



Research Article
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## A Low-Cost Venturi Ambient Air-Oxygen Blender for Neonatal Oxygen Therapy



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#### Abstract

The concentration of oxygen delivered to neonates in respiratory distress should be controlled to prevent hyperoxia. Current available oxygen blending devices have limited use in resource-limited settings due to their reliance on electricity, compressed air, skilled maintenance, and high cost. This study evaluated the ability of a novel blending device that addresses these limitations to deliver inspired concentrations of oxygen over a range of 30-100%. Our blending device was designed based on the Venturi principle. The blender consists of a nozzle, air entrainment window, and orifice. Oxygen exits the nozzle at high velocity into an air-entrainment chamber, where the low pressure surrounding the jet draws in ambient air. The mixture of air and oxygen is then transported into the orifice and thereafter further downstream via tubing. We investigated the effect of geometric factors and process variables on the delivered oxygen concentrations. The diameter of the Venturi nozzle and outlet orifice, the cross-sectional area of the air-entrainment window, the distance between the Venturi nozzle and the outlet orifice, flow rate, and temperature were each analyzed as independent variables. Understanding the geometric relationships between Venturi nozzle diameters, air-entrainment window cross-sectional areas, and Venturi nozzle to outlet orifice distances provided guidance on the design of an ultra-low-cost Venturi ambient air-oxygen blender. This study demonstrates the feasibility of manufacturing an air-oxygen blender that is low cost, does not require electricity or compressed air, and can provide accurate concentrations of oxygen for optimal delivery to neonates with respiratory distress

Keywords: Global health; Affordability; Accessibility of health services; Healthcare quality; Oxygenation; Hyperoxia; Neonatal diseases; Medical device design; Biomedical engineering; Respiratory distress and failure

Abbreviations: CPAP: Continuous Positive Airway Pressure; FiO<sub>2</sub>: Fractional Oxygen Concentration

#### Introduction

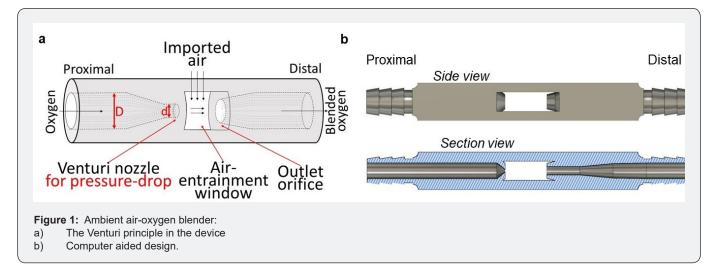
Supplemental oxygen is often necessary for preterm newborns in respiratory distress [1]. Nasal cannulas (with low flow or high flow gas), different types of continuous positive airway pressure (CPAP), nasal intermittent positive pressure ventilation, hoods, and facemasks are common noninvasive devices used to deliver

supplemental oxygen to neonates [2-7]. While supplemental oxygen is often important for these patients, high concentrations (hyperoxia) may be harmful [8]. Bronchopulmonary dysplasia and retinopathy of prematurity are two major adverse effects of administering high concentrations of inspired oxygen to preterm

neonates [9,10]. Different types of oxygen blending devices are used in high-resource settings to regulate concentrations of oxygen and prevent hyperoxia. WHO recommends initial fractional oxygen concentrations (FiO<sub>2</sub>) of 30% when using continuous positive airway pressure devices (CPAP) for premature newborns, and only increasing FiO, when absolutely necessary [11]. There generally are two types of blenders to control FiO<sub>2</sub>: 1/valve blenders which are used for neonates and older patients and 2/Venturi blending devices which are used for oxygen therapy in older patients. Valve devices have sources of air and oxygen at elevated pressures, and concentrations are adjusted by changing the relative flow of each gas. The most common blenders are valve devices that mix compressed oxygen and compressed air from individual sources by adjusting a knob without electricity. However, compressed air is difficult to find in low-resource settings and these types of blenders are expensive [12].

Other types of valve blenders use pumps for blending, such as in the Pumani and Diamedica Baby CPAP devices. Pumani devices supply oxygen from an oxygen source while Diamedica devices use electricity to supply oxygen through an oxygen concentrator. While these devices do not require compressed air, reliance on uninterrupted electricity and relatively high cost are important limitations [13,14]. Venturi blending is another mechanism to blend oxygen and air. In Venturi blenders a jet of pure oxygen is ejected from a nozzle through an open window. Based on the Venturi principle, a low-pressure environment develops immediately around the jet which entrains ambient air before the jet of mixed gas is recaptured on the other side of the

window. Venturi blenders do not use compressed air or pumps, however many (e.g. MaxVenturi, Whisper Flow) are expensive [15]. Venturi masks use a similar mechanism to blend and they are low cost yet cannot be attached to high resistance systems such as CPAP devices [16]. Additionally, while Venturi devices do not use electricity or compressed air to blend oxygen and air, they have not yet been designed for use in neonates. The lack of low-cost oxygen blender device designs for neonates and the need for electricity and compressed air are barriers to blending oxygen for neonatal therapies such as CPAP in low-resource settings [17-25]. Even if hospitals in low-resource settings were able to purchase existing blenders, most would not be able to use them since uninterrupted electricity and compressed air are scarce. In sub-Saharan Africa two thirds of health facilities do not have access to uninterrupted electricity, making pump blenders impractical and unsafe [26]. Use of pure oxygen leads to hyperoxia and potential complications of lungs, brain and eyes. A few clinicians in low-resource settings have improvised their own blenders. For example, Daga, Joshi, Gunjal, and Mhatre used an aquarium pump to provide air, but this innovative approach is limited by its dependency on electricity and inability to regulate concentrations of oxygen accurately [27]. Ninety-nine percent of all deaths in children under age five occur in resource-limited regions, in part because these settings lack the ability to safely oxygenate and ventilate their patients [28-35]. In this study, we examined a prototype ultra-low-cost Venturi blender that does not use electricity, and we tested the effect of geometrical variables and process parameters on delivered FiO2.



#### **Materials and Methods**

#### Ambient air-oxygen blender

**Device design:** We designed an ambient air-oxygen blender where oxygen travels from a tank to a small-diameter Venturi nozzle on one side of the device (Figure 1a). Oxygen ejects from the Venturi nozzle after it is accelerated through a cylinder that

rapidly shrinks from diameter D to d (Figure 1a). The progressive decrease in diameter of the channel increases the velocity of oxygen and decreases pressure in the air-entrainment chamber. The pressure differential between ambient air and the air-entrainment chamber provides a driving force to draw ambient air into the air-entrainment window and mix it with the stream of pure oxygen. The ambient air-oxygen blender is designed

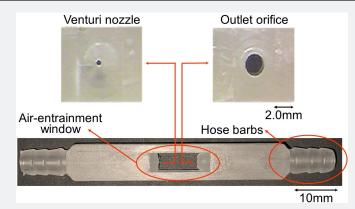
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to generate sufficient decrease in pressure to create a flow of oxygen-enriched air at a desired, fixed  ${\rm FiO_2}$ . A distal outlet orifice collects the gas mixture and delivers it to a neonate via inspiratory tubing. The principles of the Venturi effect are explained in the supplemental material section. We used parameters of the Venturi effect to design an ambient air-oxygen blender. Figure 1b displays the computer aided design of the ambient air-oxygen blender. The ambient air-oxygen blender was designed with a rectangular cross-section of 7mm  $\times$  9mm and a length of 73mm. The air-entrainment chamber has two symmetric, rectangular-shaped air-entrainment windows. The original dimensions were fixed at

- a) 0.6mm Venturi nozzle diameter,
- b) 2mm outlet orifice diameter,

- c) 4.5mm×15mm=135mm<sup>2</sup> cross-sectional areas of the airentrainment windows, and
- d) 10mm distance between the Venturi nozzle and the outlet orifice.

**Device fabrication:** Polypropylene (Mw=250,000g/mol) (Scientific Polymer Products Inc., NY) was used to fabricate the ambient air-oxygen blender. The polymer was injected into a mold at 240 °C in a one-step procedure with the use of a benchtop injection molding machine (Medium Machinery LLC, VA), and then slowly cooled to room temperature. The design of the mold is explained in the supplemental material section (Figure S2). Three grams of polymer were required per ambient air-oxygen blender. Figure 2 demonstrates the side view of an injection molded ambient air-oxygen blender.



**Figure 2:** Side view of fabricated ambient air-oxygen blender. The picture shows the original dimensions of the device with a cross-section of the air-entrainment window and hose barbs on opposite ends, a 0.6mm diameter Venturi nozzle, and a 2.0mm diameter outlet orifice through which the oxygen-enriched air exits the ambient air-oxygen blender to the nasal interface.

## FiO, evaluation

For evaluation of FiO $_2$ , cylinders containing medical USP grade, pressurized oxygen (size E aluminum cylinder, CGA-VIPR with walk-  $O_2$ -bout regulator and DISS integrated valve, Airgas, MA) delivered pure oxygen to the blenders (n=6 for all experiments). A Handi+oxygen analyzer (Maxtec, UT) was used to measure FiO $_2$ .  $\frac{1}{4}$ "(=6.35mm) ID polyethylene tubing attached blenders to the analyzer's barded adaptor. This standard diameter oxygen tubing was used to simplify the experiment due to the large variety of tubing styles and user interfaces used for oxygen therapy, CPAP, and other neonatal therapies that may use this blender. Gas exited the system through two symmetric 3 mm diameter holes in the barbed adapter (equal to one 4.24mm D circle). The holes were similar in size to the prongs found in high flow oxygen therapy and many CPAP devices.

**Evaluation of the effect of geometric variables on FiO**<sub>2</sub>: Four geometric variables were evaluated:

- a) Venturi nozzle diameter,
- b) Outlet orifice diameter,

- c) Cross-sectional area of the air-entrainment windows, and
- d) Distance between the Venturi nozzle and the outlet orifice.

All investigations of the effect of geometric variables on FiO<sub>2</sub> were performed at an oxygen flow rate of 1L/min. When one variable was evaluated, all other dimensions were fixed at the original values described previously. The effect of Venturi nozzle diameter on FiO, was evaluated by fabricating ambient airoxygen blenders with Venturi nozzle diameters of 0.5mm, 0.6mm, 0.7mm, 0.8mm, 0.9mm, and 1.0mm. Multiple side cores of the negative mold were designed and fabricated to produce ambient air-oxygen blenders with Venturi nozzles with these diameters. Additionally, the effect of the outlet orifice diameter on FiO<sub>2</sub> was evaluated by drilling separate blender outlet orifices to diameters of 2.5mm, 3.0mm, 3.5mm, and 4.0mm. The cross-sectional area of the air-entrainment window (originally 135mm<sup>2</sup>) was altered to determine the effects on FiO<sub>2</sub>. Both air-entrainment windows were simultaneously and systematically closed along a direction orthogonal to the jet flow to 78%, 65%, 34%, 12%, and 0% of their

original size. The impact of these changes on  $\mathrm{FiO}_2$  were examined. Additionally, the distances between the Venturi nozzles and the outlet orifices (originally 10mm) were altered to determine the effect on  $\mathrm{FiO}_2$ . The body of the ambient air–oxygen blender was sectioned into two parts. The parts were aligned in a track that allowed the distances between the Venturi nozzles and the outlet orifices to vary. The Venturi nozzle-outlet orifice distances were adjusted by 1mm increments from 1mm to 15mm.

The effect of process parameters on  ${\rm FiO_2}$ : The effect of variable oxygen upstream flow rates and air temperatures on  ${\rm FiO_2}$  was examined over a flow-rate range of 0.25 to 15L/min and a temperature range of 20 to 50 °C. The tubing and the ambient air-oxygen blenders were placed inside a Fisher Scientific Isotemp oven (Pittsburgh, PA) to modify and test the ambient-air temperature. The oxygen tank was safely placed outside the oven. The original blender dimensions were used for these experiments.

#### Statistical analysis

Descriptive statistics (mean ± standard deviation, and standard error of mean for error bars) were used to describe quantitative variables. The relationships between variables were assessed with the use of the paired T-test and paired analysis of variance. Any probability value (p-value) less than 0.05 was considered statistically significant.

#### Results

## The effect of ambient air-oxygen blender geometry on ${\rm FiO}_2$

The relationships between Venturi nozzle diameters, outlet orifice diameters, cross-sectional areas of the air-entrainment windows, and distances between the Venturi nozzles and the outlet orifices, on delivered  ${\rm FiO}_2$  were evaluated individually by fabricating and testing ambient air-oxygen blenders with various geometric designs.

The effects of the Venturi nozzle and outlet orifice diameters: Ambient air-oxygen blenders were fabricated with Venturi nozzle diameters ranging from 0.5mm to 1.0mm and an outlet orifice diameter of 2.0mm to evaluate the effect on  $\mathrm{FiO}_2$  (Figure 3a).  $\mathrm{FiO}_2$  percentages increased linearly from  $34.2\pm1.2\%$  to  $53.0\pm0.7\%$  as Venturi nozzle diameters increased from 0.5mm to 1.0mm (Figure 3b). This confirmed that the ambient air-oxygen blender successfully drew air into the air-entrainment chamber to create a reduced concentration of oxygen, dependent on the nozzle diameter. Ambient air-oxygen blenders with outlet orifice diameters ranging from 2.0mm to 4.0mm and a fixed Venturi nozzle diameter of 0.6 mm were fabricated to evaluate the effect on  $\mathrm{FiO}_2$  (Figure 3c). Increasing the diameters of the outlet orifices from 2.0mm to 4.0mm decreased  $\mathrm{FiO}_2$  from  $44.6\pm0.7\%$  to  $31.8\pm1.7\%$  monotonically (Figure 3d).

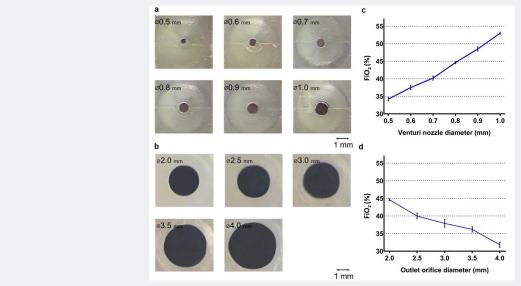


Figure 3: Venturi nozzle diameters from 0.5mm to 1.0mm.

- a) Outlet orifice diameters from 2.0mm to 4.0mm.
- b) Effect of Venturi nozzle sizes from 0.5mm to 1.0mm diameter, with an outlet orifice diameter of 2.0mm, on FiO<sub>2</sub>.
- c) Effect of outlet orifice sizes from 2.0mm to 4.0mm diameter, with a Venturi nozzle diameter of 0.6mm, on FiO<sub>2</sub> (flow rate=1L/min and, temperature=20°C).

The effect of window size and the distance between nozzle and orifice: The effect of changes in the cross-sectional areas of the air-entrainment windows and the distances between the Venturi nozzles and the outlet orifices on the exiting FiO<sub>2</sub> was studied (Figure 4a&4b). Decreases in the cross-sectional areas of the air-entrainment windows increased the FiO<sub>2</sub> exponentially

(Figure 4c). Complete closure of the air-entrainment window on both sides produced an  ${\rm FiO_2}$  of 100%. A decrease in distance between the Venturi nozzles and outlet orifices increased the FiO2 linearly (Figure 4d). The 15-mm and 0-mm Venturi nozzle-outlet orifice distances were taken to be fully open (0% decrease in the cross-sectional area) and fully closed (100% decrease in the

cross-sectional area), respectively.  ${\rm FiO}_2$  increased from 33.0±3.0% to 44.1±1.9% when the distance between the Venturi nozzle and the outlet orifice decreased from 15mm to 1mm, with a Venturi nozzle diameter of 0.5mm and an orifice diameter of 2.0mm.  ${\rm FiO}_2$ 

increased from  $55.3\pm1.1\%$  to  $83.7\pm4.4\%$  as the distance between the Venturi nozzle and the outlet orifice decreased from 15mm to 1mm, for a Venturi nozzle diameter of 1.0mm and an orifice diameter of 2.0mm (Figure 4d).

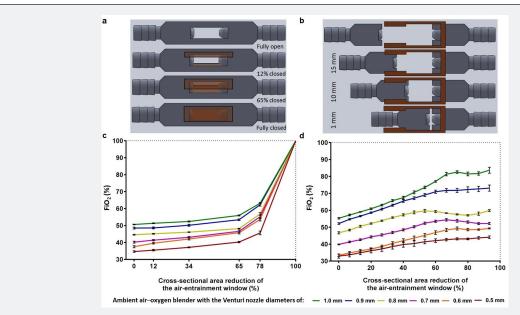


Figure 4:

- a) Cross-sectional areas of the air-entrainment windows.
- b) Distances between the Venturi nozzles and the outlet orifices.
- c) The effect on  $FiO_2$  of changes in the cross-sectional area of the air-entrainment window. 0% cross-sectional area reduction represents the fully open window of the original design.
- d) The effect on FiO<sub>2</sub> of changes in the distance between the Venturi nozzle and the outlet orifice. 0% cross-sectional area reduction represents 15mm distance between nozzle and orifice.

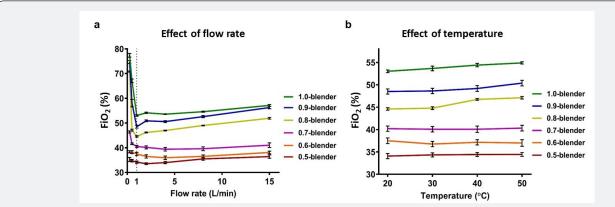


Figure 5:

- a) The effect of flow rate on FiO<sub>2</sub> at 20°C.
- b) The effect of temperature on  $FiO_2$  at a flow rate of 1 L/min. (Venturi nozzle diameter = 0.5mm to 1.0mm and outlet orifice diameter = 2.0mm).

## The effect of process variables

For Venturi nozzle diameters between 0.7mm and 1.0mm and a fixed orifice diameter of 2.0mm, the  ${\rm FiO_2}$  varied considerably for oxygen upstream flow rates ranging from 0.25 to 1L/min (Figure 5a). However, with Venturi nozzle diameters of 0.5mm and 0.6mm

with a fixed orifice diameter of 2.0mm, the  ${\rm FiO}_2$  did not change with increases in oxygen upstream flow rates (P value = 0.14 and 0.15, respectively). The  ${\rm FiO}_2$  increased slightly with increases in upstream flow rates from 1 L/min to 15 L/min for all Venturi nozzle diameters (Figure 5a). The  ${\rm FiO}_2$  increased with temperature when

the Venturi nozzle diameters were greater than 0.7mm and the orifice diameter was fixed at 2.0mm (P value <0.001, <0.001, and =0.022 for Venturi nozzle diameters of 0.8mm, 0.9mm, and 1.0mm, respectively) (Figure 5b). The largest effect of temperature on  ${\rm FiO_2}$  was observed when the Venturi nozzle diameter was 0.8mm and the orifice diameter was 2.0mm. In this case, the  ${\rm FiO_2}$  increased from 44.6±0.6 to 47.1±0.7 when the temperature increased from 20 to 50 °C.

#### Discussion

Preterm newborns and neonates with respiratory distress often need supplemental oxygen [1,36]. In high-income settings commercial oxygen blending devices are used to optimize oxygen delivery and prevent hyperoxia in these newborns. Limited designs for neonates, the need for uninterrupted electricity and compressed air when non-invasive ventilation is necessary, and high costs make these devices inaccessible across most resource-limited settings [37-42]. In this study we demonstrated that ambient air-oxygen Venturi blenders can be designed and fabricated that provide fixed oxygen concentrations in the range of FiO, necessary for quality care of neonates in respiratory distress. By controlling the diameters of the Venturi nozzle and orifice, the cross-sectional area of the air-entrainment window, and the distance between the Venturi nozzle and the outlet orifice, we were able to create a range of FiO2 from 34% to 100%. As predicted by the Venturi principle (equation 3 and Figure S1 in the supplemental material) we found that increases in Venturi nozzle diameters (Figure 3c) decreased pressure-drops in the airentrainment chamber, which consequently lessened the draw of ambient air and thereby increased FiO2. In contrast, increasing orifice diameters drew in higher volumes of ambient air and decreased FiO<sub>2</sub> (Figure 3d), while decreases in the cross-sectional area of the air-entrainment window allowed less air into the airentrainment chamber and consequently increased FiO, (Figure 4a and c). Finally, increases in distances between the Venturi nozzles and outlet orifices increased the cross-sectional area of the air-entrainment windows (Figure 4b) and thereby increased the amount of available ambient air, resulting in decreases in FiO<sub>2</sub> (Figure 4d). Control and optimization of the individual features and interdependent relationships of these four geometric parameters allowed for fabrication of a Venturi ambient airoxygen blender with tolerances necessary for care of premature newborns and infants with respiratory distress. Since treatments such as low flow oxygen therapy and CPAP require different flow rates of mixed gas, and neonates on CPAP and other sealed oxygen delivery systems require different flow rates to meet their minute ventilation requirements, we evaluated the effect of varying upstream oxygen flow rates on inspired (downstream) FiO2. Consistent with the Venturi principle (equation 3 and Figure S1), we found that when Venturi nozzle diameters were greater than 0.6mm with orifice diameters of 2.0mm, and oxygen flow rates less than or equal to 1L/min (Figure 5a), increases in upstream flow

rates increased pressure-drops, drew in more ambient air, and caused decreases in downstream  ${\rm FiO_2}$ . However, it was surprising to discover that with these same geometric parameters, once upstream flow rates surpassed 1L/min this relationship reversed and  ${\rm FiO_2}$  increased slightly with increases in oxygen flow rates. The findings from subsequent experiments that downstream  ${\rm FiO_2}$  minimally changed with increases in upstream flow rates are critical for informing the design of further blenders. It appears that greater pressure-drops with this geometry do not facilitate increased volumes of air to mix with the oxygen stream above a "saturation" value (represented by the dotted line in Figure 5a). This discovery was an important additional factor to consider in blender design so that delivered  ${\rm FiO_2}$  is not significantly affected by variations in flow rates.

To account for various climates around the world where premature newborns are cared for, we additionally examined the effect of temperature changes on FiO2 downstream from the blender. We discovered that changes in ambient air temperatures between 20 and 50°C did not affect delivered FiO2 across varying flowrates. Strengths of our novel Venturi blender include fabrication from an inexpensive thermoplastic polymer via injection molding, low-weight and handheld, no use of electricity or compressed air, and essentially maintenance free. These qualities increase the potential for use across resource-poor settings worldwide. The primary limitation of our study is that flow rates of mixed gas downstream of the blender were not measured, and they may be affected by FiO2, upstream flow rates, oxygen loss through the entrainment window, and resistance of the downstream device. Further research is needed to better understand the effects of blender geometry on FiO, and the efficiencies of different designs in capturing blended gas mixtures. While this study focused on addressing the limitations of existing blenders using a different design and evaluating the effect of geometric parameters on provision of a wide range of FiO2, future studies are required to comprehensively evaluate more variables that impact blender performance, such as resistance and oxygen loss. The authors are currently optimizing an ambient air-oxygen blender for a variety of downstream devices (low/high flow cannula, CPAP setups, etc.) with comprehensive measurements of these variables in separate studies. It is likely that unique blenders will need to be designed for individual downstream apparatus specifications.

#### Conclusion

This study provides evidence that ultra-low-cost, Venturi ambient air-oxygen blenders can be manufactured and deliver a wide range of  ${\rm FiO_2}$  without the need of electricity, motors, or compressed air, for use with neonatal therapies requiring supplemental oxygen. These properties, together with the low fabrication cost, make our ambient air-oxygen blender attractive for use in resource-poor settings.

### Acknowledgement

We thank Katelyn Chan, Mike Eisenstein, Gene Saxon, and Alice Won, MD for their contributions.

## **Supplemental Material**

#### **Materials and Methods**

Venturi principal in ambient air-oxygen blender: The diameter of the cylindrical oxygen inlet cavity (D) and the Venturi nozzle diameter (d) are device geometric dimensions which affect the pressure-drop on the Venturi nozzle side (Figure 1a). The gas flow rate and the gas density are oxygen characteristics that affect the pressure-drop [43]. The pressure-drop between the oxygen inlet cavity and the Venturi nozzle side of the ambient air-oxygen blender can be calculated with the use of the Bernoulli equation: [44]

$$P_1 + \frac{1}{2}\rho v_1^2 + \rho g h_1 = P_2 + \frac{1}{2}\rho v_2^2 + \rho g h_2$$
 equation (1)

Where P is pressure,  $1/\rho v^2$  the kinetic energy per unit volume, and  $\rho gh$  the potential energy per unit volume.

The relationship between flow velocity and volumetric flow rate is shown in the following equation:

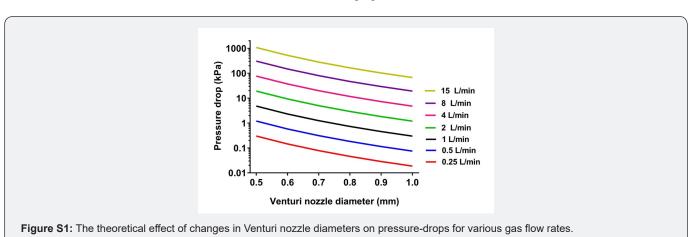
$$v = \frac{Q}{\left(D^2 x^{\pi}/4\right)}$$
 equation (2)

 $v = \sqrt[Q]{D^2 x^{\pi}/4} \text{ equation (2)}$  Where v is the flow velocity, Q the volumetric flow rate, and D the diameter of the cylindrical cavity of the ambient air-oxygen blender inlet. Since the potential energies in both the cylindrical oxygen inlet cavity and the cylindrical Venturi nozzle are identical, the pressure-drop is related to the flow rate and the geometry of the ambient air-oxygen blender per the following equation:

$$\Delta P = \left[\frac{8\rho Q^2}{\pi^2 D^4}\right] x \left[\left(\frac{D}{d}\right)^4 - 1\right] \text{ equation (3)}$$

Where  $\Delta P$  is the pressure-drop,  $\rho$  the density of oxygen\*, Q the volumetric flow rate, D the diameter of the ambient air-oxygen blender inlet, and d the Venturi nozzle diameter. The influence of the Venturi nozzle diameter and volumetric flow rate on the changes in pressure is presented by Figure S1.

\*The density of oxygen at 20°C was assumed to be 1.33g/L [45].



### Mold design

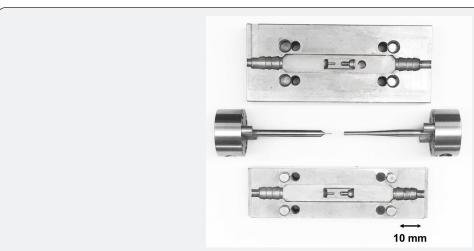


Figure S2: Ambient air-oxygen blender mold.

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To fabricate the blender, a four-piece negative mold was designed. The mold consisted of two cavity halves to produce the main body and the air-entrainment window, and two side sections to create the gas channels, the Venturi nozzle, and the outlet orifice. This design allows ambient air-oxygen blenders with various Venturi nozzle and outlet orifice sizes to be made simply by replacing the side pieces. The mold was fabricated by stainless steel (Figure S2).

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