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The Multisplit Ventilator System: Performance Testing of Respiratory Support Shared by Multiple Patients

Ventilator sharing has been proposed as a method of increasing ventilator capacity during instances of critical shortage. We sought to assess the ability of a regulated, shared ventilator system, the multisplit ventilator system, to individualize support to multiple simulated patients using one ventilator. We employed simulated patients of varying size, compliance, minute ventilation requirement, and positive end-expiratory pressure (PEEP) requirement. Performance tests were performed to assess the ability of the system, versus control, to achieve individualized respiratory goals to clinically disparate patients sharing a single ventilator following ARDSNet guidelines (Acute Respiratory Distress Syndrome). Resilience tests measured the effects of simulated adverse events occurring to one patient on another patient sharing a single ventilator. The multisplit ventilator system met individual oxygenation and ventilation requirements for multiple simulated patients with a tolerance similar to that of a single ventilator. Abrupt endotracheal tube occlusion or extubation occurring to one patient resulted in modest, clinically tolerable changes in ventilation parameters for the remaining patients. The proof-of-concept ventilator system presented in this paper is a regulated, shared ventilator system capable of individualizing ventilatory support to clinically dissimilar simulated patients. It is resilient to common adverse events and represents a feasible option to ventilate multiple patients during a severe ventilator shortage. [DOI: 10.1115/1.4053499]

Keywords: air flow, coronavirus, manufacturing, medical devices, pandemic, tidal volume, ventilation, ventilator sharing

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1 Introduction

The severe acute respiratory syndrome SARS-CoV-2 virus causes coronavirus disease (COVID-19), and was first identified in Wuhan, China in December 2019 [1]. It has since become a rapidly expanding global pandemic, and as of this writing, a total of more than 90 million cases and about 2 million deaths have been confirmed [2]. The SARS-CoV-2 virus may develop progressive viral pneumonitis in COVID-19 patients, resulting in acute respiratory distress syndrome (ARDS), in which mechanical ventilation is required [3]. It has been reported that 15–20% of the COVID-19 patients need hospitalization and 3–5% of them require critical care [4]. The global COVID-19 pandemic has resulted in a significant shortage of ventilators, extracorporeal membrane oxygenation machines, and personal protective equipment [5]. Mechanical ventilation provides benefits such as provision of sustained, proper minute volume, and blood oxygen conservation [6]. The utilization of a single modified ventilator to individually ventilate the lungs of a single patient was studied in Refs. [7] and [8]. Both of their techniques control the tidal volume to each lung in a patient, allowing separation of the exhaled gas, which results in limiting the possibility of cross-infection.

During the covid-19 crisis, the fatality rate drastically increased in areas where the number of critical patients in need of hospitalization exceeded the availability of care [3]. With the current COVID-19 pandemic, public health officials are predicting a ventilator shortage for critically ill patients in the United States. This acute shortage of this life-saving device, and the tremendous pressure and uncertainty about the future of the COVID-19 crisis, urging to search for solutions. With few companies having enough expertise and technology to produce ventilators, mass production of this device is a difficult task in the midst of the COVID-19 crisis [9]. The mechanical ventilators are technically complex and costly medical devices, and rapidly accelerating and enhancing their production is difficult [10]. In response, multiple commercial and government efforts are currently in place to increase the national ventilator capacity.

The critical shortage of mechanical ventilators raised the concept of ventilator sharing that means ventilating four similar patients' lungs by means of a single ventilator [11], and then this concept was examined adequately on adult human-sized sheep for 12 h [12]. The splitting of ventilators has raised several concerns, such as the uneven distribution of tidal volume between the patients. This concern can theoretically be avoided by matching patients by size and respiratory mechanics at the beginning of the mechanical ventilation process [13]. Ventilator sharing has not been fully investigated; the experimental and the impacts have not been completely characterized [10]. There is skepticism about shared ventilation. It was stressed that errors in ventilator sharing could be dangerous and harmful to one or both patients if not implemented correctly in Ref. [14]. They also indicated that ventilator sharing requires a closer patient monitoring to prevent any injury to the patients. Shared pressure-controlled ventilation was recommended in Ref. [15], with the inclusion of in-line pressure relief valves offers least risk for shared ventilation. Simulated ventilation of two patients with a single ventilator has been studied [16]. They highlighted three potential problems: (1) partitioning inspiratory flow between patients, (2) measuring tidal volume, and (3) providing individual positive end-expiratory pressure (PEEP).

Despite all these concerns, in the mass casualty shooting in Las Vegas in 2017, physicians reconfigured a T-tube to allow a single ventilator to be used for two patients in an acute care setting [17]. In addition, in the current crisis, ventilator sharing protocols are actively being prepared by U.S. hospitals [18,19]. To date, these reports primarily utilize a simple split system utilizing T-connectors to join patients in an open, parallel system.

An optimization model was presented to plan the procuring and sharing of ventilator resources during a stochastic and increasing demand for this device in different states at different times [20]. Many efforts have been made in rapid prototyping of ventilator alternatives during COVID-19 pandemic. Three-dimensional printed ventilators developed as a rapid solution for the COVID-19 pandemic has been reviewed in the literature [21]. One of the first projects regarding rapid ventilator production was started by the University of Vermont. The primary aims of the Vermontilator [22] were to provide a rapidly manufactured inexpensive ventilator with a long working lifespan for the COVID-19 patients. The second aim of the Vermontilator was the optimization of the airway pressure release ventilation mode [23]. A mechanical ventilator was made with control of respiratory rate, tidal volume, and inspiratory: expiratory (I:E) ratio and tested it in a porcine model [24]. A simple fully mechanical ventilation device that does not require electricity was designed and described in Ref. [25]. The operating power was provided by the pressurized breathing gas. Controllable parameters were peak inspiratory pressure, PEEP, and ventilation frequency.

Two pairs of patients were successfully ventilated in Ref. [26] for 1 h with a single ventilator with control valves, which is a system like the one presented in this paper. In this study, an independent adjustment of pressure and tidal volume was provided for each patient. Likewise, Ref. [10] presented a similar method in which a Hoffman clamp was used to adjust resistance. A mathematical model of two patients supported by a mechanical ventilator was developed as described in Ref. [27]. The model included two different setups: (1) T-splitters supplied air to two patients and 2) a modified setup with a variable resistance in each inhalation pathway and one-way valves in each exhalation pathway. Two pigs were ventilated with a system that provided individualized tidal volume and pressure as efficaciously as each pig on its own ventilator [28]. The mechanical

ventilator Milano design was introduced in Ref. [29], the electromechanical equivalent of the old Manley Ventilator, in response to the shortage of ventilators during the COVID-19 pandemic.

As of this writing, using one ventilator to support multiple patients is not an Food and Drug Administration-approved application. On Mar. 26, 2020 a position statement by the society of critical care medicine (SCCM) and others was made recommending against ventilating multiple patients with a single ventilator [30]. The important points of the Joint Statement center on concerns about patient safety and that the shared ventilator system could not be adjusted to meet the individual needs of the critically ill patient group. These concerns are specific to the chronic and difficult management problems unique to ARDS. The statement raises other concerns noting the necessity of individualized ventilation in the event of inadvertent endotracheal tube occlusion or pneumothorax as such might cause adverse and unpredictable consequences to the other patient(s). The concerns listed in the joint statement appear valid and would certainly apply to patients managed using an open unregulated shared ventilator system.

In light of this statement while also recognizing the dire consequences of a ventilator shortage, we developed a novel ventilator modification, the multisplit ventilator system (MSVS). It is imperative to scientifically study the possibilities and limitations of ventilator sharing. The Joint Statement listed several key clinical concerns that prompted the published statement advising against ventilator sharing. These concerns focused on the assumption that individualized care could not be provided to more than one patient while sharing a ventilator. Our system was designed to address many of these concerns. The MSVS is made from readily available materials and allows individualized respiratory support to multiple patients with a single ventilator. We hypothesize that the MSVS is capable of simultaneous individualized ventilator support to clinically dissimilar simulated patients. We further hypothesize that the MSVS is resilient to adverse events such as abrupt endotracheal tube occlusion or extubation (removal of the endotracheal tube), which were simulated in the experiment.

2 Materials and Methods

2.1 System Description. The MSVS uses readily available flow valves, one-way valves, and connectors that allows for individualized regulation of pressures and flows as described in Ref. [31]. Bacterial/viral filters and one-way valves were used in each inspiratory and expiratory limb to prohibit cross contamination between patients. Inspiratory flow, and thereby inspiratory pressures and tidal volumes, was individually regulated using easy to assemble flow valves consisting of medical tubing and compression clamps.

Positive end-expiratory pressure was individually controlled using an adjustable water column. Placed on the expiratory limbs, these columns functioned under the same principle as for bubble continuous positive airway pressure. This experimental system used a Hamilton G5 ventilator (Hamilton Medical AG, Bonaduz, Switzerland), which is a commonly used mechanical ventilator that features a flow sensor located close to the patient's endotracheal tube to monitor patient pressures and volumes. Patient monitoring was achieved by manipulating a three-way stopcock manifold connected to the Hamilton G5 ventilator's external flow sensors to view individual patient pressures and tidal volumes in real-time allowing for appropriate manual intervention. The ventilator's native, single flow sensor cannot provide multiple data sets for all patients at the same time. Given this limitation, this manifold enables clinicians to view one patient's pulmonary mechanics at a time. Clinicians would therefore have to sample each patient one at a time to view the pressure and flow data from the ventilator's sensors.

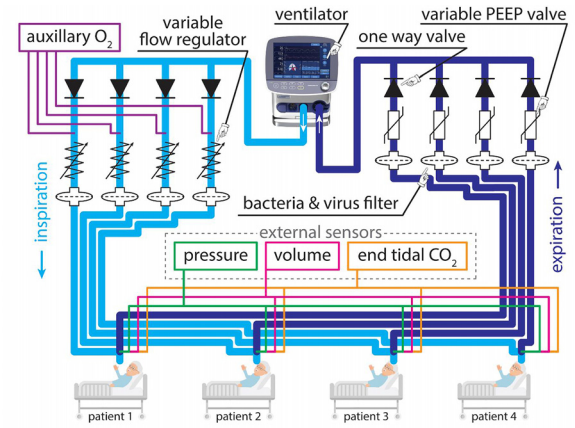
After reaching steady-state, digital and analog measurements of Ve, plateau pressure (Pplateau), and PEEP were taken. An auxiliary oxygen port was placed in line to allow for individualized fractional inspired oxygen. Oversight of all patients in parallel was achieved with the addition of in-line pressure manometers and respirometers (Fig. 1). A key feature of the system is that it is easy to assemble using common components that are widely available in hospitals and standard hardware stores (Fig. 2).

Patients were simulated by attaching 7.0 endotracheal tubes directly to standard anesthesia reservoir bags. Normal compliance was simulated by two bags connected by T-tube, representing a "healthy" model, and decreased compliance was simulated by a single bag, representing an "ARDS" model. The simulated patients were arranged in a radially dispersed layout around the MSVS to mimic patient care. A single, Hamilton G5 ventilator was connected to the MSVS.

2.2 Validation of the Simulated Patient Model. A defining feature of ARDS is decreased lung compliance. This series of experiments was designed to validate whether the simulated patient models were adequate representations of normal and diseased human lungs. One clinical feature of ARDS is a clinically significant decrease in total lung compliance and a general need for low volume/elevated PEEP ventilation strategies. In order to determine if the anesthesia bags used to simulate patient lungs represented a reasonable model, we sought to determine the compliances of the single 3 L and double 3 L anesthesia reservoir bag arrangements. The "healthy" model consisted of two 3 L adult anesthesia bags connected by T-tube. The "ARDS" model consisted of a single 3 L adult anesthesia reservoir bag. Each arrangement was connected to a 50 mL syringe and a manometer. We filled the bags with a residual volume that resulted in a static pressure of 6 cm H_2O, which was the lowest accurate range of our manometer. We used the syringe to fill the bag in 50 mL increments and measured the pressure as a function of the change in volume. This experiment was completed five times for both the "healthy," and "ARDS" models.

2.3 Performance Testing.

2.3.1 Patient Prototypes. Simulated patient prototypes were created to test the system's ability to accommodate patients of varying ideal body weight (IBW), lung compliance, minute



Description of the electrical equivalents of the components in the system shown in Fig. 1.

	One way valve (diode): valve permits flow in direction of arrow, enabling individualized pressure and flow through each limb and preventing cross contamination
	Variable flow regulator (variable resistor): adjustable compression clamps impose resistance/pressure drop, individualizing pressure and flow to each patient
	Variable PEEP valve (variable varistor): adjustable water columns impose variable pressure sensitive restrictor, preventing flow below set pressure, and allowing flow above set pressure
	Bacteria & virus filter (resistor): filters impose static resistance, preventing cross contamination

Fig. 1 Schematic diagram of the MSVS

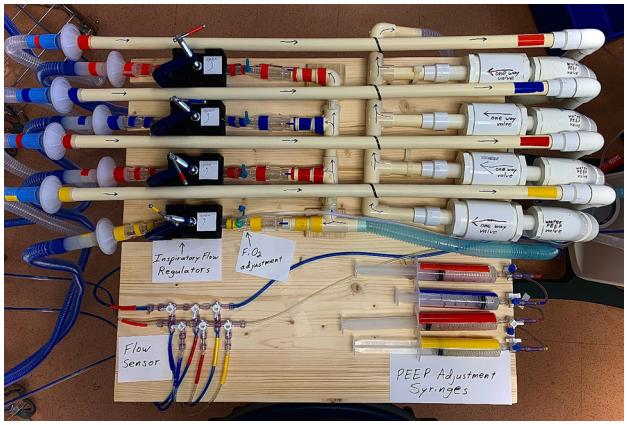


Fig. 2 MSVS system assembled using commonly available components

ventilation (Ve) requirement, and PEEP requirement. These patient prototypes were designed to represent wide variation in clinically relevant patient characteristics. The simulated prototype patients were varied by size (5′0″ F = 42 kg IBW and 6′2″ M = 86 kg IBW), lung compliance (normal = double anesthesia reservoir bag and low = single anesthesia reservoir bag), minute ventilation requirement (low = 100 mL/min/kg IBW and high = 140 mL/min/kg IBW), and PEEP requirement (8 cmH_2O and 15 cmH_2O). Tidal volumes and respiratory rates were derived by following the National Heart, Lung, and Blood Institute ARDS clinical network mechanical ventilation protocol [32]. Utilizing the patient variables resulted in sixteen different combinations, eight male patient and eight female patient prototypes.

2.3.2 Experimental Protocol. A stepwise clinical protocol was created to standardize how simulated patients would be sequentially placed on the MSVS shared ventilator system based on pressure and respiratory rate. For the system performance experiments, 32 different combinations of simulated patient pairs were tested. The MSVS is designed to support up to four patients. However, in practice, shared ventilation would likely be employed in patient pairs in the extreme scenarios of ventilator shortage. We therefore sought to perform a thorough evaluation of the system's ability to support pairs of patients of different sizes and different clinical characteristics. Though simulated patient pairs were tested, the MSVS is maintained with the third and fourth circuits connected to dummy bags. These extra circuits serve as a buffer to minimize the effects of adverse events occurring to one patient on the others. This is an important feature of the system that is necessary even when supporting only two patients. The system's ability to support three or four patients with differing clinical needs can only be surmised and has not been tested in this study which focused only on patient pairs. Further study is therefore warranted.

2.3.3 Assessment of the System's Ability to Individualize Respiratory Support. This series of experiments was designed to assess the system's ability to individualize respiratory support to patients with widely differing clinical characteristics. Experiments were created for different combinations of patient prototype pairs that differ in size, minute ventilation requirement, lung compliance, and PEEP requirement. Two different patient prototypes, one male and one female, were paired together for each experiment. A total of 16 experiments were created by choosing the combinations where all four parameters were different between the patient prototypes. This process was repeated with the order reversed to create 16 more trial replicates for a total of 32 replicates. The two patient prototypes for each experiment were put on the MSVS system. ARDSNet recommendations [32] were strictly followed while supporting the simulated patients. The system's ability to individually meet the unique respiratory support requirements of the simulated patient combinations was recorded and compared to control performance. Each simulated patient was placed on a standard 1:1 ventilator and the same outcome measurements were taken. This served as the control group.

2.3.4 Assessment of the System's Resilience to Adverse Events. This series of experiments was designed to evaluate the effects of unexpected adverse events on simulated patients supported by the MSVS. Six experimental patient pairs were selected based on varying ranges of difference in tidal volumes. Initially, other variables were held constant, and pairs of patient prototypes were placed on the MSVS and supported on a single ventilator with PEEP of 15 with a single bag (low) lung compliance. Once steady-state was achieved, baseline measurements of Ve, plateau pressure (Pplateau), and PEEP were taken.

Then four events were simulated. The first event was extubation of the first patient prototype; the second patient prototype was then closely monitored for stability, and data measurement was performed (Ve, Pplateau, and PEEP). The second event was occlusion of the endotracheal tube to the first patient prototype; and again, the second patient prototype was closely monitored for stability and data measurement was performed. This process was then reversed. The second patient prototype was extubated, the first patient prototype was closely monitored, and data measurement was collected. The second patient prototype was then occluded, the first patient prototype was monitored closely, and data measurement was collected. It should be noted that between each event, the patients were brought back to steady-state prior to performing the next event.

2.3.5 Data Collection. Data were collected after successfully achieving the parameters for each patient prototype. Data were initially taken from the digital ventilator data screen for each patient by using the MSVS's monitoring manifold. The set PEEP, respiratory rate, and Pcontrol were recorded first. Patient One's actual PEEP, Pplateau, and minute ventilation were recorded. The same three values were then recorded for patient two. Occasionally the ventilator data screen did not supply a Pplateau value despite a ventilatory hold, so the Ppeak was recorded, and this value was denoted as such. Once the digital data had been recorded, data were taken from the analog setup for each patient. A volume and a pressure gage were individually attached to each patient bag at the end of the circuit to provide accurate measurements. Patient one was measured first. The volume gage was measured over ten inspiratory breaths for an average tidal volume. This was then multiplied by the set respiratory rate for a minute ventilation. The pressure gage was then monitored for the lowest value during expiration, taken as the PEEP. An inspiratory hold was then performed to obtain a Pplateau. This process was repeated for patient two. The trial was then terminated, and the machine reset to baseline settings.

2.3.6 Statistical Analysis. Simulated patients were grouped according to the ventilator therapy they received: standard 1:1 ventilator and MSVS. Patients were stratified by ideal body weight (Low = 5′0″ F, 46 kg, and High = 6′2″ M, 82 kg), compliance (normal = double anesthesia reservoir bag, and low = single anesthesia reservoir bag), minute ventilation requirement (low = 100 mL/min/kg IBW, and high = 140 mL/min/kg IBW), and PEEP requirement (low = 8 cmH_2O, and high = 15 cmH_2O). Patients in the MSVS were further stratified by their order of being placed on the multisplit ventilator: first or second. Outcomes analyzed for the assessment of the MSVS were absolute difference from goal minute ventilation (L/min), absolute difference from goal PEEP (cmH_2O), and the binary outcome of plateau pressure less than 30 cmH_2O. The means of the ratio data type outcomes of the standard 1:1 ventilator and the multisplit ventilator groups were compared by two sample t-tests for overall and all stratifications. A generalized linear model was also conducted to test the mean difference between the two groups controlling for

all the conditions that were set. The order of being placed on the multisplit ventilator (first and second) was compared within the multisplit ventilator group. The outcome of plateau pressure less than 30 cmH_2O was analyzed subjectively as no occurrences of plateau pressure greater than 30 cmH_2O occurred in the standard 1:1 ventilator or MSVS groups. Outcomes analyzed for the assessment of MSVS resilience to adverse events (extubation and occlusion) were difference from steady-state minute ventilation (L/min), difference from steady-state PEEP (cmH_2O), and the binary outcome of plateau pressure less than 30 cmH_2O after event. Resilience to adverse events was analyzed by descriptive statistics only. This analysis was performed separately for extubation and occlusion events. Statistical significance was assigned to $p < 0.05$. Statistical analysis was performed using SAS 9.4.

3 Results

3.1 Validation of Patient Model. Figure 3 shows a plot of the recorded data from the compliance experiment. Since compliance is the ratio of change-in-volume to change-in-pressure, the change in volume is plotted as a function of the pressure. Thus, the slope of the best fit line for the data represents an effective estimate of the model's compliance. Using Microsoft Excel's "trendline" function, the compliance for the single 3 L bag ("ARDS" model) and double 3 L bag ("healthy" model) are 0.05 L/cm H_2O and 0.08 L/cm H_2O, respectively. The compliance measurement for the "healthy" model approximates the reported average compliance for a normal adult lung (0.1–0.2 L/cmH_2O) [33]. The "ARDS" model was markedly less compliant. Therefore, the anesthesia bag model was used in the performance tests as a reasonable representation of human lungs.

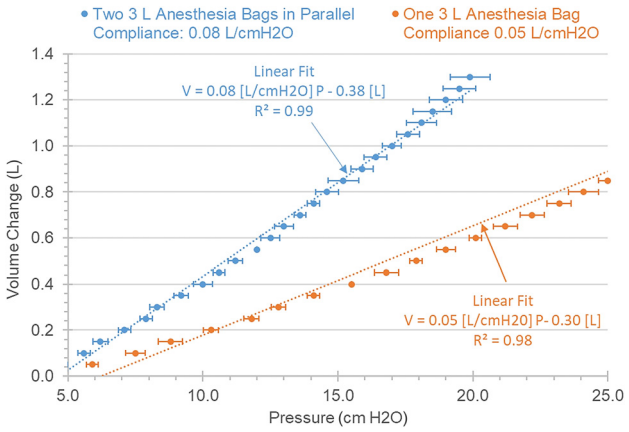


Fig. 3 Average measured static air pressure in a two parallel 3 L anesthesia bags and one 3 L anesthesia bag as a function of the volume of air added to the bag with associated standard deviation (five trials each). The slope of the line that best fits the volume/pressure relationship represents the compliance of the bag. Using Microsoft Excel's trendline function to fit a line to each dataset, the compliance of the parallel and single bags is 0.08 L/cm H_2O and 0.05 L/cm H_2O, respectively.

3.2 Performance Testing

3.2.1 Assessment of the MSVS Ability to Individualize Respiratory Support. The results of our assessment of MSVS performance are summarized in Tables 1 and 2. Table 1 shows the minute ventilation (L/min) absolute difference from goal for the standard 1:1 ventilator and MSVS groups for all of the tested stratifications as well as multivariable analysis results. An absolute difference from goal of 0.00 L/min would indicate that the system perfectly achieved the desired minute ventilation. A larger value indicates worse performance. The simulated patients in the standard 1:1 group were completely isolated from their counterparts whereas the simulated patients in the MSVS group shared the ventilator with a simulated patient of opposite ideal body weight, lung compliance, minute ventilation requirement, and PEEP requirement. The means between the standard 1:1 ventilator and multisplit ventilator groups were not significantly different for all or any stratification (p values > 0.05) and the mean of MSVS was significantly lower when we control for all the conditions (p value $= 0.0062$). Also, the difference between the first patient on the MSVS and the second did not reach statistical significance (p value $= 0.1394$). The differences all tended toward tighter tolerance for the MSVS than the standard 1:1 ventilator, which leads us to believe that the MSVS has either the same or better performance with regard to minute ventilation (L/min) absolute difference from goal. A future randomized clinical trial with rigorous sample size justification should be followed to ensure the findings between the two outcomes.

This study was designed to check feasibility of MSVS' performance as a pilot study and provide necessary information for a future study. The MSVS (two patients sharing one ventilator) was compared to the gold standard (two patients, two separate ventilators). The ability of the MSVS to achieve the goal patient support parameters was therefore compared to the gold standard's ability to achieve the same goal patient support parameters. Neither the MSVS nor the gold standard achieved exact parameters and therefore the mean absolute difference from goal was always > 0. This may seem intuitively odd but when a ventilator is set to a specific minute ventilation setting, it does not always achieve that exact number. This will oscillate around the desired set value at any given time. For this reason, the gold standard of two isolated ventilators supporting two distinct patients had mean absolute differences from goal > 0. Similarly, the MSVS had absolute differences from goal > 0. However, these differences were smaller for the MSVS compared to the gold standard indicating that the MSVS performed better (mean (SD) $= 0.12$ (0.08) for the MSVS, 0.20 (0.15) for the standard 1:1). This finding may suggest that the MSVS performs similarly compared to the gold standard and future studies with rigorous sample size justification considering potential confounding effects will be required to ensure the pattern.

Table 2 shows the PEEP (cmH_2O) absolute difference from goal for the MSVS group for all of the tested stratifications. An absolute difference from goal of 0.00 cmH_2O would indicate that the system perfectly achieved the desired PEEP value. A larger value indicates worse performance. The simulated patients in the standard 1:1 group were completely isolated from their counterparts whereas the simulated patients in the MSVS group shared the ventilator with a simulated patient of opposite ideal body weight, lung compliance, minute ventilation requirement, and PEEP requirement. Since PEEP can be accurately set on a ventilator, the gold standard of two separate patients supported by two separate and isolated ventilators was able to precisely achieve the two distinct desired PEEP values. In contrast, the MSVS uses the one ventilator to set the lowest PEEP value and then uses a water column adjustment to individually raise the PEEP value for the patient with a higher desired setting. Our results demonstrate that the MSVS is not as good as the gold standard in achieving the two distinct, desired PEEP values for the simulated patient pairs. Therefore the mean absolute differences from goal for the MSVS were consistently > 0. The mean of MSVS group was 0.69 with SD 0.61 and significantly lower compared to 1 cmH_2O (p value $< .001$). From a clinical standpoint, the MSVS was able to achieve PEEP values consistently within 1 cmH_2O from the desired value even when the two simulated patients had widely disparate desired values.

Both the standard 1:1 ventilator and the MSVS were able to achieve the ventilation and oxygenation requirements for all patients in all scenarios without delivering plateau pressures greater than 30 cmH_2O. In this regard, the standard 1:1 ventilator and the MSVS performed equally well.

Table 1 Minute ventilation (L/min) absolute difference from goal

	Standard 1:1			MSVS				
	n	Mean	SD	*n*	Mean	SD	*p*-value[a]	*p*-value[b]
All	16	0.20	0.15	64	0.12	0.08	0.0625	0.0062
Ideal body weight								
Low (5′0″, 46 kg)	8	0.20	0.19	32	0.13	0.08	0.3517	0.5130
High (6′2″, 82 kg)	8	0.20	0.11	32	0.12	0.08	0.0678	
Compliance								
Normal (double)	8	0.26	0.16	32	0.14	0.09	0.0633	0.0433
Low (single)	8	0.14	0.11	32	0.11	0.08	0.5473	
Ve requirement								
Low (100 mL/min/kg IBW)	8	0.24	0.17	32	0.12	0.09	0.0920	0.2649
High (140 mL/min/kg IBW)	8	0.16	0.12	32	0.13	0.08	0.4996	
PEEP requirement								
Low (8 cmH_2O)	8	0.19	0.10	32	0.11	0.07	0.0785	0.8489
High (15 cmH_2O)	8	0.21	0.19	32	0.14	0.09	0.3033	
Order								
First				32	0.11	0.07	0.1394	NA
Second				32	0.14	0.09		

Minute ventilation (L/min) absolute difference from goal for standard 1:1 ventilator and multisplit ventilator groups. An absolute difference from goal of 0.00 L/min would indicate that the system perfectly achieved the desired minute ventilation. A larger value indicates worse performance. The simulated patients in the standard 1:1 group were completely isolated from their counterparts, whereas the simulated patients in the MSVS group shared the ventilator with a simulated patient of opposite ideal body weight, lung compliance, minute ventilation requirement, and PEEP requirement.

[a]*p*-values were from two sample t test for each condition.

[b]*p*-values were from a generalized linear model adjusting for ideal body weight, lung compliance, minute ventilation requirement, and PEEP requirement as well as the ventilation method (standard 1:1 versus MSVS).

3.2.2 MSVS Resilience to Extubation Adverse Events. Following extubation in the event patient, the average percent change of Ve was −9.0% (range −23.3% to −0.9%), the average percent change of Pplat was −7.3% (range −15.4% to 0.0%), and the average percent change of PEEP was −5.2% (range −13.3% to 0.0%) in the nonevent patient. The absolute value of plateau pressure of the nonevent patient never exceeded 30 cmH_2O following extubation of the other patient. Qualitatively, it appeared that the greatest change occurred in situations where both patients had a high steady-state minute ventilation. This is presumed to be because the buffering and protective effect of the inspiratory limb control valve was minimized on both patients to allow a high minute ventilation.

Table 2 PEEP (cmH_2O) absolute difference from goal

MSVS				
	n	Mean	SD	*p* value[a]
All	64	0.69	0.61	<0.0001
Ideal body weight				
Low (5′0″, 46 kg)	32	0.58	0.56	0.1065
High (6′2″, 82 kg)	32	0.79	0.64	
Compliance				
Normal (double)	32	0.69	0.67	0.9128
Low (single)	32	0.68	0.55	
Ve requirement				
High (140 mL/min/kg IBW)	32	0.75	0.69	0.3185
Low (100 mL/min/kg IBW)	32	0.62	0.52	
PEEP requirement				
Low (8 cmH_2O)	32	1.04	0.44	<0.0001
High (15 cmH_2O)	32	0.33	0.53	
Order				
First	32	0.68	0.65	
Second	32	0.69	0.57	

PEEP (cmH_2O) absolute difference from goal for control (standard 1:1 ventilator) and treatment groups (multisplit ventilator). An absolute difference from goal of 0.00 cmH_2O would indicate that the system perfectly achieved the desired PEEP. A larger value indicates worse performance. The simulated patients in the standard 1:1 group were completely isolated from their counterparts, whereas the simulated patients in the MSVS group shared the ventilator with a simulated patient of opposite ideal body weight, lung compliance, minute ventilation requirement, and PEEP requirement.

[a]*p* value was obtained from a generalized linear model adjusting for ideal body weight, lung compliance, minute ventilation requirement, and PEEP requirement as well as the ventilation method (standard 1:1 versus MSVS).

3.2.3 MSVS Resilience to Occlusion Adverse Events. Following occlusion in the event patient, the average percent change of Ve was 11.4% (range −4.6% to 43.0%), the average percent change of Pplat was 5.4% (range −4.3% to 26.9%), and the average percent change of PEEP was −1.8% (range −7.1% to 6.7%) in the nonevent patient. The absolute value of plateau pressure of the nonevent patient occasionally exceeded 30 cmH_2O following occlusion of the other patient, the maximum value of which was 35 cmH_2O. Again, it appeared that the greatest change occurred in situations where both patients had a high steady-state minute ventilation, presumably because of the same decreased buffering and protective effect of the inspiratory control valve.

4 Discussion

The COVID-19 pandemic has resulted in a critical shortage of medical supplies highlighted by the lack of sufficient ventilators in hard hit areas. Using one ventilator to support multiple patients has been reported as a temporary solution [6,11,12,17]. Furthermore, on March 31, 2020, the United States Health and Humans Services Department released a technical guidance document regarding the sharing of ventilators between multiple patients as a treatment of last resort [18]. However, treating more than one patient with a single ventilator entails multiple and significant patient safety concerns as detailed in the Joint Statement released on March 26, 2020 made by the Anesthesia Patient Safety Foundation, SCCM, American Association for Respiratory Care, American Society of Anesthesiologists, American Association of Critical-Care Nurses, and American College of Chest Physicians [30] These concerns center on the inability of an open, parallel shared system to provide tailored adjustments to meet the individual needs of critically ill patients.

Our study describes the initial testing of a regulated shared ventilator system designed to address these concerns. The MSVS was

designed to individualize respiratory care by regulating peak inspiratory pressure, tidal volume, PEEP, and fractional inspired oxygen to each patient. Respiratory rate and I/E ratio would be constant between the patients. This allows for individual adjustments to meet the dynamic and unique oxygenation and ventilation requirements of each patient.

Overall, these studies were designed to assess the efficacy and safety of the MSVS as a regulated, shared ventilator system. Recently, brief communications have reported the feasibility of regulating flow while sharing a ventilator [34,35]. Han and colleagues described a "bag-in-a-box" system that can provide personalized care to multiple patients using a single ventilator. Their design is significantly different from the MSVS but further demonstrates that the concept of ventilator sharing may be safe. The report highlighted the relative safety of their system where simulated adverse events to one patient had minimal effect on the others—a finding similar to our results. They also reported a limited series of tests demonstrating the possibility of delivering individualized tidal volumes and pressures to test lungs with different compliances. In their report, different volumes and pressure were delivered, but many of the simulated patients received support that was significantly far from goal [36]. In our study, we demonstrate that the MSVS is able to consistently deliver individualized respiratory goals to simulated patients with not only different compliances, but also different sizes and minute ventilation requirements. In this manner, we believe that this report further adds to the knowledge base surrounding the principles and techniques of ventilator sharing.

Treating more than one patient with a single ventilator should only be considered when other options have been exhausted. The Joint Statement published by the SCCM, American Association for Respiratory Care, American Society of Anesthesiologists, Anesthesia Patient Safety Foundation, American Association of Critical-Care Nurses, and American College of Chest Physicians discusses numerous, valid patient safety concerns [30]. These concerns focus on sufficient individualization of respiratory support, accurate patient monitoring, and the risks of sudden adverse events [30]. Therefore, any method of ventilator sharing must consider these clinical points. Based on this early data, the MSVS described in this report may potentially address some of these concerns.

We recognize there are many limitations to this study and the MSVS. The most notable of which is the inability to individually adjust respiratory rate and I/E ratio. In addition, all patients would have to be deeply sedated or paralyzed and treated with pressure-controlled ventilation. As suggested in other reports describing nonregulated systems, a strategy whereby patients with similar clinical features are grouped together would likely need to be employed. The patient model is rudimentary. While we measured the compliances of the models and found them to be close to, and less compliant than a normal adult human lung, the actual, dynamic compliance characteristics are a limited approximation of ARDS lungs. Our experiments, designed to evaluate the capabilities and limits of the MSVS system, were only performed using this inanimate model and therefore extrapolating these capabilities to the management of actual, critically ill patients is difficult.

The system can deliver this individualized care but cannot do this automatically. The normal ventilator alarms and feedback mechanisms must be turned off while the MSVS is employed. The care team will need to rely on careful observation of clinical data and respond to this data by adjusting the MSVS/ventilator settings. They will need to do this without the benefit of alarms and automatic feedback loops. If while observing this data, they see that the patients each require different support changes, our results indicate that these individualized changes can be effectively accommodated using the MSVS. However, the system is not able to sense and perform these changes automatically.

5 Conclusion

This paper describes the design and initial testing of a regulated shared ventilator system. This unique modification was designed to partially individualize respiratory care by regulating peak inspiratory pressure, tidal volume, and peak end expiratory pressure to each patient on the MSVS. Respiratory rate and I/E ratio would be constant between the patients. Inspired oxygen fraction could be adjusted individually by flowing supplemental oxygen through a nozzle connector on each inspiratory ventilator limb. This would potentially allow for individual changes to meet the dynamic and unique oxygenation and ventilation requirements of each patient.

In the first series of experiments, the compliance of the lung models was measured. The lung models were endotracheal tubes connected to anesthesia reservoir bags. While this is clearly an extremely simplified model, it was found that the anesthesia bags were much less compliant than normal values for adult lungs. Specifically, the measured compliance for the "ARDS" lung model and close to "healthy" lung model was 0.05 L/cm H_2O and 0.08 L/cm H_2O, respectively. This compares to the reported compliance of a normal adult of 0.1–0.2 L/cmH_2O [32]. Based on these results, we felt that the patient lung models employed in this study represented simple but reasonable models of normal and ARDS lungs.

The second series of experiments demonstrated that the MSVS can be used to provide individualized care following standard ARDS net guidelines [32] to different combinations of simulated patients with widely differing clinical characteristics. The patient prototypes were designed to represent a real-world range of patient size, lung compliance, oxygenation, and minute ventilation requirements. In all cases, the MSVS and associated management protocol were able to provide care that met the individual oxygenation and ventilation needs of the different patients. The management protocol was designed as a step-by-step guideline for placing patients on and off the shared system while minimizing the effects of these movements on the remaining patient. The combinations tested in this series of experiments were purposefully extreme and it is reasonable to interpolate that the MSVS is able to adequately support combinations of more closely matched patients.

Finally, an initial adverse event analysis was done to see what effect simulated, abrupt endotracheal tube occlusion or extubation would have on the remaining patients on the shared ventilator system. In general, it was found that the changes in respiratory parameters to the remaining patient after an adverse event were acceptable with the MSVS.

The MSVS was presented as a regulated, shared ventilator system that is capable of individualizing respiratory care to clinically dissimilar simulated patients. We therefore present this option as a last resort to be considered only in a resource-limited surge scenario. It is important to understand that this system is not yet Food and Drug Administration approved and the performance will vary depending on the type of ventilator and components of the system. We strongly recommend that if there is consideration for use of a system like the one shown here, practitioners first build it out and test it in simulation to familiarize themselves with the system, monitoring, and troubleshooting. A clear understanding of its inherent weaknesses is essential before attempting its use.

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