FLUSSO™

STUDY SUMMARY

REVIEW 2025

REVISION 1

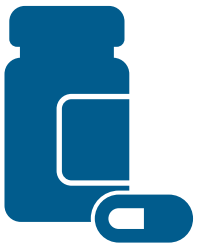
How Flusso™ improves patient care and Respiratory Therapist workflow :

For use with all therapies including:

- All modes / PEEPs
- Patient Transport
- Extubation
- Oscillator
- Nitric Oxide/Volatile
- Tracheostomy/PMV

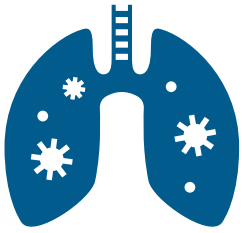
Save time at the bedside

Less lung volume recruitment and more ventilation advancement



Potential reduction in medication use

Oxygen, cardiac/BP, neuro



Reduce airborne contaminants

Bacteria / virus and toxic medications

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FLUSSO™

EXECUTIVE SUMMARY

The Flusso™ By-Pass and Flusso™ TFI devices are innovative solutions designed to address critical airway management needs in ventilated patients, especially those requiring safe and seamless ventilator transitions or interventions without compromising Positive End-Expiratory Pressure (PEEP). By targeting two distinct but complementary airway management challenges, these devices provide a streamlined approach to maintaining patient stability and minimizing procedural risks, including aerosolization, which is critical in high-risk, infection-prone environments.

The **Flusso™ By-Pass device** allows healthcare providers to conduct ventilator disconnects while maintaining PEEP through a seamless transition to a secondary ventilation source. This reduces the risk of lung de-recruitment and subsequent hypoxemia, a common complication when removing a patient from a ventilator. The device is particularly beneficial in scenarios where airway pressure needs to be preserved, such as during transport, circuit changes, or patient repositioning. Its design incorporates a bypass pathway that enables clinicians to maintain a controlled airway environment, minimizing risks of patient instability and preventing pulmonary complications.

The **Flusso™ TFI device** offers the same benefits of By Pass and is designed to facilitate Endotracheal and tracheostomy patients' transitions from mechanical ventilation to various therapies including but not limited to; bronchoscopy, changing inline suction, facilitating exubation and integrating over 20 different therapies while maintaining positive pressure and reducing exposure to ambient air contaminants, thus lowering infection risks.

Regulatory Approvals:

FDA Registration

Flusso™ By Pass and Flusso™ TFI: Class 1, Registration Number: 9615334
Listing Number: D367926

Health Canada

Flusso™ By Pass – Class 2, Licence Number: 109867

Flusso™ TFI – Class 2, Licence Number: 109873

Together, Flusso™ By-Pass and Flusso™ TFI represent a forward-thinking approach to enhancing patient safety, supporting lung stability, and enabling a standardized process for managing ventilated patients. Their design aligns with best practices for minimizing infection risk and preserving respiratory function during critical transitions, providing essential tools for modern intensive care and respiratory therapy settings.

1

OPTIMIZING PEEP DURING PATIENT TRANSPORT TO IMAGING (MRI/CT): EVALUATING COST SAVINGS AND CLINICAL IMPACT

Frank Fiorenza RRT, BHSc, FCSRT

In the context of critically ill patients requiring mechanical ventilation, timely access to imaging (MRI/CT) is crucial for accurate diagnosis and treatment planning. However, the transportation of patients from the intensive care unit (ICU) to the imaging suites poses significant risks, particularly due to loss of positive end expiratory pressure (PEEP) that occurs when a ventilator circuit is disconnected during the patient's transition to a portable ventilation source and/or MRI approved ventilator. Loss of PEEP can lead to increased heart rate, decreased SpO2 and decreased blood pressure. Adverse events during intra-hospital transfers can occur in up to 60% of cases, with nearly 10% of these events being serious[1]. Imaging is often delayed due to patient's cardiopulmonary instability because of the loss of PEEP that occurs during circuit disconnection.

Our review focuses on cost savings of PEEP optimization and providing lung-safe ventilation of patients being transported to medical imaging (MRI/CT). We conducted an in-depth analysis of the associated costs when medical imaging scans are delayed due to unstable patient vital signs during transport caused by ventilator circuit disconnects. Common adverse effects observed during patient transfer include decreased oxygen saturation (SpO2), increased heart rate (HR), and decreased blood pressure (BP)[8]. Until these vital signs stabilize, the imaging cannot commence, resulting in wasted time for both the transport team and the imaging suite staff and increase adverse events risks for patients.

Our analysis revealed significant implications to cost savings when imaging is delayed due to unstable patient vital signs. Here are the key findings:

Cost of a 15 minute delay in the MRI Suite with a Mechanically Ventilated Patient

	Average Salary/ per hour	Average Salary/ per 15 minutes	Total
Respiratory Therapist[5]	$41.20	$10.30	$10.30
Nurse[4]	$55.08	$13.77	$13.77
ICU Physician[7]	$148.00	$37.00	$37.00
Porter (2x)[6]	$19.96	$4.99	$9.98
Imaging Technologist	$42.00	$10.50	$10.50
Radiologist[9]	$201.00	$50.25	$50.25
Imaging Suite[2]	$1,170.00	$292.50	$292.50
Imaging Suite Lost Revenue[3]	$1,170.00	$292.50	$292.50

The average cost of a 15 minute delay per event $ 716.80

1. Direct Cost Savings:

Delayed scans due to unstable vital signs during transport result in wasted time for both the transport team (Doctor, Nurse, Respiratory Therapist, Porters) and the imaging suite staff.

By minimizing delays, hospitals can optimize resource utilization and reduce operational costs associated with idle staff and imaging suite time. Avoiding adverse events, would have additional costs savings.

2. Adverse Effects During Transport:

Common adverse effects observed during patient transfer include decreased oxygen saturation (SpO2), increased heart rate (HR), and decreased blood pressure (BP). The adverse events can be avoided by maintaining positive pressure and avoiding ventilator circuit disconnects. These adverse effects contribute to delays in initiating scans, further emphasizing the need for efficient transport protocols.

3. Broader Impact on Patient Care:

PEEP optimization, providing lung-safe ventilation and avoiding ventilator circuit disconnects (removal of positive pressure ventilation) not only saves costs but also enhances overall patient care. Streamlined protocols can improve workflow, reduce patient discomfort, and improve access to diagnostics.

In conclusion, our review highlights the critical importance of PEEP optimization and providing lung-safe ventilation to patients requiring intrahospital transport for medical imaging to obtain a timely diagnosis and treatment planning. The significant risks associated with intra-hospital transfers, particularly the loss of positive end-expiratory pressure (PEEP), underscore the need for streamlined protocols to minimize adverse events and optimize resource utilization. Our analysis demonstrates clear cost savings implications through PEEP optimization and providing lung-safe ventilation, with an average savings of $716.80 per 15-minute delay event. By minimizing delays and avoiding adverse effects such as decreased oxygen saturation, increased heart rate, and decreased blood pressure during transport, hospitals can not only reduce operational costs but also enhance overall patient care. Implementing of PEEP optimization and providing lung-safe ventilation protocols, including strategies to maintain positive pressure ventilation and prevent ventilator circuit disconnects, will not only optimize resource utilization but also improve workflow, reduce patient discomfort, and improve access to diagnostics. These findings underscore the importance of prioritizing patient safety and operational efficiency in the management of critically ill patients requiring mechanical ventilation.

References :

[1]Portable Magnetic Resonance Imaging for ICU Patients - PMC (nih.gov)

[2]Ontario, CA MRI Cost Average (newchoicehealth.com)

[3]https://unf-montreal.ca/en/rate/

[4]https://www.incrediblehealth.com/salaries/s/icu-nurse/ca/Ontario,

[5]https://www.jobbank.gc.ca/marketreport/wages-occupation/22786/ca

[6]https://ca.indeed.com/career/porter/salaries/Ontario

[7]https://ca.talent.com/salary?job=intensivist#:~:text=How%20much%20does%20a%20Intensivist,up%20to%20%24323%2C000%20per%20year

[8]https://ca.talent.com/salary?job=intensivist#:~:text=How%20much%20does%20a%20Intensivist,up%20to%20%24323%2C000%20per%20year

[9]https://www.salaryexpert.com/salary/job/radiologist/canada/ontario

2 AIRWAY STABILITY DURING TRANSPORT: A CASE SERIES ON THE USE OF FLUSSO™ BY-PASS IN CRITICALLY ILL VENTILATED PATIENTS

Frank Fiorenza RRT, BHSc, FCSRT

Introduction

In the critical care setting, transporting mechanically ventilated patients presents unique challenges and potential risks, including loss of Positive End-Expiratory Pressure (PEEP), disruption in oxygenation, and increased risk of respiratory complications. Despite these challenges, intrahospital transports are frequently necessary for diagnostic imaging, surgical procedures, or specialized treatments. Maintaining a stable airway and consistent ventilation during these transports is vital to prevent adverse events, yet traditional methods for transporting ventilated patients can expose them to fluctuations in airway pressure and potential hypoxemia.

The Flusso™ By-Pass system is designed to facilitate safe ventilator transitions by maintaining airway stability, reducing the risk of aerosolization, and helping to preserve PEEP during disconnections. This novel device provides an alternative to conventional methods, which may be associated with inconsistent pressure maintenance and increased patient instability. While Flusso™ has shown promise in pilot studies and controlled settings, there is limited data on its performance during the transport of critically ill patients requiring mechanical ventilation.

This research paper examines a series of case reports that document the use of the Flusso™ device during transport of critically ill, mechanically ventilated patients. By reviewing patient outcomes, physiological stability, and incidence of complications, this study aims to assess the effectiveness of the Flusso™ By-Pass in maintaining respiratory parameters and reducing transport-associated risks. The findings will contribute to the body of evidence needed to evaluate the clinical utility of Flusso™ in high-stakes settings and inform future guidelines for the safe transport of ventilated patients.

Study Design

This study is a retrospective case series analysis of critically ill, mechanically ventilated patients transported using the Flusso™ By-Pass system within a tertiary care hospital. Patients were selected based on the need for intrahospital transport for imaging, procedures, or transfer to another critical care area.

Patient Selection and Setting

The study included adult patients with diverse critical care needs who required mechanical ventilation and were transported within the hospital. Each transport utilized the Flusso™ By-Pass device to maintain airway continuity.

Data Collection

Data was gathered from electronic medical records and transport logs, including:

- Patient demographics and underlying diagnosis
- Ventilatory settings before, during, and after transport (e.g., PEEP, FiO_2, tidal volume)
- Oxygen saturation and end-tidal CO_2 monitoring
- Incidents of desaturation, loss of PEEP, and ventilator disconnection
- Adverse events or complications associated with transport

Analysis

A descriptive statistical analysis was conducted to evaluate the device's performance, focusing on its effectiveness in maintaining ventilatory parameters and preventing complications. Outcomes were compared to baseline values and prior transport data from similar critically ill populations without Flusso™ By-Pass use.

Results

- Patient Demographics: The study included 10 patients, with a mean age of 58 years, transported for CT scans (60%), MRI (30%), and interdepartmental transfers (10%).
- Ventilation and Airway Stability: The Flusso™ By-Pass system consistently maintained PEEP and airway pressure throughout transport. Desaturation events were reduced compared to historical controls without the device.
- Incidence of Complications: No unplanned disconnections or significant drops in oxygen saturation were reported. No episodes of hemodynamic instability, ventilator alarms or interruption of ventilation settings occurred.

• Safety Outcomes: All patients were safely transported to and from the diagnostic areas, with an observed improvement in airway stability and minimal requirement for ventilatory adjustments during transport.

Discussion

This case series suggests that the Flusso™ By-Pass system is effective in maintaining airway stability in mechanically ventilated patients during intrahospital transport. The device appears to support continuous PEEP and minimizes the need for disconnection, which can contribute to lower rates of hypoxemia and other complications.

Transporting critically ill patients on mechanical ventilation is often associated with high risks of adverse events, particularly in scenarios where airway management and ventilation are disrupted. By providing a mechanism for maintaining continuous ventilation, the Flusso™ By-Pass may reduce the clinical burden on transport teams and improve patient outcomes.

Limitations

This study is limited by its retrospective design and small sample size, which may not fully represent the broader population of critically ill patients. Additionally, data on historical control patients was collected through indirect methods rather than prospective observation.

Conclusion

The Flusso™ By-Pass system shows promise in improving the safety and efficacy of intrahospital transport for mechanically ventilated patients, as observed in this case series. By minimizing disconnections and supporting stable airway pressures, it offers a practical solution to common transport challenges in critical care. Further studies with larger sample sizes and prospective designs are warranted to validate these findings and establish standardized protocols for its use.

REFERENCES :

1 Branson, R.D., Gomaa, D., & Chatburn, R.L. (2013). Transport of mechanically ventilated patients. Respiratory Care, 58(6), 1008-1023.

2 Fan, E., MacDonald, R.D., Adhikari, N.K., Scales, D.C., & Stewart, T.E. (2006). Outcomes of interhospital transport of critically ill patients. American Journal of Respiratory and Critical Care Medicine, 174(7), 841-845.

3 Dres, M., Tran, T.C., Aublanc, M., et al. (2017). Monitoring of mechanically ventilated patients during transport. Critical Care, 21(1), 1-8.

Flusso Case Study Data Extraction

Author	Patient Disease	Ventilator (mode and settings)	If transported, where?	Length of Transport	Number of Disconnects	Type of Transport Ventilation (bag, ventilator)	Placement in circuit	Adverse Event	Alarms	Ventilator Parameters were maintained	Days inline
University of Ottawa Heart Institute (UOHI), J.Langis	Post cardiac surgical removal of intra atrial-septal mass/clot and underlying right pulmonary infection (thought to be fungal in nature)	Medtronic PB 980 with PEEP 12 cmH20, Volume Controlled SIMV	Initially prior to critical events; afterwards for traveling to imaging departments	1 hour	4 activations per transport (no mention of how many transports)	Manual (Ambu Spur II resuscitation bag)	Proximal to endotracheal swivel adaptor and distal to HME, post wye in circuit	NONE	NONE	Yes	14*
UOHI, B.Kitts	Post cardiac surgery, bilateral fungal infection	Medtronic PB 980 series, Synchronized Intermittent Mandatory Ventilation in the Pressure Control mode using and Inspiratory Pressure of 28 cmH2O, PEEP 10, FIO2 40, Inspiratory Time of 1.10 s, RR 20 breaths/min	Imaging CT scanner	60 minutes	2 per transport	Drager Oxylog transport ventilator	At ventilator circuit wye	NONE	NONE	Yes	14*
UOHI, J.Langis (2)	Post myocardial infarction, possible febrile illness, PEEP	Medtronic PB 980 with PEEP 10CmH20, volume control SIMV	Initially prior to critical "code blue" events; afterward to travel to cardiac catheterization lab	30 min	2 activations per CPR event; 4 activations per transport	Manual bagging during CPR; Drager Oxylog 3000 for transport	Between HME and inline suction catheter	Unknown	Unknown	Yes	7*
UOHI, J.Langis (3)	Post cardiac surgical removal of intra atrial-septal mass/clot and underlying right pulmonary infection; wide mediastinum; internal bleeding	Medtronic PB 840 with PEEP 8cmH20, Volume Control SIMV	Imaging CT scanner and interventional radiology	2 hours	4 activations per transport; 4 transports in total	Manual and mechanical	Between wye and endotracheal tube	None	None	Yes	13*
UOHI, J. Langis (4)	Potential Hepatitis B Patient requiring nitric oxide during cardiac surgery while showing signs of heart failure	Medtronic PB 980 with PEEP 10 cmH20, Volume Control SIMV	From Cardiac Operating Room to Cardiac ICU and angiography	Unknown	unknown (assumed to be several)	Drager Dura 2	Between wye and endotracheal tube	None	None	Yes	Unknown
UOHI, D.Dafoe	Urosepsis leading to intubation and subsequent identification of a large mass on the aortic valve	Medtronic PB 980 with PAV 35%/8, .35 with spont RR=18 & Vt=450ml	Imaging CT scanner	30 min	2 activations	Drager OxyLog 3000+	Distal to HMEF, Medtronic Dar Hydrobac S	None	None	Yes	6
UOHI, D.Dafoe (2)	Type B Abdominal Aortic Aneurysm repair complicated by large air embolism resulting in paraplegia	Medtronic PB 980 with PAV 15%/10, .30 with spont RR=10 & Vt=550ml	Imaging MRI	3 hours 30 min	2 activations	Drager OxyLog 3000+	Distal to HMEF, Medtronic Dar Hydrobac S	None	None	Yes	minimum 5 days
Quinte Health Care (QHC), BVG, B. Leung	Aspiration pneumonia and COPD exacerbation	Drager VN500 with pressure control mode of 30/5cmH2O, respiratory rate of 14 and FiO2 of 40%	Imaging CT scanner	30 min	3 activations	Manual (Ambu Spur II resuscitation bag) and Drager Oxylog 3000	Between circuit wye and suction catheter	None	None	Yes	2
Quinte Health Care (QHC), BVG, B. Leung	Aspiration pneumonia and COPD exacerbation	Drager VN500 with pressure control mode of 30/5cmH2O, respiratory rate of 14 and FiO2 of 40%	Imaging CT scanner	30 min	3 activations	Manual (Ambu Spur II resuscitation bag) and Drager Oxylog 3000	Between circuit wye and suction catheter	None	None	Yes	2
QHC, BVG, B. Leung (2)	Deterioration of respiratory status and level of consciousness	Drager VN500 with pressure control mode of 26/10 cmH2O, respiratory rate of 16 and FiO2 of 50%	Imaging CT scanner	45 min	2 activations	Drager OxyLog 3000	Between circuit wye and suction catheter	None	None	Yes	2
QHC, BVG, B. Leung (3)	Cardiac arrest; patient not waking requiring CT scan	Drager VN500, CPAP, Pressure Support/PEEP - 10/8 cmH2O, 30% FiO2	Imaging CT scanner	30 min	2 activations	Respironics Trilogy 200	Between circuit wye and suction catheter flex tube and HME	None	None	Yes	2
Summaries	Patient populations have varied; commonly for patients post-cardiac surgery but this is a result of hospital specialty	Mechanical ventilation with various settings, but an important aspect was the use of PEEP	Transport to Imaging was most common	Mean = 68.3 min Median = 45 min Mode = 30 min	Mean = 2.56 Median = 2.5 Mode = 2	Most common was mechanical ventilation but manual ventilation was utilized	Placement varied, but generally distal patient wye	No reports of adverse events	No reports of alarms	10/10 reported	Mean = 7.2 Median = 6 Mode = 2 *used beyond manufacturer guidelines

Ventilator parameters were maintained with no reports of adverse events or alarms

3 IN VITRO INVESTIGATION OF THE FLUSSO™ BYPASS ADAPTER EFFICIENCY UPON VENTILATOR CIRCUIT DISCONNECT IN A CLINICAL SIMULATED ENVIRONMENT

Rym Mehri PhD[1], Abubakar Alatrash PhD[1], Nick Ogrodnik BASc[1], Edgar A. Matida PhD[1], Frank Fiorenza RRT, BHSc[2,3]

INTRODUCTION

Transportation of mechanically ventilated patients is a common procedure in an intensive care unit for routine tests and patient care. During the transport, the patient is required to be briefly disconnected from the mechanical ventilator [1]. While this can pose some risks (including an increased risk of ventilator-associated-pneumonia [2]), they can be mitigated by carefully following the appropriate safety procedures, such as constant patient care and monitoring by trained staff while using appropriate user-friendly equipment [3]. These disconnects occur during normal patient care and are considered routine by health care professionals. Patient disconnection is often required to transport patients needing computed tomography or magnetic resonance imaging. Katira et al. [4] investigated the effect of abrupt discontinuation of the positive end-expiratory pressure (PEEP) on the lungs in mechanically ventilated rats to assess lung function via scanning electron microscopy and microvascular leak using Evans blue dye. The authors demonstrated that a sudden deflation of the lung after a sustained inflation, such as during an abrupt ventilator disconnection, causes a mismatch in the left ventricle load while increasing the lung hydrostatic pressure resulting in potential lung edema and acute cor pulmonale. Kubiak et al. [5] investigated the hemodynamics and lung function of four pigs with acute respiratory distress syndrome (ARDS) under continuous high-frequency oscillatory ventilation (two pigs) and after brief disconnection (two pigs). The authors showed that following disconnection, the pigs suffered from a permanent loss of lung function, whereas the pigs that remained connected to the ventilator maintained a steady improvement in lung function. Disconnects often require physician attention, which typically causes an increase in unnecessary workload [6].

The disconnection also introduces the risk of airborne contamination, which can pose a significant risk to the safety of both the patients and staff. When the ventilator is disconnected, it continues to deliver air (in some cases at an accelerated rate), thus dispersing it into the atmosphere, increasing the probability of health care workers and other patients being exposed to biological aerosols from the ventilator [7, 8]. While the largest risk factor for contamination is direct contact with patients [9], airborne contamination is still prevalent and a recognized hazard to the hospital as a whole [10], since airborne contaminants can easily spread away from the source to many different areas of the hospital [10, 11]. This is also a matter of interest when using Nitric Oxide (NO) therapy via mechanical ventilation. In fact, inhaled NO is commonly used for invasively ventilated patients as a pulmonary vasodilator used for treatment of ARDS and acute lung injury [12] and persistent pulmonary hypertension for adults and newborn infants [13]. However, NO delivered via mechanical ventilation was shown to react with the delivered oxygen, producing nitrogen oxide compounds [13, 14], which may irritate the respiratory tract. Thus, it can be concluded that avoiding disconnects can improve patient health, improve staff safety, and reduce the risk of infections by reducing the risk of contamination.

The Flusso™ Bypass (MMSI Inc., Rockton, ON) adapter was designed and developed by one of the authors (FF) to reduce the frequency of these circuits disconnects. In particular, the design features a swivel to reduce torque on the endotracheal tube, a common source of disconnections [7]. It also features a tethered port-cover (cap) to keep the ports clean. Finally, it allows for the process to be visualized (to verify that the patient's positive pressure ventilation has been secured) by using a transparent housing with a distinguishable colored valve [15].

In this paper, the binary classification (pass/fail: with pass meaning "no control-gas leakage" and fail representing detection of "control-gas leakage") was used to investigate experimentally, in an in vitro setup at a local hospital (Children's Hospital of Eastern Ontario, Ottawa, Ontario), the performance of the Flusso™ Bypass adapter by evaluating NO leakage with and without the Flusso™ Bypass adapter. This experimental setup attempts to replicate clinical settings with a planned patient disconnection (not an accidental one) where a patient (under mechanical ventilation) is briefly disconnected and reattached to a portable mechanical ventilator to be transported or disconnected for transition of therapy (e.g., changing dry ventilator circuit to heated wire circuit). For this purpose, a mechan-

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ical ventilator delivering NO (the selected control gas) was connected to a breathing simulator (spontaneously breathing patient) both with and without the Flusso™ Bypass adapter. The NO gas was used in this study to provide a measurable airborne substance, mimicking, for example, extremely small respiratory droplets (diameter with less than 2.5 µm). The circuit was briefly disconnected in both cases to measure the NO gas detected in the environment.

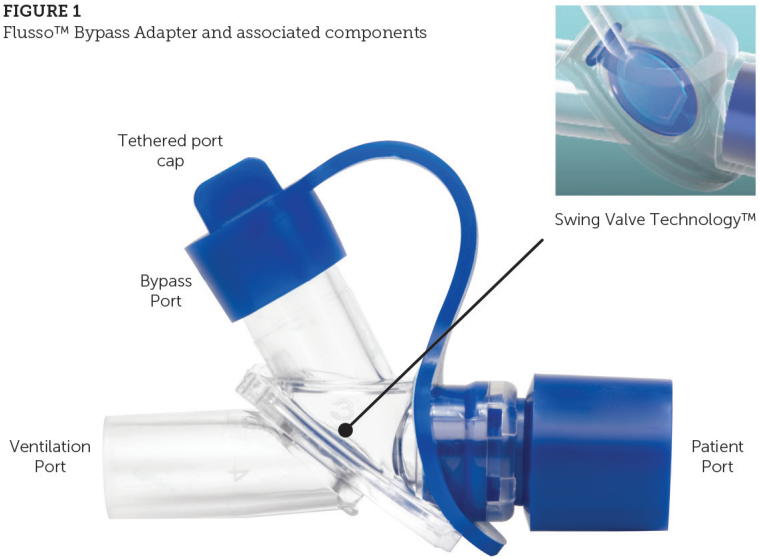
METHODS

Ethics approval was not required for this study.

Flusso™ Bypass adapter

The Flusso™ Bypass adapter (MMSI Inc., Rockton, ON, Figure 1) was designed to safely facilitate planned disconnection of mechanically ventilated patients during patient's transportation or circuit change. Due to its minimal dead space (7cc) and the standard International Organization for Standardization connections [16] designed for the different ventilator

FIGURE 1
Flusso™ Bypass Adapter and associated components



circuit ports, it can be used for standard circuits and ventilators currently available in hospitals. Using the Swing Valve Technology™ and a transparent housing, a constant closed circuit can be ensured thus minimizing potential staff exposure to hazardous airborne contaminants.

Experimental setup

The in vitro experimental setups are shown in Figures 2 and 3, detailing the different testing scenarios with and without the Flusso™ Bypass adapter. A mechanical ventilator (Servo I, Maquet Getinge, Germany), with an inspiratory flow range of 0–3.3 L/s, is used to deliver 100% oxygen with a tidal volume of 500 mL with an inspiratory length of 1 s and a positive end expiratory pressure (PEEP) of 12 cm H2O for volume-controlled ventilation. The peak inspiratory pressure for the pressure-controlled mode of ventilation was set to 28 cm H2O. During each test performed, a constant dose of NO (40 ppm) was delivered into the inspiratory ventilator circuit via a NO dosing unit (INOmax DSIR, Mallinckrodt Pharmaceuticals, USA).

Two different experimental setups were used to compare the performance of the Flusso™ Bypass adapter. In the first experimental setup without the Flusso™ adapter (Figure 2), simulating standard protocols for patient transport in clinical settings, the inspiratory and expiratory lines of the ventilator circuits were connected directly to a breathing simulator (Active Servo Lung, ASL 5000, IngMar Medical, USA), via a bacterial filter (Inter-guard filter, Intersurgical, UK), with the profile of a spontaneously breathing patient with a respiratory rate of 14 breaths per minute and an inspiratory muscle pressure of 12 cm H2O.

To test the Flusso™ adapter within the same conditions, in a second experimental setup (Figure 3) the inspiratory and expiratory lines of the ventilator circuits were connected to the ventilation port of the Flusso™ adapter while the patient port of the adapter was connected to the ASL 5000, via a filter. A resuscitation bag (Spur II, Ambu, USA) with a filter (Inter-guard filter, Intersurgical, UK) is connected to the bypass port in place of a standard disconnection. Within this configuration, the swing valve of the adapter allows transition of gas flow movement from the ventilator port to the bypass port.

To measure NO concentration from the patient during patient disconnection, an NO gas detector (GAXT-N-DL GasAlert Extreme Single Gas Detector, NO, BW by Honeywell, USA), with a resolution of 1 ppm and sampling rate of 5 s, was placed within a 5 inch radius from the disconnection site as shown in Figures 2 and 3. This distance from the disconnection site was chosen as it was shown to provide the optimal reading for the NO gas detector. The bacterial filters used in this study do not alter the NO delivery to the measurement site (disconnection site).

Experimental procedure

The experiments were performed under ambient relative humidity. To investigate the impact of the Flusso™ Bypass adapter, multiple baseline experiments without the adapter were performed. To assess the effectiveness of the Flusso™ Bypass adapter, the binary classification (pass/fail: with pass meaning "no control-gas leakage" and fail representing detection of "control-gas leakage") was used.

Without Flusso™ Bypass adapter

Using the first experimental set up, four experiments were performed varying the ventilation mode (volume-controlled or pressure-controlled) and breathing phase of disconnection (during inhalation or exhalation). Once all the components connected to the ventilator circuit as described above, the inspiratory and expiratory lines are disconnected for 3 s from the ASL 5000, releasing the NO in the ambient air, during inhalation and exhalation. The NO gas detector was used to monitor the amount of NO released after disconnection until no gas was detected. Five repeats of each test were performed.

FIGURE 2
Experimental setup without the Flusso™ Bypass Adapter.

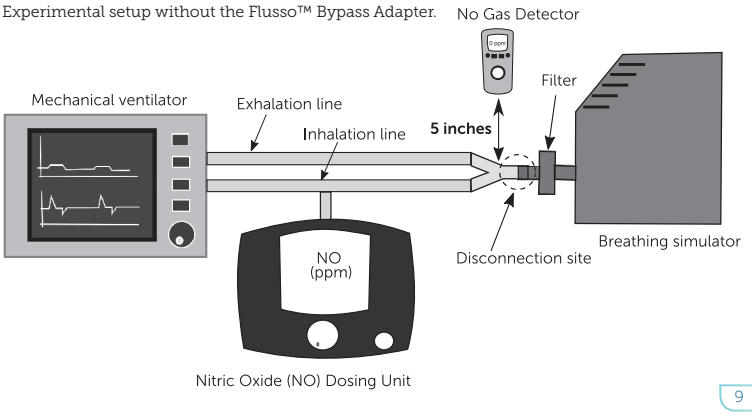
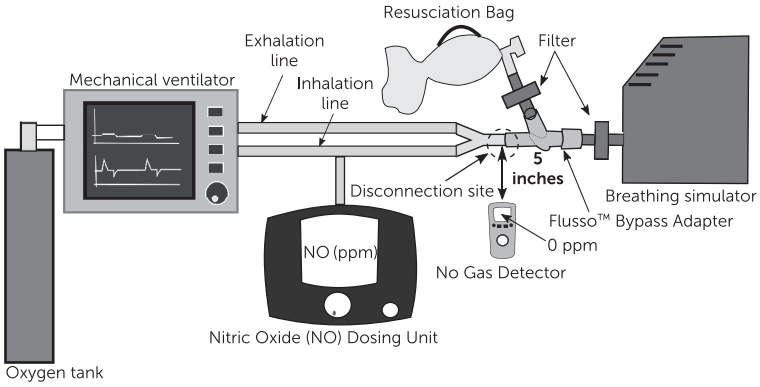


FIGURE 3
Experimental setup with the Flusso™ Bypass Adapter.



With Flusso™ Bypass adapter

Using the second experimental setup, using the Flusso™ adapter, four tests were also performed varying the ventilation mode and breathing phase of disconnection as for the previous setup. When the bypass port is not in use, the swing valve of the adapter allows flow movement between the ventilator port and patient port, hence blocking the bypass port. Before circuit disconnection, the resuscitation bag or transport ventilator is attached and activated. Upon pressurization of the bypass port, this pressure change relocates the location of the swing valve, allowing flow between the bypass port and the patient port, hence blocking the ventilation port. The ventilator is then placed in standby. The circuit is then disconnected while the resuscitation bag is providing oxygen to the ASL 5000 for 30 s. The NO was also monitored using the gas detector after disconnection until no gas was detected. Five repeats of each test were performed. During disconnection, the ventilator was set on standby mode, following the standard procedure for patient transport in hospitals.

RESULTS

The results obtained from the eight tests performed are presented in Table 1, in terms of the average nitric oxide detected in parts per million (ppm), the duration of NO detection in seconds and the maximum NO detected in parts per million with and without Flusso™ Bypass adapter, for the volume and pressure-controlled modes for circuit disconnections during inhalation and exhalation. The results are shown as average values ± standard deviation (SD).

Figure 4 shows the comparison of average NO in parts per million for the volume and pressure-controlled ventilation modes for the circuit disconnection during inhalation and exhalation without the Flusso™ Bypass adapter. The average NO detected was found to vary between 10.2 ± 1.6 and 11.5 ± 1.3 ppm to a maximum exposure of 18.4 ± 1.2, indicating leakage ("fail" classification). In fact, no significant difference was found for the average NO detected for the different ventilation modes during inhalation or exhalation.

Figure 5 shows the comparison of the duration of NO detection for both ventilator modes for circuit disconnections during inhalation and exhalation without the Flusso™ Bypass adapter. Comparing the results obtained for the volume-controlled ventilation mode, the time until a null NO reading was found to be 37.2 ± 14.4 s and 33.4 ± 18.8 s, during inhalation and exhalation, respectively, whereas for the pressure-controlled ventilator mode, the duration of NO detection was found to be 79.2 ± 21.0 s and 103.2 ± 11.0 s, during inhalation and exhalation, respectively. No significant difference was found for the volume-controlled or the pressure-controlled ventilation mode comparing the inhalation and exhalation tests performed. However, a significant difference was found in NO dissipation time comparing both modes of ventilation during inhalation ($p < 0.05$) or exhalation ($p < 0.05$).

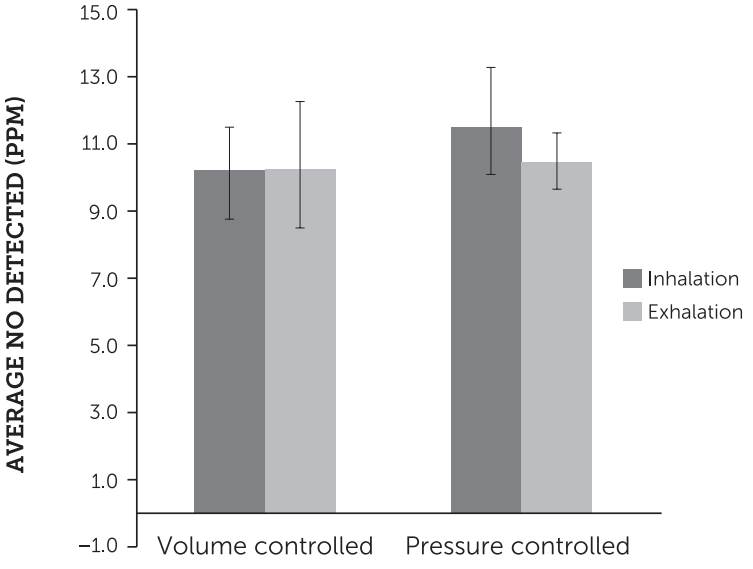
Figure 6 presents a comparison of the maximum NO detected for both ventilator modes for circuit disconnections during inhalation and exhalation without the Flusso™ Bypass adapter. Higher NO amounts were detected for the pressure-controlled mode (16.8 and 17.4 ppm during inhalation and exhalation, respectively) compared with the volume-controlled mode (18.2 and 18.4 ppm during inhalation and exhalation, respectively). However, no significant difference was found.

DISCUSSION

The findings of this study were used to evaluate the impact of the Flusso™ Bypass adapter in a hospital environment. These results presented in the previous section indicate a longer dissipation time for the NO (Nitric Oxide) released for the disconnection during exhalation especially for the pressure-controlled ventilation mode (as compared to

during inhalation and volume-controlled mode). A significant difference in the duration of NO detection was also found when comparing both

FIGURE 4
Comparison of the average Nitric Oxide (NO) detected in parts per million (ppm) for the volume and pressure-controlled ventilation modes during inhalation and exhalation disconnection without the Flusso™ Bypass adapter.



ventilation modes for the circuit disconnection during inhalation ($p < 0.05$). The same findings were noted for circuit disconnection during exhalation ($p < 0.05$). In fact, disconnection of the circuit during the pressure-controlled ventilation mode causes the ventilator to overcompensate for the pressure loss and hence an increase in flow and volume was noted. Therefore, a large volume of NO was delivered in the room, causing a long dissipation time to a null NO reading. These results can also be seen when looking at the results obtained for the maximum NO

TABLE 1

Summary of results of detected NO with and without Flusso™ Bypass adapter, for the volume controlled and pressure controlled ventilator modes for a circuit disconnection during inhalation and exhalation.

	Volume controlled		Pressure controlled	
	Without Flusso™ Bypass adapter		Without Flusso™ Bypass adapter	
	Inhalation Average ± SD	Exhalation Average ± SD	Inhalation Average ± SD	Exhalation Average ± SD
Average NO detected (ppm)	10.2 ± 1.6	10.3 ± 1.8	11.5 ± 1.3	10.5 ± 0.8
Duration of NO detection (s)	37.2 ± 14.4	33.4 ± 18.8	79.2 ± 21.0	103.2 ± 11.0
Maximum NO detected (ppm)	16.8 ± 1.5	17.4 ± 3.0	18.2 ± 0.7	18.4 ± 1.2
	With Flusso™ Bypass adapter		With Flusso™ Bypass adapter	
	Inhalation Average ± SD	Exhalation Average ± SD	Inhalation Average ± SD	Exhalation Average ± SD
Average NO detected (ppm)	0 ± 0	0 ± 0	0 ± 0	0 ± 0
Duration of NO detection (s)	0 ± 0	0 ± 0	0 ± 0	0 ± 0
Maximum NO detected (ppm)	0 ± 0	0 ± 0	0 ± 0	0 ± 0

The results are shown in terms of the average Nitric Oxide (NO) detected in parts per million (ppm), the duration of NO detection in seconds and the maximum NO detected in parts per million. The results are presented as an average ± standard deviation (SD).

detected (Figure 6),where higher NO was detected for the pressure-controlled mode compared with the volume-controlled mode. However, no significant difference was found in the maximum NO values detected for all the tests performed.

It can be noted, that no Nitric Oxide was detected (binary "pass" classification) when using the Flusso™ Bypass adapter. These results indicate that using the Flusso™ adapter, no gas leakage was detected, despite the ASL 5000 still providing 14 breaths per minute, simulating a spontaneously breathing patient's behaviour in a clinical setting where the patient is not completely paralyzed consisting of a potential hazardous exposure to the clinical staff. Therefore, it is determined that using the Flusso™ adapter minimizes the probability of staff exposure to NO and potentially to hazardous airborne droplets emanating from the patient. It is also important to note that using the Flusso™ adapter, no abrupt disconnection of the patient was experienced due to Swing Valve Technology™ and the use of the resuscitation bag, which could reduce lung injuries and alveolar over distension and collapse.

Study limitations

The results presented in this study are solely pertaining to the gas used (NO), which would not behave similarly to biological aerosols. However, it is conjectured that extremely small respiratory droplets (with aerodynamic diameters less than 2.5 μm) may be dispersed in the room similarly to NO due to their low inertia and low settling velocities (typically below 0.2 mm/s) [17, 18], but further investigation is required. It is also important to note that some of the biological droplets would be blocked by bacterial filters, hence further reducing staff exposure.

The use of NO in this study was intended as a gas marker to measure quantitatively the effect of ventilation disconnection. One concern using inhaled NO is its reaction with the oxygen delivered through the ventilator, producing nitrogen dioxide (NO2) [13, 14]. At the point of delivery, the concentration of NO2 was detected at 0.3 ppm. The concentration of NO2

FIGURE 5

Comparison of the duration of Nitric Oxide (NO) detection in seconds (s) for the volume and pressure-controlled ventilation modes during inhalation and exhalation disconnection without the Flusso™ Bypass adapter.

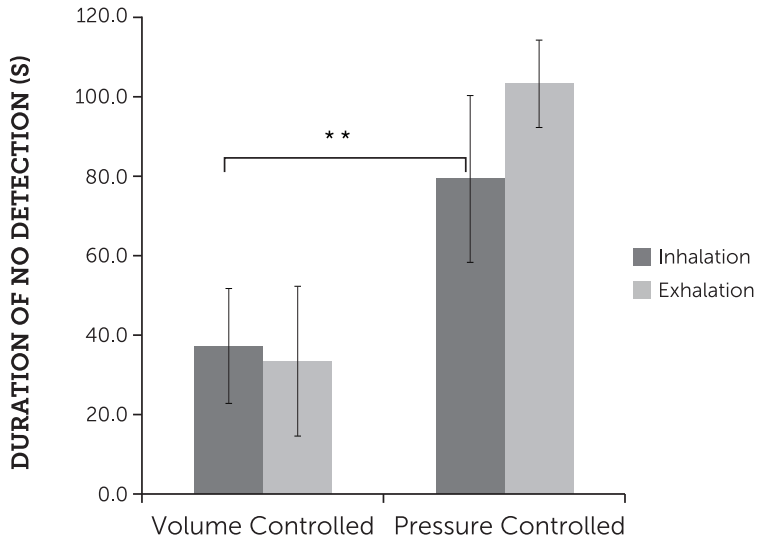
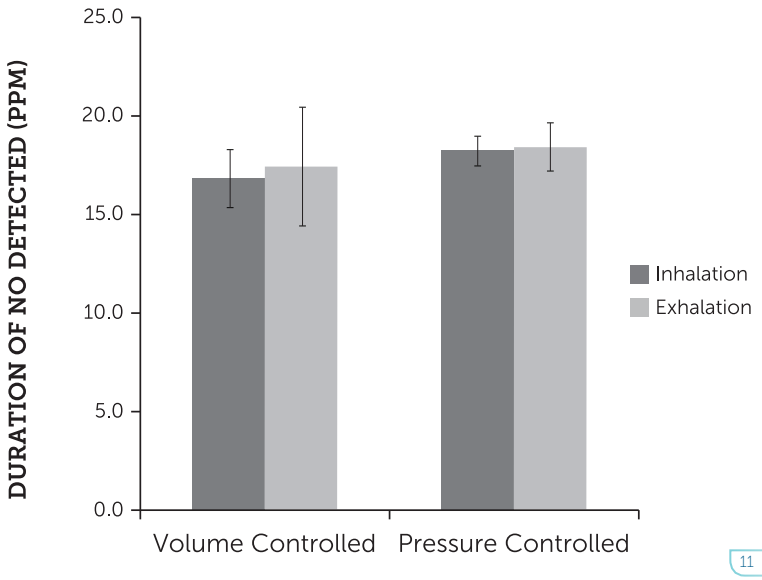


FIGURE 6

Comparison of the maximum Nitric Oxide (NO) detected in parts per million (ppm) for the volume and pressure-controlled ventilation modes during inhalation and exhalation disconnection without the Flusso™ Bypass adapter.



was not monitored throughout the study. However, this concentration is expected to be below the recommended safety limit of 5 ppm [19] since the NO is introduced in the inspiratory line of the ventilator near the lung simulator and the measurement point [12]. In fact, it was shown that inhaled NO delivered at 80 ppm was not associated with significant dose of nitrogen dioxide [13].

Using the Swing Valve Technology™ ensures continuous ventilation to the patient. However, its performance could be altered under certain conditions. High relative humidity was used for the multiple tests performed. However, no visible water droplet buildup was noted during the experiments performed and therefore did not affect the valve performance during the study. It was also believed that the type of medication delivered could affect the valve functioning, since patients under mechanical ventilation could receive different viscous drugs (steroids, antibiotics, or anticoagulants). For this purpose, the Flusso™ Bypass adapter was tested using a solution of Acetylcysteine (20 mg/mL) for three consecutive disconnection cycles and repeated after 24 h and showed no diminishing performance of the valve (no significant change in tidal volume). However, a buildup of medication was noted on the adapter's walls, which, in time, could affect the valve's performance. This adapter is recommended to be replaced every 7 days. Therefore, medication buildup would not affect the adapter's proper functioning.

CONCLUSIONS

With this work, an in vitro study was performed demonstrating the impact of the Flusso™ Bypass adapter in a hospital environment where a patient, under mechanical ventilation, is briefly disconnected and reattached to a portable mechanical ventilator to be transported. It was found that following the current standard procedures for patient transportation, with a three second disconnect, a leakage of particles delivered to the patient were dispersed in the room to which the clinical staff will be exposed. It was shown that this leakage was avoided when using the Flusso™ Bypass adapter therefore decreasing the risk of potential exposure to the clinical staff.

DISCLOSURES

Contributors

RM, AA, NO, and FF contributed to the conception design of the work, the acquisition, analysis and interpretation of data. RM, EM, and FF were involved in drafting and commenting on the paper and have approved the final version.

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Competing interests

All authors have completed the ICMJE uniform disclosure form at www. icmje.org/coi_disclosure.pdf and declare: FF owns the intellectual property for the Flusso™ device. However, Carleton University was the study lead with unrestricted rights to publish any and all findings at their discretion.

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4

COMBINED USE OF FLUSSO™ AND TIMPEL DURING VENTILATORY CIRCUIT DISCONNECT OF A MECHANICALLY VENTILATED PATIENT IN ICU: A CASE REPORT

Bianca Oliveira[1], Thais Gregol[2], Victoria Ferreira[1], 1Timpel Clinical Specialist, 2 Timpel Consultant Physician

Introduction

Disconnection of the ventilation circuit in mechanically ventilated patients is part of the ICU routine, and can occur several times a day, during suction, transport, or even by accident. Much has been learned about optimizing mechanical ventilation parameters, but there is little emphasis on disconnecting the ventilation circuit, which can cause lung injury as pulmonary edema, impaired oxygenation, and increased pulmonary vascular resistance 1, 2.

The Flusso™ Bypass (MMSI Inc., Rockton, ON) adapter (Figure 1) was designed and developed to safely facilitate planned disconnection of mechanically ventilated patients, allowing the maintenance of positive end-expiratory pressure (PEEP) during the ventilation circuit disconnection 3. Timpel is an electrical impedance tomography (EIT) device,

which is a noninvasive, radiation-free and real-time imaging method that timely measures ventilation distribution and regional changes in lung volumes. The EIT plethysmogram represents the amount of air that moves in and out of the lungs, and is a waveform derived from the sum of all pixels globally or within a given region of interest (ROI) of a relative image (frame) plotted over time. Thus, EIT is able to identify changes in pulmonary aeration (ΔEELZ) caused, for instance, by PEEP changes (Figure 2)4,5.

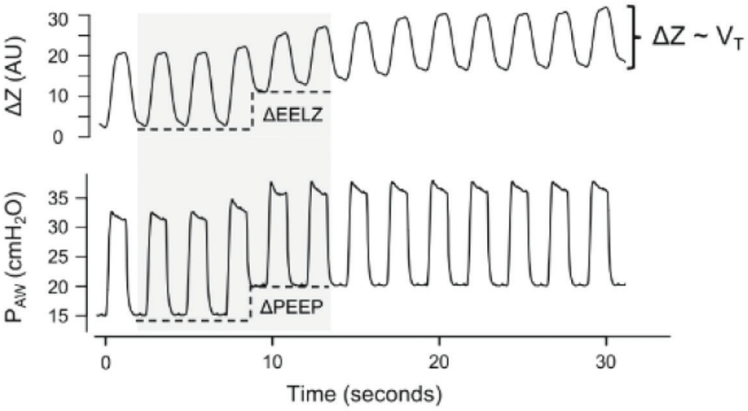


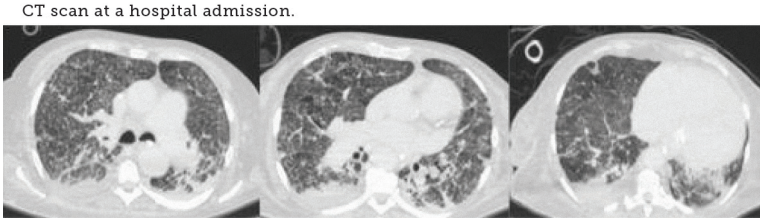
Figure 2. Global plethysmogram and airway pressure (PAW) waveforms. Increment in positive end–expiratory pressure (PEEP) increased end–expiratory lung volume (ΔEELZ).

Case Report

This is the case of a 57-year-old female patient with a previous history of pulmonary hypertension, obesity, asthma, sleep apnea, who had pulmonary thromboembolism after COVID-19 and chronic thromboembolic pulmonary hypertension.

The patient was admitted using an oxygen mask, with low oxygen saturation (86%) and tachypnea (28 breaths per minute). After support with a high-flow nasal cannula without improvement the patient required orotracheal intubation and invasive mechanical ventilation. Following CT exams (Figure 3) the diagnostic hypothesis was chronic thromboembolic

FIGURE 2
CT scan at a hospital admission.



pulmonary hypertension decompensated due to pulmonary infection.

With a PEEP of 15 cmH2O, Timpel was installed for lung monitoring. When an open disconnection was necessary for the patient to be taken

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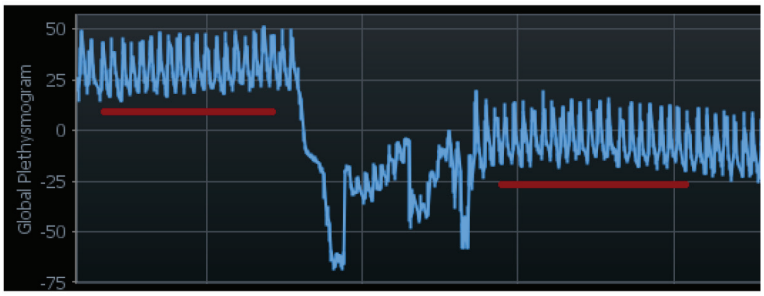
for exam, through the EIT plethysmogram baseline it was possible to see the EELZ loss globally, and even after the circuit reconnection, the EELZ did not returned to the level prior to disconnection (Figure 4).

FIGURE 4

Plethysmogram during open disconnection. The red lines indicate before and after the circuit opening.



Flusso™ was then installed to keep the PEEP and maintain EELZ and ventilation during disconnection moments. When a new disconnection was performed, now using Flusso™, it was noticed on Timpel's screen how the plethysmogram baseline remained at the same level, which represents the aeration maintenance (Figure 5).

FIGURE 5

Plethysmogram during disconnection using Flusso™. The red lines indicate before and after, where the aeration/EELZ was maintained, with no aeration loss.

The Figure 6 represents the comparison between the moments before and after the open circuit disconnection and the Figure 7 are the comparison between the moments before and after the circuit disconnections using Flusso™.

FIGURE 6

Ventilation maps before and after open disconnection. The red region on the third map represents the area that lost impedance/ventilation between the two moments.

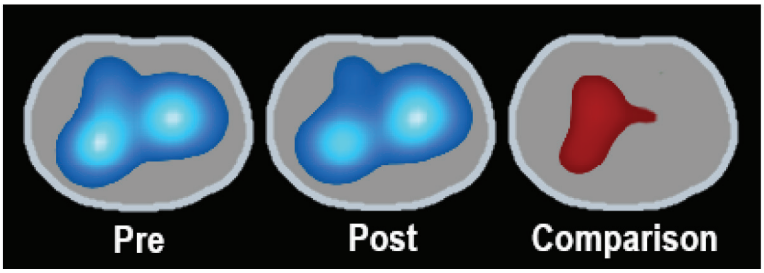
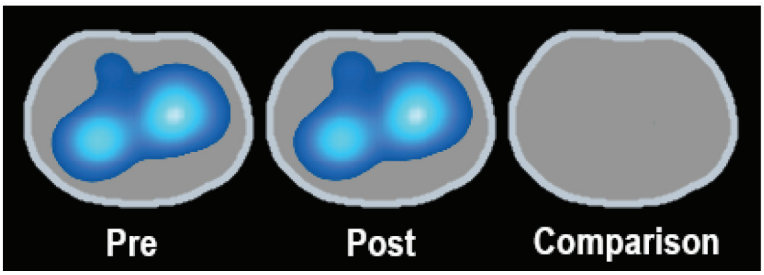


FIGURE 7

Ventilation maps before and after disconnection with Flusso. As there was no difference between the two moments, the third comparison map does not show losses or gains areas.



Timpel is a lung monitor that displays the ventilation and aeration changes in real time and radiation free, being an important tool for continuous monitoring of lung function, without adding risks to critical patients. Timpel showed how effective the Flusso™ use is in maintaining ventilation and end-expiratory lung volume, or functional residual capacity, during planned disconnections of the ventilatory circuit, avoiding ventilation and aeration losses and possible lung injury resulting from open disconnections of patients under mechanical ventilation.

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5

IN VITRO EVALUATION OF AIRFLOW RESISTANCE DURING THE FIRST BREATH AFTER ENDOTRACHEAL TUBE CLAMPING USING THE ASL5000 LUNG SIMULATOR

Frank Fiorenza RRT, BHSc, FCSRT, Mathew Eberley RRT, Patrick Nellis RRT, AA, MBA

Introduction

Patients in the intensive care unit (ICU) are frequently disconnected from mechanical ventilators for various clinical reasons, such as administering aerosol treatments, patient transport, or changing ventilators and circuit components. Temporary disconnection from the ventilator exposes the patient's airway to atmospheric pressure, potentially leading to complications such as atelectasis in dependent lung zones and worsening intrapulmonary shunting.

To mitigate these effects, some clinicians clamp the endotracheal tube (ETT) during disconnections to maintain positive pressure within the lungs. The practice of ETT clamping gained traction during the COVID-19 pandemic due to the urgent need to minimize aerosolized viral particles during airway procedures, particularly for critically ill patients requiring high levels of positive end-expiratory pressure (PEEP) to prevent alveolar collapse and facilitate gas exchange.

In addition to its potential physiological benefits, ETT clamping has been used as a safety measure to reduce healthcare worker exposure to aerosolized virus particles during airway management procedures such as extubation or ventilator transfers. A bench study by Turbil et al. demonstrated that the type of ETT and clamp significantly affect PEEP stability and lung volume loss during ventilator disconnection.

However, ETT clamping remains an off-label practice with limited clinical evidence supporting its safety or efficacy. While theoretically beneficial in mitigating adverse physiological effects during brief disconnections, its impact on airflow resistance remains unclear. This study aims to evaluate the effects of ETT clamping on airflow resistance using the ASL5000 lung simulator.

Methods

In this study, the ASL5000 lung simulator was configured to operate with a flow pump set at 60 L/min and a respiratory rate of 15 breaths per minute. Two endotracheal tubes (ETTs) of different sizes (7.0 mm and 8.0 mm internal diameter) were each cut to a standardized length of 6 inches and connected to the ASL5000.

Airflow resistance was measured both before and after ETT clamping. Each tube was clamped at a distance of 3 inches from the connector for a duration of 5 seconds. The resistance was recorded during the initial breath following clamping to assess the impact on airflow dynamics.

Results (see below) :

7.0 ETT	PRE CLAMPING	POST CLAMPING	PERCENT CHANGE
Mean flow (L/min)	38.12	38.193	0.19%
SD exp resistance	19.923	31.299	57.09%
Pat insp res work (mJ)	2277.914	2230.842	-2.06%
P_mean insp (cmH_20)	-6.755	–3.734	–44.68%
P_mean EXP (cmH_20)	5.01	7.91	57.88%
P_min (cmH_20)	–13.399	-22.826	70.30%
P_peak (cmH_20)	0.06	0.045	–25.00%

8.0 ETT	PRE CLAMPING	POST CLAMPING	PERCENT CHANGE
Mean flow (L/min)	38.193	32.091	-15.97%
SD exp resistance	14.093	85.891	509.45%
Pat insp res work (mJ)	2279.444	2140.455	-6.09%
P_mean insp (cmH_20)	-6.169	–18.465	–199.67%
P_mean EXP (cmH_20)	3.539	11.552	226.42%
P_min (cmH_20)	–12.187	-50	–310.27%
P_peak (cmH_20)	0.023	16.749	–72721.00%

Research by Bulleri et al. suggests that the efficacy of ETT clamping varies based on multiple factors, including clamp type, clamping duration, ETT size, and timing of the clamping event. Their findings indicate that for ETTs with an internal diameter of 6 mm, all clamp types yielded similar pressure and volume results. However, for larger ETTs (7 mm and 8 mm ID), only the ECMO clamp effectively maintained stable pressure and volume during disconnection.

Conclusion

ETT clamping significantly increases airflow resistance, with the magnitude of resistance varying based on tube size. Despite its use in clinical practice, ETT clamping remains an off-label technique with limited research supporting its safety and efficacy. The lack of clinical evidence raises concerns about its potential risks, including increased airway resistance and compromised ventilation. For these reasons, this study was conducted in a controlled laboratory setting rather than on patients. Given the uncertainty surrounding its impact on patient outcomes, ETT clamping should not be routinely performed in clinical settings until further research establishes its safety and effectiveness.

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