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The Life Saving Ventilator

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Abstract—The COVID-19 crisis has placed enormous strain on global healthcare due to the sudden and exorbitant caseload burdens, compounded by insufficient access to the requisite supplies and equipment necessary to treat patients. Most notably, critical shortages of mechanical ventilators, which are essential for oxygenating patients who cannot breathe on their own, have forced physicians to make difficult decisions between who will and will not receive treatment, especially in resource-limited communities. In this article, we describe the efforts undertaken by a consortium of engineers, roboticists, and clinicians from Vanderbilt University to develop an easily-reproducible mechanical ventilator out of core components that can be sourced locally, inexpensively.

Keywords—COVID-19, Mechanical Ventilator, Volume-Controlled Ventilation

INTRODUCTION

COVID-19, caused by the novel human coronavirus, is a severe acute respiratory disease that has wreaked havoc on global public health with more than 14.7 million confirmed cases and 611,000 deaths worldwide as of the summer of 2020 [1] , with 3.9 million cases [1]and over 141,000 lives lost in the USA as of this writing.

Patients presenting with COVID-19 can develop severe acute respiratory distress syndrome (ARDS), [2],[3]which is characterized by low respiratory compliance and life threatening impairment of pulmonary gas exchange[4], [5]. Approximately 20% of admitted COVID-19 patients require respiratory assistance from a mechanical ventilator to achieve adequate oxygenation[6]. The resource-intensive therapeutic requirements posed by COVID-19, coupled with the sudden and exorbitant caseload onset, have overburdened healthcare infrastructures across the globe due to dwindling supplies of the personal protective equipment (PPE) and devices (e.g. mechanical ventilators) necessary to protect frontline workers and treat patients with the disease[7].

Insufficient access to clinically-approved ventilation systems has forced physicians to make particularly difficult triage decisions, including modification or even discontinuation of care for patients for whom the outcome is bleak, in an effort to free up ventilators for those with more favorable prognoses[8].

Ventilator Shortages Galvanize Grassroots Innovation

Recognizing these critical supply shortfalls, many communities across the globe have banded together to bootstrap ad hoc solutions in an effort to bridge the supply gap.

These efforts range from breweries and alcohol distilleries bottling hand sanitizer instead of beer and whiskey, to large automotive (General Motors[10], Tesla[11]) and aerospace (Virgin Orbit[12], SpaceX, NASA) companies retrofitting and re-tooling entire factories to mass manufacture mechanical ventilators and requisite components at scale. A particularly inspiring example of grassroots ingenuity in the fight against COVID-19 comes from the engineering and 'maker' communities who have mobilized to develop custom, open-source designs for mechanical ventilators that can be rapidly manufactured with fairly simple processes and easily sourced components. These concepts range from mechatronic systems designed to compress clinically-approved bag-valve masks (Ambu bags) at digitally-programmable rates, to pneumatic systems that deliver ventilation directly through digitally-controlled valves, to hybrid systems which use a pressurized chamber to compress an Ambu-bag.

To list all of the open-source designs would require a separate article by itself, so we encourage the reader to consult for a more complete picture of the open-source ventilator landscape.

In this article, we describe the work done by a team of engineers, roboticists, and clinicians from Vanderbilt University, beginning in late March 2020, to develop an easily reproducible mechanical ventilator out of core components that can be sourced locally, inexpensively. This process resulted in an open-source design that is set apart from other solutions by its manufacturing simplicity and reliance on components that are either readily available locally or ubiquitous enough that they could be sourced quickly even in the face of pandemic-induced shortages and supply chain disruptions.

The Vanderbilt Open-Source Ventilator

The Vanderbilt Open-Source Ventilator is a volume controlled, intubation-style ventilator. We took this device from napkin sketch to a prototype in three weeks which, after a successful animal study, doctors deemed able to save a life. Over the following three weeks, we manufactured 100 units and submitted documentation to the FDA for Emergency Use Authorization clearance. Throughout this whirlwind process, we undertook multiple design iterations, informed by continuous clinical input, literature review, and experimental testing, enabling us to converge on a design that is low-cost, easily manufactured, and potentially lifesaving.

Our device implements a simple, inexpensive design; it is largely constructed from plywood, and we did away with expensive, specialized DC/stepper motors and optical encoders, instead relying on widely available windshield wiper motors and a simple reciprocating transmission design based around a scotch-yoke mechanism and drawer glides. The purpose of the device is to mechanically compress an Ambu bag, a widely available medical device that is normally squeezed by hand to transport patients to the hospital or within the hospital when they are having difficulty breathing on their own.

By leveraging medical Ambu bags and requisite ventilator/endotracheal (ET) tubing, the VOV is directly compatible with many standard oxygenation and humidification sources, and the only components that come into contact with the patient's airway are clinically-approved and disposable or otherwise subject to rigorous reprocessing protocols.

We added Arduino-based control electronics which, when combined with mechanical inputs, enables physicians to set the volume of air delivered each breath (called the tidal volume (TV)), the respiratory rate in breaths-per-minute (BPM), the amount of the breathing duty cycle devoted to inspiration vs. expiration (i.e. the I/E ratio), and the pressure thresholds at which alarms will sound during operation (designed in accordance with ISO 60601).Experimental validation in both calibrated mechanical test lungs and live animals has demonstrated that the VOV is capable of delivering consistent, repeatable, and reliable respiratory therapy under variable loading conditions.

DEVELOPMENT PROCESS

Rallying Cry and Rapid Prototype Iteration

The project began in earnest on March 21, 2020, when physicians at Vanderbilt University Medical Center deemed the risk of severe local ventilator shortages high enough that all efforts that could be brought to bear on the problem should be made. Sensing the urgency in their clinical colleagues, the engineering team quickly came together, consisting of faculty and graduate students with all of the skillsets required to quickly build a mechanical ventilator prototype. Within a matter of hours after this clinical call-to-action, a napkin sketch made by one of the engineers was converted into a first prototype that demonstrated the concept of using a motor-driven mechanism to compress an Ambu bag at a consistent rate to deliver mechanical ventilation. The need for accurate, continuous TV adjustment led to the development of Version 2.0 on March 24th, which implemented the scotch-yoke mechanism (SYM) that would become the preferred transmission mechanism of the design (described in more detail in the "Mechanical Design" section). In v2.0, the TV is adjusted by physically sliding the SYM to increase or reduce the compression of the Ambu bag on a single stroke. This TV adjustment mechanism was further improved in v3.0 (with a manually-actuated leadscrew.

At the time, the system was powered by an off-board adjustable lab power supply, meaning that only the BPM could be crudely adjusted by changing the voltage setting of the supply.
Realizing the need for more accurate control, sensors, and safety features, an embedded system (centered around an Arduino Uno) and an associated user interface (UI) was developed in parallel that would enable digital configuration and control of the ventilation profile, as well as the ability to report anomalous events to the caregiver through an ISO 60601-standardized alarm profile.
As the design progressed, extensive manufacturing and assembly instructions were created that would enable others to manufacture the VOV, which would be continually updated throughout the remainder of the project to reflect all design modifications. A complete Institutional Animal Care and Use Committee (IACUC) protocol was drafted and approved by Vanderbilt in 2 days, enabling us to move forward with animal experiments.

Concept Refinement and Testing

The integration of the UI/embedded controller with v3.0 led to the creation of v3.1 on April 2nd, which would be the first unit tested in an in vivo setting on the next day. At our first live swine experiment on April 3rd, we observed insufficient gas exchange from our device resulting in the animal breathing out of synchronization with our ventilator.
This was found to be due to the existence of substantial dead space in the ventilation circuit (specifics of which are provided in the "In Vivo and In Vitro Testing" section).

To rectify this, we integrated a pressure-sensing single-limb circuit into the design which places the valves at the patient's mouth rather than remotely at the outlet of the Ambu bag. A second 4-hour live swine experiment was conducted five days later, in which the device worked flawlessly.

Design Lock-In and Manufacturing Scale-Up

Immediately following approval from our clinical collaborators, we began working with several local Nashville companies to ramp up production. Part kits and assembly instructions were distributed to a volunteer workforce consisting of Vanderbilt graduate students, faculty, and staff, as well as local unaffiliated 'makers' and tech enthusiasts in the greater Nashville area. One hundred windshield wiper motor assemblies were generously donated by Nissan Smyrna, a local automobile assembly plant. A local marketing agency (Abel+McCallister+Abel, Nashville, TN) volunteered their facilities and personnel to CNC-route all of the plywood components, which were subsequently assembled by a group of volunteers from two local makerspaces, Fort Houston and Make Nashville. Electronic control boxes were wired and assembled by a group of Vanderbilt University graduate students. All manufacturing and assembly instructions were communicated to volunteers using the documents made available in the Supplementary Information.

Over the course of the next two weeks, we assembled the mechanical frames for 100 units (Fig. 2(j)). By April 17, twenty of these mechanical units were outfitted with fully-wired control boxes for immediate use, with parts-on-hand for 80 more if needed.

Summary of the VOV Design Process

As the previous sections highlight, VOV hardware development, refinement, and manufacture took place rapidly, and was made possible through continuous daily collaboration between engineers, clinicians, and volunteers throughout. Now that we have described the design process, the following sections of this article will address engineering specifications, as well as details regarding the mechanical and electronic design. We also provide VOV testing data in in vitro and in vivo analogous to show that the VOV can provide reliable ventilation over a range of use cases and parameter settings.

VENTILATOR REQUIREMENTS AND SPECIFICATIONS

Clinical ventilators are very complex systems with many sophisticated ventilation modes and closed-loop control abilities, much more than we sought to replicate in the VOV, and we consciously made the decision to prioritize a minimum viable ventilator with the necessary functionality to meet the immediate emergent potential needs during the pandemic. Through many conversations between clinicians and engineers, we arrived at the following understanding of what it is required to ventilate COVID-19 patients.

Dynamics of Mechanical Ventilation

Under VCV, since the ventilator is configured to deliver a fixed TV, the airway pressure profile develops passively as a function of airway mechanics and dynamics. Typical VCV waveforms generated by the VOV. The peak inspiratory pressure (P_{PIP}) is the maximum pressure delivered during inspiration at peak

airflow, and is affected by airway resistance and the lung's dynamic compliance, C_{dyn}. P_{PIP} should be monitored closely as high P_{PIP} has been linked with barotrauma (above 40hPa).

The plateau pressure (P_{plat}) is the pressure that develops within the lung when there is no airflow, and is largely dictated by the lung's static compliance, C_{stat}. Monitoring P_{plat} offers the physician a surrogate estimate of pulmonary health, and the relationship of P_{plat} with P_{PIP} can alert the physician to underlying and potentially deadly pulmonary conditions (e.g., if P_{plat} is well above 30hPa and is very close to P_{PIP},

The positive-end expiratory pressure (P_{PEEP}) is the amount of pressure held within the lungs between cycles, and is typically a therapeutic parameter set by the ventilator. Especially in COVID-19 patients who present with ARDS-like pneumonia, lung compliance can deteriorate over time, leading to an increase in airway pressure for a fixed tidal volume.

Therefore, when mechanically ventilating a patient using VCV, it is of paramount importance to be able to accurately monitor airway pressure at various points in the respiratory cycle and report anomalous or excessive pressure events to the physician, and automatically adjust tidal volume to limit P_{PIP} to within acceptable levels.

Understanding the dynamics of volume-controlled ventilation, reviewing current literature, and consulting with our clinical collaborators at Vanderbilt University Medical Center (VUMC), to guide our electromechanical design decisions with the general goal of generating a design that is low-cost, largely insensitive to supply chain disruptions and material accessibility limitations, and easy to manufacture. The range of adjustable TV, BPM, and I/E reported in Table I ensures that our design will be able to accommodate a wide range of patients suffering from compromised respiratory function. COVID-19 patients are typically ventilated at a rate of 2035BPM, and an I/E ratio of 1:1-1:2, where some outlying pathologies may require rates as high as 50 BPM and I/E ratios as low as 1:4. For TV, clinical wisdom dictates that TV should be initially selected based on patient weight (6mL/kg), and finely tuned ad hoc according to P_{late}, P_{PEEP}, and lung compliance.

Parameter	Value
Tidal Volume (TV)	0-800[mL] (Adjustable)
Max TV Deviation (long-term)	35%
Respiratory Rate	5-55 [BPM] (Adjustable)
BPM Repeatability (over 1 minute)	±1 [BPM]
I:E Ratio	1:1-1:4 (Adjustable)
Continuous Operation	>14 [days]
Maximum Deliverable P_{PIP}	>40 [hope]
PPEEP	0-25 [hope] (Adjustable)
Barotrauma Pressure Limiting?	Yes
Over/Under-Pressure Reporting?	Yes (Adjustable)

TABLE I: List of VOV Functional Requirements

MECHANICAL DESIGN

We approached the VCV design challenge by first identifying the actuator and structural materials given the general constraints of availability, cost, and manufacturability.

We selected the windshield wiper motor for its low cost, global availability, and ease of sourcing from auto manufacturers to junk yards. Furthermore, the worm gear mechanism inside the motor is designed to generate large forces at a range of speeds under extreme conditions from sub-freezing to extremely hot (>37C°) environments.

These features make windshield wiper motors excellent candidates for applications that require reciprocating, low-to-medium speed actuation for millions of cycles.

For the structural material, plywood was selected also for its availability and the relatively simple and inexpensive tools required to manufacture components. Cabinet makers, wood workers, and many hobbyists have the tools and know-how to make all the mechanical parts.

Scotch Yoke Mechanism

Given these materials and constraints, the scotch yoke mechanism offers a simple, relatively low component-count and low fabrication-precision-threshold solution to replicate the squeezing motion of the human hand. The SYM is a reciprocating motion mechanism that converts rotary motion into linear motion the pin. The linear travel of the sliding yoke in this design is constrained by ball bearing drawer glides, which can be sourced from office supplies stores, hardware stores, and offices.

A dynamic analysis of the SYM, detailed in the Supplementary File, reveals that a maximum motor torque of 4.1 N·m is required to ventilate a worst-case lung (C_{stat} = 10mL/hope and airway resistance of R_{dyn} = 50hPa/(L/s)) at the highest ventilator settings (BPM = 55, TV = 800 mL). Representative displacement and torque curves at these settings. This requirement is well within the torque capabilities of standard windshield wiper motors, which typically have nominal working.

ELECTRONICS AND CONTROL

The VOV features an embedded controller and UI, mounted to the rear of the device, that enable the physician to digitally configure and monitor critical ventilator and patient parameters.

Integrated Electronics

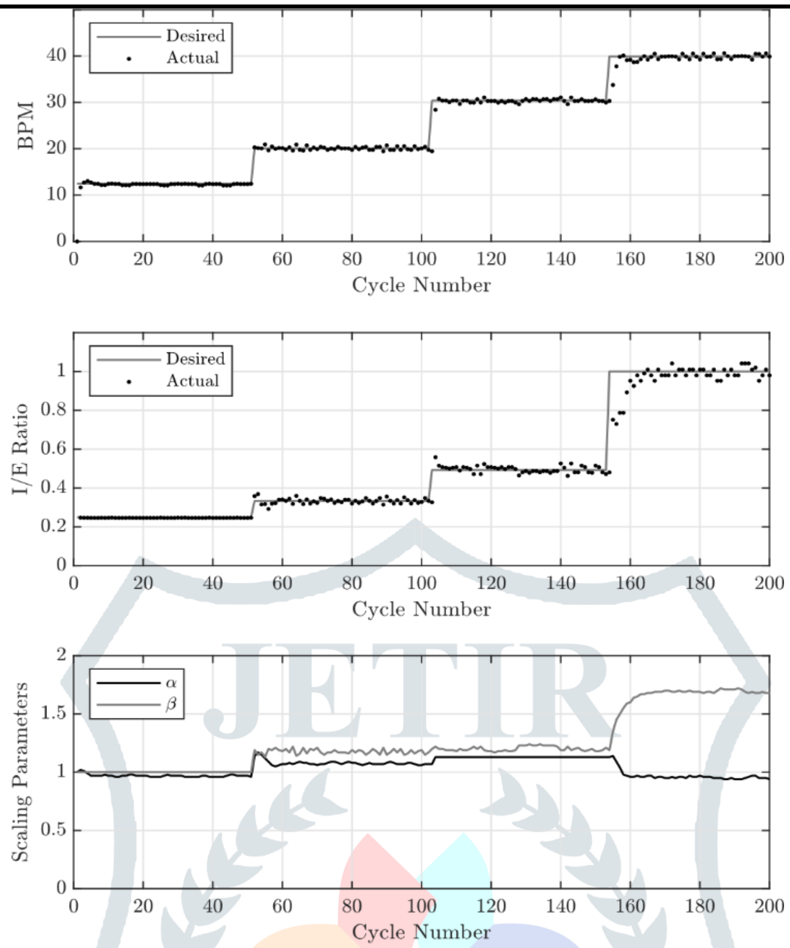
A block diagram of the electronics that comprise the embedded controller. The entire ventilator system (motor, sensors, and on-board controller) is powered by a 12VDC, 5A, ISO60601-compliant power supply. The Arduino Uno MCU (or equivalent) is responsible for executing the integrated controller, processing sensor/user interface data, and issuing motor commands. Various UI features (potentiometers, buttons, switches, and an LCD screen) allow the physician to interact with the ventilator and monitor the status of both the ventilator and the patient.

Control Architecture

The controller is implemented in the form of a finite state machine (FSM). An Alarm Manager object keeps track of various alarm conditions outside of the loop and reports them to the user through a combination of flashing LED, ringing buzzer, and a message displayed on the UI LCD.

End-Cycle Proportional Timing Control Methodology

Windshield wiper motors run in open loop, so to achieve accurate respiratory rate timing, we have implemented an endcycle proportional timing controller.



We sense the position of the motor at the two most important points in the respiratory cycle (full inspiration and full expiration) with a pair of limit switches, dead-reckon between these two points, and adjust speeds on the next cycle as necessary to meet these respiratory timing requirements based on the error between the desired and actual inspiration/expiration times.

The specific hardware implementation of the end-cycle proportional timing methodology is available in the Supplementary File. This proportional timing update capability is demonstrated experimentally in Fig. 7, where the BPM and I/E ratio were increased every 50 cycles (12BPM at 1:4I/E, 20 BPM at 1:3I/E, 30 BPM at 1:2I/E, and 40BPM at 1:1I/E) while the VOV was actively ventilating a test lung apparatus with a built-in compliance of 20mL/hope. As can be observed, the VOV is quick to converge to the new settings (within 30% of the desired setting after a single breath cycle), and with negligible steady-state error.

RESULTS

In preparation for the FDA EUA submission, the VOV has been experimentally validated using a combination of in vitro validation in a calibrated mechanical test lung, as well as live animal testing using an anesthetized swine model.

In Vivo Swine Study

Two live animal studies were performed where the VOV provided continuous ventilation to an anesthetized swine for four hours. In the first study, as mentioned in the "VOV Development Process" section, there was insufficient gas exchange due to the length of the ET tubing.

For a more detailed discussion of this please see "Insights from First In Vitro Swine Study" in the Supplementary File. In the second swine study, we corrected the problem with a pressure-sensing single-limb circuit. The swine was ventilated continuously for four hours (with average settings of 20 BPM and an I/E ratio of 1:2) as per our approved IACUC protocol.

Throughout the course of the second experiment, the swine remained hemodynamically normal, with adequate oxygenation, ventilation, and a normal pH. Subsequent histology results revealed well preserved alveolar structural integrity with no evidence of barotrauma or atelectasis.

In Vitro Parameter Variation/Durability Study

In addition to live animal tests, we also performed a series of performance characterization and durability experiments on a mechanical test lung, pursuant to testing standards set forth in ISO.

The tests were performed using a calibrated test lung (Model 1601, Michigan Instruments) with adjustable compliance and linear resistance, which was generously loaned to the project by Volunteer State Community College, Gallatin, TN.

A Siargo FS6122 pressure/flow sensor was used to capture pressure, flow rate and tidal volume waveform data at a sampling rate of 200 samples/sec. The TV was calculated by numerically integrating the flow rate data. Data were post-processed and statistically analyzed in MATLAB.

CONCLUSION

The COVID-19 pandemic has crippled healthcare infrastructures across the globe due to insufficient supplies of protective, diagnostic, and therapeutic equipment. Most notably, clinically-approved ventilator shortages have led to many preventable deaths. This shortage has motivated engineering communities to quickly mobilize and develop alternative solutions that could provide a last resort for patients who face triage. As part of this effort, the Vanderbilt Open-Source Ventilator was developed by a team of engineers, roboticists and clinicians to provide an alternative to patients who otherwise may not have access to traditional clinical mechanical ventilators. Manufactured from inexpensive and easy-to-source components, the VOV and its open-source design could serve after the 24 hour period.

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