Project Save oxygen [OxSave]: Open source oxygen conservation device for use with nasal cannula

Engineering solutions for oxygen conservation: Part 2

Disclaimer: This is a series of open-source tools we are sharing in the context of the current covid pandemic. This is not an approved medical device and we do not advise any individual implementation. We are working with industrial partners to scale up this implementation - but sharing it in open domain for other industry partners to engage as well. Please reach out to us and join the effort if you are interested in developing and validating the system for clinical evaluation.

This is a draft document and subject to change. Please read the full medical disclaimer at the end of the document.

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**Introduction:**
India is under an enormous crisis because of **shortage of oxygen** for treatment of COVID patients. Patients across the country are rushing to hospitals with no beds and many are under oxygen therapy at home. Oxygen shortage is the single biggest problem India faces at this very moment.

**Goal:**
The goal of this project is to develop an open source and rapidly manufacturable passive oxygen conservation device for treatment of mild COVID-19 patients who are on high-flow nasal cannula. During oxygen therapy when a patient exhales, oxygen is still being supplied and is thus wasted. However, by using a device that preserves the oxygen during the exhalation cycle - up to 50% of oxygen in a tank can be conserved by constructing a reservoir that collects oxygen when an individual is exhaling, and only delivering a bolus of oxygen when a patient inhales.

This is achievable either by using an electronic means or passive device (which requires no electricity). For the active device - see our proposed open source solution [here](#). This document concerns a passive implementation of this device. Commercial versions of such devices were not designed for available on the market as Oxymizer® “pendulums” or “mustaches”, but they are costly ($20-$40), can not be found in large quantities and were not designed specifically for this current covid-19 treatment in mind.

In this effort, we intend to create an open source and modular “passive” (no electronic parts) oxygen conservation device that is robust and designed for use with covid patients.

**Problem statement:** Many COVID19 patients require 2-6LPM O2 via NC. Cumulatively this is a significant strain on local oxygen supplies. Do oxymizers have potential to save oxygen in COVID19 patients with mild ARDS/low O2 requirements 2-6 LPM? Can oxymizers help increase delivered FiO2 for patients using an O2 concentrator with max output of 5 or 10LPM? Currently available devices were designed for chronic, stable outpatients who require ~2-4LPM - not those with acute respiratory failure patients.

**Hypotheses:** Oxymizers increase FiO2 if output pressure > X and low MV ventilation with diminishing performance with incr PIF, MV and incr FiO2 targets/needs… and have no benefit beyond X LPM flow or X MV/PIF. Measurements in progress to determine above parameters.

**Background/Principle:**
We breathe in inhale and exhale cycles. A continuous flow nasal cannula wastes all the oxygen when a person is exhaling. This can be as much as 50% of oxygen in a tank. In case of oxygen shortage, this can reduce the available oxygen supply for a patient to half.

In 1992, Elaine R. Abel created a simple passive valve based solution that attaches in line with the nasal cannula that preserves oxygen. The principle of the device is simple - oxygen is
delivered into a reservoir sealed by a check valve. When the patient inhales, the sum effect of the negative inhale pressure and positive reservoir pressure opens a check valve, delivering a bolus of oxygen. When the patient exhales, the normally closed check valve closes due to positive exhale pressure, allowing oxygen to be conserved in the reservoir. Thus a patient can be put on a lower flow rate (unit liters per unit, lpm) but still provide clinically the same outcome as if the person was on a higher flow rate. A clinical study done on hypoxemic patients showed that the oxygen saturation achieved by the oxygen conserving pendulum (referred to as pendant conserving nasal cannula, PNC) was equivalent at 0.5 L/min compared to 1.8L/min for steady flow nasal cannula (SNC) [2]. Figure 1 illustrates the oxygen saturation as a function of the inlet flow rate for PNC vs SNC for their specific design.

Figure 1: SaO₂ vs flow rate for PNC and SNC. The study was done for a flow rates raining from 0.5 to 4 L/min [2].

Figure 2: Image from US Patent 5,280,780, Patent granted: Jan. 25, 1994 [1].
We intend to open source the design of this device, known as oxygen conserving “pendants”, and develop it for rapid manufacturing to serve the urgent need in India.

**Overall Design:**
A preliminary design intended for rapid prototyping and testing has been developed. The current design (Figure 6) very closely replicates the design from the original patent (Figure 2). The exception is in the implementation of the one-way valve. In our current design, we have shown two basic configurations: (1) using an umbrella valve attached to the 3D-printed design or (2) using an off-the-shelf check valve (Figure 7). The connection point for the valve is a standard
ISO 15/22, hence allowing for either the 3D printed “seat” for the umbrella valve or the standard check valve to be fitted in the assembly.

**Figure 6**: Axon view diagram of current design.

**Figure 7**: Modular testing prototype design.

**Fabrication:**
This design is meant to be injection molded, however for our prototypes, we’ve 3D printed all the parts on the Form2 printer using photopolymer (clear V4) resin. For subsequent testing, the biocompatible “surgical guide” resin will be used. Note the difference between a resin-base print and a filament-base, where the resin produces a non-porous product whereas the filament produces a porous product (which is NOT ideal for this project). We also noticed that the seat for the umbrella valve needs a surface finish (i.e. highly smooth and without print flaws). Without
this, the umbrella valve may leak in its closed position. For this reason, we currently suggest using off-the-shelf check valves when the rest of the assembly is 3D printed.

Figure 8: 3D printed parts. The 3D printed check valve piece holds an umbrella valve membrane that has a tunable cracking pressure based on a preload height on the umbrella valve seat.

A friction fit ring fits over the reservoir to clamp a diaphragm that rests over its top surface. As oxygen is replenished in the reservoir, the diaphragm expands (Figure 9). During inhalation, as oxygen leaves the reservoir, the diaphragm contracts and the two guiding ridges ensure that a clear path is maintained between the inlet and outlet of the reservoir (Figure 9). In our tests so far, saran wrap was used as a proxy for the diaphragm material. The critical design criteria of the diaphragm is that it allows the reservoir to have a variable volume as a function of the input flow rate and the patient’s inhalation, while maintaining a seal around the friction ring.

Figure 9: Inhale/Exhale Diagrams. (A) Check valve is open and diaphragm collapses upon inhalation. Note that a clear pathway is
maintained between the inept and outlet. (B) Transition between inhalation and exhalation. (C) Check valve is closed and diaphragm inflates during exhalation, while patient’s exhausted air exits through nostrils.

**Capacity:**
The capacity of the reservoir is ~100mL (during exhalation) and ~25mL (during inhalation). This volume was derived by assuming a constant flow of oxygen at a rate of ~0.5L/min [3] from the oxygen tanks and if a patient takes up to about 10-12 seconds for exhalation, then the potential volume of collected oxygen is ~100mL.

**Preliminary Testing:**
Preliminary tests were conducted to determine whether the off-the-shelf check valve can seal during exhalation and open during inhalation. In order to determine this, a flow meter was placed between the check valve and reservoir, and at the inlet. The setup is illustrated in Figure 7 and the results are illustrated in Figure 8. More comprehensive clinical tests will be conducted.

![Figure 7: Preliminary bench testing setup.](image)

![Figure 8: Prototype test result. Left: flow rate measurement between check valve and reservoir. Right: inlet flow rate.](image)
Drawings/CAD files:
Click here for STEP files (latest update 4/28/21).

**Figure 9**: Top and Section views of current design
Discussion:

*Can the device be used on COVID patients?*

Several organizations have advised to use the device in management of COVID patients (see image below). In cases where no oxygen shortage exist; it does not have a significant value. But in a situation like India - with severe shortage - such a device might be of value.

With partners at UCSF (Michael Lipnick Lab), we're planning for a clinical validation on patients.
We have currently identified one tentative industrial manufacturing partner with vast experience in production of disposable medical devices (rubber/plastic/passive valves) and an extensive background in Indian regulatory system and expertise in medical device manufacturing. If you think you would like to help expedite manufacturing, clinical testing and approval process for this device - feel free to reach out to team lead (manup@stanford.edu).

What we are immediately looking for:

1. We are looking for numerical (both fluid and solid modeling) modeling teams that can model characteristics of the device so that material properties can be optimized before manufacturing/production run.
2. We are looking for prototype services - specially for modeling flexible materials during the development cycle of the project.
3. We are looking for funding to scale this project.

Reference:


Medical Disclaimer:
The following content, including but not limited to project descriptions, preliminary test results, figures/images, and prototypes, published here is meant to maximize potential public benefit during this SARS-CoV-2 (formerly CoVID-19) crisis, specifically in addressing the urgent needs in India.

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