BREATHS: A Novel Endotracheal Tube Design to Decrease the Incidence of Tracheal Lesions

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Abstract

Background

Prolonged intubation is associated with the development of tracheal stenosis due to cuff pressures causing endothelial ischemia, potentially leading to tracheal stenosis at the cuff site. This may result in airway obstructions requiring surgical intervention. Objective to develop a modification to endotracheal tube cuffs to put less pressure against the tracheal walls to decrease the risk of developing post-ventilation tracheal stenosis.

Methods

A modified endotracheal tube cuff was designed using a double balloon cuff design, with an outer fixed cuff and an inner cuff that expands and deflates with the respiratory cycle. The design allows for the cuff pressure applied to the trachea to be maximal during inspiration and minimal during expiration, coinciding with pressures required to maintain an air seal.

Results

During inspiration, the pressure on the tracheal wall is equal to that of a standard endotracheal tube. During expiration, the pressure applied on the tracheal walls is less than that of a standard endotracheal tube. The minimal pressure throughout the cycle decreased to baseline throughout the respiratory cycle due to minimal cuff inflation by the end of expiration, as most air is removed.

Conclusions

The modified cuff demonstrates an overall decreased pressure applied to the trachea, with potential to enable microvascular perfusion, improve blood flow, and decrease risk of tracheal lesions and stenosis. Further testing with more ventilatory conditions, endotracheal tube, tracheal, and lung analog sizes, and in-vivo testing efforts are required to ascertain if this innovation's clinical benefit.

Background

A common and severe complication in patients with COVID-19 is acute respiratory distress syndrome, requiring oxygen and ventilation therapies [1]. It has been demonstrated that COVID-19 patients requiring intensive care had a median duration of ventilation of 17 days with a high frequency of re-intubation [2, 3]. This increased ventilatory-need highlights the importance of addressing ventilation-associated complications.

Endotracheal (ET) tube intubation is used to secure airway access, with the endotracheal tube (ETT) being used to sustain ventilatory requirements in operating rooms and intensive care units. It is only outranked by adult medical resuscitation and ultrasound in frequency of performance by emergency departments over the last decade [4]. Given its common usage, ventilation in critical care settings produces an alarming rate of associated complications [5]..

A major complication associated with prolonged ventilation via an ETT is tracheal stenosis, characterized by a consistent pattern of damage narrowing the tracheal lumen. The location of stenosis has been observed to coincide with the location of the balloon cuff of the ETT, the inflatable component that applies circumferential pressure on the tracheal wall to maintain an airtight seal [6]. The high pressures applied on the internal tracheal walls result in an obstruction of blood flow in the tracheal mucosa, that can develop into tracheal ischemic lesions, ischemic necrosis, hyper granulation, and stenosis [7].

During ventilation, inspiratory air is pushed through the tube into the trachea, and airflow pushes back against the inflated cuff. ETT cuffs are traditionally made of low-density polyvinyl chloride (PVC), a non-rigid material that is readily deformable by external pressure. The deformability of the PVC cuff allows for the backflow of air to pass between the cuff and tracheal wall, resulting in an air leak. This air leak, then, decreases the efficiency of ventilation and is a substantial risk to the patient (Fig. 1). Historically, low-volume cuffs required a high pressure (over 180 mmHg) to maintain proper airflow during ventilation. This resulted in clinically relevant stenosis in over 20% of patients who underwent intubation [8]. The more recent, standard, high-volume low-pressure (HVLP) cuffs form an effective seal at much lower pressures by only requiring sufficient inflation to match the airway pressure, significantly decreasing the incidence of stenosis. However, tracheal ischemic lesions remain common, with one study showing over 83% of patients having some ischemia after being intubated for 48 hours [9]. While it is typical for patients present with some ischemia after ventilation, subsequent symptomatic stenosis (cases with > 75% reduction in the tracheal lumen) is reduced to 3–12% of intubated patients [10].

Current standard practice is to apply cuff pressures of ~ 30 cmH_2O (22 mmHg) with a HVLP cuff to ensure an airtight seal while still minimizing the adverse effect of applied pressures on the tracheal wall [11]. ETTs must achieve the minimum occlusive volume to form an effective seal in the trachea and avoid an airflow leak. Another factor, decreased lung compliance, increases the peak inspiratory pressure (PIP) required to maintain mechanical ventilation of a patient, causing a corresponding increase in the intracuff pressure necessary to prevent air leaks [8]. Therefore, future ETT designs should focus on reducing the minimum required pressure while avoiding air leakage.

In this work, we propose a novel ETT design (*BREATHS*) with the goal of reducing the overall time-average pressure applied on the tracheal wall by the ETT cuff and validate the design in an in-vitro setting. This, in turn, may reduce the incidence of post-intubation tracheal lesions caused by limited microvascular perfusion.

Methods

The proposed solution was created with the intention of testing its effectiveness in-vitro. We were able to create a testing apparatus capable of simulating the trachea, measuring the pressure that an ETT applies on the in-vitro trachea, and determining if an air leak is present.

Testing Apparatus

The tracheal analog (Fig. 2) involves an inner plastic membrane 18mm in diameter, sealed in larger tubing. This diameter was chosen to reflect the average size of a trachea. Once the tracheal analog is sealed, the space between the in-vitro trachea and the outer tubing is filled with water. When an ETT is placed inside the artificial trachea and presses against the tracheal wall, the pressure from the ETT cuff is transmitted to the water between the two layers of the tracheal analog. This pressure is transduced to an electrical signal by a continuous pressure monitor that measures the pressure at a frequency of 30 Hz via a microprocessor connected to a laptop for real-time pressure visualization.

The testing apparatus (Fig. 3) allows for the measurement of the pressure applied to the tracheal analog by an ETT cuff, with various ventilation conditions controlled by a bag valve mask respirator. This setup allows for the measurement of two variables: 1) the pressure applied to the walls of the tracheal analog (continuous variable), and 2) the presence of an air leak (binary variable). The presence of an air leak is determined by inflating the ETT cuff, simulating ventilation via the bag valve mask respirator, and observing the presence of bubbles in the cuff leak detector. The cuff leak detector consists of a plastic tube connected to the proximal portion of the tracheal analog. If an air leak occurs, the air will be carried to the end of the cuff leak detector, which is submerged in water. Thus, air leaks will be seen as bubbling in the cuff leak detector due to the soft seal at the proximal aspect of the setup.

This testing setup does not replicate the volume of airflow through a human trachea but does replicate the pressure of typical ventilation. Given the aim of the ETT design is solely to reduce the overall pressure applied to the trachea during intubation, this testing setup is suitable for initial testing.

The testing apparatus was validated by inflating a standard #7.0 ETT and comparing that to the readings of our tracheal analog. Only one ETT size was tested because that is the size that was appropriate for the testing apparatus. To test other ETT sizes, various tracheal analogue sizes would need to be constructed. This validation was done using two ports of the microprocessor depicted in Fig. 3 and measuring concomitant pressures.

The bag valve mask used for these experiments is equipped with a positive end-expiratory pressure (PEEP) valve and a pressure manometer. This allows for control of PEEP pressures to physiological conditions (commonly at 7.36mmHg (10cmH_2O)) and control of the inspiratory pressure. For the experiments, the bag valve mask would be squeezed while observing the pressure manometer. For each cycle, the bag mask valve would be squeezed until the pressure on the manometer reached the target inspiratory pressures.

The analog pressure readings were validated by connecting both the tracheal analog and a standard #7.0 ETT cuff to continuous pressure monitors. When pressures were manually increased in both the tracheal analog and the ETT cuff independently, the pressure transducers provided the same readings for both conditions.

BREATHS- Basic Respiratory Exhalation Associated Tracheal Health Solution

BREATHS is based on the knowledge of the pressure required to prevent an air leak over the course of the respiratory cycle. Standard HVLP cuffs maintain a constant pressure, sufficient to prevent an air leak throughout the respiratory cycle. However, as air leaks are only a concern during the inspiratory portion of the respiratory cycle, the maximal pressure applied by the standard HVLP cuffs is unnecessary for the remaining two thirds of the cycle. As previously mentioned, air leaks decrease the efficiency of ventilation and reduce the amount of air reaching the lungs. Therefore, air leaks are only an important parameter to control during inspiration.

BREATHS allows for the cuff pressure applied to the trachea to be maximal during inspiration and minimal during expiration, coinciding with the pressures required to maintain an air seal. The maximal pressure on the trachea during inspiration remains unchanged, while the pressure on the trachea during expiration is lower. As a result, the overall pressure on the tracheal wall is reduced.

We did so by remodeling the cuff of the standard ETT to have it include two cuffs superimposed on one another (Fig. 4). In doing so, we can have a system with varying pressures applied onto the tracheal walls throughout the respiratory cycle. Specifically, we designed an outer cuff that is inflated to an applied pressure, lower than that of a standard ETT. This reduced applied pressure was determined through trial and error. Specifically, the set up was used to determine when an air leak occurred. Thus, we increased the pressure of the outer cuff until a there was no detectable air leak.

The inner cuff is filled with air from the ventilator passed into the tube during inhalation, inflating it within the outer cuff to create a pressure like that of a standard ETT that forms a seal with the tracheal walls. However, during expiration, air is removed from the tube and inner cuff. Therefore, the inner cuff deflates, and the remaining pressure during exhalation is the reduced applied pressure (lower than that of a standard ETT that the outer cuff applies on the tracheal walls. Between the two cuffs is an isolated space that can be inflated independently with a syringe, like a standard cuff, to allow the system to function as a standard ETT.

We hypothesize that this solution will minimize the pressure on the tracheal walls during expiration, as the inner cuff will be deflated and the remaining pressure from the outer cuff is lower than that of the standard ETT. Minimizing this pressure will allow for microvascular perfusion to occur during expiration, promoting blood flow and decreasing the risk of tracheal lesions and stenosis.

During inspiration, air travels directly through the ETT, into the inner cuff, and eventually reaches the lungs (Fig. 4). This air inflates the inner cuff to create a tight seal with the trachea. There are various forces working together during inspiration between the inner and outer cuff and the tracheal walls.

During expiration, air travels out from the lungs, into the ETT, out of the inner cuff, and out of the ETT (Fig. 5). This deflates the inner cuff, while the outer cuff remains inflated with a reduced applied pressure onto the tracheal wall. At this expiratory stage, there remain forces between the outer cuff and the tracheal walls, however no pressure is applied by the inner cuff.

Testing was performed on a standard #7.0 ETT and the newly designed BREATHS ETT. Our testing analog diameter was best suited for #7.0 ETT. As a result, that was the only size of ETT tested. Testing was performed with a PEEP pressure of 10cmH2O (7.36mmHg) and a peak pressure of 30 cmH2O (22.07mmHg).

Results

The standard ETT applies a constant pressure on the tracheal wall, typically around 22 mmHg (Fig. 6). Traditionally, this is done to maintain a seal throughout the entire respiratory cycle to prevent an air leak. The maximum pressure of ~ 36mmHg represents the pressure at which the ventilator pushes the air in. During expiration, a constant pressure from the cuff still exists and the pressure decreases to ~ 22mmHg as air is released. This pressure negatively impacts the microvascular perfusion within the trachea, leading to tracheal lesions and potentially stenosis.

However, BREATHS is based on varying the applied pressures onto the tracheal walls during the respiratory cycle. During inspiration, the pressure on the trachea is equal to that of a standard ETT to maintain a seal and ensure no air leaks around the cuff. During expiration, however, the pressure required on the tracheal walls is less than that of the traditional ETT. This is achieved by using two cuffs; an outer cuff with a reduced applied pressure compared to standard and an inner cuff that can transmit enough pressure to the outer cuff during inspiration to form an air seal.

In addition, Fig. 7 shows that the minimal pressure throughout the cycle can decrease to baseline throughout the respiratory cycle due to minimal cuff inflation by the end of expiration, as most air will have been removed. As a result, the only pressure applied on the tracheal walls at the end of expiration is the reduced applied pressure of the outer cuff. Minimizing the pressure during expiration enables the microvascular perfusion to be relieved from stress, improving blood flow, and decreasing chances for tracheal lesions and stenosis.

Discussion

The main purpose of this experiment was to conceptualize and demonstrate the usability of a proposed ETT design that minimizes the pressure exerted on tracheal walls, to reduce the incidence of tracheal stenosis and related ischemic lesions.

Given that patients are in expiration for two-thirds of their breathing cycle, decreasing the pressure during expiration decreases the overall mean pressure applied on the tracheal walls throughout the respiratory cycle. Specifically, compared to the constant pressure of the standard ETT (19-20mmHg), the reduced applied pressure of our design (12-13mmHg) is lower during expiration. BREATHS demonstrates a reduction in applied pressure during the expiratory phase and, therefore, a corresponding decrease in mean applied pressure on the tracheal walls. Our testing apparatus was limited in that it was not time-synchronized to reflect a standard respiratory cycle with a 1:2 inspiratory:expiratory time-ratio. However, we expect that the observed pressure values during simulated inspiration and expiration would reflect a significant pressure decrease when a standard 1:2 inspiratory:expiratory time-ratio is applied.

BREATHS offers advantages in that it does not require new materials, but simply an adjustment of the current design. This maximizes device translatability from proof-of-concept to full clinical implementation and does not require significant changes to standard intubation or ventilation procedures from the perspective of the healthcare provider. The simplicity and ease of use of the BREATHS design makes it a good candidate for large-scale replacements of standard ETT.

Additionally, our results demonstrate 30–40% reduction in minimal cuff pressure required to maintain an air seal under in-vitro conditions. This study demonstrates the associated reduction in minimal cuff pressures using a #7.0 ETT under fixed ventilatory settings with a PEEP of 10 mmHg and maximum inspiratory pressures of 33 mmHg in a simulated tracheal analog, compared to a standard #7.0 ETT under the same testing conditions.

Although only #7.0 ETT were used in our testing apparatus, we anticipate that comparable results would be produced using ETT of other sizes. This study was limited in its lack of physiological in vivo testing conditions, and therefore direct conclusions cannot be made regarding the impact of our design on stenosis in ventilated patients. It is, however, hypothesized that the observed reduction in minimal cuff pressure required to maintain an air seal would subsequently result in a reduction in the incidence of post-ventilation tracheal stenosis. Future testing, with a wider range of analog lung and trachea sizes, ETT sizes, and ventilatory conditions is necessary to ascertain if this modification will provide clinical benefit. Given the dynamics of this concept model, a better evaluation of the performance of this concept would be completed by measuring the average pressure on the trachea over time during physiological ventilatory conditions using a ventilatory machine as opposed to bag valve mask ventilation. Future studies testing BREATHS may be done in vivo with animal subjects, as this is the standard for ETT testing [17][12][18].

We recognize that HVLP tubes were developed to decrease the rate of serious complications post-intubation, as they formed an effective seal at much lower pressures than previous high-pressure designs, only requiring sufficient inflation to match airway pressures. In one study, four HVLP ETTs were tested at an inner diameter of 8.5 mm and inflated at various pressures to determine the relationship between intracuff pressure and ischemia [11]. It was observed that blood flow to the antero-lateral portions of the trachea was compromised after just fifteen minutes of intubation with intracuff pressures over 30 cmH_2O

(22 mmHg) and completely obstructed at pressures over 50cmH_2O (36 mmHg). Their qualitative assessment observed no obstruction of blood flow or evidence of lesions in those intubated with pressures of 25 cmH_2O and 30 cmH_2O. This finding established a clinical guideline for cuff pressure still in use today.

Any intracuff pressure which exceeds capillary perfusion pressure (the net pressure gradient which drives blood from the arteries of the trachea to veins) will impede blood flow, potentially causing ischemia, lesions, and stenosis. This is the basis for the 30 cmH_2O guideline. While the mean capillary perfusion pressure in the trachea is 27 cmH_2O, the pressure at the venous end of the capillary bed can be as low as 16 cmH_2O. It has been suggested that even pressures at this low extreme may obstruct blood flow in the tracheal mucosa [13].

Assorted designs have been proposed in the past in attempt to mitigate the associated health risks of ventilation. Certain attempts have been made by changing the materials involved in the fabrication of ETT. A radially expanding cylindrical lattice has been used to replace the inflatable cuff, allowing larger and more evenly distributed contact forces compared to the traditional design, as demonstrated in vitro [14]. Another design removed the inflatable cuff entirely, in efforts to reduce the applied pressure on the tracheal wall. These self-sealing baffled silicon ETT use a series of baffles in place of the inflation cuff to offer a seal without tissue damage [16]. The objective was to detect an air leak above 30cmH2O, and they did not report reducing pressure on the tracheal wall. This device was more effective in both preventing leakage at the tracheal seal and removing fluid from the tracheal lumen. However, they did not release pressure when it was > 30 cm H_2O. Lastly, some studies have featured ETT coated with biomaterials such as phlorotannin and polycaprolactone that exhibit anti-inflammatory or anti-fibro genic effects can potentially prevent the development of tracheal stenosis [17].

Conclusion

The described modified ETT cuff, BREATHS, demonstrated clinically relevant results that provide exciting potential for the reduction of tracheal damage. Specifically, by minimizing the applied pressure during exhalation, the overall pressure on the tracheal walls may decrease overall throughout the entire respiratory cycle. Having two cuffs superimposed on one another offers the ability to minimize the pressure on the tracheal walls during exhalation, thus allowing for microvascular perfusion and decreasing the risk of post-intubation tracheal lesions and stenosis.

Abbreviations

ET – Endotracheal

ETT – Endotracheal Tube

HVLP – High Volume Low Pressure

PIP – Peak Inspiratory Pressure

PEEP – Positive End Expiratory Pressure

BREATHS – Basic Respiratory Exhalation Associated Tracheal Health Solution

Declarations

Ethical Approval and Consent to Participate

Not applicable

Consent for Publication

Not applicable

Availability of Data and Materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing Interests

The authors declare that they have no competing interests.

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Authors' Contributions

MC was a major contributor to writing the manuscript. SL and OT were major contributors in assisting the writing of the manuscript, editing the text, and formatting. DG was a major contributor in creating the testing apparatus, the design, testing, and execution of the study. All authors read and approved the final manuscript.

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Figures

Figure 1

Air leak in an ETT. Direction of air flow labelled by arrows.

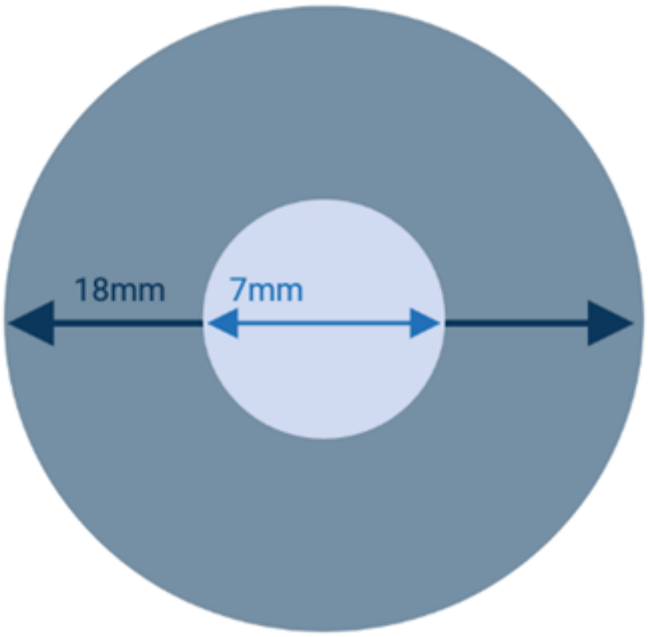

Figure 2

Schematic of The Tracheal Analog

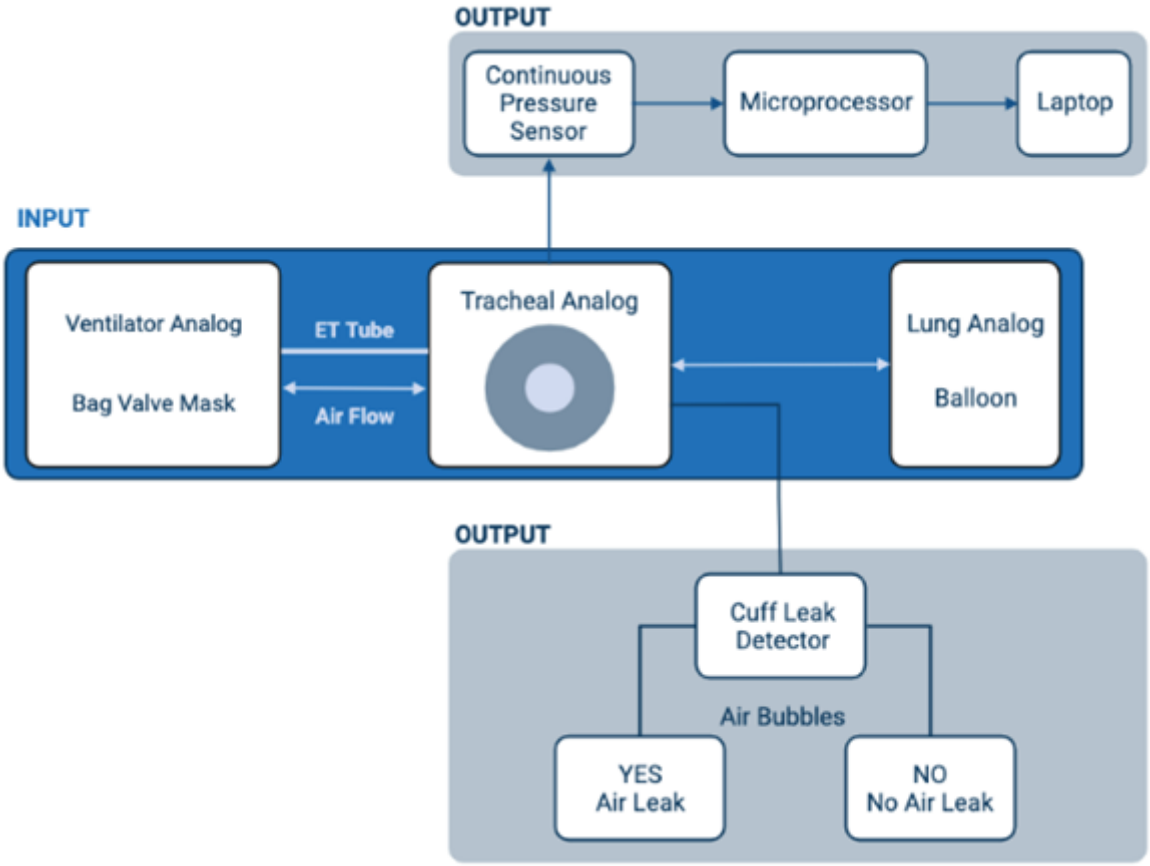

Figure 3

Testing Apparatus

Figure 4

Schematic of The Redesigned ETT During Inspiration

Figure 5

Schematic of the Redesigned ETT During Expiration

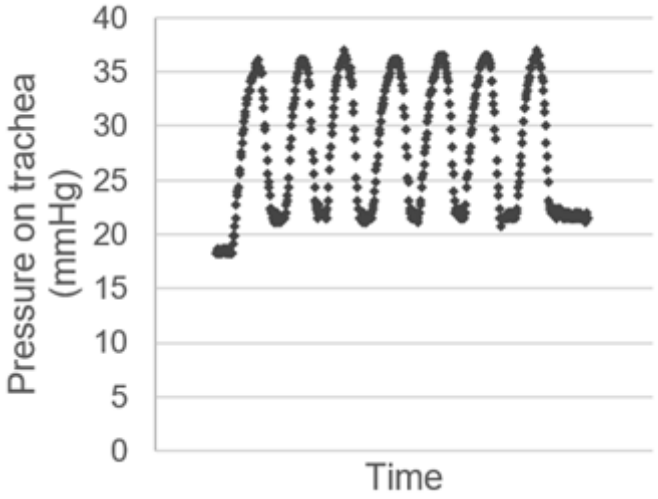

Figure 6

Applied Pressure on The Tracheal Analog for a Standard ETT

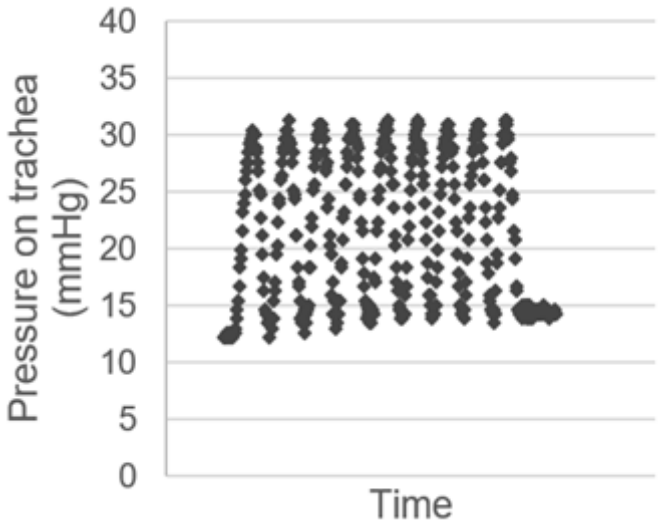

Figure 7

Applied Pressure on The Tracheal Analog for BREATHS