

Patient Powered Device for the Treatment of Obstructive Sleep Apnea

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Obstructive sleep apnea (OSA) is a common sleep disorder in which the throat repeatedly closes during sleep, interrupts breathing and then sleep, and can contribute to morbidity such as daytime sleepiness, cardiovascular consequences, and premature death. Standard treatment with a continuous positive airway pressure (CPAP) machine delivers positive pressure through a mask to splint the airway open. However, CPAP is expensive, noisy, and requires electricity, all of which can limit access and nightly adherence. A concept for a mechanical CPAP device designed to be powered by the natural work of breathing rather than an external electrical source is presented in this Design Innovation paper. [DOI: 10.1115/1.4026288]

1 Introduction

Obstructive sleep apnea arises from repeated closure of the throat during sleep when muscles that normally maintain upper airway patency relax. The area of obstruction can range from the soft palate to the base of the tongue (Fig. 1) [1].

The condition disturbs breathing during sleep, and sleep itself, in over 20 million Americans [2]. OSA affects at least 4% of men,

2% of women, and 50% of obese adults. In OSA, the upper airway closes completely, causing an apnea, or partially, causing a hypopnea, in a repetitive manner when the patient sleeps [3]. OSA can be diagnosed when apneas and hypopneas that last at least 10 s become more frequent than five per hour of sleep and cause associated symptoms [4]. Figure 2 shows a portion of a polysomnogram, recorded in a sleep laboratory, during sleep of a patient with OSA. The key observation is that airflow ceases while effort to breathe continues as reflected by persistent motion of the chest and the abdomen.

Each time the airway closes or narrows, oxygen content of the blood diminishes, carbon dioxide rises, and reflexive increases in respiratory effort eventually lead to opening of the airway, usually with arousal of the brain and disruption of sleep [5]. The repeated arousals, associated with surges in sympathetic nervous system (“flight or fight response”) activity, in addition to intermittent hypoxia, may both help to explain increased cardiovascular morbidity in patients with sleep apnea [6]. The untreated condition is also associated with daytime sleepiness, cognitive impairment, hypertension, heart failure, arrhythmia, myocardial infarction, stroke, diabetes, metabolic syndrome, and a shortened lifespan [2].

Mild OSA (5–15 apneas or hypopneas per hour of sleep) can sometimes be treated by positional therapy, such as sleeping in nonsupine positions. Mild OSA can also be treated with an appliance, placed in the mouth at bedtime, which advances the mandible and pulls the tongue away from the back of the throat.

Other patients may be candidates for surgery to enlarge the upper airway directly, advance the mandible to enlarge the airway indirectly, or reposition the tongue [7]. However, surgery is expensive and carries inherent risks. For many patients with mild OSA and most of those with moderate (15–30 apneic events per hour of sleep) or severe apnea, use of continuous positive airway pressure administered through a mask is often the best option. Overall, about 60–80% of all patients with OSA are successfully treated with CPAP or a related positive airway pressure (PAP) device. The types of OSA treatments are compared below in Table 1.

In practice, first-line treatment for OSA usually involves nightly use of a CPAP machine connected by tubing to a nasal or facial mask. CPAP was first used for OSA in the mid-1980s after positive airway pressure was shown to act as a pneumatic splint to hold the upper airway open during sleep [1]. All modern CPAP machines contain a fan, drawing air into the machine and producing a pressure specified by a physician. Observations made in a sleep laboratory determine the minimum pressure necessary for each individual patient. Air enters the CPAP machine, passes through an air filter, and enters a compartment surrounded by sound-absorbing foam. The air is pumped through a humidifier (optional), exits the machine, passes through a flexible plastic air hose and the mask, enters the nose or nose and mouth, and reaches the throat, thereby, pressurizing the airway.

Two popular commercial models are the Respironics REMstar Pro and the Probasics Zzz-Pap Silent Traveler. The REMstar Pro

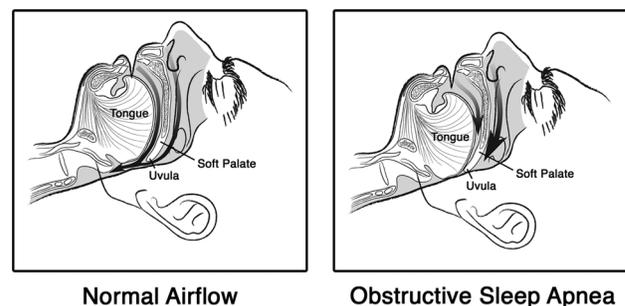


Fig. 1 Schematic illustrating the passage of air in an open airway (left panel) versus a closed airway (right panel)

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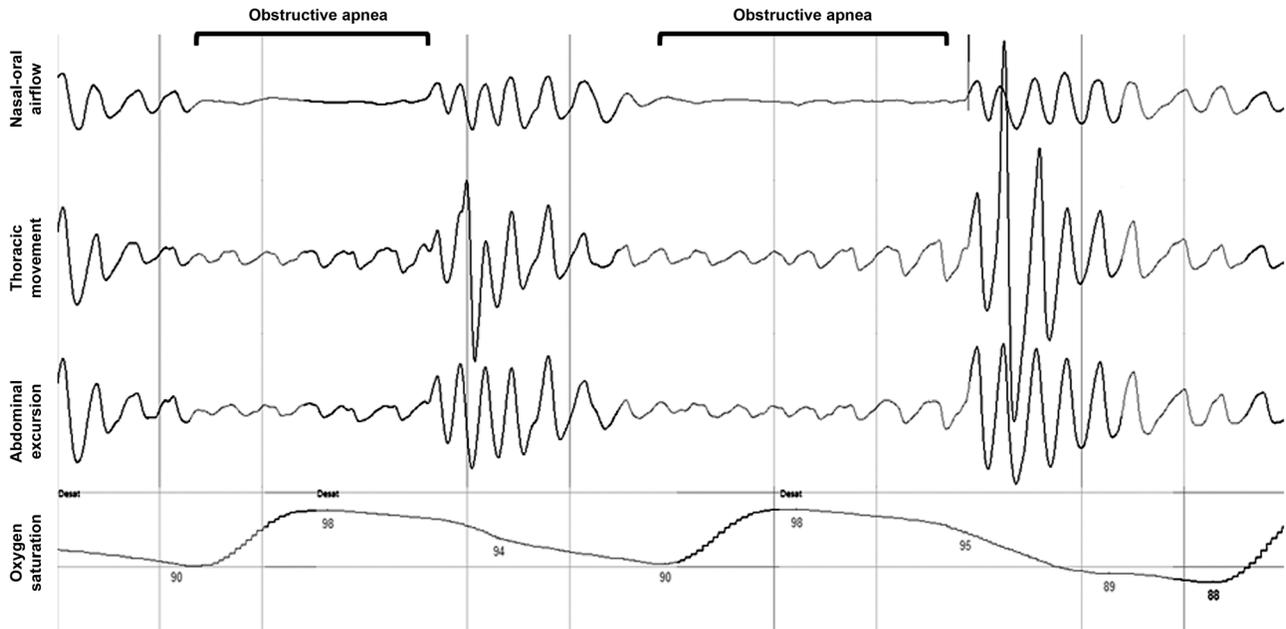


Fig. 2 Illustrative data from a clinical polysomnogram (120s) shows two obstructive apneas that occurred during stage 2 sleep. During each event, airflow ceases for more than the required 10s, chest and abdominal movements show persistent effort to breathe, and oxygen desaturations occur with a delay (while blood from the lungs reaches the finger oximetry site) after each apnea.

Table 1 Treatment option comparison

Treatment	Severity	Cost (\$)
PAP	Mild-severe	\$200-4000
Behavior therapy	Mild only	—
Surgery	Mild-severe	\$1000-50,000
Oral devices	Mild only	\$800-3000

has a $33 \times 18 \times 14 \text{ cm}^3$ footprint and weighs 2.1 kg [8]. The Zzz-Pap Silent Traveler is comparatively one of the most portable among commercial models weighing only 0.77 kg with dimensions of $24 \times 15 \times 10 \text{ cm}^3$ [8]. Both deliver 392–1960 Pa (4–20 cm water) at 30 dB, require electricity to operate, and are nearly 100% efficacious for mild, moderate, and severe OSA. With a price of \$459 per unit, the REMstar Pro is relatively expensive compared to some other models (e.g., Zzz-Pap Silent Traveler costs \$209 per unit).

The CPAP is almost always effective when used properly, but as many as 50% of patients do not use it as recommended throughout a full night of sleep seven nights per week [9]. Clinical experts report that poor adherence can result from several barriers including mask discomfort, claustrophobia, and nasal congestion. Additional important contributors to inadequate adherence can include the cost, electricity requirement, noise, weight, and suboptimal portability. An electrical source is unavailable in many parts of the world, where sleep apnea may also be highly prevalent. The \$200 or more cost for sophisticated electronic PAP machines can be a barrier to treatment of many patients who have sleep apnea. These issues motivated the development of a new approach to delivery of PAP, in a manner that could address some of these constraints and increase accessibility of PAP as treatment for sleep apnea.

This Design Innovation paper aims to introduce a proof-of-concept design, initial prototype, and preliminary results to support further development of mechanical CPAP that would require no electricity and could be considerably less expensive, quieter, and lighter than existing electronic CPAP machines. The literature review (PubMed, Google Scholar) and benchmarking study per-

Table 2 Engineering specifications and target values

Rank	Specifications	Target values
1	Electrical power	0 W
2	Pressure tolerance	<196 Pa (2 cm water)
3	Cost	<\$100
4	Dead space volume	<102 ml
5 (tie)	Size	< $20 \times 10 \times 10 \text{ cm}^3$
5 (tie)	Noise level	<30 dB
7	Weight	<2 kg

formed as part of this research, in addition to the comprehensive patent search (United States Patent Trade Office, World International Patent Organization) conducted by the University of Michigan Office of Technology Transfer did not reveal a description of a similar device or existing patent application. A patent application for the technology described in this report has been filed by the University of Michigan.

2 Methods

2.1 Engineering Specifications. Requirements for a mechanical CPAP device were determined through a user survey, interviews with sleep disorder specialists, and an interview with a local OSA support group. These requirements were translated into engineering specifications, of which the top seven (excluding safety requirements) are shown in Table 2. Pressure tolerance is the difference in inhalation and exhalation pressure as further explained in the Results section of this paper. Dead space volume, as used here, is the volume of air inherently contained between the user's mouth and fresh air. If the user breathes into tubing and then rebreathes more than approximately 100 ml of the same air before receiving fresh air distal to the previously exhaled column of air, then effective gas exchange may not occur. The dead space volume is determined mainly by the volume of the mask used because ports in the mask and connectors between the mask and tubing vent exhaled air. The powerful electronic CPAP blower maintains pressure despite the leak through the vents and makes pressure variation between inhalation and exhalation negligible.

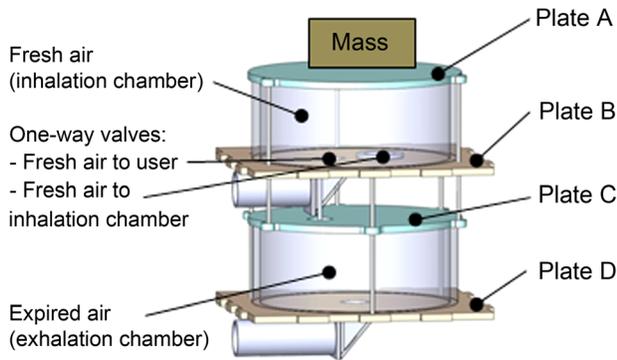


Fig. 3 Device operation after exhalation

The target values chosen were based on a benchmark, the REMstar Pro, other CPAP devices available on the market, and user feedback of desirable features.

Electronic CPAP devices generate therapeutic pressures between 392 and 1960 Pa (4–20 cm water) though most patients with OSA require settings in the range of 490–1372 Pa (5–14 cm water). The aim with the new concept design was to replicate the range of electronic PAP as closely as possible, with the expectation that higher settings used by a minority of OSA patients may not be achieved. Brainstorming and functional decomposition were used to generate 32 strategies/interventions to maintain upper airway patency during sleep during the concept-generation stage. Early-stage concepts included physical splints, interventions that might involve both mechanical and surgical approaches, novel nonelectric means for generation of PAP, methods by which electricity could be patient-generated, and behavioral approaches. Feasibility assessments, go/no-go tests, and the Pugh concept selection method were used to select the concept described below.

2.2 Concept Description. The concept developed in this study converts the energy generated from the user's exhalation into potential energy and then uses that potential energy to pressurize the subsequent inhalation of fresh air into the mask and throat; exhaled air and fresh air do not mix at any point. This concept does not require electricity but does provide PAP. The most notable feature of the concept is that the power required to operate the device is to be supplied by the user, removing any electrical dependence but also providing equivalent PAP during expiration and inspiration (i.e., CPAP), at least under ideal conditions in which friction is near zero, no leaks occur, and all energy is conserved.

The concept (Figs. 3 and 4) comprises two inflatable air chambers (exhalation and inhalation chambers) that resemble bellows, two moving plates (plates A and C), two fixed plates (plates B and D), a mass (0.8–3.7 kg), six linkage rods, three one-way valves (Fig. 5) (one is a safety valve in the exhalation chamber described later), an elbow valve, and a backflow stopping valve (Fig. 6).

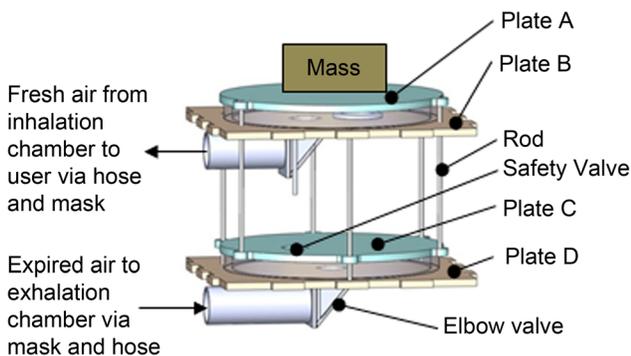


Fig. 4 Device operation after inhalation

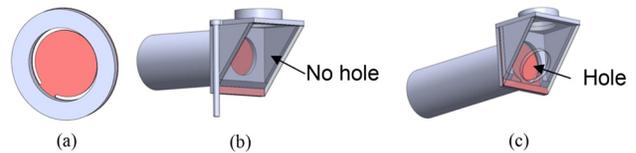


Fig. 5 CAD designs of (a) one-way valve (b) inhalation chamber L-shape valve without a hole on the other side as its only function is to let fresh air flow into a patient's breathing passage, and (c) exhalation chamber L-shape valve with a hole on the other side to allow used air out when air chamber is deflated

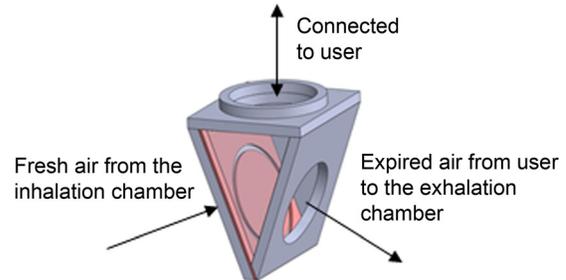


Fig. 6 Backflow stopping valve CAD design

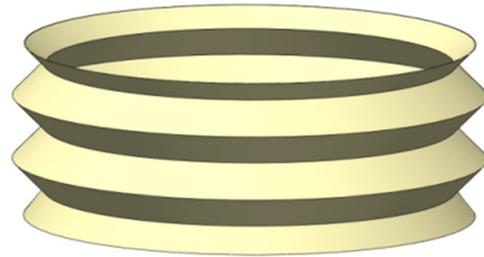


Fig. 7 Chamber/bellows CAD design

One end of each inflatable bellows chamber (Fig. 7) is mounted on the fixed plates. Two movable plates (A and C) are mounted to the other end of the chambers; these plates are connected via rod linkages that slide through guiding holes in the central mounted plate (plate B). Plates A and C move in unison, inflating and deflating the chambers together. Plate C contains a safety valve for variable breath volumes. The inhalation chamber only holds fresh air while the exhalation chamber only holds exhaled air. Two valves are mounted in plate B for the inhalation chamber, and one elbow valve is mounted in plate D.

Patients may inhale and exhale slightly different air volumes with each sequential breath. Therefore, the concept design accommodates variable breath volumes with a safety valve. For example, consider a chamber size designed to hold a moderately large breath volume (e.g., ~650 ml). At times, the user may exhale volumes exceeding this amount (e.g., ~700 ml): if a safety valve wasn't present, the user would be unable to exhale fully and might experience discomfort. The safety valve would allow the user to continue to exhale in this scenario. There may also exist occasions when the user will exhale smaller volumes (e.g., ~400 ml): in these scenarios, there is no need to use the safety valve. Conversely, if a user needs to inhale more air than the average respiratory volume provided by the pressurized inhalation chamber, the user will still receive fresh air during inhalation as it passes directly from the one-way inlet valve to the user; however, during this brief period of time, the air would not be pressurized.

A backflow stopping valve (Fig. 6) is required near the user, at the junction of the fresh air and expired air tubes. This valve prevents fresh air supplied to the user from escaping into the exhalation chamber or expired air from traveling into the inhalation chamber. Three tubes are connected to this valve (as seen in the

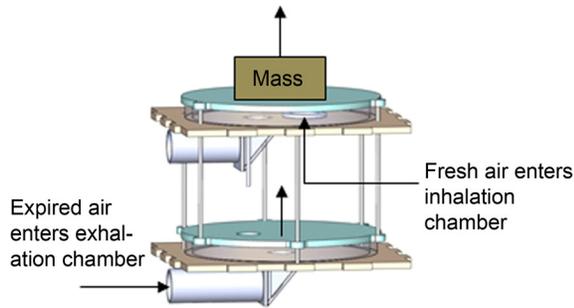


Fig. 8 Exhalation

prototype in Fig. 10). As fresh air is forced out of the inhalation chamber, the rubber flap pivots away from its resting position to close the adjacent hole such that the fresh air is directed toward the user through the mask. This approach is used in currently marketed CPAP masks.

In addition to two one-way valves located in the inhalation chamber, a valve mechanism is required for the exhalation chamber that will regulate when the user is exhaling and inflating the chambers versus when the user is inhaling and the chambers are deflating. An elbow valve that functions similarly to the backflow stopping valve is used. In this case, the valve flap pivots to cover the open hole such that the CO₂-rich air from the user only enters the exhalation chamber. When the user begins inhalation, the flap falls to its resting position and the CO₂-rich air leaves the exhalation chamber.

The cylindrical chambers of 650 ml (based upon average human breath volume [10]) serve as inflatable bellows. The hose volume is not considered, as the air is estimated to be incompressible.

A water tight container with markings corresponding to masses ranging up to 3.7 kg provides a range of deliverable pressures. The user is required to fill the container with water in the amount necessary to generate sufficient positive pressure specific to the user's breathing requirements.

The design requires two hoses: one transports air from the inhalation chamber to the mask, and a second transports expired air from the mask to the exhalation chamber. Use of two tubes eliminates dead space that would be present if a single tube were used. The volume of dead space is the amount of exhaled air that the user rebreathes during inhalation. As the dead space increases, the user receives less oxygen and more carbon dioxide. Therefore, minimal dead space is desirable.

2.3 Concept Operation. The following explanation provides a step-by-step explanation of the concept's operation; refer to Figs. 8 and 9. During exhalation (Fig. 8), expired air is forced through an elbow valve into the exhalation chamber. This action expands the exhalation chamber by raising plate C. This plate is coupled to moving plate A of the inhalation chamber via three rods such that both chambers expand in unison. As the exhalation chamber expands, the inhalation chamber expands, lowering the pressure in the inhalation chamber below ambient pressure and

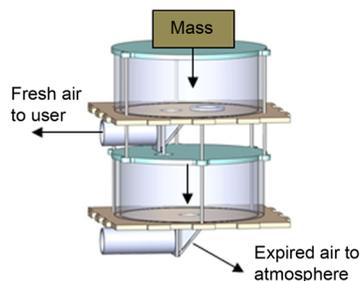


Fig. 9 Inhalation

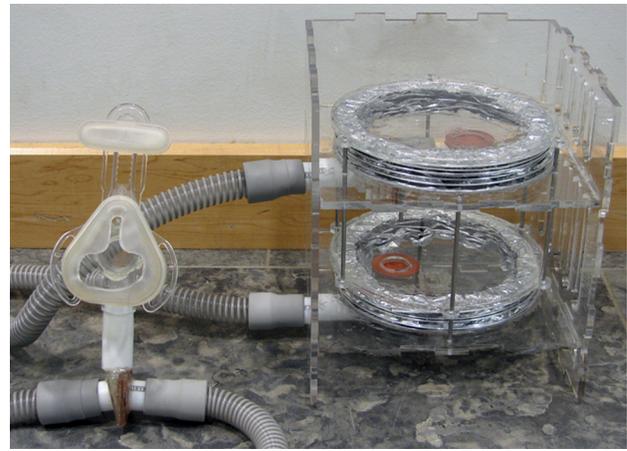


Fig. 10 Prototype

drawing in fresh air. Moving plate A of the inhalation chamber has an adjustable mass on it, which gains potential energy as the chambers inflate. This mass provides the steady force against which the user breathes, and guarantees the predetermined, patient-specific pressure needed to maintain patency of the patient's upper airway (throat) during expiration.

During inhalation (Fig. 9), the mass drives the plates downward, causes the chambers to collapse, and pushes pressurized fresh air from the inhalation chamber through a hose and mask to the user. Simultaneously, the previously expired air in the exhalation chamber is expelled via the elbow valve.

2.4 Preliminary Evaluation. To measure the exhalation chamber pressure necessary to raise the plates to the open position (and thus generate positive pressure in the inhalation chamber), a prototype was developed (see Results) and connected to a standard CPAP machine via the exhalation chamber hose. The standard machine generated constant, known pressures that could be titrated to the setting at which a test mass would just begin to rise, and this setting was taken as the expiratory pressure necessary for a given mass. This was repeated with a variety of masses.

To measure the inhalation pressures generated by the prototype, the mass-pressurized chambers were inflated to maximum capacity by the standard CPAP machine. The standard machine was then disconnected. A manometer connected to the inhalation chamber outlet tube displayed the pressure provided for inhalation. This was repeated with a variety of masses.

3 Results

The prototype developed and tested is shown in Fig. 10. Table 3 compares the initial design specifications to the results achieved during preliminary evaluation; we then describe each in detail.

The prototype functioned without any electrical power by capturing and storing the simulated exhaled air and returning

Table 3 Engineering specifications, target values, and preliminary results

Rank	Specifications	Target values	Preliminary results obtained
1	Electrical power	0 W	0 W
2	Pressure tolerance	<196 Pa (2 cm water)	~49 Pa (0.5 cm water)
3	Cost	<\$100	\$56 prototype
4	Dead space volume	<102 ml	10.8 ml > electric CPAP*
5 (tie)	Size	<20x10x10 cm ³	20 × 23 × 23 cm ³
5 (tie)	Noise level	<30 dB	~24 dB
7	Weight (kg)	<2 kg	1.7 kg

pressurized fresh air during simulated inhalation using the simple experimental setup described above. For example, given a 0.5 kg mass, the chambers required 490 Pa (5 cm water) to inflate and returned 441 Pa (4.5 cm water). All experimental pressures reported are relative (gauge) pressures. Additional testing is required because inhalation and exhalation pressures could not be measured sequentially following a normal breathing cycle—separate measurements were made for the pressure required to inflate the chambers and the pressure provided by the chambers.

The difference in inhalation and exhalation pressure is the pressure tolerance. The pressure tolerance is influenced by a number of factors including, but not limited to, possible air volume compression, loss in the valves, and damping loss in the transfer of force between the inhalation and exhalation chambers. Expiration volumes exceeding 650 ml are accommodated by a safety valve that enables excess volume to exit the exhalation chamber. Inhalation volumes exceeding 650 ml are also accommodated for because more air can be inhaled by the creation of a low-pressure zone in the inhalation chamber. This low-pressure zone causes the one-way intake valve in the inhalation chamber to allow more air to pass directly into the other one-way valve leading to the user. In this way, variable breath volumes are ideally accounted for but require further evaluation to ensure that they are not decreasing effectiveness of treatment for OSA.

Although it is not feasible to compare the cost of developing a single prototype to a commercial product, prototyping costs totaled approximately \$60.

The dead space in the prototype is limited to the volume of air contained in the backflow stopping valve, the tube connection between this valve and the mask, and the mask volume itself. The dead space volume for the valve is 2 ml and the connection is 8.8 ml. Smaller masks may work better with the prototype as their dead space volume is much smaller than some larger masks. The smaller masks generally only cover the nose, instead of both the mouth and nose. To use masks designed for CPAP machines with the prototype produced for this study, the air outlet holes of the mask must be plugged to allow all exhaled air to reach the exhalation chamber and all pressurized fresh air to meet the user.

The prototype measures $20 \times 23 \times 23 \text{ cm}^3$. These dimensions exceed the target volume because the device contains two air chambers that are 650 ml when inflated. The REMstar Pro CPAP machine is $33 \times 18 \times 14 \text{ cm}^3$, which is smaller than the currently proposed device. The size of the mechanical CPAP unit could potentially be reduced, for example, by moving the position of the chambers or making them fully collapsible during periods when the machine is not in use.

The prototype produces roughly 24 dB of noise during operation. This is quieter than the REMstar Pro CPAP machine, which is quoted at 30 dB. The prototype weighs 1.7 kg, which is lighter than the REMstar Pro CPAP machine, which is quoted at 2 kg.

Both chambers were effective in capturing and storing air and providing pressurized air back to the user—this is further described below. Preliminary evaluation demonstrated that a con-

stant pressure from the user would smoothly open the chambers. It also showed the exhalation pressure is linearly related to the mass applied to the system, as shown in Fig. 11. The pressure was adjusted by adding or removing mass from plate A. The desired pressure range of 392–1569 Pa (4–16 cm water) was approximately achieved by using masses ranging from 0.4 to 3.1 kg. Expiration volumes exceeding 650 ml were accommodated by the safety valve, which enabled excess volume to exit the exhalation chamber.

Inhalation pressure during use by a patient has not yet been tested, but the pressure provided to the user when the system is connected to a pressure gauge was determined. The inhalation pressure provided to the user is linearly related to the mass applied to the system, as shown in Fig. 12. The pressure was adjusted by adding or removing mass from plate A. Typical inhalation pressures provided by current CPAP machines on the market range from 392 to 1961 Pa (4 to 20 cm water). The desired pressure range of 392–1569 Pa (4–16 cm water) was approximately achieved by using mass ranging from 0.2 to 3.7 kg.

4 Discussion

This Design Innovation paper describes the first known CPAP prototype designed to be powered entirely by the user rather than electricity. Standard CPAP machines waste the energy provided by the thorax during expiration against electricity-generated positive airway pressure. The mechanical CPAP approach described herein has the potential to capture a patient's energy of expiration and use it to return fresh air, at the required pressure, back to the patient during inhalation. The process simulates continuous positive airway pressure normally provided by an electric machine with a blower, several computer chips, and extensive programming. Initial data from the prototype suggest that the exchange of expired air for fresh air inspired under pressure could be accomplished with little loss of energy and with back-up systems to accommodate occasional unusual deviations in regular breathing patterns during sleep.

Preliminary evaluation experiments suggested a linear relationship between the pressure supplied to the exhalation chamber and the pressure fed back to the user from the inhalation chamber as determined by the mass applied. Results also suggested that the device, equipped with a working safety valve, can handle variable breath volumes, including inspirations or expirations larger than 650 ml. Although transient inspiration through an emergency inlet valve open to ambient pressure would not be pressurized, the exposure would be brief and occur during a phase of respiration (end-inspiration) that does not generally permit airway closure. This is because during inspiration, physiologic activation of upper airway muscle tone occurs, presumably to counteract anticipated effects of mild negative intraluminal pressures.

There are several limitations associated with this study. Human subject testing has not yet been conducted. The pressure provided to a human user during inhalation has not yet been measured. A commercial-grade prototype has not been fabricated and,

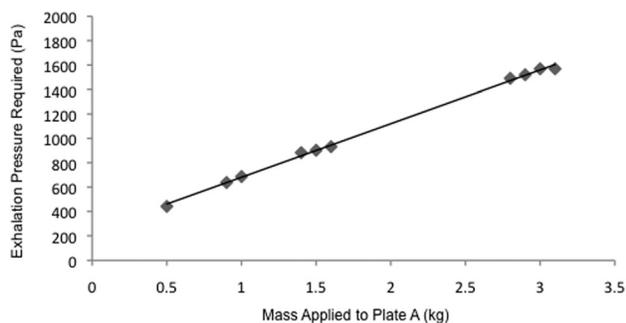


Fig. 11 Pressure required for exhalation showed a linear relationship with mass applied to plate A

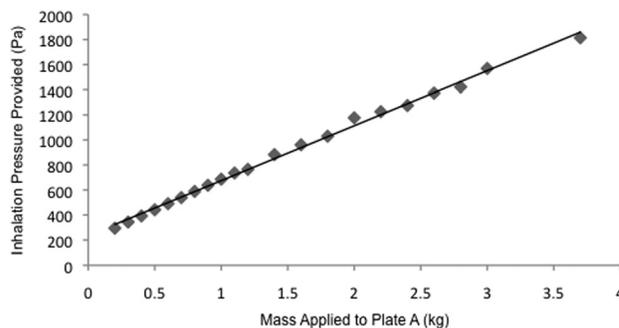


Fig. 12 Pressure provided for inhalation showed a linear relationship with mass applied to plate A

therefore, rigorous comparisons with commercially available CPAP devices have not been performed. Further design work is required to guarantee full pressure support during the entire time-line of inspiration, for example, by minimizing system air leaks. Future work also includes the possible development of a theoretical model detailing the function of the concept described in this study.

5 Conclusion

The standard approach to treatment of OSA with electronic CPAP machines has several drawbacks, including high cost, dependence on an electrical source, machine noise, and suboptimal portability (size and weight). These limitations may be addressable, for many if not all patients, through the further development of a low-cost mechanical CPAP system that does not require an electrical energy source, emits less than 30 dB, and provides easily adjustable pressures ranging from 392 to 1569 Pa (4 to 16 cm water). Although the initial mechanical prototype is slightly larger than standard CPAP units, further refinement could utilize collapsible chambers and lighter, industrial-grade materials that make it smaller and lighter for travel than is possible with conventional (electronic) units. This study describes concepts and provides preliminary data to suggest that mechanical CPAP merits further development and validation.

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