservoir or no reservoir, etc. A patient's oxygen requirements are most often assessed with pulse oximetry and sometimes with arterial blood gas measurement. Excessive oxygenation or supplemental oxygen can be detrimental to a chronic CO_2 retainer, (a common trait in severe cases of chronic obstructive pulmonary disorder; COPD), and it may also lead to absorption atelectasis by washing out nitrogen gas.[8]

Most healthcare professionals are in agreement with the primary focus of adequate oxygenation for every patient. Maintaining oxygen saturations within acceptable limits is the standard of care at most institutions. Achieving this goal can be a complex and multifaceted practice with many variables to consider. Providing flow that exceeds the patient's minute ventilation may be appropriate for some patients who must work harder to inspire and or expire. Choosing a low flow device such as a nasal cannula may be appropriate for those patients that require a low concentration of FiO_2. Additional decisions such as humidity and patient tolerance are also important to ensure compliance to their oxygen therapy.

The standard nasal cannula is the least invasive option, delivering an FiO_2 of 24-40% into the nostrils with flows up to 5 lpm. The FiO_2 is influenced by patient's respiratory rate, tidal volume and clinical condition. Nasal cannulas have been known to cause irritation in the nose and behind the ears when worn for a prolonged period of time.

A venturi mask entrains room air to mix with oxygen creating high flows with somewhat specific FiO_2 (24%, 28%, 31%, 35%, and 40% oxygen). This mask has traditionally been used when clinicians are concerned with CO_2 retention. Delivering too much oxygen to a patient that is a chronic CO_2 retainer (as seen with severe COPD), will reduce their drive to breath. Venturi masks do not allow the caregiver to titrate oxygen as easily nor as precisely as may be indicated due to having to repeatedly change venturi adapters. Failure to provide the suitable adaptor, or alterations in a patient's breathing pattern may alter desired FiO_2 delivery. Most clinicians agree that best practice is to titrate liter flow to meet the patient's blood oxygen saturation requirement, which is not easily achieved with the venturi mask.

A simple face mask is commonly used in healthcare settings for patients that complain of discomfort with nasal cannulas, pediatric patients or primarily mouth breathers. This device delivers an FiO_2 in the range of 40%-60%. However, it can be obtrusive, uncomfortable and confining. This almost completely closed mask, muffles the patient's speech, obstructs cough efforts and does not allow patients to eat or drink without the full removal of the mask.[9] Most importantly, the simple mask requires the caregiver to be aware that adequate oxygen flow must be delivered (>5 lpm) to prevent the patient from rebreathing their own CO_2. This is a potentially serious safety risk that could lead to an unanticipated sentinel event in the healthcare setting resulting in death or serious physical injury to the patient.

In situations where the patient requires more than 40% oxygen, a non-rebreather mask is commonly used. It can provide up to 90% oxygen when flows of 8-10 lpm are delivered into a reservoir bag. This mask may be quite uncomfortable for a patient as it must be tightly secured to a patient's face[9]. The non-rebreather mask shares the same risks as the simple mask, creating the potential of CO_2 retention, particularly at inadequate oxygen flow rates or when a patient's minute ventilation exceeds flow delivered. A non-rebreather mask necessitates health care professional application as visualization of the reservoir bag and the monitoring of patient breathing effort is required.

Similarly, a partial rebreather mask has a reservoir and requires a minimum oxygen flow rate of 8 lpm. These masks provide less FiO_2 than a non-rebreather mask as it is partially open for room air entrainment. Similar issues around patient comfort, compliance and patient safety exist with the partial non-rebreather mask as they do with the other older technology oxygen masks.

High-flow nasal oxygen can be administered at flows ranging from 10-60 lpm. When this oxygen is warmed to body temperature and saturated to full humidity, it is comfortable for the patient. The moist gas is delivered at flows high enough to meet a patient's entire inspiratory demand. Studies have shown that specific populations benefit from this device, however, it is expensive and may be cost prohibitive at some institutions.

4. Introducing OxyMask™

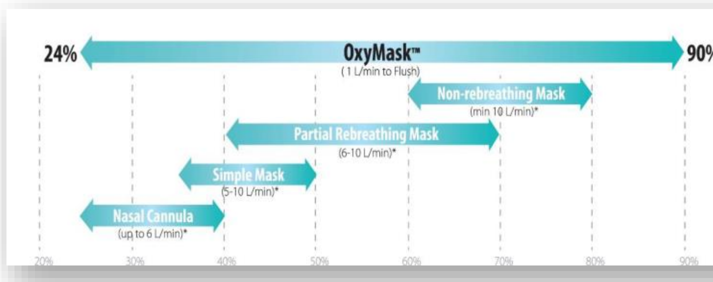

Figure 1. Fractional inspired oxygen percent (FiO2%) for a range of respiratory products. AARC Clinical Practice Guideline Reprinted from RESPITATORY CARE (Respir Care 2002: 47(6): 717-720)

OxyMask™ is a significant breakthrough in advanced oxygen delivery technology, featuring an open mask design that is ideal for patients whose oxygen requirements vary throughout their hospital stay. Clinicians can now respond to the patient's changing oxygen needs and deliver 24%-90% FiO_2 by simply increasing or decreasing oxygen flows from 1 lpm to flush (>15 lpm) to maintain the desired $Sp0_2$ percentage. (Figure 1).

OxyMask™ delivers supplemental oxygen via a 'virtual reservoir' formed by a vortex of concentrated oxygen flow directed at the patient's mouth and nose (Figure 2). This open mask design does not require added humidity as humid room air is entrained into the mask as the patient inhales.

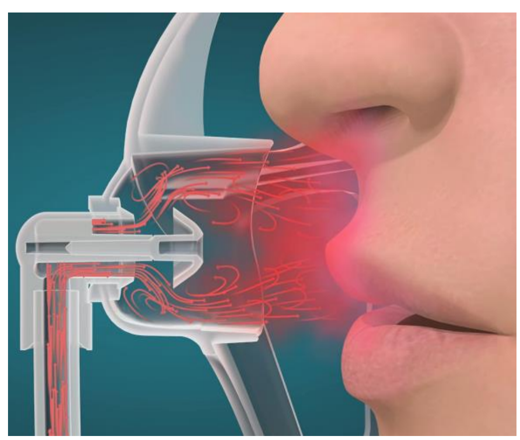

Figure 2: OxyMask™ Pin and Diffusor assembly redefines oxygen, creating a virtual reservoir in front of the mouth and nose

The large openings in the OxyMask™ design allow a patient to speak without being muffled and drink fluids through a straw (Figure 3). This allows the patient to be comfortable and compliant with their prescribed oxygen therapy.

Figure 3: The openings in OxyMask™ allow access for patients to drink through a straw.

For the clinician, the large openings in the mask allow easy access to the nose and mouth for food and drink, medication delivery, suctioning, oral care and even laryngoscopy or bronchoscopy procedures.

As traditional oxygen devices must fit tightly onto the face, there is not easy access should a patient require a nasogastric tube. With open design of OxyMask™, the mask does not need to be secured tightly onto a patients' face and it provides easy access.

Many institutions are focused on non-ventilator associated pneumonia events which has resulted in a renewed focus on oral care. Research suggests that brushing patient's teeth and/or performing basic oral care four times per day while in a hospital will reduce the likelihood of hospital acquired pneumonia.[10] Traditional closed oxygen masks do not allow for adequate oral care without having to remove the device, which poses a risk of hypoxemia with those patients requiring high levels of oxygen.

OxyMasks' open design does not create intrinsic PEEP at flows greater than 15 lpm and it is not dependent on patients breathing habits (nose or mouth; or variable). Intrinsic PEEP occurs when a patient does not expire completely prior to the initiation of the next breath. This leads to progressive air trapping (hyperinflation) which can lead to a critical situation including respiratory failure.

Most importantly, the open mask design increases patient safety by reducing the risk of CO_2 rebreathing as CO_2 leaves the mask upon exhalation. A minimum flow rate is *not* required to remove retained CO_2 which is often required when treating with a traditional, closed oxygen mask.

Positive patient outcomes depend largely on the ability of clinicians to administer consistent, safe and effective care to their patients. Hospitals are particularly focused on safety and many have developed Safety Committees, on-line error reporting tools and a highly reliable culture of safety. Clinicians are empowered to be transparent and forthcoming with concerns about safe patient care. Hospital administrations are increasingly focused on providing the most efficient, consistently delivered best practice tools for clinicians. OxyMasks' open mask design provides an opportunity to eliminate risks associated with supplemental oxygen delivery. It allows caregivers to respond immediately to a patient's changing oxygen needs without delaying care while a new oxygen device is obtained.

5. The technology

The mushroom-shaped pin redirects the flow of oxygen, forming an organized pattern of vortices and a cloud of concentrated oxygen. The triangular directional diffuser refines the shape of the oxygen vortices and directs the flow towards the patient's nose and mouth.

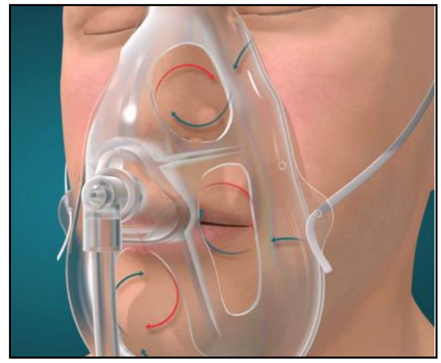

Figure 4: Oxygen is mixed with room air and entrained into the mask when the patient inhales

During the patient's inhalation, oxygen flow is mixed with room air drawn in through the mask openings. Respiratory mechanics and breathing patterns determine how room air combines with the delivered oxygen (Figure 4).

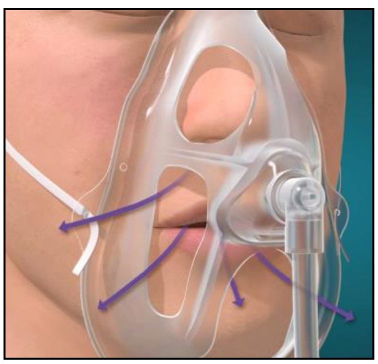

Figure 5: $C0_2$ escapes the mask through the large openings when the patient exhales

The concentration of oxygen received during the breath is a function of the oxygen flow compared to the patient's inspiratory flow and tidal volume. This results in the required concentration of oxygen being delivered to the patient.

During exhalation the mask openings allow expired carbon dioxide to escape (Figure 5).

6. Overcoming the barriers of change

Clinicians are becoming more conscious of the positive impact made by reducing the total cost of patient care rather than focusing on the individual medical product costs. OxyMask™ reduces the total cost of care by eliminating the need for multiple oxygen delivery devices masks that have traditionally followed the patient throughout their hospital stay. For example, a clinician may choose a non-rebreathing mask for a new patient's admission, but may then move to a partial rebreather as the patient's condition improves. As the patient continues to recover, a simple mask or a nasal cannula may then be utilized to wean the patient off of oxygen therapy. With OxyMask™, clinicians now require only one mask throughout the patient's hospital stay. Using less product positively impacts the total cost of patient care. Additionally, the institutional waste management costs will also decrease.

A comfortable oxygen mask will cause less stress to the patient. Patients that are relaxed and have decreased dyspnea require less oxygen. With OxyMask™, clinicians can titrate oxygen levels, delivering only what is required by the patient... This increased patient comfort and ease of titration by the clinician may result in a decrease in bulk oxygen gas consumption resulting in significant cost savings to a hospital or healthcare system.

Healthcare professionals are frequently expected to increase in the number of tasks they do in their daily routines. Traditionally, when a patient's oxygen therapy needs change, the caregiver is required to begin a local search to obtain a different oxygen device. This can use up valuable time and energy. The introduction of OxyMask™, a single device for oxygen therapy, will free up the clinician's time to focus on urgent and more important tasks.

The safety benefits of OxyMask™ have appealed to many hospitals that have experienced sentinel events using traditional oxygen masks, reporting that these devices are not consistently being set at adequate oxygen flows rates. As OxyMask™ reduces risk of oxygen toxicity and CO_2 rebreathing, a conversion to OxyMask™ would resolve these patient safety issues.

As OxyMask™ can cover a broad range of oxygen delivery, and is available in adult and pediatric sizes. This mask is commonly chosen by those overseeing disaster preparedness, mass casualty and pandemic situations, as there is less inventory to stock and store.

Implementation of an open design oxygen mask which includes removal of all traditional mask type oxygen devices requires committed, focused clinical education. Staff need to be supported through the process as it may be difficult for some to "buy in" to the fact that FiO_2 delivery amount via the open design mask is often more efficient than traditional devices. Support for the clinical change to an open mask design is generally swift. Confidence and trust builds with usage.

7. Summary

Healthcare is always changing. Clinicians across multiple disciplines strive to innovate new tools and procedures that will improve patient outcomes. Healthcare personnel are continuously expected to evaluate current data, processes and equipment to consistently deliver care that is as safe, precise and efficient as possible. Since the dawn of oxygen therapy, there have been numerous changes in practice and innovations that have improved the patient experience. The open design of OxyMask™ raises the bar in oxygen therapy. It allows for improved safety, reduced risk of CO_2 rebreathing, improved patient comfort, increased efficiency of clinician workflow, and potentially reduced overall cost of care. OxyMask™ is the preferred oxygen delivery device as it helps clinicians efficiently and safely achieve patient care and healthcare system goals.

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