High Flow Oxygen Therapy – Complications, risks and potential rewards

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DOI: https://doi.org/10.53097/JMV.10077
Cite: Tunnell S. High Flow Oxygen Therapy – Complications, risks and potential rewards. J Mech Vent; 2023; 4(2):73-82.

Abstract

Introduction
High Flow Oxygen Therapy via Nasal Cannula (HFNC) has advantages over conventional oxygen therapy (COT). However, complications and risks associated with higher flows have not been exhaustively studied. Two important considerations during the use of HFNC are provision of adequate humidity to prevent inspissated secretions and whether the pressure generation by higher flows may lead to gastric insufflation increasing the risk of aspiration. An additional risk involves the protocolized use of the ROX index when not matching flow to patient inspiratory demand, the result of which is a false positive level of FiO_2. Some High Flow devices and High Flow modes on ventilators offer higher flow rates up to 80 liters per minute. I examined whether the use of higher flows up to 80 liters per minute would create an increased risk of inspissated secretions, gastric insufflation and possibly aspiration, and whether higher flows might improve the accuracy of FiO_2 based indices.
Methods
To examine these complications and risks, I studied the peak inspiratory flows of non-invasive ventilatory support devices and known levels of peak flow demand stated in the literature. Then I calculated oxygen concentration levels and the possibility of dilution by failure to exceed peak flow. To examine the risk of inspissated secretions I reviewed the international standard for humidity delivery during noninvasive support and reviewed the available data on compliance with humidity standards. To study whether higher flows up to 80 liters per minute would pose a risk. A bench study using an anatomical model was performed to compare the pressures generated using different flow rates in two commercially available HFNC devices in three different conditions: Open and closed system (mouth) breathing, breathing against active exhalation, and complete downstream occlusion.
Results
A literature evaluation of peak flows in patients with high inspiratory demand, showed flows often exceed 100 liters per minute. Devices that provide up to 80 lpm may not exceed the inspiratory demand of patients leading to unknown FiO_2. Evaluation of CE marked devices studied demonstrated compliance to international standards and provision of >12mg/L. The bench study found that high flow rate therapy did not elevate airway pressures to a level that would result in gastric distention and potential aspiration. In the open mouth test, pressure ranged from minimum 0.2 to maximum of 1.3 cmH_2O (± 0.1), and from 0.52 to 5.27 cmH_2O (± 0.1) in the closed mouth test. In the active breathing test, the pressures ranged from 1.5 to 6 cmH_2O (± 0.1). In the complete occlusion test, the pressures ranged from 0.37 to 4.49 cmH_2O (± 0.1).
Conclusion
Higher flows provided during HFNC that closely match the high inspiratory demands of patients improve the accuracy of FiO_2 related ratios, such as the ROX index. Devices that provide higher flowrates and meet the international standards (CE marked) for humidity provision do not pose an increased risk of inspissated secretions. Flows provided during HFNC therapy do not pose a hazard of creating high pressures which exceed esophageal opening pressure and pose a risk of gastric distention. The higher flow rates may reduce the risk associated with the potential false positive prediction of HFNC failure when therapy is not set to match the patient's inspiratory peak flow demand. The benefit of higher flows to match the inspiratory demand provides a rarely recognized additional benefit of improving the accuracy of predictive indices such as the ROX index and allows for high flow therapy to more fully achieve its intended use.

Keywords: High flow nasal canula, Flow rates, ROX index

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Conflict of interest/Disclosures: Evaluation of esophageal pressures bench study was funded by Telesair on a time and material basis.
Funding: Telesair provided the Bonhawa and Lungtreater CRO equipment and measuring instruments were used.

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Introduction

High flow oxygen therapy via nasal cannula (HFNC) has documented advantages over conventional oxygen therapy (COT). [1] It's been noted to improve the survival rate among patients with acute hypoxemic respiratory failure, [2] and potentially reduce the incidence of more invasive care.

Adjustable oxygen concentration and higher flows that match the inspiratory demand of the patient with respiratory distress result in less entrainment of room air, which dilutes the fraction of inspired oxygen (FiO_2) and therefore reduces effectiveness of intended use. [1,3] Higher flows have been demanded by the clinical community and are associated with a reduction of both $PaCO_2$ and metabolic work. [4,5] New high flow devices and newer ventilator modes offer higher flow rates up to 80 liters per minute.

Today, very few contra-indications and complications have been identified in the literature and it's important to separate contraindications from complications. A contraindication is a reason that a patient should not receive HFOT because it may be harmful. Absolute contraindications have been identified as facial trauma and unresolved tension pneumothorax. Complications are issues that arise from the application of therapy. Complications of HFOT can be drying of secretions from higher gas flows than COT. [6,7] HFOT benefits arise from the creation of positive airway pressure; however, with all non-invasive ventilatory (NIV) support the risk of gastric insufflation and possible aspiration exist from generated pressures above the glottic opening pressure. [8,9]

An unrecognized possibility in the literature is the false positive assessment of high flow risk of failure from the use predictive indices such as the ROX index [10] that are dependent on the FiO_2. This is based on the belief that the oxygen concentration ($\%O_2$) setting of the non-invasive device is equal to the FiO_2 of the patient. That's only true if the clinician successfully matches the patient's inspiratory flow demand with flow in excess of the peak. If the patient's inspiratory demand is greater than the clinician provided flow, then the result is room air entrainment and dilution of FiO_2 leading to an inaccurate FiO_2 value. The falsely high FiO_2 results in a falsely low ROX value. With this in mind it's important to assure sufficient flow is delivered to the patient during HFNC while assuring complications and risks from therapy are minimal.

Commercially available devices claim to meet the ISO standard for humidity delivery throughout their operating ranges mitigating the complication of inspissated secretions. So, we turned the attention of this study to focus on pressure generation.

The purpose of this study was to examine if the use of high flowrates, 60 liters per minute and higher, might present high airway pressures, which may lead to gastric distention and the potential for aspiration. To avoid gastric distention, ventilating airway pressures should be less than the normal esophageal opening pressures of 20 to 25 cmH_2O. [7,8]

Methods

A clinical evaluation of peer reviewed literature was conducted to characterize peak flow rates of patients with high inspiratory demand. The literature review involved key words of inspiratory demand, high flow oxygen therapy, and respiratory distress. A comparison of inspiratory demand levels to high flow oxygen concentration was performed to estimate the effects failure to match inspiratory demand may have on calculated indices that use fraction of inspired Oxygen (FiO_2).

Objective and rationale for the test:
The objective of this study was to examine whether flows of 80 liters per minute resulted in airway pressures that are greater than the current clinical practice requiring airway pressures during non-invasive ventilatory assistance to be below 20 cmH_2O.

Bench testing ensued between the Bonhawa Respiratory Humidifier, from Telesair Inc., a device capable of 80 liters per minute, and a commonly used device in clinical practice, the Airvo2 Respiratory Humidifier, from Fisher & Paykel Healthcare, a device with 60 lpm as its upper flow range. Various flow settings were employed to determine the amount of airway pressure created; and whether it posed a risk of attaining esophageal opening pressure leading to gastric insufflation. Both models were tested at their highest levels of flow to determine if generated pressures would pose risk to the patient. The largest nasal interfaces of both devices were employed to assure there was not a restrictive reduction in flow.

Figure 1: Large Airvo 2 cannula (above) and Large Bonhawa cannula (below)

The test method was constructed to measure airway pressures of both the devices at their highest flow levels in several conditions:

- Open and closed system (mouth) breathing
- Breathing against active exhalation
- Complete downstream occlusion

With the exception of neonates, which these devices are not generally intended for, patients in respiratory distress typically breathe in a mouth open position. [4] In some conditions, however, patients close their mouth intermittently. Also, studies of the Airvo2 device have been published demonstrating that flow levels and their consequential nasopharyngeal pressures vary between mouth open and closed. [7] Therefore a t-piece system was used with a one-way valve to quickly move between open and closed positions. Pressures were measured and recorded in the bench model to capture the associated pressures of the two devices during open and closed mouth simulation positions.

Additionally, active breathing was analyzed to determine whether active exhalation against incoming high flowrates would generate pressures above the esophageal opening pressure. Pressures were measured and recorded in both devices at their highest flowrates, which would produce the highest potential for airway pressure.

A contra-indication for high flow nasal cannula therapy in the literature is unresolved tension pneumothorax. To assess whether the higher flow rates of both the devices, in the presence of a complete occlusion, would result in pressures that are above the esophageal opening pressure a complete obstruction of the airway downstream, was created, to emulate a check valve obstruction (active tension pneumothorax) and drove the flow into the channel. Measurements of pressure were made and recorded for both devices at their highest levels. Pressures measured during these three conditions were assessed to determine if airway pressures were above the known guidelines for avoidance of gastric distention (20 cmH_2O).

Equipment employed:
The Airvo2 and its accessories were obtained from a local authorized rental dealer to ensure that the device represented what a US hospital user would experience during application of the Airvo2 device. The Bonhawa Respiratory Humidifier was obtained from the manufacturer and was also representative of the manufactured product a hospital would receive. Both devices utilized in this study were operated with their required accessories and both devices employed the largest patient interface to assure no restrictive forces dampened the delivered flow rates and therefore the pressures measured.

Flow accuracies of the Respiratory Humidifier devices were verified using a calibrated TSI model 5320 Rev A 5300 Series Flowmeter and IMT Flow analyzer model PF300. Prior to all pressure recordings the IMT pressure sensor high flow channel was zeroed. Recordings of data were made using the IMT CITREX Flow lab device (Buchs, Switzerland) software version 5.0.5.

Active breathing was facilitated using a Michigan TTL model 2601i dual test lung employing the TTL connector lock between the device to create a controlled spontaneous breathing pattern and active exhalation was established with the compliance set to 30ml/cmH_20 in order drive an aggressive exhalation back pressure.

To establish an active uniform breathing pattern a Philips V60 ventilator was employed to drive one of the single lung compartments of the Michigan TTL. Pressure controlled mode was employed at a Rate of 20 and EPAP of 04 and IPAP of 24 cmH_2O. Exhaled volume was 600 ml ± 10.

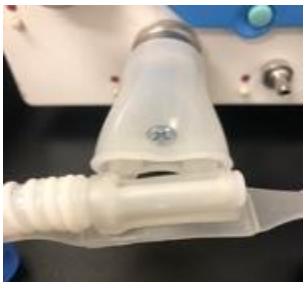
Anatomical Model:
Basic physics tells us that when continuous flow is driven through a cylinder, the pressure against the wall is uniform. [11] This means that the precision of this model is not critical, however we wanted to establish a model that was reflective of the lowest patient range claimed by these devices (20kg). Therefore, pediatric patients using the subject devices would be 20 kg or greater.

Anatomical dead space is estimated in the human as 2.0 ml / kilogram weight or 1ml / pound. [12] As an example, 150 ml is considered the norm for a 150 pound, ideal body weight adult. For a pediatric patient weighing 44 lb. (20kg) and estimated dead space of 44 ml is reasonable. [13] The nasopharynx is estimated to be 2 centimeters in diameter by 4 centimeters long in adults. [14] This later information was used to establish the nasal connector for this study. While this anatomical information is presented to establish an understanding for the reader, it is vital for the reader to understand that airway pressures and effects of airway pressures including gastric insufflation and esophageal opening pressures are similar between adults and children.

According to IMT, the manufacturer of the PF300 high flow channel, the dead-space is 44.8 ml. This makes the channel an ideal model for measurement of airway pressures. Again, pressure is transmitted equally throughout the channel, but for modeling purposes this channel is optimal to associate airway pressures to esophageal opening pressures.

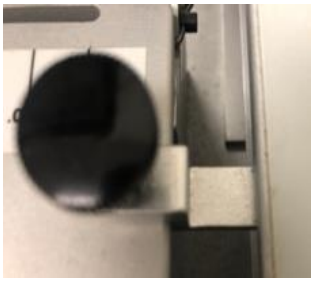
Silicone tubing was modeled to place the nasal cannulas from both device's interfaces into the

channel and sufficient room around the openings was created to emulate the standard of care. 2mm of room was provided as an opening around the cannula placement and the silicone nares. The standard of care in application of high flow nasal cannula therapy is not to have the nares fully occluded as this results in nasal pressure sores. The cannula was secured within the silicone nares using the straps provided with the interface accessory (Figure 2).



Optiflow cannula in place

Bonhawa cannula in place



Spontaneous test model

T-piece check valve

Figure 2: Testing procedures

As described above in the test rationale flows were then driven into the model and three conditions were created and measured: open and closed mouth breathing; breathing against active exhalation; and complete downstream occlusion.
Results are presented below.

Predefined test pass fail criteria:
The risk is associated with the opening pressure of the esophagus, which is known to be above 20 cmH_2O. The application of higher flows should result in pressures below 20 cmH_2O in order to mitigate this known risk.

Results

A clinical evaluation of the regulatory data for both commercial devices indicated that both devices meet the international standard, 80601-2-74, for provision of humidity levels greater than 12mg/L.

A calculated comparison of spontaneous peak flow to delivered flow showed the level of dilution can easily be 30% and the figure below illustrates how FiO_2 can change the calculation of ROX indices.

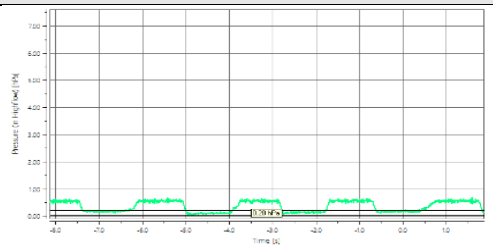
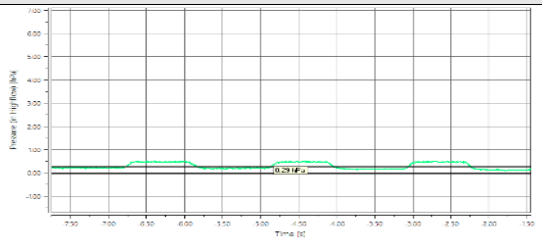
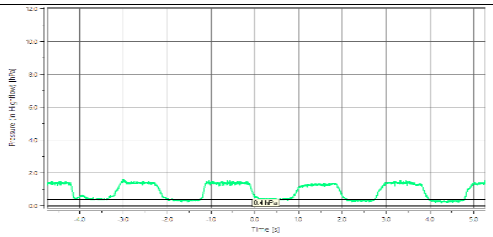
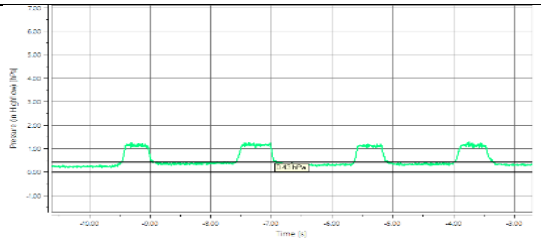
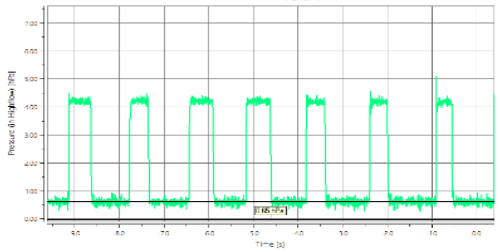
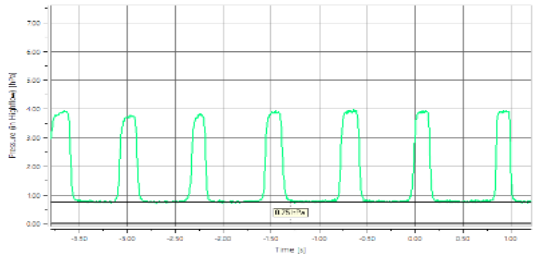
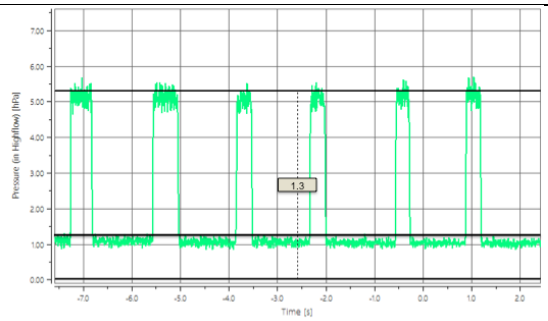
Bench test results are summarized in tables 1-3.

In the open mouth test, the pressure ranged from minimum 0.2 to maximum of 1.3 cmH_2O, and from minimum of 0.52 to 5.27 cmH_2O in the closed mouth test. In the active breathing test, the pressures ranged from minimum 1.5 to 6 cmH_2O. In the complete occlusion test, the pressures ranged from minimum 0.37 to 4.49 cmH_2O. SD ± 0.1 cmH_2O.

	SF ratio				ROX
	SpO2%	FiO2	SF	Rf	
Non Dilution	90	1.00	90	20	4.5
Dilution 30%	90	0.76	118	20	5.9
Non Dilution	88	1.00	88	20	4.4
Dilution 30%	88	0.76	116	20	5.8
Non Dilution	86	1.00	86	20	4.3
Dilution 30%	86	0.76	113	20	5.7

Table 1: shows a calculated impact dilution of FiO_2 based on inability to exceed peak flow of 100 lpm inspiratory demand. The initial row shows the actual ROX index if flow meets inspiratory demand and there is no dilution. The second row indicates the entrainment of Inspiratory volume by 30%. Rf: respiratory frequency, SF: SPO_2:FiO_2, SpO_2: oxygen saturation, FiO_2: fraction of inspired oxygen. ROX scores greater than or equal to 4.88 measured at 12 hours predicts lower risk of progressing to mechanical ventilation.

Tables 1A & 1B: Open and closed mouth test results summary
Subject device pressure measured at 20, 40, 60, and 80 lpm nasal flow (BTPS). Maximum pressure at 80 lpm with closed mouth was 5.27 cmH_2O. This is 14.73 cmH_2O below the pressure risk level for gastric insufflation, 20 cmH_2O during closed mouth simulation. BTPS: body temperature, pressure, water vapor saturated correction, lpm: liter per minute flow.

	Airvo 2	**Bonhawa**
Flow settings	Open mouth Pressure cmH_2O	Open mouth Pressure cmH_2O
20 lpm		
20 lpm	0.20 (± 0.1)	0.29 (± 0.1)
40 lpm		
40 lpm	0.40 (± 0.1)	0.43 (± 0.1)
60 lpm		
60 lpm	0.65 (± 0.1)	0.75 (± 0.1)
80 lpm	Not Available	
80 lpm	Not Available	1.30 (± 0.1)

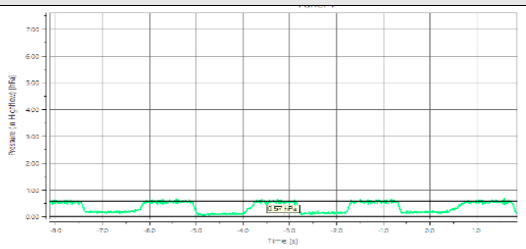
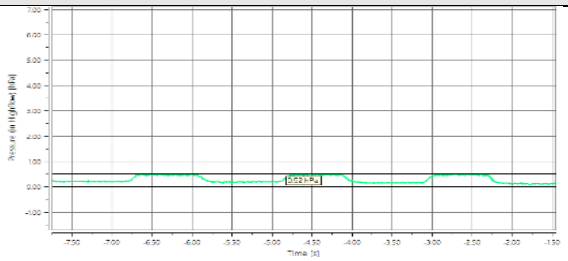
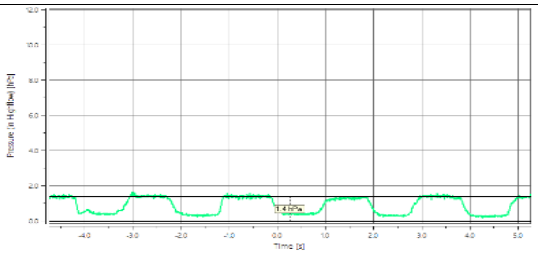
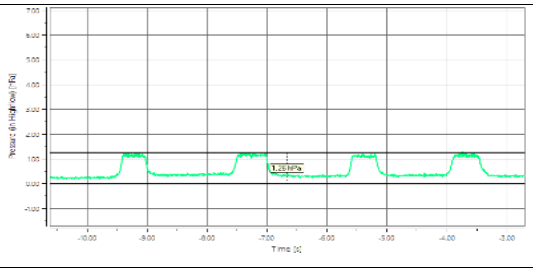
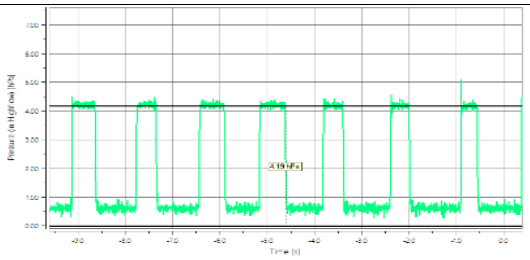
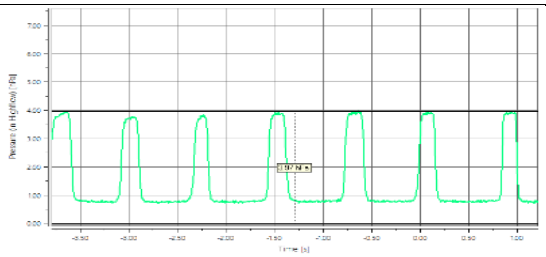
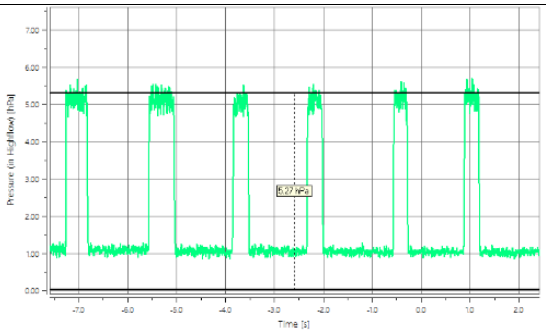
	Airvo 2	**Bonhawa**
Flow settings	Closed mouth Pressure cmH_2O	Closed mouth Pressure cmH_2O
20 lpm		
20 lpm	0.57 (± 0.1)	0.52 (± 0.1)
40 lpm		
40 lpm	1.40 (± 0.1)	1.26 (± 0.1)
60 lpm		
60 lpm	4.09 (± 0.1)	3.97 (± 0.1)
80 lpm	Not Available	
80 lpm	Not Available	5.27 (± 0.1)

Table 2: Active breathing test results
Subject device pressure measured at 20, 40, 60, and 80 lpm nasal flow. Maximum pressure at 80 lpm with active breathing was 6.0 cmH_2O. This is 14.0 cmH_2O below the pressure risk level for gastric insufflation, 20 cmH_2O during active exhalation breaths. BTPS: body temperature, pressure, water vapor saturated correction, lpm: liter per minute flow.

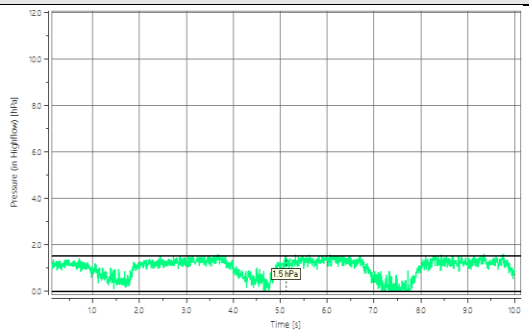
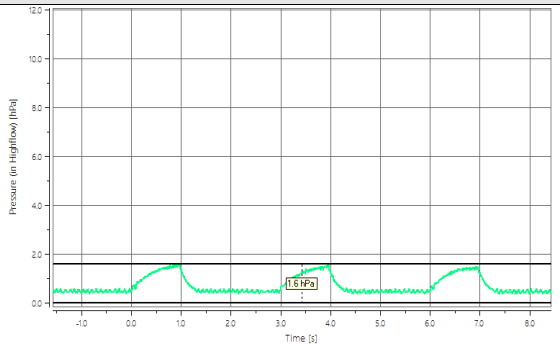
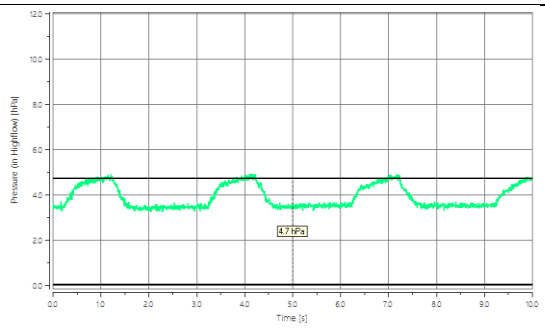
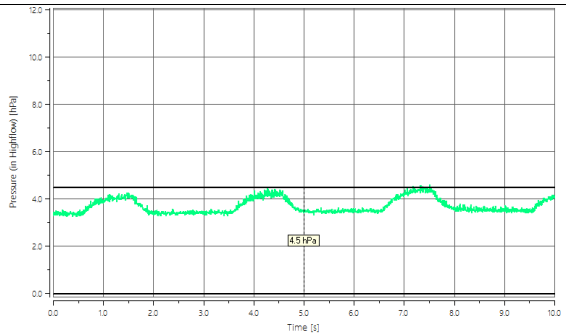
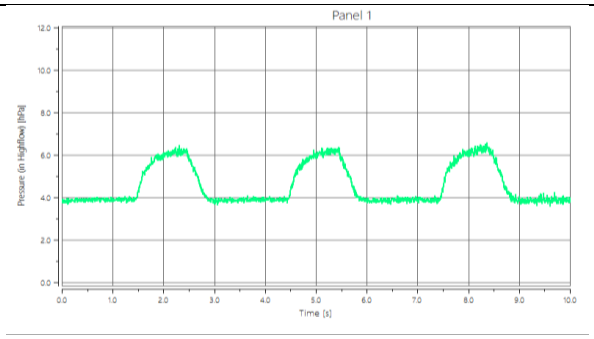
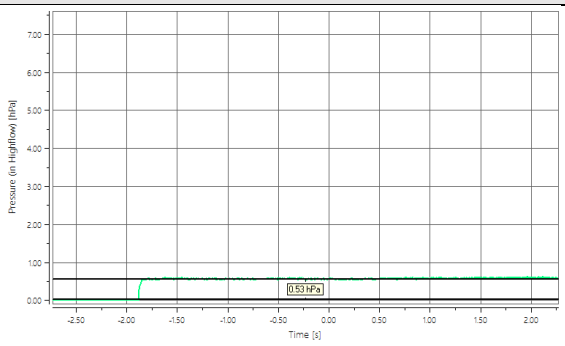
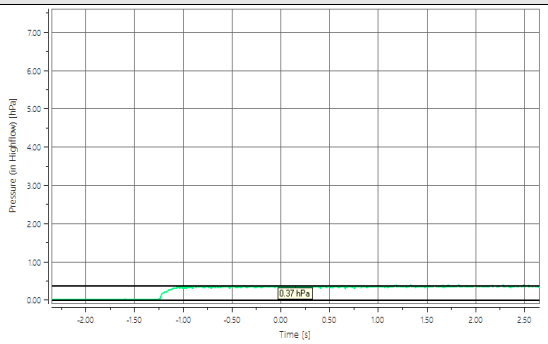
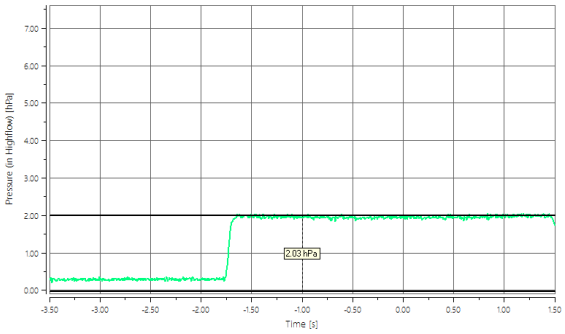
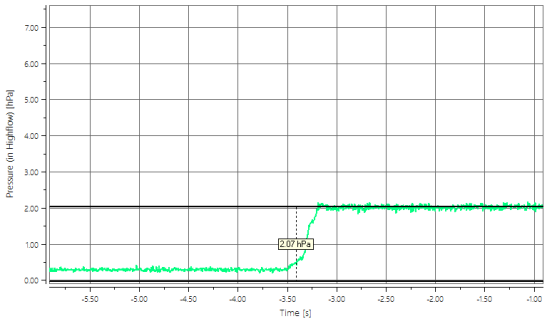
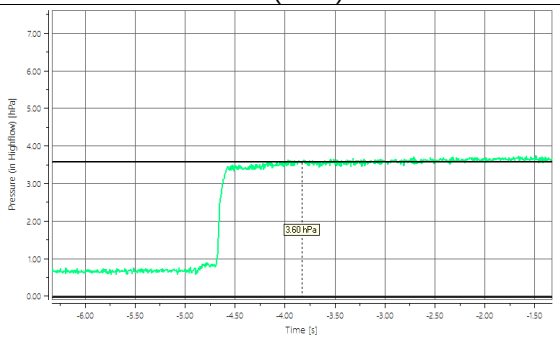
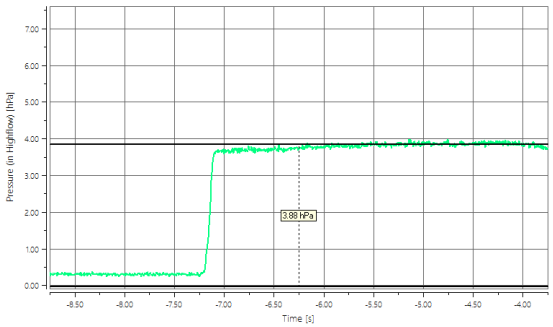
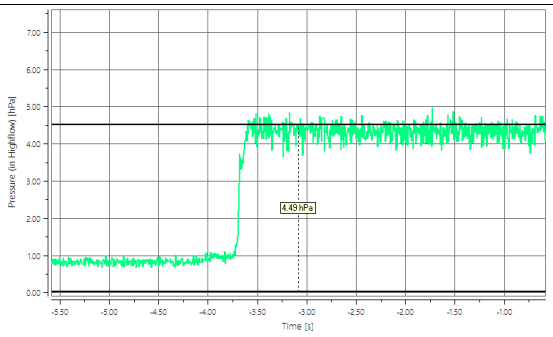
Flowrates	**Airvo 2** Pressure cmH_2O	**Bonhawa** Pressure cmH_2O
40 lpm		
40 lpm	1.50 (± 0.1)	1.6 (± 0.1)
60 lpm		
60 lpm	4.70 (± 0.1)	4.5 (± 0.1)
80 lpm	Not Available	
80 lpm	Not Available	6.0 (± 0.1)

Table 3: Complete Occlusion test results
Subject device pressure measured at 20, 40, 60, and 80 lpm nasal flow. Maximum pressure was 4.49 cmH_2O. This is 15.51 cmH_2O below the pressure risk level for gastric insufflation, 20 cmH_2O during downstream occlusion. BTPS: body temperature, pressure, water vapor saturated correction, lpm: liter per minute flow.

Flowrates	**Airvo 2** Pressure cmH_2O	**Bonhawa** Pressure cmH_2O
20 lpm		
20 lpm	0.53 (± 0.1)	0.37 (± 0.1)
40 lpm		
40 lpm	2.03 (± 0.1)	2.07 (± 0.1)
60 lpm		
60 lpm	3.6 (± 0.1)	3.88 (± 0.1)
80 lpm	Not Available	
80 lpm	Not Available	4.49 (± 0.1)

Discussion

Since Frat and colleagues' article in 2015, [2] which showed treatment with high-flow oxygen therapy (HFOT) improved the survival rate among patients with acute hypoxemic respiratory failure, HFOT has grown in popularity and indications for use. Today indications for HFOT and HFNC applications are larger in scope, as seen by regulatory approved intended use statements for marketed devices. Broad statements for the treatment of respiratory insufficiency and for spontaneously breathing patients that would benefit from heated and humidified respiratory gases are now the standard.

Oczkowski and colleagues [6] have published evidence-based practice guidelines for HFOT. Moderate certainty of evidence has been recommended for use of HFNC over COT with acute hypoxemic respiratory failure and for patients at high risk. Other uses with less evidence are also employed.

Benefits from the application of HFOT and HFNC over COT are documented in the literature. [1] Improved oxygenation, reduced anatomic dead space due to pharyngeal and upper airway washout, decreased metabolic cost of breathing and reduced carbon dioxide generation, positive nasopharyngeal pressure and tracheal airway pressure, improved work of breathing, humidification and warming of inspired gas, maintained secretion clearance, superior comfort, and reduced room air entrainment are described as physiologic benefits of use. [1]

The intent of this study was to examine whether the use of 80 liters per minute high flow setting from the Bonhawa and 60 liters per minute on the Airvo 2 would create an increased risk of inspissated secretions, gastric insufflation and possibly aspiration.

Both high flow devices have integrated humidity delivery systems and these devices meet the international standard, ISO 80601-2-74, for delivery of required humidity throughout the operating range of the device. The presence of the CE mark on both devices indicates a notified regulatory body has studied the technical data from each device and that they both meet this important international standard.

The bench model was established to drive higher exhalation force. The results demonstrated that 80 liters per minute fall well below the risk level associated with higher pressures, which may lead to gastric distention. Standard clinical practice is to avoid gastric distention by keeping airway pressures below the normal esophageal opening pressures of 20 to 25 cmH_2O. [8,9] All pressures measured in both devices were significantly below the gastric distention pressure of concern.

Benefits of High Flow therapy are well described. Some benefits include advantages over Non-Invasive ventilation and CPAP. Vieira and colleagues [15] demonstrated in their bench study that HFNC generates positive airway pressure and reduces respiratory frequency when the subject's mouth was kept closed. They showed that an increased resistance to breathing induces a longer expiratory phase, leading to decreased respiratory frequency and minute volume, and which decreased respiratory workload, counterbalancing the increased pressure-time product per liter. They noted that these benefits are not observed with continuous positive airway pressure. [15] Concerns of non-invasive and invasive ventilation can be avoided by the use of high flow devices.

In order to achieve unison between set oxygen concentration (O_2%) and the user intended fraction of inspired oxygen (FiO_2), inspiratory airflow demand must be matched by the delivered flow of the therapy device. [1,3]

CPAP and Pressure support devices currently available in the market allow for up to 180 lpm to match inspiratory demand. These devices provide O_2 concentration at the user desired and set levels. These ventilator products however are not integrated with humidifier functions to assure delivered humidity to reduce the risk of compromised bronchial hygiene and the potential for inspissated secretions as required and recognized the international humidification standard, ISO 80601-2-74.

High Flow flowmeters and air/oxygen blenders that are capable of providing mixed O_2 flows of 100 liters per minute are in use but they may not provide sufficient alarm systems. These devices are coupled with humidifiers, such as the MR850, in US hospitals to provide high flow therapy above the limit of 60 lpm. Delivered flows below the inspiratory demand of the patient may limit the effectiveness of therapy and may not adequately mitigate complications associated with use of higher flows.

The blowers of these devices are not necessarily spinning at rates different from each other. It is also understood that the Bonhawa device to generate higher flows may or may not be spinning higher or lower, as it is dependent upon the user provision of source gas and clinicians intended O_2 concentration. It is safe to assume that if 80 liters per minute are needed that the user would be providing a higher input oxygen flow in order to maintain a similar O_2

concentration. In many cases the user would not create a change in blower speed as the device would instead produce a lower speed or equal speed to allow for the higher O_2 concentration. This comparative test supports that higher flows such as 80 lpm does not raise new or different risk concerns. The technology of generating gas flow and the implementation of alarms similar in both devices tested.

Conclusion

The results of this evaluation demonstrates that the presence of CE marking on High Flow devices means that sufficient humidity is delivered and that complication of inspissated secretions can be adequately mitigated. The bench test which included measurement of pressures in three conditions, complete occlusion, open and closed mouth simulation, and active expiratory breathing demonstrated findings similar to the clinical literature that flows provided during HFNC therapy do not pose a hazard of creating high pressures which exceed esophageal opening pressure and pose a risk of gastric distention. The highest pressure generated during 80 liters per minute, 6.0 cmH_2O during active exhalation provided more than three times the headroom of safety in relation to gastric distention pressures, 20 cmH_2O, and was shown to be 70% below the limit of concern.

The benefit of higher flows to match inspiratory demand provides a rarely recognized additional benefit of improving the accuracy of predictive indices such as the ROX index. The ROX index is used in protocol care to predict HFNC failure and the need for intubation. FiO_2 is not equal to set O_2 concentration on devices unless peak inspiratory demand is matched with continuous high flow. When it is not matched indices such as ROX that utilize FiO_2 as a denominator may result in inappropriate assessment. Proper allocation of flows that match inspiratory demand allows for high flow therapy to more fully achieve its intended use.

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