Wearable On-Demand Oxygen Therapy

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ABSTRACT

Oxygen concentration devices currently on the market have many shortcomings. They are bulky and difficult to carry. They alter a patient’s outward image with a visual mark of disability. They do not change oxygen delivery in any way to adjust to the patient’s health. They also lack indicators to help the patient decide when to begin or end a therapy session. Some patient’s decide not to take oxygen therapy as a result of these shortcomings. Those that use these devices may receive over oxygenation or under oxygenation due to the mentioned pitfalls. Any of the shortcomings described can be life threatening to the patient.

The present innovation is a proposed system for oxygen delivery that adjusts flow rate based on the patient health and requires no user input to begin or end a therapy session. This paper presents a unique wearable device design for delivering oxygen in a pressure based concentration system.

1 INTRODUCTION

The objective of this research was to design a connected technology solution that helps keep mobility issues faced by seniors with Chronic Obstructive Pulmonary Disease (COPD). Oxygen concentration technology is what drives therapy, and devices are becoming smaller and more portable, however none integrate blood oxygen monitoring with oxygen delivery even though the technology is available.

Multiple companies are designing increasingly portable oxygen concentrators to meet the demand, while air quality continues to decline in the urban areas we live in. The technology for non-invasive monitoring of blood-oxygen levels, pulse rate, and breathing patterns all exist in other spaces, but are yet to be integrated into a smart delivery oxygen concentrator.

2 BACKGROUND

2.1 Chronic Obstructive Pulmonary Disease (COPD)

Chronic obstructive pulmonary disease (COPD) is globally the 3rd leading cause of death. It is an obstructive lung disease that is characterized by chronically poor airflow, and currently has no cure [1]. There are two main causes of COPD; in more industrialized economies, smoking and second-hand smoke are the main causes; in less industrialized economies, the cause is primarily indoor air pollution from using biomass and coal inside the home for cooking and/or heating [2]. It is primarily diagnosed in middle-aged or older adults, but the disease develops slowly from early onset [3]. A recent study indicates that most COPD patients receiving oxygen therapy in the US are low income white females, on average 75 years old, with two or more other health conditions [4].

COPD causes hypoxemia, low oxygen levels in one’s blood, which can lead to hypoxia, low oxygen levels in one’s tissues. Not having enough oxygen in blood and/or tissues causes the body to not function properly, and can cause shortness of breath and mobility loss, among other symptoms [5]. Symptoms often worsen over time and can limit your ability to do routine activities. Severe COPD may prevent you from doing even basic activities like walking, cooking, or taking care of yourself [6, 7]. Losing mobility is an accelerator for chronic conditions due to psychological effects, and has a severe impact on longevity [8]. Oxygen therapy is the treatment for COPD, helping patients to overcome hypoxemia and hypoxia, and regain their mobility, in addition to helping with shortness of breath, fatigue, and increased lifespan [9]. Oxygen therapy technologies are reviewed next.

2.2 Oxygen Delivery Technology

Oxygen therapy is the means by which oxygen is delivered to COPD patients. Most oxygen therapy is delivered through nasal cannula, which is a tube that attaches the oxygen supply to the patient’s nose. The cannula has to be changed once a month due to stiffening of the material [6]. To conserve oxygen, there have been a number of devices designed to increase the flow rate of oxygen during inhale and decrease the flow rate during exhale. There is a special type of cannula called a reservoir cannula, which stores oxygen in a reservoir while the patient is exhaling, requiring lower flow rates and resulting in slower oxygen consumption. Oxygen can also be delivered through a catheter placed into the trachea, called transtracheal oxygen. This method can reduce the flow rate 30-50% from the traditional...
cannula flow rate [6]. On-demand devices use a sensor to detect when inhalation is occurring, and deliver a pulse of oxygen at that time. Congestion, mouth breathing, and battery life are barriers to the performance of these devices. At the very cutting edge, researchers have developed a substance that can be injected into a patient and deliver intravenous oxygen therapy through microparticles [10].

2.3 Oxygen Storage Technology
The oldest method for oxygen therapy is with the use of oxygen cylinders, which carry compressed oxygen in large, heavy steel cylinders that have to be changed often due to fast consumption of oxygen. There are smaller cylinders, and ones made from aluminum, to increase portability, but these are consumed even faster [6].

Oxygen becomes a liquid at -183° C, which allows it to be stored much more efficiently than in gas form. Liquid oxygen is used in most hospitals and is stored in large tanks. At home, smaller tanks are filled from the larger tank, and the larger tank can be regularly refilled by a delivery service [6].

Oxygen concentrators work by collecting oxygen from the air in a room, using an electricity-drive filtration system. Due to limited storage, all stored oxygen is delivered to the patient. The device is on wheels, but weighs 50 pounds [6]. Considering the storage systems reviewed in this section, it can be understood why mobility can be limited once oxygen therapy is prescribed.

2.4 Blood-Oxygen Measurement Technology
To measure the level of oxygen in a patient’s blood, there are a number of techniques, classified by invasive and non-invasive measurement. Invasive measurement uses a blood sample to measure arterial blood gas, and is very accurate but not preferred for those on oxygen therapy due to its invasive nature [11]. Non-invasive measurement, also called transcutaneous (across the skin), can work by measuring three different metrics: SpO₂, saturation of arterial blood with oxygen, PaO₂, partial pressure of oxygen in arterial blood, or PaCO₂, partial pressure of carbon dioxide in arterial blood.

Oxygen saturation, SpO₂, can be measured using pulse oximetry [11], which is often a sensor device placed on a person’s finger. The drawbacks include that it does not measure the partial pressure of oxygen, PaO₂, and doesn’t give any information about ventilation in the patient.

The partial pressure of oxygen, PaO₂, can be measured by sensing the oxygen gradient across the skin to the ambient air [12, 13]. The partial pressure of carbon dioxide, PaCO₂, can be measured in a similar fashion, or through the measurement of respiratory gases (capnography) [13]. Newer technology allows for the measure of both simultaneously accurately, and reliably [14, 15], such as the TCM CombiM monitor [16].

2.5 Breathing Pattern Measurement/Technology
Understanding a patient’s breathing pattern is useful for many diagnostic scenarios. For this context, the interest comes from oxygen conservation to enable storage and delivery devices to last longer. The tradition, manual way of measuring breathing patterns is called Manual Assessment of Respiratory Motion (MARM), in which a trained physician uses their hands to assess the range of motion of the rib cage during breathing to determine if the breathing pattern is normal. This has been translated to a camera based technology, opto-electronic plethysmography (OEP), using trackers on a patient’s abdomen to assess breathing patterns in similar way [17]. Respiratory Induction Plethysmography (RIP) uses bands that detect expansion of the upper and lower rib cage to assess breathing patterns [18].

Recently, a small microphone has been developed which allows for the measurement of pressure in the nose of the patient. The microphone is only 1 mm in diameter [19]. Algorithms to analyze the data collected by these microphones have been developed, as well [20].

3 DESIGN METHOD
The design process followed for the development of the present innovation was a double diamond process [21], involving four main phases:

1. Discover: The initial research phase, during which a broader design problem is explored, with the goal of better understanding that problem and searching for opportunities to address unmet needs for key stakeholders. This phase is a convergent phase. Many of the research finding from this phase are reviewed in Section 2 of this paper. The broader goal was to design a connected technology solution that helps improve the health and life of seniors, specifically focusing on addressing the role of time in the lives of seniors, targeting those living with a disability, such as a heart disease or dementia, for instance.

2. Define: The goal of this phase is to specify the specific design problem to be addressed with the analysis and synthesis of the information gathered in the Discover phase. This phase is a convergent phase. The specific problem in this design process was defined to be: Design a connected technology solution that helps mobility issues faced by seniors with Chronic Obstructive Pulmonary Disease (COPD).

3. Develop: This phase is the idea generation phase, where concepts are explored to address the problem identified in the Define phase. This phase is a divergent phase. For brevity, the concepts explored in this phase are not included in this paper.

4. Deliver: This phase is the detail design and refinement phase, in which a final concept is chosen from those generated in the Develop phase, and a plan for implementation of the concept into the real world product mark is delivered. This phase is a convergent phase. The outcome of the Deliver phase for this product is shown in detail in Sections 4 and 5.

3.1 Target User
Barring ergonomics modifications, the proposed system could be used to help any individual with a need for supplementary oxygen. This includes fire fighters, runners, others with respiratory disease, etc. However this research will
focus on strength impaired COPD patients that require the use of oxygen therapy, as they were found to be a group in critical need of such a technology.

1. Specifically for those in an advanced stage of COPD who have strength concerns.
2. Those are kept at home because they cannot carry their oxygen tank with them.
3. Those that are living independently and have no one to help them carry their tank, or those that do not want to be helped constantly and want to be independent.
4. Those that do not want to rely on their judgment on when to take oxygen.

3.2 Success/Design Criteria

Based on the background research and stakeholder analysis, the following design or success criteria were defined.

The design solution MUST:
1. Be able to monitor patient blood-oxygen levels in real-time.
2. Be able to achieve variable flowrate delivery between 1 – 6 liters per minute [28] that is directly tied to real-time patient health.
3. Have a minimum of 17 hours of battery life under continuous use. This duration will cover the recommend awake time for a healthy adult [22].
4. Be able to be worn comfortably by a COPD patient with strength issues.

The design solution SHOULD:
1. Be aesthetically designed.
2. Be durable.
3. Be easy to put on and take off.

NICE TO HAVE attributes:
1. Be able to check additional vital signs, such as heart rate.

3.3 Competition

There are three main competitors on the market for higher-mobility enabling oxygen therapy, which are derivatives of the technologies reviewed in Section 2. It should be noted that no device currently on the market monitors patient health to directly influence the flowrate of therapy and no device has the ability to automatically detect when to start and stop therapy. Hence there is nothing on the market that can avoid the possibility of patient over and under oxygenation.

3.3.1 Portable Oxygen Concentrators [23]

Portable oxygen concentrators are the scaled down version of the household concentrator discussed in Section 2. They are more lightweight, and powered by batteries rather than household electrical power. Batteries have to be replaced or recharged often.

3.3.2 Wheeled Oxygen Tanks [23]

This product is a version of the steel oxygen cylinders, which has been either scaled down or made from a lighter material, such as aluminum in place of steel. All tank systems come with wheels, to allow users to move about a house or beyond. Nonetheless, this is the oldest technology, and remains cumbersome and heavy.

3.3.3 Portable liquid oxygen devices [23]

Portable liquid oxygen devices are a version of the previously presented liquid oxygen systems, still needing to be refilled from a larger tank of liquid oxygen. One advantage to portable liquid oxygen systems is that they don’t rely on a power source to function. However, they are not permitted on airplanes, like the technologies reviewed in Sections 3.3.1 and 3.3.2.

4 DESIGN SOLUTION

In order to meet the success criteria identified in Section 3.2, the first step taken was to conduct a prior art and literature review to understand what inputs would be needed to enable an on-demand oxygen therapy device. The data fusion model shown in Fig. 1 was developed based on the findings. This model proposes that on-demand oxygen therapy can be achieved by utilizing real time patient blood-oxygen and respiration data to drive the delivery. The next step was to utilize this model to design a medical device that met all the criteria set in Section 3.2, using existing technology. The proposed device design is described via rationale for major component selection, a sensor fusion diagram, external device views, internal circuit diagram, sensor communication equation sets, and pseudocode for device operation. As technology progresses, more effective designs can be made utilizing the framework in Fig. 1. However the device detailed in this paper is designed to showcase that it is possible right now to develop on-demand oxygen therapy solutions.

5 COMPONENT RATIONALE

5.1 Crystalline Cobalt
In order to design an oxygen concentration device that is comfortable to wear, easy to take off and easy to put back on, overall weight needed to be reduced significantly. To accomplish this, the proposed device design utilizes crystalline cobalt, shown in Fig. 2, as the capture and release mechanism for oxygen concentration. The crystalline cobalt material was developed by researchers at the University of Southern Denmark in 2014 and has been observed to absorb and release oxygen many times without losing the ability. During an interview with the researchers who developed the material, they stated that a few grains of crystalline cobalt would contain enough oxygen for one breath. The cobalt absorbs oxygen when exposed to ambient air and it is stored until the material is subject to low oxygen pressures. Due to this novel crystalline cobalt’s material superior efficiency in oxygen absorption and desorption, only a few crystal grains will be needed in using the oxygen concentrator device. This significantly reduces the weight and power consumption of the device.

5.3 Wearable Pulse Oximetry

The device design will utilize a combination of an on-board Bluetooth receiver and a wearable pulse oximeter to record patient data, shown in Fig. 3. Although current day transcutaneous monitors provide a larger range of metrics, the electronics required for processing that data is not yet wearable. Pulse oximetry devices, however, have been wearable and able to broadcast data wirelessly for some time now. The inclusion of an on-board Bluetooth receiver paired with a wearable pulse oximeter will give the proposed device a real time stream of oxygen saturation data. Electronics on-board the device can utilize this data to determine when to start and stop oxygen therapy, in addition to determining the volume of oxygen needed during therapy.

5.4 Shielded Microphone

Continuous flow (CF) oxygen delivery is the industry standard. CF wastes 50% of the energy and oxygen output because there is no oxygen intake during exhalation. The design solution to this wastage problem is a pulse dose, or bolus oxygen delivery. This method only pumps air when the patient is breathing in. Pulse dose cuts the energy required in half, allowing for devices to become slimmer and more portable. A pulse oxygen delivery method can only be effective if the respiration pattern can be accurately mapped. Cross comparison studies have shown that using a shielded microphone to record sound pressure data is one of the most accurate methods of tracking respiration. These microphones are lightweight components and will be embedded on-board the proposed device. This allows the device to stay compact while also enabling bolus oxygen delivery.

5.5 Micro Air Pumps

Nasal cannula flow rates for COPD patients are between 1 – 6 liters per minute. Currently there are commercially available DC micro pumps that can achieve these flow rates at a weight of 5 ounces. These micro pumps will allow for controlled air flow to enable bolus and on-demand oxygen delivery, without adding a significantly amount of weight.

5.6 Oxy-View Frames

In order to encourage an aesthetic look to the overall device solution, Oxy-View lenses, Fig. 4, would be used as the delivery system in place of a nasal canulla during the daytime. Wearing a nasal canulla gives off a visual mark of disability to the patient, while the Oxy-View is designed to reduce that effect.

5.7 Magnetic Resonance Charging

Many COPD patients require oxygen therapy at all times in the day. In order to accommodate for this, the device design
utilizes a wireless system. The device will contain a rechargeable battery and a magnetic resonance coil. A secondary coil connected to an AC outlet will be placed under the pillow. So when a patient goes to sleep while wearing the device, the batteries will begin to recharge. Magnetic resonance is able to transfer energy between two coils at efficiencies of up to 95% [31], can charge even when the coils are unaligned, and is safe to use with patients [32].

6 CONCEPT DESIGN
6.1 Core Framework

![FIGURE 5: HIGH LEVEL SENSOR FUSION DIAGRAM](image)

How the components in Section 5 work together at a systems level can be seen in Fig. 5. Included in this system are a vibration motor, pressure gauge, and two apertures. Though these are vital components to the device design, they were not mentioned in Section 5 because they did not relate to any particular design criteria. In Fig. 5, it can be seen that blood-oxygen and respiration data are required for the device to properly function. This data can either be captured by an in-built sensor, or an external sensor. Components (11) and (18) handle data collection. Either the component is a sensor for capturing data or the component is a wireless data receiver that can pick up values from an external sensor. The external sensors are (23) and (24) respectively. If an external sensor is used for either oxygenation, respiration, or both value sets, then its respective data collection component will be a wireless receiver. If the sensor is built in, then the external sensor is not needed.

6.2 Concept Device 1

![FIGURE 6: CONCEPT 1 SENSOR FUSION DIAGRAM](image)

Multiple product concepts could be generated from Fig. 5, however the paper will only examine one configuration, Concept 1, as a test case, depicted in Fig. 6-9. In the case of Concept 1, an external blood-oxygen sensor (23), wireless data receiver (11), and internal respiration sensor (18) were used.
to deliver a controlled mix of oxygen and air that will return or maintain the patient at homeostasis, based on the oxygenation and respiration values recorded. This happens by the collected data being sent to the microprocessor (13), which sends specific commands to components (14), (15A), (15B), (16), (17A), and (17B), to deliver the correct mix of oxygen and air.

7 SENSOR COMMUNICATION

7.1 User Scenario
In order to describe the component interaction in more detail, a test scenario is played out. The test case patient is one with COPD and obstructive sleep apnea (OSA), who is required to take supplemental oxygen during sleep. For those with this condition, oxygen saturation levels should be maintained at 98%, while any value below 92% results in an ineffective treatment. Concept 1 is used to treat the patient, with delivery device (10) being in wireless communication with a pulse oximeter, component (23). Under normal circumstances, it would be impractical for the patient to make certain that their saturation levels have not fallen below 92% during sleep time and manually adjust their delivery if that was the case. For the patient the benefit of using Concept 1 is that the device (10) will automatically adjust delivery based on real-time oxygen saturation values so that levels never fall below 92%. In addition, the wearable form allows for the patient to sleep naturally without having to worry about being tangled by a nasal cannula.

7.2 Communication Equations
Below are a set of equations that will be the framework for component communication in device (10) for treating the patient in the given test case.

\[ V_T = \begin{cases} \text{Male:} & 6 \times (50.0 + 2.3 \times [\text{height(inches)}] - 60) \\ \text{Female:} & 6 \times (45.5 + 2.3 \times [\text{height(inches)}] - 60) \end{cases} \]  

\[ K_{BON} = 98\% / I_{11} \]

\[ K_{BO} = K_{BO} \times K_{BON} \]

Through the duration of the device life, the \( K_{BO} \) will be kept in memory. This allows the delivery device (10) to become increasingly efficient at giving a personalized level of care.

\[ V_O = .21 \times V_T \times K_{BO} \] \( \text{(4)} \)

\( V_O \) is the volume of oxygen that will be delivered during the next breath. \( 21 \times V_T \) is the natural amount of oxygen taken. \( K_{BO} \) determines how much this volume quantity should be altered to bring the patient to a 98% oxygen saturation, based on previous saturation values.

\[ T_X = V_O / K_X \] \( \text{(5)} \)

\( T_X \) is the amount of time that the crystal structures inside the device need to within a vacuum to extract the volume of oxygen \( V_O \). \( K_X \) is a conversion factor that determines how long \( T_X \) needs to be in order to extract \( V_O \).

Eq. 6, 7, and 8 will be explained in the Pseudocode.

\[ T_E = T_i - T_e \] \( \text{(6)} \)

\[ T_i = T_e - T_i \] \( \text{(7)} \)

\[ \dot{V} = V_O / T_i \] \( \text{(8)} \)

7.3 Pseudocode
7.3.1 First Use

First Use

1. User height is inputted by the manufacturer to calibrate \( V_T \) using Eq. 1.
2. Waits for microphone (18) to signal the start of first exhale.

7.3.1 Exhale

\[ \text{FIGURE 9: CONCEPT 1 EXTERNAL VIEW} \]

\[ \text{FIGURE 10: CONCEPT 1 OXYGEN CAPTURE} \]
Oxygen Capture
1. Opens aperture (17A) to allow the crystal (22) to become entranced with oxygen. A process shown in Fig. 10.
2. Uses $I_{11}$ value in Eq. 2 to calculate next breath correction factor $K_{B_{11}}$.
3. Uses $K_{B_{11}}$ value in Eq. 3 to calculate the system correction factor $K_{B_{0}}$.
4. Determines what oxygen volume $V_{O}$ will return homeostasis, using Eq. 4.
5. Uses $V_{O}$ to calculate extraction time $T_{X}$ in Eq. 5.

Oxygen Delivery
9. Marks down the start of inhale as $T_{i}$.
10. Uses $T_{i}$ in Eq. 6 to calculate the last exhalation duration, $T_{E}$.
11. Opens the crystal aperture (17A), turns on supply pump (15 A).
12. Supplies $V_{O}$ along with ambient air pulled through the crystal aperture (17A). A process shown in Fig. 11.
13. Marks the start of exhalation as $T_{e}$, replacing the past value.
14. Uses the new $T_{e}$ in Eq. 7 to calculate the last inhalation duration, $T_{I}$. In order to determine the flowrate $\dot{V}$ using Eq. 8 of the next oxygen delivery, it will be assumed that the patient’s next inhalation will be equal to the duration of this inhalation $T_{i}$.
15. Loop back to Oxygen Capture.

8 SUMMARY AND FUTURE DIRECTIONS
This paper presents an innovation in the sphere of oxygen therapy for individuals suffering from COPD. The design incorporates crystal technology for highly compact oxygen concentration [24], microphone nasal pressure breathing pattern detection for on-demand delivery of oxygen at the time of inhalation [20], magnetic resonance charging to recharge the battery power for the device while the patient is wearing the device during sleep [31, 32], and integrated blood oxygen measurement. The design addresses issues of weight, size, mobility, refilling and electrical power requirements, in which current solutions fall short. Future directions include the commercialization of this technology, which will include user testing through clinical trials, and refinement of the configuration of components and ergonomics based on user feedback.

REFERENCES
[1-33]


[33] "Tidal Volume Settings in Adult Mechanical Ventilation."